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Message from DIA Global Chief Executive

Dear Colleagues,

We are thrilled you are joining us for the DIA 2015 51st Annual Meeting in Washington, DC—a meeting of the minds in the heart of our nation’s capital. This year’s meeting is all about helping you to advance your work in the health care product development industry—whether it be learning about new regulatory developments or hearing about how innovations such as the use of mHealth are shaping the future of product development. There is an African proverb that says, “If you want to go fast, go alone. If you want to go far, go together.” I encourage you to take time at the meeting to connect with your colleagues and discuss ways to Develop. Innovative. Advance., both in your own career and across our industry.

This year’s keynote speaker is sure to inspire much discussion on new developments that are driving change in our industry. Daniel Burrus, considered to be one of the world’s leading futurists on global trends and innovation, will join us to talk about the trends that are expected to make a big impact in our industry in the coming years.

Bringing safe, effective, and value-focused health care products to patients is a global endeavor. Therefore, we are pleased to have professionals from over twenty six countries in attendance at DIA 2015, including senior regulatory officials and health authorities from across the globe. I am confident we will all leave DIA 2015 having expanded our professional networks and with a greater awareness of the challenges and opportunities we all face on a global level.

Our industry is changing rapidly, and DIA is proud to provide you with the knowledge you need to anticipate and respond to changes in our industry before they become the status quo. I encourage you to make the most of this year’s Annual Meeting by engaging with the presenters, attendees, exhibitors, and by joining the conversation on Twitter using #DIA2015. We’ve already accomplished so much. Let’s see how much further we can go together.

Sincerely Yours,

Barbara Lopez Kunz
DIA Global Chief Executive

Program Co-Chairs

Michael Rosenblatt, MD
Executive Vice President and Chief Medical Officer
Merck & Co., Inc.

Scientist, educator, hospital and global health care company executive, Michael Rosenblatt, MD, is chief medical officer at Merck. He is the company’s primary external advocate on medical issues and represents the voice of the patient inside the company.

Previously, he was Dean of Tufts University School of Medicine; the George R. Minot Professor of Medicine at Harvard Medical School; and president, Beth Israel Deaconess Medical Center (BIDMC). He was the Harvard faculty dean and senior vice president for academic programs at BIDMC and director, Harvard-MIT Division of Health Sciences and Technology.

Christopher P. Austin, MD
Director
National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health (NIH)

Chris Austin leads NCATS’ work to improve the translation of observations in the laboratory, clinic and community into interventions for patients—from diagnostics and therapeutics to medical procedures and behavioral changes. Austin first joined NIH in 2002 as a translational research senior advisor at the National Human Genome Research Institute. He became NCATS’ pre-clinical innovation director in 2011, and was appointed the Center’s director in 2012. Prior to the NIH, Austin worked at Merck, directing programs on genome-based discovery of novel targets and drugs.
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### SCHEDULE AT-A-GLANCE

#### SATURDAY, JUNE 13

**Registration Hours:**  
9:00 AM-5:00 PM  
Exhibitor 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 2015 51st Annual Meeting Orientation and Networking

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

#### SUNDAY, JUNE 14

**Registration Hours:**
- **8:00-9:00 AM**
- **8:00 AM-6:00 PM**
- **12:30-1:00 PM**
- **3:00-6:00 PM**

**Schedule:**
- **8:30 AM-12:00 PM**  
Registration for Full Day, Morning Preconference Tutorials*
- **9:00 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

#### MONDAY, JUNE 15

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

**Schedule:**
- **7:30-8:20 AM**  
DIA 2015 51st Annual Meeting Orientation and Networking and Coffee
- **7:45-8:30 AM**  
Coffee and Breakfast Breads
- **8:30-10:00 AM**  
Educational Opportunities
- **8:30-10:00 AM**  
Student Forum
- **9:30 AM-4:30 PM**  
Student Poster Session (Exhibit Hall Entrance A)
- **9:30 AM-6:00 PM**  
Exhibit Hall Open
- **10:00-11:00 AM**  
Coffee Break
- **11:00 AM-12:30 PM**  
Educational Opportunities
- **12:30-2:30 PM**  
Lunch (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **2:30-4:00 PM**  
Plenary Session & Keynote Address
- **4:00-6:00 PM**  
Opening Reception (Exhibit Hall)

#### TUESDAY, JUNE 16

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

**Schedule:**
- **7:15-8:00 AM**  
Coffee and Breakfast Breads
- **8:00-9:30 AM**  
Educational Opportunities
- **9:00 AM-4:00 PM**  
Professional Poster Session #1 (Exhibit Hall Entrance A)
- **9:00 AM-5:00 PM**  
Exhibit Hall Open
- **9:30-10:30 AM**  
Coffee Break (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **10:30-10:30 AM**  
Oral Presentations-Professional Poster Session #1A (Exhibit Hall Entrance A)
- **10:30 AM-12:00 PM**  
Educational Opportunities
- **11:30 AM-1:30 PM**  
Lunch (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **11:30 AM-1:30 PM**  
Oral Presentations-Professional Poster Session #1B (Exhibit Hall Entrance A)
- **12:30 PM**  
Student Poster Award Ceremony (DIA Booth #1523)
- **12:30-1:30 PM**  
Community Meet & Eat (Exhibit Hall)
- **1:30-3:00 PM**  
Educational Opportunities
- **1:30-3:30 PM**  
Exhibit Guest Passes
- **2:30-3:10 PM**  
Oral Presentations-Professional Poster Session #1C (Exhibit Hall Entrance A)
- **2:30-3:30 PM**  
Refreshment Break (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **3:30-5:00 PM**  
Educational Opportunities

#### WEDNESDAY, 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
- **8:00-9:30 AM**  
Educational Opportunities
- **9:00 AM-4:00 PM**  
Professional Poster Session #2 (Exhibit Hall Entrance A)
- **9:00 AM-4:00 PM**  
Exhibit Hall Open
- **9:30-10:30 AM**  
Coffee Break (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **9:30-10:30 AM**  
Oral Presentations-Professional Poster Session #2A (Exhibit Hall Entrance A)
- **10:30 AM-12:00 PM**  
Educational Opportunities
- **11:30 AM-1:30 PM**  
Lunch (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **11:30 AM-1:30 PM**  
Oral Presentations-Professional Poster Session #2B (Exhibit Hall Entrance A)
- **1:30-3:00 PM**  
Educational Opportunities
- **1:30-3:30 PM**  
Exhibit Guest Passes
- **2:30-3:10 PM**  
Oral Presentations-Professional Poster Session #2C (Exhibit Hall Entrance A)
- **2:30-3:30 PM**  
Refreshment Break (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **3:30-5:00 PM**  
Educational Opportunities

#### THURSDAY, JUNE 18

**Registration Hours:**  
7:00 AM-5:00 PM  
Attendee and Speaker Registration

**Schedule:**
- **8:00-11:00 AM**  
Attendee, Speaker Registration
- **8:00 AM-9:30 AM**  
Educational Opportunities
- **9:00 AM-10:30 AM**  
Coffee Break (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **9:00 AM-10:30 AM**  
Oral Presentations-Professional Poster Session #1C (Exhibit Hall Entrance A)
- **10:30 AM-12:00 PM**  
Educational Opportunities
- **11:30 AM-1:30 PM**  
Lunch (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **11:30 AM-1:30 PM**  
Oral Presentations-Professional Poster Session #2B (Exhibit Hall Entrance A)
- **1:30-3:00 PM**  
Educational Opportunities
- **1:30-3:30 PM**  
Exhibit Guest Passes
- **2:30-3:30 PM**  
Oral Presentations-Professional Poster Session #2C (Exhibit Hall Entrance A)
- **2:30-3:30 PM**  
Refreshment Break (Exhibit Hall)  
Innovation Theater Presentations (Exhibit Hall Entrance B)
- **3:30-5:00 PM**  
Educational Opportunities

As of April 28, 2015. Schedule subject to change.
With this year’s theme, Develop. Innovative. Advance., DIA is pleased to have Daniel Burrus as the Keynote Speaker for the DIA 2015 51st Annual Meeting. Daniel is considered one of the World’s Leading Futurists on global trends and innovation. Daniel, President and CEO of Burrus Research, helps professionals define game-changing strategies to identify technological, social, and business forces that are converging to create enormous, untapped opportunities.

Daniel’s accurate predictions date back to the early 1980s where he became the first and only futurist to accurately identify the twenty technologies that would become the driving force of business and economic change for decades to come. Since then, Daniel has continued to establish a worldwide reputation for his exceptional record of predicting the future of technology driven change and its direct impact on the business world.

The New York Times has referred to Daniel as one of the top three business gurus in the highest demand as a speaker. Daniel is also the author of the best selling book Flash Foresight and is a featured writer on the topics of innovation, Change, and the future for CNBC, Huffington Post, and Wired Magazine to name a few.

---

The Walking Gallery
June 15 | 4:00–6:00 PM | DIA Booth #1523

Join us during the Opening Reception 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.

We are the Gallery that walks. We are the Patients that wear our story on our backs.
#136 International Regulatory Convergence: Collaboration, Cooperation and Global Governance
Monday, June 15 | 11:00–12:30 PM

- **Anil Arora**
  Assistant Deputy Minister, Health Products and Food Branch, Health Canada

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

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

- **Stephen M. Ostroff, MD**
  Acting Commissioner FDA

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

- **Guido Rasi, MD**
  Principal Adviser, European Medicines Agency European Union

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

#223 PMDA Town Hall
Tuesday, June 16 | 8:00–9:30 AM

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

- **Toshiyoshi Tominaga, PhD**
  Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

- **Tomiko Tawaragi**
  Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

- **Takao Yamori, PhD**
  Director of Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#265 Tuesday Plenary Session: Disruptive Forces in Health Care Innovation: Where Are They Leading Us?
Tuesday, June 16 | 1:30–3:00 PM

- **Jack Andraka**
  Inventor of Early Diagnostic Test for Pancreatic Cancer, Visionary Teenage Scientist

- **Angela Dunn**
  Trends Analyst, healthiscool

- **Patricia Furlong, BSN**
  Founding President and CEO, Parent Project Muscular Dystrophy

- **Jeffrey Kasher, PhD**
  President, Patients Can’t Wait, LLC

- **Duane Schulthess, MBA**
  Managing Director, VitalTransformation, Belgium
#291 CDRH Town Hall
Tuesday, June 16 | 3:30–5:00 PM

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

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

William H. Maisel, MD, MPH
Deputy Director for Science and Chief Scientist, Director, ODE (Acting), CDRH, FDA

Jeffrey Shuren, JD, MD
Director
CDRH, FDA

#312 21st Century Cures: Which Are the Most Transformative Provisions and How Do They Accomplish Major Change?
Wednesday, June 17 | 8:00–9:30 AM

Clay Alspach, JD
Chief Majority Health Counsel, House Energy and Commerce Committee

Nancy Bradish Myers, Esq, JD
President, Catalyst Healthcare Consulting, Inc

Ellen V. Sigal, PhD
Founder and Chairperson, Friends of Cancer Research

Janet Woodcock, MD
Director, CDER FDA

#320 The Future of Clinical Trial Data Sharing
Wednesday, June 17 | 8:00–9:30 AM

Jarilyn Dupont, JD
Director of Regulatory Policy, Office of Policy Office of the Commissioner, FDA

David Eichmann, PhD
Director, Library Science & Info Science; Chair, Graduate Program Informatics, University of Iowa

Michael Rosenblatt, MD
Executive Vice President and Chief Medical Officer Merck & Co., Inc.

Andrzej Rys, MD
Director of Health Systems and Products European Commission

Stephen P. Spielberg, MD, PhD
Editor-in-Chief, DIA Publications DIA

Joanne Waldstreicher, MD
Chief Medical Officer, IOM Committee Member, Johnson & Johnson Pharmaceutical Research & Development, L.L.C
#411 An Insider’s View of Cooperation Between the EMA and CDER/FDA: Question Time
Thursday, June 18 | 9:00–10:30 AM

New this year! Join us for this unique opportunity that includes members from EMA and CDER/FDA Leadership. This first of its kind forum will provide an opportunity for both agencies to explore, at a roundtable discussion, areas covered by the EMA/FDA confidentiality arrangements and discuss how both agencies contribute to global development and supervision of medicines. Experts from both agencies, who have been at the forefront of EMA/CDER/FDA collaboration, will explore topics such as pharmacovigilance, adaptive pathways, quality by design, and patient involvement in the development of medicines. See page 99 for more information.

Enrica Alteri, MD
Head of Human Medicines Evaluation, European Medicines Agency, European Union

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

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

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

Sabine Haubenreisser, PhD, MSc
EMA Liaison Official to the US FDA European Medicines Agency, European Union

Sandra L. Kweder, MD, FACP
Deputy Director, Office of New Drugs, CDER, FDA

Karen Midthun, MD
Director, CBER FDA

Celia M. Witten, MD, PhD
Director, Office of Cellular, Tissue and Gene Therapy, CBER, FDA

Christine M. V. Moore, PhD
Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Theresa M. Mullin, PhD
Director, Office of Strategic Programs, CDER, FDA

Guido Rasi, MD
Principal Adviser, European Medicines Agency, European Union

Robert J. Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA
DIA understands 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 patient advocates not only to network and learn from experts from around the world, but also to participate in the process of bringing safe and effective therapies to market.

Twenty 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 2015 51st Annual Meeting.

Meet the Patient Fellows at Booth #1721
Join the Conversation.
Follow #DIA2015Patients for real-time updates.

Class of 2015 Patient Advocate Fellowship Organizations:
Innovation Theater Presentations
Exhibit Hall Entrance B

Participating Exhibiting Companies will showcase their expertise and solutions in this year’s schedule.

Monday, June 15

QUINTILES
12:45 PM
#137 Improve Clinical Development by Enhancing Site Relationships, Technology, and Patient Engagement

ConvergeHEALTH by Deloitte
1:30 PM
#138 ConvergeHEALTH by Deloitte Innovation Theater Presentation

Tuesday, June 16

COVANCE
9:45 AM
#225 Advances in Risk-Based Monitoring: Transforming Drug Development Through Efficient Workflows, Big Data and Elegant Software

QUINTILES
12:00 PM
#249 Transform Clinical Development – Modernizing for Smarter Trials

Wednesday, June 17

jmp
9:45 AM
#322 Benefit and Risk Signal Detection in Clinical Trials

SAS
12:00 PM
#347 Accelerate Value-Based Drug Development With Analytics

QUINTILES
12:45 PM
#348 Driving Better Decision-Making with Real-World Data and Analytics

3:00 PM
#375 Formula One Study Start-up: How To Get a 94% Reduction in Time By Going Paperless
Membership & Community Activities

DIA Member Lounge
Exhibit Hall Entrance B

Are you looking for a space to relax or connect with your colleagues? Stop by the DIA Member Lounge located at the entrance of Exhibit Hall B. This lounge offers you a place to take an important call, charge your device, utilize a workstation, or just relax. Free WiFi is also available for your convenience. Becoming a DIA member was your first step to joining a global network where you play an important role advancing health care product development through global collaboration, communication, and education.

DIA Communities – The More You Put In, the More You Get Out

This exclusive DIA member benefit helps members stay connected even after the meeting ends! Continue the networking and information sharing as part of DIA’s member Communities. DIA Communities provide a way for members across the globe to interact with their peers or to form cross-disciplinary teams. It is here that members share information, raise concerns, mentor one another, and find answers together—accomplishing more as a group than any one person could accomplish alone.

- Keep up to date on hot topics and Community-generated content
- Share best practices, knowledge resources, articles, and more
- Members get involved, issues are resolved, health care evolves

Join as many as you like at DIAGlobal.org/Communities

DIA Community Networking Area
Exhibit Hall Entrance B

A dedicated area is available for you to meet with your fellow Community members throughout the week or to learn more about DIA’s Global Communities. Each table will include a sign related to a specific Community Interest Area. Look for the designated area in Exhibit Hall B, near the Member Lounge, and Lunch Voucher Exchange Area, where you can relax and enjoy an informal opportunity to network.

DIA Community Meet & Eat
Tuesday, June 16 | 12:30–1:30 PM

On Tuesday, the DIA Community Meet & Eat will be held in this Community Networking Area where all Community members and interested attendees can learn more about community and volunteer opportunities.

New This Year!
Professional Poster Oral Presentations - Five Minutes of Quick Content
See page 104 for the schedule
Networking Opportunities

Opening Reception
Network with 7,000+ attendees and 450+ Exhibiting Companies at the Opening Reception in the Exhibit Hall.
Monday, June 15  4:00–6:00 PM

Student Opportunities
Student attendees are encouraged to attend the DIA 2015 Student Forum: Job Hunter’s Toolkit - Some Things Change, Some Stay the Same. This is a great opportunity to network with other students attending this year’s Annual Meeting.
Monday, June 15  8:30–10:00 AM
See session 115 for more information.

Student Networking Area
Tables will be available in DIA Community Networking Area for students to network, plan their day, and meet for lunch.

Student Poster Session
Exhibit Hall Entrance A
Monday, June 15 | 9:30 AM–4:30 PM
Twenty students from around the world will showcase their research in this year’s Student Poster Session. See page 104 for this year’s student poster presenters.

Student Poster Award Ceremony
Tuesday, June 16 | 12:30 PM | DIA Booth #1523
Join us as we present the awards for the first, second, and third place student poster winners.

Professional Poster Sessions
Exhibit Hall Entrance A
80+ Posters will be on display where you will learn about the latest research results on various topics.
Session 1: Tuesday, June 16
9:00 AM–4:00 PM
Session 2: Wednesday, June 17
9:00 AM–4:00 PM

See page 104 for a complete listing as well as schedule for oral poster presentations where presenters will provide a 5 minute overview of their work.

Cast your vote! Select the best Professional Poster from this year’s program for a chance to win a Kindle Fire HD.

Annual Meeting Orientation and Networking
First time at the DIA Annual Meeting? Bring your business cards to Meeting Room 144 to network with fellow Annual Meeting first-timers and learn how to make the most of your Annual Meeting experience. Both orientation sessions include a time for Speed Networking.
Sunday, June 14  4:00–5:00 PM
Monday, June 15  7:30–8:20 AM

Refreshment Breaks
Meet up with your colleagues at the start of each day to plan your day and discuss what you learned the day before. Coffee and breakfast breads will be available in the Meeting Room 145–147 Concourse as noted below:
Monday, June 15 | 7:45–8:30 AM
Tuesday, June 16 | 9:15–10:00 AM
Wednesday, June 16 | 7:15–8:00 AM & 2:30–3:30 PM
Thursday, June 17 | 8:15–9:00 AM & 10:30–10:45 AM

Mid-morning and mid-afternoon breaks will also be held in designated areas of the Exhibit Hall:
Monday, June 15  10:00–11:00 AM
Tuesday, June 16  9:30–10:30 AM & 2:30–3:30 PM
Wednesday, June 17  9:30–10:30 AM & 2:30–3:30 PM

Extended Lunch Hours
Enjoy extended lunch hours to visit 450+ Exhibiting Companies in the Exhibit Hall.
Monday, June 15  12:30–2:30 PM
Tuesday, June 16  11:30 AM–1:30 PM
Wednesday, June 17  11:30 AM–1:30 PM
Program Committee

J. Lynn Bass, PharmD, RPh
Jazz Pharmaceuticals

Daniel Bollag, PhD
Ariad Pharmaceuticals, Inc.

Linda Bowen, MS, RAC
Sanofi

Jonca Bull, MD
Office of the Commissioner, FDA

Bill Byrom, PhD
Consultant

Joy Cavagnaro, PhD, RAC
Access BIO

Karla Childers, MS
Johnson & Johnson

Leah Christl, PhD
CDER, FDA

Betsy Fallen, RN
BAFallen Consulting, LLC

Ron Fitzmartin, PhD, MBA
CDER, FDA

Michael Folkendt, MS
CDER, FDA

Elizabeth Garrard, PharmD, RPh
United Therapeutics Corporation

Jonathan Haddad, MPH, MT
GlaxoSmithKline

Martin Harvey Allchurch, LLM
European Medicines Agency,
European Union

Jonathan Helfgott, MS
Stage 2 Innovations

Deborah Henderson, MSN
Merck & Co., Inc.

Rima Izem, PhD
CDER, FDA

Janet Jenkins-Showalter
Genentech, A Member of
the Roche Group

John Kamp, JD, PhD
Wiley Rein LLP; Coalition for
Healthcare Communication

Ellen Kelso
Chesapeake IRB

Lisa Palladino Kim, MS
Rutgers, The State University
of New Jersey

Lynn King, MHA
TKL Research

Agnes Klein, DrPH, MD
Health Canada

Stephen Knowles, MD, MRCP
Eli Lilly and Company

Mark Kryah, PMP
Eli Lilly and Company

JeanMarie Markham
Clinlogix, LLC

Philomena McArthur, JD
Johnson & Johnson International

Ann Meecker-O’Connell, MS
Janssen Pharmaceuticals, Inc.

Jon Meyer, MBA, MSc
Life Science Strategy Group, LLC

Mary Murray, MBA
Bristol-Myers Squibb Company

Bob Muzerall
ForeignExchange Translations

Nancy Myers, JD
Catalyst Healthcare Consulting, Inc

Jane Myles, MS
Genentech, A Member of
the Roche Group

Roger Nosal, MA, MS
Pfizer Inc

Pradip Paul, MD, MS
Strategic Pharmacovigilance
and Risk Management

Kirsten Paulson, MS, RAC
Pfizer Inc

Julia Petses, PharmD
Sanofi

Christine Pierre, RN
Society for Clinical
Research Sites

James Polli, PhD
University of Maryland School
of Pharmacy
General Information

Accessing Presentations
To access presentations, visit DIAGlobal.org/DIA2015 for more information.

Baggage Check
There will be an area adjacent to Attendee Registration where attendees can check their belongings ($3.00 per item) Monday through Thursday. The Baggage Check will be available:

Monday, June 15-Wednesday, June 17 | 7:00 AM–6:30 PM
Thursday, June 18 | 7:00 AM–1:00 PM

Business Center
The Capital Business Center, located off the Mount Vernon Street Lobby of the Convention Center, offers an array of business services and products, tailored to meet your needs. The phone number is 202-289-5233.

DIA Career Center
DIA’s interactive Career Center, located near Meeting Room 151, 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 DIAGlobal.org/Career-Center

WiFi and Cyber Café
The Walter E. Washington Convention Center provides free basic wireless internet access in all public space of the Convention Center. Wireless Internet is not available in the meeting rooms or Exhibit Hall. To utilize this service, simply connect to Free DC Convention WiFi. A password is not needed. DIA is also providing workstations near Meeting Room 151 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 front of Exhibit Hall A. In case of emergency dial 3333 from any house phone or 202-249-3333 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 West Registration Area, Mount Vernon Street entrance, until the end of the event. Items remaining at the close of the DIA 2015 51st Annual Meeting will be turned over to the Walter E. Washington Convention Center. At that point, you can call 202-249-4111.
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.

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

In order to expedite your lunch service each day, please reference the lunch voucher flyer included in your registration bag for a list of menu items and additional instructions for your voucher exchange.

Meeting Name Badge

Participants will incur a $25 fee for badge reprints. If you require a badge reprint, please visit the Cashier at Attendee Onsite Registration. Identification will be required. Additionally, the QR code on your conference badge contains your contact information. Allowing exhibitors to scan the QR code will provide them with your information.

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

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.

Getting Around Washington, DC

A variety of transportation options are available in Washington, DC.

Metrorail & Metrobus
Washington, DC has one of the safest, cleanest, and most efficient transportation systems in the world. Metrorail is the most convenient ways to get around DC. The Walter E. Washington Convention Center has a dedicated Metro station (MT VERNON SQ/7TH ST-CONVENTION CENTER) and is serviced by the yellow and green lines. Many hotels are conveniently located near Metro stations or bus routes. Visit www.wmata.com and use the Metro Trip Planner to determine your travel time and fare to/from the airport, hotel, convention center etc. Metrobus provides connections for locations not serviced by Metrorail.

Taxi Service
Taxis are easily accessible at the Convention Center, major hotels, and other downtown locations and attractions. Pick-up and drop-off occurs at the Mt. Vernon Place entrance of the Convention Center. Visit www.taxifarefinder.com to find your taxi fare and travel time to/from the airport, hotel, Convention Center, etc.

DC Circulator
The DC Circulator is incredibly affordable at just $1, and travels along five specific routes designed for easy-on, easy-off access at points of interest throughout the District. It’s routes include neighborhoods such as Anacostia, Adams Morgan, Dupont Circle, Georgetown, Woodley Park/ Cleveland Park, U Street and more with the Circulator. Buses arrive at stops every 10 minutes, making your travels are the District a breeze. Visit www.dccirculator.com for routes and schedules.

DIA Courtesy Shuttle to/from Convention Center
Complimentary shuttle service will be provided between the Convention Center and DIA hotels that are not within walking distance of the Convention Center, Monday through Thursday. The shuttle will be available in the morning and the conclusion of DIA events each day. Please note that you must be staying at a DIA hotel to utilize the complimentary shuttle. A shuttle pass and shuttle schedule will be provided to all participants when checking into their hotel, and use of the shuttle pass will be strictly enforced.
Navigate DIA Meetings from Your Smart Device with DIA’s New App

The DIA Global app is designed to enhance your meeting experience and provide valuable information in one place.

Benefits of App:
• Activity stream provides real-time updates
• Manage your meeting agenda
• Connect and network with meeting attendees
• Interactive floor plans
• View Exhibiting Companies with their booth numbers
• Earn points and badges for activity within the app, tallied within the Leaderboard
• Integration with your social media channels

Login using your email address (used at registration) and select “Reset Password.” An email will be sent to you.

DIA Membership Appreciation Meeting
Tuesday, 10:15–11:00 AM | DIA Member Lounge

Come to meet the new DIA Board of Directors, learn how to make the most of your membership, and have an opportunity to ask questions about the future of DIA. You’ll also have an opportunity to win some fun raffle prizes, including free registration to a DIA Annual Meeting in any region. Must be present to win, so please join us.

Win Prizes. Make Connections.

Get Social!
Stay connected with your colleagues around the world and all of the innovation happening in Washington DC by following #DIA2015 with social media.
• Upload pictures to Instagram
• Tweet updates
• Connect with colleagues on LinkedIn
• Share the excitement with colleagues on Facebook.

Search DrugInfoAssn to follow DIA.

#DIA2015

| Discover | Interact | Accomplish
Play Games and Win Prizes
• Exhibitor Passport
• Scavenger Hunt on DIA App
• DIA App Leaderboard

For more details, check the flyer in your registration bag.
Thank You to our Media Partners

Thank you for showing your support and appreciation for Medical Heroes!

For 2016 5K Event Information or Sponsorship Opportunities:
Visit www.ciscrp.org/medhero5K
Email medhero5k@ciscrp.org
Toll Free 1-(877)-MED-HERO

Let’s Continue the Momentum with CISCRP’s Museum Initiative!

The Medical Heroes traveling museum exhibit will engage children and families in interactive learning about the clinical research process and the role that clinical trials play in advancing public health. With authentic stories and voices of clinical research volunteers, visitors will gain valuable new perspectives.

As we approach the final stages of development, we need your support to launch this exciting initiative in cities across the country!

Please contact jillmcnair@ciscrp.org for more information and interest in providing support.
The DIA 2015 51st Annual Meeting is the premier event designed for individuals involved in the discovery, development, and life cycle management of health care 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 2015 51st 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
- Identify and describe product development/project management practices and project-related finance practices used in the industry and project management practices within regulatory agencies
- Discuss new project management practices and systems used in global product development
- 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: PRECLINICAL AND TRANSLATIONAL DEVELOPMENT / EARLY PHASE CLINICAL DEVELOPMENT
- Explain some of the latest preclinical 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 drug advertising and promotion

TRACK 06: MEDICAL COMMUNICATION/ MEDICAL WRITING AND MEDICAL SCIENCE LIASON
- Identify opportunities to collaborate and meet the expectations of 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: TECHNOLOGY/DATA/RECORDS AND SUBMISSIONS
- Discuss best practices for the use of standards, technologies and processes in clinical trials
- Describe novel uses of existing/emerging technologies and processes
- Identify how technical and procedural innovations transform the clinical trial life cycle

TRACK 08: REGULATORY AFFAIRS
- Discuss the latest global regulatory trends and developments that impact the industry, health authorities and other stakeholders

TRACK 09: MEDICAL DEVICES, IN VITRO DIAGNOSTICS, AND COMBINATION PRODUCTS
- Discuss ways to further enhance the abilities of drug companies to meet the regulatory challenges created by innovative 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 CER (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 QUANTITATIVE THINKING
- Discuss current information on statistical solutions to issues associated with the evidence and regulatory review of drugs, diagnostics/devices, and biologics
- Examine the role statistical professionals have in raising awareness and providing information in an continuously evolving environment
- Discuss the cross-functional exchange of ideas and problem-solving for statisticians and other stakeholders

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 and diagnostics 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: LATE-BREAKING TOPICS
- Discuss late-breaking hot topics in the pharmaceutical, biotechnology and/or medical device industry

Select program offerings (including sessions, forums, workshops, symposia, TURBO offerings) will offer AMA PRA Category 1 Credits™, pharmacy or nursing contact hours, or Project Management Institute (PMI) professional development units (PDUs) and will be clearly identified in the program with applicable) will be shown in all meeting rooms.
ACREDITATION 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 (DIA). PIM is accredited by the ACCME to provide continuing medical education for physicians. 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)

DIA 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 the pharmacy-certified program offerings, please refer to pages 126–128.

ACPE Credit Requests MUST BE SUBMITTED by WEDNESDAY, JULY 29, 2015

DIA is required by the ACPE to report pharmacy-requested CEUs through the CPE Monitor. All ACPE-certified activity credit requests need to be submitted through DIA’s My Transcript within 45 days post activity. If ACPE credit requests are not submitted within date noted above, the ACPE credit request will not be processed to the CPE Monitor. Pharmacists will need to provide their NABP e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpmonitor.net.

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.

Project Management Institute (PMI)

DIA has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI). Participants may receive up to 10 professional development units (PDUs) for attending the Annual Meeting program offerings. PMI #: 2166-000165

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

International Association for Continuing Education and Training (IACET)

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET). As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA 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 2015 51st Annual Meeting, please complete your state’s application for credit and submit accordingly. If you require additional information, please contact Karen.Tenaglia@DIAGlobal.org.

CE CREDIT ALLOCATION

MONDAY-THURSDAY, JUNE 15-18

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 nursing contact hours
- 1.5 pharmacy contact hours
- 1.5 PMI PDUs
- 1.5 pharmacy CEUs
- 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
- 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 certificate programs noted below:
- Clinical Research: 12 Elective Units
- Clinical Safety and Pharmacovigilance: 4 Elective Units
- Project Management: 8 Elective Units
- Regulatory Affairs: 12 Elective Units

Visit DIAGlobal.org/certificateprograms for more information.

STATEMENT OF CREDIT

Participants who would like to receive continuing education credits for the DIA 2015 51st Annual Meeting must scan their DIA name badge at each program offering to record their attendance. 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 will be recorded.

To request a statement of credit, please go to DIAGlobal.org, select “Login to My DIA” and you will be prompted for your user ID and password. Select “My Transcript” (left side bar), the DIA 2015 51st Annual Meeting “Credit Request” and select the applicable credit request for each program offering and for each day of the meeting. My Transcript will open on Tuesday, June 23, 2015. If you experience any difficulties, please contact DIA at mytranscript@DIAGlobal.org

DISCLOSURE OF CONFLICTS OF INTEREST

Postgraduate Institute for Medicine (PIM) and DIA assess conflicts of interest with its instructors, planners, managers and other individuals who are in a position to control the content of CME/CE activities. All relevant conflicts of interest that are identified are thoroughly vetted by PIM and DIA for fairness, scientific objectivity of studies utilized in this activity, and patient care recommendations. PIM and DIA are committed to providing its learners with high quality CME/CE activities and related materials that promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest. Disclosure statements are found on pages 118-124.

EVALUATION

Access to DIA 2015 51st Annual Meeting online evaluations are found at www.DIAglobal.org/DIA2015Seva1s. All participant scanned data will be uploaded into the evaluation portal, so that only the offerings you attended will appear. Attendees will sign in to the evaluation portal utilizing their email address and Badge ID.

Evaluation feedback is very important to DIA. To thank you for your feedback, DIA will conduct a drawing with a chance for one attendee to win a free registration to the DIA 2016 52nd Annual Meeting. Eligible attendees must complete all program offering evaluations from each educational offering time frame during the Annual Meeting.

DIA will also offer one winner a $100 American Express gift card from a random drawing of the attendees who complete the Overall evaluation form. During the week of July 20, the winners will be announced.

Deadline for submitting evaluation feedback is Wednesday, July 15, 2015.

The content noted on this page was made available to DIA as of May 5, 2015.

DIAGlobal.org/DIA2015
### MEETING SCHEDULE BY DAY AND TIME

#### DIA 2015 51st ANNUAL MEETING TRACKS AND INTEREST AREAS

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<th>Interest Area</th>
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<td>Track 01</td>
<td>Clinical Operations</td>
<td>Academic Health Centers/Investigative Sites (AHC/IS), Clinical Research (CR), Clinical Supplies (CS), Manufacturing (MF), Research and Development (RD)</td>
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<tr>
<td>Track 02</td>
<td>Project/Portfolio Management and Strategic Planning</td>
<td>Financing (FI), Project Management (PM), Strategic Planning (SP)</td>
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<tr>
<td>Track 03</td>
<td>Innovative Partnering Models and Outsourcing Strategies</td>
<td>Outsourcing (OS)</td>
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<tr>
<td>Track 04</td>
<td>Preclinical and Translational Development/Early Phase Clinical Development</td>
<td>Biotechnology (BT), Nonclinical (NC), Pharmacology (PC)</td>
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<td>Track 05</td>
<td>Regulation of Product Advertising and Marketing in an Ever-changing World</td>
<td>Advertising and Promotion (AP), Marketing (MA)</td>
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<tr>
<td>Track 06</td>
<td>Medical Communication/Medical Writing and Medical Science Liaisons</td>
<td>Medical Communications (MC), Medical Science Liaisons (MSL), Medical Writing (MW)</td>
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<tr>
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<td>Information Technology (IT), eClinical (EC), Clinical Data Management (CDM), Document Management (DM), Study EndPoints/Clinical Outcomes Assessment (SE), Submissions (SUBS), Validation (VA)</td>
</tr>
<tr>
<td>Track 08</td>
<td>Regulatory Affairs</td>
<td>Regulatory Affairs (RA)</td>
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<tr>
<td>Track 09</td>
<td>Medical Devices/In Vitro Diagnostics, and Combination Products</td>
<td>Combination Products (CmbP), Medical Devices and Diagnostics (MDD)</td>
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<tr>
<td>Track 10</td>
<td>Public Policy/Health Care Compliance/Law</td>
<td>Public Policy, Health Care Compliance/Law (PPLC)</td>
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<tr>
<td>Track 11</td>
<td>Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice</td>
<td>Good Clinical Practice (GCP), Quality Assurance, Quality Control (QA/QC)</td>
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<tr>
<td>Track 12</td>
<td>Pharmaceutical Quality</td>
<td>Chemistry, Manufacturing and Controls/Good Manufacturing Practices (CMC/GMP)</td>
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<td>Track 13</td>
<td>Comparative Effectiveness Research/Global Health Outcomes and Economics</td>
<td>Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine (CEHTAEBM), Pricing and Reimbursement (PR)</td>
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<td>Track 14</td>
<td>Clinical Safety and Pharmacovigilance</td>
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<td>Track 15</td>
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<td>Track 16</td>
<td>Professional Development</td>
<td>Professional Education, Training, and Development (PETD)</td>
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<td>Track 17</td>
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<td>Track 18</td>
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<td>Track 19</td>
<td>Late-breaking Topics</td>
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<td>Track 20</td>
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<td>ALL</td>
</tr>
</tbody>
</table>

#### CONTENT LEVEL GUIDE

The difficulty level of each offering has been determined by the program offering chair 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.
# Meeting Schedule

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<thead>
<tr>
<th>Offering Number</th>
<th>Title of Offering</th>
<th>Room Number</th>
<th>Type of Format</th>
<th>Level of Difficulty</th>
<th>Track Number</th>
<th>Interest Area(s)</th>
<th>Continuing Education Credits</th>
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<td>Patient-Centricity: Buzzword or Method to Improve Operational Efficiency? ▲</td>
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<td>SESSION</td>
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<td>#109</td>
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<td>The Growing Role of the Patient Leading Into PDUFA VI: Negotiations and 2016</td>
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<td>Comprehensive Control Strategy: Building Confidence in Quality</td>
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<td>Level: ■ Track 18</td>
<td>RA, CR</td>
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<td>The Emerging Role of Medical Affairs in Biopharmaceutical Organizations: Challenges and Opportunities</td>
<td>152A</td>
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<td>Ebola Virus Disease Case Study: Global Harmonization to Increase Power and Accelerate Outcomes in Clinical Research Data</td>
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**MONDAY, JUNE 15**

8:30–10:00 AM

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<td>Pediatric Clinical Trials: Learning from Patients, Parents, and Investigative Sites</td>
<td>145A</td>
<td>SESSION</td>
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<td>The Clinical Trials Transformation Initiative Data Monitoring Committee Project: Findings and Next Steps</td>
<td>145B</td>
<td>SESSION</td>
<td>Level: ◆ Track 01B</td>
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<td>Codevelopment of a Drug in the Pharmaceutical Industry: Is It Ever Fun?</td>
<td>101</td>
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<td>#122</td>
<td>How to Achieve Value of Operational Transformation: It Requires Innovation, Process Excellence, and Adoption</td>
<td>147A</td>
<td>WORKSHOP</td>
<td>Level: ◆ Track 02B</td>
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<td>What Contract Research Organizations Value in a Partner: Results of a Perception Survey ▲</td>
<td>150A</td>
<td>SESSION</td>
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9:30–4:30 PM  Student Poster Session, Exhibit Hall (Entrance A)  see page 104 for more details

11:00–12:30 PM

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# Meeting Schedule

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<td>#124</td>
<td>Next Generation Nanomedicines and Nanosimilars: Regulators’ Perspective △</td>
<td>103B</td>
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<td>Engaging Patients and Health Care Professionals Through Social Media and Big Data Systems</td>
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<td>Global Drug Development in China: Opportunities and Challenges for Innovation</td>
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<td>Clinical Quality by Design: From Theory to Practice</td>
<td>102AB</td>
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<td>REMS Integration into the Health Care System: Three Perspectives in an Evolving Environment</td>
<td>207B</td>
<td>SESSION</td>
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<td>Track 14</td>
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<td>#133</td>
<td>Statistical Evaluation of Therapeutic Equivalence for Locally-Acting Generic Products</td>
<td>204BC</td>
<td>SESSION</td>
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<td>Track 15</td>
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<td>#134</td>
<td>The What, Why and How of Coaching and Its Application in the Work Place</td>
<td>147B</td>
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<td>Facilitating Rare Disease Patient Participation in Clinical Trials</td>
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<td>#136</td>
<td>International Regulatory Convergence: Collaboration, Cooperation and Global Governance</td>
<td>143ABC</td>
<td>FORUM</td>
<td>Level:  ●</td>
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**MONDAY, JUNE 15 (CONTINUED)**

### 12:45–1:15 PM

- **#137** Quintiles Innovation Theater Presentation: Improve Clinical Development by Enhancing Site Relationships, Technology, and Patient Engagement
  - Exhibit Hall (Entrance B)
  - Special Session
  - Level:  ●
  - Track 20
  - CR, IT, CEHTAeBM
  - No CE available

### 1:30–2:15 PM

- **#138** ConvergeHEALTH by Deloitte Innovation Theater Presentation
  - Exhibit Hall (Entrance B)
  - Special Session
  - Level:  ●
  - Track 20
  - No CE available

### 2:30–4:00 PM

**PLENARY SESSION & KEYNOTE ADDRESS • BALLROOM**

Welcome Remarks, Awards, and Keynote Address

All registrants are encouraged to attend.

**Welcome Remarks**
Per Spindler, DVM, MBA, MSc
DIA President and Chair, Board of Directors; Director, Biopeople, University of Copenhagen, Denmark

**Program Co-Chair**
Michael Rosenblatt, MD
Executive Vice President and Chief Medical Officer Merck & Co., Inc.

**Program Co-Chair**
Christopher P. Austin, MD
Director, National Center for Advancing Translational Sciences, National Institutes of Health (NIH)

**Keynote Address**
Daniel Burrus
President and CEO, Burrus Research Associates, Inc.
## Offering Number | Title of Offering                                                                 | Room Number     | Type of Format | Level of Difficulty | Track Number | Interest Areas | Continuing Education Credits                  |
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<tr>
<td>#140</td>
<td>BBK Worldwide Innovation Theater: Are You Patient-Centric? Why Your Answer Must Be Yes</td>
<td>Exhibit Hall (Entrance B)</td>
<td>Special Session</td>
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<td>Teuteberg Innovation Theater: Expanding Patient Recruitment Globally With Social Media</td>
<td>Exhibit Hall</td>
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### MONDAY, JUNE 15 (CONTINUED)

#### 4:15–4:45 PM

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<td>The Development of Patient Power: From Consumer to Active Participant!</td>
<td>145A</td>
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<td>#202</td>
<td>The Role of Innovation in Clinical Trial Advocacy: Developing and Executing Patient-Centered Strategies and Partnerships Throughout the Continuum</td>
<td>145B</td>
<td>FORUM</td>
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<td>#203</td>
<td>The Art and Science of Portfolio Management</td>
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<td>Centralized Ethics: How a Unique Partnership Between a CRO and an IRB Is Changing the Regulatory and Ethics Review Process</td>
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<td>A Biopharmaceutical Company/Services Provider Partnership: Value to Both Companies and Progress to Date</td>
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<td>Regulatory Examination of Nonclinical Testing Requirements and Juvenile Animal Studies</td>
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<td>Prescription Drug Marketing Regulatory Primer</td>
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<td>International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP): Will Your Company Be Ready by 2016?</td>
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<td>Pediatric Therapeutic Development: From Policy to Portfolios to Patients</td>
<td>146B</td>
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<td>FDA GCP Compliance and Enforcement Updates</td>
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<td>Learning By Doing: Regulatory Applications for Breakthrough Therapies</td>
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### Meeting Schedule

#### Turbo offering: ● Basic-level content; ■ Primarily intermediate-level content; ◆ Primarily advanced-level content

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<td>TUESDAY, JUNE 16 (CONTINUED)</td>
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<tr>
<td>9:00 AM–4:00 PM</td>
<td>Professional Poster Session #1, Exhibit Hall (Entrance A) see page 104 for more details</td>
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| 9:30–10:30 AM  | #224 Tuesday Oral Presentations—Professional Poster Session 1A  
See page 51 for presentation titles and times. | Exhibit Hall (Entrance A) | SYMPOSIUM | Level: ● Track 21 | No CE available |
<p>| 9:45–10:15 AM  | #225 Covance Innovation Theater: Advances in Risk-Based Monitoring: Transforming Drug Development Through Efficient Workflows, Big Data and Elegant Software | Exhibit Hall (Entrance B) | Special Session | Level: ■ Track 20 | CR, IT | No CE available |
| 10:30 AM–12:00 PM | #226 How Pharmaceutical Companies Can Engage Responsibly with Patients Online | | FORUM | Level: ■ Track 01 | PT | No CE available |
| 10:30 AM–12:00 PM | #227 Better Team Performance in Drug Development: Effective Relationship Building Across Cultures, Especially the West and Asia | | FORUM | Level: ● Track 02A | PETD | CME, IACET, RN |
| 10:30 AM–12:00 PM | #228 Recent Trends in Facilitating Decision Making in Drug Development | | FORUM | Level: ◆ Track 02B | RD, PM | CME, IACET, RN |
| 10:30 AM–12:00 PM | #229 Taking the Pulse of Outsourcing Relationship Structures and Their Impact | | FORUM | Level: ◆ Track 03 | OS, CS | CME, IACET, RN |
| 10:30 AM–12:00 PM | #230 Navigating Complex Biological and Regulatory Pathways to Bring Novel Gene and Cell Therapies to the Clinic | | FORUM | Level: ■ Track 04 | NC, RA | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #231 FDA Enforcement Update: Advertising and Promotion | | FORUM | Level: ■ Track 05 | RA | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #232 Efficient Authoring of Submission Documents | | SYMPOSIUM | Level: ● Track 06 | MW | CME, IACET, RN |
| 10:30 AM–12:00 PM | #233 FDA Study Data Technical Conformance Guide (Part 1 of 2): An Overview | | SESSION | Level: ■ Track 07A | CDM, RA | CME, IACET, RN |
| 10:30 AM–12:00 PM | #234 How to Trust Data from Wearable Devices Used in Clinical Trials | | SESSION | Level: ● Track 07B | VA, CR, MDD | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #235 Good Regulatory Practice (GRP): A Regulatory Affairs Quality System for the 21st Century | | SESSION | Level: ■ Track 08A | OS, CR | CME, IACET, RN |
| 10:30 AM–12:00 PM | #236 The State of Pediatric Research in the United States | | SESSION | Level: ■ Track 08B | CR | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #237 Impact of FDA Oversight of Laboratory-Developed Tests Upon Innovation in the Targeted Therapy Setting | | FORUM | Level: ■ Track 09 | RA, MDD | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #238 Risk-Based Quality Management in Clinical Trials: From the Vision to Its Regulation and Implementation | | SESSION | Level: ■ Track 11 | CR, RA | CME, IACET, RN |
| 10:30 AM–12:00 PM | #239 Office of Pharmaceutical Quality Update | | FORUM | Level: ■ Track 12 | RA | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #240 Breakthrough Medicines or Affordable Health Care: Do We Have to Choose? | | FORUM | Level: ■ Track 13 | RD, PR, CR | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #241 21st Century Pharmacovigilance: Improving Outcome Traceability for Products Across the Complexity Continuum, From Generics to Biologics and Vaccines | | FORUM | Level: ■ Track 14 | NC, RA | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #242 The Use of Adaptive and Bayesian Approaches in Clinical Trials: Sharing Experiences and Case Studies | | FORUM | Level: ● Track 15 | CR | ACPE, CME, IACET, RN |
| 10:30 AM–12:00 PM | #243 Networking: It's Not What You Know, But Who You Know! | | WORKSHOP | Level: ● Track 16 | PETD | IACET |
| 10:30 AM–12:00 PM | #244 Rare Disease Organizations and Industry Players: Collaborating Effectively to Advance R&amp;D for Rare Disease Patients | | SESSION | Level: ■ Track 17 | RD, CR | CME, IACET, RN |
| 10:30 AM–12:00 PM | #245 FDA’s International Posts: International Efforts, Regulatory System Strengthening and Inspections | | FORUM | Level: ■ Track 18 | RA, CR | ACPE, CME, IACET, RN |</p>
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**TUESDAY, JUNE 16 (CONTINUED)**

**11:35 AM – 1:30 PM**

**12:00 – 12:45 PM**

**12:30 – 12:45 PM** Student Poster Award Ceremony, DIA Booth #1523

**1:00 – 1:30 PM**

**1:30 – 3:00 PM**

**The content noted on this page was made available to DIA as of April 24.**

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<td>BBK Worldwide Innovation Theater: mHealth: Enhanced Engagement + Better Data = Improved Outcomes</td>
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<td>Bringing Clinical Trial Practices into the 21st Century</td>
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<td>Pediatric Clinical Trials: One Size Does Not Fit All</td>
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<td>How Biomarkers Can Be Leveraged to Improve Return on Investment in Drug Development</td>
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<td>Progress Report on Emerging Nations and Regulatory Capacity Building</td>
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<td>Managing Protocol Deviations: Applying the Protocol Deviations Working Group SOP for Handling Protocol Deviations in Clinical Trials</td>
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### TUESDAY, JUNE 16 (CONTINUED)

#### 8:00–9:30 AM

| #301            | Leveraging Diverse Patient Insights                      | 146A        | SYMPOSIUM      | Level: ▼           | Track 01A    | PT, CR            | ACPE, CME, IACET, RN          |
| #302            | Patient Registries: Design, Development, and Recruitment | 147A        | WORKSHOP       | Level: ○           | Track 01B    | PT, CR            | ACPE, CME, IACET, RN          |
| #303            | Keys to Managing a Successful Regulatory Strategy and Submission | 101         | FORUM          | Level: ◆           | Track 02     | RA, SUBS          | CME, IACET, RN               |
| #304            | How to Make a Strategic Partnership Model Work at the Country/Site Level in Asia Pacific and Insight from a Regulatory Inspector | 150A        | SESSION        | Level: ■           | Track 03A    | CR, SP            | CME, IACET, RN               |
| #305            | Transforming Industry Through Centralization of Key Business Practices: A Focus on Prequalification of Niche Suppliers | 152A        | FORUM          | Level: ■           | Track 03B    | OS, IT            | CME, IACET, RN               |
| #306            | Innovative Approaches to Predictive Clinical Safety and Signal Detection Utilizing Clinical Pharmacology Concepts | 103A        | SESSION        | Level: ■           | Track 04     | PC, CP            | ACPE, CME, IACET, RN          |
| #307            | Returning Results to Study Participants: Health Literacy and Effective Language | 206         | SESSION        | Level: ■           | Track 06     | MC, RA            | ACPE, CME, IACET, RN          |
| #308            | CDISC SHARE Repository: Laying the Tracks and Building the Stations for This New Metadata Train | 201         | SESSION        | Level: ■           | Track 07A    | CDM               | CME, IACET, RN               |
| #309            | Mapping the Future for Trial Master File: Advancing Standards by Harmonizing Clinical and Technical Strengths | 202B        | SESSION        | Level: ■           | Track 07B    | DM, CR            | CME, IACET, RN               |
| #310            | Recent Experiences with Adaptive Licensing and Facilitated Regulatory Pathways | 150B        | FORUM          | Level: ■           | Track 08A    | CR                | CME, IACET, RN               |
| #311            | Update: FDA CDER’s Progress to Adapting Standardized Data to Select Clinical Sites for Inspection | 151A        | SESSION        | Level: ■           | Track 08B    | SUBS, CR          | CME, IACET, RN               |
| #312            | 21st Century Cures: Which Are the Most Transformative Provisions and How Do They Accomplish Major Change? | 143ABC       | FORUM          | Level: ▼           | Track 10     | RA                | ACPE, CME, IACET, RN          |
| #313            | Changes in Regulations That May Impact How Inspections Are Conducted: Regulatory Perspectives | 102AB       | SESSION        | Level: ■           | Track 11     | RA                | CME, IACET, RN               |
| #314            | Challenges in Managing Global Regulatory Divergence | 151B         | FORUM          | Level: ■           | Track 12     | QC, RA            | CME, IACET, RN               |
| #315            | Real-World Use of Multi-Criteria Decision Analysis for Benefit-Risk Assessment: Lessons Learned in the Industrial Setting | 209AB       | SESSION        | Level: ■           | Track 13     | CEHTAeM           | ACPE, CME, IACET, RN          |
| #316            | Pharmacovigilance Concerns with the Use of Experimental Medicines for Ebola and Enterovirus B-68 | 103B        | SESSION        | Level: ■           | Track 14     | RA, CR            | ACPE, CME, IACET, RN          |
| #317            | Benefit-Risk Assessment of Medicines: Three Perspectives on Current Methodologies and the Statistician’s Role in Implementation | 204BC       | SESSION        | Level: ○           | Track 15     | ST                | ACPE, CME, IACET, RN          |
| #318            | Rare Diseases and Subgroups Defined by Tumor Evolution: Common Themes and Challenges | 145B        | SESSION        | Level: ■           | Track 17     | CR, BT            | ACPE, CME, IACET, RN          |
| #319            | The Impact of the eLabeling Rule on Industry and Stakeholders | 207A         | FORUM          | Level: ■           | Track 19A    | RA                | ACPE, CME, IACET, RN          |
| #320            | The Future of Clinical Trial Data Sharing | 146B         | FORUM          | Level: ■           | Track 19B    | CR, RA, IT        | CME, IACET, RN               |

### 9:00 AM–4:00 PM

**PROFESSIONAL POSTER SESSION #2, Exhibit Hall (Entrance A)**

### 9:30–10:30 AM

| #321            | Wednesday Oral Presentations—Professional Poster Session 2A See page 76 for presentation titles and times. | Exhibit Hall (Entrance A) | SYMPOSIUM | Level: ○ | Track 21 | No CE available |
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#### 9:45–10:15 AM

| #322             | SAS Institute Inc., JMP Division Innovation Theater: Benefit and Risk Signal Detection in Clinical Trials | Exhibit Hall (Entrance B) | Special Session | Level: ■ Track 20 | CP, CR | No CE available |

#### 10:30 AM–12:00 PM

| #323             | Direct-to-Patient Strategies That Are Changing the Landscape of Clinical Trials | 147A WORKSHOP | Level: ■ Track 01A | CR | CME, IACET, RN |
| #324             | Putting It All Together: A Shared, Comprehensive, Integrated Global System for Clinical Research | 102AB FORUM | Level: ◆ Track 01B | CR, PM | ACPE, CME, IACET, RN |
| #325             | Incremental Innovation: How to Strategically and Practically Move Innovative Ideas into Action Within Your Company and Research Programs △ | 101 SESSION | Level: ■ Track 02A | SP, CR, RD | CME, IACET, RN |
| #326             | Utilizing an Effective Project Management Framework to Manage Clinical and Biopharmaceutical Projects With Better Results △ | 103B SESSION | Level: ■ Track 02B | FI, CR | CME, IACET, PMI, RN |
| #327             | Emerging and Mid-Sized Biopharmaceutical Companies Building Successful CRO Relationships: Overcoming the Challenges by Applying Alliance Management Principles and Technology | 150A FORUM | Level: ◆ Track 03 | CR, IT | CME, IACET, RN |
| #328             | Implications of Clinical Test Result and ECG Variability on the Design, Conduct, and Interpretation of Early Phase Clinical Studies | 103A SESSION | Level: ■ Track 04 | PC, CR | ACPE, CME, IACET, RN |
| #329             | How Collective Insights of Medical Affairs Customer-Facing Teams Work to Inform Strategy | 206 SESSION | Level: ■ Track 06 | MC | ACPE, CME, IACET, RN |
| #330             | Electronic Standardized Data in Regulatory Submissions | 201 SESSION | Level: ■ Track 07A | CDM, SUBS | CME, IACET, RN |
| #331             | Digitization of Clinical Trials: Check the Pulse on Bringing Benefits to Patients | 202B SYMPOSIUM | Level: ■ Track 07B | EC, PT, IT | ACPE, CME, IACET, RN |
| #332             | Medicine Development and Authorization: A Patient-Centered Approach | 150B SESSION | Level: ■ Track 08A | PT | ACPE, CME, IACET, RN |
| #333             | Opening the Door to Data Transparency: What’s the Verdict? | 151A SESSION | Level: ■ Track 08B | PT, CR | ACPE, CME, IACET, RN |
| #334             | The Role of Labeling in Successful Human Factors Studies | 152A FORUM | Level: ■ Track 09 | RA, PT | ACPE, CME, IACET, RN |
| #335             | Precision Medicine: Where Is the Technology Taking Us, How Fast and Who Is Driving? | 146B FORUM | Level: ■ Track 10 | RA, CR | ACPE, CME, IACET, RN |
| #336             | Good Clinical Practice and Pharmacovigilance Issue Management and CAPA Effectiveness | 202A SESSION | Level: ■ Track 11 | CP | CME, IACET, RN |
| #337             | How Can International Guidelines Enable Global Regulatory Convergence? | 151B SESSION | Level: ■ Track 12 | RA, QC | ACPE, CME, IACET, RN |
| #338             | FDA Sentinel Initiative | 209AB SESSION | Level: ■ Track 13A | CEHTAEbM | CME, IACET, RN |
| #339             | Best Evidence Generation: Regulatory Perspectives △ | 207B SESSION | Level: ■ Track 13B | RA | ACPE, CME, IACET, RN |
| #340             | Integrated Cardiac Safety | 204BC SESSION | Level: ■ Track 14A | CR | ACPE, CME, IACET, RN |
| #341             | Pharmacovigilance Inspections: Achieving Compliance in a Global Environment | 207A SESSION | Level: ■ Track 14B | RA | CME, IACET, RN |
| #342             | The Role of the Clinical Statistician in Understanding and Using ADaM Data Standards | 145A FORUM | Level: ■ Track 15 | CR, ST | ACPE, CME, IACET, RN |
| #343             | DEVELOP Excellent Presentations to INNOVATE the Way You Communicate Information and ADVANCE Your Career | 147B WORKSHOP | Level: ■ Track 16B | CR, RA, PETD | ACPE, CME, IACET, RN |
| #344             | Orphan Drug Development Challenges: Case Studies | 145B SYMPOSIUM | Level: ■ Track 17 | CR | ACPE, CME, IACET, RN |
| #345             | Power Up! Give Your Brain a Break! | 152B FORUM | Level: ● Track 19 | PETD | No CE available |
## Meeting Schedule

**Turbo offering:** ● Basic-level content; ■ Primarily intermediate-level content; ◆ Primarily advanced-level content

### WEDNESDAY, JUNE 17 (CONTINUED)

#### 11:35 AM–1:30 PM

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<td>SAS Innovation Theater: Accelerate Value-Based Drug Development With Analytics</td>
<td>Exhibit Hall (Entrance B)</td>
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<td>Quintiles Innovation Theater: Driving Better Decision-Making with Real-World Data and Analytics</td>
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<td>Special Session</td>
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#### 1:30–3:00 PM

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<td>146C</td>
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<td>CR, CP</td>
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<td>#350</td>
<td>Is Facebook Hurting Your Trial? Social Media and the Introduction of Bias in Clinical Studies</td>
<td>146A</td>
<td>SESSION</td>
<td>■ Track 01B</td>
<td>CR</td>
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<td>#351</td>
<td>Project Management in Context: Reflections on the Project Manager Role from Other High-Risk Industries</td>
<td>101</td>
<td>SESSION</td>
<td>■ Track 02A</td>
<td>PETD</td>
<td>CME, IACET, PMI, RN</td>
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<td>#352</td>
<td>Issue Resolution in Clinical Partnerships</td>
<td>103B</td>
<td>FORUM</td>
<td>■ Track 02B</td>
<td>CR</td>
<td>CME, IACET, RN</td>
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<td>#353</td>
<td>The Voice of the Sites: Collaborating to Build a Site Partnership Model to Enable Study Start-Up</td>
<td>150A</td>
<td>FORUM</td>
<td>■ Track 03</td>
<td>CR</td>
<td>CME, IACET, RN</td>
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<td>#354</td>
<td>Effective Discovery, Development and Use of Biomarkers in Early Drug Development</td>
<td>103A</td>
<td>SYMPOSIUM</td>
<td>■ Track 04</td>
<td>NC, CR</td>
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<td>#355</td>
<td>Globalization of Field Medical Science Liaisons: How to Take It to the Next Level</td>
<td>206</td>
<td>SESSION</td>
<td>■ Track 06</td>
<td>MSL</td>
<td>ACPE, CME, IACET, RN</td>
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<td>#356</td>
<td>Searching for the Gold Nuggets: Text Analysis in Clinical Data</td>
<td>201</td>
<td>SESSION</td>
<td>■ Track 07A</td>
<td>IT, CDM, SE</td>
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<td>#357</td>
<td>Frontier Issues in Electronic Information Integrity Today</td>
<td>202B</td>
<td>SYMPOSIUM</td>
<td>■ Track 07B</td>
<td>VA, IT</td>
<td>CME, IACET, RN</td>
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<td>#358</td>
<td>Expediting Drug Development Through FDA’s Breakthrough Therapy Designation</td>
<td>150B</td>
<td>SESSION</td>
<td>■ Track 08A</td>
<td>CR, PPLC</td>
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<td>#359</td>
<td>Does Bioequivalent Always Mean Therapeutically Equivalent? Impact of FDA’s Proposed Rule on Generic Labeling</td>
<td>151A</td>
<td>SESSION</td>
<td>● Track 08B</td>
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<td>#360</td>
<td>Regulatory Framework for Medical Devices in Europe</td>
<td>152A</td>
<td>SESSION</td>
<td>■ Track 09</td>
<td>MDD, CR, CP</td>
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<td>#361</td>
<td>The Challenges, Solutions and Right To Try Surrounding Expanded Access</td>
<td>146B</td>
<td>FORUM</td>
<td>■ Track 10</td>
<td>CR, RA</td>
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<td>#362</td>
<td>Using Data Analytics to Detect Quality Issues</td>
<td>202A</td>
<td>SESSION</td>
<td>■ Track 11</td>
<td>CR</td>
<td>CME, IACET, RN</td>
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<td>#363</td>
<td>Risk-Based Inspections and Compliance</td>
<td>151B</td>
<td>FORUM</td>
<td>■ Track 12</td>
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<td>#364</td>
<td>Operationalizing the Pragmatic Clinical Trial: The Role of PCORI and the Pharmaceutical Industry</td>
<td>209AB</td>
<td>SESSION</td>
<td>● Track 13</td>
<td>CR</td>
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<td>#365</td>
<td>A Proactive and Systematic Approach to Managing Product Risk Across the Life Cycle</td>
<td>204BC</td>
<td>SESSION</td>
<td>■ Track 14A</td>
<td>RD</td>
<td>ACPE, CME, IACET, RN</td>
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<tr>
<td>#366</td>
<td>Measuring the Impact of Regulatory Pharmacovigilance in Europe and the United States</td>
<td>207A</td>
<td>SESSION</td>
<td>■ Track 14B</td>
<td>RA</td>
<td>CME, IACET, RN</td>
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<tr>
<td>#367</td>
<td>Big and MultiStream Data for Drug Evaluation: The Promise and Cautions</td>
<td>145A</td>
<td>FORUM</td>
<td>■ Track 15</td>
<td>CP, CR</td>
<td>CME, IACET, RN</td>
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<td>#368</td>
<td>Conducting Courageous Conversations as a Strategy to Work with Difficult People</td>
<td>147A</td>
<td>WORKSHOP</td>
<td>■ Track 16A</td>
<td>PETD</td>
<td>ACPE, CME, IACET, RN</td>
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<tr>
<td>#369</td>
<td>Using Games and Play to Create an Innovative Learning Experience</td>
<td>147B</td>
<td>WORKSHOP</td>
<td>● Track 16B</td>
<td>PETD</td>
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<td>#370</td>
<td>A Global Update on Orphan Drugs</td>
<td>145B</td>
<td>SYMPOSIUM</td>
<td>□</td>
<td>Track 17</td>
<td>RA</td>
<td>ACPE, CME, IACET, RN</td>
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<tr>
<td>#371</td>
<td>CBER Town Hall: Innovation and Public Health Response</td>
<td>152B</td>
<td>FORUM</td>
<td>□</td>
<td>Track 18</td>
<td>RA</td>
<td>ACPE, CME, IACET, RN</td>
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<tr>
<td>#372</td>
<td>No More Crying Wolf: FDA Issues Final Rule on Changes to Pregnancy and Lactation Information in Drug Labeling</td>
<td>207B</td>
<td>SESSION</td>
<td>□</td>
<td>Track 19A</td>
<td>RA</td>
<td>ACPE, CME, IACET, RN</td>
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<td>#373</td>
<td>TransCelerate Collaboration: Harmonization Efforts to Find Solutions to Critical Industry Challenges</td>
<td>102AB</td>
<td>SESSION</td>
<td>○</td>
<td>Track 19B</td>
<td>CR</td>
<td>CME, IACET, RN</td>
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**2:30–3:10 PM**

