Governor, State of Illinois

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.
FEATURES

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

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

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

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

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

WHAT’S HAPPENING

Schedule at-a-Glance
DIA 2011 Tracks
Keynote Speaker
Plenary Sessions
Global Agency Track 16
Interoperability Showcase
Patient Fellowship Program
Networking Opportunities
Student/Professional Posters
Program Committee
Getting Around Chicago
Continuing Education Information
General Information
Meeting Schedule
Meeting Agenda
- Saturday, June 18 - Monday, June 20
- Tuesday, June 21
- Wednesday, June 22
- Thursday, June 23
Poster Presentations
Tutorial Instructors
2011 Award Winners
Speaker Index
Speaker Disclosure Statements
Exhibit Directory
- List of Exhibitors
- Exhibit Hall Floor Plan
- Exhibitor Directory
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 ShowcaseSM
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

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 ShowcaseSM
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
4:45 – 5:45 PM Interoperability Town Hall

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.

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

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.
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.

**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

**TUESDAY PLENARY SESSION**

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

**Featured Speaker:**  
Kalipso Chalkidou, MD, PhD  
NICE International, UK

**Featured Speaker:**  
Freda Lewis-Hall, MD  
Pfizer Inc.

**Featured Speaker:**  
Michael S. Lauer, MD, FACC  
Divisions of Cardiovascular Sciences, NHLBI, NIH

**Featured Speaker:**  
Steve E. Phurrough, MD, MPA  
Center For Medical Technology Policy

**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

**Featured Speaker:**  
Kalipso Chalkidou, MD, PhD  
NICE International, UK

**Featured Speaker:**  
Michael S. Lauer, MD, FACC  
Divisions of Cardiovascular Sciences, NHLBI, NIH

**Featured Speaker:**  
Freda Lewis-Hall, MD  
Pfizer Inc.

**Featured Speaker:**  
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.

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

**Chair:**  
Mitchell A. Katz, PhD  
Purdue Pharma L.P.

**Chair:**  
Craig Coffman  
Endo Pharmaceuticals

**Chair:**  
Sharon Callahan  
The Vue Group & LLNS

**Chair:**  
Stuart P. Ingis, JD  
Venable LLP

**Chair:**  
Mike Myers, MBA  
Palio, an inVentiv Health Company

**Chair:**  
Christopher M. Schroeder  
HealthCentral

**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

**Chair:**  
Sharon Callahan  
The Vue Group & LLNS

**Chair:**  
Mike Myers, MBA  
Palio, an inVentiv Health Company

**Chair:**  
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: W185c)
#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:
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.

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.

NEW EXPERIENCES

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.
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.

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:

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.
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.
PROGRAM COMMITTEE

John Aitken, PhD  
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Teresa Ancukiewicz, MA  
Boston Scientific Corporation

Solomon Babani, MBA  
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Jeffrey Litwin, MD  
ERT

Sandra Milligan, MD, JD  
Amgen Inc.

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

Kris Walters, PhD, MS  
University of North Carolina Wilmington

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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
EXECUTIVE ADVISORY COMMITTEE

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MedImmune

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Outcome Sciences Inc.

Alberto Grignolo, PhD
PAREXEL Consulting

Christopher Milne, DVM, JD, MPH
Tufts University

John Roberts, MBA
InfoLogix, Inc.

THANK YOU TO OUR PROGRAM COMMITTEE FOR DEVELOPING A GREAT PROGRAM!
SO MANY OFFERINGS, SO LITTLE TIME?

DIA 2011 is jam packed with valuable learning opportunities, and the size and scope of the meeting once made attending everything you wanted virtually impossible—until now.

The DIA Live Learning Center provides you with access to all the content you missed!

The LLC provides you with DIA 2011 content in digital format – WHENEVER you want it – captured live and available to you online via the DIA Live Learning Center! View the online (as released for inclusion*), captured as true multimedia recreations with synchronized slides, handouts, and much more. You can even download in MP3 format to your iPod for portable listening! Listen to a motivating, informative offering you may have missed. This is an excellent training tool and informational resource for missed content.

DIA Live Learning Center is available to full conference registrants for a period of 6 months and will not be made available to non-attendees. You must attend the meeting to take advantage of this value.

Welcome to the DIA Live Learning Center. www sof conference.com/DIA

*Workshops will not be recorded and therefore not included in the LLC.

PROVIDE YOUR FEEDBACK

DIA 2011 IS GOING PAPERLESS

New this year! DIA 2011 is going paperless and evaluating all Annual Meeting educational opportunities ONLINE via the DIA Live Learning Center (LLC)!

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. If a participant attends multiple program offerings, within the same time frame, the last scanned entry will be recorded. You will receive an email notification at the end of each day, requesting your feedback on the program offerings you attended.

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 distributed the week of July 11, 2011.

Please note: If you would like to receive continuing education credits for the Annual Meeting, your DIA name badge must be scanned at each educational offering you attend. If you do not scan your name badge within 45 minutes of each program offering start time, you will not be eligible to request the available continuing education credits.
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.


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<th>Tutorial Fee: $405.00</th>
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<td>Tutorial 21 FDA Enforcement: Understanding the Agency’s Authority, How Violations Occur, How to Prevent Them, and How to Respond if Violations Do Occur</td>
<td>See page 15 for details.</td>
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<tr>
<td>Tutorial 22 Utilizing Chemistry, Manufacturing, and Controls in Drug Development</td>
<td>See page 16 for details.</td>
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<tr>
<td>Tutorial 23 Fourteen Steps from Research to Development</td>
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<tr>
<td>Tutorial 25 A Device Primer: 510(k)s, PMAs, IDEs</td>
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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.
**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.

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**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.

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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.

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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

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.

Instructor

Barry S. Sall
Principal Consultant
PAREXEL International Corporation

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

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.

Instructor

Michael Laddin, MBA, MS
CEO
LeaderPoint, LLC

Instructor

Brenton E. James, FTOPRA
Consultant, Strategic Regulatory Affairs in the European Union, UK

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

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 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.

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 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.

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CANCELLLED

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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.

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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.

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**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.

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**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.

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**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.

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**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

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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.

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**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.

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**TUTORIAL 43  
Clinical Statistics for Nonstatisticians**

**Interest Area:** Track 1

**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.

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**TUTORIAL 44  
Who’s Monitoring the Monitor?**

**Explore Trends, Management Techniques, and a Reality Check for Sponsors Utilizing CRO- and Alliance-based Site Monitoring**

**Interest Area:** Track 1

**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.

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**CANCELLED**
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
Interactive lecture and hands-on workshop training methods will provide you with the tools you need to 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
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.
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 multinational 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
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.
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.

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.

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

**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.

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

### 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.

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<thead>
<tr>
<th>Number</th>
<th>Title of Offering</th>
<th>Track Number</th>
<th>Type of Format</th>
<th>Level of Difficulty</th>
<th>Room Number</th>
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<tbody>
<tr>
<td></td>
<td><strong>SUNDAY, JUNE 19</strong> 3:00 PM – 5:00 PM</td>
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<tr>
<td></td>
<td>STUDENT FORUM Jobs That Did Not Exist When the Old Guard Began Their Careers</td>
<td>–</td>
<td>Forum</td>
<td>LEVEL ●</td>
<td>W185a</td>
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<tr>
<td></td>
<td><strong>MONDAY, JUNE 20</strong> 8:30 AM – 10:00 AM</td>
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<td></td>
<td>OPENING PLENARY SESSION Welcome Remarks, Keynote Presentation, and Award Presentations</td>
<td>Plenary Session</td>
<td>ALL</td>
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<tr>
<td></td>
<td><strong>MONDAY, JUNE 20</strong> 10:30 AM – 12:00 PM</td>
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<tr>
<td>#101</td>
<td>Site Selection Process Workshop: Identifying, Selecting, and Defining a Quality Investigator Site</td>
<td>TRK 1 (A)</td>
<td>Workshop*</td>
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<td>W475a</td>
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<tr>
<td>#102</td>
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<tr>
<td>#103</td>
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<td>Protocol Design and Subsequent Amendments: Understanding the Benefits of Well Designed Protocols</td>
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<td>#105</td>
<td>Asian Global Development and Regulatory Strategies</td>
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*Due to their interactive format, Workshops will not be recorded.
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<thead>
<tr>
<th>Number</th>
<th>Title of Offering</th>
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<th>Type of Format</th>
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<td>Blurring the Boundaries Between Technologies: Examples of Next Generation Clinical</td>
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<td>Real-world Applications of BRIDG</td>
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<td>Experiences with the Development of Disease-specific Standards for Data, Terminology, and Use Cases for Regulatory Science</td>
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<td></td>
<td>Working Group, Q4B Harmonization of Compendial Test Chapters</td>
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<tr>
<td>#114</td>
<td>Issues in Pediatric Global Development</td>
<td>TRK 9 (C)</td>
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<tr>
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<td>Recent Reformation on Medical Device Regulatory Systems in the Asia-Pacific Region</td>
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| #125   | Factors Impacting Investigative Site Performance and Investigator Participation in | TRK 1 (A)    | Symposium      | LEVEL ●            | W175abc     |
|        | a Clinical Study                                                                  |              |                |                    |             |
| #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   | TRK 1 (C)    | Workshop*      | LEVEL ■            | W475a       |
|        | Study Outcomes                                                                    |              |                |                    |             |
| #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:   | TRK 3        | Forum          | LEVEL ■            | W178ab      |
|        | Results from a 2011 Industry Survey                                               |              |                |                    |             |
| #131   | CBERTherapeutic 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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| #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       |

*Due to their interactive format, Workshops will not be recorded.*
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| #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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<td>#369</td>
<td>The New Frontier in Outsourcing: Regulatory Affairs and Safety</td>
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<tr>
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<td>The Eyes Have It! The Unique Advantages of Clinical Research in Ophthalmology Trials: PK/PD and Biomarkers in Ophthalmology</td>
<td>TRK 4 (A)</td>
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<td>Prescription Drug Marketing Regulatory Primer</td>
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<td>#373</td>
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<td>Quality Risk Management in Clinical Trials: Regulators’ and Industry’s Points of View</td>
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<td>NDA/BLA Analysis Files: Improving Specifications and Communication</td>
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<td>#380</td>
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**THURSDAY, JUNE 23 9:00 AM – 10:30 AM**

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*Due to their interactive format, Workshops will not be recorded.*
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<td>Research Collaboration in the Cloud: How NCI and Research Partners Are Using Digital Identities to Accelerate Medical Advance</td>
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<td>Vendor Qualification Audits for SaaS Suppliers</td>
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| 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 — DIA 2011 STUDENT FORUM

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

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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, CSCRCP

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.

