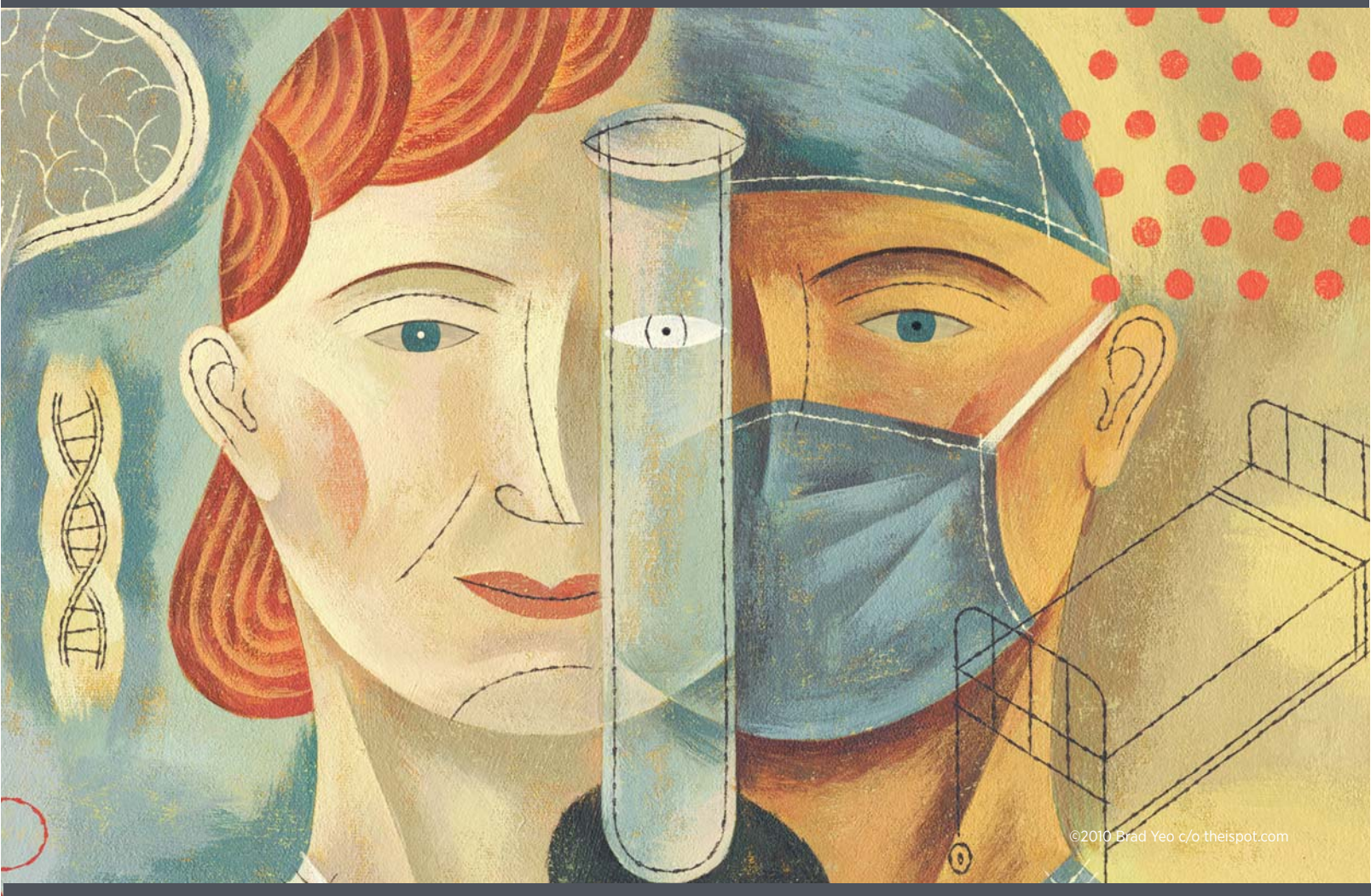
FINAL PROGRAM

DIA 2011

Convergence of Science, Medicine, and Health

www.diahome.org

47th Annual Meeting | June 19-23, 2011
Chicago, IL | McCormick Place West



Follow @DrugInfoAssn on Twitter and use #DIA2011.

WELCOME TO CHICAGO

CHAIRPERSON'S MESSAGE

KENNETH A. GETZ, MBA

Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

Welcome to DIA 2011 in Chicago!

This year's annual meeting celebrates and explores the theme of "Convergence": The convergence of science, medicine, and health; of scientific and operating functions and technology solutions; of internal and contract service personnel; of research professionals, health care providers, patients and the public. As we transition through a very turbulent period, convergence is the essence of successful pharmaceutical innovation as we enter a new era of open and integrated R&D.

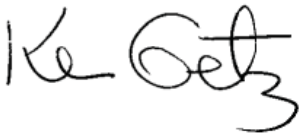
Through networking opportunities and rich educational programs, DIA 2011 holds great promise in facilitating a deeper understanding of the many facets and ongoing impact of convergence. We've made numerous changes to this year's event to reinforce our theme. We've consolidated tracks and combined topics that were historically separated, incorporated recent and emerging developments, encouraged study volunteer and public perspectives throughout the event, and added new programming.

Ultimately, convergence is about mutual respect, working together, and being open to new ideas and learning from each other. To that end, DIA 2011 is an excellent opportunity to meet with people from all over the world, share your views and knowledge, network, collaborate, and build new relationships.

Speakers representing a wide range of stakeholder groups from around the world — from industry, government, academia, associations, foundations, and patient organizations — will lead tutorials, sessions, forums, workshops, and symposia on all topics related to the discovery, development, and life cycle management of traditional pharmaceuticals, biopharmaceuticals, medical devices, and other health interventions. The event also brings together attendees and exhibitors from an equally wide variety of international stakeholder groups.

Thank you to the many people who poured their hearts and ideas into this year's event. DIA 2011 would not have been possible without the hard work and dedication from the DIA staff and my outstanding program committee.

I am looking forward to our paths converging at DIA 2011. I wish you all an enjoyable and productive meeting.



GOVERNOR'S MESSAGE

Greetings!

As Governor of the State of Illinois, I am pleased to welcome everyone gathered for DIA 2011.

I commend DIA and your members for your dedication to promote continuously improved professional practice in your field. I hope that this event provides everyone in attendance with ample opportunities to connect and network with others in your industry and share valuable ideas and information. I am certain that this year's meeting will serve to further your organization's goal of providing a forum for the exchange of knowledge that fosters innovation to raise the level of health and well-being worldwide.

I would also like to offer a special welcome to those traveling from outside of Illinois for this event. During your stay, I encourage you to explore and discover the many sites and attractions that this great state has to offer. From historic landmarks and world-renowned museums, to first-class dining and theater experiences, to the scenic beauty of our small towns and prairies, there is truly a wide array of interests represented across the Land of Lincoln.

On behalf of the people of Illinois, I offer my best wishes for an enjoyable and productive convention.

Governor, State of Illinois

INSIDE

FEATURES

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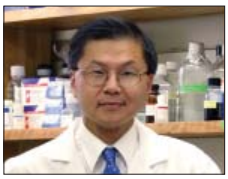


Keynote Speaker

Dr. David D. Ho,
Founding Scientific Director and Chief Executive Officer, Aaron Diamond AIDS Research Center; Irene Diamond Professor, Rockefeller University

4

Plenary Sessions

Expert speakers discuss the areas of health care reform, comparative effectiveness, clinical outsourcing, and social media

6

New Experiences

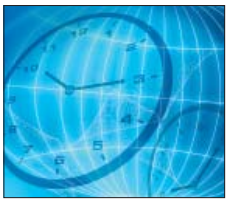
Learn about standards-based IT solutions and join the conversation about the patient's role in medical product development

8

Networking Opportunities

Participate in a variety of networking opportunities with more than 8,000 professional colleagues

18



Meeting Schedule

Plan your schedule and make the most of your DIA 2011 experience

Get timely announcements and updates. Follow @DrugInfoAssn on Twitter using #DIA2011.

WHAT'S HAPPENING

SCHEDULE AT-A-GLANCE

Saturday, June 18

Registration Hours:

9:00 AM – 5:00 PM	Exhibitor Registration

Sunday, June 19

Registration Hours:

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

Schedule:

8:30 AM – 12:00 PM	Half-day Preconference Tutorials*
8:30 AM – 5:00 PM	Training Courses
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 20

Registration Hours:

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

Schedule:

7:15 - 8:15 AM	Orientation/Networking and Coffee for DIA 2011 First Timers
7:30 – 8:15 AM	Coffee and Breakfast Breads
8:30 – 10:00 AM	Opening Plenary Session
9:00 AM – 6:30 PM	Exhibition Hall Open
9:00 AM – 6:30 PM	HIMSS Interoperability Showcase℠
10:00 – 10:30 AM	Coffee Break
10:00 – 10:30 AM	Orientation and Coffee for DIA 2011 First Timers
10:00 AM – 6:30 PM	Student Poster Session
10:30 AM – 12:00 PM	Concurrent Educational Opportunities
12:00 – 1:30 PM	Lunch with Optional Networking Lunch Area
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

Tuesday, June 21

Registration Hours:

7:00 AM - 5:30 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 – 4:30 PM	Exhibition Hall Open
9:00 AM – 4:30 PM	HIMSS Interoperability Showcase℠
9:30 – 10:00 AM	Coffee Break
10:00 – 11:30 AM	Concurrent Educational Opportunities
11:30 AM – 1:30 PM	Extended Lunch with Optional Networking Lunch Area
11:30 AM – 1:30 PM	Professional Poster Session
1:30 – 3:00 PM	Concurrent Educational Opportunities
3:00 – 3:30 PM	Refreshment Break
3:00 – 4:30 PM	Exhibit Guest Passes
3:30 – 4:30 PM	Concurrent Educational Opportunities
4:45 – 5:45 PM	Interoperability Town Hall

Wednesday, June 22

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 AM – 4:00 PM	Exhibition Hall Open
9:00 AM – 4:00 PM	HIMSS Interoperability Showcase℠
9:30 – 10:00 AM	Coffee Break
10:00 – 11:30 AM	Concurrent Educational Opportunities
11:30 AM – 1:30 PM	Extended Lunch with Optional Networking Lunch Area
11:30 AM – 1:30 PM	Professional Poster Session
1:30 – 3:00 PM	Concurrent Educational Opportunities
3:00 – 3:30 PM	Refreshment Break
3:30 – 5:00 PM	Concurrent Educational Opportunities

Thursday, June 23

Registration Hours:

7:30 - 10:45 AM	Speaker Registration
8:00 - 10:45 AM	Attendee 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 AM – 12:15 PM	Concurrent Educational Opportunities

**Space is limited for preconference tutorials. Availability for onsite registration is not guaranteed.*

DIA 2011 TRACKS

DIA 2011 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 event will help you develop a holistic and integrated program for your entire team while increasing their access to training and expanded professional opportunities.

2010	2011
Clinical Research/Clinical Supplies Project Management Academic Health Centers/Investigative Sites	**Track 1: Clinical Operations**
Clinical Research Development Finance	**Track 2: Development Planning**
Outsourcing	**Track 3: Outsourcing Strategies and Innovative Partnering Models**
Biotechnology Nonclinical	**Track 4: Nonclinical and Early Clinical Translational Development** **New Area: Clinical Pharmacology**
Advertising Marketing	**Track 5: Product Advertising and Communications**
Medical Communications Medical Writing	**Track 6: Medical Writing and Communications**
Information Technology eClinical Validation	**Track 7: IT Methods and Technologies**
Clinical Data Management Document Management	**Track 8: Research Data and Content Management** **New Area: Study Endpoints**
Regulatory Affairs Chemistry, Manufacturing, Controls and Good Manufacturing Practices Good Clinical Practices e-Submissions	**Track 9: Regulatory Affairs and Science, Quality and GXP Compliance**
Public Policy/Law/Corporate Compliance	**Track 10: Public Policy/Health Care Compliance**
Clinical Safety and Pharmacovigilance	**Track 11: Clinical Safety and Pharmacovigilance**
Statistics	**Track 12: Statistics**
Health Economics and Outcomes	**Track 13: Health Economics and Outcomes (HEO)/ Comparative Effectiveness Research (CER)/ Health Technology Assessment (HTA)**
Medical Devices	**Track 14: Medical Devices New Track!**
Professional Development and Training	**Track 15: Professional Development** **New Area: Career/Professional Development** **New Area: Profession-related Learning and/or Teaching**
	Track 16: Global Agency New Track!
	Track 17: SIAC Showcase New Track!
	Track 18: Late-breaking Topics New Track!

NEW 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.

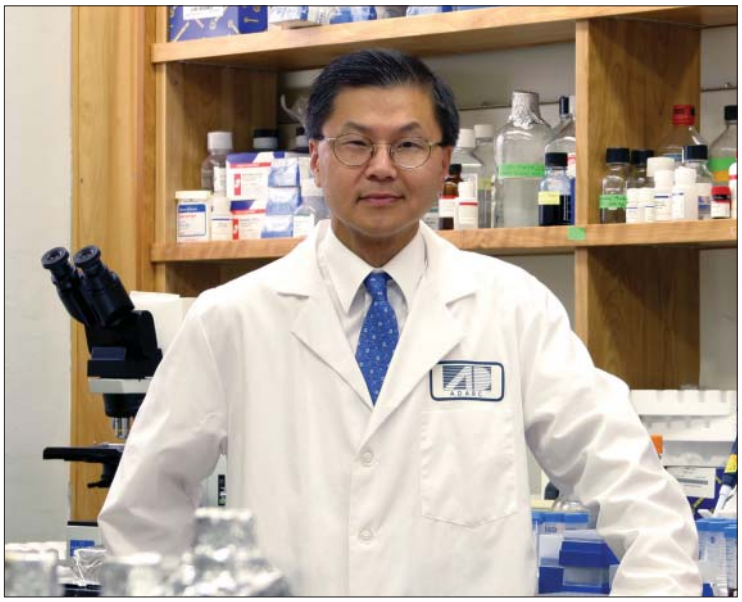
SYMPOSIUM: A 90-minute offering consisting of several shorter presentations such as case studies and presentations from multiple perspectives.

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.

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

MONDAY PLENARY SESSION

Keynote Speaker — Monday, June 20, 8:30 - 10:00 AM | Room: W375cde



DAVID D. HO, MD

Founding Scientific Director and Chief Executive Officer,
Aaron Diamond AIDS Research Center;
Irene Diamond Professor, Rockefeller University

Dr. David Ho has been at the forefront of AIDS research for 29 years. His elegant studies, beginning in 1994, unveiled the dynamic nature of HIV replication in vivo and revolutionized our basic understanding of this horrific disease. He has been the driving force behind a massive international effort to bring life-saving AIDS treatments to millions of patients in developing nations. Dr. Ho is now leading a consortium of Chinese and American organizations to help address the crisis of HIV/AIDS in China. Dr. Ho was named *Time Magazine*'s Man of the Year in 1996 and received the Presidential Medal in 2001. He is a member of the American Academy of Arts and Sciences, Academia Sinica (Republic of China), Chinese Academy of Engineering, and the Institute of Medicine, National Academy of Science in the United States. Dr. Ho was inducted into the California Hall of Fame in 2006.

TUESDAY PLENARY SESSION

Voice of the Patient: Stories That Touch Us — Tuesday, June 21, 8:00 - 9:30 AM | Room: W375b

Chair:
Diane Simmons

Center for Information and Study on Clinical Research Participation (CISCRP)

Join a panel of patients whose profound decision to participate in a clinical trial benefited public health and advanced medical knowledge, regardless of whether their investigational treatment proved safe and effective or harmful and ineffective. Each of these volunteers gave the "gift of participation" in clinical research and we recognize them as Medical Heroes.

See page 49 for additional details on speakers.

WEDNESDAY PLENARY SESSION

Rethinking Pharmaceutical Development: The Impact of Health Reform

Wednesday, June 22, 8:00 - 9:30 AM
Room: W375b

Two prominent experts will share their insights and perspectives on how health care reform will impact the biopharmaceutical industry. Our speakers will discuss the key components of reform and how they may reshape the landscape of drug development and the delivery of therapeutics in the future. Submit your questions in advance to **annualmeetingprogram@diahome.org** Subject: Impact of Health Reform Session

Chair:
Nancie E. Celini, MPH, DrPH(c)
CAB Inc.

Featured Speaker:
David B. Nash, MD, MBA
Jefferson School of Population Health, Thomas Jefferson University

Featured Speaker:
Gail R. Wilensky, PhD, MA
Project HOPE

SPECIAL SESSIONS

Comparative Effectiveness Research and Health Technology Assessment: How National Agencies Are Addressing the Challenge

Monday, June 20, 3:30 - 5:00 PM
Room: W183c

This session will discuss the work of government-funded agencies in the implementation of comparative effectiveness research (CER) and how these efforts might affect the development and life cycle management of biopharmaceuticals and medical devices.

Chair:
Joshua S. Benner, DrSc, PharmD
Engleberg Center for Health Care Reform, The Brookings Institution

Kalipso Chalkidou, MD, PhD
NICE International, UK

Michael S. Lauer, MD, FACC
Divisions of Cardiovascular Sciences, NHLBI, NIH

Freda Lewis-Hall, MD
Pfizer Inc.

Steve E. Phurrough, MD, MPA
Center For Medical Technology Policy

A Close Look at Clinical Outsourcing Strategies: An Executive Roundtable

Wednesday, June 22, 1:30 - 3:00 PM
Room: W178ab

Executives from three companies will discuss clinical outsourcing strategies, the rationale and the circumstances that led to the creation of these strategies, and how they expect these approaches to evolve over the next five years.

Chair:
Patricia Leuchten
The Avoca Group Inc.

Peter A. Carberry, MD, MBA
Astellas Pharma Global Development, Inc.

Craig Coffman
Endo Pharmaceuticals

Mitchell A. Katz, PhD
Purdue Pharma L.P.

The Problems and Promise of Using Social Media to Improve Patient Care

Wednesday, June 22, 1:30 - 3:00 PM
Room: W375b

Regulatory and marketing experts will detail the regulatory challenges and marketing opportunities facing the use of digital and social media by drug, device, and biologic companies for product promotion and education.

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

Sharon Callahan
The Vue Group & LLNS

Stuart P. Ingis, JD
Venable LLP

Mike Myers, MBA
Palio, an inVentiv Health Company

Christopher M. Schroeder
HealthCentral

DIA 2011 FEATURES GLOBAL AGENCY TRACK 16

This new track provides you with a unique opportunity to have your questions answered by global and regional regulatory agencies.

Monday, June 20

#122 Annual CDER eSubmission Update: Review and Technical Perspectives (Room: W186abc)
#123 European Heads of Medicines Agencies (HMA) Town Hall (Room: W183c)
#145 European Medicines Agency (EMA) Town Hall (Room: W186abc)
#146 FDA Discussion on Biosimilar Legislation and Implementation (Room: W187abc)
#167 Future Directions: Submitting Promotional Material to CDER FDA in eCTD Format (Room: W186abc)
#168 Update From the Therapeutic Goods Administration (TGA) (Room: W185d)

Tuesday, June 21

#254 Regulatory Update from the Office of New Drug Quality Assessment, Office of Biotechnology Products, Office of Generic Drugs, Office of Compliance, and Office of Regulatory Affairs (Room: W187abc)
#255 India Regulatory Agency Town Hall (Room: W186abc)

Wednesday, June 22

#334 The Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall (Room: W187abc)
#335 Working for Harmonization on Regulations for Clinical Trials in Latin America (Room: W185d)
#362 The State of Electronic Submissions at CDER, CBER, and CDRH (Room: W187abc)
#363 APEC (Asia-Pacific Economic Cooperation) Town Hall (Room: W185d)
#387 Regulatory Updates from Canada Including Special Projects (Room: W185d)
#388 CBER Town Hall (Room: W185a)

Thursday, June 23

#415 CDER Town Hall: Part 1 (Room: W187abc)
#428 CDER Town Hall: Part 2 (Room: W187abc)

HIMSS INTEROPERABILITY SHOWCASE℠

DIA is proud to partner with HIMSS, CDISC, IHE International and IHE USA for our first interoperability showcase of standards-based IT solutions to improve health data information exchange between systems, providers and organizations to optimize clinical care and research.

LOCATION: Exhibit Hall
SHOWCASE HOURS: Monday, June 20, 9:00 AM - 6:30 PM
Tuesday, June 21, 9:00 AM - 4:30 PM
Wednesday, June 22, 9:00 AM - 4:00 PM

Tour the Interoperability Showcase Demonstration Area

Tours feature two use cases: a regulated clinical study and a device safety reporting case that will be used to demonstrate the exchange among EHR vendors, EDC vendors, Integration Services and Regulators. *Tours are free!*

Each tour begins on the half hour.

Showcase Theater Perspectives

Complementary theater perspectives are available during Showcase hours and feature topics such as:

- Europe's EHR4CR Project
- European Regulatory Perspective
- US Regulatory Perspective
- Tennessee's HIE
- HL7 Perspective
- CDISC Perspective

Times may vary. Visit the showcase area for detailed schedule.

CONFIRMED SUPPORTERS AND PARTICIPANTS AS OF MAY 18:

PATIENT FELLOWSHIP PROGRAM

For the first time, DIA announces a special Patient Fellowship Program to enhance the participation of patient group representatives at DIA 2011 and to develop, strengthen, and support their collaborations with policy makers, health professionals, industry representatives, and academia. The goal of the program is to:

- Increase the knowledge and understanding of patient groups, government, and industry about key issues central to the promotion of patient-centered health care
- Develop the capacity of patient groups to advocate for change
- Improve alliances between patient groups and other health care stakeholders
- Stimulate cooperation, promote dialogue, and share best practices

Fifteen patient organizations were selected to attend the DIA 2011 program as part of the Patient Fellowship Program.

To join the conversation about the patient perspective, visit our new LinkedIn sub-group and be sure to stop by the Patient Fellowship Booth # 1317, located near the DIA Information Booth.

PARTICIPATING ORGANIZATIONS:

AGS Alliance
American Kidney Fund
American Autoimmune Related Diseases Association, Inc.
aafa Asthma and Allergy Foundation of America
Caring Ambassadors
ippf
MGFA Myasthenia Gravis Foundation of America, Inc.
National Alopecia Areata Foundation
Pancreatic Cancer Action Network®
Spinal Muscular Atrophy Foundation
Susan G. Komen for the Cure®
Parkinson's Disease Foundation
Uniting Against Lung Cancer
Women's Heart Foundation

NEW! DIA 2011 RESOURCE CENTER

Participate in hands-on demonstrations of all DIA online educational and networking opportunities including eLearning modules, online training courses, live and on-demand (archived) webinars, DIA ConneX, and other DIA online products and services. A schedule of demonstrations can be found in the *Show Daily* and on the DIA 2011 Mobile App. The DIA Resource Center is located in the Exhibit Hall next to the DIA Booth #1301.

DIA 2011 AT YOUR FINGERTIPS

Free mobile apps are available in all of the most popular platforms, including iPhone®, BlackBerry®, Android™, as well as mobile web. Download the mobile app to access a wide range of DIA 2011 information as well as the ability to:

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

Download instructions at **www.diahome.org/dia2011mobile** or visit the DIA booth #1301 in the Exhibit Hall.

NETWORKING OPPORTUNITIES

SPECIAL EVENTS FOR DIA 2011 FIRST TIMERS

Bring your business cards to network with fellow Annual Meeting first timers and learn some hints to help you make the most of your Annual Meeting experience.

Orientation and Speed Networking (Room: W375a)

Monday, June 20, 7:15 - 8:15 AM

Orientation (Room: W375a)

Monday, June 20, 10:00 - 10:30 AM

MORNING REFRESHMENTS

Meet with your colleagues to plan your day and discuss what you learned the day before while networking with other attendees each morning in the meeting room concourse of the Convention Center (Ballroom Foyer Level 3 prior to the Monday Plenary). Mid-morning and mid-afternoon breaks will be held in designated areas of the Exhibit Hall.

EXTENDED LUNCH HOURS IN EXHIBIT HALL

Tuesday, June 21, 11:30 AM - 1:30 PM

Wednesday, June 22, 11:30 AM - 1:30 PM

STUDENT FORUM (Room: W185a)

Sunday, June 19, 3:00 - 5:00 PM

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 29.

STUDENT POSTER SESSION

Monday, June 20, 10:00 AM - 6:30 PM

Monday, June 20, 3:15 PM (Award Presentation)

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

PROFESSIONAL POSTER SESSIONS

Tuesday, June 21, 11:30 AM - 1:30 PM

Wednesday, June 22, 11:30 AM - 1:30 PM

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. **Location:** Exhibit Hall.

DIA 2010 STUDENT POSTER WINNERS

NEW THIS YEAR!

DIA WELCOME RECEPTION

Monday, June 20, 5:00 - 6:30 PM

Join us in the Exhibit Hall for the DIA 2011 Welcome Reception, which is included in your registration fee. 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 nonexhibiting participants.

Thank you to our host companies:

HCL

EMC²

CCCRI Cape Cod Clinical Research, Inc.

Lionbridge LIFE SCIENCES

UBC United BioSource Corporation Evidence Matters

LUNCH VOUCHER

To provide you with a variety of food options, DIA 2011 is implementing a lunch voucher program in lieu of boxed lunches. Your vouchers were included in your badge envelope that you received when you registered. Please keep your coupon in a safe place since replacement vouchers will not be issued. The voucher is redeemable for up to $15.00 (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 during the following hours:

Monday, June 20, 11:30 AM - 1:30 PM

Tuesday, June 21, 11:00 AM - 1:30 PM

Wednesday, June 22, 11:00 AM - 1:30 PM

Please note: There are 4 food distribution areas in the Exhibit Hall; one on each side of the Interoperability Showcase area, as well as one in the café area located above it. There is also one located in the 100 aisle, near the Networking Luncheon Area. See map on page 9.

NETWORKING LUNCH AREA

Take advantage of this special lunch seating area in the Exhibit Hall that will provide an opportunity to network with colleagues from your professional discipline.

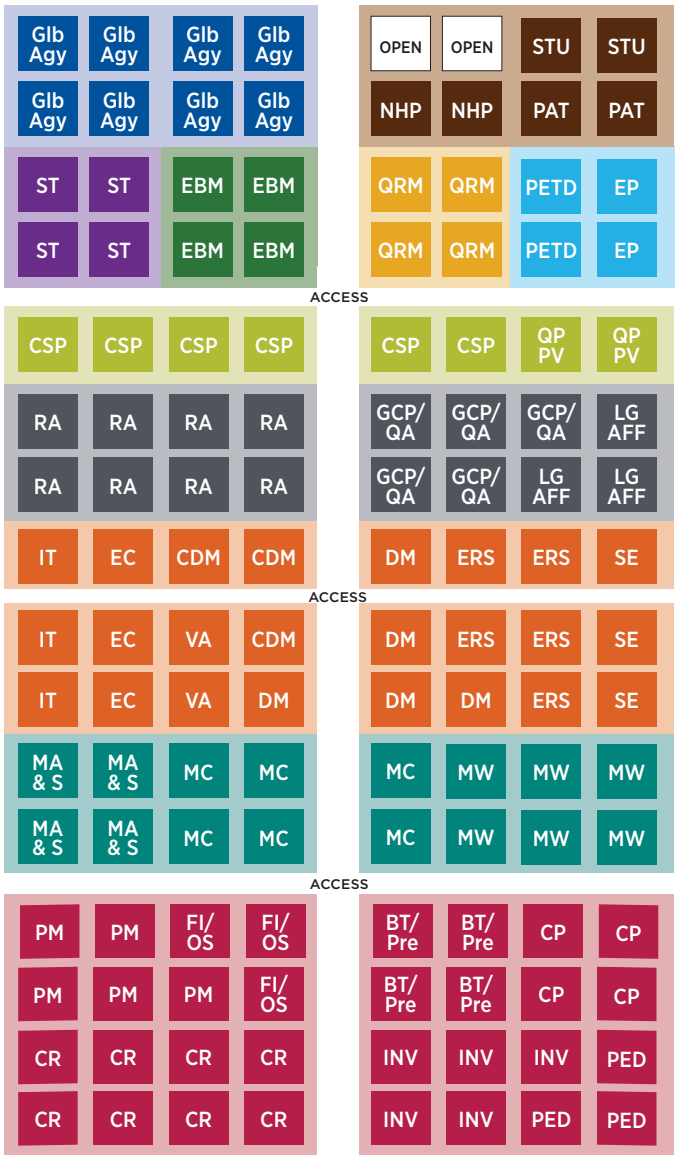
Continue discussions from a program offering that you attended or take the opportunity to reconnect or meet with members of a SIAC (Special Interest Area Community).

This seating area is organized by program track while tables are labeled by specific area of interest/SIAC.

YOUR KEY TO THE NETWORKING LUNCHEON AREA

Step #1: Select a Program Track from the list of 17 to the right. Note the color code that's assigned to that track, and the abbreviation for your specific areas of interest/ SIAC associated with that track.

Step #2: Utilizing the color coded map to the right, locate the table that is designated with that abbreviation.



- **Track 1: Clinical Operation**
  - CR – Clinical Research
  - INV – Investigator & Investigative Sites
  - PED – Pediatric
- **Track 2: Development Planning**
  - PM – Project Management
- **Track 3: Outsourcing Strategies and Innovative Partnering Models**
  - FI/OS – Finance and Outsourcing
- **Track 4: Nonclinical and Early Clinical Translational Development**
  - BT/Pre – Biotechnology & Innovative Preclinical Sciences
  - CP – Clinical Pharmacology
- **Track 5: Product Advertising and Communications**
  - MA & S – Marketing & Sales
- **Track 6: Medical Writing and Communications**
  - MC – Medical Communications
  - MW – Medical Writing
- **Track 7: IT Methods and Technologies**
  - IT – Information Technology
  - EC – eClinical
  - VA – Validation
- **Track 8: Research Data and Content Management**
  - CDM – Clinical Data Management
  - DM – Document and Records Management
  - ERS – Electronic Regulatory Submissions
  - SE – Study Endpoints
- **Track 9: Regulatory Affairs and Science, Quality and GXP Compliance**
  - GCP/QA – Good Clinical Practices & Quality Assurance
  - RA – Regulatory Affairs
- **Track 10: Public Policy/Health Care Compliance**
  - LG AFF – Legal Affairs
- **Track 11: Clinical Safety and Pharmacovigilance**
  - CSP – Clinical Safety and Pharmacovigilance
  - Qualified Persons for Pharmacovigilance
- **Track 12: Statistics**
  - ST – Statistics
- **Track 13: Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)**
  - EBM – Evidence-based Medicine
- **Track 14: Medical Devices**
  - QRM – Quality Risk Management
- **Track 15: Professional Development**
  - EP – Emerging Professionals
  - PETD – Professional Education, Training & Development
- **Track 16: Global Agency**
- **Track 18: Hot Topics/Late Breaker**
  - NHP – Natural Health Products
  - Patients
  - Students

PROGRAM COMMITTEE

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Boston Scientific Corporation

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Novartis Pharmaceuticals Corporation Greater China

Health Canada

Agnes Klein, DrPH, MD
Health Canada

FDA

Leah Christl, PhD
CDER, FDA

Hot Topics

Stephen E. Wilson, DrPH
CDER, FDA

European Union

Martin Harvey-Allchurch, LLM
European Medicines Agency, EU

Japan

Tatsuo Kurokawa, PhD
Chiba University Graduate School of Pharmaceutical Sciences, Japan

C. Latham Mitchell, MD
Erudita Biotechnical

Elaine Morefield, PhD
FDA

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PHT Corporation

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PPD, Inc

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MedImmune, LLC

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InVentiv Health

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Cardiac Safety Research Consortium
National Pharmaceutical Council (NPC)
Tufts Center for the Study of Drug Development — Tufts University

TUTORIALS — Sunday, June 19 (as of May 24 2011)

DIA 2011 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 DIA 2011. 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 are indicated to the right of the tutorial title.

Monitor **www.diahome.org/registerDIA2011** frequently for updates to the Preconference 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 15 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 15 for details.*
Tutorial 22	**Utilizing Chemistry, Manufacturing, and Controls in Drug Development**	*See page 16 for details.*
Tutorial 23	**Fourteen Steps from Research to Development**	*See page 16 for details.*
Tutorial 24	**Global Market Access: Essential Knowledge for Clinical Trial Design**	*See page 16 for details.*
Tutorial 25	**A Device Primer: 510(k)s, PMAs, IDEs**	*See page 17 for details.*

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 17 for details.*
Tutorial 31	**Leadership: How to Organize and Lead People in Group Work**	*See page 17 for details.*
Tutorial 32	**Designing, Operating, and Evaluating Patient Registries**	*See page 18 for details.*
Tutorial 33	**Hot Topics in Pharmacovigilance in the EU: EudraVigilance Access Policy, International Standardization Work E2B and Identification of Medicinal Products, Signal Detection, Duplicate Management**	*See page 18 for details.*
Tutorial 34	**CANCELLED** Developing Standard Operating Procedures (SOPs)	*See page 18 for details.*
Tutorial 35	**Early Clinical Studies: An Overview**	*See page 19 for details.*

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 19 for details.*
Tutorial 41	**Advanced CRO-vendor Management: Quality, Performance, and Compliance**	*See page 20 for details.*
Tutorial 42	**Regulatory Affairs for Biologics**	*See page 20 for details.*
Tutorial 43	**Clinical Statistics for Nonstatisticians**	*See page 21 for details.*
Tutorial 44	**CANCELLED** Who's Monitoring the Monitor? Explore Trends, Management Techniques, and a Reality Check for Sponsors Utilizing CRO- and Alliance-based Site Monitoring	*See page 21 for details.*

Register for these tutorials and the Annual Meeting online or fax the completed registration form on page 87 to DIA at +1.215.442.6199.

MORNING TUTORIALS, HALF-DAY

8:30 AM-12:00 PM Fee: $405.00

TUTORIAL 20 *Interest Area:* **Track 9**

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 Credits

Instructor
Robert R. Fike, MS, PhD
President
Robert R. Fike & Associates, LLC

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. Post-market 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 *Interest Area:* **Track 9**

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 Credits

Instructor
Michael A. Swit, Esq., JD
Vice President, Life Sciences
The Weinberg Group Inc.

This tutorial will review and discuss the legal, regulatory, and practical challenges of: (1) FDA enforcement priorities for 2010 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 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 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 2010 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 *Interest Area:* **Track 9**

Utilizing Chemistry, Manufacturing, and Controls in Drug Development

Continuing Education Credit: IACET – .3 CEUs
Regulatory Affairs Certificate Program: 2 Elective Credits

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 *Interest Area:* **Track 9**

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 Credits

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.

TUTORIAL 24 *Interest Area:* **Track 16**

Global Market Access: Essential Knowledge for Clinical Trial Design

Continuing Education Credit: IACET – .3 CEUs
Clinical Research Certificate Program: 2 Elective Credits

Instructor
John Brennick, MPA
Worldwide Market Access
Johnson & Johnson

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 25 *Interest Area:* **Track 14**

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 Credits

Instructor
Barry S. Sall
Principal Consultant
PAREXEL International Corporation

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.

AFTERNOON TUTORIALS, HALF-DAY

1:00 PM-4:30 PM **Fee: $405.00**

TUTORIAL 30 *Interest Area:* **Track 9**

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 Credits

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 *Interest Area:* **All Tracks**

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 Credits

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 *Interest Area:* **Track 13**

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 (286-000-11-501-L04-P)

Clinical Research Certificate Program: 2 Elective Credits

Regulatory Affairs Certificate Program: 2 Elective Credits

Instructor
Richard Gliklich, MD
President and CEO
Outcome Sciences Inc.

Instructor
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); HIPAA and Common Rule issues; and useful analytic approaches.

Instructors will also describe how sponsors should expect registries to be evaluated by decision makers for quality. Registries designed for safety (including REMS), effectiveness, and quality purposes will be used as examples.

Learning Objectives

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

- Identify key characteristics of registries
- Design and utilize registries for specific goals
- Apply good 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 *Interest Area:* **Track 9**

Hot Topics in Pharmacovigilance in the EU: EudraVigilance Access Policy, International Standardization Work E2B, and Identification of Medicinal Products, Signal Detection, Duplicate Management

Continuing Education Credit: CME – 3.25 *AMA PRA Category 1 Credit(s)™*; IACET – .3 CEUs

Clinical Research Certificate Program: 2 Elective Credits

Clinical Safety and Pharmacovigilance Certificate Program: 2 Elective Credits

Regulatory Affairs Certificate Program: 2 Elective Credits

Instructors
Sabine Brosch, PharmD, PhD
Scientific Administrator, Pharmacovigilance and Risk Management, European Medicines Agency, European Union

Deborah Yaplee (not pictured)
CBER, FDA

This tutorial has been prepared to provide attendees with an overview on current hot topics in pharmacovigilance in the EU. The attendees will be offered the opportunity to discuss the latest developments related to the implementation of the new EudraVigilance Access Policy, the finalization of the new international standards related to individual case safety reports (ICSR) and the identification of medicinal products (IDMP), practical approaches in signal detection, and duplicate management in light of recent inspection findings.

Learning Objectives

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

- Describe the latest developments in obtaining access to EudraVigilance
- Identify the main changes related to E2B and the reporting of medicinal product information
- Discuss approaches in signal detection and duplicate management

Target Audience

This tutorial is designed for EU qualified persons responsible for pharmacovigilance, regulatory affairs, quality assurance (clinical), data management and systems operation in pharmacovigilance.

CANCELLED

TUTORIAL 34 *Interest Area:* **All Tracks**

Developing Standard Operating Procedures (SOPs)

Continuing Education Credit: IACET – .3 CEUs

Clinical Research Certificate Program: 2 Elective Credits

Project Management Certificate Program: 2 Elective Credits

Regulatory Affairs Certificate Program: 2 Elective Credits

Instructor
Bernadette Ott
Consultant
Good Clinical Practices/Quality Assurance

One of the best ways to ensure that organizations meet their business and regulatory obligations is to follow standard operating procedures (SOPs). Standard operating procedures are the "procedures" and processes that you use and "operate" under that have been "standardized" to ensure that you do them the same way each time. SOPs are clearly written descriptions of how particular tasks are to be performed. This tutorial will explore what SOPs are, their uses, and how to write them.

Learning Objectives

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

- Describe what SOPs are and their importance to an organization
- Explain how SOPs will standardize organizational processes, with the goal of functioning consistently and well
- Define various formats for SOPs, as well as the content for each section of the SOP
- Write and/or revise an SOP
- Recognize the importance of training with respect to SOPs
- Implement SOPs in your organization

Target Audience

This tutorial is designed for anyone involved in determining processes and procedures, or writing the associated SOPs, whether at a pharmaceutical company (sponsor, CRO), an investigative site, or an IRB. Although the examples and exercises may be focused primarily on clinical trials, the information related directly to the formulation of SOPs is applicable to many different settings within these organizations.

TUTORIAL 35 *Interest Area:* **Track 3**

Early Clinical Studies: An Overview

Continuing Education Credit: CME – 3.25 *AMA PRA Category 1 Credit(s)™*; IACET – .3 CEUs; Nursing – 3.25 contact hours

Clinical Research Certificate Program: 2 Elective Credits

Instructor
Mary L. Westrick, PhD
Executive Director, Global Clinical Pharma and Exploratory Development Operations
Astellas Pharma Global Development

Instructor
Howard E. Greenberg, MD, MBA, MS
Senior Medical Director
Clinilabs Inc.

The goal of this tutorial is to demonstrate the purpose, strategy, limitations, and analysis of early clinical studies. A contrast of early- versus late-phase clinical trials will be provided. First-in-human studies will be discussed, including limitations of preclinical data, regulations, safety considerations, interpretation of safety signals, patient versus healthy volunteers, and overall strategy. Label information will be used to indicate those portions which are generated from early clinical trials. Flexible protocol design and the use of DSMBs and biomarkers will be presented. Strategy for supportive clinical pharmacology studies (DDIs, special populations, AME, etc.) and their timing will also be discussed.

Learning Objectives

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

- Describe the purpose, and strategy of early phase clinical studies
- Explain the safety issues and management of participant safety in early phase trials
- Recognize the differences between early- and late-phase clinical trials
- Identify the benefits of a clinical pharmacology strategy for supporting studies

Target Audience

This tutorial is designed for clinical research and development professionals as well as regulatory affairs, clinical operations, and drug safety professionals interested in learning about the benefits and methodology of early clinical studies.

FULL-DAY TUTORIALS

9:00 AM-5:00 PM **Fee: $755.00**

TUTORIAL 40 *Interest Area:* **Track 9**

Understanding and Navigating the Regulatory System in China

Continuing Education Credit: IACET – .7 CEUs

Regulatory Affairs Certificate Program: 4 Elective Credits

Instructor
Laurence Huang, MS
Regulatory Affairs Director
AstraZeneca, China

Instructor
Ling Su, PhD
Senior Vice President and
Head of Development, Greater China
Novartis Pharmaceuticals Corporation

Instructor
Wendy Yan, PharmD
Director, Global Regulatory Strategist
BSP China
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 *Interest Area:* **Track 3**

Advanced CRO-vendor Management: Quality, Performance, and Compliance

Continuing Education Credit: IACET – .7 CEUs
Project Management Certificate Program: 4 Elective Credits

Instructor/Panelist
Liz Wool, BSN, RN, CCRA, CMT
President and CEO
QD-Quality and Training Solutions, Inc.
Member, Board of Trustees, Association of Clinical Research Professionals

Instructor/Panelist
Brianne Martin
Independent Consultant

In 2010 and 2011, FDA's communication to industry includes their current efforts in assessing oversight of CROs by Sponsors. Whereas this is not a new expectation for Sponsors, or vendors that utilize subcontractors/contractors, the FDA's focus is a new communication.

This current FDA communication resonates the 2009 FDA Sponsor Warning Letter citing "inadequate CRO oversight" that resulted in nonapproval of an NDA that alerted industry to the requirement to manage CROs beyond the receipt of the deliverable and the requirement to implement a prospective set of quality standards, controls, and metrics, especially for outsourced monitoring activities, that are included in the CRO-vendor Quality Management Plan. The quality standards, metrics and associated controls (CRO-vendor Quality Management Plan), serve as the critical communication tool to the CRO regarding performance expectations and how deliverables will be evaluated for quality and compliance with regulations and study requirements! Further, this plan outlines for Sponsor internal staff/teams a standardized, uniform approach to prospectively, in real-time, evaluate and track CRO performance during a clinical trial. As the regulators state, "Sponsors do not delegate accountability for the quality of work transferred to a CRO." The Sponsor maintains accountability at all times during a clinical trial for the quality and performance of work conducted on their behalf.

This hands-on tutorial utilizes a case study approach, focusing on outsourced site monitoring/site management activities. Participants will practice composing a CRO-vendor Quality Management Plan utilizing proven ISO quality standards. The implementation of this plan requires modifications to the development of study budgets and CRO-vendor contract terms that will be examined in this tutorial.

PANEL DISCUSSION: Implementing CRO-vendor Quality Plans — Resources, Budgets, and Contracts!

Learning Objectives

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

- Identify the risks and associated risk mitigation strategies for outsourced activities through systematic review of the "CRO-vendor infrastructure" and "personnel" assigned to their study
- Describe and compose the CRO-vendor quality plan that is to be included in the CRO-vendor management plan for each outsourced clinical trial with a focus on outsourced site monitoring/site management activities
- Appraise vendor performance for outsourced activities
- Identify modifications to the development of study budgets and CRO-vendor contract terms

Target Audience

This tutorial is designed for professionals involved in clinical research, clinical operations, outsourcing, regulatory affairs, quality-compliance, project managers, contract officers, commercial-medical affairs, sponsors, CROs, ACROs, AROs, NIH, DoD, and VA.

TUTORIAL 42 *Interest Area:* **Track 9**

Regulatory Affairs for Biologics

Continuing Education Credit: IACET – .7 CEUs; Pharmacy – 6.5 contact hours or .65 CEUs (286-000-11-502-L04-P)
Regulatory Affairs Certificate Program: 4 Elective Credits

Instructor
Carol H. Danielson, MS, DrPH
President
Regulatory Advantage

In this tutorial, participants will discuss proven strategies to achieve regulatory compliance for the development of biologics.

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 specific regulatory requirements for biologics regulated by CBER
- Define expectations of CBER and how they differ from those of CDER
- Identify the unique aspects in the development of specific biologics such as vaccines and gene therapy
- Assess unique characteristics of biologics and why their development differs from that of small molecules
- Compare the differences in regulatory needs and requirements for biologics and small molecules

Target Audience

This tutorial is designed for professionals involved in regulatory affairs, quality assurance, and project management.

TUTORIAL 43

Interest Area: **Track 1**

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 (286-000-11-503-L04-P)

Clinical Research Certificate Program: 4 Elective Credits

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 and contrast 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.

CANCELLED

TUTORIAL 44

Interest Area: **Track 1**

Who's Monitoring the Monitor? Explore Trends, Management Techniques, and a Reality Check for Sponsors Utilizing CRO- and Alliance-based Site Monitoring

Continuing Education Credit: IACET – .7 CEUs

Clinical Research Certificate Program: 4 Elective Credits

Project Management Certificate Program: 4 Elective Credits

Instructor
Alicia Pouncey, MEd
Managing Director
Aureus Research Consultants, LLC

Explore trends, management techniques, and get a reality check in current site monitoring activities! What's working; what is not. This tutorial will cover ideas on how we can improve this time-intensive activity through a better understanding of the regulatory requirements and the current environment in clinical operations responsibilities, including interaction and oversight of outsourced monitors. The tutorial will also afford sponsor or contract research organization (CRO) site monitor managers an opportunity to see and discuss current trends regarding site monitoring activity, including new considerations for managing this resource.

Professionals who work with or manage site monitors will learn current trends and new ideas and considerations for site monitoring, including suggestions for improving management techniques.

Learning Objectives

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

- Define the purpose of site monitoring
- Identify sponsor responsibilities relative to site monitoring
- List trends in drug development, clinical operations, and study sites that impact site monitoring
- Compare current resourcing strategies in site monitoring
- Define ICH requirements for site monitoring
- Identify trends in the task of site monitoring
- List common errors made in site monitoring
- Identify trends in FDA warning letters relative to site monitoring
- Identify warning signs of problems with site monitors
- Define industry expectations for documentation of a routine site monitoring visit
- Identify categories to measure site monitor performance
- Discuss the most effective communication methods for site monitors
- Identify best practices in managing site monitors

Target Audience

This tutorial is designed for site monitor managers, project managers, CRA managers, medical monitors, resourcing managers, and sponsors from small- to mid-size pharmaceutical, biotechnology, and device companies.

CONTACT US

Accounting/Registration Payment Issues
Jean.Zane@diahome.org or
Vicki.Adkinson@diahome.org

Advertising Opportunities
MBoucher@ki-lipton.com or
+1.267.893.5686 (Michael Boucher)

Continuing Education
Jennifer.Webb@diahome.org or
+1.215.442.6118

CSRC/DIA Think Tank and Executive Sessions
Tim.Hershey@diahome.org or
+1.215.442.6157

Exhibits
Jeff.Korn@diahome.org or
Shannon.Lewis@diahome.org

Poster Sessions
AnnualMeetingProgram@diahome.org

Press Passes/Press List/Press Releases
Joe.Krasowski@diahome.org or
+1.215.293.5812

Special Interest Area Community (SIAC) Events
Mary.Hildebrandt@diahome.org or
+1.215.442.6151

Speaker Information
AnnualMeetingProgram@diahome.org

Student Opportunities
Donna.Mayer@diahome.org or
+1.215.293.5817

Training
Colleen.Buckley@diahome.org

Tutorials
AnnualMeetingProgram@diahome.org

DOUBLE YOUR LEARNING OPPORTUNITIES

DIA 2011 provides many expanded learning opportunities, including full- or half-day PRECONFERENCE TUTORIALS (see page 14) and one- to three-day training courses.

You will save $100 when you register for DIA 2011 AND one of the training courses listed below. Courses will be held at McCormick Place West in Chicago prior to DIA 2011. **Register for one of the below training courses by May 27 at the member early-bird rate and save an additional $100 off the course!**

Clinical Project Management, June 17-19
Roll up your sleeves and participate in practical hands-on activities that will help you create a custom road map for your next clinical trial.

Continuing Education: Project Management PDUs, IACET

Fundamentals of Clinical Research Monitoring, June 17-19
CANCELLED

Interactive lecture and hands-on workshop training methods will provide you with the tools to design and manage clinical studies.

Continuing Education: Pharmacy, IACET

Introduction to Good Clinical Practices and Auditing, June 17-19
Gain a working understanding of Good Clinical Practices (GCP) regulations, the GCP quality assurance audit process, and GCP concepts to help you design and manage studies.

Continuing Education: Nursing, IACET

Regulatory Affairs Part I: The IND Phase, June 17-19
Learn how to apply regulatory concepts to ensure compliant IND submissions to FDA. The course focuses on drug and well-characterized biological products and not the regulatory process for devices, generic products, or traditional biologics.

Continuing Education: IACET

New Drug Product Development and Lifecycle Management, June 18-19
At the end of this two-day course, you will be able to explain the phases, major work streams, key players and interrelationships within the new drug development and life cycle management processes. Interactive exercises include creating a simple drug development plan based on the desired target product profile.

Continuing Education: Project Management PDUs, IACET

Risk Management and Safety Communication Strategies, June 18-19
Learn proven new strategies to improve product safety, maximize patient benefits, and minimize risk.

Continuing Education: Pharmacy, IACET

Art of Writing a Clinical Overview, June 19
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).

Continuing Education: IACET

Pre-registration required for all training courses. Group discounts also available for these training courses. For additional discount information, course descriptions, and to register, go to **www.diahome.org/DIA-2011training** or contact Colleen.Buckley@diahome.org

GETTING AROUND CHICAGO

TRANSPORTATION BETWEEN THE AIRPORT AND CONVENTION CENTER/ DIA HOTELS

GO AIRPORT EXPRESS

For your convenience, **Go Airport Express** will offer direct service from McCormick Place West Gate 40 (Lobby on Level 1) to both O'Hare and Midway Airports on Wednesday, June 22 and Thursday, June 23.

Go Airport Express staff will be available in the Lobby on Level 1 of the West Building on both days from 9:00 AM until 5:30 PM for ticket sales.

Shuttles will depart every half hour from 12:00 PM to 5:30 PM on Wednesday, June 22. On Thursday, June 23, the shuttle will operate from 10:00 AM until 1:00 PM and depart every 30 minutes.

TAXIS

Taxis are available at the Lower Level curb front of Chicago-O'Hare International Airport (ORD) and Chicago-Midway International Airport (MDW).

There are no flat rates because all taxis run on meters. The fare is approximately $40 from O'Hare and $30 from Midway to the downtown area.

For wheelchair accessible vehicles, please call United Dispatch at +1.800.281.4466.

CTA RAIL

You can utilize the Chicago Transit Authority (CTA) to get to and from Chicago's airports, and to downtown Chicago by bus and elevated/subway trains.

For additional information, visit **www.chicagotransit.org.**

DIA COURTESY SHUTTLE

New this year! **You must have verification that you are staying at one of the 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 outside the entrance to the Exhibit Hall, and one will be provided after verifying your reservation 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.

Please note that mid-day service will not be available.

- **Best Western Grant Park**
  1100 South Michigan Avenue
- **Chicago Essex Inn**
  800 South Michigan Avenue
- **Doubletree Chicago Magnificent Mile**
  300 East Ohio Street
- **Fairmont Chicago**
  200 North Columbus Drive
- **Hampton Majestic Chicago Theater District**
  22 West Monroe Street
- **Hard Rock Hotel Chicago**
  230 North Michigan Avenue
- **Hilton Chicago**
  720 South Michigan Avenue
- **Hotel 71**
  71 East Wacker Drive
- **Hotel Monaco Chicago, a Kimpton Hotel**
  225 North Wabash Avenue
- **Hyatt Regency Chicago**
  151 East Wacker Drive
- **Palmer House Hilton**
  17 East Monroe Street
- **Renaissance Blackstone Chicago Hotel**
  636 South Michigan Avenue
- **Renaissance Chicago Hotel**
  1 West Wacker Drive
- **Sheraton Chicago Hotel and Towers**
  301 East North Water Street
- **Silversmith Hotel & Suites**
  10 South Wabash Avenue
- **Swissotel Chicago**
  323 East Wacker Drive
- **W Chicago Lakeshore**
  644 North Lake Shore Drive
- **Westin Chicago River North**
  320 North Dearborn Street

The **Hyatt Regency McCormick Place,** 2233 South Martin Luther King Drive, is within walking distance of McCormick Place West and will not offer shuttling.

CONTINUING EDUCATION

The DIA 2011 Annual Meeting is the premier event designed for professionals involved in the discovery, development, and life-cycle management of pharmaceuticals, medical devices, and related products. In an effort to streamline the program and focus on the hottest topics, this year's program will offer 17 preconference tutorials, seven preconference training courses, and 18 content-area tracks comprising approximately 275 sessions, with presentations geared to attendees at all disciplines, work settings, and experience levels. The DIA Annual Meeting, above all others, offers valuable professional cross-functional learning and networking experiences.

Educational Objectives

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

- Compare the current regional regulatory and public policy environment pertaining to pharmaceuticals and related products
- Discuss the regulatory and economic factors that impact the global biopharmaceutical industry
- Recognize the challenges facing regulatory agencies and industry in research study design and statistical methodology
- Assess the progress toward integrated, state-of-the-art document management systems
- Identify legal, advertising, and marketing issues related to providing product information
- Apply principles of risk assessment and management to development and postmarket phases of new healthcare products
- Summarize issues in safety reporting and data analysis regarding adverse events
- Distinguish regional approaches to integration of evidence-based medicine and comparative effectiveness research into health care decision making
- Describe current issues in designing and implementing clinical trials, including patient recruitment, site selection, and management of multiregional clinical trials
- Identify current opportunities and challenges in the area of personalized medicine for disease treatment
- Provide appropriate support to the clinical trial process that will ultimately impact patient care

Target Audience

This program is designed for individuals involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products. The program 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 and will be clearly identified in the program with the statement of CME, Pharmacy, and Nursing credits, or PMI PDUs offered. IACET continuing education units (CEUs) are offered for ALL program offerings.

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

Accreditation Council for Continuing Medical Education

PIM | Postgraduate Institute for Medicine

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.

Credit Designation

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.

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.

Type of Activity: Knowledge

Track 1: **Clinical Operations**
286-000-11-504-L04-P

Track 4: **Nonclinical and Early Clinical Translational Development**
286-000-11-505-L04-P

Track 5: **Product Advertising and Communications**
286-000-11-506-L04-P

Track 6: **Medical Writing and Communications**
286-000-11-507-L04-P

Track 7: **IT Methods and Technologies**
286-000-11-508-L04-P

Track 8: **Research Data and Content Management**
286-000-11-509-L04-P

Track 9: **Regulatory Affairs and Science, Quality and GXP Compliance**
286-000-11-510-L04-P

Track 10: **Public Policy/Health Care Compliance**
286-000-11-511-L04-P

Track 11: **Clinical Safety and Pharmacovigilance**
286-000-11-512-L04-P

Track 12: **Statistics**
286-000-11-513-L04-P

Track 13: **Health Economics and Outcomes (HEO)/ Comparative Effectiveness Research (CER)/ Health Technology Assessment (HTA)**
286-000-11-514-L04-P

Track 14: **Medical Devices**
286-000-11-515-L04-P

Track 15: **Professional Development**
286-000-11-516-L04-P

Track 17: **SIAC Showcase**
286-000-11-517-L04-P

Track 18: **Late-breaking Topics**
286-000-11-518-L04-P

The Drug Information Association has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102; +1.703.506.3275.

The Drug Information Association is authorized by IACET to offer 1.9 CEUs for this program.

Nursing

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.

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.

Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending DIA 2011, please complete your state's application for credit and submit accordingly.

For additional information to complete your application, such as a certificate of attendance, please contact ***Karen Wetzel*** *at* ***karen.wetzel@diahome.org*** *for assistance.*

TO CALCULATE YOUR CREDITS FROM THE ANNUAL MEETING PROGRAM OFFERINGS

Monday, June 20 through Thursday, June 23, 2011

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

A maximum of 19 continuing education credits are available.

PLEASE NOTE: The program offering on Tuesday, June 21 at 3:30 PM offers up to 1 hour of the above-mentioned credits.

No credit is offered for the Plenary Session on Monday morning.

NEW THIS YEAR! **DIA Certificate Programs**

If you're enrolled in the following DIA Certificate Programs, you can receive up to 14 elective units for attending DIA 2011.

- Project Management
- Clinical Research
- Clinical Safety and Pharmacovigilance
- Regulatory Affairs

STATEMENT OF CREDIT

Participants who would like to receive continuing education credits for DIA 2011 **must scan their DIA name badge at *each program offering*** to record his/her 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 badge 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 Continuing Education from the left menu bar, and then select My Transcript. You will be prompted for your user ID and password which will then take you to your transcript. Select the Annual Meeting from the grid and choose Credit Request in the bottom of the right pane. My Transcript will be available for all Annual Meeting participants to request credit on Tuesday, June 28.

Please keep in mind that to receive continuing education credit, YOU MUST:

- **Scan your DIA name badge at each program offering**
- **Complete an 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 its 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 its learners with high quality CME activities and related materials that promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.

The **faculty's,** 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 CME activity are noted on pages 114-120.

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

New this year! In an effort to go green, DIA 2011 is going paperless and evaluating all DIA 2011 educational opportunities *ONLINE!*

In order to simplify the evaluation process all attendee badges will be scanned upon entry to all meeting rooms, up to 45 minutes after the program offering start time. ***This will enable DIA to ensure that you receive evaluations for only those program offerings that you attend.*** You will receive an email notification at the end of each day, 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 all attendees who completed program offering evaluations each day of the conference. The winner will receive (1) complimentary registration to attend DIA 2012 which will be held June 24-28, 2012, in Philadelphia, PA. The winner will be announced and the prize will be distributed the week of July 11, 2011.

Please note: **All attendees that would like to receive continuing education credits for DIA 2011 *must ensure that their DIA name badge is scanned* to record his/her attendance at each educational offering attended. Attendees who do not scan their name badge will not be eligible to request the available continuing education credits.**

GENERAL INFORMATION

Baggage Check

Taxis and DIA shuttles will drop off attendees at the Main Lobby of the West Building of McCormick Place (Gates 40 for taxis and 43 and 44 for DIA shuttles.) There will be an area of this lobby reserved for attendees to check their belongings if necessary. The Baggage Check Area will be available at the times listed below:

Sunday, June 19	8:00 AM – 5:30 PM
Monday, June 20	7:00 AM – 7:00 PM
Tuesday, June 21	7:00 AM – 5:00 PM
Wednesday, June 22	7:00 AM – 5:30 PM
Thursday, June 23	7:30 AM – 1:00 PM

Note: There will be a $4.00 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/Kinkos is the official business center for McCormick Place West, providing full service business needs. They are located on Level 2 of McCormick Place West and are open during the following hours:

Sunday, June 19	9:00 AM – 4:00 PM
Monday, June 20	8:30 AM – 5:00 PM
Tuesday, June 21	8:30 AM – 5:00 PM
Wednesday, June 22	8:30 AM – 6:00 PM
Thursday, June 23	8:30 AM – 1:00 PM

Phone number: 312.949.2100 | *Fax number:* 312.842.3516

Career Center

DIA's interactive Career Center, in the main lobby on Level 1 of McCormick Place West, is your premiere resource for online employment connections!

Looking for that 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.**

Dress Code

The dress code for DIA 2011 is business casual. Neckties, business suits, or other business attire are acceptable, but not necessary. McCormick Place West may be chilly so bring a sweater or jacket, and comfortable shoes are a must!

First Aid Center

First Aid is available for routine health problems and emergency care. The First Aid Center is located on Level 1 of McCormick Place West, near Gate 43. **In case of an emergency dial 6060 from any house phone or 312.791.6060 from a landline or cell phone.** McCormick Place Security will dispatch medical personnel at once.

Internet Access/Cyber Cafe

Free wireless internet access will be available to attendees at DIA 2011 throughout McCormick Place West. Connectivity is not guaranteed. Simply connect to the McCormick wifi network, launch your internet browser and you will be authenticated on the wireless system. Visit the ETS Service Desk in the Exhibit Hall, near booths 2053 – 2067, with any questions.

DIA is also providing workstations on Level 1 of McCormick Place West, near Gate 43, for those who do not have laptop computers with wireless capability.

Live Learning Center

Full-conference registrants will receive FREE access to all available sessions, as released for inclusion (the majority within 48 hours). ***Please note that due to their interactive nature, workshops will not be recorded.*** The full conference will be available no later than three weeks after DIA 2011. These sessions will be available online for a period of 6 months on a 24/7 basis.

All full-conference registrants will be notified by email when the posting is complete. Experience the sessions captured in digital audio with synchronized Power Point presentations. Review the sessions you attended or view the ones you missed.

Demonstrations on how to access the DIA Live Learning Center will be available at the DIA Resource Center in the Exhibit Hall during the refreshment and lunch breaks during the hours below.

Monday, June 20
10:00 AM – 10:30 AM, 12:00 PM – 1:30 PM, and 3:00 PM – 3:30 PM

Tuesday, June 21
9:30 AM – 10:00 AM, 11:30 AM – 1:30 PM, and 3:00 PM – 3:30 PM

Wednesday, June 22
9:30 AM – 10:00 AM, 11:30 AM – 1:30 PM, and 3:00 PM – 3:30 PM

Lost & Found

Misplaced items will be stored at the DIA Information Booth, located on Level 1 of McCormick Place West, near Gate 43 until the end of the event. Items remaining at the close of DIA 2011 at 12:00 PM on Thursday, June 23, will be turned over to McCormick Place Security.

At that point you can contact the McCormick Place Lost & Found Hotline at 312.791.6250.

Americans with Disabilities Act: 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 46th 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.

MedDRA® User Group Meeting

MedDRA® User Group will meet on Thursday, June 23 from 12:30 PM to 5:00 PM in Room W185bc, on Level 1.

Misplaced Your Badge?

New this year! Participants will incur a $25 fee for badge reprints. If you require a badge reprint, please visit the Cashier at Attendee Registration, located outside the Exhibit Hall entrance on Level 3 of McCormick Place West. *Identification will be required.*

Poster Sessions

The student and professional poster sessions will provide excellent opportunities for the presenters to share their research results with a diverse audience of clinical research professionals.

The posters present scientific developments related to topics addressed in tutorials and offerings at DIA 2011 and will be displayed in the Exhibit Hall on Level 3 of McCormick Place West.

Student Poster Session	Monday, June 20, 10:00 AM to 6:30 PM
Professional Poster Session #1	Tuesday, June 21, 11:30 AM to 1:30 PM
Professional Poster Session #2	Wednesday, June 22, 11:30 AM to 1:30 PM

Press Registration Policies and Procedures

DIA welcomes qualified representatives of news organizations to attend DIA 2011 for the purpose of reporting and publishing/airing articles/stories. DIA reserves the right to screen all requests and refuse the registration of those who are not considered to be qualified. In order to obtain a press pass, applicants must be affiliated with an established media outlet and possess an editorial/reporting title.

Publications and marketing materials may not be distributed at DIA 2011 without the express and written permission of DIA. All media must present a copy of their press credential confirmation letter from DIA and official press credentials at the DIA event check-in location. The press room is located in the Exhibit Hall on Level 3, and will be open during Exhibit Hall hours.

Publishers, sales representatives and other noneditorial staff will not be granted a press pass. To obtain your press credential, contact **Joe Krasowski at +1.215.293.5812 orJoe.Krasowski@diahome.org.**

Private Social Functions Policy

DIA does not allow hospitality functions to be held during any DIA 2011 offerings, scheduled exhibit hours, or social events. Therefore, the hours noted below are the only hours that are acceptable for hospitality functions:

Saturday, June 18	All times are acceptable
Sunday, June 19	All times are acceptable
Monday, June 20	Before 8:15 AM and after 6:30 PM
Tuesday, June 21	Before 8:00 AM and after 4:30 PM
Wednesday, June 22	Before 8:00 AM and after 5:00 PM
Thursday, June 23	Before 9:00 AM and after 12:15 PM

Reception

DIA's expanded Welcome Reception will be held on Monday, June 20, 5:00 PM – 6:30 PM, in the Exhibit Hall on Level 3.

