FINAL PROGRAM

Develop | Innovate | Advance

DIA 2015

51ST Annual Meeting

JUNE 14–18 | WASHINGTON, DC

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Global Development
Global Launch
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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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Develop | Innovate | Advance

DIA 2015

51ST Annual Meeting

JUNE 14–18 | WASHINGTON, DC

SCHEDULE AT-A-GLANCE

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:

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*

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) 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)
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) 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:

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

Schedule:

8:15–9:00 AM	Coffee and Breakfast Breads
9:00–10:30 AM	Educational Opportunities
10:30–10:45 AM	Coffee Break
10:45 AM–12:15 PM	Educational Opportunities

As of April 28, 2015. Schedule subject to change.

Program Highlights

Keynote Speaker:
Daniel Burrus

President and CEO, Burrus Research Associates Inc.
Monday, June 15 | 2:30 PM | Ballroom

One of the World's Leading Futurists on Global Trends and Innovation

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

Guido Rasi, MD
Principal Adviser
European Medicines Agency
European Union

#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

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

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

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

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#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

Program Highlights

#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

#371 CBER Town Hall: Innovation and Public Health Response

Wednesday, June 17 | 1:30–3:00 PM

Steven A. Anderson, PhD
Director, Office of Biostatistics and Epidemiology, CBER, FDA

Theresa M. Finn, PhD
Associate Director for Regulatory Policy, Office of Vaccine Research and Review, CBER, FDA

Karen Midthun, MD
Director, CBER
FDA

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

#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

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

Patient Advocate Fellowship Program

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:

GLI Global Liver Institute

Myeloma Canada — Making Myeloma Matter

NEPHCURE Kidney International — Saving Kidneys • Saving Lives

Colon Cancer Alliance

mitocanada — awareness • support • research

YSC Young Survival Coalition — Young women facing breast cancer together

ABDA — American Behcet's Disease Association

The Life Raft Group

PHA Pulmonary Hypertension Association — Empowered by hope

CHI Congenital Hyperinsulinism International

The Hope Foundation — Because answers to cancers come from clinical trials

FARA Friedreich's Ataxia Research Alliance

SAVINGCASE

Allergy & Asthma Network

CDCN Castleman Disease Collaborative Network

National Brain Tumor Society

National Scoliosis Foundation

Cystinosis Research Network

Canadian Association for Porphyria

Association Canadienne de Porphyrie

The Transverse Myelitis Association

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

BBK WORLDWIDE

4:15 PM
#140 Are You Patient-Centric? Why Your Answer Must Be Yes

TEUTEBERG INCORPORATED

5:00 PM
#141 Expanding Patient Recruitment Globally With Social Media

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

Veeva

1:00 PM
#250 2015 Paperless Trial Master File (TMF) Survey: Trends and Insights

BBK WORLDWIDE

3:00 PM
#267 mHealth: Enhanced Engagement + Better Data = Improved Outcomes

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

SIGNiX

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.

DIA and You: Driving Ideas to Action

Learn more about the benefits you get as a DIA Member

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 7:15–8:00 AM
Wednesday, June 17 7:15–8:00 AM
Thursday, June 18 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


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Deborah Henderson, MSN
Merck & Co., Inc.


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


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Chesapeake IRB


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Rutgers, The State University
of New Jersey


Lynn King, MHA
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Agnes Klein, DrPH, MD
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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


Sarah Pope Miksinski, PhD
CDER, FDA


Badri Rengarajaran, DrMed
International Pemphigus and Pemphigoid Foundation


Matthew Rotelli, PhD
Eli Lilly and Company


Leslie Sam
Eli Lilly and Company


Abdul Sankoh, PhD, MA, MS
Synageva Biopharma


Suzanne Sensabaugh
Hartmann Willner LLC


Ashley Slagle, PhD, MS
CDER, FDA


Nancy Smerkanich, MSc
University of Southern California


Maureen Smith, MEd
Canadian Organization for Rare Disorders (CORD)


William Smith, MD
New Orleans Center For Clinical Research and Volunteer Research Group


Ling Su, PhD
Sidley Austin LLP, China


Sameer Thapar, PharmD
Rutgers, The State University of New Jersey


Toshiyoshi Tominaga, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)


Linda Wood, MPH, RN
MedWrite, Inc.

2015 DIA Fellows


Minnie Baylor-Henry, RPh, JD
(Incoming Chair)
President, B-Henry & Associates


Gaby L. Danan, MD, PhD
Pharmacovigilance Expert


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


Noriaki Murao, MS
Representative, NM Consulting


Jennifer L. Riggins, PharmD
Advisor, Digital Channels and eCapabilities, Eli Lilly and Company

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Canadian Organization For Rare Disorders (CORD)

Ning Xu, MD, MBA (ACC Chair)
Covance Pharmaceutical R&D (Beijing)

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.

Stay Connected

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

ANDROID APP ON Google play

Available on the App Store

HTML

DIA

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

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CenterWatch www.centerwatch.com

www.ciscrp.org/medhero5K-DC

MEDICAL HEROES APPRECIATION Walk

CISCRP

Medical Heroes Appreciation Walk

Monday, June 15, 2015 | 6:30–8:15 AM

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

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

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.

For 2016 5K Event Information or Sponsorship Opportunities:

Visit www.ciscrp.org/medhero5K
Email medhero5k@ciscrp.org
Toll Free 1-(877)-MED-HERO

CONTINUING EDUCATION

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

PROJECT MANAGEMENT

- 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

PORTFOLIO MANAGEMENT

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

STRATEGIC PLANNING

- Discuss project and portfolio management practices for strategic planning

TRACK 03: INNOVATIVE PARTNERING MODELS AND OUTSOURCING STRATEGIES

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

TRACK 04: 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 LIAISONS

- 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 the statement of CME, Pharmacy, Nursing, or PMI PDUs. IACET continuing education units (CEUs) are offered for all program offerings. Continuing education credits **are not available** for the Opening Plenary Session, Program Offerings # 226, 246, and 345, Student or Professional Poster Sessions/ Oral Presentations (Track 21), and Innovation Theater offerings (Track 20). Learning objectives for each program offering (and preconference tutorial, if applicable) will be shown in all meeting rooms.*

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

ACCREDITATION AND CREDIT DESIGNATION STATEMENTS

Accreditation Council for Continuing Medical Education (ACCME)

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Postgraduate Institute for Medicine (PIM) and the Drug Information Association (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.cpemonitor.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.

DISCLAIMER

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patient's conditions and possible contraindications on dangers in use, review of any applicable manufacturer's product information, and comparison with recommendations of other authorities. Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the DIA. Speakers, agenda, and CE information are subject to change without notice. Recording of any DIA educational material in any type of media is prohibited without prior written consent from DIA.

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 pharmacy contact hours or .15 pharmacy CEUs
- 1.5 nursing contact hours
- 1.5 PMI PDUs
- .2 IACET CEUs

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

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

DIA CERTIFICATE PROGRAMS

Individuals enrolled in DIA Certificate Programs may receive elective units for the designated 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 fair balance, 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/DIA2015evals. 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.

MEETING SCHEDULE BY DAY AND TIME

DIA 2015 51ST ANNUAL MEETING TRACKS AND INTEREST AREAS

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

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.

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

MONDAY, JUNE 15

8:30–10:00 AM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#101	Patient-Centricity: Buzzword or Method to Improve Operational Efficiency? △	145A	SESSION	Level: ■	Track 01A	PT, FI	CME, IACET, RN
#102	Next Generation Feasibility: How to Predict the Unpredictable and Plan for Success	145B	SYMPOSIUM	Level: ■	Track 01B	CR, RD	CME, IACET, RN
#103	Project Management of Adaptive Trials: Infrastructure and Methodology	101	FORUM	Level: ■	Track 02	PM, CR	CME, IACET, RN
#104	Adventures in Strategic Planning: Is the Functional Service Provider Model Dead? △	150A	FORUM	Level: ■	Track 03	SP	CME, IACET, RN
#105	In Vitro and In Vivo Preclinical Testing of Biosimilars: What Have We Learned?	103B	SESSION	Level: ■	Track 04	NC, RA, RD	CME, IACET, RN
#106	Communicating Pharmaceutical Risks and Benefits: Why Is It So Hard and How Can We Do Better?	206	FORUM	Level: ■	Track 06	MC	ACPE, CME, IACET, RN
#107	How Pharmaceutical Companies and CROs Are Harnessing Big Data and Cloud Computing to Increase R&D Innovation, Efficiency, and Collaboration	201	SESSION	Level: ■	Track 07A	EC, IT, RD	CME, IACET, RN
#108	How Sponsors Are Solving the Unique Data Collection Challenges of Late-Stage Studies	202B	SESSION	Level: ■	Track 07B	EC, IT	CME, IACET, RN
#109	Forward Progress Through Collaboration: Internal and External to the FDA	150B	FORUM	Level: ■	Track 08	CR	CME, IACET, RN
#110	Enabling Next Generation Sequencing Within Global Clinical Trials	151A	SESSION	Level: ■	Track 09	MDD, CR, RA	ACPE, CME, IACET, RN
#111	The Growing Role of the Patient Leading Into PDUFA VI: Negotiations and 2016	146B	FORUM	Level: ■	Track 10	RA, PT	ACPE, CME, IACET, RN
#112	Clinical Quality Management Systems in the New Millennium	102AB	SESSION	Level: ■	Track 11	CR	CME, IACET, RN
#113	Comprehensive Control Strategy: Building Confidence in Quality	151B	FORUM	Level: ■	Track 12	CMC/GMP	CME, IACET, PMI, RN
#114	Risk Management Plans Ten Years On: Where Are We Now and Where Are We Going?	207B	SESSION	Level: ■	Track 14	RA	ACPE, CME, IACET, RN
#115	DIA 2015 Student Forum: Job Hunter's Toolkit—Some Things Change, Some Stay the Same	147B	FORUM	Level: ■	Track 16	PETD	IACET
#116	Health Canada's Approach to Achieve Regulatory Harmonization: An Update	103A	FORUM	Level: ■	Track 18	RA, CR	CME, IACET, RN
#117	The Emerging Role of Medical Affairs in Biopharmaceutical Organizations: Challenges and Opportunities	152A	FORUM	Level: ■	Track 19A	SP	ACPE, CME, IACET, RN
#118	Ebola Virus Disease Case Study: Global Harmonization to Increase Power and Accelerate Outcomes in Clinical Research Data	152B	FORUM	Level: ●	Track 19B	CR	ACPE, CME, IACET, RN

9:30–4:30 PM Student Poster Session, Exhibit Hall (Entrance A) see page 104 for more details

11:00–12:30 PM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#119	Pediatric Clinical Trials: Learning from Patients, Parents, and Investigative Sites	145A	SESSION	Level: ●	Track 01A	CR, AHC/IS	ACPE, CME, IACET, RN
#120	The Clinical Trials Transformation Initiative Data Monitoring Committee Project: Findings and Next Steps	145B	SESSION	Level: ●	Track 01B	CR, PM	CME, IACET, RN
#121	Codevelopment of a Drug in the Pharmaceutical Industry: Is It Ever Fun?	101	FORUM	Level: ■	Track 02A	SP, RD	CME, IACET, RN
#122	How to Achieve Value of Operational Transformation: It Requires Innovation, Process Excellence, and Adoption	147A	WORKSHOP	Level: ◆	Track 02B	CR, PETD	CME, IACET, RN
#123	What Contract Research Organizations Value in a Partner: Results of a Perception Survey △	150A	SESSION	Level: ●	Track 03	CR, RD	CME, IACET, RN

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
	MONDAY, JUNE 15 (CONTINUED)						
#124	Next Generation Nanomedicines and Nanosimilars: Regulators' Perspective △	103B	SESSION	Level: ■	Track 04	BT, RA	CME, IACET, RN
#125	Engaging Patients and Health Care Professionals Through Social Media and Big Data Systems	206	SYMPOSIUM	Level: ■	Track 06	MC, PETD, RA	ACPE, CME, IACET, RN
#126	Integrating Patient Engagement with EHR Data and eSource for Better Studies △	201	SESSION	Level: ■	Track 07A	EC, PT	ACPE, CME, IACET, RN
#127	Evolving Your Regulatory Information Management Strategy to Meet the Changing Business Environment △	202B	SESSION	Level: ■	Track 07B	RA, SUBS	CME, IACET, RN
#128	Global Drug Development in China: Opportunities and Challenges for Innovation	150B	FORUM	Level: ●	Track 08	CR, RD	ACPE, CME, IACET, RN
#129	New Pandemics: Lessons Learned from the Ebola Experience	146B	FORUM	Level: ■	Track 10	RA	ACPE, CME, IACET, RN
#130	Clinical Quality by Design: From Theory to Practice	102AB	SESSION	Level: ■	Track 11	CR	CME, IACET, RN
#131	Reducing Drug Shortages	151B	SESSION	Level: ■	Track 12	RA	ACPE, CME, IACET, RN
#132	REMS Integration into the Health Care System: Three Perspectives in an Evolving Environment	207B	SESSION	Level: ■	Track 14	RA	ACPE, CME, IACET, RN
#133	Statistical Evaluation of Therapeutic Equivalence for Locally-Acting Generic Products	204BC	SESSION	Level: ■	Track 15	ST	ACPE, CME, IACET, RN
#134	The What, Why and How of Coaching and Its Application in the Work Place	147B	WORKSHOP	Level: ●	Track 16	PETD	CME, IACET, RN
#135	Facilitating Rare Disease Patient Participation in Clinical Trials	103A	SYMPOSIUM	Level: ●	Track 17	CR, PETD	CME, IACET, RN
#136	International Regulatory Convergence: Collaboration, Cooperation and Global Governance	143ABC	FORUM	Level: ●	Track 18	RA	CME, IACET, RN
	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						

#139

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.

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

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
MONDAY, JUNE 15 (CONTINUED)							
4:15–4:45 PM							
#140	BBK Worldwide Innovation Theater: Are You Patient-Centric? Why Your Answer Must Be Yes	Exhibit Hall (Entrance B)	Special Session	Level: ■	Track 20	CR, PT	No CE available
5:00–5:45 PM							
#141	Teuteberg Innovation Theater: Expanding Patient Recruitment Globally With Social Media	Exhibit Hall	Special Session	Level: ●	Track 20	CR, PT	No CE available
TUESDAY, JUNE 16							
8:00–9:30AM							
#201	The Development of Patient Power: From Consumer to Active Participant!	145A	SESSION	Level: ●	Track 01A	PT	ACPE, CME, IACET, RN
#202	The Role of Innovation in Clinical Trial Advocacy: Developing and Executing Patient-Centered Strategies and Partnerships Throughout the Continuum	145B	FORUM	Level: ■	Track 01B	CR, PT	ACPE, CME, IACET, RN
#203	The Art and Science of Portfolio Management	101	FORUM	Level: ■	Track 02	PM	CME, IACET, PMI, RN
#204	Centralized Ethics: How a Unique Partnership Between a CRO and an IRB Is Changing the Regulatory and Ethics Review Process △	150A	SESSION	Level: ■	Track 03A	RA, PM	CME, IACET, RN
#205	A Biopharmaceutical Company/Services Provider Partnership: Value to Both Companies and Progress to Date △	152A	SESSION	Level: ■	Track 03B	OS, CR	CME, IACET, RN
#206	Regulatory Examination of Nonclinical Testing Requirements and Juvenile Animal Studies	103A	SYMPOSIUM	Level: ■	Track 04	NC, RA	CME, IACET, RN
#207	Prescription Drug Marketing Regulatory Primer	152B	WORKSHOP	Level: ●	Track 05	RA	ACPE, CME, IACET, RN
#208	New Approaches to Submission Components	206	SYMPOSIUM	Level: ■	Track 06	MW, CR	CME, IACET, RN
#209	Implementing Risk-Based Monitoring	201	SYMPOSIUM	Level: ■	Track 07A	CDM, CR	ACPE, CME, IACET, RN
#210	International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP): Will Your Company Be Ready by 2016?	202B	SESSION	Level: ■	Track 07B	CDM, IT	CME, IACET, RN
#211	Can We Talk? Alternative Strategies for Communicating with FDA	150B	SESSION	Level: ■	Track 08A	CR, PETD	ACPE, CME, IACET, RN
#212	Global Regulation of Advanced Therapies	151A	SESSION	Level: ■	Track 08B	CR	ACPE, CME, IACET, RN
#213	Pediatric Therapeutic Development: From Policy to Portfolios to Patients	146B	FORUM	Level: ■	Track 10	RA	ACPE, CME, IACET, RN
#214	FDA GCP Compliance and Enforcement Updates	102AB	SESSION	Level: ■	Track 11	EC, CR, RA	CME, IACET, RN
#215	Learning By Doing: Regulatory Applications for Breakthrough Therapies △	151B	SESSION	Level: ■	Track 12	CMC/GMP	ACPE, CME, IACET, RN
#216	Remember That? Choosing Recall Intervals for Patient-Reported Outcome Measures	209AB	SESSION	Level: ■	Track 13A	SE, RA	ACPE, CME, IACET, RN
#217	Emerging Practices in Product Commercialization Planning: How Cross Collaboration Is Redefining Product Development Planning	207B	SYMPOSIUM	Level: ■	Track 13B	PR	CME, IACET, RN
#218	Social Media: Opportunities and Challenges in Pharmacovigilance and Clinical Research	207A	SESSION	Level: ■	Track 14A	CR	ACPE, CME, IACET, RN
#219	Safety in Special Situations: Vaccines, Stem Cells and Beyond	202A	SESSION	Level: ■	Track 14B	BT, CmbP	ACPE, CME, IACET, RN
#220	New Challenges for a Data Monitoring Committee	204BC	SESSION	Level: ■	Track 15	CR, ST	ACPE, CME, IACET, RN
#221	Moving the Role of the CRC and CRA into the 21st Century: Opportunities and Challenges △	103B	SESSION	Level: ■	Track 16	CR, PETD	CME, IACET, RN
#222	How to Succeed in Orphan Drug Regulatory Affairs △	146A	SESSION	Level: ■	Track 17	RA	CME, IACET, RN
#223	PMDA Town Hall	146C	FORUM	Level: ■	Track 18	RA, CP	CME, IACET, RN

TUESDAY, JUNE 16 (CONTINUED)

9:00 AM–4:00 PM Professional Poster Session #1, Exhibit Hall (Entrance A) see page 104 for more details

9:30–10:30 AM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#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

9:45–10:15 AM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#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

