Don’t miss the event of the year for the pharmaceutical and related industries!

Attend presentations and case studies from more than 1,000 speakers

Hear representatives from the FDA, EMEA and other global regulatory agencies

27 tracks offered over 3½ days

35+ preconference tutorials

Over 450 exhibitors
Exhibit space is still available!

43rd Annual Meeting

Georgia World Congress Center

PROGRAM CHAIRPERSON
Alberto Grignolo, PhD
PAREXEL Consulting

June 17–21, 2007 | Atlanta, Georgia
Number 43 is finally here! And so are we all, ready to immerse ourselves fully into the energy and substance of the 43rd Annual Meeting of DIA.

Forty-three years after the 1st DIA Annual Meeting, the world is rather different – including that particular, specialized pharmaceutical world that DIA has mirrored and influenced for more than four decades. Through the yearly gathering of thousands of its members, DIA’s Annual Meeting has chronicled events of profound impact to the development of medicines; has offered a forum to innovators, critics, thought leaders, regulators and students of our field; has attracted an ever-expanding multinational constituency like a powerful magnet and has nurtured both learning and debate; has evolved into the must-attend event of the year for so many in our particular world.

Welcome to Atlanta! Whether for the 1st time or the 43rd, you will reap the benefits of the imagination, dedication and intellectual diversity of those who have labored to craft a program of vast breadth and complexity to stimulate you, engage you, challenge you and inform you. We were fortunate to receive more than twice as many session abstracts as we can accommodate in four days; as a result, we, the Program Committee, have selected the best of the best in our quest for relevance and excellence, and have designed an Annual Meeting that is timely, topical and transforming.

Dr. Julie Gerberding, Director of the Atlanta-based Centers for Disease Control and Prevention (CDC) will deliver the Keynote Address. Features this year include nearly 400 regular, plenary, and tutorial sessions with over 1,000 speakers, and our first multitrack plenary session, Drug Safety Reform: Actions and Implications. More than 500 exhibitors will help expand our awareness of services and technologies relevant to the interests of DIA members everywhere. Across 27 Tracks, we have mapped for you such themes as Global Clinical Trials, Critical Path, Personalized Medicine, and Adaptive Trials/Adaptive Methods to help you identify the sessions of greatest interest to you. And for the first time this year, to facilitate your personal scheduling, we have listed all sessions on a website (www.diahome.org) that allows you to click on specific sessions and download their titles, times and locations automatically to your Blackberry or PDA calendar! Throughout, the opportunities for making new friends and reconnecting with your established network will abound.

For the 43rd straight year, the content experts from industry, government and academia from around the world and the phenomenal DIA staff have collaborated diligently to bring you a timely, relevant and diverse Annual Meeting program. The City of Atlanta, home of CNN, the CDC, the world’s busiest airport, the 1996 Summer Olympic Games, art, culture, glorious peaches and innumerable attractions, welcomes you with warm Southern hospitality.

DIA 43rd in Atlanta – a prime number, a prime location! Welcome!

Alberto Grignolo, 2007 Annual Meeting Program Chairperson
◆ ACADEMIC HEALTH CENTERS
Stanley A. Edlavitch, PhD, MA
University of Missouri-Kansas City, USA
Melvyn Greberman, MD, MS, MPH
Public Health Resources, LLC, USA

◆ ADVERTISING
Neal Collins, MD
Pfizer Inc, USA
John F. Kamp, JD, PhD
Coalition for Healthcare Communication, USA
Wayne L. Pines
APCO Worldwide, USA

◆ BIOTECHNOLOGY
Joy A. Cavagnaro, PhD
Access Bio, USA
Bernard D. “Barney” King, MD, MBA
Macnas Consulting International, USA

◆ CHEMISTRY, MANUFACTURING, AND
CONTROLS / GOOD MANUFACTURING
PRACTICES
Chi-wan Chen, PhD
FDA, USA
Charles P. Hoiberg, PhD
Pfizer Inc, USA

◆ CLINICAL DATA MANAGEMENT
Jonathan Haddad, MPH
Synta Pharmaceuticals Corp., USA

◆ CLINICAL RESEARCH AND DEVELOPMENT
Larry A. Blankstein, PhD
Genzyme Corp., USA
Craig Lipset, MPH
Pfizer Inc, USA

◆ CLINICAL SAFETY AND PHARMACOVIGILANCE
Brian D. Edwards
Johnson & Johnson PRD, UK
Arnold J. Gordon, PhD, MS
Pharmaceutical Consultant, USA
Annette Stemhagen, DrPH, MPH
United Biosource Corp., USA

◆ CLINICAL TRIAL MANAGEMENT /
CLINICAL SUPPLIES
Patricia A. Moore, MBA
Genentech, USA

◆ ELECTRONIC REGULATORY SUBMISSIONS /
DOCUMENT MANAGEMENT
A. Kay Bross, MEd
Procter & Gamble Co., USA
Mary L. Collins
Image Solutions, Inc., USA

◆ eCLINICAL
Charles Jaffe, MD, PhD
HL7, USA

◆ GOOD CLINICAL PRACTICES
Michael R. Hamrell, PhD
MORIAH Consultants, USA
Beat E. Widler, PhD
Roche Products Ltd., UK

◆ IMPACT OF MEDICAL PRODUCTS AND
THERAPIES
C. Daniel Mullins, PhD
University of Maryland School of Pharmacy, USA

◆ INVESTIGATOR SITES
Karen E. Woodin, PhD
JKK Consulting LLC, USA

◆ MARKETING AND SALES
Douglas A. Reagan
iMetrikus, Inc., USA

◆ MEDICAL COMMUNICATIONS
Rebecca A. Vermeulen, RPH
Eli Lilly and Company, USA

◆ MEDICAL/SCIENTIFIC WRITING
Barbara R. Kamm
Allergan Inc., USA
Jean H. Soul-Lawton, DrPH
GlaxoSmithKline R&D, UK
Virginia I. Watson
Cardinal Health, UK

◆ NATURAL HEALTH PRODUCTS
Hubertus Cranz, PhD, PharmD, MS
AEGSP, Belgium
Freddie Ann Hoffman, MD
HeteroGeneity, LLC, USA

◆ NONCLINICAL LABORATORY SAFETY
ASSESSMENT
Joseph J. DeGeorge, PhD
Merck & Co., Inc., USA
Per Spindler, DVM, MSc, MBIRA
BioLogue/University of Copenhagen, Denmark

◆ OUTSOURCING
Gregory M. Hockel, PhD, MBA
PharmaNet, Inc., USA

◆ PROJECT MANAGEMENT / FINANCE
Martin D. Hynes, III, PhD
Eli Lilly and Company, USA
John Sun, PhD, MBA
sanofi-aventis, USA

◆ PUBLIC POLICY / LAW
John C. Marlow, MD
Advanstar Communications, Inc., USA
Peter H. Rheinstein, MD, JD, MS
Severn Health Solutions, USA

◆ REGULATORY AFFAIRS
Ian Laws
GlaxoSmithKline Pharmaceuticals, UK
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GlaxoSmithKline, USA
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UCB, Inc., USA
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◆ R&D STRATEGY
Kenneth I. Kaitin, PhD
Tufts Center for the Study of Drug Development, Tufts University, USA

◆ STATISTICS
Jerald S. Schindler, DrPH
Merck Research Laboratories, USA
Stephen E. Wilson, DrPH, CAPT. USPHS
CDER, FDA, USA
Peiling Yang
FDA, USA

◆ TRAINING
Betty R. Kuhnert, PhD, MBA
Betty R. Kuhnert, PhD, MBA, LLC, USA
Monika M. Pietrek, MD, PhD, MSc
PRA International, Germany

◆ VALIDATION
Joanne S. Malia, MS
Neurogen Corporation, USA

Advisors:
EU/EMEA ISSUES
Daniel Brasseur, MD, PhD
CHMP Chairman
Ministry of Public Health, Belgium

FDA ISSUES
Nancy D. Smith, PhD
CDER, FDA, USA

HEALTH CANADA ISSUES
Agnes V. Klein, MD, DrPH
Health Canada, Canada

JAPAN ISSUES
Tatsuo Kurokawa, PhD
MHLW, Japan
Networking Reception back by popular demand…

Previously, Dr. Gerberding was Acting Deputy Director of the National Center for Infectious Diseases (NCID), where she played a major role in leading CDC’s response to the anthrax bioterrorism events of 2001. She joined CDC in 1998 as Director of the Division of Healthcare Quality Promotion, NCID, where she developed CDC’s patient safety initiatives and other programs to prevent infections, antimicrobial resistance, and medical errors in healthcare settings. Dr. Gerberding also served as a faculty member at the University of California at San Francisco (UCSF) where she directed the Prevention Epicenter, a multidisciplinary research, training, and clinical service program that focused on preventing infections in patients and their healthcare providers.

Dr. Gerberding is a member of Phi Beta Kappa, Alpha Omega Alpha (medical honor society), American Society for Clinical Investigation (ASCI), American College of Physicians, Infectious Diseases Society of America, the American Epidemiology Society, the National Academy of Public Administration, and the Institute of Medicine. Over the course of her career, Dr. Gerberding served as a member of CDC’s National Center for Infectious Diseases’ Board of Scientific Counselors, the CDC HIV Advisory Committee, and the Scientific Program Committee, National Conference on Human Retroviruses. She has also been a consultant to the NIH, the AMA, the CDC, OSHA, the National AIDS Commission, the Congressional Office of Technology Assessment, and the WHO.

Dr. Gerberding has contributed to the *Annals of Internal Medicine*, the *American Journal of Medicine*, and numerous internal medicine, infectious diseases, and epidemiology journals.

The Georgia Aquarium

The Georgia Aquarium is located in downtown Atlanta across from Centennial Olympic Park, in very close proximity to the Convention Center.

Where?

The Georgia Aquarium is located in downtown Atlanta across from Centennial Olympic Park, in very close proximity to the Convention Center.

What is there to do at the Georgia Aquarium?

What does it cost?

The Networking Reception will take place from 7:00 to 9:00 pm on Sunday, June 17th, at the Georgia Aquarium.

As you enter the huge atrium inside the building, you will be led into the facility by “a wall of fish” guiding you inside. You then can enter one of five galleries: Georgia Explorer has a light house; River Scout displays a cascading waterfall; Cold Water Quest has an ice covered cliff; Ocean Voyager offers a peek window into the huge habitat; and Tropical Diver has two video screens displaying the perspective of a fish on a reef. There are 80 habitats at the Georgia Aquarium with 12,000 square feet of viewing windows. The largest habitat holds 6.2 million gallons of water and measures 263’ long x 126’ wide x 33’ deep, at its largest points. It was specially designed to house whale sharks alongside tens of thousands of other animals that typically live along a coral reef and in the open ocean. The Georgia Aquarium boasts a 100-foot long tunnel and one of the largest aquarium windows in the world with views into whale shark habitat. The second largest habitat, 800,000 gallons, was specially designed to simulate the natural habitat of beluga whales.

The cost of the Networking Reception is $70.00*, which includes:

- Shuttle transportation to/from the Convention Center, although the aquarium is a short walk through Centennial Park.
- Exclusive access to Georgia Aquarium! The aquarium is usually occupied by several thousand guests throughout the day.
- First-class food and beverages provided by Wolfgang Puck Catering, including Southern Flair, Pan-Asian, pasta and dessert stations. Complimentary soft drinks, wine, and beer will also be included.
- UNLIMITED NETWORKING OPPORTUNITIES!

*TBA indicate that you’ll be attending this reception on your meeting registration form. Space is limited and onsite registration cannot be guaranteed. Registration for Networking Reception only is not available. You must be registered for the meeting as an attendee, speaker, track or session chair, or exhibitor to register for the Networking Reception. Your meeting badge, available at the DIA registration desk, will be required for entrance into the aquarium for the reception.
Meet the Attendees Who Have Benefited from the DIA Annual Meeting Since 1964!

The DIA Annual Meeting is the event of the year for the pharmaceutical and related industries – and this year is no exception. With more than 1,000 speakers from the FDA, EMEA, and other regulatory agencies, 27 content-area tracks, and nearly 400 sessions, the 43rd Annual Meeting is geared to attendees of all professional, degree, and functional responsibility levels.

The results are in …
the 2006 DIA Annual Meeting attracted:

- over 8,500 attendees
- 1,114 speakers
- 768 exhibiting companies

“The networking opportunities have opened up new doors, both personally and professionally.”

Partner, Health & Life Sciences Group, Accenture

Professional Category

“Aan educational event I look forward to every year.”

Executive Director, Global Regulatory Affairs, Amgen, Inc.

Degrees Held

“T he most well-resourced and well-organized event I have ever attended.”

Vice President, International Regulatory Affairs, Wyeth Pharmaceuticals
The pharmaceutical industry continues to make dramatic improvements to public health around the world. These improvements have created both tremendous opportunities and posed fundamental challenges. So while we are optimistic about the health of the pharmaceutical industry moving forward, we must successfully address some very difficult challenges. To this end, DIA remains steadfast in its commitment to providing:

• Global and regional forums for the exchange of information, education, and training
• Extensive multidisciplinary networking opportunities
• Rewarding volunteer leadership experiences
• High-quality professional development opportunities

The 43rd Annual Meeting will include everything you've come to expect from this annual event – a neutral forum for sharing information that optimizes the process of drug development and lifecycle management, knowledge-based and technology-driven pharmaceutical solutions, professional cross-functional learning, robust networking opportunities, a sold-out exhibit hall – plus a whole lot more.

International Experts
Finding solutions to industry challenges requires comprehensive approaches that draw on the expertise of international and multidisciplinary thought leaders from academia, regulatory agencies, and private industries. Representatives from more than 65 countries will be attendance at this year’s Annual Meeting, including:

• Academic institutions from Brazil, Canada, Denmark, India, Japan, Korea, Panama, Taiwan, Tokyo, Europe, and US
• Government agencies from Argentina, Australia, Belgium, Canada, Europe, India, Japan, Korea, South Africa, Taiwan, and US
• Representatives from FDA, MHRA, WHO, Health Canada, CDE-Taiwan, EMEA, PMDA-Japan, SFDA-China, and Centers for Disease Control and Prevention (CDC)

Students and Emerging Professionals

• **Student Forum** (Tuesday, June 19, 10:00 am-12:00 pm) See page 59 for complete details.
  
  The Student Forum will provide students with up-to-the-minute industry information as well as an opportunity to provide input to the DIA.

• **Emerging Professionals Networking Reception**
  
  Wednesday, June 20 (5:00 pm-6:00 pm)
  
  This reception provides the perfect opportunity for individuals with six years or less of professional experience to come together during an informal networking reception.

FEATURED EVENTS

➤ **CDER Town Hall – Parts 1 and 2** (Thursday, June 21)

As in past years, the FDA Center for Drug Evaluation and Review (CDER) will hold its Annual Town Hall – an interactive session where attendees can submit questions to senior CDER leaders.

➤ **First Multitrack Plenary Session**

**Drug Safety Reform: Actions and Implications**

(Tuesday, June 19, 8:00 am-9:30 am) See page 48 for complete details.

Hear discussions on the IOM recommendations, as well as actions of the FDA, Congress, PhRMA, and other key players, including an update on the current status of the Prescription Drug User Fee Act and other legislative initiatives.

Chairpersons
Melvyn Greberman, MD, MS, MPH, FACPM, Public Health Resources, LLC
Stanley A. Edlavitch, PhD, MA, University of Missouri-Kansas City School of Medicine

Panelists
Steven Galson, MD, MPH, Center for Drug Evaluation and Research, FDA
David Dorsey, JD, Senate Committee on Health, Education, Labor and Pensions, US Senate (Senator Edward Kennedy’s Office)
Amy Muhlberg, PhD, Senate Committee on Health, Education, Labor and Pensions, US Senate (Senator Michael B. Enzi’s Office)
James G. Kotsanos, MD, MS, FACPM, FISPE, Eli Lilly and Company (representing PhRMA)
Kathleen Stratton, PhD, Study Director, Institute of Medicine

Exciting Networking Opportunities

Networking remains a hallmark of the DIA Annual Meeting – from the daily continental breakfasts and afternoon refreshment breaks to the more formal Networking Receptions. This year we have expanded some of these opportunities to allow attendees to reap all the benefits of a complete Annual Meeting experience. Visit the exhibit hall for an up-close look at the industry’s latest and greatest products and services.

➤ **New! Extended Luncheon Hours**
  
  Tuesday, June 19, 11:30 am-2:00 pm

➤ **New! Additional Exhibit Hall Reception**
  
  Tuesday, June 19, 5:30 pm-6:30 pm

➤ **Networking Reception at the Georgia Aquarium**

Sunday, June 17, 7:00 pm-9:00 pm

Enjoy great food, a host bar, and exclusive access to the world’s largest aquarium. The more informal networking reception was extremely well received in 2006, as it provided more networking opportunities for attendees to interact with their colleagues.
DIA has never been more optimistic about its ability to facilitate open discussion on the industry’s hottest topics. In addition to the traditional tracks that have made the DIA Annual Meeting the event of the year for the pharmaceutical and related industries, this year’s meeting boasts 27 tracks featuring sessions on the latest hot topics in drug development. Also look for the sessions scheduled as of February 12, 2007, listed below, that offer the latest information on these four themes.

### Adaptive Trials/Adaptive Methods

**Clinical Research and Development**
- Adaptive Trials Case Study in eClinical
- We Can Get a Lot Smarter about Site Monitoring and Data Analysis
- The Use of Adaptive Design and Enrichment Designs to Speed Oncology Drug Development

**Clinical Trial Management/Clinical Supplies**
- Improving the Clinical Supply Chain Management Process
- A Simple Solution for Removing Clinical Supplies as a Rate Limiting Step for the Adaptive Trial Design

**eClinical**
- The Role of Electronic Data Capture in Adaptive Clinical Trials

**Statistics**
- Adaptive Methods in Phase 2 Trials in Practice
- Early Successes with Adaptive Designs

### Critical Path

**Biotechnology**
- Research and Development of Response Prediction Molecular Markers and their Integration into Clinical Drug Development in Oncology

**Clinical Safety and Pharmacovigilance**
- Data Mining in Pharmacovigilance: Misconceptions and Misunderstanding in Data Mining and Signal Detection

**Clinical Research and Development**
- The Business Case for CDISC Standards: Implementation Approaches and Metrics
- Renal Biomarker Qualification for Decision Making

**eClinical**
- NIH Roadmap Program and Development of Therapeutic Area Data Standards: Case Studies in TB and Cardiology

**Electronic Regulatory Submissions/Document Management**
- Structured Product Labeling: An FDA Update and the Industry Perspective

**Information Technology**
- Standard Controlled Terminology: A Successful Partnership between CDISC and NCI Enterprise Vocabulary Services

**Nonclinical Laboratory Safety Assessment**
- Predictive Safety Testing Consortium
- Drug-induced Liver Toxicity
- Nonclinical Development of Nanopharmaceuticals: How Much is Covered by Existing Guidance?

**Natural Health Products**
- Challenges and Solutions in the Evaluation of Traditional Chinese Medicine

**Regulatory Affairs**
- Imaging and Drug Development
- Critical Path: Biomarker from Concept to Action

### Personalized Medicine

**Clinical Research and Development**
- Personalized Medicine and Personalized Drug Development: Case Studies and Progress to Date – Parts 1 and 2

**Public Policy/Law**
- Personalized Medicine: A Perspective beyond Science

### Global Clinical Trials

**Academic Health Centers**
- Opportunities for Global Clinical Trials in India: Prospects and Challenges

**Biotechnology**
- Gene Therapy: Challenges and Hurdles in Planning and Conducting Global Clinical Trials

**Clinical Data Management**
- Outsourcing in Data Management: Thinking Global, but Still Acting Local?

**Clinical Research and Development**
- Clinical Research and Drug Registrations in Developing Countries (BRIC – Brazil, Russia, India and China)
- Clinical R&D Outsourcing to India: What Do You Outsource to Whom?
- Update to Radical Change in Clinical Development
- The Country Study Manager Survey: 2006 Research Data Makes the Case for a New Approach

**Clinical Trial Management/Clinical Supplies**
- Clinical Trials in Asia Pacific: Advantages and Challenges
- Multinational Clinical Trial in China
- Identifying and Overcoming Site Initiation Delays in Multinational Clinical Trials
- Recruitment of Minority Sites for Clinical Trials

**eClinical**
- Global Adoption of eClinical Technologies

**Investigator Sites**
- Recruitment and Retention Strategies and Solutions for Visible Minorities into Clinical Trials

**Medical/Scientific Writing**
- The Evolving Role of the Investigator Brochure in Global Submissions – Parts 1 and 2
- Outsourcing On-shore and Off-shore

**Outsourcing**
- Outsourcing Clinical Trials in Australia
- Outsourcing Clinical Trials in China: Opportunity vs. Difficulties

**Regulatory Affairs**
- CMC Challenges and Considerations for Clinical Trial and Marketing Applications in China
- Global New Drug Development: Regulatory Challenges, Successes and Recommendations from a US-based Company
- PMDA Challenges for Global Drug Development including Japan
- Running Clinical Trials in Latin America: A Review of the Regulatory Framework in Argentina, Brazil and Mexico

**R&D Strategy**
- Globalization of Industry-sponsored Clinical Trials: Evidence on Recent Trends

**Statistics**
- Strategies for Ethnic Comparison in Global Cooperative Clinical Trials

**Validation**
- Current Regulatory Issues: SOX and Beyond?
Dress Code
The dress code for the Annual Meeting is business casual. Neckties, business suits, or other business attire are acceptable, but not necessary. The Convention Center may be chilly so bring a sweater or jacket, and comfortable shoes are a must!

Hotel Reservations
See pages 112-113 for the hotel reservation form and the hotel locator map. The Atlanta Housing Bureau is coordinating all reservations, and arrangements for housing must be made through this housing bureau. All hotel reservation forms must be received by May 15, 2007. **DIA does not process hotel reservations.**

MedDRA® User Group Meeting
MedDRA® User Group will meet on Thursday, June 21 from 12:30 pm to 5:00 pm. The specific location will be included in the final program.

Poster Sessions
The student and professional poster sessions will provide excellent opportunities for the presenters to share their research results with a diverse audience of clinical research professionals. The posters present scientific developments related to topics addressed in meeting tutorials and sessions, and will be displayed outside the entrance to the Exhibit Hall on Level 3 of Building A.

Student Poster Session  Monday, June 18, 10:00 am to 6:00 pm
Professional Poster Session  Tuesday, June 19, 10:00 am to 6:30 pm

The chairpersons for the poster sessions are Françoise G. Pradel, PhD and Francis B. Palumbo, PhD, JD, both from the University of Maryland School of Pharmacy, along with Stephen A. Sonstein, PhD from Eastern Michigan University.

Press Registration Policies and Procedures
DIA events are attended by a number of international and domestic journalists who represent a variety of well-respected media outlets. DIA welcomes qualified representatives of news organizations to attend these events 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. In order 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. Upon arrival, all media must present a copy of their press credential confirmation letter received from DIA and official press credentials at the DIA event check-in location.

To obtain your press credential confirmation letter, download the Press Pass Request Form from http://www.diahome.org/DIAHome/AboutDIA/Resources/Docs/DIAPressPassFinal.pdf. Return the form at least one week prior to the event, to Ashley Reppert of Toplin & Associates, Inc. by email to Ashley@Toplin.com or by fax to +1-215-793-4244. If you have any questions, please call Ashley Reppert at +1-215-793-4666.

Private Social Functions Policy
DIA does not allow hospitality functions to be held during any DIA meeting sessions, scheduled exhibit hours or social events. Therefore, the hours noted below are the only hours which are acceptable for hospitality functions:

<table>
<thead>
<tr>
<th>Day</th>
<th>Acceptable Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 16</td>
<td>All times are acceptable</td>
</tr>
<tr>
<td>June 17</td>
<td>Only after 8:00 pm</td>
</tr>
<tr>
<td>June 18</td>
<td>Only after 6:00 pm</td>
</tr>
<tr>
<td>June 19</td>
<td>From 7:00 am-8:15 am and any time after 6:30 pm</td>
</tr>
<tr>
<td>June 20</td>
<td>From 7:00 am-8:15 am and any time after 5:00 pm</td>
</tr>
<tr>
<td>June 21</td>
<td>From 7:00 am-8:15 am and any time after 12:00 pm</td>
</tr>
</tbody>
</table>

Contact Brynne Hunter for an DIA Exhibitor-sponsored Hospitality Event Application Form, which is required to book hospitality function space: Brynne Hunter, DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA, tel +1-215-442-6122, fax +1-215-293-5908, email Brynne.Hunter@diahome.org.

Receptions
DIA will host two receptions: Monday, June 18, 5:00 pm-6:00 pm and Tuesday, June 19, 5:30 pm-6:30 pm, both in the Exhibit Hall.

Tours
PRA Destination Management Atlanta has organized several tours of the highlights of Atlanta on Sunday, June 17 through Wednesday, June 20. Tour descriptions begin on page 114 and the tour order form can be found on page 117.

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. The Exhibit Hall is located on Level 1 of Building A of the Georgia World Congress Center.

Employment Opportunities
The DIA Job Bank 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 at the back of the Exhibit Hall throughout the DIA Annual Meeting.

Exhibit Locator
Exhibit Locator workstations, located in the entrance to the Exhibit Hall, will find an exhibiting company by booth number, will search by company name or the services it provides, and the “keyword” function will search for terms used in the company description found in the 2007 Exhibitors’ Services Summaries.

Continuing Education

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 global regulatory agencies
- Discuss the international regulations and economic factors that impact the global biopharmaceutical industry
- Recognize the challenges facing regulatory agencies and the pharmaceutical industry in areas such as research study design and statistical methodology
- Recognize state-of-the-art clinical and statistical systems and implementations
- Recognize the written and communication 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.

PARTICIPANTS WITH DISABILITIES
DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Arrangements can be made for sensory-impaired persons who contact the DIA office to indicate their needs at least 15 days prior to the meeting. If you require a scooter or wheelchair, rentals are available by contacting Scootaround Inc. at their toll-free hotline: 888-441-7575. You can also submit a rental inquiry on the web at www.scootaround.com or by fax at +1-204-478-1172.
Continuing Education Credit
Select tutorials and sessions will offer AMA PRA Category 1 Credit(s)™, pharmacy contact hours, nursing contact hours, or PMI professional development units. IACET continuing education units are offered for all tutorials and sessions. Credits for tutorials are clearly identified in this program, and the credits for sessions will be indicated in the final program.

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 29.25 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 (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 has awarded up to 2.9 continuing education units (CEUs) to participants who successfully complete the tutorials and annual meeting sessions.

The maximum number of credits noted above includes attendance at tutorials and the annual meeting sessions; this does not include the Plenary Session on Monday morning.

NURSING
The Drug Information Association will offer nursing credits for various tutorials and 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.

PMI
The Drug Information Association has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI).

Tutorials
June 16-17, 2007 – Half-day tutorials (8:30 am-12:00 pm or 1:00 pm-4:30 pm) up to 3.25 AMA PRA Category 1 Credit(s)™ or contact hours (.325 CEUs), or .3 IACET CEUs per tutorial
June 17, 2007 – Full-day tutorials (9:00 am-5:00 pm) up to 6.5 AMA PRA Category 1 Credit(s)™ or contact hours (.65 CEUs), or .7 IACET CEUs per tutorial

Annual Meeting Sessions
June 18-21, 2007 – 286-000-07-501-L04; up to 19.5 AMA PRA Category 1 Credit(s)™ or contact hours (1.95 CEUs), or 2 IACET CEUs (up to 1.5 hours per session)

To Receive a Statement of Credit
If you would like to receive a statement of credit, you must attend the program (and tutorial, if applicable), and complete the online credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on Friday, June 22.

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 disclosure will be included in the course materials.

Explore the Benefits of DIA Membership
Register as a NONMEMBER and attend the 2007 Annual Meeting for $1280

Register and become a MEMBER and attend the 2007 Annual Meeting for $1280

and receive at NO EXTRA COST:

- Networking with 20,000 worldwide colleagues
- Discounted event registration fees
- Members-only website
- DIA job bank
- Searchable membership directory
- Special interest area communities
- Volunteer opportunities
- Member discount program

FREE PUBLICATIONS – All available online
- Drug Information Journal*
- CSO Directory
- DIA Today/Forum*

To join the DIA network, please visit the Membership & Communities page on www.diahome.org
Getting to Atlanta

Nation’s “Best” Airport: The mission of Hartsfield-Jackson Atlanta International Airport is to be the world’s best airport by exceeding customer expectations. We know many of our attendees will be flying into town and Atlanta has an airport that is second to none when it comes to flight transportation. Atlanta’s airport is just 15 minutes from downtown Atlanta and the Georgia World Congress Center. Here are some other reasons Hartsfield-Jackson Airport makes Atlanta a great convention city:

- Over 80 percent of the US population is within a two-hour flight of Atlanta
- The airport is served by 2,400 flights to 250 destinations…every day
- Taxi and shuttle service make downtown a short 10-minute ride away
- MARTA (Metro Atlanta Rapid Transportation Authority) provides train service from baggage claim straight to downtown Atlanta and the Georgia World Congress Center
- Airport recognized as “The Best in Overall Passenger Satisfaction” (ATA Survey, 2002)

AirTran Airways is offering discounted air travel and unique benefits for DIA meeting attendees. These benefits include the following:

- A 10% discount on the lowest available AirTran Airways one-way fare
- No minimum stay length or Saturday night requirement
- Advance seat assignments at time of booking
- Confirmed upgrade to Business Class, when available, for passengers booking in the “B” and “Y” fare levels
- A one-time waiver of Change Fee per reservation for any name or itinerary change
- Attendees have the option of contacting the EventSavers Desk directly or they may book their reservations through their designated travel agency
- Travel Agents must book all EventSavers reservations directly with the EventSavers Desk to receive the 10% discount. Reservations booked through a travel agent General Data System or the Internet will not qualify for the 10% discount
- Attendees may travel three (3) days prior to the event start date and three (3) days after the event close date if they wish to spend any additional time at the event location

To take advantage of this special program, contact the AirTran Airways EventSavers Desk at 1-866-683-8368 for reservations. Please provide the Event Savers Coordinator with Event Code: ATL061707 and start saving today!

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 577AH.

This special offer applies to travel on domestic segments of all United Airlines, United Express, TED, and United code share flights (UA, operated by US Airways, US Airways Express and Air Canada).

Getting around Atlanta

The Link

The Atlanta Link is an exclusive shuttle service to and from the Hartsfield-Jackson Atlanta International Airport and the main areas of downtown, midtown and Buckhead. With an extensive fleet of vehicles making multiple stops at the Georgia World Congress Center, the Link is a fast, convenient, and affordable means of travel. The Link provides reliable, clean, safe, and dependable service at an excellent value. The rates for the Atlanta Link from the airport are:

<table>
<thead>
<tr>
<th>One-Way</th>
<th>Round Trip</th>
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<tbody>
<tr>
<td>To GWCC</td>
<td>$16.50</td>
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<tr>
<td>To Downtown</td>
<td>$16.50</td>
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<tr>
<td>To Midtown</td>
<td>$18.50</td>
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<tr>
<td>To Buckhead</td>
<td>$20.50</td>
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</table>

To save $4.00 off the round-trip rate, call 1-866-545-9633 and provide the agent with DIA07 as the group/corporate code or go to www.diahomes.org, click on the annual meeting icon, go to the hotel information tab, and drop down to transportation.

Taxis

Atlanta’s professional taxi cab drivers know the city’s streets like the backs of their hands. Atlanta has more than 1,500 taxis available to take attendees to and from their hotel throughout Atlanta. Preset rates for trips between the airport, downtown, and Buckhead, provide an economical mode of transportation. All DIA registration is between Buildings A and B, so request to be dropped at the International Boulevard Entrance of the Georgia World Congress Center.

Flat Rate Fees from/to the Airport

Downtown: $30.00 Midtown: $32.00

There is a $2.00 charge for each additional person.

Flat Rate Fees within Downtown and Midtown

Fares originating from a business and concluding at a business within the zone of Downtown or Midtown have a rate of $8.00 for one person. There is a $2.00 charge for each additional person.

Public Transportation

The Metropolitan Atlanta Rapid Transit Authority (MARTA) is Atlanta’s state-of-the-art public transportation bus and rail system that connects all parts of Atlanta. MARTA’s mission is to provide the highest level of safe, clean, reliable, and affordable transportation. A single $1.75 fare covers one-way bus or train trips, including transfers.

MARTA has a rail station located at the north end of Hartsfield-Jackson Atlanta International Airport, near baggage claim. This service is the quickest and least expensive way to travel between downtown Atlanta’s hotels and the Georgia World Congress Center.

The GWCC is MARTA-accessible at two stations. DIA’s Annual Meeting, in Buildings A and B, is steps away from the Dome/GWCC/Philips Arena/CNN Center Station (W-1). For more information on MARTA, visit www.itsmarta.com

Driving

From the airport and the South: I-75/85 north to the Andrew Young International Boulevard (Exit 248C). Turn left onto Andrew Young International Boulevard; left onto Centennial Olympic Park Drive; right onto Marietta Street. The Green Lot is on the left past the Omni Hotel.

From the North: I-75/85 south to Williams Street (Exit 249C). Williams Street bears to the right. Go five blocks on Williams and turn right onto Andrew Young International Boulevard. Go one block and turn left onto Centennial Olympic Park Drive. Turn right onto Marietta Street. The Green Lot is on the left past the Omni Hotel.

From the West: I-20 east to Spring Street (Exit 56B). Turn left onto Spring Street and left onto Marietta Street. The Green Lot is on the left past the Omni Hotel.

From the East: I-20 west to Spring Street (Exit 56B). Turn right onto Spring Street; left onto Marietta Street. The Green Lot is on the left past the Omni Hotel.

Parking

The GWCC offers more than 4,500 parking spaces in five surface lots and two parking decks, all within the convention, sports and entertainment campus. Parking is $10 or less for all-day parking and never increases due to event day activity in downtown. All lots are gated with attendants on duty during all event hours. The Green Lot on Marietta Street is hourly parking at $3.00 per hour, capped at $15.00. Our public safety force patrols the lots and decks to ensure your safety. Emergency vehicle assistance is available.

The GWCC provides a free Campus Courtesy Shuttle to attendees between parking lots and the event. The shuttle stops at all parking lots, decks, and main entrances to the building. It makes continuous loops around the campus during show days. Look for the Campus Courtesy Shuttle sign.
Questions about the DIA Annual Meeting?

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

— AIRPORT SHUTTLE
Atlanta Link – exclusive shuttle service to and from Hartsfield-Jackson Atlanta International Airport and the main areas of downtown, midtown, and Buckhead: +1-866-545-9633

— CONTINUING EDUCATION (CE)
Jennifer.Webb@diahome.org or +1-215-442-6128

— EXHIBITS
Exhibiting companies A-L, product locator, or company summary book:
Jeff.Korn@diahome.org or +1-215-442-6184
Exhibiting companies M-Z, exhibitor mailings, or exhibitor kiosk:
Erin.Gilliland@diahome.org or +1-215-442-6149
Hotel room drops: Eileen.Roth@diahome.org or +1-215-442-6191
Hospitality suites or vendor events:
Brynne.Hunter@diahome.org or +1-215-442-6122

— HOTEL RESERVATIONS
The Atlanta Housing Bureau at 866-413-5150 (domestic) and 506-637-0311 (international)
Speakers should contact Brynne.Hunter@diahome.org or +1-215-442-6122

— JOB POSTINGS/EMPLOYMENT OPPORTUNITIES
Nontechnical questions: Vicki.Adkinson@diahome.org or +1-215-442-6162
Technical questions: Madel.Meneses@diahome.org or +1-215-442-6148

— NETWORKING RECEPTION
Lori.Risboskin@diahome.org or +1-215-442-6174

— PRESS PASSES/PRESS LIST
Ashley Reppert at Ashley@Toplin.com or +1-215-793-4666

— PRESS RELEASE PROGRAM
Megan Toplin of Toplin and Associates at Megan@Toplin.com or +1-215-793-4666

— REGISTRATION STATUS/FEES
Jean.Zane@diahome.org or +1-215-442-6185
Vicki.Adkinson@diahome.org or +1-215-442-6162
Marilyn.Ginsberg@diahome.org or +1-215-442-6135

— SPECIAL INTEREST AREA COMMUNITY (SIAC) EVENTS
Mary.Hildebrandt@diahome.org or +1-215-442-6151
Mike.McGovern@diahome.org or +1-215-442-6129

— SHUTTLE SERVICE
Lori.Risboskin@diahome.org or +1-215-442-6174

— TOURS
PRA Destination Management Atlanta at +1-404-760-4229

— TUTORIALS
Constance.Burnett@diahome.org or +1-215-442-5800
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 within the tutorial description. Complementary tracks are indicated by the track acronym placed to the right of the tutorial title.

Tutorials will take place on Saturday, June 16 and Sunday, June 17, 2007, 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**

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<thead>
<tr>
<th>AD</th>
<th>Advertising</th>
<th>ERS/DM</th>
<th>Electronic Regulatory Submissions/Document Management</th>
<th>NC</th>
<th>Nonclinical Laboratory Safety Assessment</th>
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<tr>
<td>AHC</td>
<td>Academic Health Centers</td>
<td>FI</td>
<td>Finance</td>
<td>NHP</td>
<td>Natural Health Products</td>
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<tr>
<td>BT</td>
<td>Biotechnology</td>
<td>GCP</td>
<td>Good Clinical Practices</td>
<td>OS</td>
<td>Outsourcing</td>
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<td>CDM</td>
<td>Clinical Data Management</td>
<td>IMP</td>
<td>Impact of Medical Products and Therapies</td>
<td>PM</td>
<td>Project Management</td>
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<tr>
<td>CMC/GMP</td>
<td>Chemistry, Manufacturing, and Controls/Good Manufacturing Practices</td>
<td>IS</td>
<td>Investigator Sites</td>
<td>PP</td>
<td>Public Policy/Law</td>
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<tr>
<td>CP</td>
<td>Clinical Safety and Pharmacovigilance</td>
<td>IT</td>
<td>Information Technology</td>
<td>RA</td>
<td>Regulatory Affairs</td>
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<tr>
<td>CR</td>
<td>Clinical Research and Development</td>
<td>MA</td>
<td>Marketing and Sales</td>
<td>RD</td>
<td>R&amp;D Strategy</td>
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<td>CTM/CS</td>
<td>Clinical Trial Management/Clinical Supplies</td>
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<td>EC</td>
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- Tutorial instructors and schedule are subject to change without notice.
- Recording of tutorial information, in any type of media, is prohibited at all DIA events 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 16, 2007**

1:00-4:30 pm

Tutorials #30 through #35  
Fee $375

**Tutorial #30**  
**CR, CTM/CS, RD**

**Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People, and Process**

Laurie Halloran, MS, CCRA  
President and Chief Executive Officer, Halloran Consulting Group  
.3 IACET CEUs

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.

**Tutorial #31**  
**GCP, PM, TR**

**Leadership: How to Organize and Lead People in Group Work**

Mike Laddin, MS, MBA  
President, LeaderPoint  
.3 IACET CEUs

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.
This tutorial is designed to provide the biotechnology/pharmaceutical professionals with the basis of the project management process. The course will include presentations as well as class participation to enhance the understanding of the project management process so that participants can return home and put their newly acquired knowledge to work on the job.

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 biotechnology/pharmaceutical professionals who are looking to learn more about the project management process and how to apply it to their specific job responsibility.

Tutorial #34

Project Management for the Nonproject Manager

Robert L. Judd
CEO, Robert Judd Associates (RJA)

.3 IACET CEUs

This tutorial is designed for biotechnology/pharmaceutical professionals 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.
**Tutorial #40**

**Clinical Statistics for Nonstatisticians**

Rafe Donahue, PhD

Research Associate Professor, Vanderbilt University Medical Center

6.5 AMA PRA Category 1 Credit(s)™; 7 IACET CEUs; 6.5 nursing contact hours; 286-000-07-502-L04; 6.5 pharmacy contact hours (.65 CEUs)

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 coursework, 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.

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**Tutorial #41**

**European Regulatory Requirements for the Conduct of Clinical Trials**

Regina Freunsch

Head of Quality Assurance, Accovion GmbH, Germany

6.5 AMA PRA Category 1 Credit(s)™; 7 IACET CEUs

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

This interactive tutorial will provide 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 be discussed. US FDA requirements will not be the subject of this tutorial.

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**Tutorial #42**

**Pharmacokinetics and Pharmacodynamics: A Gentle Introduction**

Michael J. Fossler, PharmD, PhD, FCP

Director, GlaxoSmithKline

.7 IACET CEUs; 6.5 nursing contact hours

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 tutorial, 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:
   - Clearance
   - Volume of distribution
   - Half-life
   - Relative and absolute bioavailability
   - Steady state
   - Population pharmacokinetics/pharmacodynamics
2. Define the following pharmacodynamics concepts:
   - Emax
   - EC50
   - Direct and indirect response models
3. Discuss differences between linear and nonlinear 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.
Tutorial #43

**Principles of Safety Surveillance**

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

Ralph E. Bobo, MD  
Executive Vice President, Pharmacovigilance Practice, Medical Safety Officer, Sentrx

6.5 AMA PRA Category 1 Credit(s)™; .7 IACET CEUs; 6.5 nursing contact hours; 286-000-07-503-L04; 6.5 pharmacy contact hours (.65 CEUs)

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 post-marketing surveillance.

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Tutorial #44

**Developing Realistic Drug Development Project Plans**

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

Randy Dunson, MBA, PMP  
President and Principal, Equinox Consulting, LLC

.7 IACET CEUs

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 pharma and biotech organizations. Following an hour of presentation and discussion between 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 workshop 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.

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Tutorial #45

**Excelling as a Supervisor or Manager in the Clinical Research Industry**

Mary E. Briggs  
Chief Training Officer, Focus Inc.

.7 IACET CEUs

“Excelling as a Supervisor or Manager in the Clinical Research Industry” provides a clear sense of how to work, lead, and communicate effectively with your team in the clinical trial industry. This entertaining and fast-paced tutorial is ideal for all clinical research managers who want to positively impact performance by effectively influencing others into their way of thinking.

This tutorial will allow participants to gain the essential skills and knowledge needed to become a great manager or supervisor in the clinical research industry. Learn practical approaches to communicating, conflict resolution, and performance enhancement.

“Excelling as a Supervisor or Manager in the Clinical Research Industry” is a fast-paced, interactive tutorial that focuses on the number one goal for successful drug development organizations – great managers!

**Learning Objectives**

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

- Communicate more effectively with individuals by recognizing four primary personality types, and quickly adapting to individual differences and preferences
- Gain compliance by using proven effective style adaptation techniques
- Recognize your own individual communication style and differentiate between passive, aggressive, and assertive communication
- Diminish on-the-job conflict and confrontation by practicing the four-step assertive communication cycle
- Differentiate between and effectively apply coaching, mentoring, and counseling in the clinical research industry
- Distinguish between the three primary root causes of performance problems in the clinical research industry

**Target Audience**

This tutorial is designed for supervisors and managers in the clinical research industry, including site managers, clinical trial managers, data managers, technical managers and other supervisors and managers in the drug development industry.

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Tutorials #50 through #59

**Pharmacovigilance Audit**

Steve Jolley  
Vice President, Pharmacovigilance, Taratec Development Corporation

Gregory J. Fiore, MD  
Senior Director, Drug Safety, The Medicines Company

Jamie Portnoff  
Senior Consultant, Taratec Development Corporation

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs

As large and small pharmaceutical companies alike face an increasingly complex set of international regulations, they need to ensure they are following good pharmacovigilance practices to demonstrate their commitment to patient safety. The size of their organizations leads to differing challenges and therefore differing methods to meet international requirements most effectively.
This tutorial will offer participants an opportunity to learn how a pharmacovigilance audit captures the requirements of all applicable regulatory bodies, and reviews company practices across the product lifecycle, inspects detailed documentation on case processing and decision making, evaluates related information systems, and documents successes, failures and improvements.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Recognize the impact of ICH, CIOMS, EU, FDA, and MHLW regulations on international safety reporting and review methods to meet requirements
- Identify the objects and components of a pharmacovigilance audit

**Target Audience**
This tutorial is designed for managers and directors in drug safety, pharmacovigilance, regulatory affairs, and quality assurance.

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**Tutorial #51**  
**Fourteen Steps from Research to Development**

**Judi Weissinger, PhD**
President and CEO, Weissinger Solutions, Inc.

Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

.3 IACET CEUs; 3.25 nursing contact hours

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.

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**Tutorial #52**  
**Preparation of Integrated Clinical and Statistical Reports for Individual Studies**

George H. D’Addamio, PhD
President, PharmConsult, Inc.

.3 IACET CEUs; 3.25 nursing contact hours

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.

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**Tutorial #53**  
**Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development**

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

.3 IACET CEUs

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. Postmarket 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 postmarket 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 postapproval 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.
Tutorial #54 CP, CR, RA

A Compliance-driven Nonstatistical Risk Detection Process in Drug Safety
Pradip K. Paul, MBBS, MS
Head, Case Medical Evaluation Group, Global Pharmacovigilance and Epidemiology, sanofi-aventis Pharmaceuticals, Inc.

Carol L. Krueger, RN
Consumer Safety Officer, Division of Compliance, Risk Management, and Surveillance, CDER, FDA

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs

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 detection (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 post-marketing 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.

Tutorial #55 CR, RA, RD

Alcohol-drug Interaction Studies: Understanding the Regulatory Requirements and Study Design Issues
Edward M. Sellers, MD, PhD, FRCP
President and CEO, Ventana Clinical Research Corporation
Beatrice Setnik, PhD
Research Scientist, Ventana Clinical Research Corporation

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs

Recent discovery of alcohol-drug interaction in vivo with hydromorphone (Palladone®) contributed to its withdrawal from the market. However, when do in vitro changes in dissolution or in vivo pharmacokinetic increases in drug concentration represent an important clinical or public health risk? Are studies to detect pharmacodynamic interactions needed? Answering these questions may require a combination of different clinical research approaches. Many extended-release, as well as immediate-release, psychotropic drug formulations, may be susceptible to the effects of alcohol.

This tutorial will explore various aspects of alcohol interaction studies, including regulatory requirements, in vitro and in vivo study design, and the interpretation of such data. Knowledge of regulatory frameworks and methodological issues will enable participants to make informed decisions regarding the development pathways of their products, with respect to the evaluation of potential interactions with alcohol.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Recognize FDA expectations with respect to determining the potential for alcohol-drug interactions
- Identify principles and issues involved in the design, analysis, and interpretation of alcohol interaction studies and other relevant data in order to meet the regulatory requirements

Target Audience
This tutorial is designed for research professionals involved in drug development including scientists, program and project managers, and others involved in clinical research.

Tutorial #56 RA

Market Access for Prescription Drugs and Biologics in Canada
Anne M. Tomalin, RAC
President, CanReg Inc., Canada

This tutorial will explore the processes through which a New Drug Submission is approved in Canada, through a Notice of Compliance or Conditional Notice of Compliance. Time frames for reviews will be compared. The new legislation dealing with data exclusivity and pediatric exclusivity will also be addressed. After approval, products with a patent need to have their price reviewed by the PMPRB. This process will be explored, and the data requirements that are required to be submitted annually will also be discussed. Provinces have developed the Common Drug Review for reimbursement of drugs in Canada; the CDR process will also be explored. In addition, the importance of provincial formularies will be discussed. Finally, the seminar will address Canada’s National Pharmaceutical Strategy, which is trying to address catastrophic drug needs and reimbursement of expensive drugs for rare diseases.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Explain the registration process for New Drug Submissions through Health Canada (either the Therapeutic Products Directorate or the Biologic and Genetic Therapies Directorate)
- Apply new data exclusivity and pediatric exclusivity legislation approved in October 2006
- Define the role of the pricing review through the Patented Medicines Pricing Review Board
- Explain the Common Drug Review and provincial formulary listings in Canada
- Describe the current status of the National Pharmaceutical Strategy

Target Audience
This tutorial is designed for regulatory personnel responsible for or dealing with Canada, such as marketing individuals responsible for international pricing and reimbursement strategy, and those who want to understand the pricing of pharmaceuticals in Canada.

This Tutorial has been cancelled.
Tutorial #57

Producing Structured Product Labeling (SPL): XML and Data Elements

Kate Hamilton
Associate, Alschuler Associates, LLC

Lonnie D. Smith
Project Specialist, Office of the Director, CDER, FDA

This tutorial will provide an overview of what eClinical trials are and how to achieve them. Specifically, it will cover basics on the planning and implementation of eClinical trials, including process redesign, metrics, data quality, regulations, technology and industry standards.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Define processes for a true eClinical trial (contrast with EDC, RDE)
- Recognize ways to leverage new technologies in clinical trials
- Discuss relevant standards and their value to eClinical trials
- Identify appropriate metrics for measuring success

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.

Tutorial #58

Producing Structured Product Labeling (SPL): XML and Data Elements

David P. Iberson-Hurst
Chief Executive Officer, Assero Limited, UK

This tutorial is designed for people working with SPL who want or need to understand its characteristics and to create valid and correct files.

Learning Objectives
- Describe the benefits expected from a structured-markup system and how SPL provides these benefits
- Differentiate content from format, recognize the types of markup in an SPL file, and be able to use the related subject-matter vocabulary
- Discuss differences between a word-processing production environment and an XML-based production environment, and assess the XML- and SPL-specific features of an SPL editor
- Perform validation of an SPL file, and diagnose errors reported or seen

Target Audience
This tutorial is designed for people working with SPL who want or need to understand its characteristics and to create valid and correct files.
Tutorial #71

Evaluation of Risk Management Programs Using Existing Databases

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

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs; 3.25 nursing contact hours; 286-000-07-505-L04; 3.25 pharmacy contact hours (.325 CEUs)

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.

Tutorial #72

Regulations, Guidance, Dockets, Specifications and Manual of Policies and Procedures (MAPPs): A Primer for Pharmaceutical Professionals

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

.3 IACET CEUs; 286-000-07-506-L04; 3.25 pharmacy contact hours (.325 CEUs)

This tutorial will provide an overview of the work involved in creating those regulatory documents that have a significant impact on the science and processes associated with the development of new drug products. This is important knowledge for all professionals (eg, pharmacists, clinicians, trial monitors, statisticians, regulatory personnel) who work with the Agency to provide evidence for the approval of new drugs and biologics. Using examples of documents relevant to the conduct of clinical trials, and of communication with the Agency and electronic submissions, this course will enable students to become familiar with the content and format, the processes, the practical application, and the rationale, for regulatory documents.

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

- Describe the basic format and content of regulations, guidance, specifications and CDER SOPs (MAPPs)
- Recognize the need for regulations, guidance, specifications and MAPPs
- Explain how CDER develops and uses regulation, guidance, specifications, and MAPPs
- Identify some important regulations, guidances, and MAPPs that pertain to clinical trials, regulatory processes and electronic submissions

Target Audience
This tutorial is designed for regulatory and research personnel who would like to hear an “insider’s” view of the whys, whats and hows of giving advice and changing review processes.

Tutorial #73

Analysis of Safety Data from Clinical Trials

Joachim Vollmar, MSc
International Clinical Development Consultants, LLC

Jürgen Kübler, PhD
Global Head, Integrated Safety and Health Economics Biostatistics, Novartis Pharma AG, Switzerland

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs

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 tutorial 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.

Tutorial #74

GCP, Clinical Trial Safety, and Pharmacovigilance Compliance: How Global Pharmaceutical Companies Can Cope in Interesting Times

Stephen A. Goldman, MD, FAPM, FAPA
Managing Member, Stephen A. Goldman Consulting Services, LLC
Adjunct Assistant Professor of Psychiatry, Uniformed Services University of the Health Sciences

Louise N. Lisansky, MS
President, LNL Clinical Research Consulting, Inc.

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs; 3.25 nursing contact hours; 286-000-07-507-L04; 3.25 pharmacy contact hours (.325 CEUs)

With increasing globalization of pharmaceutical and biotechnology companies, concerns about risks to patients participating in clinical trials and using marketed pharmaceuticals have heightened. It has never been more critical for companies to ensure compliance with both national and international clinical safety and postmarketing pharmacovigilance regulatory requirements. For this to occur, industry professionals must be familiar with the latest regulatory actions within and outside the US, and understand good clinical practice (GCP), premarketing clinical safety and postmarketing pharmacovigilance regulatory inspectional programs. This tutorial will address current challenges in safety-related compliance in the global environment.

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

- Discuss clinical safety and pharmacovigilance-related inspectional approaches in the US and EU
- Describe good clinical practice (GCP) and its implications for patient safety
- Identify strategies for optimizing quality and compliance when outsourcing clinical trials
- Explain the importance of quality written processes to pharmaceutical safety and risk management regulatory compliance
### Target Audience
This tutorial is designed for pharmaceutical and biotechnology professionals involved in postmarketing surveillance/pharmacovigilance, premarketing clinical safety, clinical research, regulatory affairs, quality assurance, safety data management/analysis, risk management, project management and biostatistics.

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### Tutorial #75  BT, CR, IS

**Planning and Conducting Clinical Trials in Oncology**

Ronald Harning, PhD  
Director, Clinical Research, Teijin America, Inc.

*3.25 AMA PRA Category 1 Credits™; .3 IACET CEUs*

Cancer is the leading cause of death in the US for persons 85 years of age and younger. Approximately 1.5 M new cases of invasive cancer have been reported in 2006. Total funding for US and worldwide trials in oncology is larger than for any other therapeutic area.

This tutorial will include discussions and presentations on the following topics: an introduction to the biology of tumor growth and metastasis; protocol development for oncology protocols for phases 1-3; and discussions from the current literature concerning issues important to clinical sites involved with the recruitment and enrollment of cancer patients into clinical trials.

**Learning Objectives:**
- Recognize the incidence and prevalence of cancer in the US and the importance of conducting clinical trials in oncology
- Explain the tumor growth and metastasis process
- Identify and recall the essential components of phase 1, 2, and 3 oncology protocols
- Recognize important clinical issues relevant to conducting trials in oncology such as informed consent and patient recruitment

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

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### Tutorial #76  EC, GCP, IS

**The CRA Role for GCP Compliance with Electronic Data Capture (EDC)**

Teri Stokes, MS, MT, PhD  
Director, GXP International  
*3 IACET CEUs; 3.25 nursing contact hours*

Monitoring data quality and integrity has long been the CRA role in GCP-compliant clinical studies. Now that this data is most often electronic, the CRA is faced with new challenges. This tutorial provides both training and tools for non-IT-oriented CRAs to help them fulfill their compliance monitoring role. It will examine the regulations (GCP, HIPAA, and 21 CFR Part 11) and guidance (CSUCT) for common themes, and explore the site-level impact on data integrity of EDC technologies for eCRFs, eDiaries, and interactive voice response (IVR) systems. Participants will be actively involved in tutorial discussions, group work, and case study analysis using tools they can apply to future studies.

**Learning Objectives:**
- Prepare and follow a protocol-based risk assessment plan for EDC systems used in a clinical trial
- Identify and address the site-level regulatory compliance issues for using electronic signatures on eCRFs, interactive voice response (IVR), and diary systems
- Instruct study coordinators and other site personnel on the impact of GCP, HIPAA, and 21 CFR Part 11 regulations for computerized systems used in clinical studies
- Define the CRA monitoring role for electronic data in a clinical trial

**Target Audience**
This tutorial is designed for CRAs, monitors, study coordinators, and protocol teams that develop and conduct clinical trials using electronic data capture such as electronic case report forms (eCRFs), interactive voice response (IVR) systems for randomization and management of supplies or patient response by phone, and electronic patient diaries (eDiaries) using PDAs and other devices.

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### Tutorial #77  CR, RA, RD

**Collecting Abuse Liability Data During CNS Drug Development**

Edward M. Sellers, MD, PhD, FRCP  
President and CEO, Ventana Clinical Research Corporation

Kerri Schoedel, PhD  
Research Scientist, Ventana Clinical Research Corporation  
*3.25 AMA PRA Category 1 Credits™; .3 IACET CEUs*

This tutorial will detail abuse liability data collection methodology during the CNS drug development cycle. The tutorial will focus on issues of study and data collection system design, data analysis, and interpretation of abuse liability studies and other relevant data.

The abuse of prescription drugs has received increasing media and regulatory attention in recent years. Sponsors developing drugs with central nervous system activity that have the “potential for abuse” must submit all data relevant to the abuse liability of their drug. But what is meant by “potential for abuse”? What data must be submitted? When and how is this data collected? This tutorial will provide answers to these questions by detailing the methods involved in collecting abuse liability data during CNS drug development. The tutorial will begin with an overview of what types of products require an abuse liability evaluation, what data are required, and when different types of data are collected during the product cycle. The tutorial will then focus on how abuse liability studies and data collection systems are designed. Analysis and interpretation will be discussed, both for individual studies or data, as well as for the overall patterns across the different types of data. This will include a discussion of the limitations and issues involved for the various types of data or studies. Participants will gain a firm understanding of the what, when, and how of abuse liability data collection, in order to meet increasingly stringent regulatory requirements for CNS products.

**Learning Objectives:**
- Determine whether your CNS product will require an abuse liability evaluation
- Identify what data are required throughout the CNS product development cycle
- Describe methodologies for the collection of abuse liability data
- Discuss issues involved in the design, analysis, and interpretation of abuse liability studies and understanding the overall abuse liability of your product

**Target Audience**
This tutorial is designed for research professionals involved in CNS drug development including scientists, program and project managers, and others involved in basic or clinical research in the CNS area.
Tutorial #78  
Development of Stem Cells-based Therapeutics, including Human Embryonic Stem Cells, from Proof of Concept to Clinical Trials  
Judith Weissinger, PhD  
President and CEO, Weissinger Solutions, Inc.  
3.25 AMA PRA Category 1 Credit(s)™; 3 IACET CEUs

To date, stem cells from both adult cells, and numerous embryonic stem cell (ESCs) lines have been derived from donated excess in vitro fertilization embryos and shown to be both immortal and pluripotent. Embryonic stem cells can be cultivated indefinitely in vitro in an undifferentiated state. Upon induction with media supplements, embryonic stem cells can differentiate into representatives of all of the cell lineages of the body. Adult stem cells have some proliferative capacity, though their utility is also predicated upon that capacity. Nonclinical studies have advanced to show that cells of potential therapeutic relevance can be produced from hESCs and can be transplanted successfully in animal models of human disease.