Restaurant Information Booth

Chicago is such a food lovers' paradise that you will face just one dilemma: How to choose from so many delicious options? The Chicago Convention and Tourism Bureau wants to help you make the most of your dining experience in Chicago.

To find Chicago's best dining options, stop by the Restaurant Reservation Booth on Level 3 of McCormick Place West, near the entrance to the Exhibit Hall. They'll even make reservations for you!

The hours are as follows:

Sunday, June 19	3:00 PM – 6:00 PM
Monday, June 20	10:00 AM – 6:30 PM
Tuesday, June 21	10:00 AM – 5:30 PM
Wednesday, June 22	10:00 AM – 3:00 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.

Exhibit Hall Opportunities

Scientific Exhibits: In the Exhibit Hall on Level 3, nearly 500 vendors will showcase their company's innovations, products, and services to meeting attendees from industry, academia, and regulatory agencies who use these services in the conduct of their professions.

Exhibit Locator: Find the exhibitors you wish to visit using DIA's exhibit locator near the DIA Booth in the Exhibit Hall on Level 3. You can utilize this workstation to find an exhibiting company by booth number, by company name, or by the services the company provides.

The "keyword" function will search for terms used in the company description in the 2011 Exhibitor Directory section of the final program.

Play Exhibitor Bingo

- Visit any 40 booths in the exhibit hall
- Have your card signed by each of the companies you visit
- Return your card to the DIA Booth and be entered to win great prizes

Bingo cards can be found in your attendee bag and at the DIA Booth.

DIA 2012 Headed to Philadelphia

Take a key from Philadelphia's own Benjamin Franklin, then stop by the DIA Booth to see if your key opens a treasure chest filled with great prizes.

- DIA 2012 Registration
- Dinner at a Five Star Philadelphia Restaurant
- William Penn Special Gift Basket ... *and more*

DIA 2011 MEETING SCHEDULE

DIFFERENT FORMATS FOR DIFFERENT LEARNERS

FORUM
A 90-minute blended presentation and panel discussion

SESSION
A 90-minute presentation delivered lecture-style from the podium

SYMPOSIUM
A blend of three 20-minute presentations

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

DIA 2011 TRACK CONTENT AREAS

See page 3 for 2010–2011 Track comparison.

Track 1: Clinical Operations
Track 2: Development Planning
Track 3: Outsourcing Strategies and Innovative Partnering Models
Track 4: Nonclinical and Early Clinical Translational Development
New Area: Clinical Pharmacology
Track 5: Product Advertising and Communications
Track 6: Medical Writing and Communications
Track 7: IT Methods and Technologies
Track 8: Research Data and Content Management
New Area: Study Endpoints
Track 9: Regulatory Affairs and Science, Quality and GXP Compliance
Track 10: Public Policy/Health Care Compliance
Track 11: Clinical Safety and Pharmacovigilance
Track 12: Statistics
Track 13: Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)
Track 14: Medical Devices ***New Track!***
Track 15: Professional Development
New Area: Career/Professional Development
New Area: Profession-related Learning and/or Teaching
Track 16: Global Agency ***New Track!***
Track 17: SIAC Showcase ***New Track!***
Track 18: Late-breaking Topics ***New Track!***

Content Level Guide
Components are organized and presented according to the content areas defined in the chart above. The difficulty level of each offering has been determined by the chairperson and is indicated by one of the following symbols, providing a guide for registrants in their selection of sessions to attend.

- ● **Basic Level Content** — Appropriate for individuals new to the topic/subject area.
- ■ **Primarily Intermediate Level Content** — Appropriate for individuals who already have a basic understanding of the topic/subject area.
- ◆ **Primarily Advanced Level Content** — Appropriate for individuals with an in-depth knowledge of the topic/subject area.

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
SUNDAY, JUNE 19	3:00 PM – 5:00 PM				
STUDENT FORUM	Jobs That Did Not Exist When the Old Guard Began Their Careers	—	Forum	LEVEL ●	W185a
MONDAY, JUNE 20	8:30 AM – 10:00 AM				
	OPENING PLENARY SESSION Welcome Remarks, Keynote Presentation, and Award Presentations *All registrants are encouraged to attend.*	Plenary Session		ALL	Skyline Ballroom W375cde, Level 3
MONDAY, JUNE 20	10:30 AM – 12:00 PM				
#101	Site Selection Process Workshop: Identifying, Selecting, and Defining a Quality Investigator Site	TRK 1 (A)	Workshop*	LEVEL ■	W475a
#102	Innovative Clinical Operations Methodology for Global Trial Management	TRK 1 (B)	Symposium	LEVEL ■	W175abc
#103	Clinical Research in Emerging Regions: A Forum for Exchange	TRK 1 (C)	Forum	LEVEL ■	W176abc
#104	Protocol Design and Subsequent Amendments: Understanding the Benefits of Well Designed Protocols	TRK 2 (A)	Session	LEVEL ■	W179a
#105	Asian Global Development and Regulatory Strategies	TRK 2 (B)	Symposium	LEVEL ■	W179b

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
MONDAY, JUNE 20 10:30 AM – 12:00 PM *continued*					
#106	Alliance Management: How to Start and Maintain Alliance Teams and Create Value	TRK 3	Workshop*	LEVEL ■	W474b
#107	The Role of Biomarkers in the Rapid Development of New Medicines: A Scientific and Regulatory Perspective	TRK 4	Session	LEVEL ■	W183a
#108	Incorporating Compliance into Everyday Practice	TRK 6	Session	LEVEL ■	W184bc
#109	Blurring the Boundaries Between Technologies: Examples of Next Generation Clinical Trial Technology Integration	TRK 7 (A)	Session	LEVEL ●	W471a
#110	Real-world Applications of BRIDG	TRK 7 (B)	Session	LEVEL ●	W470a
#111	Experiences with the Development of Disease-specific Standards for Data, Terminology, and Use Cases for Regulatory Science	TRK 8	Session	LEVEL ■	W470b
#112	Managing Liability and Risk from GCP Noncompliance	TRK 9 (A)	Session	LEVEL ■	W185bc
#113	Update on ICH Topics: Q11 Small Molecules and Biotech, Q8/9/10 Implementation Working Group, Q4B Harmonization of Compendial Test Chapters	TRK 9 (B)	Session	LEVEL ■	W185a
#114	Issues in Pediatric Global Development	TRK 9 (C)	Forum	LEVEL ■	W185d
#115	Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials	TRK 10	Workshop*	LEVEL ●	W180
#116	Natural History of Disease: An Often Overlooked Study Concept	TRK 11 (A)	Session	LEVEL ■	W184a
#117	Global Pharmacovigilance Systems: Foundations for Compliance	TRK 11 (B)	Symposium	LEVEL ■	W183b
#118	Hot Topics in Statistics	TRK 12	Session	LEVEL ■	W181bc
#119	The Patient Perspective: Start Leveraging This Important Stakeholder to Maximize Commercial Potential	TRK 13	Symposium	LEVEL ■	W181a
#120	Recent Reformation on Medical Device Regulatory Systems in the Asia-Pacific Region	TRK 14	Session	LEVEL ■	W184d
#121	Current Status of Global Clinical Research and Pharmaceutical Medicine Education	TRK 15	Session	LEVEL ●	W474a
#122	Annual CDER eSubmission Update: Review and Technical Perspectives	TRK 16 (A)	Session	LEVEL ■	W186abc
#123	European Heads of Medicines Agencies (HMA) Town Hall	TRK 16 (B)	Forum	LEVEL ●	W183c
#124	Vaccines for Low- and Middle-income Countries: Navigating Unique Regulatory Challenges	TRK 18	Session	LEVEL ●	W471b
MONDAY, JUNE 20 1:30 PM – 3:00 PM					
#125	Factors Impacting Investigative Site Performance and Investigator Participation in a Clinical Study	TRK 1 (A)	Symposium	LEVEL ●	W175abc
#126	Electronic Medical Records for Patient Recruitment: Is It the Holy Grail?	TRK 1 (B)	Session	LEVEL ■	W176abc
#127	Pediatric Protocol: Designing Clinical Trials to Minimize Child Risk and Enhance Study Outcomes	TRK 1 (C)	Workshop*	LEVEL ■	W475a
#128	Building Competencies in a Global Project Management Department	TRK 2 (A)	Forum	LEVEL ■	W179a
#129	Designing and Implementing a Drug Strategy Approach	TRK 2 (B)	Session	LEVEL ■	W179b
#130	Reducing Micro-management of CROs While Maintaining Effective Quality Oversight: Results from a 2011 Industry Survey	TRK 3	Forum	LEVEL ■	W178ab
#131	CBER Therapeutic and Preventive Vaccines Update	TRK 4	Session	LEVEL ■	W183a
#132	The Growing Role of Medical Communications in Promotional Review	TRK 6	Session	LEVEL ■	W184bc

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Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
MONDAY, JUNE 20 1:30 PM – 3:00 PM *continued*					
#133	Smashing Silos and Building Relationships: Understanding and Measuring Value that Clinical IT Brings to Drug Development	TRK 7	Session	LEVEL ■	W470a
#134	Measuring Symptoms: Methodological Considerations	TRK 8	Session	LEVEL ◆	W470b
#135	FDA and European Medicines Agency Update on GCP Inspections and the Conduct of Clinical Trials	TRK 9 (A)	Session	LEVEL ■	W185bc
#136	Electronic Labeling and Indexing Data Elements: Structured Product Labeling	TRK 9 (B)	Session	LEVEL ■	W185a
#137	Japan Registration and Global Drug Development: Post-2007 Case Studies	TRK 9 (C)	Session	LEVEL ■	W185d
#138	GMP Inspection and Compliance Issues	TRK 9 (D)	Session	LEVEL ■	W183c
#139	Marketing Practices on Trial	TRK 10	Workshop*	LEVEL ●	W180
#140	Postmarketing Risk Management: Evolving Implementation for ETASUs	TRK 11 (A)	Session	LEVEL ■	W183b
#141	Creating Customized MedDRA® Queries	TRK 11 (B)	Workshop*	LEVEL ■	W474b
#142	SPERT: Trials, Troubles, and Tribulations with Safety Planning	TRK 12	Session	LEVEL ■	W181bc
#143	The Revision and Recast of the Medical Device Directives: Where the Pressures Lie for Change	TRK 14	Session	LEVEL ■	W184d
#144	My Big Break: Stories from Top Pharmaceutical Executives	TRK 15	Forum	LEVEL ●	W474a
#145	European Medicines Agency (EMA) Town Hall	TRK 16 (A)	Forum	LEVEL ■	W186abc
#146	FDA Discussion on Biosimilar Legislation and Implementation	TRK 16 (B)	Forum	LEVEL ■	W187abc
MONDAY, JUNE 20 3:30 PM – 5:00 PM					
#147	Ethical Issues in Clinical Trials Workshop: It's All Shades of Gray	TRK 1 (A)	Workshop*	LEVEL ■	W475a
#148	Building a Quality Framework to Provide Efficient and Effective Oversight of Transferred Obligations: A Collaborative Approach	TRK 1 (B)	Forum	LEVEL ◆	W176abc
#149	A Creative Approach for Improving the Probability of Commercial Success	TRK 2 (A)	Session	LEVEL ■	W179a
#150	Risk Assessment Process for Pediatric Protocol Development	TRK 2 (B)	Session	LEVEL ■	W179b
#151	Quality by Design: Planning Quality on Multiple Fronts	TRK 2 (C)	Session	LEVEL ■	W175abc
#152	Better Cooperation Between Stakeholders in Drug Development: Is It Inevitable?	TRK 3	Session	LEVEL ■	W178ab
#153	Early Drug Development and Early Interaction with Governmental Agencies	TRK 4	Session	LEVEL ■	W183a
#154	The Past, Present, and Future: A Glimpse at the Emergence of the Medical Science Liaison Role	TRK 6	Session	LEVEL ■	W184bc
#155	Advanced IT Methods for Clinical Trials	TRK 7 (A)	Symposium	LEVEL ■	W470a
#156	ePRO: Which Technologies and Data Management Strategies Provide Maximum Benefit for Your Trial	TRK 7 (B)	Session	LEVEL ■	W471a
#157	Adopting a Risk-based Approach to Clinical Data Quality	TRK 8	Symposium	LEVEL ■	W470b
#158	Global Innovative Monitoring and Auditing Tools for Bioresearch Monitoring Activities	TRK 9 (A)	Session	LEVEL ■	W185a
#159	Global Harmonization Beyond ICH	TRK 9 (B)	Forum	LEVEL ■	W185bc
#160	Recent Advancement of Biosimilars in the Asia-Pacific Region	TRK 9 (C)	Session	LEVEL ■	W184a

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Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
MONDAY, JUNE 20	3:30 PM – 5:00 PM *continued*				
#161	Civil and Regulatory Liability from Clinical Trials	TRK 10	Forum	LEVEL ●	W180
#162	Practical Risk Management on a Global Scale: Navigating the REMS and RMP Regulatory Waterways	TRK 11	Symposium	LEVEL ■	W183b
#163	Innovative Graphical Approaches to Display Safety Data Collected in Clinical Trial Research	TRK 12	Session	LEVEL ■	W181bc
#164	Benefit-risk Methodology: An Interactive Workshop	TRK 13	Workshop*	LEVEL ■	W474a
#165	Understanding Medical Device Trial Regulation and Operational Challenges in Latin America	TRK 14	Session	LEVEL ●	W184d
#166	Presenting ... YOU! Tips, Tricks, and Advice on Making You and Your Presentations Unforgettable: An Interactive Workshop	TRK 15	Workshop*	LEVEL ●	W474b
#167	Future Directions: Submitting Promotional Material to CDER FDA in eCTD Format	TRK 16 (A)	Session	LEVEL ■	W186abc
#168	Update from the Therapeutic Goods Administration (TGA)	TRK 16 (B)	Forum	LEVEL ●	W185d
#169	Comparative Effectiveness Research and Health Technology Assessment: How National Agencies Are Addressing the Challenge	TRK 18	Session	LEVEL ■	W183c
TUESDAY, JUNE 21	8:00 AM – 9:30 AM				
#201	PLENARY SESSION — Voice of the Patient: Stories That Touch Us	TRK 1 (A)	Session	LEVEL ●	W375b
#202	Investigator Budgets and Sponsor Identification/Selection Processes: Impact on Patient Enrollment	TRK 1 (B)	Session	LEVEL ■	W176abc
#203	Project Team Effectiveness: Multidisciplinary Team and the Temperament Factor	TRK 2	Session	LEVEL ●	W179a
#204	Regulatory, Clinical, and Quality Challenges in Contracting and Due Diligence: The Forgotten Keys to Biopharmaceutical Transactions	TRK 3	Session	LEVEL ■	W179b
#205	Designing Robust Protocols	TRK 6	Session	LEVEL ■	W184bc
#206	International eClinical Experience	TRK 7	Symposium	LEVEL ■	W470a
#207	The Benefit-risk Assessment of Medicines: How Can This Be Communicated Effectively to Different Stakeholders?	TRK 9	Session	LEVEL ■	W185bc
#208	Issues and Challenges in Designing Central Nervous System Clinical Trials	TRK 12	Session	LEVEL ■	W181bc
#209	Managing Generation Gaps in the Clinical Research Industry	TRK 15 (A)	Session	LEVEL ■	W474a
#210	Presenting ... YOU! Tips, Tricks, and Advice on Making You and Your Presentations Unforgettable: An Interactive Workshop	TRK 15 (B)	Workshop*	LEVEL ●	W474b
TUESDAY, JUNE 21	10:00 AM – 11:30 AM				
#211	ePatient Recruitment, Study Sites, and the Digital Divide	TRK 1 (A)	Session	LEVEL ■	W175abc
#212	Optimizing Site Performance: Select High-performing Sites, and Diagnose/ Repair Poor or Less-experienced Sites	TRK 1 (B)	Session	LEVEL ■	W176abc
#213	Monitoring and Source Verification: New Approaches to Quality	TRK 1 (C)	Symposium	LEVEL ■	W181a
#214	Does Your Leadership Effectively Work for Your Team Members Who Come from Different Organizations and Countries?	TRK 2 (A)	Session	LEVEL ●	W179a

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Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
TUESDAY, JUNE 21	10:00 AM – 11:30 AM *continued*				
#215	Early-phase Clinical Development: Strategies for Early Decision Making	TRK 2 (B)	Session	LEVEL ■	W179b
#216	Committing to Two Partners: A Look at a Strategic CRO Sourcing Initiative	TRK 3	Forum	LEVEL ■	W178ab
#217	Lessons Learned in the Translational Development of Patient-specific Therapies	TRK 4	Session	LEVEL ■	W183a
#218	Comparative Effectiveness and the Impact on Medical Communications	TRK 6	Session	LEVEL ●	W184bc
#219	Optimizing Aftermarket Research on Medical Therapies	TRK 7	Session	LEVEL ■	W470a
#220	Managing the Content and Data	TRK 8	Symposium	LEVEL ■	W470b
#221	Defining Quality in Clinical Trials	TRK 9 (A)	Session	LEVEL ■	W186abc
#222	Electronic Submissions for Regulatory Affairs Professionals	TRK 9 (B)	Workshop*	LEVEL ●	W474b
#223	Expectations and Issues Related to INDs, Clinical Hold, and Refuse to File	TRK 9 (C)	Session	LEVEL ■	W185a
#224	Regulatory Roundtable on Biosimilar Policies	TRK 9 (D)	Forum	LEVEL ■	W185bc
#225	Protecting Patients in Clinical Research	TRK 10 (A)	Forum	LEVEL ■	W180
#226	Pharmaceutical Pricing and Reimbursement Policies and Practices in Asia Pacific and Latin America: Impact on Drug Development	TRK 10 (B)	Session	LEVEL ■	W183b
#227	Social Media and Pharmacovigilance	TRK 11 (A)	Symposium	LEVEL ■	W184a
#228	Development of an Integrated Framework for Quantitative Risk Benefit Assessment	TRK 11 (B)	Workshop*	LEVEL ■	W475a
#229	Statistical Methods in Comparative Effectiveness Research	TRK 12	Forum	LEVEL ■	W181bc
#230	Regulatory Updates on Patient-reported Outcomes (PROs)	TRK 13	Session	LEVEL ■	W183c
#231	International Harmonization Pathways for Medical Devices	TRK 14	Session	LEVEL ■	W184d
#232	Fame, Fortune, and F-Tests: Something for Everyone	TRK 15	Symposium	LEVEL ●	W474a
TUESDAY, JUNE 21	1:30 PM – 3:00 PM				
#233	Taking the Clinical Trial into the Cloud: Implementing a Web-based Study Community Oriented to the Investigator Site	TRK 1 (A)	Session	LEVEL ■	W175abc
#234	Site Selection Process Workshop: Identifying, Selecting, and Defining a Quality Investigator Site	TRK 1 (B)	Workshop*	LEVEL ■	W474b
#235	How to Build and Run an Adaptive Design: A "Hands-on" Workshop	TRK 2 (A)	Workshop*	LEVEL ■	W475a
#236	Global Pharmaceutical Development in Emerging Markets	TRK 2 (B)	Symposium	LEVEL ■	W179a
#237	Using Simulation Models to Inform Product Development and Portfolio Planning Decisions	TRK 2 (C)	Session	LEVEL ●	W179b
#238	An Innovative Strategic Partnering Relationship: Can This Approach Revolutionize Drug Development?	TRK 3	Session	LEVEL ■	W178ab
#239	ICH Guidelines on Genotoxic Impurities and Residual Metals: CMC and Safety Issues	TRK 4	Session	LEVEL ■	W183a
#240	Publications: Does Your Company Policy Pass the Red-faced Test?	TRK 6	Forum	LEVEL ■	W184bc
#241	New eClinical Technology: Risks, Benefits, Security, Planning, Workflow, and Outcomes	TRK 7	Session	LEVEL ■	W470a
#242	What Is an Endpoint? A Disease-specific Discussion of Study Endpoints	TRK 8	Forum	LEVEL ■	W470b
#243	Ensuring GCP Compliance in Emerging Regions	TRK 9 (A)	Session	LEVEL ●	W183c

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Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
TUESDAY, JUNE 21 1:30 PM – 3:00 PM *continued*					
#244	Knowledge Management Throughout the Pharmaceutical Product Life Cycle	TRK 9 (B)	Session	LEVEL ■	W185a
#245	Orphan Drug Development: Regulatory Challenges and Initiatives	TRK 9 (C)	Session	LEVEL ■	W185bc
#246	The Impact of Transparency Requirements for BPCA and PREA	TRK 9 (D)	Session	LEVEL ■	W185d
#247	Partnering with Patients in Clinical Research	TRK 10 (A)	Session	LEVEL ■	W180
#248	Clinical Trial Disclosure Requirements: Coping with Multiple Governmental Registries	TRK 10 (B)	Session	LEVEL ■	W183b
#249	Medical Review of Individual Cases – Enough is Enough: A Waste of PV Resources, or Core PV Activity?	TRK 11 (A)	Session	LEVEL ■	W184a
#250	Practical Applications of MedDRA® for Safety Data Analysis: Industry and Regulatory Perspectives	TRK 11 (B)	Forum	LEVEL ■	W176abc
#251	Statistical Methods to Enable Tailored Therapeutics	TRK 12	Session	LEVEL ■	W181bc
#252	Comparative Effectiveness Research: What Is the Current Direction?	TRK 13	Session	LEVEL ■	W184d
#253	Calculating Return on Investment for Teaching Intangibles and What to Analyze: Maximizing Resources for Professional Development	TRK 15	Session	LEVEL ●	W474a
#254	Regulatory Update from the Office of New Drug Quality Assessment, Office of Biotechnology Products, Office of Generic Drugs, Office of Compliance, and Office of Regulatory Affairs	TRK 16 (A)	Forum	LEVEL ■	W187abc
#255	India Regulatory Agency Town Hall	TRK 16 (B)	Forum	LEVEL ●	W186abc
TUESDAY, JUNE 21 3:30 PM – 4:30 PM					
#256	First-in-human Dosing for Small and Large Molecules: Similarities and Differences	TRK 17 (A)	SIAC	LEVEL ■	W181a
#257	Moving from Managing Data to Managing Information	TRK 17 (B)	SIAC	LEVEL ■	W470a
#258	Health Care Reform: Charting New Strategies for Clinical Trials	TRK 17 (C)	SIAC	LEVEL ●	W178ab
#259	Drug Safety and Pharmacovigilance Inspections: MHRA Approaches	TRK 17 (D)	SIAC	LEVEL ■	W183a
#260	EDM and TMF Reference Models: The Path Forward	TRK 17 (E)	SIAC	LEVEL ●	W183b
#261	Comparative Effectiveness: Where Do We Stand Today?	TRK 17 (F)	SIAC	LEVEL ●	W180
#262	Hot Topics in eClinical	TRK 17 (G)	SIAC	LEVEL ■	W176abc
#263	Hot Topics in eSubmissions: A Panel Discussion	TRK 17 (H)	SIAC	LEVEL ■	W179a
#264	How to Avoid Warning Letters: Knowing Your Good Clinical Practice (GCP) Responsibilities	TRK 17 (I)	SIAC	LEVEL ●	W175abc
#265	Doing More with Less: A Review of the Industry's Response to Financial Pressures and the Outlook for Service Providers	TRK 17 (J)	SIAC	LEVEL ■	W179b
#266	Drive IT and Business Alignment to Increase Value	TRK 17 (K)	SIAC	LEVEL ■	W470b
#267	Social Media: Proceeding with Caution	TRK 17 (L)	SIAC	LEVEL ■	W184a
#268	The Medical Writer's Strategic Impact on Regulatory Documents and Peer-reviewed Publications	TRK 17 (M)	SIAC	LEVEL ●	W184bc
#269	Change in Global Perspectives for Natural Health Products	TRK 17 (N)	SIAC	LEVEL ■	W184d
#270	Challenges for Pediatric Drug Development: Are Clinical Trials ALWAYS Needed? When and How Can We Extrapolate from Prior Data?	TRK 17 (O)	SIAC	LEVEL ■	W185a

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Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
TUESDAY, JUNE 21	3:30 PM – 4:30 PM *continued*				
#271	Through the Eyes of Others: What We Can Learn from Nonpharma Industries About Learning in 2011	TRK 17 (P)	SIAC	LEVEL ●	W474a
#272	Project Management in Biopharmaceuticals: The Last Two Decades of Innovation Provide the Foundation for the Next Ten Years	TRK 17 (Q)	SIAC	LEVEL ■	W181bc
#273	Hot Topics in Regulatory Affairs	TRK 17 (R)	SIAC	LEVEL ■	W187abc
#274	Hot Topics in Study Endpoints: Q&A with an Expert Panel	TRK 17 (S)	SIAC	LEVEL ■	W185bc
#275	The Evolution of the Statistics SIAC as a Hub for Collaboration and Interaction Among Industry, Academia, and Government	TRK 17 (T)	SIAC	LEVEL ■	W186abc
#276	FDA Part 11 Inspection Program Results	TRK 17 (U)	SIAC	LEVEL ■	W185d
#277	Biologics: Changing the Phase 1 Clinical Landscape	TRK 17 (V)	SIAC	LEVEL ■	W183c
TUESDAY, JUNE 21	4:30 PM – 5:00 PM				
#278A	Workforce Training Needs in Real-world Outcomes: Survey Results	TRK 18A	Session	LEVEL ■	W180
TUESDAY, JUNE 21	4:45 PM – 5:45 PM				
#278B	Interoperability Showcase Town Hall	TRK 18B	Forum	LEVEL ■	W187abc
WEDNESDAY, JUNE 22	8:00 AM – 9:30 AM				
#301	Integration of Project Management Capabilities into R&D Functional Areas: Opportunity to Optimize Project Team Performance?	TRK 2	Session	LEVEL ■	W179a
#302	Reverse Vaccinology: In Silico Tools for the Prediction of Unwanted Immunogenicity of Therapeutic Proteins	TRK 4	Session	LEVEL ■	W183a
#303	FDA Enforcement Update: Regarding Advertising and Promotion	TRK 5	Session	LEVEL ■	W183b
#304	New Drug Application: Integrated Summaries, Clinical Summaries, and Clinical Overview	TRK 6	Forum	LEVEL ■	W184bc
#305	The Integration of the ISO IDMP Standard with SPL	TRK 7	Session	LEVEL ■	W470a
#306	Metrics: A Cross-functional Collaboration	TRK 8	Session	LEVEL ■	W470b
#307	Outlook for Changes in the Japanese Regulatory and Clinical Development Environment	TRK 9	Session	LEVEL ■	W185bc
#308	SPECIAL PLENARY SESSION — Rethinking Pharmaceutical Development: The Impact of Health Reform	TRK 10	Session	LEVEL ●	W375b
#309	CDISC/ADaM and the FDA: Working Together to Improve Statistical Review	TRK 12	Session	LEVEL ■	W181bc
WEDNESDAY, JUNE 22	10:00 AM – 11:30 AM				
#310	Goals, Challenges, Likes, and Dislikes of the Recruited	TRK 1 (A)	Session	LEVEL ■	W175abc
#311	The Expanding Role of the Clinical Trial Manager: Will the Balloon Break?	TRK 1 (B)	Session	LEVEL ■	W176abc
#312	Productivity Simulation: Capacity School for Big and Small Pharma	TRK 2 (A)	Workshop	LEVEL ■	W474b
#313	When, How, and Why: Optimizing Resource Planning to Get the Most from Your Existing Resources	TRK 2 (B)	Forum	LEVEL ◆	W179a
#314	Organizational Challenges in Moving to a New Outsourcing Model: Overcoming Resistance to Change	TRK 3	Session	LEVEL ◆	W178ab
#315	Therapeutic Drug Development for Alzheimer's, Tumors, and Bacterial Infections	TRK 4 (A)	Symposium	LEVEL ■	W179b

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Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
WEDNESDAY, JUNE 22	10:00 AM – 11:30 AM *continued*				
#316	Translational Medicine-driven Multicomponent Predictive Biomarkers and Biomarkers for Earlier Efficacy Assessment	TRK 4 (B)	Session	LEVEL ■	W183a
#317	Policy and Enforcement Issues Faced by Industry	TRK 5	Session	LEVEL ■	W183b
#318	Constructing Key Clinical Documents for Global Use	TRK 6	Session	LEVEL ■	W184bc
#319	The Ethical Ramifications of Integrating Electronic Health Records and Electronic Clinical Trials	TRK 7	Session	LEVEL ◆	W470a
#320	Innovation in Clinical Development: Where Is It Going?	TRK 8 (A)	Session	LEVEL ●	W470b
#321	Using Patient-reported Outcomes to Assess Comparative Safety and Tolerability: Methodological and Regulatory Issues	TRK 8 (B)	Session	LEVEL ●	W471a
#322	Dealing with an FDA Inspection: What We Can Learn from Warning Letters and Audits	TRK 9 (A)	Session	LEVEL ●	W185bc
#323	Pursuing Standards to Enhance eCTD Deliverables: PhRMA Electronic Regulatory Submissions (ERS) Group Annual Update	TRK 9 (B)	Session	LEVEL ■	W471b
#324	Quality Risk Management in Product Development: The Assessment, Identification, and Control of Potential Risk	TRK 9 (C)	Session	LEVEL ■	W185a
#325	Postmarketing Commitments: Is It Time for Industry and FDA to Seek Therapy?	TRK 9 (D)	Session	LEVEL ■	W183c
#326	International Cooperation Among Registration Agencies	TRK 10 (A)	Session	LEVEL ■	W180
#327	Drug Product Liability in the United States and the European Union	TRK 10 (B)	Session	LEVEL ■	W181a
#328	Good and Bad Behaviors During a PV Inspection	TRK 11 (A)	Workshop*	LEVEL ■	W475a
#329	Medical Potpourri: Blood Pressure, Patient Safety, and Nanomedicine	TRK 11 (B)	Symposium	LEVEL ■	W184a
#330	Missing Data: Where Are We Now?	TRK 12	Session	LEVEL ■	W181bc
#331	Emerging Trends in the Economics of the Biopharmaceutical Industry	TRK 13	Session	LEVEL ●	W184d
#332	Implications of Shifting Regulations for Combination Products: A Comprehensive Review	TRK 14	Session	LEVEL ■	W186abc
#333	Learning on the Go: Mobile Tools for Pharmaceutical Professionals	TRK 15	Session	LEVEL ●	W474a
#334	The Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall	TRK 16 (A)	Forum	LEVEL ■	W187abc
#335	Working for Harmonization on Regulations for Clinical Trials in Latin America	TRK 16 (B)	Session	LEVEL ●	W185d
#336	Establishing a Framework for CER Assessment: How Do Managed Care Decision Makers Consider the Evidence?	TRK 18	Session	LEVEL ■	W475b
WEDNESDAY, JUNE 22	1:30 PM – 3:00 PM				
#337	Leveraging Ethics	TRK 1 (A)	Symposium	LEVEL ■	W175abc
#338	How Do We Ensure Proper Sponsor Oversight When Conducting Global Clinical Trials?	TRK 1 (B)	Session	LEVEL ■	W176abc
#339	Project Team Dynamics: Enhancing Performance, Improving Results	CANCELLED			
#340	Scheduling Product Development: Current Industry Practices and New Techniques	TRK 2 (B)	Forum	LEVEL ◆	W179a
#341	A Close Look at Clinical Outsourcing Strategies: An Executive Roundtable	TRK 3	Forum	LEVEL ■	W178ab
#342	Technology in Early-phase Research: Optimizing Methods	TRK 4 (A)	Symposium	LEVEL ■	W179b

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Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
WEDNESDAY, JUNE 22	1:30 PM – 3:00 PM *continued*				
#343	Clinically Driven Nonclinical Testing for Combined Advanced Therapy Medicinal Products (ATMPs)	TRK 4 (B)	Forum	LEVEL ■	W183a
#344	SPECIAL PLENARY SESSION: The Problems and Promise of Using Social Media to Improve Patient Care	TRK 5	Forum	LEVEL ■	W375b
#345	Risk Management Assessment Reports: The New Medical Writing Challenge	TRK 6	Session	LEVEL ■	W184bc
#346	What Happens When the Paper Goes Away? Clinical Data Process, Standards, and Quality Where EHR and EDC Meet	TRK 7	Symposium	LEVEL ■	W470a
#347	Quality Through Standards	TRK 8 (A)	Symposium	LEVEL ◆	W470b
#348	ePRO Industry Update: What the Literature Says, Mixed Modalities, and ePRO for Monitoring	TRK 8 (B)	Symposium	LEVEL ■	W471a
#349	Virtual Realities: Quality Considerations When Using Outsource Providers	TRK 9 (A)	Symposium	LEVEL ■	W185bc
#350	Key Considerations for Development of Biologic Therapeutics	TRK 9 (B)	Session	LEVEL ■	W183b
#351	Scientific Advice in Europe: How to Get the Best Out of It?	TRK 9 (C)	Session	LEVEL ◆	W185a
#352	Global Marketing Authorization: Expected Regulatory Agency Review Timelines and Practical Experience	TRK 9 (D)	Session	LEVEL ●	W471b
#353	Off-label Use: Practical and Legal Issues	TRK 10 (A)	Session	LEVEL ■	W180
#354	Economic Transparency of Drug Development	TRK 10 (B)	Symposium	LEVEL ■	W181a
#355	Signal Detection, Strengthening, and Management Based on Clinical Trial, Spontaneous Claims, and EHR Data	TRK 11 (A)	Symposium	LEVEL ■	W184a
#356	Pharmacovigilance: How to Do More with Less	TRK 11 (B)	Forum	LEVEL ●	W183c
#357	Statistical Consideration for Assessment of Follow-on Biologics	TRK 12	Session	LEVEL ■	W181bc
#358	Using Real-world Data for Making Real-world Decisions	TRK 13	Symposium	LEVEL ■	W184d
#359	Roadmap to Efficient Development of Companion Diagnostics	TRK 14	Session	LEVEL ■	W186abc
#360	Growing Through Giving: Professional Development Through Patient Advocacy and Volunteerism	TRK 15 (A)	Session	LEVEL ●	W474a
#361	Job Insurance: Career Planning that Prepares You for the Expected … and the Unexpected	TRK 15 (B)	Workshop*	LEVEL ●	W475a
#362	The State of Electronic Submissions at CDER, CBER, and CDRH	TRK 16 (A)	Session	LEVEL ●	W187abc
#363	APEC (Asia-Pacific Economic Cooperation) Town Hall	TRK 16 (B)	Forum	LEVEL ●	W185d
WEDNESDAY, JUNE 22	3:30 PM – 5:00 PM				
#364	Global Clinical Trials	TRK 1 (A)	Symposium	LEVEL ■	W175abc
#365	Pharmacogenetic Research and Informed Consent	TRK 1 (B)	Session	LEVEL ■	W176abc
#366	The Clinical Study Process: What Is Wrong? What Can Be Done?	TRK 1 (C)	Symposium	LEVEL ■	W183a
#367	Tools and Techniques for Optimal Drug Development Portfolio Planning: Portfolio Selection, Resource Allocation, and Risk Mitigation	TRK 2	Session	LEVEL ◆	W179a
#368	Innovative Partnering in Early R&D	TRK 3 (A)	Session	LEVEL ●	W178ab

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
WEDNESDAY, JUNE 22	3:30 PM – 5:00 PM *continued*				
#369	The New Frontier in Outsourcing: Regulatory Affairs and Safety	TRK 3 (B)	Session	LEVEL ■	W183b
#370	The Eyes Have It! The Unique Advantages of Clinical Research in Ophthalmology Trials: PK/PD and Biomarkers in Ophthalmology	TRK 4 (A)	Session	LEVEL ●	W179b
#371	Model-based Drug Development: How In-silico Approaches Are Reshaping the Clinical Enterprise	TRK 4 (B)	Forum	LEVEL ■	W184a
#372	Prescription Drug Marketing Regulatory Primer	TRK 5	Workshop*	LEVEL ●	W474b
#373	Using the Medical Writing Competency Model to Take Charge of Your Personal and Professional Development	TRK 6	Session	LEVEL ■	W184bc
#374	Why Is It So Hard to Combine Data Streams Collected in Clinical Trials?	TRK 7	Session	LEVEL ■	W470a
#375	Best Practices in Managing External Data	TRK 8	Session	LEVEL ■	W470b
#376	Quality Risk Management in Clinical Trials: Regulators' and Industry's Points of View	TRK 9 (A)	Forum	LEVEL ■	W185bc
#377	Co-development of Two Novel Investigational Drugs for Use in Combination	TRK 9 (B)	Session	LEVEL ■	W186abc
#378	The Challenges of Improving the Science of Regulatory Decision Making	TRK 9 (C)	Forum	LEVEL ■	W187abc
#379	NDA/BLA Analysis Files: Improving Specifications and Communication	TRK 9 (D)	Session	LEVEL ■	W471a
#380	Risk Communication in an Age of Uncertainty: The Legal, Regulatory and Compliance Implications of Disclosing Safety Information	TRK 10	Symposium	LEVEL ■	W180
#381	Good and Bad Behaviors During a PV Inspection	TRK 11 (A)	Workshop*	LEVEL ■	W475a
#382	REMS Model for Drug Safety	TRK 11 (B)	Session	LEVEL ●	W183c
#383	Adaptation and Decision Making at the Development Program Level	TRK 12	Session	LEVEL ■	W181bc
#384	Encouraging Comparative Effectiveness Research While Protecting Privacy: Can We Develop a Research Safe Harbor for CER?	TRK 13	Forum	LEVEL ■	W184d
#385	Pediatric Cardiovascular Drug and Devices Development	CANCELLED			
#386	The Importance of Figuring Human Resources into the Professional Development Formula	TRK 15	Session	LEVEL ●	W474a
#387	Regulatory Updates from Canada Including Special Projects	TRK 16 (A)	Forum	LEVEL ■	W185d
#388	CBER Town Hall	TRK 16 (B)	Forum	LEVEL ■	W185a
THURSDAY, JUNE 23	9:00 AM – 10:30 AM				
#401	Fit for Purpose Patient Recruitment Staffing: Evolving Patient Recruitment Organizations Within Sponsors and CROs	TRK 1	Session	LEVEL ■	W175abc
#402	Strategic Development Planning: Designing Fast and Efficient Programs	TRK 2 (A)	Workshop*	LEVEL ■	W474b
#403	Managing R&D Projects with Limited Resources: Small to Medium Biopharmaceutical/Biotechnology Enterprises (SMBEs)	TRK 2 (B)	Session	LEVEL ■	W179a
#404	New Global CRO Models for Small-sized CROs	TRK 3	Session	LEVEL ■	W178ab
#405	Strategic Regulatory Input to Nonclinical and Early Clinical Development: Minimizing Risk and Maximizing Health Authority Interest	TRK 4	Session	LEVEL ■	W183a
#406	Virtually Impossible? How to Create a Great Virtual Medical Writing Team in the Global Workplace	TRK 6	Symposium	LEVEL ◆	W184bc

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

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

Number	Title of Offering	Track Number	Type of Format	Level of Difficulty	Room Number
THURSDAY, JUNE 23	9:00 AM – 10:30 AM *continued*				
#407	Managing a Private Cloud Computing Environment	TRK 7	Forum	LEVEL ■	W470a
#408	Research Collaboration in the Cloud: How NCI and Research Partners Are Using Digital Identities to Accelerate Medical Advance	TRK 8	Session	LEVEL ■	W470b
#409	Vendor Qualification Audits for SaaS Suppliers	TRK 9	Session	LEVEL ◆	W185d
#410	Drug Shortages in the Treatment of Rare and Orphan Diseases: Challenges, Compromises, and Choice	TRK 10	Session	LEVEL ■	W180
#411	The Public Health Burden of Acetaminophen Poisonings: Risk Management Efforts to Mitigate It	TRK 11	Session	LEVEL ●	W184a
#412	Adaptive Designs for Clinical Trials: Novel Case Studies	TRK 12	Session	LEVEL ■	W181bc
#413	Critical Issues Related to Evidence Generation, Evaluation, and Standards for Comparative Effectiveness Research	TRK 13	Symposium	LEVEL ■	W184d
#414	Training: Hot Issues	TRK 15	Symposium	LEVEL ■	W474a
#415	CDER Town Hall: Part 1	TRK 16	Forum	LEVEL ●	W187abc
THURSDAY, JUNE 23	10:45 AM – 12:15 PM				
#416	Tips on Negotiating a Clinical Trial Agreement and Budget	TRK 1 (A)	Session	LEVEL ◆	W175abc
#417	Electronic Patient-reported Outcomes (ePRO): How to Maximize Patient-reported Information for Your Studies	TRK 1 (B)	Session	LEVEL ■	W176abc
#418	Quality Risk Management in Clinical Drug Development: A New Approach to De Novo Risk Identification and Proactive De-risking	TRK 2	Session	LEVEL ■	W179a
#419	Innovative Measurement and Improvement Techniques for Strategic Partnerships: A Pharma/CRO Collaboration Experience	TRK 3	Session	LEVEL ■	W178ab
#420	Cytokine Release Syndrome: Past, Present, and Future	TRK 4	Session	LEVEL ■	W183a
#421	Experiencing the Integration of Authoring, Information Management, and Submission Publishing: Topic-based Structured Content	TRK 6	Workshop*	LEVEL ●	W474b
#422	Journey to the Cancer Knowledge Cloud: Enabling 21st Century Drug Discovery and Development	TRK 7	Session	LEVEL ■	W470a
#423	MedDRA® Coding: Quality Issues and Relationship to CTCAE	TRK 8	Symposium	LEVEL ■	W470b
#424	China-Japan-Korea Joint Research on Ethnic Factors in Clinical Data	TRK 9	Session	LEVEL ■	W185d
#425	How Clinical Trials Can Contribute to Europe's 2020 Agenda	TRK 10	Session	LEVEL ■	W180
#426	Implementing Adaptive Designs	TRK 12	Session	LEVEL ■	W181bc
#427	"Reportedly" Trained? Uncovering the Industry's Dirty Little Secret Regarding Training Effectiveness	TRK 15	Forum	LEVEL ●	W474a
#428	CDER Town Hall: Part 2	TRK 16	Forum	LEVEL ●	W187abc

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

Saturday, June 18 – Monday, June 20

Saturday, June 18

9:00 AM – 5:00 PM **Exhibitor Registration**
Exhibit Hall Entrance, Level 3

Sunday, June 19

8:00 – 9:00 AM **Registration for Full-day and Morning Preconference Tutorials**
Exhibit Hall Entrance, Level 3

8:00 AM – 6:00 PM **Exhibitor Registration**
Exhibit Hall Entrance, Level 3

12:30 – 1:00 PM **Registration for Afternoon Preconference Tutorials**
Exhibit Hall Entrance, Level 3

3:00 – 6:00 PM **Attendee and Speaker Registration**
Exhibit Hall Entrance, Level 3

Sunday, June 19 — DIA 2011 STUDENT FORUM

3:00 PM – 5:00 PM LEVEL: ● Format: **FORUM**
Room W185a

Jobs That Did Not Exist When the Old Guard Began Their Careers

CHAIRPERSON

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

Today's job landscape in the pharmaceutical/device industry is dramatically different than it was 20 years ago. Several events in the early 1990s, primarily the passage of the Prescription Drug User Fee Act (PDUFA), created changes in the way that the US Food and Drug Administration regulated the drug development process and provided opportunities to fund upgraded technology for expediting the review process. The International Conference on Harmonisation's efforts to provide standardized approval processes affected the therapeutic industries worldwide. These events had a global impact on the types of skills needed and positions available in the industries.

This student forum will explore the evolution of the current set of available positions and describe the opportunities that have been created because of the changes implemented over the past two decades.

STUDENT FORUM PANELISTS

How Times Have Changed: A Case Study
Rebecca J. Anderson, PhD
Freelance Technical Writer

Regulatory Operations Perspective on the Evolution of Submission Publishing Years
Laura J. Sherman, MBA
Managing Partner, Distributed Compliance Solutions, LLC

Monday, June 20

7:00 AM – 6:30 PM **Speaker Registration**
Exhibit Hall Entrance, Level 3

7:15 – 8:15 AM **Orientation/Speed Networking and Coffee for DIA 2011 First Timers**
W375a, Level 3

7:30 – 8:15 AM **Coffee and Breakfast Breads**
Skyline Ballroom Lobby, Level 3

7:30 AM – 6:30 PM **Attendee Registration**
Exhibit Hall Entrance, Level 3

7:30 AM – 6:30 PM **Exhibitor Registration**
Exhibit Hall Entrance, Level 3

8:30 – 10:00 AM **Opening Plenary Session**
Skyline Ballroom, W375cde, Level 3

9:00 AM – 6:30 PM **Exhibition Hall Open**
Level 3

10:00 – 10:30 AM **Orientation and Coffee for DIA 2011 First Timers**
W375a, Level 3

10:00 AM – 6:30 PM **Student Poster Session**
Exhibit Hall, Level 3

5:00 – 6:30 PM **Welcome Reception**
Exhibit Hall, Level 3

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Start, join, and engage in discussions around DIA 2011 and receive up-to-the-minute information on hot topics, new speakers, and networking events.

Participate in discussions and stay up to date on DIA 2011 happenings. "Like" DIA on Facebook.

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Speakers 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.

8:30 AM – 10:00 AM **OPENING PLENARY SESSION**

Skyline Ballroom, W375cde, Level 3

Welcome Remarks and Awards Presentation

Richard O. Day, MD, PhD
Professor of Clinical Pharmacology, Therapeutics Centre, St. Vincent's Hospital, Australia

Opening Remarks

DIA 2011 Program Chairperson
Kenneth A. Getz, MBA
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

Keynote Address

David D. Ho, MD
Founding Scientific Director and CEO
The Aaron Diamond AIDS Research Center
Irene Diamond Professor, Rockefeller University

10:00 AM – 10:30 AM **REFRESHMENT BREAK**

Exhibit Hall, Level 3 (See Floor Plan, page 131)

ANNUAL MEETING OFFERINGS BEGIN

#101 Track 1 (A): Clinical Operations

10:30 AM – 12:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W475a *CME and Nursing credits offered*

Site Selection Process Workshop: Identifying, Selecting, and Defining a Quality Investigator Site

CHAIRPERSON

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

This workshop will also be offered on Tuesday, June 21, at 1:30 PM.

Less presentation … more discussion! This workshop will offer sponsors, CROs, and investigator sites an interactive environment to discuss the site selection process and establish how to define quality at the site level.

The workshop will consist of three, short presentations from a sponsor, CRO, and investigator site followed by roundtable breakout sessions. At the conclusion of roundtables, a chairperson from each table will present conclusive findings followed by a Q&A session.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

Partnering for Better Performance: Sponsor, Site, and CRO Views on Best Practices in Clinical Trial Conduct
Kevin E. Renahan, MSc, MBA
Executive Director, Investigator Relations, Clinical Development Services, Covance Inc.

Feasibility: Sailing into Uncharted Waters by Doing More with Less – Plans to Reduce Time, Cost, and Percentage of Nonactive Sites
Nye G. Pelton
Clinical Portfolio Consultant - Enrollment, Eli Lilly and Company

#102 Track 1 (B): Clinical Operations

10:30 AM – 12:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W175abc *CME and Nursing credits offered*

Innovative Clinical Operations Methodology for Global Trial Management

CHAIRPERSON

Ross D. Pettit, MBA
Vice President, Clinical Operations, AMAG Pharmaceuticals, Inc.

This symposium will include presentations on successfully managing multiprovider trials, managing and conducting large international trials by patchwork teams, and best practices and strategies in subject recruitment and retention in the field.

Yours, Mine, and Ours: Optimize Patchwork Operations
Regina Freunscht
Director, Clinical Operations, Marketing and Communications, Accovion GmbH, Germany

Why Can't We All Get Along: Managing Multiprovider Trials
Rikki Hansen Bouchard, MPA
President and Chief Executive Officer, RH Bouchard & Associates Inc.

Re-empowering the Sponsors and CRAs in Patient Recruitment
Joseph Kim, MBA
Director of Clinical Operations, Shire PLC

#103 Track 1 (C): Clinical Operations

10:30 AM – 12:00 PM LEVEL: ■ Format: **FORUM**
Room W176abc *CME and Nursing credits offered*

Clinical Research in Emerging Regions: A Forum for Exchange

CHAIRPERSON

Nancy Meyerson-Hess, MSc
Compound Development and Branding, Grunenthal, Germany

Today's clinical research requires adaptation. This forum will address and propose tactics for use in integrating emerging regions into global projects. Experts will present case histories and provide practical input.

The Joys and Pains of Running Clinical Studies in Latin America
Eduardo F. Motti, MD
Regional Head, Clinical Operations, Pfizer Inc, Brazil

Targeted Clinical Trials in Asia: Part of Global IND or NDA for China and Japan?
Yan Wu, MD
Director, Medical and Clinical Development, Biogen Idec Inc., China

Quality of Clinical Data Generated in Emerging Regions: Regulatory Perspective
Cynthia Kleppinger, MD
Medical Officer, Division of Scientific Investigations, Office of Compliance, CDER, FDA

#104 Track 2 (A): Development Planning

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W179a *CME and Nursing credits offered*

Protocol Design and Subsequent Amendments: Understanding the Benefits of Well Designed Protocols

CHAIRPERSON

Anne B. Cropp, PharmD
Executive Director, Pfizer Inc

This session will provide data on the causes of protocol amendments, the direct and indirect impact amendments, and techniques, metrics, and benchmarks that can be used to enhance study design up front in order to minimize the burdens and costs imposed by protocol amendments.

Overview
Anne B. Cropp, PharmD
Executive Director, Pfizer Inc

Protocol Design and Subsequent Amendments: Understanding the Data
Rachael Zuckerman, MPH
Senior Research Analyst, Center for the Study of Drug Development, Tufts University

The Hidden Costs of Protocol Amendments
Anna L. Hindle, MSc
Director, Head of Medical Writing Operations, Biogen Idec

Challenging Study Design to Reduce Cost and Complexity
Michelle Marlborough
Manager, Product Management, Medidata Solutions Worldwide

#105 Track 2 (B): Development Planning

10:30 AM – 12:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W179b *CME and Nursing credits, PMI PDUs offered*

Asian Global Development and Regulatory Strategies

CHAIRPERSON

Gregg Schneider
Director, R&D Financial Management, Otsuka Pharmaceutical Commercialization & Development

This symposium will include presentations that will address meeting global regulatory requirements in Asian countries while keeping cultural barriers, critical chain implementation, and varying needs of a global virtual team in mind. A review of the changing regulatory and economic environment in Asian countries will be presented as well as regulatory strategies for simultaneous global drug development in those countries.

Regulatory Strategies for Simultaneous Global Drug Development in Northeast Asia
Herng-Der Chern, MD, PhD
Distinguished Research Fellow, Center for Drug Evaluation, Taiwan

Asian Country Perspective as Part of Global Development and Registration Strategy
Hideo Yoshida
Director, Regulatory Affairs – Japan, Amgen Inc.

Integrating Japan into a Global Submission Plan
Jim L. Vandergriff, II
Project Management Consultant, Eli Lilly and Company

#106 Track 3: Outsourcing Strategies and Innovative Partnering Models

10:30 AM – 12:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W474b *CME and Nursing credits offered*

Alliance Management: How to Start and Maintain Alliance Teams and Create Value

CHAIRPERSON

Ailsa Mendez, MBA, PMP
Senior Director, Program and Alliance Management, Functional Genetics

Success in drug development lies in team leadership as well as the characteristics of the biopharmaceutical drug. This workshop will discuss alliance management involvement in contract negotiation and start-up and maintenance of alliance teams.

Attendees will work in small groups to discuss case studies, create an alliance roadmap and work on alliance tools and templates.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

David Chapnick
Senior Consultant, Vantage Partners

#107 Track 4: Nonclinical and Early Clinical Translational Development

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W183a *CME and Nursing credits offered*

The Role of Biomarkers in the Rapid Development of New Medicines: A Scientific and Regulatory Perspective

CHAIRPERSON

Cecil J. Nick, MS, FTOPRA
Vice President (Technical), PAREXEL Consulting, UK

This session will address the potential role for biomarkers in accelerating and facilitating development of new medicines and initiatives introduced by the regulatory agencies such as the EMA and FDA.

EMA Perspective
Spiros Vamvakas, MD
Head of Scientific Advice, European Medicines Agency, European Union

Biomarkers in Drug Development and Biomarker Qualification: A View from FDA
Marc K. Walton, MD, PhD
Associate Director, Office of Translational Sciences, CDER, FDA

#108 Track 6: Medical Writing and Communication

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W184bc *CME, Nursing, and Pharmacy credits offered*

Incorporating Compliance into Everyday Practice

CHAIRPERSON

Joyce Martin, PharmD
Senior Manager, Quality Assurance, Compliance, and Training, MA Compliance, Genentech, Inc.

This session will discuss evolving compliance topics faced by medical communications professionals and describe areas of consideration for evaluating compliance and building an inspection-ready department.

Medical Communications and Compliance: Aiming for Inspection Readiness
Joyce Martin, PharmD
Senior Manager, Quality Assurance, Compliance, and Training, MA Compliance, Genentech, Inc.

Bridging Clinical Product Knowledge Gaps by Training Key Opinion Leaders to Function as Medical Science Liaisons
Tamar S. Yarkoni, PharmD
Manager, Medical Information, sanofi-aventis

#109 Track 7 (A): IT Methods and Technologies

10:30 AM – 12:00 PM LEVEL: ● Format: **SESSION**
Room W471a *CME and Nursing credits offered*

Blurring the Boundaries Between Technologies: Examples of Next Generation Clinical Trial Technology Integration

CHAIRPERSON
Bill Byrom, PhD
Senior Director of Product Strategy, Perceptive Informatics, UK

Clinical trials have become more global and complex. With this, we have seen an increased use of technology and an increased expectation of the way technologies will improve processes, workflow, study management and conduct. Biopharmaceutical companies and investigators face the problem that the operation of clinical trials requires access to multiple applications and data sources which can complicate workflow and create additional activity in keeping the information in each aligned.

This session will explore some practical examples of integration and convergence of technology applications and data to simplify clinical trial operation.

Decision Support Methodology Implemented on a Clinical Trial
Rebecca Wilgus, BSN, MSN
Project Lead, Clinical Research Informatics, Duke Clinical Research Institute

Adaptive Research Infrastructure: Clinical–IT Alignment
Maulik Shah, MS
Senior Vice President, MaxisIT Inc.

Blurring the Boundaries Between Technologies
Bill Byrom, PhD
Senior Director of Product Strategy, Perceptive Informatics, UK

#110 Track 7 (B): IT Methods and Technologies

10:30 AM – 12:00 PM LEVEL: ● Format: **SESSION**
Room W470a *CME and Nursing credits offered*

Real-world Applications of BRIDG

CHAIRPERSON
Dave Parrish, MS, MT
Chief Architect for Health Informatics, Digital Infuzion Inc.

This session will examine the challenges that companies face as well as the value obtained from implementing BRIDG in the real world, as a common data model for systems integration and interoperability and to enable content re-use.

BRIDG: Moving from a Domain Analysis Model to a Common Data Model – A Case Study
Terry D. Hardin
Director, Technology Integration and Data Standards, PAREXEL International

Application of the BRIDG to a Clinical Information Management Strategy
Irene S. Dubman, MA
Senior Director, Global Biomedical Informatics, Genzyme Corporation

#111 Track 8: Research Data and Content Management

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W470b *CME, Nursing, and Pharmacy credits offered*

Experiences with the Development of Disease-specific Standards for Data, Terminology, and Use Cases for Regulatory Science

CHAIRPERSON
Christine Tolk
Director, Terminology, CDISC

This session will outline the background, current status, and future direction in the development of disease standards collaboration between CDISC and CPath.

The Standardized Data Collection for Cardiovascular Trial Initiative
Brian J. McCourt
Associate Director, Clinical Research Informatics, Duke Clinical Research Institute

Standardized Data for Alzheimer's Disease
Jonathan Neville
Assistant Program Director, CAMD, Critical Path Institute

Data Standardization for Polycystic Kidney Disease
Dana Miskulin, MD, MSc
Clinical Staff, Nephrology Research, Tufts Medical Center

#112 Track 9 (A): Regulatory Affairs and Science, Quality, and GXP Compliance

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W185bc

Managing Liability and Risk from GCP Noncompliance

CHAIRPERSON
Kevin Quinley, MA
Vice President, Risk Services, Berkley Life Sciences, LLC

Drug companies can face legal liabilities and costs of liability claims. Companies must be aware of liability risks from the clinical trial process and need to be prepared with risk management strategies and techniques to manage clinical trials.

Risk in Clinical Trials
Bruce M. Wagman, MBA, RN, RAC
Vice President, Regulatory Affairs and Quality Assurance Services, Covance Inc.

Managing Liability and Risk from GCP Noncompliance
Lisa Balcerak, MBA
Senior Director, Global Risk Management, Quintiles

Walter (Pete) Swayze, III, JD
Managing Partner, Segal McCambridge Singer & Mahoney, Ltd.

#113 Track 9 (B): Regulatory Affairs and Science, Quality, and GXP Compliance

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W185a *CME and Nursing credits offered*

Update on ICH Topics: Q11 Small Molecules and Biotech, Q8/9/10 Implementation Working Group, Q4B Harmonization of Compendial Test Chapters

CHAIRPERSON

Robert G. Baum, PhD
United States

In this session, the latest activities of the ICH Q8, Q9, Q10 implementation working group will be discussed. Participants will receive an update on the development of the ICH guideline Q11 on the development and manufacture of drug substances (chemical and biotechnological entities), and an overview of the achievements in the area of harmonization of compendial test chapters.

Update on ICH Quality Guidelines Q8, Q9, Q10 Implementation Working Group
Moheb M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA

ICH Q11: Development and Manufacture of Drug Substances – New Chemical Entities and Biotechnological Entities
Betsy P. Fritschel
Director, Quality & Compliance Worldwide, Johnson & Johnson

Overview of ICH Q4B: Harmonization of Compendial Test Chapters
Janeen Skutnik-Wilkinson
Director, Quality and Regulatory Policy, Pfizer Inc

#114 Track 9 (C): Regulatory Affairs and Science, Quality, and GXP Compliance

10:30 AM – 12:00 PM LEVEL: ■ Format: **FORUM**
Room W185d *CME and Nursing credits offered*

Issues in Pediatric Global Development

CHAIRPERSON

Samuel D. Maldonado, MD, MPH
Vice President, Head of Pediatric Drug Development Center of Excellence, Johnson & Johnson Pharmaceuticals Research & Development, LLC

US and European laws and regulations are driving pediatric drug development within the pharmaceutical industry. However, the regulatory processes in the US and EU are significantly different including the timing when regulators expect to discuss pediatric drug development plans with industry. Due to these differences, there are difficulties in constructing a global pediatric plan at least initially. In addition to this, there has been criticism on the geographical scope of some pediatric programs.

Dirk Mentzer, DrMed
Vice Chair of PDCO; Head of Pharmacovigilance Unit, Paul-Ehrlich-Institut, Germany

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

#115 Track 10: Public Policy/Health Care Compliance

10:30 AM – 12:00 PM LEVEL: ● Format: **WORKSHOP**
Room W180 *Pharmacy credits offered*

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. McCormick Place 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.

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

#116 Track 11 (A): Clinical Safety and Pharmacovigilance

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W184a *CME, Nursing, and Pharmacy credits offered*

Natural History of Disease: An Often Overlooked Study Concept

CHAIRPERSON

Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management, United BioSource Corporation

The benefits of natural history of disease studies, their application across the drug development life cycle focused on safety, and how they are designed and conducted will be discussed. A case study will be shared to demonstrate its application to the product's risk profile.

Use of Clinical Trial Data to Inform Natural History Studies
Christine Velicer, PhD
Associate Director, Epidemiology, Department of Epidemiology, Merck & Co., Inc.

Understanding Natural History of Disease as Treatment Paradigms Are Evolving
Gregory F. Keenan, MD
Vice President, Medical Affairs, Human Genome Sciences, Inc.

Why Study the Natural Disease?
Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management, United BioSource Corporation

#117 Track 11 (B): Clinical Safety and Pharmacovigilance

10:30 AM – 12:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W183b *CME and Nursing credits offered*

Global Pharmacovigilance Systems: Foundations for Compliance

CHAIRPERSON

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

This symposium of presentations will examine foundations of pharmacovigilance compliance on a global scale, including the selection of a safety system, the essentials of safety data exchange agreements, and the creation of effective company core data sheets.

Configuration of Safety Systems: What It Buys You and What It Costs You!
John Whitebrook, PhD
Drug Safety Practice Partner/UK Country Manager, Intrasphere Technologies Ltd., UK

The Essentials of Effective Safety Data Exchange Agreements: Dos and Don'ts
Anthony Castrilli, Jr., JD
Operations Director, Global Regulatory Affairs and Safety, Amgen Inc.

Creating an Effective Company Core Data Sheet
Kosta Cvijovic, PhD, MPharm
Manager, Pharmacovigilance, i3 CanReg, Canada

#118 Track 12: Statistics

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W181bc

Hot Topics in Statistics

CHAIRPERSON

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

This session will highlight emerging topics of relevance and interest to statistics.

Statisticians as Leaders: Why It Is Increasingly Important and What It Means
Walter W. Offen, PhD
Senior Research Fellow, Global Statistical Sciences, Eli Lilly and Company

Important Findings Generated by the Observational Medical Outcomes Partnership
David Madigan, PhD
Professor and Chair, Department of Statistics, Columbia University

Patient-reported Outcomes: The Need for Statistical Innovation
Lisa A. Kammerman, PhD
Mathematical Statistician (Biomedical), Office of Biostatistics, Office of Translational Sciences, CDER, FDA

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

10:30 AM – 12:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W181a *CME, Nursing, and Pharmacy credits offered*

The Patient Perspective: Start Leveraging This Important Stakeholder to Maximize Commercial Potential

CHAIRPERSON

Jean Paty, PhD, MS
Founder and Senior Vice President, Scientific, Quality and Regulatory Affairs, invivodata, Inc.

This symposium will discuss how patient-reported endpoints can influence the product life cycle from instrument development and validation, to integration into product labeling, and to tracking real-world effectiveness post launch. In addition to how data is used, this symposium will discuss traditional and emerging methods for patient data collection.

Measuring Treatment Satisfaction with Medication from Patients' Perspective: Conceptual Models and a Review of Measures
Eric Karel Gemmen, MA
Senior Director, Epidemiology and Outcomes Research, Quintiles, Inc.

Don't Forget about the Patient! How Online Communities Present New Opportunities for Health Economics Outcomes Research (HEOR) and CER
Elisa F. Cascade, MBA
Vice President, MediGuard

Patient-reported Outcome Measures of Treatment Benefit
Jean Paty, PhD, MS
Founder and Senior Vice President, Scientific, Quality and Regulatory Affairs, invivodata, Inc.

#120 Track 14: Medical Devices

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W184d

Recent Reformation on Medical Device Regulatory Systems in the Asia-Pacific Region

CHAIRPERSON

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

Asian agencies are reforming their regulatory systems for new medical devices. The Taiwan FDA is emphasizing medical devices in its systems, and Korea and Japan are improving the efficiency of theirs. This session will discuss the advancement of Asian device regulatory pathways and their impact on industry.

Updating for the Device Regulations in Taiwan
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Representative Invited
Food and Drug Administration, Department of Health, Taiwan

Recent Regulatory Environment of Asia: An Industry Perspective
Kathy Harris, MBA
Director, Regulatory Strategy - Asia Pacific, Depuy Franchise, a Johnson & Johnson Company

The Current Reformation of Regulatory System in Korea
Representative Invited
Deputy Director, Korean Food and Drug Administration, Republic of Korea

#121 Track 15: Professional Development and Training

10:30 AM – 12:00 PM LEVEL: ● Format: **SESSION**
Room W474a *PMI PDUs offered*

Current Status of Global Clinical Research and Pharmaceutical Medicine Education

CHAIRPERSON

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

Academic programs have been developed globally to educate new clinical trial personnel. This session will discuss the evolving academic discipline and efforts to define core competencies and develop personnel certification and academic program accreditation standards.

Challenges and Solutions of Clinical Research Training in the Emerging Markets
Jean-Paul M.F. Deslypere, MD, PhD
CEO, Aesculape CRO Pte Ltd., Singapore

Current Status of Global Clinical Research and Pharmaceutical Medicine Education
Antony Melvin Paul, MSc
Senior Manager, Learning and Development, Clintec International Pvt. Ltd., India

#122 Track 16 (A): Global Agency

10:30 AM – 12:00 PM LEVEL: ■ Format: **SESSION**
Room W186abc

Annual CDER eSubmission Update: Review and Technical Perspectives

CHAIRPERSON

Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, CDER, FDA

As CDER moves towards an all-electronic environment, tools must be implemented and challenges faced. This session provides practical information and advice regarding eCTD and SDTM formats, current issues faced and how to achieve submission success.