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#226	How Pharmaceutical Companies Can Engage Responsibly with Patients Online	145A	FORUM	Level: ■	Track 01	PT	No CE available
#227	Better Team Performance in Drug Development: Effective Relationship Building Across Cultures, Especially the West and Asia	101	FORUM	Level: ●	Track 02A	PETD	CME, IACET, RN
#228	Recent Trends in Facilitating Decision Making in Drug Development	103B	FORUM	Level: ◆	Track 02B	RD, PM	CME, IACET, RN
#229	Taking the Pulse of Outsourcing Relationship Structures and Their Impact △	150A	SESSION	Level: ■	Track 03	OS, CS	CME, IACET, RN
#230	Navigating Complex Biological and Regulatory Pathways to Bring Novel Gene and Cell Therapies to the Clinic	103A	SESSION	Level: ■	Track 04	NC, RA	ACPE, CME, IACET, RN
#231	FDA Enforcement Update: Advertising and Promotion	152B	FORUM	Level: ■	Track 05	RA	ACPE, CME, IACET, RN
#232	Efficient Authoring of Submission Documents △	206	SYMPOSIUM	Level: ●	Track 06	MW	CME, IACET, RN
#233	FDA Study Data Technical Conformance Guide (Part 1 of 2): An Overview	202A	SESSION	Level: ■	Track 07A	CDM, RA	CME, IACET, RN
#234	How to Trust Data from Wearable Devices Used in Clinical Trials	202B	SESSION	Level: ●	Track 07B	VA, CR, MDD	ACPE, CME, IACET, RN
#235	Good Regulatory Practice (GRP): A Regulatory Affairs Quality System for the 21st Century	151B	SESSION	Level: ■	Track 08A	OS, CR	CME, IACET, RN
#236	The State of Pediatric Research in the United States	151A	SESSION	Level: ■	Track 08B	CR	ACPE, CME, IACET, RN
#237	Impact of FDA Oversight of Laboratory-Developed Tests Upon Innovation in the Targeted Therapy Setting	150B	FORUM	Level: ■	Track 09	RA, MDD	ACPE, CME, IACET, RN
#238	Risk-Based Quality Management in Clinical Trials: From the Vision to Its Regulation and Implementation	102AB	SESSION	Level: ■	Track 11	CR, RA	CME, IACET, RN
#239	Office of Pharmaceutical Quality Update	146B	FORUM	Level: ■	Track 12	RA	ACPE, CME, IACET, RN
#240	Breakthrough Medicines or Affordable Health Care: Do We Have to Choose?	209AB	FORUM	Level: ■	Track 13	RD, PR, CR	ACPE, CME, IACET, RN
#241	21st Century Pharmacovigilance: Improving Outcome Traceability for Products Across the Complexity Continuum, From Generics to Biologics and Vaccines	207B	FORUM	Level: ■	Track 14	NC, RA	ACPE, CME, IACET, RN
#242	The Use of Adaptive and Bayesian Approaches in Clinical Trials: Sharing Experiences and Case Studies	204BC	FORUM	Level: ●	Track 15	CR	ACPE, CME, IACET, RN
#243	Networking: It's Not What You Know, But Who You Know!	147A	WORKSHOP	Level: ●	Track 16	PETD	IACET
#244	Rare Disease Organizations and Industry Players: Collaborating Effectively to Advance R&D for Rare Disease Patients	145B	SESSION	Level: ■	Track 17	RD, CR	CME, IACET, RN
#245	FDA's International Posts: International Efforts, Regulatory System Strengthening and Inspections	152A	FORUM	Level: ■	Track 18	RA, CR	ACPE, CME, IACET, RN

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Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
	TUESDAY, JUNE 16 (CONTINUED)						
#246	Using Registries to Support Recruitment in Alzheimer's Disease (AD) Prevention or Delay-of-Onset Studies	146C	SESSION	Level: ●	Track 19A	CR	No CE available
#247	Regulation of Combination Products in the 21st Century	201	FORUM	Level: ■	Track 19B	CmbP	ACPE, CME, IACET, RN
	11:35 AM–1:30 PM						
#248	Tuesday Oral Presentations—Professional Poster Session 1B See page 57 for presentation titles and times.	Exhibit Hall (Entrance A)	SYMPOSIUM	Level: ●	Track 21		No CE available
	12:00–12:45 PM						
#249	Quintiles Innovation Theater: Transform Clinical Development – Modernizing for Smarter Trials	Exhibit Hall (Entrance B)	Special Session	Level: ●	Track 20	CR, IT, AHC/IS	No CE available
	12:30–12:45 PM Student Poster Award Ceremony, DIA Booth #1523						
	1:00–1:30 PM						
#250	Veeva Innovation Theater: 2015 Paperless Trial Master File (TMF) Survey: Trends and Insights	Exhibit Hall (Entrance B)	Special Session	Level: ■	Track 20	IT, MW, SUBS	No CE available
	1:30–3:00 PM						
#251	Engaging Patients as Partners: Effective Trial Communications to Build Trust and Improve Patient Participation	146A	FORUM	Level: ●	Track 01A	PT, MC	CME, IACET, RN
#252	Implementing Risk-Based Monitoring: Best Practices from Pharmaceutical Industries to Contract Research Organizations	145B	SESSION	Level: ■	Track 01B	CR	CME, IACET, RN
#253	Life Cycle and Portfolio Management: Regulatory Agency and Pharmaceutical Company Approaches	101	SESSION	Level: ●	Track 02	PM, CP	CME, IACET, RN
#254	Collaborate to Innovate: Exploring a Seconds Market △	150A	SESSION	Level: ■	Track 03	RD	CME, IACET, RN
#255	Essential Approaches to Promotional Review of Mobile Health Apps: Technology That Is Here to Stay and Evolving Fast	152B	SESSION	Level: ■	Track 05	IT, MA, AP	ACPE, CME, IACET, RN
#256	Tool Is a Good Four-Letter Word	206	SYMPOSIUM	Level: ■	Track 06	MW, IT, SUBS	CME, IACET, RN
#257	Developing Online Communities: Perspectives for Site and Patient Engagement △	202B	SYMPOSIUM	Level: ■	Track 07A	EC, PT	ACPE, CME, IACET, RN
#258	FDA Study Data Technical Conformance Guide (Part 2 of 2): An Interactive Q&A Session	202A	FORUM	Level: ■	Track 07B	CDM, SUBS	CME, IACET, RN
#259	Transatlantic Collaboration on Pediatric Study Plan/ Pediatric Investigation Plan: Recent Experience	151A	SESSION	Level: ■	Track 08	SUBS	ACPE, CME, IACET, RN
#260	Success from Bench to Launch: Challenges and Opportunities with Development of Companion Diagnostics	150B	SESSION	Level: ■	Track 09	MDD	ACPE, CME, IACET, RN
#261	The Challenges and Opportunities of Digital Health Care: What Does the Future Hold?	146B	FORUM	Level: ■	Track 10	MDD	ACPE, CME, IACET, RN
#262	Roadmap to Measuring Clinical Trial Quality	102AB	SESSION	Level: ■	Track 11	CR	CME, IACET, RN
#263	Continuous Improvement and Innovation in Manufacturing Approaches △	152A	FORUM	Level: ■	Track 12	MF, CM	CME, IACET, RN
#264	European Medicines Agency Scientific Guidance on Postauthorization Efficacy Studies	151B	SESSION	Level: ●	Track 19A	RD	CME, IACET, RN
#265	Disruptive Forces in Health Care Innovation: Where Are They Leading Us?	143ABC	FORUM	Level: ■	Track 19B; All Tracks	CR, RA, IT	ACPE, CME, IACET, RN

TUESDAY, JUNE 16 (CONTINUED)

2:30–3:10 PM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#266	Tuesday Oral Presentations—Professional Poster Session 1C See page 62 for presentation titles and times.	Exhibit Hall (Entrance A)	SYMPOSIUM	Level: ●	Track 21		No CE available

3:00–3:30 PM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#267	BBK Worldwide Innovation Theater: mHealth: Enhanced Engagement + Better Data = Improved Outcomes	Exhibit Hall (Entrance B)	Special Session	Level: ■	Track 20	CR, IT, CDM	No CE available

3:30–5:00 PM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#268	Bringing Clinical Trial Practices into the 21st Century	146A	SYMPOSIUM	Level: ■	Track 01A	CR	ACPE, CME, IACET, RN
#269	Pediatric Clinical Trials: One Size Does Not Fit All	145B	SESSION	Level: ●	Track 01B	CR, PM	ACPE, CME, IACET, RN
#270	A Critical Examination of the Strengths and Weaknesses of Different Project Management Models	101	FORUM	Level: ◆	Track 02A	PM, PETD	CME, IACET, PMI, RN
#271	How Biomarkers Can Be Leveraged to Improve Return on Investment in Drug Development	102AB	FORUM	Level: ◆	Track 02B	CR, MDD	CME, IACET, RN
#272	Incorporating a VAT Tax Strategy Into Your Global Investigator Payment Plan △	103B	FORUM	Level: ■	Track 03A	FI, CR	IACET
#273	Getting More Out of Outsourcing Agreements: Value Additions Through Synergies and Process Optimization △	150A	SESSION	Level: ■	Track 03B	PM	CME, IACET, RN
#274	Striking a Balance Between Ethical Treatment and Impact on Nonclinical Safety and Animal Rule Efficacy Study Interpretation When Using Prophylactic or Supportive Care	103A	SESSION	Level: ■	Track 04	NC, RA	CME, IACET, RN
#275	The Free Exchange of Truthful and Non-Misleading Medical Information	152B	FORUM	Level: ■	Track 05	MC, RA, PPLC	ACPE, CME, IACET, RN
#276	Leadership and Process in Medical Writing	206	SYMPOSIUM	Level: ■	Track 06	MW, PETD	CME, IACET, RN
#277	How Risk-Based Monitoring and eSource Methodologies are Impacting Clinical Sites, Patients, Regulators and Sponsors	201	SYMPOSIUM	Level: ■	Track 07A	EC, CR, RA	ACPE, CME, IACET, RN
#278	Data and Evaluation Needed for Robust Evidence: Regulators' Challenges	202B	SESSION	Level: ■	Track 07B	CDM, RA	ACPE, CME, IACET, RN
#279	Getting the Most Out of Scientific Advice in the US and EU	151A	SESSION	Level: ■	Track 08A	CR	CME, IACET, RN
#280	Optimizing Patient Labeling: A Panel Discussion Between Industry, Academia, and Prescribers	151B	FORUM	Level: ■	Track 08B	PT, MC, AP	ACPE, CME, IACET, RN
#281	Continuing Growth in Combination Products: More Products, More Questions—Perspectives from FDA and Industry	150B	SESSION	Level: ■	Track 09	CmbP, RA, PPLCC	ACPE, CME, IACET, RN
#282	Progress Report on Emerging Nations and Regulatory Capacity Building	146B	SESSION	Level: ■	Track 10	RA	CME, IACET, RN
#283	Managing Protocol Deviations: Applying the Protocol Deviations Working Group SOP for Handling Protocol Deviations in Clinical Trials	147A	WORKSHOP	Level: ■	Track 11	GCP, CR	CME, IACET, RN
#284	CMC/GMP: Risk-Based Regulatory Review	152A	FORUM	Level: ■	Track 12	QC, CMC/GMP	ACPE, CME, IACET, PMI, RN
#285	Innovative Approaches to Patient Registries for Evaluating Outcomes	209AB	FORUM	Level: ■	Track 13	SE, IT, CR	ACPE, CME, IACET, RN
#286	Translating New Knowledge from Regulatory Science into Postmarketing Safety Practice	202A	FORUM	Level: ■	Track 14A	RA	ACPE, CME, IACET, RN
#287	Has the New Format PSUR/PBRER Achieved What Was Originally Intended?	207B	SESSION	Level: ■	Track 14B	RA	CME, IACET, RN
#288	Predictive Subgroup Methodologies and Molecular Basket Designs	204BC	SESSION	Level: ■	Track 15	CR	ACPE, CME, IACET, RN
#289	Conflict Resolution: Helping Teams Manage Through Conflict	147B	WORKSHOP	Level: ●	Track 16	PETD	ACPE, CME, IACET, RN
#290	Pediatric Drug Development △	145A	SESSION	Level: ■	Track 17	CR, RA	ACPE, CME, IACET, RN

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Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
TUESDAY, JUNE 16 (CONTINUED)							
#291	CDRH Town Hall	146C	FORUM	Level: ■	Track 18A	MDD, CmbP	ACPE, CME, IACET, RN
#292	Chinese Drug Development: An Update	207A	FORUM	Level: ■	Track 18B	RA	CME, IACET, RN
WEDNESDAY, JUNE 17							
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	CEHTAEbM	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

WEDNESDAY, JUNE 17 (CONTINUED)

9:45–10:15 AM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#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

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#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 Guidances 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

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

WEDNESDAY, JUNE 17 (CONTINUED)

11:35 AM–1:30 PM

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
#346	Wednesday Oral Presentations—Professional Poster Session 2B See page 82 for presentation titles and times.	Exhibit Hall (Entrance A)	SYMPOSIUM	Level: ●	Track 21		No CE available

12:00–12:30 PM

#347	SAS Innovation Theater: Accelerate Value-Based Drug Development With Analytics	Exhibit Hall (Entrance B)	Special Session	Level: ■	Track 20	IT, RD	No CE available

12:45–1:30 PM

#348	Quintiles Innovation Theater: Driving Better Decision-Making with Real-World Data and Analytics	Exhibit Hall (Entrance B)	Special Session	Level: ●	Track 20	CEHTAEbM, CR, IT	No CE available

1:30–3:00 PM

#349	Cardiac Safety Considerations in Pediatric Drug Development	146C	SESSION	Level: ■	Track 01A	CR, CP	ACPE, CME, IACET, RN
#350	Is Facebook Hurting Your Trial? Social Media and the Introduction of Bias in Clinical Studies	146A	SESSION	Level: ■	Track 01B	CR	ACPE, CME, IACET, RN
#351	Project Management in Context: Reflections on the Project Manager Role from Other High-Risk Industries	101	SESSION	Level: ■	Track 02A	PETD	CME, IACET, PMI, RN
#352	Issue Resolution in Clinical Partnerships	103B	FORUM	Level: ■	Track 02B	CR	CME, IACET, RN
#353	The Voice of the Sites: Collaborating to Build a Site Partnership Model to Enable Study Start-Up	150A	FORUM	Level: ■	Track 03	CR	CME, IACET, RN
#354	Effective Discovery, Development and Use of Biomarkers in Early Drug Development	103A	SYMPOSIUM	Level: ■	Track 04	NC, CR	ACPE, CME, IACET, RN
#355	Globalization of Field Medical Science Liaisons: How to Take It to the Next Level	206	SESSION	Level: ■	Track 06	MSL	ACPE, CME, IACET, RN
#356	Searching for the Gold Nuggets: Text Analysis in Clinical Data	201	SESSION	Level: ■	Track 07A	IT, CDM, SE	ACPE, CME, IACET, RN
#357	Frontier Issues in Electronic Information Integrity Today	202B	SYMPOSIUM	Level: ■	Track 07B	VA, IT	CME, IACET, RN
#358	Expediting Drug Development Through FDA's Breakthrough Therapy Designation	150B	SESSION	Level: ■	Track 08A	CR, PPLC	ACPE, CME, IACET, RN
#359	Does Bioequivalent Always Mean Therapeutically Equivalent? Impact of FDA's Proposed Rule on Generic Labeling	151A	SESSION	Level: ●	Track 08B	AP	ACPE, CME, IACET, RN
#360	Regulatory Framework for Medical Devices in Europe △	152A	SESSION	Level: ■	Track 09	MDD, CR, CP	CME, IACET, RN
#361	The Challenges, Solutions and Right To Try Surrounding Expanded Access	146B	FORUM	Level: ■	Track 10	CR, RA	ACPE, CME, IACET, RN
#362	Using Data Analytics to Detect Quality Issues	202A	SESSION	Level: ■	Track 11	CR	CME, IACET, RN
#363	Risk-Based Inspections and Compliance	151B	FORUM	Level: ■	Track 12	CP	ACPE, CME, IACET, RN
#364	Operationalizing the Pragmatic Clinical Trial: The Role of PCORI and the Pharmaceutical Industry	209AB	SESSION	Level: ●	Track 13	CR	ACPE, CME, IACET, RN
#365	A Proactive and Systematic Approach to Managing Product Risk Across the Life Cycle	204BC	SESSION	Level: ■	Track 14A	RD	ACPE, CME, IACET, RN
#366	Measuring the Impact of Regulatory Pharmacovigilance in Europe and the United States	207A	SESSION	Level: ■	Track 14B	RA	CME, IACET, RN
#367	Big and MultiStream Data for Drug Evaluation: The Promise and Cautions	145A	FORUM	Level: ■	Track 15	CP, CR	CME, IACET, RN
#368	Conducting Courageous Conversations as a Strategy to Work with Difficult People	147A	WORKSHOP	Level: ■	Track 16A	PETD	ACPE, CME, IACET, RN
#369	Using Games and Play to Create an Innovative Learning Experience	147B	WORKSHOP	Level: ●	Track 16B	PETD	CME, IACET, RN

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
	WEDNESDAY, JUNE 17 (CONTINUED)						
#370	A Global Update on Orphan Drugs	145B	SYMPOSIUM	Level: ■	Track 17	RA	ACPE, CME, IACET, RN
#371	CBER Town Hall: Innovation and Public Health Response	152B	FORUM	Level: ■	Track 18	RA	ACPE, CME, IACET, RN
#372	No More Crying Wolf: FDA Issues Final Rule on Changes to Pregnancy and Lactation Information in Drug Labeling	207B	SESSION	Level: ■	Track 19A	RA	ACPE, CME, IACET, RN
#373	TransCelerate Collaboration: Harmonization Efforts to Find Solutions to Critical Industry Challenges	102AB	SESSION	Level: ●	Track 19B	CR	CME, IACET, RN
	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 08	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

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

Offering Number	Title of Offering	Room Number	Type of Format	Level of Difficulty	Track Number	Interest Area(s)	Continuing Education Credits
WEDNESDAY, JUNE 17 (CONTINUED)							
#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
#412	Mobile Health, Telemedicine, and Remote Sensors in Clinical Investigations: A New Era in Clinical Trial Design?	146C	FORUM	Level: ●	Track 19	EC	ACPE, 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

Drug Safety:

Are You and Your Staff Prepared?

DIA's Drug Safety eLearning Program is Your Training Solution to Reduce Risk

Drug safety is a primary concern throughout the medical product development life cycle. Developed with DIA expertise to meet the unique needs of our stakeholders and members, this online safety program provides the knowledge you and your staff needs, from regulations and requirements through premarket review and postmarket monitoring.

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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*

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:

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.*

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers/instructors are their own opinion and not necessarily that of the organization they represent, or that of the DIA. Speakers/instructors and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media is prohibited without prior written consent from DIA.

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)
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

8:30–9:30 AM △ Level: ■ Format: SESSION
Room 145A *CME and Nursing*

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 DiBiaso, 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

#102 Track 01B – Clinical Operations

Related Interest Area(s): CR, RD

8:30–10:00 AM | Level: ■ | Format: SYMPOSIUM
Room 145B | *CME and Nursing*

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.