#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

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**#105 Track 2 (B): Development Planning**
10:30 AM – 12:00 PM  LEVEL:  ■  Format: SYMPOSIUM
Room W179b  CME and Nursing, 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

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**#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

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**#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

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**#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.

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Monday, June 20

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, MaxiIT 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**  
**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**  
**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**  
**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**  
**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**  
**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 frameworks 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

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**#118  Track 12: Statistics**

**10:30 AM – 12:00 PM**  
**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

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

**10:30 AM – 12:00 PM**  
**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.

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**#120  Track 14: Medical Devices**

**10:30 AM – 12:00 PM**  
**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
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 Cuypere
Chief Executive Officer, Federal Agency for Medicines and Health Products (FAMHP), Belgium

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

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

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 affect 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 Vaccine 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.

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

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

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 success factors, any change management issues and a retrospective analysis 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.

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.

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

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

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 Klepinger, 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 Kari 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
Room W180
Format: WORKSHOP
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
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
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 W181bcd  
**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

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#143   **TRACK 14: MEDICAL DEVICES**  
1:30 PM – 3:00 PM  
LEVEL: ★  
Format: SESSION  
Room W184d  
**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

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#144   **TRACK 15: PROFESSIONAL DEVELOPMENT AND TRAINING**  
1:30 PM – 3:00 PM  
LEVEL: ★  
Format: FORUM  
Room W474a  
**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

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#145   **TRACK 16 (A): GLOBAL AGENCY**  
1:30 PM – 3:00 PM  
LEVEL: ★  
Format: FORUM  
Room W186abc  
**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.

- **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

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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, and group discussions on major ethical considerations of some case studies. The presentations will focus on the importance of ethics in GCP, and 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.
#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

- **Executive Program that Won’t Fail**
  Michael A. Walega, MSc
  Six Sigma Master Black Belt, Covance Inc.

- **Dose Timing, PK Time Sampling, and Number of Samples**
  Barry Mangum, PharmD
  Director, Clinical Pharmacology, Duke University Medical Center

#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
  Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

- **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:** ![Intermediate](https://example.com/icon)  
**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 Lily 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:** ![Intermediate](https://example.com/icon)  
**Format:** SYMPOSIUM  
**Room W470a**  
**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:** ![Intermediate](https://example.com/icon)  
**Format:** SESSION  
**Room W471a**  
**ePRO: Which Technologies and Data Management Strategies Provide Maximum Benefit for Your Trial**  
**CHAIRPERSON**  
Brian Tipplady, 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:** ![Intermediate](https://example.com/icon)  
**Format:** SYMPOSIUM  
**Room W470b**  
**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.
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 Freunsccht
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

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

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. Himman, PhD
Global Head, Early Development and BD&L, Novartis Pharmaceuticals Corporation

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

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

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

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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.

**Benefit-risk Methodology: An Interactive Workshop**

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.
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 lifecycle 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
#201  **Track 1 (A): Clinical Operations**

**PLENARY SESSION**

**Voice of the Patient: Stories That Touch Us**

**CHAIRPERSON:**

**Diane Simmons**  
President and CEO, Center for Information and Study on Clinical Research (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

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#202  **Track 1 (B): Clinical Operations**

**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

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#203  **Track 2: Development Planning**

**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: </br>Format: SESSION</br>Room W179b</br>Regulatory, Clinical, and Quality Challenges in Contracting and Due Diligence: The Forgotten Keys to Biopharmaceutical Transactions</br>CHAIRPERSON</br>Michael A. Swit, JD</br>Vice President, The Weinberg Group Inc.</br>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.</br>Regulatory Challenges in Due Diligence</br>Gary L. Yingling, JD</br>Partner, K&L Gates</br>What Lies Beneath? The Underpinnings of GCP Compliance in Due Diligence</br>Caroline Susan LaPlaca, MSc</br>Independent Consultant for Ardea Biosciences</br>Contractual Clauses Essential in Biopharmaceutical Transactions</br>Maureen Bennett, Esq.</br>Partner, Squire Sanders

#205 Track 6: Medical Writing and Communication
8:00 AM – 9:30 AM LEVEL: Format: SESSION</br>Room W184bc</br>CME, Nursing, and Pharmacy credits offered</br>Designing Robust Protocols</br>CHAIRPERSON</br>Jesse A. Berlin, DrSc</br>Vice President, Pharmacoepidemiology, Johnson & Johnson Pharmaceutical Research and Development, LLC</br>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.</br>Clinical Trial Protocols: Current Status, Challenges, and Opportunities</br>An-Wen Chan, MD, PhD, FRCPC</br>Assistant Professor and Phelan Scientist WCRI, University of Toronto; Women’s College Hospital, Canada</br>The SPIRIT Initiative: Developing Standard Protocol Items for Randomized Trials</br>Jennifer M. Tetzlaff, MSc</br>Research Coordinator, Ottawa Health Research Institute, Canada</br>Implementation of the CDISC Protocol Model</br>David Gemzik</br>Vice President, Implementation Services, Medidata Solutions Worldwide

#206 Track 7: IT Methods and Technologies
8:00 AM – 9:30 AM LEVEL: Format: SYMPOSIUM</br>Room W470a</br>International eClinical Experience</br>CHAIRPERSON</br>Scott W. Dixon</br>Senior Director, Oracle Health Sciences</br>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.</br>Online/Offline ICT Platform for Health Research in Africa</br>Eugenia Rinaldi, MS</br>Project Manager, CINECA Inter-University Consortium, Italy</br>Postmarketing Surveillance in Japan and the Failure of Traditional EDC</br>Scott W. Dixon</br>Senior Director, Oracle Health Sciences</br>Ongoing IT Projects: NCA Point of View</br>Christa Wirthumer-Hoche, PhD</br>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</br>Room W185bc</br>CME and Nursing credits offered</br>The Benefit-risk Assessment of Medicines: How Can This Be Communicated Effectively to Different Stakeholders?</br>CHAIRPERSON</br>Stuart Walker, PhD</br>Founder, Center For Innovation in Regulatory Science, UK</br>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.</br>Benefit-risk Evaluation of a New Medicine by a Pharmaceutical Company and Its Communication for a Regulatory Decision</br>Sinan Bardakci Sarac, MD</br>Industrial PhD Student, Novo Nordisk A/S, Denmark</br>Communication of the Benefit-risk Balance by Regulatory Authorities to Physicians and Patient</br>Stuart Walker, PhD</br>Founder, Center For Innovation in Regulatory Science, UK</br>Communication of Benefit-risk Information to Patients by Physicians, Pharmacists, and Nurses for Shared Decision Making</br>Sam Salek, PhD, RPh</br>Director, Centre for Socioeconomic Research, Welsh School of Pharmacy, Cardiff University, UK
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.

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#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,
Merk 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

#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.
Tuesday, June 21

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

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

#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

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

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 Keeever-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
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, Fayer 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
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.
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

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**#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

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

10:00 AM – 11:30 AM  LEVEL: Format: SESSION
Room W185sa  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

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**#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

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**#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

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

#226 Track 10 (B): Public Policy/Health Care Compliance
10:00 AM – 11:30 AM LEVEL: Format: SESSION Room W183b
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
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.

#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.

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
Tuesday, June 21

#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 Papadopoulous, 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

#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.

#231 Track 14: Medical Devices

10:00 AM – 11:30 AM LEVEL: Format: SESSION Room W184d

International Harmonization Pathways for Medical Devices

Chairperson

Steve Caffee, 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

#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.

Partnersing 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 guide 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 Glansczpigel, 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
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.

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. Kaufman, 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

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, CONNEXTON Healthcare

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

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**

**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, Theravertix, 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**

**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. Dobias
  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**

**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**

**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.

#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

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**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.
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
CHIEF
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
Comparative Effectiveness Research: What Is the Current
Direction?
CHIEF
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
CHIEF
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
CHIEF
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
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

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, guidelines, 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)

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
Lorraine 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

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.

#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
Tuesday, June 21

**#265 Track 17 (J): SIAC Showcase**

3:30 PM – 4:30 PM LEVEL: Format: SIAC
Room W179b


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.*

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**#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.*

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**#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.*

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**#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.*

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**#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.*
#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.

#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
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

END OF TUESDAY SESSIONS
Wednesday, June 22

#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 Vaii, 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
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.

Organizational Challenges in Moving to a New Outsourcing Model: Overcoming Resistance to Change

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

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

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 and Biomarkers for Earlier Efficacy Assessment

Jonathan R. Smith, PhD
Vice President, Research & Development, Adaptive Plus, LLC

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.

Policy and Enforcement Issues Faced by Industry

Wayne L. Pines
President, Regulatory Services and Health Care, APCO Worldwide Inc.

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

Translational Medicine-driven Multicomponent Predictive Biomarkers and Biomarkers for Earlier Efficacy Assessment

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

Policy and Enforcement Issues Faced by Industry

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.
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 Pettrillo, 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
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 guidelines 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

Drug Product Liability in the United States and the European Union

CHAIRPERSON
Anjelique 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. Lismian, LLM, MPharm
Lawyer, Lismian 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

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.

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 interaction, 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.
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

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

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

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.

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.

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 Keshea, MS  
Senior Consultant, WCI Consulting Limited

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
CHIEF PERSON
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
CHIEF PERSON
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

Augustina Bisio
Director, Drug Evaluation Agency, ANMAT, Argentina

#336 Track 18: Late Breaker
10:00 AM – 11:30 AM LEVEL: ● Format: SESSION
Room W475b

Establishing a Framework for CER Assessment: How Do Managed Care Decision Makers Consider the Evidence?
CHIEF PERSON
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.

