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DIA®
Drug Information Association

# June 18–22, 2006 | Philadelphia, PA

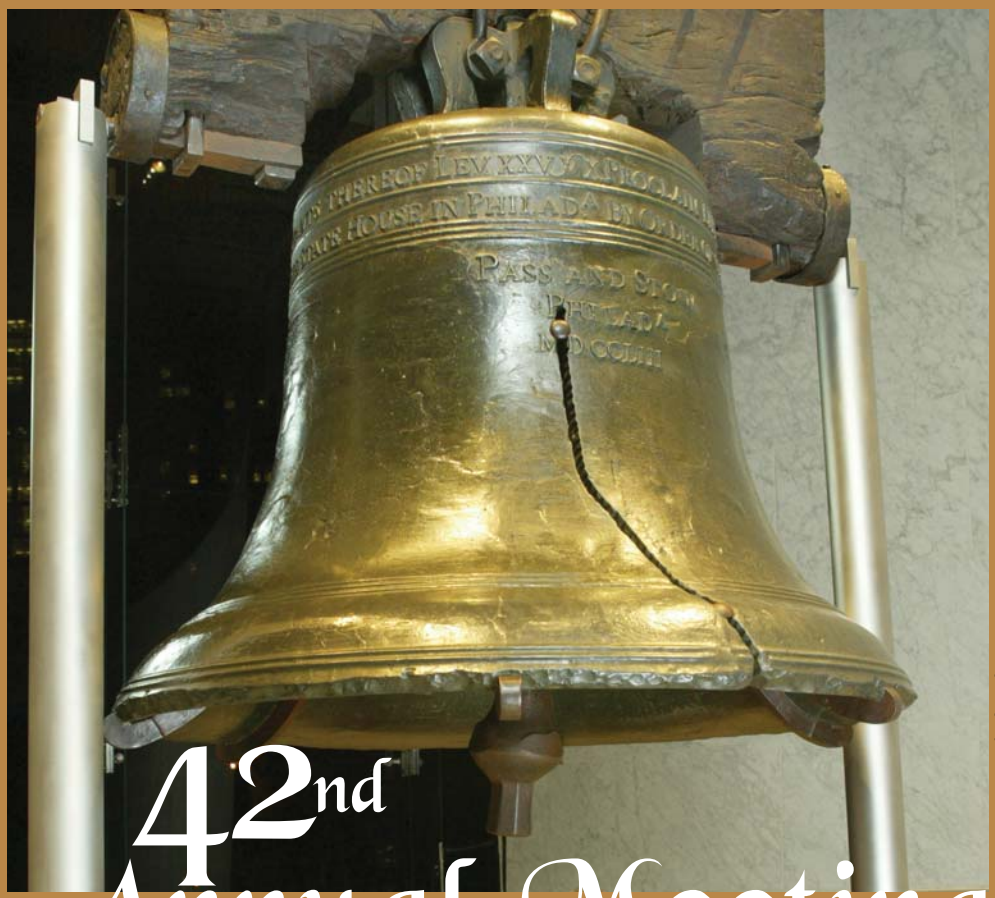


Photo by R. Kennedy for GPTMC

# 42nd Annual Meeting

Pennsylvania Convention Center

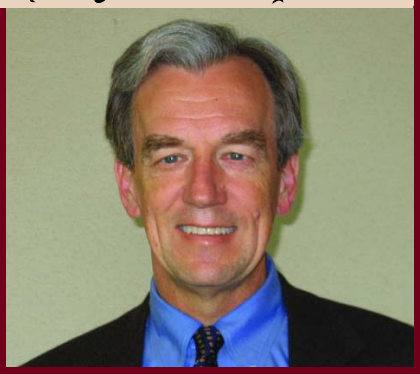
PROGRAM CHAIRPERSON
Charles C. Depew, PharmD
GlaxoSmithKline

***DIA's 42nd Annual Meeting – A Neutral Forum for Industry, Academia, and Regulatory Professionals from Around the World***

- *Attend presentations and case studies from more than 1,000 speakers*
- *Hear representatives from the FDA, EMEA and other regulatory agencies*
- *Choose from sessions in 29 tracks offered over 3½ days*
- *Network with over 475 exhibiting companies*
- *Attend one of over 40 preconference tutorials*
- *Participate in the Networking Reception at the National Constitution Center*
- *Visit student and professional poster sessions*
- *Keynote presentation by Sanjay Gupta, MD Senior Medical Correspondent for CNN*

***Don't Miss the Event of the Year for the Pharmaceutical and Related Industries!***

## Program Chairperson



Charles (Chuck) Depew, PharmD

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# The DIA 42ND Annual Meeting

June 18-22, 2006 | Philadelphia, Pennsylvania

## Dear Colleague,

Welcome to the Drug Information Association's 42nd Annual Meeting, an event attended by pharmaceutical, biotechnology, and regulatory professionals from around the world. With over 350 sessions, more than 1,000 speakers, and approximately 40 tutorials, this year's meeting has something for everyone. This is the one meeting where professionals who bring new medicines and vaccines to populations around the world gather to learn about best practices and the latest in regulations governing those practices. This is the single meeting that provides multiple opportunities for networking with your colleagues and peers from around the world, individuals who, like you, work to develop and deliver new safe and effective medicines.

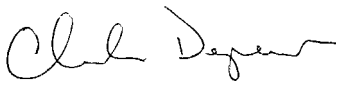
DIA continually strives to enhance the quality of the content offered at the Annual Meeting. To further this goal, we offer training opportunities on meeting procedures and processes to all track and session chairs. Several meetings are held throughout the year with track chairs to minimize session overlap and to place late-developing or "hot" topics into the program. Instituted last year, a guide to the level of session difficulty will again be included in the program to assist attendees in selecting sessions that make the most efficient use of their time. A special plenary session with the FDA, Office of the Commissioner will be held this year on Tuesday afternoon, followed by a reception to recognize the 100th year of the FDA. We have several sessions in which speakers from the FDA and EMEA will be on the same panel, addressing current guidelines and what to expect in the future. A roadmap will be provided to highlight sessions or presentations that address the Critical Path Initiative(s). There will be both student and professional poster sessions, and, as always, we will have the CDER Town Hall.

The DIA Annual Meeting is one of the largest venues in the industry for exhibitors. The Annual Meeting exhibit hall presents an extraordinary opportunity to network with a wide range of service providers in the biopharmaceutical industry, in a single location. With representation from CROs, technology providers, and academic research site centers, the exhibit hall is a favorite spot for attendees to visit throughout the meeting.

Because the 2006 Annual Meeting will be held in Philadelphia, in the center of the pharmaceutical industry corridor, many of your professional, academic, and regulatory colleagues will be attending. Philadelphia, the fifth largest city in the United States, has many extraordinary restaurants, historic sites, museums, and shopping areas to visit.

This meeting could not happen without the hard work and dedication of the DIA staff and the many volunteers who serve as track chairs, session chairs, and speakers. I would like to personally thank each volunteer and staff member for devoting the time and energy needed to make this the best meeting experience for biopharmaceutical and regulatory professionals in 2006.

On behalf of the program committee and the DIA Board of Directors, I invite you to join the global community of colleagues who will be coming to the DIA Annual Meeting in Philadelphia, June 18-22, 2006.



Charles (Chuck) Depew, PharmD
2006 Annual Meeting Program Chairperson

Charles (Chuck) Depew, joined GlaxoSmithKline in 1995 as head of Product Professional Services. Since 2001, he has headed up the Regulatory Operations organization in US Regulatory Affairs. Prior to joining GSK, he was Director of Medical and Drug Information at The Upjohn Company. He has worked as a pharmacist, primarily in acute care settings at Yale-New Haven Hospital, New Haven, Connecticut and at Stanford University Hospital, Stanford, California.

Chuck received a BA in Zoology from the University of California, Los Angeles and a PharmD from the University of California, San Francisco. He completed a residency in Hospital Pharmacy at Yale-New Haven Hospital, New Haven, Connecticut.

He has served on the DIA Steering Committee of North America, the DIA Board of Directors, and currently serves on the DIA Foundation.

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## Keynote Speaker

Sanjay Gupta, MD

Dr. Sanjay Gupta is senior medical correspondent for the health and medical unit at CNN. Gupta, a practicing neurosurgeon and an assistant professor of neurosurgery, plays an integral role in the network's medical coverage, which includes daily packages, the half-hour weekend show *House Call with Dr. Sanjay Gupta* and coverage of breaking medical news. Based in Atlanta, he also co-hosts *Accent Health* for Turner Private Networks, provides medical segments for the syndicated version of *ER* on TNT, contributes health news stories to CNN.com and writes a column for *TIME* magazine.

Gupta joined CNN in the summer of 2001 and became part of the network team covering the September 11 attacks in New York City. In 2003, Gupta spent time in Iraq and Kuwait, reporting on various medical aspects of escalating tension with Iraq, and provided live coverage from a desert operating room of the first operation performed during the war. He traveled to the 2004 international AIDS conference in Bangkok, Thailand, where he reported on the pandemic for CNN/U.S. and in December, Gupta was sent to Sri Lanka to cover the disaster and aftermath of the tsunami that took more than 155,000 lives in South Asia.

In addition to his work for CNN, Gupta is a member of the staff and faculty of the department of neurosurgery at the Emory University School of Medicine in Atlanta and performs surgery weekly at Emory University Hospital and Grady Memorial Hospital, where he serves as chief of neurosurgery.

Before joining CNN, Gupta was a neurosurgeon at the University of Tennessee's Semmes-Murphy clinic, and before that, the University of Michigan Medical Center. He became partner of the Great Lakes Brain and Spine Institute in 2000 and in 1997, he was chosen as a White House Fellow, one of only 15 fellows appointed. He served as special advisor to the first lady.

Gupta has been published in a variety of scientific journals and has received numerous accolades, including a National Headliner Award this year for "The First Patient: Health and the Presidency", a prime-time, health-related television special. In 2004, the Atlanta Press Club named him "Journalist of the Year." He has won the Humanitarian Award from the National Press Photographers Association, a GOLD Award from the National Health Care Communicators and a finalist honor for the International Health and Medical Media award known as the "Freddie."

He is a member of several organizations, including the American Association of Neurological Surgeons, Congress of Neurological Surgeons, Do Something Foundation, Healing the Children Foundation, the Council of Foreign Relations and the Brain Foundation. Gupta is also a certified medical investigator.

Gupta received his undergraduate degree from the University of Michigan and a doctorate of medicine from the University of Michigan Medical Center.

# What's New in Networking Opportunities?

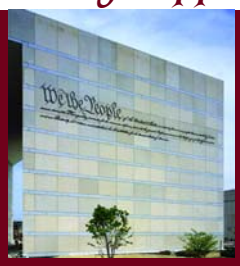
The Networking Dinner, which previously was a formal, sit-down dinner, has been changed to a more informal Networking Reception. We feel that this more informal reception structure will encourage attendees to interact with more of their colleagues and open up more networking opportunities. In addition to enjoying great food, DIA guests interested in exploring will have exclusive access to the permanent exhibits of the Constitution Center during this reception.

## When?

The Networking Reception will take place from 6:30 to 8:30 PM on Sunday, June 18, at the National Constitution Center.

## Where?

The National Constitution Center is located on the third block of Philadelphia's historic Independence Mall. It tells the story of the US Constitution through more than 100 interactive and multimedia exhibits, photographs, sculpture, text, film and artifacts. This is the only museum in the world dedicated to honoring and explaining the US Constitution and is a great way to welcome international attendees to the United States and all attendees to the Philadelphia region.



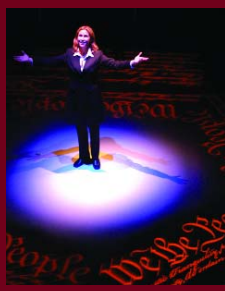

## What is there to do at the Constitution Center?

You can experience "Freedom Rising," a multimedia production combining film, a live actor, and video projection on a 360-degree screen, which highlights the major themes of the Constitution from 1787 to the present day, presented in the 350-seat, star-shaped Kimmel Theater. In the DeVos Hall's American Experience, you can enjoy interactive, family-oriented exhibits that show the significant role the Constitution has played throughout history. You can vote for your all-time favorite President, take the Presidential Oath of Office, take the seat of a Supreme Court Justice, honor the service people who have fought for and defended the Constitution.

You can explore Signers' Hall, which contains 42 life-size bronze statues of the 39 men who signed the Constitution, as well as the three who dissented. You'll also be able to email elected officials and monitor contemporary constitutional issues.

## What does it cost?

The cost of the Networking Reception is $65.00, which includes:



- Shuttle transportation to/from the Convention Center
- Exclusive access to permanent and changing exhibits of the National Constitution Center
- First-class food and beverages, including pasta station, cheese station, dessert tables, butlered hors d'oeuvres, soft drinks, wine, and beer
- UNLIMITED NETWORKING OPPORTUNITIES

**From the initial stages of R&D to clinical trials through regulatory approval and product marketing, the pharmaceutical and biotechnology industries must continually respond to critical advancements and changing regulatory requirements. Join more than 8,000 industry, academia, and regulatory professionals from across the world at DIA's 42nd Annual Meeting – the largest neutral forum in the life sciences field dedicated to biopharmaceutical life cycle challenges – on June 18-22, 2006 at the Pennsylvania Convention Center.**

**Hosted in Philadelphia – the heart of the pharmaceutical industry corridor, where DIA was founded and remains headquartered – the meeting offers attendees more than 350 sessions with 1,000+ speakers, including representatives from the FDA, EMEA and other regulatory agencies. Industry professionals can register for one of 40+ premeeting tutorials, select from sessions in 29 tracks and network with representatives from approximately 500 exhibiting companies including clinical research organizations (CROs), technology providers and academic research site centers.**

**This year's meeting also offers the unique opportunity to commemorate the 100th year of the FDA with a special plenary session hosted by the FDA's Office of the Commissioner, on Tuesday, June 20 at 3:30 pm, immediately followed by a celebratory reception.**

**Here are just some of the sessions you don't want to miss!**

## Monday, June 19 *Impact, eClinical, and Regulatory Affairs Sessions*

### Patient-reported Outcome Instruments: Overview and Comments on the FDA Draft Guidance

**IMP** – 10:30 am-12:00 pm

Chairperson: **Laurie Beth Burke, RPh, MPH, CAPT. USPHS,** Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

FDA has issued a draft guidance for industry on the proper development and use of patient-reported outcome measures in clinical trials to support medical product labeling claims. In response, a public docket contains many comments from industry, academia and other researchers concerning the contents of the draft guidance. This session will summarize the draft guidance in the context of the comments received to date. The intent of this session is to have a dialogue between the agency and stakeholders on this draft guidance. Representatives from FDA have been invited to participate in this session.

### Electronic Patient-reported Outcomes (ePRO) Technology and the FDA Draft PRO Guidance: A Town Meeting to Discuss Industry's Response

**EC1** – 3:30 pm-5:00 pm

Chairperson and Moderator: **John M. Weiler, MD,** President, CompleWare Corporation

This session will address the implications of the FDA's Draft PRO Guidance (http://www.fda.gov/cber/gdlns/prolbl.pdf) issued in early February, 2006 as it applies to ePRO Technology (lines 813-858). Panel members and attendees will participate in a town meeting setting to explore options for industry to deal with the electronic aspects of this draft guidance. Sponsor and CRO representatives have been invited to join the panelists below.

**Valdo Arnera, MD,** General Manager, Europe, PHT Corporation

**Jean Paty, PhD,** Founder and Senior Vice President, invivodata, inc.

### Prescription Drug Labeling: Implementation of FDA's New Regulation for the Content and Format of the USPI and Accompanying Guidance Documents

**RA2** – 3:30 pm-5:00 pm

Chairperson: **Steven W. Bass, PhD,** Group Director, Global Labeling and Promotion Compliance, Bristol-Myers Squibb Company

On January 24, 2006, the FDA released the long awaited Final Rule for the "Requirements on Content and Format of Labeling for Human Prescriptions and Biological Products." This was accompanied by two Final Guidances on the Adverse Reaction Section and the Clinical Studies Section and a Draft Guidance on the Warning and Precautions, Contraindications, and Boxed Warning Sections and a Draft Guidance on Implementing the New Content and Format Requirements.

This session will review the format and content of the new regulation and accompanying guidance documents, the time frame for implementation of the "new format" and the changes from the current regulations for the content and format of the US Package Insert (CFR 201.56 and CFR 201.57). It will also provide a forum to discuss both the FDA's and industry's questions and expectations regarding the implementation of the proposed labeling changes. The new format is a major change to the way we have been delivering safety and efficacy information to healthcare professionals and to patients. Therefore, this "long awaited and anxiously anticipated session" should be highly informative and interactive. Speakers include:

**Steven W. Bass, PhD,** Bristol-Myers Squibb Company

**Laurie Beth Burke, RPh, MPH, CAPT. USPHS,** CDER, FDA

Highlighted Sessions continue on page 6

## Tuesday, June 20 *Regulatory Affairs/Clinical Research Sessions*

### CBER Hot Topics

**RA5** – 10:30 am-12:00 pm

Chairperson: **Diane Maloney, JD,** Associate Director for Policy, CBER, FDA

This session will highlight two hot topics in CBER. Celia Witten, MD, Director of CBER's Office of Cellular, Tissue and Gene Therapies will discuss cell and gene therapies and Marion Gruber, PhD, Associate Director for Policy in CBER's Office of Vaccine Research and Review, will discuss pandemic influenza vaccines.

**Celia M. Witten, MD,** Director, Office of Cellular, Tissue and Gene Therapies, CBER, FDA

**Marion F. Gruber, PhD,** Associate Director for Policy, Office of Vaccine Research and Review, CBER, FDA

### Update from the FDA Office of the Commissioner

**RA/CR Plenary** – 3:30 pm-5:30 pm

Chairperson: **Charles C. Depew, PharmD**, GlaxoSmithKline

In recognition of the 100th anniversary of the US Food and Drug Administration, the Office of the Commissioner will provide an overview of the Agency's agenda for 2007 to 2010. This includes the Critical Path Initiative, PDUFA IV, Advisory Committees, Risk Minimization, National and International Public Health Issues, Product Registration, and Regulatory Decision Making.

Attendees of the DIA Annual Meeting will be able to submit questions for the Q&A panel discussion with the Deputy Commissioners. More details regarding how to submit these questions will be available closer to the meeting.

Following this session, there will be a reception recognizing the FDA for its 100th anniversary. Panelists include:

***Janet Woodcock, MD,*** Deputy Commissioner of Operations and Chief Operating Officer, Office of the Commissioner, FDA

***Murray M. Lumpkin, MD, MSc,*** Deputy Commissioner for International and Special Programs, Office of the Commissioner, FDA

## Wednesday, June 21 *Regulatory Affairs Sessions*

### CDER Hot Topic – Update: Drug Safety Initiatives

**RA5** – 10:30 am-12:00 pm

Chairperson: **Susan K. Cummins, MD, MPH,** Executive Director, Drug Safety Oversight Board, CDER, FDA

In 2005 FDA launched a drug safety initiative with the goal of giving healthcare professionals, patients, and consumers up-to-date information about medicines and making the drug review and monitoring process as transparent as possible. The FDA also began providing information for healthcare professionals and patients on its website about emerging and important drug safety concerns. A reorganization in CDER was also announced to place greater emphasis on safety policy and communication. The impact of increased funding earmarked for postmarketing surveillance and epidemiology will also be discussed. This session will review the first year of progress and activities for FDA's Drug Safety Oversight Board, and the impact of the changes and initiatives focused on safety. Additional participants include:

**Paul J. Seligman, MD, MPH,** Director, Office of Pharmacoepidemiology and Statistical Sciences, CDER, FDA

**Gerald Dal Pan, MD, MHS,** Director, Office of Drug Safety, CDER, FDA

### CDER Hot Topic: Physicians' Labeling Rule

**RA5** – 3:30 pm-5:00 pm

Chairperson: **Rachel E. Behrman, MD, MPH,** Deputy Director, Office of Medical Policy, CDER, FDA

This session will begin with an overview of the Physician Labeling Rule. This will be followed by a panel discussion where the audience can ask specific questions and clarifications about the ruling and guidances of an FDA panel. Additional participants include:

**Colleen Locicero, RPh,** Associate Director for Regulatory Affairs, Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

**Elizabeth Sadove, JD,** Regulatory Counsel, Office of Regulatory Policy, CDER, FDA

## Thursday, June 22 *Regulatory Affairs Sessions*

### CDER Town Meeting – Parts 1 & 2

**RA1** – 8:30 am-10:00 am & 10:30 am-12:00 pm

Chairperson: **Nancy D. Smith, PhD,** Director, Office of Training and Communications, CDER, FDA

This interactive session will allow members of the audience to submit questions to senior leaders from the Center for Drug Evaluation and Research. The topics discussed will depend on the interests of the audience.

## Learning Objectives

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

- Describe the current regulatory and public policy environment pertaining to pharmaceuticals with an emphasis on the Food and Drug Administration;
- Discuss the international regulations and economic factors that impact the global biopharmaceutical industry;
- Recognize the challenges facing the FDA and the pharmaceutical industry in areas such as research study design and statistical methodology;
- Recognize the state of the art clinical and statistical systems and implementations;
- Recognize the written and communications skills needed to promote your career and your company's objectives;
- Enhance your working relationship with colleagues, both locally and internationally;
- Describe legal, advertising, and marketing issues related to providing product information;
- Discuss statistics, economics, and quality of life science;
- Enhance your knowledge of risk assessment and management in the areas such as computer systems validation and drug safety and pharmacovigilance;
- Discuss issues in safety reporting, data analysis, epidemiology, and regulations regarding adverse events.

## Target Audience

This program is designed for the full continuum of disciplines in the pharmaceutical and related industries to improve your understanding and skills as related to issues and solutions for a variety of pharmaceutical development interest areas.

## Continuing Education

*Select sessions will offer AMA PRA Category 1 Credits™, pharmacy contact hours, nursing contact hours, or PMI professional development units. These sessions are clearly identified in the program with the statement of CME, Pharmacy, Nursing, or PMI credits offered. IACET continuing education units are offered for all sessions. Continuing education credits are not available for the plenary session on Monday morning. Learning objectives for each session will be shown as a slide in the session room.*

**Accreditation and Credit Designation**

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 19.5 *AMA PRA Category 1 Credit(s)™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants may earn up to 19.5 contact hours or 1.95 continuing education units (CEUs) for participating in the annual meeting sessions.

**Nursing** The Drug Information Association will offer nursing credits for various sessions in collaboration with Corexcel. Corexcel is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Participants may receive up to 23.4 nursing contact hours for attending the annual meeting sessions.

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA will award up to 2.6 continuing education units (CEUs) to participants who successfully complete the annual meeting sessions.

SM Project Management Institute R.E.P.

**PMI** The Drug Information Association has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI). Participants may receive up to 19.5 professional development units (PDUs) for attending the annual meeting sessions.

**Annual Meeting Sessions**

June 19-22, 2006 – 286-000-06-501-L04; up to 1.5 *AMA PRA Category 1 Credits™* or pharmacy contact hours (.15 CEUs); 1.8 nursing contact hours; 1.5 PMI professional development units; or .2 IACET CEUs per session ***(does not include the plenary session Monday morning).***

**DIA is proud to announce the launch of its new online credit request system, "My Transcript."** The system allows you to go to the DIA website to request credit and download certificate(s) for this meeting. To request a statement of credit, please go to www.diahome.org. Select "Educational Offerings" from the top menu bar, then choose "Continuing Education" on the left menu and then select "My Transcript." You will be prompted for your username 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. *If you experience any difficulties, please contact Tricia Wilson at tricia.wilson@diahome.org.*

**Disclosure Policy**

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty may have disclosed one or more of the following: grants/research support, consultancy relationships, speaker's bureau participation, significant equity (stock) positions, and sources of honoraria/expenses.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the Drug Information Association or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures begin on page 142.

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

## Audio CDs and Track CD-ROMs

Audio CDs for individual sessions will be available this year, both on site and after the meeting. Track CD-ROMS (with PowerPoint and audio) will also be available. The sales desk for these products is located on the Arch Street Bridge, 2nd floor of the Convention Center.

## Baggage Check

An area in the Meeting Room Foyer on the 1st floor of the Convention Center at the 12th and Arch Street entrance has been reserved for attendees to check their belongings if necessary. The cost of this service to the attendees is $2.00 per item checked. The Baggage Check Area will be available at the times listed below:

| | | | |
|---|---|---|---|
| **Saturday, June 17** | 12:00 pm-5:00 pm | **Tuesday, June 20** | 7:00 am-6:30 pm |
| **Sunday, June 18** | 8:00 am-6:30 pm | **Wednesday, June 21** | 7:00 am-5:30 pm |
| **Monday, June 19** | 7:00 am-6:30 pm | **Thursday, June 22** | 7:00 am-1:00 pm |

***Note:*** 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.

**Participants with Disabilities:** *DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.*

**PLEASE NOTE** **Seating for sessions is on a first come, first served basis. Attendees should be prepared with an alternate session selection in the event that a session room is filled to capacity.**

**Business Center** Located on the 2nd floor of the Convention Center, near the entrance to Exhibit Hall B, the Business Center is equipped with fax and copy machines as well as Internet access for attendees' convenience. The Convention Center Business Center will be available for the business needs of attendees during the hours noted below. Tel +1-215-418-2326, Fax +1-215-418-2246.

**Monday, June 19 through Thursday, June 22** 9:00 am-5:00 pm

**Kinko's,** located in the lobby of the Marriott Hotel, is also available for DIA attendees. Kinko's is open 24 hours a day, 7 days a week. Tel +1-215-923-2520, Fax +1-215-923-2360.

**Cyber Café** The entire Convention Center has wireless capability except in the meeting rooms and in Grand Hall. This access is provided by the Convention Center and for legal reasons, individual support for personal computers is not available. Eight permanent workstations will be available at the Cyber Café on the 3rd floor of the Convention Center for those who do not have laptops.

**Dress Code** The dress code for the Annual Meeting is business casual. Slacks and casual dresses are encouraged for wear throughout the meeting. Neckties, business suits, or other business attire are acceptable, but not necessary. *The Convention Center may be chilly so bring a sweater or jacket and comfortable shoes are a must!*

**Lost & Found** Misplaced items will be stored at the DIA Information Booth in Grand Hall until the end of the event. Items remaining at the close of the Annual Meeting at 12:00 pm on Thursday, June 22, will be turned over to Convention Center security.

**MedDRA® User Group Meeting** MedDRA® User Group will meet at the conclusion of the Annual Meeting on Thursday, June 22, 12:30-5:00 pm in Room 201B on the 2nd floor.

**Message Centers** Stay in touch with your family and colleagues through the DIA Electronic Message and Information Center. To receive messages during the DIA Annual Meeting, just give the DIA Message Center Number – **215-418-2151 –** to your family and colleagues.

Check often for messages posted on video monitors. For **display and retrieval**, visit the Message Center in Grand Hall on the 2nd floor of the Convention Center. **Display only** is available in the Entrance to Exhibit Hall A, 2nd floor and **retrieval** of messages is available on the Arch Street Bridge, 2nd floor.

| | | | |
|---|---|---|---|
| **Saturday, June 17** | 12:00 pm-5:00 pm | **Tuesday, June 20** | 7:30 am-6:30 pm |
| **Sunday, June 18** | 8:00 am-6:30 pm | **Wednesday, June 21** | 7:30 am-5:30 pm |
| **Monday, June 19** | 7:30 am-6:00 pm | **Thursday, June 22** | 7:30 am-12:30 pm |

**New Member Breakfast** If you are a new member of DIA, you won't want to miss the New Member Breakfast, Tuesday, June 20, 7:00-8:15 am in Franklin Hall A on the 4th Floor of the Marriott Hotel.

**Poster Sessions** An area has been set aside for students and professionals to exhibit scientific developments associated with the pharmaceutical development and registration process. The **Students' Poster Session** will take place on Monday, June 19, 10:00 am-6:00 pm, on the Arch Street Bridge on the 2nd floor of the Convention Center. The **Professionals' Poster Session** will take place on Tuesday, June 20, 10:00 am-6:30 pm in the same location.

**Posting of Presentations** Speaker presentations, as made available, will be posted to DIA's website – www.diahome.org – within 2 weeks of the conclusion of the meeting and will be available online for a period of 6 months from the post date.

**Press Room/Registration** DIA welcomes qualified representatives of news organizations for the purpose of reporting and publishing/airing articles/stories. Press passes will be given to all who are determined, by DIA and/or its public relations firm, to be qualified members of the press. DIA and/or its public relations firm reserves the right to screen all requests and refuse the registration of those who are not considered to be qualified. To obtain a press pass, applicants must be affiliated with an established media outlet and possess an editorial/reporting title. Publishers, sales representatives and other noneditorial staff will not be granted a press pass. Publications and marketing materials may not be distributed at DIA conferences without the express and written permission of DIA. All media must present a copy of their press credential confirmation letter from DIA and official press credentials at the DIA event check-in location. The press room, in Exhibit Hall A on the 2nd floor, will be open during Exhibit Hall hours.

**Private Social Functions Policy** Social functions to which attendees are invited ***are not permitted to occur*** during any DIA activity. For further information contact DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA, by phone +1-215-442-6100, by fax +1- 215-442-6199, or by email to dia@diahome.org.

## Receptions

- **Networking Reception:** Sunday, June 18, 6:30-8:30 pm, National Constitution Center. See page 8 for details. *On-site registration cannot be guaranteed.*
- **Opening Reception:** Monday, June 19, 5:00-6:00 pm, Exhibit Halls A and B, 2nd Floor, Convention Center
- **FDA 100th Anniversary Reception:** Tuesday, June 20, 5:30-6:30 pm, Grand Hall, 2nd Floor, Convention Center
- ***New!*** **Young Professionals Networking Reception:** Wednesday, June 21, 5:00-6:00 pm, Ballroom Foyer, 3rd Floor, Convention Center. *All those with 6 or fewer years of experience in the industry, or students, are invited.*

**Tours** Centipede Tours will staff a tour desk in Grand Hall on the 2nd floor of the Convention Center during the hours noted below. At press time, the only tours taking place are those listed below. A limited number of tickets is still available for each of these tours. All tour tickets should be picked up at the tour desk during the hours noted below.

| Tour Desk Hours | Scheduled Tours |
|---|---|
| Sunday, June 18, 3:00-6:30 pm | No tours. Ticket purchase and pick-up only |
| Monday, June 19, 7:30 am-6:00 pm | Historic Philadelphia *(1:00-5:00 pm)*<br>Ducks & Pasta *(5:30-10:00 pm)*<br>Atlantic City *(5:30 pm-1:00 am)* |
| Tuesday, June 20, 7:30 am-6:30 pm | Moonlight & Cheesesteaks & Lights of Liberty *(6:30-10:30 pm)*<br>Lion King *(8:00-10:30 pm)* |

## Exhibit Hall Opportunities

**Scientific Exhibits** In the Exhibit Hall, approximately 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 Halls A and B, located on the second floor of the Convention Center, host these exhibits.

**Employment Opportunities** The DIA Job Bank, on the Arch Street Bridge on the second floor, will be online to help DIA members at the meeting find new professional employment opportunities, and to help companies extend professional opportunities to interested DIA members. Companies will be able to purchase, publish, and receive replies to, job postings, and interested DIA members will be able to submit their qualifications for these job postings. These online workstations will be available throughout the DIA Annual Meeting.

**Exhibit Locator** Exhibit Hall visitors can use the Exhibit Locator workstations to locate an exhibiting company by booth number. The locator will search by company name or by the services that company provides; the "keyword" function will search for terms used in the company description published in the 2006 Exhibitors' Services Summaries. Exhibit Locator workstations will be located in the entrance to Exhibit Hall A.

# Getting to Philadelphia

**Located at the crossroads of the Northeast and Mid-Atlantic states, Philadelphia is a four-hour drive from 40 percent of the U.S. population. For driving directions to the Convention Center, go to www.paconvention.com and click on directions in the left navigation bar. Traveling to Philadelphia is also incredibly convenient by air or rail. Philadelphia International Airport (PHL) and Philadelphia's 30th Street Station, the second-busiest Amtrak station in the country, are connected to downtown and the Pennsylvania Convention Center by light rail. And once you have arrived, there's no need for a car in Philadelphia's wonderfully walkable downtown.**

### UNITED AIRLINES & US AIRWAYS *Save through Area Pricing and Discount Fees*

To obtain schedule information and the best fares, call United Airlines' Specialized Meeting Reservations Center at 1-800-521-4041. **Make sure you refer to Meeting ID Number 571AK**. Dedicated reservationists are on duty 7 days a week from 8:00 am to 10:00 pm EST. This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

### AMTRAK *Discount pricing available!*

Amtrak offers a 10% discount off the lowest available fare to Philadelphia, PA between June 15 and June 25, 2006. Travel dates are approved three days prior to the convention start date and three days following the last day of the meeting. To book your reservation, call Amtrak at **+1-800-872-7245** or contact your local travel agent. Conventions cannot be booked via Internet. **Please be sure to refer to Convention Fares Code X22J-954** when making your reservation. This offer is not valid on Auto Train. Fare is valid on Metroliner and Acela service for all departures seven days a week, except for holiday blackouts. Offer valid with Sleepers, Business Class or First Class seats with payment of the full applicable accommodation charges.

# Getting around Philadelphia

## Airport Transportation

- **Lady Liberty** provides airport shuttle service to all Philadelphia hotels and the Pennsylvania Convention Center. The one-way fare between Philadelphia International Airport and Center City Philadelphia is $8.00 per adult, $4.00 per child 6 to 12 years, and free for children less than 6 years of age. The one-way fare to City Avenue hotels is $12.00 per adult, $4.00 per child 6 to 12 years, and free for children less than 6 years of age. Two pieces of luggage plus one carry-on piece per passenger are allowed. Excess luggage will be charged at the discretion of the dispatcher and driver. Reservations are not required for airport arrivals. Lady Liberty is at the airport from 5:00 am-12:00 midnight. Upon arrival at the airport and after claiming luggage, passengers should proceed to the ground transportation counter located inside each baggage claim area and dial #27 from the free counter telephones for Lady Liberty. There will also be counter personnel to assist you should you need help. The shuttle vans wait in a holding lot at the airport and are dispatched into the terminals once a call is received. The average waiting time is 10 to 15 minutes.

  Early morning reservations for return to the airport (before 9:00 am) must be made the night before by 9:00 pm. All other reservations should be made at least 3 hours in advance. We recommend that a minimum of 2 to 2.5 hours be allowed between pickup time and flight time for domestic flights and 3 to 3.5 hours for international flights.

- **Taxi Service** – Taxis are readily available outside the baggage claim area of the Philadelphia International Airport. All taxi rates are based per trip, not per person. Most taxis can accommodate up to 3 passengers. In some cases certain vehicle types can accommodate 4 passengers. Taxi fare from the airport to the Central Philadelphia Area is a $25.00 flat rate, one-way, not including an optional gratuity.

- **SEPTA Regional Rail** – The R1 Airport High Speed Rail Line (entrance on pedestrian bridges and commercial roadway, $5.50 one-way) goes direct to the Convention Center (Market East Station stop.)

- **Executive Airport and Limousine Service – Tropiano Transportation**, the leader in chauffeured transportation to and from the Philadelphia International Airport, can provide the option of a town car or limousine from the airport to your hotel. Reservations must be made at least 48 hours in advance. Town car service is $75.60, which includes gratuity. By providing your flight information details in advance, arrangements can be made for a car to pick you up at the airport upon your arrival. Your driver will meet you in the baggage claim area of the airport. Town cars can hold up to 4 people comfortably.

  Limousine service is also available from the airport to your hotel and can accommodate up to 8 people comfortably. The cost of limousine service is $120.00, including gratuity. Reservations for a town car or limousine can be made through Tropiano Transportation by calling +1-215-616-5370 or 800-559-2040.

## Philadelphia Public Transportation

- **SEPTA** – SEPTA is the public transit system in Philadelphia which includes regional rail trains, buses, subways and trolleys. Many SEPTA routes go to the Convention Center, which is conveniently located at the Market East Station stop. From Market East Station, follow the signs to the Pennsylvania Convention Center. SEPTA has over 13 routes servicing the region including New Jersey and Delaware. Average rates are from $3.00-$8.00 one-way depending on zone. For schedules and fares, contact SEPTA at +1-215-580-4000 or visit www.septa.org.

- **Parking** – There are over 40 parking lots within the vicinity of the Pennsylvania Convention Center. Daily rates range from $12.00-$24.00. Go to **www.paconvention.com** for locations of local area parking garages. Please be aware that DIA's presence in Philadelphia during the Annual Meeting will increase the demand for parking. However, Philadelphia has an excellent public transportation system. Attendees are strongly encouraged to take advantage of the various options to avoid the challenge of traffic and parking.

# Questions about the DIA Annual Meeting?

## CONTACT INFORMATION

**DRUG INFORMATION ASSOCIATION**

**http://www.diahome.org**

800 Enterprise Road
Suite 200
Horsham, PA 19044-3595
USA

Tel +1-215-442-6100

Fax +1-215-442-6199

email dia@diahome.org

Hours: Monday through Friday
8:00 am-5:00 pm EST

**PENNSYLVANIA CONVENTION CENTER**

**http://www.paconvention.com**

1101 Arch Street
Philadelphia, PA 19107
USA

Tel +1-215-418-4700

Open daily 8:00 am-5:00 pm EST

### ADVERTISING OPPORTUNITIES

Leslie Ringe at lringe@ki-lipton.com or +1-267-893-5687

### AIRPORT SHUTTLE

Lady Liberty Airport Shuttle at +1-215-724-8888

Tropiano Transportation at +1-215-616-5370

### CE (CONTINUING EDUCATION)

Tricia Wilson at Tricia.Wilson@diahome.org or +1-215-442-6177

### EXHIBITS

Jeff Korn at Jeff.Korn@diahome.org or +1-215-442-6184
*OR*
Erin Gilliland at Erin.Gilliland@diahome.org or +1-215-442-6149

### HOTEL RESERVATIONS

Welcome Philadelphia at 800-650-6835 (domestic) and
847-282-2515 (international)

### JOB POSTINGS

Maureen Lamplugh at Maureen.Lamplugh@diahome.org or
+1-215-442-6115

### PRESS PASSES/PRESS LIST

Linda Cler at Linda.Cler@diahome.org or +1-215-442-6159

### PRESS RELEASE PROGRAM

Heather Toplin at heather@toplin.com or +1-215-793-4666

### REGISTRATION STATUS/REGISTRATION FEES

Inquiries should be directed to
Jean.Zane@diahome.org or +1-215-442-6185
*OR*
Vicki.Adkinson@diahome.org or +1-215-442-6162
*OR*
Maureen.Lamplugh@diahome.org or +1-215-442-6115

### SPECIAL INTEREST AREA COMMUNITY (SIAC) EVENTS

Mary Hildebrandt at Mary.Hildebrandt@diahome.org or +1-215-442-6151
*OR*
Mike McGovern at Mike.McGovern@diahome.org or +1-215-442-6129

### SHUTTLE SERVICE

Lori Risboskin at Lori.Risboskin@diahome.org or +1-215-442-6174

### TOURS

Centipede Tours at +1-215-735-3123

### TUTORIALS

Julie Ho at Julie.Ho@diahome.org or +1-215-442-6179

# Tutorials (as of May 10, 2006)

Maximize your Annual Meeting experience by attending DIA's preconference tutorials. Tutorials are full- or half-day offerings designed to increase your knowledge of specific subject areas. Most tutorials offer continuing education credit, such as CME, IACET, nursing, and pharmacy, and the applicable credits are indicated below the tutorial title. Complementary tracks are indicated by the track acronym placed to the right of the tutorial title.

Tutorials will take place on Saturday, June 17 and Sunday, June 18, 2006, prior to the Annual Meeting. The content of many tutorials has been updated, and new topics have been added. Tutorial topics range from professional development to specialized areas within the pharmaceutical industry. DIA may continue to add tutorials to the overall schedule at this year's Annual Meeting, so check **www.diahome.org** for the latest information.

### Track Titles and Acronyms

| | | | | | |
|---|---|---|---|---|---|
| AD | Advertising | EC | eClinical | NHP | Natural Health Products |
| AHC | Academic Health Centers | FI | Finance | OS | Outsourcing |
| BT | Biotechnology | GCP | Good Clinical Practices | PM | Project Management |
| CDM | Clinical Data Management | IMP | Impact of Medical Products and Therapies | PP | Public Policy/Law |
| CMC | Chemistry, Manufacturing, and Controls/Good Manufacturing Practices | IS | Investigator Sites | RA | Regulatory Affairs |
| CP | Clinical Safety and Pharmacovigilance | IT | Information Technology | RD | R&D Strategy |
| CR | Clinical Research and Development | MA | Marketing and Sales | ST | Statistics |
| CS | Clinical Supplies | MC | Medical Communications | TR | Training |
| CTM | Clinical Trial Management | MW | Medical/Scientific Writing | VA | Validation |
| DM | Document Management | NC | Nonclinical Laboratory Safety Assessment | | |

*Tutorial instructors and schedule are subject to change without notice. Recording of any DIA tutorial information in any type of media, is prohibited without prior written consent from DIA. Statements made by instructors are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.*

## Saturday, June 17, 2006 — 1:00–4:30 pm

**Tutorials #30 through #39 Fee $350**

### #30 Investigator Site and Monitor Training to Improve Data Quality and Optimize MedDRA® Coding and Analysis — CR, IS, TR

*.3 IACET CEUs; 3.9 nursing contact hours*

**Judy Harrison, MD**
Clinical Research Consultant, Harrison Clinical Consulting, LLC
(Consultant to Northrop Grumman/MedDRA MSSO)

The quality of initial data collected from investigator sites has a direct impact on the quality of the data that is encoded and analyzed using MedDRA. Companies involved in clinical research have employed various strategies to improve the quality of the initial data, including training programs for investigator site and company personnel. This tutorial will focus on the characteristics of MedDRA that affect coding and analysis based on the quality of the initial data and will describe specific examples of training strategies.

**Learning Objectives**

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

- Describe how the quality of initial data from investigators impacts MedDRA coding and subsequent data analysis
- Describe the training strategies for investigator site and company personnel that have been employed in the effort to improve the quality of initial data

**Target Audience**

This tutorial is designed for CRAs, physicians, data managers and CRO personnel engaged in clinical research; clinical safety personnel, investigators and study coordinators; training managers.

### #31 An Overview of the 21 CFR 11 Regulations and Guidance: Practical Considerations in Planning and Achieving Regulatory Compliance of Electronic Records, Signatures, and Systems — IT, RA, VA

*.3 IACET CEUs*

**Kim W. Nitahara, MBA, MIT**
Chief Executive Officer, META Solutions, Inc

FDA's "Electronic Records: Electronic Signatures" regulations (21 CFR Part 11) apply to all electronic records that are "created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations," including predicate regulations for GLPs, GCPs, GMPs, and regulatory submissions. The FDA's guidance document, "21 CFR 11 Scope and Application," indicates that Part 11 remains in effect and provides FDA's "current thinking" about enforcement discretion, overall approach, and narrowing interpretation of scope. This tutorial will provide a comprehensive overview of the regulations and the guidance and their impact on existing and new computer systems in the R&D environment. Practical information and approaches for meeting the requirements will be presented and discussed with participants, using actual inspection results from recent FDA-483's and warning letters regarding electronic records, electronic signatures, computerized systems, and validation observations.

**Learning Objectives**

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

- Discuss and analyze the scope and application of the 21 CFR 11 regulations
- Interpret the changes in FDA guidance and expectations
- Justify your company's 21 CFR 11 plans and standards

### Target Audience
This tutorial is designed for R&D, IT, regulatory and QA personnel and functional managers who are responsible for computerized systems and electronic records in a regulated environment.

## #32 The Building Blocks for Patient Recruitment — CR, CTM, PM

*.3 IACET CEUs*

**Elizabeth A. Moench**
President and Chief Executive Officer, MediciGroup® Inc.

When today's patient recruitment processes are riddled with inefficiencies that slow, sideline, and sometimes stop clinical trials, and more than three-quarters of all clinical trials fail to meet their recruitment deadlines, steps to streamline processes, accelerate patient recruitment and improve the margin of study success are critical. This workshop will address ways to ensure recruitment success.

### Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Apply realistic recruitment forecasts and budgets to set up for success and avoid future budget creep
- Define the critical steps to recruitment strategy design
- Distinguish which performance metrics to collect to track recruitment effectiveness and where to direct ongoing investment
- Manage and motivate sites to deliver on recruitment milestones based on performance metrics

### Target Audience
This tutorial is designed for sponsors, therapeutic area leaders, clinical team leaders, clinical directors/managers, clinical directors/project managers, clinical operations, clinical procurement professionals, clinical outsourcing and product marketing.

## #33 Advanced Human Subject Protections — PM, PP, RA

*3.25 category 1 credits; .3 IACET CEUs, 3.9 nursing contact hours; 286-000-06-506-L04; 3.25 pharmacy contact hours (.325 CEUs)*

**Adil E. Shamoo, PhD**
Professor and Consultant
University of MD School of Medicine and Shamoo Consulting

**This Tutorial has been cancelled.**

This t… rials on h… man… are to: increase knowledge and sensitivity, improve the ability of trial staff to make ethical decisions in terms of subject selections, and comply with the regulatory requirement for the vulnerable population such as children and the decisionally impaired.

### Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Discuss federal regulation governing human subject protections
- Analyze and apply the ethical standards and federal regulations to human subject protections
- Translate the regulations as applied to vulnerable subjects
- Demonstrate a proper ethical decision-making scheme for the use of children and the decisionally impaired in research

### Target Audience
This tutorial is designed for clinical investigators, regulatory affairs, project managers, research coordinators, monitors, quality assurance, public policy, auditors, and safety officers.

## #34 Negotiating Meaningful Investigator Agreements — CR, CTM, IS

*.3 IACET CEUs*

**Ira G. Asherman**
Consultant, Asherman Associates Inc.

**Barry Sagotsky, MBA**
Consultant, Magnolia Lane Consulting

**This Tutorial has been cancelled.**

This p… term agree… small-group… rticipants will work through the above objectives in real-life practice simulations and case studies.

### Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Describe the importance of trust to negotiating long-term investigator agreements
- Outline the six-step Successful Negotiator methodology
- Describe the elements of effective planning
- Describe the behaviors utilized by the Successful Negotiator

### Target Audience
This tutorial is designed for people who work and negotiate with site personnel as well as site personnel who negotiate with sponsors. Among the people who will find this program valuable are medical monitors, clinical research associates, study coordinators and investigators.

## #35 Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People, and Process — CR, CTM, RD

*.3 IACET CEUs*

**Laurie Halloran, MS, CCRA**
President and Chief Executive Officer, Halloran Consulting Group

What *are* clinical operations and why are some of the most successful companies realizing the importance of it? How does the clinical operations function contribute to the overall success of the organization, and where do we find someone to get it started? Many organizations struggle to determine how and when to establish this function. Professionals new to the position quickly realize that there is very little available information on how to do their job effectively. This tutorial will explore these questions and challenges and present suggestions about how to get started and where to get help and information.

### Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Describe and explain the role, responsibilities and activities of a clinical operations management position
- Identify the competencies for a successful clinical operations manager/director
- Translate the components and priorities of a clinical operations functional infrastructure into a plan for reorganization within a pharmaceutical company
- Design a clinical operations plan for a new biopharmaceutical organization

### Target Audience
This tutorial is designed for executives considering the establishment of clinical operations to improve their development organizations and for seasoned clinical research professionals who are considering or have recently made a change into a position in clinical operations.

## #36 Clinical Trial Performance Analysis: "How to" and Key Results from Earned Value Methods — CR, CTM, PM

*.3 IACET CEUs*

**Wolfgang Seifert, MD, PMP, MFPM**
Advisor, Drug Development, Schering AG, Germany

**This Tutorial has been cancelled.**

The re…ent perfor… cost and d…ing and risk management. This tutorial focuses on the method of EV calculation, on infrastructure and process needs, and on the key input variables. The resulting reports will be thoroughly explained. As a basic input to performance management systems, the method can be applied retrospectively on finished trials, or prospectively on running trials. The generic approach allows comparison of the performances of different trials.

### Learning Objectives

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

- Create an infrastructure for performance analyses in clinical trials
- Identify the key input variables for Earned Value Analysis
- Describe and apply the calculation method and distinguish between retrospective and prospective approaches
- Use results of Earned Value Analysis for rolling adaptive budget planning

### Target Audience

This tutorial is designed for project managers, study managers, staff performing clinical trials, and controllers.

## #37 Leadership: How to Organize and Lead People in Group Work — GCP, PM, TR

*.3 IACET CEUs*

**Mike Laddin, MS, MBA**
President, LeaderPoint

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 assist in the group to 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
- Demonstrate an effective response to distracting influences on group work to minimize impact on quality of work

### 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 the teams and are interested in learning how to exert influence over group behavior, and for individuals to whom project managers report.

In addition, past participants in The DIA Leadership Experience will find this an excellent review as well as an opportunity to cover new materials.

## #38 Developing Realistic Drug Project Plans — CR, CTM, PM

*.3 IACET CEUs*

**Peter Harpum, MSc, MAPM**
Director, Life Science Practice Leader, Harpum Consulting Ltd

This tutorial will cover the theory of drug project planning, explaining what makes drug development planning different from planning in other sectors. The nature of what makes a plan realistic will be explored, as opposed to the often unrealistic project plans created in pharmaceutical and biotech organizations. Following an hour of presentation and discussion among the participants, the tutorial participants will be invited to form small teams. These teams will then work with the tutorial facilitator to create a realistic drug development project plan, integrating scope, schedule, budget, and human resource requirements. The tutorial will close with a review of lessons learned by the participants.

### Learning Objectives

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

- Discuss the theory of drug project planning
- Outline the components of a drug development project plan
- Differentiate realistic from unrealistic drug project plans
- Develop a realistic drug project plan from a fictitious case study

### Target Audience

This tutorial is designed for pharmaceutical and biotechnology program and project managers, functional project and sub-project managers, functionally based managers running large studies or groups of studies, and product and brand directors who wish to understand drug project planning in detail.

## #39 Analysis of Safety Data from Clinical Trials — CR, MW, ST

*3.25 category 1 credits; .3 IACET CEUs*

**Joachim Vollmar, MSc**
Consultant

**Jürgen Kübler, PhD**
Director, Global Head PRO/ES, Novartis Pharma AG, Switzerland

The tutorial is a combination of theory, guidelines, practical considerations and real-life solutions for those working in the clinical development environment (pharmaceutical, biotech industry, or CRO). The aim of this course is to provide a basic understanding of the underlying methodology and the current guidelines on safety data. Aspects of the planning of clinical trials as well as the problems and pitfalls during the analysis of safety data will be presented. The presentations will also include case studies.

### Learning Objectives

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

- Contribute to safety analysis plans
- Assess statistical safety analysis
- Identify pitfalls in safety analysis

### Target Audience

This tutorial is designed for biostatisticians, medical writers, clinical researchers, drug safety specialists, project managers, and investigators.

## Sunday, June 18, 2006 — 9:00 am–5:00 pm

**Tutorials #40 through #47 Fee $600**

### #40 Data Mining, Data Flow Modeling, Data Warehousing, and Knowledge Management — CDM, CP, IT

*.7 IACET CEUs*

**Andrew Kusiak, PhD**
Professor, University of Iowa

This tutorial will introduce novel concepts of data mining, data flow modeling, data warehousing, knowledge management, and data integration. Basic steps needed to understand the flow of data, data flow and knowledge management, and justification of data warehouses will be presented. Any large data repository, for example a data warehouse, has implications for the data and knowledge management and supporting applications. One of the most significant drivers of data warehousing technology is data mining. Data mining tools extract knowledge from data repositories for use in downstream applications. The new knowledge can be applied, for example, for customized drug labeling, predicting adverse drug reactions, to increase understanding of genetic data, and improve bioprocesses. The knowledge discovery approach is integrated with process modeling methods for systematic data capture and management. The concepts introduced in the tutorial will be illustrated with methodologies and software for data flow modeling and data mining.

**Learning Objectives**

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

- Categorize and assess data mining tools
- Apply data mining techniques for knowledge discovery and management
- Perform data mining tasks and quality analysis
- Design process models and improve processes

**Target Audience**

This tutorial is designed for data analysts, data and knowledge managers, process improvement professionals, data flow experts, data quality experts, clinicians interested in modern data analysis tools, biotech experts, physicians, IT experts, professionals involved in data mining and data warehousing projects, and pharmaceutical industry experts interested in getting more value from data and process improvements.

### #41 Clinical Statistics for Nonstatisticians — CR, MC, MW

*6.5 category 1 credits; .7 IACET CEUs; 7.8 nursing contact hours; 286-000-06-508-L04; 6.5 contact hours (.65 CEUs)*

**Rafe Donahue, PhD**
Research Associate Professor, Department of Biostatistics and Section of Surgical Sciences, Vanderbilt University School of Medicine Medical Center

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 basic statistical terminology with ease
- Discuss 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.

### #42 Regulatory Requirements for the Conduct of Clinical Trials in Europe — CR, GCP, RA

*.7 IACET CEUs*

**Regina Freunscht**
Head of Quality Assurance, Accovion GmbH, Germany

The European clinical trial legislation has an impact on clinical trial management, conduct, adverse event surveillance and reporting, with consequences for sponsors, investigators, ethical committees, and regulatory authorities.

This full-day, interactive tutorial will offer an overview of the European legislation affecting clinical trials and provide information on the content of each document: What is new, and what are the consequences for the conduct of clinical trials? Which documents have to be prepared, which SOPs might need a review? What are the considerations for safety reporting in Europe? Where can I find current and useful further information? Points of discussion will be the clinical trials directive 2001/20/EC and the corresponding detailed guidance on the clinical trial application process, notification of substantial amendments, declaration of end of trial, the ethical committee opinion processes, the EUDRACT and EudraVigilance databases, and the reporting of adverse events.

Furthermore, relevant content and likely impact of the European data protection directive 95/46/EC, the revised Annex 13 of GMP, the GCP Directive 2005/28/EC and archiving requirements of essential documents will also be discussed.

**Learning Objectives**

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

- Recognize the regulatory requirements for the conduct of clinical trials in Europe
- Analyze the impact of these regulations on drug development programs and company SOPs
- Discuss drug safety reporting requirements from clinical trials in Europe
- Plan and manage your future clinical trials more effectively

**Target Audience**

This tutorial will benefit any research professional involved with or supportive of clinical trial programs in Europe. This includes, but is not limited to, heads of clinical research departments, study or project managers, CRAs, monitors, trial investigators, and CRCs. Furthermore, any person involved in QA, regulatory affairs, or training should attend this tutorial. Participants should have a sound knowledge of GCP.

### #43 Pharmacokinetics and Pharmacodynamics: A Gentle Introduction — CR

*.7 IACET CEUs; 7.8 nursing contact hours*

**Michael J. Fossler, PharmD, PhD, FCP**
Director, GlaxoSmithKline

Pharmacokinetic/pharmacodynamic modeling (PK/PD) is assuming an increasingly important role in the drug development process. Go/no-go, dosing regimen and study design decisions are now made using PK/PD information. However, for the pharmaceutical professional not specifically trained in this area, the terminology and mathematics can be a bit overwhelming. In this full-day tutor-

ial, the morning session will be devoted to explaining the basics of PK/PD using familiar terms and as little math as possible. The afternoon will be spent reviewing some special topics (building on the morning session), including population PK/PD modeling and clinical trials simulation, to provide the regulatory professional with a conceptual grasp of this important field.

**Learning Objectives**

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

1. Define the following pharmacokinetics concepts:
   a. Clearance
   b. Volume of distribution
   c. Half-life
   d. Relative and absolute bioavailability
   e. Steady state
   f. Population pharmacokinetics/pharmacodynamics
2. Define the following pharmacodynamics concepts:
   a. Emax
   b. EC50
   c. Direct and indirect response models
3. Discuss differences between linear and non-linear pharmacokinetics
4. Define (in a general way) what population pharmacokinetics is. Explain how simulation is used in contemporary drug development

**Target Audience**

This tutorial is designed for regulatory affairs professionals, physicians, nurses, CRO personnel, medical writers, project managers, or anyone working in the pharmaceutical industry who desires some additional information about pharmacokinetics and pharmacodynamics.

## #44 Principles of Safety Surveillance — CP, RA, TR

*6.5 category 1 credits; .7 IACET CEUs; 7.8 nursing contact hours; 286-000-06-505-L04; 6.5 pharmacy contact hours (.65 CEUs)*

**Stanley B. Garbus, MD, MPH**
Chief Medical Officer, Sentrx

**Ralph E. Bobo, MD**
Vice President, Pharmacovigilance Operations, Sentrx

New safety surveillance monitors need to understand the concepts of pharmacovigilance, understanding that risk monitoring and surveillance systems are critical for assessing the risk:benefit ratio of products, recognizing that changing regulatory requirements of global pharmacovigilance regulations are complex but must be followed, and that the future of adverse drug reaction reporting will use the Internet. This full-day tutorial will deal with the key concepts and elements of safety surveillance.

**Learning Objectives**

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

- Define key elements and definitions of safety surveillance
- Apply methods for risk monitoring and surveillance systems to capture and process suspected adverse drug reactions
- Demonstrate compliance when reporting adverse events to regulatory authorities
- Summarize the value of utilizing web-based pharmacovigilance

**Target Audience**

This tutorial is designed for those new to safety surveillance and to update others on current safety, risk management, and regulatory issues in postmarketing surveillance.

## #45 Computer Validation from A to Z: Practical Reality for User Acceptance of GXP Systems — IT, VA

*.7 IACET CEUs*

**Teri Stokes, MT (ASCP), MBA, PhD**
Director, GXP International

**Richard Chamberlain, MS, PhD**
President, Executive Consultant Services

**This Tutorial has been cancelled.**

Con g prac-
tice nse way.
Exp at for the noncomputer professional or the IT person who is new to the area of computer validation to GXP standards.

For hands-on testing, attendees should bring the following:

- laptop with a USB port and MS EXCEL (98 or higher) to test a spreadsheet
- laptop powerpack

Without the laptop you can still participate as a witness or recorder of the testing. We will cover computer validation from A to Z!

**Learning Objectives**

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

- Compare and contrast the content and focus of IQ, OQ, and PQ system validation packages and roles/responsibilities for producing each package
- Identify key components for auditable test documentation and experience formal testing practices by executing a test script

**Target Audience**

This tutorial is designed for any manager with a GXP system to be validated, end-user and IT teams facing a systems validation project, quality assurance professionals auditing GXP systems, suppliers of GXP systems (applications, eDiaries), and suppliers of GXP data services (CROs).

## #46 Design and Statistical Analysis of Bioequivalence Studies — PM, RA, ST

*6.5 category 1 credits; .7 IACET CEUs; 7.8 nursing contact hours*

**Scott D. Patterson, MSc, PhD**
Director, Statistical Sciences, GlaxoSmithKline

**Byron Jones, MSc, PhD, FSS, CSat**
Senior Director, Development Operations, Pfizer Inc

This tutorial will review the design and analysis of bioequivalence trials from their inception in the 1970s to the present day. These studies play a key role in the drug development process when manufacturers change methods or site of formulation and when generic manufacturers attempt to gain market access following patent expiration. The use of cross-over trials to evaluate average bioequivalence will be described. This and the use of population and individual metrics for bioequivalence assessment will be illustrated using case studies. Particular attention will be paid to the regulatory issues related to bioequivalence trials.

**Learning Objectives**

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

- Design and analyze bioequivalence trials
- Summarize the history and place of bioequivalence trials within drug development

**Target Audience**

This tutorial is designed for statisticians in the pharmaceutical industry, universities, and international regulatory agencies. Clinical pharmacologists, pharmacokineticists, physicians, and nursing staff in the pharmaceutical industry and universities, as well as professionals working in international regulatory agencies with an interest in this subject would also benefit from attending this tutorial.

## #47 Clinical Trial Contracting: What Do You Have to Lose? CTM, IS, PP

*6.5 category 1 credits; .7 IACET CEUs*

**Nadina Jose, MD, CPI, MBA**
President/Chief Executive Officer, Research Strategies, Inc.

**Arthur Gertel, PhD, MS**
Vice President, Clinical Services, Regulatory and Medical Writing
Beardsworth Consulting Group, Inc.

**J. Andrew Lemons, Esq., JD**
Attorney, Baker, Donelson, Bearman, Caldwell & Berkowitz

Clinical trials are necessary steps in bringing the many benefits of new therapies to untold numbers of patients. As with any process involving the unknown, there are associated risks to participants in these trials. While all efforts are made to avoid unnecessary negative outcomes, there will be subjects who are exposed to potential harm by virtue of their participation in these trials. In reviewing risk, liability, and indemnity, one must consider the multitude of parties involved in the clinical trial process. These include, but are not limited to:

- Subjects
- Investigators
- Site staff
- Study supply providers
- Pharmaceutical personnel
- CROs
- Families of subjects
- Regulatory authorities
- Ethics committees
- Ethicists
- Safety committees
- Attorneys

Each of these parties may have a role in mitigating adverse consequences. At this tutorial, attendees will learn from three instructors who bring specific expertise as a clinical trial principal investigator, a CRO executive, and an attorney, respectively. The tutorial will include exercises in the review of contracts and other clinical trial documents. Review checklists will be provided to ensure complete due diligence as the participants undertake clinical trial responsibilities.

### Learning Objectives

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

- Identify the areas of risk that investigators, sponsors, and CROs might be subject to in the context of conducting a clinical trial
- Differentiate the roles and responsibilities of these parties as they pertain to clinical trial activities, as set forth in regulatory guidance
- Evaluate strategies to mitigate risk through the use of good contracting practices
- Apply the tutorial knowledge through an exercise involving the critique of contractual documents associated with clinical trial conduct

### Target Audience

This tutorial is designed for principal investigators (or physicians considering participating in clinical trials), pharmaceutical clinical staff (clinical directors, CRAs, contract managers), CRO clinical staff (project managers, CRAs, contract managers), attorneys involved in health care or pharmaceuticals, legal staff, and regulatory affairs staff.

# Sunday, June 18, 2006 8:30 am–12:00 pm

**Tutorials #50 through #62 Fee $350**

## #50 Best Practices when Using MedDRA® CDM, CP

*.3 IACET CEUs*

**JoAnn Medbery, RN, BSN**
Director, Dictionary Management Systems
Johnson & Johnson Benefit Risk Management

This tutorial will help MedDRA users with the identification of "best practices" when implementing or using MedDRA in organizations. MedDRA is a complex terminology; therefore, having "best practices" will guide users to practical, useful solutions from the implementation to the ongoing use of MedDRA. The "best practices" will assist with data standardization, consistency, and quality.

### Learning Objectives

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

- Summarize "MedDRA's Best Practices"
- Analyze the need for establishment of "MedDRA's Best Practices" within their environment
- Describe at least two "MedDRA Best Practices" and how they could be implemented within your organization

### Target Audience

This tutorial is designed for professionals who use MedDRA or are responsible for the use of MedDRA within their organization. This includes the use of MedDRA for either eClinical trial or postmarketing data.

## #51 Evidence-based Medicine throughout the Clinical Drug Development and Product Life Cycle CP

*3.25 category 1 credits; .3 IACET CEUs*

**Matthew W. Reynolds, PhD**
Senior Director, Risk Management and Safety Services
MetaWorks, Inc.

**Isabella Sledge, MD, MPH**
Associate Medical Director, MetaWorks, Inc.

It is not always necessary to conduct expensive studies to acquire new information when there is a wealth of existing, easily accessible evidence that can help to promote better, quicker, and more affordable answers to scientific questions in clinical development. Evidence-based medicine is the application of currently available best evidence to guide the clinical research decision process. The principles of evidence-based medicine should be applied early and often in the clinical drug development process to assist in making optimal decisions based on available clinical evidence from early phase clinical trials though post-launch activities. Drug development programs should utilize evidence-based tools, such as systematic reviews of the literature, to better understand disease characteristics and progression, alternative treatments, and characteristics of competitor drugs from both safety and efficacy perspectives. This tutorial will identify and present a variety of evidence-based tools for use in improving research in clinical drug development. Case studies and group exercises will be used to illustrate a variety of applications for these tools, such as determining optimal clinical trial sample size, identification of optimal trial endpoints, placing safety issues into appropriate population context, improving the prediction of efficacy and safety outcomes, and determining new possible indications, among others.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Discuss the concept of evidence-based medicine
- Identify a variety of evidence-based tools and methods for use in improving efficiency in the clinical drug development process
- Apply evidence-based medicine principles to the clinical drug development process

**Target Audience**
This tutorial is designed for individuals who are involved in clinical drug development (Phase I, II, III, and postmarketing) epidemiology, biostatistics, regulatory affairs, medical affairs, and outcomes research.

## #52 Fourteen Steps from Research to Development — RA, RD

*.3 IACET CEUs; 3.9 nursing contact hours*

**Judi Weissinger, PhD**
President and Chief Executive Officer, Weissinger Solutions, Inc.

**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:
- Discuss the terminology and process involved in product development
- Identify ways to tailor the development, streamline the process and interact with FDA for unique products
- Explain the specialties and resources needed to develop a product
- Design processes to guide your company smoothly through the progression of research and development through the preclinical process into early clinical programs

**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.

## #53 Preparation of Integrated Clinical and Statistical Reports for Individual Studies — CR, MW, RA

*.3 IACET CEUs; 3.9 nursing contact hours*

**George H. D'Addamio, PhD**
President, PharmConsult, Inc.

This tutorial is intended for clinical research professionals, including medical monitors, with less than two years of experience in preparing integrated study reports, individuals in related disciplines such as data management, statistics, and clinical research associates, and managers interested in an overview of the reporting process. The tutorial will focus on the activities of the clinical team, interaction with supporting disciplines, and documents needed for preparing a report. The ICH guideline for report structure and content (ICH E3) will be reviewed, and samples of key tables will be discussed. Participants are encouraged to ask questions, exchange ideas, and address problem areas in generating reports.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Discuss how an integrated study report supports the overall development process
- Identify critical documents and personnel required to prepare an integrated study report
- Outline a process for preparing an integrated study report in a matrix organization
- Describe information required for key sections of the integrated report

**Target Audience**
This tutorial is designed for clinical research professionals, including medical monitors, with less than two years of experience in preparing integrated study reports, individuals in related disciplines such as data management, statistics, and clinical research associates, and managers interested in the reporting process.

## #54 Critical Issues and Important Considerations for Outsource Contracting — OS, PP

*.3 IACET CEUs*

**Daniel J. O'Connor**
Assistant Vice President, Legal, ImClone Systems Incorporated
President and Chief Executive Officer, Milestone Research, Inc.

This tutorial will cover important issues and considerations for: (1) sponsor/CRO contracts, (2) sponsor/consultant contracts, and (3) sponsor/CRO/investigator/site contracts. The tutorial will explain, without using "legalese" the legal and operational considerations for preparing and then managing these types of contracts. Participants in this tutorial will learn how to approach and negotiate difficult contractual issues, including: (1) the respective obligations of the parties to the contracts, e.g., sponsor/CRO; (2) clearly establishing the project costs vs. change orders; (3) payment schedule: fee-for-service vs. milestones; (4) insurance; (5) term and termination provisions; (6) confidentiality; (7) ownership of inventions and other intellectual property; (8) publication; (9) limitation of liability; (10) indemnification; (11) exclusive assignment of study personnel; (12) regulatory compliance; inspections, warranties; and (13) delays. Each topic will be illustrated, analyzed, and discussed, using sample contract language.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Identify and describe the important legal and operational issues regarding certain outsourcing contracts
- Design appropriate outsourcing contracts which will address the issues

**Target Audience**
This tutorial is designed for all professionals involved in the selection, hiring, contracting and/or negotiating process that occurs between biopharmaceutical companies and their service providers, such as CROs, investigators, and institutions.

## #55 Auditing the Vendor: Keys to Making It Work Before and After the Audit — CS, GCP, OS

*.3 IACET CEUs*

**Jonathan R. Andrus, MS, CQA**
Vice President, QA and Compliance, Phoenix Data Systems

This tutorial is intended to provide participants with information they can use to effectively select, audit, and manage their vendors. The management of vendors, after the initial selection, is one of the most important aspects of the vendor-

sponsor relationship. Audits are a snapshot in time, and as such, vendors must be continuously evaluated, and expectations must be clearly defined to avoid potential misinterpretation and misunderstanding.

**Learning Objectives**

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

- Prepare for pre-contract success
- Perform the audit process
- Explain and manage corrective actions
- Create effective communication documents between organizations and manage change throughout the relationship

**Target Audience**

This tutorial is designed for QA managers, vendor managers, project managers, outsourcing specialists, vendors, and purchasing personnel.

## #56 *NEW TITLE!* Structured Product Labeling (SPL) in the US and the EudraVigilance Medicinal Product Dictionary (EVMPD) in the EU: How the Standards Will Interoperate in the Frame of ICH M5 "Data Elements and Standards for Drug Dictionaries" CP, TR

*.3 IACET CEUs*

**Sabine Brosch, MSc, PhD**
Deputy Head of Sector, Pharmacovigilance, EMEA

**Lonnie D. Smith**
Project Specialist, FDA

The goal of this tutorial is to discuss the requirements for the provision of medicinal product information by sponsors of clinical trials conducted in the EEA and marketing authorization holders to the EMEA. The data structure of the EudraVigilance Medicinal Product Dictionary (EVMPD) and its practical use in pharmacovigilance will also be addressed. Further, this tutorial will allow attendees to discuss the ICH M5 initiatives on Data Elements and Standards for Drug Dictionaries and the link with the EVMPD.

**Learning Objectives**

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

- Explain the objectives of the ICH M5 initiatives on Data Elements and Standards for Drug Dictionaries
- Discuss the requirements for the provision of investigational medicinal product data for clinical trials conducted in the EEA and authorized medicinal product data in the EVMPD
- Compare the data structure of the EVMPD with the M5 data structure and analyze the use of the EVMPD in the frame of ICH
- Manage medicinal product data using the EVMPD in the pre- and post-authorization phase on the basis of different technical tools

**Target Audience**

This tutorial is designed for regulatory staff dealing with medicinal product information in pharmaceutical companies, data management staff, and information technology staff.

## #57 Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development RA

*.3 IACET CEUs*

**Robert Fike, MS, PhD**
Assistant Vice President, Regulatory Affairs Japan, Wyeth Research Division of Wyeth

**Akio Uemura, PhD**
Program Team Leader, Pharmaceutical Project Management, Lilly Research Laboratories, Eli Lilly and Company

Major changes in the Japanese pharmaceutical regulations are impacting the development of new drugs in Japan. This tutorial will describe the impact of the new Pharmaceutical and Medical Device Agency (PMDA), and regulatory processes during development (consultations) and CTD review. Several development strategies necessary to meet Japanese requirements for new drug approval will be identified, and the interest and results of bridging strategies will be analyzed. Post-market surveillance and pricing reimbursement process will be reviewed, and finally, the impact of the changing regulatory system on global strategies will be identified throughout development, registration, and post-market stages.

**Learning Objectives**

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

- Identify the major elements of the Japanese regulatory system including the newly created agency
- Describe the regulatory processes during development, registration, and post-approval safety and pricing in Japan
- Discuss specific attributes in the Japanese regulatory system and their impact on multinational development strategies

**Target Audience**

This tutorial is designed for pharmaceutical industry and regulatory agency employees with an interest in Japanese drug development, registration, pricing and postmarketing support.

## #58 Successfully Recruiting Minorities for Clinical Trials CR, CTM

*.3 IACET CEUs*

**Cara Brant**
Account Executive, Clinical Trial Media

**John J. Needham**
General Manager, Patient Recruitment Strategy, LLC

**This Tutorial has been cancelled.**

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Subsequently, instructors will identify successful and effective methods for recruiting minority patients.

**Learning Objectives**

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

- List and assess common obstacles to recruiting minority patients for clinical trials
- Identify how to effectively reach out to minorities through community outreach and patient recruitment advertising

**Target Audience**

This tutorial is designed for individuals who are involved with patient recruitment at pharmaceutical companies, CROs, patient recruitment firms, or clinical research sites.

## #59 A Compliance-driven Nonstatistical Risk Detection Process in Drug Safety CP, CR, RA

*3.25 category 1 credits; .3 IACET CEUs*

**Pradip K. Paul, MBBS, MS**
Head, Case Medical Evaluation Group, Global Pharmacovigilance and Epidemiology, sanofi-aventis Pharmaceuticals, Inc.

**Representative Invited**
Center for Drug Evaluation and Research, FDA

This tutorial will discuss the planning, development, implementation, assessment and modification of a standard risk detection workflow that can be customized to support scientific goals and meet regulatory compliance standards. Risk detec-

tion (RD) is the critical foundation for risk management (RM) activities to develop product safety profiles. A meaningful safety profile can only be achieved if a powerful risk detection program is in place. In a typical pharmaceutical or biotech company setup, RM is a multidepartmental function, with critical contributions from the RD performed by the drug safety (DS) department. RD generates a pool of AE data which can be analyzed and utilized to reduce product risk. RD activities establish and follow workflow procedures for adequate collection and analysis of AE data that support effective risk management. An imperfectly planned or executed risk detection scheme may produce a faulty risk management outcome, which may lead to serious scientific and regulatory consequences. The FDA inspectional program monitors postmarketing RD efforts to ensure that adequate data is available to support product safety analysis.

**Learning Objectives**

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

- Describe the role of the FDA CDER postmarketing inspection program in monitoring performance of risk management and risk detection activities
- Identify risk management activities that can affect FDA compliance
- Demonstrate optimized risk detection workflow leading towards risk management through newly learned processes
- Design risk detection procedures within drug safety that support scientific goals and regulatory compliance

**Target Audience**

This tutorial is designed for professionals in drug safety, regulatory affairs, clinical development, outcomes research, and CROs.

## #60 The Fundamentals of Enterprise Project Management — PM

*.3 IACET CEUs*

**Martin D. Hynes, III, PhD, MS**
Director of PR&D Operations, Eli Lilly and Company

**Raymond G. Starrett, MLS**
Director, Corporate Project Management, MedImmune, Inc.

As the pharmaceutical and biotech industry deals with the rapidly escalating cost of new drug development, many companies are turning to enterprise project management (EPM) systems as part of the solution to these rising costs, driven by the old adage that you cannot manage what you cannot measure. These systems hold much promise; however, their implementation can be perilous. This tutorial is designed to provide participants with an overview of EPM tools and their utility. Most important, it will review the common pitfalls that can derail an EPM implementation, with disastrous consequences. It will further provide participants with tools and techniques to help them address and overcome these challenges, thereby ensuring a successful implementation, and allowing the described benefits from the EPM implementation to be achieved.

**Learning Objectives**

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

- Describe the essence of enterprise project management
- Summarize critical success factors for achieving meaningful implementation of enterprise project management
- Identify barriers to success
- Explain how to overcome barriers to success

**Target Audience**

This tutorial is designed for project managers, capacity planners, and portfolio managers.

## #61 Targeted Auditing of Clinical Research Systems for Validation — CR, GCP, IT

*.3 IACET CEUs*

**Earl W. Hulihan, MEd**
Vice President, Regulatory Affairs and Quality Assurance
Medidata Solutions, Inc.

**Joanne S. Malia, MS, MS**
Computer Systems Validation Manager, Neurogen Corporation

This interactive tutorial is intended to provide practical training to auditors and auditees alike. We will focus on clinical systems involved in clinical research settings such as clinical trial management, data management, information systems, and biostatistics. Systems and programs that use and/or report data from clinical trials will be explored. The documentation package and its ability to verify the quality and integrity of such data will be reviewed. We will explore various system-specific issues in reviewing validation documentation for completeness and quality attributes. The current expected risk-based approach will be explored in discussions and small groups.

**Learning Objectives**

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

- State what regulatory inspectors are generally looking for when reviewing a computerized system and the documentation surrounding it
- Identify the critical points/issues of data capturing systems that are used for today's clinical studies
- Describe the regulatory expectations of a complete clinical research system

**Target Audience**

This hands-on, interactive tutorial is designed for personnel who have responsibility for clinical research systems within their company, such as senior management, project managers, monitors, medical monitors, clinical scientists, clinical associates, data managers, IT administrators, investigators, corporate-level managers, statisticians, site coordinators, and quality assurance, regulatory compliance, and regulatory affairs.

## #62 Effective Presentation Skills for Clinical Trial Professionals — CR, CTM, PM

*.3 IACET CEUs; 286-000-06-507-L04; 3.25 pharmacy contact hours (.325 CEUs)*

**Mary E. Briggs**
Chief Training Officer, Focus Inc.

This tutorial focuses on the number one goal for effective speakers in the clinical trial industry ... credibility! Participants will get a crash course on effective delivery skills and techniques to reduce performance anxiety. This fast-paced tutorial provides updated information on mental organization, as well as how to add some pizzazz to your business talks.

**Learning Objectives**

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

- Apply presentation fundamentals (preparation, delivery and style) to future business/clinical talks
- List ways to build confidence with personal presentation style
- Identify methods to gain credibility as a speaker in the clinical trial industry
- Recognize and manage symptoms of performance anxiety

**Target Audience**

This tutorial is designed for clinical trial professionals who need or want to speak effectively at a variety of industry-specific meetings, including investigator meetings, launch meetings, annual meetings, team meetings, sales functions, and various drug association events.

## Sunday, June 18, 2006 — 1:00–4:30 pm

**Tutorials #70 through #81 Fee $350**

### #70 European Regulatory Affairs: Current Regulatory Procedures and New Medicines Legislation Effective November 2005 — CR, PM, RA

*.3 IACET CEUs*

**Brenton E. James, FBIRA**
Consultant in Strategic Regulatory Affairs in the European Union

The current regulatory procedures, Centralized and Mutual Recognition, will be discussed in detail, as well as business strategies that impact on the choice of procedures for a new chemical entity. A detailed review of the significant changes in regulatory procedures (Centralized, Mutual Recognition, and Decentralized), which took place in November 2005, will also be discussed.

**Learning Objectives**

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

- Explain the development of the European Union
- Evaluate both Centralized and Mutual Recognition Procedures
- Analyze the key business reasons for choosing the optional route
- Describe the impact of changes in the New Medicines Legislation

**Target Audience**

This tutorial is designed for anyone with an interest in European regulatory affairs, including professionals working in regulatory affairs, clinical research, and project management.

### #71 Evaluation of Risk Management Programs Using Existing Databases — CP, RA

*3.25 category 1 credits; .3 IACET CEUs; 286-000-06-502-L04; 3.25 pharmacy contact hours (.325 credits)*

**Annette Stemhagen, DrPh, FISPE**
Vice President, Epidemiology and Risk Management
United Biosource Corporation

A critical component of any risk minimization action plan is defining how success of the plan will be measured. Not only must the evaluation metrics be established *a priori*, but the methods for evaluation and the data required to complete an evaluation must be determined. This tutorial will provide an overview of risk management evaluation strategies, including surveys, audits, and registries. It will also describe use of epidemiologic and *ad hoc* databases for evaluation of risk management programs. A final segment will discuss why your marketing department is an untapped resource in evaluation endeavors!

**Learning Objectives**

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

- Discuss the range of evaluation methods that can be used to evaluate risk management interventions
- Choose the most appropriate evaluation tools for the circumstances

**Target Audience**

This tutorial is directed to safety, regulatory, and risk management groups who are actively working in development of risk minimization actions plans (RiskMAPs), risk management programs and their evaluation strategies.

### #72 New Challenges to IRBs, Sponsors, and Investigators — IS, PP

*3.25 category 1 credits; .3 IACET CEUs; 3.9 nursing contact hours; 286-000-06-503-L04; 3.25 pharmacy contact hours (.325 CEUs)*

**Paul W. Goebel, Jr., CIP**
President and Founder, Paul W. Goebel Consulting, Inc.

**Jill C. Alvarez, JD, LIM in Taxation**
Partner, Nixon Peabody LLP

FDA compliance actions against investigators, IRBs, and sponsors often come as a surprise. It is easy to be preoccupied with day-to-day business and fail to see the changing compliance landscape. An analysis of recent cases shows the shortcomings that invite actions, either by FDA or by private parties. The latest private action cases show that no one involved with the study is immune from being named as a defendant. This tutorial will discuss the recent actions and outline practices that are frequently named in complaints.

**Learning Objectives**

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

- Compare/contrast litigation-based and regulation-based penalties of noncompliance
- Identify the common causes of action cited in law suits filed by research subjects
- Describe the FDA enforcement process for noncompliance
- Identify the first steps to take in reorganizing your procedures to assure best practices are always observed

**Target Audience**

This tutorial is designed for IRB administrators, members, chairs, clinical investigators, sponsors, contract research organizations, and others with an interest in the changing legal aspects of protection of human research subjects.

### #73 FDA Enforcement: Understanding the Agency's Enforcement Authority, How Violations Can Occur, How to Prevent Them, and How to Respond if Violations Do Occur — CTM, GCP, RA

*.3 IACET CEUs*

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

This tutorial will review and discuss the legal, regulatory, and practical nuances of (1) FDA enforcement priorities for 2006 and beyond (e.g., application of data 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). It will also address how to handle an FDA enforcement action should you face one, particularly in the wake of an inspection or warning letter. 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 2006 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.

## #74 Effective, Legal Rx Drug Promotion for the Year 2006: A Regulatory Primer — MA, RA

*3.25 category 1 credits; .3 IACET CEUs; 286-000-06-504-L04; 3.25 pharmacy contact hours (.325 CEUs)*

**Lucy Rose, MBA, PA-C**
President, Lucy Rose and Associates, LLC

This highly interactive tutorial will provide a basic primer of US law and regulations affecting the promotion of prescription drugs to health care providers and consumers. Additionally, the tutorial will address the FDA's enforcement of those regulations, utilizing actual enforcement actions as examples for discussion, and the potential impact of those enforcement activities on pharmaceutical manufacturers. We will also address such topics as how to work with FDA on promotional issues, challenges and opportunities of recent court decisions impacting the promotion of Rx drugs, opportunities and pitfalls of preapproval promotional activities, use of public relations activities, what is meant by "fair balance," continuing medical education, and many other topics.

The tutorial will be conducted in a very informal manner, providing a highly interactive environment designed to elicit audience participation and will address those issues most important to the attendees. It is designed to provide timely information for multiple disciplines, such as legal, regulatory, marketing, medical/clinical, communications/public relations, and training.

### Learning Objectives

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

- Describe the current regulatory and legal environment impacting the promotion of Rx drugs
- Describe the FDA regulatory basics and FDA review process governing the regulation of Rx drugs
- Apply, on an introductory level, FDA regulations on Rx drugs to many common advertising and promotional programs

### Target Audience

This tutorial is designed for professionals new to the area of Rx drug advertising and promotion regulation, regulatory professionals looking for a refresher or update in this area, and other professionals from related disciplines desiring an introduction to this subject matter.

## #75 New Release of Volume 9 and EU Regulatory Requirements: Pharmacovigilance in the Pre-and Postmarketing Phase and eReporting — CP, RA

*.3 IACET CEUs*

**Sabine Brosch, MSc, PhD**
Deputy Head of Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy, EMEA

**Gaby L. Danan, MD, PhD**
Expert, Global Pharmacovigilance and Epidemiology, sanofi-aventis, France

This half-day tutorial will allow attendees to discuss the main changes of Volume 9 "Notice to Marketing Authorisation Holders" and the potential implications of the new requirements on pharmaceutical companies' business processes. The main emphasis will be on adverse reaction management during the postauthorization phase, including mandatory electronic reporting and the role and responsibilities of the qualified persons responsible for pharmacovigilance, as well as the requirements of having a pharmacovigilance system established.

### Learning Objectives

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

- Interpret the potential implications of the new requirements on pharmaceutical companies' business processes
- Perform adverse reaction management during the postauthorization phase including the mandatory electronic reporting in the EEA
- Describe the role of the qualified person responsible for pharmacovigilance
- Explain the requirements for establishing a pharmacovigilance system in line with the new Community legislation

### Target Audience

This tutorial is designed for people responsible for pharmacovigilance, project team leaders, people in charge of risk management, and regulatory experts.

## #76 The CDISC Standard: Four Models Working in Harmony — CDM, CR, IT

*.3 IACET CEUs*

**Frank T. Newby**
Vice President, Education and Member Relations, CDISC

**David Iberson-Hurst**
Chief Executive Officer, Assero Limited, UK

This tutorial will advance participants who are novices regarding CDISC and its standards to a position of understanding how the four main CDISC models – the Operational Data Model (ODM), the Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), and the Laboratory Model (LAB) – work end-to-end to move data from the point of capture to submission and subsequent long-term archive.

### Learning Objectives

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

- Outline the basics of the production SDTM, ODM, define.xml, LAB and ADaM standards as well as the emerging protocol standard
- Describe the CDISC standards and their value to eClinical trials
- Discuss how data flows, using the CDISC standards, from clinician to submission
- Describe how to leverage the standards to improve regulatory compliance
- Discuss the further integration of the SDTM and ODM standards to permit submission metadata and data to be sent to the FDA in an XML format

### Target Audience

This tutorial is designed for anyone who is involved in implementing new technologies and/or data standards to streamline clinical trials, especially project managers, CRAs, data managers and those involved in managing or implementing trials across departments.

## #77 Project Management for the Nonproject Manager — BT, CTM, PM

*.3 IACET CEUs*

**Martin D. Hynes, III, PhD, MS**
Director of PR&D Operations, Eli Lilly and Company

**Robert L. Judd**
Director, Program Management, Kosan Biosciences, Inc.

This tutorial demonstrates the fundamentals of project management and team-building and how to apply them to meet specific project needs through presentation, discussion, and hands-on interactive practice of project management techniques and tools in the biotech or pharmaceutical industry.

### Learning Objectives

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

- Explain how to clarify, collaborate, coordinate and close a project
- Describe how the project team is a critical part of the project management process

### Target Audience

This tutorial is designed for those who are involved in project work but are not designated as the project manager, specifically, project team members, project sponsors, functional managers to whom team members report, subcontractors, and vendors.

## #78 Planning and Conducting Clinical Trials in Oncology — CR, CTM

*3.25 category 1 credits; .3 IACET CEUs*

**Ronald Harning, PhD**
Executive Director of Clinical Affairs, Palatin Technologies, Inc.

Cancer is currently the leading cause of death for US citizens less than 85 years of age. Approximately 1.4M new cases of invasive cancer are reported each year. Total funding (US and ex-US) for trials in clinical oncology is greater than in any other therapeutic area.

This tutorial will include an introduction to the biology of tumor growth and metastasis, protocol development for Phases 1-3, regulatory issues unique to cancer research including accelerated approval, and discussions concerning clinical site issues such as enrollment and recruitment of patients, patient safety, cancer treatment, and informed consent issues.

### Learning Objectives

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

- Discuss the incidence of cancer in the US and the importance of clinical trials in oncology
- Identify biologic and environmental factors important in the initiation and progression of cancer
- Outline the appropriate steps required for developing Phase 1-3 protocols in the therapeutic area of oncology
- Summarize important issues in the clinic which are specific to conducting clinical trials in oncology

### Target Audience

This tutorial is designed for entry- and intermediate-level professionals involved with the protocol development, monitoring, data management, and clinical site aspects of conducting trials in oncology.

