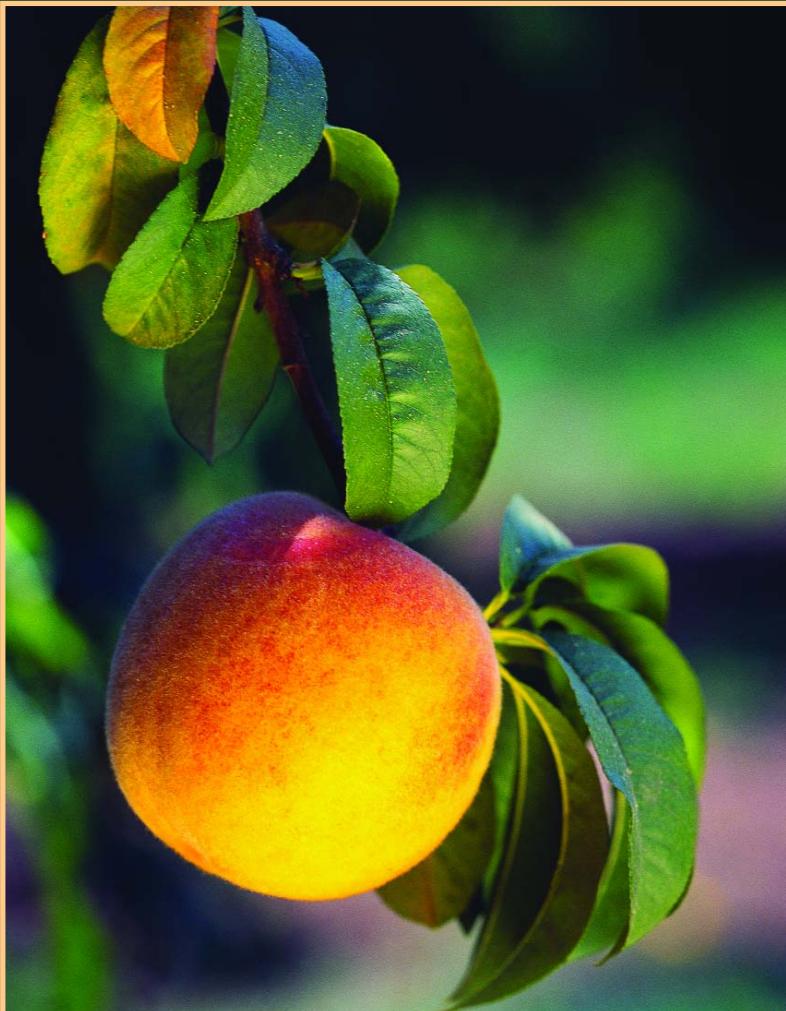


June 17-21, 2007 | Atlanta, Georgia

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

Program Chairperson



Alberto Grignolo, PhD

Alberto Grignolo, PhD, is Corporate Vice President and General Manager of the Drug Development Consulting Practice in PAREXEL Consulting. For the past fourteen years he has been responsible for PAREXEL's regulatory services, including worldwide drug development consulting and registration strategies and submissions, regulatory compliance and clinical quality assurance for pharmaceuticals, biologics and medical devices. He leads a worldwide

staff of professional consultants and advises clients in the areas of drug development strategy, regulatory negotiation and best regulatory practices.

Prior to joining PAREXEL, he served as President of FIDIA Pharmaceutical Corporation and held regulatory positions at SmithKline & French Laboratories. Having completed his undergraduate degree at Duke University, he earned his doctorate in Experimental Psychology from the University of North Carolina and conducted postdoctoral research in neuropharmacology at Duke University Medical Center.

Dr. Grignolo has been an active member of DIA since 1984, served on the board of DIA from 2000 until 2004, was the Chair of the Regulatory Track of the 2001, 2002 and 2003 DIA Annual Meetings and is an Instructor on the DIA Regulatory Training Faculty.

He serves on the Graduate Faculty of the Massachusetts College of Pharmacy and Health Sciences in Boston as an Adjunct Associate Professor.

A native European who has also lived in Latin America and speaks four languages, Dr. Grignolo is a frequent speaker, instructor, and participant at international conferences, seminars, workshops and courses on drug development, regulatory affairs and good clinical practice.

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

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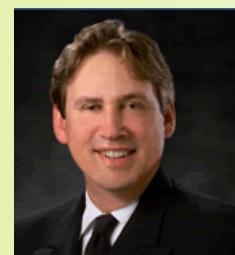
Keynote Speakers

DIA is pleased to announce two keynote speakers for the 43rd Annual Meeting Plenary Session on Monday, June 18 in the Thomas B. Murphy Ballroom. They will replace the originally scheduled speaker, Julie Gerberding.



Dr. James Canton is a renowned global futurist, social scientist, author, and sought-after business advisor. For the past twenty-five years, he has been insightfully forecasting the impact of future trends and innovations on business, customers and society. Dr. Canton is Chairman and CEO of the Institute for Global Futures, an internationally-recognized San Francisco-based think tank he founded in 1990, to help clients better anticipate the future. Dr. Canton advises Fortune 1000 corporations and governments worldwide. A highly sought-after public speaker, Dr. Canton has spoken to thousands of organizations on five

continents. He is noted for his unique and entertaining ability to blend fascinating forecasts of trends and breakthroughs that will shape the future. *Successful Meetings Magazine* named him as one of the top presenters in the nation.



In January 2006, **Bradley A. Perkins, MD, MBA**, was named the Acting Chief, Office of Strategy and Innovation (OSI), Office of the Director, Centers for Disease Control and Prevention (CDC). Dr. Perkins has served as the Deputy Director for OSI since May 2004. He joined CDC in 1989 as an Epidemic Intelligence Service Officer and has served in such capacities as Chief of the Meningitis and Special Pathogens Branch and Associate Director for Bioterrorism in the Division of Bacterial and Mycotic Diseases and, most recently, as Deputy Director of the Office of Strategy and Innovation.

◆ 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

◆ INFORMATION TECHNOLOGY

Paul A. Bleicher, MD, PhD
Phase Forward, USA
Barbara E. Tardiff, MD, MBA, MS
Merck & Co., Inc., USA
Srinivas Vangala
Forest Research Institute, 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
AESGP, 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
Craig A. Metz, PhD
GlaxoSmithKline, USA
Robert A. Paarberg, MS
UCB, Inc., USA
Lynne M. Tracey
P&G Pharmaceuticals, Inc., USA

◆ 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

Keynote Speaker



Julie Louise Gerberding, MD, MPH, is Director of the Centers for Disease Control and Prevention (CDC) and the Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR).

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.

Networking Reception back by popular demand...



The Georgia Aquarium

The change from a formal, sit-down dinner to a more informal networking reception was extremely well received in 2006. Comments indicated that the more informal reception encouraged attendees to interact with more of their colleagues and opened up more networking opportunities. This year, In addition to enjoying great food and a host bar, DIA guests will have exclusive access to the world's largest aquarium.

When?

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



Ocean Voyager

Where?

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

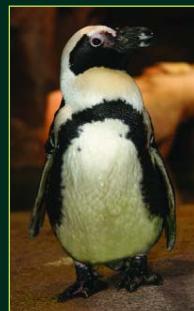
What is there to do at the Georgia Aquarium?

With more than eight million gallons of fresh and marine water, 100,000 animals representing 500 species from around the globe and more than 505,000 square feet of total space, you're sure to see things you've never seen before! The Georgia Aquarium promises wonder and excitement around every corner.



Ocean Voyager

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 60 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



Cold Water Quest

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.



Tropical Diver

What does it cost?

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!**



Ocean Voyager

*Please 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.

The DIA Experience – Connecting You to the Industry’s Best and Brightest

Meet the Attendees Who Have Benefited from the DIA Annual Meeting Since 1964!