#337 Track 1 (A): Clinical Operations
1:30 PM – 3:00 PM LEVEL: ● Format: SYMPOSIUM
Room W175abc

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

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: Primarily intermediate-level content; Format: WORKSHOP
Room W474b

**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 members with different skills and expertise and learn how to create efficient and effective teams. 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.

*This Session has been cancelled.*

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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.

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**#340 Track 2 (B): Development Planning**

1:30 PM – 3:00 PM LEVEL: Primarily advanced-level content; Format: FORUM
Room W179a

**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, Celereon, Canada

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**#341 Track 3: Outsourcing Strategies and Innovative Partnering Models**

1:30 PM – 3:00 PM LEVEL: Advanced-level content; 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

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**#342 Track 4 (A): Nonclinical and Early Clinical Translational Development**

1:30 PM – 3:00 PM LEVEL: Primarily intermediate-level content; Format: SYMPOSIUM
Room W179b

**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**

**Chairperson**
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
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.

#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
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**  

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**#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

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**#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.

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**#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  
**Room W183b**

**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 process.

*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.

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#351  **Track 9 (C): Regulatory Affairs and Science, Quality, and GXP Compliance**
1:30 PM – 3:00 PM  
**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

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#352  **Track 9 (D): Regulatory Affairs and Science, Quality, and GXP Compliance**
1:30 PM – 3:00 PM  
**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

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#353  **Track 10 (A): Public Policy/Health Care Compliance**
1:30 PM – 3:00 PM  
**Room W180**

**Pharmacy credits offered**

**Off-label Use: Practical and Legal Issues**

**CHAIRPERSON**
John A. Lismann, LLM, MPH  
Lawyer, Lismann 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. Lismann, LLM, MPH  
Lawyer, Lismann 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  
**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  

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**#355 Track 11 (A): Clinical Safety and Pharmacovigilance**

1:30 PM – 3:00 PM  
**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  

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**#356 Track 11 (B): Clinical Safety and Pharmacovigilance**

1:30 PM – 3:00 PM  
**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.

**Economic Transparency of Drug Development: How to do More with Less**  
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  

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**#357 Track 12: Statistics**

1:30 PM – 3:00 PM  
**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  

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

1:30 PM – 3:00 PM  
**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  

**Using Real-world Data for Making Real-world Decisions**  
Matthew D. Rousculp, PhD, MPH  
Director, Health Outcomes and Pharmacoeconomics, MedImmune, LLC  

**Economic Transparency of Drug Development: How to do More with Less**  
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  

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References:  
1. Dorfman, Howard L.  
Consultant, FDA Regulatory, Compliance, and Risk Management, H.L. Dorfman & Associates Consulting Services  

2. Fatzinger, Geoff  
Executive Director, Regulatory Affairs and Strategic Product Development, Europe and Asia Pacific, INC Research, UK  

3. Pepe, Sondra A.  
Product Manager, Medidata Solutions Worldwide  

4. Jolley, Steve  
Principal, SJ Pharma Consulting  

5. Chow, Shein-Chung  
Professor, Department of Biostatistics and Bioinformatics, Duke University School of Medicine  

6. Liao, Jason  
Director, Teva Branded Pharmaceutical Products R&D, Inc.  

7. Zhang, Nan  
Biostatistics Manager, Amgen Inc.  

8. Barker, Kerry B.  
Senior Director, Leadership, Bio-Therapeutics Research, Pfizer Inc  

9. Rousculp, Matthew D.  
Director, Health Outcomes and Pharmacoeconomics, MedImmune, LLC  

10. Ehrlich, Jay M.  
Vice President, Global Pharmacovigilance, Baxter Healthcare  

11. Robinson, Jill E.  
Senior Vice President, Global Patient Safety and Risk Management, Genzyme Corporation  

12. Kedia, Kapil  
Principal Product Manager, Oracle Health Sciences  

13. Dorfman, Howard L.  
Consultant, FDA Regulatory, Compliance, and Risk Management, H.L. Dorfman & Associates Consulting Services  

14. Fatzinger, Geoff  
Executive Director, Regulatory Affairs and Strategic Product Development, Europe and Asia Pacific, INC Research, UK  

15. Pepe, Sondra A.  
Product Manager, Medidata Solutions Worldwide  

16. Jolley, Steve  
Principal, SJ Pharma Consulting  

17. Chow, Shein-Chung  
Professor, Department of Biostatistics and Bioinformatics, Duke University School of Medicine  

18. Liao, Jason  
Director, Teva Branded Pharmaceutical Products R&D, Inc.  

19. Zhang, Nan  
Biostatistics Manager, Amgen Inc.  

20. Barker, Kerry B.  
Senior Director, Leadership, Bio-Therapeutics Research, Pfizer Inc  

21. Rousculp, Matthew D.  
Director, Health Outcomes and Pharmacoeconomics, MedImmune, LLC  

22. Ehrlich, Jay M.  
Vice President, Global Pharmacovigilance, Baxter Healthcare  

23. Robinson, Jill E.  
Senior Vice President, Global Patient Safety and Risk Management, Genzyme Corporation  

24. Kedia, Kapil  
Principal Product Manager, Oracle Health Sciences
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

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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.

**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
Wednesday, June 22

#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 Hamnett
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

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 generalizable.

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 Hornec, PhD
eClinical Expert, Maxclinical, Germany

#367  **TRACK 2: DEVELOPMENT PLANNING**
3:30 PM – 5:00 PM  LEVEL: ◆  Format: SESSION
Room W179a

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
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 interaction, 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 Pro-
fessional 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

#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 neuro-
logical 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
Zhao Hui 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?
Zhao Hui John Cai, MD, PhD
Biomedical Informatics Director, AstraZeneca
#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 v1.1.

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.

**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 W18abc  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 to avoid these problems.

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.

**Note:** This text is formatted for readability and may not reflect the exact layout of the original document.
#382  **Track 11 (B): Clinical Safety and Pharmacovigilance**

**3:30 PM – 5:00 PM**  
**LEVEL:**  
**Format:** SESSION  
**Room W183c**  
**FACILITATORS**  
Elizabeth E. Garrard, PharmD  
Chief Safety Officer, Drug Safety Alliance, Inc.  
Suzanne Tepper, PharmD, RPh  
Vice President, Pharmacovigilance Operations, APCER Pharma Solutions, Inc.

## REMS Model for Drug Safety

**CHAIRPERSON**  
Dean Michael Pratt, MBA, PMP  
Consulting Program Manager, Intraphore 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**  
**FACILITATORS**  
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.

### Encouraging Comparative Effectiveness Research While Protecting Privacy: Can We Develop a Research Safe Harbor for CER?

- **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

**This Session has been cancelled.**
Track 15: Professional Development and Training

#386  3:30 PM – 5:00 PM  Format: SESSION  LEVEL:

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

Track 16 (A): Global Agency

#387  3:30 PM – 5:00 PM  Format: FORUM  LEVEL:

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.

Track 16 (B): Global Agency

#388  3:30 PM – 5:00 PM  Format: FORUM  LEVEL:

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

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- Discounts on industry products and services

For more information, visit www.diahome.org and click on Membership.
#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.
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

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

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

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
Basic-level content; Primarily intermediate-level content; Primarily advanced-level content

Thursday, June 23

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#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

#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)

#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

#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, Aptevo Solutions
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

#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 ADApative 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
#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  
- **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 Program Director, 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.

#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. Dai 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
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.
**Poster Presentations**

**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
Poster Presentations

**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
Kunihiro 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
Jeanine Benson, MBA
Director, Health Services Research CSoE, 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 Nichols, MS
Director, Biostatistics, Almac Clinical Technologies LLC

**W 23** Protection of Clinical Trial Subjects in India
Nermee 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
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
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.

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

DRUG INFORMATION JOURNAL AWARDS

The Donald E. Francke Award:
Overall Excellence in Journal Publishing

Sina Djali, MS/MSE
United States

Sue-Jane Wang, PhD
United States

Student Journal Award: Excellence in Publishing by a Student Contributor

Sampada S. Vaidya, MBBS MS
United States

The Thomas W. Teal Award:
Excellence in Statistics Publishing

Sue-Jane Wang, PhD
United States
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No Relationship or Conflicts of Interest (Nothing to Disclose) continued

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Disclosure Statements (as of May 12, 2011)

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.
Speaker Disclosure Statements