- #374 Wednesday Oral Presentations—Professional Poster Session 2C See page 90 for presentation titles and times. Exhibit Hall (Entrance A) SYMPOSIUM Level: ○ Track 21 No CE available

**3:00–3:30 PM**

- #375 SIGNiX Worldwide Innovation Theater: Formula One Study Start-up: How To Get a 94% Reduction in Time By Going Paperless Exhibit Hall (Entrance B) Special Session Level: ○ Track 20 IT, DM, CR No CE available

**3:30–5:00 PM**

- #376 Best Practices for Effective Engagement with Patient Groups Around Clinical Trials 146C FORUM Level: ○ Track 01A PT, CR CME, IACET, RN
- #377 Optimizing Investigative Site/Country Selection Using Online Feasibility Tools, Big Data, and Disruptive Technologies 146A SYMPOSIUM Level: □ Track 01B RD, CR CME, IACET, RN
- #378 Pediatric Product Development in the 21st Century: Developing Research Networks to Get the Job Done 101 FORUM Level: □ Track 02 RD, PPLC CME, IACET, RN
- #379 Outing Innovation: How Partnerships Help (and Hinder) the Movement Toward Novel Approaches to Clinical Development 150A FORUM Level: □ Track 03 OS, CR CME, IACET, RN
- #380 Accountable Care Organizations and Integrated Health Care 206 SESSION Level: □ Track 06 CEHTAEbM, MC, MSL ACPE, CME, IACET, RN
- #381 CFAST Initiative: Potential to Dramatically Increase ROI and Reduce Timelines in the Conduct of Clinical Trials 201 SESSION Level: ○ Track 07A CDM, PM CME, IACET, RN
- #382 The Critical Role of Document Management Supporting Submissions: Regulatory Operations, IT and Vendor Perspectives △ 202B SESSION Level: □ Track 07B SUBS, RA, IT CME, IACET, RN
- #383 Dynamic Changes in Regulatory Landscape in Asia: Regulations for Global Drug Development 151A SESSION Level: □ Track 09 CR, RD CME, IACET, RN
- #384 Enhanced Collaborative Strategies: FDA and Device Makers Focusing on Improved Device Clearance Processes 152A SESSION Level: ○ Track 09 MDD, RA ACPE, CME, IACET, RN
- #385 Enforcement Update and Trends From a Global Perspective 146B FORUM Level: □ Track 10 RA ACPE, CME, IACET, RN
- #386 Adapting Risk Management Principles to Nontraditional R&D Settings 202A SESSION Level: ○ Track 11 RD, BT, CR CME, IACET, RN
- #387 Knowledge Management for the Product Life Cycle 151B SESSION Level: □ Track 12 MF, PM CME, IACET, RN
- #388 Making Evidence at Launch More Real-World: Pragmatic Trials, Current Developments and Operational Challenges 147B WORKSHOP Level: □ Track 13 CR ACPE, CME, IACET, RN
- #389 Developing Innovative Approaches to Postmarketing Safety Data Collection in Pregnant Women 204BC SESSION Level: □ Track 14A RA, CR ACPE, CME, IACET, RN
- #390 CIOMS IX: Practical Approaches to Risk Minimization and Its Evaluation 207A SESSION Level: □ Track 14B RA CME, IACET, RN
- #391 Statistical Support of Risk-Based Monitoring 145A SESSION Level: □ Track 15 CR, ST ACPE, CME, IACET, RN
- #392 Speaking and Publishing Opportunities with DIA 147A WORKSHOP Level: ○ Track 16 PETD IACET
- #393 Rare Diseases: Patients, Caregivers and Advocates as Equal Partners in Clinical Trial Process △ 145B FORUM Level: □ Track 17 PETD, CR CME, IACET, RN
# Offering Number | Title of Offering | Room Number | Type of Format | Level of Difficulty | Track Number | Interest Areas(s) | Continuing Education Credits
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#394 | Asia Town Hall: Asia as a Drug R&D Center in the World | 152B | SESSION | Level: ■ | Track 18A | RA, RD | CME, IACET, RN
#395 | The State of Informatics at CDER and CBER | 207B | FORUM | Level: ■ | Track 18B | IT, CDM, SUBS | CME, IACET, RN

**THURSDAY, JUNE 18**

**9:00–10:30 AM**

#401 | Lung-Map: A Future Clinical Trial with a Master Protocol Happening Now and the Value to Patients △ | 152A | SESSION | Level: ■ | Track 01A | PT, CR | ACPE, CME, IACET, RN
#402 | The Ultimate in Patient-Centered Trials: Bringing Study Visits into the Home △ | 145B | SESSION | Level: ■ | Track 01B | PT, CR | CME, IACET, RN
#403 | Survey Results: How Project Managers Leverage Tools and Techniques | 147A | WORKSHOP | Level: ■ | Track 02 | CR, RD | CME, IACET, PMI, RN
#404 | Innovations in Strategic Alliances and Overcoming Obstacles | 150A | SYMPOSIUM | Level: ■ | Track 03 | CR, PM | CME, IACET, RN
#405 | Tired of Reinvesting in Old R&D Systems? Several Large Pharmaceutical Companies and Other Leaders Are Flipping Paradigms | 146B | FORUM | Level: ● | Track 07A | IT, RD | ACPE, CME, IACET, RN
#406 | Bring Your Own Device (BYOD) Approaches to the Collection of Electronic Patient-Reported Outcome Data in Clinical Trials | 150B | SESSION | Level: ■ | Track 07B | SE | ACPE, CME, IACET, RN
#407 | Accidental Drugs: A Historical Look at How Certain Drugs Came to Market and Policy Pathway Opportunities | 151A | SESSION | Level: ■ | Track 08 | PPLC | ACPE, CME, IACET, RN
#408 | Novel Data Sources and Tools for Pharmacovigilance △ | 151B | SESSION | Level: ■ | Track 14 | EC, IT | CME, IACET, RN
#409 | Innovative Designs for Cardiovascular Outcome Safety Trials in Type 2 Diabetes | 145A | SESSION | Level: ■ | Track 15 | CR, ST | ACPE, CME, IACET, RN
#410 | Aha: Moments of Breakthrough Thinking Leading to New Opportunities △ | 152B | FORUM | Level: ● | Track 16 | PETD | ACPE, IACET
#411 | An Insider’s View of Cooperation Between the EMA and CDER/FDA: Question Time | 143ABC | FORUM | Level: ■ | Track 18 | RA, CP, CMC/GMP | CME, IACET, RN

**10:45 AM–12:15 PM**

#413 | DEVELOP Risk-Based Monitoring Strategies to INNOVATE Study Oversight and ADVANCE Study Execution | 145B | FORUM | Level: ■ | Track 01 | CR, RD | ACPE, CME, IACET, RN
#414 | A Systematic Approach to Study Start-Up △ | 145A | SESSION | Level: ■ | Track 02 | SP, CR | CME, IACET, RN
#415 | Just the Facts: A Model for Evaluating the ROI of Outsourcing Investigator Payments | 150A | FORUM | Level: ■ | Track 03 | OS, FI, AHC/IS | CME, IACET, PMI, RN
#416 | mHealth / mClinical and Clinical Trials: A Candid Discussion on Opportunities and Risks | 146B | SESSION | Level: ■ | Track 07 | EC, CR, RA | CME, IACET, RN
#417 | Global Developments in the Regulation of Biological Therapeutics | 151A | SESSION | Level: ■ | Track 08 | CR, BT | CME, IACET, RN
#418 | The Future of Pharmacovigilance Operations | 151B | FORUM | Level: ■ | Track 14 | IT, PM | ACPE, CME, IACET, RN
#419 | Making Technology a Key Component of Your Learning Strategy △ | 150B | SESSION | Level: ■ | Track 16 | IT, PETD | ACPE, CME, IACET, RN
#420 | CDER Town Hall | 143ABC | FORUM | Level: ■ | Track 18 | RA, CR | ACPE, CME, IACET, RN
#421 | Leveraging Electronic Health Record Data in Close Collaboration with Health Systems to Accelerate Precision Medicine △ | 146C | FORUM | Level: ■ | Track 19 | CEHTAEbM | ACPE, CME, IACET, RN

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- Drug Safety
- Regulatory Requirements
- Premarketing
- Clinical Trial Safety
- Postmarketing
- Safety Management
- Basics of Signal Detection and Pharmacoepidemiology
- Safety Audits and Inspections
The following agenda details were made available to DIA on April 24. Speaker names identified as “Invited” will be published once confirmation and disclosure forms are completed.

● Basic-level content; ■ Primarily intermediate-level content; ◆ Primarily advanced-level content

SUNDAY, JUNE 14

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 2015 51st Annual Meeting Orientation/Networking

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

SATURDAY JUNE 13

Registration Hours:
9:00 AM–5:00 PM  Exhibitor Registration

SUNDAY, JUNE 14

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:
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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 2015 51st Annual Meeting Orientation/Networking

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

MONDAY, JUNE 15

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

Schedule:
7:30–8:20 AM  DIA 2015 51st Annual Meeting Orientation/Networking and Coffee
7:45–8:30 AM  Coffee and Breakfast Breads
8:30–10:00 AM  Educational Opportunities
8:30–10:00 AM  Student Forum
9:30 AM–4:30 PM  Student Poster Session (Exhibit Hall Entrance A)
9:30 AM–6:00 PM  Exhibit Hall Open
10:00–11:00 AM  Coffee Break
11:00 AM–12:30 PM  Educational Opportunities
12:30–2:30 PM  Lunch (Exhibit Hall)
2:30–4:00 PM  Innovation Theater Presentations (Exhibit Hall Entrance B)
2:30–4:00 PM  Plenary Session & Keynote Address

Keynote Address
Daniel Burrus
President and CEO, Burrus Research Associates, Inc.

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

#101 Track 01A – Clinical Operations

Related Interest Area(s): FI, PT

Format: SESSION

8:30–9:30 AM  CME and Nursing
Room 145A

Patient-Centricity: Buzzword or Method to Improve Operational Efficiency?

Chairperson
James Kremidas
Lead Investigator, CenterWatch

In this session, we will review real world data recently collected regarding the use of patient-centric approaches to clinical trial execution. Our goal is to define return on investment measures and share best practices.

Optimizing Patients and Sites Input to Accelerate Milestones
Victoria DiBlaso, MPH, RN
Associate Vice President, Head of Patient Participation & Preferred Partnerships, Genzyme Corporation, A Sanofi Company

Patient-Centricity: Painting the Landscape and Building the Framework
Jane E. Myles, MS
Global Head, Recruitment Strategy, Genentech, A Member of the Roche Group

The following agenda details were made available to DIA on April 24. Speaker names identified as “Invited” will be published once confirmation and disclosure forms are completed.

● Basic-level content; ■ Primarily intermediate-level content; ◆ Primarily advanced-level content

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The content noted on this page was made available to DIA as of April 27.
#102 Track 01B – Clinical Operations

Related Interest Area(s): CR, RD

8:30-10:00 AM  
Room 145B

Next Generation Feasibility: How to Predict the Unpredictable and Plan for Success

CHAIRPERSON
Ira Charles Spector, PhD, MBA
Executive Vice-President, Analytics and Consulting, ICON Clinical Research

The use of data analytics provides a significant opportunity to change site selection from previous traditional approaches. The application of algorithmic methods to identifying sites, based on their likelihood to enroll and retain subjects and contribute valid results will be discussed.

Panelists
- P Is for Patients as Well as for P Values, But Site Performance Influences Both
  Ira Charles Spector, PhD, MBA
  Executive Vice-President, Analytics and Consulting, ICON Clinical Research

- Data-Driven Study Feasibility Assessment and Impact on Successful Execution of Clinical Trial Protocols
  William W. Gwinn, Jr., MBA
  Vice President, Clinical Informatics Solutions, Optum

- Feasibility for Clinical Trials in Acute Conditions: How to Predict the Unpredictable and Plan for Success
  Rachel Wilder McCorkie
  Associate Feasibility Manager, Quintiles Inc.

- Next Generation Feasibility Analysis: Using a Data-Driven Approach to Ensure Accurate and Predictable Outcomes
  Otis Johnson, MPA
  Vice President, Clinical Research Services, Clinical Trial Recruitment Solutions, inVentiv Health

#103 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, CR

8:30-10:00 AM  
Room 101

Project Management of Adaptive Trials: Infrastructure and Methodology

CHAIRPERSON
Patrick Phillips
Vice President, Clinical Affairs, Health Decisions

This forum will identify critical issues and success factors in management of adaptive trials, including requirements for streaming information to enable the decision making at the heart of all adaptive design techniques.

Panelists
- Platform Trials and Bayesian Adaptive Designs
  Donald A. Berry, PhD
  Professor, Department of Biostatistics, The University of Texas

- Enabling Dose Response Adaptive Trials
  Tom Parke
  Consultant, Tessella, United Kingdom

- Industry Perspective
  Judith Quinlan, MSc
  Vice President, Innovations Center, ICON Clinical Research

#104 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): SP

8:30-9:30 AM  
Room 150A

Adventures in Strategic Planning: Is the Functional Service Provider Model Dead?

CHAIRPERSON
Andrew Townshend
Vice President, Alliance Development, INC Research

Strategic partnerships, alliances, preferred partnerships and functional service provider (FSP) partnerships are interpreted differently. This forum will discuss whether the advent of broader alliances and strategic partnerships mean the end of FSP outsourcing in the industry.

Panelists
- Thomas Verish, MS
  Group Director, Data Operations, Bristol-Myers Squibb Company

- Bev Paperiello
  Senior Director, Clinical Program Management, Astellas Pharma Global Development

#105 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

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

8:30-10:00 AM  
Room 103B

In Vitro and In Vivo Preclinical Testing of Biosimilars: What Have We Learned?

CHAIRPERSON
David R. Jones, MS
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

This session will examine the nonclinical requirements for the safety assessment of biosimilars. We will also review EU and US regulatory requirements and efforts to harmonize approaches.

Panelists
- Introduction to Biosimilars and Global Regulatory Guidelines
  David R. Jones, MS
  Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

  Iris Grossman, PhD
  Vice President, Global Head of Personalized Medicine and Pharmacogenomics, Teva Pharmaceutical Industries Ltd., Israel

- Animal Studies With Biosimilars: Where Do We Stand?
  Paul Baldrick, PhD
  Executive Director, Covance Laboratories Ltd., United Kingdom
**#106 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons**

**8:30–10:00 AM**  
**Room 206**  
**Format: Session**

**Level: MC**  
**CME, Pharmacy, and Nursing**

**Communicating Pharmaceutical Risks and Benefits: Why Is It So Hard and How Can We Do Better?**

**Chairperson**  
Jonathan Palmer

**Principal Consultant, Pharmacovigilance and Drug Safety, NDA Group, United Kingdom**

Pharmaceuticals are developed for patients who behave according to perceptions, not just facts, about medicines. How should we respond to demands for higher quality information, greater openness and transparency with round-the-clock media scrutiny? What is the role of trust and how can we strengthen trustworthiness in communication? How should the evidence behind good communication impact regulatory processes? How can we assess whether communication is effective in changing behavior? Questions like these will be discussed in this forum as we aim to address this core risk minimization activity for any pharmaceutical organization.

**Risk Communication: Time For a New Approach Yet Again**

Brian David Edwards, MD, MRCP  
Principal Consultant, Pharmacovigilance and Drug Safety, NDA Group, United Kingdom

**Communicating Benefits and Risks of Medicines: Challenges and Opportunities**

Dinah Duarte, PharmD, MSc  
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

**Risk-Benefit Communications of Medicines Based on Advances in Cognitive Behavioral Science Research**

Sweta Chakraborty, PhD  
Associate Director, Institute on Science for Global Policy (ISGP)

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**#107 Track 07A – Technology/Data/Records and Submissions**

**8:30–10:00 AM**  
**Room 201**  
**Format: Session**  
**Level: EC, IT, RD**  
**CME and Nursing**

**How Pharmaceutical Companies and CROs Are Harnessing Big Data and Cloud Computing to Increase R&D Innovation, Efficiency, and Collaboration**

**Chairperson**  
Jonathan Palmer

**Senior Director, Product Strategy, Clinical Warehousing and Analytics, Oracle Health Sciences, United Kingdom**

This session explores new enabling technology and approaches that can help trial sponsors and clinical research organizations (CRO) fundamentally change, adapt and collaborate more effectively. Speakers will share opportunities, use cases, and vision in areas such as data integration, clinical warehousing, cloud, big data, wearable devices, ‘omics’, and analytics to illustrate innovative ways to accelerate clinical development, drive new science, and enable new dynamic business models.

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**#108 Track 07B – Technology/Data/Records and Submissions**

**8:30–10:00 AM**  
**Room 202B**  
**Format: Session**  
**Level: EC, IT**  
**CME and Nursing**

**How Sponsors Are Solving the Unique Data Collection Challenges of Late-Stage Studies**

**Chairperson**  
Jennifer Bush, MS

**Director, Life Sciences Product Strategy, Oracle Health Sciences**

Today’s eClinical suites are primarily focused on phase 2–3 research needs. This session will provide an overview of eClinical needs specific to late-stage studies and discuss how and why those needs differ from phase 2–3 research needs.

**Solving Unique Data Collection Challenges**

Sean D. Kennedy  
Executive Director/Principal, Late Stage Scientific Affairs, Real World Evidence, inVentiv Health

**Unique Data Collection Challenges of Late-Stage Studies**

John Reites  
Senior Director, Product and Strategy, Health Engagement and Communications, Quintiles Inc.

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**#109 Track 08 – Regulatory Affairs**

**8:30–10:00 AM**  
**Room 150B**  
**Format: Forum**  
**Level: CR**  
**CME and Nursing**

**Forward Progress Through Collaboration: Internal and External to the FDA**

**Chairperson**  
Kevin Bugin, MS, RAC

**Senior Regulatory Health Project Manager, Office of New Drugs, CDER, FDA**

The FDA’s Center for Drug Evaluation and Research utilizes multiple processes and methods to collaborate. This forum will review select processes and provide a forum to discuss case studies in which a high level of collaboration was achieved.

**Internal Consultative or Collaborative Reviews at FDA**

Patricia Y. Love, MD, MBA  
Deputy Director, Office of Combination Products, Office of Special Medical Programs, Office of Medical Products and Tobacco, OMPT, FDA

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**Data-Driven Clinical: Exploiting the Digital Age**

Jonathan Palmer  
Senior Director, Product Strategy, Clinical Warehousing and Analytics, Oracle Health Sciences, United Kingdom

**Clinical Data Integration: An Unmet Need Asking for Creative Solutions**

Victor Lobanov  
Executive Director, Data Sciences, Covance Inc.

**A Walk in the Cloud: Exploring the Brave New World of Big Data**

Thomas Grundstrom, MA  
Vice President, Integrated Technology and Informatics, ICON plc

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The content noted on this page was made available to DIA as of April 27.
#110  **Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products**

**8:30–10:00 AM**  
**Room 151A**  
**Related Interest Area(s): CR, RA, MDD**  
**Format: Session**  
**CME, Pharmacy, and Nursing**

**Enabling Next Generation Sequencing Within Global Clinical Trials**

**CHAIRPERSON**  
Sabah Malek  
Associate Director, Global Regulatory Affairs, Eisai Inc.

As targeted therapies are being increasingly developed by pharmaceutical companies, there is a keen interest in identifying and stratifying patients by genetic alterations. Next generation sequencing can provide this and the ability to potentially screen high volumes of patients to be matched to trials. However, the use of next generation sequencing within these clinical trials provides its own set of challenges, including actionability of genomic information, use of local testing, utilization within clinical trials, and regulatory hurdles. All of these considerations covered within the session can influence a program’s clinical strategy and design.

**Impact of Local Testing in a Targeted Therapy Setting with Companion Diagnostic Development**

Sabah Malek  
Associate Director, Global Regulatory Affairs, Eisai Inc.

**Enabling Next Generation Sequencing within Global Clinical Trials: Clinical and Regulatory Concerns**

Douglas Robinson, PhD  
Global Head, Biomarkers and Diagnostics Biometrics, Novartis Institutes for BioMedical Research (NIBR)

**FDA Perspective**

Jennifer S. Dickey, PhD  
Regulatory Reviewer, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA

#111  **Track 10 – Public Policy/Health Care Compliance/Law**

**8:30–10:00 AM**  
**Room 146B**  
**Related Interest Area(s): RA, PT**  
**Format: Forum**  
**CME, Pharmacy, and Nursing**

**The Growing Role of the Patient Leading Into PDUFA VI: Negotiations and 2016**

**CHAIRPERSON**  
James E. Valentine, JD  
Associate, Hyman, Phelps & McNamara, PC

FDA’s Patient-Focused Drug Development (PFDD) initiative is three years old. Not only have the meetings generated a great deal of information on patients’ perspectives, but they’ve also generated a lot of questions. How can this growing body of information be translated into a useful set of data for the agency? How has the agency started incorporating these patient perspectives into regulatory decision-making, and what’s been the impact? What are the lessons learned that can inform future patient-focused efforts in PDUFA VI and beyond? Are there other models that may take shape as PFDD 2.0? How can stakeholders engage and collaborate with FDA as negotiations and stakeholder consultations move forward for PDUFA VI? These questions, and more, will be explored by FDA officials and other stakeholders involved in the PFDD initiative.

**Looking Forward for PDUFA VI: Opportunities for Patient Engagement with FDA**

Theresa M. Mullin, PhD  
Director, Office of Strategic Programs, CDER, FDA

**The Patient Perspective: Assessment of the Current Program and Future Opportunities**

Diane D. Edquist Dorman  
Rare Disease Community Consultant

**Perspective From Industry**

Mary O’Donovan, MS  
Executive Director, Biogen Idec

**FDA Perspective**

Jean M. Mulind, MD  
Senior Policy Advisor, Division of Clinical Compliance Evaluation, Office of Scientific Investigations, Office of Compliance, CDER, FDA

**Industry Perspective**

Ann Meeker-O’Connell, MS  
Head, Risk Management and External Engagement, Bio Research Quality and Compliance, Janssen Pharmaceuticals, Inc.

**Issue Management**

Leslie M. Sam  
Director, Global Quality Systems, Eli Lilly and Company
The content noted on this page was made available to DIA as of April 27.

#113  Track 12 – Pharmaceutical Quality  
Related Interest Area(s): CMC/GMP
8:30–10:00 AM  LEVEL: ■  FORMAT: FORUM
Room 151B  CME, Nursing, and PMI PDUs

**Comprehensive Control Strategy: Building Confidence in Quality**

**CHAIRPERSON**
John Groskoph, MBA
Senior Director, Global CMC, Pfizer Inc

This forum will present and facilitate discussion on the concept of control strategy and its preeminence in conveying confidence in quality. In particular, the session will highlight various control strategy approaches and their relevance for the patient, regulators, and industry.

**Panelists**
Eric Ahuja
Executive Director, Global Science Technology and Commercialization, Merck & Co., Inc.

Christine M. V. Moore, PhD
Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Paul Motchnik, PhD
Associate Director, Genentech, A Member of the Roche Group

#114  Track 14 – Clinical Safety and Pharmacovigilance  
Related Interest Area(s): RA
8:30–10:00 AM  LEVEL: ■  FORMAT: SESSION
Room 207B  CME, Pharmacy, and Nursing

**Risk Management Plans Ten Years On: Where Are We Now and Where Are We Going?**

**CHAIRPERSON**
Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

ICH E2E on pharmacovigilance planning reached step four in 2004. Since then risk management has become a key part of licensing applications in many countries. Experts will discuss evolution over the last ten years and speculate on future developments.

**Industry Perspective**
Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

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

**Industry Perspective**
Valerie E. Simmons, MD, FFPM
EU QPPV, Global Patient Safety, Eli Lilly and Company Ltd, United Kingdom

**Japan Perspective**
Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Eisai Co., Ltd., Japan

#115  Track 16 – Professional Development  
Related Interest Area(s): PETD
8:30–10:00 AM  LEVEL: ■  FORMAT: FORUM
Room 147B  CME and Nursing

**DIA 2015 Student Forum: Job Hunter’s Toolkit - Some Things Change, Some Stay the Same**

**CHAIRPERSON**
Danny Benau
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia

The main contents of the job hunter’s toolkit have been the same for decades: resume, business card, elevator speech, and networking. In addition to having the basic tools, today’s job hunter needs to have experience with the self-promotion changes made in recent years brought about by the increasing number of and newly focused electronic job boards, integrated social media sites, and the use of instant communications. Each platform offers job hunters a unique opportunity to search for jobs and more importantly to communicate job experience. Knowing the differences between the platforms is key to successfully receiving leads. This forum will explore changes that have reshaped the concept of networking and finding job openings, while incorporating and updating the job toolkit basics that are still important such as business cards and alternatives to the classical resume.

**Fun and Serious Games with Business Cards**
Danny Benau
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia

**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

**Social Media and Job Hunting**
Robin Whitsell
President, Whitsell Innovations, Inc.

**Seize Opportunities Along the Career Path**
Lisa Palladino Kim, MS
Adjunct Assistant Professor, Rutgers, The State University of New Jersey

#116  Track 18 – Global Regulatory  
Related Interest Area(s): RA, CR
8:30–10:00 AM  LEVEL: ■  FORMAT: FORUM
Room 103A  CME and Nursing

**Health Canada’s Approach to Achieve Regulatory Harmonization: An Update**

**CHAIRPERSON**
Agnes V. Klein, DrPH, MD
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

Health Canada has had a somewhat unique approach to regulating therapeutics. Over the years, Canada had interpreted the regulations in light of scientific advances, mainly because its regulations dated from the early 60’s. Most recently, however, Canada has started to modernize its regulations, particularly in ensuring that the right authorities to regulate therapeutics with a life cycle approach were to be in place. In this session, the following will be highlighted: Bill C-17 dubbed Vanessa’s Law, the current status of orphan drug regulations and the approached to be used in managing therapeutics postmarket. In all these areas, Canada has...
endeavored to be harmonized with international approaches. However, there are some unique features in how these elements are approached.

Advances and New Canadian Regulations
Agnes V. Klein, DrPH, MD
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

C-17: Protecting Canadians From Unsafe Drugs Act - Vanessa’s Law
David Edwards, JD
Senior Counsel, Health Canada

Overview of Postmarket Activities
Duc Vu, PhD
Director, Marketed Biologicals, Biotechnology, Natural Health Products
HPD, Health Canada

#117  TRACK 19A - LATE-BREAKING TOPICS

Related Interest Area(s): SP

The Emerging Role of Medical Affairs in Biopharmaceutical Organizations: Challenges and Opportunities

CHAIRPERSON
Honorio Silva, MD
President-Elect, International Federation of Associations of Pharmaceutical Physicians (IFAPP)

Medical affairs organizations within the pharmaceutical industry are emerging to provide patient and physician-centered services as part of a new business model aimed to provide value in health care. The challenges and opportunities for further growth will be analyzed.

Panelists
Richard Murray, MD
Vice President and Deputy Chief Medical Officer, Merck & Co., Inc.

Pol Vandenbroucke, MD, MBA, MS, FFPM
Regional Head Medical Affairs, North America, Pfizer Inc

Greg Koski, MD, PhD
President and CEO, Co-Founder, Alliance For Clinical Research Excellence and Safety (ACRES)

#118  TRACK 19B - LATE-BREAKING TOPICS

Related Interest Area(s): CR

Ebola Virus Disease Case Study: Global Harmonization to Increase Power and Accelerate Outcomes in Clinical Research Data

CHAIRPERSON
Shannon Labout
Vice President, Education, CDISC

Africa is ravaged by the worst outbreak of Ebola virus disease ever witnessed. This forum will discuss how catalyzed by this crisis, a global consortia is collaborating to deliver unprecedented data standardization to maximize the scientific output of collective research.

Panelists
Laura Merson
Head of Clinical Trials Unit, Oxford University Clinical Research Unit, Vietnam

Maura A. Kush
Research Assistant/Documentation Specialist, PharmaStat

Dionne Price, PhD
Director, Division of Biometrics IV, Office of Biostatistics, Office of Translational Science, CDER, FDA

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

#119  TRACK 01A - CLINICAL OPERATIONS

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

Pediatric Clinical Trials: Learning from Patients, Parents, and Investigative Sites

CHAIRPERSON
Lisa Palladino Kim, MS
Adjunct Assistant Professor, Rutgers, The State University of New Jersey

The number of pediatric drug trials is growing rapidly, but many of these trials have proven extremely difficult to enroll. Drug developers can vastly increase their chances for success by listening to and collaborating with study sites and parents/patients. This session presents best practices for engaging study sites and parents/patients as partners in the trial process.

Parents as Partners: Overcoming Unique Challenges to Recruitment and Retention
Donald Sickler
Group Account Supervisor, CAHG

Pediatric Clinical Trials: Learning from Investigative Sites
Kathryn Bohannon
Vice President, Global Project Management, inVentiv Health

International Children’s Advisory Network (iCAN): Providing a Voice for Children and Families
Charles A. Thompson
Global Lead, Pediatric Center of Excellence, Pfizer Inc

Panelist
Hadleigh Thompson
Youth Advisor, ICAN
#120  Track 01B — Clinical Operations

**Related Interest Area(s): CR, PM**

**11:00 AM–12:30 PM**
**Room 145B**
**Level: ●**
**Format: SESSION**

**The Clinical Trials Transformation Initiative Data Monitoring Committee Project: Findings and Next Steps**

**CHAIRPERSON**
Susan S. Ellenberg, PhD
Professor, Biostatistics; Associate Dean for Clinical Research, University of Pennsylvania

Findings from the Clinical Trials Transformation Initiative (CTTI) Data Monitoring Committee (DMC) Project survey and focus groups will be presented. Specific topic areas include: use, conduct, communication practices and training issues related to DMCs.

- **Introduction to the Clinical Trials Transformation Initiative Data Monitoring Committees Project**
  - Karim Calis, PharmD, MPH
  - Senior Clinical Analyst, Office of Medical Policy, CDER, FDA

- **Data Monitoring Committee Communication Practices Among Key Stakeholders**
  - Raymond P. Bain, PhD
  - Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

- **Data Monitoring Committee Qualification, Composition and Training**
  - Jane Perlmutter, PhD, MBA
  - Founder and President, Gemini Group

#121  Track 02A — Project/Portfolio Management and Strategic Planning

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

**11:00 AM–12:30 PM**
**Room 101**
**Level: ■**
**Format: FORUM**

**Codevelopment of a Drug in the Pharmaceutical Industry: Is It Ever Fun?**

**CHAIRPERSON**
Jayanthi Reddy, MBA, MS, PMP
Director and Cardiovascular Pipeline Leader, Global Project Management, Merck & Co., Inc.

A culture of collaboration with external partners is one of the key drivers of future success. This forum will focus on the challenges and barriers in codevelopment and the business models being adopted to ensure a healthy collaboration.

- **Panelists**
  - Douglas E. Wilson, PharmD
  - Alliance Director, GlaxoSmithKline
  - Karla D’Alessio, PMP
  - Executive Director, Merck & Co., Inc.
  - Elizabeth Somers, MSc, PMP
  - Director, Project Management, Icahn Institute for Genomics & Multiscale Biology, Icahn School of Medicine at Mount Sinai

#122  Track 02B — Project/Portfolio Management and Strategic Planning

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

**11:00 AM–12:30 PM**
**Room 147A**
**Level: ◆**
**Format: WORKSHOP**

**How to Achieve Value of Operational Transformation: It Requires Innovation, Process Excellence, and Adoption**

**CHAIRPERSON**
Shannon Adkins, MBA
Vice President, Service Delivery and Life Sciences, Future State

In a continuously evolving health care system, operational transformation only succeeds and delivers the anticipated value when the practices of innovation, process excellence, and adoption are integrated. Investments in new technologies, processes, and approaches can cost millions of dollars, and far too often fail. To increase your chances of success, we will examine a few case studies of operational transformation across global organizations to understand common pitfalls and challenges, and develop solutions that will drive employee engagement, adoption of new ways of working, and greater return on investment. This workshop provides the tools to success.

*Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington 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**
Samantha Forde, PMP
Head, Process Excellence Global Clinical Operations, Roche Products Limited, United Kingdom

#123  Track 03 — Innovative Partnering Models and Outsourcing Strategies

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

**11:00 AM–12:00 PM**
**Room 150A**
**Level: ○**
**Format: SESSION**

**What Contract Research Organizations Value in a Partner: Results of a Perception Survey**

**CHAIRPERSON**
Lea Studer
Vice President of Marketing Communications, SCORR Marketing

A 2014 contract research organization (CRO) perception survey rated sponsors on a number of key criteria. Based on these survey results and overall satisfaction levels, we will examine the key criteria, what is valued in a partnership from a CRO perspective, as well as insights on how CRO-sponsor relationships can be improved.

**Panelists**
- Joan Chambers
  - Chief Operating Officer, CenterWatch
- Lea Studer
  - Vice President of Marketing Communications, SCORR Marketing

The content noted on this page was made available to DIA as of April 27.
#124 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): BT, RA

11:00 AM–12:00 PM △ Level: ■ Format: SESSION
Room 103B  CME and Nursing

Next Generation Nanomedicines and Nanosimilars: Regulators’ Perspective

CHAIRPERSON
Suzanne Sensabaugh
President and Principle Consultant, HartmannWillner LLC

Recent advances in nanoscience are bringing novel opportunities to master matter at a nano-scale size, leading to the creation of even more complex, hybrid structures by both new top-down fabrication and bottom-up manufacturing techniques. This is paving the way for a wave of new pharmaceuticals, imaging agents and combination products—so called “next generation” nanomedicines. Given the degree of complexity of these products, a need to adapt current regulatory scientific requirements has been noted. In this session, we will address recent regulatory activities such as an international collaboration on guidance development of nanomedicines and nanosimilars, as well as examine regulatory strategies and harmonization in nanomedicines, particularly in the Asia Pacific region.

The Regulatory Convergence Challenge for Nanomedicines
Jo-Feng Chi
Section Chief, Medical Products Division, Taiwan Food and Drug Administration (TFDA), Taiwan

The Next Generation of Nanomedicine: FDA/CDER Perspective
Katherine Tyner, PhD
Chemist, Office of Pharmaceutical Quality, CDER, FDA

#125 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): MC, PETD, RA

11:00 AM–12:30 PM △ Level: ■ Format: SYMPOSIUM
Room 206  CME, Pharmacy, and Nursing

Engaging Patients and Health Care Professionals Through Social Media and Big Data Systems

CHAIRPERSON
Poonam A. Bordoloi, PharmD
Senior Manager, Medical Information Services Internal Medicine and BioSurgery, Sanofi

The increase of internet-driven technologies has revolutionized medical communications and engagement of patients and health care professionals. This symposium will discuss how FDA is leveraging social media tools to reach audiences that are both diverse and segmented, providing greater opportunities to access information on FDA-regulated medical products. It will explore barriers to adoption of social media by medical information (MI) teams, and provide examples of how MI teams can provide value by embracing social media as a channel for communication and education. Lastly, we will explore and interpret interactive data visualizations demonstrating how health care professionals have adapted to new and emerging channels and how their networks of influence can be used to gain deep insight about unmet medical information needs.

#126 Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): EC, PT

11:00 AM–12:00 PM △ Level: ■ Format: SESSION
Room 201  CME, Pharmacy, and Nursing

Integrating Patient Engagement with EHR Data and eSource for Better Studies

CHAIRPERSON
Douglas Bain
Founder and Chief Executive Officer, eClinicalHealth Limited, United Kingdom

Patient engagement solutions are opening the door for the enhanced involvement of patients in a clinical trial. This session will examine the value of patient engagement, and in particular the opportunities brought by eSource and electronic health records (EHR)/electronic medical records (EMR) integration.

The Changing Landscape of EMR/EHR Clinical Data Integration with EDC Systems
Glenn Keet
Chief Executive Officer, Clinovo

Facilitating Clinical Trials Using Routinely Collected Electronic Health Records (EHR)
Tim Williams, PhD, MSc
Head of Research, The Clinical Practice Research Datalink Group (CPRD), United Kingdom

#127 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): RA, SUBS

11:00 AM–12:00 PM △ Level: ■ Format: SESSION
Room 202B  CME and Nursing

Evolving Your Regulatory Information Management Strategy to Meet the Changing Business Environment

CHAIRPERSON
Austin Nesseth
Manager, Advisory Services, Kinapse Inc.

Complexity is growing in the global regulatory environment with new regulations coming into play (regulated product submission (RPS), identification of medicinal products (IDMP), social media, etc.). Additionally, new highly virtual collaborative business models are emerging and will be common in the near future. In this session, a summary of key trends that impact a regulatory information management (RIM) strategic plan will be...
Adapting Business Process to Support Global RIMS  
Michelle L. Charles, MPH  
Associate Director, Regulatory Affairs, Merck & Co., Inc.

Evolving RIM Strategies  
Christopher P. Hanna, PhD, MSc, PMP  
Principal Kattner-Thalmann Partners

Global Drug Development in China: Opportunities and Challenges for Innovation  
CHAIRPERSON  
Joseph C. Scheeren, PharmD  
Senior Vice President, Head Global Regulatory Affairs, Pharma and Consumer Care, Bayer Consumer Care AG, Switzerland

Understanding Regulatory Laws and Policies  
Shaoyu Chen, JD  
Managing Director, China Food and Drug Practice; Partner, Covington & Burling LLP, China

Status and Requirements of Regulatory Registration for IND/NDA in China  
Daniel Liu, PhD  
Chief Scientific Officer, Beijing Clinical Service Center, China

How to Design Global Regulatory Drug Development Strategies in China  
Patrick K. Brady, PharmD  
Science and Regulatory Affairs, Pharmaceutical Research and Manufacturers of America (PhRMA)

New Pandemics: Lessons Learned from the Ebola Experience  
CHAIRPERSON  
Diane Berry, PhD  
Vice President, Global Health Policy and Government Affairs, Sarepta Therapeutics

New Pandemics: Regulatory Challenges  
Kerstin Adolph, DrSc  
Senior Clinical Project Manager, Clinlogix LLC, Germany

New Pandemics: Regulatory Challenges  
Luciana Borio, MD  
Acting Chief Scientist, Office of the Chief Scientist, Office of the Commissioner, FDA

Clinical Quality by Design: From Theory to Practice  
CHAIRPERSON  
Ann Meeker-O’Connell, MS  
Head, Risk Management and External Engagement, Bioresearch Quality and Compliance, Janssen Pharmaceuticals, Inc.

QbD emphasizes building quality into a process from the beginning and has been successfully applied in the manufacturing arena. Applied in clinical development, QbD prospectively examines a trial's objectives and identifies the factors that are critical to meeting these objectives. Understanding these “critical to quality” aspects is essential to subsequently identifying and managing important and likely risks to trial quality. To support organizations seeking to implement QbD, a Clinical Trials Transformation Initiative (CTTI) project team is currently developing a portfolio of learning and operational tools. In addition, we will review these tools and highlight effective strategies that may aid in adoption of a QbD approach. This session will also discuss how pragmatic protocol design drawing on data standards and simulations may augment trial design and examine ways of leveraging insights from health care providers and payers to inform and improve protocol design.

From Principles to Practice: An Industry Perspective  
Coleen M. Glessner  
Vice President, Clinical Trial Process and Quality, Pfizer Inc

Towards More Effective Protocols and Safer Trials Starting With Standards and Simulating Designs  
James Streeter  
Senior Director, Life Sciences Product Strategy, Oracle Health Sciences

FDA Point of View  
Jean M. Mulinde, MD  
Senior Policy Advisor, Division of Clinical Compliance Evaluation, Office of Scientific Investigations, Office of Compliance, CDER, FDA
Monday, June 15

#131  Track 12 – Pharmaceutical Quality

Reducing Drug Shortages

CHAIRPERSON

Jeannie C. David, MS
Senior Program Management Officer, CDER Drug Shortage Staff, Office of the Center Director, FDA

This session will discuss major quality challenges that may impact drug supply, Current Good Manufacturing Practice (cGMP) inspectional issues, and proactive/collaborative regulatory approaches with global health authorities to prevent, mitigate, and resolve drug shortages.

Inspections, Regulatory Compliance and Drug Shortages
Ramani Raghavan, MS, MSc
Senior Regulatory Program Director, Genentech, A Member of the Roche Group

Preventing and Addressing Drug Shortages
Jeannie C. David, MS
Senior Program Management Officer, CDER Drug Shortage Staff, Office of the Center Director, FDA

Shortages of Medicinal Products as a Result of Quality Defects or GMP Noncompliance
Anabela Marcal, PharmD
Head of Compliance and Inspections Department, European Medicines Agency, European Union

#132  Track 14 – Clinical Safety and Pharmacovigilance

Room 151B

CME, Pharmacy, and Nursing

REMS Integration into the Health Care System: Three Perspectives in an Evolving Environment

CHAIRPERSON
Michael A. Cronin, PharmD
Post-Doctoral Fellow, Regulatory Affairs, NPS Pharmaceuticals, Inc.

How do we optimize risk evaluation and mitigation strategies (REMS) to improve drug safety in the evolving health care environment? Speakers from FDA, health care, and industry will provide their perspective on REMS integration efforts and discuss how to further advance the standard of pharmaceutical risk management in the US.

Standardizing and Evaluating REMS: An FDA Update
Theresa A. Toigo, MBA, RPh
Associate Director for Drug Safety Operations, Office of the Center Director, CDER, FDA

Challenges of Implementing and Evaluating REMS
Paul J. Seligman, MD, MPH
Executive Director, Global Regulatory and R&D Policy, Amgen Inc.

Navigating REMS In An Academic Medical Center
Katie Stabi, PharmD
Clinical Coordinator, Drug Use Policy and Compliance, Dept of Pharmacy Services, University of Chicago Medicine

#133  Track 15 – Statistical Science and Quantitative Thinking

Room 204BC

CME, Pharmacy, and Nursing

Statistical Evaluation of Therapeutic Equivalence for Locally-Acting Generic Products

CHAIRPERSON
Stella C. Grosser, PhD
Senior Program Management Officer, CDER Drug Shortage Staff, Office of Translational Science, CDER, FDA

Bioequivalence of generic drugs to innovator products has traditionally been evaluated using pharmacokinetic studies with endpoints such as mean area under the concentration curve and analyses such as calculating confidence intervals around the ratio of means. However, the evaluation of bioequivalence for locally-acting products is complicated by the fact that such pharmacokinetic studies do not capture the information necessary for determining equivalence. This session will outline the statistical issues involved and offer examples of innovative approaches to solving the problem. Such issues relate to the choice of the design, the formulation of the statistical hypotheses and the factors that affect the power of the statistical test.

Special Cases for the Statistical Evaluation of Bioequivalence: An Example of In Vitro Skin Permeation Test Data
Elena Rantou, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Measurement of Average Bioequivalence or Noninferiority
Wanjie Sun, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Science, CDER, FDA

Design and Data Analysis Challenges for Establishing Therapeutic Equivalence in Clinical Endpoint Studies
Keith Gallicano, PhD
Vice President, Scientific Affairs, Novum Pharmaceutical Research Services

#134  Track 16 – Professional Development

Room 147B

CME and Nursing

The What, Why and How of Coaching and Its Application in the Work Place

CHAIRPERSON
Mieke Jobsis
Director, Quality and Risk Management, GlaxoSmithKline

There has been a boost in the practice of coaching, whether it is personal, life, health or business coaching, in all aspects of life. Why are some companies in the pharmaceutical industry embedding coaching programs and building coaching into their core skill set? This session will build an
understanding of what coaching is and look at how business coaching has been applied in different settings of the pharmaceutical industry.

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Facilitators
Nicky Rousseau, CPA
Senior Director, Program Management, Quintiles Inc.
Mieke Jobsis
Director, Quality and Risk Management, GlaxoSmithKline

#135 TRACK 17 – RARE/ORPHAN DISEASES
11:00 AM–12:30 PM   LEVEL: ●   FORMAT: SYMPOSIUM
Room 103A
CME and Nursing
Facilitating Rare Disease Patient Participation in Clinical Trials
CHAIRPERSON
Maureen Smith, MEd
Patient Advocate/Secretary, Canadian Organization For Rare Disorders (CORD), Canada

In rare disease trials, patients are difficult to find and also hard to retain. Patients may be located far from the investigative site, too debilitating to travel, or may not be able to come to the investigative site for the numerous visits required per the protocol. This symposium will present three innovative initiatives to facilitate rare disease patient participation in clinical trials. It will provide attendees with insights that will have positive impacts on recruitment, study completion and patient satisfaction. The initiatives include the use of mobile nursing in rare and pediatric studies and the challenges; optimizing the use of home health care providers for patient visits and travel agencies for patient travel to the investigative site; and rare disease Patient Service Centers - creating outstanding patient engagement via a holistic approach.

The Use of Mobile Nursing in Rare and Pediatric Disease Studies
Juliet Hulse
Research Nursing Team Manager, Research Nurses Limited, United Kingdom

Managing Home Health Care Visits and Patient Travel in Rare Disease Trials
Kristi Clark, MBA
Vice President, Project Management and Clinical Operations, Agility Clinical Inc.

Rare Disease Patient Service Centers: Creating Outstanding Patient Engagement Via a Holistic Approach
Thomas Rudolf Lembck, MBA
Co-Founder, Orphan Drug Solutions

#136 TRACK 18 – GLOBAL REGULATORY
11:00 AM–12:30 PM   LEVEL: ●   FORMAT: FORUM
Room 143ABC
CME and Nursing
International Regulatory Convergence: Collaboration, Cooperation and Global Governance
CHAIRPERSON
Emer Cooke, MBA
Head of International Affairs, European Medicines Agency, European Union

The audience will hear from the top level senior leadership of four of the most influential global regulators and explore current multilateral and bilateral initiatives aimed to facilitate better interaction and coordination. This forum will examine initiatives to avoid duplication and increase mutual reliance between regulators and their impact on industry.

Panelists
Guido Rasi, MD
Principal Adviser, European Medicines Agency, European Union
Stephen M. Ostroff, MD
Acting Commissioner, FDA
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Anil Arora
Assistant Deputy Minister, Health Products and Food Branch, Health Canada

12:30–2:30 PM
Lunch & Innovation Theater Presentations in Exhibit Hall

#137 TRACK 20 – INNOVATION THEATER
12:45–1:15 PM   LEVEL: ●   FORMAT: SPECSESS
Exhibit Hall
No CE available
Quintiles Transnational Innovation Theater: Deploy Disruptive Improve Clinical Development by Enhancing Site Relationships, Technology, and Patient Engagement

#138 TRACK 20 – INNOVATION THEATER
1:30–2:15 PM   LEVEL: ●   FORMAT: SPECSESS
Exhibit Hall
No CE available
ConvergeHEALTH by Deloitte Innovation Theater Presentation
#139 Plenary Session & Keynote Address
2:30–4:00 pm  
**Level:** ●  
**Format:** FORUM  
**No CE available**
Ballroom

Join us for the DIA 2015 51st Annual Meeting Opening Plenary.

**Welcome Remarks**
Per Spindler, DVM, MBA, MSc  
DIA President and Chair, Board of Directors; Director, Biopeople, University of Copenhagen, Denmark

**Opening Remarks**
Christopher P. Austin, MD  
Director, National Center for Advancing Translational Sciences, National Institutes of Health (NIH)  
Program Co-Chair

**Opening Remarks**
Michael Rosenblatt, MD  
Executive Vice President and Chief Medical Officer, Merck & Co., Inc.  
Program Co-Chair

**Keynote Address**
Daniel Burrus  
President and CEO, Burrus Research Associates, Inc.

4:00-6:00 PM
Opening Reception & Innovation Theater Presentations in Exhibit Hall

#140 Track 20 – Innovation Theater
4:15–4:45 pm  
**Related Interest Area(s): CR, PT**  
**Level:** ■  
**Format:** SPECESS  
**No CE available**
Exhibit Hall

**BBK Worldwide Innovation Theater: Are You Patient-Centric? Why Your Answer Must Be Yes**

No longer a nice-to-have, patient centricity is a critical component of any study’s success. Join our panel of patient centricity experts and advocates including Bonnie A. Brescia, Co-founder, BBK, Claire Meunier, VP, Research Engagement, The Michael J. Fox Foundation, and Christel Aprigliano, CEO, Diabetes Collective, as they discuss thoughtful and effective patient-centric recruitment and engagement strategies that can be employed throughout the entire clinical trial process.

#141 Track 20 – Innovation Theater
5:00–5:45 pm  
**Related Interest Area(s): CR, PT**  
**Level:** ●  
**Format:** SPECESS  
**No CE available**
Exhibit Hall

**Teuteberg Innovation Theater: Expanding Patient Recruitment Globally With Social Media**

Social media and online marketing is one of the least utilized, yet most cost effective ways to recruit patients for clinical trials. Online marketing a great tool in the US, but it can be very beneficial globally as well. In Europe, 70% of people are active Internet users, which presents a huge opportunity for recruiting worldwide. Digital media’s unique targeting can recruit up to 50% more study referrals at a more cost effective rate than traditional media.

Attend this presentation to learn how to utilize digital marketing to boost recruitment, while reviewing a case study.

The Walking Gallery
4:00–6:00 pm  
DIA Booth #1523

Join us during the Opening Reception 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.

Download DIA’s app by searching DIAGlobal in your App Store.
Tuesday, June 16

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

Schedule:
7:15–8:00 AM Coffee and Breakfast Breads
8:00–9:30 AM Educational Opportunities
9:00 AM–4:00 PM Professional Poster Session #1 (Exhibit Hall Entrance A)
9:00 AM–5:00 PM Exhibit Hall Open
9:30–10:30 AM Coffee Break (Exhibit Hall)
9:30–10:30 AM Oral Presentations-Professional Poster Session #1A (Exhibit Hall Entrance A)
10:30 AM–12:00 PM Educational Opportunities
11:30 AM–1:30 PM Lunch (Exhibit Hall)
11:30 AM–1:30 PM Oral Presentations-Professional Poster Session #1B (Exhibit Hall Entrance A)
12:30 PM Student Poster Award Ceremony (DIA Booth #1523)
12:30–1:30 PM Community Meet & Eat (Exhibit Hall)
1:30–3:00 PM Educational Opportunities
1:30–3:30 PM Exhibit Guest Passes
2:30–3:10 PM Oral Presentations-Professional Poster Session #1C (Exhibit Hall Entrance A)
2:30–3:30 PM Refreshment Break (Exhibit Hall Entrance B)
3:30–5:00 PM Educational Opportunities

#201 Track 01A – CLINICAL OPERATIONS
Related Interest Area(s): PT
8:00–9:30 AM Format: SESSION
Room 145A CME, Pharmacy, and Nursing
The Development of Patient Power: From Consumer to Active Participant!
CHAIRPERSON Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

Collecting views and data directly from patients may provide information which is critical to understanding how medicines are used. The role of patients is changing from simple consumer to being a key part of the drug development program.

Patient-Centric Clinical Trials: What Does It Mean and How Do I Do It?
Joan M. Meyer
Executive Director, Operational Strategy and Planning, Covance Inc.

#202 Track 01B – CLINICAL OPERATIONS
Related Interest Area(s): CR, PT
8:00–9:30 AM LEVEL: ■ FORMAT: FORUM
Room 145B CME, Pharmacy, and Nursing
The Role of Innovation in Clinical Trial Advocacy: Developing and Executing Patient-Centered Strategies and Partnerships Throughout the Continuum
CHAIRPERSON Lisa Palladino Kim, MS
Adjunct Assistant Professor, Rutgers, The State University of New Jersey

Industry is embracing the importance of diversifying the clinical trial patient population in an increasingly challenging recruitment landscape. The pharmaceutical industry’s involvement with patient groups has historically focused on one-way communications, typically offering short-term results. A combination of new media and strategic communications leads to richer community engagement and increased responses.

Clinical Trial Advocacy: Developing and Executing Advocacy Strategies from Discovery Through Drug Development
Lori B. Abrams, MSc
Director, Advocacy, Diversity & Patient Engagement, Bristol-Myers Squibb Company

Patient Advocate Perspective
Andrea Stern Ferris
President and Chairman, LUNGevity Foundation

Activating Patients for Clinical Trials Through Meaningful Education and Advocacy
Kristin Nicole Voorhees, MA
Director of Healthcare Initiatives, National Foundation for Celiac Awareness

#203 Track 02 – PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING
Related Interest Area(s): PM
8:00–9:30 AM LEVEL: ■ FORMAT: FORUM
Room 101 CME, Nursing, and PMI PDUs
The Art and Science of Portfolio Management
CHAIRPERSON Karla Childers, MS
Director, Strategic Projects, Johnson & Johnson
In this forum, experienced portfolio managers will share their observations on the type of skills required and critical activities undertaken to manage a portfolio of innovative products. Learn how portfolio management may fit into your current career development plans. Panelists will also give insight into some of the different models with which they have experience.

Overview of the Different Types of Portfolio Management in a Large Pharmaceutical Company
Frank P. DePaoli
Director, Pharmaceutical/Life Sciences R&D, PricewaterhouseCoopers LLP

Overview of the Skills Required and Different Approaches to Enabling Effective Portfolio Management in the Pharmaceutical Industry
Matthew Studney
Director, MRL Global Project Management, Merck & Co., Inc.

Panelist
James Wescott, MBA
Vice President, Project Management, Actavis plc

#204 Track 03A – INNOVATIVE PARTNERING MODELS AND OUTSOURCING STRATEGIES

Related Interest Area(s): RA, PM
8:00–9:00 am △ Level: M Format: SESSION
Room 150A CME and Nursing

Centralized Ethics: How a Unique Partnership Between a CRO and an IRB Is Changing the Regulatory and Ethics Review Process
CHAIRPERSON
Jennifer Lynn Peterson, RAC
Director, Site Start-Up and Regulatory, North America, INC Research

This session will examine how a contract research organization and an institutional review board have established a partnership to solidify an efficient, high-quality start-up process that expands its reach well past regulatory and ethics reviews.

Panelists
Jennifer Lynn Peterson, RAC
Director, Site Start-Up and Regulatory, North America, INC Research

Nicholas Slack
Chief Growth Officer, WIRB-Copernicus Group

#205 Track 03B – INNOVATIVE PARTNERING MODELS AND OUTSOURCING STRATEGIES

Related Interest Area(s): OS, CR
8:00–9:00 am △ Level: M Format: SESSION
Room 152A CME and Nursing

A Biopharmaceutical Company/Services Provider Partnership: Value to Both Companies and Progress to Date
CHAIRPERSON
Stacie Yonkin
Senior Vice President and Managing Director, Quintiles Inc.

This session will focus on the rationale and benefits of establishing a sole source partnership between two companies that are leaders in the clinical development space and possess complementary areas of expertise and company culture.

CRO Perspective
Stacie Yonkin
Senior Vice President and Managing Director, Quintiles Inc.

Pharma Perspective
Murray Alexander Abramson, DrMed, MPH
Vice President, Global Clinical Operations, Biogen Idec

#206 Track 04 – PRECLINICAL AND TRANSLATIONAL DEVELOPMENT/EARLY PHASE CLINICAL DEVELOPMENT

Related Interest Area(s): NC, RA
8:00–9:30 am Level: M Format: SYMPOSIUM
Room 103A CME and Nursing

Regulatory Examination of Nonclinical Testing Requirements and Juvenile Animal Studies
CHAIRPERSON
David R. Jones, MS
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

This symposium will examine the issues surrounding nonclinical testing requirements to support clinical trials in rare diseases, the importance and value of nonclinical juvenile animal studies for oncology products, as well as the role of juvenile animal studies in global pediatric product development. Juvenile animal studies can contribute significantly to risk assessment and safety in pediatric clinical trials and for drug product labeling, and their usefulness will be examined, primarily from a regulatory standpoint.

Nonclinical Requirements for Clinical Trials in Rare Diseases
David R. Jones, MS
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Nonclinical Support and the Role of Juvenile Animal Studies in Global Pediatric Product Development
Ikram Elayan, PhD
Senior Pharmacology/Toxicology Reviewer, OND, CDER, FDA

Juvenile Animal Studies in Oncology Medicines for Children
Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

#207 Track 05 – REGULATION OF PRODUCT ADVERTISING AND MARKETING IN AN EVER-CHANGING WORLD

Related Interest Area(s): RA
8:00–9:30 am Level: ● Format: WORKSHOP
Room 152B 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.
Sponsor Perspective on Changes Made Within the Organization to Implement Risk-Based Monitoring
Roland Rich
Operational Expert, Quality and Compliance DevQA, Novartis Pharma AG, Switzerland

Therapeutic Area Key Risk Indicators: Digestive Disease
Tammy Finnigan
Head of Operations, Triumph Consultancy Services, United Kingdom

Ensuring Data Quality and Detecting Potential Fraud
Erik Doffagne, MSc
Product Manager, CluePoints, Belgium

#208 TRACK 06 – MEDICAL COMMUNICATION/MEDICAL WRITING AND MEDICAL SCIENCE LIASIONS
Related Interest Area(s): MW, CR
8:00–9:30 AM LEVEL: ■ FORMAT: SYMPOSIUM
Room 206 CME and Nursing
New Approaches to Submission Components
CHAIRPERSON
Janet K. Stoltenborg, MBA, MS
Global Head, Medical Communications Science, AstraZeneca Pharmaceuticals LP
The world of clinical trial reporting continues to evolve with increasing requests for information and the ever-present need to be more efficient in delivery. This symposium provides the medical writer with new approaches to streamline clinical study reporting while meeting new transparency requirements.

Ready, Set, Go! Initiating the New Clinical Report Redaction
Janet K. Stoltenborg, MBA, MS
Global Head, Medical Communications Science, AstraZeneca Pharmaceuticals LP

CAPITALize Your Time and Efficiency: Streamlining Appendices Compilation
Carrie McKenzie
Project Manager, WebbWrites LLC

Web-based Tool for the Programmatic Generation of Tabular Listings of Clinical Studies for Regulatory Documents
Jennifer Seamon
Principal Medical Writing Scientist, Janssen Research & Development, LLC

#209 TRACK 07A – TECHNOLOGY/DATA/RECORDS AND SUBMISSIONS
Related Interest Area(s): CDM, CR
8:00–9:30 AM LEVEL: ■ FORMAT: SYMPOSIUM
Room 201 CME, Pharmacy, and Nursing
Implementing Risk-Based Monitoring
CHAIRPERSON
Willie Muehlhausen, DVM
Head of Innovation, ICON Clinical Research, Ireland
Risk-based monitoring (RBM) promises to improve quality in clinical research, and may help limit the growing cost of clinical trials. Recommendations have been outlined by regulatory bodies including FDA’s Guidance on RBM, and EMA’s reflection paper. Transcelerate BioPharma has also published a position paper on implementation. This symposium will look at several aspects of RBM implementation, using a number of case examples to explore and contrast the data analytics approach using central statistical monitoring and the development and use of key risk indicators. Importance will be placed on how the cause of the findings can be identified and classed by seriousness—from poor protocol understanding to intent to cheat. We will also discuss the operational implications of the findings in terms of the resulting corrective actions.

#210 TRACK 07B – TECHNOLOGY/DATA/RECORDS AND SUBMISSIONS
Related Interest Area(s): CDM, IT
8:00–9:30 AM LEVEL: ■ FORMAT: SESSION
Room 202B CME and Nursing
International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP): Will Your Company Be Ready by 2016?
CHAIRPERSON
Niels Gronning, MSc
Principal Consultant, NNIT A/S, Denmark
New regulations for the IDMP currently being finalized by the EMA and the FDA will fundamentally alter the way data is standardized and shared across the pharmaceutical industry. ISO IDMP and the associated implementation guidelines collectively define how data should be standardized across authorized products, investigational products and substances (drug substances and excipients). Set to be implemented in the EU by July 2016 and with no official implementation guidelines, available pharmaceutical companies struggle to devise strategies that support compliance and continuous maintenance. Will you wait until the official implementation guideline is published (thereby possibly not meeting the deadline) or will you use the draft implementation guideline published by ISO as a blueprint for your strategy? How can IDMP be transformed from yet another regulatory burden into a value adding activity that supports enterprise architecture activities across your company?