This tutorial will address how the technology for culture and differentiation of stem cells and hESCs has matured to allow consideration of stem cells for therapeutic use and hESC-derived cells for clinical studies.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Explain the development of stem cell and hESC-based therapies from their early discovery, proof of concept studies, preclinical investigations, and manufacturing for clinical application
- Identify regulatory pathways that must be considered in developing the new stem and hESC-based therapies
- Recognize the specialties and resources needed to develop a cell-based therapy product

Target Audience
This tutorial is designed for pivotal staff in companies developing cell-based therapies and tissue engineering; in pharmaceutical/biological companies that have yet to file INDs or are in IND development; and all personnel who want to broaden general knowledge of biological cell therapy product development.

Tutorial #79  
Maximizing the Impact of Clinical Site Monitors  
Ken Light, MS  
Solutions Partner, BusinessEdge Solutions, Inc.

Graham Nicholls  
Product Development Manager, ClinPhone Limited

3.25 AMA PRA Category 1 Credit(s)™; 3 IACET CEUs

Until recently, the impact of the clinical site monitor on the conduct of the study has been underestimated. Evidence suggests that the monitor plays an important role in site performance, including recruitment and compliance that go beyond a traditional study "auditor" role. Companies that realize the therapeutic use and hESC-derived cells for clinical studies.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Describe the basic functionality available to them in managing trial supplies and performing randomization using IVR/IWR (Interactive Voice Response/Interactive Web Response) systems
- Compare the different randomization techniques and restate the situations under which they could be implemented
- Discuss the different medication management algorithms and decide which method would be most appropriate to apply to their trial design
- Determine whether a study is a good candidate for using IVR/IWR and be effective in working with an IVR vendor in determining the requirements of an IVR system
- Examine the way in which IVR can be used to facilitate the management of adaptive trial designs

Target Audience
This tutorial is designed for pivotal staff in companies developing cell-based therapies and tissue engineering; in pharmaceutical/biological companies that have yet to file INDs or are in IND development; and all personnel who want to broaden general knowledge of biological cell therapy product development.

Tutorial #80  
Randomization and Trial Supply Management Using IVR: A Tutorial for Study Teams  
Geoff Garabedian  
Solutions Partner, BusinessEdge Solutions, Inc.

Judi Weissinger, PhD  
President and CEO, Weissinger Solutions, Inc.

This tutorial will start with an overview of how IVR systems operate to control the clinical supply chain. It will cover in depth the variety of randomization methodologies including "static" randomization methods and dynamic allocation procedures and discuss how to select the most appropriate method. Special considerations in maintaining the unpredictability of the randomization scheme in open label studies will also be discussed. The tutorial will further explain how IVR systems operate to control the clinical supply chain and dispensing to patients, and identify the implications of this approach in terms of medication packing and labeling compared to traditional methods.

The tutorial will explore simple study designs through to more complex study design issues, looking at the issues that occur repeatedly and how IVR/IWR solutions can be used effectively in each situation. Multiple treatment arms, dose titration studies, open label studies, studies with scarce and/or expensive medication, and expiry date management will be considered. It will also explore how IVR/IWR solutions can be used to implement adaptive trial designs, including both response adaptive designs and multiple stage designs. By the end of this tutorial, participants will be able to determine for themselves when to use IVR in their studies, and will be able to work effectively with a vendor in determining the requirements of an IVR/IWR application.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Identify the technology and process mechanisms that can be put in place to optimize efficiency, enhance quality, and save time and money for the sponsor, the site, and the monitoring staff

Target Audience
This tutorial is designed for clinical monitors and their management, clinical project managers, CRO personnel, site personnel, IT staff who support clinical trials, quality assurance personnel, and finance personnel who budget and provide resources for clinical trials.
Target Audience
This tutorial is designed for professionals in regulatory affairs, clinical research, project management and related fields.

Tutorial #84

Pediatric Clinical Trials: The Way Forward
Barry Mangum, PharmD
Faculty Pediatrics, Duke Clinical Research Institute (DCRI)

3.25 AMA PRA Category 1 Credit(s)™; 3 IACET CEUs; 3.25 nursing contact hours

Pediatric clinical research has lagged behind adult research for decades. Legislation has been developed in the US and EU which requires pharmaceutical companies to perform clinical trials on pediatric patients. Many investigators, study coordinators, and pharmaceutical employees are very motivated but are research naïve regarding this unique niche population.

Many aspects of pediatric research will be discussed, including the present and future of pediatric clinical trials presented from the perspective of current and pending legislation from the FDA and EMEA. There will be a full range of training provided including protocol development, medical monitor role, drug formulation, drug dosing, analysis, and results. Lessons learned from pediatric trials and current FDA projects will be shared.
Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Outline the current regulatory guidelines in the US and the EU
- Explain the future of pediatric clinical trials
- Develop and implement meaningful pediatric clinical trials using GCPs
- Identify strategies for overcoming challenges of pediatric trials
- Interpret the current regulatory guidelines when applying for pediatric exclusivity in the US
- Assess the relevant cost of performing a pediatric clinical trial
- Design a pediatric clinical program directed to meet the FDA and EMEA guidance documents to obtain exclusivity and/or pediatric approval

Target Audience
This tutorial is designed for pharmaceutical industry professionals engaged in any aspect of product development and product launch. This will include individuals in business development, clinical trials, commercial operations, managed care and reimbursement, marketing, research and development, sales – and every other aspect of pharmaceutical industry launches. Because the landscape of pharmaceutical industry is dynamic, ever-changing, this tutorial will appeal to both novices and experts alike.

Tutorial #85
The Changing Landscape of Pharmaceutical Product Launches
William R. Hahn
Vice President, Marketing and Business Development, Shaw Science Partners, Inc.
.3 IACET CEUs
Successful product launches shape an organization’s operational positioning within the pharmaceutical industry. To ensure success, individual functions must achieve independent and collaborative goals across intra-departments within an organization. In addition, to meet raised levels of expectations, intra-department collaboration will redefine these elements through assessment of product quality and value, its customers, competition and collaboration throughout the company.
This tutorial will focus on initiatives for the changing landscape of pharmaceutical product launches, in innovative markets that successfully integrate all corporate functions. At the conclusion of this tutorial, attendees will have gained at least one new tool to ensure the successful launch of products in the pharmaceutical industry.
Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Describe the fundamental changes in the landscape of pharmaceutical product launches from the perspective of multiple organization vantage points
- Describe the independent contributions of divisions within a pharmaceutical firm to a successful product launch
- Describe the cross-division relationships and contributions required for a successful pharmaceutical product launch
- Implement effective methods to integrate cross-division synergies in order to ensure a successful pharmaceutical product launch

Target Audience
This tutorial is designed for principal investigators, study coordinators, and staff at clinical sites. This course will also benefit clinical staff working in pharmaceutical and academic research organizations including project managers, medical directors, monitors, and statisticians.

Tutorial #86
The CDISC Standard: Four Models Working in Harmony
David P. Iberson-Hurst
Chief Executive Officer, Assero Limited, UK
.3 IACET CEUs
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.

Tutorial #87
New Release of EU Regulatory Requirements: Pharmacovigilance in the Pre- and Postmarketing Phase and eReporting
Representative Invited
EMEA, EU
Gaby L. Danan, MD, PhD
Expert, Global Pharmacovigilance and Epidemiology, sanofi-aventis, France
.3 IACET CEUs
This tutorial will allow participants to discuss the main changes to Volume 9 “Notice to Marketing Authorization Holders” and the potential implications of the new requirements on pharmaceutical companies’ business processes. The tutorial will focus on adverse reaction management during the postauthorization phase including mandatory electronic reporting in EEA and responsibilities of the qualified person responsible for pharmacovigilance, as well as the responsibilities of the qualified person responsible for pharmacovigilance system.
Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Interpret the potential implications of the new requirements for pharmaceutical companies’ business processes
- Adhere to adverse reaction management during the postauthorization phase, including the mandatory electronic reporting in the EEA
- Recognize 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 who are responsible for pharmacovigilance, project team leaders, people in charge of risk management, and regulatory experts.

This Tutorial has been cancelled.
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 a secondary interest area.

Please note that this program was printed in early February and changes in the schedule may occur prior to the meeting. A final program will be printed in June and distributed to attendees on site.

### Meeting Schedule

#### Track Titles and Acronyms

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<td>Academic Health Centers</td>
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<td>Clinical Data Management</td>
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<td>Impact of Medical Products and Therapies</td>
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<td>Clinical Safety and Pharmacovigilance</td>
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#### Monday, June 18, 8:30 am-10:00 am

**ALL**

**Plenary Session**

#### Monday, June 18, 10:30 am-12:00 pm

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<th>AD</th>
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<td>Individual Case Safety Reports (ICSRs): Fostering Quality Data via Stimulation of Healthcare Professional Reporting, Active Query, Applied Clinical Expertise and Efficient Case Handling</td>
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<tr>
<td>CR1</td>
<td>CTM/CS</td>
<td>Different Approaches: The Use of Key Enrollment Optimization Processes, Clinical Investigative Networks and eClinical Processes to Impact Clinical Trial Efficiency</td>
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<td>CR2</td>
<td>GCP</td>
<td>How to Work with Your IRB!</td>
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<td>CR3</td>
<td>CTM/CS</td>
<td>A Case Study: Challenges and Suggestions on Patient Recruitment and Retention</td>
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<td>CR4</td>
<td>RA</td>
<td>Surrogate Endpoints in Cardiovascular Drug Development</td>
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<td>CDM</td>
<td>CTM/CS</td>
<td>The Implementation of a CTMS System</td>
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<td>ERS/DM</td>
<td>RA</td>
<td>FDA: eCTD Compliance – Part 1 of 2</td>
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<tr>
<td>FI</td>
<td>PM</td>
<td>Finance Is from Mars, Clinical Development Is from Venus: Financial Accruals and Forecasting</td>
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<tr>
<td>GCP</td>
<td>CR</td>
<td>Clinical Trial Registries and Results Databases: Are You Ready for the Audit?</td>
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<td>IS</td>
<td>OS</td>
<td>When Sponsors Sue Sites: A Real-life Case History</td>
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<td>IT</td>
<td>CDM</td>
<td>Next Generation Application Integration Using Web Services</td>
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<tr>
<td>MW</td>
<td>ERS/DM</td>
<td>Submitting an IND in eCTD Format: Lessons Learned</td>
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</tbody>
</table>

| PM1 | CTM/CS | Application of Six Sigma Methodology |
| PM2 | RD | Evolving Operational Models in the Pharmaceutical Industry: Project Management Perspective |
| PP | IMP | Personalized Medicine: A Perspective Beyond Science |
| RA1 | RD | Nanomedicine: The Way Forward |
| RA2 | ERS/DM | Best Practices for Addressing Pharmaceutical Multilingual XML Requirements |
| RA3 | RD | Development of Oncology Products in the EU and US: Can It Be Better and Faster? |
| RA4 | CR | Running Clinical Trials in Latin America: A Review of the Regulatory Framework in Argentina, Brazil, and Mexico |
| RD | CR | Experimenting with Clinical R&D Management Metrics Using the Latest Computer Technology |
| TR1 | CR | A Blended Learning Approach to Establishing a Global Standards and Practices Program for Clinical Study Documentation |
| TR2 | CR | Self-guided Mentoring Program Administered by Training |

#### Monday, June 18, 1:30 pm-3:00 pm

<table>
<thead>
<tr>
<th>AD</th>
<th>RA</th>
<th>How Fraud and Abuse Cases Are Changing the Corporate Landscape</th>
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<tr>
<td>CDM</td>
<td>EC</td>
<td>Case Studies on Time-critical Data Access Using Phase 1 EDC Programs by a Sponsor, Site and Software Provider</td>
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</tbody>
</table>
Meeting Schedule

Monday, June 18, 3:30 pm-5:00 pm

| CP1 | RD | Selection, Implementation and Validation of Vendor Safety Systems |
| CP2 | CR | Clinical Safety Risk Management in Preapproval Drug Development |
| CR1 | RA | Personalized Medicine and Personalized Drug Development: Case Studies and Progress to Date – Part 1 of 2 |
| CR2 | PM | Targeted Site Start-up Support Strategy in Clinical Research |
| CR3 | GCP | Regulatory Requirements in Late Phase Studies: Do We Really Know What They Are? |
| CTM/CS | CR | Clinical Trials in Asia Pacific: Advantages and Challenges |
| ERS/DM | RA | FDA: eCTD Compliance – Part 2 of 2 |
| FI | RD | Sustainability of Pharmaceutical Development Pipelines |
| GCP | CR | Conducting Effective CAPA Following an Audit |
| IS | CTM/CS | Investigator Budgets and Reimbursement: The Impact on Patient Enrollment and Retention Objectives |
| IT | CDM | Clinical Data Warehouse: Approaches and Pitfalls |
| MW | EC | The HL7/CDISC Glossary: Mapping the R&D Process with a Common Vocabulary |
| OS | CR | Lessons Learned: A Nonconfrontational Technique to Improve Sponsor-provider Team Performance – Part 2 of 2 |
| PM1 | RD | Utilization of Six Sigma Methodology in a Research and Development Setting |
| PM2 | RD | Integrated US/Japan Effective Team Management |
| PP | RA | Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials |
| RA1 | IS | Site Selection Risk Models for FDA Inspections and Theoretical Considerations |
| RA2 | PP | FDA Regulations and Guidelines: How to Make Comments Count |
| RA3 | RD | Good Review Management Principles (GRMPs): How Far Have We Come? |
| RA4 | CP | Strengthening the Infrastructure: Supporting Drug Safety Policy Development, Risk Communication and Healthcare Community Outreach |
| RA5 | PM | Effective Milestone Meetings with FDA |
| RD | CR | Mapping the Clinical Investigator Landscape |
| ST | CR | Design and Analysis Issues in Analgesic Trials |
| TR | GCP | Bringing Global Staff to Headquarters for Training |

Tuesday, June 19, 8:00 am-9:30 am

Multitrack Plenary

AHC (CP, CR, PP, RA) | Drug Safety Reform: Actions and Implications |
| BT | CR | Progress in Systems Biology: Advances in Knowledge-based Drug Development |
| CDM | IT | Data Warehousing Concepts for SDTM-compliant Information |
### Multitrack Plenary

<table>
<thead>
<tr>
<th>CMC/GMP</th>
<th>RA</th>
<th>Update on FDA Initiatives for Postapproval CMC Changes</th>
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</thead>
</table>

#### CP & CR (AHC, PP, RA)

| CR1 | IS | Results of a Survey among Sponsors Examining Best Practices in Investigator Meetings |
| CR2 | RD | Common Issues and Solutions for Thorough QT ECG Trial Design |
| CTM/CS | GCP | Multinational Clinical Trials in China |
| EC | IT | NIH Roadmap Program and Development of Therapeutic Area Data Standards: Case Studies in TB and Cardiology |

#### ERS/DM

| CDM | CR | eCTD for Small Pharma |

#### GCP

| CR | How to Be Prepared for an FDA Audit |

#### IMP

| EC | Clinical Endpoint (PRO, CRO, ePRO) Validation: The State of the Science |
| IS | GCP | IRB Site Visits and Audits |
| IT | CDM | Utilizing Open-source Software in GCP-compliant Environments |
| MC | MW | Standardizing Information Sharing between Medical Information Professionals and Regional Medical Liaisons by Developing Tools to Ensure Compliance and Consistency |
| MW | RA | CTD Summaries as Key Reviewer Tools |
| OS | CR | Benefits and Challenges of Implementing Standards in Outsourced Studies |
| PM1 | RD | Driving Growth and Innovation through Portfolio Management |
| PM2 | CTM/CS | PMs as Global Project CEOs and the Effective Project Manager’s Tool Chest |

#### Multitrack Plenary

<table>
<thead>
<tr>
<th>PP &amp; RA (AHC, CP, CR)</th>
<th>Drug Safety Reform: Actions and Implications</th>
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<tr>
<td>RA1</td>
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<td>RA2</td>
<td>MC</td>
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<td>RD</td>
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<td>GCP</td>
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### Tuesday, June 19, 10:00 am-11:30 am

| AD | RA | Enforcement Update from the FDA |
| BT | CR | Hot Topics in Biotechnology |
| CDM | CR | Convergence of Healthcare and Life Sciences: Enhancing the Value Chain |
| CMC/GMP | RA | Lessons Learned from CMC Pilot Program: An FDA Perspective |
| CP1 | RA | Regulatory Inspections of Industry Pharmacovigilance Operations |
| CP2 | IMP | Risk Management for Vaccine Products |
| CR1 | PM | Pediatric Clinical Trials: Lessons Learned from the Field |
| CR2 | CTM/CS | Update to Radical Change in Clinical Development |
| CR3 | RD | Assessing the Impact of Increasing Protocol Complexity on Study Conduct Performance |
| CTM/CS1 | IS | Recruitment of Minority Sites for Clinical Trials |
| CTM/CS2 | CR | Finding Top Performing Sites: A Considered Approach |
| EC | CDM | Debate: The Pros and Cons of ePROs … Resolved that Electronic Technology Should Be Used to Capture Patient-reported Outcome (PRO) Data in All Clinical Trials in which PROs are Captured |
| ERS/DM1 | CDM | Structured Product Labeling: An FDA Update and the Industry Perspective |
| ERS/DM2 | CDM | Records Management |
| GCP | CR | Good Clinical Practices (GCPs) and ISO 9000: A Winning Combination |
| IMP | CP | Data Mining: Perils, Pitfalls and Pragmatism |
| IS | CTM/CS | Feet on the Street: Using Community Outreach to Recruit Study Subjects |
| IT | CDM | Protecting Intellectual Property |
| MC | MA | Establishing Principles to Support Co-marketed Products between Medical Information Departments |
| MW | MC | Outsourcing On-shore and Off-shore |
| NHP | CP | Safety and Pharmacovigilance of Natural Health Products (NHPs): International Efforts |
| OS | CR | Transforming Five New Clinical Development Strategies into Real Results and What We Can Learn from the Industries that Have Done It |
| PM | BT | Considerations in Managing the Development of a Biologic from Initiation through Life-cycle Management |
| PP | MC | Personal Health Records in Pharmaceutical Development |
| RA1 | PP | New Directions and Innovations in Canadian Drug Regulations: The Canadian Approach to Draw a Critical Path to Better Drug Regulations and Development |
| RA2 | GCP | Highlights Data Elements (HLDEs): One-year Experience with Computer-processable Highlights for US Prescribing Information |
| RA3 | RD | Scientific Advice in the EU |
| RA4 | CR | Combination Products: Preapproval Challenges and Opportunities – Part 1 of 2 |
| RD | OS | Globalization of Industry-sponsored Clinical Trials: Evidence on Recent Trends |
| ST | CR | Graphical Analysis of Clinical Safety and Efficacy Data |
| TR | CR | Getting the Message Across: It’s All about the Presentation |

### Special Event

| Student Forum | Student Forum |

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### Meeting Schedule

**Tuesday, June 19, 2:00 pm-3:30 pm**

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<tr>
<th>AD</th>
<th>RA</th>
<th>Direct-to-consumer Update from the FDA</th>
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<tbody>
<tr>
<td>BT</td>
<td>CP</td>
<td>Transitioning from Stem Cell Research to Commercial Applications</td>
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<tr>
<td>CDM</td>
<td>CTM/CS</td>
<td>Outsourcing in Data Management: Thinking Global, but Still Acting Local?</td>
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<tr>
<td>CMC/GMP</td>
<td>RA</td>
<td>Lessons Learned from CMC Pilot Program: An Industry Perspective</td>
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<tr>
<td>CP1</td>
<td>IMP</td>
<td>Can Risk Communication Be Improved? Pitfalls and Progress</td>
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<td>CR</td>
<td>Postmarketing Safety Studies and Intensive Event Monitoring Techniques: What Have We Learned?</td>
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<tr>
<td>CR1</td>
<td>CTM/CS</td>
<td>Patient Recruitment: Strategic Approaches to Optimize Outcomes</td>
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<td>CR2</td>
<td>NC</td>
<td>Renal Biomarker Qualification for Decision Making</td>
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<tr>
<td>CR3</td>
<td>CTM</td>
<td>Clinical Trials Transparency: Issues, Perspectives and Goals</td>
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<tr>
<td>CMT/CS</td>
<td>CR</td>
<td>Identifying and Overcoming Site Initiation Delays in Multinational Clinical Trials</td>
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<td>CDM</td>
<td>Global Adoption of eClinical Technologies</td>
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<td>Second Annual CDER eSubmission Update</td>
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<td>GCP</td>
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<td>Working with and Managing Contract Auditors</td>
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<td>IMP</td>
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<td>Accident or the Potential of Saving Lives with Remote Ultrasound Technology</td>
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<td>GCP</td>
<td>Hurricane Katrina: Lessons Learned One Year Later</td>
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<td>CDM</td>
<td>Issues and Case Studies in Safety Data Migration</td>
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<td>Sharing Medical Information Online: Weighing the Risks versus Benefits</td>
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<td>Providing Data Displays to Support Communication of Safety Information</td>
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<td>Carcinogenicity Testing Database</td>
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<td>NHP</td>
<td>CMC/GMP</td>
<td>Developing NHPs as Drugs: CMC and Quality Control/Quality Assurance Considerations</td>
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<td>OS</td>
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<td>Improving CRO Negotiations to Accelerate Time to Market</td>
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<td>PM1</td>
<td>CP</td>
<td>Risk Management in Clinical Trials</td>
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<tr>
<td>PM2</td>
<td>CR</td>
<td>Development of an Integrated Molecule and Nonmolecule Forecast</td>
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<td>PP</td>
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<td>Product Liability</td>
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<td>Achieving Success in Registration: Avoiding Pitfalls in Drug Development</td>
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<td>RA3</td>
<td>CR</td>
<td>Best Practices in Preparing for and Participating in a Pre-IND Meeting</td>
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<td>RA4</td>
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<td>Combination Products: Preapproval Challenges and Opportunities – Part 2 of 2</td>
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<td>RD</td>
<td>RA</td>
<td>Japan Challenges to Global Simultaneous Drug Development: Adapting Japanese Environments to Worldwide Drug Development</td>
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**Tuesday, June 19, 4:00 pm-5:30 pm**

<table>
<thead>
<tr>
<th>ST</th>
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<th>Statistics in Drug Safety and Health Economics and Outcomes Research: Anything in Common?</th>
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<tr>
<td>TR</td>
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<td>Rapid Development/Rapid Delivery of eLearning Solutions to External Clinical Trial Personnel</td>
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<th>AD</th>
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<th>The Future of DTC Policy: Guiding Patient Progress amid Policy and Creative Tension</th>
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<tr>
<td>BT</td>
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<td>Research and Development of Response Prediction Molecular Markers and their Integration into Clinical Drug Development in Oncology</td>
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<td>EC</td>
<td>Good Registry Practice: Standards, Design, Use, and Evaluation of Patient Registries and Methods and Best Practices</td>
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<td>CMC/GMP</td>
<td>RD</td>
<td>Potential Methodologies for Design Space Determination</td>
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<td>Global Approaches to Risk Management Plans: The View from Japan and Europe</td>
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<td>CR1</td>
<td>RA</td>
<td>Clinical Research and Drug Registrations in Developing Countries (BRIC – Brazil, Russia, India, and China)</td>
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<td>CR2</td>
<td>RD</td>
<td>Arsenic and Old Lace: How to Avoid a Comedy of Errors when a Thorough QT/QTc Study Cannot Be Performed</td>
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<tr>
<td>CR3</td>
<td>GCP</td>
<td>Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done?</td>
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<td>CMT/CS</td>
<td>CR</td>
<td>Improving the Clinical Supply Chain Management Process</td>
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<td>EC</td>
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<td>Using CDISC Standards and eClinical Technologies to Improve Patient Safety Monitoring during the Conduct of Clinical Trials</td>
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<td>ERS/DM1</td>
<td>CDM</td>
<td>Is There a Cure for the Ills of Electronic Document Management in the Contemporary Biopharmaceutical Industry? And If So, What Is the Medicine?</td>
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<td>ERS/DM2</td>
<td>RA</td>
<td>Product Information Management (PIM) Is Live in the EU: Update and Experience</td>
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<td>GCP</td>
<td>RA</td>
<td>GCP Town Meeting Session: Quality Systems and the QA Role in Small- to Medium-sized Companies</td>
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<td>IMP</td>
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<td>Using Electronic Medical Records for Clinical Research</td>
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<td>Emergency Procedures for when a Sponsor Goes Bad</td>
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<td>EC</td>
<td>Leveraging Electronic Health Records in Clinical Research</td>
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<td>Health Education: Teaching Consumers about the Safe Use of Medicines</td>
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<td>Writing for Patients</td>
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<td>Adverse Effects of Anticancer Drugs: A Problem of the Past</td>
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<td>NHP</td>
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<td>Phytomedicine Development in Latin America: Interphase between Science and Development</td>
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<td>Outsourcing Clinical Trials in Australia</td>
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<tr>
<td>PM1</td>
<td>FI</td>
<td>The Methodology of Process Metrics in Leading an Organization to Success</td>
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<tr>
<td>PM2</td>
<td>RD</td>
<td>Ending the Isolation of Project Management in Drug Development</td>
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</table>
Meeting Schedule

Wednesday, June 20, 8:30 am-10:00 am

AD  MC  Redefining the Roles of Medical Science Liaisons and Sales Representatives: Separating Science from Marketing
BT  RA  Process Validation during Clinical Development of Biological Medicinal Products
CDM CR  Implementing a Comprehensive Lab Data Management Strategy
CMC/GMP BT  Implementation of QbD for Biotechnological Products
CP1 RA  Data Mining in Pharmacovigilance: Misconceptions and Misunderstanding in Data Mining and Signal Detection
CP2 CDM  Streamlining Adverse Event Case Management
CR1 CTM/CS  Cost Containment in Clinical Research: What is Being Done?
CR3 RD  Human Phase 0 Microdose Studies: What Will They Deliver?
CTM/CS CR  A Simple Solution for Removing Clinical Supplies as a Rate-limiting Step for the Adaptive Trial Design
EC CDM  2012: eClinical Odyssey
ERS/DM CDM  eCTD Case Studies
GCP CR  Quality Risk Management in GCP: The Essentials
IT1 CDM  Using Information Visualization to Link Decision Making across a Matrixed Organization
IT2 VA  Best Practices for Technology Implementation
MA CP  Maximizing ROI (Return on Information)
MC CR  Medical Liaison Survey #3: Assessing Practice Trends across the Pharmaceutical Industry
MW CR  Overview of Publication Writing
NC RA  Predictive Safety Testing Consortium
NHP CR  Characterizing Variability of Botanical Products: Impact on Scientific Research and Product Development
OS CTM/CS  Clinical Trials in China: Opportunity versus Difficulties
PM1 CR  The Evolving Role of Project Management in Drug Development
PM2 RD  Value of Project Management Function in Drug Development in Japan
PP MA  Off-label Promotion and Physician Liability
RA1 PP  Partnership in Regulatory Harmonization: Revival of the Pharmaceutical Evaluation Report (PER) Scheme in Asia
RA2 CP  Prescription Drug Labeling: FDA’s New Regulation for the Content and Format of the USPI – One Year Later
RA3 CTM/CS  Clinical Trial Disclosure: Getting Ready for the Regulations
RD CTM/CS  Improvement in Japan’s Clinical Trial Environment: A Sponsor Company Perspective
ST EC  Statistical Computing Environments: Establishing the Need, Setting Forth Requirements
TR CR  Networking as a Personal Disaster Preparation Plan: Helping You Stay Up when the Sizing is Down
VA PM  Assessing and Auditing of Clinical Computerized Systems

Wednesday, June 20, 10:30 am-12:00 pm

AHC CR  Integrating Research and Clinical Care in Academic Health Centers
BT NC  Transition from Preclinical to Clinical Studies with Biopharmaceuticals
CDM EC  The Path to the Future: eCDM or No CDM
CMC/GMP RA  Challenges in Implementing ICH Q8 and Q9 Guidelines in Global Submissions
CP CDM  Using the FDA’s Adverse Event Reporting System (AERS) Quarterly Data Extracts
CR1 OS  Clinical R&D Outsourcing to India: What Do You Outsource to Whom?
CR2 CTM/CS  Actuarial Methods within Pharmacoeconomics and Clinical Trials
CR3 CP  Oversight of Research: Data Safety Monitoring Committees (DMC): A Systems Approach
CTM/CS CR  Becoming a Sponsor of Choice for Clinical Investigators
EC CDM  The Role of Electronic Data Capture in Adaptive Clinical Trials
ERS/DM RA  FDA Data Exchange Standards: Update
GCP CR  Virtual Realities: Quality Considerations when Using Outsource Providers
IT1 VA  GMP, GLP, GCP… Why Not GSP – Good Systems Practice?
IT2 VA  Deploying Life Science IT Using IEEE Methods
MA EC  Defining the Value of Pharmaceuticals
MC ERS/DM  The Emergent Role of the Medical Scientist in the Evidence-based Payer Environment: A Fundamental Source for Qualitative and Quantitative Information
MW RA  The “Other Documents” that Medical Writers Impact
NC CR  Drug-induced Liver Toxicity
Meeting Schedule

NHP CR Validating Botanicals for the Management of Diabetes Mellitus

OS CR The State of Clinical Outsourcing: Results from Avoca’s 2007 Industry Survey with a Focus on Change Orders – The Challenges, the Impact and the Effect on Relationships

PM1 CR Creating Dynamic Product Development Teams

PM2 CTM/CS Who is This Jack-of-all-trades: The Pharmaceutical R&D Project Manager?

PP RA BPCA Report Card

RA1 IT FDA’s Drug Establishment Registration and Drug Product Listing System

RA2 RD Global New Drug Development: Regulatory Challenges, Successes and Recommendations from a US-based Company

RA3 PP PMDA Challenges for Global Drug Development including Japan

RA4 CR Optimizing EU Regulatory Strategy

ST CP Statistical Methodologies for Safety Assessments

TR Podcasting, Interactive Simulations and On-demand Web Assistants: Delivering Your Courses via the Latest Technologies

VA IT Business Continuity and Disaster Recovery for Laboratory Systems and Potential Migration/Upgrade of GxP Applications: A Practical View

Wednesday, June 20, 1:30 pm-3:00 pm

AHC CR Producing Epidemiologic Data in Latin America through Registries: Collaboration between Academia and the Pharmaceutical Industry

BT CR Phase 0/Phase 1: Successful Transition to Clinical Supplies

CDM IT Overall Data Integrity Plans for Working with Data from Multiple Vendors

CMC/GCP RA Implementing CMC Quality-by-design (QbD) Strategies for Emerging Companies

CP RD The Use of Patient and Disease Registries for Product Life-cycle Management

CR1 IS Factors Influencing the Speed of Clinical Trial Study Completion

CR2 RD Managing the Placebo Response in Psychiatric Clinical Trials

CR3 ST The Use of Adaptive Design and Enrichment Designs to Speed Oncology Drug Development

CTM/CS TR Delivering Effective Feedback for Clinical Research Managers

ERS/DM1 CDM Content Management

ERS/DM2 RA How Public-private Partnerships Can Facilitate Electronic Regulatory Submissions

GCP TR Successful Implementation of a Quality Management System

IT1 CDM Standard Controlled Terminology: A Successful Partnership between CDISC, the FDA, and NCI Enterprise Vocabulary Services

IT2 VA Semantic Web Technologies in Drug Development

MA AD Lifestyle-based Analytics: A Revolutionary Marketing Approach

MC MA Approach, Design and Development of Medical Science Liaison Portal

MW CP Medical Writing for Risk Management and Pharmacovigilance

NC BT Preclinical Safety Assessment of Biopharmaceuticals – Part 1 of 2

NHP RA Global Regulation of Natural Health Products

OS PM Outsourcing Late-phase Studies: What to Do, What Not to Do and Why

PM Plenary Reinventing the Drug Development Paradigm

PP RA Update on Current Legal and Policy Developments in the US and EU

RA1 CR EMEA Guideline on Pharmaceuticals in the Environment (PfE)

RA2 IMP Imaging and Drug Development

RA3 BT Biosimilars in Europe


RA5 RD Postmarketing Commitments: Operational Issues and Public Perceptions

ST CR Strategies for Ethnic Comparison in Global Cooperative Clinical Trials

TR CR Practical Models for Training Clinical Research Monitors

VA IT Validation Quality and Costs: It’s All about the Risk

Wednesday, June 20, 3:30 pm-5:00 pm

AHC GCP Global Challenges with Bioethics in IRB’s Training

BT RA Similar (Comparable) Biological Medicinal Products: Scientific Challenges, Regulatory Positions and Experience to Date

CDM IT Clinical Data Management without a CDMS

CMC/GMP RA Updates on ICH Q8 (R) and Q10 Guidelines

CP CR Detecting Safety Signals in Clinical Trials

CR1 EC The Business Case for CDISC Standards: Implementation Approaches and Metrics

CR2 CDM The Country Study Manager Survey: Research Data Makes the Case for a New Approach

CR3 RA Global Clinical Trials and Polyethnic Patient Enrollment: Implications for Regulatory Approval of Marketing Applications

CTM/CS IS Understanding Clinical Trial Volunteer Experiences and Examining Financial Challenges of Investigative Sites

ERS/DM1 CDM eCTD Life-cycle Management for Authors

ERS/DM2 RA Introducing eCDR: A Technical Perspective

GCP CR The Uses of Technology to Improve Consent: What Are They and Are They Effective?

IT EC Evolving Technologies for Interoperability

MC TR Elevating Scientific Expertise via Formal Assessments
| NC  | BT   | Preclinical Safety Assessment of Biopharmaceuticals – Part 2 of 2 |
| NHP | PP   | Follow-on Products: Scientific, Legal, and Regulatory Topics that Impact Chemically Complex and Polymolecular New Drugs |
| OS  | CDM  | Functional Service Providers and the Next Stage of Evolution for Clinical Data Management |
| PM1 | RD   | Project Management as a University Research Tool |
| PM2 | TR   | Negotiation and Decision Making: The Art of Conflict Resolution |
| PP1 | RA   | New Paradigms of Drug Regulation |
| PP2 | IMP  | Access to Controlled Medications: Impact for Millions |
| RA1 | RD   | Challenges for Global Labeling: New FDA and European Requirements |
| RA2 | CMC/GMP | CMC Requirements and Considerations for Clinical Trials and Marketing Applications in China |
| RA3 | CR   | Compassionate Use Supply of Unlicensed Products in Europe and Beyond |
| RA5 | RD   | Biomarkers and Labeling: Critical Path – From Concept to Action |
| ST  | CR   | Early Successes with Adaptive Designs |
| TR  | CR   | Post-hire Assessment Pilot and Mapped Training Curriculum to Speed On-boarding Process |
| VA  | RA   | Current Regulatory Issues: SOX and Beyond? |

**Thursday, June 21, 10:30 am-12:00 pm**

| AHC | IS   | Clinical Trials from Sponsor Viewpoint and Strategies to Improve Contract Negotiations |
| BT  | CR   | The "OMICS" Initiative: Leveraging Genomics, Proteomics, and Metabolomics for Diagnostics Development |
| CDM | EC   | Independent Imaging/Medical Oncology Assessments: Planning for the Challenges |
| GCP | IS   | The Challenges of Auditing an Investigational Site Using Electronic Data Capture (EDC) |
| NC  | BT   | The Utility of Humanized Metabolic Mouse Models in Drug Development |
| NHP | CR   | Challenges and Solutions in Evaluation of Traditional Chinese Medicine |
| OS  | IS   | A Case Study of a Successful Functional Service Provider (FSP) Relationship: Outsourcing Study Start-up Responsibilities |
| PM  | CTM/CS | The Playing Field of Project Management: A Dynamic Investigation of a Team and their Winning Strategy |
| RA1 | CR   | CDER Town Meeting – Part 2 of 2 |
| RA2 | CR   | Phase 3: Are You Studying the Right Dose? |
| ST  | EC   | CDISC and Statisticians: Implications and Implementations |
| TR  | CR   | Searching PubMed®, Trade Secrets From Three, Four-Star Medical Library Scientists |
| VA  | IT   | Measurement of Quality: A Necessary Step |
Saturday, June 16 – Monday, June 18

**Saturday, June 16**

12:00 pm-1:00 pm  
**TUTORIAL REGISTRATION**  
Registration for Saturday tutorials ONLY  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

12:00 pm-5:00 pm  
**EXHIBITOR REGISTRATION**  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

**Sunday, June 17**

8:00 am-9:00 am  
**TUTORIAL REGISTRATION**  
Registration for Sunday morning or full-day tutorials ONLY  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

8:00 am-7:00 pm  
**EXHIBITOR REGISTRATION**  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

12:30 pm-1:00 pm  
**TUTORIAL REGISTRATION**  
Registration for Sunday afternoon tutorials ONLY  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

3:00 pm-7:00 pm  
**ATTENDEE REGISTRATION**  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

3:00 pm-7:00 pm  
**SPEAKER REGISTRATION**  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

4:00 pm-6:00 pm  
**EXHIBITS OPEN**  
Exhibit Hall, Building A, Level 1, GWCC

7:00 pm-9:00 pm  
**NETWORKING RECEPTION**  
Georgia Aquarium

**Monday, June 18**

7:30 am-6:00 pm  
**ATTENDEE REGISTRATION**  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

7:30 am-6:00 pm  
**EXHIBITOR REGISTRATION**  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

7:30 am-6:00 pm  
**SPEAKER REGISTRATION**  
Building A/B Registration Hall, International Boulevard at Philips Drive Entrance, GWCC

7:30 am-8:15 am  
**CONTINENTAL BREAKFAST**  
Thomas B. Murphy Ballroom Foyer, Building B, Level 5, GWCC

10:00 am-6:00 pm  
**STUDENTS’ POSTER SESSION**  
Enterance to Exhibit Hall, Building A, Level 3

10:00 am-6:00 pm  
**EXHIBITS OPEN**  
Exhibit Hall, Building A, Level 1, GWCC

5:00 pm - 6:00 pm  
**MONDAY RECEPTION**  
Exhibit Hall, Building A, Level 1, GWCC

8:30 am-10:00 am  
**Plenary Session**  
Thomas B. Murphy Ballroom, Building B, Level 5

**Welcome and Awards Presentation**

**Opening Remarks**

**Keynote Address**

10:00 am-10:30 am  
**REFRESHMENT BREAK**  
Building A – Exhibit Hall A Only  
Building B – Levels 3 & 4, Meeting Room Corridors

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 information, in any type of media, is prohibited at all DIA events 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**
  Session is appropriate for individuals new to the topic/subject area.

- **Primarily Intermediate Level Content**
  Session is appropriate for individuals who already have a basic understanding of the topic/subject area.

- **Primarily Advanced Level Content**
  Session is appropriate for individuals with an in-depth knowledge of the topic/subject area.

### SESSION 101
**AD - ADVERTISING, RA**
10:30 am-12:00 pm
Room A301
Pharmacy credits offered

**A Primer on Advertising Regulation**

**SESSION CHAIRPERSON(s)**
Janet L. (“Lucy”) Rose, MBA, PA-C
President, Lucy Rose and Associates, LLC

This interactive session will provide a basic introduction to the regulation of prescription drug advertising and promotion. The leaders will cover such important information as fair balance, required claim support, comparative claims, preapproval activities, and medical conventions.

**A Primer on Advertising Regulation**
Janet L. (“Lucy”) Rose, MBA, PA-C
President, Lucy Rose and Associates, LLC

### SESSION 102
**CP - CLINICAL SAFETY AND PHARMACOVIGILANCE, CR**
10:30 am-12:00 pm
Room A302
CME and Nursing credits offered

**Individual Case Safety Reports (ICSRs): Fostering Quality Data via Stimulation of Healthcare Professional Reporting, Active Query, Applied Clinical Expertise and Efficient Case Handling**

**SESSION CHAIRPERSON(s)**
Stephen A. Goldman, MD, DFAPA, FAPM
Managing Member, Stephen A. Goldman Consulting Services, LLC; Adjunct Assistant Professor of Psychiatry, Uniformed Services University of the Health Sciences

Data mining, interactive medical databases and active surveillance offer promising avenues to enhance safe use of marketed pharmaceuticals, and potential utility in premarking study. However, these advances are as dependent on high quality data for optimal use as traditional methods.

Experienced clinical research and drug safety personnel are critical to collecting such safety information as serious adverse event reports from clinical trial sites and subsequent postmarketing reports from healthcare professionals and consumers. Providing important data used in the ongoing evaluation of an agent’s benefit/risk profile, it is essential that reporter information be of the highest possible quality.

This is underscored in FDA’s 2003 proposed rule on drug and biologic safety reporting, in which an individual case safety report (ICSR) full data set in both pre- and postmarketing is to contain a “concise medical narrative of the case”, with “active query” by a healthcare professional required when data acquisi-
A Different Approach: The Clinical Network Model  
Lee S. Scheible, RPh  
Senior Medical Consultant, Eli Lilly and Company  
International Adaptation of Recruitment and Retention Programs to Maximize Trial Acceleration  
Elizabeth Carfioli  
Account Director, Fast4wD Ogilvy

**SESSION 104**  
**CR2 - CLINICAL RESEARCH AND DEVELOPMENT, GCP**  

10:30 am-12:00 pm  
Room B408  
**How to Work with Your IRB!**  
**SESSION CHAIRPERSON(S)**  
Louise N. Lisansky, MS  
President, LNL Clinical Research Consulting, Inc.  
Sponsors and investigators sites can be uncertain as to what documents need to be sent to the IRB for review and what to expect from their IRB. The session will focus on the perspectives of the IRB, sponsor, and investigator site as they pertain to expectations, issues, and challenges being faced.

**IRB Perspective: Is Anyone Listening?**  
Loren Ferro  
QA Analyst, Western Institutional Review Board

**Sponsor Perspective: Understanding, Control, and Support**  
Verena M. von Dehn, MBA, PMP  
Director, GCP Compliance, XenoPort, Inc.

**Investigator Site Perspective: Determining What to Send and When**  
Louise N. Lisansky, MS  
President, LNL Clinical Research Consulting, Inc.

**SESSION 105**  
**CR3 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS**  

10:30 am-12:00 pm  
Room B409  
**A Case Study: Challenges and Suggestions on Patient Recruitment and Retention**  
**SESSION CHAIRPERSON(S)**  
Jingyu Julia Luan, PhD  
Mathematical Statistician, CDER, FDA  
This session will focus on the experiences of a clinical study participant and an investigator who has successfully organized and conducted many clinical studies. Successful mechanisms of recruiting and retaining clinical study participants will be discussed.

**Challenges and Successes: Perspective from a Clinical Volunteer**  
Tammy Jeanne Massie, MS  
Mathematical Statistician, Office of Biostatistics and Epidemiology, CBER, FDA

**Overview of Successful Patient Recruitment and Retention**  
Jingyu Julia Luan, PhD  
Mathematical Statistician, CDER, FDA

**Patient Recruitment and Retention: Successes and Suggestions**  
Christine K. Pierre, RN  
President and Chief Executive Officer, Rx Trials, Inc.

**SESSION 106**  
**CR4 - CLINICAL RESEARCH AND DEVELOPMENT, RA**  

10:30 am-12:00 pm  
Room B407  
**Surrogate Endpoints in Cardiovascular Drug Development**  
**SESSION CHAIRPERSON(S)**  
Robert J. Temple, MD  
Associate Director for Medical Policy, CDER, FDA  
Atherosclerotic vascular disease is among the most frequent causes of death worldwide. It is the consequence of complex interactions between many pathogenic mechanisms including alterations in lipoprotein metabolism, fibrinolysis, coagulation, and vessel-wall structure. Surrogate measures for cardiovascular disease events have the potential to greatly increase the efficiency of clinical trials, thus speeding the access to potentially life-saving medicines. A number of initiatives aimed at identifying and validating early markers predicting clinical outcomes are ongoing. This session will review some of these initiatives and provide a constructive view from involved stakeholders (industry, academia and regulators) on the difficulties encountered in the development and validation of surrogates.

**Surrogate Markers in Cardiovascular Disease: An FDA Perspective**  
Robert J. Temple, MD  
Associate Director for Medical Policy, CDER, FDA

**Surrogate Markers in Cardiovascular Disease: An EU Perspective**  
Satish S. Singh, MD, FRCPC  
Senior Medical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**Surrogate Markers in Cardiovascular Disease: An Industry Perspective**  
James H. Revkin, MD  
Director, Cardiovascular and Metabolic Diseases, Pfizer Global Clinical Research and Development

**SESSION 107**  
**CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, CDM**  

10:30 am-12:00 pm  
Room B405  
**The Implementation of a CTMS System**  
**SESSION CHAIRPERSON(S)**  
Peter Bayer  
Clinical Data Manager, Novo Nordisk A/S, Denmark  
The session will cover implementation and rollout of a CTMS system, including technical issues and support, and organization including a review of processes. Strategies for implementation and how to identify success criteria will be discussed along with training and support issues.

**Rolling Out a CTMS Efficiently**  
Dorte Pedersen, RN  
Head of Section, Clinical Support, H. Lundbeck A/S, Denmark

**Integrating CTMS, CDMS and IVR to Provide a Single Source of Study Metrics**  
Richard A. Nelson, MS  
Vice President, Specialized Pharmaceutical Services, PharmaNet, Inc.

**CTMS: The CRO Challenges**  
Helen M. Lingard, PMP  
Director, IT Clinical Solutions, Quintiles, Inc.
Ready for the Audit?
Clinical Trial Registries and Results Databases: Are You
Room B406AB
Nursing credits offered
10:30 am-12:00 pm
LEVEL: ●
SESSION CHAIRPERSON (S)

Pamela A. Rose, BSN, RN
Director, Clinical Trial Information Registries R&D, TAP Pharmaceutical Products Inc.

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.

Panelists
Gary M. Gensinger, MBA
Director, Regulatory Review Support Staff, CDER, FDA

Bronwyn E. Collier, BSN, RN
Associate Director, Regulatory Affairs, Office of Drug Evaluation III, CDER, FDA

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

Norman R. Schmuff, PhD
Branch Chief, Division of Premarketing Assessment II, Office of New Drug Quality Assessment, CDER, FDA

Donovan F. Duggan, MBA
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

Finance Is from Mars, Clinical Development Is from Venus:
Financial Accruals and Forecasting
Room B301
10:30 am-12:00 pm
LEVEL: ●
SESSION CHAIRPERSON (S)

Chris Chan, MBA
Associate Director, Financial Planning and Analysis, Exelixis, Inc.

Learn how to generate and maintain clinical trials accruals and forecasts in a relatively pain-free manner. By understanding the major reasons behind these processes and utilizing effective modeling strategies, you can achieve an ongoing win-win collaboration with your accounting/finance department.

Financial Accruals and Forecasting from a Finance Perspective
Chris Chan, MBA
Associate Director, Financial Planning and Analysis, Exelixis, Inc.

Financial Accruals and Forecasting from a Clinical Development Perspective
Sarah V. Morrone
Director, Clinical Operations, CV Therapeutics, Inc.

The biopharmaceutical industry has used clinical trial registries and results databases as one way to increase clinical trial transparency and public trust. In the last few years, that clinical trial information has been posted on various public websites where there has been a slight change in public attitude; however, the public concern is that, although there has been an increase in the quantity of clinical trial information posted, how does the public know that the information is accurate? This session will examine one company’s experience with having their clinical trial registry and results database audited by an independent third party. Attendees will learn the results of the audit and lessons learned from the audit of both the registry and results database.

Preparing the Plan for Auditing Clinical Trial Registration and Results
John C. McKenney
Senior Vice President, SEC Associates Inc.

Preparation for the Audit of Clinical Trial Registration
Maureen A. Strange
Associate Medical Business Operations Consultant, CTR Initiated Gatekeeper, Eli Lilly and Company

Preparation for the Audit of Clinical Trial Results
Tracy J. Beck, PhD
Associate Consultant, Eli Lilly and Company

Next Generation Application Integration Using Web Services
Room A305
10:30 am-12:00 pm
LEVEL: ■
SESSION CHAIRPERSON (S)

Kimberly Sierk
Product Manager, United BioSource Corporation

As next generation IVRS/EDC applications are being developed and deployed using the latest web service features, integration between clinical data systems has greater potential for real-time data synchronization. Integration is more about interaction between systems rather than simple data sharing.

Effectively Using Web Services to Close the Loop on the Supply Chain
Timothy Elliott
President, Clinapps, Inc.

When Sponsors Sue Sites: A Real-life Case History
Room B303
10:30 am-12:00 pm
LEVEL: ■
SESSION CHAIRPERSON (S)

David M. Vulcano, MBA, MSW, CIP
Director, Clinical Trials, Psychiatric Solutions, Inc.

This session will follow the course of a real-life lawsuit successfully filed by a sponsor against an investigative site. What started out as a small pilot study with a 200k budget exploded into a multimillion dollar litigation involving allegations of fraud, misrepresentation, breach of contract, lost profits and much more. The session will review the case as it unfolded from the original allegations, went to trial, appeals court and applied for state supreme court hearing. Documents from the case will be reviewed as well as scripts from the testimonials.

Legal Issues
J. Andrew Lemons, JD
Attorney at Law, Baker, Donelson, Bearman, Caldwell & Berkowitz PC

Overview and Conclusion
David M. Vulcano, MBA, MSW, CIP
Director, Clinical Trials, Psychiatric Solutions, Inc.

Next Generation Application Integration Using Web Services
Room A305
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Next Gen Application Integration Using Web Services
Kimberly Sierk
Product Manager, United BioSource Corporation

Extending the Supply Chain through Seamless Integration
Vikram Marla, MS
Chief Technology Officer, Aptuit Inc.

SESSION 113  MW - MEDICAL/SCIENTIFIC WRITING, ERS/DM
10:30 am-12:00 pm  LEVEL: ■
Room A315

Submitting an IND in eCTD Format: Lessons Learned
SESSION CHAIRPERSON(s)
Peggy M. Boe, RN
Director, Professional Services and Medical Writing, Image Solutions, Inc.

This session will help members of the pharmaceutical and biotechnology industries understand how and why sponsors are now submitting IND applications in the eCTD format. Speakers will present an historical perspective, a case study of a submission and best practice tips on medical writing for life-cycle management.

Submitting INDs in eCTD Format: What’s the Next Step?
Michael Brennan, PhD
Vice President, Global Regulatory Operations, Centocor, Inc.

Submitting an IND in eCTD Format to CDER: Determining Appropriate Placement of Clinical Information
Sandra J. Hecker, RAC
President, Hecker and Associates, LLC

Challenges in Submitting an IND in eCTD Format to CBER for the First Time
Kenny Seaver, MS
Manager, Regulatory Affairs, Solvay Pharmaceuticals

SESSION 114  OS - OUTSOURCING, CR
10:30 am-12:00 pm  LEVEL: ◆
Room B401

Lessons Learned: A Nonconfrontational Technique to Improve Sponsor-provider Team Performance – Part 1 of 2
SESSION CHAIRPERSON(s)
John R. Vogel, PhD
Drug Development Consultant, John R. Vogel Associates Inc.

Part 2 of this session will take place on Monday at 1:30 pm.

This will be a two-part session. In Part 1 (Monday at 10:30 am) the panel will describe a lessons learned process and review the results of a lessons learned performed between a sponsor and a vendor. At the end of Part 1 attendees will actually participate in a lessons learned process by using a dial-up toll free number to answer questions about their most recent sponsor/vendor experience. Part 2 will be held Monday at 1:30 pm. The results from the Part 1 audience participation will be reviewed as part of a lessons learned meeting. The survey results will be used to discuss better ways to design and manage outsourced projects.

Larry A. Blankstein, PhD
Senior Director, Clinical Research, Genzyme Corporation
Ronny K. Schnel, MA
Executive Director, Business Development and Client Services, Criterium, Inc.

SESSION 115  PM1 - PROJECT MANAGEMENT, CTM/CS
10:30 am-12:00 pm  LEVEL: ●
Room B403  Project Management units offered

Applying Six Sigma Methodology
SESSION CHAIRPERSON(s)
Louise Doll, MS
Associate Director, Merck & Co., Inc.

Six Sigma methodologies enable breakthrough improvements to product quality, cycle time, customer satisfaction and ultimately a company’s profit margin. This interactive session is designed to present what Six Sigma means to the non-Six Sigma professional.

What is Lean Six Sigma?
Rajesh Kuppuswamy, PhD
Management Consultant, Capgemini

Six Sigma within the Pharma/Biotech Industry
Christopher Perth Beganski, MSc
Manager, Continuous Improvement, Alkermes, Inc.

Six Sigma Outside Pharma Industry Example: What Can Be Learned?
Gerald Jackson
Senior Manager, Operational Excellence, Accenture

SESSION 116  PM2 - PROJECT MANAGEMENT, RD
10:30 am-12:00 pm  LEVEL: ◆
Room B402  Project Management units offered

Evolving Operational Models in the Pharmaceutical Industry: Project Management Perspective
SESSION CHAIRPERSON(s)
Surya P. Chitra, PhD, MBA
Principal Consultant, Savio Technologies - Health Solutions

The pharmaceutical industry is unraveling the business and operational models across the value chain to create a new industry picture. The current operational model of vertical integration from the laboratory to the pharmacy is more of an art than science in managing the drug development process. Project management and the drug development strategies play a vital role in the current challenging pharmaceutical environment. Senior managers need a short, coherent list of initiatives to mobilize the organization, tell outside stakeholders where the company is headed, and reach the next industry playing field before the industry business model shifts again. The session presents different perspectives from various industry leaders on how to address these challenges and take advantage of the opportunities for growth.

Case Study: Implementing the Learn and Confirm Paradigm of Clinical Development
Mathew Bell, PhD
Senior Director, Wyeth Research

Novel Delivery Solutions for Clinical Development
Mary P. Callahan-Squire
Executive Director, Project Management, AstraZeneca

Leveraging FDA Initiatives to Support New Operational Models
Ajaz S. Hussain, PhD
Vice President and Global Head, Biopharmaceutical Development, Sandoz

SESSION 117  PP - PUBLIC POLICY/LAW, IMP
10:30 am-12:00 pm  LEVEL: ■
Room A410  CME and Pharmacy credits offered

Personalized Medicine: A Perspective Beyond Science
SESSION CHAIRPERSON(s)
Felix W. Frueh, PhD
Associate Director, Genomics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA
Personalized medicine is a field that depends on good science, as well as on societal, legal and financial aspects, among others. We will take a look at the issues beyond the science and focus on public policy, evidence-based reimbursement, and other issues that have surfaced over the last 12 months.

**Personalized Medicine: The Future May Be Closer than You Think**

**Geoffrey S. Ginsburg, MD**

Founding Member, Personalized Medicine Coalition

**A Legislative View on Personalized Medicine: The Genomics and Personalized Medicine Act**

**Dora L. Hughes, MD, MPH**

Legislative Assistant, Senator Barack Obama’s Office, US Senate

**The Road to Reimbursement: Evidence-based Decision Making in Personalized Medicine**

**Joanne Armstrong, MD, MPH**

Regional Medical Director, Women’s Health, Aetna US Healthcare

**Panel Discussion – Personalized Medicine: The View Beyond Science**

**Lawrence J. Lesko, PhD**

Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA

**SESSION 118 RA1 - REGULATORY AFFAIRS, RD**

10:30 am-12:00 pm LEVEL: ■

Room A402

**Nanomedicine: The Way Forward**

SESSION CHAIRPERSON(S)

**Robert A. Paarberg, MS**

Director, Global Regulatory Policy and Intelligence, UCB, Inc.

Nanotechnology holds a significant promise for the design, manufacture and delivery of many types of novel medical products. The application of nanotechnology has been identified by both FDA in the Critical Path Initiative and in the European Technology Platform. This session will discuss critical issues in both the US and EU necessary to provide an environment to accelerate the development and translation of nanotechnology into providing treatments for serious diseases.

**Nanotechnology: An FDA Perspective**

**Nakissa Sadrieh, PhD**

Associate Director, Research Policy and Implementation, Office of Pharmaceutical Science, CDER, FDA

**Nanotechnology for Targeted Cancer Therapy: Promises for Improving Efficacy and Reducing Toxicity**

**Shuming Nie, PhD**

Professor, Biomedical Engineering, Emory University

**NanoMedicine: The European Approach**

**Laurent Bochereau, DrSc, MS**

Head, Science Technology and Education, Delegation of the European Commission

**SESSION 119 RA2 - REGULATORY AFFAIRS, ERS/DM**

10:30 am-12:00 pm LEVEL: ●

Room A404

**Best Practices for Addressing Pharmaceutical Multilingual XML Requirements**

SESSION CHAIRPERSON(S)

**Matthias Heyn, MA**

Vice President, EMEA Solutions, SDL International, Belgium

Regulatory authorities are demanding information in local languages while industry leaders are challenged to meet EMEA’s Central Procedure milestones. This session looks at best practices and technologies (authoring, CMS, translation, publishing) needed to address corporate initiatives for multilingual XML requirements.

**Multilingual XML Capabilities: Interfacing with PIM**

**Matthias Heyn, MA**

Vice President, EMEA Solutions, SDL International, Belgium

**The Challenges of Making PIM Submissions in the Centralized Procedure in Europe**

**Andrew P. Marr, PhD**

Director, eRegulatory Development, Global Regulatory Operations, GlaxoSmithKline, UK

**Enabling Global Content Reuse with Structured Content and XML**

**Andrew Glemser**

Chief Technology Officer, Glemser Technologies

**SESSION 120 RA3 - REGULATORY AFFAIRS, RD**

10:30 am-12:00 pm LEVEL: ■

Room A406

**CME and Pharmacy credits offered**

**Development of Oncology Products in the EU and US: Can It Be Better and Faster?**

SESSION CHAIRPERSON(S)

**Ionel Mitrica, PhD, RAC**

Clinical Development, Oncology MDC, GlaxoSmithKline

It is apparent that the scientific advances of the last decade have not been quickly converted into innovative pharmaceutical products. This session will attempt a comparative review of regulatory experience and future plans for facilitating the development of oncology products in the EU and US.