Shantal Feltham  OTHER SUPPORT – Owner of Stiris
John Ferguson  STOCK SHAREHOLDER – Novartis, Pfizer Inc
Bryant Fields  OTHER SUPPORT – Bayer Healthcare Pharmaceuticals, STOCK SHAREHOLDER – Bayer Healthcare Pharmaceuticals
Robert Fike  STOCK SHAREHOLDER – Pfizer Inc
Gregory Fiore  CONSULTANT – Auxilium, OTHER SUPPORT – Schering Plough/Merck & Co., STOCK SHAREHOLDER – Safety Sells, Inc.
Karsten Fogh  Ho-Langng  STOCK SHAREHOLDER – Employee of NNIT A/S, STOCK SHAREHOLDER – Novo Nordisk A/S
Betsy Fritschel  STOCK SHAREHOLDER – Johnson & Johnson
Stephen From  STOCK SHAREHOLDER – EyeGate Pharma
Louis Garrison  GRANT SUPPORT – National Pharmaceutical Council
Nicolle Gatto  OTHER SUPPORT – Employee of Pfizer Inc, STOCK SHAREHOLDER – Pfizer Inc
Helle Gawrylewski  STOCK SHAREHOLDER – Johnson & Johnson
Robin Geller  STOCK SHAREHOLDER – Baxter Healthcare Corporation
David Gemzik  OTHER SUPPORT – Medidata Solutions, STOCK SHAREHOLDER – Medidata Solutions
Richard Gliklich  GRANT SUPPORT – Agency for Healthcare Research and Quality, STOCK SHAREHOLDER – Employee of Outcome Sciences, Inc
Sigfried Gold  STOCK SHAREHOLDER – Phase Forward
Beth Harper  STOCK SHAREHOLDER – Centerphase Solutions.com
Peter Harpum  CONSULTANT – GlaxoSmithKline, Talecris, Novartis
Judy Harrison  OTHER SUPPORT – Consultant (contractor) to MedDRA MSSO
Jeremy Hobart  CONSULTANT – Acorda, Bayer, Biogen Idec, Merck & Co., Schering, GRANT SUPPORT – Biogen Idec
Alan Hochberg  OTHER SUPPORT – Employee of Roche
Chris Holland  OTHER SUPPORT – Employee of MacroGenics
Feng Hong  OTHER SUPPORT – Employee of Amgen, Inc., STOCK SHAREHOLDER – Amgen, Inc.
Joseph Horrigan  OTHER SUPPORT – Employee of GlaxoSmithKline
Florence Houn  STOCK SHAREHOLDER – Celgene Corporation, Abbott
Kit Howard  OTHER SUPPORT – Employee of Kestrel Consultants, Inc.
Deborah Howe  STOCK SHAREHOLDER – Bristol-Myers Squibb
Eunhee Hwang  OTHER SUPPORT – Pfizer Inc
Daniel Jacob  OTHER SUPPORT – Baxter Healthcare, STOCK SHAREHOLDER – Baxter Healthcare
Brenton James  STOCK SHAREHOLDER – GlaxoSmithKline
Steve Jolley  CONSULTANT – SJ Pharma Consulting
Angelika Joos  STOCK SHAREHOLDER – Merck & Co.
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<td>John Kamp</td>
<td>STOCK SHAREHOLDER – Medical related companies including biopharma companies - Abbott, Allergan, American Medical, Amgen Inc., Amylin, Beckton Dickinson, Bristol-Myers Squibb, Celgene, Healthways, Johnson &amp; Johnson, Medicus, Medtronic, Merck &amp; Co., Novo Nordisk, Scilir, Sucombo, and Vertex, and media and marketing companies, including Omnicom, Publicis, WPP &amp; IPG, and medical sales companies including Target, Walgreens and WalMart</td>
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<td>OTHER SUPPORT – Abbott, STOCK SHAREHOLDER – Abbott</td>
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<td>Lutz Mueller</td>
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<td>Mike Myers</td>
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<td>Joe Selby</td>
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<td>Paula Stafford</td>
<td>OTHER SUPPORT – External Advisory to UNGCH CTSA Grant, STOCK SHAREHOLDER – Quintiles Transnational Holdings</td>
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The following PIM planners and managers, Jan Hixon, RN, BSN, MA, Trace Hutchinson, 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 Wetzol, 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, Charles Depew, 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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<td>Yoh</td>
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### EXHIBITOR DIRECTORY (as of May 4, 2011)

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<th>Company</th>
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<th>Contact</th>
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<td><a href="mailto:sonja.riebel@accovion.com">sonja.riebel@accovion.com</a></td>
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<td>Brandon Griffin</td>
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<td><strong>Aerotek, Inc.</strong></td>
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<tr>
<td><strong>ACRI-Phase I, LLC</strong></td>
<td>1331</td>
<td>Patrick McLaughlin</td>
<td><a href="mailto:pm@agmg.com">pm@agmg.com</a></td>
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<td><a href="mailto:pm@agmg.com">pm@agmg.com</a></td>
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Contact: Monica Roberts  
E-mail: monica.roberts@abbott.com  
Website: www.abbott.com

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E-mail: schitnis@accelclinical.com  
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E-mail: acurran@aerotek.com  
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E-mail: pm@agmg.com  
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The Almac Group provides a broad range of services from R&D, biomarker discovery and development, API manufacture, formulation development, clinical trial supply and IXRS technology (IVRS/IWRS), to commercial-scale manufacture. Almac provides services to the world leaders in the pharmaceutical and biotech sectors.

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E-mail: john@aspire-irb.com
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Aptiv Solutions is a global biopharmaceutical & medical device development services company, formed by the merger of Averion, ADDPLAN, ClinResearch, Fulcrum Pharma, Niphix, & Trio Clinical Resourcing. Our offerings include adaptive trial design, early phase product strategy, regulatory, pharmacovigilance, clinical resourcing & global CRO services.
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E-mail: egle.hopkins@businessdecision.com  
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Business & Decision is an international consulting and systems integration company specializing in providing Life Sciences consulting services and solutions across all business domains (R&D, Clinical/CRO, Manufacturing, Sales & Marketing) and in all industry sectors.

C&R Research  
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C&R Research, the first Korean CRO incorporated in 1997 has led Asia Pacific clinical development as an Asia Pacific CRO to provide the best services and comprehensive global phase 1-4 clinical development solutions with our best people to achieve the fast and successful delivery of clinical trials in Asia pacific market.

C3i Inc  
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C3i helps life science organizations conduct more efficient clinical trials by providing implementation, training, 24/7 multilingual helpdesk & provisioning services from its operations centers in NA, Europe, India & China. C3i also offers hosted managed services for Oracle Life Science applications, licensed in a SaaS model.

Camargo Pharmaceutical Services  
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Camargo Pharmaceutical Services is an end-to-end drug development services company, specializing in the 505(b)(2) pathway. With more than 150 FDA approvals, Camargo works with companies to develop comprehensive programs, managing every facet of the plan from formulation and testing, conducting clinical studies and FDA application submissions.

Canary Limited  
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Learn, Read, Update, Refresh and Test with Canary Ltd publishers of products to facilitate GCP compliance, including newsletters, books, posters and Q&A card sets. Sister company, Brookwood International Academy has more than 25 years experience in clinical research training and provides both face to face and online training programs.

CanReg, Inc.  
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CCCRI, an industry leader in document management solutions, provides full service CRO capabilities with their extensive network and client in-house resources working together in a seamless fashion. By utilizing this new cost efficient approach, CCCRI provides the highest level of quality while minimizing the strain on clinical trial budgets.

Cape Cod Clinical Research, Inc.  
Booth 1323  
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Cardiocore is a leading global provider of centralized cardiac testing services including ECG, ABPM, ECHO, Holter monitoring, protocol consulting and statistical analysis. The company is experienced in Phase I-IV, and Thorough QT clinical trials for Top Ten pharmaceutical companies, specialty pharmaceutical organizations and emerging biotech firms.

Catalent Pharma Solutions  
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Catalent + Talent. Our name combines these ideas. As a top global clinical services supplier, Catalent Pharma Solutions has provided innovative and
cost effective clinical supply services that our customers have relied upon for more than 20 years. From drug and biologic development services to delivery technologies to supply solutions, Catalent is the catalyst for your success.

**CCRA (Clinical Contract Research Association)**  
Booth 131

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If you are serious about the conduct of clinical trials to the highest standards and take any part in the industry (CRO or service provider to this sector) come and talk to us about membership! CCRA is the UK trade association which represents this sector and provides enhanced business opportunities, a badge of quality, and a voice for the industry.

**CDISC**  
Booth 1234

Contact: Rebecca Kush  
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Website: www.cdisc.org

The CDISC Vision: Informing patient care & safety through higher quality medical research.

The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are freely available via the CDISC website.

**Celerion**  
Booth 938

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Website: www.celerion.com

Celerion, formed through the acquisition of the early stage operations of MDS Pharma Services, is a leader in providing comprehensive clinical research, bioanalysis and consultancy services. With six locations and over 730 beds, our experience and expertise is applied to provide solutions to pharmaceutical, biotechnology and generic clients.

**CenterWatch**  
Booth 646

Contact: Amy Fontaine  
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Website: www.centerwatch.com

Founded in 1994, CenterWatch is the trusted source and recognized leader of clinical trials information for both clinical research professionals and patients offering: news, grant opportunities, drug information, career resources, market analysis, training resources and the largest online database of industry-funded clinical trial listings.

**Cerner Corporation**  
Booth 1526

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Cerner, a global leader in healthcare information technology, is solving healthcare’s many challenges by connecting the right people with the right information at the right time. Building on more than 30 years of experience and our partnerships at more than 8,500 client sites worldwide, we are finding innovative ways to deliver value to our clients.

**Cetero Research**  
Booth 1117

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Website: www.cetero.com

Cetero Research is an industry leading contract research organization (CRO) in early phase research services. With nearly 30 years of experience, Cetero has conducted more than 20,000 clinical pharmacology studies and has a proven track record of providing flexible and high quality clinical development services.

**Charles River**  
Booth 1654

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Website: www.criver.com

At Charles River, our extensive global portfolio of support services provides complementary resources and expertise to enhance your studies. We provide comprehensive bioanalytical support, pharmacokinetics and pathology for all stages of product development, from early discovery and preclinical studies through all phases of clinical development.

**Chesapeake Research Review, Inc.**  
Booth 629

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Website: www.chesapeakeirb.com

Since 1993 Chesapeake IRB has been a leading provider of IRB Services and consultative support in the area of human subject protection. Fully AAHRPP accredited, we are committed to meeting the quality and timeline requirements of our clients’ fast-paced development schedules. Our expertise spans the entire spectrum of human research.

**Chiltern**  
Booth 505

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Website: www.chiltern.com

Established in 1982, Chiltern is a leading global clinical Contract Research Organization with extensive experience conducting and staffing international Phase I to Phase IV clinical trials across a broad range of therapeutic areas in more than 40 countries, and employs around 1300 people globally.

**Cincinnati Children’s Research Foundation**  
Booth 1135

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Website: cincinnatichildren.org/clinical-trials-office

Cincinnati Children’s is a pediatric Phase I-IV (all major therapeutic areas) and select adult Phase I-IV (vaccine and cancer) clinical test site. AAHRPP accredited, it has more than 1700 active IRB approved protocols annually, more than 600 investigators, 300 GCP trained study coordinators and 80 years of pediatric research experience.

**CIRION Clinical Trial Services Inc.**  
Booth 1313

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Website: www.cirion.com

CIRION is a Contract Research Laboratory and a leading provider of Global Central Laboratory and R&D services for assay development & validation for Global Clinical Trials and Pre-Clinical studies. The company offers a complete range of project management, logistical services and a broad portfolio of safety and esoteric assays.
Citeline provides the world's most comprehensive R&D intelligence to the pharmaceutical industry, covering global clinical trial, investigator and drug intelligence. Our integrated services combine data with unlimited access to our analysts, to give you real-time information and intelligence on which to base critical competitive decisions.