Coming Into Compliance with IDMP
Lior Keet, MBA
Vice President, Life Sciences R&D, HighPoint Solutions

IDMP: Industry Versus Regulator Point of View
Greg Brolund, MS
Consultant, Chicopee Falls Consulting LLC

Enterprise Architecture and ISO IDMP: A Match Made in Heaven?
Niels Gronning, MSc
Principal Consultant, NNIT A/S, Denmark
#211  Track 08A – Regulatory Affairs  
**Related Interest Area(s):** CR, PETD  
**8:00–9:30 AM** **LEVEL:** ■ **FORMAT:** SESSION  
**Room 150B** **CME, Pharmacy, and Nursing**  
**Can We Talk? Alternative Strategies for Communicating with FDA**  
**CHAIRPERSON**  
Kim M. Quaintance  
Head, US Regulatory Policy, Bayer HealthCare Pharmaceuticals  
Experienced regulatory professionals know that formal meetings are insufficient to address all the issues that arise during drug development. Our panel will discuss best practices and innovative ways to ensure optimal communications with FDA.  

**Consultant Perspective**  
Mark A. Ammann, PharmD  
President, Catalyst Regulatory Services, LLC  

**Industry Perspective**  
Khyati Roberts, RPh  
Senior Director, Regulatory Policy and Intelligence, AbbVie  

**FDA Perspective**  
Rachel E. Hartford  
Lead Consumer Safety Officer, Office of New Drugs, CDER, FDA

#212  Track 08B – Regulatory Affairs  
**Related Interest Area(s):** CR  
**8:00–9:30 AM** **LEVEL:** ■ **FORMAT:** SESSION  
**Room 151A** **CME, Pharmacy, and Nursing**  
**Global Regulation of Advanced Therapies**  
**CHAIRPERSON**  
Gopalan Narayanan, MD, FFPM, FRCPh  
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom  
Advanced Therapies offer ground-breaking treatment for many diseases that could not be treated previously. Recently, treatments for conditions such as prostate cancer and cartilage regeneration have been approved in the EU. These innovative products are regulated differently by health authorities across the globe. Is it a biologic, a drug, a device, or a combination product? This session will examine the regulatory requirements and classification issues specific to these types of products.  

**Regulatory Perspective**  
Paula Salmikangas, PhD  
Senior Researcher; Chair, Committee for Advanced Therapies (CAT), The Finnish Medicines Agency (Fimea), Finland  

**Industry Perspective**  
Michael Halpin, MS  
Vice President, Regulatory Affairs, Genzyme Corporation, A Sanofi Company  

**Cell and Gene Therapies: How to Engage with EU Regulators**  
Gopalan Narayanan, MD, FFPM, FRCPh  
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

#213  Track 10 – Public Policy/Health Care Compliance/Law  
**Related Interest Area(s):** RA  
**8:00–9:30 AM** **LEVEL:** ■ **FORMAT:** FORUM  
**Room 146B** **CME, Pharmacy, and Nursing**  
**Pediatric Therapeutic Development: From Policy to Portfolios to Patients**  
**CHAIRPERSON**  
Timothy R. Franson, MD  
Chief Medical Officer, YourEncore  
This forum will examine the need for and challenges surrounding pediatric therapeutic development, and explore how policy makers, life science companies, and patient groups can work together to advance the development of pediatric therapies.  

**Panelists**  
Michelle Taylor McMurry-Heath, MD, PhD  
Vice President, Worldwide Regulatory Affairs, Johnson & Johnson  
Stephen P. Spielberg, MD, PhD  
Editor-in-Chief, DIA Publications, DIA  
Debra Lappin, JD  
Head, Health Biosciences Practice, FaegreBD Consulting

#214  Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)  
**Related Interest Area(s):** EC, CR, RA  
**8:00–9:30 AM** **LEVEL:** ■ **FORMAT:** SESSION  
**Room 102AB** **CME and Nursing**  
**FDA GCP Compliance and Enforcement Updates**  
**CHAIRPERSON**  
Sean Y. Kassim, PhD  
Office Director, Office of Scientific Investigations, Office of Compliance, CDER, FDA  
This FDA cross-center session will provide updates on GCP compliance and enforcement activities with a special focus on eClinical technologies in the conduct of clinical trials.  

**CDER Perspective**  
Sean Y. Kassim, PhD  
Office Director, Office of Scientific Investigations, Office of Compliance, CDER, FDA  

**CBER Perspective**  
Bhanu Kannan, MSc  
Consumer Safety Officer, Office of Compliance and Biologics Quality, CBER, FDA  

**CDRH Perspective**  
Adam C. Donat, MS  
Branch II, Division of Bioresearch Monitoring, Office of Compliance, CDRH, FDA
#215 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC/GMP

8:00–9:00 AM △ Level: ■ Format: SESSION
Room 151B
CME, Pharmacy, and Nursing

Learning By Doing: Regulatory Applications for Breakthrough Therapies

CHAIRPERSON
M. Scott Furness
Deputy Director for Review and Operations, ONDQA, Office of Pharmaceutical Quality, CDER, FDA

This session will present and facilitate discussion on the opportunities and challenges associated with breakthrough therapies with an emphasis on the innovative approaches to consider for submission of chemistry, manufacturing and control information in breakthrough (or otherwise expedited) submissions.

FDA Perspective
Suparna Wedam, MD
Medical Officer, OHOP, Office of New Drugs, CDER, FDA

FDA Perspective
M. Scott Furness
Deputy Director for Review and Operations, ONDQA, Office of Pharmaceutical Quality, CDER, FDA

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

Related Interest Area(s): SE, RA

8:00–9:30 AM Level: ■ Format: SESSION
Room 209AB
CME, Pharmacy, and Nursing

Remember That? Choosing Recall Intervals for Patient-Reported Outcome Measures

CHAIRPERSON
Chad Gwaltney, PhD
Consultant, ERT

Choosing the right recall interval—the time that patients are asked to consider—is critical when using a patient-reported outcome instrument to measure treatment outcomes. This session will include regulatory and scientific perspectives on selecting recall intervals.

Selecting Recall Intervals for PRO Instruments: An Introduction
Chad Gwaltney, PhD
Consultant, ERT

Which Recall Period? It Depends
Arthur A. Stone, PhD
Director of the Center for Self-Report Science; Professor of Psychology, University of Southern California

FDA Perspective
Elektra Johanna Papadopoulos, MD, MPH
Medical Officer, Study Endpoints Labeling Development, Office of New Drugs, CDER, FDA

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

Related Interest Area(s): PR

8:00–9:30 AM Level: ■ Format: SYMPOSIUM
Room 207B
CME and Nursing


CHAIRPERSON
Alberto Grignolo, PhD
Corporate Vice President, PAREXEL International

Economic pressures on drug pricing/reimbursement require that companies plan market access early in development, promote clinical/regulatory/commercial collaboration and execute the right studies to provide evidence to both regulators and payers.

Integrating Proof of Concept and Proof of Value in Early Development
Cyril P. Clarke, MD
Vice President, Translational Medicine, ICON Clinical Research, United Kingdom

Registration and Reimbursement Strategies in Drug Development: Merging Constructs to Maximize Return on Invested Capital
Richard N. Williams, JD, PhD
Senior Director, Global Regulatory Strategy, Covance Inc.

How Industry Pursues Internal and External Cross-Functional Collaborations During Drug Development to Optimize Market Access After Regulatory Approval
Schiffon Wong, MPH
Franchise Head Neurology, Global Evidence and Value, EMD Serono, Inc.

#218 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CR

8:00–9:30 AM Level: ■ Format: SESSION
Room 207A
CME, Pharmacy, and Nursing

Social Media: Opportunities and Challenges in Pharmacovigilance and Clinical Research

CHAIRPERSON
Martin Harvey Allchurch, Esq, LLM
International Affairs, European Medicines Agency, European Union

This session will discuss the potential of social media as a new data source in the early detection of safety issues related to medicines. Social media usage has increased substantially within the last five years, including the creation, sharing or exchange of information on health-related topics and has already shown promise in the management of disease outbreaks, for example. Therefore, the expectation is that the use of data from a real-world, large-scale population of consumers and patients will result in more comprehensive and timely information about the safe use of medicines. However, this new data source also brings a number of challenges such as compliance with data privacy requirements, ethical aspects or risks in compromising clinical research results, which will be further outlined. Lessons learned from MedWatcher Social as well as the approach towards social media analytics currently being researched in the context of the Innovative Medicines Initiative (IMI) WEB-Recognising Adverse Drug Reactions (RADR) project will be discussed.
New Challenges for a Data Monitoring Committee

Chairperson

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

Data monitoring committees (DMCs) can monitor the safety of a drug and weigh risk and benefit for stopping a trial early. In this session, we will discuss the importance of DMCs concerning the best practices of maintaining confidentiality of interim data and the recent Part 15 public hearing. The main focus will be how careful consideration of statistical inputs (e.g., planning for multiple looks) will improve DMCs’ efficiency and ensure the trial’s integrity.

The Role of DMCs in Drug Development and the Importance of Confidentiality of Interim Results

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

DMC Review of Accumulating Safety Data: Confidentiality Issues

Martin Rose, Sr., JD, MD
Medical Officer (Team Leader), Office of New Drugs, CDER, FDA

DMCs: Importance of Maintaining Confidentiality to Minimize Bias

Walter Offen, Esq, PhD
Global Head of Statistical Innovation & Safety Statistics, AbbVie

Moving the Role of the CRC and CRA into the 21st Century: Opportunities and Challenges

Chairperson

Terri Hinkley, BSN, MBA, RN
Deputy Executive Director, Association of Clinical Research Professionals (ACRP)

The clinical research industry continues to evolve at a rapid rate. Changes and/or clarification in regulatory guidelines are requiring sites to increase their quality control and trial oversight activities, typically by the clinical research coordinator (CRC) and continue to change the traditional role of the study monitor. This session will explore the changes in each role as well as the opportunities to continue the evolution of both roles. Current training needs for each role will be evaluated and the next steps required of all stakeholders will be discussed.

21st Century Clinical Monitors: How Will the Industry Address Significant Shortages in Experienced, Well-trained Talent?

Lisa C. Feeney, MBA
Vice President, Clinical Operations, ExecuPharm, Inc.

How to Succeed in Orphan Drug Regulatory Affairs

Chairperson

Timothy R. Cote, MD, MPH
President and Chief Executive Officer, Cote Orphan LLC

In this session, orphan drug thought leaders will share their insights about how to succeed in orphan regulatory affairs. Orphan drug development begins with designation, and we will explain what does not work when submitting to the Office of Orphan Products Development. Moving from designation to the review division process, we will provide a quantitative analysis of the special treatment afforded orphan drugs by the FDA’s review divisions. We will also include a European perspective on the orphan drug endeavor, reviewing the unique European approach to the way orphan drugs are designated and developed.
drugs become licensed in the European community. We will present a picture of orphan drug regulatory success drawn from thousands of regulatory actions from their collective experience.

Why Orphan Drug Designation Applications Fail
Timothy R. Cote, MD, MPH
President and Chief Executive Officer, Cote Orphan LLC

Quantum of Effectiveness Evidence in FDA's Approval of Orphan Drugs: An Update to the 2012 Seminal Analysis
James E. Valentine, JD
Associate, Hyman, Phelps & McNamara, PC

European Perspective
Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting Group, Germany

#224 Track 21 – Poster Presentations
9:30–10:30 AM LEVEL: ● FORMAT: SYMPOSIUM
Exhibit Hall (Entrance A) No CE available
Tuesday Oral Presentations - Professional Poster Session 1A
New this year! Join us in the Exhibit Hall Poster Area (Hall A Entrance) for a series of 5 minute presentations delivered by this year’s Professional Poster Presenters.

The following are scheduled in this session 1A:
- 9:35–9:40 AM—T01 Assessing the Current Landscape of Pharmaceutical Industry Post-Doctoral Fellowships
- 9:42–9:47 AM—T02 Patient Knowledge of Safe Use of ER/LA Opioid Analgesics Following Implementation of the Class-Wide REMS
- 9:49–9:54 AM—T03 Biosafety Gene Therapy: Navigating the Regulatory Maze
- 9:56–10:01 AM—T04 Clinical Relevance and Utility of Boxed Warnings in US Prescribing Information
- 10:03–10:08 AM—T05 Advancing Medical Information Services To Impact Patient Care: Collection Of Insights From Healthcare Practitioners
- 10:10–10:15 AM—T06 Steps on a Journey: Re-Use of Analysis Scripts and Standardized Tuberculosis Trial Data
- 10:17–10:22 AM—T08 Can Social Listening be Used to Augment Existing Data Sources for Monitoring the Safety of Consumer Health Care Products?
- 10:24–10:29 AM—T10 Pharmacovigilance Industry Benchmarking on Global Methodologies for Collecting and Processing Off-Label Use Reports

#225 Track 20 – Innovation Theater
9:45–10:15 AM LEVEL: ■ FORMAT: SPECSESS
Exhibit Hall No CE available
Covance Inc. Innovation Theater: Advances in Risk-Based Monitoring: Transforming Drug Development Through Efficient Workflows, Big Data and Elegant Software

Covance’s risk-based monitoring (RBM) platform provides our clients with the best-in-class implementation of the RBM principles put forth by FDA, EMA and TransCelerate, and enhanced by Covance’s operational and clinical expertise. The platform facilitates all aspects of RBM through timely, secure and integrated access to all relevant trial data, supported by a robust clinical data integration layer and a set of modern web-based interfaces.

#226 Track 01 – Clinical Operations
10:30 AM–12:00 PM LEVEL: ■ FORMAT: FORUM
Room 145A No CE available
How Pharmaceutical Companies Can Engage Responsibly with Patients Online
CHAIRPERSON
Steven Immergut
Vice President and Head of Communications, Bayer HealthCare Pharmaceuticals
Pharmaceutical companies can no longer afford to ignore online patient opinion leaders (POLs). Case studies will demonstrate how companies can successfully engage online with patients.

Panelists
Dana Lewis
Founder, #DIYPS & #OpenAPS, OpenAPS

Bob Pearson
President, W2O Group

#227 TRACK 02A – PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING

10:30 AM–12:00 PM
Room 101

Better Team Performance in Drug Development: Effective Relationship Building Across Cultures, Especially the West and Asia

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

Building trusting relationships among members is one of the keys to success for any team. We will discuss how the relationships should be formed and maintained, paying particular attention to diverse teams that comprise members from the West and Asia.

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 Co., Ltd., Japan

#228 TRACK 02B – PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING

10:30 AM–12:00 PM
Room 103B

Recent Trends in Facilitating Decision Making in Drug Development

CHAIRPERSON
Akhil Agrawal, PhD, MBA, PMP
Associate Director, Janssen Pharmaceuticals, Inc.

This forum will focus on sharing best practices on facilitating decision making while adapting to recent industry trends which impact R&D projects. Presentations including case studies will be provided followed by an open forum discussion.

The Value of Good Early Decision-Making Quality on Project Selection and Success
Jay Armstrong, MBA, MS, MSc
Principal Consultant, Pharmica Consulting

Effective Decision-Making in Late-Stage Drug Development
Cary McConlogue, PhD, MBA
Group Director, Biopharma Project Management, Bristol-Myers Squibb Company

Enhancing Your Influence in Project and Portfolio Decision Making
Jennifer Ikeda, MBA, PMP
Principal, Acuity Advantage Consulting, LLC

#229 TRACK 03 – INNOVATIVE PARTNERING MODELS AND OUTSOURCING STRATEGIES

10:30–11:30 AM
Room 150A

Taking the Pulse of Outsourcing Relationship Structures and Their Impact

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

This session examines the results and implications of a recent study conducted by the Tufts Center for the Study of Drug Development (Tufts CSDD) that looked at 43 phase 2 and 3 clinical studies completed since 2012 to evaluate actual sponsor company outsourcing practices. The study also performed an in-depth assessment of sponsor company attitudes and perceptions about their current and future outsourcing strategies. Study results indicate that sponsor companies are inconsistently mixing and matching relationship models on a study-by-study basis and that they are planning a number of major changes to their outsourcing strategies and practices.

Review and Discussion of the Study Results and Their Implications
Frances Grote, MBA
Senior Director, Clinical Operations Vendor Oversight, Biogen Idec

Review and Discussion of Study Results and Their Implications
Kenneth A. Getz, MBA
Chairman, CISCRP; Director of Sponsored Research, Tufts Center For the Study of Drug Development

#230 TRACK 04 – PRECLINICAL AND TRANSLATIONAL DEVELOPMENT/EARLY PHASE CLINICAL DEVELOPMENT

10:30 AM–12:00 PM
Room 103A

Navigating Complex Biological and Regulatory Pathways to Bring Novel Gene and Cell Therapies to the Clinic

CHAIRPERSON
Lois M. Hinman, PhD
Executive Director, Regulatory Affairs, Cell and Gene Therapy, Novartis Pharmaceuticals Corporation

An overview of the global status of regulatory guidance for cell and gene therapy will be presented. Early development and regulatory challenges for moving these novel therapies from the bench to the clinic will be discussed through case studies.
Development Challenges for Cell and Gene Therapies: A Case for Integrated Development
Gopalan Narayanan, MD, FFPM, FRCP
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

Strategies to Accelerate the Development of Cell and Gene Therapies from Preclinical to Clinical and Beyond
Anne-Virginie L. Eggimann, MS
Vice President, Regulatory Science, Bluebird Bio, Inc.

Hear Ye, Hear Ye: Preclinical Challenges in Bringing a Novel Gene Therapy for Hearing Loss to the Clinic
Timothy MacLachlan, PhD
Executive Director, Preclinical Safety, Novartis Institutes for BioMedical Research (NIBR)

Optimal Strategies for Preparing Integrated Summaries for a New Drug Application: Making it Work Under Any Circumstance
Lisa Pierchala, MPH
Principal Medical Writer, MMS Holdings Inc.

So Many Documents, So Little Time: Optimizing the Authoring of the IND From Planning to Publishing
Rachael Eckert, DVM, PhD
Principal Medical Writer, PPD, Inc.

#231 Track 05 – Regulation of Product Advertising and Marketing in an Ever-Changing World

10:30 AM–12:00 PM | Level: ■ | Format: Forum
Room 152B | CME, Pharmacy, and Nursing

FDA Enforcement Update: Advertising and Promotion
CHAIRPERSON
Philomena McArthur, JD
Senior Director, Regulatory Advertising and Promotion Pharmaceutical Group HCC, Johnson & Johnson International

FDA enforcement actions and policy guidelines need to be understood by every company because they reflect FDA’s priorities and concerns in regulating advertising and promotion. In this forum, FDA representatives will examine the latest agency enforcement actions and policies and what they mean.

CDER Point of View
Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, Office of Medical Policy, CDER, FDA

CBER Point of View
Lisa L. Stockbridge, PhD
Branch Chief, Advertising and Promotional Labeling Branch, Office of Compliance and Biologics Quality, CBER, FDA

CDRH Point of View
Representative Invited
Regulatory Counsel, Office of Compliance, CDRH, FDA

#232 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

10:30–11:30 AM | Level: ● | Format: Symposium
Room 206 | CME and Nursing

Efficient Authoring of Submission Documents
CHAIRPERSON
Linda Fossati Wood, MPH, RN
President, MedWrite, Inc.

This symposium will discuss the processes around the preparation of complex summary documents included in Investigational New Drug (IND) applications and New Drug Applications (NDA). We will explore options for planning the timing for authoring Modules 2.4 through 2.7 of the IND and integrated and clinical summaries of the NDA to maximize efficiency and capitalize on synergies between the different documents. We will discuss approaches for handling common challenges and significant changes in scope while still maintaining high-quality deliverables that meet submission deadlines.
#234 Track 07B – Technology/Data/Records and Submissions

**Related Interest Area(s): VA, CR, MDD**

**Room 202B**

**How to Trust Data from Wearable Devices Used in Clinical Trials**

**CHAIRPERSON**

Hitoshi Matsui
Executive Officer, CAC EXICARE Corporation, Japan

It appears that wearable medical devices do not pay as much attention to data quality and integrity as our GxP computerized systems that store the data. This session will identify wearable devices and discuss how to qualify data so that they meet good practice guidelines.

**Expectations and Concerns for Using Wearable Devices in Clinical Trials From a Sponsor’s Point of View**

Yumi Wakabayashi
Specialist, Healthcare Compliance Education, Medical Affairs, Chugai Pharmaceutical Co., Ltd., Japan

**The Impact of Wearables On Your Organization**

Willie Muehlhausen, DVM
Head of Innovation, ICON Clinical Research, Ireland

**Wearable Devices in Clinical Trials: How To Adapt To A New Paradigm**

Hitoshi Matsui
Executive Officer, CAC EXICARE Corporation, Japan

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#235 Track 08A – Regulatory Affairs

**Related Interest Area(s): OS, CR**

**Room 151B**

**Good Regulatory Practice (GRP): A Regulatory Affairs Quality System for the 21st Century**

**CHAIRPERSON**

Peter Deegan, Esq, MBA
Senior Director, GRP Quality Assurance, AstraZeneca Pharmaceuticals LP, United Kingdom

Regulatory affairs stands in the center of the business value-chain. The session discusses how a formal Good Regulatory Practice Quality System will de-risk key commercial strategies and increase the value-proposition of the regulatory function.

**Good Regulatory Practice: De-risking the Development and Commercial Strategies**

Peter Deegan, Esq, MBA
Senior Director, GRP Quality Assurance, AstraZeneca Pharmaceuticals LP, United Kingdom

**How Good Regulatory Practice (GRP) Can Enable an Outsourced Regulatory Solution**

Jean Samuel
Chief Quality Officer, Kinapase Ltd, United Kingdom

**How to Audit a Regulatory Affairs Value Chain**

Theresa R. Haughey, MBA
Senior Director, Regulatory Affairs Quality Assurance, GlaxoSmithKline

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#236 Track 08B – Regulatory Affairs

**Related Interest Area(s): CR**

**Room 151A**

**The State of Pediatric Research in the United States**

**CHAIRPERSON**

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

Pediatric research in the US has been evolving for the past 20 years. With the 2012 passage of permanent legislation to support pediatric research we are at the dawn of a new age to enable the availability of medicines for children.

**The Best Pharmaceuticals for Children Act: FDA/NIH Collaboration to Increase Pediatric Information in Product Labeling**

Donna L. Snyder, MD
Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

**FDA Perspective**

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

**Industry Perspective**

Ronald Portman, MD
Executive Director, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corporation

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#237 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

**Related Interest Area(s): RA, MDD**

**Room 150B**

**Impact of FDA Oversight of Laboratory-Developed Tests Upon Innovation in the Targeted Therapy Setting**

**CHAIRPERSON**

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

The recently-announced FDA framework on regulation of laboratory-developed tests will impact codevelopment and uptake of targeted therapies and their companion diagnostics. This forum will debate the merits of this evolving regulatory paradigm.

**FDA Perspective**

Elizabeth A. Mansfield, PhD
Director, Personalized Medicine Staff, Office of In Vitro Diagnostics and Radiologic Health, CDRH, FDA

**Industry Perspective**

Michael Benecky, PhD
Senior Director, Global Regulatory Affairs-Diagnostics, GlaxoSmithKline

**Laboratory Perspective**

Elissa Passiment, MEd
Executive Vice President, American Society for Clinical Laboratory Science
#238 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

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

**Panelists**
- Ni A. Khin, MD
  - Director, Division of Clinical Compliance Evaluation, Office of Scientific Investigations, Office of Compliance, CDER, FDA
- Stephanie L. Shapley, MBA
  - Health Science Policy Analyst, Office of Medical Policy, CDER, FDA

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

**Panelists**
- Hans-Georg Eichler, MD, MSc
  - Senior Medical Officer, European Medicines Agency, European Union
- Ellen V. Sigal, PhD
  - Founder and Chairperson, Friends of Cancer Research
- Margaret A. Anderson, MA
  - Executive Director, FasterCures/A Center of the Milken Institute

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

**Panelists**
- Janet Woodcock, MD
  - Director, Center for Drug Evaluation and Research, FDA
- Sarah Pope Mikinski, PhD
  - Acting Director, Office of New Drug Products, Office of Pharmaceutical Quality, CDER, FDA
- Giuseppe Randazzo
  - Acting Director, Office of Program and Regulatory Operations, Office of Pharmaceutical Quality, CDER, FDA

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

**Panelists**
- Thomas Felix, MD
  - R&D Policy Director, Amgen Inc.
Scientific Working Groups.

DIA Scientific Working Group.

Some of what will be presented is based on work by the members of the use of adaptive designs and Bayesian approaches in clinical development. In this forum, the panel will share their experience with the applications in both the learning and confirmatory phases of development for new drug products has gained momentum in recent years, The use of adaptive designs and Bayesian approaches in clinical development.

Director, Biostatistics, Merck & Co., Inc.

Weili He, PhD

Adaptive Designs
Addressing Challenges and Opportunities of “Less Well Understood” Adaptive Designs
Weili He, PhD
Director, Biostatistics, Merck & Co., Inc.

Exploring Bayesian Approaches in Drug Clinical Trials
Freda W. Cooner, PhD
Lead Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, Office of Translational Science, CDER, FDA

Panelist
Estelle Russek-Cohen, PhD
Director, Division of Biostatistics, Office of Biostatistics and Epidemiology, CBER, FDA

#243 Track 16 – Professional Development
Related Interest Area(s): PETD
10:30 AM–12:00 PM Level: ● Format: WORKSHOP
Room 147A

Networking: It’s Not What You Know, But Who You Know!
CHAIRPERSON
Bob Muzerall
Vice President, Sales and Sales Training, ForeignExchange Translations

Participants in this workshop will build the confidence to step into a variety of networking situations. Small group activities will enhance the interactive experience. Participants will leave the workshop with networking tools and techniques. For those who attended last year’s workshop, this year we will follow the same path but with added opportunities for interaction.

*Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington 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
Chris Matheus, MBA
Director, Business Development, Y-Prime

#244 Track 17 – Rare/Orphan Diseases
Related Interest Area(s): RD, CR
10:30 AM–12:00 PM Level: Format: SESSION
Room 145B

Rare Disease Organizations and Industry Players: Collaborating Effectively to Advance R&D for Rare Disease Patients
CHAIRPERSON
Ronald Joseph Bartek, MA
President/Co-Founder, Friedreich’s Ataxia Research Alliance (FARA)

Biopharmaceutical companies have increasingly shifted their efforts toward developing drugs for rare/orphan diseases. Working with rare disease organizations can be very helpful to development efforts in terms of educating development teams about patient population and unmet needs, connecting teams to scientific and clinical experts, and mobilizing patients for trial recruitment. While there are many potential benefits, there are concerns on both sides. This panel discussion will address issues and concerns from multiple perspectives with an aim to identifying best ways for organizations and companies to work comfortably and effectively with one another.

Perspectives of Umbrella Patient Organizations, Government, and Academia on Patient Organization-Industry Collaborations
Representative Invited
Executive Director, Friedreich’s Ataxia Research Alliance (FARA)

Patient Organization Perspective: Experience of Parent Project Muscular Dystrophy
Patricia Furlong, BSN
Founding President and CEO, Parent Project Muscular Dystrophy

Industry Viewpoints on Patient Organization-Industry Collaborations
Angela Wilson
Associate Director, Advocacy Relations, Genentech, A Member of the Roche Group
#245 Track 18 – Global Regulatory

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

**10:30 AM–12:00 PM**  
**Room 152A**  
**Format: Forum**  
**CME, Pharmacy, and Nursing**

**Chairperson**  
Leslie Ball, MD  
Assistant Commissioner and Deputy Director, Office of International Programs, Office of the Commissioner, FDA

This forum will include staff from FDA’s international posts in China, India, and Europe that perform outreach to foreign regulators, protect supply chains by using risk-based global surveillance, and (in China and India) perform facility inspections.

**Update from the FDA China Office**  
Christopher Jon Hickey, PhD  
Country Director, China Office, Office of International Programs, Office of the Commissioner, FDA

**Update from the FDA India Office**  
Mathew T. Thomas, MD  
Acting Country Director, India Office, Office of International Programs, Office of the Commissioner, FDA

**Update from the FDA European Office**  
Donald Prater, DVM  
Acting Regional Director, Europe Office, Office of International Programs, Office of the Commissioner, FDA, Belgium

#246 Track 19A – Late-breaking Topics

**Related Interest Area(s): CR**

**10:30 AM–12:00 PM**  
**Room 146C**  
**Format: Session**

**Chairperson**  
Craig A. Metz, PhD  
Senior Vice President, Zinfandel Pharmaceuticals, Inc.

This session will present strategic considerations for using registries to recruit subjects for trials on delay of onset of mild cognitive impairment due to Alzheimer’s Disease (AD), including development and regulatory issues and experience from an ongoing study.

**Using the Brain Health Registry for Recruitment, Assessment and Longitudinal Monitoring in Alzheimer’s Clinical Trials**  
Rachel L. Nosheny, PhD  
Research Scientist, Center for Imaging of Neurodegenerative Diseases, San Francisco VA Medical Center

**Cognitively Healthy Subject Registries for AD Delay of Onset Trials: The TOMMORROW Study Experience**  
Kathleen Anne Welsh-Bohmer, PhD  
Professor, Duke University

**Ethical Considerations for Recruiting into Preclinical Alzheimer’s Trials from Subject Registries**  
Joshua Grill, PhD  
Dept. of Psychiatry & Human Behavior, Institute for Memory & Neurological Disorders, University of California, Irvine

#247 Track 19B – Late-breaking Topics

**Related Interest Area(s): CmbP**

**10:30 AM–12:00 PM**  
**Room 201**  
**Format: Forum**  
**CME, Pharmacy, and Nursing**

**Chairperson**  
Michelle Taylor McMurry-Heath, MD, PhD  
Vice President, Worldwide Regulatory Affairs, Johnson & Johnson

This forum will focus on the regulatory challenges facing combination product development and pending US legislative proposals to address them. Panelists will explore the influence of and impact on global regulatory policy for combination products.

**US Legislative Developments on Combination Products**  
Wade Ackerman, JD  
Senior FDA Counsel, U.S. Senate Committee On Health, Education, Labor and Pensions

**Taiwan Regulatory Perspective**  
Li-Ling Liu, MS, RPh  
Director, Division of Medicinal Products, Taiwan Food and Drug Administration (TFDA), Taiwan

**FDA Perspective**  
Representative Invited  
Deputy Commissioner, Office of Medical Products and Tobacco, FDA

#248 Track 21 – Poster Presentations

**11:30 AM–1:30 PM**  
**Lunch & Innovation Theater Presentations**  
(Exhibit Hall)

**11:35 AM–1:30 PM**  
**Format: Symposium**  
**No CE available**

**Exhibit Hall (Entrance A)**

**Tuesday Oral Presentations—Professional Poster Session 1B**

New this year! Join us in the Exhibit Hall Poster Area (Hall A Entrance) for a series of 5 minute presentations delivered by this year's Professional Poster Presenters.

The following are scheduled in this session 1B:

- **11:35–11:40 AM**  
  T 12 Feasibility of Replacing the Thorough QT (TQT) Study with Intense ECG Data Collection in Early Clinical Studies

- **11:42–11:47 AM**  
  T 13 Assessing Bias in Administrative Database Studies of Vaccine Completion Due to Excluding Subjects with Incomplete Follow-up

- **11:49–11:54 AM**  
  T 14 Design and Development of an eCOA Specific Solution for Capturing Patient Data in Diabetes Clinical Trials

- **11:56–12:01 PM**  
  T 15 Engage Patients with Innovative Global Digital Patient Platform

- **12:03–12:08 PM**  
  T 19 Drug Lag and Approval Time Metrics—Are They Good Markers to Assess the Global Regulatory Environment?

- **12:10–12:15 PM**  
  T 20 Analyzing Global Recruitment Strategies to Improve Local Trial Enrollment—A Global Investigation Into “What Works Where” for Patient Recruitment and Retention Tools and Techniques

- **12:17–12:22 PM**  
  T 22 Monitoring Interactive Response Technology Vendor Implemented Randomization and Dosing Systems
### #249 Track 20 – Innovation Theater

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

**Exhibit Hall**

**Quintiles Transnational Innovation Theater:**

Transform Clinical Development – Modernizing for Smarter Trials

It is imperative we ‘modernize’ clinical trials to deliver medicines faster, at less cost, to patients who need them—while mitigating risk; shortening timelines and improving patient safety—through better protocol design, site and patient recruitment, trial execution and mobile apps.

Learn how you can:
- gauge global capabilities to model and predict better outcomes
- identify appropriate investigator sites
- deliver faster ‘analysis-ready’ data to identify trends and issues in near real time

**12:00–12:45 PM**

**STUDENT POSTER AWARD CEREMONY**

DIA Booth #1523

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### #250 Track 20 – Innovation Theater

**Related Interest Area(s): IT, MW, SUBS**

**Exhibit Hall**

**Veeva Systems, Inc. Innovation Theater:**

2015 Paperless Trial Master File (TMF) Survey: Trends and Insights

Hear results from the follow up to Veeva’s benchmark 2014 Paperless TMF Survey, which analyzed the observations of 252 trial master file (TMF) owners to identify the barriers, business drivers, and benefits of moving to fully paperless TMFs. Learn how much has changed in just one year as organizations move along the TMF maturity spectrum. See how your organization compares and discover why some benefit more than others.

**1:00–1:30 PM**

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### #251 Track 01A – Clinical Operations

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

**Room 146A**

**FORMAT: FORUM**

**CME and Nursing**

**Engaging Patients as Partners: Effective Trial Communications to Build Trust and Improve Patient Participation**

**CHAIRPERSON**

Laurin Council Mancour

Account Executive, Trial Results Communication Programs, Center For Information and Study On Clinical Research Participation (CISCRP)

In this forum, we will describe a simple and scalable process to share overall trial results in a patient-friendly format to patients who participate in a trial. We will also provide data on the impact of sharing these results with patients from patients’ and sites’ perspective, as well as risks and best practices of implementing this approach globally in a clinical trial program.

**1:30–3:00 PM**

**Closing the Trial Participation Experience Loop: Providing Overall Trial Results to Trial Patients**

Lara Chayab, MSc

Patient Recruitment Strategist, Hoffmann-La Roche Ltd., Canada

**Panelists**

Elly Cohen

Program Director, Breastcancertrials.org

Greg Koski, MD, PhD

President and CEO, Co-Founder, Alliance For Clinical Research Excellence and Safety (ACRES)

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### #252 Track 01B – Clinical Operations

**Related Interest Area(s): CR**

**Room 145B**

**FORMAT: SESSION**

**CME and Nursing**

**Implementing Risk-Based Monitoring: Best Practices from Pharmaceutical Industries to Contract Research Organizations**

**CHAIRPERSON**

Warren H. Pence

Associate Director, Adaptive and Intelligent Monitoring, PPD, Inc

This session will provide attendees with practical and useful “take-home” information and best practices that can be used by their organizations in the development and implementation of a risk-based monitoring (RBM) strategy.

**1:30–3:00 PM**

**Implementation of Off-Site Monitoring: Successes and Challenges**

Mary Arnould, BSN, MSN

Associate Director, Bristol-Myers Squibb Company

**Elements of Successful Partnering to Execute RBM: A CRO and Pharma Perspective**

Peggy Zavala, MHA

Associate Director, Clinical Monitoring-Americas, Celgene Corporation

**Managing Study Risk Through Site Health/Quality**

Warren H. Pence

Associate Director, Adaptive and Intelligent Monitoring, PPD, Inc
**#253 Track 02 – Project/Portfolio Management and Strategic Planning**

**Related Interest Area(s): PM, CP**

1:30–3:00 pm  
**Room 101**  
**CME and Nursing**

**Life Cycle and Portfolio Management: Regulatory Agency and Pharmaceutical Company Approaches**

**CHAIRPERSON**  
Mark A. Kryah, PMP  
Senior Advisor/COO, Pharmaceutical Project Management, Eli Lilly and Company

Portfolio management and life cycle management are critical elements in pharmaceutical development, key to optimizing the value of an aggregate of assets and to optimizing the value of an individual asset. This session will provide regulatory agency and industry perspectives as well as examples of these important business processes.

- **Life Cycle Management of the Pharmaceutical Program: The Approach and Lessons Learned—A Regulator’s Perspective**  
  Marilena Bassi  
  Director of Office of Planning, Performance and Review Services, Health Canada

- **An Innovative Approach to Drug Safety Life Cycle Management Using a Portfolio Management Business Model**  
  Jill Bourdage, RPh, PMP  
  Director, Project Management; Associate Director Regulatory Affairs, Office of Surveillance and Epidemiology, CDER, FDA

- **Portfolio Rationalization: A Pharma Perspective**  
  Mark A. Kryah, PMP  
  Senior Advisor/COO, Pharmaceutical Project Management, Eli Lilly and Company

**#254 Track 03 – Innovative Partnering Models and Outsourcing Strategies**

**Related Interest Area(s): RD**

1:30–2:30 pm  
**Room 150A**  
**CME and Nursing**

**Collaborate to Innovate: Exploring a Seconds Market**

**CHAIRPERSON**  
Doris Thomas Pereira, MBA  
Assistant Manager, International Operations Department, Torrent Pharmaceuticals Limited, India

In light of declining R&D productivity, increasing R&D costs and the impending patent expiration of blockbuster drugs, the pipeline attrition of molecules, especially in the advanced stages of development, where costs of conducting clinical trials are the greatest, have resulted in an alarming rise in R&D costs. With proven safety and efficacy in the initial phases, these molecules possess a potential of being developed into a blockbuster. Developing strategic alliances to outsource or sell such developmental molecules may result in the same being tried for new indications. With existing data, innovative start-ups or smaller pharmaceutical firms can develop new molecules that may cater to huge unmet patient needs across the globe in critical therapeutic areas. This session will examine these strategic partnerships as well as the advantages and challenges of developing a seconds market.”

**#255 Track 05 – Regulation of Product Advertising and Marketing in an Ever-Changing World**

**Related Interest Area(s): IT, MA, AP**

1:30–3:00 pm  
**Room 152B**  
**CME, Pharmacy, and Nursing**

**Essential Approaches to Promotional Review of Mobile Health Apps: Technology That Is Here to Stay and Evolving Fast**

**CHAIRPERSON**  
Sheetal Patel, PharmD  
Director, Regulatory Advertising and Promotion, US Pharma Group HCC, Johnson & Johnson International

Mobile health, supported by mobile devices, is expected to be a $26 billion industry by 2017. With over 97,000 health and fitness related mobile apps currently on Google Play and Apple App Store, and 4 million downloads per day, it is difficult to deny the rising popularity of the industry. Mobile apps can help people manage their own health and wellness, promote healthy living, and gain access to useful information when and where they need it. These tools are being adopted almost as quickly as they can be developed. This session will focus on how the promotion of these products is regulated, the current regulatory standards that apply, and important considerations for a company's promotional review committee.

- **Regulations Related to Wireless Health and Life Sciences**  
  Representative Invited  
  Senior Director, Government Affairs, Qualcomm Incorporated

- **Legal Aspects of Medical Mobile Apps and Social Media**  
  Jennifer De Camara, JD  
  Assistant General Counsel, Johnson & Johnson

- **Representative Invited**  
  Head of Industry, Healthcare, Google

**#256 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons**

**Related Interest Area(s): MW, IT, SUBS**

1:30–3:00 pm  
**Room 206**  
**CME and Nursing**

**Tool Is a Good Four-Letter Word**

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

This symposium will describe software tools that facilitate the creation of regulatory documents included in an electronic common technical document (eCTD)-based drug application.
### #257 TRACK 07A – TECHNOLOGY/DATA/RECORDS AND SUBMISSIONS

**Related Interest Area(s): EC, PT**

**1:30–2:30 pm △ Level: Format: SYMPOSIUM**

**Room 202B**

**Developing Online Communities: Perspectives for Site and Patient Engagement**

**CHAIRPERSON**
Bonnie A. Brescia
Founding Principal, BBK Worldwide

This symposium will explore how to leverage social media concepts and tools to provide collaborative and engaging learning and sharing between investigators involved in a clinical trial or program. Speakers will also overview experiences to date with providing and maintaining an alumni community for patient participants.

- **Building Blocks of a Clinical Trial Community: A First to Market Perspective**
  Nancy Mulligan
  Senior Director, Operations, Patient and Physician Services, UBC: An Express Scripts Company

- **Improving Global Investigator Engagement by Developing an Online Investigator Community**
  Vladimir Pyagay
  Clinical Solutions Manager, Transperfect

### #258 TRACK 07B – TECHNOLOGY/DATA/RECORDS AND SUBMISSIONS

**Related Interest Area(s): CDM, SUBS**

**1:30–3:00 pm △ Level: Format: FORUM**

**Room 202A**

**FDA Study Data Technical Conformance Guide (Part 2 of 2): An Interactive Q&A Session**

**CHAIRPERSON**
Douglas L. Warfield, PhD
Interdisciplinary Scientist, DDMSS, Office of Business Informatics, Office of Strategic Programs, CDER, FDA

This FDA guide supplements the guidance “Providing Regulatory Submissions in Electronic Format—Standardized Study Data” and provides recommendations on submitting standardized study data using FDA-supported data standards specified in the standards catalog. In this forum, the panelists will participate in an interactive Q&A with the audience.

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Part 1 will take place on Tuesday at 10:30 AM (Session #233).

**Panelists**
- **Benjamin Peter Behrang Vali, MS**
  Biostatistical Reviewer, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA
- **Helena Sviglin, MPH**
  Regulatory Information Specialist, Office of Computational Science, Office of Translational Sciences, CDER, FDA
- **Wei (Lisa) Lin, MBA**
  Senior Regulatory Analyst, Office of Strategic Programs, CDER, FDA

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**#259 TRACK 08 – REGULATORY AFFAIRS**

**Related Interest Area(s): SUBS**

**1:30–3:00 pm △ Level: Format: SESSION**

**Room 151A**

**Transatlantic Collaboration on Pediatric Study Plan/Pediatric Investigation Plan: Recent Experience**

**CHAIRPERSON**
Mette Due Thellade Thomsen, PhD
Principal Scientist, Novo Nordisk A/S, Denmark

This session will discuss the US Pediatric Study Plan (PSP) and the EU Pediatric Investigation Plan (PIP), the timing of submissions, and the significant differences that still remain in the specific requirements from the two regulatory agencies.

- **Advancing Pediatric Product Development Through International Collaboration**
  Christina Bucci-Rechtweg, DrMed, MD
  Global Head, Pediatric and Maternal Health Policy, Novartis Pharmaceuticals Corporation

- **Global Pediatric Development: Current and Future Initiatives for Increased Convergence Between Regions - FDA Perspective**
  Dianne Murphy, MD
  Director, Office of Pediatric Therapeutics, Office of Special Medical Programs, FDA

- **Global Pediatric Development: Current and Future Initiatives for Increased Convergence Between Regions - EMA Perspective**
  Kristina Larsson
  Head of Office for Orphan Medicines, European Medicines Agency, European Union

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**#260 TRACK 09 – MEDICAL DEVICES/IN VITRO DIAGNOSTICS AND COMBINATION PRODUCTS**

**Related Interest Area(s): MDD**

**1:30–3:00 pm △ Level: Format: SESSION**

**Room 150B**

**Success from Bench to Launch: Challenges and Opportunities with Development of Companion Diagnostics**

**CHAIRPERSON**
James Allen Wachholz, MBA
Vice President, Drug Development, ICON Clinical Research

Experts from the field of companion diagnostics and targeted therapy will present their individual views on companion diagnostics development...
methodology, clinical trial designs, developing efficient and optimal integration of clinical trials and diagnostic use.

**XALKORI Rx/Dx: Regulatory Innovation Along the Evolving Path to Precision Medicine**
Erling Thor Donnelly, PhD
Team Leader, Dacomitinib and Palbociclib, Oncology, Pfizer Inc

**Regulatory Considerations for Companion Diagnostic Development**
Elizabeth A. Mansfield, PhD
Director, Personalized Medicine Staff, OIR, CDRH, FDA

**Managing the Critical Factors for Successful Development of Companion Diagnostics**
Representative Invited
Head of Companion Diagnostics, Daiichi Sankyo Co., Ltd.

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**#261 Track 10 – Public Policy/Health Care Compliance/Law**
1:30–3:00 pm  
**Level:** ■  
**Format:** FORUM  
**Room 146B**  
**Related Interest Area(s): MDD**  
**CME and Nursing**

**The Challenges and Opportunities of Digital Health Care: What Does the Future Hold?**

**CHAIRPERSON**
Maria Isabel Manley, LLM
Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

This forum will explore the legal, ethical and commercial issues arising in the context of digital health and will assess how the rapid pace of innovation in this sector has impacted the dynamic of health care provision.

This forum was developed by the Legal Affairs and Ethics and Medicines Lifecycle DIA Communities.

**Panelists**
Maria Isabel Manley, LLM
Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

Wendy Louise Lipworth, MD, PhD
Senior Research Fellow, Centre for Values, Ethics and the Law in Medicine, University of Sydney, Australia

Jeffrey K. Francer, JD, MPA
Vice President and Senior Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA)

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**#262 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)**
1:30–3:00 pm  
**Level:** ■  
**Format:** SESSION  
**Room 102AB**  
**Related Interest Area(s): CR**  
**CME and Nursing**

**Roadmap to Measuring Clinical Trial Quality**

**CHAIRPERSON**
Leslie M. Sam
Director, Global Quality Systems, Eli Lilly and Company

The quality movement has not delivered the promised benefits, despite decades of promotion and the endorsement of health authorities. In this session, we will review the evolution of the quality movement, diagnose the issues, and suggest a path forward.

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**#263 Track 12 – Pharmaceutical Quality**
1:30–2:30 pm  
**Related Interest Area(s): MF, CM**  
**Room 152A**  
**Format:** FORUM  
**CME and Nursing**

**Continuous Improvement and Innovation in Manufacturing Approaches**

**CHAIRPERSON**
Patricia N. Hurter, PhD, MS
Senior Vice President, CMC & Pre-Clinical Development, Vertex Pharmaceuticals

This forum will present and facilitate discussion on the adoption and implementation of innovative manufacturing approaches, ie, continuous manufacturing and their impact on delivery of medicines to the patient, applicability for regulatory review, and benefits for industry.

**Panelists**
Michael K. O’Brien, PhD
Vice President, Leadership, Pharmaceutical Science, Technology and Innovation, Pfizer Inc

Andrew Mark Buswell, PhD, MBA
Head of Advanced Manufacturing Technologies, GlaxoSmithKline, United Kingdom

Stephanie Krogmeier, PhD, RPh
Senior Director, Global CMC Regulatory Affairs Strategy, Vertex Pharmaceuticals

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**#264 Track 19A – Late-Breaking Topics**
1:30–3:00 pm  
**Related Interest Area(s): RD**  
**Room 151B**  
**Format:** SESSION  
**CME and Nursing**

**European Medicines Agency Scientific Guidance on Postauthorization Efficacy Studies**

**CHAIRPERSON**
Kevin Blake, PhD, MBA
Clinical Epidemiologist, European Medicines Agency, European Union

The session will review the draft European Medicines Agency (EMA) guidance on postauthorization efficacy studies (PAES). PAES can be imposed by European regulators as conditions of a marketing authorization. Hear about when PAES might be required, and what you might need to include.
Strategy on Registries
Peter Richard Arlett, MRCP
Head of Pharmacovigilance, European Medicines Agency, European Union

Industry Perspective
Emma Louise Du Four, MBA
Senior Director, Regulatory Policy and Intelligence, AbbVie, United Kingdom

European Regulatory Perspective
Almath Spooner, PhD, RPh
Pharmacovigilance and Risk Management Lead, IMB and Vice Chair, PRAC, Health Products Regulatory Authority, Ireland

#265 Track 19B – Late-breaking Topics/All Tracks
Related Interest Area(s): CR, RA, IT
1:30–3:00 PM LEVEL: ■ FORMAT: FORUM
Room 143ABC CME, Pharmacy, and Nursing
Disruptive Forces in Health Care Innovation: Where Are They Leading Us?

CHAIRPERSON
Jeffrey Kasher, PhD
President, Patients Can’t Wait, LLC

A “big bang” of disruption is occurring where hardware, wearable gadgets and new medical technologies have raised the level of health care innovation including opportunities to advance research and connecting patients to their care. These discoveries have challenged regulatory science where existing organizations have become agile as trends and competition increases and where regulations are in need of review and constant update. This expert panel will discuss the impact of such technologies and where it has taken us today and into the future.

Submit your questions to this distinguished panel by emailing annualmeetingprogram@diaglobal.org; subject: Disruptive Forces Panel.

Advocate Role
Jack Andraka
Inventor of Early Diagnostic Test for Pancreatic Cancer, Visionary Teenage Scientist

Wearables Role
Angela Dunn
Trends Analyst, healthiscool

Patient Role
Patricia Furlong, BSN
Founding President and CEO, Parent Project Muscular Dystrophy

EU Perspective
Duane Schultheiss, MBA
Managing Director, VitalTransformation, Belgium

#266 Track 21 – Poster Presentations
2:30–3:10 PM LEVEL: ● FORMAT: SYMPOSIUM
Exhibit Hall (Entrance A) No CE available
Tuesday Oral Presentations—Professional Poster Session 1C
New this year! Join us in the Exhibit Hall Poster Area (Hall A Entrance) for a series of 5 minute presentations delivered by this year’s Professional Poster Presenters

The following are scheduled in this session 1C:
- 2:35–2:40 PM – T 35 Attractiveness of PRO Mixed Modes - What are Patients Saying?
- 2:42–2:47 PM – T 36 Efficient and Innovative Clinical Trial Enrollment Using Online and Social Media
- 2:49–2:54 PM – T 37 The Cost Effective Benefits of Behavioral Psychology on Improving Data Quality
- 2:56–3:01 PM – T 38 An Approach to Aggregate Safety Reporting of Drug and Device Constituent Parts of Combination Products

#267 Track 20 – Innovation Theater
Related Interest Area(s): CR, IT, CDM
3:00–3:30 PM LEVEL: ■ FORMAT: SPECSLESS
Exhibit Hall No CE available
BBK Worldwide Innovation Theater: mHealth: Enhanced Engagement + Better Data = Improved Outcomes

This presentation will cut through the hype to offer a useful look at opportunities, challenges and strategies within mHealth for enhanced patient engagement in clinical trials. For patient recruitment and engagement, mHealth has quickly become the new baseline—a minimum requirement to reach and engage with patients in today’s mobile-centric world. BBK will offer practical advice on employing the right mobile strategy to increase patient engagement, collect more and better data, and improve outcomes.

Innovator Role
Jack Andraka
Inventor of Early Diagnostic Test for Pancreatic Cancer, Visionary Teenage Scientist

Wearables Role
Angela Dunn
Trends Analyst, healthiscool

Patient Role
Patricia Furlong, BSN
Founding President and CEO, Parent Project Muscular Dystrophy

EU Perspective
Duane Schultheiss, MBA
Managing Director, VitalTransformation, Belgium

#268 Track 01A – Clinical Operations
Related Interest Area(s): CR
3:30–5:00 PM LEVEL: ■ FORMAT: SYMPOSIUM
Room 146A CME, Pharmacy, and Nursing
Bringing Clinical Trial Practices into the 21st Century

CHAIRPERSON
Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

In this symposium, we will look at how flexible, innovative mobile and digital technology can provide support throughout the product life cycle (from clinical research to real world environments). We will also take a
retrospective walk and a futuristic stroll through the patient recruitment strategies of yesterday and tomorrow, determining how the findings can be applied to provide the best participant experience when designing patient support programs. A review of technology-based patient engagement strategies will be performed, including both the barriers and recommendations for optimal implementation.

Furthermore, we will investigate the increasingly important role of the ubiquitous mobile device in running many aspects of today's clinical trials, and how the sponsors now look to specialist vendors to provide services that incorporate this now essential element into their study practices (enabling the pharmaceutical companies to focus on their core skill of drug development).

The Mobile Health Care Continuum: From Clinical Research to mHealth...and Back
Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

Bringing Clinical Trial Practices into the 21st Century
Cecilia Tran-Muchowski
Senior Clinical Program Manager, Gilead Sciences, Inc.

Nursing and Adherence Strategies to Increase Patient Engagement
Jennifer M. Allen, BSN, MBA
Senior Manager, Client Engagement, UBC: An Express Scripts Company

20/20 Foresight: Patient Recruitment in 2025
Matthew Stumm
Principal, Creative and Media Strategy, BBK Worldwide

#269 Track 01B – Clinical Operations

3:30–5:00 PM
Room 145B

Pediatric Clinical Trials: One Size Does Not Fit All
CHAIRPERSON
Kathryn Bohannon
Vice President, Global Project Management, inVentiv Health

In designing a pediatric study, each aspect must be thoughtfully considered and adjusted as necessary based upon the pediatric participants. In this session, we will examine the many factors that complicate clinical trials in children.

Pediatric Trials Networks: Capacity, Capabilities, and Complexities
Perdita Taylor-Zapata, MD
Pediatric Medical Officer, National Institute of Child Health and Human Development, NIH

The Need for Global Pediatric Clinical Trial Networks: An Industry Perspective
Ronald Portman, MD
Executive Director, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corporation

Panelist
Erik Deurrell, MD, MBA
Medical Director, Pediatric Pharmaceutical Consultants

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

3:30–5:00 PM
Room 101

A Critical Examination of the Strengths and Weaknesses of Different Project Management Models
CHAIRPERSON
Richard J. Heaslip, PhD
Founder, Programmatic Sciences LLC

This forum will review the strengths and weaknesses of project management models commonly used for managing development projects in life science organizations. It will then explore how to define the best approach(es) for managing projects in any given organization.

Improving Project Management in Life Science Organizations: Which Project Management Model Is Ideal for You?
Richard J. Heaslip, PhD
Founder, Programmatic Sciences LLC

Project Management in Strategic Partnerships Between CROs and Sponsors
Representative Invited
Vice President, Strategic Drug Development, Quintiles Transnational Corp.

Project Management in the Life Sciences Industry: Perspectives from Pharma, Devices and Diagnostics
Representative Invited
Assistant: Vice President, PMO North American Medical Affairs, Sanofi

How Biomarkers Can Be Leveraged to Improve Return on Investment in Drug Development
CHAIRPERSON
Eva Finney
Director, Global Project Management, Merck & Co., Inc.

Diminishing returns on investment have plagued the pharmaceutical industry in the last decades. This forum will explore how appropriate use of biomarkers can increase return on investment, either by facilitating earlier “no go” decisions, reducing clinical trial costs, improving the probability of success, accelerating drug development for faster time to market, or increasing access to the drug once on market. Case studies using molecular imaging will be presented. Execution challenges associated with incorporating biomarkers and companion diagnostics into a clinical program will be highlighted, as well as some solutions to these challenges. Finally, a regulatory perspective will be offered of the utility of biomarkers in clinical trial designs, including discussion of challenges and best practices for drug/test codevelopment.

The Benefits of Imaging Biomarkers in Oncology Clinical Trials
Robert Scarimbolo
Manager, Molecular Imaging, BioClinica
Effective Project Execution for Companion Diagnostics
Rachel Yarger, MBA, PMP
Senior Project Manager, Luminex Corporation

Utility of Biomarkers and Their Associated Diagnostics in Drug Development Programs: A Regulatory Perspective
Christopher Leptak, MD, PhD
Biomarker and Companion Diagnostic Lead, Office of New Drugs, CDER, FDA

Investing in CRO Partnering, Achieving Results Together
Maria Makarovskaya
Director, Strategic Sourcing, Infinity Pharmaceuticals, Inc.

#274 TRACK 04 – PRECLINICAL AND TRANSLATIONAL DEVELOPMENT/EARLY PHASE CLINICAL DEVELOPMENT

3:30–5:00 pm  LEVEL: ■  FORMAT: SESSION
Room 103A  CME and Nursing

Striking a Balance Between Ethical Treatment and Impact on Nonclinical Safety and Animal Rule Efficacy Study Interpretation When Using Prophylactic or Supportive Care

CHAIRPERSON
Simone Nicholson, PhD
Toxicologist, Medimmune, Inc.

In this session, we will review the types of prophylactic or supportive care provided during nonclinical safety studies and efficacy studies conducted under the Animal Rule, along with the challenges for interpretation of such studies. The nonclinical safety assessment process identifies an initial safe dose and subsequent dose escalation schemes for human, potential target organs for toxicity, determining reversibility, and defining safety parameters for clinical monitoring. Various factors, including the candidate molecule structure (small versus large molecule), mechanism of action, and duration of exposure, suggest that specific adverse events might be expected in repeat dose toxicity studies which will require prophylactic and/or supportive care. Under the Animal Rule, efficacy for a therapeutic candidate is derived from animal models because it is unethical or impossible to collect these data from human subjects. Study design and supportive care of the animals during these evaluations allow for predictions of efficacy in human subjects based on the animal model experience.

Case Examples from Nonclinical Safety Assessment Studies
Simone Nicholson, PhD
Toxicologist, Medimmune, Inc.

Animal Rule: Overview of Drug and Biological Product Development When Human Efficacy Studies Are Not Ethical or Feasible
Kenneth Westervelt, MS
Senior Project Manager, Regulatory Affairs, Accenture

The Veterinary Perspective on Prophylactic or Supportive Care in Safety and Animal Rule Efficacy Studies
Steven T. Shipley, DVM
Chief, Veterinary Medicine, University of Maryland, School of Medicine

Nonclinical Study Interpretation of Prophylactic or Supportive Care: A Regulatory Perspective
L. Peyton Myers, PhD
Pharmacologist, Office of New Drugs, CDER, FDA
The content noted on this page was made available to DIA as of April 27.

#275 Track 05 – Regulation of Product Advertising and Marketing in an Ever-Changing World

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

3:30–5:00 pm      LEVEL: ■      FORMAT: FORUM
Room 152B
CME, Pharmacy, and Nursing

The Free Exchange of Truthful and Non-Misleading Medical Information

CHAIRPERSON
John Kamp, JD, PhD
Attorney at Law; Executive Director, Wiley Rein LLP; Coalition For Healthcare Communication

This forum will explore new approaches to the free exchange of medical information by industry based on the requirements of the first amendment and the information needs of patients, providers and payers. Special attention will be paid to proposals to FDA by industry groups, including PhRMA and the Medical Information Working Group, and the House Energy and Commerce committee in deliberations on the proposed legislation on 21st Century Cures.

Panelists
Sandra C. Raymond
President and Chief Executive Officer, Lupus Foundation of America

Freddy A. Jimenez, JD
Assistant General Counsel, Johnson & Johnson

Clay Alspach, JD
Chief Majority Healths Counsel, House Energy and Commerce Committee

#276 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): MW, PETD

3:30–5:00 pm      LEVEL: ■      FORMAT: SYMPOSIUM
Room 206
CME and Nursing

Leadership and Process in Medical Writing

CHAIRPERSON
Robin Whitsell
President, Whitsell Innovations, Inc.

Medical writers frequently perform their roles with little authority over their teams despite high-stakes outcomes. They understand the needs of their target audiences (clinical study teams, busy health authority reviewers, and internal stakeholders) and have to create consensus and cohesion. Frequently, medical writers turn to metrics and best practices to inform the best pathway forward. This symposium will detail how to incorporate processes and leadership to streamline the document generation process and bolster the effectiveness of medical writing teams. The presenters will focus discussion around three areas: creation of high quality protocols through data-driven metrics, planning and implementing effective comment-resolution meetings, and formation of accountable teams.

He Who Cares Most Loses? How to Develop Team Ownership with Medical Writing
Robin Whitsell
President, Whitsell Innovations, Inc.

#277 Track 07A – Technology/Data/Records and Submissions

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

3:30–5:00 pm      LEVEL: ■      FORMAT: SYMPOSIUM
Room 201
CME, Pharmacy, and Nursing

How Risk-Based Monitoring and eSource Methodologies Are Impacting Clinical Sites, Patients, Regulators and Sponsors

CHAIRPERSON
Jules T. Mitchel, PhD, MBA
President, Target Health Inc.

This symposium will show how risk-based monitoring and eSource methodologies are impacting the way clinical trials are being conducted and managed.

The Time Is Now for Risk-Based Monitoring
Frances E. Nolan, MBA
Vice President, Quality and Regulatory Affairs, Medidata Solutions Worldwide

Overcoming Clinical Trial Data Collection Challenges with eSource Solution and Leveraging Mobile Technologies
Avik Kumar Pal, MBA
Chief Executive Officer, CliniOps

Innovation by Design: Using eSource to Maximize Clinical Development Productivity and Efficiency
Edward Stephen Seguine, Jr., MBA
Chief Executive Officer, Clinical Ink

#278 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, RA

3:30–5:00 pm      LEVEL: ■      FORMAT: SESSION
Room 202B
CME, Pharmacy, and Nursing

Data and Evaluation Needed for Robust Evidence: Regulators’ Challenges

CHAIRPERSON
Yoshihiko Ono, RPh
Executive Director, Head of Regulatory Affairs, Japan Development, MSD K.K., Japan

In recent years, the use of information based on the analysis of various data sources has been proactively promoted in decision-making processes of regulatory agencies. In this session, we will discuss the recent achievements and future challenges of regulatory agencies, focusing on how to make robust evidence with the efficient utilization of various data. We will also discuss the impact through the life cycle of medicinal products and common regulatory challenges.
#279 Track 08A – Regulatory Affairs  Related Interest Area(s): CR
3:30–5:00 PM  Level: ■  Format: SESSION
Room 151A  CME and Nursing

Getting the Most Out of Scientific Advice in the US and EU

CHAIRPERSON
Daniel M. Bollag, PhD
Senior Vice President, Regulatory Affairs and Quality, Ariad Pharmaceuticals Inc.

This session will focus on how to obtain the best scientific advice from US and European health authorities. Presenters will discuss the optimal times in the drug development process to seek advice, timelines for obtaining advice, case examples and tips for procuring the most useful advice, and how to leverage that advice during subsequent development and agency interactions.

Scientific Advice in the EU: How to Get the Best Out of It
Gopal Narayanan, MD, FFPM, FRCP
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

US/EU Scientific Advice Procedures: Improving Drug Development from the Authority's Perspective
Leonardo Ebeling, MD, PhD
Managing Director, Dr. Ebeling & Assoc. GmbH, Germany

Scientific Advice: What You Get and What It Takes—A Regulator's View
Andrea Laslop, MD
Head of Scientific Office, AGES, Austria

#280 Track 08B – Regulatory Affairs  Related Interest Area(s): PT, MC, AP
3:30–5:00 PM  Level: ■  Format: FORUM
Room 151B  CME, Pharmacy, and Nursing

Optimizing Patient Labeling: A Panel Discussion Between Industry, Academia, and Prescribers

CHAIRPERSON
Lina Aljuburi, PharmD, MS
Director, Global Regulatory Policy, Merck & Co., Inc.