**Accelerating Oncology Product Development in the US**

**Grant A. Williams, MD**

Clinical Development, GlaxoSmithKline

**Accelerating Oncology Product Development in the EU**

**Francesco Pignatti, MD**

Scientific Administrator, Safety and Efficacy of Medicines, Preauthorization Evaluation of Medicines for Human Use Unit, EMEA, EU

**Development of Oncology Products in the EU and US: Can It Be Better and Faster?**

**Ionel Mitrica, PhD, RAC**

Clinical Development, Oncology MDC, GlaxoSmithKline

**SESSION 121 RA4 - REGULATORY AFFAIRS, CR**

10:30 am-12:00 pm LEVEL: ●

Room A405

**Nursing credits offered**

**Running Clinical Trials in Latin America: A Review of the Regulatory Framework in Argentina, Brazil, and Mexico**

SESSION CHAIRPERSON(S)

**Manuel Fresno, MBA**

Vice President, Clinical Operations, Canada and Latin America, ICON Clinical Research

The regulatory environment of Latin America has improved in recent years and increasingly operates in accordance with international standards and guidelines. This session will review the regulatory approval process in Argentina, Brazil, and Mexico as well as provide recommendations to companies conducting the trials.

**Clinical Trials in Argentina: Ten Years of Experience**

**Analia Cristina Perez, MD**

Director of Drug Evaluation, ANMAT Ministry of Health, Argentina

**Regulatory Framework for Clinical Trials in Brazil**

**Granville Garcia de Oliveira, MD, PhD, FCP**

Clinical Trials and New Drugs Office Manager, ANVISA (National Agency of Sanitary Surveillance), Brazil
Regulatory Framework for Clinical Trials in Mexico
Matilde Damian, MD, Dr Med
Director, Clinical Research, Mexico and Central America, Bristol-Myers Squibb Company, Mexico

**SESSION 122**  RA5 - REGULATORY AFFAIRS, CR
10:30 am-12:00 pm  LEVEL: ■
Room A411

New Pediatric Legislation in the EU
SESSION CHAIRPERSON(s)
Patrick Le Courtois, MD
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

Peter Arlett, Dr Med, MRCP
Principal Administrator, Pharmaceuticals Unit, DG Enterprise and Industry, European Commission, EU

This session will provide a broad overview of the key measures in the EU pediatric regulation and summarize the priorities for implementation of the regulation from the perspective of the European Commission and of the EMEA. Similarities and differences between the US and EU legislation and consequences for companies developing products for children will be addressed.

Key Measures and Priorities for Implementation
Peter Arlett, Dr Med, MRCP
Principal Administrator, Pharmaceuticals Unit, DG Enterprise and Industry, European Commission, EU

Implementation by EMEA
Agnès Saint Raymond, MD, PhD
Head of Sector, Scientific Advice and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

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

**SESSION 123**  RA6 - REGULATORY AFFAIRS, CR
10:30 am-12:00 pm  LEVEL: ■
Room A311

Update from China: CDE Drug Review Process
SESSION CHAIRPERSON(s)
Ling Su, PhD
Director, Medical and Pharmaceutical Development, Shanghai Roche Pharmaceuticals, Ltd., China

Yuguang Wang, PhD
Senior Principal Scientist, Schering-Plough Research Institute

This session will provide an update on the drug review process in the Center for Drug Evaluation, SFDA, China. Detailed description of the review meeting system and procedures will be discussed.

The Meeting System in the Drug Technical Evaluation
Xianglin Zhang
Director-General, Center for Drug Evaluation, State Food and Drug Administration (SFDA), China

Panelists
Dong Lv
Section Chief, Evaluation III Division, Center for Drug Evaluation, State Food and Drug Administration (SFDA), China

Cai Cao
Deputy Director-General, Drug Certification Center, State Food and Drug Administration (SFDA), China

**SESSION 124**  RD - R&D STRATEGY, CR
10:30 am-12:00 pm  LEVEL: ■
Room B305

Experimenting with Clinical R&D Management Metrics Using the Latest Computer Technology
SESSION CHAIRPERSON(s)
Michael Van der Burght, MD, MBA
Director, Ferring Pharmaceuticals, Denmark

This session evaluates the IT systems and the key performance indicators (KPIs) which effectively contribute to optimizing the balance between speed, quality, and price of clinical trials. A case story of one company who introduced an experimental and challenging, quality KPI and immediately linked it to a bonus/penalty system will be presented. Hear how this choice induced challenges to the organization and the CROs to whom the method was applied. Last, a case story will be presented of what happens when good KPI principles are violated.

Consequences of Violating Good KPI Practice: A Case Story
Michael Van der Burght, MD, MBA
Director, Ferring Pharmaceuticals, Denmark

Herding Cats and Clinical R&D IT Systems
Ravin K. Warna
Vice President, Business Operations, Averion International Corp.

Experimenting with New Ways of Measuring Clinical Data Quality
Martin Nottmeier, MPharm
Clinical Project Manager, International Medical Affairs, Nycomed, Denmark

**SESSION 125**  ST - STATISTICS, CR
10:30 am-12:00 pm  LEVEL: ■
Room B309

Adaptive Designs: Dealing with Practical Problems
SESSION CHAIRPERSON(s)
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, CDER, FDA

Armin Koch
Biostatistician, BfArM, Germany

Adaptive designs in late development pose challenging new problems on those who plan and assess confirmatory clinical trials. Among these are control of information flow and the question, who should be allowed to have access to which information and the assessment of change, if design modifications are introduced into a trial.

Introduction: Who Should Be Allowed to Know What – Monitoring Infrastructure with Adaptive Design
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, CDER, FDA

Control of Information Flow from a CRO Perspective
Zoran Antonijevic, MSc
Senior Director, Strategic Development, Biostatistics, Quintiles

Trial Integrity in an Adaptive Confirmatory Study
Michael Wolf, MS
Director, Biostatistics, Amgen Inc.

Panel Discussion: Statistical Assessment of Change within Adaptive Trials
Paul P. Gallo, PhD
Director, Biostatistics, Novartis Pharmaceuticals Corporation
SESSION 126  TR1 - TRAINING, CR
10:30 am-12:00 pm  LEVEL: ●
Room B306
Pharmacy credits offered

A Blended Learning Approach to Establishing a Global Standards and Practices Program for Clinical Study Documentation
SESSION CHAIRPERSON(s)
Valerie J. Gamble, EdD
Global Training Lead, Pfizer Inc

This session will focus on the design, development, and rollout of a global blended learning solution for protocol synopsis, protocol, informed consent and study report writing, including an internal analysis of work products, processes, systems, and team roles to create a more effective documentation process.

Quality Analysis, Challenges, and Global Standards
Marie-Christine Poisson-Carvajal
Associate Director, SOPs, Training, and Processes, Pfizer Inc

Four-tier Competency Model: Training Strategy for Operational Excellence
Robert Miller, MBA
Vice President, Working Words Inc.

Critical Documents for Clinical Trials within the Business Context
Curtisy Briggs
President, Working Words Inc.

SESSION 127  TR2 - TRAINING, CR
10:30 am-12:00 pm  LEVEL: ●
Room B308

Self-guided Mentoring Program Administered by Training
SESSION CHAIRPERSON(s)
Julia A. Dillon, PharmD
Associate Scientific Communications Consultant (Training), Eli Lilly and Company

Self-guided mentoring is a career enrichment process in which an individual identifies professional strengths and possible next career steps and then self-selects a mentor. Training teams can provide support and structure to the program.

Coordinating a Self-guided Mentoring Program
Julia A. Dillon, PharmD
Associate Scientific Communications Consultant (Training), Eli Lilly and Company

Mentoring for Success: One Size Doesn’t Fit All
Karen VanKampen, CPT
Manager, PRA Institute, PRA International, Inc.

12:00 pm-1:30 pm  LUNCHEON
Building A – Exhibit Hall A Only

SESSION 128  AD - ADVERTISING, RA
1:30 pm-3:00 pm  LEVEL: ■
Room A301
Pharmacy credits offered

How Fraud and Abuse Cases Are Changing the Corporate Landscape
SESSION CHAIRPERSON(s)
Marc J. Scheineson, JD, LLM
Partner, Alston & Bird, LLP

Fraud and abuse cases have cost the pharmaceutical industry billions of dollars and have changed how companies conduct their marketing programs. This session will examine how the cases have impacted companies and what to expect for the future.

Panelists
Marc J. Scheineson, JD, LLM
Partner, Alston & Bird, LLP
Paul M. Johnson, Esq.
Senior Counsel, Amgen Inc.
Jacqueline C. Baratian, Esq.
Counsel, Alston & Bird, LLP

SESSION 129  CDM - CLINICAL DATA MANAGEMENT, EC
1:30 pm-3:00 pm  LEVEL: ●
Room A312

Case Studies on Time-critical Data Access Using Phase 1 EDC Programs by a Sponsor, Site and Software Provider
SESSION CHAIRPERSON(s)
Rajiv Prasad, MBA
Assistant Vice President, Life Sciences, Satyam Computer Services

Integrate phase 1 EDC technology to get real-time data and analysis to make critical, time-sensitive dose escalation and go/no go decisions to save time and money. Recognize the infrastructure and software needed to support the phase 1 EDC environment. Case studies from sponsors, CRO/sites and CSOs will be presented.

Case Study: Sponsor’s Perspective of Phase 1 EDC for Time-critical Data Access
Michael Goedde
Associate Director, Data Management, Kos Pharmaceuticals (a Subsidiary of Abbott)

Case Study: CRO Site Perspective of Phase 1 EDC for Time-critical Data Access
Yolanda P. Davis
Clinical Data Manager, Comprehensive Phase One

Case Study: Software Needs for Phase 1 EDC for Time-critical Data Access
Christopher Huang, MS
Director of Product Strategy, OmniComm Systems

SESSION 130  CP1 - CLINICAL SAFETY AND PHARMACOVIGILANCE, RD
1:30 pm-3:00 pm  LEVEL: ■
Room A314
CME credits offered

Selection, Implementation and Validation of Vendor Safety Systems
SESSION CHAIRPERSON(s)
A. Michael Bloh, MBA, RPh
Principal, Drug Safety Net LLC
John Whitebrook, PhD
Vice President, Pharmaceutical Practice/UK Country Manager, Intrasphere Technologies Ltd., UK

This session will discuss the implementation, validation and deployment of a vendor-based computerized adverse event safety system. This includes the decision process, selection of the foundation database package, selection of peripheral software (e.g. electronic submission, tracking, signal detection). The nuances of validation and regulatory compliance will round out the session. A panel discussion will follow featuring the presenters and invited industry experts.
We are witnessing the personalization of drug development as a platform for personalized medicine and as a new way of approaching the challenge of demonstrating that investigational drugs are effective and safe in predefined patient subsets – at the interface of science, therapeutics and regulation.

Speakers will include scientists, investigators, regulators and industry specialists; the common focus will be on the need to think outside the box and on the progress that is beginning to be made to address unmet medical needs in a more targeted and personalized way.

The Roles and Challenges of Microarrays in Personalizing Care
Noel Doheny
Senior Vice President, Molecular Diagnostics, Affymetrix, Inc.

A Pharmacogenetic Test for a Rare Serious Adverse Event: Applying Lessons Learned to Postapproval Surveillance
Carol R. Reed, MD, FACC, FACP
Senior Vice President and Chief Medical Officer, Clinical Data, Inc.

Personalized Medicine and Predicting Response to Antiglycemic Agents: Thiazolidinediones, Metformin and Glyburide
Aram Adourian, PhD
Chair, Genomics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

SESSION 131 CP2 - CLINICAL SAFETY AND PHARMACOVIGILANCE, CR
1:30 pm-3:00 pm LEVEL: ■
Room A302
Clinical Safety Risk Management in Preapproval Drug Development
SESSION CHAIRPERSON(s)
Craig Hartford, MD, PhD, MSc
Executive Director, Pfizer Inc, UK

A proactive drug safety risk management system early in drug development programs is desirable and encouraged by regulatory and other bodies, such as CIOMS, ICH, EMEA and FDA. This session will aim to describe a model of safety review teams for implementing preapproval safety risk management on drug development projects and thereby to utilize safety reviews, epidemiology and other medical sciences toward preapproval risk management strategies and periapproval risk management plans. In addition, an explanation of the principles behind, and structure of, potential safety review teams and the role of epidemiology in preapproval drug safety risk management leading up to periapproval risk management plans will be discussed.

Principles Behind, and Structure of, Safety Review Teams
Craig Hartford, MD, PhD, MSc
Executive Director, Pfizer Inc, UK

Role of Epidemiology in Preapproval Drug Safety Risk Management
Yola Moride, PhD, FISPE
Associate Professor, Faculty of Pharmacy, University of Montreal, Canada

Challenges to Pre-/periapproval Risk Management Plans
Valerie E. Simmons, MD, FFFPM
Director, EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

SESSION 132 CR1 - CLINICAL RESEARCH AND DEVELOPMENT, RA
1:30 pm-3:00 pm LEVEL: ■
Room B407
Personalized Medicine and Personalized Drug Development: Case Studies and Progress to Date – Part 1 of 2
SESSION CHAIRPERSON(s)
Alberto Grignolo, PhD
Corporate Vice President and General Manager, Drug Development Consulting Practice, PAREXEL Consulting

Part 2 of this session will take place on Monday at 3:30 pm.

The concept of personalized medicine is taking stronger hold thanks to scientific advances as well as to the focus on biomarkers and pharmacogenomics promoted by FDA’s Critical Path Initiative, which challenges the drug development community to devise new ways to both accelerate and target the discovery and application of novel therapeutics to patients in all therapeutic areas.

While skepticism exists regarding the speed at which progress will be made in the personalization of medicine, advances are quietly being made in the research and development communities and even in that presumed roadblock to niche drugs – the large pharmaceutical companies. The well-known examples of Herceptin and Gleevec are now old but they have proved the concept that drugs can be successfully targeted at predefined populations. Additional examples exist that demonstrate the success of fresh approaches such as targeting a drug at prespecified subpopulations, saving drugs from near-certain death, using genotyping to customize and accelerate a clinical program, and more.

We are witnessing the personalization of drug development as a platform for personalized medicine and as a new way of approaching the challenge of demonstrating that investigational drugs are effective and safe in predefined patient subsets – at the interface of science, therapeutics and regulation.

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Personalized Medicine and Predicting Response to Antiglycemic Agents: Thiazolidinediones, Metformin and Glyburide
Aram Adourian, PhD
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1:30 pm-3:00 pm LEVEL: ■
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1:30 pm-3:00 pm LEVEL: ■
Room B407
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Aram Adourian, PhD
Chair, Genomics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

SESSION 133 CR2 - CLINICAL RESEARCH AND DEVELOPMENT, PM
1:30 pm-3:00 pm LEVEL: ■
Room B408
Targeted Site Start-up Support Strategy in Clinical Research
SESSION CHAIRPERSON(s)
Rita Viegas
Clinical Trials Advisor, IRX Therapeutics

Industry data has shown that research sites that start their trials quickly are the most productive enrollers and have high-quality data. The site start-up support strategy described in this session was used to reduce timeline metrics and has shown dramatic improvement in starting clinical trials.

Applying Project Management to Site Start-up
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group

Targeted Site Start-up Support Strategy in Clinical Research: Case Studies
Rita Viegas
Clinical Trials Advisor, IRX Therapeutics

Large Pharma: Study Start-up Challenges and Strategic Mitigation
Kimberly S. Mishelson, BSN, RN
Director, Clinical Research Services, Amgen Inc.
India: Important Player in Clinical Trials Arena
Arun D. Bhatt, MD
President, Clinvet Research Pvt Ltd., India

Asia Pacific: Important Region in Clinical Trials
Akihiro Shimosaka, PhD
Director, EPS Co. Ltd., Japan

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**Session 134**  
**CR3 - Clinical Research and Development, CP**  
1:30 pm-3:00 pm  
**Room B409**  
**CME credits offered**  

Patient Adherence in Clinical Trials: Opportunities to Transform Development  
**SESSION CHAIRPERSON(s)**  
Craig H. Lipset, MPH  
Director, Human Health Technology, Pfizer Inc

Patient compliance (adherence) to long-term therapy is emerging as a critical challenge across the drug development and commercial continuum. Published adherence rates in clinical trials for chronic conditions range from 43% to 78%. Implications of poorly characterized patient adherence in clinical trials affect interpretation of PK, dosing, efficacy, and safety. Opportunities exist for new technologies to improve our understanding of patient adherence in clinical trials, as well as to favorably influence adherence. Proper application of novel adherence data provides the opportunity to transform critical aspects of the drug development process.

**State of Adherence in Clinical Trials**  
**John Urquhart, MD**  
Professor, Biopharmaceutical Science, Center for Drug Development Science, University of California San Francisco; Chief Scientist, AARDEX Ltd., Switzerland

**Opportunities to Transform Clinical Trials**  
**Carl C. Peck, MD**  
Adjunct Professor, Center for Drug Development Science, School of Pharmacy, Department of Biopharmaceutical Sciences, University of California San Francisco

**Applying Technology to Monitor and Influence Adherence**  
**Craig H. Lipset, MPH**  
Director, Human Health Technology, Pfizer Inc

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**Session 135**  
**CTM-CS - Clinical Trial Management/ Clinical Supplies, CR**  
1:30 pm-3:00 pm  
**Room B405**

Clinical Trials in Asia Pacific: Advantages and Challenges  
**SESSION CHAIRPERSON(s)**  
Greg Voinov, MD  
Vice President, Clinical Operations, ICON Clinical Research, SARL, France

The health care environment of Asia Pacific offers great opportunities and facilities for drug development. Pharmaceutical companies have realized that performing clinical trials in Asia is very attractive due to numerous advantages, e.g., large homogeneous patient populations, good quality data, competitive costs. After more than 15 years of clinical research in Central and Eastern European countries, the market for clinical trials started to be saturated in some of these first country players. New regions are emerging now in the world of clinical trials with big advantages in terms of patient recruitment but also some challenges (regulatory approvals, customs issues, logistic problems). A major attraction for pharmaceutical companies is Asia’s huge population, more than 2.4 billion between China and India alone. Asian patient population also represents a big advantage for clinical trials due to a large percentage of naïve treatment patients, high motivation of patients to participate in clinical trials (anxious to try latest treatments, reduced treatment costs, closer medical follow-up and significantly better overall medical care) and high level of treatment compliance. Consequently, in recent years, many sponsors have transferred an important part of their clinical research to the Asia Pacific region.

**China: Emerging Country for Clinical Trials**  
**Grace Y. C. Pei, MD**  
Director, RxCON Consulting Pty Ltd., Australia
SESSION 138  GCP - GOOD CLINICAL PRACTICES, CR
1:30 pm-3:00 pm  LEVEL: ■
Room B406
Conducting Effective CAPA Following an Audit
SESSION CHAIRPERSON(S)
Barbara Schnurr, PhD, MA
Director, Quality Management, Harrison Clinical Research, Germany
The session will present theoretical and practical aspects of corrective action/preventative action procedures and discuss strategies to implement, control, and formally close out postaudit CAPA. The follow-up process will be examined from the audited site, auditor and audit client perspectives.
Corrective and Preventative Actions: Theoretical and Practical Aspects
Valerie Willetts, BSN, RN
President, ASKA Research, a Division of Valerie Willetts & Associates Inc, Canada
How to Achieve and Maintain Compliance: A Site Perspective
Yvonne P. McCracken, MPH
President and Chief Executive Officer, Carolinas Research Associates
How to Achieve and Maintain Compliance: An Auditor and Audit Client Perspective
Barbara Schnurr, PhD, MA
Director, Quality Management, Harrison Clinical Research, Germany

SESSION 139  IS - INVESTIGATOR SITES, CTM/CS
1:30 pm-3:00 pm  LEVEL: ■
Room B303  Pharmacy credits offered
Investigator Budgets and Reimbursement: The Impact on Patient Enrollment and Retention Objectives
SESSION CHAIRPERSON(S)
Daniel M. Ulrey, MBA
President and Chief Executive Officer, Midwest Clinical Support, Inc.
The session addresses the impact investigator reimbursement has on study patient enrollment and retention objectives, as well as site profitability. It will also address sponsors processes, legal and FDA considerations regarding establishing contracts and budgets for independent for-profit sites.
A Multispecialty Site Perspective
Jeffrey M. Adelglass, MD
Chief Executive Officer, Research Across America
A Pharma Perspective
Rhoda Mull, JD
Clinical Agreement Manager, Clinical Agreement and Grant Management, AstraZeneca
A Big Pharma Perspective
Scott P. Jensen, MBA
Manager, Global Clinical Contracts and Grants, Eli Lilly and Company

SESSION 140  IT - INFORMATION TECHNOLOGY, CDM
1:30 pm-3:00 pm  LEVEL: ●
Room A305
Clinical Data Warehouse: Approaches and Pitfalls
SESSION CHAIRPERSON(S)
Ralph Bagley
Associate Director, Project Development Services, Genzyme Corporation
Clinical data warehouse (CDW) is quickly becoming a necessity in transforming complex clinical trial data into useful information for analysis and reporting. This session identifies the major CDW issues in a realistic pro-versus-con discussion aimed at helping you determine the best approach for your organization.
Working with Consulting Vendors
Stuart Henderson
Life Sciences R&D Leader, Global Business Services, IBM Corporation
CDW Data Modeling and Governance
Shiby Thomas, PhD, MBA
Director, Enterprise Analytics and Integration, Boston Medical Center
Cost Planning and Scheduling
Eyal Wultz
Associate Director, Informatics, Millennium Pharmaceuticals, Inc.

SESSION 141  MW - MEDICAL/SCIENTIFIC WRITING, EC
1:30 pm-3:00 pm  LEVEL: ■
Room A315
The Document Family Tree: A Genealogy of the HL7/CDISC Protocol Standard
SESSION CHAIRPERSON(S)
Arthur Gertel, MS
Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.
The seminal document in the process of bringing products from molecule to medicine is the study protocol. From the viewpoint of the medical writer, it is the protocol that provides the critical information for use in preparing virtually all of the documents associated with a clinical research project. HL7/CDISC have undertaken a multifaceted project to create common terminology, data structure, and protocol elements. The standardization and the ability to maintain consistency across sources of information will enhance the common understanding of terms, contribute to efficiency of information transfer, and provide an authoritative resource for training new members of the R&D community. The panel will comprise members of the HL7/CDISC committees, representing the glossary, protocol development, BRIDG, PR, AdAM, and SDTM efforts. The current status of the glossary, protocol model, and the development of machine- and human-readable formats will be discussed.
The Role of Natural Language in Interoperability Models
Stephen A. Raymond, PhD
Chief Scientific Officer and Quality Officer, PHT Corporation
Consistency in Terminology: The Clinical Trial Glossary as Common Ground
Arthur Gertel, MS
Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.
The Document Family Tree: A Genealogy of the Protocol Standard
Helle Gawrylewski, MA
Director, Medical Writing, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Mapping the Clinical Protocol: Getting from Here to There
Joel Hoffman, PhD
European Director, Life Sciences, Insightful AG, Switzerland
**Session 142**  
OS - Outsourcing, CR  
1:30 pm-3:00 pm  
Room B401  

**Lessons Learned: A Nonconfrontational Technique to Improve Sponsor-provider Team Performance – Part 2 of 2**  
SESSION CHAIRPERSON(s)  
John R. Vogel, PhD  
Drug Development Consultant, John R. Vogel Associates Inc.  

Part 1 of this session will take place on Monday at 10:30 am.  
This is Part 2 of a two-part session. Part 1 (Monday at 10:30 am) described a lessons learned process and reviewed the results of a lessons learned performed between a sponsor and a vendor. At the end of Part 1 attendees participated in a lessons learned process by using a dial-up toll-free number to answer questions about their most recent sponsor/vendor experience. In this session the results from the Part 1 audience participation will be reviewed as part of a lessons learned meeting. The survey results will be used to discuss better ways to design and manage outsourced projects.

Larry A. Blankstein, PhD  
Senior Director, Clinical Research, Genzyme Corporation  

Ronny K. Scheln, MA  
Executive Director, Business Development and Client Services, Criterion, Inc.

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**Session 143**  
PM1 - Project Management, RD  
1:30 pm-3:00 pm  
Room B403  

**Utilization of Six Sigma Methodology in a Research and Development Setting**  
SESSION CHAIRPERSON(s)  
Martin D. Hynes, Ill, PhD  
Director, Six Sigma Champion Product Research & Development, Eli Lilly and Company  

The pharmaceutical industry is faced with increasing product development timelines and costs. The increases are so significant that they threaten the long-term viability of the industry. Six Sigma methodology has proven to be useful in reducing costs and cycle time in a wide variety of industries. This session will report on the challenges and benefits of implementing Six Sigma in an R&D environment. In particular, the speakers will address the use of Six Sigma techniques to reduce costs and cycle times.

Lisa A. Shipley, PhD  
Vice President-ADME, Lilly Research Laboratories  

Jeffrey Naglestad  
Director, Business Performance Improvement, sanofi-aventis  

Mark A. Kryah, PMP  
CMC Project Manager, Eli Lilly and Company  

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**Session 144**  
PM2 - Project Management, RD  
1:30 pm-3:00 pm  
Room B402  

**Integrated US/Japan Effective Team Management**  
SESSION CHAIRPERSON(s)  
Atsushi Tsukamoto, MSc, PMP  
Global Project Manager, Daiichi Sankyo Co., Ltd., Japan  

Successfully managing a multinational cross-functional team to achieve its goals, especially a joint east-west team (for example, US-Japan), is not always easy. Teams will have different cultural backgrounds, and communication styles and motivators that will create obstacles to a project achieving its goals. This session will provide some of the key challenges and pitfalls in managing those teams, and share case studies followed by practical suggestions that can be applied to global teams of all cultural makeups.

**Effective Cross-cultural Team Management**  
Marshall Hewitt, MS  
President, Global Alignment  

Typical Expectation Differences, Misunderstanding and Successful Cases in Global Team Development from a Japanese Company Point of View  
Atsushi Tsukamoto, MSc, PMP  
Global Project Manager, Daiichi Sankyo Co., Ltd., Japan  

**Improving the Relationships and Performance of a Cross-functional Global Development Team**  
Mark A. Kryah, PMP  
CMC Project Manager, Eli Lilly and Company
FDA’s Proposed Rule and Electronic Drug Product Listing System (eLIST)

John W. Gardner, DrPh, MD
Division Director, Office of Compliance, CDER, FDA

CDER’s Risk-based Site Selection Model for CGMP Inspections

Sawye Brenda Wang, MS
Team Leader, Office of Compliance, CDER, FDA

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**SESSION 147**

**RA2 - REGULATORY AFFAIRS, PP**

1:30 pm-3:00 pm  LEVEL: ●

Room A404

**FDA Regulations and Guidelines: How to Make Comments Count**

**SESSION CHAIRPERSON(s)**

Amy N. Grant
Global Head, Regulatory Information and Intelligence, AstraZeneca LP

The purpose of this session is to learn how to submit to FDA relevant, meaningful, and focused comments on draft FDA regulations and guidelines. Presenters will share best practices from the perspective of government and industry. A panel discussion will follow brief presentations that will include case studies of draft regulations and guidelines that have major impact on drug development.

**Making Comments Count: An Industry Perspective**

Linda F. Bowen, MS
Director, Regulatory Intelligence, sanofi-aventis

**Best Practices in Commenting on Regulations and Guidelines**

Virginia Beakes-Read, BSN, JD
Director, Regulatory Policy Liaison, Genentech, Inc.

**Commenting on FDA Regulations and Guidelines from a Global Perspective**

Amy N. Grant
Global Head, Regulatory Information and Intelligence, AstraZeneca LP

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**SESSION 148**

**RA3 - REGULATORY AFFAIRS, RD**

1:30 pm-3:00 pm  LEVEL: ●

Room A410

**Good Review Management Principles (GRMPs): How Far Have We Come?**

**SESSION CHAIRPERSON(s)**

Roy J. Baranello, MS
Assistant Vice President, Global Regulatory Policy and Operations, Wyeth Pharmaceuticals

Development and implementation of guidance on GRMPs was one of the most important FDA goals adopted when PDUFA was last reauthorized in 2002. In this session FDA and industry speakers will discuss current progress and challenges toward realizing the vision of improving first cycle review efficiency.

**GRMPs: FDA Progress Report**

Kim Colangelo
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

**Industry Perspective on Implementation of GRMPs**

Taryn Rogalski-Salter, PhD
Director, US Regulatory Policy, Merck & Co., Inc.

**Best Practices for Sponsor-FDA Communication: An Industry Perspective**

David M. Cocchetto, PhD, RPh
US Regulatory Affairs, GlaxoSmithKline

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**SESSION 149**

**RA4 - REGULATORY AFFAIRS, CP**

1:30 pm-3:00 pm  LEVEL: ●

Room A402

**CME and Pharmacy credits offered**

**Strengthening the Infrastructure: Supporting Drug Safety Policy Development, Risk Communication and Healthcare Community Outreach**

**SESSION CHAIRPERSON(S)**

Paul J. Seligman, MD, MPH, CAPT. USPHS
Associate Director, Safety Policy and Communication, CDER, FDA

Developing drug safety policy and determining how best to convey information about the safe use of drugs continues to take center stage. This session will include an overview of current SPC activities and an interactive panel discussion about what might be expected in the future.

**Progress in Postmarketing Safety Policy**

Judy Racoosin, MD, MPH
Senior Safety Policy Advisor, Safety Policy and Communication Staff, CDER, FDA

**The Drug Safety Oversight Board and Early Drug Risk Communication: Recent Progress**

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

**Building the CDER Risk Communication Strategic Plan: The Roadmap to Improved Stakeholder Communication**

Mary C. Gross
Senior Policy Analyst, Safety Policy and Communication Staff, CDER, FDA

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**SESSION 150**

**RA5 - REGULATORY AFFAIRS, PM**

1:30 pm-3:00 pm  LEVEL: ◆

Room A405

**Effective Milestone Meetings with FDA**

**SESSION CHAIRPERSON(S)**

William K. Sietsema, PhD
Vice President, US Regulatory Consulting and Submissions, Kendle International

Regulations outlined in 21 CFR § 312 and 314 describe the process for obtaining meetings with FDA at specific development program points (milestone meetings). The contact between a company and the appropriate FDA review division takes place between the company’s regulatory liaison and the review division project manager. This relationship works best when contact is professional and respectful. In addition, the company’s regulatory liaison must understand the rules of engagement with each division’s information and communication needs. The development of a professional and collegial relationship opens the door for effective dialogue between the company and the division.

The major purpose of all review division meetings is to obtain a clear understanding of approval requirements and to address the inevitable drug development program complications. It is often the practice to have a pre-IND, end-of-Phase 1, end-of-Phase 2, pre-NDA and CMC-related meetings during the development process. Notwithstanding the guidance document, Formal Meetings with Sponsor and Applicant for PDUFA Products, practical experience is the best teacher. A talented panel of experts will share their knowledge as well as great and not-so-great experiences as a way to guide you in your skill development of conducting milestone meetings with FDA. We will focus on developing strategies to achieve the desired outcome from any milestone meeting. A well-thought-out meeting strategy is one of the essential elements to successful interactions with the FDA.
FDA Perspectives on Milestone Meetings: Key Insights from the FDA on Successful Meetings, Including Processes for Granting Meeting Requests, Involvement of Consulting Divisions or Office Directors, and Best Practices
Leah A. Christl, PhD
Supervisory Project Manager, Division of Nonprescription Clinical Evaluation, CDER, FDA

Preparing for an FDA Meeting: Guidance to Sponsors on Preparation for Successful FDA Meetings, including Importance of On-target Briefing Document and Questions and Premeeting Practice Sessions
Gregory T. Brophy, PhD
Director, US Regulatory Affairs, Eli Lilly and Company

Best Practices for Meeting Conduct: Meeting Management Approaches, Importance of FDA Premeeting Minutes, Effective Time Management, and Strategies to Optimize Communications
Sunita Zalani, PhD, RAC
Executive Director, Global Regulatory Affairs, Amgen Inc.

SESSION 151 RA6 - REGULATORY AFFAIRS, CR
1:30 pm-3:00 pm
Room A311

Practical Implementation of EU Pediatric Legislation
SESSION CHAIRPERSON(S)
Patrick Le Courtois, MD
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

With the EU legislation on pediatrics recently adopted, the EMEA is preparing for its full implementation and for acceptance of applications for pediatric investigation plans (PIP) and waivers. This session will address the practical elements of that implementation from an EMEA perspective and how industry is preparing for this new challenge.

EMEA Perspective
Agnès Saint Raymond, MD, PhD
Head of Sector, Scientific Advice and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

How Industry Should Prepare
Anu Tummuvuori-Liemann
Manager, EU Regulatory Affairs and Liaison, International Drug Regulatory Affairs, F. Hoffmann-La Roche Ltd., Switzerland

Panelist
Angelika Joos
Associate Director, Regulatory Policy Europe, Merck Sharp & Dohme (Europe) Inc., Belgium

SESSION 152 RD - R&D STRATEGY, CR
1:30 pm-3:00 pm
Room B305

Mapping the Clinical Investigator Landscape
SESSION CHAIRPERSON(S)
Kenneth A. Getz, MBA, MS
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CIISCPR

This session explores changes, trends and gender and ethnic disparities among the clinical investigator community. The results of an original study will be presented and insights into more effective and efficient clinical investigator management practice will be discussed.

Gender Disparities among Clinical Investigators
Laura B. Faden
Senior Research Analyst, Tufts Center for the Study of Drug Development, Tufts University

Macro Trends and Changes in the Investigator Landscape
Kenneth A. Getz, MBA, MS
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CIISCPR

Ethnic Disparities among Clinical Investigators
Alfonso Alanis
Chairman and Chief Executive Officer, Anaclim, LLC

SESSION 153 ST - STATISTICS, CR
1:30 pm-3:00 pm
Room B309
Pharmacy credits offered

Design and Analysis Issues in Analgesic Trials
SESSION CHAIRPERSON(S)
Eugene Laska, PhD, MS
Professor of Psychiatry, New York University, Nathan Kline Institute

This session will focus on the trial design and endpoint analyses in the analgesic area. Specifically, we will discuss the selection of the appropriate study design, statistical methods in dealing with patient drop-outs, and measurement and analysis issues for analgesic onset.

Things We Don’t Know about Pain Clinical Trials: Primary Outcome Measures and Covariates
Mitchell B Max, MD
Chief, Clinical Pain Research Section, NIDCR, National Institutes of Health

There Are No Missing Data in Analgesic Trials
Thomas J. Permutt, PhD
Director (Acting), Division of Biometrics II, CDER, FDA

Measurement and Analysis Issues about the Onset of Analgesia
Hong Laura Lu, PhD
Mathematical Statistician, CDER, FDA

SESSION 154 TR - TRAINING, GCP
1:30 pm-3:00 pm
Room B308

Bringing Global Staff to Headquarters for Training
SESSION CHAIRPERSON(S)
Betty R. Kuhnert, PhD, MBA
Independent Consultant, Betty R. Kuhnert Ph.D., MBA, LLC

This session will discuss how to minimize expense and maximize impact of training during the limited time an international visitor may spend at headquarters.

Maximize the Impact, Minimize the Expense of Training International Visitors
Betty R. Kuhnert, PhD, MBA
Independent Consultant, Betty R. Kuhnert Ph.D., MBA, LLC

How Affiliate (Global) Personnel Can Contribute to a Training Experience
Cathryn L. Anderson
Senior Medical Affairs Director, Shire Pharmaceuticals

What Non-US Staff Need to Succeed
Dean Foster, MA
President, Dean Foster Associates
Monday, June 18

3:00 pm-3:30 pm  REFRESHMENT BREAK
Building A – Exhibit Hall A Only
Building B – Levels 3 & 4, Meeting Room Corridors

SESSION 155  AD - ADVERTISING, MC
3:30 pm-5:00 pm  LEVEL: ■
Room A301  Pharmacy credits offered
FDA, Fair Balance, and False Claims: If and How Industry Can Provide Product Education
SESSION CHAIRPERSON(S)
Marc B. Wilenzick, JD
Senior Corporate Counsel, Pfizer Inc
This session will discuss industry’s role in distributing data about its products directly and in the support of CME and speaker programs, and the legal and regulatory scrutiny of conflicts of interest, off-label promotion, and potential for false claims scrutiny.

CME: Where We’ve Been and Where We Are Going
Mike Saxton, MEd
Senior Director, Team Leader, Medical Education Group, US Medical, Pfizer Inc

AMC Perspectives on CME and Industry-AMC Collaboration
R. Van Harrison, PhD
Director of CME, Professor of Medical Education, University of Michigan

Evolving Legal Issues Related to Industry Outreach to Prescribers
Jonathan Diedenhaus, JD
Partner, Hogan & Hartson

SESSION 156  CDM - CLINICAL DATA MANAGEMENT, CR
3:30 pm-5:00 pm  LEVEL: ■
Room A312
Meeting the Challenges for Data Monitoring Committees
SESSION CHAIRPERSON(S)
Monika M. Pietrek, MD, PhD, MSc
Executive Vice President, Global Scientific and Medical Affairs, PRA International, Germany

Important clinical trials have independent Data Monitoring Committees to evaluate benefits and risks. While regulators have provided guidance for DMCs, experience reveals challenges for DMCs, including different levels of experience of DMC members, incomplete charter, varying data quality, lack of knowledge of regulatory requirements, slow decision making and delayed implementation of DMC recommendations. This session explores critical success factors for DMCs and their interaction with steering and adjudication committees, sponsor/CROs, regulators, IRBs/ECs and investigators.

The Clinical Research Perspective
Monika M. Pietrek, MD, PhD, MSc
Executive Vice President, Global Scientific and Medical Affairs, PRA International, Germany

The Data Management Perspective
Minghua Shan, PhD
Deputy Director, Statistics, Global Biometry Leader, Oncology, Bayer Pharmaceuticals Corporation

The Committee Perspective
John C. Constant, PhD
Vice President, Scientific Affairs, PRA International, Canada

SESSION 157  CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA
3:30 pm-5:00 pm  LEVEL: ■
Room A313
CMC Regulatory Agreement
SESSION CHAIRPERSON(S)
Mohab M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA
This session will describe the concept and utility of the proposed CMC regulatory agreement from an FDA and industry perspective.

FDA Perspective
Mohab M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA

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

SESSION 158  CP1 - CLINICAL SAFETY AND PHARMACOVIGILANCE, CDM
3:30 pm-5:00 pm  LEVEL: ■
Room A302
Global Electronic ADR Exchange: Where Are We Now and What Is Next?
SESSION CHAIRPERSON(S)
William W. Gregory
Director, Safety and Risk Management, Pfizer Inc

Learn how international standards for electronic exchange of individual case safety reports are enhancing the business of pharmacovigilance for regulators and industry and how these standards are evolving to support increasingly sophisticated pharmacovigilance activities.

Experience and Perspectives on Electronic Case Safety Reporting in Japan
Kaori Nomura
Chief, Safety Information Division, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Updates on Electronic Postmarketing Case Safety Reporting within the US FDA
Roger A. Goetsch, RPh, CAPT. USPHS
Division of Surveillance, Research, and Communication Support, Office of Surveillance and Epidemiology, CDER, FDA

Panelist
Kostas Kidos, MSc
Executive Director, Regulatory Services, Merck & Co., Inc.

SESSION 159  CP2 - CLINICAL SAFETY AND PHARMACOVIGILANCE, IMP
3:30 pm-5:00 pm  LEVEL: ■
Room A314  CME and Pharmacy credits offered
Approaches to Quantifying Benefit-risk Assessments: Going beyond Intuition
SESSION CHAIRPERSON(S)
Stephen F. Hobbiger, MRCP, FFPM
Vice President, Neurosciences, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline, UK
This session will explore the need for, and some of the methodologies available in benefit risk modeling. This will include an evaluation of current processes and future utility in both a company and a regulatory environment. Risk management is an increasingly familiar concept and the speakers will explore the added value that can be derived from a more analytical approach. The session will include the use of worked examples.

The Trade-off between Benefit and Risk in the Real World
Sam Salek, PhD, RPh
Director, Centre for Socioeconomic Research, Welsh School of Pharmacy, UK

Regulatory Practice in Benefit-risk Decision Making
Richard Hill, MD
Acting Director, Adverse Drug Reactions Unit, Therapeutic Goods Administration, Australia

An Example of Net Incremental Benefit Using Lotronex
Larry D. Lynd, PhD
Assistant Professor, Faculty of Pharmaceutical Sciences, University of British Columbia, Canada

SESSION 160 CR1 - CLINICAL RESEARCH AND DEVELOPMENT, RA
3:30 pm-5:00 pm LEVEL: ●
Room B407
CME and Pharmacy credits offered

Personalized Medicine and Personalized Drug Development: Case Studies and Progress to Date — Part 2 of 2
SESSION CHAIRPERSON(S)
Lawrence J. Lesko, PhD
Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA

Part 1 of this session will take place on Monday at 1:30 pm.

The concept of personalized medicine is taking stronger hold thanks to scientific advances as well as to the focus on biomarkers and pharmacogenomics promoted by FDA’s Critical Path Initiative, which challenges the drug development community to devise new ways to both accelerate and target the discovery and application of novel therapeutics to patients in all therapeutic areas. While skepticism exists regarding the speed at which progress will be made in the personalization of medicine, advances are quietly being made in the research and development communities and even in that presumed roadblock to niche drugs – the large pharmaceutical companies. The well-known examples of Herceptin and Gleevec are now old but they have proved the concept that drugs can be successfully targeted at predefined populations. Additional examples exist that demonstrate the success of fresh approaches such as targeting a drug at prespecified subpopulations, saving drugs from near-certain death, using genotyping to customize and accelerate a clinical program, and more. We are witnessing the personalization of drug development as a platform for personalized medicine and as a new way of approaching the challenge of demonstrating that investigational drugs are effective and safe in predefined patient subsets – at the interface of science, therapeutics and regulation. Speakers will include scientists, investigators, regulators and industry specialists; the common focus will be on the need to think outside the box and on the progress that is beginning to be made to address unmet medical needs in a more targeted and personalized way.

Efficacy Pharmacogenetics: Rosiglitazone in Alzheimer’s Disease
Allen D. Roses, MD
Senior Vice President, Pharmacogenetics, GlaxoSmithKline

Drug Test Co-development in Oncology
J. Carl Barrett, PhD
Global Head, BioMarker Development Oncology, Novartis Institutes for BioMedical Research, Inc.

SESSION 161 CR2 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS
3:30 pm-5:00 pm LEVEL: ●
Room B408
CME, Nursing, and Pharmacy credits offered

Applying Lean and Six Sigma to Eliminate Waste and Streamline Planning and Execution of Clinical Trials
SESSION CHAIRPERSON(S)
Douglas E. May, MS
Solution Partner, Life Sciences, BusinessEdge Solutions

Clinical development often entails waste and unnecessary delays in protocol development, site selection, clinical supply chains, patient recruitment, and clinical data management. Now biotechnology and pharmaceutical companies are using Lean/Six Sigma principles to streamline clinical processes and eliminate waste.

Applying Lean Thinking to Clinical Development
Douglas E. May, MS
Solution Partner, Life Sciences, BusinessEdge Solutions

A Framework for Lean/Six Sigma in Clinical Development
David T. Asher, MBA
Technical Director, MBB, George Group Consulting

Case Study: Experience with Lean/Six Sigma in Clinical Development
Martin D. Hynes, Ill, PhD
Director, Six Sigma Champion Product Research & Development, Eli Lilly and Company

SESSION 162 CR3 - CLINICAL RESEARCH AND DEVELOPMENT, RD
3:30 pm-5:00 pm LEVEL: ◆
Room B409
CME, Nursing, and Pharmacy credits offered

Improving Success of Psychopharmacological Clinical Trials: A Path to Failure
SESSION CHAIRPERSON(S)
Angelo Sambunaris, MD
Medical Director, Atlanta Institute of Medicine & Research

High failure rates of anxiolytic and antidepressant drug trials in psychopharmacology are a cause of concern to clinicians, the pharmaceutical industry, and the general public.

Study Design Deficiencies from the Perspective of a CRC and Rater
Kathryn M. Zerkel
Research Director, Atlanta Institute of Medicine & Research

Troubleshooting CNS Drug Development
Don S. Robinson, MD
President, Worldwide Drug Development
**Session 163  CTM/CS - Clinical Trial Management/ Clinical Supplies, CR**

3:30 pm-5:00 pm  
Room B405

Research into the Use of Predictive Metrics to Determine Clinical Performance

SESSION CHAIRPERSON(S)

Ira C. Spector, MBA  
Vice President, Clinical Development Operation, Wyeth Research

One of the most important aspects of clinical trial success is the selection of clinical sites. However, clinical sites that have previously been successful sometimes do not yield expected enrollment and subject retention results. This session will review recent research into determining metrics that can be used to predict site performance before clinical trials are initiated, during the site selection process. This session will provide the conceptual framework for the stages of evolution of clinical sites and the relationship of each developmental stage to site performance, and discuss new research into the use of metrics to predict the performance of clinical sites. This new research could help shorten clinical study times and reduce cost by focusing on selection of sites that have a higher likelihood of success.

Research into the Use of Predictive Metrics to Determine Clinical Performance

Ira C. Spector, MBA  
Vice President, Clinical Development Operation, Wyeth Research

Using Performance Metrics for Country and Site Selection

Mark T. Ridge  
Director, Global Enrollment Planning and Performance, Wyeth Pharmaceuticals

Perspectives on Patient Recruitment Planning and Site Selection

Julie Ross  
President, Essential Patient Recruitment; Executive Vice President, Essential Group

Research into Clinical Site Performance

Harold E. Glass, PhD, MSc  
Professor, Health Policy, University of the Sciences of Philadelphia

**Session 164  EC - eClinical, IT**

3:30 pm-5:00 pm  
Room B304

Crossing the BRIDG to the Future: Implementation Case Studies of the HL7/CDISC BRIDG Model

SESSION CHAIRPERSON(S)

Lisa Chatterjee, MS  
Vice President, Healthcare Data Standards, Digital Infuzion, Inc.

This session will explore specific implementation case studies where the BRIDG, a comprehensive domain analysis model for biomedical/clinical research, is being used to support development of interoperable next-generation clinical research tools that support the clinical research lifecycle.

Crossing the BRIDG to the Future: New Generation Tools for Structured Authoring

Jeremy Gratt  
President, Modular Informatics, LLC

Trial Designer

Charles Beitz, III, MBA  
Vice President, Designer, Fast Track Systems, Inc.

The Use of the BRIDG Model in the CTMSi Project: A Real-world (Successful) Application

Smita Hastak  
Senior Analyst, ScenPro, Inc.

**Session 165  ERS/DM - Electronic Regulatory Submissions/Document Management, CDM**

3:30 pm-5:00 pm  
Room A410

International eCTDs: An Update on the US and European Regulatory Authority Experience

SESSION CHAIRPERSON(S)

Mary L. Collins  
Director, Regulatory and Public Relations, Image Solutions, Inc.

This session provides an overview and status of Agency acceptance, review and approval of electronic submissions. FDA and European regulatory authorities will discuss accepted electronic submission formats, agency readiness, progress to date, and future expectations of electronic submissions.

FDA Update

Gary M. Ginsinger, MBA  
Director, Regulatory Review Support Staff, CDER, FDA

EMEA Update

Timothy Buxton, LLB  
Head of Sector, Project Management, Communications and Networking Unit, EMEA, EU

MHRA Update

David Wheeler, PhD  
Business Relations Manager, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**Session 166  GCP - Good Clinical Practices, CR**

3:30 pm-5:00 pm  
Room B406AB

Pediatric Research: Updates and Perspectives to Increase Quality from around the Industry

SESSION CHAIRPERSON(S)

Matthew R. Baker, CIM, CIP  
President and Chief Executive Officer, Compass IRB, LLC

This session will present views from the IRB, site, and CRO ranging from reviewing, conducting, and managing pediatric research. Through better understanding and collaborative relationships, quality in pediatric research is possible. This “full-circle” perspective will enlighten and energize all those involved in pediatric research.

The IRB: Better Understanding Leads to Better Quality

Matthew R. Baker, CIM, CIP  
President and Chief Executive Officer, Compass IRB, LLC

The ABC’s of Pediatric Trials: A Site Primer

Julie M. Stover, MBA, CCRP  
Executive Vice President and Chief Operating Officer, Research Solutions, LLC

Effective, Efficient Pediatric Trial Management: A CRO’s Perspective

Shantal Feltham  
President, Stiris Research Inc., Canada

**Session 167  IS - Investigator Sites, CTM/CS**

3:30 pm-5:00 pm  
Room B303

Recruitment and Retention Strategies and Solutions for Clinical Trials: What Works, What Does Not, and Why, with a Focus on Ethnic Minority Populations

SESSION CHAIRPERSON(S)

Rayonne D. Caesar-Chavannes, MBA  
President/Senior Research Consultant, ReSolve Research Solutions, Inc., Canada
Traditional recruitment/retention strategies are not effective in improving participation in clinical trials, especially for visible minority populations. New strategies need to be considered that focus on breaking down institutional barriers to the participation for members of all cultural groups.

**Study Feasibility Analysis for Clinical Trials**

*C. Lee Jones, MBA*
Chairman, President and Chief Executive Officer, Essential Group, Inc.

**Recruitment and Retention: What Works, What Doesn’t and Why**

*Christine K. Pierre, RN*
President and Chief Executive Officer, Rx Trials Inc.

**Recruitment and Retention Strategies and Solutions for Ethnic Minorities in Clinical Trials**

*Rayonne D. Caesar-Chavannes, MBA*
President/Senior Research Consultant, ReSolve Research Solutions, Inc., Canada

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**SESSION 168 IT - INFORMATION TECHNOLOGY, CDM**

3:30 pm-5:00 pm
Room A305
Pharmacy credits offered

**The Implementation of Biological Sample Management and Biobanking Systems**

*session chairperson(s)*

*David A. Evans, MS*
Chief Information Officer, Octagon Research Solutions, Inc.

This session examines the unique challenges of biospecimen collection and biobanking for life sciences discovery and clinical informatics. Panelists will discuss the design, development and implementation of biobanking and sample management systems integrated with eClinical study management systems.

**Biobanking and Sample Management Systems in the Nonprofit Sector**

*Alicia Sable-Hunt, MBA, RN*
Consultant, Edwards-Hunt Group, LLC

**Implementation of SMS: Efficient and Quality Specimen Tracking from Discovery to Development**

*Erik M. Koenig*
Manager II, Molecular Technologies, Millennium Pharmaceuticals

**Implementation of a Biobanking System to Fuel Translational Research at a Pharmaceutical Company**

*Rebecca Lynch*
Assistant Senior Biologist, Cancer Research, Eli Lilly and Company

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**SESSION 169 MW - MEDICAL/SCIENTIFIC WRITING, RA**

3:30 pm-5:00 pm
Room A315
CME and Pharmacy credits offered

**The Evolving Role of the Investigator Brochure in Global Submissions**

*session chairperson(s)*

*Sandra J. Hecker, RAC*
President, Hecker and Associates, LLC

The investigator brochure is the cornerstone of a clinical trial application and has a central role throughout a medicinal product’s development. This session will enable attendees to write IBs for global submissions appropriate for the product, its stage of development, its target audience, and to revise the IB as needed over time.

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**SESSION 170 NHP - NATURAL HEALTH PRODUCTS, MA**

3:30 pm-5:00 pm
Room B306

**International NHP Initiatives**

*session chairperson(s)*

*Hubertus Cranz, PharmD, MBA*
Director-General, AESGP, Belgium

Regulatory approaches for natural health products in different parts of the world will be presented and their implications for economic operators will be discussed.

**Entrepreneurship, Economic Growth and Job Creation through Use of Indigenous Knowledge Systems in South Africa**

*Motlalepula Gilbert Matsabisa, PhD*
Director, South African Medical Research Council, South Africa

**Brazilian Initiatives to Develop Natural Health Products**

*Renata Aparecida Dias, MPharm*
Regulatory Affairs Manager, Febrafarma, Brazil

**Business Opportunities for Herbal Medicines**

*Werner Busse*
Director, International Division, Dr. Willmar Schwabe & Co. KG, Germany

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**SESSION 171 OS1 - OUTSOURCING, RA**

3:30 pm-5:00 pm
Room B401

**India: An Emerging Clinical Research Destination – Challenges and Advantages**

*session chairperson(s)*

*Shruti V. Shukla, MSc*
Principal and Professor, Institute of Clinical Research of India (ICRI), India

As India is developing as a hot-spot destination for conducting clinical research, it is imperative to discuss the challenges and advantages of conducting clinical research in this geographically diverse tropical country with a population of more than 1 billion!

**A Passage to India**

*Steven Jacobs*
President, Bilcare, Inc.

**Caveats for Outsourcing Clinical Data Management in India**

*Rajiv Prasad, MBA*
Assistant Vice President, Life Sciences, Satyam Computer Services

**Regulatory Environment Versus Patient Recruitment: Challenges in Developing Countries**

*Carla Blohm Bendzius Asseburg*
Director, Operations, Eurotrials Brazil

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Clinical Research in India: Challenges and Advantages

Shruti V. Shukla, MSc
Principal and Professor, Institute of Clinical Research of India (ICRI), India

SESSION 173  PM1 - PROJECT MANAGEMENT, CMC/GMP
3:30 pm-5:00 pm  LEVEL:  ◆
Room B403  Project Management units offered

Case Studies of Critical Chain Project Management in the Pharmaceutical Industry
SESSION CHAIRPERSON(s)
John C. Erickson, PhD
Director, Global Project and Portfolio Management, GlaxoSmithKline R&D

In this session, we will learn from pharmaceutical industry colleagues who have implemented critical chain project management. Since its introduction in 1984, critical chain project management has been reported to enable dramatic increases in speed and throughput of projects. In fact, the 2006 Franz Edelman Award for Achievement in Operations Research was given in recognition of the application of critical chain project management. On the other hand, several published reports have been skeptical of critical chain. In any case, few people in the pharmaceutical industry have actually tried critical chain project management for themselves. In this session, we will hear case studies from people who have been there and done it themselves.

Introduction to Critical Chain
Wendell P. Simpson, III, PhD, MS
Principal Consultant, Pro Chain Solutions, Inc.

Practical Application of Critical Chain to a Large Pharma Company’s Medical Infrastructure Modernization Programs
Greg T. Spratt, MS
Manager, Global Medical IT, Eli Lilly and Company

Case Study: Pilot of a Novel Approach to Critical Chain with Six Late-stage Drug Development Projects
John C. Erickson, PhD
Director, Global Project and Portfolio Management, GlaxoSmithKline R&D

SESSION 174  PM2 - PROJECT MANAGEMENT, FI
3:30 pm-5:00 pm  LEVEL:  ▲
Room B402  Project Management units offered

Alliance Management: Principles and Practices
SESSION CHAIRPERSON(s)
Raymond G. Starrett, MS
Director, Corporate Project Management, MedImmune, Inc.

Alliances and collaborations are very important vehicles used by companies to grow and sustain healthy portfolios. In this session, we will review some of the key principles and practices critical to the success of effective partnerships in the pharmaceutical and biotech industries.

Principles and Practices of Effective Alliance Management
Ailsa Mendez, MBA
Senior Project Manager, MedImmune Inc.

Alliance Management: Focus on Pharmaceutical Development Collaborations
Janet S. Lewis, MBA, PMP
Director, Global Project and Portfolio Management, GlaxoSmithKline

SESSION 175  PP - PUBLIC POLICY/LAW, RA
3:30 pm-5:00 pm  LEVEL:  ◆
Room A411  CME, Nursing, and Pharmacy credits offered

Civil and Criminal Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials?
SESSION CHAIRPERSON(s)
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.

Civil and Criminal Jeopardy from Clinical Research: What Are the Risks?
John M. Isidor, JD
Chief Executive Officer, Schulman Associates IRB, Inc.

Gary L. Yingling, JD
Partner, Kirkpatrick & Lockhart, Nicholson, Graham, LLP

SESSION 176  RA1 - REGULATORY AFFAIRS, CR
3:30 pm-5:00 pm  LEVEL:  ◆
Room A404  CME credits offered

How to Communicate Added Value
SESSION CHAIRPERSON(s)
Tamás L. Páll, PhD
Director-General, National Institute of Pharmacy, Hungarian Health Authority, Hungary

Presentation of the added therapeutic value of drugs is one of the topics of the Pharmaceutical Forum in the European Union. However, its right methodology (odds ratio, number needed to treat, etc.) is under debate. The session offers a forum for discussion.

Reimbursement Committee Member’s View
Haroldas Baubinas
Deputy Director, State Patient Fund, State Agency of Medicines, Lithuania
Communication of Added Therapeutic Value for Regulatory Purposes
Tamás L. Paál, PhD
Director-General, National Institute of Pharmacy, Hungarian Health Authority, Hungary

SESSION 177   RA2 - REGULATORY AFFAIRS, PP
3:30 pm-5:00 pm   LEVEL: ■
Room A412AB
Fourth Update: US-EU Agreement Regarding Exchange of Information among Regulators
SESSION CHAIRPERSON(S)
Marie A. Dray, MBA
President, Dray Regulatory Associates - International
Brenton E. James
Consultant in Strategic Regulatory Affairs in the European Union, UK

This session will update the audience on recent achievements in the field of information exchange between the US and the EU under the umbrella of the US-EU Confidentiality Arrangements. Furthermore, the audience will be provided with detailed information on the next phase of the information exchange, as agreed in the revised implementation plan.

Current Status of US-EU Agreement: FDA Viewpoint
Murray M. Lumpkin, MD, MSc
Deputy Commissioner, International and Special Programs, Office of the Commissioner, FDA

Current Status of US-EU Agreement: EMEA Viewpoint
Thomas Lönngren, Pharm, MSc
Executive Director, EMEA, EU

Panelists
Noël Wathion, Pharm
Head of Unit, Postauthorization Evaluation of Medicines for Human Use, EMEA, EU
Patrick Le Courtois, MD
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

SESSION 178   RA3 - REGULATORY AFFAIRS, RD
3:30 pm-5:00 pm   LEVEL: ■
Room A405
Achieving a Global Trademark
SESSION CHAIRPERSON(S)
Jerry Phillips, RPh
President and Chief Executive Officer, Drug Safety Institute

Achieving a global trademark is often difficult, with the new and various guidelines and policies of the three major regulatory authorities. This session will present the legal/marketing requirements of a global trademark and the safety requirements of the FDA and the EMEA on submitting a trademark for review and approval.

