DIA 2012

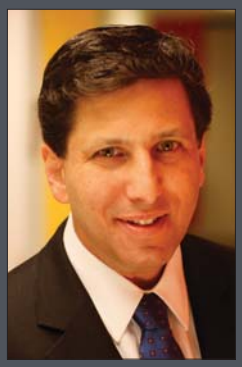
Collaborate to Innovate

FINAL PROGRAM

48th Annual Meeting
June 24-28 | Philadelphia, PA
Pennsylvania Convention Center

www.diahome.org/DIA2012

DIA®
www.diahome.org



Craig H. Lipset
Head of Clinical Innovation,
Worldwide Research &
Development,
Pfizer Inc

Dear Colleagues,

Thank you for attending the DIA 2012 48th Annual Meeting.

The theme of this year's Annual Meeting is *Collaborate to Innovate.* What does this mean? It means that over the next few days you will attend and participate in tutorials, sessions, workshops, symposia, and panel discussions to address the collaboration required among diverse partners to bring innovative new medical products to patients.

To me, that is what the DIA Annual Meeting is all about—putting new ideas into practice, producing rich content, offering robust networking opportunities, and providing access to the world's most innovative technology partners—so we can continue to make an important impact in the delivery of new therapies to patients.

"Innovation" is a very popular buzzword, but it's more than just good ideas; it's putting those ideas into practice *and* ultimately realizing value.

Thank you for attending the DIA 2012 Annual Meeting. I look forward to collaborating with each of you this week.

Sincerely,

Craig H. Lipset
Program Chair

Michael A. Nutter
Mayor of Philadelphia

Welcome to Philadelphia and to DIA's 48th Annual Meeting.

I am thrilled that the DIA 2012 48th Annual Meeting *Collaborate to Innovate* is being held right here in the Birthplace of American Medicine. Philadelphia is the perfect setting for your gathering. It is home to some of the world's most renowned institutions of higher learning, where the best and the brightest minds are leading the quest for new medical discoveries and innovations.

Philadelphia is fortunate to have DIA's global headquarters located just a few miles outside Center City—making it a part of the fabric of our great city. And we share your vision of improving health and well-being worldwide.

While you are here in Philadelphia, please take the opportunity to visit our cultural attractions and historic American landmarks and enjoy the warm hospitality of our outstanding restaurants and the independent spirit of our unique retail corridors.

I want to thank you for attending this year's DIA Annual Meeting and wish each of you a very successful four days here in the City of Brotherly Love.

Sincerely,

Michael A. Nutter
Mayor of Philadelphia

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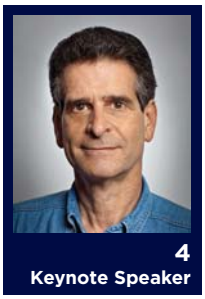

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THE MOST PRODUCTIVE FOUR DAYS YOU'LL HAVE ALL YEAR

Ultimately, convergence is about mutual respect, working together, and being open to new ideas and learning from each other. To that end, DIA 2012 provides the best opportunity to meet with people from around the world, share your views and knowledge, network, and build new relationships.

DIA ANNUAL MEETING MOBILE APP

The DIA Annual Meeting app is FREE and available on Android™, iPhone®, iPad®, as well as Mobile Web. Download the mobile app to access a wide range of DIA 2012 information as well as the ability to:

- Manage your agenda
- Receive news and announcements
- Network with fellow attendees
- Receive event information in real time

Visit the DIA booth in the Exhibit Hall for instructions or **www.diahome.org/DIA2012mobile**

DIA 2012

Collaborate to Innovate

SCHEDULE AT-A-GLANCE

SATURDAY, JUNE 23

Registration Hours:

9:00 AM–5:00 PM	Exhibitor Registration

SUNDAY, JUNE 24

Registration Hours:

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

Schedule:

8:30 AM–12:00 PM	Half-day Morning Preconference Tutorials
9:00 AM–5:00 PM	Full-day Preconference Tutorials
1:00–4:30 PM	Half-day Afternoon Preconference Tutorials
3:00–5:00 PM	Student Forum

MONDAY, JUNE 25

Registration Hours:

7:00 AM–6:30 PM	Attendee, Speaker, and Exhibitor Registration

Schedule:

7:15–8:00 AM	Coffee and Breakfast Breads
7:15–8:00 AM	Orientation/Networking and Coffee for DIA 2012 Annual Meeting First-timers
8:00–9:30 AM	Opening Plenary Session
9:30–10:00 AM	Coffee Break
9:30–10:00 AM	Orientation and Coffee for DIA 2012 Annual Meeting First-timers
10:00–11:30 AM	Concurrent Educational Opportunities
11:00 AM–6:30 PM	Exhibition Hall Open
11:00 AM–6:30 PM	Student Poster Session
11:30 AM–1:30 PM	Lunch with Optional Interest Area Seating
12:00–12:45 PM	Innovation Theater Presentation: Innovation in R&D and Commercialization through Big Data Analytics
1:30–3:00 PM	Concurrent Educational Opportunities
3:00–3:30 PM	Refreshment Break
3:30–5:00 PM	Concurrent Educational Opportunities
5:00–6:30 PM	Welcome Reception
6:00 PM	Student Poster Award Ceremony

TUESDAY, JUNE 26

Registration Hours:

7:00 AM–4:30 PM	Attendee, Speaker, and Exhibitor Registration

Schedule:

7:15–8:00 AM	Coffee and Breakfast Breads
8:00–9:30 AM	Concurrent Educational Opportunities
9:00 AM–3:30 PM	Exhibition Hall Open
9:30–10:00 AM	Coffee Break
10:00–11:30 AM	Concurrent Educational Opportunities
11:00 AM–1:30 PM	Professional Poster Session #1
11:30 AM–1:00 PM	All SIAC Luncheon Group
11:30 AM–1:30 PM	Lunch with Optional Interest Area Seating
12:00–12:45 PM	Innovation Theater Presentation: ADDPLAN PE- Innovative Software for Population Enrichment Designs in Adaptive Clinical Trials
1:30–3:00 PM	Concurrent Educational Opportunities
1:30–3:30 PM	Exhibit Guest Passes
3:00–3:30 PM	Refreshment Break
3:30–4:30 PM	Concurrent Educational Opportunities
4:30–6:30 PM	Adaptive Design Scientific Working Group

WEDNESDAY, JUNE 27

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	Concurrent Educational Opportunities
9:00–3:30 PM	Exhibition Hall Open
9:30–10:00 AM	Coffee Break
10:00–11:30 AM	Concurrent Educational Opportunities
11:00 AM–1:30 PM	Professional Poster Session #2
11:30 AM–1:30 PM	Lunch with Optional Interest Area Seating
1:30–3:00 PM	Concurrent Educational Opportunities
1:30–3:30 PM	Exhibit Guest Passes
3:00–3:30 PM	Refreshment Break
3:30–5:00 PM	Concurrent Educational Opportunities
5:15–7:00 PM	Consortium of Academic Programs in Clinical Research

THURSDAY, JUNE 28

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	Concurrent Educational Opportunities
10:30–10:45 AM	Coffee Break
10:45–12:15 PM	Concurrent Educational Opportunities
12:30–5:00 PM	MedDRA® User Group Meeting

DIA 2012 ANNUAL MEETING TRACKS

The DIA 2012 Annual Meeting is the largest multidisciplinary event for professionals involved in the discovery, development and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products.

This year's program is comprised of 22 Tracks which are related to specific interest areas as well as different formats that provide you with new opportunities and greater flexibility.

Track #	Track Title	Related Interest Areas
Track 01	Clinical Operations	Clinical Research (CR), Research and Development (RD) Investigative Sites (IS), Manufacturing (MF)
Track 02	Project/Portfolio Management and Strategic Planning	Project Management (PM), Financing (FI), Strategic Planning (SP)
Track 03	Innovative Partnering Models and Outsourcing Strategies	Outsourcing (OS)
Track 04	Nonclinical and Translational Development/Early Phase Clinical Development	Biotechnology (BT), Nonclinical (NC), Pharmacology (PC)
Track 05	Product Advertising and Marketing	Advertising and Promotion (AP), Marketing (MA)
Track 06	Medical Writing and Medical Communications	Medical Writing (MW), Medical Communication (MC)
Track 07	Processes and Technologies for Clinical Research	Information Technology (IT), eClinical (EC), Clinical Data Management (CDM), Study Endpoints (SE), Document Management (DM), Validation (VA)
Track 08	Regulatory Affairs and Submissions	Regulatory Affairs (RA), Submissions (SUBS)
Track 09	Medical Diagnostics and Devices	Combination Products (CmbP), Medical Devices and Diagnostics (MDD)
Track 10	Public Policy/HealthCare Compliance/Regulatory Law	Public Policy, Law, Corporate Compliance (PPLCC)
Track 11	Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)	Good Clinical Practices (GCP), Quality Assurance and Quality Control (QA/QC)
Track 12	Pharmaceutical Quality	Chemistry, Manufacturing and Controls (CMC)
Track 13	Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)	Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine (CEHTAEbM), Pricing and Reimbursement (PR)
Track 14	Clinical Safety and Pharmacovigilance	Clinical Safety and Pharmacovigilance (CP)
Track 15	Statistical Science and Quantitative Thinking	Statistics (ST)
Track 16	Professional Development	Professional Education, Training & Development (PETD)
Track 17	Global Regulatory	Includes program offerings hosted by a specific Regulatory Agency such as the FDA, US; SFDA, China; European Union; PMDA, Japan; Health Canada, Canada; etc. See page 6 for more information.
Track 18	Rare/Neglected Diseases	Rare and Neglected Diseases (RND)
Track 19	SIAC (Special Interest Area Community) Showcase	ALL
Track 20	Executive Program: Pioneering Partnerships	See page 7 for additional details
Track 21	Late-breaker	ALL
Track 22	White Paper Showcase	ALL

DIFFERENT FORMATS FOR DIFFERENT LEARNERS

FORUM: A 90-minute blended presentation and panel discussion that includes panelists who represent diverse work settings such as regulatory, academia, patients, and industry. Forums provide ample opportunity for active participation by attendees.

SESSION: A 90-minute standard lecture-style offering that includes speakers who represent diverse work settings. Session chairs facilitate a formal question-and-answer period.

SIAC SHOWCASE: A 60-minute presentation on a wide variety of topics developed by DIA Special Interest Area Communities.

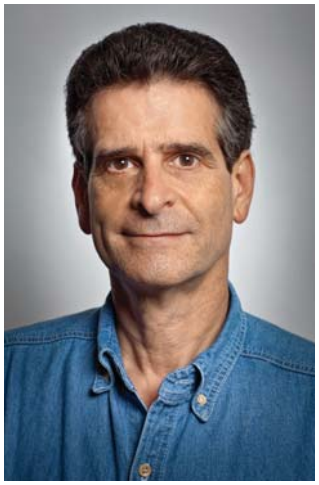
SYMPOSIUM: A 90-minute offering consisting of several shorter presentations such as case studies and presentations from multiple perspectives.

TUTORIAL: Full- and half-day preconference tutorials are led by subject matter experts who will provide in-depth instruction on some of today's hottest topics. Each preconference tutorial is designed to increase your knowledge in specific subject areas while allowing for small group interaction.

WORKSHOP: A 90-minute conceptual presentation delivered in an interactive/simulation or role-playing format. Workshops feature learning in the form of activities or demonstrations.

OPENING PLENARY SESSION

Monday, June 25
8:00–9:30 AM
Terrace Ballroom



Dean Kamen
Founder and President,
DEKA Research &
Development Corporation

Dean Kamen is founder and president of DEKA Research & Development Corporation. Examples of technologies developed by DEKA include the HomeChoice™ Portable Dialysis Machine, the iBOT™ Mobility System, the Segway™ Human Transporter, a DARPA-funded robotic arm, a new and improved Stirling Engine, and the Slingshot Water Purifier.

Dean has received many awards for his efforts, including the National Medal of Technology in 2000 and the Lemelson-MIT Prize in 2002. He was inducted into the National Inventors Hall of Fame in 2005 and has been a member of the National Academy of Engineering since 1997.

Among Dean's proudest accomplishments is founding FIRST (For Inspiration and Recognition of Science and Technology), an organization dedicated to motivating the next generation to understand, use, and enjoy science and technology.

FEATURED OFFERINGS IN THIS YEAR'S PROGRAM

#139 Regulatory Collaboration/21st Century Innovation: Views of the Heads of Health Canada, the European Medicines Agency, and the US FDA

MONDAY, 1:30–3:00 PM
Room: 120 bc

Co-Chair:
Marie Allison Dray, MA, MBA
International Regulatory Affairs Group LLC

Paul Glover, MBA
Health Canada

Margaret A. Hamburg, MD
FDA

Guido Rasi, MD
European Medicines Agency, European Union, UK

Co-Chair:
Murray M. Lumpkin, MD, MSc
FDA

#208 Meta-collaborations: A Call to Action

TUESDAY, 8:00–9:30 AM
Room: Terrace 4

Chair:
Freda Lewis-Hall, MD
Pfizer Inc

Margaret A. Anderson, MS
FasterCures

Kathy L. Hudson, PhD
National Institutes of Health

Stephen P. Spielberg, MD, PhD
FDA

#245 Collaborative Partnerships in Drug Development: An Executive Roundtable Discussion

TUESDAY, 1:30–3:00 PM
Room: 121 ab

Chair:
Ed Silverman
Pharmalot

Paula Brown Stafford, MPH
Quintiles

William J. Sharbaugh, MA, MSc
PPD

Jeffrey P. McMullen
PharmaNet/i3, an inVentiv Health Company

Josef von Rickenbach, MBA
PAREXEL International

Douglas J. Peddicord, PhD
Association of Clinical Research Organizations

John Watson
Covance Inc.

#330 Partnering for Impact in Global Health

WEDNESDAY, 10:00–11:30 AM
Room: 121 ab

Chair:
Nicole Bates, DrPH
Bill & Melinda Gates Foundation

Vincent I. Ahonkhai, MD
Bill & Melinda Gates Foundation

David Reddy, PhD
Medicines For Malaria Venture (MMV)
Switzerland

Ken Duncan, PhD
Bill & Melinda Gates Foundation

Amrit Ray, MD, MBA
Janssen Research & Development, LLC

#397 Implementation of the Physician Payment Sunshine Act: Now What?

WEDNESDAY, 3:30–5:00 PM
Room: 122 b

Chair:
John F. Kamp, JD, PhD
Coalition for Healthcare Communication

Daniel Carlat, MD
Pew Prescription Project

Marjorie E. Powell, JD
PhRMA

Sandra J. P. Dennis, JD
Biotechnology Industry Organization (BIO)

Thomas P. Stossel, MD
Brigham & Women's Hospital

John J. Lewis, MA
Association of Clinical Research Organizations

BUILDING RELATIONSHIPS WORLDWIDE

As of May 1, 2012

One of the unique features of the DIA 2012 Annual Meeting is the Global Regulatory Track that includes 15 program offerings led by a variety of global and regional regulatory agencies. Attend any of the following offerings and learn from key officials and have the unique experience to have your questions answered.

MONDAY, JUNE 25

#120	European Town Hall: Part 1 of 2 – Hot Topics in Europe	113c
#121	Pediatric Drug Development Progress: 15 Years Later and Across the Globe	116
#148	European Town Hall: Part 2 of 2 – Interacting With the European System	120bc
#174	An Update on EMA, FDA, and PMDA International Activities	113b

TUESDAY, JUNE 26

#237	International Regulatory Cooperation: A Canadian Perspective	116
#238	Latin America Town Hall	117
#260	Update from the EMA-FDA Parallel Assessment Pilot	122b
#261	SFDA Town Hall	117

WEDNESDAY, JUNE 27

#324	Risks to and Securing of Global Drug Supply Chains	115a
#368	Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall	122b
#369	CBER Town Hall	119a
#394	The State of Electronic Submissions at CDER, CBER, and CDRH	121ab
#395	India Town Hall	119a

THURSDAY, JUNE 28

#413	CDER Town Hall: Part 1 of 2	114
#425	CDER Town Hall: Part 2 of 2	114

GOVERNMENTAL AGENCIES

- Agency for Healthcare Research and Quality (AHRQ), US
- Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), Argentina
- National Health Surveillance Agency (ANVISA), Brazils
- Austrian Medicinal and Medical Device Agency (AGES), Austria
- Federal Institute for Drugs and Medical Devices (BfArM), Germany
- Center for Drug Evaluation (CDE), Taiwan
- Central Drugs Standard Control Organization (CDSCO), India
- The Federal Commission for the Protection against Sanitary Risk (COFEPRIS), Mexico
- Department of Justice (DOJ), US Attorney's Office, US
- European Medicines Agency, European Union, EU
- Food and Drug Administration (FDA), US
- Federal Agency For Medicines and Health Products (FAMHP), Belgium
- Food and Drug Administration (FDA), Department of Health, Taiwan
- Health Canada
- Health and Human Services (HHS), US
- National Authority of Medicines and Health Products (INFARMED), Portugal
- Instituto de Salud Publica de Chile (ISPCH), Chile
- Italian Medicines Agency (AIFA), Italy
- Medicines and Healthcare products Regulatory Agency (MHRA), UK
- Medicines Evaluation Board (MEB), Netherlands
- Ministry of Health, Labour and Welfare (MHLW), Japan
- National Institute of Aging, NIH, US
- National Institutes of Health (NIH), US
- National Library of Medicine, NIH, US
- The New Partnership for Africa's Development (NEPAD), South Africa
- Office of the Secretary, DHHS, US
- Pharmaceuticals and Medical Devices Agency (PMDA), Japan
- State Food and Drug Administration (SFDA), China
- Therapeutic Goods Administration (TGA), Australia
- US Army Medical Research and Material Command (USAMRMC), US

ACADEMIC INSTITUTIONS AND STAKEHOLDER ORGANIZATIONS As of May 1, 2012

(Program Offering Number)

- Alagille Syndrome Alliance (#396)
- Alfred Mann Biomedical Engineering Institute (#404)
- American Association For Cancer Research (#222)
- Bill & Melinda Gates Foundation (#330)
- Brigham & Women's Hospital (#397)
- Campbell University College of Pharmacy and Health Sciences (#373)
- Children's Hospital Colorado (#396)
- Children's Mercy Hospitals and Clinics (#221)
- Childrens National Medical Center (#346)
- CINECA Inter-University Consortium, Italy (#381)
- Columbia University (#257)
- Dana-Farber Cancer Institute (#204)
- Duke Clinical Research Institute (#117, #353, #378)
- Duke Institute for Genome Sciences and Policy (#378)
- Duke University Medical Center (#204, #274)
- Eastern Michigan University (#259, #323)
- Erasmus University Medical Center, Netherlands (#257)
- Farmaindustria, Spain (#354)
- FasterCures (#208)
- Harvard Medical School (#143)
- Harvard Pilgrim Health Care Institute (#321)
- Inter-American Foundation for Clinical Research (IAFCR) (#259, #323)
- International Cancer Advocacy Network (#312)
- International Partnership For Microbicides, South Africa (#119)
- International Society For Translational Medicine (ISTM), Austria (#119, #204)
- Keio University, Japan (#233, #385)
- London School of Economics, UK (#108, #172)
- Massachusetts Institute of Technology (MIT) (#383)
- Mayo Clinic (#334)
- Medical College of Wisconsin (#258)
- Medical University of Vienna, Austria (#353)
- Medicines For Malaria Venture (MMV), Switzerland (#330)
- Multiple Myeloma Research Foundation (#306)
- National Health Council (#312)
- National Organization For Rare Disorders (NORD) (#359, #370)
- National Pharmaceutical Council (#319)
- Nattokushite Iryou Wo Ukerukai, Japan (#385)
- Pew Prescription Project (#397)
- Pharmaceutical Advertising Advisory Board (PAAB), Canada (#354)
- Prescription Medicines Code of Practice Authority (PMCPA), UK (#354)
- SAPA (Sino-American Pharmaceutical Professionals Association) (#137)
- Seoul National University Hospital, Republic of Korea (#166)
- Shanghai Clinical Research Center (SCRC), China (#155)
- Technical University of Denmark (#377)
- Temple University (#316)
- The University of Texas (#423)
- Tufts Center for the Study of Drug Development (#362, #405)
- Tufts University (#103, #219, #247, #374)
- Tufts University School of Medicine
- University of Alabama at Birmingham (#259)
- University of Amsterdam, Netherlands (#389)
- University of Maryland University College (#392)
- University of Medicine and Dentistry of New Jersey
- University of Nebraska Medical Center (#331)
- University of North Carolina at Chapel Hill (#118)
- University of North Carolina School of Public Health (#143)
- University of Pennsylvania (#319)
- University of the Sciences in Philadelphia
- University of Washington (#335)
- Virginia Commonwealth University

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Presents the DIA 2012 Annual Meeting Executive Program: Pioneering Partnerships

TUESDAY, JUNE 26

10:00–11:30 AM
Collaborative Research with Members of the Payer Community

12:00–1:30 PM
Challenges of Precision Medicine: Diagnostics, Reimbursement, and Parnership Co-development

Visit Speaker Registration for more information.

SPECIAL FEATURES

ROLE OF PATIENTS IN DRUG DEVELOPMENT

DIA understands that patients play a key role in the drug development process. Clinical trials help to pinpoint the areas where pharma professionals need to learn more to advance scientific and patient innovation. DIA provides the perfect forum for patients not only to network with and learn from experts from around the world but also to participate in the process of bringing safe and effective therapies to market.

Twenty-one 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 DIA 2012 Annual Meeting. The conference provides a forum for sharing best practices, stimulating cooperation, and facilitating a two-way dialogue across the entire global healthcare community.

To join the conversation about the patient perspective, look for the Patient Fellowship tables in the networking lunch area and **visit the Patient Advocate Fellowship Booth #1513 for a chance to win a free registration to the DIA 2013 Annual Meeting, June 23–27, Boston, MA!**

PATIENT ADVOCATE FELLOWSHIP ORGANIZATIONS

ARPKD/CHF Alliance — improving the lives of those affected

The cholangiocarcinoma Foundation

Massachusetts General Hospital Cancer Center

MRSA Survivors Network

CORD — Canadian Organization for Rare Disorders

Avery's Angels

Soft Bones — Finding the Key to HPP

Huntington's Disease Society of America

HepTREC

nama Recovery

P²MT² Program in Personalized Medicine & Targeted Therapeutics ™

The Mastocytosis Society — In Search of a Cure

Ovarian Cancer National Alliance — We work to save women's lives

ican international cancer advocacy network — the virtual lifeline for proactive cancer patients

SWF — The Sturge-Weber Foundation

IWSA

LUPUS Foundation of America — DC • MD • VA Chapter, Inc. — Serving DC, Maryland, Northern and Central Virginia

NDRF — National Dysautonomia Research Foundation

The Bone and Joint Decade — Promoting musculoskeletal health — Keep people moving

VESTIBULAR DISORDERS ASSOCIATION

DIA 2012 RESOURCE CENTER

Learn more about DIA's online educational programs by visiting the DIA 2012 Resource Center! Explore DIA's eLearning modules, online training courses, and live and archived webinars throughout the day at your own pace, or take advantage of demonstrations highlighting these products. "Meet the Expert" sessions will also be available during lunch each day.

A schedule of demonstrations and "Meet the Expert" sessions can be found in the Show Daily and on the DIA 2012 Mobile App.
The DIA Resource Center is located at the DIA booth. We look forward to seeing you there!

GET INVOLVED BOOTH

Stop by the Get Involved Booth located in the Meeting Room Concourse

- Learn more about DIA Volunteer Opportunities
- See a demonstration of the DIA ConneX tool for global Special Interest Area Communities (SIAC) communications

Join a Community Today!

NEW EXPERIENCES

COMPANY WHITE PAPER SHOWCASE

Learn from the experts in this newly formed track called the White Paper Showcase. Eight companies will lead their own Showcase where they will highlight their company expertise and solutions in this year's program.

MONDAY, JUNE 25

#124 The New Health Report 2012: Rethinking the Risk Equation in Biopharmaceutical Development and Delivery

#150 Free Agency is Here: Exploring Workforce Impact on Clinical Outsourcing

#175 Raising the Bar for Regulatory Submission Document Quality: A Collaborative, Transitional Approach

TUESDAY, JUNE 26

#239 Value of Actigraphy in Clinical Trials

#264 The Unique Relationship between Global Patient Recruitment and Translation Management

WEDNESDAY, JUNE 27

#325 Enabling Remote Monitoring in Clinical Trials for Sponsors and Sites

#371 Implementation of Adaptive Clinical Trials

a DIA 2012 Annual Meeting Level I Supporter

#398 Accelerating Cancer Clinical Trials

LIFE SCIENCE ENTREPRENEUR PAVILION

Location: Exhibit Hall

Be sure to visit the Life Science Entrepreneur Pavilion, located in the Poster area of Exhibit Hall D, where innovative companies and entrepreneurs will be available to discuss how they are changing the future development of new medicines.

Pfizer is pleased to support the Life Science Entrepreneur Pavilion at the DIA 2012 Annual Meeting.

INNOVATION THEATER PRESENTATIONS

Location: Exhibit Hall

Take advantage of lunch time presentations in the Innovation Theater.

Monday, June 25, 12:00–12:45 PM

Innovation in R&D and Commercialization through Big Data Analytics

Developed by EMC Corporation, also host of the Monday afternoon refreshment break.

a DIA 2012 Annual Meeting Level I Supporter

Monday, June 25, 5:30–6:00 PM

Empowering Clinical Research & Development of Tomorrow

Developed by iGate

a DIA 2012 Annual Meeting Level 1 Supporter

Tuesday, June 26, 12:00–12:45 PM

ADDPLAN PE- Innovative Software for Population Enrichment Designs in Adaptive Clinical Trials

Developed by Aptiv Solutions.

a DIA 2012 Annual Meeting Level I Supporter

Additional presentations will be announced in the Show Daily and via the DIA Annual Meeting Mobile App.

NETWORKING OPPORTUNITIES

JOIN A COMMUNITY!

Meet colleagues who share your professional interests, experience and knowledge

- Network with specialists you wouldn't normally meet
- Stay on the pulse of hot topics and shared learning
- Broad choice of specialized communities

ALL SIAC LUNCH (Special Interest Area Communities)

TUESDAY, JUNE 26, 11:30 AM–1:00 PM — TERRACE BALLROOM II

Reaching Around the World to Create a Global Community

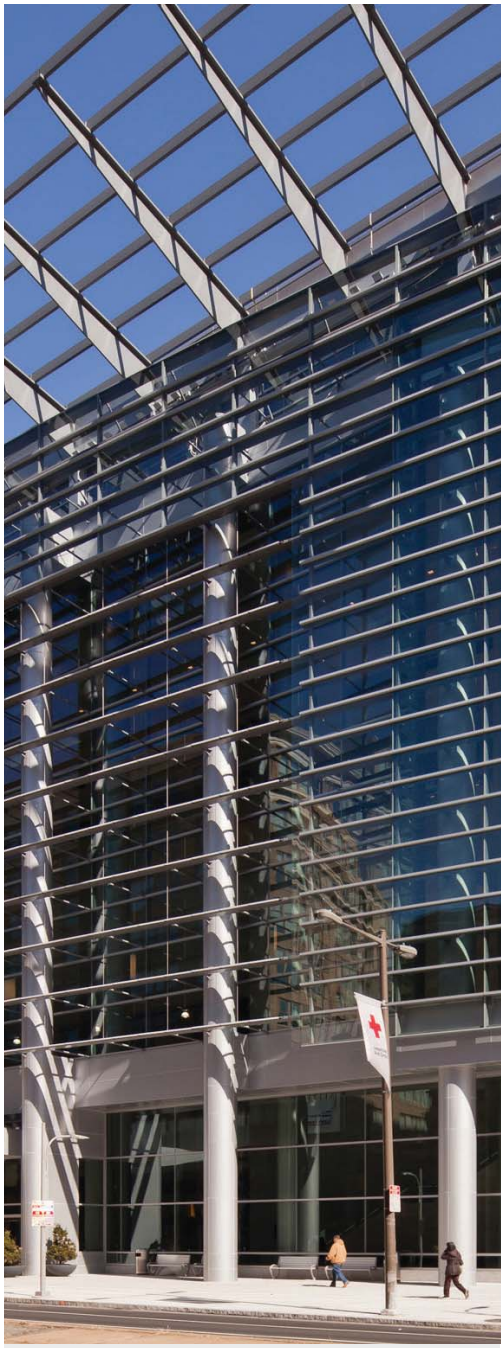
Open to all current SIAC members and all attendees interested in learning more about DIA Communities

SIACs

- Biotechnology & Innovative Preclinical Sciences
- Chemistry, Manufacturing & Controls & Quality System
- Clinical Data Management
- Clinical Pharmacology
- Clinical Research
- Clinical Safety & Pharmacovigilance
- Clinical Trial Disclosure
- Devices & Diagnostics
- Document & Records Management
- eClinical
- Electronic Regulatory Submissions
- Emerging Professionals
- Evidence Based Medicine
- Global Sourcing
- Good Clinical Practices & Quality Assurance
- Information Technology
- Investigator & Investigative Sites
- Legal Affairs
- Marketing & Sales
- Medical Communications
- Medical Writing
- Medical Science Liaison
- Natural Health Products
- Pediatric
- Professional Education, Training & Development
- Project Management
- Quality Risk Management
- Regulatory Affairs
- Statistics
- Study Endpoints
- Validation

SIAC Showcase:

The SIAC Showcase is an opportunity to attend a **content-based** offering developed to highlight the expertise of each SIAC to the attendees of the DIA 2012 Annual Meeting. The SIAC Showcase also highlights the benefits of networking with professionals who share the same responsibilities, disciplines and interests. Please see the SIAC Showcase sessions listed in the program on Tuesday, June 26 from 3:30–4:30 PM.



DISCOVER NEW BUSINESS VENTURES AND UNLOCK PRIZES

500 chances to win one of 100 prizes.
The more exhibitors you visit, the more chances you have to win!

Prizes include

- New iPads
- Microsoft Xbox 360 and Kinect
- Wii
- Free Registration to the DIA 2013 Annual Meeting
- And much more!

Be sure to ask each exhibitor you visit for a key to unlock the fun at DIA 2012!

The DIA 2012 Annual Meeting attracts the biggest names from the pharmaceutical, biotechnology, medical device, and related sectors, and features key networking opportunities.

FIRST-TIMER ORIENTATION

Is this your first time at the DIA Annual Meeting? DIA 2012 includes two opportunities to learn how to optimize your experience at DIA 2012. The first offering includes a Speed Networking opportunity. Bring your business cards to network with fellow Annual Meeting first-timers and learn how to make the most of your Annual Meeting experience.

Monday, June 25, 7:15–8:00 AM

- Includes Speed Networking

Monday, June 25, 9:30–10:00 AM

REFRESHMENT BREAKS

Meet with your colleagues to plan your day and discuss what you learned the day before, all while networking with other attendees each morning in the meeting room concourse of the Convention Center. Midmorning and mid-afternoon breaks will also be held in designated areas of the Exhibit Hall.

See Schedule At-A-Glance on page 2 for break times.

Monday afternoon break supported by:

EMC²

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LUNCH HOURS IN EXHIBIT HALL

Enjoy extended lunch hours to visit more than 550 exhibiting companies in the exhibit hall.

- Monday–Wednesday, June 25–27, 11:30 AM–1:30 PM

NETWORKING LUNCH AREA

Take advantage of this special seating area that allows you to eat and network with colleagues of the same interest. This seating area is located in the exhibit hall, and will be organized by DIA 2012 tracks. See Floor Plan on the back of the Exhibits tab in this program for exact location.

DIA WELCOME RECEPTION

Monday, June 25, 5:00–6:30 PM

We invite you to network with nearly 7,500 attendees at the DIA Welcome Reception in the exhibit hall. See old friends and make new acquaintances, while visiting more than 550 exhibiting companies. While you browse, be sure to use the complimentary beverage coupon which is included in the badge envelope for all non-exhibiting participants.

Reception hosted by DIA with support from:

TATA CONSULTANCY SERVICES

APCER PHARMA

Drexel UNIVERSITY ONLINE

UBC United BioSource Corporation *Evidence Matters®*

STUDENT FORUM

Sunday, June 24, 3:00–5:00 PM, Room 125

The Student Forum provides real-world information to students and offers them an opportunity to speak with DIA volunteers and representatives. For more information on the Student Forum see page 33.

STUDENT POSTER SESSION

Monday, June 25, 11:00 AM–6:30 PM

Join us in Exhibit Hall D as we showcase posters by students from around the world. An awards ceremony will be held at 6:00pm to award the first-, second-, and third-place student poster winner.

See page 118 for a listing of student posters.

PROFESSIONAL POSTER SESSIONS

Location: Exhibit Hall D

A selected group of professional poster presenters will share their research results in various topics. There will be two dedicated times with different posters available for view.

See page 118 for a listing of professional posters.

- Session #1 Tuesday, June 26, 11:00 AM–1:30 PM
- Session #2 Wednesday, June 27, 11:00 AM–1:30 PM

DIA 2012 ANNUAL PROGRAM COMMITTEE

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Outcome

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Novartis Pharmaceuticals Corporation

Shaghig Palanjian, MBA
Shire Human Genetic Therapies, Inc.

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James Parmentier, PhD
University of Medicine and Dentistry of New Jersey

Carolynn J. Thomas-Jones, MPH
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Albert Wertheimer, PhD, PharmD, MBA
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We look forward to seeing you in Boston!

DIA 2013 *Advancing Therapeutic Innovation & Regulatory Science*

49th Annual Meeting, June 23–27, 2013

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Photo Courtesy of Greater Boston Convention & Visitors Bureau.

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DIA WOULD LIKE TO THANK OUR CONTENT PARTNERS!

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PharmaTimes

"The Gray Sheet"

"The Pink Sheet"

TheScientist
MAGAZINE OF THE LIFE SCIENCES

Life Science Leader

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GET THE BIG PICTURE WHILE YOU ARE AT DIA 2012!

For everything DIA 2012. . .

Follow us **@DrugInfoAssn**
Get real-time announcements and updates.
Have a question? Follow us and ask.
Official hashtag is #DIA2012.

Join our group at **Drug Information Association (DIA) — Biopharmaceutical Professionals.**
Stay engaged with new announcements on hot topics, new speakers and networking events.

"Like" Us at **DrugInfoAssn**
Post your experience on DIA's wall.
Share your photos from DIA 2012.
Check-in to DIA 2012.

Follow us at **DrugInfoAssn**
Be your own paparazzi. Share your photos with us.

DrugInfoAssoc
Watch videos from DIA 2012 and past Annual Meetings.

DIA ANNUAL MEETING MOBILE APP

The DIA Annual Meeting app is FREE and available on Android™, iPhone®, iPad®, as well as Mobile Web. Download the mobile app to access a wide range of DIA 2012 information as well as the ability to:

- Manage your agenda
- Receive news and announcements
- Network with fellow attendees
- Receive event information in real time

Visit the DIA booth in the Exhibit Hall for instructions or **www.diahome.org/DIA2012mobile.**

EXPERIENCE THE CHARM OF PHILADELPHIA!

We hope you find some time to tour Philadelphia and discover what makes America's most historic city so cutting edge. Visit **www.philadelphiausa.travel** for details about:

WHAT'S FREE

Check out the free events held throughout the city, including historic sites such as Elfreth's Alley, the Liberty Bell Center, and much more.

CUISINE

Dine on some of Philadelphia's most well-known delicacies such as cheesesteaks, soft pretzels, and Tastykakes, but don't be shy about sampling new cuisine—from classic to contemporary. Visit **www.philadelphiausa.travel** for complete details.

SHOW YOUR BADGE DISCOUNTS

Show your room key or DIA 2012 Annual Meeting badge to many vendors, shops, and restaurants around the city to receive special discounts exclusively for DIA Annual Meeting attendees.

PHILLY ON THE MOVE

Download the Philadelphia Convention & Visitors Bureau mobile app at **www.philadelphiausa.mobi** to help you navigate the city, and find information on attractions, dining options, nightlife and events.

TOUR PROGRAM

Philadelphia Sightseeing Tours, Inc. will be available in the Exhibit Hall D Lobby, offering attendees a full range of fully-guided, entertaining, discounted tours of Philadelphia, "the most historic city in America". Tour desk hours are: Monday, 9:30 AM–6:30 PM; Tuesday, 9:30 AM–3:30 PM; and Wednesday, 9:30 AM–1:30 PM. To see the full tour program and to guarantee your selection, you can register online by going to www.diahome.org/DIA2012, and click on Networking, or simply stop by the tour desk during the hours noted above.

GETTING AROUND PHILADELPHIA

BY PUBLIC TRANSIT

SEPTA Rail Lines service the entire Philadelphia Region. The Market East Station is connected to the Convention Center. The Airport Line connects PHL directly to downtown Philadelphia in just 20 minutes. (To get to the Pennsylvania Convention Center, disembark at Market East Station.) From Amtrak's 30th Street Station, take the SEPTA Regional Rail to the Convention Center. A regional rail train departs every few minutes. With your Amtrak ticket, the ride to Center City is free. Other SEPTA Regional Rail Lines can shuttle you throughout the region. Please visit www.SEPTA.org or call +1.215.580.7800.

BY TAXI

Taxis are readily available to/from the airport. Taxis will depart and pick-up from 12th and Arch Streets. All taxi rates are applied on a per-trip basis, not per person. Most taxis can accommodate up to three passengers. In some cases, certain vehicle types can accommodate four passengers. There is a flat rate of $28.50 from the airport to Center City, not including optional gratuity.

DIA COURTESY SHUTTLE

You must have verification that you are staying at one of the room block hotels listed below in order to board the DIA Shuttle. A decal, which you will need to apply to your name badge, will be given to you when you check in at your hotel. Please have this decal with you when you are boarding the bus to go to the convention center, and attach it to your name badge which you will pick up at registration. If the hotel does not provide you with the decal at check in, you can stop at the Housing Desk, located in the Broad Street Lobby, and one will be provided to you after verifying your registration at one of these hotels.

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

- Crowne Plaza Downtown – 1800 Market Street
- Doubletree Philadelphia – 237 South Broad Street
- Embassy Suites City Center – 1776 Ben Franklin Parkway
- Four Seasons Philadelphia – One Logan Square
- Holiday Inn Express Midtown – 1305 Walnut Street
- Hotel Palomar – 117 South 17th Street
- Hyatt at the Bellevue – 200 South Broad Street
- Radisson Plaza Warwick – 1701 Locust Street
- Ritz Carlton – 10 Avenue of the Arts
- Sheraton Downtown – 201 North 17th Street
- Sofitel Philadelphia – 120 South 17th Street
- Westin Philadelphia – 99 South 17th Street

The following hotels are within walking distance of the convention center and will not offer shuttling.

- Courtyard by Marriott – 21 North Juniper Street
- Four Points by Sheraton City Center – 1201 Race Street
- Hampton Inn City Center – 1301 Race Street
- Hilton Garden Inn City Center – 1100 Arch Street
- Le Meridien Philadelphia – 1421 Arch Street
- Loews Philadelphia – 1200 Market Street

Philadelphia photography by Andrea Burolla, Tim Hawk, Bob Krist, Paul Loftland, Richard McMullin, Edward Savaria, Miles Weaver, and bklphoto.com for the PCVB.

GENERAL INFORMATION

ACCESSING PRESENTATIONS

During the meeting, available presentations are accessible via DIA's Live Learning Center to full conference and one-day registrants*. Please note that this does not include all of the presentations but those that were provided to DIA prior to the start of the Annual Meeting.

Post meeting audio synchronized presentations will be available to full-conference and one-day registrants* within 2 weeks after the conference. All applicable registrants will be notified by email when the postings are complete. Access to the DIA's Live Learning Center is FREE for a period of 6 months post conference. After this 6 month period, access to the meeting recordings will be available for purchase. *Please note that due to their interactivity format, workshops will not be recorded.*

Demonstrations on how to access presentations via the DIA's Live Learning Center will be available at the DIA Booth in the Exhibit Hall.

To access available presentations, visit the DIA's Live Learning Center at www.diahome.org/DIA2012LLC

If you experience technical difficulties, please contact DIA's Live Learning Center at +1.888.711.1138, extension 5400, or multiviewmediasupport@multiview.com.

*One-day registrants will have access to PowerPoint presentations that occur on the day for which you are registered.

BAGGAGE CHECK

An area of the Broad Street Lobby is available for attendees to check their belongings if necessary. The Baggage Check Area will be available as follows:

Sunday, June 24	8:00 AM–5:30 PM
Monday, June 25	7:00 AM–7:00 PM
Tuesday, June 26	7:00 AM–5:00 PM
Wednesday, June 27	7:00 AM–5:30 PM
Thursday, June 28	8:00 AM–12:30 PM

Note: There will be a $2.00 fee for each bag checked. All items checked must be collected by the close of the Baggage Check Area each day. DIA is not responsible for items left in the Baggage Check Area.

BUSINESS CENTER

FedEx is the official business center for the Pennsylvania Convention Center, providing full service business needs. The FedEx office retail storefront is located inside the Pennsylvania Convention Center on the 200 level, between Exhibit Halls B & C. It will be open throughout DIA 2012, Sunday through Wednesday, 8:00 AM–5:00PM, and Thursday, 8:00 AM–1:00 PM. The phone number is 215-925-1218 and fax is 215-925-3738.

CAREER CENTER

DIA's interactive Career Center, located on the meeting room concourse, 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 healthcare 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 www.diahome.org/DIACareerCenter.

CYBER CAFÉ AND RECHARGE STATION

DIA is providing workstations in meeting rooms 108 and 119 concourses for those who do not have laptop computers or other devices.

New this Year! Electric recharge stations are available adjacent to the workstation areas.

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!

EXHIBITOR LOCATOR

Search for an exhibiting company by company name, keyword, or service. Exhibitor Locator workstations will be available inside the entrances to Exhibit Halls C and D.

FIRST AID CENTER

First Aid is available for routine health problems and emergency care. The First Aid Center is located on the Exhibit Hall level, near the entrance to Exhibit Hall D. In case of emergency dial 4911 from any house phone or 215-418-4911 from your cell phone and provide the location of your emergency. Pennsylvania Convention Center Security will dispatch medical personnel at once. Please do not dial 911.

INFORMATION BOOTH

A DIA Information Booth will be located in the meeting room concourse near room 120. Should you have any questions throughout the event, please visit the booth for assistance. The Information Booth can also be reached by phone at 215-418-2400 during event hours.

LOST & FOUND

Misplaced items will be stored at the DIA Information Booth, located in the meeting room concourse near room 120, until the end of the event. Items remaining at the close of the DIA 2012 Annual Meeting will be turned over to the Pennsylvania Convention Center Security.

At that point, you can contact the Pennsylvania Convention Center at 215-418-4700.

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 were included in your badge envelope that you received when you registered. Please keep your vouchers in a safe place, as replacement vouchers will not be issued. The voucher is redeemable for up to $15 (inclusive of tax) for food and beverage items, and must be provided at checkout.

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

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

MISPLACED YOUR BADGE?

Participants will incur a $25 fee for badge reprints. If you require a badge reprint, please visit the Cashier at Attendee Registration, located in the Broad Street Lobby. Identification will be required.

POSTER SESSIONS

The student and professional poster sessions, located in Exhibit Hall D, provide an excellent opportunity for presenters to share their research results with attendees.

The posters present scientific developments related to the topics addressed in Annual Meeting Tracks.

Student Poster Session:	Monday, June 25, 11:00 AM–6:30 PM
Professional Poster Session #1:	Tuesday, June 26, 11:00 AM–1:30 PM
Professional Poster Session #2:	Wednesday, June 27, 11:00 AM–1:30 PM

PRIVATE SOCIAL FUNCTIONS POLICY

DIA does not allow any hospitality functions to be held during any DIA 2012 offerings, scheduled exhibit hours, or social events. Therefore the hours noted below are the only hours acceptable for hospitality functions:

Saturday, June 23	All times are acceptable
Sunday, June 24	All times are acceptable
Monday, June 25	Before 8:00 AM and after 6:30 PM
Tuesday, June 26	Before 8:00 AM and after 4:30 PM
Wednesday, June 27	Before 8:00 AM and after 5:00 PM
Thursday, June 28	Before 9:00 AM and after 12:15 PM

SELECTION OF OFFERINGS

Please note that seating for 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.

Selected program offerings will be recorded and audio synchronized presentations will be available 2 weeks via DIA's Live Learning Center. See page 18 for more information.

RESTAURANT INFORMATION BOOTH/ CITY INFORMATION

Philadelphia is such a food lovers paradise that you will face just one dilemma; how to choose from so many options? The Pennsylvania Convention and Visitors Bureau wants to help you make the most of your dining experience in Philadelphia. To find Philadelphia best dining options, stop by the City Information/Restaurant Booth located in the Broad Street Lobby.

TOUR PROGRAM

Philadelphia Sightseeing Tours, Inc. will be available in the Exhibit Hall D Lobby, offering attendees a full range of fully-guided, entertaining, discounted tours of Philadelphia, "the most historic city in America". Tour desk hours are: Monday, 9:30 AM–6:30 PM; Tuesday, 9:30 am–3:30 pm; and Wednesday, 9:30 AM–1:30 PM. To see the full tour program and to guarantee your selection, you can register online by going to www.diahome.org/DIA2012 and click on Networking, or simply stop by the tour desk during the hours noted above.

WiFi

Complimentary wireless is available in the meeting room concourses. Follow the following instructions to connect:

1. Configure your laptop or notebook computer's network settings to use DHCP (Default for MS Windows-based computers)
2. Connect to the SSID: PACONVENTION
   No password is required
3. Launch your Internet browser

Complimentary wireless is not provided inside the meeting rooms or in the exhibit hall. However there is a WiFi area, located in the back of Exhibit Hall C, supported by:

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a DIA 2012 Annual Meeting Level I Supporter

CONTINUING EDUCATION

The DIA 2012 is the premier event for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related products. In an effort to streamline the program and focus on the hottest topics, this year's program will offer 20 preconference programs and tutorials, 22 content-area tracks comprising approximately 280 program offerings, with presentations geared to attendees of all disciplines, work settings, and experience levels.

LEARNING OBJECTIVES

At the conclusion of this meeting, participants should be able to:

TRACK 1: CLINICAL OPERATIONS

- Recognize the current clinical trial challenges of costs, global execution and management by using innovative technologies and practices
- Ensure ethical and safe treatment of subjects in the modern global trial arena

TRACK 2: PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING

- Identify project management and finance current trends, practices, and systems used in global product development, including strategic planning
- Discuss portfolio asset strategy decision making, management, portfolio/product prioritization and optimization practices, including relevant methods and tools
- Describe quality design of clinical trials, complexity of study development, and building quality risk management into clinical trials

TRACK 3: INNOVATIVE PARTNERING MODELS AND OUTSOURCING STRATEGIES

- Discuss 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 4: NONCLINICAL AND TRANSLATIONAL DEVELOPMENT/EARLY PHASE CLINICAL DEVELOPMENT

- Explain some of the latest nonclinical and clinical technologies and approaches for assessing the safety of pharmaceutical products
- Discuss recent advances in coping with particularly challenging regulatory and scientific issues that arise in the early phases of novel pharmaceutical development
- List current strategies for designing successful early clinical pharmacology and experimental medicine trials

TRACK 5: PRODUCT ADVERTISING AND MARKETING

- Discuss the current regulatory landscape related to drug advertising and promotion

TRACK 6: MEDICAL WRITING AND MEDICAL COMMUNICATIONS

- Identify opportunities to collaborate and meet the expectations of multiple, global regulatory authorities, patients, payers, and other customers

TRACK 7: PROCESSES AND TECHNOLOGIES FOR CLINICAL RESEARCH

- Describe how technologies and processes are used in clinical trials
- Discuss how both technical and procedural innovations, including forward-thinking validation and qualification approaches, may transform the clinical trial life cycle in the future

TRACK 8: REGULATORY AFFAIRS AND SUBMISSIONS

- Discuss the latest global regulatory trends and developments that impact the industry
- Recognize key issues associated with evolving regulatory standards

TRACK 9: MEDICAL DIAGNOSTICS AND DEVICES

- Identify opportunities for drug companies to address changing regulations in the area of medical devices, diagnostics, and drug/device combination products

TRACK 10: PUBLIC POLICY/HEALTH CARE COMPLIANCE REGULATORY LAW

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

TRACK 11: COMPLIANCE TO GOOD CLINICAL PRACTICE (GCP), GOOD LABORATORY PRACTICE (GLP), AND QUALITY ASSURANCE (QA)

- Describe how to avoid GCP/GLP noncompliance through innovation and collaboration in a period of increasing complexity and globalization in clinical trials

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 ICH

TRACK 13: HEALTH ECONOMICS AND OUTCOMES (HEO)/ COMPARATIVE EFFECTIVENESS RESEARCH (CER)/HEALTH TECHNOLOGY ASSESSMENT (HTA)

- Build the scientific capability to measure and communicate the medical need, health impact, and economic value associated with medical products
- Describe the real-world use of Pharmacoeconomics & Outcomes Research (PEOR), Health Technology Assessments, Comparative Effectiveness, and Registries

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 products

TRACK 15: STATISTICAL SCIENCE AND QUANTITATIVE THINKING

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

TRACK 16: PROFESSIONAL DEVELOPMENT

- Discuss ways to foster collaborative innovation through professional development and educational efforts

TRACK 17: GLOBAL REGULATORY

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

TRACK 18: RARE/NEGLECTED DISEASES

- Discuss key initiatives, development and strategies involving rare diseases, special populations and orphan drugs

TRACK 19: SIAC SHOWCASES

- Discuss discipline-specific topics with a global community and share common experiences and knowledge with others in their particular field

TRACK 20: EXECUTIVE PROGRAM—PIONEERING PARTNERSHIPS

- Discuss collaborative research with members of the payer community
- Identify challenges of precision medicine associated with diagnostics, reimbursement and partnership co-development

TRACK 21: LATE-BREAKER

- Discuss the Physician Payment Act and its likely impact on the public health and all stakeholders
- Explain the importance of the CDISC/C-Path partnership toward developing therapeutic area standards and the benefits
- Recognize the readiness of EHRs to support regulated research and the potential value of EHRs for clinical research

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Target Audience

This meeting is designed for individuals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related products. The meeting is intended to strengthen professionals' understanding of the value of cross-discipline integration and to foster innovation for better health outcomes.

Continuing Education

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

*Continuing education credits are **not** available for the plenary session on Monday morning or for the white paper presentations. Learning objectives for each program offering will be shown as a slide in the meeting rooms.*

ACCREDITATION & CREDIT DESIGNATION

Accreditation Council for Continuing Medical Education (ACCME)

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and the Drug Information Association. 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 19 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Accreditation Council for Pharmacy Education (ACPE)

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants may earn up to 19 contact hours or 1.9 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 141–142.

American Nurses Credentialing Center (ANCC)

This educational activity for 19 contact hours is provided by PIM.

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

California Board of Registered Nursing

PIM is approved by the California Board of Registered Nursing, Provider Number 13485 for 19 contact hours.

Project Management Institute (PMI)

The Drug Information Association has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI). Participants may receive up to 19 professional development units (PDUs) for attending the Annual Meeting program offerings. PMI #: 2166-000142

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

International Association for Continuing Education and Training (IACET)

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Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending DIA 2012 Annual Meeting please complete your state's application for credit and submit accordingly.

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

To Calculate Your Credits from the Annual Meeting Program Offerings

Monday, June 25 through Thursday, June 28, 2012
The majority of the program offerings which indicate they are designated for credit offer **up to:**

1.5 *AMA PRA Category 1 Credit(s)*™
1.5 pharmacy contact hours or (.15 CEUs)
1.5 nursing contact hours
1.5 PMI professional development units
.2 IACET CEUs

Please note: The program offering on Tuesday, June 26 beginning at 3:30 PM offers up to 1 hour of the above-mentioned credits and/or .1 IACET CEU.

DIA Certificate Programs

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

Clinical Research Certificate Program:	14 Elective Units
Clinical Safety and Pharmacovigilance Certificate Program:	4 Elective Units
Project Management Certificate Program:	8 Elective Units
Regulatory Affairs Certificate Program:	14 Elective Units

For more information on DIA's Certificate Program, ***visit www.diahome.org/certificateprograms.***

STATEMENT OF CREDIT

Participants who would like to receive continuing education credits for the Annual Meeting **must scan their DIA name badge at each program offering** to record their attendance and **complete each program offering evaluation form.** Participants may scan their badges within 45 minutes after the start of each program 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.

To request a statement of credit, please go to **www.diahome.org,** select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" for each program offering. My Transcript will be available for all Annual Meeting participants to request credit on **Tuesday, July 3.**

Keep in mind, to receive continuing education credit you must:

- **Scan your DIA name badge at each program offering**
- **Complete an online evaluation form for each program offering you attend**
- **Request a statement of credit by visiting www.diahome.org**

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

Disclosure of Conflicts of Interest
Postgraduate Institute for Medicine (PIM) and DIA assess conflicts of interest with instructors, planners, managers, and other individuals who are in a position to control the content of CME 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 learners with high quality CME activities and related materials that promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

The faculty members', planners', and managers' financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interests related to the content of this continuing education activity are noted on pages 133–140.

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

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

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.

Evaluation
DIA 2012 Annual Meeting will continue its online evaluation process for all program offerings again this year. In order to simplify the evaluation process, all attendees' badges will be scanned upon entry to all meeting rooms, up to 45 minutes after the start for each program offering. This will enable DIA to ensure that you receive evaluations for only those program offerings that you attended. At the end of each day, you will receive an email notification requesting your feedback on the program offerings you attended. If a participant attends multiple program offerings within the same time frame, the last scanned entry will be recorded.

To ***thank you*** for your feedback, DIA will conduct a drawing from attendees who completed all program offering evaluations for *each day* of the meeting. The drawing winner (1) will receive a new iPad. The drawing will be announced and the prize distributed the week of July 16, 2012.

DIA 2012 ANNUAL MEETING SCHEDULE

DIA 2012 ANNUAL MEETING TRACKS

Track #	Track Title	Related Interest Areas
Track 01	Clinical Operations	Clinical Research (CR), Research and Development (RD) Investigative Sites (IS), Manufacturing (MF)
Track 02	Project/Portfolio Management and Strategic Planning	Project Management (PM), Financing (FI), Strategic Planning (SP)
Track 03	Innovative Partnering Models and Outsourcing Strategies	Outsourcing (OS)
Track 04	Nonclinical and Translational Development/Early Phase Clinical Development	Biotechnology (BT), Nonclinical (NC), Pharmacology (PC)
Track 05	Product Advertising and Marketing	Advertising and Promotion (AP), Marketing (MA)
Track 06	Medical Writing and Medical Communications	Medical Writing (MW), Medical Communication (MC)
Track 07	Processes and Technologies for Clinical Research	Information Technology (IT), eClinical (EC), Clinical Data Management (CDM), Study Endpoints (SE), Document Management (DM), Validation (VA)
Track 08	Regulatory Affairs and Submissions	Regulatory Affairs (RA), Submissions (SUBS)
Track 09	Medical Diagnostics and Devices	Combination Products (CmbP), Medical Devices and Diagnostics (MDD)
Track 10	Public Policy/HealthCare Compliance/Regulatory Law	Public Policy, Law, Corporate Compliance (PPLCC)
Track 11	Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)	Good Clinical Practices (GCP), Quality Assurance and Quality Control (QA/QC)
Track 12	Pharmaceutical Quality	Chemistry, Manufacturing and Controls (CMC)
Track 13	Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)	Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine (CEHTAEbM), Pricing and Reimbursement (PR)
Track 14	Clinical Safety and Pharmacovigilance	Clinical Safety and Pharmacovigilance (CP)
Track 15	Statistical Science and Quantitative Thinking	Statistics (ST)
Track 16	Professional Development	Professional Education, Training & Development (PETD)
Track 17	Global Regulatory	Includes program offerings hosted by a specific Regulatory Agency such as the FDA, US; SFDA, China; European Union; PMDA, Japan; Health Canada, Canada; etc. See page 6 for more information.
Track 18	Rare/Neglected Diseases	Rare and Neglected Diseases (RND)
Track 19	SIAC (Special Interest Area Community) Showcase	ALL
Track 20	Executive Program: Pioneering Partnerships	See page 7 for additional details
Track 21	Late-breaker	ALL
Track 22	White Paper Showcase	ALL

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
SUNDAY, JUNE 24 3:00–5:00 PM						
	DIA 2012 Student Forum		Forum	LEVEL: ●		125
MONDAY, JUNE 25 8:00–9:30 AM						
	OPENING PLENARY SESSION Welcome Remarks, Keynote Presentation, and Award Presentations All registrants are encouraged to attend.		Forum			Terrace Ballroom
MONDAY, JUNE 25 10:00–11:30 AM						
#101	Investigator Site Relationship Management WORKSHOP*	Track 01A	Workshop*	LEVEL: ■	IS, CR, PM	121c
#102	EMRs for Clinical Research: Hype versus Reality - A Management Primer	Track 01B	Session	LEVEL: ◆	CR, CDM, EC	108a
#103	Clinical Supply Chain Symposium	Track 01C	Symposium	LEVEL: ■	CR, PM, MF	109ab
#104	Overcoming Organizational Resistance to Portfolio Management	Track 02A	Session	LEVEL: ■	PM, RD	105ab
#105	Data Quality by Design (DQbD) to Improve the Quality of Clinical Trial Data in Multiregional Clinical Trials (MRCTs)	Track 02B	Session	LEVEL: ■	QAQC, CDM, CR	103c
#106	Best Practices in Managing Alliances: Using the Balanced Scorecard Methodology to Align Strategy and Operational Execution	Track 03	Workshop*	LEVEL: ■	OS, SP, PM	123

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
MONDAY, JUNE 25 10:00–11:30 AM, *continued*						
#107	First-in-human Challenges of Biologics and Biosimilars	Track 04	Session	LEVEL: ■	CP, NC, CR	124
#108	Advancing Benefit-risk Visualization and Communication	Track 06	Session	LEVEL: ◆	MW, RA, CP	108b
#109	New Ways to Learn What Happens to Patients AFTER Approval	Track 07	Session	LEVEL: ◆	CP, IT, CDM	103a
#110	Transforming Regulatory Information Into Actionable Regulatory Intelligence for Emerging Markets	Track 08A	Forum	LEVEL: ■	RA, CR, PM	115c
#111	Effective Switching from Rx to OTC Status: Maximimizing Revenue and Profit From Off-Patent Products	Track 08B	Forum	LEVEL: ■	RA, CR, PPLCC	119b
#112	Companion Diagnostics: Current and Future Developments	Track 09	Session	LEVEL: ■	RA, CR, RD	118c
#113	Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials	Track 10	Workshop*	LEVEL: ●	CP, RA, IS	120bc
#114	Defining Quality in Clinical Trials	Track 11	Session	LEVEL: ■	CR, CP, QAQC	119a
#115	ICH Update on Pharmaceutical Quality	Track 12	Forum	LEVEL: ●	CMC, RA, MF	122b
#116	The Impact of Social Media on Product Promotion and Pharmacovigilance	Track 14A	Forum	LEVEL: ●	AP, RA, MC	121ab
#117	Approaches to Postapproval Pediatric Safety Surveillance	Track 14B	Session	LEVEL: ■	CP, CDM, EC	118a
#118	Hot Topics in Statistics: Industry, CRO, Academic, and Regulatory Perspectives	Track 15	Forum	LEVEL: ■	ST, RA, OS, BT	113a
#119	Translational Medicine in Africa: Challenges and Opportunities for Product Development	Track 16	Session	LEVEL: ■	CR, RD, CP	117
#120	European Town Hall: Part 1 of 2 – Hot Topics in Europe	Track 17A	Forum	LEVEL: ■	RA, CP, CR	113c
#121	Pediatric Drug Development Progress: 15 Years Later and Across the Globe	Track 17B	Forum	LEVEL: ■	RA, PPLCC, ST	116
#122	Drug Development Strategies for Integrating Academia, Non-governmental Organizations (NGOs), and Industry Based on Experience in Neglected and Infectious Diseases	Track 18	Session	LEVEL: ■	CR, RD, SP	111ab
#123	Standards for Patients: Collaborations to Innovate Therapy Development	Track 21	Session	LEVEL: ■	CP, CDM, EC, IT	103b
#124	The New Health Report 2012: Rethinking the Risk Equation in Biopharmaceutical Development and Delivery	Track 22A	Session	LEVEL: ●	CP, PM, SP	125
#150	Free Agency is Here: Exploring Workforce Impact on Clinical Outsourcing	Track 22B	Session	LEVEL: ●	CR, RA, SP	113B
MONDAY, JUNE 25 12:00–12:45 PM						
	Innovative Theater: Innovation in R&D and Commercialization through Big Data Analytics		Special Session		RD, IT	Exhibit Hall
MONDAY, JUNE 25 1:30–3:00 PM						
#125	Increasing Protocol Complexity Places Challenges on Research Site Budgeting	Track 01A	Session	LEVEL: ◆	CR, FI, PM	109ab
#126	Social Media: The Promise and Pitfalls for Patient Recruitment	Track 01B	Symposium	LEVEL: ■	AP, MA	108a
#127	Quality by Design in Clinical Development: Blessing or Burden?	Track 02A	Session	LEVEL: ■	RA, CR	103c
#128	Get the Team to Take Charge!	Track 02B	Workshop*	LEVEL: ■	PM, PETD	121c
#129	Managing a Complex Outsourcing Collaboration	Track 03	Session	LEVEL: ■	OS, PM, SP	105ab
#130	Renal Impairment Studies Design, Conduct, and Analysis	Track 04	Forum	LEVEL: ●	NC, CR, RA	124
#131	Wrangling the Bestiary of Safety Documents: Coordination and Integration across Multiple Requirements	Track 06	Session	LEVEL: ■	MW, CP, RA	108b
#132	Capitalizing on Biometric Efficiencies: A Look at Data Start-up, Capture, Monitoring, and Reporting	Track 07A	Session	LEVEL: ●	CDM, IT, EC	103b
#133	Implications of Mobile Health and Clinical Research	Track 07B	Forum	LEVEL: ■	CDM, CR, IT	103a
#134	Regulatory Roundtable on Biosimilars	Track 08A	Forum	LEVEL: ■	RA, CR, RD	113c
#135	New Challenges from Outsourcing of Regulatory Operations	Track 08B	Session	LEVEL: ■	OS, RA	115a
#136	Regulatory Strategies to Accelerate Approval in Emerging Markets Considering the Growing Complexity of Requirements and Supply Chains	Track 08C	Session	LEVEL: ■	RA, MF, PM	119b
#137	Challenges and Opportunities for Drug Development in China	Track 08D	Session	LEVEL: ■	CR, PM, RD	116
#138	Where is the 510(k) Today	Track 09	Session	LEVEL: ●	RA, PPLCC, CmbP	118c

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
MONDAY, JUNE 25 1:30–3:00 PM, *continued*						
#139	Regulatory Collaboration/21st Century Innovation: Views of the Heads of Health Canada, the European Medicines Agency, and the US FDA	Track 10	Session	LEVEL: ■	RA	120bc
#140	Quality by Design: Is Your Clinical Trial Fit for Purpose?	Track 11A	Session	LEVEL: ◆	GCP, CP, CDM	119a
#141	Good Laboratory Practice (GLP): Design and Inspection Readiness	Track 11B	Symposium	LEVEL: ●	RD, PETD, QAQC	115c
#142	Postapproval Change Pathways in EU and US: Challenges and Opportunities for Harmonization	Track 12	Session	LEVEL: ■	PC, RA, CP	122b
#143	Demystifying Approaches to the Design and Analysis of Observational Studies of Comparative Effectiveness	Track 13	Forum	LEVEL: ■	CP, CR	107ab
#144	AE Reporting in the Era of Web 2.0: The Challenges of Having a Two-Way Conversation	Track 14A	Forum	LEVEL: ●	CR, MC, AP	121ab
#145	Epidemiologists in Industry and in CROs: Penultimate Generalists and Utterly Indispensible Scientists	Track 14B	Session	LEVEL: ●	CR, PM, ST	118a
#146	Extrapolation to Estimate Treatment Effects in Subgroups of Special Interest	Track 15	Forum	LEVEL: ■	CP, RA	113a
#147	My Big Break: Women At the Top in the Biotechnology Sector	Track 16	Forum	LEVEL: ●	CR, BT, RA	117
#148	European Town Hall: Part 2 of 2 - Interacting With the European System	MOVED TO MONDAY, JUNE 25, 3:30–5:30 PM				
#149	Challenges of Orphan Drugs in the US, EU, and Japan	Track 18	Session	LEVEL: ■	RA	111ab
#150	Free Agency is Here: Exploring Workforce Impact on Clinical Outsourcing	MOVED TO MONDAY, JUNE 25, 10:00–11:30 AM				
MONDAY, JUNE 25 3:30–5:00 PM						
#148	European Town Hall: Part 2 of 2 - Interacting With the European System	Track 17	Forum	LEVEL: ■	RA, CP	120bc
#151	A Day in the Life of a Clinical Research Site: What's Getting in the Way?	Track 01A	Forum	LEVEL: ■	CR, IS, PM	109ab
#152	ePatient Recruitment, Study Sites, and the Digital Divide	Track 01B	Forum	LEVEL: ■	CR, FI, EC	108a
#153	Enhancing Decision Making and Maximizing Portfolio Value Creation Using a Novel Portfolio Management Framework	Track 02A	Workshop*	LEVEL: ■	PM, IT	121c
#154	Keys to Successful Project Execution: Innovative Approaches to Critical Chain, Critical Path, and Risk Management	Track 02B	Session	LEVEL: ■	PM, CR, SP	103c
#155	Pharma R&D in Asia: Opportunities, Models, and Challenges	Track 03A	Symposium	LEVEL: ■	OS, RD, CR	111ab
#156	Pre-competitive Public Private Partnerships: The Changing Model of Pharmaceutical R&D	Track 03B	Session	LEVEL: ■	OS, RD, RA	105ab
#157	Drug QT Derisking: Changes in When and How	Track 04	Session	LEVEL: ■	PC, NC, CP	124
#158	Communicating Drug Safety Information Using Social Media: FDA and Industry Perspectives	Track 06	Session	LEVEL: ■	MC, CP, RA	108b
#159	PRO Measurement in Clinical Trials: Need for Education and Training	Track 07A	Session	LEVEL: ■	EC, SE, IT	103b
#160	Electronic Health Records (EHR)/Electronic Data Capture (EDC) Opportunities	Track 07B	Session	LEVEL: ■	EC, IT, CDM	103a
#161	Analysis and Impact of PDUFA V: How the Changes Will Affect the Work of Regulatory Affairs Professionals	Track 08A	Session	LEVEL: ■	RA, CR, PPLCC	113c
#162	Streamlining of Clinical Trial Review Process in Asian Pacific Region	Track 08B	Session	LEVEL: ■	RA, CR, PM	115a
#163	Vaccines: FDA and Japan Perspectives	Track 08C	Forum	LEVEL: ■	CR, RA, MC	119b
#164	Discussion with Former Center for Devices and Radiological Health (CDRH) Management	Track 09	Session	LEVEL: ◆	RA	118c
#165	Legal Jeopardy from the Conduct of Clinical Trials	Track 10	Forum	LEVEL: ●	CR, IS	116
#166	Conducting Clinical Trials in Developing Countries: Challenges in Meeting Good Clinical Practice (GCP) Compliance	Track 11A	Symposium	LEVEL: ■	RA, CR	119a
#167	Building Quality into Clinical Trials: Regulatory Perspectives and Practical Considerations	Track 11B	Session	LEVEL: ■	CR, CP, QAQC	115c
#168	Opportunities for Global Harmonization of Inspection Paradigm	Track 12	Session	LEVEL: ■	CM, MF, RA	122b
#169	Application of Quality of Evidence Assessment Tools to the Evaluation of Observational Pharmacoepidemiologic Studies	Track 13	Forum	LEVEL: ■	CP, CDM	107ab
#170	Electronic Health Records (EHR) and Medication Safety and Adherence	Track 14A	Symposium	LEVEL: ■	DM, CR, CDM	121ab