Charles K. Cooper, MD
Medical Officer, Office of Translational Sciences, CDER, FDA

Sean Y. Kassim, PhD
Pharmacologist, Office of Compliance, CDER, FDA

eCTD: A Clinical Reviewer's Side of the Story
Christine P. Nguyen, MD
Medical Officer, Division of Reproductive and Urologic Products, Office of New Drugs, CDER, FDA

#123 Track 16 (B): Global Agency

10:30 AM – 12:00 PM LEVEL: ● Format: **FORUM**
Room W183c

European Heads of Medicines Agencies (HMA) Town Hall

CHAIRPERSON

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

The network of the European Heads of Medicines Agencies is a unique model for cooperation and work sharing on statutory as well as voluntary regulatory activities. This forum aims at introducing the system, some of its main initiatives and actors.

Guido Rasi, MD
Director General, Italian Medicines Agency (AIFA), Italy

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

Christa Wirthumer-Hoche, PhD
Deputy Head, AGES PharmMed, Austria

#124 Track 18: Late Breaker

10:30 AM – 12:00 PM LEVEL: ● Format: **SESSION**
Room W471b *CME and Nursing credits offered*

Vaccines for Low- and Middle-income Countries: Navigating Unique Regulatory Challenges

CHAIRPERSON

Developed by the Bill and Melinda Gates Foundation

As the world's attention to global health increases, it is marked by mobilization of greater resources for the development of innovative health tools to prevent, diagnose, and treat diseases that disproportionately afflict the poor. There are now over 20 candidates in the pipeline for diseases that were largely neglected for many years. This is generating great optimism.

However, significant concern is emerging based on a clearer appreciation of the enormity of the task at hand. Constraints on the required infrastructure in high-burden regions currently limit the optimum use of existing tools, and limit the development, approval, and introduction of novel tools. Pneumococcal and meningococcal conjugate vaccines, along with rotavirus vaccines, are gradually being introduced in low- and middle-income countries (LMIC), with malaria and TB vaccines to follow in the coming years. LMIC often lack sufficient technical skills and resources to regulate clinical trials authorization, registration, and post-licensure oversight of vaccines. It is thus critical to fully understand the value chain of vaccine discovery through development to introduction, and finally impact assessment, in LMIC.

In this session, panelists will review the current state of understanding of regulatory constraints in LMIC, highlight solutions being developed through multistakeholder collaborations, and share relevant insights from case studies.

PANELISTS

Vincent Ahonkhai, MD
Senior Regulatory Officer, Global Health Delivery, Bill and Melinda Gates Foundation

Lembit Rägo, MD, PhD
Coordinator, Quality and Safety, Medicines, Policy, and Standards, World Health Organization, Switzerland

Sara Gagneten, PhD
Regulatory Scientist, Office of Vaccines Research and Review, Division of Vaccines and Related Products Application, CBER, FDA

12:00 PM – 1:30 PM **LUNCHEON**
Exhibit Hall, Level 3, Lunch Distribution Area (see Floor Plan, page 131.) See page 8 for instructions on using your lunch vouchers.

#125 Track 1 (A): Clinical Operations

1:30 PM – 3:00 PM LEVEL: ● Format: **SYMPOSIUM**
Room W175abc *CME and Nursing credits offered*

Factors Impacting Investigative Site Performance and Investigator Participation in a Clinical Study

CHAIRPERSON

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

The symposium will consist of three presentations. One will look at the results of a survey examining investigator perceptions about various aspects of clinical trial performance and decisions to participate in a clinical study. The second will examine the role of EHR in enhancing site selection, improving enrollment predictability, and reducing cycle times. The third will focus on the importance of proper and effective PI oversight during a trial with respect to ensuring that tasks are appropriately delegated to reduce the margin of error in future audit and potential inspection findings.

Improve Site and Study Performance Through Disciplined Review of Protocol Executability: A Case Study
Beth D. Harper, MBA
Chief Clinical Officer, Centerphase Solutions, Inc.

Establishing Collaborative Relationships Between Sites and Sponsors
Deborah Howe
Senior Recruitment Manager, Bristol-Myers Squibb Company

Maintaining Effective PI Oversight in a Clinical Trial
Kim McLaughlin
Clinical Training Manager, Kforce Clinical Research

#126 Track 1 (B): Clinical Operations

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W176abc *CME and Nursing credits offered*

Electronic Medical Records for Patient Recruitment: Is It the Holy Grail?

CHAIRPERSON

James P. Kremidas
Vice President, Global Head of Patient Recruitment, Quintiles Inc.

The use of electronic medical records (EMRs) is being hailed as the holy grail to drive better design and execution of clinical trials. This session will focus on some real-life examples of how EMR has been used to drive those goals and the outcomes of these efforts.

Current Status of EMR Systems in Clinical Trial Recruitment
Gary M. Lubin, CPA, MBA
President and CEO, Centerphase Solutions, Inc.

Electronic Medical Records: Market Overview and Data Availability
Jaime Lucove, MPH
Scientist, Allscripts

Update on HIE Development
Otis Johnson, MPA
Manager, Global Trial Optimization (GTO), Clinical Research Operations, Merck & Co., Inc.

EMR and Clinical Trials: Operational Pilots and Lessons Learned
Jane E. Myles, MS
Global Head, Patient Recruitment, Genentech, Inc.

#127 Track 1 (C): Clinical Operations

1:30 PM – 3:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W475a *CME, Nursing, and Pharmacy credits offered*

Pediatric Protocol: Designing Clinical Trials to Minimize Child Risk and Enhance Study Outcomes

CHAIRPERSON

M. Renee Simar, PhD
Principal Strategist, Pediatrics, INC Research, Inc.

This workshop will evaluate pediatric clinical trial design by analyzing the complexities of pediatric protocols. Discussants will review practical aspects of design elements, then engage workshop participants in the review of a concept protocol.

Participants will be divided into role-playing groups to stimulate perspectives on protocol objectives, study risks, feasibility and patient burden. The groups will represent key stakeholders in the conduct of pediatric trials — regulators, sponsors, investigators, ethics committees and families.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

Pediatric Protocols: Planning for Success
Joseph P. Horrigan, MD
Director, Neurosciences Medicine Development Center, GlaxoSmithKline

Ronald Portman, MD
Group Director, Bristol-Myers Squibb Company

#128 Track 2 (A): Development Planning

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W179a *PMI PDUs offered*

Building Competencies in a Global Project Management Department

CHAIRPERSON

Eric M. Towler, PhD, PMP
Director, Global Project Management and Leadership, Daiichi Sankyo Inc.

This forum will review newly defined competencies required for effective project management (PM) and actual case studies describing the installation of these competencies in a global PM department. The case studies will focus on the process undertaken to effect the change, the critical success factors, any change management issues and a retrospective evaluation. An open panel discussion will follow the presentations.

Evolving Competencies for Project Managers in the Biopharmaceutical Industry
Martin D. Hynes, III, PhD
Senior Director, Six Sigma Champion, Research & Development, Eli Lilly and Company

Installing PM Competencies in Business Acumen
David A. Clark, PhD
Vice President, Portfolio Operations and Project Management, Pfizer Inc

Installing PM Competencies in Project Management Skills
Paul R. Bunch, PhD
Vice President, Global Project Management, Covance, Inc.

#129 Track 2 (B): Development Planning

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W179b *PMI PDUs offered*

Designing and Implementing a Drug Strategy Approach

CHAIRPERSON

Peter Harpum, MSc
Managing Director, Harpum Consulting Ltd., UK

R&D strategy provides the key framework within which all drug discovery and development work takes place. This session will address how it is essential to achieve the R&D strategy by ensuring drug projects in early and late phases deliver compounds.

Conceptualizing and Developing a Project Strategy Approach for Early Drug Development
Peter Harpum, MSc
Managing Director, Harpum Consulting Ltd., UK

Realizing and Implementing the Strategy Approach at a Large Pharma
Sandra R. Teixeira, PhD, MS
Associate Director, Research Management, Novartis Institute for Biomedical Research

#130 Track 3: Outsourcing Strategies and Innovative Partnering Models

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W178ab *CME and Nursing credits offered*

Reducing Micro-management of CROs While Maintaining Effective Quality Oversight: Results from a 2011 Industry Survey

CHAIRPERSON
Denise A. Calaprice-Whitty, PhD, MS
Executive Director, The Avoca Group Inc.

In a 2011 industry survey, we asked sponsors and service providers to share their views and specific practices regarding oversight of quality for outsourced clinical trials. The survey results will be presented.

John G. Harkins, MBA
Senior Director, Business Operations Integration, Otsuka Pharmaceutical Development & Commercialization, Inc.

Wayne Langlois
Vice President and General Manager, Global Phase II-IV Clinical Development, Covance Inc.

Winifred Ann Meeker-O'Connell, MS
Policy Advisor, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Jeffrey S. Kasher, PhD
Vice President, Global Clinical Development, Eli Lilly and Company

#131 Track 4: Nonclinical and Early Clinical Translational Development

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W183a *CME, Nursing, and Pharmacy credits offered*

CBER Therapeutic and Preventive Vaccines Update

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

The first therapeutic vaccine for prostate cancer was approved in 2010. New preventive vaccines, such as against malaria, are being developed. This session will discuss and review new technologies with evolving US requirements for therapeutic and preventive vaccines.

Update on CBER Regulatory Activities of Preventive Vaccines
Sara Gagneten, PhD
Regulatory Scientist, Office of Vaccines Research and Review, Division of Vaccines and Related Products Applications, CBER, FDA

Regulatory Considerations in the Safety Assessment of Adjuvants and Adjuvanted Preventive Vaccines
Carmen M. Collazo, PhD
Primary Reviewer; Microbiologist, Office of Vaccines Research and Review, CBER, FDA

Regulatory Considerations for Therapeutic Vaccines and Immunotherapy
Bharat H. Joshi, PhD
Chemist, Office of Cellular, Tissue and Gene Therapies, CBER, FDA

#132 Track 6: Medical Writing and Communication

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W184bc

The Growing Role of Medical Communications in Promotional Review

CHAIRPERSON
Stacey M. Fung, PharmD
Senior Manager, Medical Communications, BioOncology, Genentech, Inc.

This session will provide an overview of the services offered and challenges to success, including how to get your department involved in promotional review.

Promotional Review Training for Medical Communications Personnel and External Partners
Cathryn L. Anderson
Independent Consultant

Expansion of Medical Communications: A Pilot Program as the Medical Reviewer for Promotional Review
Tamar S. Yarkoni, PharmD
Manager, Medical Information, sanofi-aventis

Development of Tools for Medical Communications Personnel Reviewing Promotional Materials
Stacey M. Fung, PharmD
Senior Manager, Medical Communications, BioOncology, Genentech, Inc.

#133 Track 7: IT Methods and Technologies

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W470a

Smashing Silos and Building Relationships: Understanding and Measuring Value that Clinical IT Brings to Drug Development

CHAIRPERSON
Paulette V. Roper, MS
Senior Manager, eSolutions, Allergan, Inc.

We will focus on how to identify and measure clinical IT value and benefit, and relate these to cost, quality, and process improvements. Case studies from clinical IT groups in three pharma companies will be presented.

Clinical IT: How to Restore a Good Idea Gone Bad
Ronald S. Waife, MPH
President, Waife & Associates, Inc.

Leveraging the Clinical Research/Information Technology Love-hate Relationship to Make it Work for You
Beth Everett, PhD
Associate Vice President, Enterprise Information Management, SAIC

Stories of Wars Won and Lost: How Clinical IT Drives Additional Value from Better Use of Data
John Kim
Manager, R&D Business Technology, Pfizer Inc

#134 Track 8: Research Data and Content Management

1:30 PM – 3:00 PM LEVEL: ◆ Format: **SESSION**
Room W470b *CME, Nursing, and Pharmacy credits offered*

Measuring Symptoms: Methodological Considerations

CHAIRPERSON

Elisabeth Piault-Louis, MA
ORISE Fellow; Advisor to SEALD, CDER, FDA

This session will focus on how to identify and measure clinical IT value and benefit, and relate these to cost, quality, and process improvements. Case studies from clinical IT groups in pharmaceutical companies will be presented.

FDA Point of View
Laurie Burke, MPH, RPh
Associate Director, Study Endpoints and Label Development, Office of New Drugs, CDER, FDA

Jeremy Hobart, MD, PhD, FRCP
Professor and Consultant Neurologist, Peninsula College of Medicine and Dentistry; Universities of Plymouth and Exeter, UK

Thomas Hare
Vice President, Development Operations, Incyte Corporation

#135 Track 9 (A): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W185bc *CME and Nursing credits offered*

FDA and European Medicines Agency Update on GCP Inspections and the Conduct of Clinical Trials

CHAIRPERSON

Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

On September 1, 2009, the FDA and European Medicines Agency launched a bilateral good clinical practices (GCP) initiative designed to ensure that clinical trials submitted in drug marketing applications in the United States and Europe are conducted uniformly, appropriately, and ethically. Products regulated by the FDA's Center for Drug Evaluation and Research in the United States, and by the European Medicines Agency for the European Union will be the focus of the initiative. This session will provide a platform to discuss the ongoing FDA-European Medicines Agency GCP initiative.

EMA Perspective
Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

FDA Point of View
Cynthia Kleppinger, MD
Medical Officer, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Charity A. Abelardo, RAC
Senior Director, Regulatory Affairs Consultant, Valeant Pharmaceuticals International, Inc.

#136 Track 9 (B): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W185a

Electronic Labeling and Indexing Data Elements: Structured Product Labeling

CHAIRPERSON

Lonnie D. Smith
Policy Analyst, Data Standards Council and Office of Critical Paths, Office of the Commissioner, FDA

This session is designed for authors and users of electronic content of labeling and other regulatory product information available in SPL format.

Electronic Content of Labeling and Indexing Data Elements in SPL Format
Lonnie D. Smith
Policy Analyst, Data Standards Council and Office of Critical Paths, Office of the Commissioner, FDA

Taking Advantage of the Structured Product Label
Thomas R. Bizzaro, RPh
Vice President, Health Policy and Industry Relations, First DataBank

Structured Product Labeling: What More Could We Do?
Theresa Brunone, MA, MS
Assistant Director, Global Labeling, GlaxoSmithKline

#137 Track 9 (C): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W185d

Japan Registration and Global Drug Development: Post-2007 Case Studies

CHAIRPERSON

Alberto Grignolo, PhD
Corporate Vice President, Global Strategy and Services, PAREXEL Consulting

Japan is addressing its "drug lag" by calling for the inclusion of Japanese patients in multinational clinical studies. The session will illustrate sponsors' response to this new stance, and the fate of Japan NDAs that include non-Japanese patients.

Patrick J. O'Malley
Senior Director, International Regulatory Affairs, Eli Lilly and Company

Joseph C. Scheeren, PharmD
Senior Vice President, Head of Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals, Inc.

Hideo Yoshida
Director, Regulatory Affairs, Japan, Amgen Inc.

#138 Track 9 (D): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W183c *Pharmacy credits offered*

GMP Inspection and Compliance Issues

CHAIRPERSON

Joseph C. Famulare
Head of External Relations and Collaboration, Genentech, a Member of the Roche Group

Global complexity has resulted in increasing regulatory inspection activities. This session will discuss issues facing today's regulators in the inspection landscape and will also provide an industry view of meeting regional requirements when manufacturing products globally. The session will highlight the current opportunities and challenges in today's pharmaceutical manufacturing environment. Various issues will be highlighted from the latest ICH developments, updates on regulatory requirements, complex supply chains, and use of contract manufacturing organizations.

Balance Value, Effort, and Risk in GMP Inspections
Stephan Karl Roenninger, DrSc
Head of External Relations Europe/Japan, F. Hoffmann-La Roche Ltd., Switzerland

Point of View from the EMA
David J. Cockburn, Esq.
Head of Manufacturing and Quality Compliance, European Medicines Agency, European Union

Point of View from the FDA
Carmelo Rosa
Branch Chief, International Compliance Branch, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

#139 Track 10: Public Policy/Health Care Compliance

1:30 PM – 3:00 PM LEVEL: ● Format: **WORKSHOP**
Room W180 *Pharmacy credits offered*

Marketing Practices on Trial

CHAIRPERSON
Sandra A. Milligan, JD, MD
Executive Director, Amgen Inc.

A mock trial will highlight issues that may arise in lawsuits brought by US state or federal authorities against pharmaceutical companies based on health care false claim and off-label promotion allegations. 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. At the conclusion of the mock trial, the judge will solicit jury (audience) questions and impressions.

As jury members, participants in this judge-led mock trial will hear and evaluate the weight of evidence against a biopharmaceutical company accused of illegal marketing practices. Following opening statements, a State's attorney general and counsel for the company will examine and cross-examine witnesses, culminating in closing arguments. Following jury instructions, the jury will be allowed to ask questions and will be polled for a verdict.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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 F. Kamp, JD, PhD
Executive Director, Coalition for Healthcare Communication

John Brownlee, JD
Partner, Holland & Knight

#140 Track 11 (A): Clinical Safety and Pharmacovigilance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W183b *CME and Nursing credits offered*

Postmarketing Risk Management: Evolving Implementation for ETASUs

CHAIRPERSON
Mary Mease, MPH, RPh
Senior Director, Quintiles, Inc

Today's technology can provide an implementation platform for the Elements to Assure Safe Use (ETASU) approach to control drug access, easing the burden to health care system and sponsors. This session will discuss this platform that is a consortium-led, open model driven by experts.

Technology: Feeding the Evolution of ETASUs
Nathan Gray
Clinical Research Strategist, Cerner Corporation

Minimizing ETASU Impact on Health Care Providers
Marcie Bough, PharmD
Senior Director, Government Affairs, American Pharmacists Association (APhA)

Leveraging Data Assets and Industry Expertise to Enhance ETASUs
Lisa Caliendo, MPH
Senior Business Consultant, SDI Health

#141 Track 11 (B): Clinical Safety and Pharmacovigilance

1:30 PM – 3:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W474b *CME and Nursing credits offered*

Creating Customized MedDRA® Queries

CHAIRPERSON
Judy E. Harrison, MD
Medical Officer, MedDRA® MSSO

This workshop focuses on how MedDRA®'s features affect safety data retrieval and includes practical demonstrations of search strategies. Participants can suggest safety issue topics as examples for query construction in an interactive format.

The workshop chair will demonstrate practical examples of constructing MedDRA® queries, and participants will be able to engage in the process by directing the identification of relevant terms for the query. Participants will also be encouraged to suggest their own topics of medical interest to be used as examples of query construction in an interactive format by the group.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

#142 Track 12: Statistics

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W181bc

SPERT: Trials, Troubles, and Tribulations with Safety Planning

CHAIRPERSON

Andreas Brueckner, MS
Principal Statistician, Bayer, Germany

In 2009 recommendations for safety planning, evaluation, and reporting were published by the safety planning, evaluation, and reporting team (SPERT). Now two years later we look at the challenges industry faces in implementing SPERT's recommendations.

Prospective Safety Planning: Implementation at a Large Pharma
Conny Berlin, MSc
Statistical Safety Leader, Novartis Pharma AG, Switzerland

Core Analyses for Program Level Safety Reviews
Brenda Jean Crowe, PhD
Research Advisor, Global Statistical Sciences, Eli Lilly and Company

Premarket Safety Planning: Key Regulatory Considerations
C. George Rochester, PhD, MA, RN, RAC
Associate Director for Safety Assessment, Office of Biostatistics, CDER, FDA

#143 Track 14: Medical Devices

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W184d *CME and Nursing credits offered*

The Revision and Recast of the Medical Device Directives: Where the Pressures Lie for Change

CHAIRPERSON

Amanda Maxwell
Manager, SFL Regulatory Affairs Consulting, UK

This session will give a notified body and competent authority view of the most recent changes to the EU's Medical Devices Directives and of more changes to come with the recast. It will provide an overview of clinical evaluation requirements in the EU, how these have been tightened, what data need to be provided by device companies, how this needs to be sourced, and Commission guidance available to support manufacturers through the EU clinical evaluation processes.

How to Comply with Changing Clinical Evaluation Requirements in the EU
Amanda Maxwell
Manager, SFL Regulatory Affairs Consulting, UK

Ongoing Legislative Changes in Europe: The Notified Body Perspective
Gert Bos, PhD, MSc
Head of Regulatory and Clinical Affairs, BSI, UK

Overview of the Competent Authority Role in the EU
Dr. Jean-Claude Ghislain
Director, Evaluation of Medical Devices, AFSSAPS, France

#144 Track 15: Professional Development and Training

1:30 PM – 3:00 PM LEVEL: ● Format: **FORUM**
Room W474a *PMI PDUs offered*

My Big Break: Stories from Top Pharmaceutical Executives

CHAIRPERSON

Robin L. Winter-Sperry, MD
President and CEO, Scientific Advantage LLC

Everyone deserves a break; will you recognize yours when it comes along? Cultural diversity, social networking, mentoring, and ambition have played a role in their success. Join this dynamic forum where top CEOs will be sharing their stories.

Leadership: A Journey of Continual Surprises, Twists, and Turns
Stuart Sowder, JD, PharmD, MBA
Vice President, External Medical Communications, Pfizer Inc

Taking Ownership of Your Career
Janet Loesberg, PharmD
Vice President, External Sciences and Medical Operations, Bristol-Myers Squibb Company

From the Bench to Global Business: Expand Your Experience to Support Your Success
Therese B. McCall, PhD, MBA
Senior Director, Global Medical Affairs, Takeda Pharmaceuticals International

#145 Track 16 (A): Global Agency

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W186abc *CME and Nursing credits offered*

European Medicines Agency (EMA) Town Hall

CHAIRPERSON

Martin Harvey-Allchurch, Esq., LLM
Head of the Office of the Executive Director, European Medicines Agency, European Union

The European Medicines Agency has developed initiatives and entry points to facilitate regulatory procedures and scientific dialogue from early development to postmarketing authorization stages. The session offers the opportunity to interact directly with a panel of European Medicines Agency staff and ask questions on recent initiatives such as the "Road Map to 2015", benefit-risk methodology, EMA-FDA joint activities, etc.

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

Hilde Boone, MPharm, MSc
EMA Liaison at the FDA, European Medicines Agency, European Union

Sabine Brosch, PharmD, PhD
Business Lead, EudraVigilance and International Standardization in PV, European Medicines Agency, European Union

Lawrence Phillips, PhD
Visiting Professor of Decision Sciences, Department of Management, London School of Economics, UK

Spiros Vamvakas, MD
Head of Scientific Advice, European Medicines Agency, European Union

#146 Track 16 (B): Global Agency

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W187abc

FDA Discussion on Biosimilar Legislation and Implementation

CHAIRPERSON

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

The Patient Protection and Affordable Care Act (Affordable Care Act) contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference product. This forum provides an overview of the legislation and the Agency's implementation of the BPCI Act.

Implementing the Biologics Price Competition and Innovation Act
Leah A. Christl, PhD
Associate Director for Biosimilars, Office of New Drugs, CDER, FDA

Approval Pathway for Biosimilar Biological Products: Overview of the BPCI Act and Selected Issues Related to Statutory Requirements
Janice L. Weiner, JD, MPH
Regulatory Counsel, Office of Regulatory Policy, CDER, FDA

Evaluation of Structural and Functional Similarity Between Protein Products: Scientific Considerations and Analytical Tools
Emily Shacter, PhD
Chief, Laboratory of Biochemistry, Office of Biotechnology Products, CDER, FDA

Robert A. Yetter, PhD
Associate Director for Review Management, Office of the Director, CBER, FDA

3:00 PM – 3:30 PM **REFRESHMENT BREAK**
Exhibit Hall, Level 3 (See Floor Plan, page 131)

#147 Track 1 (A): Clinical Operations

3:30 PM – 5:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W475a *CME and Nursing credits offered*

Ethical Issues in Clinical Trials Workshop: It's All Shades of Gray

CHAIRPERSON

Art Gertel, MS
Vice President, Strategic Regulatory Consulting, Medical Writing, and QA, Beardsworth Consulting Group Inc.

This workshop will provide an overview of ethical considerations associated with conducting clinical trials, including obtaining ethics committee clearance, subject informed consent, investigatory conflict-of-interest, fraud, and patient protections.

This workshop will consist of a combination of short presentations on relevant ethical issues, with respect to both vaccine and drug clinical trials, and group discussions on major ethical considerations of some case studies. The presentations will focus on the importance of ethics in GCP, the informed consent process, and the challenges that may arise in developing countries, the infrastructure of ethics committees, and data safety monitoring committees. Practical experience, with emphasis on ethical issues, in conducting clinical trials in India and sub-Saharan Africa, as well as considerations of authorship, will be covered.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

#148 Track 1 (B): Clinical Operations

3:30 PM – 5:00 PM LEVEL: ◆ Format: **FORUM**
Room W176abc *PMI PDUs offered*

Building a Quality Framework to Provide Efficient and Effective Oversight of Transferred Obligations: A Collaborative Approach

CHAIRPERSON

Shantal Feltham
President and CEO, Stiris Research Inc., Canada

Sponsors and CROs must develop a solid framework for ensuring quality data and shared responsibility of transferred obligations. Key performance metrics must be established along with solid processes to execute proper oversight and collaboration.

PANELISTS

Deirdre F. BeVard
Vice President, Development Operations, Endo Pharmaceuticals

Jonathan Lee
Vice President, Development Operations, Cerexa Inc.

Ann Luise Wang
Vice President, Clinical Operations, Human Genome Sciences Inc.

#149 Track 2 (A): Development Planning

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W179a *PMI PDUs offered*

A Creative Approach for Improving the Probability of Commercial Success

CHAIRPERSON

Martin D. Hynes, III, PhD
Senior Director, Six Sigma Champion, Research & Development, Eli Lilly and Company

In this session we will describe the use of Six Sigma methodology to improve the overall probability of technical and commercial success as well as reduce the cost and cycle time of drug development.

A Creative Approach for Improving the Probability of Commercial Success
Martin D. Hynes, III, PhD
Senior Director, Six Sigma Champion, Research & Development, Eli Lilly and Company

Creative Approaches for Improving Probability of Commercial Success
Kevin L. Duffin, PhD
Senior Fellow, Translational Sciences, Eli Lilly and Company

Using Six Sigma Methodology to Improve Drug Development Cycle Time
Alister Thomson, MBA
Director, Strategic Process Optimization, Bristol-Myers Squibb Company

Pragmatic Approaches to Adapt Lean Six Sigma Deployments in Times of Change
Michael A. Walega, MSc
Six Sigma Master Black Belt, Covance Inc.

#150 Track 2 (B): Development Planning

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W179b *CME and Nursing credits, PMI PDUs offered*

Risk Assessment Process for Pediatric Protocol Development

CHAIRPERSON

Barry Mangum, PharmD
Director, Clinical Pharmacology, Duke University Medical Center

Pediatric clinical research is challenging and rewarding for all parties involved in the outcome of this level of research. This session will focus on the dynamic aspect of pediatric research from a practical perspective. We will encompass protocol design, operational oversight, and simple techniques to master in providing a practical protocol for regulators, the pharmaceutical industry, and the academic sites to operationalize. We will define the risk assessment at all levels in mastering the right pediatric research program to bring into operation.

Risk of Operational/Technical/Ethical Issues that Drive Protocols
Uma Kuruganti, MS
Clinical Project Manager, Pfizer Inc

Protocol Feasibility in Pediatric Trials: How to Make an Executable Program that Won't Fail
Ronald Portman, MD
Group Director, Bristol-Myers Squibb Company

Practical Issues to Remember for the Guardian/Caregiver: Dose Timing, PK Time Sampling, and Number of Samples
Barry Mangum, PharmD
Director, Clinical Pharmacology, Duke University Medical Center

#151 Track 2 (C): Development Planning

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W175abc *CME and Nursing credits offered*

Quality by Design: Planning Quality on Multiple Fronts

CHAIRPERSON

Martin Landray, PhD, FRCP
Reader in Epidemiology and Honorary Consultant Physician, Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU), University of Oxford, UK

This session will highlight quality design of clinical trials, quality risk management in clinical trials, and statistical monitoring applied to research trials.

Regulatory Perspective
Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

An Academic Trialist's Perspective
Martin Landray, PhD, FRCP
Reader in Epidemiology and Honorary Consultant Physician, Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU), University of Oxford, UK

An Industry Sponsor Perspective
Kenneth J. Sprenger, MD, MBB Ch
Executive Director, Medicine Team Leader, Pfizer Inc

#152 Track 3: Outsourcing Strategies and Innovative Partnering Models

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W178ab

Better Cooperation Between Stakeholders in Drug Development: Is It Inevitable?

CHAIRPERSON

Ionel Mitrica, PhD
Director, Clinical Development, Oncology, GlaxoSmithKline

This session will discuss benefits, pitfalls, and points to consider, associated with collaborations between the various stakeholders involved in drug development, including perspectives from pharma, academia, and CROs. Case studies (e.g., cooperation between industry and academic cooperative groups in oncology) will be presented, with a focus on how the good and the not-so-good examples can help us work together in the future.

Future Partnering Models and Challenges Regarding Sourcing Drug Development Activities in a Changing Healthcare Environment
Theodore F. Reiss, MD
Covance, Inc.

Industry Academia Partnerships: Pharma Collaborations with Cooperative Groups as a Case Study
Ionel Mitrica, PhD
Director, Clinical Development, Oncology, GlaxoSmithKline

Academia Pharma Partnerships: Experience of a Major US Academic Cancer Center
Stanley Tucker, PhD
Director, Technical Discovery, External Collaborations, Office of Translational Research, MD Anderson Cancer Center

#153 Track 4: Nonclinical and Early Clinical Translational Development

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W183a

Early Drug Development and Early Interaction with Governmental Agencies

CHAIRPERSON

Cecil J. Nick, MS, FTOPRA
Vice President (Technical), PAREXEL Consulting, UK

This session will address the opportunities and value for early interaction with regulatory agencies in the development of novel medicines and confirm the value of early interaction with major regulatory agencies in the development of novel medicines. Such interactions are particularly important when introducing novel concepts; for pediatric development; and the development of advanced therapies and orphan medicines. The session will also cover Agency initiatives to support development of novel therapies.

EMA Perspective
Spiros Vamvakas, MD
Head of Scientific Advice, European Medicines Agency, European Union

Health Canada Perspective
Agnes V. Klein, DrPH, MD
Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

Italian Medicines Agency Perspective
Carlo Tomino, PharmD, MPharm
Head of Research and Clinical Trial, Italian Medicines Agency, Italy

#154 Track 6: Medical Writing and Communication

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W184bc

The Past, Present, and Future: A Glimpse at the Emergence of the Medical Science Liaison Role

CHAIRPERSON

J. Lynn Bass, PharmD, RPh
Senior Medical Science Liaison, Baxter Bioscience - Biotherapeutics

On an annual basis, Medical Science Liaison surveys have been conducted, which have captured data on a variety of topics. These surveys, distributed to both MSLs and MSL management, provide valuable insight into the diversity of the roles across companies. A sampling of the survey topics in the past have included demographical information of MSL teams, training processes, MSL role responsibilities, MSL value demonstration, MSL field resources, and others. This session will provide an overview of the results of these surveys and explore the collaborative interactions between MSLs and other Medical Affairs functions. New data will also be included from survey six, which is currently underway.

Medical Writing, Medical Information, and Medical Liaison Interactions to Increase Value in Medical Communications
David B. Clemow, PhD
Scientific Communications Consultant, Eli Lilly and Company

Medical Liaison Perspectives
Craig J. Klinger, RPh
Senior Medical Liaison Consultant, Lilly USA, LLC

#155 Track 7 (A): IT Methods and Technologies

3:30 PM – 5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W470a *CME and Nursing credits offered*

Advanced IT Methods for Clinical Trials

CHAIRPERSON

Jay B. Smith, MBA
Manager, Product Management, Medidata Solutions Worldwide

This symposium will discuss the adoption of new technologies and how it is important to improve trial efficiency and increase the quality of output and decision making. New software development and information technology practices are critical for lowering the cost of ownership, and the Internet and other data standards allow these disparate clinical systems to be quickly integrated into a variety of vendors.

ITIL Methodologies and Improvement in IT Results
Mary Lou Alter
Solution Partner, IT Strategy and Architecture, EMC Corporation

Policy-driven Architecture in a Regulated Environment
Johnlouis Petitbon
Development Director, Medidata Solutions Worldwide

Creating a Clinical Decision Support System with Industry Standards and Open Source Technologies: A CTMS Case Study
Mitchell Smith, MS
Chief Software Architect, Array Biopharma

#156 Track 7 (B): IT Methods and Technologies

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W471a *CME, Nursing, and Pharmacy credits offered*

ePRO: Which Technologies and Data Management Strategies Provide Maximum Benefit for Your Trial

CHAIRPERSON

Brian Tiplady, PhD
Honorary Research Fellow, University of Edinburgh, UK

Three speakers with extensive experience will guide you through the variety of technology platforms that can be used for Electronic Patient-reported Outcomes (ePRO), their strengths and limitations, and the opportunities they offer for improving the quality of clinical research.

Breakthrough New Netbook and Smart Phone Technologies: A Quantum Improvement for ePRO
Joy Hebert
Chief Operating Officer, Assistek

Choosing the Right PRO Solution for Your Clinical Program
Rauha Tulkki-Wilke, MSc
Director, Product Management, CRF Health, Finland

The Vital Role of Patient Reported Data within eClinical
Keith W. Wenzel
Senior Product Director, eClinical, Perceptive Informatics

#157 Track 8: Research Data and Content Management

3:30 PM – 5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W470b *CME, Nursing, and Pharmacy credits offered*

Adopting a Risk-based Approach to Clinical Data Quality

CHAIRPERSON

Kit Howard, MS
Owner and Principal, Kestrel Consultants, Inc.

This symposium will explore the concept of quality as it applies to clinical data, and look at some theoretical implications for different degrees of cleaning. On the practical side, results will be shared from an industry survey that examined the outcomes of not doing 100% source data verification. Finally, methods for defining, identifying, and documenting critical data for cleaning will be presented.

Applying Risk Management to Clinical Data Quality
Kit Howard, MS
Owner and Principal, Kestrel Consultants, Inc.

Survey Review: State of the Industry for Targeted Source Data Verification – Where Are We Now?
Sandra Hines, MSc
Director, Clinical Operations, Project Management Office, ePharmaSolutions

Pragmatic Approaches to Risk-based Data Review and Source Data Verification
Patrick Nadolny
Vice President, Data Management and Programming, Allergan, Inc.,

#158 Track 9 (A): Regulatory Affairs and Sciences, Quality, and GXP Compliance

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W185a *CME, Nursing, and Pharmacy credits offered*

Global Innovative Monitoring and Auditing Tools for Bioresearch Monitoring Activities

CHAIRPERSON

Jan Holladay Pierre, MPH
Quality Principal Leader, Dynaport Vaccine Company

Sponsors should put mechanisms in place such as monitoring and auditing activities to ensure compliance with ICH/FDA requirements globally, in addition to good business practices. These mechanisms should not only be aligned with regulatory compliance requirements but also take into consideration indigenous practical applications in a real-world setting. To properly design these tools, one must apply lessons learned from a regulatory compliance and quality perspective. Hear a balanced discussion on the issues from FDA and US and European industry and quality representatives.

An Examination of GCP 483 Issues in Relation to Inadequate Monitoring Activities
Tejashri Purohit-Sheth, MD
Branch Chief, GCPB2, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Regional GCP Noncompliance Issues and Solutions for Quality Clinical Trials
Regina Freunscht
Director, Clinical Operations, Marketing and Communications, Accovion GmbH, Germany

Practical Tools for Effective Monitoring and Auditing Practices
Jan Holladay Pierre, MPH
Quality Principal Leader, Dynaport Vaccine Company

#159 Track 9 (B): Regulatory Affairs and Sciences, Quality, and GXP Compliance

3:30 PM – 5:00 PM LEVEL: ■ Format: **FORUM**
Room W185bc

Global Harmonization Beyond ICH

CHAIRPERSON

Mike D. Ward
Manager, International Programs Division, Health Canada

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The forum should discuss the present situation in ICH and other global initiatives for harmonization.

The Changing Face of ICH: Expanding Participation in the Development of Guidelines
Mike D. Ward
Manager, International Programs Division, Health Canada

Twenty Years of ICH: Learning and Accomplishments – Evolution of an Idea
Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Director for International Programs, Office of the Center Director, CDER, FDA

Future Challenges and Opportunities for Medicines Regulation: Global Perspective
Lembit Rägo, MD, PhD
Coordinator, Quality Assurance and Safety for Medicines, World Health Organization (WHO), Switzerland

#160 Track 9 (C): Regulatory Affairs and Sciences, Quality, and GXP Compliance

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W184a

Recent Advancement of Biosimilars in the Asia-Pacific Region

CHAIRPERSON

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

Regulation of biosimilars has been established in Asian countries such as Japan, Korea, and Taiwan. This session will discuss regulatory pathways and impacts in Asian Pacific nations such as China, Japan, Korea, and Taiwan.

Recent Regulations of Biosimilars in Japan
Teruyo Arato, PhD
Review Director, Office of Biologics I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Regulatory and Scientific Considerations on the Development of Biosimilars in the Asian Region
Duu-Gong Wu, PhD
Executive Director, Consulting Division, Pharmanet Development Group, Inc.

MNC Overview of Biosimilars in Asia
Lois M. Hinman, PhD
Global Head, Early Development and BD&L, Novartis Pharmaceuticals Corporation

#161 Track 10: Public Policy/Health Care Compliance

3:30 PM – 5:00 PM LEVEL: ● Format: **FORUM**
Room W180 *Pharmacy credits offered*

Civil and Regulatory Liability from Clinical Trials

CHAIRPERSON

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

This interactive session will use case studies to highlight some real-life legal and regulatory issues that affect sponsors, investigators, and IRBs in the conduct of clinical trials. The session will touch upon legal and regulatory issues regarding such things as conflicts of interest, enrolling non-English-speaking subjects and enrollment incentives.

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

Gary L. Yingling, JD
Partner, K&L Gates

#162 Track 11: Clinical Safety and Pharmacovigilance

3:30 PM – 5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W183b *CME, Nursing, and Pharmacy credits offered*

Practical Risk Management on a Global Scale: Navigating the REMS and RMP Regulatory Waterways

CHAIRPERSON

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

This group of presentations will examine risk management on a global scale, including evolving concepts and evolving regulations with regards to REMS, EU-RMPs, and Post-authorization Safety Studies (PASS).

Practical Risk Management: A Structured Approach to Signaling – Avoiding the Pitfalls of Not Seeing the Woods for All the Trees
Uwe P. Trinks, PhD
Partner, Foresight Group, LLC

How Will the New European Legislation Affect the Conduct of Postauthorization Safety Studies?
Peter De Veene, MD
Deputy EU Qualified Person for Pharmacovigilance, F. Hoffmann-La Roche AG, Switzerland

Emerging Requirements for Structured Benefit Risk Optimization: Implications for REMS, PSURS, and PASS
John G. Ferguson, MD
Vice President, Global Head of Pharmacovigilance and Medical Safety, Novartis Vaccines and Diagnostics

#163 Track 12: Statistics

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W181bc

Innovative Graphical Approaches to Display Safety Data Collected in Clinical Trial Research

CHAIRPERSON
Mat Soukup, PhD
Team Lead, Office of Translational Sciences, CDER, FDA

The session will present efforts of a collaborative working group that is developing graphical approaches to enhance transparency and understanding of safety data collected in clinical trial research.

The Forest for the Trees: Visualizing Adverse Events
Andreas Brueckner, MS
Principal Statistician, Bayer, Germany

General Principles, Illustrations, and Wiki Resources for Improving Your Statistical Graphs
Brenda Jean Crowe, PhD
Research Advisor, Global Statistical Sciences, Eli Lilly and Company

Organized and Effective Interpretation of Clinical Laboratory Data: Graphs Make a Difference
Robert Gordon, MSc
Biostatistician, Johnson & Johnson

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

3:30 PM – 5:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W474a *CME, Nursing, and Pharmacy credits offered*

Benefit-risk Methodology: An Interactive Workshop

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

Participants in this workshop will be engaged in constructing a benefit-risk model to assist drug decision making. The decision-theory-based model will include favorable and unfavorable effects, uncertainties about the effects, and judgments of clinical relevance.

As quantitative modeling of the benefit-risk balance for medicines grows in importance for the pharmaceutical industry, regulators and HTAs, it becomes important to know how to incorporate judgments of clinical relevance. This interactive workshop will provide opportunities for participants to explore how those judgments can be expressed numerically for the favorable and unfavorable effects of medicines. It will also show how the integration of data with judgments by decision analysis models is being tested for its usefulness by the European Medicines Agency in research with six European Agencies on live cases.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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
Lawrence Phillips, PhD
Visiting Professor of Decision Sciences, Department of Management, London School of Economics, UK

#165 Track 14: Medical Devices

3:30 PM – 5:00 PM LEVEL: ● Format: **SESSION**
Room W184d

Understanding Medical Device Trial Regulation and Operational Challenges in Latin America

CHAIRPERSON
Cristina Nunes Ferreira, MBA
Professor, Scientific Medical Products - Brazil

This session will provide an overview of the importance of performing trials with medical devices in Latin America, the current regulatory guidelines and timeline, as well as determining the feasibility of conventional clinical efficacy studies for non-innovative products versus new products or technological innovations. We will also address the communication between the performance tests (ex vivo, biological, preclinical testing) with the clinical trial to guarantee the security and efficacy for human use.

The Importance of Performing Trials with Medical Devices in Latin America
Cristina Nunes Ferreira, MBA
Professor, Scientific Medical Products - Brazil

Latin American Medical Devices: International Strategies
Alan J. Touch, OD
Principal Strategist, INC Research, LLC

Diana Valencia, MD
CEO, Latam Clinical Trials, Colombia

#166 Track 15: Professional Development and Training

3:30 PM – 5:00 PM LEVEL: ● Format: **WORKSHOP**
Room W474b *CME and Nursing credits, PMI PDUs offered*

Presenting ... YOU! Tips, Tricks, and Advice on Making You and Your Presentations Unforgettable: An Interactive Workshop

CHAIRPERSON
Lauren Edelstein-Henry, MEd
Principal Operational Specialist, Johnson & Johnson

This workshop will also be offered on Tuesday, June 21, at 8:00 AM.

It is estimated that companies waste $252 million dollars each day on time wasted on bad presentations. Learning to create and give effective presentations not only makes the presenter look good, it generates a return on investment to the business.

The workshop will include group and small group discussion, examples of good and bad techniques, and copious amounts of Q&A and hands-on demonstrations.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

#167 Track 16 (A): Global Agency

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W186abc

Future Directions: Submitting Promotional Material to CDER FDA in eCTD Format

CHAIRPERSON

Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, CDER, FDA

This session will discuss topics such as how DDMAC envisions incorporation of the eCTD standard into the review of promotional and advertising materials. Discussion will include changes to Module 1, reviewer concerns, file types and a discussion of the planned process.

Lisa Hubbard
Senior Supervisory Regulatory Review Officer, Division of Drug Marketing, Advertising, and Communications, Office of Medical Policy, CDER, FDA

Marci C. Kiester, PharmD
Associate Director of Operations, Division of Drug Marketing, Advertising, and Communications, Office of Medical Policy, CDER, FDA

Mark A. Gray
Division Director, Division of Regulatory Review Support, Office of Business Process Support, CDER, FDA

#168 Track 16 (B): Global Agency

3:30 PM – 5:00 PM LEVEL: ● Format: **FORUM**
Room W185d

Update from the Therapeutic Goods Administration (TGA)

CHAIRPERSON

Rohan Hammett
National Manager, Department of Health and Aging, Therapeutic Goods Administration (TGA), Australia

In the last 3 years the Therapeutic Goods Administration (TGA) has embarked upon an ambitious program of modernization which aims to ensure that it is able to deliver appropriate, consistent, effective, efficient, and transparent regulation in the 21st century. This organizational reform program has improved processes of decision making and led to major recalibration of regulatory frameworks and processes applying to prescription medicines, over-the-counter medicines, complementary medicines, medical devices, and biological products. New business processes have halved approval times for prescription medicine and medical device approvals, and new linkages with Australian HTA (Health Technology Assessment)/ payers have led to opportunities for parallel completion of regulatory and reimbursement pathways in time frames that are significantly shorter than other major regulatory regions. Similarly, enhanced post market monitoring processes for all types of therapeutic products have been developed through structural and process changes that reflect 21st century recognition of the need to devote appropriate regulatory oversight once products have cleared the initial market authorization hurdle that was the hallmark of 20th century regulation.

This forum will describe in detail how the TGA, working cooperatively with industry, healthcare professionals and consumers, is transforming the way it regulates therapeutic products to ensure it is equipped to deal with the emerging challenges of healthcare innovation.

Australia's National Medicine's Policy
Richard O. Day, MD, PhD
Professor, Clinical Pharmacology, Therapeutics Center, St. Vincent's Hospital, Australia

Harry Rothenfluh
Head, Office of Scientific Services, Therapeutic Goods Administration (TGA), Australia

#169 Track 18: Late Breaker

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W183c *Pharmacy credits offered*

Comparative Effectiveness Research and Health Technology Assessment: How National Agencies Are Addressing the Challenge

CHAIRPERSON

Joshua S. Benner, DrSc, PharmD
Research Director and Fellow, Engleberg Center for Health Care Reform, The Brookings Institution

This session will discuss the work of government funded agencies in the implementation of comparative effectiveness research (CER) and how these efforts might affect the development and life cycle management of biopharmaceuticals and medical devices. While the primary focus will be on the United States, the session will also examine the implications of other nations' CER and health technology assessment (HTA) policies.

Michael S. Lauer, MD, FACC
Director, Divisions of Cardiovascular Sciences, National Heart, Blood and Lung Institute, National Institutes of Health

Kalipso Chalkidou, MD, PhD
Director, NICE International, UK

Steve E. Phurrough, MD, MPA
Chief Operating Officer and Senior Clinical Director, Center for Medical Technology Policy

Freda Lewis-Hall, MD
Chief Medical Officer and Senior Vice President, Pfizer Inc

5:00 PM **END OF MONDAY SESSIONS**

5:00 PM – 6:30 PM **WELCOME RECEPTION**
Exhibit Hall, Level 3

NOTES

NOTES

Tuesday, June 21

7:00 AM – 5:30 PM	**Speaker Registration** Exhibit Hall Entrance, Level 3
7:00 AM – 5:30 PM	**Attendee Registration** Exhibit Hall Entrance, Level 3
7:00 AM – 5:30 PM	**Exhibitor Registration** Exhibit Hall Entrance, Level 3
7:15 AM – 8:00 AM	**Coffee and Breakfast Breads** McCormick West, Lobby Entrance, Level 1
9:00 AM – 4:30 PM	**Exhibit Hall Open** Level 3
11:30 AM – 1:30 PM	**Professional Poster Session** Exhibit Hall, Level 3
3:00 PM – 4:30 PM	**Exhibit Guest Pass Registration** Exhibitor Registration at the Exhibit Hall Entrance, Level 3

#201 Track 1 (A): Clinical Operations

8:00 AM – 9:30 AM LEVEL: ● Format: **SESSION**
Room W375b *CME, Nursing, and Pharmacy credits offered*

PLENARY SESSION
Voice of the Patient: Stories That Touch Us

CHAIRPERSON

Diane Simmons
President and CEO, Center for Information and Study on Clinical Research Participation (CISCRP)

Join a panel of patients whose profound decision to participate in a clinical trial benefited public health and advanced medical knowledge, regardless of whether their investigational treatment proved safe and effective or harmful and ineffective. Each of these volunteers gave the "gift of participation" in clinical research and we recognize them as Medical Heroes.

Each patient will share details about themselves along with their experience with clinical trials, what prompted their interest in participating and the obstacles or challenges they encountered with friends and family when they told them about their participation. Finally, the patients will provide advice about participation and explain why they would or would not volunteer again.

PANELISTS

Breast Cancer Survivor
Rosemarie Rogers

Patient with Genetic Disorder (Friedreich's Ataxia)
Janet Pepitone

Parent of a Child with a Genetic Disorder (Alagille Syndrome)
Cindy Hahn

Patient with a Chronic Autoimmune Neuromuscular Disease (Myasthenia Gravis)
Jurgen Venitz, MD, PhD

Patient with a Motor System Disorder (Parkinson's Disease)
Frances Waldynski

#202 Track 1 (B): Clinical Operations

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W176abc *CME and Nursing credits, PMI PDUs offered*

Investigator Budgets and Sponsor Identification/ Selection Processes: Impact on Patient Enrollment

CHAIRPERSON

Daniel M. Ulrey, MBA
President and CEO, Midwest Clinical Support, Inc.

This session will address the issues of investigator budgets and how they impact investigator performance relating to patient enrollment. It will also present improvements to the costly processes that sponsors and sites use to initiate and conduct studies.

A Site Perspective
Christine K. Pierre, RN
President, RxTrials, Inc.

Success Is a Process
Elizabeth Miller
Vice President, NA Head of Integrated Site Services, Quintiles

Budgets, Timelines, and Site Performance: A Pharmaceutical Company Perspective
Wilbur Kim, JD
Manager, Contracting and Outsourcing, Pfizer Inc

#203 Track 2: Development Planning

8:00 AM – 9:30 AM LEVEL: ● Format: **SESSION**
Room W179a *CME and Nursing credits offered*

Project Team Effectiveness: Multidisciplinary Team and the Temperament Factor

CHAIRPERSON

Raul Soikes, MA
Senior Director, Program Management, Baxter HealthCare Corporation

This session will address how to use temperament and personality as management instruments to improve team dynamics. A contract manufacturing organization case study yielding enhanced multidisciplinary team effectiveness by understanding the team member styles and the team's dynamics will be presented.

Psychometric Measures and Project Team Performance: A Review and Example Using the Kiersey Temperament Sorter
Carl M. Briggs, PhD
Clinical Associate Professor, Operations and Decision Technologies, Indiana University

Project Team Effectiveness: A Temperament Case Study
Raul Soikes, MA
Senior Director, Program Management, Baxter HealthCare Corporation

Matrix Teams: Driving Effectiveness in Clinical Development Through Cross-functional Collaborations
Mike Menta, MBA
Vice President, Campbell Alliance Group, Inc.

#204 Track 3: Outsourcing Strategies and Innovative Partnering Models

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W179b

Regulatory, Clinical, and Quality Challenges in Contracting and Due Diligence: The Forgotten Keys to Biopharmaceutical Transactions

CHAIRPERSON

Michael A. Swit, JD
Vice President, The Weinberg Group Inc.

This session will provide drug professionals with a deeper understanding of the key regulatory, clinical, or quality issues that must be reviewed in buying a biopharmaceutical product or company and how to address those concerns in the due diligence phase.

Regulatory Challenges in Due Diligence
Gary L. Yingling, JD
Partner, K&L Gates

What Lies Beneath? The Underpinnings of GCP Compliance in Due Diligence
Caroline Susan LaPlaca, MSc
Independent Consultant for Ardea Biosciences

Contractual Clauses Essential in Biopharmaceutical Transactions
Maureen Bennett, Esq.
Partner, Squire Sanders

#205 Track 6: Medical Writing and Communication

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W184bc *CME, Nursing, and Pharmacy credits offered*

Designing Robust Protocols

CHAIRPERSON

Jesse A. Berlin, DrSc
Vice President, Pharmacoepidemiology, Johnson & Johnson Pharmaceutical Research and Development, LLC

To strengthen credibility of clinical studies, better-designed and more transparent protocols are needed. This session will discuss academic research into the successes and failures in designing robust protocols, the SPIRIT (Standard Protocol Items for Randomized Trials) initiative, and the CDISC protocol model.

Clinical Trial Protocols: Current Status, Challenges, and Opportunities
An-Wen Chan, MD, PhD, FRCPC
Assistant Professor and Phelan Scientist WCRI, University of Toronto; Women's College Hospital, Canada

The SPIRIT Initiative: Developing Standard Protocol Items for Randomized Trials
Jennifer M. Tetzlaff, MSc
Research Coordinator, Ottawa Health Research Institute, Canada

Implementation of the CDISC Protocol Model
David Gemzik
Vice President, Implementation Services, Medidata Solutions Worldwide

#206 Track 7: IT Methods and Technologies

8:00 AM – 9:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room W470a

International eClinical Experience

CHAIRPERSON

Scott W. Dixon
Senior Director, Oracle Health Sciences

This symposium will look at current pressures on global drug development, from regulatory mandates to the infrastructure challenges of working in remote regions, and examine techniques and innovative technology used to make clinical research more effective.

Online/Offline ICT Platform for Health Research in Africa
Eugenia Rinaldi, MS
Project Manager, CINECA Inter-University Consortium, Italy

Postmarketing Surveillance in Japan and the Failure of Traditional EDC
Scott W. Dixon
Senior Director, Oracle Health Sciences

Ongoing IT Projects: NCA Point of View
Christa Wirthumer-Hoche, PhD
Deputy Head, AGES PharmaMed, Austria

#207 Track 9: Regulatory Affairs and Science, Quality, and GXP Compliance

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W185bc *CME and Nursing credits offered*

The Benefit-risk Assessment of Medicines: How Can This Be Communicated Effectively to Different Stakeholders?

CHAIRPERSON

Stuart Walker, PhD
Founder, Center For Innovation in Regulatory Science, UK

There is a need to encourage an environment in which a more balanced view of benefits and risks is taken. This session will discuss the need to evaluate effective and transparent methodologies for visualizing and communicating benefit-risk assessment to various stakeholders.

Benefit-risk Evaluation of a New Medicine by a Pharmaceutical Company and Its Communication for a Regulatory Decision
Sinan Bardakci Sarac, MD
Industrial PhD Student, Novo Nordisk A/S, Denmark

Communication of the Benefit-risk Balance by Regulatory Authorities to Physicians and Patient
Stuart Walker, PhD
Founder, Center For Innovation in Regulatory Science, UK

Communication of Benefit-risk Information to Patients by Physicians, Pharmacists, and Nurses for Shared Decision Making
Sam Salek, PhD, RPh
Director, Centre for Socioeconomic Research, Welsh School of Pharmacy, Cardiff University, UK

#208 Track 12: Statistics

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W181bc *CME and Nursing credits offered*

Issues and Challenges in Designing Central Nervous System Clinical Trials

CHAIRPERSON

Yeh-Fong Chen, PhD
Mathematical Statistician, FDA

Successful CNS clinical trials involve challenges using "placebo" as a control and managing high placebo response and extensive dropouts. Speakers experienced in tackling these problems will share their perspectives and possible solutions.

Historical Control Monotherapy Studies for Regulatory Approval of Antiepileptic Drugs
Nancy Temkin, PhD, MS
Professor, Neurological Surgery, Biostatistics, University of Washington, School of Public Health

Addressing Placebo Response in Psychiatric Clinical Trials
Roy Tamura, PhD
Research Fellow, Eli Lilly and Company

Analysis of Clinical Trials with Many Dropouts Using Multiple Imputation and Robust Regression
Devan V. Mehrotra, PhD
Senior Director and Head, Early Clinical Development Statistics, Merck Research Laboratories

#209 Track 15 (A): Professional Development and Training

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W474a *CME and Nursing credits offered*

Managing Generation Gaps in the Clinical Research Industry

CHAIRPERSON

Charles Schmidt, MD
Professor, Santa Casa Medical School, Brazil

Project teams have stakeholders with different ages that create natural conflicts between generations. It is important to understand the behaviors and beliefs of each generation for better leadership of the group.

The Generational Effect on Clinical Study Teams
Armand Spoto, MS
Senior Project Manager, Lernia Training Solutions

Generations, the Great Recession, and Work-life Balance: Making It All Work at Work (or at Home)
Margaret S. Richards, PhD
Executive Director, Epidemiology and Health Outcomes, PPD, Inc.

#210 Track 15 (B): Professional Development and Training

8:00 AM – 9:30 AM LEVEL: ● Format: **WORKSHOP**
Room W474b *CME and Nursing credits, PMI PDUs offered*

Presenting ... YOU! Tips, Tricks, and Advice on Making You and Your Presentations Unforgettable: An Interactive Workshop

CHAIRPERSON

Lauren Edelstein-Henry, MEd
Principal Operational Specialist, Johnson & Johnson

This workshop will also be offered on Monday, June 20, at 3:30 PM.

It is estimated that companies waste $252 million dollars each day on time wasted on bad presentations. Learning to create and give effective presentations not only makes the presenter look good, it generates a return on investment to the business.

The workshop will include group and small group discussion, examples of good and bad techniques, and copious amounts of Q&A and hands-on demonstrations.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

9:30 AM – 10:00 AM **REFRESHMENT BREAK**
Exhibit Hall, Level 3 (See Floor Plan, page 131)

#211 Track 1 (A): Clinical Operations

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W175abc

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.

Sponsor Perspective
Joseph S. Simon, MBA, MS
Pharmaceutical Consultant, Optimum

Joseph Kim, MBA
Director of Clinical Operations, Shire PLC

Site Perspective
Adam Larrabee
Director of Business Development, Rochester Clinical Research, Inc.

Alex Harris
Director of Research, Houston Neurology & Sleep Center

#212 Track 1 (B): Clinical Operations

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W176abc *CME and Nursing credits offered*

Optimizing Site Performance: Select High-performing Sites, and Diagnose/Repair Poor or Less-experienced Sites

CHAIRPERSON

Lorraine D. Ellis, MBA, MS
President/CEO, Research Dynamics Consulting Group Limited

This session will review key attributes of high-performing sites and provide methods for measuring these attributes. Methods for analyzing performance gaps and developing CAPA-type actions to improve site performance are also discussed.

High Performance Sites: Do We Select Them, Build Them, or Both?
Lorraine D. Ellis, MBA, MS
President/CEO, Research Dynamics Consulting Group Limited

Selecting Sites from the Site Perspective, or Honestly, We Can Enroll All Your Subjects
Patricia S. Larrabee, MS, RN
CEO, Rochester Clinical Research

Major Protocol Deviations: Can We Help Investigator Site Staff to Get It Right More Often?
Brendan M. Buckley, MD, PhD
Clinical Professor of Medicine and Pharmacology, University College Cork (UCC), Ireland

#213 Track 1 (C): Clinical Operations

10:00 AM – 11:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room W181a

Monitoring and Source Verification: New Approaches to Quality

CHAIRPERSON

Martin Landray, PhD, FRCP
Reader in Epidemiology and Honorary Consultant Physician, Clinical Trial Service and Epidemiological Studies Unit (CTSU), University of Oxford, UK

This symposium will consist of three topics. First, a summary will be provided of the Clinical Trials Transformation Initiative (CTTI) Monitoring project. Second, emerging strategies for source verification will be presented. And third, the advantages of an alternative to full onsite monitoring, termed hybrid monitoring, will be discussed.

Maximizing the Value and Efficiency of Monitoring
Martin Landray, PhD, FRCP
Reader in Epidemiology and Honorary Consultant Physician, Clinical Trial Service and Epidemiological Studies Unit (CTSU), University of Oxford, UK

Producing Quality Data for Clinical Trials: Is Full Onsite Monitoring the Only Answer?
Lisa Gorman
Director, Clinical Operations-PCS, Kendle International

Beyond 100%: Emerging Strategies for Partial Source Verification
Paul Boyd
Director, User Experience Group, Oracle Corporation

#214 Track 2 (A): Development Planning

10:00 AM – 11:30 AM LEVEL: ● Format: **SESSION**
Room W179a *CME and Nursing credits, PMI PDUs offered*

Does Your Leadership Effectively Work for Your Team Members Who Come from Different Organizations and Countries?

CHAIRPERSON

Atsushi Tsukamoto, MSc, PMP
Manager, Group I, Global Project Management Department, R&D Division, Daiichi Sankyo Co., Ltd., Japan

This session will overview the typical pitfalls and insights that exist in diverse teams from a leadership point of view. Also, effective leadership styles and development plans in diverse teams will be reviewed based on various cases.

Clinical Development Partnership with Biotechs in the Asia-Pacific Region
Emily Li Chuan Tan, MSc, RPh
Executive Director, Clinical Research - Asia/Pacific, PharmaNet Pte Ltd, Singapore

Leading in a Diverse Environment: Developing the Requisite Skills
Robert A. Hilke, MA
CEO, Hilke Communications, LLC, Japan

Learning through Teaching: Leading Teams in a Diverse Business Environment
Gareth Julian Monteath
Program Director, INTEC Japan Inc., Japan

#215 Track 2 (B): Development Planning

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W179b *CME and Nursing credits, PMI PDUs offered*

Early-phase Clinical Development: Strategies for Early Decision Making

CHAIRPERSON

John Shillingford, PhD
Vice President, Operational Excellence, Averion, an Aptiv Solutions Company, Germany

This session will look at the early-phase team's decision-making processes and use of adaptive designs to facilitate studies and reduction of study times.

The Project Manager's Role in the Development of Companion Diagnostics
Sandra J. Zeckel, RPh
Advisor, Project Management, Eli Lilly and Company

Early Phase Studies and the Use of Adaptive Study Designs
Joachim Vollmar, MSc
Executive Consultant, International Clinical Development Consultants LLC

Early Phase Studies: Strategies on How to Get PoC and Dose Finding
John Shillingford, PhD
Vice President, Operational Excellence, Averion, an Aptiv Solutions Company, Germany

#216 Track 3: Outsourcing Strategies and Innovative Partnering Models

10:00 AM – 11:30 AM LEVEL: ■ Format: **FORUM**
Room W178ab

Committing to Two Partners: A Look at a Strategic CRO Sourcing Initiative

CHAIRPERSON

Joan C. Millsaps, MSN, RN
Director, Global Development Operations, Bristol-Myers Squibb Company

A major sponsor company with an increasing volume of work developed an innovative resourcing model with just two CRO partners. The CROs take increased responsibility, while the sponsor reduces its day-to-day role and oversight. In this forum, representatives from both sides of the relationship will discuss challenges and successes.

Baseline Assessment
Lisa McKay, MBA
Senior Director, Relationship Management Programs, The Avoca Group

Change Management
Joan C. Millsaps, MSN, RN
Director, Global Development Operations, Bristol-Myers Squibb Company

Innovation
Joshua Schultz
Corporate Vice President, Strategic Account Leadership, PAREXEL International

Governance
Bari Kowal, MS
Vice President, Strategic Programs, ICON Clinical Research

#217 Track 4: Nonclinical and Early Clinical Translational Development

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W183a

Lessons Learned in the Translational Development of Patient-specific Therapies

CHAIRPERSON

Seth Pauker, PhD, MPH
Principal, Biopharmstrategies

Patient-specific cellular therapies are rapidly transitioning from the bench to the bedside and present novel challenges for commercialization. This session will share lessons learned in addressing operational and organizational CMC development issues.

The Statistical Component of Translational Medicine
Dennis Cosmatos, DrPH
Senior Director, Statistical Sciences, PAREXEL International Corporation

Multicenter Manufacturing of Cellular Therapy Products for Late-phase Clinical Trials: Overcoming Regulatory Challenges
Julia S. Goldstein, MD
Senior Regulatory Officer, NIAID, National Institutes of Health (NIH)

Multicenter Manufacturing of Cellular Therapy Products for Late-phase Clinical Trials: Experiences of an Academic Medical Center Manufacturing Facility
Carolyn Anne Keever-Taylor, PhD
Professor of Medicine, Division of Hematology/Oncology, Medical College of Wisconsin

#218 Track 6: Medical Writing and Communication

10:00 AM – 11:30 AM LEVEL: ● Format: **SESSION**
Room W184bc *CME, Nursing, and Pharmacy credits offered*

Comparative Effectiveness and the Impact on Medical Communications

CHAIRPERSON

Rebecca A. Vermeulen, RPh
Vice President, Strategic Medical Marketing, VMS Biomarketing

This session will focus on the implementation of comparative effectiveness as a means to determine reasonable and adequate patient care. The role of key decision makers will be described for medical communication professionals.

Communicating Health Outcomes Information: An Industry Perspective
Amy Dreibelbis Kemner, MPH
Manager, Global Health Outcomes, Eli Lilly and Company

PANELIST
Tommy Bramley, PhD, RPh
Vice President, Payer and Outcome Solutions, Xcenda

#219 Track 7: IT Methods and Technologies

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W470a *CME, Nursing, and Pharmacy credits offered*

Optimizing Aftermarket Research on Medical Therapies

CHAIRPERSON

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

After approval of a medical therapy, abuse, misuse, overdose, underdose, unforeseen risk, morbidity, and mortality often occur and risks may be increasing. What do physicians, sponsors, and regulators envision as optimal aftermarket support for patients? Can technology options deliver on this vision?