Patient medication information that is understandable and usable by the patient is critical to the care of that patient. A panel of industry, academic, and prescriber stakeholders come together to discuss ways to improve the current situation.

#281 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products  Related Interest Area(s): CmbP, RA, PPLCC
3:30–5:00 PM  Level: ■  Format: SESSION
Room 150B  CME, Pharmacy, and Nursing

Continuing Growth in Combination Products: More Products, More Questions - Perspectives from FDA and Industry

CHAIRPERSON
Jayne C. Ware, MPH, MS
Director, Global Regulatory Policy, Merck & Co., Inc.

Forecasts predict continued growth in the global combination product market. New products and changes to marketed combination products raise regulatory issues that challenge both FDA and sponsors. In this session, we will discuss FDA and industry perspectives.

Combination Products: Industry Perspective on Current Policy Issues
Bradley Merrill Thompson, JD, MBA
General Counsel, Combination Products Coalition, Epstein, Becker and Green P.C.

Combination Products: Regulatory Perspective
Patricia Y. Love, MD, MBA
Deputy Director, Office of Combination Products, Office of Special Medical Programs, Office of the Commissioner, FDA

Combination Products: Design Control Requirements for Products Post-Launch
Karen Grinker, MBA
Senior Technical Manager, Genentech, A Member of the Roche Group

Representative Invited
Associate Director, Policy and Product Classification Officer, Office of the Commissioner, FDA

#282 Track 10 – Public Policy/Health Care Compliance/Law  Related Interest Area(s): RA
3:30–5:00 PM  Level: ■  Format: SESSION
Room 146B  CME and Nursing

Progress Report on Emerging Nations and Regulatory Capacity Building

CHAIRPERSON
Ekopimo O. Ibia, MD, MPH, FRCP
Director, Global Regulatory Policy, FDA Alumni Association International Network, Merck & Co., Inc.
This decade has seen widespread activities by nations, nonprofits, and industry engaging in global regulatory capacity building and strengthening. Hear major initiatives from the Bill and Melinda Gates Foundation, African Medicines Regulatory Harmonization program, and an academic overview of the field and its impact on health, industry, and economy.

Regulatory Systems Optimization for Products for Neglected Diseases
Murray M. Lumpkin, MD, MSc
Deputy Director, Regulatory Affairs, Lead Global Regulatory Systems Initiatives, Bill and Melinda Gates Foundation

Regional Centres of Regulatory Excellence (RCORE): Innovative Regulatory Workforce Development Initiative in Africa
Paul Kiptum Tanui, MBA, RPh
Senior Programme Officer, African Medicines Regulatory Harmonization Programme, The New Partnership For Africa’s Development (NEPAD), South Africa

Strengthening Regulatory Systems of Emerging Economies: Opportunities and Challenges
Syed Rizwanuddin Ahmad, MD, MPH, FISPE
Assistant Professor (adjunct), Georgetown University School of Medicine

#283 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Managing Protocol Deviations: Applying the Protocol Deviations Working Group SOP for Handling Protocol Deviations in Clinical Trials
CHAIRPERSON
Maryrose Petrizzo, MSc
President and Principal Consultant, Clinical Quality Assured, LLC

This workshop will provide a sample clinical trial protocol and corresponding protocol deviation handling plan (PDHP) along with the standard operating procedure (SOP) and protocol deviations reporting form. Several protocol deviations (PD) will be provided and workshop attendees will be asked to follow the PDHP to handle the classification and reporting of the PD.

This workshop was developed by the DIA Good Clinical Practice and Quality Assurance Community and the Protocol Deviations Working Group.

**Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington 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
Munish Mehra, PhD
Executive Director, Business Development & Principal Biostatistician, Tigermed
Sandy Mohan, PhD
Vice President, Quality and Compliance, Biotie Therapies

#284 Track 12 – Pharmaceutical Quality

CMC/GMP: Risk-Based Regulatory Review
CHAIRPERSON
Roger Nosal, MA, MS
Vice President and Head, Global CMC, Pfizer Inc

This forum will focus on presenting new and alternative strategies for use in implementing both risk minimization and risk mitigation processes in relation to CMC and GMP processes. In addition, we will focus on the benefits of implementing or modifying a product life cycle management program in both manufacturing and regulatory environments.

Panelists
Ganapathy Mohan, PhD
Head of Global CMC, Merck & Co., Inc.
Susan M. Rosencrance, PhD
Acting Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA
Lynne Krummen
Vice President, Technical Regulatory, Biologics, Genentech, A Member of the Roche Group

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

Innovative Approaches to Patient Registries for Evaluating Outcomes
CHAIRPERSON
Michelle Leavy, MPH
Research Manager, Health Policy, Quintiles Inc.

Patient registries are increasingly being used to conduct research on comparative effectiveness, patient outcomes, and safety. Innovative approaches to designing and operating registries are critical to support their growing use and the increasing complexity of the research questions that they address. In this forum, we will summarize key points in “Registries for Evaluating Patient Outcomes,” a widely used guide on registry best practices, and present case examples on leveraging patient-generated registries, linking registries with biorepositories, conducting multinational registries, and designing registries using external electronic medical record data. In addition, presenters will discuss an emerging area of controversy—registration of patient registries in systems such as ClinicalTrials.gov, the Registry of Patient Registries (RoPR) and the Patient REGistries INITiative (PARENT). We will discuss the rationale for registration and review and compare options for registration, both in the US and globally.

New Approaches and Emerging Challenges in Patient Registry Design and Conduct
Michelle Leavy, MPH
Research Manager, Health Policy, Quintiles Inc.
Almost Three Years On, Has the New Periodic Safety Update Report (PSUR) Achieved What Was Originally Intended?
Shelley Gandhi
Director, Pharmacovigilance and Drug Safety, NDA Group, Sweden

Global Perspective
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory, Pfizer Inc

Translating New Knowledge from Regulatory Science into Postmarketing Safety Practice

CHAIRPERSON
Gerald J. Dai Pan, MD
Director, Office of Surveillance and Epidemiology, CDER, FDA

This forum will discuss interactions between lessons learned in regulatory science and regulatory activities and the challenges met to translate results into changes of pharmacovigilance practice. This forum will include topics such as Impact, Mini-Sentinel, Protect, public health and regulatory science.

Translating New Knowledge from Regulatory Sciences into Postmarketing Safety Practice
Peter Richard Arlett, MRCP
Head of Pharmacovigilance, European Medicines Agency, European Union

The Clinical Trials Transformation Initiative IND Safety Reporting Advancement Project: Findings and Next Steps
Robert Goodwin, MBA, MSc
Vice President, Safety Evaluation and Reporting, Pfizer Inc

Predictive Subgroup Methodologies and Molecular Basket Designs

CHAIRPERSON
Robert A. Beckman, MD
Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Optimal designs for predictive biomarkers and their associated subgroups are presented from both the public health and drug developers’ perspectives. Novel basket designs grouping tumors based on molecular characteristics will be discussed.

This session has been developed by the DIA Adaptive Design Scientific Working Group.

Optimizing the Biomarker Subpopulation Strategy in Late Stage Clinical Development
Carl-Fredrik Burman, PhD
Associate Professor in Biostatistics, Chalmers Univ of Tech; Senior Principal Scientist, AstraZeneca R&D, Sweden

Design for a Confirmatory Histology Agnostic Molecular Basket Study
Robert A. Beckman, MD
Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Predictive Biomarker Classifiers and Molecular Classifiers: A Perspective
Rajeshwari Sridhara, PhD
Director, Division of Biometric V, Office of Biostatistics, Office of Translational Science, CDER, FDA

Update from the ICH E2C (R2) Expert Working Group
Almath Spooner, PhD, RPh
Pharmacovigilance and Risk Management Lead, IMB and Vice Chair, PRAC, Health Products Regulatory Authority, Ireland

Conflict Resolution: Helping Teams Manage Through Conflict

CHAIRPERSON
Jennifer Lansink
President, Total Root Concepts, Inc.

Conflict is inevitable. Problems with conflict result from poorly managed communication. This interactive workshop provides audiences with
the awareness and tools for successful navigation of intrapersonal, interpersonal, and team conflict.

**Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington 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 secure seats. Please note, as a workshop with interactivity, this offering will not be recorded.**

**#290 Track 17 – Rare/Orphan Diseases**

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

3:30–4:30 pm  
Room 145A

**Pediatric Drug Development**

**CHAIRPERSON**

Maureen Smith, MEd  
Patient Advocate/Secretary, Canadian Organization For Rare Disorders (CORD), Canada

There is greater demand from regulatory and clinical care communities to include pediatric patients in clinical development. However, inclusion of pediatric patients poses unique challenges in preclinical work, clinical trials, and navigation of regulatory processes. The aim of this panel is to describe the challenges and to offer approaches and solutions to help overcome them. We will discuss animal models and drug screening platforms, clinical trial design, unique information needs, and regulatory pathways. Attention will be given to highlighting differences in pediatric orphan drug development and regulatory frameworks in major and emerging geographies.

**Preclinical and Clinical Drug Development in Juvenile Rare Diseases**

Shu-Wha Lin  
Professor, Department of Laboratory Science Medical Biotechnology, National Taiwan University College of Medicine, Taiwan

**Regulatory Framework in Pediatric Rare Diseases**

Dinah Duarte, PharmD, MSc  
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

**#291 Track 18A – Global Regulatory**

**Related Interest Area(s): MDD, CmbP**

3:30–5:00 pm  
Room 146C

**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: CDRH’s Senior Staff Management Team; FDASIA accomplishments and activities; the view toward 2017 MDUFA Reauthorization and the impact of the House Energy and Commerce 21st Century Cures initiatives; regulatory framework for laboratory developed tests (LDTs); CDRH’s development of expedited pathways; the future of next gen sequencing and innovative approaches for companion diagnostics and personalized medicine; human factors studies; combination products; regulation of mobile and web software applications, and other new technologies and their impact on patient care.

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

**Panelists**

Jeffrey Shuren, JD, MD  
Director, Center for Devices and Radiological Health, FDA

William H. Maisel, MD, MPH  
Deputy Director for Science and Chief Scientist, Director, ODE (Acting), CDRH, FDA

Representative Invited  
Director, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA

**#292 Track 18B – Global Regulatory**

**Related Interest Area(s): RA**

3:30–5:00 pm  
Room 207A

**Chinese Drug Development: An Update**

**CHAIRPERSON**

Maureen Smith, MEd  
Patient Advocate/Secretary, Canadian Organization For Rare Disorders (CORD), Canada

There is greater demand from regulatory and clinical care communities to include pediatric patients in clinical development. However, inclusion of pediatric patients poses unique challenges in preclinical work, clinical trials, and navigation of regulatory processes. The aim of this panel is to describe the challenges and to offer approaches and solutions to help overcome them. We will discuss animal models and drug screening platforms, clinical trial design, unique information needs, and regulatory pathways. Attention will be given to highlighting differences in pediatric orphan drug development and regulatory frameworks in major and emerging geographies.

**Preclinical and Clinical Drug Development in Juvenile Rare Diseases**

Shu-Wha Lin  
Professor, Department of Laboratory Science Medical Biotechnology, National Taiwan University College of Medicine, Taiwan

**Regulatory Framework in Pediatric Rare Diseases**

Dinah Duarte, PharmD, MSc  
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

**Translational Medicine and New Drugs Innovation and Development**

**Representative Invited**

Member of Chinese Academy of Engineering; President, Chinese Pharmaceutical Association (CPA), China

Experts in translational medicine, traditional Chinese medicine, small molecules and biologic will provide an update on the development of drugs in China.

**Quality Management and Risk Control of the Biological Product**

**Representative Invited**

China National Biotec Group, China

**The Advance in Drug Delivery Systems in China**

**Representative Invited**

School of Pharmaceutical Science, Peking University; Chair, Pharmaceutical Committee, Chinese Pharmaceutical Association (CPA), China
Leveraging Patient Insights to Disrupt the Traditional Approach and Influence Change
Deborah Howe
Associate Director, Vendor and Supply Chain Management Lead, Bristol-Myers Squibb Company

Making WAVES: Holistic Approaches to Recruiting Women from the First Global All-Women’s HIV Clinical Study
Lisa Marie Montafia
Senior Clinical Trials Manager, Gilead Sciences, Inc.

Addressing the Challenges of Minority Recruitment in Clinical Trials
Bernadette Tosti
Senior Director, Head of Patient Recruitment Programs, Quintiles Inc.

#302 Track 01B – Clinical Operations
Related Interest Area(s): PT, CR

Patient Registries: Design, Development, and Recruitment
CHAIRPERSON
Ginger Spitzer, MA
Executive Director, Foundation of Sarcoidosis Research

This workshop will review how to create a patient registry, outlining major elements. Participants will work together and with the presenter to identify specific needs (based on resources, objectives) and review options and recommendations.

Facilitator
Representative Invited
Chief Operating Officer, Transparency Life Sciences

#301 Track 01A – Clinical Operations
Related Interest Area(s): PT, CR

Leveraging Diverse Patient Insights
CHAIRPERSON
Jane E. Myles, MS
Global Head, Recruitment Strategy, Genentech, A Member of the Roche Group

Incorporating patient insights in the clinical trial development process is gaining momentum industry-wide, and this symposium will share different experiences with leveraging patient insights. We will examine how a large pharmaceutical company sought a deeper understanding of attitudes and perceptions from the patient perspective and leveraged their learnings to influence change to the protocol as well as the strategic recruitment plan. Factors that contribute to recruitment of women in HIV-1 clinical trials as well as the factors which should be considered when planning a clinical trial intended to enroll women will be explored. We will also explore key drivers behind the low rates of clinical trial participation among minorities, including lack of information about ongoing trials and lack of racial and ethnic diversity among investigators.

#303 Track 02 – Project/Portfolio Management and Strategic Planning
Related Interest Area(s): RA, SUBS

Keys to Managing a Successful Regulatory Strategy and Submission
CHAIRPERSON
Lauren Michelle Neighbours, PhD, RAC
Clinical Research Scientist, Rho, Inc

This forum will discuss tools for implementing an effective regulatory submission strategy. A panel of experts will provide their insight on best practices for early, mid, and late-phase product development planning.

Targeted Labeling Is the Key to Your Marketing Application Strategy
Diana E. Bytnar Fordyce, PhD, MS, RAC
Consultant, Regulations Pharmaceuticals, Switzerland

Seven Recommendations for Building a Better NDA
Jeff Antos
Vice President, The Weinberg Group Inc.
Questions to Consider Before Assembling Your eCTD
Robert Rohde
Head of Submissions, Pharmakey LLC

#304 Track 03A – Innovative Partnering Models and Outsourcing Strategies
Related Interest Area(s): CR, SP
8:00–9:00 AM△ Level: ■ Format: SESSION
Room 150A CME and Nursing
How to Make a Strategic Partnership Model Work at the Country/Site Level in Asia Pacific and Insight from a Regulatory Inspector
CHAIRPERSON Catherine Lee, MBA, MPharm, MSc Area Head-Asia, Clinical Trial Support and Compliance, Pfizer Inc, Taiwan
Many pharmaceutical companies are building partnerships with contract research organizations (CROs). However, there are many obstacles at the country level. In this session, we will discuss how to establish the CRO/sponsor partnership in Asia. The insight of a regulatory inspector will also be shared.

Sharing Best Practices on What the True Partnership Looks Like to Drive Project Delivery in Asia Pacific Countries (from Sponsor Perspectives)
Catherine Lee, MBA, MPharm, MSc Area Head-Asia, Clinical Trial Support and Compliance, Pfizer Inc, Taiwan

Sharing Best Practices on What the True Partnership Looks Like to Drive Project Delivery in Asia Pacific Countries (from CRO Perspectives)
Jing Ping Yeo, PhD Head, Project Leadership Asia Pacific, PAREXEL International, Singapore

Impact of CRO Inspection Results in Taiwan: Insight from a Regulatory Inspector About CRO/Sponsor Partnerships
Wen-Ting (Mandy) Liu Team Leader of GCP Inspection Team, Center for Drug Evaluation (CDE), Taiwan

#305 Track 03B – Innovative Partnering Models and Outsourcing Strategies
Related Interest Area(s): OS, IT
8:00–9:30 AM Level: ■ Format: FORUM
Room 152A CME and Nursing
Transforming Industry Through Centralization of Key Business Practices: A Focus on Prequalification of Niche Suppliers
CHAIRPERSON Mitchell A. Katz, PhD Head of Medical Research and Drug Safety Operations, Purdue Pharma L.P.
This forum will present data showing industry challenges when prequalifying technical clinical service providers. Industry standards and tools will be shared that will transform the approach for future prequalification assessments.

Panelists
Janis L. Hall, MBA Senior Consultant, The Avoca Group, Inc.

#306 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development
Related Interest Area(s): PC, CP
8:00–9:30 AM Level: ■ Format: SESSION
Room 103A CME, Pharmacy, and Nursing
Innovative Approaches to Predictive Clinical Safety and Signal Detection Utilizing Clinical Pharmacology Concepts
CHAIRPERSON Howard Greenberg, MD Medical Safety Officer, Janssen Pharmaceuticals, Inc.
Pharmacovigilance analyzes spontaneous reports to assess potential safety concerns. Newer methods that may predict potential issues, coupled with enhanced observational methods using patient-generated data may complement the traditional approaches.
This session has been developed by the DIA Clinical Pharmacology Community.

Utilization of Social Media for Postmarketing Surveillance: Proof of Concept Study with PatientsLikeMe Data for Signal Detection
Amy Purrington, MD Lead, Aggregate Signal Detection, Janssen Pharmaceuticals, Inc.

Pharmacological Mechanism-Based Drug Safety Prediction: Approach to non-QT Tyrosine Kinase Inhibitor Cardiotoxicity
Darrell Abernethy, MD, PhD Associate Director for Drug Safety, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

Holistic Signal Detection: Leveraging Multiple Data Sources to Improve the Accuracy and Timeliness of Signal Detection
Rave Harpaz, PhD Senior Research Scientist, Oracle Health Sciences

#307 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons
Related Interest Area(s): MC, RA
8:00–9:30 AM Level: ■ Format: SESSION
Room 206 CME, Pharmacy, and Nursing
Returning Results to Study Participants: Health Literacy and Effective Language
CHAIRPERSON Barbara Godlew, RN President, The FAIRE Company, LLC
Beginning in 2016, the European Clinical Trial (ECT) regulation will require clinical trial sponsors to provide trial results to the participants in a format and language appropriate and understandable to the participant. This session will focus on the history and principles of return of results to participants, including the history and generation of guidance for this effort, key principles of health literacy and numeracy that can guide the effective communication of study results, including language, formatting, and the
presentation of data and discuss the integration and dissemination of health literacy principles driven by the need for clear communication for all audiences and not just those with limited literacy.

**MRCT Principles and the Mandate for Transparency**
Barbara E. Bierer, MD
Professor of Medicine, Harvard and Brigham and Women's; Co-Director MRCT, Harvard University

**Incorporation of Health Literacy Into the Corporate Structure**
Laurie M. Myers, MBA
Health Literacy and Healthcare Disparities Strategy, Merck & Co., Inc.

**Regulatory Considerations in Implementing Clinical Trial Summaries for Study Participants**
Nancy Ostrove, PhD
Principal, EXPRE

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**#308 Track 07A – TECHNOLOGY/DATA/RECORDS AND SUBMISSIONS**
**Related Interest Area(s): CDM**

8:00–9:00 AM 
CME and Nursing

**Room 201**

**CDISC SHARE Repository: Laying the Tracks and Building the Stations for This New Metadata Train**
**CHAIRPERSON**
Kenneth Stoltzfus
Clinical Data Strategies, Accelerated R&D Life Sciences, Accenture

The CDISC SHARE repository is poised to change the way the industry utilizes standards metadata for clinical trials. This session presents the sponsor, vendor, and the CDISC viewpoints on how the industry can maximize the benefits SHARE offers.

**Using Information Standards to Drive eClinical Interoperability**
Samuel W. Hume, MS
Vice President, SHARE Technology and Services, CDISC

**Maximizing the Benefits of SHARE**
Kenneth Stoltzfus
Clinical Data Strategies, Accelerated R&D Life Sciences, Accenture

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**#309 Track 07B – TECHNOLOGY/DATA/RECORDS AND SUBMISSIONS**
**Related Interest Area(s): DM, CR**

8:00–9:30 AM 
CME and Nursing

**Room 202B**

**Mapping the Future for Trial Master File: Advancing Standards by Harmonizing Clinical and Technical Strengths**
**CHAIRPERSON**
Donna W. Dorozinsky, MSN, RN
President, DWD & Associates, Inc.

Standardization has become the norm across the clinical research spectrum. The industry has embraced data standards, such as MEDRA, CDISC, and eCTD. The Trial Master File (TMF) is a collection of content that demonstrates that the sponsor conducted the study in accordance with the protocol and Good Clinical Practice. In the past several years there has been an industry move to creating best practice and standardizing the Trial Master File content. Standardized TMF content ensures completeness of regulatory submission, regulatory inspection readiness and trial execution.

The TMF standards are evolving to address the interoperability needs of collaboration, mergers, acquisitions, licensing efforts and records retention. This session will discuss the importance of standards in TMF and explore the currently available standards within the industry.

**Achieve Synergy Between Clinical and Technical TMF Standard With These Simple Steps**
Donna W. Dorozinsky, MSN, RN
President, DWD & Associates, Inc.

**Think Standard Inventory Means Technical Interoperability? Think Again**
Michael Agard, MS
Principal Consultant, Paragon Solutions, Inc.

**Just The Facts**
Eric Rubinson
Director, DD&R Business Operations, Actavis plc

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**#310 Track 08A – REGULATORY AFFAIRS**
**Related Interest Area(s): CR**

8:00–9:30 AM 
CME and Nursing

**Room 150B**

**Recent Experiences with Adaptive Licensing and Facilitated Regulatory Pathways**
**CHAIRPERSON**
Lawrence Liberti, MS, RPh, RAC
Executive Director, Centre For Innovation In Regulatory Science (CIRS)

Facilitated regulatory pathways (FRPs) and transformative adaptive licensing (AL) procedures can accelerate patient access to medicines. This forum will review recent experiences, facilitators and how barriers have been overcome for effective use of FRPs and considerations for AL pilots.

**Stakeholder Perceptions of Adaptive Licensing and Facilitated Regulatory Pathways (FRPs)**
Lawrence Liberti, MS, RPh, RAC
Executive Director, Centre For Innovation In Regulatory Science (CIRS)

**Marketing Authorizations for Earlier Patient Access: Regulatory Challenges in Japan**
Daisaku Sato, PhD
Director, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

**Bringing Innovative Medicines to Patients and Maximizing Benefits to Public Health Through Adaptive Licensing**
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

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**#311 Track 08B – REGULATORY AFFAIRS**
**Related Interest Area(s): SUBS, CR**

8:00–9:00 AM 
CME and Nursing

**Room 151A**

**Update: FDA CDER’s Progress to Adapting Standardized Data to Select Clinical Sites for Inspection**
**CHAIRPERSON**
Betsy Fallen, RN
Principal, BAFallen Consulting, LLC
This session will include an overview of the Office Of Scientific Investigation (OSI), discuss the goals of the Bioresearch Monitoring (BIMO) Program, include a review of previous challenges to the inspection system, provide an overview of CDER's Clinical Site Selection Model and Tool and provide a summary of the OSI request for information specification for preparing and submitting summary level clinical site data in the electronic common technical document (eCTD).

**Format and Content of FDA Requested Documentation and Datasets to Facilitate Bioresearch Monitoring (BIMO) Inspections**

Colleen Davenport
Senior Director, Regulatory Affairs, AnGes, Inc.

**FDA Point of View**

Kassa Ayalew, MD, MPH
Branch Chief, Office of Scientific Investigations, Office of Compliance, CDER, FDA

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### #312 Track 10 - Public Policy/Health Care Compliance/Law

**Related Interest Area(s): RA**

**Format:** ForUm

8:00–9:30 AM  
Room 143ABC  
CME, Pharmacy, and Nursing

**21st Century Cures: Which Are the Most Transformative Provisions and How Do They Accomplish Major Change?**

**CHAIRPERSON**

Nancy Bradish Myers, JD  
President, Catalyst Healthcare Consulting, Inc

It is all the buzz in DC! Congress is working with innovators, patients and policy makers to draft legislation and the House plans to these ideas forward early in 2015. The goal is to reform FDA regulatory processes in order to accelerate the discovery, development and delivery of promising new treatments. Which are the most transformative ideas and what important goals will they accomplish? How will this legislative effort dovetail with PDUFA VI negotiations? Join our panel to hear from members of Congress, FDA and other key stakeholders to better understand where this initiative is in the process, and what our panelists believe the most transformative provisions will be.

**Panelists**

Janet Woodcock, MD  
Director, Center for Drug Evaluation and Research, FDA

Clay Alspach, JD  
Chief Majority Health Counsel, House Energy and Commerce Committee

Ellen V. Sigal, PhD  
Founder and Chairperson, Friends of Cancer Research

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### #313 Track 11 - Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

**Related Interest Area(s): RA**

**Format:** SESSION

8:00–9:30 AM  
Room 102AB  
CME and Nursing

**Changes in Regulations That May Impact How Inspections Are Conducted: Regulatory Perspectives**

**CHAIRPERSON**

Sherri A. Hubby  
Director, US Quality Assurance, Premier Research Group Ltd.

Regulators will discuss changes in regulations that may impact how inspections are conducted by the FDA, EMA, and PMDA which will help sponsors, contract research organizations and study sites running clinical trials in the EU and internationally understand the important, updated compliance. Hot topics include new guidance for inspection of the electronic Trial Master File and e-Records, pre-inspectional activities, pre-announcements of inspections, inspectional risk criteria, similarities and differences in documents requested and reviewed, reportable observations as well as top inspectional findings as a result of the new guidance.

The Clinical Trial Regulation: A New Era for Europe
Anabela Marcal, PharmD  
Head of Compliance and Inspections Department, European Medicines Agency, European Union

FDA Point of View
Cynthia Kleppinger, MD  
Senior Medical Officer, Office of Scientific Investigations, Office of Compliance, CDER, FDA

PMDA Point of View
Naoyuki Yasuda  
Office Director, Office of Non-Clinical and Clinical Compliance, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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### #314 Track 12 - Pharmaceutical Quality

**Related Interest Area(s): QC, RA**

**Format:** FORUm

8:00–9:30 AM  
Room 151B  
CME and Nursing

**Challenges in Managing Global Regulatory Divergence**

**CHAIRPERSON**

Thomas W. Schultz, PhD, MS  
Senior Director, Regulatory Sciences, Global CMC Regulatory Affairs, Janssen Pharmaceuticals, Inc.

Multinational pharmaceutical companies generally manufacture the same product, the same way for every market, region and patient around the world. However, in the emerging markets, divergent, nonscientific, regulatory standards are proliferating. Increased global divergence in regulatory requirements and review times unnecessarily increase manufacturing costs, complicates the supply chain, hinders science and risk-based approaches, increases collective regulatory burden, reduces continuous improvement and innovation and delays delivery of medicines to patients. This forum will include specific examples highlighting instances where the lack of global harmonization results not only in present day challenges but potential opportunities for future convergence.
International Cooperation in the Pharmaceutical Supply Chain
Emer Cooke, MBA
Head of International Affairs, European Medicines Agency, European Union

Substandard, Falsified and Counterfeit Drugs
Howard R. Sklamberg, JD, MA
Deputy Commissioner, Global Regulatory and Policy Operations, Office of the Commissioner, FDA

Export Dossiers: Global CMC Submissions That Do Not Compromise Proprietary Information
Peter Lassoff, PharmD
Vice President and Head, Global Regulatory Affairs, Quintiles Inc., United Kingdom

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

8:00–9:30 AM
Room 209AB
CME, Pharmacy, and Nursing

Real-World Use of Multi-Criteria Decision Analysis for Benefit-Risk Assessment: Lessons Learned in the Industrial Setting

CHAIRPERSON
Kevin Marsh, PhD, MSc
Senior Director, Modeling and Simulation, Evidera, United Kingdom

There is increased demand for quantitative benefit-risk assessment (BRA). Various reviews have recommended multi-criteria decision analysis (MCDA) to undertake quantitative BRA (e.g., PROTECT). The objective of this session is learn from real examples of conducting MCDA for BRA in an industry setting.

MCDA in the Benefit-Risk Evaluation of Medicines: What Sponsor and Health Agency Applications and Perspectives Have Taught Us So Far
Filip Muszen, PhD
Vice President, Regional Regulatory Affairs, Janssen Pharmaceutica NV, Belgium

Best Practice in MCDA: An Illustrated Summary of Best Practice Guidelines
Kevin Marsh, PhD, MSc
Senior Director, Modeling and Simulation, Evidera, United Kingdom

Benefit-Risk Assessment for Multivalent Pneumococcal Conjugate Vaccine for Prevention of Pneumonia and Long-Term Opioid Therapy for Chronic Pain: What MCDA Can Add
Paul M. Coplan, DrSc, MBA, MPH
Executive Director, Risk Management and Epidemiology, Purdue Pharma L.P.

#316 Track 14 – Clinical Safety and Pharmacovigilance

8:00–9:30 AM
Room 103B
CME, Pharmacy, and Nursing

Pharmacovigilance Concerns with the Use of Experimental Medicines for Ebola and Enterovirus B-68

CHAIRPERSON
Elizabeth E. Garrard, PharmD
Senior Director, Safety Risk Management, United Therapeutics Corporation

The race is on to find a cure for Ebola which has killed more than 8000 people in West Africa and remains the largest outbreak on record. Over the last several months, the United States has experienced a nationwide outbreak of enterovirus D68 (EV-D68) associated with severe respiratory illness. The CDC and/or state public health laboratories have confirmed over 1100 people in 47 states and the District of Columbia with respiratory illness caused by EV-D68. There are no proven treatments for people with the Ebola or enterovirus D68 virus or vaccines to prevent infection in the first place. However, progress is now being made on an unprecedented scale. Trials, which would normally take years and decades, are being fast-tracked on a timescale of weeks and months. This session will discuss how fast-tracking clinical investigations has obvious shortcomings, most notably required understanding of the safety profile of the agents used to treat these epidemics. Another issue is that of ethical considerations in providing treatment during epidemics with agents that have not undergone robust clinical trials.

Antimicrobial Resistance: Issues and Concerns
Syed Rizwanuddin Ahmad, MD, MPH, FISPE
Assistant Professor (adjunct), Georgetown University School of Medicine

FDA Perspective
Representative Invited
Director, Office of Antimicrobial Products, Office of New Drugs, CDER, FDA

Accelerating the Evaluation of Potential Treatments for Ebola
Raj Long, MEd, MSc
Senior Regulatory Officer, Integrated Development, Global Health, Bill and Melinda Gates Foundation, United Kingdom

#317 Track 15 – Statistical Science and Quantitative Thinking

8:00–9:30 AM
Room 204BC
CME, Pharmacy, and Nursing

Benefit-Risk Assessment of Medicines: Three Perspectives on Current Methodologies and the Statistician’s Role in Implementation

CHAIRPERSON
Susan P. Duke, MS
Director, Benefit Risk Evaluation, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Benefit-risk framing and quantification are increasingly becoming part of a pharmaceutical company’s internal decision-making process and regulatory deliverables. Various approaches are available to companies to deploy these methods. In this session, we will focus on the statistician’s leadership role, as well as success in methodologies used, in the use of benefit-risk.
quantification for making better quality (and more timely) decisions, and for improving communication of benefit-risk assessments, including submission preparation.

Sheila Dickinson, MSc
Senior Quantitative Safety Scientist, Novartis Pharma AG, Switzerland

Choice of Summary Displays and Impact of Collaborative Tools in Benefit-Risk Assessment
Greg Anglin, PhD
Research Advisor, Safety Analytics, Eli Lilly and Company, Canada

Benefit-Risk Quantification and Methodologies Used Across the Drug Development Portfolio: A Large Pharmaceutical Company’s Experience
Susan P. Duke, MS
Director, Benefit Risk Evaluation, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

This forum will discuss the proposed labeling rule for the electronic distribution of prescribing information, what it means for industry, patients, and health care professionals.

Panelists
Tracy D. Rockney, JD
Vice President, Regulatory Affairs, Labeling, A&P, Regulatory Policy and Intelligence, AbbVie
Jeffrey J. Mesaros, JD, PharmD
Senior Legal Counsel, Pharmacy Practice, CVSHealth
Dora Cohen, MS
Executive Director, Global Labeling, Amgen Inc.

#320 Track 19B – Late-breaking Topics
Related Interest Area(s): CR, RA, IT
8:00–9:30 AM
Room 146B
CME and Nursing

The Future of Clinical Trial Data Sharing
CHAIRPERSON
Stephen P. Spielberg, MD, PhD
Editor-in-Chief, DIA Publications, DIA

The movement to enhance clinical trial transparency is a game changer for the industry. Recently, the Institute of Medicine (IOM) issued a report entitled Sharing Clinical Trial Data-Maximizing Benefits, Minimizing Risk that detailed guiding principles and a framework that included activities and strategies in sharing clinical trial data. Industry response has been positive as this could help reduce unnecessary data duplication, advance research and improve clinical care. But what are some of the barriers and roadblocks ahead, such as privacy and proprietary concerns or IT challenges (as an example) that may affect the future of clinical trial data sharing?

Submit your thoughts and questions to this distinguished panel by emailing annualmeetingprogram@diaglobal.org; subject The Future of Clinical Trial Data Sharing Q/A.

Panelists
Joanne Waldstreicher, MD
Chief Medical Officer; IOM Committee Member, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Jarilyn Dupont, JD
Director of Regulatory Policy, Office of Policy, Office of the Commissioner, FDA
David Eichmann, PhD
Director, Library Science and Information Science; Chair, Graduate Program Informatics, University of Iowa
Michael Rosenblatt, MD
Executive Vice President and Chief Medical Officer, Merck & Co., Inc.
Andrzej Rys, MD
Director of Health Systems and Products, European Commission, Belgium

#318 Track 17 – Rare/Orphan Diseases
Related Interest Area(s): CR, BT
8:00–9:30 AM
Room 145B
CME, Pharmacy, and Nursing

Rare Diseases and Subgroups Defined by Tumor Evolution: Common Themes and Challenges
CHAIRPERSON
Robert A. Beckman, MD
Prof. of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Rare diseases present a unique challenge for developing evidence to support new therapies. Molecular subgroups of cancer define equally small populations, which also evolve over time. Clinical development and treatment challenges will be discussed.

Nature and Extent of Evidence Required for Approval in Rare Diseases
Jeffrey Schwartz, PhD, MS
Senior Director, Pfizer Inc

Intratumoral Heterogeneity and Tumor Evolution Creates Dynamic Subgroups in Cancer
Robert A. Beckman, MD
Prof. of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Considerations from a Regulatory Perspective
Grant Williams, MD
President, Williams Cancer Drug Consulting, LLC

#319 Track 19A – Late-breaking Topics
Related Interest Area(s): RA
8:00–9:30 AM
Room 207A
CME, Pharmacy, and Nursing

The Impact of the eLabeling Rule on Industry and Stakeholders
CHAIRPERSON
Barbara J. Fanelli, MS
Associate Vice President, Global Regulatory Affairs Labeling, Sanofi

Submit your thoughts and questions to this distinguished panel by emailing annualmeetingprogram@diaglobal.org; subject The Future of Clinical Trial Data Sharing Q/A.

Panelists
Joanne Waldstreicher, MD
Chief Medical Officer; IOM Committee Member, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Jarilyn Dupont, JD
Director of Regulatory Policy, Office of Policy, Office of the Commissioner, FDA
David Eichmann, PhD
Director, Library Science and Information Science; Chair, Graduate Program Informatics, University of Iowa
Michael Rosenblatt, MD
Executive Vice President and Chief Medical Officer, Merck & Co., Inc.
Andrzej Rys, MD
Director of Health Systems and Products, European Commission, Belgium

9:30–10:30 AM
Coffee Break & Innovation Theater Presentation (Exhibit Hall)
The following are scheduled in this session 2A:

- 9:35–9:40 AM — W 03 Information Architecture for Publishing Stem Cell Data in Open Source Platform
- 9:42–9:47 AM — W 06 Social Listening for Pharmacovigilance: How Does the Content and Level of Detail in Social Media Compare to Spontaneous Reports
- 9:49–9:54 AM — W 07 Enhancing Pharmacokinetic Studies to Support Tier 2 Labeling Claims for Abuse Deterrent Opioids
- 9:56–10:01 AM — W 09 Using Portfolio Analysis to Maximize Innovation and Optimize R&D Strategic Planning
- 10:03–10:08 AM — W 10 Transdermal Drug Innovation from 2000 to 2014: Current Status and Future Outlook
- 10:10–10:15 AM — W 11 Establishing Normal Ranges for ECG Intervals in a Normal Healthy Population
- 10:17–10:22 AM — W 12 Failure Mode and Effects Analysis (FMEA): A Systematic and Defensible Approach to Risk Mitigation For A New Drug Regimen
- 10:24–10:29 AM — W 13 International Award for Clinical Research Workforce Excellence

### #322 Track 20 – Innovation Theater

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

9:45–10:15 AM  
**Exhibit Hall**  
**Format:** SPECSESS  
**No CE available**

SAS Institute Inc., JMP Division Innovation Theater: Benefit and Risk Signal Detection in Clinical Trials

Integrated assessment of both efficacy and safety data in clinical trials has become an increasingly common analytic goal in clinical trials. There is an intrinsic balance between the desired outcomes of a treatment versus the risks that may be incurred to achieve such outcomes. We describe how analytic capabilities tightly tied with visualization in JMP Clinical software can elucidate understanding for both safety and efficacy endpoints during the analysis process.

### #323 Track 01A – Clinical Operations

**Related Interest Area(s): CR**

10:30 AM–12:00 PM  
**Room 147A**  
**Format:** WORKSHOP  
**CME and Nursing**

Direct-to-Patient Strategies That Are Changing the Landscape of Clinical Trials

**CHAIRPERSON**

Leslie Chaney, PhD  
Global Director, Preclinical and Direct to Patient Services, Marken LLP

Home-based options in clinical trial design may allow patients to participate in trials from home. Home delivery of clinical trial materials and retrieval of biological samples may increase the number of patients who can enroll in clinical trials.

### #324 Track 01B – Clinical Operations

**Related Interest Area(s): CR, PM**

10:30 AM–12:00 PM  
**Room 102AB**  
**CME, Pharmacy, and Nursing**

Putting It All Together: A Shared, Comprehensive, Integrated Global System for Clinical Research

**CHAIRPERSON**

Greg Koski, MD, PhD  
President and CEO, Co-Founder, Alliance For Clinical Research Excellence and Safety (ACRES)

This forum will discuss collaborative efforts to build a global system for clinical research to transform the clinical trials process. Addressing such topics as standards and accreditation for sites, a culture of safety, and a unified safety database, experts from key stakeholder groups (i.e., contract research organization, regulatory agency, pharmaceutical company, site, patient groups) will present their perspectives on the desirability, feasibility and challenges to the effort. We will finish with a dynamic, moderated interactive session with the audience and panelists.

**Panelists**

- Briggs W. Morrison, MD  
  Head, Global Medicines Department, AstraZeneca Pharmaceuticals LP
- Daniel O’Connor, JD  
  Chief Business Officer, InnovoCommerce
- Debra Lappin, JD  
  Head, Health Biosciences Practice, FaegreBD Consulting
- Kimberly Irvine  
  Chief Operating Officer, Biomedical Research Alliance of New York (BRANY)

**Representative Invited**

Deputy Center Director for Science Operations, Office of the Center Director, CDER, FDA
#325 Session: Incremental Innovation: How to Strategically and Practically Move Innovative Ideas into Action Within Your Company and Research Programs

**Chairperson:** John Reites  
Senior Director, Product and Strategy, Health Engagement and Communications, Quintiles Inc.

The word “innovation” is synonymous with some of the most groundbreaking research and technologies for industry benefits from today, and it is critical to the continued evolution of our business. In this session, we will review strategies for how to act upon innovation within a company or research program based on experience gained from implementing successful pilots and novel study design approaches. We will explore insights on how to: (1) Develop a stage-gate plan with key stakeholder support to practically integrate innovation; (2) Effectively pilot solutions with a structure to scale if successful; (3) Set proper expectations from the start for all teams involved; (4) Define risks and measure success; and (5) Generate a communication plan that promotes adoption and the value of innovation. These insights will be explained in the context of various case studies in which innovative approaches were implemented into action in research programs.

**Can Investigator Crowdsourcing Be Used to Provide Insight into Compound Development?**  
Amy Loescher  
Director, Clinical Program Leader, Janssen Pharmaceuticals, Inc.

**Intrapreneurial Innovation: Move Ideas to Action in Your Company and Research**  
John Reites  
Senior Director, Product and Strategy, Health Engagement and Communications, Quintiles Inc.

#326 Session: Utilizing an Effective Project Management Framework to Manage Clinical and Biopharmaceutical Projects With Better Results

**Chairperson:** Zizi Imatorbhebhe, MBA, MS, PMP  
Principal & Managing Consultant, Alliance Bio-Pharm & Health Partners

Clinical and pharmaceutical teams are quickly realizing that effective project management is necessary to improve accuracy of timeline, budgets, scope, and quality requirements. With the high costs and risks associated with pharmaceutical product development and clinical trials, it is increasingly important that projects are managed effectively to maximize returns and meet business objectives. This session articulates the best practices of successfully managing clinical and pharmaceutical projects. It will also include insights and strategies for leading and managing technical projects in a large pharmaceutical company to inspire nontechnical leaders to take on this challenge with confidence.

#327 Session: Emerging and Mid-Sized Biopharmaceutical Companies Building Successful CRO Relationships: Overcoming the Challenges by Applying Alliance Management Principles and Technology

**Chairperson:** Keith W. Wenzel  
Senior Director, Perceptive Partner Program

During this session, speakers from virtual, small or mid-sized clinical trial sponsors and a contract research organization (CRO) will discuss the value from alliances between networked biopharmaceutical companies and CROs, as well as the changing landscape of and models for technology outsourcing. We will explore what the biopharmaceutical companies and CROs (clinical or technology) must do to build a successful, collaborative alliance for clinical trial efficiency and success.

**Panelists:**  
- Solomon Babani, MBA  
  Global Vice President, Alliance Management, Covance Inc.  
- Mitchell A. Katz, PhD  
  Head of Medical Research and Drug Safety Operations, Purdue Pharma L.P.  
- Jeffrey Cehelsky, MBA, MPharm  
  Vice President, Clinical Operations, Alnylam Pharmaceuticals, Inc.

#328 Session: Implications of Clinical Test Result and ECG Variability on the Design, Conduct, and Interpretation of Early Phase Clinical Studies

**Chairperson:** Gary L. Steinman, MS  
President, Medexetech

Variability in clinical lab and ECG results affects the design, conduct, and interpretation of phase 1 studies. This session will address lab testing, ECG measurement methods, intra/inter-subject variability, and use of results as recruiting criteria, outcome variables and adverse effect indicators.
The Effect of the Number of ECG Replicates Per Timepoint on QTc
Within Subject Variability in a QT Study
Robert Kleiman
Chief Medical Officer and Vice President, Global Cardiology, ERT

Implications of Clinical Test Result Variability on the Design, Conduct and Interpretation of Phase 1 Clinical Studies
William B. Smith, MD
President, New Orleans Center For Clinical Research and Volunteer Research Group

Little Data, Big Decisions: Plan to Minimize Early-Phase Dilemmas
Royce A. Morrison, MD, MS
Senior Consultant, Pacific Pharma Group, LLC

This session will provide an update on the binding standardized study data guidance and its impact on the requirement to submit study data in conformance with FDA supported standards.

Panelists
Benjamin Peter Behrang Vali, MS
Biostatistical Reviewer, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Lise R. Stevens
CBER Data Standards Program Chair, Bioinformatics Support Staff, Office of the Director, FDA

Colleen Ratliffe, MS
Project Management Officer, Office of Strategic Programs, CDER, FDA

How Collective Insights of Medical Affairs Customer-Facing Teams Work to Inform Strategy
CHAIRPERSON
Stacey M. Fung, PharmD
Associate Director, Medical Communications, Genentech, A Member of the Roche Group

This session will discuss available internal customer insights collected by medical affairs (MA) groups (medical communication, medical science liaison, publications, etc) and how best to review this information. Discussions will include ways to identify and analyze insights to shape tactical plans.

Advancing Text Analytics from a Local to a Global Capability
Margaret J. Carrico, MS
Advisor, Global Medical Customer Analytics and Insights, Eli Lilly and Company

The Customer Experience: Taking a Real World Approach to Create Future Customer Value - Worldwide
Sian Slade
Group Director, Global Medical Contact, Content, Insights (MCCI), Bristol-Myers Squibb Company, Australia

Customer Insights as Influencers of Business Strategy: The Role of Field-Based Medical
Joseph Gasperino, PharmD, MBA
Field Medical Director, Pain, North America Medical Affairs, Pfizer Inc

With the widespread adoption of digitized regulated content management systems, the digitization of the investigator site documents and data collection will be the next horizon to be mastered. Whether it is the document management or the inspection, audit or retention of records, digitization will allow systems, tools and business processes to increase compliance with regulations. With new processes and systems, best practices and patient education will be key to successful adoption. The adoption of technology solutions will also impact the patients. This symposium will explore the need for communicating with patients through multiple channels on the rise of mobile and digital technology and investigate related questions. We will address the need for patient education and examine how we can best share this information with patients in a health literate manner, including the use of patient-facing infographics. The eConsenting process has demonstrated benefits along the continuum of the clinical trial, among them benefits in patient enrollment and engagement as well as regulatory compliance. Examples from several recent implementations will be presented to demonstrate the potential return on investment of an eConsent system and outline the positive impact this process can have on inspection findings.

Potential ROIs of eConsent: Patient Enrollment, Engagement, Retention and Compliance
Eric Delente, MA
Chief Executive Officer, Managing Director, Enforme

Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

The Electronic Investigator Site File: What’s In It For the Patient?
Betsy Fallen, RN
Principal, BAFallen Consulting, LLC

Electronic Standardized Data in Regulatory Submissions
CHAIRPERSON
Mary Ann Slack
Deputy Director, Office of Strategic Programs, CDER, FDA

Related Interest Area(s): MC
Room 206
10:30 AM–12:00 PM
Format: SESSION

Related Interest Area(s): EC, PT, IT
Room 202B
10:30 AM–12:00 PM
Format: SYMPOSIUM

Related Interest Area(s): CDM, SUBS
Room 201
10:30 AM–12:00 PM
Format: SESSION
**#332  Track 08A – Regulatory Affairs**

**Related Interest Area(s): PT**

10:30 AM-12:00 PM  
Room 150B  
**CME, Pharmacy, and Nursing**

**Medicine Development and Authorization: A Patient-Centered Approach**

**CHAIRPERSON**
Angelika Joos, MPharm  
Executive Director, Global Regulatory Policy, MSD (Europe) Inc., Belgium

A systematic and integrated framework to enable patient involvement during the development and life cycle of medicines and associated products is not yet really established. This session will provide examples on how regulators in the US and Europe involve patients into the regulatory process and discuss how patients can bring their experience to the table.

*Patient Participation in FDA’s Advisory Committees and Panels*
Heidi C. Marchand, PharmD  
Assistant Commissioner, Office of Health and Constituent Affairs, Office of the Commissioner, FDA

*Bringing Real-Life Experience into the Evaluation of Medicines*
Martin Harvey Allchurch, Esq, LLM  
International Affairs, European Medicines Agency, European Union

*Patient Perspective*
Marc M. Boutin, JD  
Chief Executive Officer, National Health Council (NHC)

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**#333  Track 08B – Regulatory Affairs**

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

10:30 AM-12:00 PM  
Room 151A  
**CME, Pharmacy, and Nursing**

**Opening the Door to Data Transparency: What’s the Verdict?**

**CHAIRPERSON**
Robert Paarlberg, MS  
Principal, Paarlberg & Associates LLC

This session will focus on US and EU clinical trial disclosure requirements, including results reporting and how this increase in data transparency is being perceived and used by the patient community.

*Panelists*
Rebecca J. Williams, PharmD, MPH  
Assistant Director, ClinicalTrials.gov, National Library of Medicine, NIH

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

Deborah E. Collyar  
Board Member/President, The Hope Foundation/Patient Advocates In Research (PAIR)

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**#334  Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products**

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

10:30 AM-12:00 PM  
Room 152A  
**CME, Pharmacy, and Nursing**

**The Role of Labeling in Successful Human Factors Studies**

**CHAIRPERSON**
Eileen S. Kahn, MEd, MS  
Principal Labeling Associate, Sanofi

A key component of well-designed, successful human factors studies is having clear and concise labeling so the patient can use the device safely and effectively. This forum will provide some industry perspectives in how this can be accomplished.

*Panelists*
Renee Bailey  
Consultant, Evidence-based Instructional Design and Labeling, Agilis Consulting Group, LLC

Molly Follette Story, PhD  
Head, Global Usability Engineering and Risk Management, Sanofi

Irene Z. Chan, PharmD  
Associate Director, DMEPA, CDER, FDA

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**#335  Track 10 – Public Policy/Health Care Compliance/Law**

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

10:30 AM-12:00 PM  
Room 146B  
**CME, Pharmacy, and Nursing**

**Precision Medicine: Where Is the Technology Taking Us, How Fast and Who Is Driving?**

**CHAIRPERSON**
Nancy Bradish Myers, JD  
President, Catalyst Healthcare Consulting, Inc

Advances in technology and computing power are propelling us into a new era of genetics. The rise of whole genome sequencing is creating opportunities to better understand the human condition and tailor medical care to the individual in novel, innovative ways. This panel will explore where the science is taking us, help us read the roadmap to adoption and debate the best way to integrate results of genomics into clinical care.

*Panelists*
Felix W. Frueh, PhD  
Chief Scientific Officer, Human Longevity, Inc.

Robert M. Califf, MD  
Deputy Commissioner, Office of Medical Products and Tobacco, FDA

Representative Invited  
Policy Analyst, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA
Control of Genotoxic Impurities: Is ICH M7 a Paradigm Shift?
Ramani Raghavan, MS, MSc
Senior Regulatory Program Director, Genentech, A Member of the Roche Group

Elemental Impurities: Approaches for Conducting Product Assessments
Mark G. Schweitzer, PhD
Global Head, Analytical Science and Technology, Novartis Pharmaceuticals Corporation

#336 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CP

10:30 AM–12:00 PM | LEVEL: ■ | FORMAT: SESSION
Room 202A | CME and Nursing

Good Clinical Practice and Pharmacovigilance Issue Management and CAPA Effectiveness

CHAIRPERSON
Federico Feldstein, JD
Vice President, Head of Pharmaceuticals BioResearch Quality and Compliance, Janssen Pharmaceuticals, Inc.

Opportunities exist in establishing effective processes for oversight of good clinical practice/pharmacovigilance significant deviations and Corrective and Preventative Actions effectiveness. This session presents regulatory and industry perspectives, best practices, and emerging trends related to issue management.

Misconduct and Management of Serious or Persistent Noncompliance: Recognizing, Managing and Proactively Mitigating
Deborah A. Waltz, MS
Vice President, Global Compound Support, Quality Assurance, Takeda Pharmaceuticals International, Inc.

FDA Perspective
Kassa Ayalew, MD, MPH
Branch Chief, Office of Scientific Investigations, Office of Compliance, CDER, FDA

FDA Perspective
Namita Kothary, PharmD
Branch Chief (Acting), Postmarketing Safety Branch, Office of Scientific Investigations, Office of Compliance, CDER, FDA

#337 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA, QC

10:30 AM–12:00 PM | LEVEL: ■ | FORMAT: SESSION
Room 151B | CME, Pharmacy, and Nursing

How Can International Guidances Enable Global Regulatory Convergence?

CHAIRPERSON
Mark Rosolowsky, PhD
Vice President, Global Regulatory Sciences, CMC, Bristol-Myers Squibb Company

This session will focus on how international organizations such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), International Medical Device Regulators Forum (IMDRF) and International Coalition of Medicines Regulatory Authorities (ICMRA) enable global regulatory convergence in particular for quality topics. The impact of some recent quality guidances on impurities (e.g., ICH M 7 and ICH Q3D) will be discussed in detail.

Trends in Global Regulatory Convergence: ICH, IMDRF and ICMRA
Toshiyoshi Tominaga, PhD
Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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

Related Interest Area(s): CEHTAEbM

10:30 AM–12:00 PM | LEVEL: ■ | FORMAT: SESSION
Room 209AB | CME and Nursing

FDA Sentinel Initiative

CHAIRPERSON
Marsha E. Reichman, PhD
Senior Advisor/Scientific Lead Surveillance Programs, Sentinel Initiative Lead, CDER, FDA

The session will provide an overview to the FDA Sentinel Initiative. This initiative was launched in 2008 to build a postmarket risk identification and analysis system to complement FDA’s existing postmarketing surveillance capabilities. The basis of the Sentinel Initiative was the pilot, Mini-Sentinel, which originated in 2009 through a contract with Harvard Pilgrim. Mini-Sentinel developed and tested the capabilities for using electronic health care data for safety surveillance of approved medical products. In 2014, Mini-Sentinel was transitioned to a sustainable surveillance system, the Sentinel System. This transition focuses on establishing policies, procedures, and organization for the Sentinel System.

FDA Mini-Sentinel: Past, Present, and Future
Jeffrey Brown, PhD
Associate Professor, Department of Population Medicine, Harvard Pilgrim Health Care Institute/Harvard Medical School

Overview of Sentinel Query Tools
Azadeh Shoabibi, PhD, MS
Scientific Lead, Sentinel Initiative, Office of Medical Policy, CDER, FDA

CDER Use of Mini-Sentinel Tools/Resources
Marsha E. Reichman, PhD
Senior Advisor/Scientific Lead Surveillance Programs, Sentinel Initiative Lead, CDER, FDA

CBER Perspective
Steven A. Anderson, PhD
Director, Office of Biostatistics and Epidemiology, CBER, FDA
The content noted on this page was made available to DIA as of April 27.
Considerations for ADaM Implementations
Diane Piper, MSc
Director Clinical Standards, Shire Pharmaceuticals

Panelists
Rob Woolson, JD, MS
Chief Strategist, Regulatory Biostatistics and Standards, Rho, Inc.
Weiya Zhang, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Science, CDER, FDA

#343 Track 16B - Professional Development
Related Interest Area(s): CR, RA, PETD
10:30 AM–12:00 PM LEVEl: ■ FORMAT: WORKSHOP
Room 147B
CME, Pharmacy, and Nursing
DEVELOP Excellent Presentations to INNOVATE the Way You Communicate Information and ADVANCE Your Career
CHAIRPERSON
Lynn King, MHA
Senior Director, Clinical Operations, TKL Research

This fun, interactive workshop will review skills necessary for the delivery of effective, successful presentations. Participants will analyze their individual presentation skills gaps, practice important skills and receive feedback for improvement.

**Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington 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.

Appealing to the Visual Learner: How to Create an Image-Based Presentation
Robin Whitsell
President, Whitsell Innovations, Inc.

#344 Track 17 - Rare/Orphan Diseases
Related Interest Area(s): CR
10:30 AM–12:00 PM LEVEl: ■ FORMAT: SYMPOSIUM
Room 145B
CME, Pharmacy, and Nursing
Orphan Drug Development Challenges: Case Studies
CHAIRPERSON
Daniel Mazzolenis, MD, MBA
Senior Medical Director, Global Oncology Hematology, INC Research, Argentina

In this symposium, three different case studies will showcase the multiple challenges in the successful development of new therapies for orphan diseases. The first case is about adjuvant treatment for phenylketonuria (PKU) and will center on systematic analysis of the current evidence and subsequent gap analysis as the basis to inform decision-making and future research. The second case focuses on hemophilia, a field with a large corpus of knowledge regarding pathophysiology, therapeutic interventions and even comprehensive drug development guidelines. We intend to showcase precisely how the paradigms on which those guidelines are based may require revision in light of recent therapeutic developments, at the risk of regulation being an impediment to the continuous improvement. Finally, the last case will showcase how strategic planning and operational efficiency is critical for efficient and successful development of an orphan drug program.

Connecting the Dots for Fast-Track Approval for Rare Disease and Orphan Drugs
Michelle Petersen, MSc
Clinical Trial Manager, Medpace, Inc.

Challenges and Opportunities in Systematic Reviews of Rare Diseases: Adjuvant Treatment for Phenylketonuria
Melissa McPheeters, PhD, MPH
Research Associate Professor, Vanderbilt University Medical Center

Showcasing Hemophilia as a Rare/Orphan Disease: Do We Need to Update Regulatory Paradigms?
Pablo Rendo, MD
Senior Director, Physician Clinician, BeneFIX Global Clinical Lead, Pfizer Inc

#345 Track 19 - Late-breaking Topics
Related Interest Area(s): PETD
10:30 AM–12:00 PM LEVEl: ● FORMAT: FORUM
Room 152B
No CE available
Power Up! Give Your Brain a Break!

Let’s break the mold of the traditional DIA Annual Meeting Program offering and give your brain a break from all the scientific stuff! 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.

#346 Track 21 - Poster Presentations
Related Interest Area(s): CR
11:35 AM–1:30 PM LEVEl: ● FORMAT: SYMPOSIUM
Exhibit Hall (Entrance A)
No CE available
Wednesday Oral Presentations - Professional Poster Session 2B

New this year! Join us in the Exhibit Hall Poster Area (Hall A Entrance) for a series of 5 minute presentations delivered by this year’s Professional Poster Presenters.

The following are scheduled in this session 2B:
• 11:35–11:40 AM—W 14 Compliant Presentation of Important Safety Information in A More Educational Format in Promotional Educational Programs
• 11:42–11:47 AM—W 15 Strategic Considerations for Developing an Initial Pediatric Study Plan for a Proposed Biosimilar
• 11:49–11:54 AM—W 16 A Determination of the Relative Risk of Hepatotoxicity Among Anti-Epileptic Drugs in the FDA Adverse Event Reporting System
• 11:56 AM–12:01 PM—W 17 Pharmacovigilance Process Innovation: Approach to Pharmacovigilance (PV) Process Enhancements in a Large Global Biotechnology Company
• 12:03–12:08 PM—W 18 Incidence of Outcomes Relevant to Vaccine Safety Monitoring in a Large Commercially Insured Population
The body of health care data is bigger than ever. Unlocking its potential in how your therapies will meet demands for value-based care. Their influence and expectations are critical. To achieve overall treatment value you must first master data integration and analytics across a drug development pipeline. During this session, learn how advanced analytics can help improve access to data so you can develop value-based therapies that meet stakeholder expectations.

The body of health care data is bigger than ever. Unlocking its potential through access, linkage and analytics is the key to recognizing insights and driving better decision making. Learn how to use data assets and networks to:

- Better understand patient characteristics, treatment patterns and outcomes
- Gain invaluable insights on the therapeutic and competitive landscape
- Increase efficiency of clinical study planning and design
- Optimize protocol development, site feasibility and recruitment.
#351  **Track 02A – Project/Portfolio Management and Strategic Planning**

**Related Interest Area(s):** PETD  
**Format:** Session

**Room 101**

**CME, Nursing, and PMI PDUs**

**Project Management in Context: Reflections on the Project Manager Role from Other High-Risk Industries**

**CHAIRPERSON**  
Peter Harpum, PhD, MSc  
Client Director, Mannaz A/S, United Kingdom

The role of project manager in our industry is unresolved. Value achieved through project management remains in doubt. The value created by project managers in other industries will be presented by people from oil and gas, aerospace, and construction. The audience will have an opportunity to ask questions of the speakers to further understand the role each one plays in delivering value to their projects, clients, and employers.

- Project Management in Pharmaceutical R&D  
  Leigh Shultz  
  Executive Director, Global Project Management, Merck & Co., Inc.

- Project Management in the Oil and Gas Industry  
  Daniel Zweidler, PhD  
  Founder, Daniel Zweidler & Associates, Inc.

- Project Management in the Defense/Aerospace Industry  
  Representative Invited  
  Operations Analyst, Lockheed Martin Fellow, Lockheed Martin Corporate Logistics and Sustainment

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

**Related Interest Area(s):** CR  
**Format:** Forum

**Room 103B**

**CME and Nursing**

**Issue Resolution in Clinical Partnerships**

**CHAIRPERSON**  
Susan Shelby, PhD  
Vice President, Global Clinical Operations, Biomedical Systems

For each clinical trial, a hierarchy of issue escalation exists among the various vendors and within the sponsor organization. This forum includes representatives from a CRO, a biotechnology company sponsor, a pharmaceutical company sponsor, and a core laboratory executive to define how to best escalate study issues within their environments.

- Panelists  
  Susan Shelby, PhD  
  Vice President, Global Clinical Operations, Biomedical Systems

  Karen Ventrella, RAC  
  Director, Clinical Operations, Vertex Pharmaceuticals

  John Mann, MS, PMP  
  Executive Director of Project Delivery, PRA HealthSciences

#353  **Track 03 – Innovative Partnering Models and Outsourcing Strategies**

**Related Interest Area(s):** CR  
**Format:** Forum

**Room 150A**

**CME and Nursing**

**The Voice of the Sites: Collaborating to Build a Site Partnership Model to Enable Study Start-Up**

**CHAIRPERSON**  
Rupa Roychowdhury  
Associate Director, Start Up Management Office, Clinical Development Services, Covance Inc.

The voice of the site is a critical yet underutilized opportunity for efficient study start-up. In this forum, the outcome of a site/contract research organization partnership collaboration model will be shared for clinical studies to proactively assess and mitigate start-up risks.

- Collaborative Study Start-Up Model  
  Rupa Roychowdhury  
  Associate Director, Start Up Management Office, Clinical Development Services, Covance Inc.