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 McCorkle
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 | Level: ■ | Format: FORUM
Room 101 | *CME and Nursing*

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.

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 △ | Level: ■ | Format: FORUM
Room 150A | *CME and Nursing*

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 | Level: ■ | Format: SESSION
Room 103B | *CME and Nursing*

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.

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

Comparing Complex Medicines Using Multisystem Gene Expression Profiling: A Critical Piece of the "Sameness" Puzzle
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

Related Interest Area(s): MC

8:30–10:00 AM | Level: ■ | Format: FORUM
Room 206 | *CME, Pharmacy, and Nursing*

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

CHAIRPERSON
Brian David Edwards, MD, MRCP
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)

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

Related Interest Area(s): EC, IT, RD

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 201 | *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.

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

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

Related Interest Area(s): EC, IT

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 202B | *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.

#109 Track 08 – Regulatory Affairs

Related Interest Area(s): CR

8:30–10:00 AM | Level: ■ | Format: FORUM
Room 150B | *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

Harmonizing Global Regulatory Agency Collaboration in Pediatric Drug Development
Andrew E. Mulberg, MD
Deputy Division Director, Gastroenterology and Inborn Errors Products, Office of New Drugs, CDER, FDA

Collaborative Development of 2-Hydroxypropyl-ß-Cyclodextrin for Niemann-Pick Disease, Type C
Denny Porter, MD, PhD
Clinical Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH

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

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

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 151A | *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 InVitro Diagnostics and Radiological Health, CDRH, FDA

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

Related Interest Area(s): RA, PT

8:30–10:00 AM | Level: ■ | Format: FORUM
Room 146B | *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, Biomarin Pharmaceutical Inc.

#112 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR

8:30–10:00 AM | Level: ■ | Format: SESSION
Room 102AB | *CME and Nursing*

Clinical Quality Management Systems in the New Millennium

CHAIRPERSON
Deborah Driscoll, MS
Vice President, Quality Assurance, Medical Division, Pfizer Inc

This session will describe ongoing activities of a TransCelerate BioPharma workstream evaluating clinical quality management system (QMS). Panelists will discuss ongoing development of a concept paper describing a progressive clinical QMS framework designed to provide a consistent, streamlined, and proactive quality approach across all stages of clinical research.

FDA Perspective
Jean M. Mulinde, 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, Bioresearch Quality and Compliance, Janssen Pharmaceuticals, Inc.

Issue Management
Leslie M. Sam
Director, Global Quality Systems, Eli Lilly and Company

#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

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

8:30–10:00 AM | Level: ■ | Format: FORUM
Room 152A | *CME, Pharmacy, and Nursing*

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

8:30–10:00 AM | Level: ● | Format: FORUM
Room 152B | *CME, Pharmacy, and Nursing*

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

9:30 AM–4:30 PM

Student Poster Session–Exhibit Hall (Entrance A)
See page 104 for details.

10:00–11:00 PM

Coffee Break in Exhibit Hall

#119 Track 01A – Clinical Operations

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

11:00 AM–12:30 PM | Level: ● | Format: SESSION
Room 145A | *CME, Pharmacy, and Nursing*

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 | Level: ● | Format: SESSION
Room 145B | *CME and Nursing*

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 | Level: ■ | Format: FORUM
Room 101 | *CME and Nursing*

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 | Level: ◆ | Format: WORKSHOP
Room 147A | *CME and Nursing*

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 △ | Level: ● | Format: SESSION
Room 150A | *CME and Nursing*

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

#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.

FDASIA Section 1138: Meeting the Challenges and Opportunities in Outreach and Communication – Social Media Landscape
Ginneh D. Stowe, MS
Health Communication Specialist, Office of Communications, CDER, FDA

Are Medical Information Teams Using Social Media to Engage Health Care Professionals and Patients?
Omudhome Ogbru, PharmD
Business Initiative Manager, Medical Communications, ArisGlobal

Using Big Data Systems to Understand Health Care Professional Conversations in Public Social Media
Paul Grant
Chief Innovation Officer, Creation Healthcare, United Kingdom

#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

discussed. The speakers will detail how other companies are approaching these changes and evolving their RIM strategies and investment plans.

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

#128 Track 08 – Regulatory Affairs

Related Interest Area(s): CR, RD

11:00 AM–12:30 PM Level: ● Format: FORUM
Room 150B *CME, Pharmacy, and Nursing*

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

China has very dynamic regulatory policies in driving the development of innovative drugs. This forum will share experiences on regulatory opportunities and barriers that will impact development and availability of new drugs in China.

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)

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

Related Interest Area(s): RA

11:00 AM–12:30 PM Level: ■ Format: FORUM
Room 146B *CME, Pharmacy, and Nursing*

New Pandemics: Lessons Learned from the Ebola Experience

CHAIRPERSON
Diane Berry, PhD
Vice President, Global Health Policy and Government Affairs, Sarepta Therapeutics

Pandemics pop up periodically; as regulators and innovators, we try to quash them as quickly as we can. Ebola has been a frightening experience and demonstrates the speed at which a disease, previously contained by remoteness, can spread and cause panicked public reactions. On the regulatory, funding and preparedness fronts, this forum will help elucidate what we learned from 2014's Ebola outbreak, and how agencies and public health organizations are preparing for the next global challenge. We will hear some "war stories" about the challenges of coordinating a global response and the difficulties of coordinating across agencies in exigent circumstances and hear ideas of how to avoid these problems in the future.

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

FDA Point of View
Luciana Borio, MD
Acting Chief Scientist, Office of the Chief Scientist, Office of the Commissioner, FDA

#130 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR

11:00 AM–12:30 PM Level: ■ Format: SESSION
Room 102AB *CME and Nursing*

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

#131 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA

11:00 AM–12:30 PM | Level: ■ | Format: SESSION
Room 151B | *CME, Pharmacy, and Nursing*

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

Related Interest Area(s): RA

11:00 AM–12:30 PM | Level: ■ | Format: SESSION
Room 207B | *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

Related Interest Area(s): ST

11:00 AM–12:30 PM | Level: ■ | Format: SESSION
Room 204BC | *CME, Pharmacy, and Nursing*

Statistical Evaluation of Therapeutic Equivalence for Locally-Acting Generic Products

CHAIRPERSON
Stella C. Grosser, PhD
Acting Director, Division of Biometrics VIII, Office of Biostatistics, 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

Related Interest Area(s): PETD

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

***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
Nicky Rousseau, CPA
Senior Director, Program Management, Quintiles Inc.

Mieke Jobsis
Director, Quality and Risk Management, GlaxoSmithKline

#135 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, PETD

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 debilitated 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

Related Interest Area(s): RA

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

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

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

Related Interest Area(s): n/a

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

Ballroom | *No CE available*

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

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.

#140 Track 20 – Innovation Theater

Related Interest Area(s): CR, PT

4:15–4:45 PM | Level: ■ | Format: SPECSESS

Exhibit Hall | *No CE available.*

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

Related Interest Area(s): CR, PT

5:00–5:45 PM | Level: ● | Format: SPECSESS

Exhibit Hall | *No CE available*

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.

Download DIA's app by searching DIAGlobal in your App Store.

The content noted on this page was made available to DIA as of April 27.

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)
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) 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 Entrance B) Innovation Theater Presentations (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 Level: ● 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.

Collecting Research Data Directly from Consumers: The PROTECT Pregnancy Study
Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

Measuring Patient Engagement and Patient-Centricity
Michael Howley, PhD
Associate Clinical Professor; Chief Science Officer, CRO Analytics, Drexel University

Patient First Drug Development Across the Product Life Cycle
Sally Okun, RN
Vice President, Advocacy, Policy and Patient Safety, PatientsLikeMe

#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: ■ 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: ■ 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: ■ 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.

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

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

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.

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

#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, FRCP
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, FRCP
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*

Emerging Practices in Product Commercialization Planning: How Cross Collaboration Is Redefining Product Development Planning

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.

Social Media: The Impact on Clinical Studies
Alexis Reisin Miller, JD
Senior Director, Regulatory Policy and Intelligence, Eisai Inc.

Digital Drug Safety
John S. Brownstein, PhD
Manager, Computational Epidemiology Group and Associate Professor, Boston Children's Hospital and Harvard Medical School

Social Media Analytics
Martin Harvey Allchurch, Esq, LLM
International Affairs, European Medicines Agency, European Union

#219 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): BT, CmbP

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 202A | *CME, Pharmacy, and Nursing*

Safety in Special Situations: Vaccines, Stem Cells and Beyond

CHAIRPERSON
Joy A. Cavagnaro, PhD, RAC
President, Access BIO

This symposium will provide insights on the key safety considerations influenced by product specific attributes of vaccines, stem cells and novel combination therapies.

Vaccines
Julia Barrett, MD, MPH
Senior Clinical Consultant, Biologics Consulting Group, Inc.

Stem Cells
Curtis L. Scribner
Consultant, CLSCRIBS Consulting

Clinical and Regulatory Considerations for Cell Therapy Development
Alexander Fleming, MD
President and Chief Operating Officer, Kinexum

#220 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, ST

8:00–9:30 AM | Level: ■ | Format: SESSION
Room 204BC | *CME, Pharmacy, and Nursing*

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: Confidentialty 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

#221 Track 16 – Professional Development

Related Interest Area(s): CR, PETD

8:00–9:00 AM △ | Level: ■ | Format: SESSION
Room 103B | *CME and Nursing*

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.

Designing the Future of the Role of the Clinical Research Coordinator
Claudia Christy
Consultant

#222 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): RA

8:00–9:00 AM △ | Level: ■ | Format: SESSION
Room 146A | *CME and Nursing*

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 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

#223 Track 18 – Global Regulatory

Related Interest Area(s): RA, CP

8:00–9:30 AM | Level: ■ | Format: FORUM
Room 146C | *CME and Nursing*

PMDA Town Hall

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

Representatives from PMDA will explain the progress of its third Five-Year Mid-Term plan, including the future initiative/challenges for faster review and better life cycle management of drugs. The audience will be provided an opportunity to ask questions to the panel.

New Regulation in Japan and Future Direction of PMDA
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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

New Streams of Risk Management
Tomiko Tawaragi
Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

9:00 AM–4:00 PM

Professional Poster Session #1–Exhibit Hall (Entrance A)

See page 104 for details.

9:30–10:30 AM

Coffee Break & Innovation Theater Presentations (Exhibit Hall)

#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
- 9:42–9:47AM—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—T07 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

Related Interest Area(s): IT, CR

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

Related Interest Area(s): PT

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

Related Interest Area(s): PETD

10:30 AM–12:00 PM | Level: ● | Format: FORUM
Room 101 | *CME and Nursing*

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

Related Interest Area(s): RD, PM

10:30 AM–12:00 PM | Level: ◆ | Format: FORUM
Room 103B | *CME and Nursing*

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

Related Interest Area(s): OS, CS

10:30–11:30 AM △ | Level: ■ | Format: SESSION
Room 150A | *CME and Nursing*

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

Related Interest Area(s): NC, RA

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 103A | *CME, Pharmacy, and Nursing*

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)

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

Related Interest Area(s): RA

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 guidances 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

Related Interest Area(s): MW

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.

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

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

Related Interest Area(s): CDM, RA

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 202A | *CME and Nursing*

FDA Study Data Technical Conformance Guide (Part 1 of 2): An Overview

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

This session will provide an overview of the FDA supplements 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.

Part 2 will take place on Tuesday at 1:30 PM (Session #258).

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

Clinical Perspective
Eileen E. Navarro Almario, MD
Lead Medical Officer, Office of Computational Sciences, Office of Translational Sciences, CDER, FDA

eSub Perspective
Virginia Hussong
Acting Director, Division of Data Management Services and Solutions, Office of Business Informatics, Office of Strategic Programs, CDER, FDA

Industry Perspective
Scott A. Getzin
Consultant, Data Sciences - Clinical Data Flow and Technologies, Eli Lilly and Company

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

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

10:30 AM–12:00 PM | Level: ● | Format: SESSION

Room 202B | *CME, Pharmacy, and Nursing*

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

#235 Track 08A – Regulatory Affairs

Related Interest Area(s): OS, CR

10:30 AM–12:00 PM | Level: ■ | Format: SESSION

Room 151B | *CME and Nursing*

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, Kinapse Ltd, United Kingdom

How to Audit a Regulatory Affairs Value Chain
Theresa R. Haughey, MBA
Senior Director, Regulatory Affairs Quality Assurance, GlaxoSmithKline

#236 Track 08B – Regulatory Affairs

Related Interest Area(s): CR

10:30 AM–12:00 PM | Level: ■ | Format: SESSION

Room 151A | *CME, Pharmacy, and Nursing*

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 permanant 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

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

Related Interest Area(s): RA, MDD

10:30 AM–12:00 PM | Level: ■ | Format: FORUM

Room 150B | *CME, Pharmacy, and Nursing*

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

10:30 AM–12:00 PM Level: ■ Format: SESSION
Room 102AB *CME and Nursing*

Risk-Based Quality Management in Clinical Trials: From the Vision to Its Regulation and Implementation

CHAIRPERSON
Anabela Marcal, PharmD
Head of Compliance and Inspections Department, European Medicines Agency, European Union

This session will provide an overview on the regulator's vision to risk-based approaches and how some of these expectations are intended to be regulated through the ICH E6 GCP guideline and the challenges faced by industry in translating those expectations in the design and conduct of clinical trials.

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

#239 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 146B *CME, Pharmacy, and Nursing*

Office of Pharmaceutical Quality Update

CHAIRPERSON
Lawrence X. Yu, PhD
Deputy Director, Office of Pharmaceutical Quality, CDER, FDA

This forum will discuss how the new structure of the Office of Pharmaceutical Quality (OPQ) further enhances CDER's Good Manufacturing Processes (GMPs) for the 21st Century Initiative by creating an integrated drug quality program. As part of its mission, OPQ will streamline quality assessment throughout the product life cycle, including the integration of pre- and postapproval review, surveillance and inspectional functions.

One Quality Voice: Reality or Hype?
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA

Integrated Quality Assessment
Sarah Pope Miksinski, PhD
Acting Director, Office of New Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Integrated Quality Assessment: The How and What of One Quality Voice
Giuseppe Randazzo
Acting Director, Office of Program and Regulatory Operations, Office of Pharmaceutical Quality, CDER, FDA

Panelist
Representative Invited
Director, (Acting) Pharmaceutical Quality Program, Office of Regulatory Affairs, OGROP

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

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

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 209AB *CME, Pharmacy, and Nursing*

Breakthrough Medicines or Affordable Health Care: Do We Have to Choose?

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

A recent study by the Tufts Center for the Study of Drug Development reported that it cost $2.6 billion to bring a new medicine to market, more than double the cost of a decade ago. This high cost of development highlights the importance for drug sponsors to generate an adequate rate of return on their investment. However, as overall health care costs continue to rise, pharmaceutical companies are under increasing pressure to demonstrate the economic value of their products and justify prices. In this forum, panelists will explore the potentially competing demands for innovative breakthrough medicines and health care cost containment, and will examine regulatory initiatives and new business practices geared toward boosting innovation while lowering treatment costs.

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

#241 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): NC, RA

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 207B *CME, Pharmacy, and Nursing*

21st Century Pharmacovigilance: Improving Outcome Traceability for Products Across the Complexity Continuum, From Generics to Biologics and Vaccines

CHAIRPERSON
Thomas Felix, MD
R&D Policy Director, Amgen Inc.

In this forum, we will focus on the rationale for and implications of revisions to current postapproval generic manufacturer accountability expectations in the United States. Also, to better understand potential gaps that may exist in the adverse event reporting process for all medications, we will hear the results of two surveys, one assessing the experience for consumers and another detailing the experience for health professionals in various settings.

Challenges and Opportunities for Generics Postmarketing Surveillance
Leonardo Ebeling, MD, PhD
Managing Director, Dr. Ebeling & Assoc. GmbH, Germany

Improving Adverse Event Reporting: Insights on Reporters, Treatment Settings, and Health Information Systems
Stella Stergiopoulos
Senior Project Manager, Tufts Center For the Study of Drug Development

An Exploratory Study to Investigate Consumer Opinions and Experiences of Reporting Adverse Events Associated with Medicines and Vaccines
Rodney Peters
Pharmacovigilance Manager, CLEVER Collaboration, Australia

#242 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR

10:30 AM–12:00 PM | Level: ● | Format: FORUM
Room 204BC | *CME, Pharmacy, and Nursing*

The Use of Adaptive and Bayesian Approaches in Clinical Trials: Sharing Experiences and Case Studies

CHAIRPERSON
Weili He, PhD
Director, Biostatistics, Merck & Co., Inc.

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

This forum has been developed by the DIA Adaptive and the Bayesian Scientific Working Groups.

Adaptive Design Case Study
Representative Invited
Research Fellow, Advance Analytics; Head of Clinical Trial Optimization, Eli Lilly and Company

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 | *CME and Nursing*

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 | Level: ■ | Format: FORUM
Room 152A | *CME, Pharmacy, and Nursing*

FDA's International Posts: International Efforts, Regulatory System Strengthening and Inspections

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, China

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 | Level: ● | Format: SESSION
Room 146C | *No CE available*

Using Registries to Support Recruitment in Alzheimer's Disease (AD) Prevention or Delay-of-Onset Studies

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 | Level: ■ | Format: FORUM
Room 201 | *CME, Pharmacy, and Nursing*

Regulation of Combination Products in the 21st Century

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

11:30 AM–1:30 PM

Lunch & Innovation Theater Presentations (Exhibit Hall)

#248 Track 21 – Poster Presentations

11:35 AM–1:30 PM | Level: ● | Format: SYMPOSIUM
Exhibit Hall (Entrance A) | *No CE available*

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 AM–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

- 12:24–12:29 PM—T 23 Evolution of a Unique Blend of Business Process and Technology to Enhance Medical Affairs Capabilities
- 12:31–12:36 PM—T 25 A Pitfall in the Clinical Study Enrollment of Postmenopausal Females
- 12:38–12:43 PM—T 27 Lack of Inter-Ethnic Difference in QT-Susceptibility to Moxifloxacin: Two Independent TQT Studies in Caucasian and Asian Populations
- 12:45–12:50 PM—T 28 Implementing Quality Risk Management and Risk-Based Monitoring: Practical Guidelines from Sponsors and Sites
- 12:52–12:57 PM—T 29 Measurement Equivalence of the SF-36v2 on a Handheld Device and Smartphone App
- 12:59–1:04 PM—T 30 How to Maximize Data Quality in Retrospective Chart Review Studies
- 1:06–1:11 PM—T 31 Benefit-Risk Assessments (BRAs) of an Established Products' Portfolio
- 1:13–1:18 PM—T 33 Results of An Online Survey of Stakeholders Regarding Barriers and Solutions to Clinical Trial Recruitment
- 1:20–1:25 PM—T 34 Process for Ensuring Clinical Trial Product Quality

#249 Track 20 – Innovation Theater

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

12:00–12:45 PM | Level: ● | Format: SPECSESS

Exhibit Hall | *No CE available*

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

12:30–12:45 PM

STUDENT POSTER AWARD CEREMONY
DIA Booth #1523

#250 Track 20 – Innovation Theater

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

1:00–1:30 PM | Level: ■ | Format: SPECSESS

Exhibit Hall | *No CE available*

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.