Industry Experience in Pharmacovigilance and Safety Monitoring
Barton L. Cobert, MD, FACP, FPPM
President, BLCMD Associates, LLC

Perspective of a Physician Prescribing Approved Medications for the Treatment of Pain
John F. Peppin, DO, FACP
Director, Clinical Research Division, The Pain Treatment Center of the Bluegrass

#220 Track 8: Research Data and Content Management

10:00 AM – 11:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room W470b *Pharmacy credits offered*

Managing the Content and Data

CHAIRPERSON

Edward S. Tripp
President, Edward S Tripp And Associates Inc

The industry has evolved beyond document management to management of content, data, and metadata. This symposium will present approaches to manage and leverage content and data to optimize processes that utilize this information. The presentations will discuss approaches, management and governance that can be used to get the most benefit from content and data reuse.

Approaches to Improving the Use of Metadata in Content Management Systems
Edward S. Tripp
President, Edward S Tripp And Associates Inc

Demystifying Structured Authoring: Addressing Concerns and Uncovering Realities about XML
Richard Brandt, MS
Vice President, Life Sciences, Quark Inc.

#221 Track 9 (A): Regulatory Affairs and Science, Quality, and GXP Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W186abc *Pharmacy credits offered*

Defining Quality in Clinical Trials

CHAIRPERSON

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

The 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.

FDA Point of View
Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

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

Industry Point of View
Mike Sobczyk, MSc
Senior Director, Compliance, Gilead Sciences

#222 Track 9 (B): Regulatory Affairs and Science, Quality, and GXP Compliance

10:00 AM – 11:30 AM LEVEL: ● Format: **WORKSHOP**
Room W474b

Electronic Submissions for Regulatory Affairs Professionals

CHAIRPERSON

Nancy P. Smerkanich
Vice President, Global Regulatory Affairs, Octagon Research Solutions Inc.

This workshop is for regulatory affairs professionals who have not yet made the move to electronic submissions as it will address what they need to know and how to ease this transition. There will be nonpromotional use of demonstration applications and activities around regulatory requirements and how they map to electronic submissions.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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

Patrick J. Thomas, MS
Associate Director, Clinical Regulatory Affairs, GlaxoSmithKline

#223 Track 9 (C): Regulatory Affairs and Science, Quality, and GXP Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W185a *Pharmacy credits offered*

Expectations and Issues Related to INDs, Clinical Hold, and Refuse to File

CHAIRPERSON

Moheb M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA

The expectations for CMC content of INDs will be reviewed. In addition, reasons for clinical holds and refuse to file actions will be discussed.

CMC Requirements for INDs
Terrance Ocheltree, PhD, RPh
Division Director, Office of New Drug Quality Assessment II, CDER, FDA

CMC Reasons for Clinical Hold and RTF for Protein Products
Emily Shacter, PhD
Chief, Laboratory of Biochemistry, Office of Biotechnology Products, CDER, FDA

PANELIST

Sarah C. Pope Miksinski, PhD
Branch Chief, Office of New Drug Quality Assessment, CDER, FDA

#224 Track 9 (D): Regulatory Affairs and Science, Quality, and GXP Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **FORUM**
Room W185bc

Regulatory Roundtable on Biosimilar Policies

CHAIRPERSON

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

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 health authorities on how they address biosimilars and future opportunities.

PANELISTS

Spiros Vamvakas, MD
Head of Scientific Advice, European Medicines Agency, European Union

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

Teruyo Arato, PhD
Review Director, Office of Biologics I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#225 Track 10 (A): Public Policy/Health Care Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **FORUM**
Room W180 *CME, Nursing, and Pharmacy credits offered*

Protecting Patients in Clinical Research

CHAIRPERSON

Sandra A. Milligan, JD, MD
Executive Director, Amgen Inc.

With thousands of clinical trials ongoing globally, how best can the health, confidentiality, and rights of human subjects be protected? In deciding to approve a clinical trial, IRB's and Ethical Committees are informed of a drug's potential risks and benefits, but how should beneficence be quantified in weighing risk and benefit at the individual subject level?

Quantifying Beneficence in Weighing Risk: Benefit Ratios
Brent Ibata, JD, PhD, MPH, RAC
Site Director, Four Rivers Clinical Research, Inc.

Ethical Considerations in Genetics Research
Anil Sharma, MD, MBA
Medical Director and CEO, IRB Company, Inc.

Quality Assurance and the Protection of Human Subjects: The Sponsor, CRO and IRB Partnership
Tita M. Simmons, MS
Manager, Quality Assurance and Regulatory Compliance, Copernicus Group IRB

#226 Track 10 (B): Public Policy/Health Care Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W183b *Pharmacy credits offered*

Pharmaceutical Pricing and Reimbursement Policies and Practices in Asia Pacific and Latin America: Impact on Drug Development

CHAIRPERSON

Alberto Grignolo, PhD
Corporate Vice President, Global Strategy and Services, PAREXEL Consulting

Successful commercialization of medicines in Latin America and Asia depends on inclusion in local reimbursement schemes at a good price. Diverse P&R policies drive sponsors' drug development strategies, which may impact patient access to innovation.

Alexandre Schiola, MD
Head of Regional Market Access, Latin America, Bayer de Mexico, S.A. de CV, Mexico

John Brennick, MPA
Worldwide Market Access, Janssen Global Services, LLC

Raj Long
DRA Head AMAC, GEM, Latin America, Novartis Pharma AG, Switzerland

#227 Track 11 (A): Clinical Safety and Pharmacovigilance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room W184a *CME, Nursing, and Pharmacy credits offered*

Social Media and Pharmacovigilance

CHAIRPERSON

Jeffrey Litwin, MD
Executive Vice President and Chief Medical Officer, ERT

Social media represents a revolutionary change in how people communicate information with each other. This presents new channels and methods of communicating with patients and health-care providers. Traditional marketing and communication methods historically involved carefully crafted one-way messaging, designed to directly impact patients and health-care providers. With social media, the conversation has obtained a two-way dynamic with instantaneous feedback. This symposium will discuss the pending FDA regulations on social media and the impact on AE reporting and the development of Good Social Media Practices (GSMPs) within the pharmaceutical and drug safety industry.

Pharmacovigilance from Social Media
Dinesh Kasthuril, MS
Director, Pharmacovigilance, Regulatory Affairs and Clinical Operations, Sciformix Corporation, India

AE Reporting in the Era of Web 2.0: The Challenges of Having a Two-way Conversation
Elizabeth E. Garrard, PharmD
Chief Safety Officer, Drug Safety Alliance, Inc.

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

#228 Track 11 (B): Clinical Safety and Pharmacovigilance

10:00 AM – 11:30 AM LEVEL: ■ Format: **WORKSHOP**
Room W475a

Development of an Integrated Framework for Quantitative Risk Benefit Assessment

CHAIRPERSON

John J. Doyle, DrPH, MPH
Vice President and Managing Director, Consulting, Quintiles Consulting, Inc.

The aims of this workshop are to discuss the methodology and development of an integrated quantitative risk and benefit assessment (RBA) framework and illustrate its application to new drug development.

The audience will break into small groups to evaluate the framework using a therapeutic area of their choosing. Further audience participation will be encouraged through active discussion of clinical applications and policy implications.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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

Nicolle M. Gatto, PhD, MPH
Senior Director and Team Lead, WSS Epidemiology, Pfizer Inc

#229 Track 12: Statistics

10:00 AM – 11:30 AM LEVEL: ■ Format: **FORUM**
Room W181bc

Statistical Methods in Comparative Effectiveness Research

CHAIRPERSON

Melanie Poulin-Costello, MSc
Senior Manager, Biostatistics, Amgen Inc., Canada

In this forum, an introduction to appropriate analytical techniques (cost-effectiveness, sensitivity, covariate adjustment) for comparative effectiveness research (CER) will be appraised. Statistical methods for CER will be demonstrated through examples.

Reimbursement of Drugs and Devices: A Canada Perspective on CER
Robert Hopkins, MA, MBA
Biostatistician, PATH Research Institute, McMaster University, Canada

Retrospective, Observational, and Analytical Approaches to CER
Lawrence Helbers
Lead Programmer, Omnicare Clinical Research

Statistics of CER by Example Including Subgrouping
Lorinda L.H. Simms, MS
Research Scientist, Eli Lilly and Company, Canada

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

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W183c *Pharmacy credits offered*

Regulatory Updates on Patient-reported Outcomes (PROs)

CHAIRPERSON

William R. Lenderking, PhD, MA
Senior Research Scientist, United Biosource Corporation

This session will present updates on patient-reported outcome (PRO) issues from a regulatory perspective, with representatives from the FDA and EMA.

EMA Perspective
Sabine Brosch, PharmD, PhD
Business Lead, EudraVigilance and International Standardization in PV, European Medicines Agency, European Union

Evaluation of Patient-reported Outcome (PRO) Measures for Regulatory Qualification to Support Claims
Elektra Johanna Papadopoulos, DrMed, MPH
Medical Officer, Office of New Drugs, CDER, FDA

The Use of PROs in the HTA and Reimbursement Decision-making Process
Kalipso Chalkidou, MD, PhD
Director, NICE International, UK

#231 Track 14: Medical Devices

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W184d

International Harmonization Pathways for Medical Devices

CHAIRPERSON

Steve Caffe, MD

Medical devices approval and postmarketing requirements continue to evolve globally. This poses a strategic challenge to companies to establish a winning go-to-market strategy and optimize postmarket activities and to regulators to define an optimal path globally harmonized. This session will provide a high-level overview of some key issues facing industry and regulatory agencies in addressing current needs for harmonization to facilitate global market access.

International Regulatory Pathways for Medical Devices: Understand Changing Landscape to Develop Go-to-market Strategies
Alan J. Touch, OD
Principal Strategist, INC Research, LLC

The Role of Standardization in the European and Global Harmonization Context for Medical Devices
Mireille De Cre, MSc, RPh
Director, MDCPartners, Belgium

The Need for Clinical Investigations and the Significance of Risk Analysis for Medical Devices
Sunita Ahir, PhD, MSc
Regulatory Affairs Manager, Premier Research Group, Switzerland

#232 Track 15: Professional Development and Training

10:00 AM – 11:30 AM LEVEL: ● Format: **SYMPOSIUM**
Room W474a *PMI PDUs offered*

Fame, Fortune, and F-Tests: Something for Everyone

CHAIRPERSON

Morgan L. Seaman
Learning and Development Senior Manager, ResearchPoint

Careers in the clinical research industry are multifaceted, but successful careers share three common requirements: the ability to effectively communicate with your colleagues, a willingness to focus on your own professional development, and an intrinsic drive to follow your passion. This symposium will provide participants with a unique perspective on each aspect, including one person's experience with implementing the Analysis Data Model (ADaM) and its applicability to clinical trial data analysis.

I Did Not Say That! Or, How to Speak to the Media
Murtuza Vasowalla, MBA, MS
Director, Global Solutions Consulting, QUMAS

Big Business Versus Start-ups: Which Is Best in Providing a Successful Professional Development Program?
Annette M. Bernstein, MBA
Program Manager, Compliance Management, Janssen Pharmaceutical Companies of Johnson & Johnson

Follow Your Passion: Professional Development for the Numbers Folks and A Deep Dive into ADaM
Zhuoye Xu, MS
Statistical Program Analysis, Genentech, Inc.

11:30 AM – 1:30 PM **LUNCHEON**
Exhibit Hall, Level 3, Lunch Distribution Area (see Floor Plan, page 131). See page 8 for instructions on using your lunch vouchers.

#233 Track 1 (A): Clinical Operations

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W175abc *PMI PDUs offered*

Taking the Clinical Trial into the Cloud: Implementing a Web-based Study Community Oriented to the Investigator Site

CHAIRPERSON

Eileen M. Daniel
Director, Clinical Operations, Endo Pharmaceuticals Inc.

The sponsor that launches a site-centric portal can remain at the epicenter of study communication and ensure investigator sites get access to the information they need throughout the study. This session examines the benefits of a free flow of information balanced with the need for integration, alignment and control. Practical issues of implementation will be discussed and a sponsor experience will be presented.

The Globally Distributed Clinical Trial
Rob Scott, MD
Vice President, Global Development, Cardiovascular Therapeutic Head, Amgen Inc.

Site-centric Online Study Communities
James Denmark
CEO, myClin

Beyond the Investigator Meeting, Communication Planning and Execution
Joan K. Bradley, PharmD
President and CEO, The JB Ashtin Group, Inc.

#234 Track 1 (B): Clinical Operations

1:30 PM – 3:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W474b *CME and Nursing credits offered*

Site Selection Process Workshop: Identifying, Selecting, and Defining a Quality Investigator Site

CHAIRPERSON

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

This workshop will also be offered on Monday, June 20 at 10:30 AM.

Less presentation … more discussion! This workshop will offer sponsors, CROs, and investigator sites an interactive environment to discuss the site selection process and establish how to define quality at the site level.

The workshop will consist of three short presentations from a sponsor, CRO, and investigator site followed by roundtable breakout sessions. At the conclusion of roundtables, a chairperson from each table will present conclusive findings followed by a Q&A session.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

Partnering for Better Performance: Sponsor, Site, and CRO Views on Best Practice in Clinical Trial Conduct
Kevin E. Renahan, MSc, MBA
Executive Director, Investigator Relations, Clinical Development Services, Covance, inc.

Feasibility: Sailing into Uncharted Waters by Doing More with Less – Plans to Reduce Time, Cost, and Percentage of Nonactive Sites
Nye G. Pelton
Clinical Portfolio Consultant- Enrollment, Eli Lilly and Company

#235 Track 2 (A): Development Planning

1:30 PM – 3:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W475a *PMI PDUs offered*

How to Build and Run an Adaptive Design: A "Hands-on" Workshop

CHAIRPERSON

Karen Kesler, PhD
Senior Statistical Scientist, Rho, Inc.

Volunteers from the audience will be paired with adaptive design experts to build and run a hypothetical adaptive clinical trial. The volunteers will choose the direction of the study while their corresponding experts will give advice.

In this interactive game show setting, the volunteers will choose the direction of the study while their corresponding experts in clinical, data management, biostatistics, regulatory, and manufacturing will give advice. Together with the audience we will tackle the challenges of designing and conducting an adaptive design.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

#236 Track 2 (B): Development Planning

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W179a *PMI PDUs offered*

Global Pharmaceutical Development in Emerging Markets

CHAIRPERSON

Catherine K. Ohura, MS, PMP
Associate Director, Project Planning and Management, Bristol-Myers Squibb Company

This symposium will offer a view of the strategies, market opportunities, and governmental programs available when developing pharmaceutical compounds in emerging markets. Some of the emerging markets include Latin America, Japan, China/East Asia, India, and Russia.

Strategies for Developing Medicines in Developing Countries
Joao Massud, MD
Director, Trials Consulting, Brazil

Pharmaceutical Market Opportunities in Latin America, Japan, China/East Asia, India, and Russia
Diego Martin Glancszpigel, Sr., MBA
Vice President, Latin America, PAREXEL International, Argentina

Governmental Programs Fostering Global Collaborative Clinical Research
Gustavo L.F. Kesselring, MD
Executive Director, ViS Research Institute, Hospital Alemao Oswaldo Cruz, Brazil

#237 Track 2 (C): Development Planning

1:30 PM – 3:00 PM LEVEL: ● Format: **SESSION**
Room W179b

Using Simulation Models to Inform Product Development and Portfolio Planning Decisions

CHAIRPERSON

Badri Rengarajan, MD
Medical Director, Archimedes

Developing life sciences products requires substantial investment, time, and risk tolerance. Actively managing development portfolios is critical. Simulation modeling can guide trial design and portfolio decisions by revealing the short- and long-term health and cost outcomes expected under different trial design scenarios.

Using Simulation Models to Inform Product Development and Portfolio Decision Making
Badri Rengarajan, MD
Medical Director, Archimedes

Simulation and Modeling of Disease: A Brief Review and Example for HIV Treatment Decisions
Mark S. Roberts, MPP, MD
Professor and Chair, Department of Health Policy and Management, Graduate School of Public Health, University of Pittsburgh

Prioritization of Interventions in Metabolic Disease
Patrick L. McCollam, PharmD
Principal Research Scientist, Global Health Outcomes, Eli Lilly and Company

The Role of Simulation in Representing Real-world Risk in Biopharma R&D Portfolio Optimization
Davis Walp, MBA
Head, Value Based Solutions, Commercial Solutions, Quintiles

#238 Track 3: Outsourcing Strategies and Innovative Partnering Models

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W178ab

An Innovative Strategic Partnering Relationship: Can This Approach Revolutionize Drug Development?

CHAIRPERSON

Solomon Babani, MBA
Senior Director, Outsourcing and Alliance Management, Celtic Therapeutics Development

In designing the strategic partnership model for a private equity firm and a CRO, it was important to align the goals of both companies with the partnership structure and business/contracting models.

The Industry Perspective
Patricia Leuchten
CEO and President, The Avoca Group Inc.

The Sponsor Perspective
Solomon Babani, MBA
Senior Director, Outsourcing and Alliance Management, Celtic Therapeutics Development

The CRO Perspective
Kerry Toone
Executive Director, PPD Development Inc.

#239 Track 4: Nonclinical and Early Clinical Translational Development

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W183a

ICH Guidelines on Genotoxic Impurities and Residual Metals: CMC and Safety Issues

CHAIRPERSON

Dr. Lutz Müller
R&D Project Leader, Nonclinical Drug Safety, F. Hoffmann-La Roche AG, Switzerland

There are guidelines on genotoxic impurities and residual metals already implemented in the EU, and there is a draft guideline available for genotoxic impurities in the US. Two ICH expert working groups are in the process of developing harmonized guidelines on these two topics for global implementation. The ICH guidelines will supersede any regional guidelines.

This session will describe the scope of the proposed guidelines and the various issues that will be addressed. The guidelines will address safety issues, as well as quality aspects of pharmaceutical development, manufacturing, and quality assurance.

ICH Q3D Guideline on Metal Impurities: CMC Issues
John F. Kauffman, PhD, MBA
Research Chemist, Division of Pharmaceutical Analysis, CDER, FDA

ICH M7 Guidance on Mutagenic Impurities: Safety Issues as Reasons to Go for an ICH Process
Dr. Lutz Müller
R&D Project Leader, Nonclinical Drug Safety, F. Hoffmann-La Roche AG, Switzerland

#240 Track 6: Medical Writing and Communication

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W184bc *Pharmacy credits offered*

Publications: Does Your Company Policy Pass the Red-faced Test?

CHAIRPERSON

Art Gertel, MS
Vice President, Strategic Regulatory Consulting, Medical Writing and Quality Assurance, Beardsworth Consulting Group, Inc.

Industry has a scientific and ethical obligation to publish new, medically relevant information regarding their products. This forum will inform attendees about the current compliance environment regarding publication practices within the industry.

Publication Standards: How Did We Get There, Where Are We Going, and Who's Driving?
Art Gertel, MS (see above for professional details)

Publication Policy Development and Next Steps
Susan C. Glasser, PhD
Senior Director, Scientific and Medical Publications, Johnson & Johnson Pharmaceutical Research & Development LLC

Appropriate Publication Planning Agency Practices in the Current Compliance-focused Environment
Henry W. Singer
Executive Vice President; Managing Director, Publication, CONNEXION Healthcare

#241 Track 7: IT Methods and Technologies

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W470a *CME and Nursing credits offered*

New eClinical Technology: Risks, Benefits, Security, Planning, Workflow, and Outcomes

CHAIRPERSON

Susan Brink, DrPH
CEO, ConsentSolutions, Inc.

Recruitment, consenting, and monitoring are three areas that have seen the implementation of technology-based application. This session will address the security and implementation issues that present in social networking, eConsenting, and video monitoring of patient compliance.

Planning, Security, and Workflow in the Implementation of Electronic Consent
Susan Brink, DrPH
CEO, ConsentSolutions, Inc.

A Smaller World: Telecommunications in Clinical Research
Andrew A. Smith
Director, Information Technology, REGISTRAT-MAPI, Inc.

Video Dosing: Improving Patient Compliance Through Technology
Danielle Foster
Patient Recruitment Specialist I, PAREXEL International

#242 Track 8: Research Data and Content Management

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W470b *CME, Nursing, and Pharmacy credits offered*

What Is an Endpoint? A Disease-specific Discussion of Study Endpoints

CHAIRPERSON

John M. Weiler, MD, MBA
President, Compleware Corporation

Recent regulatory guidance and industry initiatives have brought a renewed focus on study endpoints and their use in clinical trials. During this forum, the speakers will review the types of endpoints in use today and detail when it is appropriate to use certain types of endpoints. This session will not only discuss patient-reported outcomes, but will also discuss clinical-reported outcomes (ClinROs) and observer rated outcomes as well as biomarkers in the context of a disease specific example to provide real-world context to the issue involved in selecting and collecting study endpoints. This unique session brings together physicians, including current and former regulators, to discuss study endpoints and their use in today's clinical trials.

Study Endpoints to Support Labeling Claims: A Regulatory View
Elektra Johanna Papadopoulos, DrMed, MPH
Medical Officer, Office of New Drugs, CDER, FDA

Scientific Considerations on Endpoint Selection: Impacts on Drug Development
John H. Powers, MD, FACP, FIDSA
Senior Medical Scientist, Support for Collaborative Clinical Research Branch, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, NIH, SAIC-Frederick Inc., National Cancer Institute at Frederick

EMA Point of View
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

#243 Track 9 (A): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ● Format: **SESSION**
Room W183c *CME and Nursing credits offered*

Ensuring GCP Compliance in Emerging Regions

CHAIRPERSON
Munish Mehra, PhD
Managing Director, Global Drug Development Experts

Ensuring GCP and regulatory compliance continues to become more difficult as trials become larger, more complex, and are run in countries with inadequate infrastructure and oversight. This session will offer insights how best to ensure compliance.

Emerging Countries: Frequent Compliance Challenges, Mitigation Strategies, and Ethical Concerns
Fernando Martinez, PhD
Executive Director, Global Operations, inVentiv Clinical Solutions, LLC, Spain

Current Update from Recent GCP Audits in Southeast Asia and Turkey
Shehnaz Kairas Vakharia, MSc
Principal Consultant, Theraverity, India

Ensuring GCP Compliance at Investigational Sites in Emerging Countries: Implementation of Site SOPs
Munish Mehra, PhD
Managing Director, Global Drug Development Experts

#244 Track 9 (B): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W185a

Knowledge Management Throughout the Pharmaceutical Product Life Cycle

CHAIRPERSON
Georges L. France, PharmD, PhD
Vice President, Quality Strategy, Global, Pfizer Ltd, UK

The enhanced approach to product quality introduced by ICH Q8, 9, and 10 provides the opportunity to more systematically generate data/information and, more importantly, knowledge, from the early development to the manufacture of a product and beyond to address the potential for continual improvement of product, processes, and the quality system. However, what does knowledge management for the industry mean in practice? Is it a completely new concept or an historical driver of a well structured, comprehensive, and efficient approach? This session will answer these questions and provide industry, regulator, and European Pharmacopeia perspectives on this topic.

The Standard for New Analytical Technology for Knowledge Management
Susanne Keitel, DrSc, RPh
Director, EDQM, France

Knowledge Management: Expectation from the Regulator
Kelli F. Dobilas
Pre-approval Manager, NWJ-DO SCSO Group 1, Office of Regulatory Affairs, FDA

#245 Track 9 (C): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W185bc *CME, Nursing, and Pharmacy credits offered*

Orphan Drug Development: 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 orphan drug development challenges, and provide information on various strategies designed to overcome these challenges from both regulatory and industry perspectives.

Standards for Clinical Trials to Support Marketing Applications and Considerations for Drug Development for Rare Diseases
Anne R. Pariser, MD
Associate Director for Rare Diseases, Office of New Drugs, CDER, FDA

Strategies for Success in Orphan Drug Development
Jonca C. Bull, MD
Vice President, Drug Regulatory Affairs, FDA Liaison Office, Novartis Pharmaceuticals Corporation

Overcoming Orphan Drug Designation Challenges
Marlene E. Haffner, MD, MPH
CEO, Haffner Associates, LLC

#246 Track 9 (D): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W185d *CME and Nursing credits offered*

The Impact of Transparency Requirements for BPCA and PREA

CHAIRPERSON
Lisa L. Mathis, MD
Associate Director, Office of New Drugs, Pediatric and Maternal Health Staff, CDER, FDA

This session reviews increased transparency requirements for studies performed in the pediatric population to include labeling, public posting of reviews, written requests, and public discussion of the safety reviews required by FDAAA.

Industry Point of View
Ronald Portman, MD
Group Director, Bristol-Myers Squibb Company

EU Point of View
Dirk Mentzer, DrMed
Vice Chair of PDCO; Head of Pharmacovigilance Unit, Paul-Ehrlich-Institut, Germany

#247 Track 10 (A): Public Policy/Health Care Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W180 *CME, Nursing, and Pharmacy credits offered*

Partnering with Patients in Clinical Research

CHAIRPERSON

Craig H. Lipset
Senior Director (Clinical Research) and Venture Partner (Pfizer Venture Capital), Pfizer Inc

Modern drug development requires creative partnerships — between pharmaceutical companies, academic researchers, and increasingly with nonprofit organizations and patient groups. This session will bring together stakeholders from pharma, nonprofits, and a patient group to discuss best practices and identify a partnering roadmap for the future.

Alzheimer's Association Perspective
Jay Thompson
Senior Associate Director, Corporate Initiatives, Alzheimer's Association

FasterCures Perspective
Kristin Schneeman
Program Director, FasterCures

Industry Perspective
Craig H. Lipset
Senior Director (Clinical Research) and Venture Partner (Pfizer Venture Capital), Pfizer Inc

#248 Track 10 (B): Public Policy/Health Care Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W183b *CME, Nursing, and Pharmacy credits offered*

Clinical Trial Disclosure Requirements: Coping with Multiple Governmental Registries

CHAIRPERSON

Robert Paarlberg, MS
Principal, Paarlberg & Associates, LLC

This session will discuss how companies are maximizing processes to cope with the increasing demand of global disclosure requirements. This session will also discuss the impact of EMA's and NLM's recent clinical trial disclosure requirements.

Strategies for Global Clinical Trial Disclosure Compliance
Erik William Lakes, MSc
Associate, Clinical Trial Registration and Results Disclosure, Takeda Global Research & Development Center, Inc.

Clinical Trial Disclosure Processes to Maximize Re-use of Data and Ensure Compliance
Sarah Doyle Larson
Regulatory Affairs Manager, Clinical Trial Transparency, Genzyme Corporation

Inconsistent Trial Disclosure Across International Registries: The Costs and Suggested Remedies
Thomas Wicks, MBA
Director, Product Management, Intrasphere Technologies Inc.

#249 Track 11 (A): Clinical Safety and Pharmacovigilance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W184a *CME and Nursing credits offered*

Medical Review of Individual Cases – Enough is Enough: A Waste of PV Resources, or Core PV Activity?

CHAIRPERSON

Mariette Boerstoel-Streefland, MD, MBA, MS
Chief Safety Officer, Vice President, Global Drug Safety, Forest Research Institute

This session will target current controversies on the added value of medical review of individual cases. Different current practices and their underlying philosophies on the need for and added value of rigorous medical case review will be shared.

Targeted Approach to Medical Review: A Case Study
Ann Marie O'Brien, MBA, MPH
Director, Case Management Group, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Back to Basics: What Are the Goals of Medical Review of Individual Case Study Reports?
Gregory J. Fiore, MD
Consultant; Former Senior Director at Merck

Benchmarking: How Companies Do Medical Review and the Implications on PV Organizations
Wilfred Peter Gilich, MBA
Principal, WCI US Life Sciences

#250 Track 11 (B): Clinical Safety and Pharmacovigilance

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W176abc *CME and Nursing credits offered*

Practical Applications of MedDRA® for Safety Data Analysis: Industry and Regulatory Perspectives

CHAIRPERSON

Alan M. Hochberg
Drug Safety Scientist, F. Hoffmann-La Roche, Ltd., Switzerland

Companies and regulators have used MedDRA® in AE reports for years. There is keen interest in best approaches for analysis of MedDRA®-coded data. Regulatory and industry experts will share useful practices for safety data analysis using MedDRA®.

FDA Point of View
Charles K. Cooper, MD
Medical Officer, Office of Translational Sciences, CDER, FDA

Industry Point of View
Makan Sarkeshik, MD
Medical Director, Safety, Amgen, Inc.

MedDRA® MSSO Point of View
Patricia Mozzicato, MD
Chief Medical Officer, MedDRA® MSSO

#251 Track 12: Statistics

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W181bc

Statistical Methods to Enable Tailored Therapeutics

CHAIRPERSON

Brian A. Millen, PhD, MS
Research Advisor, Eli Lilly and Company

This session will present current and novel statistical approaches for the design and analysis of clinical trials with tailoring objectives. Clinical trial examples will facilitate comparisons among available methods.

Statistical Considerations for Trials with Tailoring Objectives
Brian A. Millen, PhD, MS
Research Advisor, Eli Lilly and Company

Statistical Considerations and Clinical Trial Designs for Biomarker Validation
Sumithra J. Mandrekar, PhD
Biostatistician, Mayo Clinic

Potential Uses of the Fallback, the 4A, and the Consistency-insured Methods in Testing for a Targeted Subgroup of a Clinical Trial
Mohammad Huque, PhD
Director, Division of Biometrics IV, CDER, FDA

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

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W184d *Pharmacy credits offered*

Comparative Effectiveness Research: What Is the Current Direction?

CHAIRPERSON

J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality (AHRQ)

This session includes presentations from recently funded comparative effectiveness research by the Agency for Healthcare Research and Quality (AHRQ).

Comparative Effectiveness Research: Doing the Right Thing
Joe V. Selby, MD, MPH
Director, Division of Research, Kaiser Permanente

Estimating Therapeutic Effectiveness Using Observational Data: Challenges, Pitfalls, and Limitations
Bradley G. Hammill, MS
Senior Biostatistician, Duke Clinical Research Institute

Keeping Abreast of Methodological Developments for Using Observational Studies for CER: AHRQ Handbooks on Registries and Methods
Nancy Dreyer, PhD, MPH, FISPE
Chief of Scientific Affairs and Senior Vice President, Outcome

#253 Track 15: Professional Development and Training

1:30 PM – 3:00 PM LEVEL: ● Format: **SESSION**
Room W474a *PMI PDUs offered*

Calculating Return on Investment for Teaching Intangibles and What to Analyze: Maximizing Resources for Professional Development

CHAIRPERSON

Donna Ellender, PhD
Regulatory Sciences, sanofi-aventis, France

This session will address using new ideas from outside the pharmaceutical industry, how to calculate and maximize value and return on investment for learning, and communication opportunities, particularly in hard economic times. We will be sharing expertise using Communities of Practice.

How to Measure the Value of Training
Tad Waddington, PhD
Director, Performance Measurement, Accenture

Use of Communities of Practice to Help Maximize Resources for Professional Development
Donna Ellender, PhD
Regulatory Sciences, sanofi-aventis, France

#254 Track 16 (A): Global Agency

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W187abc *CME and Nursing credits offered*

Regulatory Update from the Office of New Drug Quality Assessment, Office of Biotechnology Products, Office of Generic Drugs, Office of Compliance, and Office of Regulatory Affairs

CHAIRPERSON

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

This forum will provide a brief regulatory update from the Offices, along with a panel session to allow the audience to ask questions regarding the latest FDA initiatives.

Update on What Is Happening in ORA
Myriam Sosa
Director, Investigations Branch, Office of Regulatory Affairs, FDA

PANELISTS

Moheb M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA

Carmelo Rosa
Branch Chief, International Compliance Branch, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

Keith Webber, PhD
Deputy Director, Office of Pharmaceutical Science, CDER, FDA

#255 Track 16 (B): Global Agency

1:30 PM – 3:00 PM LEVEL: ● Format: **FORUM**
Room W186abc *CME and Nursing credits offered*

India Regulatory Agency Town Hall

CHAIRPERSON

Sultan S. Ghani, MS, FACP
Director, DIA (India) Private Limited, India

New for 2011: In this first-time offered forum, representatives from India's regulatory agencies will provide updates on initiatives, guidances, and regulations in their country, and the audience will have an opportunity to address the esteemed panel.

India's Pharmaceutical Industry and Regulations
Hemant Gordhanbhai Koshia
Commissioner, Food and Drugs Control Administration, India

PANELISTS

Representative Invited
The Drug Controller General, Central Drugs Standard Control Organisation India

Representative Invited
Drugs Controller, Drug Control Department, India

3:00 PM – 3:30 PM **REFRESHMENT BREAK**
Exhibit Hall, Level 3 (See Floor Plan, page 131)

#256 Track 17 (A): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W181a *CME, Nursing, and Pharmacy credits offered*

First-in-human Dosing for Small and Large Molecules: Similarities and Differences

CHAIRPERSON

William J . Brock, PhD
Principal, Brock Scientific Consulting LLC

This showcase will offer a discussion-based approach to understanding small and large molecule drugs in development strategies, and the issues facing project teams in early first-in-human dosing concepts that result in "go or no-go" decisions.

Developed by the Biotechnology and Innovative Preclinical Sciences (BIPS) SIAC.

Principles of FIH Dose Selections: Small Molecules
Lorrene A. Buckley, PhD, MS
Research Fellow, Eli Lilly and Company

Nonclinical Data for FIH Dosing: From "Hit" to FID
William J. Brock, PhD
Principal, Brock Scientific Consulting LLC

#257 Track 17 (B): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W470a

Moving from Managing Data to Managing Information

CHAIRPERSON

Johann Pröve, PhD
Global Head, Data Management, Bayer Healthcare, Germany

CDM has shifted from managing the trial data to a broader, complex task of managing trial information. With the advent of EDC, the CDM can now provide information to the organization that is helpful in making early decisions and in managing the trial.

Developed by the Clinical Data Management (CDM) SIAC.

Moving from Managing Data to Managing Information
Teresa Ancukiewicz
Senior Manager, Boston Scientific Corporation

Turning Data into Information, and the Changing Role of CDM in the Industry
Paula Brown Stafford, MPH
President, Clinical Development, Quintiles

#258 Track 17 (C): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ● Format: **SIAC**
Room W178ab *Pharmacy credits offered*

Health Care Reform: Charting New Strategies for Clinical Trials

CHAIRPERSON

Melvyn Greberman, MD, MPH, MS, FACPM
President, Public Health Resources, LLC

Health-care reform opened clinical research models broadened with preventive health, economic and comparative effectiveness research implications. Patient group collaboration will support new strategies for clinical development pipelines and broaden the future of clinical trials.

Developed by the Clinical Research (CR) SIAC.

Partnering with Patients to Advance R&D Pipeline
Craig H. Lipset
Senior Director (Clinical Research) and Venture Partner (Pfizer Venture Capital), Pfizer Inc

Putting Patients at the Center of Research
Kristin Schneeman
Program Director, FasterCures

#259 Track 17 (D): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W183a *CME, Nursing, and Pharmacy credits offered*

Drug Safety and Pharmacovigilance Inspections: MHRA Approaches

CHAIRPERSON

Steve Jolley, MA
Principal, SJ Pharma Consulting

This showcase will feature regulatory representative(s) who will describe how to conduct drug safety and pharmacovigilance operations to ensure compliance with applicable worldwide laws, regulations, and guidance. Best practices in ensuring what to look for during an inspection as well as differences in approaches will be discussed.

Developed by the Clinical Safety and Pharmacovigilance (CSP) SIAC.

Ensuring Compliance with the Pharmacovigilance Audit
Steve Jolley, MA
Principal, SJ Pharma Consulting

Drug Safety and Pharmacovigilance Inspections: MHRA Approaches
Joanna Harper
IE&S Division, Pharmacovigilance Inspector, MHRA, UK

#260 Track 17 (E): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ● Format: **SIAC**
Room W183b

EDM and TMF Reference Models: The Path Forward

CHAIRPERSON

James M. Averback, MS
Partner, Life Science Integration Partners

Both the electronic document management (EDM) and Trial Master File (TMF) Reference models are in wide use by industry and extensions have been requested. Join us in an open forum to extend these models. Provide your input and engage in their future development.

Developed by the Document and Records Management (DRM) SIAC.

How to Extend the Use of Reference Models
James M. Averback, MS
Partner, Life Science Integration Partners

The TMF Reference Model
Lisa D. Mulcahy
TMF Document Management Consultant, Mulcahy Consulting, LLC

#261 Track 17 (F): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ● Format: **SIAC**
Room W180 *Pharmacy credits offered*

Comparative Effectiveness: Where Do We Stand Today?

CHAIRPERSON

Christopher M. Marrone, PharmD
Senior Outcomes Liaison, Eli Lilly and Company

This showcase will review the basics of Comparative Effectiveness Research (CER), as well as provide an update on the status of the government's American Recovery and Reinvestment Act (ARRA) investment in CER.

Developed by the Evidence-based Medicine (EBM) SIAC.

Joshua S. Benner, DrSc, PharmD
Research Director and Fellow, Engelberg Center for Health Care Reform, The Brookings Institution

#262 Track 17 (G): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W176abc *CME and Nursing credits offered*

Hot Topics in eClinical

CHAIRPERSON

Jonathan R. Andrus, MS
Vice President, Data and Study Operations, BioClinica, Inc.

This interactive showcase will discuss topics related to eClinical-based approaches for improving data quality, developing protocols, and clinical trial planning, risk-based approaches and how they can influence the role of monitoring. We will also touch on best practices and approaches to study start up, conduct and closeouts, and reaching across the aisle to your clinical research colleagues to affect change.

Developed by the eClinical (EC) SIAC.

Current Tools and Technologies that Impact Data Quality (EDC, ePRO, IVRS, eProtocol, eSource, Data Collection) and How Emerging Tools May Impact Tomorrow
Joseph Dustin
Senior Business Consultant, Medidata Solutions Worldwide

Valdo Arnera, MD
General Manager, Europe, PHT Corporation, Switzerland

#263 Track 17 (H): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W179a

Hot Topics in eSubmissions: A Panel Discussion

CHAIRPERSON

John Aitken, PhD
Director, Regulatory Operations, Gilead Sciences

This highly interactive showcase includes FDA, industry, and vendor representatives who will review and discuss hot topics in eSubmissions. Attendees are encouraged to bring along additional topics and share their experiences with their colleagues.

Developed by the Electronic Regulatory Submissions (ERS) SIAC.

PANELISTS

Nancy P. Smerkanich
Vice President, Global Regulatory Affairs, Octagon Research Solutions Inc.

Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, CDER, FDA

#264 Track 17 (I): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ● Format: **SIAC**
Room W175abc *CME, Nursing, and Pharmacy credits offered*

How to Avoid Warning Letters: Knowing Your Good Clinical Practice (GCP) Responsibilities

CHAIRPERSON

Munish Mehra, PhD
Managing Director, Global Drug Development Experts

Everyone involved in the design, conduct, analysis, or reporting of clinical trials must ensure that there is adherence to the requirements of GCP. This showcase provides an overview of GCPs and what your responsibilities are based on your job function.

Developed by the Good Clinical Practice and Quality Assurance (GCP & QA) SIAC.

GCP Requirements and How They Pertain to Each Job Function
Munish Mehra, PhD
Managing Director, Global Drug Development Experts

FDA Perspective
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science, Office of the Commissioner, FDA

#265 Track 17 (J): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W179b

Doing More with Less: A Review of the Industry's Response to Financial Pressures and the Outlook for Service Providers

CHAIRPERSON

Tiffany Sizemore Cherry, JD, MBA
President and Chief Executive Officer, PharmContrax

Economic conditions have forced pharmaceutical companies to adapt their sourcing strategies, affecting procurement and resource selection practices worldwide. This showcase will review the industry's response to financial pressure and the outlook for providers.

Developed by the Global Sourcing (GS) SIAC.

The Global Recession and Rebound in Health Spending
Thomas E. Getzen, PhD
Professor, Fox School of Business, Temple University
Executive Director, iHEA

#266 Track 17 (K): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W470b

Drive IT and Business Alignment to Increase Value

CHAIRPERSON

Pamela Campbell, MBA
Senior Practice Consultant, EMC

In this showcase, panelists experienced in process improvement change management, compliance, and measuring the IT/business value will discuss frameworks and best practices to enable IT/business alignment and ensure that IT is a business enabler.

Developed by the Information Technology (IT) SIAC.

PANELISTS

Skip Garrison
Quality Assurance, Forest Laboratories Inc.

Paulette V. Roper, MS
Senior Manager, Clinical Informatics, Allergan, Inc.

#267 Track 17 (L): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W184a

Social Media: Proceeding with Caution

CHAIRPERSON

Stacey M. Fung, PharmD
Senior Manager, Medical Communications, BioOncology, Genentech, Inc.

There has been a lot of buzz about using social media to facilitate communications with customers. This showcase highlights opportunities and challenges for successful utilization of these tools within the pharmaceutical industry.

Developed by the Medical Communications (MC) SIAC.

Regulatory Guidelines and Social Media: Proceed with Caution
Jennifer L. Riggins, PharmD
Director, Global Information Disclosure, Eli Lilly and Company

Why Social Media Matters for Pharma
Joan Mikardos
Senior Director, sanofi-aventis

#268 Track 17 (M): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ● Format: **SIAC**
Room W184bc

The Medical Writer's Strategic Impact on Regulatory Documents and Peer-reviewed Publications

CHAIRPERSON

Linda Fossati Wood, MPH, RN
President, MedWrite, Inc.

This showcase will explain the strategic and tactical contributions of medical writers to regulatory (drug applications, regulatory responses, periodic safety reviews, etc.) and publication documents (abstracts, manuscripts, posters, and slide sets).

Developed by the Medical Writing (MW) SIAC.

PANELISTS

David B. Clemow, PhD
Scientific Communications Consultant, Eli Lilly and Company

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

#269 Track 17 (N): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W184d

Change in Global Perspectives for Natural Health Products

CHAIRPERSON

Werner Knoess, DrSc
Scientific Director, Head of Department of HMP and CAM, BfArM, Germany

Natural health products have been used all over the world. Strategies in the marketing of NHPs are increasingly considering global perspectives. This showcase will address important categories of NHPs and discuss the impact of regulatory systems.

Developed by the Natural Health Products (NHP) SIAC.

Developing New Botanical Drugs from NHPs, Dietary Supplements, and Herbal Medicines: A Botanical Drug Reviewer's Perspective
Jinhui Dou, PhD
Botanical Review Team, Office of New Drugs, Office of Drug Evaluation IV, CDER, FDA

Targeted Botanicals from Latin American Selected Plants
Carmen Tamayo, MD
Consultant, Heterogeneity, LLC

#270 Track 17 (O): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W185a *CME, Nursing, and Pharmacy credits offered*

Challenges for Pediatric Drug Development: Are Clinical Trials ALWAYS Needed? When and How Can We Extrapolate from Prior Data?

CHAIRPERSON

Gesine Bejeuhr, PharmD
Senior Manager, Regulatory Affairs/Quality, vfa Research-Based Pharmaceutical Companies, Germany

It is understood that clinical trials with children should provide benefits for children. This showcase will discuss when previous data might reduce the need for a clinical trial and how to best address concerns of efficacy and safety.

Developed by the Pediatric Drug Development (PDD) SIAC.

What Constitutes Reasonable Extrapolation and Bridging: US View
Samuel D. Maldonado, MD, MPH
Vice President, Head of Pediatric Drug Development Center of Excellence, Johnson & Johnson Pharmaceuticals Research & Development, LLC

What Constitutes Reasonable Extrapolation and Bridging: EU View
Angelika Joos, MPharm
Head, Regulatory Policy, EU and Most of World, Merck Sharp & Dohme Inc., Belgium

#271 Track 17 (P): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ● Format: **SIAC**
Room W474a

Through the Eyes of Others: What We Can Learn from Nonpharma Industries About Learning in 2011

CHAIRPERSON

Daniel F. Mudgett
Vice President, Knowledge Management, Medidata Solutions Inc.

Learn how other industries leverage innovative learning strategies and solutions to overcome challenges and enable success in changing and complex environments.

Developed by the Professional Education Training and Development (PETD) SIAC.

The Learning Organization of the Future: Lessons from the 2011 Learning Elite
Stacey Boyle, PhD, MS
Vice President, HCM Advisory Group, Mediatec Publishing Inc.

#272 Track 17 (Q): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W181bc *PMI PDUs credits offered*

Project Management in Biopharmaceuticals: The Last Two Decades of Innovation Provide the Foundation for the Next Ten Years

CHAIRPERSON

Rajendra Mohabir, PhD
Product Development Consultant

Portfolio, capacity, and alliance management have evolved from basic project management and will be used for future complex technologies and cross-industry partnerships including personalized health care/diagnostics, stem cell research, and cleantech.

Developed by the Project Management (PM) SIAC.

Stem Cell Product Development
Katy Spink, PhD
Vice President, Operations and Regenerative Medicine Programs, Geron

Medical Device Development: A Case Study
Yu Ping Yen, DrSc
Vice President of Clinical Development and Operations, Aerovance, Inc.

#273 Track 17 (R): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W187abc *CME and Nursing credits offered*

Hot Topics in Regulatory Affairs

CHAIRPERSON

Sarah Powell
Executive Director, Regulatory Affairs, Liquent, Inc.

Join the Regulatory Affairs SIAC as we discuss the ever-evolving global regulatory affairs environment including, but not limited to issues surrounding transparency and disclosure, regulatory agency metrics and their impact on industry, and the development of biosimilars. In addition, the audience will be encouraged to share their organizations' perspectives on these issues and how they have or are planning to handle the challenges facing their regulatory departments.

Developed by the Regulatory Affairs (RA) SIAC.

PANELISTS

Linda F. Bowen, MS, RAC
Senior Director, Regulatory Policy and Intelligence, sanofi-aventis

Yasmin de Faria Krim
Manager, Regulatory Affairs, Johnson & Johnson, Belgium

#274 Track 17 (S): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W185bc *CME, Nursing, and Pharmacy credits offered*

Hot Topics in Study Endpoints: Q&A with an Expert Panel

CHAIRPERSON

John M. Weiler, MD, MBA
President, Compleware Corporation

The issues of what you want to measure, what makes for a good endpoint, when you gather endpoints, and how you make your labeling claim are complex and inter-related. This showcase gives you an opportunity to interact with an expert panel around today's pressing issues of figuring out the kinds of endpoints required based on the disorder and the important issue that all you can measure is what the patient experiences. This showcase will give attendees the opportunity to ask follow-up questions from the "What is an Endpoint" session in Track 8.

Developed by the Study Endpoints (SE) SIAC.

PANELIST

John H. Powers, MD, FACP, FIDSA
Senior Medical Scientist, Support for Collaborative Clinical Research Branch, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, NIH, SAIC-Frederick Inc., National Cancer Institute at Frederick

Elektra Johanna Papadopoulos, DrMed, MPH
Medical Officer, Office of New Drugs, CDER, FDA

#275 Track 17 (T): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W186abc

The Evolution of the Statistics SIAC as a Hub for Collaboration and Interaction Among Industry, Academia, and Government

CHAIRPERSON

Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

Early results of efforts to bring industry, academia, and government together to address key statistical issues in the development of new drugs and biologics will be discussed, along with issues and current strategies for acceptable solutions.

Developed by the Statistics (ST) SIAC.

Creating a Collaborative Environment: The Wiki Way
Joan K. Buenconsejo, PhD, MPH
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

#276 Track 17 (U): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W185d

FDA Part 11 Inspection Program Results

CHAIRPERSON

Richard L. Chamberlain, PhD, MS
President, Executive Consultant Services

FDA conducted a series of inspections for Part 11 compliance to determine the extent of industry compliance and the necessity for changes in the Regulation or Guidances. Results will be presented and discussed by industry and FDA validation experts.

Developed by the Validation (VA) SIAC.

FDA Part 11 Inspection Program Results
George R. Smith, Jr., MA
Project Management Officer, CDER, FDA

Harry C. Huss, MS
Independent Consultant

#277 Track 17 (V): SIAC Showcase

3:30 PM – 4:30 PM LEVEL: ■ Format: **SIAC**
Room W183c *CME, Nursing, and Pharmacy credits offered*

Biologics: Changing the Phase 1 Clinical Landscape

CHAIRPERSON

Stacie J. Bell, PhD
Assistant Director, Clinical Pharmacology, Array BioPharma, Inc.

As biologic and biosimilar drug development intensifies, it poses scientific, bioprocess, safety, ethical, and regulatory challenges in sharp contrast to small molecule drugs. How are clinical pharmacology professionals meeting these challenges?

Developed by the Clinical Pharmacology (CP) SIAC.

Optimal Bridging of Preclinical Data to Clinical Implementation and Trial Design
R. Stephen Porter, PharmD
President, Dragon Bio-Consultants Ltd.

Practical Implications in the Clinical Pharmacology Unit (CPU)
Matthew M. Medlock, MD
PPD Phase I Unit

#278A Track 18A: Late Breaker

4:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W180

Workforce Training Needs in Real-world Outcomes: Survey Results

This late-breaking session will reveal the results of the DIA's Real-world Outcomes Task Force Survey.

SPEAKER

Richard Gliklich, MD
President and CEO, Outcome Services, Inc.

#278B Track 18B: Late Breaker

4:45 PM – 5:45 PM LEVEL: ■ Format: **FORUM**
Room W187abc

Interoperability Showcase Town Hall

CHAIRPERSON

Rebecca D. Kush, PhD
President and CEO, CDISC

Join members of the FDA in an open panel to discuss technical solutions for using EHRs in conducting regulated clinical research and safety reporting, as shown in the DIA-CDISC-IHE-HIMSS Interoperability Showcase. In addition, the panel will be open to taking questions related to the recent eSource Draft Guidance Document that was released by FDA earlier this year.

PANELISTS

Sean Y. Kassim, PhD
Pharmacologist, Office of Compliance, CDER, FDA

Jonathan S. Helfgott
Consumer Safety Officer, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Representative Invited
Director, Office of Interoperability and Standards, Office of the National Coordinator for Health Information Technology, Office of the Secretary, Department of Health and Human Services

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Office of Biometrics III, CDER, FDA

Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Terrie Reed
Associate Director, Informatics, CDRH, FDA

4:30 PM **END OF TUESDAY SESSIONS**

NOTES

NOTES

Wednesday, June 22

7:00 AM – 5:00 PM **Attendee Registration**
Exhibit Hall, Level 3

7:00 AM – 5:00 PM **Speaker Registration**
Exhibit Hall, Level 3

7:00 AM – 5:00 PM **Exhibitor Registration**
Exhibit Hall, Level 3

7:15 AM – 8:00 AM **Coffee and Breakfast Breads**
McCormick West, Lobby Entrance, Level 1

9:00 AM – 4:00 PM **Exhibition Hall Open**
Level 3

11:30 AM – 1:30 PM **Professional Poster Session**
Exhibit Hall, Level 3

3:00 PM – 4:30 PM **Exhibit Guest Pass Registration**
Exhibitor Registration,
Exhibit Hall, Level 3

#301 Track 2: Development Planning

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W179a *PMI PDUs offered*

Integration of Project Management Capabilities into R&D Functional Areas: Opportunity to Optimize Project Team Performance?

CHAIRPERSON

Thomas J. Schulze
Senior Consultant, Action for Results, Inc.

This session will provide individual viewpoints towards an integrated hypothesis on the value of global program and project management as a key strategic, broad organizational core capability across all functional disciplines responsible for effective and efficient planning, executing and controlling an increasingly broad range of R&D program assets, from fully internal, partnered, to partially or fully outsourced.

Sustained Momentum in Program Management: Essential for Alliances
Laura Cribbins, MBA
Director, Program Management, Propharma Group, Inc.

The Value of an Established Project Management System in an Outsourcing Model for Drug Development Programs
Marija Ribar, DMD, MBA
Manager, Project Consultancy, Fulcrum Pharma Developments, Inc

#302 Track 4: Nonclinical and Early Clinical Translational Development

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W183a *CME and Nursing credits offered*

Reverse Vaccinology: In Silico Tools for the Prediction of Unwanted Immunogenicity of Therapeutic Proteins

CHAIRPERSON

Jack A. Ragheb, MD, PhD
Principal Investigator, Laboratory of Immunology, Developmental Therapeutics Program, Office of Biotechnology Products, Office of Pharmaceutical Science, CDER, FDA

Tools of reverse vaccinology such as in silico methods using different algorithms for the prediction of potential B- and T-cell epitopes and in vitro analytical assays are presented to address unwanted immunogenicity of therapeutic proteins.

Ralf Dieter Hess, PhD, MSc
Principal Consultant, PAREXEL International, Germany

In Silico Analysis and Immunogenicity
Steven J. Swanson, PhD
Executive Director, Medical Sciences, Clinical Immunology Department, Amgen Inc.

Beyond In Silico: Qualifying Predictions in Humanized Mice
Jack A. Ragheb, MD, PhD
Principal Investigator, Laboratory of Immunology, Developmental Therapeutics Program, Office of Biotechnology Products, Office of Pharmaceutical Science, CDER, FDA

#303 Track 5: Product Advertising and Communications

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W183b *Pharmacy credits offered*

FDA Enforcement Update: Regarding Advertising and Promotion

CHAIRPERSON

Wayne L. Pines
President, Regulatory Services and Health Care, APCO Worldwide Inc.

FDA enforcement actions need to be understood by every regulated company because they reflect FDA's priorities and concerns in regulating advertising and promotion. FDA professionals examine the latest Agency enforcement actions and what they mean in this session.

Thomas W. Abrams, MBA, RPh
Director, Division of Drug Marketing, Advertising and Communications (DDMAC), CDER, FDA

Lisa L. Stockbridge, PhD
Branch Chief, Advertising and Promotional Labeling Branch, CBER, FDA

#304 Track 6: Medical Writing and Communication

8:00 AM – 9:30 AM LEVEL: ■ Format: **FORUM**
Room W184bc *Pharmacy credits offered*

New Drug Application: Integrated Summaries, Clinical Summaries, and Clinical Overview

CHAIRPERSON

Pamela Lindroos, PhD
Senior Director, Medical Writing, WebbWrites, LLC

Writing the ISE, ISS, and Sections 2.7.3, 2.7.4, and Module 2.5 are key challenges for medical writers involved in preparing NDAs. This session will review current FDA guidance and approaches to writing these documents.

Common CTD Compilation for EU and US Applications
Leonardo Ebeling, DrMed, MD, PhD
General Manager, Ebeling & Associates GmbH, Germany

Approaches to Writing Module 2.5
Karen J. Devcich, MBA, MS
Senior Director, Medical Writing, Takeda Global Research & Development Center, Inc.

Clinical Summaries and the ISE and ISS
Pamela Lindroos, PhD
Senior Director, Medical Writing, WebbWrites, LLC

#305 Track 7: IT Methods and Technologies

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W470a *CME and Nursing credits offered*

The Integration of the ISO IDMP Standard with SPL

CHAIRPERSON

Lawrence Nicholas Callahan, III, PhD
Chemist, Office of the Chief Scientist, Office of Critical Path Programs, Office of the Commissioner, FDA

Speakers will present the details of the Identification of Medicinal Products (IDMP) model and the relationship with Structured Product Labelling (SPL). Particular emphasis will be placed on the substance model in IDMP and the changes in SPL to allow submission of detailed substance and product information.

Vada A. Perkins, BSN, MSc, RN
Regulatory Program Management Officer, Office of the Director, CBER, FDA

Lonnie D. Smith
Policy Analyst, Data Standards Council and Office of Critical Paths, Office of the Commissioner, FDA

Sabine Brosch, PharmD, PhD
Business Lead, EudraVigilance and International Standardization in Pharmacovigilance, European Medicines Agency, European Union

#306 Track 8: Research Data and Content Management

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W470b *Pharmacy credits offered*

Metrics: A Cross-functional Collaboration

CHAIRPERSON

Bryant P. Fields
Therapeutic Area Head, Project/Study Data Management - Oncology, Bayer HealthCare Pharmaceuticals Inc.

This session will focus on how effective clinical data management enhances the speed and quality of clinical research through seamless integration of resources. Speakers will present metrics to assess collaborative efforts. Special emphasis will be put on metrics in managing oncology trials. The strategies to improve data flow from patient to sponsor to accelerate reporting will be discussed.

The Jigsaw Puzzle Amongst CDM: The Benefit of Collaborative Relationships to Pharmaceutical
Khadijah Butler, MS
Clinical Data Manager, RPS, Inc.

Improving Clinical Trial Data Flow for Accelerated Analysis and Decision Making
Peter G. Genakos, JD
Executive Director and Global Head, Phase II/III Clinical Data Management, Covance Inc.

Data Management Metrics: Sword, Shield, or Tool?
Bryant P. Fields
Therapeutic Area Head, Project/Study Data Management - Oncology, Bayer HealthCare Pharmaceuticals Inc.

#307 Track 9: Regulatory Affairs and Science, Quality, and GXP Compliance

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W185bc

Outlook for Changes in the Japanese Regulatory and Clinical Development Environment

CHAIRPERSON

Yoshihiko Ono, RPh
Director, Regulatory Policy and Intelligence, Pfizer Japan Inc., Japan

This session will provide an update on the regulatory environment including the regulatory review performance, and also address the future perspective for clinical development and regulatory strategy with a global development program in Japan.

Introduction and Overview on Development Strategy and Regulatory Environment in Japan
Robert R. Fike, PhD, MS
President, Robert R. Fike & Associates, LLC

Trends in Clinical and Review Times for New Drugs in Japan: 2010 Update
Tatsuya Fukushima
Research Fellow, Office of Pharmaceutical Industry Research, Japan Pharmaceutical Manufacturers Association (JPMA), Japan

PMDA's Current Projects to Promote New Developments in Japan
Yukiko Komori, PhD
Reviewer, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#308 Track 10: Public Policy/Health Care Compliance

8:00 AM – 9:30 AM LEVEL: ● Format: **SESSION**
Room W375b *Pharmacy credits offered*

SPECIAL PLENARY SESSION
Rethinking Pharmaceutical Development: The Impact of Health Reform

Healthcare reform is one of the most critical topics at DIA 2011. This unique dialogue about reform and its impact on the biopharmaceutical industry features two prominent experts who are uniquely qualified to guide participants in their understanding of the key components of reform and how they are likely to reshape and dramatically alter the landscape of drug development and the delivery of therapeutics in the future. Don't miss one of this year's most important conversations about industry and reform.

Submit your questions in advance to annualmeetingprogram@diahome.org Subject: Impact of Health Reform Session

MODERATOR

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

FEATURED SPEAKERS

David B. Nash, MD, MBA
Dean, Jefferson School of Population Health, Thomas Jefferson University

Gail R. Wilensky, PhD, MA
Senior Fellow and Economist, Project HOPE

#309 Track 12: Statistics

8:00 AM – 9:30 AM LEVEL: ■ Format: **SESSION**
Room W181bc

CDISC/ADaM and the FDA: Working Together to Improve Statistical Review

CHAIRPERSON

Cathleen F. Barrows, PhD
Director, Biostatistics and Programming, Neurosciences MDC, GlaxoSmithKline

The FDA and CDISC are working together to develop standards for NDA/BLA analysis data submissions. This session will provide insights into the use of ADaM-based standard data in the analysis, regulatory submission, and regulatory review of NDA/BLA data. An update from the CDISC ADaM team on the ongoing effort to improve these processes and standards will be presented.

FDA Update on ADaM Submissions
Behrang Vali, MS
Mathematical Statistician, Division of Biometrics III, CDER, FDA

Industry Nuts and Bolts of Utilizing ADaM
Nancy L. Silliman, PhD
Vice President, Biostatistics and Epidemiology, Genzyme Corporation

CDISC ADaM Team: An Update on Ongoing Work
Nate Freimark
Senior Director, Biometrics Operating Standards Group, OmnicareCR

DISCUSSANT

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

9:30 AM – 10:00 AM **REFRESHMENT BREAK**
Exhibit Hall, Level 3 (See Floor Plan, page 131)

#310 Track 1 (A): Clinical Operations

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W175abc *CME and Nursing credits offered*

Goals, Challenges, Likes, and Dislikes of the Recruited

CHAIRPERSON

Michael S. Noone
President, Noone Consulting

This panel session will provide a focus on the challenges and proposed improvements for effective clinical research conduct in the United States, from the perspective of those who are most key to its success, the clinical study participants. These study participant panelists will describe why they chose to become involved in clinical research, the barriers which often discourage their participation, concerns which arise during study conduct, and their likes/dislikes, as these factors relate to the research process. Finally, a discussion of best practices to both recruit and retain enrollment will be addressed.

Ellen R. Kelso
Chief Executive Officer, Goodwyn IRB

Michael S. Noone
President, Noone Consulting

Patients to be identified

#311 Track 1 (B): Clinical Operations

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W176abc *CME and Nursing credits, PMI PDUs offered*

The Expanding Role of the Clinical Trial Manager: Will the Balloon Break?

CHAIRPERSON

Lisa Rana, RN
Manager, Execupharm, Inc.

The clinical trial manager (CTM) role is rapidly expanding. How do the added responsibilities potentially impact the quality component of a clinical trial? Is there a limit to CTM role expansion?

The Evolution: The CTM Role, Then and Now
Kathryn Real King, PhD
Director, Clinical Field Operations and Document Management, Abbott Laboratories

The Impact: Quality Versus Quantity – Which Way Are the Scales Tipping?
Penny S. Carlson
Head, Clinical Operations, Aileron Therapeutics

The Strategies: Can We Keep the Balloon from Bursting?
Carrie L. Melvin, BSN
Director, Clinical Operations, Millennium: The Takeda Oncology Company

#312 Track 2 (A): Development Planning

10:00 AM – 11:30 AM LEVEL: ■ Format: **WORKSHOP**
Room W474b *PMI PDUs offered*

Productivity Simulation: Capacity School for Big and Small Pharma

CHAIRPERSON

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

The goal of this workshop is to teach productivity measures and key drivers that are critical to managing a diverse portfolio of projects with limited resources, as well as how to leverage fiscally responsible decision making techniques.

The productivity simulation workshop allows participants to play an interactive board game that captures the core concepts of portfolio and resource managements in the drug development business. Attendees will be grouped into teams that comprise specific roles necessary to run a business. The goal is to teach about productivity measures and key drivers that are critical to managing a diverse portfolio of projects with limited resources.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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

Michelle R. Smith
Pharmaceutical Project Manager, Eli Lilly and Company

Thomas C. Redford
Pharmaceutical Project Manager, Eli Lilly and Company

#313 Track 2 (B): Development Planning

10:00 AM – 11:30 AM LEVEL: ◆ Format: **FORUM**
Room W179a *PMI PDUs offered*

When, How, and Why: Optimizing Resource Planning to Get the Most from Your Existing Resources

CHAIRPERSON

Todd Charles Reul
Director - Clinical Services, ClearTrial, LLC

Biopharmaceutical companies are under increased pressure to be as cost effective as possible. This forum will explore how program planning, tracking project status, and reforecasting work together to enable effective resource planning.

Graeme Currie, PhD
Head, Clinical Project Management Office, Regeneron Pharmaceuticals

John Sneed, PMP
Senior Director, Project Management, Quintiles

Deborah Bisio Dwyer, MBA
Associate Director, Clinical Outsourcing, Cerexa Inc.

#314 Track 3: Outsourcing Strategies and Innovative Partnering Models

10:00 AM – 11:30 AM LEVEL: ◆ Format: **SESSION**
Room W178ab

Organizational Challenges in Moving to a New Outsourcing Model: Overcoming Resistance to Change

CHAIRPERSON

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

Sponsor organizations are evaluating and embracing new outsourcing strategies. Adoption can cause major disruption to business as usual. This session will discuss overcoming the internal resistance that can lead to failure.

Overcoming Resistance to Change
Frances Grote, MBA
Senior Director, Clinical Outsourcing, Millenium Pharmaceuticals

Implementation of a New Outsourcing Model
Joan C. Millsaps, MSN, RN
Director, Global Development Operations, Bristol-Myers Squibb Company

#315 Track 4 (A): Nonclinical and Early Clinical Translational Development

10:00 AM – 11:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room W179b *CME and Nursing credits offered*

Therapeutic Drug Development for Alzheimer's, Tumors, and Bacterial Infections

CHAIRPERSON

Frederic J. Marsik, PhD
Clinical Microbiology Team Lead, Office of Antimicrobial Products, CDER, FDA

This symposium will provide information on the approach to drug development for Alzheimer's, tumors, and bacterial infections.