Citeline-University of Miami

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ClearTrial

Phone: 312-460-3000
E-mail: info@cleartrial.com
Website: www.cleartrial.com

ClearTrial is the leading provider of Clinical Trial Operations (CTO) software, an integrated system for clinical operations planning, forecasting, outsourcing, and project tracking. Visit us in booth #841!

ClinAudits, LLC

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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.

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ClinDatrix is committed to providing world class, full service clinical research capabilities to the biotechnology, medical device, and pharmaceutical industries. Partnering with its clients, ClinDatrix uses a personalized approach to apply knowledge and experience to the goals of managing, monitoring, collecting, validating, analyzing, reporting.

ClinForce

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For over two decades, ClinForce has earned the trust of its clients in pharmaceutical related industries through its expertise in providing creative resource solutions, contract staffing, direct hire and functional outsourcing services. ClinForce assists its clients in getting efficacious products to market in an efficient and economical fashion.

Clinical Financial Services

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Clinical Financial Services offers comprehensive business and financial management services for clinical trials. Our team brings an in-depth understanding of the clinical trial process, including clinical trial budgets and agreements, contract negotiation and administration, regulatory documentation, and finance and accounting.

Clinical Ink

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Clinical Ink’s SureSource™ is a tablet based Electronic Source Record (ESR) that eliminates SDV, reduces queries, provides remote document review and reduces monitor site visits. SureSource captures source data on eSource documents that retain the look and feel of paper forms. Source data and documents are managed on our secure web portal.

Clinical Reference Laboratory, Inc.

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Clinical Reference Laboratory is a global full service central laboratory founded on solid scientific expertise and a strong customer service focus. CRL offers a wide range of testing including Chemistries, Hematology, Urinalysis, Endocrinology, Serology, Biomarkers, DNA, RNA extraction, Genotyping, and Sequencing.

Clinical Research Advantage, Inc.

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CRA has provided experienced research sites to the pharmaceutical and CRO industry through its partnerships with independent physician investigators in community based settings for over 20 years. CRA consists of nearly 30 sites in 5 states and has conducted 1600+ phase II-IV trials in all ages and therapeutic areas with an emphasis on vaccines.

Clinical Research Malaysia

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CRM is YOUR gateway to an extensive network of 500 sites covering an entire nation of 28 million multi-ethnic people. Our 5,000 experienced investigators and excellent trial infrastructure ensure fast recruitment and reliable data quality. As a Government SMO we provide comprehensive, efficient and unrivaled value-added services.

Clinical Research Management, Inc. (ClinicalRM)

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Website: www.clinicalrm.com

ClinicalRM, a full service CRO, offers a full spectrum of services that support pre-clinical to post-approval research for Government and commercial sponsors. ClinicalRM specializes in therapeutic areas including:
- Infectious Disease
- Neuroscience
- Trauma (TBI, PTSD)
- Cardiovascular
- Medical Psychiatry
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- Resilience Training
Clinical Resource Network, LLC

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Website: www.clinicalresource.net

Clinical Resource Network, LLC - When your patients can’t get to the site, we bring the trial to their door. We are a global service provider of in-home and alternate-site trial visits that offer study patients both convenience and flexibility; resulting in dramatic improvements in recruitment, retention and compliance for your trial.

The Clinical Resource Network

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Website: www.crnspg.com

CRN is an innovative and dynamic clinical contractor and project resourcing provider. We support Sponsors/CROs with clinical professionals and project teams. Our solutions provide significant cost savings with an emphasis on quality and service delivery. If you are seeking clinical professionals or rewarding opportunities CRN sets the standard.

Clinical Site Services

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Website: www.ClinicalSiteServices.com

Clinical Site Services is an enrollment performance company. We increase enrollment and retention for pharma, CROs and investigative sites through our site-focused approach and adaptive enrollment process. Our global patient enrollment services provide for seamless planning, execution and reporting, in the U.S. and in more than 40 countries.

The Clinical Trial Company

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Formed in 2002, The Clinical Trial Company™ (TCTC), a privately owned full-service clinical research provider. Our philosophy is one of teamwork, positivity, communication, responsibility and adding value. TCTC place great emphasis on developing appropriate product road maps to suit your individual product characteristics.

Clinical Trial Media

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Clinical Trial Media is a global patient recruitment and retention company specializing in various outreach, tracking and support services to successfully complete enrollment on time and under budget. CTM has randomized study patients for thousands of clinical research studies across a wide variety of therapeutic areas since 1995.

ClinicalConnection.com

Contact: Leslie Eisenberg
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Website: www.ClinicalConnection.com

ClinicalConnection.com is your destination for patient e-recruitment. More people visit each month to search & be referred to studies than any other private clinical trials web portal. Top sponsors and CROs make the most of recruitment budgets with our customized trial listings, database recruitment & tools to enhance their studies' web presence.

ClinicallRN

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ClinicallRN is the only single resource global call center that specializes in multi-lingual clinical trial patient recruitment and retention. We employ nurses, doctors and other degreed professionals such as CRAs, which enables us to provide high quality referrals. This results in shortened recruitment timelines and saves companies time and money.

Clinical International, Ltd.

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Cliningene International, Ltd., a full-service Indian CRO, provides PI-IV solutions completed in strict compliance with all regulatory and ICH GCP requirements to global pharmaceutical and biotechnology companies. Cliningene’s expertise includes BA/BE/P1, small/large bioanalytical, CLS, clinical operations, CDMB and strategic regulatory services.

Clinilabs

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Clinilabs is a CRO that provides early-phase and specialty clinical drug development services to industry. We offer teams, processes, and technology solutions that are designed to serve single center and multicenter early-phase studies - services that can be scaled as needed to meet the requirements of any clinical development program.

Clinipace Worldwide

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Clinipace Worldwide, a global digital clinical research organization (dCRO), specializes in fully integrated clinical research services for phase I-IV trials and registries conducted by biopharmaceutical and medical device firms. Clinipace Worldwide has managed over 200 research and regulatory projects.

cliniT AG

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cliniT is a provider of information technology required to conduct all phases of clinical trials as well as non-interventional and registry projects. Our TRI@L-IT software serves as an eClinical trial management platform covering electronic and hybrid data entry, central randomisation via the web or IVRS, and all related trial management functions.

Clinlogix, LLC

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Clinlogix is a team of dedicated life science experts working as a single point of access for your clinical development, study management and execution needs. Clinlogix delivers for all of your outsourcing needs. Our difference is in our transparent business process and our attention to your budget requirements and study milestones.
ClinStar, LLC
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ClinStar is one of the most prominent CROs in the emerging markets of Eastern Europe and the Baltics. Headquartered in San Francisco, CA, ClinStar has managed more than 130 clinical trials across a wide-range of therapeutic areas from our offices in Russia, Ukraine and Belarus, with total staff of over 300 people.

ClinTec International
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ClinTec International is a Global CRO with a presence in over 40 countries worldwide. ClinTec has been providing high quality, clinical research support to the pharmaceutical, biotechnology and medical device industry since 1997. ClinTec has the capability to conduct global clinical trials as well as provide support to local projects.

Clinverse, Inc.
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Cmed Group
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Cmed Group is an innovative clinical trials services and advanced software provider that includes two divisions: Cmed Clinical Services, a full-service CRO, and Cmed Technology, an eClinical technology provider. Central to our business is Timaeus, a unified on-demand eClinical platform that supports Study Design through Reporting.

CMIC Co., Ltd.
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CMIC is a One-stop Gateway to the Asian market offering high quality preclinical and clinical research management, site management, manufacturing, sales and marketing, intellectual property development and consulting services to pharmaceutical, biotechnology and medical device companies that are tailored to fit our clients’ unique specifications.

Cognizant
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Cognizant’s Life Science Practice partners today with 27 of the top 30 global pharmaceutical/biotech organizations in addition to serving the medical devices, CRO and life sciences product companies. Cognizant is a lead-ing provider of IT, consulting, and BPO services, dedicated to helping the world’s leading companies build stronger businesses.

Compass IRB
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Compass IRB is a Central IRB located in Mesa, Arizona with full AAHRPP accreditation. Compass IRB is dedicated to outstanding customer service and the protection of human subjects. Compass IRB utilizes a customized online system “THE ANCHOR™” for online submissions and real time 24/7 tracking of all IRB documents.

CompleWare Corporation
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CompleWare Corporation, a leader in the use of eTechnology to conduct clinical trials, provides lean eClinical innovation, integration, and quality leading to increased speed and accuracy of data capture, enhanced subject compliance, and controlled study costs. CompleWare is both a full service CRO as well as a technology vendor of ePRO options.

Comprehensive Clinical Development
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Website: comprehensivecd.com

Comprehensive Clinical Development, a strategic clinical research partner, provides full-range clinical development services in various therapeutic areas with a track record of collecting early efficacy data of various patient populations; offers distinct capabilities in clinical research with consistent delivery of quality, within budget success.

COMSYS Clinical
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Contract Pharma
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Website: www.contractpharma.com

Contract Pharma is the magazine and website that defines outsourcing for the pharmaceutical and biopharmaceutical industries. We are the premier media source covering outsourcing from drug discovery to manufacturing. Our 10th annual Contracting & Outsourcing conference will be held on Sept 22 & 23 at the Hyatt in New Brunswick NJ.
Covance Inc.

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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.

Covance, Inc.

Contact: Kevin Duffy
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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.

CoreLab Partners Inc

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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

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Corporate Translations is an ISO9001:2008 and EN15038 certified and trusted provider of translation and linguistic validation solutions to the world’s top life science companies. Our proven methodology and expertise in this highly regulated industry make us well qualified to translate and format documents throughout the entire lifecycle of a drug.

CRI Worldwide & Lifetree Clinical Research

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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

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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.

Cromos Pharma, LLC

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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 Inc.

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CROMSOURCE is an international full service CRO offering clinical research services and staffing solutions to pharmaceutical and medical device 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

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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

Contact: Dr. David Surjo
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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

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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.

Contact: Kathleen Ashenfelter or Anna Majeranowski
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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.

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Cytel Inc. is a trusted provider of clinical research services, trial design and analysis technology. Pioneers in adaptive design and implementation, each of the top 25 biopharmaceutical firms use Cytel technology to plan and support their clinical studies.