Legal and Marketing Considerations of a Global Trademark
Robert E. Lee, Jr., JD, MS
Assistant General Patent Counsel, Eli Lilly and Company

Safety and Promotional Considerations of a Trademark by FDA
Carol Holquist, RPh
Director, Division of Medication Errors and Technical Support, Office of Surveillance and Epidemiology, CDER, FDA

Dorothy Linvill-Neal
Director, Global Trademark Development, Johnson & Johnson Pharmaceutical Services, LLC

SESSION 179   RA4 - REGULATORY AFFAIRS, CP
3:30 pm-5:00 pm   LEVEL: ■
Room A402
CME and Pharmacy credits offered
The Evolution of Risk Management Plans
SESSION CHAIRPERSON(S)
Evelyn M. Rodriguez, MD, MPH, FAAP, FACE, FISPE
Head, Global Pharmacoepidemiology, Bayer Healthcare Pharmaceuticals

The FDA set forth a guidance on development and use of risk minimization action plans (RiskMAPs) in March 2005. This document outlines the importance of an in-depth understanding of the benefit-risk profile of the product and the goals and objectives of a RiskMAP, the selection of appropriate interventions and tools, and the essential feature of an evaluation plan to ascertain the effectiveness of the selected interventions and tools. In addition to the guidance, the FDA established an independent drug safety and risk management advisory committee, a relatively new addition to those organized by therapeutic area.

This session will review the guidance, the evolution of risk management plans prior to, and since the publication of the guidance, by presenting specific case studies. Case studies will also illustrate the evolution of risk management plans for specific marketed products on the market. The importance of the complementary disciplines of pharmacoepidemiology, pharmacovigilance, and regulatory expertise in this evolving area in industry product teams will be emphasized.

Isotretinoin: Evolution of a Risk Management Plan
William Maier, PhD, MPH
Senior Director, Epidemiology, Elan Pharmaceuticals, UK

The Lotronex® RMP: Key Design Features and Critical Learnings from a Contemporary Exercise in Risk Management
Craig A. Metz, PhD
Vice President, US Regulatory Affairs, GlaxoSmithKline

Carmen R. Bozic, MD
Vice President, Global Head, Drug Safety and Risk Management, Biogen Idec

SESSION 180   RA5 - REGULATORY AFFAIRS, ERS/DM
3:30 pm-5:00 pm   LEVEL: ■
Room A311
Five-year Update on Regulatory Intelligence Utilization by Industry: 2002 to 2007 and Three Industry Examples of RegIntel Programs
SESSION CHAIRPERSON(S)
Neal C. Birkett, MS
Senior Manager, Amgen Inc.

Regulatory intelligence has matured considerably over the last five years. Three leading firms representing the US and EU discuss their state of the art for RegIntel, and how the function interacts with the policy function. The general opportunity to contribute to team-based strategies will be discussed.

US Perspective on RegIntel: PDL BioPharma
Meredith E.S. Brown-Tuttle
Manager, PDL BioPharma

EU Perspective on RegIntel: Pfizer UK
Nick Sykes, MSc
Director, Head, Global Regulatory Intelligence and TA Analysis, Pfizer Inc, UK

Global Perspective on RegIntel: Amgen
Neal C. Birkett, MS
Senior Manager, Amgen Inc.
Drug development in Japan is rapidly changing. The E5 guideline of 1998 allows sponsors to extrapolate existing foreign clinical data to Japan via bridging studies, thus showing drug profile similarities among foreign countries. The guideline has been extended to include simultaneous global studies through mutual extrapolation of clinical data among regions. The new innovative drug development lessens the number of Japanese patients being exposed to new drugs before approval, making the detection of racially oriented adverse events impossible. Therefore, scientific pharmacovigilance studies become critical and crucial to Japanese patients. In response, the Ministry of Health, Labour and Welfare investigated how daily patient records can build a safety network system among hospitals. We will present the findings from this investigation and discuss issues regarding the sentinel network system in Japan.

The Impact of Sentinel Systems on New Drug Development in Japan
Masahiro Takeuchi, DrSc, MPH
Professor of Biostatistics and Pharmaceutical Medicine, School of Pharmaceutical Sciences, Kitasato University, Japan

Sentinel Systems: FDA Perspective
Stephen E. Wilson, DrPh, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

The Possible Solution for Sentinel Systems in Japan: IT Perspective
Noriyuki Murakami
Senior Engineer and Consultant, Medical Systems Department, Industrial Systems Division, Hitachi Ltd., Japan

END OF MONDAY SESSIONS
**SESSION 202  BT - BIOTECHNOLOGY , CR**

8:00 am-9:30 am  
Room B304  
CME credits offered

**Progress in Systems Biology: Advances in Knowledge-based Drug Development**

**SESSION CHAIRPERSON(S)**  
Alan S. Louie, PhD

Research Director, Health Industry Insights, an IDC Company

Advances in the area of systems biology are continuing to transform how drugs are developed. This session will describe how the infusion of knowledge promises to increase efficiency, reduce costs, and strengthen new drug submissions and will conclude with a discussion of expectations for the future.

**Progress in the Use of Systems Biology in Large Pharma**  
Bruce Gomes, PhD

Head of Mathematical Modeling, Systems Biology Group, Pfizer Global Research and Development

**Programming with Models: Novel Computational Infrastructure for Systems Biology**  
Jeremy Gunawardena, PhD

Director, Virtual Cell Program, Department of Systems Biology, Harvard Medical School

**Industrial-scale Systems Biology: Translating Preclinical Data into Drug Mechanics and Clinical Studies**  
Colin Hill, MS

Chief Executive Officer, President, Chairman and Co-founder, Gene Network Sciences

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**SESSION 203  CDM - CLINICAL DATA MANAGEMENT, IT**

8:00 am-9:30 am  
Room A312

**Data Warehousing Concepts for SDTM-compliant Information**

**SESSION CHAIRPERSON(S)**  
David A. Evans, MS

Chief Information Officer, Octagon Research Solutions, Inc.

This session will focus on the design, development and implementation of clinical data warehouses and their compliance with the current industry and regulatory data standards. The speakers will present case studies of implementations of data warehouses and the impact on their information workflow.

**SDTM Plus or Minus: Integration with a Clinical Data Warehouse**  
Barry R. Cohen, MS

Director, Clinical Data Strategies, Octagon Research Solutions, Inc.

**Case Study 1: Clinical Data Warehousing and SDTM**  
Stephen J. Kopko, MS

Senior Director, Biostatistics Systems Development, Wyeth Research

**Case Study 2: Implementation of an SDTM Clinical Data Warehouse**  
Glenn Ritz, MS

Associate Technical Director, Statistical Programming, Millennium Pharmaceuticals

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**Partial Table: Session 201 - AHC - Academic Health Centers, CP, CR, PP, RA**

8:00 am-9:30 am  
Sidney J. Marcus  
Auditorium, Building A  
CME and Pharmacy credits offered

**Multitrack Plenary**

**Drug Safety Reform: Actions and Implications**

**SESSION CHAIRPERSON(S)**  
Melvyn Greberman, MD, MS, MPH, FACPM  
President, Public Health Resources, LLC

Stanley A. Edlavitch, PhD, MA  
Professor, Epidemiology and Director, Epidemiology Research, University of Missouri Kansas City School of Medicine

In response to growing concerns about health risks associated with approved drugs, the Food and Drug Administration has asked the Institute of Medicine to assess and recommend improvements in the US drug safety system. Although the IOM committee focused its attention on drug review, safety surveillance, and related activities of the FDA Center for Drug Evaluation and Research, it also considered the roles of the pharmaceutical industry, academia, Congress, and healthcare providers and consumers in improving the system. The panel will discuss the IOM recommendations, as well as actions of the FDA, Congress, PhRMA, and other key players, and their implications. The discussion will include an update on the current status of the Prescription Drug User Fee Act and other legislative initiatives.

**Panelists**

Steven Galson, MD, MPH (via videoconference)  
Director, Center for Drug Evaluation and Research, FDA

David Dorsey, JD (via videoconference)  
Senior Fellow, Senate Committee on Health, Education, Labor and Pensions, US Senate (Senator Edward Kennedy’s Office)

Amy Muhlberg, PhD (via videoconference)  
Professional Staff Member, Senate Committee on Health, Education, Labor and Pensions, US Senate (Senator Michael B. Enzi’s Office)

James G. Kotsanos, MD, MS, FACP, FISPE  
Global Product Safety, Eli Lilly and Company (representing PhRMA)

Kathleen Stratton, PhD  
Study Director, Institute of Medicine

Hugh H. Tilson, DrPH, MD, FACP, FISPE  
Chair, Steering Committee, AHRQ Centers for Education and Research on Therapeutics, University of North Carolina School of Public Health
SESSION 204  CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA

8:00 am-9:30 am  LEVEL: ■
Room A311
Update on FDA Initiatives for Postapproval CMC Changes
SESSION CHAIRPERSON(S)
Eric P. Duffy, PhD
Director, Division of Postmarketing Evaluation, Office of New Drug Quality Assessment, CDER, FDA
This session will provide an update on 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 J. Lucisano, RPh
Regional Director, GlaxoSmithKline

SESSION 205  CR1 - CLINICAL RESEARCH AND DEVELOPMENT, IS

8:00 am-9:30 am  LEVEL: ●
Room B408
Examining Best Practices in Investigator Meetings
SESSION CHAIRPERSON(S)
Mary Jo Lamberti, PhD, MA
Senior Manager, Market Intelligence, Thomson CenterWatch
A recent survey was conducted among 100 respondents (study coordinators and investigators) examining best practices for investigator meetings. Overall aspects of investigator meetings are examined as well as most effective methods of learning. This session will discuss the results of this survey and the benefits for pharmaceutical companies in helping them identify areas of improvement and strengthen both the content and overall value of these meetings.
Survey of Sponsor Best Practices for Investigator Meetings
Mary Jo Lamberti, PhD, MA
Senior Manager, Market Intelligence, Thomson CenterWatch
Successful Investigator Meetings
Carl J. Eastwood, Jr., MS
Manager, Procter & Gamble Pharmaceuticals
Global Strategic Meeting Management Best Practices
Marianne Demko-Lange, CMP, CMM
Director, Meeting Planning Support, Wyeth Pharmaceuticals

SESSION 206  CR2 - CLINICAL RESEARCH AND DEVELOPMENT, RD

8:00 am-9:30 am  LEVEL: ■
Room B407
Common Issues and Solutions for Thorough QT ECG Trial Design
SESSION CHAIRPERSON(S)
Jeffrey S. Litwin, MD
Chief Medical Officer, eResearch Technology, Inc.
The FDA QT team has been reviewing thorough ECG trial protocols for one year and there are common themes that merit further discussion. These themes will be compared to those noted by an ECG core lab that has reviewed over 80 protocols resulting in an informative discussion on protocol design.
Common Themes in QT Trials Submitted for Regulatory Review: An ECG Core Laboratory’s Perspective
Jeffrey S. Litwin, MD
Chief Medical Officer, eResearch Technology, Inc.
Common Themes in QT Trials Submitted for Regulatory Review: A Statistician’s Perspective
Joanne Zhang
Mathematical Statistician, Office of Translational Sciences, CDER, FDA
Common Themes in QT Trials Submitted for Regulatory Review: A Reviewer’s Perspective
Shari Targum, MD, FACC, FACP
Medical Officer, CDER, FDA

SESSION 207  CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, GCP

8:00 am-9:30 am  LEVEL: ■
Room B405
Multinational Clinical Trials in China
SESSION CHAIRPERSON(S)
Liang Kong, LLM
Project Manager, Apex China Co., Ltd., China
More and more multinational clinical trials have been introduced into China due to cost, its large patient pool, experienced and motivated investigators, the potential market and so on. However, there are several challenges for multinational clinical trials to succeed in China. This session will detail the challenges and provide resolutions.
Globalized versus Localized: Is China a Powerhouse to Do Multinational Clinical Trials?
Paul Dai, Dr Med
Head, ICRO, Beijing Novartis Pharma Ltd., China
Challenges in Multinational Clinical Trials in China
Debora Natalia Situmeang, MD
Regional Head, Resources Management, Asia Pacific, Bayer (South East Asia) Pte Ltd., Singapore
Regulatory Requirements to Conduct Multinational Clinical Trials in China
Cai Cao
Deputy Director-General, Drug Certification Center, State Food and Drug Administration (SFDA), China
SESSION 208  EC - eCLINICAL, IT
8:00 am-9:30 am  LEVEL: ■
Room A314  CME, Nursing, and Pharmacy credits offered

NIH Roadmap Program and Development of Therapeutic Area Data Standards: Case Studies in TB and Cardiology
SESSION CHAIRPERSON(S)
Bron Witt Kisler
Director, Terminology and Strategic Alliances, CDISC

This session will provide an overview and description of the NIH Roadmap Program and for the development of therapeutic data standards. Two case study projects will be highlighted for cardiology and tuberculosis (TB) as well as the collaboration between CDISC, Duke University and other key global stakeholders.

NIH Roadmap NECTAR Program: Lessons Learned and Best Practices Toward Interoperability
Jody G. Sachs, MD
NIH Roadmap Scientific Project Officer, NCRR, National Institutes of Health

Cardiovascular Clinical Research Networks: Why Data Standards Matter
Robert A. Harrington, MD
Professor of Medicine, Duke University Medical Center; Director, Duke Clinical Research Institute

Development of Disease-specific Data Standards: A Global Project and Case Study in Tuberculosis
Bron Witt Kisler
Director, Terminology and Strategic Alliances, CDISC

SESSION 209  ERS/DM1 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM
8:00 am-9:30 am  LEVEL: ●
Room A406

eCTD for Small Pharma
SESSION CHAIRPERSON(S)
John W. Aitken, PhD
Managing Director, West Coast Operations, Octagon Research Solutions, Inc.

CDER plans to withdraw the non-eCTD eSubmission guidances, so eCTD will be the only format for electronic INDs, NDAs and BLAs. This session is for small companies starting the transition to eCTD, and covers electronic documents and granularity, electronic document management, and eCTD compilation.

Electronic Document Management for Small Pharma
Jennifer Jaye
Principal Consultant, Jaye Solutions

Transitioning to eCTDs
Janel A. Demeter
Regulatory Operations, Octagon Research Solutions, Inc.

Getting Started with eCTDs
John W. Aitken, PhD
Managing Director, West Coast Operations, Octagon Research Solutions, Inc.

SESSION 210  ERS/DM2 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM
8:00 am-9:30 am  LEVEL: ●
Room A412AB  CME and Pharmacy credits offered

Structured Product Labeling: An FDA Update and the Industry Perspective
SESSION CHAIRPERSON(S)
Terry D. Hardin
Senior IT Architect, IBM Life Sciences

Late in 2005, Structured Product Labeling replaced PDF as the required format for electronic content of labeling submissions in the US, and in January 2006 the FDA introduced SPL PLR (the Physicians Labeling Rule). These labeling standards are based on the use of XML, and because of this are different from prior business drivers for industry, and pose continuing challenges for industry to meet these evolving requirements.

During this session the FDA will discuss the HL7 XML SPL standard and provide an update on where they are with implementing the standard to date. This session will also provide an industry perspective on the challenges in moving from PDF-based label submissions to XML submissions.

Industry Perspective
Mary Beth Wilusz
Associate Director, Global Labeling Systems, Worldwide Product Labeling, Merck & Co., Inc.

FDA Perspective
Lonnie D. Smith
Project Manager, Office of the Director, CDER, FDA
Jeffery M. Karp
Principal Analyst, Hospira, Inc.

SESSION 211  GCP - GOOD CLINICAL PRACTICES, CR
8:00 am-9:30 am  LEVEL: ■
Room B406AB  Nursing and Pharmacy credits offered

How to Be Prepared for an FDA Audit
SESSION CHAIRPERSON(S)
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

This session will describe the role of the FDA investigator and the preparation of a site for an FDA audit. The discussion will focus on helpful hints and procedural issues regarding what to do in case they are chosen for an FDA audit and will be taught some of the do’s and don’ts of an audit.

GCP Requirements and Considerations for an FDA Audit
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

Investigators Hosting FDA Inspections: Things to Consider
Sarah L. Wilson, MS
President, Wilson Quality Auditing & Training Services

Site Perspectives on FDA Audit Preparation
Gail Danhour, RN, CCRC
Executive Director, Rocky Mountain Clinical Research, Inc.
**SESSION 212**  IMP - IMPACT (IMPACT OF MEDICAL PRODUCTS AND THERAPIES), EC  
8:00 am-9:30 am  
Room B301  
Clinical Endpoint Validation: The State of the Science  
SESSION CHAIRPERSON(S)  
Keith W. Wenzel  
Product Director, ePRO, ClinPhone, Inc.  
The Food and Drug Administration has recently published draft guidance on the use of patient-reported outcomes (PROs). In addition, the FDA has publicly indicated that clinician-reported outcomes (CROs) will be held to the same rigorous standards as those applied to PROs and other clinical endpoints. The FDA’s draft guidance specifically addresses the instrument development process when modifying existing instruments for electronic collection of PROs (ePRO) and linguistic validation (translations). This guidance is expected to be finalized during 2007. These developments raise the stakes for outcomes researchers, study leaders, statisticians and data managers who must balance efficacy claims for approval and the collection of appropriate data for paying authorities. As sponsors incorporate ePRO and conduct global trials, the focus of regulatory authorities on the instrument development process and the associated validation studies is increasing. This session will present the state of the science for validation of patient-reported outcomes, clinician-assessed outcomes, ePRO and translations. Case studies will be used to highlight the development and validation processes for PROs and CROs in the context of their intended labeling claims.  
Collecting Both Clinician-assessed and Patient-reported Outcomes in Clinical Trials Using Validated Measures  
Lynne Adamczyk, BSN, MBA, RN  
Project Manager, Uniform Data System  
PRO Linguistic Validation (aka Translations): The State of the Science  
Hannah Jane O’Gorman  
ePRO Specialist, ClinPhone Inc., UK  
An Update on the Draft PRO Guidance and a Regulatory Perspective on Study Endpoints  
Laurie Beth Burke, MPH, RPh  
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

**SESSION 213**  IS - INVESTIGATOR SITES, GCP  
8:00 am-9:30 am  
Room B303  
IRB Site Visits and Audits  
SESSION CHAIRPERSON(S)  
Patricia Ann Seymour, MHA, CCRC, CIP  
Seymour Research Services  
This session will assist investigators and others to understand the purpose of an institutional review board site visit or audit. The differences between the visits will be explored as well as the ways to prepare for the IRB visit.  
What to Expect during an IRB Site Visit or Audit  
Patricia Ann Seymour, MHA, CCRC, CIP  
Seymour Research Services  
The IRB’s Perspective on Site Visits and Audits  
Cynthia M. Gates, JD, RN  
Director of Regulatory Affairs, Western Institutional Review Board
This session will present the use of the CTD summaries (Module 2) as important tools for the regulatory agency reviewers and internal reviewers, effective preparation of summaries linked to modules 3, 4, and 5, and regulatory updates.

Preparation of the Quality Overall Summary in the New Paradigm
Michelle Herrera Foster, PhD
Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

Writing an Effective Nonclinical Summary and Overview
Anneli Savinainen, MS
Scientist, Resolvix Pharmaceuticals

The Clinical Overview and Clinical Summary: What We Now Know
Teresa S. Armstrong, ELS
Associate Consultant, Global Medical Communications, Eli Lilly and Company

SESSION 217 - OS - OUTSOURCING, CR
8:00 am-9:30 am
Room B401
Benefits and Challenges of Implementing Standards in Outsourced Studies
Simin K. Baygani, MS
Project Statistician, Eli Lilly and Company
This session will provide both sponsor and CRO experience regarding benefits and challenges of using sponsor-defined standards. The use of these standards for data collection, dataset structures and analyses has brought a new factor into the working relationship between a sponsor and CRO.

Implementing Standards in Outsourced Studies: Industry Perspective
Amy S. Rosen, MS
Manager, Biostatistics, Targanta Therapeutics

Standards on Outsourced Clinical Trials: A CRO Perspective
John O. Blakeney, MPA
Senior Director, Clinical Data Management, Quintiles, Inc.

To Standardize or Not to Standardize: Perspectives on Outsourced Studies
Heather M. Irish
Protocol Data Manager, Bristol-Myers Squibb Company

SESSION 218 - PM1 - PROJECT MANAGEMENT, RD
8:00 am-9:30 am
Room B402
Driving Innovation, Growth, and Optimization through Portfolio Management
J. Mark Horn, MA
Director, Finance and R&D Portfolio Management, Wyeth Consumer Health Care
In an era of escalating costs and declining research and development productivity, effective risk and portfolio management is critical to the success of companies large and small. This session will cover portfolio management best practices and advanced strategies to drive innovation, growth, and optimization.

The Art and Science of Decision Making for Portfolio and Project Management
Surya P. Chitra, PhD, MBA
Principal Consultant, Savio Technologies - Health Solutions

Leveraging Portfolio Targets
J. Mark Horn, MA
Director, Finance and R&D Portfolio Management, Wyeth Consumer Health Care

Advanced Portfolio Strategies
Michael J. Wiebe, PEng, MBA
Principal, Stage-Gate Inc., Canada

SESSION 219 - PM2 - PROJECT MANAGEMENT, CTM/CS
8:00 am-9:30 am
Room B403
PMs as Project CEOs and the Effective Project Manager’s Tool Chest
Munish Mehra, PhD, MSc
Managing Director, Global Drug Development Experts
This session explains how an effective project manager should be considered the CEO of the project. Projects succeed or fail based upon the leadership skills of the PM. Sponsors and CROs must hire PM’s with the same traits one looks for in a good CEO. Most phase 2 and 3 clinical trials now have institutional sites in multiple countries outside North America and an increasing number of sites in Asia, East Europe and South America. An effective PM must be sensitive to different cultures and be able to work with a team across multiple time zones.

Managing Global Trials: Challenges and Opportunities for Project Managers
Michael J.B. Tansey, MD
Chief Medical Officer, Competitive Drug Development

The Effective Project CEO’s Tool Chest
Munish Mehra, PhD, MSc
Managing Director, Global Drug Development Experts

See Session 201 - PP - PUBLIC POLICY/LAW & RA - REGULATORY AFFAIRS, AHC, CP, CR
8:00 am-9:30 am
Sidney J. Marcus
Auditorium, Building A
CME and Pharmacy credits offered
Multitrack Plenary
Drug Safety Reform: Actions and Implications
See AHC on page 57 for a complete session description.
A panel discussion will share early results from industry on implementing a learn-confirm agenda into R&D. This agenda moves away from traditional approaches to R&D, and promises dramatic increases in productivity and clinical success.

Drug Development down the Road: The Last 12 Months in a Large Pharma
John J. Orloff, MD
Global Head Regulatory Strategy - Drug Regulatory Affairs, Novartis Pharmaceuticals

New Approaches to Clinical Operations: Moving CRO’s and CSO’s to the New Paradigm
Mike Collins, PhD, MS
Vice President, Worldwide Head, Phase 3b/4 Development Operations, Pfizer Inc

Regulatory Tools and their Application in the Learn-confirm Paradigm
Mehul Mehta, PhD
Director, Division of Clinical Pharmacology 1, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

Maximizing the Benefits of Medicines Information through Readability Testing
DK Theo Raynor, PhD, MRPharmS
Professor of Pharmacy Practice, University of Leeds, UK

Where Did Readability Testing Come from and Where is it Going?
DK Theo Raynor, PhD, MRPharmS
Professor of Pharmacy Practice, University of Leeds, UK

What the Regulators Look for in Readability Testing
Klaus Menges, MD
Head of Scientific Quality Assurance, BfArM, Germany

How to Get the Best Out of Readability Testing
Peter Knapp, PhD
Chief Scientific Officer, LUTO Research Ltd., UK

Effective Training of Study Site Staff for Better Clinical Trials
William D. Cooney, MBA
President and Chief Executive Officer, MedPoint Communications, Inc.
The use of proven training methods at investigator meetings has been lacking. Improved training of study site staff can produce faster study start-ups, improved performance by study sites, and better documentation. This session will explore methods for better training of study site staff.

**Advances in the Use of eMedia for Training**

*William D. Cooney, MBA*
President and Chief Executive Officer, MedPoint Communications, Inc.

**Practical Considerations in the Adoption of Advanced Training Practices**

*Pamela Sandlin*
Project Manager, PJM Program, Novartis Pharmaceuticals Corporation

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**SESSION 225 AD - ADVERTISING, RA**
10:00 am-11:30 am
Room A313

*Enforcement Update from the FDA*

**SESSION CHAIRPERSON(S)**

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

FAD enforcement actions need to be understood by every regulated company because they reflect FDA’s priorities and concerns in regulating advertising and promotion. This session examines the latest FDA enforcement actions and what they mean.

**Enforcement Update from DDMAC**

*Thomas W. Abrams, MBA*
Director, Division of Drug Marketing, Advertising and Communication (DDMAC), CDER, FDA

**Enforcement Update from APLB**

*Ele Y. Ibarra-Pratt, MPH, RN*
Branch Chief, Advertising and Promotional Labeling Branch, CBER, FDA

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**SESSION 226 BT - BIOTECHNOLOGY, CR**
10:00 am-11:30 am
Room B304

*Hot Topics in Biotechnology*

**SESSION CHAIRPERSON(S)**

*Bernard D. King, MD, MBA*
President, Macnas Consulting International

This session will present late-breaking topics important to the development of biotechnology drugs and products.

**Personalized Medicine: Hope or Hype? Opportunity or Curiosity?**

*Bernard D. King, MD, MBA*
President, Macnas Consulting International

**Challenges to Demonstrating Comparability of Biotechnology Products**

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

*Caroline Herd, PhD*
Vice President, Clinical Development, Metabolic Pharmaceuticals, Ltd., Australia

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**SESSION 227 CDM - CLINICAL DATA MANAGEMENT, CR**
10:00 am-11:30 am
Room A312

**Convergence of Healthcare and Life Sciences: Enhancing the Value Chain**

**SESSION CHAIRPERSON(S)**

*Edgar Mounib, MBA, MPH*
Global Healthcare Lead, IBM Institute for Business Value

Driven by the need for greater value from existing data, convergence of healthcare and life sciences will help improve patient health by reducing redundant/duplicate or conflicting data capture, improving the quality of data sources, improving clinical standards, and reducing medical errors.

**Promises and Prospects for Greater Convergence across Healthcare and the Life Sciences**

*Edgar Mounib, MBA, MPH*
Global Healthcare Lead, IBM Institute for Business Value

From WBDC to Online Patient Interaction and Research (OPIR)

*Elof Dimenas, PhD*
Clinical Information Strategy Director, AstraZeneca AB, Sweden

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**SESSION 228 CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA**
10:00 am-11:30 am
Room A311

*Lessons Learned from CMC Pilot Program: An FDA Perspective*

**SESSION CHAIRPERSON(S)**

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

This session will discuss the lessons learned from the CMC Pilot Program from the FDA perspective.

**Lessons Learned from CMC Pilot Program: An FDA Perspective #1**

*Stephen Miller, PhD*
Chemist, Office of New Drug Quality Assessment, CDER, FDA

**Lessons Learned from CMC Pilot Program: An FDA Perspective #2**

*Christine M. Moore, PhD*
Supervisory Chemist, Office of New Drug Quality Assessment, CDER, FDA

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**SESSION 229 CP1 - CLINICAL SAFETY AND PHARMACOVIGILANCE, RA**
10:00 am-11:30 am
Room A302

*Regulatory Inspections of Industry Pharmacovigilance Operations*

**SESSION CHAIRPERSON(S)**

*Carol L. Krueger, BSN, RN*
Consumer Safety Officer, Division of Compliance Risk Management and Surveillance, CDER, FDA
An overview of FDA and EMEA regulatory inspections of pharmacovigilance operations will be presented by a regulatory compliance officer and field investigator, and an industry representative. The significance of regulations, inspection processes, inspectional findings and corrective actions will be discussed.

**Regulatory Inspections of Pharmacovigilance Operations: A Regulatory Perspective**

Carol L. Krueger, BSN, RN  
Consumer Safety Officer, Division of Compliance Risk Management and Surveillance, CDER, FDA

**Regulatory Inspections of Pharmacovigilance Operations: An Industry Perspective**

Valerie E. Simmons, MD, FFPM  
Director, EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

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**SESSION 230**  
**CP2 - CLINICAL SAFETY AND PHARMACOVIGILANCE, IMP**

10:00 am-11:30 am  LEVEL: ■

Room A301  
CME and Pharmacy credits offered

**Risk Management for Vaccine Products**

**SESSION CHAIRPERSON(S)**

Jeffrey J. Stoddard, MD  
Vice President, Medical and Scientific Affairs, Risk Management and Post-marketing Programs, Covance

Vaccine risk management is unique relative to other products. Comprehensive risk management strategies need to be developed which include risk detection, risk assessment, risk-benefit analysis, and risk communication. This session, through numerous case studies, will present best practices for developing a risk management strategy, including risk assessment and communication.

**Vaccine Risk Management: Lessons from New Vaccines for Different Age Groups**

Adrian Dana, MD, FAAP  
Senior Director, CRMSS, Merck & Co., Inc.

Optimizing Postmarketing Vaccine Risk Assessment

Steven Black, MD  
Clinical Professor, Pediatric Infectious Diseases, Stanford University School of Medicine

Effective Vaccine Risk Communication

Allison Kennedy, MPH  
Epidemiologist, Immunization Services Division, Centers for Disease Control and Prevention

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**SESSION 231**  
**CR1 - CLINICAL RESEARCH AND DEVELOPMENT, PM**

10:00 am-11:30 am  LEVEL: ●

Room B409  
CME and Nursing credits offered

**Pediatric Clinical Trials: Lessons Learned from the Field**

**SESSION CHAIRPERSON(S)**

Peggy Schrammel, MPA  
Executive Director, Late Phase Development, PharmaNet

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**SESSION 232**  
**CR2 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS**

10:00 am-11:30 am  LEVEL: ■

Room B407

**Update to Radical Change in Clinical Development**

**SESSION CHAIRPERSON(S)**

Ira C. Spector, MBA  
Vice President, Clinical Development Operation, Wyeth Research

At the 2006 DIA Annual Meeting, Wyeth Research unveiled their program to radically change clinical development. This session will provide a one-year update regarding the Wyeth Springboard program to radically change the clinical development paradigm. Seven new initiatives were presented: global patient recruitment, 24 x 7, adaptive trials, remote data capture, process re-engineering, ECDC, learn and confirm, and clinical materials logistics. Results of these new initiatives will be described; updates on the initiatives and additional changes will be reviewed. The potential impact on clinical development times and their potential to change the pharmaceutical industry will also be presented.

Radical Change in Clinical Development: The Industry Responds to the Challenge

Ira C. Spector, MBA  
Vice President, Clinical Development Operation, Wyeth Research

Radical Change in Clinical Development at Wyeth

Jonathan L. Lange, MS  
Partner, Accenture

Radical Change in Clinical Development at Pfizer

R. Adrian Otte, MB, FFPM  
Senior Vice President, Worldwide Development Operations, Pfizer Inc

Radical Change in Clinical Development at Novartis

Ulo Palm, MD, MBA  
Global Head, Laboratory and Preclinical Quality Assurance, Novartis Pharmaceutical Corporation

Radical Change in Clinical Development at Genentech

Peter A. Carberry, MD, MBA  
Vice President, Clinical Operations, Genentech, Inc.
### SESSION 233  
**CR3 - CLINICAL RESEARCH AND DEVELOPMENT, RD**

**10:00 am-11:30 am**  
**Room B408**  
**LEVEL:** ●

**CME credits offered**

**Assessing the Impact of Increasing Protocol Complexity on Study Conduct Performance**

**SESSION CHAIRPERSON(S):**

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

Study protocols have become increasingly complex during the past decade. This session examines changes in protocol design and their impact on study conduct cycle time, budgets, and patient recruitment and retention effectiveness. Insights into better protocol design practices will be discussed.

**Efforts to Address Rising Protocol Complexity**

*William Candela, MBA*  
Director, Contract and Grants Management, Bristol-Myers Squibb Company

**Protocol Design Trends and Their Impact on Study Conduct Performance**

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

**Experience with Protocol Design Change and its Strategies to Improve Patient Recruitment Effectiveness**

*James P. Kremidas*  
Global Enrollment Optimization, Eli Lilly and Company

### SESSION 234  
**CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, CR**

**10:00 am-11:30 am**  
**Room B403**  
**LEVEL:** ■

**Records Management**

**SESSION CHAIRPERSON(S):**

*Dimitri Stamatiadis, MBA*  
Director, Medical Operations, Merck-Serono International, Switzerland

Just like a precious piece of jewelry, the eCTD pyramid shines and sparkles in the regulatory sunlight. But way below the surface, in the quiet security of corporate file rooms, behind burning firewalls lies a lot more. There, next to the eCTD constructs, one can find source documents and source data, the building bricks of past, present and future registration dossiers. These records represent the real treasure chest of our companies. Managing and preserving these valuable assets together with the virtual constructs that are our registration dossiers is crucial to the future and well being of our corporations and our patients. Good eRecords management means deep understanding of electronic files, confident mastering of records life cycle and firm control of the future of eRecords through digital archiving. So buckle up for a ride in the regulatory cyberspace.

**Data Archiving: Needs, Standards and Benefits**

*Philip W. Lord*  
Director, Digital Archiving Consultancy Limited, UK

**Drug Information at the National Library of Medicine**

*Stuart J. Nelson, MD*  
Head, Medical Subject Headings, National Library of Medicine

**RDM: It’s All about Metadata**

*Les Jordan*  
Industry Technology Strategist, Microsoft Corporation
SESSION 237  GCP - GOOD CLINICAL PRACTICES, CR
10:00 am-11:30 am  LEVEL: ●
Room B406AB  Pharmacy credits offered

Good Clinical Practices (GCPs) and ISO 9000: A Winning Combination
SESSION CHAIRPERSON(s)
Kurt Radke, MBA
Quality Assurance Director, Concentrics Research

The use of a comprehensive quality-system framework, such as ISO 9000, can provide the necessary discipline to consistently carry out clinical research in a regulatory-compliant manner. This quality-system approach will result in fewer errors, improved productivity, and is fully auditable. This session will review the origins of both ISO 9000 and GCPs and describe both the differences and similarities between these two established quality systems. The ability of the generic ISO 9000 system to be customized towards robust GCP compliance will also be demonstrated.

What Are GCPs?
Melanie Sells
IRB Administrator, Concentrics Institutional Review Board

What Is ISO 9000?
Mandy Russell
Vice President, Media Relations and Quality Assurance, Indy Tube Fabrication, LLC

Why Combine GCPs and ISO 9000?
Kurt Radke, MBA
Quality Assurance Director, Concentrics Research

SESSION 238  IMP - IMPACT (IMPACT OF MEDICAL PRODUCTS AND THERAPIES), CP
10:00 am-11:30 am  LEVEL: ●
Room B301  CME credits offered

Data Mining: Perils, Pitfalls and Pragmatism
SESSION CHAIRPERSON(s)
Manfred Hauben, MD, MPH
Medical Director, Risk Management Strategy, Pfizer Inc

Data mining is used by regulatory agencies and some pharmaceutical companies to aid in adverse event detection. This session will focus on issues of validation and explore how algorithm choice, database factors, and external forces influence the statistical results and ultimately its utility.

Measuring the Signal Contribution from Various Sources of AERS Reports
Alan M. Hochberg
Vice President, Research, ProSanos Corporation

Validation of Data Mining
Victor V. Gogolak, MA
President, DrugLogic, Inc.

Measuring and Ensuring the Effectiveness of Statistical Signal Detection: Ongoing Work at the EMEA
Jim Slattery, Esq., MSc
Scientific Administrator, Pharmacovigilance and Postauthorization Safety and Efficacy of Medicines Sector, Postauthorization Evaluation of Medicines for Human Use Unit, EMEA, EU

Panelist
Andrew Bate, PhD, MA
Manager, Research and Development, Uppsala Monitoring Centre, Sweden

SESSION 239  IS - INVESTIGATOR SITES, CTM/CS
10:00 am-11:30 am  LEVEL: ◆
Room B303

Feet on the Street: Using Community Outreach to Recruit Study Subjects
SESSION CHAIRPERSON(s)
Kelley McNamara
Project Manager, Healthcare Communications Group

Reaching special populations adds complexity to recruitment. Insulated by geography, culture or distrust of the healthcare system, these patients exist outside the databases of investigators. Grassroots outreach using unique methods and materials yields patients overlooked by traditional approaches. This session will discuss what initiatives and materials were successful and why.

Qualitative Research Perspective
Sandra Chase, MA
Director of Operations, Healthcare Communications Group

Community Outreach Perspective
Timothy Neithercott
Outreach Coordinator, New York University School of Medicine, Center for AIDS Research

SESSION 240  IT - INFORMATION TECHNOLOGY, CDM
10:00 am-11:30 am  LEVEL: ■
Room A305  Pharmacy credits offered

Protecting Intellectual Property
SESSION CHAIRPERSON(s)
Brian Martin
Information Security Manager, Lehigh Valley Health Network

Risks to protected corporate data are increasing every day. Three experts will share discrete ideas on the topic, covering the sources of risk, the penalties, and the solutions currently in use and those coming soon. Companies of all sizes are at risk, and this information can help position yours to survive.

Defining Intellectual Property (IP)
Brian Martin
Information Security Manager, Lehigh Valley Health Network

Legalities of IP
Chad Hunt
Special Agent, FBI

Protection and Compromise of IP
Greg Kelley
Chief Technology Officer, Vestige, Ltd.

SESSION 241  MC - MEDICAL COMMUNICATIONS, MA
10:00 am-11:30 am  LEVEL: ■
Room B404  Pharmacy credits offered

Establishing Principles to Support Co-marketed Products between Medical Information Departments
SESSION CHAIRPERSON(s)
Shubu O. Vaughan, MD, MS
Director, Cardiovascular/Thrombosis, Medical Information Services, sanofi-aventis

Medical information for co-marketed products may be handled through various arrangements of responsibility. Through sharing of experiences, this session will identify which processes are effective in dealing with this complex entity.
Equally Shared Medical Information Partnership: Written and Verbal Communication
Wynter J. Balcertski, PharmD
Medication Information Specialist, Cardiovascular/Thrombosis, sanofi-aventis

Medical Information Responsibilities across an Equally Shared Partnership: Interdepartmental Activities
Rupa Shah, PharmD
Associate Director, Medical Information, Cardiovascular, Bristol-Myers Squibb Company

Considerations for Effective Medical Communications Collaborations: Case Study
Stacey M. Fung, PharmD
Senior Scientist, Medical Communications, Genentech, Inc.

SESSION 242 MW - MEDICAL/SCIENTIFIC WRITING, MC
10:00 am-11:30 am LEVEL: ■
Room A315
Outsourcing On-shore and Off-shore
SESSION CHAIRPERSON(S)
Jean H. Soul-Lawton, PhD
Global Medical Writing Director, GlaxoSmithKline R&D, UK

This session will discuss, from the sponsor and contractor perspective, the expectations, advantages and challenges of contracting out medical writing. On-shoring and off-shoring experience will be described and the learnings from setting up an outsourced services unit in India will be included.

What We Expect from Contractors
Jean H. Soul-Lawton, PhD
Global Medical Writing Director, GlaxoSmithKline R&D, UK

Efficient Preparation of Regulatory Documents Using a Contract Medical Writing Group
Pamela Lindroos, PhD
Director, Medical Writing, WebbWrites

Learnings from Setting Up an Outsourced Services Business in India Targeted at Pharmaceutical/Biotechnology Companies
Hari Thrivikramji, MD, MBA, MSc
Chief Executive Officer, Strategic Analysis and Tech Solutions Ltd., UK

SESSION 243 NHP - NATURAL HEALTH PRODUCTS, CP
10:00 am-11:30 am LEVEL: ■
Room B306 Nursing and Pharmacy credits offered
Safety and Pharmacovigilance of Natural Health Products (NHPs): International Efforts
SESSION CHAIRPERSON(S)
Pulok K. Mukherjee, PhD, MPharm, RPh, FIC
Director, School of Natural Product Studies, Jadavpur University, India

Globally, NHPs play a major role in healthcare. Beside the widespread use of phytomedicine in developing countries, complementary and alternative medicine (CAM) is used in developed countries, resulting in differences in how NHPs are regulated from country to country. This session will examine how NHPs are evaluated for safety in various regions of the world, what impacts safety evaluation, as well as the recent developments in the adverse event reporting requirements for NHPs sold as dietary supplements in the US.

Perspective of Safety, Efficacy and Quality of Natural Health Products with International Coordination
Pulok K. Mukherjee, PhD, MPharm, RPh, FIC
Director, School of Natural Product Studies, Jadavpur University, India

Adulteration of Herbal Remedies with Synthetic Drugs, Heavy Metals, and Pathogens: Safety and Regulatory Implications
Harpal S. Buttar, DVM, PhD, MSc
Senior Scientist and Adjunct Professor, Reproduction and Urology Division, Therapeutic Products Directorate, Health Canada

Adverse Event Assessment and Reporting of Natural Health Products Being Marketed as Dietary Supplements: A US Perspective
Dandapani N. Sarma, PhD, RPh
Senior Scientist, Dietary Supplements Standards Division, US Pharmacopeia

SESSION 244 OS - OUTSOURCING, CR
10:00 am-11:30 am LEVEL: ■
Room B401
Transforming Five New Clinical Development Strategies into Real Results and What We Can Learn from the Industries that Have Done It
SESSION CHAIRPERSON(S)
Bruno G. Gagnon, MPharm
Senior Consultant, The Biologics Consulting Group

This session goes beyond strategy to address practical, executable solutions that have helped other industries conquer the same pressures that the pharmaceutical industry faces today. We will discuss success factors for new strategies including functional service providers, scenario planning, global development and outsourcing, and others.

Transforming New Clinical Development Strategies into Real Results and What We Can Learn from the Industries that Have Done It
Bruno G. Gagnon, MPharm
Senior Consultant, The Biologics Consulting Group

Panelists
John R. Vogel, PhD
Drug Development Consultant, John R. Vogel Associates Inc.
Anthony J. Carita
Director, Clinical Outsourcing, Otsuka Maryland Research Institute
Michael Soenen
Managing Partner, ClearTrial
Karen A. Zuklie
Director, Planning and Outsource Management, Purdue Pharma, L.P.

SESSION 245 PM - PROJECT MANAGEMENT, BT
10:00 am-11:30 am LEVEL: ■
Room B402 Project Management units offered
Considerations in Managing the Development of a Biologic from Initiation through Life-cycle Management
SESSION CHAIRPERSON(S)
Michele C. Livesey
Global Research and Development Team Leader, Roche Palo Alto, LLC

As traditional pharmaceutical companies reshape the way they are doing business to ensure continued profitability in the future, an area which is being embraced is biotechnology. Therefore, an increasing amount of experienced pharmaceutical project managers may soon be faced with managing a biologic for the first time. This session will be geared for project managers who already have a good understanding of the overall development and commercialization process but may not have had experience in dealing with a biotechnology project. Each speaker will focus on a different phase of development and commercialization highlighting aspects that a project manager should be aware of so that they can manage their team effectively.
Canada has recognized the need to design flexibility into the system to allow for timely access to therapies considered to be of significant value and to recognize technological innovations in drug development. Therefore, measures are being taken to update a regulatory regime that dates from the early sixties, provide needed authorities to oversee activities that need to be risk managed and, in general, reorient the entire approach to regulating the development of therapeutics.

**Setting the Stage: The Scientific Context**

Agnes V. Klein, MD  
Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada

**Progressive Licensing Framework: A New Regulatory Paradigm**

David K. Lee  
Director, Office of Patented Medicines Liaison, Therapeutic Products Directorate, Health Canada

**Establishing the Benefits and Risks of Therapeutic Agents: A Regulatory Perspective**

Robyn Lim, PhD  
Scientific Advisor, Progressive Licensing Project, Therapeutic Products Directorate, Health Products and Food Branch, Health Canada

**SESSION 248 RA2 - REGULATORY AFFAIRS, GCP**

10:00 am-11:30 am  
LEVEL: ●

Room A402  
Pharmacy credits offered

**Indexing SPL: FDA’s Proposed Strategy and What We Learned from Coding (Indexing) Highlights Sections**

SESSION CHAIRPERSON(s)

A. Leander Fontaine, MD  
President, Pharmaceutics LLC

This session reviews FDA’s proposed strategy for indexing structured product labeling (SPL) and important first experiences in coding (indexing) highlights information.

**FDA’s Proposed Strategy for Indexing Structured Product Labeling**

Randy Levin, MD  
Director for Health and Regulatory Data Standards, CDER, FDA

**The Ability of the Current Set of Indexing Elements to Capture Label Messages: Perspective of a Highlights Coder**

A. Leander Fontaine, MD  
President, Pharmaceutics LLC

**Strength and Limitations of SPL Terminologies for Encoding Clinical Content: An Industry Perspective**

Gwen K. Samuel  
Associate Director, Medical Encoding, Bristol-Myers Squibb Company

**SESSION 249 RA3 - REGULATORY AFFAIRS, RD**

10:00 am-11:30 am  
LEVEL: ●

Room A404

**Scientific Advice in the EU**

SESSION CHAIRPERSON(s)

Craig A. McCarthy, MBA  
Director, Regulatory Affairs and Development, CAMPHARM Ltd., France

This session will look at the strategy of obtaining scientific advice in the EU. The experiences and recommendations of two US companies will be compared and contrasted to US scientific advice procedures. The Q&A panel will include...
representatives from the three companies and other companies that are about to, or have carried out scientific advice in the EU, will also be invited to participate.

**Strategy of Scientific Advice in the EU**

Craig A. McCarthy, MBA  
Director, Regulatory Affairs and Development, CAMPHARM Ltd., France

**US Company Experience of Decentralized (National) Scientific Advice in the EU**  
Susan Hizon Caballa, MS  
Senior Vice President, Regulatory and Medical Affairs, Alimera Sciences Inc.

**US Company Experience of Centralized (EMEA/CHMP) Scientific Advice in the EU**  
Elora Gupta, PhD  
Associate Director, Bristol-Myers Squibb Company

**SESSION 250  RA4 - REGULATORY AFFAIRS, CR**

10:00 am-11:30 am  LEVEL: ■

Room A406

**Combination Products: Preapproval Challenges and Opportunities – Part 1 of 2**

SESSION CHAIRPERSON(S)  
Christine Allison, MS, RAC  
Regulatory Scientist, Eli Lilly and Company

Part 2 of this session will take place on Tuesday at 2:00 pm.

Combination products present unique challenges during the development. This session will discuss key elements to be considered during the development of the combination products. Perspectives from both the regulatory authority and industry will be presented.

**Combination Product Premarket Regulatory and Practical Approaches**  
Patricia Y. Love, MD, MBA  
Associate Director, Office of Combination Products, Office of the Commissioner, FDA

**Combination Product Development: Challenges and Opportunities from a Drug Industry Perspective**  
Andrew N. Papas, PhD, MBA, RAC  
Associate Director, Wyeth BioPharma

**Combination Product Development Challenges and Opportunities from a Device Industry Perspective**  
Julia A. Nelson, MS, RAC  
Manager, Corporate Regulatory Affairs, American Medical Systems, Inc.

**SESSION 252  RD - R&D STRATEGY, OS**

10:00 am-11:30 am  LEVEL: ■

Room B305

**Globalization of Industry-sponsored Clinical Trials: Evidence on Recent Trends**

SESSION CHAIRPERSON(S)  
Chuck Swanson  
Director, Account Management, Fast Track Systems, Inc.

Global clinical trials have increased substantially over the last five years. The growth in clinical trial participation is most pronounced in the so-called “emerging economies”. This session will discuss the geographies where this growth is occurring and the drivers behind the growth.

**SESSION 253  ST - STATISTICS, CR**

10:00 am-11:30 am  LEVEL: ■

Room B309  
CME and Pharmacy credits offered

**Graphical Analysis of Clinical Safety and Efficacy Data**

SESSION CHAIRPERSON(S)  
Michael O’Connell, PhD  
Director, Life Sciences, Insightful Corporation

The wise use of statistical graphics in the analysis of clinical data creates efficiencies in clinical drug development. Two key areas are informal review of results by clinicians and formal clinical study reports. This session covers the use of graphics in the analysis of clinical data.

**Visual Representation of Clinical Data to Elicit Safety and Efficacy Signals**  
Mat Soukup, PhD  
Mathematical Statistician, CDER, FDA

**Statistical Graphics for Clinical Development Studies**  
Michael O’Connell, PhD  
Director, Life Sciences, Insightful Corporation

**Improving Graphics Usage in Clinical Development Decision Making**  
Susan P. Duke, MS  
Assistant Director, Biostatistics and Programming Development Partners, GlaxoSmithKline

**SESSION 254  TR - TRAINING, CR**

10:00 am-11:30 am  LEVEL: ●

Room B308

**Getting the Message Across: It’s All about the Presentation**

SESSION CHAIRPERSON(S)  
Theresa Hummel-Krallinger  
Director, Training and Organizational Development, Almac Clinical Technologies

Attend this session for some great tips and demonstrations of tools and tricks that will add value and punch to your training or presentations. Also get an overview of several web-based tools that make quizzes and surveys a snap – even for the non-techies.

**Wisdom from the Trenches: Pitfalls to Avoid, Added Value to Include**  
Donna Walsh  
President, RedShoes Solutions

**Engage Your Audience with Good Instructional Techniques**  
Lauren Edelstein-Henry  
Lead Process Support Specialist, Centocor R&D Inc.

**Wow Your Audience with Technology**  
Theresa Hummel-Krallinger  
Director, Training and Organizational Development, Almac Clinical Technologies
**SPECIAL EVENT**
10:00 am-12:00 pm  LEVEL: ●
Room A304

**Student Forum**
SESSION CHAIRPERSON(s)
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 for students to provide input to the DIA.

Welcoming Remarks
Cynthia L. Kirk, PhD, RAC
Vice President, Global Regulatory Affairs, PRA International and President, Drug Information Association

Introduction of the Student Poster Winners
Françoise G. Pradel, PhD
Associate Professor, University of Maryland - Baltimore

DIA’s Student Initiative
Stephen A. Sonstein, PhD, MS
Director, Clinical Research Administration, Eastern Michigan University

Employment Opportunities in Clinical Research: The Current Job Market, the Education versus Experience Dichotomy and How to Best Market Yourself
Chris J. O’Malley
Manager, United States Recruiting, Kendle, Inc.

How to Develop a Resume
Tammy Jeanne Massie, MS
Mathematical Statistician, Office of Biostatistics and Epidemiology, CBER, FDA

Round Table/Panel Discussion
Discussion relating to speakers’ presentations and the role of students in DIA

11:30 am-2:00 pm  LUNCHEON
Building A – Exhibit Hall A Only

**SESSION 255**  AD - ADVERTISING, RA
2:00 pm-3:30 pm  LEVEL: ■
Room A313  Nursing and Pharmacy credits offered

Direct-to-consumer Update from the FDA
SESSION CHAIRPERSON(s)
Neal Collins, MD
Senior Medical Director, Pfizer Inc

This session will present an update on DTC from a broad perspective and with highlights from FDA professionals involved with this important topic.

Understanding DTC
Kathryn J. Aikin, PhD
Social Science Analyst, DTC Review Group Research Team, Division of Drug Marketing, Advertising, and Communication, CDER, FDA

Effective Utilization of DTC
Thomas W. Abrams, MBA
Director, Division of Drug Marketing, Advertising and Communication (DDMAC), CDER, FDA

Research Update
Amie C. O’Donoghue, PhD
Social Science Analyst, Division of Drug Marketing, Advertising, and Communication, CDER, FDA

**SESSION 256**  BT - BIOTECHNOLOGY, CP
2:00 pm-3:30 pm  LEVEL: ●
Room B304  CME and Pharmacy credits offered

Transitioning from Stem Cell Research to Commercial Applications
SESSION CHAIRPERSON(s)
Joy A. Cavagnaro, PhD, DABT, RAC
President, Access BIO

A core set of safeguards is required to ensure advancement of human stem cells in clinical development. These safeguards are derived through a multidisciplinary coordinated approach. Key considerations will be highlighted as they apply to manufacturing, preclinical and clinical development.

Quality Issues in Cell Therapy Development
Scott R. Burger, MD
Principal, Advanced Cell & Gene Therapy, LLC

Preclinical Issues in Cell Therapy Development
Joy A. Cavagnaro, PhD, DABT, RAC
President, Access BIO

Clinical Issues in Cell Therapy Development
Joseph Fratantoni, MD
Vice President, Medical Affairs and Clinical Development, MaxCyte, Inc.

**SESSION 257**  CDM - CLINICAL DATA MANAGEMENT, OS
2:00 pm-3:30 pm  LEVEL: ■
Room A312

Outsourcing in Data Management: Thinking Global, but Still Acting Local?
SESSION CHAIRPERSON(s)
Munish Mehra, PhD, MSc
Managing Director, Global Drug Development Experts

Data management outsourcing activities follow different models with varying requirements among companies depending on size, content and projects. The session will present sponsor experiences with global outsourcing of data management tasks and examine if sponsors and CROs can think and act globally.

The Interglobal Relation between Pharma and a CRO from a Sponsor Data Management Department Perspective
Pieter Voermans, MS
Site Head, Data Management, F. Hoffmann-La Roche Ltd., Switzerland

Does Offshoring Data Management Compromise Quality?
Ritesh Mondal, MD
Director, IT Services, RxMD Pharmaceutical Physicians Pvt. Ltd, India

Addressing Global/Local Issues: Perspectives from a Functional Outsourcing Partner
Peter M Russell
Associate Partner, Accenture Health & Life R&D

**SESSION 258**  CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA
2:00 pm-3:30 pm  LEVEL: ■
Room A311

Lessons Learned from CMC Pilot Program: An Industry Perspective
SESSION CHAIRPERSON(s)
Nirdosh Jagota, PhD
Assistant Vice President, Global Regulatory Affairs, CMC, and Conformance, Wyeth Pharmaceuticals
The session will provide industry perspective on opportunities and challenges with implementing Quality-by-design-based applications. Two case studies will be presented followed by a panel discussion.

**Implementation of Quality by Design: Challenges and Opportunities**

*Ferdinando E. Aspesi, PhD*
Senior Vice President, Global Regulatory Affairs, CMC and Global Compliance Auditing, Wyeth Research

**Development of a Quality-by-design Product and CTD Submission: Learnings to Date**

*Zena Smith, PhD*
Associate Research Fellow, Pfizer, UK

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**SESSION 259**

**CP1 - CLINICAL SAFETY AND PHARMACOVIGILANCE, IMP**

2:00 pm-3:30 pm

Room A302  
CME, Nursing, and Pharmacy credits offered

**Can Risk Communication Be Improved? Pitfalls and Progress**

SESSION CHAIRPERSON(S)

*Andrzej Czarnecki, MD, PhD*
Director, Deputy Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

The session will present and discuss risk communication from a broad perspective avoiding standard regulatory communication. The target will be intelligent information about risks that would stop or at least diminish irresponsible activities of public media and other parties from misinterpreting the data and causing unnecessary public scare or expectations.

**FDA Perspective**

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

**The Role of Risk Communication in Risk Management**

*Cherif Benattia, MD*
President and Chief Executive Officer, APhaRC, LLC

**Intelligent Risk Communications: Can We Do Better?**

*Andrzej Czarnecki, MD, PhD*
Director, Deputy Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

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**SESSION 260**

**CP2 - CLINICAL SAFETY AND PHARMACOVIGILANCE, CR**

2:00 pm-3:30 pm

Room A301  
Nursing credits offered

**Postmarketing Safety Studies and Intensive Event Monitoring Techniques: What Have We Learned?**

SESSION CHAIRPERSON(S)

*Saad A.W. Shakir, MD, FRCP*
Director, Drug Safety Research Unit, UK

Setting up safety monitoring schemes and conducting a range of studies are parts of the risk management of drugs. Broadly, the aims are to identify new adverse drug reactions and better understand those which have been incompletely characterized. The session will focus on two areas. The first is on how an intensive monitoring scheme — prescription event monitoring (PEM) — is being modified to meet the requirements of risk management. The second area is postmarketing clinical trials being conducted for safety. Such PMS studies tend to be large, randomized but open label, lengthy in duration and naturalistic. Examples of the achievements of these studies’ difficulties and positive ways to avoid them will be discussed and illustrated.

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**Avoiding Pitfalls in the Conduct of Postmarketing Trials for Safety**

*Gerald A. Faich, MD, MPH*
Senior Vice President, Epidemiology and Risk Management, United BioSource Corporation

**The Modification of Prescription Event Monitoring (PEM) to Meet the Requirements of Risk Management of Medicines**

*Saad A.W. Shakir, MD, FRCP*
Director, Drug Safety Research Unit, UK

**SESSION 261**

**CR1 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS**

2:00 pm-3:30 pm

Room B409  
Nursing credits offered

**Patient Recruitment: Strategic Approaches to Optimize Outcomes**

SESSION CHAIRPERSON(S)

*Jane E. Myles, MS*
Senior Manager, Clinical Trial Management, Genentech, Inc.

**Multifactorial barriers delay timely recruitment to clinical trials. The strategic use of vendors or in-house resources matched to trial needs can optimize recruitment outcomes. This session will focus on tactics to mitigate risks to recruitment timelines in US-based and global trials.**

**Matching Your Needs to Solutions**

*Jane E. Myles, MS*
Senior Manager, Clinical Trial Management, Genentech, Inc.

**eRecruitment Solutions to the Special Challenges of Global Studies**

*Bonnie A. Brescia*
Founding Principal, BBK Worldwide

**Recruitment Criteria: Creativity, Communication, and Collaboration**

*Amy Finck*
Consultant Trial Manager

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**SESSION 262**

**CR2 - CLINICAL RESEARCH AND DEVELOPMENT, NC**

2:00 pm-3:30 pm

Room B408  
CME credits offered

**Renal Biomarker Qualification for Decision Making**

SESSION CHAIRPERSON(S)

*Gerard Maurer, PhD*
New Technologies Office, Novartis Pharma AG, Switzerland

This session will cover all aspects of the biomarker qualification and their preclinical and clinical use. Adherence to a process is crucial when exploratory biomarkers should be qualified as known valid biomarkers that are appropriate for regulatory decision making. The elements of the biomarker qualification process map recently proposed by the FDA will be discussed and illustrated with examples of the renal biomarker projects. Also, the relevance of some of the biomarkers for clinical use will be documented as well as benefits of these new biomarkers in the current clinical practice.