## #79 Narrative Writing for Clinical/ Safety Adverse Reports — CDM, CP, MW

*3.25 category 1 credits; .3 IACET CEUs; 3.9 nursing contact hours*

**Sonja Brajovic, MD**
Manager, Medical Coding, PSI International, Inc.

**Mark Vieder, RPh**
Team Leader, AERPS/FDA, PSI International Inc.

One of the ongoing efforts in improving medication safety and ultimately patient safety is through the reporting of adverse events. The reporting may come from health care professionals, patients, family members, caretakers, and others. How these events are recorded and submitted is of paramount importance in determining the safety of medicinal/pharmaceutical products. The goal of this tutorial is the establishment of a clear, concise, and uniform approach to adverse event reporting.

### Learning Objectives

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

- Design an organized and informative adverse event report
- Create a system for obtaining data that is recognizable and usable in extraction for coding processes
- Summarize clear and accurate information for analysis

### Target Audience

This tutorial is designed for drug safety departments (pharmacovigilance), clinical safety/data managers, medical writers, medical reviewers, investigational site personnel, trainers that may exist at a company, and regulatory affairs. Professions included would be physicians, nurses, and pharmacists who may be a part of the groups listed previously.

## #80 Registration of Drugs and Biologics in Canada — BT, CR, RA

*.3 IACET CEUs*

**Anne M. Tomalin, RAC**
President, CanReg Inc., Canada

This tutorial will provide an overview of the registration process for drugs and biologics in Canada. The organization of the regulatory agency will be discussed, with particular reference to the Therapeutic Products Directorate and the Biologic and Genetic Therapies Directorate. The preparation of the CTD, eCTD, and Module 1 for Canada will be discussed. The approval process, including the use of priority reviews and conditional Notices of Compliance and the cost for reviews will be outlined. We will also discuss actual approval times in comparison to targeted approval times, using case studies. In terms of biologics, differences in biologic submissions and approaches will be addressed, together with the Canadian lot release program. Finally, we will address the appeal process.

### Learning Objectives

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

- Plan, request, set up and conduct a pre-NDS meeting with Health Canada
- Outline the approval process in Canada, including priority reviews and conditional approvals
- Prepare a module I for an NDS for Canada
- Estimate approval time based on target time frames and actual approval times

### Target Audience

This tutorial is designed for individuals from clinical and biotechnology.

## #81 Operational Aspects of Pediatric Clinical Trials — CR, CTM, IS

*3.25 category 1 credits; .3 IACET CEUs; 3.9 nursing contact hours*

**Klaus Rose, MD, MS**
Head Pediatrics, Pharmaceuticals Division, Medical Science (PDM), PDM5, F. Hoffmann-La Roche Pharmaceuticals, Switzerland

**Sergio G. Golombek, MD, MPH, FAAP**
Associate Professor, Pediatrics, New York Medical College; Regional Neonatal Center, Maria Fareri Children's Hospital; Westchester Medical Center

**Renee Simar, PhD**
Vice President, INC Pediatrics, INC Research

Pediatric drug development is in the focus of US and EU health authorities and will in the near future also include routine pediatric assessments at an early project stage. This tutorial will explain the legal framework that intends to facilitate pediatric drug development and scientific as well as practical aspects of phase I, II and III pediatric clinical trials during preparation and execution.

### Learning Objectives

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

- Summarize the essentials in the planning phase of a pediatric trial
- Discuss common bottlenecks encountered in pediatric trials
- Describe frequent objections from ethical committees
- List key issues in informed consent and assent

### Target Audience

This tutorial is designed for registration associates, medical advisors, clinical research associates, physicians, study nurses, medical directors and all other people in academia, the pharmaceutical industry, CROs, and health authorities who want to expand their background and operational knowledge of pediatric drug development.

# Conference Schedule by Day and Time

Sessions are organized and presented according to the track titles (interest area codes) defined in the chart below. Some sessions may also be of interest to professionals in other specialties or disciplines. For these sessions, the primary interest area code, displayed in bold face type, is followed by the code for secondary or tertiary interest areas.

## Level of Difficulty

The difficulty level of each session has been determined by the session 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** | Attendee has 3 years or less experience in the session topic area. |
| ■ **Primarily Intermediate Level Content** | Attendee has more than 3 years experience in the session topic area. |
| ◆ **Primarily Advanced Level Content** | Session may be a more focused topic within a content area. Attendee has mastered the topic area. (Usually only 2 speakers to allow for more in-depth presentations.) |

| | | | | | |
|---|---|---|---|---|---|
| AD | Advertising | DM | Document Management/eSubmissions | NC | Nonclinical Laboratory Safety Assessment |
| AHC | Academic Health Centers | EC | eClinical | NHP | Natural Health Products |
| BT | Biotechnology | FI | Finance | OS | Outsourcing |
| CDM | Clinical Data Management | GCP | Good Clinical Practices | PM | Project Management |
| CMC | Chemistry, Manufacturing, and Controls/ Good Manufacturing Practices | IMP | Impact of Medical Products and Therapies | PP | Public Policy/Law |
| | | IS | Investigator Sites | RA | Regulatory Affairs |
| CP | Clinical Safety and Pharmacovigilance | IT | Information Technology | RD | R&D Strategy |
| CR | Clinical Research and Development | MA | Marketing and Sales | ST | Statistics |
| CS | Clinical Supplies | MC | Medical Communications | TR | Training |
| CTM | Clinical Trial Management | MW | Medical/Scientific Writing | VA | Validation |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Interest Areas Associated | Room Number |
|---|---|---|---|---|---|
| | **MONDAY 8:30 am-10:00 am** | | | | |
| | **PLENARY SESSION**<br>Welcome, Award Presentations, Keynote Address | | **ALL** | ALL | **Ballroom AB 3rd Floor Convention Ctr.** |
| | **MONDAY 10:30 am-12:00 pm** | | | | |
| **101** | Drug Advertising and Promotion: A Regulatory Primer | LEVEL ● | **AD** | RA | **111AB** |
| **102** | Building a Data-centric Trial; or It's the Data! | LEVEL ■ | **CDM** | EC, IT | **Marriott Salon CD** |
| **103** | Implementation of a Pharmaceutical Quality Assessment System: Progress and Challenges | LEVEL ■ | **CMC** | RA | **112AB** |
| **104** | The New World of Risk Management: A Global Perspective | LEVEL ■ | **CP** | CR, RA | **Marriott Salon G** |
| **105** | Changing the Paradigm: Innovative Oncology Drug Clinical Development Programs in the Age of Critical Path and Personalized Medicine – Part 1 of 2 | LEVEL ■ | **CR1** | BT, RA | **Marriott Salon E** |
| **106** | Demonstrating Product Value: Three Unique Perspectives | LEVEL ● | **CR2** | CP, MC | **Marriott Salon IJ** |
| **107** | Feasibility Studies 101: A Clinical Operations Perspective | LEVEL ● | **CR3** | CTM, ST | **Marriott Salon AB** |
| **108** | Championing the Patient Perspective in Clinical Study Recruitment and Retention: The Role of the Sponsor, CRO, and Vendor in Successful Strategy Development | LEVEL ● | **CR4** | CTM | **Marriott Salon KL** |
| **109** | An In-depth Look at Patients' Experiences in Clinical Trials and Understanding Physician Motivation to Refer or Not Refer Patients into Clinical Trials | LEVEL ● | **CTM** | CR, IS | **107AB** |
| **110** | The Ongoing Effort to Ensure a Quality Electronic Submission | LEVEL ■ | **DM** | RA | **204C** |
| **111** | The CDISC Standard from Operational Data Model (ODM) to Biomedical Research Integrated Domain Group (BRIDG) | LEVEL ■ | **EC** | DM, IT | **Marriott Salon H** |
| **112** | Sarbanes-Oxley: Impacts in 2005 and Beyond | LEVEL ● | **FI** | PP | **203AB** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| **MONDAY 10:30 am-12:00 pm *continued*** | | | | | |
| 113 | GCP Problems as Cited on FDA 483s and in Warning Letters: Lessons Learned | LEVEL ■ | GCP | CR, TR | Marriott Salon F |
| 114 | Patient-reported Outcome Instruments: Overview and Comments on the FDA Draft Guidance | LEVEL ● | IMP | RA | 113C |
| 115 | Dilemma of Role Conflicts: Anatomy of a Site Audit | LEVEL ■ | IS | CTM, GCP | 113B |
| 116 | Approaches to Choosing and Integrating Clinical Trial Technologies to Meet Client Information Needs | LEVEL ● | IT | CDM, EC | 105AB |
| 117 | Strategic Collaboration | LEVEL ● | MW | CR, RA | 204B |
| 118 | Outsourcing Strategy for Emerging Companies | LEVEL ● | OS | CR | 109AB |
| 119 | Key Stakeholder Management: Different Perspectives and Approaches | LEVEL ■ | PM1 | – | 108A |
| 120 | Response to Changes in the External Environment in Pharmaceutical R&D: A Project Manager's Perspective | LEVEL ■ | PM2 | BT, RD | 108B |
| 121 | Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials | LEVEL ● | PP | CR, GCP | 114 Auditorium |
| 122 | Update: US-EU Agreement Regarding Parallel Scientific Advice and Exchange of Information | LEVEL ● | RA1 | PP, RD | 201A |
| 123 | Multinational Trials in Asia: Strategy, Operations, Environment | LEVEL ■ | RA2 | CR, CTM | 202AB |
| 124 | Combination Products: Global Challenges and Opportunities | LEVEL ■ | RA3 | CMC, RD | 201B |
| 125 | Accelerated Assessment and Conditional Marketing Authorizations at the Level of the EMEA | LEVEL ● | RA4 | PP, RD | 201C |
| 126 | Recent Advances in the Use of Adaptive Clinical Trials | LEVEL ■ | ST | CR | 103B |
| 127 | Training across Language and Cultural Barriers | LEVEL ● | TR | CR, GCP | 103C |
| **MONDAY 1:30 pm-3:00 pm** | | | | | |
| 128 | Enforcement Update | LEVEL ■ | AD | RA | 111AB |
| 129 | Quality Data: Starting with the End in Mind | LEVEL ■ | CDM | EC | Marriott Salon CD |
| 130 | The Office of New Drug Quality Assessment CMC Pilot Program | LEVEL ■ | CMC | RA, TR | 112AB |
| 131 | Communicating Risk Information to Providers and Patients: Issues and Controversies | LEVEL ■ | CP | IMP, MC | Marriott Salon G |
| 132 | Changing the Paradigm: Innovative Oncology Drug Clinical Development Programs in the Age of Critical Path and Personalized Medicine – Part 2 of 2 | LEVEL ■ | CR1 | BT, RA | Marriott Salon E |
| 133 | Factors Influencing the Speed of Clinical Trial Study Completion | LEVEL ● | CR2 | CTM, PM | Marriott Salon I J |
| 134 | Prevention of Fraud and Noncompliance in Clinical Research | LEVEL ● | CR3 | GCP, PP | Marriott Salon AB |
| 135 | Focus on Asia: How to Run a Successful Clinical Trial in Asia | LEVEL ■ | CR4 | CTM, RA | Marriott Salon KL |
| 136 | Clinical Supply Chain Management: Integrated Solutions/Drug Accountability | LEVEL ■ | CS | CR, CTM | 102AB |
| 137 | One-week Patient Enrollment: Opportunities from Increased Global Coverage | LEVEL ■ | CTM | CR | 107AB |
| 138 | Submission Content Authoring | LEVEL ● | DM1 | MW, RA | 204C |
| 139 | SPL and PIM: An Examination of the Difference between the Two, the Importance of Content Management, and Practical Implementation Experience | LEVEL ■ | DM2 | IT, RA | 114 Auditorium |
| 140 | Healthcare Integration | LEVEL ■ | EC | CDM, IT | Marriott Salon H |
| 141 | The Keys to Effective Partnering | LEVEL ■ | FI | CR | 203AB |
| 142 | Exploring the Concepts and Challenges of Conducting System and Process Audits in Clinical Research | LEVEL ◆ | GCP | CR | Marriott Salon F |
| 143 | Transparency at the Site Level: Are Sites and Sponsors Ready for the Challenge? | LEVEL ● | IS | CTM, GCP | 113B |
| 144 | Implications of Drug Pedigree and Authentication on the Pharmaceutical Industry | LEVEL ● | IT | CS, RA | 105AB |
| 145 | Review and Outsourcing Strategies | LEVEL ◆ | MW | OS, PM | 204B |
| 146 | Safety and Pharmacovigilance of Natural Health Products | LEVEL ● | NHP | CP, RA | 106AB |
| 147 | Designing and Managing Successful Outsourcing Relationships – Part 1 of 2 | LEVEL ◆ | OS1 | PM | 109AB |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| **MONDAY 1:30 pm-3:00 pm *continued*** | | | | | |
| **148** | CRO/SMO Present Status in Japan | LEVEL ● | **OS2** | CR | **113C** |
| **149** | Communication Skills: The Path to Successful Project Management | LEVEL ● | **PM1** | RA | **108A** |
| **150** | Enterprise Project Management: A Practical Approach | LEVEL ◆ | **PM2** | IT | **108B** |
| **151** | Civil and Criminal Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials? | LEVEL ● | **PP** | CR, RA | **113A** |
| **152** | Pharmacogenetic Tests: From Analytical Validation to Clinical Application | LEVEL ● | **RA1** | BT, CR | **201B** |
| **153** | Good Review Management Principles (GRMPs): Progress and Challenges toward Improving Review Efficiency | LEVEL ● | **RA2** | CR | **204A** |
| **154** | Clinical Trials in Latin America: A Review of the Regulatory Framework – Part 1 of 2 | LEVEL ● | **RA3** | CR, CTM | **202AB** |
| **155** | Scientific Advice at the Level of the EMEA | LEVEL ■ | **RA4** | CR, RD | **201C** |
| **156** | FDA-EMEA Joint Session on Emerging Therapies and Technologies | LEVEL ● | **RA5** | BT, RD | **201A** |
| **157** | Design and Analysis of Multicenter Trials | LEVEL ■ | **ST** | CR | **103B** |
| **158** | The Pipeline of New Personnel for the Clinical Research Enterprise | LEVEL ● | **TR** | CR, CTM | **103C** |
| **MONDAY 3:30 pm-5:00 pm** | | | | | |
| **159** | Implementing Corporate Integrity Agreements | LEVEL ■ | **AD** | PP, RA | **111AB** |
| **160** | Human Tissue-engineered Products (hTEPs): US versus EU Comparison | LEVEL ■ | **BT** | CR, RA | **113C** |
| **161** | Collaborative Clinical Study Database Design | LEVEL ■ | **CDM** | CR, ST | **Marriott Salon CD** |
| **162** | Comprehensive Quality Overall Summary | LEVEL ■ | **CMC** | RA, TR | **112AB** |
| **163** | How to Manage Risks during Drug Development | LEVEL ■ | **CP** | CR, GCP | **Marriott Salon G** |
| **164** | Oncology Phase 1 Research: Unique Challenges | LEVEL ■ | **CR1** | IS, RA | **Marriott Salon E** |
| **165** | TYSABRI: A Novel Path to Regulatory Approval and Risk Management | LEVEL ■ | **CR2** | CP | **Marriott Salon IJ** |
| **166** | Clinical Trials for Fixed-combination Drug Products | LEVEL ◆ | **CR3** | RA, ST | **Marriott Salon KL** |
| **167** | Take Two Protocols and Call Me in the Morning: Effectively Managing the Challenges of the Clinical Supply Process | LEVEL ◆ | **CS** | CMC | **102AB** |
| **168** | Reaching Subject Recruitment and Retention Goals | LEVEL ● | **CTM** | CR | **107AB** |
| **169** | eINDs | LEVEL ● | **DM** | MW, RA | **204C** |
| **170** | Electronic Patient-reported Outcomes (ePRO) Technology and the FDA Draft PRO Guidance: A Town Meeting to Discuss Industry's Response | LEVEL ■ | **EC1** | CDM, IMP | **204B** |
| **171** | Interoperability: What It Means for Clinical Researchers, Statisticians, and Information Technology Professionals *NEW 2006 SIAC Offering – SIAC-sponsored Session* | LEVEL ◆ | **EC2** | IT, ST | **Marriott Salon H** |
| **172** | Terra Incognita: Explore the Business Impact of the Clinical Trials Directive | LEVEL ● | **FI** | PP, RA | **203AB** |
| **173** | Virtual Realities: Quality Considerations when Using Contract Organizations | LEVEL ■ | **GCP** | CR, PM | **Marriott Salon F** |
| **174** | Investigator Reimbursement and Budgets: How They Affect Patient Enrollment, Retention and Time Lines | LEVEL ■ | **IS** | CTM | **113B** |
| **175** | Deploying Life Science IT Using IEEE Methods | LEVEL ■ | **IT** | RA, VA | **105AB** |
| **176** | International Initiatives for Natural Health Products | LEVEL ● | **NHP** | CR, RA | **106AB** |
| **177** | Designing and Managing Successful Outsourcing Relationships – Part 2 of 2 | LEVEL ◆ | **OS** | PM | **109AB** |
| **178** | Effective Team and Project Integrations: Principles and Lessons Learned in Collaborations | LEVEL ■ | **PM1** | CTM, RD | **108A** |
| **179** | Best Practices for Remote and Virtual Project Management in Life Sciences | LEVEL ◆ | **PM2** | BT, CTM | **108B** |
| **180** | Community Pharmacy Safety Network: Patient and Pharmacist Involvement in the Monitoring of Medications | LEVEL ■ | **PP** | CP, RA | **113A** |
| **181** | Prescription Drug Labeling: Implementation of FDA's New Regulation for the Content and Format of the USPI and Accompanying Guidance Documents | LEVEL ■ | **RA1** | CP, PP | **201A** |

**Conference Schedule by Day and Time**

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| **MONDAY 3:30 pm-5:00 pm *continued*** | | | | | |
| **182** | FDA and EMEA Experiences on Interaction with Patients | LEVEL ■ | **RA2** | IMP, MC | **201C** |
| **183** | Clinical Trials in Latin America: A Review of the Regulatory Framework – Part 2 of 2 | LEVEL ● | **RA3** | CR, CTM | **202AB** |
| **184** | Successful Drug Development: The Phase 1/2 and 2/3 Interfaces | LEVEL ● | **RA4** | RD | **201B** |
| **185** | Challenges in Quantitative Assessment of Drug Safety for Regulatory Actions | LEVEL ● | **ST1** | CP, CR | **103A** |
| **186** | Targeted Therapies: Statistical Issues in Design | LEVEL ● | **ST2** | BT, CR, RD | **103B** |
| **187** | Career Trends and Opportunities for Clinical Research Professionals | LEVEL ● | **TR** | CR | **103C** |
| **TUESDAY 8:30 am-10:00 am** | | | | | |
| **201** | How to Develop a Direct-to-consumer Ad | LEVEL ■ | **AD** | RA | **111AB** |
| **202** | Biosimilars: Current Views | LEVEL ■ | **BT** | CR | **103A** |
| **203** | Hybrid Data Capture Strategies | LEVEL ■ | **CDM** | EC, IT | **Marriott Salon CD** |
| **204** | Challenges to Drug Development during IND/Clinic Stage in the New Paradigm | LEVEL ■ | **CMC** | CS | **112AB** |
| **205** | Use of Patient and Drug Registries for Safety Monitoring and Assessment | LEVEL ● | **CP1** | CDM, ST | **Marriott Salon G** |
| **206** | International Electronic ADR Reporting: The Latest Experience | LEVEL ■ | **CP2** | CDM, EC | **Marriott Salon H** |
| **207** | Cutting Time and Cost in Phase 3 Oncology Drug Development by Innovative Designs | LEVEL ■ | **CR1** | CTM, ST | **Marriott Salon AB** |
| **208** | Dos and Don'ts of Data Monitoring Committees | LEVEL ● | **CR2** | CP, RA | **Marriott Salon IJ** |
| **209** | Diving into the Details: An Expanded Business Case for Clinical Data Standards | LEVEL ■ | **CR3** | CDM, IT | **Marriott Salon E** |
| **210** | Flexible Study Designs: Are We Ready to Adapt? | LEVEL ● | **CR4** | ST | **Marriott Salon KL** |
| **211** | From Sticky Notes to Wildcard Searches: Adapting Monitoring Techniques to EDC | LEVEL ● | **CTM** | CDM | **107AB** |
| **212** | Delivering Electronic Submissions: Sharing Experiences | LEVEL ● | **DM** | IT, RA | **204C** |
| **213** | Clinical Research and Medical Records in Today's Regulatory Environment | LEVEL ● | **GCP** | CDM, EC | **Marriott Salon F** |
| **214** | Matchmaking among Sites, Sponsors and Studies | LEVEL ■ | **IS** | CTM | **113B** |
| **215** | Get It in Writing: The SLA at the Heart of Successful Business Relationships | LEVEL ● | **IT** | CR, VA | **105AB** |
| **216** | Real-world Perspectives on Risk Management for Independent and Promotional Education Activities: Best Practices and Guidelines for Companies Addressing Separation Guidelines | LEVEL ■ | **MC** | PP, RA | **204A** |
| **217** | Building the eCTD Starting with the IND: Clinical Documents | LEVEL ■ | **MW** | RA | **204B** |
| **218** | Updates on Natural Health Products: European Union | LEVEL ■ | **NHP** | RA | **106AB** |
| **219** | Configurable IVR Systems: What You Should Know | LEVEL ● | **OS** | IT | **109AB** |
| **220** | Successful Intercultural Communication in Drug Development: More than a Time Zone Issue | LEVEL ■ | **PM1** | RA | **108A** |
| **221** | Case Studies in Project Management of Performance Improvement Projects: The Spectrum of Success through Agony | LEVEL ● | **PM2** | BT, RD | **108B** |
| **222** | Clinical Trial Registration and Transparency of Trial Results | LEVEL ● | **PP** | CR, RD | **114 Auditorium** |
| **223** | Combination Products: A Primer | LEVEL ● | **RA1** | PP | **201B** |
| **224** | Faster, Superior, More Cost Effective: Has the eCTD Delivered Its Promises? | LEVEL ● | **RA2** | DM, EC | **202AB** |
| **225** | Regulatory Update from China | LEVEL ■ | **RA3** | CR | **201A** |
| **226** | CBER Hot Topics: Vaccine Safety | LEVEL ● | **RA4** | BT | **201C** |
| **227** | Drug Safety in the 21st Century: Convergence with Biomarkers and Diagnostics Catalyzes Modernization | LEVEL ■ | **RD** | CR, CTM | **102AB** |
| **228** | Medical Imaging Trials for Classification of Disease: Issues and Challenges | LEVEL ■ | **ST** | CR | **103B** |
| **229** | Professional Presence for Clinical Research Professionals | LEVEL ● | **TR** | CR | **103C** |
| **230** | Current Regulatory Computer Validation Issues | LEVEL ■ | **VA** | IT, PP | **113C** |
| | **SPECIAL EVENT!** Student Forum (7:30 am-10:00am) | | | | **203AB** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| | **TUESDAY 10:30 am-12:00 pm** | | | | |
| 231 | Public Relations | LEVEL ■ | AD | RA | 111AB |
| 232 | Biosimilars in Europe: A Dawning Reality | LEVEL ■ | BT | CR, RA | 103A |
| 233 | Evolution of Standards: Opportunities, Benefits and Challenges | LEVEL ● | CDM | EC, IT | Marriott Salon CD |
| 234 | Postapproval CMC Changes in the New Paradigm | LEVEL ■ | CMC | RA, TR | 112AB |
| 235 | Good Pharmacovigilance Practice: What Does It Mean? | LEVEL ■ | CP | GCP, RA | Marriott Salon G |
| 236 | Strategic Oncology Clinical Program Design: Addressing Global Needs | LEVEL ■ | CR1 | RA, ST | Marriott Salon E |
| 237 | Navigating the Critical Path to Drug Development for Bioterrorist Agents: The Case of Plague and Anthrax | LEVEL ■ | CR2 | NC | Marriott Salon AB |
| 238 | Orphan Drug Development: Past, Present, Future | LEVEL ● | CR3 | RA | Marriott Salon IJ |
| 239 | Asian Clinical Trials ... and Tribulations | LEVEL ● | CR4 | CTM, RA | Marriott Salon KL |
| 240 | Best Practices for Contracting and Working with Imaging Core Labs | LEVEL ● | CTM | CR | 107AB |
| 241 | Global CTD/eCTD | LEVEL ● | DM | MW, RA | 204C |
| 242 | Future Directions in Clinical Trial Management | LEVEL ■ | EC | CTM, IT | Marriott Salon H |
| 243 | GCP Compliance at the Investigative Site and Beyond | LEVEL ■ | GCP | CR, IS | Marriott Salon F |
| 244 | Electronic Medical Record (EMR)-based Disease Management | LEVEL ● | IMP | EC | 203AB |
| 245 | Recruitment and Retention: The Potential Subject's Perspective – What Works, What Doesn't, and Why | LEVEL ■ | IS | CTM | 113B |
| 246 | Combining EHR and EDC: Finding the Right IT Architecture | LEVEL ■ | IT | CDM, CR | 105AB |
| 247 | The Perils and Pitfalls of Creating a Medical Science Liaison Department | LEVEL ● | MC | MA | 204A |
| 248 | Authoring Nonclinical Study Reports | LEVEL ■ | MW | NC | 204B |
| 249 | Natural Health Products Research and Development: Challenges and Controversies | LEVEL ■ | NHP | AHC, CR, RD | 106AB |
| 250 | The Sponsor-CRO Partnership: How Is Outsourcing Affecting Drug Development? | LEVEL ■ | OS | CR | 109AB |
| 251 | The Target Product Profile (TPP): Uses for the Management of Product Development | LEVEL ■ | PM1 | BT, RD | 108A |
| 252 | What Small Biopharmaceutical Companies Can Teach Big Ones about Project Management | LEVEL ● | PM2 | BT, RD | 108B |
| 253 | The Expandable Universe of the Critical Path: Points to Consider beyond Science; Public Policy Needed to Sustain Critical Path – Part 1 of 2 | LEVEL ● | PP | CR, RA | 114 Auditorium |
| 254 | Transforming Regulatory Information into Intelligence | LEVEL ● | RA1 | RD | 201B |
| 255 | CBER Hot Topics | LEVEL ● | RA2 | BT | 201C |
| 256 | Hot Topic in Pharmaceutical R&D in China: Intellectual Property | LEVEL ■ | RA3 | PP | 201A |
| 257 | Data Monitoring Committees | LEVEL ■ | ST | AHC, CR, GCP | 103B |
| 258 | A Training Approach: From Basics to Specifics | LEVEL ● | TR | CDM, CR | 103C |
| 259 | Delivering Quality Validation Effectively | LEVEL ● | VA | IT, RA | 113C |
| | **TUESDAY 1:30 pm-3:00 pm** | | | | |
| 260 | How the New Labeling Rule Changes the Promotional Landscape | LEVEL ● | AD | RA | 111AB |
| 261 | How to Introduce Additional Vaccines during the First Year of Age | LEVEL ■ | BT | CR, RA | 103A |
| 262 | Global Solutions: Clinical Data Management Offshore | LEVEL ■ | CDM | CR, PM | Marriott Salon CD |
| 263 | Updates on ICH Quality Guidelines Q8, Q9, and Q10 | LEVEL ■ | CMC | TR | 112AB |
| 264 | International Electronic Adverse Event Databases: Understanding the Differences and Capabilities | LEVEL ● | CP | CDM, ST | Marriott Salon G |
| 265 | Cancer Clinical Study Management: Trials and Tribulations | LEVEL ■ | CR1 | CTM, PM | Marriott Salon E |
| 266 | Springboard Radical Changes in Clinical Development | LEVEL ■ | CR2 | RD | Marriott Salon KL |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| **TUESDAY 1:30 pm-3:00 pm *continued*** | | | | | |
| **267** | Clinical Research in Africa – Creating Win/Win Situations: Meeting International Standards while Improving Local Health Care | LEVEL ● | **CR3** | CTM, IS | **Marriott Salon IJ** |
| **268** | Successful EU Clinical Trials: Migrating from FDA Oversight to the EU Clinical Trial Directive | LEVEL ■ | **CR4** | RA | **Marriott Salon AB** |
| **269** | Metrics Champion Consortium: Creating Industry Standard Performance Metrics – Labs, ECGs, CROs | LEVEL ■ | **CTM** | CR | **107AB** |
| **270** | Compliant eCTDs – Part 1 of 2 | LEVEL ● | **DM** | MW, RA | **204C** |
| **271** | Clinical Trial Registries | LEVEL ■ | **EC** | CP, PP | **Marriott Salon H** |
| **272** | GCP/QA Town Meeting: Meeting the GCP Challenges of Electronic Data Capture (EDC) | LEVEL ◆ | **GCP** | EC, IT | **Marriott Salon F** |
| **273** | Functional Outcomes' Role in Demonstrating the Efficacy of New Medical Products and Therapies | LEVEL ● | **IMP** | CR, MC | **203AB** |
| **274** | Accelerating Subject Enrollment: A New Roadmap for Sites and Sponsors | LEVEL ■ | **IS** | CTM | **113B** |
| **275** | Developing Enterprise IT Architectures and Data Models for Drug Development | LEVEL ■ | **IT1** | CDM, CTM | **106AB** |
| **276** | The National Health Information Infrastructure: Public-private Sector Initiative | LEVEL ■ | **IT2** | CR, EC | **105AB** |
| **277** | Chronicles of Mergers between Medical Information Departments: Inside and Outside of the Organization | LEVEL ● | **MC** | MA | **204A** |
| **278** | Medical Science, Affairs, and Writing in Pharmacovigilance | LEVEL ■ | **MW** | CP | **204B** |
| **279** | PPAR Agonist Toxicities: An Update | LEVEL ■ | **NC** | CR, MW | **202AB** |
| **280** | Preferred Provider Selection Process | LEVEL ■ | **OS** | PM | **109AB** |
| **281** | DIA's Project Management Standards and Training Program | LEVEL ● | **PM1** | TR | **108A** |
| **282** | Has "Phased" Clinical Development Outlived Its Useful Life? | LEVEL ■ | **PM2** | CR, CTM | **108B** |
| **283** | The Expandable Universe of the Critical Path: Points to Consider in the Marketplace; Pricing and Reimbursement – Part 2 of 2 | LEVEL ● | **PP** | CR, RA | **114 Auditorium** |
| **284** | Practical Tips for Successful Development and Approval in Different Cultures | LEVEL ■ | **RA1** | CR, GCP | **201B** |
| **285** | Biomarkers in Drug Development: A Blessing or a Curse? | LEVEL ■ | **RA2** | CR, RD | **201C** |
| **286** | EU/FDA Confidentiality Arrangements: Current Status – What's Next? | LEVEL ● | **RA3** | PP | **201A** |
| **287** | Monitoring and Managing a Changing Investigative Site Landscape | LEVEL ● | **RD** | CR, IS | **102AB** |
| **288** | EMEA Road Map and FDA Critical Path: Statistical Implications, Risks, and Opportunities | LEVEL ■ | **ST** | CR, PP, RA | **103B** |
| **289** | The Use of eLearning to Meet the Growing Need for Healthcare Compliance Training | LEVEL ● | **TR** | CR, RA | **103C** |
| **290** | Extraordinary Opportunities: Issues We Face in Meeting Regulatory Expectations and How to Address Them | LEVEL ■ | **VA** | IT, RA | **113C** |
| **TUESDAY 3:30 pm-5:00 pm** | | | | | |
| **291** | Direct-to-consumer Advertising Policy | LEVEL ■ | **AD** | RA | **111AB** |
| **292** | Vaccines and Blood Products: Recent Specific Regulatory Provisions in the EU | LEVEL ■ | **BT** | CR, RA | **103A** |
| **293** | Workflow and Metrics in Data Management: What Opportunities Does EDC Provide for Optimization? | LEVEL ● | **CDM** | EC | **Marriott Salon CD** |
| **294** | Signal Detection in Pharmacovigilance: State of the Art and Emerging Quantitative Approaches | LEVEL ■ | **CP** | CDM, ST | **Marriott Salon G** |
| **295** | Best Practices in Conducting Clinical Trials in India from Multiple Perspectives | LEVEL ■ | **CTM** | CR | **107AB** |
| **296** | Compliant eCTDs – Part 2 of 2 | LEVEL ● | **DM** | MW, RA | **204C** |
| **297** | Effectively Protecting Human Subjects in Studies Conducted Outside the US | LEVEL ■ | **GCP** | CR, IS | **Marriott Salon F** |
| **298** | Faster, Better, Cheaper: Sponsor/Site Partnerships | LEVEL ■ | **IS** | CTM | **113B** |
| **299A** | Developments in Electronic Pharmaceutical Data Archiving | LEVEL ● | **IT** | EC, RA | **105AB** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| **TUESDAY 3:30 pm-5:00 pm *continued*** | | | | | |
| **299B** | Regional Medical Liaison Survey #2: Assessing Training Techniques and Demonstrating Value of Regional Medical Liaisons across the Pharmaceutical Industry | LEVEL ● | **MC** | MA | **204A** |
| **299C** | Publication Planning: New Opportunities and Issues | LEVEL ● | **MW** | BT, CR | **204B** |
| **299D** | Peroxisome Proliferators Activated Receptors (PPARs) Agonists and Rodent Tumorigenesis: Updating the Discussions | LEVEL ◆ | **NC** | CP, MW | **202AB** |
| **299E** | Strategies and Success Stories for Integrating NHP and Conventional Medicine | LEVEL ● | **NHP** | IMP | **106AB** |
| **299F** | Intellectual Human Capital in Contract Research: Is the Market There? | LEVEL ■ | **OS** | RD | **109AB** |
| **299G** | The Future for Project Management: What Does It Look Like? | LEVEL ■ | **PM1** | OS, RD | **108A** |
| **299H** | Vendor Management: Drive Performance and Value | LEVEL ■ | **PM2** | CTM, OS | **108B** |
| **299I** | The Ethics of Authorship | LEVEL ● | **PP** | AHC, MW | **113A** |
| **299J** | PLENARY SESSION: Update from the FDA Office of the Commissioner *(Concludes at 5:30 pm)* | LEVEL ● | **RA/CR** | | **Ballroom AB** |
| **299K** | Managing Capacity to Drive Productivity in Pharmaceutical R&D | LEVEL ■ | **RD** | CR, PM | **102AB** |
| **299L** | Sequential Methodology for Pharmacogenetics | LEVEL ■ | **ST** | CR, RD | **103B** |
| **299M** | Using ADDIE (Analyze, Design, Develop, Implement, Evaluate) to Strategically Analyze and Evaluate Your Training Program | LEVEL ■ | **TR** | CDM, CR | **103C** |
| **299N** | Validation from Inside the Corporate Environment | LEVEL ● | **VA** | GCP, IT | **113C** |
| **WEDNESDAY 8:30 am-10:00 am** | | | | | |
| **301** | IND Exemptions: The Determination Process | LEVEL ■ | **AHC** | CR | **113B** |
| **302** | Vaccine Toxicology | LEVEL ■ | **BT** | CR, RA | **103A** |
| **303** | Sites without Standards | LEVEL ■ | **CDM** | EC, IT | **Marriott Salon CD** |
| **304** | Implementation of Quality-by-design: An Office of Biotechnology Products Perspective | LEVEL ■ | **CMC** | BT, TR | **112AB** |
| **305** | Global Perspective on ADR Reporting Practices | LEVEL ● | **CP** | RA | **Marriott Salon G** |
| **306** | Oncology Endpoints/Biomarkers | LEVEL ◆ | **CR1** | — | **Marriott Salon E** |
| **307** | Clinical Trials and Tribulations: Influences on Patient Recruitment and Retention | LEVEL ● | **CR2** | CTM, IS | **Marriott Salon KL** |
| **308** | Using Six Sigma to Optimize Research and Development | LEVEL ● | **CR3** | ST | **Marriott Salon IJ** |
| **309** | Clinical Trials in Central and Eastern Europe: Overcoming Technology and Logistical Challenges | LEVEL ■ | **CR4** | CTM | **Marriott Salon H** |
| **310** | Collaborating Effectively to Submit Cooperative Group Data to the FDA | LEVEL ■ | **CTM** | BT | **107AB** |
| **311** | eSubmission Standards: Industry's Perspective | LEVEL ■ | **DM** | IT, RA | **204C** |
| **312** | Where Are We in the Debate between the Biopharmaceutical Industry, the Solution Providers, and the Regulatory Authorities? What Initiatives Are Being Taken to Alleviate Issues around eSource? *NEW 2006 SIAC Offering – SIAC-sponsored Session* | LEVEL ● | **EC** | CDM, RA | **113A** |
| **313** | Update: Secretary's Advisory Committee on Human Research Protection (SACHRP) | LEVEL ■ | **GCP** | CR, PP | **Marriott Salon F** |
| **314** | Why Your Data Can't Talk to My Data | LEVEL ● | **IT** | CDM, EC | **105AB** |
| **315** | New Drug Launches and Drug Adoption | LEVEL ● | **MA** | AD, CTM, RA | **113C** |
| **316** | Medical Information as an Adjunct to Sales Training | LEVEL ■ | **MC** | MA | **204A** |
| **317** | ISS/ISE: Where Do They Fit in the CTD/eCTD? | LEVEL ■ | **MW** | BT, RA | **204B** |
| **318** | Developmental and Reproductive Toxicity Evaluations of Biological Drugs | LEVEL ● | **NC** | BT, MW | **111AB** |
| **319** | Developing Probiotics as Biologics: Regulatory and Scientific Considerations | LEVEL ● | **NHP** | AHC, CMC, RA | **106AB** |
| **320** | The State of Clinical Outsourcing: The Functional Service Provider Model | LEVEL ■ | **OS** | CR, FI | **109AB** |
| **321** | Driving High Performance Strategic Relationships | LEVEL ● | **PM1** | CTM, OS | **108A** |
| **322** | Leadership Secrets to Manage Highly Qualified Individuals | LEVEL ◆ | **PM2** | TR | **108B** |
| **323** | The QS Train Is Moving Fast at FDA | LEVEL ● | **RA1** | PM | **202AB** |
| **324** | First Experience with Risk Management Initiatives in the US and EU | LEVEL ■ | **RA2** | CP | **201C** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
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| **WEDNESDAY 8:30 am-10:00 am *continued*** | | | | | |
| **325** | QT-Dossier: The Impact of ECG Data from a Regulatory Perspective | LEVEL ● | **RA3** | CP, CR | **201B** |
| **326** | Understanding the Regulation of "Advanced Therapy Medicinal Products" in Europe | LEVEL ● | **RA4** | BT | **201A** |
| **327** | Does Innovation Pay? | LEVEL ● | **RD** | CTM | **102AB** |
| **328** | Endpoint Selection and Other Considerations in HIV Clinical Trials | LEVEL ● | **ST** | CR | **103B** |
| **329** | Online Learning: Managing the Implementation Process | LEVEL ● | **TR** | CTM, GCP | **103C** |
| **330** | Validation from the Quality Perspective | LEVEL ■ | **VA** | IT, RA | **203AB** |
| **WEDNESDAY 10:30 am-12:00 pm** | | | | | |
| **331** | IRB Training in Ethical Issues: The Brazilian Experience | LEVEL ■ | **AHC** | CR | **113B** |
| **332** | Hot Topics in Biotechnology | LEVEL ■ | **BT** | CR | **103A** |
| **333** | The Safety-clinical Data Management Interface | LEVEL ■ | **CDM** | CP | **Marriott Salon CD** |
| **334** | Implementation of Quality-by-design: An Office of Generic Drugs Approach | LEVEL ■ | **CMC** | RA, TR | **112AB** |
| **335** | Some Creative Tools and Methods in Pharmacovigilance | LEVEL ● | **CP** | CR, ST | **Marriott Salon G** |
| **336** | Pharmacogenetics: FDA/EMEA | LEVEL ■ | **CR1** | BT, RA | **Marriott Salon E** |
| **337** | A Key to Success in Bringing a Product to Market Is Proper Protocol Design | LEVEL ■ | **CR2** | ST | **Marriott Salon AB** |
| **338** | Cultural Sensitivity and Patient Recruitment: Techniques for Effective Enrollment in Global Trials | LEVEL ■ | **CR3** | CTM | **Marriott Salon IJ** |
| **339** | Leave No Patient Behind: A Model for Recovering Patients Lost to Follow-up | LEVEL ● | **CTM** | CR | **107AB** |
| **340** | FDA Standards Initiatives and Gateway Update | LEVEL ● | **DM** | CDM, RA | **204C** |
| **341** | Extreme Informed Consent | LEVEL ■ | **GCP** | CR, IS | **Marriott Salon F** |
| **342** | Real-world Clinical Trials | LEVEL ● | **IMP** | CR | **Marriott Salon KL** |
| **343** | Managing Identity and Authentication in Sensitive Healthcare Communications: How Can You Be Sure the Person at the Other End of the Electronic Communication Is Who (S)he Says (S)he Is? | LEVEL ■ | **IT** | CR, RA | **105AB** |
| **344** | Communicating with Physicians through the Power of Postapproval Research: The Impact in a Physician's Own Practice | LEVEL ■ | **MA** | CTM, MC, MW | **113C** |
| **345** | Reducing the Incidence of Medication Errors Resulting from the Use of Error-prone Abbreviations and Symbols | LEVEL ● | **MC** | CR, RA | **204A** |
| **346** | Preparing Global CTD Submission-ready Documents from IND to NDA | LEVEL ● | **MW** | RA | **204B** |
| **347** | Nonclinical Efforts to Reduce Attrition in First-time-to-man Studies | LEVEL ● | **NC** | CR, GCP | **111AB** |
| **348** | Growing Standardized, Reproducible, and Sustainable Botanicals for Medicinal Use | LEVEL ■ | **NHP** | CMC, RA | **106AB** |
| **349** | Local versus Global CRO Assignment: Is it Possible to Build a Constructive Relationship with Partners You Have Not Chosen? | LEVEL ● | **OS** | IS | **109AB** |
| **350** | EPM Information Systems: The Influence of Project Management Maturity on Implementation Strategies | LEVEL ● | **PM1** | BT, RD | **108A** |
| **351** | Twenty-first Century Team Leadership | LEVEL ■ | **PM2** | — | **108B** |
| **352** | Understanding and Reversing the Erosion of Public Trust in Clinical Research | LEVEL ● | **PP** | CR, IMP | **113A** |
| **353** | Drug Development in Japan and Acceptance of Global CMC Dossier | LEVEL ■ | **RA1** | CMC, CR | **202AB** |
| **354** | Regulatory Pathways for Medicines Addressing the Public Health Needs in the Developing World | LEVEL ● | **RA2** | PP | **201C** |
| **355** | Evolving Global Oncology Drug Registrational Environment | LEVEL ■ | **RA3** | CR | **201A** |
| **356** | Changes in the European Regulatory Environment Affecting Member States: MRC and Decentralized Procedures | LEVEL ■ | **RA4** | PP, RD | **201B** |
| **357** | CDER Hot Topic – Update: Drug Safety Initiatives | LEVEL ■ | **RA5** | CP | **114 Auditorium** |
| **358** | Randomization | LEVEL ■ | **ST** | CR, CTM | **103B** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
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| **WEDNESDAY 10:30 am-12:00 pm *continued*** | | | | | |
| 359 | Methodologies in Training Adults: Experiences Collected from Regional CROs | LEVEL ■ | TR | CR, CTM, PM | 103C |
| 360 | The IQ/OQ/PQ Challenge for Small Companies | LEVEL ■ | VA | BT, IT | 203AB |
| **WEDNESDAY 1:30 pm-3:00 pm** | | | | | |
| 361 | How to Prepare for and Conduct Investigator-initiated Research | LEVEL ● | AHC | CR | 113B |
| 362 | Systems Biology: The Realization of Intelligent Drug Development | LEVEL ■ | BT | CR | 103A |
| 363 | AJAX: A New Approach to Integrating Paper Data Entry and EDC Processes | LEVEL ● | CDM | IT | Marriott Salon CD |
| 364 | Quality-by-design: Case Studies | LEVEL ■ | CMC | TR | 112AB |
| 365 | Regulatory Inspections of Company Pharmacovigilance Operations | LEVEL ● | CP | GCP, RA | Marriott Salon G |
| 366 | Clinical Trial Execution and Informed Consent: Keys to Success | LEVEL ■ | CR1 | GCP | Marriott Salon E |
| 367 | It Is Saturday Night! Do You Know Where Your Clinical Trial Is? | LEVEL ● | CR2 | CDM, EC | Marriott Salon KL |
| 368 | Challenges and Pitfalls of Anti-TNF Drugs | LEVEL ■ | CR3 | — | Marriott Salon IJ |
| 369 | Targeted Therapeutics | LEVEL ■ | CR4 | BT | Marriott Salon AB |
| 370 | Post-trial Access to Study Medication: Is It Feasible? | LEVEL ■ | CTM | CR | 107AB |
| 371 | FDA eSubmission Update: OBPS Overview, SDTM, eSUB/eCTD Hot Issues, SPL Update | LEVEL ● | DM | IT, MW, RA | 204C |
| 372 | Quality Risk Management in Clinical Trials: A Paradigm Shift | LEVEL ■ | GCP | CR | Marriott Salon F |
| 373 | The Economics of Pharmaceutical Pricing | LEVEL ■ | IMP | MA | 108B |
| 374 | CRIX: A Shared Clinical Research Information eXchange | LEVEL ● | IT | CR, EC | 105AB |
| 375 | Marketing Your Clinical Services Organization | LEVEL ● | MA | CDM, CR, CTM | 113C |
| 376 | Role of Medical Communications in Clinical Trial Information Internet Posting | LEVEL ■ | MC | CR, MW | 204A |
| 377 | Efficient Preparation of High-quality Documents | LEVEL ■ | MW | DM, PM | 204B |
| 378 | Metabolites in Safety Testing | LEVEL ● | NC | CR, MW | 111AB |
| 379 | Managing the Quality of Natural Products | LEVEL ■ | NHP | CMC, RA, VA | 106AB |
| 380 | Predicting the Outsourcing Industry's 2010 Structure | LEVEL ● | OS | CR, PM | 109AB |
| 381 | PLENARY SESSION: Creating High-performing Cross-functional Teams | LEVEL ■ | PM | CTM | Marriott Salon H |
| 382 | Pricing and Reimbursement of Medicinal Products in the European Union | LEVEL ● | PP | FI, IMP | 113A |
| 383 | The Emerging Markets: Regulatory Issues and the Impact on Patients' Access to Medicines | LEVEL ■ | RA1 | IMP | 201B |
| 384 | Follow-on Protein Products: Scientific Issues, beyond Same Molecular Entity and Comparable Rate and Extent – Part 1 of 2 | LEVEL ■ | RA2 | BT, CMC | 201A |
| 385 | Substantial Evidence from Subpopulations and Secondary Endpoints | LEVEL ■ | RA3 | CR, ST | 201C |
| 386 | Japan's Pharmaceutical and Medical Devices Agency and Related Drug Safety Activities | LEVEL ■ | RA4 | CP, CR | 203AB |
| 387 | Human Subject Protection/Bioresearch Monitoring Initiative and Critical Path Update | LEVEL ■ | RA5 | CR, GCP | 114 Auditorium |
| 388 | Microdosing: Promise and Peril along the Critical Path | LEVEL ● | RD | CR, CTM | 102AB |
| 389 | Randomized Withdrawal Design for Evaluation of Long-term Efficacy | LEVEL ■ | ST | CR | 103B |
| 390 | Training Alternatives to Enhance Site Performance and Compliance | LEVEL ■ | TR | CTM, GCP | 103C |
| **WEDNESDAY 3:30 pm-5:00 pm** | | | | | |
| 391 | Quality Assurance in Asia: Extending across Boundaries | LEVEL ■ | AHC | CR, GCP | 113B |
| 392 | Using Modeling Software to Overcome Hurdles and Improve Productivity in the Development and Validation of Biomarkers in Clinical Trials | LEVEL ■ | BT | CR | 103A |
| 393 | Strategies for Handling MedDRA® Updates | LEVEL ● | CDM | CP, IT | Marriott Salon CD |
| 394 | Challenges in Current Dissolution Methods and Alternatives to Dissolution in the New Paradigm | LEVEL ■ | CMC | TR | 112AB |

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|---|---|---|---|---|---|
| **WEDNESDAY 3:30 pm-5:00 pm *continued*** | | | | | |
| **395** | Best Pharmaceuticals for Children Act (BPCA) Pediatric Safety | LEVEL ● | **CP** | CR, IMP | **Marriott Salon G** |
| **396** | Avoiding QT Overkill | LEVEL ■ | **CR1** | CP | **Marriott Salon E** |
| **397** | Tracking Patient Enrollment from Inquiry to Randomization and Beyond | LEVEL ■ | **CR2** | CDM, CTM | **Marriott Salon KL** |
| **398** | Global Clinical Trials Ethics: Who Is Looking after Whose Interests? | LEVEL ● | **CR3** | IMP, PP | **Marriott Salon IJ** |
| **399A** | Ensuring Diversity: Monitoring Subpopulation Participation in Clinical Trials | LEVEL ● | **CR4** | RA | **Marriott Salon AB** |
| **399B** | Multimedia Informed Consent: What Can It Bring to a Trial? | LEVEL ● | **CTM** | EC | **107AB** |
| **399C** | International Electronic Common Technical Document (eCTD) Update: The Regulatory Authority Perspective | LEVEL ● | **DM** | MW, RA | **204C** |
| **399D** | Managing Clinical Trials in Russia | LEVEL ● | **GCP** | CR | **202AB** |
| **399E** | Automated Tools for the Electronic Management of Complex Inventory in Global Studies | LEVEL ● | **IT1** | CS, CTM | **105AB** |
| **399F** | Applications of the Biomedical Research Integrated Domain Group (BRIDG) | LEVEL ● | **IT2** | CDM, CR | **113C** |
| **399G** | Effectively Communicating Outcomes Research to Enhance Product Success | LEVEL ■ | **MC** | CR, MA | **204A** |
| **399H** | Clinical Trial Registries: An Update | LEVEL ● | **MW** | CR, CTM | **204B** |
| **399I** | Animal Models of Disease in Nonclinical Development of (Orphan) Drugs | LEVEL ■ | **NC** | BT, MW | **111AB** |
| **399J** | Developing Botanical Drugs for the United States | LEVEL ■ | **NHP** | MA, RD | **106AB** |
| **399K** | Functional Outsourcing: A Comparison of Two Major Companies' Strategies | LEVEL ◆ | **OS** | CR, FI | **109AB** |
| **399L** | Fast and Fun Way to Build High-performing Cross-functional Teams | LEVEL ● | **PM1** | BT, RA | **108A** |
| **399M** | Project Teams or Product Incubators? | LEVEL ■ | **PM2** | BT, RD | **108B** |
| **399N** | RiskMAPing and Litigation | LEVEL ■ | **PP** | CP, IMP | **113A** |
| **399O** | Regulatory "Partnership in Harmonization" in APEC Region | LEVEL ■ | **RA1** | CR, GCP | **203AB** |
| **399P** | Follow-on Protein Products – Legal and Regulatory Framework for Approval: History of Hatch-Waxman and Lessons Learned – Part 2 of 2 | LEVEL ■ | **RA2** | BT, CMC | **201A** |
| **399Q** | Adding a Third Drug Class: Benefit or Burden? | LEVEL ● | **RA3** | PP | **201B** |
| **399R** | ICH E2E Implementation: National/International Perspectives | LEVEL ■ | **RA4** | CP | **Marriott Salon H** |
| **399S** | CDER Hot Topic: Physicians' Labeling Rule | LEVEL ● | **RA5** | CP, MC | **114 Auditorium** |
| **399T** | PDUFA's Pilot 1: The Continuous Marketing Application Revealed | LEVEL ■ | **RA6** | RD | **201C** |
| **399U** | An Analysis of the Success Factors of Global Applications of Biotechnology-derived Products | LEVEL ◆ | **RD** | BT, RA | **102AB** |
| **399V** | Regulatory Guidance and Standards Development: Implications for Statistical Practice and Review | LEVEL ■ | **ST** | EC, RA | **103B** |
| **399W** | Decreasing Business Risk by Ensuring Training Compliance: Three Key Strategies | LEVEL ■ | **TR** | CR, GCP | **103C** |
| **THURSDAY 8:30 am-10:00 am** | | | | | |
| **401** | Accelerating Research: Integrating Clinical Research with Clinical Care | LEVEL ◆ | **AHC** | CR | **110AB** |
| **402** | Challenges of Biotechnology Product Development | LEVEL ■ | **BT** | CR | **103A** |
| **403** | The Impact of SDTM (Study Data Tabulation Model) on the Methodology of Clinical Information Management | LEVEL ■ | **CDM** | EC, IT, ST | **204B** |
| **404** | Updates on FDA GMP (Good Manufacturing Practices) Initiatives and Guidances | LEVEL ■ | **CMC** | TR | **113B** |
| **405** | Current MedDRA® Topics: Data Retrieval and Presentation Points to Consider and Standardized MedDRA® Queries (SMQs) | LEVEL ■ | **CP** | CDM, ST | **201C** |
| **406** | Pediatric Drug Development in an Increasingly Global Context | LEVEL ● | **CR1** | PP, RA | **109AB** |
| **407** | Strategies for Outsourcing and Managing Late-phase Trials Using Naïve Sites | LEVEL ■ | **CR2** | IS, OS | **112AB** |
| **408** | Microdosing Studies: State of Technology and US Regulatory Requirements | LEVEL ■ | **CR3** | RA | **111AB** |
| **409** | Patient Randomization: At What Cost? | LEVEL ■ | **CTM** | CR | **107AB** |
| **410** | eCTD Lifecycle Management | LEVEL ● | **DM** | IT, RA | **204C** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| **THURSDAY 8:30 am-10:00 am *continued*** | | | | | |
| 411 | Good Auditing Practice: What Do We Mean by "Compliance"? | LEVEL ● | GCP | CR | 204A |
| 412 | From Electronic Data Capture to Clinical Data Warehouse | LEVEL ■ | IT | CDM, CR | 105AB |
| 413 | New Era for International Marketing: Stricter Self-regulation through New Codes of Conduct | LEVEL ■ | MA | RA | Marriott Salon AB |
| 414 | Ensuring High-quality Written Communications for Medical Communications Professionals | LEVEL ● | MC | MW | Marriott Salon CD |
| 415 | Can Biomarkers of Safety Support Safe Clinical Development? | LEVEL ■ | NC | CP, MW | 106AB |
| 416 | Hot Topics in Natural Health Products: Results of the GAIT Study and Implications for Future NSAID Development | LEVEL ■ | NHP | CR, RA, RD | Marriott Salon KL |
| 417 | Intercompany Auditing Agreement as Part of Strategic Risk Management | LEVEL ● | OS | GCP | 108A |
| 418 | Being Smart about Global vs. Local | LEVEL ● | PM | CR, CTM | 108B |
| 419 | Transatlantic Convergence in Drug Reimbursement Decisions | LEVEL ● | PP | FI, IMP | 113C |
| 420 | CDER Town Meeting – Part 1 of 2 | LEVEL ● | RA1 | CR, PP, RD | 201A |
| 421 | Trends in Warning and Determination Letters to IRBs and Investigators | LEVEL ● | RA2 | CTM, GCP | 201B |
| 422 | How to Authorize a Generic in Europe | LEVEL ■ | RA3 | PP | 202AB |
| 423 | Outlook for Changes in Japanese Regulatory and Clinical Development Environment | LEVEL ■ | RA4 | CR, CTM, GCP | 203AB |
| 424 | Clinical R&D Management by Metrics Using the Latest Computer Technology | LEVEL ■ | RD | IT, PM | 102AB |
| 425 | Statistical Contributions to the Patient-oriented Clinical Evaluation | LEVEL ■ | ST | CR | 103B |
| 426 | Pharmacogenomics and Education: When Will We See an Uptake of Pharmacogenomics? | LEVEL ● | TR | CR | 103C |
| **THURSDAY 10:30 am-12:00 pm** | | | | | |
| 427 | Improve Patient Outcomes through a Comprehensive Collaboration Model | LEVEL ■ | AHC | CR, IMP | 110AB |
| 428 | Practical Application of Scientific Advice in the Development of Biological Medicinal Products for Europe | LEVEL ● | BT | CR, RA | 103A |
| 429 | Data Management's Future: Commodity or Value-added Discipline? | LEVEL ■ | CDM | PM | 204B |
| 430 | Recent MedDRA® Developments: Medication Errors and Labeling Considerations | LEVEL ■ | CP | MC, RA | 201C |
| 431 | Planning and Conducting Successful Investigators' Meetings | LEVEL ■ | CR1 | IS, PM | 113B |
| 432 | Site-focused Strategies for Re-engineering Clinical Research | LEVEL ◆ | CR2 | IS | 112AB |
| 433 | The Impact of Ethics Committees on Competitive Recruitment in Multinational, Multicenter Clinical Trials: Opportunities and Challenges | LEVEL ■ | CR3 | IS | 111AB |
| 434 | Patient Safety Issues in Phase I Studies | LEVEL ■ | CR4 | CP | 109AB |
| 435 | How to Assure Quality when Clinical Trials Are Conducted in Developing Countries | LEVEL ■ | CTM | CR | 107AB |
| 436 | eCTD Tools: Are They ICH-compliant? | LEVEL ■ | DM | IT, RA, VA | 204C |
| 437 | Practical Pediatric Trials: Lessons from America for Europe | LEVEL ● | GCP | CR | 204A |
| 438 | IT Governance Models: Win-win Approaches for Healthcare | LEVEL ■ | IT | RA | 105AB |
| 439 | Nonclinical Development of Combination Medicinal Products | LEVEL ● | NC | CR, MW | 106AB |
| 440 | An Update on State Medicare Part D Implementation | LEVEL ● | PP | FI, IMP | 113C |
| 441 | CDER Town Meeting – Part 2 of 2 | LEVEL ● | RA1 | CR, PP, RD | 201A |
| 442 | Before It's Too Late: Risk Management throughout Product Development | LEVEL ● | RA2 | CP | 202AB |
| 443 | FDA Advisory Committees: Controversies, Challenges, and Changes | LEVEL ◆ | RA3 | PP | 203AB |
| 444 | Optimize the Development and Registration of Innovation Therapies Developed by Emerging Biotechnology | LEVEL ◆ | RD | BT, CTM | 102AB |
| 445 | Policy, Business, and Statistical Issues Related to Bayesian Approaches for Late-phase Practical Clinical Trials | LEVEL ● | ST | CR | 103B |
| 446 | Addressing Challenges Associated with Clinician-rated Scales | LEVEL ● | TR | CR, CTM | 103C |

# Conference Schedule by Interest Area

| Day | Time | Session Number | Session Title | Difficulty Level | Room Number |
|---|---|---|---|---|---|
| **AD** | **Advertising** | | | | |
| Monday | 10:30 am-12:00 pm | **101** | Drug Advertising and Promotion: A Regulatory Primer | LEVEL ● | **111AB** |
| Monday | 1:30 pm-3:00 pm | **128** | Enforcement Update | LEVEL ■ | **111AB** |
| Monday | 3:30 pm-5:00 pm | **159** | Implementing Corporate Integrity Agreements | LEVEL ■ | **111AB** |
| Tuesday | 8:30 am-10:00 am | **201** | How to Develop a Direct-to-Consumer Ad | LEVEL ■ | **111AB** |
| Tuesday | 10:30 am-12:00 pm | **231** | Public Relations | LEVEL ■ | **111AB** |
| Tuesday | 1:30 pm-3:00 pm | **260** | How the New Labeling Rule Changes the Promotional Landscape | LEVEL ● | **111AB** |
| Tuesday | 3:30 pm-5:00 pm | **291** | Direct-to-consumer Advertising Policy | LEVEL ■ | **111AB** |
| **AHC** | **Academic Health Centers** | | | | |
| Wednesday | 8:30 am-10:00 am | **301** | IND Exemptions: The Determination Process | LEVEL ■ | **113B** |
| Wednesday | 10:30 am-12:00 pm | **331** | IRB Training in Ethical Issues: The Brazilian Experience | LEVEL ■ | **113B** |
| Wednesday | 1:30 pm-3:00 pm | **361** | How to Prepare for and Conduct Investigator-initiated Research | LEVEL ● | **113B** |
| Wednesday | 3:30 pm-5:00 pm | **391** | Quality Assurance in Asia: Extending across Boundaries | LEVEL ■ | **113B** |
| Thursday | 8:30 am-10:00 am | **401** | Accelerating Research: Integrating Clinical Research with Clinical Care | LEVEL ◆ | **110AB** |
| Thursday | 10:30 am-12:00 pm | **427** | Improve Patient Outcomes through a Comprehensive Collaboration Model | LEVEL ■ | **110AB** |
| **BT** | **Biotechnology** | | | | |
| Monday | 3:30 pm-5:00 pm | **160** | Human Tissue-engineered Products (hTEPs): US versus EU Comparison | LEVEL ■ | **113C** |
| Tuesday | 8:30 am-10:00 am | **202** | Biosimilars: Current Views | LEVEL ■ | **103A** |
| Tuesday | 10:30 am-12:00 pm | **232** | Biosimilars in Europe: A Dawning Reality | LEVEL ■ | **103A** |
| Tuesday | 1:30 pm-3:00 pm | **261** | How to Introduce Additional Vaccines during the First Year of Age | LEVEL ■ | **103A** |
| Tuesday | 3:30 pm-5:00 pm | **292** | Vaccines and Blood Products: Recent Specific Regulatory Provisions in the EU | LEVEL ■ | **103A** |
| Wednesday | 8:30 am-10:00 am | **302** | Vaccine Toxicology | LEVEL ■ | **103A** |
| Wednesday | 10:30 am-12:00 pm | **332** | Hot Topics in Biotechnology | LEVEL ■ | **103A** |
| Wednesday | 1:30 pm-3:00 pm | **362** | Systems Biology: The Realization of Intelligent Drug Development | LEVEL ■ | **103A** |
| Wednesday | 3:30 pm-5:00 pm | **392** | Using Modeling Software to Overcome Hurdles and Improve Productivity in the Development and Validation of Biomarkers in Clinical Trials | LEVEL ■ | **103A** |
| Thursday | 8:30 am-10:00 am | **402** | Challenges of Biotechnology Product Development | LEVEL ■ | **103A** |
| Thursday | 10:30 am-12:00 pm | **428** | Practical Application of Scientific Advice in the Development of Biological Medicinal Products for Europe | LEVEL ● | **103A** |
| **CDM** | **Clinical Data Management** | | | | |
| Monday | 10:30 am-12:00 pm | **102** | Building a Data-centric Trial; or It's the Data! | LEVEL ■ | **Marriott Salon CD** |
| Monday | 1:30 pm-3:00 pm | **129** | Quality Data: Starting with the End in Mind | LEVEL ■ | **Marriott Salon CD** |
| Monday | 3:30 pm-5:00 pm | **161** | Collaborative Clinical Study Database Design | LEVEL ■ | **Marriott Salon CD** |
| Tuesday | 8:30 am-10:00 am | **203** | Hybrid Data Capture Strategies | LEVEL ■ | **Marriott Salon CD** |
| Tuesday | 10:30 am-12:00 pm | **233** | Evolution of Standards: Opportunities, Benefits and Challenges | LEVEL ● | **Marriott Salon CD** |
| Tuesday | 1:30 pm-3:00 pm | **262** | Global Solutions: Clinical Data Management Offshore | LEVEL ■ | **Marriott Salon CD** |
| Tuesday | 3:30 pm-5:00 pm | **293** | Workflow and Metrics in Data Management: What Opportunities Does EDC Provide for Optimization? | LEVEL ● | **Marriott Salon CD** |
| Wednesday | 8:30 am-10:00 am | **303** | Sites without Standards | LEVEL ■ | **Marriott Salon CD** |
| Wednesday | 10:30 am-12:00 pm | **333** | The Safety-clinical Data Management Interface | LEVEL ■ | **Marriott Salon CD** |
| Wednesday | 1:30 pm-3:00 pm | **363** | AJAX: A New Approach to Integrating Paper Data Entry and EDC Processes | LEVEL ● | **Marriott Salon CD** |
| Wednesday | 3:30 pm-5:00 pm | **393** | Strategies for Handling MedDRA® Updates | LEVEL ● | **Marriott Salon CD** |

| Day | Time | Session Number | Session Title | Difficulty Level | Room Number |
|---|---|---|---|---|---|
| **CDM Clinical Data Management *continued*** | | | | | |
| Thursday | 8:30 am-10:00 am | **403** | The Impact of SDTM (Study Data Tabulation Model) on the Methodology of Clinical Information Management | LEVEL ■ | **204B** |
| Thursday | 10:30 am-12:00 pm | **429** | Data Management's Future: Commodity or Value-added Discipline? | LEVEL ■ | **204B** |
| **CMC** | **Chemistry, Manufacturing, and Controls** | | | | |
| Monday | 10:30 am-12:00 pm | **103** | Implementation of a Pharmaceutical Quality Assessment System: Progress and Challenges | LEVEL ■ | **112AB** |
| Monday | 1:30 pm-3:00 pm | **130** | The Office of New Drug Quality Assessment CMC Pilot Program | LEVEL ■ | **112AB** |
| Monday | 3:30 pm-5:00 pm | **162** | Comprehensive Quality Overall Summary | LEVEL ■ | **112AB** |
| Tuesday | 8:30 am-10:00 am | **204** | Challenges to Drug Development during IND/Clinic Stage in the New Paradigm | LEVEL ■ | **112AB** |
| Tuesday | 10:30 am-12:00 pm | **234** | Postapproval CMC Changes in the New Paradigm | LEVEL ■ | **112AB** |
| Tuesday | 1:30 pm-3:00 pm | **263** | Updates on ICH Quality Guidelines Q8, Q9, and Q10 | LEVEL ■ | **112AB** |
| Wednesday | 8:30 am-10:00 am | **304** | Implementation of Quality-by-design: An Office of Biotechnology Products Perspective | LEVEL ■ | **112AB** |
| Wednesday | 10:30 am-12:00 pm | **334** | Implementation of Quality-by-design: An Office of Generic Drugs Approach | LEVEL ■ | **112AB** |
| Wednesday | 1:30 pm-3:00 pm | **364** | Quality-by-design: Case Studies | LEVEL ■ | **112AB** |
| Wednesday | 3:30 pm-5:00 pm | **394** | Challenges in Current Dissolution Methods and Alternatives to Dissolution in the New Paradigm | LEVEL ■ | **112AB** |
| Thursday | 8:30 am-10:00 am | **404** | Updates on FDA GMP (Good Manufacturing Practices) Initiatives and Guidances | LEVEL ■ | **113B** |
| **CP** | **Clinical Safety and Pharmacovigilance** | | | | |
| Monday | 10:30 am-12:00 pm | **104** | The New World of Risk Management: A Global Perspective | LEVEL ■ | **Marriott Salon G** |
| Monday | 1:30 pm-3:00 pm | **131** | Communicating Risk Information to Providers and Patients: Issues and Controversies | LEVEL ■ | **Marriott Salon G** |
| Monday | 3:30 pm-5:00 pm | **163** | How to Manage Risks during Drug Development | LEVEL ■ | **Marriott Salon G** |
| Tuesday | 8:30 am-10:00 am | **205** | Use of Patient and Drug Registries for Safety Monitoring and Assessment | LEVEL ● | **Marriott Salon G** |
| Tuesday | 8:30 am-10:00 am | **206** | International Electronic ADR Reporting: The Latest Experience | LEVEL ■ | **Marriott Salon H** |
| Tuesday | 10:30 am-12:00 pm | **235** | Good Pharmacovigilance Practice: What Does It Mean? | LEVEL ■ | **Marriott Salon G** |
| Tuesday | 1:30 pm-3:00 pm | **264** | International Electronic Adverse Event Databases: Understanding the Differences and Capabilities | LEVEL ● | **Marriott Salon G** |
| Tuesday | 3:30 pm-5:00 pm | **294** | Signal Detection in Pharmacovigilance: State of the Art and Emerging Quantitative Approaches | LEVEL ■ | **Marriott Salon G** |
| Wednesday | 8:30 am-10:00 am | **305** | Global Perspective on ADR Reporting Practices | LEVEL ● | **Marriott Salon G** |
| Wednesday | 10:30 am-12:00 pm | **335** | Some Creative Tools and Methods in Pharmacovigilance | LEVEL ● | **Marriott Salon G** |
| Wednesday | 1:30 pm-3:00 pm | **365** | Regulatory Inspections of Company Pharmacovigilance Operations | LEVEL ● | **Marriott Salon G** |
| Wednesday | 3:30 pm-5:00 pm | **395** | Best Pharmaceuticals for Children Act (BPCA) Pediatric Safety | LEVEL ● | **Marriott Salon G** |
| Thursday | 8:30 am-10:00 am | **405** | Current MedDRA® Topics: Data Retrieval and Presentation Points to Consider and Standardized MedDRA® Queries (SMQs) | LEVEL ■ | **201C** |
| Thursday | 10:30 am-12:00 pm | **430** | Recent MedDRA® Developments: Medication Errors and Labeling Considerations | LEVEL ■ | **201C** |
| **CR** | **Clinical Research and Development** | | | | |
| Monday | 10:30 am-12:00 pm | **105** | Changing the Paradigm: Innovative Oncology Drug Clinical Development Programs in the Age of Critical Path and Personalized Medicine – Part 1 of 2 | LEVEL ■ | **Marriott Salon E** |
| Monday | 10:30 am-12:00 pm | **106** | Demonstrating Product Value: Three Unique Perspectives | LEVEL ● | **Marriott Salon IJ** |
| Monday | 10:30 am-12:00 pm | **107** | Feasibility Studies 101: A Clinical Operations Perspective | LEVEL ● | **Marriott Salon AB** |
| Monday | 10:30 am-12:00 pm | **108** | Championing the Patient Perspective in Clinical Study Recruitment and Retention: The Role of the Sponsor, CRO, and Vendor in Successful Strategy Development | LEVEL ● | **Marriott Salon KL** |

| Day | Time | Session Number | Session Title | Difficulty Level | Room Number |
|---|---|---|---|---|---|
| **CR Clinical Research and Development *continued*** | | | | | |
| Monday | 1:30 pm-3:00 pm | **132** | Changing the Paradigm: Innovative Oncology Drug Clinical Development Programs in the Age of Critical Path and Personalized Medicine – Part 2 of 2 | LEVEL ■ | Marriott Salon E |
| Monday | 1:30 pm-3:00 pm | **133** | Factors Influencing the Speed of Clinical Trial Study Completion | LEVEL ● | Marriott Salon IJ |
| Monday | 1:30 pm-3:00 pm | **134** | Prevention of Fraud and Noncompliance in Clinical Research | LEVEL ● | Marriott Salon AB |
| Monday | 1:30 pm-3:00 pm | **135** | Focus on Asia: How to Run a Successful Clinical Trial in Asia | LEVEL ■ | Marriott Salon KL |
| Monday | 3:30 pm-5:00 pm | **164** | Oncology Phase 1 Research: Unique Challenges | LEVEL ■ | Marriott Salon E |
| Monday | 3:30 pm-5:00 pm | **165** | TYSABRI: A Novel Path to Regulatory Approval and Risk Management | LEVEL ■ | Marriott Salon IJ |
| Monday | 3:30 pm-5:00 pm | **166** | Clinical Trials for Fixed-combination Drug Products | LEVEL ◆ | Marriott Salon KL |
| Tuesday | 8:30 am-10:00 am | **207** | Cutting Time and Cost in Phase 3 Oncology Drug Development by Innovative Designs | LEVEL ■ | Marriott Salon AB |
| Tuesday | 8:30 am-10:00 am | **208** | Dos and Don'ts of Data Monitoring Committees | LEVEL ● | Marriott Salon IJ |
| Tuesday | 8:30 am-10:00 am | **209** | Diving into the Details: An Expanded Business Case for Clinical Data Standards | LEVEL ■ | Marriott Salon E |
| Tuesday | 8:30 am-10:00 am | **210** | Flexible Study Designs: Are We Ready to Adapt? | LEVEL ● | Marriott Salon KL |
| Tuesday | 10:30 am-12:00 pm | **236** | Strategic Oncology Clinical Program Design: Addressing Global Needs | LEVEL ■ | Marriott Salon E |
| Tuesday | 10:30 am-12:00 pm | **237** | Navigating the Critical Path to Drug Development for Bioterrorist Agents: The Case of Plague and Anthrax | LEVEL ■ | Marriott Salon AB |
| Tuesday | 10:30 am-12:00 pm | **238** | Orphan Drug Development: Past, Present, Future | LEVEL ● | Marriott Salon IJ |
| Tuesday | 10:30 am-12:00 pm | **239** | Asian Clinical Trials ... and Tribulations | LEVEL ● | Marriott Salon KL |
| Tuesday | 1:30 pm-3:00 pm | **265** | Cancer Clinical Study Management: Trials and Tribulations | LEVEL ■ | Marriott Salon E |
| Tuesday | 1:30 pm-3:00 pm | **266** | Springboard Radical Changes in Clinical Development | LEVEL ■ | Marriott Salon KL |
| Tuesday | 1:30 pm-3:00 pm | **267** | Clinical Research in Africa – Creating Win/Win Situations: Meeting International Standards while Improving Local Health Care | LEVEL ● | Marriott Salon IJ |
| Tuesday | 1:30 pm-3:00 pm | **268** | Successful EU Clinical Trials: Migrating from FDA Oversight to the EU Clinical Trial Directive | LEVEL ■ | Marriott Salon AB |
| Wednesday | 8:30 am-10:00 am | **306** | Oncology Endpoints/Biomarkers | LEVEL ◆ | Marriott Salon E |
| Wednesday | 8:30 am-10:00 am | **307** | Clinical Trials and Tribulations: Influences on Patient Recruitment and Retention | LEVEL ● | Marriott Salon KL |
| Wednesday | 8:30 am-10:00 am | **308** | Using Six Sigma to Optimize Research and Development | LEVEL ● | Marriott Salon IJ |
| Wednesday | 8:30 am-10:00 am | **309** | Clinical Trials in Central and Eastern Europe: Overcoming Technology and Logistical Challenges | LEVEL ■ | Marriott Salon H |
| Wednesday | 10:30 am-12:00 pm | **336** | Pharmacogenetics: FDA/EMEA | LEVEL ■ | Marriott Salon E |
| Wednesday | 10:30 am-12:00 pm | **337** | A Key to Success in Bringing a Product to Market Is Proper Protocol Design | LEVEL ■ | Marriott Salon AB |
| Wednesday | 10:30 am-12:00 pm | **338** | Cultural Sensitivity and Patient Recruitment: Techniques for Effective Enrollment in Global Trials | LEVEL ■ | Marriott Salon IJ |
| Wednesday | 1:30 pm-3:00 pm | **366** | Clinical Trial Execution and Informed Consent: Keys to Success | LEVEL ■ | Marriott Salon E |
| Wednesday | 1:30 pm-3:00 pm | **367** | It Is Saturday Night! Do You Know Where Your Clinical Trial Is? | LEVEL ● | Marriott Salon KL |
| Wednesday | 1:30 pm-3:00 pm | **368** | Challenges and Pitfalls of Anti-TNF Drugs | LEVEL ■ | Marriott Salon IJ |
| Wednesday | 1:30 pm-3:00 pm | **369** | Targeted Therapeutics | LEVEL ■ | Marriott Salon AB |
| Wednesday | 3:30 pm-5:00 pm | **396** | Avoiding QT Overkill | LEVEL ■ | Marriott Salon E |
| Wednesday | 3:30 pm-5:00 pm | **397** | Tracking Patient Enrollment from Inquiry to Randomization and Beyond | LEVEL ■ | Marriott Salon KL |
| Wednesday | 3:30 pm-5:00 pm | **398** | Global Clinical Trials Ethics: Who Is Looking after Whose Interests? | LEVEL ● | Marriott Salon IJ |
| Wednesday | 3:30 pm-5:00 pm | **399A** | Ensuring Diversity: Monitoring Subpopulation Participation in Clinical Trials | LEVEL ● | Marriott Salon AB |
| Thursday | 8:30 am-10:00 am | **406** | Pediatric Drug Development in an Increasingly Global Context | LEVEL ● | **109AB** |
| Thursday | 8:30 am-10:00 am | **407** | Strategies for Outsourcing and Managing Late-phase Trials Using Naïve Sites | LEVEL ■ | **112AB** |
| Thursday | 8:30 am-10:00 am | **408** | Microdosing Studies: State of Technology and US Regulatory Requirements | LEVEL ■ | **111AB** |
| Thursday | 10:30 am-12:00 pm | **431** | Planning and Conducting Successful Investigators' Meetings | LEVEL ■ | **113B** |

| Day | Time | Session Number | Session Title | Difficulty Level | Room Number |
|---|---|---|---|---|---|
| **CR Clinical Research and Development *continued*** | | | | | |
| Thursday | 10:30 am-12:00 pm | **432** | Site-focused Strategies for Re-engineering Clinical Research | LEVEL ◆ | **112AB** |
| Thursday | 10:30 am-12:00 pm | **433** | The Impact of Ethics Committees on Competitive Recruitment in Multinational, Multicenter Clinical Trials: Opportunities and Challenges | LEVEL ■ | **111AB** |
| Thursday | 10:30 am-12:00 pm | **434** | Patient Safety Issues in Phase I Studies | LEVEL ■ | **109AB** |
| **CS Clinical Supplies** | | | | | |
| Monday | 1:30 pm-3:00 pm | **136** | Clinical Supply Chain Management: Integrated Solutions/Drug Accountability | LEVEL ■ | **102AB** |
| Monday | 3:30 pm-5:00 pm | **167** | Take Two Protocols and Call Me in the Morning: Effectively Managing the Challenges of the Clinical Supply Process | LEVEL ◆ | **102AB** |
| **CTM Clinical Trial Management** | | | | | |
| Monday | 10:30 am-12:00 pm | **109** | An In-depth Look at Patients' Experiences in Clinical Trials and Understanding Physician Motivation to Refer or Not Refer Patients into Clinical Trials | LEVEL ● | **107AB** |
| Monday | 1:30 pm-3:00 pm | **137** | One-week Patient Enrollment: Opportunities from Increased Global Coverage | LEVEL ■ | **107AB** |
| Monday | 3:30 pm-5:00 pm | **168** | Reaching Subject Recruitment and Retention Goals | LEVEL ● | **107AB** |
| Tuesday | 8:30 am-10:00 am | **211** | From Sticky Notes to Wildcard Searches: Adapting Monitoring Techniques to EDC | LEVEL ● | **107AB** |
| Tuesday | 10:30 am-12:00 pm | **240** | Best Practices for Contracting and Working with Imaging Core Labs | LEVEL ● | **107AB** |
| Tuesday | 1:30 pm-3:00 pm | **269** | Metrics Champion Consortium: Creating Industry Standard Performance Metrics – Labs, ECGs, CROs | LEVEL ■ | **107AB** |
| Tuesday | 3:30 pm-5:00 pm | **295** | Best Practices in Conducting Clinical Trials in India from Multiple Perspectives | LEVEL ■ | **107AB** |
| Wednesday | 8:30 am-10:00 am | **310** | Collaborating Effectively to Submit Cooperative Group Data to the FDA | LEVEL ■ | **107AB** |
| Wednesday | 10:30 am-12:00 pm | **339** | Leave No Patient Behind: A Model for Recovering Patients Lost to Follow-up | LEVEL ● | **107AB** |
| Wednesday | 1:30 pm-3:00 pm | **370** | Post-trial Access to Study Medication: Is It Feasible? | LEVEL ■ | **107AB** |
| Wednesday | 3:30 pm-5:00 pm | **399B** | Multimedia Informed Consent: What Can It Bring to a Trial? | LEVEL ● | **107AB** |
| Thursday | 8:30 am-10:00 am | **409** | Patient Randomization: At What Cost? | LEVEL ■ | **107AB** |
| Thursday | 10:30 am-12:00 pm | **435** | How to Assure Quality when Clinical Trials Are Conducted in Developing Countries | LEVEL ■ | **107AB** |
| **DM Document Management** | | | | | |
| Monday | 10:30 am-12:00 pm | **110** | The Ongoing Effort to Ensure a Quality Electronic Submission | LEVEL ■ | **204C** |
| Monday | 1:30 pm-3:00 pm | **138** | Submission Content Authoring | LEVEL ● | **204C** |
| Monday | 1:30 pm-3:00 pm | **139** | SPL and PIM: An Examination of the Difference between the Two, the Importance of Content Management, and Practical Implementation Experience | LEVEL ■ | **114 Auditorium** |
| Monday | 3:30 pm-5:00 pm | **169** | eINDs | LEVEL ● | **204C** |
| Tuesday | 8:30 am-10:00 am | **212** | Delivering Electronic Submissions: Sharing Experiences | LEVEL ● | **204C** |
| Tuesday | 10:30 am-12:00 pm | **241** | Global CTD/eCTD | LEVEL ● | **204C** |
| Tuesday | 1:30 pm-3:00 pm | **270** | Compliant eCTDs – Part 1 of 2 | LEVEL ● | **204C** |
| Tuesday | 3:30 pm-5:00 pm | **296** | Compliant eCTDs – Part 2 of 2 | LEVEL ● | **204C** |
| Wednesday | 8:30 am-10:00 am | **311** | eSubmission Standards: Industry's Perspective | LEVEL ■ | **204C** |
| Wednesday | 10:30 am-12:00 pm | **340** | FDA Standards Initiatives and Gateway Update | LEVEL ● | **204C** |
| Wednesday | 1:30 pm-3:00 pm | **371** | FDA eSubmission Update: OBPS Overview, SDTM, eSUB/eCTD Hot Issues, SPL Update | LEVEL ● | **204C** |
| Wednesday | 3:30 pm-5:00 pm | **399C** | International Electronic Common Technical Document (eCTD) Update: The Regulatory Authority Perspective | LEVEL ● | **204C** |
| Thursday | 8:30 am-10:00 am | **410** | eCTD Lifecycle Management | LEVEL ● | **204C** |
| Thursday | 10:30 am-12:00 pm | **436** | eCTD Tools: Are They ICH-compliant? | LEVEL ■ | **204C** |

| Day | Time | Session Number | Session Title | Difficulty Level | Room Number |
|---|---|---|---|---|---|
| **eCLIN** | **eClinical** | | | | |
| Monday | 10:30 am-12:00 pm | **111** | The CDISC Standard from Operational Data Model (ODM) to Biomedical Research Integrated Domain Group (BRIDG) | LEVEL ■ | Marriott Salon H |
| Monday | 1:30 pm-3:00 pm | **140** | Healthcare Integration | LEVEL ■ | Marriott Salon H |
| Monday | 3:30 pm-5:00 pm | **170** | Electronic Patient-reported Outcomes (ePRO) Technology and the FDA Draft PRO Guidance: A Town Meeting to Discuss Industry's Response | LEVEL ■ | 204B |
| Monday | 3:30 pm-5:00 pm | **171** | Interoperability: What It Means for Clinical Researchers, Statisticians, and Information Technology Professionals *NEW 2006 SIAC Offering – SIAC-sponsored Session* | LEVEL ◆ | Marriott Salon H |
| Tuesday | 10:30 am-12:00 pm | **242** | Future Directions in Clinical Trial Management | LEVEL ■ | Marriott Salon H |
| Tuesday | 1:30 pm-3:00 pm | **271** | Clinical Trial Registries | LEVEL ■ | Marriott Salon H |
| Wednesday | 8:30 am-10:00 am | **312** | Where Are We in the Debate between the Biopharmaceutical Industry, the Solution Providers, and the Regulatory Authorities? What Initiatives Are Being Taken to Alleviate Issues around eSource? *NEW 2006 SIAC Offering – SIAC-sponsored Session* | LEVEL ● | 113A |
| **FI** | **Finance** | | | | |
| Monday | 10:30 am-12:00 pm | **112** | Sarbanes-Oxley: Impacts in 2005 and Beyond | LEVEL ● | 203AB |
| Monday | 1:30 pm-3:00 pm | **141** | The Keys to Effective Partnering | LEVEL ■ | 203AB |
| Monday | 3:30 pm-5:00 pm | **172** | Terra Incognito: Explore the Business Impact of the Clinical Trials Directive | LEVEL ● | 203AB |
| **GCP** | **Good Clinical Practices** | | | | |
| Monday | 10:30 am-12:00 pm | **113** | GCP Problems as Cited on FDA 483s and in Warning Letters: Lessons Learned | LEVEL ■ | Marriott Salon F |
| Monday | 1:30 pm-3:00 pm | **142** | Exploring the Concepts and Challenges of Conducting System and Process Audits in Clinical Research | LEVEL ◆ | Marriott Salon F |
| Monday | 3:30 pm-5:00 pm | **173** | Virtual Realities: Quality Considerations when Using Contract Organizations | LEVEL ■ | Marriott Salon F |
| Tuesday | 8:30 am-10:00 am | **213** | Clinical Research and Medical Records in Today's Regulatory Environment | LEVEL ● | Marriott Salon F |
| Tuesday | 10:30 am-12:00 pm | **243** | GCP Compliance at the Investigative Site and Beyond | LEVEL ■ | Marriott Salon F |
| Tuesday | 1:30 pm-3:00 pm | **272** | GCP/QA Town Meeting: Meeting the GCP Challenges of Electronic Data Capture (EDC) | LEVEL ◆ | Marriott Salon F |
| Tuesday | 3:30 pm-5:00 pm | **297** | Effectively Protecting Human Subjects in Studies Conducted Outside the US | LEVEL ■ | Marriott Salon F |
| Wednesday | 8:30 am-10:00 am | **313** | Update: Secretary's Advisory Committee on Human Research Protection (SACHRP) | LEVEL ■ | Marriott Salon F |
| Wednesday | 10:30 am-12:00 pm | **341** | Extreme Informed Consent | LEVEL ■ | Marriott Salon F |
| Wednesday | 1:30 pm-3:00 pm | **372** | Quality Risk Management in Clinical Trials: A Paradigm Shift | LEVEL ■ | Marriott Salon F |
| Wednesday | 3:30 pm-5:00 pm | **399D** | Managing Clinical Trials in Russia | LEVEL ● | 202AB |
| Thursday | 8:30 am-10:00 am | **411** | Good Auditing Practice: What Do We Mean by "Compliance"? | LEVEL ● | 204A |
| Thursday | 10:30 am-12:00 pm | **437** | Practical Pediatric Trials: Lessons from America for Europe | LEVEL ● | 204A |
| **IMP** | **Impact** | | | | |
| Monday | 10:30 am-12:00 pm | **114** | Patient-reported Outcome Instruments: Overview and Comments on the FDA Draft Guidance | LEVEL ● | 113C |
| Tuesday | 10:30 am-12:00 pm | **244** | Electronic Medical Record (EMR)-based Disease Management | LEVEL ● | 203AB |
| Tuesday | 1:30 pm-3:00 pm | **273** | Functional Outcomes' Role in Demonstrating the Efficacy of New Medical Products and Therapies | LEVEL ● | 203AB |
| Wednesday | 10:30 am-12:00 pm | **342** | Real-world Clinical Trials | LEVEL ● | Marriott Salon KL |
| Wednesday | 1:30 pm-3:00 pm | **373** | The Economics of Pharmaceutical Pricing | LEVEL ■ | 108B |
| **IS** | **Investigator Sites** | | | | |
| Monday | 10:30 am-12:00 pm | **115** | Dilemma of Role Conflicts: Anatomy of a Site Audit | LEVEL ■ | 113B |
| Monday | 1:30 pm-3:00 pm | **143** | Transparency at the Site Level: Are Sites and Sponsors Ready for the Challenge? | LEVEL ● | 113B |

| Day | Time | Session Number | Session Title | Difficulty Level | Room Number |
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| **IS Investigator Sites *continued*** | | | | | |
| Monday | 3:30 pm-5:00 pm | **174** | Investigator Reimbursement and Budgets: How They Affect Patient Enrollment, Retention and Time Lines | LEVEL ■ | **113B** |
| Tuesday | 8:30 am-10:00 am | **214** | Matchmaking among Sites, Sponsors, and Studies | LEVEL ■ | **113B** |
| Tuesday | 10:30 am-12:00 pm | **245** | Recruitment and Retention: The Potential Subject's Perspective – What Works, What Doesn't, and Why | LEVEL ■ | **113B** |
| Tuesday | 1:30 pm-3:00 pm | **274** | Accelerating Subject Enrollment: A New Roadmap for Sites and Sponsors | LEVEL ■ | **113B** |
| Tuesday | 3:30 pm-5:00 pm | **298** | Faster, Better, Cheaper: Sponsor/Site Partnerships | LEVEL ■ | **113B** |
| **IT** | **Information Technology** | | | | |
| Monday | 10:30 am-12:00 pm | **116** | Approaches to Choosing and Integrating Clinical Trial Technologies to Meet Client Information Needs | LEVEL ● | **105AB** |
| Monday | 1:30 pm-3:00 pm | **144** | Implications of Drug Pedigree and Authentication on the Pharmaceutical Industry | LEVEL ● | **105AB** |
| Monday | 3:30 pm-5:00 pm | **175** | Deploying Life Science IT Using IEEE Methods | LEVEL ■ | **105AB** |
| Tuesday | 8:30 am-10:00 am | **215** | Get It in Writing: The SLA at the Heart of Successful Business Relationships | LEVEL ● | **105AB** |
| Tuesday | 10:30 am-12:00 pm | **246** | Combining EHR and EDC: Finding the Right IT Architecture | LEVEL ■ | **105AB** |
| Tuesday | 1:30 pm-3:00 pm | **275** | Developing Enterprise IT Architectures and Data Models for Drug Development | LEVEL ■ | **106AB** |
| Tuesday | 1:30 pm-3:00 pm | **276** | The National Health Information Infrastructure: Public-private Sector Initiative | LEVEL ■ | **105AB** |
| Tuesday | 3:30 pm-5:00 pm | **299A** | Developments in Electronic Pharmaceutical Data Archiving | LEVEL ● | **105AB** |
| Wednesday | 8:30 am-10:00 am | **314** | Why Your Data Can't Talk to My Data | LEVEL ● | **105AB** |
| Wednesday | 10:30 am-12:00 pm | **343** | Managing Identity and Authentication in Sensitive Healthcare Communications: How Can You Be Sure the Person at the Other End of the Electronic Communication Is Who (S)he Says (S)he Is? | LEVEL ■ | **105AB** |
| Wednesday | 1:30 pm-3:00 pm | **374** | CRIX: A Shared Clinical Research Information eXchange | LEVEL ● | **105AB** |
| Wednesday | 3:30 pm-5:00 pm | **399E** | Automated Tools for the Electronic Management of Complex Inventory in Global Studies | LEVEL ● | **105AB** |
| Wednesday | 3:30 pm-5:00 pm | **399F** | Applications of the Biomedical Research Integrated Domain Group (BRIDG) | LEVEL ● | **113C** |
| Thursday | 8:30 am-10:00 am | **412** | From Electronic Data Capture to Clinical Data Warehouse | LEVEL ■ | **105AB** |
| Thursday | 10:30 am-12:00 pm | **438** | IT Governance Models: Win-win Approaches for Healthcare | LEVEL ■ | **105AB** |
| **MA** | **Marketing and Sales** | | | | |
| Wednesday | 8:30 am-10:00 am | **315** | New Drug Launches and Drug Adoption | LEVEL ● | **113C** |
| Wednesday | 10:30 am-12:00 pm | **344** | Communicating with Physicians through the Power of Postapproval Research: The Impact in a Physician's Own Practice | LEVEL ■ | **113C** |
| Wednesday | 1:30 pm-3:00 pm | **375** | Marketing Your Clinical Services Organization | LEVEL ● | **113C** |
| Thursday | 8:30 am-10:00 am | **413** | New Era for International Marketing: Stricter Self-regulation through New Codes of Conduct | LEVEL ■ | **Marriott Salon AB** |
| **MC** | **Medical Communications** | | | | |
| Tuesday | 8:30 am-10:00 am | **216** | Real-world Perspectives on Risk Management for Independent and Promotional Education Activities: Best Practices and Guidelines for Companies Addressing Separation Guidelines | LEVEL ■ | **204A** |
| Tuesday | 10:30 am-12:00 pm | **247** | The Perils and Pitfalls of Creating a Medical Science Liaison Department | LEVEL ● | **204A** |
| Tuesday | 1:30 pm-3:00 pm | **277** | Chronicles of Mergers between Medical Information Departments: Inside and Outside of the Organization | LEVEL ● | **204A** |
| Tuesday | 3:30 pm-5:00 pm | **299B** | Regional Medical Liaison Survey #2: Assessing Training Techniques and Demonstrating Value of Regional Medical Liaisons across the Pharmaceutical Industry | LEVEL ● | **204A** |
| Wednesday | 8:30 am-10:00 am | **316** | Medical Information as an Adjunct to Sales Training | LEVEL ■ | **204A** |