- Operational Expertise of Building an Efficient Study Start-Up Model for Sites  
  Representative Invited

- Panelist  
  Representative Invited  
  Assistant Professor, Department of Hematology and Medical Oncology, Emory University School of Medicine

#354  **Track 04 – Preclinical and Translational Development/Early Phase Clinical Development**

**Related Interest Area(s):** NC, CR  
**Format:** Symposium

**Room 103A**

**CME, Pharmacy, and Nursing**

**Effective Discovery, Development and Use of Biomarkers in Early Drug Development**

**CHAIRPERSON**  
Stacie J. Bell, PhD  
Senior Medical Science Liaison - Mid-Atlantic, Mallinckrodt Pharmaceuticals, Inc.

In this symposium, multiple facets of biomarker development and use will be addressed. The research surrounding identification of possible biomarkers and early evaluation will be outlined, as well as the expertise and resources required (often in collaboration) to execute these assessments. We will specifically highlight novel quantitative imaging biomarkers and techniques, as well as a rapid, multiplexed quantitative proteomics assay solution. Finally, the regulatory considerations for biomarker impact on the drug development plan and new drug application filing will be outlined, along with concerns for informed consent processes and subject samples.

This symposium has been developed with the DIA Clinical Pharmacology and Translational Medicine Communities.

- **A Quantified Picture is Worth a Thousand Words: Generating Efficient Signals of Efficacy**  
  Gregory V. Goldmacher, MD, PhD  
  Senior Director, Medical and Scientific Affairs, ICON Clinical Research
#356 Track 07A – Technology/Data/Records and Submissions

**Related Interest Area(s): IT, CDM, SE**

**1:30–3:00 PM**

**Room 201**

**Format: SESSION**

CME, Pharmacy, and Nursing

**Searching for the Gold Nuggets: Text Analysis in Clinical Data**

**CHAIRPERSON**

Timothy Kropp, PhD

Associate Director for Innovation, Office of Computational Science, Office of Translational Sciences, CDER, FDA

Textual information contains some of the most high value information among clinical data. This session will explore and discuss techniques for investigating free text information in clinical trials and for pharmacovigilance. This session will bring multiple experts together to discuss approaches to performing analysis of free text reports submitted to a new drug application such as patient narratives, postmarket reports, patient reporting and others.

**Approaches for Free Text Clinical Data Analysis**

Timothy Kropp, PhD

Associate Director for Innovation, Office of Computational Science, Office of Translational Sciences, CDER, FDA

**Natural Language Processing for Pharmacovigilance**

James Sawyer, DrMed

Medical Director, Identify.AE, Prism Ideas Ltd, United Kingdom

**Visual Analytics and Interactive Visualization of Complex Clinical Data and Health Records**

Hanming H. Tu, MSc

Director, Clinical Information Technologies, Accenture

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#357 Track 07B – Technology/Data/Records and Submissions

**Related Interest Area(s): VA, IT**

**1:30–3:00 PM**

**Room 202**

**Format: SYMPOSIUM**

CME and Nursing

**Frontier Issues in Electronic Information Integrity Today**

**CHAIRPERSON**

Teri Stokes

Director, GXP International

This symposium will address three different “on the edge” issues for electronic information integrity today.

- How do you evaluate whether validation is good business even if FDA hasn’t identified the system for GXP/Part 11 compliance?
- How can you identify and prevent bias from creeping into your risk assessment practices?
- How does one address IQ evidence expectations for SaaS and Cloud Part 11/Annex 11 compliance?

Pharmaceutical company medical information data, pharmacovigilance data, and SaaS data in the cloud all share a need for risk based integrity checks. Yet often our risk assessment practices themselves have unseen bias that can influence the integrity of electronic information. Come listen, question, and share your own electronic information integrity experiences either as a challenge or a success.
#358 Track 08A – Regulatory Affairs

**Related Interest Area(s): CR, PPLC**

1:30–3:00 PM  
**LEVEL:**  
**FORMAT:** SESSION  
**Room 150B**  
**CME, Pharmacy, and Nursing**

**Expediting Drug Development Through FDA’s Breakthrough Therapy Designation**

**CHAIRPERSON**

Todd Paporello, PharmD, MBA  
Vice President and Head of US Regulatory Affairs, Bayer HealthCare Pharmaceuticals

FDA’s Breakthrough Therapy Designation (BTD) has evolved as industry and the agency have gained experience with the program. In this session, an attorney will analyze the evidence that FDA has required for designations, FDA will discuss BTD’s impact on development and review, and industry will review lessons learned from a product approved with BTD.

- The Breakthrough Therapy Designation: An Analysis of FDA’s Precedents to Determine Eligibility Criteria and Their Value  
  Alexander Varond, JD  
  Associate, Hyman, Phelps & McNamara, PC

- CDER Breakthrough Therapy Program: What Happens Post-Designation?  
  Miranda Raggio, BSN, MA, RN  
  Breakthrough Therapy Program Manager, Office of New Drugs, CDER, FDA

- Breakthrough Therapy Policies  
  Michelle Rohrer, PhD  
  Vice President, Global Head Regulatory Regions and Policy, Genentech, A Member of the Roche Group

#359 Track 08B – Regulatory Affairs

**Related Interest Area(s): AP**

1:30–3:00 PM  
**LEVEL:**  
**FORMAT:** SESSION  
**Room 151A**  
**CME, Pharmacy, and Nursing**

**Does Bioequivalent Always Mean Therapeutically Equivalent? Impact of FDA’s Proposed Rule on Generic Labeling**

**CHAIRPERSON**

Margaret Woo, PharmD  
Global Regulatory Program Manager, Novartis Pharmaceuticals Corporation

A panel claimed that FDA failed to sufficiently monitor generics which account for 85% of drugs sold in US. This session will discuss a new proposed rule which makes it easier for generic companies to update labels, and how this change will have implications on the Federal Food, Drug and Cosmetic Act (FD&C Act), generic companies, patients, and health care providers.

- **Perspective on the Proposed Rule on Labeling**  
  Christine Simmon, JD  
  Senior Vice President, Policy and Strategic Alliances, Generic Pharmaceutical Association (GPhA)

- **Implications of the Generic Drug Labeling Rule**  
  Kurt R. Karst, JD  
  Director, Hyman, Phelps McNamara, PC

- **Concerns From the Innovators’ Perspective**  
  Jeffrey K. Francer, JD, MPA  
  Vice President and Senior Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA)

#360 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

**Related Interest Area(s): MDD, CR, CP**

1:30–2:30 PM  
**LEVEL:**  
**FORMAT:** SESSION  
**Room 152A**  
**CME and Nursing**

**Regulatory Framework for Medical Devices in Europe**

**CHAIRPERSON**

Andrzej Rys, MD  
Director of Health Systems and Products, European Commission, Belgium

In this session, we will provide an overview about the current regulatory framework in Europe for clinical trials with medical devices, highlighting similarities as well as differences to describe the range of potential variability across Europe. In addition, although medical device notified bodies are accredited by a member state to assess whether a medical device conforms to the EU Medical Devices Directive, there has been an increase in regulators requesting and performing a review of the documentation and assessment already conducted by the notified bodies. The question is raised whether this increased concern represents a lack of confidence in the notified bodies’ assessment or if it is a renewed approach from the regulators to be involved in the safety assessment of a medical device.

- **The Role of EMA Versus Notified Bodies in Ensuring Fulfillment of the Essential Requirements in the Medical Devices Directive**  
  Farzana Hussain  
  Regulatory Project Manager and Team Leader, Novo Nordisk A/S, Denmark

- **Current Situation and Potential Future Development of Regulatory Requirements**  
  Rainer Pormann, PhD  
  Head, Clinical Trial Regulatory Management - Western and Central Europe, Accovion GmbH, Germany
#361 Track 10 – Public Policy/Health Care Compliance/Law

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

**1:30–3:00 PM**  
**LEVEL:**  
**Format:** FORUM  
**Room 146B**  
**CME, Pharmacy, and Nursing**

The Challenges, Solutions and Right To Try Surrounding Expanded Access

**CHAIRPERSON**

David Vulcano, MBA, RAC  
Assistant Vice President and Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

Many states are enacting “Right to Try” legislation as an effort to provide access to investigational therapies to those in their state with terminal illnesses and seemingly nowhere else to turn. These efforts present logistical and ethical dilemmas. This forum will try and explain the ethical dilemmas surrounding Expanded Access and what industry needs to know when requesting expanded access from the FDA.

**The Challenge of “Compassionate Use”**

Alison Bateman-House, PhD, MA, MPH  
Postdoctoral Fellow, Division of Medical Ethics, New York University Langone Medical Center

**What You Need To Know When Requesting Expanded Access**

Richard Klein  
Director, Patient Network Program, Office of Health and Constituent Affairs, Office of the Commissioner, FDA

**Comparison of States “Right to Try” Legislation**

David Vulcano, MBA, RAC  
Assistant Vice President and Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

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#362 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

**Related Interest Area(s): CR**

**1:30–3:00 PM**  
**LEVEL:**  
**Format:** SESSION  
**Room 202A**  
**CME and Nursing**

Using Data Analytics to Detect Quality Issues

**CHAIRPERSON**

Leslie M. Sam  
Director, Global Quality Systems, Eli Lilly and Company

Opportunities exist to establish effective processes to detect quality issues. This session presents proven best practices and emerging trends related to the detection of quality issues during a clinical trial.

**Signal Detection of Quality Issues and Potential Misconduct in Clinical Trials**

Richard Zink, PhD  
Principal Research Statistician Developer, SAS Institute Inc., JMP Division

**How Innovative Metrics and a Holistic Quality Approach Can Move the Compliance Needle: The Facts Behind the Figures**

Maria Degeyter  
Regional Quality Lead, Janssen Pharmaceuticals, Inc., Belgium

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#363 Track 12 – Pharmaceutical Quality

**Related Interest Area(s): CP**

**1:30–3:00 PM**  
**LEVEL:**  
**Format:** FORUM  
**Room 151B**  
**CME, Pharmacy, and Nursing**

Risk-Based Inspections and Compliance

**CHAIRPERSON**

Rick Friedman, MS  
Deputy Director, Science and Regulatory Policy, Office of Compliance, CDER, FDA

This forum will provide attendees with exposure to regulators use of a quality risk management approach in its inspections and compliance activities. In particular, the forum will provide participants with the opportunity to understand regulatory expectations for maintaining an ongoing state of control throughout the life cycle by exercising good science and vigilant quality oversight.

**GMP/GDP Management System for Medicinal Products in Taiwan**

Chyn-Liang Huang, MPharm  
Chief Inspector/ Section Chief, Taiwan Food and Drug Administration (TFDA), Taiwan

**Overseas GMP Inspections from Emerging Markets**

Qing Shen, MS  
Senior Principle Technical Advisor, Shanghai Roche Pharmaceutical Ltd., China

**Compliance Update**

Rick Friedman, MS  
Deputy Director, Science and Regulatory Policy, Office of Compliance, CDER, FDA

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

**Related Interest Area(s): CR**

**1:30–3:00 PM**  
**LEVEL:**  
**Format:** SESSION  
**Room 209AB**  
**CME, Pharmacy, and Nursing**

Operationalizing the Pragmatic Clinical Trial: The Role of PCORI and the Pharmaceutical Industry

**CHAIRPERSON**

Bryan R. Luce, PhD, MBA  
Chief Science Officer, Patient-Centered Outcomes Research Institute (PCORI)

This session will address the role that pragmatic clinical trials can play in informing health care decision-making. It will deal with design issues, opportunities (and challenges) to integrate PCTs in a learning health care system context and will draw from one example being planned by the Patient-Centered Research Institute’s (PCORI) PCORnet and another executed by a pharmaceutical company. The session will end with a description of the platform response-adaptive trial design which is a novel approach that embeds the PCT concept into the routine care of a health care system.
The PCT in PCORnet: The Aspirin Demonstration Trial
Rachael Fleurence, PhD
Program Director, CER Methods and Infrastructure, Patient Centered Outcomes Research Institute (PCORI)

The Role of the Pragmatic Trial in Industry: The Salford Lung Study Example
Frank W. Rockney, PhD, MSc
Senior Vice President, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Incorporating the PCT Into the Learning Health Care System: The Platform Response-Adaptive Trial
Jason Connor
Statistical Scientist, Berry Consultants

#365 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RD

1:30–3:00 PM LEVEL: ■ FORMAT: SESSION
Room 204BC CME, Pharmacy, and Nursing

A Proactive and Systematic Approach to Managing Product Risk Across the Life Cycle
CHAIRPERSON
Brian David Edwards, MD, MRCP
Principal Consultant, Pharmacovigilance and Drug Safety, NDA Group, United Kingdom

It will be nearly seven years since CIOMS VI published their recommendations for developmental risk management planning. But what has happened to systematic life cycle management? How good are we at assimilating all the evidence about a medicine? Are we better at determining how to balance risks against benefit at all phases? There is a mass of evidence concerning systems or organizational science such as human factors engineering. How has our sector implemented this evidence? The time to apply organizational science to systematically manage the risks of medicines is overdue. This session will assess what current best practice is from industry and regulatory perspectives and how this might be improved by applying the principles of organizational science.

Safety Engineering: A Systems Approach For Analyzing Product Hazards
Brian David Edwards, MD, MRCP
Principal Consultant, Pharmacovigilance and Drug Safety, NDA Group, United Kingdom

Once Size Does Not Fit All! Risk Management by Product Life Cycle Stage
Linda Quinn, PharmD
Director, Risk Management Scientific Lead, Janssen Pharmaceuticals, Inc.

The FDA REMS Program: A Work in Progress
Syed Rizwanuddin Ahmad, MD, MPH, FISPE
Assistant Professor (adjunct), Georgetown University School of Medicine

#366 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

1:30–3:00 PM LEVEL: ■ FORMAT: SESSION
Room 207A CME and Nursing

Measuring the Impact of Regulatory Pharmacovigilance in Europe and the United States
CHAIRPERSON
Peter Richard Arlett, MRCP
Head of Pharmacovigilance, European Medicines Agency, European Union

Measuring the impact of pharmacovigilance allows us to improve performance and to demonstrate effectiveness. Frameworks for impact measurement will be discussed using EU/US situations as case studies. Views on optimal approaches will be explored.

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

Pharmacovigilance Risk Assessment Committee (PRAC) Perspective
Representative Invited

#367 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CP, CR

1:30–3:00 PM LEVEL: ■ FORMAT: FORUM
Room 145A CME and Nursing

Big and MultiStream Data for Drug Evaluation: The Promise and Cautions
CHAIRPERSON
Mark S. Levenson, PhD
Deputy Director, Division of Biometrics VI, Office of Biostatistics, CDER, FDA

This forum will discuss current and emerging large and multistream data sources for drug evaluation and the associated methods and systems. It will also highlight the promises and cautions of the data sources.

Establishing an Open-Source Community for Large-Scale Analytics and International Evidence Generation: Lessons from the Observational Health Data Sciences and Informatics Program
Patrick Ryan, PhD, MS
Head, Epidemiology Analytics, Janssen Pharmaceuticals, Inc.

FDA Active Postmarketing Drug Safety Surveillance: Mini-Sentinel to Sentinel, Current and Emerging Capabilities
Marsha E. Reichman, PhD
Senior Advisor/Scientific Lead Surveillance Programs, Sentinel Initiative Lead, CDER, FDA

Big Data and Safety Surveillance: Are We Building a Bigger Haystack?
Susan Gruber, PhD, MPH, MS
Senior Director, IMEDS-Methods Research, Reagan-Udall Foundation for the FDA
#368 Track 16A – Professional Development

1:30–3:00 PM
Room 147A
CME, Pharmacy, and Nursing

Conducting Courageous Conversations as a Strategy to Work with Difficult People

CHAIRPERSON
Valerie J. Gamble, EdD, MEd
Global Education and Performance Enhancement Lead, Pfizer Inc

Do jerks in the workplace exist? Do we know who they are? Believe it or not, jerks do exist in the workplace. They are in the form of our peers, colleagues, managers, and executives. In this workshop, you will learn about the concept of hot buttons and how these typically negative behaviors may be sabotaging success within your organization. We will discuss guidelines for conducting courageous conversations that will enable your team to work more effectively together as they excel both individually and collectively.

**Due to workshop format, seating will be limited and will be available on a first come, first served basis.**

The Walter E. Washington 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
Sue Fleischner, PhD, MA
Instructional Development and Facilitation, i3logic

#369 Track 16B – Professional Development

1:30–3:00 PM
Room 147B
CME and Nursing

Using Games and Play to Create an Innovative Learning Experience

CHAIRPERSON
Akshay Sateesh, MS
Founder and Facilitator, Ziksana Consulting

In this workshop, participants will learn the impact and application of using play and games in their workplace. Facilitators will lead the group in fun activities to explore how play can connect, encourage, and explore new ways of thinking, being, and behaving to motivate and engage those involved. Using concepts from improvisation theater, participants will design and present a training game during the workshop applied directly to their field of interest. We will close with a case study demonstrating the power and impact of games and gamification in an organization. Come have some fun and learn about the science of play and how it applies to your company!

**Due to workshop format, seating will be limited and will be available on a first come, first served basis.**

The Walter E. Washington 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.

Yes and...Using Play and Improvisation to Boost Creativity and Innovation
Akshay Sateesh, MS
Founder and Facilitator, Ziksana Consulting

The DT Olympics: A Case Study in Using Gamification to Increase Product Knowledge in Diverse Teams

Kathy Tibaldi, MA
Director, Project Management and Solution Center, DATATRAK International

Innovate Regulatory Affairs Teaching (LET’S PLAY!)
Asli Guven Santos, PharmD
Director, Catalyst Regulatory Services, LLC

#370 Track 17 – Rare/Orphan Diseases

1:30–3:00 PM
Room 145B
CME, Pharmacy, and Nursing

A Global Update on Orphan Drugs

CHAIRPERSON
Noriaki Murao, MS
Representative, NM Consulting, Japan

This symposium addresses the current status and forthcoming activities related to orphan drugs in North America, EU and Japan. Orphan drug development is considered essential in these regions, and the various provisions to accelerate the development of orphan drugs have been implemented. However, some challenges still remain for the companies and the agencies wishing to pursue development and approval of orphan drugs in these regions.

Building on the Success of 15 Years of European Orphan Drug Legislation
Kristina Larsson
Head of Office for Orphan Medicines, European Medicines Agency, European Union

Mastering Regulatory Approvals in New Orphan Drug Markets
Lewis Lau
Independent Regulatory Science Researcher, Humber-RAC Work Group, Canada

Global Development and Approval by Cooperation of Key Regulatory Agencies
Junko Sato, DrSc, PhD
International Coordination Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#371 Track 18 – Global Regulatory

1:30–3:00 PM
Room 152B
CME, Pharmacy, and Nursing

CBER Town Hall: Innovation and Public Health Response

CHAIRPERSON
Karen Midthun, MD
Director, Center for Biologics Evaluation and Research, FDA

Join us for this unique opportunity that includes members from Center for Biologics Evaluation and Research’s (CBER) leadership for an overview of CBER’s regulatory programs, including efforts related to expedited review, regulatory science, and postmarketing surveillance. We will discuss how the Center has used expedited programs in response to public health issues and how it facilitates the development of innovative products.
Collaboration among TransCelerate Biopharma Inc. (TransCelerate) member companies is driving industry innovation. In this session, we will examine how these 21 participating member companies are driving innovation to address clinical trial execution pain points through their 12 chartered work streams. We will also address the mission of TransCelerate, what solutions have been delivered so far, and what to expect in 2015 and beyond.

Panelists:

Jacalyn Kent
Senior Director, Clinical Development Information & Optimization, Eli Lilly and Company

Brett Wilson
Associate Director, Bristol-Myers Squibb Company, Canada

Edward Bowen, MBA, MS
Senior Director, Translational and Bioinformatics, Pfizer Inc

Robert A. DiCicco, PharmD
Vice President, Clinical Pharmacology Sciences and Study Operations, GlaxoSmithKline

2:30–3:30 pm
Refreshment Break & Innovation Theater Presentations (Exhibit Hall)

#373 Track 19B – Late-breaking Topics

Related Interest Area(s): CR

1:30–3:00 pm
Room 102AB
CME and Nursing

TransCelerate Collaboration: Harmonization Efforts to Find Solutions to Critical Industry Challenges

CHAIRPERSON
Andy Lee, MA
Senior Vice President, Head of Global Clinical Trial Operations, Merck & Co., Inc.

No More Crying Wolf: FDA Issues Final Rule on Changes to Pregnancy and Lactation Information in Drug Labeling

CHAIRPERSON
Tamara Johnson, MD, MS
Medical Officer, Division of Pediatrics and Maternal Health, Office of New Drugs, CDER, FDA

This session discusses the final Pregnancy and Lactation Labeling Rule which sets the new content and formatting requirements for pregnancy and breastfeeding information in labeling. Perspectives are provided from the FDA, industry, and academia.

FDA Perspective
Jeanine Best, MSN, RN
Team Lead, Maternal Health, Office of New Drugs, CDER, FDA

Industry Perspective
Christina Bucci-Rechtweg, DrMed, MD
Global Head, Pediatric and Maternal Health Policy, Novartis Pharmaceuticals Corporation

A Database on the Reproductive Effects of Chemicals, Medications, Physical Agents, and Biologics

Anthony R. Scialli, MD
Director, The Reproductive Toxicology Center

Panelist
Sandra L. Kweder, MD, FACP
Deputy Director, Office of New Drugs, CDER, FDA

#374 Track 21 – Poster Presentations

2:30–3:30 pm
Exhibit Hall (Entrance A)
No CE available

Wednesday Oral Presentations - Professional Poster Session 2C

New this year! Join us in the Exhibit Hall Poster Area (Hall A Entrance) for a series of 5 minute presentations delivered by this year’s Professional Poster Presenters.

The following are scheduled in this session 2C:

- 2:35–2:40 pm—W 34 From Concept to Reality: Developing an Operational Study Planning and Forecasting System
- 2:42–2:47 pm—W 36 Development of an Electronic Diary with Spirometer Integration to Capture Patient Data in Asthma Clinical Trials
- 2:49–2:54 pm—W 37 Use R for ESUB Module 5
- 3:03–3:08 pm—W 41 Fifteen Years of Controlled Production and Consistency of Quality Attributes for a Glycosylated Monoclonal Antibody Therapy
#375 Track 20 – Innovation Theater

**Related Interest Area(s): IT, DM, CR**

**3:00–3:30 PM**  
**LEVEL:** ●  
**FORMAT:** SPECSESS  
**Exhibit Hall**  
**SIGNIX Worldwide Innovation Theater: Formula One Study Start-up: How To Get a 94% Reduction in Time By Going Paperless**

Sarah Cannon Research Institute and SIGNIX will discuss how CROs can save time and money by going paperless. SCRI will detail the challenges faced dealing with burdensome paper processes: personnel draining workflows, costly delivery charges, regulatory compliance, and the handling of binders upon binders of paper. SCRI will then share how SIGNIX was able to eliminate these issues and meet 21 CFR 11 using PharmaDox, which brings easy, independent, digital certificate signing to life sciences.

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#376 Track 01A – Clinical Operations

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

**3:30–5:00 PM**  
**LEVEL:** ●  
**FORMAT:** FORUM  
**Room 146C**  
**CME and Nursing**  
**Best Practices for Effective Engagement with Patient Groups Around Clinical Trials**

**CHAIRPERSON**
Bray Patrick-Lake, MS  
Director of Stakeholder Engagement, Clinical Trials Transformation Initiative (CTTI)

This forum will review evidence from Clinical Trials Transformation Initiative’s Patient Groups & Clinical Trials project literature search, joint survey with DIA, and key informant interviews on practices that support effective partnerships. Value and associated metrics will also be examined.

**CTTI Patient Groups and Clinical Trials Project: Key Findings**
Wendy Selig, MS  
Founder and Chief Executive Officer, WSCollaborative

**What Industry Is Measuring Around Patient Group Partnerships**
David Leventhal  
Director, Clinical Innovation, Worldwide Research and Development, Pfizer Inc

**Patient Groups and Clinical Trials: Concepts of Value**
Matthew Harker, MBA, MPH  
Director, CHLC, Clinical Trials Transformation Initiative (CTTI)

**Panelist**
Representative Invited  
Director, Office of Clinical Research, National Institute of Neurological Disorders and Stroke, NIH

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#377 Track 01B – Clinical Operations

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

**3:30–5:00 PM**  
**LEVEL:** ■  
**FORMAT:** SYMPOSIUM  
**Room 146A**  
**CME and Nursing**  
**Optimizing Investigative Site/Country Selection Using Online Feasibility Tools, Big Data, and Disruptive Technologies**

**CHAIRPERSON**
Gustavo Kesselring, MD  
Executive Director, Latin America, Vis Research, Brazil

This symposium will address how management of big data analytics, visualization systems and social networks can accelerate and reduce cost of trial planning process through an innovative online feasibility assessment that interacts with research sites. Methods for assessing dynamic global regulatory approval timelines and their impact on the development of optimal country strategies for clinical trials will be discussed. We will conclude with an investigation of how disruptive technologies are changing processes, the performance metrics that can be collected, as well as our expectations of what constitutes acceptable performance.

**Connecting the Right Sites to Promising Trials: The Role of Online Feasibility Assessment**
Gustavo Kesselring, MD  
Executive Director, Latin America, Vis Research, Brazil

**The Metrics Evolution: Using Better Metrics to Inform Decision-Making and Streamline Clinical Trial Operations**
Linda B. Sullivan, MBA  
Co-Founder and President, Metrics Champion Consortium LLC

**Using Big Data to Supplement Traditional Performance and Capability Metrics and Optimize Investigative Site Identification and Selection**
Shawn Phillip Tedman, MBA  
Associate Director, Site Intelligence, PAREXEL International

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#378 Track 02 – Project/Portfolio Management and Strategic Planning

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

**3:30–5:00 PM**  
**LEVEL:** ■  
**FORMAT:** FORUM  
**Room 101**  
**CME and Nursing**  
**Pediatric Product Development in the 21st Century: Developing Research Networks to Get the Job Done**

**CHAIRPERSON**
Lynne P. Yao, MD  
Associate Director, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

Efficient pediatric drug development in the 21st century will require effective collaboration between industry, academia, patients, and government. This forum will gather stakeholders from these groups to explore use of pediatric research networks.

**Why a Pediatric Clinical Trials Network?**
Samuel D. Maldonado, MD, MPH  
Vice President, Head of Child Health Innovation Leadership Department, Janssen Research & Development, LLC
Successful Clinical Research Networks in Europe: Strengths and Opportunities
Mark Turner, PhD
Senior Lecturer in Neonatology, University of Liverpool, United Kingdom

Global Paradigm Shift: Getting It Done!
Pamela Simpkins, MBA, PMP
Strategy Lead, Child Health Innovation Leadership Dept. (CHILD), Janssen Pharmaceuticals, Inc.

How CROs Can Work Successfully with a Global Pediatric Research Network
Earl Seltzer, MBA
Feasibility Manager, Quintiles Inc.

#379 Track 03 – Innovative Partnering Models and Outsourcing Strategies
Related Interest Area(s): OS, CR
3:30–5:00 pm
Room 150A

Outing Innovation: How Partnerships Help (and Hinder) the Movement Toward Novel Approaches to Clinical Development
CHAIRPERSON
John Rafa, III, MBA
Executive Director, Research Services, The Avoca Group, Inc.

Results from industry research and a sharing of executive panel perspectives on clinical trial innovation will serve as a catalyst for audience discussion. This forum will discuss the impact that partnering arrangements will have on innovation.

Panelists
Craig H. Lipset
Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc

Thomas Grundstrom, MA
Vice President, Integrated Technologies and Informatics, ICON plc

Representative Invited
Vice President, Global Biostatistics, Programming and Medical Writing, PPD, Inc.

#380 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons
Related Interest Area(s): CEHTAEbM, MC, MSL
3:30–5:00 pm
Room 206

Accountable Care Organizations and Integrated Health Care
CHAIRPERSON
J. Lynn Bass, PharmD, RPh
Director, Medical Affairs, Jazz Pharmaceuticals

This session will educate professionals in the pharmaceutical, biotechnology, and device industries and government employees on how medical and health economics data is disseminated to a variety of customer segments. Participants will benefit from understanding the opportunity and need to disseminate a variety of data to both the prescribing and decision maker communities.

This session was developed by the Medical Communications, Medical Science Liaison and Medical Writing Communities.

Medical Communications Regarding Value and Outcomes to the Payer Audience
Christopher M. Marrone, PharmD
Outcomes Liaison, Eli Lilly and Company

#381 Track 07A – Technology/Data/Records and Submissions
Related Interest Area(s): CDM, PM
3:30–5:00 pm
Room 201

CFAST Initiative: Potential to Dramatically Increase ROI and Reduce Timelines in the Conduct of Clinical Trials
CHAIRPERSON
Diane E. Wold, PhD
Senior Director, Standards Development and Modeling, CDISC

The Coalition for Accelerating Standards and Therapies (CFAST) initiative has made progress in increasing the speed and number of therapeutic area (TA) standards developed. These accomplishments have the potential to dramatically increase return on investment and reduce the timeline in the conduct of clinical trials.

Recent FDA Guidance on Data Standards and CDISC Activities
Ron D. Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

CFAST: Innovative Approaches to Standards Development and ROI These Standards Can Facilitate
Diane E. Wold, PhD
Senior Director, Standards Development and Modeling, CDISC

Maximizing The Value of Data Through Collaboration
Enrique Aviles
Director, Data Standards Management, Critical Path Institute

#382 Track 07B – Technology/Data/Records and Submissions
Related Interest Area(s): IT, RA, SUBS
3:30–4:30 pm
Room 202B

The Critical Role of Document Management Supporting Submissions: Regulatory Operations, IT and Vendor Perspectives
CHAIRPERSON
Bill Leslie
Head, Global Regulatory Operations, Covance Inc.

Submissions to regulatory authorities are critical in support of clinical trials as well as marketing applications. Speakers representing regulatory operations, IT and the vendor community will discuss how to successfully select and implement a document management supporting system.
The Critical Role of Document Management Supporting Submissions:
IT Perspective
Vincent P. Heenan, MBA
Director, Information Technology, Johnson & Johnson

The Critical Role of Document Management Supporting Submissions:
Vendor Perspective
Melissa Aron
Professional Services Practice Manager, Veeva Systems

Medical Device Updates
Roshana Ahmed, MA, RAC
Senior Manager, Regulatory Affairs (Medical Devices), Mapi Group, Canada

Regulatory Reviewer Perspective
Representative Invited
Biomedical Engineer, CDRH, FDA

Human Factors for Combination Products
Molly Follette Story, PhD
Head, Global Usability Engineering and Risk Management, Sanofi

#383 Track 08 - Regulatory Affairs
Related Interest Area(s): CR, RD
3:30–5:00 PM  LEVEL: ■  FORMAT: SESSION
Room 151A  CME and Nursing
Dynamic Changes in Regulatory Landscape in Asia: Regulations for Global Drug Development

CHAIRPERSON
Akio Uemura, PhD
Corporate Director, Senior Director and Head, Clinical Operations, Allergan Japan K.K., Japan

The regulatory environment in Asia is rapidly changing and its importance for global drug development is rising high. We will hear from an Asian regulatory agency and industry and discuss how we should actively modify our development strategy based on recent changes.

New Regulations for Drug Development in Japan
Yoshiaki Uyama, PhD
Director, Division of Epidemiology, Office of Safety I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Recent Status of Regulation and Clinical Trial in Korea
Sang Ki Kim, MD
Deputy Director, Clinical Trials Management Div, Pharmaceutical Safety Bureau, Ministry of Food and Drug Safety (MFDS), Republic of Korea

Regulatory Challenges in China Drug Development
Xiling Song, MS
Associate Regulatory Program Director, Pharma Technical Regulatory, Genentech, A Member of the Roche Group

#384 Track 09 - Medical Devices/In Vitro Diagnostics and Combination Products
Related Interest Area(s): MDD, RA
3:30–5:00 PM  LEVEL: ●  FORMAT: SESSION
Room 152A  CME, Pharmacy, and Nursing
Enhanced Collaborative Strategies: FDA and Device Makers Focusing on Improved Device Clearance Processes

CHAIRPERSON
Amnon Talmor
Senior Regulatory Specialist, Global Medical Device and Compliance Lead, Premier Research Group Ltd.

This session explores device industry events that have led to increased FDA involvement with device makers in order to establish mechanisms implemented since 2009 for improved product review and market clearance.

#385 Track 10 - Public Policy/Health Care Compliance/Law
Related Interest Area(s): RA
3:30–5:00 PM  LEVEL: ■  FORMAT: FORUM
Room 146B  CME, Pharmacy, and Nursing
Enforcement Update and Trends From a Global Perspective

CHAIRPERSON
Barry A. Berger, JD, MBA
Professor of Regulatory Affairs, Temple University

This forum will address from an industry, regulator and public interest perspective some of the key current enforcement actions and trends. How can each group better address and respond to issues that present challenges to public health?

FDA Point of View
Cynthia A. Schneder, JD
Director, Office of Compliance, CDER, FDA

Viewpoint on FDA Enforcement
Douglas B. Farquhar, JD
Partner, Hyman, Phelps & McNamara, PC

Clinical Trial Enforcement Trends
Mitchell Berger, JD, MPH, RAC
Consumer Safety Officer, FDA Alumni

#386 Track 11 - Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)
Related Interest Area(s): RD, BT, CR
3:30–5:00 PM  LEVEL: ●  FORMAT: SESSION
Room 202A  CME and Nursing
Adapting Risk Management Principles to Nontraditional R&D Settings

CHAIRPERSON
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

Headline risk is of perpetual concern for companies in the biopharmaceutical and biotechnology markets. As regulatory scrutiny directed toward companies that develop vaccines, immunotherapies, recombinant DNA/gene therapies, and other biologically-derived products increases, so does public awareness of the importance of biosafety and biosecurity. Product integrity is more important than ever, and is a direct function of quality programs. This session will discuss quality assurance/
quality control programs that would benefit from a robust and integrated risk management program.

**Risk Management Considerations in Clinical Trials for Serious Diseases**
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

**Site-Specific Risk Management for Human Gene Therapy Trials**
Chris Jenkins, PhD, MPH
Senior Vice President of Biosafety and Gene Therapy, WIRB-Copernicus Group

**Considerations on the Design of Phase 2 Efficacy Studies for Ebola Therapeutics: Industry Perspective**
Thomas Moensch, MD
Chief Medical Officer, Mapp Biopharmaceutical, Inc.

**Considerations on the Design of Phase 2 Efficacy Studies for Ebola Therapeutics: Regulatory Perspective**
John Tierney
Clinical Research Oversight Manager, National Institutes of Health (NIH)

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**#387 Track 12 – Pharmaceutical Quality**

**Related Interest Area(s): MF, PM**

**3:30–5:00 PM**

**Room 151B**

**Format: SESSION**

**CME and Nursing**

**Knowledge Management for the Product Life Cycle**

**CHAIRPERSON**

Paige Kane
Director, Knowledge Management, Pfizer Inc

This session will provide an overview of the philosophy of knowledge management and its importance in life cycle management. In addition, we will focus on knowledge management as the complement to change management in a company’s pharmaceutical quality system and as a key foundational basis for the use of prior knowledge in risk assessments in the design, development and maintenance of product quality.

**Recommendations for a Streamlined, Global Assessment of CMC Changes and Optimized Dossier Preparation Process**

Kim S. Northam
Associate Manager, Regulatory Affairs, Accenture, United Kingdom

**Compliance and Change Control: Checking That the Manufacture/CMC is Maintained in Accord With the Terms of the License**

Peter Lassoff, PharmD
Vice President and Head, Global Regulatory Affairs, Quintiles Inc., United Kingdom

**Opportunities for Industry**

Paige Kane
Director, Knowledge Management, Pfizer Inc

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

**Related Interest Area(s): CR**

**3:30–5:00 PM**

**Room 147B**

**Format: WORKSHOP**

**CME, Pharmacy, and Nursing**

**Making Evidence at Launch More Real-World: Pragmatic Trials, Current Developments and Operational Challenges**

**CHAIRPERSON**

Pieter Stolk, PharmD, PhD
Project Manager, IMI GetReal, University Medical Center Utrecht, Netherlands

Pragmatic relative effectiveness (RE) trials are essential to compare treatment strategies. Designing and executing such real-world trials pre-launch is challenging. In this workshop, we will assess pragmatic study design options, their operational feasibility and methodological implications.

**Facilitators**

Thomas Rhodes
Director, Comparative Outcomes and Evidence, Merck & Co., Inc.

**Representative Invited**

Epidemiologist, Research Advisor, Center of Excellence Epidemiology, Eli Lilly and Company, United Kingdom

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**#389 Track 14A – Clinical Safety and Pharmacovigilance**

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

**3:30–5:00 PM**

**Room 204BC**

**Format: SESSION**

**CME, Pharmacy, and Nursing**

**Developing Innovative Approaches to Postmarketing Safety Data Collection in Pregnant Women**

**CHAIRPERSON**

Leyla Sahin, MD
Medical Officer, Division of Pediatric and Maternal Health, Office of New Drugs, CDER, FDA

This session will explore the challenges of conducting postmarketing studies in pregnant women. Key messages from the 2014 FDA public meeting will be presented and discussed. Industry will discuss implementation of pregnancy registries as well as methodological considerations for categorization of subjects as retrospective vs. prospective and birth outcomes, and coding of birth defects. Regulatory experts from the United States and Europe and industry will participate in a panel discussion about the current thinking and experiences in the approaches to postmarketing data collection in pregnant women.

**Product Exposure Pregnancy Registries: Experience with and Practical Advice on Data Summarization Conventions**

Catherine Sigler, DVM, PhD, MPH
Senior Director, Safety, Epidemiology, Registries and Risk Management, UBC: An Express Scripts Company
Clinical statisticians have long been pressed by their study teams to identify opportunities such as:

- Submitting an abstract for next year’s DIA 2016 52nd Annual Meeting (June 26–29 in Philadelphia, PA)
- Submitting an article for DIA’s peer-reviewed research journal Therapeutic Innovation & Regulatory Science (TIRS)
- Submitting an article for DIA’s “Global Forum” news magazine.

**Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington 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.**

**Panelists**
- Stephen P. Spielberg, MD, PhD
  Editor-in-Chief, DIA Publications, DIA
- Judy Connors, MA
  Associate Director, Editorial Services, DIA
- Alberto Grignolo, PhD
  Corporate Vice President, PAREXEL International
- Lisa Jenkins, PhD
  Vice President, Regulatory Strategy and Content Development, Virtual Regulatory Solutions, Inc.
#393 Track 17 – Rare/Orphan Diseases

3:30-4:30 pm △
Room 145B

Rare Diseases: Patients, Caregivers and Advocates as Equal Partners in Clinical Trial Process

CHAIRPERSON
Barbara Szymaszek
Advocacy, Diversity and Patient Engagement, Bristol-Myers Squibb Company

This forum will discuss ways to enhance protocol design, recruitment and retention strategies for clinical trials in rare/orphan diseases, offering both strategic and tactical approaches. We will examine lessons learned on data from over 50 rare disease studies, underscoring the critical role of referring physicians. We will address operational challenges, strategies and tactics to design and conduct protocols that are practical from the patient and caregiver perspectives, and will share a case study of the impact patient advocacy organizations make in drug development. Finally, the panel will examine the definition of return on investment and other measures of success.

Engaging Patients Every Step of the Way
Patricia Furlong, BSN
Founding President and CEO, Parent Project Muscular Dystrophy

Relationship Building in Rare Diseases: The Critical Role of Referring Physicians
Jaime Cohen
Corporate Marketing, BBK Worldwide

#394 Track 18A – Global Regulatory

3:30-5:00 pm △
Room 152B

Asia Town Hall: Asia as a Drug R&D Center in the World

CHAIRPERSON
Toshiyoshi Tominaga, PhD
Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

This session will address the current status of the regulatory environment as well as recent achievements and challenges of drug development in Asian countries.

Industry Perspective: Multiregional Clinical Trials Updates in Japan and Regulatory Convergence Among Asian Countries
Chitose Nishida
Department Manager of Regulatory Excellence, GlaxoSmithKline K.K., Japan

Panelists
Representative Invited
Director, Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Silke Vogel, PhD
Deputy Director, Center of Regulatory Excellence (CoRE); Associate Dean, Duke NUS, Singapore

#395 Track 18B – Global Regulatory

3:30-5:00 pm △
Room 207B

The State of Informatics at CDER and CBER

CHAIRPERSON
Mary Ann Slack
Deputy Director, Office of Strategic Programs, CDER, FDA

CDER and CBER are working towards all electronic environments in order to streamline and facilitate the review of electronic submissions. This forum focuses on the Centers’ goals, experiences and practical advice for sponsors and consultants.

CDER Perspective
Hilmar Hamann, PhD
Director, Office of Business Informatics, CDER, FDA

CBER Perspective
Vada A. Perkins, BSN, MSc, RN
Deputy Associate Director for Review Management (Acting), CBER, FDA

Your Opinion Matters

Complete an evaluation for each offering you attend for a chance to win great prizes.

Access online evaluations at DIAGlobal.org/DIA2015evals or stop by Evaluation Stations in the Registration Area beginning Tuesday.

Free registration to the DIA 2016 52nd Annual Meeting $100 American Express Gift Card
The content noted on this page was made available to DIA as of April 27.
This symposium will present cases studies focused on deficiencies in sponsor-provider relationships and how they have been identified, managed and overcome.

**Developing and Implementing Innovative Solutions to Obstacles in the CRO/Sponsor Relationship**

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

**Innovations in Strategic Alliances: Overcoming Challenges to Create a Lasting Partnership**

David Burnham  
Vice President, Alliance Management, INC Research

**When Mars and Venus Collide: Biggest Pees in Working with Sponsors and Vendors - From Vendors' and Sponsors' Perspectives**

Chris Chan, MBA  
Senior Director, R&D Finance, Fibrogen, Inc.

**Accidental Drugs: A Historical Look at How Certain Drugs Came to Market and Policy Pathways**

Kimberly Belsky, MS  
Executive Director, Regulatory Affairs, AdPromo, Labeling and Policy, Valeant Pharmaceuticals

This session will review how drugs have been repurposed or found to have an unintentional off-target effect, the incentives for R&D that led to FDA approval and even blockbuster status and how collaboration can shape future opportunities.

**Regulatory Innovation Incentives: Do They Work?**

Andrew S. Robertson, JD, PhD  
Director, Global Regulatory Policy, Merck & Co., Inc.

**Upgrading the Paths to Approval for Neonatal Therapies**

Lynn Diane Hudson, PhD  
Chief Science Officer, Critical Path Institute

**Tired of Reinvesting in Old R&D Systems? Several Large Pharmaceutical Companies and Other Leaders Are Flipping Paradigms**

Jonathan Burr  
Managing Director, Accelerated R&D Services, Accenture

This forum examines how an innovative partnership between several large organisations in the pharmaceutical industry is poised to re-shape, re-think and re-structure the R&D IT landscape by collaborating to change the way IT enables R&D.

**A Case Study in Life Sciences Cloud Implementation**

Sandra Tremps, MS  
Global Leader, Clinical, Regulatory, and Safety IT, Merck & Co., Inc.

**Bring Your Own Device (BYOD) Approaches to the Collection of Electronic Patient-Reported Outcome Data in Clinical Trials**

Chad Gwaltney, PhD  
Consultant, ERT

Bring Your Own Device (BYOD) approaches allow study subjects to use their personal digital devices to complete remote (i.e., offsite) patient-reported outcome measures. This session will describe key scientific, regulatory, and operational considerations when using BYOD.

**Context Setting: Why the Industry Needs to Rethink the R&D IT Paradigm**

Jonathan Burr  
Managing Director, Accelerated R&D Services, Accenture

**A Case Study in Life Sciences Cloud Implementation**

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**Accidental Drugs: A Historical Look at How Certain Drugs Came to Market and Policy Pathway Opportunities**

Kimberly Belsky, MS  
Executive Director, Regulatory Affairs, AdPromo, Labeling and Policy, Valeant Pharmaceuticals

For drug history buffs and those interested in life cycle management, this session will review how drugs have been repurposed or found to have an unintentional off-target effect, the incentives for R&D that led to FDA approval and even blockbuster status and how collaboration can shape future opportunities.

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Global Leader, Clinical, Regulatory, and Safety IT, Merck & Co., Inc.
inhibitors; (2) The openFDA website, its application programming interface, and a novel graphical user interface called the Adverse Event Explorer, which allows easy access to and query of the safety information contained in openFDA; and (3) Holistic signal detection—approaches and challenges associated with detecting, evaluating, and combining safety signals from multiple data sources such as FAERS, EHRs, the biomedical literature, and the logs of health information seeking activities on the Web.

Real-World Data-Driven Drug Safety Evaluation: Tumor Necrosis Factor Alpha (TNFa) Inhibitors Case Study
Ran Balicer, MD, PhD, MPH
Advisory Board of Data2Life, Data2life and Clalit Research Institute, Israel

Interactive Web-Based Exploration of the 3.8 Million Adverse Event Reports in the OpenFDA Database
Jeremy Wildfire, MSc
Statistical Scientist, Rho, Inc.

#409 Track 15 – Statistical Science and Quantitative Thinking
Related Interest Area(s): CR, ST
9:00–10:30 AM  LEVEL: ■ FORMAT: SESSION
Room 145A  CME, Pharmacy, and Nursing

Innovative Designs for Cardiovascular Outcome Safety Trials in Type 2 Diabetes
CHAIRPERSON
Cyrus R. Mehta, PhD
Founder and President, Cytel Inc.

This session presents strategies for designing adaptive trials that demonstrate cardiovascular safety of antidiabetic compounds.

Adaptive Designs to Demonstrate Risk Reduction in Cardiovascular Outcome Trials
Cyrus R. Mehta, PhD
Founder and President, Cytel Inc.

Clinical Development Approaches and Statistical Considerations to Assess the CV Safety of New Type 2 Diabetes Therapies
Mary Jane Geiger
Senior Director, Cardiovascular & Metabolism Therapeutics, Regeneron Pharmaceuticals, Inc.

Meta-Analysis Approach to Establish Cardiovascular Safety: Experiences and New Suggestions
Stefan Hantel, PhD
Principal Statistician, Boehringer Ingelheim Pharma Gmbh & Co. KG, Germany

Panelist
Aloka Chakravarty
Director, Division of Biometrics VII, Office of Biostatistics, Office of Translational Science, CDER, FDA

#410 Track 16 – Professional Development
Related Interest Area(s): PETD
9:00–10:00 AM  LEVEL: ● FORMAT: FORUM
Room 152B  Pharmacy

Aha: Moments of Breakthrough Thinking Leading to New Opportunities
CHAIRPERSON
Jesus Rivera, MSc
Senior Learning Manager, Bristol-Myers Squibb Company

Have you ever experienced an epiphany that led you to alter the course of your career (or life) abruptly? Our panelists will share pivotal moments in their lives when sudden insights prompted profound changes leading to new challenges and opportunities.

Panelists
Bob Muzerall
Vice President, Sales and Sales Training, ForeignExchange Translations

Donald Wolanin, PhD
Independent Trader Investor

#411 Track 18 – Global Regulatory
Related Interest Area(s): RA, CP, CMC/GMP
9:00–10:30 AM  LEVEL: ■ FORMAT: FORUM
Room 143ABC  CME and Nursing

An Insider’s View of Cooperation Between the EMA and CDER/FDA: Question Time
CHAIRPERSON
Sabine Haubenreisser, PhD, MSc
EMA Liaison Official to the US FDA, European Medicines Agency, European Union

Sandra L. Kweder, MD, FACP
Deputy Director, Office of New Drugs, CDER, FDA

New this year! Join us for this unique opportunity that includes members from EMA and CDER/FDA Leadership. This first of its kind forum will provide an opportunity for both agencies to discuss and explore at a roundtable discussion areas covered by the EMA/FDA confidentiality arrangements and discuss how both agencies contribute to global development and supervision of medicines. Experts from both agencies who have been at the forefront of EMA/CDER/FDA collaboration will explore topics such as pharmacovigilance, adaptive pathways, quality by design, and patient involvement in the development of medicines.

The audience will be invited to submit questions of general interest. Please come prepared with your questions for the EMA/CDER Question Time panel. You may submit questions and topics of interest in advance to annualmeetingprogram@diaglobal.org, and include “EMA/CDER/FDA Question Time” in the subject line.

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

Christine M. V. Moore, PhD
Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Theresa M. Mullin, PhD
Director, Office of Strategic Programs, CDER, FDA
Thursday, June 18

Robert J. Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA

Enrica Alteri, MD
Head of Human Medicines Evaluation, European Medicines Agency, European Union

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

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

Guido Rasi, MD
Principal Adviser, European Medicines Agency, European Union

#412 Track 19 – Late-Breaking Topics

9:00–10:30 AM

Level: ● Format: FORUM

Room 146C

CME, Pharmacy, and Nursing

Mobile Health, Telemedicine, and Remote Sensors in Clinical Investigations: A New Era in Clinical Trial Design?

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

This forum will discuss opportunities for mobile technologies in clinical trials, which could facilitate the measurement of novel patient-centered endpoints, decrease geographical access barriers for patients, and drive efficiencies for sponsors.

Panelists
Matthew Kirchoff, PharmD, MS
Program Management Officer, Office of Medical Policy, CDER, FDA

Ken Skodacek
Policy Analyst, Clinical Trials Program, Office of Device Evaluation, CDRH, FDA

John Marler
Medical Officer, DNP, Office of New Drugs, CDER, FDA

10:30–10:45 AM

Coffee Break (Meeting Room 145-147 Concourse)

#413 Track 01 – Clinical Operations

10:45–11:45 AM

Level: ■ Format: FORUM

Room 145B

CME, Pharmacy, and Nursing

Develop Risk-Based Monitoring Strategies to Innovate Study Oversight and Advance Study Execution

Chairperson
Lynn King, MHA
Senior Director, Clinical Operations, TKL Research

This forum will explore the lessons learned from a case study of developing and implementing a risk-based monitoring strategy for a 30-site global trial. The collaborative sponsor/contract research organization process and implications will be presented and discussed.

Panelists
Representative Invited
Director of Monitoring, GlaxoSmithKline

#414 Track 02 – Project/Portfolio Management and Strategic Planning

10:45–11:45 AM

Level: ■ Format: SESSION

Room 145A

CME and Nursing

A Systematic Approach to Study Start-Up

Chairperson

Marina Malikova
Executive Director, Surgical Translational Research Operations and Compliance, Boston University School of Medicine

Systematic assessment of risk factors and key performance indicators at a start-up phase can allow for more efficient execution of a clinical trial and ensure better accrual rates. This session will discuss best practices to expedite start-up phase.

IRB Performance Metrics: Data From 105 Institutions Defining the Current State and Implications for Clinical Trials

Stuart Horowitz, PhD, MBA
President, Institutions and Institutional Services, WIRB-Copernicus Group

Systematic Risk Assessment: A Foundation for Risk-Based Monitoring of Clinical Studies

Marc Jason DeLuca, MS
Associate Director, Clinical Consulting, Paragon Rx, an InVentiv Health Company

#415 Track 03 – Innovative Partnering Models and Outsourcing Strategies

10:45 AM–12:15 PM

Level: ■ Format: FORUM

Room 150A

CME, Nursing, and PMI PDUs

Just the Facts: A Model for Evaluating the ROI of Outsourcing Investigator Payments

Chairperson
Stu Thiede, MBA
President, Payments, DrugDev

Measure the impact of your investigator payment solution with a return-on-investment (ROI) model that can be modified to your specifications. This forum will give you the tools to determine if your outsourced program is effective.

Panelists
Stu Thiede, MBA
President, Payments, DrugDev

Darren Hart
Vice President, Clinical Services, Exelixis, Inc.

Representative Invited
Executive Director, Clinical Business Operations and Outsourcing, Nektar Therapeutics

The content noted on this page was made available to DIA as of April 27.
Thursday, June 18

#416 Track 07 – Technology/Data/Records and Submissions

10:45 AM–12:15 PM  
 LEVEL: ■  
 FORMAT: SESSION  
 Room 146B  
 CME and Nursing

**mHealth/mClinical and Clinical Trials: A Candid Discussion on Opportunities and Risks**

CHAIRPERSON  
Philip J. Coran, JD, MBA  
Senior Director of Quality and Regulatory Affairs, Medidata Solutions Worldwide

This session will focus on the proliferation of mobile health (mHealth) and mclinical devices in the consumer and medical market and how these services may enhance clinical trials. The panel will cover perspectives from a variety of stakeholders including the FDA.

- mClinical/mHealth: Opportunities and Risks  
  Craig H. Lipset  
  Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc

- mClinical/mHealth: Regulatory Insights on Risks and Opportunities  
  Phillip D. Kronstein  
  Medical Officer, Office of Scientific Investigation, Office of Compliance, CDER, FDA

- mClinical/mHealth: Regulatory Insights on Risks and Opportunities  
  Julian M. Jenkins, PhD, MSc  
  Vice President, Project Planning and Management, GlaxoSmithKline

#417 Track 08 – Regulatory Affairs

10:45 AM–12:15 PM  
 LEVEL: ■  
 FORMAT: SESSION  
 Room 151A  
 CME and Nursing

**Global Developments in the Regulation of Biological Therapeutics**

CHAIRPERSON  
Andrew S. Robertson, JD, PhD  
Director, Global Regulatory Policy, Merck & Co., Inc.

This session will discuss recent developments in global biotherapeutics regulation, including originator biologics and biosimilars. The focus is on key events, the emergence of new analytical tools, new advocacy efforts, and how these impact developed markets.

- Interdisciplinary Perspectives on Development of Naming Standards for Biosimilar Medicines  
  Harry Gewanter  
  Chairman, Alliance for Safe Biologic Medicines

- The Journey To The First Biosimilar Approach In The US: A Sponsor’s Perspective  
  Hillel Cohen, PhD  
  Executive Director, Scientific Affairs, Sandoz Inc.

- Global Biosimilars Regulations: Open Issues  
  Representative Invited  
  Director, Global Biosimilars R&D Policy, Amgen Inc.

#418 Track 14 – Clinical Safety and Pharmacovigilance

10:45 AM–12:15 PM  
 LEVEL: ■  
 FORMAT: FORUM  
 Room 151B  
 CME, Pharmacy, and Nursing

**The Future of Pharmacovigilance Operations**

CHAIRPERSON

Nicole Schumacher Crow, MS  
Manager, Life Sciences, Deloitte & Touche L.L.P.

Pharmacovigilance (PV) systems have operated the same way for years, but recent changes in regulations, increasing workloads, and availability of new technologies are motivating companies to re-examine the way operations are conducted. This forum will examine these factors impacting the current PV workload and discuss future strategies for processes, governance, IT systems, and organizational structures.

- A Workload Crisis in Pharmacovigilance, and What to Do About It  
  Alan M. Hochberg  
  Senior Process Development Leader, F. Hoffmann-La Roche Ltd., Switzerland

- Pharmacovigilance 2.0: Strategy for the Next Generation PV System  
  Nicole Schumacher Crow, MS  
  Manager, Life Sciences, Deloitte & Touche L.L.P.

- Implementation and Quality Assurance of a Global Pharmacovigilance System  
  Kerstin Geldmeyer-Hilt, PhD  
  Quality Manager, Pharmacovigilance, Dr. Ebeling & Assoc. GmbH, Germany

#419 Track 16 – Professional Development

10:45–11:45 AM  
 LEVEL: ■  
 FORMAT: SESSION  
 Room 150B  
 CME, Pharmacy, and Nursing

**Making Technology a Key Component of Your Learning Strategy**

CHAIRPERSON  
Pamela Loughner, PhD, MEd  
President, Loughner and Associates Inc.

Approximately one-third of all formal training is now delivered through eLearning and other technologies. As the use of technology continues to rise, it is important for individuals responsible for training budget and training success to understand the factors that contribute to the overall effectiveness of technology-based training, and how to evaluate a program’s effectiveness and overall merit or worth. This session explores the use of technology-based training solutions and the factors that should be considered when incorporating the use of technology in a learning strategy. Case studies providing examples relevant to session participants will be shared.

- Maximizing Training Spend: How to Determine the Worth of eLearning Solutions  
  Pamela Loughner, PhD, MEd  
  President, Loughner and Associates Inc.

- Going Hollywood with your Training Program  
  Christine Wolford  
  Learning Solutions Specialist, DATATRAK International

The content noted on this page was made available to DIA as of April 27.
#420 Track 18 – Global Regulatory

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

10:45 AM–12:15 PM  
**ROOM:** 143ABC  
**LEVEL:** ■  
**FORMAT:** FORUM  
CME, Pharmacy, and Nursing

**CDER Town Hall**

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

One of the many DIA Annual Meeting program highlights is the CDER Town Hall where leaders from the US FDA’s Center for Drug Evaluation and Research will participate in this interactive offering where members of the audience may submit questions. Topics to be discussed will be determined by the interest of the audience.

Attendees are welcome to submit questions of interest to the panel by emailing annualmeetingprogram@diaglobal.org; subject line: CDER Town Hall Q/A

**Panelists**

- **Thomas W. Abrams, MBA, RPh**  
  Director, Office of Prescription Drug Promotion, Office of Medical Policy, CDER, FDA
- **Gerald J. Dal Pan, MD**  
  Director, Office of Surveillance and Epidemiology, CDER, FDA
- **Sandra L. Kweder, MD, FACP**  
  Deputy Director, Office of New Drugs, CDER, FDA
- **Christine M. V. Moore, PhD**  
  Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA
- **Theresa M. Mullin, PhD**  
  Director, Office of Strategic Programs, CDER, FDA
- **Robert J. Temple, MD**  
  Deputy Center Director for Clinical Science, CDER, FDA

#421 Track 19 – Late-breaking Topics

**Related Interest Area(s): CEHTAEbM**

10:45 AM–11:45 AM  
**ROOM:** 146C  
**LEVEL:** ■  
**FORMAT:** FORUM  
CME, Pharmacy, and Nursing

**Leveraging Electronic Health Record Data in Close Collaboration with Health Systems to Accelerate Precision Medicine**

**CHAIRPERSON**
Brett Jason Davis  
Principal and General Manager, ConvergeHealth By Deloitte

This forum will discuss the need for collaborations between pharmaceutical organizations and health systems to progress a precision medicine initiative proposed by President Obama in the State of the Union address and describe what treatments work, for whom, why, in what context.

**Panelist**

Representative Invited  
Founder and Chief Executive Officer, M2Gen

**MedDRA® User Group Meeting (Room 147A)**

**MedDRA® User Group Meeting (Room 147A)**

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- Courses tailored to meet your specific training objectives
- Continuing education credits

For more information contact Jessica.McGrory@diahome.org or visit DIAGlobal.org/Onsite and submit a consultation request.
### PRECONFERENCE TUTORIALS

This year’s preconference tutorials were held on Sunday, June 14 and 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 instructors involved in this year’s preconference program.

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<th>The Sunshine Act: Understanding the Essentials of Compliance</th>
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<td>Michael A. Swit, Esq</td>
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<td>Senior Director, Legal, Regulatory Affairs</td>
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<td>Leadership: How to Organize and Lead People in a Work Group</td>
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<td>TUT 22</td>
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<td></td>
<td>Kathryn Weckelman, PhD, RN</td>
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<td>Senior Director, Regulatory Strategy, Consulting and Submissions</td>
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<td>TUT 23</td>
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<td>Michael R. Hamrell, PhD, RAC</td>
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<td>President</td>
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<td>Pharmacogenomics and Companion Diagnostics: The Future of Clinical Trials, New Product Development and the Practice of Medicine</td>
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<td>Michael Drues, PhD</td>
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<td>Founder and President</td>
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<td>TUT 25</td>
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<td>Joanna Faith Haas, MD, MSc, FACP, FISPE</td>
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<td>TUT 30</td>
<td>Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development</td>
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<td>Alberto Grignolo, PhD</td>
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<td>Pharmaceuticals and Medical Devices Agency (PMDA), Japan</td>
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<td>TUT 31</td>
<td>Preparing for a US FDA Advisory Committee Meeting</td>
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<td>Lisa Peluso</td>
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<td>TUT 32</td>
<td>Influencing Culture, Avoiding Bureaucracy, and Encouraging Innovation</td>
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<td>Michael Laddin, MBA, MS</td>
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<td>TUT 33</td>
<td>Large-Scale Regulatory Functional Outsourcing: Emerging Trends, Challenges, and Decision Criteria</td>
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<td>Rick Lilley, PhD</td>
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<td>Preparation of Risk Evaluation and Mitigation Strategies Assessment Reports</td>
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<td>Catherine Sigler, DVM, PhD, MPH</td>
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<td>Analysis of Safety Data from Clinical Trials</td>
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<td>TUT 41</td>
<td>Quality Oversight of CROs-Clinical Vendors</td>
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<td>TUT 42</td>
<td>Fundamentals of ANDA Submissions and FDA Expectations Under GDUFA</td>
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<td>Carol H. Danielson, DrPH, MS, RAC</td>
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<td>Clinical Statistics for Nonstatisticians</td>
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<td>TUT 44</td>
<td>Risk Management and Safety Communication Strategies</td>
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<td>Nancy D. Smith, PhD</td>
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<td>The Good Pharmacovigilance Practices in the EU: Global Applications</td>
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**DiAGlobal.org/DIA2015 103**
**Student Poster Session**
**Monday, June 15, 9:30 AM–4:30 PM |** Posters will be displayed in the Exhibit Hall (Entrance A).
*Award Ceremony Tuesday, June 16 at 12:30 PM | DIA Booth #1523*

This year’s Student Poster Program includes 20 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 which will be held on Tuesday in the DIA Booth #1523 at 12:30 PM.

**Professional Posters**
Selected Life Sciences Professionals from all fields related to the mission of DIA will participate in this year’s Professional Poster Program.

*New this year—* Oral presentations where authors will provide a 5 minute overview of their work will be delivered. Dates and Times are noted below. Presentations will be held in the Poster Area located in Entrance A of the Exhibit Hall.