Datatrial

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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

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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
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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
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Delta Pharma is soon to be Randstad Pharma! Randstad is the 2nd largest HR Services Firm in the world, with a presence in 40+ countries. We offer life science-related resource services, including Clinical, Scientific, and Technology staffing, outsourced, and vendor management services. For more information, please visit us at booth #817.

Delve
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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.
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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
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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
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DOKUMEDS is a European CRO providing a comprehensive range of services to more than 80 clients in pharma, biotechnology and medical device industry worldwide.
Focus on customer needs, trustfull relationships and quality is the core stone of Dokumeds business philosophy allowing to reach the ratio of repeated business up to 80%.

Dow Pharmaceutical Sciences
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By focusing exclusively on product development for 33 years, Dow has developed more prescription topical formulations than any company in the world. We understand the problems and how to correct or prevent them. Of the 30 topical dermatological NDAs approved by the FDA in 2005-10, Dow developed the formulations for 11. Our Focus is Your Success.

Dr. Ebeling & Assoc. GmbH
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Contact: Joon-Young Lee
E-mail: joon-young.lee@dreamcis.com
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.
Contact: Lauren Logan
E-mail: llogan@drugsafetyalliance.com
Website: www.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.

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Contact: Robin Samet
E-mail: rsamet@druglogic.com
Website: www.druglogic.com
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Contact: Jack Minster
E-mail: jminster@dsg-us.com
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**Duke Clinical Research Institute**

**Contact:** Suzanne Pfeifer  
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**Website:** www.dcri.org

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**

**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**

**Phone:** +420 244 462 241  
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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**

**Contact:** Jeff Jolin  
**E-mail:** jjoin@eliassen.com

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**

**Contact:** Howard Goldberg, Pharm.D.  
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**Website:** www.eclinso.com

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**

**Contact:** Dr. Klaus D Wiedey  
**E-mail:** klaus.wiedey@ecronacunova.com  
**Website:** www.ecronacunova.com

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.**

**Contact:** Edward Bailey  
**E-mail:** info@edetek.com  
**Website:** www.edetek.com

EDETEK provides comprehensive metadata driven clinical trial data management solutions. EDETEK’s The CDISC SuiteTM Data Management platform is a metadata driven, CDISC compliant, end-to-end, modular system delivering exceptional data quality and speed of delivery in a cost effective manner.  

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**Contact:** Chris Hoyle  
**E-mail:** choyle@eliteresearchnetwork.com  
**Website:** www.eliteresearchnetwork.com

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**Contact:** Brenda Bishop  
**E-mail:** BBishop@EMBStats.com  
**Website:** www.EMBStats.com

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**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.
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Website: www.epharmasolutions.com
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Website: www.eps.co.jp
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Contact: John Blakeley
E-mail: eresearch@ert.com
Website: www.ert.com
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Website: www.esoterixtrials.com
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Contact: Angela Lodico
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Website: www.etq.com
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European Medicines Agency
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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
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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!

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Contact: Penny Johnson
E-mail: pjohnson@execupharm.com
Website: www.execupharm.com
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Foundation for Biomedical Research  
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Website: www.fibresearch.org

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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/Ia 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.

**Healthcare Communications Group**
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Contact: Linda Kilpatrick  
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Contact: Trisha Futty  
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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.
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HRP Consulting Group, Inc.
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ICON Clinical Research plc
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Idem Translations, Inc.
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INC Research
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Inclinix, Inc.
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Inclinix provides productive investigative sites and qualified study participants to pharmaceutical, biotech and medical device companies on a performance basis. Inclinix services are offered globally with project staff based in the US, Sweden, and the UK. Sponsors benefit from 12 years of experience in global clinical research enrollment services.

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IntegReview, AAHRPP accredited, has a proven track record of customer satisfaction for applying ethics and integrity to human research while providing thorough, prompt, and knowledgeable IRB review along with multiple levels of quality control. Clients are provided instant Internet access to study documents within 1-2 days of board review.

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E-mail: admin@icrtrials.com
Website: www.icrtrials.com

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International Dermatology Research, Inc.

Contact: Silvia A. Trinidad
E-mail: info@intldermresearch.com
Website: www.intldermresearch.com

International Dermatology Research, Inc. is a research Site specializing in Dermatology and General Practice Studies. J&S has over 15 years experience conducting Phase I-IV, Pharmaco-kinetik, and in-house studies. J&S is capable of performing phase I-IV, Pharmaco-kinetik, and in-house studies. J&S has over 15 years experience conducting Dermatology and General Practice Studies.

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Contact: Janine Caldarella
E-mail: jcaldarella@intralinks.com
Website: www.intralinks.com

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investigator Support Services

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E-mail: bozena@researchsite.net
Website: www.researchsite.net

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invivodata, inc.

Contact: Jodi Andrews
E-mail: jandrews@invivodata.com
Website: www.invivodata.com

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Contact: Jennifer Bruce
E-mail: info@irbservices.com
Website: www.irbservices.com

An established and respected independent IRB since 1993. With boards in Toronto, Montreal, and Boca Raton, IRBS provides service from coast to coast, US-Canada. Human Research Protection, excellence in service, quality, and efficiency are at the core of our mission. 2-4 weekly meetings and dedicated service teams provide real reviews in real time.

Italian Medicines Agency - AIFA

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.

Contact: Jeremy Scott
E-mail: jscott@js-studies.com
Website: www.js-studies.com

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Contact: Sara Rainie  
E-mail: janixbd@janix.com  
Website: www.JANIX.com

JANIX is a full service CRO with global operations in North America, Europe, Africa, Israel, and Asia Pacific. We offer trial management, monitoring, patient recruitment, data management biostatistics, QA, RA, medical affairs, and REMS. We perform Phase I-IV pharma & device studies and marketing, registration, outcomes, nutra & cosmeceutical trials.

JCL Bioassay USA, Inc  
Contact: Jamie Klonowski  
E-mail: jamie.klonowski@jclbiousa.com  
Website: www.jclbiousa.com

A leading Bioanalytical CRO, JCL Bioassay USA has the highest quality data, exceptional researchers, and state-of-the-art instrumentation. JCL offers GLP-compliant bioanalytical services including: development of analytical methods (LC-MS/MC), method validation and bioanalysis for drug concentration.

Johnson & Johnson  
Contact: Ray Barber  
E-mail: rbarber@its.jnj.com  
Website: www.careers.jnj.com

Johnson & Johnson, through its operating companies, is the world’s most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical, and medical devices and diagnostics markets. The more than 250 Johnson & Johnson operating companies employ approximately 117,000 men and women in 57 countries and sell products throughout the world.

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Contact: Christine Leonard  
E-mail: cleonard@joulenc.com  
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Jubilant Clinsys  
Contact: Larry Veal  
E-mail: lveal@clinsys.com  
Website: www.clinsys.com

Jubilant Clinsys Inc is a scientifically focused CRO that provides pharmaceutical, biotechnology and medical device companies with a full range of services in support of Phase I - IV drug and device development. The company is a subsidiary of Jubilant Life Sciences which is an integrated pharmaceutical services provider.

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Contact: Marissa Carnevale  
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Kansas Bioscience Authority  
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E-mail: osborn@kansasbioauthority.org  
Website: www.kansasbioauthority.org

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 startups; supporting expansion of the state’s bioscience clusters; and facilitating industrial expansion and attraction.

Kaplan EduNeering  
Contact: Rich Hensler  
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Website: www.kaplaneduneering.com

Kaplan EduNeering develops technology-enabled knowledge solutions for assuring regulatory compliance, minimizing risk and improving business performance. Clients around the world rely on our cloud-computing learning solution that meets the regulatory requirements within life science, energy, health plans, and general industry.

Kayentis  
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Kayentis is the leader in Digital Pen Technology. Providing a single, integrated platform for EDC, e-PRO and any other clinical trial documents. Kayentis offers the easiest and most reliable data collection method for all Phases of Clinical Studies.

Kelly Scientific Resources  
Contact: Diane Barker, Director, Americas Product Group  
Phone: 314-439-5649  
E-mail: diane.barker@kellyservices.com  
Website: www.kellyscientificresources.com

Kelly Services specializes in clinical research solutions and has years of experience as a strategic partner to help your business reach critical goals. We build custom workforce plans as well as project-based solutions, including a synchronized approach to outsourced clinical trial management, helping you save money and increase speed to market.

Kendle  
Contact: Thom O’Donnell  
E-mail: info@kendle.com  
Website: www.kendle.com

Kendle is a leading global clinical research organization providing the full range of early-to late-stage clinical development services for the world’s biopharmaceutical industry. Our focus is on innovative solutions that reduce cycle times and accelerate the delivery of life-enhancing products to market in the benefit of patients worldwide.

Kforce Clinical Research  
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Kforce Clinical Research provides customized, scalable outsourcing solutions. We offer flexible clinical services for all phases and therapeutic areas of site and study management, programming, data services and regulatory affairs. An intelligent partner, we support our clients as they focus on the science of creating life-changing medicines.
Klein Hersh International
Contact: Jason Hersh
E-mail: jhersh@kleinhersh.com
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Klein Hersh International is the industry leader in Life Sciences executive search, consulting, and interim staffing. As a full service search firm, we provide retained & contingency search as well as contract staffing in Clinical, Regulatory, and IT functions throughout the drug development lifecycle. Visit us on the web at www.kleinhersh.com.

Korea National Enterprise for Clinical Trials (KoNECT)
Contact: julielee
E-mail: julie@konect.or.kr
Website: www.konect.or.kr

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.

KUANTUM CRO and Logistics
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Website: www.kuantum-cro.com

Founded in 2003, Kuantum is a leading provider of CRO and Clinical Supplies Management services for the Life Science industry in Turkey and in the region. We offer a comprehensive set of GCP and GDP compliant services including all clinical monitorization activities as well as importation, storage distribution, returns and destruction arrangements.

LabConnect, LLC
Contact: Jeff Mayhew
E-mail: jmayhew@labconnectllc.com
Website: www.labconnectllc.com

LabConnect provides integrated, one-stop solutions for your laboratory service needs. Through the combined expertise of our worldwide network of leading laboratories, we provide customized laboratory service solutions designed to meet the unique requirements of our clients.