**Critical Path and Biomarker Qualification**

*Federico Manuel Goodsaid, PhD*
Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

**Qualification and Validation of Renal Safety Biomarkers**

*Gerard Maurer, PhD*
New Technologies Office, Novartis Pharma AG, Switzerland

**Cross-qualification of Renal Safety Biomarkers by the C-Path Predictive Safety Testing Consortium**

*Frank D. Sistare, PhD*
Executive Director, Safety Assessment, Merck & Co., Inc.
Early and Predictive Marker of Renal Function in Man

Joseph V. Bonventre, MD, PhD
Professor of Medicine and Health Sciences and Technology, Harvard Medical School; Brigham and Women’s Hospital

**SESSION 263**

**CR3 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS**

2:00 pm-3:30 pm

**Room B407**

**Clinical Trials Transparency: Issues, Perspectives and Goals**

**SESSION CHAIRPERSON(s)**

Yves Juillet, MD, PhD
Senior Advisor, LEEM, France

Increasing transparency of clinical trials sponsored by research-based companies is considered as key. In order to reach this objective, the pharmaceutical industry has decided to disclose clinical information via registries and databases (Joint Declaration January 2005). Confirming its commitment to provide transparency, the IFPMA (International Federation of Pharmaceutical Manufacturers) has launched a new Internet search portal providing access to all data made available worldwide.

In September 2005, the IFPMA launched a new Internet search portal providing fast user-friendly access to all data made available. In this session, all aspects of clinical trials registries and databases will be considered as well as a look at the IFPMA portal implementation.

**Clinical Trial Transparency: Background, Industry Actions, the IFPMA Portal**

Beat E. Widler, PhD
Global Head of PDQ, F. Hoffmann-La Roche Ltd., Switzerland

**Influence of Disclosure on Development**

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

**Disclosure and Clinical Development: A Company Experience**

Liam Ratcliffe, MD, PhD, MBA
Senior Vice President, Head of Clinical Research and Development, Pfizer

Global Research and Development

**SESSION 264**

**CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, CR**

2:00 pm-3:30 pm

**Room B405**

**Identifying and Overcoming Site Initiation Delays in Multinational Clinical Trials**

**SESSION CHAIRPERSON(s)**

Matthew Kibby, MBA
Leader, Global Operations, BBK Worldwide

In multicenter, multinational clinical studies, the sites in various countries start to screen and enroll patients at different rates. For sponsors, achieving time-to-target starts for all sites is a considerable challenge. The factors involved include developing infrastructure, creating high-functioning teams, navigating cultural and regulatory barriers, and improving project management. This session describes the steps that must be completed to initiate multiple sites worldwide, suggests where breakdowns typically occur, and draws on expertise in the field to offer strategies for reducing initiation delays, managing the inherent unpredictability of site initiation effectively, and maximizing recruitment potentials of initiated sites. Attendees will come away with a current perspective on site initiation challenges, as well as ideas for how to improve site initiation rates moving forward.

**SESSION 265**

**EC - eCLINICAL, CDM**

2:00 pm-3:30 pm

**Room A314**

**Global Adoption of eClinical Technologies**

**SESSION CHAIRPERSON(s)**

Charles Jaffe, MD, PhD
Chief Executive Officer, HL7

Since its reference in the FDA Guidance, the role of CDISC in the global regulatory environment has continued to grow both in scope and impact. In addition to its role in the development of a clinical research domain model within the HL7 framework, CDISC has expanded its reach to preclinical data as well as to the expression of the trial protocol. The industry has begun to leverage the use of the CDISC models to amplify and streamline the clinical development process. Moreover, there is mounting evidence that implementation of the CDISC standards brings tangible returns to a broad range of industry organizations.

**CDISC: Helping Industry Implement the Standard**

David P. Iberson-Hurst
Chief Executive Officer, Assero Ltd., UK

**Global Adoption of eClinical Technologies and Data**

Rebecca D. Kush, PhD
President, CDISC

**Real-life ROI Using CDISC Standards as the Backbone for eClinical Data Exchange**

Anthony J. Costello
Vice President, Product Development and Data Services, Nextrials, Inc.

**SESSION 266**

**ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, RA**

2:00 pm-3:30 pm

**Room A412AB**

**Second Annual CDER eSubmission Update**

**SESSION CHAIRPERSON(s)**

Donovan F. Duggan, II, MBA
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

CDER is continuing to streamline processes and procedures to further facilitate the review of electronic submissions. These changes include the conversion from traditional electronic submissions to eCTD along with the development of information management project proposals, which will benefit the consumer and the pharmaceutical industry.

**FDA-wide Strategic Planning Initiatives for Electronic Submissions**

Malcolm J. Bertoni, MS
Director, Planning Staff, Office of the Commissioner, FDA

**Update on the Electronic Secure Gateway (ESG)**

Michael Faulntleroy
Director, Electronic Submissions Program, CBER, FDA
SESSION 267  **GCP - GOOD CLINICAL PRACTICES, CR**
2:00 pm-3:30 pm  LEVEL: ■
Room B406AB

**Working with and Managing Contract Auditors**

**SESSION CHAIRPERSON(S)**

**Stanley C. Rogers**
Executive Vice President, R&D Quality Assurance, SMHW Associates

Companies employ contract auditors as their audit staff or to support their staff. There are several key issues in doing this; selecting the right auditor, training to meet your needs, consistency, and reporting. Contract auditors’ issues and the auditee of a contract auditor will be discussed.

A Contract Auditor Perspective

**Edith S. Lewis-Rogers, MBA**
President, SMHW Associates, Inc.

Hosting Audits from a Contract Auditor: A CRO Perspective

**Geoffrey C. Gerard**
Director, Quality Assurance, Americas and Pacific, PRA International, Inc.

Working with and Managing Contract Auditors: A Sponsor’s Perspective

**Debra Weiss, MSN, RN**
Director, R&D Quality Assurance, Shire Pharmaceuticals

SESSION 268  **IMP - IMPACT (IMPACT OF MEDICAL PRODUCTS AND THERAPIES), IT**
2:00 pm-3:30 pm  LEVEL: ■
Room B301

**Accident or the Potential of Saving Lives with Remote Ultrasound Technology**

**SESSION CHAIRPERSON(S)**

**Bonne Farberow, RN, CCRA, CCRP**
Project Director, Division of Heart Failure/Transplant; Consultant, Clinical Research, University of Pennsylvania; Vice President, Clinical Care Experts, Inc.

There is a national emphasis on disease management, technology in the home and increased remote telemedicine. There needs to be an equivalent or should there be a higher emphasis on early screening and intervention to significantly increase quality of life, decrease patient risks and significant healthcare economic impact? Remote ultrasound technology has been implemented and tested under investigational review board approval and obtained FDA clearance to market. The initial findings have been significant and the case studies to be presented will share interesting results on the patients as well as the staff providing the training.

Remote Ultrasound Technology Case Studies and Preventative Medicine

**Bonne Farberow, RN, CCRA, CCRP**
Project Director, Division of Heart Failure/Transplant; Consultant, Clinical Research, University of Pennsylvania; Vice President, Clinical Care Experts, Inc.

**John Coleman**
Chief Scientist, Cyber MDx Inc.
Session 272  MW - Medical/Scientific Writing, CP
2:00 pm-3:30 pm  LEVEL: ■
Room A315  Pharmacy credits offered

Providing Data Displays to Support Communication of Safety Information
SESSION CHAIRPERSON(s)
Susan C. Sisk, PhD
Principal, SFP Consulting, LLC

Do the tables and listings you use to display safety data really support the writing and regulatory review process? Do you know what questions to ask when reviewing analysis plans for study reports and safety summaries? In this session, general principles and detailed suggestions for designing safety tables and listings to expedite report and summary preparation will be presented, as well as tips on how to standardize table formats. In addition, special consideration will be given to preparing listings that support writing of case narratives.

Providing Data Displays to Support Accurate Interpretation of Safety Data
Christine Uhlinger, DVM, MPH, DABVP
President, Triangle Research Communications

Providing Data Displays to Support Preparation of Case Narratives
Susan C. Sisk, PhD
Principal, SFP Consulting, LLC

Standardization of Data Analysis and Displays for Safety Reports
Michael A. Litzsinger, MS
Global Head, Statistical Programming, Schwarz BioSciences, Inc.

Session 273  NC - Nonclinical Laboratory Safety Assessment, CR
2:00 pm-3:30 pm  LEVEL: ■
Room B302  CME credits offered

Carcinogenicity Testing Database
SESSION CHAIRPERSON(s)
Joseph J. DeGeorge, PhD
Vice President, Safety Assessment, Merck & Co., Inc.

This session will focus on efforts underway, based on the extensive experience with traditional approaches, to alter the current testing paradigm to improve upon both the timeline and resource commitment necessary to assess cancer risk. Importantly, the approach discussed will preserve and potentially improve upon the protections afforded to patients. The current status of this effort as well as potential hurdles to its realization will be addressed.

Evaluation of Six- and Twelve-month Rat Toxicity Assays as Predictors of Tumorigenicity
Vijay Reddy, PhD
Senior Research Fellow, Merck & Co., Inc.

Are Two-year Carcinogenicity Studies Necessary?
Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, ONDIO, CDER, FDA

Session 274  NHP - Natural Health Products, RA
2:00 pm-3:30 pm  LEVEL: ■
Room B306

Industry’s Experience with Carcinogenicity Outcome Correlations with Histopathology Data from Tox Studies
Dan G. Morton
Drug Safety Research and Development, Pfizer Inc

SESSION 274  NHP - Natural Health Products, RA
2:00 pm-3:30 pm  LEVEL: ■
Room B306  CME credits offered

Developing NHPs as Drugs: CMC and Quality Control/Quality Assurance Considerations
SESSION CHAIRPERSON(s)
Jinhui Dou, PhD
Botanical Review Team, Office of New Drugs, CDER, FDA

This session will address the impact of quality and CMC requirements on drug development and risk assessment for botanical drugs. Several international perspectives will be presented.

Natural Health Products: How Safe and Effective Are Those?
Mohammed Razdar Khan
Director, Synergex Consulting, Canada

Indian Natural Health Care Remedies: QC and QCA and Evaluation
Vimala Devi, PhD, MPHarm
Chief Executive Officer, Visiting Professor and Research Advisor, Auro Pharma, India

Qualifying the NHP Product from the IND through the NDA Process: A US Update
Jinhui Dou, PhD
Botanical Review Team, Office of New Drugs, CDER, FDA

Session 275  OS - Outsourcing, CR
2:00 pm-3:30 pm  LEVEL: ■
Room B401

Improving CRO Negotiations to Accelerate Time to Market
SESSION CHAIRPERSON(s)
Richard K. Musselman
Managing Partner, CPO, ClearTrial LLC

CRO contract negotiations are the often overlooked culprit in time-to-market delays. We will examine how the contracting process can be streamlined starting with the expectations placed on CROs, how they are asked to bid, and culminating in the advantages/drawbacks of preferred-level relationships.

Improving CRO Negotiations to Accelerate Time to Market: A Medium Pharma Point of View
Jack Lawler
Associate Director, CRRA Information Solutions, Cephalon

Improving CRO Negotiations to Accelerate Time to Market: A Major Pharma Point of View
John Covin, MA
Global Director, Global Grants and Contracts, GlaxoSmithKline

Improving CRO Negotiations to Accelerate Time to Market: A CRO Point of View
Tom Marchisello
Senior Director, Finance and Business Development, Covance
Room B402

**SESSION 276**

**PM1 - PROJECT MANAGEMENT, CP**

2:00 pm-3:30 pm

*PROJECT MANAGEMENT units offered*

**Risk Management in Clinical Trials**

**SESSION CHAIRPERSON(S)**

Ralph D. White, PhD
Director, PPMLD Ltd., UK

Risk management is a proactive process which, simply, demands that you ask what might happen in the future, rather than react ineffectively to an unexpected, usually damaging event. It requires an open and inquiring mind and sets out to identify risks, the likelihood that they might occur and, if they do, what might be their impact. The next stage is contingency planning — to identify ways to avoid the risk or at least mitigate it, or to transfer the risk elsewhere to those better able to manage it, or, exceptionally, to accept it. The conduct of clinical trials is rich in areas for the application of risk management, and this session will examine broad aspects of the subject ranging from choice of sites and investigators in global trials, through to patient recruitment, patient safety, data integrity, legal indemnity and public relations.

**Risk Management in Clinical Trials**

Holger Liebig
Director, Project Management, PAREXEL International, Belgium

Assessing and Managing Recruitment Risks in Clinical Trials, with an Emphasis on Europe and Australia

Philippa Smit-Marshall, MBChB, MFPMP
Executive Medical Director, Medical and Scientific Affairs, PharmaNet B.V., Netherlands

Understanding and Mitigating the Risks Associated with an International Clinical Program

Bruce M. Wagman, MBA, RN, RAC
Vice President, Regulatory and Quality Assurance Services, Covance, Inc.

Room B403

**SESSION 277**

**PM2 - PROJECT MANAGEMENT, CR**

2:00 pm-3:30 pm

*PROJECT MANAGEMENT units offered*

**Development of an Integrated Molecule and Nonmolecule Forecast**

**SESSION CHAIRPERSON(S)**

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

Annually, a significant amount of R&D resources support nonmolecule work, which includes substantial efforts to develop the capabilities to meet strategic long-term goals. It is a growing strategic advantage to develop a robust, integrated approach to molecule and nonmolecule business planning.

Creating an Integrated Forecast

Michael Montesana, MA
Director/Practice Leader, Pharmaceutical R&D Business Operations, PricewaterhouseCoopers LLP

Closed-loop Planning of an Integrated Forecast

Sarah B. Wilson, MS
Senior Business Operations Associate, Eli Lilly and Company

Application of Project Management Techniques to Nonmolecule Projects

Peter Harpum, MS
Director, Harpum Consulting Ltd., UK

Tuesday, June 19
The US FDA and Health Canada are independently developing Good Review Practices (GRPs). GRPs share general fundamental values and processes for product review. This session will describe, illustrate and compare GRPs at the US FDA/CDER and Health Canada and discuss how they advance review science.

ICH’s Harmonization Efforts and Impact on GRPs
Justina A. Molzon, JD, MPharm, CAPT, USPHS
Associate Director for International Programs, CDER, FDA

Good Review Practices in the Therapeutic Products Directorate of Health Canada
Caroline Vanneste
Project Manager, Good Review Practices, Therapeutic Products Directorate, Health Canada

Development and Discussion of Good Review Practices in the US: An FDA Perspective
Howard D. Chazin, MD, MBA
Medical Officer, Guidance and Policy Team, Office of New Drugs, CDER, FDA

SESSION 281 RA3 - REGULATORY AFFAIRS, PP
2:00 pm-3:30 pm
Room A402
CME credits offered

PMDA Challenges for Global Drug Development including Japan
SESSION CHAIRPERSON(S)
Yoshiaki Uyama, PhD
Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

In this session, PMDA will explain current PMDA activities and PMDA perspective to promote appropriate global drug development including Japan.

Challenges to Promote Global Drug Development including Japan
Akira Miyajima
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Recent Examples of Approved Drugs Based on Data from Multiregional Clinical Trials
Yuki Ando, MSc
Statistical Reviewer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Perspective for Global Drug Development Strategy
Yoshiaki Uyama, PhD
Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

SESSION 282 RA4 - REGULATORY AFFAIRS, CR
2:00 pm-3:30 pm
Room A406

Combination Products: Postapproval Challenges and Opportunities – Part 2 of 2
SESSION CHAIRPERSON(S)
Christine Allison, MS, RAC
Regulatory Scientist, Eli Lilly and Company

Part 1 of this session will take place on Tuesday at 10:00 am.

Combination products present many unique postapproval challenges in terms of requirements for good manufacturing practice, postmarket safety reporting, and postapproval changes. Perspectives from both the regulatory authority and industry will be presented.

SESSION 283 RA5 - REGULATORY AFFAIRS, CR
2:00 pm-3:30 pm
Room A405

The New EMEA Scientific Advice Procedure
SESSION CHAIRPERSON(S)
Patrick Le Courtois, MD
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

The new Scientific Advice Procedure has been introduced at the EMEA and is applied by an extended Scientific Advice Working Party (SAWP). There is a parallel scientific advice pilot program ongoing between EMEA and FDA. How are these procedures being used? What is the experience from the users of the new system? Are there initial conclusions on the overall impact for EU assessment of new applications?

The New EMEA Scientific Advice Procedure
Spiros Vamvakas, MD
Acting Deputy Head of Sector, Scientific Advice and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use Unit, EMEA, EU

An Industry Perspective
Mats G. Mårfaît, MSc
Cardiovascular Portfolio Leader, European Regulatory Affairs, AstraZeneca R&D, Sweden

Scientific Advice and CHMP Opinions
Mira Pavlovic, MD
Coordinator of Scientific Advice, French Health Products Safety Agency (AFSSAPS), DEMEB, France

SESSION 284 RD - R&D STRATEGY, RA
2:00 pm-3:30 pm
Room B305

Japan Challenges to Global Simultaneous Drug Development: Adapting Japanese Environments to Worldwide Drug Development
SESSION CHAIRPERSON(S)
Toshinobu Iwasaki, PhD
Director, Shionogi & Co., Ltd., Japan
Toshimitsu Hamasaki, PhD
Associate Professor, Department of Biomedical Statistics, Osaka University Graduate School of Medicine, Japan

Efforts have been made in Japan to reform environments on clinical trials. Industry associations, JPMA, and regulatory authorities have worked together on the development strategy, infrastructures, and regulatory issues to facilitate a global study. We will introduce the result of our discussion.
Development Strategy and Study Design Perspectives  
Kimihiro Kasamo, MD  
Senior Director, Banyu Pharmaceuticals, Japan

A Sample Size of Each Region and Interpretation of Results  
Osamu Komiyama  
Senior Manager, Pfizer Japan Inc., Japan

Operational Perspectives of Study Conduct  
Tetsuto Nagata  
Chairperson of Clinical Evaluation Subcommittee, JPMA; Senior Manager, JPMA/Pfizer Japan Inc., Japan

SESSION 285  ST - STATISTICS, CP  
2:00 pm-3:30 pm  LEVEL: ■  
Room B309  CME and Pharmacy credits offered

Statistics in Drug Safety and Health Economics and Outcomes Research: Anything in Common?  
SESSION CHAIRPERSON(S)  
Jürgen Kübler, PhD  
Director, Global Head, Integrated Safety and Health Economics Biostatistics, Novartis Pharma AG, Switzerland  
Joachim Vollmar, MSc  
Consultant, International Clinical Development Consultants, LLC

Both the statistical analysis of safety data and the quantitative area of health economics and outcomes research are currently attracting growing attention. Although these areas may seem entirely distinct at first glance, both areas share several important features: limited knowledge gained from premarketing experience, need for extrapolation of results to the ‘real world’, need for observational studies, especially long-term outcome studies, and use of claims databases and registries. These features can introduce methodological challenges, especially with respect to estimating unconfounded positive and adverse effects of drugs. The objective of this session is to facilitate an exchange of knowledge and ideas and thereby stimulating further research in these areas.

Beyond Randomized Trials: Study Designs for Assessing Drug Safety Before and After Approval  
Jesse A. Berlin, DrSc  
Vice President, Pharmacoepidemiology, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

For Real-world Payors, Are Randomized Trials both Necessary and Sufficient for Establishing Value?  
David S. Sugano, DrPH  
Vice President, Health Outcomes Strategies, Schering-Plough

SESSION 286  TR - TRAINING, CR  
2:00 pm-3:30 pm  LEVEL: ●  
Room B308

Professional Education for Clinical Researchers in Asia  
SESSION CHAIRPERSON(S)  
Monika M. Pietrek, MD, PhD, MSc  
Executive Vice President, Global Scientific and Medical Affairs, PRA International, Inc., Germany

With the increasing number of clinical trials being conducted in Asia, experienced clinical research professionals are in high demand working at international sites, contract research organizations and local pharmaceutical companies. Transfer of expertise from North America and Europe remains rather limited. Therefore, the professional education of clinical researchers becomes of key importance. Education has to include good clinical practice, principles of drug development, pre- and postapproval regulatory requirements in NA and EU, importance of safety monitoring, roles and responsibilities of regulators, sponsors, ethics committees and study participants in clinical trials, cultural differences impacting management of global studies and in particular communication.

The presenters will provide an overview on initiatives related to professional education of physicians, scientists, nurses and others in India, South Korea, Singapore and Taiwan.

Feasibility of Implementing Competency-based Training Program in Singapore and Taiwan  
Edward C. Ian  
Director, Operations, Asia Pacific, PRA International, Inc., Taiwan

SESSION 287  AD - ADVERTISING, MC  
4:00 pm-5:30 pm  LEVEL: ●  
Room A313  Pharmacy credits offered

The Future of DTC Policy: Guiding Patient Progress amid Policy and Creative Tension  
SESSION CHAIRPERSON(S)  
John F. Kamp, JD  
Executive Director, Coalition for Healthcare Communication

This session will focus on the changes in the DTC policy in light of the policy debates in Washington, the self-regulatory programs of PhRMA, and marketing initiatives of individual drug companies and their advertising agencies.

Handicapping Legislative Proposals to Limit DTC Advertising  
James Davidson  
President, Davidson & Company

Creating Compelling Consumer Advertising in Challenging Times  
Anne Devereux  
Chief Executive Officer, TBWA Worldwide Health

Refining Industry Approaches to PhRMA DTC Principles  
Wesley Metheny  
Senior Vice President, PhRMA

SESSION 288  BT - BIOTECHNOLOGY, CR  
4:00 pm-5:30 pm  LEVEL: ●  
Room B304  CME credits offered

Research and Development of Response Prediction  
Molecular Markers and their Integration into Clinical Drug Development in Oncology  
SESSION CHAIRPERSON(S)  
Carolina Haefliger, MD  
Clinical Science Specialist, F. Hoffmann-La Roche Ltd., Switzerland

In recent years, molecular biomarkers for drug response prediction have come to public attention. Here, we would like to address some of the questions that arise in the process of integrating them into clinical trials, related challenges and potential ways of overcoming them.

Discovery and Validation of DNA Methylation Response Prediction Biomarker  
Tamas Rujan  
Senior Manager, Clinical Solutions, Epigenomics AG, Germany
SESSION 289  CDM - CLINICAL DATA MANAGEMENT, EC
4:00 pm-5:30 pm  LEVEL: ■
Room A312  CME and Pharmacy credits offered
Good Registry Practice: Design, Use, and Evaluation of Patient Registries and Methods and Best Practices
SESSION CHAIRPERSON(s)
Richard Gliklich, MD
President and Chief Executive Officer, Outcome Sciences, Inc., dba Outcome

This session will present the background and the process of developing the handbook "Registries for Evaluating Patient Outcomes: A User’s Guide," a collaborative effort developed under the AHRQ DECIDE research program. Panel members will explore best practices for registry development based on specific case studies.

Scott R. Smith, PhD
Director, DECIDE Network, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality

Evaluating Registries
Nancy A. Dreyer, PhD, MPH
Chief of Scientific Affairs, Outcome

SESSION 290  CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RD
4:00 pm-5:30 pm  LEVEL: ■
Room B407
Potential Methodologies for Design Space Determination
SESSION CHAIRPERSON(s)
David Christopher, MS
Associate Director, Statistics, Schering Plough Research Institute

This session will present considerations and challenges for different approaches to determination of design space consistent with FDA’s Quality-by-design initiative. One or more case studies may be presented illustrating the potential for using designed experiments.

Application of Statistical Design in Drug Formulation: A QbD Case Study
Ying-Ming Jou, PhD
Project Leader, Statistics Department, Schering-Plough Research Institute

Design Space: An FDA Perspective
Christine M. Moore, PhD
Supervisory Chemist, Office of New Drug Quality Assessment, CDER, FDA
Clinical Trials in Brazil
Granville Garcia de Oliveira, MD, PhD, FCP
Clinical Trials and New Drugs Office Manager, ANVISA (National Agency of Sanitary Surveillance), Brazil

**SESSION 293**
**CR2 - CLINICAL RESEARCH AND DEVELOPMENT, RD**
4:00 pm-5:30 pm
Room B408
CME and Pharmacy credits offered

Arsenic and Old Lace: How to Avoid a Comedy of Errors when a Thorough QT/QTc Study Cannot Be Performed
**SESSION CHAIRPERSON(S)**
William Wheeler, MD
Chief Medical Officer, Spacelabs Healthcare Clinical Trials Services

Arsenic trioxide has proven that Torsade de Pointes is more than a theoretical consideration for oncology drugs. We will discuss striking an appropriate balance between the risk of induction of life-threatening arrhythmias and potentially life-saving therapy.

Unique Challenges for Oncology Compounds in QT Assessment
**SESSION CHAIRPERSON(S)**
William Wheeler, MD
Chief Medical Officer, Spacelabs Healthcare Clinical Trials Services

FDA Perspective on QT Assessment for Oncology Compounds
Shari Targum, MD, FACC, FACP
Medical Officer, CDER, FDA

Industry Approach to QT Assessment in Oncology Programs
Kamal S. Shah, MD
Therapeutic Area Lead, Oncology, Safety Risk Management, Pfizer Global Research and Development

**SESSION 294**
**CR3 - CLINICAL RESEARCH AND DEVELOPMENT, GCP**
4:00 pm-5:30 pm
Room B409
CME credits offered

Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done?
**SESSION CHAIRPERSON(S)**
Kenneth A. Getz, MBA, MS
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. This session reviews the results of FDA and OHRP audit reports and discusses new approaches and reforms designed to prevent noncompliance and fraud in the future.

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

Why Do Noncompliance and Fraud Occur?
**Cynthia M. Gates, JD, RN, CIP**
Director, Regulatory Affairs, Western Institutional Review Board

Preventing Noncompliance: Real Experiences, Real Practices
**Nathan Segall, MD**
Principal Investigator, Clinical Research Atlanta

**SESSION 295**
**CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, CR**
4:00 pm-5:30 pm
Room B405
Pharmacy credits offered

Improving the Clinical Supply Chain Management Process
**SESSION CHAIRPERSON(S)**
Frank J. Tiano, RPh
President, Clinical Supplies Consulting Services

In the clinical environment, clinical supply groups are constantly being challenged to do more with fewer and fewer resources, meet aggressive clinical start dates, lower costs and reduce overages in clinical materials. In order for an organization to be competitive and responsive to the needs of clinical research, it must continually improve the clinical supply chain management process. This session will share experiences, information, and efforts on how major pharmaceutical companies keep clinical trial materials off the critical path, reduce overages in clinical supply materials, increase efficiencies and improve forecasts. Also, adaptive trial design, an innovative business approach to streamline the clinical supply process will be explored via the use of IVRS technology.

Keeping Clinical Trial Materials Off the Critical Path
**Sandra G. Cook, PhD**
Supply Chain Project Manager, AstraZeneca

Achieving Efficiencies in Clinical Supply Forecasts
**Susan T. Sultzbaugh, PhD**
Global Clinical Supplies Planning Manager, Schering-Plough Research Institute

Adaptive Trial Design: An Innovative Approach to Streamline the Clinical Supply Process
**Eddie Montoya, Jr.**
Director, IVRS, Covance

**SESSION 296**
**EC - eCLINICAL, IT**
4:00 pm-5:30 pm
Room A314
CME and Pharmacy credits offered

Using CDISC Standards and eClinical Technologies to Improve Patient Safety Monitoring during the Conduct of Clinical Trials
**SESSION CHAIRPERSON(S)**
Wayne R. Kubick, MBA
Senior Vice President, Phase Forward/Lincoln Technologies, Inc.

This session will explore how the application of CDISC data standards used in conjunction with eClinical technologies can improve patient safety monitoring during the blinded portion of clinical trials.

FDA Perspective: Regulatory Requirements and Opportunities
**Charles K. Cooper, MD**
Medical Officer, Office of Biostatistics, CDER, FDA

Using CDISC Standards to Improve Clinical Trial Safety Monitoring
**Wayne R. Kubick, MBA**
Senior Vice President, Phase Forward/Lincoln Technologies, Inc.

Sponsor Perspective: Using Advanced Analytics to Improve Safety Monitoring of EDC Trials
**Simon M. Brooks**
Project Manager, DCS-IT, GlaxoSmithKline R&D, UK
**SESSION 297**  
**ERS/DM1 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM**  
4:00 pm-5:30 pm  
**LEVEL:** ■  
**Room A406**  
**Is There a Cure for the Ills of Electronic Document Management in the Contemporary Biopharmaceutical Industry? And If So, What Is the Medicine?**  
**SESSION CHAIRPERSON(S)**  
**Nancie E. Celini, MPH**  
President, CAB Inc.  

For several decades, the biopharmaceutical industry has been attempting to exploit electronic document management systems (EDMS) and few could argue it has been easy or cost effective. An open, community-driven dialog must continue regarding the concept of an externally hosted, standards-based EDMS service that would allow any entity access to a shared regulatory-compliant system.

The speakers will examine the current state of enterprise EDMS including the challenges that lie ahead, recent developments (Firebird, CRIX) and some history (Sebix) that helped evolve these current and promising concepts. The interactive panel session will comprise cross-industry representatives and will take audience questions.

If you are involved in document management, in any capacity, this session is critical for you to attend. It is urgent that with the myriad of problems industry is facing, we resolve fundamental technical issues effectively so that energies can be focused on product research and development.

**R&D for R&A:Coming to a Compound Document Near You**  
**Allen E. Jones, MS**  
Director, Global Regulatory Operations, GlaxoSmithKline  

Industry Perspective  
**John C. M. Wise, MA**  
Senior Director, Informatics, Daiichi Sankyo Pharma Development, UK  

Panel Discussion: Is There a Road Map for the Industry? If So, What Might It Look Like?  
**Moderator**  
**John J. Oidtman**  
Vice President, Worldwide Regulatory Operations, Pfizer Inc  

Panelists  
**Session Chairperson and All Session Speakers**

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**SESSION 299A**  
**GCP - GOOD CLINICAL PRACTICES, RA**  
4:00 pm-5:30 pm  
**LEVEL:** ■  
**Room B406AB**  
**GCP Town Meeting Session: Quality Systems and the QA Role in Small- to Medium-sized Companies**  
**SESSION CHAIRPERSON(S)**  
**Teri E. Stokes, PhD, MS, MT**  
Director, GXP International  

Quality assurance resources are usually very limited in small- to medium-sized companies. This can make it difficult for QA professionals in those companies to obtain advice and feedback from peers for the issues and concerns that arise. Here is a forum for just that purpose.

**How Do We Assure Quality when We Outsource Anything/Everything?**  
**Virginia Viau**  
Associate Director, Quality Systems, Altus Pharmaceuticals Inc.

**What Are the Top Priorities for Establishing a Quality Management System and a Quality Assurance Function in a Small Company?**  
**Gretchen H. Craig**  
Manager, Quality Assurance, invivodata

**How Can Quality Be Put on the Corporate Business Agenda of a New, Small- or Medium-sized Organization?**  
**Teri E. Stokes, PhD, MS, MT**  
Director, GXP International

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**SESSION 299B**  
**IMP - IMPACT (IMPACT OF MEDICAL PRODUCTS AND THERAPIES), CR**  
4:00 pm-5:30 pm  
**LEVEL:** ◇  
**Room B301**  
**Using Electronic Medical Records for Clinical Research**  
**SESSION CHAIRPERSON(S)**  
**Susan D. Ross, MD, FRCPC**  
Vice President, Medical Affairs, United BioSource Corporation  

Speakers will discuss the availability and requirements for use of EMR datasets as an alternative data source for analysis of real-world clinical efficacy and safety outcomes. Actual applications in late-stage product development and commercialization settings will be presented.

**The Use of Health Information Technology in the US: Where Are We in 2007?**  
**Ashish K. Jha, MD, MPH**  
Assistant Professor of Health Policy and Management, Harvard School of Public Health
Conducting Research with EMR Data: Applications from Oncology
Robert J. Nordyke, PhD, MS
Director, Global Health Economics, Amgen Inc.

Points to Consider in Working with EMR Data for Analysis Purposes
Susan D. Ross, MD, FRCP
Vice President, Medical Affairs, United BioSource Corporation

**SESSION 299C** IS - INVESTIGATOR SITES, GCP
4:00 pm-5:30 pm  LEVEL: ■
Room B303  Pharmacy credits offered

Emergency Procedures for when a Sponsor Goes Bad
SESSION CHAIRPERSON(S)
Angelo Sambunaris, MD
Medical Director, Atlanta Institute of Medicine & Research

The FDA often views issues of data integrity to reside solely in the realm of the clinical investigator and that deviations from GCP are an investigator issue. In this session, we plan to review actual case studies and their outcomes where knowledge of GCP can protect all parties but especially the clinical investigator.

Angelo Sambunaris, MD
Medical Director, Atlanta Institute of Medicine & Research

Developing a GCP Strategy for Protecting Your Clinical Research Site
Tamera Norton-Smith, PhD
President, Norton Audits, Inc.

**SESSION 299D** IT - INFORMATION TECHNOLOGY, EC
4:00 pm-5:30 pm  LEVEL: ■
Room A305  Pharmacy credits offered

Leveraging Electronic Health Records in Clinical Research
SESSION CHAIRPERSON(S)
Paul A. Bleicher, MD, PhD
Chairman and Founder, Phase Forward

The role of electronic health records (EHR) in clinical research is currently an area of great interest. This session will be a panel discussing the potential role for EHR in clinical research. Aside from a brief introductory presentation, the panel will consist of an in-depth conversation with experts representing the various stakeholders in combining EHR and clinical research. A moderator will provide questions for the panelists along with members of the audience.

Moderator
Michael J. Barrett, JD
Managing Partner, Critical Mass Consulting

Panelists
Mark Dente, MD
Vice President, Healthcare Solutions, GE Healthcare IITS

Landen C. Bain
Healthcare Liaison, CDISC

Hugh Donovan
General Manager, Clinical Trials Business, Siemens Medical Solutions Health Services Corp.

Demetris Zambas
Assistant Director - GCDM, Schering-Plough Research Institute

**SESSION 299E** MC - MEDICAL COMMUNICATIONS, TR
4:00 pm-5:30 pm  LEVEL: ○
Room B404  CME and Pharmacy credits offered

Health Education: Teaching Consumers about the Safe Use of Medicines
SESSION CHAIRPERSON(S)
Nancy D. Smith, PhD
Director, Office of Training and Communications, CDER, FDA

This session will explore how health education in schools and communities impacts our nation’s public health, especially the use and misuse of medicines. Ways to identify educational needs and to develop and implement programs will be discussed for the FDA’s “Medicines in My Home” curriculum.

The Public Health Role of School and Community-based Health Education
Carolyn Fisher, EdD
Senior Advisor, Division of Adolescent and School Health, Centers for Disease Control and Prevention

Medicines in My Home: Program Development and Implementation
Karen B. Feibus, MD
Lead Medical Officer, Office of New Drugs, CDER, FDA

Educational Impact through Partnerships, Networking, and Promotion
Nancy D. Smith, PhD
Director, Office of Training and Communications, CDER, FDA

**SESSION 299F** MW - MEDICAL/SCIENTIFIC WRITING, MC
4:00 pm-5:30 pm  LEVEL: ■
Room A315  CME, Nursing, and Pharmacy credits offered

Writing for Patients
SESSION CHAIRPERSON(S)
Virginia I. Watson
Director, Clinical Development and Medical Writing, Cardinal Health, UK

There are occasions when medical writers have to adapt their writing style to serve the needs of the patient. Clear, unambiguous, jargon-free plain English is essential. This session will examine situations where patient information is important.

Patient/Package Leaflet (PIL) Testing: Is There a Role for the Medical Writer?
Virginia I. Watson
Director, Clinical Development and Medical Writing, Cardinal Health, UK

Is Patient Information and Informed Consent Fit for Purpose
Tine Kold Olesen, MSc
Director, Ferring Pharmaceuticals, Denmark

Creating Impactful Patient Communication
Patricia R. Flynn
Senior Director, IMPACT Group, Global Clinical Operations, Johnson & Johnson

**SESSION 299G** NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT, RD
4:00 pm-5:30 pm  LEVEL: ■
Room B302

Adverse Effects of Anticancer Drugs: A Problem of the Past
SESSION CHAIRPERSON(S)
Vivek Kadambi, PhD
Director, Drug Safety Evaluation, Millennium Pharmaceuticals Inc.
As companies focus on developing compounds to treat tumors, the emphasis moving forward will be on targeted therapies, the premise of which is not to injure normal cells. This session will be of great value to the nonclinical toxicology/pharmacology community.

**Vivek Kadambi, PhD**
Director, Drug Safety Evaluation, Millennium Pharmaceuticals Inc.

**Daniel M. Lapadula, PhD**
Regulatory Toxicology, Novartis Pharmaceuticals Corporation

**SESSIO N 299H  NHP - NATURAL HEALTH PRODUCTS, RD**
4:00 pm-5:30 pm  LEVEL: ■
Room B306

**Phytomedicine Development in Latin America: Interphase between Science and Development**
SESSION CHAIRPERSON(S)

**Mahabir P. Gupta, PhD**
Director, CIFLORPAN and Research Professor of Pharmacognosy, University of Panama

This session will highlight the status of current research and development of phytomedicines in Latin America and will showcase collaborative efforts to prepare monographs on medicinal plants of the region and development of autochthonous phytotherapeutic products.

**Current Status and Future Perspectives of Natural Products Research and Development in Latin America: Lessons Learned from Collaborative Efforts**

**Mahabir P. Gupta, PhD**
Director, CIFLORPAN and Research Professor of Pharmacognosy, University of Panama

**Monographs of Quality, Safety, and Efficacy of Latin American Medicinal Plants: A Collaborative Experience**

**Salvador Cañigueral, PhD**
Professor of Pharmacognosy, University of Barcelona, Spain

**A Brief History for the Research and Development of ACHEFLAN from the Plant Cordia Verbenacea**

**João Batista Calixto, PhD**
Full Professor of Pharmacology, Federal University of Santa Catarina, Brazil

**SESSIO N 299I  OS - OUTSOURCING, CTM/CS**
4:00 pm-5:30 pm  LEVEL: ■
Room B401

**Outsourcing Clinical Trials in Australia**
SESSION CHAIRPERSON(S)

**Miriam Dwyer**
Clinical Research Manager, AGEN Biomedical Ltd., Australia

Australia has a lot to offer in terms of outsourcing various aspects of clinical trials. Its regulatory environment is currently evolving to make conducting clinical research an attractive proposition. The quality of the data generated in Australia is second to none, and it is often a cost-effective option, however it is a long way from the USA and outsourcing to the other side of the Pacific creates its own challenges, both from a regulatory and practical standpoint. The outsourcing of “Clinical Trial Logistics” highlights a good example of the challenges in operating in another region. Logistics in this context encompasses secondary packaging, temperature-controlled storage, distribution, accountability and the ultimate destruction of unused drug products. Although the sponsor company knows its product, it may not be cognizant of the import requirements for clinical drug products and regulatory framework of working in this region.

**Conducting Clinical Trials in Australia: What Has Australia Got to Offer the Rest of the World?**

**Marisa Petersen, PhD**
Chief Executive Officer, Association of Regulatory and Clinical Scientists (ARCS Australia), Australia

**Australia’s Clinical Trial Regulatory Framework**

**Jonathon E. Rankin, MD**
Head, Experimental Drugs Section, Drug Safety and Evaluation Branch, Therapeutic Goods Administration, Australia

**Outsourcing Clinical Trial Logistics in Australia: Can Local Knowledge Pay Off?**

**Miriam Dwyer**
Clinical Research Manager, AGEN Biomedical Ltd., Australia

**SESSIO N 299J  PM1 - PROJECT MANAGEMENT, FI**
4:00 pm-5:30 pm  LEVEL: ■
Room B403  Project Management units offered

**The Methodology of Process Metrics in Leading an Organization to Success**
SESSION CHAIRPERSON(S)

**David A. Evans, MS**
Chief Information Officer, Octagon Research Solutions, Inc.

This session will focus on the methodology of metric collection and analysis as part of any research management organization. Panelists will describe process methods along with metric gathering and process management solutions that are used in their respective organizations.

**Use of a Process Management System in the Data Life-cycle Process**

**Melissa Binz, MS**
Director, Central Standards Group, Wyeth Pharmaceuticals

**Process Management and Metric Collection**

**Kirk P. Gallion**
President, Octagon Research Solutions, Inc.

**The Use of Process Metrics in the Electronic Submission Process**

**Harry L. Graham**
Associate Director, Worldwide Regulatory Operations, Merck & Co., Inc.

**SESSIO N 299K  PM2 - PROJECT MANAGEMENT, RD**
4:00 pm-5:30 pm  LEVEL: ■
Room B402  Project Management units offered

**Ending the Isolation of Project Management in Drug Development**
SESSION CHAIRPERSON(S)

**Peter Harpum, MS**
Director, Harpum Consulting Ltd., UK

Despite twenty years or more of formal project management practice in pharmaceutical (and more recently biotechnology) businesses, project management is still perceived, and often behaves as, the junior partner in drug development work. This session will contribute to the emerging dialogue on how project management can end its isolation within life science organizations by effectively harmonizing corporate, drug, and project strategy. This is critical to maximizing drug value delivery.

**The Drivers for Isolation and Overcoming Them**

**Peter Harpum, MS**
Director, Harpum Consulting Ltd., UK
Provisional: The Result of Poor Integration of Project Management with Drug Development
Randy Dunson, MBA, PMP
President and Principal, Equinox Consulting LLC

SESSION 299L PP - PUBLIC POLICY/LAW, GCP
4:00 pm-5:30 pm  LEVEL: ■
Room A410
Clinical Trial Registration: Are Registries Useful and User Friendly?
SESSION CHAIRPERSON(S)
Juhana E. Idänpään-Heikkilä, MD, PhD
Senior Advisor, CIOMS c/o WHO, Switzerland

Government, WHO, industry associations and companies have created in 2005-2006 registries of ongoing and completed clinical trials. They are to help physicians, patients and families to find potential therapies and assist research subjects to find a trial. The panel will review progress and consider improvements.

A View from Consumers
Peter Lurie, MD, MPH
Deputy Director, Public Citizen's Health Research Group

A View from NIH
Rebecca Williams, PharmD
Assistant Director, ClinicalTrials.gov, Lister Hill National Center for Biomedical Communications, US National Library of Medicine, National Institutes of Health

A View from FDA
Robert J. Temple, MD
Associate Director for Medical Policy, CDER, FDA

Discussant
Yves Juillet, MD, PhD
Senior Advisor, LEEM, France

SESSION 299M RA1 - REGULATORY AFFAIRS, CR
4:00 pm-5:30 pm  LEVEL: ■
Room A404
Clinical Development of Oncology Drugs in Japan
SESSION CHAIRPERSON(S)
Robert R. Fike, PhD
Assistant Vice President, Regulatory Affairs Japan, Wyeth Research

Yoshihiko Ono, RPh
Director, Regulatory Policy and Intelligence, PGRD Tokyo Laboratories, Pfizer Japan Inc., Japan

This session addresses the current environment and issues concerning oncology drug development in Japan, and also provides perspectives on the development strategy for oncology drugs, from research, therapeutic, regulatory and industry points of view.

The Current Status of Oncology Drug Development and Future Directions from the Viewpoint of Industry
Junichi Hashimoto, MS, RPh
Director, Clinical Research, Pfizer Japan Inc., Japan

The Current Status of Oncology Drug Development and Future Directions from the Viewpoint of a Regulatory Agency
Kazuhiko Mori, MS
Associate Center Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The Current Status of Oncology Drug Development and Future Directions from the Viewpoint of Academia
Noboru Yamamoto, MD
Division of Internal Medicine, National Cancer Center Hospital, Japan

SESSION 299N RA2 - REGULATORY AFFAIRS, CR
4:00 pm-5:30 pm  LEVEL: ■
Room A411
Fixed-dose Combination Products: Registration Strategies and Case Studies
SESSION CHAIRPERSON(S)
David M. Cocchetto, PhD, RPh
US Regulatory Affairs, GlaxoSmithKline

Regulatory affairs professionals have assisted in registering a wave of new fixed-dose combination (FDC) products in recent years. These FDC products show that multiple strategies are available to a sponsor seeking to develop and register a new FDC in the US. In this session, we will briefly review the basis in US regulation for registration of fixed-dose combination products. The majority of the session will focus on examining the wide range of regulatory precedents with specific examples of previously approved fixed-dose combination products in order to gain insight into alternative registration strategies for FDC products. Specific case studies will be discussed to illustrate the approaches and outcomes of various strategies.

Regulatory Paradigms for Registration of Fixed-dose Combination Products
David M. Cocchetto, PhD, RPh
US Regulatory Affairs, GlaxoSmithKline

Fixed-dose Combination Products: Strategic Considerations, Medical Need, and Environmental Opportunities
Craig A. Metz, PhD
Vice President, US Regulatory Affairs, GlaxoSmithKline

New Indications and Other Insights from Development of Symbyax (Olanzapine plus Fluoxetine) Capsules
Catherine A. Melfi, PhD
Scientific Director, US Regulatory Affairs, Eli Lilly and Company

SESSION 299O RA3 - REGULATORY AFFAIRS, CP
4:00 pm-5:30 pm  LEVEL: ■
Room A402
Current Experience with Risk Management Initiatives in the US and the EU
SESSION CHAIRPERSON(S)
Gerald J. Dal Pan, MD
Director, Office of Surveillance and Epidemiology, CDER, FDA

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

This session will update the audience on current experience with RiskMAPs (in the US) and RMPs (in the EU), from the points of view of both regulatory authorities and pharmaceutical industry. Lessons learned will be presented and areas for further improvement will be explored.

Practical Experience with RiskMAPs
Gerald J. Dal Pan, MD
Director, Office of Surveillance and Epidemiology, CDER, FDA
Review of Experience with EU Risk Management Plans
Stella Blackburn, MSc
Principle Scientific Administrator, Pharmacovigilance and Postauthorization Safety and Efficacy of Medicines Sector, Postauthorization Evaluation of Medicines for Human Use Unit, EMEA, EU

RiskMAPs Versus RMPs: An Industry Perspective
Valerie E. Simmons, MD, FFPM
Director, EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

**SESSION 299P**  **RD - R&D STRATEGY, PM**
4:00 pm-5:30 pm  LEVEL: ■
**Room B305**
Rainmaker for the Biopharmaceutical Industries in the Emerging Markets
SESSION CHAIRPERSON(S)
Herng-Der Chern, MD, PharmD, PhD
Executive Director, Center for Drug Evaluation, Taiwan
Who is the rainmaker for the long-awaited success of the biopharmaceutical industries in the emerging markets? This session will compare national strategies in Singapore, Korea and Taiwan for new drug development emphasizing the overall strategies, leadership, project management team and infrastructure.
Virtual Management Team, Rainmaker and Outsourcing Business Model as an Ideal Drug Development Tool for Biopharmaceutical Companies in Emerging Markets
Keith K.H. Chan, PhD
President and Chief Executive Officer, GloboAsia LLC
Leveraging Asian Regional Expertise, Insight, and Resource as Part of Global Strategy
Por-Hsiung Lai, PhD
Managing Director, Dephoron Group, Taiwan
Innovative Incubation Models and Virtual Teams
Chih-Hwa Wallace Lin, PhD
Director, Resource Development, Center for Drug Evaluation, Taiwan

**SESSION 299Q**  **ST - STATISTICS, CR**
4:00 pm-5:30 pm  LEVEL: ■
**Room B309**
Pharmacy credits offered
Statistical Analysis with Missing Data
SESSION CHAIRPERSON(S)
Gerd Rosenkranz, PhD
Scientific Officer, Biostatistics, Novartis Pharma AG, Switzerland
Despite careful planning of clinical studies, missing values will be an issue in practically all clinical studies. This session will summarize approaches to the analysis of such data, and discuss their applicability to clinical studies and their acceptability to health authorities.
Missing Data in Clinical Trials: Principles and Procedures
Michael Kenward, PhD
Professor of Biostatistics, London School of Hygiene and Tropical Medicine, UK
Missing Data in Clinical Trials: Case Studies
Jie Zhang, PhD
Program Statistician, Novartis Pharmaceuticals Corporation
A View on the Missing Data Issue from a Regulatory Perspective
Peiling Yang, PhD
Team Leader, Division of Biometrics I, Office of Biostatistics, CDER, FDA
Wednesday, June 20

7:30 am-4:00 pm  ATTENDEE REGISTRATION and EXHIBITOR REGISTRATION and SPEAKER REGISTRATION

7:30 am-4:00 pm  Building A/B Registration Hall, International Boulevard, Philips Drive Entrance, GWCC

7:30 am-8:15 am  CONTINENTAL BREAKFAST

Registration Area Foyer

9:00 am-2:30 pm  EXHIBITS OPEN

Exhibit Hall, Building A, Level 1, GWCC

5:00 pm-6:00 pm  EMERGING PROFESSIONALS NETWORKING RECEPTION

Thomas B. Murphy Ballroom Foyer, Building B, Level 5

5:15 pm  CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH MEETING

Room B301, Building B, Level 3, GWCC

SESSION 301  AD - ADVERTISING, MC
8:30 am-10:00 am  LEVEL: ■

Room A404  Pharmacy credits offered

Redefining the Roles of Medical Science Liaisons and Sales Representatives: Separating Science from Marketing

SESSION CHAIRPERSON(s)

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

This session will focus on the roles of the MSL and the sales force, particularly in situations where MSLs and detail representatives are asked to provide off-label information about a drug. The session will discuss the increasing regulatory risk faced by companies, especially in light of recent federal and state investigations of drug company marketing practices under the FDA Act and the False Claims Act. Presentations will discuss the need for clear training of all sales and MSL personnel, the development and implementation of internal procedures, and other internal regulatory controls. Presenters will emphasize both the legal and regulatory constraints as well as practical approaches to compliance within drug companies.

Robin L. Winter-Sperry, MD
President and Chief Executive Officer, Scientific Advantage, LLC

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

Peter O. Safir, JD
Partner, Covington & Burling

SESSION 302  BT - BIOTECHNOLOGY, RA
8:30 am-10:00 am  LEVEL: ■

Room B304

Process Validation during Clinical Development of Biological Medicinal Products

SESSION CHAIRPERSON(s)

Cecil Nick, MS
Principal Consultant, PAREXEL Consulting, UK

This session will explore what needs to be done in terms of process qualification and validation as clinical development progresses, focusing on viral safety and a progressive approach to process validation.

Introduction and Impact of European Directives

Cecil Nick, MS
Principal Consultant, PAREXEL Consulting, UK

Process Validation from Phase 1 to 3 Focus on Biotechnology

Mark Carver, PhD
Chief Scientific Officer, Avecia Biologics Ltd., UK

Viral Safety Including Recent EU Guidelines on Viral Safety in Clinical Trials

Jeri-Ann Boose, PhD
Senior Director, Analytical and Viral Clearance Services, BioReliance Corporation

SESSION 303  CDM - CLINICAL DATA MANAGEMENT, CR
8:30 am-10:00 am  LEVEL: ■

Room A312

Implementing a Comprehensive Lab Data Management Strategy

SESSION CHAIRPERSON(s)

Laurie S. Callen
Senior Technical Manager, Synta Pharmaceuticals Corp.

Developing a comprehensive laboratory management strategy is critical in order to achieve optimum benefit, prevent complex laboratory data issues at the end of a study and should be given high priority and begun early in the project lifecycle.

Implementing a Comprehensive Lab Management Strategy

Laurie S. Callen
Senior Technical Manager, Synta Pharmaceuticals Corp.

Patrick Fredericksen, MBA
Partner, Fountain Database Design, Inc.

Keith Fine, MA
Director, Project Management, ARS, Inc.

SESSION 304  CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, BT
8:30 am-10:00 am  LEVEL: ■

Room A301  CME credits offered

Implementation of QbD for Biotechnological Products

SESSION CHAIRPERSON(s)

Steven Kozlowski, MD
Director, Office of Biotechnology Products, CDER, FDA

This session will present Office of Biotechnology (OBP) and industry views on Quality-by-design (QbD) implementation for biotechnology products.

FDA Perspective

Steven Kozlowski, MD
Director, Office of Biotechnology Products, CDER, FDA

Industry Perspective

Michael Molony, MA
Senior Manager, Biogen Idec
SESSION 305  CP1 - CLINICAL SAFETY AND PHARMACOVIGILANCE, RA
8:30 am-10:00 am  LEVEL: ■
Room A302  CME, Nursing, and Pharmacy credits offered
Data Mining in Pharmacovigilance: Misconceptions and Misunderstanding in Data Mining and Signal Detection
SESSION CHAIRPERSON(S)
Andrew Bate, PhD, MA
Manager, Research and Development, Uppsala Monitoring Centre, Sweden
Data mining is being heavily promoted as a useful adjunct to conventional signaling techniques in pharmacovigilance. This session will challenge often repeated and widely accepted misunderstandings, misconceptions, and fuzzy concepts in the use of data mining.

The Sense and Nonsense about Data Mining
Manfred Hauben, MD, MPH
Medical Director, Risk Management Strategy, Pfizer Inc
Data Mining Patient Records versus Spontaneous Reports: What Can and Cannot Be Done
Andrew Bate, PhD, MA
Manager, Research and Development, Uppsala Monitoring Centre, Sweden
The Effects of Net Density and Comparator Selection on Data Mining Results
David Goldsmith, MD
President, Senior Consultant, Goldsmith Pharmacovigilance & Systems

SESSION 306  CP2 - CLINICAL SAFETY AND PHARMACOVIGILANCE, CDM
8:30 am-10:00 am  LEVEL: ■
Room A315
Streamlining Adverse Event Case Management
SESSION CHAIRPERSON(S)
Vlasta Pinkston
Director, Safety Systems Management, GlaxoSmithKline, UK
In this time of belt tightening and the shift to proactive pharmacovigilance, clinical safety and pharmacovigilance departments must release capacity invested in traditional safety data collection and regulatory reporting. It is possible to significantly reduce resources for routine adverse event case management.

Streamlining Case Entry
William Truhe
Vice President, BRM Informatics, Johnson & Johnson
Adverse Event Case Management in a High Throughput Environment
Ann Marie O’Brien, MBA
Director, Case Management Group, GlaxoSmithKline
Adverse Event Case Management in a Challenging Risk Management Environment
Noreen Fitzgerald, BSN, RN
Director, Case Management and Evaluation GDS, Celgene Corporation

SESSION 307  CR1 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS
8:30 am-10:00 am  LEVEL: ■
Room B408
Cost Containment in Clinical Research: What Is Being Done?
SESSION CHAIRPERSON(S)
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group
The costs of conducting clinical trials continue to escalate. Companies react to contain them. But are the reactions the best approach, or could a proactive approach have more meaningful impact? What are other companies doing to contain costs? Find out and bring home some real actions for impact.

Looking at the Big Picture: What Are Sponsor Companies Doing to Contain Costs
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group
Strategic Planning for Cost Containment
Patrick M. Nealon, MBA
Senior Director, Clinical Research, Genzyme Corporation
The Big Pharma Perspective on Cost Containment
Lisa C. Feeney, MBA
Director, Clinical Study and Data Management, Pfizer Inc

SESSION 308  CR2 - CLINICAL RESEARCH AND DEVELOPMENT, IS
8:30 am-10:00 am  LEVEL: ■
Room B407  Nursing credits offered
SESSION CHAIRPERSON(S)
David B. Millard
Associate Director, Study Management, Pfizer Inc.
The current healthcare and clinical research environment has come under public scrutiny for the lack of minority subjects in studies, with the addition of regulatory guidance and commitments calling for a focus on balanced clinical research studies. Successful ideas and strategies will be provided.

Ethnic Outreach and Inclusion in Clinical Trials and its Impact on the Pharmaceutical R&D Business
David B. Millard
Associate Director, Study Management, Pfizer Inc
Regulatory Considerations in the Outreach of Minority Inclusion in Clinical Trials
Jerome Wilson, PhD
Project Officer (MCP), Office of Public Health Emergency Medical Countermeasures, Department of Health and Human Services, FDA

SESSION 309  CR3 - CLINICAL RESEARCH AND DEVELOPMENT, RD
8:30 am-10:00 am  LEVEL: ■
Room B409  CME credits offered
Human Phase 0 Microdose Studies: What Will They Deliver?
SESSION CHAIRPERSON(S)
Lester Crawford, DVM, PhD
Consultant, Policy Directions Inc.
Human microdosing enables early pharmacokinetic information to be obtained which can aid in better candidate selection, make first into human studies safer, and reduce animal usage. This session will focus on the scientific, financial, and regulatory aspects of microdosing.

Innovative Technologies in Early Development: What Is Added Value and What Is Just Added Cost?
Roy E.S. Bullingham, MD, MA
Chief Executive Officer and President, Daiichi Medical Research

An Update on the Exploratory IND
Colin Garner, PhD
Chief Executive Officer, Xceleron Ltd., UK

The Use of Microdosing in Drug Development: Practical Experiences
Roeline Jochemsen, PharmD, PhD, RPh
Associate Director, Pharmacokinetics and Metabolism, SERVIER Research Group - IRIS, France

SESSION 310  CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, CR
8:30 am-10:00 am  LEVEL: ■
Room B404
A Simple Solution for Removing Clinical Supplies as a Rate-limiting Step for the Adaptive Trial Design
SESSION CHAIRPERSON(S)
Brian Moe, PharmD
Vice President, Business Development, CSM

There is a simple solution for meeting and exceeding clinical supply requirements for adaptive trials. It is called “on-demand.” Utilizing the on-demand with an IVR system will ensure the packaging and labeling of supplies for adaptive trials is simple, inexpensive, and timely with minimal overages.

Why Use On-demand Adaptive Trial Design?
Gerald E. Finken, MS
President, CSM

Considerations for Planning and Implementing an IVR for Adaptive Trial Design
Jagath C. Wanninayake
President and Chief Executive Officer, Clarix Informatics

Impact of On-demand Packaging on Adaptive Trial Management
Michael Krams, MD
Assistant Vice President, Adaptive Trials, Clinical Development, Wyeth Pharmaceuticals

SESSION 311  EC - eCLINICAL, CDM
8:30 am-10:00 am  LEVEL: ●
Room A314
2012: eClinical Odyssey
SESSION CHAIRPERSON(S)
Sebastien Pourchaire
BlueLinea, France

Before you know it, the year 2012 will be here tomorrow. By then, new technologies will provide us faster clinical information with new interfaces and new software. New studies will be better, faster, stronger and perhaps a Phase 5 study will be born to include interoperability between information systems. This session will discuss the potential of 2012.

2012: eClinical Odyssey: An Introduction
Sebastien Pourchaire
BlueLinea, France

SESSION 312  ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM
8:30 am-10:00 am  LEVEL:■
Room A412AB
eCTD Case Studies
SESSION CHAIRPERSON(S)
Laura J. Sherman, MBA, BSN, RN
Vice President, Enterprise Publishing Solutions, Impact Systems Inc.