**Professional Poster Session #1 | Tuesday, June 16, 9:00 AM–4:00 PM**

*T 01 Assessing the Current Landscape of Pharmaceutical Industry Post-Doctoral Fellowships
*ORAL PRESENTATION SCHEDULED: Session IA at 9:35–9:40 AM*
Brittney Ann Rule, PharmD, MBA
Rutgers, The State University of New Jersey

*T 02 Patient Knowledge of Safe Use of ER/LA Opioid Analgesics Following Implementation of the Class-Wide REMS
*ORAL PRESENTATION SCHEDULED: Session IA at 9:42–9:47 AM*
Stephan Lanes, PhD
HealthCore, Inc.

*T 03 Biosafety Gene Therapy: Navigating the Regulatory Maze
*ORAL PRESENTATION SCHEDULED: Session IA at 9:49–9:54 AM*
Chris Jenkins, MPH, PhD
WIRB-Copernicus Group

*T 04 Clinical Relevance and Utility of Boxed Warnings in US Prescribing Information
*ORAL PRESENTATION SCHEDULED: Session IA at 9:56–10:01 AM*
Christine M. Cheng, PharmD
First Databank, Inc.

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**M 01** Effect of Albumin on Stability of Silver Nanoparticles in Biological Media
Tea Crnkovic
University of Zagreb, Croatia

**M 02** A Systematic Review of Observational Studies Evaluating Cardiovascular Outcomes of Testosterone Therapy in Men
Anna Hung, PharmD
University of Maryland School of Pharmacy

**M 03** Spontaneous Reports and Electronic Health Records for Safety Signal Detection
Alexandra Paturarioiu, RPh
Erasmus Medical Center, Netherlands

**M 04** A Retrospective Study of Cutaneous Adverse Drug Reactions (CADRs) in Patients Coming to Tertiary Care Hospitals
Khyati Pramod Doshi, MD
Smt. Kashibai Navale Medical College & General Hospital, India

**M 05** Evaluation of Safety Profiles of Drugs for Blood Cancer Approved in Japan
Sachie Kubota, MSc
Josai International University, Japan

**M 06** Characteristics of Anti-Cancer Drug Studies Registered on the Chinese Clinical Trial Registry (ChiCTR) from 2007 to 2014
Menghuan Song
University of Macao, Macao

**M 07** An Assessment of the Double Medicine Dossier Submission as a Tool to Strengthen Health Regulatory System
Valery Dias Sousa, MSc
University of Brasilia - Unb, Brazil

**M 08** Regulatory Affairs Mobile Applications: Barriers, Benefits and Implications for Patients
Kamilah Rashid, PharmD
Mercer University

**M 09** Novel Strategy to Find Drugs for Autosomal Dominant Polycystic Disease
Parama Paul, MS
Stowers Institute for Medical Research

**M 10** The Signaling Effects of Stacked FDA Designations
Kathleen Miller, MS, PhD
University of North Carolina at Chapel Hill

**M 11** Role of Purinergic P2X4Rs in Regulating Dopamine Dependent Signaling Cascades within Basal Ganglia Circuitry
Sheraz Khoja, MSc
University of Southern California

**M 12** Impact of Global Warming on Malaria and Dengue in Africa: Prevention and Control through Regulation
Efstathia Sergi
Northeastern University

**M 13** A Cost-Benefit Framework for Modeling Large-Scale Implementation of Counterfeit Medicine Technologies
Catherine Y. Liang
Cornell University

**M 14** Comparative Effectiveness of Coronary Artery Bypass Grafting and Percutaneous Coronary Intervention Among Medicare Patients
Ruchitbhai Mukesh Shah, MS
University of Mississippi

**M 15** Projecting Enrollment Across Multiple Studies in a Clinical Trials Consortium: A Forecasting Tool
Jeromie Ballreich
Johns Hopkins University

**M 16** Spontaneous Adverse Drug Reactions Reporting by Patients in Canada: A Multi-Method Study
Rania Dweik
University of Ottawa, Canada

**M 17** Applying Survival Analysis to Predict Staff Attrition
Haoqin Zhai, MS
University of North Carolina at Chapel Hill

**M 18** The P2X4 Receptor: A Potential Pharmaceutical Target for Cystic Fibrosis Patients
Kristin Elizabeth Thompson, PhD
INSERM–UMR S 938, France

**M 19** Development and Validation of a Discrete Event Simulation Model to Evaluate the Use of Electronic Cigarettes in the US
Kunal Saxena, MS
Virginia Commonwealth University

**M 20** Assisted Diagnosis of Anxiety Disorders with Standard Questionnaires in Primary Care: A Spanish Cost Evaluation
Elena Olariu, MPH, RPh
Parc De Recerca Biomedica De Barcelona, Spain
**T 05** Advancing Medical Information Services To Impact Patient Care: Collection Of Insights From Healthcare Practitioners  
*ORAL PRESENTATION SCHEDULED: Session 1A at 10:03–10:08 AM*  
Roshni Patel-Romero, PharmD  
Genentech, A Member of the Roche Group

**T 06** Impact of the Nonclinical Juvenile Animal Studies on Pediatric Medicines Information  
Dinah Duarte, PharmD, MSc  
INFSARMED, Portugal

**T 07** Steps on a Journey: Re-Use of Analysis Scripts and Standardized Tuberculosis Trial Data  
*ORAL PRESENTATION SCHEDULED: Session 1A at 10:10–10:15 AM*  
Xin (Joy) Li  
FDA

**T 08** Can Social Listening be Used to Augment Existing Data Sources for Monitoring the Safety of Consumer Health Care Products?  
*ORAL PRESENTATION SCHEDULED: Session 1A at 10:17–10:22 AM*  
James Blowers  
GlaxoSmithKline

**T 09** Regulatory Gaps — Industry’s Perspectives on Asia’s Regulatory Authorities  
James Leong, PhD, MPharm  
Centre of Regulatory Excellence, Duke-Nus Graduate Medical School, Singapore

**T 10** Pharmacovigilance Industry Benchmarking on Global Methodologies for Collecting and Processing Off-Label Use Reports  
*ORAL PRESENTATION SCHEDULED: Session 1A at 10:24–10:29 AM*  
Amanda Bowies  
Deloitte Consulting, LLP

**T 11** The Case for Electronic Data Capture of Abdominal Pain in Crohn’s Disease: A Comparison of Diary Methods  
Leighann Litcher-Kelly, PhD  
ERT

**T 12** Feasibility of Replacing the Thorough QT (TQT) Study with Intense ECG Data Collection in Early Clinical Studies  
*ORAL PRESENTATION SCHEDULED: Session 1B at 11:35–11:40 AM*  
Nancy Wang, PhD  
Celeron

**T 13** Assessing Bias in Administrative Database Studies of Vaccine Completion Due to Excluding Subjects with Incomplete Follow-up  
*ORAL PRESENTATION SCHEDULED: Session 1B at 11:42–11:47 AM*  
Scott Charles Quinlan, PhD  
HealthCore, Inc.

**T 14** Design and Development of an eCOA Specific Solution for Capturing Patient Data in Diabetes Clinical Trials  
*ORAL PRESENTATION SCHEDULED: Session 1B at 11:49–11:54 AM*  
Paul O’Donohoe  
CRF Health, United Kingdom

**T 15** Engage Patients with Innovative Global Digital Patient Platform  
*ORAL PRESENTATION SCHEDULED: Session 1B at 11:56 AM-12:01 PM*  
Helen Lee  
Bristol-Myers Squibb Company

**T 16** Utilizing Regional and National Student Recruitment Events to Maximize Awareness of Post-PharmD Opportunities in Industry  
Amy Monpara, PharmD  
MCPHS University

**T 18** The Impact of the Establishment of Integrated Medicinal Product Review Office (IMPRO) in Taiwan  
Yan-Feng Chen  
Center for Drug Evaluation (CDE), Taiwan

**T 19** Drug Lag and Approval Time Metrics - Are They Good Markers to Assess the Global Regulatory Environment?  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:03–12:08 PM*  
Magdalena Bujar, MSc  
Centre For Innovation In Regulatory Science (CIRS), United Kingdom

**T 20** Analyzing Global Recruitment Strategies to Improve Local Trial Enrollment—A Global Investigation Into “What Works Where” for Patient Recruitment and Retention Tools and Techniques  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:10–12:15 PM*  
Chris Frega, MBA  
Quintiles Inc.

**T 21** Improving Hepatic-Impairment Patient Recruitment with a University Hospital Center-CRO Partnership: A Benchmarking Analysis  
Rachida Essalihi, PhD  
Algorithme Pharma Inc., Canada

**T 22** Monitoring Interactive Response Technology Vendor Implemented Randomization and Dosing Systems  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:17–12:22 PM*  
Jason McCoy, MS  
Amgen Inc.

**T 23** Evolution of a Unique Blend of Business Process and Technology to Enhance Medical Affairs Capabilities  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:24–12:29 PM*  
Manish Dave, MBA, MS  
Merck & Co., Inc.

**T 24** Implementing CDISC Standards in an Early Phase CRO: Successes and Challenges  
Pascal Guibord  
Algorithme Pharma Inc., Canada

**T 25** A Pitfall in the Clinical Study Enrollment of Postmenopausal Females  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:31–12:36 PM*  
Eunhee Chung  
SOUSEIKAI Global Clinical Research Center, Japan

**T 26** Survey of IRB Review of Urgent Patient Specific Protocols  
Bambi Grilley, RPh, RAC  
Baylor College of Medicine

**T 27** Lack of Inter-Ethnic Difference in QT-Susceptibility to Moxifloxacin: Two Independent TQT Studies in Caucasian and Asian Populations  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:38–12:43 PM*  
Yaning Wang, PhD  
FDA

**T 28** Implementing Quality Risk Management and Risk-Based Monitoring: Practical Guidelines from Sponsors and Sites  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:45–12:50 PM*  
Amita Malik, MS  
Oracle Health Sciences

**T 29** Measurement Equivalence of the SF-36v2 on a Handheld Device and Smartphone App  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:52–12:57 PM*  
Susan M. Dallabrida, PhD  
PHT Corporation

**T 30** How to Maximize Data Quality in Retrospective Chart Review Studies  
*ORAL PRESENTATION SCHEDULED: Session 1B at 12:59–1:04 PM*  
Dara Stein, MSc  
UBC: An Express Scripts Company, Canada

**T 31** Benefit-Risk Assessments (BRAs) of an Established Product’s Portfolio  
*ORAL PRESENTATION SCHEDULED: Session 1B at 1:06–1:11 PM*  
Rosa Piccirillo, MD  
Quintiles Inc.

**T 33** Results of An Online Survey of Stakeholders Regarding Barriers and Solutions to Clinical Trial Recruitment  
*ORAL PRESENTATION SCHEDULED: Session 1B at 1:13–1:18 PM*  
Elizabeth Mahon, JD  
Janssen Research & Development, LLC
**Poster Program**

**W 08 Ex-US Sites in A Multinational Study: Should They Be Included**

*T 34 Process for Ensuring Clinical Trial Product Quality*

*ORAL PRESENTATION SCHEDULED: Session 1B at 1:20–1:25 PM*

Janie B. Russell, RAC
National Institutes of Health (NIH)

*T 35 Attractiveness of PRO Mixed Modes – What are Patients Saying?*

*ORAL PRESENTATION SCHEDULED: Session 1C at 2:35–2:40 PM*

Jennifer Ross, MD, MS
Almac Group

*T 36 Efficient and Innovative Clinical Trial Enrollment Using Online and Social Media*

*ORAL PRESENTATION SCHEDULED: Session 1C at 2:42–2:47 PM*

Mark Joing, MBA
Nora Therapeutics

*T 37 The Cost Effective Benefits of Behavioral Psychology on Improving Data Quality*

*ORAL PRESENTATION SCHEDULED: Session 1C at 2:49–2:54 PM*

Shawn Levin
Quintiles Transnational Corporation

**W 05 Monoclonal Antibodies and Juvenile Animal Studies as a Model for Testing Toxicity in Children**

Dinah Duarte, PharmD, MSc
INFARMED, Portugal

**W 06 Social Listening for Pharmacovigilance: How Does the Content and Level of Detail in Social Media Compare to Spontaneous Reports**

*ORAL PRESENTATION SCHEDULED: Session 2A at 9:35–9:40 AM*

Heidi G. Bell, MD, RPh
Zerococha On Behalf of GlaxoSmithKline

**W 07 Enhancing Pharmacokinetic Studies to Support Tier 2 Labeling Claims for Abuse Deterrent Opioids**

*ORAL PRESENTATION SCHEDULED: Session 2A at 9:49–9:54 AM*

Hiren R. Mehta, PhD
INC Research, Inc., Canada

**W 08 Ex-US Sites in A Multinational Study: Should They Be Included Under a US IND or Not?**

Jacqueline M. Kline, PhD
Eisai Inc.

**W 09 Using Portfolio Analysis to Maximize Innovation and Optimize R&D Strategic Planning**

*ORAL PRESENTATION SCHEDULED: Session 2A at 9:56–10:01 AM*

Jean Yuan, MD, PhD
National Institutes of Health (NIH)

**W 10 Transdermal Drug Innovation from 2000 to 2014: Current Status and Future Outlook**

*ORAL PRESENTATION SCHEDULED: Session 2A at 10:03–10:08 AM*

Jessica Ruth Walter, MD
Northwestern University ~ McGraw Medical Center

**W 11 Establishing Normal Ranges for ECG Intervals in a Normal Healthy Population**

*ORAL PRESENTATION SCHEDULED: Session 2A at 10:10–10:15 AM*

Joy Olbertz, PharmD, PhD, RPh
Celerion

**W 12 Failure Mode and Effects Analysis (FMEA): A Systematic and Defensible Approach to Risk Mitigation For A New Drug Regimen**

*ORAL PRESENTATION SCHEDULED: Session 2A at 10:17–10:22 AM*

Anthony Gbadebo Oladipo
AbbVie

**W 13 Compliant Presentation of Important Safety Information In A More Educational Format In Promotional Educational Programs**

*ORAL PRESENTATION SCHEDULED: Session 2B at 11:35–11:40 AM*

Michael Varlotta
AbbVie

**W 14 Simultaneous Marketing Authorization Applications: Pharma Urban Legend or Reality?**

*ORAL PRESENTATION SCHEDULED: Session 2B at 11:49–11:54 AM*

Stacie O’Sullivan
Eisai Inc.

**W 15 Strategic Considerations for Developing an Initial Pediatric Study Plan for a Proposed Biosimilar**

*ORAL PRESENTATION SCHEDULED: Session 2B at 11:55–12:00 PM*

Renee Martin, PhD
PAREXEL International

**W 16 A Determination of the Relative Risk of Hepatotoxicity Among Anti-Epileptic Drugs in the FDA Adverse Event Reporting System**

*ORAL PRESENTATION SCHEDULED: Session 2B at 11:49–11:54 AM*

Roshawn Watson, PharmD, PhD, RPh
Synchrogenix, A Certara Company

**W 17 Pharmacovigilance Process Innovation: Approach to Pharmacovigilance (PV) Process Enhancements in a Large Global Biotechnology Company**

*ORAL PRESENTATION SCHEDULED: Session 2B at 11:55 AM–12:01 PM*

Sadiqa Hafeez Mian, MD, MPH
Amarin Inc.

**W 18 Incidence of Outcomes Relevant to Vaccine Safety Monitoring in a Large Commercially Insured Population**

*ORAL PRESENTATION SCHEDULED: Session 2B at 12:03–12:08 PM*

Daina B. Esposito
HealthCore, Inc.
**W 19** Global Utilization of Breast Cancer Treatment Guidelines: A Survey of International Physicians’ Practices  
*ORAL PRESENTATION SCHEDULED: Session 2B at 12:10–12:15 pm*  
Sukhleen (Sheena) Gurai, PharmD, MEH  
Genentech, A Member of the Roche Group

**W 20** Precision Medicine Basket Trial Eligibility Across Race/Ethnicity: Implications for Ethnobotanical and Clinical Application  
*ORAL PRESENTATION SCHEDULED: Session 2B at 12:17–12:22 pm*  
Todd Knepper, PharmD  
H. Lee Moffitt Cancer Center

**W 21** PMDA’s Relief Services for Drugs’ Adverse Health Effects  
*ORAL PRESENTATION SCHEDULED: Session 2B at 12:24–12:29 pm*  
Toshiyoshi Tominaga, PhD  
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

**W 22** Propensity Score Weighting and Stratification When the Relationship Between Treatment and Propensity Scores is Non-linear  
William G. Hawkes, PhD  
Quintiles Transnational Corporation

**W 23** Recent FDA GLP (Good Laboratory Practice) Inspections Conducted in China  
*ORAL PRESENTATION SCHEDULED: Session 2B at 12:31–12:36 pm*  
Zhou Chen  
FDA

**W 24** Current Drug Master File Status in Taiwan  
Shun-Lan Hsieh  
Center for Drug Evaluation (CDE), Taiwan

**W 25** Ignoring Global Feasibility and Site Networks for Your Rare Disease Study? You May Want to Re-consider  
*ORAL PRESENTATION SCHEDULED: Session 2B at 12:38–12:43 pm*  
Earl Seltzer, MBA  
Quintiles Inc.

**W 26** Exploring Phenome-wide Association Study (PheWAS) as an Option to Address Key Challenges of Pharmaceutical Industry  
*ORAL PRESENTATION SCHEDULED: Session 2B at 12:45–12:50 pm*  
Priyank Chopra, MBA, MPharm  
CitiusTech

**W 27** Japan PMDA Inspections from a CDM/EDC Perspective  
*ORAL PRESENTATION SCHEDULED: Session 2B at 12:52–12:57 pm*  
Ryan Michael Lariviere  
Gilead Sciences, Inc.

**W 28** Application of Structural Equation Modeling (SEM) in Asthma to Evaluate Small Airways Disease  
Thomas Zwingers, DrSc  
CROS NT, Germany

**W 29** Factoring in Ethnicity, Gender, and Age in Specific Clinical Studies  
*ORAL PRESENTATION SCHEDULED: Session 2B at 12:59–1:04 pm*  
Andrew Melli  
SOUSEIKAI Global Clinical Research Center, Japan

**W 30** Clinical Monitoring Liaison, a New Oversight Role as a Practical Approach to Sponsor Involvement in Ousourced Trials  
*ORAL PRESENTATION SCHEDULED: Session 2B at 1:06–1:11 pm*  
Annelies Legters, MS  
Forum Pharmaceuticals International B.V., Netherlands

**W 31** Adaptive Clinical Trial Design in Head-to-Head Comparison of Two DPP-4 Inhibitors  
*ORAL PRESENTATION SCHEDULED: Session 2B at 1:13–1:18 pm*  
Natalia Vostokova, PharmD  
IPHARMA LLC, Russian Federation

**W 32** New Approaches to Assessing Medical Publication Impact in Social Media: Altmetric, PlumAnalytics, and Augmented Reality  
Catherine Skobe, MPH  
Pfizer Inc

**W 33** Lessons Learned for Meeting Safety Reporting Requirements in Retrospective Chart Review Studies  
*ORAL PRESENTATION SCHEDULED: Session 2B at 1:20–1:25 pm*  
Catherine Sigler, DVM, PhD, MPH  
UBC: An Express Scripts Company

**W 34** From Concept to Reality: Developing an Operational Study Planning and Forecasting System  
*ORAL PRESENTATION SCHEDULED: Session 2C at 2:35–2:40 pm*  
DeAnn S. Hyder  
Quintiles Inc.

**W 35** Risk of Acute Renal Failure with Vildagliptin/Metformin Combination Use in Patients with Type 2 Diabetes  
Hong-Ah Kim, MPharm  
Korea Institute of Drug Safety and Risk Management (KIDS), Republic of Korea

**W 36** Development of an Electronic Diary with Spirometer Integration to Capture Patient Data in Asthma Clinical Trials  
*ORAL PRESENTATION SCHEDULED: Session 2C at 2:42–2:47 pm*  
Nora Ibrahimova  
CRF Health, United Kingdom

**W 37** Use R for ESUB Module 5  
*ORAL PRESENTATION SCHEDULED: Session 2C at 2:49–2:54 pm*  
Jingyuan Chen, MSc  
Hoffmann-La Roche Inc., Canada

**W 38** eRecruitment - Multi-country, Multi-language Direct to Patient for Clinical Trials  
Lani Hashimoto  
Novartis Pharmaceuticals Corporation

**W 39** Recruitment and Screening for a Multi-Site Sleep Clinical Trial: Rolling Wave Planning Leading to Study Success  
Marianne Rufiange  
Algorithme Pharma Inc., Canada

**W 40** Exploration of Protocol Complexity Factors and Impact on Protocol Variance Rates in a Subset of Clinical Trials  
*ORAL PRESENTATION SCHEDULED: Session 2C at 2:56–3:01 pm*  
Paige Ellison  
Seattle Genetics, Inc.

**W 41** Fifteen Years of Controlled Production and Consistency of Quality Attributes for a Glycosylated Monoclonal Antibody Therapy  
*ORAL PRESENTATION SCHEDULED: Session 2C at 3:03–3:08 pm*  
Amy R. Varga  
AbbVie

**W 42** Fibromyalgia Clinical Trial Analysis from 2004 to 2014  
Elan Lutinger, PharmD  
St. Johns University

**W 43** Overview of the Health Canada Updated Clinical Trial Application Regulations on Review Process and Timelines  
Julie Massicotte  
Algorithme Pharma Inc., Canada
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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.

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  Baron Peter Piot, MD, PhD, FRCP, FMedSci

- **Excellence in Service**
  Justina A. Molzon, JD, MSc
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  Alberto Grignolo, PhD
  Corporate Vice President, PAREXEL International

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*Therapeutic Innovation & Regulatory Science (TIRS)*, DIA’s official peer-reviewed scientific journal, identifies an article each year that has made a significant impact in advancing medical product development and recognizes the authors of that article as leaders in their field with the DIA Author(s) of the Year Award. This article and its authors are chosen based on two criteria: the total number of web accesses for the article on the journal website and the total number of full-text downloads the article has had during the past year.


- Ramil Abdrachitov, MD, PhD, MBA: AstraZeneca, Site Management and Monitoring, Clinical Operations, Global Medicines Development
- Stephanie Clark, MA: Research Officer/Board Member, ADHD-Europe, Belgium
- Sarah Jane Constantine, MS: Senior Manager, Clinical Trial Oversight and Compliance, Cubist Pharmaceuticals
- Karolien de Roeck, MS: Clinical Director, Abbvie, Belgium
- Jacqueline Gough, MMath: Central Monitoring, Clinical Development Innovation, Eli Lilly and Company
- David Knepper, MS, MBA: Quality Management Systems & Training, Forest Research Institute Inc.
- Andy Lawton, ASTAT: Global Head, Clinical Data Management, Boehringer Ingelheim Ltd
- Tom Provencher, BS: Senior Director, Clinical Trial Support and Compliance, Pfizer Inc.
- Brett Wilson, BSP: Associate Director, Bristol-Myers Squibb Company, Canada

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The Clinical Trials Transformation Initiative (CTTI)—cofounded by Duke University and the U.S. Food and Drug Administration (FDA), and hosted by Duke—identifies and promotes practices that will increase the quality and efficiency of clinical trials. All stakeholders in the clinical trials enterprise are engaged as equal partners to find solutions that are effective and likely to be adopted. CTTI executes its mission through the conduct of projects that generate empirical data on how aspects of clinical trials are currently conducted, including impediments to beneficial change, and lead to consensus-driven, evidence-based recommendations for improving trials. Once recommendations are issued, CTTI works to facilitate their adoption by broadly disseminating the results of its projects, developing models for others to follow, and creating tools and resources to make implementation easier. More information about CTTI and its projects is available at http://www.ctti-clinicaltrials.org www.ctti-clinicaltrials.org.

- **Excellence in Service**
  Kristin M. Neff, MS
  Vice President of Clinical Operations & Project Management, InVivo Therapeutics

- **Excellence in Service**
  Robert Paarlberg, MS
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- **Leader of Tomorrow**
  Brittany Mani
  Doctor of Pharmacy Candidate, Howard University College of Pharmacy
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in pediatrics as over 75% of
neonates products are off label.
PIPs & PSPs will be discussed,
which are PLANS to study kids; the
entire topic is about off-label use.
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<td>Alexander Fleming</td>
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<td>CONSULTANT-DrugDev, TrialReach, OTHER SUPPORT-Former Employee of Eli Lilly and Company</td>
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<td>Douglas Robinson</td>
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<td>biomarkers for hedgehog inhibitor therapy WO 2012166241 A1; biomarkers for iap inhibitor therapy WO 2013166344 A1; markers associated with mtor inhibition WO 20141844; STOCK SHAREHOLDER-Novartis Pharmaceuticals</td>
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Specific disclosures include:
- **Khyati Roberts**: STOCK SHAREHOLDER-Abbott, AbbVie.
- **Frank Rockhold**: STOCK SHAREHOLDER-GlaxoSmithKline.
- **Tracy Rockney**: STOCK SHAREHOLDER-AbbVie.
- **Michelle Rohrer**: STOCK SHAREHOLDER-Roche.
- **Matthew Rotelli**: OTHER SUPPORT-Employee of Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company.
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- **Valerie Simmons**: OTHER SUPPORT-Employee of Eli Lilly and Company, STOCK SHAREHOLDER-Eli Lilly and Company, GlaxoSmithKline.
- **Sian Slade**: OTHER SUPPORT-Employee of Bristol-Myers Squibb.
## Disclosure Statements

### Disclosure Statements (as of May 5, 2015), continued

<table>
<thead>
<tr>
<th>Name</th>
<th>Disclosure</th>
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<tr>
<td>Stephen Smith</td>
<td>OTHER SUPPORT-Employee of Medidata Solutions, Inc., STOCK SHAREHOLDER-Medidata Solutions, Inc.; Unlabeled/Unapproved discussion: This is a discussion of a clinical trial involving at least four unapproved drugs. It is not the intention to describe the drugs in detail, or to highlight benefits of one drug over another. The focus of this presentation is modern clinical trial design and governance.</td>
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<td>OTHER SUPPORT-Employee of EMD Serono Inc.</td>
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## 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:

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### TUESDAY, JUNE 16

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4C Pharma Solutions LLC
Contact: Shivakrishna Kovi
Email: info@4cpharma.com
Website: www.4cpharma.com
4C Pharma Solutions is an end-to-end pharmacovigilance service provider run by physicians with excellent domain expertise ranging from grass-root to managing operations at various manufacturers and CROs. With our deep understanding of operational challenges from personal experience, we render the most optimal results. 4C has prevalidated Oracle Argus to process and submit Adverse Events data that saves clients from IT maintenance enabling them to spend precious time in core pharma activities.

Accell Clinical Research
Contact: Svetlana Kazanskaya
Email: svetlana.kazanskaya@acellclinical.com
Website: www.acellclinical.com
A full-service CRO specializing in Phase I-IV clinical trials in Russia & Eastern Europe. Our leading indications are oncology, cardiovascular diseases, endocrinology, CNS diseases and infectious diseases. We provide fast patient recruitment, deliver high-quality data, and offer service package & project model adjusted exactly to your needs.

Accenture
Contact: Ellen Semple
Email: ellen.a.semple@accenture.com
Website: www.accenture.com/lifesciences
Accenture’s Life Sciences practice is dedicated to helping companies rethink and reshape their businesses to deliver better patient outcomes. We provide end-to-end business services as well as individual strategy, digital, technology and operations projects in all strategic and functional areas including R&D. Accenture’s Life Sciences group connects >10,000 skilled professionals in >50 countries who are committed to helping clients achieve their business goals and deliver better health outcomes.

Accovion GmbH
Contact: Sonja Riebel
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.

ACM Global Central Laboratory
Contact: Mark Engelhart
Email: mengelhart@acmlab.com
Website: www.acmgloballab.com
ACM Global Central Laboratory specializes in delivering high quality central laboratory testing services designed to optimize clinical trial outcomes. Through a powerful combination of robust global capabilities, operational and scientific expertise and unsurpassed service, ACM Global acts as an extension of our clients’ clinical teams to develop and execute Smarter Testing strategies that deliver reliable outcomes for their clinical development programs.

ACRP
Contact: Jenna Rouse
Email: jenna@acrpnet.org
Website: www.acrpnet.org
ACRP supports ethical and responsible clinical research through three cornerstone programs-professional development, certification and membership. All of these programs are now available to organizations to meet employee development goals, increase awareness of your support of essential standards for clinical research, and reach new audiences to increase visibility and brand awareness. Let our 40 years of expertise help your organization reduce risk and increase efficiency and effectiveness.

Acurian, Inc.
Contact: Kirk McPoyle
Email: kirk.mcpoyle@acurian.com
Website: www.acurian.com
Acurian, a subsidiary of PPD, is a leading full-service provider of clinical trial patient enrollment and retention solutions for the life sciences industry. The company increases the enrollment performance of investigator sites worldwide by identifying, contacting, prescreening and referring people who live in the local community but are unknown to a research site. As a result, trial sponsors complete enrollment without incurring the unexpected expense of adding sites or time.

ADAMAS Consulting LLC
Contact: Kristin Kelley
Email: kkelley@advancedclinical.com
Website: www.advancedclinical.com
Advanced Clinical provides full service, global CRO services, patient recruitment and retention services, and strategic resourcing solutions including FSP and staffing strategies to the pharmaceutical, biopharmaceutical, biotechnology and medical device industries. Through a value-based approach, we combine experience with proven tools and methodologies to deliver advanced solutions to our clients that meets or exceeds timeline and budget expectations.

Aerotek
Contact: Kristen Caswell
Email: Kcaswell@aerotek.com
Website: www.aerotek.com
Aerotek is the #1 U.S. provider of clinical and scientific staffing and provides the highest level of service through our customized recruiting solutions. By understanding your industry, our specialized recruiters are aware of hiring trends and know how to identify the necessary skills for each position.
AlCure

Contact: Adam Hanina
Website: aicure.com

Alfresco Software, Inc.

Contact: Melissa Meintert
Email: melissa.meintert@alfresco.com
Website: www.alfresco.com

Alfresco provides modern software built on open standards that unlocks the power of business-critical content. With control that IT demands and simplicity that end users love, Alfresco’s open source technology enables global organizations to collaborate more effectively across cloud, mobile, hybrid and on-premise environments.

Almac

Contact: Monica Holt
Email: monica.holt@almacgroup.com
Website: www.almacgroup.com

As a global leader in the management of clinical trial supplies and IXRS® technology, Almac offers an integrated supply chain management solution that helps pharmaceutical and biotech companies speed the process of getting new drugs to market by increasing productivity in the management of sites, patients, and clinical supplies.

Ancillare, LP

Contact: Mike Brown
Email: michael.brown@ancillare.com
Website: www.ancillare.com

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APCER Pharma Solutions, Inc.

Contact: Jill Notte
Email: jill.notte@apcерpharma.com
Website: www.apcерpharma.com

APCER Pharma is a truly global provider of medical, safety, and regulatory services. An international team of healthcare professionals, medical communicators, and data specialists respond to prescribers, patients, payers, and regulators on behalf of life sciences companies of all sizes. APCER offers local knowledge and global compliance.

Artcraft Health

Contact: Brian Schaechter
Email: bschaechter@artcrafthealth.com
Website: www.artcrafthealth.com

Artcraft Health focuses on the key elements of education, awareness, and creativity to facilitate the successful completion of clinical trials. Our solutions have been proven in hundreds of trials to reduce costs and increase recruitment and compliance, while aiding communication, consent, and retention. Our trademarked CARE™ principles underscore all of our work, ensuring that our custom tactics are Clear, Actionable, Relevant, and engaging without compromising quality. www.artcrafthealth.com

Asia CRO Alliance

Contact: Ali Burhani
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.
BBK Worldwide

Contact: Joan F. Bachenheimer and Bonnie A. Brescia
Email: info@bbkworldwide.com
Website: www.bbkworldwide.com

BBK Worldwide is the global leader in patient recruitment for the clinical trial industry. BBK’s latest innovation is the introduction of adaptive recruitment – a new specialty in clinical trial marketing proven to protect global enrollment integrity, specifically within a changing or threatened landscape. BBK is a privately held, women owned business, headquartered in Needham, Mass.

August Research

Contact: Dana Niedzielska
Email: dniedzielska@augustresearch.com
Website: www.augustresearch.com

August Research is an American-owned 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 14 years of clinical trials experience in the region, the August Research team combines deep local expertise, American-style customer service and reasonable pricing to optimize our clients’ clinical trials.

Axiom Real-Time Metrics Inc.

Contact: Andrew Schachter
Email: solutions@axiommetrics.com
Website: www.axiommetrics.com

Primary Focus: Small to Medium Biotech, Device and Pharma — Axiom delivers easy-to-use, powerful and cost-effective eClinical / EDC / Data Management solutions and services focused around your study needs and with cost effective pricing. We deliver a broad range of powerful and intuitive enterprise functionality / Modules delivered for small to medium organizations. Key features include EDC, DM, IWRS, CTMS, AE/SAE Tracking, Safety Database and 24/7 project and clinical data reporting.

BARC Global Central Laboratory

Contact: Ann De Smet
Email: ann.desmet@barclab.com
Website: www.barclab.com

BARC Global Central Laboratory was founded over 25 years ago with the mission to provide services that meet the highest quality of standards, at highly competitive prices. With laboratories in the Americas, Europe, South Africa, Australia, China, Japan, and Singapore, BARC’s global reach can meet all phase I-IV study needs from routine to esoteric testing. We pride ourselves in the development of strong sponsor relationships by offering consistency, accuracy, and exceptional project management.

Barrington James

Contact: Pippa Wilson
Email: pwilson@barringtonjames.com
Website: www.barringtonjames.com

Barrington James: Global Pharmaceutical Specialist Recruitment. With offices worldwide we have built an extensive network across all functional areas whilst delivering quality results to our clients. With dedicated consultants in each functional area, we ensure a thorough, professional approach. Our services include permanent/contract placement for contingency and retained searches.

BioPharm Insight

Contact: Mike Reynolds
Email: mreynolds@infinata.com
Website: www.biopharminsight.com

BioPharm Insight is your definitive guide to the global biopharma community, combining an online business intelligence system of comprehensive market analytics and key industry contacts with an independent investigative journalism news service. As part of the Financial Times Group, BioPharm Insight is also an acclaimed independent journalist team with a proven track record of breaking forward-looking and competitive business intelligence 6-12 months ahead of mainstream press.

Biomedsys

Contact: Kristy Galkowski
Email: kgalkowski@biomedsys.com
Website: www.biomedsys.com

Celebrating our 40th anniversary, Biomedical Systems is a premier global provider of centralized diagnostic services to pharmaceutical, medical device, biotech, and contract research organizations in support of sponsors’ regulatory requirements to meet their primary and secondary clinical trial endpoints. Our comprehensive clinical trial solutions include cardiac safety, pulmonary function, imaging, electronic clinical outcome assessment and scientific affairs. Our corporate headquarters is located in St. Louis, Missouri. Our European headquarters is located in Brussels, Belgium, with supporting offices in Japan and India.

Beijing Clinical Service Center

Contact: Alex Liu
Email: liuzhong@clinicalservice.cn
Website: www.clinicalservice.cn

Beijing Clinical Service Center, an outstanding expertise in the area of medicinal clinical research. Beijing Clinical Service Center is a full service provider of medicinal science and technology providing clinical researches, regulatory registration, medical writing, biometrics and data management, quality assurance, training and consultation services.

Benchmark Research

Contact: Richie Kahn
Email: richardkahn@benchmarkresearch.net
Website: www.benchmarkresearch.net

Benchmark Research is a fully integrated network of research sites with broad therapeutic experience and geographic reach. Standardized recruitment, retention, quality, training and site operations combined with Benchmark’s “One Voice” communication model offer unmatched financial efficiencies. Contact us today about making Benchmark Research sites the cornerstone of your next program.

BioClinica

Contact: Stephen Boccardo
Email: sales@bioclinica.com
Website: www.bioclinica.com

BioClinica is a leading global provider of specialized clinical trial services, including cloud-based eClinical technologies, medical imaging analysis, and cardiovascular safety. Our therapeutically-aligned medical and scientific experts, together with our innovative technologies, provide sponsors with high-quality data in support of regulatory approvals. BioClinica has supported the development of 80+ new medicines through all clinical trial phases in over 4000 successful trials since 1985.

Biomedical Systems

Contact: Kristy Galkowski
Email: kgalkowski@biomedsys.com
Website: www.biomedsys.com

Celebrating our 40th anniversary, Biomedical Systems is a premier global provider of centralized diagnostic services to pharmaceutical, medical device, biotech, and contract research organizations in support of sponsors’ regulatory requirements to meet their primary and secondary clinical trial endpoints. Our comprehensive clinical trial solutions include cardiac safety, pulmonary function, imaging, electronic clinical outcome assessment and scientific affairs. Our corporate headquarters is located in St. Louis, Missouri. Our European headquarters is located in Brussels, Belgium, with supporting offices in Japan and India.

August Research, headquartered in Needham, Mass.

A changing or threatened landscape. BBK is a privately held, women owned marketing proven to protect global enrollment integrity, specifically within introduction of adaptive recruitment – a new specialty in clinical trial recruitment for the clinical trial industry. BBK’s latest innovation is the

Website: www.bbkworldwide.com
Email: info@bbkworldwide.com

Bonnie A. Brescia Phone: 617-630-4477

Contacts: Joan F. Bachenheimer and
Bonnie A. Brescia
Email: info@bbkworldwide.com
Website: www.bbkworldwide.com

With more than three decades of experience across a wide variety of therapies and medicines, BBK Worldwide is the global leader in patient recruitment for the clinical trial industry. BBK’s latest innovation is the introduction of adaptive recruitment – a new specialty in clinical trial marketing proven to protect global enrollment integrity, specifically within a changing or threatened landscape. BBK is a privately held, women owned business, headquartered in Needham, Mass.

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BBK Worldwide

Contact: Joan F. Bachenheimer and Bonnie A. Brescia
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Website: www.bbbkworldwide.com

With more than three decades of experience across a wide variety of therapies and medicines, BBK Worldwide is the global leader in patient recruitment for the clinical trial industry. BBK’s latest innovation is the introduction of adaptive recruitment – a new specialty in clinical trial marketing proven to protect global enrollment integrity, specifically within a changing or threatened landscape. BBK is a privately held, women owned business, headquartered in Needham, Mass.
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<tr>
<th>BioPharma Investigator</th>
<th>Booth: 1011</th>
<th>Phone: 224-372-4100</th>
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<tr>
<td>Contact: Ana Rodríguez-Guterman</td>
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<tr>
<td>Email: <a href="mailto:gutermannana@biopharmainvestigator.com">gutermannana@biopharmainvestigator.com</a></td>
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<tr>
<td>Website: <a href="http://www.biopharmainvestigator.com">www.biopharmainvestigator.com</a></td>
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Finding productive sites is key to successful enrollment. We at BioPharma Investigator take a focused and personalized view of matching Investigators to Sponsors based on multiple criteria, including research history, medical specialty, experience, research interests, and qualifications. With more than 250,000 profiles, BioPharma Investigator can find Investigators for your studies.

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<tr>
<th>BioPoint, Inc</th>
<th>Booth: 2713</th>
<th>Phone: 781-218-3790</th>
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<td>Contact: Kevin Pike</td>
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<td>Email: <a href="mailto:info@biopointinc.com">info@biopointinc.com</a></td>
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<td>Website: <a href="http://www.biopointinc.com">www.biopointinc.com</a></td>
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BioPoint provides a flexible client driven consulting and staff augmentation engagement model to our clients in the Pharmaceutical, Biotechnology and Medical Device Industries. Our focus spans Clinical and Postmarketed Drug Safety & Pharmacovigilance, Regulatory Affairs, Quality Assurance and Health Economics & Outcomes Research.

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<tr>
<th>Biorasi</th>
<th>Booth: 524</th>
<th>Phone: 786-888-0700</th>
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<tbody>
<tr>
<td>Contact: Karen Bertoli</td>
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<tr>
<td>Email: <a href="mailto:kbertoli@biorasi.com">kbertoli@biorasi.com</a></td>
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<td>Website: <a href="http://www.biorasi.com">www.biorasi.com</a></td>
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Biorasi is an award-winning global CRO located in Miami, FL. The company conducted the first ever Biosimilar studies in the United States. Trial optimization is engrained in TALOS™, the most robust and innovative operating platform in the industry.

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<th>bioskin GmbH</th>
<th>Booth: 1220</th>
<th>Phone: 49-406-068-970</th>
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<tr>
<td>Contact: Betsy Hughes-Formella, PhD</td>
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<td>Email: <a href="mailto:info@bioskinCRO.com">info@bioskinCRO.com</a></td>
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<td>Website: <a href="http://www.bioskinCRO.com">www.bioskinCRO.com</a></td>
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bioskin® is a full-service CRO specialized in dermatological product development. With offices in Germany and the US, bioskin® offers strategic consulting and regulatory support for global programs and all core services for conduct and management of clinical trials (Phase I-IV, medical devices).

<table>
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<tr>
<th>BIOVIA</th>
<th>Booth: 2321</th>
<th>Phone: 973-805-8600</th>
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<tr>
<td>Contact: Warren Perry</td>
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<tr>
<td>Email: <a href="mailto:info@qumas.com">info@qumas.com</a></td>
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<td>Website: <a href="http://www.qumas.com">www.qumas.com</a></td>
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QUMAS, now part of BIOVIA from Dassault Systèmes, is the leader in Compliance and Quality Management Solutions for the Life Sciences industry, with more than 270 global customer deployments and domain expertise in regulatory compliance since 1994. BIOVIA QUMAS provides software solutions for Electronic Document Management (SOPs, QA Docs.), Electronic Process Management (CAPA, Deviation, Change Control, Audit), eCTD & Submission Management.

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<tr>
<th>Blinded Diagnostics</th>
<th>Booth: 2735</th>
<th>Phone: 201-291-2822</th>
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<tr>
<td>Contact: Paul Savuto</td>
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<tr>
<td>Email: <a href="mailto:paul.savuto@blindeddiagnostics.com">paul.savuto@blindeddiagnostics.com</a></td>
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<tr>
<td>Website: <a href="http://www.blindeddiagnostics.com">www.blindeddiagnostics.com</a></td>
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Blinded Diagnostics is a contract service organization providing same day lab test results for global clinical trials. We offer over 100 test analytes on accurate and proven point of care diagnostics systems. To see the test menu visit www.pointofcaresearch.com or for more information on our services go to www.blindeddiagnostics.com

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<tr>
<th>Bracket</th>
<th>Booth: 711</th>
<th>Phone: 415-963-1773</th>
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<tr>
<td>Contact: Stephane Deleger</td>
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<tr>
<td>Email: <a href="mailto:info@bracketglobal.com">info@bracketglobal.com</a></td>
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<td>Website: <a href="http://www.bracketglobal.com">www.bracketglobal.com</a></td>
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Bracket is a specialty services provider dedicated to helping pharmaceutical sponsors and contract research organizations achieve greater certainty and accurate outcomes in their clinical trials by seamlessly leveraging science, technology and operational excellence. Solutions and Support include: -Bracket RTSM™ -IVRS/IWRS -ePRO (via smartphone, web, phone) -Rater Training & Certification -Scale Management -CDR System™ -Concordant Rater Station -In-Study Ratings Reliability -Endpoint Administration

<table>
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<tr>
<th>CAC EXICARE Corporation</th>
<th>Booth: 1057</th>
<th>Phone: 81-366-678-060</th>
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<tr>
<td>Contact: Kazutoshi Izawa</td>
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<tr>
<td>Email: <a href="mailto:pharma-bto@cac.co.jp">pharma-bto@cac.co.jp</a></td>
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<tr>
<td>Website: <a href="http://www.exicare.com/en/index.html">www.exicare.com/en/index.html</a></td>
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CAC EXICARE, IT and business partner that supports drug development and contributes to creation of a society where people enjoy their healthy and happy lives. CAC EXICARE is also an IT system integrator with rich experience and knowledge related to the pharmaceutical R&D, as well as being a CRO which can provide contract services from clinical development to post-marketing surveillance.

<table>
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<tr>
<th>CAHG</th>
<th>Booth: 1142</th>
<th>Phone: 312-297-6747</th>
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<tr>
<td>Contact: Don Sickler</td>
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<td>Email: <a href="mailto:clinicaltrials@cahg.com">clinicaltrials@cahg.com</a></td>
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<td>Website: <a href="http://www.cahgttrials.com">www.cahgttrials.com</a></td>
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CAHG is a full-service patient recruitment organization, with a unique emphasis on patient insight and evidence-based strategic thinking. We provide clinical trial enrollment support services as well as specialized clinical trial consulting.

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<tr>
<th>Camargo Pharmaceutical Services</th>
<th>Booth: 1927</th>
<th>Phone: 402-829-9009</th>
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<tr>
<td>Contact: Dee Fuehrer</td>
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<td>Email: <a href="mailto:dee@scorrmarketing.com">dee@scorrmarketing.com</a></td>
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<td>Website: <a href="http://www.camargopharma.com">www.camargopharma.com</a></td>
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Camargo Pharmaceutical Services is the most experienced global strategist providing comprehensive drug development services specialized for the 505(b)(2) approval pathway and global equivalent processes. By assessing the scientific, medical, regulatory and commercial viability of product development opportunities, Camargo systematically builds and executes robust development plans every step of the way.

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<tr>
<th>Cambridge Healthtech Institute</th>
<th>Booth: 639</th>
<th>Phone: 781-972-5400</th>
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<tbody>
<tr>
<td>Contact: Bethany Gray</td>
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<tr>
<td>Email: <a href="mailto:chi@healthtech.com">chi@healthtech.com</a></td>
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<td>Website: <a href="http://www.CHICorporate.com">www.CHICorporate.com</a></td>
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CHI is the preeminent life science network for leading researchers and business experts from top pharmaceutical, biotech and academic organizations. CHI’s portfolio of products includes Cambridge Healthtech Institute Conferences, Insight Pharma Reports, Cambridge Marketing Consultants, Barnett Educational Services, Cambridge Meeting Planners and CHI’s Media Group, which includes news websites and e-newsletters including Bio-iT World and Clinical Informatics News.
Cambridge Semantics Incorporated  
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Cancer Insight  
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Canfield Scientific, Inc.  
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Cenduit, LLC  
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Website: www.cenduit.com  
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Phone: 919-998-3372

Canfield Scientific, Inc. is the global leader in photography services and products for clinical research and healthcare applications, including the pharmaceutical, biotechnology, cosmetics, medical, and skin care industries. Driven by a quality-focused mission to provide best-in-class imaging solutions and services, Canfield has achieved an industry-wide reputation for excellence and innovation throughout its product lines, industry services and customer support.

Cardinal Health focuses on SPECT, PET, CT and MR.

Cardiogene provides expertise to empower sponsors for success with a completely personalized solution for you.

Tailored solutions from a global leader. With more than 25 years of clinical trial supply experience, we have the resources and expertise to deliver cost effective and time sensitive solutions around the world. Whether you are seeking standalone support or a comprehensive package, we have the right solution for you.

CDISC is a 501(c)(3) global non-profit charitable organization, with over 350 member organizations across the clinical research and healthcare arenas. Through the efforts of volunteers around the globe, CDISC catalyzes productive collaboration to develop freely available, industry-wide clinical research data standards. The CDISC Vision is to inform patient care and safety through higher quality medical research.

Celerion leverages over 40 years’ experience, 600 clinic beds (including 24 in-hospital), and facilities located in NA, EU and Asia, to conduct and analyze First-in-Human, clinical Proof-of-Concept, Cardiovascular Safety Services, ADME and NDA-enabling clinical pharmacology studies. Celerion provides expertise on clinical data analysis as well as small and large molecule bioanalytical assay services. Regulatory, drug development and program management complement Celerion’s service offerings.

As a BioTelemetry company, Cardiogene is part of the world’s largest cardiac analytics infrastructure. We analyze 1 billion heart beats a day. We support 10,000 sites and track nearly 20,000 patients monthly. And we employ nearly 1,000 experienced professionals offering superior global cardiac testing services and expert consulting.

Cardiovascular Imaging Technologies is recognized world-wide for performing and providing support for quality cardiovascular imaging clinical and research objectives, and providing expertise, products, and support for industry and end-users of cardiovascular imaging technologies with primary focuses on SPECT, PET, CT and MR.

Nonprofit foundation that provides the highest quality research and education through our three service lines: the CRF Skirball Center for Innovation, the CRF Clinical Trials Center, and the CRF Center for Education. CRF is involved in every step of the research continuum, from initial device conception to physician training. We offer scientific leadership and expertise from pre-clinical design > FIM and global studies > physician education.
Chesapeake IRB
Contact: Ruth Boulter
Email: info@irbinfo.com
Website: www.chesapeakeirb.com

Chesapeake IRB companies have been providing central independent IRB services, throughout the US and Canada since 1993. Chesapeake IRB, AAHRPP accredited since 2004, has a history of creating innovative and adaptive solutions including our 21 CFR Part II compliant, electronic IRB management platform (CIRBI) which streamlines protocol submissions, decreases investigator review turnaround times and results in faster subject enrollment.

Chexx Inc.
Contact: Simon Venhuizen
Email: info@chexxinc.com
Website: www.chexxinc.com

Chexx Inc. offers a better way to send stipend payments to clinical trial patients around the world. We issue local currency incentive payments to trial participants in over 70 countries. Chexx Inc. checks, bank transfers and prepaid cards are easy to order, quickly delivered, and appreciated by beneficiaries everywhere.

Chiba University Hospital
Contact: Takatoshi Sato
Email: satotakatoshi@gmail.com
Website: www.chiba-crc.jp/

Chiba University Hospital is eager to carry out clinical research with new medication/treatment/etc. Projects on going are nationwide and global studies. ARO of Chiba University Hospital has many Medical Doctors, Project Managers, CRAs, Data Managers, Biostatisticians, CRCs, Pharmacists with more than 100 staff.

Chiltern International, Inc.
Contact: Spencer Jane Brunson
Email: spencer.brunson@chiltern.com
Website: www.chiltern.com

Chiltern is a leading global CRO that listens to client needs in order to customize solutions for the Biopharma industry. With 33 years in service, Chiltern’s 2,200 engaged professionals work across 45 countries to deliver flexible, responsive solutions that are “Designed Around You”.

Cincinnati Children’s Research Foundation
Contact: Mark Schuller
Email: mark.schuller@chmc.org
Website: www.cincinnatichildrens.org/clinical-trials

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, 500 GCP trained study coordinators and 84 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.
Contact: Irene Fitzgerald
Email: irene.fitzgerald@citeline.com
Website: www.citeline.com

Citeline delivers the most robust, reliable, and relevant R&D intelligence featuring an unmatched data collection of drugs, trials, investigators and sites—all with direct, unlimited analyst support. Citeline’s editorial team transforms data into knowledge through an advanced, manual, indexing process. The result is easy searching and powerful analytics to give you the specific intelligence you need, without hours of data cleaning. The right data at the right time, from the provider you trust.

CITI Program – University of Miami
Contact: David Burnham
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.

CitiusTech Inc.
Contact: Anujit Das Gupta
Email: anujit.dasgupta@citiusTech.com
Website: www.citiusTech.com

CitiusTech is a specialist provider of IT solutions and services exclusively focused on healthcare and life sciences organizations. CitiusTech offers strong expertise on clinical/operational data, real world data/evidence, investigational site mechanics along with rich experience in implementing innovative technology solutions in the social, mobility, analytics and cloud space.

Clariness
Contact: Mark Maietta
Email: info@clariness.com
Website: www.clariness.com

Clariness is the global leader in Patient Recruitment Services offering multilingual solutions on 6 continents. Focused on online advertising, Clariness runs ClinLife™, the largest International patient recruitment platform – with 42 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.

CleverCap
Contact: Moses Zonana
Email: contact@clevercaprx.com
Website: www.CleverCap.org

Introducing the CleverCap® Medication Adherence device and software platform. The CleverCap® platform helps patients stay compliant with audio and visual reminders and a dose control device that’s easy to use and child proof. Understand your study drug’s effectiveness, safety profile, and make better dosing decisions while supporting patients. www.CleverCap.org
ClinDatrix, Inc.  
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Email: matts.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: 1845  
Phone: 857-496-0054  
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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 Contract Research Association (CCRA)  
Booth: 1208  
Phone: 44-116-271-9727  
Email: mail@ccra.org.uk  
Website: www.ccra.org.uk  

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: 2011  
Phone: 336-714-7402  
Email: CRM@clinicalink.com  
Website: www.clinicalink.com  

Our proprietary software, SureSource™, is the market's first true Electronic Source Record (ESR). Unlike EDC systems, which capture only case report form data, SureSource™ offers tablet based electronic source documents. SureSource will dramatically reduce monitoring and data query resolution costs - while lowering compliance risks.

Clinical Practice Research Datalink (CPRD)  
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CPRD delivers major efficiencies to the clinical trials process via new digital platforms that enable fast access to large national data sets. Services include near real time feasibility, protocol optimisation and patient and site recruitment. Visit us to find out how a National Healthcare System approach can deliver a step change in clinical research.

Clinical Reference Laboratory  
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Email: Deborah.Felice@crlcorp.com  
Website: www.crlcorp.com  

Partnering with CRL Global Central Laboratory puts over 20 years of professional expertise to work for your study. The Clinical Trials Team at CRL is known for integrity, responsiveness, flexibility and transparency - making even the smallest biotech feel as important to us and their study is to them. With nine harmonized, integrated laboratories around the globe, CRL is everywhere your study needs to be! Visit http://www.crlcorp.com/services/global-clinical-trials/ to learn more.

Clinical Research Advantage/Radiant Research  
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Website: www.radiantresearch.com  

Clinical Research Advantage, Inc. / Radiant Research has provided experienced research sites to the pharmaceutical industry for over 22 years. We are the country’s largest Wholly Owned network of clinical trial sites with fully integrated quality systems and a database of over 2.5 million research participants. Our investigators and site personnel have successfully conducted more than 14,0000 multi-therapeutic phase I-IV studies at 75 sites nationwide.

ClinicalRM  
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Phone: 330-278-9229  
Email: atrotch@clinicalrm.com  
Website: www.clinicalrm.com  

ClinicalRM is a full-service CRO, specializing in clinical research and Phase I-IV clinical trial services for biologics, drugs, and devices. Our capabilities span the government, academic, and commercial marketplaces. Deep international collaborations and strong partnerships provide us access to thousands of clinical research professionals around the globe. With expert scientific and thought leadership, we bring together government and research organizations to provide rapid study start-up.

Clinitude  
Booth: 2252  
Contact: Sabrina Wijnen  
Website: www.clinitude.com  

Clinlogix  
Booth: 1003  
Phone: 215-855-9054  
Email: jmarkham@clinlogix.com  
Website: www.clinlogix.com  

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.

ClinTec International Ltd.  
Booth: 1118  
Phone: 617-273-8236  
Email: sbacarella@clintec.com  
Website: www.clinlogix.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.
Contact: Jeff Rogers
Email: rogers@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.
Contact: Marie-Laure Dyck
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.

Cmed Clinical Services
Contact: Anna Forster
Email: info@cmedresearch.com
Website: www.cmedresearch.com
Cmed Clinical Services is a global CRO providing services to the Biopharma industry worldwide. Cmed works with clients to not only deliver the clinical trial effectively, on time and within budget, but also by leveraging its in-depth expertise to ensure the development program and/or clinical trial is designed correctly. Cmed has particular expertise in the design and conduct of complex, oncology and rare disease trials and the provision of Biometric functional services.

CMIC HOLDINGS Co., Ltd.
Contact: Mizuho Arai
Email: mizuho-arai@cmic.co.jp
Website: www.cmic-holdings.co.jp/e/
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.

Cognizant Technology Solutions
Contact: James J. Lee
Email: inquiry@cognizant.com
Website: www.cognizant.com/life-sciences
Cognizant’s Life Science practice partners with 28 of the top 30 global pharmaceutical/biotech organizations as well as serving the medical device industry. Cognizant is a leading provider of IT, consulting, and BPO services, dedicated to helping the world’s leading companies build stronger businesses.

Compass IRB
Contact: Will Stewart
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.

Compass Research, LLC
Contact: Brandon Doan
Email: info@compassresearch.com
Website: www.compassresearch.com/sponsors/about-compass
Compass Research, LLC is one of the most experienced phase 1-4 sites in the United States. Quality and integrity has made Compass a preferred provider for many of the largest pharmaceutical companies globally, showing that experience leads to world-class data. We have conducted over 1,300 trials since 1992. We have helped get more than 78 pharmaceuticals approved with the FDA. Through our unique partnerships with private practices in Central Florida, we have direct access to special populations.

CompleWare
Contact: John Weiler or Heather Baumhauer
Email: businessdevelopment@compleware.com
Website: www.compleware.com
CompleWare is your all-in-one-and-done clinical trial partner. 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 Systems
Contact: Rick Morrison
Email: info@comprehend.com
Website: www.comprehend.com
Comprehend is a cloud-based analytics and collaboration solution developed specifically to optimize clinical operations quality management. Leading Pharma and Med Device companies use Comprehend to stand up their Study Quality Metrics, Centralized Monitoring, RBM and CRO Oversight initiatives in weeks - not months. With Comprehend, Clin Ops leaders gain insights across their existing EDC, CTMS, IRT and other clinical systems, collaborate with teams, and access a full audit trail and KRI history.

Content Analyst Company
Contact: Phillip Clary
Email: info@contentanalyst.com
Website: www.contentanalyst.com
Content Analyst’s Cerebrant™ is a secure, web-based solution that leverages the latest advances in machine learning technology to dramatically improve productivity and reveal key insights across large collections of unstructured content such as General News, Wikipedia, Pharma Industry Watch, FDA Guidelines & Drafts and Pubmed Full Text Central.
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<tr>
<th>Company</th>
<th>Booth:</th>
<th>Contact Information</th>
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<tr>
<td>Continuum Clinical</td>
<td>2343</td>
<td>Ken Shore (<a href="mailto:kshore@continuumclinical.com">kshore@continuumclinical.com</a>)</td>
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<td></td>
<td>Phone: 847-580-2229</td>
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<td>Website: <a href="http://www.continuumclinical.com">www.continuumclinical.com</a></td>
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<td>Continuum Clinical is a healthcare research and communications company. They have three businesses: Patient Recruitment for clinical trials; Late Stage Research (observational studies and health economics and outcomes research); and Medical Communications. Continuum Clinical provides a unique blend of resources and perspectives, proven expertise, and innovative solutions that ensure key development and commercial activities are optimized and fully leveraged for achieving overall strategic goals.</td>
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<tr>
<td>Contract Pharma</td>
<td>643</td>
<td>Damaris Kope (<a href="mailto:conference@contractpharma.com">conference@contractpharma.com</a>)</td>
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<td></td>
<td>Phone: 201-825-2552</td>
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<td>Website: <a href="http://www.contractpharma.com">www.contractpharma.com</a></td>
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<td>Contract Pharma is the magazine and website devoted to pharma and biopharma outsourcing. With over 20,000 subscribers and 40,000+ web visitors monthly, Contract Pharma is the key media source to connect with outsourcing decision makers. Contract Pharma conference &amp; exhibition is Sept 17 &amp; 18, Hyatt New Brunswick, NJ. Visit us for more information.</td>
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<tr>
<td>Conversis</td>
<td>2253</td>
<td>Mark Hooper (<a href="mailto:mark.hooper@conversismedical.com">mark.hooper@conversismedical.com</a>)</td>
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<td></td>
<td>Phone: +44(0)1869-255820</td>
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<td>Website: <a href="http://www.conversisglobal.com">www.conversisglobal.com</a></td>
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<td>Conversis Medical is a leading provider of translation and localisation services for the Life Science and Pharmaceutical Industry with a specialism in multi-national clinical trials. We offer medical translation services for clinical CRO, pharmaceutical companies and healthcare advertising agencies. We translate: • all materials relating to patient access and retention • patient education and training materials • investigator materials • product marketing materials • product leaflets • web campaigns</td>
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<tr>
<td>CoSign by ARX</td>
<td>744</td>
<td>Rodd Schlerf (<a href="mailto:rschlerf@arx.com">rschlerf@arx.com</a>)</td>
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<td>Phone: 415-839-8161</td>
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<td>Website: <a href="http://www.arx.com">www.arx.com</a></td>
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<td>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.</td>
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<tr>
<td>Cote Orphan Consulting, LLC</td>
<td>1544</td>
<td>Jahmai Sharp-Moore (<a href="mailto:jahmai@coteorphan.com">jahmai@coteorphan.com</a>)</td>
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<td></td>
<td>Phone: 202-759-5207</td>
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<td>Website: <a href="http://www.coteorphan.com">www.coteorphan.com</a></td>
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<td>With the outstanding clinical need for novel therapeutics in the rare disease space, it’s no surprise that almost 40% of the total market approvals currently granted by the FDA are given to orphan products. Coté Orphan can demystify FDA operations as they affect your company and provide invaluable, considered advice regarding the strategic life of your orphan product. We are available to offer the consulting services that will be most beneficial to your organization’s most challenging needs.</td>
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<tr>
<td>Court Square Group, Inc.</td>
<td>2157</td>
<td>Keith Parent, CEO (<a href="mailto:sales@courtsquaregroup.com">sales@courtsquaregroup.com</a>)</td>
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<td></td>
<td>Phone: 413-746-0054</td>
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<td>Website: <a href="http://www.courtsquaregroup.com">www.courtsquaregroup.com</a></td>
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<td>Court Square Group is a professional consultancy specializing in the needs of FDA regulated companies, including IT planning, network, security and project management. Court Square Group 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.</td>
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<tr>
<td>Covance Inc.</td>
<td>1835</td>
<td>Kenneth Nordeen (<a href="mailto:kenneth.nordeen@covance.com">kenneth.nordeen@covance.com</a>)</td>
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<td>Phone: 508-864-6488</td>
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<td>Website: <a href="http://www.covance.com">www.covance.com</a></td>
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<td>As one of the world’s largest and most comprehensive drug development service companies, we have 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.</td>
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<td>Covigilant</td>
<td>2726</td>
<td>Kenneth Nordeen (<a href="mailto:kenneth.nordeen@covance.com">kenneth.nordeen@covance.com</a>)</td>
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<td>Covigilant provides an expertly managed Argus Safety database environment, with optional hosting. We configure the database, monitor operations, and perform validation so you can focus on Drug Safety. We also handle all aspects of reporting, whether it be ad hoc listings or pre-validated reports. We provide on-site support during regulatory inspections with seasoned professionals. Covigilant’s smart configuration will give you intelligence out of your database that you never thought possible.</td>
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<tr>
<td>CRF Health</td>
<td>2427</td>
<td>Heather Bilinski (<a href="mailto:info@crfhealth.com">info@crfhealth.com</a>)</td>
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<td>Phone: 267-498-2349</td>
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<td>Website: <a href="http://www.crfhealth.com">www.crfhealth.com</a></td>
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<td>CRF Health is the leading provider of electronic Clinical Outcome Assessment (eCOA) solutions for global clinical trials. With experience in more than 625 trials, over 100 languages and across 74 countries, CRF Health's TrialMax eCOA solutions consistently demonstrate the industry’s highest data accuracy, patient and site compliance, and patient retention.</td>
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<td>CRO Analytics</td>
<td>1656</td>
<td>Peter Malamis (<a href="mailto:pmalamis@croanalytics.com">pmalamis@croanalytics.com</a>)</td>
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<td>Phone: 571-436-4835</td>
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<td>Website: <a href="http://www.croanalytics.com">www.croanalytics.com</a></td>
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<td>CRO Analytics helps the biopharma industry improve the efficiency and effectiveness of its outsourced clinical research. We collect, analyze, and report data on performance of contract research organizations and other research service providers through a proprietary, validated process. The principles of CRO Analytics are 26 year biopharma industry veteran Peter Malamis and Dr. Michael Howley an Associate Clinical Professor of Marketing at the LeBow College of Business.</td>
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<td>CROMSOURCE</td>
<td>1345</td>
<td>Margherita Mosconi</td>
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<td>Cu-Tech, LLC</td>
<td>1121</td>
<td>Kathleen Ashenfelter</td>
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<td>DAC</td>
<td>2327</td>
<td>Melynda Geurts</td>
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<td>DataMatrix</td>
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<td>Anna Davydova</td>
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<td>DataArt</td>
<td>2639</td>
<td>Daniel Piekarz</td>
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<tr>
<td>DataPharm Australia Pty Ltd</td>
<td>625</td>
<td>John Edington</td>
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<td>CTI Clinical Trial &amp; Consulting Services</td>
<td>1915</td>
<td>Allison Schroeder</td>
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<td>CROS NT</td>
<td>1111</td>
<td>Mary Wieder</td>
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<tr>
<td>Cytel Inc.</td>
<td>1611</td>
<td>Mike Weitz</td>
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<td>CSSI</td>
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<td>Charlie Speno</td>
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<tr>
<td>Datapharm Australia Pty Ltd</td>
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<td>John Edington</td>
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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. CROS NT collects, analyzes and reports clinical trial data. CTI is an international drug and device development organization that delivers successful enrollment, on time, every time. DataMatrix is a full service Data Management and Statistics company with a long list of successful clinical trials. Datapharm Australia Pty Ltd is an Australian CRO, specializing in clinical trials management, conduct, and monitoring. 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. Cytel Inc. is a pioneer in patient recruitment for clinical trials since 1992, DAC Patient Recruitment Services offers strategic site selection, country-customized patient recruitment and retention, award-winning creative services, and CEU-certified global clinical staff training. DataArt is a technology consulting firm that designs and builds custom software systems. DAC is a leader in patient recruitment for clinical trials since 1992, DAC Patient Recruitment Services offers strategic site selection, country-customized patient recruitment and retention, award-winning creative services, and CEU-certified global clinical staff training. DataMatrix is a full service Data Management and Statistics company with a long list of successful clinical trials. Datapharm Australia Pty Ltd is an Australian CRO, specializing in clinical trials management, conduct, and monitoring.
**DATATRAK International, Inc.**
Contact: Lisa Pahl  
Email: lisa.pahl@datatrak.net  
Website: www.datatrak.com

DATATRAK is an industry-leading provider of eClinical solutions and services. The DATATRAK ONE® Unified Experience™ platform removes complexities, delivering improved data quality, greater patient safety, and time and cost savings. With transformational tools that provide instant access to custom reporting across trials, get the information you need to make informed decisions faster.