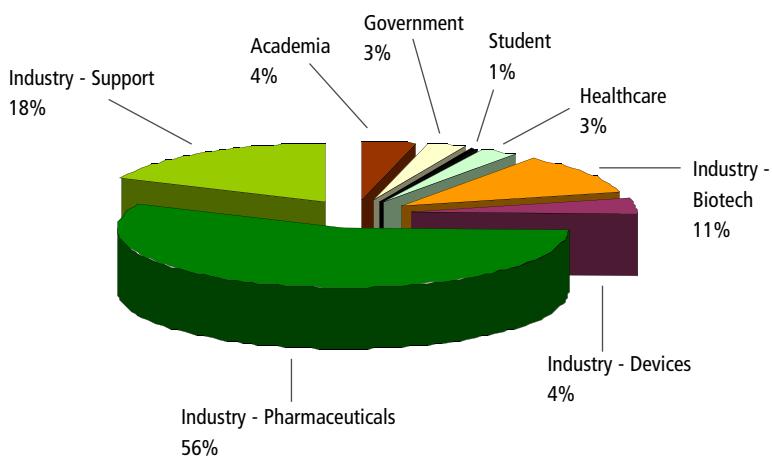
The DIA Annual Meeting is the event of the year for the pharmaceutical and related industries – and this year is no exception. With more than 1,000 speakers from the FDA, EMEA, and other regulatory agencies, 27 content-area tracks, and nearly 400 sessions, the 43rd Annual Meeting is geared to attendees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

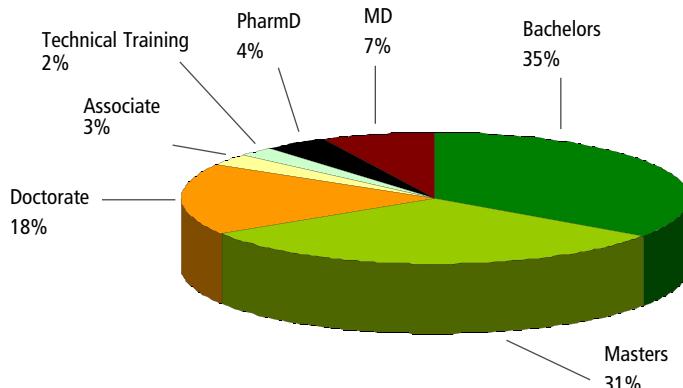
Professional Category



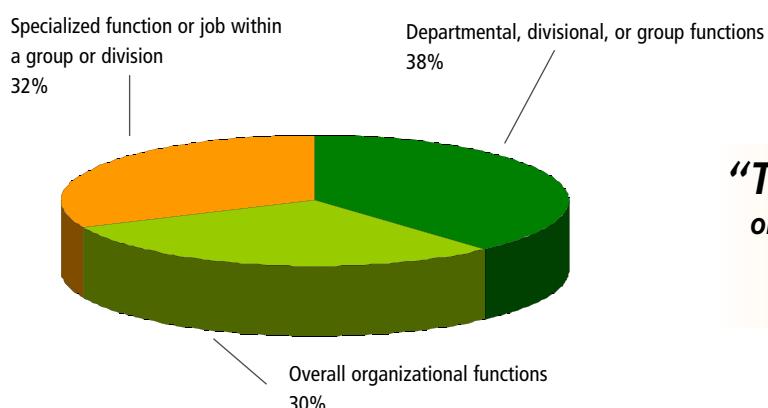
“The networking opportunities have opened up new doors, both personally and professionally.”

Partner, Health & Life Sciences Group, Accenture

Degrees Held



Level of Responsibility



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

Vice President, International Regulatory Affairs,
Wyeth Pharmaceuticals

Annual Meeting Highlights

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, FACP, 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, FACP, 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.

Cutting-edge Science Leading to Breakthrough Research

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?

General Information

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, MS 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.diahomes.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:

Saturday, June 16	All times are acceptable
Sunday, June 17	Only after 8:00 pm
Monday, June 18	Only after 6:00 pm
Tuesday, June 19	From 7:00 am-8:15 am and any time after 6:30 pm
Wednesday, June 20	From 7:00 am-8:15 am and any time after 5:00 pm
Thursday, June 21	From 7:00 am-8:15 am and any time after 12:00 pm

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@diahomes.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 is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants may earn up to 26 contact hours or 2.6 continuing education units (CEUs) for participating in the tutorials and annual meeting sessions.



The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA 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.diahomes.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

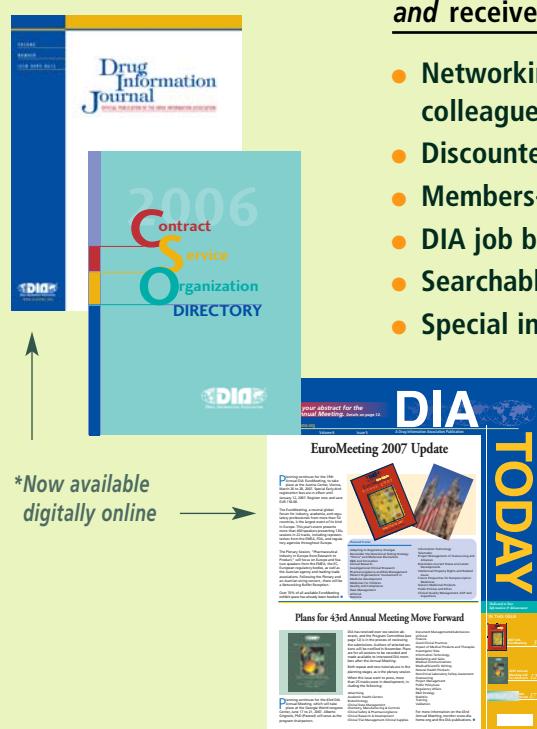
Register as a **NONMEMBER** and attend the 2007 Annual Meeting for

\$1280

OR

Register and become a **MEMBER** and attend the 2007 Annual Meeting for

\$1280



To join the DIA network, please visit the Membership & Communities page on www.diahomes.org

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**

Getting to Atlanta

Nation's "Best" Airport: The mission of Hartsfield-Jackson 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 1-866-68EVENT (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:

	One-Way	Round Trip
To GWCC	\$16.50	\$29
To Downtown	\$16.50	\$29
To Midtown	\$18.50	\$33
To Buckhead	\$20.50	\$37

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.diahome.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@diahomes.org or +1-215-442-6128

— EXHIBITS

Exhibiting companies A-L, product locator, or company summary book:

Jeff.Korn@diahomes.org or +1-215-442-6144

Exhibiting companies M-Z, exhibitor mailings, or exhibitor kiosk:

Erin.Gilliland@diahomes.org or +1-215-442-6149

Hotel room drops: Eileen.Roth@diahomes.org or +1-215-442-6191

Hospitality suites or vendor events:

Bryinne.Hunter@diahomes.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 Bryinne.Hunter@diahomes.org or +1-215-442-6122

— JOB POSTINGS/EMPLOYMENT OPPORTUNITIES

Nontechnical questions: Vicki.Adkinson@diahomes.org or +1-215-442-6162

Technical questions: Madel.Meneses@diahomes.org or +1-215-442-6148

— NETWORKING RECEPTION

Lori.Risboskin@diahomes.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

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Vicki.Adkinson@diahomes.org or +1-215-442-6162

Marilyn.Ginsberg@diahomes.org or +1-215-442-6135

— SPECIAL INTEREST AREA COMMUNITY (SIAC) EVENTS

Mary.Hildebrandt@diahomes.org or +1-215-442-6151

Mike.McGovern@diahomes.org or +1-215-442-6129

— SHUTTLE SERVICE

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

— TOURS

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

— TUTORIALS

Constance.Burnett@diahomes.org or +1-215-442-5800

CONTACT INFORMATION

DRUG INFORMATION ASSOCIATION

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email dia@diahomes.org
www.diahomes.org
Hours: Monday through Friday
8:00 am-5:00 pm EST

GEORGIA WORLD CONGRESS CENTER

<http://www.gwcc.com>

285 International Boulevard, NW
Atlanta, GA
USA
Tel +1-404-223-4000
www.gwcc.com

Tutorials (as of February 12, 2007)

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.diahomes.org for the latest information.

Track Titles and Acronyms

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

- 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.

Learning Objectives

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

- Identify the different types of work group structures and be able to predict the quality of work the group will produce
- Identify and correct dysfunctional group dynamics
- Create and maintain cooperation among team members including cross-functional teams
- Demonstrate an effective response to distracting influences on group work to minimize impact on quality of work

Target Audience

This tutorial is designed for individuals who must manage group activities on a permanent or project basis, for those who must work on teams but are not in charge of the teams and are interested in learning how to exert influence over group behavior, and for individuals to whom project managers report.

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

Tutorial #33

CR, MW, RA

The Investigator's Brochure: Best Practices for Writing and Updating**Peggy M. Boe, RN**

Director, Professional Services and Medical Writing, Image Solutions, Inc.

Sandra J. Hecker, RAC

President, Hecker & Associates, LLC

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

The Investigator's Brochure (IB) is all too often written as a required submission document without consideration of how, and by whom it will be used. IBs are updated as needed, but text often accumulates to the extent that the IB is almost useless as a practical tool for trial site investigators and the sponsor's regulatory writers. The IB should be regarded as one of the most important clinical operations tools for providing an ongoing, objective assessment of the benefits and risks of a product from the first Phase 1 trial through draft labeling and NDA.

This tutorial will identify the target audience for an IB as well as best practice points for creating a new IB and updating it with new trial data, and points on how to tailor the IB to support future labeling content.