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| **MC Medical Communications *continued*** | | | | | |
| Wednesday | 10:30 am-12:00 pm | **345** | Reducing the Incidence of Medication Errors Resulting from the Use of Error-prone Abbreviations and Symbols | LEVEL ● | **204A** |
| Wednesday | 1:30 pm-3:00 pm | **376** | Role of Medical Communications in Clinical Trial Information Internet Posting | LEVEL ■ | **204A** |
| Wednesday | 3:30 pm-5:00 pm | **399G** | Effectively Communicating Outcomes Research to Enhance Product Success | LEVEL ■ | **204A** |
| Thursday | 8:30 am-10:00 am | **414** | Ensuring High-quality Written Communications for Medical Communications Professionals | LEVEL ● | **Marriott Salon CD** |
| **MW** | **Medical/Scientific Writing** | | | | |
| Monday | 10:30 am-12:00 pm | **117** | Strategic Collaboration | LEVEL ● | **204B** |
| Monday | 1:30 pm-3:00 pm | **145** | Review and Outsourcing Strategies | LEVEL ◆ | **204B** |
| Tuesday | 8:30 am-10:00 am | **217** | Building the eCTD Starting with the IND: Clinical Documents | LEVEL ■ | **204B** |
| Tuesday | 10:30 am-12:00 pm | **248** | Authoring Nonclinical Study Reports | LEVEL ■ | **204B** |
| Tuesday | 1:30 pm-3:00 pm | **278** | Medical Science, Affairs, and Writing in Pharmacovigilance | LEVEL ■ | **204B** |
| Tuesday | 3:30 pm-5:00 pm | **299C** | Publication Planning: New Opportunities and Issues | LEVEL ● | **204B** |
| Wednesday | 8:30 am-10:00 am | **317** | ISS/ISE: Where Do They Fit in the CTD/eCTD? | LEVEL ■ | **204B** |
| Wednesday | 10:30 am-12:00 pm | **346** | Preparing Global CTD Submission-ready Documents from IND to NDA | LEVEL ● | **204B** |
| Wednesday | 1:30 pm-3:00 pm | **377** | Efficient Preparation of High-quality Documents | LEVEL ■ | **204B** |
| Wednesday | 3:30 pm-5:00 pm | **399H** | Clinical Trial Registries: An Update | LEVEL ● | **204B** |
| **NC** | **Nonclinical Laboratory Safety** | | | | |
| Tuesday | 1:30 pm-3:00 pm | **279** | PPAR Agonist Toxicities: An Update | LEVEL ■ | **202AB** |
| Tuesday | 3:30 pm-5:00 pm | **299D** | Peroxisome Proliferators Activated Receptors (PPARs) Agonists and Rodent Tumorigenesis: Updating the Discussions | LEVEL ◆ | **202AB** |
| Wednesday | 8:30 am-10:00 am | **318** | Developmental and Reproductive Toxicity Evaluations of Biological Drugs | LEVEL ● | **111AB** |
| Wednesday | 10:30 am-12:00 pm | **347** | Nonclinical Efforts to Reduce Attrition in First-time-to-man Studies | LEVEL ● | **111AB** |
| Wednesday | 1:30 pm-3:00 pm | **378** | Metabolites in Safety Testing | LEVEL ● | **111AB** |
| Wednesday | 3:30 pm-5:00 pm | **399I** | Animal Models of Disease in Nonclinical Development of (Orphan) Drugs | LEVEL ■ | **111AB** |
| Thursday | 8:30 am-10:00 am | **415** | Can Biomarkers of Safety Support Safe Clinical Development? | LEVEL ■ | **106AB** |
| Thursday | 10:30 am-12:00 pm | **439** | Nonclinical Development of Combination Medicinal Products | LEVEL ● | **106AB** |
| **NHP** | **Natural Health Products** | | | | |
| Monday | 1:30 pm-3:00 pm | **146** | Safety and Pharmacovigilance of Natural Health Products | LEVEL ● | **106AB** |
| Monday | 3:30 pm-5:00 pm | **176** | International Initiatives for Natural Health Products | LEVEL ● | **106AB** |
| Tuesday | 8:30 am-10:00 am | **218** | Updates on Natural Health Products: European Union | LEVEL ■ | **106AB** |
| Tuesday | 10:30 am-12:00 pm | **249** | Natural Health Products Research and Development: Challenges and Controversies | LEVEL ■ | **106AB** |
| Tuesday | 3:30 pm-5:00 pm | **299E** | Strategies and Success Stories for Integrating NHP and Conventional Medicine | LEVEL ● | **106AB** |
| Wednesday | 8:30 am-10:00 am | **319** | Developing Probiotics as Biologics: Regulatory and Scientific Considerations | LEVEL ● | **106AB** |
| Wednesday | 10:30 am-12:00 pm | **348** | Growing Standardized, Reproducible, and Sustainable Botanicals for Medicinal Use | LEVEL ■ | **106AB** |
| Wednesday | 1:30 pm-3:00 pm | **379** | Managing the Quality of Natural Products | LEVEL ■ | **106AB** |
| Wednesday | 3:30 pm-5:00 pm | **399J** | Developing Botanical Drugs for the United States | LEVEL ■ | **106AB** |
| Thursday | 8:30 am-10:00 am | **416** | Hot Topics in Natural Health Products: Results of the GAIT Study and Implications for Future NSAID Development | LEVEL ■ | **Marriott Salon KL** |
| **OS** | **Outsourcing** | | | | |
| Monday | 10:30 am-12:00 pm | **118** | Outsourcing Strategy for Emerging Companies | LEVEL ● | **109AB** |
| Monday | 1:30 pm-3:00 pm | **147** | Designing and Managing Successful Outsourcing Relationships – Part 1 of 2 | LEVEL ◆ | **109AB** |

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| **OS Outsourcing *continued*** | | | | | |
| Monday | 1:30 pm-3:00 pm | **148** | CRO/SMO Present Status in Japan | LEVEL ● | **113C** |
| Monday | 3:30 pm-5:00 pm | **177** | Designing and Managing Successful Outsourcing Relationships – Part 2 of 2 | LEVEL ◆ | **109AB** |
| Tuesday | 8:30 am-10:00 am | **219** | Configurable IVR Systems: What You Should Know | LEVEL ● | **109AB** |
| Tuesday | 10:30 am-12:00 pm | **250** | The Sponsor-CRO Partnership: How Is Outsourcing Affecting Drug Development? | LEVEL ■ | **109AB** |
| Tuesday | 1:30 pm-3:00 pm | **280** | Preferred Provider Selection Process | LEVEL ■ | **109AB** |
| Tuesday | 3:30 pm-5:00 pm | **299F** | Intellectual Human Capital in Contract Research: Is the Market There? | LEVEL ■ | **109AB** |
| Wednesday | 8:30 am-10:00 am | **320** | The State of Clinical Outsourcing: The Functional Service Provider Model | LEVEL ■ | **109AB** |
| Wednesday | 10:30 am-12:00 pm | **349** | Local versus Global CRO Assignment: Is it Possible to Build a Constructive Relationship with Partners You Have Not Chosen? | LEVEL ● | **109AB** |
| Wednesday | 1:30 pm-3:00 pm | **380** | Predicting the Outsourcing Industry's 2010 Structure | LEVEL ● | **109AB** |
| Wednesday | 3:30 pm-5:00 pm | **399K** | Functional Outsourcing: A Comparison of Two Major Companies' Strategies | LEVEL ◆ | **109AB** |
| Thursday | 8:30 am-10:00 am | **417** | Intercompany Auditing Agreement as Part of Strategic Risk Management | LEVEL ● | **108A** |
| **PM** | **Project Management** | | | | |
| Monday | 10:30 am-12:00 pm | **119** | Key Stakeholder Management: Different Perspectives and Approaches | LEVEL ■ | **108A** |
| Monday | 10:30 am-12:00 pm | **120** | Response to Changes in the External Environment in Pharmaceutical R&D: A Project Manager's Perspective | LEVEL ■ | **108B** |
| Monday | 1:30 pm-3:00 pm | **149** | Communication Skills: The Path to Successful Project Management | LEVEL ● | **108A** |
| Monday | 1:30 pm-3:00 pm | **150** | Enterprise Project Management: A Practical Approach | LEVEL ◆ | **108B** |
| Monday | 3:30 pm-5:00 pm | **178** | Effective Team and Project Integrations: Principles and Lessons Learned in Collaborations | LEVEL ■ | **108A** |
| Monday | 3:30 pm-5:00 pm | **179** | Best Practices for Remote and Virtual Project Management in Life Sciences | LEVEL ◆ | **108B** |
| Tuesday | 8:30 am-10:00 am | **220** | Successful Intercultural Communication in Drug Development: More than a Time Zone Issue | LEVEL ■ | **108A** |
| Tuesday | 8:30 am-10:00 am | **221** | Case Studies in Project Management of Performance Improvement Projects: The Spectrum of Success through Agony | LEVEL ● | **108B** |
| Tuesday | 10:30 am-12:00 pm | **251** | The Target Product Profile (TPP): Uses for the Management of Product Development | LEVEL ■ | **108A** |
| Tuesday | 10:30 am-12:00 pm | **252** | What Small Biopharmaceutical Companies Can Teach Big Ones about Project Management | LEVEL ● | **108B** |
| Tuesday | 1:30 pm-3:00 pm | **281** | DIA's Project Management Standards and Training Program | LEVEL ● | **108A** |
| Tuesday | 1:30 pm-3:00 pm | **282** | Has "Phased" Clinical Development Outlived Its Useful Life? | LEVEL ■ | **108B** |
| Tuesday | 3:30 pm-5:00 pm | **299G** | The Future for Project Management: What Does It Look Like? | LEVEL ■ | **108A** |
| Tuesday | 3:30 pm-5:00 pm | **299H** | Vendor Management: Drive Performance and Value | LEVEL ■ | **108B** |
| Wednesday | 8:30 am-10:00 am | **321** | Driving High Performance Strategic Relationships | LEVEL ● | **108A** |
| Wednesday | 8:30 am-10:00 am | **322** | Leadership Secrets to Manage Highly Qualified Individuals | LEVEL ◆ | **108B** |
| Wednesday | 10:30 am-12:00 pm | **350** | EPM Information Systems: The Influence of Project Management Maturity on Implementation Strategies | LEVEL ● | **108A** |
| Wednesday | 10:30 am-12:00 pm | **351** | Twenty-first Century Team Leadership | LEVEL ■ | **108B** |
| Wednesday | 1:30 pm-3:00 pm | **381** | PLENARY SESSION: Creating High-performing Cross-functional Teams | LEVEL ■ | **Marriott Salon H** |
| Wednesday | 3:30 pm-5:00 pm | **399L** | Fast and Fun Way to Build High-performing Cross-functional Teams | LEVEL ● | **108A** |
| Wednesday | 3:30 pm-5:00 pm | **399M** | Project Teams or Product Incubators? | LEVEL ■ | **108B** |
| Thursday | 8:30 am-10:00 am | **418** | Being Smart about Global vs. Local | LEVEL ● | **108B** |
| **PP** | **Public Policy/Law** | | | | |
| Monday | 10:30 am-12:00 pm | **121** | Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials | LEVEL ● | **114 Auditorium** |
| Monday | 1:30 pm-3:00 pm | **151** | Civil and Criminal Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials? | LEVEL ● | **113A** |

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| **PP Public Policy/Law *continued*** | | | | | |
| Monday | 3:30 pm-5:00 pm | **180** | Community Pharmacy Safety Network: Patient and Pharmacist Involvement in the Monitoring of Medications | LEVEL ■ | **113A** |
| Tuesday | 8:30 am-10:00 am | **222** | Clinical Trial Registration and Transparency of Trial Results | LEVEL ● | **114 Auditorium** |
| Tuesday | 10:30 am-12:00 pm | **253** | The Expandable Universe of the Critical Path: Points to Consider beyond Science; Public Policy Needed to Sustain Critical Path – Part 1 of 2 | LEVEL ● | **114 Auditorium** |
| Tuesday | 1:30 pm-3:00 pm | **283** | The Expandable Universe of the Critical Path: Points to Consider in the Marketplace; Pricing and Reimbursement – Part 2 of 2 | LEVEL ● | **114 Auditorium** |
| Tuesday | 3:30 pm-5:00 pm | **299I** | The Ethics of Authorship | LEVEL ● | **113A** |
| Wednesday | 10:30 am-12:00 pm | **352** | Understanding and Reversing the Erosion of Public Trust in Clinical Research | LEVEL ● | **113A** |
| Wednesday | 1:30 pm-3:00 pm | **382** | Pricing and Reimbursement of Medicinal Products in the European Union | LEVEL ● | **113A** |
| Wednesday | 3:30 pm-5:00 pm | **399N** | RiskMAPing and Litigation | LEVEL ■ | **113A** |
| Thursday | 8:30 am-10:00 am | **419** | Transatlantic Convergence in Drug Reimbursement Decisions | LEVEL ● | **113C** |
| Thursday | 10:30 am-12:00 pm | **440** | An Update on State Medicare Part D Implementation | LEVEL ● | **113C** |
| **RA** | **Regulatory Affairs** | | | | |
| Monday | 10:30 am-12:00 pm | **122** | Update: US-EU Agreement Regarding Parallel Scientific Advice and Exchange of Information | LEVEL ● | **201A** |
| Monday | 10:30 am-12:00 pm | **123** | Multinational Trials in Asia: Strategy, Operations, Environment | LEVEL ■ | **202AB** |
| Monday | 10:30 am-12:00 pm | **124** | Combination Products: Global Challenges and Opportunities | LEVEL ■ | **201B** |
| Monday | 10:30 am-12:00 pm | **125** | Accelerated Assessment and Conditional Marketing Authorizations at the Level of the EMEA | LEVEL ● | **201C** |
| Monday | 1:30 pm-3:00 pm | **152** | Pharmacogenetic Tests: From Analytical Validation to Clinical Application | LEVEL ● | **201B** |
| Monday | 1:30 pm-3:00 pm | **153** | Good Review Management Principles (GRMPs): Progress and Challenges toward Improving Review Efficiency | LEVEL ● | **204A** |
| Monday | 1:30 pm-3:00 pm | **154** | Clinical Trials in Latin America: A Review of the Regulatory Framework – Part 1 of 2 | LEVEL ● | **202AB** |
| Monday | 1:30 pm-3:00 pm | **155** | Scientific Advice at the Level of the EMEA | LEVEL ■ | **201C** |
| Monday | 1:30 pm-3:00 pm | **156** | FDA-EMEA Joint Session on Emerging Therapies and Technologies | LEVEL ● | **201A** |
| Monday | 3:30 pm-5:00 pm | **181** | Prescription Drug Labeling: Implementation of FDA's New Regulation for the Content and Format of the USPI and Accompanying Guidance Documents | LEVEL ■ | **201A** |
| Monday | 3:30 pm-5:00 pm | **182** | FDA and EMEA Experiences on Interaction with Patients | LEVEL ■ | **201C** |
| Monday | 3:30 pm-5:00 pm | **183** | Clinical Trials in Latin America: A Review of the Regulatory Framework – Part 2 of 2 | LEVEL ● | **202AB** |
| Monday | 3:30 pm-5:00 pm | **184** | Successful Drug Development: The Phase 1/2 and 2/3 Interfaces | LEVEL ● | **201B** |
| Tuesday | 8:30 am-10:00 am | **223** | Combination Products: A Primer | LEVEL ● | **201B** |
| Tuesday | 8:30 am-10:00 am | **224** | Faster, Superior, More Cost Effective: Has the eCTD Delivered Its Promises? | LEVEL ● | **202AB** |
| Tuesday | 8:30 am-10:00 am | **225** | Regulatory Update from China | LEVEL ■ | **201A** |
| Tuesday | 8:30 am-10:00 am | **226** | CBER Hot Topics: Vaccine Safety | LEVEL ● | **201C** |
| Tuesday | 10:30 am-12:00 pm | **254** | Transforming Regulatory Information into Intelligence | LEVEL ● | **201B** |
| Tuesday | 10:30 am-12:00 pm | **255** | CBER Hot Topics | LEVEL ● | **201C** |
| Tuesday | 10:30 am-12:00 pm | **256** | Hot Topic in Pharmaceutical R&D in China: Intellectual Property | LEVEL ■ | **201A** |
| Tuesday | 1:30 pm-3:00 pm | **284** | Practical Tips for Successful Development and Approval in Different Cultures | LEVEL ■ | **201B** |
| Tuesday | 1:30 pm-3:00 pm | **285** | Biomarkers in Drug Development: A Blessing or a Curse? | LEVEL ■ | **201C** |
| Tuesday | 1:30 pm-3:00 pm | **286** | EU/FDA Confidentiality Arrangements: Current Status – What's Next? | LEVEL ● | **201A** |
| Wednesday | 8:30 am-10:00 am | **323** | The QS Train Is Moving Fast at FDA | LEVEL ● | **202AB** |
| Wednesday | 8:30 am-10:00 am | **324** | First Experience with Risk Management Initiatives in the US and EU | LEVEL ■ | **201C** |
| Wednesday | 8:30 am-10:00 am | **325** | QT-Dossier: The Impact of ECG Data from a Regulatory Perspective | LEVEL ● | **201B** |

| Day | Time | Session Number | Session Title | Difficulty Level | Room Number |
|---|---|---|---|---|---|
| **RA Regulatory Affairs *continued*** | | | | | |
| Wednesday | 8:30 am-10:00 am | **326** | Understanding the Regulation of "Advanced Therapy Medicinal Products" in Europe | LEVEL ● | **201A** |
| Wednesday | 10:30 am-12:00 pm | **353** | Drug Development in Japan and Acceptance of Global CMC Dossier | LEVEL ■ | **202AB** |
| Wednesday | 10:30 am-12:00 pm | **354** | Regulatory Pathways for Medicines Addressing the Public Health Needs in the Developing World | LEVEL ● | **201C** |
| Wednesday | 10:30 am-12:00 pm | **355** | Evolving Global Oncology Drug Registrational Environment | LEVEL ■ | **201A** |
| Wednesday | 10:30 am-12:00 pm | **356** | Changes in the European Regulatory Environment Affecting Member States: MRC and Decentralized Procedures | LEVEL ■ | **201B** |
| Wednesday | 10:30 am-12:00 pm | **357** | CDER Hot Topic – Update: Drug Safety Initiatives | LEVEL ■ | **114 Auditorium** |
| Wednesday | 1:30 pm-3:00 pm | **383** | The Emerging Markets: Regulatory Issues and the Impact on Patients' Access to Medicines | LEVEL ■ | **201B** |
| Wednesday | 1:30 pm-3:00 pm | **384** | Follow-on Protein Products: Scientific Issues, beyond Same Molecular Entity and Comparable Rate and Extent – Part 1 of 2 | LEVEL ■ | **201A** |
| Wednesday | 1:30 pm-3:00 pm | **385** | Substantial Evidence from Subpopulations and Secondary Endpoints | LEVEL ■ | **201C** |
| Wednesday | 1:30 pm-3:00 pm | **386** | Japan's Pharmaceutical and Medical Devices Agency and Related Drug Safety Activities | LEVEL ■ | **203AB** |
| Wednesday | 1:30 pm-3:00 pm | **387** | Human Subject Protection/Bioresearch Monitoring Initiative and Critical Path Update | LEVEL ■ | **114 Auditorium** |
| Wednesday | 3:30 pm-5:00 pm | **399O** | Regulatory "Partnership in Harmonization" in APEC Region | LEVEL ■ | **203AB** |
| Wednesday | 3:30 pm-5:00 pm | **399P** | Follow-on Protein Products – Legal and Regulatory Framework for Approval: History of Hatch-Waxman and Lessons Learned – Part 2 of 2 | LEVEL ■ | **201A** |
| Wednesday | 3:30 pm-5:00 pm | **399Q** | Adding a Third Drug Class: Benefit or Burden? | LEVEL ● | **201B** |
| Wednesday | 3:30 pm-5:00 pm | **399R** | ICH E2E Implementation: National/International Perspectives | LEVEL ■ | **Marriott Salon H** |
| Wednesday | 3:30 pm-5:00 pm | **399S** | CDER Hot Topic: Physicians' Labeling Rule | LEVEL ● | **114 Auditorium** |
| Wednesday | 3:30 pm-5:00 pm | **399T** | PDUFA's Pilot 1: The Continuous Marketing Application Revealed | LEVEL ■ | **201C** |
| Thursday | 8:30 am-10:00 am | **420** | CDER Town Meeting – Part 1 of 2 | LEVEL ● | **201A** |
| Thursday | 8:30 am-10:00 am | **421** | Trends in Warning and Determination Letters to IRBs and Investigators | LEVEL ● | **201B** |
| Thursday | 8:30 am-10:00 am | **422** | How to Authorize a Generic in Europe | LEVEL ■ | **202AB** |
| Thursday | 8:30 am-10:00 am | **423** | Outlook for Changes in Japanese Regulatory and Clinical Development Environment | LEVEL ■ | **203AB** |
| Thursday | 10:30 am-12:00 pm | **441** | CDER Town Meeting – Part 2 of 2 | LEVEL ● | **201A** |
| Thursday | 10:30 am-12:00 pm | **442** | Before It's Too Late: Risk Management throughout Product Development | LEVEL ● | **202AB** |
| Thursday | 10:30 am-12:00 pm | **443** | FDA Advisory Committees: Controversies, Challenges, and Changes | LEVEL ◆ | **203AB** |
| **RA/CR** | **Regulatory Affairs/Clinical Research and Development** | | | | |
| Tuesday | 3:30 pm-5:30 pm | **299J** | **PLENARY SESSION:** Update from the FDA Office of the Commissioner | LEVEL ● | **Ballroom AB** |
| **RD** | **R&D Strategy** | | | | |
| Tuesday | 8:30 am-10:00 am | **227** | Drug Safety in the 21st Century: Convergence with Biomarkers and Diagnostics Catalyzes Modernization | LEVEL ■ | **102AB** |
| Tuesday | 1:30 pm-3:00 pm | **287** | Monitoring and Managing a Changing Investigative Site Landscape | LEVEL ● | **102AB** |
| Tuesday | 3:30 pm-5:00 pm | **299K** | Managing Capacity to Drive Productivity in Pharmaceutical R&D | LEVEL ■ | **102AB** |
| Wednesday | 8:30 am-10:00 am | **327** | Does Innovation Pay? | LEVEL ● | **102AB** |
| Wednesday | 1:30 pm-3:00 pm | **388** | Microdosing: Promise and Peril along the Critical Path | LEVEL ● | **102AB** |
| Wednesday | 3:30 pm-5:00 pm | **399U** | An Analysis of the Success Factors of Global Applications of Biotechnology-derived Products | LEVEL ◆ | **102AB** |
| Thursday | 8:30 am-10:00 am | **424** | Clinical R&D Management by Metrics Using the Latest Computer Technology | LEVEL ■ | **102AB** |
| Thursday | 10:30 am-12:00 pm | **444** | Optimize the Development and Registration of Innovation Therapies Developed by Emerging Biotechnology | LEVEL ◆ | **102AB** |

| Day | Time | Session Number | Session Title | Difficulty Level | Room Number |
|---|---|---|---|---|---|
| **ST** | **Statistics** | | | | |
| Monday | 10:30 am-12:00 pm | **126** | Recent Advances in the Use of Adaptive Clinical Trials | LEVEL ■ | **103B** |
| Monday | 1:30 pm-3:00 pm | **157** | Design and Analysis of Multicenter Trials | LEVEL ■ | **103B** |
| Monday | 3:30 pm-5:00 pm | **185** | Challenges in Quantitative Assessment of Drug Safety for Regulatory Actions | LEVEL ● | **103A** |
| Monday | 3:30 pm-5:00 pm | **186** | Targeted Therapies: Statistical Issues in Design | LEVEL ● | **103B** |
| Tuesday | 8:30 am-10:00 am | **228** | Medical Imaging Trials for Classification of Disease: Issues and Challenges | LEVEL ■ | **103B** |
| Tuesday | 10:30 am-12:00 pm | **257** | Data Monitoring Committees | LEVEL ■ | **103B** |
| Tuesday | 1:30 pm-3:00 pm | **288** | EMEA Road Map and FDA Critical Path: Statistical Implications, Risks, and Opportunities | LEVEL ■ | **103B** |
| Tuesday | 3:30 pm-5:00 pm | **299L** | Sequential Methodology for Pharmacogenetics | LEVEL ■ | **103B** |
| Wednesday | 8:30 am-10:00 am | **328** | Endpoint Selection and Other Considerations in HIV Clinical Trials | LEVEL ● | **103B** |
| Wednesday | 10:30 am-12:00 pm | **358** | Randomization | LEVEL ■ | **103B** |
| Wednesday | 1:30 pm-3:00 pm | **389** | Randomized Withdrawal Design for Evaluation of Long-term Efficacy | LEVEL ■ | **103B** |
| Wednesday | 3:30 pm-5:00 pm | **399V** | Regulatory Guidance and Standards Development: Implications for Statistical Practice and Review | LEVEL ■ | **103B** |
| Thursday | 8:30 am-10:00 am | **425** | Statistical Contributions to the Patient-oriented Clinical Evaluation | LEVEL ■ | **103B** |
| Thursday | 10:30 am-12:00 pm | **445** | Policy, Business, and Statistical Issues Related to Bayesian Approaches for Late-phase Practical Clinical Trials | LEVEL ● | **103B** |
| **TR** | **Training** | | | | |
| Monday | 10:30 am-12:00 pm | **127** | Training across Language and Cultural Barriers | LEVEL ● | **103C** |
| Monday | 1:30 pm-3:00 pm | **158** | The Pipeline of New Personnel for the Clinical Research Enterprise | LEVEL ● | **103C** |
| Monday | 3:30 pm-5:00 pm | **187** | Career Trends and Opportunities for Clinical Research Professionals | LEVEL ● | **103C** |
| Tuesday | 8:30 am-10:00 am | **229** | Professional Presence for Clinical Research Professionals | LEVEL ● | **103C** |
| Tuesday | 10:30 am-12:00 pm | **258** | A Training Approach: From Basics to Specifics | LEVEL ● | **103C** |
| Tuesday | 1:30 pm-3:00 pm | **289** | The Use of eLearning to Meet the Growing Need for Healthcare Compliance Training | LEVEL ● | **103C** |
| Tuesday | 3:30 pm-5:00 pm | **299M** | Using ADDIE (Analyze, Design, Develop, Implement, Evaluate) to Strategically Analyze and Evaluate Your Training Program | LEVEL ■ | **103C** |
| Wednesday | 8:30 am-10:00 am | **329** | Online Learning: Managing the Implementation Process | LEVEL ● | **103C** |
| Wednesday | 10:30 am-12:00 pm | **359** | Methodologies in Training Adults: Experiences Collected from Regional CROs | LEVEL ■ | **103C** |
| Wednesday | 1:30 pm-3:00 pm | **390** | Training Alternatives to Enhance Site Performance and Compliance | LEVEL ■ | **103C** |
| Wednesday | 3:30 pm-5:00 pm | **399W** | Decreasing Business Risk by Ensuring Training Compliance: Three Key Strategies | LEVEL ■ | **103C** |
| Thursday | 8:30 am-10:00 am | **426** | Pharmacogenomics and Education: When Will We See an Uptake of Pharmacogenomics? | LEVEL ● | **103C** |
| Thursday | 10:30 am-12:00 pm | **446** | Addressing Challenges Associated with Clinician-rated Scales | LEVEL ● | **103C** |
| **VA** | **Validation** | | | | |
| Tuesday | 8:30 am-10:00 am | **230** | Current Regulatory Computer Validation Issues | LEVEL ■ | **113C** |
| Tuesday | 10:30 am-12:00 pm | **259** | Delivering Quality Validation Effectively | LEVEL ● | **113C** |
| Tuesday | 1:30 pm-3:00 pm | **290** | Extraordinary Opportunities: Issues We Face in Meeting Regulatory Expectations and How to Address Them | LEVEL ■ | **113C** |
| Tuesday | 3:30 pm-5:00 pm | **299N** | Validation from Inside the Corporate Environment | LEVEL ● | **113C** |
| Wednesday | 8:30 am-10:00 am | **330** | Validation from the Quality Perspective | LEVEL ■ | **203AB** |
| Wednesday | 10:30 am-12:00 pm | **360** | The IQ/OQ/PQ Challenge for Small Companies | LEVEL ■ | **203AB** |

# Saturday, June 17 – Monday, June 19 *(some speaker changes will occur before the event)*

## Saturday, June 17

12:00 pm-1:00 pm **TUTORIAL REGISTRATION**
Registration for Saturday tutorials ONLY
Grand Hall, 2nd Floor, Convention Center

12:00 pm-5:00 pm **EXHIBITOR REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

## Sunday, June 18

8:00 am-9:00 am **TUTORIAL REGISTRATION**
Registration for Sunday morning or full-day tutorials ONLY
Grand Hall, 2nd Floor, Convention Center

8:00 am-6:30 pm **EXHIBITOR REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

12:30 pm-1:00 pm **TUTORIAL REGISTRATION**
Registration for Sunday afternoon tutorials ONLY
Grand Hall, 2nd Floor, Convention Center

3:00 pm-6:30 pm **ATTENDEE REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

3:00 pm-6:30 pm **SPEAKER REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

4:00 pm-6:00 pm **EXHIBITS OPEN**
Exhibit Halls A and B, 2nd Floor, Convention Center

6:30 pm-8:30 pm **NETWORKING RECEPTION**
National Constitution Center

## Monday, June 19

7:30 am-6:00 pm **ATTENDEE REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-6:00 pm **EXHIBITOR REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-6:00 pm **SPEAKER REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-8:15 am **CONTINENTAL BREAKFAST**
Grand Hall and Meeting Rooms 201-204 Concourse, 2nd Floor, Convention Center

10:00 am-6:00 pm **STUDENTS' POSTER SESSION**
Arch Street Bridge, 2nd Floor, Convention Center

10:00 am-6:00 pm **EXHIBITS OPEN**
Exhibit Halls A and B, 2nd Floor, Convention Center

5:00 pm - 6:00 pm **MONDAY RECEPTION**
Exhibit Halls A and B, 2nd Floor, Convention Center

8:30 am-10:00 am

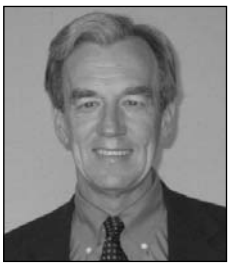
## Plenary Session

**Ballroom AB, 3rd Floor, Convention Center**

### Welcome and Awards Presentation

***THERESA KANE MUSSER***
**Executive Director**
**Development Operations**
**Rigel Pharmaceuticals, Inc.**
***President, DIA***

### Opening Remarks



***CHARLES C. DEPEW, PharmD***
**GlaxoSmithKline**
***2006 DIA Annual Meeting Chairperson***

### Keynote Address

***SANJAY GUPTA, MD***
**Senior Medical Correspondent**
**Health and Medical Unit at CNN**
**Faculty, Department of Neurosurgery**
**Emory University School of Medicine**

10:00 am-10:30 am **REFRESHMENT BREAK**
**Exhibit Halls A and B, 2nd Floor, Convention Center**
**Ballroom Foyer, 5th Floor, Marriott Hotel**

**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 DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.**

**The difficulty level of each session is indicated by one of the following symbols, providing a guide for registrants in their selection of sessions to attend.**

- ● **Basic Level Content**
  Attendee has 3 years or less experience in the session topic area.
- ■ **Primarily Intermediate Level Content**
  Attendee has more than 3 years experience in the session topic area.
- ◆ **Primarily Advanced Level Content**
  Session may be a more focused topic within a content area. Attendee has mastered the topic area. (Usually only 2 speakers to allow for more in-depth presentations.)

## Session 101 AD - Advertising, RA

10:30 am-12:00 pm LEVEL: ●

Room 111AB *Pharmacy credits offered*

### Drug Advertising and Promotion: A Regulatory Primer

Session Chairperson

***Glenn N. Byrd, MBA, RAC***

Director, Regulatory Affairs, PDL BioPharma, Inc.

Drug advertising and promotion are a major topic in today's regulatory and political environment. Direct-to-consumer (DTC) advertising, the PhRMA guidelines, FDA enforcement actions, and off-label promotion are all prominent news items.

**Introduction**
***Glenn N. Byrd, MBA, RAC***
Director, Regulatory Affairs, PDL BioPharma, Inc.

**Advertising: Regulatory Overview**
***Lesley R. Frank, MS, PhD, JD***
Senior Advisor, Regulatory Counsel, Office of Medical Policy, CDER, FDA

**Advertising: Working with DDMAC**
***Jean Ah-Kang, PharmD***
Senior Regulatory Affairs Consultant, SAIC

## Session 102 CDM - Clinical Data Management, EC, IT

10:30 am-12:00 pm LEVEL: ■

Marriott Salon CD

### Building a Data-centric Trial; or It's the Data!

Session Chairperson

***John W. Snapp***

Manager, Technical Resources, Duke Clinical Research Institute

In data management, we frequently cannot see the dead trees because of the forest. Often, much effort goes into looking at and reporting on all the data rather than quickly identifying suspected problem areas and dealing with them. This session will look at how the data manager can work with other trial team members to establish working mechanisms for quickly identifying suspected data problems in a trial and dealing with them.

**What Does It Take to Create an Electronic Trial for Clinical Data Management?**
***Debra C. Tolsma, MS***
Clinical Data Analyst, Duke Clinical Research Institute

**Getting Patient Data "Clean" in an Electronic Trial**
***Anne E. Holland, RN***
Project Manager, Mayo Clinical Trial Services

**How Can You Implement an Electronic Trial? The Technology Used**
***Robert C. Case, MS***
Global EDC Development Manager, Procter & Gamble Pharmaceuticals

## Session 103 CMC - Chemistry, Manufacturing, and Controls, RA

10:30 am-12:00 pm LEVEL: ■

Room 112AB

### Implementation of a Pharmaceutical Quality Assessment System: Progress and Challenges

Session Chairperson

***Moheb M. Nasr, PhD***

Director, Office of New Drug Quality Assessment, CDER, FDA

This session will provide an overview of the progress and challenges of the new CMC review paradigm in the Office of New Drug Quality Assessment (ONDQA) from an FDA and an industry perspective.

**FDA Perspective**
***Moheb M. Nasr, PhD***
Director, Office of New Drug Quality Assessment, CDER, FDA

**Industry Perspective**
***Diane J. Zezza, PhD***
Vice President, Global Regulatory Affairs, CMC, Schering-Plough Corporation

## Session 104 CP - Clinical Safety and Pharmacovigilance, CR, RA

10:30 am-12:00 pm LEVEL: ■

Marriott Salon G

### The New World of Risk Management: A Global Perspective

Session Chairpersons

***David B. Jefferys, MD, FRCPC***
Senior Regulatory Strategic Advisor, Eisai Europe Ltd., UK

***Noël Wathion, Pharm***
Head of Unit, Postauthorization Evaluation of Medicines for Human Use, EMEA, EU

This session will present a practical update on the new requirements for risk management.

**Implementing Risk Management Planning Globally**
***David B. Jefferys, MD, FRCPC***
Senior Regulatory Strategic Advisor, Eisai Europe Ltd., UK

**PRISMAP: A Risk Management Program for Drugs with Abuse Potential**
***Kenneth Hintze, PhD, ScD***
Director, Global Safety and Pharmacovigilance, Kendle

**PRISMAP: A Risk Management Program for Drugs with Abuse Potential**
***Meredith Y. Smith, PhD, MPA***
Director, Risk Management and Health Policy, Purdue Pharma L.P.

**A New Model for Optimizing Clinical Data Management**
***Xavier Kurz, MD, PhD***
Scientific Administrator, EMEA, EU

## Session 105 CR1 - Clinical Research and Development, BT, RA

10:30 am-12:00 pm LEVEL: ■

Marriott Salon E *CME and Nursing credits offered*

### Changing the Paradigm: Innovative Oncology Drug Clinical Development Programs in the Age of Critical Path and Personalized Medicine – Part 1 of 2

Session Chairperson

***Alberto Grignolo, PhD***

Corporate Vice President and General Manager, Drug Development Consulting, PAREXEL Consulting

*Part 2 of this session will be held on Monday at 1:30 pm.*

This two-part session will discuss recent and anticipated innovations in the development of anticancer medicines, in light of recent failures to achieve regulatory approval for a number of investigational drugs despite earlier promising results. The prospects for integrating scientific advances with innovative clinical program designs in the setting of oncology drug development will be illustrated by speakers from the research, therapeutic, regulatory, and industry perspectives.

**The Use of Biomarkers and Surrogate Endpoints to Accelerate Oncologic Drug Development**
***Gary J. Kelloff, MD***
Special Advisor, Division of Cancer Treatment and Diagnosis, National Cancer Institute

**The Nexavar Story**
***Aileen C. Ryan, PhD, MA***
Director, Global Regulatory Affairs, Therapeutic Area Oncology, Bayer Pharmaceuticals Corporation

**FDA Perspective on Innovative Clinical Trial Designs in Oncology**
***Vicki Goodman, MD***
Medical Officer, Office of New Drugs, CDER, FDA

## Session 106 CR2 - Clinical Research and Development, CP, MC

10:30 am-12:00 pm LEVEL: ●

**Marriott Salon IJ**

### Demonstrating Product Value: Three Unique Perspectives

Session Chairperson
***Peggy Schrammel, MPA***
Executive Director, Late Stage Development, PharmaNet

Postmarketing studies represent valuable tools for demonstrating product value to fiscally-constrained healthcare providers and healthcare-savvy consumers. However, a proactive approach toward program design, with a focus on intended audience and communication methods, is needed if physicians and patients are to find the data from these studies useful.

**Demonstrating Product Value: The CRO Perspective**
***Peggy Schrammel, MPA***
Executive Director, Late Stage Development, PharmaNet

**Demonstrating Product Value: The Sponsor Perspective**
***Erin M. Sullivan, MPH, PhD***
Director, Reimbursement and Outcomes Planning, Boston Scientific

**Demonstrating Product Value: The Public Policy Perspective**
***Alison Rein, MS***
Assistant Director, Food and Health Policy, National Consumers League

## Session 107 CR3 - Clinical Research and Development, CTM, ST

10:30 am-12:00 pm LEVEL: ●

**Marriott Salon AB** *CME credits offered*

### Feasibility Studies 101: A Clinical Operations Perspective

Session Chairperson
***Cheryl Gay, MS***
Clinical Trial Manager, Genentech, Inc.

Feasibility studies are emerging in various forms as useful clinical operations tools. These studies are not restricted to use in particular settings and are conducted globally by varied groups at all levels of development. This session will cover three areas of interest to participants who are new to feasibility studies: reasons to conduct different feasibility study types, how to implement and manage feasibility studies, and analyzing feasibility results and their study predictive value.

**Why Conduct a Feasibility Study?**
***Cheryl Gay, MS***
Clinical Trial Manager, Genentech, Inc.

**How to Conduct a Feasibility Study**
***Lynette A. Glidden***
Global Project Director, PRA International

**What Is the Prognostic Value of Feasibility Study Results?**
***Chester G. Elias, III***
Senior Manager, Global Study Planning and Technical Services, Amgen Inc.

## Session 108 CR4 - Clinical Research and Development, CTM

10:30 am-12:00 pm LEVEL: ●

**Marriott Salon KL**

### Championing the Patient Perspective in Clinical Study Recruitment and Retention: The Role of the Sponsor, CRO, and Vendor in Successful Strategy Development

Session Chairperson
***Peter A. DiBiaso, MHA***
Director, Clinical Trial Recruitment Services, Pfizer Global Research and Development, Worldwide Development Operations

This session will explore several different best-practice examples (from a sponsor, CRO, and communications vendor) of when and how to best consider the patient perspective when designing an effective recruitment and retention strategy.

**The Role of the Sponsor in Successful Strategy Development**
***Peter A. DiBiaso, MHA***
Director, Clinical Trial Recruitment Services, Pfizer Global Research and Development, Worldwide Development Operations

**Identifying/Overcoming Patient Recruitment Barriers to Maximize Patient Recruitment**
***Janet Jones, PhD***
Director, Feasibility and Patient Recruitment, Kendle, UK

**Meeting the Challenge of Retaining Patients in Long-term Safety Studies**
***David Davenport-Firth***
Director, Creativity and Behavioral Medicine, Ogilvy Healthworld, UK

## Session 109 CTM - Clinical Trial Management, CR, IS

10:30 am-12:00 pm LEVEL: ●

**Room 107AB** *CME credits offered*

### An In-depth Look at Patients' Experiences in Clinical Trials and Understanding Physician Motivation to Refer or Not Refer Patients into Clinical Trials

Session Chairperson
***Mary Jo Lamberti, PhD, MA***
Senior Manager, Market Intelligence, Thomson CenterWatch

Thomson CenterWatch has collected data from two recently conducted surveys. One survey examines patients' clinical trial experiences, and the second survey looks at physicians' reasons for referring or not referring a patient into a clinical trial.

**Understanding Clinical Trial Volunteer Experiences**
***Dan McDonald***
Vice President, Thomson CenterWatch

**Understanding Physician Motivation to Refer or Not Refer Patients into Clinical Trials**
***Mary Jo Lamberti, PhD, MA***
Senior Manager, Market Intelligence, Thomson CenterWatch

## Session 110 DM - Document Management/ eSubmissions, RA

10:30 am-12:00 pm LEVEL: ■

Room 204C

### The Ongoing Effort to Ensure a Quality Electronic Submission

Session Chairperson
***Frans A. Eikelboom, MD***
Director, Docu Center, NV Organon, Netherlands

Many companies have overwhelming QM documentation and difficulties in controlling their systems and obtaining compliance from their staff. Facilitating the use of such documents increases transparency, motivation, awareness, and therefore compliance levels. This session will address the project approach, milestones, timelines, and the actual situation of our combined process.

**Management Systems and Documentation: Make It More Transparent**
***Frans A. Eikelboom, MD***
Director, Docu Center, NV Organon, Netherlands

**Electronic Submissions**
***Constance Robinson-Kuiperi***
Senior Regulatory Associate, Pfizer Inc

**An Assessment of How Regulatory Authorities and Industry Are Building Quality into the Review Process**
***J. A. Neil McAuslane, PhD, MSc***
Chief Scientific Officer, CMR International Ltd., UK

## Session 111 EC - eClinical, DM, IT

10:30 am-12:00 pm LEVEL: ■

Marriott Salon H

### The CDISC Standard from Operational Data Model (ODM) to Biomedical Research Integrated Domain Group (BRIDG)

Session Chairperson
***Edward D. Helton, PhD***
Chief Strategist, Regulatory and Biomedical Affairs, SAS Institute Inc.

This session will describe and demonstrate the semantic interoperability of CDISC standard data from electronic capture to the electronic submission, review, and approval process.

**The CDISC Standard Support of eProtocol, ePRO, EDC, and the eSource Document**
***Rebecca D. Kush, PhD***
President, CDISC

**The eClinical Trial: CDISC's Roadmap for a Better Process**
***David P. Iberson-Hurst***
CEO, Assero Limited, UK

**The ADaM/SDTM Pilot Project for the FDA eSubmission**
***Cathleen F. Barrows, PhD***
Assistant Director, Statistics and Programming, Psychiatry, GlaxoSmithKline
***Edward D. Helton, PhD***
Chief Strategist, Regulatory and Biomedical Affairs, SAS Institute, Inc.

## Session 112 FI - Finance, PP

10:30 am-12:00 pm LEVEL: ●

Room 203AB

### Sarbanes-Oxley: Impacts in 2005 and Beyond

Session Chairperson
***Joseph Curran, CPA, MBA***
Senior Advisor, Relevante, Inc.

Sarbanes-Oxley has proven to be a significant and costly initiative for publicly traded companies. The impact on companies both public and private has been profound. This seminar will update on the costs, best practices, and key learnings from the year of implementation.

**Sarbanes-Oxley Impacts in 2005 and Beyond**
***Joseph Curran, CPA, MBA***
Senior Advisor, Relevante, Inc.

**Sarbanes-Oxley Impacts in 2005 and Beyond in the Pharmaceutical Industry**
***Robert Rausch, CPA***
Consultant

## Session 113 GCP - Good Clinical Practices, CR, TR

10:30 am-12:00 pm LEVEL: ■

Marriott Salon F

### GCP Problems as Cited on FDA 483s and in Warning Letters: Lessons Learned

Session Chairperson
***Douglas R. Mackintosh, MBA, DrPH***
President, GCPA, Inc.

This session will present FDA 483s and warning letters collected and analyzed by a working group of the GCP SAIC. Presentations will highlight key citations that demonstrate inspection findings and lessons learned about clinical compliance issues.

**Problems with Source Documents and Record Keeping as Cited on 483s and in Warning Letters: Lessons Learned**
***Maryrose Petrizzo, MS***
Senior Clinical Quality Assurance Analyst, Boston Scientific Corporation

**Principal Investigator-staff Delegation Problems as Cited on 483s and in Warning Letters: Lessons Learned**
***Vernette J. Molloy, MBA, RN***
Vice President, GCPA, Inc.

***Pamela A. Rose, RN***
Director, Clinical Trial Information Registries, TAP Pharmaceuticals Inc.

## Session 114 IMP - Impact, RA

10:30 am-12:00 pm LEVEL: ●

Room 113C *CME, Nursing, and Pharmacy credits offered*

### Patient-reported Outcome Instruments: Overview and Comments on the FDA Draft Guidance

Session Chairperson
***Laurie Beth Burke, RPh, MPH, CAPT. USPHS***
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

FDA has issued a draft guidance for industry on the proper development and use of patient-reported outcome measures in clinical trials to support medical product labeling claims. In response, a public docket contains many comments from industry, academia and other researchers concerning the contents of the draft guidance. This session will summarize the draft guidance in the context of the comments received to date. The intent of this session is to have a dialogue between the agency and stakeholders on this draft guidance.

**Conceptual Framework**
***Edwin P. Rock, MD, PhD***
Medical Officer, Division of Drug Oncology Products, Office of New Drugs, CDER, FDA

**Validation and Study Design**
***John H. Powers, MD, FACP***
Lead Medical Officer, Office of Antimicrobial Products, Office of New Drugs, CDER, FDA

**Analysis and Interpretation**
***Robert T. O'Neill, PhD***
Director, Office of Biostatistics, CDER, FDA

## Session 115 IS - Investigator Sites, CTM, GCP

10:30 am-12:00 pm **LEVEL:** ■

**Room 113B** *CME and Pharmacy credits offered*

### Dilemma of Role Conflicts: Anatomy of a Site Audit

Session Chairperson
***Yvonne P. McCracken, MPH, CCRC***
President and CEO, Carolinas Research Associates

This session will look at the conflicts when commingling the roles of a clinical caregiver with that of the investigator. We will examine these roles, the paradoxes that exist, and the regulations and ethical principals that guide clinicians through this labyrinth. A case study of a site audit will be used to demonstrate the role conflicts and how they impact the treatment of research subjects within a clinical practice.

**Case Study of a Site Audit**
***Yvonne P. McCracken, MPH, CCRC***
President and CEO, Carolinas Research Associates

**Conflicting Roles of Physician versus Physician-investigator**
***Ernest D. Prentice, PhD***
Associate Vice Chancellor for Academic Affairs, University of Nebraska Medical Center

## Session 116 IT - Information Technology, CDM, EC

10:30 am-12:00 pm **LEVEL:** ●

**Room 105AB**

### Approaches to Choosing and Integrating Clinical Trial Technologies to Meet Client Information Needs

Session Chairperson
***Joseph J. Donaghy, MS***
Manager, Strategic Technology Planning, PharmaLinkFHI, Inc.

The expansion in the number of available EDC, safety, laboratory, clinical trial management, and report systems, data warehouse technology, ePro technology, and industry standards such as CDISC, have complicated both the selection choices and the approach to integrating these technologies. Overlaps in the different technologies have added to the complexity. This session will focus on strategic approaches to selecting and integrating technologies for clinical trials and/or registries.

**Can an EDC System Be Your Integration Hub?**
***Keith L. Howells***
Vice President, Engineering, Medidata Solutions

**Developing a Strategy for System Integration**
***Joseph J. Donaghy, MS***
Manager, Strategic Technology Planning, PharmaLinkFHI, Inc.

**Lessons Learned while Pursuing a Multivendor EDC Strategy**
***David Fritsche, MBA***
Senior Director, EDC and Database Systems, Genzyme Corporation

## Session 117 MW - Medical/Scientific Writing, CR, RA

10:30 am-12:00 pm **LEVEL:** ●

**Room 204B**

### Strategic Collaboration

Session Chairperson
***Virginia I. Watson***
Director of Clinical Development and Medical Writing, Cardinal Health, UK

Collaboration across disciplines creates opportunities to optimize collective efforts, simultaneously eliminating duplication of effort and leading to enhanced communication. Proactive partnering through streamlined processes and strategies results in seamless coordination and continuity for more efficient production of high-quality deliverables.

**Opportunities for Collaboration across Regulatory Affairs and Medical Writing**
***Belinda J. Schluchter, PhD***
Associate Regulatory Consultant, Eli Lilly and Company

**Medical Writing: Therapeutic Alignment**
***Leslie A. Locke, PhD***
Medical Writing Director, GlaxoSmithKline

**The Small Company Perspective**
***Kathryn N. Knapp, MS***
Senior Specialist, Clinical Development, Pharmion Corporation

## Session 118 OS - Outsourcing, CR

10:30 am-12:00 pm **LEVEL:** ●

**Room 109AB**

### Outsourcing Strategy for Emerging Companies

Session Chairperson
***Rikki Hansen Bouchard, MPA***
President and CEO, RH Bouchard & Associates, Inc.

Biotechnology and small pharmaceutical companies are maturing rapidly. Many are making the transition from early stage development to their first Phase 2 trials. For a variety of reasons, they cannot conduct their clinical trials in-house. The right outsourcing strategy can be critical to their success. With all of the outsourcing models available, how do they choose the right one to meet their corporate objectives?

***Karen M. Brennan, RN, MBA***
Senior Director, Clinical Operations, RenaMed Biologics

***Jennifer R. Goodfellow, MS***
Director, Clinical Outsourcing, Sepracor Inc.

***Kathleen Findlen***
Senior Director, Clinical Operations, CombinatoRx, Inc.

## Session 119 PM1 - Project Management

10:30 am-12:00 pm LEVEL: ■

**Room 108A** *Project Management Institute credits offered*

### Key Stakeholder Management: Different Perspectives and Approaches

Session Chairperson

***John Z. Sun, MBA, PhD***
Senior Manager, Global Strategic and Operational Project Planning Management, sanofi-aventis

Stakeholder management is an important process in project management. This session will identify some of the key stakeholders and present their different expectations, perspectives, and priorities. Practical approaches will also be offered to ensure smooth progression and timely completion of the project.

**Lead and Influence Team Members without Apparent Authority**
***Raymond G. Starrett, MLS***
Director, Corporate Project Management, MedImmune, Inc.

**Working with Project Team Leaders to Synergistically Manage the Project Team**
***Paul G. Conway, PhD***
Vice President, Global Strategic and Operational Project Planning Management, sanofi-aventis

**The Art of Managing Management**
***Robin G. Foldesy, PhD***
Vice President, Project Management, Wyeth Research

## Session 120 PM2 - Project Management, BT, RD

10:30 am-12:00 pm LEVEL: ■

**Room 108B** *Project Management Institute credits offered*

### Response to Changes in the External Environment in Pharmaceutical R&D: A Project Manager's Perspective

Session Chairperson

***Siddhartha Roychoudhury, PhD***
Project Manager, R&D Management Operations, Centocor R&D

In pharmaceutical R&D projects, there are often unanticipated new developments in the scientific, clinical, competitive, financial, and business landscapes that alter the project scope, timelines, resource needs, and deliverables. A variety of strategies, tactics, and tools can help the project respond to these developments while ensuring the achievement of the ultimate project goal, i.e., meeting unmet needs of patients.

**Changes in the Scientific Landscape: Expanding Drug Development into a New Therapeutic Area**
***Siddhartha Roychoudhury, PhD***
Project Manager, R&D Management Operations, Centocor R&D

**Changes in the Clinical Strategy: The Role of Project Management**
***Sandra J. Zeckel***
Manager, Project Management, Pharmaceuticals, Eli Lilly and Company

**Best Practices in Dealing with Regulatory Changes**
***Melanie A. Bruno, PhD, MBA***
Vice President, Regulatory Affairs and Quality, Kendle International

## Session 121 PP - Public Policy/Law, CR, GCP

10:30 am-12:00 pm LEVEL: ●

**Room 114** Auditorium *CME, Nursing, and Pharmacy credits offered*

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

Session Chairperson

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

In this session, 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 the conclusion of the mock trial, the lawyers will entertain questions about the mock trial.

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

***John F. Kuckelman, JD***
Attorney, Shook Hardy & Bacon LLP

## Session 122 RA1 - Regulatory Affairs, PP, RD

10:30 am-12:00 pm LEVEL: ●

**Room 201A**

### Update: US-EU Agreement Regarding Parallel Scientific Advice and Exchange of Information

Session Chairpersons

***Marie A. Dray, MBA***
President, International Regulatory Affairs Group, LLC

***Brenton E. James, FBIRA***
Consultant in Strategic Regulatory Affairs in the EU

Since the establishment of the US-EU Arrangement to Exchange Information, reports on progress with exchanges of personnel and documents have only been provided publicly via DIA Annual Meetings. This session, third in a series, will update the audience, to the extent not limited by confidentiality of applications, on the success of the pilots during which parallel scientific advice was provided jointly by FDA and EMEA to sponsors who requested it.

**Introduction to the Session and the Panelists**
***Marie A. Dray, MBA***
President, International Regulatory Affairs Group, LLC
***Brenton E. James, FBIRA***
Consultant in Strategic Regulatory Affairs in the EU

**Introduction to the US-EU Agreement**
***Melinda K. Plaisier, MS***
Assistant Commissioner for International Programs, Office of the Commissioner, FDA

**Panelists**

***Murray M. Lumpkin, MD, MSc***
Deputy Commissioner for International and Special Programs, Office of the Commissioner, FDA

***Thomas Lönngren, Pharm, MSc***
Executive Director, EMEA, EU

***Melinda K. Plaisier, MS***
Assistant Commissioner for International Programs, Office of the Commissioner, FDA

***Françoise de Crémiers, PharmD, MS, ML***
Senior Vice President, Chief Scientific and Stakeholder Officer, Europe/Middle East/Africa, Wyeth Research, France

## Session 123 RA2 - Regulatory Affairs, CR, CTM

10:30 am-12:00 pm LEVEL: ■

**Room 202AB**

### Multinational Trials in Asia: Strategy, Operations, Environment

Session Chairpersons

***Tetsuto Nagata***

Chairperson of Clinical Evaluation Subcommittee, Japan Pharmaceutical Manufacturers Association (JPMA); Senior Manager, Pfizer Japan Inc., Japan

***Toshimitsu Hamasaki, PhD***

Associate Professor, Department of Biomedical Statistics, Osaka University Graduate School of Medicine, Japan

This session will review the current situation on global study, focusing on the Asian regions.

**How Does the Japanese Regulatory Agency Accept Global Development Strategy? From the Glacial Age to Now**

***Shunsuke Ono, PhD***

Priority Review Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

**New Era of Global Study in Japan**

***Toshinobu Iwasaki, RPh***

Deputy Director, Shionogi & Co., Ltd., Japan

***Ken Kobayashi, MD, FACP***

Head, Oncology Early Clinical Development, Novartis Pharma K.K., Japan

**Comments on Asian Studies**

***Katsuyoshi Shimatani***

Senior Vice President, External Affairs, Pfizer Japan Inc., Japan

## Session 124 RA3 - Regulatory Affairs, CMC, RD

10:30 am-12:00 pm LEVEL: ■

**Room 201B**

### Combination Products: Global Challenges and Opportunities

Session Chairperson

***Christine Allison, MS, RAC***

Associate Regulatory Consultant, Eli Lilly and Company

Regulations governing combination products vary from country to country. Companies that wish to market combination products globally need to adjust their regulatory strategies accordingly to meet unique challenges for each market. This session will provide an overview of the global regulatory requirements for combination products especially in the three major markets, US, EU, and Japan. The industry presenters will provide examples to demonstrate the challenges and opportunities in development of combination products to meet global regulatory requirements. The presenters will also identify the areas that present opportunities for global harmonization.

**FDA Regulatory and Practical Approaches for Combination Products**

***Patricia Y. Love, MD, MBA***

Associate Director, Office of Combination Products, Office of the Commissioner, FDA

**Drug/Device Combination Products: Global Regulatory Perspectives**

***LeeAnn L. Chambers, MS***

Associate Regulatory Consultant, Eli Lilly and Company

**Convergent Technologies: Combination Product Development**

***Douglas J. Kehoe***

Executive Director, Quality and Compliance Services, Johnson & Johnson

## Session 125 RA4 - Regulatory Affairs, PP, RD

10:30 am-12:00 pm LEVEL: ●

**Room 201C**

### Accelerated Assessment and Conditional Marketing Authorizations at the Level of the EMEA

Session Chairperson

***Patrick Le Courtois, MD***

Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

This session will focus on the changes introduced by the new European pharmaceutical legislation with regard to both Conditional Marketing Authorizations and Accelerated Assessment. The scope and current situation as regards their implementation, including an overview of the related guidelines, will be discussed.

**Conditional Marketing Authorization**

***Francesco Pignatti, MD***

Scientific Administrator, EMEA, EU

**Accelerated Assessment**

***Bruno Flamion, MD***

Chairman, EMEA Scientific Advice Working Party; Professor of Medicine, FUNDP, University of Namur - Ministry of Health, Belgium

**Industry Point of View**

***Alison Harrison, MA***

Vice President, European Regulatory Affairs, AstraZeneca, Belgium

## Session 126 ST - Statistics, CR

10:30 am-12:00 pm LEVEL: ■

**Room 103B** *CME and Pharmacy credits offered*

### Recent Advances in the Use of Adaptive Clinical Trials

Session Chairperson

***Jerald S. Schindler, DrPH***

President, Cytel Pharmaceutical Research

This session will present an overview and update of recent activity in the development of adaptive trials.

**Adaptive Designs: Risks and Opportunities**

***Frank Miller, PhD***

Senior Statistician, Biostatistics, AstraZeneca R&D, Sweden

**Exact Confidence Intervals Following an Adaptive Design**

***Cyrus R. Mehta, PhD***

President, Cytel Software Corporation

**Progress Report from the PhRMA Adaptive Trials Working Group**

***Michael Krams, MD***

Assistant Vice President, Adaptive Trials, Clinical Development, Wyeth Research

**Tools to Ease the Transition to the Use of Adaptive Clinical Trials**

***Jerald S. Schindler, DrPH***

President, Cytel Pharmaceutical Research

## Session 127 TR - Training, CR, GCP

10:30 am-12:00 pm LEVEL: ●

**Room 103C**

### Training across Language and Cultural Barriers

Session Chairperson

***Betty R. Kuhnert, PhD, MBA***

Assistant Vice President, Asia Pacific Medical Affairs, Wyeth Research

Pharmaceutical regulations require training, and market forces require globalization. Unfortunately, sending well-meaning but naive trainers from headquarters to do global training may result in essential information being "lost in translation." This session will provide tips for understanding cultural limitations and tools for providing effective training in spite of language and cultural barriers.

**Making the Most of Cultural Differences**
***Dean Foster, MA, ABD***
President, Dean Foster Associates

**Use of Adult Learning Principles for Promotional Review Training**
***Cathryn L. Anderson, RPh***
Senior Medical Affairs Director, Shire Pharmaceuticals

**GCP Training around the Globe: Similarities and Differences**
***Janet F. Zimmerman, MS***
Senior Director, Training Services, PharmaNet

12:00 pm-1:30 pm **LUNCHEON**
**Exhibit Hall C, 2nd Floor, Convention Center**

## Session 128 AD - Advertising, RA

1:30 pm-3:00 pm LEVEL: ■
**Room 111AB** *Pharmacy credits offered*

### Enforcement Update

Session Chairperson
***Wayne L. Pines***
President, Regulatory Services and Healthcare, APCO Worldwide

This session will discuss the latest enforcement actions and policies by the FDA in the regulation of advertising and promotion.

**Update from CDER**
***Thomas W. Abrams, MBA, RPh***
Director, Division of Drug Marketing, Advertising, and Communications, CDER, FDA

**Update from CBER**
***Maryann R. Gallagher***
Advertising and Promotional Labeling Branch, Office of Compliance and Biologics Quality, Division of Case Management, CBER, FDA

## Session 129 CDM - Clinical Data Management, EC

1:30 pm-3:00 pm LEVEL: ■
**Marriott Salon CD** *CME credits offered*

### Quality Data: Starting with the End in Mind

Session Chairperson
***Kathy Clark, RN***
Senior Clinical Data Management Coordinator, Eli Lilly and Company

The pharmaceutical industry has experienced increasing scrutiny of clinical trial data utilized to support claims of product safety and efficacy. It is implicit that an accurate reporting database is the basis of obtaining meaningful conclusions from a clinical study. This session will explore methods to insure that the database meets rigorous quality standards and will provide data that are accurate and reliable.

**Database Quality Review: Starting with the End in Mind**
***Kathy Clark, RN***
Senior Clinical Data Management Coordinator, Eli Lilly and Company

**Impact on Data Review Burden: Paper vs. Electronic Diaries**
***Stephen A. Raymond, PhD***
Chief Scientific Officer and Quality Officer, PHT Corporation

**A Critical Examination of Database Audits: Research Project Results to Date**
***Kit Howard, MPH, MS***
Associate Director, Data Quality Research Institute; Principal, Kestrel Consultants

## Session 130 CMC - Chemistry, Manufacturing, and Controls, RA, TR

1:30 pm-3:00 pm LEVEL: ■
**Room 112AB**

### The Office of New Drug Quality Assessment CMC Pilot Program

Session Chairperson
***Chi-wan Chen, PhD***
Deputy Director, Office of New Drug Quality Assessment, CDER, FDA

This session will provide an FDA and an industry perspective of the CMC Pilot Program.

**FDA Perspective**
***Chi-wan Chen, PhD***
Deputy Director, Office of New Drug Quality Assessment, CDER, FDA

**Industry Perspective 1**
***Patricia Tway, PhD***
Vice President, Regulatory and Analytical Sciences, CMC, Merck Research Laboratories

**Industry Perspective 2**
***Nirdosh K. Jagota, DrPH***
Assistant Vice President, Worldwide Regulatory Affairs, CMC, Wyeth Pharmaceuticals

**Industry Perspective 3**
***Jeffrey J. Blumenstein, PhD***
Vice President, Regulatory CMC and QA, Pfizer Global Research and Development

## Session 131 CP - Clinical Safety and Pharmacovigilance, IMP, MC

1:30 pm-3:00 pm LEVEL: ■
**Marriott Salon G** *CME, Nursing, and Pharmacy credits offered*

### Communicating Risk Information to Providers and Patients: Issues and Controversies

Session Chairpersons
***Norman S. Marks, MD, MHA***
Medical Director, MedWatch Program, Office of Drug Safety, CDER, FDA
***Andrzej Czarnecki, MD, PhD, DSc***
Director, Deputy EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

The session will cover the risk communication tools from the perspective of the FDA and academia. It will also discuss the issues of appropriate perspective of providing the information on risk and its interpretation.

**FDA Initiatives in Risk Communication: Providing Clinicians with New Safety Information for Medications Used in Daily Care**
***Norman S. Marks, MD, MHA***
Medical Director, MedWatch Program, Office of Drug Safety, CDER, FDA

**From DTC to DHCP: Common Problems in Risk Communication**
***Ruth S. Day, PhD***
Director, Medical Cognition Laboratory, Duke University

**Safety Information in the Right Perspective?**
***Andrzej Czarnecki, MD, PhD, DSc***
Director, Deputy EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

## Session 132 CR1 - Clinical Research and Development, BT, RA

1:30 pm-3:00 pm LEVEL: ■

Marriott Salon E *CME and Nursing credits offered*

### Changing the Paradigm: Innovative Oncology Drug Clinical Development Programs in the Age of Critical Path and Personalized Medicine – Part 2 of 2

Session Chairperson
***Joseph C. Scheeren, PharmD***
Senior Vice President, Head, Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals

*Part 1 of this session will be held on Monday at 10:30 am.*

This two-part session will discuss recent and anticipated innovations in the development of anticancer medicines, in light of recent failures to achieve regulatory approval for a number of investigational drugs despite earlier promising results. The prospects for integrating scientific advances with innovative clinical program designs in the setting of oncology drug development will be illustrated by speakers from the research, therapeutic, regulatory, and industry perspectives.

**European Perspective on Oncology Clinical Trial Design and Endpoints**
***Bertil Jonsson, MD, PhD***
Medical Products Agency, Sweden

**How FDA Will Work with Sponsors to Accelerate Oncology Drug Development in the Era of Critical Path**
***Robert L. Justice, MD***
Medical Officer, CDER, FDA

**Innovative Clinical Trial Designs in Oncology**
***Grant A. Williams, MD***
Clinical Development, GlaxoSmithKline; Former Deputy Director, Division of Oncology Drug Products, CDER, FDA

## Session 133 CR2 - Clinical Research and Development, CTM, PM

1:30 pm-3:00 pm LEVEL: ●

Marriott Salon IJ *CME credits offered*

### Factors Influencing the Speed of Clinical Trial Study Completion

Session Chairperson
***Harold E. Glass, PhD***
Professor of Pharmaceutical Business, University of the Sciences in Philadelphia

Building on the methodological presentation at the 2005 Annual Meeting, this session presents the first-stage results of an empirical analysis of over 100 phase 3 studies, and 3,000 sites. Eight major pharmaceutical companies supplied data from five indications.

**Site Level Considerations in Study Speed Completion**
***Jeffrey J. DiFrancesco, MSc, MEng***
Partner, PrécisTrial LLC

**Project Management Factors Influencing Study Speed Completion**
***Holly Squires, MA***
Partner, TTC, llc

**Overview of Key Factors Influencing Study Speed Completion**
***Harold E. Glass, PhD***
Professor of Pharmaceutical Business, University of the Sciences in Philadelphia

## Session 134 CR3 - Clinical Research and Development, GCP, PP

1:30 pm-3:00 pm LEVEL: ●

Marriott Salon AB *CME and Nursing credits offered*

### Prevention of Fraud and Noncompliance in Clinical Research

Session Chairperson
***Kenneth A. Getz, MS, MBA***
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

The incidence of noncompliant and fraudulent activity by institutions and investigative sites continues to rise. Recent regulatory changes in disclosure and privacy have the potential to drive higher levels of noncompliance. This session reviews recent and historical inspection audit reports issued by FDA and OHRP and discusses new approaches that regulatory agencies, research sponsors, and investigative sites are pursuing to prevent noncompliance and fraud in the future.

**Review of FDA Inspection Results and Other Measures of Noncompliance**
***Kenneth A. Getz, MS, MBA***
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

**Thoughts on Why Fraud and Noncompliance Occur**
***David M. Cocchetto, PhD, RPh***
US Regulatory Affairs, GlaxoSmithKline

**A Legal Perspective on Reducing and Preventing Fraud and Noncompliance**
***Dara S. Katcher, JD***
Attorney, Hyman, Phelps & McNamara, P.C.

## Session 135 CR4 - Clinical Research and Development, CTM, RA

1:30 pm-3:00 pm LEVEL: ■

Marriott Salon KL *CME and Pharmacy credits offered*

### Focus on Asia: How to Run a Successful Clinical Trial in Asia

Session Chairperson
***Karen Chu, PharmD***
Executive Director, International Clinical Operations, APEX International Clinical Research Co., Ltd., Taiwan

Because the Asia region, including China, is developing into a strong player in global clinical research, there is a greater need to understand overall project handling in that region. The incorporation of Asia into global development programs has become inevitable, and with strong recruitment power, a well-rounded ethnic clinical data package, and excellent cost-benefit, it is crucial to understand how to incorporate the Asia region into a global program.

**Critical Path: Perspectives from Emerging Countries of Asia**
***Chih-Hwa Lin, PhD***
Director, Center for Drug Evaluation, Taiwan

**Management of Multinational Trials in Asia: How to Be Successful**
***Lisia Lubiansky***
Director, Clinical Operations, Valeant Pharmaceuticals International

**Managing the Challenges of Conducting Global Trials in Asia Pacific**
***Janice Myers, RN, CCRA***
Clinical Project Manager - CRO Liaison, Boston Scientific Corporation

## Session 136 CS - Clinical Supplies, CR, CTM

1:30 pm-3:00 pm LEVEL: ■

**Room 102AB** *Pharmacy credits offered*

### Clinical Supply Chain Management: Integrated Solutions/ Drug Accountability

Session Chairperson
***Graham J. Nicholls, MSc***
Product Manager, Randomization and Supply Chain Management Services, ClinPhone Group Ltd., UK

Effective trial supplies management calls for a holistic approach where "end of trial" accountability, reconciliation, returns and destruction of investigational product is proactively considered during the study planning stages. We will discuss the largely manual practices currently utilized for tracking trial supplies and review how applications can use IVR data to alleviate some of the pains/ frustrations. In considering solutions, three IVR providers will examine extensions to the IVR functionality and integration with other eClinical systems such as clinical supplies management (CSM).

**Integration between Clinical Supplies Management (CSM) and IVR/EDC Systems**
***Kimberly Sierk***
Product Manager, United BioSource Corporation

**Clinical Supplies: Assuring Accountability, Reconciliation, and Destruction of Clinical Trial Material**
***Monica English***
Senior Project Manager, IVRS, Covance, Inc.

**Accountability, Reconciliation, Returns, and Destruction of Clinical Trial Material Using an Automated Solution**
***Nikki Dowlman, PhD***
Product Development Specialist, ClinPhone Group Ltd., UK

## Session 137 CTM - Clinical Trial Management, CR

1:30 pm-3:00 pm LEVEL: ■

**Room 107AB** *Pharmacy credits offered*

### One-week Patient Enrollment: Opportunities from Increased Global Coverage

Session Chairperson
***Andrew Lee, MA***
Vice President, Clinical Study and Data Management, Pfizer Global Research and Development

Although the advantages of one-week patient enrollment are well known, there remain obstacles to successful implementation. These include patient availability, investigator cooperation, and resource management. Based on our favorable experiences beyond North America and Western Europe, we know that there exist unique opportunities in these countries for one-week patient enrollment. This session will discuss approaches to achieving this prized objective.

**Rapid Patient Enrollment and Data Reporting for Early-stage Clinical Trials**
***Diane K. Jorkasky, MD, FACP***
Senior Vice President, Global Clinical Pharmacology Department, Pfizer Inc

**Why Is It So Hard to Achieve One-week Patient Enrollment in Late-stage Clinical Trials**
***Nermeen Y. Varawalla, MD, PhD, MBA***
Vice President, PRA International, UK

## Session 138 DM1 - Document Management/ eSubmissions, MW, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 204C**

### Submission Content Authoring

Session Chairperson
***Carol M. Stretch***
Senior Manager, Clinical Information and Technology (CITy), Novo Nordisk Inc.

In this session, you will learn if your organization is ready to prepare and submit applications in CTD and eCTD format for submissions and submission components. You will learn to understand the issues and challenges as you move the entire organization from paper to electronic processes.

For medical writers, regulatory publishers, and information technology support groups, it is important to understand each role and how they affect one another. Developing fully integrated processes and working relationships is the key to a successful submission.

Non-US regions are requiring the paper CTD format for submissions; however, the US prefers an electronic format for all submissions. Learn how to build a core CTD submission accepted in all regions, and produce an electronic NDA/CTD hybrid submission using the core CTD content.

**Developing Symbiotic Standards to Produce Exceptional Submissions**
***Marc J. Stern***
Assistant Director, Document Formats and Standards, Forest Research Institute

**Preparing eSubmission-ready Documents for CTD/eCTD**
***Carol M. Stretch***
Senior Manager, Clinical Information and Technology (CITy), Novo Nordisk Inc.

**Building a Core CTD Submission for Simultaneous Region Submissions**
***Robin L. Zumbrunnen***
Associate Director, Regulatory Operations, Quintiles, Inc.

## Session 139 DM2 - Document Management/ eSubmissions, IT, RA

1:30 pm-3:00 pm LEVEL: ■

**Room 114** Auditorium

### SPL and PIM: An Examination of the Difference between the Two, the Importance of Content Management, and Practical Implementation Experience

Session Chairperson
***Terry D. Hardin, MA***
Senior IT Architect, IBM Life Sciences

Late in 2005, structured product labeling (SPL) and product information management (PIM) replaced PDF as the required format for electronic content of labeling submissions in the US and the EU. This session will provide a brief overview of the standards, examine the implications for industry, the importance of content management, and provide a brief overview of the differences between SPL and PIM.

**What Is PIM, and How Does It Differ from SPL?**
***Claire Edwards, MBA***
Administrator, EMEA, EU

**The SPL Experience: Navigating the Technical and Regulatory Issues – A Guide**
***Jeffery M. Karp***
Principal Analyst, Hospira, Inc.

## Session 140 EC - eClinical, CDM, IT

1:30 pm-3:00 pm LEVEL: ■

Marriott Salon H

### Healthcare Integration

Session Chairperson

***Charles Jaffe, MD, PhD***

Senior Global Strategist, Digital Healthcare, Intel Corporation

The processes inherent to both patient care and to clinical research have remained distinct and poorly integrated. Much the same way, the information defined and codified within each domain is almost never interoperable and is rarely reusable. Recent developments both in technology and standards have made the promise of integration an attainable vision.

**Integration and Interoperability of Clinical Systems**

***David B. Stein***

Director, Product Strategy, ClinPhone, Inc.

**This Is Not Your Father's EDC: Moving from Implementation to Integration**

***Joseph S. Anderson***

Principal Associate, Waife & Associates, Inc.

***Douglas B. Fridsma, MD, PhD, FACP***

Assistant Professor of Medicine, University of Pittsburgh School of Medicine

## Session 141 FI - Finance, CR

1:30 pm-3:00 pm LEVEL: ■

Room 203AB

### The Keys to Effective Partnering

Session Chairperson

***Kimberly Warner, MS***

Director, Operations, Applied Clinical Intelligence LLC

Pharmaceutical companies are increasingly finding themselves with the need to outsource parts of their clinical trials to outside vendors. With this comes the necessity for all companies involved to have effective partnering skills. At the end of this session, the participant should have the necessary skills to be able to effectively work in a partnered relationship.

**Unique Partnering Challenges of a Small Pharmaceutical Company**

***Barry Sachais, PhD***

Vice President, Clinical Development, Neuromed Pharmaceuticals, Inc.

**An Evolution towards Successful Partnering Relationships**

***Camille Logue Orman, PhD***

Director, Biostatistics and Data Management, McNeil Consumer & Specialty Pharmaceuticals

**Tools to Bridge the Partnering Gap**

***Mario Moussa, PhD, MBA***

Principal, Center for Applied Research, Inc.

## Session 142 GCP - Good Clinical Practices, CR

1:30 pm-3:00 pm LEVEL: ◆

Marriott Salon F

### Exploring the Concepts and Challenges of Conducting System and Process Audits in Clinical Research

Session Chairperson

***Cheri A. Wilczek, MS***

President, ClinAudits, LLC

Although sponsors can transfer their obligations to CROs for a number of capabilities, they are still required to maintain oversight of the process; one way to ensure compliance is to conduct system and process audits. Understanding from an auditor's view the thinking behind system and process audits is mandatory in all sections of the clinical research area. This session will explore concepts of system and process audits, case studies of audits, along with common observations. The Six Sigma concept will also be explored, as well as how it could apply to system and process auditing. When sponsors transfer their obligations to conduct all aspects of clinical research, this represents a major investment in money and time, especially when it involves phase 3 pivotal trials. The sponsor is still required to maintain oversight of the transfer of obligation process and, from time to time, conduct due diligence and routine or for cause audits. Audits of investigator sites occur frequently; less frequently conducted are system and process audits of the capabilities, which the sponsor contracted with a CRO. This could involve a specialty laboratory, central laboratory, CRO (prequalification and postcapability), IRB/EC, final study report, adverse event reporting system, etc.

**Applying the Six Sigma Concept to System and Process Auditing in Clinical Research**

***Anna Marie C. McSorley, RN***

Six Sigma Black Belt, i3 Research

**A Practical Review of System and Process Auditing as It Applies to Clinical Research**

***Patricia M. Tenthorey***

President, Tenthorey Consulting LLC

## Session 143 IS - Investigator Sites, CTM, GCP

1:30 pm-3:00 pm LEVEL: ●

Room 113B *CME and Pharmacy credits offered*

### Transparency at the Site Level: Are Sites and Sponsors Ready for the Challenge?

Session Chairperson

***Nadina C. Jose, MD, CPI, MBA***

President/CEO, Research Strategies, Inc.

Transparency is hard to find in clinical trials, largely due to a culture of propriety and secrecy. We recognize that now is the time for change, as there are demonstrable consequences of these practices. There can be much gained from transparency, such as in collaboration of pooled resources and accountability; both aspects positively change the way all team members conduct trials.

**Transparency at the Site Level: Are Sites and Sponsors Ready for the Challenge?**

***Nadina C. Jose, MD, CPI, MBA***

President/CEO, Research Strategies, Inc.

**Sites Want Respect: Can Transparency Be the Answer? What Are the Risks and Benefits to the Site?**

***Sooji Lee-Rugh, MD***

President/Co-founder, True Trials, Inc.

**Planning for Success: The Right Timing and Appropriate Questions to Ask During the Investigator Site Identification and Selection Process**

***Peter A. DiBiaso, MHA***

Director, Clinical Trial Recruitment Services, Pfizer Global Research and Development, Worldwide Development Operations

## Session 144 IT - Information Technology, CS, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 105AB**

### Implications of Drug Pedigree and Authentication on the Pharmaceutical Industry

Session Chairperson

***Eric G. Brown***

Vice President, Research Director, Healthcare and Life Science, Forrester Research

While consumer goods retailers move rapidly to adopt sensor-based technologies, such as radio frequency identification (RFID), to manage inventory and streamline the supply chain, the pharmaceutical industry faces even greater challenges associated with line-item-level tracking and regulatory controls. Federal, state, and licensing agencies have pushed pedigree regulations ahead this year, hoping that both the industry and RFID technology can rise to meet their demands. This session explores the implications of drug supply chain automation and regulation – and how key pharmaceutical firms will address the requirements imposed on a safe and secure drug supply – as Florida enacts the first drug pedigree law in less than two weeks after this session occurs.

**New Initiatives and Activities in the Safe and Secure Pharmaceutical Supply Chain**

***Robin T. Koh, MBA, MS***

Chief Strategy Officer, SupplyScape Corporation

**Responding to Drug Pedigree Requirements**

***Bruce A. Harder***

Senior Manager, Healthcare and Life Sciences Solutions, VeriSign

## Session 145 MW - Medical/Scientific Writing, OS, PM

1:30 pm-3:00 pm LEVEL: ◆

**Room 204B**

### Review and Outsourcing Strategies

Session Chairperson

***Sandra J. Hecker***

President, Hecker and Associates, LLC

Medical writing teams often face ever-shortening timelines. We will discuss solutions for surviving and even thriving in this environment, and learn strategies for writing high-quality documents while meeting these demanding timelines through using standardizing text elements, maximizing teamwork during authoring and review, and outsourcing appropriate tasks. The key role of communication between all parties in the document-production process will be highlighted. Case studies will demonstrate how thorough planning and strong communication skills can substantially influence the time/quality/cost relationship for document production.

**You Made a Decision to Outsource a Medical/Scientific Writing Project**

***Milan Kovacevic, MD, PhD***

Executive Director, Clinical Development, GenVec, Inc.

**Achieving an Effective Process Quickly**

***Sandra J. Hecker***

President, Hecker and Associates, LLC

**Innovative Roundtable Strategies Accelerate Timelines**

***Susan C. Sisk, PhD***

Principal, SFP Consulting, LLC

## Session 146 NHP - Natural Health Products, CP, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 106AB** *CME, Nursing, and Pharmacy credits offered*

### Safety and Pharmacovigilance of Natural Health Products

Session Chairperson

***Pulok K. Mukherjee, PhD, MPharm, RPh, FIC***

Director, School of Natural Product Studies, Department of Pharmaceutical Technology, Jadavpur University, India

Considering every aspect of efficacy, safety, and toxicity, herbal pharmacovigilance is the major thrust for the assessment and evaluation of botanicals. With the increased use of botanicals, the chances for drug interaction, toxic indication, and adverse drug effects also increase, which makes surveillance necessary for botanicals used in complementary and alternative medicine (CAM).

**Exploring Safety of Botanicals in Complementary and Alternative Medicine**

***Pulok K. Mukherjee, PhD, MPharm, RPh, FIC***

Director, School of Natural Product Studies, Department of Pharmaceutical Technology, Jadavpur University, India

**Postmarket Surveillance of NHPs: Canadian Regulatory System**

***Mano Murty, MD***

Manager, Clinical Section, Marketed Natural Health Products, Health Canada

**Adverse Event Monitoring of the Botanical Products**

***Pradip K. Paul, MBBS, MS***

Head, Case Medical Evaluation Group, Global Pharmacovigilance and Epidemiology, sanofi-aventis Pharmaceuticals, Inc.