#251 Track 01A – Clinical Operations

Related Interest Area(s): PT, MC

1:30–3:00 PM | Level: ● | Format: FORUM

Room 146A | *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.

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)

#252 Track 01B – Clinical Operations

Related Interest Area(s): CR

1:30–3:00 PM | Level: ■ | Format: SESSION

Room 145B | *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.

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 | Level: ● | Format: SESSION
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 △ | Level: ■ | Format: SESSION
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."

Reducing Clinical Development Budgets by Smart Trial Design
Nermeen Y. Varawalla
Executive Vice President, Global Clinical Trials, Lambda Therapeutic Research, United Kingdom

Globally Networked Polycentric Innovation: Future of Pharma R&D
Rashmi Barbhaiya, PhD
Chief Executive Officer and Managing Director, Advinus Therapeutics Ltd., India

#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 | Level: ■ | Format: SESSION
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 | Level: ■ | Format: SYMPOSIUM
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.

The Next Step in Good Regulatory Writer Practices (GRWP) Applies the Strategy of Topic Authoring and Content Management: Use this Tool to Save Time, Save Money, and Improve Quality
Susan Bairnsfather, MSc
CEO, Regulatory Writer, Regulatory Affairs Professional and Statistical Analyst, EPharmaTech LLC

Text Analytics Software to Alleviate Writers Pain Points
Nancy R. Katz, PhD
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.

Structured Content Management: Today's Best Practice
Ann Rockley, MLIS
President, The Rockley Group Inc., Canada

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

Related Interest Area(s): EC, PT

1:30–2:30 PM △ Level: ■ Format: SYMPOSIUM
Room 202B *CME, Pharmacy, and Nursing*

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 *CME and Nursing*

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. 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

#259 Track 08 – Regulatory Affairs

Related Interest Area(s): SUBS

1:30–3:00 PM Level: ■ Format: SESSION
Room 151A *CME, Pharmacy, and Nursing*

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

CHAIRPERSON
Mette Due Theilade 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

#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 *CME, Pharmacy, and Nursing*

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

methdology, 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.

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

Related Interest Area(s): MDD

1:30–3:00 PM | Level: ■ | Format: FORUM
Room 146B | *CME, Pharmacy, 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)

#262 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 102AB | *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.

Can We Get Quality and Performance Metrics Right?
Michael Howley, PhD
Associate Clinical Professor; Chief Science Officer, CRO Analytics, Drexel University

Quality Metrics
Linda B. Sullivan, MBA
Co-Founder and President, Metrics Champion Consortium LLC

Predictive GCP Quality Analytics
Beth Soffer, MEd
Global Lead, Compliance Analytics and Intelligence, Pfizer Inc

#263 Track 12 – Pharmaceutical Quality

Related Interest Area(s): MF, CM

1:30–2:30 PM △ | Level: ■ | Format: FORUM
Room 152A | *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.

A Transformational Approach to Development, Manufacturing and Distribution
Michael K. O'Brien, PhD
Vice President, Leadership, Pharmaceutical Science, Technology and Innovation, Pfizer Inc

Return On Investment from Manufacturing Technology Innovation: Opportunities and Realities
Andrew Mark Buswell, PhD, MBA
Head of Advanced Manufacturing Technologies, GlaxoSmithKline, United Kingdom

Innovation in the Pharmaceutical Industry: Regulatory Opportunities and Challenges
Stephanie Krogmeier, PhD, RPh
Senior Director, Global CMC Regulatory Affairs Strategy, Vertex Pharmaceuticals

#264 Track 19A – Late-breaking Topics

Related Interest Area(s): RD

1:30–3:00 PM | Level: ● | Format: SESSION
Room 151B | *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.

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 Perspectuve
Duane Schulthess, 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
- 3:03–3:08 PM—T 40 How IDMP Can Help Structure Product Information/ Labeling

2:30–3:30 PM

Refreshment Break & Innovation Theater Presentations (Exhibit Hall)

#267 Track 20 – Innovation Theater

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

3:00–3:30 PM | Level: ■ | Format: SPECSESS
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.

#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

Related Interest Area(s): CR, PM

3:30–5:00 PM | Level: ● | Format: SESSION
Room 145B | *CME, Pharmacy, and Nursing*

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 Deurell, MD, MBA
Medical Director, Pediatric Pharmaceutical Consultants

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

Related Interest Area(s): PM, PETD

3:30–5:00 PM | Level: ◆ | Format: FORUM
Room 101 | *CME, Nursing, and PMI PDUs*

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

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

Related Interest Area(s): CR, MDD

3:30–5:00 PM | Level: ◆ | Format: FORUM
Room 102AB | *CME and Nursing*

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

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

Related Interest Area(s): FI, CR

3:30–4:30 PM △ Level: ■ Format: FORUM
Room 103B

Incorporating a VAT Tax Strategy Into Your Global Investigator Payment Plan

CHAIRPERSON
April Mulroney, CPA
Vice President–Tax Services, DrugDev, United Kingdom

This forum will discuss key strategies in addressing VAT tax implications when developing an investigator payment plan. We will discuss considerations for managing often overlooked tax implications and understanding the tax laws when creating a global trial budget.

Panelists
Alex Cotopoulis
Senior Manager, US VAT Practice, Ernst & Young LLP

Nicole McElroy
Contracts Manager, Shire Pharmaceuticals

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

Related Interest Area(s): PM

3:30–4:30 PM △ Level: ■ Format: SESSION
Room 150A *CME and Nursing*

Getting More Out of Outsourcing Agreements: Value Additions Through Synergies and Process Optimization

CHAIRPERSON
Anja Leo
Head of Vendor and Quality Management, Global Clinical Application Support, Boehringer Ingelheim Pharma Gmbh & Co. KG, Germany

If applied strategically and made subject to continuous improvement and process optimization, managed services can enhance service opportunities and add value. This allows for easy expansion of the outsourced services by reducing the internal efforts for these services at the same time. With such a scalable and flexible service organization, in-house resources can even further focus on their core responsibilities, ensuring high throughput and high quality deliveries.

Service Troika: An Integrated Managed Service Concept
Anja Leo
Head of Vendor and Quality Management, Global Clinical Application Support, Boehringer Ingelheim Pharma Gmbh & Co. KG, Germany

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

Related Interest Area(s): NC, RA

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

#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.

Improving Quality and Reducing Risk through Data-Driven Protocol Design and Review
David Gemzik
Vice President, Implementation Services, Medidata Solutions Worldwide

Make Every Comment Resolution Meeting Worth Your Team's Time
Steven C. Sibley, MS
Vice President, Global Submissions and Submissions Leadership, Synchrogenix Information Strategies Inc., a Certara Company

#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.

PMDA Perspective: Challenges For Postmarketing Drug Safety Measures Using Electronic Health Care Database
Kaori Yamada
Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

EMA Perspective
Kevin Blake, PhD, MBA
Clinical Epidemiologist, European Medicines Agency, European Union

FDA Perspective
Solomon Iyasu, MD, MPH
Director, Office of Pharmacovigilance and Epidemiology, Office of Surveillance and Epidemiology, CDER, FDA

#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
Gopalan 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.

Patient Medication Information: Reaching the Patient
Lina Aljuburi, PharmD, MS
Director, Global Regulatory Policy, Merck & Co., Inc.

Principles of Health Literacy
Michael S. Wolf, PhD, MPH
Associate Professor, Medicine and Learning Sciences, Associate Division Chief, Northwestern University

Prescriber Perspective
Marina Serper, MD, MS
Department of Gastroenterology, University of Pennsylvania Health System

#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)

Related Interest Area(s): GCP, CR

3:30–5:00 PM | Level: ■ | Format: WORKSHOP
Room 147A | *CME and Nursing*

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

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

3:30–5:00 PM | Level: ■ | Format: FORUM
Room 152A | *CME, Pharmacy, Nursing, and PMI PDUs*

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

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

3:30–5:00 PM | Level: ■ | Format: FORUM
Room 209AB | *CME, Pharmacy, and Nursing*

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.

Evaluating an Innovative Approach to a Prospective Patient Registry Design Using Electronic Medical Record Data
Susan Meredith Fish, MS
Senior Statistical Programmer Analyst, Genentech, A Member of the Roche Group

Registration of Observational Studies: Where, Why, and How?
Vanja Pajic
Project Manager, Croatian Institute for Public Health, Croatia (Hrvatska)

#286 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

3:30–5:00 PM | Level: ■ | Format: FORUM
Room 202A | *CME, Pharmacy, and Nursing*

Translating New Knowledge from Regulatory Science into Postmarketing Safety Practice

CHAIRPERSON
Gerald J. Dal 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

#287 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 207B | *CME and Nursing*

Has the New Format PSUR/PBRER Achieved What Was Originally Intended?

CHAIRPERSON
Stephen Knowles, MD, MRCP
Senior Director, Global Patient Safety, Eli Lilly and Company

With the implementation of the European Good Pharmacovigilance Regulation and adoption of ICH E2C (R2), the content and purpose of the periodic safety update report (PSUR) has fundamentally changed. Increasingly, the periodic benefit-risk evaluation report (PBRER) is accepted by regulatory authorities around the world as the acceptable format for the PSUR. This session will review the process for developing the PBRER, lessons learned and discuss the impact of the PBRER on managing the benefit risk balance of medicines.

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

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

#288 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 204BC | *CME, Pharmacy, and Nursing*

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

#289 Track 16 – Professional Development

Related Interest Area(s): PETD

3:30–5:00 PM | Level: ● | Format: WORKSHOP
Room 147B | *CME, Pharmacy, and Nursing*

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.

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#290 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, RA

3:30–4:30 PM | Level: ■ | Format: SESSION
Room 145A | *CME, Pharmacy, and Nursing*

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 | Level: ■ | Format: FORUM
Room 146C | *CME, Pharmacy, and Nursing*

CDRH Town Hall

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

This forum will provide a unique opportunity to hear from the director of the Center for Devices and Radiological Health (CDRH) who will report on the state of CDRH and its vision for the future. Topics to be addressed include: 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 | Level: ■ | Format: FORUM
Room 207A | *CME and Nursing*

Chinese Drug Development: An Update

CHAIRPERSON
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.

Translational Medicine and New Drugs Innovation and Development
Representative Invited
Member of Chinese Academy of Engineering; President, Chinese Pharmaceutical Association (CPA), 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

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 #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

#301 Track 01A – Clinical Operations

Related Interest Area(s): PT, CR

8:00–9:30 AM LEVEL: ■ FORMAT: SYMPOSIUM
Room 146A *CME, Pharmacy, and Nursing*

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.

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

8:00–9:30 AM LEVEL: ● FORMAT: WORKSHOP
Room 147A *CME, Pharmacy, and Nursing*

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.

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Facilitator
Representative Invited
Chief Operating Officer, Transparency Life Sciences

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

Related Interest Area(s): RA, SUBS

8:00–9:30 AM LEVEL: ■ FORMAT: FORUM
Room 101 *CME and Nursing*

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.

Jerry Jennings
Director of Clinical Quality Management, Baxter Healthcare Corporation

Scott GV Harris
Global Category Manager, Sanofi

#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

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

Related Interest Area(s): CDM

8:00–9:00 AM △ Level: ■ Format: SESSION
Room 201 *CME and Nursing*

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

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

Related Interest Area(s): DM, CR

8:00–9:30 AM Level: ■ Format: SESSION
Room 202B *CME and Nursing*

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

#310 Track 08A – Regulatory Affairs

Related Interest Area(s): CR

8:00–9:30 AM Level: ■ Format: FORUM
Room 150B *CME and Nursing*

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

#311 Track 08B – Regulatory Affairs

Related Interest Area(s): SUBS, CR

8:00–9:00 AM △ Level: ■ Format: SESSION
Room 151A *CME and Nursing*

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

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

Related Interest Area(s): RA

8:00–9:30 AM Level: ■ Format: FORUM
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

#313 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): RA

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

#314 Track 12 – Pharmaceutical Quality

Related Interest Area(s): QC, RA

8:00–9:30 AM Level: ■ Format: FORUM
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

Related Interest Area(s): CEHTAEbM

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

Related Interest Area(s): RA, CR

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

Related Interest Area(s): ST

8:00–9:30 AM | Level: ● | Format: SESSION
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.

Getting Everyone on the Same Page: Experiences Using the Benefit-Risk Action Team Structured Benefit-Risk Framework to Support Submissions
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

#318 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, BT

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

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 | Level: ■ | Format: FORUM
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

9:30–10:30 AM

Coffee Break & Innovation Theater Presentation (Exhibit Hall)

#321 Track 21 – Professional Poster Session #2

9:30 AM - 4:00 PM Level: ● Format: SYMPOSIUM
Exhibit Hall (Entrance A) *No CE available*

Wednesday Oral Presentations—Professional Poster Session 2A

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 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 Level: ■ Format: SPECSESS
Exhibit Hall *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 Level: ■ Format: WORKSHOP
Room 147A *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.

***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
Gail Adinamis
Chief Executive Officer, GlobalCare Clinical Trials

#324 Track 01B – Clinical Operations

Related Interest Area(s): CR, PM

10:30 AM–12:00 PM Level: ◆ Format: FORUM
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 Track 02A – Project/Portfolio Management and Strategic Planning

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

10:30–11:30 PM △ Level: ■ Format: SESSION

Room 101 *CME and Nursing*

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 our 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 action 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 Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): CR, FI

10:30 AM–11:30 PM △ Level: ■ Format: SESSION

Room 103B *CME, Nursing, and PMI PDUs*

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.

Got Confidence? Leading Technical Expert Teams While Not Being an Expert Yourself
Alexandra Florea, PMP
Principal Project Manager, Genentech, A Member of the Roche Group

Making Your Projects Successful with Best Practices, Tools and Processes
Zizi Imatorbhebhe, MBA, MS, PMP
Principal & Managing Consultant, Alliance Bio-Pharm & Health Partners

#327 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, IT

10:30 AM–12:00 PM Level: ◆ Format: FORUM

Room 150A *CME and Nursing*

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 networks of 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 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): PC, CR

10:30 AM–12:00 PM Level: ■ Format: SESSION

Room 103A *CME, Pharmacy, and Nursing*

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

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

Related Interest Area(s): MC

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 206 | *CME, Pharmacy, and Nursing*

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

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

Related Interest Area(s): CDM, SUBS

10:30 AM–12:00 PM | Level: ■ | Format: SESSION
Room 201 | *CME and Nursing*

Electronic Standardized Data in Regulatory Submissions

CHAIRPERSON
Mary Ann Slack
Deputy Director, Office of Strategic Programs, CDER, FDA

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

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

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

10:30 AM–12:00 PM | Level: ■ | Format: SYMPOSIUM
Room 202B | *CME, Pharmacy, and Nursing*

Digitization of Clinical Trials: Check the Pulse on Bringing Benefits to Patients

CHAIRPERSON
Betsy Fallen, RN
Principal, BAFallen Consulting, LLC

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

The Rise of Mobile and Digital Health Care: Let's Tell the Patients
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

#332 Track 08A – Regulatory Affairs

Related Interest Area(s): PT

10:30 AM–12:00 PM Level: ■ Format: SESSION
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 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)

#333 Track 08B – Regulatory Affairs

Related Interest Area(s): PT, CR

10:30 AM–12:00 PM Level: ■ Format: SESSION
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)

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

Related Interest Area(s): RA, PT

10:30 AM–12:00 PM Level: ■ Format: FORUM
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

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

Related Interest Area(s): RA, CR

10:30 AM–12:00 PM Level: ■ Format: FORUM
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 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

#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

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

#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 Initative 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 Shoaibi, 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 Initative Lead, CDER, FDA

CBER Perspective
Steven A. Anderson, PhD
Director, Office of Biostatistics and Epidemiology, CBER, FDA

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

Related Interest Area(s): RA

10:30 AM–12:00 PM Level: ■ Format: SESSION
Room 207B *CME, Pharmacy, and Nursing*

Best Evidence Generation: Regulatory Perspectives

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

The traditional model of medicines regulation sees decisions made based on evidence submitted by pharmaceutical companies. More recently, however, regulators are supplementing this evidence with that from other sources including research by independent third-parties or established networks. These other sources also include data and information generated by regulators themselves, e.g., the EMA using e-health data from The Health Improvement Network (THIN) and IMS. The issues around regulators conducting such research are explored in this session including details of some of the research conducted and how the results have translated into outcomes and also some of the challenges posed, such as ensuring transparency.

Best Evidence Generation: The European Medicines Agency Approach to In-House Analysis of e-Health Data
Kevin Blake, PhD, MBA
Clinical Epidemiologist, European Medicines Agency, European Union

FDA's Approach to Incorporating Studies Using Electronic Health Care Data Into Regulatory Decision-Making
Judy Anne Staffa, PhD, RPh
Director, Division of Epidemiology II, Office of Surveillance and Epidemiology, CDER, FDA

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

#340 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CR

10:30 AM–12:00 PM Level: ■ Format: SESSION
Room 204BC *CME, Pharmacy, and Nursing*

Integrated Cardiac Safety

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

This session will discuss the evolution of cardiac safety and changes since the ICH E14 inception. Speakers will address why the TQT trial design is phasing out and discuss alternative options.

Risk of Drug-Induced QT Interval Prolongation by Monoclonal Antibody Medicines: A Review of Data From an EU Database
Joerg Seebeck, DrMed, MD
Chief Medical Officer, PrimeVigilance Ltd, United Kingdom

Integrated Cardiac Safety in the Post E14 Era
Tim Callahan, PhD
Chief Scientific Officer, Biomedical Systems

Clues to Proarrhythmic Potential of Drugs From the Human ECG
David Strauss, MD, PhD
Medical Officer, Office of Science and Engineering Laboratories, CDRH, FDA

#341 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

10:30 AM–12:00 PM Level: ■ Format: SESSION
Room 207A *CME and Nursing*

Pharmacovigilance Inspections: Achieving Compliance in a Global Environment

CHAIRPERSON
Anabela Marcal, PharmD
Head of Compliance and Inspections Department, European Medicines Agency, European Union

The session will provide an overview on the coordination of pharmacovigilance inspections in the EU and the US (including pharmacovigilance inspection metrics). There will be an opportunity to discuss common pharmacovigilance inspection findings and to identify and discuss the areas where there are differences in the requirements. The challenges in the conduct of pharmacovigilance in a global environment will also be identified and discussed from the industry perspective with the aim to collect proposals for the future.