**DaVita Clinical Research**
Contact: Adam Patton  
Email: DCRmarketing@davita.com  
Website: www.davitaclinicalresearch.com

For 30 years, DCR has used its extensive database and realworld 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 others. Our capabilities span the product lifecycle and include health outcomes research, realworld data, and medical communications.

**ConvergeHEALTH by Deloitte**
Contact: Tess Cunard  
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.

**DIA Patient Advocate Fellowship**
Contact: Elizabeth Lincoln  
Email: Elizabeth.Lincoln@diaglobal.org  
Website: www.DIAGlobal.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 20 patient fellows and learn more about the DIA Patient Advocate Fellowship Program.

**DIA**
Contact: Courtney Ingram  
Email: DIA@diaglobal.org  
Website: www.DIAGlobal.org

Since 1964, DIA (originally the Drug Information Association) has been the global connector in the health care product development life cycle. Our association of more than 30,000 key stakeholders builds productive relationships by bringing together regulators, life sciences professionals and academics, patient advocates and other influencers to exchange knowledge and collaborate in a neutral setting. DIA’s network creates unparalleled opportunities for the exchange of knowledge and brings together interdisciplinary experience to prepare for future developments.

**DITA Exchange**
Contact: Jim Nichols  
Email: jim.nichols@ditaexchange.com  
Website: www.ditaexchange.com

DitaExchange simplifies the way organizations create, manage, share and deliver important content though structured content management solutions built to run on the SharePoint platform. By helping companies produce and maintain important information quickly and by following compliance guidelines, employees spend less time keeping up with regulations and more time reaching company goals.

**Dohmen Life Science Services**
Contact: Herb Lee  
Email: hlee@medcomsol.com  
Website: www.dohmensafety.com

For more than 155 years, Dohmen has been connecting life science companies with their customers in the most efficient way possible. Now we’ve introduced Dohmen Life Science Services (DLSS), a new kind of service partner for BioPharma and MedTech innovators. We’ve assembled the industry leading brands that more than 600 life science companies have come to rely on to get their products to market and keep them there.

**Dora Wirth (Languages) Ltd.**
Contact: Samuel Wirth  
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**
Contact: Dr. Leonardo Ebeling  
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**
Contact: Kevin Williams  
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.
DIA 2015 51st Annual Meeting

Exhibitor Directory

DSG, Inc. Booth: 719
Contact: Jack Minster
Email: jminster@dsg-us.com
Website: www.dsg-us.com

DSG, Inc. celebrates over 23 years of full service clinical trial data collection and management with a fully integrated suite of innovative technology solutions: Award-winning eCaseLink EDC & DSG Designer for Enterprise licensing using CDISC standards; Risk Based Monitoring, eSource, specialized Clinical Data Management services, IWRS Randomization and Clinical Supply, Drug Safety, Patient Profiles, ePRO, CTMS, Site Payment, Protocol Violations, and digital on-demand Clinical Printing software.

D- Wise Technologies Booth: 1402
Contact: Keith Ward
Email: kward@d-wise.com
Website: www.d-wise.com

At d-Wise, we believe that Life Sciences Technology shouldn’t be complex and modernizing existing systems for lasting success is possible in this changing global business environment. Innovation and the application of new ideas to improve efficiency, effectiveness, and overall competitive advantage are what we are known for. We help life science clients worldwide implement robust, reliable, and compliant data infrastructures that are optimized for analytics and decision support.

ClinPlus/DZS Clinical Services Booth: 1610
Contact: Bob Borysko and Greg Ambra
Email: bborysko@clinplus.com
Website: www.clinplus.com

DZS has been providing clinical software solutions and CRO services utilizing our ClinPlus® software platform since 1998. More than 70 life science organizations currently depend on our clinical services or utilize our software for Trial Management, Data Management/EDC, Medical Coding, and Statistical Reporting through our ClinPlus® software tools and services division.

EastHORN Clinical Services in CEE, Ltd. Booth: 2109
Contact: Iain Gordon
Email: iain.gordon@easthorn.eu
Website: www.easthorn.com/geographical-reach/

Founded in Prague in 2004, EastHORN is one of the leading CROs in Central and Eastern Europe. Present in Germany, Austria and 17 countries in the CEE region, our experience is driven largely by the availability of patient populations in CEE and covers areas such as oncology, cardiology, gastroenterology, immunology, ophthalmology, rheumatology, nephrology, metabolic, central nervous system, women’s health disorders and paediatric indications.

eClinicalHealth Ltd. Booth: 510
Contact: Kai Langel
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.

EDETEK, Inc. Booth: 1855
Contact: Marina Yu
Email: info@edetek.com
Website: www.edetek.com

EDETEK, a proud CDISC Registered Solution Provider, provides innovative end-to-end data management solutions. Key products and services include eClinical (EDC, IWRS, Patient Recruiting, Site Management, Study Calendar, Financial Management), eInformatics (Data Integration, Standardization, Analysis, Reporting), and eSubmission Solutions. We deliver quality services in every aspect of trial design, conduction, analysis, and regulatory submission.

Elite Research Institute Booth: 757
Contact: Kai Langel
Email: klangel@eclinicalhealth.com

Elite Research Network, LLC Booth: 1206
Contact: Christopher Hoyle
Email: choyler@eliteresearchnetwork.com
Website: www.eliteresearchnetwork.com

Founded in 2004, Elite Research Network is a group of independently owned investigator sites which conduct clinical studies in all therapeutic areas and phases, including Phase I. We have earned a reputation for quick study start up time lines, high enrollment and providing our clients with quality data. Our sites utilize central IRBs.

EMB Statistical Solutions, LLC Booth: 1014
Contact: Brenda Bishop
Email: bbishop@embstats.com
Website: www.embstats.com

EMB is a CRO specializing in the Data Management and Statistical Analysis/Reporting of clinical research data. EMB was formed in 2000 with a dedicated team of senior level associates each with over 15 years of industry experience and a proven track record of success. With experience on more than 40 NDAs, EMB associates streamline the process, effectively represent your results, & support your presentations to the FDA. EMB is associate owned, has had ZERO turnover, and is “Powered by Experience”.

Emerson Process Management Booth: 1555
Contact: Bob Dvorak
Email: Robert.Dvorak@Emerson.com
Website: www2.emersonprocess.com/en-us/brands/syncode

Emerson Process Management is a leading supplier of document management and manufacturing products and solutions in the Life Sciences. Emerson’s Syncode Smart Operation Management Suite is the leading Operations Management software for process industries. Syncode’s integrated document management and training management solutions help assure compliance, while the suite of manufacturing solutions provide coordinated control of materials, equipment, personnel, documents, and batch records.

Endpoint Booth: 927
Contact: Ryan Keane
Email: rkeane@endpointclinical.com
Website: www.endpointclinical.com

endpoint is an innovative company dedicated to the development of the leading technology platform to support the life sciences industry. Our founding team has been developing Interactive Response Technology (IRT) systems for clinical trials since 1998. We have excelled at the critical aspect of marrying the latest technology to unsurpassed client service in order to continuously exceed client expectations.
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<td>Enforme Interactive</td>
<td>1249</td>
<td>Contact: Eric Delente, CEO Email: <a href="mailto:info@secureconsent.com">info@secureconsent.com</a> Website: <a href="http://www.secureconsent.com">www.secureconsent.com</a></td>
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<td>Enforme Interactive Inc. is a developer of electronic systems for informed consent for clinical trials. The Secure Consent system expedites drug and medical therapy approvals, reduces consent-related FDA citations, and provides remote multiple-site monitoring and recruitment efforts. Product development is customized for individual clients with custom design of your consent process; an informative, multi-media presentation; a multi-site dashboard for management; and an amendment element.</td>
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<tr>
<td>ENNOV</td>
<td>1145</td>
<td>Contact: Marie Cambet Email: <a href="mailto:mcambet@ennoov.com">mcambet@ennoov.com</a> Website: <a href="http://www.ennoov.com">www.ennoov.com</a></td>
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<td>With over 15 years of experience, Ennov Solutions Inc is a software vendor specialized in Quality (SOPs, CAPAs, Training, etc.), Regulatory Affairs (eCTD submissions, RIM, etc.) and Clinical Trial (eCRF, CTMS) Management Systems for the Life Science &amp; Health Care industries. Our solutions are cost effective, user-friendly, highly configurable, &amp; web based. Available in SaaS mode &amp; fully iPad compatible, Ennov is the ideal solution for managing all your electronic content &amp; corporate workflows.</td>
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<tr>
<td>Entimo AG</td>
<td>2220</td>
<td>Contact: Dimitri Kutsenko Email: <a href="mailto:dkutsenko@entimo.com">dkutsenko@entimo.com</a> Website: <a href="http://www.entimo.com">www.entimo.com</a></td>
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<td>Entimo is a product oriented life sciences and regulatory informatics company. It delivers high-quality IT products, custom solutions and services which shorten the drug research and development processes of the pharmaceutical industry. Entimo uses current IT standards, methods and tools to create and deliver regulatory compliant and cost saving products as well as professional services that cover the customers' needs in the pre-clinical and clinical development areas.</td>
</tr>
<tr>
<td>ePharmaSolutions</td>
<td>734</td>
<td>Contact: Lance Converse Email: <a href="mailto:lconverse@epharmasolutions.com">lconverse@epharmasolutions.com</a> Website: <a href="http://www.epharmasolutions.com">www.epharmasolutions.com</a></td>
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<td>ePharmaSolutions is a leading provider of eClinical solutions to the life sciences industry servicing over 300,000 clinical researchers in 130 countries. ePharmaSolutions' fully integrated Clinical Trial Portal, User Management, and eTMF solutions can be configured in minutes and externalized to study team and sites with single credential access to 15 of the leading eClinical applications.</td>
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<tr>
<td>EPS Holdings, Inc.</td>
<td>905</td>
<td>Contact: Askold Kozbur Email: <a href="mailto:akozbur@epsgrp.com">akozbur@epsgrp.com</a> Website: <a href="http://www.eps-holdings.co.jp/en">www.eps-holdings.co.jp/en</a></td>
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<td>EPS Holdings, Inc. is a comprehensive provider of clinical research outsourced solutions. EPS operates in Japan, China, South Korea, Singapore, Taiwan, Thailand, Philippines, Australia, New Zealand, Malaysia, Vietnam, India, Indonesia, and Hong Kong. EPS Group Companies provide R&amp;D support to pharmaceutical, biotech, and medical device companies. EPS also provides SMO, IT, Professional Support Call Center, Pre-clinical Study Agent, and Contract Sales Organization services in Asia Pacific.</td>
</tr>
<tr>
<td>ERT</td>
<td>2025 &amp; 2000</td>
<td>Contact: Sheryl Walder Email: <a href="mailto:eresearch@ert.com">eresearch@ert.com</a> Website: <a href="http://www.ert.com">www.ert.com</a></td>
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<td>ERT is a leading provider of high-quality patient safety and efficacy endpoint data collection solutions for use in clinical drug development. ERT delivers solutions in: Centralized Cardiac Safety including ambulatory blood pressure monitoring (ABPM), Respiratory Services, Clinical Outcome Assessments (COA) –ePRO, eClirRO, eObsRO, Suicide Risk Assessment, and related consulting. ERT is a global organization with headquarters in Philadelphia, PA &amp; offices in the U.S., U.K., Japan, &amp; Germany.</td>
</tr>
<tr>
<td>Eurofins</td>
<td>2540</td>
<td>Contact: Elena Logan Email: <a href="mailto:ElenaLogan@eurofinsus.com">ElenaLogan@eurofinsus.com</a> Website: centrallab.eurofins.com</td>
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<td>Eurofins Central Laboratory: Results that matter. At Eurofins, we are proud to call our central lab services hardcore. Central laboratory testing is our sole focus and 100% resource dedicated. We are the most devoted group of professionals available to execute and array of services ensuring that any clinical trial sample is collected, transported, managed, analyzed, reported and stored to meet the objectives of your study. With worldwide coverage - let us take you to the next level.</td>
</tr>
<tr>
<td>European Medicines Agency</td>
<td>1528</td>
<td>Contact: Beatrice Fay Email: <a href="mailto:beatrice.fayl@ema.europa.eu">beatrice.fayl@ema.europa.eu</a> Website: <a href="http://www.ema.europa.eu">www.ema.europa.eu</a></td>
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<td>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.</td>
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<tr>
<td>EUROTRIALS</td>
<td>1815</td>
<td>Contact: Cláudia Carvalho Email: <a href="mailto:claudia.carvalho@eurotrials.com">claudia.carvalho@eurotrials.com</a> Website: <a href="http://www.eurotrials.com">www.eurotrials.com</a></td>
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<td>Eurotrials is a privately held full-service CRO with more than 20 years of experience, specialized in clinical research and scientific consultancy in Europe and Latin America. Eurotrials has been validated by international R&amp;D companies and has several Master Agreements. Our services span from Clinical Research to Epidemiology, Regulatoy Affairs, Pharmacovigilance, Health Economics, Data Management and Biostatistics.</td>
</tr>
<tr>
<td>Everest Clinical Research</td>
<td>2048</td>
<td>Contact: Brian Wettlaufer Email: <a href="mailto:brian.wettlaufer@ecrscorp.com">brian.wettlaufer@ecrscorp.com</a> Website: <a href="http://www.ecrscorp.com">www.ecrscorp.com</a></td>
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<td>Everest Clinical Research Inc. is a CRO providing Biostatistics, Clinical Data Management, Medical and Scientific Writing, IWRS, and other services to pharmaceutical, biotechnology, and medical device companies worldwide. We provide quality, customer-focus, and flexibility, working with many of the most advanced drugs in development today. Welcome to our corporate website <a href="http://www.ecrscorp.com">www.ecrscorp.com</a></td>
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Flex Databases
Contact: Natalia Blagodarova
Email: contactus@flexdatabases.com
Website: www.flexdatabases.com

Flex Databases is a software company specializing in pharmaceutical research by providing 21 CFR Part 11 software solutions for CROs and pharmaceutical companies. The platform approach adopted by us allows to eliminate manual re-entry of data, as information from each part of the system is shared across the platform. Covered areas: CTMS (subject tracking, site payments, CRA site visits, risk-based monitoring), Project Management, EDC, IWRS, eTMF, SOP and training management.

Foresight Group International AG
Contact: Scott Fonseca
Email: sfonseca@foresightgroup.com
Website: www.foresightgroup.com

Foresight Group is a global management and technology consulting company focused exclusively on drug safety and risk management services and solutions. We provide hosted safety solutions and specialize in PV process design and optimization, safety database implementation, ad hoc and custom reporting, signal management, risk management and inspection readiness and response.

Formedix Inc.
Contact: Nicola Rogerson
Email: nicolarogerson@formedix.com
Website: www.formedix.com

Formedix has been the go-to provider of clinical trial software and consultancy services for CROs, biotechs and pharmaceutical companies since 2000. Our solutions enable the removal of manual, expensive and inefficient tasks from the study setup, EDC build, validation and submission processes. We work closely with organizations like CDISC to develop and advance clinical data standards, and to automate the end-to-end clinical trial process. Formedix - Your clinical trials automated. Everywhere.

Frenova Renal Research
Contact: Brigid Flanagan, MS, RN, CCRC
Email: research@fmc-na.com
Website: www.fmcna.com

Frenova Renal Research is your only clinical development partner dedicated exclusively to renal research. We offer complete Phase I-IV clinical services and exceptional bioinformatics capabilities, along with a world-class network of resources and access to 390,000+ active CKD and 183,000+ active ESRD patients. Trust the partner that’s completely renal—Frenova!

Fresenius Medical Care North America
Contact: Mark Pass
Email: mark.pass@fmc-na.com
Website: www.jobs.fmcna.com

Fresenius Medical Care North America (FMCNA) is proud that our unwavering commitment to our patients has made us the global leader in dialysis healthcare. Our caring professionals touch the lives of over 160,000 patients and their families, combining innovative care with profound personal connections. With a Regulatory Affairs career at FMCNA, you’ll take pride in knowing you’re making a meaningful difference in the lives of patients affected by kidney disease.

Frontage Labs
Contact: Colleen Haywood
Email: chaywood@frontagelab.com
Website: www.frontagelab.com

Frontage is a global CRO focused on early stage drug development, delivering services including bioanalysis, DMPK, Phase I-IIA clinical studies, and CMC product development. Our team of dedicated scientists and skilled business professionals across multiple business units gives us the ability to maneuver the drug development process in a timely and cost-effective manner. We work with small and large molecules for novel biopharmaceuticals as well as generic-equivalent and consumer products.

GA International Inc.
Contact: George Ambartsoumian
Website: www.ga-international.com

GA International is a global company focused exclusively on health regulatory submissions to our clients in pharmaceutical, biotechnology and medical device industries. Our goal is to provide our clients smarter regulatory affairs services with GA International’s global delivery, BPO, technology and domain expertise in consulting, project support and outsourced regulatory affairs activities globally. We combine Pharmalink’s specialized knowledge in regulatory affairs with GA International’s global delivery, BPO, technology and analytics offerings for the global life sciences market.

GCP ClinPlus Co., Ltd.
Contact: Xiaoyu Deng
Email: xiaoyu.deng@gcp-clinplus.com
Website: www.gcp-clinplus.com

GCP ClinPlus Co., Ltd. (GCP), founded in 2003, is a leading CRO in China GCP provides clinical research solutions which are customized, of international standards and making full use of various network and resources. Our services include the evaluation and counseling of new drug R&D, regulatory affairs, clinical trial monitoring and management, data management, statistical analysis, medical affair and training, involving fields of pharmaceutical, biological product and medical device.

Genpact Pharmalink
Contact: J. Michael Haley
Email: commercial@pharmalinkconsulting.com
Website: www.pharmalinkconsulting.com

Genpact Pharmalink transforms the way Life Sciences companies manage regulatory affairs activities globally. We combine Pharmalink’s specialized domain expertise in consulting, project support and outsourced regulatory affairs services with Genpact’s global delivery, BPO, technology and analytics offerings for the global life sciences market.

GenPro International
Contact: Shobha Menon
Email: info@genprointl.com
Website: www.genprointl.com

GenPro is a CRO with a mission to provide the highest quality services in the areas of biostatistics, statistical programming, medical writing, and regulatory submissions to our clients in pharmaceutical, biotechnology and medical device industries. Our goal is to provide our clients smarter and efficient approaches to reach their goals of successful drug/device development. GenPro has the right team to deliver the quality and timeliness to ensure clinical development process stay on track.
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<tr>
<th>Global Center of Excellence in Clinical Trials, Asan Medical Center</th>
<th>Booth: 1651</th>
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<tbody>
<tr>
<td>Contact: Sung Ho Beck</td>
<td>Phone: 82-2-3010-7149</td>
</tr>
<tr>
<td>Email: <a href="mailto:beck.sung.ho@amc.seoul.kr">beck.sung.ho@amc.seoul.kr</a></td>
<td>Website: ctc.amc.seoul.kr</td>
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Asan is Korea’s largest medical institution, with 1,600 physicians, 3,100 nurses, 2,680 beds, and 67 operating rooms, occupying more than four million square feet. A typical day at AMC sees 2,500 inpatients and 10,000 outpatients treated. We are focusing on accelerated “PoC” trials as Global Center of Excellence in Clinical Trials. Clinical Trial Center covers all therapeutic areas and it supports investigators to perform about 300 clinical trials per year.

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<tr>
<th>Global Center of Excellence in Clinical Trials, Inje University Busan Paik Hospital</th>
<th>Booth: 1651</th>
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<tr>
<td>Contact: In Hae Hwang</td>
<td>Phone: 82-51-890-6436</td>
</tr>
<tr>
<td>Email: <a href="mailto:ihhwang@busanpaik.ac.kr">ihhwang@busanpaik.ac.kr</a></td>
<td>Website: <a href="http://www.paikctc.ac.kr">www.paikctc.ac.kr</a></td>
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Inje University Busan Paik Hospital Clinical Trial Center is a complete full-service clinical trial center in Busan, South Korea. As a Government appointed Global Center of Excellence, Inje Paik CTC plays an essential role in advancing and developing clinical research infrastructure in Korea’s Southeast region; steadfastly striving to be a global leader in clinical trials by providing highly qualified, time efficient, and cost-effective clinical trials which meet and exceed global expectations.

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<tr>
<th>Global Center of Excellence in Clinical Trials, Samsung Medical Center</th>
<th>Booth: 1651</th>
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<tr>
<td>Contact: Jung Ryul Kim</td>
<td>Phone: 82-2-3410-3686</td>
</tr>
<tr>
<td>Email: <a href="mailto:jungryul.kim@samsung.com">jungryul.kim@samsung.com</a></td>
<td>Website: ctc.samsunghospital.com</td>
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“We are striving for PARTNERS to be a partner”. PARTNERS is the initials for Personalized & precision clinical trial consortium based on Advanced Research Tools, Network in biomedical Ecosystem and Robust Support system. Our research domains are composed of 4 main categories which are panomics based clinical trial, stem cell trial, image biomarker, metabolite biomarker. We also offer a wide-range of services for drug development such as consulting, coordination, commercialization and education.

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<th>Global Institute For Research</th>
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<tr>
<td>Contact: Chris Lewis</td>
<td>Phone: 42-359-866-81</td>
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<th>Global Instrumentation LLC</th>
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<tr>
<td>Contact: James DeMaso</td>
<td>Phone: 315-727-6659</td>
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<tr>
<td>Website: <a href="http://www.GlobalInstrumentation.com">www.GlobalInstrumentation.com</a></td>
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Global Instrumentations M12R ECG acquisition units combined with the M12A Enterprise application provide a turn-key solution to meet the requirements of clinical research. This platform supports a seamless exchange of ECG data from investigator sites to a centralized location including the export of FDA-HL7 data.

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<th>Global Language Solutions</th>
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<tr>
<td>Contact: Inna Kassatkina</td>
<td>Phone: 949-798-1400</td>
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<tr>
<td>Email: <a href="mailto:info@globallanguages.com">info@globallanguages.com</a></td>
<td>Website: <a href="http://www.globallanguages.com">www.globallanguages.com</a></td>
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Global Language Solutions (GLS) is an ISO 9001:2008 and EN 15038 certified translation and interpreting company specializing in pharmaceutical and clinical research translations in over 100 languages. Our regulatory experts and medical linguists have the knowledge that regulated industries demand plus extensive experience translating protocols, ICFs, labels, patient-reported outcomes (PROs), clinical trial agreements, websites, IVR/IWR & EDC applications. GLS is a certified WBE founded in 1994.

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<th>GlobalCare Clinical Trials, LTD</th>
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<tr>
<td>Contact: Gail Adinamis</td>
<td>Phone: 847-282-3280</td>
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<tr>
<td>Email: <a href="mailto:gadinamis@globalcarect.com">gadinamis@globalcarect.com</a></td>
<td>Website: <a href="http://www.globalcarect.com">www.globalcarect.com</a></td>
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GlobalCare conducts study visits (eg. blood draws, drug admin) at patients’ homes or other convenient locations via its global network of traveling clinicians to facilitate trials in a variety of indications and all phases and age groups. Globalcare’s patient-centric approach provides faster patient recruitment and better compliance/retention.

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<tr>
<th>Global Center of Excellence in Clinical Trials, Yonsei University Health System</th>
<th>Booth: 1651</th>
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<tr>
<td>Contact: Yeon-Tae Kim</td>
<td>Phone: 82-222-280-464</td>
</tr>
<tr>
<td>Email: <a href="mailto:kytzg86@yuhs.ac">kytzg86@yuhs.ac</a></td>
<td>Website: ocr.yuhs.ac/CTCEng/CTCEngIndex.aspx</td>
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The SCI Consortium (SCI-C), consisting of clinical trials centers (CTCs) from the three leading medical institutions in Korea: Severance Hospitals of Yonsei University Health System, Catholic University Seoul St. Mary’s Hospital, and Inha University Hospital has set out to fulfill the unmet needs of our clients with drug development initiatives. Our innovative model of CTCs consortium provides solutions for operational excellence and scientific consultation. Join us for a true companionship.

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<th>goBalto, Inc.</th>
<th>Booth: 1241</th>
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<tr>
<td>Contact: Kim Mason</td>
<td>Phone: 510-409-4882</td>
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<tr>
<td>Email: <a href="mailto:kmason@gobalto.com">kmason@gobalto.com</a></td>
<td>Website: <a href="http://www.gobalto.com">www.gobalto.com</a></td>
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goBalto develops next-generation solutions that simplify and accelerate clinical study startup in the pharmaceutical, biotechnology, and medical device industries. Our management team has over 100 years of combined experience in life sciences and enterprise software. We’ve worked for companies including Amgen, Genentech, Quintiles, Roche, Johnson & Johnson, and Model N. Visit us at www.gobalto.com.

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<th>GP Strategies</th>
<th>Booth: 1306</th>
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<tr>
<td>Contact: Scott Metker, Ph.D</td>
<td>Phone: 443-539-8563</td>
</tr>
<tr>
<td>Email: <a href="mailto:smetker@gpstrategies.com">smetker@gpstrategies.com</a></td>
<td>Website: <a href="http://www.gpstrategies.com">www.gpstrategies.com</a></td>
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GP Strategies is a global provider of human and operational performance improvement solutions in the Life Sciences industry. Through our medical authoring, case management and response fulfillment solution, infoMaestro, our clients can deliver timely, consistent, customized, and compliant responses from around the globe.

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<th>Green Key Resources</th>
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<tr>
<td>Contact: Kim York</td>
<td>Phone: 212-683-1988</td>
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<tr>
<td>Email: <a href="mailto:kim@greenkeyllc.com">kim@greenkeyllc.com</a></td>
<td>Website: <a href="http://www.greenkeyllc.com">www.greenkeyllc.com</a></td>
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Green Key Resources is one of the fastest growing professional recruitment firms offering a complete portfolio of staffing solutions, including permanent placement, temporary and contract staffing for leading Pharmaceutical, Biotechnology, Medical Device, and CRO companies nationwide.

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<th>Greenhiere</th>
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<tr>
<td>Contact: Jennifer Peters</td>
<td>Phone: 215-948-9269</td>
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<tr>
<td>Email: <a href="mailto:jennifer.peters@greenhiere.com">jennifer.peters@greenhiere.com</a></td>
<td>Website: <a href="http://www.greenhiere.com">www.greenhiere.com</a></td>
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Greenhiere is the industry leader of clinical payment technology, designed to improve the way research professionals work. We leverage our proprietary payments platform and workflow automation to help clients improve operational efficiency; reduce costs, mitigate regulatory risks; improve the patient and site experience and produce quantifiable results that improve clinical operations and strategic planning.
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Booth: 2538  
Contact: Shuzhuang Peng  
Phone: 86-15915826620  
Website: www.kingmed.com.cn/  

As a pioneering and leading commercial clinical laboratory in China, KingMed is accredited by CAP (15 disciplines), ISO15189, ISO/IEC17025, ISO9001, NSGP Level 1 Laboratory, and follows GLP, US 21 CFR Part 11, ICH-GCP and other applicable laws and regulations. KingMed provides clinical tests, consumable materials management, logistic service and specimen management services for clinics, hospitals, international pharmaceutical companies, CROs and biotech companies.

Hangzhou Tigermed Consulting Co., Ltd.  
Booth: 746  
Contact: Wen Chen  
Phone: 86-21-32503700  
Email: bd@tigermed.net  
Website: www.tigermed.net  

Hangzhou Tigermed Consulting Co., Ltd is the leading CRO in China dedicated to provide professional full clinical trial services. Tigermed operates 25 subsidiaries, 50+ offices across China and 9 overseas offices in Hong Kong, Taiwan, Canada, USA, Korea, Australia, Japan, Malaysia and Singapore, serviced more than 400 local and global clients in the conduct of over 400 clinical trials. Tigermed is recognized as “The Innovative CRO” in China, owning to our involvement of 50 innovative drugs.

HCL America Inc.  
Booth: 1635  
Contact: Abhishek Singh  
Phone: 732-642-2860  
Email: contact.lsl@hcl.com  
Website: www.hcltech.com  

HCL is a $6.8Bn leading global technology and IT enterprise. Founded in 1976, HCL is one of India’s original IT garage start-ups. The HCL team consists of over 105,000 professionals of diverse nationalities, who operate from 31 countries including over 500 points of presence in India. HCL has partnerships with several leading global 1000 firms, including leading IT and technology firms. Its range of offerings includes product engineering, custom applications, BPO, IT infrastructure services and SI.

Health Decisions, Inc.  
Booth: 821  
Contact: Leslie Hammill  
Phone: 919-967-111-520  
Website: www.healthdec.com  

Health Decisions is a full-service CRO+ providing excellence in every aspect of clinical research. We are the CRO of choice for forward-looking biopharma and medical device companies. We use insight and agility to reduce timelines and risk and increase quality and returns for sponsors worldwide. For 25 years, we have improved the efficiency of clinical development through innovations that enable earlier, better decisions that consistently deliver clinical development success for our sponsors.

HealthCarePoint  
Booth: 1757  
Contact: Al Pacino  
Phone: 512-302-3113  
Website: www.HealthCarePoint.com  

HealthCarePoint is focused on creating user-based and business-to-business networking technologies. Members use our cutting-edge networks to streamline business and compliance processes by connecting organizations, their employees and contractors through a series of VIP Opt-In collaborative networks, seamlessly integrated to perform daily tasks and activities in order to exchange and update information in real time. Members also use our purchasing club to lower other costs within our industry.

Hummingbird IRB  
Booth: 824  
Contact: Ms. Linda Morrison  
Phone: 855-447-2123  
Website: www.hummingbirdirb.com  

Hummingbird IRB was founded on and values high-performing practices, pertinent, effective, and efficient systems to provide the highest caliber of scientific and ethical review to ensure human subject protection. HIRB has brought together the IRB community’s most experienced and trusted professionals. Formed by experts who have worked and served for many years on IRBs in academic and commercial settings. Hummingbird IRB’s review process is always relevant, thoughtful, and trusted.

Hurley Consulting Associates Ltd.  
Booth: 955  
Contact: Zina Suriano  
Phone: 908-273-8490  
Website: www.hurleyconsulting.com  

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Hurley Write, Inc.  
Booth: 2727  
Contact: Pam Hurley  
Phone: 910-233-7670  
Website: www.hurleywrite.com  

iCardiac Technologies  
Booth: 2102  
Contact: Sasha Latypova  
Email: deepika.gosain@icardiac.com  
Website: www.icardiac.com  

iCardiac Technologies, Inc. is a technologically-differentiated cardiac core lab providing the industry’s most sophisticated ICH E14 compliant cardiac safety assessment methodologies for clinical studies, supported by scientific expertise, project management, worldwide site and equipment logistics, customer support and regulatory data submission.

ICON plc  
Booth: 503  
Contact: Vanessa Byrne  
Email: vanessa.byrne@iconplc.com  
Website: www.iconplc.com  

ICON plc is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. The Company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. ICON currently has approximately 10,600 employees, operating from 83 locations in 38 countries. Further information is available at www.iconplc.com

IDT Australia  
Booth: 1746  
Contact: Jane Kelly  
Email: jane.kelly@cmax.com.au  
Website: www.cmax.com.au  

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<td>ImageIQ, Imaging CRO</td>
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<td><a href="mailto:apeters@image-iq.com">apeters@image-iq.com</a></td>
<td><a href="http://www.image-iq.com">www.image-iq.com</a></td>
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<td>Contact Andrea Peters</td>
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<td>IMS Health</td>
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<td><a href="http://WWW.IMSHealth.COM">WWW.IMSHealth.COM</a></td>
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<td>Contact Nina Pruitt</td>
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<td>Inamed GmbH</td>
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<td>Contact Patrick McManus</td>
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<td>INC Research</td>
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<td><a href="http://www.inresearch.com">www.inresearch.com</a></td>
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<td>Contact Kayla King</td>
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<td>InnovoCommerce LLC</td>
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<td><a href="mailto:holliev@innovocommerce.com">holliev@innovocommerce.com</a></td>
<td><a href="http://www.innovocommerce.com">www.innovocommerce.com</a></td>
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<td>Contact Hollie Van Dyke</td>
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<td>Innovate Business Information</td>
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<td>Information Builders, Inc.</td>
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<td>Contact Ann Mahoney</td>
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<td>Information Builders helps organizations transform data into business value.</td>
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<td>Our software solutions for business intelligence and analytics, integration, and data integrity empower people to make smarter decisions, strengthen customer relationships, and drive growth. Our dedication to customer success is unmatched in the industry. Visit informationbuilders.com and follow @infobldrs on Twitter.</td>
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<td>Integrative Print &amp; Media Group</td>
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<td>Contact Gilbert Rolon</td>
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<td>Integrated Clinical Systems, Inc.</td>
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<td>Contact Eric Herbel</td>
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<td>Integrated Clinical Systems - developers of Integrated Review™ and JReview® the fastest and easiest way to review, graph, visualize, report, analyze, do patient profiles and patient narratives, and Risk Based Monitoring for your clinical data. Works with OC, Clintrial, SAS datasets, Oracle LSH, SAS DD, Medidata Rave, EntimICE.</td>
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Integrated Development Associates Co., Ltd.  
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International Dermatology Research, Inc. is a research Site specializing in dermatology. Headquartered in Miami, FL, it provides state-of-the-art facilities, highly qualified staff and 9 additional sites in Latin America. Over the past 23 years IDR has gained excellent recognition for conducting successful Phase II, III and IV studies.

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inVentiv Health  
Booth: 1517  
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Phone: 609-951-6800  
Website: www.inVentivHealth.com/Clinical

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Investigational Cancer Therapeutics – MD Anderson  
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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.

IPHARMA / ChemDiv  
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Contact: Patti Shugarts  
Website: kcrnresearch.com

KCR  
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Email: rich.dwyer@kcrcro.com  
Website: www.kcrcro.com

KCR is a Contract Research Organization (CRO) operating across 19 countries in Europe as well as the U.S. The company is a strategic solutions provider for pharmaceutical and biotechnology firms who are looking for a reliable alternative to top-tier CROs. Over 300 professionals offer full service capabilities in three main product lines: Trial Execution, Functional Service Provision (FSP) and Late Phase, across a wide range of therapeutic areas. KCR: We see human behind every number.

KCRN M&C  
Website: kcrnresearch.com

Kelly Scientific Resources  
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Website: www.kellyservices.com

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Klein Hersh International  
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Website: www.kleinhersh.com

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KlinEra Global Services  
Contact: Chris Fernandez  
Email: Admin@KlinEra.com  
Website: www.KlinEra.com

Since 2005, KlinEra has partnered with the largest pharmaceutical, biotech and device companies to provide innovative and customized clinical trial and research services with a focus on clinical trials in India. To date, we’ve successfully completed over 50 large-scale Phase 1, 2 and 3 trials through full service offerings including: clinical trial management, medical monitoring, data management and site management services all utilizing high quality protocols and GCP’s.

KoNECT  
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Email: my.kim@konect.or.kr  
Website: konect.or.kr

As a government funded organization responsible for further development of Korea clinical trial infrastructure and capability to a global excellence level, Korea National Enterprise for Clinical Trials (KoNECT) strives for the vision to be a global clinical trial hub and a preferred partner for global drug development, ultimately to contribute to earlier access of patients to innovative treatment to be developed either in Korea or outside Korea.

Korea Clinical Trials Global Initiative (KCGI)  
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Kuantum CRO and Logistics  
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Founded in 2003, Kuantum is a leading provider of CRO and Clinical Supplies Management Services for the life science industry in Turkey and in the region. We offer a comprehensive set of cGCP and cGDP compliant services including all clinical monitoring activities as well as IMP/materials importation, storage, distribution, returns and destruction arrangements. Both of our facilities are inspected and approved by the Turkish Ministry of Health. We are your eye on clinical research in Turkey.

LabConnect, LLC  
Contact: Dan Knabb  
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LabCorp  
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Lambda Therapeutic Research Inc.  
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Lambda Therapeutic Research (LTR) is a leading, Clinical Development Solutions provider offering end-to-end full spectrum CRO services. Our strategic global footprint with locations in India, Europe and North America, ensure premium access to a unique& highly competent of human expertise, processing full capabilities of leveraging upon our state-of-the-art infrastructure in the most efficient yet cost effective way. we would welcome the opportunity to discuss your clinical development needs.

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Langland is the world’s most creatively awarded healthcare advertising agency. Named 2014 Cannes Lions Health agency of the Year, we combine healthcare intelligence with creative engagement to develop patient recruitment and retention strategies for studies of every imaginable type. From rare diseases to paediatrics to large scale studies in chronic conditions, we’ve helped recruit 300,000+ patients in 300+ studies across 75 countries.

Life Science Leader  
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Linical is a full service premier global CRO headquartered in Osaka, Japan, listed in the prime segment of the Tokyo Stock exchange, and dedicated to serve its client as a true partner in development. Linical has presence in a total of ca. 25 countries in Asia-Pacific including Japan, Europe and N. America via its own offices and entities. We have more than 20 years experience and track record in the conduct of clinical studies with a focus on Oncology, Immunology and CNS.

Lambda Clinical Research Consulting  
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Longboat Clinical Ltd.  
Contact: Jim Lane  
Email: info@longboat.com  
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MakroCare  
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Life Science Leader strives to be an essential business tool for Life Science executives. The editorial is designed to provide readers with content pertaining to the life cycle of Life Science products and services. Our goal is to provide information that helps high-level industry personnel improve profits and overcome hurdles within the industry.

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Medidata Solutions, Inc.  Booths: 2201 & 2641  
Contact: Craig Strauss  
Phone: 212-918-1800  
Website: www.mdsol.com

Medidata is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting.

MEDIX  Booth: 1846  
Contact: Dan Dumrauf  
Phone: 847-321-1629  
Website: www.medixteam.com

Medix Clinical Research delivers quality trials on time and under budget through a sustainable workforce solution. Through projecting your needs and pipelining potential talent, we can provide your organization the flexibility and agility you need to tackle new projects. In addition, through our Medix Match process, we will enable you to match the aptitude, culture fit, skills and experience of our candidates to your top performers.

MedNet Solutions, Inc.  Booth: 1838  
Contact: Dirk Nelson  
Phone: 763-258-2735  
Email: contact@mednetsstudy.com  
Website: www.mednetsstudy.com

MedNet Solutions is a leading healthcare technology company specializing in electronic data solutions designed for the global life sciences community. Since 2001, MedNet’s flexible and intuitive cloud-based eClinical systems have been trusted by pharmaceutical, medical device, biotechnology and Contract Research Organizations (CROs) around the world. Visit our booth to see iMedNet eClinical...an affordable solution that allows sponsors and CROs to quickly and easily build their own studies.

Medpace Inc.  Booth: 1801  
Contact: Jennifer Hammonds  
Email: j.hammonds@medpace.com  
Website: www.medpace.com

Medpace is a leading global full-service clinical research organization providing Phase I-IV core development services. With expertise in multiple therapeutic specialties, Medpace has assembled the industry’s most experienced teams to execute at every level of the company’s operations, providing complete and seamless drug development services. Medpace operates with 2000+ employees and clinical trial experience in over 50 countries.

MedPoint Digital, Inc.  Booth: 2517  
Contact: William Cooney  
Email: bill.cooney@medpt.com  
Website: www.medpt.com

MedPoint Digital develops specialty eClinical platforms for clinical trial portals, interactive modules, virtual investigator meetings, and mobile patient apps. Our digital solutions enable sites, sponsors and CROs to be more productive, with online study training, study eBinders (eISF), digital study alerts and SUSARs, visit guides, single sign-on and metrics displays.

Medrio, Inc.  Booth:1202  
Contact: Megan Lomazzi  
Email: mlomazzi@medrio.com  
Website: www.medrio.com

Medrio offers an eClinical Software as a Service (SaaS) application with a fully hosted Electronic Data Capture (EDC) system that allows for studies to be built online with no programming. With over 1000 studies, over 500 customers, and a 98% customer satisfaction rate, Medrio provides simple, fast, and affordable tools for the collection of data in clinical trials, including a specialized product for Phase I.

MedSource  Booth: 1935  
Contact: Eric Lund  
Email: eric@medsource.com  
Website: www.medsource.com

MedSource, a therapeutically focused CRO, specializes in providing support for the most complex clinical trials. Be it a challenging therapeutic area or a sophisticated trial design, our highly experienced team always exceeds expectations. By focusing on our core service offerings, MedSource provides quality results and client satisfaction.

MedTrials  Booth: 1346  
Contact: Jamie Edwards  
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Website: www.medtrials.com

MedTrials offers professional clinical development services to the pharmaceutical, biotech and medical device industries including clinical trial management, monitoring, data management, statistical analysis and reporting in all phases and types of clinical trials. MedTrials’ compliance experts conduct GxP audits at investigational sites, sponsors, manufacturers, IRBs and other third party vendors. MedTrials is a WBENC-certified, diverse supplier.

Merge eClinical  Booth: 2209  
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Website: eclinicalos.com

Merge eClinical offers eClinicalOS, a single, scalable cloud-based platform you configure to suit your precise needs. From building your study and managing randomization to endpoint adjudication and archiving results, you pay only for the options you use. Available worldwide in any language, eCOS can be ready to launch within days.

MESM Ltd  Booth: 2042  
Contact: Taj Dhaliwal  
Email: taj.dhaliwal@mesm.co.uk  
Website: www.mesmglobal.com

MESM provide Global Equipment Solutions to the Clinical Trials industry. Currently supporting clinical studies in over 70 countries, MESM take care of all aspects of the medical equipment, consumables and related products for studies from initial enquiry through to end of study removal. MESM have officially partnered with Abbott and Abaxis to announce the launch of GRTD (Quantitative Real Time Diagnostics) for use of their diagnostic devices/services for the global clinical trials market.

META Solutions, Inc.  Booth: 2021  
Contact: David Pfennig  
Email: kim.nitahara@metasol.com  
Website: www.metasol.com

META Solutions, Inc. is a regulatory compliance consultancy with 25 years of experience assisting over 300 biopharmaceutical and related service companies in managing their regulatory compliance risk by assessing non-compliance and developing and implementing practical solutions with expert guidance and training. Our core expertise includes GxP auditing, computer validation remediation and consulting, data management, and monitoring services.
MMG
Contact: Michael Rosenberg
Email: mrosenberg@mmgct.com
Website: www.mmgct.com
MMG is a full-service global patient recruitment company. For more than 25 years, MMG has accelerated recruitment in hundreds of trials for pharmaceutical, biotech, and government clients, including the U.S. National Institutes of Health. As part of the Omnicom Group and Ketchum we reach more than 70 countries in over 700 locations.

MNX Global Logistics
Contact: Kenneth Ying
Email: kenneth.ying@mnx.com
Website: www.mnx.com
MNX understands the incredible challenges of logistics within the life sciences industry, and we’re uniquely qualified to preserve the security of your supply and help ensure the success of your clinical trial. By synchronizing every aspect of your logistics needs and providing you with complete visibility to our processes, we empower organizations from across the life sciences spectrum to advance their mission of saving or enhancing patients’ lives. MNX, where Security + Simplicity = Serenity

MonitorForHire.com
Contact: Scott Freedman
Email: scott.freedman@monitorforhire.com
Website: www.monitorforhire.com
Clinical trial sponsors should be able to locate independent clinical trial monitors anywhere in the world, fast. MonitorForHire.com is a patented web based resourcing tool with over 5,000 registered and pre-qualified monitors in 60 countries including the US, Europe, Asia & MENA. For more information contact us at: +1 (610) 862 0909.

Montrium, Inc.
Contact: Oliver Pearce
Email: vparadis@montrium.com
Website: www.montrium.com
Montrium is a knowledge based company, that focuses on leveraging its deep understanding of GxP processes and technologies to provide cost-effective solutions to life science organizations. Montrium’s industry leading SharePoint Solution, Montrium Connect, offers a truly collaborative and compliant document and quality management environment on the cloud or on-premise. Montrium is a Global Leader in Cloud-based Compliance Solutions and GxP Consulting Services for the Life Sciences

Morningside Translations
Contact: Ethan Perlson
Email: ny@morningtrans.com
Website: www.morningtrans.com
Morningside is a leading provider of translations to global pharma and biotech companies. We provide translation and linguistic validation for clinical trials and translate regulatory documents for submission to agencies worldwide. We also offer medical interpretation and medical writing services. We localize into 100+ languages, and our translations are fully ISO 9001:2008 certified.

Mortara Instrument, Inc.
Contact: Myra Wilson
Email: myra.wilson@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.

National Death Index
Contact: Michelle Goodier
Email: mgoodier@cdc.gov
Website: www.cdc.gov/ndi.htm
The National Death Index (NDI) is a central computerized index of death record information on file in the state vital statistics offices. Working with these states, NCHS established the NDI as a resource to aid epidemiologists and other health and medical investigators with their mortality ascertainment activities.

NCGS Incorporated
Contact: Kimberly Flotta
Email: kflotta@ncgs.com
Website: www.ncgs.com
NCGS, Incorporated, an international CRO, leverages integrated technology to mitigate risk and provide agile management. SERVICES: Trial, Grants, and Data Management; eTMF, CTMS, EDC, ePRO, IWRS, RBM; Full or Strategic Sourcing; Trial Rescue. RESULTS: Approval or expanded labeling of 31 products in 31 years of operation; Zero 483s. WBENC Diversity Certified.

NeoGenomics Laboratories
Contact: Tony Tran
Email: totran@neogenomics.com
Website: www.neogenomics.com
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
Contact: Tina Soulis
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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 Orleans Center for Clinical Research
Contact: Dr. William Smith
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NOCCR / VRG is an academic hospital based research company. We conduct research in a wide range of medical specialties for the pharmaceutical, biotechnical and device industries. NOCCR Knoxville is primarily a 52 bed Phase I unit, well suited for conducting first-in-human trials. VRG and NOCCR New Orleans are primarily focused on conducting later phase studies.

Next Phase Research
Contact: Victoria Alvarez

NextDocs
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NextDocs is a global leader in compliance innovation, enabling businesses in regulated industries to achieve compliance with FDA, EMA and other agencies while innovating processes, increasing efficiency and reducing costs. NextDocs provides solutions for managing regulatory documents, SOPs and clinical documents and a full set of quality processes from CAPA to complaints. All solutions are 100% browser-based and deploy in the cloud or on-premises. Visit www.nextdocs.com or follow us on LinkedIn.

Nexxtials, Inc.
Contact: Brooke Puffer
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Website: www.nextrials.com

Nextrials is an award-winning innovative leader in software solutions for clinical research. Prism®, Nextrials’ clinical trial management software, brings together clinical trial management, EDC and EHR integration in a single package enabling clinical researchers to derive more value from their data, accelerate time to market and lower costs.

NNIT
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NNIT is one of Europe’s leading consultancies in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry’s strictest requirements for quality. For over a decade, we have applied the latest advances in technology to make our clients’ software, business processes and communication more effective.

Norav Medical
Contact: Jeffrey Kurn
Email: www.norav.com

LUMEDX and NORAV are the market leaders in fully integrated electrocardiography devices, cardiovascular information and PACS systems (CVIS), and pioneers in cloud-powered analytics and research solutions. Our comprehensive suite of wired and wireless ECG instruments, software, and services enable high-performance cardiology workflows, and optimal integration of clinical and research data. LUMEDX and NORAV products and services are utilized throughout the world for research and healthcare.

Nova Language Services Ltd.
Contact: Arun Mathew
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Website: www.nova-transnet.com

NOVA is a specialised ISO 9001:2008 and UNE EN 15038 certified multilingual medical communication company supplying high quality translation to the CRO/Regulatory/Patient Recruitment sector globally. From clinical trial protocols to SAE to websites, we will fulfil all your translation requirements with expertise, accuracy and reliability in all languages. NOVA has been included in the top ten translation providers in Southern Europe by Common sense advisory group.

Novella Clinical
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Novella Clinical, a Quintiles company, is a full-service clinical research organization (CRO) with headquarters in Morrisville, N.C. and operations in the Americas, Europe and Asia. Novella specializes in serving the unique needs of small and mid-sized oncology companies, and medical device companies of all sizes. Novella integrates deep clinical and therapeutic expertise, operational excellence, and a superior level of customer service to streamline product development. www.novellaclinical.com

November Research Group
Contact: Seth Warhaftig
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Website: www.novemberresearch.com

November Research Group is a professional services firm that provides a complete spectrum of software and services to pharmacovigilance organizations. We have extensive experience in the implementation and production support for the Argus Safety Suite. Our flagship software tools are designed to work seamlessly with both Argus Safety and AERS: PRIMO for streamlined intake, review and triage of adverse events, product complaints; and WebReports for true ad hoc reporting in English and Japanese.

Novotech
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Website: www.novotech-cro.com

Internationally recognized as the leading Australian CRO, Novotech is a full service clinical CRO with operations in Australia, across the Asia Pacific and South Africa. We assist biotechnology and pharmaceutical companies bring new products to market by offering a full range of ICH compliant clinical services from first human exposure through to completion of Phase III trials.

NSF Health Sciences
Contact: Trish Jaksch
Website: www.nsf.org

NSF is a non-profit organization that helps businesses and non-profit organizations in the healthcare sector adhere to regulations and standards. NSF brings together regulation and compliance professionals from all phases of drug development to share best practices and solve challenges in the regulatory environment.

Nuventra Pharma Sciences
Contact: Daniel Roy
Email: discover@nuventra.com
Website: nuventra.com

The success of your drug development program relies on expertise in the analysis and communication of PK/PD outcomes and the ability to translate your findings into actionable insights and regulatory reports. With Nuventra, the industry’s go-to resource for PK/PD based drug development, you benefit from our collective experience to make better clinical and non-clinical decisions and avoid costly mistakes.
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With over 30 years of experience developing Logistics Solutions worldwide, OCASA’s Bio-Pharmaceutical logistic service offers tailor made solutions for the Pharma industry including export, import, distribution, fulfillment, and temperature controlled warehousing for: Diagnostic Specimens, Medication/Vaccines, Experimental Drugs, Controlled Substances, Dangerous Goods, and Medical Supplies.

**Ohio Clinical Trials Collaborative**

OmniComm Systems, Inc.

Contact: Dennis Constantinou

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Website: www.omnicomm.com

OmniComm provides comprehensive solutions for clinical research with extensive global experience from over 4,000 clinical trials dedicated to helping life sciences organizations maximize the value of their clinical research investments. OmniComm drives efficiency in clinical development, manage risks, ensure compliance and improve clinical operating performance. Visit us at booth 2135 to see why 4 of the top 5 CROs and 7 of the 10 largest Phase I Clinics run OmniComm EDC technologies.

**Online Business Applications**

Contact: Reed McLaughlin

Email: reed.mclaughlin@irmsonline.com

Website: www.irmsonline.com

Online Business Applications provides advanced software solutions for the Pharmaceutical, Biotechnology, and Medical Device industries in the areas of Medical Communications and Drug Safety. We utilize proven leading-edge technologies, anticipate our clients’ needs, and deliver solutions that exceed expectations.

**OpenClinica**

Contact: Rob Rittberg

Email: rrittberg@openclinica.com

Website: www.openclinica.com

OpenClinica is the world’s leading open source platform for clinical research data capture and management. With thousands of implementations at biopharmaceutical, contract research organizations, and academic organizations worldwide, the OpenClinica software increases the speed of collection and quality of data in clinical trials. OpenClinica supports HIPAA, 21 CFR Part 11, and other regulatory guidelines and is designed as an extensible and modular platform. Visit - http://www.openclinica.com.

**Orlando Clinical Research Center**

Contact: Thomas Marbury

Email: tmarbury@ocrc.net

Website: www.ocrc.net

OCRC is a cutting edge independent Phase I – IV custom-built 35,000 sq. ft. research site. Designed specifically for Phase I clinical trials, OCRC includes 110 in-house volunteer beds, dual lead digital telemetry, CCTV security system, and cardkey access. A special treatment/observation area has 12 hospital beds (6 used for onsite Hemodialysis studies). OCRC specializes in Phase I trials with an emphasis in PK, QTc, and SAD/MAD studies in healthy, hepatic, hemodialysis, renal, and diabetic.

**Otto Trading, Inc.**

Contact: Adem Kutlug

Email: ademkutlug@gmail.com

Website: www.otto-trading.com

Otto Trading, Inc. is a supplier for the Pharma industry including export, import, distribution, fulfillment, and temperature controlled warehousing for: Diagnostic Specimens, Medication/Vaccines, Experimental Drugs, Controlled Substances, Dangerous Goods, and Medical Supplies.

**Pacific Bridge Medical**

Contact: Ames Gross

Email: adgross@pacificbridgemedical.com

Website: www.pacificbridgemedical.com

Pacific Bridge Medical is a consulting firm dedicated to assisting international medical companies with business development and regulatory affairs in Asia. We have helped hundreds of companies achieve success in the Asian medical markets since our founding in 1988. Our consultants are experts in business/regulatory strategies, product registration, distributor search, local agent representation, and more. We have offices in China, Japan, Singapore, and Hong Kong, and partners throughout Asia.

**Palm Beach CRO**

Contact: Arthur Simon

Email: ASimon@PalmBeachCRO.com

Website: www.palmbeachcro.com

Palm Beach CRO is a full-service Clinical Research Organization (CRO) providing clinical trial support to pharmaceutical (RX and OTC), biotechnology, nutraceutical and medical device companies. Our teams of seasoned professionals are proactive in the clinical processes, enabling timely completion of projects, helping to reduce costs and preventing overruns of budgets, without compromising on quality.

**Paragon International, Inc.**

Contact: Dave Rock

Email: dave.rock@paragonmeetings.com

Website: www.paragonmeetings.com

Since 2001 Paragon has supported sponsors and CROs by producing highly effective investigator meeting training programs. Our new Clinical Trial Patient Logistics provides a complete transportation service dedicated 100% to the needs of your trial study subjects. Using our transportation service in conjunction with our Paragon Patient Expense MasterCard program, will provide your internal and site partners with a simple and efficient means for managing study patient travel and payments.

**Paragon Solutions**

Contact: Jamie O’Keefe

Email: jokeefe@consultparagon.com

Website: www.consultparagon.com

Paragon Solutions is an advisory consulting and systems integration firm that focuses on clinical and regulatory operations collaboration, document management, and information insight and governance. We partner with clients to define and deliver optimal business outcomes by applying proven methodologies, technology frameworks and best practices to successfully blend people, process and technology.
PAREXEL International Booth: 1535
Contact: Heather Puffer
Phone: 781-487-9900
Email: info@parexel.com
Website: www.parexel.com

For over 30 years, PAREXEL has helped clients get their new and innovative drug treatments into the hands that need them most by simplifying their journey to market. Our global regulatory expertise, Phase I-IV clinical research services, integrated eClinical technologies, and advanced commercialization services all work together to move you through the development journey more smoothly and cost-effectively from beginning to end. PAREXEL operates in 81 locations throughout 51 countries.

PatientPoint Booth: 1545
Contact: Tim Brown
Phone: 888-479-5600
Email: LearnMore@PatientPoint.com
Website: www.PatientPoint.com

PatientPoint® is the leader and innovator of patient and physician engagement solutions at the point of care. PatientPoint award-winning patient education programs and care coordination platform drive meaningful outcomes for patients, healthcare providers and program sponsors. Our newest solution leverages our technology and expertise in patient engagement into an innovative way of accelerating recruitment and increasing patient retention in clinical trials. Learn more at www.patientpoint.com.

PCM TRIALS Booth: 2733
Contact: Julie Church-Thomas/Rick Heth
Phone: 888-628-9707
Email: info@pcmtrials.com
Website: www.pcmtrials.com

PCM TRIALS has provided clinical trial home visits for over 100+ protocols for 50+ sponsors since 2008. PCM TRIALS recruits, screens, hires, trains, tests (does not contract with local home health care agencies) and manages their own unique Certified Mobile Research Nurses (CMRN)s who understand the critical requirements of mobile clinical research. All CMRNs are trained in GCP, Nurse Guidelines, IATA and trial specific protocols. Services available in the U.S., Canada and ROW.

Pennside Partners, Ltd. Booth: 2518
Contact: Anthony Arleth
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Website: www.pennside.com

Pennside Partners has a 25+ year track record in providing business development and launch support for the pharmaceutical/biotechnology industries. Our core competency is to be able to provide clinical, commercial and regulatory guidance based on our analysis of companies facing similar challenges. Our staff is comprised of solution-oriented and experienced teams to support our clients’ business decisions.

PerkinElmer, Inc. Booth: 513
Contact: Rebecca Laborde
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Website: www.perkinelmer.com

At PerkinElmer, we’re taking action to improve the health and safety of people and their environment. PerkinElmer conceives and delivers scientific solutions, software and services to meet our society’s ever-changing needs. We’re committed to transforming risk into safety, mystery into knowledge and ideas into action for a healthier today and a better tomorrow.

Personify Booth: 1756
Contact: Jonathan Gardow
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Website: personifysearch.com

Personify is an international award-winning, complete recruitment solutions provider. Our recruiters are industry specialists in the areas that they recruit, and our business systems allow us to effectively provide an extension from our companies to the talent in each market we recruit in. Our strong focus in CRO allows us to recruit and retain top talent in Business Development, Clinical Operations, Biostatistics and Data Management, QA/QC, and Drug Safety.

Pharma Start Booth: 1148
Contact: Carolyn Durham
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Email: cdurham@pharma-start.com
Website: www.pharma-start.com

Pharma Start is a functional outsourcing firm focusing on the pharmaceutical, biotechnology, and devices industries. We combine our functional outsourcing delivery model with in-house expertise in scientific and medical research to offer a single, reliable bridge into the drug development realm. Our services include clinical development, in-home clinical trial visits, clinical pharmacology and nonclinical assessment, library intelligence, medical writing, and regulatory lifecycle management.