Learning Objectives

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

- Describe the true purpose of writing and updating the IB
- List three best practices for updating an IB
- Create an outline for the IB that will support future labeling text

Target Audience

This tutorial is designed for people who are involved in writing or reviewing an IB for the pharmaceutical or biotechnology industry, including medical writers, regulatory affairs, and nonclinical or clinical operations personnel.

Tutorial #34

CR, CTM/CS, PM

Project Management for the Nonproject Manager**Robert L. Judd**

CEO, Robert Judd Associates (RJA)

.3 IACET CEUs

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:

- Decide when work effort should be treated as a project
- Use the four-step model to manage projects
- Apply motivational and team-building techniques to gain support and buy-in
- Employ practical leadership and communication skills to ensure coordination and collaboration during the project

Target Audience

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

Tutorial #35

CR, PM, RA

The Scientific and Economic Benefits of Flexible Adaptive Trials Methodology Designed to Achieve Early Registration and Robust Results: Raptiva® as a Case Study**Cyrus R Mehta, PhD**

Professor of Biostatistics, Harvard University

.3 IACET CEUs

This tutorial will focus on one innovative adaptive design that has recently been employed and will highlight its benefits for achieving early registration and robust results. The main challenge of the Clinical Experience Acquired with Raptiva® in Europe (CLEAR) study was to establish overall efficacy in patients with moderate or severe psoriasis as early as possible while simultaneously ensuring that the sample size was adequate to establish efficacy in a "high need" subgroup. Because of limited prior experience, these two goals could not be met by conducting a large traditional fixed sample trial. The flexible adaptive design was applied and utilized, gaining European regulatory approval while optimizing costs and timelines. A single trial was planned with no opportunity to replicate the results in the postmarketing environment. Tremendous value was placed on convincing the treating physicians and reimbursement payers of the robustness of the findings. Therefore, a longitudinal trial was designed with flexibility to alter the duration of patient follow-up and thereby increase the chances of successes.

Learning Objectives

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

- Describe the adaptive design for clinical trials including sample size adjustment, examples of modifications, statistical concepts and methodologies
- Discuss the challenges and results of the Clinical Experience Acquired with Raptiva® in Europe (CLEAR) study
- Explain the clinical trial design and development; and provide the scientific and economic benefits of the flexible adaptive trial design applied in the RAPTIVA clinical trial

Target Audience

This tutorial is designed for pharmaceutical professionals in clinical research, project management, biostatistics, regulatory affairs and related fields.

Tutorials

Sunday, June 17, 2007	9:00 am-5:00 pm
Tutorials #40 through #45	Fee \$650

Tutorial #40 *CR, MC, MW*

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 course work, or on-the-job experience) that is equivalent to an introductory statistics course. While a few formulae are included for individuals who are interested in computational details, the overall emphasis of the tutorial will be on the application of statistical concepts to clinical investigation.

Learning Objectives

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

- Discuss basic statistical concepts such as variability, confidence intervals, hypothesis testing and p-values
- Compare and contrast various study designs and identify techniques to avoid bias
- Use basic statistical terminology with ease
- Discuss information needed for determining sample size

Target Audience

This tutorial is designed for professionals in the pharmaceutical industry involved in clinical research, medical affairs, medical writing, and other disciplines who need to be familiar with statistical concepts.

Tutorial #41 *CR, GCP, RA*

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.

Learning Objectives

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

- Recognize the applicable EU regulatory requirements for the conduct of clinical trials in Europe
- Analyze the impact of these regulations on drug development programs and company SOPs
- Assess European drug safety reporting requirements from clinical trials
- Plan, improve and manage their future clinical trials

Target Audience

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

Tutorial #42 *CR*

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 regimens 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:
 - a. Clearance
 - b. Volume of distribution
 - c. Half-life
 - d. Relative and absolute bioavailability
 - e. Steady state
 - f. Population pharmacokinetics/pharmacodynamics
2. Define the following pharmacodynamics concepts:
 - a. Emax
 - b. EC50
 - c. Direct and indirect response models
3. Discuss differences between linear and 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 *CP, RA, TR*

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.

Tutorial #44 *CR, CTM/CS, PM*

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.

Tutorial #45 *CR, CTM/CS, PM*

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.

Sunday, June 17, 2007

8:30 am-12:00 pm

Tutorials #50 through #59

Fee \$375

Tutorial #50

CP, GCP, RA

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.

Tutorials

This tutorial will offer participants an opportunity to learn how a pharmacovigilance audit captures the requirements of all applicable regulatory bodies, 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.

Tutorial #51

RA, RD

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.

Tutorial #52

CR, MW, RA

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.

Tutorial #53

RA

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, FRCPC**

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 extended-release microparticulate formulations may have broad safety and efficacy implications. The detection of a pharmacokinetic 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

.3 IACET CEUs

This tutorial will explore the process of market access for prescription drugs and biologics in Canada. The process will be followed through a Notice of Compliance (NOC) and a Patent Exclusivity Order of Compliance. Time frames for reviews will be discussed, and the respective processes for drugs and biologics 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.

Tutorials

Tutorial #57

CDM, CR, EC, PM

eClinical: Optimizing the Clinical Trial Process

David P. Iberson-Hurst

Chief Executive Officer, Assero Limited, UK

.3 IACET CEUs

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

CP, EC, IT

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

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs; 286-000-07-504-L04;
3.25 pharmacy contact hours (.325 CEUs)

SPL relies on structured markup. This is more than just another kind of word-processing, its unusual characteristics have significant publishing benefits. To make easy use of these benefits you need to know what they are, and how they are achieved. The first part of this tutorial introduces the differences between structured-markup and word-processing environments. Then we look in detail at SPL markup and processing, with attention to checking tools that can assist in finding and correcting file errors.

Learning Objectives

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

- 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 #59

CDM, CP

Best Practices Using MedDRA®

JoAnn Medbery, RN

Director, Dictionary Management Systems, Johnson & Johnson Benefit Risk Management

.3 IACET CEUs

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

Learning Objectives

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

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

Target Audience

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

Sunday, June 17, 2007

1:00-4:30 pm

Tutorials #70 through #87

Fee \$375

Tutorial #70

CTM/CS, GCP, RA

FDA Enforcement: Understanding the Agency's Authority, How Violations Occur, How to Prevent Them, and How to Respond If Violations Do Occur

Michael A. Swit, Esq., JD

Vice President, Life Sciences, The Weinberg Group, Inc.

.3 IACET CEUs

This tutorial will review and discuss the legal, regulatory, and practical nuances of (1) FDA enforcement priorities for 2007 and beyond (e.g., application of data integrity policy and GMP/GCP requirements), (2) FDA administrative enforcement weapons and how the Agency uses them (e.g., inspections, warning letters, publicity, recalls, and investigator disqualification proceedings), and (3) the civil and criminal penalties for violations (e.g., seizure, injunction, criminal prosecution). It will also address how to handle an FDA enforcement action should you face one, particularly in the wake of an inspection or warning letter. These interactive discussions will focus on how FDA operates and makes decisions and how to respond effectively, using tactics ranging from negotiation to, when appropriate, litigation.

Learning Objectives

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

- Discuss FDA's enforcement priorities for 2007 and beyond
- Describe FDA's compliance review and decision-making process
- Identify the legal risks and penalties for noncompliance
- Respond appropriately to FDA enforcement

Target Audience

This tutorial is designed for all personnel responsible for ensuring compliance with FDA requirements, particularly those under the GMP and GCP rules, regardless of whether in a supervisory or direct role.

Tutorial #71 CP, RA

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 CR, PM, RA

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 CR, MW, ST

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 CP, CR, GCP, RA

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

Tutorials

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.

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 Credit(s)TM; .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

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

- 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.

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:

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

- 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.

Tutorial #77

CR, RA, RD

Collecting Abuse Liability Data During CNS Drug Development

Edward M. Sellers, MD, PhD, FRCPC

President and CEO, Ventana Clinical Research Corporation

Kerri Schoedel, PhD

Research Scientist, Ventana Clinical Research Corporation

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

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

- 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

CR, PM

Development of Stem Cells-based Therapeutics, including Human Embryonic Stem Cells, from Proof of Concept to Clinical Trials**Judi Weissinger, PhD**

President and CEO, Weissinger Solutions, Inc.

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

To date, stem cells have been derived from adult cells, and numerous human embryonic stem cell (hESCs) lines have been derived from donated excess material from 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 therapeutics from their early discovery, proof of concept studies, preclinical investigations, and manufacture for clinical application
- Identify regulatory pathways that must be considered in developing the new stem and hES cell-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

CTM/CS, GCP, IS

Maximizing the Impact of Clinical Site Monitors**Ken Light, MS**

Solutions Partner, BusinessEdge Solutions, Inc.

Geoff Garabedian

Solutions Partner, BusinessEdge Solutions, Inc.