Pharmacovigilance Audits: Is the US Behind the Curve?
Michael Oluseun Baptist
Quality Assurance Manager, Medpace, Inc.

FDA Perspective
Douglas B. Pham, JD, PharmD
Regulatory Counsel, Office of Scientific Investigations, Office of Compliance, CDER, FDA

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

#342 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, ST

10:30 AM–12:00 PM Level: ■ Format: FORUM
Room 145A *CME, Pharmacy, and Nursing*

The Role of the Clinical Statistician in Understanding and Using ADaM Data Standards

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

Analysis data model (ADaM) datasets and associated documentation are critical elements in PFDUA V-mandated, CDISC-compliant biologics license application and new drug application submissions. Clinical statisticians must know how to create and use ADaM-based standards. This forum will briefly review ADaM concepts and will describe approaches currently used by a sponsor and a contract research organization to successfully meet submission requirements. Regulatory perspectives will also be examined.

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 Biostatistcs, 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 corps 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.

11:30 AM–1:30 PM

Lunch & Innovation Theater Presentations (Exhibit Hall)

#346 Track 21 – Poster Presentations

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

- 12:10–12:15 PM—W 19 Global Utilization of Breast Cancer Treatment Guidelines: A Survey of International Physician Practices
- 12:17–12:22 PM—W 20 Precision Medicine Basket Trial Eligibility Across Race/Ethnicity: Implications for Ethnobridging and Clinical Application
- 12:24–12:29 PM—W 21 PMDA's Relief Services for Drugs' Adverse Health Effects
- 12:31–12:36 PM—W 23 Recent FDA GLP (Good Laboratory Practice) Inspections Conducted in China
- 12:38–12:43 PM—W 25 Ignoring Global Feasibility and Site Networks for Your Rare Disease Study? You May Want to Re-consider
- 12:45–12:50 PM—W 26 Exploring Phenome-wide Association Study (PheWAS) as an Option to Address Key Challenges of Pharmaceutical Industry
- 12:52–12:57 PM—W 27 Japan PMDA Inspections from a CDM/EDC Perspective
- 12:59–1:04 PM—W 29 Factoring in Ethnicity, Gender, and Age in Specific Clinical Studies
- 1:06–1:11 PM—W 30 Clinical Monitoring Liaison, a New Oversight Role as a Practical Approach to Sponsor Involvement in Outsourced Trials
- 1:13–1:18 PM—W 31 Adaptive Clinical Trial Design in Head-to-Head Comparison of Two DPP-4 Inhibitors
- 1:20–1:25 PM—W 33 Lessons Learned for Meeting Safety Reporting Requirements in Retrospective Chart Review Studies

#347 Track 20 – Innovation Theater

Related Interest Area(s): IT, RD

12:00–12:30 PM | Level: ■ | Format: SPECSESS

Exhibit Hall | *No CE available*

SAS Institute Inc. Innovation Theater: Accelerate Value-Based Drug Development With Analytics

You most likely feel pressure from stakeholders who have an interest 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.

#348 Track 20 – Innovation Theater

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

12:45–1:30 PM | Level: ● | Format: SPECSESS

Exhibit Hall | *No CE available*

Quintiles Transnational Innovation Theater: Driving Better Decision-Making with Real-World Data and Analytics

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.

#349 Track 01A – Clinical Operations

Related Interest Area(s): CR, CP

1:30–3:00 PM | Level: ■ | Format: SESSION

Room 146C | *CME, Pharmacy, and Nursing*

Cardiac Safety Considerations in Pediatric Drug Development

CHAIRPERSON

Rick Turner, PhD
Senior Scientific Director, Quintiles Inc.

There is great interest in reviewing scientific and public health policy issues pertaining to sudden cardiac death (SCD) occurring in apparently healthy individuals in pediatric populations. This session will first provide fundamental information underlying the rationale for developing a sustainable national health care resource in the domain of pediatric SCD prevention. It will also review discussions from the February 2015 Cardiac Safety Research Consortium (CSRC) Think Tank, and describe the resultant initiatives. Finally, it will invite thoughts and suggestions from attendees with regard to additional contributions and refinements to these initiatives.

Academic Perspective
Tess Vickers Saarel
Associate Professor, Pediatric Cardiology, University of Utah

Hospital Perspective
Mitchell I. Cohen, DrMed
Co-Director Heart Center, Phoenix Children's Hospital

Industry Perspective
Albert John Allen, MD, PhD, MSc
Senior Medical Fellow, Bioethics & Pediatric Capabilities, Eli Lilly and Company

FDA Perspective
Hari Cheryl Sachs, MD
Lead Medical Officer, Office of New Drugs, CDER, FDA

#350 Track 01B – Clinical Operations

Related Interest Area(s): CR

1:30–3:00 PM | Level: ■ | Format: SESSION

Room 146A | *CME, Pharmacy, and Nursing*

Is Facebook Hurting Your Trial? Social Media and the Introduction of Bias in Clinical Studies

CHAIRPERSON

Lindsay McNair, MD, MPH, MS
Chief Medical Officer, WIRB-Copernicus Group

In this session, we will discuss the potential complications of social media interaction between study participants, and will present practical ideas for maintaining respect for the autonomy of participants, while protecting the integrity of the clinical trial.

Is Facebook Hurting Your Trial?
Lindsay McNair, MD, MPH, MS
Chief Medical Officer, WIRB-Copernicus Group

Engaging with Research Participants About Social Media
Craig H. Lipset
Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc

Best Practices for Engaging Patient Social Networks in Clinical Trials and Burden of Disease Research: Case Studies from the Past Year
Eric J. Peacock, MBA
Cofounder and Chief Executive Officer, MyHealthTeams

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

Related Interest Area(s): PETD

1:30–3:00 PM | Level: ■ | 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

1:30–3:00 PM | Level: ■ | 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

1:30–3:00 PM | Level: ■ | 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

1:30–3:00 PM | Level: ■ | 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

Implications for Useful Biomarker Discovery and Early Clinical Development
Gordon Vansant, PhD
Regional Director, Western US, SomaLogic

Effective Development and Utilization of Biomarkers in Early Drug Development
Representative Invited
Executive Director and Head of TLM, QPS, LLC

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

Related Interest Area(s): MSL

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 206 | *CME, Pharmacy, and Nursing*

Globalization of Field Medical Science Liaisons: How to Take It to the Next Level

CHAIRPERSON
Lisa Cesario, RPh
Director, Medical Liaison Oncology, Hoffmann-La Roche Ltd., Canada

Many companies today have established functional excellence in globalization of medical science liaisons (MSLs.) How do you balance the needs of the global organization while ensuring your local team's resources are focused on your local priorities? How do leaders achieve internal collaboration, recognizing flexibility and respect for cultural differences that are key to a successful model? This session will provide an overview of how Canadian MSL leaders have established an industry forum, which will be showcased as a successful case study demonstrating industry wide collaboration. The speakers will also explore how this can be adapted to other industry leaders and other markets. Speakers will share best practices on how to strike the right balance. In addition, the speakers will address compliance implications when instituting any new best practice and share their global expertise on how to ensure success in global MSL functions.

The Value of Collaborating Internally to Create an Internal Forum of MSL Leaders
Donna A. Holder, PharmD
Consultant, Global Medical Consulting

Best Practices for Industry Wide Collaboration: How to Ensure Success in Global MSL Functions
Debra Israel, MBA
Director, Global Medical Affairs Center of Excellence, Eli Lilly and Company, Canada

Update From the Canada MSL Forum
Arlene M. Nugent, MSc
Medical Affairs, AbbVie, Canada

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

Related Interest Area(s): IT, CDM, SE

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 201 | *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

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

Related Interest Area(s): VA, IT

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM
Room 202B | *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.

Medical Information Database: To Validate or Not to Validate—That Is The Question
Andrew Harbrow, RPh
Global Medical Services Manager, PrimeVigilance Ltd, United Kingdom

The Missing Link in Validation Today: IQ Evidence from SaaS and Cloud Providers
Teri Stokes
Director, GXP International

The Risk of Risk Assessment
Breffni Kennedy Martin
Legal Representative, Data Controller, Consultant, Regintel Ltd, Ireland

#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 Porrmann, 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 dilemnas. This forum will try and explain the ethical dilemnas 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)

#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

Using Analytics to Detect Quality Issues
Roland Rich
Operational Expert, Quality and Compliance DevQA, Novartis Pharma AG, Switzerland

#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

#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 Initative 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

Related Interest Area(s): PETD

1:30–3:00 PM | Level: ■ | Format: WORKSHOP

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 Fleschner, PhD, MA

Instructional Development and Facilitation, i3logic

#369 Track 16B – Professional Development

Related Interest Area(s): PETD

1:30–3:00 PM | Level: ● | Format: WORKSHOP

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

Related Interest Area(s): RA

1:30–3:00 PM | Level: ■ | Format: SYMPOSIUM

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

Related Interest Area(s): RA

1:30–3:00 PM | Level: ■ | Format: FORUM

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.

Attendees are welcome to submit questions to the panel by emailing annualmeetingprogram@diaglobal.org; subject line: CBER Town Hall Q/A.

Panelists
Theresa M. Finn, PhD
Associate Director for Regulatory Policy, Office of Vaccines Research and Review, CBER, FDA

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

Steven A. Anderson, PhD
Director, Office of Biostatistics and Epidemiology, CBER, FDA

#372 Track 19A – Late-breaking Topics

Related Interest Area(s): RA

1:30–3:00 PM | Level: ■ | Format: SESSION
Room 207B | *CME, Pharmacy, and Nursing*

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

#373 Track 19B – Late-breaking Topics

Related Interest Area(s): CR

1:30–3:00 PM | Level: ● | Format: SESSION
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.

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)

#374 Track 21 – Poster Presentations

2:30–3:10 PM | Level: ● | Format: SYMPOSIUM
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
- 2:56–3:01 PM—W 40 Exploration of Protocol Complexity Factors and Impact on Protocol Variance Rates in a Subset of Clinical Trials
- 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 | *No CE available*

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.

#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

#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

#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 | Level: ■ | Format: FORUM
Room 150A | *CME and Nursing*

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 | Level: ■ | Format: SESSION
Room 206 | *CME, Pharmacy, and Nursing*

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 | Level: ● | Format: SESSION
Room 201 | *CME and Nursing*

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 △ | Level: ■ | Format: SESSION
Room 202B | *CME and Nursing*

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

#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.

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

#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)

#387 Track 12 – Pharmaceutical Quality

Related Interest Area(s): MF, PM

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 151B | *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

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

Related Interest Area(s): CR

3:30–5:00 PM | Level: ■ | Format: WORKSHOP
Room 147B | *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.

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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

#389 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, CR

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 204BC | *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

Key Messages From the FDA 2014 Meeting
Melissa S. Tassinari, PhD
Senior Clinical Advisor, Division of Pediatric and Maternal Health, Office of New Drugs, CDER, FDA

EMA Point of View
Kevin Blake, PhD, MBA
Clinical Epidemiologist, European Medicines Agency, European Union

#390 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 207A | *CME and Nursing*

CIOMS IX: Practical Approaches to Risk Minimization and Its Evaluation

CHAIRPERSON
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory, Pfizer Inc

Routine risk minimization applies to all medicinal products. However, in certain instances, additional risk minimization tools may be necessary to ensure that product benefits outweigh risks and the product remains available to patients. In these cases, it is important to appropriately characterize the risk and frame the goals for the non-routine interventions. These first steps are followed by selection of the least burdensome tool(s) that are implementable and, at the same time, will also achieve the desired goals under real-world conditions. Knowing which tools to use, how to measure their effectiveness, and when to make modifications are key to success. In this session, three members of the Council for International Organizations of Medical Sciences (CIOMS) IX Working Group will review concepts, practical considerations, and implications for the biopharmaceutical industry.

Practical Approaches to Selecting Non-Routine Tools for Risk Minimization
Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

Practical Approach to Future Efficiencies in Risk Minimization
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory, Pfizer Inc

Representative Invited
Global Pharmacovigilance, Head of Center of Excellence Risk Management Sciences, Bayer HealthCare Pharmaceuticals, Germany

#391 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, ST

3:30–5:00 PM | Level: ■ | Format: SESSION
Room 145A | *CME, Pharmacy, and Nursing*

Statistical Support of Risk-Based Monitoring

CHAIRPERSON
Jonathan Haddad, MPH, MT
Director, Clinical Statistics, GlaxoSmithKline

Risk-based monitoring (RBM) is rolling out across the industry and new guidance documents have given industry a shove out onto the dance floor. Clinical statisticians have long been pressed by their study teams to identify analysis-oriented data queries to support data quality. Other aspects of RBM include statistical process control and signal-detection to evaluate performance and identify problems, areas in which clinical statisticians can make important contributions. This session will cover the role of the clinical statistician in the suppport of RBM, through several case studies by sponsors and contract research organizations.

Risk-Based Monitoring: Case Studies of Successful Implementation
Jill Woodward Collins, MEd, MS
Senior Director Clinical Innovation, INC Research

Integrating Central Statistical Monitoring in a Quality by Design Approach for Clinical Trials
Francois Torche, MBA
Chief Executive Officer, CluePoints, Belgium

TransCelerate's Data Integrity and GCP Misconduct Detection Best Practice Recommendations for Clinical Statisticians in the Context of RBM
Yodit Seifu, PhD
Senior Manager II, Allergan, Inc.

#392 Track 16 – Professional Development

Related Interest Area(s): PETD

3:30–5:00 PM | Level: ● | Format: WORKSHOP
Room 147A

Speaking and Publishing Opportunities with DIA

CHAIRPERSON
Julie Ho
Senior Manager, Annual Meeting Content Development, DIA

There are many opportunities within DIA for subject matter professionals to share their knowledge and expertise. Join us as we provide an overview of 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

Related Interest Area(s): PETD, CR

3:30–4:30 PM △ | Level: ■ | Format: FORUM

Room 145B | *CME and Nursing*

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

Related Interest Area(s): RA, RD

3:30–5:00 PM | Level: ■ | Format: SESSION

Room 152B | *CME and Nursing*

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

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

3:30–5:00 PM | Level: ■ | Format: FORUM

Room 207B | *CME and Nursing*

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

THURSDAY, JUNE 18

Registration Hours:

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

Schedule:

8:15–9:00 AM Coffee and Breakfast Breads (Meeting Room 145–147 Concourse)

9:00–10:30 AM Educational Opportunities

10:30–10:45 AM Coffee Break

10:45 AM–12:15 PM Educational Opportunities

#401 Track 01A – Clinical Operations

Related Interest Area(s): PT, CR

9:00–10:00 AM △ Level: ■ Format: SESSION

Room 152A *CME, Pharmacy, and Nursing*

Lung-Map: A Future Clinical Trial with a Master Protocol Happening Now and the Value to Patients

CHAIRPERSON

Stephen Smith, MA

Senior Director, Patient Value, Medidata Solutions Worldwide

This session will provide an overview of a future clinical trial design happening now: Lung-Map. We will include a description of the design, milestones attained, and observations about biostatistics, reduced patient burden, efficiencies, and increased chances of success. The value to patients is explored including aspects of this trial design that overcome traditional problems with clinical trial design.

LungMAP Progress to Date and Next Steps
Stephen Smith, MA
Senior Director, Patient Value, Medidata Solutions Worldwide

LungMAP Trial Design and the Value to Patients
Mary Redman, PhD
Lead Biostatistician, SWOG Lung Committee/LungMap, Fred Hutchinson Cancer Research Center

#402 Track 01B – Clinical Operations

Related Interest Area(s): PT, CR

9:00–10:00 AM △ Level: ■ Format: SESSION

Room 145B *CME and Nursing*

The Ultimate in Patient-Centered Trials: Bringing Study Visits into the Home

CHAIRPERSON

Robin Marcus, BSN, RN

Vice President, Business Development & Strategic Initiatives, GlobalCare Clinical Trials

This session will review the results of the Tufts Center for the Study of Drug Development 2014 Homecare Survey and the implications in implementing this service model in clinical trials. We will examine case studies and examples of where homecare has been used and the outcomes achieved. We will also identify patient populations that benefit most from receiving home visits and discuss its application globally.

The Ultimate in Patient-Centered Trials: Bringing Study Visits into the Home
Stella Stergiopoulos
Senior Project Manager, Tufts Center For the Study of Drug Development

Latest Trends in In-Home Clinical Services
Nicki M. Norris, MBA
Chief Executive Officer, Symphony Clinical Research

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

Related Interest Area(s): CR, RD

9:00–10:30 AM Level: ■ Format: WORKSHOP

Room 147A *CME, Nursing, and PMI PDUs*

Survey Results: How Project Managers Leverage Tools and Techniques

CHAIRPERSON

Laura Vitale, MSc, PMP

Director, Program Management, Mallinckrodt Pharmaceuticals, Inc.

Since 1950, the number of FDA drugs approved has halved every nine years based on inflation-adjusted dollars spent, drastically affecting pharmaceutical companies' ability to reinvest into new technologies. Application of project management techniques for pharmaceutical R&D activities is becoming more widely held as a best practice in organizations, improving results. There are many different ways to apply project management tools and techniques; learning from one another's successes and failures offers the chance for pharmaceutical project managers to gain understanding without living through each aspect in real project time which is often over ten years from project start. How are other pharmaceutical project managers leveraging project management tools and techniques? What value are they obtaining from their PMP certifications? This workshop will provide an opportunity to learn from your colleagues through results of a pre-meeting survey. An additional survey will also be conducted within the workshop.

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Facilitators
Jim L. Vandergriff, II
Manager, CTMS Supply Planning, CT Material Supply Chain Planning, Eli Lilly and Company

Lei C. Chuang, MSc, PMP
Associate Director, Global Project Management, Morphotek, Inc.

#404 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, PM

9:00–10:30 AM Level: ■ Format: SYMPOSIUM

Room 150A *CME and Nursing*

Innovations in Strategic Alliances and Overcoming Obstacles

CHAIRPERSON

Rikki Hansen Bouchard, MPA

President and Chief Executive Officer, RH Bouchard & Associates Inc.

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 Peeves in Working with Sponsors and Vendors - From Vendors' and Sponsors' Perspectives
Chris Chan, MBA
Senior Director, R&D Finance, Fibrogen, Inc.

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

Related Interest Area(s): IT, RD

9:00–10:30 AM | Level: ● | Format: FORUM
Room 146B | *CME, Pharmacy, and Nursing*

Tired of Reinvesting in Old R&D Systems? Several Large Pharmaceutical Companies and Other Leaders Are Flipping Paradigms

CHAIRPERSON
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.