## Session 147 OS1 - Outsourcing, PM

1:30 pm-3:00 pm LEVEL: ◆

**Room 109AB**

### Designing and Managing Successful Outsourcing Relationships – Part 1 of 2

Session Chairperson

***John R. Vogel, PhD***

Drug Development Consultant, John R. Vogel Associates Inc.

*Part 2 of this session will be held on Monday at 3:30 pm.*

This two-part, audience-participation session will begin with a discussion on why relationship building and management is critical for project success, the experience of other industries, and how to design and manage the sponsor-provider relationship at the executive level. The second part of the session will focus on designing and managing the sponsor-provider relationship at the project team level.

**Panelists**

***Brenda Muldrow, MBA***

Executive Director, Customer Relations, INC Research

***David W. Gillogly, MBA***

Senior Director, Global Strategic Planning, Sankyo Pharma Development

## Session 148 OS2 - Outsourcing, CR

1:30 pm-3:00 pm LEVEL: ●

**Room 113C**

### CRO/SMO Present Status in Japan

Session Chairperson

***Takatoshi Sato, PhD***

Chairman, HyCLIPS K.K., Japan

The present status of clinical study, which has been changing drastically during the past couple of years in Japan will be presented. CRO and SMO activity has also been changing as they adopt the ongoing new product development process. This information would be helpful for global development.

**The Client Perspective**
***Hironobu Saito, MS***
Vice Director, Clinical Development Department and Head of Asian Drug Development, Sankyo Co., Ltd., Japan

**The SMO Perspective**
***Masakatsu Nomura***
Manager, Sogo Clinical Pharma Ltd., Japan

**The CRO Perspective**
***Keiko Kunisawa***
Manager, CTL, Quintiles Transnational Japan

## Session 149 PM1 - Project Management, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 108A** *Project Management Institute offered*

### Communication Skills: The Path to Successful Project Management

Session Chairperson
***Jean A. Yager, PhD, PMP***
Director, Development Operations, Pfizer Inc

This session will be an interactive audience session with project management experts. It is designed to enhance team communication skills by discussing communication venues utilized by project management, including communication planning and case studies identifying competencies needed to communicate effectively in the work environment, demonstrating the importance of effective communications through a team exercise.

**Communicating for Success**
***Gail H. Sherman***
Vice President, Education; Director, TRI, PDA

**Successful Communication: FDA Perspective**
***Virginia L. Behr***
Chief, Project Management Staff, Division of Antiviral Products, CDER, FDA

## Session 150 PM2 - Project Management, IT

1:30 pm-3:00 pm LEVEL: ◆

**Room 108B** *Project Management Institute credits offered*

### Enterprise Project Management: A Practical Approach

Session Chairperson
***Raymond G. Starrett, MLS***
Director, Corporate Project Management, MedImmune, Inc.

The session will provide three case studies on design and implementation of enterprise project management within the pharmaceutical industry. Each case study will highlight its critical success factors and how to apply them to achieve success in your organization.

**EPM Implementation: The Critical Role of Change Management**
***Martin D. Hynes, III, PhD***
Director, Product Research and Development, Lilly Research Laboratories, Eli Lilly and Company

**A Comprehensive Approach to Successfully Implementing an Enterprise Project Management System**
***Augustus J. Cicala, MS***
CEO, Project Assistants, Inc.

## Session 151 PP - Public Policy/Law, CR, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 113A** *CME and Pharmacy credits offered*

### Civil and Criminal Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials?

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

This session will include presentations on current legal and regulatory issues that affect sponsors, investigators, and IRBs in the conduct of clinical trials. The session will also feature preselected members of the audience playing a game utilizing a very popular television game show format. The questions will primarily be limited to legal and regulatory issues. It will be a lot of fun and the winner will be awarded a fabulous (but modest) prize.

**Clinical Trials: Legal and Regulatory Jeopardy**
***John M. Isidor, JD***
CEO, Schulman Associates IRB, Inc.

**Clinical Trials: Legal and Regulatory Jeopardy**
***Ann Begley, JD***
Partner, Kirkpatrick & Lockhart, Nicholson, Graham, LLP

## Session 152 RA1 - Regulatory Affairs, BT, CR

1:30 pm-3:00 pm LEVEL: ●

**Room 201B** *CME credits offered*

### Pharmacogenetic Tests: From Analytical Validation to Clinical Application

Session Chairpersons
***Felix W. Frueh, PhD***
Associate Director, Genomics, Office of Clinical Pharmacology, CDER, FDA
***Lawrence J. Lesko, PhD***
Director, Office of Clinical Pharmacology, CDER, FDA

The use of pharmacogenomic information in the care of patients is intimately linked to clinical assays that measure one or more genomic biomarkers. This session will discuss the critical success factors to move the informational content of these tests, and with it the field of pharmacogenomics, into clinical practice.

**Pharmacogenomic Tests: Five Ingredients for a Successful Ride Down the Regulatory Trail**
***Steven I. Gutman, MD***
Director, Office of In-Vitro Diagnostics, CDRH, FDA

**Development and Implementation of the UGT1A1 Invader Assay**
***Amy Brower, PhD***
Executive Director, Medical Informatics and Genetics, Third Wave Technologies, Inc.

**A New Type of Molecular Diagnostics: Highly Parallel Genotyping Using the Amplichip Platform**
***Walter Koch, PhD***
Vice President, Head of Research, Roche Molecular Systems, Inc.

## Session 153 RA2 - Regulatory Affairs, CR

1:30 pm-3:00 pm LEVEL: ●

**Room 204A**

### Good Review Management Principles (GRMPs): Progress and Challenges toward Improving Review Efficiency

Session Chairperson
***Roy J. Baranello, MS***
Assistant Vice President, Worldwide Regulatory Affairs, Wyeth Pharmaceuticals

Development and implementation of guidance on good review management principles (GRMPs) was one of the major new FDA performance objectives adopted during the reauthorization of PDUFA in 2002. This session will examine the specific objectives of GRMPs, the content of the guidance document, FDA's implementation progress, and challenges to achieving the full promise of this important initiative.

**GRMPs Implementation: CDER Perspective**
***Kim Colangelo***
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

**GRMPs Implementation: CBER Perspective**
***Robert A. Yetter, PhD***
Associate Director for Review Management, Office of the Director, CBER, FDA

**Industry Perspective: Progress and Challenges**
***Taryn Rogalski-Salter, PhD***
Director, US Regulatory Policy, Merck Research Laboratories

## Session 154 RA3 - Regulatory Affairs, CR, CTM

1:30 pm-3:00 pm LEVEL: ●

**Room 202AB** *CME credits offered*

### Clinical Trials in Latin America: A Review of the Regulatory Framework – Part 1 of 2

Session Chairperson
***Manuel Fresno, MBA***
Managing Director, Latin America, MDS Pharma Services, Argentina

*Part 2 of this session will be held on Monday at 3:30 pm.*

Latin America has recently become one of the most active regions for clinical trials in the world. The regulatory environment of Latin America has improved over the last years and increasingly operates in accordance with international standards and guidelines. This session will present a review of the approval process across several countries in Latin America (Argentina, Brazil, Colombia, Costa Rica, Chile, Mexico, and Peru).

**Regulatory Framework for Clinical Trials in Argentina**
***Patricia Eriksson, PhD***
Regional CRA Manager, Sanofi Pasteur S.A., Argentina

**Regulatory Framework for Clinical Trials in Chile**
***Luis Eduardo Johnson, PhD***
Manager, Office of Clinical Trials and Bioethics, Institute of Public Health, Chile

**Regulatory Framework for Clinical Trials in Peru**
***Silvia Zieher, MD***
Clinical Research Director, MDS Pharma Services, Argentina

**Regulatory Framework for Clinical Trials in Colombia**
***Diana Valencia, MD***
Director of Clinical Operations, Siplas Research Organization

## Session 155 RA4 - Regulatory Affairs, CR, RD

1:30 pm-3:00 pm LEVEL: ■

**Room 201C**

### Scientific Advice at the Level of the EMEA

Session Chairperson
***Bruno Flamion, MD***
Chairman, EMEA Scientific Advice Working Party; Professor of Medicine, FUNDP, University of Namur - Ministry of Health, Belgium

The session will focus on the changes introduced by the revised EU pharmaceutical legislation regarding the new procedure for scientific advice at the EMEA, including broader advice and patients' representatives involvement and what to expect from scientific advice for the new conditional marketing authorization. The viewpoint of industry will also be provided.

**The New EMEA Procedure for Scientific Advice**
***Agnès Saint-Raymond, MD, PhD***
Head of Sector, Scientific Advice and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

**Scientific Advice for the New Conditional Marketing Authorization**
***Andrea Laslop, MD***
Head of Unit, Science and Information, Austrian Medicines Agency, Austria

**Industry Viewpoint**
***Claire Bouzy***
Associate Vice President, sanofi-aventis

## Session 156 RA5 - Regulatory Affairs, BT, RD

1:30 pm-3:00 pm LEVEL: ●

**Room 201A** *Nursing credits offered*

### FDA-EMEA Joint Session on Emerging Therapies and Technologies

Session Chairpersons
***Marisa Papaluca-Amati, MD***
Deputy Head of Sector, Safety and Efficacy of Medicines, EMEA, EU
***Federico Manuel Goodsaid, PhD***
Senior Staff Scientist, Office of Clinical Pharmacology, CDER, FDA

This session will provide a comprehensive update of the main strategy pursued in the two regions to foster innovation; special focus will be on the relevance to selected areas, including pharmacogenomics, cell therapy and gene therapy. The speakers, from both the industry and regulatory side, will present the current initiatives in the industry and in the regions to support and monitor implementation of new technologies in the development of new therapies.

The focus will then move in detail in describing and discussing benefits and limitations of the joint EMEA/FDA activities already in place, e.g. voluntary genomic briefings, joint discussions, and parallel scientific advice. Finally a conclusive session, in the format of a roundtable, will allow the stakeholders to express their expectations, proposals and recommendations for further joint activities.

**Joint FDA/EU Pharmacogenetics and Initiatives**
***Federico Manuel Goodsaid, PhD***
Senior Staff Scientist, Office of Clinical Pharmacology, CDER, FDA

**Joint FDA/EU Initiatives on Gene and Cell Therapy**
***Klaus Cichutek***
Head, Department of Medical Biotechnology; Deputy Acting Director of Paul Ehrlich Institute (PEI)

**Panelist**

***Eric Abadie, MBA, MD***
CHMP Vice Chairman, EMEA, EU; ICH Steering Committee Member; Director, AFSSAPS, France

## Session 157 ST - Statistics, CR

1:30 pm-3:00 pm **LEVEL: ■**

**Room 103B** *CME and Pharmacy credits offered*

### Design and Analysis of Multicenter Trials

Session Chairperson

***Byron Jones, PhD, MSc***

Senior Director, Clinical Research and Development, Pfizer Global Research and Development, UK

This session will consider the design and analysis of multicenter trials for both normal and binary data. For continuous data, fixed-effects and random effects models will be described and compared to the random effects model used to determine the optimal number of patients and centers. The choice of design of the trial to minimize cost and recruitment time will be considered. The use of simulation to model and forecast recruitment will be described, as will approaches to compare alternative recruitment strategies. Prototype software to simulate recruitment will be illustrated.

**Design and Analysis of Multicenter Trials (Continuous Data)**
***Byron Jones, PhD, MSc***
Senior Director, Clinical Research and Development, Pfizer Global Research and Development, UK

**Design and Analysis of Multicenter Trials (Binary Data)**
***Valerii V. Fedorov, PhD, DSc***
Group Director, GlaxoSmithKline Pharmaceuticals

**Modeling and Forecasting Patient Recruitment**
***Nitin R. Patel, PhD***
Chief Technology Officer, Cofounder, Cytel Software Corporation

## Session 158 TR - Training, CR, CTM

1:30 pm-3:00 pm **LEVEL: ●**

**Room 103C**

### The Pipeline of New Personnel for the Clinical Research Enterprise

Session Chairperson

***Stephen A. Sonstein, PhD, MS***

Director, Clinical Research Administration, Eastern Michigan University

This session will explore the issues surrounding the need for personnel that is occurring due to the expansion of the clinical research enterprise. Information will be presented that explains and quantifies the need for new personnel. The hiring authorities (sites, CROs, and the pharmaceutical industry) will explain the process of finding, training, and evaluating the qualifications of potential hires. The dilemmas faced by the new entry-level applicant will also be discussed. The audience will be encouraged to participate with the speakers in a panel discussion following the presentations.

**Emerging Trends and Their Impact on the Clinical Research Enterprise**
***Joan A. Kroll-Chambers***
Director of Strategic Marketing and Development, Tufts Center for the Study of Drug Development, Tufts University

**Where Do We Get Monitors for Our Clinical Trials: Human Resource Issues within the Pharmaceutical Industry and CROs**
***William R. McHale***
Senior Vice President - Global, i3 Pharma Resourcing

**Education versus Experience: The Dilemma for the Entry-level Person**
***Stephen A. Sonstein, PhD, MS***
Director, Clinical Research Administration, Eastern Michigan University

**New Hires: The Impact of Education and Previous Experience on Training Needs Analysis**
***Kathleen S. Badeaux, MS, CCRA***
Clinical Research Associate, MedTrials, Inc.

3:00 pm-3:30 pm **REFRESHMENT BREAK**
**Exhibit Halls A and B, 2nd Floor, Convention Center**
**Ballroom Foyer, 5th Floor, Marriott Hotel**

## Session 159 AD - Advertising, PP, RA

3:30 pm-5:00 pm **LEVEL: ■**

**Room 111AB**

### Implementing Corporate Integrity Agreements

Session Chairperson

***Stephan Vincze, JD, LLM, MBA***

Vice President, Ethics and Compliance Officer/Privacy Officer, TAP Pharmaceutical Products Inc.

This session will discuss the key challenges organizations face in implementing a corporate integrity agreement and the recommended steps to address those challenges successfully. Moreover, it will address techniques that extract the greatest value and positive outcomes from an otherwise negative event. This session will feature a former Inspector General of Health and Human Services (HHS), a partner from a leading "final four" auditing firm with extensive experience in CIA implementation and oversight, and the Ethics and Compliance Officer from TAP, which has been cited as a leader in Ethics and Compliance Program development and implementation since its landmark settlement and CIA in 2001.

**Panelists**

***Janet Rehnquist, Esq.***
Healthcare Partner, Venable LLP

***Jonathan L. Kellerman***
Partner, Pricewaterhouse Coopers

## Session 160 BT - Biotechnology, CR, RA

3:30 pm-5:00 pm **LEVEL: ■**

**Room 113C**

### Human Tissue-engineered Products (hTEPs): US versus EU Comparison

Session Chairperson

***Riccardo Sciabica, PharmD***

Senior Editor - IDRAC, Thomson Scientific, France

This session is intended first to highlight the current difficulties to find a scientifically valid and legally sustainable definition of human tissue-engineered products (hTEPs). It will focus on the impact of the new EU proposal on hTEPs and other advanced therapies, which the EU Commission issued in November 2005. It will then give an overview of the US experience, where the new regulatory approach to human cells, tissues, and cellular and tissue-based products has been in place since May 2005. Finally, this session will detail the consequent development issues for hTEPs from an industry perspective.

**Introduction to Human Tissue-engineered Products**
***Riccardo Sciabica, PharmD***
Senior Editor - IDRAC, Thomson Scientific, France

**EU Proposal on Human Tissue-engineered Products and Other Advanced Therapies**
***Linda R. Horton, JD, LLM***
Partner, Hogan & Hartson L.L.P., Belgium

**Current US Regulatory Approach for Human Cellular and Tissue-based Products**
***Jill Hartzler Warner, JD***
Senior Policy Advisor and Counselor, CBER, FDA

**Human Tissue-engineered Products: Industry's Point of View**
***Laura Mondano***
Associate Director, Regulatory Affairs, Genzyme Corporation

## Session 161 CDM - Clinical Data Management, CR, ST

3:30 pm-5:00 pm LEVEL: ■

Marriott Salon CD

### Collaborative Clinical Study Database Design

Session Chairperson
***Robbert P. Van Manen, MSc***
Worldwide Technical Director, Lincoln Technologies

Designing clinical trial databases involves many different disciplines, each with its own specialists, who may be located in geographically distinct locations and different time zones, but all have to work together effectively to produce an optimal result in the shortest possible time. This session describes requirements for a collaborative infrastructure based on component libraries to support global cooperation in the design and implementation of clinical study databases, both from the perspective of standards, such as those developed by the CDISC PRG and BRIDG teams, and from the viewpoint of first-hand user experience evaluating the functionality of an innovative collaborative clinical study design environment.

**Collaborative Development of a Comprehensive Data Standard for Protocol-driven Research**
***Diane E. Wold, PhD***
Director, Data Standards Development and Management, GlaxoSmithKline

**Analysis Data in a Standards-based Collaborative Environment**
***Gregory Anglin, PhD***
Principal Research Scientist, Statistics, Eli Lilly Canada Inc., Canada

**A Collaborative Infrastructure for Clinical Study Database Design**
***Crystal Steiner***
Data Management Analyst, Eli Lilly and Company

## Session 162 CMC - Chemistry, Manufacturing, and Controls, RA, TR

3:30 pm-5:00 pm LEVEL: ■

Room 112AB

### Comprehensive Quality Overall Summary

Session Chairperson
***Robert G. Baum, PhD***
Executive Director, Pfizer Global R&D

This session will discuss the proposed comprehensive quality overall summary (CQOS) from both a regulatory and an industry perspective.

**Industry Perspective**
***Robert G. Baum, PhD***
Executive Director, Pfizer Global R&D

**FDA Perspective**
***Guirag K. Poochikian, PhD, FACP***
Associate Director, Regulatory Science and Policy, Office of New Drug Quality, CDER, FDA

**EU Perspective**
***Jean-Louis Robert, PhD***
Head of Unit, Department of Quality Control of Medicines, National Health Laboratory, Luxembourg

## Session 163 CP - Clinical Safety and Pharmacovigilance, CR, GCP

3:30 pm-5:00 pm LEVEL: ■

Marriott Salon G *CME and Pharmacy credits offered*

### How to Manage Risks during Drug Development

Session Chairpersons
***Monika M. Pietrek, PhD, MD, MSc***
Executive Vice President, Global Scientific and Medical Affairs, PRA International, Germany
***Ellis Unger***
Deputy Director, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

Early risk management activities will protect patients from potential/unnecessary harm and potentially result in reduced development cost and time. This session will focus on key strategies to optimize risk identification and investigation as well as risk minimization during drug development. Individual tools for ongoing safety review and the capabilities of aggregated data analyses will be discussed, using practical examples. Benefits and shortcomings of current and future approaches will be presented.

**Background and Overview of the CIOMS VII Project: The DSUR**
***Ellis Unger***
Deputy Director, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

**Clinical Trials: Pharmacovigilance at the Cutting Edge?**
***Malcolm Barratt-Johnson, MBBS***
Medical Assessor, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**Practical Examples**
***Monika M. Pietrek, PhD, MD, MSc***
Executive Vice President, Global Scientific and Medical Affairs, PRA International, Germany

**Panelist**

***Arnold J. Gordon, PhD***
Pharmaceutical Consultant

## Session 164 CR1 - Clinical Research and Development, IS, RA

3:30 pm-5:00 pm LEVEL: ■

Marriott Salon E *CME credits offered*

### Oncology Phase 1 Research: Unique Challenges

Session Chairperson
***Mark Grose***
Managing Director (US), Endpoint Research

Phase 1 oncology studies have unique challenges. This session will address these challenges as well as offer potential solutions to ensure study success – essential to developing new oncology treatments.

**Phase 1 Oncology Protocol Design**
***Susan Jerian, MD***
President, OncoRD, Inc.

**Site Selection for Phase 1 Oncology Research**
***Diane Paul, MS, RN***
Vice President, Oncology Research Program, National Comprehensive Cancer Network

**Patient Recruitment for Phase 1 Oncology Studies**
***Brenda Kowaleski, RN***
Research Nurse Coordinator, Juravinski Cancer Centre, Canada

## Session 165 CR2 - Clinical Research and Development, CP

3:30 pm-5:00 pm **LEVEL:** ■

**Marriott Salon IJ** *CME and Pharmacy credits offered*

### TYSABRI: A Novel Path to Regulatory Approval and Risk Management

Session Chairperson
***Michael A. Panzara, MD, MPH***
Vice President, Chief Medical Officer, Biogen Idec

Natalizumab (TYSABRI) was approved for the treatment of relapsing forms of multiple sclerosis (MS) in November 2004 based upon outstanding efficacy and a favorable safety profile demonstrated after a 1-year analysis of data from the ongoing 2-year Phase 3 trials. Three months following the approval, the occurrence of a rare and unexpected adverse event, progressive multifocal leukoencephalopathy (PML), prompted a voluntary suspension of TYSABRI dosing and removal from the US market. In the months that followed, Biogen Idec and Elan embarked on an extensive safety evaluation of TYSABRI-treated patients to determine whether there were any undiagnosed cases of PML. No additional cases were found, leading to a total of 3 confirmed cases. This presentation will review the Phase 3 program that led to the initial approval of TYSABRI for the treatment of MS and the steps taken after the dose suspension to evaluate safety and resume dosing. In addition, the sponsors' approach to the development of a Risk Minimization Action Plan (RiskMAP) will be reviewed.

**Initial Approval and Assessment of Safety**
***Michael A. Panzara, MD, MPH***
Vice President, Chief Medical Officer, Biogen Idec

**TYSABRI RiskMAP**
***Carmen Bozic, MD***
Vice President, Global Head, Drug Safety and Risk Management, Biogen Idec

## Session 166 CR3 - Clinical Research and Development, RA, ST

3:30 pm-5:00 pm **LEVEL:** ◆

**Marriott Salon KL** *CME and Nursing credits offered*

### Clinical Trials for Fixed-combination Drug Products

Session Chairperson
***Michael A. Swit, JD***
Vice President, Life Sciences, The Weinberg Group Inc.

"Conventional wisdom" is that clinical studies for fixed-combination drug products must conform to a classic "factorial" model. This session will reveal why the conventional wisdom is wrong and that approval can be obtained sometimes with just a single study arm.

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

## Session 167 CS - Clinical Supplies, CMC

3:30 pm-5:00 pm **LEVEL:** ◆

**Room 102AB**

### Take Two Protocols and Call Me in the Morning: Effectively Managing the Challenges of the Clinical Supply Process

Session Chairperson
***Frank J. Tiano, RPh***
President, Clinical Supplies Consulting Services

Discover how to effectively handle the demands of clinical research and to mobilize clinical supply units to produce acceptable deliverables.

**Proactive Planning for CTM Success**
***Frank J. Tiano, RPh***
President, Clinical Supplies Consulting Services

**Best Practices for the Clinical Supply Chain**
***David F. Bernstein, PhD, MS***
Vice President, Pharmaceutical Sciences and Regulatory Compliance, Bernstein CMC Regulatory Consulting

## Session 168 CTM - Clinical Trial Management, CR

3:30 pm-5:00 pm **LEVEL:** ●

**Room 107AB**

### Reaching Subject Recruitment and Retention Goals

Session Chairperson
***Bryce D. Bartruff, PhD, MBA***
Manager, Clinical Infectious Disease Research, PharmaNet

The process of attracting and maintaining patients in a clinical trial can be best achieved by learning what motivates potential subjects and providing them with the ingredients they need to make an informed decision. This session provides foundational principles and specific techniques both the sponsor and the site can use to develop a plan that addresses the unique needs of their specific study.

**Reaching Subject Recruitment and Retention Goals**
***Bryce D. Bartruff, PhD, MBA***
Manager, Clinical Infectious Disease Research, PharmaNet

**Reaching Subject Recruitment and Retention Goals**
***Diana L. Anderson, PhD, MSN, RN***
President and CEO, D. Anderson & Company

## Session 169 DM - Document Management/ eSubmissions, MW, RA

3:30 pm-5:00 pm **LEVEL:** ●

**Room 204C**

### eINDs

Session Chairperson
***John W. Aitken, PhD***
Senior Director, Regulatory Operations, Elan Pharmaceuticals

Since FDA issued guidance on providing eINDs electronically in eCTD format, many companies are now submitting eINDs as eCTDs. This session will include the following eIND-related topics: the benefits of filing eINDs electronically in eCTD format; mapping IND documents to the eCTD structure; submitting granular documents; managing study tagging files; lifecycle management of eIND documents and submissions; case studies on preparing eINDs in eCTD format; and applying eCTD operators and metadata.

**Compiling an IND in eCTD Format**
***John W. Aitken, PhD***
Senior Director, Regulatory Operations, Elan Pharmaceuticals

**IND as eCTD: Where Granular Publishing Pays Off**
***Janel A. Demeter***
Senior Regulatory Associate, Teva Neuroscience, Inc.

**eCTD: Building from IND to Marketing Application**
***Matthew J. Neal, MA***
Senior Manager, Regulatory Operations, Amgen Inc.

## Session 170 EC1 - eClinical, CDM, IMP

3:30 pm-5:00 pm LEVEL: ■

Room 204B *Nursing credits offered*

### Electronic Patient-reported Outcomes (ePRO) Technology and the FDA Draft PRO Guidance: A Town Meeting to Discuss Industry's Response

Session Chairperson
***John M. Weiler, MD***
President, CompleWare Corporation

This session will address the implications of the FDA's Draft PRO Guidance (http://www.fda.gov/cber/gdlns/prolbl.pdf) issued in early February, 2006 as it applies to ePRO Technology (lines 813-858). Panel members and attendees will participate in a town meeting setting to explore options for industry to deal with the electronic aspects of this draft guidance.

**Moderator**

***John M. Weiler, MD***
President, CompleWare Corporation

**Panelists**

***Valdo Arnera, MD***
General Manager, Europe, PHT Corporation, Switzerland

***Jean Paty, PhD***
Founder and Senior Vice President, invivodata, inc.

***Christine A. Getter***
Outcomes Research Senior Associate, Pfizer Inc

***Stephen E. Wilson, DrPH, CAPT. USPHS***
Director, Office of Business Process Support and Deputy Director, Division of Biometrics II, CDER, FDA

## Session 171 EC2 - eClinical, IT, ST

3:30 pm-5:00 pm LEVEL: ◆

Marriott Salon H

### Interoperability: What It Means for Clinical Researchers, Statisticians, and Information Technology Professionals

***NEW 2006 SIAC Offering – SIAC-sponsored Session***

Session Chairpersons
***Susan P. Duke, MS, MS***
Assistant Director, Biomedical Data Sciences, GlaxoSmithKline
***Russell W. Helms, PhD, MS***
Vice President, Technology, Rho, Inc.
***Munish Mehra, PhD, MS, MSc***
Senior Vice President, Clinical Research Services, Medifacts International

Interoperability has been defined as "the ability of software and hardware on different machines from different vendors to share data." Interoperability has been achieved in many industries, and we have it in our personal lives as well. However, the healthcare and pharmaceutical industries have a long way to go. Ironically, we can withdraw money from our bank from anywhere in the world through ATMs, but we cannot expect to easily access information relevant to safety concerns. The challenge of the lack of standards and interoperability in the healthcare and clinical research arenas seems to be gaining momentum. The goal of this session is to bring experts together to share their visions and get a glimpse of some of the challenges and opportunities that lie ahead.

This session, sponsored by DIA's eClinical, Statistics, and Information Technology SIACs, hosts an expert panel on this topic. Each panelist will briefly present views on the key aspects to achieving this goal, key barriers, who the stakeholders are, what value they can look forward to, and when they can expect to use it.

**The Platform Perspective**
***Jason Burke, MA***
Senior National Life Sciences Industry Strategist, SAS Institute Inc.

**Industry Standards Perspective**
***Joel Hoffman, PhD***
Vice President, Pharmaceutical Practice, Intrasphere Technologies

**The Platform Perspective**
***Les Jordan***
Industry Technology Strategist, Life Sciences, Microsoft Corporation

**PhRMA Perspective**
***Michael Brennan, PhD, MS***
Vice President, Global Regulatory Operations, Centocor - Johnson & Johnson

**A Pharmaceutical Company's IT Perspective**
***Daljeet Sahni***
Principal Architect, AstraZeneca

**The Biostatistician's Perspective**
***Jerald S. Schindler, DrPH***
President, Cytel Pharmaceutical Research

## Session 172 FI - Finance, PP, RA

3:30 pm-5:00 pm LEVEL: ●

Room 203AB

### Terra Incognita: Explore the Business Impact of the Clinical Trials Directive

Session Chairperson
***Marc S. Ginsky, JD, MBA***
Associate General Counsel and Assistant Secretary, Covance Inc.

The implementation of the European Clinical Trials Directive has been the subject of intense debate already. However, this session explores an underexposed angle: there are also major financial and contractual impacts which should not be ignored. This session helps you understand the impact for biotechnology/pharmaceutical companies, insurers, and drug development service companies.

**Understanding the Commercial Impact of the Clinical Trials Directive to Sponsors, Sites and CROs**
***Marc S. Ginsky, JD, MBA***
Associate General Counsel and Assistant Secretary, Covance Inc.

**A Biotechnology Point of View on Budgeting for International Clinical Trials**
***Bill Hansen***
Associate Director, Contracts Management, InterMune, Inc.

**An Insurer's Point of View on the Impact of the Directive**
***Jill E. Wadlund, ALCM***
Vice President and World Life Sciences Casualty Manager, Chubb Group of Insurance Companies

## Session 173 GCP - Good Clinical Practices, CR, PM

3:30 pm-5:00 pm LEVEL: ■

**Marriott Salon F**

### Virtual Realities: Quality Considerations when Using Contract Organizations

Session Chairperson

***Deborah A. Waltz, MS, CIP***

Senior Director, R&D Quality, King Pharmaceuticals

In this session we will explore some of the less obvious risks that sponsors should consider when they are contracting significant responsibilities to external consultants and contract research organizations. Participants will learn some of the symptoms of dysfunctional organizations. The session will provide perspectives from regulators, international auditors and quality experts on strategies for assuring sound quality systems are in place throughout all stages of clinical development. The session will also provide effective techniques for dealing with "bumps in the road" and provide insight on how to motivate others toward quality improvements.

The timing of this session will be strictly controlled to guarantee participants opportunity for interactive discussion, audience participation through a question and answer period. Audience participants are encouraged to bring "hypothetical" or generalized real examples of challenges they are dealing with or have dealt with to this session.

**Auditing Specialty Vendors: Beyond GCP Regulations**
***Louise N. Lisansky, MS, MSc***
President, LNL Clinical Research Consulting, Inc.

**Quality Relationships: What to Look for, What to Run from**
***Deborah A. Waltz, MS, CIP***
Senior Director, R&D Quality, King Pharmaceuticals

**FDA Perspective: Who's Responsible for Quality when Activities Are Outsourced?**
***Joseph P. Salewski***
Deputy Director, Division of Scientific Investigations, CDER, FDA

## Session 174 IS - Investigator Sites, CTM

3:30 pm-5:00 pm LEVEL: ■

**Room 113B** *CME and Pharmacy credits offered*

### Investigator Reimbursement and Budgets: How They Affect Patient Enrollment, Retention and Time Lines

Session Chairperson

***Daniel M. Ulrey, MBA***

President and CEO, Midwest Clinical Support, Inc.

This session will address the sensitive issue of the why, how, and what of sponsor reimbursement and investigator budgets and their impact on site and investigator overall study performance with emphasis on patient enrollment and retention. Speakers will present metrics, processes, and legal and governmental considerations used in establishing budgets for independent for-profit investigative sites.

**A CRO Perspective**
***Leslie M. Cate, MS***
Vice President, Global Access to Patients, Quintiles, Inc.

**A Big Pharma Perspective on Clinical Budgeting and Reimbursement**
***Scott P. Jensen, MBA***
Team Leader, Global Clinical Contracts and Grants, Eli Lilly and Company

**Establishing Intelligent Budgets and Using Fair Negotiating to Help Ensure Success**
***Lori Shields***
Vice President, Operations, Fast Track Systems, Inc.

## Session 175 IT - Information Technology, RA, VA

3:30 pm-5:00 pm LEVEL: ■

**Room 105AB**

### Deploying Life Science IT Using IEEE Methods

Session Chairperson

***Thomas Quinn***

President, CISSP, The Hollis Group, Inc.

This session is an introduction to the IEEE model for Systems and Software Engineering (S&SE) as applied to life science IT projects. The session will include a methodology description and case studies of IT projects that have been completed using IEEE methods.

**Building a Paperless Clinical Supply System Using IEEE Methods**
***Barbara L. Meserve***
Vice President, Quality Assurance, AccuLogix, Inc.

**Impact of the Utah Medical Decision on IT Methodologies**
***Tam D. Woodrum, JD, MS***
Senior Director, IT Quality and Compliance, Nektar Therapeutics

**Using ISO 17799 for Compliance**
***Amer S. Malik***
Associate Director, IT, Family Health International

## Session 176 NHP - Natural Health Products, CR, RA

3:30 pm-5:00 pm LEVEL: ●

**Room 106AB**

### International Initiatives for Natural Health Products

Session Chairperson

***Helmi Hussien, PhD, MSc***

Acting/Unit Head Clinical Trials, Health Canada

This session will showcase current status of discovery, research, production, and development of herbal medicines in North and Latin America, Europe and other countries within the framework of international "botanical drug discovery programs." The application of new research methods to develop science-based products will be presented, and their impact on a company's overall R&D strategy will be explored. This session will also outline the detailed quality requirements of NHPs for clinical trials submissions from a regulatory perspective in Canada, discuss and compare the regulatory procedures for filing applications for IND of herbal products in China and Taiwan, and disclose the guidelines on examination and registration of traditional Chinese medicines in China and Taiwan.

**Impact of International Initiatives in the Evaluation of Herbal Medicines**
***Mahabir P. Gupta, PhD***
Director, CIFLORPAN and Research Professor of Pharmacognosy, University of Panama

**Clinical Trial Management in Traditional Chinese Medicine (TCM)**
***James Fan, MD***
Medical Director, Protech Pharmaservices Corporation, Taiwan

**Quality Requirements of Natural Health Products for Clinical Trial Submissions**
***Helmi Hussien, PhD, MSc***
Acting/Unit Head Clinical Trials, Health Canada

## Session 177 OS - Outsourcing, PM

3:30 pm-5:00 pm LEVEL: ◆

**Room 109AB**

### Designing and Managing Successful Outsourcing Relationships – Part 2 of 2

Session Chairperson

***John R. Vogel, PhD***

Drug Development Consultant, John R. Vogel Associates Inc.

*Part 1 of this session will be held on Monday at 1:30 pm.*

This two-part, audience-participation session will begin with a discussion on why relationship building and management are critical for project success, the experience of other industries, and how to design and manage the sponsor-provider relationship at the executive level. The second part of the session will focus on designing and managing the sponsor-provider relationship at the project team level.

**Panelists**

***David W. Gillogly, MBA***

Senior Director, Global Strategic Planning, Sankyo Pharma Development

***Brenda Muldrow, MBA***

Executive Director, Customer Relations, INC Research

## Session 178 PM1 - Project Management, CTM, RD

3:30 pm-5:00 pm LEVEL: ■

**Room 108A** *Project Management Institute credits offered*

### Effective Team and Project Integrations: Principles and Lessons Learned in Collaborations

Session Chairperson

***Cynthia L. Palka, MSc, CEC, RAC***

Vice President, Global Leadership, The Chalfont Project, UK

This session will look at what often happens when teams in R&D merge due to restructuring or mergers and acquisitions (M&A) and a new project team emerges. Most heads of R&Ds are concerned about processes, project management and systems integration, and little thought is given to the issue of how people in teams work together on a daily basis. Attendees will learn about the importance of looking at the people issues and how a new team can be formed and maintained by creating mutual trust without loss of productivity.

**Fast Integration of Teams: Debunking the Myth of Long and Painful Alignment of Teams in M&As or Internal Consolidations**

***Cynthia L. Palka, MSc, CEC, RAC***

Vice President, Global Leadership, The Chalfont Project, UK

**Lessons in Integrations and Collaborations: A Critical Review of Mergers and Alliances**

***Kati M. Seiffer***

Senior Analyst II, Statistical Submissions Specialist, Biogen Idec, Inc.

## Session 179 PM2 - Project Management, BT, CTM

3:30 pm-5:00 pm LEVEL: ◆

**Room 108B** *Project Management Institute credits offered*

### Best Practices for Remote and Virtual Project Management in Life Sciences

Session Chairperson

***Peter M. Smith, PhD***

Project Manager, Taratec Development Corporation

Remote and virtual project management require special skills to ensure successful projects. Managing projects where all team members work in the same remote location (remote project management) involves logistical challenges. Managing projects when team members are geographically dispersed (virtual project management) creates additional challenges. Both require expertise beyond conventional project management. This session examines methods to manage these challenges.

**Remote Project Management**

***Peter M. Smith, PhD***

Project Manager, Taratec Development Corporation

**A Case Study in Virtual Project Management**

***Bernd Doetzkies, MA***

Director, Informatics, Daiichi Medical Research

**Leading Teams across Continents and Companies: Challenges and Opportunities**

***C. David Zarley, PhD***

Senior Director, Project Management, Wyeth Research

***William Jacobson, PhD***

Director, Project Management, Women's Health and Bone Neuroscience, Inflammatory Diseases, Wyeth Research

## Session 180 PP - Public Policy/Law, CP, RA

3:30 pm-5:00 pm LEVEL: ■

**Room 113A** *CME and Pharmacy credits offered*

### Community Pharmacy Safety Network: Patient and Pharmacist Involvement in the Monitoring of Medications

Session Chairperson

***Lisa Higgins, MPH***

Associate Director for Safe-Path, The Critical Path Institute

The Community Pharmacy Safety Network (CPSN) is a prospective, patient self-reported safety surveillance system for new drugs. This session will provide an overview of the model utilized to detect patient self-reported ADEs, the perspective from a community pharmacy chain with six months' experience implementing this model and the objectives of FDA in analyzing the data obtained.

**Active Surveillance as a Postmarketing Drug Safety Tool**

***Gerald J. Dal Pan, MD, MHS***

Director, Office of Surveillance and Epidemiology, CDER, FDA

**The Critical Path Institute's Mission on Patient Safety**

***Raymond L. Woosley, MD, PhD***

President, The Critical Path Institute

**The Community Pharmacy Implementation of a Safety Program**

***Don Featherstone, RPh***

Pharmacy District Manager: Southern Arizona, Bashas' United Drug

## Session 181 RA1 - Regulatory Affairs, CP, PP

3:30 pm-5:00 pm LEVEL: ■

**Room 201A** *CME, Nursing, and Pharmacy credits offered*

### Prescription Drug Labeling: Implementation of FDA's New Regulation for the Content and Format of the USPI and Accompanying Guidance Documents

Session Chairperson

***Steven W. Bass, PhD***

Group Director, Global Labeling and Promotion Compliance, Bristol-Myers Squibb Company

On January 24, 2006, the FDA released the long awaited Final Rule for the "Requirements on Content and Format of Labeling for Human Prescriptions and Biological Products." This was accompanied by two Final Guidances on the Adverse Reaction Section and the Clinical Studies Section and a Draft Guidance on the Warning and Precautions, Contraindications, and Boxed Warning Sections and a Draft Guidance on Implementing the New Content and Format Requirements.

This session will review the format and content of the new regulation and accompanying guidance documents, the time frame for implementation of the "new format" and the changes from the current regulations for the content and format of the US Package Insert (CFR 201.56 and CFR 201.57). It will also provide a forum to discuss both the FDA's and industry's questions and expectations regarding the implementation of the proposed labeling changes. The new format is a major change to the way we have been delivering safety and efficacy information to healthcare professionals and to patients. Therefore, this "long awaited and anxiously anticipated session" should be highly informative and interactive.

**Background and Overview**
***Steven W. Bass, PhD***
Group Director, Global Labeling and Promotion Compliance, Bristol-Myers Squibb Company

**FDA Presentation**
***Laurie Beth Burke, RPh, MPH, CAPT. USPHS***
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

## Session 182 RA2 - Regulatory Affairs, IMP, MC

3:30 pm-5:00 pm **LEVEL:** ■

**Room 201C**

### FDA and EMEA Experiences on Interaction with Patients

Session Chairperson
***Noël Wathion, Pharm***
Head of Unit, Postauthorization Evaluation of Medicines for Human Use, EMEA, EU

Both the FDA and the EMEA have developed various interactions with patients. This session will provide an update on the current situation, in particular the Cancer Liaison Program at the FDA and recent initiatives at the EMEA, including experience in the field of HIV. Participants will include regulators, patients, and pharmaceutical industry representatives.

**The Patient Liaison Program**
***Representative to be determined***
FDA

**The Patient Liaison Program: Patient Perspective**
***Representative to be determined***

**The Framework on the Integration between the EMEA and Patients' and Consumers' Organizations**
***Isabelle Moulon, MD***
Head of Sector, Medical Information, EMEA, EU
***Nikos Dedes***
European AIDS Treatment Group (EATG), Belgium

**Pharmaceutical Industry Experience on Interaction with Patients in Regulatory Activities**
***Catarina Edfjall***
Actelion Pharmaceuticals Ltd.

**Panelist**

***Tomas Salmonson, PhD***
CHMP Member, EMEA, EU; Medical Products Agency, Sweden

## Session 183 RA3 - Regulatory Affairs, CR, CTM

3:30 pm-5:00 pm **LEVEL:** ●

**Room 202AB** *CME credits offered*

### Clinical Trials in Latin America: A Review of the Regulatory Framework – Part 2 of 2

Session Chairperson
***Manuel Fresno, MBA***
Managing Director, Latin America, MDS Pharma Services, Argentina

*Part 1 of this session will be held on Monday at 1:30 pm.*

Latin America has recently become one of the most active regions for clinical trials in the world. The regulatory environment of Latin America has improved over the last few years and increasingly operates in accordance with international standards and guidelines. This session will present a review of the approval process across several countries in Latin America (Argentina, Brazil, Colombia, Costa Rica, Chile, Mexico, and Peru).

**Regulatory Framework for Clinical Trials in Costa Rica**
***Jorge Lopez, PharmD***
Operations Manager, Bio-Trials, Costa Rica

**Regulatory Framework for Clinical Trials in Brazil**
***Sergio De Andrade Nishioka, MD, PhD, MSc***
Manager, Office of New Drugs, Research and Clinical Trials, ANVISA (National Health Surveillance Agency), Brazil

**Regulatory Framework for Clinical Trials in Mexico**
***Itzigueri Robles, MSc***
Clinical Research Director, MDS Pharma Services, Mexico

**Working Group on GCPs of the Pan American Health Organization (PAHO)**
***Luis Eduardo Johnson, PhD***
Manager, Office of Clinical Trials and Bioethics, Institute of Public Health, Chile

## Session 184 RA4 - Regulatory Affairs, RD

3:30 pm-5:00 pm **LEVEL:** ●

**Room 201B**

### Successful Drug Development: The Phase 1/2 and 2/3 Interfaces

Session Chairperson
***Evan B. Siegel, MS, PhD***
President and CEO, Ground Zero Pharmaceuticals, Inc.

Key to the success of the process is the battleground of critical developmental interfaces: Phase 1 "First in Man" trials into dose-defining and expanded Phase 2 studies; and Phase 2 data into substantial evidence ("Phase 3") trials. Appropriate organizational structures, project planning and management, and realistic expectations and assessments increase the probability of facilitated product development and sound decisions to be made at the Phase 1/2 and 2/3 interfaces.

**Successful Planning and Execution of Phase 1/2 and 2/3 Interactions: The Consultant's Point of View**
***Chaline S. Brown, PharmD***
Senior Manager, Clinical Affairs, Ground Zero Pharmaceuticals, Inc.

**The Sponsor's Role in Effective Phase 1/2 and 2/3 Consultations with the FDA**
***Brian S. Kersten, PhD***
Senior Director, Regulatory Affairs/Quality Assurance, Nuvelo Inc.

**Successful Phase 1/2 and Phase 2/3 Meetings: The CDER/FDA Point of View**
***Kim Colangelo***
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

## Session 185 ST1 - Statistics, CP, CR

3:30 pm-5:00 pm LEVEL: ●

**Room 103A** *CME and Pharmacy credits offered*

### Challenges in Quantitative Assessment of Drug Safety for Regulatory Actions

Session Chairperson

***C. George Rochester, PhD, RAC***

Lead Mathematical Statistician (Drug Safety), Office of Biostatistics, CDER, FDA

This session will cover issues relevant to the design and conduct of clinical studies in which drug safety information is collected to support regulatory actions including drug labeling and risk management action plans. The statistical analysis plan will be discussed as a unifying framework in which to design, conduct and present safety data to regulators. Data collection, summarization and presentation of analyses will be emphasized. Ensuring that safety risks are appropriately identified and communicated to clinical and statistical reviewers is critical in the review of drug safety. Case studies to illustrate current practices and provide recommendations for future improvements in how safety information is collected, analyzed, and presented will provide immediate application to clinical, statistical, and data management professionals.

**The Growing Role of the Statistician in Safety Assessment of Clinical Trials for Regulatory Approval**

***Michael L. Nessly, MS***

Director, Clinical Biostatistics and Research Decision Sciences, Merck Research Laboratories

**Current Practices and Future Thinking in Analysis of Drug Safety**

***Charles K. Cooper, MD***

Medical Officer, Office of Biostatistics, CBER, FDA

**Safety Analysis Plans for Premarketing Safety**

***C. George Rochester, PhD, RAC***

Lead Mathematical Statistician (Drug Safety), Office of Biostatistics, CDER, FDA

## Session 186 ST2 - Statistics, BT, CR, RD

3:30 pm-5:00 pm LEVEL: ●

**Room 103B** *CME and Pharmacy credits offered*

### Targeted Therapies: Statistical Issues in Design

Session Chairperson

***Jorgen Seldrup, PhD***

Development Director, Biostatistics - Europe, Quintiles, France

Pharmacogenetics and personalized medicine: Is a new drug development paradigm needed? This session will focus on statistical, ethical and regulatory issues in the brave new world.

**Translational Medicine and Biomarkers: Their Place in Drug Development**

***John Brown, MD***

Executive Director, Global Strategic Drug Development, Quintiles PLC, UK

***Kevin Carroll, PhD***

Chief Statistical Expert, AstraZeneca

**Confirmatory Clinical Trials with an Adaptive Design**

***Armin Koch***

Biostatistician, Federal Institute for Drugs and Medical Devices (BfArM), Germany

## Session 187 TR - Training, CR

3:30 pm-5:00 pm LEVEL: ●

**Room 103C**

### Career Trends and Opportunities for Clinical Research Professionals

Session Chairperson

***Joan A. Kroll-Chambers***

Director of Strategic Marketing and Development, The Tufts Center for the Study of Drug Development, Tufts University

This session provides a detailed review and discussion of the trends surrounding clinical research positions, specifically the strategies hiring authorities implement to identify, recruit, and retain employees in this competitive market. This session also offers a first-hand look at how key clinical positions' skill sets, roles, and responsibilities have evolved and what career opportunities there may be to further their careers in the clinical trials industry and what steps are needed to reach this goal.

**Industry Trends and Hiring Strategies Surrounding Clinical Research Positions**

***Joan A. Kroll-Chambers***

Director of Strategic Marketing and Development, The Tufts Center for the Study of Drug Development, Tufts University

**Personal Perspectives on Roles and Responsibilities Evolving in Response to Industry's Changes**

***Jeffrey Souza, BSN, MT***

US Director, i3 Pharma Resourcing

**Personal Perspectives on Career Opportunities in the Clinical Trials Industry**

***Laurie A. Halloran, MS***

President, Halloran Consulting Group

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

5:00 pm-6:00 pm **MONDAY RECEPTION**
**Exhibit Halls A and B, 2nd Floor**
**Convention Center**

7:30 am-6:30 pm **ATTENDEE REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-6:30 pm **EXHIBITOR REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-6:30 pm **SPEAKER REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-8:15 am **CONTINENTAL BREAKFAST**
Grand Hall and Meeting Rooms 201-204 Concourse, 2nd Floor, Convention Center
Ballroom Foyer, 5th Floor, Marriott Hotel

10:00 am-6:30 pm **PROFESSIONALS' POSTER SESSION**
Arch Street Bridge, 2nd Floor, Convention Center

9:00 am-5:30 pm **EXHIBITS OPEN**
Exhibit Halls A and B, 2nd Floor, Convention Center

5:30 pm-6:30 pm **RECEPTION FOR THE 100th ANNIVERSARY OF THE FDA**
Grand Hall, 2nd Floor, Convention Center

## Session 201 AD - Advertising, RA

8:30 am-10:00 am **LEVEL:** ■

**Room 111AB** *CME and Pharmacy credits offered*

### How to Develop a Direct-to-consumer Ad

Session Chairperson
***Neal Collins, MD***
Senior Medical Director, Pfizer Inc

With patient care as a first priority, this session will focus on how we can create effective direct-to-consumer (DTC) advertisements.

**Health Literacy as It Applies to DTC**
***Lisa Dieter, MS***
Director, Marketing Innovation, Pfizer Inc

**Putting Clear Health Communication into Action**
***Janet Ohene-Frempong, MS***
President, JO Frempong and Associates

## Session 202 BT - Biotechnology, CR

8:30 am-10:00 am **LEVEL:** ■

**Room 103A**

### Biosimilars: Current Views

Session Chairperson
***Gopalan Narayanan, FRCPC, MD***
Head of Biologicals and Biotechnology Unit, Medicines and Healthcare products Regulatory Agency, UK

Demonstration of similarity between two nonidentical biotechnology-derived products is often complex, requiring varying degrees of evidence. This session will address some of the key issues.

**Biosimilarity and Comparability**
***Gopalan Narayanan, FRCPC, MD***
Head of Biologicals and Biotechnology Unit, Medicines and Healthcare products Regulatory Agency, UK

**A Balanced Approach: View of a Product Developer**
***Louis-Christian Clauss, PharmD***
Director, Regulatory Affairs, Global NPB Biologics, Baxter, France

**Similar Biological Medicinal Products: Technical Assessment and Scientific Issues**
***James D. Green, MS, PhD***
Senior Vice President, Preclinical and Clinical Development Sciences, Biogen Idec Inc.

**Regulatory Considerations: European Approach**
***Marisa Papaluca-Amati, MD***
Deputy Head of Sector, Safety and Efficacy of Medicines, EMEA, EU

## Session 203 CDM - Clinical Data Management, EC, IT

8:30 am-10:00 am **LEVEL:** ■

**Marriott Salon CD**

### Hybrid Data Capture Strategies

Session Chairperson
***James A. Downhower, MSE***
Director, Information Technology, PharmaNet, Inc.

The advantages of using EDC have been widely discussed. Its adoption has been slow but increasing. There are industry studies about the number of EDC clinical trials. EDC has lots of advantages, but we should not assume that it renders all other data capture methods useless. Hybrid data capture is about combining different types of data capture technologies to utilize the strengths of each. The result is more effective data capture than can be provided by any single type of data capture used alone. There are numerous ways to combine these technologies, and depending on the circumstances, different approaches should be used. We will discuss how different scenarios may be addressed. We will also discuss the issues associated with implementing hybrid data capture.

**Operational Considerations when Conducting Hybrid Data Capture Studies**
***Kim H. Sanford***
Director, Data Management, PharmaNet, Inc.

**Transitioning from Paper to eClinical: An Integrated Approach**
***Nicolas Schaltenbrand, PhD***
Director, Data Management, Quintiles, France

**Challenges in Implementing EDC: Can You Avoid the Paper?**
***Krystyna Kowalczyk***
Vice President, Clinical Operations, PharmaLinkFHI, Inc.

## Session 204 CMC - Chemistry, Manufacturing, and Controls, CS

8:30 am-10:00 am **LEVEL:** ■

**Room 112AB**

### Challenges to Drug Development during IND/Clinic Stage in the New Paradigm

Session Chairperson
***Patricia Tway, PhD***
Vice President, Regulatory and Analytical Sciences, CMC, Merck Research Laboratories

This session will address the challenges facing sponsors during IND development stages in the new paradigm by FDA and industry representatives.

**Industry Perspective**
***Scott P. Boudreau, PhD***
Associate Director, Pharmaceutical and Analytical R&D, AstraZeneca

**FDA Perspective**
***Richard Lostritto, PhD***
Chemist, CDER, FDA

## Session 205 CP1 - Clinical Safety and Pharmacovigilance, CDM, ST

8:30 am-10:00 am LEVEL: ●

Marriott Salon G *CME, Nursing, and Pharmacy credits offered*

### Use of Patient and Drug Registries for Safety Monitoring and Assessment

Session Chairperson

***Gerald A. Faich, MD, MPH***

Senior Vice President, Epidemiology and Risk Management, United Biosource Corporation

Registries are increasingly being used. There are differing definitions as to what constitutes a registry, how to conduct a registry, and the utility of registries. This session will address these issues.

**Establishing Efficient and Effective Processes in a Safety Surveillance Registry**

***Annette Stemhagen, DrPH, MPH***

Vice President, Epidemiology and Risk Management, United Biosource Corporation

**Developing Registries for Postmarketing Risk Assessment: Successes and Challenges**

***Deborah Covington, DrPH, MS***

Director, Registries and Epidemiology, Charles River Laboratories

**Experiences with Registries: Lessons Learned**

***Carmen Bozic, MD***

Vice President, Global Head, Drug Safety and Risk Management, Biogen Idec Inc.

## Session 206 CP2 - Clinical Safety and Pharmacovigilance, CDM, EC

8:30 am-10:00 am LEVEL: ■

Marriott Salon H *CME credits offered*

### International Electronic ADR Reporting: The Latest Experience

Session Chairpersons

***William W. Gregory, PhD***

Director, Harmonization Worldwide, Pfizer Inc

***Sabine Brosch, MSc, PhD***

Deputy Head of Sector, Pharmacovigilance and Postauthorization Safety and Efficacy, EMEA, EU

Increasingly, more stakeholders are gaining practical experience in the electronic trading of individual case safety reports (ICSRs) on an expedited basis to support sophisticated pharmacovigilance activities. This includes multiple partner electronic trading, which requires high-fidelity transmission of ICSRs and associated data from a point source to trusted downstream intermediaries and customers. Complexity of these transactions increases with the need for electronic records that demonstrate compliance with reporting timelines and desired message content. Nonexpedited ICSRs are also being transmitted electronically among various trading partners. The role of data standards in this increasingly complex technological and regulatory environment has become more and more important in these business transactions to support interoperability and better understanding of available data.

This session will explore the latest experiences using ICH data standards, and their controlled evolution, in electronic trading of ICSRs from data sourced in the EEA, Japan, and the US. The perspectives presented by regulators and industry will cast a global setting for the panel discussion that will cap this session.

**Electronic Trading: The Changing Landscape Has a Baseline**

***William W. Gregory, PhD***

Director, Harmonization Worldwide, Pfizer Inc

**EMEA Perspectives on Electronic Trading in the EEA**

***Sabine Brosch, MSc, PhD***

Deputy Head of Sector, Pharmacovigilance and Postauthorization Safety and Efficacy, EMEA, EU

**Latest Developments on Electronic Trading with the US FDA**

***Roger A. Goetsch, RPh, PharmD***

Director, Regulatory Affairs, Office of Drug Safety, Division of Surveillance, Research, and Communication Support, CDER, FDA

**East Meets West: Global Perspectives on High-fidelity Data Exchange**

***Teiki Iwaoka, PhD, MS***

Director, Drug Safety Outsourcing Planning, CAC Corporation, Japan

**Panelist**

***Kostas Kidos, MSc***

Senior Director, Clinical and Regulatory Information Services, Merck & Co., Inc.

## Session 207 CR1 - Clinical Research and Development, CTM, ST

8:30 am-10:00 am LEVEL: ■

Marriott Salon AB *CME and Pharmacy credits offered*

### Cutting Time and Cost in Phase 3 Oncology Drug Development by Innovative Designs

Session Chairperson

***Jonathan R. Smith, PhD, MSc***

Vice President, Strategic Development, Biostatistics, Quintiles, Inc.

This session will discuss recent developments within innovative study designs which for many compounds (whether cytotoxics, cytostatics, or cancer vaccines) under Phase 3 stage of development in the oncology area provide for the possibility of decreasing the study duration, cutting the costs of such studies, and/or increasing the chance that the studies will be positive.

**Practical Use of Innovative Design Approaches for Phase III Oncology Trials**

***Jonathan R. Smith, PhD, MSc***

Vice President, Strategic Development, Biostatistics, Quintiles, Inc.

**Adaptive Bayesian Designs in Oncology**

***Donald A. Berry, PhD, FACP***

Chair, Biostatistics and Applied Math, The University of Texas M.D. Anderson Cancer Center

## Session 208 CR2 - Clinical Research and Development, CP, RA

8:30 am-10:00 am LEVEL: ●

Marriott Salon IJ *CME credits offered*

### Dos and Don'ts of Data Monitoring Committees

Session Chairperson

***Jonathan Seltzer, MD, MBA***

President and CEO, Applied Clinical Intelligence

After a brief review of current regulatory guidance, topics to be covered will include how to select the proper data monitoring committee (DMC) members, how the DMC should communicate with the sponsor, optimal strategies for timely reporting of safety issues, and the strategic role of DMCs in drug development.

**Statistical Dos and Don'ts of DMCs**
***Janet Wittes, PhD***
President, Statistics Collaborative Inc.

**Operational Dos and Don'ts for DMCs**
***Jonathan Seltzer, MD, MBA***
President and CEO, Applied Clinical Intelligence

**Challenges to a Data Monitoring Committee: A Case Study**
***Frederick Duncanson, MD***
Executive Director, Clinical Operations, DOV Pharmaceuticals

## Session 209 CR3 - Clinical Research and Development, CDM, IT

8:30 am-10:00 am LEVEL: ■

**Marriott Salon E** *CME credits offered*

### Diving into the Details: An Expanded Business Case for Clinical Data Standards

Session Chairperson
***Rebecca D. Kush, PhD***
President, CDISC

Interest in using CDISC clinical data standards is significant and growing. Gartner estimates that data standards, with technology and processes, could save the industry between $5.8 and $6.6 billion dollars annually. Still, many biopharmaceutical companies are stymied in their implementation efforts due to the difficulty in developing a defendable business case for standards. A detailed business case will be presented, including FDA experiences with CDISC standards for eSubmissions.

**Benefits of Industry Standards for Clinical Research and Healthcare**
***Carol Rozwell***
Research Vice President, Life Sciences, Gartner Manufacturing Industry Advisory Services

**The CDISC Business Case**
***Edward D. Helton, PhD***
Chief Strategist, Regulatory and Biomedical Affairs, SAS Institute Inc.

**FDA Perspective on Standards for Regulatory Submissions**
***Stephen E. Wilson, DrPH, CAPT. USPHS***
Director, Office of Business Process Support and Deputy Director, Division of Biometrics II, CDER, FDA

## Session 210 CR4 - Clinical Research and Development, ST

8:30 am-10:00 am LEVEL: ●

**Marriott Salon KL** *CME credits offered*

### Flexible Study Designs: Are We Ready to Adapt?

Session Chairperson
***Amjad Iqbal, PharmD, RPh***
Postdoctoral Fellow, Regulatory Affairs, St. John's University College of Pharmacy and Allied Health Professions, Forest Research Institute

Flexible (adaptive) study designs have the potential to revolutionalize the conduct of clinical trials by allowing for "real-time" data-driven modification of basic study design parameters. Wider dissemination of and dialogue on this concept will be beneficial in understanding its impact to the drug development process. Representatives will be invited from the pharmaceutical industry, FDA, NIH, and academia to provide further insight into this emerging science.

**Strategies for the Use of Adaptive Designs to Increase the Success of the Drug Portfolio**
***Jerald S. Schindler, DrPH***
President, Cytel Pharmaceutical Research

**The Landscape of Adaptive Designs in Drug Development from Thirty Thousand Feet**
***Vladimir Dragalin, PhD***
Senior Director, Research Statistics, Biomedical Data Sciences, GlaxoSmithKline

**Implementation of Adaptive Designs: A Clinical Perspective**
***Michael Krams, MD***
Assistant Vice President, Adaptive Trials, Clinical Development, Wyeth Pharmaceuticals

## Session 211 CTM - Clinical Trial Management, CDM

8:30 am-10:00 am LEVEL: ●

**Room 107AB**

### From Sticky Notes to Wildcard Searches: Adapting Monitoring Techniques to EDC

Session Chairperson
***Denise DeRenzo Lacey, MA, MS***
Associate, Waife & Associates, Inc.

Transitioning from paper to electronic data capture (EDC) is often more difficult on the monitors than it is on the sites. To get the most out of an EDC system, monitors must change from paper-focused, labor-intensive processes to techniques that take advantage of the relational database and associated tools. This session presents case studies of companies who reinvented the monitoring visit and realized the benefits.

**How Monitoring Goals Inform EDC Roles**
***Denise DeRenzo Lacey, MA, MS***
Associate, Waife & Associates, Inc.

**Monitoring in EDC: How Much Change Can We Take?**
***Jens Reinhold, MD***
EDC Implementation Manager, Schering AG, Germany

**Trial or Data Manager: Shifting Roles in EDC**
***Kelly Blackburn, MHA, MEd***
Director, Clinical and Safety Operations, Millennium Pharmaceuticals, Inc.

## Session 212 DM - Document Management/ eSubmissions, IT, RA

8:30 am-10:00 am LEVEL: ●

**Room 204C**

### Delivering Electronic Submissions: Sharing Experiences

Session Chairperson
***Diane L. Cavender***
Associate Director, US Clinical Document Management, AstraZeneca

This session shares experiences and challenges of implementing and supporting a global system and associated processes within a clinical organization and the process challenges within a regulatory operations organization managing the assembling and delivery of regulatory submissions.

**A Global Approach to Clinical Document Management: Sharing Experiences**
***Debbie J. Stanier***
Group Manager, UK Clinical Document Management, AstraZeneca, UK
***Jennica Senneberg***
Group Manager, Sweden Clinical Document Management, AstraZeneca, Sweden

**Successfully Supporting a Global Clinical Document Management User Community**
***Suketu Patel, MS***
Principal Document Management Specialist, AstraZeneca
***Susan Schultz-Rachman, MBA***
Principal Document Management Specialist, AstraZeneca

**Submission Management: Process Challenges**
***Amanda Keller, MS***
Regulatory Operations Specialist, Merck & Co., Inc.

## Session 213 GCP - Good Clinical Practices, CDM, EC

8:30 am-10:00 am LEVEL: ●

**Marriott Salon F** *CME and Pharmacy credits offered*

### Clinical Research and Medical Records in Today's Regulatory Environment

Session Chairperson
***Earl W. Hulihan, MEd***
Vice President, Global Regulatory Affairs and Quality Assurance, Medidata Solutions, Inc.

This session will provide the audience with the opportunity to hear a panel of experts from within the medical, clinical research, and international regulatory communities address current issues surrounding source documentation and data integrity for paper- and electronic-based systems. The panel will focus on medical charting in today's regulatory environment.

**Inspection of (e)Medical Records**
***Helena Van den Dungen, PhD***
Senior Inspector for Clinical Trials, Ministry of Health, Netherlands

**Recognizing Source Data**
***Stanley C. Rogers, MEd***
Vice President, R&D Quality Assurance, Shire Pharmaceuticals

**Source Data from the Clinician Perspective**
***Nelson P. Kopyt, DO***
Clinician

## Session 214 IS - Investigator Sites, CTM

8:30 am-10:00 am LEVEL: ■

**Room 113B** *CME credits offered*

### Matchmaking among Sites, Sponsors and Studies

Session Chairperson
***Eric F. Hayashi, MBA***
President and CEO, LabConnect

The key to most studies' success lies in selecting the right investigative sites. However, very few sponsors utilize reliable site profiling processes. This presentation will summarize challenges incurred within the site selection process and provide suggestions for an improved methodology from both the investigative site and sponsor perspectives.

**Matchmaking among Sites, Sponsors, and Studies: Site Perspective**
***Eric F. Hayashi, MBA***
President and CEO, LabConnect

**Matchmaking among Sites, Sponsors, and Studies: Independent Perspective**
***Mark A. Hovde, MBA***
Senior Vice President, Marketing, Pharsight Corporation

**Matchmaking among Sites, Sponsors, and Studies: Sponsor Perspective**
***Ira C. Spector, MBA***
Vice President, Clinical Development Operations and Vice Chief of Operations, Wyeth Pharmaceuticals

## Session 215 IT - Information Technology, CR, VA

8:30 am-10:00 am LEVEL: ●

**Room 105AB**

### Get It in Writing: The SLA at the Heart of Successful Business Relationships

Session Chairperson
***Ronald S. Waife, MPH***
President, Waife & Associates, Inc.

IT departments, clinical development departments, and clinical software vendors are all interdependent. Over the past two decades, their mutual success and satisfying each other's needs have been strained. One key factor in successful relationships is putting things down in writing, in what are called service level agreements (SLAs). This session explains why, when, and how to write an effective SLA and what can be expected from them.

**SLAs for Your NDA: Documenting Collaborative Dependencies**
***Ronald S. Waife, MPH***
President, Waife & Associates, Inc.

**Breaking Down Silos among CDM, Clinical and Their Vendors**
***Susan Bornstein, MPH***
Director, Product Management, Serono Inc.

## Session 216 MC - Medical Communications, PP, RA

8:30 am-10:00 am LEVEL: ■

**Room 204A**

### Real-world Perspectives on Risk Management for Independent and Promotional Education Activities: Best Practices and Guidelines for Companies Addressing Separation Guidelines

Session Chairperson
***Peter O. Safir, JD***
Partner, Covington & Burling

This session provides a real-world perspective on the continuum of risk management responses to separation guidelines by companies involved in CME (accredited/nonaccredited providers, pharmaceutical company funding sources). Compliance with regulations clearly is not yet a reality, since regulatory experts and industry thought leaders continue to see inappropriate and ineffective strategies being employed. The panel will provide answers to practical questions, share best practices from pioneering companies, and offer suggestions for adequate compliance with guidelines.

**Expert Insights: Exploring the Strategic Imperatives behind Today's Separation Guidelines**
***Peter O. Safir, JD***
Partner, Covington & Burling

**Experience Speaks: Expectations and Insights on Educational Separation from the Pharmaceutical Perspective**
***Jennifer Spear Smith, PhD, FACME***
Senior Director, Professional Education Support, Wyeth Pharmaceuticals

**Experience Speaks: Lessons on Living the Separation from the Educational Provider's Perspective**
***Susan Torroella***
President and CEO, Columbia MedCom Group

**Incorporating Outcomes Measures, Firewall Policies and Other Trends in Independent Medical Education**
***Douglas A. Young, PhD***
Executive Director, Independent Medical Education and Grants, Bristol-Myers Squibb Company

## Session 217 MW - Medical/Scientific Writing, RA

8:30 am-10:00 am LEVEL: ■

**Room 204B**

### Building the eCTD Starting with the IND: Clinical Documents

Session Chairperson
***Victoria E. Seidenberger***
Director, Training Quality and Compliance, Wyeth Research

This session will present strategies for planning the eCTD from the IND and planning differently for the presubmission packages.

**Starting Module 5 Assembly with the IND**
***Henry W. Founds, MS, PhD***
Senior Director, Toxicology and Regulatory Affairs, Immunomedics, Inc.

**eIND: Whether to Choose the Road Less Traveled**
***Susan J. Galle, MS***
Executive Director, Regulatory Strategies, SCIREX Corporation

## Session 218 NHP - Natural Health Products, RA

8:30 am-10:00 am LEVEL: ■

**Room 106AB** *CME credits offered*

### Updates on Natural Health Products: European Union

Session Chairperson
***Konstantin Keller, PhD***
Director and Professor, Federal Ministry of Health and Social Security, Germany

This session will present an update of the European Union system of natural health products.

**Updates on the European Union**
***Konstantin Keller, PhD***
Director and Professor, Federal Ministry of Health and Social Security, Germany

**Industry Expectations Concerning Herbal (Medicinal) Products in the European Union**
***Hubertus Cranz, PhD, PharmD, MS***
Director-General, Association of the European Self-medication Industry (AESGP), Belgium

**Natural Health Products: Division between Foods and Medicines**
***Arnold J. Vlietinck***
University of Antwerp, Belgium

## Session 219 OS - Outsourcing, IT

8:30 am-10:00 am LEVEL: ●

**Room 109AB**

### Configurable IVR Systems: What You Should Know

Session Chairperson
***Marisa L. Ehinger***
Director, New Products and Services, ICTI

Pharmaceutical and biotechnology companies are continually searching for ways to decrease cost and development time for clinical trials and are looking to reconfigurable clinical trial support systems to facilitate this. It takes more than just "reusing software code" to achieve the payoff of a configurable system. You will need to have a sound system architecture, flexible database design and committed business partners, plus the ability to see three years into the future.

**Configurable IVR Systems: Will They Pay Off?**
***Marisa L. Ehinger***
Director, New Products and Services, ICTI

**Re-configurable IVR Systems: One Pharmaceutical Company's Perspective**
***Jean M. Norton, MS***
Associate Director of Randomization and IVRS, Clinical Supply Operations, Bristol-Myers Squibb Company

**Quality by Design: Designing, Implementing and Managing Electronic Configurable Services**
***Michael James Thompson***
Senior Manager, Planning and Technical Services, Amgen Inc.

## Session 220 PM1 - Project Management, RA

8:30 am-10:00 am LEVEL: ■

**Room 108A** *Project Management Institute credits offered*

### Successful Intercultural Communication in Drug Development: More than a Time Zone Issue

Session Chairpersons
***Carolyn H. Kruse, MSc***
President, Kruse Consulting Group, Inc.
***Atsushi Tsukamoto, MSc, PMP***
Senior Project Manager, Sankyo Pharma R&D Headquarters, Japan

Communication is considered to be one of the most important skills, if not the most important one, in project management. Good managers spend up to 90 percent of their time communicating with others. Since communication facilitates the process of generation, collection, dissemination, storage, and disposition of project information, timely and appropriate communication is critical for project success. In global development, however, people often find difficulty in communicating due to differences in communication style, language, knowledge, and inherited practices. Much of this is influenced by their cultural backgrounds. This session will begin with an overview of the general pitfalls in communication among people from the US, Europe, and Japan, the underlying cultural and language aspects, followed by presentations of case studies and solutions from the perspective of Western and Japanese pharmaceutical companies.

**Communicating across Cultures: Pitfalls and Solutions**
***Marshall Hewitt***
Managing Director, Head of Intercultural Programs, World Learning for Business

**Sharing the Context and Sharing the Facts: How Much Can You Handle?**
***Craig Alan Davenport, RPh***
Managing Director, Drug Development, Eli Lilly Japan K.K., Japan

**Our Experience on Ways to Avoid Unnecessary Miscommunication between Japan and the US in Intercountry Development Processes**
***Atsushi Tsukamoto, MSc, PMP***
Senior Project Manager, Sankyo Pharma R&D Headquarters, Japan

## Session 221 PM2 - Project Management, BT, RD

8:30 am-10:00 am LEVEL: ●

**Room 108B** *Project Management Institute credits offered*

### Case Studies in Project Management of Performance Improvement Projects: The Spectrum of Success through Agony

Session Chairperson
***Glen Potvin, MBA***
Principal, Splash Consulting

Key learning points have been distilled from over 15 years of managing projects with leading pharmaceutical firms across manufacturing, clinical development, regulatory, quality, labeling, and drug safety.

Practical case presentations will be presented and discussed with panel members and the audience toward achieving consensus on elements of successful project management.

**Studies in Project Management: The Sponsor's Perspective**
***Mary Ellen Turner, MD, MPH***
Vice President, Risk Management, Wyeth Pharmaceuticals

**Studies in Project Management: The Project Team Leader's Perspective**
***Carol Zapapas, MBA***
Manager, Clinical Operations for Acute Care and Oncology, Eli Lilly and Company

## Session 222 PP - Public Policy/Law, CR, RD

8:30 am-10:00 am LEVEL: ●

**Room 114** Auditorium

### Clinical Trial Registration and Transparency of Trial Results

Session Chairperson
***Juhana E. Idänpään-Heikkilä, MD, PhD***
Professor; Secretary-General, Council for International Organizations of Medical Sciences (CIOMS), c/o World Health Organization, Switzerland

Requests that results of clinical trials be made publicly available have inspired governmental institutions, WHO, industry associations, and companies to set up registries. The panel for this session will review the progress made and consider completeness, usefulness and quality of data, and access to and transparency of the registries.

**Panelists**

***Nicholas Ide, MS***
Chief Architect, ClinicalTrials.gov, US National Library of Medicine

***Caroline Loew, MD***
Vice President, Scientific and Regulatory Affairs, PhRMA

***Robert J. Temple, MD***
Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

***John Hoey, MD***
Former Editor, *The Canadian Medical Association Journal*

***Yves M. Juillet, MD, PhD***
Senior Advisor, LEEM (Pharmaceutical Industry Association), France

## Session 223 RA1 - Regulatory Affairs, PP

8:30 am-10:00 am LEVEL: ●

**Room 201B**

### Combination Products: A Primer

Session Chairperson
***Breffni K. Martin***
Director, CanReg (Europe) Ltd., Ireland

This session will discuss how to register a combination product worldwide with an emphasis on the device regulations.

**Gaining Worldwide Registration of a Combination Product**
***Patricia R. Anderson, RAC (EU)***
Vice President, Regulatory Services, CanReg Inc., Canada

**Combination Product Development: FDA Regulatory Perspectives**
***Patricia Y. Love, MD, MBA***
Associate Director, Office of Combination Products, Office of the Commissioner, FDA

**Combination Products: The Canadian Perspective**
***Agnes V. Klein, MD, MPH***
Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Canada

## Session 224 RA2 - Regulatory Affairs, DM, EC

8:30 am-10:00 am LEVEL: ●

**Room 202AB**

### Faster, Superior, More Cost Effective: Has the eCTD Delivered Its Promises?

Session Chairperson
***Olaf Schoepke***
Senior Consultant, Lorenz Life Sciences, Germany

With the electronic Common Technical Document (eCTD), electronic submissions are now reality. A transport format has been defined, but can it actually deliver marketing applications faster, in better quality and be more cost-effective to the benefit of our patients?

**Impact of eCTD on the Business Process**
***S. Albert Edwards, PharmD***
Director, Regulatory Affairs Operations, TAP Pharmaceutical Products

**Moving from Paper to Electronic Processes within an Agency**
***Caroline Auriche***
Clinical Assessor, AFSSAPS, France

**Keeping Up with Ever-changing Regulations in All Regions**
***Sven Harmsen***
Manager, Document Management System, Astellas Pharma GmbH, Germany

## Session 225 RA3 - Regulatory Affairs, CR

8:30 am-10:00 am **LEVEL:** ■

**Room 201A**

### Regulatory Update from China

Session Chairpersons

***Wenzuo Chang***

Director General, Department of International Cooperation, State Food and Drug Administration (SFDA), Peoples' Republic of China

***Ling Su, PhD, MS***

Medical and Pharma Development Director, Shanghai Roche Pharmaceuticals Ltd., Peoples' Republic of China

In this session, regulatory and industry speakers will present and discuss technical requirements for and the process of drug evaluation in China and GLP regulatory initiatives.

**Process of Drug Evaluation in China**

***Xianglin Zhang***

Director, Center for Drug Evaluation, State Food and Drug Administration (SFDA), Peoples' Republic of China

**Principles of Evaluation in Innovative Medicines**

***Dr. Ying Shao***

Head, Review Division III, Center for Drug Evaluation, State Food and Drug Administration (SFDA), Peoples' Republic of China

**Update on GLP Regulations in China**

***Wenya Wang, PhD***

Department of Drug Safety and Supervision, State Food and Drug Administration (SFDA), Peoples' Republic of China

## Session 226 RA4 - Regulatory Affairs, BT

8:30 am-10:00 am **LEVEL:** ●

**Room 201C** *CME and Pharmacy credits offered*

### CBER Hot Topics: Vaccine Safety

Session Chairperson

***Mary A. Foulkes, PhD***

Director, Office of Biostatistics and Epidemiology, CBER, FDA

The safety of products often provided to healthy individuals for the purpose of disease prevention is a paramount consideration. The overall risk:benefit ratio for vaccines continues to be favorable. In order to continue to assure the safety of vaccines, the evaluation of new vaccines prior to marketing involves an integrated assessment of the safety profile. Once a vaccine is in general use, post-marketing evaluation involves the utilization of information from a variety of sources. Implications of safety concerns to the vaccine development process will also be discussed.

**Prelicensure Evaluation of Vaccine Safety**

***Amelia Dale Horne, DrPH***

Chief, Vaccine Evaluation Branch, Division of Biostatistics, Office of Biostatistics and Epidemiology, CBER, FDA

**Safety Evaluations in Clinical Development of Vaccines**

***Ivan S.F. Chan, PhD***

Director, Clinical Biostatistics, Merck Research Laboratories

**Postlicensure Evaluation of Vaccine Safety**

***Robert Ball, MD, MPH***

Chief, Vaccine Safety Branch, Division of Epidemiology, CBER, FDA

## Session 227 RD - R&D Strategy, CR, CTM

8:30 am-10:00 am **LEVEL:** ■

**Room 102AB** *Nursing and Pharmacy credits offered*

### Drug Safety in the 21st Century: Convergence with Biomarkers and Diagnostics Catalyzes Modernization

Session Chairperson

***Susan Flood***

Principal Global Strategist, Life Sciences, SAS Institute Inc.

Given the regulatory and industry developments over the past year, there is a compelling drive to uncover safety risks by embracing biomarkers and defining diagnostic tests during clinical R&D. But these aren't your father's biomarkers anymore, and their utilization within the drug development framework and beyond is being redefined. We will investigate how organizations are incorporating these innovative technologies to catalyze change in their traditional drug development programs.

**From Drugs and Tests to Drug-test Co-development: A Paradigm for Personalized Medicine in the 21st Century**

***Felix W. Frueh, PhD***

Associate Director, Genomics, Office of Clinical Pharmacology, CDER, FDA

**Obstacles to Applying Emerging Technologies to Drug Development: Potential Path Forward**

***Richard Deane Hockett, MD***

Senior Clinical Research Physician, Eli Lilly and Company

**Leveraging Biomarkers: How to Inject Molecular Knowledge into the Clinical Development Process**

***Susan Flood***

Principal Global Strategist, Life Sciences, SAS Institute Inc.

## Session 228 ST - Statistics, CR

8:30 am-10:00 am **LEVEL:** ■

**Room 103B** *CME and Pharmacy credits offered*

### Medical Imaging Trials for Classification of Disease: Issues and Challenges

Session Chairpersons

***Mike Welch, PhD***

Associate Director, Division of Biometrics V, Office of Biostatistics, CDER, FDA

***Usha Halemane, MA, MBA***

Executive Director, Corporate Medical Biometrics, Bracco Diagnostics, Inc.

Methods for clinical studies of therapeutic drugs are well established. Key strategies for validating diagnostic imaging drugs and biomarkers, however, remain a significant challenge for the regulatory agencies. In this session, we discuss study designs and statistical procedures that are useful for evaluating diagnostic tests. Emphasis is on problems that arise in confirmatory studies of imaging drugs for use in disease detection and diagnosis.

**Persistent Issues in Analysis of Clinical Trials of Diagnostic Contrast Agents**

***Robert G. Lehr, MS***

Senior Clinical Statistician, Berlex Pharmaceuticals

**Weighted Methods for Sensitivity and Specificity when Multiple Correlated Binary Diagnoses Are Present within Subject**

***John R. Ventre, MS***

Senior Manager, Statistics, GE Healthcare

**Combining Reader Statistics in Imaging Trials**
***Anthony G. Mucci, PhD***
Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, CDER, FDA

## SESSION 229 TR - TRAINING, CR

8:30 am-10:00 am LEVEL: ●

**Room 103C**

### Professional Presence for Clinical Research Professionals

Session Chairperson
***Mary E. Briggs, MS***
Senior Director, Strategic Accounts, Kendle International

In the clinical research world where change is constant, we have to build our relationships rapidly or we get lost in the dust. Professional presence can help you master social skills, high-tech communications, and avoid no-win business situations with grace and savvy. Attend this session and learn how to project confidence, competence, and credibility in the clinical research industry.

**Professional Presence for Clinical Research Professionals**
***Mary E. Briggs, MS***
Senior Director, Strategic Accounts, Kendle International
***Dana Raines***
Senior Manager, R&D Training, Amgen Inc.
***Nancy Muirhead, MPA, MS***
Associate Director, Clinical Development, Pfizer Inc

## SESSION 230 VA - VALIDATION, IT, PP

8:30 am-10:00 am LEVEL: ■

**Room 113C**

### Current Regulatory Computer Validation Issues

Session Chairperson
***Harry C. Huss, MS***
Director, Compliance Policy and Program Support Services, Charles River Laboratories

This session will address three contemporary, high-profile, computer validation-related topics: the current status of 21 CFR Part 11 – the Electronic Records/Signature Rule, a discussion of the PhRMA SAFE (Secure Access For Everyone) program process and objectives, and an explanation of the Sarbanes-Oxley (SOX) regulation and the relationship to computer validation requirements.

**SOX in the Pharmaceutical Industry**
***James J. Bardunias***
Director of Stelex University, Stelex Inc.

**The SAFE Standard and the Adoption of Healthcare IT**
***Tam D. Woodrum, JD, MS***
Senior Director, IT Quality and Compliance, Nektar Therapeutics

**21 CFR Part 11: Where Are We Now?**
***Harry C. Huss, MS***
Director, Compliance Policy and Program Support Services, Charles River Laboratories

## SPECIAL EVENT

7:30 am - 10:00 am

**Room 203AB**

### Student Forum

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

The Student Forum has been designed to provide information of interest to students and an opportunity to provide input to the DIA. The agenda for the Student Forum is as follows:

7:30 am–8:15 am
Continental Breakfast for Students

8:15 am-8:30 am
**Welcoming Remarks**
***Theresa Kane Musser***
Executive Director, Development Operations, Rigel Pharmaceuticals, Inc.
President, Drug Information Association
***Cynthia Kirk, PhD, RAC***
Global Vice President, Regulatory Affairs, PRA International
President Elect, Drug Information Association

8:30 am-9:00 am
**Perspectives on Career Choices and Employment Opportunities in Clinical Research**
***Joan A. Kroll-Chambers***
Director of Strategic Marketing and Development, The Tufts Center for the Study of Drug Development, Tufts University

9:00 am-9:30 am
**Evolving Degree Programs for Professional Development**
***Dan Benau, PhD***
Associate Professor of Biomedical Writing, University of the Sciences, Philadelphia

9:30 am-10:00 am
**Roundtable/Panel Discussion**
Role of Students in the DIA

*Student Forum concludes at 10:00 am.*

10:00 am-10:30 am **REFRESHMENT BREAK**
**Exhibit Halls A and B, 2nd Floor, Convention Center**
**Ballroom Foyer, 5th Floor, Marriott Hotel**

## SESSION 231 AD - ADVERTISING, RA

10:30 am-12:00 pm LEVEL: ■

**Room 111AB**

### Public Relations

Session Chairperson
***Lucy Rose, MBA, PA-C***
President, Lucy Rose and Associates

Public relations is an integral feature of marketing and corporate programs, and are subject to FDA regulation as well as scrutiny from other government agencies. This session will discuss the regulatory aspects of PR – how does the government regulate it, and what should companies, legal and regulatory counsel and PR agencies be focused on as they manage PR for products and companies.

**Regulatory Spotlight on DTC PR: Update and Perspective from a PR Professional**
***Ilyssa Levins***
President, HCIL Consulting

**Regulatory View of PR Activities**
***Glenn N. Byrd, MBA, RAC***
Director, Regulatory Affairs, PDL BioPharma, Inc

**A New Approach to the Review of Public Affairs Activities**
***Paul James Savidge, JD***
Vice President, Global Labeling and Promotion Compliance, Bristol-Myers Squibb Company

## Session 232 BT - Biotechnology, CR, RA

10:30 am-12:00 pm LEVEL: ■

Room 103A

### Biosimilars in Europe: A Dawning Reality

Session Chairperson
***Cecil Nick, MSc***
Director, PAREXEL Consulting, UK

The CHMP have issued draft guidelines for public comment covering the development of four biosimilar products – insulin, somatropin, G-CSF, and erythropoetin. These guidelines promise to be helpful but there are still many issues to be clarified. This session explores how to optimize clinical development of biosimilars in the EU.

**Challenges in Developing an Acceptable Quality, Nonclinical and Clinical Data Package**
***Cecil Nick, MSc***
Director, PAREXEL Consulting, UK

**Allaying Immunogenicity Concerns**
***Paul D. Chamberlain, PhD***
Director, Biopharmaceuticals, Drug Development Program, MDS Pharma Services, France

**Biosimilars: Risk Management Postmarketing**
***Adrian P. Thomas, MD, FRACP***
Vice President, Benefit-risk Management, Johnson & Johnson Pharmaceutical Research and Development

**Risk Management Case Studies**
***Colin D'Cunha, MBBS, MHSc, FRCPC***
Director, Global Pharmacovigilance, Apotex Inc., Canada

## Session 233 CDM - Clinical Data Management, EC, IT

10:30 am-12:00 pm LEVEL: ●

Marriott Salon CD

### Evolution of Standards: Opportunities, Benefits and Challenges

Session Chairperson
***David A. Olagunju, MS***
Global Director, Oncology Statistical Reporting, Novartis Pharmaceuticals Corporation

The evolution of standards has become reality with the FDA endorsement of the Study Data Tabulation Model (SDTM) and more than a dozen external standards organizations committed to promoting standards as tools of enhancing efficiency, productivity, data submissions, and data quality. This session will provide an overview of external standards, benefits, and challenges of implementing standards.

**Overview of External Standards**
***Isabelle Marie de Zegher, MD, MSc***
Global Head, Account Management CD&MA, Novartis Pharma AG, Switzerland

**Benefits of Standards**
***Jules T. Mitchel, PhD, MBA, MS***
President, Target Health Inc.

**Challenges of Standardizations**
***Terry Katz, MS, CQE***
Senior Director, Biostatistics and Data Management, ImClone Systems, Inc.

## Session 234 CMC - Chemistry, Manufacturing, and Controls, RA, TR

10:30 am-12:00 pm LEVEL: ■

Room 112AB

### Postapproval CMC Changes in the New Paradigm

Session Chairperson
***Eric P. Duffy, PhD***
Director, Division of Postmarketing Evaluation, Office of New Drug Quality Assessment, CDER, FDA

This session will discuss how to assess postapproval changes in the new paradigm.