Pharmaceutical eConsulting Booth: 1650
Contact: Yolanda Hall
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Email: yh@pec-services.com
Website: www.pec-services.com

Pharmaceutical eConsulting (PeC) is a leading provider in delivering electronic submissions services for the global life sciences industry. PeC has customers spanning from small to large pharmaceutical companies to developing bio-tech. Our core mission is to support marketing filing efforts (eCTD, Nees or Paper submission) to the Regulatory Authorities (FDA, EMA, Health Canada, Rest of World). PeC is headquartered in Copenhagen with offices in Boston and London.

Pharmaceutical Packaging Professionals Pty Ltd. Booth: 2120
Contact: Craig Rogers
Phone: 61-3-9673-1003
Website: www.pharmpackpro.com

Pharmaceutical Packaging Professionals is an Australian based clinical trial manufacturing, warehousing and distribution CRO, servicing international pharmaceutical companies. PPP has TGA audited cGMP facilities in Australia offering finished product manufacturing services, packaging and labelling and controlled warehousing and distribution of clinical trial supplies. The company has been providing these services for 6 years and has acted as a central depot for more than 200 clinical studies.

Pharmaceuticals and Medical Devices Agency (PMDA) Booth: 1520
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.
PharmApprove is a strategic, regulatory and scientific communications firm that partners with pharmaceutical and biotechnology development teams to assist in the preparation and delivery of their products’ key messages at critical, high-profile regulatory events in both the United States and Europe.

PharmaQuest Ltd – a division of the RWS Group – are specialists in the translation and linguistic validation of PRO measures. Our services also include translatability assessments, ePRO migration and usability testing and clinician reviews of ClinRos to an extensive client base which includes global pharmaceutical companies and research bodies. As part of RWS’s Medical Translation Division, we are able to cover the full spectrum of clinical trial documentation.

PharmaSeek Companies is a group of interrelated businesses focused on expediting clinical research activities. Supporting businesses include PharmaSeek Investigative Site Network, a network of 240 research sites, PatientWise, a patient recruitment and healthcare marketing firm, and PharmaSeek Financial Services, a provider of outsourced business solutions for research sites.

PharmaSys, Inc. is a full service compliance & consulting firm specializing in FDA regulated industries & offering a wide range of services including computer validation, audit services, compliance training, commissioning, equipment/process validation, & QA consulting. Visit us at www.pharma-sys.com or call (919) 468-2547.

PharmaVOICE magazine provides readers with insightful and thought-provoking commentary about the challenges and trends impacting the life-sciences industry in a multiple-perspective format through articles covering a range of issues from molecule through market. PharmaVOICE’s more than 41,000 BPA-qualified subscribers are also kept abreast of the latest trends and information through additional media resources, including WebLinx Interactive WebSeminars, Podcasts, Videocasts, and White Papers.

Pharm-Olam International Ltd. is a multi-national contract research organization offering a wide range of comprehensive, clinical research services to the pharmaceutical, biotechnology and medical device industries. From Phase I to Phase IV, Pharm-Olam focuses on delivering the highest quality data, achieving targeted enrollment and meeting projected timelines. For further information about Pharm-Olam, please visit www.pharm-olam.com.

Phlexglobal is a specialist provider of technology enabled TMF document management solutions & support services, offering a unique combination of clinical trial knowledge, document management skills, regulatory understanding & technical expertise to deliver clinical research support solutions. We combine our core services that focus on people provision, document management & system support to deliver a range of flexible, cost-effective, targeted & efficient business solutions to our clients.

Pilgrim Quality Solutions is a leading global provider of enterprise quality management software and services for the Life Sciences and other highly regulated industries. For more than 20 years, our solutions have automated thousands of processes that ensure the quality of life’s most important products. Product quality and patient safety increase while risks decline. With Pilgrim Quality Solutions as your partner, you are prepared to succeed. For more information, visit www.pilgrimquality.com.

Planet Pharma is a professional staffing and recruitment company specializing in strategic solutions for the pharmaceutical, biotechnology, device and related industries. Planet Pharma provides experienced staff across numerous therapeutic and functional areas for all phases of the clinical trial process. Our service offerings include: - Contract / Contract-to-Hire, - Permanent Placement - Functional Service Provider - Payrolling Services

PleaseTech specializes in document co-authoring and review software. Our flagship product, PleaseReview, is a proven collaborative review and co-authoring solution for Microsoft Word and other document types and is used extensively by Life Sciences organizations. It facilitates controlled, simultaneous collaboration for the review and editing of documents, including comment and change reconciliation, review management and metrics, and accommodates both online and offline reviewers.

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Popsi Cube
Contact: Guy Maestre
Email: info@popsicube.com
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Looking for a new way to run clinical trials? Think Popsi Cube! Popsi Cube is a full-service CRO specializing in the development of customized IT tools and applications specific to the health industry: custom EDC, Digital Pen & Paper, bio captors, web platforms, clinical registries. Dedicated partner all along your study, we tailor our approach to what you specifically need and expect. We are based in Europe, North America, China and North Africa and work all over the world with local partners.

PPD
Contact: Account Development
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Website: www.ppd.com

PPD is a leading global contract research organization providing drug discovery, development, lifecycle management and laboratory services. With offices in 46 countries and more than 13,500 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a commitment to quality to help clients and partners accelerate the delivery of safe and effective therapeutics and maximize the returns on their R&D investments. Visit www.ppd.com.

PRA Health Sciences
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As a leading CRO, PRA is transforming clinical trials through our people, innovation and transparency. We combine therapeutic and operational expertise with local knowledge to serve clients across all phases of drug development. Our successful history of helping to bring new drugs to market demonstrates our successful approach to clinical research.

Proforma Giraffe Graphics, Inc.
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Technology enhanced print media marketing solutions. Focusing on educational materials for the pharmaceutical and healthcare sector. To improve patient adherence and compliance.

Premier Research
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Website: www.premier-research.com

Premier Research is a leading contract research organization serving the needs of biotechnology, pharmaceutical and medical device companies worldwide. The company has a wealth of experience in the execution of global, regional, and local clinical development programs with a special focus on unmet needs in areas such as analgesia, CNS, rare diseases, medical device and diagnostics, and pediatric research. Premier Research operates in 50 countries and employs more than 1,000 professionals.

Pretium
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Drawing on a comprehensive range of skills and over a decade of experience in Australia, Pretium provides services in clinical research, disease management, health economics and market intelligence. Pretium has the largest network of GP investigators and patients in Australia and an on-the-ground study coordinator team. Pretium supports the ethical conduct of trials designed to collect safety and efficacy data, generalisable from a representative sample of subjects in a real world environment.

PrimeVigilance
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Website: www.primevigilance.com

PrimeVigilance is a global service provider dedicated to deliver high quality, compliant and cost-effective Pharmacovigilance & Medical Information. PrimeVigilance sits between large CROs who focus on clinical trial and small service providers who lack critical mass, expertise/international presence needed for reliable scientific & safety services. Since its creation in the UK in 2008 PrimeVigilance has built a reputation in the industry as a leading Pharmacovigilance & Medical Services provider.

PRL Central Laboratory Services
Contact: Dan Robson
Email: dan.robson@prlnet.com
Website: www.prlwe-care.com

PRL is a full service Central Laboratory which specializes in customer service for CROs and midsized and emerging biopharmaceutical companies. We deliver comprehensive diagnostic testing, with a focus on protocol requirements. We serve all phases of clinical research on a global basis, providing each client with accurate study set-up, timely results delivery and validated data transfers.

PRL
Contact: Guy Maestre
Email: info@popsicube.com
Website: www.popsicube.com

Precision for Medicine is a specialized scientific services partner that helps life science innovators develop and commercialize next generation medical products. We deploy a unique combination of best-in-class scientific expertise and rational infrastructure to build direct pathways between products and patients. Our company has been engineered to help clients accelerate research, engage patients, enable market adoption, and enhance clinical outcomes.
Exhibitor Directory

Projecis, Inc.  Booth: 1645  Phone: 949-390-8260
Contact: Paul TanPiengo
Email: paul@projecis.com
Website: www.projecis.com

Projecis is a cloud-based platform that enables project stakeholders (sponsors, sites, CROs, and others) to connect teams, organize data, and share information for better trial outcomes. Users have access to Project Status, Assignment tracking, Gantt chart, File Repository, VoIP, Discussions, Project Alerts, Binder, Resource Allocation and a host of workflow tools. Team collaboration is further cultivated through the integration of Skype*, IM/chat, email, text, phone, etc. FREE trial available!

PSKW, LLC  Booth: 1053  Phone: 973-769-4233
Contact: Larry Buzbee
Email: lbuzbee@pskw.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.

PROSAR, a Pro Pharma Group Company  Booth: 2206  Phone: 651-917-6116
Contact: Mike Bieniek
Email: mbieniek@prosarcorp.com
Website: www.prosarsafety.com

PROSAR, a Pro Pharma Group Company, is a global provider of pharmacovigilance and medical information services to the pharmaceutical and biotech industries. Our 24/7 contact centers are staffed by pharmacists and nurses that provide adverse event intake & processing, medical information and product complaint services. Our international medical information call centers can support inquiries in more than 25 languages. We provide the expertise and services you need to stay in compliance.

ProTrials Research, Inc.  Booth: 1108  Phone: 650-864-9195
Contact: Wendy Powers
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

Quality Associates, Inc.  Booth: 1607  Phone: 410-884-9100
Contact: Paul Swidersky
Email: psandersky@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: 1334  Phone: 919-287-5830
Contact: Shawn Strait
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.

Pyxant Labs Inc  Booth: 1950  Phone: 719-593-1165
Contact: Amy Danenberg
Email: adanenberg@pyxant.com
Website: www.pyxant.com

Pyxant Labs Inc. is a contract research lab with a team of bioanalytical specialist supporting non-clinical through Phase III clinical. Pyxant Labs supports small molecule, peptide, and RNA therapeutics drug development programs, from regulatory method development and GLP validation through sample analysis phases. We have provided successful bioanalytical support for more than 1,200 FDA studies. We have been audited by the FDA five times, all successful. Our mission is “Quality Data. On Time.”
QuantifiCare started as a responsive full-services CRO for imaging. Seven of the top ten pharma companies, are routinely trusting QuantifiCare for their clinical trials. Over the years, we specialized in skin evaluation bringing our expertise to pharmaceutical, biotech and cosmetic industries. We provide dedicated 2D or 3D photographic hardware and our services include image procedure definition, Investigator training, image centralization, real time quality check and query resolution follow up.

Queensland Clinical Trials Network
Contact: Mario Pennisi
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
Contact: Florence McEvoy
Email: florence.c.mcevoy@questdiagnostics.com
Website: www.questdiagnostics.com
Quest Diagnostics Clinical Trials provides a wide range of laboratory solutions through our unsurpassed global central laboratory and comprehensive biomarker services, diagnostics and esoteric testing, and anatomic pathology services. Quest Diagnostics Clinical Trials has the scientific expertise, innovation, and global reach to support your clinical program.

Quintiles
Contact: Sandra Woodlief
Email: global.marketing@quintiles.com
Website: www.quintiles.com
Quintiles is the world’s largest provider of biopharmaceutical development and commercial outsourcing services. With a network of >32,000 employees conducting business >100 countries, we helped develop or commercialize all of 2013’s top 100 best-selling drugs on the market. Quintiles applies the breadth and depth of our service offerings along with extensive therapeutic, scientific and analytics expertise to help our customers improve their probability of success.

Quorum Review IRB
Contact: Business Development
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
Contact: Marijo Police
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
Contact: Ben Sparks
Email: b.sparks@realstaffing.com
Website: www.realstaffing.com
Real Life Sciences is a global leader in the provision of pharmaceutical, biotechnology and medical devices staffing services. We are one of the world’s most extensive pharma, biotech and medical devices recruiters and have one of the largest networks of specialist recruiters globally. Our premise is a simple one: by recognising talent and valuing relationships we are able to consistently deliver local, global and industry expertise which in turn ensures success time after time.

RegCheck
Contact: Zina Suriano
Email: zsuriano@myregcheck.com
Website: www.myregcheck.com
RegCheck™ provides a standardized, proven method for users to objectively evaluate study documentation and identify deficiencies with suggested corrective actions. RegCheck™ helps to avoid costly late-stage rework and potential delays by detecting potential issues that could prolong regulatory authorities’ review and approval. RegCheck™ is annotated to applicable 21 CFR and guidance documents. This easy to use tool can address multiple team objectives.

Regeneron Pharmaceuticals
Contact: Marina Yurovitsky
Website: www.regeneron.com
Regeneron is a leading science-based biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for eye diseases, colorectal cancer, rare inflammatory conditions, and has product candidates in development in other areas of high unmet medical need. Areas such as hypercholesterolemia, oncology, rheumatoid arthritis, allergic asthma, and atopic dermatitis.

Regxia
Contact: McGregor
Email: mcgregor@regxia.com
Website: www.regxia.com
Regxia is a unique scientific and regulatory consulting firm serving the pharmaceutical and biotech industries. Supporting products at all stages of development and throughout their lifecycle as part of overall project management or on a stand-alone basis. Regulatory; Clinical; Quality & Training Services: US-FDA, Health Canada, EMA: Dossier Compilation & Management; cCTD (compilation & publishing); CMC, CTAs, IND, NDS, ANDS, etc.; Monitoring; online ICH GCP Certificate Training.
RR Donnelley’s unmatched portfolio of communication products and services enables life science companies to deliver the right message, to the right audience, in the right way, at the right time—every time. From the inbox to the mailbox we can provide targeted, compliant and personalized communications designed to inform and inspire. Whether it’s expert linguistic solutions, product packaging or marketing collateral, we transform your communication from the essential to exceptional.

**Research Across America**

**Contact:** Gaye Corbin  
**Phone:** 610-779-7061  
**Website:** [www.researchacrossamerica.com](http://www.researchacrossamerica.com)

Research Across America is an Independent Site Network-ISM (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.

**Rx Trials Inc.**

**Contact:** Anne-Marie Baughn, RN MSN  
**Phone:** 410-465-2455-103  
**Website:** [www.rxtrialsinc.com](http://www.rxtrialsinc.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 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.

**San Diego State University – Regulatory Science Programs**

**Contact:** Lorah Bodie  
**Phone:** 619-594-0124  
**Website:** [regsci.sdsu.edu](http://regsci.sdsu.edu)

Regulatory Affairs (RA) Programs at San Diego State University provide online education for scientists in the pharma, biotech & medical device industries. Masters & Certificate Programs cover laws, regs, & manufacturing processes mandated by FDA & international agencies. Discovery, development, testing, manufacture, commercialization, & post-market surveillance of pharma, biologic, & medical device products are core content. A new Joint Certificate in Intellectual Property & RA begins Fall ’15.

**SanaClis s.r.o.**

**Contact:** Adriana Kuzmisinova  
**Phone:** 31-631-780-668  
**Website:** [www.sanaclis.eu](http://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.  
Contact: Janet Forbes  
Website: www.sas.com/dia15  
Booth: 2127  
Phone: 919-677-8000  
As the leader in advanced analytics, SAS helps you quickly visualize, analyze and share clinical, research and business data to bring therapies to the market faster. One hundred percent of biopharmaceutical companies on the Fortune Global 500® chose SAS®, the industry standard. Since 1976, SAS has given users THE POWER TO KNOW®. sas.com/dia15

SAS Institute Inc., JMP Division  
Contact: Walter Teague  
Website: www.jmp.com  
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Website: www.jmp.com  
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Phone: 919-531-7395  
JMP® is the SAS® software designed for dynamic data visualization on the desktop. JMP Clinical shortens the drug development process by streamlining safety reviews of clinical trials data. It helps clinicians and biostatisticians migrate into the modern review environment using CDISC data. Intuitive dashboards create a visual framework for rigorous statistical analysis.

Schlafender Hase Inc.  
Contact: Chris Anderson  
Website: www.text-verification.com  
Email: us@sh-p.com  
Website: www.text-verification.com  
Booth: 2012  
Phone: 617-607-4900  
The Text Verification Tool (TVT) developed by Schlafender Hase GmbH is the leading global standard solution in computer-driven proofreading and text and image comparison. It helps global pharma, biotech and medical device companies save time, money, improve quality, and avoid embarrassment and legal costs that can result from avoidable mistakes in labels, cartons, IFUs, translations and text conversions. Designed to support all standard file types including SPL.

Schlitt Group, Inc.  
Contact: Breland Atkinson  
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Website: www.scarrittgroup.com  
Booth: 1844  
Phone: 520-780-7167  
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.

Sharp Clinical Services  
Contact: John Phillips  
Email: info@sharpcclinical.com  
Website: www.sharpcservices.com  
Booth: 1305  
Phone: 800-310-4445  
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.

Signix, Inc.  
Contact: Jessi Lanza  
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Email: jlanza@signix.com  
Website: www.signix.com  
Booth: 2739  
Phone: 423-305-7080  
SIGNIX has a scalable solution that allows you to use one provider for signing electronically across your organization; true digital signatures for internal signing, digital signatures in a 21 CFR 11 workflow for clinical documents, and for those high level documents such as EMA submissions, Qualified Digital Certificates in our 21 CFR 11 workflow. SIGNIX can be employed through our workflow solution or through API calls, integrating with your current workflows.

Society for Clinical Research Sites – SCRS  
Contact: Christine Pierre  
Email: allyson.small@myscrs.org  
Website: www.myscrs.org  
Booth: 1548  
Phone: 410-696-5080  
The Society for Clinical Research Sites (SCRS) 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.

Seaview Research  
Contact: Celina R. Alvarez  
Email: calvarez@seaviewresearch.net  
Website: www.seaviewresearch.net  
Booth: 1944  
Phone: 305-649-6556  
Seaview Research is celebrating its 20th anniversary as an independently owned and operated CRO with locations in Miami and Jacksonville, Florida. Having a total bed capacity of 320, Seaview prides itself in the timely performance of large and complex protocols. Our experienced and credentialed staff have performed over 650 clinical trials to date.
Sonic Clinical Trials
Contact: Paullette Azar-Tannous
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.

SOUSEIKAI Global Clinical Research Center
Contact: Yukie Suzuki
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Website: www.ita-med.com/SouseikaiGlobal

Souseikai Global Clinical Research Center is one of the largest and oldest clinical research centers dedicated to clinical trials in Japan. During our 28 year history we have conducted over 4,000 pivotal Phase I-IV clinical trials with world leading pharmaceutical companies and CROs. Our powerhouse of 5 CRUs located in Tokyo and Kyushu cover almost any study in any population, advancing medical research for a better future with better treatment.

Spaulding Clinical Research
Contact: Tyler Borst
Email: tyler.borst@spauclingeneral.com
Website: www.spauldingclinical.com

Spaulding Clinical provides sponsors with innovative, cost effective Clinical Pharmacology and Cardiac Safety Core Laboratory Clinical Research services. Additionally, Spaulding Clinical is the manufacturer of an award winning, clinical trial specific ECG device. Spaulding Clinical operates a paperless, 155-bed clinical pharmacology unit with 96-beds of telemetry in West Bend, Wisconsin.

Statistics & Data Corporation (SDC)
Contact: Jim Townsend
Email: jtownsend@sdcclinical.com
Website: www.sdcclinical.com

SDC is committed to providing experienced teams who will take ownership of your needs and are positively engaged in your projects. With biostatistics, clinical data management, and electronic data capture (EDC) services at our core, SDC also offers scalable full service clinical trial solutions via our diverse and complementary strategic partnerships. With experience on over 150 clinical trials and scalable services tailored to your needs, SDC is The Right Fit For You.

The Speaking Book addresses the worldwide issue of low literacy which threatens over a billion adults. By pioneering the use of these books for Clinical Trials, Pfizer, GSK, Lilly and Merck and many CROs have been able to deliver their messages in any language, that are always seen, read, heard and understood. Endorsed by WMA as making a major contribution to the Informed Consent process and supporting the Declaration of Helsinki All our Clinical Trial Speaking Books are on display at our booth.
Stefanini
Contact: Michelle Cummings
Phone: 248-263-3440
Website: www.stefanini.com

Stefanini is an industry-recognized leader in IT outsourcing services, offering onshore, offshore & nearshore support to mid-size and large corporations. Service offerings include: IT help desk outsourcing, desktop managed services, IT asset management, SAP advisory, Microsoft SharePoint services, mainframe modernization, mobility services, and strategic staffing solutions. At a glance: 76 offices – 50 countries – 32 languages – 17,000 resources globally. www.stefanini.com

Sterling IRB
Contact: Kathye Richards
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Website: www.sterlingirb.com

For more than 20 years, Sterling IRB has helped lead the way in safeguarding the rights and welfare of clinical research participants. Our approach places the focus on your specific needs – complete with caring, responsive service and a single-point-of-contact you can always count on. Sterling IRB is fully accredited by AAHRPP, and has oversight capabilities in the U.S. and Canada. www.sterlingirb.com

Stiris Research Inc.
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-III 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 for successful partnerships.

SymBio, LLC
Contact: Betsey Zbyszynski
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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.

Syngene International Limited
Contact: Ismail Katta
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Website: www.syngeneintl.com

Syngene is a leading Asian CRO that provides a broad range of discovery, development, manufacturing & clinical development solutions to bio-pharma companies. Syngene comprises 2200+ expertise scientists & have more than 20+ years of track record in supporting IND/NDA/BLA/ANDA submissions in regulated markets. Our facilities have been inspected by several regulatory agencies, incl. US-FDA and EMA. Our animal facilities and bioanalytical labs are GLP certified and our central lab in CAP-accredited

Synchrogenix
Contact: Lauren Sobocinski
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Synchrogenix Information Strategies, Inc.
Contact: Trisha Vonder Reith
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Website: www.synchrogenix.com

Synchrogenix, powered by ClinGenuity, is a global regulatory/medical writing company of over 80 in-house writers and editors. We partner with pharmaceutical, biotech, and medical device companies providing technical and scientific writing in support of documents, filings, and communications to regulatory agencies worldwide. Our support is cross-functional; nonclinical, clinical, CMC, and drug safety; from pre-IND/IMPD through post-approval.

Synowledge
Contact: David Ingraham
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Website: www.synowledge.com

Synowledge is a global life sciences solutions company providing drug safety, regulatory affairs and relevant IT services. We provide industry thought leadership and competence in technology to innovate, optimize and maintain drug safety applications, business processes and other critical IT applications. Synowledge has offices in Miami (FL) (HQ), Greenwich (CT), Ireland, Germany, India, and Japan. In addition, a significant number of Synowledge experts work on client sites across the globe.

Syntheplast
Contact: Nagnath Jadhav
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Syntheplast (Nasdaq:SYNT) is leading global provider of digital transformation, information technology and knowledge process services. Our 24,000+ employees worldwide combine deep industry knowledge, a flexible Global Delivery Model and a collaborative partnership approach to create innovative solutions, sustainable business value and competitive advantage for our clients. Learn more at www.synthelinc.com.

SynteractHCR
Contact: Trisha Vonder Reith
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SynteractHCR is a full-service CRO with a successful track record supporting biotech, medical device and pharma companies in Phases I-IV clinical trials. With our “Shared Work – Shared Vision” philosophy we provide customized services collaboratively and cost effectively, ensuring on-time delivery of quality data. We deliver trials internationally in 16 countries, offering expertise across many therapeutic areas.
Target Health Inc.  
Contact: Warren Pearlson  
Email: wpearlson@targethealth.com  
Website: www.targethealth.com

Target Health Inc. is a New York City-based eCRO with staff dedicated to all aspects of Regulatory Affairs and Strategic Planning, Chemistry Manufacturing and Controls, Clinical Research, Biostatistics, Data Management and Medical Writing. Target Health has developed innovative web-based software that provides a transparent paperless environment and significant productivity edge.

Tarius A/S  
Contact: Eva L. Petersen  
Email: elp@tarius.com  
Website: www.tarius.com

Tarius’ Web Portals provide easy answers to your global FAQ’s! Subscribing to Tarius enables online access to updated regulatory information on Human Drugs, Biologics, Medical Devices and IVDs across 85 countries. Excel-tables enable quick comparison across countries. Experts’ summaries describe national regulatory procedures. Comprehensive compilations of local regulations ensure compliance. FDA Scientific Advisory Committee special reporting, Tarius SAC Tracker, keep you informed.

Tata Consultancy Services  
Contact: Mark Sekula  
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Website: www.tcs.com/clinicalresearch

TCS is one of the largest pure-play professional services, consulting and business solutions organization in the world in terms of market capitalization. 12 of the top 15 pharma & biotech, & 8 of the top 10 medical device companies leverage TCS services which cover: CDM, biostatistics, medical writing, regulatory, drug safety, drug discovery, drug development, manufacturing, pharma sales and distribution. TCS has 15,000+ consultants globally with 1800+ dedicated Clinical Research Professionals.

Technical Resources International, Inc.  
Contact: Anais Colin  
Email: acolin@tech-res.com  
Website: www.tech-res.com

As a CRO+, TRI possesses all the essential resources to offer first-class functional, project-based, and outsourcing services: quality operational, strategic, technical, and regulatory solutions, long-standing clinical trial expertise, and deep therapeutic knowledge. TRI offers health communication services such as multi-level event planning and execution, design and implementation of marketing and outreach campaigns, multimedia design, focus groups, surveys, trainings, and product launches.

Technology Catalysts International  
Contact: Sandra E Erb  
Email: info@technology-catalysts.com  
Website: www.technology-catalysts.com

TCI provides industry with analysis-driven consulting to achieve technology & business goals necessary for open innovation and product line growth & differentiation. Our expertise is in technology assessments, in- and out-licensing, business intelligence, market research, and mergers & acquisitions. TCI can help you identify the right strategic partners for future growth. TCI serves the Rx & OTC Pharmaceutical, Drug Delivery, Biotechnology, Diagnostic, Nutrition, and Personal Care industries.

Teuteberg Incorporated  
Contact: Meagan Guse  
Email: mguse@teuteberg.com  
Website: www.trialrecruitment.com

Teuteberg Incorporated is a global marketing services company specializing in Online and Social Media Marketing for Clinical Trial Patient Recruitment. We combine our extensive knowledge of online and social media marketing with rich analytics to create highly targeted campaigns that reduce the time and expense required to recruit patients.

Telerx  
Contact: Linda Comp  
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Telerx is an industry-leading business process outsourcer specializing in the multi-channel engagement of consumers, patients, healthcare professionals, and enterprise personnel via a network of global contact centers. Our unique customer-centric approach has made us the partner-of-choice for some of the world’s most trusted brands. For more than 30 years, we have been servicing Fortune 500 consumer goods and life sciences companies. Telerx supports clients 24/7, +100 countries and 30 languages.

TecHorizon  
Contact: Silvio Severini  
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TecHorizon is the alternative high technology service provider to the clinical research and healthcare industry. Our products are validated to GAMP5 standards, and data is securely hosted in our cutting edge infrastructure. If you are looking for an alternative technology partner who is more advanced and cost effective, you should consider TecHorizon.

TFDA / Center for Drug Evaluation, Taiwan  
Contact: Ms. Chiao-Yu Chan  
Email: cychan590@cde.org.tw  
Website: www.cde.org.tw

Taiwan Food and Drug Administration is the regulator of medical product registration in Taiwan, and Center for Drug Evaluation was established to assist in technical dossier review. Taiwan has one of fastest regulatory submissions processes in the Asia and hosts more than 100 clinical research sites, providing high quality medical care and clinical data. Taiwan adopts and recognizes all ICH guidelines, which are applied to NDA, BSE, IND submissions processes in the Asia and hosts more than 100 clinical research sites, providing high quality medical care and clinical data. Taiwan adopts and recognizes all ICH guidelines, which are applied to NDA, BSE, IND review process and GMP inspection.

The Clinical Resource Network  
Contact: David Iannucci  
Email: diannucci@crnspg.com  
Website: www.spccrn.com

CRN is an innovative and dynamic clinical contractor and project resourcing provider. We support Sponsors/CROs with Clinical Professionals, Data Management, SAS, Biostatistics, Pharmacovigilance, and Project Teams. Our solutions provide significant cost savings with an emphasis on quality and service delivery. If you are seeking clinical/data professionals or rewarding opportunities CRN sets the standard.
The Geneva Foundation
Contact: Bobbi Jo Briggs
Email: bbriggs@genevausa.org
Website: www.genevausa.org

As a leading foundation serving the military medical community, The Geneva Foundation has specialized capabilities in supporting federally funded research, conducting FDA-regulated clinical trials, and hosting conferences and events. The Geneva Foundation collaborates with experienced and novice researchers in military and academic settings within a wide variety of therapeutic areas. We support our military researchers by making the research process possible and accessible.

The Patient Recruiting Agency
Contact: Lance Nickers
Email: lance@tprausa.com
Website: www.patientrecruiting.com

TPRA's data-driven IN-HOUSE SOLUTIONS include: creative production, patient/physician outreach, site selection plus website & call prescreening. Now with RADIUS365™, TPRA's online platform to track & manage all response, referral, randomization & retention activities in real-time, TPRA is the Leader in Successful PATIENT RECRUITING & RETENTION.

The Uppsala Monitoring Centre
Contact: Mats Persson
Email: sales@umc-products.com
Website: www.umc-products.com

A non-profit foundation and WHO Collaborating Centre, managing the technical and scientific operations of the WHO Medicines Safety Programme. To be able to perform effective data management and signal detection, Uppsala Monitoring Centre (UMC) also manages VigiBase™, the WHO Drug Dictionaries and WHO-ART with their related tools and services.

Theorem Clinical Research
Contact: Sara Davis
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Website: www.theoremclinical.com

Theorem Clinical Research Inc. is a global provider of comprehensive clinical services with staff throughout the Americas, Europe and Asia-Pacific and a client base comprised of the world's leading biopharmaceutical and medical device companies. With industry-leading experts, unparalleled therapeutic expertise and innovative, groundbreaking technology, Theorem is focused on analytics-based development, combination trials and personal data applications to simplify complex trials.

Therapak Corporation
Contact: Arbi Harootoonian
Email: info@therapak.com
Website: www.therapak.com

Therapak is the global leader in providing 3rd party kit assembly and distribution services to pharmaceutical and laboratory organizations. Therapak's menu of services include assembly of lab convenience kits for collection of samples, temperature sensitive shipping systems, requisition and label printing and ancillary supply distribution direct to sites on a global basis. Therapak is a CGMP compliant organization with facilities in the US, UK and Singapore.

Therapeias Health Management
Contact: Bill Work

Therapeias, Inc. is The Dermatology CRO with unparalleled dermatology expertise & decades of experience. A full service CRO with numerous product approvals, TI designs and executes PHI-4 multicenter trials in acne, psoriasis, dermatitis, rosacea, alopecia, tissue fillers, inflammation, & all pediatric/adult derm categories. Guiding strategy, CMC, nonclin + clinical development, regulatory, trial management, DM+statistics, & life cycle management: concept, design, project planning/management.

Thomson Reuters
Contact: Thomson Reuters
Website: science.thomsonreuters.com/pharma

Thomson Reuters Life Sciences supports R&D productivity across the Pharma lifecycle with respected and comprehensive intelligence solutions. Offering unbiased scientific, competitive, regulatory, and generics information, analytics, and expertise for your organization, Thomson Reuters Life Sciences empowers and enables effective, evidence-based decision-making at every stage from discovery to launch and beyond. science.thomsonreuters.com/pharma

ThreeWire, Inc.
Contact: Bruce Gould
Email: bgould@threewire.com
Website: www.threewire.com

ThreeWire is a global patient recruitment, enrollment and management provider focused on accelerating patient recruitment and enrollment for the medical device, pharmaceutical, and biotech industries. We utilize a proven, flexible, systematic approach with predictable and measurable outcome-based strategies backed by performance-based pricing. Our customized recruitment programs provide valuable solutions and benefits for sponsors, CROs, sites and patients in North American and Europe.

TKL Research, Inc.
Contact: Lee R. Schwartz
Email: lschwartz@tklresearch.com
Website: www.tklresearch.com

TKL Research, Inc. is a full-service, Global CRO providing comprehensive trial management for Phase 1 - 4 studies. TKL now offers Pharmacovigilance Services and a fully renovated state-of-the-art Phase 1 and inpatient facility, located in Fairlawn, N.J. In addition, we have several specialized outpatient research clinics, conveniently located throughout the Metro Area. Since 1944, TKL has continued to deliver the highest level of services to Pharmaceutical and Biotech Industries

Total Clinical Trial Management
Contact: Aaron Berg
Email: aberg@totalcro.com
Website: www.totalcro.com

Total Clinical Trials Management (TCTM), is an emerging contract research organization based in Dallas, Texas. TCTM has a unique perspective on emphasizing the relationship with the clinical research site as a primary driver for successful clinical trial completion. TCTM has a wide range of therapeutic expertise with recent areas of focus including pain, orthopedic injury, dermatology, cosmetics, over-the-counter (OTC) and generic studies.
TransPerfect Booth: 1025
Contact: Ryan Simper  
Email: rsimper@transperfect.com  
Website: www.transperfect.com

TransPerfect leads the way in life sciences translation services and solutions. Our next-generation approach centers around innovation, combining cutting-edge workflow technologies with the industry's only quality management system fully certified to EN 15038:2006 and ISO 9001:2008. When it comes to clinical development, we speak your language.

Trifecta Booth: 1921
Contact: Dale Jackson  
Email: sales@trifectaclinical.com  
Website: www.trifectaclinical.com

Trifecta is a leading global clinical technology solutions provider, producing more than 350 live, on-demand, and web-based Investigator meetings each year in 87 countries. Trifecta's pioneering innovative training and portal solutions improve trial quality, speed study start-up and Site readiness, and improve workflow and communication between Sites, Sponsors and CROs.

Unanet Booth: 1152
Contact: Alexandra Nel
        
Website: www.unanet.com

Unanet Booth: 2401
Contact: Brett Huselton  
Email: info@ubc.com  
Website: www.ubc.com

UBC unites unsurpassed experience in generating real-world evidence of product safety, value, and effectiveness, with the strength of its parent company, Express Scripts, one of the nation’s largest healthcare companies. UBC leads the market in providing integrated, comprehensive preapproval, safety, and commercialization services.

University of Florida Booth: 1551
Contact: Rebecca Wilcox  
Email: rebecca.wilcox@apollidon.com  
Website: onlinepop.pharmacy.ufl.edu

The University of Florida Online MS in Pharmaceutical Outcomes & Policy is designed for working professionals to expand their career options. Tailor your degree to fit your goals. Choose from: Applied Pharmacoeconomics, Patient Safety & Medication Risk Management, Drug Regulatory Affairs, Pharmacy Regulation & Policy, and more.

University of Maryland Online MS in Regulatory Science Booth: 1147
Contact: Sharese Essien  
Email: sessien@rx.umaryland.edu  
Website: www.pharmacy.umaryland.edu/regulatoryscience

The University of Maryland School of Pharmacy’s Master of Science in Regulatory Science program is part-time and exclusively online - no classroom required. It’s a science-driven program focused on drug product development and regulation. The master’s degree is earned through completion of five online courses in less than two years.

University of Utah Clinical Trials Office Booth: 1725
Contact: Jaci Skidmore  
Email: jaciskidmore@hsc.utah.edu  
Website: utahclinicaltrialsoffice.org

The University of Utah Clinical Trials Office was established with a mission to provide clinical investigators and sponsors with comprehensive support services, research tools, personnel and facilities to conduct clinical research studies. Our experience includes working with special populations including neonatal, pediatric, adolescent, young adult, pregnant and geriatric participants. We offer services from protocol design, IND/IDE submissions, site activation, close-out and analysis.

UTMB Sealy Center for Vaccine Development Booth: 1657
Contact: Diane Barrett  
Email: dfbarret@utmb.edu  
Website: www.utmb.edu/scvd/

The Sealy Center for Vaccine Development (SCVD) at the University of Texas Medical Branch (UTMB) is a comprehensive vaccine center that develops and supports multidisciplinary programs in discovery, basic and applied research/preclinical development, clinical trials and clinical research, public health policy, community outreach and education/training.

Valesta Clinical Research Solutions Booth: 2629
Contact: Doug Fearon  
Email: info@us.valesta.com  
Website: www.valesta.com

Valesta Clinical Research Solutions is a proven industry leader in placing skilled clinical research professionals at all career levels in project-based, contract-to-hire, and direct hire opportunities, both locally and globally. We have a long track record of making successful job matches in specialized areas, including clinical data, clinical monitoring, medical writing, biometrics, and regulatory affairs.
MUSA is a service provider with specific expertise in the Life Sciences industry. Where GxP meets Technology, MUSA’s strategic compliance planning, scientific application support, Laboratory Services Program and Validated Cloud services fill the gap between traditional service providers and the business requirements of the BioPharma and Medical Devices industries.

Veeva Systems, Inc.
Contact: Brittany Machion
Email: contact@veeva.com
Website: www.veeva.com

Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 275 customers, ranging from the world’s largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Europe, Asia, and Latin America. For more information, visit www.veeva.com.

Verified Clinical Trials
Contact: Mitchell Efron
Email: DrEfrons@verifiedclinicaltrials.com
Website: www.verifiedclinicaltrials.com

Verified Clinical Trials is a research subject clinical trials database registry designed to prevent dual enrollment and several key protocol violations critical to a clinical trials success. VCT will improve safety and data quality in clinical trials. This will reduce adverse events and placebo rates. VCT has many functions that enhance the trial experience and safety while reducing liabilities in many arenas. VCT is partnered with a great number of the world’s largest research companies.

Veristat, Inc.
Contact: JoAnn Vormschlag
Email: info@veristat.com
Website: www.veristat.com

Veristat is a leading full-service clinical research organization and CDISC Solution Provider that provides strategic consulting, biostatistics, SAS programming, CDISC implementation and conversion, medical writing, clinical monitoring and safety, project management, and clinical data management services to speed the development of safe and effective drugs and therapeutics. Veristat provides robust regulatory submission strategies and can help with all regulatory preparation and representation.

Vingle & Associates Clinical Research
Contact: Sarah Stapleton
Email: info@vinceandassociates.com
Website: www.vinceandassociates.com

Vingle & Associates Clinical Research has been providing clinical research services to the global biopharmaceutical industry for fifteen years. Our premier clinical pharmacology unit conducts clinical trials with both HNVs and special populations. We have become one of the premier US clinical research sites by utilizing the Physician Research Model of operation where study teams are led by highly experienced Principal Investigators intricately involved in all aspects of the clinical trial process.

Viracor-IBT Laboratories
Contact: Dawn Denny
Email: dawn.denny@ViracorIBT.com
Website: www.viracoribt.com

Viracor-IBT Laboratories provides clinical trial biomarker testing services and large molecule/biologic support with expertise in custom assay transfer, design optimization and validation for phase I-IV trials. Our CAP/CLIA and NY state accredited laboratory has over 30 years of experience in molecular testing, immune response monitoring, vaccine safety/efficacy assessment, allergy and hypersensitivity testing. For more information, visit www.viracoribt.com

Viroclinics Biosciences
Contact: Cindy van Hagen
Email: vanhagen@viroclinics.com
Website: www.viroclinics.com

As a virology service organization, Viroclinics Biosciences performs preclinical studies, phase I – IV clinical trials studies including high throughput serology, virology and molecular assays, assay development services and clinical trial logistics services. By operating at a global level and being the virology testing laboratory for the top 10 biopharmaceutical companies, Viroclinics accelerate the development of vaccines, antivirals and in vitro diagnostics.

VirtualScopics
Contact: Carolyn Carpenter
Email: Carolyn_Carpenter@virtualscopics.com
Website: www.virtualscopics.com

VirtualScopics is a global imaging core lab with proven medical, imaging, operational and project management capabilities. Our expertise and experience includes integrating MRI, CT, DAX, PET, X-Ray, and ultrasound into the therapeutic areas of oncology, hematology, muscle disease, metabolic disease, and neuroscience for clinical trials.

Vitalograph, Inc.
Contact: John Buchholz
Email: john.buchholz@vitalograph.com
Website: www.vitalograph.com

Vitalograph is an industry leading manufacturer of cardio-respiratory diagnostic medical devices for use in clinics and in pharmaceutical clinical development. Vitalograph provide Standardized Equipment and Centralized Services for Spirometry, Cardiac Safety and eCOA data collection. Vitalograph offer independent, quality over-read services by industry experts in accordance with regulatory, industry and protocol requirements. Vitalograph, providing data you can rely on by people you can trust.

Voluntis
Contact: Sterenn Hamon
Website: www.voluntis.com

Voluntis believes in the necessity and complexity to manage jointly: technology, data, disease and patients. At Voluntis, we embrace this challenge by developing Therapeutic Companion Software. These are mobile or web applications that help the patient in their daily lives to manage his disease and his treatment. For example, by monitoring side-effects, by recommending dose treatment, ensuring adherence, providing connectivity between patient and HCP.
**WCCT Global**  
Contact: Matt Miller  
Email: Matt.Miller@wcct.com  
Website: www.wcct.com  

WCCT Global is a multi-site, full service pharmaceutical contract research organization (CRO) of outsourced early drug development and late phase services to the pharmaceutical, biotechnology and medical device industries. WCCT has extensive experience with healthy volunteer studies including First-in-Human (FIH), as well as specific therapeutic expertise in Allergy, Asthma, HCV, Ophthalmology, Dermatology, Influenza Challenge, Ethnobridging, Gastroenterology, Pain Management, and many more.

**WebbWrites, LLC**  
Contact: Laura A. Webb-Murrah  
Email: webb@webbwrites.com  
Website: www.webbwrites.com  

Extensive experience in regulatory document preparation, ability to provide a full range of statistical services, and provision of superior products due to continuity of personnel, flexibility to work onsite with clients, unsurpassed customer service, & capacity to meet aggressive timelines. WebbWrites has prepared > 86 NDAs in 17 years.

**Whitsell Innovations, Inc.**  
Contact: Natalie Becker  
Email: info@whitsellinnovations.com  
Website: www.whitsellinnovations.com  

At Whitsell Innovations, Inc., Medical and Scientific Writing Solutions, our expertise is regulatory and safety writing for clinical and CMC development. WI offers preclinical to postmarketing authoring, reviewing, and publishing from individual documents to full submissions. CSRs? Manuscripts? PBREs? Stability Reports? WI is your partner for all of your writing needs

**Wincere, Inc.**  
Contact: Linda Oshkou  
Email: info@wincere.com  
Website: www.wincere.com  

Wincere is a leading global Consulting CRO. We optimize, accelerate and transform your development cycle through a full suite of expert operational and emerging technological solutions: • Patented Trial Design Platforms • App-Enabled Flexible Processes • Tailored Risk-Based Monitoring Solutions • Clinical Data Management using leading EDC applications • Predictive Analytics • Cross-Industry Collaborations • Streamlined Clinical Support  

Develop a sustained competitive advantage with Wincere today.

**Wingspan Technology Inc.**  
Contact: Kathie Clark  
Email: kclark@wingspan.com  
Website: www.mywingspan.com  

Wingspan Technology, Inc, the leading provider of Documentum to SharePoint integration software, is the maker of DocWay and Wingspan eTMF. Founded in 1996, Wingspan boasts a talented engineering team, which provides in-depth industry knowledge and experience to companies in the life sciences and pharmaceutical industries.

**WIRB-Copernicus Group**  
Contact: Cara Deieso  
Email: cdeieso@wcgclinical.com  
Website: www.wcgclinical.com  

WIRB-Copernicus Group (WCG) is the world’s largest provider of regulatory and ethical solutions for clinical research. We provide IRB and IBC reviews, and our technology offerings include IRB workflow management solutions, clinical trial management software for sponsors and CROs, and Part-11 compliant online learning solutions for research professionals. WCG empowers clients to accelerate life-saving advancements, while ensuring that the risks of progress never outweigh the value of human life.

**Women in Life Sciences - WILS**  
Contact: Monique Garrett  
Email: mgarrett@prismworksonline.com  
Website: www.WOMENinLS.com  

Women in Life Sciences is a networking group that enables professional women to share ideas, insights, subject matter expertise and resources. We understand the power of collaboration, respectful dialogue and varying perspectives. We have regional meetings to discuss opportunities to advance women in the industry, promote mentorship and invite high profile speakers to share their insights and experiences. Learn more at www. WOMENinLS.com

**Woodley Equipment Company**  
Contact: Vijay Manchha  
Email: enquiries@woodleyequipment.com  
Website: www.woodleyequipment.com  

Woodley Equipment Company is a specialist global supplier of medical and laboratory equipment solutions to the Clinical Trials Industry. Woodley has 25 years experience of providing a full service from initial enquiry to global delivery and collection of equipment from multiple sites, technical support, servicing, calibration and training options.

**Worldwide Clinical Trials**  
Contact: Enrico de Leon, Jr, BS  
Email: info@wwctrials.com  
Website: www.wwctrials.com  

Worldwide Clinical Trials balances science, medicine, operations and commercial intelligence to help our clients achieve successful drug development. Our full-service capabilities, spanning all phases of development, combined with recognized therapeutic expertise—most notably in CNS, Cardiovascular, and Oncology—and a robust global operations platform, enable us to foster the development of life-changing medicines.

**X Factor Advertising**  
Contact: Autumn Foster  
Email: afoster@xfactoradvertising.com  
Website: www.xfactoradvertising.com  

X FACTOR ADVERTISING (XFA) is an industry leader in patient recruitment services. As a full-service agency, we specialize in the development and implementation of creative, media and tracking strategies to assist in the recruitment and retention of patients for clinical trials through the exclusive SMART™ System. XFA works with individual sites, CROs and pharmaceutical companies.
XClinical Services America Inc.  Booth: 2006  
Contact: Cathy Hlinka  
Email: cathan.hlinka@xclinical.com  
Website: www.xclinical.com

XClinical - Your complete package for post-marketing studies. eClinical software and services including flexible EDC, ePRO, CTMS, Randomization, CDM, coding, risk based monitoring, etc. Supporting multiple language capabilities, MARVIN EDC offers multiple alert capabilities; including patient reminders and SAE information delivered by customized, automatic emails.

XenoBiotic Laboratories, Inc.  Booth: 1903  
Contact: Heidi Schulze  
Email: heidi_schulze@xbl.com  
Website: www.XBL.com

XenoBiotic Laboratories(XBL), Inc. provides (non-)clinical bioanalytical, ADME/DMPK(in vitro/vivo) services to the pharmaceutical, animal health and agrochemical industries. XBL is AAALAC-accredited, FDA-/USDA-registered, NJ-licensed for work with radioisotopes, USDA-licensed for research on Schedule 1-5 controlled substances. XBL now is a subsidiary of WuXi PharmaTec Inc.(NYSE:WX) Lab Testing Division, a leading pharmaceutical, biotechnology, and medical device R &D outsourcing company.

Xerimis Inc.  Booth: 628  
Contact: Kevin Clover  
Email: kevin.clover@XERIMIS.com  
Website: www.XERIMIS.com

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Y-Prime Inc.  Booth: 1910  
Contact: Adam Blackburn  
Email: ablackburn@yprime.com  
Website: www.yprime.com

Working for industry leaders worldwide, we harness information to help clients effectively plan and manage clinical trials on time and within budget. By applying novel techniques to software, processes, and individuals within the enterprise, YPrime creates innovative and visual understanding of the sensitive ecosystem of companies involved in a clinical trial. Our collaborative approach to influence a successful project ultimately provides you with the peace of mind you seek.

Zigzag Associates Ltd  Booth: 1450  
Contact: Julie Beal  
Email: info@zigzag.eu.com  
Website: www.zigzag.eu.com

Our experienced, global team provides a full range of Quality Assurance services across the Good Practices. With a completely flexible approach, we provide you with the right resource, wherever you need it. Our global services include: auditing, including management of audit programmes; building PV systems for drug development and marketed products; training; inspection readiness and post-inspection support; gap analysis; QMS development; SOP writing and review; CAPA management; and general consultancy.
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>3500A</td>
<td>FDA form for mandatory reporting of adverse events</td>
</tr>
<tr>
<td>AD</td>
<td>Alzheimer's disease</td>
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<tr>
<td>ADaM</td>
<td>analysis data model</td>
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<tr>
<td>ADE</td>
<td>adverse drug event</td>
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<tr>
<td>ADR</td>
<td>adverse drug report or adverse drug reaction</td>
</tr>
<tr>
<td>AE</td>
<td>adverse event</td>
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<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Quality and Research</td>
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<tr>
<td>AL</td>
<td>adaptive licensing</td>
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<tr>
<td>ANDA</td>
<td>abbreviated new drug application</td>
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<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
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<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
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<tr>
<td>BA/BE</td>
<td>bioavailability/bioequivalence</td>
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<tr>
<td>BB IND</td>
<td>biological investigational new drug</td>
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<tr>
<td>BCE</td>
<td>beneficial clinical event</td>
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<tr>
<td>BDPA</td>
<td>Bureau of Drug Policy and Administration (China)</td>
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<td>BDS</td>
<td>Bureau of Drug Surveillance (Canada)</td>
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<tr>
<td>BISTIC</td>
<td>Biomedical Information Science and Technology Initiative Consortium (NIH)</td>
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<tr>
<td>BLA</td>
<td>biologics license application</td>
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<tr>
<td>BPA</td>
<td>Bureau of Pharmaceutical Assessment (Canada)</td>
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<td>BRA</td>
<td>benefit-risk assessment</td>
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<td>BTD</td>
<td>breakthrough therapy designation</td>
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<tr>
<td>BYOD</td>
<td>bring your own device</td>
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<tr>
<td>CCFDIE</td>
<td>China Center for Food and Drug International Exchange</td>
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<tr>
<td>CDASH</td>
<td>Clinical Data Acquisition Standards Harmonization</td>
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<td>CDDI</td>
<td>Collaboration for Drug Development Improvement</td>
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<td>CDISC</td>
<td>Clinical Data Interchange Standards Consortium</td>
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<td>CDM</td>
<td>clinical data management</td>
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<tr>
<td>CFAST</td>
<td>Coalition for Accelerating Standards and Therapies</td>
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<tr>
<td>CFDA</td>
<td>China Food and Drug Administration</td>
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<tr>
<td>CEN</td>
<td>Comite Europeen de Normalisation (European Committee for Standardization)</td>
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<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
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<tr>
<td>cGMP</td>
<td>current good manufacturing practice</td>
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<tr>
<td>CIOMS</td>
<td>Council for International Organizations of Medical Sciences</td>
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<tr>
<td>CLIA</td>
<td>Clinical Laboratory Improvement Amendments of 1988</td>
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<tr>
<td>CMS</td>
<td>Centers for Medicare and Medicaid Services</td>
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<td>CPMP</td>
<td>Committee for Proprietary Medicinal Products (EMA)</td>
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<tr>
<td>CRA</td>
<td>clinical research associate</td>
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<td>CRADA</td>
<td>cooperative research and development agreement</td>
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<td>CRC</td>
<td>clinical research coordinator</td>
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<td>CRF</td>
<td>case report form</td>
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<td>CRIX</td>
<td>Clinical Research Information Exchange (FDA and NCI)</td>
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<td>CRO</td>
<td>contract research organization</td>
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<td>CSA</td>
<td>clinical study agreement</td>
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<tr>
<td>CSDD</td>
<td>Center for the Study of Drug Development (Tufts University)</td>
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<tr>
<td>CSM</td>
<td>Committee on Safety of Medicines (UK)</td>
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<tr>
<td>CSR</td>
<td>clinical study report</td>
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<tr>
<td>CTA</td>
<td>clinical trial application</td>
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<td>CTD</td>
<td>common technical document</td>
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<tr>
<td>CTMS</td>
<td>Clinical Trial Management System</td>
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<tr>
<td>CTTI</td>
<td>Clinical Trials Transformation Initiative</td>
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<tr>
<td>DMC</td>
<td>data monitoring committee</td>
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<td>DSMB</td>
<td>Data Safety Monitoring Board</td>
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<td>DTC</td>
<td>direct-to-consumer</td>
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<td>DTP</td>
<td>direct-to-patient</td>
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<tr>
<td>DUR</td>
<td>drug utilization review</td>
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<tr>
<td>EAB</td>
<td>Ethics Advisory Board</td>
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<tr>
<td>eCTD</td>
<td>electronic common technical document</td>
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<tr>
<td>EDMS</td>
<td>Electronic Document Management System</td>
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<tr>
<td>EDQM</td>
<td>European Directorate for the Quality of Medicines</td>
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<tr>
<td>eIND</td>
<td>electronic investigational new drug application</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Records</td>
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<tr>
<td>EMA (EMEA)</td>
<td>European Medicines Agency (formerly European Medicines Evaluation Agency)</td>
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<td>EMR</td>
<td>Electronic Medical records</td>
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<td>ERB</td>
<td>Ethics Review Board</td>
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<td>ERS</td>
<td>electronic regulatory submission</td>
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<td>eSubs</td>
<td>electronic submissions</td>
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<td>ETASU</td>
<td>Elements to Assure Safe Use</td>
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<td>FAERS</td>
<td>FDA's Adverse Event Reporting System</td>
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<td>FD&amp;C Act</td>
<td>Federal Food, Drug and Cosmetic Act</td>
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<td>FDASIA</td>
<td>Food and Drug Administration Safety and Innovation Act</td>
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<tr>
<td>FIH</td>
<td>first-in-human (clinical trials)</td>
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<td>FPE</td>
<td>First Patient Enrolled</td>
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<td>FPI</td>
<td>First Patient In</td>
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<td>FRP</td>
<td>facilitated regulatory pathway</td>
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<td>FSP</td>
<td>functional service provider</td>
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<td>FU</td>
<td>Farmacopea Ufficiale (Italian Pharmacopoeia)</td>
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<tr>
<td>GAAP</td>
<td>Greater Access to Affordable Pharmaceuticals Act of 2003</td>
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<tr>
<td>GCP</td>
<td>good clinical practice</td>
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<td>GDUFA</td>
<td>Generic Drug User Fee Act</td>
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<td>GLP</td>
<td>good laboratory practice</td>
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<td>GMP</td>
<td>good manufacturing practice</td>
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<td>GRP</td>
<td>good regulatory practice</td>
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<td>GRWP</td>
<td>Good Regulatory Writer Practices</td>
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<td>GSP</td>
<td>Good Statistics Practice</td>
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<td>GXP</td>
<td>Good (any type) Practice</td>
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<td>HF</td>
<td>human factor</td>
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<td>HPB</td>
<td>Health Protection Board (Canada)</td>
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<td>IC</td>
<td>informed consent</td>
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<tr>
<td>ICD-9-CM</td>
<td>International Classification of Diseases, ninth revision, clinical modification</td>
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<tr>
<td>ICH</td>
<td>International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)</td>
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<td>ICMRA</td>
<td>International Coalition of Medicines Regulatory Authorities</td>
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<td>ICSR</td>
<td>Individual Case Safety Reports</td>
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<td>IDE</td>
<td>investigational device exemption</td>
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<td>IDMP</td>
<td>identification of medicinal products</td>
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<tr>
<td>IMDRF</td>
<td>International Medical Device Regulators Forum</td>
</tr>
<tr>
<td>IMI</td>
<td>Innovative Medicines Initiative</td>
</tr>
<tr>
<td>IND</td>
<td>investigational new drug</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
</tr>
<tr>
<td>IRB</td>
<td>Investigational Review Board</td>
</tr>
<tr>
<td>IRS</td>
<td>Incident Reporting System</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>LDT</td>
<td>laboratory developed test</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Lowest Observed Adverse Effect Level</td>
</tr>
<tr>
<td>LPE</td>
<td>Last Person Enrolled</td>
</tr>
<tr>
<td>LPI</td>
<td>Last person In</td>
</tr>
<tr>
<td>LPLV</td>
<td>Last Patient Last Visit</td>
</tr>
<tr>
<td>MAH</td>
<td>marketing authorization holder</td>
</tr>
<tr>
<td>MCA</td>
<td>Medicines Control Agency (part of MHRA)</td>
</tr>
<tr>
<td>MCDA</td>
<td>multi-criteria decision analysis</td>
</tr>
<tr>
<td>MedDRA</td>
<td>Medical Dictionary for Regulatory Activities</td>
</tr>
</tbody>
</table>
The following are divisions and offices within the US Food and Drug Administration (FDA)

**Glossary of Terms**

- MEDLARS: Medical Literature Analysis and Retrieval System (NLM)
- MedSuN: Medical Product Safety Network
- MFDS: Ministry of Food and Drug Safety (Republic of Korea)
- mHealth: mobile health
- MHLW: Ministry of Health, Labor and Welfare (Japan)
- MHRA: Medicines and Healthcare products Regulatory Agency (UK)
- MPA: Medical Products Agency (Sweden)
- MSL: medical science liaison
- 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)
- PAES: postauthorization efficacy study
- PAHO: Pan American Health Organization (WHO)
- PBRER: periodic benefit-risk evaluation report
- PCORI: Patient-Centered Outcomes Research Institute
- PCT: Pragmatic Clinical Trials
- PD: pharmacodynamics; protocol deviation
- PDHP: protocol deviation handling plan
- PDR: Physician’s Desk Reference
- PDUFA: Prescription Drug User Fee Act
- PFDD: Patient-Focused Drug Development (FDA initiative)
- PI: principal investigator
- PIP: Pediatric Investigational Plan
- PMDA: Pharmaceuticals and Medical Devices Agency (Japan)
- POL: patient opinion leader
- PPI: patient package insert
- PRAC: Pharmacovigilance Risk Assessment Committee
- PSP: Pediatric Study Plan
- PSUR: periodic safety update report
- PV: pharmacovigilance
- QbD: quality by design
- QL: quality of life
- QMS: quality management system
- RADR: WEB-Recognising Adverse Drug Reactions
- RBM: risk-based monitoring
- REMS: risk evaluation and mitigation strategies
- RIM: regulatory information management
- RMS: regulatory management system
- ROI: return on investment
- RoPR: Registry of Patient Registries
- RPS: regulated product submission
- 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
- SNA: social network analysis
- sNDA: supplemental new drug application
- SNOMED-RT: Systematized Nomenclature of Medicine Reference Terminology
- SCD: sudden cardiac death
- SUD: sudden unexpected death; single-use device
- TBP: therapeutic biologic product
- TE: therapeutic equivalence
- TFDA: Taiwan Food and Drug Administration
- THIN: The Health Improvement Network
- TIND: treatment investigational new drug
- TMF: trial master file
- 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
- **OBD**: Office of Biostatistics and Epidemiology
- **OBRR**: Office of Blood Research and Review
- **OCBQ**: Office of Compliance and Biologics Quality
- **OC**: Office of Compliance
- **OCBQ**: Office of Compliance and Business Informatics
- **OCTGT**: Office of Cellular, Tissue and Gene Therapies
- **OD**: Office of the Director
- **OM**: Office of Management
- **OVRR**: Office of Vaccines Research and Review
- **CDER**: Center for Drug Evaluation and Research Organization, FDA
- **OAP**: Office of Antimicrobial Products
- **OB**: Office of Biostatistics
- **OM**: Office of Manufacturing
- **OPQ**: Office of Pharmaceutical Quality
- **OPDP**: Office of Prescription Drug Promotion
- **OPI**: Office of Medical Policy
- **OMPI**: Office of Medical Policy Initiatives
- **OMC**: Office of Medical Policy Initiatives
- **OND**: Office of New Drugs
- **OR**: Office of Research
- **ORM**: Office of Regulatory Management
- **OPAAF**: Office of Pediatric Affairs and Federal Affairs
- **ORAM**: Office of Regulatory Affairs Management
- **ORC**: Office of Regulatory Compliance
- **ORP**: Office of Regulatory Programs
- **OSD**: Office of Science and Development
- **OSR**: Office of Science and Research
- **OVT**: Office of Veterinary Therapeutics
- **OTI**: Office of Therapeutics Integration
- **OTM**: Office of Therapeutic Medicine
- **OVP**: Office of Veterinary Policy
- **OVR**: Office of Veterinary Research

The content noted on this page was made available to DIA as of April 24.
Glossary of Terms

**OPRO**  Office of Program and Regulatory Operations
**OPSA**  Office of Program and Strategic Analysis
**ORP**  Office of Regulatory Policy
**OSE**  Office of Surveillance and Epidemiology
**OSI**  Office of Scientific Investigations
**OSP**  Office of Strategic Programs
**OTS**  Office of Translational Sciences
**OUDLC**  Office of Unapproved Drugs and Labeling Compliance

**CDRH**  Center for Devices and Radiological Health, FDA
**OC**  Office of Compliance
**OCDD**  Office of the Center Director
**OCE**  Office of Communication and Education
**ODE**  Office of Device Evaluation
**OIR**  Office of In Vitro Diagnostics and Radiologic Health
**OMO**  Office of Management Operations
**OSEL**  Office of Science and Engineering Laboratories
**OSB**  Office of Surveillance and Biometrics

**OC**  Office of the Commissioner, FDA
**OCC**  Office of the Chief Counsel
**OCS**  Office of the Chief Scientist
**OEA**  Office of External Affairs
**OL**  Office of Legislation
**OMH**  Office of Minority Health
**OPP**  Office of Policy and Planning
**OWH**  Office of Women's Health
**OGROP**  Office of Global Regulatory Operations and Policy, FDA
**OIP**  Office of International Programs
**OMPT**  Office of Medical Products and Tobacco, FDA (OC)
**OCP**  Office of Combination Products
**OGCP**  Office of Good Clinical Practice
**OOPD**  Office of Orphan Products Development
**OPT**  Office of Pediatric Therapeutics
**OSMP**  Office of Special Medical Programs
**ORA**  Office of Regulatory Affairs, FDA (OGROP)
**OCQPM**  Office of Communications and Quality Program Management
**OCI**  Office of Criminal Investigations
**OEIO**  Office of Enforcement and Import Operations
**OMPTO**  Office of Medical Products and Tobacco Operations
**OP**  Office of Partnerships
**OPRM**  Office of Policy and Risk Management
**ORM**  Office of Resource Management
**ORO**  Office of Operations
**ORS**  Office of Regulatory Science

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**SAE It Isn’t So**

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