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
Sandra Tremps, MS
Global Leader, Clinical, Regulatory, and Safety IT, Merck & Co., Inc.

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

Related Interest Area(s): SE

9:00–10:30 AM | Level: ■ | Format: SESSION
Room 150B | *CME, Pharmacy, and Nursing*

Bring Your Own Device (BYOD) Approaches to the Collection of Electronic Patient-Reported Outcome Data in Clinical Trials

CHAIRPERSON
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.

Strengths of BYOD Approaches
Hannah O'Gorman
ePRO Specialist, Exco InTouch, United Kingdom

Challenges Associated with BYOD
Paul O'Donohoe
Director Health Outcomes, CRF Health, United Kingdom

Open Scientific, Regulatory, and Operational Questions Regarding BYOD
Stephen Joel Coons, PhD
Executive Director, PRO Consortium, Critical Path Institute

#407 Track 08 – Regulatory Affairs

Related Interest Area(s): PPLC

9:00–10:30 AM | Level: ■ | Format: SESSION
Room 151A | *CME, Pharmacy, and Nursing*

Accidental Drugs: A Historical Look at How Certain Drugs Came to Market and Policy Pathway Opportunities

CHAIRPERSON
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.

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

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

#408 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): EC, IT

9:00–10:00 AM △ | Level: ■ | Format: SESSION
Room 151B | *CME and Nursing*

Novel Data Sources and Tools for Pharmacovigilance

CHAIRPERSON
Rave Harpaz, PhD
Senior Research Scientist, Oracle Health Sciences

The session will discuss the use of new data sources and tools for pharmacovigilance, including: (1) A real-time system that integrates and analyzes safety evidence from FDA's adverse event reporting system (FAERS), electronic health records (EHRs), and the social media, with application to the safety profiling of tumor necrosis factor alpha (TNFa)

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

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

Related Interest Area(s): EC

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

Related Interest Area(s): CR, RD

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.

Panelist
Representative Invited
Director of Monitoring, GlaxoSmithKline

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

Related Interest Area(s): SP, CR

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

Related Interest Area(s): OS, AHC/IS, FI

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

#416 Track 07 – Technology/Data/Records and Submissions

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

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

Related Interest Area(s): CR, BT

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

Related Interest Area(s): IT, PM

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

Related Interest Area(s): IT, PETD

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

#420 Track 18 – Global Regulatory

Related Interest Area(s): RA, CR

10:45 AM–12:15 PM | Level: ■ | Format: FORUM

Room 143ABC | *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

10:45–11:45 AM △ | Level: ■ | Format: FORUM

Room 146C | *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

12:30–4:30 PM

MedDRA® User Group Meeting (Room 147A)

The content noted on this page was made available to DIA as of April 27.

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.

TUT 20 The Sunshine Act: Understanding the Essentials of Compliance
Michael A. Swit, Esq
Senior Director, Legal, Regulatory
Illumina, Inc.

TUT 21 Leadership: How to Organize and Lead People in a Work Group
Michael Laddin, MBA, MS
Chief Executive Officer
LeaderPoint

TUT 22 Successful Drug Development: Best Practices for Clinical Trial Design, Agency Interactions, and Regulatory Document Writing
Kathryn Wekselman, PhD, RN
Senior Director, Regulatory and Scientific Affairs
CTI Clinical Trial and Consulting Services

Elaine B. Taylor
Senior Director, Regulatory Strategy, Consulting and Submissions
INC Research

TUT 23 How to Prepare for an FDA Inspection
Michael R. Hamrell, PhD, RAC
President
MORIAH Consultants

TUT 24 Pharmacogenomics and Companion Diagnostics: The Future of Clinical Trials, New Product Development and the Practice of Medicine
Michael Drues, PhD
Founder and President
Vascular Sciences

TUT 25 Signal Detection: Identifying and Managing Safety Signals
Joanna Faith Haas, MD, MSc, FACP, FISPE
Founding Partner
Haas and Partners LLC

David Fram
Vice President, Research
Commonwealth Informatics Inc.

TUT 30 Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development
Alberto Grignolo, PhD
Corporate Vice President
PAREXEL International

Yoshiaki Uyama, PhD
Director, Division of Epidemiology, Office of Safety I
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

TUT 31 Preparing for a US FDA Advisory Committee Meeting
Lisa Peluso
Associate Director, Communications
PharmApprove

TUT 32 Influencing Culture, Avoiding Bureaucracy, and Encouraging Innovation
Michael Laddin, MBA, MS
Chief Executive Officer
LeaderPoint

TUT 33 Large-Scale Regulatory Functional Outsourcing: Emerging Trends, Challenges, and Decision Criteria
Rick Lilley, PhD
Senior Vice President, Global Regulatory Affairs
Vertex Pharmaceuticals

Kimberly Christopher
Head, BioDev Operational Excellence
UCB, Inc.

Paul A. Bridges, PhD, RPh
Corporate Vice President
PAREXEL International, United Kingdom

Katie Connelly
Vice President, Strategic Resourcing & Operations
PAREXEL International

TUT 34 Preparation of Risk Evaluation and Mitigation Strategies Assessment Reports
Catherine Sigler, DVM, PhD, MPH
Senior Director, Safety, Epidemiology, Registries and Risk Management
UBC: An Express Scripts Company

Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management
UBC: An Express Scripts Company

Matthew A. Lee, PharmD
Director, Regulatory Affairs
Marathon Pharmaceuticals, LLC

TUT 35 Ethical Issues in Clinical Trials
Art Gertel, PhD
President and Principal Consultant
MedSciCom, LLC

TUT 40 Analysis of Safety Data from Clinical Trials
Jürgen Kübler, PhD
Global Head, Quantitative Safety Sciences
CSL Behring GmbH, Germany

Joachim Vollmar
Executive Consultant
International Clinical Development Consultants, LLC

TUT 41 Quality Oversight of CROs-Clinical Vendors
Jennifer J. Poulakos, PhD
Director, Development Quality Assurance
Agensys, Inc

Liz Wool, BSN, RN, CCRA, CMT
President and Chief Executive Officer
QD-Quality and Training Solutions, Inc.

Joan B. Versaggi, BS, MBA
Principal
QPM Solutions, LLC

TUT 42 Fundamentals of ANDA Submissions and FDA Expectations Under GDUFA
Carol H. Danielson, DrPH, MS, RAC
President
Regulatory Advantage, LLC

TUT 43 Clinical Statistics for Nonstatisticians
Michael C. Mosier, PhD
Director, Biostatistics
EMB Statistical Solutions, LLC

TUT 44 Risk Management and Safety Communication Strategies
Nancy D. Smith, PhD
Adjunct Professor
Temple University, FDA Alumni

TUT 45 The Good Pharmacovigilance Practices in the EU: Global Applications
Peter Richard Arlett, MRCP
Head of Pharmacovigilance
European Medicines Agency, European Union

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

Steve Jolley, MA
Chief Executive Officer
SJ Pharma Consulting, LLC

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

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 Pacurariu, 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
Varley 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
Haojin 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

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 1A at 9:35–9:40 AM
Brittny 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 1A at 9:42–9:47 AM
Stephan Lanes, PhD
HealthCore, Inc.

***T 03 Biosafety Gene Therapy: Navigating the Regulatory Maze**
ORAL PRESENTATION SCHEDULED: Session 1A 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 1A at 9:56–10:01 AM
Christine M. Cheng, PharmD
First Databank, Inc

***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
INFARMED, 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 Bowles
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
Celerion

***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 17 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 Recruitement 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: Session1B 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 Products' 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

***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, MEd, 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

***T 38 An Approach to Aggregate Safety Reporting of Drug and Device Constituent Parts of Combination Products**
ORAL PRESENTATION SCHEDULED: Session 1C at 2:56–3:01 PM
Xaymara Roman, RN
AbbVie, Inc.

T 39 Analyzing the Relative Recruitment Performance between Highly-Utilized and Low-Utilized Sites in 5 TAs in 4 Asian Countries
Hyunjoo Rhee, MPharm
Quintiles Transnational Korea Co., Ltd., Republic of Korea

***T 40 How IDMP Can Help Structure Product Information / Labeling**
ORAL PRESENTATION SCHEDULED: Session 1C at 3:03–3:08 PM
Romuald Braun
uanotau, Switzerland

T 41 Simultaneous Marketing Authorization Applications: Pharma Urban Legend or Reality?
Stacie O'Sullivan
Eisai Inc.

T 42 Results Reporting to ClinicalTrials.gov and EudraCT – A Consolidated Approach and First-hand Experiences
Mathias Poensgen, PhD
ArisGlobal GmbH, Germany

Professional Poster Session #2 | Wednesday, June 17, 9:00 AM–4:00 PM

W 01 Expanding Knowledge of Pharmaceutical Industry Careers to PharmD Students: Impact of National Webinars
Corey Robinson
MCPHS University

W 02 EHR for Identifying and Recruiting Patients in Clinical Trials: Feasibility Study of Myocardial Infarction Using the CPRD
Antonis A. Kousoulis, DrMed, MS
The Clinical Practice Research Datalink Group (CPRD), United Kingdom

***W 03 Information Architecture for Publishing Stem Cell Data in Open Source Platform**
ORAL PRESENTATION SCHEDULED: Session 2A at 9:35–9:40 AM
Bhanu Bahl, PhD, MA, PMP
Harvard Medical School

W 04 Review of Adherence Measures for Use in Phase IV Studies and Recommendations for a New Standardized Generic Measure
Colleen A. McHorney, PhD
ERT

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 9:42–9:47 AM
Heidi G. Bell, MD, RPh
Zerochaos 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 14 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
Janssen Biotech, Inc.

***W 15 Strategic Considerations for Developing an Initial Pediatric Study Plan for a Proposed Biosimilar**
ORAL PRESENTATION SCHEDULED: Session 2B at 11:42–11:47 AM
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 11:56 AM-12:01 PM
Sadiqa Hafeez Mian, MD, MPH
Amgen 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 Physician Practices**
ORAL PRESENTATION SCHEDULED: Session 2B at 12:10–12:15 PM
Sukhleen (Sheena) Gurai, PharmD, MEd
Genentech, A Member of the Roche Group

***W 20 Precision Medicine Basket Trial Eligibility Across Race/Ethnicity: Implications for Ethnobridging 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 Outsourced 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

AWARD WINNERS

DIA Awards recognize significant individual or group accomplishments in the discovery, development or life cycle management of biopharmaceutical, device or related therapeutic health care products, and/or exceptional volunteer contributions to advancing DIA's Mission and Vision.

GLOBAL INSPIRE AWARDS

Evaluated and selected by the DIA Fellows. Approved by DIA Board of Directors.

President's Award for Outstanding Contribution to Global Health
Baron Peter Piot, MD, PhD, FRCP, FMedSci

Excellence in Service
Justina A. Molzon, JD, MSc
FDA (Retired)

Global Connector
Alberto Grignolo, PhD
Corporate Vice President, PAREXEL International

DIA Author(s) of the Year Award

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 it's 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.

Defining a Central Monitoring Capability: Sharing the Experience of TransCelerate BioPharma's Approach, Part 1 (TIRS: Sept 01, 2014: Issue 48: pages 529-535)

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

REGIONAL INSPIRE AWARDS: AMERICAS

Outstanding Contribution to Health

CTTI

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
Principal, Paarlberg & Associates LLC

Leader of Tomorrow
Brittany Mani
Doctor of Pharmacy Candidate, Howard University College of Pharmacy

Accelerated Professional Development for a Global Safety Audience

Whether you are new to the industry, considering a career change, or just want to build your professional development portfolio, DIA's **Clinical Safety and Pharmacovigilance Accelerated Certificate Program** is the perfect educational platform for you.

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- Receive a certificate upon completion of the program requirements by December 31, 2015
- Customize your package with the choice of face-to-face meetings, training courses, and online learning to best meet your needs
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Package includes the **DIA 2015 51ST Annual Meeting** as an option towards completion of the program.

Upcoming Training Included in the Package

Pragmatic Approaches to Drug Safety Across the Premarketing and Postmarketing Continuum
August 10-12 | Sheraton Boston Hotel | Boston, MA
Course Level: Intermediate

Clinical Statistics for Nonstatisticians
September 28-29 | DIA Global Center | Dupont Circle, Washington, DC
Course Level: Beginner

Risk Management and Safety Communication
October 26-27 | DIA Global Center | Dupont Circle, Washington DC
Course Level: Intermediate

Postmarketing Drug Safety & Pharmacovigilance
November 9-10 | Sheraton Philadelphia University City | Philadelphia, PA
Course Level: Intermediate

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Keith Wenzel	OTHER SUPPORT-Employee of PAREXEL
James Wescott	OTHER SUPPORT-Employee of Actavis Inc.
Angela Wilson	OTHER SUPPORT-Employee of Genentech, A Member of the Roche Group
Diane Wold	OTHER SUPPORT-Employee of GlaxoSmithKline, STOCK SHAREHOLDER-GlaxoSmithKline
Michael Wolf	CONSULTANT-Abbott Labs, Deborah Adler, CVS/Caremark, Data Solutions, Luto UK, Merck & Co., Inc., Vivus, GRANT SUPPORT-Merck & Co., Inc., Sharpe & Dohme, United Healthcare
Schiffon Wong	OTHER SUPPORT-Employee of EMD Serono Inc.
Weiya Zhang	OTHER SUPPORT-Employee of Otsuka

The following DIA planners and managers, Susan Cantrell, Tracy Collier, Julie Ho, Meredith Kaganovskiy, Stephanie Ritter, Holly Stevens, Karen Tenaglia, and Bethany Watson hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months. Maureen Lamplugh has reported stock shareholder of Express Scripts and Merck & Co., Inc., and Debra Michaels has reported stock shareholder of Abbott, AbbVie, and Genzyme (Sanofi).

The following PIM planners and managers, Trace Hutchison, PharmD, Samantha Mattiucci, PharmD, CHCP, Judi Smelker-Mitchek, RN, BSN and Jan Schultz, RN, MSN, CHCP, hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months.

The following DIA Pharmacy Committee members have disclosed the following: Alan F. Boyd, RPh, stock shareholder of CNS Vital Signs, LLC, David M. Cocchetto, RPh, PhD, employee of Duke University Health System and stock shareholder of GlaxoSmithKline, Poxen and Teva, Charles C. Depew, PharmD, employee and stock shareholder of GlaxoSmithKline, Teresa P. Dowling, PharmD, employee and stock shareholder of Vertex Pharmaceuticals, Truus Janse-de Hoog, PharmD, MSc, no financial relationships; J. Christopher Prue, RPh, MBA, employee of BioDelivery Sciences International, former employee of Cerenis Therapeutics.

The following project management professional reviewer Jayna M. Rose, PhD, PMP has disclosed employee of Amgen.

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2015-16 ANNUAL MEETINGS

November 15-17, 2015
12th Annual Meeting
DIA Japan 2015
Tokyo, Japan

April 6-8, 2016
28th Annual EuroMeeting
Hamburg, Germany

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June 26-30, 2016
DIA 2016 52nd Annual Meeting
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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:

MONDAY, JUNE 15

Number	Session Title	Assigned UAN	Type of Activity
106	Communicating Pharmaceutical Risks and Benefits: Why Is It So Hard and How Can We Do Better?	0286-0000-15-526-L04-P	Knowledge
110	Enabling Next Generation Sequencing Within Global Clinical Trials	0286-0000-15-552-L04-P	Knowledge
111	The Growing Role of the Patient Leading Into PDUFA VI: Negotiations and 2016	0286-0000-15-558-L04-P	Knowledge
114	Risk Management Plans Ten Years On: Where Are We Now and Where Are We Going?	0286-0000-15-578-L04-P	Knowledge
117	The Emerging Role of Medical Affairs in Biopharmaceutical Organizations: Challenges and Opportunities	0286-0000-15-612-L04-P	Knowledge
118	Ebola Virus Disease Case Study: Global Harmonization to Increase Power and Accelerate Outcomes in Clinical Research Data	0286-0000-15-615-L01-P	Knowledge
119	Pediatric Clinical Trials: Learning from Patients, Parents, and Investigative Sites	0286-0000-15-508-L04-P	Knowledge
125	Engaging Patients and Health Care Professionals Through Social Media and Big Data Systems	0286-0000-15-527-L04-P	Knowledge
126	Integrating Patient Engagement with EHR Data and eSource for Better Studies	0286-0000-15-532-L04-P	Knowledge
128	Global Drug Development in China: Opportunities and Challenges for Innovation	0286-0000-15-542-L04-P	Knowledge
129	New Pandemics: Lessons Learned from the Ebola Experience	0286-0000-15-559-L01-P	Knowledge
131	Reducing Drug Shortages	0286-0000-15-566-L04-P	Knowledge
132	REMS Integration into the Health Care System: Three Perspectives in an Evolving Environment	0286-0000-15-579-L04-P	Knowledge
133	Statistical Evaluation of Therapeutic Equivalence for Locally-Acting Generic Products	0286-0000-15-589-L04-P	Knowledge

TUESDAY, JUNE 16

Number	Title	Assigned UAN	Type of Activity
201	The Development of Patient Power: From Consumer to Active Participant!	0286-0000-15-509-L04-P	Knowledge
202	The Role of Innovation in Clinical Trial Advocacy: Developing and Executing Patient-Centered Strategies and Partnerships Throughout the Continuum	0286-0000-15-513-L04-P	Knowledge
207	Prescription Drug Marketing Regulatory Primer	0286-0000-15-522-L04-P	Application
209	Implementing Risk-Based Monitoring	0286-0000-15-533-L04-P	Knowledge
211	Can We Talk? Alternative Strategies for Communicating with FDA	0286-0000-15-545-L04-P	Knowledge
212	Global Regulation of Advanced Therapies	0286-0000-15-547-L04-P	Knowledge
213	Pediatric Therapeutic Development: From Policy to Portfolios to Patients	0286-0000-15-560-L04-P	Knowledge
215	Learning By Doing: Regulatory Applications for Breakthrough Therapies	0286-0000-15-567-L04-P	Knowledge
216	Remember That? Choosing Recall Intervals for Patient-Reported Outcome Measures	0286-0000-15-576-L04-P	Knowledge
218	Social Media: Opportunities and Challenges in Pharmacovigilance and Clinical Research	0286-0000-15-583-L04-P	Knowledge
219	Safety in Special Situations: Vaccines, Stem Cells and Beyond	0286-0000-15-588-L04-P	Knowledge
220	New Challenges for a Data Monitoring Committee	0286-0000-15-590-L04-P	Knowledge
230	Navigating Complex Biological and Regulatory Pathways to Bring Novel Gene and Cell Therapies to the Clinic	0286-0000-15-518-L04-P	Knowledge
231	FDA Enforcement Update: Advertising and Promotion	0286-0000-15-523-L04-P	Knowledge
234	How to Trust Data from Wearable Devices Used in Clinical Trials	0286-0000-15-538-L04-P	Knowledge
236	The State of Pediatric Research in the United States	0286-0000-15-548-L04-P	Knowledge
237	Impact of FDA Oversight of Laboratory-Developed Tests Upon Innovation in the Targeted Therapy Setting	0286-0000-15-553-L04-P	Knowledge
239	Office of Pharmaceutical Quality Update	0286-0000-15-568-L04-P	Knowledge
240	Breakthrough Medicines or Affordable Health Care: Do We Have to Choose?	0286-0000-15-617-L04-P	Knowledge
241	21st Century Pharmacovigilance: Improving Outcome Traceability for Products Across the Complexity Continuum, From Generics to Biologics and Vaccines	0286-0000-15-580-L04-P	Knowledge
242	The Use of Adaptive and Bayesian Approaches in Clinical Trials: Sharing Experiences and Case Studies	0286-0000-15-591-L04-P	Knowledge
245	FDA's International Posts: International Efforts, Regulatory System Strengthening and Inspections	0286-0000-15-606-L04-P	Knowledge
247	Regulation of Combination Products in the 21st Century	0286-0000-15-616-L04-P	Knowledge
255	Essential Approaches to Promotional Review of Mobile Health Apps: Technology That Is Here to Stay and Evolving Fast	0286-0000-15-524-L04-P	Knowledge