FDA's Current Thinking on Microbiological Data for the Development of Systemic Drug Products
Frederic J. Marsik, PhD
Clinical Microbiology Team Lead, Office of Antimicrobial Products, CDER, FDA

The Importance of Good Neighbors: Considering the Tumor Microenvironment in Oncology Drug Development
Kate Sasser, PhD
Associate Director of Biomarkers, Labconnect, LLC

Alzheimer's Disease: Early Clinical Drug Development Challenges and Strategies
James Frederick Pritchard, PhD, MSc
Vice President, Drug Development Services, Celerion

#316 Track 4 (B): Nonclinical and Early Clinical Translational Development

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W183a *CME and Nursing credits offered*

Translational Medicine-driven Multicomponent Predictive Biomarkers and Biomarkers for Earlier Efficacy Assessment

CHAIRPERSON

Jonathan R. Smith, PhD
Vice President, Research & Development, Adaptive Plus, LLC

Predictive biomarkers have been recognized for several years to be a critical enabler of personalized medicine, but there have not been many examples where they have been used successfully in clinical practice, and few where they have been identified prospectively. Reasons for the relatively low use of predictive biomarkers in a prospective manner include insufficient understanding of the disease process at the molecular level, and because many factors often exist which each provide important contributions to whether or not (or to what extent) a given drug will benefit a particular patient. This session will cover methods by which our updated knowledge of the molecular basis of a particular disease process can be used to derive multicomponent predictive biomarkers. It will also cover different kinds of biomarkers that have very recently started to be developed to provide much earlier assessments of efficacy including those using Quantitative 18-F FLT-PET and 18-F FDG-PET imaging within multicenter trials.

Translational Medicine-driven Multicomponent Predictive Biomarkers as an Emerging Enabler of Personalized Medicine
Jonathan R. Smith, PhD
Vice President, Research & Development, Adaptive Plus, LLC

Quantitative PET Imaging with F-18 FDG and F-18 FLT: Using Imaging Biomarkers in Multicenter Clinical Trials
Peter S. Conti, MD, PhD
Professor, Biomedical Engineering, Radiology, Pharmacy, University of Southern California PET Imaging Center

#317 Track 5: Product Advertising and Communications

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W183b *Pharmacy credits offered*

Policy and Enforcement Issues Faced by Industry

CHAIRPERSON

Wayne L. Pines
President, Regulatory Services and Health Care, APCO Worldwide Inc.

Companies face very challenging policy and internal implementation issues as they seek to be in compliance with FDA regulations while at the same time conducting marketing and PR programs. This session will address how companies address these challenges and what companies need to do next to be sure they remain in compliance.

Bhavana Desai, MBA
Senior Director, Advertising and Promotional Compliance, Allergan, Inc.

Thomas M. Casola
Vice President, Advertising and Promotion, Regulatory Affairs, Spire Specialty Pharmaceuticals

Speaker to be announced

#318 Track 6: Medical Writing and Communication

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W184bc *Pharmacy credits offered*

Constructing Key Clinical Documents for Global Use

CHAIRPERSON

Sandra J. Hecker, RAC
US Agent; Regulatory Consultant, Hecker & Associates, LLC

This session will focus on exactly how a medical writer/project manager can enable documents to be filed for one study in many regions through their regulatory authorities to minimize rework thus saving time and money.

Global Clinical Research and Medical Writing: Planning for Success in Asia
Kent Cochran, III, MS
Associate Director, Janssen Pharmaceutical Companies of Johnson & Johnson

European Submissions
Jo Vibe Tolshave, MSc
Specialist, Medical Writing, MW Mood and Anxiety Disorders, H. Lundbeck A/S, Denmark

Planning for International Success for Postapproval Clinical and Safety Documents
Aaron Van Etten, MS
Director, Regulatory Writing, Amgen Inc.

#319 Track 7: IT Methods and Technologies

10:00 AM – 11:30 AM LEVEL: ◆ Format: **SESSION**
Room W470a *CME, Nursing, and Pharmacy credits offered*

The Ethical Ramifications of Integrating Electronic Health Records and Electronic Clinical Trials

CHAIRPERSON

Thomas Quinn
President, CISSP, The Hollis Group Inc.

This session will include a discussion among a panel of academia, industry, patient advocacy, and health-care professionals and will discuss the ethical ramifications of Electronic Health Records (EHR)/Electronic Clinical Trials (ECT) information, including such questions as: Does de-identification relieve us of the obligation of informed consent? Is patient recruitment in an emergency situation acceptable? How do we prevent care skewing to EHR-instrumented entities/locations? What level of diligence is required to prevent re-identification? The session will be conducted in an interactive format, with audience participation encouraged from the start to the finish.

Keith M. Parent, MS
Chief Executive Officer, Court Square Group Inc.

Kathleen McDermott, JD
Partner, Morgan, Lewis & Bockius LLP

Felix A. Khin-Maung-Gyi, PharmD, MBA, RAC
Chief Executive Officer, Chesapeake Research Review Inc.

#320 Track 8 (A): Research Data and Content Management

10:00 AM – 11:30 AM LEVEL: ● Format: **SESSION**
Room W470b *Pharmacy credits offered*

Innovation in Clinical Development: Where Is It Going?

CHAIRPERSON

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

This session will underscore the need for a robust informatics strategy that is no longer confined to technology alone but must consider the socioeconomic and global characteristics of our changing nation in the face of healthcare reform and how we work within a world community.

Innovation in Clinical Development: Where Are We Now?
Ron Fitzmartin, PhD, MBA
Managing Partner, Decision Analytics, LLC

The Standards Landscape: Connecting the Health Care Environment
Edward S. Tripp
President, Edward S Tripp And Associates Inc

A Perspective from Large Pharma: What's Next?
John J. Oidtman
Vice President, Clinical Operations - Emerging Markets, Pfizer Inc

#321 Track 8 (B): Research Data and Content Management

10:00 AM – 11:30 AM LEVEL: ● Format: **SESSION**
Room W471a *CME, Nursing, and Pharmacy credits offered*

Using Patient-reported Outcomes to Assess Comparative Safety and Tolerability: Methodological and Regulatory Issues

CHAIRPERSON

Chad Gwaltney, PhD
Senior Scientist, PRO Consulting

Patient-reported outcomes (PROs) may be used to assess the relative safety and tolerability of active treatments in comparative studies. This session will outline methodological and regulatory issues in using PROs in this manner and describe applied examples.

Industry Perspective on Using Patient-reported Outcomes to Assess Safety and Tolerability
Jennifer Petrillo, PhD
PRO Expert, Novartis Pharmaceuticals Corporation

The Scientific Rationale for Using Patient-reported Outcomes to Assess Adverse Events in Clinical Research
Bryce B. Reeve, PhD, MA
Associate Professor, University of North Carolina at Chapel Hill

FDA Point of View
Laurie Burke, MPH, RPh
Associate Director, Study Endpoints and Label Development (SEALD), Office of New Drugs, CDER, FDA

#322 Track 9 (A): Regulatory Affairs and Science, Quality, and GXP Compliance

10:00 AM – 11:30 AM LEVEL: ● Format: **SESSION**
Room W185bc *Pharmacy credits offered*

Dealing with an FDA Inspection: What We Can Learn from Warning Letters and Audits

CHAIRPERSON

Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

This session will cover the audit from different perspectives and focus on helpful hints and procedural issues regarding what to do. There will be a discussion on how to host the audit and best prepare for the actual audit.

Dealing with an FDA Inspection: What to Expect
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

A Day in the Life of an FDA Inspection: A Site Perspective
Melissa Mau, MS
Director, Clinical Research Core, Indiana School of Dentistry, Oral Health Research Institute

Responding to an FDA Inspection
Darshan Kulkarni, Esq., JD, PharmD, MS
Principal Attorney, The Kulkarni Law Firm

#323 Track 9 (B): Regulatory Affairs and Science, Quality, and GXP Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W471b

Pursuing Standards to Enhance eCTD Deliverables: PhRMA Electronic Regulatory Submissions (ERS) Group Annual Update

CHAIRPERSON

Matthew J. Neal, MA
Director, Global Regulatory Affairs and Safety, Amgen Inc.

The PhRMA Electronic Regulatory Submissions (ERS) group presents their annual progress report on the hottest key subteams involved in the pursuit of standards to facilitate efficient and effective electronic submissions and at least two new Hot Topics. This session will include roundtable discussion and active Q&A with industry experts.

Cynthia F. Piccirillo
Director, Global Dossier Management eStrategy, Bristol-Myers Squibb Company

Robert F. Birmingham
Director, Global Regulatory Affairs, Strategic Policy, The Americas, Johnson & Johnson Pharmaceutical R&D LLC

PhRMA Electronic Regulatory Submissions Group Overview
Daniel P. Clark
Senior Manager, Strategic Regulatory Innovation, Novo Nordisk Inc.

#324 Track 9: (C) Regulatory Affairs and Science, Quality, and GXP Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W185a *CME and Nursing credits offered*

Quality Risk Management in Product Development: The Assessment, Identification, and Control of Potential Risk

CHAIRPERSON

Stephan Karl Roenninger, DrSc
Head of External Relations Europe/Japan, F. Hoffmann-La Roche Ltd., Switzerland

Using quality risk management more formally is new in a submission. Questions on practical implementation during development will be addressed in this session as well as the thoughts on how assessors see these new details in submissions.

Quality Risk Management in Product and Process Development: Bi-layer Tablets
Sivakumar Vaithiyalingam, PhD
Chemistry, Manufacturing, and Controls Reviewer, Office of Pharmaceutical Science, CDER, FDA

Reviewer Approach Using Quality Risk Management
Terrance Ocheltree, PhD, RPh
Director, Division of New Drug Quality Assessment II, Office of New Drug Quality Assessment, CDER, FDA

The Role of Quality Risk Management During Product and Process Development
Stan Shimizu, PhD
Senior Manager, Global Risk Management, Amgen Inc.

#325 Track 9 (D): Regulatory Affairs and Science, Quality, and GXP Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W183c *Pharmacy credits offered*

Postmarketing Commitments: Is It Time for Industry and FDA to Seek Therapy?

CHAIRPERSON

Lynne Fahey McGrath, PhD, MPH
Head, Vice President, Drug Regulatory Affairs, Oncology, Novartis Pharmaceuticals Corporation

Both FDA and industry are becoming increasingly frustrated with postmarket trial commitments and timeliness issues. The panel will explore the rising tension and potential solutions from the perspectives of FDA, industry, patients, and researchers.

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

Marc M. Boutin, JD
Executive Vice President and Chief Operating Officer, National Health Council

Richard L. Schilsky, MD
Professor of Medicine; Chief, Hematology-Oncology; Deputy Director, Comprehensive Cancer Center, University of Chicago

#326 Track 10 (A): Public Policy/Health Care Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W180 *Pharmacy credits offered*

International Cooperation Among Registration Agencies

CHAIRPERSON

Marie A. Dray, MA, MBA
President, International Regulatory Affairs Group LLC

Since 2004, the United States Food and Drug Administration and the European Union's European Medicines Agency (EMA) have exchanged guidances and staff. This DIA session provides an opportunity for executives from FDA, EMA, and other stakeholders, to share their experiences since they are not reported elsewhere.

FDA Point of View
Murray M. Lumpkin, MD, MSc
Deputy Commissioner for International Programs, Office of the Commissioner, FDA

EMA Point of View
Martin Harvey-Allchurch, Esq., LLM
Head of the Office of the Executive Director, European Medicines Agency, European Union

Industry Point of View
Brenton E. James, FTOPRA
Consultant, Strategic Regulatory Affairs in the European Union, UK

PANELIST

Hilde Boone, MSc
EMA Liaison Official at the FDA, European Medicines Agency, European Union

#327 Track 10 (B): Public Policy/Health Care Compliance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W181a *CME, Nursing, and Pharmacy credits offered*

Drug Product Liability in the United States and the European Union

CHAIRPERSON

Angelique Winzenrieth
Regulatory Affairs Director, Quintiles, France

This session will discuss the legal aspects of drug safety and management of risks associated with drug product liability. An overview will be given of product liability law and practice both in the US and EU with a focus on drugs and biologicals.

Liability and Pharmacovigilance in Europe: Impact of New Legislation
John A. Lisman, LLM, MPharm
Lawyer, Lisman Legal Life Sciences B.V., Netherlands

Drug Product Liability in the European Union
Gizzy Klink, JD
Senior Associate, NautaDutilh N.V., Netherlands

US Perspective on Drug Product Liability
Paul W. Schmidt, JD
Partner, Pharmaceutical Litigation and Investigations, Covington & Burling LLP

#328 Track 11 (A): Clinical Safety and Pharmacovigilance

10:00 AM – 11:30 AM LEVEL: ■ Format: **WORKSHOP**
Room W475a

Good and Bad Behaviors During a PV Inspection

CHAIRPERSON

Barton L. Cobert, MD, FACP, FFPM
President, BLCMD Associates, LLC

This workshop will also be offered on Wednesday, June 22, at 3:30 PM.

During a pharmacovigilance inspection, behavior can play as big a role as the content of a person's answers. This workshop will demonstrate good and bad behaviors during an inspection and will identify the steps to take to avoid these problems.

Several scenarios will be distributed to the audience. The presenters and audience volunteers will be invited to join in as either auditors or auditees in a nonconfrontational (for the audience) manner to act through the scenarios. Some of the scenarios will be audits of excellent companies with few or no problems. Others will have major faults and failings that the auditees must defend. There will be coaching during and after each scenario and re-plays of the scenarios as appropriate.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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

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

Suzanne Tepper, PharmD, RPh
Vice President, Pharmacovigilance Operations, APCER Pharma Solutions, Inc.

#329 Track 11 (B): Clinical Safety and Pharmacovigilance

10:00 AM – 11:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room W184a *CME, Nursing, and Pharmacy credits offered*

Medical Potpourri: Blood Pressure, Patient Safety, and Nanomedicine

CHAIRPERSON

Jeffrey Litwin, MD
Executive Vice President and Chief Medical Officer, ERT

This symposium will cover a variety of medically related topics including: a) How should blood pressure be captured and reviewed as part of overall cardiac safety assessments? b) The role of the safety physician throughout the product life cycle; and c) The EMA guideline on safety and efficacy follow-up, risk management of advanced therapies, and the ICH E2F guidance on development safety update reports that have opened new possibilities in designing plans that could include the management of both benefits and risks of medicines. They help establish the mindset needed for the preparation of safety specifications of innovative medicines, starting early in the drug development. A comprehensive checklist of safety issues will be presented to the participants, with suggestions for the most useful designs of studies for further characterization of these issues.

Blood Pressure as a Cardiac Safety Marker
Merat Bagha, MS
President, Tiba Medical Inc.

Medical Assessment in Patient Safety: Strategic and Pragmatic Challenges from Individual Case Reports to Aggregate Data
Arpad Simon, MD
Therapeutic Area Head, Pfizer Inc

Risk Management of Advanced Therapies and Nanomedicines
Jan Petracek, MD, MSc
CEO, Director of Pharmacovigilance Services, European Pharminvent Services, s.r.o., Czech Republic

#330 Track 12: Statistics

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W181bc *Pharmacy credits offered*

Missing Data: Where Are We Now?

CHAIRPERSON
Bruce Binkowitz, PhD, MA
Senior Director, Clinical Biostatistics, Merck Research Laboratories

Regulatory authorities on both sides of the Atlantic have recently emphasized the importance of the problem of missing data in clinical trials. Both the National Academy of Science report and the European Medicines Agency's guidance on missing data stressed the importance of prevention and highlighted the importance of reasonable assumptions with regard to missing data, and planning accordingly. This session will also discuss the challenges surrounding the recent recommendations.

Using Regulatory Guidance to Get Credible Results with Missing Data
Michael P. O'Kelly, PhD, MA
Senior Director, Centre for Statistics in Drug Development, Innovation, Quintiles Ireland Ltd., Ireland

Hypotheses, Endpoints, and Analyses for Incomplete Longitudinal Clinical Trial Data
Craig H. Mallinckrodt, PhD
Senior Research Advisor, Eli Lilly and Company

A Clinician's Perspective
Marc Bennett Stone, MD
Senior Medical Reviewer, Office of New Drugs, CDER, FDA

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

10:00 AM – 11:30 AM LEVEL: ● Format: **SESSION**
Room W184d *Pharmacy credits offered*

Emerging Trends in the Economics of the Biopharmaceutical Industry

CHAIRPERSON
Joseph A. DiMasi, PhD
Director, Economic Analysis, Tufts University

This session will examine data on drug development times, technical success rates, development costs, and market dynamics for new drugs, and their relationship to R&D productivity and innovation incentives.

Rasilez Place in Therapy: A Proposal to Displacement Rasilez from AIFA Register Monitoring to General Practitioners
Paolo Daniele Siviero
Head of Economic Strategies and Pharmaceutical Policy Department, Italian Medicines Agency - AIFA, Italy

Are You CERtain? How Comparative Effectiveness Research (CER) Impacts Drug Development, Reimbursement, and Regulatory Decisions
Jeffrey N. Stuart, PhD, RAC
Associate Director, Regulatory Affairs, Novartis Pharmaceuticals Corporation

Challenges for New Drug Development in a Changing Economic Environment
Joseph A. DiMasi, PhD
Director, Economic Analysis, Tufts University

#332 Track 14: Medical Devices

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W186abc *Pharmacy credits offered*

Implications of Shifting Regulations for Combination Products: A Comprehensive Review

CHAIRPERSON
Steven Cox
Director, Global Product Safety, Hospira Worldwide, Inc.

Changes in regulations and interpretations of regulations are shifting how drug/device combination products are classified. This session will look at what these changes mean and the effect this has on the organization.

Changing FDA Regulations and the Perspective from a Manufacturer of Both Drug and Device Combination Products
Steven Cox
Director, Global Product Safety, Hospira Worldwide, Inc.

Regulatory Reporting: Medical Device Manufacturer's Perspective
Patrick Caines, PhD, MBA
Director, Postmarket Surveillance, Boston Scientific

An Overview and Implications from an Industry Networking Group Including Guiding Principles
Ajay Keshava, MS
Senior Consultant, WCI Consulting Limited

#333 Track 15: Professional Development and Training

10:00 AM – 11:30 AM LEVEL: ● Format: **SESSION**
Room W474a *PMI PDUs offered*

Learning on the Go: Mobile Tools for Pharmaceutical Professionals

CHAIRPERSON
Angela Hamilton
Researcher, Mixed Emerging Integration Laboratory, Institute for Simulation and Training, University of Central Florida

Explore how learning, knowledge, and information delivery are changing based on the latest mobile technologies. This session will address how our roles are changing as our society becomes more mobile.

Learning on the Go
Paul A. Bejgrowicz, MBA
Principal Consultant, RWD Technologies

Angela Hamilton
Researcher, Mixed Emerging Integration Laboratory, Institute for Simulation and Training, University of Central Florida

#334 Track 16 (A): Global Agency

10:00 AM – 11:30 AM LEVEL: ■ Format: **FORUM**
Room W187abc

The Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall

CHAIRPERSON

Kyoichi Tadano, PhD
Director, Division of Planning and Coordination, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PMDA will explain the current services and Japanese regulation and answer your questions about its services and future initiatives/challenges for faster review and better life-cycle management of drugs.

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

Current Status of New Drug Reviews and Challenges to Promote Global Drug Development
Representative Invited
Executive Director and Director, Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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

Yoshiaki Uyama, PhD
Director, Regulatory Science Research Division, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#335 Track 16 (B): Global Agency

10:00 AM – 11:30 AM LEVEL: ● Format: **SESSION**
Room W185d

Working for Harmonization on Regulations for Clinical Trials in Latin America

CHAIRPERSON

Paul J. Seligman, MD, MPH
Regional Director, Latin America Regional Office, FDA, Costa Rica

Join members of various Latin American agencies as they discuss individual country-specific regulatory framework and strategies for clinical trial procedures. In addition, harmonization among these regions will be discussed.

Regulatory Framework in Chile
Luis Eduardo Johnson Rojas, PhD
Manager, Office of Clinical Trials and Bioethics
Instituto De Salud Pública De Chile (ISPCH), Chile

An Update of the Regulatory Harmonization in Latin America
Martha Parra Diaz
New Molecules and Research Director, COFEPRIS, Mexico

PANELIST

Augustina Bisio
Director, Drug Evaluation Agency, ANMAT, Argentina

#336 Track 18: Late Breaker

10:00 AM – 11:30 AM LEVEL: ■ Format: **SESSION**
Room W475b *CME, Nursing, and Pharmacy credits offered*

Establishing a Framework for CER Assessment: How Do Managed Care Decision Makers Consider the Evidence?

CHAIRPERSON

Robert W. Dubois, MD, PhD
Chief Science Officer, National Pharmaceutical Council

Payers are utilizing a variety of methods to compel a tighter relationship between evidence comparisons and treatment decisions; however, the absence of accepted principles for the generation, evaluation and interpretation of comparative effectiveness research (CER) results in wide variability in the coverage and formulary decision making process. This session will present viewpoints from those who will conduct CER, the pharmaceutical industry working to demonstrate drug value, and those from managed care who will be the ultimate consumers/decision makers for much of that information. *This session was developed by the National Pharmaceutical Council.*

Steven D. Pearson, MD, MSc, FRCP
President, Institute for Clinical and Economic Review (ICER)

J. Russell Teagarden
Vice President, Clinical Practices and Therapeutics, Medco Health Solutions, Inc.

11:30 AM – 1:30 PM **LUNCHEON**
Exhibit Hall, Level 3, Lunch Distribution Area (see Floor Plan, page 131). See page 8 for instructions on using your lunch vouchers.

#337 Track 1 (A): Clinical Operations

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W175abc *CME and Nursing credits offered*

Leveraging Ethics

CHAIRPERSON

Ellen R. Kelso
Chief Executive Officer, Goodwyn IRB

This symposium will present topics that provide an overview of the principles and regulations of subject protection, review the conflicting goals of the informed consent process and explore methods for improvement, and discuss ethical aspects related to placebo trials.

A Three Page Consent ... Really!
Steven Steinbrueck, MPH
President, Stonebridge GCP Consulting Inc.

Understanding the IRB: Ethics, Regulations, and What You Need to Know to Work with IRBs for Efficient Protocol Reviews
Lindsay McNair, DrMed, MPH
Principal Consultant, Equipoise Consulting LLC

Use of Placebo in Clinical Trials: A Revision of the Ethical Aspects
Cecilia Ferro, DDS
Project Manager, RPS, Inc. (Research Pharmaceutical Services, Inc.), Colombia

#338 Track 1 (B): Clinical Operations

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W176abc *PMI PDUs offered*

How Do We Ensure Proper Sponsor Oversight When Conducting Global Clinical Trials?

CHAIRPERSON

Carol Ann Lewis-Cullinan, BSN, MSN, RN
Senior Director, Clinical Operations, Amag Pharmaceuticals, Inc.

Outsourcing global clinical trial work to CROs obligates sponsors to proactively build and maintain effective quality oversight plans to ensure standardization of quality and compliance of outsourced efforts. This session will address the complexities of overseeing teams of global CROs, share experiences, exchange solutions around the GCP compliance issue of clinical vendor (CRO) oversight, and discuss solutions to ensure quality management of outsourced work.

PANELISTS

Christine H. Wang, MSc
Executive Director, CLINPath, BioBridges

Michael Lauw, MS
Senior Project Manager, ICON Clinical Research

#339 Track 2 (A): Development Planning

1:30 PM – 3:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W474b *CME and Nursing credits, PMI PDUs offered*

Project Team Dynamics: Enhancing Performance, Improving Results

CHAIRPERSON

Lisa DiTullio
Principal, Your Project Office

Companies that embrace the power of collaboration realize that the best way to solve complex problems is to build cohesive teams made up of mer cien

This Session has been cancelled.

During this workshop, groups will learn how to conduct a Rules of Engagement exercise through a guided discussion that results in a documented contract among team members for how to treat each other with dignity and respect. This tool will help the team identify and document the various elements of behavior critical to the success of team performance.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

#340 Track 2 (B): Development Planning

1:30 PM – 3:00 PM LEVEL: ◆ Format: **FORUM**
Room W179a *PMI PDUs offered*

Scheduling Product Development: Current Industry Practices and New Techniques

CHAIRPERSON

Leigh Shultz, PhD, PMP
Project Leader, Merck & Co., Inc.

This forum will blend short presentations and panel discussion to explore the current project scheduling practices in the pharmaceutical industry and expose participants to new concepts useful in the management of product development projects.

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

Jayna Rose, PhD, PMP
Director, Global Program Manager, Amgen Inc.

Nita Ichhpurani, PMP
Director, Drug Development, Celerion, Canada

#341 Track 3: Outsourcing Strategies and Innovative Partnering Models

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W178ab

A Close Look at Clinical Outsourcing Strategies: An Executive Roundtable

CHAIRPERSON

Patricia Leuchten
CEO and President, The Avoca Group Inc.

In an effort to achieve greater levels of efficiency, many companies, particularly the large pharma and biotech companies, have moved toward concentrating their clinical outsourcing spending with fewer preferred suppliers. This forum will explore how small- to mid-size pharmaceutical companies are addressing the need for increased efficiency in outsourcing and whether they are following suit with the trend and movement toward fewer partners. Executives from three companies will present their clinical outsourcing strategies, the rationale and the circumstances that led them to these strategies, and how they expect these approaches to evolve over the next five years. Each presenter will cover the specific approach to selecting potential CRO partners, the criteria for selection, and the attributes that their companies look for in these partners.

Peter A. Carberry, MD, MBA
Senior Vice President, Global Development Operations, Astellas Pharma Global Development, Inc.

Mitchell A. Katz, PhD
Executive Director, Medical Research Operations, Purdue Pharma L.P.

Craig Coffman
Director, Clinical Business Operations and Outsourcing, Endo Pharmaceuticals

#342 Track 4 (A): Nonclinical and Early Clinical Translational Development

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W179b *CME and Nursing credits offered*

Technology in Early-phase Research: Optimizing Methods

CHAIRPERSON

Royce A. Morrison, MD, MS
Director of Clinical Strategy, Charles River

In implementing early-phase research technologies, optimal methods evolve as experience accrues and change occurs in endpoints, related technologies, devices, and regulatory expectations. This symposium will enable attendees to recognize early-phase application opportunities and to refine decision paths to optimally plan: 1) radiolabeled investigational product (IP) studies to fully and efficiently identify metabolites, characterize pathways and meet regulatory requirements for Metabolites in Safety Testing (MIST) and related ICH M3(R2); 2) radiolabeled IP intravenous administration and accelerator mass spectrometry (AMS) analysis, added to standard phase 1 PK studies to provide quantitative ADME, bioavailability and comparative PK data; and 3) electrocardiographic (ECG) data acquisition, analysis, and interpretation methods in screening volunteers, real-time safety assessment in study conduct, immediate or deferred repolarization de-risking, and method continuity throughout the development program.

ECGs in Early-phase Research: Challenges in Screening and Conduct
Royce A. Morrison, MD, MS
Director of Clinical Strategy, Charles River

Gold Standard to Address MIST and ICH M3 (R2) Requirements: 14C Macrotracer Nonclinical and Clinical Drug Studies
Robert George Kochan, PhD
US Clinical Pharmacology Radiation Safety Officer, Covance CRU Inc.

Quantitative Metabolism and Intravenous Pharmacokinetics in Phase I Using Accelerator Mass Spectrometry
Graham Lappin, PhD
Chief Scientific Officer, Xceleron Ltd., UK

#343 Track 4 (B): Nonclinical and Early Clinical Translational Development

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W183a

Clinically Driven Nonclinical Testing for Combined Advanced Therapy Medicinal Products (ATMPs)

CHAIRPERSON
Suzanne R. Thornton-Jones, PhD, MS
Director, Regulatory Labeling, sanofi-aventis

The forum will emphasize the importance of understanding the product design, the clinically driven combined ATMP product development strategy, and the impact on the nonclinical development plan. The most expeditious development involves a priori flexible design of the combined ATMP product and a clear clinical development strategy. With a defined product design and clinical strategy, a more robust nonclinical plan can be developed.

Novel Paradigms for Nonclinical Testing of ATMPs
David Pepperl, PhD
Senior Consultant, Biologics Consulting Group, Inc.

Development of Stem Cell Therapeutics
C. Randal Mills, PhD
President and CEO, Osiris Therapeutics Inc.

EU Perspective on Nonclinical Testing for ATMPs
Anders Neil, PhD
Principal Consultant, PAREXEL Consulting, UK

#344 Track 5: Product Advertising and Communications

1:30 PM – 3:00 PM LEVEL: ■ Format: **FORUM**
Room W375b *CME, Nursing, and Pharmacy credits offered*

SPECIAL PLENARY SESSION: The Problems and Promise of Using Social Media to Improve Patient Care

CHAIRPERSON
John F. Kamp, JD, PhD
Executive Director, Coalition for Healthcare Communication

Experts with regulatory and marketing expertise will detail the regulatory challenges and marketing opportunities facing the use of digital and social media by drug, device, and biological companies for product promotion and education. Marketing experts will cite existing company efforts by companies to use digital and social media to reach doctors, patients, and caregivers. Regulatory and legal experts will outline the challenging regulatory environment posed by evolving FDA policy, as well as concerns about public relations and private legal risk posed by the public, the plaintiffs bar, and state and federal law enforcement agencies.

SPECIAL SPEAKER
Christopher M. Schroeder
Chief Executive Officer and Board Member, HealthCentral

PANELISTS
Mike Myers, MBA
President, Palio, an inVentiv Health Company

Sharon Callahan
CEO, The Vue Group & LLNS

Stuart P. Ingis, JD
Partner, Venable LLP

#345 Track 6: Medical Writing and Communication

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W184bc *Pharmacy credits offered*

Risk Management Assessment Reports: The New Medical Writing Challenge

CHAIRPERSON
Michael D. Hoffman, MS
Senior Director, Medical Writing and Regulatory Operations, United BioSource Corporation

Risk management assessment reports can differ from clinical reports in scope and format. Experience from writing more than 20 assessment reports filed with agencies will be shared, and comparisons/contrasts with clinical reports will be highlighted.

Risk Management Assessment Reports: A Cumulative Experience
Michael D. Hoffman, MS
Senior Director, Medical Writing and Regulatory Operations, United BioSource Corporation

The EU RMP: How a Writer Can Facilitate the Creation of the Initial Plan
Caryn Cramer, PhD
Director, Scientific Reporting, Genzyme Corporation

The EU Risk Management Plan from a Writer's Perspective
BethAnn Garni-Wagner, PhD
Medical Regulatory Writer, Eli Lilly and Company

#346 Track 7: IT Methods and Technologies

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W470a *CME and Nursing credits offered*

What Happens When the Paper Goes Away? Clinical Data Process, Standards, and Quality Where EHR and EDC Meet

CHAIRPERSON
Kit Howard, MS
Owner and Principal, Kestrel Consultants, Inc.

With the increasing use of electronic health records and the growing sophistication of electronic data capture systems, more clinical trials are flirting with eSource, i.e., data captured directly into an electronic medium with no paper CRF. Numerous traditional data practices no longer apply, not least because the lack of paper CRFs and source documents renders impossible many of the CRA's and CDM's tasks. In addition, porting data seamlessly from EHR to EDC is difficult when there are few agreed-upon data standards.

This symposium considers some of the questions on the boundaries of current practice, such as what changes in the monitor's role when the paper goes away, what happens to how we define and ensure data quality when CRF and source as we know them no longer exist, and how do we transfer the data electronically from EHR to EDC when little standardization exists. The speakers will provide their insights and share some recent developments that can shape the way we approach these challenges.

Data Quality Challenges in the World of eSource
Kit Howard, MS
Owner and Principal, Kestrel Consultants, Inc.

Keeping Source as Source: Effect of Data Extraction from Electronic Health Records on Clinical Monitoring
Gavin David Nichols, MBA
Vice President, Customer Alliances and Partnerships, Quintiles Transnational Corp.

EHR Integration: A Real-world Approach to Leveraging Health Care Data
Chris Connor
Solutions Architect, Health and Life Science Global Practice, SAS Institute Inc.

#347 Track 8 (A): Research Data and Content Management

1:30 PM – 3:00 PM LEVEL: ◆ Format: **SYMPOSIUM**
Room W470b *Pharmacy credits offered*

Quality Through Standards

CHAIRPERSON
Julia Zhang, PhD
Associate Director, Genzyme Corporation

This symposium will provide a case study on a large pharmaceutical company's project to ensure the quality of standards-based information exchange with third parties. Specific focus will be on best practices, tools, and governance processes for standards-based information exchange. Next, the focus will be on the assembly of an eCRF library using standard variables from CDASH, SDTM, and CDISC SHARE, with specific strategies to maximize reuse of the library. Then, discussion will concentrate on ensuring quality while implementing these standards in India and China.

Ensuring Quality of Standards-based Information Exchange
Julia Zhang, PhD
Associate Director, Genzyme Corporation

Improving the Efficiency of SDTM and EDC Setup Operations with a CDISC-based eCRF Library
Mike Havener
Director, PAREXEL International

Measurable Data Quality in Data Conversion Projects
Hanming Tu, MSc
Director, Octagon Research Solutions, Inc.

#348 Track 8 (B): Research Data and Content Management

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W471a *CME, Nursing, and Pharmacy credits offered*

ePRO Industry Update: What the Literature Says, Mixed Modalities, and ePRO for Monitoring

CHAIRPERSON
Keith W. Wenzel
Senior Product Director, eClinical, Perceptive Informatics

This symposium brings together experts in electronic patient-reported outcomes to discuss the latest advancements and industry developments. Presenters will discuss how ePRO can be used to complement, enhance and reinforce monitoring. Another presentation will discuss the issues surrounding the use of mixed ePRO modalities including ensuring measurement equivalence, optimizing data quality, and minimizing missing data. The final presentation will review the current state of ePRO literature and the trends and significant findings that have been published in this field.

Optimizing Clinical Monitoring and Data Management with ePRO
John Hutchin
Senior Director, Technical Support, CRF Health

Evolution of ePRO: A Review of the Literature and the Regulatory and Technological Environment from 1993 to Today
Jill V. Platko, PhD
Scientific Advisor, PHT Corporation

Are Any Data Better than No Data? Considerations for Use of Mixed Methods of Data Collection of Patient-reported Outcomes in Clinical Trials
Sonya L. Eremenco, MA
ePRO Manager, United BioSource Corporation

#349 Track 9 (A): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W185bc *Pharmacy credits offered*

Virtual Realities: Quality Considerations When Using Outsource Providers

CHAIRPERSON
Deborah A. Waltz, MS
Senior Director, Scientific Operations Quality, Pfizer Pharmaceuticals Inc

This session will provide information on FDA expectations for the responsibility of assuring GCP compliance as well as practical steps that can be implemented. The panel will include representatives from the FDA Division of Scientific Investigations, and industry experts.

Later-stage Product Development: Ensuring Regulatory Compliance During Clinical Trials
Michael P. Swiatocha, MS
Practice Leader, R&D Compliance and Bioresearch Monitoring Services, Quintiles Consulting

FDA Point of View
Constance Cullity, MD, MPH
Branch Chief, Division of Scientific Investigations, Office of Compliance, CDER, FDA

A Risk-based Approach to Vendor Management
Shiela McLaughlin
International Director, Quality Assurance, DATATRAK International, Inc.

#350 Track 9 (B): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W183b *Pharmacy credits offered*

Key Considerations for Development of Biologic Therapeutics

CHAIRPERSON

Sunita Zalani, PhD
Executive Director, Global Regulatory Affairs, Amgen Inc.

Experts from FDA and industry will provide insights on the key differences at each stage of nonclinical and clinical development for small molecules and biologics with a focus on those differences that affect the overall development and approval time.

Clinical Perspective for Development of Biologics
Patricia Keegan, MD
Director, Division of Biologic Oncology Products, Office of Orphan Products Development, Office of New Drugs, CDER, FDA

Nonclinical Development of Biologics Relative to Small Molecules for Nonadvanced Cancer
Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs, Immediate Office, CDER, FDA

Key Considerations for Development of Biologic Therapeutics
John T. Sullivan, MD, FACP
Executive Medical Director, Global Regulatory Affairs and Safety, Amgen Inc.

#351 Track 9 (C): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ◆ Format: **SESSION**
Room W185a

Scientific Advice in Europe: How to Get the Best Out of It?

CHAIRPERSON

Gopalan Narayanan, MD, MRCP, FRCP
Medical Assessor, Biologicals and Biotechnology Unit, MHRA, UK

This session will discuss the scientific advice procedure in Europe and the principles behind various options available to plan development in a pragmatic manner. Oncology and cell and gene therapy examples will be used to illustrate these principles.

EMA Point of View
Spiros Vamvakas, MD
Head of Scientific Advice, European Medicines Agency, European Union

Scientific Advice in the EU
Cecil J. Nick, MS, FTOPRA
Vice President (Technical), PAREXEL Consulting, UK

Working with EU Regulatory Authorities to Establish a Safe Starting Dose in a Nonstandard Oncology Setting
Robert M. Miller, MD, FFPM
Chief Consultancy Physician, Aptiv Solutions, UK

#352 Track 9 (D): Regulatory Affairs and Science, Quality, and GXP Compliance

1:30 PM – 3:00 PM LEVEL: ● Format: **SESSION**
Room W471b

Global Marketing Authorization: Expected Regulatory Agency Review Timelines and Practical Experience

CHAIRPERSON

Regina Ballinger, RN
Senior Manager, Thomson Reuters

Regulatory approval time is used to evaluate the performance of regulatory agencies and is used by companies to plan product launches. Global timelines, how to interpret best use of this information, and a regulator's perspective will be discussed.

Planning for Submission: Agency Target Times Versus Actual Approval Times for New Medicines – What Does This Tell Us about Agencies' Processes and Practices?
Neil McAuslane, PhD, MSc
Director, Centre for Innovation in Regulatory Science, UK

How Transparent Are Regulatory Agencies with Regard to Review Timelines? A Global Review
Rosanna Melchior, PharmD, MSc
Senior Manager, Regulatory Intelligence, Thomson Reuters, France

The Importance of Target Times to Providing a Framework for the Approval Process and Managing the Expectation of a Regulatory Agency's Stakeholders
Petra Doerr, PharmD
Head of Management Services and Networking, Swissmedic, Swiss Agency for Therapeutic Products, Switzerland

#353 Track 10 (A): Public Policy/Health Care Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W180 *Pharmacy credits offered*

Off-label Use: Practical and Legal Issues

CHAIRPERSON

John A. Lisman, LLM, MPharm
Lawyer, Lisman Legal Life Sciences B.V., Netherlands

This session will look into positive and negative aspects of off-label use of medicines and devices and explain reasons for the existence of the practice. Both the EU and the US situations will be discussed.

Legal Aspects of Off-label Use in Theory and Practice
John A. Lisman, LLM, MPharm
Lawyer, Lisman Legal Life Sciences B.V., Netherlands

Clinical Challenges on How to Optimize the Use of Drugs Beyond the Label
Yechiel Hekster
Professor of Clinical Pharmacy, Medicines Evaluation Board, Netherlands

Practical Issues of Off-label Use in the US
Albert I. Wertheimer, PharmD, PhD, MBA
Professor, Temple University School of Pharmacy

#354 Track 10 (B): Public Policy/Health Care Compliance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W181a *Pharmacy credits offered*

Economic Transparency of Drug Development

CHAIRPERSON

Howard L. Dorfman, JD
Consultant, FDA Regulatory, Compliance, and Risk Management, H.L. Dorfman & Associates Consulting Services

With today's spotlight on drug costs, industry must justify the health economic value of drug development and new products to payers, physicians, and consumers. Recent initiatives highlight the various financial perspectives industry must consider as it progresses a product through the drug development life cycle.

Connecting Clinical Trials to Health Economics: Why It Makes Sense to Evaluate Drug Development as Part of Health Care Budget
Geoff Fatzinger
Executive Director, Regulatory Affairs and Strategic Product Development, Europe and Asia Pacific, INC Research, UK

Public, Industry, and Physician Perceptions of Industry-Physician Payment Relationships
Sondra A. Pepe
Product Manager, Medidata Solutions Worldwide

#355 Track 11 (A): Clinical Safety and Pharmacovigilance

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W184a *CME and Nursing credits offered*

Signal Detection, Strengthening, and Management Based on Clinical Trial, Spontaneous Claims, and EHR Data

CHAIRPERSON

Steve Jolley, MA
Principal, SJ Pharma Consulting

This symposium will review many aspects of signal detection. It will demonstrate practical mechanisms for signal detection, and how to assess, triage, strengthen, and manage signals and safety concerns. The presentations will show how to detect and manage signals from multiple data sources including clinical trial data, spontaneous adverse event reports, claims data, and electronic health records used in Integrated Delivery Networks.

Signal Detection: US and European Regulatory Requirements
Steve Jolley, MA
Principal, SJ Pharma Consulting

Decision Making and Safety in Clinical Trials: Graphs Make a Difference!
Susan P. Duke, MS
Manager, Biostatistics Development Partners, GlaxoSmithKline

Using Visualization to Explore Claims and EHR Data for Signal Strengthening
Sigfried Gold, MA, PMP
Medical Informaticist, Oracle Corporation

#356 Track 11 (B): Clinical Safety and Pharmacovigilance

1:30 PM – 3:00 PM LEVEL: ● Format: **FORUM**
Room W183c *CME and Nursing credits offered*

Pharmacovigilance: How to Do More with Less

CHAIRPERSON

Axel Hagel
Practice Manager, Intrasphere Technologies, Inc., Canada

This forum will examine simple techniques and concepts that can be employed to achieve higher efficiencies and throughput in pharmacovigilance-related activities and withstand the ever mounting workload and reduction in resources.

Jay M. Ehrlich, MD
Vice President, Global Pharmacovigilance, Baxter Healthcare

Jill E. Robinson, MBA, RPh
Senior Vice President, Global Patient Safety and Risk Management, Genzyme Corporation

Kapil Kedia, MBA
Principal Product Manager, Oracle Health Sciences

#357 Track 12: Statistics

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W181bc

Statistical Consideration for Assessment of Follow-on Biologics

CHAIRPERSON

Shein-Chung Chow, PhD
Professor, Department of Biostatistics and Bioinformatics, Duke University School of Medicine

As more innovative biological products are going off patent, the evaluation and approval of follow-on biologics have attracted much attention. This session will provide statistical considerations for assessing biosimilarity of follow-on biologics.

Biocomparability Study: The Success Key for Biosimilars
Jason Liao, PhD
Director, Teva Branded Pharmaceutical Products R&D, Inc.

Impact of Variability on the Criteria of Biosimilarity in Assessing Follow-on Biologics
Nan Zhang, PhD
Biostatistics Manager, Amgen Inc.

Horse Shoes and Hand Grenades: Close Also Counts for Biosimilars
Kerry B. Barker, PhD
Senior Director, Leadership, Bio-Therapeutics Research, Pfizer Inc

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

1:30 PM – 3:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W184d *CME, Nursing, and Pharmacy credits offered*

Using Real-world Data for Making Real-world Decisions

CHAIRPERSON

Matthew D. Rousculp, PhD, MPH
Director, Health Outcomes and Pharmacoeconomics, MedImmune, LLC

This symposium will include presentations addressing global issues related to health outcomes/economics and comparative effectiveness research.

The Monitoring Registers and Application of Risk Sharing After the MA Process: The Experience of the Italian Medicines Agency
Luca De Nigro, PMP
Project Manager RFOM, Italian Medicines Agency, Italy

In-patient Cost and Reimbursement for Patients with Progressive Malignant Thoracic Neoplasm in Germany
Florian Eichmann, PhD, MSc
Director, Registries and Health Outcomes, Kendle, Germany

EHR-driven Health Economics and Comparative Effectiveness with the US Department of Defense: The Opportunities Will Surprise You!
Harry J. Fisher
President, Health ResearchTx LLC

#359 Track 14: Medical Devices

1:30 PM – 3:00 PM LEVEL: ■ Format: **SESSION**
Room W186abc *CME and Nursing credits offered*

Roadmap to Efficient Development of Companion Diagnostics

CHAIRPERSON
Libbie J. Mansell, PhD, MBA, RAC
President, White Oak BioPharma Solutions

Consistent with the goal of personalized medicine, tandem Rx/Dx development can facilitate delivery of optimized cancer therapy for patients. The regulatory and clinical landscape for companion diagnostics will be clarified for session attendees.

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

Enhancing Drug Development and Commercialization with Companion Diagnostics
Libbie J. Mansell, PhD, MBA, RAC
President, White Oak BioPharma Solutions

Ensuring Added Value: Practical Considerations for Developing Companion Diagnostics
Carol Berry, MBA
Senior Vice President and General Manager, Asuragen, Inc.

#360 Track 15 (A): Professional Development and Training

1:30 PM – 3:00 PM LEVEL: ● Format: **SESSION**
Room W474a *Pharmacy credits offered*

Growing Through Giving: Professional Development Through Patient Advocacy and Volunteerism

CHAIRPERSON
James E. Valentine, MSc, MHS
Program Analyst, Office of Special Health Issues, Office of the Commissioner, FDA

The patient perspective adds value when making decisions that ultimately impact health. Patient advocate, regulatory, and industry perspectives will provide a discussion of why patient advocacy and volunteerism are vital for 2011 and beyond.

Regaining a Vision of Ourselves for the Good
C. Latham Mitchell, MD
Managing Principal, Erudita Biotechnical LLC

Beyond Borders: Challenging Professional Skills Beyond Pharma
Christine D. Loch, BSN, MSN
Clinical Scientist, GlaxoSmithKline

Patient Advocacy in the Workplace: A Mutually Beneficial Experience
James E. Valentine, MSc, MHS
Program Analyst, Office of Special Health Issues, Office of the Commissioner, FDA

#361 Track 15 (B): Professional Development and Training

1:30 PM – 3:00 PM LEVEL: ● Format: **WORKSHOP**
Room W475a *PMI PDUs offered*

Job Insurance: Career Planning that Prepares You for the Expected … and the Unexpected

CHAIRPERSON
Amy N. Grant, MS
Director, Regulatory Strategy and Science, ViroPharma Incorporated

The work environment has changed, as have many of your responsibilities. The economic climate and major pharmaceutical business trends have resulted in the displacement of many long-term, life-science industry professionals. This workshop will provide stories, tips, and tools to help you build a solid career plan to provide "job insurance" for the future. It will include audience participation with brief presentations, interactive discussions, and activities.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

Unexpected Career Transitions: Where Do I Go from Here?
Daniel F. Orfe, MS
President and CEO, Regulatory eSubmissions, LLC

Creating a Professional Presence Utilizing Online Social Media
Bridgid Nelson
Executive Recruiter, Liberty Consulting Group

#362 Track 16 (A): Global Agency

1:30 PM – 3:00 PM LEVEL: ● Format: **SESSION**
Room W187abc

The State of Electronic Submissions at CDER, CBER and CDRH

CHAIRPERSON

Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, CDER, FDA

CDER and CBER 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.

Electronic Submissions at CDER
Virginia Hussong
Supervisory Program Analyst, FDA

Electronic Submissions at CBER
Michael B. Fauntleroy
Program Manager, CBER, FDA

Electronic Submissions at CDRH
Terrie Reed
Associate Director, Informatics, CDRH, FDA

PANELIST

Mark A. Gray
Director, Division of Review Support, Office of Business Process Support, CDER, FDA

#363 Track 16 (B): Global Agency

1:30 PM – 3:00 PM LEVEL: ● Format: **FORUM**
Room W185d

APEC (Asia-Pacific Economic Cooperation) Town Hall

CHAIRPERSON

Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Director for International Programs, Office of the Center Director, CDER, FDA

Regulatory agencies within APEC (Asia-Pacific Economic Cooperation) will participate in this inaugural Town Hall to discuss initiatives, achievements, and updates in various topics such as adaptation and implementation of ICH clinical guidelines. This is an open question and answer forum.

Churn-Shiouh Gau, PhD
Executive Director; Research Fellow, Taiwan FDA Center for Drug Evaluation, Taiwan

Daniel Tan, MD, MBA
Director, Policy Legislation and Operations, Health Products Regulation Group, Health Sciences Authority, Singapore

Mike D. Ward
Manager, International Programs Division, Health Canada

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

Rohan Hammett
National Manager, Department of Health and Aging, Therapeutic Goods Administration (TGA), Australia

3:00 PM – 3:30 PM **REFRESHMENT BREAK**
Exhibit Hall, Level 3 (See Floor Plan, page 131)

#364 Track 1 (A): Clinical Operations

3:30 PM – 5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W175abc *CME and Nursing credits offered*

Global Clinical Trials

CHAIRPERSON

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

As clinical trials continue to shift to emerging markets, industry professionals, scientists, and regulators must contend with how globalization will affect both the art and science of clinical research. Long a reality, the gradual shift of clinical trials from developed countries to emerging markets continues to be steeped in assumptions, misunderstandings, outdated facts, and inaccurate data. This symposium aims to infuse current misconceptions with a fresh, first-hand look at the reality of clinical trial conduct in emerging markets, specifically Latin America, Central and Eastern Europe, and Asia.

The Impact of the Changing Landscape in Japan and Asia on How Companies Organize for Success
Chris R. Albani, MBA
Managing Director, Pharmaceutical Industry Lead, PRTM Management Consultants, Japan

Impact of Culture and Language on Global Clinical Trials: The Shift Eastward
Inna Kassatkina
President, Global Language Solutions

Ending the Myths: Best Practice in Trial Conduct in Latin America
Katie Margules, PharmD, MSc
Global Vice President, Alliance Management, Covance Inc., Mexico

#365 Track 1 (B): Clinical Operations

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W176abc *CME and Nursing credits offered*

Pharmacogenetic Research and Informed Consent

CHAIRPERSON

Linda M. Coleman, Esq., JD
Director, Regulatory Affairs and General Counsel, Quorum Review IRB

This session will present an exploration of pharmacogenetic research, specifically how information should be presented in pharmacogenetic consent forms and an illustration of how sites can effectively describe the process, scope, and risks/benefits to subjects in these studies.

A Sponsor's Perspective
Feng Hong, PhD
Research Operations Senior Manager, Molecular Sciences Biobank Management Group, Amgen Inc.

A Monitor's Perspective
Cynthia M. Sinsel
Clinical Project Manager, MedTrials, Inc.

A Health Literacy Organization's Perspective
Eileen Hanlon, MS
Senior Program Officer and Co-director, Health Literacy Practice, Academy for Educational Development

An IRB's Perspective
Linda M. Coleman, Esq., JD
Director of Regulatory Affairs and General Counsel, Quorum Review IRB

#366 Track 1 (C): Clinical Operations

3:30 PM – 5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W183a *CME, Nursing, and Pharmacy credits offered*

The Clinical Study Process: What Is Wrong? What Can Be Done?

CHAIRPERSON

J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality (AHRQ)

In the United States, it is asserted that 96% of all clinical trials go beyond target timelines and over budget. By examining the painful clinical study process, speakers will discuss their major bottlenecks, how they overcame them (sort of), and what web-based tools improved efficiency for them. Is centralizing support functions to be a best practice? These functions have to be defined and negotiated with the study team. Additionally, while more than half of clinical research professionals rely on Excel, web-based networks can generate real-time measures to benefit site identification and activation. These benchmarks may be generalizeable.

Monkey in the Middle: Supporting Clinical Study Teams (A Cautionary Tale)
Denise DeRenzo Lacey, MA, MS
Senior Director, of Business Development, Gobalto

Reinventing Clinical Study Startup
Daniel T. Manak
Senior Director, Business Development, goBalto

Controlling the Game: Implementation of an eClinical Solution in an RSP Organization – Stakeholder Integration and Systems for Data Driven Project Management
Max Horneck, PhD
eClinical Expert, Maxclinical, Germany

#367 Track 2: Development Planning

3:30 PM – 5:00 PM LEVEL: ◆ Format: **SESSION**
Room W179a *PMI PDUs offered*

Tools and Techniques for Optimal Drug Development Portfolio Planning: Portfolio Selection, Resource Allocation, and Risk Mitigation

CHAIRPERSON

Vladimir Shnaydman, PhD
President, ORBee Consulting

Portfolio planning is crucial for developing long-term company strategy. The goal is to meet strategic objectives, select the "best" portfolio of drug development programs, align company goals and resources, and mitigate portfolio risk.

Process and Portfolio Decision Making in Complex R&D Situations
Otto Ritter, PhD
IS Informatics Science Director, AstraZeneca

Implementing a Common Analytic Platform to Optimize Late-stage Pipeline Portfolio Evaluation
Carlos Nunes, MS
Director, Portfolio Valuation and Prioritization, Pfizer Inc

Analysis of Optimal Portfolio Selection, Capacity Planning, Risk Assessment and Mitigation
Vladimir Shnaydman, PhD
President, ORBee Consulting

#368 Track 3 (A): Outsourcing Strategies and Innovative Partnering Models

3:30 PM – 5:00 PM LEVEL: ● Format: **SESSION**
Room W178ab

Innovative Partnering in Early R&D

CHAIRPERSON

Anand Subramony, PhD, MSc
Principal Fellow/Head, Novartis Institutes for Biomedical Research, Inc.

Innovative partnering in early research and development will highlight collaborative opportunities between novel technologies and early-stage pipeline molecules for new product development and life-cycle management opportunity.

Developing Novel Products Through Technology Innovation and New Partnership Models
Anand Subramony, PhD, MSc
Principal Fellow/Head, Novartis Institutes for Biomedical Research, Inc.

Partnership Models for an Ocular Drug Delivery Platform Company
Stephen From, CPA
President and CEO, EyeGate Pharma

Broadening Commercialization Through Novel Partnering: A Case Study from Intelimer Technology
Steven Bitler, PhD
Vice President, Corporate Technology, Landec Corporation

#369 Track 3 (B): Outsourcing Strategies and Innovative Partnering Models

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W183b

The New Frontier in Outsourcing: Regulatory Affairs and Safety

CHAIRPERSON

Benedict J. Chu, MS
Director, Global Regulatory Affairs and Safety Operations, Amgen Inc.

Companies have traditionally performed regulatory affairs and safety work internally. They recognize the cyclical nature of this work and the opportunity for efficiencies, and are pursuing innovative sourcing strategies in this area.

Outsourcing Regulatory Strategy: Models and Critical Success Factors
Mark A. Ammann, PharmD
President, Catalyst Regulatory Services, LLC

Trends in Outsourcing Safety Operations
David J. Balderson, PhD
Executive Director, Safety Operations, Global Regulatory Affairs and Safety, Amgen Inc.

Oversight of Outsourced Activities: Quality and Compliance Considerations
Winifred Ann Meeker-O'Connell, MS
Policy Advisor, Division of Scientific Investigations, Office of Compliance, CDER, FDA

#370 Track 4 (A): Nonclinical and Early Clinical Translational Development

3:30 PM – 5:00 PM LEVEL: ● Format: **SESSION**
Room W179b *CME and Nursing credits offered*

The Eyes Have It! The Unique Advantages of Clinical Research in Ophthalmology Trials: PK/PD and Biomarkers in Ophthalmology

CHAIRPERSON

C. James Kissling, MD, DrMed
Medical Director, Covance Clinical Research Unit in Dallas, Covance

The human eye/visual axis provides the ability to directly observe neurological tissues, pigmented epithelium, and blood vessels without overlying skin interference. Learn how to apply PK/PD and biomarkers in eye research to your R&D program.

Unique Advantages and Challenges of Clinical Research in Ophthalmology Using On-target and Off-target Study Drugs
C. James Kissling, MD, DrMed
Medical Director, Covance Clinical Research Unit in Dallas, Covance

PK Considerations in Study Design for Clinical Research in Ophthalmology
Nathan Teuscher, PhD, MS
Associate Director, Clinical Pharmacology, Alcon Laboratories

Biomarkers and PD Considerations in Clinical Research in Ophthalmology: Historical Examples, and Which Test to Order and When
David G. Birch, PhD
Chief Scientific and Operating Officer, Retina Foundation of the Southwest

Overview of the Leading Causes of Blindness: Current Research Including the Role of Animal Models in Human Clinical Research
T. Michael Nork, MD, MS
Associate Professor, Comparative Ophthalmic Research Laboratories (CORL)

#371 Track 4 (B): Nonclinical and Early Clinical Translational Development

3:30 PM – 5:00 PM LEVEL: ■ Format: **FORUM**
Room W184a

Model-based Drug Development: How In-silico Approaches Are Reshaping the Clinical Enterprise

CHAIRPERSON

Zhaohui John Cai, MD, PhD
Biomedical Informatics Director, AstraZeneca

This forum will demonstrate how the application of advanced in-silico methods for predictive modeling and information integration look set to change the way that clinical drug development is conducted in the future.

A New Bridge Between Early Drug Discovery and Clinical Drug Development: Translational Informatics
Lixia Yao, PhD
Computational Biologist, GlaxoSmithKline

Modeling Clinical Biomarkers and Endpoints for Drug Development: What Are We Missing?
Zhaohui John Cai, MD, PhD
Biomedical Informatics Director, AstraZeneca

EHR Data in the Drug Development Process: From Protocols to Pharmacovigilance
Michael N. Cantor, MD
Director, Business Intelligence, Pfizer Inc

#372 Track 5: Product Advertising and Communications

3:30 PM – 5:00 PM LEVEL: ● Format: **WORKSHOP**
Room W474b *Pharmacy credits offered*

Prescription Drug Marketing Regulatory Primer

CHAIRPERSON

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

This interactive workshop will provide a basic introduction to the regulation of prescription drug advertising and promotion. 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. McCormick Place 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
Catherine B. Gray, PharmD
Management Advisor, Division of Drug Manufacturing, Advertising and Communications (DDMAC), Office of Medical Policy, CDER, FDA

#373 Track 6: Medical Writing and Communication

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W184bc *Pharmacy credits offered*

Using the Medical Writing Competency Model to Take Charge of Your Personal and Professional Development

CHAIRPERSON

Peggy Boe, RN
Independent Contractor

The Medical Writing Competency Model (MWCM) was designed by DIA's Medical Writing SIAC. This session will demonstrate ways the MWCM can be used to enhance personal career growth, build the professional status of medical writers, improve in-house training, and promote research on best practices

Calling All Medical Writers: How to Achieve Your Highest Professional Goals
Peggy Boe, RN
Independent Contractor

Growing a Medical Writer
Frances Pu, PhD
Director, Medical and Technical Writing, Daiichi Sankyo Inc.

Beyond Competencies: Research, Cases, Education
Lili F. Velez, PhD
Assistant Professor, Towson University

#374 Track 7: IT Methods and Technologies

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W470a

Why Is It So Hard to Combine Data Streams Collected in Clinical Trials?

CHAIRPERSON

Christopher Ernenwein
Product Senior Software Engineer II, PHT Corporation

Data need to flow between sites, CROs, technology providers, sponsors, and regulatory authorities. Efficient communication starts when the requirements are understood by all parties. This session vividly contrasts typical versus standards-based exchange.

Greg Moody
Director, Clinical Informatics, Millennium: The Takeda Oncology Company

#375 Track 8: Research Data and Content Management

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W470b *Pharmacy credits offered*

Best Practices in Managing External Data

CHAIRPERSON

Teresa Ancukiewicz
Senior Manager, Boston Scientific Corporation

Data managers working in oncology studies are often required to utilize imaging data to derive or assess standard response criteria. We present methods to efficiently manage RECIST (Response Evaluation Criteria in Solid Tumors) data, a commonly used response criterion, and highlight the changes incorporated in RECIST v.1.1.

We provide suggestions for developing practices to maintain and process data generated in these studies and describe methods to coordinate site vs. central review analyses to ensure the quality of these data sources.

Alternative Approaches to Normal Laboratory Ranges Management for Local Labs: Pros and Cons
Vadim Tantsyura, DrPH, MA, MS
Director, Data Management, Infinity Pharmaceuticals

Comparison of RECIST 1.0 and 1.1: Impact on Data Management Processes
Kevin F. Shea
Senior Solutions Architect, C3i, Inc.

Managing the Three R's of External Data Handling: Receipt, Review, and Reconciliation
George Keller
Vertex Pharmaceuticals

#376 Track 9 (A): Regulatory Affairs and Science, Quality, and GXP Compliance

3:30 PM – 5:00 PM LEVEL: ■ Format: **FORUM**
Room W185bc *CME and Nursing credits offered*

Quality Risk Management in Clinical Trials: Regulators' and Industry's Points of View

CHAIRPERSON

Beat E. Widler, PhD
Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Quality risk management is the new paradigm in quality management. It is discussed by regulators and industry alike and is at the verge of becoming the industry standard. Representatives from the regulatory arena and industry will discuss this interesting topic.

Define, Measure, and Control Quality: A Scientific Framework to Manage Quality and Compliance in Pharmaceutical GXP Operation
James Huang, PhD
Manager, Deloitte and Touche LLP

FDA Point of View
Jean Mulinde, MD
Acting Team Lead, Good Clinical Practice Team 2, CDER, FDA

#377 Track 9 (B): Regulatory Affairs and Science, Quality, and GXP Compliance

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W186abc *Pharmacy credits offered*

Co-development of Two Novel Investigational Drugs for Use in Combination

CHAIRPERSON

Jon Sang Wong, PhD
Vice President, Global Regulatory Affairs, Oncology, Eisai Limited, UK

In recognition of increasing interest in the development of two, or more, novel investigational drugs intended to be used together to treat a disease or condition, the FDA has solicited input on methodological and regulatory issues associated with such a development program from industry and other areas. The FDA has issued a general draft guidance to address the issues raised. However, many questions remain for sponsors engaging in ongoing global development activities in this area. This session will discuss the FDA draft guidance as well as addressing EMA's view on co-development of novel agents. Industry's experience in this emerging field will also be shared at this session.

Industry Viewpoint on the FDA Draft Guidance
Robert T. Clay, MBA, MSc
Vice President, Regulatory Affairs, Oncology and Infection Therapeutic Areas, AstraZeneca, UK

EMA Point of View
Spiros Vamvakas, MD
Head of Scientific Advice, European Medicines Agency, European Union

Industry Point of View
Krishnan Viswanadhan, PharmD, MBA
Director, Regulatory Affairs Product Development, Roche

#378 Track 9 (C): Regulatory Affairs and Science, Quality, and GXP Compliance

3:30 PM – 5:00 PM LEVEL: ■ Format: **FORUM**
Room W187abc *CME, Nursing, and Pharmacy credits offered*

The Challenges of Improving the Science of Regulatory Decision Making

CHAIRPERSON

Stanley A. Edlavitch, PhD, MA
Professor, Epidemiology, University of Missouri Kansas City - School of Medicine

This session will ask regulators to comment on progress in determining how the best regulatory decisions can be made taking into account scientific evidence, public desires, public health, economics, political, media, and other societal factors.

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

EMA Point of View
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Academic Point of View
Louis Garrison, PhD
Professor and Associate Director, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington

#379 Track 9 (D): Regulatory Affairs and Science, Quality, and GXP Compliance

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W471a

NDA/BLA Analysis Files: Improving Specifications and Communication

CHAIRPERSON

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

CDER's Computational Science Center (CSC) is working to improve specifications and communications for submission of analysis files for NDAs/BLAs. This session will describe progress made in improving specifications and processes for data submission.

FDA Effort to Standardize Data Submission: Antiviral Experience
Wen Zeng, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Practical Industry Issues in ADaM Implementation and Submission: Are We Facilitating Regulatory Clinical Review?
Michael Nessly, MS
Director and Area Head, Global Biostatistics, Shire Pharmaceuticals

Up and ADaM: Best Practices for Common Problems with ADaM Implementation
Chris Holland, MS
Director, Biostatistics, MacroGenics Inc.

#380 Track 10: Public Policy/Health Care Compliance

3:30 PM – 5:00 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W180 *CME, Nursing, and Pharmacy credits offered*

Risk Communication in an Age of Uncertainty: The Legal, Regulatory and Compliance Implications of Disclosing Safety Information

CHAIRPERSON

Howard L. Dorfman, JD
Consultant, FDA Regulatory, Compliance, and Risk Management, H.L. Dorfman & Associates Consulting Services

The focus on the early detection and disclosure of safety-related information has become a dominant theme for regulatory agencies and health authorities worldwide. The panel will address the thorny issues impacting the process of communicating timely and accurate risk information to a wide range of audiences, including government agencies, health-care providers and the public, as well as the means by which such information may be provided.