.3 IACET CEUs

Until recently, the role of the site monitor on the conduct of the study has been undervalued. 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 advantages of process optimization, technology improvements, and onsite representation can positively impact the investigator relationship and gain a significant advantage for their studies over companies that follow the status quo in their site monitoring activities.

Learning Objectives

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

- Recognize how a monitoring organization can positively impact the relationship with the site to gain a significant advantage for their studies
- Describe the evolving role of site monitors as educators, relationship builders, and conduits to the quality conduct of a clinical study

- 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.

Tutorial #80

CR, CTM/CS

Randomization and Trial Supply Management Using IVR: A Tutorial for Study Teams**Nikki Dowlman, PhD, DSc**

Product Development Manager, ClinPhone Limited

Graham Nicholls

Product Development Manager, ClinPhone Limited

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

The tutorial will start with an overview of how IVR can be used to manage randomization of patients in a clinical trial supply chain. It will cover the basic concepts of randomization methodologies including 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 packaging 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:

- 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 study teams working with or considering the use of IVR systems. The material will be aimed at a basic entry-level audience and build knowledge and understanding throughout the tutorial via discussion, brainstorming, presentations, and exercises. The tutorial is further aimed at providing clinical trial leaders, therapy area heads, program managers, clinical supply managers, supplies coordinators, statisticians, and IVR/IWR outsourcing managers with the necessary tools to implement IVR/IWR successfully in their clinical trial.

Tutorials

Tutorial #81

CR, RA, RD

Pharmacogenomics as a Tool to Accelerate Drug Development

William Lee, PhD, RAC

Senior Regulatory Scientist, Cato Research

Michael P. Murphy, MSc

President and CEO, Gentrис Corporation

.3 IACET CEUs

Pharmacogenomics is a tool for accelerating drug development. New tools are currently being developed for use in clinical trials in order to: 1) enrich trials with specific patient types, 2) stratify patients according to disease response, and 3) exclude patients who will experience adverse events based on their genotype. Pharmacogenomics as a tool for use in clinical trials has been endorsed by the FDA, and Guidance documents have been released regarding the submission to the FDA of pharmacogenomic data from clinical trials.

This tutorial will focus on utilizing pharmacogenomics when designing protocols for clinical trials, regulatory requirements for submitting pharmacogenomic data to the FDA, and highlight areas where time and cost have been reduced by utilizing pharmacogenomics.

Learning Objectives

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

- Recognize the influence of pharmacogenomics to accelerate drug development
- Apply pharmacogenomics in designing clinical trials

Target Audience

This tutorial is designed for clinical scientists and regulatory associates.

Tutorial #82

CR, IS, MW, PM

Introduction to Biomedical and Health Informatics

H. Dominic Covvey

Professor, NSERC/Agfa Research Chair in Health Informatics

Director, Waterloo Institute for Health Informatics Research, Canada

John H. Holmes, PhD

Assistant Professor of Medical Informatics in Epidemiology at HUP Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine

.3 IACET CEUs

This tutorial will introduce the participant to the knowledge of informatics to the participant. It will introduce the applications of this discipline by examining what the discipline is about and how it helps address key challenges in the health field. Major objectives of the tutorial include enhancing the value of the conference to the participant and helping the participant discover specific topics of interest that can be explored both during and after the conference. This tutorial targets the high profile areas of informatics such as clinical or health care informatics, bioinformatics, and public health informatics, and points the participants in the direction of broader and deeper enquiry. It will also point the participant to online AMIA and other resources to enhance this tutorial.

This tutorial was developed by the American Medical Informatics Association (AMIA).

Learning Objectives:

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

- Discuss the current landscape of the science and practice of health informatics
- Explain how to better determine and define your areas of interest in informatics
- Identify and utilize health informatics information resources

Target Audience

This tutorial is designed for healthcare professionals (physicians, nurses, and allied professionals), health system administrators, CIOs and managers, medical librarians, other information professionals, and academics from other fields interested in health informatics.

Tutorial #83

CR, PM, RA

Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in EU

Brenton James, FTOPRA

Consultant in Strategic Regulatory Affairs in the European Union

.3 IACET CEUs

This tutorial will present an overview of the evolution of the registration procedures for medicinal products (prescription, generics and consumer health) in the European Union since 1995.

It reviews the Centralized, Mutual Recognition, and Decentralized Procedures in detail, and discusses major changes introduced in November 2005. Regulatory strategy as it effects commercial and business arrangements will be described.

Learning Objectives

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

- Explain the procedures for registration on medicinal products in the European Union and recognize what route is available for each type of product
- Discuss the key issues concerning the registration procedures, including patents, trademarks, co-marketing and co-promotion
- Identify the major changes to regulatory affairs in EU
 - Conditional approval
 - Accelerated assessment
 - Sunset clause
 - Market exclusivity (8+2+1)
 - Transparency introduced by the New Medicines Legislation

Target Audience

This tutorial is designed for professionals in regulatory affairs, clinical research, project management and related fields.

Tutorial #84

CR, RA, TR

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 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 #85

CR, MC, RA

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 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 #86

CDM, CR, IT

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

CP, RA

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 the EEA and responsibilities of the qualified person responsible for pharmacovigilance, as well as the requirements for establishing a 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.

Meeting Schedule

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.

Track Titles and Acronyms

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

Monday, June 18, 8:30 am-10:00 am

ALL Plenary Session

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

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

OS **CR** Lessons Learned: A Nonconfrontational Technique to Improve Sponsor-provider Team Performance – Part 1 of 2

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

AD	RA	How Fraud and Abuse Cases Are Changing the Corporate Landscape
CDM	EC	Case Studies on Time-critical Data Access Using Phase 1 EDC Programs by a Sponsor, Site and Software Provider

Meeting Schedule

CP1	RD	Selection, Implementation and Validation of Vendor Safety Systems	CP2	IMP	Approaches to Quantifying Benefit-risk Assessments: Going beyond Intuition
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 2 of 2
CR1	RA	Personalized Medicine and Personalized Drug Development: Case Studies and Progress to Date – Part 1 of 2	CR2	CTM/CS	Applying Lean and Six Sigma to Eliminate Waste and Streamline Planning and Execution of Clinical Trials
CR2	PM	Targeted Site Start-up Support Strategy in Clinical Research	CR3	RD	Improving Success of Psychopharmacological Clinical Trials: A Path to Failure
CR3	GCP	Regulatory Requirements in Late Phase Studies: Do We Really Know What They Are?	CTM/CS	CR	Research into the Use of Productive Metrics to Determine Clinical Performance
CTM/CS	CR	Clinical Trials in Asia Pacific: Advantages and Challenges	EC	IT	Crossing the BRIDG to the Future: Implementation Case Studies of the HL7/CDISC BRIDG Model
ERS/DM	RA	FDA: eCTD Compliance – Part 2 of 2	ERS/DM	CDM	International eCTDs: An Update on the US and European Regulatory Authority Experience
FI	RD	Sustainability of Pharmaceutical Development Pipelines	GCP	CR	Pediatric Research: Updates and Perspectives to Increase Quality from around the Industry
GCP	CR	Conducting Effective CAPA Following an Audit	IS	CTM/CS	Recruitment and Retention Strategies and Solutions for Clinical Trials: What Works, What Does Not, and Why, with a Focus on Ethnic Minority Populations
IS	CTM/CS	Investigator Budgets and Reimbursement: The Impact on Patient Enrollment and Retention Objectives	IT	CDM	The Implementation of Biological Sample Management and Biobanking Systems
IT	CDM	Clinical Data Warehouse: Approaches and Pitfalls	MW	RA	The Evolving Role of the Investigator Brochure in Global Submissions
MW	EC	The HL7/CDISC Glossary: Mapping the R&D Process with a Common Vocabulary	NHP	MA	International NHP Initiatives
OS	CR	Lessons Learned: A Nonconfrontational Technique to Improve Sponsor-provider Team Performance – Part 2 of 2	OS1	RA	India: An Emerging Clinical Research Destination – Challenges and Advantages
PM1	RD	Utilization of Six Sigma Methodology in a Research and Development Setting	OS2	RD	R&D Outsourcing in Japan: Maturing, but at a Japanese Pace
PM2	RD	Integrated US/Japan Effective Team Management	PM1	CMC/GMP	Case Studies of Critical Chain Project Management in the Pharmaceutical Industry
PP	RA	Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials	PM2	FI	Alliance Management: Principles and Practices
RA1	IS	Site Selection Risk Models for FDA Inspections and Theoretical Considerations	PP	RA	Civil and Criminal Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials?
RA2	PP	FDA Regulations and Guidances: How to Make Comments Count	RA1	CR	How to Communicate Added Value
RA3	RD	Good Review Management Principles (GRMPs): How Far Have We Come?	RA2	PP	Fourth Update: US-EU Agreement Regarding Exchange of Information among Regulators
RA4	CP	Strengthening the Infrastructure: Supporting Drug Safety Policy Development, Risk Communication and Healthcare Community Outreach	RA3	RD	Achieving a Global Trademark
RA5	PM	Effective Milestone Meetings with FDA	RA4	CP	The Evolution of Risk Management Plans
RD	CR	Mapping the Clinical Investigator Landscape	RA5	ERS/DM	Five-year Update on Regulatory Intelligence Utilization by Industry: 2002 to 2007 and Three Industry Examples of RegIntel Programs
ST	CR	Design and Analysis Issues in Analgesic Trials	RD	PP	Emerging Trends in the Economics of New Drug Development
TR	GCP	Bringing Global Staff to Headquarters for Training	TR	CR	eClinical Meets eLearning: Theory to Practice to Best Practice