**FDA Perspective**
***Eric P. Duffy, PhD***
Director, Division of Postmarketing Evaluation, Office of New Drug Quality Assessment, CDER, FDA

**Industry Perspective**
***Leo Lucisano, RPh***
Director, North America Postapproval CMC Regulatory Affairs, GlaxoSmithKline

## Session 235 CP - Clinical Safety and Pharmacovigilance, GCP, RA

10:30 am-12:00 pm LEVEL: ■

Marriott Salon G *CME, Nursing, and Pharmacy credits offered*

### Good Pharmacovigilance Practice: What Does It Mean?

Session Chairpersons
***Monika M. Pietrek, PhD, MD, MSc***
Executive Vice President, Global Scientific and Medical Affairs, PRA International, Germany
***Dr. June Raine***
Director, Division of Vigilance Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Recent legislation and litigation reflect the change in emphasis of pharmacovigilance, focusing on good pharmacovigilance practices (GPvP). While FDA has provided a detailed guidance on GPvP, most other regulators have not. This session will review the effect of global GPvP on pharmacovigilance operations now and in the future to meet regulatory, legal and pharmaceutical company challenges.

**Interpretation of Good Pharmacovigilance Practices from the European Regulatory Perspective**
***Xavier Kurz, MD, PhD***
Scientific Administrator, EMEA, EU

**Practical Experience of Good Pharmacovigilance Practices in the US**
***Steve T. Jolley, MA***
Vice President, Pharmacovigilance, Taratec Development Corporation

**Industry Needs for Good Pharmacovigilance Practices from a Global Perspective**
***Andrzej Czarnecki, MD, PhD, DSc***
Director, Deputy EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

## Session 236 CR1 - Clinical Research and Development, RA, ST

10:30 am-12:00 pm LEVEL: ■

Marriott Salon E *CME credits offered*

### Strategic Oncology Clinical Program Design: Addressing Global Needs

Session Chairperson
***Albert L. Kraus, PhD, MS***
Vice President, Regulatory Affairs, Kosan Biosciences

Divergent medical and regulatory realities in different world regions impact oncology clinical trial/program choices and registrational acceptability. This session will provide an overview of key areas of regional divergence, discuss key risks of alternate trial design choices, and discuss registrational implications of these choices in various world regions.

**Global Oncology Clinical Registrational Program and Trial Design: Clinical Considerations and Issues**
***Rachel Humphrey, MD***
Vice President, Global Development, Bristol-Myers Squibb Company

**Contemporary Oncology Trial Design Considerations: Statistical and Other Design Considerations**
***Kevin Carroll, PhD***
Chief Statistical Expert, AstraZeneca, UK

**Clinical Registrational Oncology Trial and Program Design: FDA Viewpoints and Global Considerations**
***Edwin P. Rock, MD, PhD***
Medical Officer, Division of Drug Oncology Products, Office of New Drugs, CDER, FDA

## Session 237 CR2 - Clinical Research and Development, NC

10:30 am-12:00 pm LEVEL: ■

Marriott Salon AB *CME and Pharmacy credits offered*

### Navigating the Critical Path to Drug Development for Bioterrorist Agents: The Case of Plague and Anthrax

Session Chairperson
***Lewis Schrager, MA, MD***
Lead Medical Officer, Division of Counterterrorism, Office of Counterterrorism and Pediatric Drug Development, CDER, FDA

Efforts to develop drug countermeasures against terrorist agents, such as plague and anthrax, are constrained by both ethical and practical considerations. This panel will describe nonhuman primate animal models of pneumonic plague and inhalational anthrax that may prove critical in evaluating the efficacy of interventions for these diseases under the Animal Rule (21 CFR 314 Subpart I).

**Antimicrobial Efficacy in an African Green Monkey Model of Pneumonic Plague**
***Lewis Schrager, MA, MD***
Lead Medical Officer, Division of Counterterrorism, Office of Counterterrorism and Pediatric Drug Development, CDER, FDA

**Pharmacokinetic Studies of Antimicrobials in an African Green Monkey Model of Pneumonic Plague: Important Considerations under the Animal Rule**
***Francis R. Pelsor, PharmD, MS***
Pharmacologist, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, FDA

**Development of an African Green Monkey Model of Anthrax Disease: Addressing an Important Obstacle to the Development of Anthrax Interventions under the Animal Rule**
***M. Louise Pitt, PhD***
Director, Center for Aerobiological Sciences, US Army Medical Institute of Infectious Diseases

## Session 238 CR3 - Clinical Research and Development, RA

10:30 am-12:00 pm LEVEL: ●

Marriott Salon IJ *CME and Pharmacy credits offered*

### Orphan Drug Development: Past, Present, Future

Session Chairperson
***Edward D. Purich, PhD, MS, RPh***
President/CEO, ChiRhoClin, Inc.

This session will provide an update on the current status of the Orphan Drug Initiative and how it continues to be implemented by the Food and Drug Administration and industrial sponsors.

**Survey of the Orphan Drug Program**
***Christopher P. Milne, DVM, MPH, JD***
Assistant Director, Tufts Center for the Study of Drug Development, Tufts University

**FDA Orphan Drug Perspective**
***Marlene E. Haffner, MD, MPH***
Director, Office of Orphan Products Development, Office of the Commissioner, Rear Admiral, USPHS, FDA

**Experiences of a Small Company Sponsor**
***Edward D. Purich, PhD, MS, RPh***
President/CEO, ChiRhoClin, Inc.

**Experience of a Large Company Sponsor**
***Bradley J. Glasscock, PharmD***
Senior Manager, Regulatory Affairs, Amgen Inc.

## Session 239 CR4 - Clinical Research and Development, CTM, RA

10:30 am-12:00 pm LEVEL: ●

Marriott Salon KL *CME credits offered*

### Asian Clinical Trials ... and Tribulations

Session Chairperson
***Vis Niranjan, MD***
President, RxMD Private Limited, India

Change is a constant in emerging clinical trial destinations. In this session, regulators/experts will outline the current clinical trial application process in India and China; review the FDA's oversight/inspection experience and interactions with regulatory authorities in these countries and elsewhere in Asia; and review recent international GCP initiatives. Sponsors will share their strategies for successful recruitment and study conduct.

**Indian Clinical Trials**
***Ashwini Kumar, MPharm***
Drugs Controller General of India, Central Drugs Standard Control Organization, India

**FDA Requirements and Experiences in Asian Clinical Trials**
***David A. Lepay, MD, PhD***
Senior Advisor for Clinical Science and Director, GCP Programs, Office of Science and Health Coordination, Office of the Commissioner, FDA

**Clinical Trials in China and the Far East**
***Ling Su, PhD, MS***
Medical and Pharma Development Director, Shanghai Roche Pharmaceuticals Ltd., Peoples' Republic of China

## Session 240 CTM - Clinical Trial Management, CR

10:30 am-12:00 pm LEVEL: ●

**Room 107AB** *Pharmacy credits offered*

### Best Practices for Contracting and Working with Imaging Core Labs

Session Chairperson
***Terri A. Binder, MS, DMD, PhD***
Medical Imaging Manager, Amgen Inc.

This is an interactive panel presentation using case scenarios to illustrate when, why, and how to make the best use of imaging core labs to independently assess clinical trial endpoints. Take advantage of an opportunity to learn tips and best practices from representatives of several imaging core labs and sponsor companies, and also to share your experiences with the speakers and audience.

**Panelists**

***James P. Golando***
Vice President, Clinical Operations and Sponsor Relations, RadPharm, Inc.

***Dawn E. Flitcraft, CNMT, RDMS***
Vice President, Client Services, Bio-Imaging Technologies, Inc.

***Ted Gastineau***
Chief Executive Officer, Beacon BioScience

***Craig H. Lipset, MPH***
Senior Program Director, Oncology, Compound Therapeutics, Inc.

## Session 241 DM - Document Management/ eSubmissions, MW, RA

10:30 am-12:00 pm LEVEL: ●

**Room 204C**

### Global CTD/eCTD

Session Chairperson
***Daniel F. Orfe, MS***
Associate Director, Worldwide Regulatory Operations, Merck & Co., Inc.

This session will provide insights into how industry sponsors are meeting the challenge of producing eCTDs for delivery to various regulatory agencies. The technical, process, organizational, and regulatory obstacles faced by industry to reach this goal will be discussed along with the projected benefits associated with eCTD submission. Some specifics covered will include problems with regional process harmonization, simultaneous eCTD release strategies, and EMEA eCTD specification considerations.

**Global eCTD Filings: Implications for Small- and Mid-sized Companies**
***Ted Hanebach***
Director, CanReg Inc., Canada

**Providing MAAs and Responses to Questions to EMEA in eCTD Format**
***John W. Aitken, PhD***
Senior Director, Regulatory Operations, Elan Pharmaceuticals

**Challenges and Rewards: Global Simultaneous Release of eCTDs**
***Daniel F. Orfe, MS***
Associate Director, Worldwide Regulatory Operations, Merck & Co., Inc.

## Session 242 EC - eClinical, CTM, IT

10:30 am-12:00 pm LEVEL: ■

**Marriott Salon H**

### Future Directions in Clinical Trial Management

Session Chairperson
***Charles E. Barr, MD, MPH***
Director, Medical Data Analytics, Roche Laboratories Inc.

This session will explore the current status and future directions in clinical trial management, including: the value of standards (e.g., CDISC) which enable linkage of technology and tools into an integrated electronic trial environment, the use of shared frameworks (e.g., ADaM and BRIDG) for specification of statistical analysis planning and reporting, and the value of open architecture for end-to-end solutions of the clinical trial process. This session will present specific examples of standards and tools and their integration in cost-effective solutions to the challenges of clinical trial activities.

**The Holy Grail – Protocol to Submission: A Fully Electronic Trial Environment**
***Ed Seguine, MBA***
CEO, Fast Track Systems, Inc.

**Future Standards-based Tools in Drug Evaluation: Tool Specification**
***Joel Hoffman, PhD***
Vice President, Pharmaceutical Practice, Intrasphere Technologies

**A Standards-based eClinical Framework for Improved Trial Management**
***Robert Hayden, MS***
Enterprise Architect, Hewlett-Packard Company

## Session 243 GCP - Good Clinical Practices, CR, IS

10:30 am-12:00 pm LEVEL: ■

**Marriott Salon F** *CME credits offered*

### GCP Compliance at the Investigative Site and Beyond

Session Chairperson
***Yvonne P. McCracken, MPH, CCRC***
President and CEO, Carolinas Research Associates

The planning and organization of the study can affect the quality of the data collected and the acceptability of the clinical data by the regulatory agency. Understanding these issues can help to minimize the risk and reduce the exposure for both the sponsor and the investigator. This session will consider current compliance issues that plague clinical trials and the methods used to identify them. A case study of a site management organization (SMO) needs analysis will be discussed, outlining the steps taken to establish an effective compliance program while maintaining a cost-effective site.

**GCP Compliance at Clinical Sites: GCP Experience Examples**
***Michael R. Hamrell, PhD, RAC***
President, MORIAH Consultants

**SMOs: Setting the Standard for Compliance**
***Mark L. Lacy***
President and CEO, Benchmark Research

## Session 244 IMP - Impact, EC

10:30 am-12:00 pm LEVEL: ●

**Room 203AB** *CME, Nursing, and Pharmacy credits offered*

### Electronic Medical Record (EMR)-based Disease Management

Session Chairperson
***Michael Lieberman, MD, MS***
Director of Informatics, Physician Office, GE Healthcare

The electronic medical record (EMR) has been widely touted as an essential tool to improve the quality of medical care. We will explore how the EMR can be used to implement disease management programs. We will also review a lipid management program that has been implemented throughout the United States.

**Assessing the Impact of EMR-based Disease Management**
***James M. Gill, MD, MPH***
Principal, Delaware Valley Outcomes Research

**A Pharmaceutical Company Perspective on EMR-based Disease Management**
***Michael J. McNally***
Director, eBusiness Strategies and Solutions, Merck & Co., Inc.

**Use of EMRs to Enhance Clinical Trial Recruitment**
***Peter J. Embi, MD, MS***
Assistant Professor of Medicine, University of Cincinnati Medical Center

## Session 245 IS - Investigator Sites, CTM

10:30 am-12:00 pm LEVEL: ■

**Room 113B** *CME and Pharmacy credits offered*

### Recruitment and Retention: The Potential Subject's Perspective – What Works, What Doesn't, and Why

Session Chairperson
***Christine K. Pierre, RN***
President and CEO, Rx Trials Inc.

This presentation will explore the key elements that were learned during a recently completed research project and provide compelling statistics to suggest there are more effective methods in recruiting and retaining subjects then we are currently utilizing and at a reasonable cost.

**Patient Recruitment and Retention: What Works, What Doesn't, and Why**
***Christine K. Pierre, RN***
President and CEO, Rx Trials Inc.

**Trends and Insights into Patient Recruitment and Retention**
***Joan A. Kroll-Chambers***
Director of Strategic Marketing and Development, The Tufts Center for the Study of Drug Development, Tufts University

## Session 246 IT - Information Technology, CDM, CR

10:30 am-12:00 pm LEVEL: ■

**Room 105AB**

### Combining EHR and EDC: Finding the Right IT Architecture

Session Chairperson
***Paul A. Bleicher, PhD, MD***
Chairman and Founder, Phase Forward

As electronic data capture (EDC) becomes mainstream in clinical research, many are turning their attention to the possibility of a direct link between electronic health records (EHR) and EDC. This would eliminate redundant data entry at the site and transcription errors, and would reduce resource costs at both the site and sponsor. However, there are many complexities from a technical, logistic, regulatory, and practical perspective for each. This session will present an overview of various issues raised by EHR/EDC integration, followed by a panel of EHR, EDC, and pharmaceutical stakeholders with different views on this topic, moderated by a consultant with expertise in the area.

**Moderator**

***Michael J. Barrett, JD***
Managing Partner, Critical Mass Consulting

**Panelists**

***Barbara E. Tardiff, MD, MS, MPhil, MBA***
Executive Director, Merck & Co., Inc.

***Hugh Donovan***
General Manager, Clinical Trials Business, Siemens Medical Solutions Health Services Corp.

***Landen Bain***
CDISC Liaison to Healthcare; Independent Consultant

***Paul A. Bleicher, PhD, MD***
Chairman and Founder, Phase Forward

## Session 247 MC - Medical Communications, MA

10:30 am-12:00 pm LEVEL: ●

**Room 204A**

### The Perils and Pitfalls of Creating a Medical Science Liaison Department

Session Chairperson
***Robin L. Winter-Sperry, MD***
President, Scientific Advantage, LLC

There are essential elements that need to be encompassed in the building and refining of medical liaison departments. A medical science liaison (MSL) team can bring a company to the leading edge of science or the FDA's sword. This session will describe how to create a dynamic MSL organization as well as how to navigate in the crossfire between corporate objectives and appropriate clinical opportunities.

**Inside the World of an MSL: Training and Lifelines of Communication**
***Susan McGaurn, PharmD***
Director, Medical Science Liaisons, Cephalon, Inc.

**MSL Team Structure and Going Global**
***Mario F. Sylvestri, PharmD, PhD***
Senior Director, Regulatory and Medical Information, Amylin Pharmaceuticals, Inc.

**Demonstrating Value: Internal Marketing and "Sales" of MSLs**
***Robin L. Winter-Sperry, MD***
President, Scientific Advantage, LLC

## Session 248 MW - Medical/Scientific Writing, NC

10:30 am-12:00 pm LEVEL: ■

**Room 204B**

### Authoring Nonclinical Study Reports

Session Chairperson
***Lori A. Thomae, ELS***
President, LAB Communications Inc.

Authoring nonclinical study reports is often a key requirement for research scientists who work in drug discovery. Few, however, have professional experience or formal training in writing. This session presents the key aspects of writing reports and defines the format requirements for regulatory review to save time, costs, and rework of noncompliant reports.

**Authoring Nonclinical Study Reports**
***Lori A. Thomae, ELS***
President, LAB Communications Inc.

**Preclinical Research: The Pathway towards Clinical Trials**
***Anneli Savinainen***
Scientist, Resolvyx Pharmaceuticals

**CTD Safety Overview: Format and Content**
***Klaus Olejniczak, DVM, FACP***
Preclinical Assessor, BfArM, Germany

## Session 249 NHP - Natural Health Products, AHC, CR, RD

10:30 am-12:00 pm **LEVEL:** ■

**Room 106AB** *CME and Pharmacy credits offered*

### Natural Health Products Research and Development: Challenges and Controversies

Session Chairperson
***Carmen Tamayo, MD***
DIA NHP SIAC Chair; Director, Research and Development, Flora, Inc.

Worldwide, the natural health products (NHP) industry has been expanding its efforts to enhance credibility and acceptance of its products by mainstream healthcare. In order to succeed, R&D departments must not only address the quality and consistency of complex NHPs, but also whether conventional clinical trial modalities can produce meaningful data for this product class and how to gather and use data using the Internet to inform research programs and product development.

How and where to disseminate NHP research results has brought into question whether the current array of journals and peer-review systems are adequate or prepared to address the needs of this burgeoning new area of product development.

These and other issues challenging the NHP development community will be discussed in this session. Three presentations will tackle some of the challenges and opportunities for innovation in the R&D and publication processes:

**Importance of Characterizing Test Articles in Natural Health Product Clinical Trials**
***Joseph M. Betz, PhD***
Director, Dietary Supplements Methods and Reference Materials Program, National Institutes of Health

**Research and Development of Natural Health Products in the XXI Century: It Is Time for Innovation**
***Alejandro "Alex" Jadad, MD, PhD, FRCPC***
Director, Centre for Global eHealth Innovation, University Health Network, University of Toronto, Canada

**Facilitating a True Review by Peers**
***Anna Marie C. McSorley, RN***
Six Sigma Black Belt, i3 Research

## Session 250 OS - Outsourcing, CR

10:30 am-12:00 pm **LEVEL:** ■

**Room 109AB** *Pharmacy credits offered*

### The Sponsor-CRO Partnership: How Is Outsourcing Affecting Drug Development?

Session Chairperson
***Douglas J. Peddicord, PhD***
Executive Director, Association of Clinical Organizations (ACRO)

In this session, industry experts and analysts will discuss the use of clinical outsourcing to strategically manage clinical trials in the biomedical product development process. By examining current opinions from industry leaders and trends in outsourcing, the session panel will discuss the benefits and challenges of outsourcing in successfully managing today's clinical trials.

**Quantifying CRO Contribution to Development Speed and Quality**
***Kenneth A. Getz, MS, MBA***
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

**The Evolution of Outsourcing: How Will CROs Continue to Impact Drug Development?**
***Sean Russell***
Vice President, Corporate Marketing, Quintiles Transnational

**The Sponsor/CRO Partnership**
***Lorraine Waring***
Senior Director, Contracts and Outsourcing, Pfizer Global Research & Development

## Session 251 PM1 - Project Management, BT, RD

10:30 am-12:00 pm **LEVEL:** ■

**Room 108A** *CME and Project Management Institute credits offered*

### The Target Product Profile (TPP): Uses for the Management of Product Development

Session Chairperson
***David J. Fontana, PhD, PMP***
Vice President, Project Management and Regulatory Affairs, Archemix Corporation

The target product profile (TPP) is generally accepted as a tool for setting the strategic foundation for drug development – "planning with the end in mind." More recently, an expanded use of the TPP in development planning, clinical and commercial decision making, regulatory agency interactions, and risk management has started to evolve. This session will cover the various uses of the TPP as a management tool.

**The Target Product Profile: A Roadmap for Product Development**
***Rajendra Mohabir, PhD***
Oncology Therapeutic Area Head, R&D Project Management, Amgen Inc.

**Using the TPP for Maximizing Regulatory Interactions**
***David J. Fontana, PhD, PMP***
Vice President, Project Management and Regulatory Affairs, Archemix Corporation

**Taking the "T" out of the Target Product Profile: Commercial Utility**
***Barbara Rosengren, MS***
Vice President, Strategic Product Development, Momenta Pharmaceuticals, Inc.

## Session 252 PM2 - Project Management, BT, RD

10:30 am-12:00 pm LEVEL: ●

**Room 108B** *Project Management Institute credits offered*

### What Small Biopharmaceutical Companies Can Teach Big Ones about Project Management

Session Chairperson

***Laurie A. Halloran, MS***

President, Halloran Consulting Group

Small biopharmaceutical companies have become more visible recently because they develop products with a fraction of the resources of large companies. As large pharmaceutical companies struggle with organizing and reorganizing into productive teams, small companies do more with less. This session examines the contribution project management makes to these successes.

**Strategic Planning to Meet Operational Objectives**

***John W. Hadden, II, MBA***

Chief Operating Officer, IRX Therapeutics

**Managing Pharmaceutical Partnerships and Alliances**

***Dennis J. LaCroix, JD***

Senior Director and Senior Counsel, Genzyme Corporation

**Growing Small Companies for Global Programs**

***Scott L. Young, MPH***

Chief Operating Officer, OXiGENE

## Session 253 PP - Public Policy/Law, CR, RA

10:30 am-12:00 pm LEVEL: ●

**Room 114** Auditorium *CME and Pharmacy credits offered*

### The Expandable Universe of the Critical Path: Points to Consider beyond Science; Public Policy Needed to Sustain Critical Path – Part 1 of 2

Session Chairperson

***Chin C. Koerner***

Executive Director, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

*Part 2 of this session will be held on Tuesday at 1:30 pm.*

Even as Critical Path and translational medicine move from concept to action, it is generally recognized that Critical Path must be a long-term investment. Many members of the pharmaceutical industry have stepped up to FDA's call to action, but many more will need to join and sustain the effort for years to come if this innovative initiative is to bring meaningful results. How do we sustain the momentum that has been created? Is now the right time to consider policy issues such as alternative marketing approval paradigms and IP incentives to help sustain the Critical Path?

**Moderator**

***Mathias Hukkelhoven, PhD***

Senior Vice President, Global Head, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

**Panelists**

***Janet Woodcock, MD***

Deputy Commissioner of Operations and Chief Operating Officer, Office of the Commissioner, FDA

***Raymond L. Woosley, MD, PhD***

President, The Critical Path Institute

***John E. (Jack) Calfee, PhD***

Resident Scholar, American Enterprise Institute

***Gillian Woollett, MA, DPhil***

Chief Scientist, Biologics and Biotechnology, Engel and Novitt, LLP

***Schumarry Chao, MD, MBA***

School of Medicine and School of Pharmacy, University of Southern California

## Session 254 RA1 - Regulatory Affairs, RD

10:30 am-12:00 pm LEVEL: ●

**Room 201B**

### Transforming Regulatory Information into Intelligence

Session Chairperson

***Amy N. Grant***

Global Head, Regulatory Information and Intelligence, AstraZeneca

We are flooded with regulatory information every day. What are some techniques for managing, analyzing, and communicating the information in an intelligent, usable manner?

**Challenges and Solutions in Creating a Regulatory Intelligence Function**

***Douglas Sporn, MBA***

Divisional Vice President, Abbott Laboratories

**Standing on the Shoulders of Others: How to Use Tools Available under Freedom of Information Act (FOIA) for Transforming FDA and Related Information into Intelligence without Starting from Scratch**

***Marlene Bobka, MLS***

Vice President, FOI Services, Inc.

**Using Regulatory Information Databases to Create Regulatory Intelligence**

***Meredith Brown Tuttle***

Manager, Regulatory Affairs, PDL BioPharma, Inc.

## Session 255 RA2 - Regulatory Affairs, BT

10:30 am-12:00 pm LEVEL: ●

**Room 201C** *CME and Pharmacy credits offered*

### CBER Hot Topics

Session Chairperson

***Diane Maloney, JD***

Associate Director for Policy, CBER, FDA

This session will highlight two hot topics in CBER. Celia Witten, MD, Director of CBER's Office of Cellular, Tissue and Gene Therapies will discuss cell and gene therapies and Marion Gruber, PhD, Associate Director for Policy in CBER's Office of Vaccine Research and Review, will discuss pandemic influenza vaccines.

**Cell and Gene Therapies**

***Celia M. Witten, MD***

Director, Office of Cellular, Tissue and Gene Therapies, CBER, FDA

**Pandemic Influenza Vaccines**

***Marion F. Gruber, PhD***

Associate Director for Policy, Office of Vaccine Research and Review, CBER, FDA

## Session 256 RA3 - Regulatory Affairs, PP

10:30 am-12:00 pm LEVEL: ■

**Room 201A**

### Hot Topic in Pharmaceutical R&D in China: Intellectual Property

Session Chairpersons

***James Cai***

Vice President, R&D, AstraZeneca Pharmaceutical Co., Ltd., Peoples' Republic of China

***Ling Su, PhD, MS***

Medical and Pharma Development Director, Shanghai Roche Pharmaceuticals Ltd., Peoples' Republic of China

In this session, speakers from the government and the industry will examine and discuss the important issue of intellectual property in China in the context of global drug development.

**The Overview of the Patent Protection for Medical Invention in China**
***Xiyuan Zhao***
Division Director, Bureau of Patents, State Intellectual Property Office, Peoples' Republic of China

**Pharmaceutical Patent Litigation in China**
***Hong Ai, Esq.***
ZY & Partners, Peoples' Republic of China

## Session 257 ST - Statistics, AHC, CR, GCP

10:30 am-12:00 pm **LEVEL:** ■

**Room 103B** *CME and Pharmacy credits offered*

### Data Monitoring Committees

Session Chairperson
***Mary A. Foulkes, PhD***
Director, Office of Biostatistics and Epidemiology, CBER, FDA

In March 2006, the Agency, recognizing the important role that sponsors have in monitoring the conduct of clinical trials, issued a draft guidance entitled "Guidance for Clinical Trial Sponsors — Establishment and Operation of Clinical Trial Data Monitoring Committees". The guidance "is intended to assist clinical trial sponsors in determining when Data Monitoring Committees (DMCs) may be useful for study monitoring, and how such committees should operate." Statisticians play important roles as members of DMCs. Presentations in this session will explore and discuss the "hows" and "whys" associated with the experience with the planning and conduct of these committees.

**Data and Safety Monitoring: An NIH Perspective**
***Lawrence M. Friedman, MD***
Consultant; Former Director, Division of Epidemiology and Clinical Applications, National Heart, Lung and Blood Institute, National Institutes of Health

**European Guidance: Why and What?**
***Simon Day, PhD***
Manager, GI, Nutritional and Blood Therapies; Manager, Statistics Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**DMC Issues from a Pharmaceutical Industry Perspective**
***Steven M. Snapinn, PhD***
Senior Director of Biostatistics, Amgen Inc.

**Panelist**
***Susan S. Ellenberg, PhD***
Professor of Biostatistics, Associate Dean for Clinical Research, University of Pennsylvania School of Medicine

## Session 258 TR - Training, CDM, CR

10:30 am-12:00 pm **LEVEL:** ●

**Room 103C**

### A Training Approach: From Basics to Specifics

Session Chairpersons
***Pati Stone***
Principal Consultant, Helios Consulting Services, LLC
***Mark Vieder, RPh***
Medical Coding/Drug Safety, PSI International, Inc.

This session will deal with the development of a training program, taking it from the basics of what the program intends to accomplish within a training program, the obstacles to overcome, as well as the positives that are a part of the training program. From the basics, we will move into the realm of specific job functions and the more detailed training that is needed. Specifically, we will talk about clinical data management and the technical and soft skills that are required in the development of data managers. We will explore the specifics of a training program within a pharmaceutical company. Diversity exists between departments, but the need and the goal of achieving a uniformity as a basis within the company will be shown.

**Mentor-protégé Approach in Training**
***Mark Vieder, RPh***
Medical Coding/Drug Safety, PSI International, Inc.

**Developing a Generic Clinical Data Management T&D Plan**
***Pati Stone***
Principal Consultant, Helios Consulting Services, LLC

**MedDRA® Training: Before and After Implementation**
***Mary S. Joseph***
Associate Director, Wyeth Research

## Session 259 VA - Validation, IT, RA

10:30 am- 12:00 pm **LEVEL:** ●

**Room 113C**

### Delivering Quality Validation Effectively

Session Chairperson
***Breffni K. Martin***
Director, CanReg (Europe) Ltd., Ireland

This session will examine the validation lessons that may be learned from disciplines outside the pharmaceutical industry, particularly in regard to the use of software.

**Model-based Systems Engineering: A Methodology for "X" Systems Validation**
***Stuart T. Booth***
Principal Systems Engineer, Vitech Corporation

**Applications of Engineering Methodology in Other Areas of the Pharmaceutical Industry**
***Cliff Campbell***
Managing Director, Cliff Campbell & Associates Ltd, Ireland

**Increasing Productivity with Self-documenting Systems**
***Glen De Vries, PhD***
Chief Technology Officer, Medidata Solutions, Inc.

12:00 pm-1:30 pm **LUNCHEON**
**Exhibit Hall C, 2nd Floor, Convention Center**

## Session 260 AD - Advertising, RA

1:30 pm-3:00 pm **LEVEL:** ●

**Room 111AB** *Pharmacy credits offered*

### How the New Labeling Rule Changes the Promotional Landscape

Session Chairperson
***Minnie Baylor-Henry, JD, RPh***
Vice President, Medical and Regulatory Affairs, McNeil Consumer & Specialty Pharmaceuticals (J&J)

After years of internal and external debate, FDA has issued the final labeling rule. While this rule addresses issues governing the content and format of the package insert, it also provides a clear picture as to what FDA and the company consider to be important. We must now examine how the "highlights" section will affect promotional materials, public relations messages, and marketing practices in the future.

**General Overview of the Labeling Rule and Possible Impact on Promotion: FDA's Perspective**
***Iris P. Masucci***
Labeling Reviewer, Division of Drug Marketing, Advertising and Communications, CDER, FDA

**Does the Labeling Rule Make Promotional Decisions Easier or More Difficult for Industry?**
***John F. Kamp, JD, PhD***
Executive Director, Coalition for Healthcare Communication

**Overview of a Hypothetical Product with Labeling in the New Format and Proposed Promotional Labeling**
***Minnie Baylor-Henry, JD, RPh***
Vice President, Medical and Regulatory Affairs, McNeil Consumer & Specialty Pharmaceuticals (J&J)

## Session 261 BT - Biotechnology, CR, RA

1:30 pm-3:00 pm LEVEL: ■

Room 103A *CME and Pharmacy credits offered*

### How to Introduce Additional Vaccines during the First Year of Age

Session Chairperson
***Bernard Fritzell, MD***
Vice President, Scientific and Clinical Affairs, Wyeth Vaccines, France

New vaccines still need to be developed; bacterial as well as viral diseases still exist against which no vaccine is available yet. In fact, in order to develop vaccines efficiently to prevent those diseases, new therapies, techniques, or adjuvants have to be used. Other issues, due to the recent development of pediatric vaccines, deal with the co-administration of independent vaccines in babies (safety, efficacy).

**European Requirements for Co-administration of Vaccines**
***Pieter J. H. Neels, MD***
Clinical Assessor, CHMP Member; Directorate General, Medicinal Products, Federal Public Service, Belgium

**Adding New Bacterial Conjugate Vaccines in the Classical Vaccines Priming Schedule**
***Bernard Fritzell, MD***
Vice President, Scientific and Clinical Affairs, Wyeth Vaccines, France

## Session 262 CDM - Clinical Data Management, CR, PM

1:30 pm-3:00 pm LEVEL: ■

Marriott Salon CD

### Global Solutions: Clinical Data Management Offshore

Session Chairperson
***David J. Sabritt***
President, Sabritt Solutions LLC

Clinical data management, like other professional functions, is affected by broader factors in the global workplace, including the growth of offshore business centers. Major American and European companies, for example, have based their data operations at sites in India, China, and elsewhere in Asia. This session will examine case studies in the process and impact of moving clinical data operations offshore, and explore the trend's implications for the organization of clinical development.

**Clinical Data Management and the Cultural Landscape of India's Pharmaceutical and Clinical Research Industry**
***Nailesh A. Bhatt, MS***
Managing Director, Proximare Inc.

**Offshore Data Management: Evaluating the Business Models**
***Surinder Kher, MD***
Chief Executive Officer, Jubilant Clinsys Limited, India

**The Challenges of Globalizing Data Management: A CRO Perspective**
***Paula Brown Stafford, MPH***
Executive Vice President, Global Data Management, Quintiles Transnational Corp.

## Session 263 CMC - Chemistry, Manufacturing, and Controls, TR

1:30 pm-3:00 pm LEVEL: ■

Room 112AB

### Updates on ICH Quality Guidelines Q8, Q9, and Q10

Session Chairperson
***Charles P. Hoiberg, PhD***
Executive Director, Pfizer Inc

This session will discuss the current status and technical issues associated with pending ICH guidelines from a regulatory and an industry perspective.

**Industry Perspective**
***John C. Berridge, PhD***
Vice President, Pharmaceutical Sciences Europe, Pfizer Global Research & Development, UK

**Regulatory Perspective**
***Jean-Louis Robert, PhD***
Head of Unit, Department of Quality Control of Medicines, National Health Laboratory, Luxembourg

## Session 264 CP - Clinical Safety and Pharmacovigilance, CDM, ST

1:30 pm-3:00 pm LEVEL: ●

Marriott Salon G *CME and Pharmacy credits offered*

### International Electronic Adverse Event Databases: Understanding the Differences and Capabilities

Session Chairperson
***Renan A. Bonnel, PharmD, MPH***
Drug Safety Evaluator, Office of Drug Safety, Division of Drug Risk Evaluation, CDER, FDA

Electronic databases containing spontaneous adverse event reports are essential tools for drug safety. Through the recent advances in technology, these databases now have the potential to receive reports, allow electronic exchange of drug safety data, create safety reports, and provide an access to other countries for queries related to drug safety. This session provides an overview of the international spontaneous reporting databases for adverse drug monitoring to achieve global drug safety.

**The WHO Global Database (Vigibase): A Resource for Patient Safety**
***Marie Lindquist, PhD, MSc***
Deputy Director, General Manager, Science and Technology Division, The Uppsala Monitoring Centre, Sweden

**EudraVigilance: A Tool to Support EU Risk Management**
***Sabine Brosch, MSc, PhD***
Deputy Head of Sector, Pharmacovigilance and Postauthorization Safety and Efficacy, EMEA, EU

**Using the FDA's Adverse Event Reporting System (AERS) in Postmarketing Surveillance**
***Joyce P. Weaver, PharmD***
Safety Evaluator, Office of Drug Safety, CDER, FDA

## Session 265 CR1 - Clinical Research and Development, CTM, PM

1:30 pm-3:00 pm **LEVEL:** ■

**Marriott Salon E** *CME, Nursing, and Pharmacy credits offered*

### Cancer Clinical Study Management: Trials and Tribulations

Session Chairperson
***Lee Schacter, MD***
Executive Medical Director, MDS Pharma Services

The organization and management of clinical trials for cancer drugs differ in many ways from studies in other therapeutic areas. The types of patients treated in all phases is quite specific, the toxicity spectrum of most cancer drugs is significantly different from agents used to treat benign disease, and the end points usually include survival. Organizing a cancer trial requires an understanding of how these patients are treated, differences in standards of care between countries and the roles of scientific review boards at academic institutions, and contracting with cooperative groups and academic centers.

**Costing Oncology Projects: Feasibility, Evaluating Timelines, Vendors, Team Selection, Site Management**
***Vito Romita, PhD***
Senior Director, Project Management, MDS Pharma Services

**Operational Differences: Organization and Management/Contract Negotiations/Approval Process/Recruitment/Cooperative Groups/Local Laboratories/Site Management**
***Julienne B. Orr, RPh***
Consultant, MODoc Research Services, Inc.

**Endpoints, Efficacy, and Safety in Oncology Trials**
***Gary Jones, MD***
Director, Medical Development Group - Oncology, Berlex Laboratories

## Session 266 CR2 - Clinical Research and Development, RD

1:30 pm-3:00 pm **LEVEL:** ■

**Marriott Salon KL**

### Springboard Radical Changes in Clinical Development

Session Chairperson
***Ira C. Spector, MBA***
Vice President, Clinical Development Operations, and Vice Chief of Operations, Wyeth Pharmaceuticals

In order to respond to the extreme pressures facing the pharmaceutical industry, Wyeth Research has embarked on a major reorganization and reinvention of the company. All aspects of Wyeth are under scrutiny, and a new model for R&D is being developed. As part of the new model, the Springboard initiative has carefully examined clinical development and has created seven key initiatives for radical change. This presentation will review these seven initiatives, the rationale behind them, and the expected results. Data used to justify each initiative will be presented, and progress to date will be discussed. This is expected to be a significant change in pharmaceutical clinical development with far-reaching implications for the future of the industry.

**Overview of the Springboard Radical Changes in Clinical Development**
***Ira C. Spector, MBA***
Vice President, Clinical Development Operations, and Vice Chief of Operations, Wyeth Pharmaceuticals

**Panelist**
***Larry A. Blankstein, PhD***
Senior Director, Clinical Research, Genzyme Corporation

## Session 267 CR3 - Clinical Research and Development, CTM, IS

1:30 pm-3:00 pm **LEVEL:** ●

**Marriott Salon IJ** *CME and Pharmacy credits offered*

### Clinical Research in Africa – Creating Win/Win Situations: Meeting International Standards while Improving Local Health Care

Session Chairperson
***Maria João Queiroz, PhD***
Executive Director, Eurotrials, SA, Portugal

The ability to perform clinical trials in Africa where HIV, tuberculosis, and malaria are highly prevalent is an urgent need and an opportunity. This can be done by upgrading local health centers, thus contributing to significant improvement in the service provided to the population, while complying with international standards.

Clinical trials in Africa promote the training of local scientists in an environment of excellence, while sustaining the global effort to develop new drugs or therapeutic strategies. In this session, we will discuss the issues involved in conducting clinical research in Africa, analyzing how the different perspectives can be harmonized to create synergies that contribute to addressing a major global health threat.

**The Challenges and Learning Experiences from Setting Up a New Site for a Vaccine Trial in Sub-Saharan Africa: An Industry Perspective**
***Opokua Ofori-Anyinam, PhD***
Manager, Clinical Development, GlaxoSmithKline Biologicals, Belgium

**Clinical Trials in Africa: How to Overcome the Hurdles in Order to Meet the Requirements of Scientific Development**
***Remko van Leeuwen***
Director, Business Development, International Antiviral Therapy Evaluation Centre (IATEC), Netherlands

**Opportunities and Challenges for the Development of Clinical Trials Centers in Africa: The Example of Mozambique**
***Ricardo Thompson, PhD***
Scientific Director, National Institute of Health, Mozambique

## Session 268 CR4 - Clinical Research and Development, RA

1:30 pm-3:00 pm **LEVEL:** ■

**Marriott Salon AB** *CME credits offered*

### Successful EU Clinical Trials: Migrating from FDA Oversight to the EU Clinical Trial Directive

Session Chairperson
***Fabio Marazzi, LLM***
Managing Director, M+Biolaw, Italy

This session will demonstrate how clinical research professionals can successfully bridge the US FDA regulatory statutes and the EU Clinical Trial Directive.

**The Benchmark: FDA Oversight of US Clinical Trials**
***Kate Duffy Mazan, MS, LLB***
Managing Partner, CTTG

**Clinical Research in Europe: The Appeal of 25 Countries under One Directive**
***Pedro Crisanto, PharmD, RPh***
Business Development Manager, Eurotrials, SA, Portugal

**A Case Study: Operational and Business Metrics of a Successful EU Clinical Trial**
***Bonnie A. Brescia***
Founding Principal, BBK Worldwide

## Session 269 CTM - Clinical Trial Management, CR

1:30 pm-3:00 pm LEVEL: ■

**Room 107AB**

### Metrics Champion Consortium: Creating Industry Standard Performance Metrics – Labs, ECGs, CROs

Session Chairperson
***Brian P. Schrock, MBA, MS***
Manager, Diagnostic and Experimental Medicine, Eli Lilly and Company

*New in 2006: Metrics Champion Consortium!!!* The Metrics Champion Consortium mission is to develop and support service provider performance metrics within the biotechnology and pharmaceutical industry with the intent to jointly encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls. Attendees will learn about this important industry initiative, see the first products that have been delivered, and hear about future deliverables underway and planned.

**Metrics Champion Consortium: How to Get Engaged**
***Brian P. Schrock, MBA, MS***
Manager, Diagnostic and Experimental Medicine, Eli Lilly and Company

**Implementing the Performance Metrics for Central Laboratories: Service Provider Perspective**
***James R. Dixon***
Vice President, Global Quality Assurance, Covance Central Laboratory Services

**Kick-off of ECG Performance Metrics Initiatives**
***Nenad Sarapa, MD***
Global Head of Translational Medicine, Daiichi Sankyo Pharma Development

## Session 270 DM - Document Management/ eSubmissions, MW, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 204C**

### Compliant eCTDs – Part 1 of 2

Session Chairperson
***Gary M. Gensinger***
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

*Part 2 of this session will be held on Tuesday at 3:30 pm.*

This session is Part 1 of Guidance-compliant eCTDs and will provide an overview of FDA's eCTD Guidance and a practical discussion on developing a guidance-compliant format for an eCTD submission.

**eCTD Guidance Overview**
***Gary M. Gensinger***
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

**eCTD Module 1**
***Bronwyn E. Collier, RN***
Associate Director for Regulatory Affairs, CDER, FDA

**Module 2 Summaries**
***Virginia R. Ventura***
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

**Panelists**
***Armando Oliva, MD***
Associate Director for Policy, Office of New Drugs, CDER, FDA
***Norman R. Schmuff, PhD***
Branch Chief, Branch 4, Office of New Drug Quality Assessment, CDER, FDA

## Session 271 EC - eClinical, CP, PP

1:30 pm-3:00 pm LEVEL: ■

**Marriott Salon H**

### Clinical Trial Registries

Session Chairperson
***Charles Jaffe, MD, PhD***
Senior Global Strategist, Digital Healthcare, Intel Corporation

All stakeholders in clinical research are seeking better solutions to enhance information sharing and improve transparency of clinical trials. Globally, efforts are under way from sponsors, journal publishers, trade organizations, regulatory authorities, and standards development bodies. Many are calling for a single solution that supports the needs and interests of these disparate parties. Improvement in research quality and safety can be realized if these ends are met.

**The National Register of Clinical Trials: Efficacious Tool and Source of Information**
***Stefano Marini, MD***
General Manager, Dimensions Ricerca s.r.l., Italy
***Carlo Tomino, PharmD***
Head, Clinical Trials and Research, National Medicines Agency Ministry of Health, Italy

**Beyond Trial Registration: A Global Trial Bank for Clinical Trial Reporting**
***Don E. Detmer, MD***
President and CEO, American Medical Informatics Association (AMIA)

## Session 272 GCP - Good Clinical Practices, CDM, EC, IT

1:30 pm-3:00 pm LEVEL: ◆

**Marriott Salon F**

### GCP/QA Town Meeting: Meeting the GCP Challenges of Electronic Data Capture (EDC)

Session Chairperson
***Teri E. Stokes, MT (ASCP), MS, PhD***
Director, GXP International

Sponsors, CROs, and investigator sites are now moving from theory into practice with EDC and eSource, and it is important to share real experiences with each other. A panel will present views from an EDC-experienced sponsor/CRO, an investigator, and technology to kick off this discussion session.

**The Investigator Site View of EDC Challenges**
***Yvonne P. McCracken, MPH, CCRC***
President and CEO, Carolinas Research Associates

**The Technology View of EDC Challenges for Global Trials**
***David M. Fishbach***
Consulting Manager, Phase Forward

## Session 273 IMP - Impact, CR, MC

1:30 pm-3:00 pm LEVEL: ●

**Room 203AB** *CME and Pharmacy credits offered*

### Functional Outcomes' Role in Demonstrating the Efficacy of New Medical Products and Therapies

Session Chairperson
***Lynne Adamczyk, RN, MBA***
Project Manager, Uniform Data System

To fully understand the impact of a new medical product or therapy, a comprehensive assessment of functional status should be completed. Maintenance or improvement in physical and/or cognitive function may extend beyond the hypothesized benefits for which the medical product/therapy was originally developed. Follow-up remote monitoring of patients' functional status can demonstrate the lasting benefits of new, innovative therapies.

**Functional Outcomes: What Are They and Why Do They Matter?**
***Lynne Adamczyk, RN, MBA***
Project Manager, Uniform Data System

**Telephonic Data Collection: Its Role in Global Clinical Trials**
***Amy Hayward***
Vice President, Operations/Clinical Trials, MedTel Outcomes, LLC

**Enhanced External Counterpulsation: Comprehensive Analysis of Functional Status in Heart Disease Patients Demonstrates Continued Benefit of an Innovative Medical Therapy**
***Debra Braverman, MD***
Founder, Braverman EECP Heart Centers

## Session 274 IS - Investigator Sites, CTM

1:30 pm-3:00 pm LEVEL: ■

**Room 113B** *CME credits offered*

### Accelerating Subject Enrollment: A New Roadmap for Sites and Sponsors

Session Chairperson
***Louis C. Kirby, MD***
Medical Director and Founder, Pivotal Research Centers

Subject enrollment has become the most pressing issue in clinical development – yet no one has figured out how to crack that nut. Part of the issue is the recurring mistakes made by all players from site selection to amateurish subject recruitment. Sponsors and sites urgently need to become more sophisticated in both their knowledge base and in their execution. This session goes to the heart of the recruitment problem and directly identifies the suite of remedies required by sponsors and sites. This is not the same old prescription but an entirely divergent and comprehensive look at how to fix a wounded system. This is for sponsors and advanced sites that are willing to consider a different way to do their job. The results, and they are starting to emerge from the more innovative companies, show that there are important operational changes that make a difference and are long overdue.

This session will clearly and specifically discuss the real-world approaches to reducing recruitment delays in ways that both sponsors and sites can take home and employ tomorrow plus a framework for building a system to consistently outperform current results.

**Accelerating Subject Enrollment: A New Roadmap for Sites and Sponsors**
***Louis C. Kirby, MD***
Medical Director and Founder, Pivotal Research Centers

## Session 275 IT1 - Information Technology, CDM, CTM

1:30 pm-3:00 pm LEVEL: ■

**Room 106AB**

### Developing Enterprise IT Architectures and Data Models for Drug Development

Session Chairperson
***Munish Mehra, PhD, MS, MSc***
Senior Vice President, Clinical Research Services, Medifacts International

With the continued increase in the adoption of standards, EDC, the eCTD, the move to electronic health records (EHRs) as well as the significant and continued growth in moving IT tasks offshore, it is important to understand these changes and how new IT enterprise architectures and data models need to be developed. IT staff can help the pharmaceutical industry finally embrace technology and leverage it to become more efficient.

**Defining Standards for Global IT**
***Pamela S. Campbell, MBA***
Consultant, Computer Systems Compliance Services, BusinessEdge Solutions

**Interoperability: External versus Internal Standards**
***Daljeet Sahni***
Principal Architect, AstraZeneca

**A Collaborative Strategy for Architecting Pharmaceutical Research into the Healthcare Domain**
***Steven T. Ward***
Manager, External Business Integration, Global Medical and Regulatory IT, Eli Lilly and Company

## Session 276 IT2 - Information Technology, CR, EC

1:30 pm-3:00 pm LEVEL: ■

**Room 105AB**

### The National Health Information Infrastructure: Public-private Sector Initiative

Session Chairperson
***Melvyn Greberman, MD, MS, MPH, FACPM***
President, Public Health Resources, LLC

Public and private sector leadership and investments are needed for the development and implementation of a national health information infrastructure to facilitate the flow of information needed for healthcare decisions while providing connectivity among providers, patients, payers, and researchers. The panel will discuss activities under way and planned relevant to how the public and private sectors are working together nationally and internationally to address issues relevant to the NHII.

**Health Information Technology: The Federal Landscape**
***J. Michael Fitzmaurice, PhD***
Senior Science Advisor for Information Technology, Agency for Healthcare Research and Quality, HHS

**Personal Health Information: Consumer Views and Their Implications**
***Helga E. Rippen, MD, PhD, MPH***
Senior Advisor, Health Informatics, Department of Health and Human Services

## Session 277 MC - Medical Communications, MA

1:30 pm-3:00 pm LEVEL: ●

**Room 204A** *Pharmacy credits offered*

### Chronicles of Mergers between Medical Information Departments: Inside and Outside of the Organization

Session Chairperson

***Heather A. Schiappacasse, PharmD, RPh***
Manager, Metabolism Medical Information Services, sanofi-aventis

Medical information services (MIS) are often the first line of contact for the customer within a pharmaceutical company. Any disruption to the day-to-day activities of a medical information department can potentially be detrimental not only to the customer but to the internal functioning of the department. A merger in medical information can potentially lead to increased product support leading to an increase in volume of submitted inquiries. Head count evaluation, system support, and processes all need to be considered. The merger of two major pharmaceutical companies and how the distracting nature of the merger was kept to a minimum will be chronicled. In addition, the merger of two MIS departments within the same organization will be addressed. The discussion will include timelines used and activities performed to bring two separate entities together into one solid, unified department. Lessons learned from the merging of contact centers will also be shared.

**A Merger between Two Major Pharmaceutical Companies and Its Impact on Medical Information Services**
***Heather A. Schiappacasse, PharmD, RPh***
Manager, Metabolism Medical Information Services, sanofi-aventis

**Harmonization of Two Medical Communications Departments: Successes and Challenges**
***Tina Vatanapradit, PharmD***
Assistant Director, Primary Care, Ortho McNeil Janssen Scientific Affairs, LLC

**Retrospective Look at Lessons Learned from Merging Contact Centers**
***Terry E. Meisner, RN***
Director, Customer Communications Center, Ortho-McNeil Janssen Scientific Affairs, LLC

## Session 278 MW - Medical/Scientific Writing, CP

1:30 pm-3:00 pm LEVEL: ■

**Room 204B** *CME and Pharmacy credits offered*

### Medical Science, Affairs, and Writing in Pharmacovigilance

Session Chairperson

***Peggy M. Boe, RN***
Director, Medical Writing, Image Solutions, Inc.

Collection of safety data and reporting of adverse drug reactions (ADRs) continues well beyond approval of marketing applications and even beyond pharmaceutical patent expiration when generics are marketed. This session will present a cost-efficient system for the retrieval of ADRs and assessing causality in the generics market, for expedited ADR reporting to regulatory authorities. Benefits of developing and using postmarketing safety update report (PSUR) templates for concise and consistent reporting will be described. Finally, the critical role that medical writers play in reporting postmarketing safety will be explained.

**How Do I Cost Efficiently Search and Assess Potential Adverse Drug Reaction Cases and Write the ICSR?**
***Leonardo C.I. Ebeling, MD, PhD***
General Manager, Dr. Ebeling & Assoc. GmbH, Germany

**Key Issues in Cost-efficient Medical Writing Based on IT-assisted Postmarketing Safety Update Report Templates**
***Reingart Bordel, PhD***
Head of Pharmacovigilance, DiapharmGroup, Germany

**Safety and Risk Assessment: What Medical Writers Contribute and What They Need to Know**
***Theresa Hoffman, PhD, ELS***
Medical Writer, Image Solutions, Inc.

## Session 279 NC - Nonclinical Laboratory Safety, CR, MW

1:30 pm-3:00 pm LEVEL: ■

**Room 202AB** *CME credits offered*

### PPAR Agonist Toxicities: An Update

Session Chairperson

***Kenneth Hastings, DrPH, DABT***
Associate Director, Office of New Drugs, CDER, FDA

This session will be a review of toxicology issues with PPAR agonists as determined in nonclinical studies.

**Risk Assessment of PPAR-induced Cardiovascular Effects**
***Beth Huggins Romach, PhD, DABT***
Director, Safety Assessment Projects, GlaxoSmithKline

**Molecular and Physiological Studies on the Adverse Effects of PPAR Gamma Ligands**
***Joel Berger, PhD***
Distinguished Senior Investigator, Metabolic Disorders and Diabetes, Merck Research Laboratories

**Preclinical and Clinical Cardiac Safety Profiles of PPAR Agonists**
***Jeri D. El Hage, PhD***
Pharmacology Supervisor, CDER, FDA

## Session 280 OS - Outsourcing, PM

1:30 pm-3:00 pm LEVEL: ■

**Room 109AB**

### Preferred Provider Selection Process

Session Chairperson

***Cory Gutterman, MS, MPH***
Operations Manager, Outsourcing, Abbott Laboratories

Preferred provider relationships offer multiple advantages for both sponsors and CROs. Moving from the practice of tactical outsourcing to the creation of preferred provider relationships, however, is not as simple as creating a master agreement. The process of selecting a preferred provider should align the sponsor's needs with CRO capabilities.

**CRO Preferred Provider Programs: How to Strategically Select Suppliers for Your Program**
***Jenny Dart***
Senior Manager, Strategic Outsourcing Initiatives Global Pharmaceutical R&D, Abbott Laboratories

***Redge Santos, MBA, RN***
Senior Director, Clinical Trial Support USMA, sanofi-aventis

***Nicky Helen Van Rensburg***
Director, Clinical Operations, Covance, Inc.

## Session 281 PM1 - Project Management, TR

1:30 pm-3:00 pm LEVEL: ●

**Room 108A** *Project Management Institute credits offered*

### DIA's Project Management Standards and Training Program

Session Chairperson

***Martin D. Hynes, III, PhD***
Director, Product Research and Development, Lilly Research Laboratories, Eli Lilly and Company

This session will review the project management standard for project managers in the pharmaceutical/biotechnology industry. It will also highlight the courses that will be available to project managers in support of the standards.

**Project Management Competency Areas in the Pharmaceutical Industry and the Training Program to Support Them**
***Jean A. Yager, PhD, PMP***
Director, Development Operations, Pfizer Inc

**Project Management Training Course Results Achieved to Date**
***Robert Lund Judd, MS***
Director, Program Management, Kosan Biosciences, Inc.

## Session 282 PM2 - Project Management, CR, CTM

1:30 pm-3:00 pm LEVEL: ■

**Room 108B** *Project Management Institute credits offered*

### Has "Phased" Clinical Development Outlived Its Useful Life?

Session Chairperson
***Charles T. Gombar, PhD***
Vice President, Project Management, Wyeth Research

For decades the pharmaceutical industry and regulators have divided clinical drug development into three major phases (Phase 1-3). What was the genesis of the phase designation, and is the rationale for the categorization still relevant? While the phase definitions are generally understood by scientists, clinicians, and regulators, the question to ask is whether this categorization stifles innovative thinking. Moreover, there are data suggesting that a substantial amount of time can be spent between the phases, in some cases months. Is this time being used productively to analyze and understand data, or is it only "white space"? More and more novel molecules are entering development, and clinical pharmacology is providing more tools to study these molecules in humans. Is it necessary, therefore, to continue to use the phase categorization? If not, what is the alternative to the phased approach? In this session, these questions will be explored from the perspective of pharma, regulators, and industry consultants.

**Challenging the Current Development Paradigm: A Case for Change**
***Navjot Singh, PhD, MBA***
Associate Principal, McKinsey and Co.

**New Approaches to Clinical Development: Wyeth Experience**
***Charles T. Gombar, PhD***
Vice President, Project Management, Wyeth Research

**New Approaches to Clinical Development: Novartis Experience**
***John J. Orloff, MD***
Vice President, Development, Novartis Pharma AG

**Keeping Phased Development, But Not the Lessons Learned, Is a Bad Idea**
***Lawrence J. Lesko, PhD***
Director, Office of Clinical Pharmacology, CDER, FDA

## Session 283 PP - Public Policy/Law, CR, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 114** Auditorium *Pharmacy credits offered*

### The Expandable Universe of the Critical Path: Points to Consider in the Marketplace; Pricing and Reimbursement – Part 2 of 2

Session Chairperson
***Chin C. Koerner***
Executive Director, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

*Part 1 of this session will be held on Tuesday at 10:30 am.*

The future vision under the Critical Path is for more targeted products with more predictable efficacy and safety, personalized medicine. The implication of this paradigm is to be able to identify those patients that are more likely to respond during drug development and eventually at the point-of-care. How should the added costs of validating biomarkers, developing diagnostics and manufacturing for a reduced patient population add up to a sustainable business model? The Blockbuster mentality will need to be revisited to reconcile what is envisioned under Critical Path and current practices.

**Moderator**

***John E. (Jack) Calfee, PhD***
Resident Scholar, American Enterprise Institute

**Panelists**

***M.J. Finley Austin, PhD***
Director, Public Policy, Hoffmann-La Roche Inc.

***Jens Grueger, PhD***
Global Head, Health Economics and Disease Management, Novartis Pharma AG, Switzerland

***Schumarry Chao, MBA, MD***
School of Medicine and School of Pharmacy, University of Southern California

## Session 284 RA1 - Regulatory Affairs, CR, GCP

1:30 pm-3:00 pm LEVEL: ■

**Room 201B**

### Practical Tips for Successful Development and Approval in Different Cultures

Session Chairperson
***Shunsuke Ono, PhD***
Priority Review Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Although there are many internationally harmonized guidelines for clinical development, the behaviors and decision making of pharmaceutical professionals in private and public sectors do not seem fully harmonized. Recognition of regional differences at a personnel level is imperative for planning and implementing efficient development strategies. This session highlights regional backgrounds leading to differences in clinical development and NDA approval process between the regions.

**Successful Clinical Development in Japan: What Assumptions Work? What Assumptions Don't Work?**
***E. Stewart Geary, MD***
Director, Eisai Co., Ltd., Japan

**Comparison of Drug Development Practices and Cultural Aspects between Japan and the West**
***Atsushi Tsukamoto, MSc, PMP***
Senior Project Manager, Sankyo Pharma R&D Headquarters, Japan

**How Do You Protect Your Drugs from the Regulatory Agency in the Consultation and Review Process?**
***Shunsuke Ono, PhD***
Priority Review Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

## Session 285 RA2 - Regulatory Affairs, CR, RD

1:30 pm-3:00 pm LEVEL: ■

**Room 201C** *CME, Nursing, and Pharmacy credits offered*

### Biomarkers in Drug Development: A Blessing or a Curse?

Session Chairperson

***Alberto Grignolo, PhD***

Corporate Vice President and General Manager, Drug Development Consulting, PAREXEL Consulting

This session will provide a comprehensive perspective on the role and influence of biomarkers in current and future drug development, leading the audience to a better understanding of the key issues, advantages, and limitations of the use of biomarkers.

**FDA Perspective on Biomarkers in Drug Development**

***Felix W. Frueh, PhD***

Associate Director, Genomics, Office of Clinical Pharmacology, CDER, FDA

**Establishing a Regulatory Framework for Genomic Biomarkers**

***Cheryl B. Anderson, PharmD***

Director, US Regulatory Affairs, Eli Lilly and Company

**Hurdles to the Full Implementation of Biomarkers**

***Joseph C. Scheeren, PharmD***

Senior Vice President, Head, Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals

## Session 286 RA3 - Regulatory Affairs, PP

1:30 pm-3:00 pm LEVEL: ●

**Room 201A**

### EU/FDA Confidentiality Arrangements: Current Status – What's Next?

Session Chairpersons

***Thomas Lönngren, Pharm, MSc***

Executive Director, EMEA, EU

***Murray M. Lumpkin, MD, MSc***

Deputy Commissioner, International and Special Programs, Office of the Commissioner, FDA

The EU/FDA Confidentiality Arrangements have been in operation for almost 2 years. This session will describe the extent of the regulatory cooperation and will also provide insight on experience obtained (in terms of positive and less positive experience). Finally, the initiatives taken to further improve the regulatory cooperation will be described. Speakers will include EMEA and FDA representatives. Pharmaceutical industry participants will comment on the current situation and the way forward.

**Status Report on the EU/FDA Confidentiality Arrangements: Achievements to Date and Identified Opportunities for Improvement**

***Noël Wathion, Pharm***

Head of Unit, Postauthorization Evaluation of Medicines for Human Use, EMEA, EU

**Next Steps and Revised Implementation Plan**

***Melinda K. Plaisier, MS***

Assistant Commissioner for International Programs, Office of the Commissioner, FDA

**Industry Experience on the Implementation of the EU/FDA Confidentiality Arrangements and Expectations for the Next Phase**

***Mathias Hukkelhoven, PhD***

Senior Vice President, Global Head, Drug Regulatory Affairs, Novartis Pharmaceuticals

**Panelist**

***Patrick Le Courtois, MD***

Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

## Session 287 RD - R&D Strategy, CR, IS

1:30 pm-3:00 pm LEVEL: ●

**Room 102AB** *Pharmacy credits offered*

### Monitoring and Managing a Changing Investigative Site Landscape

Session Chairperson

***Kenneth A. Getz, MS, MBA***

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

This session will review and discuss structural and longitudinal changes among investigative sites. An update to a well-attended session offered in 2005, the speakers will present original research on the changing investigative site market and offer insights into ways that sponsors can more effectively and efficiently manage their investigative sites.

**R&D Trends and Their Impact on the Study Conduct Market**

***Christopher P. Milne, DVM, MPH, JD***

Assistant Director, Tufts Center for the Study of Drug Development, Tufts University

**Overview of Investigative Site Market and Operating Changes**

***Kenneth A. Getz, MS, MBA***

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

**Direct Experience and Observations in Today's Operating Environment**

***James W. Maloy, PharmD***

Investigator, Drug Research and Analysis Corp.

## Session 288 ST - Statistics, CR, PP, RA

1:30 pm-3:00 pm LEVEL: ■

**Room 103B** *CME and Pharmacy credits offered*

### EMEA Road Map and FDA Critical Path: Statistical Implications, Risks, and Opportunities

Session Chairperson

***Simon Day, PhD***

Manager, GI, Nutritional and Blood Therapies; Manager, Statistics Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Efficiency gains and new ways of thinking about the drug development process and licensing process may yield a quicker route for new products to get to patients. EMEA and FDA have each been considering how changes to usual practice might be beneficial. This session will consider the EMEA and FDA documents from a statistical perspective and try to identify opportunities and any potential risks.

**The EMEA Road Map: Words and Deeds and Rocking the Boat**

***Michael P. O'Kelly, PhD, MA***

Statistical Consultant, Quintiles Ireland, Ltd., Ireland

**FDA Critical Path: The Statistician's Role in Improving the Efficiency of the Pharmaceutical Industry**

***Steven M. Snapinn, PhD***

Senior Director of Biostatistics, Amgen Inc.

**Discussant**

***Robert J. Temple, MD***

Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

## Session 289 TR - Training, CR, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 103C**

### The Use of eLearning to Meet the Growing Need for Healthcare Compliance Training

Session Chairperson

***Douglas E. May, MS***

Director, Strategy/Life Sciences, RWD Applied Technology Solutions

The HHS OIG guidances and the PhRMA code on interaction with healthcare professionals have now been codified in laws in several states and more laws are coming. While the provisions of the guidances, codes, and laws are not identical, all of them require that people in life sciences companies who interact with healthcare professionals receive initial and follow-up training in their company's comprehensive compliance program. eLearning provides an ideal vehicle for delivering this training.

**Review of Healthcare Compliance Guidances, Codes and Laws**
***Douglas E. May, MS***
Director, Strategy/Life Sciences, RWD Applied Technology Solutions

**Case Study: Developing an eLearning Strategy and Competency Center**
***John P. Sjovall, Jr.***
Director, Training, Daiichi Sankyo Inc.

**Case Study: The Use of eLearning for Compliance Training**
***Elizabeth Snyder***
Training Manager, Healthcare Compliance, Ortho-McNeil Janssen Pharmaceutical Services

## Session 290 VA - Validation, IT, RA

1:30 pm-3:00 pm LEVEL: ■

**Room 113C**

### Extraordinary Opportunities: Issues We Face in Meeting Regulatory Expectations and How to Address Them

Session Chairperson

***Earl W. Hulihan, MEd***

Vice President, Global Regulatory Affairs and Quality Assurance, Medidata Solutions, Inc.

This session will focus on the "real-life" application of core validation basics to achieve results consistent with good industry validation practices for data reliability and integrity. This will be achieved through a sharing of practical principles and examples, as well as attendee/panel Q&A.

**PAT and CSV: Applying the Same Concepts**
***Lisa A. Olson***
Principal Compliance Consultant, SEC Associates Inc.

**Validation: What Have We Learned?**
***Frances E. Nolan, MBA***
Vice President Consultant, Taratec Development Corporation

**A Regulatory Perspective on Computer Application and Data Integration in GCP and GLP Studies**
***Earl W. Hulihan, MEd***
Vice President, Global Regulatory Affairs and Quality Assurance, Medidata Solutions, Inc.

3:00 pm-3:30 pm **REFRESHMENT BREAK**

**Exhibit Halls A and B, 2nd Floor, Convention Center**
**Ballroom Foyer, 5th Floor, Marriott Hotel**

## Session 291 AD - Advertising, RA

3:30 pm-5:00 pm LEVEL: ■

**Room 111AB** *Pharmacy credits offered*

### Direct-to-consumer Advertising Policy

Session Chairperson

***John F. Kamp, PhD, JD***

Executive Director, Coalition for Healthcare Communication

This session will cover the latest developments in regulation and self-regulation of direct-to-consumer (DTC) advertising, including the creative challenges posed by regulation, self-regulation and consumer concerns in the age of safety concerns and aggressive class action suits.

**Rising above DTC Challenges: Creative Excellence in Changing Times**
***Steven Pashkoff***
Chief Creative Officer, Quantum/CommonHealth Communications

**Improving the Education of Patients and Providers about New Prescription Medicines**
***Lorie Wall Reilly***
Vice President, Policy and Research, PhRMA

**DTC: From the First Amendment to the PhRMA Principles**
***Arnold I. Friede, JD***
Senior Corporate Counsel, Pfizer Inc

## Session 292 BT - Biotechnology, CR, RA

3:30 pm-5:00 pm LEVEL: ■

**Room 103A** *Pharmacy credits offered*

### Vaccines and Blood Products: Recent Specific Regulatory Provisions in the EU

Session Chairperson

***Jean-Marc Spieser, RPh***

European Directorate for Quality of Medicines, European Pharmacopeia, France

New regulatory developments have set up specific procedures such as Vaccine Antigen Master File and Plasma Master File. In addition, the recent regulations on variations to a marketing authorization involve various requirements for biological medicinal products. Also relevant is the role of the European Pharmacopoeia in controlling biologicals.

**Role and Actions of the European Pharmacopoeia in Control and Batch Release of Biological Medicinal Products**
***Jean-Marc Spieser, RPh***
European Directorate for Quality of Medicines, European Pharmacopeia, France

## Session 293 CDM - Clinical Data Management, EC

3:30 pm-5:00 pm LEVEL: ●

**Marriott Salon CD**

### Workflow and Metrics in Data Management: What Opportunities Does EDC Provide for Optimization?

Session Chairperson

***Donald F. Fortin, MD, PhD***

President and CEO, Versigenics, Inc.

This session proposes to explore how the introduction of EDC tools can proactively assist data management departments in the real-time generation of metrics. The presentations will provide an examination of business process monitoring practices from the pharmaceutical company and CRO perspectives.

**Workflow and Metrics: A Sponsor's Wish List**
***William Gluck, PhD***
Director, Clinical Data Management, Gilead Sciences, Inc.

**A Review of the Current State of the Art: A Vendor's Perspective**
***Wolfgang Summa, PhD***
Vice President, Clinical Operations, DATATRAK International, Germany

**Where Do We Go from Here and How Do We Measure It?**
***Donald F. Fortin, MD, PhD***
President and CEO, Versigenics, Inc.

## Session 294 CP - Clinical Safety and Pharmacovigilance, CDM, ST

3:30 pm-5:00 pm LEVEL: ■

Marriott Salon G *CME and Pharmacy credits offered*

### Signal Detection in Pharmacovigilance: State of the Art and Emerging Quantitative Approaches

Session Chairperson
***Manfred Hauben, MD, MPH***
Medical Director, Risk Management Strategy, Pfizer Inc; Department of Medicine, New York University School of Medicine, Departments of Pharmacology and Community and Preventive Medicine, New York Medical College

Data mining algorithms are being heavily promoted to enhancing signal detection. This session will demonstrate the latest developments and practical application of these technologies as well as the latest research directions.

**Knowledge Finding: Data Mining in Patient Record Data**
***Andrew Bate, PhD, MA***
Manager, Research and Development, Uppsala Monitoring Centre, Sweden

**Indicators of the Quality of Reports in Relation to Signal Detection**
***Eugene P. van Puijenbroek***
Head of Scientific Department, Netherlands Pharmacovigilance Centre Lareb, Netherlands

**The MedDRA® Hierarchy and Data Mining**
***David Goldsmith, MD, FISPE***
President, Senior Consultant, Goldsmith Pharmacovigilance & Systems

## Session 295 CTM - Clinical Trial Management, CR

3:30 pm-5:00 pm LEVEL: ■

Room 107AB *Pharmacy credits offered*

### Best Practices in Conducting Clinical Trials in India from Multiple Perspectives

Session Chairperson
***James D. Utterback, MS***
CEO, SCIREX Corporation

This session will bring together a panel of representatives from industry and local Indian government to discuss clinical trial conduct in India. This will be a combined open forum and Q&A session, including advantages, challenges and best practices from the perspective of each member of the panel.

**Industry-wide Lessons Learned on Clinical Development in India**
***Ajay Dhankhar, PhD***
Principal, McKinsey and Company

**Complying with the Indian Government: How to Smooth the Transition to Clinical Research in India**
***Ashwini Kumar, MPharm***
Drugs Controller General of India, Central Drugs Standard Control Organization, India

**Successfully Utilizing Data from India: Sponsor Perspective**
***Robert J. Maguire, MD***
Vice President and Chief of Operations, Clinical R&D, Wyeth Research

**Clinical Research in India: Adding Value, Not Just Cutting Costs**
***Atignal Arvind, MD***
Chief Operating Officer, Clinigene, India

## Session 296 DM - Document Management/ eSubmissions, MW, RA

3:30 pm-5:00 pm LEVEL: ●

Room 204C

### Compliant eCTDs – Part 2 of 2

Session Chairperson
***Gary M. Gensinger***
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

*Part 1 of this session will be held on Tuesday at 1:30 pm.*

This session is Part 2 of Guidance-compliant eCTDs and will provide an overview of FDA's eCTD Guidance and a practical discussion on developing a guidance-compliant format for an eCTD submission.

**Ensuring an Effective Submission**
***Gary M. Gensinger***
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

**Modules 4 and 5 Overview**
***Armando Oliva, MD***
Associate Director for Policy, Office of New Drugs, CDER, FDA

**eCTD Quality/CMC Issues**
***Norman R. Schmuff, PhD***
Branch Chief, Branch 4, Office of New Drug Quality Assessment, CDER, FDA

**Panelists**

***Bronwyn E. Collier, RN***
Associate Director for Regulatory Affairs, CDER, FDA

***Virginia R. Ventura***
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

## Session 297 GCP - Good Clinical Practices, CR, IS

3:30 pm-5:00 pm LEVEL: ■

Marriott Salon F *CME and Pharmacy credits offered*

### Effectively Protecting Human Subjects in Studies Conducted Outside the US

Session Chairperson
***Sharon Hill Price, MS***
CEO, Copernicus Group IRB

As pharmaceutical companies move a significantly larger percentage of their research outside the US (OUS), the need to identify appropriately constituted and trained ethical review committees becomes of increasing concern. This session wrestles with the question of capacity building for ethics committees in the developing countries and options for supporting the process while infrastructure catches up with demand.

**The Imperative for Capacity Building in Ethical Review Committees Outside the US**
***Melody H. Lin, PhD***
Director of International Activities, Department of Health and Human Services

**Challenges of Research in Developing Country Settings**
***Roberto Rivera, MD***
Director, Office of International Research Ethics, Family Health International

**Pharmaceutical Company Considerations when Placing Studies Outside the US**
***Charles E. Mueller, PhD***
Head, North America Clinical, GlaxoSmithKline

## Session 298 IS - Investigator Sites, CTM

3:30 pm-5:00 pm **LEVEL:** ■

**Room 113B** *CME credits offered*

### Faster, Better, Cheaper: Sponsor/Site Partnerships

Session Chairperson
***Norman M. Goldfarb, MBA***
Managing Partner, First Clinical Research

Investigative sites determine a substantial part of the cost, time and quality of a clinical trial, and directly influence another substantial part. We can improve quality, reduce costs, and shorten timelines simultaneously by following the retail, automotive, and other industries into customer/supplier partnerships.

**Faster, Better, Cheaper: Sponsor/Site Partnerships**
***Norman M. Goldfarb, MBA***
Managing Partner, First Clinical Research

**Winning with Preferred Sites: Site, Sponsor, and CRO Benefits**
***Adam Chasse***
Director, Global Access to Patients, Quintiles, Inc.

**Site Contracting: An Outsourced Model – Can It Deliver?**
***Andrew Townshend***
Director, Investigator Relations, Contracts and Outsourcing, Pfizer Inc

## Session 299A IT - Information Technology, EC, RA

3:30 pm-5:00 pm **LEVEL:** ●

**Room 105AB**

### Developments in Electronic Pharmaceutical Data Archiving

Session Chairperson
***Philip W. Lord, MSc***
Director, Digital Archiving Consultancy Limited, UK

This session will present an updated overview of the current needs and drivers for electronic data archiving, placing these in the context of business processes and the current regulatory framework. It will describe good practice for electronic data archiving from those actively involved in a GAMP archiving SIG, an industry grouping which has worked on formulating this over the last two years.

Archiving is a data interchange across time. The development of a standards-based industry architecture would enable information and application interoperability between and across the converging provider and pharmaceutical industries, both contemporaneously and over time, and we summarize briefly the factors enabling successful data sharing over time. Specifically, we will discuss real-world scenarios of how this architecture would also facilitate specific improvements in clinical research and patient health by leveraging standards such as CDISC and HL7.

**Electronic Data Archiving: The Regulatory and Business Background**
***Frank R. Woods***
Director, European Computer Systems Compliance, GlaxoSmithKline, UK

**Archiving Best Practices in the Pharmaceuticals Sector**
***Per Olsson, MSc***
Principal Consultant, ABB, UK

**Successful Data Sharing over Time**
***Alison Macdonald, MA***
Director, Secure Sciences Limited, UK

**Crossing the Convergence Chasm Using Standards**
***Jason Burke, MA***
Senior National Life Sciences Industry Strategist, SAS Institute Inc.

## Session 299B MC - Medical Communications, MA

3:30 pm-5:00 pm **LEVEL:** ●

**Room 204A** *Pharmacy credits offered*

### Regional Medical Liaison Survey #2: Assessing Training Techniques and Demonstrating Value of Regional Medical Liaisons across the Pharmaceutical Industry

Session Chairperson
***Christopher M. Marrone, PharmD***
Medical Liaison Consultant, Eli Lilly and Company

This session will review results of a survey that was conducted to identify approaches used by pharmaceutical companies to develop and conduct medical liaison training. In addition, this survey assessed how the value of medical liaison programs are determined and shared with business colleagues.

**Survey Background and Results**
***Christopher M. Marrone, PharmD***
Medical Liaison Consultant, Eli Lilly and Company

**Survey Results 1**
***J. Lynn Bass, PharmD***
Regional Medical Liaison II, Amgen, Inc.

**Survey Results 2**
***Craig J. Klinger, RPh***
Medical Liaison Consultant, Eli Lilly and Company

## Session 299C MW - Medical/Scientific Writing, BT, CR

3:30 pm-5:00 pm **LEVEL:** ●

**Room 204B** *CME and Pharmacy credits offered*

### Publication Planning: New Opportunities and Issues

Session Chairperson
***Robert Norris, MBA***
President and Founder, Complete Healthcare Communications, Inc.; President, International Society for Medical Publication Professionals

Strategically planned and professionally managed publication plans are a required component of any new drug development program. With this emergence comes a whole new list of issues. These issues compound the role of biopharmaceutical companies, investigators, authors, and regulatory bodies and their impact on peer-reviewed publications. This session attempts to address these issues and give guidance on how to deal with them.

**Strategic Publication Planning: Key Component of a Medical Marketing Plan**
***Robert Norris, MBA***
President and Founder, Complete Healthcare Communications, Inc.; President, International Society for Medical Publication Professionals

**Current Issues Surrounding Publication Planning and Medical Writing**
***Richard F. Lamb***
Director, Medical Education and Publications, Rimonabant, sanofi-aventis

**Creating Oncology Manuscripts CD: A Tool for Quality Manuscript Preparation**
***Mary Alice Miller, PhD***
Principal Research Scientist, Eli Lilly and Company

## Session 299D NC - Nonclinical Laboratory Safety, CP, MW

3:30 pm-5:00 pm LEVEL: ◆

**Room 202AB** *CME credits offered*

### Peroxisome Proliferators Activated Receptors (PPARs) Agonists and Rodent Tumorigenesis: Updating the Discussions

Session Chairperson
***Beatriz Silva Lima, PhD, PharmD***
Professor, Pharmacology; Chair, SWPO, University of Lisbon and INFARMED, Portugal

The peroxisome proliferators activated receptors (PPARs)-induced tumorigenesis will be discussed in the context of the mechanistic explanation using bladder tumors as example. The perspective and discussions being held in the European regulatory environment with regard to developing molecules of the same class will be presented.

**PPAR Agonist-related Bladder Tumorigenesis: Evidence for Pharmacologically Mediated Urine Compositional Changes as the Mode of Action**
***Mark Dominick, DVM, PhD***
Distinguished Research Fellow, Drug Safety Evaluation, Bristol-Myers Squibb Company

**Assessing the Tumorigenic Potential of PPAR Agonists: The European Regulatory Dilemma**
***Beatriz Silva Lima, PhD, PharmD***
Professor, Pharmacology; Chair, SWPO, University of Lisbon and INFARMED, Portugal

**PPARgama-related Bladder Tumorigenesis: Receptor-mediated or Crystal-mediated Effect?**
***Lars Iversen, DVM, MD***
Principal Scientist, Novo Nordisk A/S, Denmark
***Martin Oleksiewicz, DVM, PhD***
Principal Scientist, Preclinical Development, Novo Nordisk A/S, Denmark

## Session 299E NHP - Natural Health Products, IMP

3:30 pm-5:00 pm LEVEL: ●

**Room 106AB** *CME, Nursing, and Pharmacy credits offered*

### Strategies and Success Stories for Integrating NHP and Conventional Medicine

Session Chairperson
***Daniel Labriola, ND***
Director, Northwest Natural Health-Specialty Care Clinic

Natural health products have increasingly demonstrated clinical efficacy and safety in quality investigational trials but have not gained widespread acceptance in conventional clinical settings. This session reviews the strategies that have resulted in the successful introduction of natural health products from a production, medical, and pharmaceutical perspective.

**Strategies and Success Stories for Integrating NHP and Conventional Medicine**
***Daniel Labriola, ND***
Director, Northwest Natural Health-Specialty Care Clinic

**Chinese Herbal Medicines in Conventional Clinical Practice**
***Edmund M. K. Lui, PhD, MPharm***
Associate Professor, University of Western Ontario, Canada

**Impact of Natural Health Products on the Management of Women's Health and Quality of Life**
***Waqar Bhatti, PhD, MS, RPh***
Professor, College of Pharmacy, Butler University

## Session 299F OS - Outsourcing, RD

3:30 pm-5:00 pm LEVEL: ■

**Room 109AB**

### Intellectual Human Capital in Contract Research: Is the Market There?

Session Chairperson
***Michael E. Laird, RPh***
Vice President, Worldwide Business Development, PharmaNet

The contract research industry has only been mildly successful in marketing human intellectual capital to its pharmaceutical customers. The market could be made stronger by focusing on different types of customers and niche services while building a reputation in this area. It is our intent to discover whether expert consultative services can be a profitable long-term investment for CROs.

***Akira Kato, PhD, DVM***
Vice President, Kureha America Inc.

***Bruce H. Morimoto, PhD***
Vice President, Drug Development, Allon Therapeutics

## Session 299G PM1 - Project Management, OS, RD

3:30 pm-5:00 pm LEVEL: ■

**Room 108A** *Project Management Institute credits offered*

### The Future for Project Management: What Does It Look Like?

Session Chairperson
***Allen C. Sarapu, PhD***
President, Value-Added Drug Development, LLC

The pharmaceutical/biotechnology industry is experiencing profound changes in the business environment that will affect R&D in a number of ways. The old model may be considered inadequate, but what is going to replace it, and how do we know whether it is better? Understanding important trends in the future of R&D organizations and how project management can or should play a role will be discussed by representatives spanning a cross-section of the industry, from large pharma to small biotech.

**The Future for Project Management: Managing Projects and Portfolios**
***Lori S. Shafner, PhD***
Vice President, Worldwide Development Portfolio Management, Pfizer Inc

**The Future for Project Management: Managing Projects and Operations**
***Leah Goldbroch, MS***
Director, R&D Operations, Abbott Laboratories

**The Future for Project Management: Emerging Roles in Small Pharma/Biotech**
***Jane Bainbridge, MSc***
Vice President, Project Management, Celgene Corporation

## Session 299H PM2 - Project Management, CTM, OS

3:30 pm-5:00 pm LEVEL: ■

**Room 108B** *Project Management Institute credits offered*

### Vendor Management: Drive Performance and Value

Session Chairperson
***Patterson Shafer***
Vice President, Practice Manager, Strategy, Intrasphere Technologies

Vendor management is the proactive management of supplier relationships, moving from cost-minimization approaches to value-creating partnerships. The move away from adversarial positions towards collaboration affords opportunity for substantial increases in quality and performance, with potential rewards to be shared by vendor and customer. This session will touch on key elements of the contracting lifecycle, from implementing master services agreements through post-award management.

**Strategic Commitment Management**
***Timothy Cummins***
Executive Director, IACCM

## Session 299I PP - Public Policy/Law, AHC, MW

3:30 pm-5:00 pm LEVEL: ●

**Room 113A**

### The Ethics of Authorship

Session Chairperson
***Susanna J. Dodgson, PhD***
Director, Graduate Programs in Biomedical Writing, Professor, Biomedical Writing, University of the Sciences in Philadelphia

The International Committee of Medical Journal Editors (ICMJE) and medical writers associated with AMWA and EMWA agree that authors are professionals intimately involved with all parts of the study and manuscript preparation, including data analysis. We will discuss the ethics of authorship, authorship guidelines, how to detect guest authors, possible alternatives to guest authorship, and advantages to the pharmaceutical industry of eliminating this practice.

**Authorship: Pharmaceutical Companies**
***Susanna J. Dodgson, PhD***
Director, Graduate Programs in Biomedical Writing, Professor, Biomedical Writing, University of the Sciences in Philadelphia

**Authorship: Ethics and Laws**
***Linda Macdonald Glenn, JD, LLM***
Consultant, Clinical Ethicist

**Authorship: Clinicians**
***Adriane Fugh-Berman, MD***
Complementary and Alternative Medicine Master's Program, Georgetown University School of Medicine

**Authorship: Universities**
***Jennifer Long, MJ, MS***
Senior Editor, Children's Hospital of Philadelphia

## Session 299J RA/CR Plenary - Regulatory Affairs/Clinical Research

3:30 pm-5:30 pm LEVEL: ●

**Ballroom AB** *Nursing credits offered*

### Update from the FDA Office of the Commissioner

Session Chairperson
***Charles C. Depew, PharmD***
GlaxoSmithKline

In recognition of the 100th anniversary of the US Food and Drug Administration, the Office of the Commissioner will provide an overview of the Agency's agenda for 2007 to 2010. This includes the Critical Path Initiative, PDUFA IV, Advisory Committees, Risk Minimization, National and International Public Health Issues, Product Registration, and Regulatory Decision Making.

Attendees of the DIA Annual Meeting will be able to submit questions for the Q&A panel discussion with the Deputy Commissioners. More details regarding how to submit these questions will be available closer to the meeting. Following this session, there will be a reception recognizing the FDA for its 100th anniversary.

**Question & Answer Period**

**Moderator**
***Charles C. Depew, PharmD***
GlaxoSmithKline

**Panelists**

***Janet Woodcock, MD***
Deputy Commissioner of Operations and Chief Operating Officer, Office of the Commissioner, FDA

***Murray M. Lumpkin, MD, MSc***
Deputy Commissioner for International and Special Programs, Office of the Commissioner, FDA

**Special Guests**

***Thomas Lönngren, Pharm, MSc***
Executive Director, EMEA, EU

***Neil Yeates***
Assistant Deputy Minister, Health Products and Food Branch, Health Canada

## Session 299K RD - R&D Strategy, CR, PM

3:30 pm-5:00 pm LEVEL: ■

**Room 102AB**

### Managing Capacity to Drive Productivity in Pharmaceutical R&D

Session Chairperson
***James Guyton, MA***
Principal, PRTM Management Consultants

The challenge of R&D productivity has captured the attention of the pharmaceutical industry. This session will explore how companies align their resource planning and organizational structures in support of strategic portfolio decisions. Attendees will discover the most effective levers for driving productivity through capacity management.

**Time Tracking for Resource Management in Research and Development**
***William J. Palumbo, MBA, PE***
Director, Planning, Portfolio and Operations Management, Research Information Services, Merck Research Laboratories

**Making the Matrix Organization Work for Clinical Development**
***Laura Hagan, MS***
Group Director, Planning, Resource Management and Performance Measures, Global Clinical Development, Bristol-Myers Squibb

**A Change in Plans: Productivity through Continuous Capacity Management**
***Colleen K. Dixon***
Project Management Consultant, Eli Lilly and Company

## Session 299L ST - Statistics, CR, RD

3:30 pm-5:00 pm LEVEL: ■

Room 103B *CME and Pharmacy credits offered*

### Sequential Methodology for Pharmacogenetics

Session Chairperson
***Patrick J. Kelly, PhD***
Research Fellow, MPS Research Unit, The University of Reading, UK

Pharmacogenetics, the use of genetics to develop drugs that are tailored to be both safe and effective for patients, is becoming increasingly important in drug development. There is enormous potential for using sequential analyses to help identify important genetic markers as soon as possible. In this session some sequential methods that have been proposed for pharmacogenetics are described. Opportunities for and barriers to the application of sequential methods in this area are also discussed.

**Sequential Testing in Genetic Studies: An Overview**
***Inke Koenig, PhD***
Genetic Statistician, Institute of Medical Biometry and Statistics, University of Luebeck, Germany

**Sequential Genome-wide Association Studies for Pharmacovigilance**
***Patrick J. Kelly, PhD***
Research Fellow, MPS Research Unit, The University of Reading, UK

**A Regulatory Perspective of Pharmacogenetics Studies**
***Sue-Jane Wang, PhD, MA, MS***
Associate Director, Office of Biostatistics, Office of Pharmacoepidemiology and Statistical Science, CDER, FDA

## Session 299M TR - Training, CDM, CR

3:30 pm-5:00 pm LEVEL: ■

Room 103C

### Using ADDIE (Analyze, Design, Develop, Implement, Evaluate) to Strategically Analyze and Evaluate Your Training Program

Session Chairpersons
***Claudia Lappin, JD, MS***
Eli Lilly and Company
***Janet F. Zimmerman, MS***
Senior Director, Training Services, PharmaNet

Planning and developing a training program can be a challenge, even for experienced trainers. How does one start? What are the steps involved? Using ADDIE, this session will describe the process for planning a training program from concept to development to evaluation. Particular emphasis will be placed on performing a needs assessment; determining the target audience, learning objectives, and content; selecting instructional methodologies; and strategic use of evaluation planning and methodologies, including testing, using case studies and industry examples. By taking a strategic approach to training evaluation, organizations can enhance their internal metrics with a professional training evaluation program. Systematically implementing a training program with evaluation aligns training metrics with business results and provides a basis upon which to gauge the success of the training on employee performance and productivity.