Laboratorio Hidalgo S.A.
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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
Contact: Sara Fragata
E-mail: sara.fragata@langland.co.uk
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
Contact: Jill Huentejelma
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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
Contact: David Blaeser
E-mail: dblaeser@libramed.com
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Contact: Kaarin Gordon
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Liquent, Inc.
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E-mail: info@liquent.com
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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
Contact: Giles Wilson
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Website: www.logostechnologies.com

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<td>625</td>
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<td>MedDRA MSSO</td>
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<td>Tim Divane</td>
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<td><a href="mailto:info@medfocus.com">info@medfocus.com</a></td>
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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.

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The MRN is a unique independent 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.

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MEDTOX Laboratories
Contact: Mike Bunkers
E-mail: mbunkers@medtox.com
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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.

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E-mail: jmclintick@medtrials.com
Website: www.medtrials.com

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Contact: Kim Nitahara
E-mail: kim.nitahara@metasol.com
Website: www.metasol.com

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.

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Midlands IRB (MLIRB) Booth 1555
Contact: Cathy Owen
E-mail: cathyo@midlandsirb.com
Website: www.midlandsirb.com

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.

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E-mail: cjoslin@mission3.com
Website: www.mission3.com

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Website: www.wegetpatients.com

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MPI Research Booth 404
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Contact: Lorann Morse
E-mail: sales@myoderm.com
Website: myoderm.com

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 bulk sourcing for comparators and CentralSource provides sourcing and direct to clinical site distribution management.

National Death Index Booth 2012
Contact: Robert Bilgrad
E-mail: ndi@cdc.gov
Website: www.cdc.gov/nchs/ndi.htm

The National Death Index (NDI) is a central computerized index of death record information on file in the state vital statistics offices. Working with these states, NCHS established the NDI as a resource to aid epidemiologists and other health and medical investigators with their mortality ascertainment activities.

National Pharmaceutical Council (NPC) Booth 634
Contact: Kathryn Gleason
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.

New England IRB  
Contact: James Saunders  
E-mail: james.saunders@neirb.com  
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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  
Contact: John W. Lacey or Jenifer O'Quinn  
Phone: +1-865-305-9100  
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  
Contact: Gilbert Molina  
Phone: 609-524-2501  
E-mail: gmolina@newcardio.com  
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  
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  
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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.  
Contact: Alan Arroyo  
E-mail: aaarroyo@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 management 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  
Contact: Joseph Miller  
E-mail: info@norwichpharma.com  
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)  
Contact: Arun Mathew  
E-mail: arun.mathew@nova-transnet.com  
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NOVA is a well respected provider of multilingual language services to the CRO/Regulatory affairs sectors. From clinical trial protocols to marketing authorisation dossiers, we will fulfil all your translation requirements with expertise, accuracy and reliability in all European languages. NOVA is ISO 9001:2008 and UNE EN 15038 certified.

Novella Clinical  
Contact: Kristi Robison  
E-mail: krobison@novellaclinical.com  
Website: www.novellaclinical.com

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  
Contact: Seth Warhaftig  
E-mail: sETH@novemberresearch.com  
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  
Contact: Julia Jones  
E-mail: julia.jones@novotech-cro.com  
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
Contact: Michael Brown
E-mail: mbrown@nspirehealth.com
Website: www.nspirehealth.com
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
Contact: Marcelo Reggiardo
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.

Octagon Research Solutions, Inc.
Contact: Kathleen Bouldin
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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
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E-mail: swentz@odysseyresearch.org
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
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Website: www.omnicareCR.com
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.

OmnComm Systems, Inc.
Contact: Bev Hudson, SVP of Global Business Development
Phone: 954-473-1254
E-mail: info@omnicomm.com
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
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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
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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
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Website: www.openclinica.com
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.

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Contact: Darrell Ethell
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Website: www.optum.com
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.
Contact: Matthew Chapin
E-mail: mchapin@oraclinical.com
Website: www.oraclinical.com
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
Contact: Cheryl Gray
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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.
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**Orlando Clinical Research Center**  
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Phone: 407-240-7878

Contact: Thomas Marbury, MD  
E-mail: tmarbury@occr.net  
Website: www.occr.net

OCRC is an independent Phase I-IV custom-built 35,000 sq. ft. research site designed for Phase I 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).

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Booth 1302

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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**  
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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

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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 schedule.

**Paragon International, Inc.**  
Booth 935  
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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.

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**The Patient Recruiting Agency (TPRA)**  
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TPRA’s data-driven IN-HOUSE SOLUTIONS include: creative production, patient/physician outreach, site selection plus website & call prescreening. Now with RADIUS365™, TPRA’s online platform to track & manage all response, referral, randomization & retention activities in real-time, TPRA is the Leader In Successful PATIENT RECRUITING & RETENTION.

**PCM TRIALS**  
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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.**  
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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.**  
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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**  
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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**  
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Pharm-Olam International  
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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  
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Pharmaceutical Executive  
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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  
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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)  
Contact: Kyoichi Tadano, Ph.D  
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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.  
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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.  
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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  
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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.  
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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  
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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  
Contact: Taren Grom  
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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.
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**PharMed Alliance**

Contact: Kelly Willenberg  
E-mail: info@pharmadalliance.com  
Website: www.pharmadalliance.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**

Contact: Kristen Boatman  
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**

Contact: Karen Redding  
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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**

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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.

**PRA International**

Contact: Tami Klerr-Naivar  
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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.

**Premier Research Group Limited**

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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.

**Piramal Healthcare**

Contact: Karen Scott  
E-mail: karen.scott@piramal.com  
Website: www.piramal.com

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Contact: David Cornwell  
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Website: www.pleasetech.com

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Contact: Fabrice Beauchene  
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.

**Praxis Communications**

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PraxiX 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.

**Prestium**

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Prestium, 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. Prestium is customer focused, delivering projects with outstanding patient recruitment and compliance, quality data and rapid start-up.
PrimeVigilance Limited  
Contact: Jonathan West  
E-mail: jonathan.west@primevigilance.com  
Website: www.primevigilance.com  
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Contact: Scot Stubenhofer  
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)  
Contact: Maggie Smith  
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.

Projects  
Contact: Russell Holmes  
E-mail: russ@projectis.com  
Website: www.projectis.com  
Projects, 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  
Contact: Christopher Gallant  
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Website: www.prometrika.com  
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Website: www.prosarsafety.com  
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Protrials Research  
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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  
Contact: Ekaterina Nikolaevskaya  
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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  
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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 solutions and to see the latest in our Auditca™ and Audit Utopia™.

PSI  
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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. PSIs 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  
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Website: www.qlikview.com  
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**QPS**

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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.**

Contact: Jason Bertram  
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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)**

Contact: Lora Martin  
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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

**Quanticate, Inc.**

Contact: Andrew MacGarvey  
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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).**

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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**

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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.

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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**

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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**

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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**

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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.**

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Based in Cincinnati, Ohio, Radiant is a comprehensive clinical research and development company serving the biopharmaceutical and medical device industry. We offer full service CRO capabilities, Radiant Trial Support, Patient Recruitment and dedicated research centers across the US and India.

**Randox Pharma Services**

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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

Contact: Kevin Boos
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 Staffing Group

Contact: Tom Froggatt
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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

Contact: Ben McGinty
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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, data-base creation, and web archiving services.

REGISTRAT-MAPI

Contact: Amy Wynn
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Website: www.registratmapi.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)

Contact: kbowler@securesubinc.com
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.

Contact: Betty Cory
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

Contact: Mary A. Raines, Director of Business Development
Phone: 972-241-1222
E-mail: mraines@researchacrossamerica.com
Website: www.researchacrossamerica.com

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

Contact: Hal J. Mann
E-mail: hmann@researchdx.com
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

Contact: Roseanna Shipley
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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.

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Contact: Joan Parks
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.

Contact: Jessica Friendly
E-mail: jfriendly@rpsweb.com
Website: www.rpsweb.com

RPS, The Next Generation CRO, provides comprehensive global Phase I-IV clinical development solutions to the pharmaceutical, biotechnology and medical device industries.

RWD Technologies

Contact: Mike Yamark
E-mail: M.Yamark@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.
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Booth 1349
Contact: Miriam Norris
E-mail: tradeshows@sas.com
Website: www.sas.com/dia

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**Schlafender Hase GmbH**
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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.

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E-mail: BusinessDevelopment@sairb.com
Website: www.sairb.com

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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.

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Website: www.rxlogix.com

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SGS is a leading contract service organization providing clinical research services, analytical development, biologics characterization, and quality control testing, serving pharmaceutical, 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
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Website: www.sharpcorporation.com

Sharp is a market leader in customer focused solutions in contract-packaging 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.

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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.

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Booth 1457
Contact: Sarah Dye
E-mail: sarah.dye@smallplanetmeetings.com
Website: www.smallplanetmeetings.com

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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  
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E-mail: cduggan@snbl-cpc.com  
Website: www.snbl-cpc.com

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
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Website: www.soltexconsulting.com

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  
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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  
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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  
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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  
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Website: www.spauldingclinical.com

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
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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
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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)  
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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  
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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
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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
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Website: www.stirisresearch.com

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  
Contact: Kurt Wagner  
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  
Contact: Betsey Zbyszynski  
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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  
Contact: Dr. Ravindra Bhavsar  
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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.  
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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, bioavailability, data management, glucose clamp studies, dermatological studies like dermatopharmacokinetic and skin blanching studies.

Synergy Research Group  
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Website: www.synrg-pharm.com
Synergy Research Group (Synteract) 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. Synteract is a client-oriented company - through close cooperation we eliminate territorial issues and work proactively to ensure success of the project.