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

AD	MC	FDA, Fair Balance, and False Claims: If and How Industry Can Provide Product Education
CDM	CR	Meeting the Challenges for Data Monitoring Committees
CMC/GMP	RA	CMC Regulatory Agreement
CP1	CDM	Electronic Case Safety Reports: Considerations in Europe Following Issue of Volume 9A

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

CMC/GMP	RA	Update on FDA Initiatives for Postapproval CMC Changes	CP1	RA	Regulatory Inspections of Industry Pharmacovigilance Operations
Multitrack Plenary					
CP & CR (AHC, PP, RA)		Drug Safety Reform: Actions and Implications	CP2	IMP	Risk Management for Vaccine Products
CR1	IS	Results of a Survey among Sponsors Examining Best Practices in Investigator Meetings	CR1	PM	Pediatric Clinical Trials: Lessons Learned from the Field
CR2	RD	Common Issues and Solutions for Thorough QT ECG Trial Design	CR2	CTM/CS	Update to Radical Change in Clinical Development
CTM/CS	GCP	Multinational Clinical Trials in China	CR3	RD	Assessing the Impact of Increasing Protocol Complexity on Study Conduct Performance
EC	IT	NIH Roadmap Program and Development of Therapeutic Area Data Standards: Case Studies in TB and Cardiology	CTM/CS1	IS	Recruitment of Minority Sites for Clinical Trials
ERS/DM	CDM	eCTD for Small Pharma	CTM/CS2	CR	Finding Top Performing Sites: A Considered Approach
GCP	CR	How to Be Prepared for an FDA Audit	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
IMP	EC	Clinical Endpoint (PRO, CRO, ePRO) Validation: The State of the Science	ERS/DM1	CDM	Structured Product Labeling: An FDA Update and the Industry Perspective
IS	GCP	IRB Site Visits and Audits	ERS/DM2	CDM	Records Management
IT	CDM	Utilizing Open-source Software in GCP-compliant Environments	GCP	CR	Good Clinical Practices (GCPs) and ISO 9000: A Winning Combination
MC	MW	Standardizing Information Sharing between Medical Information Professionals and Regional Medical Liaisons by Developing Tools to Ensure Compliance and Consistency	IMP	CP	Data Mining: Perils, Pitfalls and Pragmatism
MW	RA	CTD Summaries as Key Reviewer Tools	IS	CTM/CS	Feet on the Street: Using Community Outreach to Recruit Study Subjects
OS	CR	Benefits and Challenges of Implementing Standards in Outsourced Studies	IT	CDM	Protecting Intellectual Property
PM1	RD	Driving Growth and Innovation through Portfolio Management	MC	MA	Establishing Principles to Support Co-marketed Products between Medical Information Departments
PM2	CTM/CS	PMs as Global Project CEOs and the Effective Project Manager's Tool Chest	MW	MC	Outsourcing On-shore and Off-shore
Multitrack Plenary					
PP & RA (AHC, CP, CR)		Drug Safety Reform: Actions and Implications	NHP	CP	Safety and Pharmacovigilance of Natural Health Products (NHPs): International Efforts
RA1	TR	Fast Track! Accelerated Approval! Priority Review! A Primer in US Regulatory Paths to Approval	OS	CR	Transforming Five New Clinical Development Strategies into Real Results and What We Can Learn from the Industries that Have Done It
RA2	MC	Maximizing the Benefits of Medicines Information through Readability Testing	PM	BT	Considerations in Managing the Development of a Biologic from Initiation through Life-cycle Management
RD	PM	Drug Development down the Road	PP	MC	Personal Health Records in Pharmaceutical Development
ST	IT	Open-source Statistical Software in Pharmaceutical Research and Development: Validation, Legal Issues, and Regulatory Requirements	RA1	PP	New Directions and Innovations in Canadian Drug Regulations: The Canadian Approach to Draw a Critical Path to Better Drug Regulations and Development
TR	GCP	Effective Training of Study Site Staff for Better Clinical Trials	RA2	GCP	Highlights Data Elements (HDEs): One-year Experience with Computer-processable Highlights for US Prescribing Information
Tuesday, June 19, 10:00 am-11:30 am					
AD	RA	Enforcement Update from the FDA	RA3	RD	Scientific Advice in the EU
BT	CR	Hot Topics in Biotechnology	RA4	CR	Combination Products: Preapproval Challenges and Opportunities – Part 1 of 2
CDM	CR	Convergence of Healthcare and Life Sciences: Enhancing the Value Chain	RD	OS	Globalization of Industry-sponsored Clinical Trials: Evidence on Recent Trends
CMC/GMP	RA	Lessons Learned from CMC Pilot Program: An FDA Perspective	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

Meeting Schedule

Tuesday, June 19, 2:00 pm-3:30 pm			Tuesday, June 19, 4:00 pm-5:30 pm		
AD	RA	Direct-to-consumer Update from the FDA	ST	CP	Statistics in Drug Safety and Health Economics and Outcomes Research: Anything in Common?
BT	CP	Transitioning from Stem Cell Research to Commercial Applications	TR	CR	Rapid Development/Rapid Delivery of eLearning Solutions to External Clinical Trial Personnel
CDM	CTM/CS	Outsourcing in Data Management: Thinking Global, but Still Acting Local?			
CMC/GMP	RA	Lessons Learned from CMC Pilot Program: An Industry Perspective			
CP1	IMP	Can Risk Communication Be Improved? Pitfalls and Progress			
CP2	CR	Postmarketing Safety Studies and Intensive Event Monitoring Techniques: What Have We Learned?			
CR1	CTM/CS	Patient Recruitment: Strategic Approaches to Optimize Outcomes			
CR2	NC	Renal Biomarker Qualification for Decision Making			
CR3	CTM	Clinical Trials Transparency: Issues, Perspectives and Goals			
CTM/CS	CR	Identifying and Overcoming Site Initiation Delays in Multinational Clinical Trials			
EC	CDM	Global Adoption of eClinical Technologies			
ERS/DM	RA	Second Annual CDER eSubmission Update			
GCP	CR	Working with and Managing Contract Auditors			
IMP	CR	Accident or the Potential of Saving Lives with Remote Ultrasound Technology			
IS	GCP	Hurricane Katrina: Lessons Learned One Year Later			
IT	CDM	Issues and Case Studies in Safety Data Migration			
MC	CR	Sharing Medical Information Online: Weighing the Risks versus Benefits			
MW	CP	Providing Data Displays to Support Communication of Safety Information			
NC	CR	Carcinogenicity Testing Database			
NHP	CMC/GMP	Developing NHPs as Drugs: CMC and Quality Control/Quality Assurance Considerations			
OS	CR	Improving CRO Negotiations to Accelerate Time to Market			
PM1	CP	Risk Management in Clinical Trials			
PM2	CR	Development of an Integrated Molecule and Nonmolecule Forecast			
PP	RA	Product Liability			
RA1	CR	Achieving Success in Registration: Avoiding Pitfalls in Drug Development			
RA2	TR	Good Review Practices in the US and Canada: A Comparison of Attempts to Standardize Product Review Practices among Regulatory Organizations			
RA3	CR	Best Practices in Preparing for and Participating in a Pre-IND Meeting			
RA4	CR	Combination Products: Preapproval Challenges and Opportunities – Part 2 of 2			
RD	RA	Japan Challenges to Global Simultaneous Drug Development: Adapting Japanese Environments to Worldwide Drug Development			

PP	GCP	Clinical Trial Registration: Are Registries Useful and User Friendly?
RA1	CR	Clinical Development of Oncology Drugs in Japan
RA2	CR	Fixed-dose Combination Products: Registration Strategies and Case Studies
RD	PM	Rainmaker for the Biopharmaceutical Industries in the Emerging Markets
ST	CR	Statistical Analysis with Missing Data
TR	CR	Training Investigators and Study Coordinators: Alternatives/Supplements to Investigator Meetings
VA	IT	Risk-based Software Validation Techniques