**Using ADDIE to Develop a Training Program: Needs Assessment to Evaluation**
***Janet F. Zimmerman, MS***
Senior Director, Training Services, PharmaNet

**Overview of the "E" in ADDIE: Evaluating Training for Business Results**
***Claudia Lappin, JD, MS***
Eli Lilly and Company

**Evaluation and Testing to Enhance Qualifications Programs**
***Steven P. Steinbrueck, MPH***
President, Stonebridge GCP Consulting, Inc.

## Session 299N VA - Validation, GCP, IT

3:30 pm-5:00 pm LEVEL: ●

Room 113C

### Validation from Inside the Corporate Environment

Session Chairperson
***Bradley D. Wong***
Senior Manager, R&S Information Systems, Allergan

All computerized system validations have inherent risks, whether it is the system, the participants, the process or some other unforeseen event. The ease, or difficulty, that you will have in managing these risks will be dictated by the process framework that you have developed for carrying out your validations. Then, when your validation throws you a curve ball, you can be sure you will know what to do. This session will begin by looking at some different solutions that were employed to manage risk points during the validation process. The final presentation will wrap up by providing an example of an approach to a computerized system validation that posed "special challenges."

**Process Mapping: The Cornerstone to Validation Efficiency and Effectiveness**
***Joanne S. Malia, MS, MS***
Computer Systems Validation Manager, Neurogen Corporation

**Manage System Life-cycle Processes by Controlling Content and Using Software Tools**
***Richard M. Siconolfi, MS***
Director, Computer Systems Validation and System Life Cycle, Procter & Gamble Pharmaceuticals Inc.

**Validating a Configurable LIMs System for Clinical Support**
***Philip E. Sax, MPA***
Principal/President, FDA Compliance Solutions

5:00 pm **END OF TUESDAY SESSIONS**

5:30 pm-6:30 pm **FDA'S 100TH ANNIVERSARY RECEPTION**
**Grand Hall, 2nd Floor, Convention Center**

7:30 am-4:00 pm **ATTENDEE REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-4:00 pm **EXHIBITOR REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-4:00 pm **SPEAKER REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-8:15 am **CONTINENTAL BREAKFAST**
Grand Hall and Meeting Rooms 201-204 Concourse, 2nd Floor, Convention Center
Ballroom Foyer, 5th Floor, Marriott Hotel

9:00 am-3:30 pm **EXHIBITS OPEN**
Exhibit Halls A and B, 2nd Floor, Convention Center

5:15 pm **CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH MEETING**
Room 202AB, Convention Center

## Session 301 AHC - Academic Health Centers, CR

8:30 am-10:00 am **LEVEL:** ■

**Room 113B** *CME and Pharmacy credits offered*

### IND Exemptions: The Determination Process

Session Chairperson
***Harvey M. Arbit, PharmD, MBA, RAC***
Director, IND/IDE Assistance Program, Academic Health Center, University of Minnesota

Investigator-initiated drug research may require the submission of an IND. Some of this clinical research may be exempt from the IND requirements. Some researchers and IRBs do not understand the criteria for exemption and may incorrectly determine that an IND is not needed. The FDA's guidance document addressing IND exemptions for studies of lawfully marketed drugs for the treatment of cancer should be used as a reference for all IND applicability assessments.

**An FDA Perspective**
***Joseph P. Griffin, JD***
Deputy Director, Office of Medical Policy, CDER, FDA

**A University of Pennsylvania Perspective**
***Gregg J. Fromell, MD***
Executive Director, Office of Human Research, School of Medicine, University of Pennsylvania

**A University of Minnesota Perspective**
***Harvey M. Arbit, PharmD, MBA, RAC***
Director, IND/IDE Assistance Program, Academic Health Center, University of Minnesota

## Session 302 BT - Biotechnology, CR, RA

8:30 am-10:00 am **LEVEL:** ■

**Room 103A** *CME and Nursing credits offered*

### Vaccine Toxicology

Session Chairperson
***Jan Willem Van der Laan, PhD***
Head, Pharmacology Toxicology Assessment, RIVM, Netherlands

Toxicological testing of vaccines is an increasing business as more and more the understanding is growing that a thorough testing during development may reduce batch release testing. Guidance documents are now released by WHO and CHMP on nonclinical testing of vaccines and adjuvants. These guidance documents are now increasingly implemented in the development of new vaccines.

**Safety Testing of Adjuvants in Human Vaccines**
***Jan Willem Van der Laan, PhD***
Head, Pharmacology Toxicology Assessment, RIVM, Netherlands

**Risk of Integration and Insertional Mutagenesis by Plasmid DNA and Adenovirus-vectored Vaccines**
***Brian J. Ledwith, PhD, MBA***
Senior Director, Safety Assessment, Merck Research Laboratories

**Preclinical Development of a Modern Vaccine**
***François Verdier, PhD, PharmD***
Associate Vice President, Regulatory Affairs France, Sanofi Pasteur, France

## Session 303 CDM - Clinical Data Management, EC, IT

8:30 am-10:00 am **LEVEL:** ■

**Marriott Salon CD** *CME credits offered*

### Sites without Standards

Session Chairperson
***Rebecca D. Kush, PhD***
President, CDISC

The current clinical trial technology environment for investigative sites is not conducive to increasing recruitment of new investigators or subjects. Factors that may improve this situation include a stronger link between health care and clinical research processes and systems. This session will explore initiatives of the Clinical Data Interchange Standards Consortium (CDISC) and others (e.g. HL7, NIH, FDA) to streamline clinical trials for sites through technology and data standards.

**The eSource Data Interchange Initiative and Benefits to Sites**
***David P. Iberson-Hurst***
CEO, Assero Limited, UK

**Restructuring the National Cancer Clinical Trials Enterprise**
***John H. Speakman***
Director, Clinical Research Informatics, Memorial Sloan-Kettering Cancer Center

**The NIH Roadmap and a Network Approach to Data Standards**
***Robert A. Harrington, MD, FACC, FSCAI***
Professor of Medicine, Division of Cardiology; Director, Cardiovascular Clinical Trials, Duke Clinical Research Institute

## Session 304 CMC - Chemistry, Manufacturing, and Controls, BT, TR

8:30 am-10:00 am **LEVEL:** ■

**Room 112AB**

### Implementation of Quality-by-design: An Office of Biotechnology Products Perspective

Session Chairperson
***Steven Kozlowski, MD***
Director, Office of Biotechnology Products, CDER, FDA

This session will present the Office of Biotechnology Products' views on Quality-by-design (QbD).

**FDA Perspective**
***Steven Kozlowski, MD***
Director, Office of Biotechnology Products, CDER, FDA

**Industry Perspective**
***John F. Haury, PhD***
Senior Quality Engineer, Amgen Inc.

**Panel Discussion and Q&A Period**

## Session 305 CP - Clinical Safety and Pharmacovigilance, RA

8:30 am-10:00 am LEVEL: ●

Marriott Salon G *CME and Pharmacy credits offered*

### Global Perspective on ADR Reporting Practices

Session Chairpersons
***Kate Gelperin, MD, MPH***
Medical Epidemiologist, CDER, FDA
***Sabine Brosch, MSc, PhD***
Deputy Head of Sector, Pharmacovigilance and Postauthorization Safety and Efficacy, EMEA, EU

This session provides a review of postmarketing adverse drug reaction reporting systems in selected countries and offers a global perspective on ADR reporting systems and future developments. The session will include the organization of adverse drug reporting (central versus decentralized), the source of reports, the analysis of reports, initiatives to counter underreporting, and the interaction of centers with reporters.

**Global ADR Reporting Practices: An Industry Perspective**
***Linda S. Hostelley***
Executive Director, Worldwide Product Safety and QA, Merck Research Laboratories

**Global ADR Reporting Practices: A Regulatory Perspective**
***Sabine Brosch, MSc, PhD***
Deputy Head of Sector, Pharmacovigilance and Postauthorization Safety and Efficacy, EMEA, EU

**Industry-wide, In-depth Survey of Pharmacovigilance Practices in Japan**
***Gregory S. Meline, MBA***
Manager, PRTM Management Consultants

**Panelist**
***Kaori Nomura***
Visiting Expert, Unit of Postauthorization Evaluation of Medicines for Human Use, EMEA, EU; Principal Official for Electronic Data Submissions, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

## Session 306 CR1 - Clinical Research and Development

8:30 am-10:00 am LEVEL: ◆

Marriott Salon E *CME and Pharmacy credits offered*

### Oncology Endpoints/Biomarkers

Session Chairperson
***Francesco Pignatti, MD***
Scientific Administrator, EMEA, EU

Biomarkers play an increasingly important role in the development of new drugs. It is expected that they will contribute to increase the rate of success of new developments and to expedite the development of drugs. This session presents the current status, challenges, and future trends for use of biomarkers and surrogate endpoints from the perspective of FDA, EMEA, and industry.

**US/FDA Viewpoint**
***Adrian Senderowicz, MD***
Medical Officer, Office of Oncology Drug Products, Office of New Drugs, CDER, FDA

**EU/EMEA Viewpoint**
***Francesco Pignatti, MD***
Scientific Administrator, EMEA, EU

**The Dilemma of Agreeing Meaningful Endpoints in Oncology**
***Peter Cheverton, MBChB, MMedRadT***
Senior Director, Oncology Medical Research, CR&D Europe, Wyeth Research

**Panelist**
***Eric Abadie, MD, MBA***
Vice Chairman, CHMP, EMEA, EU; ICH Steering Committee Member; Director, AFSSAPS, France

## Session 307 CR2 - Clinical Research and Development, CTM, IS

8:30 am-10:00 am LEVEL: ●

Marriott Salon KL *CME, Nursing, and Pharmacy credits offered*

### Clinical Trials and Tribulations: Influences on Patient Recruitment and Retention

Session Chairperson
***Tammy Jeanne Massie, PhD, MS***
Mathematical Statistician, CDER, FDA

This session will focus on experiences of clinical trial participants and investigators. Based on firsthand experiences from participants and others involved in clinical trials creation and implementation, mechanisms which are successful at recruiting and retaining subjects in clinical trials will be discussed. The goal of this session is to illustrate positive and negative aspects of a clinical trial to assist those who create and implement them in improving how clinical trials are executed.

**Recruitment and Retention in Clinical Trials: Reflections from a Clinical Trial Volunteer**
***Tammy Jeanne Massie, PhD, MS***
Mathematical Statistician, CDER, FDA

**Recruitment and Retention in Clinical Trials: Utilizing Focus Groups to Optimize Participation**
***Cindy Rodenberg, PhD***
Statistician, Procter & Gamble

**Recruitment and Retention from a Clinician's Perspective**
***Jean G. Ford, MD***
Associate Professor, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health

**Panelist**
***Elizabeth A. Moench***
President, MediciGroup® Inc.

## Session 308 CR3 - Clinical Research and Development, ST

8:30 am-10:00 am LEVEL: ●

Marriott Salon IJ

### Using Six Sigma to Optimize Research and Development

Session Chairperson
***Tim G. Strauss, MS***
Executive Director, Business Process Improvement, Covance

In addition to a brief and concise overview of the Six Sigma methodology, this session will provide three different perspectives (CRO, pharmaceutical industry, and the FDA) on how Six Sigma is being deployed in our industry. Following three short case studies, the speakers will form a panel to take questions and discuss the current and future impact of Six Sigma on our industry.

**Six Sigma at a CRO: A Powerful Deployment at Covance**
***Tim G. Strauss, MS***
Executive Director, Business Process Improvement, Covance

**A Biotech Case Study: Creating Breakthrough Performance in Amgen's R&D Organization**
***Benedict J. Chu, MS***
Associate Director, Clinical Research Services, Amgen Inc.

**Customizing Your Approach to Deploying Six Sigma**
***Bob Silvers***
Executive Consultant, Six Sigma Academy

## Session 309 CR4 - Clinical Research and Development, CTM

8:30 am-10:00 am LEVEL: ■

**Marriott Salon H**

### Clinical Trials in Central and Eastern Europe: Overcoming Technology and Logistical Challenges

Session Chairperson
***Bela E. Toth, MD, PhD***
Director of Clinical Operations, PRA International, Hungary

It has become increasingly common to include sites in Central and Eastern Europe as part of a global clinical development program. In parallel, clinical trials are increasingly leveraging new technologies, such as EDC and Medical Imaging. This session will discuss the intersection of these trends, addressing the technical and logistical challenges for clinical trials in this region. Presentations will include real-world strategies proven to mitigate risk when addressing technology or logistics with trials in CEE.

**Clinical Operations Perspectives**
***Bela E. Toth, MD, PhD***
Director of Clinical Operations, PRA International, Hungary

**Electronic Data Capture and eDiary Deployment and Support**
***Mark Wren, MBA***
Director of International eServices Support, Phase Forward, UK

**Medical Imaging Standardization and Central Collection**
***Joanne Groller***
Supervisor, Project Management, Bio-Imaging Technologies, Inc.

## Session 310 CTM - Clinical Trial Management, BT

8:30 am-10:00 am LEVEL: ■

**Room 107AB** *Pharmacy credits offered*

### Collaborating Effectively to Submit Cooperative Group Data to the FDA

Session Chairperson
***Jane E. Myles***
Senior Manager, Medical Affairs, Genentech, Inc.

Biotechnology and pharmaceutical companies are increasingly collaborating with NCI-sponsored cooperative groups to conduct both proof of concept and large Phase 3 trials in a wide range of oncology indications and settings. Successful collaboration has been achieved in part by creating agreed-upon communication norms, roles, and responsibilities for both parties, especially in preparation for submitting pivotal data to the FDA for supplemental Biologic License Applications (sBLAs). The focus of this session is to review the approaches used by different molecule teams and cooperative groups to successfully submit data to FDA.

**Teaching a Sponsor New Tricks: Preparing Cooperative Group Data for FDA Submission**
***Jane E. Myles***
Senior Manager, Medical Affairs, Genentech, Inc.

**Making It Happen: Helping Prepare Cooperative Group Data for FDA Submission**
***Mary E. Steele***
Director, Group Administration, Eastern Cooperative Oncology Group Coordination Center

## Session 311 DM - Document Management/ eSubmissions, IT, RA

8:30 am-10:00 am LEVEL: ■

**Room 204C**

### eSubmission Standards: Industry's Perspective

Session Chairperson
***Gary G. Walker***
Associate Regulatory Director, Global Data Management, Quintiles Transnational Corp.

This session will look at three important facets of eSubmission standards: electronic signatures, strategic planning, and the continuing development of eCTD standards.

**Electronic Signatures for the Pharmaceutical Industry**
***Rodd W. Schlerf***
Sales Manager, ARX, Inc.

**The Future of eCTD**
***Kenneth R. VanLuvanee***
President and CEO, Apyx Inc.

**Developing an Overall Strategy Vision and Plan for eSubmission Standards**
***Michael Brennan, PhD, MS***
Vice President, Global Regulatory Operations, Centocor - Johnson & Johnson

## Session 312 EC - eClinical, CDM, RA

8:30 am-10:00 am LEVEL: ●

**Room 113A**

### Where Are We in the Debate between the Biopharmaceutical Industry, the Solution Providers, and the Regulatory Authorities? What Initiatives Are Being Taken to Alleviate Issues around eSource?

***NEW 2006 SIAC Offering – SIAC-sponsored Session***

Session Chairpersons
***Valdo Arnera, MD***
General Manager, Europe, PHT Corporation, Switzerland
***Colleen M. Cox***
Manager, Data Management, PROMETRIKA, LLC

eSource has been defined on Webopedia as "source data captured initially into a permanent electronic record." There has been much interest and discussion over the past few years regarding EDC and ePROs and the opportunity to enhance clinical trial conduct through quality, efficiency, and safety gains. However, several surveys have consistently shown that regulatory uncertainty remains the primary challenge for the implementation of EDC and ePROs and is the main reason for delay in adopting this technology. The premise is that electronic health records already exist and clinical trial sponsors need to determine if and how to use it within the framework of the existing regulations surrounding clinical trials. Like sites and sponsors, FDA personnel are transitioning from the paper world to the eWorld and, to fully comprehend the issues being encoun-

tered by sites and sponsors during this transition period, they have had ongoing discussions with technology providers. The FDA has encouraged the formation of the eSource Data Interchange Group (eSDI) within CDISC to provide a vendor neutral forum for the discussion of industry issues and the development of recommendations relevant to eSDI for clinical trials. The eSDI has issued a White Paper which will serve as the base of discussions by an expert panel in this session, which is sponsored by DIA's eClinical and CDM SIACs.

**Panelists**

***Mike Bartlett***
System Project Manager, H. Lundbeck A/S, Denmark

***Joseph P. Salewski***
Deputy Director; Division of Scientific Investigations, CDER, FDA

***Stephen A. Raymond, PhD***
Chief Scientific Officer and Quality Officer, PHT Corporation

***Wayne R. Kubick, MBA***
Vice President, Phase Forward/Lincoln Technologies, Inc.

***Christian G. Reich, MD***
Associate Director, Clinical Informatics, Millennium Pharmaceuticals, Inc.

***David P. Iberson-Hurst***
CEO, Assero Ltd., UK

## Session 313 GCP - Good Clinical Practices, CR, PP

8:30 am-10:00 am LEVEL: ■

**Marriott Salon F** *CME credits offered*

### Update: Secretary's Advisory Committee on Human Research Protection (SACHRP)

Session Chairperson
***Thomas L. Adams, LHD, CAE***
President and CEO, Association of Clinical Research Professionals

The Secretary's Advisory Committee on Human Research Protections (SACHRP formerly known as the National Human Research Protections Advisory Committee) was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects. This session, led by the Chair of SACHRP, will address the activities of the committee to date.

**Recommendations of the HHS Secretary's Advisory Committee to Enhance Human Subject Protection and Reduce Regulatory Burden**
***Ernest D. Prentice, PhD***
Associate Vice Chancellor for Academic Affairs, University of Nebraska Medical Center

**Overview of the Change to the HHS Secretary's Advisory Committee on Human Subject Research Protections**
***Thomas L. Adams, LHD, CAE***
President and CEO, Association of Clinical Research Professionals

## Session 314 IT - Information Technology, CDM, EC

8:30 am-10:00 am LEVEL: ●

**Room 105AB**

### Why Your Data Can't Talk to My Data

Session Chairperson
***Jamie P. Romanowski***
Technical Manager, ICTI

Every pharmaceutical and biotechnology company, in one way or another, has to share data among systems or with other companies. Setting up a company wide data exchange strategy can be a difficult process. You need to ensure that you have a flexible system that will be able to support multiple formats and secure transmission methods. There are several design considerations that will ease data exchange and set your company up for a well-defined, repeatable, and validated process.

**Data Integration Strategies**
***Jamie P. Romanowski***
Technical Manager, ICTI

**Sharing Data Using the CDISC Operational Data Model**
***Chris Decker, MS***
Pharmaceutical Software Development, Systems Engineer, SAS Institute Inc.

**Data Integration Projects from the Ground Level**
***Miriam Hill***
Worldwide Computer Supplies, Procter & Gamble Pharmaceuticals

## Session 315 MA - Marketing and Sales, AD, CTM, RA

8:30 am-10:00 am LEVEL: ●

**Room 113C**

### New Drug Launches and Drug Adoption

Session Chairperson
***Harold E. Glass, PhD***
Professor of Pharmaceutical Business, University of the Sciences in Philadelphia

Examining the prescribing behavior of over 3,500 physicians, the research examines the factors most directly influencing the adoption of new drugs. In addition the research explores how the introduction of new drugs affects the prescribing patterns of other drugs from the company behind the launch of the new drug.

**The Profile of the Early Adopter and Company Prescribing Loyalty**
***Larry Poli, PhD***
Executive Director, Center for Performance Excellence, LLC

**Understanding the Role of the Clinical Investigator in New Drug Adoption**
***Harold E. Glass, PhD***
Professor of Pharmaceutical Business, University of the Sciences in Philadelphia

## Session 316 MC - Medical Communications, MA

8:30 am-10:00 am LEVEL: ■

**Room 204A** *CME and Pharmacy credits offered*

### Medical Information as an Adjunct to Sales Training

Session Chairperson
***Christine Wyble, PharmD***
Director, Oncology Medical Information Services, sanofi-aventis

Through collaboration with sales training, medical information services can add value to the education of field-based sales personnel. The development of an educational bulletin by the medical information services department of a pharmaceutical company will be described, as well as the role of medical information services in the development of sales training classes. In addition, the results of a survey completed by the field-based sales force to assess the value of the educational bulletin will be reviewed.

**Sales Training and Development of a Specialty Field Force**
***Barbara Lupinacci, RPh***
Director, Oncology Sales Training, sanofi-aventis

**The Evolving Relationship between Medical Information and Sales Training**
***Edmund J. Cunningham, PharmD***
Product Services Specialist, Eisai, Inc.

**An Educational Bulletin to Communicate Medical Information to Field Sales Personnel**
***Christine Wyble, PharmD***
Director, Oncology Medical Information Services, sanofi-aventis

## Session 317 MW - Medical/Scientific Writing, BT, RA

8:30 am-10:00 am LEVEL: ■

**Room 204B**

### ISS/ISE: Where Do They Fit in the CTD/eCTD?

Session Chairperson
***Justina A. Molzon, MS Pharm, JD, CAPT. USPHS***
Associate Director for International Programs, CDER, FDA

The CTD format of the NDA has been readily accepted by sponsors and represents the format used for the majority of applications being submitted to the FDA. Progress is also being made in submitting applications in the eCTD format. However, there continue to be questions from sponsors on how the ISS/ISE fits into the CTD or eCTD. The panel will explain the agency's perspective and provide examples to demonstrate the proper way to submit the ISS/ISE in both the CTD and eCTD formats.

**Background on CTD Efficacy and ISS/ISE**
***Robert J. Temple, MD***
Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

**Review of the CTD Efficacy and ISS/ISE**
***Armando Oliva, MD***
Associate Director for Policy, Office of New Drugs, CDER, FDA

**eCTD Efficacy Submission Format**
***Gary M. Gensinger***
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

## Session 318 NC - Nonclinical Laboratory Safety, BT, MW

8:30 am-10:00 am LEVEL: ●

**Room 111AB** *CME credits offered*

### Developmental and Reproductive Toxicity Evaluations of Biological Drugs

Session Chairperson
***Shawn M. Heidel***
Senior Toxicologist, Eli Lilly and Company

The regulatory and scientific expectations for developmental and reproductive toxicology testing of biological drugs are complex and often not straightforward. Current practices and decision matrices for these studies will be presented and discussed.

**Comparison of Reproductive Toxicity with a Human Protein in Cynomolgus Monkeys and a Surrogate Murine Protein in Mice**
***Jeanine L. Bussiere, PhD, DABT***
Director of Toxicology, Amgen Inc.

**Developmental Reproduction Toxicity Assessment of Alefacept, LFA-3/IgG1 Human Fusion Protein**
***Janet B. Clarke, PhD, DABT***
Senior Director, Pharmacotoxicology, Biogen Idec Inc.

**Regulatory Considerations for Developmental Toxicity Testing of Biological Drugs**
***Melanie Hartsough, PhD***
Pharmacologist, CDER, FDA

## Session 319 NHP - Natural Health Products, AHC, CMC, RA

8:30 am-10:00 am LEVEL: ●

**Room 106AB** *CME credits offered*

### Developing Probiotics as Biologics: Regulatory and Scientific Considerations

Session Chairperson
***Jennifer J. Ross, PhD***
Regulatory Reviewer, Project Manager, Division of Vaccines and Related Product Applications, CBER, FDA

Intended use determines how FDA regulates a substance. Preparations of live microorganisms used with the intention of having a therapeutic effect in humans are regulated as biological products. This session will present regulatory issues faced in the development of preparations of live microorganisms for clinical indications in the US.

**Probiotics for Use as Biologic Products: Chemistry, Manufacturing, and Control Issues**
***Siba Bhattacharyya, PhD***
Chemist, CBER, FDA

**It's Been Food for Centuries, So Why Do I Now Have to Get an IND? Regulatory Impact on the Science of Probiotics**
***Patricia L. Hibberd, MD, PhD***
Professor of Medicine and Pediatrics, Tufts University School of Medicine; Director, Division of Clinical Research Resources, Institute for Clinical Research and Health Policy Studies, Tufts New England Medical Center

**Developing Probiotics as Drugs: An Industry Perspective**
***Harunobu Amagase, PhD***
Director of Research & Development, Wakunaga of America Co., Ltd.

## Session 320 OS - Outsourcing, CR, FI

8:30 am-10:00 am LEVEL: ■

**Room 109AB**

### The State of Clinical Outsourcing: The Functional Service Provider Model

Session Chairperson
***Patricia Leuchten***
President, The Avoca Group, Inc.

This session will explore the opportunities, issues and challenges of the functional service provider (FSP) model of outsourcing and discuss the impact on the industry if large pharmaceutical companies shift from global, full-service outsourcing to the FSP model. Data from a 2006 State of Clinical Outsourcing Industry Survey will be shared.

**The INC Research Point of View**
***John G. Potthoff, PhD***
President, INC Research

**The Pfizer Global R&D Point of View**
***James E. Taylor***
Worldwide Head, Contracts and Outsourcing, Pfizer Global R&D

**The Quintiles Point of View**
***Paula Brown Stafford, MPH***
Executive Vice President, Global Data Management, Quintiles Transnational

**The Pain Therapeutics Point of View**
***Peter G. Butera***
Director Clinical Operations, Pain Therapeutics

## Session 321 PM1 - Project Management, CTM, OS

8:30 am-10:00 am LEVEL: ●

Room 108A *Project Management Institute credits offered*

### Driving High Performance Strategic Relationships

Session Chairperson

***Timothy J. Noffke***

Vice President, Life Sciences, Integrated Project Management Co., Inc.

"Managing alliances is now as important as building a top-notch in-house research team," according to a quote from a recent *Wall Street Journal* article. While nearly 400 new collaborations were created last year, an estimated half will not succeed, with most failures attributed to a critical need for improved alliance management. This session will explore how to drive value through effective alliance management at the project team level.

**Lessons Learned in Alliance Management**
***Andrew S. Eibling***
Alliance Manager, Office of Alliance Management, Eli Lilly and Company

**Forming a New Alliance Management Organization**
***Jenny Rohde, MBA***
Director, Alliance Management, TAP Pharmaceutical Products Inc.

**Managing Alliances from a Small Biotechnology Perspective**
***Annette Gilchrist, PhD***
President, Cue BIOtech

## Session 322 PM2 - Project Management, TR

8:30 am-10:00 am LEVEL: ◆

Room 108B *Project Management Institute credits offered*

### Leadership Secrets to Manage Highly Qualified Individuals

Session Chairperson

***Munish Mehra, PhD, MS, MSc***

Senior Vice President, Clinical Research Services, Medifacts International

This session shares our experience in what it takes to manage a cross-functional team of highly talented individuals. Very bright people often are difficult to manage due to their egos and their strong opinions. The speakers will share their experience and some of the new management techniques now being used.

**The Key to Rapid Course Correction: Collaboration with Multiple Vendors across Three Continents and Internal Senior Management on the Floor Above**
***Jim Mather***
Senior Director, Clinical Operations, Encysive Pharmaceuticals

**Leading and Developing the Project Leaders**
***John A. Faulkes***
Consultant, TeamCommunications Development, UK

**The Essence of Leadership: From Ancient Wisdom to Modern Techniques**
***Munish Mehra, PhD, MS, MSc***
Senior Vice President, Clinical Research Services, Medifacts International

## Session 323 RA1 - Regulatory Affairs, PM

8:30 am-10:00 am LEVEL: ●

Room 202AB

### The QS Train Is Moving Fast at FDA

Session Chairperson

***Lana L. Pauls, MPH***

Director, Quality Assurance Staff, CDER, FDA

The FDA has required industry to use quality systems for many years. Now, we are requiring it of ourselves. This session was developed to help the audience see the implementation efforts and the progress made to date.

**QMS: The Impact on Drug Safety Process Improvement**
***Lana L. Pauls, MPH***
Director, Quality Assurance Staff, CDER, FDA

**QMS for CMC: Update and Progress**
***Jon E. Clark, MS***
Information Technology Expert, Office of New Drug Chemistry, CDER, FDA

**What Do You Mean when You Say Quality System?**
***Deborah Jansen, PhD***
Laboratory Quality Manager, CBER, FDA

## Session 324 RA2 - Regulatory Affairs, CP

8:30 am-10:00 am LEVEL: ■

Room 201C

### First Experience with Risk Management Initiatives in the US and EU

Session Chairpersons

***Paul J. Seligman, MD, MPH, CAPT. USPHS***

Associate Director for Safety Policy and Communication, CDER, FDA

***Noël Wathion, Pharm***

Head of Unit, Postauthorization Evaluation of Medicines for Human Use, EMEA, EU

RiskMAPs/Risk Management Plans (RMPs) are now submitted by pharmaceutical companies in the US and the EU with the aim to detect, assess, and minimize important risks at an early stage after approval of medicinal products. ICH E2E has provided a common framework for the presentation of pharmacovigilance plans (PvP) but has not addressed risk minimization activities. Requirements regarding the submission, content, and presentation of these documents also vary across regions. It is therefore useful to review the practical experience of RiskMAPs/RMPs from the points of view of both regulatory authorities and industry. This session will address situations where RiskMaps/RMPs have been required, gaps in PvP and risk minimization plans, and potential areas of improvement.

**Practical Experience with Risk Management Plans in the US**
***Claudia B. Karwoski, PharmD***
Scientific Coordinator, Office of Drug Safety-IO, CDER, FDA

**Lessons Learned from Risk Management Plans Submitted for Centrally Authorized Products in the EU**
***Xavier Kurz, MD, PhD***
Scientific Administrator, EMEA, EU

**Risk Management Plans: An Industry Perspective**
***Mitchell S. Gandelman, MD, PhD***
Associate Director, Pfizer Inc

## Session 325 RA3 - Regulatory Affairs, CP, CR

8:30 am-10:00 am LEVEL: ●

Room 201B

### QT-Dossier: The Impact of ECG Data from a Regulatory Perspective

Session Chairperson

***Jeffrey Heilbraun, MSc***

Senior Director, Corporate Development - Strategic Partnerships, Medifacts International

With the implementation of the ICH E14 guidance document, the role of ECG data in the regulatory submission process has gained greater focus. No longer is the data solely a medical and patient safety consideration, but also a key factor in the regulatory process.

**ECG Activity in Drug Development: Pharmaceutical Company Perspective – ECGs in Drug Development – Key Considerations and Planning**
***John K. Finkle, MD***
Medical Director, GlaxoSmithKline

**ECG Evaluation from a Cardiac Safety Core Lab Perspective: Background on the ECG in Clinical Research – Operational and Regulatory Considerations**
***Jean Toby Barbey, MD***
Medical Director, Core Cardiology Laboratory, Medifacts International

**ECG Activity: A Regulatory Perspective – Interaction and Considerations when Working with the ECG Data in Clinical Trials**
***Shari Targum, MD***
Medical Officer, CDER, FDA
***Douglas C. Throckmorton, MD***
Deputy Director, CDER, FDA

## Session 326 RA4 - Regulatory Affairs, BT

8:30 am-10:00 am **LEVEL:** ●

**Room 201A**

### Understanding the Regulation of "Advanced Therapy Medicinal Products" in Europe

Session Chairperson
***Christopher J. Holloway, PhD***
Group Director of Regulatory Affairs and CSO, ERA Consulting Group, UK

"Advanced therapy medicinal products," first defined in Directive 2003/63/EC, cover gene, somatic cell, and human tissue-engineered products. In response to scientific progress and the lack of specific guidance for these products, a new regulatory basis has been developed, including, for the first time, tissue-engineered products. This session will address the regulation of advanced therapy medicinal products in the EU and provide practical advice relating to the development of these products.

**The Regulation of Cell Therapy and Tissue-Engineered Products in the EU**
***Ralf Sanzenbacher, PhD***
Federal Agency for Sera and Vaccines, Paul Ehrlich Institute (PEI), Germany

**The Regulation of Gene Therapy Products in the EU**
***Lincoln Tsang, PhD, MRPharmS***
Barrister, Arnold & Porter LLP, UK

**Regulatory Strategies to Support the Development of Advanced Therapy Medicinal Products in the EU**
***Christopher J. Holloway, PhD***
Group Director of Regulatory Affairs and CSO, ERA Consulting Group, UK

## Session 327 RD - R&D Strategy, CTM

8:30 am-10:00 am **LEVEL:** ●

**Room 102AB** *Pharmacy credits offered*

### Does Innovation Pay?

Session Chairperson
***Jeffrey S. Handen, PhD***
Associate Director, Business Performance Improvement, Merck Research Laboratories

The pharmaceutical industry, as a whole, is arguably suffering from an innovation deficit as it struggles to cope with a host of factors. Various analysts estimate that at present, approximately only 1/3 to 1/2 of R&D budgets are allocated to novel R&D efforts, with the rest actually focused on line extensions and "me too" drugs. This session will explore the challenge presented by these observations and discuss if innovation can be balanced against risk and return on investment.

**The Impact of Innovation on R&D Operations**
***Neil Patel, PharmD***
Director, Pharmaceutical Advisory Services, PricewaterhouseCoopers, LLP

**Partnering for Innovation**
***Melinda S. Shockley, PhD***
Senior Director, Business Development, Medarex, Inc.

## Session 328 ST - Statistics, CR

8:30 am-10:00 am **LEVEL:** ●

**Room 103B** *CME and Pharmacy credits offered*

### Endpoint Selection and Other Considerations in HIV Clinical Trials

Session Chairperson
***Greg Soon, PhD***
Statistician, CDER, FDA

Because the focus of HIV drug development has been shifted from naïve population to treatment-experienced population, more viral load-based endpoints need to be evaluated as a replacement for the traditional endpoint. We will study the properties of these endpoints and their relationships with each other as well as with clinical endpoints.

**HIV RNA as Surrogate Endpoint in Treatment-experienced Populations**
***Michael D. Hughes, PhD***
Professor of Biostatistics, Harvard School of Public Health, Harvard University

**Statistical Issues in Endpoint Selection**
***Greg Soon, PhD***
Statistician, CDER, FDA

**Clinical Perspectives in the Endpoint Selection in HIV Trials in Treatment-experienced Populations**
***Jeffrey S. Murray, MD***
Deputy Director, Division of Antiviral Drug Products, CDER, FDA

## Session 329 TR - Training, CTM, GCP

8:30 am-10:00 am **LEVEL:** ●

**Room 103C**

### Online Learning: Managing the Implementation Process

Session Chairperson
***Janet F. Zimmerman, MS***
Senior Director, Training Services, PharmaNet

Introducing online learning to an organization that is accustomed to a traditional model of instructor-led, classroom-based training can be a bumpy process. Implementation issues may include unrealistic expectations, resistance, and underestimating the resources needed to successfully execute the online training. Will the learning be synchronous or asynchronous? Using a case study model, presenters will describe their experiences in bringing online learning to their organization, focusing on constraints and challenges that were encountered and how they were managed. At the conclusion of the presentations, the audience will be encouraged to briefly share their experiences implementing online learning.

**A Few ABC's of Online Learning**
***Janet F. Zimmerman, MS***
Senior Director, Training Services, PharmaNet

**Implementing a Synchronous Learning Program**
***Steven P. Steinbrueck, MPH***
President, Stonebridge GCP Consulting, Inc.

**Implementing an Asynchronous Learning Program**
***Robert C. Morrison***
Manager, Training Services, PharmaNet

## Session 330 VA - Validation, IT, RA

8:30 am-10:00 am LEVEL: ■

**Room 203AB**

### Validation from the Quality Perspective

Session Chairperson

***Stephan Bachmann***

Associate Director, Merck Research Laboratories

This session will discuss the elements of risk involved in computer system validation in a regulated environment. In addition to defining these risk areas, the session will highlight the business and regulatory impact. The session will also explore techniques for assessing and managing risk and include a case study illustrating implementation of a risk-based approach.

**Risk Assessment and Management Specific to Computer Validation**
***Leonard A. Grunbaum, MBA***
Partner, The Practical Solutions Group, LLC

**Quality System Framework Approach to Risk Management in Computer Validation**
***James Huang, PhD***
Director, Quality Assurance and Regulatory Compliance, ICTI

**A Statistical Approach to 21 CFR Part 11 Risk Analysis and Compliance Measurements**
***Maria Frantz, MS***
Computer Validation Compliance Associate, Merck & Co., Inc.

10:00 am-10:30 am **REFRESHMENT BREAK**
**Exhibit Halls A and B, 2nd Floor, Convention Center**
**Ballroom Foyer, 5th Floor, Marriott Hotel**

## Session 331 AHC - Academic Health Centers, CR

10:30 am-12:00 pm LEVEL: ■

**Room 113B** *CME and Pharmacy credits offered*

### IRB Training in Ethical Issues: The Brazilian Experience

Session Chairperson

***Gustavo L. F. Kesselring, MD***

Director, Clinical Operations, IBIC Clinical Research Center, Brazil

The recent increase in clinical research in emerging countries imposes new ethical dilemmas for local ethics committees (IRBs). Lack of training in this area may cause noncompliance with regulations and guidelines and can delay the time to start CTs. The Brazilian experience in training members to face these new dilemmas will be presented. This session will discuss the urgent need to train IRB members to face new dilemmas in clinical research in countries where CTs are growing faster than their capacity to manage it and discuss the Brazilian experience in this training.

**Brazilian Regulatory Approval Process**
***Sergio De Andrade Nishioka, MD, PhD, MSc***
Manager, Office of New Drugs, Research and Clinical Trials, ANVISA - Brazilian National Regulatory Agency, Brazil

**IRB Training in Ethical Issues: Brazilian Experience**
***Jose O. M. Pestano, MD, PhD***
Head of Transplantation Unit/Head of Ethics Committee, São Paulo Hospital; Federal University of São Paulo, Brazil

**Future Perspectives in Improving Brazilian Regulatory Approval Process**
***Moises Goldbaum, MD, PhD***
General Secretary of Science and Technology, Brazilian Ministry of Health, Brazil

## Session 332 BT - Biotechnology, CR

10:30 am-12:00 pm LEVEL: ■

**Room 103A** *CME and Pharmacy credits offered*

### Hot Topics in Biotechnology

Session Chairperson

***Bernard D. King, MD, MBA***

President, Macnas Consulting International

This session will pesent late-breaking topics important to the development of biotechnology drugs and products.

**Systems Biology and New Drug Discovery**
***Bernard D. King, MD, MBA***
President, Macnas Consulting International

**Faster Development through Faster Decisions: Integrating Data, Processes, and Adaptive Strategies**
***Michael J. Rosenberg, MD, MPH***
President and CEO, Health Decisions, Inc.

**Drugs, Vaccines, and Diagnostics for Bioterror Agents: Fact and Fancy**
***Mark D. Dibner, PhD, MBA***
President, BioAbility, LLC

## Session 333 CDM - Clinical Data Management, CP

10:30 am-12:00 pm LEVEL: ■

**Marriott Salon CD**

### The Safety-clinical Data Management Interface

Session Chairperson

***Barry W. Burnstead***

Head of International Commercial Development, Phase Forward Europe Ltd., UK

Regulatory pressures and technological advances have increased the areas of common interest to clinical data managers and pharmacovigilance (PV) professionals. Serious adverse event (SAE) data have always been of mutual interest, but historically data have been managed by parallel processes with an emphasis on data reconciliation. Today common dictionaries are leading operations into centralizing coding operations. Furthermore, safety databases have increased the laboratory data content that are generated under the clinical trial protocol and hence related to reported SAEs. EDC has also changed the dynamics for SAE notification, and novel solutions for capturing SAE information are being introduced.

**Single-source Collection of SAE Data from Clinical Trials via EDC**
***Barbara J. Devens***
Clinical Safety Scientist, GlaxoSmithKline

**Contrasting Standards in the Safety and CDM Worlds**
***Barry W. Burnstead***
Head of International Commercial Development, Phase Forward Europe Ltd., UK

**Centralized Laboratory Data Management for Safety and CDM**
***Thomas E. Morrow***
Associate Medical Consultant, Eli Lilly and Company

**Contrasting Coding, Dictionary Usage, and Signal Detection in Safety and CDM Databases**
***Robbert P. Van Manen, MSc***
Worldwide Technical Director, Lincoln Technologies

## Session 334 CMC - Chemistry, Manufacturing, and Controls, RA, TR

10:30 am-12:00 pm LEVEL: ■

Room 112AB

### Implementation of Quality-by-design: An Office of Generic Drugs Approach

Session Chairperson

***Lawrence X. Yu, PhD***

Deputy Director for Science, Office of Generic Drugs, CDER, FDA

This session will present the new initiatives undertaken by the Office of Generic Drugs to implement quality-by-design.

**FDA Perspective**

***Lawrence X. Yu, PhD***

Deputy Director for Science, Office of Generic Drugs, CDER, FDA

**Industry Perspective**

***John Kovaleski, PhD***

Director, Analytical Research and Development, Teva Pharmaceuticals USA

**Panel Discussion and Q&A Period**

## Session 335 CP - Clinical Safety and Pharmacovigilance, CR, ST

10:30 am-12:00 pm LEVEL: ●

Marriott Salon G *CME and Pharmacy credits offered*

### Some Creative Tools and Methods in Pharmacovigilance

Session Chairperson

***Alan M. Hochberg***

Vice President, Research, ProSanos Corporation

A number of creative responses have been launched to improve postmarket drug safety monitoring. These include better visualization of safety data, specialized postmarketing surveillance programs, and active mining of healthcare provider data for safety information. This session will allow participants to understand the positive impact of these new approaches, and what they might mean for the future of pharmacovigilance.

**Graphical Analysis and Reporting of Safety Data**

***Michael O'Connell, PhD, MSc***

Director, Life Science Solutions, Insightful Corporation

**Use of Postmarketing Surveillance Programs to Monitor a Known or Unknown Safety Issue**

***Eleanor S. Segal, MD***

Vice President and Head, Global Drug Safety, Actelion Pharmaceuticals, Ltd.

**Active ADR Surveillance via Alliance of Regulatory Agency and Sentinel Hospitals**

***Herng-Der Chern, PhD, MD, PharmD***

Executive Director, Center for Drug Evaluation, Taiwan

## Session 336 CR1 - Clinical Research and Development, BT, RA

10:30 am-12:00 pm LEVEL: ■

Marriott Salon E *CME credits offered*

### Pharmacogenetics: FDA/EMEA

Session Chairperson

***Ronald A. Salerno, PhD***

Director, Translational Medicine Liaison, Worldwide Regulatory Affairs, Wyeth Research

This session will aim to provide a global update of how the FDA Critical Path and EMEA Roadmap are enabling the application and use of genomic biomarkers in drug discovery and development. The presentations and discussion will highlight practical outcomes of sharing information with agencies voluntarily and provide insight on how pharmacogenomics is impacting clinical development.

**How Has VGDS Changed Industry and FDA Thinking about PGx?**

***Lawrence J. Lesko, PhD***

Director, Office of Clinical Pharmacology, CDER, FDA

**Current PGx Development in the EU**

***Eric Abadie, MD, MBA***

Vice Chairman, CHMP, EMEA, EU; ICH Steering Committee Member; Director, AFSSAPS, France

**Impact of Pharmacogenomics "Regulatory" Initiatives on the Use of Genomics in Drug Development**

***Ronald A. Salerno, PhD***

Director, Translational Medicine Liaison, Worldwide Regulatory Affairs, Wyeth Research

## Session 337 CR2 - Clinical Research and Development, ST

10:30 am-12:00 pm LEVEL: ■

Marriott Salon AB *CME credits offered*

### A Key to Success in Bringing a Product to Market Is Proper Protocol Design

Session Chairperson

***Lynda Y. Sutton***

COO and Chief Regulatory Officer, Cato Research, Ltd.

Success in bringing a drug to market depends on factors that must be addressed long before initiating clinical trials. One such factor is proper protocol design. A good protocol depends on specific, carefully conceived objectives. Without clear objectives, the chance for success is at risk.

**Avoid the Landmines: Concentrate on the Right Objectives**

***Allen E. Cato, MD, PhD***

President, Cato Bioventures

**Examples of Where Protocol Design Became a Critical Factor in the Success or Failure of a Product**

***Robert J. Temple, MD***

Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

## Session 338 CR3 - Clinical Research and Development, CTM

10:30 am-12:00 pm LEVEL: ■

Marriott Salon IJ *CME and Nursing credits offered*

### Cultural Sensitivity and Patient Recruitment: Techniques for Effective Enrollment in Global Trials

Session Chairpersons

***William W. Gwinn, Jr., MBA***

Director, Clinical Trial Solutions, Thomson Medstat Inc.

***Linda Wolf, MS***

Emerging Markets and Services, BBK Worldwide

As patient recruitment goes global, techniques must be adapted to cultures and subcultures of patient populations depending on country and region. Outside North America, the importance of communicating health-related information to patients is growing, including clinical trial opportunities. In the US, minorities represent subcultures requiring specific recruitment strategies. This session will describe a process for adapting a centralized "tool kit" of patient recruitment materials to multiple countries for cost-efficient and culturally relevant patient

recruitment campaigns as well as present data about US minorities that can be used to support effective approaches to recruitment.

**Cultural Adaptation: Shaping Effective Patient Recruitment Techniques for Global Studies**
***Linda Wolf, MS***
Emerging Markets and Services, BBK Worldwide

**The State of Minority Recruitment in the US and the World, and Recruitment Techniques that Work**
***Dan McDonald***
Vice President, Thomson CenterWatch

**Cultural Adaptation Case Study: A Rheumatoid Arthritis Study in Spain and South America**
***Fernando Arias***
Principal, BBK Worldwide/GAP, Spain

**What the Data Show: An Analysis of Patient Recruitment of Minorities in the US**
***William W. Gwinn, Jr., MBA***
Director, Clinical Trial Solutions, Thomson Medstat Inc.

## Session 339 CTM - Clinical Trial Management, CR

10:30 am-12:00 pm LEVEL: ●

**Room 107AB** *Nursing and Pharmacy credits offered*

### Leave No Patient Behind: A Model for Recovering Patients Lost to Follow-up

Session Chairperson
***Helen E. West***
Director, Client Relations, Matthews Media Group

Competition for study participants and the general public's mistrust of clinical research make locating, recruiting, and retaining patients increasingly more difficult and costly. Losing enrolled patients to follow-up adds to the obstacles study sponsors face in completing studies on time and on budget. Learn about a HIPAA-compliant method, applicable globally, to successfully locate and recover disconnected study participants.

**Patient Search Program Coordination**
***Helen E. West***
Director, Client Relations, Matthews Media Group

**Patient Search Execution**
***Kirk Rutherford***
Director, Patient Locator, Inc.

## Session 340 DM - Document Management/ eSubmissions, CDM, RA

10:30 am-12:00 pm LEVEL: ●

**Room 204C**

### FDA Standards Initiatives and Gateway Update

Session Chairperson
***Stephen E. Wilson, DrPH, CAPT. USPHS***
Director, Office of Business Process Support and Deputy Director, Division of Biometrics II, CDER, FDA

FDA is actively pursuing data standards and technical solutions designed to streamline and expedite the regulatory review process. This session will focus on the need for data standards, current FDA data standardization initiatives, the FDA Electronic Submissions Gateway, and the anticipated benefits of these initiatives. In addition, this session will address the concept and status of Cooperative Research and Development Agreements, and how they impact the regulatory process.

**Update on Standards**
***Randy Levin, MD***
Associate Director, Medical Informatics, CDER, FDA

**The FDA Electronic Submissions Gateway Status Report**
***Mark A. Gray***
PDUFA IT Program Manager, Gateway Project, Office of the Chief Information Officer, Office of the Commissioner, FDA

**Cooperative Research and Development Agreements: How Partnering Is Working and the Road Ahead**
***Stephen E. Wilson, DrPH, CAPT. USPHS***
Director, Office of Business Process Support and Deputy Director, Division of Biometrics II, CDER, FDA

## Session 341 GCP - Good Clinical Practices, CR, IS

10:30 am-12:00 pm LEVEL: ■

**Marriott Salon F** *CME credits offered*

### Extreme Informed Consent

Session Chairperson
***Darren B. McDaniel, MS***
CEO, Managing Officer, Coast IRB, LLC

Are you bored with hearing the same information over and over again about informed consent? If so, this is a must attend session! Informed consent is the single most important aspect in clinical research and a major problem in the conduct of clinical trials. Speakers will discuss the current problems of informed consent using real-life examples; as well as address the inadequacies of current federal laws. This session will present the philosophy of informed consent as well as many practical and tangible ways to do informed consent that you have never heard before.

**Does Modern Medicine Do Informed Consent Well Enough?**
***Darren B. McDaniel, MS***
CEO, Managing Officer, Coast IRB, LLC

**The Philosophy of Informed Consent: Is True Informed Consent Possible?**
***Adam Dodd, MD***
Practicing Clinician (Board-certified OB/GYN)

**Practical Ways to Radically Improve the Informed Consent Process that You Never Heard Before**
***Michael Lichtman***
Independent Consultant

## Session 342 IMP - Impact, CR

10:30 am-12:00 pm LEVEL: ●

**Marriott Salon KL** *CME and Pharmacy credits offered*

### Real-world Clinical Trials

Session Chairpersons
***Deborah Marshall, PhD, MHSA***
Director, Research and Development, Health Economics and Outcomes Research, Innovus Research Inc., Canada
***Lawrence A. Meinert, MD, MPH***
Vice President, Medical and Scientific Affairs, Covance

Real-world effectiveness has become an increasingly important concept in health care from multiple perspectives. Practitioners are interested in optimal treatments for their patients. Payers are interested in restricting reimbursement to the most effective treatments. Industry/manufacturers are concerned with optimal use of their products. This session will discuss the use of epidemiological tools and clinical practice trials to answer questions regarding real-world effectiveness that cannot be answered by regulatory trials alone.

**Generalizing Clinical Research Programs to Account for the "Real World"**
***Lawrence A. Meinert, MD, MPH***
Vice President, Medical and Scientific Affairs, Covance

**Real-world Clinical Trials: Answering Questions that RCTs Alone Cannot**
***Deborah Marshall, PhD, MHSA***
Director, Research and Development, Health Economics and Outcomes Research, Innovus Research Inc., Canada

**Creating Opportunities to Conduct "Real-world" Assessments of Clinical Effectiveness, Safety and Economic Evaluation**
***Mitchell A. H. Levine, MD, MSc, FRCPC, FISPE***
Professor, Department of Clinical Epidemiology and Biostatistics, McMaster University; Director, Center for Evaluation of Medicines, Canada

## Session 343 IT - Information Technology, CR, RA

10:30 am-12:00 pm **LEVEL:** ■

**Room 105AB**

### Managing Identity and Authentication in Sensitive Healthcare Communications: How Can You Be Sure the Person at the Other End of the Electronic Communication Is Who (S)he Says (S)he Is?

Session Chairperson
***Mollie Shields Uehling, MS***
President and CEO, SAFE-BioPharma Association

The purpose of this session is to debate the importance of identity management and digital signatures in broadly adopting health information technologies. Will strong identity management and authentication impede the use of information technologies by doctors and others? Will the release of sensitive health information turn public opinion away from permitting electronic health transmissions? How do we balance ease of uptake with the need for security and privacy? What are the key issues in managing change from paper-based to electronic information exchanges?

**Panelists**

***Keith J. Heilner***
Director, Information Security, Merck & Co., Inc.

***Claire Broome, MD***
Senior Advisor to the Director for Integrated Health Information Systems, Centers for Disease Control and Prevention

## Session 344 MA - Marketing and Sales, CTM, MC, MW

10:30 am-12:00 pm **LEVEL:** ■

**Room 113C** *CME credits offered*

### Communicating with Physicians through the Power of Postapproval Research: The Impact in a Physician's Own Practice

Session Chairperson
***Richard E. Gliklich, MD***
President and CEO, Outcome Sciences, Inc.

This session will explore the background, methods, technologies, regulations, and results for implementing postapproval programs that can have a positive influence on provider and patient communication, education, and behavior. Speakers will present examples of postapproval programs that have successfully influenced behavior, including programs from the American Heart Association, the American Orthopaedic Association, and pharmaceutical industry-sponsored programs.

**Data at the Point of Care**
***Richard E. Gliklich, MD***
President and CEO, Outcome Sciences, Inc.

**Communicating and Changing Behavior through Postapproval Data**
***Stephen A. Goldman, MD, FAPM, FAPA***
Managing Member, Stephen A. Goldman Consulting Services, LLC

**The American Heart Association's "Get with the Guidelines" Program: Changing Physician Behavior and Improving Quality of Care through a Postapproval Research Program**
***Kenneth A. Labresh, MD, FAHA, FACC***
Chair, Get with the Guidelines QI Subcommittee, American Heart Association; Vice President, MassPRO

## Session 345 MC - Medical Communications, CR, RA

10:30 am-12:00 pm **LEVEL:** ●

**Room 204A** *CME and Pharmacy credits offered*

### Reducing the Incidence of Medication Errors Resulting from the Use of Error-prone Abbreviations and Symbols

Session Chairperson
***John A. Friel, JD***
Deputy Director, Office of Training and Communications, CDER, FDA

Medication errors cause injury and death to over one million Americans annually, and the common practice of using abbreviations, symbols, and dose designations often contributes to confusion and harmful error. The FDA has joined with the Institute for Safe Medication Practices (ISMP) to publicize the results of a study conducted by ISMP and the United States Pharmacopoeia which identifies commonly used abbreviations and symbols that contribute to errors. This report will be discussed at the session.

**Helping Health Professionals Improve Prescription Communication**
***Michael R. Cohen, RPh, MS, ScD***
President, Institute for Safe Medication Practices

**FDA's Education Campaign on Proper Use of Abbreviation**
***Ellen Shapiro***
Director, Division of Public Affairs, Office of Training and Communications, CDER, FDA

**Avoiding Name, Label, Labeling, and Packaging Confusion**
***Carol Holquist, RPh***
Director, Division of Medication Errors and Technical Support, Office of Drug Safety, Office of Pharmacoepidemiology and Statistical Science, CDER, FDA

## Session 346 MW - Medical/Scientific Writing, RA

10:30 am-12:00 pm **LEVEL:** ●

**Room 204B** *Pharmacy credits offered*

### Preparing Global CTD Submission-ready Documents from IND to NDA

Session Chairperson
***Michelle Herrera Foster, PhD***
Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

This session will discuss preparation of eCTD-compliant submission documents in CMC, nonclinical, and clinical sections of the NDA that are prepared in the IND stage, enhancing efficiency of the drug development process. The use of templates, customized for each product/program, will be explored to enable gap analysis, project management, and expansion of IND to NDA documents, including premeeting packages, drug master files, and other applications.

**Introduction to the CTD and Submission-ready Reports: Applications in Module 3**
***Michelle Herrera Foster, PhD***
Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

**Modules 4 and 5: What Exactly Are CTD-ready Reports?**
***Tammy J. Sarnelli, MPAHC, RAC***
Assistant Director, Regulatory Affairs, Biogen Idec Inc.

**Charting a Successful Course and Navigation of Module 2**
***Taylor Burtis, MBA***
Vice President, Regulatory, Quality and Compliance, Novelos Therapeutics, Inc.

**Panelist**
***Pamela C. Cafiero, PhD***
Senior Associate Director, Regulatory Affairs, Boehringer Ingelheim Pharmaceuticals, Inc.

## Session 347 NC - Nonclinical Laboratory Safety, CR, GCP

10:30 am-12:00 pm LEVEL: ●

**Room 111AB** *CME credits offered*

### Nonclinical Efforts to Reduce Attrition in First-time-to-man Studies

Session Chairperson
***David R. Jones, MSc***
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency, (MHRA), UK

High attrition rates in early clinical trials are a concern to both regulators and industry. The session will review new regulatory and industry initiatives being developed to improve success rates.

**EU Regulatory Perspective on Early Clinical Trials**
***David R. Jones, MSc***
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**Single-dose Toxicity Studies to Support First-time-in-man Studies**
***Paul Baldrick, PhD***
Head of Department, Pharmaceutical Regulatory Affairs, Covance Laboratories Europe, UK

**EU Initiatives for Nonclinical Support for First-time-in-man Studies**
***Phil Wilcox, PhD***
Vice President, Nonclinical Safety Project, Safety Assessments, GlaxoSmithKline R&D, UK

## Session 348 NHP - Natural Health Products, CMC, RA

10:30 am-12:00 pm LEVEL: ■

**Room 106AB**

### Growing Standardized, Reproducible, and Sustainable Botanicals for Medicinal Use

Session Chairperson
***Jinhui Dou, PhD***
Botanical Review Team, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA

Control of the product is the first step in the development process of a botanical (or naturally heterogeneous) drug product. The discussion will review the key components of the requirements for the Investigational New Drug (IND) application, as it applies to the growing, harvesting and processing of a botanical drug and explore the inherent product development hurdles facing this class of drugs.

**Impact of US Regulations on Producing Reproducible Botanicals for Drug Development**
***Jinhui Dou, PhD***
Botanical Review Team, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA

**Biomass Quality: It All Starts Here**
***James D. McChesney, PhD***
Chief Scientific Officer of Natural Products, Tapestry Pharmaceuticals, Inc.

## Session 349 OS - Outsourcing, IS

10:30 am-12:00 pm LEVEL: ●

**Room 109AB**

### Local versus Global CRO Assignment: Is it Possible to Build a Constructive Relationship with Partners You Have Not Chosen?

Session Chairperson
***Laura Luchini, PhD, MD***
Executive Director, Eurotrials Scientific Consultants, Brazil

Local sponsor subsidiaries often feel uncomfortable working with a CRO selected for global projects when they are not involved in the CRO selection process. Study sponsors, CROs, and site representatives will discuss real cases where open communication was the key for trial conduct success.

**Experiencing an Arranged Marriage: Tips for Success**
***Denise de la Reza, MD***
Clinical Research Unit Head, sanofi-aventis, Brazil

**Building a Constructive Relationship at an Arranged Marriage**
***Laura Luchini, PhD, MD***
Executive Director, Eurotrials Scientific Consultants, Brazil

**Site-sponsor-CRO Triangle: Investigator Perspective**
***Luciana Abarno da Costa, MD***
Center for Diabetes Research, Brazil

## Session 350 PM1 - Project Management, BT, RD

10:30 am-12:00 pm LEVEL: ●

**Room 108A** *Project Management Institute credits offered*

### EPM Information Systems: The Influence of Project Management Maturity on Implementation Strategies

Session Chairperson
***James M. Huebner, MS***
Director, Project Management, Dr. Reddy's Laboratories, North America

One way to streamline the development process for human pharmaceutical new products is to utilize the data generated in discovery and development more efficiently, with the aim of increasing project attrition prior to embarking on costly, late-stage clinical development programs. This session will review lessons learned from the implementation of project information management systems in organizations differing in size, complexity, and overall project management maturity.

**Design, Implementation, and Operations of a PM Information System in a Small Biotechnology Company**
***Robert Lund Judd, MS***
Director, Program Management, Kosan Biosciences, Inc.

**Transformation of Project Management Processes and Systems in a Rapidly Growing Biopharmaceutical Organization**
***Ray Sanchez-Pescador, PhD, PMP***
Associate Director, Project Management, Genentech, Inc.

**Does Project Management Maturity Drive the System or Does the System Drive Project Management Maturity?**
***Martin D. Hynes, III, PhD***
Director, Product Research and Development, Lilly Research Laboratories, Eli Lilly and Company

## Session 351 PM2 - Project Management

10:30 am-12:00 pm **LEVEL:** ■

**Room 108B** *Project Management Institute credits offered*

### Twenty-first Century Team Leadership

Session Chairperson
***Jay J. Armstrong, MS, MSc***
Director, Project Management, Benefit Risk Management, Johnson & Johnson Pharmaceutical Research and Development, LLC

Breakthrough project deliverables do not arise by accident, but rather have as their foundation an inspired and dedicated team. The capability to identify, form, develop, and lead effective teams is a skill that can be easily mastered and provides a powerful competitive edge to pharmaceutical organizations. We will explore and present the characteristics that build effective teams and lead them to breakthrough results.

**Building and Energizing Winning Teams**
***Heidi Christina Thompson, MS, MBA, PMP***
Associate Director, HECOR, Medical Affairs, Centocor, Inc.

**Leading Successful Projects**
***Jennifer Carothers, MBA, ScD***
Associate Director, Project Management and Communications, Benefit Risk Management, Johnson & Johnson

## Session 352 PP - Public Policy/Law, CR, IMP

10:30 am-12:00 pm **LEVEL:** ●

**Room 113A** *CME, Nursing, and Pharmacy credits offered*

### Understanding and Reversing the Erosion of Public Trust in Clinical Research

Session Chairperson
***Arthur Gertel, PhD, MS***
Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.

There has been a significant erosion of public trust in the pharmaceutical industry and, as a corollary, in clinical trials. This session examines public attitudes and perceptions of clinical trials and how they have changed over the past five years. Panelists will discuss results from surveys and focus groups, assess events leading to these perceptions, and recommend strategies to improve public trust and confidence in the clinical research enterprise.

**How Did We Fall So Far, So Fast?**
***Arthur Gertel, PhD, MS***
Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.

**Survey Says ...**
***Kenneth A. Getz, MS, MBA***
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

**Direct Impact of Waning Public Trust on Conducting Clinical Trials**
***Diana L. Anderson, PhD, MSN, RN***
President and CEO, D. Anderson & Company

## Session 353 RA1 - Regulatory Affairs, CMC, CR

10:30 am-12:00 pm **LEVEL:** ■

**Room 202AB**

### Drug Development in Japan and Acceptance of Global CMC Dossier

Session Chairperson
***Leyna T. Mulholland, PhD, PharmD***
Associate Director, Japan Pharmaceutical Development, Merck & Co., Inc.

Many clinical trials are conducted as multinational trials, including Japan and other Asian countries. Japanese requirements and preferences need to be considered during the drug development process in order to provide truly global commercial material. In addition, many regulatory changes have happened recently in Japan which have impacted the CMC dossier. The Drug Master File (DMF) Procedure was adopted in Japan; however, the use of DMF for JNDA application has been limited. Additionally, the Japanese pharmaceutical affairs law (JPAL) has caused changes in how information is presented in the CMC dossier. This session will focus on the critical nature of drug development for Japan with respect to formulation, final market image, and CMC dossier preparation for the JNDA application. This session will include presentations from a Japanese regulatory agent and an industry perspective using case studies.

**Drug Master File Procedure in Japan and the Impact on CMC Dossier**
***Leyna T. Mulholland, PhD, PharmD***
Associate Director, Japan Pharmaceutical Development, Merck & Co., Inc.

**Preparing a CMC Dossier for a Successful JNDA**
***Carol Van Auwelaer, RPh***
Regulatory Consultant, Eli Lilly and Company

## Session 354 RA2 - Regulatory Affairs, PP

10:30 am-12:00 pm **LEVEL:** ●

**Room 201C**

### Regulatory Pathways for Medicines Addressing the Public Health Needs in the Developing World

Session Chairperson
***Lembit Rägo, MD, PhD***
Coordinator, Quality Assurance and Safety Medicines Department of Essential Drugs, World Health Organization, Switzerland

Products specifically designed to address the public health needs and emergencies in the developing world have often met regulatory obstacles. Many developing country regulators have no resources to carry out more sophisticated regulatory assessments and rely on the regulatory approval by well resourced stringent regulatory authorities. However, due to the lack of market incentives or other obstacles (administrative, regulatory, various exclusivity rights), it is often difficult for manufacturers to find the regulatory pathway that could ensure appropriate scientific assessment of their products. This particularly concerns certain drugs for neglected diseases and certain vaccines. Without trusted local authority regulatory assessment, it may be difficult to market these products in developing countries.

Three regulatory pathways have recently been set up and are listed by order they started to be functional: WHO prequalification program, US FDA tentative approval process of antiretrovirals under the President's emergency plan for AIDS relief, and EU Article 58 procedure. Legislation adopted on May 1, 2004 by the EC (Article 58 of Council Regulation (EEC) No 2309/93), created a new regulatory pathway whereby the European Medicines Agency (EMEA) may give assessment advice, in the context of cooperation with the WHO, for the evaluation of certain medicinal products intended exclusively for markets outside the Community. All these procedures contribute to getting much needed products to the patients in need and this session provides insight into the objectives, requirements and experience of these procedures.

**WHO Prequalification Program: Objectives, Procedures, and Lessons Learned**
***Lembit Rägo, MD, PhD***
Coordinator, Quality Assurance and Safety Medicines Department of Essential Drugs, World Health Organization, Switzerland

**US FDA Tentative Approval Process for Antiretrovirals**
***Murray M. Lumpkin, MD, MSc***
Deputy Commissioner for International and Special Programs, Office of the Commissioner, FDA

**EU Scientific Opinions: New Procedure for Access to Medicines (Article 58 of the EU Legislation)**
***Patrick Le Courtois, MD***
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

**Canada's Access to Medicines Regime**
***David K. Lee***
Director, Office of Patented Medicines and Liaison, Therapeutic Products Directorate, Health Canada

## Session 355 RA3 - Regulatory Affairs, CR

10:30 am-12:00 pm LEVEL: ■

**Room 201A**

### Evolving Global Oncology Drug Registrational Environment

Session Chairperson
***Albert L. Kraus, PhD, MS***
Vice President, Regulatory Affairs, Kosan Biosciences

In 2005, the US FDA, the EU CHMP, and PMDA of Japan released draft oncology clinical development guidances. This session will overview these guidances, highlight the evolving directions, and identify convergences and divergences important to consider in global clinical registrational strategy development at the protocol and program level.

**Overview of US FDA Draft Guidance on Oncology Clinical Trial Endpoints**
***Kaushikkumar Shastri, MD***
Medical Team Leader, Office of Oncology Drug Products, Division of Biological Oncology Products, CDER, FDA

**Overview of European Union Guidance on Clinical Development for Oncology Drugs**
***Robert A. Milsted, MD, MRCP***
Vice President, Oncology Regulatory Affairs, AstraZeneca, UK

**Overview of Recent Japanese Oncology Development Guidance**
***Albert L. Kraus, PhD, MS***
Vice President, Regulatory Affairs, Kosan Biosciences

**Overview of Global Development Issues Driven by Regional Differences**
***Albert L. Kraus, PhD, MS***
Vice President, Regulatory Affairs, Kosan Biosciences

**Panelists**
***Grant A. Williams, MD***
Clinical Development, GlaxoSmithKline; Former Deputy Director, Division of Oncology Drug Products, CDER, FDA
***Jurij Petrin, MD***
President, Pharmaceutical Regulatory Services, Inc.

## Session 356 RA4 - Regulatory Affairs, PP, RD

10:30 am-12:00 pm LEVEL: ■

**Room 201B**

### Changes in the European Regulatory Environment Affecting Member States: MRC and Decentralized Procedures

Session Chairperson
***Anu M. Tummavuori-Liemann***
Manager, EU Regulatory Liaison, F. Hoffmann-La Roche Ltd., Switzerland

This session provides an overview of the new framework for the national registration routes on the EU following the implementation of the New Medicines Legislation.

**The Industry Point of View**
***Anu M. Tummavuori-Liemann***
Manager, EU Regulatory Liaison, F. Hoffmann-La Roche Ltd., Switzerland

**The Regulatory Point of View**
***Peter Bachmann***
Head of Unit, Mutual Recognition Procedures, BfArM, Germany

## Session 357 RA5 - Regulatory Affairs, CP

10:30 am-12:00 pm LEVEL: ■

**Room 114** Auditorium *CME, Nursing, and Pharmacy credits offered*

### CDER Hot Topic – Update: Drug Safety Initiatives

Session Chairperson
***Susan K. Cummins, MD, MPH***
Director, Drug Safety Oversight Board Staff, CDER, FDA

In 2005 FDA launched a drug safety initiative with the goal of giving healthcare professionals, patients, and consumers up-to-date information about medicines and making the drug review and monitoring process as transparent as possible. The FDA also began providing information for healthcare professionals and patients on its website about emerging and important drug safety concerns. A reorganization in CDER was also announced to place greater emphasis on safety policy and communication. The impact of increased funding earmarked for post-marketing surveillance and epidemiology will also be discussed. This session will review the first year of progress and activities for FDA's Drug Safety Oversight Board, and the impact of the changes and initiatives focused on safety.

**Drug Risk Communication and the Drug Safety Oversight Board**
***Susan K. Cummins, MD, MPh***
Director, Drug Safety Oversight Board Staff, CDER, FDA

**Update and Overview of Drug Safety Initiatives**
***Paul J. Seligman, MD, MPH, CAPT. USPHS***
Associate Director for Safety Policy and Communication, CDER, FDA

**Office of Drug Safety Update**
***Gerald J. Dal Pan, MD, MHS***
Director, Office of Surveillance and Epidemiology, CDER, FDA

## Session 358 ST - Statistics, CR, CTM

10:30 am-12:00 pm LEVEL: ■

**Room 103B** *CME and Pharmacy credits offered*

### Randomization

Session Chairperson
***Vance W. Berger, PhD***
Mathematical Statistician, National Cancer Institute, National Institutes of Health

This session will deal with various aspects in the design and analysis of randomized clinical trials. Issues to be discussed include: (1) the handling of missing data; (2) the prevention, detection, and correction of selection bias arising from a lack of allocation concealment; and (3) the value of simulations in clinical trials.

**Managing Selection Bias in Clinical Trials**
***Vance W. Berger, PhD***
Mathematical Statistician, National Cancer Institute, National Institutes of Health

**Handling of Missing Data in Clinical Trials**
***Linda Yau, PhD***
Principal Statistician, GlaxoSmithKline

**Simulations for Designing and Analyzing Clinical Trials**
***Stephan Ogenstad, PhD***
Vice President, Biometrics, Vertex Pharmaceuticals Inc.

## Session 359 TR - Training, CR, CTM, PM

10:30 am-12:00 pm **LEVEL:** ■

**Room 103C**

### Methodologies in Training Adults: Experiences Collected from Regional CROs

Session Chairperson
***Maria Fernández Freire, MD***
Director, Thywill LatAm Solutions, Argentina

Training adults has always been a great challenge. Large companies are constantly trying new techniques from role playing to neurolinguistics. These have proven very useful, but our main identified problems are not the technical points but the political ones, learned only with good, soft skills training.

**Training Programs in Clinical Research in India: Needs and Methodologies**
***Suresh K. Gupta, DrSC, MSc***
Dean, Institute of Clinical Research, India

**R&D Training: Sites, Sponsors, and CROs: Oceania Region Experience**
***Alek Safarian***
CEO, Novotech, Australia

**Methodologies in Adult Training in R&D: Experiences Collected from Latin America**
***Maria Fernández Freire, MD***
Director, Thywill LatAm Solutions, Argentina

## Session 360 VA - Validation, BT, IT

10:30 am-12:00 pm **LEVEL:** ■

**Room 203AB**

### The IQ/OQ/PQ Challenge for Small Companies

Session Chairperson
***Teri E. Stokes, MT(ASCP), MS, PhD***
Director, GXP International

Regulatory compliance for computerized systems in GXP environments is required for companies both large and small. This can be a rude awakening for new CROs, software suppliers, and biotech/device/drug start-ups, but experience has shown that it can be achieved. It can even be good for the business.

Small can be beautiful if the approach to computer validation is based on a practical approach sized to company needs. The use of standard documents and good system practices can actually help a new company operate in a compliant way that both encourages and supports steady growth. Speakers who have trod the path of small company compliance to GXP regulations will share their challenges and triumphs and ongoing practical strategies.

**Part 11 Compliance and the Small CRO Experience**
***Ajay G. Sadhwani, MS***
President, ARS, Inc.

**Meeting the IQ/PQ Challenge for Reality-based Disaster Recovery and Business Continuity Practices in a Small Company**
***Cheryl M. McCarthy***
Manager, Quality Assurance, BattelleCRO

**Augmenting a Business Strategy by Moving to Regulated Product Offerings as a Small Company Provider**
***Chip Sheerin***
Vice President of Services and Technology, InfoMedics, Inc

12:00 pm-1:30 pm **LUNCHEON**
**Exhibit Hall C, 2nd Floor, Convention Center**

## Session 361 AHC - Academic Health Centers, CR

1:30 pm-3:00 pm **LEVEL:** ●

**Room 113B** *CME and Pharmacy credits offered*

### How to Prepare for and Conduct Investigator-initiated Research

Session Chairperson
***Harvey M. Arbit, PharmD, MBA, RAC***
Director, IND/IDE Assistance Program, Academic Health Center, University of Minnesota

A clinical researcher who files an IND application becomes the sponsor of that IND as well as the investigator. The FDA regulations at 21CFR312 Subpart D that specify the responsibilities of sponsors and investigators must be followed to be in compliance.

**Considerations Relating to Federal Requirements: FDA, IRB**
***Harvey M. Arbit, PharmD, MBA, RAC***
Director, IND/IDE Assistance Program, Academic Health Center, University of Minnesota

**Considerations Relating to State and Medicare/Medicaid Requirements**
***David D. Bloomer, MHA***
Director, Clinical Research Administration, LSU Health Sciences Center

**Considerations Relating to Local and University Requirements**
***Michael R. Jacobs, PharmD***
Chairman, Institutional Review Board for Medical Interventions, Temple University School of Pharmacy

## Session 362 BT - Biotechnology, CR

1:30 pm-3:00 pm **LEVEL:** ■

**Room 103A**

### Systems Biology: The Realization of Intelligent Drug Development

Session Chairperson
***Alan S. Louie, PhD***
Research Director, Health Industry Insights, an IDC Company

Systems biology is an emerging area in drug development that offers great potential. The present and future of systems biology will be presented from the perspectives of academia, the commercial systems biology company, and the pharmaceutical industry. In this evolving field, panelists will be challenged to predict how systems biology will transform drug development and impact the healthcare marketplace.

**The Commercial Advance towards Knowledge-based Drug Development**
***Alan S. Louie, PhD***
Research Director, Health Industry Insights, an IDC Company

**The Utility of Systems Biology in Large Pharmaceutical Companies**
***Bruce Gomes, PhD***
Head of Mathematical Modeling, Systems Biology Group, Pfizer Pharmaceuticals

**A Causal Framework for Systems Modeling in Drug Development**
***Keith O. Elliston, PhD***
President and CEO, Genstruct, Inc.

**Building Computational Models to Accelerate Drug Discovery**
***Herbert M. Sauro, PhD***
Assistant Professor, Keck Graduate Institute

## Session 363 CDM - Clinical Data Management, IT

1:30 pm-3:00 pm LEVEL: ●

Marriott Salon CD

### AJAX: A New Approach to Integrating Paper Data Entry and EDC Processes

Session Chairperson
***Nicholas Richards***
Chief Operating Officer, DataLabs, Inc.

Integrating thick-client paper data entry data management systems with new thin-client EDC systems has been challenging and costly, because the systems are based on different technologies that require different work processes. A new approach to web-based applications called AJAX (asynchronistic java and XML) allows web-based systems to provide the functionality of a heads-down data entry process in a thin-client, web-based system.

**Deployment in a Hybrid Environment**
***Greg A. Johnson, MS***
Vice President, Global Data Management, PRA International, Canada

**Next Generation eClinical Technologies**
***Les Jordan***
Industry Technology Strategist, Life Sciences, Microsoft Corporation

## Session 364 CMC - Chemistry, Manufacturing, and Controls, TR

1:30 pm-3:00 pm LEVEL: ■

Room 112AB

### Quality-by-design: Case Studies

Session Chairperson
***Dhiren N. Shah, PhD***
Head, Regulatory Affairs, Martec Pharmaceuticals, Inc.

This session will present examples of quality-by-design from industry representatives.

**Industry Case Study 1**
***John Towns, PhD***
Director, Global CMC Regulatory Affairs, Eli Lilly and Company

**Industry Case Study 2**
***Richard P. Poska, RPh***
Director, Global Pharmaceutical Regulatory Affairs, CMC-GPRD Small Molecule Support, Abbott Laboratories

**Industry Case Study 3**
***Larry Rosen, PhD***
Senior Research Fellow, Pharmaceutical Commercialization Technology - Core Group, Merck Manufacturing Division, Merck & Co., Inc.

## Session 365 CP - Clinical Safety and Pharmacovigilance, GCP, RA

1:30 pm-3:00 pm LEVEL: ●

Marriott Salon G *CME credits offered*

### Regulatory Inspections of Company Pharmacovigilance Operations

Session Chairperson
***Carol L. Krueger, RN***
Consumer Safety Officer, Division of Compliance, Risk Management, and Surveillance, CDER, FDA

An overview of FDA and EMEA regulatory inspections of pharmacovigilance and postmarketing adverse drug experience reporting operations will be presented by a regulatory compliance officer, a regulatory field inspector, and an independent auditor. The significance of regulations, inspection processes, inspectional findings and corrective actions will be discussed.

**Postmarketing Adverse Drug Experience Inspectional Program**
***Thomas R. Berry, RPh, CDR USPHS***
Investigator, Senior Regulatory Operations, Office of Regulatory Affairs, FDA

**The Reality of Pharmacovigilance Inspections in Europe**
***Valerie E. Simmons, MD***
Director, EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company, Ltd., UK

## Session 366 CR1 - Clinical Research and Development, GCP

1:30 pm-3:00 pm LEVEL: ■

Marriott Salon E *CME and Pharmacy credits offered*

### Clinical Trial Execution and Informed Consent: Keys to Success

Session Chairperson
***Michael R. Hamrell, PhD, RAC***
President, MORIAH Consultants

The key to the successful execution of a clinical trial relates in part to a proper informed consent process. This session will focus on some of the key success factors in GCP compliance and the informed consent process that meets all of the regulatory and legal requirements.

**Successful Informed Consent and Compliance**
***Michael R. Hamrell, PhD, RAC***
President, MORIAH Consultants

**Informed Consent and Readability Consideration**
***Kris Terzotis, MS***
Clinical Research Program Coordinator, University of North Carolina, School of Nursing

**Informed Consent Comprehension and Understanding**
***Erica Heath, MS, CIP***
President, Independent Review Consulting IRB

## Session 367 CR2 - Clinical Research and Development, CDM, EC

1:30 pm-3:00 pm LEVEL: ●

Marriott Salon KL

### It Is Saturday Night! Do You Know Where Your Clinical Trial Is?

Session Chairperson
***Claudia Gross, PhD***
Associate Director, Project Management, Cato Research

For the biotechnology company, time is of the essence. Knowing the progress of the clinical program on a minute-by-minute basis may be critical to achieving important milestones (or at least to achieving sleep for the CEO). But is it worth the costs? Proper implementation of electronic data collection translates into significant cost and time savings.

**EDC: Process Change and Advantages when Using a CRO**
***Claudia Gross, PhD***
Associate Director, Project Management, Cato Research

**Successful Implementation and Getting the Most Out of eClinical Technologies**
***Richard J. Piazza, PharmD***
Vice President, Product Strategy, etrials Worldwide, Inc.

**Successful EDC Implementation: The New Business Model and Beyond**
***Adrian Hsing, MS***
Director, Clinical Data Management, Gilead Sciences, Inc.

## Session 368 CR3 - Clinical Research and Development

1:30 pm-3:00 pm LEVEL: ■

**Marriott Salon IJ**

### Challenges and Pitfalls of Anti-TNF Drugs

Session Chairpersons
***Tomas Salmonson, PhD***
CHMP Member, EMEA, EU; Medical Products Agency, Sweden
***Françoise de Crémiers, PharmD, MS, ML***
Senior Vice President, Chief Scientific and Stakeholder Officer, Europe/Middle East/Africa, Wyeth Research, France

Anti-TNF-α drugs represent a major breakthrough in the treatment of certain inflammatory autoimmune diseases, such as rheumatoid arthritis and Crohn's disease. The safety profiles of anti-TNF-α drugs may be different. This session will address the management of postmarketing surveillance from regulator and industry points of view, addressing detection of signals, their assessment, and the balanced way to communicate to the different stakeholders.

**EMEA/MPA Point of View**
***Tomas Salmonson, PhD***
CHMP Member, EMEA, EU; Medical Products Agency, Sweden

**A Unique Benefit-risk Experience: The Anti-TNF Drugs**
***Robert J. Spiegel, MD***
Chief Medical Officer and Senior Vice President, Medical Affairs, Schering-Plough

**Industry Point of View**
***Debra Feldman, MD***
Senior Director, Medical Pharmacovigilance, Wyeth Pharmaceuticals

**Panelist**
***Bruno Flamion, MD***
Chairman, EMEA Scientific Advice Working Party; Professor of Medicine, FUNDP, University of Namur - Ministry of Health, Belgium

## Session 369 CR4 - Clinical Research and Development, BT

1:30 pm-3:00 pm LEVEL: ■

**Marriott Salon AB** *Nursing credits offered*

### Targeted Therapeutics

Session Chairperson
***Peter Colbourne***
Director, Business Development, CIRION Clinical Trial Services Inc., Canada

This presentation is designed to provide a sound understanding of the role of clinical biomarker assays from identification in-situ to assay validation based upon current ICH-Q2A/B guidelines.

**Biomarker Identification and Selection**
***Pieter Muntendam, PhD***
President and CEO, BG Medicine, Inc.

**Biomarker Assay Development and GLP Validation**
***Peter Colbourne***
Director, Business Development, CIRION Clinical Trial Services Inc., Canada

## Session 370 CTM - Clinical Trial Management, CR

1:30 pm-3:00 pm LEVEL: ■

**Room 107AB** *Pharmacy credits offered*

### Post-trial Access to Study Medication: Is It Feasible?

Session Chairperson
***Sonia Mansoldo Dainesi, MD, MBA***
Medical Manager, Clinical Research, Hospital das Clinicas-FMUSP, Brazil

Recently, a new challenge has emerged in the clinical research setting mainly when performed in the developing world: the possibility of assuring poststudy medication. Even with moral reasons that justify this approach, establishing such a procedure is quite complex. All the issues related to the topic will be discussed during this challenging session.

**Ethical Considerations on the Differences between Conducting Clinical Trials in Developed and Developing Worlds**
***Christine Grady, RN, PhD***
Department of Clinical Bioethics, National Institutes of Health

**Legal Aspects on the Provision of Study Medication after the Completion of the Trial**
***Octavio L. M. Ferraz, PhD, MA***
Senior Research Assistant of the UN Special Rapporteur on the Right to Health, Human Rights Centre, University of Essex, UK

**The Pros and Cons on the Study Medication Distribution after the Trial End**
***Gustavo L. F. Kesselring, MD***
Director, Clinical Operations, IBIC Clinical Research Center, Brazil

## Session 371 DM - Document Management/ eSubmissions, IT, MW, RA

1:30 pm-3:00 pm LEVEL: ●

**Room 204C**

### FDA eSubmission Update: OBPS Overview, SDTM, eSUB/eCTD Hot Issues, SPL Update

Session Chairperson
***Gary M. Gensinger***
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

CDER has made several significant changes in the past year to advance and facilitate the review of electronic regulatory submissions. These include spear-heading projects to standardize information management processes, publish regulations, guidance documents and MaPPs to support electronic submissions, and facilitate the development of information management project proposals, which will benefit the consumer and the pharmaceutical industry.

**The Office of Business Process Support: Overview, Initiatives and Status Report**
***Linda A. Sigg***
Lead Project Manager, Office of Business Process Support, CDER, FDA

**The Study Data Tabulation Model Update**
***Gary M. Gensinger***
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

**eSUBs and eCTDs: Practical Advice and Pitfalls to Avoid**
***Virginia R. Ventura***
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

**Structured Product Labeling Update**
***Lisa Stockbridge, PhD***
Business Program Manager for SPL, Office of Business Process Support, CDER, FDA

## Session 372 GCP - Good Clinical Practices, CR

1:30 pm-3:00 pm LEVEL: ■

**Marriott Salon F** *CME and Nursing credits offered*

### Quality Risk Management in Clinical Trials: A Paradigm Shift

Session Chairperson
***Peter J. Schiemann, PhD, MPharm***
Global Planning Manager, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Risk management is becoming increasingly important in the pharmaceutical industry. The first step was taken by introducing the ICH Q9 guideline in manufacturing. Quality assurance in GCP still follows the long-established approach of sampling to build confidence in the data and ensure patients' safety by drawing conclusions from a limited number of audits, data reviewed, and clinical trial centers assessed. Is this approach still valid?

**Quality Risk Management in Clinical Trials: A Paradigm Shift**
***Peter J. Schiemann, PhD, MPharm***
Global Planning Manager, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

**Efficient Clinical Quality Assurance for Pedestrians**
***Hans F. Poland, PhD***
Head of Global Clinical Quality Assurance, Schering AG, Germany

**FDA Quality Risk Management Approaches and Initiatives**
***David A. Lepay, MD, PhD***
Senior Advisor for Clinical Science and Director, GCP Programs, Office of Science and Health Coordination, Office of the Commissioner, FDA

**Next Generation GCP Quality Risk Management**
***Matthias Buente, PhD***
Director, Booz, Allen, Hamilton, Switzerland

## Session 373 IMP - Impact, MA

1:30 pm-3:00 pm LEVEL: ■

**Room 108B** *CME and Pharmacy credits offered*

### The Economics of Pharmaceutical Pricing

Session Chairperson
***Anita Burrell, MA, MBA***
Director, Global Health Outcomes and Market Access, sanofi-aventis

This session helps participants assume an active role in the pricing of health technologies. The format will include presentations on case studies, and participants will be encouraged to discuss the appropriate application of health economics to pricing decisions during an interactive discussion.

**The Economic Framework of Pharmaceutical Pricing**
***Anita Burrell, MA, MBA***
Director, Global Health Outcomes and Market Access, sanofi-aventis

**Outcomes Research and Pharmaceutical Pricing**
***Jonothan C. Tierce, CPhil***
Principal, ValueMedics Research, LLC

**Economic Modeling and Pharmaceutical Pricing**
***Pippa M. Anderson, MSc***
Director, Fourth Hurdle Consulting Ltd., UK

## Session 374 IT - Information Technology, CR, EC

1:30 pm-3:00 pm LEVEL: ●

**Room 105AB**

### CRIX: A Shared Clinical Research Information eXchange

Session Chairperson
***Betsy Fallen, RN***
Manager, Worldwide Regulatory Coordination, Merck & Co., Inc

The National Cancer Institute is collaborating with academia, government, healthcare providers, and the pharmaceutical industry to establish a cost-efficient flow of high-quality clinical research data to the regulatory authority. The purpose of this effort is to instantiate a trusted hosting service, known as the Clinical Regulatory Information eXchange (CRIX), that will provide a sustainable, secure infrastructure for electronic submissions.

**FIREBIRD: Implementation of an Online Investigator Registry**
***Kamal Narang, MS***
Project Manager, CRIX/Firebird, Capital Technology Information Services, Inc.