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Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
MONDAY, JUNE 25 3:30–5:00 PM, *continued*						
#171	Use It Early and Often: Epidemiology's Many Roles in Clinical Development and Beyond	Track 14B	Session	LEVEL: ■	CR, RD, RA	118a
#172	Rates and Weights: Quantifying Clinical Impact and Judgment in Benefit-risk Assessment	Track 15	Session	LEVEL: ■	CP, CR	113a
#173	Building International Competence in Drug Development Teams	Track 16	Symposium	LEVEL: ■	CR, RA, PM	117
#174	An Update on EMA, FDA, and PMDA International Activities	Track 17	Session	LEVEL: ●	RA, PPLCC	113b
#175	Raising the Bar for Regulatory Submission Document Quality: A Collaborative, Transitional Approach	Track 22	Session	LEVEL: ●	RA, MW, DM	125
TUESDAY, JUNE 26 8:00–9:30 AM						
#201	Optimizing Drug Development Portfolios: An Integrated Approach	Track 02A	Session	LEVEL: ■	PM, FI, SP	103c
#202	Project and Program Management Competency Models for the (Bio) Pharmaceutical Industry	Track 02B	Session	LEVEL: ■	PM, SP	113b
#203	The New Reality - Strategic Partnerships under Scrutiny: Are They Working, and How Long Will It Take to Ensure Success?	Track 03	Forum	LEVEL: ■	OS, SP, CR	105ab
#204	Novel Imaging Techniques Symposium	Track 04	Symposium	LEVEL: ■	BT, NC, PC	124
#205	Medical Contributions to Promotional Tactics	Track 06	Session	LEVEL: ■	MC, AP, CDM	108b
#206	Defining Study Endpoints in 2012: The Journey Continues	Track 07A	Session	LEVEL: ■	SE, RA, CEHTAEbM	103a
#207	Evolving eContent Design and Exchange for Clinical Studies	Track 07B	Symposium	LEVEL: ■	CDM, EC, IT	103b
#208	Meta-collaborations: A Call to Action	Track 08A	Forum	LEVEL: ■	RA, CEHTAEbM, SP	Terrace 4
#209	Electronic Drug Registration and Listing: FDA and Industry	Track 08B	Session	LEVEL: ■	DM, SUBS, RA	120bc
#210	Legal Aspects of Clinical Trial Compliance	Track 10	Session	LEVEL: ◆	RA, CR	113c
#211	Quality Risk Management WORKSHOP*	Track 12	Workshop*	LEVEL: ●	QAQC	123
#212	Recent Advancement of HTA and Its Impact on Health Care Reform and Product Life Cycle Management in the Asian Pacific Region	Track 13	Session	LEVEL: ■	CR, RA, RD	107ab
#213	Data Monitoring Committee (DMC): When You Need One and When You Don't!	Track 14	Session	LEVEL: ■	GCP, CR, RA	121ab
#214	NDA/BLA Statistical Review and the CDISC ADaM Data Standards	Track 15	Forum	LEVEL: ■	CDM	113a
TUESDAY, JUNE 26 10:00–11:30 AM						
#215	Understanding Risk-based Monitoring: Is It Art, Science, or Both?	Track 01A	Symposium	LEVEL: ■	CP, EC, RA	108a
#216	The Next Patient Recruitment Frontier: Leveraging Mobile Health Care Technology (mHealth) to Recruit Patients for Clinical Trials	Track 01B	Forum	LEVEL: ■	CR, IT, PM	111ab
#217	Update on Collaborative Projects of the Clinical Trials Transformation Initiative (CTTI)	Track 01C	Session	LEVEL: ■	CP, IS	109ab
#218	Optimizing Performance in Outsourced Projects in China and Other Asian Countries	Track 02A	Session	LEVEL: ●	OS, PM	113b
#219	Improving Protocol Design: Current Industry Practices and New Approaches	Track 02B	Session	LEVEL: ■	FI, PM, CR	103c
#220	The Unintended Consequences of Strategic Partnerships	Track 03	Session	LEVEL: ●	OS, SP, CR	105ab
#221	Skin-drug Biotransformation: What Testing Should We Do?	Track 04	Session	LEVEL: ◆	NC, CP, PC	124
#222	Publish or Perish: Retracted Scientific Literature	Track 06	Forum	LEVEL: ■	MC	108b
#223	Labeling Claims Based on Patient-reported Outcome Measures: It Takes a Village!	Track 07A	Forum	LEVEL: ●	EC, SE, CDM	103a
#224	Lessons Learned from FDA-sponsored ARRA PCOR (American Recovery and Reinvestment Act Patient Centered Outcomes Research) Data Standardization Efforts	Track 07B	Session	LEVEL: ■	CDM, IT, RA	103b
#225	Pediatric Development in the US: Implementation of 2007 PREA and BPCA Against a Backdrop of the EU Pediatric Legislation	Track 08A	Session	LEVEL: ■	CR, PPLCC	119b
#226	Drug Shortages 2012: Rewind, Repeat, Recovery	Track 08B	Session	LEVEL: ■	RA, CP, MF	120bc
#227	Combination Products	Track 09	Symposium	LEVEL: ●	CmbP, RA	118c

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
TUESDAY, JUNE 26 10:00–11:30 AM, *continued*						
#228	Product Liability in the US and the EU	Track 10	Session	LEVEL: ●	CP, RA	113c
#229	Misconduct and Management of Serious or Continued Noncompliance: What Are the Differences and Similarities?	Track 11	Session	LEVEL: ◆	RA, CR, IS	115c
#230	Preparing for CMC Meetings with the FDA	Track 12	Session	LEVEL: ●	CMC, RA, CR	119a
#231	The Effects of NICE Technology Assessments on Prescribing and Cost-sharing Behavior in the US	Track 13	Session	LEVEL: ●	PR, CR, RA	107ab
#232	Comparison of National-level Drug Utilization Patterns from Large Commercial Health Care Databases with Mini-Sentinel	Track 14A	Session	LEVEL: ■	CR, CDM, EC	121ab
#233	Pharmacovigilance in Japan and Risk Management Plans	Track 14B	Symposium	LEVEL: ■	CR, RA	118a
#234	FDA Draft Guidance on Multiple Endpoints in Clinical Trials	Track 15	Session	LEVEL: ■	CR, RA	113a
#235	Advanced Presentation Skills	Track 16A	Workshop*	LEVEL: ■	PETD	121c
#236	Introduction to Narrative Medicine	Track 16B	Workshop*	LEVEL: ●	CR, RD, CP	123
#237	International Regulatory Cooperation: A Canadian Perspective	Track 17A	Forum	LEVEL: ■	RA, CR, PM	116
#238	Latin America Town Hall	Track 17B	Forum	LEVEL: ●	CR, RA	117
#239	Value of Actigraphy in Clinical Trials	Track 22	Session	LEVEL: ●	CR, RA, CDM	125
TUESDAY, JUNE 26 12:00–12:45 PM						
	Innovative Theater ADDPLAN PE- Innovative Software for Population Enrichment Designs in Adaptive Clinical Trials	Special Session		LEVEL: ●	ST, CR	Exhibit Hall
TUESDAY, JUNE 26 1:30–3:00 PM						
#240	Effective and Efficient Monitoring as a Component of Quality Assurance in the Conduct of Clinical Trials	Track 01A	Forum	LEVEL: ■	CR, IS, QAQC	109ab
#241	Investigator Budgets' Impact on Patient Enrollment and Retention: How to Improve Sponsor/CRO/Site Selection Processes	Track 01B	Session	LEVEL: ■	CR, PR, RD	108a
#242	Sponsors and CROs: Don't Be Misled By Your Site Performance Data	Track 01C	Workshop*	LEVEL: ■	CR, IS, CDM	123
#243	Planning Your Drug's Development Life Cycle	Track 02A	Symposium	LEVEL: ■	PM, RD, CR	113b
#244	Leaping the Valley of Death: Keys to Successfully Going from the Lab to the Clinic for Pharmaceutical Products	Track 02B	Session	LEVEL: ■	PM, SP, CR	103c
#245	Collaborative Partnerships in Drug Development: An Executive Roundtable Discussion	Track 03	Forum	LEVEL: ◆	OS, CR, SP	121ab
#246	Product Candidate to Proof-of-concept: An Integrated Approach to Accelerate Programs	Track 04	Session	LEVEL: ■	NC, PC, CP	124
#247	From Design to Disclosure: Pleasing Multiple Masters	Track 06	Symposium	LEVEL: ■	MW, CR, RA	108b
#248	Implementing Adaptive Clinical Trials: A Practical Perspective	Track 07A	Session	LEVEL: ■	CDM, EC, ST	103a
#249	Innovative Ways of Looking at Computer System Validation	Track 07B	Forum	LEVEL: ■	VA, IT, QAQC	103b
#250	An Ocean Apart? Integrating Distinct Health Authority Philosophies on Personalized Medicines and Companion Assays	Track 08	Session	LEVEL: ■	PR, CmbP, MDD	120bc
#251	Funding Innovation and Creating Opportunities in the Device, Diagnostic, and Drug Interface	Track 09	Session	LEVEL: ■	FI, RD	118c
#252	Drug Rediscovery as an Innovative Tool to Meet Unmet Medical Needs	Track 10	Session	LEVEL: ●	RA, RD	113c
#253	What Should You Put in a Clinical Quality Assurance (CQA) Agreement	Track 11	Session	LEVEL: ■	CR, CDM, QAQC	115c
#254	Practical Implementation of Knowledge Management	Track 12	Session	LEVEL: ■	CMC, RA, IT	119a
#255	Registries for Evaluating Patient Outcomes: Emerging Areas of Controversy	Track 13	Forum	LEVEL: ●	CR, RD, RA	107ab
#256	Noninterventional Minimal Risk Research: A 360° Perspective	Track 14A	Session	LEVEL: ■	IS, RA	119b
#257	Stepping Up and Doing It Step by Step: Lessons Learned from Initial Endeavors Exploring Health Care Data for Signal Detection	Track 14B	Session	LEVEL: ■	CDM, CR, EC	118a
#258	Noninferiority Trial Designs: Perspectives from Academia, Industry, and a Regulatory Agency	Track 15	Session	LEVEL: ■	CR, RA	113a

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
TUESDAY, JUNE 26 1:30–3:00 PM, *continued*						
#259	Definition and Validation of Core Competencies to Enhance the Quality of Clinical Trials and Those Who Conduct Them	Track 16	Workshop*	LEVEL: ■	CR, IS, PETD	121c
#260	Update from the EMA-FDA Parallel Assessment Pilot	Track 17A	Session	LEVEL: ●	CMC, RA	122b
#261	SFDA Town Hall	Track 17B	Forum	LEVEL: ●	CMC, CR, RA	117
#262	Understanding the Challenges of Conducting Studies for Orphan Indications and Rare Diseases	Track 18	Session	LEVEL: ■	PM, RD	111ab
#263	A Challenge for the Industry: What Will it Take for a Sponsor to Use EHRs With a Regulated Research Protocol?	Track 21	Forum	LEVEL: ●	CR, IT, RA	105ab
#264	The Unique Relationship Between Global Patient Recruitment and Translation Management	Track 22	Session	LEVEL: ●	CR, RA, MW	125
TUESDAY, JUNE 26 3:30–4:30 PM						
#265	Beyond Taxonomy	Track 19A	SIAC	LEVEL: ■	SE, CDM, EC	103a
#266	Breaking News Update: Cutting Edge Statistical Methods in Clinical Development	Track 19B	SIAC	LEVEL: ■	ST, CR, RA	103b
#267	CDER Electronic Submissions Standards Update	Track 19C	SIAC	LEVEL: ●	SUBS, DM, CDM	121ab
#268	Controversial Guidance, eSource, and Standards: How Does It All Fit Together in an eClinical World?	Track 19D	SIAC	LEVEL: ■	EC, CDM, RA	103c
#269	Cross-sector Innovation Brings Tailored Therapies to Patients	Track 19E	SIAC	LEVEL: ●	CR, BT, SP	108a
#270	Electronic Data Capture (EDC): How Much Quality is Enough?	Track 19F	SIAC	LEVEL: ■	CDM, EC, SE	105ab
#271	Emerging Professionals: Optimize your Transition into the Pharmaceutical Arena	Track 19G	SIAC	LEVEL: ●	PETD, CR, RA	107ab
#272	Evidence for the Marketplace: Bridging the Gap Between Industry, Payer, Providers, and Patients	Track 19H	SIAC	LEVEL: ■	CEHTAEbM, PR, CR	108b
#273	Reference Models and the Framework for the Destruction of Paper: How They Are Changing Our Industry	Track 19I	SIAC	LEVEL: ■	DM, RA, SUBS	109ab
#274	Globalization of Phase 1: Trends and Challenges	Track 19J	SIAC	LEVEL: ■	CP, PC, CR	111ab
#275	Good Pharmacovigilance Practice in a Global Environment	Track 19K	SIAC	LEVEL: ■	CP, RA, CR	113a
#276	Hot Topics in Clinical Trial Disclosure (CTD)	Track 19L	SIAC	LEVEL: ■	MW, CR, QAQC	113b
#277	Hot Topics in Regulatory Affairs Forum	Track 19M	SIAC	LEVEL: ■	RA, CR, PM	120bc
#278	How Medical Writers Are Improving Global Practice and Collaboration	Track 19N	SIAC	LEVEL: ■	MW, MC, RA	113c
#279	Leveraging Technology in an Age of Readily Available Information	Track 19O	SIAC	LEVEL: ■	MC, IT, AP	116
#280	Meet the Regulators: Helping You Ensure GCP Compliance by Knowing the Most Frequent and Serious Findings	Track 19P	SIAC	LEVEL: ■	QAQC, GCP, RA	115c
#281	Navigating the Intersection of Outsourcing and Quality Oversight	Track 19Q	SIAC	LEVEL: ■	OS, PM, QAQC	117
#282	New Guidances on Quality Risk Management by FDA and EMA: Implications for Industry	Track 19R	SIAC	LEVEL: ■	CR, RA, CP	118a
#283	Pediatric Clinical Trials: Modeling and Simulation to Support the Bridging of Data	CANCELLED				
#284	The Future of Project Management in the Pharmaceutical Industry: What Competencies Will Be Critical?	Track 19T	SIAC	LEVEL: ■	PM, CR, RA	119a
#285	Re-energize Your Career!	Track 19U	SIAC	LEVEL: ●	PETD, RA, CR	119b
#286	Rx: A New World in Natural Health Products (NHP)	Track 19V	SIAC	LEVEL: ■	CR, RD, RA	121c
#287	Status of the Use of Electronic Health Records (EHR) in Clinical Research	Track 19W	SIAC	LEVEL: ■	CDM, CR, VA	125
#288	Who Owns the Service? Challenges in Collaboration Between IT and the Business	Track 19X	SIAC	LEVEL: ■	IT, SP, ST	124
TUESDAY, JUNE 26 4:30- 6:00 PM						
	Open Business Meeting for the Adaptive Design Scientific Working Group				ST	120a

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
WEDNESDAY, JUNE 27 8:00–9:30 AM						
#301	How Industry Can Partner with FDA in Defining a Risk-based Monitoring Program	Track 01A	Session	LEVEL: ■	CR, RA, CP	108a
#302	Collaboration and Globalization of Clinical Trials: What Does It Mean to Pharmaceutical Project Managers?	Track 01B	Forum	LEVEL: ■	PM, CR, IT	109ab
#303	Integrating Pharmacogenomics and Companion Diagnostic Development into the Integrated Clinical Development Plan	Track 02A	Session	LEVEL: ■	CR, PM, MC	105ab
#304	Asian Regulatory Agencies Relocated into Biotech Science Park as a Strategy for Global Drug Development	Track 02B	Session	LEVEL: ■	RA, SP, PM	103c
#305	Risk-sharing Partnerships: Models for Managing Risk across the Clinical-commercial Continuum	Track 03A	Forum	LEVEL: ■	OS, SP, FI	108b
#306	Patient Advocacy and Your Next Generation of Research: How Nonprofit Organizations Can Accelerate Product Development	Track 03B	Session	LEVEL: ●	OS, CR, SP	111ab
#307	Nanotechnology: Regulatory Challenges and Opportunities	Track 04	Session	LEVEL: ●	BT, PC, NC	124
#308	Prescription Drug Marketing Regulatory Primer	Track 05	Workshop*	LEVEL: ●	RA, CP, MC	113b
#309	Implementing Structured Authoring: Understanding the DITA Model and Its Applicability for Content and Metadata Management	Track 06	Workshop*	LEVEL: ●	MW, CMC, DM	121c
#310	Combining Patient Self-report and Clinician Oversight: Are Two Heads Better than One?	Track 07A	Session	LEVEL: ■	CDM, EC, SE	103a
#311	eClinical Interoperability: Imagination, Integration, Implementation	Track 07B	Session	LEVEL: ■	EC, CDM, IT	103b
#312	Patient Advocacy in Medical Product Development: The Evolving Relationship Between FDA and Its Patient Stakeholders	Track 08A	Session	LEVEL: ●	RA, CR, CP	119a
#313	Future Directions for eCTD Module 1	Track 08B	Session	LEVEL: ●	DM, SUBS, RA	120bc
#314	Clinical Trial Disclosures: A US and EU Regulatory Update	Track 08C	Session	LEVEL: ■	RA, CR, MW	119b
#315	Oncology Medications: State-of-the-art Identification and Management of Potential CV Safety Issues During Development	Track 09	Session	LEVEL: ●	CP	118c
#316	Policy and Enforcement Trends: Are Regulators and Industry Heading in the Right Direction?	Track 10	Forum	LEVEL: ■	RA	113c
#317	FDA and European Medicines Agency Collaboration: GCP Inspections and Beyond	Track 11	Session	LEVEL: ■	GCP, RA, QAQC	121ab
#318	Auditing Pharmaceutical Quality Systems	Track 12	Session	LEVEL: ■	CMC, MF	122b
#319	Environment for Health Care Decision Making: The Role of CER, Evidence-based Medicine, Quality, and Value	Track 13	Session	LEVEL: ■	PR	107ab
#320	How to Be Prepared for Shifting Regulations on Combination Products	Track 14A	Session	LEVEL: ■	CmbP, RA, CR	115c
#321	Active Surveillance Using Large, Electronic Health Care Data Networks	Track 14B	Session	LEVEL: ■	EC, CDM, ST	118a
#322	Statistical Methods for Analysis of Integrated Safety Data	Track 15	Session	LEVEL: ■	CEHTAEbM, CR, CDM	113a
#323	Emerging Needs in Clinical Research and Drug Development Sciences Education and Certification	Track 16	Session	LEVEL: ■	CR, PM, PETD	117
#324	Risks to and Securing of Global Drug Supply Chains	Track 17	Forum	LEVEL: ■	RA, MF, CP	115a
#325	Enabling Remote Monitoring in Clinical Trials for Sponsors and Sites	Track 22	Session	LEVEL: ●	CR, RA, PM	125
WEDNESDAY, JUNE 27 10:00–11:30 AM						
#326	Clinical Research in Emerging Regions Around the World	Track 01A	Symposium	LEVEL: ■	CR, PM, SP	109ab
#327	Applying Longstanding Ethical Principles in a Period of Dynamic Change	Track 01B	Symposium	LEVEL: ■	PM, IT	108a
#328	Achieving Alignment in a Difficult and Diverse Environment	Track 02A	Forum	LEVEL: ●	MC, PETD, PM	105ab
#329	Project Risk Management Simulation for Product Development	Track 02B	Workshop*	LEVEL: ■	CP, CR	121c
#330	Partnering for Impact in Global Health	Track 03	Forum	LEVEL: ●	RA, SP, PM	121ab
#331	Can Human Carcinogenic Risk Be Communicated Without a Rodent Bioassay?	Track 04	Forum	LEVEL: ◆	BT, PC	124
#332	FDA Enforcement Update: Advertising and Promotion	Track 05	Session	LEVEL: ■	RA, MC	113b

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
WEDNESDAY, JUNE 27 10:00–11:30 AM, *continued*						
#333	Efficient Regulatory Medical Writing for Global Submissions Including "ICH Outlier" Authorities	Track 06	Session	LEVEL: ◆	MW, DM, RA	108b
#334	Identity Management Technologies in Clinical Trials	Track 07A	Session	LEVEL: ■	IT, CR, QAQC	103b
#335	Clinical Outcome Assessments in the Evaluation of Medical Products in Pediatrics	Track 07B	Session	LEVEL: ■	EC, CR, CDM	103a
#336	Building the Benefit-risk Toolbox: Is There a Consensus on a Scientifically Acceptable Framework?	Track 08A	Session	LEVEL: ■	RA, CP	119a
#337	Global Product Development: Resolving Conflicting Scientific and Regulatory Advice from Multiple Health Authorities	Track 08B	Session	LEVEL: ■	RA, CR	119b
#338	Pursuing Standards to Enhance eCTD Deliverables: PhRMA Electronic Regulatory Submissions (ERS) Group Annual Update	Track 08C	Forum	LEVEL: ■	DM, SUBS, RA	120bc
#339	Current Advancement of Regulatory Reform for Medical Devices in Asia Pacific and Its Strategic Impact	Track 09	Symposium	LEVEL: ●	RA, CR	118c
#340	Meeting the Therapeutic Needs of Older Patients: A Sustainable Collaborative Approach	Track 10	Session	LEVEL: ■	RA, CR	113c
#341	Regulatory Updates on Current Trends in Drug Quality and Manufacturing	Track 12	Forum	LEVEL: ■	CMC, MF, RA	122b
#342	REMS: Are Our Written Communications Truly Mitigating Risks to Patients?	Track 14A	Session	LEVEL: ■	CR, RA, RD	115c
#343	The Out-Sourcing/In-Sourcing/Out-Sourcing Model for Pharmacovigilance	Track 14B	Symposium	LEVEL: ●	OS	118a
#344	From Adverse Events to Adverse Drug Reactions: Statistical Issues in Safety Labeling	Track 15	Session	LEVEL: ■	CP, DM, MW	113a
#345	Employee Engagement	Track 16	Symposium	LEVEL: ●	CR, RA, PM	117
#346	Natural History Studies for Rare Diseases and Orphan Conditions	Track 18	Session	LEVEL: ■	CR, RD, RA	111ab
WEDNESDAY, JUNE 27 1:30–3:00 PM						
#347	Clinical, Statistical, and Data Management Considerations for Developing Clinical Trial Protocols	Track 01A	Session	LEVEL: ■	CR, ST, CDM	109ab
#348	New Regulations and Guidance for Clinical Trials and Human Subject Protection	Track 01B	Session	LEVEL: ■	CR, RA	108a
#349	Building Clinical Site Capacity for Research	Track 01C	Session	LEVEL: ■	CR, PM, SP	105ab
#350	Drug Development Strategies and Incorporation of an Established Project Management System	Track 02	Session	LEVEL: ■	PM, OS, SP	103c
#351	Thinking Small! A Virtual Pharma Gets Big Work Done with Like-minded Partners	Track 03A	Session	LEVEL: ●	SP, OS, CR	111ab
#352	Functional Service Provider Symposium	Track 03B	Symposium	LEVEL: ■	OS, FI, CR	118a
#353	Microdosing: Past Experience and Future Role in Translational Medicine	Track 04	Session	LEVEL: ■	PC, NC, CDM	124
#354	International Advertising/Promotion Coordination	Track 05	Session	LEVEL: ■	MC, MA	113b
#355	Global Medical Information in Real-life Situations	Track 06A	Session	LEVEL: ■	MC, DM, OS	108b
#356	What Medical Writers Need to Know about MedDRA	Track 06B	Workshop*	LEVEL: ■	CP, CDM	121c
#357	Innovations Aimed at Improving Effectiveness and Speed of the Therapeutic Development Process	Track 07A	Session	LEVEL: ●	IT, CDM, MC	103a
#358	Business Applications in the Cloud	Track 07B	Forum	LEVEL: ■	CDM, IT, VA	103b
#359	Orphan Drug Development: Global Regulatory Challenges and Initiatives	Track 08A	Session	LEVEL: ■	RA, CR, PM	120bc
#360	Operationalizing SDTM	Track 08B	Session	LEVEL: ●	DM, SUBS, RA	119b
#361	Update on Revision of European Medical Device Directives and Impact on Industry	Track 09	Symposium	LEVEL: ■	RA, PPLCC	118c
#362	Emerging Development and Policy Trends in the Economics of the Biopharmaceutical Industry	Track 10	Session	LEVEL: ●	RD, BT	113c
#363	The Changing Face of Clinical Compliance: Regulatory, Technology, and Services	Track 11	Symposium	LEVEL: ■	GCP, CR, EC	121ab
#364	Quality Risk Management WORKSHOP*	Track 12	Workshop*	LEVEL: ●	CM, MF, CP	123

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
WEDNESDAY, JUNE 27 1:30–3:00 PM, *continued*						
#365	The Use of Health Technology Assessment (HTA) for Access and Resource Allocation Decision Making: International Examples	Track 13	Symposium	LEVEL: ■	PR, RA, PPLCC	107ab
#366	Data Sources for Monitoring Usage of Drug Products and How to Use These Sources to Support Safety and REMS Evaluations	Track 14	Forum	LEVEL: ●	CDM, RA, CR	115c
#367	Impact of Bayesian Methods in Medical Product Development	Track 15	Session	LEVEL: ■	CP	113a
#368	Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall	Track 17A	Session	LEVEL: ■	RA, CR, RD	122b
#369	CBER Town Hall	Track 17B	Forum	LEVEL: ●	RA, CR	119a
#370	Social Media 2.0: The Power of Online Rare Disease Communities to Connect and Engage ePatients	Track 18	Forum	LEVEL: ■	AP, CR	115a
#371	Implementation of Adaptive Clinical Trials	Track 22	Session		ST, CR, EC	125
WEDNESDAY, JUNE 27 3:30–5:00 PM						
#372	Standard of Care: Challenges for Sponsors, Sites, and Patients in Clinical Trial Budgets	Track 01A	Session	LEVEL: ■	IS, PR, PPLCC	109ab
#373	Special Populations Symposium	Track 01B	Symposium	LEVEL: ●	CR, PM, IS	105ab
#374	Optimizing Study Monitoring Performance and Efficiency	Track 01C	Symposium	LEVEL: ■	CR, PM, CDM	108a
#375	Planning and Execution of a Global Oncology Program	Track 02	Session	LEVEL: ■	PM, RA, CR	103c
#376	Effectively Managing Global Trials Within a CRO Alliance Structure	Track 03A	Forum	LEVEL: ■	OS, PM, CR	111ab
#377	Sites, CROs, and Sponsor Relationship Obstacles and Opportunities	Track 03B	Symposium	LEVEL: ■	CR, IS, OS	118a
#378	Biomarker Focused Strategies for Personalized Medicine	Track 04	Session	LEVEL: ●	NC, BT	124
#379	Leveraging Drug Development and Advertising/Promotion Regulatory Expertise to Drive a Robust Target Product Profile Process	Track 05	Session	LEVEL: ■	RA, MC, CP	113b
#380	Recent Advances in Adaptive Clinical Trial Designs for Medical Writers	Track 06	Session	LEVEL: ■	MW, RA, ST	108b
#381	Sharing Clinical Data: Examples of What to Share and Benefits to Research and Patients	Track 07A	Session	LEVEL: ■	IT, CDM, RD	103a
#382	Automation Through CDISC Standard Models: eProtocol, Data Submission, and Safety Reporting	Track 07B	Symposium	LEVEL: ■	CDM, EC, SUBS	103b
#383	Adaptive Licensing: Bane or Boon for Drug Development?	Track 08A	Session	LEVEL: ■	RA, CR, ST	119b
#384	Update on Biosimilar Developments in the US	Track 08B	Session	LEVEL: ◆	RA, CR, PPLCC	120bc
#385	Emerging Role of the Patient Voice on Drug Policy in Japan	Track 10A	Session	LEVEL: ●	PPLCC, CP, RA	118c
#386	Regulatory Capacity Building from 360 Degrees	Track 10B	Forum	LEVEL: ■	CP	113c
#387	Good Clinical Practices (GCPs) through Good Documentation Practices (GDPs)	Track 11	Workshop*	LEVEL: ■	GCP, CR, CDM	121c
#388	The Role of Meta-analyses in Drug Safety: Methodological Considerations	Track 13A	Forum	LEVEL: ■	CP, CR	107ab
#389	Benefit Versus Risk of Harm: Assessing Therapeutic Response and Interpreting Benefit/Risk with Patients	Track 13B	Session	LEVEL: ■	CP	125
#390	Doping Abuse of Medicines in Sport: The Challenge to Industry and Regulators	Track 14	Session	LEVEL: ■	CR, RD, PPLCC	115c
#391	Statistical Comparative Effectiveness Research (CER): Closing the Gaps in the Consideration of Observational Evidence	Track 15	Session	LEVEL: ■	CEHTAEbM	113a
#392	Learning Through Knowledge Sharing and Virtual Worlds	Track 16A	Symposium	LEVEL: ●	CR, PM, PETD	117
#393	DIA 2013: Helpful Hints in Submitting an Abstract	Track 16B	Workshop*	LEVEL: ●	ALL	123
#394	The State of Electronic Submissions at CDER, CBER, and CDRH	Track 17A	Session	LEVEL: ●	SUBS, RA, IT	121ab
#395	India Town Hall	Track 17B	Forum	LEVEL: ■	RA	119a
#396	Rare Disease Clinical Research Consortia: Immediate and Rich Sources of Translational Research Data, Partnering Opportunities	Track 18	Session	LEVEL: ●	CR, RD	115a
#397	Implementation of the Physician Payment Sunshine Act: Now What?	Track 21	Forum	LEVEL: ■	CR, PM, RA, PPLCC, QC	122b
#398	Accelerating Cancer Clinical Trials	Track 22	Session	LEVEL: ●	CR, RD	125

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Interest Area(s)	Room Number
THURSDAY, JUNE 28 9:00–10:30 AM						
#401	Clinical Trial Metrics Symposium	Track 01	Symposium	LEVEL: ■	CR, FI, CDM	113c
#402	Managing Drug Development Portfolios in a Safety-heightened Environment	Track 02	Session	LEVEL: ◆	PM, CP, CDM	105ab
#403	Integrated Partnership: A Vaccine Case Study	Track 03A	Forum	LEVEL: ■	OS, SP, CR	111ab
#404	Multistakeholder Development Partnerships: Harnessing Differing Perspectives, Objectives, and Strengths for Success	Track 03B	Symposium	LEVEL: ■	OS, SP, CR	109ab
#405	Hot Topics Symposium	Track 04	Symposium	LEVEL: ■	BT, RA, NC	124
#406	Study Recruitment Challenges, Tailored Medical Information Requests - OH MY! Have You Maximized All Your Options	Track 06	Session	LEVEL: ■	MC, CR, CP	108b
#407	Cloud Computing in Regulated Environments	Track 07A	Workshop*	LEVEL: ■	IT, VA, CP	121c
#408	The Cross-over Between Direct-to-patient Studies, Social Media, and EDC	Track 07B	Session	LEVEL: ■	EC, IT, SE	107ab
#409	The Role of Corrective and Preventive Action (CAPA) in GCP/GLP Audit Quality Management Systems	Track 11	Symposium	LEVEL: ■	GCP, CR, RA	121ab
#410	Coding with Confidence	Track 14	Workshop*	LEVEL: ■	CDM, CP, DM	123
#411	Open Source Statistical Software in Drug Development: Challenges and Opportunities	Track 15	Session	LEVEL: ■	CDM, IT	113a
#412	Left to Your Own Devices	Track 16	Symposium	LEVEL: ●	MC, CmbP, PM	125
#413	CDER Town Hall: Part 1 of 2	Track 17	Forum	LEVEL: ●	RA, CP, CR	114 AUD
THURSDAY, JUNE 28 10:45–12:15 PM						
#414	Strategically Reduce Study Cost by Controlling Study Design Cost Drivers, with Attention to Studies with Biomarkers	Track 02	Session	LEVEL: ■	CR, PM, FI	105ab
#415	Preferred Provider Relationships: Yesterday's Obstacles, Today's Successes, and Tomorrow's Vision	Track 03A	Session	LEVEL: ■	OS, CR	111ab
#416	Using Technology to Build Successful Strategic Outsourcing Partnerships	Track 03B	Session	LEVEL: ■	OS, IT, CR	109ab
#417	Strategies for Implementing Dried Blood Spot Drug Development and How the Technology Supports the 3Rs Principles	Track 04	Session	LEVEL: ●	NC, CP, RD	103b
#418	Medical Writing Competencies and Best Practices in the Global Environment	Track 06	Symposium	LEVEL: ■	MW, OS, IT	108b
#419	Data Warehousing: Buzz Word or Panacea?	Track 07A	Symposium	LEVEL: ■	CDM, VA, EC	103a
#420	Economic Considerations and Management in the Modern Day Clinical Trial	Track 07B	Symposium	LEVEL: ◆	EC, CDM, FI	103c
#421	Regulatory Handling of Ethnic Factors in Asian Clinical Trial Data #3, Implication for Simultaneous Global Development (SGD)	Track 08	Session	LEVEL: ■	RA, CDM, CR	107ab
#422	Immunogenicity of Therapeutic Peptides: Regulatory Science Implications	Track 14	Session	LEVEL: ◆	NC, CR, RA	113c
#423	Increasing Clinical Program Success with Modeling and Simulation	Track 15	Session	LEVEL: ●	CR, RD	113a
#424	Building Rapport and Managing Communication Filters for Breakthrough Collaborations	Track 16	Symposium	LEVEL: ●	PETD, SP, MC	113b
#425	CDER Town Hall: Part 2 of 2	Track 17	Forum	LEVEL: ●	RA, CP, CR	114 AUD

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

NOTES

SATURDAY, JUNE 23 — MONDAY, JUNE 25

The information that was made available to DIA as of 4/30/2012 is included in the following agenda. Speaker names identified as "Invited" will be published once confirmation and disclosure forms are completed. Visit **www.diahome.org/DIA2012sessions** *for the most up-to-date information.*

SATURDAY, JUNE 23

Registration Hours:

9:00 AM–5:00 PM — Exhibitor Registration
Exhibit Hall D Lobby

SUNDAY, JUNE 24

Registration Hours:

8:00 AM–9:00 AM — Registration for Full-day, Morning Preconference Program/Tutorials
Broad Street Lobby

8:00 AM–6:00 PM — Exhibitor Registration
Exhibit Hall D Lobby

12:30 PM–1:00 PM — Registration for Afternoon Preconference Program/Tutorials
Broad Street Lobby

3:00 PM–6:00 PM — Attendee and Speaker Registration
Broad Street Lobby

Sunday, June 24 — DIA 2012 STUDENT FORUM

3:00 PM–5:00 PM LEVEL: ● FORMAT: **FORUM**

Room 125

DIA 2012 Student Forum "Getting a Job"

CHAIRPERSON

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

This year's student forum will concentrate on helpful hints in networking, resume building, and how to interact with potential employers, and will include information that may not be provided in standard career counseling. We will also discuss the best ways to take advantage of the incredible networking opportunity at the DIA 2012 Annual Meeting. Bring personal business cards and a sample resume.

Communicating Your Capabilities
Kelleen Flaherty, MS
Assistant Professor, University of the Sciences In Philadelphia

Education Versus Experience
Stephen A. Sonstein, PhD, MS
Director, Clinical Research Administration, Eastern Michigan University

MONDAY, JUNE 25

Registration Hours:

7:00 AM–6:30 PM — Attendee and Speaker Registration
Broad Street Lobby

7:00 AM–6:30 PM — Exhibitor Registration
Exhibit Hall D Lobby

Schedule:

7:15 AM–8:00 AM — Coffee and Breakfast
Terrace Ballroom Lobby

7:15 AM–8:00 AM — Orientation/Networking and Coffee for DIA 2012 Annual Meeting First-timers
Exhibit Hall E Lobby

8:00 AM–9:30 AM — Opening Plenary Session
Terrace Ballroom

9:30 AM–10:00 AM — Coffee Break
Meeting Rooms 108 and 119 Concourse

9:30 AM–10:00 AM — Orientation and Coffee for DIA 2012 Annual Meeting First-timers
Exhibit Hall E Lobby

10:00 AM–11:30 AM — Concurrent Educational Opportunities

11:00 AM–6:30 PM — Exhibition Hall Open

11:00 AM–6:30 PM — Student Poster Session
Exhibit Hall D

11:30 AM–1:30 PM — Lunch with Optional Interest Area Seating
Exhibit Hall

1:30 PM–3:00 PM — Concurrent Educational Opportunities

3:00 PM–3:30 PM — Refreshment Break
Exhibit Hall

3:30 PM–5:00 PM — Concurrent Educational Opportunities

5:00 PM–6:30 PM — Welcome Reception
Exhibit Hall

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 Drug Information Association. 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.

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OPENING PLENARY SESSION

Terrace Ballroom

8:00 AM–9:30 AM

Welcome Remarks and Awards Presentation

Yves Juillet, MD
Senior Vice President
Industrie Sante, France

Opening Remarks

Craig H. Lipset
Head of Clinical Innovation
Worldwide Research & Development
Pfizer Inc

Keynote Address

Dean Kamen
Founder and President
DEKA Research & Development Corporation

9:30 AM–10:00 AM

COFFEE

Meeting Rooms 108 and 119 Concourse

ANNUAL MEETING OFFERINGS BEGIN

#101 Track 01A – Clinical Operations

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

10:00 AM–11:30 AM LEVEL: ■ Format: **WORKSHOP**

Room 121c *CME, Nursing, and PMI PDUs*

Investigator Site Relationship Management Workshop

CHAIRPERSON

Christopher J. Hoyle, MBA
Executive Director, Elite Research Network

Determining which sites will meet enrollment goals and provide quality data remains a challenge for sponsors and CROs. In order to improve the site selection process and decrease the number of zero enrolling sites, many sponsors/CROs have implemented dedicated staff or entire departments which focus on improving communication with sites to better understand their capabilities, experience, and access to patients. This interactive workshop offers sponsors, CROs, and investigator sites an opportunity to openly discuss innovative approaches and organizational models focused on investigator site relationship management. Discussions will address best practices of how sponsors and CROs are communicating accurate information to investigator sites and how sites are being selected. Conclusive findings from last year's workshop will be presented along with two brief presentations from a sponsor and investigative site.

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

Investigator Site Relationship Management: Sponsor Perspective
Nye G. Pelton
Clinical Portfolio Consultant-Enrollment, Eli Lilly and Company

Investigator Site Relationship Management: Site Perspective
Deena E. Bernstein, MS
Director of Clinical Research, Sheridan Healthcare, Inc.

#102 Track 01B – Clinical Operations

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

10:00 AM–11:30 AM LEVEL: ◆ Format: **SESSION**

Room 108a

EMRs for Clinical Research: Hype versus Reality – A Management Primer

CHAIRPERSON

Edward Stephen Seguine, Jr., MBA
CEO, Clinical Ink

Electronic medical records (EMRs) are often touted as the miraculous solution to reduce clinical trial costs in the future. This session focuses on the business model implications of using EMRs for clinical research and how that could affect whether EMRs are really the solution.

Fact versus Fiction: Real Data on EMR Data Quality and Suitability for Clinical Research
Edward Stephen Seguine, Jr., MBA
CEO, Clinical Ink

More Common Compliance Challenges Implementing and Using EMRs
Dennis Edward Marquis
Director, Global Quality and Regulatory Compliance, Bristol-Myers Squibb Company

CDER Perspective: Use of EHRs in Clinical Research
Jonathan S. Helfgott, MSc
Consumer Safety Officer, Division of Scientific Investigations, Office of Compliance, CDER, FDA

#103 Track 01C – Clinical Operations

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SYMPOSIUM**

Room 109ab *PMI PDUs*

Clinical Supply Chain Symposium

CHAIRPERSON

Mary Jo Lamberti, PhD, MA
Senior Project Manager, Tufts Center for the Study of Drug Development, Tufts University

The symposium will include three presentations. The first will relate key findings from a Tufts CSDD study on the global supply chain market. The findings examine the challenges to management of the supply chain in several areas and explores strategies that supply professionals use to optimize management of the supply chain. The second will examine the role of communication and use of best practices in the relationships between supply chain providers and sponsors. The third will include a discussion of a systemic approach for monitoring, warning, and forecasting systems (including

mid-study supply simulations using real study data) and its impact upon supply chain efficiencies and costs.

Results of a Global Clinical Supply Chain Market Study
Mary Jo Lamberti, PhD, MA
Senior Project Manager, Tufts Center for the Study of Drug Development, Tufts University

Optimizing Efficiencies between the Sponsor and IVRS and Drug Packaging/Distribution Vendors
Leslie Darling
Senior Project Manager, Almac Clinical Technologies

Maximizing Supply Chain Efficiency During the Course of a Study Through Use of Systematic Monitoring
Andrey Gurachevsky, MSc
Associate Clinical Logistics Leader, PAREXEL International, Germany

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

Related Interest Area(s): PM, RD

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 105ab *PMI PDUs*

Overcoming Organizational Resistance to Portfolio Management

CHAIRPERSON
Peter Ray, MBA
Executive Director, Portfolio and Asset Strategy, Bristol-Myers Squibb Company

Organizations need to tailor their portfolio management approach to their specific needs and their relative level of organization maturity, considering the size of the portfolio being managed, the phases of development, and the degree of resource constraint being faced, all with the right balance of speed and rigor. The panel discussion will involve a cross-section of practitioners from industry, sharing experiences of what has and has not worked at their organizations.

Implementing Portfolio Management at a Large Pharma
Peter Ray, MBA
Executive Director, Portfolio and Asset Strategy, Bristol-Myers Squibb Company

Introducing Portfolio Strategy Practices at a Growing Biotech
Elizabeth Ng, MBA
Director, Portfolio Strategy, Biomarin Pharmaceuticals

Panelist
Aron Cogswell, MBA
Executive Director, Integrated Business Operations, Pfizer Inc

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

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 103c

Data Quality by Design (DQbD) to Improve the Quality of Clinical Trial Data in Multiregional Clinical Trials (MRCTs)

CHAIRPERSON
Khin Maung U, DrMed, MD, MSc
Senior Medical Officer, Division of Cardiovascular Renal Products, Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

Moving towards a data quality by design (DQbD) approach at all stages of drug development — from planning, design, site selection, study conduct, data collection and transfer, and statistical analyses — will improve the quality of data in multiregional clinical trials (MRCTs). This session will bring together the pharmaceutical industry, data management organization, and regulatory/review perspectives, with case examples illustrating how the DQbD approach can be applied to ensure patient safety, promote protocol adherence, improve the quality and integrity of the data that are generated, processed and analyzed, and enhance the overall efficiency to bring important therapeutic products to patients who need them.

Moving to a Quality by Design, Proactive Approach to Planning and Executing Clinical Trials: An Industry Collaborative Effort
Guy Andre Mascaro
President, Metrics Champion Consortium

Using Quality by Design Approaches in Clinical Trial Planning and Execution to Improve Patient Safety, Data Quality/Integrity and GCP Compliance: An Industry Perspective
Nick Astley, MSc
Senior Director, Business Performance and Analytics, Pfizer Inc

Data Quality by Design (DQbD): Regulatory Clinical Review Perspectives to Improve Data Quality in Multiregional Clinical Trials (MRCTs)
Khin Maung U, DrMed, MD, MSc
Senior Medical Officer, Division of Cardiovascular Renal Products, Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

#106 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, SP, PM

10:00 AM–11:30 AM LEVEL: ■ Format: **WORKSHOP**
Room 123 *PMI PDUs*

Best Practices in Managing Alliances: Using the Balanced Scorecard Methodology to Align Strategy and Operational Execution

CHAIRPERSON
Tara Mylenski, MBA
Alliance Management, Quintiles

Alliances are usually defined by what each side will contribute, not by what each hopes to gain. The Balanced Scorecard Management System helps companies switch their alliance focus from contributions and operations to strategy and commitment. In this workshop, attendees will learn how to create a strategy map that integrates a partnership strategy with the management of operations, as well as how to translate this information

to a balanced scorecard so that this tool can be used to run effective governance meetings.

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

Facilitator
Kim Fookes
Director, Clinical Operations Strategy, Takeda Global Research & Development Center, Inc.

Facilitator
Kathleen T. Dolan, MBA
Senior Director, CDARO Project Integration, Covance, Inc.

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

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 124 *CME and Nursing*

First-in-human Challenges of Biologics and Biosimilars

CHAIRPERSON
Royce A. Morrison, MD, MS
Principal Investigator/Chief Medical Officer, Comprehensive Clinical Development

Prepare to move your biologic (or biosimilar) drug to a First-in-Human study. Hear from leading preclinical and Phase I investigators on how to identify safety risks and plan to mitigate them.

Biologics and Biosimilars: First-in-human Challenges
Royce A. Morrison, MD, MS
Principal Investigator/Chief Medical Officer, Comprehensive Clinical Development

Nonclinical Pre-IND Experiments: Biologics Experience Informing Phase 1 Trial Designs
Lauren E. Black, PhD
Senior Scientific Advisor, Charles River Laboratories

Biologics Clinical Trials: Experiments Not Demonstrations — The Importance of Active Thinking
Cyril P. Clarke, MD
Vice President Translational Medicine, ICON PLC, UK

#108 Track 06 – Medical Writing and Medical Communications

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

10:00 AM–11:30 AM LEVEL: ◆ Format: **SESSION**
Room 108b *CME, Pharmacy, and Nursing*

Advancing Benefit-risk Visualization and Communication

CHAIRPERSON
Marilyn A. Metcalf, PhD
Director, Benefit Risk Evaluation, GlaxoSmithKline

This session will provide a discussion of the continuum of benefit-risk assessment models, ranging from personal mental models to more formal qualitative and quantitative models.

IMI Project Work Package 5: Case Study
Marilyn A. Metcalf, PhD
Director, Benefit Risk Evaluation, GlaxoSmithKline

Benefit-risk Communication: From Implicit and Qualitative to Explicit and Quantitative
Lawrence Phillips, PhD
Visiting Professor of Decision Sciences, Department of Management, London School of Economics, UK

Visualizing Benefit and Risk
James Felli, PhD
Research Advisor, Eli Lilly and Company

#109 Track 07 – Processes and Technologies for Clinical Research

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

10:00 AM–11:30 AM LEVEL: ◆ Format: **SESSION**
Room 103a *CME, Pharmacy, and Nursing*

New Ways to Learn What Happens to Patients AFTER Approval

CHAIRPERSON
Stephen A. Raymond, PhD
Chief Scientist, Quality Officer and Founder, PHT Corporation

This session explores new ways to help physicians monitor and support individual patients for whom they prescribe medications. A physician will present on the topic, and the chair is seeking discussion from attendees with medical experience.

How Patients and Physicians Can Obtain Actionable Information Now and Possible Improvements on the Horizon
Donald C. Manning, MD, PhD
Chief Medical Officer, Adynxx, Inc.

FDA Point of View
Melissa A. Robb, RN
Associate Director, Regulatory Affairs, Office of Medical Policy Initiatives, CDER, FDA

Using Patient Reported Outcomes to Assess Drug Safety and Tolerability
Chad Gwaltney, PhD
Senior Scientist, PRO Consulting

#110 Track 08A – Regulatory Affairs and Submissions

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

10:00 AM–11:30 AM LEVEL: ■ Format: **FORUM**
Room 115c *Pharmacy*

Transforming Regulatory Information Into Actionable Regulatory Intelligence for Emerging Markets

CHAIRPERSON
Kim M. Quaintance
Senior Director, Global Regulatory Policy and Intelligence, Eisai Inc.

Industry representatives and an emerging market health authority will discuss gathering and management of regulatory intelligence from rapidly evolving emerging markets.

Working With Emerging Markets: A Case Study
Linda F. Bowen, MS, RAC
Head, Regulatory Policy and Intelligence-US, Sanofi

Gathering and Leveraging News from Emerging Markets
Brooke Casselberry, MS
Senior Manager, Regulatory Affairs and Writing Services, Liquent, Inc.

Panelists

Augustina Bisio
Director, Drug Evaluation Agency, ANMAT, Argentina

Representative Invited
Manager, Research and Clinical Trials, ANVISA, Brazil

#111 Track 08B – Regulatory Affairs and Submissions

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

10:00 AM–11:30 AM LEVEL: ■ Format: **FORUM**
Room 119b *Pharmacy*

Effective Switching from Rx to OTC Status: Maximizing Revenue and Profit From Off-Patent Products

CHAIRPERSON
Peter M. Lassoff, PharmD
Vice President and Head of Global Regulatory Affairs, Quintiles, UK

This session will provide an insight into the complex regulatory issues associated with switching of medicines to OTC status and strategic insights into how to use OTC switching to extend protection against competitor companies as patent expiry approaches.

EU Perspective
Peter M. Lassoff, PharmD
Vice President and Head of Global Regulatory Affairs, Quintiles, UK

FDA Point of View
Charles J. Ganley, MD
Director, Office of Drug Evaluation IV, Office of New Drugs, CDER, FDA

US Industry Point of View: Rx to OTC Switch
David Schifkovitz
Vice President, Regulatory Affairs, GlaxoSmithKline Consumer Healthcare

#112 Track 09 – Medical Diagnostics and Devices

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 118c *CME, Pharmacy, and Nursing*

Companion Diagnostics: Current and Future Developments

CHAIRPERSON
Paul Van Dongen, LLM, MS
Lawyer, NautaDutilh N.V., Netherlands

Companion diagnostics, in vitro diagnostics that accompany treatments, are a major development in personalized medicine. This session looks into the regulatory and scientific aspects of this innovative approach.

IVDs as Companion Diagnostics in Personalized Medicine: A Medical Device Perspective
Barry S. Sall, RAC
Principal Consultant, PAREXEL Consulting

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

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

10:00 AM–11:30 AM LEVEL: ● Format: **WORKSHOP**
Room 120bc *CME, Pharmacy, and Nursing*

Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials

CHAIRPERSON
Mark C. Hegarty, JD
Partner/Attorney, Shook, Hardy & Bacon LLP

In this workshop, experienced lawyers will conduct a mock trial involving issues that may arise in clinical trial lawsuits. The mock trial will include opening statements and closing arguments, as well as realistic direct and cross-examination of the primary witnesses in the case, including video evidence. At its conclusion, the lawyers will entertain questions about the mock trial.

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

John M. Isidor, JD
Senior Director and Co-Founder, Schulman Associates IRB, Inc.

Jeffrey N. Gibbs, JD
Director, Hyman Phelps & McNamara, PC

Adrienne Hernandez, JD
Associate, Shook, Hardy & Bacon LLP

#114 Track 11 – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 119a *CME, Pharmacy, and Nursing*

Defining Quality in Clinical Trials

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

Latest progress in FDA and EMA initiatives on developing a new approach to quality in clinical trials, together with current expectations and practical examples from recent experience, will be analyzed and discussed.

A View from Industry
Mike Sobczyk, MSc
Senior Director, Regulatory Compliance, Gilead Sciences, Inc.

A View from the EMA
Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

A View from the FDA
Leslie Ball, MD
Acting Director, Office of Scientific Investigations, CDER, FDA

#115 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC, RA, MF

10:00 AM–11:30 AM | LEVEL: ● | Format: **FORUM**

Room 122b | *Pharmacy*

ICH Update on Pharmaceutical Quality

CHAIRPERSON

Elaine Morefield, PhD
Deputy Office Director, Office of New Drug Quality Assessment, CDER, FDA

This forum will discuss ICH topics related to pharmaceutical quality, including the new guideline for drug substances (Q11) and the Q8, Q9, and Q10 points to consider document.

Q11 Update: Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)
Betsy P. Fritschel
Director, Enterprise Regulatory Compliance, Johnson & Johnson

Q3D: Metal Impurities Guidance
John F. Kauffman, PhD, MBA
Research Chemist, Division of Pharmaceutical Analysis, Office of Pharmaceutical Science, Office of Translational Sciences, CDER, FDA

Update on the Quality Implementation Working Group (QIWG) Points to Consider Document
Elaine Morefield, PhD
Deputy Office Director, Office of New Drug Quality Assessment, CDER, FDA

#116 Track 14A – Clinical Safety and Pharmacovigilance

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

10:00 AM–11:30 AM | LEVEL: ● | Format: **FORUM**

Room 121ab | *CME, Pharmacy, and Nursing*

The Impact of Social Media on Product Promotion and Pharmacovigilance

CHAIRPERSON

Julie Anne Zawisza, MA
Director, Office of Communications, CDER, FDA

Social media creates challenges and opportunities for the promotion and safety of drugs and other medical products. FDA and industry are working to optimize truthful product information and ways to gather adverse event data utilizing this resource.

FDA Perspective: Advertising
Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, CDER, FDA

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

Industry Perspective: Advertising
Paul James Savidge, JD, MBA
Vice President and Associate General Counsel, Bristol-Myers Squibb Company

Industry Perspective: Pharmacovigilance
Elizabeth E. Garrard, PharmD, RPh
Chief Safety Officer, Drug Safety Alliance, Inc.

#117 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP, CDM, EC

10:00 AM–11:30 AM | LEVEL: ■ | Format: **SESSION**

Room 118a | *CME, Pharmacy, and Nursing*

Approaches to Postapproval Pediatric Safety Surveillance

CHAIRPERSON

Robert Reynolds, DrSc, MSc, FISPE
Vice President, Global Head, Epidemiology, Pfizer Inc

This session describes the use of observational data sources and methods, including electronic health care data, cohorts and registries to conduct postapproval safety surveillance in pediatric populations.

Data Sources and Methodological Challenges: Conducting Epidemiologic Pediatric Safety Studies
Susan Oliveria, DrSc, MPH, FISPE
Principal Epidemiologist, EpiSource

Designing a Comprehensive RMP for Pediatric Drug Approval: Example in Pediatric Rheumatology
Rachel E. Sobel, DrPH
Specialty Care & Established Products BU Group Head, Epidemiology, Worldwide Safety Strategy, Pfizer Inc

The Sertraline Pediatric Registry for the Evaluation of Safety (SPRITES): Design & Implementation of a Pragmatic Incident Cohort Study
John March, MD, MPH
Director, Division of Neurosciences Medicine, Duke Clinical Research Institute

#118 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST, RA, OS, BT

10:00 AM–11:30 AM | LEVEL: ■ | Format: **FORUM**

Room 113a | *CME, Pharmacy, and Nursing*

Hot Topics in Statistics: Industry, CRO, Academic, and Regulatory Perspectives

CHAIRPERSON

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

What do we need to do and think about in order to "push the statistical envelope"? The most pressing issues facing statisticians involved in the development of new drugs and biologics today will be discussed from a variety of viewpoints. Following a brief introduction from a regulatory perspective, speakers representing the statistical leadership of a large pharmaceutical company, a mid-sized biotechnology company, and a global contract research organization will discuss what they perceive to be critical issues in statistical methodology and/or application. The impact of these hot topics on drug development and regulatory decision-making, both locally and globally, as well as ideas for addressing each issue will be discussed. An academic perspective, particularly with respect to ways forward in developing real-world solutions, will also be provided.

Panelists
Stephen J. Ruberg, PhD
Distinguished Research Fellow; Scientific Leader, Advanced Analytics, Eli Lilly and Company

Laura J. Meyerson, PhD, MA
Vice President, Biostatistics, Biogen Idec

Andrew Garrett, PhD, MSc
Vice President, Global Biostatistics, Medical Writing and Regulatory Affairs, Quintiles, UK

Discussant
Gary G. Koch, MS
Director, Biometric Consulting Lab. Biostatistics; Professor, Biostatistics, University of North Carolina at Chapel Hill

#119 Track 16 – Professional Development

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 117

Translational Medicine in Africa: Challenges and Opportunities for Product Development

CHAIRPERSON
Nyasha Bakare, MD, MPH
Global Medical Safety Physician, Infectious Diseases, Janssen Research & Development, LLC

Africa is a critical venue in view of the increased focus on novel tools to prevent, diagnose, and treat diseases disproportionately affecting low and middle-income countries. This session will discuss key topics around product development in Africa.

Translational Medicine: To Enhance Health Care Delivery and Better Patient Care
Aamir Shahzad, MD, DrMed
Secretary General and Director of Administration, International Society For Translational Medicine (ISTM), Austria

Regulatory Challenges for Translational Medicine in Africa
Paul K. Tanui
Senior Programme Officer, NEPAD Planning and Coordinating Agency, South Africa

The Conduct of Multi-country Clinical Trials in Africa: Opportunities and Challenges
Annalene Nel
Chief Medical Officer, International Partnership For Microbicides, South Africa

#120 Track 17A – Global Regulatory

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

10:00 AM–11:30 AM LEVEL: ■ Format: **FORUM**
Room 113c *CME and Nursing*

European Town Hall: Part 1 of 2 – Hot Topics in Europe

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

Part 2 of this forum will take place on Monday, June 25 at 3:30 PM.

The European medicines system offers different ways of bringing new medicines to the patient, whether through the European Medicines Agency centralized route or through the European national agencies' decentralized route. This first part of the European Town Hall offers the possibility to hear from the senior leadership from both the EMA and national agencies on a number of important topics in European regulatory network. A second part offers insights on practical interactions with the European system.

Submit questions in advance to annualmeetingprogram@diahome.org
Subject: European Town Hall

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

Aginus A. W. Kalis, MD
Executive Director, Medicines Evaluation Board, Netherlands

#121 Track 17B – Global Regulatory

Related Interest Area(s): RA, PPLCC, ST

10:00 AM–11:30 AM LEVEL: ■ Format: **FORUM**
Room 116

Pediatric Drug Development Progress: 15 Years Later and Across the Globe

CHAIRPERSON
William J. Rodriguez, MD, PhD
Science Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

Cooperative efforts between EMA and FDA have resulted in addressing many study issues. The benefits of these exchanges and existing issues with extrapolation and formulations will be discussed.

Extrapolation from Adult Clinical Data to Pediatric Population(s): FDA Experience
William J. Rodriguez, MD, PhD
Science Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

Extrapolation from Adult Clinical Data to Pediatric Population(s): EMA Experience
Agnès Saint-Raymond, MD
Head, Human Medicines, Special Areas, European Medicines Agency, European Union

Formulation Strategies for Pediatric Dosage Forms: FDA Experience
Mansoor Khan
Director, Division of Product Quality Research, Office of Testing and Research, Office of Pharmaceutical Science, CDER, FDA

Formulation Strategies for Pediatric Dosage Forms: EMA Experience
Agnès Saint-Raymond, MD
Head, Human Medicines, Special Areas, European Medicines Agency, European Union

Advantages of Sharing Information Prospectively with Overseas Colleagues
William J. Rodriguez, MD, PhD
Science Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

#122 Track 18 – Rare/Neglected Diseases

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 111ab *CME and Nursing*

Drug Development Strategies for Integrating Academia, Non-governmental Organizations (NGOs), and Industry Based on Experience in Neglected and Infectious Diseases

CHAIRPERSON
Melynda Watkins, RAC
Manager, Product Development, Clinton Health Access Initiative (CHAI)

This session will describe drug development strategies for integrating academia, non-governmental organizations (NGOs), and industry based

on experience for the development of drugs for neglected and infectious diseases in the global health arena.

Discovery and Development of Novel Orally-active Compounds for Treatment of African Sleeping Sickness: Challenges and Solutions to Drug Discovery for a Neglected Tropical Disease
Robert T. Jacobs, PhD
Director of Chemistry, SCYNEXIS, Inc.

Delivering Innovation for Neglected Diseases: A Biotech Perspective
Eric Easom
Program Leader, Neglected Diseases, Anacor Pharmaceuticals

Integrating Cross-functional Global Groups in Drug Development for Neglected Diseases: A Case Study
Melynda Watkins, RAC
Manager, Product Development, Clinton Health Access Initiative (CHAI)

#123 Track 21 – Late Breaker

Related Interest Area(s): CP, CDM, EC, IT

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**

Room 103b *CME and Nursing*

Standards for Patients: Collaborations to Innovate Therapy Development

CHAIRPERSON

Bron Witt Kisler
Vice President, Strategic Initiatives, CDISC

This session will highlight the CDISC/C-Path Partnership, which has launched therapeutic area projects to develop disease-specific standards, as well as provide an overview of therapeutic area data standards, the FDA regulatory viewpoint and roadmap for developing priority therapeutic area standards, and important viewpoints from a practicing clinician and patient advocate. Nine projects are currently underway addressing cardiovascular disease, infectious diseases, neurological disorders and kidney disease, and these have proven how clinicians, researchers, and patient advocates play a pivotal role in the often technical world of standards development. The blending of clinical knowledge, patient experiences and technical expertise into the standards development process is the key to ensuring that standards ultimately benefit the patient.

FDA Regulatory Priorities for Therapeutic Area Data Standards
Charles K. Cooper, MD
Medical Officer, Office of Translational Sciences, CDER, FDA

CDISC and C-Path Partnership: The Coalition for Accelerated Standards and Therapies (CFAST)
Bron Witt Kisler
Vice President, Strategic Initiatives, CDISC

#124 Track 22A – White Paper Showcase

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

10:00 AM–11:30 AM LEVEL: ● Format: **SESSION**

Room 125

The New Health Report 2012: Rethinking the Risk Equation in Biopharmaceutical Development and Delivery

CHAIRPERSON

Adam Istas
Director, Thought Leadership, Quintiles

Based on a survey of biopharmaceutical executives, payers, patients and investors, The New Health Report 2012 builds upon previous calls for multi-stakeholder collaboration by exploring the often misunderstood element of risk as it relates to biopharmaceutical development and delivery.

Brought to you by Quintiles.

***Attendee badges scanned for this White Paper Showcase will be shared with the company hosting this offering. If you prefer not to have your badge scanned, please inform the DIA staff member.*

Panelists

John J. Doyle, DIPH, MPH
Vice President and Practice Leader for Market Access, Quintiles

Patrick Jordan, MBA
Vice President, Global Customer Solutions, Quintiles

#150 Track 22B – White Paper Showcase

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

NEW TIME: 10:00 AM–11:30 AM LEVEL: ● Format: **SESSION**

Room 13B

Free Agency is Here: Exploring Workforce Impact on Clinical Outsourcing

CHAIRPERSON

Alan Edwards
Vice President, Americas Product Group, Science, Kelly Services, Inc.

In the past decade clinical trials have become increasingly costly and more therapeutically specific, both yielding new challenges in the global coordination of these programs. Additionally, the need for global population engagement, combined with increasing regulatory requirements, has stretched the capability of current business models, particularly as it pertains to efficient management of a workforce to achieve your company's strategic initiatives.

Brought to you by Kelly Services, Inc.

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Mark Lanfear
Global Practices Leader, Clinical Operations, Kelly Services, Inc.

11:30 AM–1:30 PM **LUNCHEON**
Exhibit Hall

12:00 PM–12:45 PM

EMC Corporation Innovation Theater

Related Interest Area(s): RD, IT

See the map located on the back of the Exhibitors tab for location.

SPECIAL SESSION

Innovation in R&D and Commercialization through Big Data Analytics

The transforming R&D environment demands tight coordination of a complex network of partners and suppliers, as well as information resources. Blended cloud environments (public, private, community, and hybrid) will provide rapid, secure and dynamic collaboration areas for organizations and partners. The ability to analyze and synthesize this data for commercialization will be a differentiator for high performing firms.

We believe that clinical and research organizations have an opportunity to utilize these new IT consumption models for a competitive advantage in the marketplace. EMC will discuss our innovations in 3 areas that we feel will be critical for driving R&D and commercial success.

Collaboration: Seamlessly share information assets & develop knowledge in real time.

Fast Data: Leverage resources distributed across the partner network, with ability to flexibly aggregate, process, and analyze large quantities of information.

Cloud: Flexibly engage partners and information sources anywhere in the world, at any time.

#125 Track 01A – Clinical Operations

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

1:30 PM–3:00 PM | LEVEL: ◆ | Format: **SESSION**

Room 109ab | *PMI PDUs*

Increasing Protocol Complexity Places Challenges on Research Site Budgeting

CHAIRPERSON

Michael Jay, MA

Vice President, RxTrials, Inc.

The challenges that research sites face with respect to clinical trial budgeting is that they do not know how much the different activities cost or how to synthesize them into one overall budget plan. Additionally, a number of factors have contributed to the deceleration of grants ranging from sponsors funding fewer clinical trials, sponsors spending more on late-phase clinical trials overseas, to more complex protocols requiring smaller numbers of patients per investigative site and more difficult to administer. This session will focus solely on clinical trial budgeting at the site level. Exploration of the costs of personnel, recruitment, startup, close-out activities, monitoring, document storage, and more will be thoroughly examined and combined into one overall trial budget.

Sites Challenged with Securing Grants Amidst Increasing Protocol Complexity
Joan A. Chambers
Chief Operating Officer, CenterWatch, Inc.

A Site's Perspective on the Challenges of Clinical Trial Budget Negotiation
Michael Jay, MA
Vice President, RxTrials, Inc.

Challenges in Clinical Trial Budgeting: A Sponsor's Perspective
Allison Burmeister, MBA
Clinical Business Operations Manager, Janssen AI R&D, LLC

#126 Track 01B – Clinical Operations

Related Interest Area(s): AP, MA

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SYMPOSIUM**

Room 108a | *CME and Nursing*

Social Media: The Promise and Pitfalls for Patient Recruitment

CHAIRPERSON

Jane E. Myles, MS

Global Head, Patient Recruitment, Genentech, A Member of the Roche Group

Social media has huge potential as a new set of tools to drive patient recruitment. How do you use it and what happens when you do? In this symposium, we will offer both successes and lessons learned from trying social media as a recruitment strategy.

Is Social Media the New Technology for Helping Patients Find Clinical Trials?
Richard Mayewski
Global Trial Optimization Specialist, Merck & Co., Inc.

Finding the "ePatient" for Your Clinical Trial
Rodney William Butt, MBA, MSc, MT
Principal Consultant, Clinical Operations, Hamilton Medical Consultants Group, Canada

When Social Media Undermines Clinical Trial Performance
Elizabeth A. Moench
President and Chief Executive Officer, MediciGlobal

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

Related Interest Area(s): RA, CR

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**

Room 103c

Quality by Design in Clinical Development: Blessing or Burden?

CHAIRPERSON

Barbara Leishman, MA

Head, Quality Risk Management–Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

By reviewing current regulatory and industry initiatives, this session aims to provide clarity in a changing environment, and provide the impetus and information to support those seeking to apply QbD/QRM to add value in their own environment.