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?
CR2	IS	Ethnic Outreach and Inclusion in Clinical Trials and its Impact on the R&D Business, Regulatory and Clinical Development Process in the Pharmaceutical Industry
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 (PiE)
RA2	IMP	Imaging and Drug Development
RA3	BT	Biosimilars in Europe
RA4	CR	Outlook for Changes in Japanese Regulatory and Clinical Development Environment
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/DM	CDM	eCTD Life-cycle Management for Authors
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
RA4	CR	Critical Path in Japanese Drug Development Strategy Using Foreign Data
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, 8:30 am-10:00 am

AHC	TR	Opportunities for Global Clinical Trials in India: Prospects and Challenges
BT	CR	Gene Therapy: Challenges and Hurdles in Planning and Conducting Global Clinical Trials
CDM	IT	EHR Considerations for Clinical Data Management
CMC/GMP	RA	cGMPs and Manufacturing Modernization in the 21st Century
CP	CDM	Standardized MedDRA® Queries and the Data Retrieval and Presentation: Points to Consider Document
CR1	GCP	Successful Phase 1 Clinical Trials
CR2	CTM/CS	We Can Get a Lot Smarter about Site Monitoring and Data Analysis
CTM/CS	IS	The Great Debate: Can Site Performance Be Predicted?
ERS/DM	CDM	eCTD Standards: Now and the Future
GCP	CR	It Doesn't Need to Hurt: Meeting the Challenges of SOP Development
IT	EC	The Future of Information Technology in Clinical Development and R&D
NC	RA	Nonclinical Development of Nanopharmaceuticals: How Much Is Covered by Existing Guidance?
NHP	RA	Asia Strategy on the Research and Development and Regulation for the Modernization of Herbal Medicine

OS	CR	Functional Outsourcing: Beyond Data Management
PM1	GCP	Preparing Product Launch Teams Using a War Game Simulation
PP	FI	Strategies for Maximizing the Financial Portfolio through Intellectual Property
RA1		CDER Town Meeting – Part 1 of 2
RA2	EC	Implications of Patient-reported Outcomes Guidance on Electronically Collected (ePRO) Data
RA3	PM	Drug Development in Japan: Drug Development Models to Ensure Acceptance of Preclinical Data Requirements as Part of Global Drug Development
ST	CR	Adaptive Methods in Phase 2 Trials in Practice
TR	CR	Utilizing Training within a Mentor-protégé Approach: Clinical Trial Environment and Compliance to Regulatory Agencies
VA	IT	Red Apple II

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
CP	CDM	Adverse Event and Medication Error Coding: Is MedDRA® Up to the Task?
CR1	EC	Enhancing Patient Compliance in Clinical Trials with eTechnology
CR2	GCP	Practical Aspects of Implementing Adaptive Trials
CTM/CS	AHC	New Techniques for Maximizing Enrollment at Academic Health Centers
ERS/DM	CDM	IND in eCTD Format
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		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 Entrance 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
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Welcome and Awards Presentation



CYNTHIA L. KIRK, PhD, RAC

Vice President
Global Regulatory Affairs
PRA International, Inc.
President, DIA

Opening Remarks



ALBERTO GRIGNOLO, PhD

Corporate Vice President and
General Manager, Drug Development
Consulting Practice,
PAREXEL Consulting
2007 DIA Annual Meeting Chairperson

Keynote Address



JULIE GERBERDING, MD, MPH

Director, Centers for Disease Control
and Prevention (CDC) and Adminis-
trator, Agency of Toxic Substances
and Disease Registry (ATSDR)

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 LEVEL: ●

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

A Primer on Advertising Regulation

Kristin I. Davis, JD

Deputy Director, Division of Drug Marketing, Advertising and Communications, Office of Medical Policy, CDER, FDA

SESSION 102 CP - CLINICAL SAFETY AND PHARMACOVIGILANCE, CR

10:30 am-12:00 pm LEVEL: ■

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 premarketing 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 spontaneous 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-

tion is incomplete. FDA's 2005 "Good Pharmacovigilance Practices and Pharma-coepidemiologic Assessment" guidance emphasized good reporting practice. Improved ICSR quality is intertwined with optimal case assessment. Knowing of the underlying disease state under study or treatment, coupled with understanding of the agent's pharmacological properties and adverse event profile, is of necessity in performing high-quality case review.

Factors affecting healthcare professional reporting of adverse events will be reviewed, along with interventions designed to both stimulate reporting and foster higher quality reports (including targeted questioning) in both premarketing clinical trial and postmarketing pharmacovigilance realms. Harmonization of ICSR handling in global pharmaceutical companies through greater efficiency, and current challenges and controversies involving this critical compliance and risk management function, will also be discussed.

Interventions to Stimulate Reporting of Pharmaceutical-associated Adverse Events by Healthcare Professionals

Rohan Hammett, MBBS, FRACP

Principal Medical Adviser, Therapeutic Goods Administration, Australia

Fostering Quality Adverse Event Data in Pre- and Postmarketing Safety via Active Query and Applied Clinical Expertise

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

Individual Case Safety Report (ICSR) Handling: Challenges, Controversies and Possible Improvements

L. Paul Starkey, MD, FAAFP

Senior Medical Director, Medical and Safety Services, PRA International, Inc.

SESSION 103 CR1 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS

10:30 am-12:00 pm LEVEL: ■

Room B404 *CME credits offered*

Different Approaches: The Use of Key Enrollment Optimization Processes, Clinical Investigative Networks and eClinical Processes to Impact Clinical Trial Efficiency

SESSION CHAIRPERSON(S)

Michael A. Pozsgai, MLS

Global Enrollment Optimization Consultant, Eli Lilly and Company

Different approaches can be used to shorten the trial initiation phase, increase FPV milestone compliance, maintaining steady enrollment rates throughout the life of the trial and increasing overall trial quality and compliance while maintaining trial budgets. During this session, we will discuss:

Enrollment optimization

- Study enrollment forecasting
- Site selection
- Study enrollment, retention, and acceleration

Clinical investigative networks

- Network model efficiencies
- Network analysis and selection process
- Network key elements

eClinical processes and tools to maximize trial efficiency

- Distance learning
- Document repositories and secure document distribution
- EDC, eSource documents

eClinical Technology Solutions Enabling Study Performance Optimization

Kenneth A. Getz, MBA, MS

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

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 LEVEL: ●

Room B408 *CME credits offered***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 LEVEL: ■

Room B409 *CME and Nursing credits offered***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

LEVEL: ■

Room B407*CME and Pharmacy credits offered***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

LEVEL: ■

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.

SESSION 108 ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, RA

10:30 am-12:00 pm LEVEL: ●

Room A412AB

FDA: eCTD Compliance – Part 1 of 2

SESSION CHAIRPERSON(S)

Gary M. Gensinger, MBA

Director, Regulatory Review Support Staff, CDER, FDA

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

This session is part 1 of guidance-compliant eCTDs and will provide an overview of FDA's eCTD Guidance and a practical discussion on developing a guidance-compliant format for an eCTD submission.

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

SESSION 109 FI - FINANCE, PM

10:30 am-12:00 pm LEVEL: ●

Room B301

Finance Is from Mars, Clinical Development Is from Venus: Financial Accruals and Forecasting

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.

SESSION 110 GCP - GOOD CLINICAL PRACTICES, CR

10:30 am-12:00 pm LEVEL: ●

Room B406AB *Nursing credits offered*

Clinical Trial Registries and Results Databases: Are You Ready for the Audit?

SESSION CHAIRPERSON(S)

Pamela A. Rose, BSN, RN

Director, Clinical Trial Information Registries R&D, TAP Pharmaceutical Products 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

SESSION 111 IS - INVESTIGATOR SITES, OS

10:30 am-12:00 pm LEVEL: ■

Room B303

When Sponsors Sue Sites: A Real-life Case History

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.

SESSION 112 IT - INFORMATION TECHNOLOGY, CDM

10:30 am-12:00 pm LEVEL: ■

Room A305

Next Generation Application Integration Using Web Services

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.

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 CME credits offered

Nanomedicine: The Way Forward

SESSION CHAIRPERSON(s)

Robert A. Paarlberg, 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

Anália Cristina Perez, MS

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

Panelist*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

CME and Pharmacy credits offered

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.

Vendor System Selection and Planning**A. Michael Bloh, MBA, RPh**

Principal, Drug Safety Net LLC

Safety System Implementation**John Whitebrook, PhD**

Vice President, Pharmaceutical Practice/UK Country Manager, Intrasphere Technologies Ltd., UK

Safety System Validation**Uwe P. Trinks, PhD**

Chief Information Officer, Sentrx

SESSION 131 CP2 - CLINICAL SAFETY AND PHARMACOVIGILANCE, CR

1:30 pm-3:00 pm

LEVEL: ■

Room A302 CME, Nursing, and Pharmacy credits offered**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, FPPM**

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 CME and Pharmacy credits offered**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 discov-

ery 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.