**Advancing the Clinical Research Information eXchange (CRIX) Toward Implementation**
***John H. Speakman***
Director, Clinical Research Informatics, Memorial Sloan-Kettering Cancer Center

**Future Possibilities for CRIX**
***Randy Levin, MD***
Associate Director, Medical Informatics, CDER, FDA

## Session 375 MA - Marketing and Sales, CDM, CR, CTM

1:30 pm-3:00 pm LEVEL: ●

**Room 113C**

### Marketing Your Clinical Services Organization

Session Chairperson
***Robert Whitman***
Sales Manager, Vice President, Marketing, Innovative Print and Media Groups, Inc.

This session will help you to create new and innovative ideas for an effective marketing and branding plan for your company.

**Outsourcing/Purchasing Perspective**
***David W. Gillogly, MBA***
Senior Director, Global Strategic Planning, Sankyo Pharma Development

**Panelists**

***Anthony M. Cavaliere, MBA***
Vice President, Global Data Division, MDS Pharma Services

***Elizabeth Thiele, MA***
Vice President, Sales, ICON Clinical Research

## Session 376 MC - Medical Communications, CR, MW

1:30 pm-3:00 pm **LEVEL:** ■

**Room 204A** *Pharmacy credits offered*

### Role of Medical Communications in Clinical Trial Information Internet Posting

Session Chairperson

***Stacey M. Fung, PharmD***

Senior Medical Communications Scientist, Genentech, Inc.

Organizations have initiated the posting of unpublished clinical trial results on company-sponsored websites, federally-sponsored websites, or association websites (PhRMA). This session will discuss what role the medical communications department may have with this activity. In addition, how this activity could potentially impact the medical communications department will be described. Proactive activities that can be initiated to address this potential impact will also be considered. Other issues will include the legal and regulatory concerns for the department and organization.

**The History of Clinical Trial Registries**
***Julie A. Birt, PharmD***
Team Leader, Global Medical Information, Eli Lilly and Company

**The Posting of Clinical Trial Information on the Web: Roles, Responsibilities, and Processes**
***Mario F. Sylvestri, PharmD, PhD***
Senior Director, Regulatory and Medical Information, Amylin Pharmaceuticals, Inc.

**The Impact of the Clinical Trials Registry on Medical Information**
***Colette M. Boyle, PharmD***
Director, Strategic Services, Ortho Biotech Clinical Affairs, LLC

## Session 377 MW - Medical/Scientific Writing, DM, PM

1:30 pm-3:00 pm **LEVEL:** ■

**Room 204B**

### Efficient Preparation of High-quality Documents

Session Chairperson

***Susan C. Sisk, PhD***

Principal, SFP Consulting, LLC

Medical writing teams often face ever-shortening timelines. We will discuss solutions for surviving and even thriving in this environment, and learn strategies for writing high-quality documents while meeting these demanding timelines through using standardizing text elements, maximizing teamwork during authoring and review, and outsourcing appropriate tasks. The key role of communication between all parties in the document-production process will be highlighted. Case studies will demonstrate how thorough planning and strong communication skills can substantially influence the time/quality/cost relationship for document production.

**Developing a Library of Standard Text Elements to Create Scientific Documents**
***Karen P. Heraty***
Scientific Communications Consultant, Eli Lilly and Company

**From Database Lock to Signed Report: Efficiency without Sacrificing Quality**
***Karen L. Hoff, MS***
Manager, Medical Writing, Encysive Pharmaceuticals

**Managing Contract Writers for Timely Delivery of Quality Writing Services**
***Susan C. Sisk, PhD***
Principal, SFP Consulting, LLC

## Session 378 NC - Nonclinical Laboratory Safety, CR, MW

1:30 pm-3:00 pm **LEVEL:** ●

**Room 111AB**

### Metabolites in Safety Testing

Session Chairperson

***Mark N. Milton, PhD***

Senior Director, Development DMPK, Millennium Pharmaceuticals, Inc.

Over the past few years there has been great debate regarding the assessment of the safety of metabolites of NCEs, and the need for assessing the safety of metabolites has been incorporated into several regulatory guidances. Consensus has not yet been achieved regarding when testing is required and, if so, the level of testing required. This session will discuss the different approaches to identifying different approaches for risk identification and assessment for metabolites.

**Metabolites in Safety Testing: The Industry Perspective**
***Mark N. Milton, PhD***
Senior Director, Development DMPK, Millennium Pharmaceuticals, Inc.

**Metabolites in Safety Testing: The European Perspective**
***David R. Jones, MSc***
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency, (MHRA), UK

**Metabolites in Safety Testing: The FDA Perspective**
***Jeri D. El Hage, PhD***
Pharmacology Supervisor, CDER, FDA

## Session 379 NHP - Natural Health Products, CMC, RA, VA

1:30 pm-3:00 pm **LEVEL:** ■

**Room 106AB** *CME and Pharmacy credits offered*

### Managing the Quality of Natural Products

Session Chairperson

***Agnes A. Nguyenpho, PhD***

Research Chemist, CDER, FDA

The manufacturers and regulatory authorities face difficulties in selecting suitable standards for herbal medicinal products as these products are quite complex in nature. For many years people have been using herbals in traditional forms such as infusions, decoctions and tinctures. Some of these herbals are now described in pharmacopoeial monographs. Analytical examination of single plant or tincture does not usually create many problems. However, herbal products are now being marketed as tablets and capsules filled with mixture of various plant extracts. These products are also believed to be efficacious and safe. According to present regulations, regulatory agencies require assays for the active substance or group of substances of known or presumed therapeutic activity. The question of appropriate standards is then raised. Shall the laboratory use standard plant extracts or pure substances whenever possible? How can we assure absence of adulterants in finished products?

**Regulatory Considerations on the Development of Botanical Drug Products in the US**
***Duu-Gong Wu, PhD***
Executive Director, Consulting Division, PharmaNet

**Quality Control of Multicomponent Herbal Medicinal Products: Different Approach**
***Urszula Krawczyk, MPharm, PharmD, PhD***
Head of the Department of Natural Products, National Institute of Public Health, Poland

**The Development and Manufacturing of Botanical Products**
***Trevor P. Castor, MS, PhD***
Founder, Chairman, President and Chief Executive Officer, Aphios Corporation

## Session 380 OS - Outsourcing, CR, PM

1:30 pm-3:00 pm LEVEL: ●

Room 109AB

### Predicting the Outsourcing Industry's 2010 Structure

Session Chairperson

***Michael A. Martorelli, CFA, MBA***

Research Partner, Fairmount Partners

Traditional CROs are facing competition from nontraditional types of outsourcing providers. Some of these new industry entrants may be on their way to becoming more powerul forces than the original full-service CROs, most of which are still headed by their founders.

**The Pharmaceutical Industry in 2010**

***Martin Edward Zuzulo, MS***

Associate Partner, Healthcare and Life Science Practice, IBM Business Consulting Services

**A Survey of Providers**

***Mary Jo Lamberti, PhD, MA***

Senior Manager, Market Intelligence, Thomson CenterWatch

**The Need for Shifting Business Models**

***Gary S. Tyson***

Vice President, Clinical Development Practice, Campbell Alliance

## Session 381 PM Plenary - Project Management, CTM

1:30 pm-3:00 pm LEVEL: ■

Marriott Salon H *Project Management Institute credits offered*

### Creating High-performing Cross-functional Teams

Session Chairpersons

***Michele C. Livesey***

Global Research Development Team Leader, Roche Palo Alto, LLC

***Robin G. Foldesy, PhD***

Vice President, Project Management, Wyeth Research

For the last two years, the project management plenary session has been looking to the future to see what changes are required in pharmaceutical/biotech practices to ensure its continued growth. Although it is no longer a question that maintaining the status quo is unacceptable, the matrix team environment remains a focal point for drug development. Many people continue to view cross-functional teams as one of the most efficient ways to bring drugs to market. That being said, we are not resting on our laurels, but instead continue our efforts to improve team performance.

Why are some teams highly effective, impactful, and satisfying to work on, while others are dysfunctional, ineffective, and stressful for its members? Team leaders and project managers in the pharmaceutical industry generally focus all their attention on what their teams are working on, at the expense of how well their team members work together. The art of bringing people together to form effective, cohesive teams has been the subject of hundreds of studies, articles, and books, yet the Holy Grail for project management, the high-performing team, still eludes most of us. How do top-performing teams rise above the noise and do so well? To answer that question, a group of team and organizational development experts at Johnson & Johnson Pharmaceuticals engaged in one of the most comprehensive scientific research studies in the pharmaceutical industry to pinpoint the specific characteristics that differentiate its highly successful teams. This presentation will focus on the quantitative and qualitative study results showing clearly that specific strategies and actions used by a team, its leader, and management make a meaningful difference in its performance. These strategies and actions, identified as "drivers" of team effectiveness in high-performing teams, will be described by representatives of the study team.

***Vanessa Druskat, PhD***

Associate Professor of Organizational Behavior, University of New Hampshire

***Matthew Mangino, MS***

Consulting Director, Johnson & Johnson Consulting Group

***Steven L. Brooks, PhD, PMP***

Program Manager, Johnson & Johnson Pharmaceutical Research and Development, LLC

## Session 382 PP - Public Policy/Law, FI, IMP

1:30 pm-3:00 pm LEVEL: ●

Room 113A *CME credits offered*

### Pricing and Reimbursement of Medicinal Products in the European Union

Session Chairperson

***David Van Passel, Master of Law***

Covington & Burling, Belgium

This session will provide an overview of the different pricing and reimbursement systems in the EU (including a discussion of general trends). In addition, the specific situation in a few EU countries will be explained as examples.

**Overview of Pricing and Reimbursement in the European Union**

***Liz Eagan***

Research Fellow, London School of Economics, UK

**Pricing and Reimbursement in the Netherlands and Poland**

***Carla Schoonderbeek, JD***

NautaDutilh, Netherlands

**Pricing and Reimbursement in Germany and Basic Principles of Public Procurement**

***David Van Passel, Master of Law***

Covington & Burling, Belgium

## Session 383 RA1 - Regulatory Affairs, IMP

1:30 pm-3:00 pm LEVEL: ■

Room 201B *Nursing credits offered*

### The Emerging Markets: Regulatory Issues and the Impact on Patients' Access to Medicines

Session Chairperson

***J. A. Neil McAuslane, PhD, MSc***

Chief Scientific Officer, CMR International Ltd., UK

The emerging markets, especially those in the newly industrializing countries in Southeast Asia, Latin America, Middle East, and Africa are becoming increasingly important to pharmaceutical companies in their global marketing strategies.

At the country level, companies need to be aware of the key regulatory practices and issues that may be encountered when bringing new products to the market, including requirements for information and testing that fall outside the generally accepted "norm" for medicinal product development.

This session will discuss the findings from a study conducted among 24 countries and 10 major companies on what are the key issues, how these differ by regions of the developing world, and which areas both companies and agencies are working on to remove the major hurdles for delivering new medicines to patients.

**A Cross-regional Comparison of Southeast Asia, Latin America, and Middle East and Africa: What Are the Similarities and Differences in the Regulatory Issues which Impact on Patients' Access to Medicines?**

***J. A. Neil McAuslane, PhD, MSc***

Chief Scientific Officer, CMR International Ltd., UK

**How Can Agencies with Limited Resources Ensure that They Are Not Building Unnecessary Delays into the Approval Process? What Are the Potential Solutions? A Regulatory Perspective**
***Herng-Der Chern, PhD, MD, PharmD***
Executive Director, Center for Drug Evaluation, Taiwan

**How Can Agencies with Limited Resources Ensure that They Are Not Building Unnecessary Delays into the Approval Process? What Are the Potential Solutions? A Company Perspective**
***Mary Jane Nehring, MBA***
Executive Director, Global Regulatory Affairs, Schering-Plough Research Institute

## Session 384 RA2 - Regulatory Affairs, BT, CMC

1:30 pm-3:00 pm LEVEL: ■

**Room 201A** *CME credits offered*

### Follow-on Protein Products: Scientific Issues, beyond Same Molecular Entity and Comparable Rate and Extent – Part 1 of 2

Session Chairperson
***D. Bruce Burlington, MD***
Executive Vice President, Quality, Regulatory and Safety, Wyeth

*Part 2 of this session will be held on Wednesday at 3:30 pm.*

This three-hour session will review the background of Hatch-Waxman as the approval framework for generic drugs from both a legal-public policy viewpoint and from a scientific-public health point of view. How follow-on macromolecules have been approved and how regulatory policy about them has developed in the US both under and outside of Hatch-Waxman will be presented. This framework will be used to explore the scientific, regulatory, legal, and public policy implications for a potential new approval structure for follow-on protein drugs or biological products.

**How Can In Vitro Comparability Be Established?**
***Anthony S. Lubiniecki, ScD***
Vice President, Technology Transfer and Project Planning, Centocor R&D

**What Do We Need to Know about PK and PD?**
***Carole S. Ben-Maimon, MD***
President and COO, Duramed Research, Inc.

**What Do We Need to Know about Immunogenicity?**
***Philip Noguchi, MD***
Director, Regulatory Affairs, Amgen Inc.

**How Do We Understand and Balance Benefits and Risks?**
***D. Bruce Burlington, MD***
Executive Vice President, Quality, Regulatory and Safety, Wyeth

## Session 385 RA3 - Regulatory Affairs, CR, ST

1:30 pm-3:00 pm LEVEL: ■

**Room 201C**

### Substantial Evidence from Subpopulations and Secondary Endpoints

Session Chairperson
***Gregory G. Enas, PhD***
Director, US Regulatory Affairs, Eli Lilly and Company

Pharmacogenomic and other indicators of pathogenesis will play an increasingly important role in clinical trials. Targeted therapies will be investigated across various patient subgroups and multiple surrogate or clinical endpoints. The strength of evidence required to achieve label language regarding these findings will be enabled by appropriate subset analyses and replicated analysis of multiple, including secondary, endpoints.

**Secondary Analyses and Confirmatory Clinical Trials**
***Jonathan S. Denne, PhD***
Principal Regulatory Scientist, Eli Lilly and Company

**Substantial Evidence of Effect**
***Lawrence A. Gould, PhD***
Senior Director, Scientific Staff, Clinical Biostatistics, Merck Research Laboratories

**Discussant**
***Robert J. Temple, MD***
Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

## Session 386 RA4 - Regulatory Affairs, CP, CR

1:30 pm-3:00 pm LEVEL: ■

**Room 203AB**

### Japan's Pharmaceutical and Medical Devices Agency and Related Drug Safety Activities

Session Chairperson
***Deborah Yaplee, PharmD, RPh***
Senior Program Management Officer, Office of Compliance, Division of Compliance Risk Management and Surveillance, CDER, FDA

This session will be used to provide an overview and update on the PMDA and its postmarketing drug safety activities.

**Pharmacovigilance Activities Update at the PMDA**
***Kaori Nomura***
Visiting Expert, Unit of Postauthorization Evaluation of Medicines for Human Use, EMEA, EU; Principal Official for Electronic Data Submissions, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

**Postmarket Pharmacovigilance Practice in FDA**
***Lanh Green, MPH***
Postmarketing Safety Reviewer, Office of Drug Safety, CDER, FDA

**Drug Safety in Japan: A Global Perspective**
***Jennifer E. Driscoll, MSc***
Director, Pharmacovigilance Management, Banyu Pharmaceutical Co., Ltd., Japan

## Session 387 RA5 - Regulatory Affairs, CR, GCP

1:30 pm-3:00 pm LEVEL: ■

**Room 114** Auditorium

### Human Subject Protection/Bioresearch Monitoring Initiative and Critical Path Update

Session Chairperson
***Janet Woodcock, MD***
Deputy Commissioner for Operations and Chief Operating Officer, Office of the Commissioner, FDA

This session will discuss the current initiative on human subject protection and bioresearch monitoring (HSP/BIMO) as well as an update on Critical Path. With the globalization of clinical trials, electronic record keeping and greater participation by vulnerable subjects in clinical trials, the Agency believes there must be a modernization of the clinical trial process. Therefore, a little more than 1 year ago the Agency launched a significant new initiative concerning the protection of human subjects and the integrity of data submitted to the agency and formed a steering committee to oversee this initiative.

**Overview of the HSP/BIMO Initiative and How It Relates to Critical Path**
***Janet Woodcock, MD***
Deputy Commissioner for Operations and Chief Operating Officer, Office of the Commissioner, FDA

**Ethics in Clinical Trials**
***Sara F. Goldkind, MD***
Ethicist, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

**Data Integrity**
***Stephen E. Wilson, DrPH, CAPT. USPHS***
Director, Office of Business Process Support and Deputy Director, Division of Biometrics II, CDER, FDA

## Session 388 RD - R&D Strategy, CR, CTM

1:30 pm-3:00 pm LEVEL: ●

**Room 102AB** *Pharmacy credits offered*

### Microdosing: Promise and Peril along the Critical Path

Session Chairperson
***Christopher P. Milne, DVM, MPH, JD***
Assistant Director, Tufts Center for the Study of Drug Development, Tufts University

The FDA believes that existing regulations allow a great deal of flexibility in terms of the amount of data that need to be submitted with an IND application, but that sponsors have not taken full advantage of the flexibility that such techniques as microdose studies could provide. Among the many issues explored by the presenters in this session will be the FDA's current thinking on the technique and its role in the Critical Path Initiative, as well as industry representatives discussing the pros and cons of microdosing from the perspective of a firm that has employed the technique and one that is taking a wait-and-see attitude.

**Microdosing as a Strategy for Addressing R&D Stress Points**
***Christopher P. Milne, DVM, MPH, JD***
Assistant Director, Tufts Center for the Study of Drug Development, Tufts University

**Use of Phase 0 Human Microdosing to Accelerate Drug Development**
***R. Colin Garner, PhD, DSc, FRCPath***
Chief Executive Officer, Xceleron Ltd., UK

**FDA Perspective on Microdosing, Exploratory INDs and the Critical Path**
***Robert Powell, PharmD***
Director, Pharmacometrics, Office of Clinical Pharmacology, CDER, FDA

## Session 389 ST - Statistics, CR

1:30 pm-3:00 pm LEVEL: ■

**Room 103B** *CME and Pharmacy credits offered*

### Randomized Withdrawal Design for Evaluation of Long-term Efficacy

Session Chairperson
***Peiling Yang, PhD***
Mathematical Statistician, Division of Biometrics I, Office of Biostatistics, CDER, FDA

For some disease indications, where long-term placebo-controlled clinical trials may not be ethical, randomized withdrawal design is adopted. This session will discuss the pros and cons of such a design, including its impact on regulatory approval.

**Enrichment in Randomized Withdrawal Studies**
***Cornelia Dunger-Baldauf, PhD***
Expert Statistician, Novartis Pharma AG, Switzerland

**How Long Should Antidepressant Drugs Be Continued to Prevent Relapse?**
***Yeh-Fong Chen, PhD***
Mathematical Statistician, CDER, FDA

**Long-term Evaluation of Antipsychotic Drugs**
***Eugene Laska, PhD***
Professor, Nathan Kline Institute, NYU School of Medicine

## Session 390 TR - Training, CTM, GCP

1:30 pm-3:00 pm LEVEL: ■

**Room 103C**

### Training Alternatives to Enhance Site Performance and Compliance

Session Chairpersons
***Debra A. Jendrasek***
US EDC Manager, Chiltern International
***Lynn D. Palmer, MBA, CCRA, RAC***
CEO, MedTrials, Inc.

Effective training can increase site performance and compliance in conducting clinical research. This session will examine innovative strategies and training alternatives to optimize clinical research programs. Training needs to be built into each project and should be process driven above and beyond the basics of GCP in order to meet rigorous industry and regulatory standards. Site personnel must know how to apply regulations and guidelines to their practice, and, therefore, training initiatives need to use more application-driven methodology. The session will be solution oriented, and case study results will be presented.

**How to Boost Site Performance and Compliance**
***Lynn D. Palmer, MBA, CCRA, RAC***
CEO, MedTrials, Inc.

**EDC Training Alternatives**
***Debra A. Jendrasek***
US EDC Manager, Chiltern International

3:00 pm-3:30 pm **REFRESHMENT BREAK**
**Exhibit Halls A and B, 2nd Floor, Convention Center**
**Ballroom Foyer, 5th Floor, Marriott Hotel**

## Session 391 AHC - Academic Health Centers, CR, GCP

3:30 pm-5:00 pm LEVEL: ■

**Room 113B** *CME and Pharmacy credits offered*

### Quality Assurance in Asia: Extending across Boundaries

Session Chairperson
***Shirley Suresh, MD***
Operations Manager, Clinical Research, SGS Life Science Services, Singapore

Clinical research has extended over boundaries with collaborative networks set up across institutions and countries. Establishment of quality management systems is a challenge when it crosses areas with differing requirements, policies, or regulations.

This session will look at how standardized QA procedures were established across different research areas within an academic research organization as well as at national and regional levels in Asia.

**Introduction of Quality Assurance in Academic Health Centers throughout Asia**
***Jean-Paul M. Deslypere, MD, PhD***
Business Development Manager Asia-Pacific, Clinical Research, SGS Life Science Services, Singapore

**Clinical Trials in Asia from an Industry Perspective: Partnering with AHCs, IECs and Regulatory Authorities to Achieve Global GCP Standard**
***Allan Kloeve Johansen, DVM***
Head, Clinical Trial Assurance - Asia Pacific, India and South Africa, Roche Products Pty., Ltd., Australia

**Toward International Standard Clinical Trials in Lower Income Asian Countries**
***Paul E. Kilgore, MD, MPH***
Research Scientist, International Vaccine Institute, Republic of Korea

## Session 392 BT - Biotechnology, CR

3:30 pm-5:00 pm LEVEL: ■

Room 103A

### Using Modeling Software to Overcome Hurdles and Improve Productivity in the Development and Validation of Biomarkers in Clinical Trials

Session Chairperson
***Terry W. Osborn, PhD, MBA***
President and CEO, Pharmaceutical Development Consultants

Pharmacogenomics is clearly an area of great promise, but how do we turn tomorrow's promise into today's reality? Some of the fundamental questions and development hurdles are addressed in the development of successful genomic biomarkers for use in clinical trials. Novel software modeling approaches will accelerate the gene to drug process. Software tools can be used as individual modules or can be automated for high throughput processing by setting up required filtering criteria at each stage of the drug lead and biomarker design process. This presentation will provide case examples and demonstrations of model-driven informatics to show how this approach has improved productivity.

**The Use of Genetic Programming to identify Biomarkers Associated with Metastasis in Bladder Cancer**
***Bill Worzel, PhD***
Chief Technology Officer, Genetics Squared, Inc.

**Software Tools for Gene to Drug "Insilico Pathway for Gene to Drug"**
***Srinivasa Reddy Gurram***
Technical Manager, Biopharma R&D Practice, HCL Technologies, Global Life Sciences and Healthcare Practice, India
***B. Jayaram, PhD***
Professor, Indian Institute of Technology, India

**Model-driven Informatics: The Next Generation of Laboratory Informatics**
***Matthew Shanahan***
Chief Marketing Officer, Teranode Corporation

## Session 393 CDM - Clinical Data Management, CP, IT

3:30 pm-5:00 pm LEVEL: ●

Marriott Salon CD

### Strategies for Handling MedDRA® Updates

Session Chairperson
***Patrick Revelle***
Director, MedDRA® MSSO, Northrop Grumman

This session is designed to provide techniques to address MedDRA® version analysis and to update existing MedDRA®-coded data to new versions of MedDRA®.

**An Industry Perspective for Managing MedDRA® Updates: Views from Drug Safety and Clinical Trials**
***JoAnn Medbery, RN***
Director, Dictionary Management Systems, Johnson & Johnson Benefit Risk Management

**The FDA Process of Updating MedDRA® Versions**
***Timothy L. Rigg***
IT Specialist, Office of Information Technology, CDER, FDA

**Strategies for Handling MedDRA® Updates**
***Patrick Revelle***
Director, MedDRA® MSSO, Northrop Grumman

## Session 394 CMC - Chemistry, Manufacturing, and Controls, TR

3:30 pm-5:00 pm LEVEL: ■

Room 112AB

### Challenges in Current Dissolution Methods and Alternatives to Dissolution in the New Paradigm

Session Chairperson
***Karen B. Main, PhD, RPh***
Associate Director, Pharmaceutical and Analytical R&D, AstraZeneca

This session will discuss, from a regulatory and an industry perspective, the challenges associated with current dissolution methods and alternative approaches to dissolution by using quality-by-design principles.

**FDA Perspective**
***Moheb M. Nasr, PhD***
Director, Office of New Drug Quality Assessment, CDER, FDA

**Industry Perspective**
***Mary Oates, PhD***
Vice President, Quality Operations Center, Pfizer Inc

## Session 395 CP - Clinical Safety and Pharmacovigilance, CR, IMP

3:30 pm-5:00 pm LEVEL: ●

Marriott Salon G *CME, Nursing, and Pharmacy credits offered*

### Best Pharmaceuticals for Children Act (BPCA) Pediatric Safety

Session Chairperson
***Adrienne Rothstein, PharmD***
Safety Evaluator, CDER, FDA

This session provides an overview of the background and key components of the Best Pharmaceuticals for Children Act (BPCA) and summarizes the US FDA's collaborative process for conducting these mandated BPCA 1-year post-exclusivity reviews of all adverse events associated with a pharmaceutical granted pediatric exclusivity. The session will also summarize the BCPA reviews of postmarketed safety data conducted in 2004 and 2005 and discuss the significant safety findings from these reviews.

**Implementation of the Best Pharmaceuticals for Children Act: The FDA Pediatric Postmarketing Safety Review Experience**
***Alan M. Shapiro, MD, PhD***
Medical Officer, OCTAP, Division of Pediatric Drug Development, CDER, FDA

**Best Pharmaceuticals for Children Act: Pediatric Safety Review and the Medical Officer**
***John J. Alexander, MD***
Lead Medical Officer, CDER, FDA

**Pediatric Postmarketing Safety Review: How They Are Done and What Have We Found**
***Kathleen M. Phelan, RPh***
Safety Evaluator, CDER, FDA

**Panelist**

***Agnès Saint-Raymond, MD, PhD***
Head of Sector, Scientific Advice and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

## Session 396 CR1 - Clinical Research and Development, CP

3:30 pm-5:00 pm LEVEL: ■

Marriott Salon E *CME credits offered*

### Avoiding QT Overkill

Session Chairperson
***Polina Voloshko, MD***
Vice President, Clinical Cardiovascular Services, Gentiae Clinical Research

ICH E14 is not simply an instruction to spend more money. Thorough QT studies are not necessary in many cases. This session will run through the decision-making process of whether or not to undertake such a study. We will also discuss alternatives to the QT study, along with strategies to simplify, design and make the most of a requisite thorough QT study.

**Issues in Planning and Designing QT Studies from a Statistical Perspective**
***Cheryl L. Rossi, MPH***
President, BioConsult

**Avoiding QT Overkill: Phase 1 Site Perspective**
***Stuart I. Harris, MD, PhD***
Principal Investigator, SeaView Research

**ECG Collection during Early Clinical Development: Practical Considerations of $E_{14}$**
***Paul Frohna, MD, PhD, PharmD***
Senior Director, Clinical Development, Fibrogen

## Session 397 CR2 - Clinical Research and Development, CDM, CTM

3:30 pm-5:00 pm LEVEL: ■

Marriott Salon KL

### Tracking Patient Enrollment from Inquiry to Randomization and Beyond

Session Chairperson
***James P. Kremidas***
Global Enrollment Optimization and Innovation, Eli Lilly and Company

How does a sponsor know if its centralized patient recruitment effort has been effective? There is a gap in current data management systems when it comes to answering these questions. This session will explore the data systems and sources currently available to track patient recruitment data and explore methods for integrating systems to provide the complete picture of patient enrollment results.

**Utilizing Phone and Web Technology to Qualify Candidates and Provide Integrated Recruitment Campaign Metrics**
***David B. Stein***
Director, Product Strategy, ClinPhone Group Ltd., UK

**Track Enrollment and Adjust Ad Spending Allocations by Integrating IVRS, Market, Clinical Trial Management Systems (CTMS) and Phone Center Data**
***David S. Davenport***
Senior Director, Business Development, Perceptive Informatics, Inc.

**A Sponsor's Perspective on the Use of Clinical Trial Systems to Track Enrollees**
***Nancy Dynes, MBA***
Data Steward, Global Enrollment Optimization, Eli Lilly and Company

## Session 398 CR3 - Clinical Research and Development, IMP, PP

3:30 pm-5:00 pm LEVEL: ●

Marriott Salon IJ *CME, Nursing, and Pharmacy credits offered*

### Global Clinical Trials Ethics: Who Is Looking after Whose Interests?

Session Chairperson
***Judith E. Beach, PhD, JD***
Vice President and Senior Associate General Counsel, Regulatory Affairs, Quintiles Transnational Corp.

The recent establishment within a global CRO of an internal organization called the Council on Research Ethics (CORE), chartered to address and resolve ethical issues that arise during the conduct of international clinical trials, will be discussed. The panel will discuss examples of ethical concerns in international clinical trials, particularly those conducted in developing countries, with suggested resolutions.

**Ethics, Clinical Trials, and the Developing World: Is It Possible to "Do the Right Thing"?**
***Oren J. Cohen, MD***
Chief Medical and Scientific Officer, Quintiles Transnational Corporation

**Building and Managing Ethical Clinical Trials Capacity in India: Some Issues and Imperatives**
***Falguni Sen, PhD***
Professor of Management, Graduate School of Business, Fordham University

## Session 399A CR4 - Clinical Research and Development, RA

3:30 pm-5:00 pm LEVEL: ●

Marriott Salon AB *CME credits offered*

### Ensuring Diversity: Monitoring Subpopulation Participation in Clinical Trials

Session Chairperson
***Katherine A. Hollinger, DVM, MPH***
Senior Supervisory Health Promotions Officer, Office of Women's Health, Office of the Commissioner, FDA

The session will review the FDA's policies on inclusion of subpopulations in clinical trials. An overview of the FDA's plan to monitor and assess subpopulation inclusion in clinical trials will be presented.

**FDA Policies and Subpopulations**
***Katherine A. Hollinger, DVM, MPH***
Senior Supervisory Health Promotions Officer, Office of Women's Health, Office of the Commissioner, FDA

**Enrollment of Women in Clinical Trials: A View from the Published Literature**
***Pamela Scott, MS, PhD***
Health Programs Coordinator, Office of Women's Health, Office of the Commissioner, FDA

**Tracking Enrollment of Women in New Drug Applications**
***Ellen E. Pinnow, MS***
Health Programs Coordinator, Office of Women's Health, Office of the Commissioner, FDA

**Barriers to Recruiting Women and Minority Populations: Why Clinical Trial Registries Don't Work – Yet**
***Angela Silverman, MSN, CANP***
Stop Atherosclerosis in Native Diabetics Study (SANDS) Trial Coordinator, Medstar Research Institute

## Session 399B CTM - Clinical Trial Management, EC

3:30 pm-5:00 pm LEVEL: ●

**Room 107AB** *Pharmacy credits offered*

### Multimedia Informed Consent: What Can It Bring to a Trial?

Session Chairperson
***Susan Brink, DrPH***
President, Consent Solutions

This session will provide an in-depth view of the creation of an online consent process designed to facilitate and improve the patient consent process. An online consent currently being employed at a research hospital will be demonstrated. Issues raised by stakeholders representing the sponsor, investigator, study coordinator, and patient perspectives will be presented.

**Multimedia Informed Consent: Can It Contribute to Patient Recruitment and Retention?**
***Helen E. West***
Director, Client Relations, Matthews Media Group

**Where in Our Trials Is It Appropriate to Use Multimedia Online Consent?**
***Andrew Lee***
Vice President, Clinical Study and Data Management, Pfizer Global Research and Development

**Multimedia Informed Consent: Formative Evaluation Results**
***Susan Brink, DrPH***
President and CEO, Consent Solutions

## Session 399C DM - Document Management/ eSubmissions, MW, RA

3:30 pm-5:00 pm LEVEL: ●

**Room 204C**

### International Electronic Common Technical Document (eCTD) Update: The Regulatory Authority Perspective

Session Chairperson
***Mary L. Collins***
Director, Regulatory Affairs, Image Solutions, Inc.

This session will provide the regulatory authority perspective on lessons learned as their experience continues to grow with accepting and reviewing eCTDs. Topics will include authority readiness, initiatives to support eCTD review and evaluation, and specific regional challenges and opportunities.

**US Electronic Submissions Update**
***Gary M. Gensinger***
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

**EU Electronic Submissions Update**
***Claire Edwards, MBA***
Administrator, EMEA, EU

**eCTD Update in Japan**
***Hitoshi Matsui***
Executive Consultant, CAC Corporation, Japan

## Session 399D GCP - Good Clinical Practices, CR

3:30 pm-5:00 pm LEVEL: ●

**Room 202AB**

### Managing Clinical Trials in Russia

Session Chairperson
***Bruce M. Wagman, MBA, RN***
Vice President, Regulatory and Quality Assurance Services, Covance, Inc.

The speakers in this session have conducted hundreds of clinical trials in Russia. The session will provide the audience with examples of situations that they have encountered in managing clinical research in Russia. These examples will include both the correct and incorrect methods of complying with Russian clinical trial regulations.

**Clinical Trials in Russia and Eastern Europe: Risk Management**
***Sergei Varshavsky, MD, PhD***
Chief Executive Officer, Evidence Clinical & Pharmaceutical Research

***Natalie L. Gershman, MD***
CEO, Medical Director, GENY Research Corp.

## Session 399E IT1 - Information Technology, CS, CTM

3:30 pm-5:00 pm LEVEL: ●

**Room 105AB**

### Automated Tools for the Electronic Management of Complex Inventory in Global Studies

Session Chairperson
***Scott A. Hamilton, PhD***
Clinical Assistant Professor, Stanford University Medical Center; Biostatistician and Founder, UBC Clinical Technologies Group

The challenges of managing drug retest and expiry dates can be monumental. Coordination of replacement supply as well as reconciliation of returned drug can be an extremely time-consuming and expensive project. This session will discuss ways automated tools can be implemented to increase efficiency and decrease costs surrounding expiring drug supplies.

**Using IVRS to Effectively Manage Inventories at Global Depots**
***James M. Benkendorf***
Executive Vice President, Xerimis Inc.

**New Technologies to Track Global Clinical Supplies and Monitor Temperature Conditions**
***Robert Misher, MBA***
Consultant, Misher Pharmaceutical Consulting Services

**Drug Return Handling Using a Web Interface and the IVRS Database**
***Scott A. Hamilton, PhD***
Clinical Assistant Professor, Stanford University Medical Center; Biostatistician and Founder, UBC Clinical Technologies Group

## Session 399F IT2 - Information Technology, CDM, CR

3:30 pm-5:00 pm LEVEL: ●

Room 113C

### Applications of the Biomedical Research Integrated Domain Group (BRIDG)

Session Chairperson

***Douglas B. Fridsma, MD, PhD, FACP***

Assistant Professor of Medicine, University of Pittsburgh School of Medicine

The BRIDG model is a comprehensive domain analysis model representing biomedical/clinical research intended to serve as the foundation for developing data interchange standards and technology solutions for biomedical/clinical research and healthcare arenas. This session will explore specific examples in which the BRIDG model is being used to support development of next-generation clinical protocol-authoring tools, the Cancer Biomedical Informatics Grid, and NIAID Division of AIDS initiatives.

**Model-driven Protocol Authoring**

***Peter Abramowitsch***

Chief Technical Officer, FastTrack Systems

**Model-driven Application Development for Adverse Event Reporting: Harmonizing with BRIDG**

***Joyce C. Niland, PhD***

Chair and Professor, Information Sciences, City of Hope National Medical Center

**The BRIDG in an Enterprise Class Clinical Data Management System**

***Lisa Chatterjee***

Vice President, Process Engineering Group, Digital Infuzion, Inc.

## Session 399G MC - Medical Communications, CR, MA

3:30 pm-5:00 pm LEVEL: ■

Room 204A

### Effectively Communicating Outcomes Research to Enhance Product Success

Session Chairperson

***Deborah Marshall, PhD, MHSA***

Director, Research and Development, Health Economics and Outcomes Research, Innovus Research Inc., Canada

Evidence demonstrating economic benefit and product value is complex and generally under-exploited in communication with relevant stakeholders. This session will explore case studies where health economic and outcomes product value is clearly disseminated in a variety of formats to a number of audiences with benefits to both researchers and recipients outlined.

**Research Design Considerations to Optimize Stakeholder Communication**

***Deborah Marshall, PhD, MHSA***

Director, Research and Development, Health Economics and Outcomes Research, Innovus Research Inc., Canada

**Maximizing Technology and Tools for Communication of Outcomes Research**

***Allen Lising***

Managing Director, Operations, Dymaxium Inc., Canada

## Session 399H MW - Medical/Scientific Writing, CR, CTM

3:30 pm-5:00 pm LEVEL: ●

Room 204B

### Clinical Trial Registries: An Update

Session Chairperson

***Arthur Gertel, PhD, MS***

Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.

Now that mandated clinical trial registries have been online for a year, this session will examine the factors that have facilitated or impeded the successful use of this resource. The panel will discuss issues of content/presentation/follow-up that may be addressed through the effective use of professional medical writers.

**How Did We Get Here?**

***Arthur Gertel, PhD, MS***

Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.

**The Global Big Pharma Perspective**

***Jean H. Soul-Lawton***

Medical Writing Director, GlaxoSmithKline R&D, UK

## Session 399I NC - Nonclinical Laboratory Safety, BT, MW

3:30 pm-5:00 pm LEVEL: ■

Room 111AB *CME credits offered*

### Animal Models of Disease in Nonclinical Development of (Orphan) Drugs

Session Chairpersons

***Per Spindler, DVM, MBA, MSc***

Head of BioLogue®, University of Copenhagen, Denmark

***Beatriz Silva Lima, PhD, PharmD***

Professor, Pharmacology; Chair, SWPO, University of Lisbon and INFARMED, Portugal

The development of medicinal products for rare genetic diseases poses difficulties in identifying relevant animal species for safety assessment to support clinical trials, although the mice models are frequently used to predict in vivo pharmacodynamic responses. Whereas nonclinical safety studies to support clinical development are often conducted with healthy animals, it might be speculated that the genetically modified disease models, usually mice, are more relevant for the clinical situation. The experience and usefulness of animal disease models, usually genetically-modified mice, for safety assessment will be addressed and discussed from US and EU regulatory perspectives and from an industry perspective.

**A Notion from a US Regulatory Perspective, Including Case Examples**

***Abigail C. Jacobs, PhD***

Associate Director of Pharmacology and Toxicology, Office of New Drugs, CDER, FDA

**A Notion from an EU Regulatory Perspective, Including Case Examples**

***Beatriz Silva Lima, PhD, PharmD***

Professor, Pharmacology; Chair, SWPO, University of Lisbon and INFARMED, Portugal

**An Industry Perspective on the Use of Genetically-modified Models for Nonclinical Safety Assessment**

***Alain Stricker-Krongrad***

US Senior Director of Preclinical Services, Charles River Laboratories

## Session 399J NHP - Natural Health Products, MA, RD

3:30 pm-5:00 pm **LEVEL:** ■

**Room 106AB** *CME credits offered*

### Developing Botanical Drugs for the United States

Session Chairperson

***Freddie Ann Hoffman, MD***

CEO/Managing Member, HeteroGeneity, LLC

Although most botanicals and other "natural health products" are currently being sold in the US as foods, companies need to be aware of when and how these products might be developed as drugs. This session will explore the rationale behind developing and marketing botanicals as drugs, as well as to develop an understanding of the various potential routes to market this class of ingredients in the US. An overview of the current status of botanical drug development in the US will be presented, along with a summary of the potential ways such development projects can be funded.

**The Dollars and "Sense" of Developing Botanicals and Other Naturally-derived Products as "Drugs"**
***Freddie Ann Hoffman, MD***
CEO/Managing Member, HeteroGeneity, LLC

**Current US Regulatory Environment for Developing Botanicals as Drugs**
***Leslie A. Vaccari, RAC***
Regulatory Health Project Manager, CDER, FDA

**Show Me the Money! Finding Funding for Botanical Drug Development: A Beginner's Overview**
***Catherine Zhang***
Principal, Towerview Capital Management, LLC

## Session 399K OS - Outsourcing, CR, FI

3:30 pm-5:00 pm **LEVEL:** ◆

**Room 109AB**

### Functional Outsourcing: A Comparison of Two Major Companies' Strategies

Session Chairperson

***Kristin Ellis***

Group President, Kforce Clinical Research Staffing

A new clinical research outsourcing strategy is gaining popularity among the top biopharmaceutical companies – functional outsourcing. Rather than outsource work on a per-project basis, these companies are outsourcing certain clinical research functions across multiple projects. This session will compare and contrast through case studies how two top-10 biopharmaceutical companies have implemented the functional outsourcing strategy for regional monitoring, as well as the challenges and clinical outcomes 18 months into their new model. In addition, a case study for a more mature relationship will be presented to discuss functional outsourcing outcomes after more than 3 years.

***Mary Ann Szabo***
Director, Head of Regional Monitoring Network, Hoffmann-La Roche, Inc.

***Brett Barber, MSc***
Regional Head, North American Monitoring Group, Pfizer Inc

## Session 399L PM1 - Project Management, BT, RA

3:30 pm-5:00 pm **LEVEL:** ●

**Room 108A** *Project Management Institute credits offered*

### Fast and Fun Way to Build High-performing Cross-functional Teams

Session Chairperson

***Usha Rafferty, MS***

Partner, Michael & Usha Rafferty Consultants, LLC

This session is geared towards leaders in small- to mid-size biotechnology companies with the desire or need to build high-performing cross-functional teams with limited time and resources. The session provides some steps and tips to build these teams in a short time and have fun in the process. The attendees may have an opportunity to ask questions and discuss any specific experiences with the panelists.

**Team Chemistry: Achieving Commitment through Balance**
***Nancy P. Mathias, MS***
President and Founder, Focus Leadership Development, LLC

**Simplifying the Mystery of Team Development**
***Kate Miller, PhD***
Senior Partner, Design Training Collaborative

**Team Building at FDA: We Are More Alike than You Think**
***David Roeder, MS***
Associate Director, Regulatory Affairs, Office of New Drugs, Office of Antimicrobial Products, Office of Drug Evaluation IV, CDER, FDA

## Session 399M PM2 - Project Management, BT, RD

3:30 pm-5:00 pm **LEVEL:** ■

**Room 108B** *Project Management Institute credits offered*

### Project Teams or Product Incubators?

Session Chairperson

***Cynthia L. Palka, MS, CEC, RAC***

Vice President, Global Leadership, The Chalfont Project, UK

"To be organized in project teams" is today a meaningless statement. There are dozens of, if not a hundred, types of project teams. The levels of authority, accountability, and other dynamics within the team make project teams very different. It is not until the operating model of the specific team has been defined that we can confidently describe the team as such. This session explores the spectrum of models and proposes alternatives to traditional structures and ways of working.

**Next Generation Project Teams**
***Cynthia L. Palka, MS, CEC, RAC***
Vice President, Global Leadership, The Chalfont Project, UK

**Resource and Project Management in a Discovery Organization**
***Jonathan S. Cook, PhD, PMP***
Section Head - Target ID and Validation, Procter & Gamble Pharmaceuticals

## Session 399N PP - Public Policy/Law, CP, IMP

3:30 pm-5:00 pm LEVEL: ■

**Room 113A**

### RiskMAPing and Litigation

Session Chairperson

***Myron S. Weinberg, PhD***

Chairman Emeritus, THE WEINBERG GROUP LLC

As biologically active materials, all old or new drugs are vulnerable to litigation. It is necessary to minimize the risks associated with the use of such pharmaceuticals both to the user/prescriber axis and to the company. It is also necessary to identify, consider, and minimize all of the vulnerabilities as one seeks new uses for existing active entities and new drug substances. Approaches to managing, preparing, and minimizing these risks will be discussed.

**RiskMAPing and Litigation: Characterization**
***Robert P. Brady, Esq.***
Partner, Hogan & Hartson LLP

**RiskMAPing and Litigation: Management Perspectives**
***Myron S. Weinberg, PhD***
Chairman Emeritus, THE WEINBERG GROUP LLC

**RiskMAPing and Litigation: Legal Perspectives**
***James E. Tyrrell, Jr., Esq.***
Patton Boggs LLC

## Session 399O RA1 - Regulatory Affairs, CR, GCP

3:30 pm-5:00 pm LEVEL: ■

**Room 203AB**

### Regulatory "Partnership in Harmonization" in APEC Region

Session Chairperson

***Herng-Der Chern, MD, PhD, PharmD***

Executive Director, Center for Drug Evaluation, Taiwan

How non-ICH countries adopt and interpret the ICH guidance without discrepancies is an imperative question for industries. APEC, as the most populous and potential pharmaceutical market, became the first challenge to this question. Major harmonization trends of the regulatory environment in major Asian countries including Japan, China, Korea, Taiwan, and ASEAN countries will be discussed. Non-ICH harmonization initiatives such as APEC LSIF, APEC network of pharmaceutical regulatory sciences, and ICH-GCG will be reviewed.

**Global Drug Development, Application, and Approval Involving Japan and Other Asian Countries**
***Osamu Doi, PhD***
Senior Executive Director, Society of Japanese Pharmacopeia, Japan

**Regulatory Harmonization through APED Life Science Innovation Forum**
***Sumol Pavittranon, PhD***
Toxicology and Biochemistry Laboratory, National Institute of Health, Ministry of Public Health, Thailand

**Regulatory Harmonization through AED Network of Pharmaceutical Regulatory Science**
***Chi-Chou Liao, PhD***
Director General, Bureau of Pharmaceutical Affairs, Department of Health, Taiwan

## Session 399P RA2 - Regulatory Affairs, BT, CMC

3:30 pm-5:00 pm LEVEL: ■

**Room 201A** *CME credits offered*

### Follow-on Protein Products – Legal and Regulatory Framework for Approval: History of Hatch-Waxman and Lessons Learned – Part 2 of 2

Session Chairperson

***Geoffrey Levitt, JD***

Vice President and Chief Counsel, Regulatory and Research, Wyeth Pharmaceuticals

*Part 1 of this session will be held on Wednesday at 1:30 pm.*

This session will review the background of Hatch-Waxman as the approval framework for generic drugs from both a legal-public policy viewpoint and from a scientific-public health point of view. How follow-on macromolecules have been approved and how regulatory policy about them has developed in the US both under and outside of Hatch-Waxman will be presented. This framework will be used to explore the scientific, regulatory, legal, and public policy implications for a potential new approval structure for follow-on protein drugs or biological products.

**What Does "Sameness" Mean for a Follow-on Protein Product?**
***Edward L. Korwek, PhD***
Partner, Hogan & Hartson LLP

**What Legislative Steps Will Be Needed to Make Follow-on Biologics Legally Viable?**
***Amy Muhlberg***
Professional Staff Member, Senate Committee on Health, Education, Labor and Pensions, US Senate

**What Intellectual Property Issues Need to Be Resolved?**
***Steven J. Lee, PhD***
Partner, Kenyon & Kenyon LLP

**What Impact Will the EU Experience and Other Precedents Have?**
***Richard F. Kingham, JD***
Partner, Covington & Burling

## Session 399Q RA3 - Regulatory Affairs, PP

3:30 pm-5:00 pm LEVEL: ●

**Room 201B**

### Adding a Third Drug Class: Benefit or Burden?

Session Chairperson

***Sejal A. Parikh, PharmD***

Postdoctoral Fellow, Regulatory Affairs, St. John's University College of Pharmacy and Allied Health Professions, Forest Research Institute

Currently there are two classes of drugs in the US: prescription and over-the-counter (OTC). There has been much controversy over the creation of a new drug class for medications that are not unsafe enough to require a prescription but are not safe enough to be available to all patients without medical supervision. This session will bring to light a variety of issues surrounding implementation of such a new class and whether it should be done at all.

**Choice, Convenience and Competition: The US Rx and OTC Distribution System Serves Consumers Well**
***Linda A. Suydam, DPA, MA***
Past Senior Associate Commissioner, FDA; President, Consumer Healthcare Product Association

**Pros and Cons of a Hybrid Distribution System to the Consumer: A Pharmacist's Perspective**
***Delores J. Wong, PharmD, MBA, RPh***
Principal Business Consultant, D. J. Wong & Associates; Past Medical Director, Global Clinical Research, Bristol-Myers Squibb Company

***James C. Appleby, MPH, RPh***
Senior Vice President, Business Development, American Pharmacists Association

## Session 399R RA4 - Regulatory Affairs, CP

3:30 pm-5:00 pm **LEVEL:** ■

**Marriott Salon H** *CME and Pharmacy credits offered*

### ICH E2E Implementation: National/International Perspectives

Session Chairperson
***Stephen A. Goldman, MD, FAPM, FAPA***
Managing Member, Stephen A. Goldman Consulting Services, LLC

This session will examine current perspectives and approaches in the US, EU and Japan regarding pharmacovigilance planning, given the challenges that industry will confront in implementing the ICH E2E Guideline (including necessary multidisciplinary collaboration) in the face of other pharmaceutical safety initiatives.

**Pharmacovigilance Planning and Risk Management in the US: Integrating E2E and FDA-specific Guidances**
***Stephen A. Goldman, MD, FAPM, FAPA***
Managing Member, Stephen A. Goldman Consulting Services, LLC

**Pharmacovigilance Planning and Risk Management in the EU: Balancing Regulatory Expectations with Company Practicalities**
***Elliot G. Brown, MB, MRCGP, DPM, FFPM***
Managing Director, Elliot Brown (Consulting) Ltd., UK

**Pharmacovigilance Planning and Risk Management in Japan: Implementing E2E and Other New Regulatory Requirements**
***Shinya Yamauchi***
Director, Global Pharmacovigilance, Otsuka Pharmaceutical Co., Ltd., Japan

## Session 399S RA5 - Regulatory Affairs, CP, MC

3:30 pm-5:00 pm **LEVEL:** ●

**Room 114** Auditorium *CME and Pharmacy credits offered*

### CDER Hot Topic: Physicians' Labeling Rule

Session Chairperson
***Rachel E. Behrman, MD, MPH***
Deputy Director, Office of Medical Policy, CDER, FDA

This session will begin with an overview of the Physicians' Labeling Rule. This will be followed by a panel discussion where the audience can ask specific questions and clarifications about the ruling and guidances of an FDA panel.

**The New Content and Format Requirements for Prescription Drug Labeling: Leaner, Cleaner, More Precise**
***Rachel E. Behrman, MD, MPH***
Deputy Director, Office of Medical Policy, CDER, FDA

**Labeling Section Guidances**
***Robert J. Temple, MD***
Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

**Labeling for Human Prescription Drug and Biological Products: Implementing the New Content ad Format Requirements ("Implementation Guidance")**
***Colleen Locicero, RPh***
Associate Director for Regulatory Affairs, Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

**Moderator and Panelist**

***Elizabeth Sadove, JD***
Regulatory Counsel, Office of Regulatory Policy, CDER, FDA

**Panelists**

***Rachel E. Behrman, MD, MPH***
Deputy Director, Office of Medical Policy, CDER, FDA

***Colleen Locicero, RPh***
Associate Director for Regulatory Affairs, Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

***Robert J. Temple, MD***
Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

## Session 399T RA6 - Regulatory Affairs, RD

3:30 pm-5:00 pm **LEVEL:** ■

**Room 201C**

### PDUFA's Pilot 1: The Continuous Marketing Application Revealed

Session Chairperson
***Jenny L. Peters, RPh***
Associate Director, Global Regulatory Affairs, Amgen Inc.

The Prescription Drug User Fee Act (PDUFA) was reauthorized by the US Congress for a second time on 12 June 2002, as PDUFA 3. Included in PDUFA 3 are pilot 1 and pilot 2 of the continuous marketing application (CMA) that are available only for drugs and biologics that are granted fast-track designation. The continuous marketing application concept builds on the current practice of interaction between the Food and Drug Administration (FDA) and an applicant during the drug-development phase and application review, and proposes improvements in the processes. Specifically, pilot 1 provides for the review of a limited number of presubmitted portions of an applicant's marketing application (reviewable units) based on the terms and conditions agreed to by the applicant and the FDA. The pilot provides feedback from the FDA after 6 months in the form of discipline review letters. The pilot programs are intended to provide important information concerning the utility of the program to improve the efficiency of the drug development and the review processes and shorten review time. Shortening the review time has important implications not only for health professionals but also for patients who are waiting for new therapies.

We will present the experiences and recommendations of the 3 companies and 3 products (OSI/Genentech, erlotinib; Amgen, palifermin; and Eyetech/Pfizer, pegaptanib) who were first to receive marketing approval using the CMA. FDA will share their perspective. A panel discussion will include representatives from the 3 companies and FDA. Come hear if pilot users would repeat the experience. Which processes worked well for them and which processes offered challenges. Would these firms do it again? What recommendations do they have for other firms? What advice does the Agency have?

**Tarceva – CMA Case Study #1**
***Christine Boisclair***
Vice President, Global Regulatory Affairs, OSI Pharmaceuticals Inc.

**Macugen – CMA Case Study #2**
***Karen R. Fleshman, PhD***
Senior Director, CMC Regulatory Affairs, OSI EyeTech Pharmaceuticals Inc.

**Kepivance – CMA Case Study #3**
***Julie Lepin***
Associate Director, Amgen Inc.

**Continuous Marketing Applications: FDA Experience**
***Sally Loewke, MD***
Assistant Director for Guidance and Policy, CDER, FDA

## Session 399U RD - R&D Strategy, BT, RA

3:30 pm-5:00 pm LEVEL: ◆

**Room 102AB** *CME and Pharmacy credits offered*

### An Analysis of the Success Factors of Global Applications of Biotechnology-derived Products

Session Chairperson
***Gabriele Schaeffner, PhD***
Principal Consultant, Parexel International GmbH, Germany

While FDA and EMEA have independently published principal papers acknowledging the pipeline problem (decreasing numbers of applications for new drugs), these initiatives need to be put into action, and industry needs to develop new concepts to expedite drug development. This session will provide an analysis of the factors behind the success or failure of recent global biotechnology drug development applications and will compare them with the principal ideas of the FDA and the EMEA.

**Factors for Successful Marketing Authorizations: The Perspective of an EU Regulator**
***Christian Schneider, MD***
Acting Head of Section, Mono- and Polyclonal Antibodies, Paul-Ehrlich-Institut, Germany

**Regulatory Issues for Global Technical Development of Biotech Products**
***Ines Kraemer, PhD***
Head of Technical Regulatory Affairs, Pharmaceutical Biotech Production and Development, Roche Diagnostics

**Factors Related to the Clinical Development Behind the Success of Recent Global Drug Development Applications**
***Gabriele Schaeffner, PhD***
Principal Consultant, Parexel International GmbH, Germany

## Session 399V ST - Statistics, CDM, EC, RA

3:30 pm-5:00 pm LEVEL: ■

**Room 103B** *CME and Pharmacy credits offered*

### Regulatory Guidance and Standards Development: Implications for Statistical Practice and Review

Session Chairperson
***Stephen E. Wilson, DrPH, CAPT. USPHS***
Director, Office of Business Process Support and Deputy Director, Division of Biometrics II, CDER, FDA

CDER has published guidance and specifications encouraging the submission of both analysis files and CDISC-defined standard (STDM or standard tabulation data model) data. The CDISC ADaM (analysis data modeling) workgroup has issued and is developing guidance on the content and description of analysis files. Additional guidance from CDER/CBER describing "good review management practices" defines expectations for processes associated with the review and evaluation of NDAs and BLAs. These initiatives and a number of others involving both standards and review should change the way we do our "business," both statistical practice in the industry and statistical review at the agency. This session will describe early experiences associated with this "paradigm shift" to our new world of standard data and managed review.

**Review Management, Standards, the eCTD and Statistical Review: A Statistical Review Perspective**
***Feng Zhou***
Statistician, CDER, FDA

**Standardization: Understanding the Implications for Statistical Practice**
***Jonathan G. Levine***
Mathematical Statistician, Office of Pharmacoepidemiology and Statistical Sciences, CDER, FDA

**CDISC ADaM Workgroup Update: General Considerations and Data Models**
***Michael L. Nessly, MS***
Director, Clinical Biostatistics and Research Decision Sciences, Merck Research Laboratories

## Session 399W TR - Training, CR, GCP

3:30 pm-5:00 pm LEVEL: ■

**Room 103C**

### Decreasing Business Risk by Ensuring Training Compliance: Three Key Strategies

Session Chairperson
***Shawn C. Milheim, MS***
Centocor R&D

In light of public perception, one constant challenge is ensuring compliance with the increasing amount of training required for new and revised regulations. This session will describe the integration of three key strategies to ensure the success of meeting the training compliance goal by creating personalized training curricula and tracking compliance; developing a multilayered communication plan; and designing effective training through the use of instructional design techniques.

**Creating Personalized Training Curricula**
***Patricia S. Moskwa***
Assistant Director, R&D Training and Procedural Documents, Centocor R&D

**Tracking Training Compliance**
***Marjorie H. Carkhuff, MEd, RN***
President, Principal Consultant, Carkhuff Associates

**Developing a Multilayered Communication Plan**
***Harriet Stein, MS***
Senior Manager, Centocor R&D

**Designing Effective Training through the Use of Instruction Design Techniques**
***Shawn C. Milheim, MS***
Centocor R&D

5:00 pm **END OF WEDNESDAY SESSIONS**

5:15 pm **CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH MEETING**
Room 202AB, 2nd Floor, Convention Center

7:30 am-10:30 am **ATTENDEE REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-10:30 am **SPEAKER REGISTRATION**
Grand Hall, 2nd Floor, Convention Center

7:30 am-8:15 am **CONTINENTAL BREAKFAST**
Grand Hall and Meeting Rooms 201-204 Concourse, 2nd Floor, Convention Center
Ballroom Foyer, 5th Floor, Marriott Hotel

12:30 pm-5:00 pm **MedDRA® USER GROUP MEETING**
Room 201B, 2nd Floor, Convention Center

## Session 401 AHC - Academic Health Centers, CR

8:30 am-10:00 am **LEVEL:** ◆

**Room 110AB** *CME, Nursing, and Pharmacy credits offered*

### Accelerating Research: Integrating Clinical Research with Clinical Care

Session Chairperson
***Michael Nourie, MBA***
President and Chief Technology Officer, Accelere, Inc.

Today's academic clinical research environment faces new challenges that will be addressed: competing for NIH funding for increasingly complex studies, finding and enrolling patients given complex inclusion/exclusion criteria and complex timing constraints (i.e., acute conditions), maintaining patient confidentiality in accordance with HIPAA guidelines while conducting research, and integrating care and research activities on the hospital floor.

This panel focuses on the proven strategies and implementations that radically improve the process of how clinical studies can be planned and conducted within an academic medical setting. The panel will focus specifically on investigator screening, real-time patient screening and recruitment, and research workflow in parallel with quality care.

**Technology Challenges in Performing Research at Academic Medical Centers**
***Stephen K. Woody***
Chief Information Officer, Duke Clinical Research institute

**Case Examples of Research Challenges, Particularly with Recruitment**
***Andra Joy Schemera***
Clinical Project Manager/Clinical Research Associate

## Session 402 BT - Biotechnology, CR

8:30 am-10:00 am **LEVEL:** ■

**Room 103A**

### Challenges of Biotechnology Product Development

Session Chairperson
***Robert Butz, PhD***
Vice President, Global Regulatory Affairs, MDS Pharma Services

Early-stage biotechnology companies face unique logistical and financial challenges in developing new drugs. This session will explore these challenges, with a special focus on oncology product development.

**Exploratory IND Strategies for Biotechnology Product Development**
***Robert Butz, PhD***
Vice President, Global Regulatory Affairs, MDS Pharma Services

**Premises, Paradigms, and Paradoxes in Oncology Drug Development**
***Al Blunt, MD***
Senior Medical Director, Oncology, Covance, Inc.

**The Unique Business Challenges Biotechnology Faces when Entering the Clinic**
***Wendy Porter***
President, Endpoint Research Ltd., Canada

## Session 403 CDM - Clinical Data Management, EC, IT, ST

8:30 am-10:00 am **LEVEL:** ■

**Room 204B**

### The Impact of SDTM (Study Data Tabulation Model) on the Methodology of Clinical Information Management

Session Chairperson
***David A. Evans, MS***
Chief Information Officer, Octagon Research Solutions, Inc.

This session will focus on the theory, development and practice of using SDTM metadata in the clinical information lifecycle. The assembled panel of speakers will present case studies on the use of SDTM metadata in automating clinical information processes.

**The Use of SDTM in an Integrated Clinical Management Environment**
***Peter Smilansky, MS***
Assistant Vice President, Global Medical Applications, Wyeth Pharmaceuticals

**Methodology of Legacy Data Conversion to SDTM for Submission to the FDA**
***Thomas S. Guinter***
Vice President, Clinical Data Strategies, Octagon Research Solutions, Inc.

**A Trial Design System for Producing Clinical Trial and SDTM Metadata**
***Norman Stockbridge, MD, PhD***
Acting Director, Division of Cardio-renal Drug Products, CDER, FDA

## Session 404 CMC - Chemistry, Manufacturing, and Controls, TR

8:30 am-10:00 am **LEVEL:** ■

**Room 113B**

### Updates on FDA GMP (Good Manufacturing Practices) Initiatives and Guidances

Session Chairperson
***Joseph C. Famulare***
Acting Director, Office of Compliance, CDER, FDA

This session will discuss the current initiatives and guidances on good manufacturing practices (GMPs), including risk-based inspections, the pharmaceutical inspectorate, and quality systems, from a regulatory and an industry perspective.

**FDA Compliance Perspective**
***Joseph C. Famulare***
Acting Director, Office of Compliance, CDER, FDA

**Industry Perspective**
***Gerald P. Migliaccio***
Vice President, Global Quality and EHS Operations, Pfizer Global Manufacturing

## Session 405 CP - Clinical Safety and Pharmacovigilance, CDM, ST

8:30 am-10:00 am **LEVEL:** ■

**Room 201C**

### Current MedDRA® Topics: Data Retrieval and Presentation Points to Consider and Standardized MedDRA® Queries (SMQs)

Session Chairperson
***Patricia Mozzicato, MD***
Medical Officer USA, MedDRA® MSSO, Northrop Grumman Corporation

There have been two recent developments with MedDRA® (the Medical Dictionary for Regulatory Activities) to aid in the retrieval and presentation of MedDRA®-coded information for subsequent analysis. The *"Data Retrieval and Presentation: Points to Consider"* was created to present a set of data retrieval and presentation options and to promote accuracy and consistency in the output of MedDRA®-coded data; and Standardized MedDRA® Queries (SMQs) have been developed to facilitate retrieval of MedDRA®-coded cases by presenting a list of terms related to a condition of interest (e.g., anaphylactic reaction). This session will describe the development and content of the new *"Points to Consider"* document; it will also present an overview of the SMQs (including examples of individual SMQs) and describe the practical aspects of how SMQs are implemented in databases.

**Understanding the New ICH Points to Consider Document: Data Retrieval and Presentation**
***JoAnn Medbery, RN***
Director, Dictionary Management Systems, Johnson & Johnson Benefit Risk Management

**Current MedDRA® Topics: Focus on Retrieval and Presentation of MedDRA®-coded Data**
***Patricia Mozzicato, MD***
Medical Officer USA, MedDRA® MSSO, Northrop Grumman Corporation

**Standardized MedDRA® Queries: Current Status and Practical Experience**
***Judy Harrison, MD***
Consultant to MedDRA® MSSO, Harrison Clinical Consulting, LLC

## Session 406 CR1 - Clinical Research and Development, PP, RA

8:30 am-10:00 am **LEVEL:** ●

**Room 109AB** *CME and Pharmacy credits offered*

### Pediatric Drug Development in an Increasingly Global Context

Session Chairperson
***Klaus Rose, MD, MS***
Head, Pediatrics Pharmaceuticals Division, F. Hoffmann-La Roche AG, Switzerland

The US pediatric legislation has stimulated a lot of pediatric research. A European debate has also been initiated, and European pediatric research structures will be built up in the near future. Key representatives from US and EU health authorities as well as from the pharmaceutical industry will outline their views on the existing legislation, interactions between US and EU health authorities and how in their respective views the pediatric legislation should be prolonged or modified.

**Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA): What Has Worked and What Could Be Improved?**
***Mary Diane Murphy, MD***
Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

**What Will Be the Short- and Middle-term Impact of the EU Pediatric Regulation?**
***Klaus Rose, MD, MS***
Head, Pediatrics Pharmaceuticals Division, F. Hoffmann-La Roche AG, Switzerland

**Global Pharmaceutical Drug Development and the US and EU Pediatric Legislations: Where Do We Stand Now and Where Should We Stay in 10 Years?**
***Samuel D. Maldonado, MD, MPH***
Assistant Vice President, Global Regulatory Affairs, Wyeth Research

## Session 407 CR2 - Clinical Research and Development, IS, OS

8:30 am-10:00 am **LEVEL:** ■

**Room 112AB** *CME and Pharmacy credits offered*

### Strategies for Outsourcing and Managing Late-phase Trials Using Naïve Sites

Session Chairperson
***Hani S. Zaki***
Vice President, Business Development, PharmaNet

"First-time" study investigators and study sites can be an essential part of conducting large late-phase trials, such as disease, or drug registries and safety surveillance programs. The success of these studies will depend on a thorough understanding of what can and can't be achieved in working with naïve sites, and how far one can push these limitations. Essential lessons in outsourcing and managing these types of trials will be discussed.

**Industry Perspective: Lessons from the Front Lines**
***Karen L. Wilson***
Associate Director, US Phase IV, Bayer Corporation

**Getting "the Best" from Naïve Sites**
***Peggy Schrammel, MPA***
Executive Director, Late Stage Development, PharmaNet

## Session 408 CR3 - Clinical Research and Development, RA

8:30 am-10:00 am **LEVEL:** ■

**Room 111AB** *CME credits offered*

### Microdosing Studies: State of Technology and US Regulatory Requirements

Session Chairperson
***David Skarinsky, RAC***
Principal Consultant, PAREXEL International

Trace-dose screening human ADME (absorption, distribution, metabolism and excretion) studies, known as microdosing Phase 0 studies, allow for faster and more intelligent candidate selection by analyzing drug and metabolite concentrations in body fluids over time. Microdosing studies are covered under FDA's Critical Path Initiative. The session will review the technology, examine requirements for exploratory IND submissions, explore clinical development benefits, and consider practical implementation issues.

**Microdosing Technology Background**
***J. Scott Tarrant***
Vice President, Xceleron Inc.

**Development Strategy and Regulatory Requirements for Initiating Microdosing Studies**
***David Skarinsky, RAC***
Principal Consultant, PAREXEL International

**State of Technology and Clinical Application of Microdosing**
***Nachum Kaplan, PhD***
Vice President, Microbiology, Affinium Pharmaceuticals, Canada

**Panelist**
***David Jacobson-Kram, PhD, DABT***
Associate Director for Pharmacology and Toxicology, Office of New Drugs, CDER, FDA

## Session 409 CTM - Clinical Trial Management, CR

8:30 am-10:00 am **LEVEL:** ■

**Room 107AB** *Pharmacy credits offered*

### Patient Randomization: At What Cost?

Session Chairperson

***Richard Malcolm, PhD***

CEO, Acurian, Inc.

Many in the clinical trial management area still consider patient recruitment to be black magic: lots of money goes in, very little comes out. And what ultimately DOES come out is fewer-than-expected patients and higher-than-expected prices. This session examines the economics attributed to patient recruitment to give clinical trial managers a leg up on evaluating costs and negotiating better contracts.

**Introduction**

***Richard Malcolm, PhD***

CEO, Acurian, Inc.

**Clinical Operations**

***Cheryl K. Fiedler, PharmD***

Director, Study Strategy and Planning, Bristol-Myers Squibb

**Panelist**

***Shawn A. Crockem***

Clinical Project Leader, CNS, sanofi-aventis

## Session 410 DM - Document Management/ eSubmissions, IT, RA

8:30 am-10:00 am **LEVEL:** ●

**Room 204C**

### eCTD Lifecycle Management

Session Chairperson

***Nancy P. Smerkanich***

Vice President, Regulatory Affairs, Octagon Research Solutions

This session will introduce the concepts of eCTD life-cycle management from both an industry and a regulatory perspective across the various ICH regions, specifically the US and Europe. The use of the eCTD format presents both opportunities and challenges for managing the life cycles of documents and dossiers. The regional requirements, technical rules, and a multitude of scenarios will be presented.

**US Regulatory Approach to eCTD Lifecycle Management**

***Gary M. Gensinger***

Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

**US Industry Approach to eCTD Lifecycle Management**

***Joseph A. Cipollina***

Director, New Technologies, Global Regulatory Informatics, Bristol-Myers Squibb Company

**EU Regulatory Approach to eCTD Lifecycle Management**

***Claire Edwards, MBA***

Administrator, EMEA, EU

## Session 411 GCP - Good Clinical Practices, CR

8:30 am-10:00 am **LEVEL:** ●

**Room 204A** *Nursing credits offered*

### Good Auditing Practice: What Do We Mean by "Compliance"?

Session Chairperson

***Barbara Schnurr, PhD, MA***

Chief Quality Assurance Manager, Harrison Clinical Research, Germany

The session will show how quality management professionals from small- and large-size enterprises, from biotechnology companies, and from European regulatory authorities deal with the challenges posed by the principles of good quality practice.

**Auditing in the EU from an Auditor's Perspective**

***Barbara Schnurr, PhD, MA***

Chief Quality Assurance Manager, Harrison Clinical Research, Germany

**Auditing in the US: Differences and Similarities to Europe**

***Sharon W. Moore, MD, MPH, MBA***

Vice President, Medical Affairs and Quality, CTMS, Inc.

**Prepare to Show Compliance**

***Omega Norton-Crable***

Associate Director, Johnson & Johnson Pharmaceutical Research and Development

## Session 412 IT - Information Technology, CDM, CR

8:30 am-10:00 am **LEVEL:** ■

**Room 105AB**

### From Electronic Data Capture to Clinical Data Warehouse

Session Chairperson

***Marisa De Rosa, PhD***

Head of Systems and Services for Health Department (SISS), CINECA Inter-University Consortium, Italy

Clinical data warehouses constitute an added value for clinical trial-related organizations when a large volume of activity is involved. The characteristics and the details of such IT tools should follow a rigorous methodological approach in order to be really helpful to the decision-making individuals.

**The Importance of Standards in the Perspective of a Clinical Data Warehouse**

***Rebecca D. Kush, PhD***

President, CDISC

**Data Warehouses to Support All Trial Data Needs for Pharmaceutical Companies**

***Dieter Ley, MEng***

Manager, Data Warehouse and Analysis Systems, Novartis Pharmaceuticals Corporation

**The New Clinical Data Warehouse of Italian Medicines Agency**

***Antonio Addis, MD***

Head of Drug Information Office, Italian Medicines Agency - Ministry of Health, Italy

## Session 413 MA - Marketing and Sales, RA

8:30 am-10:00 am **LEVEL:** ■

**Marriott Salon AB**

### New Era for International Marketing: Stricter Self-regulation through New Codes of Conduct

Session Chairperson

***Richard Bergström, MS, RPh***

Managing Director, The Swedish Association of the Pharmaceutical industry (LIF), Sweden

This session targets people who are involved in international (non-US) sales and marketing, as well as others who need to be aware of codes and regulations for promotion in international markets, such as regulatory affairs, corporate affairs, and legal affairs staff.

**IFPMA Code of Conduct, Including New Complaint Procedure**
***Harvey E. Bale***
Director-General, IFPMA

**New European (EFPIA) Code of Conduct**
***Richard Bergström, MS, RPh***
Managing Director, The Swedish Association of the Pharmaceutical industry (LIF), Sweden

**How Global Companies Work with Compliance**
***Steve Mohr, Esq.***
Compliance Officer, AstraZeneca

## Session 414 MC - Medical Communications, MW

8:30 am-10:00 am LEVEL: ●

**Marriott Salon CD** *Nursing and Pharmacy credits offered*

### Ensuring High-quality Written Communications for Medical Communications Professionals

Session Chairperson
***Stacey M. Fung, PharmD***
Senior Medical Communications Scientist, Genentech, Inc.

Communicating medical information through various channels is a key role of a medical communications department. The ability to provide clear and concise written drug information can be a challenge for large organizations employing individuals with diverse backgrounds. Written communications include standard response documents, email, and slide presentations. To ensure consistent and high-quality written communications, various techniques have been used. This session will discuss training for medical writing (for medical communications professionals), development and use of departmental style guides, implementing writing clinics, and other methods.

**Unsolicited Standard Medical Letters: The Quality Assurance Review and Usage of a Guidance for Writing Responses**
***William Lai, PharmD, RPh***
Medical Communications Scientist III, Global Medical Affairs, Wyeth Pharmaceuticals

**A Path to Consistent, High-quality Medical Writing: Implementing Workshop Clinics**
***J. Michael Spivey, PharmD***
Director, Medical Information Neurology, Ortho-McNeil Janssen Scientific Affairs, LC

**sanofi-aventis Medical Information Services: Written Communications**
***Donna H. Savulich, PharmD***
Director, Medical Information Services, sanofi-aventis

## Session 415 NC - Nonclinical Laboratory Safety, CP, MW

8:30 am-10:00 am LEVEL: ■

**Room 106AB** *CME credits offered*

### Can Biomarkers of Safety Support Safe Clinical Development?

Session Chairperson
***Klaus Olejniczak, DVM, FACP***
Preclinical Assessor, BfArM, Germany

The use of proteomics to identify potential biomarkers of safety and examples of useful biomarkers will be presented and discussed in this session. In addition the question will be raised: Which safety biomarkers will be accepted for regulatory submission?

**Biomarkers for Cardiovascular Functions**
***Gerd Bode, MD***
Consultant, Germany

**Applying New Bridging Biomarkers in Early Development**
***Frank D. Sistare, PhD***
Executive Director, Merck & Co., Inc.

**Biochemical Cardiovascular Markers in Drug Development**
***Martin W. Elmlinger, PhD***
Medical Expert, ALTANA Pharma AG, Germany

## Session 416 NHP - Natural Health Products, CR, RA, RD

8:30 am-10:00 am LEVEL: ■

**Marriott Salon KL** *CME and Pharmacy credits offered*

### Hot Topics in Natural Health Products: Results of the GAIT Study and Implications for Future NSAID Development

Session Chairperson
***Shaw T. Chen, MD, PhD***
Associate Director and Botanical Review Team Leader, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA

Since the passage of the US Dietary Supplement Health and Education Act in 1994, botanicals and other naturally derived products have been major "news makers." This session will report on the "news," products in development and the marketplace, and emerging policy discussions and issues.

**Dietary Supplements: Important US Regulatory Updates for 2006–2007**
***Leila G. Saldanha, PhD, RD***
CEO, NutrIQ, LLC

**Botanical Drug Development: Clinical Trials Issues**
***Shaw T. Chen, MD, PhD***
Associate Director and Botanical Review Team Leader, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA

**Results of the "GAIT" Study (Glucosamine-chondroitin Sulfate Arthritis Intervention Trial) and Implications for Further Development of Glucosamine and/or Chondroitin Sulfate for Arthritis**
***Domenic J. Reda, PhD***
Acting Director, Cooperative Study Program Coordinating Center, Department of Veterans' Affairs

## Session 417 OS - Outsourcing, GCP

8:30 am-10:00 am LEVEL: ●

**Room 108A** *Pharmacy credits offered*

### Intercompany Auditing Agreement as Part of Strategic Risk Management

Session Chairperson
***Brian B. O'Neill, PhD***
Global Head, Clinical Quality Assurance Management, External Alliances, F. Hoffmann-La Roche AG, Switzerland

Sponsor companies can maximize efficiencies related to risk management of outsourced R&D by cooperating strategically in the planning and reporting of vendor audits of mutual interest. There are also advantages for vendors who may hope to reduce the number of similar type audits to which they are subjected. This session will bring together the different stakeholders, pharmaceuticals, service providers, and their associations to examine strategies for such maximizing of efficiencies.

**Pharma Development Quality Management of Third-party Service Providers**
***Joseph C. Near***
Director, Worldwide Clinical Compliance, GlaxoSmithKline Research & Development

**Intercompany Auditing Agreement as Part of Strategic Risk Management**
***Brian B. O'Neill, PhD***
Global Head, Clinical Quality Assurance Management, External Alliances, F. Hoffmann-La Roche AG, Switzerland

**Quality Management Oversight by the Sponsor: The Service Providers' Perspective**
***John Goodacre, MBA***
Senior Vice President, Global Risk Management and Quality Assurance, Quintiles Transnational Corporation

## Session 418 PM - Project Management, CR, CTM

8:30 am-10:00 am LEVEL: ●

**Room 108B**

### Being Smart about Global vs. Local

Session Chairperson
***Mary F. Stober, MBA***
President, Global Project Resources, LLC

As drug development expands globally, today's pharmaceutical project managers need to master management techniques, tools and measures that transcend language and cultural barriers. This panel of global project managers will discuss when to localize and when to internationalize drug development project management content and processes, reviewing questions for assessing tools that allow users to work in multiple languages to support decision making and to streamline operations.

**Crossing Frontiers in Drug Development: An Overview**
***Mary F. Stober, MBA***
President, Global Project Resources, LLC

**Centralizing the Language Translation Process throughout a Drug's Life Cycle**
***Inna Kassatkina, MBA***
President, Global Language Solutions

**Best Practices in Localization and Globalization**
***Don de Palma***
President and Chief Research Officer, Common Sense Advisory, Inc.

## Session 419 PP - Public Policy/Law, FI, IMP

8:30 am-10:00 am LEVEL: ●

**Room 113C** *Pharmacy credits offered*

### Transatlantic Convergence in Drug Reimbursement Decisions

Session Chairperson
***Joshua P. Cohen, PhD***
Senior Research Fellow, Tufts Center for the Study of Drug Development Tufts University

This session will explore the trend towards transatlantic convergence in relation to the policy objectives of prescription drug cost containment, improvement in and more equitable access to pharmaceuticals, and minimization of variation in clinical practice. Policymakers in the US and Europe are resorting to similar evidence-based tools to achieve their policy objectives. We identify safety, cost-effectiveness, budget impact, and disease burden as the main factors underlying drug reimbursement decision making with respect to newly approved drugs in the US and Europe. Finally, using examples of implementation of fourth hurdles in the US and Europe (new drug appraisals, clinical practice guidelines, reference pricing), we will illustrate how the development and implementation of evidence-based approaches are not only a function of (global) evidence, but also of politics.

**Pharmacoeconomic Evaluations in the Netherlands**
***Elly Stolk, PhD***
Senior Research Associate, Institute for Medical Technology Assessment, Erasmus University, Netherlands

**How the French Transparency Commission Assesses Pharmaceutical Value**
***François Meyer, PhD***
Director, Pharmaceutical Evaluation, French Transparency Commission, France

**How US and European Drug Reimbursement Differ**
***Joshua P. Cohen, PhD***
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University

## Session 420 RA1 - Regulatory Affairs, CR, PP, RD

8:30 am-10:00 am LEVEL: ●

**Room 201A**

### CDER Town Meeting – Part 1 of 2

Session Chairperson
***Nancy D. Smith, PhD***
Director, Office of Training and Communications, CDER, FDA

*Part 2 of this session will be held on Thursday at 10:30 am.*

This interactive session will allow members of the audience to submit questions to senior leaders from the Center for Drug Evaluation and Research. The topics discussed will depend on the interests of the audience.

**Panelists**

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

***Randy Levin, MD***
Associate Director, Medical Informatics, CDER, FDA

***Paul J. Seligman, MD, MPH, CAPT. USPHS***
Associate Director for Safety Policy and Communication, CDER, FDA

***Robert J. Temple, MD***
Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

## Session 421 RA2 - Regulatory Affairs, CTM, GCP

8:30 am-10:00 am LEVEL: ●

**Room 201B** *CME credits offered*

### Trends in Warning and Determination Letters to IRBs and Investigators

Session Chairperson
***David M. Vulcano, MBA, MSW, CIP***
Chief Research Officer, Psychiatric Solutions, Inc.

This session will provide a summary of the most recent warning letters to both IRBs and clinical investigators. The session will look at themes throughout these letters and responses.

**Trends in FDA Warning Letters to IRBs**
***David M. Vulcano, MBA, MSW, CIP***
Chief Research Officer, Psychiatric Solutions, Inc.

**Trends in FDA Warning Letters to Investigators**
***J. Andrew Lemons, JD***
Attorney at Law, Baker, Donelson, Bearman, Caldwell & Berkowitz PC

**Trends in OHRP Determination Letters**
***Karena Cooper, JD, MSW***
Division of Compliance Oversight, Office for Human Research Protection (OHRP)

## Session 422 RA3 - Regulatory Affairs, PP

8:30 am-10:00 am LEVEL: ■

Room 202AB

### How to Authorize a Generic in Europe

Session Chairperson
***John A. Lisman, MPharm, LLM***
Policy Advisor, Medicines Evaluation Board, Netherlands

Generic applications in Europe differ from the US procedures. Since Review 2001 new provisions will regulate the EU generic applications.

**New Medicines Legislation in Europe and the Authorization of Generics**
***John A. Lisman, MPharm, LLM***
Policy Advisor, Medicines Evaluation Board, Netherlands

**The Authorization Procedures for Generics: Regulator's Perspective**
***Jan Welink***
Pharmacokineticist, Medicines Evaluation Board, Netherlands

**The Authorization Procedures for Generics: Industry Perspective**
***Koosje van Lessen Kloeke, LLM***
Stibbe, Netherlands

## Session 423 RA4 - Regulatory Affairs, CR, CTM, GCP

8:30 am-10:00 am LEVEL: ■

Room 203AB

### Outlook for Changes in Japanese Regulatory and Clinical Development Environment

Session Chairpersons
***Hiroshi Matsumori, MS***
Senior Director, Regulatory Affairs, PGRD, Tokyo Laboratories, Pfizer Japan, Inc., Japan
***Robert R. Fike, PhD***
Assistant Vice President, Regulatory Affairs Japan, Wyeth Pharmaceuticals

This session will provide an update on the regulatory environment in Japan including the regulatory review process and performance, implementation of ICH guidelines, and the impacts on clinical development. This session will also address the future perspective for clinical development and regulatory strategy with a global development program in Japan.

**Regulatory Review Performance in Japan**
***Craig Alan Davenport, RPh***
Managing Director, Drug Development, Eli Lilly Japan K.K., Japan

**Perspective on Global Development Strategy in Japan**
***Yoshihiko Ono***
Director, Regulatory Policy and Intelligence, PGRD Tokyo Laboratories, Pfizer Japan, Inc., Japan

**Changes in the Japanese Regulatory Environment from the Reviewer's Viewpoint**
***Yoshiaki Uyama, PhD***
Deputy Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

## Session 424 RD - R&D Strategy, IT, PM

8:30 am-10:00 am LEVEL: ■

Room 102AB

### Clinical R&D Management by Metrics Using the Latest Computer Technology

Session Chairperson
***Michael Van der Burght, MD, MBA***
Director, Ferring Pharmaceuticals Inc.

Key performance indicators (KPIs) have been embraced by many industries including the pharmaceutical industry. New opportunities and a wealth of data rapidly emerge with the advent of new technologies such as electronic data capture. This session will show the technological set-up of three different companies and give pros and cons of using KPIs in clinical R&D organizations.

**Setting the Scene: KPIs and Metrics as a Management Tool – Which KPIs are Valuable to Collect?**
***Michael Van der Burght, MD, MBA***
Director, Ferring Pharmaceuticals Inc.

**Fish in a Barrel: Optimal Data Mining from an Optimal Data Environment**
***Ravin K. Warna, MS***
Director of Operations, Averion Inc.

**Experimenting with Quality Measures**
***Martin Nottmeier, MSc, MPharm***
Clinical Project Manager, Nycomed, Denmark

## Session 425 ST - Statistics, CR

8:30 am-10:00 am LEVEL: ■

Room 103B *CME and Pharmacy credits offered*

### Statistical Contributions to the Patient-oriented Clinical Evaluation

Session Chairperson
***Toshiyuki Sato, PhD***
Assistant Manager, Data and Biostatistics Center, R&D Division, Daiichi Pharmaceutical Co., Ltd., Japan

Recently, many researchers think that larger trials have been producing more solid evidence of a drug's risk/benefit, but is it the aim of biostatisticians to fully comprehend the profile of a virtually average individual? Essentially, biostatisticians should further investigate in detail clinical phenomena for useful knowledge that is beneficial to individual patients. Here, in the process of patient-oriented clinical evaluation, we will try to challenge the view of statistical investigation.

**Statistical Contributions to the Patient-oriented Clinical Evaluation: From the View of Data Synthesis**
***Toshiyuki Sato, PhD***
Assistant Manager, Data and Biostatistics Center, R&D Division, Daiichi Pharmaceutical Co., Ltd., Japan

**Individual Dose Optimization Based on PK Exposure/Response Relationship in Clinical Trials**
***Yasuhiko Imai, MSc***
Director, Clinical Pharmacology Development, Astellas Pharma Inc., Japan

**Extraction and Evaluation of Patient Profiles Suitable or Adaptive to Therapeutics**
***Toshio Shimokawa, PhD***
Assistant Professor, Department of Ecosocial System Engineering, Faculty of Engineering, University of Yamanashi, Japan

**Discussant**
***Stephen E. Wilson, DrPH, CAPT. USPHS***
Director, Office of Business Process Support and Deputy Director, Division of Biometrics II, CDER, FDA

## Session 426 TR - Training, CR

8:30 am-10:00 am LEVEL: ●

Room 103C

### Pharmacogenomics and Education: When Will We See an Uptake of Pharmacogenomics?

Session Chairperson

***Federico Manuel Goodsaid, PhD***

Senior Staff Scientist, Office of Clinical Pharmacology, CDER, FDA

Pharmacogenomics is transitioning from basic to applied science and clinical use. Education is a crucial part of this transition, yet only over the last year have some publications increased awareness in the field. Few pharmacogenomics courses are offered and the discipline is not part of curricula at US medical schools. This session will highlight needs, strategies and results of efforts undertaken by the FDA and others to inform about pharmacogenomics and its role in medicine.

**Personalized Medicine: From Theory to Practice**

***Barry Dickinson, PhD***

Director, Science Policy, American Medical Association

**Pharmacogenomics Training in Pharmaceutical Companies**

***Klaus Lindpaintner, PhD, MD, MPH***

Head of Genetics and Director, Center for Medical Genomics, F. Hoffmann-La Roche AG, Switzerland

**Who Needs Training in Personalized Medicine?**

***Wayne A. Rosenkrans, Jr., PhD***

Scientific and Medical Strategy Director, External Scientific Affairs, AstraZeneca Pharmaceuticals; Vice Chairman, Personalized Medicine Coalition

10:00 am-10:30 am **REFRESHMENT BREAK**

**Meeting Rooms 201-204 Concourse, 2nd Floor, Convention Center Only**

## Session 427 AHC - Academic Health Centers, CR, IMP

10:30 am-12:00 pm LEVEL: ■

Room 110AB *CME, Nursing, and Pharmacy credits offered*

### Improve Patient Outcomes through a Comprehensive Collaboration Model

Session Chairperson

***John H. Mackey***

Director, Life Sciences Practice, Edgewater Technology, Inc.