Quality by Design: The Winding Road to Quality as a Culture in Clinical Development
Jeffrey S. Kasher, PhD
Vice President, Global Clinical Development, Eli Lilly and Company

Can the Pharmaceutical Industry Afford to Implement QRM?
Kenneth J. Sprenger, MD, PhD
Executive Director, Medicine Team Leader, Pfizer Inc

FDA Perspective
Leslie Ball, MD
Acting Director, Office of Scientific Investigations, CDER, FDA

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

Related Interest Area(s): PM, PETD

1:30 PM–3:00 PM | LEVEL: ■ | Format: **WORKSHOP**

Room 121c | *PMI PDUs*

Get the Team to Take Charge!

CHAIRPERSON

John A. Faulkes, MSc
Consultant, TeamCommunications Development, UK

This workshop will enable people in a project environment to make teams more self-starting, proactive, and act with full ownership of business objectives. It will feature simulation case studies, small-team exercises, and learning from others' experiences.

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

#129 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, PM, SP

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**

Room 105ab | *PMI PDUs*

Managing a Complex Outsourcing Collaboration

CHAIRPERSON

Andrew Eibling, MBA
Vice President, Alliance Management, Covance, Inc.

Pharma/CRO relationships have emerged as a critical success factor in the continued growth of the pharma industry. However, managing these relationships continues to be a challenge for many companies. A groundbreaking pharma/CRO partnership has demonstrated that strategic partnerships can deliver value beyond traditional transactional models. Best practices have emerged regarding the management of such a complex relationship, and this session will review key success factors as well as a model for managing large complex partnerships, examining metrics, governance, and transaction versus collaboration.

Bringing Structure to Life: The Anatomy of Successful Governance
Adrienne R. Takacs, PhD
Senior Director, LRL Operations, Eli Lilly and Company

Collaborative Challenges: Skill Sets and Behaviors Essential for Success
Andrew Eibling, MBA
Vice President, Alliance Management, Covance, Inc.

Framing the Challenge: Understanding the Current Environment and Various Outsourcing Models
Andy Lee, MA
Senior Vice President, Global Clinical Operations, Genzyme Corporation

Developing Potential Solutions: Value Creation
Jacques Mulder
Principal, Pharmaceutical R&D Practice Leader, Deloitte Consulting LLP

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

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

1:30 PM–3:00 PM | LEVEL: ● | Format: **FORUM**

Room 124 | *CME and Nursing*

Renal Impairment Studies Design, Conduct, and Analysis

CHAIRPERSON

Harry W. Alcorn, Jr.
Chief Scientific Officer, DaVita Clinical Research

Renal studies are a critical part of an IND submission (medications and renal clearance) with our aging population and increase in the chronic kidney disease (CKD) population. Study design and implementation is critical to quality data and timelines being met by the site. This forum will include presenters from the FDA, industry and a clinical trial site who have knowledge, experience, and publications that support their position in the industry and current information as it relates to the FDA guidelines, industry needs, and clinical trial site conduct.

CKD Studies Conduction, Specialty Population Recruitment and Enrollment
Harry W. Alcorn, Jr.
Chief Scientific Officer, DaVita Clinical Research

A Comparison of Renal Function Estimation Equations
Nancy Xu, MD
Medical Officer, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

Design, Conduct, and Interpretation of Cinical Studies in CKD Patients
Marc Pfister, MD
Chief Medical Officer, Quantitative Solutions, Inc.

#131 Track 06 – Medical Writing and Medical Communications

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

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**

Room 108b | *CME and Nursing*

Wrangling the Bestiary of Safety Documents: Coordination and Integration across Multiple Requirements

CHAIRPERSON

Aaron Van Etten, MS
Global Regulatory Writing, Amgen Inc.

Medical writers' approaches to authoring pre- and postmarketing safety documents will be discussed with emphasis on meeting multiple, international requirements for products at various stages of development.

A Writer's Perspective on Safety Documents Written Prior to the Marketing Application
Sandra J. Hecker, RAC
US Agent; Regulatory Consultant, Hecker & Associates, LLC

A Writer's Perspective on Safety Documents in the Peri-approval Period
Michael D. Hoffman, MS
Senior Director, Medical Writing and Regulatory Operations, United BioSource Corporation

A Writer's Perspective on Safety Documents After Approval
Jan Sechler, PhD
Manager, Regulatory Medical Writing, Janssen Research & Development, LLC

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

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

1:30 PM–3:00 PM LEVEL: ● FORMAT: **SESSION**

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

Capitalizing on Biometric Efficiencies: A Look at Data Start-up, Capture, Monitoring, and Reporting

CHAIRPERSON

Jessica Merryfield
Manager, Project Management, Premier Research Group Ltd.

This session will explore efficient approaches for streamlining biometrics activities. Best practices to ensure successful biometric deliverables from start-up to study completion will be shared, including data capture and monitoring solutions.

Managing Biometric Timelines: Key Factors to Success
Jessica Merryfield
Manager, Project Management, Premier Research Group Ltd.

Electronic Patient-reported Outcomes (ePRO): Equivalent to Paper? Or Better and More Versatile?
Brian Tiplady, PhD
Senior Clinical Scientist, invivodata, Inc., UK

Implementation, Benefits and Results of Centralized Monitoring
James DeSanti
President and CEO, PharmaVigilant

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

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

1:30 PM–3:00 PM LEVEL: ■ FORMAT: **FORUM**

Room 103a *CME and Nursing*

Implications of Mobile Health and Clinical Research Studies

CHAIRPERSON

Nancie E. Celini, DrPH, MPH
Chief Learning Consultant, CAB Inc.

What is mHealth? What does mHealth offer (or threaten) for clinical research? This forum presents diverse accounts of mHealth at work in the real world in order to consider the implications (both promise and threats) for the conduct of clinical research trials.

Soldiers and Babies: Learning What is Happening to Them So Timely Actions Can be Taken — A View From the Field
Ronald K. Poropatich, MD
Deputy Director, Telemedicine and Advanced Technology Research Center (TATRC), US Army Medical Research and Material Command (USAMRMC)

Crowd Sourced Health Care Studies: Implications for Pharma
David Lee Scher, MD, FACC
Director, DLS Healthcare Consulting, LLC

Disruptive Innovation: Virtual Clinical Trials — Fact or Fiction
Miguel Orri, MD
Senior Director, Pfizer Ltd., UK

#134 Track 08A – Regulatory Affairs and Submissions

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

1:30 PM–3:00 PM LEVEL: ■ FORMAT: **FORUM**

Room 113c *Pharmacy*

Regulatory Roundtable on Biosimilars

CHAIRPERSON

Joseph C. Scheeren, PharmD
Senior Vice President, Head Global Regulatory Affairs, Bayer Healthcare Pharmaceuticals

This forum will explore the challenges of biosimilars in light of the recent policy developments in the US, EU, and Asia. Participants will hear from a roundtable of authorities on how to address biosimilars and the opportunities for the future.

FDA Point of View: Developing Biosimilar Products
Leah A. Christl, PhD
Associate Director for Biosimilars, Office of New Drugs, CDER, FDA

Asia Point of View
Representative Invited

EMA Point of View
Peter J. Richardson, PhD
Head of Biologics, Quality of Medicines Sector, European Medicines Agency, European Union

#135 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): OS, RA

1:30 PM–3:00 PM LEVEL: ■ FORMAT: **SESSION**

Room 115a

New Challenges from Outsourcing of Regulatory Operations

CHAIRPERSON

Steve R. Hasler
CEO, Originex Limited, UK

With the focus on cost reduction, the industry is progressing outsourcing of regulatory operations business processes, bringing new challenges and issues. This session will focus on how these are being overcome and the business benefits that result.

The Benefits and Challenges in Regulatory Outsourcing
Steve R. Hasler
CEO, Originex Limited, UK

Practical Experience, Results, and Key Learnings
John M. Joseph, III, MA
Executive Director, Global Dossier Management, Bristol-Myers Squibb Company

Experience to Date and Future Direction
Allen Jones
Director, Global Regulatory Operations, GlaxoSmithKline

#136 Track 08C – Regulatory Affairs and Submissions

Related Interest Area(s): RA, MF, PM

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 119b

Regulatory Strategies to Accelerate Approval in Emerging Markets Considering the Growing Complexity of Requirements and Supply Chains

CHAIRPERSON

Elaine Whiting
Associate Director, Regulatory Policy, Intelligence and Labelling, AstraZeneca Pharmaceuticals LP, UK

This session is designed to discuss the strategies for accelerating approval and market access in emerging markets in the context of increasingly demanding regulatory requirements and the growing complexity of manufacturing supply chains.

WHO Perspective
Lembit Rago, MD
Coordinator, Quality Assurance and Safety for Medicines, World Health Organization (WHO), Switzerland

EMA Perspective
Francesca Cerreta, PharmD, MPharm, MS
Scientific Administrator, European Medicines Agency, European Union

Regulatory Strategies to Accelerate Approval in Emerging Markets
Fraser Stodart
Senior Director, Global Regulatory Affairs, Emerging Markets, Eisai Limited, UK

#137 Track 08D – Regulatory Affairs and Submissions

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 116

Challenges and Opportunities for Drug Development in China

CHAIRPERSON

Laura Hong, MD, PhD
President, SAPA (Sino-American Pharmaceutical Professionals Association)

This session will provide enriched discussions on the current status and unique challenges for drug development in China, the increasing role of China in global development of drug products, and opportunities for China's SFDA and pharmaceutical industry to improve, succeed, and excel.

This session is hosted by Sino-American Pharmaceutical Professionals Association (SAPA).

Representative Invited
CEO and Chief Scientific Officer, Zhejiang Beta Pharma Inc., China

Representative Invited
Chief Scientific Officer, Pharmaron Beijing, Co. Ltd., China

Representative Invited
Vice President, Head of R&D, Johnson & Johnson, China

#138 Track 09 – Medical Diagnostics and Devices

Related Interest Area(s): RA, PPLCC, CmbP

1:30 PM–3:00 PM LEVEL: ● Format: **SESSION**

Room 118c

Where is the 510(k) Today

CHAIRPERSON

Heather Rosecrans
Vice President, Regulatory Affairs, Medical Device Manufacturers Association (MDMA)

This session will discuss the 510(k) Program, post IOM 510(k) Report, and where FDA stands on the list of their action items related to the 510(k) Program.

The State of the 510(k) Pathway Post-IOM Report
Barry S. Sall, RAC
Principal Consultant, PAREXEL Consulting

MDUFA III: Efforts to Improve Predictability and Transparency
Mark B. Leahey, JD
President and CEO, Medical Device Manufacturers Association (MDMA)

#139 Track 10 – Public Policy/HealthCare Compliance/Regulatory Law

Related Interest Area(s): RA

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 120bc *Pharmacy*

Regulatory Collaboration/21st Century Innovation – Views of the Heads of Health Canada, the European Medicines Agency, and the US FDA

CHAIRPERSONS

Marie Allison Dray, MA, MBA
President, International Regulatory Affairs Group LLC

Murray M. Lumpkin, MD, MSc
Commissioner's Senior Advisor and Representative for Global Issues, Immediate Office of the Commissioner, Office of International Activities and Strategic Initiatives, FDA

After working to harmonize technical requirements under the ICH, establishing confidentiality arrangements, collaborating on inspection pilots, exchanging working level scientific and regulatory policies, procedures, and reports, and implementing technical level "clusters" of agency reviewers … what are the next challenges and next steps in 21st century regulatory cooperation?

In this session, the audience will be privileged to hear views from the leaders of three of the most influential drug regulatory agencies — HPFB of Health Canada, the European Medicines Agency, & the US FDA — on these important issues.

- How do agencies meet their domestically-focused mission in an increasingly global environment?
- What will regulatory collaboration look like as we go further into the 21st century?
- How do you integrate local community perspectives and needs into efforts to increase collaborative efforts with other agencies to innovate public health worldwide?
- How does an agency share international values with its primarily local constituents, especially parliamentary overseers?

Panelists

Point of View from Health Canada
Paul Glover, MBA
Assistant Deputy Minister, Health Products and Food Branch, Health Canada

Point of View from the FDA
Margaret Hamburg, MD
Commissioner, FDA

Point of View from the EMA
Guido Rasi, MD
Executive Director, European Medicines Agency, European Union

#140 Track 11A – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

Related Interest Area(s): GCP, CP, CDM

1:30 PM–3:00 PM LEVEL: ◆ Format: **SESSION**
Room 119a *CME, Pharmacy, and Nursing*

Quality by Design: Is Your Clinical Trial Fit for Purpose?

CHAIRPERSON
Regina Freunscht
Director, Marketing and Communications, Accovion GmbH, Germany

This session facilitates the development of a systematic, prioritized, risk-based approach to quality management of clinical trials that supports the principles of GCP and complements existing quality practices, requirements, and standards.

Examples of System Break Down In Clinical Trials: Could "Quality by Design" Have Saved the Day?
Jean Mulinde, MD
Medical Officer, Office of Scientific Investigations, CDER, FDA

Quality Risk Management (QRM): Bringing a Data-driven Decision Methodology to GCP and Pharmacovigilance
Peter Schiemann, PhD
Managing Partner, Widler & Schiemann, Switzerland

Is Quality By Design (QbD) Really Possible? What Does It Mean? Key Success Factors to Integrate QbD Principle into QMS
James Huang, PhD
Associate Director, Forest Research Institute

#141 Track 11B – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

1:30 PM–3:00 PM LEVEL: ● Format: **SYMPOSIUM**
Room 115c

Good Laboratory Practice (GLP): Design and Inspection Readiness

CHAIRPERSON
David Brodish, MA
Director, Regulatory and Quality Assurance, RTI International

This symposium reviews the different types of regulations and standards for the design of laboratory services for both research and health care delivery. These include GLP, GCLP, ISO 15189, ISO 17025 and others. The basics of each standard are highlighted showing key considerations for human and laboratory animal research. A scalable training program is described, that matches a series of one hour live and web-based tutorials with the regulations, standards, guidance, advisories, and compliance program guidance from a variety of regulatory agencies. The fulfillment of training requirements, leads to a well prepared organization that can withstand regulatory scrutiny. In this regard, the speakers will review GLP inspection readiness, including what documentation is expected to be readily available and how to avoid inspection findings.

Which Is the Right Laboratory Standard: GLP, GCLP, ISO, SLMTA?
Janet E. Robinson, DrSc, RAC
Global Director, Laboratory Sciences and Regional Director, Research FHI 360, Thailand

Developing a Scalable and Efficient GLP Training Program
David Brodish, MA
Director, Regulatory and Quality Assurance, RTI International

Good Laboratory Practices and Inspection Readiness
Paul Swidersky
President, Quality Associates, Inc.

#142 Track 12 – Pharmaceutical Quality

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**
Room 122b

Postapproval Change Pathways in EU and US: Challenges and Opportunities for Harmonization

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

This session will discuss the pathways, similarities, and differences for submitting postapproval changes to an approved Marketing Authorization to the EMA and a supplement to an approved NDA/ANDA to the USA. Speakers from FDA, EMA, and industry will provide a forward-looking view on current challenges of postapproval changes and on potential opportunities for expansion of risk and science based approaches.

FDA Point of View
Christine M. V. Moore, PhD
Acting Director, Office of New Drug Quality Assessment, CDER, FDA

Industry Point of View
Moheb M. Nasr, PhD, MS
Vice President, Regulatory CMC Strategy, GlaxoSmithKline

EMA Point of View
Emer Cooke, MBA
(Acting) Head of International and European Cooperation, European Medicines Agency, European Union

#143 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

Related Interest Area(s): CP, CR

1:30 PM–3:00 PM LEVEL: ■ Format: **FORUM**
Room 107ab *CME, Pharmacy, and Nursing*

Demystifying Approaches to the Design and Analysis of Observational Studies of Comparative Effectiveness

CHAIRPERSON
Nancy Dreyer, PhD, MPH, FISPE
Senior Vice President, Scientific Affairs, Outcome

Observational research is becoming increasingly important for comparative effectiveness research (CER). An overview of epidemiologic methods for design and analysis of observational CER will be presented, along with quality guides from US and Europe.

Analytic Issues in Comparative Effectiveness Studies
Robert J. Glynn, PhD
Professor of Medicine (Biostatistics), Harvard Medical School and Harvard School of Public Health

Design Issues in Nonexperimental Comparative Effectiveness Studies
Til Stürmer, MD, MPH
Professor, Epidemiology; Director, UNC-GSK CEPPH, University of North Carolina School of Public Health

ENCePP and Quality Standards for European Observational Research
Stella Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
EMA Risk Management Development and Scientific Lead, European Medicines Agency, European Union

#144 Track 14A – Clinical Safety and Pharmacovigilance

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

1:30 PM–3:00 PM | LEVEL: ● | Format: **FORUM**
Room 121ab | *CME and Nursing*

AE Reporting in the Era of Web 2.0: The Challenges of Having a Two-Way Conversation

CHAIRPERSON
Elizabeth E. Garrard, PharmD, RPh
Chief Safety Officer, Drug Safety Alliance, Inc.

This session will focus on the specific types of social media currently being used by pharmaceutical companies with discussion on their successes and challenges. In addition, discussions on AE identification and collection while emphasizing the need for practices and guidance on the use of social media.

Embracing and Incorporating New Technology (eg. Social media, iPad) into a Modern Pharmacovigilance System
Gregory J. Fiore, MD
President, SSI Strategy

Safety and Social Media: Returning the Intention to Report: Adding the Human Factor Back to High Tech
Michael A. Ibara, PharmD
Head of Safety Innovation, Pfizer Inc

#145 Track 14B – Clinical Safety and Pharmacovigilance

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

1:30 PM–3:00 PM | LEVEL: ● | Format: **SESSION**
Room 118a | *CME and Nursing*

Epidemiologists in Industry and in CROs: Penultimate Generalists and Utterly Indispensible Scientists

CHAIRPERSON
Margaret S. Richards, PhD, MPH
Executive Director, Epidemiology and Health Outcomes, PPD

Three speakers from the industry/CRO setting who have successfully integrated epidemiology into their product development programs will describe this integration from a structural and functional viewpoint, as well as share best practices for leveraging epidemiologic talent. The session includes a description of a typical "day in the life" of an industry- or CRO-located epidemiologist.

The Pharmacoepidemiologist: Supporting Drug Safety Assessment Throughout the Life Cycle
Denise M. Oleske, PhD
Director, Global Surveillance & Pharmacoepidemiology, Abbott Laboratories

Epidemiologists in Industry: Stakeholders and Value Added to Drug Development
Michael Irizarry, MD, MPH
Worldwide Epidemiology, GlaxoSmithKline

A Day In the Life of a CRO Epidemiologist
Margaret S. Richards, PhD, MPH
Executive Director, Epidemiology and Health Outcomes, PPD

#146 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CP, RA

1:30 PM–3:00 PM | LEVEL: ■ | Format: **FORUM**
Room 113a | *CME and Nursing*

Extrapolation to Estimate Treatment Effects in Subgroups of Special Interest

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

The independent demonstration of treatment effects in subgroups of special interest such as the pediatric population may not be feasible because of limited resources and patient populations. However, if there is prior knowledge available that suggest that efficacy and/or safety may be at least partly extrapolated from other populations that have already been investigated, there may be less need for independent evidence in the subgroup. To safeguard for the possibility that the extrapolation paradigm does not hold, in general, subgroup validation studies will be required. The problems of statistical inference in such settings will be discussed from a regulatory and industry perspective.

Assessment Strategies for Clinical Trials of Populations of Special Interest: The FDA Perspective
Sue-Jane Wang, PhD, MA
Adaptive Design and Pharmacogenomics, CDER, FDA

Issues in the Justification of Extrapolation for Inference on Medicines for Small Populations
Frank Bretz, PhD
Global Head of Statistical Methodology, Novartis Pharma AG, Switzerland

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

Robert J. Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA

#147 Track 16 – Professional Development

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

1:30 PM–3:00 PM LEVEL: ● Format: **FORUM**

Room 117

My Big Break: Women At the Top in the Biotechnology Sector

CHAIRPERSON

C. Latham Mitchell, MD
Managing Principal, Erudita Biotechnical LLC

This forum will highlight women who have truly "arrived" as top executives in the biotechnology space, and let you in on how they got to where they are today. Pointers, pitfalls, and the prescriptions for your success will be addressed.

Leslie Williams, MBA, RN
Director, Founder, President, and Chief Executive Officer, ImmusanT

Carole Sable, MD
Vice President Project and Pipeline Leader, Merck & Co., Inc.

Yvonne Greenstreet, MD
Senior Vice President, Medicines Development Group, Pfizer Inc

#148 Track 17 – Global Regulatory

Related Interest Area(s): RA, CP

NEW TIME: 3:30 PM–5:00 PM LEVEL: ■ Format: **FORUM**

European Town Hall: Part 2 of 2 – Interacting With the European System

CHAIRPERSON

Christa Wirthumer-Hoche, PhD
Deputy Head, Austrian Medicinal and Medical Device Agency (AGES), Austria

Part 1 of this forum will take place on Monday, June 25 at 10:00am.

The European medicines system offers different ways of bringing new medicines to the patient, whether through the European Medicines Agency centralized route or through the European national agencies' decentralized route. This second part offers insights on the different initiatives and entry points to facilitate regulatory procedures and scientific dialogue from early development to post-marketing authorization stages. The forum offers the opportunity to interact directly with a panel of staff from the European Medicines Agency and European national agencies.

MOVED TO 3:30 PM
SEE PAGE 53

Submit questions in advance to annualmeetingprogram@diahome.org
Subject: European Town Hall

Xavier De Cuyper
Chief Executive Officer, Federal Agency For Medicines and Health Products (FAMHP), Belgium

Peter Bachmann, DrSc
Senior Expert; Chair, Coordination Group for Mutual Recognition and Decentralise, BfArM, Germany

Agnès Saint-Raymond, MD
Head, Human Medicines, Special Areas, European Medicines Agency, European Union

#149 Track 18 – Rare/Neglected Diseases

Related Interest Area(s): RA

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 111ab

Challenges of Orphan Drugs in the US, EU, and Japan

CHAIRPERSON

Noriaki Murao, MS
Representative, Merz Pharmaceuticals GmbH, Japan

This session addresses the current status and forthcoming activities related to orphan drugs in the US, EU, and Japan. Orphan drug development is obviously essential in these regions, and the provisions in place on drugs including rare diseases are often passed over. We will also address the unique market situation of orphan drugs in the US and development and commercialization strategies of orphan drugs in each region.

Orphan Diseases in Adults and Children: Scientific and Regulatory Challenges in Europe and Worldwide
Klaus Rose, MD, MS
Chief Executive Officer, Klausrose Consulting, Switzerland

FDA Perspective
Gayatri R. Rao, JD, MD
Acting Director, Office of Orphan Products Development, Office of the Commissioner, FDA

Asia Perspective
Representative Invited

#150 Track 22B – White Paper Showcase

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

NEW TIME: 10:00 AM–11:30 AM LEVEL: ● Format: **SESSION**

Free Agency is Here: Exploring Workforce Impact on Clinical Outsourcing

CHAIRPERSON

Alan Edwards
Vice President, Americas Product Group, Science, Kelly Services, Inc.

In the past decade clinical trials have become increasingly costly and more therapeutically specific, both yielding new challenges in the global coordination of these eed for global population engagement, co latory requirements, has stretched the capability of current business models, particularly as it pertains to efficient management of a workforce to achieve your company's strategic initiatives.

MOVED TO 10:00 AM
SEE PAGE 40

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***Attendee badges scanned for this White Paper Showcase will be shared with the company hosting this offering. If you prefer not to have your badge scanned, please inform the DIA staff member.*

Mark Lanfear
Global Practices Leader, Clinical Operations, Kelly Services, Inc.

3:00 PM–3:30 PM **REFRESHMENT BREAK**
Exhibit Hall

#148 See page 53

#151 Track 01A – Clinical Operations

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

3:30 PM–5:00 PM | LEVEL: ■ | Format: **FORUM**

Room 109ab | *CME and Nursing*

A Day in the Life of a Clinical Research Site: What's Getting in the Way?

CHAIRPERSON

Anne-Marie Baughn, MSN, RN
Director, Business Development, RxTrials, Inc.

Results from a 2011 nationwide survey will be presented. Sites will report on the factors they face on a daily basis that compete for their time, resources, and productivity. The "not so well understood" issues that sites face will be highlighted.

Suzanne Wentz
President, Odyssey Research

Kerri M. Mallory, MSc
Site Development Manager, GlaxoSmithKline Biologicals

Katherine Tranotti, BSN, MBA, RN
Vice President, Clinical Operations, ICON Clinical Research

#152 Track 01B – Clinical Operations

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

3:30 PM–5:00 PM | LEVEL: ■ | Format: **FORUM**

Room 108a

ePatient Recruitment, Study Sites, and the Digital Divide

CHAIRPERSON

Elizabeth A. Moench
President and Chief Executive Officer, MediciGlobal

ePatient recruitment has come too fast for many trial sites. Their expertise has not kept pace with online marketing. Sites face a dilemma; return on investment of local media budgets is diminishing as eClinical consumers seek clinical trials online.

Setting Sites Up for Success in the New Digital Environment
Gretchen Goller, MA
Senior Director, Patient Access and Retention Services, PRA International

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

Related Interest Area(s): PM, IT

3:30 PM–5:00 PM | LEVEL: ■ | Format: **WORKSHOP**

Room 121c | *PMI PDUs*

Enhancing Decision Making and Maximizing Portfolio Value Creation Using a Novel Portfolio Management Framework

CHAIRPERSON

Richard Bayney, PhD, MBA
President and Founder, Project & Portfolio Value Creation

CREOPM™ is a novel portfolio management framework that improves decision-making under risk and uncertainty. To complement this framework, a portfolio management capability maturity model assessment is proposed. This workshop will enable participants to approach portfolio management in a systematic, holistic, and analytically sound manner to enable portfolio decision-making in the context of an organization's business and strategic goals. Specifically, while portfolio selection across much of the pharma and biotech industry has been traditionally achieved through one form or another of project ranking and selection, the prescribed framework focuses on portfolio optimization in the context of the organization's constrained budgetary and human resources.

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

Facilitators
David Richard Reggi, MA
Principal, DRR Pharmaceutical R&D Solutions, LLC

Alka Shrikhande
Senior Therapeutic Area Advisor, BioXcel

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

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

3:30 PM–5:00 PM | LEVEL: ■ | Format: **SESSION**

Room 103c | *PMI PDUs*

Keys to Successful Project Execution: Innovative Approaches to Critical Chain, Critical Path, and Risk Management

CHAIRPERSON

Jim L. Vandergriff, II
Pharmaceutical Project Management, Eli Lilly and Company

During project execution, a project manager must be diligent to monitor the progress of the work and be ready to intervene when risks or challenges threaten to derail the project. Good monitor and control processes and related tools are essential enablers. This session will present case studies that exemplify how project managers can achieve project goals of delivering on time, on budget, and providing the full scope of work while maintaining quality output.

Leveraging Critical Chain Methodology for Successful Project Execution: A Story of Two Case Studies
Jim L. Vandergriff, II
Pharmaceutical Project Management, Eli Lilly and Company

Why Have a Critical Path Schedule, We All Know What's Important?
Timothy M. Phelan, PhD
Senior Group Leader, Merck & Co., Inc.

Keys to the Successful Application of Portfolio Risk Management in Clinical Development
Kristin Mauri, MBA
Director, Clinical Services, ClearTrial, LLC

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

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

3:30 PM–5:00 PM | LEVEL: ■ | Format: **SYMPOSIUM**

Room 111ab | *PMI PDUs*

Pharma R&D in Asia: Opportunities, Models, and Challenges

CHAIRPERSON

Frank Ulrich Flöther, DrSc, PharmD
President, Dr. Flöther Consulting, Switzerland

The center of the global pharmaceutical industry is shifting. Part of that shift is also the outsourcing of pharma R&D to Asia by various means and models. This symposium will highlight that strategic move in general but also discuss a clinical CRO alliance model and, furthermore, zoom into the Chinese clinical CRO business.

Outsourcing to/Partnering with Asian Companies: Benefits, Opportunities, and Risks for Western Pharmacos
Frank Ulrich Flöther, DrSc, PharmD
President, Dr. Flöther Consulting, Switzerland

CRO Alliance in Asia
Young Jack Lee, PhD
President, LSK Global PS, Republic of Korea

The Challenges of Chinese CROs' Business
Jack Xu, MD
Senior Vice President, Shanghai Clinical Research Center (SCRC), China

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

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 105ab

Pre-competitive Public Private Partnerships: The Changing Model of Pharmaceutical R&D

CHAIRPERSON
Ruth Tal-Singer, PhD
Vice President, Clinical Discovery, Respiratory Therapy Area Unit, GlaxoSmithKline

This session will focus on an emerging approach to R&D using specific examples for public-private partnerships in chronic obstructive pulmonary disease and oncology. The role of biomarkers and patient-reported outcomes in research and development of new medicines, the current regulatory environment for biomarker and endpoint qualification, and key success factors for public-private partnerships will be discussed.

Partnering to Qualify Biomarkers for Chronic Obstructive Pulmonary Disease (COPD)
Ruth Tal-Singer, PhD
Vice President, Clinical Discovery, Respiratory Therapy Area Unit, GlaxoSmithKline

PRO Consortia: A Success Story
Nancy Kline Leidy, PhD
Senior Vice President, Scientific Affairs, United BioSource Corporation

Public/Private Partnerships in Conducting Observational Studies: The Experience of the Italian Cancer Drugs Register
Luca De Nigro, MS
Coordinator, Drugs Monitoring Register, Italian Medicines Agency (AIFA), Italy

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

Related Interest Area(s): PC, NC, CP

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 124 *CME and Nursing*

Drug QT Derisking: Changes in When and How

CHAIRPERSON
William Wheeler, MD
Independent Cardiovascular Consultant, Wheeler Biopharm Consulting, LLC

QT "derisking," mandated for all drugs, has become simpler and inexpensive to confidently achieve in early-phase clinical studies. Learn how to acquire continuous ECG data with small N and analyze by methods translated from preclinical to human.

The Use of Positive Controls in Derisking
William Wheeler, MD
Independent Cardiovascular Consultant, Wheeler Biopharm Consulting, LLC

Translating Preclinical Repolarization Data to Guide Clinical Studies
Gary Gintant, PhD, MA
Research Fellow, Abbott Laboratories

QT Derisking with Continuous ECG Data Analysis
Royce A. Morrison, MD, MS
Principal Investigator/Chief Medical Officer, Comprehensive Clinical Development

#158 Track 06 – Medical Writing and Medical Communications

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 108b *CME, Pharmacy, and Nursing*

Communicating Drug Safety Information Using Social Media: FDA and Industry Perspectives

CHAIRPERSON
Catherine Yu Chew, PharmD
Acting Deputy Director, Division of Drug Information, CDER, FDA

FDA relays the latest drug safety information through drug safety communications which are disseminated using social media tools. This session provides FDA and industry perspectives on the development, communication, dissemination, and impact of drug safety communications.

Communicating Drug Safety Information: FDA Perspective
Catherine Yu Chew, PharmD
Acting Deputy Director, Division of Drug Information, CDER, FDA

Communicating Drug Safety Information: FDA Perspective
Gregory Busse, PhD
Senior Writer/Editor, Team Lead for Drug Safety Communications, CDER, FDA

Communicating Drug Safety Information: Industry Perspective
Sue E. James
Vice President, Global Regulatory and Quality, Consumer Healthcare, GlaxoSmithKline

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

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 103b *CME, Pharmacy, and Nursing*

PRO Measurement in Clinical Trials: Need for Education and Training

CHAIRPERSON
Josephine M. Norquist, MS
PRO Specialist, Merck Sharp & Dohme Corp.

This session will present two examples of initiatives in pharmaceutical companies for PRO education and training as well as present the current initiatives being developed through the PRO Consortium, a partnership between pharmaceutical companies and the FDA to develop qualified, PRO endpoints to support product labeling claims.

How to 'DeVISE' Clinical Trial Endpoints to Meet Regulatory Requirements for Labeling Claims
Josephine M. Norquist, MS
PRO Specialist, Merck Sharp & Dohme Corp.

Initiative for PRO Education and Training
Clarice (Risa) P. Hayes, PhD
Research Advisor, Global Health Outcomes, Eli Lilly and Company

FDA Point of View
Laurie Burke, MPH, RPh
Director for Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

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

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 103a *CME, Nursing, and PMI PDUs*

Electronic Health Records (EHR)/Electronic Data Capture (EDC) Opportunities

CHAIRPERSON
Frances E. Nolan, MBA
Vice President, Quality and Regulatory Affairs, Medidata Solutions Worldwide

In an electronic health care world, drug developers have the opportunity to leverage the advantages of EHRs for patients, physicians, regulators, and the developers themselves. This session will discuss various use cases to explore the use of data from EHRs in accelerating a variety of processes associated with clinical trials and drug development across typical health care settings and research processes.

Semantic Search Technology to Mine Electronic Patient Records for Clinical Research and Personalized Medicine
Joerg F. Kraenzlein, DrMed, PhD
Director Clinical Research, CSC, Germany

Seamlessly Moving Patients Utilizing EHRs: Case Study at Walter Reed Army Medical Center
Harry J. Fisher
President, Health ResearchTx LLC

Exploring the Use of Data from EHR's in Accelerating a Variety of Processes Associated with Clinical Trials and Drug Development
Steven P. Schwartz
Senior Vice President, Corporate Business Development, Allscripts

#161 Track 08A – Regulatory Affairs and Submissions

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 113c

Analysis and Impact of PDUFA V: How the Changes Will Affect the Work of Regulatory Affairs Professionals

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

The PDUFA V agreement will become effective on October 1, 2012. Prescription drug regulatory professionals need to understand the rationale for changes, their impact, and how to use the new framework toward achieving more first cycle approvals.

PDUFA V: Charting the Course
Andrew Emmett
Managing Director, Science and Regulatory Affairs, The Biotechnology Industry Organization (BIO)

FDA Roadmap: How Key Changes Will Impact the Review of Applications
Beth Duvall
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

Navigating the New Course: Industry Perspective
Robert J. Meyer, MD
Head, Global Regulatory Strategy, Policy and Safety, Merck, Sharp & Dohme Corp.

#162 Track 08B – Regulatory Affairs and Submissions

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 115a

Streamlining of Clinical Trial Review Process in Asian Pacific Region

CHAIRPERSON
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

With global development, Asian regulatory agencies are streamlining the clinical trial process. Taiwan is adapting the Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX). system. Korea and Japan have enhanced the review of the clinical trial. This session will discuss revolutionary measures and impacts.

Integrated Review Office: Experience on an Innovative Review Team on Clinical Trials in Taiwan
Representative Invited
Director General, Food and Drug Administration, Department of Health, Taiwan

Good Review Practice in Asia Pacific
Neil McAuslane, PhD, MSc
Director, Centre For Innovation In Regulatory Science (CIRS), UK

Challenges and Opportunity For Clinical Trials in the Asia Pacific From a Pharmaceutical Industry Perspective
Shun Jin, MBA
Associate Director, Takeda Global Research & Development Center, Inc., Singapore

#163 Track 08C – Regulatory Affairs and Submissions

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

3:30 PM–5:00 PM LEVEL: ■ Format: **FORUM**
Room 119b *CME and Nursing*

Vaccines: FDA and Japan Perspectives

CHAIRPERSON
Florence Houn, MD, MPH, FACP
Co-chair, FDAAA International Network, FDA Alumni Association

Perspectives from FDA CBER vaccines office on vaccine development and external communications policies, along with industry views on regulation and development from Japan will be presented.

Japan Update on Vaccine Developments and Regulations
Yoshikata Furuya, MSc
Manager, Regulatory and Vaccine Policy, Health Policy and Access, MSD K.K., Japan

CBER Vaccine Regulatory Update
Sara Gagneten, PhD
Regulatory Scientist, Office of Vaccines, CBER, FDA

FDA's Office of Vaccines Research and Review Considerations on Vaccine Communication
Maureen Hess, MPH
Health Science Advisor, Office of Vaccines Research and Review, CBER, FDA

#164 Track 09 – Medical Diagnostics and Devices

Related Interest Area(s): RA

3:30 PM–5:00 PM LEVEL: ◆ Format: **SESSION**
Room 118c

Discussion with Former Center for Devices and Radiological Health (CDRH) Management

CHAIRPERSON
Daniel G. Schultz, MD
Senior Vice President, Medical Devices & Combination Products, Greenleaf Health, LLC

Join this moderated panel discussion with former CDRH Directors and Management. The session will focus on the evolving face of medical devices, the interface between drugs and devices, new challenges and opportunities, and the changing regulatory landscape.

David W. Feigal, Jr., MD, MPH
Partner, NDA Partners, LLC

Donna-Bea Tillman, PhD
Senior Consultant, Biologics Consulting Group

Timothy Alan Ulatowski, MS
Director, Medical Devices, Becker & Associates Consulting, Inc.

#165 Track 10 – Public Policy/Health Care Compliance/Regulatory Law

Related Interest Area(s): CR, IS

3:30 PM–5:30 PM LEVEL: ● Format: **FORUM**
Room 116 *Pharmacy*

Legal Jeopardy from the Conduct of Clinical Trials

CHAIRPERSON
Mark C. Hegarty, JD
Partner/Attorney, Shook, Hardy & Bacon L.L.P.

This forum will address a wide range of regulatory and legal issues governing modern clinical research. Using a well known game show format, experts will compete to show their knowledge of the elements of informed consent, IRB requirements, FDA regulations, the history of clinical investigations, and other key topics.

Jeffrey N. Gibbs, JD
Director, Hyman Phelps & McNamara, PC

John M. Isidor, JD
Senior Director and Co-Founder, Schulman Associates IRB, Inc.

#166 Track 11A – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

Related Interest Area(s): RA, CR

3:30 PM–5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room 119a *CME and Nursing*

Conducting Clinical Trials in Developing Countries: Challenges in Meeting Good Clinical Practice (GCP) Compliance

CHAIRPERSON
Sherri A. Hubby
Director, US Quality Assurance, Premier Research Group Ltd

With the challenges in recruitment and placing more global studies in developing countries, regulatory agencies have raised concerns over ethical and data quality standards. Cultural diversity, variability in ethical review, difficulty in recruiting investigators with GCP experience and different regulatory standards in non ICH countries constitute major challenges to pharmaceutical industries and marketing authorization agencies related to compliance with GCP and ethical standards. This symposium covers local laws, specific customs within developing regions such as Asia, Africa, and South America and examples of effective methods for dealing with and managing the trial requirements, managing risks and providing solutions for developing local partners and cooperative efforts with foreign regulators and IRBs.

Conducting Clinical Trials in Developing Countries: A Comparison Between Expectations of the FDA, EMA, and ANMAT Regulators
Sherri A. Hubby
Director, US Quality Assurance, Premier Research Group Ltd.

Fostering Quality Assurance in Ethical Review in Asia: Towards Harmonization of IRB Procedures with GCP Standards
Ock-Joo Kim, MD, PhD, MS
Director, Center for Human Subject Protection, Seoul National University Hospital, Republic of Korea

An Exploratory Study to Identify Challenges to Full Good Clinical Practice (GCP) Compliance in Sub-Saharan Africa
Ghiorghis Belai, MS
Senior Clinical Research Manager, FHI 360

ANMAT Perspective
Augustina Bisio
Director, Drug Evaluation Agency, ANMAT, Argentina

#167 Track 11B – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 115c

Building Quality into Clinical Trials: Regulatory Perspectives and Practical Considerations

CHAIRPERSON
Winifred Ann Meeker-O'Connell, MS
Acting Associate Director, Risk Science, Intelligence, and Prioritization, Office of Scientific Investigations, Office of Compliance, CDER, FDA

Current models for clinical trial oversight have become outmoded in a global, complex environment. This session describes recent efforts to foster new models that employ risk-based approaches and that build quality into clinical trials.

EMA Perspective: Quality Risk Management in Clinical Development
Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

FDA CDER Perspective: Building Quality into Trial Design, Conduct, and Reporting
Winifred Ann Meeker-O'Connell, MS
Acting Associate Director, Risk Science, Intelligence, and Prioritization, Office of Scientific Investigations, Office of Compliance, CDER, FDA

#168 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CM, MF, RA

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 122b

Opportunities for Global Harmonization of Inspection Paradigm

CHAIRPERSON
Stephan Karl Roenninger, DrSc
Head, External Collaboration Europe/Japan/CEMA, F. Hoffmann-La Roche Ltd., Switzerland

Industry has experienced a large increase in the number of Good Manufacturing Practice (GMP) related inspections of their manufacturing sites around the world. It is acknowledged that this is partly due to the increasing global complexity of pharmaceutical supply chains and consequent dissemination of regulatory oversight to multiple worldwide inspections. This session will discuss how emerging regulatory requirements put additional hurdles on resource management and facilitate a more effective use and oversight of companies' efficiencies, and enforcement policies as driven by pharmaceutical quality systems in inspectorates and industry.

Regulatory Perspective: Quality Systems in Inspectorates Support Harmonized Inspection Management
Ian Jackson
Operations Manager, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Perspective From Industry: Considerations on Inspection Practices
Stephan Karl Roenninger, DrSc
Head, External Collaboration Europe/Japan/CEMA, F. Hoffmann-La Roche Ltd., Switzerland

A Regulator's Perspective: The Value of PIC/S Membership
Representative Invited
Branch Chief, International Compliance Branch, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

#169 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

Related Interest Area(s): CP, CDM

3:30 PM–5:00 PM LEVEL: ■ Format: **FORUM**
Room 107ab *CME, Pharmacy, and Nursing*

Application of Quality of Evidence Assessment Tools to the Evaluation of Observational Pharmacoepidemiologic Studies

CHAIRPERSON
George Neyarapally
Interdisciplinary Scientist, Office of Surveillance and Epidemiology, CDER, FDA

The assessment of the benefits and risks associated with drug exposure take into consideration data from pharmacoepidemiologic studies and from other data streams. This forum will address potential applications of quality assessment tools to the evaluation of pharmacoepidemiologic safety studies and the development of a tool to assess observational CER studies. A panel will discuss these issues and their implications.

Epidemiologic Drug Safety Data: The Need for Quality Assessment
Tarek A. Hammad, MD, PhD, MS
Deputy Division Director, Division of Epidemiology-I, CDER, FDA

Review of Quality of Evidence Assessment Tools for the Evaluation of Observational Pharmacoepidemiologic Safety Studies
George Neyarapally
Interdisciplinary Scientist, Office of Surveillance and Epidemiology, CDER, FDA

GRACE Checklist: A Validated Tool for Rating the Quality of Observational Studies of Comparative Effectiveness
Nancy Dreyer, PhD, MPH, FISPE
Senior Vice President, Scientific Affairs, Outcome

Panelist
Alexander M. Walker
Principal, World Health Information Science Consultants (WHISCON)

#170 Track 14A – Clinical Safety and Pharmacovigilance

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room 121ab *CME, Pharmacy, and Nursing*

Electronic Health Records (EHR) and Medication Safety and Adherence

CHAIRPERSON
Edward Fotsch, MD
Chief Executive Officer, PDR Network

Recent, rapid advances in Health Information Technology (HIT), the ever-widening deployment of new electronic systems, as well as new FDA goals for EHRs now make it possible to both generate positive health outcomes at the point of care and identify important drug-related safety issues that may have previously gone undetected. Medication adherence can now be pursued using communication to both provider and patient using EHRs. Adverse Drug Event (ADE) reporting tools can now operate both independently and as components within existing EHR/EMR systems, and the data that they capture and generate can be combined with new tools and approaches to data mapping, safety analysis, and interoperability. With these new advancements comes the potential to improve the validation and correlation of safety signal data. As provider workflow evolves from a fragmented traditional approach into one that is more integrated and cohesive, EHR-centric systems are emerging as important pharmacovigilance tools which may prove crucial to the advancement of ADE reporting, early warning systems and safety signal detection.

Using GIS to Identify Safety Signals in FDA's Adverse Event Reporting System (AERS) Database
Joseph Tonning, MD, MPH, RPh
Medical Officer, Office of Surveillance and Epidemiology, CDER, FDA

Electronic Health Records: The Powerful New Platform for Product, Risk Management and Safety Communications
Edward Fotsch, MD
Chief Executive Officer, PDR Network

ICD-9-CM to MedDRA® Mapping: How Well Do the Two Terminologies Correlate
Anna C. Zhao-Wong, MD
Medical Officer, MedDRA® MSSO

Electronic Health Records: The Powerful New Platform for Product, Risk Management and Safety Communication
Linda J. Scarazzini, MD
Director of Division of Pharmacovigilance I, CDER, FDA

#171 Track 14B – Clinical Safety and Pharmacovigilance

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 118a *CME and Nursing*

Use It Early and Often: Epidemiology's Many Roles in Clinical Development and Beyond

CHAIRPERSON
Nataliya Volkova, PhD, MPH
Director, Epidemiology, Pfizer Inc

Seasoned epidemiologists use a framework of investigational, filing and post-marketing activities to bring to life the role of epidemiology in product support. Real world examples from actual projects are the basis for this session.

Uses of Epidemiology in Clinical Drug Development
Nancy A. Brandenburg, PhD, MPH
Senior Director, PV and Epidemiology, Celgene Corporation

The Role of Epidemiologists in the Peri-approval Period: REMS, RMPs and Beyond
Nataliya Volkova, PhD, MPH
Director, Epidemiology, Pfizer Inc

Epidemiologic Studies as Part of Risk Management Strategies for Marketed Products
Catherine Sigler, DVM, MPH
Senior Epidemiologist, United BioSource Corporation

#172 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CP, CR

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 113a *CME and Nursing*

Rates and Weights: Quantifying Clinical Impact and Judgment in Benefit-risk Assessment

CHAIRPERSON
Bennett Levitan, MD, PhD
Director, Epidemiology, Janssen Research & Development, LLC

Complex benefit-risk assessments require quantifying tradeoffs between multiple benefits and risks. This session examines an assessment for triptans in migraine and compares two different weighting methods that incorporate patient or clinical judgment.

Preference Weight Approach to Triptans Benefit-risk Assessment
Brett Hauber, PhD
Senior Economist, RTI International

Multicriteria Decision Analysis Approach to Triptans Benefit-risk Assessment
Lawrence Phillips, PhD
Visiting Professor of Decision Sciences, Department of Management, London School of Economics, UK

Panelists
Telba Irony, PhD
Chief, General Surgical Devices Branch, CDRH, FDA

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

#173 Track 16 – Professional Development

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room 117

Building International Competence in Drug Development Teams

CHAIRPERSON
Mary S. Murray, MBA
Learning Manager, Bristol-Myers Squibb Company

This symposium introduces learning tools and concepts employed to develop the capabilities needed among a global clinical staff through different drug development stages. Special emphasis is placed on training requirements and strategies to advance drug development in Japan and the BRICT countries (Brazil, Russia, India, China, Turkey). Presenters offer case studies, lessons learned experiences and a job aid to help participants design and develop their own training programs for clinical staff and regulatory scientists.

New Approaches for Pharmaceutical Medicine Training
Joao Massud, MD
CEO, Trials Consulting, Brazil

Fostering Global Competence for Regulatory Scientists in an Age of Simultaneous Global Drug Development
Junichi Nishino, MPharm, RPh
Group Manager, Process Improvement and Excellence Group, Drug Regulatory Affairs, Novartis Pharma K.K., Japan

Clinical Staff Training in Eastern Europe
Andrei Kravchenko, MD, PhD
Head of Representative Office in Ukraine, Harrison Clinical Research Deutschland GmbH, Ukraine

Preparing for Clinical Development BRICT by BRICT
Mary S. Murray, MBA
Learning Manager, Bristol-Myers Squibb Company

#148 Track 17 – Global Regulatory

Related Interest Area(s): RA, CP

NEW TIME: 3:30 PM–5:00 PM LEVEL: ■ Format: **FORUM**
Room 120bc

European Town Hall: Part 2 of 2 – Interacting With the European System

CHAIRPERSON
Christa Wirthumer-Hoche, PhD
Deputy Head, Austrian Medicinal and Medical Device Agency (AGES), Austria

Part 1 of this forum will take place on Monday, June 25 at 10:00am.

The European medicines system offers different ways of bringing new medicines to the patient, whether through the European Medicines Agency centralized route or through the European national agencies' decentralized route. This second part of the European Town Hall offers insights on the different initiatives and entry points to facilitate regulatory procedures and scientific dialogue from early development to post-marketing authorization stages. The forum offers the opportunity to interact directly with a panel of staff from the European Medicines Agency and European national agencies.

Submit questions in advance to annualmeetingprogram@diahome.org
Subject: European Town Hall

Xavier De Cuyper
Chief Executive Officer, Federal Agency For Medicines and Health Products (FAMHP), Belgium

Peter Bachmann, DrSc
Senior Expert; Chair, Coordination Group for Mutual Recognition and Decentralise, BfArM, Germany

Agnès Saint-Raymond, MD
Head, Human Medicines, Special Areas, European Medicines Agency, European Union

#174 Track 17 – Global Regulatory

Related Interest Area(s): RA, PPLCC

3:30 PM–5:00 PM LEVEL: ● Format: **SESSION**

Room 113b

An Update on EMA, FDA, and PMDA International Activities

CHAIRPERSON

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

EMA, FDA and Japan's MHLW/PMDA have been each implementing unique global strategies, while cooperating with each other. This session discusses their international activities and accomplishments.

EMA Update
Emer Cooke, MBA
(Acting) Head of International and European Cooperation, European Medicines Agency, European Union

FDA Update
Mary Lou Valdez
Associate Commissioner for International Programs, Office of the Commissioner, FDA

PMDA Update
Yuki Ando
Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#175 Track 22 – White Paper Showcase

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

3:30 PM–5:00 PM LEVEL: ● Format: **SESSION**

Room 125

Raising the Bar for Regulatory Submission Document Quality: A Collaborative, Transitional Approach

CHAIRPERSON

Mauricha F. Marcussen, MBA
Program Manager, Life Sciences, Agano Solutions

This White Paper Showcase explores the needs of regulatory affairs operations and the medical writing community in regards to the delivery of comprehensive, quality content, and uncovers the document-related risks associated with the submission process.

Brought to you by Microsystems.

***Attendee badges scanned for this White Paper Showcase will be shared with the company hosting this offering. If you prefer not to have your badge scanned, please inform the DIA staff member.*

5:00 PM **END OF MONDAY OFFERINGS**

5:00 PM–6:30 PM **WELCOME RECEPTION**
Exhibit Hall

NOTES

NOTES

TUESDAY, JUNE 26

Registration Hours:

7:00 AM–4:30 PM — Attendee and Speaker Registration
Broad Street Lobby

7:00 AM–4:30 PM — Exhibitor Registration
Exhibit Hall D Lobby

Schedule:

7:15–8:00 AM — Coffee and Breakfast Breads
Meeting Rooms 108 and 119 Concourse

8:00–9:30 AM — Concurrent Educational Opportunities

9:00 AM–3:30 PM — Exhibition Hall Open

9:30–10:00 AM — Coffee Break
Exhibit Hall

10:00–11:30 AM — Concurrent Educational Opportunities

11:00 AM–1:30 PM — Professional Poster Session
Exhibit Hall D

11:30 AM–1:30 PM — Lunch with Optional Interest Area Seating
Exhibit Hall

1:30–3:00 PM — Concurrent Educational Opportunities

1:30–3:30 PM — Exhibit Guest Passes

3:00–3:30 PM — Refreshment Break
Exhibit Hall

3:30–4:30 PM — Concurrent Educational Opportunities

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

Related Interest Area(s): PM, FI, SP

8:00 AM–9:30 AM — LEVEL: ■ — Format: **SESSION**
Room 103c — *PMI PDUs*

Optimizing Drug Development Portfolios: An Integrated Approach

CHAIRPERSON
Zoran Antonijevic, MSc
Senior Director, Center for Statistics in Drug Development, Innovations, Quintiles

This session will demonstrate an integrated, value-driven approach as a basis for pharmaceutical portfolio planning and management. In this approach, decisions are defined such that the expected value of pharmaceutical portfolios is maximized.

Value-based Drug Development
Zoran Antonijevic, MSc
Senior Director, Center for Statistics in Drug Development, Innovations, Quintiles

Challenges of Portfolio Management and Optimization
Charles Persinger, MBA
Senior Research Scientist, Decision Sciences, Eli Lilly and Company

Maximizing Portfolio Value under Budget Constraints
Nitin R. Patel, PhD, MBA
Chairman and Chief Technology Officer, Cytel, Inc.

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

Related Interest Area(s): PM, SP

8:00 AM–9:30 AM — LEVEL: ■ — Format: **SESSION**
Room 113b — *PMI PDUs*

Project and Program Management Competency Models for the (Bio) Pharmaceutical Industry

CHAIRPERSON
Richard J. Heaslip, PhD
President and Founder, Programmatic Sciences

This session will explore approaches to the development of competency models that are specifically tailored to organizational needs. It will include a discussion of best practices and case studies from companies with different management philosophies.

Critical Considerations in the Development of Project Management Competency Models in the Pharmaceutical Industry (and the Dangers of Getting It Wrong!)
Richard J. Heaslip, PhD
President and Founder, Programmatic Sciences

Development of a Project Management/Project Leadership Competency Model
Leigh Shultz, PhD, PMP
Senior Group Leader, Merck & Co., Inc.

Sponsor versus CRO Project Management: Are Different Competency Models Needed?
Paul R. Bunch, PhD
Vice President, Global Project Management, Covance, Inc.

#203 Track 03 – Innovative Partnering Models and Outsourcing Strategies

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

8:00 AM–9:30 AM — LEVEL: ■ — Format: **FORUM**
Room 105ab — *PMI PDUs*

The New Reality — Strategic Partnerships under Scrutiny: Are They Working, and How Long Will It Take to Ensure Success?

CHAIRPERSON
Patricia Leuchten
CEO and President, The Avoca Group Inc.

This forum will explore CROs' and sponsors' assessment of the realities of implementing new outsourcing strategies. Data from the 2012 State of Clinical Outsourcing research will be shared. A panel of industry experts will provide their perspective.

Paul D. Spreen
Senior Vice President and Global Head, Customer Solutions Management Group, Quintiles

Peter A. DiBiaso, MHA
Senior Director, Head, Clinical Business Operations, Vertex Pharmaceuticals

Chris Davis, RPh
Director, External Sourcing, Eli Lilly and Company

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

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

8:00 AM–9:30 AM | LEVEL: ■ | Format: **SYMPOSIUM**

Room 124 | *CME and Nursing*

Novel Imaging Techniques Symposium

CHAIRPERSON

Barry Mangum, PharmD
Director, Clinical Pharmacology, Duke University Medical Center

Developing techniques to better understand the adsorption, distribution, metabolism and excretion (ADME) of novel investigational compounds presents unique challenges for the clinical research facility, academic or nonacademic, as well as the pharmaceutical industry. In this symposium, three differing approaches to examining the use of radio-labeled compounds will be explored. These different aspects of imaging technology are highly desirable tools in understanding drug mechanisms of action and deposition within either tumor spaces or other sites of action.

Quantitative PET Imaging with F-18 FDG and F-18 FLT: Using Imaging Biomarkers in Multicenter Clinical Trials
Jeffrey T. Yap, PhD
Senior Diagnostic Physicist, Dana-Farber Cancer Institute

Utilization of USP<797> to Enable On-site Compounding of IV 14C Microtracer or IV 14C/3H Macrotracer Dose for Human AME Study
Robert George Kochan, PhD
US Clinical Pharmacology Radiation Safety Officer, Covance Clinical Development Services

The Use of Fluorescence Correlation Spectroscopy (FCS) as an Alternative Biomarker Detection Technique
Aamir Shahzad, MD, DrMed
Secretary General and Director of Administration, International Society For Translational Medicine (ISTM), Austria

#205 Track 06 – Medical Writing and Medical Communications

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

8:00 AM–9:30 AM | LEVEL: ■ | Format: **SESSION**

Room 108b | *CME and Nursing*

Medical Contributions to Promotional Tactics

CHAIRPERSON

David B. Clemow, PhD
Clinical Research Scientist, Eli Lilly and Company

This session will describe the who, what, why, and how of the contributions of medical personnel to US product promotions, and medical's role in checking clinical data to ensure medical/scientific accuracy, label-alignment, and clinical relevance.

Medical Contribution to Promotion: Who, What, and Why
David B. Clemow, PhD
Clinical Research Scientist, Eli Lilly and Company

Medical Contribution to Promotion: Development, Net Impression, and Avoiding Enforcement Letters
Janet L. "Lucy" Rose, MBA
President, Lucy Rose and Associates, LLC

Medical Contribution to Promotion: How
Kristin Fox Goettner, PharmD
Associate Director, Medical Information, Janssen Scientific Affairs, LLC

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

Related Interest Area(s): SE, RA, CEHTAEbM

8:00 AM–9:30 AM | LEVEL: ■ | Format: **SESSION**

Room 103a | *CME, Pharmacy, and Nursing*

Defining Study Endpoints in 2012: The Journey Continues

CHAIRPERSON

John M. Weiler, MD, MBA
President, CompleWare Corporation

This session will bring together life sciences professionals including regulatory authorities to discuss the taxonomy used for study endpoints and the importance of identifying what is meaningful to be measured before focusing on how to measure it.

FDA Point of View
Laurie Burke, MPH, RPh
Director for Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

Panelist
John H. Powers, III, MD, FACP
Senior Medical Scientist, Collaborative Clinical Research Branch, NIAID, SAIC/National Institutes of Health

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

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

8:00 AM–9:30 AM | LEVEL: ■ | Format: **SYMPOSIUM**

Room 103b | *CME, Nursing, and PMI PDUs*

Evolving eContent Design and Exchange for Clinical Studies

CHAIRPERSON

George Waidell
Vice President, Life Sciences Practice, Intralinks, Inc.

As the prevalence of technology during all stages of the development process continues to expand, the importance of leveraging both existing and new technology and moving beyond basic implementation into true business value and efficiencies is critical. This symposium will explore three different areas of applications of both design and content sharing that apply current technologies with the opportunity to extend and drive further process integration.

Moving Safety Reporting to the Cloud: How to Leverage SaaS-based Solutions for Safety Reporting
George Waidell
Vice President, Life Sciences Practice, Intralinks, Inc.

The Integration of Medical Imaging into eTMF Systems for Endpoint Collection
James DeSanti
President and CEO, PharmaVigilant

The Re-use of define.xml as Metadata for CRF Design
Philippe Verplancke, PhD
Managing Director, XClinical GmbH, Germany

#208 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CEHTAEbM, SP

8:00 AM–9:30 AM LEVEL: ■ Format: **FORUM**

Room Terrace 4

Meta-collaborations: A Call to Action

CHAIRPERSON

Freda Lewis-Hall, MD
Chief Medical Officer and Senior Vice President, Pfizer Inc

What are the barriers that are keeping ideas from turning into action, and how can these barriers be broken to develop new models for innovation and collaboration? Senior-level thought leaders will address these questions and discuss how industry, academia, government, and patients, through meta-collaborations, can take drug discovery to the next level by creating opportunities for moving forward and coming up with solutions faster.

Government Initiatives to Stimulate Innovation in Medical Health Sciences
Stephen P. Spielberg, MD, PhD
Deputy Commissioner, Medical Products and Tobacco, Office of the Commissioner, FDA

Panelists
Margaret A. Anderson, MS
Executive Director, FasterCures

Kathy L. Hudson
Deputy Director for Science, Outreach, and Policy, National Institutes of Health

#209 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): DM, SUBS, RA

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 120bc

Electronic Drug Registration and Listing: FDA and Industry

CHAIRPERSON

Leyla Rahjou-Esfandiary, PharmD
Pharmacist, Office of Compliance, CDER, FDA

This session will provide a regulatory overview of drug establishment registration and drug listing requirements, FDA's National Drug Code (NDC) Directory, the Drug Establishments Current Registration Site (DECRS), some recent updates, and also industry's perspective; challenges and benefits.

FDA Point of View
Lieutenant Soo Jin Park, PharmD
Pharmacist, Office of Compliance, CDER, FDA

Industry Point of View
Patricia L. Cowall-Hanover, PhD, MBA, RAC
Regulatory Consultant, Eli Lilly and Company

#210 Track 10 – Public Policy/Health Care Compliance/Regulatory Law

Related Interest Area(s): RA, CR

8:00 AM–9:30 AM LEVEL: ◆ Format: **SESSION**

Room 113c

CME, Pharmacy, and Nursing

Legal Aspects of Clinical Trial Compliance

CHAIRPERSON

Darshan Kulkarni, JD, PharmD, MS
Principal Attorney, The Kulkarni Law Firm

This session will provide a broad-based review of the various laws and regulations that impact clinical trials. This discussion will focus primarily on issues including the Foreign Corrupt Practices Act, False Claims Act, anti-kickback laws, determination of fair market value, and HIPAA. There will also be a discussion on the non-FDA governmental organizations that may get involved in clinical trial compliance including HHS and the US Attorney's Office.

Legal and Compliance Issues in Clinical Trials
Darshan Kulkarni, JD, PharmD, MS
Principal Attorney, The Kulkarni Law Firm

Panelists
Catherine Dabney Clemons, JD, MBA
Corporate Counsel, Daiichi Sankyo Inc.

Stacey Smith, JD
Attorney, Department of Justice, US Attorney's Office

#211 Track 12 – Pharmaceutical Quality

Related Interest Area(s): QAQC

8:00 AM–9:30 AM LEVEL: ● Format: **WORKSHOP**

Room 123

Quality Risk Management Workshop

CHAIRPERSON

Fritz Erni, DrSc
Consultant, Switzerland

This interactive workshop will give a brief overview of simple quality risk management (QRM) tools. In small groups, participants will work with common QRM tools such as Process Maps, Fishbone Diagrams and Failure Mode Effects Analysis (FMEA) to determine product critical quality attributes and critical process steps for a simple manufacturing process.

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

Moderators
Stephan Karl Roenninger, DrSc
Head, External Collaboration Europe/Japan/CEMA, F. Hoffmann-La Roche Ltd., Switzerland

Celia N. Cruz, PhD
Chemist, Office of New Drug Quality Assurance, Office of Pharmaceutical Science, CDER, FDA

#212 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

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

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 107ab

Recent Advancement of HTA and Its Impact on Health Care Reform and Product Life Cycle Management in the Asian Pacific Region

CHAIRPERSON

Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Systems for health technology assessments (HTAs) have been established in Taiwan and Korea. China is considering establishing a system similar to NICE. The session will discuss and compare HTA practices in the Pacific region, including Canada and the US.

Mapping the Regulatory, HTA, and Payer Processes: A Key to Multi-stakeholder Understanding
Lawrence E. Liberti, MS, RPh, RAC
Executive Director, Centre for Innovation in Regulatory Science (CIRS)

HTA in Asia Pacific: Trends in Use of Health Economics and Managed Entry Agreements
Abdulkadir Keskinaslan
Pricing Director Region AMAC and China, Novartis Pharma AG, Switzerland

Pharmacoeconomics and Outcomes Research of Innovative Vaccines
Leona E. Markson
Executive Director, Global Health Outcomes, Merck & Co., Inc.

#213 Track 14 – Clinical Safety and Pharmacovigilance

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

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 121ab *CME and Nursing*

Data Monitoring Committee (DMC): When You Need One and When You Don't!

CHAIRPERSON

Barton L. Cobert, MD, AHIP, FACP
President, BLCMD Associates, LLC

This session describes what a Data Monitoring Committee (DMC) is, how it is constituted, when it is needed, its duties, responsibilities, charter, actions, interim analyses and consequences of its actions. Ethical issues, complexities, examples and problems will be discussed.

Data Monitoring Committee (DMC)
Barton L. Cobert, MD, AHIP, FACP
President, BLCMD Associates, LLC

Operational Issues: Herding the DMC Cats
Art Gertel, MS
Vice President, Strategic Regulatory Consulting, Medical Writing, and QA, Beardsworth Consulting Group Inc.

Mapping the Charter
Gil Price, MD
President, Drug Safety Solutions

#214 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CDM

8:00 AM–9:30 AM LEVEL: ■ Format: **FORUM**

Room 113a

NDA/BLA Statistical Review and the CDISC ADaM Data Standards

CHAIRPERSON

Stephen E. Wilson, USPHS, DrPH
Director, Division of Biometrics III, CDER, FDA

This forum will describe the receipt and statistical review of analysis files based on the ADaM standards at the Center for Drug Evaluation and Research. The panel will discuss problems and potential improvements.

ADaM Review from a CDER Statistical Reviewer's Perspective
Behrang Vali, MS
Regulatory Reviewer, Division of Biometrics 3, Office of Translational Sciences/Office of Biostatistics, CDER, FDA

CDISC ADaM Implementation: Present Impact and Future Directions
Michael Nessly, MS
Biostatistics Group Leader, Shire Specialty Pharmaceuticals

Standardized ADaM Data Sets for Submissions: A Case Study with Patient Reported Outcomes (PRO)
James R. Johnson, PhD, MS
Director, Head Global Statistical Programming, UCB BioSciences Inc.

9:30 AM–10:00 AM **COFFEE BREAK**
Exhibit Hall

#215 Track 01A – Clinical Operations

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SYMPOSIUM**

Room 108a *CME and Nursing*

Understanding Risk-based Monitoring: Is It Art, Science, or Both?

CHAIRPERSON

Kathleen Findlen
Director, Clinical Operations, Collegium Pharmaceutical

FDA has recently issued two important and related draft guidance documents covering electronic source and risk-based monitoring. FDA now clearly expects sponsors to take better advantage of electronic data capture (EDC) technology by implementing a targeted, risk-based approach to monitoring data remotely. Targeted source document verification (SDV) can be a highly effective and low-cost method of implementing an innovative monitoring strategy where 100% monitoring of site data is costly and not needed. Yet, in light of these potential cost savings, targeted SDV is still more of a frequent discussion topic rather than a reality. This symposium will provide perspectives on how this guidance could change the day-to-day relationships of sites/sponsors/monitors.

Targeted Source Document Verification: The Decision Makers' Perspective on "To SDV or Not to SDV"
Jennifer Abrams Stier
Senior Director, Product Management, Medidata Solutions Worldwide

Risk-based Monitoring: Challenges and Opportunities for Field Monitors and Data Managers
Steve Shevel, MBA
Associate, Waife & Associates Inc.

Changing the Monitor/Site/Sponsor Relationship through Electronic Source Documents
Edward Stephen Seguine, Jr., MBA
CEO, Clinical Ink

#216 Track 01B – Clinical Operations

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

10:00 AM–11:30 AM LEVEL: ■ Format: **FORUM**
Room 111ab *CME and Nursing*

The Next Patient Recruitment Frontier: Leveraging Mobile Health Care Technology (mHealth) to Recruit Patients for Clinical Trials

CHAIRPERSON
Neil Weisman
Executive Vice President and General Manager, Blue Chip Patient Recruitment

How can patient recruitment capitalize on the rapid growth of mobile health technology? This forum will discuss how sponsors, sites and CROs can improve patient recruitment efforts using mobile technology.