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, FACP, 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**

Vice President, BG Medicine, Inc.

Panelist**Felix W. Frueh, PhD**

Associate Director, 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. Michelson, BSN, RN**

Director, Clinical Research Services, Amgen Inc.

SESSION 134 CR3 - CLINICAL RESEARCH AND DEVELOPMENT, CP

1:30 pm-3:00 pm

Room B409

LEVEL: ●

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

SESSION 135 CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, CR

1:30 pm-3:00 pm

Room B405

LEVEL: ■

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

India: Important Player in Clinical Trials Arena

Arun D. Bhatt, MD

President, ClinInvent Research Pvt Ltd., India

Asia Pacific: Important Region in Clinical Trials

Akihiro Shimosaka, PhD

Director, EPS Co. Ltd., Japan

SESSION 136 ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, RA

1:30 pm-3:00 pm

Room A412AB

LEVEL: ●

FDA: eCTD Compliance – Part 2 of 2

SESSION CHAIRPERSON(s)

Gary M. Gensinger, MBA

Director, Regulatory Review Support Staff, CDER, FDA

Part 1 of this session will take place on Monday at 10:30 am.

This session is part 2 of guidance-compliant eCTDs and will provide an overview of FDA's eCTD Guidance and a practical discussion on developing a guidance-compliant format for an eCTD submission.

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, II, MBA

Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

SESSION 137 FI - FINANCE, RD

1:30 pm-3:00 pm

Room B301

LEVEL: ■

Pharmacy credits offered

Sustainability of Pharmaceutical Development Pipelines

SESSION CHAIRPERSON(s)

Wolfgang Seifert, Dr Med

Clinical Pharmacologist, PMP Analyst, Seifert Research Berlin, Germany

Analysis of the development pipeline uses mostly risk-adjusted NPV calculations bearing the risks of covering only late-stage projects and suffering from the enormous complexity of input. A new approach describes pipeline sustainability and allows forecasting of launches over time.

Implications of Forecasting the Output from Pharmaceutical Development Pipelines

Wolfgang Seifert, Dr Med

Clinical Pharmacologist, PMP Analyst, Seifert Research Berlin, Germany

How Companies Present their Development Pipelines on the Web

Judith Faechner

Student of Journalism, Analyst's Assistant, Freie Universität, Germany

Analysis of the Value and Productivity of Development Pipelines

Kerstin M. Bode-Greuel, MD, PhD

Partner, BioScience Valuation BSV GmbH, Germany

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

LEVEL: ◆

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. Schnel, MA

Executive Director, Business Development and Client Services, Criterium, Inc.

SESSION 143 PM1 - PROJECT MANAGEMENT, RD

1:30 pm-3:00 pm

LEVEL: ■

Room B403 *Project Management units offered*

Utilization of Six Sigma Methodology in a Research and Development Setting

SESSION CHAIRPERSON(S)

Martin D. Hynes, III, 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 usefulness of Six Sigma techniques in reducing costs and cycle times.

Lean Six Sigma Implementation in an R&D Organization

Lisa A. Shipley, PhD

Vice President-ADME, Lilly Research Laboratories

Application of Lean Six Sigma to Clinical Trial Operations

Jeffrey Naglestad

Director, Business Performance Improvement, sanofi-aventis

Sustaining Improvements: Some Strategic and Tactical Methods that Work

Ronald D. Snee, PhD

Principal, Process and Organizational Excellence, Tunnell Consulting

SESSION 144 PM2 - PROJECT MANAGEMENT, RD

1:30 pm-3:00 pm

LEVEL: ■

Room B402 *Project Management units offered*

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

SESSION 145 PP - PUBLIC POLICY/LAW, RA

1:30 pm-3:00 pm

LEVEL: ■

Room A411

CME, Nursing, and Pharmacy credits offered

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

SESSION CHAIRPERSON(S)

Mark C. Hegarty, JD

Partner/Attorney, Shook, Hardy & Bacon, LLP

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

Mark C. Hegarty, JD

Partner/Attorney, Shook, Hardy & Bacon, LLP

John F. Kuckelman, JD

Attorney, Shook, Hardy & Bacon LLP

SESSION 146 RA1 - REGULATORY AFFAIRS, IS

1:30 pm-3:00 pm

LEVEL: ●

Room A406

CME credits offered

Site Selection Risk Models for FDA Inspections and Theoretical Considerations

SESSION CHAIRPERSON(S)

John W. Gardner, DrPH, MD

Division Director, Office of Compliance, CDER, FDA

This session will provide an overview of FDA use of risk management in creating risk models for the selection of sites to undergo routine FDA inspections. It will include a discussion of the factors used in the model and their risk significance. It will also present a discussion of the theory of risk-based prioritization.

Multicriteria Decision Analysis (MCDA) Theory for Risk Ranking

H. Gregg Claycamp, PhD, MS

Associate Director, Risk Analysis and Strategic Policy Assessment, Office of Compliance, CDER, FDA

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*Sawyei Brenda Wang, MS*

Team Leader, Office of Compliance, CDER, FDA

SESSION 147 RA2 - REGULATORY AFFAIRS, PP

1:30 pm-3:00 pm

LEVEL: ■

Room A404**FDA Regulations and Guidances: 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 guidances.

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 guidances 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 Guidances*Virginia Beakes-Read, BSN, JD*

Director, Regulatory Policy Liaison, Genentech, Inc.

Commenting on FDA Regulations and Guidances from a Global Perspective*Amy N. Grant*

Global Head, Regulatory Information and Intelligence, AstraZeneca LP

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

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

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, Kindle 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 LEVEL: ■

Room A311

Practical Implementation of EU Pediatric Legislation

SESSION CHAIRPERSON(S)

Patrick Le Courtis, 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 Tummavuori-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 LEVEL: ●

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, CISCRP

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, CISCRP

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

LEVEL: ■

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

LEVEL: ●

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

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 Diesenhaus, 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 road-block 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.

Drugs and Tests: A Reality Check

Klaus Lindpaintner, MD, PhD, MPH

Head, Roche Genetics and Roche Center for Medical Genomics, F. Hoffmann-La Roche AG, Switzerland

Panelist

Felix W. Frueh, PhD

Associate Director, Genomics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

SESSION 161

CR2 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS

3:30 pm-5:00 pm

LEVEL: ■

Room B408

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, III, 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 LEVEL: ♦

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 LEVEL: ●

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 LEVEL: ●

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. Gensinger, 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 LEVEL: ■

Room B406AB CME, Nursing, and Pharmacy credits offered

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 LEVEL: ♦

Room B303 Nursing credits offered

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

SESSION 168 IT - INFORMATION TECHNOLOGY, CDM

3:30 pm-5:00 pm LEVEL: ■

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

SESSION 169 MW - MEDICAL/SCIENTIFIC WRITING, RA

3:30 pm-5:00 pm LEVEL: ■

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 keystone 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.

Organize and Integrate the IB for Clarity and Purpose

Christopher J. Preston, PhD

International Documentation Manager, F. Hoffmann-La Roche Ltd., Switzerland

Tailoring the IB to IMP Development Status and Region

Sandra J. Hecker, RAC

President, Hecker and Associates, LLC

IMPD versus IB: What Additional Information Is Needed?

Irene Gander-Meisterernst, DrSc, PhD

Senior Director, Regulatory Affairs, MediGene AG, Germany

SESSION 170 NHP - NATURAL HEALTH PRODUCTS, MA

3:30 pm-5:00 pm LEVEL: ■

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

SESSION 171 OS1 - OUTSOURCING, RA

3:30 pm-5:00 pm LEVEL: ●

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

Clinical Research in India: Challenges and Advantages

Shruti V. Shukla, MSc

Principal and Professor, Institute of Clinical Research of India (ICRI), India

SESSION 172 OS2 - OUTSOURCING, RD

3:30 pm-5:00 pm LEVEL: ■

Room B404

R&D Outsourcing in Japan: Successes and Challenges

SESSION CHAIRPERSON(S)

Chris R. Albani, MBA

Partner, Pharmaceutical Industry Lead, Pittiglio, Rabin, Todd & McGrath, Japan

While outsourcing is an established practice around the world in pharmaceutical R&D, it is still a relatively immature practice in Japan. New survey data and practical experiences shed light on the changing practices and opportunities in this key outsourcing market – which will likely become a key foundation for both global and pan-Asia trials.