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257	Developing Online Communities: Perspectives for Site and Patient Engagement	0286-0000-15-534-L04-P	Knowledge
259	Transatlantic Collaboration on Pediatric Study Plan (PSP)/Pediatric Investigation Plan (PIP): Recent Experience	0286-0000-15-543-L04-P	Knowledge
260	Success from Bench to Launch: Challenges and Opportunities with Development of Companion Diagnostics	0286-0000-15-554-L04-P	Knowledge
261	The Challenges and Opportunities of Digital Health Care: What Does the Future Hold?	0286-0000-15-561-L04-P	Knowledge
265	Disruptive Forces in Health Care Innovation: Where Are They Leading Us?	0286-0000-15-619-L04-P	Knowledge
268	Bringing Clinical Trial Practices into the 21st Century	0286-0000-15-510-L04-P	Knowledge
269	Pediatric Clinical Trials: One Size Does Not Fit All	0286-0000-15-514-L04-P	Knowledge
275	The Free Exchange of Truthful and Non-Misleading Medical Information	0286-0000-15-525-L04-P	Knowledge
277	How Risk-Based Monitoring and eSource Methodologies Are Impacting Clinical Sites, Patients, Regulators and Sponsors	0286-0000-15-535-L04-P	Knowledge
278	Data and Evaluation Needed for Robust Evidence: Regulators' Challenges	0286-0000-15-539-L04-P	Knowledge
280	Optimizing Patient Labeling: A Panel Discussion Between Industry, Academia, and Prescribers	0286-0000-15-549-L04-P	Knowledge
281	Continuing Growth in Combination Products: More Products, More Questions - Perspectives from FDA and Industry	0286-0000-15-555-L04-P	Knowledge
284	CMC/GMP: Risk-Based Regulatory Review	0286-0000-15-569-L04-P	Knowledge
285	Innovative Approaches to Patient Registries for Evaluating Outcomes	0286-0000-15-572-L04-P	Application
286	Translating New Knowledge from Regulatory Science into Postmarketing Safety Practice	0286-0000-15-584-L04-P	Knowledge
288	Predictive Subgroup Methodologies and Molecular Basket Designs	0286-0000-15-592-L04-P	Knowledge
289	Conflict Resolution: Helping Teams Manage Through Conflict	0286-0000-15-597-L04-P	Application
290	Pediatric Drug Development	0286-0000-15-602-L01-P	Knowledge
291	CDRH Town Hall	0286-0000-15-607-L04-P	Knowledge

WEDNESDAY, JUNE 17

Number	Title	Assigned UAN	Type of Activity
301	Leveraging Diverse Patient Insights	0286-0000-15-511-L04-P	Knowledge
302	Patient Registries: Design, Development, and Recruitment	0286-0000-15-515-L04-P	Application
306	Innovative Approaches to Predictive Clinical Safety and Signal Detection Utilizing Clinical Pharmacology Concepts	0286-0000-15-519-L04-P	Knowledge
307	Returning Results to Study Participants: Health Literacy and Effective Language	0286-0000-15-528-L04-P	Knowledge
312	21st Century Cures: Which Are the Most Transformative Provisions and How Do They Accomplish Major Change?	0286-0000-15-562-L04-P	Knowledge
315	Real-World Use of Multi-Criteria Decision Analysis for Benefit-Risk Assessment: Lessons Learned in the Industrial Setting	0286-0000-15-573-L04-P	Knowledge
316	Pharmacovigilance Concerns with the Use of Experimental Medicines for Ebola and Enterovirus B-68	0286-0000-15-581-L04-P	Knowledge
317	Benefit-Risk Assessment of Medicines: Three Perspectives on Current Methodologies and the Statistician's Role in Implementation	0286-0000-15-593-L04-P	Knowledge
318	Rare Diseases and Subgroups Defined by Tumor Evolution: Common Themes and Challenges	0286-0000-15-603-L01-P	Knowledge
319	The Impact of the eLabeling Rule on Industry and Stakeholders	0286-0000-15-613-L04-P	Knowledge
324	Putting It All Together: A Shared, Comprehensive, Integrated Global System for Clinical Research	0286-0000-15-516-L04-P	Knowledge
328	Implications of Clinical Test Result and ECG Variability on the Design, Conduct, and Interpretation of Early Phase Clinical Studies	0286-0000-15-520-L04-P	Knowledge
329	How Collective Insights of Medical Affairs Customer-Facing Teams Work to Inform Strategy	0286-0000-15-529-L04-P	Knowledge
331	Digitization of Clinical Trials: Check the Pulse on Bringing Benefits to Patients	0286-0000-15-540-L04-P	Knowledge
332	Medicine Development and Authorization: A Patient-Centered Approach	0286-0000-15-546-L04-P	Knowledge
333	Opening the Door to Data Transparency: What's the Verdict?	0286-0000-15-550-L04-P	Knowledge
334	The Role of Labeling in Successful Human Factors Studies	0286-0000-15-556-L04-P	Knowledge
335	Precision Medicine: Where Is the Technology Taking Us, How Fast and Who Is Driving?	0286-0000-15-563-L04-P	Knowledge
337	How Can International Guidances Enable Global Regulatory Convergence?	0286-0000-15-570-L04-P	Knowledge
339	Best Evidence Generation: Regulatory Perspectives	0286-0000-15-577-L04-P	Knowledge

340	Integrated Cardiac Safety	0286-0000-15-585-L01-P	Knowledge
342	The Role of the Clinical Statistician in Understanding and Using ADaM Data Standards	0286-0000-15-594-L04-P	Knowledge
343	DEVELOP Excellent Presentations to INNOVATE the Way You Communicate Information and ADVANCE Your Career	0286-0000-15-601-L04-P	Application
344	Orphan Drug Development Challenges: Case Studies	0286-0000-15-604-L01-P	Knowledge
349	Cardiac Safety Considerations in Pediatric Drug Development	0286-0000-15-511-L01-P	Knowledge
350	Is Facebook Hurting Your Trial? Social Media and the Introduction of Bias in Clinical Studies	0286-0000-15-517-L04-P	Knowledge
354	Effective Discovery, Development and Use of Biomarkers in Early Drug Development	0286-0000-15-521-L04-P	Knowledge
355	Globalization of Field Medical Science Liaisons: How to Take It to the Next Level	0286-0000-15-530-L04-P	Knowledge
356	Searching for the Gold Nuggets: Text Analysis in Clinical Data	0286-0000-15-536-L04-P	Knowledge
358	Expediting Drug Development Through FDA's Breakthrough Therapy Designation	0286-0000-15-618-L04-P	Knowledge
359	Does Bioequivalent Always Mean Therapeutically Equivalent? Impact of FDA's Proposed Rule on Generic Labeling	0286-0000-15-551-L04-P	Knowledge
361	The Challenges, Solutions and Right To Try Surrounding Expanded Access	0286-0000-15-564-L04-P	Knowledge
363	Risk-Based Inspections and Compliance	0286-0000-15-571-L04-P	Knowledge
364	Operationalizing the Pragmatic Clinical Trial: The Role of PCORI and the Pharmaceutical Industry	0286-0000-15-574-L04-P	Knowledge
365	A Proactive and Systematic Approach to Managing Product Risk Across the Life Cycle	0286-0000-15-586-L04-P	Knowledge
368	Conducting Courageous Conversations as a Strategy to Work with Difficult People	0286-0000-15-600-L04-P	Application
370	A Global Update on Orphan Drugs	0286-0000-15-605-L04-P	Knowledge
371	CBER Town Hall: Innovation and Public Health Response	0286-0000-15-608-L04-P	Knowledge
372	No More Crying Wolf: FDA Issues Final Rule on Changes to Pregnancy and Lactation Information in Drug Labeling	0286-0000-15-614-L01-P	Knowledge
380	Accountable Care Organizations and Integrated Health Care	0286-0000-15-531-L04-P	Knowledge
384	Enhanced Collaborative Strategies: FDA and Device Makers Focusing on Improved Device Clearance Processes	0286-0000-15-557-L04-P	Knowledge
385	Enforcement Update and Trends From a Global Perspective	0286-0000-15-565-L04-P	Knowledge
388	Making Evidence at Launch More Real-World: Pragmatic Trials, Current Developments and Operational Challenges	0286-0000-15-575-L04-P	Application
389	Developing Innovative Approaches to Postmarketing Safety Data Collection in Pregnant Women	0286-0000-15-587-L05-P	Knowledge
391	Statistical Support of Risk-Based Monitoring	0286-0000-15-595-L04-P	Knowledge

THURSDAY, JUNE 18

Number	Title	Assigned UAN	Type of Activity
401	Lung-Map: A Future Clinical Trial with a Master Protocol Happening Now and the Value to Patients	0286-0000-15-512-L01-P	Knowledge
405	Tired of Reinvesting in Old R&D Systems? Several Large Pharmaceutical Companies and Other Leaders Are Flipping Paradigms	0286-0000-15-537-L04-P	Knowledge
406	Bring Your Own Device (BYOD) Approaches to the Collection of Electronic Patient-Reported Outcome Data in Clinical Trials	0286-0000-15-541-L04-P	Knowledge
407	Accidental Drugs: A Historical Look at How Certain Drugs Came to Market and Policy Pathway Opportunities	0286-0000-15-544-L04-P	Knowledge
409	Innovative Designs for Cardiovascular Outcome Safety Trials in Type 2 Diabetes	0286-0000-15-596-L01-P	Knowledge
410	Aha: Moments of Breakthrough Thinking Leading to New Opportunities	0286-0000-15-598-L04-P	Knowledge
412	Mobile Health, Telemedicine, and Remote Sensors in Clinical Investigations: A New Era in Clinical Trial Design?	0286-0000-15-610-L04-P	Knowledge
413	DEVELOP Risk-Based Monitoring Strategies to INNOVATE Study Oversight and ADVANCE Study Execution	0286-0000-15-507-L04-P	Knowledge
418	The Future of Pharmacovigilance Operations	0286-0000-15-582-L04-P	Knowledge
419	Making Technology a Key Component of Your Learning Strategy	0286-0000-15-599-L04-P	Knowledge
420	CDER Town Hall	0286-0000-15-609-L04-P	Knowledge
421	Leveraging Electronic Health Record Data in Close Collaboration with Health Systems to Accelerate Precision Medicine	0286-0000-15-611-L04-P	Knowledge

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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.

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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.

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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.

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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.

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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.

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If you are struggling with integration of clinical study data from multiple systems and platforms, Adaptive Clinical Systems offers a simple, secure, validated, compliant, and cost-effective solution for clinical data integration. The Adaptive eClinical Bus, a cloud-based hosted service, will integrate with your EDC, ePRO, CTMS, Medical Imaging, IVR/IWR, and analytical/data visualization systems to ensure accurate and efficient transfer of clinical data for any study of any complexity.

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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.

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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.

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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.

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Applied Clinical Trials is the authoritative, peer-reviewed resource and thought leader for the global community that designs, initiates, manages, conducts and monitors clinical trials. Industry professionals learn effective and efficient solutions to strategic and tactical challenges within the tightly regulated, highly competitive pharmaceutical environment.

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ArisGlobal is the leading provider of integrated solutions for pharmacovigilance & safety, regulatory affairs, clinical research, and quality & compliance for medical inquiries. Life science companies using ArisGlobal's solutions can better build and maintain the trust they need with their customers, medical practitioners and regulatory bodies around the world.

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Arivis provides integrated solutions for Life Science companies and is unique in the breadth of its solutions, the integration of its technology, and the flexibility of its cloud-based models. Arivis was first to the cloud with regulatory document management for Life Sciences helping companies that want reliable, easy-to-use, and quick-to-implement solutions that meet all of their regulatory needs including compliance with eCTD and CFR 21 Part 11.

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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

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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.

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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.

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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.

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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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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.

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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.

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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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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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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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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
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Founded in 1976, Cardinal Health Regulatory Sciences (CHRS) assists companies with worldwide development of pharmaceutical, biotechnology, and medical device products. CHRS provides regulatory and product development planning, program management, global regulatory authority interaction, medical writing, global regulatory documentation preparation (investigational and marketing applications), regulatory publishing (eCTD and paper), and global compliance programs.

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As a BioTelemetry company, Cardiocore 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
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Cardiovascular Research Foundation
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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.

Catalent
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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.

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Center for Information and Study on Clinical Research Participation (CISCRP)
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The Center for Information and Study on Clinical Research Participation (CISCRP) is a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. CISCRP is committed to engaging and building relationships among members of the public, clinical research volunteers, and clinical research professionals.

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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 11 compliant, electronic IRB management platform (CIRBI) which streamlines protocol submissions, decreases investigator review turnaround times and results in faster subject enrollment.

Chexx Inc.
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Chiba University Hospital
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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
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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.

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

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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.

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Clinical Ink
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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.

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Clinical Research Advantage/ Radiant Research
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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.

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CluePoints, Inc.
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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.

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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.

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Compass IRB
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Compass Research, LLC
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CompleWare
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Comprehend Systems
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Content Analyst Company
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CoSign by ARX
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Covance Inc.
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CRO Analytics
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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.

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CTI Clinical Trial & Consulting Services
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CTI is an international drug and device development organization that delivers a full spectrum of clinical trial and consulting services from bench to commercialization, with a passion for helping life-changing therapies succeed in complex and critically ill patient populations. This focused therapeutic approach provides pharmaceutical and emerging biotechnology companies with clinical and disease area expertise from a unique mix of academic, medical, and industry specialists.

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Cu-Tech, LLC is a full-service CRO, celebrating over two decades of premier service to the pharmaceutical industry, specializing in Dermatology clinical trials management, conduct, and monitoring. Cu-Tech professionals offer a complete array of services and consultation to the client from the inception to completion of a project. We maintain an extensive database of the finest dermatologists in North America and abroad. Our clients can attest to our personal hands-on approach.

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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 DEVELOP INNOVATE ADVANCE

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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.

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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.

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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!

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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.

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Foresight Group International AG
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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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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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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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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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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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As a pioneering and leading commercial clinical laboratory in China, KingMed is accredited by CAP (13 disciplines), ISO15189, ISO/IEC17025, ISO9001, NGSP 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.

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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.

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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.

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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.

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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.

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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.

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Inamed is an international contract research organization with true respiratory expertise. Complementing our solid experience in conducting clinical trials, Inamed's team of inhalation and clinical experts provides our sponsors with a unique spectrum of services. Besides our clinical trial operations Phase IIb-IV and fully staffed, in-house Phase I-IIa unit with 18 beds, Inamed performs in-vitro studies in our own labs and is leading in performing scintigraphic lung deposition studies.

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Integrated Development Associates Co., Ltd. (IDA) is a Japanese consultancy with offices in Tokyo and Osaka that assists biopharmaceutical companies increase the value of their products through the integration of Japan and Asia into global drug development. Since 2004 IDA has enabled over 50 clients to conduct bridging development programs, integrate Japan into global trials, obtain and maintain Orphan Drug Designation as well as successfully partner their products in Japan.

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inVentiv Health
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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.

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KlinEra Global Services **Booth: 2110**
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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 perferred 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) **Booth: 1651**

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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 opportuniy to discuss your clinical development needs.

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MakroCare is a global development and consulting firm that delivers measurable impact to clients by integrating expertise, global resources and proven processes. Through offices in USA, UK, Europe and Asia, MakroCare provides consulting, regulatory, clinical, risk and technology services to pharmaceutical, biotechnology, and medical device industries.

Mapi
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Mapi is the leading Patient-Centered Research Company serving academia, life science researchers, and the pharmaceutical industry for 40 years. Our commitment to patients is reflected through our wide range of services, including Real World Evidence, HEOR, Linguistic Validation, Strategic Market Access, and our Mapi Research Trust. Visit http://www.mapigroup.com for more information.

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Masimo is a global medical technology company that develops and manufactures innovative noninvasive technologies, medical devices and sensors that may enable earlier detection and treatment of potentially life-threatening conditions—offers numerous award-winning patient monitoring solutions, including Masimo SET®, Masimo rainbow SET® noninvasive and continuous hemoglobin (SpHb®), acoustic respiration rate (RRa™), Masimo SafetyNet™, and SEDLine® (EEG-based) Brain Function Monitors.

Massachusetts College of Pharmacy and Health Sciences
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Massachusetts College of Pharmacy and Health Sciences (MCPHS) offers exciting opportunities for those interested a graduate education in health care. Students can enroll in many programs as full-time or part-time students at either our Boston Campus or Online Campus.We are the oldest institution of higher education in the entire city of Boston and the second-oldest university of pharmacy in the United States. We have over 65 programs and approximately 6,600 students from 44 countries worldwide.

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MasterControl Inc. produces software solutions that enable pharmaceutical companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl solutions include clinical management, quality management, document management, audit management, training management, supplier management, submissions document management, and more. MasterControl provides our customers with a complete information management solution across the entire enterprise.

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At MaxisIT®, we improve how pharmaceutical, life sciences companies, and academia leverage information and make decisions in support of clinical research and development. Our cloud-based, integrated technology platform optimizes the information flow across the entire clinical value stream ranging from the data capture technologies to external CROs, vendors, and partners.

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McGuire Research Institute (MRI) was established in 1989 and conducts Phase 1-4 clinical trials. MRI is affiliated with the Richmond VA Medical Center and has a 35,000 patient panel. IRB meets weekly, AAHRPP accredited human research protection program. Special expertise in diabetes, lipids, Crohn's, colitis, interventional cardiology, liver disease, electrophysiology, DVT, Parkinson's, traumatic brain injury.