Redesigning the Future of Clinical Trials: A Collaborative Approach Harnessing the Power of Mobile Technology
Tim Davis
CEO and Co-founder, Exco InTouch, UK

Is Patient Recruitment Ready for Mobile Health Technology? A Survey Analysis
Neil Weisman
Executive Vice President and General Manager, Blue Chip Patient Recruitment

How a CRO Is Using Mobile Health Technology
Owen Garrick, MD, MBA
Chief Operating Officer, Bridge Clinical Research

#217 Track 01C – Clinical Operations

Related Interest Area(s): CP, IS

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 109ab *CME and Nursing*

Update on Collaborative Projects of the Clinical Trials Transformation Initiative (CTTI)

CHAIRPERSON
Jose M. Vega, MD
Vice President, Amgen Global Safety, Amgen Inc.

This session will present results of three Clinical Trials Transformation Initiative (CTTI) projects conducted by representatives of FDA, industry, academia, patients, and others: 1) Premarket Safety Management, 2) Central IRBs in Multicenter Trials, and 3) Site Metrics for Study Start-up.

IND Safety Assessment and Communication: Biopharmaceutical Industry Perspective
Jose M. Vega, MD
Vice President, Amgen Global Safety, Amgen Inc.

IND Safety Assessment and Communication: FDA Perspective
Patrick Archdeacon
Medical Officer, Office of Medical Policy, CDER, FDA

Central IRBs for Multicenter Clinical Trials
Cynthia Hahn
Administrator, Office of Research Compliance, The Feinstein Institute for Medical Research

Site Metrics for Study Start-up
Christine K. Pierre, RN
President, RxTrials, Inc.

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

Related Interest Area(s): OS, PM

10:00 AM–11:30 AM LEVEL: ● Format: **SESSION**
Room 113b

Optimizing Performance in Outsourced Projects in China and Other Asian Countries

CHAIRPERSON
John Z. Sun, PhD, MBA, PMP
Global Program Team Director, Novartis Pharmaceuticals Corporation

Outsourcing and participation in clinical trials in China and other Asian countries have expanded dramatically in recent years. Many global companies now have ongoing or newly initiated collaboration with their local subsidiaries or selected CRO in the Asia-Pacific region. Along with the apparent advantages and fast-paced development, the global and local project teams often face various unforeseen challenges that may result from the cultural differences leading to misalignment and frustration on both sides. In the sponsor-CRO collaboration, these variances include different expectations and project management practices ranging from project planning, risk management, and communication. This session will discuss the key differences and challenges of project management practice through case studies, and identify better ways to optimize the project performance internally within the matrix environment or when collaborating with a CRO.

Optimizing Project Performance in a Matrix Environment: CRO Perspective in Asia Context
Jing Ping Yeo, PhD
Director, PAREXEL International, Singapore

Working with Project Teams from China
Jenny Zhang, MD, MHA
Director, Business Development (USA), ACRP China Chapter President, Tigermed Consulting Ltd.

Oversight for Strategic Outsourcing Projects in China and Asia Countries: From the Sponsor Perspective
Catherine Lee, MBA, MPharm, MSc
Area Head-Asia, Clinical Trial Support and Compliance, Pfizer Inc, Taiwan

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

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 103c

Improving Protocol Design: Current Industry Practices and New Approaches

CHAIRPERSON
Linda B. Sullivan, MBA
Vice President, Metrics Champion Consortium

This session will examine current costs and issues associated with poorly designed protocols and explore new approaches being developed and utilized by organizations to improve protocol design and reduce the incidence of protocol amendments.

Quantifying the Impact of Protocol Design Complexity on Drug Development Cost and Performance
Kenneth A. Getz, MBA
Tufts Center for the Study of Drug Development, Chairman, The Center for Information and Study on Clinical Research Participation (CISCRP), Tufts University

Getting It Right the First Time: Utilizing a Protocol Quality Evaluation Tool to Improve Protocol Design
Linda B. Sullivan, MBA
Vice President, Metrics Champion Consortium

Structured Study Design Driving Trial Efficiencies
Michelle Marlborough
Director, Product Management, Medidata Solutions Worldwide

#220 Track 03 – Innovative Partnering Models and Outsourcing Strategies

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

10:00 AM–11:30 AM | LEVEL: ● | Format: **SESSION**
Room 105ab | *PMI PDUs*

The Unintended Consequences of Strategic Partnerships

CHAIRPERSON
Michael A. Martorelli, MBA
Director, Fairmount Partners

Sponsors and CROs have entered numerous long-term strategic partnerships. Public CROs have begun to describe some unintended financial consequences of these relationships. This session will help audience members cope with these problems.

Reviewing Selected Unintended Consequences
Michael A. Martorelli, MBA
Director, Fairmount Partners

A Sponsor's View of Unexpected Partnership Issues
Ian C. Lauf
Outsourcing Manager, Boehringer-Ingelheim

Strategic Outsourcing: The Next Big Model
Michael J. Rosenberg, MD, MPH
President and CEO, Health Decisions Inc.

Improving Drug Development Partnerships
Anthony J. Carita
President, CTB Solutions, Inc.

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

Related Interest Area(s): NC, CP, PC

10:00 AM–11:30 AM | LEVEL: ◆ | Format: **SESSION**
Room 124 | *CME, Pharmacy, and Nursing*

Skin-drug Biotransformation: What Testing Should We Do?

CHAIRPERSON
Keith K. Burkhart, DrMed
Senior Advisor, Medical Toxicology, Office of New Drugs, CDER, FDA

AERS data mining supports the hypothesis that drugs associated with Stevens Johnson Syndrome (SJS) undergo biotransformation. Reviews of the role of drug metabolism and SJS and preclinical testing for skin hypersensitivity are provided.

Carbamazepine Hypersensitivity. A Case Study of Bioactivation to B*1502
J. Steven Leeder, PharmD, PhD
Professor of Pediatrics and Pharmacology, Children's Mercy Hospitals and Clinics

Nonclinical Testing of Skin Hypersensitivity in Drug Development
Jessica Whritenour, MS, PhD
Immunotoxicology Center for Emphasis, Drug Safety Research and Development, Pfizer Inc

Many Drugs Highly Associated with Stevens Johnson Syndrome Undergo Biotransformation by CYP2C9 and CYP3A4
Keith K. Burkhart, DrMed
Senior Advisor, Medical Toxicology, Office of New Drugs, CDER, FDA

#222 Track 06 – Medical Writing and Medical Communications

Related Interest Area(s): MC

10:00 AM–11:30 AM | LEVEL: ■ | Format: **FORUM**
Room 108b | *CME, Pharmacy, and Nursing*

Publish or Perish: Retracted Scientific Literature

CHAIRPERSON
Art Gertel, MS
Vice President, Strategic Regulatory Consulting, Medical Writing, and QA, Beardsworth Consulting Group Inc.

This forum will consider the increasing number of retractions by scientific and medical journals, and the potential impact of retracted data that remain in play. Putative causes, mitigation, and prevention will be discussed.

Publish or Perish: The Legacy of Retracted Scientific Literature
Art Gertel, MS
Vice President, Strategic Regulatory Consulting, Medical Writing, and QA, Beardsworth Consulting Group Inc.

The Good, The Bad, and The Ugly: What Retractions Say About Scientific Transparency
Ivan Oransky, MD
Executive Editor, Reuters Health

Correcting the Literature: Mistake or Misconduct
Diane Scott-Lichter, MA
Publisher, American Association For Cancer Research

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

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

10:00 AM–11:30 AM | LEVEL: ● | Format: **FORUM**
Room 103a | *CME, Pharmacy, Nursing, and PMI PDUs*

Labeling Claims Based on Patient-reported Outcome Measures: It Takes a Village!

CHAIRPERSON
J. Jason Lundy, PhD
Director, ePRO Consortium, Critical Path Institute

A pragmatic overview will be provided that delineates the series of activities necessary to properly develop and implement a patient-reported outcome (PRO) measure in a clinical trial for the purposes of product approval and labeling. During this interactive forum, a real-world example will be used to illustrate the considerations and associated resources that a clinical trial sponsor may face when using a PRO instrument as an efficacy endpoint.

Labeling Claims Based on Patient-reported Outcome Measures
J. Jason Lundy, PhD
Director, ePRO Consortium, Critical Path Institute

FDA Point of View
James P. Stansbury, PhD, MPH
Endpoints Reviewer, Study Endpoints and Labeling Development Staff, CDER, FDA

Sponsor Point of View
Clarice (Risa) P. Hayes, PhD
Research Advisor, Global Health Outcomes, Eli Lilly and Company

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

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 103b *CME, Pharmacy, and Nursing*

Lessons Learned from FDA-sponsored ARRA PCOR (American Recovery and Reinvestment Act Patient Centered Outcomes Research) Data Standardization Efforts

CHAIRPERSON
Crystal Allard, RAC
Consumer Safety Officer, Office of Chief Scientist, Office of the Commissioner, FDA

FDA would like to share their experiences in standardization of data at each center. Each speaker will discuss the most valuable lessons they have learned during the conversion process including outstanding technical and policy issues.

Amy Malla, MT, PMP
Consumer Safety Officer, Office of the Director, CBER, FDA

Helena Sviglin, MPH
Regulatory Information Specialist, Office of Translational Sciences, CDER, FDA

Ted Peterson, MS
Division of Biostatistics, Orise Fellow, CDRH, FDA

Lilliam Rosario, PhD
Associate Director, Office of the Chief Scientist, Office of the Commissioner, FDA

#225 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): CR, PPLCC

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 119b *CME and Nursing*

Pediatric Development in the US: Implementation of 2007 PREA and BPCA Against a Backdrop of the EU Pediatric Legislation

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

With the passage of the US and EU pediatric legislation, companies are challenged to meet the requirements of FDA and EMA. Differing timelines, processes and standards require well managed interactions with health authorities to achieve consensus.

Negotiating Pediatric Drug Development With FDA and EMA: Operational Guidance and Essential Background Information
Klaus Rose, MD, MS
Chief Executive Officer, Klausrose Consulting, Switzerland

FDA Point of View
Lisa L. Mathis, MD
Associate Director, Office of New Drugs, Pediatric and Maternal Health Staff, CDER, FDA

Industry Perspective
Ronald Portman, MD
Group Director, Bristol-Myers Squibb Company

#226 Track 08B – Regulatory Affairs and Submissions

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 120bc *CME, Pharmacy, and Nursing*

Drug Shortages 2012: Rewind, Repeat, Recovery

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

This session will focus on characterizing the current issues surrounding shortages of medically necessary drug products. Speakers will focus on history, repetitive patterns of problems, and our path forward. This will include present initiatives underway and strategies under consideration for effectively dealing with, and mitigating existing drug shortage situations, and for preventing new drug shortages from developing. The respective roles of both industry and the FDA in addressing drug shortage situations will be discussed.

Emily T. Thakur, RPh
Senior Program Management Officer, Drug Shortage Program, Office of New Drugs, CDER, FDA

Laina Bush, MBA
Associate Deputy Assistant Secretary, Planning and Evaluation, HHS

Jonathan Kafer
Vice President, Sales and Marketing, Teva Pharmaceuticals

#227 Track 09 – Medical Diagnostics and Devices

Related Interest Area(s): CmbP, RA

10:00 AM–11:30 AM LEVEL: ● Format: **SYMPOSIUM**
Room 118c *CME, Pharmacy, and Nursing*

Combination Products

CHAIRPERSON
Stephen Paul Holcroft
Vice President, Regulatory Affairs, Johnson & Johnson Vision Care, Inc.

This symposium will discuss the shifting borderlines between medicines and other product both a continuing concern and an opportunity for all companies, and the role of clinical trials in establishing the best treatment of care using both drugs and devices. We will also identify regulatory issues related to safety, performance and effectiveness.

The Frontier Edges Between Medicines, Medical Devices, Cosmetics, Biocides and Other Health Care Regulated Products
Peter M. Lassoff, PharmD
Vice President and Head of Global Regulatory Affairs, Quintiles, UK

Drug Device Combination Products: Regulatory Path to Approval in Global Perspective Including New Requirements on Use Safety

Two-arm Double Randomized Clinical Trial Using Drugs and Devices
Sunita Prem Ahir, PhD, MSc, RAC
Regulatory Affairs Manager, D-Target, a Premier Research Company, Switzerland

#228 Track 10 – Public Policy/Health Care Compliance/Regulatory Law

Related Interest Area(s): CP, RA

10:00 AM–11:30 AM LEVEL: ● Format: **SESSION**
Room 113c *Pharmacy*

Product Liability in the US and the EU

CHAIRPERSON
Gizzy Klink, JD
Senior Associate, NautaDutilh N.V., Netherlands

In this session, an overview will be given of both legislation and case law with respect to product liability on both sides of the Atlantic. The session will provide hands-on information for advice to clients and will discuss current case law.

Managing Product Liability Risks in the EU
Gizzy Klink, JD
Senior Associate, NautaDutilh N.V., Netherlands

What Life Science Companies Need to Know About Product Liability But Are Afraid to Ask: Focus on Research Risks
Becki Kanjirathinkal, MS
Risk Control Consulting Director, CNA Healthpro

Understanding and Minimizing Product Liability Risk for Prescription Drugs Marketed in the United States
Linda Pissott Reig, JD
Shareholder, Buchanan Ingersoll & Rooney PC

#229 Track 11 – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

10:00 AM–11:30 AM LEVEL: ◆ Format: **SESSION**
Room 115c

Misconduct and Management of Serious or Continued Noncompliance: What Are the Differences and Similarities?

CHAIRPERSON
Deborah A. Waltz, MS
Senior Director, Scientific Operations Quality, Pfizer Inc

This session will provide regulatory perspective on new enforcement directives which place greater emphasis on accountability for compliance for all parties involved in the research enterprise.

What Does FDA Really Enforce and How? A Comprehensive Research, Review, and Trending Analysis of FDA GxP Enforcement Practice
James Huang, PhD
Associate Director, Forest Research Institute

Panelist
Constance Cullity, MD, MPH
Branch Chief, Division of Scientific Investigations, Office of Compliance, CDER, FDA

#230 Track 12 – Pharmaceutical Quality

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

10:00 AM–11:30 AM LEVEL: ● Format: **SESSION**
Room 119a *CME and Nursing*

Preparing for CMC Meetings with the FDA

CHAIRPERSON
Michael Folkendt, MS
Associate Director for Regulatory Affairs, Office of New Drug Quality Assurance, Office of Pharmaceutical Science, CDER, FDA

Meetings with the FDA are an important part of the drug development process. This session will provide insight on how and when to best meet with the FDA, how to successfully request and plan for a CMC meeting for CDER NDAs, BLAs, and supplements.

CMC Meetings With the FDA: Tips to a Successful Meeting
Jeannie C. David, MS
Regulatory Health Project Manager, Office of New Drug Quality Assurance, Office of Pharmaceutical Science, CDER, FDA

Considerations for Planning a CMC Meeting with the FDA
Toni-Marie Nearing
Senior Director, Global Regulatory Affairs, Quintiles

CMC Meetings with the FDA: Timing, Preparation, and Execution
Antoinette Paone, MBA, MSc
Senior Director, Global CMC Regulatory Affairs Strategy, Vertex Pharmaceuticals Incorporated

#231 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

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

10:00 AM–11:30 AM LEVEL: ● Format: **FORUM**
Room 107ab *CME, Pharmacy, and Nursing*

The Effects of NICE Technology Assessments on Prescribing and Cost-sharing Behavior in the US

CHAIRPERSON
John J. Doyle, DrPH, MPH
Vice President and Practice Leader for Market Access, Quintiles

As US health care increasingly looks towards proven clinical effectiveness for reimbursement decisions, it has been hypothesized that health technology assessments (HTAs) published by NICE would influence drug prescribing and patient cost-sharing expenditures in the US according to the nature of the published guidance. HTAs are multidisciplinary policy analyses that examine the medical, economic, social, and ethical implications of the incremental value, diffusion and use of a medical technology in health care. The assessment function entails the process of collecting, evaluating, and systematically reviewing all available evidence for the technology under consideration. As a result, inherent elements of the technology appraisal process include differential analysis and implementation by different payers around the world and varied adoption of recommendations by all stakeholders including health care providers, patients and advocacy groups, and payers.

The Effects of NICE Health Technology Assessments on Prescribing in the US: Overview
John J. Doyle, DrPH, MPH
Vice President and Practice Leader for Market Access, Quintiles

How the Same Licensing Data Are Differently Evaluated by Payers
Pietro Folino Gallo, DrMed
Head of European Assessment Unit, Italian Medicines Agency (AIFA), Italy

The Evolution of Health Technology Assessments in the US
Joseph DiCesare, MPH
Vice President, Global Health Economics and Outcomes Research, Novartis Pharmaceuticals Corporation

Indicators of Health Technology Adoption in the US
Josephine A. Sollano
Head, Global Health Economics and Outcomes Research, Pfizer Inc

#232 Track 14A – Clinical Safety and Pharmacovigilance

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 121ab *CME and Nursing*

Comparison of National-level Drug Utilization Patterns from Large Commercial Health Care Databases with Mini-Sentinel

CHAIRPERSON
Laura Governale, PharmD
Deputy Director for Drug Use, Office of Surveillance and Epidemiology, FDA

This session will present and discuss information generated by the Mini-Sentinel Summary Tables and Modular Programs compared with similar analyses using nationally representative commercial drug utilization databases for selected drug products.

FDA Perspective — Overview of Mini-Sentinel
Marsha E. Reichman, PhD
Senior Advisor, Office of Surveillance and Epidemiology, CDER, FDA

Comparison of Commercial Drug Utilization Data to Mini-Sentinel Data
Laura Governale, PharmD
Deputy Director, Division of Epidemiology II, CDER, FDA

Advancing Safety Surveillance through Collaboration
Representative Invited
Head of Clinical Analytics, Quintiles

#233 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CR, RA

10:00 AM–11:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room 118a *CME and Nursing*

Pharmacovigilance in Japan and Risk Management Plans

CHAIRPERSON
Stewart Geary, MD
Vice President, Eisai Co., Ltd., Japan

This symposium will provide an update on the latest developments in pharmacovigilance in Japan with speakers from the regulatory authority and the pharmaceutical industry based in Japan. Discussions will provide both an overall description of the current system of drug safety regulation, as well as recently implemented changes and the prospects for further developments in drug safety regulation in Japan.

The Japan Pharmaceutical Affairs Law
Tatsuo Kurokawa, PhD
Professor, Regulatory Sciences, Faculty of Pharmacy, Keio University, Japan

Pharmacovigilance in Japan: Regulator Perspective
Junko Sato, PhD
Director for Risk Management, Office of Safety II, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Trend of Pharmacovigilance Practices in Japan
Yorozu Tabata, MA
Manager, PRTM Japan

#234 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, RA

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 113a *CME, Pharmacy, and Nursing*

FDA Draft Guidance on Multiple Endpoints in Clinical Trials

CHAIRPERSON
Bruce Binkowitz, PhD, MSc
Senior Director, Clinical Biostatistics, Merck Research Laboratories

Clinical trials evaluate effects of one or more treatments typically on multiple primary and secondary endpoints. This raises multiplicity issues if there are alternative paths in the trial for winning for treatment effects. In addition, clinical trials frequently evaluate treatment effects on subpopulations, perform interim analyses and use adaptive designs which add yet another dimension of multiplicity. All these increase the risk of making false conclusions about the treatment effects, if not handled properly. FDA, upon recognizing the importance of multiplicity, has recently developed draft guidance on this topic. This session will address issues of multiple comparison and the new draft guidance.

FDA Perspective
Kathleen S. Fritsch, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

An Industry Perspective
Frank Bretz, PhD
Global Head of Statistical Methodology, Novartis Pharma AG, Switzerland

Panelist
Robert J. Temple
Deputy Center Director for Clinical Science, CDER, FDA

#235 Track 16A – Professional Development

Related Interest Area(s): PETD

10:00 AM–11:30 AM LEVEL: ■ Format: **WORKSHOP**
Room 121c

Advanced Presentation Skills

CHAIRPERSON
Lauren Edelstein Henry, MEd
Principal Operational Specialist, Janssen Pharmaceutical Companies of Johnson & Johnson

This workshop will delve deeper into presentation skills. Topics include how to handle a hostile/overly inquisitive audience, presenting via web/teleconference, multicultural presenting, presenting scientific data and more.

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

So You Think You Want to Work Remotely?
Betty R. Kuhnert, PhD, MBA
President, BRKuhnert LLC

Facilitator
Matthew C. Henry, PhD
Investigator, GlaxoSmithKline

#236 Track 16B – Professional Development

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

10:00 AM–11:30 AM LEVEL: ● Format: **WORKSHOP**
Room 123 *CME, Pharmacy, and Nursing*

Introduction to Narrative Medicine

CHAIRPERSON

Jesús Rivera
Senior Learning Manager, Bristol-Myers Squibb Company

Illness unfolds as a complex and interconnected set of narratives. This workshop will introduce participants to the skills and habits of reflective writing and listening in order to better recognize, receive, absorb, interpret, and honor stories of illness towards the goal of achieving narrative competence. Clinical practice fortified by the knowledge of what to do with stories can result in better patient care and health outcomes.

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

#237 Track 17A – Global Regulatory

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

10:00 AM–11:30 AM LEVEL: ■ Format: **FORUM**
Room 116

International Regulatory Cooperation: A Canadian Perspective

CHAIRPERSON

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

Health Canada has engaged in various forms of international cooperation over the years, from information sharing to harmonization and mutual recognition. This forum will look at current trends, drivers and opportunities for more effective cooperation and sort through the growing number of terms used to describe such activities. Specific examples will be presented as a basis for discussion, including the exploration of an international model for worksharing in the area of generic drug review.

A New Era in International Regulatory Cooperation: What You Need to Know
Mike D. Ward
Manager, International Programs Division, Health Canada

The Formation of a New International Initiative on the Review of Generic Drugs: A Regulator's Perspective
Andrew M. Adams
Director, Bureau of Pharmaceutical Sciences, Health Canada

The Formation of a New International Initiative on the Review of Generic Drugs: An Industry Perspective
Nicholas Cappuccino, PhD, MBA
CEO, Pharmaceutical Intellectual Resource Services, LLC

#238 Track 17B – Global Regulatory

Related Interest Area(s): CR, RA

10:00 AM–11:30 AM LEVEL: ● Format: **FORUM**
Room 117

Latin America Town Hall

CHAIRPERSON

Representative Invited
Associate Commissioner for International Programs, Office of the Commissioner, FDA

Join members of various Latin American agencies as they discuss individual country-specific regulatory framework and strategies related to the field of bioethics. Given the rapid growth of the clinical trials industry in the region, the Bioethics Committees topic has become more prominent as an area of research, public discussion and debate. It is no longer a subject that can be confined to science, medicine, and academia. As such, regulatory bodies across the region are facing the need of responding with an optimal framework that serves the whole industry while complying with the ethical aspect of the case. This forum has been designed as a frank, open dialogue among regulators to share their experiences in creating and implementing their sets of regulations covering Bioethics Committees (BECs)."

Bioethics Committees Regulation.
Luis Eduardo Johnson Rojas, Sr., MPH
Manager, Office of Clinical Trials and Bioethics, Instituto de Salud Publica de Chile (ISPCH), Chile

Panelists
Representative Invited
New Molecules and Research Director, COFEPRIS, Mexico

Augustina Bisio
Director, Drug Evaluation Agency, ANMAT, Argentina

Representative Invited
Manager, Research and Clinical Trials, ANVISA Brazil

#239 Track 22 – White Paper Showcase

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

10:00 AM–11:30 AM LEVEL: ● Format: **SESSION**
Room 125

Value of Actigraphy in Clinical Trials

CHAIRPERSON

Barry T. Peterson, PhD
Senior Manager, Clinical Affairs, Phillips Respironics

This White Paper Showcase will describe the current applications of actigraphy in clinical trials, important considerations when including actigraphy in the protocol, regulatory aspects, and current research that can increase the value of actigraphy in the near future.

Brought to you by Phillps Respironics.

Attendee badges scanned for this White Paper Showcase will be shared with the Company hosting this offering. If you prefer not to have your badge scanned, please inform the DIA staff member.

Jeremiah J. Trudeau, PhD
Director, Psychometrics and Outcomes, Analgesic Solutions

Susan M. Vallow, MA, MBA
Director, Patient Reported Outcomes, Janssen Global Services, LLC

John P. Breeden
Senior Manager Clinical Operations, Philips Respironics

11:30 AM–1:30 PM

LUNCHEON

Exhibit Hall

12:00 PM–12:45 PM LEVEL: ●

Aptiv® Solutions Innovation Theater

Related Interest Area(s): RD, IT

See the map located on the back of the Exhibitors tab for location.

SPECIAL SESSION

ADDPLAN PE- Innovative Software for Population Enrichment Designs in Adaptive Clinical Trials

There is a growing interest among regulators and sponsors in using personalized medicine approaches that allow for targeted patients to receive maximum benefit from the correct dose of a specific drug. Population enrichment designs offer a specific adaptive trial methodology to study the effect of experimental treatments in various subpopulations of patients under investigation. ADDPLAN PE is the first and only software available for the design and simulation of population enrichment trials.

#240 Track 01A – Clinical Operations

Related Interest Area(s): CR, IS, QAQC

1:30 PM–3:00 PM LEVEL: ■ Format: **FORUM**

Room 109ab *CME and Nursing*

Effective and Efficient Monitoring as a Component of Quality Assurance in the Conduct of Clinical Trials

CHAIRPERSON

Joan Harley, BSN, RN

Training Consultant and eLearning Developer, Training Extension, Division of Pastor Consulting, Inc.

The forum will present data collected from the Clinical Trials Transformation Initiative (CTTI) survey on clinical trial monitoring and auditing practices used by organizations to address regulatory requirements, provide a rationale for the re-evaluation of these practices, and summarize new industry trends in the areas of monitoring and auditing of clinical trials.

Training, Site Selection, and Human Subject Protection: Factors to Consider When Developing a Monitoring Plan
Cynthia Kleppinger, MD
Senior Medical Officer, Office of Scientific Investigations, CDER, FDA

Source Data Verification: Targeting Critical Elements
Cynthia R. Zacharias
Executive Director, Clinical Operations-Americas, Celgene Corporation

Range of Practices for the Monitoring of Clinical Trials
Jennifer K. Giangrande, PharmD
Senior Regional Manager, Hoffmann-La Roche Inc.

Panelist
Jules T. Mitchel, PhD, MBA
President, Target Health Inc.

#241 Track 01B – Clinical Operations

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 108a *CME, Nursing and PMI PDUs*

Investigator Budgets' Impact on Patient Enrollment and Retention: How to Improve Sponsor/CRO/Site Selection Processes

CHAIRPERSON

Daniel M. Ulrey, MBA

President and CEO, Midwest Clinical Support, Inc.

Study budgets and site identification and selection processes continue to result in study timelines being extended and a significant loss of experienced investigators. Senior executives from industry will discuss how identification and selection processes can be improved as well as how to achieve real fair market value in site study budgets and payment terms. These methods and processes continue to cause a dramatic reduction in the number of GCP-qualified US-based investigators and have dramatically extended study timelines and added significant cost to Pharma, resulting in severe Pharma employee reductions and cost shifting of R&D expense to CROs. It remains to be seen if this strategy will result in increased productivity.

Sites Tackle the Financial Challenges of Conducting Clinical Research
Joan A. Chambers
Chief Operating Officer, CenterWatch, Inc.

Planning for and Executing a Successful Study Start
Kellie Malloy
Vice President & General Manager, Pain & Inflammatory Disease/CV and Metabolic, Pharmanet/i3

Does Site Reimbursement Support Patient Recruitment and Retention?
Debby Brown
Senior Vice President, Clinical Operations, ICON Clinical Research

#242 Track 01C – Clinical Operations

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

1:30 PM–3:00 PM LEVEL: ■ Format: **WORKSHOP**

Room 123

Sponsors and CROs: Don't Be Misled by Your Site Performance Data

CHAIRPERSON

Adam Chasse, MHA

Vice President, Corporate Development, RxTrials, Inc.

More sponsors/CROs are using historical performance data for site selection and partnering decisions. However, many companies fall into decision traps because they collect the wrong data and/or interpret them inappropriately. This workshop will address the development of metrics, as well as discuss their interpretation and the common decision traps that project managers fall into when considering predictive value of metrics.

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Facilitator
Christopher J. Hoyle, MBA
Executive Director, Elite Research Network

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

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SYMPOSIUM**

Room 113b

Planning Your Drug's Development Life Cycle

CHAIRPERSON

Gregg Schneider
Director, R&D Financial Management, Otsuka Pharmaceutical

This symposium will focus on issues surrounding a drug's development life cycle, the use of simulation modeling to enhance development strategy and portfolio decision making, as well as new approaches in portfolio risk assessment and mitigation.

Planning Your Drug's Development Life Cycle: A Primer
Scott A. Simmons, MA
Consultant, Pharmaceutical Project Management, Eli Lilly and Company

Using Simulation Modeling to Support Development Strategy and Portfolio Management
Badri Rengarajan, DrMed
Medical Director, Archimedes

Strategic Portfolio Planning for Global Drug Development: Approaches, Techniques, and Tools
Vladimir Shnaydman, PhD
President, ORBee Consulting

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

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 103c

Leaping the Valley of Death: Keys to Successfully Going from the Lab to the Clinic for Pharmaceutical Products

CHAIRPERSON

Michael A. Swit, JD
Special Counsel, Duane Morris, LLP

Going from the lab to the clinic is the first huge leap in drug development. This session will explore how to ensure that the jump over the "valley of death" is smooth and avoids the sponsor falling into an abyss of bad decisions and poor results.

Unique Advantages of an Integrated Vertical in the Drug Discovery and Development Process
Zia Haque, MA
Senior Director, Clinical Data Management, Jubilant Clinsys

If Moses Could Cross the Red Sea, You Can Traverse the Valley of Death
Gerald J. Yakatan, PhD
Chairman, CEO, and Founder, IriSys, Inc.

#245 Track 03 – Innovative Partnering Models and Outsourcing Strategies

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

1:30 PM–3:00 PM LEVEL: ◆ Format: **FORUM**

Room 121ab *PMI PDUs*

Collaborative Partnerships in Drug Development: An Executive Roundtable Discussion

CHAIRPERSON

Ed Silverman
Editor, Pharmalot, UBM

Hear from top executives as they share their vision for the future of pharmaceutical development. What will it look like in five years, and how do we get there? What trends do we see? Have we seen the end of risk- and equity-sharing models in partnering? What are the pressures of private versus public ownership?

Submit your questions to the panel to annualmeetingprogram@diahome.org, Subject: collaborative partnerships

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

Panelists
Jeffrey P. McMullen
President and CEO, PharmaNet/i3, an inVentiv Health Company

William J. Sharbaugh, MA, MSc
Chief Operating Officer, PPD

Josef von Rickenbach, MBA
Chairman and CEO, PAREXEL International

Paula Brown Stafford, MPH
President, Clinical Development, Quintiles

John Watson
Chief Commercial Officer, Corporate Senior Vice President, and President of Strategic Partnering, Covance Inc.

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

Related Interest Area(s): NC, PC, CP

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 124 *CME and Nursing*

Product Candidate to Proof-of-concept: An Integrated Approach to Accelerate Programs

CHAIRPERSON

John Shillingford, PhD
Vice President, Strategic Initiatives, Aptiv Solutions, Germany

This session will look at the Early Phase Team's decision-making processes, use of adaptive designs to facilitate studies, and reduction of study times. An integrated approach with the aim to facilitate rapid development go/no-go decisions.

Into Patients, Timely but Safely, Using Integrated and Adaptive Design Approaches
John Shillingford, PhD
Vice President, Strategic Initiatives, Aptiv Solutions, Germany

Use of Adaptive Designs in Dose Finding Studies
Joachim Vollmar, MSc
Chief Executive Officer, Prescos LLC

Adaptive Optimal Model-based Designs in Drug Development
Abdul J. Sankoh
Senior Director, Vertex Pharmaceuticals

#247 Track 06 – Medical Writing and Medical Communications

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room 108b *CME, Pharmacy, and Nursing*

From Design to Disclosure: Pleasing Multiple Masters

CHAIRPERSON
Kenneth A. Getz, MBA
Tufts Center for the Study of Drug Development, Chairman, The Center for Information and Study on Clinical Research Participation (CISCRP), Tufts University

Regulatory, scientific and operating requirements, concerns and objectives are contributing to: (1) increased complexity in protocol designs, clinical study report submissions, and study results reporting; (2) higher levels of planning and operating inefficiency. This symposium explores opportunities to realize substantial cycle time and cost savings through improvements in protocol design planning, standardized clinical study report authoring and the implementation of best disclosure practices.

Minimizing Irrelevant and Unused Protocol Data and Reducing Protocol Amendments
Kenneth A. Getz, MBA
Tufts Center for the Study of Drug Development, Chairman, The Center for Information and Study on Clinical Research Participation (CISCRP), Tufts University

Clarifying ICH E3
Helle Gawrylewski, MA
Senior Director, Medical Affairs/Alliance Management, Regulatory Medical Writing CoE, Janssen Pharmaceutical Companies of Johnson & Johnson

Mutually Exclusive Public Disclosure Regulatory Requirements
Uma Swaminathan, MBA, MSc
Senior Manager, Web Disclosure, Biologicals, GlaxoSmithKline, Belgium

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

Related Interest Area(s): CDM, EC, ST

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**
Room 103a *CME, Pharmacy, and Nursing*

Implementing Adaptive Clinical Trials: A Practical Perspective

CHAIRPERSON
Bill Byrom, PhD
Senior Director of Product Strategy, Perceptive Informatics, UK

During the past decade we have seen increasing interest in adaptive trial designs, and with the release of regulatory agency guidelines a cautious encouragement and acceptance of the methodology now prevails. Nevertheless, while the promise of these designs is acknowledged, the operational challenges in their implementation are less well understood. Through three presentations, this session explores different aspects of practical implementation of adaptive clinical trials in clinical development programs. We will focus on practical implementation learning using case study illustrations where possible.

Managing the Drug Supply Demands of Adaptive Trial Designs
Graham J. Nicholls, MS
Director, Biostatistics, Almac Clinical Technologies LLC, UK

Practical Considerations in Designing and Monitoring Adaptive Clinical Trials
Martin Kimber, PhD
Project Manager, Adaptive Clinical Trials, Tessella plc, UK

Practical Implementation of Bayesian Response Adaptive Designs: Case Studies of Technology Approaches
Bill Byrom, PhD
Senior Director of Product Strategy, Perceptive Informatics, UK

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

Related Interest Area(s): VA, IT, QAQC

1:30 PM–3:00 PM LEVEL: ■ Format: **FORUM**
Room 103b *Pharmacy*

Innovative Ways of Looking at Computer System Validation

CHAIRPERSON
Frances E. Nolan, MBA
Vice President, Quality and Regulatory Affairs, Medidata Solutions Worldwide

Much has been proselytized on computer systems validation (CSV) for years. However, as the pharmaceutical industry has changed, and is still changing, so the established dogma of CSV, with its associated mysticism and time-consuming and costly practices is still proving stubbornly resistant to modernization. This interactive panel session will discuss the key issues, address the hurdles to change, and present a set of clear recommendations.

Computerized Systems Validation: What if We Used Common Sense?
Uwe P. Trinks, PhD
Partner, Foresight Group, LLC

Panelists
Eric Staib
Director, Global IT Quality, Covance, Inc.

Keith M. Parent, MS
Chief Executive Officer, Court Square Group Inc.

#250 Track 08 – Regulatory Affairs and Submissions

Related Interest Area(s): PR, CmbP, MDD

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**
Room 120bc

An Ocean Apart? Integrating Distinct Health Authority Philosophies on Personalized Medicines and Companion Assays

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

Recently FDA and EMA released guidance to assist with co-development, but creation of a global registration strategy remains challenging. This session will bridge diverse regulatory perspectives to accelerate global co-development efforts.

Focus on Co-development: Issues to Consider when Contemplating the Process
Elizabeth A. Mansfield, PhD
Director, Personalized Medicine, Office of In Vitro Diagnostics, CDRH, FDA

Genomics Biomarkers Contribution to Personalized Medicines
Marisa Papaluca-Amati, MD
Head of Scientific Support and Projects, European Medicines Agency, European Union

Charting the Regulatory Course for Global Co-Development of a Therapeutic Product and Companion Diagnostic
Linda J. Burdette, PhD
Director, Hoffman-La Roche Inc.

#251 Track 09 – Medical Diagnostics and Devices

Related Interest Area(s): FI, RD

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**
Room 118c

Funding Innovation and Creating Opportunities in the Device, Diagnostic, and Drug Interface

CHAIRPERSON
Daniel R. Matlis, MS
President, AXENDIA, Inc.

Funding is the lifeblood of innovation. In the current economic climate, funding sources have become more difficult to obtain. This session will cover the current environment for supporting innovation in the US, recent trends, and identify strategies and sources for funding at the device, diagnostic, and drug interface.

Panelists
Donna Usiskin
Principal, Edison Ventures

Tom Olenzak
Managing Director, Drexel Partners, LLC

#252 Track 10 – Public Policy/Health Care Compliance/Regulatory Law

Related Interest Area(s): RA, RD

1:30 PM–3:00 PM LEVEL: ● Format: **SESSION**
Room 113c *CME, Pharmacy, and Nursing*

Drug Rediscovery as an Innovative Tool to Meet Unmet Medical Needs

CHAIRPERSON
John A. Lisman, LLM, MPharm
Lawyer, Lisman Legal Life Sciences B.V., Netherlands

Drug Rediscovery is the science dealing with the use of old active substances to develop new treatments. This session focuses on the benefits and challenges of drug rediscovery.

Introduction to Drug Rediscovery
John A. Lisman, LLM, MPharm
Lawyer, Lisman Legal Life Sciences B.V., Netherlands

Inhaled Buformin for Lymphangioleiomyomatosis and Lung Cancer
Steven Lehrer, MD
President, Fermata Pharma Inc.

Drug Rediscovery in the Netherlands: 6-TG
Chris J. J. Mulder
Professor, Gastroenterology, VU University Medical Center, Netherlands

#253 Track 11 – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**
Room 115c *CME, Pharmacy, and Nursing*

What Should You Put in a Clinical Quality Assurance (CQA) Agreement

CHAIRPERSON
Neil McCullough, PhD, MSc
Vice President, Global Quality and Compliance, PPD

This session will focus on how to properly develop, organize, and initiate a Clinical Quality Assurance (CQA). Discussions will include examples of content categories, content, and experiences from speakers who have developed and implemented a CQA.

Sponsor QA Perspectives and Case Studies
JoAnna R. Brodie
Director, Clinical Quality Assurance Americas, GlaxoSmithKline

CRO QA Perspectives and Case Studies
Cassandra Kennedy
Senior Vice President, Global Quality Assurance, Quintiles

Current Industry Focus and Opportunities
Lisa McKay, MBA
Senior Director, Relationship Management Programs, The Avoca Group Inc.

#254 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC, RA, IT

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**
Room 119a

Practical Implementation of Knowledge Management

CHAIRPERSON
Georges L. France, PharmD, PhD
Head of Quality Assurance and Compliance, EU Region, Novartis Consumer Health S.A., Switzerland

This session will discuss knowledge management (KM) during and after QbD development. We will discuss key data to be considered, IT tools support, practical experience and debate about regulatory expectations.

FDA Point of View
Tara R. Gooen, MS
Team Leader, Office of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

Industry Point of View
Stephan Karl Roenninger, DrSc
Head, External Collaboration Europe/Japan/CEMA, F. Hoffmann-La Roche Ltd., Switzerland

Industry Point of View
Carol A. Bye
Vice President, Head of Pharmaceutical Sciences Quality Assurance, Pfizer Ltd., UK

#255 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

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

1:30 PM–3:00 PM | LEVEL: ● | Format: **FORUM**

Room 107ab | *CME, Pharmacy, and Nursing*

Registries for Evaluating Patient Outcomes: Emerging Areas of Controversy

CHAIRPERSON

Richard Gliklich, MD
President, Outcome

Presenters will introduce the third edition of "Registries for Evaluating Patient Outcomes," a widely used guide describing best practices for registries, and discuss emerging areas of controversy in registry design, operations, and analysis.

Introduction
Elise Berliner, PhD
Director, Technology Assessment Program, Agency for Healthcare Research and Quality (AHRQ)

Emerging Areas of Controversy in the Use of Patient Registries
Richard Gliklich, MD
President, Outcome

#256 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): IS, RA

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**

Room 119b | *CME and Nursing*

Noninterventional Minimal Risk Research: A 360° Perspective

CHAIRPERSON

Linda M. Coleman, JD
Director of Regulatory Affairs and General Counsel, Quorum Review IRB

In this interactive session, experts will explore the various types of noninterventional minimal risk studies (including postapproval noninterventional studies, registries, safety-surveillance, and REMS) and their design to ensure compliance with regulatory requirements. The session will also explore the IRB, industry, and site perspective including the value of noninterventional minimal risk studies and models for streamlining the IRB review process.

Industry Perspective
Kathleen A. Mandziuk, BSN, MPH, RN
Senior Scientific Affairs Director, PRA International

IRB Perspective
Linda M. Coleman, JD
Director of Regulatory Affairs and General Counsel, Quorum Review IRB

Industry Perspective
Lindsay Crampton
Project Manager, PPD

FDA Perspective
Winifred Ann Meeker-O'Connell, MS
Acting Associate Director, Risk Science, Intelligence, and Prioritization, Office of Scientific Investigations, Office of Compliance, CDER, FDA

#257 Track 14B – Clinical Safety and Pharmacovigilance

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

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**

Room 118a | *CME and Nursing*

Stepping Up and Doing It Step by Step: Lessons Learned from Initial Endeavors Exploring Health Care Data for Signal Detection

CHAIRPERSON

Preciosa M. Coloma, MD, MSc, RPh
Researcher, Erasmus University Medical Center, Netherlands

Health care records are valuable data sources that can complement spontaneous reports. Experts from pioneering international initiatives will share experiences and discuss challenges and lessons learned from preliminary efforts using electronic health records (EHR) for signal detection.

Does Spontaneous Report Data Mining Have a Future?
Alan M. Hochberg
Integrated Safety Risk Manager, F. Hoffmann-La Roche Ltd., Switzerland

Lessons from the Observational Medical Outcomes Partnership
Patrick Ryan, MS
Head, Epidemiology, Janssen Research & Development, LLC

The EU-ADR Project and Perspectives on Inter-continental Collaboration
Martijn Schuemie, PhD
Assistant Professor; Visiting Research Scientist, Observational Medical Outcomes, Columbia University

#258 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, RA

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**

Room 113a | *CME, Pharmacy, and Nursing*

Noninferiority Trial Designs: Perspectives from Academia, Industry, and a Regulatory Agency

CHAIRPERSON

Weishi Yuan, PhD
Biomed Statistician, Office of Translational Sciences, CDER, FDA

There are more clinical trials done using noninferiority design in recent years. In this session, we have invited experts from these three fields to discuss their perspectives on noninferiority designs, method, and experiences.

Not Noninferiority: Active Controlled Randomized Trial
Kevin J. Carroll, MSc
Statistician, AstraZeneca Pharmaceuticals LP, UK

Non-inferiority Trials in Oncology: A Regulatory Perspective
Rajeshwari Sridhara, PhD
Director, Division of Biometric V, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Issues in Design and Analysis of Noninferiority Trials
Brent Logan, PhD
Professor, Division of Biostatistics, Medical College of Wisconsin

#259 Track 16 – Professional Development

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

1:30 PM–3:00 PM LEVEL: ■ Format: **WORKSHOP**

Room 121c

Definition and Validation of Core Competencies to Enhance the Quality of Clinical Trials and Those Who Conduct Them

CHAIRPERSON

Stephen A. Sonstein, PhD, MS
Director, Clinical Research Administration, Eastern Michigan University

Several groups have developed documents of core competencies required of those involved in conduct of clinical research. This workshop will discuss these efforts and provide participants an opportunity to validate competencies from the stakeholder perspective.

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

Competencies for Principal Investigators and Pharmaceutical Physicians
Honorio Silva, MD
President, Inter-American Foundation for Clinical Research (IAFCR)

Clinical Research Nurse Coordinator Competencies-Evolutions and Collaborations
Carolynn J. Thomas-Jones, BSN, MPH, RN
Faculty Instructor, School of Nursing, University of Alabama at Birmingham

#260 Track 17A – Global Regulatory

Related Interest Area(s): CMC, RA

1:30 PM–3:00 PM LEVEL: ● Format: **SESSION**

Room 122b

Update from the EMA-FDA Parallel Assessment Pilot

CHAIRPERSON

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

This session will describe the scope of the EMA-FDA Parallel Assessment Pilot for applications containing Quality-by-Design Information. The purpose of this pilot, initiated in March 2011, is to help ensure consistent implementation of ICH quality guidelines and to harmonize regulatory decisions to the greatest extent possible. The progress on EMA-FDA parallel assessment to date and perceived challenges will be addressed.

FDA Point of View
Christine M. V. Moore, PhD
Acting Director, Office of New Drug Quality Assessment, CDER, FDA

EMA Point of View
Emer Cooke, MBA
(Acting) Head of International and European Cooperation, European Medicines Agency, European Union

#261 Track 17B – Global Regulatory

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

1:30 PM–3:00 PM LEVEL: ● Format: **FORUM**

Room 117

SFDA Town Hall

CHAIRPERSON

Ning Li, MD, PhD
Vice President, GRA Head, Medical Policy, Asia, Sanofi, China

Representatives from the State Food and Drug Administration, P.R. China will provide updates on initiatives, guidances, and regulations in their country, and the audience will have an opportunity to address the esteemed panel.

Clinical Trial Management in China
Jianan Wang
Pharmacist, State Food and Drug Administration (SFDA), China

Introduction to Newly Revised GMP Requirements
Huiping Chen
Senior Engineer, Center for Drug Certification, State Food and Drug Administration (SFDA), China

#262 Track 18 – Rare/Neglected Diseases

Related Interest Area(s): PM, RD

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 111ab *CME, Pharmacy, and Nursing*

Understanding the Challenges of Conducting Studies for Orphan Indications and Rare Diseases

CHAIRPERSON

Jackie Brown
Senior Project Manager, Premier Research Group Ltd.

Conducting a research study for an orphan indication and/or rare disease involves unique considerations in addition to the more common challenges of clinical research. Key logistical and operational considerations will be discussed including sharing of specific, relevant examples from different therapeutic areas and clinical settings as well as strategies and techniques to navigate the challenges. The session will also address specific examples of materials, procedures and techniques developed and utilized for protocol/study design development, site identification and support, IRB/EC approval, subject recruitment and retention, subject support, and program timeline and budget management.

Protocol Development Considerations
H. Jeffrey Wilkins, MD
Chief Medical Officer, Ceptaris Therapeutics

Project Management Considerations
Jackie Brown
Senior Project Manager, Premier Research Group Ltd.

Subject Recruitment and Site Considerations
Tara O'Meara
Director, Clinical Operations, Synageva BioPharma Corporation

#263 Track 21 – Late Breaker

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

1:30 PM–3:00 PM LEVEL: ● Format: **FORUM**

Room 105ab

A Challenge for the Industry: What Will it Take for a Sponsor to Use EHRs With a Regulated Research Protocol?

CHAIRPERSON

Rebecca D. Kush, PhD
President and CEO, CDISC

This forum will begin with a brief overview of current readiness for EHRs to support regulated research and provide an opportunity for open discussion with representatives of FDA and the HHS in terms of their views on the use of EHRs for regulated research and the concerns that have discouraged research sponsors from bringing this available opportunity into reality. A challenge will be issued to sponsors to bring a protocol forward to use EHRs for clinical research in an actual regulated research study. The forum will also discuss value and opportunities for sponsors who lead the way for the industry in leveraging EHRs to increase research capacity and efficiency.

Representative Invited
Director, Office of Interoperability and Standards, Office of the National Coordinator, Office of the Secretary, DHHS

Jonathan S. Helfgott, MSC
Consumer Safety Officer, Division of Scientific Investigations, CDER, FDA

Jane Griffin, RPh
Director, Research Client Connect, Cerner Corporation

#264 Track 22 – White Paper Showcase

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

1:30 PM–3:00 PM LEVEL: ● Format: **SESSION**

Room 125

The Unique Relationship Between Global Patient Recruitment and Translation Management

CHAIRPERSON

Diana L. Anderson, BSN, PhD, MSN
President, DAC Patient Recruitment Services

This White Paper Showcase explores solutions to key challenges clinical trial sponsors face in the recruitment arena including. 1) Ensuring the Literal and Colloquial Accuracy of Translations; 2) Coordinating Communication and Managing Data Files and 3) Managing the Complexities and Time Involved in Translation of Materials for Patient Recruitment.

Brought to you by DAC Patient Recruitment Services.

Attendee badges scanned for this White Paper Showcase will be shared with the Company hosting this offering. If you prefer not to have your badge scanned, please inform the DIA staff member.

Panelist
Erica Kay Manning, JD
Project Manager, ClinicaLingua

3:00 PM–3:30 PM **REFRESHMENT BREAK**
Exhibit Hall

#265 Track 19A – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 103a *CME, Pharmacy, and Nursing*

Beyond Taxonomy

CHAIRPERSON

John M. Weiler, MD, MBA
President, CompleWare Corporation

This showcase will discuss the taxonomy of study endpoints and how this is important in study design.

Developed by the Study Endpoints (SE) SIAC.

John H. Powers, III, MD, FACP
Senior Medical Scientist, Collaborative Clinical Research Branch, NIAID, SAIC/National Institutes of Health

Laurie Burke, MPH, RPh
Director for Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

#266 Track 19B – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 103b *CME and Nursing*

Breaking News Update: Cutting Edge Statistical Methods in Clinical Development

CHAIRPERSON

Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

The statistical methods used in drug development are changing rapidly. This showcase will highlight the tip of the iceberg of the most important and controversial methods just beginning to be deployed. We will also discuss FDA reaction.

Developed by the Statistics (ST) SIAC.

Industry Perspective
Matthew D. Rotelli, PhD, MS
Director – PK/PD, Bio-Medicines, Eli Lilly and Company

FDA Perspective
Stephen E. Wilson, USPHS, DrPH
Director, Division of Biometrics III, CDER, FDA

#267 Track 19C – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ● Format: **SIAC**

Room 121ab

CDER Electronic Submissions Standards Update

CHAIRPERSON

Charles K. Cooper, MD
Medical Officer, Office of Translational Sciences, CDER, FDA

This showcase will explore CDER's ongoing efforts to move towards electronic standards and how those standards will help the Center effectively perform its critical public health mission. Topics include CDISC SDTM, ADaM and the OSI site-level dataset.

Hosted by the Electronic Regulatory Submissions (ERS) SIAC.

CDER Data Standards Program: Challenges and Progress
Mary Ann Slack
Deputy Director, Office of Planning and Informatics, CDER, FDA

Site-Level Dataset Request for Clinical Investigator Site Selection
Paul Okwesili, Jr., MS
Operations Research Analyst, Office of Scientific Investigations, Office of Compliance, CDER, FDA

Panelist
Joy Mele, MS
Statistical Reviewer, Office of Medical Products and Tobacco, Office of Biostatistics, Office of Translational Science, CDER, FDA

#268 Track 19D – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**
Room 103c

Controversial Guidance, eSource and Standards: How Does It All Fit Together in an eClinical World?

CHAIRPERSON
Jonathan R. Andrus, MS
Vice President, Data and Study Operations, BioClinica, Inc.

This showcase will aim to address the intricacies of navigating an ever changing eClinical world. Presentations will be shared from a technology, regulatory and standards perspective with an emphasis on how it all fits together. With recently issued draft guidance, clinical research professionals are being encouraged to be more electronic in their approach to clinical trials and to use more remote and central monitoring for clinical trials. The end of the research silo era is near.

Developed by the eClinical (EC) SIAC.

The Draft eSource Guidance — What Does It Mean to Me As a Site, CRA and Data Manager
Joseph Dustin
Senior Business Consultant, Medidata Solutions Worldwide

The Draft Risk Based Monitoring Guidance — What Does It Mean For eClinical?
Joseph Schenk, MS
CEO, QA Edge, Inc.

#269 Track 19E – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ● Format: **SIAC**
Room 108a *CME, Pharmacy, and Nursing*

Cross-sector Innovation Brings Tailored Therapies to Patients

CHAIRPERSON
Melvyn Greberman, MD, MPH, MS, FACPM
President, Public Health Resources, LLC

This showcase will discuss targeted tailored therapy and its integral role in the innovation of patient-centered care. The delivery of targeted tailored therapies requires multidisciplinary collaborative product development and continuous evaluation from bench to bedside. Innovation through translational research models, decision-making efforts during drug development, and companion development of technology and devices are keys to the future successful delivery of targeted tailored therapies and expansion of diseases that may be treated.

The showcase was developed by the Clinical Research (CR) SIAC, and presentations and attendee/speaker discussions will be used to develop future CR SIAC initiatives and collaborations.

Bioinformatics and Biotechnology: Issues of Complexity and Collaboration
J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality (AHRQ)

Recent Questions about the Effective Use of Biomarkers
Richard M. Tresley, MD, PhD
Executive Director, Astellas Pharma US

#270 Track 19F – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**
Room 105ab *CME, Nursing, and PMI PDUs*

Electronic Data Capture (EDC): How Much Quality Is Enough?

CHAIRPERSON
Laurie S. Callen
Director, Clinical Data Management, Sunovion Pharmaceuticals

This is a complicated question that challenges many clinical study teams, particularly with respect to Electronic Data Capture (EDC) systems. In an effort to provide direction to these teams, a Clinical Data Management (CDM) SIAC Working Group is exploring the changing expectations of data quality as a result of EDC and the processes, procedures and tools recommended to optimize data quality.

Developed by the Clinical Data Management (CDM) SIAC.

Ensuring Quality Control for Electronic Data Capture Systems
Scott Brand, PhD
Director of Strategic Planning and Quality Assurance, KAI Research Inc.

Electronic Data Capture Quality: Define, Measure, and Deliver
Ellen Hinkle, MA
Clinical Data Specialist II, Vertex Pharmaceuticals

#271 Track 19G – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ● Format: **SIAC**
Room 107ab

Emerging Professionals: Optimize your Transition into the Pharmaceutical Arena

CHAIRPERSON
Yasmin de Faria Krim, PharmD
Manager, Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium

This showcase will highlight key points for optimizing the emerging professional's transition into the pharma industry, including skill building, the benefits of mentoring, and having a professional development plan.

Developed by the Emerging Professional Group (EP) SIAC.

Emerging Professionals: Pearls of Wisdom for Career Success
Sandra A. Wiejowski, PharmD, RPh
Senior Director, Global Medical Review, Abbott Laboratories

#272 Track 19H – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 108b *CME, Pharmacy, and Nursing*

Evidence for the Marketplace: Bridging the Gap Between Industry, Payer, Providers, and Patients

CHAIRPERSON

Christopher M. Marrone, PharmD
Outcomes Liaison, Eli Lilly and Company

This showcase will draw on senior experts from industry, payer, provider, and patient stakeholder groups to offer unique perspectives on evidence. Analyzing at times competing viewpoints of similar evidence, the panel will offer insight into how similar evidence and outcomes can be viewed differently by various market segments. Similarly, this panel will highlight evidence needs that are specific to their needs in the hope of providing a more complete picture of what constitutes a comprehensive definition of "evidence of the market."

Developed by the Evidence Based Medicine (EBM) SIAC.

#273 Track 19I – SIAC Showcase

Related Interest Area(s): DM, RA, SUBS

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 109ab

Reference Models and the Framework for the Destruction of Paper: How They Are Changing Our Industry

CHAIRPERSON

Lisa D. Mulcahy
TMF Content Management Consultant, Mulcahy Consulting, LLC

The recent release of the Framework for the Destruction of Paper adds to the already widely used reference models that have been developed by the very active members of the Document and Records Management (DRM) SIAC. Join this session to review the DRM SIAC's mission and ongoing activities already underway including the released version 2.0 expansions of the Trial Master File Reference Model, the recent updates to the EDM-Submission Reference Model and introduce the very newly finalized Framework for the Destruction of Paper.

Developed by the Document and Records Management (DRM) SIAC.

TMF Reference Model: Introduction and Version 2.0 Expansions
Karen Jane Redding, MPharm
Director, Global Business Development, Phlexglobal Limited, UK

EDM-Submission Reference Model: Introduction and Recent Expansions
Antoinette M. Azevedo
General Manager, Sage Submissions

#274 Track 19J – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 111ab *PMI PDUs*

Globalization of Phase 1: Trends and Challenges

CHAIRPERSON

Barry Mangum, PharmD
Director, Clinical Pharmacology, Duke University Medical Center

This showcase will discuss trends, challenges and perspectives with speakers/panelists who are directly involved in the globalization of early phase research.

Developed by Clinical Pharmacology (CP) SIAC.

Recent Development of Activities in Phase 1 Studies in Korea
Min Soo Park, MD, PhD
Professor, Vice President, Yonsei University; KoNECT, Republic of Korea

Early Drug Development in India- Opportunities and Challenges
Savita Dhillon, DrMed, MD
Medical Director, Medanta Duke Research Institute, India

#275 Track 19K – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 113a *CME, Nursing, and PMI PDUs*

Good Pharmacovigilance Practice in a Global Environment

CHAIRPERSON

Steve Jolley, MA
Principal, SJ Pharma Consulting

This showcase will present the challenges in conducting drug safety and pharmacovigilance operations on a global basis and presents approaches to the harmonization of good pharmacovigilance practice across regions to accommodate many, if not most, regional requirements, while addressing specific local requirements. Safety and risk management practices in the EU, US, and Japan, including the new European pharmacovigilance legislation, are covered.

Developed by the Clinical Safety and Pharmacovigilance (CSP) SIAC.

Good Pharmacovigilance Practice
Sally Van Doren, PharmD
President & Chief Executive Officer, BioSoteria, Inc.

What Are We Afraid of Against New EU Regulations?
Teiki Iwaoka, PhD, MS
Executive Consultant, Director of Drug Safety Outsourcing Planning, CAC Corporation, Japan

#276 Track 19L – SIAC Showcase

Related Interest Area(s): MW, CR, QAQC

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 113b *CME and Nursing*

Hot Topics in Clinical Trial Disclosure (CTD)

CHAIRPERSON

Robert Paarlberg, MS
Principal, Paarlberg & Associates LLC

This showcase will discuss the ever changing clinical trial disclosure (CTD) landscape, the impact on industry, and how companies change their processes to maximize efficiencies to meet the increasing demands of global CTD requirements. Emerging CTD requirements in selected countries will be highlighted. The showcase will also focus on results disclosure in the EU as well as discuss the challenges and complexities companies face in meeting global CTD requirements. An update will be provided on the status of NLM's Notice of Proposed Rulemaking. In addition, the audience will be encouraged to share their organizations' perspectives on these issues and how they are meeting the challenges of clinical trial disclosure. Benefits of participating in the SIAC will also be discussed.

Developed by the Clinical Trial Disclosure (CTD) SIAC.

Significant Disclosure Developments in Selected Countries
John C. McKenney
President, SEC Associates, Inc.

The EU Clinical Trials Register: Practical Hurdles from a Company Perspective
Merete Joergensen, MBA, MSc
Director, Global Clinical Registry, Novo Nordisk A/S, Denmark

#277 Track 19M – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**
Room 120bc *CME and Nursing*

Hot Topics in Regulatory Affairs Forum

CHAIRPERSON
Linda F. Bowen, MS, RAC
Head, Regulatory Policy and Intelligence-US, Sanofi

During this showcase, leaders from the labeling and regulatory intelligence working groups will discuss hot and emerging topics in regulatory affairs. Learn about current trends in industry, how companies are handling the ever changing regulatory environment, and share approaches your organization may be leveraging.

Developed by the Regulatory Affairs (RA) SIAC.

Labeling Overview: Physicians Labeling Rule (PLR) and Beyond and Updates in 2011–2012
Steven W. Bass, PhD
President, Bass Biopharm Consulting Group LLC

Regulatory Intelligence Topics
Brooke Casselberry, MS
Senior Manager, Regulatory Affairs and Writing Services, Liquent, Inc.

#278 Track 19N – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**
Room 113c

How Medical Writers Are Improving Global Practice and Collaboration

CHAIRPERSON
Jeannine Hanson, MS
Senior Manager, Global Regulatory Writing, Amgen Inc.

In this showcase, we will examine how medical writers in the SIACs are participating in regulatory and professional forums to improve the exchange of information, and describe what those changes may look like. We will focus on what we need to accomplish in the next 5 to 10 years to better meet medical communication needs. Our objective is to inform members about policy discussions and to encourage SIAC members to participate in these forums.

Developed by the Medical Writing (MW) SIAC.

Defining Medical Writing Profession: Contributions to Competency and Certification
David B. Clemow, PhD
Clinical Research Scientist, Eli Lilly and Company

Contribution to Guidelines: DIA MW SIAC ICH E3 Task Force Influences Q&A to ICH E3 Guidance
Nancy R. Katz, PhD
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.

#279 Track 19O – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**
Room 116 *CME, Pharmacy, Nursing, and PMI PDUs*

Leveraging Technology in an Age of Readily Available Information

CHAIRPERSON
Natalie C. Gearhart, PharmD
Associate Director, Medical Information Center, Janssen Scientific Affairs, LLC

With the evolution of technology tools like smart phones and iPads, readily available information is our current reality. This showcase will focus on new ways to leverage technology to provide information and engage customers while building trust and credibility. Attendees will learn how to utilize technology as an enabler in responding to requests.

Developed by the Medical Communications (MC) SIAC.

Advanced Use of Technology in Medical Affairs Communications
William R. Hahn, Jr.
President, Science Branding Communications

Medical Communications in the Pharmaceutical Industry: Stone Age or Ahead of the Curve?
Natalie C. Gearhart, PharmD
Associate Director, Medical Information Center, Janssen Scientific Affairs, LLC

#280 Track 19P – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**
Room 115c *CME, Nursing, and PMI PDUs*

Meet the Regulators: Helping You Ensure GCP Compliance by Knowing the Most Frequent and Serious Findings

CHAIRPERSON
Munish Mehra, PhD
Managing Director, Quantum Biopharma

This showcase will bring together regulatory authority compliance experts from FDA and EMA who will share their perspective on inspections and common areas of GCP noncompliance.

Perspective from FDA/CDER
Leslie Ball, MD
Acting Director, Office of Scientific Investigations, CDER, FDA

EMA Perspective
Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

Developed by the Good Clinical Practice and Quality Assurance (GCP) SIAC.

#281 Track 19Q – SIAC Showcase

Related Interest Area(s): OS, PM, QAQC

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 117 *PMI PDUs*

Navigating the Intersection of Outsourcing and Quality Oversight

CHAIRPERSON

Tiffany Sizemore Cherry, JD, MBA
CEO, Pharmcontrax, LLC

This showcase will explore regulatory expectations for managing service providers via well-defined project governance and oversight processes. Trends in the post-contract award process, including deliverable management and quality control where clinical trial sponsors are ultimately responsible for the integrity of the data generated by their third-party vendors will be discussed. Explore various structures of governance and oversight and the outsourcing strategies they best support. In addition, panelists will make recommendations on ways to ensure the process is effective, efficient, and how to keep the operational teams focused on execution.

Developed by the Global Sourcing (GS) SIAC.

Designing an Optimal Third-Party Quality Oversight Program
John R. Wilson, PhD
Senior Vice President, Beaufort LLC

Service Provider Governance and Oversight: Examples from the Industry on the Balance Between Effectiveness and Efficiency
Todd Charles Reul
Clinical Outsourcing Consultant, Gilead Sciences, Inc.

#282 Track 19R – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 118a *CME, Nursing, and PMI PDUs*

New Guidances on Quality Risk Management by FDA and EMA: Implications for Industry

CHAIRPERSON

Kenneth J. Sprenger, MD, PhD
Executive Director, Medicine Team Leader, Pfizer Inc

Recent publications by FDA on risk-based monitoring and EMA's guidance in risk-based quality management in clinical trials and the current discussions at Clinical Trial Transformation Initiative (CTTI) will have a major influence on how clinical studies will be designed and conducted in the future. Regulators have issued guidances that discuss and describe how an approach to future quality management in clinical studies should look like. The implications for clinical trials will be discussed by a Sponsor and a CRO representative.

Developed by the Quality Risk Management (QRM) SIAC.

Risk-based Approaches in Clinical Trials: A Regulatory Perspective
Winifred Ann Meeker-O'Connell, MS
Acting Associate Director, Risk Science, Intelligence, and Prioritization Office of Scientific Investigations, Office of Compliance, CDER, FDA

Panelist
Representative Invited
Vice President, Clinical Quality Assurance, Quintiles, UK

#283 Track 19S – SIAC Showcase

Related Interest Area(s): CDM, CP

3:30 AM–4:30 AM LEVEL: ■ Format: **SIAC**

CME, Pharmacy, and Nursing

Pediatric Clinical Trials: Modeling and Simulation to Support the Bridging of Data

CHAIRPERSON

Gesine Bejeuhr, PharmD
Senior Manager, Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany

This showcase will provide **CANCELLED** illustrate the use of modeling and simulation in the planning and interpretation of pediatric clinical trials, such as contraceptives in adolescents. How much do we know? Which data can be extrapolated?

Developed by the Pediatric (PED) SIAC.

Representative Invited
Director, GlaxoSmithKline

#284 Track 19T – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 119a *PMI PDUs*

The Future of Project Management in the Pharmaceutical Industry: What Competencies Will Be Critical?

CHAIRPERSON

Martin D. Hynes, III, PhD
Senior Director, Six Sigma Champion, Research & Development, Eli Lilly and Company

The biopharmaceutical industry has been employing novel drug development models in order to bring new drugs to the market in a timely and cost-effective manner. This showcase will address the impact of these changes on the discipline of pharmaceutical project management. The core competencies for the pharmaceutical project manager of the future will be described.

Developed by the Project Management (PM) SIAC.

Managing Projects in the Pharmaceutical Industry: Why Is It So Hard?
Richard J. Heaslip, PhD
President and Founder, Programmatic Sciences

Innovative Drug Development Models: What Difference Can They Make?
Charles T. Gombar, PhD
Senior Vice President, Project Management, Endo Pharmaceuticals Holdings Inc.

#285 Track 19U – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ● Format: **SIAC**

Room 119b

Re-energize Your Career!

CHAIRPERSON

Daniel F. Mudgett
Vice President, Knowledge Management, Medidata Solutions Worldwide

This showcase is directed at those professionals who seek more out of their careers. Speakers will help provide the motivation and the techniques for

self-improvement and personal satisfaction through career growth. The panelist will help you take charge of your career right now! Proven steps to move ahead and make your career more enjoyable and more rewarding will be presented.

Developed by the Professional Education, Training & Development (PETD) SIAC.

Position Yourself for Long-term Success With Three Proven, Yet Underutilized Strategies
Ilyssa Levins
President, Center For Communication Compliance (CCC)

#286 Track 19V – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 121c

Rx: A New World in Natural Health Products (NHP)

CHAIRPERSON
Pradip K. Paul, MD, MS
Pharmacovigilance Consultant, Pharmacovigilance Consultant

Natural Health Products (NHP) is a rapidly growing area in the pharmaceutical and allied industry. Use of NHP as dietary, nutritional supplement or herbal remedies is getting through revolutionary changes — particularly with new initiatives of obtaining regulatory approvals. This showcase will focus on the observed recent trends.