Risk Evaluation and Mitigation Strategies (REMS): New Regulatory, Legal, and Commercial Requirements in Pharmaceutical Risk Management for the Pharmaceutical and Biotech Industries
Howard L. Dorfman, JD
Consultant, FDA Regulatory, Compliance, and Risk Management, H.L. Dorfman & Associates Consulting Services

Reactive and Proactive Risk Communication About Counterfeit Medicines: Principles, Models, and Practical Experiences
Domenico Di Giorgio, PhD
Chairman, CoE/EDQM Committee on Counterfeit Medicines; Director, Counterfeits Unit, Italian Medicines Agency (AIFA), Italy

#381 Track 11 (A): Clinical Safety and Pharmacovigilance

3:30 PM – 5:00 PM LEVEL: ■ Format: **WORKSHOP**
Room W475a

Good and Bad Behaviors During a PV Inspection

CHAIRPERSON

Barton L. Cobert, MD, FACP, FFPM
President, BLCMD Associates, LLC

This workshop will also be offered on Wednesday, June 22, at 10:00 AM.

During a pharmacovigilance inspection, behavior can play as big a role as the content of a person's answers. This workshop will demonstrate good and bad behaviors during an inspection and will identify the steps to take to avoid these problems.

Several scenarios will be distributed to the audience. The presenters and audience volunteers will be invited to join in as either auditors or auditees in a nonconfrontational (for the audience) manner to act through the scenarios. Some of the scenarios will be audits of excellent companies with few or no problems. Others will have major faults and failings that the auditees must defend. There will be coaching during and after each scenario and re-plays of the scenarios as appropriate.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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

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

Suzanne Tepper, PharmD, RPh
Vice President, Pharmacovigilance Operations, APCER Pharma Solutions, Inc.

#382 Track 11 (B): Clinical Safety and Pharmacovigilance

3:30 PM – 5:00 PM LEVEL: ● Format: **SESSION**
Room W183c *Pharmacy credits offered*

REMS Model for Drug Safety

CHAIRPERSON

Dean Michael Pratt, MBA, PMP
Consulting Program Manager, Intrasphere Technologies

A REMS model is proposed which allows the modeler to evaluate and weigh risks, resulting in a numeric risk score for a particular drug which may be predictive of regulatory approval.

Specific Considerations within the Risk Framework
Daniel Jacob, MD
Director, Risk Management, Baxter Healthcare Corporation

Trends in REMS Design, Implementation, and Assessment
Kelly D. Davis, MD
Vice President, Safety, Epidemiology, Registries, and Risk Management, United BioSource Corporation

REMS Implications for Global Commercializations
Robin Lee Geller, PhD
Director, Pharmacovigilance Intelligence/Safety Writing, Baxter Healthcare Corporation

#383 Track 12: Statistics

3:30 PM – 5:00 PM LEVEL: ■ Format: **SESSION**
Room W181bc

Adaptation and Decision Making at the Development Program Level

CHAIRPERSON

Jose C. Pinheiro, PhD
Senior Director, Quantitative Decision Strategies, Johnson & Johnson Pharmaceuticals Research & Development, LLC

Innovative approaches in drug development, such as adaptive designs, have focused at the trial level. Extending this type of innovative thinking to the level of development programs is more challenging, but also more impactful and relevant.

Investment Decisions and Option Values in Development Programs
Carl-Fredrik Burman, PhD
Senior Principal Scientist, AstraZeneca R&D, Sweden

Designing Adaptive Programs for Neuropathic Pain
Nitin R. Patel, PhD, MBA
Chairman and Co-founder, Cytel, Inc.

Optimizing Type 2 Diabetes Drug Development
Zoran Antonijevic, MSc
Senior Director, Center for Statistics in Drug Development, Quintiles

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

3:30 PM – 5:00 PM LEVEL: ■ Format: **FORUM**
Room W184d *CME, Nursing, and Pharmacy credits offered*

Encouraging Comparative Effectiveness Research While Protecting Privacy: Can We Develop a Research Safe Harbor for CER?

CHAIRPERSON

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

Many researchers believe that HIPAA and the Common Rule significantly impede research, including CER and other information-based research. This forum explores whether a new policy framework that encourages CER and protects privacy can be developed.

Ann B. Waldo, JD
Partner, Wittie, Letsche, and Waldo, LLP

Felix A. Khin-Maung-Gyi, PharmD, MBA, RAC
Chief Executive Officer, Chesapeake Research Review Inc.

Tina Olson Grande, MSc
Senior Vice President, Policy, Healthcare Leadership Council

#385 Track 14: Medical Devices

3:30 PM – 5:00 PM LEVEL: ● Format: **SESSION**
Room W475b *CME, Nursing, and Pharmacy credits offered*

Pediatric Cardiovascular Drug and Devices Development

CHAIRPERSON

Mitchell W. Krucoff, MD, FACC
Professor, Medicine/Cardiology; Director, Cardiovascular Devices Unit; Director, eECG Core Laboratory, Duke University Medical Center/ Duke Clinical Research Institute

This Session has been cancelled.

Ethi… safe… bee… …ally …or long-term follow up through periods of physical and psychosocial change, and ethical concerns for protection of vulnerable patients constitute major challenges to research and development pathways. Direct address and a collaborative approach to these issues are critical to the safety of children, both in optimal medical practice and in the advance of new therapies.

In this session the Cardiac Safety Research Consortium brings together regulatory, academic, industry and patient advocate stakeholders to discuss challenges, lessons learned, and future potential solutions to advance the landscape of pediatric cardiovascular safety and medical therapeutics.

Ethical, Biological and Developmental Issues in Pediatric CV Safety
Speaker to be announced

Pediatric CV Safety and Drug Development: Challenges and Case Studies
Speaker to be announced

Pediatric CV Safety and Device Development: Challenges and Case Studies
Representative Invited
Speaker to be announced

#386 Track 15: Professional Development and Training

3:30 PM – 5:00 PM LEVEL: ● Format: **SESSION**
Room W474a *PMI PDUs offered*

The Importance of Figuring Human Resources into the Professional Development Formula

CHAIRPERSON

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

Find out what you always wanted to know about HR but were afraid to ask! This plain-speaking session run by veteran HR professionals is an absolute must for everyone in biotech, management, and nonmanagement alike.

Demystifying the HR Partnership
Asmi C. Vohra, MS
Senior Manager, Business Human Resources, Abbott Laboratories

Career Preventive Medicine and HR
C. Latham Mitchell, MD
Managing Principal, Erudita Biotechnical LLC

#387 Track 16 (A): Global Agency

3:30 PM – 5:00 PM LEVEL: ■ Format: **FORUM**
Room W185d

Regulatory Updates from Canada Including Special Projects

CHAIRPERSON

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

This session will provide an overview of new regulatory changes in Canada and how a jurisdiction of the size of Canada is dealing with-modernizing regulatory requirements, including issues surrounding consultation, simultaneously with Industry and specific interest groups from the public.

David K. Lee
Director, Office of Legislative and Regulatory Modernization, Health Canada

Mike D. Ward
Manager, International Programs Division, Health Canada

Postmarket Drug Safety Active Surveillance
Bruce Carleton
Director, Pharmaceutical Outcomes and Policy Innovations Program, University of British Columbia, Canada

#388 Track 16 (B): Global Agency

3:30 PM – 5:00 PM LEVEL: ■ Format: **FORUM**
Room W185a *CME and Nursing credits offered*

CBER Town Hall

CHAIRPERSON

Robert A. Yetter, PhD
Associate Director for Review Management, Office of the Center Director, CBER, FDA

This session will provide an overview of CBER's current work on ongoing initiatives, guidances, and regulations.

Electronic Data Submission Guidance
Amy Malla, MT, PMP
Consumer Safety Officer, Office of the Director, CBER, FDA

SPL
Vada A. Perkins, BSN, MSc, RN
Regulatory Program Management Officer, Office of the Director, CBER, FDA

Adverse Event Reporting
Deborah Yaplee
Senior Program Manager, CBER, FDA

5:00 PM **END OF WEDNESDAY SESSIONS**

NOTES

NOTES

Thursday, June 23

7:30 AM – 10:45 AM **Attendee Registration**
Exhibit Hall Entrance, Level 3

7:30 AM – 10:45 AM **Speaker Registration**
Exhibit Hall Entrance, Level 3

8:15 AM – 9:00 AM **Coffee and Breakfast Breads**
McCormick West, Lobby Entrance, Level 1

12:30 PM – 5:00 PM **MedDRA® User Group Meeting**
Room W185bc

#401 Track 1: Clinical Operations

9:00 AM – 10:30 AM LEVEL: ■ Format: **SESSION**
Room W175abc *CME and Nursing credits offered*

Fit for Purpose Patient Recruitment Staffing: Evolving Patient Recruitment Organizations Within Sponsors and CROs

CHAIRPERSON

Jane E. Myles, MS
Global Head, Patient Recruitment, Genentech, Inc.

What's the best way to set up your organization so clinical trial teams meet or exceed recruitment goals? Come hear about at least three different ways to support patient recruitment goals. Common best practices, and any "watch-outs" will be shared.

Driving Patient Recruitment from Within a CRO
James P. Kremidas
Vice President, Global Head of Patient Recruitment, Quintiles Inc.

Patient Recruitment Success Through Innovation and Accountability
Melanie L. Goodwin, MSc
Manager, Global Trial Optimization, Clinical Research Operations, Merck & Co., Inc.

Patient Recruitment Staffing: Creativity in Times of Change
Jane E. Myles, MS
Global Head, Patient Recruitment, Genentech, Inc.

#402 Track 2 (A): Development Planning

9:00 AM – 10:30 AM LEVEL: ■ Format: **WORKSHOP**
Room W474b *PMI PDUs offered*

Strategic Development Planning: Designing Fast and Efficient Programs

CHAIRPERSON

William K. Sietsema, PhD
Vice President, Regulatory Consulting and Submissions, Kendle International Inc.

Development planning is critical to the success of any product. A complete plan should be developed early so as to fully understand the timing and challenges. The plan can serve as a platform for change as the program evolves.

Workshop attendees will then have an opportunity to discuss their own strategic development plans with the workshop leaders. Attendees are encouraged to each bring a development program case study for discussion.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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

Jody Roth, MS, PMP, RAC
Director, Global Regulatory Affairs, Eli Lilly and Company

#403 Track 2 (B): Development Planning

9:00 AM – 10:30 AM LEVEL: ■ Format: **SESSION**
Room W179a *PMI PDUs offered*

Managing R&D Projects with Limited Resources: Small to Medium Biopharmaceutical/Biotechnology Enterprises (SMBEs)

CHAIRPERSON

Surya P. Chitra, PhD, MBA
Biostatistics and Pharmacology, Pharmanet Development Group, Inc.

The small and medium biopharmaceutical enterprises (SMBEs) will drive innovation in the pharmaceutical industry. Their limited resources and funding forces them to manage their R&D projects very efficiently and effectively to sustain their growth.

Adaptive Survival of Small/Medium Biopharm/Biotech Companies: A Sponsor's Perspective
Jane Wing-Sang Fang, MD
Consultant, Clinical Research and Regulatory Affairs, Pharmaessentia/RSJ Consulting

Transitioning from Early-stage R&D to Clinical Product Development
Vidadi Yusibov, PhD
Executive Director, Fraunhofer, Center for Molecular Biotechnology

Adaptive Clinical Services Model for Small to Medium Biopharmaceutical Enterprises: A CRO's Perspective
Surya P. Chitra, PhD, MBA
Biostatistics and Pharmacology, Pharmanet Development Group, Inc.

#404 Track 3: Outsourcing Strategies and Innovative Partnering Models

9:00 AM – 10:30 AM LEVEL: ■ Format: **SESSION**
Room W178ab

New Global CRO Models for Small-sized CROs

CHAIRPERSON

Dan P. Diaz
Vice President, Business Development, Beardsworth Consulting Group Inc.

In 2008 and 2009, economic conditions required CROs to be flexible and open to new models for operational growth. To expand the business opportunities, an experienced group of regional CROs combined forces to develop a new global offering.

Flexible Models Using Specialty Providers: A Small Pharma Client Perspective
David E. Morgenstern, PhD
Director, Clinical Affairs, Endocyte Inc.

Small Business Models for Central and Eastern European CROs
Malgorzata Szerszeniewska, MD
CEO, EastHORN Clinical Services CEE, Poland

The New Frontier: Cross-border Strategic Alliances Among CROs and Sponsors and Contractual Structures for Protecting the Constituents
Alexander P. Woollcott, JD
Partner, Morris, Manning & Martin, LLP

#405 Track 4: Nonclinical and Early Clinical Translational Development

9:00 AM – 10:30 AM LEVEL: ■ Format: **SESSION**
Room W183a

Strategic Regulatory Input to Nonclinical and Early Clinical Development: Minimizing Risk and Maximizing Health Authority Interest

CHAIRPERSON
Richard Mountfield, PhD
Director, Drug Regulatory Affairs, Novartis Institutes for Biomedical Research, Inc.

An overview of strategies and case studies with respect to early regulatory affairs support to nonclinical and early clinical projects will be provided in an environment of novel therapies, personalized medicine, and unmet medical needs.

Enabling Studies for Novel Routes of Administration
Kenneth Hastings, DrPH
Associate Vice President, Regulatory Policy, sanofi-aventis

Pre-INDs and Strategic Approaches to FDA Interactions
Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs, Immediate Office, CDER, FDA

A Clinician's Perspective of Early Regulatory Interactions: Case Studies
Lloyd Klickstein
Head of Translational Medicine, New Indication Discovery Unit, Novartis Institutes for Biomedical Research Inc.

#406 Track 6: Medical Writing and Communication

9:00 AM – 10:30 AM LEVEL: ◆ Format: **SYMPOSIUM**
Room W184bc *Pharmacy credits offered*

Virtually Impossible? How to Create a Great Virtual Medical Writing Team in the Global Workplace

CHAIRPERSON
Julie A. Ely, PhD
Senior Medical Writer, Proscribe Medical Communications, Australia

Medical writing is ideally suited to the virtual office and global teams, but how do you develop an efficient, productive, and happy virtual medical writing team? This symposium will give you the evidence and tips needed for medical writers to thrive … virtually!

Managing Virtual Medical Writing Teams: How to Create a Great Workplace When There Is No Workplace!
Julie A. Ely, PhD
Senior Medical Writer, Proscribe Medical Communications, Australia

Virtual Collaboration: Plan, Write, Review
Helle Gawrylewski, MA
Head, Alliance Management, Regulatory Medical Writing CoE, Johnson & Johnson Pharmaceuticals Research & Development, LLC

Leading Virtual Medical Writing Teams to Highest Quality Performance
Michael John Mihm, PhD
Director, Strategic Alliances, i3 Statprobe

#407 Track 7: IT Methods and Technologies

9:00 AM – 10:30 AM LEVEL: ■ Format: **FORUM**
Room W470a *CME and Nursing credits offered*

Managing a Private Cloud Computing Environment

CHAIRPERSON
Cheryl M. McCarthy
Associate Director, Quality Assurance, eClinical Solutions, a Division of Eliassen Group

This forum will focus on the progressing adoption of cloud computing environments. IT Infrastructure and validation experts will lead discussions with attendees on the current challenges of evaluating and implementing a cloud computing solution.

Enabling Cloud Computing Within Life Sciences: How to Overcome the Compliance Gap Existing with Non-GxP SaaS Providers
Karsten Fogh Ho-Lanng
Chief Technology Officer, NNIT A/S, Denmark

Deploying a Compliant Cloud
Michael Ambrose
Life Science Industry Solutions Manager, EMC Corporation

Cloud Computing: Validation Expectations
Richard M. Siconolfi, MS
Section Manager (Director), Validation and Quality Compliance, Procter & Gamble Company

#408 Track 8: Research Data and Content Management

9:00 AM – 10:30 AM LEVEL: ■ Format: **SESSION**
Room W470b *CME, Nursing, and Pharmacy credits offered*

Research Collaboration in the Cloud: How NCI and Research Partners Are Using Digital Identities to Accelerate Medical Advance

CHAIRPERSON
Cindy Cullen, MSc
Associate Director, Digital Signature Services, Bristol-Myers Squibb Company

This session will discuss how large pharmaceutical companies and the NCI's Cancer Therapy Evaluation Program (CTEP) are collaborating using digital identities to eliminate reliance on paper-based forms in research projects associated with drug development and clinical trials.

High-assurance Trust Architecture for eGovernment
Peter S. Alterman, PhD
Senior Advisor to the CIO for Strategic Initiatives, Office of the Director, National Institutes of Health

Trusted Identities and Digital Signatures: Fundamental to Collaboration in the Cloud
Mollie Shields-Uehling
President and CEO, SAFE-BioPharma Association

Research Collaboration in the Cloud: How NCI and Research Partners Are Improving Business Processes
Steve H. Friedman, MHA
Chief, Clinical Trials Operations and Informatics Branch, Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program, National Cancer Institute, National Institutes of Health

#409 Track 9: Regulatory Affairs and Science, Quality, and GXP Compliance

9:00 AM – 10:30 AM LEVEL: ◆ Format: **SESSION**
Room W185d *CME and Nursing credits offered*

Vendor Qualification Audits for SaaS Suppliers

CHAIRPERSON

Charles L. Lankford
CEO, PharmaSys Inc.

This interactive session will provide an outline of the vendor qualification audit process for Software as a Service (SaaS) suppliers and data centers. It will present important information on how to organize, plan, conduct, and evaluate audits.

Risky Business: Data Integrity and Risk-based Approaches
Judy Baushke, MT, PMP, RAC
Manager, Analysis and Quality Services, Rho, Inc.

Quality Management Systems: Audits from the Vendor's Point of View
Cathy A. Smith, MA, MBA, PMP
Compliance Manager, SAS Solutions OnDemand

#410 Track 10: Public Policy/Health Care Compliance

9:00 AM – 10:30 AM LEVEL: ■ Format: **SESSION**
Room W180 *CME, Nursing, and Pharmacy credits offered*

Drug Shortages in the Treatment of Rare and Orphan Diseases: Challenges, Compromises, and Choices

CHAIRPERSON

Lynne P. Yao, MD
Medical Officer Team Leader, Office of New Drugs, Office of Drug Evaluation 3, CDER, FDA

Recently, drug shortages have affected patients with rare diseases including Pompe, Fabry and Gaucher diseases. The session will examine the role of industry, regulators, and health-care providers in managing drug shortages for rare diseases

Anne R. Pariser, MD
Associate Director for Rare Diseases. Office of New Drugs, CDER, FDA

Jethro Ekuta, DVM, PhD
Vice President, Regulatory Affairs, Genzyme Corporation

Mary E. Cobb
Senior Vice President, Membership and Organizational Strategy, National Organization for Rare Disorders (NORD)

#411 Track 11: Clinical Safety and Pharmacovigilance

9:00 AM – 10:30 AM LEVEL: ● Format: **SESSION**
Room W184a *CME, Nursing, and Pharmacy credits offered*

The Public Health Burden of Acetaminophen Poisonings: Risk Management Efforts to Mitigate It

CHAIRPERSON

Syed Rizwanuddin Ahmad, MD, MPH, FISPE
Medical Epidemiologist, Office of Surveillance and Epidemiology, CDER, FDA

Acetaminophen (paracetamol) is a very popular analgesic/antipyretic. It is one of the leading causes of poisonings in the US and the UK. This session will give an overview of the risk management efforts to mitigate its risk.

Point of View from the FDA
Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

Paracetamol: UK Risk Minimization Measures and Their Impact on Self-poisoning
Alison Cave, PhD
Expert Scientific Assessor, Vigilance, and Risk Management of Medicines, MHRA, UK

#412 Track 12: Statistics

9:00 AM – 10:30 AM LEVEL: ■ Format: **SESSION**
Room W181bc *CME, Nursing, and Pharmacy credits offered*

Adaptive Designs for Clinical Trials: Novel Case Studies

CHAIRPERSON

Eva R. Miller, PhD, MS
Director, Biostatistics, ICON Clinical Research

Implementation of adaptive designs is still relatively new and the impact of the draft FDA Guidance is being experienced. Three novel case studies will be shared including study designs, study objectives and endpoints, and benefits.

Designing an Confirmatory Adaptive Study with Multiple Endpoints
Jeff D. Maca, PhD
Senior Associate Director, Biostatistics, Novartis Pharmaceuticals

Novel Adaptive Design of VALOR, a Phase 3 Trial in Patients with First Relapsed or Refractory Acute Myeloid Leukemia
Cyrus R. Mehta, PhD
President, Cytel, Inc.

A Bayesian Adaptive Design for a Dose Ranging Study with Co-primary Efficacy Endpoints
Eunhee Hwang, PhD
Director, Biostatistics - Primary Care, Pfizer Inc

DISCUSSANT

Vladimir Dragalin, PhD
Senior Vice President, Aptiv Solutions

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

9:00 AM – 10:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room W184d *Pharmacy credits offered*

Critical Issues Related to Evidence Generation, Evaluation, and Standards for Comparative Effectiveness Research

CHAIRPERSON

Bryan R. Luce, PhD, MBA
Director, Pragmatic Approaches to Comparative Effectiveness (PACE)

The comparative effectiveness research national agenda in the US poses special challenges in developing, evaluating, and making use of real-world evidence to inform health-care decision making. One challenge is designing efficient and flexible trials, another is making maximum use of observational data, and a third is coming to grips with appropriate evidentiary standards for health-care decisions. This symposium addresses these three challenging issues.

Gaining Efficiency, Flexibility, and Applicability for CER Trials: The READAPT (REsearch in ADAptive Methods for Pragmatic Trials) Study Design
Jack Ishak, PhD
Director, Biostatistics and Data Analysis, United Biosource Corporation

Automated Interpretation of Observational Health Care Data: Challenges and Experiences
Eric C. Brinsfield, MS
Director, Health and Life Sciences R&D, SAS Institute Inc.

Evidentiary Standards for the Use of Comparative Effectiveness Research: The Need for a Balanced and Flexible Approach
Louis Garrison, PhD
Professor and Associate Director, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington

#414 Track 15: Professional Development and Training

9:00 AM – 10:30 AM LEVEL: ■ Format: **SYMPOSIUM**
Room W474a *PMI PDUs offered*

Training: Hot Issues

CHAIRPERSON

Pamela Loughner, PhD, MEd
President, Loughner and Associates Inc.

Savvy training professionals recognize the positive impact that well-designed training can have on an organization. Improved operational efficiency, reduced rework, and enhanced problem solving capabilities are but a few examples. The presentations in this symposium provide divergent examples of training practices that enhance the impact of training on an organization.

English on the Go
Betty R. Kuhnert, PhD, MBA
Executive Director, Training Services, PharmaNet Development Group, Inc.

Training Within an IRB: The Importance of Quality Training Programs for IRB Board Members and IRB Staff
Sydney C. Douglas, MS
Corporate Trainer, Copernicus Group IRB

Knowledge Retention and Transfer
Jay Liebowitz, DrSc
Orkand Endowed Chair in Management and Technology, University of Maryland University College

#415 Track 16: Global Agency

9:00 AM – 10:30 AM LEVEL: ● Format: **FORUM**
Room W187abc

CDER Town Hall: Part 1

CHAIRPERSON

Nancy D. Smith, PhD
ORISE Fellow at FDA; Adjunct Professor, Temple University

Part 2 of this forum will take place on Thursday, June 23 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.

Thomas W. Abrams, MBA, RPh
Director, Division of Drug Marketing, Advertising and Communications (DDMAC), CDER, FDA

Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, CDER, FDA

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

Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Director for International Programs, Office of the Center Director, CDER, FDA

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

10:30 AM – 10:45 AM **REFRESHMENT BREAK**
McCormick West, Lobby Entrance, Level 1

#416 Track 1 (A): Clinical Operations

10:45 AM – 12:15 PM LEVEL: ◆ Format: **SESSION**
Room W175abc *PMI PDUs offered*

Tips on Negotiating a Clinical Trial Agreement and Budget

CHAIRPERSON

Darshan Kulkarni, Esq., JD, PharmD, MS
Principal Attorney, The Kulkarni Law Firm

This session discusses techniques to optimize contract negotiations. While applicable to multiple settings, we will specifically address negotiating clinical trial agreements.

Trial Contract Payment Terms and Their Effects on Cash Flow at the Site
Michael Jay, MA
Vice President, Rx Trials Inc

Advanced Negotiation Considerations for Budgets and Agreements
Darshan Kulkarni, Esq., JD, PharmD, MS
Principal Attorney, The Kulkarni Law Firm

#417 Track 1 (B): Clinical Operations

10:45 AM – 12:15 PM LEVEL: ■ Format: **SESSION**
Room W176abc *CME and Nursing credits offered*

Electronic Patient-reported Outcomes (ePRO): How to Maximize Patient-reported Information for Your Studies

CHAIRPERSON

Jennifer Ross, MEd, MS
Senior Biostatistician, Almac Clinical Technologies

ePRO is becoming more prevalent in clinical trials. Decision making is a critical part in the planning phase and can lead to higher rates of compliance. This session provides guidance in making decisions to optimize patient compliance and the overall patient experience based on speaker expertise and survey data.

Enhancing Subject Compliance: Is Big Brother Watching?
Jay Udani, MD
CEO and Medical Director, Medicus Research

Today's Patient-centric Clinical Trial: How ePRO Technology Improves Retention and Compliance
Judith Teall, RN
Director of Patient Recruitment, Exco InTouch, UK

Which ePRO Technology Do I Choose?
Linda S. Deal, MS
Senior Director, Patient Report Outcomes, Johnson & Johnson PRD

#418 Track 2: Development Planning

10:45 AM – 12:15 PM LEVEL: ■ Format: **SESSION**
Room W179a *PMI PDUs offered*

Quality Risk Management in Clinical Drug Development: A New Approach to De Novo Risk Identification and Proactive De-risking

CHAIRPERSON

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

Quality risk management has wide potential in clinical development, both in regulated and unregulated activities. A prerequisite is reliable prospective risk identification. This session will focus on experience and opportunities with novel approaches to prospective risk identification and management in clinical development.

Proactive Risk Assessment and Mitigation to Optimize Quality in Clinical Trials: Experience with a Pilot Project with FDA
David F. Nickerson, PMP
Global Project Manager, Pfizer Inc

Michael B. Faletto, PhD
Senior Director, Global Regulatory Affairs, Celgene Corporation

Using Prospective, Structured Risk Identification, Assessment and Management Techniques to Optimize Design of Clinical Development Programs, Processes and Infrastructure
Barbara Leishman
Head, Quality Risk Management - Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

#419 Track 3: Outsourcing Strategies and Innovative Partnering Models

10:45 AM – 12:15 PM LEVEL: ■ Format: **SESSION**
Room W178ab

Innovative Measurement and Improvement Techniques for Strategic Partnerships: A Pharma/CRO Collaboration Experience

CHAIRPERSON

Nina H. Spiller
Senior Director, Clinical Operations and Management, Otsuka Pharmaceutical Development and Commercialization Inc.

A pharmaceutical company and a CRO have developed innovative measures and improvement strategies to make their collaboration successful. This session will discuss specific metrics, monitoring, and improvement strategies as well as provide tips to continuously improve collaborations.

Measuring Relationship Integration
Nina H. Spiller
Senior Director, Clinical Operations and Management, Otsuka Pharmaceutical Development and Commercialization Inc.

Measuring Relationship Collaboration
David S. Zuckerman, MS
President, Customized Improvement Strategies LLC

Measuring Relationship Payoff
Paul R. Bunch, PhD
Vice President, Global Project Management, Covance, Inc.

#420 Track 4: Nonclinical and Early Clinical Translational Development

10:45 AM – 12:15 PM LEVEL: ■ Format: **SESSION**
Room W183a

Cytokine Release Syndrome: Past, Present, and Future

CHAIRPERSON

Peter Bugelski, PhD
Senior Research Fellow and Head of Experimental Pathology, Centocor Research & Development Inc.

Cytokine Release Syndrome (CRS) is a serious toxicity of some monoclonal antibodies. Awareness of antibody features that contribute to CRS, appropriate integrated in vitro and in vivo testing, and improved clinical awareness can minimize CRS risks.

History of Drug-induced Cytokine Release Syndrome and Severe Infusion Reactions
Christopher Horvath, DVM, MS
Vice President, Preclinical Sciences, Taligen Therapeutics

Human Cytokine Release with a B-cell Depleting mAb: Defining the Mechanism and Mitigating the Risk
Laura Dill Morton, DVM, PhD
CVM Therapeutic Area Head, Preclinical Safety, Novartis

How to Avoid a Medical Disaster: Doing a FIH with a High-risk Biologic
Diane K. Jorkasky, MD, DrMed, FACP
Consultant in Drug Development

#421 Track 6: Medical Writing and Communication

10:45 AM – 12:15 PM LEVEL: ● Format: **WORKSHOP**
Room W474b *Pharmacy credits offered*

Experiencing the Integration of Authoring, Information Management, and Submission Publishing: Topic-based Structured Content

CHAIRPERSON

Michael Brennan
Director, Informatics, Johnson & Johnson Pharmaceuticals Research & Development, LLC

This workshop will address the shift to topic-based structured content, an effective means of unlocking information value in a dynamic integration of the authoring, metadata tagging, content management, and submission publishing processes.

The attendees will be presented with a series of information mapping challenges designed to expose the patterns of reuse and re-purposed information exhibited in the information maps. During a "poster session" period, facilitators will be positioned at each information map to provide explanation and encourage dialogue and networking as participants walk through.

Due to workshop format, seating will be limited and will be available on a first-come, first-served basis. McCormick Place 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.

Experience in Implementing Topic-based Structured Content
Brooke Hinkson
Associate Director Program Management, Global Biomedical Informatics, Genzyme Corporation

Implementing Topic-based Structured Content in Clinical Documentation
James M. Averback, MS
Partner, Life Science Integration Partners

#422 Track 7: IT Methods and Technologies

10:45 AM – 12:15 PM LEVEL: ■ Format: **SESSION**
Room W470a *CME, Nursing, and Pharmacy credits offered*

Journey to the Cancer Knowledge Cloud: Enabling 21st Century Drug Discovery and Development

CHAIRPERSON

Kenneth H. Buetow, PhD
Associate Director for Biomedical Informatics and Information Technology, National Cancer Institute, National Institutes of Health

The Cancer Knowledge Cloud is a novel informatics-based approach to solving key challenges in biomedicine and health care. In the cloud, all stakeholders have seamless access to tools, data, and computational power so that R&D may be expedited.

Power to the Patients: Engaging Consumers to Achieve 21st Century Biomedicine
Kenneth H. Buetow, PhD
Associate Director for Biomedical Informatics and Information Technology, National Cancer Institute, National Institutes of Health

caBIG® in the Cloud: Hosted Solutions to Enable Personalized Healthcare
William A. Tulskie, MS
CEO, Healthcare IT, Inc.

Network Approaches to Research and Drug Development
Michael King Jolly, PharmD
Senior Vice President, Innovation, Quintiles

#423 Track 8: Research Data and Content Management

10:45 AM – 12:15 PM LEVEL: ■ Format: **SYMPOSIUM**
Room W470b *Pharmacy credits offered*

MedDRA® Coding: Quality Issues and Relationship to CTCAE

CHAIRPERSON

Gwen K. Samuel
Director, Global Medical Encoding, Bristol-Myers Squibb Company

This symposium will focus first on how to achieve quality coding with MedDRA® to promote optimal safety data analysis. Examples of common coding errors will be shown. A second focus will be on the recently revised CTCAE classification and how it relates to MedDRA® based on practical experience from a pharmaceutical company.

MedDRA® Coding Quality: How to Avoid Common Pitfalls
Patricia Mozzicato, MD
Chief Medical Officer, MedDRA® MSSO

FDA Point of View
Sonja Brajovic, MD
Medical Officer, Office of Surveillance and Epidemiology, Office of New Drugs, CDER, FDA

Ensuring Coding Quality
Gwen K. Samuel
Director, Global Medical Encoding, Bristol-Myers Squibb Company

#424 Track 9: Regulatory Affairs and Science, Quality, and GXP Compliance

10:45 AM – 12:15 PM LEVEL: ■ Format: **SESSION**
Room W185d *Pharmacy credits offered*

China-Japan-Korea Joint Research on Ethnic Factors in Clinical Data

CHAIRPERSON

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

China's SFDA, Japan's MHLW/PMDA, and Korea's KFDA have been jointly conducting research on ethnic factors in clinical data in cooperation with the industry. The results, including results of actual PK studies conducted by MHLW, will be presented.

Ethnic Similarities and Differences in Pharmacokinetics of East Asian Populations
Masahiro Tohkin, PhD
Section Chief, Division of Medical Safety Science, National Institute of Health Sciences, Japan

Mee Ryung Ahn, PhD
Deputy Director, Division of Gastroenterology and Metabolism Product, Drug Evaluation, KFDA, Republic of Korea

Wen Chang, PharmD
Vice President, Bristol-Myers Squibb, China

#425 Track 10: Public Policy/Health Care Compliance

10:45 AM – 12:15 PM LEVEL: ■ Format: **SESSION**
Room W180 *Pharmacy credits offered*

How Clinical Trials Can Contribute to Europe's 2020 Agenda

CHAIRPERSON

Angelika Joos, MPharm
Head, Regulatory Policy, EU and Most of World, Merck Sharp & Dohme Inc., Belgium

The regulatory framework for clinical trials is evolving in Europe and a legal revision will be initiated in 2011. How can policy makers use this opportunity to create a research and innovation friendly environment and what needs to be achieved?

Current EU Policy: Environment and Stakeholder Views
Angelika Joos, MPharm
Head, Regulatory Policy, EU and Most of World, Merck Sharp & Dohme Inc., Belgium

Industry Experience and Suggestions for Improvements to Retain R&D Competitiveness
Nick Sykes, MSc
Senior Director, Regulatory Portfolio Lead and EU Regulatory Policy, Pfizer, UK

Preparing the EU Legislative Decision Making and Next Steps
Genevieve Michaux, LLM
Of Counsel, Covington & Burling LLP, Belgium

#426 Track 12: Statistics

10:45 AM – 12:15 PM LEVEL: ■ Format: **SESSION**
Room W181bc *Pharmacy credits offered*

Implementing Adaptive Designs

CHAIRPERSON

Xiaolong Luo, PhD, MBA
Senior Research Fellow, Statistics, Biostatistics and Statistical Programming, Celgene Corporation

This session will focus on the practical issues encountered when implementing adaptive designs. Special consideration will be given to systems and processes that help minimize bias and maintain trial integrity.

Practical Considerations for Adaptive Design Trial Implementations
Weili He, PhD
Associate Director, Merck & Co., Inc.

Implementing Adaptive Designs: Using Technology to Protect Trial Integrity, Reduce Operational Bias, and Build Regulatory Trust
Eric J. Silva
Manager, Enterprise and Hosted Solutions, Cytel, Inc.

DISCUSSANT

Sue-Jane Wang, PhD, MA, MS
Associate Director, Office of Translational Sciences, CDER, FDA

#427 Track 15: Professional Development and Training

10:45 AM – 12:15 PM LEVEL: ● Format: **FORUM**
Room W474a *PMI PDUs credits offered*

"Reportedly" Trained? Uncovering the Industry's Dirty Little Secret Regarding Training Effectiveness

CHAIRPERSON

Kristina R. Spitler
Training Manager, Almac Clinical Services

This forum will explore beyond the "reportedly trained" realm and identify how we can ensure that our employees are really trained. By identifying the common root causes of ineffective training and using innovative techniques for correcting and avoiding them, your organization may be able to avoid becoming the next compliance spectacle. It takes more than a signature to prove employees are trained. Knowing how to evaluate training effectiveness is a key facet to operating in a robust quality environment. The true measure of your organization's training effectiveness is a secret that you cannot afford to keep quiet.

"Reportedly Trained" or Really Trained: What's the Difference?
Kristina R. Spitler
Training Manager, Almac Clinical Services

Perspectives on SOP Training: Is It Time to Change the Way We Think?
Steven Steinbrueck, MPH
President, Stonebridge GCP Consulting Inc.

#428 Track 16: Global Agency

10:45 AM – 12:15 PM LEVEL: ● Format: **FORUM**
Room W187abc

CDER Town Hall: Part 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 23 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.

Thomas W. Abrams, MBA, RPh
Director, Division of Drug Marketing, Advertising and Communications (DDMAC), CDER, FDA

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

Gary M. Gensinger, MBA
Deputy Director, Office of Business Informatics, CDER, FDA

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

Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Director for International Programs, Office of the Center Director, CDER, FDA

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

12:15 PM **ANNUAL MEETING ADJOURNED**

12:30 PM – 5:00 PM **MedDRA® USER GROUP MEETING**
Room W185bc

POSTER PRESENTATIONS

Two professional poster sessions provide an excellent opportunity for the presenters to share their research results with a diverse audience of research professionals. The posters present scientific developments related to topics addressed in DIA 2011 offerings. The posters will be displayed in the Exhibit Hall, Level 3. Professional Poster Session #1 takes place on Tuesday, June 21 from 11:30 AM to 1:30 PM and Professional Poster Session #2 takes place on Wednesday, June 22, from 11:30 AM to 1:30 PM.

Student Poster Session

Monday, June 20, 10:00 AM - 6:30 PM

M 01 **Lawyer Reporting Creates False Data Mining Signals in FDA's Adverse Event Reporting System (AERS)**
Nicholas Schluterman
University of Maryland, Baltimore

M 02 **Meta-analysis of the Efficacy and Safety Data Supporting Marketing Authorization of Anticancer Drugs for Advanced Cancers**
Anne-Sophie Auroux
Eudipharm

M 03 **Comparisons of the Gulf States and Pharmaceutical Companies' Perspective on the Effectiveness of the GCC Centralized Procedure**
Mohammed Al Rubaie
Cardiff University, Welsh College of Pharmacy

M 04 **Selecting Candidates for Randomized Phase II Oncology Trials with a Progression-free Survival (PFS) Endpoint**
Jie Sun
University of Michigan

M 05 **R&D Expenditure Disclosure of Listed Pharmaceutical Companies in China and Its Influencing Factor: An Empirical Study**
Jingjing Liu
University of Macau

M 06 **'P' Drug: Knowledge, Attitude, and Practice Among Undergraduate Medical Students**
Kaushal Sheth
Government Medical College, Bhavnagar

M 07 **The Impact of FDA Priority, Accelerated, and Fast-track Reviews on Approval Times and Postapproval Regulatory Activity**
Gabriel Meister
Temple University

M 08 **Estimating Subject-specific Treatment Differences for Risk-benefit Assessment with Competing Risk Event-time Data**
Brian Claggett
Harvard University

M 09 **Assessment of the Degree of Awareness Among Physicians and Patients About Drug Package Inserts**
Danish Arora
Topiwala National Medical College

M 10 **Multiple Sclerosis and Depression: A Cross-sectional Study Among Medicare Beneficiaries**
Manasi Datar
University of Mississippi

M 11 **Factors that Motivate Volunteers to Consent for Nontherapeutic Studies: Results from a Tertiary Referral Center in India**
Shaunak Kulkarni
Seth G.S. Medical College and K.E.M. Hospital

M 12 **Medication Therapy Management as a Potential Risk Evaluation and Mitigation Strategy: Identifying Benefits and Impediments**
Michelle Pernice
St. John's University

M 13 **The Role of University Global Access Licensing in Increasing Access to Biomedical Innovations**
Andrew York
Universities Allied for Essential Medicines

M 14 **Intention to Provide Drug Information Regarding Behind-the-counter Drug Programs Among Clinical Pharmacy Faculty in the USA**
Digvijay Yeola
University of Houston

M 15 **Evaluation of Barriers to Minority Recruitment and Retention in Clinical Trials: A Qualitative Approach**
Joseph Mburu
Campbell University

M 16 **Optimizing Clinical Trial Operations in Emerging Markets: Latin America and Central and Eastern European (CEE) Countries**
Nikita Somani
Northeastern University

Professional Poster Session #1

Tuesday, June 21, 11:30 AM - 1:30 PM

T 01 **Pioneering Social Media for Use in Oncology Clinical Trials**
Jacqueline Cole, MSc
Clinical Portfolio Consultant, Eli Lilly and Company

T 02 **FDA Approved Drug Labels 2007-10: Dose Adjustments for Women Based on Exposure**
Vanessa Copeland
ORISE Fellow, FDA

T 03 **Integration of CTMS and IVRS Data into EDC to Automate User Accounts, Enrollment, and Key Data Points for Mega Trials**
Arleen Eppinger, MT
Program Manager, Data Management, Duke Clinical Research Institute

T 04 **An Application of Imputation Techniques to Improve Data Availability from Electronic Medical Records**
Alex Exuzides, PhD
Director, ICON Late Phase and Outcomes Research

T 05 **Integrated Technology Solution for Financial and Resource Planning and Forecasting**
Rebecca Greenberg, MA, PMP
Associate Director, Millennium: The Takeda Oncology Company

T 06 **Enhancing Effectiveness and Efficiency of Clinical Trial Monitoring: Implementing a New QA Tool**
Kathleen Bridle
Clinical Research Monitor, Ozmosis Research Inc.

T 07 **Integrating Network and Database Technologies to Support an Imaging Platform for Diagnostic Imaging Central Reviews in Cancer Clinical Trials**
Fran Laurie
Director of Operations, QARC (Quality Assurance Review Center)

T 08 **A Probability Model for Enrollment Projection for a Clinical Trial with Two-step Screening**
Gloria Lin, PhD
Director of Clinical Operations, Essentials Inc

T 09 **Using Electronic Health Record Data to Determine Hypertension Prevalence: A Comparison to NHANES Data**
Jaime Lucove, MPH
Scientist, Allscripts

T 10 **Creating a Novel Patient Reported Outcome (PRO) to Measure Patient Perspective**
Elsie Mathews, MPH
Director, Global Data Operations, Bristol-Myers Squibb

T 11 **Straight from the Patient: What Patients Would Like to Improve in Their Electronic Diary Experience**
Hannah O'Gorman
ePRO Product Manager, Almac Group Ltd

T 12 **Participation of Women and Sex Analyses in Late Phase Clinical Trials of Drugs and Biologics Approved by the FDA in 2007-2009**
Rita Poon
Orise Fellow, FDA

T 13 **Electronic Versus Paper Data Collection of Patient Reported Outcomes: What Do the Patients Think?**
Jennifer Ross, MEd, MS
Senior Biostatistician, Almac Clinical Technologies

T 14 **Failure in Clinical Supplier Quality Management System – Regulatory Impact and Subject Safety Risk**
Eva Ruth, MS
Quality Associate, Baxter HealthCare Corporation

T 15 **Medical Device Safety Monitoring**
Wendy Ye, MD, MPH
Senior Safety Specialist, Novartis-Alcon Labs

T 16 **An Improved Allergy Alert for All Medicines Using OTC Ibuprofen as a Case Example**
R. William Soller, PhD
Executive Director, Center for Consumer Self Care; Professor, School of Pharmacy, University of California San Francisco

T 17 **Portable EDC Solution for Remote Geography Investigator Sites**
Aman Thukral, MPharm
Consultant, Clinical Systems Centre of Excellence, Cognizant Technology Solutions Corporation

T 18 **Prediction of Human Pharmacokinetics of a Novel Anticancer Small Molecule from Preclinical Oxicokinetic Data Using Allometry**
Kevin Trimm, MSc
Manager, Global Statistics and Pharmacokinetics, Charles River Clinical Services

T 19 **Mastering the Clinical Investigation – JHU/CDRH BIMO Internship**
Marci Macpherson, MS
Senior Quality Assurance Auditor, Celgene Corporation

T 20 **Education of Pre-teens by Health Care Providers Closes Knowledge Gaps in the Appropriate Use of Over-the-counter Medicines**
Leona Blustein, PharmD
Medical Affairs Associate, McNeil Consumer Healthcare/ Johnson & Johnson

T 21 **Which Are the Most Important Factors in CRO Selection?**
Margherita Mosconi
Director, Client Project Development, CROMSOURCE

T 22 **IVR and Web System Management of Early Phase Cohort Studies**
Kurt Lumsden
Director, Client Services, Perceptive Informatics

T 23 **Assessment of the Value of Patient Medical Information Services Provided by a Pharmaceutical Company**
Amarita Randhawa, PharmD
Medical Information and Education Resident, Ortho-McNeil Janssen Scientific Affairs, LLC

T 24 **Integration of a Generic Form Review Module within Clinical Trial Management System**
Keith Pauls
Computer Programmer, Medical University of South Carolina

T 25 **Flexible Randomization Scheme: An Application in Independent Blinded Read of Efficacy in Diagnostic Imaging Development**
Gajanan Bhat, PhD
Director of Global Biostatistics, DM, and Medical Writing, Lantheus Medical Imaging Inc.

T 26 **Comparison of Adverse Events Using Proportions**
Chitra Lele, PhD
Chief Scientific Officer, Sciformix Corporation

T 27 **Can We Use Clinical Terms to Describe Symptoms for Labeling Claims?**
Kathryn Lasch, PhD, MA
Director, Patient Reported Outcomes, MAPI Values

T 28 **Detection Tactics and Strategies to Identify Fabricated Data in Clinical Trials Using Digital Analysis**
Sujatha Bonagiri, MS
Associate Statistical Programmer, Quintiles Technologies (India) Private Limited

Professional Poster Session #2

Wednesday, June 22, 11:30 AM - 1:30 PM

W 01 **Inconsistencies of Dosage Measurements on the Internet for Pediatric OTC Liquid Medicines**
Robert Bothwell
McNeil Consumer and Specialty Pharmaceuticals

W 02 **I Was Blind, But Now I See: A Site's Perspective and Lessons Learned**
Patricia Brown
Clinical Administrator/Investigator, CNS Healthcare

W 03 **Effective Travel Reimbursement to Support Oncology Clinical Trial Enrollment**
Nye Pelton
Clinical Portfolio Consultant - Enrollment, Eli Lilly and Company

W 04 **Overview of Biomarker Use in Clinical Trials**
Kunihiko Hayashi, MBA, MSc
Research Fellow, Japan Pharmaceutical Manufacturers Association

W 05 **Feasibility and Implementation of a Centralized Office of Clinical Trials in a Community Hospital**
Suzanne House, PhD, MS
Assistant Director of Clinical Trials, Danbury Hospital

W 06 **Improving the Source Data Verification Process through Data Modeling and Simulation**
DeAnn Hyder
Operational Effectiveness Director, Quintiles

W 07 **Antitrust Law and Patent Prosecution of Investigational Drugs – Paragraph IV Certifications and Walker Process Claims**
Brent Ibata, JD, PhD, MPH, RAC
Site Director, Four Rivers Clinical Research, Inc.

W 08 **A Foundation of Data Standards and a Clinical Data Warehouse to Re-focus Clinical Research Efforts on Value-add Activities**
Sarah Kaulfuss
Manager, Business Analysis, Millennium: The Takeda Oncology Company

W 09 **Two Year REMS Analysis for FDA Approved Drugs and Biologics with a Comparison of US-REMS versus EU-RMP**
Alejandra Muntanola, RPh
Editorial Manager, Regulatory Intelligence, Thomson Reuters

W 10 **Implementation of EDC Solutions to Improve Operation Efficiencies, Data Quality and Minimizing Data Queries in Clinical Trial**
Rajyalakshmi Nimmagadda, MS
Director, Clinical Data Management and Clinical Technology, Corelab Partners Inc

W 11 **Uncommon Labeling in a Common Technical Dossier Environment: How to Make Label Maintenance Commonplace**
Lori Palmer
Principal Consultant, PAREXEL Consulting

W 12 **The Assessment of Raters in an Alzheimer's Study: Experience in Asia**
Qi (Gina) Shen, MD, PhD
Clinician, Clinical Science, Primary Care Business Unit, Pfizer Inc

W 13 **Are Virtual Meetings Between MSLs and Their KOLs a Valuable Alternative to Face-to-face Meetings in Certain Situations?**
Alisha Valdez, PharmD
Manager, Medical Communications, The Medical Affairs Company

W 14 **Mixed Distribution Consideration for Global Trials**
Tohru Uwoi, PhD
Invited Professor, Osaka University

W 15 **Evaluation of Community Pharmacists Drug Information Services in Riyadh City, Saudi Arabia**
Mohamed Al-Arifi, PhD
Assistant Professor, Clinical Pharmacy, Department Director, Drug and Poison Information Center, King Saud University

W 16 **Best Practices for Designing and Implementing Effective Data Capture of Clinical Trial Samples and Associated Data**
Lori Ball, MBA
Chief Operating Officer, Biostorage Technologies, Inc

W 17 **Optimizing the Organization: Migrating Health Economics and Outcomes Research Operations into the Collaborative Science CoE**
Jeannine Benson, MBA
Director, Health Services Research CSCoE, Bristol-Myers Squibb Company

W 18 **Using Service-based Interoperable Clinical Trials Applications to Achieve Continuity of Care**
William Dyer
Clinical Trials Management Systems Representative, NIH

W 19 **Optimal Investigational Sites Deconstructed: Analyzing and Reporting Operational Site Metrics After a Study**
Teresa Flegel, BSN, RN
Associate Clinical Study Manager, Astellas Pharma Global Development, Inc

W 20 **Qualitative Overview of Health Professional Communications by the FDA's Office of Special Health Issues (OSHI)**
Synim Rivers, MPH
Program Analyst, FDA

W 21 **Exploring the Ethnic Sensitive Disposition Pathway from Bridging Evaluation: A 10-year Experience Report from Taiwan**
Chao-Yi Wang, MSc
Senior Specialist, Division of Drug and New Biotechnology Products, Food and Drug Administration, Department of Health, Taiwan

W 22 **Improving Data Collection Methods: Identifying Patients' Reasons for Noncompliance in ePRO Studies**
Graham Nicholls, MS
Director, Biostatistics, Almac Clinical Technologies LLC

W 23 **Protection of Clinical Trial Subjects in India**
Nermeen Varawalla, MD, PhD, MBA
Founder and CEO, ECCRO

W 24 **Intellectual Property Strategies Used by the Innovator Pharmaceutical Industry to Extend the Life Cycle of Drugs**
Enrique Seoane-Vazquez, PhD
Associate Professor, Department of Pharmaceutical Sciences, Massachusetts College of Pharmacy and Health Sciences

TUTORIAL INSTRUCTORS

DIA would like to take this opportunity to thank all of the instructors at DIA 2011's tutorials for their continued support, thorough preparation, and professional presentations. The tutorials took place on Sunday, June 19.

TUT 20 **Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development**
Robert R. Fike, MS, PhD
President, Robert R. Fike & Associates, LLC

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
Vice President, Life Sciences, The Weinberg Group Inc.

TUT 22 **Utilizing Chemistry, Manufacturing, and Controls in Drug Development**
Priya Jambhekar
President, PBS Regulatory Consulting Group Inc.

TUT 23 **Fourteen Steps from Research to Development**
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

TUT 24 **Global Market Access: Essential Knowledge for Clinical Trial Design**
John Brennick, MPA
Worldwide Market Access, Johnson & Johnson

TUT 25 **A Device Primer: 510(k)s, PMAs, IDEs**
Barry S. Sall
Principal Consultant, PAREXEL International Corporation

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, LLC

TUT 32 **Designing, Operating, and Evaluating Patient Registries**
Richard Gliklich, MD
President and CEO, Outcome Sciences Inc.
Leanne Larson, MHA
Vice President, Strategic Development, Outcome

TUT 33 **Hot Topics in Pharmacovigilance in the EU: EudraVigilance Access Policy, International Standardization Work E2B, and Identification of Medicinal Products, Signal Detection, Duplicate Management**
Sabine Brosch, PharmD, PhD
Business Lead, EudraVigilance and International Standardization in PV, European Medicines Agency, European Union
Deborah Yaplee
Senior Program Manager, CBER, FDA

TUT 35 **Early Clinical Studies: An Overview**
Mary L. Westrick, PhD
Executive Director, Global Clinical Pharma and Exploratory Development Operations, Astellas Pharma Global Development
Howard E. Greenberg, MD, MBA, MS
Senior Medical Director, Clinilabs Inc.

TUT 40 **Understanding and Navigating the Regulatory System in China**
Laurence Huang, MS
Regulatory Affairs Director, AstraZeneca, China
Ling Su, PhD
Senior Vice President and Head of Development, Greater China Novartis Pharmaceuticals Corporation
Wendy Yan, PharmD
Director, Global Regulatory Strategist, BSP China, Bayer Healthcare Co. Ltd.

TUT 41 **Advanced CRO-vendor Management: Quality, Performance, and Compliance**
Liz Wool, BSN, RN, CCRA, CMT
President and CEO, QD-Quality and Training Solutions, Inc.
Brianne Martin
Independent Consultant

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

2011 AWARD WINNERS

DIA awards recognize significant individual or group accomplishments in the discovery, development, or life cycle management of pharmaceuticals, devices, or related products, and/or acknowledge significant volunteer contributions in the advancement of DIA's mission and vision.

DISTINGUISHED CAREER AWARD

Dr. Martin Terberger, Germany

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 who 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.

COMMUNITY AWARD

In recognition of an Outstanding Community which fosters the professional growth of their constituents while advancing the mission of DIA.

Electronic Document Management Reference Model Working Group (EDM)

FOUNDERS SERVICE AWARD

The Founders Service Award is named after the group of 30 professionals who founded 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. Having previously received the Outstanding Service Award, this next award level would be given with the highest recognition and appreciation for volunteerism in the DIA organization. It recognizes those individuals who have contributed to the advancement of the mission, vision, and values of DIA and fostered its growth and development through their dedicated and sustained volunteerism.

Sabine Brosch, PharmD, PhD
European Union

Stephen E. Wilson, DrPH, CAPT. USPHS
United States

PRESIDENT'S AWARD FOR OUTSTANDING ACHIEVEMENT IN WORLD HEALTH

This award recognizes the significant, innovative contributions of an individual, group of individuals, or organization to the improvement of world health.

CAPRISA 004 Leadership Team

Qu Willard Cates, Jr., MD, MPH; Arraisha Abdool Karim, PhD; Henry L. Gabelnick, PhD; Carl Montague, PhD, MBA; James F. Rooney, MD; Jeff Spieler, PhD (Hon), MSc

EXCELLENCE IN VOLUNTEER LEADERSHIP AWARD

Teresa Pete Dowling, PharmD, United States

This award is given to recognize the individual who has demonstrated outstanding effective leadership during their dedication and extensive voluntary service to DIA. For 10 years or more, 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 should 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.

DRUG INFORMATION JOURNAL AWARDS

The Donald E. Francke Award: Overall Excellence in Journal Publishing

Sina Djali, MS/MSE
United States

The Thomas W. Teal Award : Excellence in Statistics Publishing

Sue-Jane Wang, PhD
United States

Student Journal Award: Excellence in Publishing by a Student Contributor

Sampada S. Vaidya, MBBS MS
United States

OUTSTANDING SERVICE AWARDS

The DIA Outstanding Service Award is given to recognize those individuals who consistently, through their volunteer efforts, have made contributions to the DIA mission and vision over the past several years. These individuals have exceeded expectations in their volunteer activities with DIA.

Carol H. Danielson, MS, DrPH, RAC
United States

Lisa Mulcahy, BS
United States

Gesine Bejeuhr, PharmD
Germany

Pierre Yves Lastic, PhD
France

Yoshihiko Ono
Japan

Kihito Takahashi, MD, PhD
Japan

Yoshiaki Uyama, PhD
Japan

Lili Cao, MSc
China

SPEAKER INDEX

SPEAKER DISCLOSURE STATEMENTS (as of May 12, 2011)

No Relationship or Conflicts of Interest (Nothing to Disclose)

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Thomas Abrams
Sunita Ahir
Syed Ahmad
Mee Ryung Ahn
Vincent Ahonkhai
John Aitken
Chris Albani
Mary Lou Alter
Peter Alterman
Michael Ambrose
Mark Ammann
Teresa Ancukiewicz
Jonathan Andrus
Zoran Antonijevic
Teruyo Arato
James Averback
Solomon Babani
Lisa Balcerak
David Balderson
Leslie Ball
Regina Ballinger
Cathleen Barrows
Judy Baushke
Gesine Bejeuhr
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Following are the disclosures received by press time, May 12, 2011. Disclosure statements received after this date will be listed on the Final Addendum that is included in the meeting materials distributed on site.

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Paul Schmidt	CONSULTANT – clients of Covington & Burling
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Joe Selby	GRANT SUPPORT – Federal from NIH
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William Sietsema	STOCK SHAREHOLDER – Kendle
Nancy Silliman	OTHER SUPPORT – Employee of Genzyme
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Paula Stafford	OTHER SUPPORT – External Advisory to UNGCH CTSA Grant, STOCK SHAREHOLDER – Quintiles Transnational Holdings

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Alastair Wood	CONSULTANT – Lexicon, OTHER SUPPORT – Symphony Capital LLC, STOCK SHAREHOLDER – OXiGENE
Yan Wu	OTHER SUPPORT – Employee of Biogen Idec, STOCK SHAREHOLDER – Biogen Idec
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Sandra Zeckel	STOCK SHAREHOLDER – Eli Lilly & Company
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The following PIM planners and managers, Jan Hixon, RN, BSN, MA, Trace Hutchison, PharmD, Julia Kimball, RN, BSN, Samantha Mattiucci, PharmD, Jan Schultz, RN, MSN, CCMEP, and Patricia Staples, MSN, NP-C, CCRN hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months.

The following DIA planners and managers, Jennifer Andree-Webb, 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 Merck & Co. and Medco.

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, Charles Depew, PharmD, stock shareholder of GlaxoSmithKline, Teresa P. Dowling, PharmD, stock shareholder of AstraZeneca, Truus Janse-de Hoog, no financial relationships, Monica Kwarcinski, PharmD, employee of Purdue Pharma, and J. Christopher Prue, MBA, RPh, employee of Cerenis Therapeutics.

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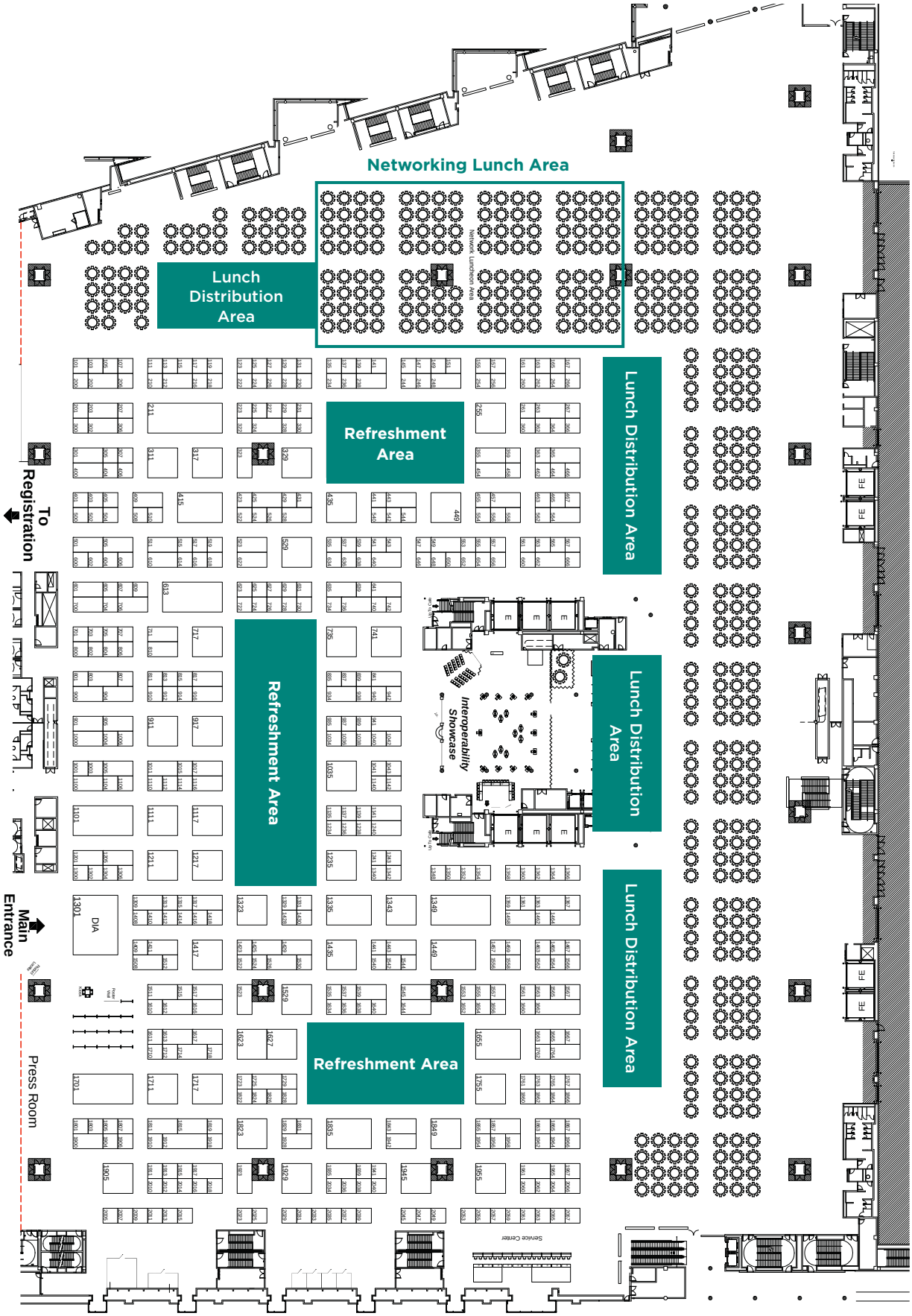

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BioPharm Insight is the leading provider of intelligence to the biotechnology & pharmaceutical industry. We provide: detailed company profiles; listings on investigational & approved drugs; contact info for industry contacts; licensing agreement synopses; product forecasts through 2018; and exclusive editorial intelligence.

bioskin GmbH
Booth 1545

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Booth 1443

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Biotec Services International Limited
Booth 728

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Website: www.biotec-uk.com

Biotec is a pharmaceutical services company specialising in the import, QP certification, labelling, assembly, storage and distribution of Phase I to IV clinical trial supplies through to commercial supplies. In recognition of it's export achievement, in 2009 Biotec were awarded the Queen's Award for Enterprise in the International Trade category.

Blue Chip Patient Recruitment
Booth 1862

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Brand Institute
Booth 726

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Booth 266

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Booth 2014

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Booth 940

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BURG has been translating documents into over 60 languages since 1936. We specialize in translations for the Life Sciences, specifically pharmaceutical, medical device, chemical and bio-tech subject matter. BURG is ISO 9001:2008 and EN 15038:2006 certified, and offers turn-around times as quickly as 24-48 hours, depending on word count.

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C&R Research
Booth 524

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C3i Inc
Booth 1225

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Camargo Pharmaceutical Services
Booth 519

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Booth 561

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Booth 1323

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Booth 2018

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Booth 131

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Booth 1234

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Booth 938

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Booth 646

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Cerner Corporation

Booth 1526

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Chesapeake Research Review, Inc.

Booth 629

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Booth 505

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Cincinnati Children's Research Foundation

Booth 1135

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Phone: 513-636-0314

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Booth 1313

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CITI Program-University of Miami
Booth 467

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ClearTrial
Booth 841

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Booth 254

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ClinAudits specializes in GXP (GCP, GMP and GLP) quality assurance and regulatory compliance audits and consulting services. We conduct domestic and international audits. Our auditors are based in US, Canada, and Europe. We conduct investigator site, CRO, Central Lab, CTS, CSR, CVS, Phase 1, mock FDA, and GMP/GLP audits.

ClinDatrix, Inc.
Booth 1350

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Booth 1805

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Clinical Reference Laboratory, Inc.
Booth 409

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Clinigene International, Ltd. — Booth 1801

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Clinipace Worldwide — Booth 1634

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clinIT AG — Booth 1524

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Clinlogix, LLC — Booth 1326

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ClinTec International — **Booth 1929**
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Clinverse, Inc. — **Booth 302**
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Cmed Group — **Booth 1662**
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CMIC Co., Ltd. — **Booth 317**
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Compass IRB — **Booth 916**
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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.

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Contract Pharma — **Booth 227**
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Copernicus Group IRB — Booth 740

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CoreLab Partners Inc — Booth 1035

Contact: Kevin Duffy
Phone: 609 936 2600
E-mail: kduffy@corelabpartners.com
Website: www.corelabpartners.com

CoreLab Partners is a leading independent core lab providing centralized cardiac safety & efficacy services & advanced medical image assessment solutions. With experience supporting 650+ clinical trials, and more oncology studies than any ICL, our clients are global pharmaceutical, biotechnology and medical device sponsors of Phase I-IV studies.