This session will focus on the challenges and successes of creating an initial and subsequent regional eCTDs. Best practices will be discussed, based on industry experiences, as well as the associated trials and tribulations encountered during the transition to eCTDs for adhering to global ICH, and US and European regional standards including the various types of EU filings. The session will also address internal and external considerations for implementation approaches and obstacles to overcome, along with key learnings and general considerations for seamlessly producing guidance-compliant submissions, including the importance of incorporating global standards, template granularity and impact identification when initiating and developing a fully integrated business process and systems to support eCTDs. The role of change management and the importance of project planning will also be addressed.

Submitting an IND in eCTD Format
Paula Petrilla
Regulatory Submission Manager, AstraZeneca

Preparing Submissions in eCTD Format: The Preparation, Challenge and Success
Carol R. Wood
Director, Regulatory Operations, Apyx, Inc.

eCTD Implementation in Europe: Reconcile Divergent Requirements in a Streamlined Approach
Said Ikazban
Associate Director, Merck Sharp & Dohme, Inc., Belgium

SESSION 313  GCP - GOOD CLINICAL PRACTICES, CR
8:30 am-10:00 am  LEVEL:■
Room B406AB  Pharmacy credits offered
Quality Risk Management in GCP: The Essentials
SESSION CHAIRPERSON(S)
Peter J. Schiennmann, PhD
Quality Risk Management Project Leader, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Quality risk management feeds primarily on data produced by regular business processes. But how do we ensure the availability of data to be evaluated? How should we fill critical information gaps? How can we evaluate risks? How to define “risk signals” and how to act on them? What do they tell us?

Update on Relevant Interest/Initiatives in Quality Risk Management at FDA
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science; Director, Good Clinical Practice Programs, Office of Science and Health Coordination, Office of the Commissioner, FDA
SESSION 314  IT1 - INFORMATION TECHNOLOGY, CDM
8:30 am-10:00 am  LEVEL: ■
Room A313
Using Information Visualization to Link Decision Making across a Matrixed Organization
SESSION CHAIRPERSON(s)
Mark Schindler, MA
Chief Technology and Innovation Officer, Visual i/o

After installing systems to manage resources, trials and regulatory submissions, many R&D organizations are seeing the problem of having too much information. As dashboards and reports proliferate, will new approaches like SOA, EII and data visualization finally enable a common view across R&D? This session will present case studies from large and small industry, as well as from solution providers and attempt to provide a rounded picture of current key issues and approaches in this area.

Introduction: Using Information Visualization to Link Decision Making across a Matrixed Organization
Mark Schindler, MA
Chief Technology and Innovation Officer, Visual i/o

Integrating Information across the Organization: An Example from Safety
Robbert P. Van Manen, MSc
Senior Consultant, Phase Forward

SESSION 315  IT2 - INFORMATION TECHNOLOGY, VA
8:30 am-10:00 am  LEVEL: ■
Room A305
Best Practices for Technology Implementation
SESSION CHAIRPERSON(s)
Kevin Bishop
Senior Vice President, IVRS Business Unit, ClinPhone, Inc.

Individual study teams are often required to learn first hand how best to implement technology solutions such as ePRO, EDC and IVR. Speakers experienced in working with multiple technology vendors will share their experiences and discuss how best practices can be implemented across organizations.

Best Practice for Implementation of EDC Standards and Technology
Lauren M. Shinaberry, MS, CCDM
Senior Manager, Clinical Data Management, PRA International, UK

Development and Implementation of Standards to Support Development of Configurable IVRS
Karen Gram, MPharm
Clinical Supplies Coordinator, Novo Nordisk A/S, Denmark

Quality by Design: Outsourced Electronic Service Oversight
Michael J. Thompson
Technical Services, Electronic Trial Operations, Amgen Inc.

SESSION 316  MA - MARKETING AND SALES, CP
8:30 am-10:00 am  LEVEL: ■
Room B301
Maximizing ROI (Return on Information)
SESSION CHAIRPERSON(s)
Susan Elliott, PhD, MBA
Director, Strategic/Scientific Consulting, Axiom Real-Time Metrics, Canada

Real-time registry technology can transform the concept of drug life-cycle management. Yet, industry has favored more traditional activities. This session will examine the return on information realized via registries and discuss how safety and commercial objectives are not mutually exclusive.

Informational Needs in the Changing Pharmaceutical Landscape
Cheryl Silberman, PhD, MPH
Senior Director, Global Health Economics and Outcomes Research, Pharmacovigilance, Epidemiology, and Outcomes Research, Takeda Global Research and Development

Optimization of Product Commercialization Using Registry-derived Data
Clay Earl
Director, Marketing, Rheumatology Business Unit, Hoffmann-La Roche Limited, Canada

The Impact of Registry-derived Data in the Clinic
Jay Fishman, MD
Associate Professor of Medicine, Harvard Medical School Director, Massachusetts General Hospital

SESSION 317  MC - MEDICAL COMMUNICATIONS, CR
8:30 am-10:00 am  LEVEL: ■
Room B302
Medical Liaison Survey #3: Assessing Practice Trends across the Pharmaceutical Industry
SESSION CHAIRPERSON(s)
J. Lynn Bass, PharmD
Senior Regional Medical Liaison, Amgen Inc.

The purpose of this 3rd annual survey of medical liaison practices is to gather information on the following topics: 1) nontraditional medical liaison staffing options, 2) compliance environment, 3) medical liaison role in the health outcomes environment, and 4) competitive intelligence. In contrast to our previous efforts, this survey will be administered to both medical liaisons and medical liaison managers across the industry. We plan to assess similarities, differences, and trends surrounding these topics with both groups.

Survey Background and Results on Nontraditional Medical Liaison Staffing Options
Craig J. Klinger
Senior Medical Liaison Consultant, Eli Lilly and Company

Results on the Medical Liaison’s Role in the Competitive Intelligence and Health Outcomes Environments
Christopher M. Marrone, PharmD
Medical Liaison Consultant, Eli Lilly and Company

Survey Summary and Results on the Medical Liaison’s Role in the Compliance Environment
J. Lynn Bass, PharmD
Senior Regional Medical Liaison, Amgen Inc.
The Evolving Role of Project Management in Drug Development

**SESSION 322**  
8:30 am-10:00 am  
Room B402  
Project Management units offered

**Session Chairperson(s)**  
**Eric M. Towler, PhD, PMP**  
Associate Project Director, Project Management, Merck & Co., Inc.

The purpose of this session will be to review different approaches taken by major pharmaceutical companies to streamline drug development processes and increase business acumen and the impact on project management responsibilities.

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**Characterizing Variability of Botanical Products: Impact on Scientific Research and Product Development**  
**SESSION CHAIRPERSON(S)**  
**Carmen Tamayo, MD**  
Director, Research and Development, Flora, Inc.

The variability and variability of botanical products is a critical factor in the development of new therapeutic agents. The purpose of this session is to explore the impact of variability on scientific research and product development. This will include a discussion of the methods used to characterize variability and the implications for regulatory agencies.

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**CME and Pharmacy credits offered**
Learn-and-verify Drug Development: An Innovative Approach to Enhancing Productivity  
*Mark A. Lane, PhD, MS*  
Director, Project Management, Wyeth Research

**SESSION 323**  
**PM2 - PROJECT MANAGEMENT, RD**  
8:30 am-10:00 am  
**Room B403**  
**Project Management units offered**

**Value of Project Management Function in Drug Development in Japan**  
**SESSION CHAIRPERSON(s)**  
*Hideo Yoshida*  
Director, R&D Operations Japan, Bristol-Myers K.K., Japan

This session provides the basic concept and practical aspects of the project management function in drug development in Japan. The functions and responsibilities of Japanese project management teams, in both the stand-alone and the global development environments, will be reviewed.

**Project Management Overview: Timeline and Resource Projection**  
*Hideo Yoshida*  
Director, R&D Operations Japan, Bristol-Myers K.K., Japan

**Project Management of Drug Development in Japan: A US Perspective**  
*Steven F. Innaimo, MS*  
Associate Director, Full Development and LCM Project Management, Bristol-Myers Squibb Company

**Project Management Activities in a Japanese Pharmaceutical Company**  
*Gregory P. Moser*  
Director, Project Management, Kyowa Pharmaceutical, Inc.

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**SESSION 324**  
**PP - PUBLIC POLICY/LAW, MA**  
8:30 am-10:00 am  
**Room A410**  
**CME and Pharmacy credits offered**

**Off-label Promotion and Physician Liability**  
**SESSION CHAIRPERSON(s)**  
*Shane H. Freedman, JD*  
Counsel, Patton Boggs LLP

The recent prosecution of Dr. Peter Gleason, a Maryland psychiatrist, for promoting the drug Xyrem brings into focus the expanding scope of prosecutorial activity in off-label promotion of pharmaceutical products. Former state and federal prosecutors will discuss the regulatory framework in the context of this case.

**Off-label Promotion; Background and Regulatory Framework**  
*Laurence J. Freedman, JD*  
Partner, Patton Boggs LLP

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**SESSION 325**  
**RA1 - REGULATORY AFFAIRS, PP**  
8:30 am-10:00 am  
**LEVEL:**  
**Room A406**

**Partnership in Regulatory Harmonization: Revival of the Pharmaceutical Evaluation Report (PER) Scheme in Asia**  
**SESSION CHAIRPERSON(s)**  
*Herng-Der Chern, MD, PharmD, PhD*  
Executive Director, Center for Drug Evaluation, Taiwan

The revival of the pharmaceutical evaluation report (PER) scheme has been proposed in Asia to overcome the limited regulatory capacity in new drug approval for many small regulatory agencies. This proposal has gained considerable interest among Japan, Korea, Switzerland, Australia, Taiwan and many global pharmaceutical companies. The session will review the progress of this initiative with a focus on the achievements among Japan, Korea, PhRMA and Taiwan.

**Strategies for Global Drug Development and Regulatory Submission of New Actives Substances in Asia**  
*Stuart Walker, PhD*  
Vice President and Founder, CMR International Institute for Regulatory Science, UK

**Partnership in Regulatory Harmonization in Asia: Perspective of the Regulatory Agency**  
*Chi-Chou Liao, PhD*  
Director General, Bureau of Pharmaceutical Affairs, Department of Health, Taiwan

**Regulatory Dialogue and Harmonization Initiatives for Korea’s FDA**  
*Kyung Won Seo, PhD*  
Director, Gastrointestinal, Urinary, and Metabolic Drug Team, CDE, Korea Food and Drug Administration (KFDA), Republic of Korea

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**SESSION 326**  
**RA2 - REGULATORY AFFAIRS, CP**  
8:30 am-10:00 am  
**LEVEL:**  
**Room A411**  
**CME and Pharmacy credits offered**

**Prescription Drug Labeling: FDA’s New Regulation for the Content and Format of the USPI – One Year Later**  
**SESSION CHAIRPERSON(s)**  
*Steven W. Bass, PhD*  
Group Director, Global Labeling and Promotion Compliance, Bristol-Myers Squibb Company

On January 24, 2006, the FDA released the final rule for the new content and format of labeling (effective June 30, 2006). This session with FDA and industry will provide a forum to reflect on the significant events of the past year in US labeling.

**Overview of Final Rule and Guidance Documents**  
*Steven W. Bass, PhD*  
Group Director, Global Labeling and Promotion Compliance, Bristol-Myers Squibb Company

**Common PLR Issues and Questions**  
*Jamie M. Fava, PharmD*  
Manager, Global Labeling, Bristol-Myers Squibb Company

**Update from the FDA Perspective: Implementation of the Final Rule and Guidance Documents — Issues and Answers**  
*Laurie Beth Burke, MPH, RPh*  
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA
### Session 327 - RA3 - Regulatory Affairs, CTM/CS
8:30 am-10:00 am  
Room A402

**Clinical Trial Disclosure: Getting Ready for the Regulations**

**Session Chairperson(s):**

- Patricia A. Teden, MBA  
  Senior Director, SRM Strategic Business Functions, Pfizer Inc

This session will summarize emerging regulations from different geographies, describe current clinical trial disclosure operations for a global pharma company, and then have a panel predict the impact that the emerging regulations will have on disclosure operations for global study sponsors.

#### Overview of Emerging Regulations/Guidances Regarding Clinical Trial Transparency in the US

**Shawn Pelletier**  
Associate Director, R&D Operations, Bristol-Myers Squibb Company

Adapting Global Clinical Trial Disclosure Operations to Prepare for the Emerging Regulations

**Maureen A. Strange**  
Associate Medical Business Operations Consultant, CTR Initiated Gatekeeper, Eli Lilly and Company

#### Measuring Clinical Trial Site Performance in Japan

**Patrick Floody**  
Director, Study Management Group, Pfizer Japan

Investigator Motivation: Implications

**Tadaaki Taniguchi, DrMed, MD**  
Executive Director, Deputy Head of Japan Development, Banyu Pharmaceutical Co. Ltd., Japan

Practical Learnings from Actual Sites

**Suzuko Oikawa**  
Clinical Strategy Manager, R&D, Bristol-Myers K.K., Japan

Perspective from a Leading Japanese Site

**Yoshihiro Arakawa, PhD**  
Associate Professor, Vice Director, The University of Tokyo, Japan

### Session 328 - RA4 - Regulatory Affairs, CR
8:30 am-10:00 am  
Room A405

**Best Practices in Preparing for and Participating in a Pre-IND Meeting**

**Session Chairperson(s):**

- Charles G. Lineberry, PhD  
  Chief Scientific Officer, Constella Group, LLC

The pre-IND meeting is a crucial step in drug development and a well-planned and well-executed pre-IND meeting minimizes the risk of a clinical hold. Experienced industry and FDA scientists will present best practices for preparing for and participating in a pre-IND meeting.

Practical Lessons for Planning and Participating in a Pre-IND Meeting for Start-up Pharmaceutical Companies

**Charles G. Lineberry, PhD**  
Chief Scientific Officer, Constella Group, LLC

Strategic Considerations for Engaging the FDA in Early Drug Development Dialogue: The Pre-IND Meeting

**Craig A. Metz, PhD**  
Vice President, US Regulatory Affairs, GlaxoSmithKline

CDER Perspective on Pre-IND Meetings: What You Really Want to Know

**Kim Colangelo**  
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

### Session 329 - RD - R&D Strategy, CTM/CS
8:30 am-10:00 am  
Room B303

**Improvement in Japan’s Clinical Trial Environment: A Sponsor Company Perspective**

**Session Chairperson(s):**

- Chris R. Albani, MBA  
  Partner, Pharmaceutical Industry Lead, Pittiglio Rabin Todd & McGrath, Japan

There has been much talk lately about improving the clinical trial environment in Japan. Sponsored by PhRMA, a team of local company experts set out to influence change at the site level. The team’s research provides a unique perspective on what is happening in Japan today as compared with some best practices from other regions. In this session, we will review new data regarding the current clinical trial environment in Japan, including the current performance of clinical trial sites as well as the hurdles for change.

### Session 330 - ST - Statistics, EC
8:30 am-10:00 am  
Room B309

**Statistical Computing Environments: Establishing the Need, Setting Forth Requirements**

**Session Chairperson(s):**

- Susan P. Duke, MS  
  Assistant Director, Biostatistics and Programming Development Partners, GlaxoSmithKline

In the pharmaceutical R&D environment, some functions are involved in most aspects of the process, causing individuals in these roles to be increasingly busy. This session will focus on the specific case of improving computing environments for the heavily collaborative role of statisticians. Making statisticians’ electronic tools easy to use and easy to connect to the many things they do will improve their productivity, allowing them to spend more time on what they’ve been trained for. This session is a panel discussion of statisticians, a database and statistical programming expert and an IT interoperability expert, setting forth their views on requirements for statistical computing environments. There will also be time for the audience to participate in this discussion.

The Statistical Computing Environment: Definition, Requirements and Current Practices

**John Brega, MA**  
Senior Consultant, PharmaStat LLC

An FDA Perspective: Serving the Needs of the Reviewers

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

Vendor Perspective: Achieving Interoperability

**Jason Burke, MA**  
Director, Life Sciences Strategy and Solutions, SAS Institute, Inc.

Emerging CDISC Standards and Process Implications for Statisticians

**Greg Anglin, PhD**  
Principal Research Scientist, Statistics, Eli Lilly Canada Inc., Canada

Future Visions for the SCE

**Alan Hopkins, PhD**  
Senior Director, Biometrics, Theravance.com
SESSION 331  TR - TRAINING, CR
8:30 am-10:00 am  LEVEL: ●
Room B308
Networking as a Personal Disaster Preparation Plan: Helping You Stay Up when the Sizing is Down
SESSION CHAIRPERSON(S)
Danny A. Benau, PhD
Associate Professor, Biomedical Writing, University of the Sciences in Philadelphia
Career networking is difficult for most people. However, networking and network communications are especially important when the business climate is fluid. This session will explore some simple techniques that can be of help when events seem to be compromising your career and career plans.

Networking and Your Career
Dana Marko, MSc
Senior Career Coach, Lee Hecht Harrison
Alumni Networking
Alan M. Barstow, PhD
Director, Academics and Outreach for Organizational Dynamics, University of Pennsylvania
Networking as Disaster Planning
Danny A. Benau, PhD
Associate Professor, Biomedical Writing, University of the Sciences in Philadelphia

SESSION 332  VA - VALIDATION, PM
8:30 am-10:00 am  LEVEL: ■
Room A311
Assessing and Auditing of Clinical Computerized Systems
SESSION CHAIRPERSON(S)
Earl W. Hulihan, MEd
Vice President, Global Regulatory Affairs and Quality Assurance, Medidata Solutions Worldwide
All too often there is a war of words from different sides as to how much effort our companies must put forth in computer system validation. Managers attending this session will learn clear guiding principles, effective strategies and common sense – to have data integrity and data privacy.

Lessons Learned in the World of Security as It Relates to Computerized Clinical Systems
Nelson P. Kopyt, DO, CCRI, FACP, FASN
Director of Research, Northeast Clinical Research Center; Associate Chief of Nephrology, Lehigh Valley Hospital; Clinical Professor of Medicine, Temple University
Ensuring Security and Integrity of Data in EDC Systems
Sourav (Neil) Banerjee
Quality Assurance Manager, Validation, ICON Clinical Research
Setting the Bar for Information Security Education
Brian Martin
Information Security Manager, Lehigh Valley Health Network

SESSION 333  AHC - ACADEMIC HEALTH CENTERS, CR
10:30 am-12:00 pm  LEVEL: ◆
Room B303
Integrating Research and Clinical Care in Academic Health Centers
SESSION CHAIRPERSON(S)
Michael Nourie, MBA
President and Chief Technology Officer, Accelere, Inc.
Today’s academic clinical research environment faces new challenges: 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); and maintaining patient confidentiality.

Accelerating Research: Summary of Integrating Clinical Research in Clinical Care at Academic Health Centers
Michael Nourie, MBA
President and Chief Technology Officer, Accelere, Inc.
Which Came First: Care or Research?
Stephen K. Woody
Chief Information Officer, Duke Clinical Research Institute
Information Technologies and Infrastructure: Keeping Pace with Translational Medicine and Personalized Medicine
John D. Rootenberg, MD
JDR Consulting
Panelist
David Chen, MS
Chief Executive Officer, Accelere, Inc.

SESSION 334  BT - BIOTECHNOLOGY, NC
10:30 am-12:00 pm  LEVEL: ●
Room B304
CME credits offered
Transition from Preclinical to Clinical Studies with Biopharmaceuticals
SESSION CHAIRPERSON(S)
Jennifer Sims, PhD
Director, Preclinical Safety for Biologicals, AstraZeneca, UK
Joy A. Cavagnaro, PhD, DABT, RAC
President, Access BIO
The generation of data which addresses relevant questions regarding safety assessment of biopharmaceuticals and understanding the predictive value of such data is addressed in other sessions at this conference. This session will discuss the interpretation of the data generated and, using case studies, illustrate how to select a safe starting dose for first-in-human studies. Regulatory experts will outline the current expectations from the regulatory view, and a clinical scientist will provide a perspective on the translation of preclinical data to first-in-human clinical trials and issues relating to study design.

Selection of a Safe Starting Dose: Case Studies from Industry
Jennifer Visich, PhD
Director, Preclinical Development, Pharmacokinetics and Pharmacodynamics, ZymoGenetics, Inc.
Regulatory View of Selection of a Safe Starting Dose Post-Tegenero
David Jacobson Kram, PhD
Associate Director for Pharmacology and Toxicology, Office of New Drugs, CDER, FDA
Design of FIH Clinical Study: A Clinician’s View
Richard W. Peck, MD
Director, European Exploratory Medicine, Eli Lilly and Company, Ltd., UK
Panelists

David R. Jones, MSc
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Beatriz Silva Lima, PharmD, PhD
Professor, Pharmacology, University of Lisbon and Preclinical Expert, INFARMED, Portugal; Member, CHMP and Scientific Advice Working Group; Chair, Safety Working Party, EMEA, EU

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**Session 335**

**CDM - Clinical Data Management, EC**

10:30 am-12:00 pm 

**Room A312**

**The Path to the Future: eCDM or No CDM**

**Session Chairperson(s)**

Joseph S. Anderson
Principal Associate, Waife & Associates, Inc.

This session will discuss ways of responding to the changes experienced in CDM: the use of EDC, the multiplication of other technologies, and the interest in remote DM (offshoring). Speakers will provide strategies for responding and ways that data managers can adapt their careers to them.

**The CDM Organization of the Future**

Brooks Wade Fowler
Director, Clinical System Operations, Global EDC Project Office, Abbott Laboratories

**CDM Offshore Challenge: Does Your Dogma Bite?**

Dean A. Gittleman, MSc
Senior Director, Global Operations Head, Data Management, Eisai, Inc.

**The Golden Opportunity: Data Management as a Career**

Joseph S. Anderson
Principal Associate, Waife & Associates, Inc.

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**Session 336**

**CMC/GMP - Chemistry, Manufacturing, and Controls/Good Manufacturing Practices, RA**

10:30 am-12:00 pm 

**Room A301**

**Challenges in Implementing ICH Q8 and Q9 Guidelines in Global Submissions**

**Session Chairperson(s)**

Charles P. Hoiberg, PhD
Executive Director, Pfizer Inc

This session will discuss the challenges associated with implementing the ICH Q8 (pharmaceutical development) and Q9 (quality risk management) guidelines in Japanese and Taiwanese regulatory CMC submissions.

**Change in Policy of CMC Regulation in Japan**

Haruhiro Okuda, PhD
Director, Division of Organic Chemistry, National Institute of Health Sciences, Ministry of Health, Labour, and Welfare (MHLW), Japan

**Global CMC Strategy with New Pharmaceutical Affairs Law in Japan: An Industry Perspective**

Kimiya Okazaki, PharmD
Director, Pfizer Japan Inc., Japan

**CMC Risk-based Critical Path Evaluation**

Wender Wan, PhD, JD
Reviewer, Taiwan Center for Drug Evaluation, Taiwan

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**Session 337**

**CP - Clinical Safety and Pharmacovigilance, CDM**

10:30 am-12:00 pm 

**Room A302**

**Using the FDA’s Adverse Event Reporting System (AERS) Quarterly Data Extracts**

**Session Chairperson(s)**

John Quinn, MS, RPh
Software Engineer, Office of Surveillance and Epidemiology, CDER, FDA

A subset of the Food and Drug Administration’s Center for Drug Evaluation and Research Adverse Event Reporting System (AERS) data is available for downloading at CDER’s webpage (http://www.fda.gov/cder/aers/extract.htm). Advantages and constraints of this data set will be discussed.

**AERS Database Elements: Field Content, Comparison with the Overall AERS Database, Issues, Suggestions**

Lynette Swartz, MBA, Med
Technical Information Specialist, Office of Surveillance and Epidemiology, CDER, FDA

**MedDRA® Coding Impact on Data Retrieval and Analysis within FDA AERS**

Amarilys Vega, MD, MPH
Pharmacoepidemiologist/MedDRA® Specialist, PSI International, Inc.

**Using AERS Data Extract Files: A Practical Example**

William S. Calvert, MPH
Associate Director, Pharmacoepidemiology, Purdue Pharma

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**Session 338**

**CR1 - Clinical Research and Development, OS**

10:30 am-12:00 pm 

**Room B407**

**Clinical R&D Outsourcing to India: What Do You Outsource to Whom?**

**Session Chairperson(s)**

Vis Niranjan, MD
President, RxMD Private Limited, India

Indian outsourcing service providers may be classified into business process outsourcing (BPO), contract research outsourcing (CRO) and knowledge process outsourcing (KPO). The BPO and KPO are at opposite ends of the domain expertise, with the CRO in between. KPOs, also called non-CROs, are capable of doing the high-end tasks most sponsors have been reluctant to outsource. With a BPO at one end of the spectrum and a KPO at the other end, the question is: How much do you want to outsource? Attendees will learn how to enhance their current outsourcing strategies in India.

**Overview of Outsourcing to India and Knowledge Process Outsourcing**

Vis Niranjan, MD
President, RxMD Private Limited, India

**Choosing the Right Indian CRO**

Munish Mehra, PhD, MSc
Managing Director, Global Drug Development Experts

**The Role of Indian IT Companies as Clinical R&D Service Providers**

Shirish D. Sherlekar, MD
Consultant, Tata Consultancy Services, India
**SESSION 339**  
**CR2 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS**  
10:30 am-12:00 pm  
**Room B408**  
**Actuarial Methods within Pharmacoeconomics and Clinical Trials**  
SESSION CHAIRPERSON(s)  
*Chris Stehno, MBA, MS*  
Senior Manager, Deloitte Consulting  

For over 100 years, actuaries have studied diseases and their associated risks. Recently, a new breed of actuaries has branched out into the pharmaceutical industry. Learn what special skills and knowledge this profession is bringing to the table.  

*An Actuarial Perspective of Pharmaceuticals and Disease Management*  
*Aree Bly, MS*  
Consulting Actuary, Milliman  

**An Actuarial Methods within Pharmacoeconomics and Clinical Trials: Overview**  
*Chris Stehno, MBA, MS*  
Senior Manager, Deloitte Consulting  

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**SESSION 340**  
**CR3 - CLINICAL RESEARCH AND DEVELOPMENT, CP**  
10:30 am-12:00 pm  
**Room B409**  
**Oversight of Research: Data Safety Monitoring Committees (DMC) – A Systems Approach**  
SESSION CHAIRPERSON(s)  
*Darren B. McDaniel, MS*  
Chief Executive Officer, Managing Officer, Coast IRB, LLC  

The need for major systems reforms to human subject protection in research has resulted in proposals to split research review and oversight functions between IRB and data monitoring committees (DMCs). This session will review research data from 2005 in respect to a novel approach of DMC utilization.  

**The Role of the IRB**  
*Koren Barrett, ND*  
Naturopathic Doctor, Institute for Progressive Medicine  

**A Proposed Model for Ethical Research Oversight Combining IRB and DMC Review**  
*Darren B. McDaniel, MS*  
Chief Executive Officer, Managing Officer, Coast IRB, LLC  

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**SESSION 341**  
**CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, CR**  
10:30 am-12:00 pm  
**Room B404**  
**Becoming a Sponsor of Choice for Clinical Investigators**  
SESSION CHAIRPERSON(s)  
*Gary Tyson*  
Vice President, Clinical Development Practice, Campbell Alliance  

A company must do everything it can to be the sponsor with which sites prefer to work. Being the sponsor of choice involves understanding what investigators value most. This session will provide the tools required to get ahead in the increasingly competitive race for trial participants.  

*Clinical Study Sites and Sponsor Relationships: Building Stronger Partnerships through Mutual Understanding*  
*Andrew Lee, MA*  
Vice President, Clinical Study and Data Management, Pfizer Global R&D  

*Becoming a Sponsor of Choice for Clinical Investigators*  
*Sandra S. Vose*  
Executive Director, Clinical Operations, Celgene Corporation  

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**SESSION 342**  
**EC - eCLINICAL, CDM**  
10:30 am-12:00 pm  
**Room A314**  
**The Role of Electronic Data Capture in Adaptive Clinical Trials**  
SESSION CHAIRPERSON(s)  
*Glen de Vries, PhD*  
Co-founder and Chief Technology Officer, Medidata Solutions, Inc.  

Implementing adaptive clinical trials can potentially save sponsors up to $200 million a year by identifying ineffective drugs earlier and refining their trial designs. This is only possible with the ability to access and analyze clinical data more often via an EDC system.  

*Security Models and Technology Considerations for Adaptive Clinical Trials*  
*Glen de Vries, PhD*  
Co-founder and Chief Technology Officer, Medidata Solutions, Inc.  

*Jerald S. Schindler, DrPH, PharmD*  
Vice President, Biostatistics and Research Division Sciences, Merck Research Laboratories  

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**SESSION 343**  
**ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, RA**  
10:30 am-12:00 pm  
**Room A412AB**  
**FDA Data Exchange Standards: Update**  
SESSION CHAIRPERSON(s)  
*Randy Levin, MD*  
Director for Health and Regulatory Data Standards, CDER, FDA  

This session will provide an overview of important FDA data exchange standard initiatives including the importance and benefit of the data exchange standard to FDA and industry, an update on the progress of the standard development, adoption and implementation and potential future initiatives.  

**Overview of Data Exchange Standards**  
*Armando Oliva, MD, CAPT. USPHS*  
Medical Officer, Office of the Commissioner, FDA  

**Regulated Product Submission Standard Update**  
*Peggy R. Leizear*  
Program Analyst, Office of the Commissioner, OPPL/OPL/PS, FDA  

**Structured Product Labeling Update**  
*Lonnie D. Smith*  
Project Manager, Office of the Director, CDER, FDA  

**Individual Case Safety Report Update**  
*Lise R. Stevens-Hawkins*  
Data Standards Coordinator, Office of the Director, CBER, FDA  

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**THIS SESSION HAS BEEN CANCELLED**
Managing Code Changes during Testing
Barbara L. Meserve
Director, IT Quality, AccuLogix, Inc.

Coordinating Document, System, and Infrastructure Changes
Michael S. Tarle
Senior Computer Validation Specialist, Nektar Therapeutics

Update on the Utah Medical Case
Thomas Quinn
President, CISSP, The Hollis Group, Inc.

SESSION 347  MA - MARKETING AND SALES, EC
10:30 am-12:00 pm  LEVEL: ●
Room B301  Pharmacy credits offered
Defining the Value of Pharmaceuticals
SESSION CHAIRPERSON(S)
Kristin Eilenberg, MBA
Manager, Global Customer Solutions, Eli Lilly and Company

Volumes of data about the safety and effectiveness of pharmaceutical products is being collected, aggregated, and analyzed by healthcare providers and payer systems. This new source of information is being utilized to measure the value of pharmaceutical innovations.

HIT Overview: How HIT Is Improving the Standard of Care
Charles Safran, MD
Chief, Division of Clinical Computing, Beth Israel Deaconess Medical Center

HIT Secondary Data Uses: Defining the Value of HIT for Pharma
Joseph Volpe
Director, Physician Connectivity/Technology, Johnson & Johnson Health Care Systems, Inc.

HIT Landscape: Where, When, and How Will Pharma Get Engaged?
Steven E. Labkoff, MD
Director, Healthcare Informatics, Pfizer Inc

SESSION 348  MC - MEDICAL COMMUNICATIONS, ERS/DM
10:30 am-12:00 pm  LEVEL: ●
Room B302  CME and Pharmacy credits offered
The Emergent Role of the Medical Scientist in the Evidence-based Payer Environment: A Fundamental Source for Qualitative and Quantitative Information
SESSION CHAIRPERSON(S)
Eric M. Hillson, PhD, MBA, MSc, RPh
Director, Economic, Clinical and Health Outcome (ECHO) Scientist Group, Centocor, Inc.

This session is intended for those interested in learning about the evolving responsibilities of field-based medical teams to communicate science-based and value-based information to key health policy decision makers (HPDMs). This session will include three unique discussions: 1) insights into the various segments and profiles of today’s health policy decision makers (HPDMs); 2) characterization of traditional and innovative tools (with examples) used to support the evidence-based decision-mapping process; and 3) inside-out perspective from an experienced health policy decision makers (HPDM) on needs assessment, best interaction model and scientific relationship with field-based medical scientists. The presenters will utilize slides to introduce fundamental concepts and then engage the audience in a constructive discussion.

Segmentation Exercise of Today’s Health Policy Decision Makers (HPDMs)
Eric M. Hillson, PhD, MBA, MSc, RPh
Director, Economic, Clinical and Health Outcome (ECHO) Scientist Group, Centocor, Inc.
Pharmacological and toxicological studies, using in vitro and/or in vivo tests, evaluation of hepatotoxicity could be a stepwise procedure using conventional continuing to clinical trials and postmarketing experiences. The detection and toxic effects is a continuous process starting from nonclinical findings, and to decrease the risk of clinical adverse liver reactions. The collection of hepatic and report early nonclinical effects of drug-induced hepatotoxicity in order approved drug is liver toxicity. This session will address how to identify, collect and prepare other postmarketing regulatory documents, often against aggressive timelines.

The Medical Writer’s Role on the Regulatory Rapid Response Team: Lessons from a Simultaneous NDA-MAA Submission

Susan F. Gonsalves, PhD, MBA
Director, Safety and Risk Management, Pfizer Inc

If you think the contribution of medical writers at pharmaceutical companies is limited to clinical study reports and summary documents, think again. This session will focus on the ways medical writers work with their teams during the review cycle and again after product launch to address regulatory queries and prepare other postmarketing regulatory documents, often against aggressive timelines.

The Medical Writer’s Role on the Regulatory Rapid Response Team: Lessons from a Simultaneous NDA-MAA Submission

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Director, Safety and Risk Management, Pfizer Inc

My Drug is Approved – Now What? Medical Writer’s Role in Postapproval Regulatory Response

Cathy D. Caldwell, MS
Senior Scientific Communications Associate, Eli Lilly and Company

My Drug is Approved – Now What? Medical Writer’s Role in Postapproval Regulatory Response

Cathy D. Caldwell, MS
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Beyond the CTD: The Medical Writer’s Role in Peri- and Postapproval Documents

SESSION CHAIRPERSON(S)
Susan F. Gonsalves, PhD, MBA
Director, Safety and Risk Management, Pfizer Inc

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Cathy D. Caldwell, MS
Senior Scientific Communications Associate, Eli Lilly and Company

My Drug is Approved – Now What? Overview of Required Postapproval Documents

Julia Cooper, PhD
Senior Director, Worldwide Head of Medical Writing Services, PAREXEL International Ltd., UK

Validating Botanicals for the Management of Diabetes Mellitus

SESSION CHAIRPERSON(S)
Pradeep Visen, PhD
Research Scientist, Risk Factor Modification Centre, St. Michael's Hospital, University of Toronto, Canada

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My Drug is Approved – Now What? Overview of Required Postapproval Documents

Julia Cooper, PhD
Senior Director, Worldwide Head of Medical Writing Services, PAREXEL International Ltd., UK

Drug-induced Liver Toxicity

SESSION CHAIRPERSON(S)
Klaus Olejniczak, DVM, FACP
Scientific Director, BfArM, Germany

One of the most frequent reasons for the withdrawal from the market of an approved drug is liver toxicity. This session will address how to identify, collect and report early nonclinical effects of drug-induced hepatotoxicity in order to decrease the risk of clinical adverse liver reactions. The collection of hepatotoxic effects is a continuous process starting from nonclinical findings, and continuing to clinical trials and postmarketing experiences. The detection and evaluation of hepatotoxicity could be a stepwise procedure using conventional pharmacological and toxicological studies, using in vitro and/or in vivo tests, and developing new mechanistic methods to increase the predictability of hepatotoxicity.

The State of Clinical Outsourcing: Results from Avoca’s 2007 Industry Survey with a Focus on Change Orders – The Challenges, the Impact and the Effect on Relationships

SESSION CHAIRPERSON(S)
Patricia Leuchten
President, The Avoca Group, Inc.

One of the most frequent reasons for the withdrawal from the market of an approved drug is liver toxicity. This session will address how to identify, collect and report early nonclinical effects of drug-induced hepatotoxicity in order to decrease the risk of clinical adverse liver reactions. The collection of hepatotoxic effects is a continuous process starting from nonclinical findings, and continuing to clinical trials and postmarketing experiences. The detection and evaluation of hepatotoxicity could be a stepwise procedure using conventional pharmacological and toxicological studies, using in vitro and/or in vivo tests, and developing new mechanistic methods to increase the predictability of hepatotoxicity.
provocative session, quantitative and qualitative data including current practices, challenges, and opportunities with maintaining control of costs will be presented. Executives from Merck, J&J, PharmaNet and Quintiles will present case studies and best practices for pharma as well as for CROs.

Panelists

James Tiede, PhD
Vice President, Integrated Data Services, Johnson & Johnson LLC

Denise R. Rue
Associate Director, External Services, MRL Clinical Development, Merck & Co., Inc.

Paula Brown Stafford, MPH
Executive Vice President, Global Data Management, Quintiles Transnational Corp.

George C. Butler, MS
Vice President, Corporate Project Management, PharmaNet, Inc.

SESSION 353 PM1 - PROJECT MANAGEMENT, CR
10:30 am-12:00 pm  LEVEL: □
Room B403  Project Management units offered
Creating Dynamic Product Development Teams
SESSION CHAIRPERSON(S)
Sarah B. Wilson, MS
Senior Business Operations Associate, Eli Lilly and Company

This session will highlight ideas for project managers leading product development teams to convert cross-functional groups of technical experts into high-performance teams quickly and effectively. Such teams generate more value, achieve results more rapidly, and yield better results.

Team Effectiveness Factors
Michele C. Livesey
Global Research and Development Team Leader, Roche Palo Alto, LLC

Team Selection Criteria
Terry Cooke-Davies, PhD
Executive Chairman, Human Systems International Ltd., UK

Effective On-boarding Techniques
Ray Sanchez-Pescador, PhD, PMP
Associate Director, Product Portfolio Management, Genentech, Inc.

SESSION 354 PM2 - PROJECT MANAGEMENT, CTM/CS
10:30 am-12:00 pm  LEVEL: ●
Room B402  Project Management units offered
Who is This Jack-of-all-trades: The Pharmaceutical R&D Project Manager?
SESSION CHAIRPERSON(S)
Georg A. Mathis, DVM, MD, PhD, MBA
Head, Project and Life-cycle Management, Head, Clinical Research, Siegfried Ltd., Switzerland

Project managers in the pharmaceutical industry are often rather haphazardly appointed without consideration of the complexity of the job. We will present hands-on approaches to recruit, train and coach project managers in order to ensure project success.

How to Select Successful Pharmaceutical Project Managers
Georg A. Mathis, DVM, MD, PhD, MBA
Head, Project and Life-cycle Management, Head, Clinical Research, Siegfried Ltd., Switzerland

Training Project Managers in the Pharmaceutical Industry
Paul S. Hara, PMP
Director, Program Management, MDS Pharma Services

The eClinical Project Manager: Challenges and Best Practices
Brian R. Dakin, MBA, PMP
Principal, Rhombus Consulting, Inc.

21st Century Project Management: Using Collaborative Technology to Achieve the "New" Project Management
Augustus J. Cicala, MS
President and Chief Executive Officer, Project Assistants, Inc.

SESSION 355 PP - PUBLIC POLICY/LAW, RA
10:30 am-12:00 pm  LEVEL: □
Room A410
BPCA Report Card
SESSION CHAIRPERSON(S)
Chin C. Koerner, MS
Executive Director, FDA Liaison and Policy, Novartis Pharmaceuticals

The US now has almost two decades of experience in public policy intended to stimulate pediatric research. Most experts agree that it is under FDAMA and BPCA with pediatric exclusivity provisions, that the greatest strides have been made. BPCA sunsets this year with great debates on the Hill of whether renewal is necessary when, after all, there is PREA. In this session you will hear about the successes, lessons learned, and failures under BPCA. You will also hear about efforts to implement a similar policy in Europe, and what lies ahead for the US in the next go-around of pediatric legislation.

The EU Perspective
Melissa S. Tassinari, PhD, DABT
Senior Director, Strategic Policy Management, Worldwide Regulatory Policy and Intelligence, Pfizer Inc.

BPCA Report Card: How is BPCA Working from a Policy Perspective?
Christopher P. Milne, DVM, JD, MPH
Assistant Director, Tufts Center for the Study of Drug Development, Tufts University

What Lies Ahead?
Sharon N. Olmstead
Vice President, Regulatory Policy and Intelligence, Schering-Plough

Panelist: EU Insider Perspective
Fabio Marazzi, LLM
Managing Director, M+BioLaw Spa, Italy

Panelist: EU Insider Perspective

SESSION 356 RA1 - REGULATORY AFFAIRS, IT
10:30 am-12:00 pm  LEVEL: ●
Room A402
FDA’s Drug Establishment Registration and Drug Product Listing System
SESSION CHAIRPERSON(S)
Middleton John Coburn, MBA, MPharm
Team Leader, Drug Registration and Listing, Office of Compliance, DCRMS, CDER, FDA

This session will provide an overview of FDA’s drug registration and listing system (DRLS), and proposed registration and listing rule changes requiring use of an electronic web-based interface will be discussed.

FDA’s Proposed Rule and Electronic Drug Product Listing System (eLIST)
John W. Gardner, DrPH, MD
Division Director, Office of Compliance, CDER, FDA

FDA’s Electronic Drug Establishment Registration System (DFRM)
Middleton John Coburn, MBA, MPharm
Team Leader, Drug Registration and Listing, Office of Compliance, DCRMS, CDER, FDA
Wednesday, June 20

**SESSION 357**  
**RA2 - REGULATORY AFFAIRS, RD**  
10:30 am-12:00 pm  
LEVEL: ■

**Room A405**

**Global New Drug Development: Regulatory Challenges, Successes and Recommendations from a US-based Company**

**SESSION CHAIRPERSON(S)**

**Jean M. Conaway, MBA, RPh, RAC**
Regulatory Advisor, TAP Pharmaceutical Products, Inc.

An effective global drug development strategy is critical in order to expedite the drug development process. A US-based company explains the regulatory challenges and successes it experienced with some of its large global programs and provides recommendations on how to streamline the global drug development process.

**Ex-USA Regulatory Affairs Strategy**

**Kay Mason, MS**
Senior Regulatory Affairs Manager, Quintiles Limited, UK

**International Drug Distribution Challenges**

**Harry Edward Storey**
Project Manager, Clinical Logistics, Fisher Clinical Services, UK

**International IVRS**

**Jennifer C. Ross**
Clinical Project Manager, Clinphone, Inc.

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**SESSION 358**  
**RA3 - REGULATORY AFFAIRS, CR**  
10:30 am-12:00 pm  
LEVEL: ■

**Room A406**

**Optimizing EU Regulatory Strategy**

**SESSION CHAIRPERSON(S)**

**Cecil Nick, MS**
Principal Consultant, PAREXEL Consulting, UK

In the EU, the regulatory professionals need to wrestle with a spectrum of opinions, cultures and approaches. Yet getting the strategy right, e.g. in terms of scientific advice, the submission route, the content and structure of the MAA and possessing the requisite infrastructure is critical to success. This session looks at how to optimize EU regulatory strategy focusing on critical issues rather than process.

**Dealing with a Spectrum of Opinions, Cultures and Approaches**

**Cecil Nick, MS**
Principal Consultant, PAREXEL Consulting, UK

**Optimizing the Clinical Program for Europe**

**Louis-Christian Clauss, PharmD**
Director, Regulatory Affairs, Global NPB Biologics, Baxter, France

**Working with the EMEA**

**Agnés Saint Raymond, MD, PhD**
Head of Sector, Scientific Advice and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

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**SESSION 359**  
**ST - STATISTICS, CP**  
10:30 am-12:00 pm  
LEVEL: ■

**Room B309**

**Statistical Methodologies for Safety Assessments**

**SESSION CHAIRPERSON(S)**

**Christopher Holland, MS**
Mathematical Statistician, Quantitative Safety and Pharma Epidemiology Group, Office of Translational Sciences, CDER, FDA

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**SESSION 360**  
**TR - TRAINING**  
10:30 am-12:00 pm  
LEVEL: ■

**Room B308**

**Podcasting and Training: Delivering Your Courses via the Latest Technologies**

**SESSION CHAIRPERSON(S)**

**Joan Harley, BSN, RN**
Training Consultant and eLearning Developer, Training Extension, Inc.

In this session, we will analyze the use of podcasting in training. The session will focus on background and statistics of podcasting, its advantages and limitations, how instructional design can minimize its limitations, and how to develop and implement podcasts. We will also present on how podcasts can be repurposed to add value to different types of learning situations. Examples will be presented and discussed.

**Background and Statistics on the Use of the Podcasting in Training**

**Nicole Curry, MBA, MS**
Manager, Learning and Professional Development, Ortho-McNeil Janssen Scientific Affairs, LLC

**Creative Instructional Design to Increase Retention of Information Presented in Training Podcasts**

**Joan Harley, BSN, RN**
Training Consultant and eLearning Developer, Training Extension, Inc.

**Implementation of Podcasting within a Large Pharmaceutical Company**

**A.J. Ford**
Senior Analyst, Johnson & Johnson Information Technology

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**SESSION 361**  
**VA - VALIDATION, IT**  
10:30 am-12:00 pm  
LEVEL: ■

**Room A311**

**Business Continuity and Disaster Recovery for Laboratory Systems and Potential Migration/Upgrade of GxP Applications: A Practical View**

**SESSION CHAIRPERSON(S)**

**Teri E. Stokes, PhD, MS, MT**
Director, GxP International
GXP/Part 11 systems need all three, but too often BCP is unwieldy, DRP is not done and there is no standard practice to migrate or upgrade existing GxP applications to new platforms. A right sized, practical approach to all three is needed and this session shares some real experience and case study views for practitioners.

Case Study: Upgrade of GxP Applications
Nagesh Sarma, MS
Managing Director, Validation Services, Valiance Partners

Disaster Recovery Planning
Bradley D. Wong
Senior Manager, IS Compliance, Allergan

Business Continuity Planning
Teri E. Stokes, PhD, MS, MT
Director, GXP International

12:00 pm-1:30 pm  LUNCHEON
Building A – Exhibit Hall A Only

SESSION 362  AHC - ACADEMIC HEALTH CENTERS, CR
1:30 pm-3:00 pm  LEVEL: ■
Room B303
Producing Epidemiologic Data in Latin America through Registries: Collaboration between Academia and the Pharmaceutical Industry
SESSION CHAIRPERSON(S)
Laura Luchini, MD, PhD
Executive Director, Eurotrials Scientific Consultants, Brazil

Observational studies are of great importance to offer data that support public health policies and clinical decisions, but they are expensive and complex to conduct. Academia and pharmaceutical industry/CROs will be invited to share their experience on joint observational studies conduct.

Setting Up Basis for Collaboration between Academia and the Pharmaceutical Industry
Laura Luchini, MD, PhD
Executive Director, Eurotrials Scientific Consultants, Brazil

Academia Point of View of the Collaboration with the Pharmaceutical Industry in Registry Studies
Paulo A. Lotufo, DrPH, MD, MPH
Superintendent, Hospital of the University of São Paulo, Brazil

Challenges and Opportunities in Planning and Conducting Registry Studies in Latin America: The Role of the Pharmaceutical Industry
Jaderson Socrates Lima, MD, MSc
Medical Director, sanofi-aventis, Brazil

SESSION 363  BT - BIOTECHNOLOGY, CR
1:30 pm-3:00 pm  LEVEL: ●
Room B304
Phase 0/Phase 1: Successful Transition to Clinical Supplies
SESSION CHAIRPERSON(S)
Michele Coulaloglou, MS
Senior Project Manager, CMC, NuPathe, Inc.

Transition from preclinical to clinical testing supplies requires additional manufacturing controls to increase the likelihood of success of the Phase 0/1 trials. Serious adverse reactions can occur when a biologic is not sterile, contains endotoxins, mycoplasma, viruses, or has cross contamination from other development products. The inability to differentiate adverse reactions resulting from a poorly manufactured process rather than other causes can result in the product not advancing into later phases of clinical testing. Introduction into the human subject requires that the biologic meet sterility requirements. Absolute sterility cannot be determined without the testing of each unit of the clinical supply. Subsequently, other control methods are needed to assure the asepsis of the process. Virus removal processes and viral testing need to be added at the initiation of clinical trial manufacturing. Choice of the manufacturing/packaging and testing site for clinical trial material requires an assessment of whether the current production facility can meet these requirements. Use of a university laboratory or pilot scale laboratory may require additional capital expenditures and increased time for clinical supply production. Outsourcing might be a viable alternative.

Integration Strategies for Transferring Technology to Phase 1: Production, Quality, and Safety
K. Jeff Wilson, PhD
Vice President, Product Development, Inimex Pharmaceuticals Inc.

Dawn J. Chan, MBA
Founder and Principal, Technology Link

Phase 1 Clinical Supplies: Plan for Success
Michele Coulaloglou, MS
Senior Project Manager, CMC, NuPathe, Inc.

SESSION 364  CDM - CLINICAL DATA MANAGEMENT, IT
1:30 pm-3:00 pm  LEVEL: ■
Room A312
Overall Data Integrity Plans for Working with Data from Multiple Vendors
SESSION CHAIRPERSON(S)
Rita Nespeca, MSc
Senior Manager, Data Management, AAIPharma, Canada

The role of the data manager is transforming into that of a data integrator. With the many vendors taking part in clinical trials combining multiple sources into a study database is key to success.

Data Manager as the Middle Person
Colleen M. Cox
Manager, Data Management, PROMETRIKA, LLC

Upfront Planning for Vendor Integration Equates to a Quality Finish
Carmen Weese
Associate Director, Data Services, INC Research

Importing and Exporting Data Using CDISC Standards to Facilitate Interoperability between Vendors
Philip D. Quarles
Chief Information Officer, LifeTree eClinical

SESSION 365  CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA
1:30 pm-3:00 pm  LEVEL: ■
Room A301
Implementing CMC Quality-by-design (QbD) Strategies for Emerging Companies
SESSION CHAIRPERSON(S)
Irach B. Taraporewala, PhD
Senior Consultant, PAREXEL Consulting

This session covers the principles of CMC Quality by design (QbD), and demonstrates how emerging companies applying these early in the game can help expedite their product’s path to market.
The Advantages of Quality-by-design (QbD) Implementation for Emerging Companies
Irach B. Taraporewala, PhD
Senior Consultant, PAREXEL Consulting

The Impact of FDA’s Quality-by-design Initiative on Biologics Development
David Lin, PhD, MBA
Senior Consultant, Biologics Consulting Group LLC

The Role of Contract Development and Contract Manufacturing Organizations in Quality-by-design (QbD) Implementation
Michael Healy, MS
Director, Quality Assurance, Formatech, Inc.

SESSION 366 CP - CLINICAL SAFETY AND PHARMACOVIGILANCE, RD
1:30 pm-3:00 pm LEVEL: ■
Room A302 CME and Nursing credits offered

The Use of Patient and Disease Registries for Product Life-cycle Management
SESSION CHAIRPERSON(S)
Annette Stemhagen, DrPH, MPH
Vice President, Epidemiology and Risk Management, United Biosource Corporation

Disease registries document natural history of a disease and burden of illness. They can be used for planning for secondary and tertiary prevention and may also be a source of subjects for clinical research. This session explores the value of disease registries to pharmaceutical and biotechnology companies and to state healthcare agencies.

Designing and Implementing Disease Registries
Annette Stemhagen, DrPH, MPH
Vice President, Epidemiology and Risk Management, United Biosource Corporation

Why Would a State Want to Establish a Disease Registry?
Bernard G. Schreurs, PhD
Professor, Department of Physiology and Pharmacology, West Virginia School of Medicine

A View from Inside the Pharmaceutical Industry
Omar Dabbous, MD, MPH
Associate Director, Centocor, Inc.

SESSION 367 CR1 - CLINICAL RESEARCH AND DEVELOPMENT, IS
1:30 pm-3:00 pm LEVEL: ■
Room B407 CME credits offered

Factors Influencing the Speed of Clinical Trial Study Completion
SESSION CHAIRPERSON(S)
Harold E. Glass, PhD, MSc
Professor, Health Policy, University of the Sciences in Philadelphia

Building on the methodological presentation at the 2005 Annual Meeting, and an initial results presentation at the 2006 Annual Meeting, this session examines the descriptive, quantitative variables which distinguish better performing sites from poorer performing sites.

Prestudy Site Characteristics of the Best Performing Sites
Malcolm C. Bohm, MSc
President, trialitics inc

Understanding the Three Components of Successful Clinical Study Planning
Jeffrey J. DiFrancesco, MS, MSc
Director, Merck & Co., Inc.

Determinants of Successful Clinical Trial Completion: An Empirical Study of Site Performance
Harold E. Glass, PhD, MSc
Professor, Health Policy, University of the Sciences in Philadelphia

SESSION 368 CR2 - CLINICAL RESEARCH AND DEVELOPMENT, RD
1:30 pm-3:00 pm LEVEL: ◆
Room B408 CME and Pharmacy credits offered

Managing the Placebo Response in Psychiatric Clinical Trials
SESSION CHAIRPERSON(S)
Charles G. Lineberry, PhD
Chief Scientific Officer, Constella Group, LLC

High placebo response can cause trials to fail to demonstrate the efficacy of effective medications by producing significant improvements in patients receiving placebo. This session will explore the factors contributing to high placebo response, and approaches used to mitigate its influence.

Impact of Factors Associated with Clinician Ratings on Placebo Response
Kenneth Kobak, PhD
Vice President, Research, MedAvante

Contributors to High Placebo Response and Approaches to Minimize their Influence
Charles G. Lineberry, PhD
Chief Scientific Officer, Constella Group, LLC

Neurobiological Mechanisms of the Placebo Effect
Helen S. Mayberg, MD
Professor, Psychiatry and Neurology, Emory University School of Medicine

SESSION 369 CR3 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS
1:30 pm-3:00 pm LEVEL: ◆
Room B409 CME credits offered

Perspectives on Clinical Trials: The Present and the Future
SESSION CHAIRPERSON(S)
David S. Lester, PhD
Senior Director, Human Health Technology, Pfizer Inc

This session will provide three distinct perspectives – pharmaceutical, payer and academic – on the present state of clinical trials and the potential future directions. It will investigate how clinical trials could be significantly improved in terms of optimizing value from existing studies and connecting the information to how these studies can be linked to the clinical practice environment, where these potential therapeutic interventions will be used. It will address topics such as adherence methodologies, data capture and management, remote patient monitoring, biomarkers and diagnostics.

A Look into the Future of Clinical Trials Processes
David S. Lester, PhD
Senior Director, Human Health Technology, Pfizer Inc

Perspectives on the State of Clinical Trials
William C. Crawford
Center for Biomedical Innovation, Harvard Medical School
Public-private partnerships can be employed as a cost-efficient pathway to deliver electronic information to health authorities. This session will focus on the role of public-private partnerships to facilitate the flow of electronic information across the healthcare domain including clinical research. This session will also provide an update on efforts of the National Cancer Institute (NCI) who has been working with academia, healthcare providers, and the pharmaceutical industry to establish a public-private partnership known as the Clinical Research Information Exchange (CRIX).

The Role of Public-private Partnerships in Enhanced Information Management

John Speakman
Associate Director, Clinical Trials Products and Programs, NCI Center for Bioinformatics, Office of the Director, National Cancer Institute

Advancing the Public-private Partnership Concept for Information Management through CRIX (the Clinical Research Information Exchange)

Alice B. McNeil
Associate Director, Regulatory and Healthcare Informatics, Pfizer Global Research and Development

FDA’s Vision for an All-electronic Regulatory Review Environment

Armando Oliva, MD, CAPT. USPHS
Medical Officer, Office of the Commissioner, FDA

Successful Implementation of a Quality Management System

Regina Freunscht, MSc
Head, Quality Assurance, Accovion GmbH, Germany

Effective quality management systems are key for reliable quality data. Different parties have different requirements on a QMS. However, the design, its implementation and continuous maintenance of a system that serves all is not easy. This session will benefit senior clinical research professionals, QA specialists, and auditors not looking only for the evident data but also behind the usual. They will learn to identify triggers leading to possible errors, omissions or contradictions and identify methods to improve productivity in study conduct and management. Essential elements of the US FDA Bioresearch Monitoring Program will be discussed focusing on quality control of high value site activities in order to gain a better understanding of compliance.

Successful Implementation of a Quality Management System:

Introduction

Regina Freunscht, MSc
Head, Quality Assurance, Accovion GmbH, Germany

Improving Efficiencies and Effectiveness in Sponsor-site Relationship

Jan Holladay, MPH
Director, Compliance and Education, Rx Trials, Inc.

Medical Triggers for Auditing

Jean-Paul P. Eycken, MS, MBA
Chief Executive Officer, FormaliS SA, Luxembourg
### Session 374  IT1 - INFORMATION TECHNOLOGY, CDM
1:30 pm-3:00 pm  LEVEL: ■
Room A305

**Standard Controlled Terminology: A Successful Partnership between CDISC, the FDA, and NCI Enterprise Vocabulary Services**

**SESSION CHAIRPERSON(s)**

**Bron Witt Kislis**  
Director, Terminology and Strategic Alliances, CDISC

This session will provide an overview of controlled terminology initiatives across CDISC and the FDA. Within CDISC, controlled terminology is being developed and published for the study data tabulation model (SDTM), and for the FDA terminology activities are underway for the structured product label (SPL) and other key areas. The partnership with NCI Enterprise Vocabulary Services (EVS) will be highlighted, which enables effective delivery of standard controlled terminology to the global community. The terminology standards will be leveraged for one of CDISC’s newest initiatives, CDASH (Clinical Data Acquisition Standards Harmonization), included in the FDA Critical Path Initiative.

**CDISC Standard Controlled Terminology across the Clinical Trial Continuum**

**Bron Witt Kislis**  
Director, Terminology and Strategic Alliances, CDISC

**NCI Enterprise Vocabulary Services and Federal Terminology Initiatives**

**Margaret W. Haber, RN**  
Co-director, NCI Enterprise Vocabulary Services (EVS), Office of the Director, National Cancer Institute

**CDASH: An Update on the Initiative to Develop Standards for the Acquisition of CRF Data**

**Gary G. Walker**  
Associate Regulatory Director, Global Data Management, Quintiles Transnational Corp.

### Session 375  IT2 - INFORMATION TECHNOLOGY, VA
1:30 pm-3:00 pm  LEVEL: ■
Room A313

**Semantic Web Technologies in Drug Development**

**SESSION CHAIRPERSON(s)**

**Eric Neumann, PhD**  
Senior Director of Strategy, Teranode Corp.

Issues surrounding drug safety and efficacy continue to be central to discussions on improving overall drug R&D. The effective use and analysis of complex data around nonclinical experiments and clinical studies is a major goal for realizing translational research. In short, how do we get smarter using all the information we are producing from all parts of the drug development pipeline, even across projects? This session will explore how semantic web technologies will enable the translational research vision, and what steps it will take to make such a framework practical. Issues around data resource aggregation, semantic and ontological mapping, collaborative annotation sharing, and security access will be addressed.