Developed by the Natural Health Products (NHP) SIAC.

Why Big Pharmaceuticals Will Not Develop Polymolecular Natural Health Products as Ethical (RX) Drugs
Freddie Ann Hoffman, MD
CEO, HeteroGeneity LLC

Development of Botanical New Drug: Update on Regulatory Issues
Jinhui Dou, PhD
Botanical Review Team, Office of New Drugs, Office of Drug Evaluation IV, CDER, FDA

#287 Track 19W – SIAC Showcase

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

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 125 *CME and Nursing*

Status of the Use of Electronic Health Records (EHR) in Clinical Research

CHAIRPERSON
Richard L. Chamberlain, PhD, MS
President, Executive Consultant Services

The showcase will discuss the current status of the use of Electronic Medical Records (EMR) data in clinical research. Speakers will discuss their actual experience with the use (or non-use) of these data.

Developed by the Validation (VA) SIAC.

Connecting Healthcare and Clinical Research
Mitra Rocca, MS
Senior Medical Informatician, Office of Translational Sciences, CDER, FDA

FDA CDER Perspective: Use of EHRs in Clinical Research
Jonathan S. Helfgott, MSc
Consumer Safety Officer, Division of Scientific Investigations, Office of the Commissioner, CDER, FDA

Real (and Practical) Electronic Healthcare Information System Considerations
Earl W. Hulihan, MEd
Principal, ew hulihan and associates, inc.

#288 Track 19X – SIAC Showcase

Related Interest Area(s): IT, SP, ST

3:30 PM–4:30 PM LEVEL: ■ Format: **SIAC**

Room 124

Who Owns the Service? Challenges in Collaboration Between IT and the Business

CHAIRPERSON
Pamela Campbell, MBA
Senior Consultant, EMC Corporation

This showcase will examine how collaboration between IT and business users can be improved through processes and tools while improving a company's competitive edge in an industry currently experiencing economic and regulatory stress. Case studies will be presented.

Developed by the Information Technology (IT) SIAC.

Implementing A Complex Statistical Analysis Environment With An IT Savvy Business
Paulette V. Roper, MS
Director, Clinical Data Management THV, Edwards Lifesciences LLC

Maintaining Service Quality in a Shared Service Environment
Skip Garrison
Quality Assurance, Forest Laboratories, Inc.

4:30 PM **END OF TUESDAY OFFERINGS**

Open Business Meeting

4:30 PM–6:30 PM

Room 120A

Adaptive Design Scientific Working Group

The DIA Adaptive Design Scientific Working Group (ADSWG) is a multidisiplinary forum that enables noncompetitive collaboration on adaptive designs. The group's vision is to ensure that adaptive designs are a well-understood, accepted, and broadly utilized approach (where and when applied appropriately) in clinical research. In this session, an introduction to the ADSWG, current activities and opportunities for getting involved will be presented with opportunity for audience discussion. Also, recent results from 2 of the topic focused sub-teams (Data Monitoring Committee Processes and Approaches to Precision Medicine) will be presented.

NOTES

NOTES

WEDNESDAY, JUNE 27

Registration Hours:

7:00 AM–5:00 PM — Attendee and Speaker Registration
Broad Street Lobby

7:00 AM–5:00 PM — Exhibitor Registration
Exhibit Hall D Lobby

Schedule:

7:15 AM–8:00 AM — Coffee and Breakfast Breads
Meeting Rooms 108 and 119 Concourse

8:00 AM–9:30 AM — Concurrent Educational Opportunities

9:00 AM–3:30 PM — Exhibition Hall Open

9:30 AM–10:00 AM — Coffee Break
Exhibit Hall

10:00 AM–11:30 AM — Concurrent Educational Opportunities

11:00 AM–1:30 PM — Professional Poster Session #1 (see page 118)
Exhibit Hall D

11:30 AM–1:30 PM — Lunch with Optional Interest Area Seating
Exhibit Hall

1:30 PM–3:00 PM — Concurrent Educational Opportunities

1:30 PM–3:30 PM — Exhibit Guest Passes

3:00 PM–3:30 PM — Refreshment Break
Exhibit Hall

3:30 PM–5:00 PM — Concurrent Educational Opportunities

5:15 PM–7:00 PM — Consortium of Academic Programs in Clinical Research
Room 117

#301 Track 01A – Clinical Operations

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

8:00 AM–9:30 AM — LEVEL: ■ — Format: **SESSION**
Room 108a — *CME, Nursing, and PMI PDUs*

How Industry Can Partner with FDA in Defining a Risk-based Monitoring Program

CHAIRPERSON

Jan Holladay Pierre, MPH
Quality Principal Leader, Dynport Vaccine Company, LLC CSC

FDA encourages more effective monitoring of clinical trials through their August 2011 draft guidance. Risk-based monitoring strategies and approaches will be discussed from the FDA, sponsor and site perspectives, and a focus on expected key changes in FDA's bioresearch monitoring (BIMO) inspection program will be provided.

Responding to FDA's Guidance on Risk-based Monitoring
Terry Winchell
Consultant, GCP Innovative Dynamics, LLC

What Risk-based Monitoring Means to a CRA
Robert Johnalan Milford
CRA, Beardsworth Consulting Group Inc.

What Does a Risk-based Monitoring Program Look Like? A QA Perspective
Jan Holladay Pierre, MPH
Quality Principal Leader, Dynport Vaccine Company, LLC CSC

#302 Track 01B – Clinical Operations

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

8:00 AM–9:30 AM — LEVEL: ■ — Format: **FORUM**
Room 109ab — *CME, Nursing, and PMI PDUs*

Collaboration and Globalization of Clinical Trials: What Does It Mean to Pharmaceutical Project Managers?

CHAIRPERSON

Matthew J. Kiernan, MBA
Partner, Pharmica Consulting

Tools to help study personnel have not kept pace with the needs of global projects. With the advent of Web 2.0 technology, portals are a necessary tool to manage trials. This forum will discuss how Web 2.0 fits into the clinical trial space.

Collaboration and Globalization of Clinical Trials: What Does It Mean to Pharmaceutical Project Managers?
Matthew J. Kiernan, MBA
Partner, Pharmica Consulting

R&D Collaboration: Enabling Drug Teams with SharePoint
Mark Yuzuk
Director of Collaboration Services, Bristol-Myers Squibb Company

SharePoint as a Collaborative Global Project Management Portal
Michael J. Connolley, MBA
Associate Director, Global Project Management, Daiichi Sankyo Inc.

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

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

8:00 AM–9:30 AM — LEVEL: ■ — Format: **SESSION**
Room 105ab

Integrating Pharmacogenomics and Companion Diagnostic Development into the Integrated Clinical Development Plan

CHAIRPERSON

Michelle R. Smith, MS, PMP
Pharmaceutical Project Manager, Eli Lilly and Company

By integrating pharmacogenomics (PGx) and companion diagnostics (CDx) into the clinical development plan in the early stages of drug development, the clinical team can maximize their opportunity for tailored therapies and minimize the risk of a CDx registration holding up drug approval.

Integrating Pharmacogenomics into Clinical Development: Unraveling the Mystery
Michelle R. Smith, MS, PMP
Pharmaceutical Project Manager, Eli Lilly and Company

The Integration of IVD and Drug Development: Getting Started
Diane Rintzler Yen, PhD, PMP
Senior Project Manager, Merck Research Laboratories

K-Ras: A Case Study in Diagnostic Development
Christopher T. Harbison, PhD
Principal Scientist, Bristol-Myers Squibb Company

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

Related Interest Area(s): RA, SP, PM

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 103c

Asian Regulatory Agencies Relocated into Biotech Science Park as a Strategy for Global Drug Development

CHAIRPERSON

Herng-Der Chern, MD, PhD
Distinguished Research Fellow, Center for Drug Evaluation, Taiwan

Asian regulatory agencies, like the Singapore Health Sciences Authority and the Korea FDA, were relocated into biotech science parks, and Taiwan has developed a strategy of a supra-incubator center to become a proactive supporter of global drug development. In this session, we will examine these strategies and outcomes of new drug development from Singapore, Korea, and Taiwan.

Regulatory Consultation of Taiwan Supra Integrated and Incubation Center (SIIC) for Drug Development
Herng-Der Chern, MD, PhD
Distinguished Research Fellow, Center for Drug Evaluation, Taiwan

Regulatory Authorities and Company Co-location in Science Parks: Industry Perspective
Romi Singh, PhD
Executive Director, Global Regulatory Affairs and Safety, Amgen Inc.

PMDA Perspective
Tsuyoshi Ando, PhD
Deputy Manager, Office of Review Management, Pharmaceutical Affairs Consultation Group on R&D Strategy, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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

Related Interest Area(s): OS, SP, FI

8:00 AM–9:30 AM LEVEL: ■ Format: **FORUM**

Room 108b *PMI PDUs*

Risk-sharing Partnerships: Models for Managing Risk across the Clinical-Commercial Continuum

CHAIRPERSON

Patrick Jordan, MBA
Vice President, Global Customer Solutions, Quintiles

In the current health care landscape, never has there been so much risk or opportunity to develop and commercialize new therapeutics. In this forum, we will share different perspectives on nontraditional pharma partnerships that are designed to reduce risk and enhance innovation, including a CRO perspective to talk about ways to manage operational risk, a third-party capital perspective on managing financing risk, and a payer perspective on how pharma can manage commercial risk by partnering earlier on reimbursement strategy.

Case Study: Innovative Partnering Models for More Profitable Drug Development
Tim Dietlin, MBA
Vice President, Alliance Development, INC Research, Inc.

Product-Based Investing in BioPharma
William Robb, MBA
Partner, NovaQuest Capital Management

Risk-sharing Partnerships: Opportunity for Access and Quality
Edmund Pezalla, MD, MPH
National Medical Director for Pharmacy Policy and Strategy, Aetna

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

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

8:00 AM–9:30 AM LEVEL: ● Format: **SESSION**

Room 111ab

Patient Advocacy and Your Next Generation of Research: How Nonprofit Organizations Can Accelerate Product Development

CHAIRPERSON

Craig Martin
Chief Executive Officer, Feinstein Kean Healthcare

This session provides insights into the rapidly emerging world of collaborations between pharma and patient advocacy organizations to accelerate basic and clinical research by leveraging the data and participation from patients.

Advocacy 3.0: A New Model Through Technological Innovation
William Anthony Tulskie, MS
CEO, Healthcare IT, Inc.

Accelerating Personalized Medicine in Myeloma: Foundation Perspective
Louise Perkins, PhD, MS
Chief Scientific Officer, Multiple Myeloma Research Foundation

Accelerating Personalized Medicine in Myeloma: Pharmaceutical Perspective
George J. Mulligan, PhD
Senior Scientist, Milennium Pharmaceuticals

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

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

8:00 AM–9:30 AM LEVEL: ● Format: **SESSION**

Room 124 *CME and Nursing*

Nanotechnology: Regulatory Challenges and Opportunities

CHAIRPERSON

Joseph C. Scheeren, PharmD
Senior Vice President, Head Global Regulatory Affairs, Bayer Healthcare Pharmaceuticals

This session will provide an overview on FDA's approach on regulating products with nanotechnology. There will also be a focus on industry case studies on experiences and challenges with nanotechnology development.

FDA's Approach on Regulating Products with Nanotechnology
Ritu Nalubola, PhD
Senior Policy Advisor, Office of Policy, Office of the Commissioner, FDA

Frontiers in Nanomedical Development: An Academic Perspective
Kathleen K. Eggleson, PhD
Research Scientist, Center for Nano Science and Technology, University of Notre Dame

Industry Perspective
Representative Invited
Co-Founder, President and Chief Executive Officer, CytImmune Sciences, Inc.

#308 Track 05 – Product Advertising and Marketing

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

8:00 AM–9:30 AM | LEVEL: ● | Format: **WORKSHOP**

Room 113b | *Pharmacy*

Prescription Drug Marketing Regulatory Primer

CHAIRPERSON

Janet L. "Lucy" Rose
President, Lucy Rose and Associates, LLC

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

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

FDA Point of View
Michael A. Sauers
Lead Consumer Safety Officer, Office of Prescription Drug Promotion, Office of Medical Policy, CDER, FDA

#309 Track 06 – Medical Writing and Medical Communications

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

8:00 AM–9:30 AM | LEVEL: ● | Format: **WORKSHOP**

Room 121c | *CME, Pharmacy, and Nursing*

Implementing Structured Authoring: Understanding the DITA Model and Its Applicability for Content and Metadata Management

CHAIRPERSON

Michael J. Brennan, PhD
Director, Informatics, Johnson & Johnson Pharmaceutical Research & Development, LLC

This workshop will describe the applicability of the DITA (Darwin Information Typing Architecture) Model for the creation and management of pharmaceutical documentation. This workshop will describe the experience of different pharmaceutical companies to implement content design.

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

The Paradigm Shift to Structure Content Management: Bringing Change and Agility
Michael Robbins, MS
Domain Manager, TIM Solutions Delivery and Integration, CSM, Sanofi

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

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

8:00 AM–9:30 AM | LEVEL: ■ | Format: **SESSION**

Room 103a | *CME, Pharmacy, and Nursing*

Combining Patient Self-report and Clinician Oversight: Are Two Heads Better than One?

CHAIRPERSON

John Greist, MD
CEO, Distinguished Senior Scientist, Madison Institute of Medicine, Healthcare Technology Systems

This session will address the roles of patients in providing, and clinicians in acquiring and evaluating, subjective patient experiences and the process of converting patient experience into analyzable data. Factors addressed will include accessibility to subjective experience, competence to judge symptomatology, subject sensitivity, method of assessment, and variability between patient reports and professional assessments. Using suicidality as an example, approaches to balancing different but overlapping perspectives and integrating them into an accurate whole will be discussed.

Challenges in Developing Composite Clinical Endpoints: Clinician and Patient Reported Outcomes in Aesthetic Indications
Jean Paty, PhD
Founder and Senior Vice President, Scientific, Quality and Regulatory Affairs, invivodata, Inc.

Suicidality Monitoring: The Time for Technology Has Come
John Greist, MD
CEO, Distinguished Senior Scientist, Madison Institute of Medicine, Healthcare Technology Systems

A Sponsor's Experience Managing Data From Patient and Clinician Perspectives on Suicidality
Carl Gommoll, MS
Director, Clinical Development, Forest Research Institute

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

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

8:00 AM–9:30 AM | LEVEL: ■ | Format: **SESSION**

Room 103b

eClinical Interoperability: Imagination, Integration, Implementation

CHAIRPERSON

Anne M. Zielinski, MBA
Vice President, Alliances, Medidata Solutions Worldwide

Moving from the vision of end-to-end interoperability to reality requires informed decisions, reformed processes, and realistic planning and expectations. This session examines clinical systems' interoperability, starting with the end in mind.

Using Information Standards to Drive eClinical Interoperability
Samuel W. Hume, MS
Director, IS Architecture, AstraZeneca Pharmaceuticals LP

A Measured Approach to Clinical Systems Integration
Kenneth Grice
Associate Director, ePRO Operations, Bayer Healthcare Pharmaceuticals

Interoperable Systems: Implications for Process Design and Change Management
Christie Mahoney
Partner, Soltex Consulting

#312 Track 08A – Regulatory Affairs and Submissions

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

8:00 AM–9:30 AM LEVEL: ● Format: **SESSION**

Room 119a *CME and Nursing*

Patient Advocacy in Medical Product Development: The Evolving Relationship Between FDA and Its Patient Stakeholders

CHAIRPERSON

James E. Valentine, MHS
Program Analyst, Office of Special Health Issues, Office of the Commissioner, FDA

This session will explore the role of patient advocates in FDA decision-making. FDA will describe its patient advocacy programs and the value they have added. A patient representative will discuss their interactions and experience with the agency.

Patrick Frey
Director, Office of Planning and Analysis, CDER, FDA

Marcia K. Horn
President and CEO, International Cancer Advocacy Network

Marc M. Boutin, JD
Executive Vice President and Chief Operating Officer, National Health Council

#313 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): DM, SUBS, RA

8:00 AM–9:30 AM LEVEL: ● Format: **SESSION**

Room 120bc

Future Directions for eCTD Module 1

CHAIRPERSON

Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, Center for Drug Evaluation and Research, FDA

Discussion will include key changes to Module 1, including incorporating the eCTD standard into the review of promotional materials. Also included will be reviewer concerns, file types accepted and presentation of specific examples.

eCTD Module 1 Update
Constance Robinson, RAC
Regulatory Information Specialist, Office of Business Informatics, Office of Planning and Informatics, CDER, FDA

Panelists
Marci C. Kiester, PharmD
Associate Director, Office of Prescription Drug Promotion, CDER, FDA

Mark A. Gray
Director, Division of Data Management Services & Solutions, CDER, FDA

#314 Track 08C – Regulatory Affairs and Submissions

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

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 119b *CME and Nursing*

Clinical Trial Disclosures: A US and EU Regulatory Update

CHAIRPERSON

Barbara Godlew, RN
President, The FAIRE Company, LLC

This session focuses on US and EU requirements for clinical trial disclosures. Information obtained during this session will include results reporting as it applies to regulatory, clinical operations, medical writing, and other related areas.

Operational Challenges of Coordinating Submissions to ClinicalTrials.gov and European Medicine's Agency Clinical Trial Registry
Tracy J. Beck, PhD
Consultant-Clinical Trial Registry Office, Eli Lilly and Company

EMA Point of View
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, EU

NIH Point of View
Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov, National Library of Medicine, NIH

#315 Track 09 – Medical Diagnostics and Devices

Related Interest Area(s): CP

8:00 AM–9:30 AM LEVEL: ● Format: **SESSION**

Room 118c *CME, Pharmacy, and Nursing*

Oncology Medications: State-of-the-art Identification and Management of Potential CV Safety Issues During Development

CHAIRPERSON

Philip T. Sager, MD, FACC
President, Sager Consulting Experts

Increasingly cardiac safety issues have arisen as a concern in the development of oncology medications. This session will focus on the potential safety issues of cardiotoxicity and QT prolongation and arrhythmogenesis and discuss their identification and potential management strategies. In addition, a state-of-the-art framework for collecting potential cardiac safety adverse events will be discussed and audience participation will be encouraged. The attendee will gain deeper theoretical and practical insight into the cardiac safety evaluation and risk-management of oncology medications during their development.

This session is hosted by Cardiac Safety Research Consortium (CSRC).

QT, Electrocardiographic and Arrhythmia Assessment for Oncologic Agents
Philip T. Sager, MD, FACC
President, Sager Consulting Experts

Overview of Myocardial Cardiotoxicity Assessment During Development
Daniel J. Lenihan
Director of Clinical Research; Honorary Member of the International CardiOncolog, Vanderbilt University

Proactive Assessment of Potential Cardiac AE's Using Standardized Methodology
John K. Finkle, MD
Director, Cardiovascular Therapeutic Area, GCSP, GlaxoSmithKline

Panelist
Robert J. Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA

#316 Track 10 – Public Policy/Health Care Compliance/Regulatory Law

Related Interest Area(s): RA

8:00 AM–9:30 AM LEVEL: ■ Format: **FORUM**
Room 113c *Pharmacy*

Policy and Enforcement Trends: Are Regulators and Industry Heading in the Right Direction?

CHAIRPERSON
Barry A. Berger, JD, MBA
Professor of Regulatory Affairs, Temple University

This forum will explore policy and enforcement trends and explore issues addressing questions related to the issue of whether regulators/industry are heading in the right direction. As globalization and collaboration become more relevant, can we do better?

FDA Perspective on Policy and Enforcement Trends
Eric M. Blumberg, JD
Deputy Chief Counsel for Litigation, Office of the Chief Counsel, Office of the Commissioner, FDA

Industry Perspective
William Kitchens, JD
Partner, Arnall Golden Gregory LLP

Industry Perspective
William W. Vodra, JD
Retired Partner, Arnold & Porter LLP

#317 Track 11 – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**
Room 121ab

FDA and European Medicines Agency Collaboration: GCP Inspections and Beyond

CHAIRPERSON
Leslie Ball, MD
Acting Director, Office of Scientific Investigations, CDER, FDA

This session will discuss the progress of the FDA and EMA GCP initiative, present areas of current focus, and preview future collaborations on inspections as well as GCP policy and guidance.

EMA Perspective
Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

FDA Perspective
Karena Cooper, JD
Regulatory Counsel, Office of Compliance, CDER, FDA

#318 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC, MF

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**
Room 122b *CME and Nursing*

Auditing Pharmaceutical Quality Systems

CHAIRPERSON
Joseph C. Famulare
Global Head of Compliance and External Collaboration, Genentech, A Member of the Roche Group

A robust pharmaceutical quality system includes a well thought-out auditing program for self audits of contract manufacturing organizations, suppliers and their distribution chain. This provides senior management key information to ensure quality.

Internal Audits: US Policy and Benefits Under a US Quality System Representative Invited
Branch Chief, International Compliance Branch, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

Leveraging Independent Audits to Enhance Your Quality System: An Industry Perspective
Elain Eborall
Director, Audit Americas, Genentech, A Member of the Roche Group

European View of Benefits and Requirements to Perform Internal GMP Audits
Ian Jackson
Operations Manager, Medicines and Healthcare products Regulatory Agency (MHRA), UK

#319 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

Related Interest Area(s): PR

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**
Room 107ab *CME, Pharmacy, and Nursing*

Environment for Health Care Decision Making: The Role of CER, Evidence-based Medicine, Quality, and Value

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

This session will provide an overview of the role of comparative effectiveness research (CER) in the current environment for health care decision making. Specific components will include the results of two rounds of surveys of health care influentials on the state of the environment for health care decisions, good practice principles for CER, and case studies focusing on the synergy between CER and quality measures.

Stakeholder Survey: The State of CER and the Environment for Decision Making
Kimberly Westrich, MA
Research Director for Health Services Research, National Pharmaceutical Council

Good Practice Principles for CER
J. Sanford Schwartz, MD
Professor of Medicine, Health Care Management, and Economics, University of Pennsylvania

Comparative Effectiveness Research (CER): A Tool for Driving Payment and Delivery Reform Case Studies
Nader Halim, PhD, MBA, MPH
Senior Consultant, Quintiles

#320 Track 14A – Clinical Safety and Pharmacovigilance

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

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 115c

How to Be Prepared for Shifting Regulations on Combination Products

CHAIRPERSON

Representative Invited

Regulations for combination products have remained in flux in recent times, which has affected the approach and execution of safety processes. This session will examine what re-tooling is required by companies in light of new regulations.

Overview of the Continuing Global Regulatory Landscape Changes Relating to Post Market Surveillance of Combination Products and Practical Challenges and Implications: An Industry Perspective
Representative Invited

An Overview and Implications From an Industry Networking Group, Including Guiding Principles
Ajay Keshava, MS
Managing Consultant, WCI Consulting Limited

Regulatory Reporting on Combination Products: Device Manufacturer's Perspective
Patrick Caines, PhD, MBA
Director, Postmarket Surveillance, Boston Scientific Corporation

#321 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): EC, CDM, ST

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 118a *CME and Nursing*

Active Surveillance Using Large, Electronic Health Care Data Networks

CHAIRPERSON

Robert Reynolds, DrSc, MSc, FISPE
Vice President, Global Head, Epidemiology, Pfizer Inc

This session will provide a summary of the key operational and methodological issues facing the implementation of active surveillance in electronic health care data, drawing on lessons learned from the FDA's Sentinel Initiative and pilot project, Mini-Sentinel and the Observational Medical Outcomes Project (OMOP). Speakers will identify which approaches have been successful and the challenges that lie ahead.

This session is hosted by the International Society for Pharmacoepidemiology (ISPE).

Distributed Electronic Health Data Networks for Medical Product Safety Surveillance
Jeffrey Brown, PhD
Assistant Professor, Department of Population Medicine, Harvard Pilgrim Health Care Institute/Harvard Medical School

Opportunities for Leveraging National Surveillance Research Efforts to Improve Industry Pharmacovigilance Operations
Patrick Ryan, MS
Head, Epidemiology, Janssen Research & Development, LLC

Core Methodologies in Safety Surveillance Systems: Quantifying Success and Identifying New Directions
Jeremy Rassen, DrSc
Assistant Professor of Medicine; Division of Pharmacoepidemiology & Pharmacoeconomics, Brigham & Women's Hospital, Harvard Medical School

#322 Track 15 – Statistical Science and Quantitative Thinking

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

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 113a *CME and Nursing*

Statistical Methods for Analysis of Integrated Safety Data

CHAIRPERSON

Xiaoming Li, PhD
Director, Biostatistics, Gilead Sciences, Inc.

In clinical development, safety profile of the candidate pharmaceutical/biological product became more and more important, given that there is more likely an existing treatment for the target disease on the market and the potential target population growth. Accordingly, development of statistical methods that can be applied for safety analyses have drawn much attention lately. In this session, industry and regulatory agency speakers will discuss the new developments in this important area.

Multivariate Bayesian Logistic Regression for Analysis of Clinical Trial Safety Issues
William DuMouchel, PhD
Chief Statistician, Oracle Health Sciences

Integrated Summaries of Safety: Evaluating a Difference in Proportions across Potentially Heterogeneous Studies
David Radley
Associate Director, Biostatistics and Research Decision Science, Merck & Co., Inc.

FDA Perspective
Ram Tiwari, PhD
Associate Director for Statistics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

#323 Track 16 – Professional Development

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

8:00 AM–9:30 AM LEVEL: ■ Format: **SESSION**

Room 117

Emerging Needs in Clinical Research and Drug Development Sciences Education and Certification

CHAIRPERSON

Honorio Silva, MD
President, Inter-American Foundation for Clinical Research (IAFCR)

The preliminary results of an international initiative aimed to assess the training and education needs, and the perceived value of certification to ensure quality will be contrasted with the profile of core professional competencies for clinical researchers. The status of clinical research and pharmaceutical medicine in Asia and the potential value of regional programs will also be discussed.

Aligning Competencies and Education Needs
Stephen A. Sonstein, PhD, MS
Director, Clinical Research Administration, Eastern Michigan University

Pharmaceutical Medicine and Clinical Research Education in Asia
Jean-Paul M.F. Deslypere, MD, PhD
CEO, Proclin Therapeutic Research, Singapore

Certification Systems for Trial Professionals: Effective Measure for Quality Assurance?
Min Soo Park, MD, PhD
Professor, Vice President, Yonsei University; KoNECT, Republic of Korea

#324 Track 17 – Global Regulatory

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

8:00 AM–9:30 AM LEVEL: ■ Format: **FORUM**
Room 115a

Risks to and Securing of Global Drug Supply Chains

CHAIRPERSON
Connie T. Jung, PhD, RPh
Acting Associate Director, Policy and Communications, Office of Drug Security, Integrity & Recalls, Office of Compliance, CDER, FDA

This town hall is intended to be an open forum discussion on the risks to human drugs created by complex global supply chains, greater foreign sourcing of products and the increase in volume of imports along with current efforts by regulators and industry to ensure product safety and quality.

Threats and Vulnerabilities to Supply Chain Security
S. Leigh Verbois, PhD
Acting Deputy Director, Division of Supply Chain Integrity, Office of Drug Security, Integrity & Recalls, FDA

Targeting Counterfeit Drugs
Gregg Goneconto
Special Agent, Office of Criminal Investigations, FDA

Compliance and Inspection Sector
Christa Wirthumer-Hoche, PhD
Deputy Head, Austrian Medicinal and Medical Device Agency (AGES), Austria

#325 Track 22 – White Paper Showcase

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

8:00 AM–9:30 AM LEVEL: ● Format: **SESSION**
Room 125

Enabling Remote Monitoring in Clinical Trials for Sponsors and Sites

CHAIRPERSON
William Baker, MBA
President/CEO, Cape Cod Clinical Research, Inc. (CCCRI)

This White Paper Showcase will interpret the FDA's 2011 "Draft Guidance for Industry Oversight of Clinical Investigation-A Risk-based Approach" and highlight the implications for organizations conducting clinical research. It will also explore alternative methods to monitoring and detail how sponsors and investigative sites can incorporate remote monitoring into their future trial design and monitoring plans.

Brought to you by Cape Cod Clinical Research, Inc.

Attendee badges scanned for this White Paper Showcase will be shared with the Company hosting this offering. If you prefer not to have your badge scanned, please inform the DIA staff member.

Donna W. Dorozinsky, MSN, RN
President, DWD & Associates, Inc.

Patrick D. Stone, MS
Founder, TradeStone QA LLC

Joshua Sharlin, PhD
President, Sharlin Consulting

9:30 AM–10:00 AM **COFFEE BREAK**
Exhibit Hall

#326 Track 01A – Clinical Operations

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room 109ab *CME and Nursing*

Clinical Research in Emerging Regions Around the World

CHAIRPERSON
Ashok K. Ghone, PhD
Vice President, Global Services, MakroCare

Regions such as Asia Pacific Emerging Countries, Central and Eastern Europe, and Latin America are the dynamic emerging markets and preferred destinations for clinical trials. This symposium will cover current conditions and will demonstrate key factors of success in planning and managing clinical trials in the regions, based on lessons learned.

Clinical Trials in Emerging Regions: Focus on Asia Pacific Region
Ashok K. Ghone, PhD
Vice President, Global Services, MakroCare

Programming Success in Clinical Trials: Focus on Russia, Ukraine and other ex-USSR Countries (from Feasibility to Close Out)
Andrei Kravchenko, MD, PhD
Head of Representative Office in Ukraine, Harrison Clinical Research Deutschland GmbH, Ukraine

Which Were the Challenges in a Real Case Epidemiological Population-based Trial in Brazil Comparing with a Clinical Trial?
Daniel Prado
Clinical Research Manager, RPS (ReSearch Pharmaceutical Services, Inc.), Brazil

#327 Track 01B – Clinical Operations

Related Interest Area(s): PM, IT

10:00 AM–11:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room 108a *CME and Nursing*

Applying Longstanding Ethical Principles in a Period of Dynamic Change

CHAIRPERSON
Bonnie A. Brescia
Founding Principal, BBK Worldwide

Review boards and regulatory committees are increasingly challenged by new technologies that impact patient protections and ethical considerations in clinical study planning. This symposium will explore how IRBs and ethics committees can apply basic principles of research ethics in the context of evolving value considerations in clinical research. The speakers will address issues such as: new definitions of autonomous action in a digitally enabled information age; applying the height of efficacy bar in the review process; the ongoing struggle to obtain true informed consent; and the cultural and generational differences in the definition of privacy.

Protecting Study Participants: The Ethics of Privacy, Transparency, and Trust in a Digital Age
Bonnie A. Brescia
Founding Principal, BBK Worldwide

IRB Reviews. How High Must the "Efficacy Bar" Be?
Jon Holmlund, DrMed
Medical Director, Aspire IRB

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

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

10:00 AM–11:30 AM LEVEL: ● FORMAT: **FORUM**

Room 105ab

Achieving Alignment in a Difficult and Diverse Environment

CHAIRPERSON

Atsushi Tsukamoto, MSc, PMP
Global Project Manager, Global Project Management Department, Daiichi Sankyo Co., Ltd., Japan

Smooth communication is a critical success factor in the recently diverse global environment. Panelists will offer concrete frameworks to apply in determining the best methods of communication in various situations, e.g., managing difficult people and senior management.

Establishing and Policing Ground Rules and Protocols for Successful Meetings in Diverse Teams
Robert A. Hilke, MA
CEO, Hilke Communications, LLC, Japan

Different Styles of Decision-making in Global Teams
Gareth Julian Monteath, MBA, MS
Program Director, INTEC Japan Inc., Japan

Global Pharmaceutical Project Team Case
Atsushi Tsukamoto, MSc, PMP
Global Project Manager, Global Project Management Department, Daiichi Sankyo Co., Ltd., Japan

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

Related Interest Area(s): CP, CR

10:00 AM–11:30 AM LEVEL: ■ FORMAT: **WORKSHOP**

Room 121c *PMI PDUs*

Project Risk Management Simulation for Product Development

CHAIRPERSON

Karla Childers
Project Manager, Merck Research Laboratories

This workshop will give participants hands-on experience in facilitating an interactive project risk management exercise, including practice in risk identification and prioritization and group facilitation.

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

#330 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RA, SP, PM

10:00 AM–11:30 AM LEVEL: ● FORMAT: **FORUM**

Room 121ab

Partnering for Impact in Global Health

CHAIRPERSON

Nicole Bates, DrPH
Senior Program Officer, Global Health Policy and Advocacy, Bill and Melinda Gates Foundation

This forum will provide an overview of the Bill & Melinda Gates Foundation's work and describe its "Decade of Vaccines" effort. Panelists will also address a partnership for tuberculosis drug discovery, examples of product development partnerships, and a project on postmarket drug and vaccine surveillance in low- and middle-income countries.

A Partnership for Tuberculosis Drug Discovery
Ken Duncan, PhD
Deputy Director, Global Health Discovery, Bill & Melinda Gates Foundation

Introduction to the Gates Foundation's Global Health Strategy and Regulatory Priorities
Vincent I. Ahonkhai, MD
Senior Regulatory Officer, Global Health Delivery, Bill & Melinda Gates Foundation

Opportunities for Transformation: Strategies for Patient Safety Surveillance in Low- and Middle-income Countries
Amrit Ray, MD, MBA
Chief Safety Officer; Head Global Medical Safety, Janssen Research & Development, LLC

Article 58 — Pyramax
David Reddy, PhD
Chief Executive Officer, Medicines For Malaria Venture (MMV), Switzerland

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

Related Interest Area(s): BT, PC

10:00 AM–11:30 AM LEVEL: ◆ FORMAT: **FORUM**

Room 124 *CME, Pharmacy, and Nursing*

Can Human Carcinogenic Risk Be Communicated Without a Rodent Bioassay?

CHAIRPERSON

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

Has our understanding of carcinogenicity advanced sufficiently that data from alternative assays could be used to support decisions that are as protective of the public health as are current approaches?

The Two-year Bioassay as a Carcinogenesis Screen: A Useless and Often Misleading Waste of Resources
Samuel M. Cohen, MD, PhD
Professor of Pathology and Microbiology, University of Nebraska Medical Center

Carcinogenicity Risk of Biotechnology-derived Pharmaceuticals: Assessment of Carcinogenic Risk Without a 2-Year Bioassay
Ronald W. Steigerwalt, PhD
Preclinical Director, Toxicology, Amgen Inc.

A Proposed Vision on the Future of Carcinogenicity Testing
David Jacobson-Kram, PhD
Associate Director for Pharmacology and Toxicology, Office of New Drugs, CDER, FDA

#332 Track 05 – Product Advertising and Marketing

Related Interest Area(s): RA, MC

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**

Room 113b *Pharmacy*

FDA Enforcement Update: Advertising and Promotion

CHAIRPERSON

Wayne L. Pines
President, Regulatory Services and Healthcare, APCO Worldwide Inc.

FDA enforcement actions need to be understood by every company because they reflect FDA's priorities and concerns in regulating advertising and promotion. In this session, FDA professionals will examine the latest agency enforcement actions and what they mean.

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

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

#333 Track 06 – Medical Writing and Medical Communications

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

10:00 AM–11:30 AM LEVEL: ◆ Format: **SESSION**

Room 108b *CME and Nursing*

Efficient Regulatory Medical Writing for Global Submissions Including "ICH Outlier" Authorities

CHAIRPERSON

Justina A. Molzon, USPHS, JD, MPharm
Associate Director for International Programs, Office of the Center Director, CDER, FDA

This session will explore global medical writers' proven strategies for authoring regulatory submission documents for clinical trial and marketing applications with overlapping content being submitted virtually simultaneously to different regional authorities.

CTA Requirements in Europe
Beate Roder, PhD
Director, PAREXEL International, Germany

Opportunities for Optimization
Carlos Dufeu, RPh
Regulatory Manager, Pfizer Inc, Chile

Asian Markets: Clinical Requirements Beyond ICH
Frank C. Hubbard, PhD
Group Manager, Scientific Communications, Astrazeneca Pharmaceuticals LP

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

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**

Room 103b *CME and Nursing*

Identity Management Technologies in Clinical Trials

CHAIRPERSON

Jay B. Smith, MBA
Director, Product Management, Medidata Solutions Worldwide

This session will provide an overview of several new identity management technologies, standards, and practices, as used in software developed for the clinical market. Best practices for each new method or technology will be described, as well as how each might be used in software or clinical development to improve efficiencies and raise quality.

Integrating a SAML Based Federated Identity Management System for Cancer Clinical Trials at Cancer Trials Support Unit (CTSU) of National Cancer Institute (NCI)
Ravi Rajaram, MS, PMP
Assistant Project Director, CTSU, Westat

Who Are You ... Really? Enabling Inter-organizational Researcher Collaboration Using Federated Identity Management
Kevin Swank, MS, PMP
Lead IT Analyst/Programmer, BioInformatics Systems Unit, Mayo Clinic

Approaches to Identity Management Used in Clinical Trials
Jay B. Smith, MBA
Director, Product Management, Medidata Solutions Worldwide

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

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**

Room 103a *CME, Pharmacy, Nursing, and PMI PDUs*

Clinical Outcome Assessments in the Evaluation of Medical Products in Pediatrics

CHAIRPERSON

Elektra Johanna Papadopoulos, DrMed, MPH
Medical Officer, Office of New Drugs, CDER, FDA

This session will discuss considerations for selection and/or development of well defined and reliable pediatric clinical outcome assessment tools.

A Regulatory Viewpoint
Carla L. Epps, DrMed, MPH
Medical Officer, Division of Gastroenterology and Inborn Errors Products, CDER, FDA

Developing Parent Observer Reports in Infants and Young Children
Donald L. Patrick, PhD, MPH
Professor, Health Services, School of Public Health, University of Washington

#336 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CP

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**

Room 119a *CME, Pharmacy, and Nursing*

Building the Benefit-risk Toolbox: Is There a Consensus on a Scientifically Acceptable Framework?

CHAIRPERSON

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

This session will review the current perspectives from ongoing initiatives to develop benefit-risk methodologies, examine the tool box of methodologies from the regulators and industry perspective, and discuss if stakeholders can agree on a general scientifically accepted framework.

The Current Status of Benefit-risk Assessment Within Agencies and Companies: A Major Survey
Neil McAuslane, PhD, MSc
Director, Centre For Innovation In Regulatory Science (CIRS), UK

A Pilot Study Using a Shared Framework by the TGA, Health Canada, Swissmedic, and HSA in Singapore
Jason Ferla, MD, MPH
Director, Office of Medicines Authorisation, Therapeutic Goods Administration (TGA), Australia

The Outcome of a Pilot Study Across a Number of Companies Using the BRAT (Benefit-risk Action Team) Methodology for Benefit-risk Assessment
Rebecca A. Noel, DrPH, MPH
Research Scientist, Global Patient Safety, Eli Lilly and Company

#337 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CR

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**

Room 119b *CME and Nursing*

Global Product Development: Resolving Conflicting Scientific and Regulatory Advice from Multiple Health Authorities

CHAIRPERSON

Shannon P. Strom, PhD, RAC
Associate Director, Regulatory Affairs, Pearl Therapeutics, Inc.

When a company seeks regulatory or scientific advice from multiple health authorities, the regulators can provide divergent recommendations. This session will discuss strategies to resolve differing feedback and develop a global development strategy.

Agency Advice: Getting the Most From Your Meetings
Jamie Lynn Gault
Senior Director, Regulatory Affairs, Aptiv Solutions

Conflicting Scientific and Regulatory Advice: An EU Perspective
Stephen Thompson, PhD
Director, Regulatory Affairs, S-Cubed, Ltd., UK

Conflicting Advice From Regulatory Authorities on Endpoints for Pivotal Trials: Moving Beyond Harmonization
Cynthia J. Girman, DrPH
Senior Director, Epidemiology, Merck Research Laboratories

#338 Track 08C – Regulatory Affairs and Submissions

Related Interest Area(s): DM, SUBS, RA

10:00 AM–11:30 AM LEVEL: ■ Format: **FORUM**

Room 120bc

Pursuing Standards to Enhance eCTD Deliverables: PhRMA Electronic Regulatory Submissions (ERS) Group Annual Update

CHAIRPERSON

John W. Kiser, MSc
Senior Director, Global Pharmaceutical Regulatory Affairs Operations, Abbott Laboratories

The PhRMA Electronic Regulatory Submissions group presents their annual progress report on the hottest key subteams involved in the pursuit of standards to facilitate efficient and effective electronic submissions.

Regulated Product Submission: Progress and Status of the New Standard
Joseph A. Cipollina, MSc
Director, eStrategy Liaison, Bristol-Myers Squibb Company

Proposed PDUFA V Data Standards and IT Commitments Through 2017
Steven T. Ward
Director/Advisor, IT Strategy, Eli Lilly and Company

Electronic Submission Efficiencies: Bookmarking and Hypertext Linking
Michelle Charles
Submissions Development Lead, Merck & Co., Inc.

#339 Track 09 – Medical Diagnostics and Devices

Related Interest Area(s): RA, CR

10:00 AM–11:30 AM LEVEL: ● Format: **SYMPOSIUM**

Room 118c *CME and Nursing*

Current Advancement of Regulatory Reform for Medical Devices in Asia Pacific and Its Strategic Impact

CHAIRPERSON

Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

The symposium will discuss the current advancement of regulatory pathway, the reform of related regulations, and the impact on industry. The harmonization effort initiated by Global Harmonization Task Force (GHTF), Asian Harmonization Working Party (AHWP), and the Regional Harmonization Steering Committee of APEC Life Science Forum will be discussed. Experience will be shared from industrial and regulatory perspectives.

Regulatory Convergence of Medical Device by GHTF/AHWP in Asian Pacific Region
Mike D. Ward
Manager, International Programs Division, Health Canada

The Recent Reform on the Taiwanese Regulatory Structure of Medical Devices
Hsien-Yi Lin, PhD
Senior Reviewer, Division of Medical Devices and Cosmetics, Food and Drug Administration, Department of Health, Executive Yuan, Taiwan

Medical Device Clinical Trials in China: A Proposed Strategic Regulatory and Clinical Trial Model
Alan J. Touch
Principal Stategist, Medical Devices and In-vitro Diagnostics, INC Research, Inc.

#340 Track 10 – Public Policy/Health Care Compliance/Regulatory Law

Related Interest Area(s): RA, CR

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 113c *CME, Pharmacy, and Nursing*

Meeting the Therapeutic Needs of Older Patients: A Sustainable Collaborative Approach

CHAIRPERSON

Susanna Del Signore, MD
Associate Vice President, Global Regulatory Affairs, Sanofi, France

Regulators will discuss how to facilitate the implementation of affordable development programs for unmet therapeutic needs of older patients, in line with the existing regulatory guidance for geriatric medicines.

PMDA Perspective on Data Evaluation of Drugs Used in Geriatric Population
Yasuko Asahina, PhD
Researcher, Office of Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

EMA Geriatric Strategy
Francesca Cerreta, PharmD, MPharm, MS
Scientific Administrator, European Medicines Agency, European Union

New Approach to Geriatric Syndromes
Luigi Ferrucci, MD, PhD
Senior Investigator, Scientific Administrator, National Institute of Aging, NIH

Panelist
Yoshiaki Uyama, PhD
Director, Division of Regulatory Science Research, Office of Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#341 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC, MF, RA

10:00 AM–11:30 AM LEVEL: ■ Format: **FORUM**
Room 122b *Pharmacy*

Regulatory Updates on Current Trends in Drug Quality and Manufacturing

CHAIRPERSON

Steven Lynn, MSc
Director (acting), Office of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

This session will attempt to link regulatory and scientific aspects related to pharmaceutical quality issues occuring in manufacturing. A regulatory update will be provided on recent compliance actions related to product recalls and drug shortages. Industry speakers will follow, discussing how scientific understanding and manufacturing controls can help mitigate risks to product quality in the future.

FDA Point of View
Steven Lynn, MSc
Director (acting), Office of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

Detection and Mitigation of 2, 4, 6-Tribromoanisole and 2, 4, 6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Health Care Industries
Anil Sawant, PhD
Vice President, Regulatory Compliance, Johnson & Johnson Consumer Companies, Inc.

Martin VanTrieste
Vice President, Quality, Commercial Operations, Amgen Inc.

#342 Track 14A – Clinical Safety and Pharmacovigilance

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**
Room 115c *CME, Pharmacy, and Nursing*

REMS: Are Our Written Communications Truly Mitigating Risks to Patients?

CHAIRPERSON

Sally Van Doren, PharmD
President & Chief Executive Officer, BioSoteria, Inc.

This session will discuss and present information on which REMS communication tools have actually been shown to positively influence prescriber and patient knowledge and behaviors leading to mitigation of product risk in patients. Published papers on past communication effectiveness will be reviewed. The importance of what and how a communication is written will be discussed for effective communication practices. New innovative approaches to communication beyond paper information leaflets will be presented.

Do Written Communications Mitigate Patient Risk? A Review of the Published Literature
Sally Van Doren, PharmD
President & Chief Executive Officer, BioSoteria, Inc.

Role of Medical Information Contact Centers in Optimizing Safe Outcomes for Patients
Herbert B. Lee, PharmD, MBA
President, Medcom Solutions LLC

Risk and Benefit Communication: An Evidence-based Guide to Effective Messaging
Kala L. Paul, MD, MS
President, The Corvallis Group LLC

#343 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): OS

10:00 AM–11:30 AM LEVEL: ● Format: **SYMPOSIUM**
Room 118a

The Out-Sourcing/In-Sourcing/Out-Sourcing Model for Pharmacovigilance

CHAIRPERSON

Graeme A. Ladds, PhD
Director, PharSafer Associates Ltd., UK

The symposium will focus upon how to set up an outsourcing model that allows client oversight and future flexibility to in-source at a point in the future. Such a system can also be left open such that in times of need there is remaining flexibility once in-sourced to immediately out-source some aspects if the need arises. This will be a case study showing the scope, plan for transition, and what items to leave open for ensuring adaptability once in-sourced.

The Out-In-Out Sourcing Model of Pharmacovigilance
Graeme A. Ladds, PhD
Director, PharSafer Associates Ltd., UK

Outsourcing Pharmacovigilance, Know What You Need and How To Get It
Elizabeth E. Garrard, PharmD, RPh
Chief Safety Officer, Drug Safety Alliance, Inc.

#344 Track 15 – Statistical Science and Quantitative Thinking

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**

Room 113a *CME and Nursing*

From Adverse Events to Adverse Drug Reactions: Statistical Issues in Safety Labeling

CHAIRPERSON

Andreas Brueckner
Principal Statistician, Bayer Pharma AG, Germany

This session will highlight statistical issues that arise during this review process, discussing approaches for screening, identification, quantification and presentation of individual adverse drug reactions for drug safety labeling.

Data Consolidation for Labeling: Statistical Considerations
Conny Berlin, MS
Statistical Fellow, Novartis Pharma AG, Switzerland

Cumulative Meta-analyses of Clinical Trial Safety Data: Issues in Interpretation and Dissemination
Ed Whalen, PhD
Director, Biostatistics, Pfizer Inc

Regulatory Perspective on Statistical Issues in Product Labeling
LaRee A. Tracy, PhD, MA
Statistical Team Leader, Office of Biostatistics, CDER, FDA

#345 Track 16 – Professional Development

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

10:00 AM–11:30 AM LEVEL: ● Format: **SYMPOSIUM**

Room 117

Employee Engagement

CHAIRPERSON

Cathryn L. Anderson
Independent Consultant

Throughout the biopharmaceutical industry, employee engagement has become an integral part of organizational strategies to develop and retain talent. This symposium will present three types of engagement that can contribute to increased professional satisfaction and performance.

Communication and Meeting Management in the World of the Remote Office
Cathryn L. Anderson
Independent Consultant

Job Insurance through Networking
Bridgid Nelson
Executive Recruiter, Liberty Consulting Group

Is Employee Engagement Part of Your Company's Culture? Staff Retention Strategies for Creating Highly Functioning Teams
Gary M. Bufferd
Associate Director, Clinical Client Liaison, RPS (ReSearch Pharmaceutical Services, Inc.)

#346 Track 18 – Rare/Neglected Diseases

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

10:00 AM–11:30 AM LEVEL: ■ Format: **SESSION**

Room 111ab *CME, Pharmacy, and Nursing*

Natural History Studies for Rare Diseases and Orphan Conditions

CHAIRPERSON

Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management, United BioSource Corporation

This session presents an overview of the design, conduct, and benefits of natural history studies of rare diseases and orphan conditions from varied perspectives of researchers, patients and a regulatory agency.

Overview of Strategies and Study Designs to Evaluate Rare Diseases and Orphan Conditions
Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management, United BioSource Corporation

Longitudinal Studies of Patients with Rare Diseases and Opportunities for Drug Development
Anne R. Pariser, MD
Associate Director for Rare Diseases, Office of New Drugs, CDER, FDA

Case Study from the Rare Diseases Clinical Research Network (RDCRN) Urea Cycle Disorder Consortium
Marshall Summar, MD
Chief, Genetics and Metabolism, Childrens National Medical Center

11:30 AM–1:30 PM **LUNCHEON**
Exhibit Hall

#347 Track 01A – Clinical Operations

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 109ab *CME and Nursing*

Clinical, Statistical, and Data Management Considerations for Developing Clinical Trial Protocols

CHAIRPERSON

Suresh R. Siddhanti, PhD
Development Clinical Director, Amgen Inc.

Experts from FDA and industry will provide insights on the key aspects of developing a phase 3 clinical trial protocol. They will also discuss the impact of standardization of data collection terminology during the clinical development program.

From Drug Approval to Clinical Trial: Reverse Engineering a Drug Approval
Robert Kane, MD
Director, Division of Oncology Drug Products, CDER, FDA

Clinical Trials in the 21st Century: How Your Data Can Survive and How You Can Survive Your Data
Sylvia Engelen, MSc
Director, Head Clinical Statistics, US, Bayer Healthcare Pharmaceuticals

Key Success Factors in Protocol Design: Clinical/Development Perspective
Sunil Gupta, MD, FRCPC
Associate Vice President, Sanofi Oncology

#348 Track 01B – Clinical Operations

Related Interest Area(s): CR, RA

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**
Room 108a | *CME and Nursing*

New Regulations and Guidance for Clinical Trials and Human Subject Protection

CHAIRPERSON

Cynthia M. Gates, JD, RN
Vice President, Education and Consulting Services, Western Institutional Review Board

This session will cover recent changes to regulations and guidances as well as proposed changes by the Office for Human Research Protections (OHRP) and FDA. Attendees will learn how the changes might affect their day-to-day workflow, how to identify compliance gaps and how to correct the gaps.

New US Regulations and Guidance for Clinical Trials
Cynthia M. Gates, JD, RN
Vice President, Education and Consulting Services, Western Institutional Review Board

New US Regulations and Guidance for Clinical Trial Billing
Michael C. Roach, JD
Partner, Meade and Roach, LLP

New Regulations and Guidance for Conducting Clinical Trials Outside of the US
Nancy Meyerson-Hess, MSc
Compound Development and Branding, Gruenenthal, Germany

#349 Track 01C – Clinical Operations

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

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**
Room 105ab | *CME and Nursing*

Building Clinical Site Capacity for Research

CHAIRPERSON

Peggy L. Coyle, MS, RN
Senior Manager, Clinical Research Team, FHI 360

The South East Asia Infectious Disease Clinical Research Network (SEAICRN), a collaborative partnership of hospitals and institutions in Thailand, Vietnam, Indonesia, and Singapore, embarked on a significant clinical research capacity building effort. Its key objective was to establish an experienced clinical research team comprising doctors, nurses, study coordinators, research pharmacists, lab technicians, data management and administrative personnel. To support this effort, the SEAICRN developed a new model for clinical trials support through the establishment of local clinical trials support specialists (CTSS). This session will present experiences with this new model and show how it can be applied successfully, as well as describe a capacity development project for a local ethics committee.

Developing Site Capacity for International Research: US Government Strategies
Christian P. Yoder, MPH, RN
Clinical Research Specialist, National Institute of Allergy and Infectious Disease, National Institutes of Health

A Real Life Example: Developing Site Capacity in Southeast Asia
Julia D. Welch, MS
Senior Clinical Project Manager, Clinical Monitoring Research Program, SAIC-Frederick, Inc.

Translating the Model: On the Ground Experience in Vietnam
Peggy L. Coyle, MS, RN
Senior Manager, Clinical Research Team, FHI 360

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

Related Interest Area(s): PM, OS, SP

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**
Room 103c | *PMI PDUs*

Drug Development Strategies and Incorporation of an Established Project Management System

CHAIRPERSON

Marija Ribar, DMD, MBA
Director, Product Development Consultancy, Aptiv Solutions

This session will look at strategic planning as a foundation upon which a drug development program defines the tasks that need to be completed, when they must be completed, the associate cost, the key personnel and use of established PM system.

Designing and Implementing a Drug Planning Framework
Peter Harpum, PhD, MSc
Managing Director, Harpum Consulting Ltd., UK

Cross-function Project Management for an Initial IND: CMC Perspective
Alexander D. Smith
General Manager, ADS Pharma Consulting, LLC

Integrated Drug Development: Case Study
Marija Ribar, DMD, MBA
Director, Product Development Consultancy, Aptiv Solutions

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

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

1:30 PM–3:00 PM | LEVEL: ● | Format: **SESSION**
Room 111ab | *PMI PDUs*

Thinking Small! A Virtual Pharma Gets Big Work Done with Like-minded Partners

CHAIRPERSON

Jean A. Hendrickson
Vice President, Novella Clinical Inc.

This informative session will provide attendees with a unique case study highlighting an innovative, collaborative, and dynamic partnering model that is distinctive as compared to traditional outsourcing methods.

Lisa Zimmerman, MS
Vice President, Clinical Operations, POZEN, Inc.

Jean A. Hendrickson
Vice President, Novella Clinical Inc.

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

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

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SYMPOSIUM**
Room 118a | *PMI PDUs*

Functional Service Provider Symposium

CHAIRPERSON

Susan Torchio, BSN, RN
Global Clinical Operation Lead for Cardiovascular/Immunology/Inflammation, Teva Pharmaceuticals

There are many ways to partner with a functional service provider (FSP). This symposium will provide case studies of how several of these models

have worked and how the appropriate model was selected, as well as discuss performance metrics/key performance indicators (KPIs) and governance and infrastructure of the various models. Pricing strategies including unit costing, cost savings and risk sharing, will also be explored.

Functional Service Provider Partnering: Choosing the Right Model to Achieve Strategic Success
Ian Birks
Vice President, Global Functional Resourcing, Quintiles

Implementing Unit Pricing in Strategic Functional Service Provider (FSP) Relationships
Anne Marie L. Inglis, PhD
Director, US Clinical Operations, Biologicals, GlaxoSmithKline

Strategic Partnering to Enhance Timelines Through Resource Management and KPI Risk Sharing
Jennifer Charron
Director, Embedded Clinical Programs, RPS (ReSearch Pharmaceutical Services, Inc.)

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

Related Interest Area(s): PC, NC, CDM

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**
Room 124 | *CME and Nursing*

Microdosing: Past Experience and Future Role in Translational Medicine

CHAIRPERSON
Tal Burt, MD
Scientific Director, Duke Global Proof-of-Concept Research Network, Duke Clinical Research Institute

Microdosing holds the promise of increasing drug selection efficiency through the introduction of subpharmacological doses of test articles to humans. The session examines existing data, potential applications and future role of microdosing.

Microdosing: Past and Future
Graham Lappin, PhD
Chief Scientific Officer, Xceleron Ltd., UK

PET-Microdosing: Unique Capabilities, Challenges, and Opportunities for Drug Development
Martin Bauer, MD
Research Associate, Department of Clinical Pharmacology, Medical University of Vienna, Austria

Use of Microdosing in Drug Development: Is the Evidence Convincing?
Joseph S. Bertino, Jr., PharmD
Principal, Bertino Consulting

#354 Track 05 – Product Advertising and Marketing

Related Interest Area(s): MC, MA

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**
Room 113b | *Pharmacy*

International Advertising/Promotion Coordination

CHAIRPERSON
Thomas M. Casola, MBA
Vice President, Global Regulatory Affairs, Advertising, Promotion & Labeling, Shire Specialty Pharmaceuticals

Companies are increasingly looking for consistency in marketing campaigns across the globe. This raises challenges for the advertising/promotion review process in determining appropriate company review standards and finding efficient ways to achieve regulatory approval of promotional materials. This session will discuss how to remain compliant in the international marketing arena.

Jose Zamarriego, MBA
Head Code of Practice Surveillance Unit, Farmaindustria, Spain

Heather Simmonds
Director, Prescription Medicines Code of Practice Authority (PMCPA), UK

Ray Chepesiuk, MBA, RPh
Commissioner, Pharmaceutical Advertising Advisory Board (PAAB), Canada

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

#355 Track 06A – Medical Writing and Medical Communications

Related Interest Area(s): MC, DM, OS

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**
Room 108b | *CME and Nursing*

Global Medical Information in Real-life Situations

CHAIRPERSON
Lillian Auberson, PhD
Senior Director, Head of Global Medical Information, Actelion Pharmaceuticals Ltd, Switzerland

It is easy to resonate with the vision and goals of a globalized medical information service which enables a pharmaceutical company to speak with one voice with its customers. In most models for a globalized service, workflows and tools are put in place for streamlining information gathering and dissemination. Stewardship for the content of medical information response documents is provided by a global team, operating under internal governance for content development and appropriate information disclosure. This session will explore the resiliency and vulnerability of global medical information services in real-life situations.

International Medical Information Service: Can We All Speak the Same Language?
Robert M. Winslow, PharmD
Global Director, Medical Information Services, Lifecycle Safety, Quintiles

Global Medical Information Teams: Working Together to Deliver Results
Purnima J. Topiwala, PharmD
Associate Director, Medical Information, Janssen Scientific Affairs, LLC

Global Medical Information in Times of Transition
David Ryan Perkins, RPh
Global Vice President, Medical Information, Genzyme Corporation

Panelist
J.C. Muyl, MA
Executive Vice President, C3i, Inc.

#356 Track 06B – Medical Writing and Medical Communications

Related Interest Area(s): CP, CDM

1:30 PM–3:00 PM LEVEL: ■ Format: **WORKSHOP**
Room 121c *CME, Pharmacy, and Nursing*

What Medical Writers Need to Know about MedDRA®

CHAIRPERSON

Patricia Mozzicato, MD
Chief Medical Officer, MedDRA® MSSO

This workshop will present ways for medical writers to avoid missteps in interpreting safety data and optimize presentation and analysis of MedDRA® data. Exercises highlighting MedDRA's features and ICH "Points to Consider" principles will be given.

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

Moderator
Judy E. Harrison, MD
Senior Medical Officer, MedDRA® MSSO

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

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

1:30 PM–3:00 PM LEVEL: ● Format: **SESSION**
Room 103a *CME, Pharmacy, Nursing, and PMI PDUs*

Innovations Aimed at Improving Effectiveness and Speed of the Therapeutic Development Process

CHAIRPERSON

Alexander Fleming, MD
President and Chief Operating Officer, Kinexum

Three complementary innovations will be presented in an interactive discussion with a senior FDA official and the audience. The connecting thread is addressing unmet need and improving clinical outcomes by applying maturing science, new technologies, and partnerships to the therapeutic development and evaluation processes.

Innovative Use of People, Process, and Technology to Execute Risk-based Monitoring
Margaret M. Keegan
Global Head, Integrated Processes and Technologies, Quintiles

Data Collection for Companion Diagnostics in Clinical Trials
Cari Deloa
Senior Data Manager, Genentech, Inc.

FDA Point of View
Robert J. Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA

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

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

1:30 PM–3:00 PM LEVEL: ■ Format: **FORUM**
Room 103b

Business Applications in the Cloud

CHAIRPERSON

Venkatesan Thangaraj
Radiant Sage, LLC

This session will address how cloud technology is applied to specific business needs.

Cloud Based Medical Image Management in Clinical Trials
Kris Kokomoor, MSc
Associate Director, Clinical Informatics and Innovation, Pfizer Inc

Cloud Services for 21st Century WHO DRUG Coding and Best Practices
Ola Strandberg, MSc
Vendor Liasion Officer, The Uppsala Monitoring Centre, Sweden

Conceptual Model of the Use of Tablets and Cloud Services to Conduct a Clinical Trial
David Plante, MS
Director, Information Technology, Aegerion Pharmaceuticals, Inc.

#359 Track 08A – Regulatory Affairs and Submissions

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

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**
Room 120bc *CME, Pharmacy, and Nursing*

Orphan Drug Development: Global Regulatory Challenges and Initiatives

CHAIRPERSON

Kinnari Patel, PharmD
Associate Director, Global Regulatory Sciences, Bristol-Myers Squibb Company

This session will focus on critical need for developing orphan drugs, review of global orphan drug development challenges, and provide information on various strategies designed to overcome these challenges.

Summary of NORD Activities/Initiatives
Timothy R. Cote, MD, MPH
National Organization For Rare Disorders (NORD)

Regulatory Challenges and Initiatives: Strategies for Success
Jonca C. Bull, MD
Vice President, Drug Regulatory Affairs, FDA Liaison Office, Novartis Pharmaceuticals Corporation

Obtaining Orphan Product Development: Challenges and Pitfalls
Marlene E. Haffner, MD, MPH
President and CEO, Haffner Associates, LLC

#360 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): DM, SUBS, RA

1:30 PM–3:00 PM | LEVEL: ● | Format: **SESSION**

Room 119b | *CME and Nursing*

Operationalizing SDTM

CHAIRPERSON

Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, CDER, FDA

This session will provide practical advice and feedback to industry regarding submission of CDISC SDTM data to CDER and CBER. The session should allow sponsors to gain answers to common questions and issues that arise with SDTM submitted to FDA.

Douglas L. Warfield, PhD
Regulatory Information Specialist, Office of Business Informatics, CDER, FDA

Dhananjay R. Chhatre, MS, RAC
Operations Research Analyst, Office of Business Informatics, CDER, FDA

Amy Malla, MT, PMP
Consumer Safety Officer, Office of the Director, CBER, FDA

#361 Track 09 – Medical Diagnostics and Devices

Related Interest Area(s): RA, PPLCC

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SYMPOSIUM**

Room 118c

Update on Revision of European Medical Device Directives and Impact on Industry

CHAIRPERSON

Shayesteh Fuerst-Ladani, MBA, MS
Director, SFL Regulatory Affairs and Scientific Communication, Switzerland

This symposium will provide an overview of the latest development and EU Commission's proposals on the Revision of Medical Device Directives including In-Vitro Diagnostics Directive in comparison to the current legislation will be provided. Notified Body representative will analyze the impact of the revised legislation will have on the system of third party assessment in Europe; and highlight those elements changed in the supervision by the third parties on industry and other stakeholders as consequence of the revised legislation. Further, the impact of the revised legislation on the company procedures and strategy will be provided. Additionally, an overview on the current and future reporting of serious adverse events from medical device trials in Europe will be provided.

An Overview on the Revision of the EU Medical Device Directives Including In-Vitro Diagnostics
Shayesteh Fuerst-Ladani, MBA, MS
Director, SFL Regulatory Affairs and Scientific Communication, Switzerland

Notified Body View on EU Revision of Medical Device Legislation
Ibim B. Tariah
Technical Director, Healthcare, BSI

The Impact of the EU Medical Devices Directives' Revision on Company Procedures and Strategy
Sunita Prem Ahir, PhD, MSc, RAC
Regulatory Affairs Manager, D-Target, a Premier Research Company, Switzerland

Current and Future Reporting of Serious Adverse Events from Medical Device Trials in Europe
Regina Freunscht
Director, Marketing and Communications, Accovion GmbH, Germany

#362 Track 10 – Public Policy/Health Care Compliance/Regulatory Law

Related Interest Area(s): RD, BT

1:30 PM–3:00 PM | LEVEL: ● | Format: **SESSION**

Room 113c | *Pharmacy*

Emerging Development and Policy Trends in the Economics of the Biopharmaceutical Industry

CHAIRPERSON

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

The implications of industry practices and public policies for R&D productivity and the incentives to innovate will be examined.

Trends in the Economics of New Drug and Biologics Development
Joseph A. DiMasi, PhD
Director, Economic Analysis, Tufts Center for the Study of Drug Development, Tufts University

Challenges and Opportunities in Biotechnology
Raymond G. Starrett, MS
Senior Director, Project Management, Targacept Inc.

Emerging US Biosimilar Policy
Kathleen Basmadjian, PhD, MSc
Senior Director, Global Regulatory Policy and Intelligence, Janssen Research & Development, LLC

#363 Track 11 – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SYMPOSIUM**

Room 121ab | *Pharmacy*

The Changing Face of Clinical Compliance: Regulatory, Technology, and Services

CHAIRPERSON

Penelope Przekop, MSc
Senior Director, Global Quality Assurance and Training, Theradex Systems

The face of clinical compliance is changing based on regulatory and technological advances. Long accepted industry standard practices require change. These changes are impacting pharmaceutical companies as well as their service providers. Quality professionals are key partners for ensuring that appropriate industry changes continue to reflect current regulations and protect patient safety. This symposium features clinical quality assurance experts who will address one of these key aspects of our changing environment: regulatory, technology, and service.

GCP Audit Implications of the New Clinical Monitoring Guidance Document
Carol Bognar, MSN, RN
QA Consultant, Carol Bognar Consulting, LLC

A Whole New World: CRO Clinical Quality Assurance
Penelope Przekop, MSc
Senior Director, Global Quality Assurance and Training, Theradex Systems

The Role of Quality Assurance in eClinical Environments — When to Dive in
Shiela McLaughlin
International Director, Quality Assurance, DATATRAK International

#364 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CM, MF, CP

1:30 PM–3:00 PM LEVEL: ● Format: **WORKSHOP**

Room 123

Quality Risk Management Workshop

CHAIRPERSON

Fritz Erni, DrSc
Consultant, Switzerland

This interactive workshop will give a brief overview of simple quality risk management (QRM) tools. In small groups, participants will work with common QRM tools such as Process Maps, Fishbone Diagrams and Failure Mode Effects Analysis (FMEA) to determine product critical quality attributes and critical process steps for a simple manufacturing process.

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

Moderators
Celia N. Cruz, PhD
Chemist, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

Stephan Karl Roenninger, DrSc
Head, External Collaboration Europe/Japan/CEMA, F. Hoffmann-La Roche Ltd., Switzerland

#365 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

Related Interest Area(s): PR, RA, PPLCC

1:30 PM–3:00 PM LEVEL: ■ Format: **SYMPOSIUM**

Room 107ab *CME, Pharmacy, and Nursing*

The Use of Health Technology Assessment (HTA) for Access and Resource Allocation Decision Making: International Examples

CHAIRPERSON

Christopher M. Marrone, PharmD
Outcomes Liaison, Eli Lilly and Company

To maximize the value of medicines while managing limited medical resources, many national and private insurers are applying a Health Technology Assessment (HTA) as a support for the decision-making process. This symposium will cover the use of HTA in three international examples, including discussions of comparative effectiveness analysis, managed entry agreements, and risk share agreements.