Synknowledge Drug Safety Solutions  
Contact: Sam Stein  
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Website: www.synknowledge.com
Synknowledge 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.
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ThreeWire, Inc.  
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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.  
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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.  
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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  
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TrainingCampus.com is the first global Education Management Network. An aggregator/consolidator of resources used by healthcare/c 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.
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Trident Clinical Research

Contact: Karen West
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

Contact: Dax Kiger
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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

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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

Contact: Michael Shaub
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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

Contact: Suzanne Conlon
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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

Contact: Mark Hutson, MSEd, VP, Business Development, North America
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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)

Contact: Toshikazu Goto
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

Contact: Robert D. Thompson, CCRC
E-mail: thomprd@ufl.edu
Website: www.med.ufl.edu/cctr

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Contact: Chris Miciek
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the Uppsala Monitoring Centre

Contact: Mats Perssson
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.
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E-mail: carena@utahclinicaltrials.com  
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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.

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Website: www.veevasystems.com  
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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  
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Website: www.veristat.com  
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Virtify, Inc.  
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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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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  
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Website: www.virtualscopics.com  
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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 organizations; helping to implement solutions which assure compliance and boost performance.

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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  
Contact: Talia Nikolao  
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)  
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.  
Contact: Sasha Lauks, Business Development Associate  
Phone: +1 508- 625 1693  
E-mail: sales@woodleyequipment.com  
Website: www.woodleyequipment.com  

Whitsell 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.

Woodley Equipment Company Ltd  
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.  
Contact: Georgette Caracciolo  
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  
Contact: Emilio Cordova  
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  
Contact: Peter Oudheusden  
E-mail: info@writeresult.com  
Website: www.writeresult.com  

WriteResult 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. WriteResult’s experienced professional services team helps organizations maximize performance and efficiency.

Xybion Corporation  
Contact: Sherry Cordery  
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  
Contact: Jennifer McDonald  
E-mail: jennifer.mcdonald@yoh.com  
Website: www.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.

<table>
<thead>
<tr>
<th>DIA 2011 HOTELS</th>
<th>Hotel Address</th>
<th>Single Room Rates* start at</th>
<th>Distance to Convention Center</th>
<th>Shuttle Offered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Best Western Grant Park</td>
<td>1100 South Michigan Avenue</td>
<td>$139</td>
<td>1.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>2 Chicago Essex Inn</td>
<td>800 South Michigan Avenue</td>
<td>$164</td>
<td>1.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>3 Doubletree Chicago Magnificent Mile</td>
<td>300 East Ohio Street</td>
<td>$189</td>
<td>3.6 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>4 Fairmont Chicago</td>
<td>200 North Columbus Drive</td>
<td>$229</td>
<td>3.0 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>5 Hampton Majestic Chicago Theater District</td>
<td>22 West Monroe Street</td>
<td>$179</td>
<td>2.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>6 Hard Rock Hotel Chicago</td>
<td>230 North Michigan Avenue</td>
<td>$189</td>
<td>3.4 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>7 Hilton Chicago</td>
<td>720 South Michigan Avenue</td>
<td>$249</td>
<td>1.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>8 Hotel 7</td>
<td>71 East Wacker Drive</td>
<td>$199</td>
<td>2.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>9 Hotel Monaco Chicago, a Kimpton Hotel</td>
<td>225 North Wabash Avenue</td>
<td>$209</td>
<td>3.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>10 Hyatt Regency Chicago</td>
<td>151 East Wacker Drive</td>
<td>$269</td>
<td>3.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>11 Hyatt Regency McCormick Place</td>
<td>2233 South Martin Luther King Drive</td>
<td>$289</td>
<td>Adjacent</td>
<td>No</td>
</tr>
<tr>
<td>12 Palmer House Hilton</td>
<td>17 East Monroe Street</td>
<td>$239</td>
<td>2.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>13 Renaissance Blackstone Chicago Hotel</td>
<td>636 South Michigan Avenue</td>
<td>$229</td>
<td>2.5 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>14 Renaissance Chicago Hotel</td>
<td>1 West Wacker Drive</td>
<td>$229</td>
<td>3.0 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>15 Sheraton Chicago Hotel and Towers</td>
<td>301 East North Water Street</td>
<td>Reduced Rate! $229</td>
<td>4.0 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>16 Silversmith Hotel &amp; Suites</td>
<td>10 South Wabash Avenue</td>
<td>$179</td>
<td>3.2 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>17 Swissotel Chicago</td>
<td>323 East Wacker Drive</td>
<td>Reduced Rate! $199</td>
<td>4.0 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>18 W Chicago Lakeshore</td>
<td>644 North Lake Shore Drive</td>
<td>$239</td>
<td>3.6 Miles</td>
<td>Yes</td>
</tr>
<tr>
<td>19 Westin Chicago River North</td>
<td>320 North Dearborn Street</td>
<td>$259</td>
<td>4.0 Miles</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* 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.
DIA 2011 Hotels

1. Best Western Grant Park
2. Chicago’s Essex Inn
3. Doubletree Chicago Magnificent Mile
4. Fairmont Chicago
5. Hampton Majestic Chicago Theater District
6. Hard Rock Hotel Chicago
7. Hilton Chicago
8. Hotel 71
9. Hotel Monaco Chicago, a Kimpton Hotel
10. Hyatt Regency Chicago
11. Hyatt Regency McCormick Place
12. Palmer House Hilton
13. Renaissance Blackstone Chicago Hotel
14. Renaissance Chicago Hotel
15. Sheraton Chicago Hotel and Towers
16. Silversmith Hotel & Suites
17. Swissotel Chicago
18. W Chicago Lakeshore
19. Westin Chicago River North
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.

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.

<table>
<thead>
<tr>
<th>Tutorial #</th>
<th>Fee</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MEMBER FEE

Join DIA now to qualify for all the benefits of membership for one year! www.diahome.org

US $1500

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

<table>
<thead>
<tr>
<th>Government (full-time)**</th>
<th>Member</th>
<th>Nonmember</th>
</tr>
</thead>
<tbody>
<tr>
<td>US $630</td>
<td>US $770</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Charitable Nonprofit/Academia (full-time)**</th>
<th>Member</th>
<th>Nonmember</th>
</tr>
</thead>
<tbody>
<tr>
<td>US $1,025</td>
<td>US $1,165</td>
<td></td>
</tr>
</tbody>
</table>

** If paying a nonmember fee, please indicate your membership preference above.
** Includes access to post-meeting presentations.

ONE-DAY REGISTRATION FEES†

You must indicate which day you plan to attend.

<table>
<thead>
<tr>
<th>Day</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>MON, June 20</td>
<td>US $825</td>
</tr>
<tr>
<td>TUES, June 21</td>
<td>US $965</td>
</tr>
<tr>
<td>WED, June 22</td>
<td></td>
</tr>
<tr>
<td>THUR, June 23</td>
<td></td>
</tr>
</tbody>
</table>

† One-day attendees will receive access to post-meeting presentations for that day ONLY.
** If paying a nonmember fee, please check preferred membership option 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.

Card Type: Visa MC AMEX

Exp Date ______________________________

Card # __________

Signature

Last Name First Name M.I.

Dr. Mr. Ms.

Degrees

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.

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.

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.

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.

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.

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

TOTAL PAYMENT DUE
Include all applicable fees

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:
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.

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PAYMENT IS REQUIRED ONLY IF REGISTERING FOR TUTORIALS.

Please check payment method below:

- CREDIT CARD Complete this form and fax to +1.215.442.6199 or mail to: Drug Information Association Inc., P.O. Box 95000-1240, Philadelphia, PA 19195-1240, 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., 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA. Please include a copy of this registration form to facilitate identification of attendee.

- BANK TRANSFER

Completed form should be faxed to +1.215.442.6199

Please Note:
This page must be completed and submitted for each person attending any portion of this event.

DIA 2011
47th Annual Meeting
McCormick Place, Chicago, IL
ID # 11001
June 19-23, 2011

Last Name ____________________________ First Name ____________________________

City ____________________________ State ____________ Zip/Postal Code ____________ Country ____________________________

Mail Stop ____________ Telephone Number ____________________________ Fax Number ____________________________

Email Address ____________________________ (required for confirmation)
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

PAYMENT OPTIONS: 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 # __________________________________________________________
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. ☐ Dr. ☐ Mr. ☐ Ms.
Degrees
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)

TOTAL PAYMENT DUE Include all applicable fees $ __________

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:
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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
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:  

<table>
<thead>
<tr>
<th>Training Course</th>
<th>Early-bird Member Fee</th>
<th>Member Fee After MAY 27, 2011</th>
<th>Nonmember Fee</th>
<th>Discounted Fees</th>
<th>Member Government/Academia</th>
<th>Nonmember Government/Academia</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clinical Project Management</td>
<td>$1720 ☑</td>
<td>$1820 ☑</td>
<td>$2010 ☑</td>
<td>$1000 ☑</td>
<td>$1900 ☑</td>
<td>$1190 ☑</td>
</tr>
<tr>
<td>• Fundamentals of Clinical Research Monitoring</td>
<td>CANCELLED</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Introduction to Good Clinical Practices and Auditing</td>
<td>$1720 ☑</td>
<td>$1820 ☑</td>
<td>$2010 ☑</td>
<td>$1000 ☑</td>
<td>$1900 ☑</td>
<td>$1190 ☑</td>
</tr>
<tr>
<td>• Regulatory Affairs Part I: The IND Phase</td>
<td>$1500 ☑</td>
<td>$1600 ☑</td>
<td>$1790 ☑</td>
<td>$760 ☑</td>
<td>$900 ☑</td>
<td></td>
</tr>
<tr>
<td>• New Drug Product Development and Lifecycle Management</td>
<td>$1035 ☑</td>
<td>$1135 ☑</td>
<td>$1325 ☑</td>
<td>$625 ☑</td>
<td>$680 ☑</td>
<td></td>
</tr>
<tr>
<td>• Risk Management and Safety Communication Strategies</td>
<td>$1375 ☑</td>
<td>$1475 ☑</td>
<td>$1665 ☑</td>
<td>$810 ☑</td>
<td>$1000 ☑</td>
<td></td>
</tr>
<tr>
<td>• Art of Writing a Clinical Overview</td>
<td>$840 ☑</td>
<td>$940 ☑</td>
<td>$1130 ☑</td>
<td>$520 ☑</td>
<td>$710 ☑</td>
<td></td>
</tr>
</tbody>
</table>

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 #:  
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 ID #1001 must be included on the transfer document to ensure payment to your account.  

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.