Delivered in a case study format, this session will provide attendees with a high-level "roadmap" that presents a systematic approach for incorporating the latest research findings into clinical decision making, resulting in a higher standard of care. Attendees will gain knowledge regarding the process, lessons learned, and tools available to design and implement a comprehensive system that addresses all facets of the continuum.

**Realizing the Program Objective of Total Cancer Care**

***Jan Marshburn, MPH***

Program Manager, Total Cancer Care, H. Lee Moffitt Cancer Center

**Aligning Technology with Scientific Clinical and Business Objectives**

***Hugh Cruse***

Information Technology Project Manager, Total Cancer Care, H. Lee Moffitt Cancer Center

**Benefits and Challenges of Developing an In-house Clinical Research Data Collection System at a Research Hospital**

***Cheryl M. Chanaud, PhD, CCRP***

Executive Director, Clinical Innovation and Research, Office of Research, Memorial Hermann Hospital

## Session 428 BT - Biotechnology, CR, RA

10:30 am-12:00 pm LEVEL: ●

Room 103A

### Practical Application of Scientific Advice in the Development of Biological Medicinal Products for Europe

Session Chairperson

***Christopher J. Holloway, PhD***

Group Director of Regulatory Affairs and CSO, ERA Consulting Group, UK

To ensure that development resources are appropriately assigned, interaction with key European regulators prior to the submission of a marketing authorization application has become a common tool during the development of biological medicinal products. In recent years, both the EMEA and national agencies in Europe have formalized the route of approach with various scientific advice procedures. This session will discuss when best to leverage the formal procedures available.

**Requesting and Obtaining Scientific Advice through the European Medicines Agency (EMEA)**

***Francesco Pignatti, MD***

Scientific Administrator, EMEA, EU

**Requesting and Obtaining Scientific Advice through EU Member State Regulatory Agencies**

***Dianne Jackson-Matthews, PhD***

Deputy Group Director, Regulatory Affairs, ERA Consulting Group

**Practical Experience with Scientific Advice Procedures in Europe**

***J. Bruce McClain, MD***

Chief Medical Officer, Clinical Development, Regulatory Affairs and Quality Assurance, Aeras Global TB Vaccine Foundation

## Session 429 CDM - Clinical Data Management, PM

10:30 am-12:00 pm LEVEL: ■

Room 204B

### Data Management's Future: Commodity or Value-added Discipline?

Session Chairperson

***Joseph S. Anderson***

Principal Associate, Waife & Associates, Inc.

The future of clinical data management is up for grabs. Many, especially at high levels of pharmaceutical management, are asking whether data management activities can be effectively outsourced, "offshored," combined with other roles, etc. Such views are often driven by attitudes about technologies and role changes that imply a commoditization of data management deliverables. What are the arguments for and against these ideas? Can both approaches have validity within the industry? Will one come to dominate? Come, listen, and join in the discussion.

**Is Data Management Necessary? Understanding the Task and the Goal**

***Joseph S. Anderson***

Principal Associate, Waife & Associates, Inc.

**Adding Value to the Clinical Trial Enterprise: Offshoring Data Management Operations to India**

***J. Rajagopal***

Executive Vice President, Global Life Sciences and Healthcare, TATA Consultancy Services, India

**The Changing Role of CDM at Pfizer**

***Lauri S. Sirabella, MEd, MS***

Executive Director and Site Head, Clinical Study and Data Management, Pfizer Global Research and Development

## Session 430 CP - Clinical Safety and Pharmacovigilance, MC, RA

10:30 am-12:00 pm LEVEL: ■

**Room 201C** *CME and Pharmacy credits offered*

### Recent MedDRA® Developments: Medication Errors and Labeling Considerations

Session Chairperson

***Anna C. Zhao-Wong, PhD, MD***

Manager, MedDRA® Terminology Development, MedDRA® MSSO, Northrop Grumman Corporation

This session reviews the expansion of MedDRA® terminology with medication error terms and the changes in medication error reporting as the result of the expansion. The potential use of MedDRA® in product labeling will also be discussed.

**Medication Error Reporting from the FDA Perspective**

***Linda Kim-Jung***

Lead Pharmacist, CDER, FDA

**Medication Errors Surveillance**

***Judith McMeekin, PharmD***

Medical Coder, PSI International

**Key Rules for the Use of MedDRA® in Labeling**

***A. Leander Fontaine, MD, PhD***

President, Pharmiceutics LLC

## Session 431 CR1 - Clinical Research and Development, IS, PM

10:30 am-12:00 pm LEVEL: ■

**Room 113B**

### Planning and Conducting Successful Investigators' Meetings

Session Chairperson

***Nicola T. Burke, MSc***

Manager, PAREXEL

Is there an ideal sponsor organizational structure that would improve the scientific, financial, and logistical issues inherent in investigators' meeting organization and execution? Why are so many meetings poorly attended and unsuccessful? In this session, learn about the key drivers affecting the success of an investigators' meeting and alternative strategies for planning and conducting a successful meeting.

**Reshaping the Approach to Investigators' Meetings: The IMIn Initiative**

***Martino W. Laurenzi, MD, MPH***

Executive Medical Director, Specialty Products, Merck & Co., Inc.

**Organizational Structures and Successful Investigator Meeting Planning**

***Marianne Demko-Lange, CMP, CMM***

Director, Medical Meetings, Wyeth Pharmaceuticals

**Best Practices for Meeting the Site Training Needs in Today's Technology-driven Clinical Trials**

***Lisa LaLuna***

Vice President, Business Development and Integration, ePharmaLearning

## Session 432 CR2 - Clinical Research and Development, IS

10:30 am-12:00 pm LEVEL: ◆

**Room 112AB** *CME and Pharmacy credits offered*

### Site-focused Strategies for Re-engineering Clinical Research

Session Chairperson

***Mary Ann Sellers, MSN***

Operations Manager, Duke Clinical Research Institute

Conducting research is growing increasingly difficult for clinical sites. How can we streamline clinical trial methodology and develop a more customer-focused approach to ease these challenges and enhance site recruitment, and improve site performance and satisfaction?

**The NIH Roadmap: A Vision for Re-engineering the Clinical Research Enterprise**

***Jody G. Sachs, MD***

Scientific Project Officer, NHLBI, National Institutes of Health

**Sharing Best Practices: Easing the Burden on the Investigative Site**

***Kathy Kioussopoulos, RN***

Clinical Research Director, Interventional Cardiology, University of Colorado at Denver and Health Sciences Center

**Building Relationships for the Long Term: The Investigative Site as Customer**

***Michael M. Kitt, MD***

Senior Vice President, Development, Theravance

## Session 433 CR3 - Clinical Research and Development, IS

10:30 am-12:00 pm LEVEL: ■

**Room 111AB** *CME and Pharmacy credits offered*

### The Impact of Ethics Committees on Competitive Recruitment in Multinational, Multicenter Clinical Trials: Opportunities and Challenges

Session Chairperson

***Matthew Kibby, MBA***

Leader, Global Operations, BBK Healthcare, Inc.

In Europe and other world regions, direct-to-consumer advertising (DTCA) for prescription medication is prohibited (e.g., Directive 2001/83/EC bans DTCA in the EU). However, in the milieu of increased pressure to reduce drug development time, direct-to-patient communications (often mistakenly labeled as "advertising") for clinical research has been implemented in most EU countries, raising some interesting issues. This session will present perspectives on the ethical, legal, and cultural acceptability of competitive patient recruitment techniques and their impact on investigators, CSMs, CROs, and sponsors in Europe and other world regions.

**Ethics Committees and Global Patient Recruitment: The Real Story**

***Matthew Kibby, MBA***

Leader, Global Operations, BBK Healthcare, Inc.

**Competitive Recruitment in Global Multicenter Trials: Different Perspectives**

***Laura Luchini, PhD, MD***

Executive Director, Eurotrials Brazil Consultores Cientificos, Brazil

**Surveying Ethical Review Practices in Europe**

***Arianna Greco, JD, PhD***

Practice Leader, M+BIOLAW

## Session 434 CR4 - Clinical Research and Development, CP

10:30 am-12:00 pm LEVEL: ■

**Room 109AB** *Nursing credits offered*

### Patient Safety Issues in Phase I Studies

Session Chairpersons

***Philip Leese, MD***

Vice President of Medical and Scientific Affairs, Quintiles Transnational

***Royce A. Morrison, MD, MS***

Director of Medical Affairs, Northwest Kinetics Inc.

The current strong demand for phase I studies required to feed the pharmaceutical industry new product pipeline has resulted in a significant increase in the number of Phase I beds worldwide. The increased complexity of Phase I studies coupled with the industry need to rapidly understand the safety and efficacy of new products is challenging. In meeting these challenges it is paramount that the safety of subjects is ensured. This session will provide attendees with insight on patient safety considerations from principal investigators and clinicians who are thought leaders in phase I clinical conduct. Speakers will provide their perspective on phase I patient safety in the following clinical conduct settings: academic institutions, pharma-owned, and free-standing CRO facilities.

**Understanding Potential Hepatotoxicity in Phase I Studies**
***Howard D. Uderman, MD***
Medical Director, Pfizer-New Haven Clinical Research Unit

**Phase I Subject Safety in the UK**
***Darren Wilbraham, MBBS, DCPSA***
Medical Manager, Guy's Drug Research Unit, Quintiles Ltd., UK

## Session 435 CTM - Clinical Trial Management, CR

10:30 am-12:00 pm LEVEL: ■

**Room 107AB** *Pharmacy credits offered*

### How to Assure Quality when Clinical Trials Are Conducted in Developing Countries

Session Chairperson
***Diego Glancszpigel, MBA***
Director, Latin America, PAREXEL International Inc., Argentina

The session will review the development of strategies to assure quality in clinical trials conducted in developing countries.

**How to Assure Quality when Clinical Trials Are Conducted in Asia Pacific**
***Albert Ge-Shean Liou, MS***
Chairman and CEO, APEX International Clinical Research Co., Ltd., Taiwan

**How to Assure Quality when Clinical Trials Are Conducted in Latin America**
***Diego Glancszpigel, MBA***
Director, Latin America, PAREXEL International Inc., Argentina

**How to Assure Quality when Clinical Trials Are Conducted in Eastern Europe**
***Milen N. Vrabevski, MD***
Medical Director/CEO, Comac Medical Ltd., Bulgaria

## Session 436 DM - Document Management/ eSubmissions, IT, RA, VA

10:30 am-12:00 pm LEVEL: ■

**Room 204C**

### eCTD Tools: Are They ICH-compliant?

Session Chairperson
***Harv W. Martens***
President, ING America, Inc.

The number of eCTD submissions being filed to agencies is increasing rapidly. It is critical that loading and processing of submissions runs smoothly. This isn't the case at the moment because current eCTD building and reviewing tools are not always interoperable. To promote a more consistent interpretation of the specification by the tool vendors, and subsequent tool interoperability, the speakers in this session, all members of a subgroup of the ICH M2, will ask vendors to analyze a set of sample eCTDs and report the results to this subgroup.

This session will focus on common misunderstandings, key problem areas, and potential resolutions. Questions most frequently asked of regulators and best practices for creating eCTDs will also be discussed.

**eCTD: If I Build It, Can They Review It?**
***Andrew P. Marr, PhD***
Director, eRegulatory Development, European and International Regulatory Affairs, GlaxoSmithKline, UK

**eCTD: Working towards a Truly Common Exchange Format**
***Joseph A. Cipollina***
Director, New Technologies, Global Regulatory Informatics, Bristol-Myers Squibb Company

**eCTD FAQs and Best Practices**
***Claire Edwards, MBA***
Administrator, EMEA, EU

## Session 437 GCP - Good Clinical Practices, CR

10:30 am-12:00 pm LEVEL: ●

**Room 204A** *CME and Pharmacy credits offered*

### Practical Pediatric Trials: Lessons from America for Europe

Session Chairperson
***Alan Davies, MB, MRCP, MD***
European Medical Director, Kendle, UK

Learn from practical experience in the United States and Europe and from the European Commission about the forthcoming changes in pediatric drug development regulation in Europe and some of the practical issues surrounding pediatric trials and pediatric drug development in the US and the EU.

**The Draft European Pediatric Regulations**
***Agnès Saint-Raymond, MD, PhD***
Head of Sector, Scientific Advice and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

**Pediatric Research: The IRB Perspective**
***Matthew R. Baker, CIM, CIP***
Regulatory and Quality Consultant

**Practical Pediatric Trials: A European Perspective**
***Alan Davies, MB, MRCP, MD***
European Medical Director, Kendle, UK

## Session 438 IT - Information Technology, RA

10:30 am-12:00 pm LEVEL: ■

**Room 105AB**

### IT Governance Models: Win-win Approaches for Healthcare

Session Chairperson
***William B. Stinchcomb***
Associate Director, QA Process Improvement, Global Pharmaceutical R&D, Abbott Laboratories

Several IT governance models are available today as a reference framework for controls and security in IT systems. These models support pharmaceutical needs to align healthcare IT with standards to ensure proper controls over electronic record security. Control Objectives for Information and related Technology (COBIT), Sarbanes-Oxley (SOX), and International Standards Organization (ISO 9001) are a few of these models that IT organizations can use. Balancing IT governance models with global regulatory expectations for patient safety, data integrity, and computerized system validation can establish a win-win environment. This session will compare and contrast IT governance models, the impact of process improvement and business process management to address control gaps, and sharing of success stories on how patient safety has been improved.

**IT Governance**
***William Williams***
Program Manager, Systems Planning, Kindred Healthcare

**Governance Issues in Linking EHR and EDC Systems**
***Landen Bain***
CDISC Liaison to Healthcare; Independent Consultant

**Health Information Technology: Improving Patient Safety and Quality**
***Paul Jonathan White, MD***
Health IT Portfolio Manager, Agency for Healthcare Research and Quality, US Department of Health and Human Services

## Session 439 NC - Nonclinical Laboratory Safety, CR, MW

10:30 am-12:00 pm **LEVEL:** ●

**Room 106AB** *CME credits offered*

### Nonclinical Development of Combination Medicinal Products

Session Chairperson
***Per Spindler, DVM, MBA, MSc***
Head of BioLogue®, University of Copenhagen, Denmark

The development of a fixed combination drug or drugs that can be used in combination requires different nonclinical considerations and safety studies depending on the situation. The development of the guidance documents in the EU and the US will be presented, as well as the regulatory experiences, and the views from industry and regulators.

**Nonclinical Safety Evaluation of Drug Combinations: The FDA View**
***Abigail C. Jacobs, PhD***
Associate Director, Pharmacology/Toxicology, CDER, FDA

**Nonclinical Development of Fixed Combinations of Medicinal Products: The EU View**
***Jan Willem Van der Laan, PhD***
Head, Pharmacology Toxicology Assessment, RIVM, Netherlands

**Industry Perspective on Nonclinical Safety Evaluation of Drug Combinations: Global Product Development**
***Derek R. Newall, PhD***
Senior Director, Safety Assessment, GlaxoSmithKline R&D

## Session 440 PP - Public Policy/Law, FI, IMP

10:30 am-12:00 pm **LEVEL:** ●

**Room 113C** *CME and Pharmacy credits offered*

### An Update on State Medicare Part D Implementation

Session Chairperson
***Vincent C. Yan, PharmD***
Postdoctoral Fellow, St. John's University/Forest Research Institute

Many states are facing the challenge of coordinating existing state pharmacy programs with the Medicare Part D Prescription Benefit, which began January 1, 2006. This session will provide an update on the progress made with concerns and issues identified during the implementation process.

**Medicare Part D: An Overview**
***John M. Coster, PhD, RPh***
Vice President, Policy and Programs, National Association of Chain Drug Stores (NACDS)

**State Pharmaceutical Assistance Programs (SPAPs): How New York Is Responding to Part D**
***Julie Naglieri***
Director, Elderly Pharmaceutical Insurance Coverage (EPIC) Program, Office of Medicaid Management, New York State Department of Health

**OIG Update: Early Implementation Results**
***Erin B. Lemire***
Program Analyst, Office of Inspector General, Office of Evaluation and Inspections, US Department of Health and Human Services

## Session 441 RA1 - Regulatory Affairs, CR, PP, RD

10:30 am-12:00 pm **LEVEL:** ●

**Room 201A**

### CDER Town Meeting – Part 2 of 2

Session Chairperson
***Nancy D. Smith, PhD***
Director, Office of Training and Communications, CDER, FDA

*Part 1 of this session will be held on Thursday at 8:30 am.*

This interactive session will allow members of the audience to submit questions to senior leaders from the Center for Drug Evaluation and Research. The topics discussed will depend on the interests of the audience.

**Panelists**

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

***Randy Levin, MD***
Associate Director, Medical Informatics, CDER, FDA

***Paul J. Seligman, MD, MPH, CAPT. USPHS***
Associate Director for Safety Policy and Communication, CDER, FDA

***Robert J. Temple, MD***
Director, Office of Medical Policy; Acting Director, Office of Drug Evaluation I, CDER, FDA

## Session 442 RA2 - Regulatory Affairs, CP

10:30 am-12:00 pm **LEVEL:** ●

**Room 202AB**

### Before It's Too Late: Risk Management throughout Product Development

Session Chairperson
***Gerald Haase, MB, ChB, FRCPath***
Principal Consultant, Drug Development Consulting Practice, PAREXEL Consulting, UK

This session discusses the latest experience in industry and in the regulatory authorities, looks at the benefits of introducing sound risk management planning early in drug development, and explores how such a program impacts the development process.

***Dr. June Raine***
Director, Division of Vigilance Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), UK

## Session 443 RA3 - Regulatory Affairs, PP

10:30 am-12:00 pm LEVEL: ◆

**Room 203AB**

### FDA Advisory Committees: Controversies, Challenges, and Changes

Session Chairperson

***Jane S. Ricciuti, RPh, MS***

Director and Executive Editor, IDRAC US, Thomson Scientific

Recently there has been controversy surrounding the conflict of interests of sitting advisory committee members. Speakers will highlight the issues with financial conflicts of interest and changes to the regulatory process that will change FDA's processes.

**Background and Potential Conflict of Interest Issues**

***Jane S. Ricciuti, RPh, MS***

Director and Executive Editor, IDRAC US, Thomson Scientific

**Impact on Qualified Advisory Committee Members**

***Robert M. Nelson, MD, PhD***

Associate Professor of Anesthesiology and Critical Care, Department of Anesthesiology and Critical Care, University of Pennsylvania School of Medicine, The Children's Hospital of Philadelphia

## Session 444 RD - R&D Strategy, BT, CTM

10:30 am-12:00 pm LEVEL: ◆

**Room 102AB**

### Optimize the Development and Registration of Innovation Therapies Developed by Emerging Biotechnology

Session Chairperson

***Angelique Winzenrieth, PharmD***

Regulatory Affairs Director, Quintiles Benefit France

Most of the innovative medicinal products are developed by emerging biotechnology companies. These often do not have the capacity and the expertise to develop their compounds themselves and enter into partnerships or call upon CROs to support their development and registration strategy. The objective of this session is to discuss the options for these small companies to bring their product on the market, the challenges met, and potential solutions to overcome them.

**View of the Contract Research Organization**

***Angelique Winzenrieth, PharmD***

Regulatory Affairs Director, Quintiles Benefit France

**View of the Small Company**

***Robert P. Ryan***

Vice President, Regulatory Affairs and Pharmacovigilance, Atherogenics

**View of the Pharmaceutical Partner**

***Martine Zimmermann-Laugel, PharmD***

Head of Department, Presubmission Division, Worldwide Regulatory Affairs, Science Union (Servier), France

## Session 445 ST - Statistics, CR

10:30 am-12:00 pm LEVEL: ●

**Room 103B** *CME and Pharmacy credits offered*

### Policy, Business, and Statistical Issues Related to Bayesian Approaches for Late-phase Practical Clinical Trials

Session Chairperson

***Ruthanna Davi, MS***

Statistical Reviewer, Division of Biometrics II, Office of Biostatistics, CDER, FDA

A number of policy and business forces may be converging to demand practical solutions to developing real-world comparative effectiveness and cost-effectiveness evidence for informed healthcare decision making. In this session, we explore the rationale and potential usefulness of Bayesian trial designs to meet this demand.

**Policy, Business, and Statistical Issues Related to Bayesian Approaches for Late-phase Practical Clinical Trials**

***Bryan R. Luce, PhD, MBA***

Senior Vice President, Science Policy, The MEDTAP Institute at United BioSource Corporation

**Innovative and Efficient Bayesian Designs for Clinical Trials**

***Donald A. Berry, PhD, FACP***

Chair, Biostatistics and Applied Math, The University of Texas M.D. Anderson Cancer Center

**Bayesian Considerations in Economic Evaluation of Clinical Trials**

***Christopher J. Hollenbeak, PhD***

Assistant Professor of Surgery and Health Evaluation Sciences, Penn State College of Medicine

## Session 446 TR - Training, CR, CTM

10:30 am-12:00 pm LEVEL: ●

**Room 103C**

### Addressing Challenges Associated with Clinician-rated Scales

Session Chairperson

***Catherine Spear, MBA***

Group President, Training and Education Group, United BioSource Corporation

Clinician-rated scales are selected as pivotal endpoints across many diseases. Often, these scales rely on clinical subjectivity which can cause variability across raters. The potential for ratings discordance with clinician-rated scales can be mitigated by well-designed training and certification programs that address protocol design challenges, study population issues, rating instrument subjectivity, cultural biases, language barriers, rater turnover, and rater drift.

**Study Design and Rating Scale Selection**

***Amir H. Kalali, MD***

Global Scientific Head, Quintiles, Inc.

**Inter-rater Reliability as an Indicator of Definitive Study Outcome**

***Steven Targum, MD***

Principal Scientific Advisor, Training and Education Group, United BioSource Corporation

**Implications of Study Design on Study Outcomes**

***Georges Gharabawi, MD***

Group Director, Janssen Medical Affairs

12:00 pm **END OF THURSDAY SESSIONS**

**ANNUAL MEETING ADJOURNED**

12:30 pm-5:00 pm **MedDRA® MSSO USER GROUP MEETING**

Room 201B, 2nd Floor, Convention Center

# Exhibiting Companies

| | |
|---|---|
| AAIPharma | Booth 1437 |
| Abt Associates, Inc. | Booth 1547 |
| Accelovance | Booth 1257 |
| Accovion | Booth 1537 |
| ACM-Pivotal Global Central Laboratory | Booth 409 |
| ACS Clinical | Booth 129 |
| ACTIVA-CRO | Booth 949 |
| Acurian | Booth 516 |
| Adlib Software | Booth 148 |
| Adobe Systems, Inc | Booth 144 |
| ADVANCE GmbH | Booth 117 |
| Advanced Biologics, LLC | Booth 1129 |
| Advanced Biomedical Research, Inc. | Booth 615 |
| Advanced Clinical Research Services | Booth 817 |
| Advanced Clinical Services LLC | Booth 1510 |
| Advanced Clinical Software | Booth 1652 |
| Advion BioServices, Inc. | Booth 118 |
| Aerotek Scientific | Booth 414 |
| Algorithme Pharma Inc. | Booth 756 |
| Allergan | Booth 1426 |
| Allphase Clinical Research | Booth 260 |
| Almac Clinical Services (formerly CTS) | Booth 1737 |
| Almac Clinical Technologies (formerly ICTI) | Booth 1836 |
| Amadeus International Inc. | Booth 1761 |
| Amarex Clinical Research | Booth 938 |
| American Medical Writers Association | Booth 1816 |
| AmeriTrial OTC Research | Booth 1430 |
| Amgen Inc. | Booth 518 |
| APEX International Clinical Research Co., Ltd. | Booth 945 |
| Applied Clinical Trials Magazine | Booth 1449 |
| Aptuit Inc. | Booth 417 |
| Apyx | Booth 440 |
| Arbour Group | Booth 145 |
| ArisGlobal | Booth 1345 |
| Arrowhead Electronic Healthcare | Booth 361 |
| Arroyo Research, Inc. | Booth 1744 |
| ARS, Inc. | Booth 910 |
| ARX | Booth 1118 |
| Asian Clinical Trials Ltd | Booth 1357 |
| ASKA Research | Booth 1058 |
| Aspire IRB | Booth 630 |
| Assist Technologies | Booth 461 |
| AstraZeneca | Booth 548 |
| Averion Inc. | Booth 1138 |
| Axiom Real-Time Metrics | Booth 259 |
| B & C Group | Booth 352 |
| The Bandish Group, LLC | Booth 315 |
| BARC | Booth 846 |
| BASi (Bioanalytical Systems, Inc.) | Booth 1501 |
| BattelleCRO | Booth 646 |
| Baxa Corporation | Booth 958 |
| BBK Worldwide | Booth 1114 |
| Beacon Bioscience | Booth 1628 |
| Beardsworth | Booth 1421 |
| Benchmark Research | Booth 1208 |
| Bilcare, Inc. | Booth 123 |
| Bio-Imaging Technologies | Booth 723 |
| BioCor | Booth 607 |
| BioExecutive International | Booth 1549 |
| Biomedical Systems | Booth 336 |
| bioRASI | Booth 1559 |
| BioResearch Monitors, Inc. | Booth 715 |
| bioskin GmbH | Booth 1920 |
| BioSpace | Booth 1056 |
| BioStorage Technologies Inc. | Booth 1610 |
| Biosys | Booth 1240 |
| Biovail Contract Research | Booth 1036 |
| Biovista Inc. | Booth 360 |
| Bridge Pharmaceuticals, Inc. | Booth 1054 |
| Bristol-Myers Squibb | Booth 300 |
| BT | Booth 121 |
| BusinessEdge Solutions | Booth 1060 |
| California Clinical Trials | Booth 529 |
| Camargo Pharmaceutical Services | Booth 1718 |
| The Cambridge Group Ltd | Booth 852 |
| Cambridge Neurotechnology | Booth 153 |
| Canadian Arthritis Network/Canadian Rheumatology Research Consortium | Booth 1053 |
| CanReg Inc. | Booth 816 |
| Cardinal Health | Booth 311 |
| Cardiocore | Booth 747 |
| CardioDynamics | Booth 1960 |
| CardioLabs, Inc. | Booth 353 |
| Carpermor, SA de CV | Booth 1558 |
| CCA, Inc. | Booth 1805 |
| CCL Label | Booth 1842 |
| CDISC | Booth 631 |
| CEDRA Corporation | Booth 1453 |
| Center for Drug Evaluation, Taiwan | Booth 415 |
| CentraLabS Clinical Research Ltd | Booth 1714 |
| Cerner Corporation | Booth 244 |
| Charles River Laboratories Clinical Services | Booth 1839 |
| Children's Hospital of Orange County (CHOC) | Booth 1440 |
| Chiltern International, Inc. | Booth 1049 |

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|---|---|
| Christiana Care Research Institute | Booth 1617 |
| Cincinnati Children's Research Foundation | Booth 911 |
| CIRION Clinical Trial Services Inc. | Booth 1516 |
| Citeline, Inc. | Booth 248 |
| City List Co., Inc. | Booth 521 |
| Clarix LLC | Booth 230 |
| ClinAudits, LLC | Booth 228 |
| ClinForce, Inc. | Booth 1515 |
| Clinical Business Solutions | Booth 355 |
| Clinical DataFax Systems Inc. | Booth 1636 |
| Clinical Financial Services | Booth 936 |
| Clinical Research Networks, Inc. | Booth 1124 |
| The Clinical Resource Network | Booth 710 |
| Clinical Resources, a Medical Staffing Network, Inc. Company | Booth 1815 |
| Clinical Trial Media | Booth 1331 |
| Clinical Trial Services (CTS) – see Almac Clinical Services | |
| Clinimetrics | Booth 1023 |
| CliniRx Research Pvt Ltd | Booth 1942 |
| ClinLogic LLC | Booth 628 |
| Clinlogix | Booth 216 |
| ClinPhone Inc. | Booth 1009 |
| ClinPro, Inc. | Booth 339 |
| Clinsys | Booth 737 |
| Clintest International | Booth 323 |
| CMAX - A Division of IDT Australia Ltd | Booth 1857 |
| CMIC Co., Ltd. | Booth 1015 |
| Coast IRB | Booth 1014 |
| Cogenics, A Division of Clinical Data | Booth 140 |
| Cognitive Drug Research | Booth 1727 |
| Community Research | Booth 802 |
| CompleWare Corporation | Booth 1823 |
| Concepts Worldwide | Booth 711 |
| Constella Group (formerly registered as Constella Clinical Informatics) | Booth 1339 |
| Contract Pharma | Booth 543 |
| Copernicus Group IRB | Booth 1837 |
| Cordium Links LLC | Booth 1356 |
| Covance, Inc. | Booth 1709 |
| CRF Inc. | Booth 1523 |
| CRI-Worldwide | Booth 558 |
| Criterium, Inc. | Booth 1226 |
| CRL.Medinet | Booth 1506 |
| Cromos Pharma | Booth 150 |
| CSA Associates, LLC | Booth 920 |
| CSM | Booth 1261 |
| CTI Network | Booth 252 |
| CTMS, Inc. | Booth 1914 |
| Cu-Tech, LLC | Booth 1428 |
| Cuadra Associates, Inc. | Booth 1228 |
| Cytel Inc. | Booth 939 |
| D. Anderson & Company | Booth 347 |
| Data Communique International | Booth 1136 |
| DataCeutics, Inc. | Booth 707 |
| Datafarm, Inc. | Booth 658 |
| DataLabs, Inc. | Booth 1829 |
| Datapharm Australia Pty Ltd | Booth 1660 |
| DATATRAK International | Booth 1952 |
| Datatrial | Booth 1224 |
| DaVita Clinical Research | Booth 1215 |
| DCL Medical Laboratories | Booth 1358 |
| Delta Pharma, Inc. | Booth 552 |
| Dendrite Clinical Solutions | Booth 838 |
| DGP Group | Booth 1818 |
| Diabetes and Glandular Disease Research Associates | Booth 460 |
| Dimensional HealthCare, Inc. | Booth 660 |
| DOCS International | Booth 836 |
| Dorevitch Pathology & QML Pathology | Booth 1061 |
| Drug Safety Alliance, Inc. | Booth 1638 |
| DrugLogic Inc. | Booth 245 |
| DSA | Booth 1853 |
| DSG, Inc. | Booth 237 |
| Duke Clinical Research Institute | Booth 238 |
| DxS Ltd | Booth 642 |
| DZS Software Solutions, Inc. | Booth 1308 |
| eclinics Solutions | Booth 1248 |
| ECLA | Booth 757 |
| ECRON | Booth 1725 |
| Edgewater Technology, Inc. | Booth 1938 |
| Edinger Medical Group and Research Center | Booth 1154 |
| Elite Research Network, LLC | Booth 937 |
| Elpro | Booth 1010 |
| Elsevier | Booth 317 |
| EMC Corporation | Booth 1230 |
| Endogen | Booth 307 |
| Endpoint Research | Booth 728 |
| Engel Publishing Partners | Booth 1759 |
| entimo AG | Booth 1531 |
| ePharmaceuticals | Booth 1152 |
| ePharmaSolutions, Inc. | Booth 1858 |
| EPIDAUROS Biotechnologie AG | Booth 457 |
| Epiphany Cardiography Products | Booth 1148 |
| EPS Co. Ltd. | Booth 811 |
| ERA Consulting Group | Booth 639 |
| eResearchTechnology, Inc. | Booth 1637 |

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|---|---|
| Esoterix Clinical Trials Services | Booth 515 |
| Essential Group | Booth 1045 |
| eStudySite | Booth 708 |
| etrials Worldwide | Booth 1627 |
| European Medicines Agency (EMEA) | Booth 404 |
| EuroPharm Research Limited | Booth 116 |
| Eurotrials Scientific Consultants | Booth 236 |
| Examination Management Services, Inc. (EMSI) | Booth 1205 |
| Excel PharmaStudies Inc. | Booth 914 |
| EXTEDO (an IABG Life Sciences Solutions company) | Booth 1656 |
| F-D-C Reports, Inc, an Elsevier Company | Booth 306 |
| Falcon Consulting Group | Booth 1859 |
| Fast Track Systems | Booth 947 |
| Fast4wD Ogilvy | Booth 456 |
| Favorite Healthcare Staffing, Inc. | Booth 256 |
| FDA/CDER | Booth 400 |
| FDA/Center for Biologics Evaluation and Research | Booth 402 |
| FDAnews | Booth 1819 |
| Ferraris Respiratory | Booth 1561 |
| First Consulting Group | Booth 1742 |
| Fisher Clinical Services Inc. | Booth 425 |
| Fleury Diagnostics S.A | Booth 1158 |
| Focus Bio-Inova | Booth 1719 |
| FOI Services, Inc. | Booth 316 |
| ForeignExchange Translations | Booth 318 |
| ForeSite Publishing | Booth 340 |
| Forest Laboratories, Inc. | Booth 131 |
| Formedix | Booth 445 |
| Galderma Research & Development, Inc. | Booth 1059 |
| Galt Associates, Inc | Booth 1029 |
| Gateway Medical Research, Inc. | Booth 960 |
| Genaissance Pharmaceuticals, Inc. | Booth 1657 |
| Genentech, Inc. | Booth 161 |
| Gentiae | Booth 523 |
| Gentris Corporation | Booth 357 |
| Geny Research Group, Inc | Booth 720 |
| Genzyme | Booth 1223 |
| Glemser Technologies | Booth 255 |
| GleneaglesCRC | Booth 138 |
| Global Languages & Cultures, Inc. | Booth 1804 |
| Global Medical Institutes, Inc. (GMI) | Booth 1705 |
| Global Spectrum Clinical Research | Booth 861 |
| GlobalSubmit, Inc. | Booth 1646 |
| Green Mountain Logic | Booth 1520 |
| GroupNet | Booth 549 |
| Guideline | Booth 1361 |
| Harrison Clinical Research | Booth 1701 |
| Hawaii Clinical Research Center | Booth 1149 |
| Health Decisions | Booth 1420 |
| Health Industry Insights | Booth 246 |
| Health Market Science | Booth 426 |
| Health Research Association, Inc. | Booth 309 |
| Healthcare Communications Group | Booth 1320 |
| Hertford Cardiology | Booth 657 |
| Hesperion Ltd. | Booth 1052 |
| Hibernia College | Booth 359 |
| Hill Top Research | Booth 561 |
| Howard M. Proskin & Associates, Inc. | Booth 1217 |
| HP | Booth 215 |
| Hurley Consulting Associates Ltd. | Booth 1729 |
| i3 Drug Safety | Booth 1615 |
| i3 Research | Booth 437 |
| i3 Statprobe | Booth 429 |
| i4i Inc. | Booth 1353 |
| IBM | Booth 1847 |
| IBT Reference Laboratory | Booth 1608 |
| ICON | Booth 537 |
| iGATE Clinical Research | Booth 736 |
| IIT Research Institute (IITRI) | Booth 1653 |
| Image Solutions Inc. (ISI) | Booth 1824 |
| iMedRIS Data Corporation | Booth 753 |
| IMIC - Instituto Mexicano de Investigacion Clinical, S.A. de C.V. | Booth Not Available |
| Impact Clinical Trials | Booth 1654 |
| Imperial Clinical Research Services, Inc. | Booth 1006 |
| IMRO TRAMARKO | Booth 823 |
| INC Research | Booth 901 |
| Inclinix (formerly PharmaTech Solutions) | Booth 1544 |
| InferMed Limited | Booth 1659 |
| Informa Healthcare | Booth 1258 |
| Innovative Print & Media Group, Inc. | Booth 755 |
| Insightful Corporation | Booth 1655 |
| Institute of Clinical Research India | Booth 322 |
| Integrated Clinical Systems, Inc. | Booth 1407 |
| IntegReview Ethical Review Board | Booth 1522 |
| Interactive Clinical Technologies (ICTI) – see Almac Clinical Technologies | |
| Intermountain Clinical Research | Booth 1411 |
| International Dermatology Research, Inc. | Booth 629 |
| IntraLinks, Inc. | Booth 1001 |
| inVentiv Clinical Solutions | Booth 1458 |
| invivodata, inc. | Booth 801 |
| IRB Services | Booth 860 |
| Itamar Medical Ltd. | Booth 136 |

| | |
|---|---|
| IVRAS Inc. | Booth 1222 |
| J&S Studies, Inc. | Booth 1210 |
| Jeiven Pharmaceutical Consulting, Inc. | Booth 1454 |
| Johnson & Johnson Family of Companies | Booth 1247 |
| Joulé Clinical Staffing Solutions | Booth 1246 |
| Judge Scientific | Booth 819 |
| Kansas City University of Medicine and Biosciences | Booth 1109 |
| Kelly Scientific Resources | Booth 1039 |
| Kendle | Booth 428 |
| Kforce Clinical Research Staffing | Booth 508 |
| Klein Management Systems | Booth 1403 |
| LabConnect | Booth 718 |
| Laboratorio Hidalgo | Booth 1509 |
| LabWare, Inc. | Booth 1003 |
| Latin American CRO Mmatiss | Booth 120 |
| LatinTrials LLC | Booth 856 |
| Leake, Inc. | Booth 348 |
| Lernia Training Solutions | Booth 1348 |
| Liberty IRB | Booth 249 |
| Lifecord Stat-Korea Co., Ltd. | Booth 218 |
| LifeTree eClinical | Booth 1201 |
| LipoScience, Inc. | Booth 241 |
| Logos Technologies Ltd | Booth 1037 |
| LORENZ Life Sciences Group | Booth 1720 |
| Los Angeles Biomedical Research Institute | Booth 127 |
| Louisiana State University Health Sciences Center-Shreveport | Booth 800 |
| Lovelace Scientific Resources, Inc. | Booth 1800 |
| M+BIOLAW | Booth 1115 |
| Maaguzi, LLC | Booth 617 |
| MAJARO InfoSystems, Inc. | Booth 1111 |
| Makro | Booth 1717 |
| Marken, Ltd. | Booth 559 |
| Maximax International | Booth 644 |
| Mayo Clinical Trial Services | Booth 839 |
| McElroy Translation Company | Booth 908 |
| McGuire Research Institute | Booth 1514 |
| MDS Pharma Services | Booth 553 |
| MeadWestvaco Healthcare Packaging | Booth 1159 |
| MedDRA MSSO | Booth 624 |
| MedFocus LLC | Booth 509 |
| Medica Sur - CIFBIOTEC | Booth 959 |
| Medicademy | Booth 406 |
| MediciGroup®, Inc. | Booths 921, 1018 |
| Medicines and Healthcare products Regulatory Agency | Booth 408 |
| Medidata Solutions | Booth 229 |
| Medifacts International | Booth 1316 |
| Medpace, Inc. | Booth 1621 |
| MedPoint Communications | Booth 1648 |
| MedSource | Booth 1237 |
| MEDTOX Laboratories | Booth 1160 |
| MedTrials, Inc. | Booth 915 |
| menox | Booth 1560 |
| Merck Research Laboratories | Booth 1415 |
| META Solutions Inc. | Booth 907 |
| MetaClin Research, Inc. | Booth 1814 |
| MIC Medical Corp. | Booth 115 |
| Microsoft Corporation | Booth 401 |
| Microsystems | Booth 1820 |
| Mid*Lands IRB | Booth 1419 |
| Midwest Research Specialists | Booth 1102 |
| MMG | Booth 132 |
| MMS | Booth 119 |
| Monitorforhire.com | Booth 1401 |
| Monitoring Force Group | Booth 453 |
| Mortara Instrument, Inc. | Booth 1122 |
| MSOURCE Medical Development | Booth 1940 |
| Myoderm Medical | Booth 424 |
| National Death Index, National Center for Health Statistics, CDC | Booth 314 |
| National Institute of Allergy and Infectious Diseases | Booth 717 |
| Neeman Medical International | Booth 1253 |
| NeuroRx Research | Booth 556 |
| New England Institutional Review Board | Booth 742 |
| New Orleans Center for Clinical Research | Booth 1314 |
| Nextrials | Booth 1352 |
| Northrop Grumman | Booth 1300 |
| Northwest Kinetics, Inc | Booth 1529 |
| Novasys | Booth 258 |
| Novotech | Booth 528 |
| OCASA Logistics Solutions | Booth 421 |
| Octagon Research Solutions | Booth 1809 |
| Odyssey Research Services | Booth 961 |
| Office of Clinical Trials Research - University of Vermont/ Fletcher Allen Health Care | Booth 1249 |
| Omnicare Clinical Research | Booth 827 |
| Omnicia Inc. | Booth 761 |
| OmniComm Systems, Inc | Booth 1144 |
| On Assignment Clinical Research | Booth 422 |
| Ontario Institute for Cancer Research | Booth 1626 |
| Open Text Corporation | Booth 303 |
| Oracle Corporation | Booth 545 |
| Origin (now Constella Group) | Booth 1417 |
| Orlando Clinical Research Center | Booth 754 |

| | |
|---|---|
| Outcome | Booth 1315 |
| Pacific Biometrics, Inc. | Booth 706 |
| Pacific Coast Oncology | Booth 1156 |
| Pacific Data Designs | Booth 511 |
| Palm, Inc | Booth 139 |
| Paragon Biomedical | Booth 1153 |
| PAREXEL International | Booth 1024 |
| Patheon Inc. | Booth 449 |
| Patient Interaction | Booth 1715 |
| The Patient Recruiting Agency | Booth 1749 |
| PDL Biopharma | Booth 1120 |
| PDP Courier Services Ltd | Booth 1503 |
| Penn Pharmaceutical Services Ltd | Booth 610 |
| Perceptive Connection, LLC | Booth 122 |
| Perceptive Informatics, Inc. | Booth 925 |
| Perlegen Sciences, Inc. | Booth 1057 |
| Pfizer Global Research and Development | Booth 1055 |
| Pharm-Olam International | Booth 1846 |
| Pharmaceutical C-Trials, Inc. | Booth 918 |
| Pharmaceutical Executive | Booth 1447 |
| Pharmaceutical Research Plus | Booth 1355 |
| Pharmaceutical Resource Corporation | Booth 1309 |
| PharmaLinkFHI | Booth 807 |
| PharmaNet | Booth 845 |
| PharmaSeek, LLC | Booth 922 |
| PharmaSys, Inc. | Booth 637 |
| PharmaTech Solutions – see Inclinix | |
| PharmaVigilant | Booth 344 |
| PharmaVOICE | Booth 1100 |
| Pharsight Corporation | Booth 1658 |
| Phase Forward | Booth 1427 |
| Phoenix Data Systems | Booth 329 |
| Phoenix Software International | Booth 1346 |
| Phoenix Translations | Booth 1255 |
| PHT Corporation | Booths 524, 525 |
| PII | Booth 1918 |
| Placemart Personnel Service | Booth 1924 |
| Planisware USA | Booth 130 |
| PleaseTech Ltd | Booth 1337 |
| PPD | Booth 452 |
| PPD, Pharmaceutical Product Development | Booth 455 |
| PRA International | Booth 1101 |
| PRACS Institute, Ltd. | Booth 1104 |
| Premier Research Group plc | Booth 1038 |
| PriVia, The Research Centers of Via Christi | Booth 1760 |
| PRL Central Laboratory Services | Booth 1801 |
| Prologue Research | Booth 1600 |
| Promedica International | Booth 301 |
| PROMETRIKA | Booth 1260 |
| ProSanos Corporation | Booth 1021 |
| PROSAR | Booth 1802 |
| ProTrials Research, Inc. | Booth 1500 |
| PS Research BV | Booth 126 |
| PSI International Incorporated | Booth 1216 |
| PSI Pharma Support Intl | Booth 1219 |
| PTC | Booth 124 |
| Purdue University | Booth 554 |
| Quality and Compliance Consulting, Inc. | Booth 1511 |
| Quality Associates, Inc. | Booth 219 |
| Quality Data Services, Inc. | Booth 1117 |
| Quatern | Booth 137 |
| Queensland Clinical Trials Network Inc. | Booth 1606 |
| Quest Diagnostics | Booth 436 |
| Quest Pharmaceutical Services | Booth 814 |
| Quintiles | Booths 601, 701 |
| QUMAS | Booth 623 |
| Radiant Research | Booth 1044 |
| RadPharm, Inc. | Booth 1243 |
| RCRC IRB | Booth 128 |
| Recruitech International | Booth 653 |
| Reed Technology and Information Services Inc. | Booth 1661 |
| Regional Clinical Research, Inc. | Booth 1507 |
| REGISTRAT, Inc. | Booth 1647 |
| Regulatory Pharma Net | Booth 1553 |
| Relsys International, Inc. | Booth 1227 |
| Research Across America | Booth 837 |
| Research Solutions, LLC | Booth 806 |
| Research Testing Laboratories | Booth 1137 |
| ResearchPoint | Booth 1861 |
| Rho, Inc. | Booth 1436 |
| Richmond Pharmacology Ltd | Booth 142 |
| RPS, Inc. | Booths 1752, 1753 |
| RTI International | Booth 225 |
| RWD Technologies | Booth 308 |
| SAIC-Frederick | Booth 659 |
| sanofi-aventis | Booth 446 |
| SANYO Scientific | Booth 1614 |
| SAS Institute Inc. | Booth 1321 |
| Schering-Plough | Booth 253 |
| Schulman Associates Institutional Review Board, Inc. | Booth 714 |
| SciAn Services Inc. | Booth 1936 |
| SCIREX Corporation | Booth 1643 |
| Sentrx | Booth 544 |
| SFBC Anapharm | Booth 853 |

| | |
|---|---|
| SGS Life Science Services - Clinical Research | Booth 953 |
| Shanghai SLG CRO Co., Ltd | Booth Not Available |
| Smith Hanley Consulting Group LLC | Booth 906 |
| SNBL CPC Inc | Booth 1127 |
| Source4 | Booth 1452 |
| Southeast Research Institute | Booth 1860 |
| Spacelabs Medical Data | Booth 1327 |
| Sparta Systems, Inc. | Booth 752 |
| Spectra Clinical Research | Booth 1342 |
| Spectrum Regulatory Solutions | Booth 149 |
| Spotfire | Booth 1123 |
| SRG Woolf Group | Booth 621 |
| Statistical Solutions | Booth 1758 |
| STATKING Consulting, Inc. | Booth 1803 |
| Stelex | Booth 1147 |
| Stiris Research Inc. | Booth 821 |
| Strata | Booth 514 |
| Symbiance, Inc. | Booth 341 |
| SYMFO Inc | Booth 1548 |
| Synarc, Inc. | Booth 620 |
| Synchron Research Services Pvt. Ltd. | Booth 254 |
| Synteract, Inc. | Booth 1900 |
| TAKE Solutions Inc. | Booth 661 |
| Tandem Labs | Booth 611 |
| Taratec | Booth 1640 |
| Target Health Inc. | Booth 1956 |
| Tarius A/S | Booth 304 |
| Technical Language Service | Booth 223 |
| TechTeam Global, Inc. | Booth 147 |
| Tepnel Life Sciences | Booth 759 |
| Teradata, a division of NCR | Booth 1555 |
| TGen Drug Development Services | Booth 337 |
| ThesIS (Thesaurus Information and Strategies, Inc.) | Booth 1445 |
| ThinSpring | Booth 1161 |
| Thomson CenterWatch | Booth 641 |
| Thomson Medstat | Booth 738 |
| Thomson PDR | Booth 740 |
| Thomson Scientific | Booth 647 |
| Thywill Latam Solutions S.R.L | Booth 458 |
| Tidewater Clinical Research, Inc. | Booth 1259 |
| TKL Research. Inc. | Booth 214 |
| TNT Express | Booth 739 |
| TranSenda, LLC | Booth 1527 |
| TransPerfect Translations | Booth 1743 |
| TRC Clinical | Booth 325 |
| Trial Management Group Inc. | Booth 1236 |
| TrialStat Corporation | Booth 1016 |
| Trident Clinical Research Pty Ltd | Booth 134 |
| Triligent International | Booth 507 |
| Trio Clinical Research, LLC | Booth 1209 |
| Twin Image Recruiting, LLC | Booth 1344 |
| UCSD, Clinical Trials Administrative Services and Research Compliance | Booth 810 |
| UF Center for Clinical Trials Research | Booth 1141 |
| Ultra-Scan Corporation | Booth 722 |
| Uniform Data System | Booth 1703 |
| United BioSource Corporation | Booth 1601 |
| University Clinical Research Deland, LLC | Booth 1541 |
| University of Kentucky | Booth 940 |
| University of the Sciences in Philadelphia | Booth 1456 |
| UPM Pharmaceuticals, Inc. | Booth Not Available |
| The Uppsala Monitoring Centre | Booth 1902 |
| VA Cooperative Studies Program | Booth 758 |
| Velos, Inc. | Booth 546 |
| Ventana Clinical Research Corporation | Booth 226 |
| Veritas Medicine | Booth 1125 |
| VIASYS Healthcare | Booth 729 |
| Virtify, Inc. | Booth 114 |
| VirtualScopics, Inc. | Booth 320 |
| Vital Path | Booth 221 |
| Vitalograph Ltd | Booth 1214 |
| VOCEL | Booth 1958 |
| Volt Life Sciences | Booth 1756 |
| Waban Software, Inc. | Booth 1424 |
| Washington University in St. Louis | Booth 410 |
| WCI | Booth 919 |
| WebbWrites Clinical Writing & Statistics | Booth 1844 |
| WellSpring Pharmaceutical | Booth 957 |
| West Coast Clinical Trials | Booth 854 |
| Wiley Pharmafile | Booth 358 |
| Windhover Information Inc. | Booth 247 |
| Wolters Kluwer Health, Adis | Booth 447 |
| Woodley Equipment Company Ltd | Booth 815 |
| World Courier | Booth 1609 |
| WorldCare Clinical, Inc. | Booth 459 |
| Wyeth | Booth 1616 |
| Xceleron Inc | Booth 327 |
| XERIMIS INC. | Booth 606 |
| Xerox DocuShare | Booth 1459 |
| XTrials Research Services | Booth 859 |
| Yoh | Booth 1557 |

# Tutorial Pricing Guide

The tutorials being offered as of May 10, 2006, are listed below. Please continue to monitor www.diahome.org for tutorial updates and online registration. ***Space is limited so register early!***

## Half-day Afternoon Tutorials

**Saturday, June 17, 2006 1:00 pm-4:30 pm**

**TUTORIAL FEE $350**

#30 Investigator Site and Monitor Training to Improve Data Quality and Optimize MedDRA® Coding and Analysis — **CR, IS, TR**

#31 An Overview of the 21 CFR 11 Regulations and Guidance: Practical Considerations in Planning and Achieving Regulatory Compliance of Electronic Records, Signatures, and Systems — **IT, RA, VA**

#32 The Building Blocks for Patient Recruitment — **CR, CTM, PM**

#33 **This Tutorial has been cancelled.** Advanced Human Subject Protections — **PM, PP, RA**

#34 **This Tutorial has been cancelled.** Negotiating Meaningful Investigator Agreements — **CR, CTM, IS**

#35 Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People, and Process — **CR, CTM, RD**

#36 **This Tutorial has been cancelled.** Clinical Trial Performance Analysis: "How to" and Key Results from Earned Value Methods — **CR, CTM, PM**

#37 Leadership: How to Organize and Lead People in Group Work — **GCP, PM, TR**

#38 Developing Realistic Drug Project Plans — **CR, CTM, PM**

#39 Analysis of Safety Data from Clinical Trials — **CR, MW, ST**

## Full-day Tutorials

**Sunday, June 18, 2006 9:00 am-5:00 pm**

**TUTORIAL FEE $600**

#40 Data Mining, Data Flow Modeling, Data Warehousing, and Knowledge Management — **CDM, CP, IT**

#41 Clinical Statistics for Nonstatisticians — **CR, MC, MW**

#42 Regulatory Requirements for the Conduct of Clinical Trials in Europe — **CR, GCP, RA**

#43 Pharmacokinetics and Pharmacodynamics: A Gentle Introduction — **CR**

#44 Principles of Safety Surveillance — **CP, RA, TR**

#45 **This Tutorial has been cancelled.** Computer Validation from A to Z: Practical Reality for User Acceptance of GXP Systems — **IT, VA**

#46 Design and Statistical Analysis of Bioequivalence Studies — **PM, RA, ST**

#47 Clinical Trial Contracting: What Do You Have to Lose? — **CTM, IS, PP**

## Half-day Morning Tutorials

**Sunday, June 18, 2006 8:30 am-12:00 pm**

**TUTORIAL FEE $350**

#50 Best Practices when Using MedDRA® — **CDM, CP**

#51 Evidence-based Medicine throughout the Clinical Drug Development and Product Life Cycle — **CP**

#52 Fourteen Steps from Research to Development — **RA, RD**

#53 Preparation of Integrated Clinical and Statistical Reports for Individual Studies — **CR, MW, RA**

#54 Critical Issues and Important Considerations for Outsource Contracting — **OS, PP**

#55 Auditing the Vendor: Keys to Making It Work Before and After the Audit — **CS, GCP, OS**

#56 EudraVigilance Medicinal Product Dictionary (EVMPD) and ICH M5 Data Elements and Standards for Drug Dictionaries — **CP, TR**

#57 Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development — **RA**

#58 **This Tutorial has been cancelled.** Successfully Recruiting Minorities for Clinical Trials — **CR, CTM**

#59 A Compliance-driven Nonstatistical Risk Detection Process in Drug Safety — **CR, CP, RA**

#60 The Fundamentals of Enterprise Project Management — **PM**

#61 Targeted Auditing of Clinical Research Systems for Validation — **CR, GCP, IT**

#62 Effective Presentation Skills for Clinical Trial Professionals — **CR, CTM, PM**

## Half-day Afternoon Tutorials

**Sunday, June 18, 2006 1:00 pm-4:30 pm**

**TUTORIAL FEE $350**

#70 European Regulatory Affairs: Current Regulatory Procedures and New Medicines Legislation Effective November 2005 — **CR, PM, RA**

#71 Evaluation of Risk Management Programs Using Existing Databases — **CP, RA**

#72 New Challenges to IRBs, Sponsors, and Investigators — **IS, PP**

#73 FDA Enforcement: What You Need to Know to Avoid or Respond to FDA — **CTM, GCP, RA**

#74 Effective, Legal Rx Drug Promotion for the Year 2006: A Regulatory Primer — **MA, RA**

#75 New Release of Volume 9 and EU Regulatory Requirements: Pharmacovigilance in the Pre- and Postmarketing Phase and eReporting — **CP, RA**

#76 The CDISC Standard: Four Models Working in Harmony — **CDM, CR, IT**

#77 Project Management for the Nonproject Manager — **BT, CTM, PM**

#78 Planning and Conducting Clinical Trials in Oncology — **CR, CTM**

#79 Narrative Writing for Clinical/Safety Adverse Reports — **CDM, CP, MW**

#80 Registration of Drugs and Biologics in Canada — **BT, CR, RA**

#81 Operational Aspects of Pediatric Clinical Trials — **CR, CTM, IS**

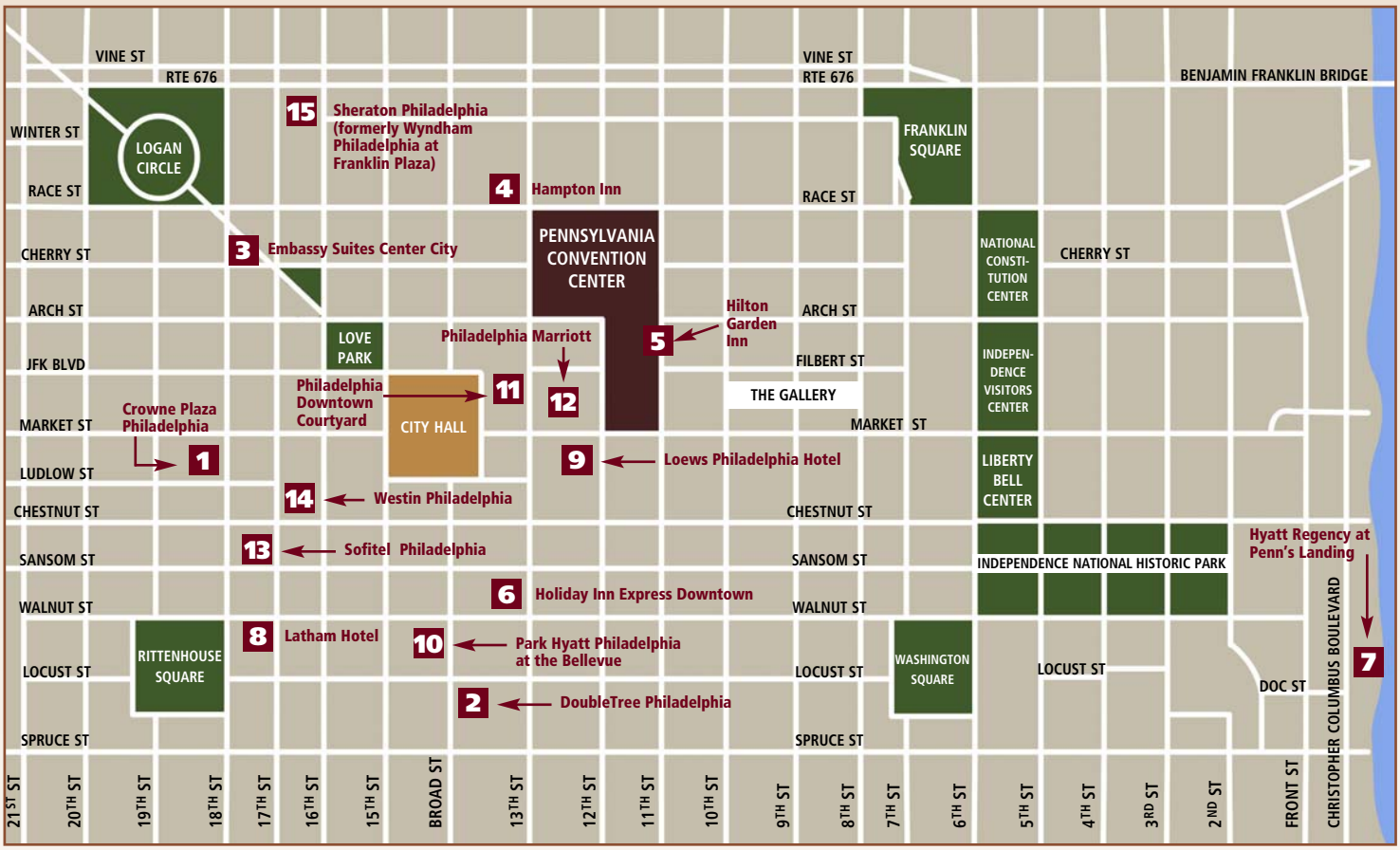
*Please indicate the tutorials you plan to attend on the registration form on page 118.*

# Hotel Reservations Instructions (After May 16, 2006)

**As of May 16, 2006, all hotel reservations, changes and cancellations must be made directly with the Philadelphia hotels and the DIA room block room rate is no longer guaranteed.**

**All hotel reservations require a one-night, nonrefundable deposit. The deposit amount is payable by credit card, which will be charged immediately, or by check in US dollars, drawn on a US bank (by mail only). No wire transfers will be accepted. No reservation will be processed without a deposit. Also, should a guest not arrive by their scheduled arrival date, the full reservation will be cancelled and the full deposit will be forfeited.**

## Hotel Locator Map



**DIA room rates can no longer be guaranteed**

| Hotel | Address | Single Rate | Double Rate | Distance to Convention Center | Shuttle Offered |
|---|---|---|---|---|---|
| **1** **Crowne Plaza Philadelphia** 215-561-7500 SOLD OUT | 1800 Market Street | Per Hotel | Per Hotel | 6 Blocks North 1 Block West | Yes |
| **2** **DoubleTree Philadelphia** 215-893-1600 SOLD OUT | 237 South Broad Street | Per Hotel | Per Hotel | 2 Blocks East 3 Blocks North | Yes |
| **3** **Embassy Suites Center City** 215-561-1776 | 1776 Benjamin Franklin Parkway | Per Hotel | Per Hotel | 1 Block East 2 Blocks South | Yes |
| **4** **Hampton Inn** 215-665-9100 SOLD OUT | 13th & Race Streets | Per Hotel | Per Hotel | 1 Block North | Walking Distance |
| **5** **Hilton Garden Inn** 215-701-5704 | 1100 Arch Street | Per Hotel | Per Hotel | Across the Street | Walking Distance |
| **6** **Holiday Inn Express Midtown** 215-735-9300 SOLD OUT | 1305 Walnut Street | Per Hotel | Per Hotel | 5 Blocks South 2 Blocks East | Yes |
| **7** **Hyatt Regency at Penn's Landing** 215-928-1234 SOLD OUT | 201 South Christopher Columbus Boulevard | Per Hotel | Per Hotel | 13 Blocks West | Yes |
| **8** **Latham Hotel** 215-563-7474 SOLD OUT | 135 South 17th Street | Per Hotel | Per Hotel | 5 Blocks South 5 Blocks East | Yes |
| **9** **Loews Philadelphia Hotel** 215-627-1200 SOLD OUT | 1200 Market Street | Per Hotel | Per Hotel | 1 Block North | Walking Distance |
| **10** **Park Hyatt Philadelphia at the Bellevue** 215-790-2860 SOLD OUT | 1415 Chancellor Court, Broad and Walnut Streets | Per Hotel | Per Hotel | 2 Blocks East 3 Blocks North | Yes |
| **11** **Philadelphia Downtown Courtyard** 215-496-3200 | 21 Juniper Street | Per Hotel | Per Hotel | 1 Block North | Walking Distance |
| **12** **Philadelphia Marriott** 215-625-2900 SOLD OUT | 1201 Market Street | Per Hotel | Per Hotel | Connected | Walking Distance |
| **13** **Sofitel Philadelphia** 215-569-8300 SOLD OUT | 120 South 17th Street | Per Hotel | Per Hotel | 5 Blocks East 3 Blocks North | Yes |
| **14** **Westin Philadelphia** 215-563-1600 SOLD OUT | 99 South 17th Street | Per Hotel | Per Hotel | 5 Blocks East 2 Blocks North | Yes |
| **15** **Sheraton Philadelphia (formerly Wyndham Philadelphia at Franklin Plaza)** 215-448-2000 SOLD OUT | 17th and Race Streets | Per Hotel | Per Hotel | 4 Blocks East | Yes |

## ADDITIONAL HOTELS

| | | | | | |
|---|---|---|---|---|---|
| **Radisson Plaza - Warwick Hotel Philadelphia** 215-735-6000 | | Per Hotel | Per Hotel | 8 Blocks from Convention Center | **NO Shuttling Available** |
| **Renaissance Hotel Philadelphia** 610-521-5900 ext. 6117 or email a.stagliano@columbiaussex.com | | Per Hotel | Per Hotel | | **NO Shuttling Available** |
| **Philadelphia Airport Marriott** 1-800-228-9290 or 215-492-9000 | Connected to Terminal B of the airport and to the SEPTA train to Center City $5.50 each way | Per Hotel | Per Hotel | | **NO Shuttling Available** |
| **Hilton Philadelphia City Avenue** 800 HILTONS | 5 miles from Convention Center | Per Hotel | Per Hotel | | **NO Shuttling Available** |

## #1 CANDLELIGHT STROLL WITH DINNER

**6:30 pm to 10:30 pm**
**$85 per person**
**Dinner included**

Stroll through Society Hill, the historic district's most charming and evocative neighborhood. You will be delighted with its 18th century ambiance as you view the elegantly restored townhouses, hidden gardens and courtyards, and historic Head House Market. See Tennis Houses, carriage steps and busybodies, as your guide acquaints you with the customs and lifestyles of its colonial residents.

CLOSED

Enjoy dinner at The City Tavern where you can still feel the spirit of our forefathers. John Adams once called the tavern, "the most genteel tavern in America."

## #2 HISTORIC PHILADELPHIA

**1:00 pm to 5:00 pm**
**$38 per person**

King Charles II granted William Penn, an English Quaker, a parcel of land in the new World in 1682 as payment for a debt the Crown owed Penn's father. The city grew rapidly, becoming the second largest English-speaking city in the world just before the American Revolution. Philadelphia was then the Revolutionary War capitol, except for nine months of the British occupation.

No trip to Philadelphia is complete without a visit to the "… most historic square mile in the country." You will see the Liberty Bell, the hallowed symbol of our nation's freedom; see where the Declaration of Independence was adopted; Congress Hall where Congress sat while Philadelphia was the capitol of the United States from 1790 to 1800; Franklin Court, the site of the house and print shop of one of Philadelphia's most prominent citizens, Benjamin Franklin, and more.

## #3 DUCKS and PASTA

**5:30 pm to 10:00 pm**
**$78 per person**
**Dinner included**


Philadelphia's newest attraction is land and water sightseeing fun. ALL IN ONE! Ride The Ducks for 80 minutes of entertainment and information as you tour the historic district, South Street and more. Splash into the Delaware River for a relaxing cruise – all on board one amazing vehicle.

Next is dinner at The Spaghetti Warehouse where you'll have a choice of your favorite pasta. This restaurant continues old-world Italian traditions with abundance in hearty, made-from-scratch dishes. A festive atmosphere to end your evening of Land and Sea.

## #4 ATLANTIC CITY

**5:30 pm to 1:00 am**
**$50 per person**

Spend the day or evening in the Las Vegas of the East where a cash bonus awaits you upon arrival. Atlantic City is a must if you've never been there, and is always recommended for repeat fun.

A beautiful boardwalk beside the Atlantic Ocean, excellent restaurants, and wonderful shopping offer endless adventure. The Walk is a haven for outlet shopping. Some of the top designers are located here. And, of course, there is an extensive selection of casinos for your gambling pleasure. And a cash bonus will await you upon arrival.

## #5 VALLEY FORGE

**1:00 pm to 5:00 pm**
**$38 per person**

CLOSED

Of all places associated with America's War for Independence, none conveys the suffering, sacrifice, and ultimate triumph more than Valley Forge. No battles were fought, no bayonet charges or artillery bombardments took place in Valley Forge, but thousands of American soldiers died during the bitter winter of 1777-78. Here you'll tour Washington's headquarters, visit the soldiers' huts, and see the Memorial Arch. A visit to the Memorial Chapel is also included.

Valley Forge is the story of an army's epic struggle to survive against terrible odds – hunger, disease, and the unrelenting forces of nature.

## MOONLIGHT and CHEESESTEAKS and LIGHTS OF LIBERTY #6

**6:30 pm to 10:30 pm**
**$60 per person**
**Dinner included**

Enjoy the city at night and see the lights that make the Benjamin Franklin Parkway come alive. The parkway was modeled after the Champs Élysées and many magnificent buildings line this boulevard. Here you will pass by the Franklin Institute, Rodin Museum, and Museum of Art where you can run up the steps, just like Rocky. Continue your tour by riding along the Avenue of the Arts where many of our theaters are located.

Next stop is for a local favorite – Philly Cheesesteaks at Pat's in the Italian Market.

Time to walk off those calories by taking the "Lights of Liberty Tour." This award winning sound and light show depicts the beginnings of the American Revolution.

## PHILLY's KITCHEN #7

**9:30 am to 11:30 am**
**$42 per person**
**Transportation not needed**


CLOSED

With Philadelphia's long tradition of eclectic eateries and star chefs, this tour allows guests to get a first-hand peek into the techniques and personalized secrets of one of Philly's own. Tour begins at the wonderful Reading Terminal Market where our guide will tour the facility with groups of 15 guests introducing the merchants who will offer samplings of their products. Then, off to the Market's demonstration kitchen where a local chef will host a cooking class where guests get more samplings of the delicious dishes.

## BATTLESHIP & SEAPORT #8

**1:00 pm to 5:00 pm**
**$59 per person**

CLOSED

Tour the Battleship New Jersey. This battleship, one of the most decorated battleships in U.S. naval history, is a floating city. The Battleship New Jersey had a complement of nearly 3,000 men during World War II.

Enjoy the skyline of Philadelphia as you take a ferry on the Delaware back to Philadelphia. Once on land you'll visit the Independence Seaport Museum where you'll learn the history of the Delaware River and tour a World War II Submarine.

## ITALIAN MARKET TOUR #9

**2:00 pm to 5:00 pm**
**$40 per person**

CLOSED

Philadelphia's Italian Market is the oldest and largest working outdoor market in the United States. Still predominantly Italian, it offers the best of many cultures and cuisines to the shopper.

Termini Brothers Bakery, a Philadelphia landmark, is one of our most unique and treasured traditions for over 75 years. Termini's offers a stop into the past where technology takes a back seat to individual skill and ingenuity. Using recipes and tools dating back to 1890, Termini's depicts the "The Way It Was" and of course, offers samples.

Another family-owned and operated business for over 50 years is DiBruno Brother's "House of Cheese." This old-world European style cheese shop features over 400 different types of cheeses and an overwhelming variety of gourmet food from around the world.

## #10 THE LION KING

**8:00 pm to 10:30 pm**
**$77 per person**
**Transportation not included.**

Marvel at the breathtaking spectacle of animals miraculously brought to life "in a blaze of fabulous imagination" by a cast of over 40 actors. Giraffes strut, birds swoop, gazelles leap!

The entire savanna comes to life and as the music soars, Pride Rock slowly rises out of the stage.

This is "The Lion King."

## #11 PENNSYLVANIA DUTCH COUNTRY

**8:30 am to 4:30 pm**
**$75 per person**
**Lunch included**

Journey back in time as you travel through the pastoral countryside of Lancaster County. Your guide will acquaint you with the customs and lifestyles of these quiet people who live without the modern conveniences we all take for granted.

You will visit an Amish house/farm and enjoy a real Pennsylvania Dutch style lunch with all of the trimmings including country-baked ham, fried chicken, mashed potatoes, sausage, noodles, chow chow, shoo fly pie and much more.

There will be some time for shopping at Kitchen Kettle in Intercourse for Amish specialties such as jams and relishes, quilts and other crafts before returning to the hotel and the 21st Century.

CLOSED

The tour is based on a minimum of 35/maximum of 44 and includes transportation, Centipede guide, admissions and lunch.

## #12 MORNING #13 FITNESS #14

**6:30 am to 7:30 am**
**Complimentary**
**Maximum capacity of 25 persons**

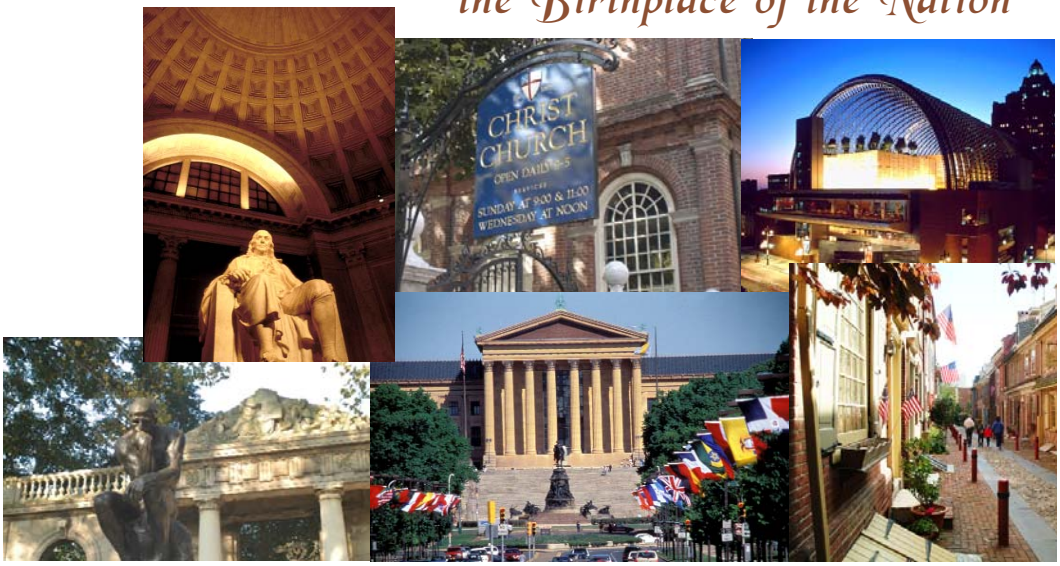
**#12 Monday, June 19:** A fitness expert will stretch with the group and then take them walking around the city. It's a great way to wake up and see Philadelphia.

**#13 Tuesday, June 20:** Begin your day with an aerobic workout that will get your day started off in the right way.

CLOSED

**#14 Wednesday, June 21:** Another walk and another part of the city to enjoy as the sun rises over the city.

## *Explore Philadelphia, the Birthplace of the Nation*




*Top row, left to right:* **Benjamin Franklin National Memorial**, in the rotunda of the Franklin Institute Science Museum; **Christ Church**, founded in 1695 and still active, George Washington, John Adams, and Betsy Ross worshipped here; **The Kimmel Center for the Performing Arts**, the jewel of the Avenue of the Arts.

*Bottom row, left to right:* **The Rodin Museum**, guarded by one of the world's most famous statues, The Thinker; **Philadelphia Museum of Art**, the nation's third largest art museum and the site of the "Rocky" steps; **Elfreth's Alley**, the oldest continuously occupied street in the US.

*The Lion King illustration courtesy of The Kimmel Center, Inc. Pennsylvania Dutch photos courtesy of the Pennsylvania Dutch Convention & Visitors Bureau. All other photos courtesy of the Philadelphia Convention & Visitors Bureau.*

# Optional Tours Registration Form

## Drug Information Association

| Date/Time | Tour Title | Price per Person | | Number of Persons | | Amount Due per Tour |
|---|---|---|---|---|---|---|
| **Sunday, June 18** | | | | | | |
| 6:30 pm to 10:30 pm | # 1 Candlelight Stroll with Dinner | CLOSED | x | _____ | = | $ _____ |
| **Monday, June 19** | | | | | | |
| 6:30 am to 7:30 am | #12 Morning Fitness | CLOSED Complimentary* | x | _____ | = | $ _____ |
| 1:00 pm to 5:00 pm | # 2 Historic Philadelphia | $ 38.00 | x | _____ | = | $ _____ |
| 5:30 pm to 10:00 pm | # 3 Ducks & Pasta | $ 78.00 | x | _____ | = | $ _____ |
| 5:30 pm to 1:00 am | # 4 Atlantic City | $ 50.00 | x | _____ | = | $ _____ |
| **Tuesday, June 20** | | | | | | |
| 6:30 am to 7:30 am | #13 Morning Fitness | CLOSED Complimentary* | x | _____ | = | $ _____ |
| 8:30 am to 12:30 pm | # 2 Historic Philadelphia | CLOSED | x | _____ | = | $ _____ |
| 1:00 pm to 5:00 pm | # 5 Valley Forge | CLOSED | x | _____ | = | $ _____ |
| 6:30 pm to 10:30 pm | # 6 Moonlight and Cheesesteaks and Lights of Liberty | $ 60.00 | x | _____ | = | $ _____ |
| 8:00 pm to 10:30 pm | #10 The Lion King | $ 77.00 | x | _____ | = | $ _____ |
| **Wednesday, June 21** | | | | | | |
| 6:30 am to 7:30 am | #14 Morning Fitness | CLOSED Complimentary* | x | _____ | = | $ _____ |
| 8:30 am to 4:30 pm | #11 Pennsylvania Dutch Country | CLOSED | x | _____ | = | $ _____ |
| 9:30 am to 11:30 am | # 7 Philly's Kitchen | CLOSED | x | _____ | = | $ _____ |
| 1:00 pm to 5:00 pm | # 8 Battleship & Seaport | CLOSED | x | _____ | = | $ _____ |
| 2:00 pm to 5:00 pm | # 9 Italian Market | CLOSED | x | _____ | = | $ _____ |
| * Maximum capacity of 25 persons | | | | **TOTAL TICKETS** | | **TOTAL AMOUNT DUE** |
| | | | | _____ | = | $ _____ |

Reservations and payments must be received no later than **June 12, 2006**. Written cancellations must be received by **MAY 22, 2006** for refunds less $3 per ticket handling charge. **NO REFUNDS after May 22, 2006**. Centipede reserves the right to cancel any tour that does not reach its minimum and will refund all monies. Tickets will not be mailed but will be held for pick up at the Tour Desk located in the Grand Hall of the Convention Center.

All tours will depart from the Pennsylvania Convention Center at 12th & Arch Streets. Please arrive 10 minutes prior to tour time.

Any questions please call 215-735-3123.

***ALL TOURS GO – RAIN OR SHINE!*** Please wear comfortable shoes. **All tours include transportation except for #7 Philly's Kitchen and #10 The Lion King.**

**Tour registration forms should be returned by fax or mail to Centipede Tours. Do not return this form to DIA.**
**1315 Walnut Street, Philadelphia, PA 19107, USA | Fax: +1-215-735-9790. Any questions, please call +1-215-735-3123.**

**PAYMENT** (please check one):

❑ Check (payable to Centipede Inc., drawn on U.S. Bank only) ❑ Visa ❑ MasterCard ❑ American Express ❑ Discover

Card # _____ Expiration Date _____

Name on Card (please print) _____

Signature _____

Registrant's Name (please print) _____

Address _____

City _____ State _____ Zip/Postal Code _____ Country _____

Daytime Phone #_____

# ATTENDEE REGISTRATION FORM

**Attendees may register online at WWW.DIAHOME.ORG**
**Online registration is *not* available to speakers or exhibitors.**

## 42nd Annual Meeting ID #06001
**June 18-22, 2006, Philadelphia, PA, USA**

All registrations received at the DIA office in Horsham, PA, USA by 5:00 PM on May 12, 2006 were included in the Advance Registration Attendee List.

**PLEASE NOTE: This page must be completed and submitted for each person attending any portion of this event.**

**PAYMENT METHODS:** REGISTER ONLINE AT www.diahome.org or check payment method:

❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199.
You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to the currency conversion rate at the time of the charge.

❑ VISA ❑ MC ❑ AMEX Exp. Date _____

Card # _____

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, USA 19044-3595. Please include a copy of this registration form to facilitate identification of attendee.

### CANCELLATION POLICY

All cancellations must be in writing and be received at the DIA office by 5:00 PM on June 2, 2006. Registrants who do not cancel by June 2, 2006 and do not attend will be responsible for the full applicable fee. **Registrants are responsible for cancelling their own 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 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. **Cancellations received in writing on or before June 2, 2006 will be processed as follows.**

FULL MEETING CANCELLATION
Government/Nonprofit/Academia – Registration fee paid minus $100 = Refund Amount
All Others – Registration fee paid minus $200 = Refund Amount

ONE-DAY REGISTRATION CANCELLATION
There will be NO REFUNDS given for cancellations of one-day registrations or one-day no shows.

NETWORKING RECEPTION CANCELLATION
On or before June 2, 2006 = Full Refund

TUTORIAL CANCELLATION
On or before June 2, 2006 – Registration fee paid minus $75 = Refund Amount

PARTICIPANTS WITH DISABILITIES
DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Arrangements can be made for sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

This registration form should be used by paying **ATTENDEES ONLY.** If paying by credit card, mail this completed form to DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA or fax to +1-215-442-6199. If paying by check, follow instructions under Payment Methods.

**FULL-MEETING REGISTRATION** (attendance of 2 or more days) includes admission to all scientific sessions, exhibits, refreshment breaks, luncheons and receptions. ***If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. All fees are in US dollars.***

**TUTORIALS** See bookmarks for tutorial descriptions and tutorial pricing guide. Space is limited and preregistration is encouraged. Please indicate the I.D. # and fee for each tutorial you plan to attend.

Tutorial # _____ Fee _____
Tutorial # _____ Fee _____
Tutorial # _____ Fee _____ Tutorial Subtotal _____

**PREREGISTRATION FEES** ***A surcharge of $150 has been included in the registration fees for all registrations received on or after June 10, 2006 (does not apply to one-day registrations).***

| | Before June 10 | On or after June 10 |
|---|---|---|
| **MEMBER FEE** | US $1125 ❑ | US $1275 ❑ |
| **Join DIA now to qualify for the member fee and to enjoy the benefits of membership for a full year!** www.diahome.org | US $ 130 ❑ | US $ 130 ❑ |

| | Before June 10 | On or after June 10 |
|---|---|---|
| **NONMEMBER FEE** | **US $1255 ❑** | **US $1405 ❑** |

A one-year membership to DIA is available to those paying a NONMEMBER meeting registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.
**I do ❑ I do NOT ❑ want to be a DIA member**

**DISCOUNT FEES**

| | MEMBER | | NONMEMBER* | |
|---|---|---|---|---|
| | Before June 10 | On or after June 10 | Before June 10 | On or after June 10 |
| Government (Full-time) | US $300 ❑ | US $450 ❑ | US $430 ❑ | US $580 ❑ |
| Charitable Nonprofit/Academia (Full-time) | US $675 ❑ | US $825 ❑ | US $805 ❑ | US $955 ❑ |

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

**ONE-DAY REGISTRATION FEES** MEMBER NONMEMBER*
***You must indicate which day you will attend.*** US $ 620 ❑ US $ 750 ❑
Monday, June 19 ❑ Tuesday, June 20 ❑ Wednesday, June 21 ❑ Thursday, June 22 ❑
*If paying a nonmember fee, please check one box above, indicating whether you want membership.

**NETWORKING RECEPTION** (Must be registered for meeting in order to attend) **US $65 ❑**
**Registration for Networking Reception Only is not available.**

Applicable Meeting Registration Fee **US $** _____
Tutorial Registration Fee **US $** _____
Networking Reception Fee **US $** _____
**TOTAL PAYMENT DUE** **US $** _____

Last Name First Name MI

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Mailing Address

City State Zip/Postal Code Country

Telephone # Fax # email **(email address is required for confirmation)**

# Add TUTORIALS and/or NETWORKING RECEPTION to an Existing Meeting Registration

DRUG INFORMATION ASSOCIATION

**42nd Annual Meeting ID #06001**
**June 18-22, 2006, Philadelphia, PA, USA**

**This registration form should be used by attendees, speakers, or exhibitors who wish to add Tutorials or the Networking Reception to an existing meeting registration, or by someone who wishes to register for Tutorials only.**

If paying by credit card, mail this completed form to DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA or fax to +1-215-442-6199. If paying by check, follow instructions under Payment Methods.

## PAYMENT METHODS: Please check payment method:

❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199.
You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to the currency conversion rate at the time of the charge.

❑ VISA ❑ MC ❑ AMEX Exp. Date _____

Card # _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to:
Drug Information Association, Inc., PO Box 95000-1240, Philadelphia, PA, USA 19195-1240.
Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Meeting I.D. #06001 must be included on the transfer document to ensure payment to your account.

## CANCELLATION POLICY

All cancellations must be in writing and be received at the DIA office by 5:00 PM on June 2, 2006. Registrants who do not cancel by June 2, 2006 and do not attend will be responsible for the full applicable fee. **Registrants are responsible for cancelling their own 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 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. **Cancellations received in writing on or before June 2, 2006 will be processed as follows.**

FULL MEETING CANCELLATION
Government/Nonprofit/Academia – Registration fee paid minus $100 = Refund Amount
All Others – Registration fee paid minus $200 = Refund Amount

NETWORKING RECEPTION CANCELLATION
On or before June 2, 2006 = Full Refund

TUTORIAL CANCELLATION
On or before June 2, 2006 – Registration fee paid minus $75 = Refund Amount

**PLEASE NOTE: This page must be completed and submitted for each person attending any portion of this event.**

❑ **YES,** I am registered for the meeting and I would like to add the Networking Reception and/or the following Tutorials to my registration.

❑ **NO,** I do not wish to register for the meeting, but I would like to register for the following Tutorials.

## TUTORIALS

See pages 10-11 for tutorial prices and schedule. Space is limited and preregistration is encouraged. Please indicate the I.D. # and fee for each tutorial you plan to attend.

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____ Tutorial Subtotal _____

**Join DIA now to save on future meeting registration fees and to enjoy the benefits of membership for a full year!** www.diahome.org US $ 130 ❑

## NETWORKING RECEPTION (Must be registered for meeting in order to attend) US $65 ❑

Registration for Networking Reception Only is not available.

**TOTAL PAYMENT DUE** US $ _____

PARTICIPANTS WITH DISABILITIES
DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Arrangements can be made for sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

Last Name First Name MI

Degrees DIA PIN # (optional) ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Mailing Address

City State Zip/Postal Code Country

Telephone # Fax # email **(email address is required for confirmation)**

# EXHIBITOR REGISTRATION FORM

**ONLINE REGISTRATION IS *NOT* AVAILABLE TO EXHIBITORS.**

**Exhibitors should return this form to the attention of the Exhibits Department at DIA.**

## 42ND ANNUAL MEETING ID #06001 June 18-22, 2006, Philadelphia, PA, USA

If registering for tutorials or the networking reception and paying by credit card, return this completed form to DIA by fax to **+1-215-442-6199** or by mail to 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA. If paying by check, follow instructions under Payment Methods below.

**All registrations received at the DIA office in Horsham, PA, USA by 5:00 PM on May 12, 2006 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.**

**PLEASE NOTE: This page must be completed and submitted for each person attending any portion of this event.**

**PAYMENT METHODS: Check payment method:**

❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199.
You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to the currency conversion rate at the time of the charge.

❑ VISA ❑ MC ❑ AMEX Exp. Date _____

Card # _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association, Inc., PO Box 95000-1240, Philadelphia, PA, USA 19195-1240. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Meeting I.D. #06001 must be included on the transfer document to ensure payment to your account.

**CANCELLATION POLICY** All cancellations must be in writing and be received at the DIA office by 5:00 PM on June 2, 2006. Registrants who do not cancel by June 2, 2006 and do not attend will be responsible for the full applicable fee. **Registrants are responsible for cancelling their own 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 nonmember fee, if applicable.**

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NETWORKING RECEPTION CANCELLATION
On or before June 2, 2006 = Full Refund

TUTORIAL CANCELLATION
On or before June 2, 2006 –
Registration fee paid minus $75 = Refund Amount

**FULL-MEETING REGISTRATION**
(attendance of 2 or more days) includes admission to all scientific sessions, exhibits, coffee breaks, luncheons and receptions.

**ONE-DAY ONLY REGISTRATION FEE**
Will be available closer to the meeting date at a cost of $620 for members and $750 for nonmembers.

**TUTORIALS**
See the website for the tutorial schedule. Space is limited and preregistration is encouraged. Please indicate the I.D. # and fee for each tutorial you plan to attend.

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____ Tutorial Subtotal _____

**Join DIA now to qualify for the member fee and to enjoy the benefits of membership for a full year!** www.diahome.org/docs/Membership **US $ 130** ❑

**NETWORKING RECEPTION**
**(Must be registered for meeting in order to attend)** **US $65** ❑
Registration for Networking Reception Only is not available.

**TOTAL PAYMENT DUE US $_____**

PARTICIPANTS WITH DISABILITIES DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Arrangements can be made for sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

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Last Name First Name MI

Degrees DIA PIN # (optional) ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Mailing Address

City State Zip/Postal Code Country

Telephone # Fax # email **(email address is required for confirmation)**

DIA Drug Information Association

800 Enterprise Road, Suite 200, Horsham, PA 19044-3595 USA