Access to Innovation and HTAs Enforced by Managed Entry Agreements in Combination with Treatment Registers
Luca De Nigro, MS
Coordinator, Drugs Monitoring Register, Italian Medicines Agency (AIFA), Italy

HTA Application for Medical Resources Allocation in National Health Insurance Scheme: A Case Study for Osteoporosis in Taiwan
Herng-Der Chern, MD, PhD
Distinguished Research Fellow, Center for Drug Evaluation, Taiwan

Comparative Effectiveness Research: Impact and Need for Risk Share Agreements
Stephen J. Clark
Vice President, Market Access and Value Strategy, OptumInsight

#366 Track 14 – Clinical Safety and Pharmacovigilance

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

1:30 PM–3:00 PM LEVEL: ● Format: **FORUM**

Room 115c *CME, Pharmacy, and Nursing*

Data Sources for Monitoring Usage of Drug Products and How to Use These Sources to Support Safety and REMS Evaluations

CHAIRPERSON

Juliane Mills
United Biosource Corporation

This forum will present several options for monitoring opioid drug usage within the US and discuss ways to incorporate these monitoring sources to support safety and REMS evaluations.

RADARS® System: Mosaic Approach to Opioid Surveillance & REMS Evaluation
Jody L. Green, PhD
Director of Research Administration, Denver Health, Rocky Mountain Poison & Drug Center

Real-time Data Streams and Their Potential Utility in REMS Assessment
Kevin Zacharoff, MD
Vice President, Medical Affairs, Inflexxion, Inc.

#367 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CP

1:30 PM–3:00 PM LEVEL: ■ Format: **SESSION**

Room 113a

Impact of Bayesian Methods in Medical Product Development

CHAIRPERSON

Karen Lynn Price, PhD, MA
Principal Research Scientist, Eli Lilly and Company

Bayesian methods play an important role throughout the medical product development process. The DIA Bayesian Scientific Working Group, a coordinated effort from academia, regulatory, and industry, helps ensure that methods are well understood, accepted, and utilized.

An Overview of Bayesian Evidence Synthesis Techniques with Applications in Safety Evaluation and Comparative Effectiveness
David Ohlssen, PhD
Senior Expert Methodologist, Novartis Pharmaceuticals Corporation

The Use of Subjective Priors in Drug Development
Nelson M. Kinnersley, MSc
Associate Director, Biostatistics, Roche Products ltd, UK

Bayesian Approaches for Data Mining for Spontaneous Adverse Events
Ram Tiwari, PhD
Associate Director for Statistics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

#368 Track 17A – Global Regulatory

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

1:30 PM–3:00 PM | LEVEL: ■ | Format: **SESSION**

Room 122b

CME and Nursing

Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall

CHAIRPERSON

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

PMDA will explain its current services and the Japanese drug regulation and answer your questions on these and PMDA's future initiatives/challenges for faster review and better life cycle management of drugs.

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

Hideo Utsumi, PhD
Executive Director and Director, Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Kenichi Tamiya
Deputy Director, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare (MHLW), Japan

#369 Track 17B – Global Regulatory

Related Interest Area(s): RA, CR

1:30 PM–3:00 PM | LEVEL: ● | Format: **FORUM**

Room 119a

CME and Nursing

CBER Town Hall

CHAIRPERSON

Karen Midthun, MD
Director, CBER, FDA

This session will provide an overview of CBER's current work on ongoing initiatives, guidances, and regulations.

Robert A. Yetter, PhD
Associate Director for Review Management, Office of the Director, CBER, FDA

Karen Midthun, MD
Director, CBER, FDA

#370 Track 18 – Rare/Neglected Diseases

Related Interest Area(s): AP, CR

1:30 PM–3:00 PM | LEVEL: ■ | Format: **FORUM**

Room 115a

CME, Pharmacy, and Nursing

Social Media 2.0: The Power of Online Rare Disease Communities to Connect and Engage ePatients

CHAIRPERSON

Julia Nable
Director of Marketing Strategy, SandorMax

Relevant case studies will be presented to demonstrate how online patient communities and social media are revolutionizing how patients gain access to disease and treatment information.

RareConnect: A Global Social Network for Rare Disease Communities and Patients
Tai Spargo
Assistant Director of Communications, National Organization for Rare Disorders (NORD)

The Power of Patient-driven Research and Rare Disease Online Communities: The SCAD Ladies and Beyond
Brian Loew
CEO, Inspire

Biopharma and Social Media: A Case Study
Eric Grinstead
Senior Vice President, Commercial Operations, Synageva Biopharma Corporation

#371 Track 22 – White Paper Showcase

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

1:30 PM–3:00 PM | LEVEL: ● | Format: **SESSION**

Room 125

Implementation of Adaptive Clinical Trials

CHAIRPERSON

Corey B. Dunham
Senior Vice President, Global Data Management, Aptiv Solutions

Although adaptive design concepts have been available for some time, only recently has implementation been achievable. This breakthrough is possible because of the development of integrated technologies and operational processes specifically designed to support the execution of adaptive trials.

Brought to you by Aptiv Solutions.

Attendee badges scanned for this White Paper Showcase will be shared with the Company hosting this offering. If you prefer not to have your badge scanned, please inform the DIA staff member.

Judith A. Quinlan, MSc
Senior Vice President, Adaptive Trial Design Implementation, Aptiv Solutions

Vladimir Dragalin, PhD
Senior Vice President, Clinical Trial Innovation Strategies, Aptiv Solutions

3:00 PM–3:30 PM **REFRESHMENT BREAK**
Exhibit Hall

#372 Track 01A – Clinical Operations

Related Interest Area(s): IS, PR, PPLCC

3:30 PM–5:00 PM | LEVEL: ■ | Format: **SESSION**

Room 109ab

Standard of Care: Challenges for Sponsors, Sites, and Patients in Clinical Trial Budgets

CHAIRPERSON

Sondra A. Pepe
Product Manager, Medidata Solutions Worldwide

A sponsor and site share methods for identifying standard of care, including case studies that express the real-world impact on sites and patients. A novel patient survey explores the public perception of free care in the context of clinical trials.

Prepare Budgets for Projects with Coverage Analysis
Kelly M. Willenberg, BSN, MBA
Consultant, SYNERGISM, LLC

Sponsors' Responsibilities with Coverage Analysis
Soo Y. Bang, MHA
Director, Global Site Contracts, Celgene Corporation

#373 Track 01B – Clinical Operations

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

3:30 PM–5:00 PM LEVEL: ● Format: **SYMPOSIUM**

Room 105ab *CME and Nursing*

Special Populations Symposium

CHAIRPERSON

Brenda Jamerson, PharmD
Associate Professor, Clinical Research, Campbell University College of Pharmacy and Health Sciences

Recruitment and retention of a diverse population in clinical trials is becoming increasingly important. In order to adequately address efficacy and safety targets in specific subsets of the population, clinical trials must include a broad range of participants across the spectrum of race, ethnicity and age. This symposium will present practical insights for clinical trial operational planning that optimizes recruitment and retention of Blacks, Latinos, and geriatric participants in clinical trials.

Strategies to Enhance Recruitment and Retention of Ethnically Diverse Populations in Clinical Trials
Brenda Jamerson, PharmD
Associate Professor, Clinical Research, Campbell University College of Pharmacy and Health Sciences

A Winning Messaging and Media Strategy for Latino Patient Recruitment: As Easy as Uno, Dos, Tres
Carmen R. Gonzalez, JD
Manager, Strategy and Communications, Healthcare Communications Group, Inc.

Special Populations: Clinical Trial Planning Considerations for Geriatric Patients in Clinical Trials
Kelly Larrabee, MBA, MS, RN
Senior Director, Clinical Services, ClearTrial, LLC

#374 Track 01C – Clinical Operations

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SYMPOSIUM**

Room 108a *CME, Nursing, and PMI PDUs*

Optimizing Study Monitoring Performance and Efficiency

CHAIRPERSON

Kenneth A. Getz, MBA
Tufts Center for the Study of Drug Development, Chairman, The Center for Information and Study on Clinical Research Participation (CISCRP), Tufts University

The global CRA workforce plays a vital role in assessing clinical trial compliance, maintaining relationships with investigative sites, monitoring patient safety and ensuring data quality. During the past decade, study monitor workload has increased and utilization has changed dramatically, with wide variability by geographic region. This symposium explores key characteristics, responsibilities and capacity of the global CRA workforce, notes trends impacting study monitor performance, and explores practices and solutions designed to improve CRA capacity, efficiency and effectiveness.

Characterizing Global CRA Workforce Workload and Utilization
Kenneth A. Getz, MBA
Tufts Center for the Study of Drug Development, Chairman, The Center for Information and Study on Clinical Research Participation (CISCRP), Tufts University

The Role of Data Visualization in Clinical Monitoring
Michael J. Brennan, PhD
Director, Informatics, Johnson & Johnson Pharmaceutical Research & Development, LLC

Optimizing the Monitoring Visit with Standardized Practices and Innovative Technology
Lisa Rhiner
Clinical Study Lead, Kforce Inc., Now Part of Inventiv Health

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

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**

Room 103c

Planning and Execution of a Global Oncology Program

CHAIRPERSON

Eric M. Towler, PhD, PMP
Director, Global Project Management and Leadership, Daiichi Sankyo Inc.

This session will describe actual case studies of successful oncology development programs. Presenters will focus on the key success factors to a productive collaboration and lessons learned from their own experiences.

Gaining Global Consensus on the WHAT of a Clinical Program
Anthony P. Wiemelt, DrSc, PhD
Senior Project Manager, Pipeline Leader Infectious Disease, Merck & Co., Inc.

How Innovation and Collaboration Kept Pharmaceutical Sciences Off Critical Path to Filing
Richard S. Hutchins, PhD
Pharmaceutical Sciences Oncology Business Unit Lead, Pfizer Inc

Global Development: Towards Simultaneous Global Submissions and Approvals
Mann Fung, MD, MBA, FACP
Compound Development Team Leader – PCI32765 and Cell Therapy Teams, Johnson & Johnson Pharmaceutical Research & Development, LLC

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

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

3:30 PM–5:00 PM LEVEL: ■ Format: **FORUM**

Room 111ab *PMI PDUs*

Effectively Managing Global Trials Within a CRO Alliance Structure

CHAIRPERSON

Michael J. O'Brien
President, CEO, Beardsworth Consulting Group Inc.

This forum explores one key challenge confronting global alliances of regional CROs: aligning motivations and expectations of sponsor and alliance members to achieve an optimal multicultural, multinational result.

Global Alliance Model from Concept to Reality
Michael J. O'Brien
President, CEO, Beardsworth Consulting Group Inc.

Global Studies: Lessons and Observations from the Asia Pacific
Alek Safarian, MBA, RPh
CEO, Novotech (Australia) Pty Ltd, Australia

Challenges in Global Trials Management: Central and Eastern Europe Partner Perspective
Malgorzata Szerszeniewska, MD
CEO, EastHORN Clinical Services CEE, Poland

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

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

3:30 PM–5:00 PM | LEVEL: ■ | Format: **SYMPOSIUM**
Room 118a

Sites, CROs, and Sponsor Relationship Obstacles and Opportunities

CHAIRPERSON
Suzanne Collins, BSN
Director of Operations, Trifecta Multimedical

In this symposium, prerecorded interviews from site personnel will be a backdrop for discussions on how evolving sponsor/CRO relationships have affected sites, if the current paradigm is allowing sites to transfer their knowledge gained during clinical trials effectively, what sites ultimately need from the sponsor and CRO to consistently produce valuable data.

Site, CRO, and Sponsor Communication Challenges
Suzanne Collins, BSN
Director of Operations, Trifecta Multimedical

A Boat Won't Float Without Water: The Effect of Sponsor/CRO Partnerships on Sites
Rikki Hansen Bouchard, MPA
President and Chief Executive Officer, RH Bouchard & Associates Inc.

Knowledge Transfer in Clinical Trials: Is the Collaboration with Investigative Sites Utilized?
Marie Smed, MSc
PhD Student, Technical University of Denmark, Denmark

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

Related Interest Area(s): NC, BT

3:30 PM–5:00 PM | LEVEL: ● | Format: **SESSION**
Room 124 | *CME and Nursing*

Biomarker Focused Strategies for Personalized Medicine

CHAIRPERSON
Renee Pridgen
Assistant Director, Clinical Operations, Duke Clinical Research Institute

Clinical care centers on standards based on epidemiological studies of large cohorts. However, these studies do not take into account genetic variability. This session discusses the pursuit of personalized medicine through biomarker collection.

Cell-based Systems as Platforms to Identify Unique Biomarkers in Drug Discovery
Kenneth J. Pennline, PhD
Vice President and Global Head, Cytometry Services, Labcorp Clinical Trials

The Role of Biobanks in Developing Better Biomarkers
E. David Litwack, PhD
AAAS Science and Technology Policy Fellow, National Cancer Institute, National Institutes of Health

Pharmacogenomics as a Model for Biomarker Discovery and Translation
Deepak Voora, MD
Instructor of Medicine, Division of Cardiology; Associate Investigator, Duke Institute for Genome Sciences and Policy

#379 Track 05 – Product Advertising and Marketing

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

3:30 PM–5:00 PM | LEVEL: ■ | Format: **SESSION**
Room 113b | *Pharmacy*

Leveraging Drug Development and Advertising/Promotion Regulatory Expertise to Drive a Robust Target Product Profile Process

CHAIRPERSON
Michele L. Sharp, PharmD
Senior Director, Global Regulatory Affairs – US, Eli Lilly and Company

In March 2007, FDA issued a draft guidance entitled, Target Product Profile — A Strategic Development Process Tool. This FDA Guidance could be used to facilitate the connections between clinical planning, label statements, and scientific communications to customers. Today, several challenges exist in associating seamless integration of clinical development data into the label and then into promotional communications. This expert panel will explore ways to leverage the targeted product profile tool in your company's drug development process maximizing both the drug development and advertising/promotion regulatory expertise. The panel will also consider how to effectively incorporate the targeted product profile tool into discussions with FDA.

FDA Point of View
Laurie Burke, MPH, RPh
Director for Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

Industry Point of View
Tracy Rockney
Divisional Vice President, Abbott Laboratories

Industry Point of View
Amy A. Jennings, PhD
Director, Global Regulatory Sciences, Bristol-Myers Squibb Company

#380 Track 06 – Medical Writing and Medical Communications

Related Interest Area(s): MW, RA, ST

3:30 PM–5:00 PM | LEVEL: ■ | Format: **SESSION**
Room 108b | *CME, Pharmacy, and Nursing*

Recent Advances in Adaptive Clinical Trial Designs for Medical Writers

CHAIRPERSON
William K. Sietsema, PhD
Vice President, Regulatory Strategy, Consulting, and Submissions, INC Research, Inc.

In this session, speakers will review the types of adaptations that can be built into clinical trials and the types of concerns these adaptations raise with regulators and the scientific community. Statistical methodologies will also be reviewed.

Overview of Adaptive Design Concepts and Common Types of Adaptations
William K. Sietsema, PhD
Vice President, Regulatory Strategy, Consulting, and Submissions, INC Research, Inc.

Implications of Adaptive Designs for Preparation of Protocols, Statistical Analysis Plans, Clinical Study Reports, and Elements of Marketing Authorization Applications
Annie C. Solterbeck, PhD, MSc
Director, Statistical Revelations, Australia

A Regulatory Perspective on Adaptive Designs in Drug Development
H.M. James Hung, PhD
Division Director, Office of Translational Science, CDER, FDA

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

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 103a *CME, Pharmacy, and Nursing*

Sharing Clinical Data: Examples of What to Share and Benefits to Research and Patients

CHAIRPERSON
Michael N. Cantor, MD
Senior Director, Biomedical Informatics, Pfizer Inc

This session will highlight the importance of robust systems that promote data sharing. Moving from the general to the specific, the session will examine strategies that promote data transparency and access, a database that promotes data integration for biospecimens, and a database that integrates administrative and clinical data for quality and research.

Data Without Borders: IT Strategy Enabling Research and Development
Michael N. Cantor, MD
Senior Director, Biomedical Informatics, Pfizer Inc

Italian Population-based Linked Database to Measure Health Performance in the Real World
Marisa De Rosa
Head of Systems and Services for Health Department (SISS), CINECA Inter-University Consortium, Italy

Integrating Advanced IT Systems that Streamline Management of Biospecimen Inventories and Associated Clinical Data
Lori Ball, MBA
Chief Operating Officer, BioStorage Technologies, Inc.

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

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room 103b *CME and Nursing*

Automation Through CDISC Standard Models: eProtocol, Data Submission, and Safety Reporting

CHAIRPERSON
Richa Singh, MPharm
Business Analyst, Cognizant Technology Solutions Corporation, India

This symposium will include discussions on automated solutions based on CDISC and CDASH data standard models that can bring significant effort reduction and process optimization across the clinical data management framework.

Clinical Study Setup Automation with eProtocol
Richa Singh, MPharm
Business Analyst, Cognizant Technology Solutions Corporation, India

Chain of Custody: CDASH to Data Submission
Janet Stuelpner, MA, MS
Solutions Architect, SAS Institute

Single Source SAE Data Collection via EDC in Relation to Centralized Monitoring
Wim Verreth, DrMed, MS
SGS Life Science Services, Belgium

#383 Track 08A – Regulatory Affairs and Submissions

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 119b

Adaptive Licensing: Bane or Boon for Drug Development?

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

Regulatory decisions are of necessity based on incomplete data. Traditional drug licensing approaches are based on binary approval decisions which reduce the uncertainty of an experimental therapy to a fully vetted, safe, and efficacious market authorization. Adaptive licensing (AL) proposals would contrast this precedent providing iterative phases of data gathering followed by regulatory evaluation and would allow the approval process to align more closely with patient needs such as timely access to new technology and the information required to inform medical decisions. Adaptive licensing would build on and broaden existing elements of drug regulation, including accelerated approval (in US) or conditional marketing authorization (in EU). This session summarizes a number of recent AL proposals and discusses how AL might be translated into practice.

Paving the Way to Adaptive Licensing
Robyn R. Lim, PhD
Scientific Advisor, Progressive Licensing Project, TPD, HPFB, Health Canada

Panelists
Thomas Unger, PhD
Executive Director, Worldwide Regulatory Strategy, Pfizer Inc

Kenneth Oye, PhD
Associate Professor, Political Science; Co-Director, Program on Emerging Technologies, Massachusetts Institute of Technology (MIT)

#384 Track 08B – Regulatory Affairs and Submissions

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

3:30 PM–5:00 PM LEVEL: ◆ Format: **SESSION**
Room 120bc *Pharmacy*

Update on Biosimilar Developments in the US

CHAIRPERSON
Nikhil Mehta, PhD
Vice President, Biologics, Global Regulatory Affairs, Merck & Co., Inc.

Statutory framework for biosimilars was approved in the US in March 2010. This session will discuss progress in defining regulatory standards for approval of biosimilars.

Global Development of Biologics and the On-Going Need for Regulatory Harmonization Being Applied to Biosimilars
Mark McCamish, MD, PhD
Global Head of Biopharmaceutical Development, Sandoz Biopharmaceuticals, a Novartis Company, Germany

Regulatory Standards for Biosimilars: Balancing Risk and Access
Jay P. Siegel, MD
Chief Biotechnology Officer, Global Head Regulatory Affairs, Johnson & Johnson

Panelist
Leah A. Christl, PhD
Associate Director for Biosimilars, Office of New Drugs, CDER, FDA

#385 Track 10A – Public Policy/Health Care Compliance/Regulatory Law

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

3:30 PM–5:00 PM | LEVEL: ● | Format: **SESSION**
Room 118c | *Pharmacy*

Emerging Role of the Patient Voice on Drug Policy in Japan

CHAIRPERSON

Tatsuo Kurokawa, PhD
Professor, Regulatory Sciences, Faculty of Pharmacy, Keio University, Japan

Patients and lay people in Japan now form one of the major groups that support current drug development, safety, supply, and regulatory affairs. This session will discuss recent change and the significant effect of the patient voice on drug policy and the progress of the amendment of the Pharmaceutical Affairs Law.

Hiromi Matsumoto, Esq.
Patient Advocate, Nattokushite Iryou Wo Ukerukai (Patient Understand Medical Care With Own Decision), Japan

Keiko Ebihara, DrPH
Director, Regulatory and Vaccine Policy Group, Health Policy and Access, MSD K.K., Japan

Representative Invited
Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#386 Track 10B – Public Policy/Health Care Compliance/Regulatory Law

Related Interest Area(s): CP

3:30 PM–5:00 PM | LEVEL: ■ | Format: **FORUM**
Room 113c | *CME and Nursing*

Regulatory Capacity Building from 360 Degrees

CHAIRPERSON

Ekopimo O. Ibia, MD, MPH, FRCP
Director and US Regulatory Policy Lead, Global Regulatory Strategy, Policy, and Safety, Merck & Co., Inc.

Regulatory capacity building is a critical activity to ensure the global access and supply of safe and effective pharmaceuticals. Health authorities, non-profit entities, and international organizations priorities and activities will be presented.

FDA's Point of View on Global Regulatory Capacity Building
Katherine C. Bond, PhD
Supervisory Management Analyst, Office of International Activities and Strategic Initiatives, Office of the Commissioner, FDA

WHO's Goals and Priorities
Lembit Rago, MD
Coordinator, Quality Assurance and Safety for Medicines, World Health Organization (WHO), Switzerland

Sustainable Capacity Building For Regulatory Workforce in Africa
Paul K. Tanui
Senior Programme Officer, NEPAD Planning and Coordinating Agency, South Africa

#387 Track 11 – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

3:30 PM–5:00 PM | LEVEL: ■ | Format: **WORKSHOP**
Room 121c

Good Clinical Practice (GCP) through Good Documentation Practices (GDPs)

CHAIRPERSON

Paul Swidersky
President, Quality Associates, Inc.

The requirements for providing credibility to clinical study data require that each site assure full reconstructibility of the data that is generated by each of its personnel. Good Documentation Practices (GDPs) require attributes of data that will be defined and explained. They include not only recording the data directly and promptly, but assuring legibility, attributability, and durability. The reconstructibility of records will be shown to include linking study-specific data to site-specific records, such as which equipment was used for each subject, temperature logs, calibration records, qualification and training records, and addressing data recording issues in the subject's diary. Proper correction techniques will be described for manual data entries. Examples will illustrate gaps that auditors routinely identify in clinical data.

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

Quality Assurance Expert, Clinical and Pre-clinical Studies
Molly Butler
Consultant, Quality Associates, Inc.

#388 Track 13A – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

Related Interest Area(s): CP, CR

3:30 PM–5:00 PM | LEVEL: ■ | Format: **FORUM**
Room 107ab | *CME, Pharmacy, and Nursing*

The Role of Meta-analyses in Drug Safety: Methodological Considerations

CHAIRPERSON

Simone P. Pinheiro, DrSc, MSc
Epidemiologist, Team Lead, Office of Surveillance and Epidemiology, CDER, FDA

Although the value of meta-analyses in drug efficacy is established, their role in evaluating harm needs consideration. The role of meta-analyses and the reporting of methodological considerations in published meta-analyses will be discussed. The panel will also focus on additional questions such as when are these studies most useful to inform clinical and/or regulatory decision making, and what are the critical elements that should be included

in a framework to assess reporting of methodological considerations of meta-analyses in drug safety?

Secondary Use of Randomized Controlled Trials to Evaluate Drug Safety
Tarek A. Hammad, MD, PhD, MS
Deputy Division Director, Division of Epidemiology-I, CDER, FDA

Design and Analysis Reporting in Meta-analyses of Randomized Controlled Trials with Focus on Drug Safety
Simone P. Pinheiro, DrSc, MSc
Epidemiologist, Team Lead, Office of Surveillance and Epidemiology, CDER, FDA

Panelists
C. George Rochester, PhD, MA, RN, RAC
Associate Director for Safety Assessment, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Soledad Cepeda
Director, Epidemiology, Johnson & Johnson

#389 Track 13B – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

Related Interest Area(s): CP

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 116 *CME, Pharmacy, and Nursing*

Benefit Versus Risk of Harm: Assessing Therapeutic Response and Interpreting Benefit/Risk with Patients

CHAIRPERSON
Lee S. Simon, MD
Consultant, SDG LLC

This session will highlight the importance of interpretation of the benefits versus the risks of harm when assessing responsiveness to a therapeutic agent and how different stakeholder groups interpret these results. Discussions will include calculations of number needed to treat for benefit and number needed to treat for placing patients at risk of harm. They will also address how patient-reported outcomes may impact these data and what this can tell stakeholders about the usefulness of a therapy.

This session is hosted by Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT).

OMERACT: An International Effort to Develop Data Driven Consensus Regarding Outcomes in Rheumatic Disease Studies — Collaborating with Patients in Determining the Important Outcomes for Efficacy and Safety
Lee S. Simon, MD
Consultant, SDG LLC

Patient-centered Research: The OMERACT Model, How and Why It Works
Amye Leong, MBA
President & CEO, Healthy Motivation, Patient Research Partner, OMERACT

Credible, Useful Patient Decision Aids: The Power of the OMERACT Model for Patient Collaboraton in Design and Development
Thasia G. Woodworth, MD
Visiting Clinical Researcher, Geffen School of Medicine, UCLA, OMERACT, Canada

The OMERACT 3x3 Table: A First Step to Assess Harm and Benefit in Clinical Trials in One Scale
Maarten Boers
Professor of Clinical Epidemiology, Department of Epidemiology and Biostatistics, University of Amsterdam, Netherlands

#390 Track 14 – Clinical Safety and Pharmacovigilance

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

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 115c *CME, Pharmacy, and Nursing*

Doping Abuse of Medicines in Sport: The Challenge to Industry and Regulators

CHAIRPERSON
Barbara Leishman, MA
Head, Quality Risk Management – Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

Ahead of the 2012 Olympics, this session will highlight the many and varied ways in which medicines are misused for performance enhancement and address opportunities for companies to work proactively with World Anti-Doping Agency (WADA) to mitigate the risk of abuse.

Why Should We Collaborate with the World Anti-Doping Agency (WADA)?
Olivier Rabin, PhD
Science Director, World Anti-Doping Agency (WADA), Canada

Early Cooperation with World Anti-Doping Agency (WADA) within R&D
Mark A. Luttmann
World Anti-Doping Agency Cooperation Coordinator, Glaxosmithkline

The Scourge of Doping with Our Medicines: What Should We Do?
Steven Elliott, PhD
Scientific Executive Director (retired), Amgen Inc.

#391 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CEHTAEbM

3:30 PM–5:00 PM LEVEL: ■ Format: **SESSION**
Room 113a *CME, Pharmacy, and Nursing*

Statistical Comparative Effectiveness Research (CER): Closing the Gaps in the Consideration of Observational Evidence

CHAIRPERSON
Joan K. Buenconsejo, PhD, MPH
Statistics Team Lead, Division of Biometrics II, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

As health care costs continue to rise and as new diagnostic and treatment alternatives become available, it is natural to ask which approaches work best. Comparative effectiveness research (CER) or patient-centered outcomes research aims to address this. Ideally, randomized trials could be conducted to formally test superiority or non-inferiority of alternative treatments. However, such trials are not always feasible or ethical, can be very large, of long duration, and costly, and it is not clear whose responsibility it should be to fund and conduct the trials. Many of these trials do not reflect real-world conditions of product use for either patients or health care providers. Interested groups are more often turning to observational data to address relative effectiveness questions. Unlike the primary analysis of a well-designed randomized trial, the operating characteristics of even a similarly well-designed observational study are not known. Randomized pragmatic trials with limited exclusion criteria, no blinding and

observational follow-up can be an alternative but are still subject to biases. This session focuses on ways to quantify and improve the reliability and validity of observational evidence generated by CER.

FDA Perspective
LaRee A. Tracy, PhD, MA
Statistical Team Leader, Office of Biostatistics, CDER, FDA

The Challenges of Multiplicity from Subgroups and Multiple Outcomes in Comparative Observational Research
Cynthia J. Girman, DrPH
Senior Director, Epidemiology, Merck Research Laboratories

Evaluating the Impact of Unmeasured Confounding in Comparative Observational Research
Douglas E. Faries, PhD
Senior Research Advisor, Eli Lilly and Company

#392 Track 16A – Professional Development

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

3:30 PM–5:00 PM LEVEL: ● Format: **SYMPOSIUM**
Room 117

Learning Through Knowledge Sharing and Virtual Worlds

CHAIRPERSON
Donna Ellender, PhD
Regulatory Sciences, Sanofi, France

This symposium will address how knowledge management and collaboration can lead to and aid in innovation — setting up, and building on, knowledge management systems, using ideas from academia and the pharmaceutical industry.

Best Practices for Virtual 3D Learning and Collaboration
Glenn Wise
Associate Director, PPD

Fostering Research and Scholarship Through Knowledge Sharing
Jay Liebowitz, DrSc
Orkand Endowed Chair in Management and Technology, University of Maryland University College

Industry Perspectives on Transforming Pharmaceutical Companies into Knowledge Organizations
Marcus Droege, PhD, MBA
Director, Global Medical Affairs, Takeda Pharmaceuticals International, Inc.

#393 Track 16B – Professional Development

Related Interest Area(s): ALL

3:30 PM–5:00 PM LEVEL: ● Format: **WORKSHOP**
Room 123

DIA 2013: Helpful Hints in Submitting an Abstract

CHAIRPERSON
Julie Ho
Manager, Annual Meeting Content Development, DIA

Join members of the DIA 2013 Program Committee and the DIA Annual Meeting Team for tips and helpful hints as you submit a proposal for next year's Annual Meeting.

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#394 Track 17A – Global Regulatory

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

3:30 PM–5:00 PM LEVEL: ● Format: **SESSION**
Room 121ab *CME and Nursing*

The State of Electronic Submissions at CDER, CBER, and CDRH

CHAIRPERSON
Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, CDER, FDA

CDER, CBER, and CDRH are working towards all-electronic environments, in order to streamline and facilitate the review of electronic submissions. This session focuses on Center goals, experiences and practical advice for sponsors and consultants.

CDRH Update
Terrie Reed, MLS, MS
Associate Director, Informatics, CDRH, FDA

CBER Update
Michael Blanchard Fauntleroy
Program Manager, CBER, FDA

CDER Update
Virginia Hussong
Team Leader, Electronic Submission Support, Office of Business Informatics, CDER, FDA

Panelist
Hilmar Hamann, PhD
Director, Office of Business Informatics, CDER, FDA

#395 Track 17B – Global Regulatory

Related Interest Area(s): RA

3:30 PM–5:00 PM LEVEL: ■ Format: **FORUM**
Room 119a

India Town Hall

CHAIRPERSON
Kaushik Desai
Director, DIA India, DIA (India) Private Limited, India

Representatives from the regulatory authority of India will provide updates on initiatives, guidances and regulations in their country, and the audience will have an opportunity to address the esteemed panel.

Representative Invited
Deputy Drugs Controller, Central Drugs Standard Control Organization, India

#396 Track 18 – Rare/Neglected Diseases

Related Interest Area(s): CR, RD

3:30 PM–5:00 PM LEVEL: ● Format: **SESSION**
Room 115a *CME and Nursing*

Rare Disease Clinical Research Consortia: Immediate and Rich Sources of Translational Research Data, Partnering Opportunities

CHAIRPERSON
Cindy Luxhoj Hahn
President and CEO, Alagille Syndrome Alliance

Rare disease clinical research consortia offer a rich data source for translational research. Investigating diseases from porphyria to pediatric cholestasis, they present an array of collaborative opportunities for the pharmaceutical industry.

The Rare Diseases Clinical Research Network (RDCRN)
Rashmi Gopal-Srivastava, PhD, MSc
Director, Extramural Research Program, Office of Rare Diseases Research, National Institutes of Health

The Childhood Liver Disease Research and Education Network (ChiLDREN)
Ronald J. Sokol, MD
Chief, Section of Pediatric Gastroenterology, Hepatology and Nutrition, Children's Hospital Colorado

The Patient Group Role in Rare Disease Research Consortia
Cindy Luxhoj Hahn
President and CEO, Alagille Syndrome Alliance

#397 Track 21 – Late Breaker

Related Interest Area(s): CR, PM, RA, PPLCC, QC

3:30 PM–5:00 PM LEVEL: ■ Format: **FORUM**

Room 122b *CME and Nursing*

Implementation of the Physician Payment Sunshine Act: Now What?

CHAIRPERSON

John F. Kamp, JD, PhD
Executive Director, Coalition for Healthcare Communication

This controversial provision of the Affordable Care Act has its proponents and its critics, but, as it goes into effect, this panel will focus on its likely impact on the public health and all the stakeholders — government, lawyers and accountants, the pharmaceutical and medical device industries, researchers and investigators, physicians, and others. The panelists, representing a cross-section of interest areas, will take a look at the burdens and benefits, the potential impact on clinical research, the advantages offered by the resultant transparency and how all of this will play out with the public and organized medicine.

John J. Lewis, MA
Vice President, Public Affairs, Association of Clinical Research Organizations (ACRO)

Thomas P. Stossel, MD
Director, Translational Medicine Unit and Center for Medical Innovation, Brigham & Women's Hospital

Sandra J. P. Dennis, JD
Deputy General Counsel, Biotechnology Industry Organization (BIO)

Daniel Carlat, MD
Director, Pew Prescription Project

Marjorie E. Powell, JD
Senior Assistant General Counsel, PhRMA

#398 Track 22 – White Paper Showcase

Related Interest Area(s): CR, RD

3:30 PM–5:00 PM LEVEL: ● Format: **SESSION**

Room 125

Accelerating Cancer Clinical Trials

CHAIRPERSONS

Martin Lee, MD
Executive Vice President, Clinical Trial Services, DAVA Oncology, LP

Slower than anticipated enrollment in cancer clinical trials is a common problem. In this white paper showcase, we will describe the unique challenges in cancer trials and efforts that have been made to increase enrollment. Recommendations for best practice and areas for further research will be highlighted.

Brought to you by DAVA Oncology, LP.

***Attendee badges scanned for this White Paper Showcase will be shared with the company hosting this offering. If you prefer not to have your badge scanned, please inform the DIA staff member.*

Panelist
Mark Levonyak
President, DAVA Oncology, LP, United States

5:00 PM **END OF WEDNESDAY OFFERINGS**

5:15 PM–7:30 PM

Room 117

Consortium of Academic Programs in Clinical Research

NOTES

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THURSDAY, JUNE 28

Registration Hours:

8:00 AM–11:00 AM Attendee and Speaker Registration
Broad Street Lobby

Schedule:

8:15 AM–9:00 AM Coffee and Breakfast Breads
Meeting Room 108 and 119 Concourse

9:00 AM–10:30 AM Concurrent Educational Opportunities

10:30 AM–10:45 AM Coffee Break
Meeting Room 108 and 119 Concourse

10:45 AM–12:15 PM Concurrent Educational Opportunities

12:30 PM–5:00 PM MedDRA® User Group Meeting
Room 108A

#401 Track 01 – Clinical Operations

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

9:00 AM–10:30 AM LEVEL: ■ FORMAT: **SYMPOSIUM**
Room 113c *CME, Nursing, and PMI PDUs*

Clinical Trial Metrics Symposium

CHAIRPERSON
Keith W. Wenzel
Senior Director, Perceptive Informatics

This symposium will present and discuss the key metrics that should be considered by sponsors to effectively monitor and manage the operational, financial and clinical progress of their clinical drug/device trials.

The Vital Role of Patient-reported Data for Monitoring Study Compliance and Overall Performance
Keith W. Wenzel
Senior Director, Perceptive Informatics

Metrics and Benchmarks: Using Data to Improve Clinical Operations
Otis Johnson, MPA
Manager, Global Trial Optimization (GTO), Clinical Research Operations, Merck & Co., Inc.

Integrating Site Metrics into the Site Selection, Planning, and Contracting Process to Improve Performance and Reduce Risk
Melissa Bolanos Hutchens
Consultant, KMR Group, Inc.

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

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

9:00 AM–10:30 AM LEVEL: ◆ FORMAT: **SESSION**
Room 105ab *PMI PDUs*

Managing Drug Development Portfolios in a Safety-heightened Environment

CHAIRPERSON
William K. Sietsema, PhD
Vice President, Regulatory Strategy, Consulting, and Submissions, INC Research, Inc.

Portfolio management is changing to place more emphasis on the risk/benefit ratio. Since most new molecular entities can treat more than one disease, companies may select for initial development diseases which have a greater tolerance for potential risks.

Portfolio Management Theory Overview
William K. Sietsema, PhD
Vice President, Regulatory Strategy, Consulting, and Submissions, INC Research, Inc.

Development of a Framework for Benefit-risk Considerations in FDA/CDER
Patrick Frey
Director, Office of Planning and Analysis, CDER, FDA

Commercial Valuation Considerations in Portfolio Management
Keith Ruark, MBA
Vice President, Avos Consulting

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

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

9:00 AM–10:30 AM LEVEL: ■ FORMAT: **FORUM**
Room 111ab *PMI PDUs*

Integrated Partnership: A Vaccine Case Study

CHAIRPERSON
Raul Soikes, MA
Senior Director, Program Management R&D, Baxter HealthCare Corporation

Parties need to recognize that alignment in objectives and complementary expertise are needed to nurture a partnership and move from a transactional relationship to a skill and resource integrated commercialization strategy. In this session, we will explore the degree to which a partnership was mutually beneficial to each of the involved parties, the novelty of the business model and strategic relationship, and the long-term future and development of the partnership.

Client Perspective
Kimberly S. Hartman, MS
Director/Team Lead, External Supply, Pfizer Inc

Supplier Perspective
Matthew Crowley
Global Account Manager, BD Medical Pharmaceutical Systems

Developing a Trusted Partnership
Colleen K. Dixon, MS, PMP
Site Director, Project Management, MedImmune

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

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

9:00 AM–10:30 AM LEVEL: ■ FORMAT: **SYMPOSIUM**
Room 109ab

Multistakeholder Development Partnerships: Harnessing Differing Perspectives, Objectives, and Strengths for Success

CHAIRPERSON
Karen E. Jaffe, MBA, MS
Regulatory Research, Alfred Mann Biomedical Engineering Institute

The symposium will use case studies to detail operational lessons with integration of multiple stakeholders in medical development processes. Innovation centers bridge gaps between biomedical invention and creation of successful products that improve lives.

Harnessing the Power of Innovation in Academia
Karen E. Jaffe, MBA, MS
Regulatory Research, Alfred Mann Biomedical Engineering Institute

Collaboration with IMPAACT for a Pediatric Registration Program: An Example of a Partnering Model between Pharma and Academia
Xia Xu, PhD
Senior Biometrician, Merck Research Laboratories

Multistakeholder Product Development Partnerships to Accelerate Development for Neglected and Underserved Indications
Karl D. Whitney, PhD
Director, Product Development, Rho, Inc.

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

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

9:00 AM–10:30 AM | LEVEL: ■ | Format: **SYMPOSIUM**
Room 124 | *CME and Nursing*

Hot Topics Symposium

CHAIRPERSON
Cecil J. Nick, MS
FTOPRA, Vice President (Technical), PAREXEL Consulting, UK

This symposium will highlight topics of relevance in the nonclinical and early phase arenas. The first presentation will discuss current perspectives on drug-transporter interactions in drug development and how results are applied to add value to clinical development. The second presentation will address efforts made to map and benchmark the process flow from non-clinical to early development. The third presentation will focus on the need for early consideration of pediatric investigation plans (PIPs) to support an indication in pediatric population, leading to an increased focus on the relevance of nonclinical studies in juvenile animals.

Drug-Transporter Interactions: Regulatory Perspectives and Clinical Relevance
Richard Ridgewell
Associate Director, Drug Metabolism, Covance, Inc.

Mapping the Nonclinical to Early Clinical Drug Development Arena
Stella Stergiopoulos
Project Manager, Tufts Center for the Study of Drug Development

Juvenile Animal Studies and Pediatric Drug Development: Experience from 5 Years of Pediatric Investigation Plans, after European Pediatric Regulation
Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

#406 Track 06 – Medical Writing and Medical Communications

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

9:00 AM–10:30 AM | LEVEL: ■ | Format: **SESSION**
Room 108b | *CME, Pharmacy, and Nursing*

Study Recruitment Challenges, Tailored Medical Information Requests – OH MY! Have You Maximized All Your Options

CHAIRPERSON
David L. Cram, PharmD
Vice President, Medical Affairs RSS Team, Allergan, Inc.

A Medical Science Liaison's value proposition is that they are in the field working with health care practitioners and they may be able to assist with their home office colleagues' needs. This session will explore those areas where successful collaborations have occurred.

Medical Science Liaisons: Home Office Collaborations
Suzana Giffin
Executive Director, Medical Information, Scientific Affairs, Amgen Inc.

The Medical Science Liaison: An Integral Part of the Clinical Study Team
Jannell Ribera DePalantino, PharmD, RPh
Associate Director, Medical Affairs Strategic Trials Team, Janssen Services, LLC

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

Related Interest Area(s): IT, VA, CP

9:00 AM–10:30 AM | LEVEL: ■ | Format: **WORKSHOP**
Room 121c | *CME, Pharmacy, and Nursing*

Cloud Computing in Regulated Environments

CHAIRPERSON
Arik Gorban
Associate Vice President, Compliance and Quality, iGATE Patni Life Sciences

Traditional validation, qualification, and risk management practices are not feasible in cloud-based systems, and expectations for certain documentation cannot be met. This workshop will discuss how to manage compliance in a cloud-based environment.

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

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

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

9:00 AM–10:30 AM | LEVEL: ■ | Format: **SESSION**
Room 107ab | *CME and Nursing*

The Cross-over Between Direct-to-patient Studies, Social Media, and EDC

CHAIRPERSON
Douglas Bain
Founder and CEO, eClinicalHealth Limited, UK

The traditional boundaries between ePRO, Electronic Data Capture (EDC) and community health information sharing are blurring as community principles of social media and direct-to-patient studies emerge. This session examines how Patient Data Capture (PDC) has evolved in recent years, and how this will impact the evolution of data acquisition in clinical trials.

How Much Are ePROs Better than Paper PROs?
Valdo Arnera, MD
General Manager Europe, PHT Corporation, Switzerland

EDC's Evolution to PDC: Patient Data Capture
Douglas Bain
Founder and CEO, eClinicalHealth Limited, UK

Patient Perspective
Ben Heywood, MBA
President and Co-founder, PatientsLikeMe Inc.

#409 Track 11 – Compliance to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Quality Assurance (QA)

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

9:00 AM–10:30 AM LEVEL: ■ Format: **SYMPOSIUM**

Room 121ab

The Role of Corrective and Preventive Action (CAPA) in GCP/GLP Audit Quality Management Systems

CHAIRPERSON

Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

Corrective and Preventive Action (CAPA) have become an integral part of a GCP Quality Management System approach. A formal program for CAPA is becoming an integral means for meeting FDA and global regulatory expectations for clinical trial quality. The relationship between documentation, deviations and corrective actions is becoming more clear with each 483 letter issued by the FDA. The ability to effectively manage your SOPs, track training and associate them to CAPA resolution is vital.

Utilizing Monitoring Findings to Identify Events Requiring a CAPA
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

Deviation Management: SOPs and CAPAs for GCP, GLP and GMP
Warren Perry
Compliance Consultant, QUMAS

Automating GCP/GLP Audit Reporting Processes in a Quality Management System
KR Karu
Industry Principal, Sparta Systems

#410 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CDM, CP, DM

9:00 AM–10:30 AM LEVEL: ■ Format: **WORKSHOP**

Room 123 *CME and Nursing*

Coding with Confidence

CHAIRPERSON

Judy E. Harrison, MD
Senior Medical Officer, MedDRA MSSO

This workshop will provide an overview of coding safety data with MedDRA®. Participants will apply the key principles in the "MedDRA® Term Selection: Points to Consider" document by engaging in practical coding exercises in an interactive format.

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Practical Experience Applying Coding Principles and Conventions
Jean D. Cole, PharmD
Associate Director, Drug Safety and Public Health, Gilead Sciences, Inc.

#411 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CDM, IT

9:00 AM–10:30 AM LEVEL: ■ Format: **SESSION**

Room 113a

Open Source Statistical Software in Drug Development: Challenges and Opportunities

CHAIRPERSON

Jose C. Pinheiro, PhD
Senior Director, Quantitative Decision Strategies, Janssen Research & Development, LLC

Use of open source software in clinical drug development has been hampered by the incorrect perception that it cannot be validated and, therefore, is not acceptable for regulatory submissions. This session will discuss the challenges, perceived and real, to the broader utilization of open source statistical software in drug development (in industry, as well as in NIH-sponsored trials), and opportunities for addressing those challenges. It will feature speakers with practical experience with the use of open source software in drug development.

FDA Perspective and Experience with Open Source Software
Mat Soukup, PhD
Team Lead, Office of Translational Sciences, Center for Drug Evaluation and Research, FDA

Developing and Utilizing Open Source Software for Clinical Drug Development in a Biopharma Industry Environment
Vladimir Dragalin, PhD
Senior Vice President, Clinical Trial Innovation Strategies, Aptiv Solutions

The Qualification and Validation of Open Source Software
Seth Berry, PhD
Director, Quintiles

#412 Track 16 – Professional Development

Related Interest Area(s): MC, CmbP, PM

9:00 AM–10:30 AM LEVEL: ● Format: **SYMPOSIUM**

Room 125

Left to Your Own Devices

CHAIRPERSON

Matthew Pepe
Division Director, Workforce Integration

In today's market, professionals look to move between pharmaceuticals and the medical device industry for the experience, to innovate, and frankly out of necessity. In this symposium, through examples from the device industry, you will discuss what it takes to transition from one industry to the other, industry and academic collaborative educational programs, and to recognize cultural imperatives to save face and devise project management approaches to mitigate the organizational and business risks of this. All are valuable and interesting on their own merit, and have applications to any other regulated industry.

Career Transitions Between Device and Pharma: Why the Stigma?
Matthew Pepe
Division Director, Workforce Integration

Saving Your Project from Your Team's Need to Save Face
Nermeen Y. Varawalla, MD, PhD, MBA
Founder & CEO, ECCRO, UK

Innovative Learning Opportunities: A Collaboration between Industry and Academics
William Gluck, PhD, MS
Vice President, DCCS, DATATRAK International

#413 Track 17 – Global Regulatory

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

9:00 AM–10:30 AM | LEVEL: ● | Format: **FORUM**
Room 114 AUD | *CME and Nursing*

CDER Town Hall: Part 1 of 2

CHAIRPERSON
Nancy D. Smith, PhD
ORISE Fellow at FDA/Adjunct Professor, Temple University

Part 2 of this forum will take place on Thursday, June 28th at 10:45 AM.

The leadership team of CDER will be invited to participate in this forum. The topics that will be discussed will depend on the audience and on areas that are of current importance within the CDER community.

Submit your questions in advance to annualmeetingprogram@diahome.org Subject: CDER Town Hall.

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

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

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

Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Center Director for International Programs, CDER, FDA

Robert J. Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA

Julie Anne Zawisza, MA
Director, Office of Communications, CDER, FDA

10:30 AM–10:45 AM **COFFEE BREAK**
Meeting Rooms 108 And 119 Concourse

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

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

10:45 AM–12:15 PM | LEVEL: ■ | Format: **SESSION**
Room 105ab

Strategically Reduce Study Cost by Controlling Study Design Cost Drivers, with Attention to Studies with Biomarkers

CHAIRPERSON
Michael Palmer, MS
President, Adaptive Pharmacogenomics, LLC

Development planning, including modeling study cost, is critical to the success of any product. A rigorous methodology based on research done with the FDA and a large pharma exists for objectively and quantitatively modeling and understanding study cost, including studies with biomarkers. Guided by this modeling, the clinical development strategist can revise study strategy to save money while preserving objectives.

Strategic Development Planning: Designing Fast and Efficient Programs
William K. Sietsema, PhD
Vice President, Regulatory Strategy, Consulting, and Submissions, INC Research, Inc.

Evaluating Cost and Complexity of a GI Cancer Study Design Using an FDA Software Tool
Philip Dehazya, PhD
Program Director, Oncology Business Unit, Aptiv Solutions

Strategies for Controlling Study Costs
Michael Palmer, MS
President, Adaptive Pharmacogenomics, LLC

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

Related Interest Area(s): OS, CR

10:45 AM–12:15 PM | LEVEL: ■ | Format: **SESSION**
Room 111ab | *PMI PDUs*

Preferred Provider Relationships: Yesterday's Obstacles, Today's Successes, and Tomorrow's Vision

CHAIRPERSON
Melinda K. Davis
Senior Director, Clinical Services, ClearTrial, LLC

This session will focus on the evolution of the preferred provider relationship. Representatives from pharmaceutical companies and CROs will share how they make this relationship work, as well as their thoughts on how this trend will continue to evolve.

Sponsor-CRO Relationships: Insights into Current Practices, Industry Challenges, and Future Opportunities
Patricia Leuchten
CEO and President, The Avoca Group Inc.

Strategic Alliances: Key Learnings and Emerging Models from the CRO Perspective
Tim Dietlin, MBA
Vice President, Alliance Development, INC Research, Inc.

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

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

10:45 AM–12:15 PM | LEVEL: ■ | Format: **SESSION**
Room 109ab | *PMI PDUs*

Using Technology to Build Successful Strategic Outsourcing Partnerships

CHAIRPERSON
Robert Nichols, MSc
Senior Director, Global CRO Partnerships, Oracle Health Sciences, UK

Utilizing technology has long been seen as a key tactic to drive efficiencies in the clinical development process. Strategic partnerships see this value amplified as technology becomes an underlying part of the pharma-CRO relationship.

New Frontiers: Using Technology to Build Partnerships
Thomas C. Grundstrom, MA
Vice President, Integrated Process and Technology, Quintiles

Business Technology Approaches to Enable Successful Clinical Trial Operations Partnerships

David Pasirstein, MS
Director Architecture, Global Clinical Development, MRL IT, Merck & Co., Inc.

Information: A Strong Foundation for Successful Partnerships
Raghu S. Chintala
Vice President, Project Management, ICON PLC

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

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

10:45 AM–12:15 PM LEVEL: ● Format: **SESSION**
Room 103b *CME and Nursing*

Strategies for Implementing Dried Blood Spot Drug Development and How the Technology Supports the 3Rs Principles

CHAIRPERSON
Fumin Li, PhD
Senior Staff Scientist, Covance, Inc.

Dried blood spot (DBS) sampling is gaining momentum as an alternative to plasma in support of drug discovery and development. DBS provides significant ethical benefits with reduced animal usage, using the 3Rs principle (animal reduction, refinement, and replacement), and higher data quality in safety assessment.

Strategies for Use of DBS in Discovery through Early Clinical Development
Patricia A. Zane, PhD
Associate Director, Sanofi

Adopting Dried Blood Spot Sampling to Support Drug Development
Enaksha Wickremsinhe, PhD
Principal Research Scientist, Drug Disposition, Eli Lilly and Company

Moving Forward with Microsampling: DBS, Whole Blood, Plasma
John A. Dunn, PhD
Director, GlaxoSmithKline

#418 Track 06 – Medical Writing and Medical Communications

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

10:45 AM–12:15 PM LEVEL: ■ Format: **SYMPOSIUM**
Room 108b *CME, Pharmacy, and Nursing*

Medical Writing Competencies and Best Practices in the Global Environment

CHAIRPERSON
Thomas J. Purcell, MS
Principal and Owner, Urtech Medical Writing & Consultancy, LLC

Many companies outsource various tasks that could be performed by the company itself. In the biopharmaceutical industry, one form of outsourcing is known as functional outsourcing and one such function that has been identified for functional outsourcing is medical writing. This symposium will address ways in which to maximize the role of in-house writers with their external counterparts and their internal customers, show the challenges and benefits of implementing a company-wide style guide or rule book for use by internal and external writers and editors, and present tried and true strategies for developing strong document review teams and setting the ground rules for team roles and responsibilities, particularly in instances in which team members are geographically dispersed and represent a diverse cross section of the organization.

Mastering the Role of the Single Point of Contact: The Changing Role of the US, EU-based Medical Writer
Thomas J. Purcell, MS
Principal and Owner, Urtech Medical Writing & Consultancy, LLC

Who's Got Style? How to Create or Modify Company Style Guides for the Best Results
Dawn Pirozzi Maxemow
Senior Medical Editor, INC Research, Inc.

Maximizing Time and Talent: Stakeholder Management in Medical Writing Document Reviews
Lisa Pierchala, MPH
Manager, BioStatistics and Medical Writing, MMS Holdings Inc.

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

Related Interest Area(s): CDM, VA, EC

10:45 AM–12:15 PM LEVEL: ■ Format: **SYMPOSIUM**
Room 103a *CME and Nursing*

Data Warehousing: Buzz Word or Panacea?

CHAIRPERSON
Dimitri Kutsenko, MA, MBA
Entimo AG, Germany

The data warehousing symposium will illuminate this current trend in the pharmaceutical industry from entirely different perspectives. We will critically look at the topic and analyze the reasons which make data warehousing projects a failure or success. The symposium will offer a platform to share experiences and shape ideas on future data warehousing developments in the pharmaceutical industry. We would like to invite all critical and visionary people to join the symposium and to discuss this "new" data warehousing trend.

The Virtual Biobank a Paradigm Shift
Andreas Wenger, MSc
Solution Manager, F. Hoffmann-La Roche AG, Switzerland

The Network of Postmarketing: the Sixty-three Italian Drugs Registries
Entela Xoxi, PharmD, PhD, MSc
Pharmacologist, Clinical Trial Office, Italian Medicines Agency (AIFA), Italy

How to Leverage Clinical Data Warehousing with Smart Metadata Handling?
Dimitri Kutsenko, MA, MBA
Entimo AG, Germany

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

Related Interest Area(s): EC, CDM, FI

10:45 AM–12:15 PM LEVEL: ◆ Format: **SYMPOSIUM**
Room 103c *PMI PDUs*

Economic Considerations and Management in the Modern Day Clinical Trial

CHAIRPERSON
Keith W. Wenzel
Senior Director, Perceptive Informatics

Efficient fiscal management of clinical trials has always been important, but in today's environment of decreased R&D spending, the pressures for effective fiscal management of a drug or device trial have risen to an all time high. This session brings together a biopharmaceutical company

representative and an eClinical vendor expert to discuss the economics and fiscal management of today's clinical trials.

Get Serious about Reducing Costs: Deploying Technology that Actually Has an ROI
Edward Stephen Seguine, Jr., MBA
CEO, Clinical Ink

The Holy Grail of CTMS: Paying Investigators on Clean Data
John E. Humphreys, MS
Product Director, CTMS, Perceptive Informatics

Measurement with an EDC Yardstick: Engaging Your Study Team to Create and Optimize Useful Metrics
Dan Miller
Senior Study Data Manager, Genentech, Inc.

#421 Track 08 – Regulatory Affairs and Submissions

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

10:45 AM–12:15 PM LEVEL: ■ Format: **SESSION**
Room 107ab *CME and Nursing*

Regulatory Handling of Ethnic Factors in Asian Clinical Trial Data #3, Implication for Simultaneous Global Development (SGD)

CHAIRPERSON
Akio Uemura, PhD
Director and Head, Regulatory Affairs, Japan, Allergan Japan K.K., Japan

Countries in Asia are increasing requirements for clinical data generated in their own region. In this session, we will outline expectations for handling ethnic factors by both regulators and the industry, and discuss possible future regulations.

Asian Ethnic Similarities and Differences: PMDA Point of View
Yoshiaki Uyama, PhD
Director, Division of Regulatory Science Research, Office of Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Asian Clinical Data Utilization for NDAs in Japan
Yoshihiko Ono, RPh
Director, Regulatory Policy and Intelligence, Pfizer Japan Inc., Japan

Experience in Utilizing Asian Clinical Data in Asian Drug Development
Representative Invited
Vice President, Regulatory Affairs, Asia Pacific, Allergan, Inc., China

#422 Track 14 – Clinical Safety and Pharmacovigilance

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

10:45 AM–12:15 PM LEVEL: ◆ Format: **SESSION**
Room 113c *CME, Pharmacy, and Nursing*

Immunogenicity of Therapeutic Peptides: Regulatory Science Implications

CHAIRPERSON
Jill Conner, PhD, MS
Director, Teva Pharmaceuticals

Like proteins, synthetic peptide-based non-biologic complex drugs (NBCD) are immunogenic and can be immunotoxic. This session will review causes of immunotoxicity and suggests regulatory guidelines to ensure immunologic safety of new or follow-on peptide-based NBCD.

Immunogenicity Risk Assessment for Therapeutic Peptides
Laura Salazar Fontana, PhD
Reviewer, Office of Pharmaceutical Science, Division of Therapeutic Proteins, CDER, FDA

Immunogenicity Assessment of Glatiramoids — Lessons Learned
Ety Klinger, PhD, MBA
Vice President, Research and Development, Proteologics, Ltd., Israel

Immunogenicity of Therapeutic Peptides
S. Russ Lehrman, PhD
Principal, Lehrman Biopharma

#423 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, RD

10:45 AM–12:15 PM LEVEL: ● Format: **SESSION**
Room 113a

Increasing Clinical Program Success with Modeling and Simulation

CHAIRPERSON
Olga V. Marchenko, PhD, MS
Vice President, Innovation, Quintiles

In this session, the presenters will share their experience and ideas on how modeling and simulation can increase clinical program success and enable program teams to make better decisions through the drug development process.

Improving Clinical Study Design and Understanding Via Modeling and Simulation
Jose C. Pinheiro, PhD
Senior Director, Quantitative Decision Strategies, Janssen Research & Development, LLC

Utilizing Modeling and Simulation to Optimize Phase 2 for Decision Making
Brenda L. Gaydos, PhD
Research Fellow, Eli Lilly and Company

Improving Oncology Clinical Program by Use of Innovative Designs and Comparing via Simulations
Donald A. Berry, PhD, FACP
Professor, Department of Biostatistics, M.D. Anderson Cancer Center, The University of Texas

#424 Track 16 – Professional Development

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

10:45 AM–12:15 PM LEVEL: ● Format: **SYMPOSIUM**
Room 113b

Building Rapport and Managing Communication Filters for Breakthrough Collaborations

CHAIRPERSON
Lynn King
Assistant Vice President, Clinical Operations, Rho, Inc.

Communication filters are those perceptions or outlooks that each of us brings to every conversation we experience. Our filters have a profound impact on the effectiveness of our communication. This session will help participants recognize these communication filters and how to set them aside during conversation to allow for successful collaborations.

What's Getting Through? Building Rapport & Managing Communication Filters for Breakthrough Collaborations
Lynn King
Assistant Vice President, Clinical Operations, Rho, Inc.

Whose Learning Is It Anyway? Evaluating Training Effectiveness
Kristina R. Barkhouser
Training Manager, Almac Diagnostics

Optimizing Hybrid Knowledge-sharing and Training when Combining Media Events with Practical Experience-sharing Sessions
Brett Allen Thompson
Assistant Director, Regulatory Sciences, Global Regulatory Policy Sanofi

#425 Track 17 – Global Regulatory

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

10:45 AM–12:15 PM LEVEL: ● FORMAT: **FORUM**
Room 114 AUD *CME and Nursing*

CDER Town Hall: Part 2 of 2

CHAIRPERSON
Nancy D. Smith, PhD
ORISE Fellow at FDA/Adjunct Professor, Temple University

Part 1 of this forum will take place on Thursday, June 28th at 9:00 AM.

The leadership team of CDER will be invited to participate in this forum. The topics that will be discussed will depend on the audience and on areas that are of current importance within the CDER community.

Submit your questions in advance to annualmeetingprogram@diahome.org Subject: CDER Town Hall.

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

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

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

Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Center Director for International Programs, CDER, FDA

Robert J. Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA

Julie Anne Zawisza, MA
Director, Office of Communications, CDER, FDA

12:15 PM **ANNUAL MEETING ADJOURNED**

12:30 PM–5:00 PM
Room 108A

MedDRA® User Group Meeting

NOTES

PRECONFERENCE PROGRAM & TUTORIALS

Each Annual Meeting Preconference Program and Tutorial was led by a subject matter expert(s) who provided in-depth instruction on some of the today's hottest topics. DIA would like to take this opportunity to thank all of the preconference program speakers and tutorials instructors that were involved in the Sunday, June 24 event.

TUTORIALS

TUT 20: Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development
Alberto Grignolo, PhD
Corporate Vice President, Global Strategy and Services, PAREXEL Consulting

TUT 21 FDA Enforcement: Understanding the Agency's Authority, How Violations Occur, How to Prevent Them, and How to Respond If Violations Do Occur
Michael A. Swit, Esq., JD
Special Counsel, Duane Morris, LLP

TUT 22 Utilizing Chemistry, Manufacturing, and Controls in Drug Development
Priya Jambhekar
President, PBS Regulatory Consulting Group Inc.

TUT 23 Global Market Access: Essential Knowledge for Clinical Trial Design
John Brennick, MPA
Worldwide Market Access, Janssen Global Services, LLC

TUT 24 A Device Primer: 510(k)s, PMAs, IDEs
Barry S. Sall, RAC
Principal Consultant, PAREXEL Consulting

TUT 25 Benefit and Harm: A Process to Express this Ratio Determined by Consensus-driven Evidence
Lee S. Simon, MD
Consultant, SDG LLC

Maarten Boers, MD, PhD, Msc
Professor of Clinical Epidemiology, Department of Epidemiology and Biostatistics, University of Amsterdam, Netherlands

TUT 30 Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in the EU
Brenton E. James, FTOPRA
Consultant, Strategic Regulatory Affairs in the European Union, UK

TUT 31 Leadership: How to Organize and Lead People in Group Work
Michael Laddin, MBA, MS
CEO, LeaderPoint

TUT 32 Designing, Operating, and Evaluating Patient Registries
Richard Gliklich, MD
President, Outcome

Barbara Isquith Arone, MS
Director of Professional Services, Outcome

TUT 33 Understanding Comparative Effectiveness Research (CER)/ Health Technology Assessment (HTA) in the Biopharmaceutical Industry
Nancie E. Celini, MPH, DrPH
Chief Learning Consultant, CAB Inc.

Vadim Tantsyura, MS, MA, DrPH
Director, Data Management, Infinity Pharmaceuticals

TUT 34 Fourteen Steps from Research to Development
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

TUT 40 Understanding and Navigating the Regulatory System in China
Laurence Bin Huang, MS
Executive Director Regulatory Affairs & Branded Generics Development, AstraZeneca Pharmaceutical Co., Ltd., China

Wendy Yan, PharmD
Global Regulatory Strategist, Bayer Healthcare Co. Ltd, China

TUT 41 Quality Oversight of CROs – Clinical Vendors
Liz Wool, BSN, RN, CCRA, CMT
President and Chief Executive Officer, QD-Quality and Training Solutions Inc.

Jennifer J. Poulakos, PhD
Director, Clinical Quality Assurance, Astellas

Linda B. Sullivan, MBA
Vice President, Operations, Metrics Champion Consortium

TUT 42 Regulatory Affairs for Biologics
Carol H. Danielson, MS, DrPH
President, Regulatory Advantage

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

TUT 44 Early Phase Research: Navigating the 21st Century Landscape for Phase 1 Trials
Nancy A. Lass, MD
President and Principal Consultant, NL Specialty Consulting, Inc.

Stacie J. Bell, PhD
Assistant Director, Clinical Pharmacology, Array BioPharma, Inc.

Donna W. Dorozinsky, MSN, RN
President, DWD & Associates

Howard E. Greenberg, MD, MS, MBA
Principal, HEG Associates

TUT 45 Preparing for a US FDA Advisory Committee Meeting
Pete Taft
Founder and CEO, Taft and Partners/PharmApprove

TUT 46 Fundamentals of Project Management for Non-project Managers
Joan Knutson, PMP
PM Guru Unlimited

TUT 47 Overview of Drug Development
George H. D'Addamio, PhD
President, PharmConsult, Inc.

TUT 48 Art of Writing a Clinical Overview
Patricia A. Matone, PhD
President, Scientific Information Services, LLC

PRECONFERENCE PROGRAMS

SAFE-BioPharma®: Trusted Identities for Cloud Collaboration

SAFE-BioPharma®
The Industry Standard

APCR: Win-win Strategies for the Sponsor-investigator Relationship

APCR
Academy of Physicians in Clinical Research

POSTER PROGRAM

Professionals and Students from all fields related to the mission of DIA will present their original research at this year's DIA 2012 Annual Meeting. Posters will be displayed in the Exhibit Hall, Level 2.

Student Poster Session

Monday, June 24, 11:00 AM–6:30 PM*
*Award Ceremony at 6:00PM

M 01 **Effect Of Formulation pH On Micropore Closure In Microneedle Enhanced Transdermal Drug Delivery**
Priyanka Ghosh, MS
University of Kentucky

M 02 **Improvement of Obstetrics and Gynecology Patient Health by Using Patient Safety Reporting System**
Neha Dhananjay Nandedkar
Bharati Vidyapeeth's College Of Pharmacy, India

M 03 **An Evaluation of the Gulf Cooperation Council (GCC) Centralized Regulatory Review Process for Pharmaceutical Products**
Mohammed Hamdan Al Rubaie, MPharm
Cardiff University, Welsh College of Pharmacy, United Kingdom

M 04 **Psychotropic Drug Use Among Autistic Individuals Enrolled In A State Medicaid Fee-for-service Program**
Krutika Jariwala, MS
University of Mississippi

M 05 **Using Stochastic Control Methods and Pharmacokinetics to Individualise Drug Therapy**
Ben Francis, MSc
University of Liverpool, United Kingdom

M 06 **Seeking Predictable Subject Characteristics That Influence Clinical Trial Discontinuation**
Jai Shankar Kishore Babu Yadlapalli, MS
University of Arkansas for Medical Sciences

M 07 **Evaluating Consumer Understanding of Prescription Label Information: An Assessment of USP 2011 Recommendations**
Megan Elizabeth Bensi
Ohio Northern University

M 08 **Development and Application of a Universal Benefit-risk Assessment Framework for Medicines**
James Leong, MPharm
Health Sciences Authority, Singapore

M 09 **Examination of the Adoption of FDA's Bio-pharmaceutics Classification System (BCS): A Qualitative Study**
Namita Joshi, MSc
University of Mississippi

M 10 **Influence of Patient and Hospital Level Characteristics on Emergency Department (ED) Wait Time in US**
Hemalkumar B. Mehta, MS
University of Houston

M 11 **Bias Assessment in Progression-Free Survival Analysis Using Interval-censored Methods**
Chen Hu, MS
University of Michigan

M 12 **Contract Research Organizations in China: Current and Future**
Yunzhen Shi, MS
University of Macau, Macao

M 13 **The Death of New Racemic Drugs Was an Exaggeration**
Enav Zipora Zusman
The Hebrew University of Jerusalem, Israel

M 14 **Drug Adverse Events Surveillance with CDISC Standards for Multiple Trials**
Boram Wang
The Catholic University of Korea, Korea

M 15 **Unmet Drug Information Needs and Clinical Adherence to Immunosuppressant Drugs of Kidney Transplant Recipients**
Minghui Li, MSc
University of Maryland

M 16 **Pharmacovigilance and Drug Repurposing Model and Application: A Case Study Using Electronic Health Record Data**
Krystl Haerian, MD
Columbia University

M 17 **Pursuing Orphan Designation in Japan: Benefits and Process**
Monique Meigio
West Chester University

M 18 **Influence of Clinical Research Investigator Fraud on Clinical Trial Participation**
Purnachandra Garimella, MS
University of Michigan

M 19 **Recommendations for Improving e-Prescribing Technology Design and Use in Pharmacies**
Olufunmilola Odukoya, MS, RPh
University of Wisconsin System

M 20 **A Probabilistic Sensitivity Analysis to Estimate the Impact of Data Errors in a Randomized Trial to Eradicate H. pylori**
Elisa L. Priest, MPH
University of North Texas

Professional Poster Session #1

Tuesday, June 26, 11:00 AM–1:30 PM

T 01 **Risk Evaluation and Mitigation Strategy (REMS): 18-Month Assessment Report of Dalfampridine Extended Release 10 mg Tablets**
Calvin Mai
Acorda Therapeutics, Inc.