Corporate Translations — Booth 1005

Contact: Ted Gawlicki
Phone: 860-727-6000
E-mail: tgawlicki@corptransinc.com
Website: www.corptransinc.com

Corporate Translations is an ISO9001:2008 and EN15038 certified and trusted provider of translation and linguistic validation solutions to the world's top life science companies. Our proven methodology and expertise in this highly regulated industry make us well qualified to translate and format documents throughout the entire lifecycle of a drug.

CORRONA, Inc. — Booth 1352

Contact: James Cavan
E-mail: JCavan@corrona.org
Website: www.corrona.org

CORRONA's mission is to advance rheumatology research and improve the quality of patient care. CORRONA is an independent observational disease registry gathering data in the US, Eastern Europe, India and Latin America. It is run by experienced academic and clinical rheumatologists working with an established network of clinical sites.

Court Square Group, Inc. — Booth 1354

Contact: Keith Parent, CEO
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E-mail: sales@courtsquaregroup.com
Website: www.courtsquaregroup.com

CSG is a professional consultancy specializing in the needs of FDA regulated companies, including IT planning, network, security and project management. CSG has expertise in business process optimization, auditing and quality (including validation), clinical data services, application development, and provides secure hosted and managed systems.

Covance Inc. — Booth 741

Phone: 1-888-COVANCE +1-888-268-2623-
E-mail: info@covance.com
Website: www.covance.com

Covance, with headquarters in Princeton, NJ, is one of the world's largest & most comprehensive drug development services companies, with annual revenues greater than $1.8 billion and more than 10,000 employees in more than 55 countries.

CPC Clinical Trial Hospital, Medipolis Medical Research Institute — Booth 228

Contact: Robert Phillips
Phone: + 81 0- 99 259 5243
E-mail: robert@cpc-jp.com
Website: www.cpc-jp.com

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CRF Health — Booth 1100

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E-mail: info@crfhealth.com
Website: www.crfhealth.com

CRF Health is a leading global provider of electronic Patient Reported Outcomes (ePRO) solutions for the Life Sciences industry. At CRF Health our goal is to help bring new drugs to market, quickly, cost effectively, and safely through the electronic collection of patient reported data.

CRI Worldwide & Lifetree Clinical Research — Booth 1815

Contact: Lawrence Brownstein or Alice Jackson
Phone: +1-856-533-5024 or +1-801-269-9415 Ext- 331
E-mail: cri@criww.com or alicej@lifetreeresearch.com
Website: CRIWW.com and lifetreeresearch.com

CRI Worldwide and Lifetree Clinical Research provide high quality clinical research services. The recent combination enriches the early stage clinical research landscape for clients, enabling them to tap into CRI's leadership in Psychiatry and patient population trials, as well as Lifetree's expertise in Pain Management and Human Abuse Liability.

Cromos Pharma, LLC — Booth 155

Contact: Vladimir Bogin, MD
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E-mail: vbogin@cromospharma.com
Website: www.cromospharma.com

Cromos Pharma is a CRO that specializes in clinical outsourcing to Russia and EE. Cromos is part of a 3C Alliance. Our partners are Clinical Trial Support–service provider in customs clearance and legal support, and Clinical Research Solutions–a depot and courier service. Alliance provides an all-inclusive service to Pharma operating in Russia.

CROMSOURCE — Booth 431

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E-mail: margherita.mosconi@cromgroup.com
Website: www.cromsource.com

CROMSOURCE is an international full service CRO offering clinical research services and staffing solutions to pharmaceutical and medical devices industries, with more than 18 years experience. CROMSOURCE (ISO certified) provides high quality services with unparalleled innovation and flexibility. CROMSOURCE means "Expertise you can rely on..."

CROS NT — Booth 701

Contact: Gudrun Skiba
E-mail: gudrun.skiba@crosnt.com

CROS NT Group is a CRO providing quality services in all phases of clinical development. CROS highly qualified professionals have expertise in many therapeutic areas with special focus on Oncology and Respiratory, completing more than 800 quality clinical trials. The CROS NT IT branch, ARITHMOS, provides technology solutions for clinical projects.

CRS - Clinical Research Services — Booth 145

Contact: Dr. David Surjo
Phone: +49 2632 99 27 84
E-mail: david.surjo@crs-group.de
Website: www.crs-group.de

CRS Clinical Research Services – your full service partner in Clinical Development Phase I-IV with its Human Pharmacology Infrastructure of 186 bed in 3 clinics, GLP-certified Bioanalytics, GMP-certified Pharmacy, Project Management, Monitoring, Biostatistics, Datamanagement, QA, Medical Writing and Non-interventional studies.

CTI Clinical Trial and Consulting Services — Booth 601

Contact: Nick Schatzman
Phone: 513-598-9290
E-mail: nschatzman@ctifacts.com
Website: www.ctifacts.com

CTI is a fully integrated specialty CRO that provides services to clients developing therapies for End-Stage Organ Disease, Solid Organ Transplant, Immunology, Metabolic Diseases and Hematology/Oncology. Operationally, CTI has validated systems and processes that allow us to achieve and maintain high standards in trial execution.

Cu-Tech, L.L.C. — Booth 1644

Contact: Kathleen Ashenfelter or Anna Majeranowski
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E-mail: kashenfelter@cu-tech.com
Website: www.cu-tech.com

Cu-Tech is a full service CRO offering a complete array of services to the client from the inception of a project. Cu-Tech professionals specialize in Dermatology clinical trial management and monitoring. We maintain an extensive database of the finest dermatologists in the US and abroad. Our clients can attest to our personal hands-on approach.

Cytel Inc. — Booth 323

Contact: Steve Herbert, VP Business Development
Phone: 617-661,2011
E-mail: info@cytel.com
Website: www.cytel.com

Cytel Inc. is a trusted provider of clinical research services, trial design and anlalysis technology. Pioneers in adaptive design and implementation, each of the top 25 biopharmaceutical firms use Cytel technology to plan and supoort their clinical studies.

d-Wise Technologies — Booth 107

Contact: Bud Whitmeyer
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E-mail: bwhitmeyer@d-wise.com
Website: www.d-wise.com

d-Wise Technologies is a technology and software consulting company focused on delivering technology strategy, integrated clinical systems, and data standards implementation across the Life Sciences industry. d-Wise has experience in a wide range of technologies including both commercial and open source solutions.

DAC Patient Recruitment Services — Booth 1941

Contact: David Berger
Phone: 800-466-1774
E-mail: dberger@dandersoncompany.com
Website: www.DACprs.com

With experience in more than 66 countries and 40 indications, DAC Patient Recruitment Services develops patient recruitment and retention campaigns for global clinical trials. Core competencies include site selection, patient recruitment and retention, creative services and clinical staff training.

DataCeutics, Inc. — Booth 1001

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Website: www.dataceutics.com

DataCeutics is a leading Functional Service Provider and Outsourcing Partner to the Life Sciences Industry. We forge strategic partnerships with clients that outsource Statistical Computing, Clinical Data Management and Compliance/Validation functions. The relationships we build are predicated upon our commitment to becoming a “Partner of Choice”.

Datapharm Australia — Booth 1467

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E-mail: helenallars@datapharm.com.au
Website: datapharmaustralia.com

Private full service CRO est. 1987, Australian based with many solutions to assist product development through clinical trial processes. Experienced highly qualified in-house teams of monitors,data managers,programmers, statisticians,and medical writers. Experience in auditing CROs/sites across South East Asia. Ask about our networked “effice”.

DATATRAK International — Booth 735

Contact: Lisa Pahl
Phone: +1-440-443-0082
E-mail: marketing@datatrak.net
Website: www.datatrak.net

DATATRAK International is a global technology and services provider of clinical enterprise solutions for the clinical trials industry. Our single vision for product and service delivery, DATATRAK ONE™, provides increased patient safety, process efficiencies, real-time data access, reduced costs and a unified user experience.

Datatrial Limited — Booth 1638

Contact: Julie Wright
Phone: +44 0- 191 226 3500
E-mail: julie.wright@datatrial.com

Datatrial is an oncology-focused boutique clinical data organization that provides the reliability of a big company, but the personalized service and flexibility of a more nimble provider. We design your study with insight and expertise, backed by comprehensive data management, bio-statistical and consulting services.

DaVita Clinical Research — Booth 1517

Contact: Business Development
Phone: 888- 345-2567
E-mail: contactdcr@davita.com
Website: www.davitaclinicalresearch.com

No company offers a greater depth of knowledge in renal research and clinical development than DaVita Clinical Research (DCR). Our relationship with physicians, medical groups, and dialysis centers nationwide gives us seamless access to over 115,000 renal and specialty patients, allowing DCR to quickly fill and conduct Phase I-IV trials.

Delmar Chemicals
Booth 1913

Contact: John Brady, Greg Bydlinski
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E-mail: delmar@delmarchem.com
Website: www.delmarchem.com

Delmar specializes in process R&D and cGMP custom synthesis of APIs and intermediates. Delmar can also perform process development and validation, analytical method development and validation, and stability studies. Manufacturing capabilities include laboratory scale, pilot plant and commercial-scale production.

Delta Pharma, a Randstad company
Booth 817

Contact: Megan Arsmtrong
Phone: 847-757-1080
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Delve
Booth 1762

Contact: Kay L. Savio
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Website: www.delve.com

Delve is a full service data collection company for market research that supports qualitative, quantitative and clinical methodologies. Delve stands out among other data collection companies through our ability to act as a CRO, SMO, quality recruitment of patients & project management. Delve has 10 state of the art facilities across the country.

DiagnoSearch Life Sciences, Inc.
Booth 2005

Contact: Jennifer Gidley
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Website: diagnosearch.com

DiagnoSearch is a full service CRO with headquarters in India with 14+ years of Phase I-IV experience across a broad therapeutic spectrum, having supported 135+ clinical trials, passed 160+ CQA audits with 135 professionals across Clinical Operations, Data Management, Biostatistics, CAP Accredited Central Laboratory, Pharmacovigilance & Consulting.

Doctor Evidence
Booth 216

Contact: Jim Langford
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Website: www.doctorevidence.com

Doctor Evidence is the leader in the development of digital software technologies and services that find/store/translate and deliver evidence from clinical studies to Life Science organizations. Our solutions allow you to differentiate your products with evidence and identify effectiveness gaps with study endpoint meta-analysis simulations.

DOKUMEDS CRO
Booth 161

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Website: www.dokumeds.com

DOKUMEDS is a European CRO providing a comprehensive range of services to more than 80 clients in pharma, biotechnology and medical device industry worldwide.

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Dow Pharmaceutical Sciences
Booth 616

Contact: Patty Irving
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Dr. Ebeling & Assoc. GmbH
Booth 454

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DreamCIS, Inc.
Booth 604

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Website: www.dreamcis.com

DreamCIS is Korea-based CRO with subdivisions in CR, PV&PMS and Data Management.

In the history of advancement in research environment in Korea, we have been there all along, contributing significantly to the progress. Now, we are the representing CRO of Korea and we have partnership with overseas affiliate in China, Japan, India and many more.

Drug Safety Alliance, Inc.
Booth 736

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Website: DrugSafetyAlliance.com

DSA provides PV expertise to pharmaceutical and biotechnology companies to ensure patient safety. DSA is uniquely focused to provide high-quality pre & post-market drug safety services including adverse event case management, risk management, global regulatory compliance, & IT professional services. DSA is a privately held, woman-owned business.

DrugLogic, Inc.
Booth 937

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For over 10 years, DrugLogic has been dedicated to developing tools and providing analytic expertise to the pharmaceutical industry to support their requirements for risk management, drug safety surveillance and pharmacovigilance. Today, our clients included more than 30 global pharmaceutical companies and research organizations.

DSG, Inc.
Booth 1129

Contact: Jack Minster
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E-mail: jminster@dsg-us.com
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Contact: Pam Lazor
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Phone: 315-689-3407

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Duke Clinical Research Institute — Booth 1523

Contact: Suzanne Pfeifer
E-mail: help@dcri.duke.edu
Website: www.dcri.org
Phone: 919-668-8700 or 877-693-DUKE

The Duke Clinical Research Institute (DCRI) offers the full-service operational capabilities of a major contract research organization combined with clinical expertise, academic leadership, and business acumen that translates into sound research results. The DCRI... From Thought Leadership to Clinical Practice.

DZS Software Solutions-Clinplus — Booth 1544

Contact: Patrick Champoux
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DZS Software Solutions (www.clinplus) provides clinical trials software for data management, analysis, reporting and trial

management to Life Science clients worldwide. DZS Solutions improve productivity, maximize the value of clinical research investments, gain client competitive advantage and get medicines and products to market faster.

EastHORN Clinical Services in CEE — Booth 1636

Phone: +420 244 462 241
E-mail: info@easthorn.eu

EastHORN (Health Outcomes Research Network) Clinical Services in CEE is a full-service CRO that offers high-value Phases I through IV clinical trial capabilities in Central and Eastern Europe. EastHORN consistently achieves the last-patient-out milestone within the proposed budget and schedule. We are the ideal regionally-focused CRO.

eClinical Solutions, a division of Eliassen Group — Booth 1000

Contact: Jeff Jolin
E-mail: jjolin@eliassen.com
Phone: 781-205-8157

eClinical Solutions, a division of Eliassen Group, takes a strategic approach to managing clinical trial data by combining data management with statistical programming, reporting and customized training solutions integrated with a clinical data repository to deliver a complete end-to-end data management solution.

ECLINSO — Booth 1710

Contact: Howard Goldberg, Pharm.D.
E-mail: goldbergh@eclinso.com
Website: www.eclinso.com
Phone: 201-372-1465

ECLINSO is an innovative provider of Clinical Technology solutions and support services to enhance the conduct of clinical trials. ECLINSO provides Managed IT services, Software as a Service, Electronic Document Management, Regulatory Solutions and Services, Electronic Data Capture, 24 Hour Support Services and Professional and Consulting Services.

Ecron Acunova GmbH — Booth 547

Contact: Dr. Klaus D Wiedey
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Website: www.ecronacunova.com
Phone: +49 69 6680300

Ecron Acunova (EA) is a full-service expert CRO with 24 years of track record, offering phase I-IV clinical research to pharma, biotech, device and diagnostic companies. EA covers more than 25 countries and operates each region as a priority market with Asian-Pacific HQ at Bangalore (IN), European HQ at Frankfurt (DE) and US HQ at Princeton.

EDETEK, Inc. — Booth 1236

Contact: Edward Bailey
E-mail: info@edetek.com
Website: www.edetek.com
Phone: 1-609-720-0888 Ext-305

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Elite Research Network — Booth 1205

Contact: Chris Hoyle
E-mail: choyle@eliteresearchnetwork.com
Website: www.eliteresearchnetwork.com
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Elite Research Network is a network of independently owned investigator sites located throughout the US and Latin America which conduct clinical research in all therapeutic areas from Phase I - IV. Each of our sites has a dedicated research staff and ability to use central IRB.

EMB Statistical Solutions, LLC — Booth 631

Contact: Brenda Bishop
E-mail: BBishop@EMBStats.com
Website: www.EMBStats.com
Phone: 913-322-6555

EMB is a CRO specializing in the Data Management and Statistical Analysis/Reporting of clinical research data. EMB was formed in 2000 with a dedicated team of senior level associates each with over 10 years of industry experience and a proven track record of success. EMB is associate owned, has had ZERO turnover, and is "Powered by Experience".

EMC — Booth 638

Contact: Jon Louis
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Phone: +1.508.249.6170

EMC Consulting is a part of EMC Corporation, the world's leading developer and provider of information infrastructure technology and solutions. We provide strategic guidance and technology expertise to help organizations exploit information to its maximum potential. EMC Consulting drives execution for its Global Fortune 500 clients.

Emphusion — Booth 614

Contact: Heidi Hudson
E-mail: heidi.hudson@emphusion.com
Website: www.emphusion.com

Emphusion provides expertise in the execution and delivery of clinical trial services; such as project management, clinical monitoring, data management, biometrics, programming, medical writing, and safety/pharmacovigilance. Our proprietary EDC focuses on intuitive data collection, rapid deployment (6 weeks build time), and real-time data outputs.

Endpoint Clinical Inc.
Booth 542

Contact: Phu Phan
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E-mail: phu.t.phan@gmail.com

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Booth 307

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ePharmaSolutions
Booth 1112

Contact: Mary Yakulis
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E-mail: myakulis@epharmasolutions.com
Website: www.epharmasolutions.com

ePharmaSolutions is a clinical services provider that helps the top 20 pharmaceutical companies in the world accelerate and improve their clinical studies. Our technology-enhanced solutions have supported the qualification and activation of more than 200,000 clinical researchers in 120 countries.

EPS Co., Ltd.
Booth 700

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EPS is a CRO established in 1991 with more than 3,000 group employees that provides a full range of clinical development services in Japan, China and Southeast Asia for new drugs and medical devices. EPS also has SMO, CSO, IT solution and staffing arms to provide support throughout the clinical as well as business development in Asia.

ERT, Inc.
Booth 1335

Contact: John Blakeley
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E-mail: eresearch@ert.com
Website: www.ert.com

ERT is the leading provider of cardiac safety, respiratory & multi-mode ePRO solutions to the global biopharm industry. ERT harnesses internet & telecom technology & services to streamline the clinical trials process by enabling its customers to automate the collection, analysis & distribution of data in all phases of clinical development.

Esoterix Clinical Trials Services
Booth 1811

Contact: Shailesh Maingi
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Website: www.esoterixtrials.com

Esoterix Clinical Trials Services, a LabCorp division, combines international laboratory capabilities with sophisticated diagnostic technologies to provide a broad portfolio of clinical assays to support drug and diagnostic clinical studies. Our dedicated scientific team provides extensive support for protocol design and custom assay development.

Ethicare Clinical Trial Services
Booth 455

Contact: +919825585119
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E-mail: milansatia@ethicare-cro.com
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Ethicare Clinical Trial Services providing end to end clinical development services (Phase I-IV) to global pharmaceutical and biopharmaceutical companies. We offer reliable, high quality clinical services at affordable prices. Choosing Ethicare implies collaborating with a professional and experienced team within a competent framework.

EtQ, Inc.
Booth 1956

Contact: Angela Lodico
Phone: 516-293-0949
E-mail: alodico@etq.com
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EtQ's FDA Compliance Management software is an integrated quality management and FDA compliance management software system that has been designed to maintain compliance to various regulatory requirements and adapt to business processes. Key modules include MedWatch Plus, Compliant Handling, CAPA, Document Control, Change Management and more.

European Medicines Agency
Booth 1409

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E-mail: beatrice.fayl@ema.europa.eu
Website: www.ema.europa.eu

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by member states for the evaluation, supervision, and pharmacovigilance of medicinal products.

Eurotrials
Booth 1954

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E-mail: mj.madeira@eurotrials.pt
Website: www.eurotrials.com

Eurotrials is a private independent company founded in 1995, Lisbon, providing CRO services in R&D and general consulting in the Health sector in Europe and Latin America. Eurotrials is in Brazil since 2001 from where is currently expanding activities to other countries as Argentina and Chile. We are small enough to care and big enough to deliver!

Exco InTouch Ltd
Booth 1429

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Exco InTouch is the leading provider of interactive mobile communication solutions for Patient Recruitment, Retention, Compliance, ePRO/eDiary and Post Marketing Studies. Using a combination of software and services, Exco InTouch enables sponsors, CRO's and patient recruitment agencies to maintain patient engagement throughout the clinical process.

ExecuPharm, Inc
Booth 300

Contact: Penny Johnson
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E-mail: pjohnson@execupharm.com
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ExL Pharma — Booth 328

Contact: Michael Goldberg
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Experis Clinical Practive — Booth 1458

Contact: Jim Balcom
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E-mail: jim.balcom@experis.com
Website: www.experis.com

Experis Clinical Practice (formerly COMSYS Clinical) is a leading provider of Data Management, Clinical Programming, Biostatistics, Medical Writing and Translation services. Since 1982, we have been providing our Pharmaceutical, Biotechnology, CRO and Medical Device clients with strategic solutions that help them to improve their clinical trial process while reducing costs.

Explorys, Inc. — Booth 1961

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Website: www.explorys.net

Formed in conjunction with Cleveland Clinic and several major integrated health systems, Explorys has quickly become one of the largest EHR-based clinical outcomes datasets in US. With billions of events already online, we power the next generation of life sciences R&D, comparative effectiveness, performance management, and treatment safety.

EXTEDO — Booth 900

Contact: Ellie Stone
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EXTEDO is the key solutions and services provider in the field of eRegulatory Affairs.The complete EXTEDOsuite covers Product Registration Planning & Tracking, Submission Management, Labeling Management and Document Management. We provide configurable Off-the-Shelf products, as well as customized and integrated solutions.

Falcon Consulting Group, LLC — Booth 218

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Falcon offers specialized consultancy and evaluation perspectives related to regulatory compliance and clinical QA for research and development with a focus on Good Clinical Practice to minimize regulatory risk. Falcon offers (but not limited to) Clinical QA Auditing Support Services, Global GCP and Virtual QA Services, and Inspection Readiness.

Fast4wD Ogilvy — Booth 522

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FDA - Center for Biologics Evaluation and Research — Booth 1410

Contact: Office of Communication, Outreach and Development
Phone: 301-827-2000
E-mail: ocod@fda.hhs.gov
Website: www.fda.com

Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration's (FDA) - a U.S. government agency that regulates biological products such as vaccines, blood, blood products, allergenics, cells, tissues, and gene therapy products for human use. Knowledgeable staff provides information on the regulation of biological products.

FDA/CDER — Booth 1408

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Website: www.fda.gov

The FDA's Center for Drug Evaluation and Research (CDER) makes sure that safe and effective drugs are available to improve the health of the American people. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks.

Firecrest Clinical — Booth 501

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FORENAP — Booth 463

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FORENAP is the CNS CRO offering consulting services, preclinical research services, phase I studies in our 72 beds centre, Proof of principle and Proof of Concept studies for early Go/No Go, phase II/III as well as phase IB studies in patients with CNS/pain disorders as well as new solutions for portable pharmacodynamic tools worldwide.

Foresight Group International AG — Booth 210

Contact: Joe Rymsza
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Foresight Group is a global provider of drug safety & risk management services. Services for Argus Safety, Empirca, AERS & ARISg include system installation & configuration, upgrades, data migration, custom report development, validation. We also provide PV business process design/improvement/remediation, SOP, signal management & REMS services.

Forest Laboratories Inc. — Booth 802

Contact: Robert Azzara Sr. Human Resources Manager, Talent Acquisition
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Website: www.frx.com

Forest Laboratories (www.frx.com) develops and markets pharmaceutical products that make a positive difference in people's lives. In addition to our franchises in the central nervous and cardiovascular systems therapeutic areas, our current pipeline includes product candidates in all stages of development, across a wide range of therapeutic areas.

Forma Life Science Marketing — Booth 1362

Contact: Lilly Ferrick
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Website: www.formalifesciencemarketing.com

Forma is the leading marketing firm for life science, biotech and pharma companies. We distill and communicate complicated messages to sophisticated audiences.

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Contact: Sharon Forrester
Phone: 781 685 4995
E-mail: wecanhelp@formedix.com
Website: www.formedix.com

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Fortis Clinical Research Limited (FCRL) — Booth 2016

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E-mail: shruti.shukla@fortis-cro.com
Website: www.fortis-cro.com

FCRL is a full service CRO in India, having 78 bedded CPU (DCGI, ANVISA, AFSSAPS, FDA approved), Bio Analytical Laboratory, Phase II–IV Clinical Trial Management expertise, 56 Fortis hospitals across India, and NABL and CAP Accredited Central Labs to cater to the entire needs of providing full service to pharmaceutical and biotechnology companies.

Foundation for Biomedical Research — Booth 565

Contact: Paul McKellips
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Website: www.fbresearch.org

Established in 1981, the Foundation for Biomedical Research (FBR) is the nation's oldest and largest organization dedicated to improving human and veterinary health by promoting public understanding and support for humane and responsible animal research.

Frontage Laboratories — Booth 2010

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Frontage is a dynamic contract research, development & manufacturing organization, offering a full range of pharmaceutical R&D services. As a rapidly expanding global CRO with a ten-year successful history of its high quality GXP services, Frontage has established an int'l standard in pharmaceutical product research, quality & management systems.

Fujitsu Limited — Booth 564

Contact: Hajime Kosuge
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Future Science Group — Booth 554

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Website: www.future-science-group.com

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GE Healthcare — Booth 1860

Contact: Tracy Reszczynski
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Contact: Jim DeMaso
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Phone:
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Global Language Solutions is an ISO 9001:2008 and EN 15038 certified translation and interpreting company specializing in pharmaceutical, biotechnology, and medical device translations in over 100 languages. Our medical linguists have experience translating IFUs, ICFs, patents, manuals, packaging and labels, and websites. GLS is a certified WBE.

Global Vision Inc — Booth 364

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E-mail: info@globalvisioninc.com
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GlobalCare Clinical Trials, Ltd — Booth 115

Contact: Gail Adinamis
Phone: +1 847-282-3270
E-mail: info@globalcarect.com
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Green Key Resources, LLC — Booth 225

Contact: Deloris Jones
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E-mail: djones@greenkeyllc.com
Website: www.greenkeypharma.com

Green Key Resources is one of the fastest growing professional recruitment firms offering a complete portfolio of staffing solutions, including temporary and contract staffing, executive search, and payroll services to leading Pharmaceutical, Biotechnology, Medical Device, and CRO companies nationwide.

Greenphire, LLC — Booth 231

Contact: Samuel Whitaker
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Website: www.greenphire.com

Greenphire provides electronic payment and messaging solutions for use in clinical research. Solutions are designed to manage subject payments through the ClinCard System, global investigator payments through the ClinicalGPS solution and study specific electronic messaging programs through its Subject Messaging System. Visit us at booth 231.

Greenway Medical Technologies — Booth 656

Contact: Laura Mendenhall
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E-mail: info@greenwaymedical.com
Website: www.greenwaymedical.com

Greenway Medical Technologies' PrimeResearch Network leverages Greenway's award-winning and certified Electronic Health Record (EHR) - to ease feasibility, increase recruitment, simplify data collection and provide remote monitoring - a smarter way to achieve research.

H&J CRO International, Inc — Booth 666

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HCL Technologies Ltd — Booth TBD

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HCRAmerica is a division of Harrison Clinical Research Group GmbH, an international CRO with offices throughout Europe, the USA and in Israel, offering you a full service solution for your clinical research projects, both globally and locally. Our services range from Phase I-IV including our Phase I/IIa clinic in Munich, Germany.

Health Canada - Health Products and Food Branch — Booth 1412

Website: www.hc-sc.gc.ca

HPFB is the Canadian federal authority responsible for the regulation of health products and food. HPFB takes an integrated life-cycle approach to maximize the safety, quality and effectiveness of products and to assess, manage and communicate health-related risks and benefits, so that Canadians can make informed decisions about their health.

Health Decisions — Booth 523

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E-mail: adaptive@healthdec.com
Website: www.healthdec.com

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Healthcare Communications Group — Booth 904

Contact: Linda Kilpatrick
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HHS Supply Service Center — Booth 1915

Contact: Trisha Futty
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Website: sscweb.psc.gov

The HHS Supply Service Center is an operating division of the Department of Health and Human Services offering pharmaceuticals, medical supplies, logistical support and clinical trial services to other government facilities in the U.S. and throughout the world.

Hoffmann-La Roche
Booth 1361

HRP Consulting Group, Inc.
Booth 1462

Contact: Nicholas Slack
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i3
Booth 640

iCardiac Technologies
Booth 1537

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ICON Clinical Research plc
Booth 1211

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ICON is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. We specialize in the strategic development, management and analysis of programs that support Clinical Development- from compound selection to Phase I-IV clinical studies.

Idem Translations, Inc.
Booth 1428

Contact: Nancy Kellen
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INC Research
Booth 1217

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Inclinix, Inc.
Booth 1904

Contact: Kristin Sacre
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INNOPHARMA S.r.L.
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Integrated Clinical Systems, Inc — Booth 941

Contact: Eric S Herbel
Phone: 908-996-3312
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Integrated Clinical Systems - developers of Integrated Review(tm) and JReview(r) the fastest and easiest way to review, graph, visualize, report, analyze, do patient profiles and patient narratives for your clinical data. Works with OC,Clintrial,SAS datasets, Oracle LSH, SAS DD, Waban CDR, Rave, Inform, etc.

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Intermountain Clinical Research — Booth 1553

Contact: Jill Hemsley
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International Dermatology Research, Inc. — Booth 707

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Website: www.intldermresearch.com

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Italian Medicines Agency - AIFA — Booth 1411

Contact: Carlo Tomino
E-mail: c.tomino@aifa.gov.it
Website: www.agenziafarmaco.it

The Italian Medicines Agency (AIFA) is the national authority responsible for drug regulation in Italy. The Agency is competent for: marketing authorisation of medicinal products; pharmacovigilance; clinical trials; inspections of products and manufacturing process; independent information; price and reimbursement.

J&S Studies, Inc. — Booth 618

Contact: Jeremy Scott
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JANIX CRO — Booth 1558

Contact: Sara Rainie
E-mail: janixbd@janix.com
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JCL Bioassay USA, Inc — Booth 1565

Contact: Jamie Klonowski
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Contact: Ray Barber
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Joulé Clinical Staffing Solutions — Booth 939

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Jubilant Clinsys — Booth 324

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The Kansas Bioscience Authority is a $581 million investment fund that is advancing Kansas' national bioscience leadership by building world-class research capacity; fostering the formation and growth of bioscience start-ups; supporting expansion of the state's bioscience clusters; and facilitating industrial expansion and attraction.

Kaplan EduNeering — Booth 224

Contact: Ellen Leinfuss
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Kayentis — Booth 322

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Kelly Scientific Resources — Booth 1563

Contact: Diane Barker, Director, Americas Product Group
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Kforce Clinical Research — Booth 449

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Klein Hersh International — Booth 403

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Korea National Enterprise for Clinical Trials (KoNECT) — Booth 1418

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As a government funded organization responsible for expanding infrastructure of clinical trials in Korea, KoNECT manages regional clinical trial centers, operates clinical trials training academy and provides clinical trial technology development programs. KoNECT is leading the way in promoting Korea as the global hub of clinical trials.

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LabConnect, LLC — Booth 641

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Laboratorio Hidalgo S.A. — Booth 1556

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E-mail: fabiola.santelli@laboratoriohidalgo.com
Website: www.laboratoriohidalgo.com

Located in Buenos Aires, Argentina, Laboratorio Hidalgo provides Clinical Laboratory Services related to the development of Clinical Trials in South America: reliable results and an effective logistics. The group is dedicated to meet the ever-changing demands of today's market.

Langland — Booth 1036

Contact: Sara Fragata
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Website: www.langland.co.uk/

Langland is a leading full-service advertising agency, providing global programs that accelerate recruitment and aid retention of patients for clinical trials. Langland is the world's most creatively awarded healthcare agency and ranked number one by the IPA. Our expertise has made a difference to the success of over 100 clinical trials.

Lernia Training Solutions — Booth 558

Contact: Jill Huentelman
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E-mail: huentej@lernia-ts.com
Website: www.lernia-ts.com/

Founded in 2000, Lernia Training Solutions specializes in the creation, delivery and management of training for the life sciences industry. We design customized training programs for companies of all sizes in order to meet regulatory requirements and equip employees with the working knowledge of the subject matter at hand.

Libra Medical — Booth 101

Contact: David Blaeser
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Website: www.LibraMed.com

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Lionbridge Life Sciences — Booth 1725

Contact: Kaarin Gordon
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Website: www.lionbridge.com/lifesciences

Lionbridge LS helps the leading Pharmaceuticals, Biotech, Medical Devices and Healthcare organizations achieve their globalization objectives with flexible, integrated localization solutions and application development capabilities delivered on a global scale. Lionbridge Life Sciences is also your dedicated partner for PIM translation solutions.

Liquent, Inc. — Booth 248

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E-mail: info@liquent.com
Website: www.liquent.com

Liquent regulatory solutions provide software and related regulatory and clinical services for the life sciences industry. These solutions and services help ensure clients meet the strict standards of regulatory authorities across the world helping them achieve quality, accuracy, and data integrity to deliver regulatory reports and submissions.

Logos Technologies Inc — Booth 1441

Contact: Giles Wilson
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E-mail: contact@logostechnologies.com
Website: www.logostechnologies.com

ALPHADAS® is a world-class, proactive,eSource clinical trials system that is mobile, schedule-driven & provides real-time bedside or station-based Direct Data Capture. It meets the changing demands of early phase trials, accelerates data throughput & enhances data quality, offering an immediate & significant ROI for both clients and sponsors alike.

LORENZ International LLC — Booth 1042

Contact: Yaprak Eisinger
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E-mail: info@lorenz.cc
Website: www.lorenz.cc

LORENZ is the most established provider of e-regulatory software and services in the world, focused on submission management, labelling and tracking. The products don't require the purchase of continual services to get the job done. LORENZ' solutions foster independence, empowering customers to develop their own processes.

Lovelace Scientific Resources — Booth 625

Contact: Darlene Harbour
E-mail: dharbour@Lrri.org
Website: www.Lsrtrials.com
Phone: 505-348-9500

Lovelace Scientific Resources is a clinical trials company that specializes in conducting phase II-IV outpatient, multi-therapeutic trials with some overnight capability. Our research facilities are independently operated and are affiliated with Physician Investigator practices. Locations include Albuquerque NM, Austin TX, Sarasota, / Venice FL.

MAJARO InfoSystems, Inc. — Booth 1006

Contact: Martin J. Rosenberg, Ph.D.
E-mail: mrosenberg@majaro.com
Website: www.majaro.com
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MaxisIT, Inc — Booth 734

Contact: Maulik Shah
E-mail: mshah@maxisit.com
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Phone: 732-494-2005

MaxisIT is pioneer in eClinical Integration and Adaptive Decision Support software; CT Renaissance™ clinical enterprise suite solutions can integrate and orchestrate under one uniform or hybrid plug-n-play architecture supporting end-to-end functionalities with required interoperability, reusability and scalability - Real time Harmonization.

McGuire Research Institute — Booth 1557

Contact: Robert Dresch
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Phone: 804-675-5151

McGuire Research Institute is an inpatient and outpatient clinical research site with a 35,000 patient panel. Conducting Phase 1-4 studies since 1989. Weekly IRB meetings, ACRP certified coordinators, AAHRPP accredited human research protection program.

McKesson Corporation — Booth 567

Contact: Suzanne Obst
E-mail: Suzanne.Obst@McKesson.com
Website: www.mckesson.com
Phone: 415-983-9737

McKesson Corporation, currently ranked 14th on the FORTUNE 500, is a healthcare services and information technology company dedicated to helping its customers deliver high-quality healthcare by reducing costs, streamlining processes, and improving the quality and safety of patient care.

MD Events Inc. — Booth 2034

Contact: Debbie Liberio
E-mail: debbie.liberio@mdevents.us.com
Website: www.md-events.com
Phone: 610- 825-2660

MD Events are experts in the planning & delivery of clinical meetings worldwide. With offices in the US, UK & Russia we work with both CRO & Sponsor companies to deliver over 150 meetings per year worldwide. We produce regulatory compliant meetings including Investigator & CRA Training meetings, Advisory Boards, Satellite Symposia & Web Meetings.

MedAssurant — Booth 662

Contact: Ralph Parker
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Phone: 301- 809-4000

MedAssurant focuses on the importance of healthcare data and its ability to drive dramatic, objective improvements in clinical and quality outcomes. The MORE2 registry contains a comprehensive dataset covering 70 million Americans with over 4.8 billion medical events to drive CER, pre/post-marketing activities and pharmacosurveillance programs.

MedDRA MSSO — Booth 806

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Website: www.meddramsso.com
Phone: 877-258-8280

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, consulting).

MedFocus, an inVentiv Clinical company — Booth 1041

Contact: Tim Divane
E-mail: info@medfocus.com
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Phone: 800- 256-4625

MedFocus offers clinical research contract outsourcing and staffing specifically to the pharmaceutical, biotechnology, and medical device industries. MedFocus allows you to maintain consistency with high quality consulting while managing variability in clinical work demand without headcount issues.

Medical International Research USA, Inc. — Booth TBD

The Medical Research Network (MRN) — Booth 123

Contact: Stuart Redding, Director
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Website: www.themrn.co.uk
Phone: +44 0-1908 261 153

The MRN is a unique independant nursing focused patient recruitment and retention company, offering research nurses & coordinators to trial sites and home healthcare teams globally in clinical trials. Headquartered in the UK and now with a North American office, MRN is the only truly global organisation offering services of this type.

Medical Staffing Network Clinical Research — Booth 555

Contact: Vanessa Janus
E-mail: clinicalresearch@msnhealth.com
Website: www.msnclinicalreserach.com
Phone: 877-605-2500

MSN Clinical Research is a recruiting & staffing agency that focuses on positions involved in a clinical trial to include: clinical operations, data management, drug safety, biostatistics, medical writing, regulatory affairs, and more. We offer contract, contract to hire, direct hire/executive search and large project-based staffing solutions.

The Medicines Evaluation Unit
Booth 236

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Website: www.meu.org.uk

The Medicines Evaluation Unit Ltd is one of the UK's leading contract research organisations offering extensive Pharmaceutical, Scientific and Clinical expertise within a state of the art hospital based research unit. Specialising in Respiratory/Inflammatory medicine and Healthy Volunteer studys. MHRA Phase I Standard and Supplementary Accredited.

Medidata Solutions
Booth 1101

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Website: www.mdsol.com

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
Booth 425

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Phone: 866-258-2735
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Website: www.mednetstudy.com

MedNet Solutions is a leading healthcare technology company specializing in clinical study management systems designed for the global life sciences market. Since 2000, MedNet has delivered powerful, flexible and easy-to-use web-based EDC/eClinical systems that support clinical studies, registries and investigator initiated trials around the world.

Medpace
Booth 660

Contact: Catherine Soldano
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E-mail: info@medpace.com
Website: www.medpace.com

Medpace, established in 1992, is a full-service, global contract research organization (CRO) that works in partnership with pharmaceutical, biotech and device companies to bring innovative drugs/products to market. Medpace manages global studies and regulatory submissions, providing clinical trial support for all phases of drug development.

MedPoint
Booth 119

Contact: Bill Cooney, President
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Website: www.medpt.com

MedPoint produces innovative digital solutions to lower costs and expedite clinical research. We've supported over 1000 trials with Virtual Investigator Meetings, Trial ePortals, Training Modules and Document Exchange. Since 1990 we've assisted global trials with targeted technologies that are powerful, practical to deploy and intuitive to use.

MedSource
Booth 635

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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 1566

Contact: Mike Bunkers
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Website: www.medtox.com/clinicaltrials

MEDTOX Laboratories, located in St. Paul, MN offers an advanced, highly efficient central laboratory and a full range of preclinical and clinical bioanalytical services, as well as biomarkers and other specialty testing.

MedTrials, Inc.
Booth 1857

Contact: Jamie McClintick
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Website: www.medtrials.com

MedTrials is a full-service CRO specialized in providing project specific clinical trial management solutions. We are committed to exceptional service and 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 Healthcare
Booth 1955

Contact: Courtney Smith
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E-mail: courtney.smith@merge.com
Website: www.merge.com/eclinical

Merge offers a robust eClinical portal that enables users to access the tools to collect, manage & report their clinical trial data from one easy to use, single sign on portal. Gain access to proven EDC, IVRS/IWRs, ePRO, Event Adjudication & Clinical Imaging solutions with core support functionality including medical coding, reporting & exports.

META Solutions, Inc.
Booth 1340

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META Solutions, Inc. is a regulatory compliance consultancy with 24 years of experience assisting over 300 biopharmaceutical and related service companies to manage their regulatory compliance risk by assessing non-compliance and developing and implementing practical solutions with expert guidance and training.

Miami Children's Hospital Research Institute
Booth 2040

The Micron Group
Booth 230

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Website: www.micron-research.com

Founded in 1996 the Micron Group is an international CRO, with offices in the UK, USA and South Africa that provides services and consultancy in all aspects of Anti-Infective drug development, from the initial investigation of candidate molecules, through the clinical development programme, product launch, pharmacovigilance and marketing support.

Microsoft Corporation
Booth 1111

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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.

Microsystems
Booth 1522

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Website: www.microsystems.com

Microsystems helps leading pharmaceutical companies improve document quality and prevent eleventh-hour eCTD submission delays. DocXtools software integrates with Microsoft™ Word, automates the quality checklist and navigates to issues found. To learn how DocXtools improves authoring and QC efficiency, please visit www.microsystems.com.

MidLands IRB (MLIRB)
Booth 1555

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MLIRB is an AAHRPP fully-accredited IRB that specializes in providing customized, personalized, and responsive services for its client partners. MLIRB provides IRB review for clients nationwide for all phases of research in all therapeutic areas. MLIRB has extensive experience in multi-site trials, with two Boards that meet weekly.

Mission3, Inc.
Booth 151

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Mission3 is a premier Regulatory Information Management software provider for the Life Sciences industry. Our innovative software solutions help Life Science companies of all sizes handle their electronic data management, regulatory submission planning and publishing, Virtual Data Rooms, collaborative authoring, and world-wide registration.

MMG
Booth 528

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MMG is an innovator in global clinial trial patient recruitment and retention. For more than 20 years study teams have trusted us to provide strategy and services that deliver results. MMG's industry leading strategists have the resources and reach to accelerate enrollment, achieve retention goals, and maximize ROI. We are MMG. We get patients.

MNX
Booth 1958

monitorforhire.com
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Contact: Scott Freedman
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Website:

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.

Montrium Inc.
Booth 1763

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Montrium is a consulting group focused on the delivery of technology solutions to improve management of clinical research and pharmaceutical operations. We offer pre-configured pharma solutions based on the SharePoint platform.

Moravia
Booth 1364

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Website: www.moraviaworldwide.com

Moravia is an ISO 9001 certified leading global translation provider that helps you bring new drugs to market. We offer translation, localization for Phase I-IV, validation & cognitive debriefing, IVRS/IWR translation & recording, regulatory translations using strict SOP's, terminology & translation memory and multimedia localization for training.

Mortara Instrument
Booth 1918

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Website: www.mortara.com

From ECG acquisition at the investigator site to ECG Warehouse development for FDA, Mortara has developed a unique platform to help marshal a study smoothly from site to submission. The "Rx" platform of ECG products are specifically designed for clinical research requirements.

MPI Research
Booth 404

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MPI Research is a preclinical CRO that provides discovery, safety evaluation, bioanalytical, and analytical services. Responsiveness, scientific knowledge and experience, teamwork, and strong, enduring Sponsor relationships characterize MPI Research as a high-performance, high-quality organization.

Myoderm
Booth 704

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Myoderm is a global leader in the sourcing and distribution of pharmaceutical products and supplies for pharmaceutical and biotech companies, CROs and clinical trial packagers. GlobalSource provides bulks sourcing for comparators and CentralSource provides sourcing and direct to clinical site distribution management.

National Death Index
Booth 2012

Contact: Robert Bilgrad
Phone: 301-458-4444
E-mail: ndi@cdc.govq
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.

National Pharmaceutical Council (NPC)
Booth 634

Contact: Kathryn Gleason
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E-mail: kgleason@npcnow.org
Website: www.npcnow.org

The National Pharmaceutical Council, a policy research organization, promotes scientific analyses of the appropriate use of biopharmaceuticals and the clinical and economic value of improved health outcomes through innovation.

View NPC research at www.npcnow.org. Subscribe to the CER Daily Newsfeed at www.npcnow.org/cernewsfeed.

New England IRB

Booth 722

Contact: James Saunders
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Website: www.neirb.com

New England IRB is an AAHRPP-accredited IRB providing full review services, Phases I - IV, throughout the U.S., Canada, and Mexico. NEIRB provides:

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New Orleans Center for Clinical Research

Booth 1515

Contact: John W. Lacey or Jenifer O'Quinn
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E-mail: jlacey@noccr.com or joquinn@noccr.com
Website: NOCCR.com

NOCCR and VRG 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.

NewCardio, Inc

Booth 1660

Contact: Gilbert Molina
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Website: www.newcardio.com

NewCardio mission is to commercialize a three dimensional (3D) approach to electrocardiography for acute and chronic heart disease and for evaluating cardiac safety of new drugs. Our proprietary 3D approaches can significantly enhance the ECG's diagnostic utility, reduce its complexity, and improve its ease of use for the medical professional.

Next Generation Clinical Research

Booth 539

Contact: Christine Wood-Tank
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E-mail: info@nextgenclinical.com
Website: www.nextgenclinical.com

Founded in 1999, Next Generation provides trial management services to niche and emerging biopharma organizations. We command particular expertise in Critical Care, Nephrology and Neurology, while specializing in complex projects and innovative product applications. Services:Trial Management, Clinical Monitoring, Data Management and Medical Safety.

NextDocs

Booth 717

Contact: Erik Smith
Phone: 610-265-9474
E-mail: esmith@nextdocs.com
Website: www.NextDocs.com

NextDocs is the worldwide leader in providing Microsoft SharePoint-based document and quality management solutions to life sciences organizations. It enables businesses in regulated industries to achieve compliance with FDA and other agencies while automating processes, improving efficiency and dramatically reducing costs.

Nextrials, Inc.

Booth 905

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E-mail: aarroyo@nextrials.com
Website: www.nextrials.com

Nextrials is an award winning, innovative leader in software solutions for clinical research. Prism is a fully integrated EDC product with clinical trial managment functionality that provides both standard data management capabilities and value-added tools for managing clinical trials. Prism also integrates with Electronic Health Records (EHR).

Norwich Clinical Services

Booth 556

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Website: www.norwichpharma.com

Norwich Clinical Services is a contract research organization providing Bioanalytical Services, Pharmacovigilance and Clinical Research Programs. Offering one solution for the product lifecycle, the Norwich advantage features streamlined capabilities from product development to scale-up and commercial manufacturing through clinical services.

Nova Language Services Ltd (NOVA)

Booth 135

Contact: Arun Mathew
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For over a decade, Novella Clinical has been an active partner in supporting the medical device and biopharmaceutical industries with early phase through post-marketing development programs. From protocol development through final clinical study report — we integrate deep clinical expertise with industry-leading technologies.

November Research Group

Booth 807

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Website: www.novemberresearch.com

November Research Group is a professional services firm that provides a complete spectrum of software and services to the pharmacovigilance departments in the biopharmaceutical industry. We have extensive experience in the implementation and support for the Oracle Argus Safety Suite, Oracle AERS, ARISg, and other commercial AE systems.

Novotech

Booth 1141

Contact: Julia Jones
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Website: www.novotech-cro.com

Novotech is a full-service clinical CRO based in Australia and operating out of 8 countries and 15 locations across Asia Pacific. Our services offering is designed for sponsors with no presence on the ground. Talk to our experts at the Novotech booth, and find out why so many companies choose to use Novotech as their CRO of choice in the region.

nSpire Health — Booth 914

Contact: Michael Brown
Phone: 800-574-7374
E-mail: mbrown@nspirehealth.com
Website: www.nspirehealth.com/clinical

nSpire Health supplies pharmaceutical companies, CROs, & clinical researchers advanced technology, precise instrumentation, & expert professional services to accelerate drug trials worldwide. We continue to redefine accuracy and establish new standards for diagnosing, treating, & managing lung disease; delivering the shortest path to data lock.

Ocasa Logistics Solutions — Booth 1900

Contact: Marcelo Reggiardo
Phone: 1 212- 758 0101
E-mail: contactus@ocasa.com
Website: www.ocasa.com

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.

OCT — Booth 366

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Website: www.oct-clinicaltrials.com

OCT is a full-service CRO operating in Central and Eastern Europe. Based in St. Petersburg, offices in Ukraine, Belarus, Bulgaria, Latvia, Lithuania, Estonia, Poland and Czech Republic. Operating since 2005; 90 people on staff. Phase I-IV trials, various therapeutic areas. OCT:cost-and time-effectiveness, high quality, compliance with requirements

Octagon Research Solutions, Inc. — Booth 329

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Octagon Research Solutions, Inc. is the leader in the electronic transformation of clinical R&D. We offer a suite of regulatory, clinical, process and IT solutions to the life sciences industry. Our integrated suite of offerings is built upon deep domain knowledge, cross-functional eSub expertise, a holistic process approach and integrated solutions.

Odyssey Research — Booth 1824

Contact: Suzanne Wentz
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Website: www.odysseyresearch.org

Odyssey Research is a Trial Management Organization dedicated to advancing medicine & enhancing lives through the management of clinical research services for physicians and patients. Odyssey & their associated physician network have eleven years of clinical research experience focusing on quality, integrity, and high level performance metrics.

Omnicare Clinical Research — Booth 529

Contact: Barry Broughton
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Omnicare Clinical Research is a global, full-service CRO serving the biopharmaceutical and medical device industries from our offices in 32 countries. We deliver operational excellence through our client-focused business units: Early Phase, Phase II/III, Late Phase, Medical Devices, Technical Services and Pharmaceutics.

OmniComm Systems, Inc. — Booth 203

Contact: Bev Hudson, SVP of Global Business Development
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Website: www.omnicomm.com

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 203 for a demo of our comprehensive product suite.

On Assignment Clinical Research — Booth 1729

Contact: Kelly Mastrosimone
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E-mail: clinical.research@onassignment.com
Website: www.oaclinicalresearch.com

On Assignment Clinical Research is an industry leader offering skilled clinical research professionals at all career levels in project-based, contract-to-hire, and direct hire opportunities. In 2010, The Cambridge Group joined On Assignment Clinical Research to provide the most effective staffing solutions in the field of Clinical Research.

Online Business Applications — Booth 1942

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Website: www.irmsonline.com

Online Business Applications is committed to providing advanced software solutions for the Pharmaceutical, Biotech, and Medical Device industries in the areas of Medical Communications, Drug Safety, Quality Assurance, and other related fields. Our product, IRMS, has become the most widely used medical information system in the industry.

OpenClinica / Akaza Research — Booth 1843

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OpenClinica is a revolutionary approach to EDC. By leveraging open source technology, OpenClinica provides a flexible, powerful, and cost effective way to securely collect and manage clinical trial data over the Web. Its attractive model has made OpenClinica the world's fastest growing clinical trials software.

Optum — Booth 1945

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The regulatory strategists of CanReg, patient-reported outcomes (PRO) experts of QualityMetric, and clinical informatics specialists of Ingenix are now Optum. Bringing Industry-leading expertise in regulatory affairs and real world evidence to your next development project or product launch.

Ora, Inc. — Booth 562

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Ora, Inc. (www.oraclinical.com), a full-service ophthalmic CRO, has achieved 32 FDA approvals over the last 30 years. Ora's experienced team, scientific rigor and operational excellence are key to the successful delivery of strategic clinical-regulatory guidance, technology-based solutions and molecule-to-marketplace clinical services.

Oracle — Booth 211

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Oracle is a leading strategic software solutions provider to the health sciences industry, helping pharmaceutical, biotechnology, medical device, and healthcare organizations become the most successful in the world by offering the most innovative products and services that deliver the most compelling customer and shareholder value.

Orlando Clinical Research Center — Booth 1328

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OCRC is an independent Phase I-IV custom-built 35,000 sq. ft. research site designed for Phase 1 trials located in the heart of Central Florida. Facility includes 100 in-house volunteer beds, dual lead digital telemetry, and secure cardkey access. A special treatment/observation area has 12 hospital beds (6 used for onsite Hemodialysis studies)

Outcome — Booth 1302

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Phone:
E-mail: info@outcome.com

Outcome is the market leader in patient registries, peri- and post-approval studies, and integrated technologies for evaluating real-world outcomes. We provide services and technologies focused on evaluating the safety, effectiveness, value, and quality of healthcare products, therapies, and services.

Palm Beach CRO — Booth 535

Contact: Arthur Simon, PhD
Phone: 561-200-3344
E-mail: ASimon@PalmBeachCRO.com
Website: www.PalmBeachCRO.com

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 Biomedical — Booth 1928

Contact: Clareece West
Phone: +1 949-224-2800
E-mail: CorporateCommunications@parabio.com
Website: www.paragonbiomedical.com

Paragon Biomedical is a global, full-service CRO providing high quality Phase I-IV clinical trial support to biopharmaceutical and medical device companies with less than 20% staff turnover rate in last 4 years; 88% repeat business rate; 6-8 week rapid start-up; and 93% of studies on or ahead of targeted enrollment, with 67% exceeding enrollment targets.

Paragon International, Inc. — Booth 935

Contact: Christopher Diehl
Phone: 888-429-5875
E-mail: cdiehl@paragonmeetings.com
Website: www.paragonmeetings.com

Paragon Int'l, Inc. has produced successful meetings and events for pharma companies worldwide since 1995, with client satisfaction guaranteed service. In-house travel agent & audio-visual production services, joined with responsive 24/7 accessibility, highlight our world-class events and service. Discover Paragon's people & services at Booth #935.

PAREXEL International — Booth 1623

Contact: Heather Puffer
Phone: 781-487-9900
E-mail: info@PAREXEL.com
Website: www.PAREXEL.com

PAREXEL knows scientific drug development throughout the product development cycle. 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.

The Patient Recruiting Agency (TPRA) — Booth 1667

Contact: Lance Nickens
Phone: 512-345-7788
E-mail: lance@tprausa.com
Website: www.tprausa.com

TPRA's data-driven IN-HOUSE SOLUTIONS include: creative production, patient/physician outreach, site selection plus website & call prescreening. Now with RADIUS365™, TPRA's online platform to track & manage all response, referral, randomization & retention activities in real-time, TPRA is the Leader In Successful PATIENT RECRUITING & RETENTION.

PCM TRIALS — Booth 157

Contact: Julie Church-Thomas
Phone: +1-888-976-CMRN
E-mail: julie.churchthomas@pcmtrials.com
Website: PCMTRIALS.com

PCM TRIALS'offers convenient alternative site visits by our own Certified Mobile Research Nurses (CMRN) who have completed over 4,000 visits across the U.S. The CMRNs' are screened, trained and managed by us not a third party agency.CMRN's provide infusions, injections, blood draws, assessments, etc. in the subject's home or office.

PDR Network, LLC. — Booth 202

Contact: Kim Marich
Phone: 201-358-7200
E-mail: kim.marich@pdr.net
Website: www.PDRnetwork.com

PDR Network provides effective, cost-efficient services that distribute specialty-specific FDA-approved drug information, updates, patient safety communications and REMS programs electronically to help fulfill the regulatory and compliance needs of manufacturers. New services include an adverse event reporting tool for drug, device and EHR systems.

Pegasystems Inc. — Booth 207

Contact: Lauren St. Amand
Phone: 617-866-6387
E-mail: staml@pega.com
Website: www.pega.com

PegaBPM enables life sciences organizations to increase efficiencies across the product development lifecycle by automating and streamlining business processes across people, applications, rules and enterprise systems. Focus areas include Clinical Trial Case Management, Spend Management, CRM and Regulatory Compliance.

Penn Pharma — Booth 623

Contact: Britton Jimenez
Phone: +44 0- 1495 711 222
E-mail: enquiries@pennpharm.com
Website: www.pennpharm.com

Penn Pharma is a leading CDMO providing integrated product development & custom manufacturing services to the international healthcare industry. Based in the UK Penn Pharma is ideally located to assist non-EU clients import & distribute pharmaceutical & clinical trial material throughout the EU & the world through our PharmacEUtical Portal service.

Perceptive Informatics — Booth 1627

Contact: Heather Puffer
Phone: +1 866 289 4464
E-mail: info@perceptive.com
Website: www.perceptive.com

Perceptive Informatics® offers industry-leading eClinical solutions including medical imaging, RTSM, EDC, CTMS, ePRO and integration services, as well as portals, tracking tools and investigator databases.

Pharm-Olam International — Booth 1227

Contact: John Hovre
Phone:
E-mail: info@pharm-olam.com

Pharm-Olam International delivers full service, quality clinical services to pharma and biotech sponsors across all therapeutic areas in more than 40 countries. Our access to large patient populations reduces time to market and overall costs while maximizing sales potential.

Pharma Publications — Booth 1867

Contact: Mark Barker
Phone: +440-207 2375685
E-mail: mark@pharmapubs.com
Website: www.jforcs.com, www.ipimedia.com, www.jforpc.com

Pharma Publications, is a dynamic media and publishing group, providing contemporary journals to the Lifesciences Industry. Our journals are - Journal for clinical Studies - Your Resource for multisite Studies & Emerging Markets, IPI - International Pharmaceutical Industry & Journal for Patient Compliance - Strategies to enhance health Outcomes.

Pharmaceutical Executive — Booth 705

Contact: Cecilia Asuncion
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E-mail: casuncion@advanstar.com
Website: www.pharmexec.com

Pharmaceutical Executive is the only publication that truly covers the intersectionbetween business and policy. No one can compare to Pharm Exec's award-winning content. From strategy, to regulation, to marketing, to the best new ideas about R&D, finance, and IT, Pharmaceutical Executive covers it all.

Pharmaceutical Outsourcing — Booth 111

Contact: Svetlana Varkonyi
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E-mail: svetlana.varkonyi@russpub.com
Website: pharmoutsourcing.com

Pharmaceutical Outsourcing, is a journal dedicated to pharmaceutical and biopharmaceutical contract services, we bring the most complete coverage of trends and issues in the industry to our 15,000 readers in North America. For more information please visit our website at pharmoutsourcing.com.

Pharmaceutical Safety Services, LLC — Booth 2057

Contact: Thomas S. Mingot
Phone: +1 601-246-3891
E-mail: mingot84@comcast.net
Website: PharmSafetyServ.com

Pharmaceutical Safety Services, LLC, is dedicated to provide the pharmaceutical, biotech, and device companies, as well as, contract research organizations, a complete range of services to plan, set up, and implement the data and safety monitoring board process in the conduct of clinical research programs.

Pharmaceuticals and Medical Devices Agency (PMDA) — Booth 1414

Contact: Kyoichi Tadano, Ph.D
Phone: +81-3-3506-9456
E-mail: tadano-kyoichi@pmda.go.jp
Website: www.pmda.go.jp

The Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency that reviews applications for marketing approval of pharmaceuticals and medical devices, monitors product safety, and provides financial relief to people suffering from adverse drug reactions, in collaboration with the Ministry of Health, Labour and Welfare.

Pharmalink Consulting, Inc. — Booth 147

Contact: Stephen Loughrey
Phone: 1 .800.434.5808
E-mail: sloughrey@pharmalinkconsulting.com
Website: www.pharmalinkconsulting.com

Pharmalink Consulting is one of the world's leading independent Regulatory Affairs specialist, with offices in US, UK and India. We assist Regulatory Affairs functions of the world's leading companies from development to market & beyond. Our consultants are experts in Pharma, Biotech, Clinical, Consumer Health, Medical Device and Nutraceuticals.

PharmaNet Development Group Inc. — Booth 1655

Contact: Greg Skalicky, SVP, Global Business Development
Phone: 609-951-6800
E-mail: gskalicky@pharmanet.com
Website: www.pharmanet.com

PharmaNet Development Group, a recognized leader of global drug development services to the pharmaceutical, biotechnology, generic drug, and medical device industries, provides comprehensive capabilities in Phase I-IV clinical development, bioanalytical and bioequivalence services, regulatory, staffing, and therapeutic solutions.

PharmaSeek — Booth 1306

Contact: Nicolas Cindric
Phone: 608-664-9000
E-mail: ncindric@pharmaseek.com
Website: www.pharmaseek.com

PharmaSeek partners with Sponsors and CROs to identify investigative sites for clinical trials. PharmaSeek's network is comprised of multi-specialty practices, research-only facilities and academic institutions. PharmaSeek also provides receivables management and short-term study financing on a fee-for-service basis to sites outside its Network.

PharmaSys, Inc. — Booth 544

Contact: Charles Lankford
Phone: 919-468-2547
E-mail: anne@pharma-sys.com
Website: www.pharma-sys.com

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 — Booth 255

Contact: Meghan Morrissey
Phone:
E-mail: info@pharmavigilant.com
Website: www.pharmavigilant.com

PharmaVigilant is a SaaS company offering a full suite of clinical trial technology and services including: Electronic Data Capture (InSpire); electronic Trial Master File system (I-Vault); remote Source Document Verification (I-Vault rSDV); data warehousing (I-Warehouse); study building (I-Builder); and an automated site payment system (PaySite).

PharmaVOICE — Booth 1423

Contact: Taren Grom
Phone: 215-483-6904
E-mail: tgrom@pharmavoice.com
Website: www.pharmavoice.com

PharmaVOICE magazine addresses the challenges and trends impacting the life-sciences industry. PharmaVOICE's subscribers are also kept abreast of the latest trends through additional media resources, including WebSeminars, Podcasts, Videocasts, and White Papers.

PharMed Alliance — Booth 125

Contact: Kelly Willenberg
Phone: 864-473-7209
E-mail: info@pharmedalliance.com
Website: www.pharmedalliance.com

PharMed Alliance wants to bridge the regulatory gap between pharma and medical device companies with clinical sites. We can help you efficiently implement clinical trials and lower overall costs by providing billing coverage analysis. Consider PharMed Alliance as a partner with all of the sites you work with and you will see improved negotiations!

Philips Respironics — Booth 457

Contact: Kristen Boatman
Phone:
E-mail: kristen.boatman@philips.com

Philips is a global leader in health and well being. We understand customer needs and deliver innovative products that exhibit Sense and Simplicity. Actiwatch devices record physical activity and subjectively scored self-report inputs from subjects living their everyday lives. This technology helps you conduct trials efficiently and effectively.

Phlexglobal Limited — Booth 222

Contact: Karen Redding
Phone: +44 0-1494 720420
E-mail: kredding@phlexglobal.com
Website: www.phlexglobal.com

Established in 1997, Phlexglobal is a specialist CRO offering global support for Trial Master File management and clinical trial administration through its flexible resourcing, system and document support solutions. Full outsourcing of Trial Master File management can be achieved through the use of PhlexEview, Phlexglobal's unique electronic Trial Master File system.

Phoenix Software International — Booth 1348

Contact: John Brayman
Phone: 919-841-4545
E-mail: johnbrayman@phoenixsoftware.com
Website: www.phoenixsoftware.com

Entrypoint Plus is a complete system for creating, deploying, and administering custom EDC applications for clinical trials. Entrypoint is built around a scalable client-server network architecture using ODBC to interface with SQL databases. Other Entrypoint features include a set of CRF templates, a built-in ATF and a key-from-image interface.

PHT Corporation — Booths 1612 & 1613

Contact: Sheila Rocchio, Vice President of Marketing
Phone: 877-360-2901
E-mail: srocchio@phtcorp.com
Website: www.phtcorp.com

PHT Corporation is the industry's only dedicated full-service ePRO provider, enabling sponsors to collect patient data via mobile, tablet and smartphone devices – and the Internet. Patient experiences captured firsthand by PHT's ePRO System have been used successfully in at least 16 regulatory submissions and 13 approvals to date. www.phtcorp.com

Piramal Healthcare — Booth 167

Contact: Karen Scott
Phone: +44 1670 562400
E-mail: karen.scott@piramal.com
Website: www.piramal.com

Piramal Healthcare is one of the world's top 10 contract development and manufacturing organisations (CDMO). We are recognised for best-in-class services in the supply of early and late phase APIs and Formulations. This combined with outstanding program management differentiates both our quality and our competitive ability.

PleaseTech Ltd — Booth 1243

Contact: David Cornwell
Phone: 877-205-4940
E-mail: david.cornwell@pleasetech.com
Website: www.pleasetech.com

PleaseReview ™ is a proven document review and co-authoring solution for Microsoft Word and other document types. Offering unique functionality, owner control and comprehensive reporting, it supports secure, simultaneous and collaborative review within the organization and with third parties. PleaseReview is available integrated with leading DMS.

POPSI CUBE — Booth 406

Contact: Fabrice Beauchene
Phone: +33 1 80905080
E-mail: contact@popsicube.fr
Website: www.popsicube.com

POPSI CUBE, the next generation CRO, provides eTrial solutions & services (e.g. custom EDC, Digital Pen & Paper, iPad/iPhone data capture) for PI to IV clinical trials. We combine extensive trial management experience with a unique expertise in IT solutions. We are based in France, US and Tunisia. POPSI CUBE, a new way of doing Clinical Research.

PRA International — Booth 1701

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E-mail: endpoints@praintl.com
Website: www.prainternational.com

PRA is a global CRO performing trials in all phases and therapeutic areas of pharmaceutical and biotech drug development. We offer expertise in oncology and hematology, neurosciences, infectious diseases, cardiovascular, and respiratory. During the last five years, PRA has supported more than 3000 clinical trials in 80+ countries on 6 continents.