**Panelists**

**Stephen Dobson, PhD**  
Pharmacogenomics Informatics Scientist, Pfizer Inc

**Uwe P. Trinks, PhD**  
Chief Information Officer, Sentrx

**Robbert P. Van Manen, MSc**  
Worldwide Technical Director, Phase Forward

### Session 376  MA - MARKETING AND SALES, AD
1:30 pm-3:00 pm  LEVEL: ■
Room B301

**Lifestyle-based Analytics: A Revolutionary Marketing Approach**

**SESSION CHAIRPERSON(s)**

**Chris Stehno, MBA, MS**  
Senior Manager, Deloitte Consulting

A critical challenge when marketing to consumers is getting product information into the hands of the correct individuals. A new actuarial-based statistical data mining technique known as lifestyle-based analytics is fulfilling this critical need in a HIPAA-compliant manner.

**Addressing the Consumer: A DTC Marketing Approach**

**Ken Shore**  
Executive Vice President, Client Services, Blue Chip Marketing & Communications

**Lifestyle-based Analytics: A Revolutionary Marketing Approach – An Overview**

**Chris Stehno, MBA, MS**  
Senior Manager, Deloitte Consulting

### Session 377  MC - MEDICAL COMMUNICATIONS, MA
1:30 pm-3:00 pm  LEVEL: ■
Room B302

**Approach, Design and Development of Medical Science Liaison Portal**

**SESSION CHAIRPERSON(s)**

**John H. Mackey**  
Practice Director, Life Sciences, Infosys Technologies Limited

This panel discussion will focus on lessons learned during the design and development of a web-based portal used to assist with medical science liaisons in support of investigator-initiated trials. Presentations will review the driving industry challenges, detailed methodology and processes.

**Case Study: Development of MSL Portal**

**David Samuel Lange, MS**  
Associate Director, MAIS, Celgene Corporation

**Technical Considerations and Lessons Learned**

**James Wright**  
Director of Technology, Edgewater Technology, Inc.

**Implications of Emerging Technologies on Medical Science Liaisons**

**Paul Mattes**  
US Director, Pharmaceutical Solutions Group, Microsoft Corporation

### Session 378  MW - MEDICAL/SCIENTIFIC WRITING, CP
1:30 pm-3:00 pm  CME, Nursing, and Pharmacy credits offered  LEVEL: ■
Room B405

**Medical Writing for Risk Management and Pharmacovigilance**

**SESSION CHAIRPERSON(s)**

**Stephen A. Goldman, MD, DFAPA, FAPM**  
Managing Member, Stephen A. Goldman Consulting Services, LLC;
Adjunct Assistant Professor of Psychiatry, Uniformed Services University of the Health Sciences

This session will emphasize the importance of medical writing in ensuring quality in safety documents through project management, quality control, signal detection, making benefit-risk decisions, and asking probing and pertinent questions. In this way, medical writers should better understand how organizationally they should be best placed to deliver these tasks and what training is required.
Session 379  NC - Nonclinical Laboratory Safety Assessment, BT
1:30 pm-3:00 pm  LEVEL: ■
Room B305
Preclinical Safety Assessment of Biopharmaceuticals – Part 1 of 2
SESSION CHAIRPERSON(S)
Shawn M. Heidel, PhD, DVM
Head, Nonclinical Safety Assessment, Eli Lilly and Company
Ruth M. Lightfoot-Dunn, PhD
Vice President, Preclinical Safety Assessment, Amgen Inc.

Part 2 of this session will take place on Wednesday at 3:30 pm.

The predictive values of preclinical pharmacology and toxicology studies are important elements of translating safety assessment from preclinical in silico/modelling, in vitro, ex vivo, and animal studies into the clinical settings of first-in-man studies and follow-on clinical development of biopharmaceuticals. The rational for selecting scope and type of preclinical studies typically differs between biopharmaceuticals and small molecule pharmaceuticals, and industries and regulators are often challenged with the complexity of implementing preclinical development programs for biopharmaceuticals, and the complexity of translating the preclinical data sets into the decision-making process of selection of relevant animal species, immunogenicity, dose selection in first-in-man studies, specific safety monitoring in clinical studies, and considerations of carcinogenic potential. In these sessions, we will share experiences of development programs highlighting the above challenges that are specific for proteins, monoclonal antibodies and other biopharmaceutical classes as compared to small molecule pharmaceuticals.

Selection of Relevant Species for Toxicity Testing of Biopharmaceuticals
Laura Andrews, PhD
Vice President, Genzyme Corporation

Defining a Preclinical Safety Plan for Biopharmaceuticals
Jennifer Sims, PhD
Director, Preclinical Safety for Biologicals, AstraZeneca, UK

Panel Discussion: Case Studies
Shawn M. Heidel, DVM, PhD
Head, Nonclinical Safety Assessment, Eli Lilly and Company

Panelists
David R. Jones, MSc
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK
Barbara Wilcox, PhD
Pharmacologist, CDER, FDA

Session 380  NHP - Natural Health Products, RA
1:30 pm-3:00 pm  LEVEL: ■
Room B306
Global Regulation of Natural Health Products
SESSION CHAIRPERSON(S)
Freddie Ann Hoffman, MD
Chief Executive Officer, HeteroGenuity, LLC

Botanicals are used worldwide, however, there are significant variations in their regulatory status from country to country. The requirements for CMC, safety and efficacy also vary based on existing laws, regulations and policies in different regions around the globe. This session will explore the current regulatory status of products regulated in India, the EU, and North America. Is there a chance for harmonization? What is the current status of new drug development for botanicals in the United States? These and other topics of global interest will be discussed.

New Drug Approval Process for Botanicals: US Update
Jinhui Dou, PhD
Botanical Review Team Leader, Office of New Drugs, CDER, FDA

Regulatory Harmonization in the Field of Botanicals
Subhash C. Mandal, PhD
Inspector of Drugs, Directorate of Drugs Control, India

Regulation of Natural Health Products: EU and Canada – A Comparison with the US
Anne M. Tomalin, RAC
President, CanReg Inc., Canada

Session 381  OS - Outsourcing, PM
1:30 pm-3:00 pm  LEVEL: ◆
Room B401
Outsourcing Late-phase Studies: What to Do, What Not to Do, and Why
SESSION CHAIRPERSON(S)
Ramita Tandon
Director, Project Management, PAREXEL International

Successful outsourcing of late-phase projects begins in program design. Unique issues associated with the periapproval phase and programs answering nonproduct-related questions must be recognized. Scoping considerations prior to bid, process identification and budgeting will be explored.

Outsourcing with a CRO from a Customer/Partner’s Perspective
Leo G. Bianchi, MBA
Clinical Operations Team Leader, Eli Lilly and Company

Session 382  PM Plenary - Project Management, CR
1:30 pm-3:00 pm  LEVEL: ■
Room B406AB  Project Management units offered

Reinventing the Drug Development Paradigm
SESSION CHAIRPERSON(S)
Robin G. Foldesy, PhD
Vice President, Project Management, Wyeth Research

It is well documented that the challenges of successfully bringing drugs with competitive profiles to market are increasing. The novelty of our drug and disease targets is increasing. The complexity of the science needed to develop our products properly continues to challenge us. Regulatory agencies are requiring more studies and studies with larger patient populations, both of
The expectations from physicians, patients, and payers for products that add value are raising the bar on what is needed to achieve success in the marketplace, all of which leads to longer, more risky development programs. Only those companies that find ways to increase the probabilities of achieving market success through new development paradigms while wringing out operational inefficiencies will survive long term. Because of our broad, comprehensive view of development, project management is well positioned to reinvent and institutionalize new ways of moving drugs through the pipeline. But what does reinvention entail and where do project managers fit in? More importantly, what will it demand of us, and how many of us are up to the task?

The Realities of Reinventing the Drug Development Paradigm
Robin G. Foldesy, PhD
Vice President, Project Management, Wyeth Research

One Approach to Reinventing the Drug Development Paradigm
Christine J. Cioffe, DVM, MS
Vice President, R&D Portfolio Management, Merck & Co., Inc.

Chorus: Efficiently Translating Preclinical Promise into Clinical Reality
Michael D. Clayman, MD
Vice President, Lilly Research Laboratories, Eli Lilly and Company

Are We Brave Enough to Reinvent the Drug Development Paradigm?
Charles T. Gombar, PhD
Vice President, Project Management, Wyeth Research

Environmental Assessment of Drugs: The EU Approach
Per Spindler, DVM, MBA, MSc
Head, BioLogue®, University of Copenhagen, Denmark

Testing Strategies for the Environmental Risk Assessment of Drugs
Hector F. Galicia, PhD, MSc
Visiting Scientist, Bioagri, Switzerland

EMEA Guideline on Pharmaceuticals in the Environment (PiE)
David J. Cocker, Esq.
Chief Executive Officer, Ecotrac n.v., Belgium

Update on Current Legal and Policy Developments in the US and the EU
SESSION CHAIRPERSON(s)
David K. M. Van Passel, LL.M
Associate, Covington & Burling LLP, Belgium

This session will provide an overview of key legal and policy developments taking place in the US and the EU. Specific attention will be devoted to public registries of clinical trials as an example.

Public Registries on Clinical Trials: What Do Citizens Want?
Carlo Tomino, PharmD
Head, Clinical Trials and Research, National Medicines Agency Ministry of Health, Italy

Overview of Legal and Policy Developments in the US
Scott D. Danzis
General Attorney, Office of General Counsel, FDA

Overview of Legal and Policy Developments in the EU
David K. M. Van Passel, LL.M
Associate, Covington & Burling LLP, Belgium

Biosimilars in Europe
SESSION CHAIRPERSON(s)
Sandy M. Eisen, MD, MA
Chief Medical Officer, TEVA Pharmaceuticals Europe, UK

This session will review the operation of the new EU legislation on biosimilars with presentations on practical aspects of submission and interactions with the EU competent authorities.

Does the EU Concept of Biosimilarity Make Legal and Clinical Sense?
Peter Feldschreiber, JD, MD, FFPM
Senior Medical Assessor and Special Litigation Coordinator, Medicines and Healthcare products Regulatory Agency (MHRA), UK

The EU Regulatory Environment for Biosimilars
Gerald Haase, MB, ChB, FRCPath
Principal Consultant, Drug Development Consulting Practice, PAREXEL Consulting, UK

How is the EU System for Biosimilars Working in Practice?
Sandy M. Eisen, MD, MA
Chief Medical Officer, TEVA Pharmaceuticals Europe, UK
**SESSION 387**  RA4 - Regulatory Affairs, CR  
1:30 pm-3:00 pm  LEVEL: ■  
Room A406  
Outlook for Changes in Japanese Regulatory and Clinical Development Environment  
SESSION CHAIRPERSON(s)  
Robert R. Fike, PhD  
Assistant Vice President, Regulatory Affairs Japan, Wyeth Research  
Noriaki Murao, MS  
Representative Director, Schwarz Pharma Co., Ltd., Japan  

This session describes the factors that have contributed to the delay in availability of drugs already approved in western countries. The company strategy and efforts to overcome these factors to achieve simultaneous new drug approvals will be described. Finally, recent changes in the regulatory system that will enable the elimination of the drug lag will be discussed.

**From Drug Lag to Simultaneous Approval: Challenge and Opportunity**  
Robert R. Fike, PhD  
Assistant Vice President, Regulatory Affairs Japan, Wyeth Research  

Overcoming the Hurdles to Simultaneous Global Drug Development in Japan  
Hiroshi Matsumori, MS  
Executive Director, Regulatory Affairs, PGRD, Tokyo Laboratories, Pfizer Japan Inc., Japan  

PMDA’s Challenges to Reduce the Drug Lag  
Kazuhiko Mori, MS  
Associate Center Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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**SESSION 388**  RA5 - Regulatory Affairs, RD  
1:30 pm-3:00 pm  LEVEL: ■  
Room A405  
Postmarketing Commitments: Operational Issues and Public Perceptions  
SESSION CHAIRPERSON(s)  
Belinda J. Schluchter, PhD  
Operations Manager, US Regulatory Affairs, Eli Lilly and Company  

At this session, we will explore recent surveys related to postmarketing commitments (PMC) and the Office of Inspector General’s report related to FDA’s monitoring of PMCs. There will also be discussion to share industry best practices for tracking and updating the FDA on the status of PMCs.

**Industry Experience with Postmarketing Commitments: What Message for the Public?**  
Christopher P. Milne, DVM, JD, MPH  
Assistant Director, Tufts Center for the Study of Drug Development, Tufts University  

**Industry Best Practice for Tracking and Updating PMCs and an Overview of OIG’s Report, FDA’s Monitoring of Postmarketing Study Commitments**  
Anne N. Stokley, MPH  
Senior Director, Regulatory Policy, Intelligence Education, GlaxoSmithKline  

PhRMA’s Best Practices Working Group Survey: Overview and Recommended Process Improvements  
Mark C. Bokelman  
Director, Regulatory Policy and Operations, Wyeth Research  

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**SESSION 389**  RA6 - Regulatory Affairs, CP  
1:30 pm-3:00 pm  LEVEL: ●  
Room A315  
Creating a Third Class of Drugs in the US: Issues and Opportunities  
SESSION CHAIRPERSON(s)  
Minnie Baylor-Henry, JD  
Vice President, Global Regulatory Affairs, OTC, and Nutritional, McNeil Consumer Healthcare  

Historically, there have been two categories of drug products in the United States – Rx and over-the-counter. By contrast, in many other parts of the world, there is another class. Depending on the country, this class may be referred to by the term pharmacist only, or simply called, behind-the-counter products. Regardless of the nomenclature, products in this category generally represent items that require some degree of healthcare professional intervention, before the product is sold. This hot topic session will explore the merits of a third class of products, examine lessons learned from other countries, and evaluate the pros and cons of instituting such a system in the United States.

**Scott Gottlieb**  
American Enterprise Institute for Public Policy Research

**A Third Class of Drugs: The Pharmacist’s Perspective**  
Marcie Bough  
Director, Federal Regulatory Affairs, AphA

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**SESSION 390**  ST - Statistics, CR  
1:30 pm-3:00 pm  LEVEL: ■  
Room B309  
Strategies for Ethnic Comparison in Global Cooperative Clinical Trials  
SESSION CHAIRPERSON(s)  
Kyoungah See, PhD, MSc  
Senior Research Scientist, Eli Lilly and Company  

Simultaneous study of ethnically diverse datasets is the trend in drug development. Statistical strategies and plans associated with today’s global cooperative clinical trials will be discussed with representatives from the pharmaceutical industry, regulatory agency, and academia.

**Design and Inference in Multinational Clinical Trials**  
Yoko Tanaka, PhD  
Primary Research Scientist, Eli Lilly and Company  

**Design Considerations for Bridging Clinical Trials and Global Clinical Trials**  
H.M. James Hung, PhD  
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA  

**Constructing Size-adjusted Bridging Data Based on Resampling Methods that Incorporate the ANCOVA Model**  
Kyoungah See, PhD, MSc  
Senior Research Scientist, Eli Lilly and Company  

**A Bayesian Approach to Evaluation of Bridging Evidence**  
Chin-Fu Hsiao, PhD  
Associate Investigator, National Health Research Institutes, Taiwan
SESSION 391  TR - TRAINING, CR
1:30 pm-3:00 pm  LEVEL: ■
Room B308  Nursing credits offered

Practical Models for Training Clinical Research Monitors
SESSION CHAIRPERSON(S)
Janet F. Zimmerman, MS, RN  
Senior Director, Training Services, PharmaNet

In the regulated clinical research environment, training of new and experienced monitors is a critical and never-ending pursuit. Like most training programs, the development and implementation of monitor training nearly always has a financial and time constraint as well as other resource issues. Using case studies, presenters will describe their experiences training monitors, focusing on development and implementation challenges that were encountered and how they were managed.

Developing Educational Programs for Clinical Research Coordinators in South Korea
Ihnsook Jeong, PhD, MPH, RN  
Assistant Professor, Pusan National University, Republic of Korea

A Training and Apprenticeship Program for Monitors
Janet F. Zimmerman, MS, RN  
Senior Director, Training Services, PharmaNet

Developing a Multiple-language, Web-based Training Program
Hal R. Ward, PharmD  
Executive Director, Global Head of Drug Safety, Covance

SESSION 392  VA - VALIDATION, IT
1:30 pm-3:00 pm  LEVEL: ■
Room A311

Validation Quality and Costs: It’s All about the Risk
SESSION CHAIRPERSON(S)
Leonard A. Grunbaum, MBA  
Partner, The Practical Solutions Group, LLC

“Good quality is cheap; it’s poor quality that is expensive.” This 1998 quote from Money Magazine provides the premise for this session, which is that computer systems validation should be of value to the business without putting the business out of business. The key questions here are: what should be validated? how much is enough? and, how do I figure it all out? The answer to these questions involves understanding of risk. This session will focus on the concept of risk, in the context of computer systems validation, to address these questions.

Hands-on Risk Analysis
Douglas Patrick Stephens  
Director, North America, FormaLiS North America, Canada

Inspection Readiness: A Challenge for Validation
Imtiaz H. Mohiuddin, PhD  
Manager, Systems Validation, Otsuka Maryland Research Institute, Inc

A Layered Approach to Managing Computer Validation Risks: A Case Study of Different Computer Layers and Validation Approaches
James Huang, PhD  
Director, Quality Assurance and Regulatory Compliance, Almac Clinical Technologies

SESSION 393  AHC - ACADEMIC HEALTH CENTERS, GCP
3:30 pm-5:00 pm  LEVEL: ■
Room B303  CME and Pharmacy credits offered

Global Challenges with Bioethics in IRB’s Training
SESSION CHAIRPERSON(S)
Gustavo L.F. Kesselring, MD  
President, Brazilian Society of Pharmaceutical Medicine, BRA, Brazil

Clinical trials (CT) are now a global enterprise that can only start after a careful bioethical review and an approval of the entire project. Training IRB members is an urgent need, and representatives from the US, EU, and Latin America will be invited to present and compare their experiences.

US IRB Training Programs: What Is in Place and Is It Enough?
Gary L. Chadwick, PharmD, MPH  
Associate Provost and Director, Office for Human Subject Protection, University of Rochester

Latin American Experiences in IRB’s Training Programs
Luis F. Collia, MD, FFPM  
President, IFAPP, Argentina

European Initiatives in IRB’s Training Programs
Gerfried K. Nell, MD  
Director, NPC Nell Pharma Connect GmbH, Austria

SESSION 394  BT - BIOTECHNOLOGY, RA
3:30 pm-5:00 pm  LEVEL: ■
Room B304

Similar (Comparable) Biological Medicinal Products: Scientific Challenges, Regulatory Positions and Experience to Date
SESSION CHAIRPERSON(S)
Christopher J. Holloway, PhD  
Group Director, Regulatory Affairs and CSO, ERA Consulting Group, UK

This session will convey many less-than-straightforward issues relating to similar (comparable) biological medicinal products and how difficulties may be resolved. CMC, nonclinical and clinical aspects will be covered, illustrating primarily European difficulties encountered with such products.

Legal and Regulatory Status of Similar/Comparable Biological Medicinal Products in Europe and the US: Key Similarities/Differences
Christopher J. Holloway, PhD  
Group Director, Regulatory Affairs and CSO, ERA Consulting Group, UK

Quality Issues and the Spectrum of Complexity
Cecil Nick, MS  
Principal Consultant, PAREXEL Consulting, UK

Nonclinical Issues: How to Approach These in the View of a Regulator
Gopalan Narayanan, MD  
Head, Biologicals and Biotechnology Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

SESSION 395  CDM - CLINICAL DATA MANAGEMENT, IT
3:30 pm-5:00 pm  LEVEL: ■
Room A312

Virtual Data Management Models
SESSION CHAIRPERSON(S)
Catherine Celingant, MA  
Director, Clinical Data Management, Millennium Pharmaceuticals, Inc.
As pharmaceutical companies look for nimble, efficient, and cost-effective approaches to drug development, the data management discipline is increasingly finding itself at the forefront of innovation. The purpose of this session is to explore technology and process alternatives to traditional clinical data management systems (CDMS). The presenters will describe their current solutions, the rationale behind them, benefits and challenges, and next steps in their quest for advances.

**John D. Mestler**  
Group Manager, Oral Care, Procter & Gamble, UK  

**Seema Bhat, MA**  
Manager, Clinical Data Management, Bayer Pharmaceuticals

**SESSION 396**  
**CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA**

3:30 pm-5:00 pm  
Room A301

**Updates on ICH Q8 (R) and Q10 Guidelines**  
**SESSION CHAIRPERSON(S)**  
Karen B. Main, PhD, RPh  
Regional Associate Director, UK/US Investigational Products, AstraZeneca

The session will update the audience on the most recent activities involving the International Conference on Harmonization documents entitled ICH Q8 (R): Pharmaceutical Development and ICH Q10: Pharmaceutical Quality System.

**ICH Q8 (R) Guideline: Current Status**  
Karen B. Main, PhD, RPh  
Regional Associate Director, UK/US Investigational Products, AstraZeneca

**ICH Q10 Guideline: Current Status**  
Monica E. Caphart, MS  
Consumer Safety Officer, Division of Manufacturing and Product Quality, Office of the Commissioner, CDER, FDA

**SESSION 397**  
**CP - CLINICAL SAFETY AND PHARMACOVIGILANCE, CR**

3:30 pm-5:00 pm  
Room A302

**Detecting Safety Signals in Clinical Trials**  
**SESSION CHAIRPERSON(S)**  
Stephen Gerard Buckley, PharmD  
Director, Safety Evaluation Risk Management, GlaxoSmithKline

This session will discuss new signal management techniques currently being piloted (or considered for use) in drug development. These include clinical trials signal detection software, advanced statistical techniques for analyzing integrated safety databases and graphical displays to facilitate review of safety data. Presentations will demonstrate some of these techniques using examples from actual clinical trials.

**Safety Signal Detection in Clinical Trials: State of the Industry**  
Mark Perrott, PhD  
WCI Consulting Ltd., UK

**Safety Signal Detection in Clinical Trials: Considerations in Developing an Automated Tool**  
Robert J. Zambarano, PhD  
Senior Project Manager, Lincoln Technologies, a Division of Phase Forward

**Session 398**  
**CR1 - CLINICAL RESEARCH AND DEVELOPMENT, EC**

3:30 pm-5:00 pm  
**LEVEL: ■**  
Room B405

**The Business Case for CDISC Standards: Implementation Approaches and Metrics**  
**SESSION CHAIRPERSON(S)**  
Rebecca D. Kush, PhD  
President, CDISC

Despite known improvements in clinical trial performance through use of CDISC standards, companies’ implementation efforts can be stymied due to lack of a defensible business case for the adoption of standards. This session presents recent findings which support the case for standards adoption.

**Approaches and Metrics for Implementing Standards**  
Carol Rozwell  
Vice President and Distinguished Analyst, Life Sciences, Gartner, Inc.

**A Case Study in the Implementation of CDISC Standards for Regulatory Submission**  
Edward D. Helton, PhD, MA  
Chief Scientist, Regulatory and Biomedical Affairs, SAS Institute, Inc.

**The SciBusiness Case for Standards**  
Stephen E. Wilson, DrPH, CAPT. USPHS  
Director, Division of Biometrics III, CDER, FDA

**Session 399A**  
**CR2 - CLINICAL RESEARCH AND DEVELOPMENT, CDM**

3:30 pm-5:00 pm  
**LEVEL: ■**  
Room B409

**The Country Study Manager Survey: Research Data Makes the Case for a New Approach**  
**SESSION CHAIRPERSON(S)**  
Jaime Cohen  
Strategic and Tactical Specialist, BBK Worldwide

This session presents data from a survey that measured the natural aptitudes and work styles of country study managers. The results reflect a discrepancy in current skill sets with the requirements of the job in the new global environment, sparking discussion about industry response.

**The Application of Predictive Index Modeling to the Role of Country Study Manager**  
Todd Harris, PhD  
Director, Research, PI Worldwide

**Collaborating with Country Study Managers to Optimize Global Enrollment**  
Karen Rumrill  
Global Operations, TCN e-Systems

**Case Study: Applying the CSM Research Results to Spain**  
Fernando Arias  
Principal, Gonzales, Arias and Partners, Spain
Global Clinical Trials and Polyethic Patient Enrollment: Implications for Regulatory Approval of Marketing Applications

Alberto Grignolo, PhD
Corporate Vice President and General Manager, Drug Development Consulting Practice, PAREXEL Consulting

Clinical trials are increasingly enrolling large numbers of patients from non-traditional countries located outside the ICH regions due to the relative dearth of sufficient numbers of available study patients in the US, EU and Japan, especially for very large studies. The emergence of Latin America, China, India, Eastern Europe and Africa as sources of treatment-naïve patients for megatrials is clear and growing. This phenomenon raises questions about whether the regulatory authorities of many countries, including the ICH members, are prepared to review, assess and ultimately accept these studies as pivotal for marketing approval support. A panel of regulators and industry experts will illustrate and discuss aspects, perspectives and possible approaches to this emerging issue.

Panelists
Murray M. Lumpkin, MD, MSc
Deputy Commissioner, International and Special Programs, Office of the Commissioner, FDA
Tatsuo Kurokawa, PhD
Councilor for Pharmaceutical Affairs, Ministry of Health, Labour, and Welfare, Japan
Yves Juillet, MD, PhD
Senior Advisor, LEEM, France
Agnes V. Klein, MD
Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada
Herng-Der Chern, MD, PharmD, PhD
Executive Director, Center for Drug Evaluation, Taiwan

Examine Financial Challenges of Investigative Sites
Mary Jo Lamberti, PhD, MA
Senior Manager, Market Intelligence, Thomson CenterWatch

Understanding Clinical Trial Volunteer Experiences and Examining Financial Challenges of Investigative Sites

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

Thomson CenterWatch is currently conducting two surveys: one survey examines clinical trial experiences of nearly 2,000 patient volunteers who have participated in a trial and whether their experience was a positive one. The second survey looks at an investigative site from a financial perspective.

An In-depth Look at Patients’ Experiences in Clinical Trials
Paul Dewberry
Research Analyst, Thomson CenterWatch

Examining Financial Challenges of Investigative Sites
Mary Jo Lamberti, PhD, MA
Senior Manager, Market Intelligence, Thomson CenterWatch
Elevating Scientific Expertise via Formal Assessments

**SESSION 399G**  
**MC - MEDICAL COMMUNICATIONS, TR**  
3:30 pm-5:00 pm  
Room B302  
Pharmacy credits offered

**Don Rosen**  
Principal, Don Rosen Consulting

Pharmaceutical/biotechnology companies are faced with two major problems: how to integrate information and functionality across multiple new and legacy systems within the organization to allow holistic management of changing information and end-to-end processes and how to achieve the same interoperability with multiple and changing partners, health care providers, patients and regulatory authorities.

These problems are being addressed in pharma by evolving data standards from CDISC/HL7 and with new technologies (such as SOA/Webservices) for distributed applications pioneered in other industries. However, effectively addressing the issue of application interoperability within and across organizational boundaries most likely will require, as it has in other industries, the definition of standard enterprise and industry architectures addressing logistics, security, workflow, etc. This session will provide an understanding of the issues, implications, and trends for such architectures, and describe the progress being made towards defining them for the pharmaceutical industry.

The Business Case for Application Interoperability

**Don Rosen**  
Principal, Don Rosen Consulting

Fostering Community Interoperability: Key Initiatives

**Sue Dubman,** MA  
Vice President, Information Technology and Informatics, Theravance, Inc.

Architectural Trade-offs in Clinical Research Data Repositories

**Tim Rochford**  
Chief Technical Officer, Phase Forward

Life Sciences Industry Architecture: Report to Industry

**Jason Burke,** MA  
Director, Life Sciences Strategy and Solutions, SAS Institute, Inc.

**SESSION 399H**  
**NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT, BT**  
3:30 pm-5:00 pm  
Room B305  
Pharmacy credits offered

**Joy A. Cavagnaro,** PhD, DABT, RAC  
President, Access BIO

**David R. Jones,** MSc  
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Part 1 of this session will take place on Wednesday at 1:30 pm.

The predictive values of preclinical pharmacology and toxicology studies are important elements of translating safety assessment from preclinical (in silico modelling, in vitro, ex vivo, and animal studies) into the clinical settings of first-in-man studies and follow-on clinical development of biopharmaceuticals. The rational for selecting scope and type of preclinical studies typically differs between biopharmaceuticals and small molecule pharmaceuticals, and industries and regulators are often challenged with the complexity of implementing preclinical development programs for biopharmaceuticals, and the complexity of translating the preclinical data sets into the decision-making process of selection of relevant animal species, immunogenicity, dose selection in first-in-man studies, specific safety monitoring in clinical studies, and considerations of carcinogenic potential. In this session, we will share experiences of development programs highlighting the above challenges that are specific for proteins, monoclonal antibodies and other biopharmaceutical classes as compared to small molecule pharmaceuticals.

**Considerations in Defining NOAEL and MFD for Biopharmaceuticals**

**Maggie Dempster,** PhD  
Safety Assessment, GlaxoSmithKline Research and Development Ltd., UK

**Use of Animal Models of Disease to Improve Predictive Value of Preclinical Development Programs for Biopharmaceuticals**

**Renger F. Witkamp,** PhD  
Professor, Department of Human Nutrition; Director, Wageningen University; TNO Quality of Life, Netherlands

**Communicating Tumorigenic Risks of Immunomodulatory Biopharmaceuticals**

**Peter Bugelski,** PhD  
Senior Research Fellow and Head of Experimental Pathology, Centocor Research & Development, Inc.

Panel Discussion: Are Considerations in the Design of Preclinical Safety Evaluation Programs for Biopharmaceuticals Relevant for Pharmaceuticals?

**Joy A. Cavagnaro,** PhD, DABT, RAC  
President, Access BIO

**SESSION 399I**  
**NHP - NATURAL HEALTH PRODUCTS, PP**  
3:30 pm-5:00 pm  
Room B306  
Pharmacy credits offered

**Freddie Ann Hoffman,** MD  
Chief Executive Officer, HeteroGeneity, LLC

Food and Drug Administration has recently approved two complex, poly-molecular natural health products as drugs for the US market: a fish oil product for hypertriglyceridemia Type V (Nov. 2004) and a topical green tea extract for genital warts (Oct. 2006). With the current debate over the
the processes of an interdepartmental team of professors from a university in order to increase the commercial quality of research. This session will review portfolio and project management to an academic research environment in more frequently, universities are seeking to utilize principles of industry Translational Scientific Officer, BioCrossroads Cynthia Helphingstine, PhD SESSION CHAIRPERSON (S) Project Management as a University Research Tool Project Management units offered Room B403 3:30 pm-5:00 pm LEVEL: • Project Management as a University Research Tool SESSION CHAIRPERSON(S) Cynthia Helphingstine, PhD Translational Scientific Officer, BioCrossroads More frequently, universities are seeking to utilize principles of industry portfolio and project management to an academic research environment in order to increase the commercial quality of research. This session will review the processes of an interdepartmental team of professors from a university that is exploring innovative and potentially radical approaches to funding, managing and resourcing research activity that is being advanced for clinical application. From Bedside to Bench: Mapping Experimental Designs in the Academic Environment Mark Kelley, PhD Academic ITRAC Program Leader, Indiana University Cancer Center Approaches to Funding, Managing and Resourcing Research Activities Marietta L. Harrison, PhD Associate Director, Purdue University Cancer Center Project Mapping: A Funder’s Perspective James Ruckle, PhD Executive Vice President, Walther Cancer Institute

SESSION 399L PM2 - PROJECT MANAGEMENT, TR 3:30 pm-5:00 pm LEVEL: • Room B402 Project Management units offered Negotiation and Decision Making: The Art of Conflict Resolution SESSION CHAIRPERSON(S) Julie G. Bukar, MBA Managing Director, JGB BioPharma Consulting, Inc. This session will focus on the processes of negotiation, decision making, and conflict management which are key in all team environments. Removing Barriers and Making Decisions Philip M. Zack, DVM, PhD Executive Director, Project Management and Strategic Operations, Amgen Inc. Negotiating from the Bottom Up Julie G. Bukar, MBA Managing Director, JGB BioPharma Consulting, Inc. Leadership and Conflict Resolution Liz Homans, MBA Executive Director, Project and Portfolio Management, Jazz Pharmaceuticals, Inc.

SESSION 399M PP1 - PUBLIC POLICY/LAW, RA 3:30 pm-5:00 pm LEVEL: ■ Room A410 New Paradigms of Drug Regulation SESSION CHAIRPERSON(S) John A. Lisman, PharmD, LLM, MPharm Attorney, NautaDutilh, Netherlands In recent years the crisis in drug development and regulation has cast shadows on the pharmaceutical industry and drug regulators. In spite of attention for the emerging crisis and the growing lack of trust in the industry and regulators, this session will discuss those initiatives for fundamental change. Do Patents Deliver Enough Innovation? John A. Lisman, PharmD, LLM, MPharm Attorney, NautaDutilh, Netherlands Does the Regulatory System Really Add to Public Health? Lembít Rägo, MD, PhD Coordinator, Quality Assurance and Safety Medicines Department of Essential Drugs, WHO, Switzerland Can We Overcome the “Credibility Crisis” for the Pharmaceutical Industry and Regulators by Means of Transparency? Frits Lekkerkerker, Dr Med Chairman, Medicines Evaluation Board, Netherlands
**Access to Controlled Medications: Impact for Millions**

**SESSION CHAIRPERSON(S)**

Willem K. Scholten, PharmD, MPA  
Technical Officer, Quality Assurance and Safety: Medicines, World Health Organization (WHO), Switzerland

The World Health Organization (WHO) estimates that over 600 million people in over 150 countries are affected at some time by bad access to medicines controlled under the international drug conventions, including opioid analgesics. This session will discuss WHO’s access to controlled medications program which provides the optimal balance between access for medical use and prevention of abuse.

**Controlled Medications: Success Stories and Challenges for WHO and its Member States**

Willem K. Scholten, PharmD, MPA  
Technical Officer, Quality Assurance and Safety: Medicines, World Health Organization (WHO), Switzerland

**Opioid Agonist Treatment of Opioid Dependence: Beyond Reach … But Why?**

Timothy Baxter, MD, MRCP  
Global Medical Director, Reckitt Benckiser Pharmaceuticals, Inc.

**The Right to Be Free of Pain: A Fata Morgana?**

Frank Laschewski, DrMed, MD  
Head, Drug Safety Medical Evaluation, Gruenenthal GmbH, Germany

**Challenges for Global Labeling: New FDA and European Requirements – Case Studies**

**SESSION CHAIRPERSON(S)**

Margaret E. Hurley, MD  
President/Chief Executive Officer, Hurley Consulting Associates Ltd.

This session will compare and contrast the final US labeling rule (January 2006) and the European Guideline on Summary of Product Characteristics (October 2005). Using case studies, the session will examine new requirements, implications, and implementation strategies.

**Case Study**

Timothy M. Cunniff, PharmD  
Vice President, Global Regulatory Affairs, Pharmacovigilance and Clinical Quality Assurance, Ovation Pharmaceuticals, Inc.

**Case Study: Adverse Events**

Margaret E. Hurley, MD  
President/Chief Executive Officer, Hurley Consulting Associates Ltd.

**Biomarkers and Labeling: Critical Path – From Concept to Action**

**SESSION CHAIRPERSON(S)**

Chin C. Koerner, MS  
Executive Director, FDA Liaison and Policy, Novartis Pharmaceuticals

It’s been almost three years since FDA published the Critical Path: Innovation or Stagnation White Paper. Since then biomarkers have been identified as a major area of focus for industry and FDA. Even as industry and FDA are debating how best to validate biomarkers, biomarker information is making its way into labeling. During this session we will explore the universe of biomarkers in FDA labeling, recent case studies of biomarkers in the clinical setting, and a discussion about what is the FDA’s standards for when and what biomarker information should appear in the label.
The Current Universe of Clinical Biomarkers and FDA Labeling
Soraya Madani, PhD
Director, FDA Liaison and Policy Office, Novartis Pharmaceuticals

Case Study: Herceptin
Lawrence W. Davenport, PhD
Director, Clinical/Commercial Regulatory Affairs, Genentech Development, Genentech, Inc.

SESSION 399S RA5 - REGULATORY AFFAIRS, CR
3:30 pm-5:00 pm LEVEL: ●
Room A313

The Target Product Profile Practical Implementation: FDA and Sponsor Perspective
SESSION CHAIRPERSON(S)
Cheryl Beal Anderson, PharmD, RAC
Director, US Regulatory Affairs, Eli Lilly and Company

The target product profile (TPP) is an FDA-PhRMA endorsed initiative to increase efficiency between FDA and sponsors and expedite drug development. A TPP is a nonbinding document that sponsors voluntarily submit to the FDA to facilitate discussion of the strategic intent and labeling goals of a clinical drug development program. The objective of this session is to provide practical advice by FDA and PhRMA companies on developing and using a TPP.

TPP: Overview of the Draft Guidance and an FDA Perspective
Laurie Beth Burke, MPH, RPh
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

TPP: Practical Implementation during FDA Meetings
Daniel R. Brady, PhD, RAC
Manager, US Regulatory Affairs, Eli Lilly and Company

TPP: Practical Implementation within the Company
Teresa P. Dowling, PharmD
Director, Promotional Regulatory Affairs, AstraZeneca

SESSION 399T ST - STATISTICS, CR
3:30 pm-5:00 pm LEVEL: ■
Room B309
Pharmacy credits offered

Early Successes with Adaptive Designs
SESSION CHAIRPERSON(S)
W. Tad Archambault, PhD
Principal, Virtu Stat, Ltd.

There are many adaptive techniques for reviewing data in an ongoing clinical trial. Most preserve the Type I error rate while allowing creative study modifications. This session will focus on some positive results using these techniques.

Team Spirit Rising to the Challenge ... Breaking Down Hurdles to Implement CRM for a Migraine Phase 2b Proof-of-concept Study
Judith A. Quinlan, MSc
Director, Statistics, Biopharm CEDD, GlaxoSmithKline

Blinded Sample Size Re-estimation in a Phase 3 NonInferiority/ Superiority Mortality Trial
Allen I. Fleishman
Principal, Allen Fleishman Biostatistics Inc.

NitroMed’s A-HeFT Trial of BiDil: Unblinded Sample Size Re-estimation in a Phase 3 Heart Failure Study
W. Tad Archambault, PhD
Principal, Virtu Stat, Ltd.
Thursday, June 21

7:30 am-10:30 am  ATTENDEE REGISTRATION and SPEAKER REGISTRATION
Building A/B Registration Hall, International Boulevard, Philips Drive Entrance, GWCC

7:30 am-8:15 am  CONTINENTAL BREAKFAST
Registration Area Foyer

12:30 pm-5:00 pm  MedDRA® USER GROUP MEETING
Room A410, Building A, Level 4, GWCC

SESSION 401  AHC - ACADEMIC HEALTH CENTERS, TR
8:30 am-10:00 am  LEVEL: •
Room B302
Opportunities for Global Clinical Trials in India: Prospects and Challenges
SESSION CHAIRPERSON(S)
Suresh K. Gupta, DrSc, PhD
Dean and Director General, Institute of Clinical Research, India

India is fast emerging as a preferred destination for clinical trials. Major reasons for its popularity include large diverse therapy naive population, vast gene pool, improved regulatory environment, implementation of patent regime, cost-effective technical services and data management services. The session will provide an excellent opportunity to discuss key findings, trends and comparisons for its potential outsourcing capacity. The global pharmaceutical industry will have the up-to-date information for setting up new operations in India.

FDA GCP Experiences in India
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science; Director, Good Clinical Practice Programs, Office of Science and Health Coordination, Office of the Commissioner, FDA

Current Regulatory Environment in India
Mamidanna Venkateswarlu
Drug Controller General, Ministry of Health and Human Welfare, Government of India

Capacity Building: Education and Training Opportunities
Anthony C. Woodman, PhD, MS
Professor and Director of Education, Cranfield Health, Cranfield University, UK

Challenges in Conducting Clinical Research in India
Vijai Kumar, MD
President and Chief Medical Officer, Excel Life Sciences, Inc.

Clinical Trials: Good Review Practices
Mehul Mehta, PhD
Director, Division of Clinical Pharmacology I, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

SESSION 402  BT - BIOTECHNOLOGY, CR
8:30 am-10:00 am  LEVEL: ■
Room B301
Gene Therapy: Challenges and Hurdles in Planning and Conducting Global Clinical Trials
SESSION CHAIRPERSON(S)
Milan Kovacevic, MD, PhD, MS
Vice President, Clinical Operations, GenVec, Inc.

Representatives from pharmaceutical/biotechnology companies and CROs will present their views of challenges in global gene therapy research programs, and propose ways on how to overcome them and successfully conduct and complete such projects.

Gene Therapy: Challenges and Hurdles in Planning and Conducting Global Clinical Trials
Milan Kovacevic, MD, PhD, MS
Vice President, Clinical Operations, GenVec, Inc.

Gene Therapy Regulations for EU Clinical Trials: Navigating the Maze
Cecil Nick, MS
Principal Consultant, PAREXEL Consulting, UK

Development of Plasmid-based Vaccines and Therapeutics: Case Studies
Alain Rolland, PharmD, PhD
Senior Vice President, Product Development, Vical Incorporated

SESSION 403  CDM - CLINICAL DATA MANAGEMENT, IT
8:30 am-10:00 am  LEVEL: ●
Room A312
EHR Considerations for Clinical Data Management
SESSION CHAIRPERSON(S)
Anthony J. Costello
Vice President, Product Development and Data Services, Nextrials, Inc.

Can the marriage of EHR and EDC systems really lead to clinical trial efficiency? This session will explore real case examples of how EHR implementation and standards could change data acquisition in the years to come.

CDISC/IHE/HIMSS: Demonstrating Healthcare to Clinical Research Interoperability
Landen C. Bain
Healthcare Liaison, CDISC

A Tale of Two Markets: Impact of EHR/EDC Integration
Chris Connor
Senior Research Analyst, IDC Health Industry Insights

EHR Redefines the Source Document: A Reality Check on Future EHR to EDC Integration
Anthony J. Costello
Vice President, Product Development and Data Services, Nextrials, Inc.

SESSION 404  CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA
8:30 am-10:00 am  LEVEL: ■
Room A315
cGMPs and Manufacturing Modernization in the 21st Century
SESSION CHAIRPERSON(S)
Edwin Rivera-Martinez
Branch Chief, Office of Compliance, Division of Manufacturing and Product Quality, CDER, FDA

This session will provide an update on inspectional and drug quality trends and FDA’s continuing implementation of the cGMPs for the 21st century objectives. Specific topics will include the progress of ICH Q10, ongoing refinements to process validation policy, risk-based approaches to meet cGMPs in accord with ICH Q9, the newly issued quality systems and out-of-specification test results guidance documents, and FDA’s application to join PIC/S (Pharmaceutical Inspectorate Convention Scheme).

Update on Guidance, Policy, and International Issues/Inspectional and Drug Quality Trends
Edwin Rivera-Martinez
Branch Chief, Office of Compliance, Division of Manufacturing and Product Quality, CDER, FDA
Update on FDA cGMP Initiatives and Guidelines

Monica E. Caphart, MS
Consumer Safety Officer, Division of Manufacturing and Product Quality, CDER, FDA

**Session 405**  
**CP - Clinical Safety and Pharmacovigilance, CDM**

8:30 am-10:00 am  
**Room A402**  
CME credits offered

**Standardized MedDRA® Queries and the Data Retrieval and Presentation: Points to Consider Document**

**Session Chairperson(s)**

Patricia Mozzicato, MD  
Senior Medical Officer USA, Northrop Grumman Corporation/MedDRA® MSSO

Standardized MedDRA® Queries (SMQs) are a tool to assist in retrieval of cases from a MedDRA®-coded database. SMQs are groupings of terms from one or more MedDRA® System Organ Classes that relate to a defined medical condition or area of interest (e.g., rhabdomyolysis/myopathy). SMQs have been developed jointly by a CIOMS Working Group and ICH. Once an area of interest has been identified by the Working Group, a list of terms is generated and tested on databases available to CIOMS Working Group members. Upon completion of this phase, SMQs are then provided to MedDRA® subscribers in the production phase by the MedDRA® Maintenance and Support Services Organization (MSSO) which maintains the SMQs via a subscriber-generated change request process. The ICH-endorsed Data Retrieval and Presentation: Points to Consider document describes the characteristics of MedDRA® that provide both advantages and challenges to data retrieval and presentation. The document presents a variety of approaches and options to optimize accuracy and consistency of retrieval of MedDRA®-coded data in a broader context than SMQs. Following a general review of SMQs and the Points to Consider document, this session will then present two case studies: one will describe experience with using SMQs for signal detection, and the other will provide a practical example of the principles described in the Data Retrieval and Presentation: Points to Consider.

**Implementation of Standardized MedDRA® Queries: Practical Aspects**

Gregory G. Gribko, PharmD, MPH, RPh  
Director, Regulatory Analysis and Documentation, Pfizer Inc

SMQs and Signal Detection: EMEA Experience

Jim Slattery, Esq., Msc  
Scientific Administrator, Pharmacovigilance and Postauthorization Safety and Efficacy of Medicines Sector, Postauthorization Evaluation of Medicines for Human Use Unit, EMEA, EU

MedDRA® Data Retrieval and Presentation: Points to Consider Document – Practical Application

Jean Morrone  
Manager, Global Clinical Coding, UCB Pharma

**Session 406**  
**CR1 - Clinical Research and Development, GCP**

8:30 am-10:00 am  
**Room B308**  
CME, Nursing and Pharmacy credits offered

**Successful Phase 1 Clinical Trials**

**Session Chairperson(s)**

Erica Elefant, RN, BSN, MSW  
Senior Clinical Scientist, Bristol-Myers Squibb Company

This session will examine the importance of phase 1 assessments in drug development, the issues commonly associated with conducting a phase 1 trial and suggestions to improve study compliance in order to produce quality data. An overview of conducting phase 1 studies in Asia will also be provided.

**Session 407**  
**CR2 - Clinical Research and Development, CTM/CS**

8:30 am-10:00 am  
**Room B309**

**We Can Get a Lot Smarter about Site Monitoring and Data Analysis**

**Session Chairperson(s)**

Norman M. Goldfarb, CRCP  
Managing Director, First Clinical Research LLC

This session will present adaptive, risk-based methods for site monitoring/management and data analysis/management that can dramatically improve data quality, slash costs, and enhance investigator performance.

**Are Site Monitoring and Data Cleaning a Waste of Time?**

Norman M. Goldfarb, CRCP  
Managing Director, First Clinical Research LLC

Adaptive, Risk-based Site Monitoring and Management

Michael J. Rosenberg, MD, MPH  
President and Chief Executive Officer, Health Decisions, Inc.

Risk-based, Adaptive Strategies for Detecting Systemic Data Quality Issues

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

**Session 408**  
**CTM/CS - Clinical Trial Management/ Clinical Supplies, IS**

8:30 am-10:00 am  
**Room B404**

**The Great Debate: Can Site Performance Be Predicted?**

**Session Chairperson(s)**

Sooji Lee-Rugh, MD  
Chief Executive Officer, Co-founder, TrueTrials, Inc.

Can site performance be predicted? What factors should be considered? This point-counterpoint session will include an overview of site selection and protocol feasibility assessment processes.

**Does Transparency in Site Performance Data Influence Actual Performance?**

Sooji Lee-Rugh, MD  
Chief Executive Officer, Co-founder, TrueTrials, Inc.

Is Predicting Site Performance More or Less Important than Managing Site Performance?

Beth D. Harper, MBA  
President, Clinical Performance Partners, Inc.
How Much Does Protocol Design Influence Site Performance Success?
David S. Zuckerman, MS
President, Customized Improvement Strategies LLC
Panelist
Jason R. Lindow
Senior Manager, Clinical Trial Management, Genentech, Inc.

SESSION 409  ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM
8:30 am-10:00 am  LEVEL: ■
Room A412AB

eCTD Standards: Now and the Future
SESSION CHAIRPERSON(S)
Gary G. Walker
Associate Regulatory Director, Global Data Management, Quintiles Transnational Corp.

This session will present a review of the current status and near future view of three important submission standardization initiatives: HL7’s Regulated Product Submission Message (RCSRIM), the FDA Electronic Submission Gateway, and eSubmission developments in ICH.

Progress Report of the HL7 RCSRIM Submission Message
Edward S. Tripp
Program Director, eSubmissions, Abbott Laboratories

Status of eSubmission Development in ICH
Andrew P. Marr, PhD
Director, eRegulatory Development, Global Regulatory Operations, GlaxoSmithKline, UK

The FDA Electronic Submission Gateway
Michael Fauntleroy
Director, Electronic Submissions Program, CBER, FDA

SESSION 410  GCP - GOOD CLINICAL PRACTICES, CR
8:30 am-10:00 am  LEVEL: ■
Room B405

It Doesn’t Need to Hurt: Meeting the Challenges of SOP Development
SESSION CHAIRPERSON(S)
Steven Steinbrueck, MPH
President, Stonebridge GCP Consulting Inc.

This session will provide a framework for successful SOP development in multiple industry settings. Using an interactive lecture and case study approach, the speakers will share best practices from their experiences working with multiple sponsors, CROs, and investigational sites.

Major Challenges
Steven Steinbrueck, MPH
President, Stonebridge GCP Consulting Inc.

Focus on Sponsor Organizations
Thomas R. Whitman
Consultant - Process Analyst, Innovative Consulting Partners

Focus on Investigational Sites
Donna W. Dorozinsky, MSN, RN
President, DWD & Associates

SESSION 411  IT - INFORMATION TECHNOLOGY, EC
8:30 am-10:00 am  LEVEL: ■
Room A314

The Future of Information Technology in Clinical Development and R&D
SESSION CHAIRPERSON(S)
George Laszlo, MBA, MS
Managing Partner, Laszlo Consulting

A panel discussion on the application of information technologies and the key issues related to their adoption over the next five years will be conducted with participation by industry thought leaders from a biopharmaceutical firm, an IT vendor, and a market research firm. The discussion will focus on the real-world implementation of new technologies and their integration into the existing IT infrastructure and business landscape.

Panelists
George Laszlo, MBA, MS
Managing Partner, Laszlo Consulting
Alan S. Louie, PhD
Research Director, Health Industry Insights, an IDC Company
Paul A. Bleicher, MD, PhD
Chairman and Founder, Phase Forward
Sue Dubman, MA
Vice President, Information Technology and Informatics, Theravance, Inc.

SESSION 412  NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT, RA
8:30 am-10:00 am  LEVEL: ◆
Room B305

CME credits offered
Nonclinical Development of Nanopharmaceuticals: How Much Is Covered by Existing Guidance?
SESSION CHAIRPERSON(S)
Beatriz Silva Lima, PharmD, PhD
Professor, Pharmacology, University of Lisbon and Preclinical Expert, INFARMED, Portugal; Member, CHMP and Scientific Advice Working Group; Chair, Safety Working Party, EMEA, EU

This session will provide an update on types of nanoparticles in marketed and developing pharmaceuticals and will discuss their safety implications among regulators, academia and industry, and will address the need for adapted nonclinical studies.

Update on Nanopharmaceuticals, Types of Developing Nanoparticles and the Rationale for Their Use
Rogério S. Gaspar, PhD
Professor, Faculty of Pharmacy, University of Lisbon, Portugal

Potential Immunoactivity of Nanoparticles: Rationale and Possible Methods of Prediction
Janos Szebeni, DrSc, MD, PhD
Head, Department of Nanomedicine, Bay Zoltan Institute of Nanotechnology, Hungary

Appropriateness of Existing Guidance for Nonclinical Assessment of Nanopharmaceuticals: A European Regulatory Perspective
Beatriz Silva Lima, PharmD, PhD
Professor, Pharmacology, University of Lisbon and Preclinical Expert, INFARMED, Portugal; Member, CHMP and Scientific Advice Working Group; Chair, Safety Working Party, EMEA, EU
Interactive War Gaming Simulations (WGS) can help multidiscipline teams make better business decisions by giving them a window into the future. WGS can also be used to develop competitive responses and build effective team decision making. This session reviews different types of WGS, scenario planning, and applications for WGS use. After reviewing the types of war games and their possible applications, participants will be broken into teams for an actual war game simulation. Each participant will be assigned a role either within a launch team or within a competitive response team. Team decisions will be fed into the market simulator. The market simulator will show likely market outcomes from team decisions. The power of WGS supporting launch preparation will be discussed after the simulation.

Understanding War Game Simulations and Their Utility when Planning a Product Launch
Rebecca O’Donnell, MBA, MS
Associate Director, Pfizer Inc.

Preparing for a War Game Simulation: What Do the Models Actually Forecast?
Hari Thrivikramji, MD, MBA, MSc
Chief Executive Officer, Strategic Analysis and Tech Solutions Ltd., UK

Developing a War Game Model
Abhinav Gupta
President, Strategic Analysis and Tech Solutions, India
Panelists

Sandra L. Kweder, MD  
Deputy Director, Office of New Drugs, CDER, FDA

Randy Levin, MD  
Director for Health and Regulatory Data Standards, CDER, FDA

Paul J. Seligman, MD, MPH, CAPT, USPHS  
Associate Director, Safety Policy and Communication, CDER, FDA

Robert J. Temple, MD  
Associate Director for Medical Policy, CDER, FDA

SESSION 418  RA2 - REGULATORY AFFAIRS, EC
8:30 am-10:00 am  LEVEL: ■
Room A404  Nursing credits offered

Implications of Patient-reported Outcomes Guidance on Electronically Collected (ePRO) Data
SESSION CHAIRPERSON(s)

Jeff Ralston
Head, Quality Assurance, ClinPhone Inc.

The release of FDA’s draft PRO guidance and EMEA’s reflection paper on regulatory guidance for HRQL shows the regulatory emphasis now being brought to patient-reported outcomes. This session will explore essential components for electronically collected PRO data (ePRO).

The Application of FDA’s PRO Guidance in an Electronic Environment
Jeff Ralston
Head, Quality Assurance, ClinPhone Inc.

An Update of the FDA’s Draft PRO Guidance
Laurie Beth Burke, MPH, RPh
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

SESSION 419  RA3 - REGULATORY AFFAIRS, PM
8:30 am-10:00 am  LEVEL: ■
Room A405

Drug Development in Japan: Drug Development Models to Ensure Acceptance of Preclinical Data Requirements as Part of Global Drug Development
SESSION CHAIRPERSON(s)

Leyna T. Mulholland, PharmD, PhD  
Associate Director, Japan Pharmaceutical Development, Merck & Co., Inc.

When a global drug development process is considered, alignment of development strategy has to start early in the drug development process by considering practical timelines, CMC and preclinical data requirements in addition to acceptable global study protocol. This session will focus on the critical nature of drug development for Japan (formulation, final market image, and CMC dossier preparation) for the JNDA application with respect to different drug development models. 

Preparing a CMC Dossier for a Successful J-CTD
Patrick A. Collier
Associate Regulatory Consultant, Eli Lilly and Company

Streamlined Global Drug Development and Acceptance of Preclinical Data
Leyna T. Mulholland, PharmD, PhD  
Associate Director, Japan Pharmaceutical Development, Merck & Co., Inc.

Marketing Use of Preclinical Data in Postmarketing Phase
Kaori Nomura
Chief, Safety Information Division, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

SESSION 420  ST - STATISTICS, CR
8:30 am-10:00 am  LEVEL: ■
Room B304  CME, Nursing, and Pharmacy credits offered

Adaptive Methods in Phase 2 Trials in Practice
SESSION CHAIRPERSON(s)

James A. Bolognese, MS  
Senior Director, Scientific Staff, Experimental Medicine Statistics, Merck Research Laboratories

Dose-adaptive study design can combined proof-of-concept and dose-finding objectives into a single trial with potential to skip phase 2b. Frequentist and Bayesian designs will be presented. An adaptive decision-theoretic model to reduce “white space” between phases 2 and 3 by starting CMC work while Phase 2 is in progress will also be presented.

Bayesian Approaches to Combine Proof-of-concept and Dose-ranging within a Single Dose-adaptive Phase 2 Design
Nitin R. Patel, PhD, MBA  
Chief Technology Officer, Co-founder, Cytel, Inc.

Examples of Dose-adaptive Designs for Proof-of-concept Trials
James A. Bolognese, MS  
Senior Director, Scientific Staff, Experimental Medicine Statistics, Merck Research Laboratories

Optimizing the Manufacturing of Phase 3 Material During Phase 2 Trials
François Vandenhende, PhD  
Chairman and Executive Consultant, ClinBAY, Belgium

SESSION 421  TR - TRAINING, CR
8:30 am-10:00 am  LEVEL: ●
Room B303

Utilizing Training within a Mentor-protégé Approach: Clinical Trial Environment and Compliance to Regulatory Agencies
SESSION CHAIRPERSON(s)

Mark Vieder, RPh  
Medical Coding Specialist/AERS-FDA Team Leader, PSI International, Inc.

Training within an organization is an aspect that has importance for success to be achieved. This session will emphasize training from a pharmacovigilance approach of mentor-protégé, clinically by overcoming diversity in a multitherapeutic environment and from the regulatory perspective of compliance and lessons learned.

Global Cultural Transformation
David C. Dasso, BSN  
Merits PMO Deputy Project Manager, USAMRMC Merits PMO

MedDRA® Training: A Mentor-protégé Approach
Mark Vieder, RPh  
Medical Coding Specialist/AERS-FDA Team Leader, PSI International, Inc.

Carol L. Krueger, BSN, RN  
Consumer Safety Officer, Division of Compliance, Risk Management, and Surveillance, CDER, FDA

SESSION 422  VA - VALIDATION, IT
8:30 am-10:00 am  LEVEL: ■
Room A313  Red Apple II

Adapting Validation Plans to the Global Landscape
SESSION CHAIRPERSON(s)

Bryan John Doherty  
Director, Global IS Quality and Compliance, AstraZeneca, UK

Marketing Use of Preclinical Data in Postmarketing Phase
Kaori Nomura  
Chief, Safety Information Division, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Thursday, June 21

This session will discuss the current text developed jointly by recognized regulatory and industry experts on computerized systems for GLP (preclinical). The principles discussed will have application to all GXP computerized system practices.