T 02 **Which ePRO Modality is Appropriate for Your Study?**
Jennifer Ross, MEd, MS
Almac Clinical Technologies

T 03 **Situational Analysis of the Pharmacovigilance Activities in Brazilian Public Industries: Collaborate to Innovate is Essential**
Paulo Roberto Gomes dos Santos
Bio-Manguinhos | Fiocruz, Brazil

T 04 **The "Storyline Document", A New Document Format for the Use in Pre-submission Meetings**
Sybille M. Eibert
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

T 05 **VVSymQ™: A Simple, Validated Measure of Varicose Vein (VV) Symptoms That Can Be Administered Daily Using a Personal Digital Assistant (PDA)**
Ellen Evans
BTG International Inc.

T 06 **Modeling and Simulation in Early Drug Development**
Nancy Wang, PhD
Celerion

T 07 **Clinical Research and Development on Western Drug and Traditional Chinese Medicine Interaction in Taiwan**
Huang Yuan-Chao, PharmD
Committee on Chinese Medicine and Pharmacy, Taiwan

T 08 **CDISC ODM End-to-End: One Sponsor's Approach**
Stephane Auger
Danone Research, France

T 09 **Safety Database Migration: Use of Standard E2B Files with Automated Loading as an Alternative to Traditional Migration**
Arvind Nagaraj
Deloitte Consulting, LLP

T 10 **Survey of Pharmaceutical Industry Outcomes Liaison Practices**
Christopher M. Marrone, PharmD
Eli Lilly and Company

T 11 **Making the Point: Emphasis of Claims in Prescription and Nonprescription Television Advertising**
Adrienne Faerber, MS
University of Wisconsin

T 12 **The Effect of A-Bromo-4-Chlorocinnamaldehyde on Coxsackie Virus B3-induced Myocarditis and the Mechanisms**
Siwang Wang Sr, MS
Fourth Military Medical University, China

T 13 **Novel Approach to Literature Surveillance for Adverse Events using OvidSP and EndNote Auto-import Function and Customization**
Neal J. Grabowski
Genzyme, A Sanofi Company

T 14 **Capitalizing On US Public Use Files To Answer Pharmacoeconomic Questions**
Alex Exuzides, PhD
ICON

T 15 **Ustekinumab Risk Evaluation and Mitigation Strategy: Embarking and Executing on the New Era in Drug Safety**
Jack McGowen
Janssen Services, LLC

T 16 **Infliximab Risk Evaluation and Mitigation Strategy: Embarking and Executing on the New Era in Drug Safety**
Brenda Sarokhan
Janssen Services, LLC

T 17 **Golimumab Risk Evaluation and Mitigation Strategy: Embarking and Executing on the New Era in Drug Safety**
Ralph DeHoratius, MD, FACP
Janssen Services, LLC

T 18 **Systematic MedDRA® Upgrade in Clinical and Post-marketing Safety Databases**
Susan Li, DrMed, PhD
Kai Research, Inc.

T 19 **Automated Semantic Web-mining for Analyzing Changes in Trial Records Over Time and Identifying Rescue Countries**
David J. Cocker
MDC Partners

T 20 **Managing Standards with Governance and a Data Warehouse**
John Garrity
Millennium Pharmaceuticals, Inc.

T 21 **Corporate Integrity Agreements: Comparison of Technology and Procedures and How They Have Changed Since Onset to Most Recent**
Tracy A. England, MBA
OpenQ

T 22 **Efficiency and Cost Benefit Analysis of Narrative Automation Using Six Sigma as Compared to Industry-wide Benchmarking of Narrative Writing Using Traditional Methods and Resources**
Grace Lee, MA
PA Consulting

T 23 **Clinical and Regulatory Considerations for the Development of Therapeutic HIV Vaccines**
Kelly Denice Whitley De Padilla, PharmD, RPh
PPD

T 24 **Building an Analytical Roadmap to Support the New Risk-Based Site and Data Monitoring Strategy**
DeAnn S. Hyder
Quintiles

T 25 **R&D Knowledge Management Starts with Higher Quality Data**
Robert O'Hara, MS
ResultWorks

T 26 **Social Media and Pharmacovigilance: New Space for Signal Detection & Socialvigilance**
Maria Alejandra Vazquez-Gragg
RTI Health Solutions

T 27 **Regulatory Labeling Experiences with the PSUR Worksharing Process**
Eileen S. Kahn, MS
Sanofi

T 28 **Implementation Status of CTD, eCTD and Paper-free Applications: A Global Overview**
Rosanna Melchior, PharmD, MSc
Thomson Reuters

T 29 **Autovaccine B7-H1IgV induced Antitumor Immunity and Enhanced HER2 DNA Vaccine-derived Immune Responses**
Yingqi Zhang, DrMed
Fourth Military Medical University, China

Professional Poster Session #2

Wednesday, June 27, 11:00 AM–1:30 PM

W 01 **A Comparison of Adverse Event Coding of Ophthalmic Medical Device Reports: MedDRA® and FDA Patient Problem Codes**
Osas Ayela-Uwangue, MD, MPH
Alcon Laboratories, Inc.

W 02 **Patient Preferences for Reminders in Clinical Trials: Improving Both Compliance and Patient Experience**
Graham Nicholls, MS
Almac Clinical Technologies, United Kingdom

W 03 **Feasibility of Remote Medical Monitoring in Clinical Research Utilizing Web-based Electronic Medical Record System**
Joshua Zhang, MD
ARIAD Pharmaceuticals, Inc.

W 04 **Virtual Technology Solutions: Gain Efficiencies and Increase Control Over Global Sample Inventories During Clinical Research**
Lori Ball, MBA
Biostorage Technologies

W 05 **Application of Control Charting for Pharmacovigilance Signal Detection**
Neal J. Grabowski
Genzyme, A Sanofi Company

W 06 **Preparation of Compassionate Use Data for Quality Regulatory Submissions: Experience with Glucarpidase Development for Methotrexate Toxicity**
Claire Daugherty
BTG International Inc.

W 07 **The Impact of Patient Recruitment Methods on Data Quality**
Patricia Brown, PhD
CNS Healthcare

W 08 **The Gap Between Clinical Trials and Comparative Effectiveness: A Case Study**
Rachel L. Jao, MPH
Context Matters Inc.

W 09 **The MURDOCK Community Registry and Biorepository: Collaboration as the Driving Core of a Translational Research Engine**
Douglas Wixted, MS
Duke Translational Medicine Institute

W 10 **Identification of Biomarkers in Gastric Cancer of Chinese Based on SNPs Screening and its Evaluation in Clinical Application**
Zhen Yan, MD, PhD
Fourth Military Medical University, China

W 11 **Study of Unique Feature of Regulatory Framework Under Japanese Pharmaceutical Affairs Law in Japan**
Michel Mikhail, PhD
Fresenius Kabi Deutschland GmbH, Germany

W 12 **Validation of New Patient/Clinician Reported Outcome Tool-Capturing the Visual Impact of Varicose Veins**
Elizabeth Orfe
BTG International Inc.

W 13 **Innovative Strategies to Enhance Minority Recruitment for Clinical Trials**
Lenore Threadgill Coleman, PharmD
Healing Our Village of Maryland, Inc.

W 14 **Regulatory CMC BLA and NDA Submissions: Differences and Correlations from Regulatory and Scientific Perspectives**
David Donne, PhD
Janssen R&D, Johnson & Johnson

W 15 **Medical Device Development Project Management: Is a Paradigm Shift Needed?**
Bernard Tyrrell
Mass College of Pharmacy & Health Sciences

W 16 **Results of Patient and Physician Survey regarding Mobile Social Media Adoption and Preferences**
Jim Zuffoletti, MBA
OpenQ

W 17 **Implementation of a Pharma Company's Publication Policy that Ensures Compliance in an Increasingly Scrutinized Environment**
Michelle Kissner, PharmD, RPh
Pfizer Inc

W 18 **Pharma Quality Agreements**
Gloria Katherine Miller, RAC
Premier Research Group

W 19 **Creating a Data-Driven and Quantitative Site Index Score for Optimal Site Selection**
Elizabeth Nielsen, MS
Quintiles, Inc.

W 20 **Informatics - Linchpin or Afterthought of a Business Externalization Strategy**
Susan Butler, PMP
ResultWorks

W 21 **Post-Doctoral Pharmaceutical Industry Fellowships: Perceptions of Required Core Skills by Trainees and Preceptors/Managers**
Erica Hosek, PharmD, RPh
Rutgers, The State University of New Jersey

W 22 **Statistical Evaluation of the Power of the Arc Sine Test against the CMH Test for Stratified Data for Smaller Proportions**
Hewa Saranadasa
Symbiance, Inc.

W 23 **Building Novel Clinical Research Capacity in Resource-Limited Settings: Lessons Learned at Three Mozambique Sites**
Kathleen Walker, PhD
U.S. Military HIV Research Program (MHRP)

W 24 **Preparing to Share CDISC SDTM Data: A Practical Evaluation of Potential Error Sources and Effective Review Processes**
Steve Kirby, JD, MS
Viropharma Incorporated

W 25 **Current Drug Master File (DMF) Status in Taiwan**
Fu-Chieh Lu, MSc
Center For Drug Evaluation, Taiwan

W 26 **Producing Rules for Portugal to Improve Rational Prescribing**
Pedro Caetano
Faculdade De Ciências Médicas, Universidade Nova De Lisboa (nova Medical School), Portugal

W 27 **To Develop a Process to Help Patients Adhere to a Prescribed Haemophilia Therapy Regime**
Christopher D. Watson, PhD
Exco InTouch, United Kingdom

AWARD WINNERS

DIA Awards recognize significant individual or group accomplishments in the discovery, development or lifecycle management of pharmaceutical, devices, or related products, and/or acknowledge significant volunteer contributions in the advancement of DIA's mission and vision.

DISTINGUISHED CAREER AWARD

Daniel Brasseur, MD, PhP
PDCO Chairman
Federal Agency Medicines & Health Products
Belgium

The Distinguished Career Award recognizes and honors an individual with a distinguished career in the discovery, development, regulation, surveillance, or marketing of pharmaceuticals or related products. The recipient of this award has shown extraordinary service and dedication to the advancement of health-care through career contributions to pharmaceutical and related industries that benefit industry, government and the patient.

FOUNDERS' SERVICE AWARD

Marie A. Dray
President
International Regulatory Affairs Group LLC
United States

The Founders Service Award is named after the group of 30 professionals who founded the DIA in 1964 with a fundamental value that the Association is member driven and fueled by the pharmaceutical industry's need for a neutral forum. This award is given with the highest recognition and appreciation for volunteerism in DIA. It recognizes those individuals who have contributed to the advancement of the mission, vision and values of the DIA and fostered its growth and development through their dedicated and sustained volunteerism.

EXCELLENCE IN VOLUNTEER LEADERSHIP AWARD

Linda F. Bowen, MS, RAC, FRAPS
Senior Director, Regulatory Policy and Intelligence-US
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Deborah Dolan, MBA
Vice President, Key Accounts
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Janet E. Davies, BPharm, MRPharmS, HonFPIPA
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Gilead Sciences
United Kingdom

This award is given to recognize the individual who has demonstrated outstanding effective leadership during their dedicated and extensive voluntary service to DIA. This individual has made consistent and significant contributions to the Association, not only as a volunteer, but as a volunteer-leader in various DIA roles. Some of these roles include leadership positions in the following areas: meetings/workshops, communities, special committee positions, advisory council, editorial board, author or DIA board membership. The breadth and depth of their service as a leader to DIA should have a lasting, positive effect in contributing to the fulfillment of the mission and vision of the association.

JOURNAL AWARDS

THE THOMAS W. TEAL AWARD FOR EXCELLENCE IN STATISTICS PUBLISHING

Lee Kaiser, PhD
Director, Statistical Methods and Research
Genentech Inc.
United States

This award recognizes the importance of articles on statistics in the journal. It is named after Thomas W. Teal, a DIA member since the mid-seventies, former DIA executive director for 15 years, and editor-in-chief of the Drug Information Journal for 18 years.

THE DONALD E. FRANCKE AWARD FOR OVERALL EXCELLENCE IN JOURNAL PUBLISHING

David Coutant, PhD
Principal Research Scientist
Eli Lilly and Company
United States

This award is chosen by the Journal's editorial board and recognizes the most significant and outstanding article published in the Journal in 2011.

STUDENT JOURNAL AWARD

Clive M. Mendonca, BPharm, MS
Graduate Student, Department of Pharmacy Administration and Center for Pharmaceuticals Marketing and Management, University of Mississippi School of Pharmacy

This award is selected by the DIJ editorial board and presented to student contributors for articles published in the 2011 Drug Information Journal.

OUTSTANDING SERVICE AWARD

The DIA Outstanding Service Award is given to recognize those individuals who consistently, through their volunteer efforts, have made contributions to DIA's mission and vision over the past several years. These individuals have exceeded expectations in their volunteer activities with DIA.

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Dr Arun D. Bhatt, MD, FICA (India), FICR (UK)
President
Clininvent Research Pvt. Ltd.
India

COMMUNITY AWARD

Regulatory Affairs SIAC

The DIA Community Award is given to recognize a particular community that has demonstrated its ability to be instrumental in fostering the professional growth of their constituents while also advancing the mission, vision and overall goals of DIA. This commitment to professional excellence is shown through the variety of events and opportunities that the community has made available. The outcome of these activities increases a group or individual's professional development and global networking opportunities while working to achieve the DIA's mission and vision.

Award Accepted by Regulatory Affairs SIAC Chair:

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Disclosure Statements (as of May 9, 2012)

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Disclosure Statements (as of May 9, 2012), *continued*

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Disclosure Statements (as of May 9, 2012)

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The following DIA planners and managers, Jennifer Andree-Webb; Susan Cantrell; Julie Ho; Laura Parker; Paul Pomerantz; Holly Stevens; and Karen Wetzel, hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months. The DIA planner and manager, Maureen Lamplugh, has disclosed that she is a stock shareholder of Medco and Merck & Co., Inc.

The following DIA Pharmacy Committee members have disclosed the following: Alan Boyd, RPh, stock shareholder of CNS Vital Signs, LLC; David Cocchetto, PhD, RPh, stock shareholder of GlaxoSmithKline, Teva; former employee of GlaxoSmithKline; consultant to Cempra Pharmaceuticals, Chimerix, Inc., and POZEN Inc.; Charles Depew, PharmD, stock shareholder of GlaxoSmithKline; Teresa P. Dowling, PharmD, stock shareholder of AstraZeneca and Merck & Co., Inc.; Truus Janse-de Hoog, PharmD, MSc, no financial relationships; Monica Kwarcinski, PharmD, employee of Purdue Pharma; Karin Mueller, PharmD, RPh, MBA, stock shareholder of AstraZeneca and Wyeth; J. Christopher Prue, MBA, RPh, no financial relationships.

The following project management professionals have disclosed the following: Thomas R. Dunson, MBA, PMP, no financial relationships; Cris Howard, MBA, MEd, PMP, stock shareholder of Emergent BioSolutions, Johnson & Johnson, Merck & Co., Inc.; Leigh Shultz, PhD, PMP, stock shareholder and other support Merck & Co., Inc.

UNIVERSAL ACTIVITY NUMBERS

Below is a list of the pharmacy designated Universal Activity Number (UAN) and type of activity that is applicable for the following program offerings.

MONDAY, JUNE 25, 2012

Number	Title of Offering	Assigned UAN	Type of Activity
#108	Advancing Benefit-risk Visualization and Communication	286-12-000-506-L04-P	Knowledge
#109	New Ways to Learn What Happens to Patients AFTER Approval	286-12-000-507-L04-P	Knowledge
#110	Transforming Regulatory Information Into Actionable Regulatory Intelligence for Emerging Markets	286-12-000-508-L04-P	Knowledge
#111	Effective Switching from Rx to OTC Status: Maximizing Revenue and Profit From Off-Patent Products	286-12-000-509-L04-P	Knowledge
#112	Companion Diagnostics: Current and Future Developments	286-12-000-510-L04-P	Knowledge
#113	Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials	286-12-000-523-L04-P	Application
#114	Defining Quality in Clinical Trials	286-12-000-512-L04-P	Knowledge
#115	ICH Update on Pharmaceutical Quality	286-12-000-513-L04-P	Knowledge
#116	The Impact of Social Media on Product Promotion and Pharmacovigilance	286-12-000-514-L04-P	Knowledge
#117	Approaches to Postapproval Pediatric Safety Surveillance	286-12-000-515-L04-P	Knowledge
#118	Hot Topics in Statistics: Industry, CRO, Academic, and Regulatory Perspectives	286-12-000-516-L04-P	Knowledge
#134	Regulatory Roundtable on Biosimilars	286-12-000-517-L04-P	Knowledge
#139	Regulatory Collaboration/21st Century Innovation: Views of the Heads of Health Canada, the European Medicines Agency, and the US FDA	286-12-000-518-L04-P	Knowledge
#140	Quality by Design: Is Your Clinical Trial Fit for Purpose?	286-12-000-519-L04-P	Knowledge
#143	Demystifying Approaches to the Design and Analysis of Observational Studies of Comparative Effectiveness	286-12-000-520-L04-P	Knowledge
#158	Communicating Drug Safety Information Using Social Media: FDA and Industry Perspectives	286-12-000-521-L04-P	Knowledge
#159	PRO Measurement in Clinical Trials: Need for Education and Training	286-12-000-522-L04-P	Knowledge
#165	Legal Jeopardy from the Conduct of Clinical Trials	286-12-000-511-L04-P	Knowledge
#169	Application of Quality of Evidence Assessment Tools to the Evaluation of Observational Pharmacoepidemiologic Studies	286-12-000-524-L04-P	Knowledge
#170	Electronic Health Records (EHR) and Medication Safety and Adherence	286-12-000-525-L04-P	Knowledge

TUESDAY, JUNE 26, 2012

Number	Title of Offering	Assigned UAN	Type of Activity
#206	Defining Study Endpoints in 2012: The Journey Continues	286-12-000-530-L04-P	Knowledge
#210	Legal Aspects of Clinical Trial Compliance	286-12-000-531-L04-P	Knowledge
#221	Skin-drug Biotransformation: What Testing Should We Do?	286-12-000-532-L04-P	Knowledge
#222	Publish or Perish: Retracted Scientific Literature	286-12-000-533-L04-P	Knowledge
#223	Labeling Claims Based on Patient-reported Outcome Measures: It Takes a Village!	286-12-000-534-L04-P	Knowledge
#224	Lessons Learned from FDA-sponsored ARRA PCOR (American Recovery and Reinvestment Act Patient Centered Outcomes Research) Data Standardization Efforts	286-12-000-535-L04-P	Knowledge
#226	Drug Shortages 2012: Rewind, Repeat, Recovery	286-12-000-536-L04-P	Knowledge
#227	Combination Products	286-12-000-537-L04-P	Knowledge
#228	Product Liability in the US and the EU	286-12-000-538-L04-P	Knowledge
#231	The Effects of NICE Technology Assessments on Prescribing and Cost-sharing Behavior in the US	286-12-000-539-L04-P	Knowledge
#234	FDA Draft Guidance on Multiple Endpoints in Clinical Trials	286-12-000-540-L04-P	Knowledge
#236	Introduction to Narrative Medicine	286-12-000-541-L04-P	Application
#247	From Design to Disclosure: Pleasing Multiple Masters	286-12-000-543-L04-P	Knowledge
#248	Implementing Adaptive Clinical Trials: A Practical Perspective	286-12-000-544-L04-P	Knowledge
#249	Innovative Ways of Looking at Computer System Validation	286-12-000-545-L04-P	Knowledge
#252	Drug Rediscovery as an Innovative Tool to Meet Unmet Medical Needs	286-12-000-546-L04-P	Knowledge
#253	What Should You Put in a Clinical Quality Assurance (CQA) Agreement	286-12-000-547-L04-P	Knowledge
#255	Registries for Evaluating Patient Outcomes: Emerging Areas of Controversy	286-12-000-548-L04-P	Knowledge
#258	Noninferiority Trial Designs: Perspectives from Academia, Industry, and a Regulatory Agency	286-12-000-549-L04-P	Knowledge
#262	Understanding the Challenges of Conducting Studies for Orphan Indications and Rare Diseases	286-12-000-550-L04-P	Knowledge
#265	Beyond Taxonomy	286-12-000-551-L04-P	Knowledge

#269	Cross-sector Innovation Brings Tailored Therapies to Patients	286-12-000-552-L04-P	Knowledge
#272	Evidence for the Marketplace: Bridging the Gap Between Industry, Payer, Providers, and Patients	286-12-000-553-L04-P	Knowledge
#279	Leveraging Technology in an Age of Readily Available Information	286-12-000-554-L04-P	Knowledge

WEDNESDAY, JUNE 27, 2012

Number	Title of Offering	Assigned UAN	Type of Activity
#308	Prescription Drug Marketing Regulatory Primer	286-12-000-556-L04-P	Application
#309	Implementing Structured Authoring: Understanding the DITA Model and Its Applicability for Content and Metadata Management	286-12-000-557-L04-P	Application
#310	Combining Patient Self-report and Clinician Oversight: Are Two Heads Better than One?	286-12-000-558-L04-P	Knowledge
#315	Oncology Medications: State-of-the-art Identification and Management of Potential CV Safety Issues During Development	286-12-000-559-L04-P	Knowledge
#316	Policy and Enforcement Trends: Are Regulators and Industry Heading in the Right Direction?	286-12-000-560-L04-P	Knowledge
#319	Environment for Health Care Decision Making: The Role of CER, Evidence-based Medicine, Quality, and Value	286-12-000-561-L04-P	Knowledge
#331	Can Human Carcinogenic Risk Be Communicated Without a Rodent Bioassay?	286-12-000-562-L04-P	Knowledge
#332	FDA Enforcement Update: Advertising and Promotion	286-12-000-563-L04-P	Knowledge
#335	Clinical Outcome Assessments in the Evaluation of Medical Products in Pediatrics	286-12-000-564-L04-P	Knowledge
#336	Building the Benefit-risk Toolbox: Is There a Consensus on a Scientifically Acceptable Framework?	286-12-000-565-L04-P	Knowledge
#340	Meeting the Therapeutic Needs of Older Patients: A Sustainable Collaborative Approach	286-12-000-566-L04-P	Knowledge
#341	Regulatory Updates on Current Trends in Drug Quality and Manufacturing	286-12-000-567-L04-P	Knowledge
#342	REMS: Are Our Written Communications Truly Mitigating Risks to Patients?	286-12-000-568-L04-P	Knowledge
#346	Natural History Studies for Rare Diseases and Orphan Conditions	286-12-000-569-L04-P	Knowledge
#354	International Advertising/Promotion Coordination	286-12-000-570-L04-P	Knowledge
#356	What Medical Writers Need to Know about MedDRA	286-12-000-571-L04-P	Application
#357	Innovations Aimed at Improving Effectiveness and Speed of the Therapeutic Development Process	286-12-000-572-L04-P	Knowledge
#359	Orphan Drug Development: Global Regulatory Challenges and Initiatives	286-12-000-573-L04-P	Knowledge
#362	Emerging Development and Policy Trends in the Economics of the Biopharmaceutical Industry	286-12-000-574-L04-P	Knowledge
#363	The Changing Face of Clinical Compliance: Regulatory, Technology, and Services	286-12-000-575-L04-P	Knowledge
#365	The Use of Health Technology Assessment (HTA) for Access and Resource Allocation Decision Making: International Examples	286-12-000-576-L04-P	Knowledge
#366	Data Sources for Monitoring Usage of Drug Products and How to Use These Sources to Support Safety and REMS Evaluations	286-12-000-577-L04-P	Knowledge
#370	Social Media 2.0: The Power of Online Rare Disease Communities to Connect and Engage ePatients	286-12-000-578-L04-P	Knowledge
#379	Leveraging Drug Development and Advertising/Promotion Regulatory Expertise to Drive a Robust Target Product Profile Process	286-12-000-579-L04-P	Knowledge
#380	Recent Advances in Adaptive Clinical Trial Designs for Medical Writers	286-12-000-580-L04-P	Knowledge
#381	Sharing Clinical Data: Examples of What to Share and Benefits to Research and Patients	286-12-000-581-L04-P	Knowledge
#384	Update on Biosimilar Developments in the US	286-12-000-582-L04-P	Knowledge
#385	Emerging Role of the Patient Voice on Drug Policy in Japan	286-12-000-583-L04-P	Knowledge
#388	The Role of Meta-analyses in Drug Safety: Methodological Considerations	286-12-000-584-L04-P	Knowledge
#389	Benefit Versus Risk of Harm: Assessing Therapeutic Response and Interpreting Benefit/Risk with Patients	286-12-000-585-L04-P	Knowledge
#390	Doping Abuse of Medicines in Sport: The Challenge to Industry and Regulators	286-12-000-586-L04-P	Knowledge
#391	Statistical Comparative Effectiveness Research (CER): Closing the Gaps in the Consideration of Observational Evidence	286-12-000-587-L04-P	Knowledge

THURSDAY, JUNE 28, 2012

Number	Title of Offering	Assigned UAN	Type of Activity
#406	Study Recruitment Challenges, Tailored Medical Information Requests - OH MY! Have You Maximized All Your Options	286-12-000-526-L04-P	Knowledge
#407	Cloud Computing in Regulated Environments	286-12-000-527-L04-P	Application
#418	Medical Writing Competencies and Best Practices in the Global Environment	286-12-000-528-L04-P	Knowledge
#422	Immunogenicity of Therapeutic Peptides: Regulatory Science Implications	286-12-000-529-L04-P	Knowledge

NOTES

NOTES

LIST OF EXHIBITORS

(As of May 4 2012)
Addendum available at Exhibior Registration

Exhibiting As	Booth No.	Page No.
Flex Databases	Booth: 3209	164
Foresight Group, LLC	Booth: 3238	164
Formedix Inc	Booth: 2148	164
Forte Reseach Systems, Inc	Booth: 1951	164
Frontage	Booth: 1116	164
Fujitsu Limited	Booth: 1449	164
Fundacion De Investigacion	Booth: 3048 Business Suite: BS6	164
Global Instrumentation LLC	Booth: 1641	164
Global Language Solutions	Booth: 2108	164
GlobalCare Clinical Trials, LTD	Booth: 1148	164
GlobalSubmit, Inc.	Booth: 1203	165
goBalto, Inc.	Booth: 1114	165
Green Key Resources	Booth: 1743	165
Greenphire	Booth: 3125	165
Greenway Medical Technologies	Booth: 2503	165
H&J CRO International, Inc.	Booth: 2633	165
HCRAmerica	Booth: 2744	165
Healthcare Communications Group	Booth: 1413	165
Heat In A Click	Booth: 1548	165
High Point Solutions	Booth: 1033	165
I.D.E.A. Ltd.	Booth: 2050	165
iCardiac Technologies	Booth: 1526	165
ICON plc	Booth: 2701	166
Idem Translations, Inc.	Booth: 2848	166
IFAPP	Booth: 1848	166
Illingworth Research	Booth: 1948	166
Imperial	Booth: 2600	166
IMS Health/DecisionView	Booth: 2851	166
Inamed GmbH	Booth: 2501	166
INC Research	Booth: 1901	166
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INNOPHARMA S.r.L.	Booth: 2630	166
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Joule Clinical Staffing Solutions	Booth: 1832	168
Jubilant Clinsys Inc.	Booth: 3424	168
The Judge Group	Booth: 1543	168
Kansas Bioscience Authority	Booth: 1019	168
Kayentis	Booth: 1348	168
Kelly Scientific Resources	Booth: 1200	168
Klein Hersh International	Booth: 3213	168
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Aspire IRB
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The Avoca Group
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Blue Sky Broadcast specializes in delivering virtual meetings and web based training for life sciences programs. Our state of the art webcasting platforms and Learning Portals combined with our attentive, hands on project management has made us a respected leader in the industry.

Bracket Global **Booth: 2201**
Contact: Jen Burstedt Phone: 415-293-1369
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Bracket is a specialty services provider dedicated to helping pharmaceutical sponsors and contract research organizations achieve greater certainty and accurate outcomes in their clinical trials by seamlessly leveraging science, technology and operational excellence. Products and services include: -IVRS/IWRS -ePRO (via smartphone, web, phone) -Rater Training & Certification -Scale Management -CDR System (computerized cognitive testing) -Concordant Rater Station -VERIFIED -In-Study Ratings Reliability

Brand Institute **Booth: 2445**
Contact: Joseph Doerfler Phone: 305-374-2500
Website: www.brandinstitute.com

Brand Institute is a premier international branding agency that partners with healthcare, pharmaceutical and consumer companies to develop brand names. In operation since 1993, Brand Institute offers a comprehensive list of branding services including brand strategy/architecture, name development, market research, regulatory, and visual identity solutions. With regional offices strategically located, we offer the highest level of in-house expertise.

Business & Decision **Booth: 3305**
Contact: Keri Collette Phone: 508-395-6439
Website: www.businessdecision-lifesciences.com/

Business & Decision is a multi-national consulting and systems integration company specializing in services and solutions for the Life Sciences Industry. Our Life Sciences experts apply their industry knowledge, collaborate with clients and share insights on critical industry issues to deliver value through business optimization and the use of appropriate technology.

C3i, Inc. **Booth: 2425**
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Website: www.c3i-inc.com

From its integrated operation centers in North America, Europe, India and China, C3i helps life science companies conduct more efficient global clinical trials. C3i's portfolio of end-to-end technology services for EDC, IVRS, CTMS, ePRO applications includes: end-user training, 24x7 multi-lingual contact center, hardware provisioning, application hosting.

Cactus Communications **Booth: 2141**
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Website: www.cactusmed.com

Cactus Communications is celebrating its 10th year in the industry! CACTUS has offices in the United States, Japan, India, China, and South Korea. CACTUS undertakes medical writing, publication support, regulatory writing, scientific editing, literature analysis, transcription, translation, and medical writing training projects on behalf of pharmaceutical and medical device clients.

Camargo Pharmaceutical Services
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Website: www.camargopharma.com/

Camargo Pharmaceutical Services is an end-to-end drug development service provider specializing in the 505(b)(2) approval pathway. Camargo works with companies to develop comprehensive programs, managing every facet of the plan from formulating and testing the drug product, to conducting clinical studies and FDA application submissions. Connect with Camargo on the President's blog www.camargoblog.com or visit www.camargopharma.com for more information.

Cape Cod Clinical Research, Inc.
Booth: 2409
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Since 1998, Cape Cod Clinical Research, Inc. (CCCRI) has been providing the pharmaceutical and biotech industry with regulatory document management service (TrialDOCS), project management, monitoring, GCP auditing, site assessments and training programs for research personnel. Our client approach has involved a commitment to understanding and sharing your clinical development goals, while keeping your budgets in mind. For more information, please visit www.cccri.com, or email info@cccri.com.

Cardiac Safety Research
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Email: cardiacsafety@mc.duke.edu
Website: www.cardiac-safety.org

The Cardiac Safety Research Consortium (CSRC) was launched in 2006 through a MOU with Duke University to support research into the evaluation of cardiac safety of medical products. CSRC supports research by engaging stakeholders from industry, academia, and government to share data and expertise. Outputs of the CSRC include research projects taking advantage of waveforms released from the FDA ECG warehouse, "Think Tank Incubator" programs, and consensus white papers.

Cardio Analytics Ltd.
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Cardio Analytics has been providing high quality Centralised Cardiology Services for clinical trials Phase I to III for over 18 years. Carrying out 12-Lead digital ECG (including TQT Studies), 12-Lead and 3-Lead Holter, Telemetry, Echo and ABP Measurement and Analysis.

Cardiocore
Booth: 1300
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Cardiocore is a leading cardiac core lab that delivers superior global services, expert scientific consulting and state-of-the-art data and information management. With core lab locations near Washington, DC, South San Francisco, CA, and London, UK, Cardiocore's global services include Phase I-IV and Thorough QT trials for Top Ten pharmaceutical organizations, specialty pharmaceutical firms and emerging biotech companies.

Catalent Pharma Solutions
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From drug and biologic development services to delivery technologies to supply solutions, we are the catalyst for your success. With over 75 years of experience, we have the deepest expertise, the broadest offerings, and the most innovative technologies to help you get more molecules to market faster, enhance product performance and provide superior, reliable manufacturing and packaging results. Catalent. More products. Better treatments. Reliably supplied.™

CDISC
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CDISC is a 501(c)(3) non-profit organization, with nearly 300 member organizations from across the clinical research and healthcare arenas. CDISC catalyzes productive collaboration to develop industry-wide data standards enabling the harmonization of clinical data and streamlining research processes. The CDISC Vision is to inform patient care and safety through higher quality medical research.

Celerion
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Celerion is the premier provider of innovative early stage clinical research solutions. A full spectrum of resources is available for Phase 0 through IIa proof-of-concept studies. With six locations and over 730 beds, our experience and expertise is applied to provide solutions to pharmaceutical, biotechnology and generic clients.

Cenduit, LLC
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Cenduit is a leading global provider of Interactive Response Technologies (IRT) and a privately owned joint venture of Quintiles and Fisher Clinical Services, part of Thermo Fisher Scientific. Cenduit has a global staff of over 200 quality and customer service-driven IRT experts dedicated to optimizing patient randomization and drug supply management.

CenterWatch
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Founded in 1994, CenterWatch is a trusted source and global destination of clinical trials information for both professionals and patients. CenterWatch provides a wide variety of information services including study leads for investigative sites; business development leads for service providers; career opportunity resources; clinical trial listings; advertising and promotional opportunities; and proprietary market research on the global clinical trials industry. Visit www.centerwatch.com.

Cerner Corporation
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Cerner, a global leader in healthcare information technology, is solving healthcare's many challenges by connecting the right people with the right information at the right time. With more than 30 years of experience and our partnerships at more than 9300 client sites worldwide, we are now focusing on improving healthcare by leveraging technology, data and expertise to improve research – Healthcare improves when Research improves.

Cetero Research
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Cetero Research is an industry leading contract research organization (CRO) in early phase research services. With nearly 30 years of experience, Cetero has conducted more than 20,000 clinical pharmacology studies and has a proven track record of providing flexible and high quality clinical development services.

Chesapeake IRB
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Chesapeake IRB has been providing central independent IRB services since 1993. Chesapeake IRB earned AAHRPP accreditation in 2004 and was reaccredited a second time in June 2010. Chesapeake IRB offers a 21 CFR Part 11 compliant, electronic IRB platform (CIRBI) which streamlines protocol submissions and decreases investigator review turnaround times resulting in faster subject enrollments.

Children's Hospital of Orange County
Booth: 1642
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Located in an ethnically diverse Southern California community with one of the largest demographics of children in the nation, CHOC Children's is the only hospital in Orange County exclusively serving pediatric patients. CHOC maintains facilities, regulatory and administrative infrastructure in support of basic, translational and clinical research - with over 300 clinical trials across a wide range of therapeutic areas, currently integrated into our continuum of care.

Chiltern International, Inc.
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Chiltern is a leading, full service, global Contract Research Organization with extensive experience in the management of Phase I-IV clinical trials across a broad range of therapeutic areas and contract staffing solutions. With nearly 1,300 people located around the world, we are ready to meet the challenges of clinical trials.

Cincinnati Children's Research Foundation
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Website: www.cincinnatichildrens.org/clinical-trials-office

Cincinnati Children's is a pediatric academic medical center and clinical research test site conducting Phase I-IV (all major therapeutic areas) and select adult Phase I-IV studies. AAHRPP accredited, it has more than 1900 active IRB approved protocols annually, more than 700 investigators, 300 GCP trained study coordinators and more than 80 years of pediatric research experience.

CIRION Clinical Trial Services
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CIRION is a leading Contract Research Laboratory providing R&D services for Assay Development & Validation and Global Central Laboratory for Global Clinical and Pre-Clinical studies. The company offers high level scientific expertise with large molecules (biologics/biosimilars) and biomarkers in virology, immunology, molecular biology and microbiology. We offer a complete range of project management and logistical services with a broad portfolio of safety and esoteric assays.

Citeline Inc.
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Citeline provides the world's most comprehensive R&D intelligence to the pharmaceutical industry, covering global clinical trial, investigator and drug intelligence. Our integrated services combine data with unlimited access to our analysts, to give you real-time information and intelligence on which to base critical competitive decisions.

CITI Program - University of Miami
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The Collaborative Institutional Training Initiative (CITI) at the University of Miami offers customized web-based training in Human Subjects Research, Good Clinical Practice, Information Privacy and Security, Animal Care and Usage, Biosafety and Biosecurity, Responsible Conduct of Research and Export Control Regulations.

ClearTrial, LLC
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ClearTrial is the leading provider of Clinical Trial Operations (CTO) software, an integrated system for clinical operations planning, forecasting, outsourcing, and project tracking. Visit us in booth #2030.

ClinAudits LLC
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Website: www.clinaudits.com

Since 1994, ClinAudits has provided QA and regulatory compliance auditing and consulting services to the pharma, biotech, medical device and biologics industries; specifically GCP, GMP, and GLP. While specializing in GXP audits, services extend from pre-clinical to commericalization of pharmaceuticals, medical devices, biotechnology, biologicals, and gene therapy agents, and Rx to OTC drugs, both domestically and internationally. ClinAudits can serve as your virtual QA unit or preferred vendor.

ClinDatrix, Inc.
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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 uses a personalized approach to apply knowledge and experience to the goals of managing, monitoring, collecting, validating, analyzing, reporting, and delivering quality clinical data with efficiency and accuracy.

ClinForce, Inc.
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ClinForce provides resource solutions through functional outsourcing, contract staffing, and direct placement services. With over two decades of experience, ClinForce is trusted by its clients to identify skilled industry professionals to help get their products to market faster, and/or complete contracted projects on time and within budget.

Clinical Financial Services
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Clinical Financial Services (CFS) is a specialty provider focused on the business and financial management activities for clinical trials. The company offers a unique blend of contract, regulatory, and investigator grant payment management services which operate in unison to accelerate cycle times, manage compliance and risk, and stimulate investigator relationships. The company provides focused expertise, innovative processes, and integrated technology ensuring high quality service solutions.

Clinical Ink
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Clinical Reference Laboratory
Booth: 1540
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Clinical Reference Laboratory (CRL Global Services) is a global full service central laboratory founded on solid scientific expertise and a strong customer service focus. CRL has been serving the pharmaceutical industry since 1995 and offers a wide range of testing including Chemistry, Hematology, Urinalysis, Endocrinology, Serology, Biomarkers, DNA,RNA extraction, Genotyping and Sequencing. Worldwide global services include the USA, EU, Australia, Japan, South Africa, Singapore, and South America.

Clinical Research Advantage
Booth: 2325
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Clinical Research Advantage (CRA) has provided experienced research sites to the pharmaceutical and CRO industry through its partnerships with independent physician investigators in community based settings since 1992. CRA is the largest Integrated Site Network in the industry with 33 sites in 7 states having conducted 1800+ studies in diverse therapeutic areas and ages. CRA places an emphasis on vaccines and has enrolled 10,721 patients across 146 vaccine studies exceeding enrollment by 158%!

Clinical Research Malaysia
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Clinical Research Malaysia (CRM) is a non-profit Government Trial Management Network providing access to all clinical trial sites of the Ministry of Health, Malaysia. CRM is a project of the National Key Economic Areas and is responsible to develop the national contract research industry.

Clinical Resource Network, LLC
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At Clinical Resource Network, LLC, we make clinical trials "patient-centric" by bringing the clinical study to patients wherever they live, work or play. We have been deploying our international network of in-home nurses since 2003 to increase patient enrollment and retention. Perfecting how we conduct mobile clinical trials is our sole focus. Our highly experienced teams with diverse backgrounds allow us to execute well. As a result, we deliver evaluable results on time and on budget.

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.

Clinical Site Services
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Clinical Site Services is an enrollment performance company. We increase enrollment and retention for pharma, CROs and investigative sites through our site-focused approach and adaptive enrollment process. Our global patient enrollment services provide for seamless planning, execution and reporting, in the U.S. and in more than 40 countries.

Clinical Trial Media
Booth: 1433
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Clinical Trial Media is a global patient recruitment and retention company specializing in outreach, call center, tracking and support services to successfully complete enrollment on time and under budget. CTM has randomized study patients for thousands of clinical research studies across a wide variety of therapeutic areas since 1995.

ClinicalConnection, Inc.
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ClinicalConnection offers e-recruitment services to sponsors, CROs and research sites. With a quarter of a million visitors each month seeking clinical trial participation via its web portal, http://www.ClinicalConnection.com, has become the leading non-government web destination for clinical trial searches and patient referrals. Services include custom clinical trial listings, patient referrals, member database recruitment, and development of branded recruitment and site support websites.

clinicalRSVP
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Clinlogix
Booth: 1745
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Clinlogix is a full service, multi-therapeutic Clinical Research Service Organization that provides expert outsourcing on a functional basis - globally. We offer customized, metric-driven, essential services such as Project management, Monitoring, Data management, Vendor management and Investigator Site identification and Management. Clinlogix delivers support with highly experienced and therapeutically aligned professionals on a flexible and scalable global platform.

ClinStar, LLC
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ClinStar is a Western managed CRO with local operations in Russia, Ukraine, Belarus and the Baltics. We have 12 years of experience in Phase I-IV clinical trials across multiple therapeutic areas. Unlike many global CROs, we offer a substantial local presence across all areas of operations, providing us with unique local knowledge and personal relationships that benefit your clinical trial.

ClinTec International Ltd.
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ClinTec International is a Global CRO with a presence in over 40 countries worldwide. ClinTec has been providing high quality, clinical research support to the pharmaceutical, biotechnology and medical device industry since 1997. ClinTec has the capability to conduct global clinical trials as well as provide support to local projects.

Clinverse – eClinical Commerce Network
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Clinverse provides the industry's first SaaS eCommerce Network for investigator and vendor payments. ClinPay™, automates the entire investigator payment process from contract execution through site payment, providing transparency for Sponsors, CROs and Investigators: ClinPay prepares Sponsors for the Physician Payment Sunshine Act. We are integrated with various e-Clinical systems and our patent-pending technology supports secure payments in 140 currencies and configures to your workflow needs.

Cmed Group
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Cmed Group is an innovative clinical trials services and advanced software provider which includes two divisions: Cmed Clinical Services, a full-service CRO specialized in the design and delivery of pre-phase III traditional and innovative clinical studies, and Cmed Technology, an eClinical technology provider. Central to our business is Timaeus, a cloud-based eClinical platform that supports Study Design through Reporting.

CMIC HOLDINGS Co., Ltd.
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CMIC - Your Strategic Partner to Lead You into the Asian Market CMIC is a one-stop gateway to the Asian market supporting pharmaceutical, biotechnology and medical device companies. Our quality services include preclinical and clinical research management, site management, manufacturing, sales and marketing and consulting services which will be tailored to fit your unique specifications.

Cognizant
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Cognizant's Life Science Practice partners today with 27 of the top 30 global pharmaceutical/biotech organizations in addition to serving the medical devices, CRO and life sciences product companies. Cognizant is a leading provider of IT, consulting, and BPO services, dedicated to helping the world's leading companies build stronger businesses.

Compass IRB
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Compass IRB is a Central IRB located in Mesa, Arizona with full AAHRPP accreditation. Compass IRB is dedicated to outstanding customer service and the protection of human subjects. Compass IRB utilizes a customized online system "THE ANCHOR™ for online submissions and real time 24/7 tracking of all IRB documents.

CompleWare Corporation
Booth: 2539
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CompleWare Corporation is a full service contract service organization (CRO) and eClinical provider with a focus on respiratory clinical studies. This includes full centralized spirometry and electrocardiogram (ECG) capture as well as home subject data capture and management with a variety of electronic patient reported outcome (ePRO) collection options. CompleWare is able to increase the speed and accuracy of data capture, control study costs, and increase subject compliance.

Compliance Insight
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Compliance Insight specializes in Regulatory and Quality Assurance consulting and training for pharmaceutical, nutraceutical, medical device, chemical, and bio-technology companies in North America, Europe and Asia.

Comprehend Clinical
Booth: 2516
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Comprehend Systems creates next-generation clinical visualization and analytics software. Comprehend's first product, Comprehend Clinical, provides realtime dashboards, ad-hoc reporting, and drill down across disparate clinical datasources.

Comprehensive Clinical Research
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Comprehensive Clinical Research is a dedicated Phase I-IV Research Facility with 22 years of experience conducting trials in multiple therapeutic areas. A highly experienced team of investigators, clinical research coordinators, QA experts and regulatory affairs specialists, enable CCR to meet critical project timelines while maintaining the highest standards of quality.

Consent Solutions, Inc.
Booth: 3248
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ConsentSolutions, Inc provides e-consent. SecureConsent enables trial candidates to review approved consent documents with embedded education and handwritten digital signatures. ConsentSolutions provides e-consent localization and clinical site training. CS offers clinical trial teams a staff with over 15 years of experience in the areas of online data management and patient education.

Contract Pharma
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Conversis
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CoreLab Partners, Inc.
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CoreLab Partners, with offices in North America, Europe and Asia, provides medical image assessment and cardiac safety services to the bio-pharmaceutical and medical device industries. Driven by best-in-class science, emerging technologies and service quality, CoreLabs' is a global leader providing imaging sciences in all major modalities complemented by service offerings in the conduct of automated ECG, Thorough QT, Holter Monitoring, Ambulatory Blood Pressure Monitoring & Pulse Wave Analysis.

Corporate Translations
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Corporate Translations is an ISO9001:2008 and EN15038 certified and trusted provider of translation and linguistic validation solutions to the world's top life science companies. Our proven methodology and expertise in this highly regulated industry make us well qualified to translate and format documents throughout the entire lifecycle of a drug.

Cost Management Incentives, Inc.
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Covance Inc.
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Covance is one of the world's largest and most comprehensive drug development services companies with more than 10,000 employees in 60 countries. Through its discovery, nonclinical, clinical and commercialization services, Covance has helped pharmaceutical and biotech companies develop one-third of all prescription medicines in the market today.

CPC Clinical Trial Hospital, Medipolis Medical Research Institute
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We are a 60-bed Phase I Unit; in Japan, committed to quality, safety and innovation: Quality: ISO15189 Accredited Clinical Laboratory Safety: ACLS trained staff; hospital design incorporates numerous safety features Innovation: Phase-I, Bridging, tQT, FIM studies in numerous therapeutic areas; PD technology including Flow Cytometry, Platelet Aggregation/Function etc; International capabilities for overseas sponsors.

CRF Health
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CRF Health is a global leader in eCOA (eClinical Outcomes Assessments) solutions for the life sciences industry. eCOA encompasses PRO (Patient Reported Outcomes), ObsRO (Observer Reported Outcomes) and ClinRO (Clinician or Rater Reported Outcomes). Through innovative technology, a thorough understanding of drug development, and mobile computing, CRF Health is driving the change to higher quality outcomes and more efficient paper-free clinical trials.

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CRI Lifetree is a leader in early stage research with expertise in pain, abuse liability, psychiatry, neurology and diabetes. CRI Lifetree offers a range of Phase I-IV services to meet the requirements of complex clinical trials and conducts inpatient and outpatient trials in Philadelphia, New Jersey and Salt Lake City.

CROMSOURCE srl
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Website: www.lyotechnology.com

Lyophilization Technology, Inc. is a Contract Development and Manufacturing Organization providing development and technical services focused on lyophilized products. The comprehensive range of services includes product design, formulation development, process engineering, clinical supplies manufacturing for freeze dried pharmaceuticals, biologics, diagnostics, biopharmaceuticals and fine chemicals. Technical services encompass consulting, compliance support and training.

MakroCare
Booth: 1833

Contact: Subrata Biswas
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Email: subrata.biswas@makrocare.com

Website: www.makrocare.com
MakroCare is a global drug development and commercialization services firm that has 12 international offices and serves clients through 5 main divisions — DDi, CRO, SMO, Commercialization and Regulatory Consulting. It offers integrated and innovative services in USA, Europe and Asia by its unique blend of regulatory, medical, clinical, project management backed by completely validated eClinical suite including mEDC, mCTMS, mIWRS, mCoder and other tools.

Malvern Consulting Group, Inc.
Booth: 3348

Contact: Sue Sharr
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Website: www.malvernconsultinggroup.com

Malvern Consulting Group is comprised of a team of professionals with diverse backgrounds and expertise encompassing all disciplines of product development: pre-clinical, clinical, regulatory, quality, manufacturing, and packaging.

MASIMO
Booth: 3250

Contact: Scott Baldwin
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Website: www.masimo.com

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
Booth: 3005

Contact: Julie George
Phone: 617-732-2988
Website: www.mcphs.edu

Massachusetts College of Pharmacy and Health Sciences (MCPHS) offers exciting opportunities for those interested a graduate education in health care. To accommodate unique personal and professional schedules, students can enroll in programs as full-time or part-time studies at either our Boston Campus or Online Campus.

Master Control
Booth: 1441

Contact: Emily O'Driscoll
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MasterControl Inc. produces software solutions for the life sciences industry which include management solutions for enterprise quality assurance/control, enterprise documents, product lifecycle, GxP audit, training, bill of materials, suppliers, submission organization and archiving, clinical trial master files and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with complete solution across the entire enterprise.

MaxisIT Inc.
Booth: 2417

Contact: Maulik Shah
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MaxisIT offers integrated data, analytics and regulatory content management platform CTRenaissance® as managed hosting and software-as-a-service, which empowers pharmaceuticals, life sciences and academic organizations with web-based and scalable environment to design, manage, monitor clinical trials as well as analyze and submit data on-demand in most efficient manner. A unique and successful blend of clinical trial software and services in compliance to regulatory and industry data standards.

McGuire Research Institute
Booth: 1836

Contact: Robert Dresch
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Website: vaww.research.va.gov

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, Hep C, Crohn's, colitis, interventional cardiology, electrophysiology, DVT, Parkinson's, spinal cord injury, traumatic brain injury.

MedDRA MSSO
Booth: 1201

Contact: Char Guy
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Website: www.meddramsso.com

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).

Medical Research Network Ltd.
Booth: 2745

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Established in 2006, the MRN is the world's leading provider of home healthcare nursing for patients in clinical trials, with coverage now spanning 4 continents. Our focus is patient recruitment and retention, as well as offering at home visits, we can also provide nursing staff to sites where resources may be constrained.

Medicines Evaluation Unit
Booth: 1026

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Website: meu.org.uk

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

Medidata Solutions Worldwide
Booth: 3101

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Medidata Solutions is a leading global provider of SaaS clinical development solutions that enhance the efficiency of clinical trials. Our advanced solutions lower the total cost of clinical development by optimizing trials from concept to conclusion, serving a diverse and growing customer base.

MedNet Solutions, Inc. **Booth: 3017**
Contact: Dirk Nelson
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MedNet is a leading eClinical technology solutions company specializing in electronic data capture (EDC) and clinical study management systems. Since 2000, MedNet's proven web-based solutions have successfully supported research initiatives worldwide. Visit our booth to see iMedNet EDC...an affordable new solution that allows sponsors and CROs to quickly and easily build their own studies.

Medpace Inc. **Booth: 2413**
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Medpace, Inc. is a global, full-service Contract Research Organization specializing in the therapeutic areas of cardiology, metabolism, oncology, neurology, and infectious disease. Our guiding philosophy is to provide the best therapeutic and regulatory expertise at each stage of the drug/device development process. Medpace provides central reference laboratory services, bioanalytical laboratory services, human pharmacology, imaging core lab, ECG reading support, and device trial management.

MedSource **Booth: 1417**
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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.

MEDTOX Laboratories **Booth: 2439**
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MedTrials **Booth: 1930**
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MedTrials is a full-service CRO specialized in providing project specific clinical trial management solutions. We are committed to exceptional service and high quality results throughout all phases of clinical development. MedTrials is a WBENC-certified, women-owned business, and is positioned to meet your supplier diversity needs.

Merge eClinical **Booth: 2601**
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Merge Healthcare is a leading provider of enterprise imaging and interoperability solutions. Merge solutions facilitate the sharing of images to improve the electronic healthcare experience. Merge provides solutions for radiology, cardiology, orthopaedics, eye care, clinical trials, financial and pre-surgical management; electronic health record and practice management solutions; applications that fuel the largest modality vendors in the world, and a network of patient-centric wellness stations.

META Solutions, Inc. **Booth: 2517**
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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.

M-Files Inc. **Booth: 1132**
Contact: Sasha Vaynman
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Email: sales@m-files.com
Website: www.m-files.com/eng/qms.asp

M-Files QMS is an out-of-the-box solution for daily quality management. With M-Files QMS, all quality documents and data are linked together within a single system, enabling organizations to optimize quality processes while streamlining compliance activities and audit requirements.

Microsoft Corporation **Booth: 1325**
Business Suite: BS4
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Email: askls@microsoft.com
Website: www.microsoft.com/lifesciences

Life sciences organizations are under pressure to meet regulatory requirements and reduce the time it takes to develop drugs and take them to market. Microsoft and partners have developed cost-effective solutions that enable organizations to streamline processes that improve productivity and deliver information whenever and wherever it is needed. www.microsoft.com/lifesciences

Microsystems **Booth: 1928**
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Website: www.microsystems.com

Microsystems offers DocXtools, a collection of document assessment, cleanup and problem-solving tools that helps medical writers, submission authors and QC/Compliance departments prevent document problems and produce high-quality Word documents more quickly. Pharmaceutical companies rely on DocXtools to ensure conformity with house styles and FDA/EMA guidelines prior to eCTD submissions.

Mission3
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Mission3 is the premier Regulatory Information Management software provider for the Life Sciences industry. Mission3 provides the only platform-based and integrated Regulatory Information Management solution, GlobalTrack, a business intelligence platform that provides companies with increased visibility into their global regulatory initiatives. GlobalTrack is built on the Microsoft's SharePoint 2010 and Project Server platform, increasing user compatibility with their current systems.

MMG
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MMG is a global, full-service patient recruitment and retention firm with offices in the US and UK.

MonitorForHire.com
Booth: 1926
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Website: www.monitorforhire.com

MonitorForHire.com is a patented Internet-based staffing tool for quickly connecting pharmaceutical, biotechnology, medical device companies, academic institutions and contract research organizations (CROs) with available independent clinical trial monitors. Today, the company has a network of more than 4,000 registered monitors in 60 countries, and nearly 900 clinical trial sponsors. For more information, please visit www.monitorforhire.com or call +1-610-862-0909.

Montrium, Inc.
Booth: 2844
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Website: www.montrium.com

Montrium is a GxP consulting group focused on providing technological solutions to the life sciences industry. Montrium is unique in that it provides an integrated set of pre-configured SharePoint based workspaces for records, quality, systems and clinical process management, as well as consulting services for systems strategy, implementation and validation. Montrium Workspaces can be used in our validated SharePoint cloud 'Montrium Connect' or within your existing SharePoint environment.

Moravia
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Mortara Instrument, Inc.
Booth: 1317
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From ECG acquisition at the investigator site to FDA ECG Warehouse development, Mortara has developed a unique platform to help smoothly marshal a study from site to submission. Mortara's Rx platform of ECG products was specifically developed with clinical research in mind. www.mortara.com

myClin
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Study Sites, Sponsors, Service Providers - CONNECTED! myClin provides a secure online social collaboration platform for clinical research teams to use in phase I-IV clinical trials, patient registries and device trials. Use myClin to conduct site feasibility, share documents, facilitate site initiation, answer questions, provide training, centralize operational information and communicate with your entire clinical trial community.

Myoderm Medical
Booth: 1630
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Myoderm is a leading service provider for global procurement of commercial pharmaceuticals including drugs utilized for comparator, rescue, adjunctive or concomitant therapy. We utilize our experience, knowledge, supplier and manufacturer network to provide clients with critical information and accurate delivery of product. In addition, Myoderm can act as the Central Rx for direct to clinical site distribution as an alternative to local site sourcing.

National Death Index
Booth: 1205
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Email: mgoodier@cdc.gov
Website: www.cdc.gov/nchs/ndi.htm

The National Death Index (NDI) is a central computerized index of death record information on file in the state vital statistics offices. Working with these states, NCHS established the NDI as a resource to aid epidemiologists and other health and medical investigators with their mortality ascertainment activities.

New England Institutional Review Board
Booth: 1725
Contact: Carolyn Newman
Phone: 617-243-3924
Email: carolyn.newman@neirb.com
Website: www.neirb.com

New England IRB (NEIRB) is an independent IRB providing ethical review of research involving human subjects, including phase I - V single and multi-site studies. NEIRB offers: • Review across North America • Free Protocol Consultation • One-week Protocol Review • 24-Hour Site Review • Full AAHRPP Accreditation • In good standing with FDA (2011 inspection)

New Orleans Center for Clinical Research
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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.

NextDocs
Booth: 1125
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NextDocs is the global leader in providing Microsoft SharePoint-based compliance and quality management solutions to life sciences organizations. It enables businesses in regulated industries to achieve compliance with FDA, EMA and other agencies while automating processes, improving efficiency and dramatically reducing costs. NextDocs customers include, pharmaceutical companies, biotech firms, device manufacturers and contract research organizations. Visit us at www.nextdocs.com.

Nextrials, Inc.
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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.

Norwich Clinical Services
Booth: 2317
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Website: www.norwichpharma.com/

Norwich Clinical Services is a global CRO that conducts Phase I-III clinical trials, Phase IV post market surveillance, BA/BE studies, pharmacovigilance, laboratory and analytical services for the pharmaceutical and biotech industries. NCS offers study management, project coordination for clinical trial recruitment, and investigator collaboration led by physician teams with targeted therapeutic experience having completed more than 50 clinical trial programs and over 2,000 biostudies.

Nova Language Services Ltd.
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NOVA is a full service translation provider of multilingual language services to the CRO/Regulatory affairs sectors in Europe. From clinical trial protocols to marketing authorization dossiers, we will fulfill all your translation requirements with expertise, accuracy and reliability in all European languages. NOVA is ISO 9001:2008 and UNE EN 15038 certified. Nova has been included in the top ten translation providers in Southern Europe by Common sense advisory group.

Novella Clinical
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Novella Clinical, Inc. is a full service contract research organization with dual headquarters in Research Triangle Park, N.C and Stevenage, England. For more than a decade, Novella has served as an active partner to the oncology, biopharma and medical device industries. As the first global eCRO, Novella integrates deep clinical expertise with industry-leading technologies and a proven approach to support, streamline and expertly resource the entire product development process.

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 use of Oracle Argus Safety, Oracle AERS, and ARISg. We are pleased to announce the availability of PRIMO, our streamlined data capture system for adverse events, registries, and product complaints, targeted for use by call centers, safety data mgmt groups, affiliates and partners.

Novotech
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Internationally recognized as the leading Australian CRO, Novotech is a full service clinical CRO with operations in Australia and across the Asia Pacific. Together with our strategic partners on six continents, 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.

nSpire Health, Inc.
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Website: www.nspirehealth.com
nSpire Health offers Centralized Spirometry, Pulmonary Diagnostics, Challenge Testing, eDiary, and Data Management for Phase I-IV Clinical Trials including Asthma, COPD, and inhaled therapeutics. We have provided services to over 225 trials in the past 10 years and global support to over 5,000 investigative sites in more than 50 countries. Our quality review team has reviewed more than 1 million PFT's. Our experience includes clinical trials as large as 500 sites spanning 34 countries.

Ocasa Logistics Solutions
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With over 25 years of experience, OCASA's Bio-Pharmaceutical logistic service offers tailor-made solutions for the Pharma industry including export, import, distribution, fulfillment, & temperature controlled warehousing for: Diagnostic Specimens, Medication/Vaccines, Experimental Drugs, Controlled Substances, Dangerous Goods, & Medical Supplies.

Octagon Research Solutions, Inc.
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Octagon is the leader in transforming clinical R&D through an integrated suite of regulatory, clinical, process and technology solutions. Octagon's eCTD and CDISC solutions provide the people, process and technology required to optimize drug development from clinical data collection to regulatory submission.

OMERACT
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OMERACT strives to improve endpoint outcome measurement through a data driven, iterative consensus process involving relevant stakeholder groups. The term OMERACT was originally established in 1992 to mean "Outcome Measures in Rheumatoid Arthritis Clinical Trials". Since then the OMERACT initiative has turned into an international informal network, with working groups and gatherings interested in outcome measurement across the spectrum of rheumatology intervention studies.

OmniComm Systems, Inc.
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OmniComm provides customer-driven eClinical internet solutions to companies that conduct clinical trial research. We deliver products and services that ensure ease of use, faster study build, ease of integration, and better performance. Please visit us at booth 3301 for a demo of our comprehensive product suite.

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.

OpenClinica
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OpenClinica is an open source clinical trials software solution for electronic data capture and clinical data management. It has been successfully used in thousands of clinical trials across some very diverse settings in all phases of clinical trials. OpenClinica offers 2 editions: Community and Enterprise. Visit us at www.openclinica.com.

OpenQ, Inc.
Booth: 2740
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OpenQ helps life science companies harness the power of medical networks to compliantly and efficiently reach influencers and stakeholders. Their software and data solutions offer commercial and research professionals the industry-leading support for regulatory compliance needed for these critical, but high-risk relationships.

Optum
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Oracle Corporation
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Orlando Clinical Research Center
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Palm Beach CRO
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Palm Beach CRO provides clinical services that meet the highest quality standards with appropriate client timelines. PBCRO manages the entire clinical trial process from site selection, investigator meetings, monitoring, IRB, regulatory affairs, data management, statistical analysis and final reports of multi-center trials throughout the USA.

Paragon International, Inc.
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Paragon Solutions
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Paragon Solutions is an advisory consulting and systems integration firm that focuses on Clinical Trial Operations collaboration, document management and information insight and governance. Our mission is to partner with clients to define and deliver optimal business outcomes through business process consulting, systems implementation and change management services. Visit our website at www.consultparagon.com.

PAREXEL International
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An innovative leader for 30 years, PAREXEL knows drug development from end-to-end of the product development cycle: clinical development, integrated technologies, regulatory affairs, market access, and commercialization services. We complement your capabilities with our global reach, strategic insight, deep scientific knowledge, and tactical expertise—providing you support and guidance to secure strategic advantage. We provide the precise fit of expertise when, where and how you need it.

Patient Recruiters International, Inc.
Booth: 2304
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Patient Recruiters International (PRI) is an innovative patient recruitment organization that combines powerful direct patient access strategies with time-tested methods to achieve recruitment objectives. PRI has built confidence and reliability with its innovative tools including targeted direct patient access, online patient communities, customized social media initiatives, and risk-shared contracting models.

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.

PCM TRIALS
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PCM TRIALS has been providing clinical trial home visits for all therapeutic areas and phases of clinical trials since 2008. PCM TRIALS recruits, screens, hires (does not contract with local home health care agencies) trains 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, SOPs, IATA and trial specific protocol. Services available in the U.S. and abroad.

PDR Network, LLC
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Pediatric Pharmacokinetic Consortium
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The PPKC is an Academic Site Management Organization developed as a consortium between four pediatric medical centers. The PPKC offers a "turn-key" platform for the conduct of phase I and II clinical trials over the entire age spectrum that comprises pediatrics and in the vast majority of pediatric subspecialty areas.

Penn Pharma
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As one of the longest established pharmaceutical services companies, Penn Pharma has 30 years of experience in providing integrated drug development, clinical trial supply and manufacturing services to the international healthcare industry. Penn Pharma is privately owned and operates from a single site facility in South Wales, UK where we employ over 280 highly skilled staff.

Perceptive Informatics
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Perceptive Informatics®, an industry-leading eClinical solutions provider, combines clinical knowledge and experience with leading technology to decrease time to market, risk and cost associated with clinical trials. Our portfolio includes medical imaging, RTSM, EDC, CTMS, ePRO and integration services, as well as portals, tracking tools and investigator database solutions.

Pharmaceutical Executive
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Pharmaceuticals and Medical Devices

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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.

Pharmalink Consulting Inc.
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Pharmalink is the world's leading Regulatory Affairs Consultancy with over 400 consultants working at their offices in the USA, UK, India and Singapore complemented by the Pharmalink Affiliate Network of consultants on the ground in 103 countries worldwide. They provide strategic and sustainable regulatory affairs consulting and support to clients within the Pharmaceutical, Biotech, Consumer Health, Medical Device, and Generics industries.

PharmaLive.com
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PharmaNet/i3
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PharmaNet/i3, the inVentiv Health clinical segment, is a leading provider of global development services to pharmaceutical, biotechnology, generic drug, and medical device companies, including therapeutically specialized capabilities for Phase I-IV clinical development, bioanalytical services, and staffing from a single clinical professional to an entire functional team. For intelligent solutions to accelerate development programs of all sizes around the world, PharmaNet/i3 works for you.

PharmaSeek
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PharmaSys, Inc.
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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.

PharmaVigilant
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PharmaVigilant is an eClinical company founded to provide broader solutions to streamline the clinical trial process for biopharmaceutical companies. Its full suite of SaaS solutions automate the collection, management and analysis of clinical trial data: EDC (InSpire EDC), Data Warehousing (I-Warehouse), eTMF (I-Vault eTMF), Remote Monitoring (I-Vault rSDV), Study Building (I-Builder), Automated Site Payments (PaySite), Study Administration (InSpire Control Center), and Data Entry (I-Monitor).

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Pharm-Olam International Ltd.
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Philips Respironics
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PHT Corporation
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PRA
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PRL Central Laboratory Services
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Quality Associates, Inc. **Booth: 2639**
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Quanticate, Inc. **Booth: 2643**
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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.

Queensland Clinical Trials Network **Booth: 2301**
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QCTN is the primary point of contact for domestic and international organizations 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. Accompanying members include: Clinical Network Services, The Wesley Research Institute and Q-Pharm.

Quest Diagnostics Clinical Trials
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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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Research Across America is an Independent Site Network-ISN (Non-SMO) that manages and conducts Phase I thru Phase IV and Post marketing trials utilizing their 7 regional multi-specialty sites located in Dallas, TX, El Paso, TX, Houston TX, Suburban Houston-Katy, TX, New York, NY, Santa Ana, CA, Reading/Lancaster, PA, and most having Satellite Sites in their surrounding areas. The physicians affiliated with Research Across America have conducted over 1800 clinical trials since 1989.

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ResearchPoint Global is a full-service CRO providing drug, device and biologic development services worldwide. With expertise spanning all major therapeutic areas, ResearchPoint Global delivers a unique blend of experience combined with the creativity, responsiveness, and customer focus of a highly nimble organization.