Praxis Communications — Booth 800

Contact: Tricia Barrett
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E-mail: tbarrett@gopraxis.com
Website: www.gopraxis.com

Praxis provides the pharmaceutical and biotech industries with a wide range of global services for patient recruitment and retention for clinical trials including patient profiling, recruitment planning, centralized fulfillment, media relations, digital strategy, advertising and program management. Visit www.gopraxis.com to learn more.

Premier Research Group Limited — Booth 311

Contact: Jessica Barag
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E-mail: jessica.barag@premier-research.com
Website: www.premier-research.com

Premier Research is a customer focused CRO providing premier people, premier process and premier performance to biopharmaceutical and medical device companies worldwide. The company is a leader in performing clinical research in the analgesia, oncology, pediatrics, medical device and CNS areas. Additionally, it offers flexible strategic sourcing.

Pretium — Booth 1463

Contact: Joyce Lloyd
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E-mail: joyce.lloyd@pretium.com.au
Website: www.pretium.com.au

Pretium, headquartered in Australia, supports clinical research and post marketing requirements with a primary care network and study coordinators to conduct large phase III and IV trials efficiently. Pretium is customer focused, delivering projects with outstanding patient recruitment and compliance, quality data and rapid start-up.

PrimeVigilance Limited — Booth 238

Contact: Jonathan West
Phone: +44 0-1483 688 349
E-mail: jonathan.west@primevigilance.com
Website: www.primevigilance.com

PrimeVigilance is dedicated to compliant and cost-effective pharmacovigilance solutions. PrimeVigilance fills the gap between large CROs not geared towards small and medium sized clients and small service providers who lack the critical mass, expertise or wide international presence needed to ensure that patients and products will be protected.

PRL Central Laboratory Services — Booth 706

Contact: Scot Stubenhofer
Phone: +1-913-339-0489
E-mail: scot.stubenhofer@prlwecare.com
Website: www.prlwecare.com

PRL Central Laboratory Services is one of the best kept secrets in the business. We specialize in comprehensive diagnostic testing, with a focus on protocol requirements. We serve all phases of clinical research on a global basis, providing each client with accurate study set-up, timely results delivery and validated data management.

Progressive Impressions International (Pii) — Booth 423

Contact: Maggie Smith
Phone: 954-956-3422
E-mail: mmsmith@whateverittakes.com
Website: www.whateverittakes.com

Progressive Impressions International (Pii) provides communication services to support patient recruitment, sales training, physician detailing and consumer education. Our staff includes writers and designers who specialize in healthcare marketing. Our technology solution Conductor makes online ordering of print materials easy and cost-effective.

Projecis — Booth 511

Contact: Russell Holmes
E-mail: russ@projecis.com
Website: www.projecis.com

Projecis, a cloud-based platform, enables project stakeholders – sponsors, sites, CROs – to connect teams, organize data, and share info for better trial outcomes. Users access project status, costs, files, profiles (including LinkedIn®), video updates via secure site. Team exchange is improved with Skype®, IM/chat, email, text, phone. FREE trial!

PROMETRIKA, LLC — Booth 639

Contact: Christopher Gallant
Phone: +1-617-844-0240
E-mail: cgallant@prometrika.com ; dalvarado@prometrika.com
Website: www.prometrika.com

PROMETRIKA is a full-service CRO located in Cambridge, MA providing innovative solutions in helping pharmaceutical, biotechnology & medical device companies successfully complete their development programs & move treatments to market. PROMETRIKA has a foundation of experience in a wide variety of therapeutic indications & successful NDA submissions.

PROSAR — Booth 1712

Contact: Cari Lombardi
Phone: 651-917-6113
E-mail: clombardi@prosarcorp.com
Website: www.prosarsafety.com

PROSAR is a leading provider of pharmacovigilance and medical information services to the pharmaceutical and biotech industries. We provide the following:

- adverse event intake and processing including MedWatch 3500A completion
- medical information services
- product complaint services
- 24/7 call center staffed by healthcare professionals

Protrials Research — Booth 901

Contact: Wendy Powers
Phone: 650 864-9195
E-mail: wpowers@protrials.com
Website: www.protrials.com

ProTrials provides experienced professionals to pharmaceutical, biotechnology, and medical device companies. ProTrials focuses on clinical operations services including project management, quality assurance, clinical monitoring, SOP development, and clinical staff training in a wide range of therapeutic areas with 90% repeat business.

PRUDENTAS LLC — Booth 363

Contact: Ekaterina Nikolaevskaya
Phone: +74956283802
E-mail: ekaterina.nikolaevskaya@prudentas.com
Website: www.prudentas.com

PRUDENTAS is a CRO organizing BE and Phase I — IV clinical trials in all therapeutic areas in Russia and Ukraine with fast recruitment and high quality. We would be happy to offer services of our highly experienced clinical research professionals to accelerate the clinical development of your compounds.

PSC Biotech — Booth 541

Contact: John Clapham
Phone: 1-909-784-3350
E-mail: JClapham@biotech.com
Website: biotech.com

PSC Biotech is an established compliance consulting company that specializes in the creation and validation of custom software, computerized systems, facilities, processes, and equipment. Please stop by booth #541 to learn more about our compliance soutions and to see the latest in our Auditing Software, Auditca™ and Audit Utopia™.

PSI — Booth 1610

Contact: Ginny Payeur
Phone: 6503439501
E-mail: ginny.payeur@psi-cro.com
Website: www.psi-cro.com

PSI is a full-service CRO operating in 30+ countries. PSI's key strength is predictable patient enrollment across multiple therapeutic areas. PSI's high repeat business rate is the best testimony to our proactive and determined project management philosophy that leads the industry with on -time results while ensuring high quality data.

QlikTech Inc — Booth 942

Contact: Amanda Gammons
Phone: 484-685-0600
E-mail: infous@qlikview.com
Website: www.qlikview.com

QlikTech (NASDAQ: QLIK) is the leader in Business Discovery, user-driven Business Intelligence (BI). Its QlikView platform enables intuitive user-driven analysis that can be implemented in days or weeks rather than months or years. Headquartered in Radnor, PA, QlikTech has offices around the world serving more than 18,000 customers worldwide.

QPS
Booth 1917

Contact: Andrew Nehls
Phone: 402-895-2022
E-mail: bhavna.malhotra@qps-usa.com
Website: www.qps-usa.com

QPS is a GCP/GLP-compliant CRO supporting discovery, preclinical, and clinical development. QPS provides quality services in bioanalysis, preclinical DMPK and toxicology, translational medicine, early and late phase clinical research at our sites in Newark, DE; Springfield, MO; Groningen, The Netherlands; Hyderabad, India; and Taipei, Taiwan.

Quality and Compliance Consulting, Inc.
Booth 1611

Contact: Jason Bertram
Phone: 424-208-3340
E-mail: qc2@qc2.com
Website: www.qc2.com

Audits of investigative sites, Phase I units, laboratories, data management systems, CSV, clinical/project management/safety systems, reading centers, vendors, IRBs, clinical trial reports, data listings, and study files; SOP review and preparation; GCP and GLP training.

Quality Associates, Inc. (QAI)
Booth 517

Contact: Lora Martin
Phone: 410-884-9100
E-mail: lmartin@qualityassociatesinc.com

Quality Associates, Inc. (QAI) was established to provide quality assurance/regulatory services to the pharmaceutical and agrochemical industries. QAI provides consulting services in the areas of GLP and GCP to regulated companies. Specialize in quality assurance, and provides scientific support. 410-884-9100 or qualityassociatesinc.com

QualityMetric Incorporated
see Optum

Quanticate Inc
Booth 1912

Contact: Andrew MacGarvey
Phone: +1 857 998 6860
E-mail: andrew.macgarvey@quanticate.com
Website: www.quanticate.com

Quanticate, with headquarters in the UK and USA, is a specialist CRO primarily focused on the management, analysis and reporting of data from clinical trials and post-marketing surveillance. We deliver scalable on and off-site data management, statistical consultancy, programming & analysis, medical writing and pharmacovigilance services.

Queensland Clinical Trials Network Inc . (QCTN).
Booth 600

Contact: Mario Pennisi
Phone: +61 7 3331 3999
E-mail: mario.pennisi@qctn.com.au
Website: www.qctn.com.au

QCTN is the primary point of contact for organisations seeking to undertake preclinical and clinical research in Australia. It is a member-based, industry-focused group representing national and international businesses which have a presence in Queensland, Australia. These organisations are life sciences service providers.

Quest Diagnostics
Booth 1819

Contact: Florence McEvoy
E-mail: florence.mcevoy@questdiagnostics.com
Website: www.questdiagnostics.com

Quest Diagnostics Clinical Trials offers unsurpassed global central laboratory services, biomarker services, esoteric testing, combined with one of the world's largest clinical laboratory, global database, and unparalleled logistical support.

Quintiles
Booth 613

Contact: Rachael Fones
Phone: US Only: +1-866-267-4479 Intl: +800-7627-5381
E-mail: global.marketing@quintiles.com
Website: www.quintiles.com

Quintiles is the only fully integrated biopharmaceutical services company offering clinical, commercial, consulting and capital solutions worldwide. The Quintiles network of more than 20,000 engaged professionals in 60 countries helps biopharmaceutical companies navigate risk and seize opportunities in an environment where change is constant.

QUMAS
Booth 606

Contact: Colleen Carlisi
Phone: 973-805-8600
E-mail: info@qumas.com
Website: www.qumas.com

QUMAS a leader in Enterprise Regulatory Compliance with over 250 deployments and over a decade of experience helping companies in highly regulated industries provide a proactive regulatory defense. QUMAS solutions for life sciences are designed to achieve compliance with industry and government standards for Quality, R&D, and Regulatory Affairs.

Quorum Review IRB
Booth 1935

Contact: Arri Burgess
Phone:
E-mail: aburgess@quorumreview.com
Website: www.quorumreview.com

Quorum Review is an independent ethics review board that is fully accredited by 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.

R&D Directions - UBM Canon
Booth 1104

Contact: Steve Everly
Phone: 610-705-8705
E-mail: steve.everly@ubm.com
Website: www.pharmalive.com

R&D Directions provides insight into pharmaceutical research and development, from discovery through clinical trials and submission. Leaving the hard science to other publications, R&D Directions focuses on pharmaceutical companies' R&D business strategies and decisions. R&D Directions reaches over 12,000* key decision makers. www.pharmalive.com

Radiant Research, Inc.
Booth 1855

Contact: Julie McHugh
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E-mail: juliemchugh@radiantresearch.com
Website: www.radiantresearch.com

Based in Cincinnati, Ohio, Radiant is a comprehensive clinical research and development company serving the biopharmaceutical and medical device industy. We offer full service CRO capabilities, Radiant Trial Support, Patient Recruitment and dedicated research centers across the US and India.

Randox Pharma Services
Booth 305

Contact: Mr Chris Moriarty
Phone: +1 304 728 2890
E-mail: marketing@randox.com
Website: www.randox.com

Randox Pharma Services - Supplying diagnostic and Biomarker solutions to your lab.

In recognition of the vital role biomarkers play in drug development programmes, Randox Pharma Services supplies a comprehensive range of technologies and solutions direct to Pharmaceutical companies, CRO's and central laboratories.

RDP Clinical Outsourcing — Booth 465

Contact: Kevin Boos
Phone: +1-415-374-8895
E-mail: info@RDPClinical.com
Website: www.RDPClinical.com

RDP Clinical Outsourcing is pioneering the Strategic Clinical Outsourcing model which specializes in building highly experienced clinical project teams that are a custom fit for specific study demands/ needs. We maximize efficiency through a variety of means resulting in more experienced staff and a reduction in overall study costs - i.e. Value.

Real Data Medical Research, Inc. — Booth TBD

Real Staffing Group — Booth 1866

Contact: Tom Froggatt
Phone: +1 212-707-8499
E-mail: t.froggatt@realstaffing.com
Website: www.realstaffing.com

Real Staffing Group - a global, diverse Staffing business, and one of the world's leading Pharmaceutical recruiters. From our hubs in New York, San Francisco, London, Paris, Amsterdam, Frankfurt and Zurich, we supply top-class talent to the world's largest Pharma companies, most cutting-edge Biotechs, and specialised CROs.

Reed Technology — Booth 1828

Contact: Ben McGinty
Phone: 215-441-6466
E-mail: bmcginty@reedtech.com
Website: www.ReedTech.com

Providing SPL conversions and e-submissions, SPL XML composition and printing services for print- and web-ready promotional materials, content lifecycle management, PLR and labeling consulting, LabelDataPlus (online animal health drug labeling/listing database), digitization, indexing, database creation, and web archiving services.

REGISTRAT-MAPI — Booth 934

Contact: Amy Wynn
Phone: 859-223-4334
E-mail: awynn@registratmapi.com
Website: www.registratmpapi.com

REGISTRAT-MAPI is the industry's largest global CRO dedicated exclusively to "real-world" clinical research. We provide strategic and operational expertise as well as services in the design and conduct of late phase studies and are committed to developing true partnerships with our clients.

Regulatory Compliance Initiatives (RCI) & Secure Submissions Inc. (SSI) — Booth 201

Contact: kbowler@securesubinc.com
Phone: 702- 914-0798
E-mail: inquiries@regulatorycomp.com
Website: www.regulatorycomp.com www.securesubinc.com

ACCELERATE SUCCESS. With over 100 years of collective expertise, Regulatory Compliance Initiatives (RCI) and Secure Submissions, Inc. (SSI) deliver exceptional results. We filed the first electronic DMF with FDA and continue to lead the industry with 100's of eCTD (IND, NDA, ANDA & DMF) & SPL filings. RCI & SSI: Agile, Accurate. Trusted Assurance.

Regxia Inc. — Booth 1040

Contact: Betty Cory
Phone: 416-620-5236 x233
E-mail: bcory@regxia.com
Website: www.Regxia.com

Regxia is a unique scientific and regulatory consulting firm servicing the pharmaceutical and biotech industries. With a primary focus of collaborating with our customers, we provide knowledge, experience and innovation. Regxia - Your partner throughout all phases of development and marketing.

Research Across America — Booth 1540

Contact: Mary A. Raines, Director of Business Development
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E-mail: mraines@researchacrossamerica.com
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Research Across America is an Independent Site Network-ISN (Non-SMO) with 6 regional multi-specialty sites located in Dallas, TX, El Paso, TX, Suburban Houston-Katy, TX, New York, NY, Reading/Lancaster, PA, and their surrounding areas. The physicians affiliated with Research Across America have conducted over 1300 clinical trials since 1989.

ResearchDx, LLC — Booth 1238

Contact: Hal J. Mann
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Website: www.ResearchDx.com

ResearchDx is a Contract Diagnostics Organization (CDO) – a CRO specializing in diagnostics/companion diagnostics development services. We offer the full range of development services from overall program plans, through assay discovery & validation, project management, site selection & management, monitoring, FDA submission and cGMP manufacturing.

ResearchPoint — Booth 1714

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E-mail: rshipley@researchpoint.com
Website: www.researchpoint.com

ResearchPoint is a full-service (CRO) providing drug,device and biologic development services worldwide. With expertise spanning all major therapeutic areas, ResearchPoint delivers a unique blend of an experienced team, combined with the creativity, responsiveness, and customer focus of a highly nimble organization.

Rho, Inc. — Booth 301

Contact: Joan Parks
Phone: 919-408-8000
E-mail: joan_parks@rhoworld.com
Website: www.rhoworld.com

Rho is a CRO that provides a full range of services across the drug development process. For 26 years, Rho has been a trusted partner to leading pharma, biotech, and medical device companies, as well as academic and government organizations. Our commitment to excellence, innovation, and expertise leads to an exceptional customer experience.

RPS, Inc. — Booth 1449

Contact: Jessica Friendy
Phone: 215-540-0700
E-mail: jfriendy@rpsweb.com
Website:

RPS, The Next Generation CRO, provides comprehensive global Phase I-IV clinical development solutions to the pharmaceutical, biotechnology and medical device industries.

RWD Technologies — Booth 2009

Contact: Mike Yamarik
Phone: 410-869-7094
E-mail: MYamarik@RWD.com
Website: www.rwd.com

RWD's focus is to assist its clients operationalize their business strategies and transform their knowledge workers. In the pharmaceutical industry, RWD's infoMaestro™ solution enables rapid access and delivery of Regulated or Time-Sensitive Information across an enterprise. Employees can better author, manage, and distribute information.

Rx Trials, Inc.
Booth 1723

Contact: Anne-Marie Baughn, RN MSN
Phone: 410-465-2455
E-mail: anne-marie.baughn@rxtrialsinc.com
Website: www.rxtrialsinc.com

RxTrials is an elite Investigative Site Network comprised of private physician practices, clinics, and hospitals. Since1994, our inpatient and outpatient sites have successfully completed over 1,000 clinical research studies with more than 100 Sponsors and CRO's. We set the standard for quality in study coordination and site management services.

RxLogix Corporation
Booth 1764

Contact: Raj More
Phone: 949-362-1247
E-mail: raj.more@rxlogix.com
Website: www.rxlogix.com

RxLogix is the foremost provider of business advice and technology services for Safety and Pharmacovigilance.We our domain experts and will bring experience of best practices across all areas.We understand the Business and technology challenges,our solutions will allow you to implement,upgrade and validate your systems faster and at lower cost.

SAS Institute Inc.
Booth 1349

Contact: Miriam Norris
Phone: 919-677-8000
E-mail: tradeshows@sas.com
Website: www.sas.com/dia

SAS is the leader in business analytics software. For 34 years, SAS® has helped the life sciences industry accurately analyze research, clinical and business data. SAS is the industry standard and choice for 100 percent of biopharmaceutical companies on the FORTUNE Global 500®. Since 1976, SAS has given customers THE POWER TO KNOW®. www.sas.com/dia

Schlafender Hase GmbH
Booth 1363

Contact: Sabine Altenhoener
Phone: +1 973 685-6123
E-mail: dia@sh-p.de
Website: www.text-verification.com

The Text Verification Tool (TVT) developed by Schlafender Hase GmbH is the global standard solution in computer-driven proofreading. It helps global pharmaceutical leaders save time, money, improve quality, avoid embarrassment and legal costs that can result from avoidable mistakes. Especially suited for SPL and PIM files.

Schulman Associates IRB
Booth 508

Contact: Stephanie Pyle
Phone: 513-761-4100
E-mail: BusinessDevelopment@sairb.com
Website: www.sairb.com

Schulman Associates IRB has been a leading provider of review services in the US and Canada since 1983. Schulman is AAHRPP accredited and has an unparalleled FDA audit history. Through our industry-leading suite of e-tools and reputation for quality, we've helped define the expectations. Now we're redefining the experience.

SDL
Booth 549

Contact: Liz Grotzke
Phone: 781-464-6249
E-mail: egrotzke@sdl.com
Website: www.sdl.com

SDL is the leader in Global Information Management which enables companies to engage with their customers throughout the customer journey across languages, cultures and channels. SDL solutions drive down the cost of content creation, management, translation and publishing. It has a global infrastructure of more than 60 offices in 35 countries.

Sentrx
Booth 1235

Contact: Janice Scheider
Phone: 973-812-7575
E-mail: janice.scheider@sentrx.com
Website: www.sentrx.com

We are drug safety experts focused in safety technology, adverse event management and medical affairs. Our solutions are customized, integrated and scalable. Our experience is unmatched serving bio-pharmaceutical clients, including CROs. To learn more about Sentrx, visit our new website at www.sentrx.com

SGS Life Science Services
Booth 1309

Contact: Ronald Baker
Phone: 1-877-677-2667
E-mail: clinicalresearch@sgs.com
Website: www.sgs.com/CRO

SGS is a leading contract service organization providing clinical research services, analytical development, biologics characterization, and quality control testing, serving pharma, biopharma, and medical device manufacturers. SGS Life Science Services is truly global with approximately 1,250 employees, located in 25 facilities, in 14 countries.

Sharp Corporation
Booth 2023

Contact: Bob Macadangdang
Phone: 610-366-8784
E-mail: bob.mac@sharpcorporation.com
Website: www.sharpcorporation.com

Sharp is a market leader in customer focused solutions in contractpackaging services to the pharmaceutical and allied industries. For more than 80 years, pharmaceutical, personal care and nutraceutical companies worldwide have trusted the name Sharp Corporation for timely, innovative contract packaging solutions.

SIRO Clinpharm
Booth 355

Contact: Aniruddh Patwardhan
Phone: +91-22-2584 8000
E-mail: aniruddh.patwardhan@siroclinpharm.com
Website: www.siroclinpharm.com

SIRO is a full service CRO offering services to Bio-Pharmaceutical and Medical Devices sectors in compliance with ICH-GCP standards. The company has offices in India, Malaysia, USA, Israel and in France, Germany, Romania, Estonia, Greece, Czech Republic and Spain with strategic alliances in South Korea and Taiwan for Clinical Operations.

Small Planet Meetings Ltd
Booth 1457

Contact: Sarah Dye
Phone: +44 0- 1628 478325
E-mail: sarah.dye@smallplanetmeetings.com
Website: www.smallplanetmeetings.com

Small Planet has over 15 years experience within event management, delivering engaging and motivational events for the pharmaceutical industry; we specialise in Investigator Meetings, and other events include internal sales conferences, CRA training, advisory boards and steering meetings.

An experienced event planner required? Come and see us!

Smith Hanley Consulting Group, an inVentiv Clinical company
Booth 1041

Contact: Roger Whiteman
Phone: 800-684-9921
E-mail: smithhanleyjobs@smithhanley.com
Website: www.smithhanleyconsulting.com

Founded nearly 30 years ago and with 12 offices throughout the United States, Smith Hanley Consulting Group is a specialized services organization offering recruiting, consulting, outsourcing and related services to pharmaceutical, life sciences, financial and marketing services organizations.

SNBL Clinical Pharmacology Center — Booth 226

Contact: Cheryl Duggan
E-mail: cduggan@snbl-cpc.com
Website: www.snbl-cpc.com
Phone: 410-706-8960

SNBL-CPC is a 96-bed Phase I facility focused on supporting complex, multifaceted, early stage clinical development programs. Experienced with multiple trial designs including First in Human, DDI, Infection challenge, PK/PD, POC, ADME, tQT, healthy normal volunteers. Our units features accredited clinical lab, Pharmacy with certified clean room.

Soltex Consulting — Booth 1015

Contact: Christie Mahoney
E-mail: info@soltexconsulting.com
Website: www.soltexconsulting.com
Phone: 609-955-3516

Soltex Consulting advises our clients on driving efficiencies throughout the clinical trial lifecycle. Soltex employs an innovative framework to analyze business problems-examining them through the lens of People, Processes and Technology. We then recommend value-driven strategies and implement solutions to tackle our clients' most critical issues.

Sonic Clinical Trials — Booth 1459

Contact: Paullette Azar-Tannous
E-mail: pazar@sonicclinicaltrials.com
Website: www.sonicclinicaltrials.com
Phone: +61 2 9855 6000

Sonic Clinical Trials (SCT) is a subsidiary of Sonic Healthcare; one of the world's largest medical diagnostic companies. SCT is a dedicated central laboratory with over 15 years clinical trials experience. SCT provides a superior and flexible central laboratory service to the pharmaceutical and biotech industries across the Asia Pacific region.

Southern Star Research Pty Ltd — Booth 1567

Contact: Dr David Lloyd
E-mail: david@southernstarresearch.com
Website: www.southernstarresearch.com
Phone: +61 417 248 350

Southern Star Research is an Australian CRO, dedicated to providing a high quality of service and always aiming to exceed our client's expectations. Pharmaceutical & Medical Device expertise. Services include; Project Management, Monitoring, Patient recruitment, Local safety reporting, local study regulatory sponsorship & Medical Monitoring.

Sparta Systems — Booth 1137

Phone: 732-203-0400
E-mail: info@spartasystems.com
Website: www.spartasystems.com

Sparta Systems, Inc. is the industry leader for global quality and compliance management systems. Its TrackWise product is a web-based software application used by quality, manufacturing, and regulatory affairs professionals to manage quality and compliance issues across the enterprise.

Spaulding Clinical — Booth 1905

Contact: Kathy Forde
E-mail: Kathy.Forde@spauldingclinical.com
Website: www.spauldingclinical.com
Phone: 414-303-1912

Spaulding Clinical, a Phase I, Data Management, and Cardiac Core Lab solutions company, offers a full range of global services integrating state-of-the-art technology including our new Spaulding IQ electrocardiograph. Our comprehensive approach to data integration eliminates errors and speeds data, in a way that the industry has never seen before.

Spectra Clinical Research — Booth 1822

Contact: Charles Keyes
Phone: +1 201-767-2349 / +1-800-517-7157
E-mail: sales.spectraclinicalresearch@fmc-na.com
Website: www.spectraclinicalresearch.com

As a global provider of central laboratory services, Spectra Clinical Research is backed by over a decade of clinical trial expertise and nearly 30 years of central laboratory experience in renal disease. We support diverse clinical trials of all sizes – making each trial and each patient our highest priority.

SRA Global Clinical Development — Booth 515

Contact: Kim Borchert
E-mail: kim_borchert@sra.com
Website: www.sra.com/cro
Phone: 919-544-8500

SRA Global Clinical Development is a full-service, global CRO with extensive expertise in every phase of the development process and across multiple therapeutic areas. We specialize in working with small to mid-size companies to help them plan for and effectively navigate any or every step of the development process.

Statistics & Data Corp. (SDC) — Booth 537

Contact: Jim Townsend
E-mail: jtownsend@sdcclinical.com
Website: www.sdcclinical.com
Phone: 480-632-5468

SDC is focused on delivering superior biostatistics and data management services to the life sciences industry. SDC combines deep functional expertise and gold standard technology to provide total quality assurance, risk mitigation, and rapid study execution from proof of concept through post-approval.

STATKING Clinical Services — Booth 1826

Contact: Jeff Osterhaus
Phone: 513-858-2989 Ext- 329
E-mail: jeff@statkingconsulting.com
Website: www.statkingconsulting.com

Since 1989, STATKING Clinical Services has provided strategic protocol development and data related services (Biostatistics, Data Management, Clinical Monitoring, Medical Writing, Project Management and Clinical Trial Management) for clinical trials performed to obtain regulatory approval of new pharmaceutical and medical device products.

StatWorks, Inc. — Booth 1038

Contact: Mark Morrison
E-mail: mark.morrison@statworks.net
Website: www.statworks.net
Phone: 919-237-4311

StatWorks is a full service CRO located in Research Triangle Park, NC. We offer Biostatistics, Data Management, Medical Writing, Project Management, EDC, Clinical Monitoring, and other drug development services. Our 14 year history of excellent service and quality has allowed us to grow organically through customer referrals and repeat business.

Stiris Research Inc. — Booth 1139

Contact: Julie Stover
E-mail: jstover@stirisresearch.com
Website: www.stirisresearch.com
Phone: 519-652-5327

Stiris Research is a client focused CRO specialized in providing highly experienced Project Management and Monitoring professionals to conduct Phase I-IV clinical trials across North America. Stiris delivers highly efficient, cost effective solutions to outsourcing - designed to meet the individual needs of our clients in this changing environment.

Strata Company
Booth 229

Contact: Kurt Wagner
Phone: 610-941-6100
E-mail: kwagner@gostrata.com
Website: www.gostrata.com

Strata Company meets the special needs of the pharmaceutical clinical research industry by providing print and distribution of Case Report Forms as well as training, education and recruitment support materials. Strata offers an online campaign and document management system, StrataTracks (R), for clinical drug trials and direct marketing programs.

Symbio LLC
Booth 401

Contact: Betsey Zbyszynski
Phone: 619-955-8926
E-mail: bzbyszynski@symbioresearch.com
Website: www.symbioresearch.com

Symbio is a full-service CRO with the expertise in dermatology. Since 2002, we have a proven track record of successfully managing Phase I-IV clinical trials. By partnering with our Sponsors, we are involved with strategic planning throughout the entire product development cycle.

Synapse Labs Private Limited
Booth 458

Contact: Dr. Ravindra Bhavsar
Phone: +91-020-27014555
E-mail: ravindrabhavsar@synapselabs.com
Website: www.synapselabs.com

Synapse Labs is a Contract Research Organization offering a range of services to the Pharmaceutical and Biotechnology industry. Following services are offered: Bioavailability/Bioequivalence Studies, Pharmacodynamic Studies, Therapeutic Equivalence Studies for generic products, Phase II-IV clinical trials, Clinical Data Management and Biometrics.

Synchron Research Services Pvt. Ltd.
Booth 267

Contact: Mr. Piyush Pandya
Phone: +91 9909966342
E-mail: piyush@synchronresearch.com
Website: www.synchronresearch.com

Synchron is a leading Indian CRO based in Ahmedabad with an outstanding reputation.Synchron provides a complete spectrum of services in clinical research. We offer Phase I to IV clinical trials. Bioequivalence, bioavaibility ,data management , glucose clamp studies , dermatological studies like dermatopharmatokinetic and skin blanching studies.

Synergy Research Group
Booth TBD

Contact: Anna Ravdel
Phone: +1-401-884-2071
E-mail: ravdel@synrg-pharm.com
Website: www.synrg-pharm.com

Synergy Research Group (SynRG™) is a Russian CRO successfully assisting pharmaceutical and biotechnology companies, as well as global CROs to conduct clinical trials in Russia and other CIS countries. SynRG is a client-oriented company - through close cooperation we eliminate territorial issues and work proactively to ensure success of the project.

Synowledge Drug Safety Solutions
Booth 113

Contact: Sam Stein
Phone: 1-203-504-2561
E-mail: samuel.stein@synowledge.com
Website: www.synowledge.com

Synowledge is a global provider of drug safety and Pharmacovigilance services and related IT solutions to pharmaceutical and biotechnology companies. We offer end-to-end pharmacovigilance services, including compliance assessments, audit readiness, business process improvement, offshore/onshore case management, and signal surveillance.

Synteract, Inc.
Booth 1201

Contact: Ali Sadighian
Phone: 760-268-8019
E-mail: asadighian@synteract.com
Website: www.synteract.com

Established in 1995, Synteract is a privately held, full-service contract research organization, dedicated to meeting the clinical needs of biotechnology, medical device, and pharmaceutical companies. The company's mission is to provide high quality personal service, working closely with our sponsors as though a department within their company.

TAKE Solutions Inc.
Booth 127

Contact: Shalini Daga
Phone: +1-479-273-1295
E-mail: shalini.daga@takesolutions.com
Website: www.takesolutions.com

TAKE is a global business & technology solutions company with domain excellence in Life Sciences.TAKE has software products and deep domain expertise in the areas of R&D, commercial applications and operations. Presence in 8 countries. CMMI Level 5, PCMM Level 3 certified. 150+ Fortune-1000 customers. Gold Partners of Microsoft, Oracle & SAP BO.

Target Health Inc
Booth 1464

Contact: Warren Pearlson
Phone: 212- 681-2100
E-mail: WPearlson@TargetHealth.com
Website: www.TargetHealth.com

Target Health Inc., is a full service e*CRO with expertise in Regulatory Affairs, Project and Data Management, EDC, Biostatistics, Medical Writing, Strategic Planning and Clinical Trial Software. There are 19 approved products that used Target e*CRF for their pivotal trials. Other software products include Target Document, Target e*CTMS, et al.

Tarius
Booth 1004

Contact: Eva L. Petersen
Phone: 4540552300
E-mail: elp@tarius.com
Website: www.tarius.com

Tarius Web Portal provides easy answers to global regulatory FAQ's.

In need of Human Drugs, Biologics, Medical Device, IVD, Combination Product regulatory information? Tarius 'one-stop solution' consolidates your selection among 75+ countries into one web portal available for all staff members.

It's "Google-like", hassle-free and updated daily.

Tata Consultancy Services
Booth 260

Contact: Vikrant Gaikwad
Phone: 732-874-2068
E-mail: vikrant.gaikwad@tcs.com
Website: www.tcs.com

TCS is a Leader in Drug Development Services with global delivery capabilities, domain expertise, highly skilled workforce & quality standards. Our services include Clinical Data Management, Biostatistics, Medical Writing & Pharmacovigilance with over 1800 associates globally working in the Drug Development Programs of Leading Pharma Companies.

TecHorizon
Booth 429

Contact: Silvio Severini
Phone: +39 0458222811
E-mail: silvio.severini@techorizon.com
Website: www.techorizon.com

TecHorizon is a full technology service provider supporting the pharmaceutical, medical device and biotechnology industry supplying advanced solutions & services integrating people, process and technology. Information technology providers can also make use of TecHorizon's experience and expertise in enhancing their business processes.

Techsol Corporation — Booth 256

Contact: Fahd Khan
Phone: +91 - 8886035847
E-mail: fahd.khan@techsolcorp.com
Website: www.techsolcorp.com

Techsol Corporation is a Global Technology Service provider for Life Sciences, Pharmaceutical, Biotechnology, CRO and Healthcare industries. We are certified Gold Partner of Oracle health sciences and provide support on full range of Clinical Development, Safety/Pharmacovigilance and Healthcare Analytics technology services to the global companies.

TechTeam Global — Booth 244

Contact: Guido Roumans
Phone: +32 2 706 25 11
E-mail: eclinical@techteam.com
Website: www.techteam.com

TechTeam specializes in global, multilingual IT outsourcing services for eClinical trials. TechTeam's 'one-stop-shop' model helps Pharmaceutical and Biotech companies conduct clinical trials across the globe.

TekVault Corporation — Booth 2011

TFDA/Center for Drug Evaluation, Taiwan — Booth 1416

Contact: Dr. Wallace Lin
E-mail: wallacelin@cde.org.tw
Website: www.cde.org.tw and www.fda.gov.tw

Center for Drug Evaluation and Taiwan Food and Drug Administration (TFDA), regulatory agencies, review investigational new drug, new drug application, investigational device exemption, pre-market approval, and provide health technology assessment, consultation and regulatory science on the regulation of medicinal products.

That's Nice LLC — Booth 462

Contact: Katie Bartasevich
Phone: 2123664455
E-mail: katie@thatsnice.com
Website: www.thatsnice.com

That's Nice is our parent business and has provided full service brand and marketing management with value-added business support for over 15 years.

Therapak Corporation — Booth 1530

Contact: Arbi Harootoonian
E-mail: arbih@therapak.com

Therapak provides 3rd party kit assembly and logistics solutions to pharmaceutical and laboratory organizations. Therapak's menu of services include assembly of lab convenience kits for collection of samples, temperature sensitive shipping systems, requisition and label printing and ancillary supply distribution direct to sites on a global basis.

Therapeutics Inc — Booth 839

Thomson Reuters — Booth 1617

E-mail: scientific.lifesciences@thomsonreuters.com
Website: science.thomsonreuters.com

Thomson Reuters is the world's leading source of intelligent information for pharmaceutical and healthcare professionals, supported by the world's most trusted news organization. Our solutions provide life science professionals the tools to make informed, early decisions to manage and support drug discovery, development and partnering activities.

ThreeWire, Inc. — Booth 1807

Contact: Mark Summers
Phone: 952-852-5555
E-mail: msummers@threewire.com
Website: www.threewire.com

ThreeWire is a patient recruitment, enrollment and management provider focused on accelerating patient recruitment and enrollment for the medical device, pharmaceutical, and biotech industries. We utilize a proven, flexible, systematic approach with predictable and measurable outcome-based strategies backed by performance-based pricing.

TIBCO Software Inc. — Booth 263

Contact: Ben McGraw
Phone: 617-702-1536
E-mail: bmcgraw@tibco.com
Website: spotfire.tibco.com

From early stage discovery to clinical development to marketing and sales force optimization, Spotfire helps the world's leading pharmaceutical, medical device, and biotech companies discover new therapeutics, develop their pipeline of assets, launch their drugs to the market, and align marketing and sales campaigns.

TKL Research, Inc. — Booth 1034

Contact: Reid Tripp
Phone: 201-5878-0500
E-mail: rtripp@tklresearch.com
Website: www.tklresearch.com

TKL Research,Inc. is a full-service, International CRO providing comprehensive clinical trial management services for Phase 1-4 trials. We offer an inpatient Phase 1 facility and specialized outpatient research clinics. Since 1944, TKL continues to deliver the highest level of clinical services to clients in Pharmaceutical and Healthcare markets.

Total Root Concepts, Inc. — Booth 1803

Contact: Jennifer Lansink
E-mail: info@TotalRootConcepts.com
Website: www.TotalRootConcepts.com

Total Root Concepts is a training and communications company providing Investigator Solutions for more effective program delivery. This includes: Face-to-Face & Online Investigator Meetings, Regional Update Meetings, Study-Specific Websites, eLearning, & DVD creation. With Total Root Concepts, we create a different message to drive BETTER results!

TrainingCampus.com — Booth 540

Contact: Al O. Pacino II
Phone: 512-302-3113
E-mail: alpacino@trainingcampus.com
Website: www.TrainingCampus.com

TrainingCampus.com is the first global Education Management Network. An aggregator/consolidator of resources used by healthcare/clinical researchers. Members of our network use our FREE Cloud-Based Education Management Systems in order to develop-deliver-track and document training and education activities for compliance to over 250k network users.

TransPerfect — Booth 1835

Contact: Ryan Simper
Phone: 212-689-5555
E-mail: rsimper@transperfect.com
Website: www.transperfect.com

TransPerfect leads the way in life sciences language services and solutions. Our next-generation approach centers around innovation, combining cutting-edge workflow technologies with the industry's only quality management system fully certified to EN 15038:2006 and ISO 9001:2008. When it comes to clinical development, we speak your language.

Trident Clinical Research — Booth 1114

Contact: Karen West
Phone: +61 0- 08 8447 3500
E-mail: kwest@tridentclinicalresearch.com
Website: www.tridentclinicalresearch.com

Trident is a full service CRO with diverse therapeutic experience and a reputation as a leading provider of contract clinical research services unparalleled by any other CRO in the region. With offices in Australia, New Zealand and India we can provide high quality, low cost solutions for your requirements.

Trifecta Multimedical — Booth 1755

Contact: Dax Kiger
Phone: 310-385-8642
E-mail: dax.kiger@trifectamultimedical.com
Website: www.trifectamultimedical.com

Trifecta Multimedical is a global provider of solutions specifically designed to address challenges in clinical trials. We accelerate studies while delivering significant cost savings to study sponsors, CROs and clinicians. Our services have a proven track record of increasing the quality, consistency and power of clinical trials.

Trio Clinical Resourcing — Booth 917

Contact: Betsy Brown
Phone: 919-401-1800
E-mail: info@trioclinicalresearch.com
Website: www.trioclinical.com

Trio Clinical Resourcing, an Aptiv Solutions company, is a clinical resourcing company supporting the pharmaceutical, biotechnology and medical device industries in their quest to bring novel products to the market. Trio provides clinical research resourcing services across a wide-range of therapeutic areas in Phase I-IV clinical research.

TTC, llc — Booth 803

Contact: Michael Shaub
Phone: 215-243-4136
E-mail: mshaub@ttc-llc.com
Website: www.ttc-llc.com

TTC, headquartered in Philadelphia and founded by Dr. Harold Glass, offers the largest current database of investigator budgets from 60 countries. TTC carries five distinctive products that deliver state of the art cost benchmarking tools. TTC stands ready to serve all companies with specific programs tailored to meet their customized requirements.

United BioSource Corporation — Booths 911 & 1011

Contact: Suzanne Conlon
Phone: 781-960-0304
E-mail: suzanne.conlon@unitedbiosource.com
Website: www.unitedbiosource.com

United BioSource Corporation is a global scientific and medical affairs organization that partners with life science companies to develop and commercialize their products.

We help generate authoritative, real-world evidence of product effectiveness, safety and value to assist health care decisions and enhance patient care.

unithink — Booth 1717

Contact: Mark Hutson, MSEd, VP, Business Development, North America
Phone: +1-224-372-7271
E-mail: mark.hutson@unithink.com
Website: www.unithink.com

unithink creates innovative eClinical technologies that encompass all aspects of clinical research, from site support to data submission. unithink's state-of-the-art solutions enable global clients to make critical decisions faster, while nurturing and progressing their partners. unithink has offices in Belgium, India, Germany and the U.S.

University Hospital Clinical Trial Alliance (UHCT Alliance) — Booth 441

Contact: Toshikazu Goto
Phone: +81-3-5800-8752
E-mail: uhctalliance-office@umin.net
Website: plaza.umin.ac.jp/UHCTA

The University Hospital Clinical Trial Alliance was established in 2006 to promote global trials in Japan. It consists of seven leading national university hospitals in the heart of Japan with more than 3,000 MDs including many academic leaders in Japan, 6,000 beds and 14,000 outpatients per day. The office is in The University of Tokyo Hospital.

University of Florida, Center for Clinical Trials Research — Booth 1106

Contact: Robert D. Thompson, CCRC
Phone: 352- 273-5500
E-mail: thomprd@ufl.edu
Website: www.med.ufl.edu/cctr

A University (ARO) Academic Research Organization with a 48-bed Phase I Unit that is radioactive licensed and telemetry equipped. The Center prides itself in conducting quality, difficult Phase I Trials in all therapeutic specialties in a timely, cost-effective, innovative manner for Pharmaceutical, CRO's, Biotechnological and Industry Sponsors.

University of Iowa Pharmaceuticals — Booth 557

Contact: Randhall Yeates
Phone: 319-335-8674
E-mail: randhall-yeates@uiowa.edu

Our technical advisors have a wide range of experiences in the formulation development of small molecules, proteins, and vaccines. Let us help take your molecule from discovery into Pre-clinical and clinical evaluation.

University of the Sciences — Booth 117

Contact: Chris Miciek
Phone: 2155968597
E-mail: c.miciek@usp.edu

Founded in 1821 in Philadelphia, University of the Sciences is a private, coeducational institution that focuses on advancements in applied health, pharmacy, and natural sciences. USciences has launched and enhanced thousands of successful careers. Plus, six of the leading pharmaceutical companies were founded by university graduates.

the Uppsala Monitoring Centre — Booth 1425

Contact: Mats Persson
Phone: 4618656344
E-mail: sales@umc-products.com
Website: www.umc-products.com

The Uppsala Monitoring Centre's main product WHO Drug Dictionary Enhanced is used globally for coding and analyses of concomitant medication data collected in Clinical Trials & Drug Safety Operations. We are now introducing a Chinese Drug Dictionary and a Japanese Cross reference table, come to our booth for a demonstration.

Utah Clinical Trials, LLC — Booth 553

Contact: Charles Arena, M.D.
Phone: 801-268-1610
E-mail: carena@utahclinicaltrials.com
Website: www.utahclinicaltrials.com

Utah Clinical Trials is a privately owned and independently operated corporation that conducts pharmaceutical and device trials with private investigators.

Our excellent location enables us to work with a number of local specialists to ensure maximum results in all of our clinical research trials.

Veeva Systems — Booth 813

Contact: Christine Myers
Phone: 925-452-6500
E-mail: christine.myers@veevasystems.com
Website: www.veevasystems.com

Veeva Systems is the leader in cloud-based business solutions for the global life sciences industry. Veeva Vault, our regulated content management application works in the cloud to enable organizations of all sizes to find content quickly, share with partners easily, adapt to change rapidly, and maintain regulatory compliance. www.veevavault.com.

Veridex, LLC — Booth 1829

Contact: Peggy Robinson
E-mail: PRobins2@its.jnj.com
Website: veridex.com

Veridex's Clinical Research Solutions provide tools and services that may be used for the selection, identification and enumeration of targeted rare cells in peripheral blood for the identification of biomarkers, aiding scientists in their search for new, targeted therapies.

Veristat — Booth 223

Contact: Cindy Henderson
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E-mail: cindy.henderson@veristat.com
Website: www.veristat.com

Veristat is a full service CRO with expertise in supporting clinical trials and regulatory submissions for pharmaceutical, biotechnology, and medical device and diagnostic companies. Veristat has extensive therapeutic area expertise in particular in the areas of oncology, anti-infectives, vaccines, and diagnostics and is an RSP for CDISC services.

Virtify, Inc. — Booth 443

Contact: Deeksha Taneja
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Website: www.virtify.com

Virtify is the market leader in Structured Content Management software solutions for life sciences. Organizations rely on Virtify software suite to reduce costs, mitigate risk, and accelerate time-to-market by managing and automating the complex regulatory compliance and content exchange requirements throughout the product life cycle.

Virtual Clinical Solutions, Inc. — Booth 609

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E-mail: djackson@virtualclincial.com
Website: www.virtualclinical.com

Virtual Clinical Solutions (VCS) has over 11 years experience working with the Pharmaceutical and Biotech Industry delivering virtual training to investigational sites and study teams. VCS has supported over 500 clinical studies and worked with over 30,000 investigational sites in over 65 countries.

VirtualScopics — Booth 1229

Contact: Chris Gilman
Phone: +1-585-249-6231
E-mail: chris_gilman@virtualscopics.com
Website: www.virtualscopics.com

VirtualScopics is a leading imaging core lab providing central reads and quantitative imaging solutions for drug and medical device clinical trials. Therapeutic area expertise includes: oncology, musculoskeletal, neurology,cardiovascular and medical devices utilizing MRI, PET, CT, Ultrasound, DEXA, Bone Scans and X-Ray imaging modalities.

Vitalograph — Booth 1329

Contact: Lewis Weidman
Phone: +1-913-888-4221
E-mail: lewis.weidman@vitalograph.com
Website: www.vitalograph.com

We provide innovative EDC solutions in respiratory clinical trials:

1. Spirotrac® Centralized Spirometry
2. NEW In2itive e-Diary for ePRO solutions
3. Integrated Spirometry, Diary and FeNO
4. VIEWER web portal
5. VitaloJAK Cough Monitor

Currently providing our services in global Phase II, III, and IV studies with regular repeat business

WCI Consulting Limited — Booth 1656

Contact: Kate Derham
Phone: +44 0- 2392 268133
E-mail: kate.derham@wcigroup.com
Website: www.wcigroup.com

Founded in 1986, WCI is the leading Life Science consulting practice focusing on Patient Safety, Risk Management, and Quality and Compliance. We have worked with over 50 pharmaceutical, biotechnology, consumer health, medical device, and dietary supplement organisations; helping to implement solutions which assure compliance and boost performance.

WebbWrites, LLC — Booth 730

Contact: Stephanie Dedrick
Phone: 919-384-8850
E-mail: dedrick@webbwrites.com
Website: www.webbwrites.com

Extensive experience in regulatory document preparation, ability to provide statistical consulting services, and provision of superior products due to continuity of personnel, flexibility to work onsite with clients, unsurpassed customer service, and capacity to meet aggressive timelines. WebbWrites has prepared more than 66 NDAs in 13 years.

WebWise Learning, Inc. — Booth 504

Contact: Marge Krohn
Phone: 952-883-0800
E-mail: marge.krohn@webwiselearning.com
Website: www.webwiselearning.com

WebWise Learning brings extensive industry knowledge together with instructional design experience and technology expertise to develop effective interactive online learning and job support tools for the pharmaceutical, biotech, medical device, and healthcare industries. We offer off-the-shelf, customizable, and custom company-specific solutions.

WellCRO — Booth 261

Contact: Denis COMET, MD
Phone: +33 0-1 56 38 21 50
E-mail: dcomet@axonal.fr
Website: www.wellcro.com

WellCRO is one of the best international CRO supplier for a real global reach with responsiveness, flexibility, quality and cost-effectiveness. WellCRO has a deep expertise in specialised fields and provides a highly qualified work thanks to their experienced teams. WellCRO is "the best local expertise for everyone everywhere!".

West Coast Clinical Trials — Booth 804

Contact: Talia Nikolao
Phone: 714-252-0700
E-mail: mgr@wcct.com
Website: www.wcct.com

WCCT is a full service early development CRO with 2 locations in Orange County, California. We provide regulatory support for IND filing, drug development planning, clinical study execution, project management, back-end data management and report services. We focus on healthy volunteer trials as well as special populations.

Western Institutional Review Board (WIRB) — Booth 435

Contact: Linda Morrison, Vice President, Marketing/Client Development
Phone: 360-252-2443
E-mail: lmorrison@wirb.com
Website: www.wirb.com

At the forefront of human research safety for over 40 years, the Western Institutional Review Board (WIRB) continues to deliver leadership, proven expertise and quality services to Researchers worldwide. WIRB was the first independent IRB to be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Whitsell Innovations, Inc. — Booth 2039

Wipro Technologies — Booth 212

Contact: Philip Wentworth
Phone: 203-832-5301
E-mail: philip.wentworth@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.

Woodley Equipment Company Ltd — Booth 1640

Contact: Sasha Lauks, Business Development Associate
Phone: +1 508- 625 1693
E-mail: sales@woodleyequipment.com
Website: www.woodleyequipment.com

Woodley Equipment Company Ltd specialise in the International rental of medical and laboratory Point Of Care equipment to the clinical trials industry. Woodley have been providing equipment solutions for over 20 years and can provide a full level of service from initial enquiry, calibration and maintenance, global training to final collection.

World Courier, Inc. — Booth 1923

Contact: Georgette Caracciolo
Phone: 516-354-2600
E-mail: contact@worldcourier.com
Website: www.worldcourier.com

With over 140 offices in 50 countries – all ISO 14001 certified- World Courier has the network, trained personnel and resources to manage the most demanding research project, biologic , or pharmaceutical shipment.

Worldwide Clinical Trials Drug Development Solutions — Booth 1511

Contact: Emilio Cordova
Phone: +1 512- 834-7766
E-mail: sales@wwctrials.com
Website: www.wwctrials.com

Worldwide Clinical Trials Drug Development Solutions is ready to be a vital part of your drug development program, from preclinical and bioanalytical analysis to late-phase (Phase I–IV) clinical trials by combining modern clinical research and state-of-the-art bioanalytical work with a direct link to our Worldwide Clinical Trials global sites.

WriteResult — Booth 1367

Contact: Peter Oudheusden
Phone: 908- 272-4787
E-mail: info@writeresult.com
Website: www.writeresult.com

Patient & Physician Reported Outcomes ePRO for global Clinical Trials using only the most intuitive technologies. WriteResult is a full-service provider of ePRO; we work with you from draft protocol to db lock and promise to exceed your expectations for Rapid Startup, Proactive Data Management, and Timely DB Lock. Put it in Writing to get Results.

XClinical GmbH — Booth 1906

Contact: Dr. Philippe Verplancke
E-mail: info@xclinical.com
Website: www.xclinical.com

XClinical GmbH, an innovative EDC-CDM system vendor based in Munich provides solutions for the electronic conduct of all types of clinical trials, post-marketing studies and registries.

XClinical develops and markets MARVIN, a CDISC ODM-certified online platform for Electronic Data Capture, Clinical Data Management and Clinical Trial Management.

XERIMIS INC. — Booth 622

Contact: Kevin Clover, Business Development Executive
Phone: 215-794-1817
E-mail: kevin.clover@xerimis.com
Website: www.XERIMIS.com

GLOBAL CLINICAL PACKAGING SERVICES for pharmaceutical/ biotech firms & CRO's of all sizes. Customized Primary & Secondary Clinical Packaging - Project Management - Monitoring & Distribution Services - Returns & Accountability Services. DEA Schedule III-V Capabilities. Quality and customer service is our primary focus. YOUR PROJECT-YOUR TIMELINE

Xybion Corporation — Booth 466

Contact: Sherry Cordery
Phone: 215-638-9700
E-mail: scordery@xybion.com
Website: www.xybion.com

Xybion offers a comprehensive portfolio of solutions: Governance/Risk/Compliance, Quality Management, Preclinical R&D Data Management, Enterprise Asset Management, Content/Records Management, and Validation/Testing. Xybion's experienced professional services team helps organizations maximize performance and efficiency.

Yoh — Booth 1652

Contact: Jennifer McDonald
Phone: 919-232-2906
E-mail: jennifer.mcdonald@yoh.com
Website: yoh.com

A workforce leader since 1940, Yoh delivers superior Life Sciences staffing services and comprehensive workforce solutions to top pharmaceutical, biotechnology, medical device and manufacturing companies nationwide that drive research, development and quality in today's leading innovations. For more information, visit yoh.com.

HOTEL INFORMATION

New This Year! **ONLY attendees who book through Travel Planners** will have access to DIA courtesy shuttle buses.

PLEASE NOTE: Travel Planners is the *exclusive housing provider* for DIA 2011. Third-party providers may contact DIA 2011 attendees to book their hotel reservations. These providers may require reservations to be fully prepaid, are nonrefundable, and may be subject to steep cancellation and change fees. **If you choose to book with any provider other than Travel Planners, DIA will not be able to assist you with any issues you may encounter with the terms of a third-party agreement.**

Travel Planners is coordinating all reservations for DIA, and arrangements for housing must be made through them and NOT with the hotel directly. For best availability, **please book prior to May 31, 2011**. After this date, rooms will be available on a space-available basis until the start of the meeting. **DIA does not process hotel reservations.** Hotel reservations can be made:

- **ONLINE:** Log on to **www.diahome.org**, double click on the DIA 2011 icon and click on the Hotel Information tab. Here you will find details for making your reservation online.
- **BY PHONE:**
  +1.800.221.3531 (domestic) / +1.212.532.1660 (international)

  Please have all of the information below ready along with a credit card number and expiration date.

  - Name of convention: DIA 2011, June 19-23, 2011
  - 1st, 2nd, 3rd choice of hotel
  - Arrival/departure dates
  - Number of rooms requested
  - Type of room (single/double/triple/quad)
  - Number of group and persons in your party
  - Credit card type, account number, expiration date
  - Names of all room occupants
  - Daytime phone number and fax number
  - eMail address to which confirmation will be sent
  - Mailing address

CREDIT CARD:
Your credit card will be used as a guarantee but will not be charged immediately. The hotel may charge the deposit to your credit card on or around May 31, 2011 when they receive the reservations for processing from Travel Planners. Most major credit cards are accepted. Each hotel will honor the Travel Planners acknowledgement.

CHANGES/CANCELLATIONS:
Until June 8, 2011, all changes and cancellations should be made directly online with Travel Planners.

CANCELLATION POLICY:
Please refer to your confirmation information for specific details about the hotel's cancellation policy.

If a guest does not arrive by their scheduled arrival date, the full reservation will be cancelled by the hotel and any applicable deposit or charges will be assessed.

DIA 2011 HOTELS	Hotel Address		Single Room Rates* start at	Distance to Convention Center	Shuttle Offered †
1 Best Western Grant Park	1100 South Michigan Avenue		$139	1.5 Miles	Yes
2 Chicago Essex Inn	800 South Michigan Avenue		$164	1.5 Miles	Yes
3 Doubletree Chicago Magnificent Mile	300 East Ohio Street		$189	3.6 Miles	Yes
4 Fairmont Chicago	200 North Columbus Drive		$229	3.0 Miles	Yes
5 Hampton Majestic Chicago Theater District	22 West Monroe Street		$179	2.5 Miles	Yes
6 Hard Rock Hotel Chicago	230 North Michigan Avenue		$189	3.4 Miles	Yes
7 Hilton Chicago	720 South Michigan Avenue		$249	1.5 Miles	Yes
8 Hotel 71	71 East Wacker Drive		$199	2.5 Miles	Yes
9 Hotel Monaco Chicago, a Kimpton Hotel	225 North Wabash Avenue		$209	3.5 Miles	Yes
10 Hyatt Regency Chicago	151 East Wacker Drive		$269	3.5 Miles	Yes
11 Hyatt Regency McCormick Place	2233 South Martin Luther King Drive		$289	Adjacent	No
12 Palmer House Hilton	17 East Monroe Street		$239	2.5 Miles	Yes
13 Renaissance Blackstone Chicago Hotel	636 South Michigan Avenue		$229	2.5 Miles	Yes
14 Renaissance Chicago Hotel	1 West Wacker Drive		$229	3.0 Miles	Yes
15 Sheraton Chicago Hotel and Towers	301 East North Water Street	***Reduced Rate!***	$229 ~~$249~~	4.0 Miles	Yes
16 Silversmith Hotel & Suites	10 South Wabash Avenue		$179	3.2 Miles	Yes
17 Swissotel Chicago	323 East Wacker Drive	***Reduced Rate!***	$199 ~~$229~~	4.0 Miles	Yes
18 W Chicago Lakeshore	644 North Lake Shore Drive		$239	3.6 Miles	Yes
19 Westin Chicago River North	320 North Dearborn Street		$259	4.0 Miles	Yes

** Hotel rates do not include current tax of 15.4% or applicable surcharges; subject to change.*

† Shuttle service will be provided in the morning and afternoon only. Mid-day service will NOT be available.

HOTEL LOCATOR MAP

DIA 2011 ATTENDEE REGISTRATION FORM

47th Annual Meeting | June 19-23, 2011 | McCormick Place, West Building, Chicago, IL | Event #11001

www.diahome.org

The rates on this registration form are applicable after JUNE 3, 2011.

All registrations that were received at the DIA office in Horsham, PA, USA by 5:00 pm on May 13, 2011 were 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.**

PREREGISTRATION FEES **A surcharge of $150 has been included in the registration fees for all registrations received after June 3, 2011** (does not apply to one-day registrations). ***An email address must be included below for confirmation process.***

Attendees may register online at **www.diahome.org**

ONLINE REGISTRATION IS NOT AVAILABLE TO SPEAKERS OR EXHIBITORS.

Each paying attendee registering for any portion of this event must complete and submit this page to DIA.

All MEMBER and NONMEMBER fees below include access to ALL available postmeeting audio synchronized Power Point presentations.

TUTORIALS

Registration for TUTORIALS ONLY is not available. You must be a paid attendee, speaker, or exhibitor to register for these tutorials. Visit www.diahome.org 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 _____

MEMBER FEE — US $1500 ❑

Join DIA now to qualify for all the benefits of membership for one year! **www.diahome.org** — **US $140 ❑**

NONMEMBER STANDARD FEE** — US $1640 ❑

Nonmember fee includes access to post-meeting presentations and a one-year membership option. *Please indicate your preference below.*

❑ I **DO** want DIA membership ❑ I **DO NOT** want DIA membership

DISCOUNT FEES

	Member	Nonmember
Government (full-time) **	US $630 ❑	US $770 ❑
Charitable Nonprofit/Academia (full-time) **	US $1,025 ❑	US $1,165 ❑

** *If paying a nonmember fee, please check preferred membership option above.*
** *Includes access to post-meeting presentations.*

ONE-DAY REGISTRATION FEES †

	Member	Nonmember
You must indicate which day you plan to attend.	US $825 ❑	US $965 ❑

❑ **MON,** June 20 ❑ **TUES,** June 21 ❑ **WED,** June 22 ❑ **THUR,** June 23

† *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 $** _____

PAYMENT OPTIONS: Register online at **www.diahome.org** or complete the credit card payment information below.

❑ **CREDIT CARD**

Complete this form and fax to Drug Information Association, at **+1.215.442.6199.** Non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

❑ Visa ❑ MC ❑ AMEX Exp Date _____

Card # _____

Name (printed) _____

Signature _____

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 3, 2011.

If you do not cancel by JUNE 3, 2011 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 3, 2011 will be:

- **Full Meeting**
  Government/Nonprofit/Academia:
  Refund Amount = Registration fee paid minus $100
  All Others: Refund Amount = Registration fee paid minus $200
- **Tutorial –** Refund Amount = Registration fee paid minus $75
- **One-day Registration –** NO REFUNDS

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 47th 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 2011 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 13, 2011 will be included in the Advance Registration Attendee List.

DIA 2011
47TH Annual Meeting
McCormick Place, Chicago, IL
ID # 11001
June 19-23, 2011

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

Registration for tutorials ONLY is not available. You must be a paid attendee, speaker, or exhibitor to register for these tutorials. Visit www.diahome.org 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 _____

JOIN DIA NOW *to qualify for all the benefits of membership for one year!* **www.diahome.org** US $140 ❑

TOTAL PAYMENT DUE
Include all applicable fees **US $** _____

CANCELLATION POLICY

All cancellations must be received in writing at DIA's office by 5:00 pm, JUNE 3, 2011.

If you do not cancel by JUNE 3, 2011 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 3, 2011:

- **Tutorial –** Refund Amount = Registration fee paid minus $75

Participants with Disabilities:
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Photography Policy:
By attending the DIA 47th 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.

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.

❑ 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)**

DIA 2011

47th Annual Meeting | June 19-23, 2011
McCormick Place West, Chicago, IL | Event #11001

www.diahome.org

Already Registered? ADD TUTORIALS to Your Existing Registration

This registration form should be used by attendees, speakers, program committee members, or exhibitors who wish to add Tutorials to an existing registration. *This form must be completed and submitted for EACH preregistered person who wishes to add tutorials to their existing registration.* **Please fax this completed form to +1.215.442.6199**

❑ **YES**, I am registered for DIA 2011 and I would like to add the following tutorials 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

Registration for tutorials ONLY is not available. You must be a paid attendee, speaker, chair, or exhibitor to register for these tutorials. Visit www.diahome.org/DIA2011Tutorials for topics and fees, OR see the program pdf file at www/diahome.org.
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 $ _____

TOTAL PAYMENT DUE
Include all applicable fees US $ _____

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❑ **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 _____

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Position

Company

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Mail Stop

City State

Zip/Postal Code Country

email Address **(required for confirmation)**

Telephone Number Fax Number **(required for confirmation)**

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- **One-day Registration –** NO REFUNDS

DIA 2011

47th Annual Meeting | June 19-23, 2011
McCormick Place West, Chicago, IL | Event #11001

www.diahome.org

Already Registered? ADD A TRAINING COURSE to Your Existing Registration and SAVE $100*

This form must be completed and submitted for EACH ***preregistered paid attendee*** who wishes to add a training course to an existing DIA 2011 registration. **Please fax this completed form to +1.215.442.6199**

❑ **YES**, I am registered for DIA 2011 and I would like to add the following training course to my registration.

Please check the appropriate fee for the Training Course you wish to attend:	Early-bird Member Fee On or before MAY 27, 2011	Member Fee After MAY 27, 2011	Nonmember Fee	DISCOUNTED FEES Member Government/Academia	DISCOUNTED FEES Nonmember Government/Academia
• Clinical Project Management	$1720 ❑	$1820 ❑	$2010 ❑	$1000 ❑	$1190 ❑
• Fundamentals of Clinical Research Monitoring	**CANCELLED**				
• Introduction to Good Clinical Practices and Auditing	$1720 ❑	$1820 ❑	$2010 ❑	$1000 ❑	$1190 ❑
• Regulatory Affairs Part I: The IND Phase	$1500 ❑	$1600 ❑	$1790 ❑	$760 ❑	$900 ❑
• New Drug Product Development and Lifecycle Management	$1035 ❑	$1135 ❑	$1325 ❑	$625 ❑	$680 ❑
• Risk Management and Safety Communication Strategies	$1375 ❑	$1475 ❑	$1665 ❑	$810 ❑	$1000 ❑
• Art of Writing a Clinical Overview	$840 ❑	$940 ❑	$1130 ❑	$520 ❑	$710 ❑

Join DIA now to qualify for the early-bird fee (if applicable), and enjoy all the benefits of membership for a full year! **MEMBERSHIP FEE:** $140 ❑

**** This offer is only available to attendees who have already paid for a DIA 2011 meeting registration. The rates above do not reflect the $100 discount. Your $100 savings will appear on your Total Order Summary (Annual Meeting and Training Course).***

PAYMENT METHODS: Register online at **www.diahome.org** 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 # _____

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Zip/Postal Code Country

email Address **(required for confirmation)**

Telephone Number Fax Number **(required for confirmation)**

TRAINING COURSE CANCELLATION & TRANSFER POLICIES

On or before JUNE 5, 2011:
$200 administrative fee will be deducted.

Cancellations: Cancellations must be made by June 5 with a $200 administrative charge deducted from fee. Cancellations must be in writing and received in the DIA office by the date above. After this date, there will be no refunds. Registrants are responsible for cancelling their own hotel and travel reservations. Registrants who do not cancel prior to the course and do not attend will be responsible for the full registration fee. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants. Cancellation voids all discounts.Transfers: You may transfer your registration to a colleague at any time but membership is not transferable. Please notify the DIA North American office of such transfers in writing as soon as possible. Substitute registrants will be responsible for the nonmember fee, if applicable.

NEW FOR 2011! GROUP DISCOUNTS

Register 3 individuals from the same company for this course and receive complimentary registration for a 4th to attend this course! All 4 individuals must register and prepay at the same time – no exceptions. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

❑ Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.

1. _____
2. _____
3. _____

• **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 2011, 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.*