**Why It was Time to Update the 1978 Red Apple I Document**

_Earl W. Hulihan, Med_

Vice President, Global Regulatory Affairs and Quality Assurance, Medidata Solutions Worldwide

**The Process Taken and Likely Outcome from Red Apple II Program**

_James F. McCormack, PhD_

Corporate Vice President, Regulatory Affairs and Compliance, Charles River Laboratories

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**REFRESHMENT BREAK**

Building A – Exhibit Hall A Only

Building B – Levels 3 & 4, Meeting Room Corridors

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**SESSION 423**

**AHC - Academic Health Centers, RA**

10:30 am-12:00 pm  LEVEL: ■

Room B302

**Medical Informatics Opportunities to Improve the Benefit-risk Assessment of Drugs**

_SESSON CHAIRPERSON(S)_

_Melvyn Grebberman, MD, MS, MPH, FACPM_

President, Public Health Resources, LLC

Medical, health, and biomedical informatics include the planning, development, implementation, and evaluation of systems and methods to improve the access, analysis, understanding, organization, management, communication, and use of information, including data, in many areas, including health care, research, and regulatory applications. In its response to the 2006 IOM report The Future of Drug Safety – Promoting and Protecting the Health of the Public, FDA recognized the importance of informatics as part of an interdisciplinary approach to benefit and risk analysis, the postmarket assessment of drugs, and drug safety. Electronic systems that use standards and information technology to facilitate the use of health information in diverse locations and for multiple applications are of increasing importance to public-private sector efforts to improve the benefit-risk assessment of drugs. Investments in applications of medical informatics by AHRO, FDA, and NLM are speeding drug information from clinical trials to the public via the use of health data standards and the DailyMed Web site. The panel will discuss the current and future benefits of such systems, the building blocks that permit health information to flow to the point of care, and research and implementation investments in health informatics applications. In addition, the panel will discuss scientific issues that must be addressed in order to take full advantage of these emerging information resources to ensure that drugs are used effectively and safely. Investigators and regulators faced with multiple drug exposure/outcome associations will need to consider potential patient and physician biases, confounders, and other biases that may explain risk/benefit pictures that emerge from these large data resources. Additional topics that will be discussed include major health system issues, current federal health information standards activities, and paying for performance.

**Informatics Building Blocks and their Applications: Accelerating the Flow of Drug Information from Clinical Trials to the Consumer**

_J. Michael Fitzmaurice, PhD, FACMI_

Senior Science Advisor for Information Technology, Agency for Healthcare Research and Quality, Department of Health and Human Services

**The Importance of Data Standards and Review Tools for Improving NDA Review**

_Charles K. Cooper, MD_

Medical Officer, Office of Biostatistics, CDER, FDA

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**SESSION 424**

**BT - Biotechnology, CR**

10:30 am-12:00 pm  LEVEL: ■

Room B301

**CME and Pharmacy credits offered**

**The "OMICS" Initiative: Leveraging Genomics, Proteomics, and Metabolomics for Diagnostics Development**

_SESSION CHAIRPERSON(S)_

_Gordon Vansant, PhD_

Director, Biomarker Development, Analytical Services, Althea Technologies, Inc.

This session will provide valuable information regarding the recent applications of the different “omic” strategies to define biomarkers for diagnostic development. Speakers will include experts in the fields of genomics, proteomics, and metabolomics.

**Metabolomic Analysis for Identification of Biomarkers of Prostate Cancer**

_Bruce J. McCreedy, PhD_

Vice President, Strategic and Clinical Development, Metabolon, Inc.

**Diagnosis of Cancers Using Multiplex PCR and Genes Identified by Microarrays**

_Gordon Vansant, PhD_

Director, Biomarker Development, Analytical Services, Althea Technologies, Inc.

**Industrialized Proteomics: A Foundation for Systems-based Studies in Drug and Diagnostic Development**

_Peter Juhasz, PhD_

Senior Director, Proteomics, BG Medicine, Inc.

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**SESSION 425**

**CDM - Clinical Data Management, EC**

10:30 am-12:00 pm  LEVEL: ■

Room A312

**Independent Imaging/Medical Oncology Assessments: Planning for the Challenges**

_SESSION CHAIRPERSON(S)_

_Maria V. Cincotta, MS_

Associate Director, Medical Research - Oncology, Wyeth Research

This will be a forum for data management and clinical personnel to learn about challenges experienced by industry colleagues responsible for management of pivotal oncology trials with event-based, efficacy-based endpoints based on analysis of independent radiology/medical oncology vendor assessments.

**Medical Imaging in Clinical Trials: Lessons Learned and Critical Issues from a Medical Perspective**

_Robert Ford, MD_

Founder and Chief Medical Officer, RadPharm, Inc.

**Imaging Processes and Site-related Issues in Oncology Clinical Trials**

_James P. Golando_

Vice President, Clinical Operations and Sponsor Relations, RadPharm, Inc.

**CDM Considerations for Independent Radiology Assessment**

_Regina Sisk_

Associate Director, Data Management, Wyeth Pharmaceuticals

_Jennifer L. Duff, MS_

Associate Director, Clinical Data Management, Accenture

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**Scientific Challenges in Employing Emerging Information Resources**

_Stanley A. Edlavitch, PhD, MA_

Professor, Epidemiology and Director, Epidemiology Research, University of Missouri Kansas City School of Medicine
Session 426  CP - Clinical Safety and Pharmacovigilance, CDM
10:30 am-12:00 pm  Level: ■  Room A402  CME and Nursing credits offered
Adverse Event and Medication Error Coding: Is MedDRA® Up to the Task?
Session Chairperson(s)
Marie Lou Gacusan Munson, MD
Associate Director, Elan Biopharmaceuticals
Judith McMeekin, PharmD
Medical Coding Specialist, PSI International, Inc.

This session will provide a brief overview of MedDRA®, innovative techniques and approaches for coding difficult verbatim terms, proficiency training, and MedDRA® up-versioning. In addition, the expansion of medication error terms within MedDRA® and current term descriptions will be presented along with practical cases illustrating the corresponding medication error terms. A real-life application of an adverse event/medication error surveillance project will also be discussed.

Unlocking the Language of Adverse Events: The Use of MedDRA® as a Tool
Marie Lou Gacusan Munson, MD
Associate Director, Elan Biopharmaceuticals

Utilization of Medication Error Terms within MedDRA®
Judith McMeekin, PharmD
Medical Coding Specialist, PSI International, Inc.

Adverse Event Surveillance in Ambulatory Patients: Examples from the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance Project (NEISS-CADES)
Daniel Budnitz, MD, MPH
Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention (CDC)

Session 427  CR1 - Clinical Research and Development, EC
10:30 am-12:00 pm  Level: ○  Room B308  CME and Nursing credits offered
Enhancing Patient Compliance in Clinical Trials with eTechnology
Session Chairperson(s)
Brenda Jamerson, PharmD
Associate Professor, Clinical Research, Campbell University School of Pharmacy

Patient-reported outcomes (PROs) are a component of many clinical trials. Electronic technologies to collect PROs are designed to yield higher quality data. This session will focus on eTechnologies (i.e., electronic diaries, actigraphy, medication monitoring) that enhance patient protocol compliance.

The Role of eDiaries in Driving and Monitoring Patient Compliance to Clinical Trial Procedures
Jean Paty, PhD, MS
Founder and Senior Vice President, Quality and Regulatory Affairs, invivodata, inc.

Application of Actigraphy-based Monitoring to Identify Patient Compliance in Clinical Trials
Jack E. McKenzie, PhD
Director, Clinical Affairs, Mini Mitter, a Respironics Company

Session 428  CR2 - Clinical Research and Development, GCP
10:30 am-12:00 pm  Level: ■  Room B309  CME credits offered
Practical Aspects of Implementing Adaptive Trials
Session Chairperson(s)
Stephen Boccardo
Vice President, Sales and Marketing, Phoenix Data Systems, Inc.

At a rapid pace three hot factors have recently converged to transform the concept of adaptive trials from the realm of theoretically possible to hot. These forces are creative statisticians, willing managers and regulators, and enabling technology. This session will explore the practical aspects of implementing adaptive trials in the current regulatory environment. Speakers will outline the process and rationale for choosing an adaptive trial design and discuss the decision and approval processes as well as the implementation planning. Key regulatory considerations of adaptive trial implementation will also be reviewed.

Technology plays a key role in successful adaptive trial implementations. This session will detail experiences using EDC, IVRS and SAS technologies to implement a real-time adaptive trial capability. Systems integration, testing simulations, and well-designed processes are required to enable this real-time capability. This session will also identify the system features that create an optimal environment for implementing adaptive designs and make possible real-time adaptability.

Case studies will present the key elements necessary for planning and implementing adaptive trials based on real-world experiences. Practical topics such as study blinding issues, managing drug supplies, how design changes can be hidden from investigators, and training requirements will be covered. The presentations in this session assume that attendees have a basic understanding of the definition of an adaptive trial. This session will not cover the statistical details that support adaptive designs. A basic understand of EDC terminology is also assumed.

Kevin J. Carroll, MS
Chief Statistical Expert, AstraZeneca, UK

The Implementation of Randomization Algorithm Adaptations via Centralized Randomization and Trial Supply Management Systems
Graham J. Nicholls, MS
Product Manager, Randomization and Trial Supply Management, ClinPhone plc, UK

Session 429  CTM/CS - Clinical Trial Management/ CLINICAL SUPPLIES, AHC
10:30 am-12:00 pm  Level: ■  Room B404
New Techniques for Maximizing Enrollment at Academic Health Centers
Session Chairperson(s)
James A. Moran, JD
Assistant Dean for Clinical Trials, Washington University in St. Louis

Assessing Clinical Trial Compliance Using Medication Monitoring Technologies
Brent I. Fox, PharmD, PhD
Assistant to the Dean for Educational Technology, Harrison School of Pharmacy, Auburn University

The Implementation of Randomization Algorithm Adaptations via Centralized Randomization and Trial Supply Management Systems
Graham J. Nicholls, MS
Product Manager, Randomization and Trial Supply Management, ClinPhone plc, UK
This session will discuss proactive participant recruitment strategies implemented at Washington University in St. Louis used to dramatically improve research participant recruitment.

**Participant Enrollment: The Industry Perspective**  
*Caryl K. Fiedler, PharmD*  
Director, Study Strategy and Planning, Bristol-Myers Squibb Company

**Enrollment Project Overview**  
*David S. Zuckerman, MS*  
President, Customized Improvement Strategies LLC

**Participant Enrollment: The Site Perspective**  
*James A. Moran, JD*  
Assistant Dean for Clinical Trials, Washington University in St. Louis

**SESSION 430**  
ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM  
10:30 am-12:00 pm  
Room A412AB  
eIND  
SESSION CHAIRPERSON(s)  
*Jeannie Kwon*  
Associate Director, Professional Services, Image Solutions, Inc.

This session will focus on experiences with the submission of INDs in the eCTD format, covering the preparation of granular components, mapping IND documents to the eCTD structure, lifecycle management of the IND in eCTD, and the benefits and challenges of this submission format.

**Transitioning from Paper IND to eCTD IND: Are Your Documents Ready?**  
*Robin L. Zumbrunnen*  
Director, Regulatory Operations, Quintiles, Inc.

**Case Study: IND in eCTD Format – Outsourcing Perspective**  
*Aarati Sridharan*  
Senior Regulatory Affairs Associate, EPIX Pharmaceuticals, Inc.

**Case Study: IND in eCTD Format – Insourcing Perspective**  
*Tara Washlack, RAC*  
Supervisor, Publishing and Documentation, Abraxis BioScience, Inc.

**SESSION 431**  
GCP - GOOD CLINICAL PRACTICES, IS  
10:30 am-12:00 pm  
Room B405  
Nursing credits offered

**The Additional Challenges of Auditing an Investigational Site Using Electronic Data Capture (EDC)**  
SESSION CHAIRPERSON(s)  
*Shari Stark*  
Manager, Quality Assurance and Compliance, PharmaNet

As more sites move toward electronic data capture and/or hybrid systems, this poses additional challenges to CRAs, auditors and regulatory inspectors. This session is intended to explore those challenges and educate those involved in the review of data in an electronic data capture environment.

**Defining the Appropriate QC of Patient Data Collected via Hybrid EDC or via Integration of Multiple External Sources**  
*Richard A. Nelson, MS*  
Vice President, Specialized Pharmaceutical Services, PharmaNet, Inc.

**Auditing in an EDC Environment**  
*Susan Flynn*  
Chief Quality Officer, Clinsys Clinical Research, Inc.
Application of Humanized Transgenic Mice to Assess Toxicity of Human- and Mouse-specific Metabolites: An Industry Perspective

Mark Powley, PhD
Senior Research Biochemist, Merck & Co., Inc.

Use of Humanized Transgenic Mice to Assess Toxicity of Unique Human Metabolites: A Regulatory Perspective

David Jacobson Kram, PhD
Associate Director, Pharmacology and Toxicology, Office of New Drugs, CDER, FDA

SESSION 434  NHP - NATURAL HEALTH PRODUCTS, CR
10:30 am-12:00 pm  LEVEL: ■
Room B306

Challenges and Solutions in Evaluation of Traditional Chinese Medicine

Edmund M. K. Lui, PhD, MS
Associate Professor, Department of Physiology and Pharmacology, University of Western Ontario, Canada

Several primary goals of the US FDA’s Critical Path objectives are to generate scientific approaches that enable product sponsors to predict and evaluate the safety and effectiveness of candidate products, make product development less risky, and enable individualization of therapy to improve effectiveness and avoid side effects. This session will provide a brief overview of the philosophical basis of traditional Chinese medicine (TCM), addressing the personalization of therapeutic interventions through the balancing of efficacy against potentially toxic elements (yin-yang). It will then focus on recent developments on the use of TCM as a monotherapy and as an add-on to conventional treatment. It will discuss challenges and solutions in evidence-based evaluation of Chinese herbal products, including the use of multiresearch methodologies.

Metabolic Interaction of TCM with Small Molecular Therapeutics: Challenges in Safety, Opportunity in Efficacy, and Optimization of Methods for Solutions

Zhuohan Hu
Chief Executive Officer/Chief Scientific Officer, Deputy Director, National Shanghai Center, New Drug Evaluation and Research, Research Institutes for Liver Diseases, China

Methodical Meandering in Evaluating Chinese Medicine

Lyren Chiu
Assistant Professor, University of British Columbia, Canada

Challenges of Scientifically Evaluating Chinese Herbal Medicine

Yong-Liang Zhu, PhD
Senior Scientist, Phytoceutix Inc.

SESSION 435  OS - OUTSOURCING, IS
10:30 am-12:00 pm  LEVEL: ■
Room B403

A Case Study of a Successful Functional Service Provider (FSP) Relationship: Outsourcing Study Start-up Responsibilities

David F. Fenske
Senior Director, Investigator Contracts and Grant Administration, ICON Clinical Research

As more companies are exploring alternative approaches to traditional outsourcing models, many are looking towards functional service provider (FSP) agreements as a possible way to capture synergies and efficiencies in the process. This session will feature a case study of how a large pharmaceutical company and two CROs have formed a successful partnership in the outsourcing of investigator site contracts and regulatory document collection. Representatives of both CROs and the pharmaceutical company will provide insight into why and how the partnership was formed, benefits received by all parties, and valuable lessons learned in creating and rolling out the relationship.

A Case Study of a Successful Functional Service Provider (FSP) Relationship: Outsourcing Study Start-up Responsibilities

David F. Fenske
Senior Director, Investigator Contracts and Grant Administration, ICON Clinical Research

Panelists

Andrew Townshend
Senior Director, Contracts and Outsourcing, Pfizer Inc

Todd Esporas, JD, MBA
Director, Contracts and Functional Services, INC Research, Inc.

SESSION 436  PM - PROJECT MANAGEMENT, CTM/CS
10:30 am-12:00 pm  LEVEL: ■
Room B402

The Playing Field of Project Management: A Dynamic Investigation of a Team and their Winning Strategy

Jennifer Lansink
Founder and Chief Executive Officer, Total Root Concepts, Inc.

New players, new rules, a new playing field: CLOSE YOUR ENROLLMENT EIGHT MONTHS EARLY! On a limited budget with research naive sites and dissemination in the ranks, learn from this sponsor/CRO/vendor partnership how to effectively manage through change, resolve conflict, and create action, while beating timelines. We’re never too experienced to take new tactics. This interactive session will dive deep into a case study of a recently completed and successful trial.

Vendor and Program Relations

Jennifer Lansink
Founder and Chief Executive Officer, Total Root Concepts, Inc.

Sponsor Responsibilities

Bernice Kuca, MS
Senior Project Manager, Oscient Pharmaceuticals Corp.

Client and Site Coordination, Team Management

Sarah Pniak
Clinical Operations Lead, Quintiles, Inc.

SESSION 437  RA1 - REGULATORY AFFAIRS, CR
10:30 am-12:00 pm  LEVEL: ■
Room A411

CDER Town Meeting – Part 2 of 2

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

Part 1 of this session will take place 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

Sandra L. Kweder, MD
Deputy Director, Office of New Drugs, CDER, FDA

Randy Levin, MD
Director for Health and Regulatory Data Standards, CDER, FDA

Paul J. Seligman, MD, MPH, CAPT, USPHS
Associate Director, Safety Policy and Communication, CDER, FDA

Robert J. Temple, MD
Associate Director for Medical Policy, CDER, FDA

**SESSION 438**  
RA2 - Regulatory Affairs, CR  
10:30 am-12:00 pm  
Room A404  
CME credits offered  

**Phase 3: Are You Studying the Right Dose?**  
SESSION CHAIRPERSON(S)  
Amjad M. Iqbal, PharmD  
Assistant Director, Regulatory Affairs, Forest Research Institute

One of the most important goals of phases 1 and 2 drug development is to identify what dose to study in phase 3. Conducting thorough dose-finding studies early in development can help to avoid failed phase 3 studies. This session will explore various study designs that can be used for dose finding.

Efficient Clinical Trial Designs for Dose Finding  
Lawrence J. Lesko, PhD  
Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA

Jeffrey S. Barrett, PhD, FCP  
Research Associate Professor, Pediatrics; Director, Pediatric Pharmacology Research Unit, The Children’s Hospital of Philadelphia; KMAS (Kinetic Modeling & Simulation) Institute for Translational Medicine, University of Pennsylvania

**SESSION 439**  
ST - Statistics, EC  
10:30 am-12:00 pm  
Room B304  

**CDISC and Statisticians: Implications and Implementations**  
SESSION CHAIRPERSON(S)  
Cathleen F. Barrows, PhD  
Associate Director, Statistics and Programming, Psychiatry, GlaxoSmithKline

The impact of CDISC on statisticians is broader than just clarifying the need for analysis datasets in a submission. This session will describe current progress in the evolution of CDISC standards to meet sponsor and reviewer statistical needs.

Standards for AdAm Implementation  
Susan J. Kenny, PhD  
Director, Statistical Programming, Inspire Pharmaceuticals

Using CDISC Models for the Analysis of Safety Data  
Edward D. Helton, PhD, MA  
Chief Scientist, Regulatory and Biomedical Affairs, SAS Institute, Inc.

A CDISC Environment for Statisticians: More than Just Analysis Datasets  
Greg Anglin, PhD  
Principal Research Scientist, Statistics, Eli Lilly Canada Inc., Canada

**SESSION 440**  
TR - Training, CR  
10:30 am-12:00 pm  
Room B303  

**Searching PubMed®: Trade Secrets From Three, Four-star Medical Library Scientists**  
SESSION CHAIRPERSON(S)  
Carol L. Mitchell, MD  
Associate Global Medical Information Consultant, Eli Lilly and Company

Professionals all over the world use PubMed® to search the MEDLINE® database. In this session, hear presentations geared to our quest for up-to-date drug information from expert medical library scientists who will share PubMed® and other searching tricks of the trade.

**PubMed®: For Handheld and Other New Frontiers**  
Toni Caprice Yancey, MLS  
SE Region Outreach Coordinator, National Network of Libraries of Medicine, US National Library of Medicine

**Demystifying the Language of Searching**  
Timothy Lammers, MLS  
Library Specialist, Woodruff Health Sciences Center Library, Emory University School of Medicine

**The Power of Personalizing PubMed®: My NCBI**  
Carolyn M. Brown, MLS, AHIP  
Reference Librarian, Woodruff Health Sciences Center Library, Emory University School of Medicine

**SESSION 441**  
VA - Validation, IT  
10:30 am-12:00 pm  
Room A313  

**Measurement of Quality: A Necessary Step**  
SESSION CHAIRPERSON(S)  
Richard L. Chamberlain, MS, PhD  
President, ECS, Inc.

When working with the development and use of information systems, the product is information. Documenting the quality as a number can be very difficult. For example, what is the quality of a requirements document? How do you measure it? What is the quality of the information we produce represented as a number? Being able to do this is a necessary requirement if we are going to increase quality.

**A Lean, Mean Testing Machine: Process Improvement**  
Marsha Rehrer  
Director, Software Testing, ALMAC Clinical Technologies

**The Role of Quality Measurements in Procedures**  
Frances E. Nolan, MBA  
Senior Director, Quality Assurance, Medidata Solutions, Inc.

END OF THURSDAY SESSIONS  
ANNUAL MEETING ADJOURNED  

**12:30 pm - 5:00 pm**  
**MedDRA® MSSO USER GROUP MEETING**  
Room A410, Building A, Level 4, GWCC
### Exhibiting Companies

**THE Networking Event in the Pharmaceutical Industry**

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. From CROs and technology vendors to site research centers, academia, and much more, the DIA Annual Exhibit Hall is one of the busiest places during the meeting. Visitors to the Exhibit Hall will be able to easily obtain an exhibiting company’s booth number by searching electronically using the exhibitor locator workstations conveniently located in the entrance to the Exhibit Hall. Meet with a wide range of companies to learn about new offerings and technologies, all in one event – DIA’s 43rd Annual Meeting.

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#### Top Reasons Why People Attend DIA’s Annual Meeting

- Networking opportunities
- Timeliness of topics
- Breadth and depth of topics
- Quality and value of information in speaker presentations
- Relevance of content to their profession

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**Limited Space Is Still Available!** DIA invites you to showcase your company to this network of qualified professionals in one of the world’s most dynamic pharmaceutical markets. Visit www.diahome.org for an application form or contact one of the Exhibit Associates.

- For companies A-L – Jeff Korn / Phone +1-215-442-6184 / email Jeff.Korn@diahome.org
- For companies M-Z – Erin Gilliland / Phone +1-215-442-6149 / email Erin.Gilliland@diahome.org

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**Exhibiting companies registered as of February 7, 2007**

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<tr>
<th>Aagami, Inc.</th>
<th>Atcor Medical, Inc.</th>
<th>CEDRA Corporation</th>
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<tr>
<td>AAI Pharma</td>
<td>Averion International Corp.</td>
<td>Center for Drug Evaluation, Taiwan</td>
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<td>AbCRO, Inc.</td>
<td>Axiom Real-Time Metrics</td>
<td>Cerner Galt</td>
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<td>Abt Associates Inc.</td>
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<td>Charles River Laboratories Clinical Research Services - Northwest Kinetics</td>
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<td>BASI (Bioanalytical Systems, Inc.)</td>
<td>Chesapeake Research Review Inc.</td>
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<td>Chiltern International, Inc.</td>
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<td>Acurian</td>
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<td>Cincinnati Children’s Research Foundation</td>
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<td>Adobe Systems, Inc.</td>
<td>Beacon Bioscience</td>
<td>CIRION Clinical Trial Services Inc.</td>
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<td>ClinAudits LLC</td>
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<td>Advanced Clinical Services LLC</td>
<td>Bilcare, Inc.</td>
<td>ClinForce, LLC</td>
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<td>Advanced Clinical Software</td>
<td>Bio-Imaging Technologies</td>
<td>Clinical DataFax Systems Inc.</td>
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<td>Aerotek Scientific</td>
<td>Biomedical Systems</td>
<td>Clinical Financial Services</td>
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<td>Allergan, Inc.</td>
<td>Bio-Optronics, Inc.</td>
<td>The Clinical Resource Network</td>
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<td>BioPharm Insight</td>
<td>Clinical Technology Transfer Group</td>
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<td>Canadian Arthritis Network/Canadian Rheumatology Research Consortium</td>
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<td>CanReg, Inc.</td>
<td>CompleWare® Corporation</td>
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<td>Concepts Worldwide</td>
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<td>Asuragen, Inc.</td>
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Exhibiting Companies (registered as of February 7, 2007)

Covance Inc.
CRF Inc.
Criterium, Inc.
CRL.Medinet
CTI Clinical Trial & Consulting Services
CTMS, Inc.
Cu-Tech, LLC
Cytel Inc.
D. Anderson & Company
Data Systems Analysts
DataCeutics, Inc.
Datafarm, Inc.
DATATRAK International
Datatrial
DaVita Clinical Research
Delta Pharma, Inc.
Dendrite Clinical Solutions
Diabetes & Glandular Disease Research Associates
Doublebridge Technologies, Inc.
Drexel University Online
Drug Safety Alliance, Inc.
DrugLogic Inc.
DSG, Inc.
DUCK FLATS Pharma, LLC
Duke Clinical Research Institute
DZS Software Solutions, Inc.
ECLA
ECRON
Edgewater Technology
Elite Research Network, LLC
Encore Research Group, LLC
Encorium
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eResearchTechnology, Inc.
Esoterix Clinical Trials Services, Inc.
Essential Group, Inc.
EtQ, Inc.
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Eurofins Medinet, Inc.
European Medicines Agency (EMEA)
Eurotrials Scientific Consultants
Examination Management Services, Inc.
Excel Life Sciences
Excel PharmaStudies, Inc.
Fast Track Systems
Fast4wD Ogilvy
Favorite Healthcare Staffing
FDA/CDER
FDAnews
Ferraris Respiratory
First Consulting Group

Fisher Clinical Services
Fleury SA
FOI Services, Inc.
Forest Laboratories, Inc.
Formedix Ltd.
Formosa Biomedical Technology Corp.
Fraunhofer Institute of Toxicology and Experimental Medicine (ITEM)
Future Science Group
Galdema Research & Development
GB Pharma Services & Consulting s.r.l.
Genetia Clinical Research
Gentris Corporation
Genzyme
Glenser Technologies
Global Languages & Cultures, Inc.
Global Lifescience Solutions, LLC
Green Mountain Logic, Inc.
GroupNet
Harrison Clinical Research
Hawaii Clinical Research Center
Health Decisions
Health Industry Insights
Healthcare Communications Group
Hibernia College
Howard M. Proskin & Associates, Inc.
i3 Research
i4i
IBT Reference Laboratory
ICON Clinical Research
iGATE Clinical Research International
Image Solutions, Inc.
iMedRIS Data Corporation
IMIC - Mexican Institute of Clinical Research
Impact Clinical Trials
Imperial Clinical Research Services, Inc.
IMRO TRAMARKO
INC Research
Inclinix
Innovative Print & Media Group
Institute of Clinical Research India
Integrated Clinical Systems, Inc.
Integrated Development Associates Co., Ltd.
IntegReview Ethical Review Board
Integrum - Integrex
International Dermatology Research
IntraLinks, Inc.
invidodata
iProcess Inc
IRL (Pvt) Ltd
J&S Studies, Inc.
Johnson & Johnson Family of Companies
Joule Clinical Staffing Solutions
Kendle
Kforce Clinical Research Staffing
Klein Management Systems
KMI Diagnostics, Inc.
LabConnect, LLC
Laboratorio Hidalgo
Lernia Training Solutions
Lifecord Stat-Korea Co., Ltd.
Lionbridge
Logos Technologies Ltd.
LORENZ Life Sciences Group
Los Angeles Biomedical Research Institute
Lovelace Scientific Resources
LSUHSC-Shreveport
Maaguzi, LLC
MAJARO InfoSystems
Makro Technologies
MasterControl, Inc.
Mayo Clinical Trial Services
McElroy Translation Company
McGuire Research Institute, Inc.
MD Events Limited
MD Pharma Services
MedDRA® MSSO
MedFocus, LLC
Medica Sur - CIBIOBIC
Medical Graphics
The Medical Letter
Medical Staffing Network
Medidata Solutions
Medfacts International
MedNet Solutions
Medpace, Inc.
MedSignals
MedSource
MEDTOX Laboratories
MedTrials, Inc.
Merck Research Laboratories
META Solutions, Inc.
MetaClin Research Inc
MIC Medical Corp.
Microsoft Corporation
Micsystems
Mid* Lands IRB
MMG
Monitorforhire.com
Monitoring Force Group
Mortara Instrument, Inc.
MPI Research
MSOURCE Medical Development
National Center for Health Statistics
National Institute of Allergy and Infectious Disease
NDA Regulatory Science Ltd.
NERI - New England Research Institutes
New Orleans Center for Clinical Research
Next Generation Clinical Research
NextDocs Corporation
Exhibiting Companies (registered as of February 7, 2007)

Northrop Grumman
Novotech
OCASA Logistics Solutions
Octagon Research Solutions
Omnicare Clinical Research
Omnicia, Inc.
OmniComm Systems, Inc.
On Assignment Clinical Research
Open Text Corporation
Organon USA
Outcome
Pacific Biometrics, Inc.
Pacific Data Designs
Paragon Biomedical, Inc.
PAREXEL International
Patheon Inc.
Patient Interaction (Pi)
The Patient Recruiting Agency
PDP Courier Services Ltd
Synteract Inc.
TAKE Solutions Inc.
Tandem Labs Taratec Target Health Inc.
Tarius A/S
TNT Express Total Root Concepts, Inc.
TranSenda TransPerfect Trial Management Group Inc.
Trialstat Corporation Trident Clinical Research Pty Ltd.
Trilgent International Trio Clinical Research, LLC TTC, LLC UK Clinical Research Organization United BioSource Corporation University Clinical Research Deland University of California San Diego University of Florida Center for Clinical Trials Research University of Rochester Medical Center Uppsala Monitoring Centre Velos Inc
Veritas Medicine VIASYS Healthcare Virtify, Inc.
VirtualScopics Inc.
Vitalograph Ltd.
Volt Life Sciences Waban Software WebbWriters, LLC WebWise Learning, Inc.
Wellspring Pharmaceutical Wiley Pharmafile Wolters Kluver Health Woodley Equipment Company Ltd.
Working Words Inc.
World Courier Inc.
WorldCare Clinical Inc
Worldwide Translations Inc
Xceleron Inc
XERIMIS Inc.
Do You Know About DIA Webinars?

What are they?
DIA is a leading provider of online seminars for the drug development industry. Get “just-in-time” information without leaving your office. Webinars are virtual, real-time, seminars. With Internet access, you can log on to hear experts on current and timely topics. You can even ask questions right from your computer through a Q&A function.

How do I sign up?
Visit www.diahome.org and click on “Educational Offerings.” Once registered, you’ll receive an email with all the materials and instructions you’ll need. Group site registration is also available.

How much does it cost?
- Standard: $250
- Government (Full time): $125
- Charitable Nonprofit/Academia: $175
- Group Site: $799

Multiple Discounts Available:
Receive a 15% discount on multiple group-site registrations for an individual webinar. Valid for online purchase only.

Missed a webinar?
No problem. Archived webinars are available for purchase 30 - 60 days after the LIVE presentation. You get all the same content in a format you can easily download to your computer at your convenience. Visit www.diahome.org for a complete listing of archived webinars.

Suggest a webinar or organize one yourself.
DIA depends on volunteers like you for our success. If you want to suggest a webinar topic or would like to volunteer to organize a webinar, we want to hear from you. Please contact Colleen Braun at 215-442-6160 or by email at Colleen.Braun@diahome.org

Still have questions?
For more information or questions about DIA webinars, please contact Colleen Braun at 215-442-6160, or by email at Colleen.Braun@diahome.org. You may also visit www.diahome.org to download registration information.

Monitor www.diahome.org for upcoming webinars as they become available and archived webinars that have already taken place.
DIA In-company Training

QUALITY CONTENT AND DELIVERY
WITHOUT THE TRAVEL

MAXIMIZE YOUR TRAINING BUDGET
DIA understands the importance of a comprehensive, quality training program at a reasonable price. With DIA’s in-company training program, you provide the students and a learning-friendly environment, we supply the instructors and the learning materials—all at your company location!

Recognized industry-wide as the gold standard, DIA boasts more than 15 years of training experience. Exclusive benefits of DIA’s in-company training program include:

- Expert training from professionals in the pharmaceutical and related industries
- Quality content and delivery—all within your company location
- Courses tailored to meet your specific training objectives
- Continuing education credits
- Company provides students, audiovisual equipment, and learning-friendly environment

SCHEDULE A COURSE

For a complete list of in-company training courses or to schedule a course, log on to:

www.diahome.org/DIAHome/Education/InCompanyTraining.aspx

or contact Katie Hill at +1-215-442-6130
or Katie.Hill@diahome.org.
The tutorials being offered as of April 7, 2007, are listed below. Please continue to monitor www.diahome.org for tutorial updates and online registration.

Space is limited so register early!

Saturday, June 16, 2007 1:00-4:30 pm
Tutorials #30 through #35  Fee $375

#30 Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People, and Process  CR, CTM/CS, RD
#31 Leadership: How to Organize and Lead People in Group Work  GCP, PM, TR
#33 The Investigator’s Brochure: Best Practices for Writing and Updating  CR, MW, RA
#34 Project Management for the Nonproject Manager  CR, CTM/CS, PM
#35 The Scientific and Economic Benefits of Flexible Adaptive Trial Methodology Designed to Achieve Early Registration and Robust Results: Raptiva and Fabrazyme® as Case Studies  CR, PM, RA

Sunday, June 17, 2007 9:00 am-5:00 pm
Tutorials #40 through #45  Fee $650

#40 Clinical Statistics for Nonstatisticians  CR, MC, MW
#41 European Regulatory Requirements for the Conduct of Clinical Trials  CR, GCP, RA
#42 Pharmacokinetics and Pharmacodynamics: A Gentle Introduction  CR
#43 Principles of Safety Surveillance  CP, RA, TR
#44 Developing Realistic Drug Development Project Plans  CR, CTM/CS, PM
#45 Excelling as a Supervisor or Manager in the Clinical Research Industry  CR, CTM/CS, PM

Sunday, June 17, 2007 8:30 am-12:00 pm
Tutorials #50 through #59  Fee $375

#50 Pharmacovigilance Audit  CP, GCP, RA
#51 Fourteen Steps from Research to Development  RA, RD
#52 Preparation of Integrated Clinical and Statistical Reports for Individual Studies  CR, MW, RA
#53 Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development  RA
#54 A Compliance-driven Nonstatistical Risk Detection Process in Drug Safety  CP, CR, RA
#55 Alcohol-drug Interaction Studies: Understanding the Regulatory Requirements and Study Design Issues  CR, RA, RD
#56 Market Access for Prescription Drugs and Biologics in Canada  RA
#57 eClinical: Optimizing the Clinical Trial Process  CDM, CR, EC, PM
#58 Producing Structured Product Labeling (SPL): XML and Data Elements  CP, EC, IT
#59 Best Practices Using MedDRA®  CDM, CP

Sunday, June 17, 2007 1:00-4:30 pm
Tutorials #70 through #87  Fee $375

#70 FDA Enforcement: Understanding the Agency’s Authority, How Violations Occur, How to Prevent Them, and How to Respond If Violations Do Occur  CTM/CS, GCP, RA
#71 Evaluation of Risk Management Programs Using Existing Databases  CP, RA
#72 Regulations, Guidance, Dockets, Specifications and Manual of Policies and Procedures (MAPPs): A Primer for Pharmaceutical Professionals  CR, PM, RA
#73 Analysis of Safety Data from Clinical Trials  CR, MW, ST
#74 GCP, Clinical Trial Safety, and Pharmacovigilance Compliance: How Global Pharmaceutical Companies Can Cope in Interesting Times  CP, CR, GCP, RA
#75 Planning and Conducting Clinical Trials in Oncology  BT, CR, IS
#76 The CRA Role for GCP Compliance with Electronic Data Capture (EDC)  EC, GCP, IS
#77 Collecting Abuse Liability Data During CNS Drug Development  CR, RA, RD
#78 Development of Stem Cells-based Therapeutics, including Human Embryonic Stem Cells, from Proof of Concept to Clinical Trials  CR, PM
#79 The Expanding Role of Clinical Site Monitors  CTM/CS, GCP, IS
#80 Randomization and Trial Supply Management Using IVR: A Tutorial for Study Teams  CR, CTM/CS
#81 Pharmacogenomics as a Tool to Accelerate Drug Development  CR, RA, RD
#82 Introduction to Biomedical and Health Informatics  CR, IS, MW, PM
#83 Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in EU  CR, PM, RA
#84 Pediatric Clinical Trials: The Way Forward  CR, RA, TR
#85 The Changing Landscape of Pharmaceutical Product Launches  CR, MC, RA
#86 The CDISC Standard: Four Models Working in Harmony  CDM, CR, IT

Please indicate the tutorials you plan to attend on the registration form on page 118.
Explore the Benefits of a DIA Membership

- Networking with 20,000 Worldwide Colleagues
- Discounted Event Registration Fees
- Members-only Website
- DIA Job Bank
- Searchable Membership Directory
- Special Interest Area Communities
- Volunteer Opportunities
- Member Discount Program

To join the DIA network, please visit the Membership & Communities page on www.diahome.org
As of May 15, 2007, all hotel reservations, changes, and cancellations must be made directly with the Atlanta hotels and the DIA room block is no longer guaranteed.

See page 113 for a list of hotels that can be called to inquire about room availability.

DIA DOES NOT PROCESS HOTEL RESERVATIONS.

NO LONGER APPLICABLE
Attendees should make hotel reservations early to guarantee rates and availability.

As of May 15, 2007, all hotel reservations, changes, and cancellations must be made directly with the Atlanta hotels and the DIA room block is no longer guaranteed. Following is a list of hotels that can be called to inquire about room availability.

<table>
<thead>
<tr>
<th>Hotel</th>
<th>Address</th>
<th>Telephone Number</th>
<th>Distance to Congress Center</th>
<th>Shuttle Offered</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Atlanta Marriott Marquis</td>
<td>265 Peachtree Center Avenue</td>
<td>T +1-404-521-0000  F +1-404-586-6299</td>
<td>8 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>#2 Embassy Suites Hotel Atlanta Centennial Olympic Park</td>
<td>267 Marietta Street</td>
<td>T +1-404-223-2300  F +1-404-223-0925</td>
<td>Across the street from Congress Center</td>
<td>No</td>
</tr>
<tr>
<td>#3 Hilton Atlanta &amp; Towers</td>
<td>255 Courtland Street NE</td>
<td>T +1-404-659-2000  F +1-404-221-6368</td>
<td>9 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>#4 Hyatt Regency Atlanta</td>
<td>265 Peachtree Street, NE</td>
<td>T +1-404-577-1234  F +1-404-588-4137</td>
<td>7 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>#5 Omni Hotel @ CNN</td>
<td>100 CNN Center</td>
<td>T +1-404-659-0000  F +1-404-525-5050</td>
<td>Across the street from Congress Center</td>
<td>No</td>
</tr>
<tr>
<td>#6 Westin Peachtree Plaza</td>
<td>210 Peachtree Street, NW</td>
<td>T +1-404-659-1400  F +1-404-589-7424</td>
<td>6 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>#7 AmeriSuites Downtown</td>
<td>330 Peachtree Street, NE</td>
<td>T +1-404-577-1980  F +1-404-688-3706</td>
<td>9 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>#8 Days Inn</td>
<td>300 Spring Street</td>
<td>T +1-404-523-1144  F +1-404-522-1694</td>
<td>5 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>#9 Holiday Inn Atlanta Downtown</td>
<td>101 Andrew Young International Boulevard</td>
<td>T +1-404-524-5555  F +1-404-221-0702</td>
<td>3 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>#10 Sheraton Atlanta</td>
<td>165 Courtland Street</td>
<td>T +1-404-659-6500  F +1-404-524-1259</td>
<td>9 blocks</td>
<td>Yes</td>
</tr>
</tbody>
</table>
These activities provide an opportunity to enjoy the Atlanta area. A registration form follows on page 117, or you can register online. Log on to www.diahome.org, click the Annual Meeting icon, click the Networking Opportunities tab at the top of the screen, and select Tours. All tours depart from and return to the Georgia World Congress Center and will take place rain or shine.

STONE MOUNTAIN PARK
Sunday, June 17, 2007 • 11:00 am-5:00 pm
$72.00 per person

The largest bas-relief sculpture in the world, the Confederate Memorial Carving pays tribute to three Civil War heroes – Confederate President Jefferson Davis and Generals Robert E. Lee and Thomas J. “Stonewall” Jackson.

The rock’s top attraction is The Summit Skyride. This high-speed Swiss cable car provides a stunning view of the Confederate Memorial Carving as it transports guests more than 825 feet above ground to the top of Stone Mountain.

Visit the Antebellum Plantation and Farmyard to enjoy scenes of life in the 1800s. At the Stone Mountain Museum at Memorial Hall guests see and hear the story behind Stone Mountain and view true-to-scale elements from the world’s largest relief carving.

Visit the Crossroads area and transport yourself to a 1870s Southern town bustling with activity. Take an exciting amphibious sightseeing experience on land and in water. You’ll find Duck tours entertaining and interactive, culminating with a big splash into Stone Mountain Lake.

A THIRST FOR ATLANTA
Sunday, June 17, 2007 • 1:00 pm-5:00 pm
$49.00 per person

The World of Coca-Cola is an experience unique to Atlanta that cannot be found anywhere else in the world. Catch the excitement through exhibits and unique architectural style. Pass under an enormous three-dimensional Coca-Cola globe suspended 18-feet above the entrance, and step into a spectacular three story, sky-lit atrium.

Guests move at their own pace through an easy-to-follow series of fun and fascinating exhibit galleries.

Guests depart the World of Coke and take a short drive to the CNN Center to enjoy a guided tour of the world-famous news studio. The studio tour features a number of behind-the-scenes demonstrations where guests learn how CNN makes images, like weather maps appear behind anchors and correspondents. Guests then take a guided tour of the 21-acre Centennial Olympic Park. The park, developed for the 1996 Summer Olympic Games, is the largest new City Park created in the United States in 20 years.

NOBELISTS OF GEORGIA
THIS TOUR HAS BEEN CANCELLED.
Monday, June 18, 2007 • 1:00 pm-5:00 pm

Celebrate the lives and principles of two Georgians who, using different paths, pursued a common goal: freedom and justice for all people. Both winners of the Nobel Peace Prize, Reverend Martin Luther King, Jr. and former President Jimmy Carter are best described as peace-makers. These two Georgians answered an individual calling to lead and motivate others in promoting fundamental human and civil rights for people around the world.
First, guests visit the Martin Luther King, Jr. National Historic Site located in the historic “Sweet Auburn” neighborhood. This site includes King’s birth home, the Ebenezer Baptist Church, and his gravesite. Guests can view in-depth exhibits of the civil rights movement and King’s life and legacy along with poignant documentaries.

After viewing the park, guests enjoy a short ride to the graceful Jimmy Carter Library and Museum. The museum includes photographs and memorabilia from the Carter presidency (1976-1981). The Jimmy Carter Library chronicles the Nobel Peace Prize winner’s White House years. Of particular interest are a replica of the Oval Office, Carter’s Nobel Peace Prize, a video on Camp David and presidential gifts from world leaders and constituents.

WELCOME TO TARA
Monday, June 18, 2007 • 5:30 pm-10:00 pm
$82.00 per person

As guests step into the grounds of Stately Oaks Plantation located in Jonesboro, Georgia, they almost believe that it’s 1863 and they are back in the days of Rhett and Scarlett. Stately Oaks has a history as expansive and magnificent as its rooms. The home, built in 1839 is the epitome of Southern history and hospitality. It served as the model for Tara, the home of the famous Scarlett O’Hara in Gone with the Wind. The plantation is a stunning example of the past. The home was moved to its present location from outside of Jonesboro and named for the large trees surrounding it. Previously, it had housed both Northern and Southern troops during the Civil War in 1864. Everything from the white columns to the rocking chairs on the porch represents Southern living in the nineteenth century.

Costumed docents give guests a full tour of the antebellum home allowing guests to step back two centuries to antebellum life. Guests tour the downstairs including the original log kitchen and the upstairs bedrooms. After the tour, guests shop Judy’s Country Store which dates from 1894 for some southern gifts to bring home. After shopping, guests view the grounds including the blacksmith’s cottage and are led into the authentic one-room school house for a delicious southern dinner buffet. While enjoying Peach Cobbler and coffee, guests are treated to stories of the south and Civil War by an entertaining storyteller.

FROM PAGE TO STAGE
THIS TOUR HAS BEEN CANCELLED.
Tuesday, June 19, 2007 • 9:30 am-1:30 pm

Guests visit the Atlanta of the past and present featuring an author and a dazzling theater. The tour begins with a narrated drive down Atlanta’s most famous street – Peachtree Street. As guests approach the Fox Theater, the tour guide points out the interesting architecture of this magnificent building. The “fabulous” Fox Theatre is one of the most lavish performing arts venues in the country. Guests explore the mysterious interior of the Fox Theatre, one of the few remaining exotic movie palaces of the 1920s. Middle Eastern and Egyptian designs create a dreamlike spectacle of grandeur. In addition to exceptional architectural design, the Fox Theatre also houses the second largest theater organ in the world, a Moller organ affectionately known as “Mighty Mo,” as well as its original period furniture collection.

Next is a visit to the treasured place that helped put Atlanta on the map. The story of Margaret Mitchell and her work is crucial to understanding the history and culture of the city she loved, and The Margaret Mitchell House and Museum stands as a testament to the past. From 1925 until 1932, Margaret Mitchell wrote her Pulitzer prize-winning novel, Gone with the Wind at her apartment in this home. Margaret Mitchell’s apartment is the only interior space of the restored house that is preserved as an apartment with all furnishings of the period. Architectural features include the famous leaded glass window out of which Margaret looked while writing.
VISIT THE CDC
This tour will be offered on both Tuesday and Wednesday. Be sure to select the desired day on the registration form.

THE CDC TOUR ON TUESDAY IS CLOSED.
Tuesday, June 19, 2007 • 1:00 pm-4:00 pm
$39.00 per person
Wednesday, June 20, 2007 • 1:00 pm-4:00 pm
$39.00 per person

Please note: A government-issued ID is required for entry into the CDC. The CDC does not allow access to the laboratories or research areas of the campus.

Celebrating its 60th year in 2006, it was founded in 1946 to help control malaria and has remained at the forefront of public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats. Guests enjoy the exhibit area of the CDC.

The “Global Symphony” features three, three-minute stories that describe in depth CDC’s contributions to the elimination of polio, the eradication of Legionnaire’s disease, and the battle to stem the rise of obesity in the United States. The stories are complemented by a wide range of statistics on public health topics ranging from HIV/AIDS to worker safety.

The “Roots of CDC” traces the origins and early history of CDC through 1976. The story is told through documents, photographs and objects such as an early 20th century quarantine sign, the microscope of Dr. Joseph Mountin – the founder of CDC, early CDC bulletins, and an iron lung.

The featured traveling exhibit in June is “Deadly Medicine: Creating the Master Race”. Created by the U.S. Holocaust Memorial Museum, this exhibition explores the history of Nazi eugenic programs during the Third Reich and features artifacts, photographs, video testimonies and film footage.

After guests tour the permanent and traveling exhibits with a CDC guide, they enjoy a private speaker on a topic to be determined who will provide more insight into the CDC. A question and answer session will complete the CDC tour.

BUCKHEAD HOMES AND HISTORY
THIS TOUR HAS BEEN CANCELLED.
Wednesday, June 20, 2007 • 9:30 am-1:30 pm

Buckhead has a reputation as Atlanta’s most affluent and elegant district. But its name preserves the legacy of its frontier beginnings, when hunting in the virgin forests was the main local enterprise. Now Buckhead is the jewel of Atlanta, an area of gracious homes, elegant hotels, shopping centers and some of the cities best restaurants.

A drive along West Paces Ferry Road provides a view of the most exclusive homes in Atlanta. The first stop is Georgia’s elegant Governor’s Mansion, a stunning example of Classical Revival architecture. After a short drive, guests arrive at the Atlanta History Center which features a museum housing memorabilia from Atlanta’s past. The exhibits are open for guests to experience the Civil War, Georgia’s Native Americans, the legendary Atlanta golfer Bobby Jones, and the newest exhibit on the 1996 Centennial Olympic Games held in Atlanta.

After walking the beautiful grounds of the History Center, guests visit The Swan House, a former private home, built for Edward Inman and his wife in 1929. The Swan motif appears in every room of this 1920s masterpiece and the home sits on beautiful gardens.

In comparison, the Tullie Smith Farm, an Atlanta “plantation plain-style” farmhouse of the 1840s, has been completely restored and authentically furnished. It is an actual working farm one might have found around Atlanta before the Civil War complete with docents working the garden. Guests enjoy browsing among the several outbuildings, including a wonderful detached kitchen, a blacksmith shop and stables.
Optional Tours Registration Form

Drug Information Association  •  Atlanta, Georgia  •  June 17-20, 2007

ALL TOURS ARE BASED ON A MINIMUM OF 35 GUESTS. Tours must meet this minimum guest requirement in order to run. In the event tours don’t make this minimum, the tour will be cancelled and guests will receive a full refund. The registration deadline is Monday, May 14, 2007. All requests for refunds must be received prior to this date. No refunds will be accepted after this date.

Please RETURN THIS FORM, WITH CHECK ATTACHED, OR CREDIT CARD DETAILS COMPLETED (US funds only) to:


Make checks payable to: PRA Destination Management Atlanta, 3525 Piedmont Road, Five Piedmont Center, Suite 300, Atlanta, GA 30305, USA
Tel. (404) 760-4229  •  Fax (404) 264-1956

Tour tickets may be picked up at the Tour Registration Desk located in the GWCC registration area. Please indicate the quantity of tickets for each activity.

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Tour Title</th>
<th>Price per Person</th>
<th>Number of Persons</th>
<th>Amount Due per Tour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sunday, June 17</td>
<td>Stone Mountain Park</td>
<td>$ 72.00</td>
<td>x</td>
<td>$ _____________________</td>
</tr>
<tr>
<td>1:00 pm-5:00 pm</td>
<td>A Thirst for Atlanta</td>
<td>$ 49.00</td>
<td>x</td>
<td>$ _____________________</td>
</tr>
<tr>
<td>Monday, June 18</td>
<td>Nobelists of Georgia</td>
<td></td>
<td>x</td>
<td>$ _____________________</td>
</tr>
<tr>
<td>5:30 pm to 10:00 pm</td>
<td>Welcome to Tara</td>
<td>$ 82.00</td>
<td>x</td>
<td>$ _____________________</td>
</tr>
<tr>
<td>Tuesday, June 19</td>
<td>From Page to Stage</td>
<td></td>
<td>x</td>
<td>$ _____________________</td>
</tr>
<tr>
<td>Wednesday, June 20</td>
<td>Buckhead Homes and History</td>
<td>$ 39.00</td>
<td>x</td>
<td>$ _____________________</td>
</tr>
</tbody>
</table>

TOTAL # of TICKETS TOTAL AMOUNT DUE

___________________ = $ _____________________

WAIVER

Enclosed are funds in the amount of $ ______________ as full payment for the Tour Program. I understand that this is non-refundable after May 14, 2007, unless the minimum number of participants required to operate the tour is not met. Neither PRA Atlanta, nor DIA is responsible for lost or damaged articles, traffic delays, accidents, strikes, riots, war, governmental action or regulation, acts of God, or other causes over which the parties have no control. In the event any or all of the Tours are canceled because of reasons beyond the parties’ control, neither party shall incur any liability or obligation, and PRA Atlanta shall refund all deposits to participants. I further represent that I (and/or my children) am (are) in proper physical condition to participate in all requested activities and waive all claims for myself, my heirs, and assigns against Atlanta, DIA and all event sponsors and their representatives, successors, and assigns for any injury or illness which may result from my (or my children’s) participation.

Signature of participant ___________________________________ ______________________________________________ Date _________ ______________

Completed Forms may be FAXED to (404) 264-1956 or follow the instructions on page 114 to register for tours online.
ATTENDEE REGISTRATION FORM

43rd ANNUAL MEETING  ID #07001 June 17-21, 2007, Atlanta, GA, USA

This registration form should be used by paying ATTENDEES ONLY. If paying by credit card, return this completed form to DIA by mail to 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA or by fax to +1-215-442-6199. 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 11, 2007 will be 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  AX  Exp. Date

- 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 or before June 1, 2007. Registrants who do not cancel by June 1, 2007 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 1, 2007 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 1, 2007 = Full Refund

TUTORIAL CANCELLATION
On or before June 1, 2007 – Registration fee paid minus $75 = Refund Amount

ONE-DAY REGISTRATION
There will be NO REFUNDS given for cancellations of one-day registrations or one-day no shows.

PREREGISTRATION FEES
A surcharge of $150 has been included in the registration fees for ALL registrations received after JUNE 8, 2007 (does not apply to one-day registrations).

<table>
<thead>
<tr>
<th>Component</th>
<th>MEMBER</th>
<th>NONMEMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member Fee</td>
<td>US $1300</td>
<td>US $130</td>
</tr>
<tr>
<td>Join DIA now to qualify for the member fee and to enjoy the benefits of membership for a full year! <a href="http://www.diahome.org">www.diahome.org</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonmember Fee</td>
<td>US $1430</td>
<td>US $1430</td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I do ☐ I do NOT ☐ want to be a DIA member</td>
<td></td>
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</tr>
<tr>
<td>Discount Fees</td>
<td>MEMBER</td>
<td>NONMEMBER</td>
</tr>
<tr>
<td>Government (Full-time)</td>
<td>US $450</td>
<td>US $580</td>
</tr>
<tr>
<td>Charitable Nonprofit/Academia (Full-time)</td>
<td>US $825</td>
<td>US $955</td>
</tr>
<tr>
<td>*If paying a nonmember fee, please check one box above, indicating whether you want membership.</td>
<td></td>
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<tr>
<td>ONE-DAY REGISTRATION FEES</td>
<td>MEMBER</td>
<td>NONMEMBER</td>
</tr>
<tr>
<td>You must indicate which day you will attend.</td>
<td>US $690</td>
<td>US $820</td>
</tr>
<tr>
<td>Monday, June 18 ☐ Tuesday, June 19 ☐ Wednesday, June 20 ☐ Thursday, June 21 ☐</td>
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<td>*If paying a nonmember fee, please check one box above, indicating whether you want membership.</td>
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<tr>
<td>NETWORKING RECEPTION (Must be registered for meeting in order to attend)</td>
<td>US $70</td>
<td></td>
</tr>
<tr>
<td>Networking Reception Only is not available.</td>
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Applicable Meeting Registration Fee
Tutorial Registration Fee
Networking Reception Fee
TOTAL PAYMENT DUE

| Applicable Meeting Registration Fee | US $ ________________ |
| Tutorial Registration Fee | US $ ________________ |
| Networking Reception Fee | US $ ________________ |
| TOTAL PAYMENT DUE | US $ ________________ |

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<th>Last Name</th>
<th>First Name</th>
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<th>Degrees</th>
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<tbody>
<tr>
<td>Dr. ☐</td>
<td>Mr. ☐</td>
</tr>
<tr>
<td>Ms. ☐</td>
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<th>Company</th>
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<tr>
<th>Mailing Address</th>
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<table>
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<tr>
<th>City</th>
<th>State</th>
<th>Zip/Postal Code</th>
<th>Country</th>
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</table>

<table>
<thead>
<tr>
<th>Telephone #</th>
<th>Fax #</th>
<th>email (email address is required for confirmation)</th>
<th></th>
</tr>
</thead>
</table>
Add TUTORIALS and/or NETWORKING RECEPTION to an Existing Meeting Registration

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 change.

☐ 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. #07001 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 or before June 1, 2007. Registrants who do not cancel by June 1, 2007 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 1, 2007 will be processed as follows.

FULL MEETING 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 1, 2007 – Full Refund

TUTORIAL CANCELLATION On or before June 1, 2007 – Registration fee paid minus $75 = Refund Amount

ONE-DAY REGISTRATION There will be NO REFUNDS given for cancellations of one-day registrations or one-day no shows.

CANCELLATION POLICY

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 $70 ☐

Registration for Networking Reception Only is not available.

Please note the following:

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.

Please note that this page must be completed and submitted for each person attending any portion of this event.

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. I am registered as:
   ☐ Attendee ☐ Speaker ☐ Track Chair
   ☐ Session Chair ☐ Exhibit Personnel

☐ NO, I do not wish to register for the meeting, but I would like to register for the following Tutorials.

TUTORIALS

See pages 14-15 in the online brochure 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 __________________

TOTAL PAYMENT DUE US $ ____________________
EXHIBIT PERSONNEL REGISTRATION FORM

Exhibitors should return this form to the attention of the Exhibits Department at DIA.

43rd ANNUAL MEETING  ID #07001  June 17-20, 2007, Atlanta, GA 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 11, 2007 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

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 # __________________________

☐ 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.

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NETWORKING RECEPTION CANCELLATION On or before June 1, 2007 – Full Refund

TUTORIAL CANCELLATION On or before June 1, 2007 – Registration fee paid minus $75 – Refund Amount

Each 10’ x 10’ booth includes: one (1) complimentary full-meeting registration and three (3) exhibit booth personnel registrations.

Once you have utilized the four (4) badges provided per each 10’ x 10’ booth, any additional personnel must register as an attendee (not as an exhibitor).

Log on to www.diahome.org and download the ATTENDEE Registration Form, complete and return it as per the instructions on the form.

FULL-MEETING REGISTRATION (attendance of 2 or more days) includes admission to all 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 $690 for members and $820 for nonmembers.

TUTORIALS See pages 14-15 in the online brochure for the tutorial schedule and prices. 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

US $ 130 ☑

NETWORKING RECEPTION (Must be registered for meeting in order to attend) US $ 70 ☑

Registration for Networking Reception Only is not available.

TOTAL PAYMENT DUE US $ ________________

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Last Name  First Name  MI

Degrees

Job Title

Company

Mailing Address

City  State  Zip/Postal Code  Country

Telephone #  Fax #  email (email address is required for confirmation)

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