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Rho, Inc.
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RTI Health Solutions
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RTI Health Solutions (RTI-HS) provides consulting and research expertise to help pharmaceutical, biotechnology, diagnostics and medical device companies develop and commercialize their products.

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Schlafender Hase GmbH
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Sentrx
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SGS
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Sino-American Pharmaceutical Professionals Association (SAPA)
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SNBL Clinical Pharmacology Center
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SNM Clinical Trials Network
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Soltex Consulting LLP
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Sonic Clinical Trials
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Spaulding Clinical Research
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Phone: 360-252-2443
Website: www.wirb.com

At the forefront of human research safety for more than 40 years, WIRB continues to deliver leadership, proven expertise, and quality services to medical researchers worldwide. WIRB's expertise ensures indisputable review quality safeguarding both Investigator and human subjects. WIRB's customized services, training, and consulting accelerate research review and implementation. WIRB helped forge and remains the gold standard in research today for protecting human subjects and advancing research.

Whitsell Innovations, Inc.
Booth: 1740
Contact: Natalie Becker
Phone: 919-636-5839
Email: info@whitsellinnovations.com
Website: www.whitsellinnovations.com

Whitsell Innovations, Inc. is a medical and scientific writing company. We provide regulatory documents for clinical and pharmaceutical development (pre-clinical through post-marketing), including full submissions. We write meeting packages, CMC development reports, validation and stability protocols and reports, clinical protocols, clinical study reports, narratives, manuscripts, CME content, and literature reviews. Our singular focus is perfect communication for our clients' target audience.

Wingspan Technology Inc.
Booth: 1128
Contact: Meghan McKeown
Phone: 610-941-6500
Email: mmckeown@wingspan.com
Website: www.wingspan.com

Wingspan Technology, Inc, the leading provider of Documentum to SharePoint integration software, is the maker of the DocWay products and Wingspan eTMF. Founded in 1996, Wingspan provides innovative technology solutions and offers in-depth industry knowledge and experience to companies in life sciences and pharmaceutical industries.

Wipro Technologies
Booth: 2900
Email: info@wipro.com
Website: www.wipro.com

Wipro (NYSE: WIT), services 5 of the top 10 Pharmas globally and exceeds $6B in annual revenue as a global leader in consulting, technology, BPO and R&D solutions. We are the leader in providing pharma with a range of services and accelerators with best practices covering EDC, CTMS, Safety, Collaboration Portal and CDR in a SaaS delivery model.

World Courier, Inc.
Booth: 1213
Contact: Nicole Murback
Phone: 516-354-2600
Email: nmurback@worldcourier.com
Website: www.worldcourier.com

With over 150 offices in 51 countries – all ISO 9001 certified- World Courier has the network, trained personnel and resources to manage the most demanding research project, biologic , or pharmaceutical shipment.

Worldwide Clinical Trials
Booth: 1913
Contact: Freyja Cheng
Phone: +86-21 54298073
Email: freyja.cheng@adicon.com.cn
Website: www.adicon.com.cn

ADICON Clinical Trial Center, a leading full-service central lab for clinical trials in China, conducts activities to support new pharmaceutical developments including clinical trials and CRO (contract research organization) business. The company's comprehensive support for clinical trials contributes to realizing rapid and high quality pharmaceutical development.

X Factor Advertising **Booth: 2313**
Contact: Mike Lakey
Phone: 503-235-6249
Email: mlakey@xfactoradvertising.com
Website: www.xfactoradvertisting.com

X FACTOR ADVERTISING (XFA) is an industry leader in patient recruitment services. As a full-service agency we specialize in the development and implementation of creative, media and tracking strategies to assist in the recruitment and retention of patients for clinical trials. XFA works with individual sites, CRO's and pharmaceutical companies and has developed successful campaigns supporting recruitment in 11 countries throughout North America, South America and Europe.

Xerimis Inc. **Booth: 1916**
Contact: Kevin Clover,
Business Development Executive
Phone: 856-727-9940
Email: kevin.clover@XERIMIS.com

Website: www.XERIMIS.com
CUSTOMIZED CLINICAL PACKAGING - "Your Project, Your Timeline" * Phase I-IV Project Mgmt. * DEA Lic.: Sched. III-V * Protocol Analysis, Package/Label Design, Supply/Distrib. Strategies * "CAPS" - Customized Accelerated Packaging Solutions * Primary/Secondary Packaging - Thermoform/Coldform Blistering - Auto./Manual Bottle Fill * Multi-Lingual Label Generation * Monitoring/Global Distrib.: Controlled Room Temp., Refrig./Frozen Conditions * Import/Export Coord. * Returned Supplies Accountability/Destruction

Y-Prime LLC **Booth: 1138**
Contact: David Espenshade
Phone: 610-675-6373
Email: despenshade@y-prime.com
Website: www.y-prime.com

Y-Prime LLC is a premier eClinical products and consulting company that leverages groundbreaking platform technology and systems intelligence to provide novel, personalized decision making solutions to life sciences companies. Since 2006, Y-Prime has developed a robust franchise of enterprise, clinical and operations solutions that offer the potential to dramatically accelerate time to market while significantly reducing costs.

Zinc Ahead, Inc. **Booth: 3149**
Contact: Hamish Miller
Phone: 212-971-9710
Website: www.zinc-ahead.com

Developed and refined over the course of almost a decade, Zinc MAPS is the world's leading promotional compliance solution designed specifically for the life science industry. A web–based application which places the entire approval process online, Zinc MAPS drives compliance, quality and efficiency into approval processes. With clients in over 100 countries, Zinc Ahead is the world's leading provider of promotional compliance solutions designed specifically for the life science industry.

NOTES

PRECONFERENCE PROGRAMS AND TUTORIALS — Sunday, June 24 (as of February 1, 2012)

DIA 2012 features many extended opportunities for you to network and learn. The Annual Meeting Preconference Tutorial Program is an excellent opportunity to jump start your learning before the DIA 2012 Annual Meeting. Each preconference tutorial is led by subject matter experts who will provide in-depth instruction on some of today's hottest topics. Each preconference tutorial is designed to increase your knowledge in specific subject areas while allowing for small group interaction. Offerings are either full-or half-day opportunities. Related tracks/interest areas are indicated to the right of the tutorial title.

Monitor **www.diahome.org/registerDIA2012** frequently for updates to the Preconference Programs and Tutorials.

Morning Tutorials, Half-day — 8:30 AM–12:00 PM — *Tutorial Fee: $405.00*

Tutorial 20	**Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development**	*See page 192 for details.*
Tutorial 21	**FDA Enforcement: Understanding the Agency's Authority, How Violations Occur, How to Prevent Them, and How to Respond if Violations Do Occur**	*See page 192 for details.*
Tutorial 22	**Utilizing Chemistry, Manufacturing, and Controls in Drug Development**	*See page 193 for details.*
Tutorial 23	**Global Market Access: Essential Knowledge for Clinical Trial Design**	*See page 193 for details.*
Tutorial 24	**A Device Primer: 510(k)s, PMAs, IDEs**	*See page 193 for details.*
Tutorial 25	**Benefit and Harm: A Process to Expres** CANCELLED **sus-driven Evidence**	

Afternoon Tutorials, Half-day — 1:00 PM–4:30 PM — *Tutorial Fee: $405.00*

Tutorial 30	**Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in the EU**	*See page 194 for details.*
Tutorial 31	**Leadership: How to Organize and Lead People in Group Work**	*See page 194 for details.*
Tutorial 32	**Designing, Operating, and Evaluating Patient Registries**	*See page 194 for details.*
Tutorial 33	**Understanding Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA) in the Biopharmaceutical Industry**	*See page 194 for details.*
Tutorial 34	**Fourteen Steps from Research to Development**	*See page 194 for details.*

PRECONFERENCE PROGRAMS

9:00 AM-6:30 PM **SAFE-BioPharma®: Trusted Identities** CANCELLED

1:00 PM-6:00 PM **APCR: Win-win Strategies for the Sp**

Full-day Tutorials — 9:00 AM–5:00 PM* — *Tutorial Fee: $755.00*

Tutorial 40	**Understanding and Navigating the Regulatory System in China**	*See page 196 for details.*
Tutorial 41	**Quality Oversight of CROs - Clinical Vendors**	*See page 197 for details.*
Tutorial 42	**Regulatory Affairs for Biologics**	*See page 197 for details.*
Tutorial 43	**Clinical Statistics for Nonstatisticians**	*See page 198 for details.*
Tutorial 44	**Early Phase Research: Navigating the** CANCELLED **Trials**	
Tutorial 45	**Preparing for a US FDA Advisory Committee Meeting** *ADJOURNS AT 3:45 PM	*See page 199 for details.*
Tutorial 46	**Fundamentals of Project Management for Nonproject Managers** *ADJOURNS AT 4:30 PM	*See page 199 for details.*
Tutorial 47	**Overview of Drug Development**	*See page 199 for details.*
Tutorial 48	**Art of Writing a Clinical Overview**	*See page 199 for details.*

Register for these tutorials and the Annual Meeting online or fax the completed registration form on page 204 to DIA at +1 215.442.6199.

MORNING TUTORIALS, HALF-DAY

8:30 AM-12:00 PM Fee: $405.00

TUTORIAL 20 **Track 08**

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

Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development

Continuing Education Credit: IACET – .3 CEUs
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Alberto Grignolo, PhD
Corporate Vice President
Global Strategy and Services
PAREXEL Consulting

Major changes in Japanese pharmaceutical regulations are impacting the development of new drugs in Japan as well as global development programs. This tutorial will describe the major elements of the regulatory system including the Pharmaceuticals and Medical Devices Agency (PMDA), regulatory processes during development (consultations), and J-CTD review. Several development strategies necessary to meet Japanese requirements for new drug approval will be identified. Postmarket surveillance and pricing reimbursement processes will be reviewed, and finally, the impact of the changing regulatory system on global strategies will be identified throughout development, registration, and postmarket stages.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Explain the major elements of the Japanese regulatory system
- Describe the regulatory processes during development, registration, and postapproval
- Discuss specific attributes in the Japanese regulatory system and their impact on multinational development strategies

Target Audience

This tutorial is designed for professionals in regulatory affairs, project management, and clinical development who are involved with global development projects involving Japan.

TUTORIAL 21 **Track 08**

Related Interest Area(s): RA, QAQC

FDA Enforcement: Understanding the Agency's Authority, How Violations Occur, How to Prevent Them, and How to Respond if Violations Do Occur

Continuing Education Credit: IACET – .3 CEUs
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Michael A. Swit, Esq., JD
Founder
Law Offices of Michael A. Swit

This tutorial will review and discuss the legal, regulatory, and practical challenges of (1) FDA enforcement priorities for 2012 and beyond (e.g., application integrity policy and GMP/GCP requirements), (2) FDA administrative enforcement weapons and how the Agency uses them (e.g., inspections, warning letters, publicity, recalls, and investigator disqualification proceedings), and (3) the civil and criminal penalties for violations (e.g., seizure, injunction, criminal prosecution). Included in our focus will be FDA's renewed commitment to enforcement as articulated in an August 2009 speech by Commissioner Margaret Hamburg. We also will address how to handle an FDA enforcement action should you face one, particularly in the wake of an inspection or Warning Letter and the impact of the new initiatives related to responding to 483s and Warning Letters implemented in 2009 following Commissioner's Hamburg's pledge to boost enforcement. These interactive discussions will focus on how FDA operates and makes decisions and how to respond effectively, using tactics ranging from negotiation to, when appropriate, litigation.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Discuss FDA's enforcement priorities for 2012 and beyond
- Describe FDA's compliance review and decision-making process
- Identify the legal risks and penalties for noncompliance
- Respond appropriately to FDA enforcement

Target Audience

This tutorial is designed for all personnel responsible for ensuring compliance with FDA requirements, particularly those under the GMP and GCP rules, regardless of whether in a supervisory or direct role.

TUTORIAL 22 **Track 12**

Related Interest Area(s): CMC, RA, QAQC

Utilizing Chemistry, Manufacturing, and Controls in Drug Development

Continuing Education Credit: IACET – .3 CEUs
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Priya Jambhekar
President
PBS Regulatory Consulting Group Inc.

This tutorial will provide you with the tools to write or assemble CM&C sections of regulatory submissions and other regulatory documents, and adequately prepare you for CM&C meetings with the FDA.

Participants will discuss all the CM&C components of INDs and NDAs/CTDs, provide appropriate tools to write or assemble CM&C sections of regulatory submissions and documents, prepare for CM&C meetings with FDA, and navigate through the myriad guidelines and guidance documents.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Recognize FDA's regulatory expectations and the regulatory framework
- Outline the CM&C sections of INDs/NDAs/CTDs/DMFs
- Assemble the CM&C sections of INDs and NDAs/CTDs
- Describe regulatory documents affected by CM&C

Target Audience

This tutorial is designed for regulatory affairs professionals, quality assurance and compliance personnel, and manufacturing personnel.

TUTORIAL 23 **Track 13**

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

Global Market Access: Essential Knowledge for Clinical Trial Design

Continuing Education Credit: IACET – .3 CEUs
Clinical Research Certificate Program: 2 Elective Units

Instructor
John Brennick, MPA
Worldwide Market Access
Janssen Global Services, LLC

Reimbursement approvals from payers (reimbursers) have become as important as regulatory approvals for pharmaceutical product success and providing access to patients. Even with reimbursement approval, payer restrictions such as step edits and individual patient approval significantly impact product usage. This tutorial will provide an overview of global reimbursement systems including health technology assessments (e.g., NICE), and discuss ways in which evidence of value from clinical trials can help or limit market access.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Summarize the evidence demands of global payer customers
- Discuss the growing importance of the reimbursement hurdle to patient access to your medicine
- Recognize how aspects of clinical trial design, such as dosing and comparator choice, can impact reimbursement potential

Target Audience

This tutorial is designed for pharmaceutical industry employees not familiar with market access (pricing, reimbursement, health economics) issues.

TUTORIAL 24 **Track 09**

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

A Device Primer: 510(k)s, PMAs, IDEs

Continuing Education Credit: CME – 3.25 *AMA PRA Category 1 Credit(s)™;* IACET – .3 CEUs
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Barry S. Sall, RAC
Principal Consultant
PAREXEL Consulting

Get up to speed on medical device clearances and approvals! This tutorial demystifies FDA's medical device requirements. We will explain and provide a decision matrix for 510(k)s and PMAs, as well as a matrix to clarify IDE requirements. Attendees will use that matrix to determine the appropriate pathway for public record/fictional products and explore the strategic implications behind the submission and its indications. We will examine investigational device exemptions, and discuss the role of IRBs and the level of FDA oversight as the trial proceeds.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Distinguish between 510(k)s and PMAs and their strategic advantages
- Describe the scope of IDEs (exempt, nonexempt, SR)
- Explain the nature and type of IRB including sponsor oversight
- Identify major risks and the impact of new regulatory initiatives

Target Audience

This tutorial is designed for regulatory affairs (RA) managers, business development managers and staff; principal investigators, IRB members, clinical research associates (CRAs), academic sites; lawyers, R&D, and those working on combination products, cross-functional medical products and those wishing an introduction to devices.

TUTORIAL 25 **Track 14**

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

Benefit and Harm: A Process to Express this Ratio Determined by Consensus-driven Evidence

Continuing Education Credit: CME – 3.25 *AMA PRA Category 1 Credit(s)™;* IACET – .3 CEUs; Nursi

CANCELLED

Clinical Research Certificate Program: 2 Elective Units

Instructors
Lee S. Simon, MD
Consultant
SDG LLC

Maarten Boers, MD, PhD, Msc
Professor of Clinical Epidemiology
University of Amsterdam, Netherlands

The importance of defining the benefits and potential harm of a therapy are well known; however stakeholders perceive the expressed benefit of any therapy differently. This tutorial will address how to measure the understanding of benefit and harm by all stakeholders including patients, and how to develop programs which ensure that all voices are heard. This will encourage a better understanding of how best to measure this information.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Recognize the importance of expressing benefit and harm in a way that is understandable by all stakeholders including patients
- Describe a process to define the benefit and harm of therapeutic interventions

Target Audience

This tutorial is designed for anyone interested in developing drugs for treatment of patients including clinical trialists, pharmacists, and professionals in the field of marketing, regulatory affairs, sales, pharmacovigilance, medical affairs, device makers and developers.

AFTERNOON TUTORIALS, HALF-DAY

1:00 PM-4:30 PM **Fee: $405.00**

TUTORIAL 30 **Track 08**

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

Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in the EU

Continuing Education Credit: IACET – .3 CEUs
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Brenton E. James, FTOPRA
Consultant, Strategic Regulatory Affairs in the European Union, UK

This tutorial will provide an overview of the three regulatory procedures in the European Union — centralized, decentralized, and mutual recognition — including details on the review time to approval and opportunities for sponsor/agencies dialogue from scientific advice to granting the Marketing Authorization. It will discuss which procedure is available for NCE including orphan drugs, OTC, and generic products, and examine the business strategic opportunities for each procedure.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Explain the background of the development of the European Union
- Describe the three regulatory procedures for a marketing application in the European Union for NCE, OTC, and generic products
- Identify the business considerations of translations, co-marketing, co-promotion, patents, and trademarks

Target Audience

This tutorial is designed for attendees with an interest in European regulatory affairs (regulatory affairs staff, clinical research and development managers, and project managers).

TUTORIAL 31 **Track 16**

Related Interest Area(s): All

Leadership: How to Organize and Lead People in Group Work

Continuing Education Credit: IACET – .3 CEUs; PMI – 3.25 PDUs, PMI #: 2166-000127

Project Management Certificate Program: 2 Elective Units

Instructor
Michael Laddin, MBA, MS
CEO
LeaderPoint, LLC

The role of a leader in organizing and leading a group is often misunderstood and, as a consequence, the group may not perform up to expectations, or it may spend a considerable amount of time dealing with dysfunctional group dynamics instead of the work to be accomplished. This tutorial addresses those issues by exploring the types of work groups, how they can be more effective, and how individuals can correct group dynamics and help the group achieve higher levels of performance.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Identify the different types of work group structures and be able to predict the quality of work the group will produce
- Identify and correct dysfunctional group dynamics
- Create and maintain cooperation among team members including cross-functional teams

Target Audience

This tutorial is designed for individuals who must manage group activities on a permanent or project basis, for those who must work on teams but are not in charge of teams and are interested in learning how to exert influence on group behavior, and for individuals to whom project managers report.

TUTORIAL 32 **Track 13**

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

Designing, Operating, and Evaluating Patient Registries

Continuing Education Credit: CME – 3.25 *AMA PRA Category 1 Credit(s)™*; IACET – .3 CEUs; Nursing – 3.25 contact hours; Pharmacy – 3.25 contact hours or .325 CEUs (knowledge) (286-000-12-501-L04-P)

Clinical Research Certificate Program: 2 Elective Units

Regulatory Affairs Certificate Program: 2 Elective Units

Instructors
Richard Gliklich, MD
President and CEO
Outcome

Leanne Larson, MHA
Vice President, Strategic Development
Outcome

In this interactive tutorial, the instructors will discuss practical issues in designing and operating patient registries including: when a registry is an appropriate approach to a requirement or research question; how to design and plan patient registries to address different purposes; operational issues (site recruitment, patient retention, and data management); issues and implications of secondary data use; HIPAA and Common Rule issues; and useful analytic approaches.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Identify key characteristics of patient registries
- Design registries for specific goals
- Apply best practice and enhancement recommendations to create a high-quality registry
- Discuss emerging challenges with registries and how they are being addressed

Target Audience

This tutorial is designed for regulatory affairs professionals, epidemiologists, drug safety professionals, medical affairs professionals, pharmacovigilance and quality management professionals, and clinical affairs professionals.

TUTORIAL 33 **Track 13**

Related Interest Area(s): CEHTAEbM

Understanding Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA) in the Biopharmaceutical Industry

Continuing Education Credit: CME – 3.25 *AMA PRA Category 1 Credit(s)™*; IACET – .3 CEUs; Nursing – 3.25 contact hours; Pharmacy – 3.25 contact hours or .325 CEUs (knowledge) (286-000-12-504-L04-P)

Clinical Research Certificate Program: 2 Elective Units

Instructors
Nancie E. Celini, MPH, DrPH
Chief Learning Consultant
CAB, Inc.

Vadim Tantsyura, MS, MA, DrPH
Director, Data Management
Infinity Pharmaceuticals

Health care reform has amplified interest in Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA). CER/HTA may sound threatening without a realistic context for what it is, how it has evolved, what it is intended to do and its limitations. A brief introduction and overview of Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA) will be presented through lecture, interactive discussions and case study. This tutorial will present a perspective of CER/HTA in the context of clinical trials and health care policy and provide timely insights for today's biopharmaceutical professionals.

This tutorial will provide:

- An introduction to origins of CER/HTA and key terminology and concepts
- Overview of some of the entities with responsibility for CER/HTA
- A brief review of current literature
- Components of CER/HTA using a case study as an example
- Recommended resources for continued learning

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Describe the origins of the models for conducting Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)
- Identify methodological problems and solutions in developing the evidence base and the role of CER/HTA
- Discuss CER/HTA examples applicable to the biopharmaceutical industry

Target Audience

This tutorial is designed for professionals in the biopharmaceutical industry who are interested in gaining practical insights into how CER/HTA evolved, what the literature says about its use in industry, and the basics of how it is performed, as well as its benefits and limitations. This tutorial is ideal for those new to CER/HTA and interested in pursuing further study in this field.

TUTORIAL 34 **Track 08**

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

Fourteen Steps from Research to Development

Continuing Education Credit: CME – 3.25 *AMA PRA Category 1 Credit(s)™*; IACET – .3 CEUs

Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Michael R. Hamrell, PhD, RAC
President
MORIAH Consultants

There are 14 steps from research to development (R to D) and initiation of phase 3 clinical studies; the majority of time committed to drug development occurs during this period. A discussion of the 14 critical steps from R to D will include identifying ways to streamline the process and interactions with FDA. With each of the 14 steps used to develop the optimal strategic plan, discussion will address the resources and various approaches to tailoring the plan to a sponsor's specific product under development and obtaining FDA concurrence with the strategic plan. A smooth progression through the preclinical process into early clinical programs will be presented in this half-day tutorial targeted to familiarize pivotal staff in start-up companies with the required terminology and functions, pharmaceutical/biological companies that have yet to file INDs, and those who want to improve their early development approach.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Identify ways to tailor the development, streamline the process, and interact with FDA
- Explain the specialties and resources needed to develop a product
- Design processes to guide your company smoothly through the progression of research and development

Target Audience

This tutorial is designed for pivotal staff in start-up companies, pharmaceutical/biological companies that have yet to file INDs, and all personnel who want to broaden their knowledge of product development.

FULL-DAY TUTORIALS

9:00 AM-5:00 PM **Fee: $755.00**

TUTORIAL 40 **Track 08**

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

Understanding and Navigating the Regulatory System in China

Continuing Education Credit: IACET – .7 CEUs

Regulatory Affairs Certificate Program: 4 Elective Units

Instructors
Laurence Bin Huang, MS
Regulatory Affairs Director
AstraZeneca Pharmaceutical Co., Ltd., China

Wendy Yan, PharmD
Global Regulatory Strategist
Global Regulatory Affairs, Asia
Bayer Healthcare Co. Ltd.

This tutorial will provide an overview of the regulatory system in China, including the agencies and institutions at the central government and provincial levels, as well as their roles and responsibilities. Various regulations for product registration, clinical trials, and safety reporting will be presented, and the regulatory pathways and strategic considerations for

clinical trial and marketing applications will be discussed. A step-by-step roadmap of how to navigate the regulatory system in China for clinical trial approval and product registration will also be discussed. This discussion will include key points to consider, strategies, and tactics.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Describe the regulatory system in China, including the agencies and institutions and their roles and responsibilities in the regulatory processes for clinical trial and registration approval, as well as safety reporting
- Explain the history and the recent changes in the regulatory system in China and future perspectives
- Describe the regulatory pathways and strategic considerations for successful clinical trial and marketing applications in China
- Discuss how to navigate the regulatory system in China for clinical trial approval and product registration

Target Audience

This tutorial is designed for professionals involved in regulatory affairs, clinical research, pharmacovigilance/drug safety, project management, R&D strategies, and quality assurance and quality control.

TUTORIAL 41 **Track 03**

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

Quality Oversight of CROs - Clinical Vendors

Continuing Education Credit: IACET – .7 CEUs

Clinical Research Certificate Program: 4 Elective Units

Project Management Certificate Program: 4 Elective Units

Instructors

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

NO PHOTO AVAILABLE

Jennifer J. Poulakos, PhD
Director, Clinical Quality Assurance
Astellas

Linda B. Sullivan, MBA
Vice President, Operations
Metrics Champion Consortium

FDA and EMA communicate at industry conferences, FDA-CTTI meetings, and regulatory agency public meetings. Sponsors and CRO-vendors who are transferred the responsibilities for trial conduct must have in place a vendor management-oversight program and methods, as well as a quality management system and risk management framework for the execution of clinical trials. Building upon this framework and benchmarking to ISO-9001: 2008, Quality Management Systems, this tutorial describes Quality Oversight of Vendors, with the focus on quality systems, quality attributes, and performance monitoring.

PANEL DISCUSSION:
Quality Oversight of CROs - Clinical Vendors

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Discuss quality management systems principles and methods in the context of clinical program management and vendor oversight
- Identify two (2) key elements of an internal communication plan for vendor oversight that supports both business and team successes
- Identify two (2) metrics for utilization when outsourcing a clinical trial to a vendor

Target Audience

This tutorial is designed for professionals involved in clinical research, clinical operations, outsourcing, regulatory affairs, quality compliance, project management and commercial-medical affairs. Sponsors, CROs, ACROs, AROs, as well as personnel from the NIH, DoD, and VA will also find this tutorial valuable.

TUTORIAL 42 **Track 08**

Related Interest Area(s): RA, QAQC, PM

Regulatory Affairs for Biologics

Continuing Education Credit: IACET – .7 CEUs; Pharmacy – 6.5 contact hours or .65 CEUs (knowledge) (286-000-12-502-L04-P)

Regulatory Affairs Certificate Program: 4 Elective Units

Instructor

Carol H. Danielson, MS, DrPH
President
Regulatory Advantage

Participants in this tutorial will learn the differences between traditional biologics and biotechnology products, the regulatory needs and requirements for biologics, the unique aspects in the development of specific biologics such as vaccines and gene therapy, and the different ways that CBER and CDER view product development.

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Discuss product jurisdiction and how it affects the review of biologic products
- Identify the unique aspects of biologics and how their development compares to that of small molecules

- Describe the unique CMC compliance reporting aspects of biologics
- Discuss the regulatory mechanisms available to speed biologics development
- Explain the current regulatory, global, and public opinion trends that have the potential to impact biologics

Target Audience
This tutorial is designed for professionals involved in regulatory affairs, quality assurance, and project management.

TUTORIAL 43 **Track 01**
Related Interest Area(s): CR, ST, MW

Clinical Statistics for Nonstatisticians

Continuing Education Credit: CME – 6.5 *AMA PRA Category 1 Credit(s)™*; IACET – .7 CEUs; Pharmacy – 6.5 contact hours or .65 CEUs (knowledge) (286-000-12-503-L04-P)
Clinical Research Certificate Program: 4 Elective Units

Instructor
Michael C. Mosier, PhD
Director, Biostatistics
EMB Statistical Solutions, LLC

This tutorial will introduce basic statistical concepts that are fundamental to clinical research. It is designed for individuals with some exposure to statistics (either through course work or on-the-job experience) that is equivalent to an introductory statistics course. While a few formulae are included for individuals who are interested in computational details, the overall emphasis of the tutorial will be on the application of statistical concepts to clinical investigation.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:

- Discuss basic statistical concepts such as variability, confidence intervals, hypothesis testing, and p-values
- Compare various study designs and identify techniques to avoid bias
- Use statistical terminology with ease
- Distinguish information needed for determining sample size

Target Audience
This tutorial is designed for professionals in the pharmaceutical industry involved in clinical research, medical affairs, medical writing, and other disciplines, who need to be familiar with statistical concepts.

TUTORIAL 44 **Track 04**
Related Interest Area(s): PC, CR, RD

Early-phase Research: Navigating the 21st Century Landscape for Phase 1 Trials

CANCELLED

Continuing Education ...*ategory 1 Credit(s)™*; IACET – .7 CEUs; Nursing – 6.5 contact hours

Instructors
Nancy A. Lass, MD
President and Principal Consultant
NL Specialty Consulting, Inc.

Stacie J. Bell, PhD
Assistant Director, Clinical Pharmacology
Array BioPharma, Inc.

Donna W. Dorozinsky, MSN, RN
President
DWD & Associates

Howard E. Greenberg, MD, MS, MBA
Principal
HEG Associates

This tutorial will provide an overall approach to Phase 1 study operations in three sections. The first section will address the scientific considerations underlying study protocols and key concepts for successful conduct of the study. The second section will provide an overview of regulatory concepts, e.g. Good Clinical Practice, working with IRBs, essential regulatory documents and reporting, and aspects of monitoring and auditing studies, etc. The final section will cover business aspects and site operational management, e.g. site selection and personnel, recruitment, facilities management, budgets and contracts, etc. Opportunities for practical application of concepts will be included.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:

- Describe at least two commonly used Phase 1 study designs including a basic protocol design for each
- Identify at least three essential regulatory documents for Phase 1 clinical studies
- Define at least two examples of high-quality clinical practices for investigators, sponsors and clinical trial protocols
- List at least four site operational processes that are core to the conduct of an early phase study

Target Audience
This tutorial is designed for individuals involved in early phase research at the investigational site, contract research organizations or as sponsors, who are interested in a basic overall understanding of Phase 1 study operations. Topics covered will be relevant for investigators and medical oversight, clinical managers and monitors, project managers, business managers, regulatory affairs managers, quality assurance auditors and other areas of study support.

TUTORIAL 45 Track 08

Related Interest Area(s): RA, CR

Preparing for a US FDA Advisory Committee Meeting

**** ADJOURNS AT 3:45 PM**

Continuing Education Credit: IACET – .5 CEUs
Regulatory Affairs Certificate Program: 4 Core Units

Instructor
Pete Taft
Founder and CEO
Taft and Partners/PharmApprove

What are the critical factors when preparing for an FDA Advisory Committee meeting? Appearing before an FDA Advisory Committee can be one of the most challenging and grueling experiences for any drug, device, or biologic team. In just eight short hours with the FDA Advisory Committee, you not only must thoroughly explain but also defend, in detail, your product in a highly visible, high-stakes public meeting. This course teaches best practices for preparing for an FDA Advisory Committee meeting.

What You Will Learn
- What is an Advisory Committee?
- What does an Advisory Committee look like?
- Critical factors for Advisory Committee preparation
- How to design the most applicable preparation program for your team
- Top ten “Best Practices” and “Must Avoids”

Learning Objectives
At the conclusion of this tutorial, participants should be able to:

- Identify the critical factors in preparing for a successful Advisory Committee meeting
- Recognize and evaluate those factors that are most applicable to your team
- Design the most effective preparation for your team(s)

Target Audience
This tutorial is designed for professionals in regulatory affairs, clinical research leads, and corporate executives.

TUTORIAL 46 Track 02

Related Interest Area(s): PM, BT, MDD

Fundamentals of Project Management for Non-project Managers

**** ADJOURNS at 4:30 PM**

Continuing Education Credit: IACET – .6 CEUs; PMI – 6 PDUs, PMI #: 2166-000132
Clinical Research Certificate Program: 4 Elective Units

Instructor
Joan Knutson, PMP
PM Guru Unlimited

This tutorial will focus on the basic principles of project management, and how they can be applied to best meet the needs of your projects. You will take away a set of project management skills and techniques that can be immediately put to use.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:

- Decide when work effort should be treated as a project
- Use the four-step model to manage projects
- Apply motivational and team-building techniques to gain support and buy-in
- Employ practical leadership and communication skills to ensure coordination and collaboration during the project

Target Audience
This tutorial is designed for biotechnology/pharmaceutical/medical device professionals who are looking to learn more about the project management process and how to apply it to their specific job responsibility.

TUTORIAL 47 **Track 16**

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

Overview of Drug Development

Continuing Education Credit: IACET – .7 CEUs; PMI – 6.5 PDUs, PMI #: 2166-000131
Clinical Research Certificate Program: 4 Core Units
Regulatory Affairs Certificate Program: 4 Elective Units

Instructor
George H. D'Addamio, PhD
President
PharmConsult, Inc.

This tutorial will provide an introduction to the drug development process under FDA and ICH Guidelines, including how various parts of companies fit into the overall process of pharmaceutical development.

What You Will Learn

- How the pharmaceutical industry identifies new products and brings them to market
- Contributions of key groups within the company and how they interact
- FDA and regulation of the industry
- Basics of filing a New Drug Application (NDA)
- Ethical considerations in conducting clinical research
- Concepts and functions associated with ensuring overall study quality

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Recognize the process of discovering and developing new pharmaceutical products
- Describe the activities associated with conducting clinical research and reporting the results and responsibilities of various departments in accomplishing these activities
- Discuss institutional review, informed consent, and financial disclosure
- Explain the concepts and functions associated with ensuring overall quality of studies
- Describe the organization of the FDA, their authority, and interactions with sponsor companies

Target Audience

This tutorial is designed for professionals who work in the following areas: clinical research, project management, administrative support, quality assurance, regulatory affairs, manufacturing, medical writing, and business support.

TUTORIAL 48 **Track 06**

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

Art of Writing a Clinical Overview

Continuing Education Credit: IACET – .7 CEUs
Clinical Research Certificate Program: 4 Core Units
Regulatory Affairs Certificate Program: 4 Elective Units

Instructor
Patricia A. Matone, PhD
President
Scientific Information Services LLC

This tutorial provides an in-depth analysis of the preparation of a Clinical Overview for pharmaceutical products (drugs and biologics) in accordance with ICH guidelines concerning development of Module 2.5 of a Common Technical Document (CTD).

What You Will Learn

- Objectives, structure, and format of the Clinical Overview is explored, with attention given to developing a document suitable for multi-region submissions
- Inclusion and presentation of clinical and nonclinical data, with emphasis on how to effectively use the other technical summaries within the CTD
- Insight is provided on how to prepare a document that successfully communicates the benefits and risks of the investigational product
- How to frame the different sections of the Clinical Overview to best communicate the product's unique attributes
- How to develop the Clinical Overview for other types of submissions

Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Communicate the role of a Clinical Overview (Module 2.5) in a CTD
- Describe the structure and format of a Clinical Overview in accordance with ICH guidelines
- Develop strategies regarding the placement and presentation of information in different sections of the Clinical Overview
- Explain how to effectively cross-reference to other components of the CTD
- Develop a submission-ready Clinical Overview that successfully communicates all available information concerning the benefits and risks of an investigational product
- Recognize how to modify the Clinical Overview for different submission types

Target Audience

This tutorial is designed for clinical research and development professionals, medical writers, and regulatory affairs personnel involved in the preparation or review of Module 2.5 of a CTD.

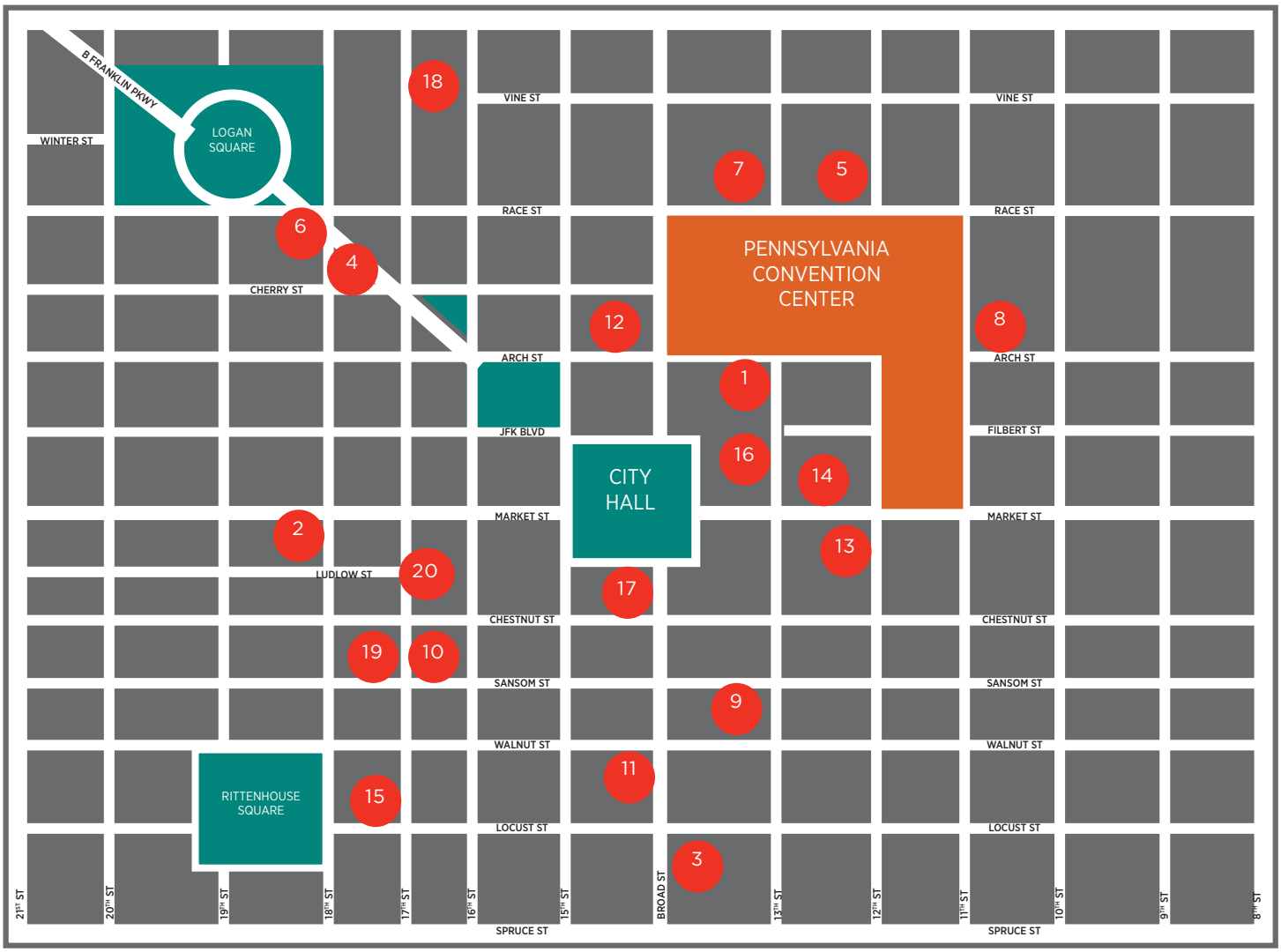
HOTEL LOCATOR MAP

Please Note: Only attendees who book reservations at designated DIA hotels will have access to the DIA courtesy shuttle.

DIA is proud to partner with Travel Planners to offer you the lowest rates available for your conference hotel needs in Philadelphia. Log on to www.diahome.org/dia2012 and click on the hotel information tab to view a complete list of DIA hotels, many of which offer early-bird rates and amenities exclusive to DIA attendees. In order to receive discounted rates and amenities, reservations must be made through Travel Planners and not directly through the hotel. For best availability, please book prior to May 25, 2012. After this date, rooms will be available on a space-available basis.

Online reservation is strongly encouraged, though hotel reservations can also be made by phone:
Monday – Friday, 9:00 AM–7:00 PM
+1.800.221.3531 (US/Canada) or +1.212.532.1660 (International)
dia@tphousing.com

Note: Travel Planners Inc. is the exclusive provider for all DIA 2012 hotel reservations. Please be advised that unauthorized third-party providers may contact you to book your reservations through them. These providers may require non-refundable, fully pre-paid reservations that may be subject to steep cancellation and change fees. If you make a reservation with any provider other than Travel Planners, DIA will not be able to assist you with any problems you may encounter with the terms of a third-party agreement.



HOTEL INFORMATION

DIA 2012 HOTELS	DISTANCE TO CONVENTION CENTER	EARLY-BIRD SINGLE RATE*/ EXPIRES	POST EARLY-BIRD SINGLE ROOM RATE*	SHUTTLE**	AMENITIES
1. Courtyard by Marriott Philadelphia Downtown 21 N. Juniper Street	1 Block	N/A	$216	No	Free Wi-Fi
2. Crowne Plaza Philadelphia Downtown 1800 Market Street	8 Blocks	$172 – 4 night minimum required 3/30/12	$182	Yes	Free Wi-Fi, local calls
3. Doubletree by Hilton Hotel Philadelphia Center City 237 S. Broad Street	8 Blocks	$175 1/31/12	$185	Yes	Free Wi-Fi, local calls, daily drawing for dinner for two
4. Embassy Suites Philadelphia Center City 1776 Ben Franklin Parkway	6 Blocks	N/A	$195	Yes	Free Wi-Fi, full breakfast, evening reception
5. Four Points by Sheraton Center City 1201 Race Street	1 Block	N/A	$179	No	Free Wi-Fi, local calls, complimentary coffee vouchers, daily bottled water
6. Four Seasons Hotel Philadelphia One Logan Square	8 Blocks	$254 3/30/12	$269	Yes	Free Wi-Fi, local calls
7. Hampton Inn Center City 1301 Race Street	1 Block	$166 3/30/12	$169	No	Free W-Fi, local calls, full breakfast, 24-hour coffee and tea
8. Hilton Garden Inn Philadelphia Center City 1100 Arch Street	.5 Block	N/A	$208	No	Free Wi-Fi, daily coffee service, drawing for dinner for two
9. Holiday Inn Express Philadelphia Midtown 1305 Walnut Street	6 Blocks	N/A	$172	Yes	Free Wi-Fi, local calls, continental breakfast
10. Hotel Palomar Philadelphia 117 South 17th Street	8 Blocks	N/A	$224	Yes	Free Wi-Fi for Kimpton In-Touch members, coffee/tea bar, wine hour
11. Hyatt at The Bellevue 200 South Broad Street	8 Blocks	N/A	$245	Yes	Free Wi-Fi, 20% off food and beverage in XIX Café and Restaurant
12. Le Meridien Philadelphia 1421 Arch Street	1 Block	$259 3/30/12	$275	No	Free Wi-Fi, drawing for dinner for two
13. Loews Philadelphia Hotel 1200 Market Street	1 Block	$215 4/6/12	$225	No	Free Wi-Fi, local calls, complimentary coffee vouchers, daily drawing for dinner for two, daily drawing for complimentary spa treatment
14. Philadelphia Marriott Downtown 1201 Market Street	Adjacent	N/A	$239	No	Daily drawing for dinner for two
15. Radisson Plaza-Warwick Hotel Philadelphia 1701 S. Locust Street	11 Blocks	$175 4/14/12	$185	Yes	Free Wi-Fi, local calls, daily bottled water, complimentary coffee vouchers, daily drawing for dinner for two
16. Residence Inn by Marriott Philadelphia Center City 1 East Penn Square	2 Blocks	N/A	$229	No	Free Wi-Fi, local calls, complimentary continental breakfast
17. Ritz-Carlton Philadelphia 10 Avenue of the Arts	4 Blocks	N/A	$254	Yes	Free Wi-Fi, local calls, shoe shine
18. Sheraton Philadelphia Downtown 201 North 17th Street	4 Blocks	$183 – 4 night minimum required 3/30/12	$193	Yes	Free Wi-Fi, complimentary coffee vouchers, daily drawing for dinner for two
19. Sofitel Philadelphia 120 South 17th Street	9 Blocks	$215 4/11/12	$219	Yes	Free Wi-Fi
20. Westin Philadelphia 99 South 17th Street	6 Blocks	$259 6/1/12	$269	Yes	Free Wi-Fi, local calls, daily drawing for dinner for two, daily drawing for two-night complimentary stay

* Hotel rates do not include 15.2% tax.

**Shuttle service will be provided in the morning and end of day to guests staying at designated DIA hotels. Mid-day service will not be available.

DIA 2012 ATTENDEE REGISTRATION FORM

48th Annual Meeting | June 24 - 28, 2012 | Pennsylvania Convention Center, Philadelphia, PA | Event #12001

www.diahome.org

Attendees may register online at **www.diahome.org/dia2012**.

*Online registration is **NOT** available to speakers or exhibitors.* All registrations received at the DIA office in Horsham, PA, USA **by 5:00 PM EST on May 18, 2012** will be included in the Advance Registration Attendee List.

FULL-MEETING REGISTRATION (attendance of 2 or more days) includes admission to all sessions, exhibits, coffee breaks, luncheons and receptions. **If DIA cannot verify your membership, you will be charged the nonmember fee. All fees are in US dollars.**

All MEMBER and NONMEMBER fees below include access to all available postmeeting audio synchronized Power Point presentations.

PRECONFERENCE PROGRAM/TUTORIALS

Visit **www.diahome.org/dia2012/tutorials** for topics and fees. Space is limited and preregistration is encouraged. Please indicate the tutorial # and fee.

Tutorial # _____ Fee _____
Tutorial # _____ Fee _____ Subtotal _____

MEMBER STANDARD

(AVAILABLE ON NONDISCOUNT MEMBER STANDARD FEE ONLY)

• **MEMBERS registering after FEB. 29, 2012** **US $1350** ❑

NONMEMBER STANDARD

US $1490 ❑

Nonmember fee **includes** a one-year membership option.
Please indicate your preference below.

❑ I **DO** want DIA membership ❑ I **DO NOT** want DIA membership

Join DIA now to qualify for all the benefits of membership for one year!

DISCOUNT FEES

	Member	Nonmember
Government (full-time)*	US $480 ❑	US $620 ❑
Charitable Nonprofit/Academia (full-time)	US $875 ❑	US $1,015 ❑

If paying a nonmember fee, please check preferred membership option above.

**Government rate is subject to eligibility requirements. Identification and proof of eligibility will be required on site. Failure to provide proof of eligibility/ID upon request will require paying the higher standard registration fee.*

ONE-DAY REGISTRATION FEES

	Member	Nonmember
You must indicate which day you plan to attend.	US $825 ❑	US $965 ❑

❑ **MON,** June 25 ❑ **TUES,** June 26 ❑ **WED,** June 27 ❑ **THUR,** June 28

One-day attendees will receive access to post-meeting presentations for that day ONLY.

*** If paying a nonmember fee, please indicate your membership preference above.*

TOTAL PAYMENT DUE

Include all applicable fees **US $** _____

A **student** rate of $250 is available. Contact Donna.Mayer@diahome.org for eligibility requirements and a student rate application form. Also available is an **Executive Program: Pioneering Partnerships.** Contact Melissa.Matta@diahome.org for more information and a registration form.

PAYMENT OPTIONS: Register online at www.diahome.org/dia2012 or by:

❑ **CREDIT CARD** Complete this form and fax to +1.215.442.6199 or mail to: **Drug Information Association, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595,** USA. Non-U.S. credit card payment is subject to the currency conversion rate at the time of the charge.

❑ Visa ❑ MC ❑ AMEX Exp Date _____

Card # _____

Name (printed) _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: **Drug Information Association Inc., P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA**. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** Upon completion of your registration, DIA will send an email to the address on the form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name, company, and Event I.D. #11001 must be included on the transfer document to ensure payment to your account.

Last Name First Name M.I.

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Position

Company

Mailing Address *(as required for postal delivery to your location)*

Mail Stop

City State

Zip/Postal Code Country

email Address **(required for confirmation)**

Telephone Number Fax Number **(required for confirmation)**

CANCELLATION POLICY

All cancellations must be received in writing at DIA's office by 5:00 PM, June 8, 2012.

If you do not cancel by June 8, 2012 and do not attend, you are responsible for the full applicable fee. **Registrants are responsible for cancelling their airline and hotel reservations.** You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. **Substitute registrants will be responsible for the nonmember fee, if applicable. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.** Speakers and program agenda are subject to change.

Refunds for cancellations received in writing ON OR BEFORE JUNE 8, 2012 will be:

- **Full Meeting**
  Government/Nonprofit/Academia:
  Refund Amount = Registration fee paid minus $100
  All Others: Refund Amount = Registration fee paid minus $200
- **Preconference Program/Tutorials –** Refund Amount = Registration fee paid minus $75
- **One-day Registration –** NO REFUNDS
- Cancelling any portion of your program registration will void any multiple purchase discounts that may have been applied.

Participants with Disabilities:
DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

Photography Policy:
By attending the DIA 2012 Annual Meeting you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by the DIA in promotional materials, publications, and website and waive any and all rights including, but not limited to compensation or ownership.

DIA 2012 48th Annual Meeting | June 24-28, 2012
PA Convention Center, Philadelphia, PA | Event #12001

www.diahome.org

Already Registered? ADD A PRECONFERENCE PROGRAM/TUTORIAL to Your Existing Registration

This registration form should be used by attendees, speakers, program committee members, or exhibitors who wish to add a Preconference Program /Tutorial to an existing registration. *This form must be completed and submitted for EACH preregistered person who wishes to add* a Preconference Program /Tutorial *to their existing registration.*

Please fax this completed form to +1.215.442.6199

❑ **YES**, I am registered for DIA 2012 and I would like to add the following preconference program/tutorial to my registration.

I am registered as:

- ❑ Attendee
- ❑ Speaker
- ❑ Session, Forum, Symposium, or Workshop Chair
- ❑ Exhibitor (Full Meeting or Booth Personnel)
- ❑ Program Committee Member

TUTORIALS

Visit www.diahome.org/dia2012/tutorials for topics and fees,
Space is limited and preregistration is encouraged.
Please indicate the ID # and fee for tutorials you plan to attend.

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____

Subtotal US $ _____

PRECONFERENCE PROGRAMS

SAFE BioP CANCELLED ❑
"Trusted Id
APCR
"Win-Win Strategies for the Sponsor-Investigator Relationship" **US $399** ❑

TOTAL PAYMENT DUE

Include all applicable fees US $ _____

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If you do not cancel by JUNE 8, 2012 and do not attend, you are responsible for the full applicable fee. **Registrants are responsible for cancelling their airline and hotel reservations.** You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. **Substitute registrants will be responsible for the nonmember fee, if applicable. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.** Speakers and program agenda are subject to change.

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- **Full Meeting**
  Government/Nonprofit/Academia:
  Refund Amount = Registration fee paid minus $100
  All Others: Refund Amount = Registration fee paid minus $200
- **Preconference Program/Tutorial –** Refund Amount = Registration fee paid minus $75
- **One-day Registration –** NO REFUNDS
- Cancelling any portion of your program registration will void any multiple purchase discounts that may have been applied.

DIA 2012 EXHIBIT PERSONNEL REGISTRATION FORM

Online registration is ***NOT*** available to exhibit personnel.

www.diahome.org

If registering for tutorials and paying by credit card, return this completed form to DIA by fax to +1.215.442.6199 or by mail to 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA. If paying by check, follow instructions under Payment Methods below.

All registrations received at the DIA office in Horsham, PA, USA by 5:00 pm on May 18, 2012 will be included in the Advance Registration Attendee List.

DIA 2012
48TH Annual Meeting
Pennsylvania Convention Center, Philadelphia, PA
ID # 12001
June 24 - 28, 2012
Completed form should be faxed to
+1.215.442.6199

Each 10' x 10' booth includes: **one (1) complimentary full-meeting registration and three (3) exhibit booth personnel registrations.**

Please fill out a separate form for each exhibitor registrant.

To expedite your registration, please check the appropriate category:

❑ **Complimentary Full-meeting Registration** ❑ **Exhibit Booth Personnel**

Once you have utilized the four (4) badges provided per each 10' x 10' booth, any additional personnel must register as an attendee (*NOT* as an exhibitor).

Log on to www.diahome.org and download the ATTENDEE Registration Form, complete and return it as per the instructions on the form.

Please Note:
This page must be completed and submitted for each person attending any portion of this event.

FULL MEETING REGISTRATION (attendance of 2 or more days) includes admission to all sessions, exhibits, coffee breaks, luncheons and receptions.

TUTORIALS
Visit **www.diahome.org/dia2012/tutorials** for topics and fees. Space is limited and preregistration is encouraged. Please indicate the ID #12001 and fee for tutorials you plan to attend.

Tutorial # _____ Fee _____
Tutorial # _____ Fee _____ Subtotal _____

Join DIA now to qualify for all the benefits of membership for one year! **www.diahome.org** **US $175** ❑

**To qualify for the early-bird discount, registration form and accompanying payment must be received by the applicable date above.*

TOTAL PAYMENT DUE
Include all applicable fees **US $** _____

A STUDENT rate of $250 is available. Contact Donna.Mayer@diahome.org for eligibility requirements and a student rate application form.

CANCELLATION POLICY

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Refunds for cancellations received in writing ON OR BEFORE JUNE 8, 2012:

• **Tutorial –** Refund Amount = Registration fee paid minus $75

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PAYMENT IS REQUIRED *ONLY* IF REGISTERING FOR TUTORIALS.
Please check payment method below:

❑ **CREDIT CARD** Complete this form and fax to +1.215.442.6199 or mail to: **Drug Information Association**, **800 Enterprise Road, Suite 200, Horsham, PA 19044-3595,** USA. Non-U.S. credit card payment is subject to the currency conversion rate at the time of the charge.

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Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Position

Company

Mailing Address *(as required for postal delivery to your location)*

Mail Stop

City State

Zip/Postal Code Country

email Address **(required for confirmation)**

Telephone Number Fax Number **(required for confirmation)**

NOTES

DIA

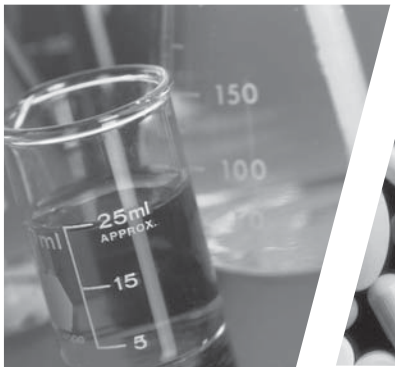
Certificate Programs

Your Professional Development Pathway

DIA Certificate Programs offer a certificate of completion to a learner after completing the requirements for a specific program. Benefits include:

- Many courses offer Continuing Education Credits
- Highly interactive program engages participants while remaining convenient for the working professional
- Expert instructors will teach you the necessary skills to excel in the real world
- Complete the program at your own pace
- Enrollment in our certificate program is FREE! Fees for each course vary based on length

For more information go to **www.diahome.org/certificateprograms**



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Your FDA submission documents are serious. So are their translations.

When translating documents for FDA submission such as dossiers, CRFs, labeling, adverse event reports, and product information, Corporate Translations understands the critical need for accuracy Our rigorous translation process includes multiple quality inspections, guaranteeing the most accurate translations quickly and cost-effectively. We stand by the quality of our translations by providing a certification of accuracy with each document. Partnering with Corporate Translations allows you to prepare your submissions with confidence. That's why Corporate Translations is the preferred supplier of ISO 9001 translation and linguistic validation solutions to the world's leading life science companies.

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CORPORATE TRANSLATIONS

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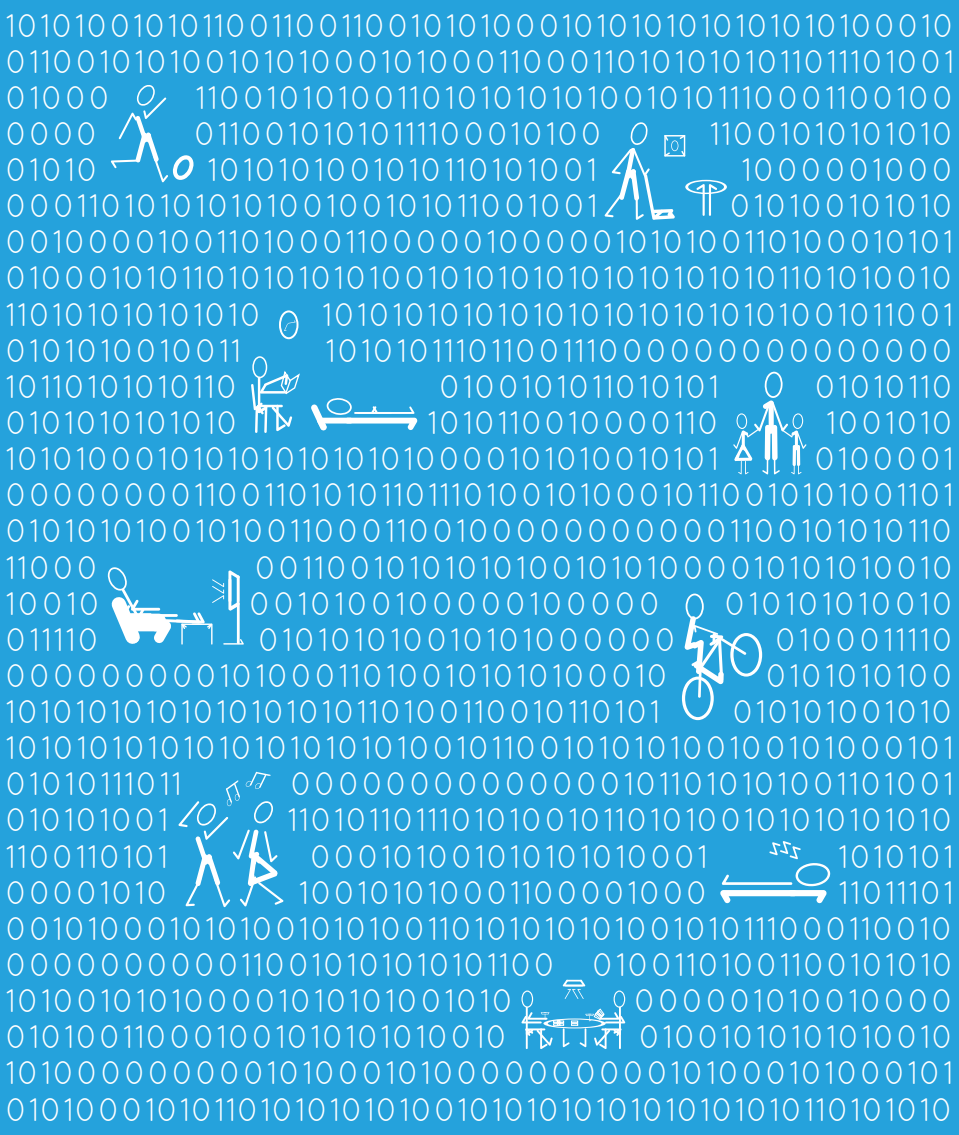

Our easy-to-use electronic clinical outcome assessment (eCOA) solutions promote a positive patient experience, enabling us to consistently generate industry leading compliance rates.[2] Talk to us today to learn more.

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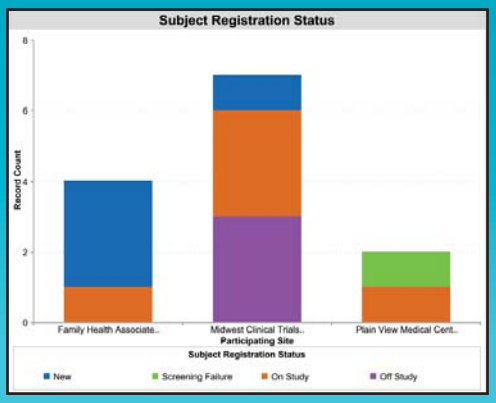

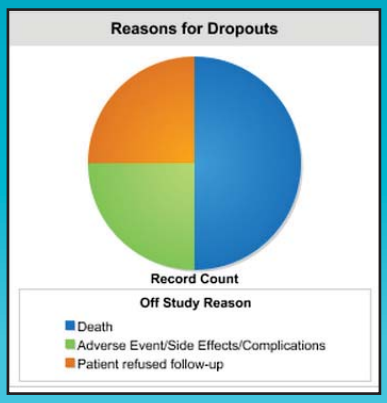

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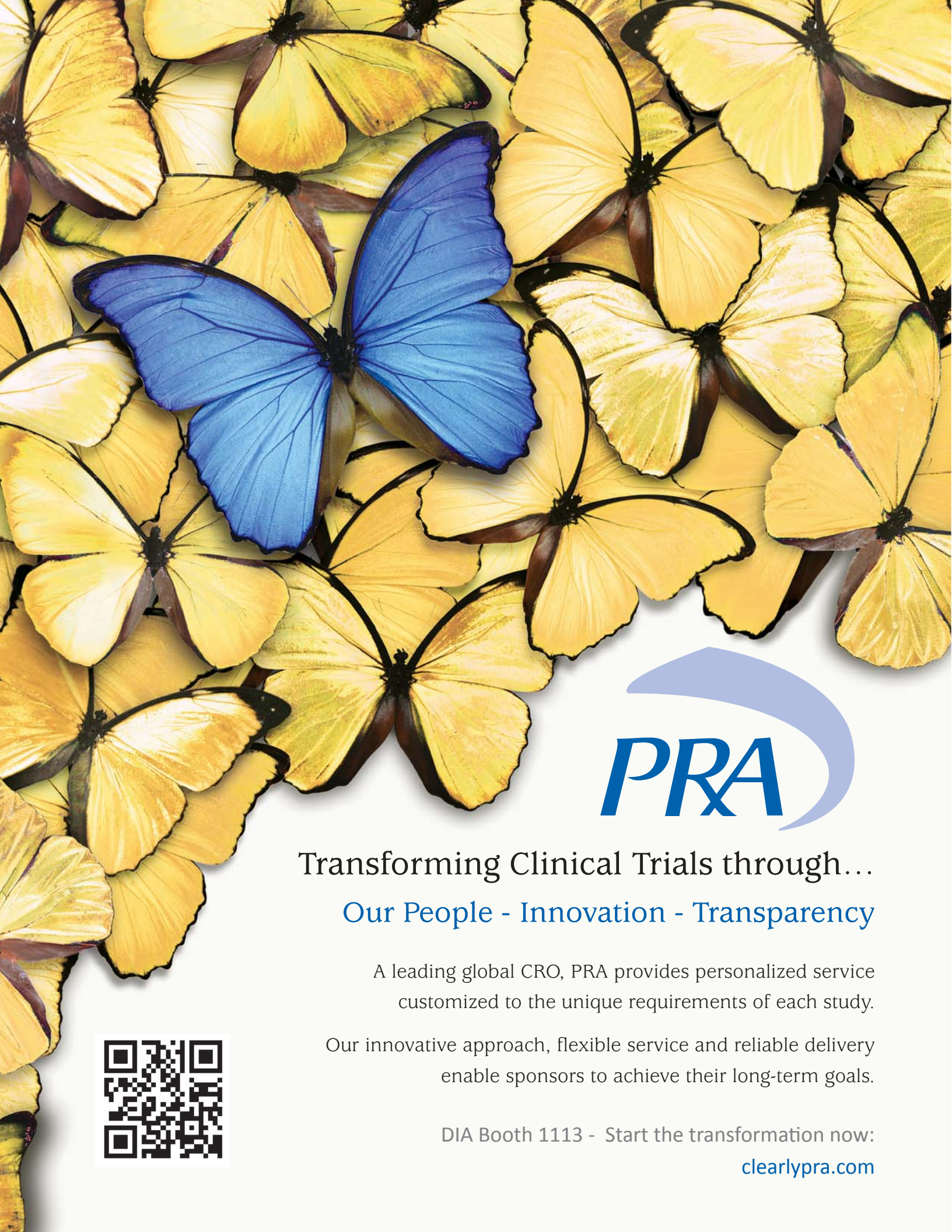
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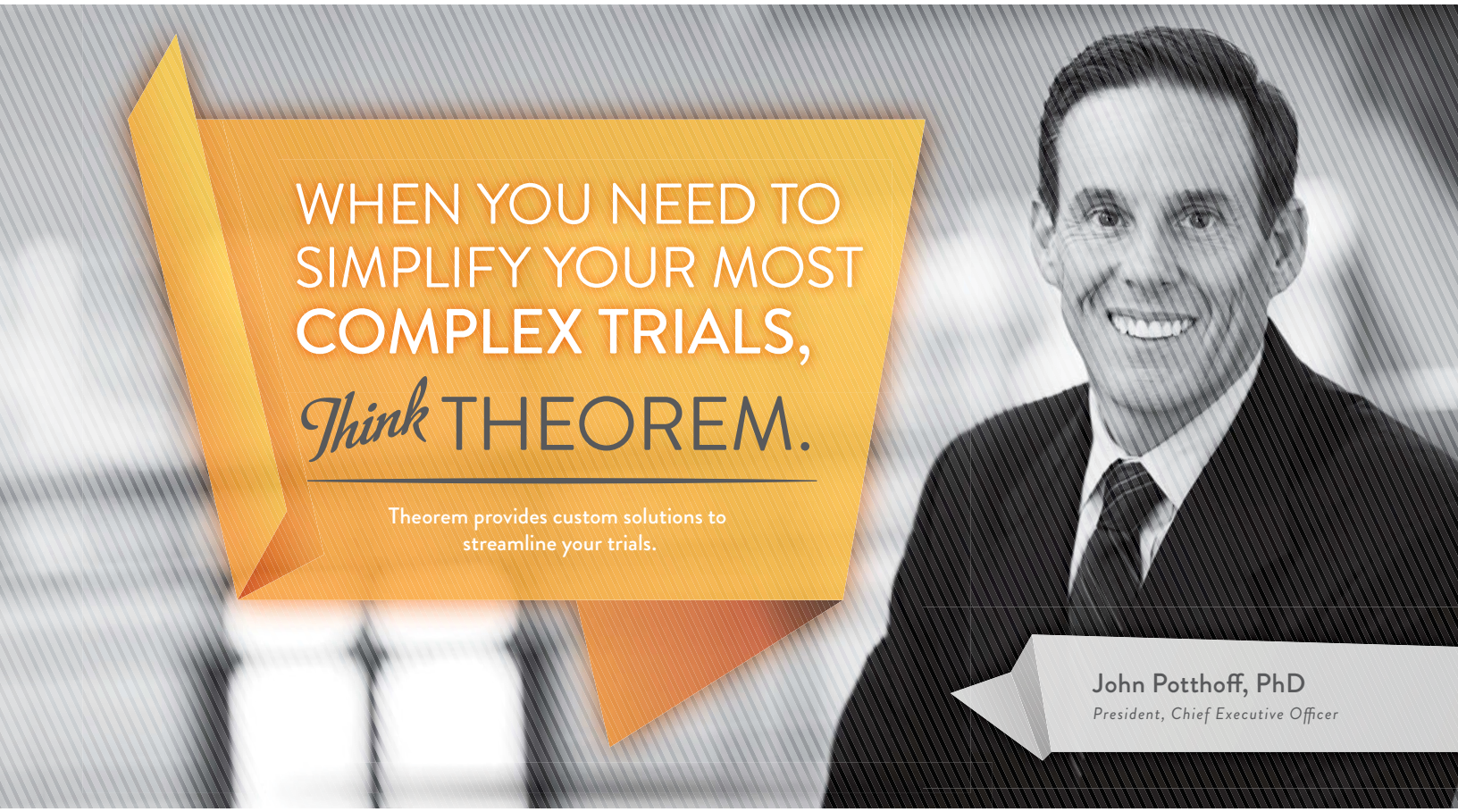

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