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MDCPartners applies the principles of semantic web mining to address pharma business intelligence challenges posed by an expanding complex data offering, driven by transparency in drug development and healthcare. Our ta-Scan platform is fast becoming the industry standard for clinical research planning and operations. The tool enables a prevailing snapshot on any therapeutic area, revealing data relationships between drugs, trials, patient populations and researchers.

Med Fusion
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MedDRA is a clinically validated terminology used for encoding adverse events for the biopharmaceutical industry and regulators. The MSSO maintains MedDRA and provides support services (e.g., training, data conversion, consulting).

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Established in 2006, the MRN is the world's leading provider of home healthcare for patients in clinical trials; taking the trial to the patient makes participation more convenient and appealing for the patients and boosts recruitment rates considerably (from 60% upwards). This ease of participation also significantly improves patient retention, consistently above 95%.

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Medical Vigilance Solutions (MVS) specializes in Pharmacovigilance, Medical Communications and 24/7 Contact Center Services supporting pharmaceutical, biotech, medical device and consumer health organizations. With 30 years of industry experience, MVS provides comprehensive outsourced solutions that fit seamlessly into your process. Let's get started. 855-752-3742

Medicines Evaluation Unit
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The Medicines Evaluation Unit (MEU) is a clinical trials unit that specialises in respiratory diseases, including Asthma and COPD.

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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
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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.
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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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 QRTD (Quantitative Real Time Diagnostics) for use of their diagnostic devices/services for the global clinical trials market.

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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.

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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
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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
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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.

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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
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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.

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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
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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
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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.

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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.

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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.

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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
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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.

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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.

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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
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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.

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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.

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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
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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.

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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
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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.

Ocasa Logistics Solutions
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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.

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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 operations performance. Visit us at booth 2135 to see why 4 of the 5 top CROs and 7 of the 10 largest Phase I Clinics run OmniComm EDC technologies.

Online Business Applications
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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.

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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.

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Optum™ helps pharmaceutical, biotechnology and medical device companies successfully address product development and commercialization challenges by delivering a full range of integrated solutions—in the areas of strategic insight, value assessment, evidence development, alignment to commercial needs, and launch support.

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OCRC is a cutting edge independent Phase I – IV custom-built 35,000 sq. ft. research site. Designed specifically for Phase 1 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.

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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.

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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.

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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.

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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.

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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.

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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
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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 (CMRNs) 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.

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Pennside Partners has a 25+ year track record in providing business development and launch support for the pharmaceutical/biotechnology industries. Our core competency is our ability 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.

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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.

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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
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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
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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.
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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)
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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
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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.

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PharmaQuest – 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
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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.

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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
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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.

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Pharm-Olam International 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 Inc.
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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
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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

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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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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.ppdi.com.

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Praxis provides focused patient recruitment to the world's leading pharmaceutical and biotech companies. It's all we do. Each study is unique, and so is each Praxis patient recruitment campaign. We believe that understanding the patient for each study is key to developing a strategic campaign that resonates with your patient population. Visit www.gopraxis.com to learn more.

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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.

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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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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
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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.

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Projecis, Inc.
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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!

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PROSAR, a ProPharma 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.

Proteus Digital Health, Inc.
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To help researchers more effectively track and manage the use of medication during clinical trials, Proteus Digital Health has developed a novel system that continuously captures precise and timely data about medication adherence. Our solution provides deeper insight into drug efficacy and safety. It can also help to shorten trial duration, which can, in turn, reduce costs and increase trial success rates.

ProTrials Research, Inc.
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As a clinical research organization serving the pharmaceutical, biotechnology and device industries for more than 17 years, ProTrials professionals provide one of the industry's highest average years of experience. We offer a suite of services focused on clinical operations experience: • Experience in a broad range of therapeutic areas • Phase I-IV clinical trials • Highly-skilled project management services • Operational experience in North America and throughout Europe

PSKW, LLC
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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.

Pyxant Labs Inc
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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."

Q2 Business Intelligence
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Q2 (Q-square Business Intelligence) is a global Clinical Research Organization, with over 16 years pharmaceutical research and development experience, providing a broad range of services. Our principle is "Quality Work for Quality World". Janus Clinical Research Institute (Janus) is a Q2 based company in China. Janus possesses the capacity with extraordinary talented people for any large or small projects in clinical research.

QPS, LLC
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Founded by Dr. Ben Chien in 1995, QPS has Bioanalysis and Preclinical testing and Clinical Research facilities at its Newark, DE headquarters, in Groningen, Netherlands and in Taipei, Taiwan. Early-phase clinical facilities are located in Springfield, MO, Taipei, Taiwan, and Groningen, Netherlands. Business development offices are maintained in the US, Europe, and Asia.

Quality and Compliance Consulting, Inc.
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QC2 provides worldwide audit and consulting services, including: GCP, GLP, and cGMP Audits; Bioanalytical Laboratory Audits; Clinical Pathology Laboratory Audits; Sponsor, CRO, and Vendor Audits; Computerized System Validation Audits; Standard Operating Procedures Review and Preparation; GCP, GLP, QA, and SOP Training; and Consulting.

Quality Associates, Inc.
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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).

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Quanticate strives to help our clients maximize the value of their clinical data. Quanticate offers an extensive suite of Biometric Solutions that standardize the collection, analysis, and reporting of clinical trial data. As the largest fully dedicated clinical biometrics company we utilize top industry talent and leading technology to ensure our customers bring their drugs to market more quickly than ever before.

QuantifiCare
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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
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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
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Quintiles
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Quorum Review IRB
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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.

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Real Staffing Group
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RegCheck
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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
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Regeneron is a leading science-based biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets 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 Inc.
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Research Across America
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Research Across America is an Independent Site Network-ISN (Non-SMO) that conducts Phase I through Phase IV and Post marketing trials utilizing their many regional multi-specialty sites. Our site locations include Dallas, El Paso and Plano TX, New York, NY and Reading, PA. The physicians affiliated with Research Across America have conducted over 1850 clinical trials since 1992. Our sites are under one corporate umbrella but have the flexibility of negotiating their own contracts and budgets.

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ReSolution Latin America is a CRO/clinical consultancy company completely focussed on clinical development in Latin America and we specialize in providing clinical research solutions for development companies that are interested in Latin America for their clinical development programs. We provide the opportunity to work with a credible regional niche CRO provider that is able to successfully deliver clinical research conducted in Latin America to international quality standards and expectations.

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RWS Group – Medical Translation Division
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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.

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RxLogix is the foremost provider of business and technology solutions and services for Drug Safety and Pharmacovigilance. Our experienced team of experts offer consulting and strategic software solutions. We bring best practices across all areas of drug safety. RxLogix Solutions have been developed by the leading experts on the Oracle Argus Safety suite and Drug Safety.

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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.

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Website: www.sas.com/dia15

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SAS Institute Inc., JMP Division
Booth: 1744
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Website: www.jmp.com

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.

Scarritt Group, Inc.
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Website: www.scarrittgroup.com

Scarritt Group is a global meeting planning company specializing in the execution of clinical meetings specific to the drug development process. Our business is designed to meet the unique needs of pharmaceutical companies and CROs regardless of size or meeting locale. With a collective 200 years of experience in hotel and logistics management, Scarritt Group's relationships allow us to provide our clients with an exceptional meeting experience at the most competitive price.

Schlafender Hase Inc.
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Email: us@sh-p.com
Website: www.text-verification.com

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.

Schulman Associates IRB
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Schulman IRB provides high quality, rigorous IRB reviews for all research phases in North America via streamlined processes, customized technology and responsive customer service. We offer dedicated, AAHRPP-accredited IRB services for sponsors, CROs, sites and institutions and also offer CQA and HRP consulting via our partner Provision Research Compliance Services.

SeaView Research
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Seaview Research is celebrating it's 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.

Sharp Clinical Services
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Sharp Clinical Services IVRS/IWRS provides a sophisticated method of optimizing & managing clinical trials through dynamic resupply algorithms, data integration with eCRF, labs & real-time study data access. Our Management Team provides guidance and advice on packaging design and distribution as well as randomization scheme and visit schedule. We optimize your clinical trial experience with the foresight to include all study requirements before "GO LIVE" reducing out of scope and change control.

Sidus Biodata
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Website: www.sidusbiodata.com

Sidus BioData provides secure, compliant data hosting solutions for the Life Sciences/Medical Device and Health IT industries. Sidus BioData is committed to the highest level of quality in the management, security, integrity and availability of regulated data. In addition, Sidus' culture of compliance ensures all regulatory goals are met with our premium service offerings.

Signix, Inc.
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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.

SNBL Clinical Pharmacology Center
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SNBL CPC is a 96-bed, full service clinical pharmacology research facility based in Baltimore, Maryland. Our team specializes in executing complex early phase clinical research studies, including adaptive design, proof of concept, challenge, TQT, and ethnobridging trials. SNBL CPC offers ancillary trial support services including protocol consulting and design, IRB submissions, laboratory services, data management, safety monitoring, and more.

Society for Clinical Research Sites – SCRS
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The Society for Clinical Research Sites (SRCS) was founded in 2012 in response to the growing need for a trade organization to represent the global voice and community of research sites within the clinical research enterprise. The goals of the Society include providing sites with resources, mentorship, and new ideas through a membership organization dedicated only to research sites.

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Sonic Clinical Trials
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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
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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.

Southern California Research
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Southern California Research is dedicated to the development of new therapies for the treatment of allergic, dermatologic, immunologic, respiratory and other medical conditons. We have provided access to investigational and innovative treatments to thousands of individuals throughout Southern California since 1985. We are a premier research facility located in Mission Viejo, California, in South Orange County with a population of over 3 million people.

Southern Star Research
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Southern Star Research is a leading Australian CRO, providing flexible and high quality clinical research services, using highly experienced clinical research professionals. Expertise covers Ph I-IV trials in Pharmaceutical, Medical Device & Biotechnology projects. Services incl; Project Management, Monitoring, In-house staff placement, Patient Recruitment, Safety Reporting, Medical Monitoring & local study sponsorship. Staff are located across Australia, New Zealand and the United Kingdom.

Sparta Systems
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Website: www.spartasystems.com

Sparta Systems Inc. quality management solutions enable organizations to safely and efficiently deliver products and services to market. Its TrackWise® Enterprise Quality Management Software, trusted standard among highly regulated industries, is used by quality, manufacturing and regulatory affairs professionals to manage compliance, reduce risk and improve safety across the enterprise.

Spaulding Clinical Research
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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.

Speaking Books
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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

SPRI Clinical Trials - Global
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SPRI Clinical Trials is expanding its reach and services. SPRI has expanded its US operations and is happy to announce its new operations in Mexico and Turkey. With our continuing expertise in Central/Eastern Europe and United States, having these other regions is making SPRI a Global Solution provider. Whether you are a sponsor and want us to run the program or a CRO and want us to work with you, come see us. SPRI's focus- Bring together Science and Patients to promote health on a global scale.

Springer
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Statistics & Data Corporation (SDC)
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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.

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Stefanini
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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 – 30 countries – 32 languages – 17,000 resources globally. www.stefanini.com

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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.
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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
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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.

Symogen
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Symphony Clinical Research
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Symphony Clinical Research, formerly known as Clinical Resource Network, LLC, takes clinical study visits to patients where they live, work or study. We provide alternate-site care on six continents. Sponsor benefits include accelerated recruitment, enhanced retention, improved compliance, increased site productivity and increased patient satisfaction. A Certified Women Owned Business Enterprise.

Synchrogenix Information Strategies, Inc.
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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.

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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

Synowledge
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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.

Syntel, Inc.
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Syntel (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.syntelinc.com.

SynteractHCR
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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.
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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
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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
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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.
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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
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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.

TecHorizon
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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.

Telerx
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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.

Teuteberg Incorporated
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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.

TFDA / Center for Drug Evaluation, Taiwan
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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 review process and GMP inspection.

The Clinical Resource Network
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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.

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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 accessible and feasible.

The Patient Recruiting Agency
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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
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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 VigiBaseTM, the WHO Drug Dictionaries and WHO-ART with their related tools and services.

Theorem Clinical Research
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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 analytic-based development, combination trials and personal data applications to simplify complex trials.

Therapak Corporation
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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
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Therapeutics, Inc. is The Dermatology CRO with unparalleled dermatology expertise & decades of experience. A full service CRO with numerous product approvals, TI designs and executes Ph1-4 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
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ThreeWire, Inc.
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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.
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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
Booth: 2725
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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.

Total Root Concepts, Inc.
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TransPerfect
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Trifecta
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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.

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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 periapproval, safety, and commercialization services.

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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
Phone: 410-706-7241
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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 the Sciences
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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.

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GLOSSARY OF TERMS

3500A	FDA form for mandatory reporting of adverse events
AD	Alzheimer's disease
ADaM	analysis data model
ADE	adverse drug event
ADR	adverse drug report or adverse drug reaction
AE	adverse event
AHRQ	Agency for Healthcare Quality and Research
AL	adaptive licensing
ANDA	abbreviated new drug application
ANSI	American National Standards Institute
API	active pharmaceutical ingredient
BA/BE	bioavailability/bioequivalence
BB IND	biological investigational new drug
BCE	beneficial clinical event
BDPA	Bureau of Drug Policy and Administration (China)
BDS	Bureau of Drug Surveillance (Canada)
BISTIC	Biomedical Information Science and Technology Initiative Consortium (NIH)
BLA	biologics license application
BPA	Bureau of Pharmaceutical Assessment (Canada)
BRA	benefit-risk assessment
BTD	breakthrough therapy designation
BYOD	bring your own device
CCFDIE	China Center for Food and Drug International Exchange
CDASH	Clinical Data Acquisition Standards Harmonization
CDDI	Collaboration for Drug Development Improvement
CDISC	Clinical Data Interchange Standards Consortium
CDM	clinical data management
CFAST	Coalition for Accelerating Standards and Therapies
CFDA	China Food and Drug Administration
CEN	Comite Europeen de Normalisation (European Committee for Standardization)
CFR	Code of Federal Regulations
cGMP	current good manufacturing practice
CIOMS	Council for International Organizations of Medical Sciences
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMS	Centers for Medicare and Medicaid Services
CPMP	Committee for Proprietary Medicinal Products (EMA)
CRA	clinical research associate
CRADA	cooperative research and development agreement
CRC	clinical research coordinator
CRF	case report form
CRIX	Clinical Research Information Exchange (FDA and NCI)
CRO	contract research organization
CSA	clinical study agreement
CSDD	Center for the Study of Drug Development (Tufts University)
CSM	Committee on Safety of Medicines (UK)
CSR	clinical study report
CTA	clinical trial application
CTD	common technical document
CTMS	Clinical Trial Management System
CTTI	Clinical Trials Transformation Initiative
DMC	data monitoring committee
DSMB	Data Safety Monitoring Board
DTC	direct-to-consumer
DTP	direct-to-patient
DUR	drug utilization review
EAB	Ethics Advisory Board
eCTD	electronic common technical document
EDMS	Electronic Document Management System
EDQM	European Directorate for the Quality of Medicines
eIND	electronic investigational new drug application
EHR	Electronic Health Records
EMA (EMEA)	European Medicines Agency (formerly European Medicines Evaluation Agency)
EMR	Electronic Medical records
ERB	Ethics Review Board
ERS	electronic regulatory submission
eSubs	electronic submissions
ETASU	Elements to Assure Safe Use
FAERS	FDA's Adverse Event Reporting System
FD&C Act	Federal Food, Drug and Cosmetic Act
FDASIA	Food and Drug Administration Safety and Innovation Act
FIH	first-in-human (clinical trials)
FPE	First Patient Enrolled
FPI	First Patient In
FRP	facilitated regulatory pathway
FSP	functional service provider
FU	Farmacopea Ufficiale (Italian Pharmacopoeia)
GAAP	Greater Access to Affordable Pharmaceuticals Act of 2003
GCP	good clinical practice
GDUFA	Generic Drug User Fee Act
GLP	good laboratory practice
GMP	good manufacturing practice
GRP	good regulatory practice
GRWP	Good Regulatory Writer Practices
GSP	Good Statistics Practice
GXP	Good (any type) Practice
HF	human factor
HPB	Health Protection Board (Canada)
IC	informed consent
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICMRA	International Coalition of Medicines Regulatory Authorities
ICSR	Individual Case Safety Reports
IDE	investigational device exemption
IDMP	identification of medicinal products
IMDRF	International Medical Device Regulators Forum
IMI	Innovative Medicines Initiative
IND	investigational new drug
IOM	Institute of Medicine
IRB	Investigational Review Board
IRS	Incident Reporting System
ISO	International Organization for Standardization
LDT	laboratory developed test
LOAEL	Lowest Observed Adverse Effect Level
LPE	Last Person Enrolled
LPI	Last person In
LPLV	Last Patient Last Visit
MAH	marketing authorization holder
MCA	Medicines Control Agency (part of MHRA)
MCDA	multi-criteria decision analysis
MedDRA	Medical Dictionary for Regulatory Activities

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MEDLARS	Medical Literature Analysis and Retrieval System (NLM)
MedSuN	Medical Product Safety Network
MFDS	Ministory 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
OBE	Office of Biostatistics and Epidemiology
OBRR	Office of Blood Research and Review
OCBQ	Office of Compliance and Biologics Quality
OCD	Office of the Center Director
OCOD	Office of Communication, Outreach and Development
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
OBI	Office of Business Informatics
OC	Office of Communications
OC	Office of Compliance
OCD	Office of the Center Director
OCP	Office of Clinical Pharmacology
OCS	Office of Computational Science
ODE I	Office of Drug Evaluation I
ODE II	Office of Drug Evaluation II
ODE III	Office of Drug Evaluation III
ODE IV	Office of Drug Evaluation IV
ODSIR	Office of Drug Security, Integrity, and Recalls
OGD	Office of Generic Drugs
OHOP	Office of Hematology and Oncology Products
OM	Office of Management
OMP	Office of Medical Policy
OMPI	Office of Medical Policy Initiatives
OMQ	Office of Manufacturing Quality
OND	Office of New Drugs
OPDP	Office of Prescription Drug Promotion
OPQ	Office of Pharmaceutical Quality

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
OCD	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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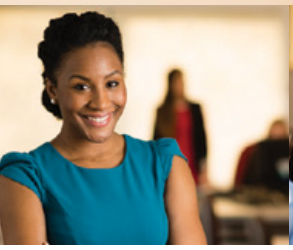
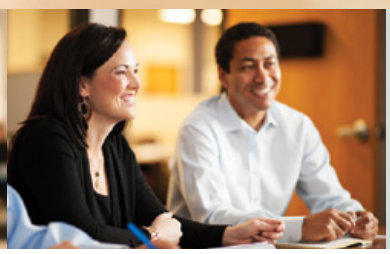


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