Outsourcing from the Perspective of "Big" Pharma

Patrick Floody

Director, Study Management Group, Pfizer Japan Inc., Japan

Clinical Outsourcing from the Japanese CRO Perspective

Keiko Oishi, MS

Senior Managing Director, CMIC Co., Ltd., Japan

Strategic Outsourcing for Mid-size Pharma Players

Chris Brünger, MD

Chairman, Integrated Development Associates Co., Ltd., Japan

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. Paál, 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 Lönnqvist, 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.

SESSION 181**RA6 - REGULATORY AFFAIRS,
CMC/GMP**

3:30 pm-5:00 pm

LEVEL: ■

Room A406

CMC Requirements and Considerations for Clinical Trials and Marketing Applications in China

SESSION CHAIRPERSON(S)

H. Samantha Gao-Sheridan, PhD

Senior Manager, Global Regulatory Affairs, Wyeth Pharmaceuticals

This session presents CMC requirements and regulatory review process for clinical trial and marketing applications in China, including challenges and case studies.

Industry Perspective: CMC Reviews for China Import Drug License Submissions*Jeffrey R. Ferguson*

Manager, Global Regulatory Affairs (CM&C), Eli Lilly and Company

China Regulatory Perspective*Dong Lv*

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

CMC Requirement and Points to Be Considered for an IND/CSA in China*Janet Lu, RPh*

Associate Director, Regulatory Affairs, MSD China Pharmaceutical Co., Ltd., China

SESSION 182**RD - R&D STRATEGY, PP**

3:30 pm-5:00 pm

LEVEL: ●

Room B305

Emerging Trends in the Economics of New Drug Development

SESSION CHAIRPERSON(S)

Joseph A. DiMasi, PhD

Director, Economic Analysis, Tufts Center for the Study of Drug Development, Tufts University

This session will examine data on development times, success rates, development costs, and market dynamics for new drugs. Implications for R&D productivity and incentives to innovate will be examined.

How Recent Changes in Patent Law May Affect Drug Development*Robert E. Silverman, JD, PhD*

Vice President and General Counsel, Concert Pharmaceuticals, Inc.

The Economics of New Drug Development: Trends in Time, Risk, and Cost*Joseph A. DiMasi, PhD*

Director, Economic Analysis, Tufts Center for the Study of Drug Development, Tufts University

The Future Environment for Pharmaceuticals: Public Policy and Economics*Richard Manning, PhD*

Senior Director, Corporate Policy, Pfizer Inc

SESSION 183**ST - STATISTICS, CR**

3:30 pm-5:00 pm

LEVEL: ■

Room B309

Our Experience and Significance in a Japanese Sentinel Network System

SESSION CHAIRPERSON(S)

Masahiro Takeuchi, DrSc, MPH

Professor of Biostatistics and Pharmaceutical Medicine, School of Pharmaceutical Sciences, Kitasato University, Japan

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

SESSION 184 **TR - TRAINING, EC**

3:30 pm-5:00 pm

LEVEL: ■

Room B308

eClinical Meets eLearning: Theory to Practice to Best Practice

SESSION CHAIRPERSON(S)

Pamela Loughner, PhD, MEd

President, Loughner and Associates, Inc.

This session chronicles the design, development, implementation, and evaluation of eLearning delivered globally to investigator sites and pharmaceutical company professionals to support the implementation of six eClinical technologies. Key strategic decisions, training methods and procedures, and best practices will be explored.

Key Decisions in the Development of a Global Training Strategy*Pamela Loughner, PhD, MEd*

President, Loughner and Associates, Inc.

Just-in-time Training for a Global Audience: Instructional Methods and Materials*Malena Moore Gittler, PhD, MS*

Senior Consultant, Loughner and Associates, Inc.

Getting from Point A to Point B: Managing Global Instructional Design Projects*Marian Caroselli, MS*

Clinical Learning and Development Senior Advisor, AstraZeneca

5:00 pm

END OF MONDAY SESSIONS

5:00 pm-6:00 pm

RECEPTION IN THE EXHIBIT HALL

7:30 am-6:30 pm	ATTENDEE REGISTRATION and EXHIBITOR REGISTRATION and SPEAKER REGISTRATION Building A/B Registration Hall, International Boulevard, Philips Drive Entrance, GWCC
7:15 am-8:00 am	CONTINENTAL BREAKFAST Registration Area Foyer
10:00 am-12:00 pm	SPECIAL EVENT: STUDENT FORUM Room A304, Building A, Level 3, GWCC
10:00 am-6:30 pm	PROFESSIONALS' POSTER SESSION Entrance to Exhibit Hall, Building A, Level 3, GWCC
11:00 am-6:30 pm	EXHIBITS OPEN (Extended Luncheon Hours) Exhibit Hall, Building A, Level 1, GWCC
5:30 pm-6:30 pm	TUESDAY RECEPTION Exhibit Hall, Building A, Level 1, GWCC

SESSION 201 AHC - ACADEMIC HEALTH CENTERS, CP, CR, PP, RA

8:00 am-9:30 am	LEVEL: ■
Sidney J. Marcus Auditorium, Building A	<i>CME and Pharmacy credits offered</i>
Multitrack Plenary	
Drug Safety Reform: Actions and Implications	
SESSION CHAIRPERSON(s)	

Melvyn Greberman, MD, MS, MPH, FACP
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 202 BT - BIOTECHNOLOGY, CR

8:00 am-9:30 am	LEVEL: ■
Room B304	<i>CME credits offered</i>
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

SESSION 203 CDM - CLINICAL DATA MANAGEMENT, IT

8:00 am-9:30 am	LEVEL: ■
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

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

SEE SESSION 201**CP - CLINICAL SAFETY AND PHARMACOVIGILANCE & CR - CLINICAL RESEARCH AND DEVELOPMENT, AHC, PP, RA**

8:00 am-9:30 am LEVEL: ■

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.

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

CME and Pharmacy credits offered

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

LEVEL: ■

Room B301*Pharmacy credits offered***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

LEVEL: ●

Room B303*CME, Nursing, and Pharmacy credits offered***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

SESSION 214**IT - INFORMATION TECHNOLOGY, CDM**

8:00 am-9:30 am

LEVEL: ■

Room A305**Utilizing Open-source Software in GCP-compliant Environments**

SESSION CHAIRPERSON(S)

Cal Collins

Chief Executive Officer, Akaza Research

Institutions are looking towards more transparent, standards-based systems to meet challenges of flexibility, interoperability, and cost in clinical trials. This session focuses on how the collaborative open-source model can be employed to meet these needs and produce robust, GCP-compliant products.

Understanding and Deploying Open-source Software in Clinical Development*Mark M. Paul, MBA*

Vice President, StatWorks, Inc.

The Use of Open Source Software in a 21CRF11 Regulated Environment*R. Mark Adams, PhD*

Senior Associate, Booz Allen Hamilton

Project Manager, NCI's Cancer Biomedical Informatics Grid (caBIG)

SESSION 215**MC - MEDICAL COMMUNICATIONS, MW**

8:00 am-9:30 am

LEVEL: ■

Room B404*Pharmacy credits offered***Standardizing Information Sharing between Medical Information Professionals and Regional Medical Liaisons by Developing Tools to Ensure Compliance and Consistency**

SESSION CHAIRPERSON(S)

Christine Wyble, PharmD

Director, Oncology/Urology Medical Information Services, sanofi-aventis

Electronic solutions to ensure consistency and standardization when disseminating off-label information by medical information professionals and regional medical liaisons will be described. This session will also focus on the effective sharing of information between the two groups.

Establishing a Cross-functional Team Is the Cornerstone to Sharing Medical Information*Edmund J. Cunningham, PharmD*

Medical Science Liaison, Eisai, Inc.

Utilization of a Web-based Tool for Medical Slides and Implementation through an eLearning Module*Christine Wyble, PharmD*

Director, Oncology/Urology Medical Information Services, sanofi-aventis

Electronic Solutions Allow Effective Utilization of Medical Information Resources for Medical Liaisons*Sandra Dean, PharmD*

Medical Science Liaison Trainer, Genentech, Inc.

SESSION 216**MW - MEDICAL/SCIENTIFIC WRITING, RA**

8:00 am-9:30 am

LEVEL: ■

Room A315**CTD Summaries as Key Reviewer Tools**

SESSION CHAIRPERSON(S)

Michelle Herrera Foster, PhD

Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

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.

Preparing 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

LEVEL: ■

Room B401

Benefits and Challenges of Implementing Standards in Outsourced Studies

SESSION CHAIRPERSON(S)

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. Blakenev, 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

LEVEL: ◆

Room B402 *Project Management units offered*

Driving Innovation, Growth, and Optimization through Portfolio Management

SESSION CHAIRPERSON(S)

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

LEVEL: ■

Room B403

Project Management units offered

PMs as Project CEOs and the Effective Project Manager's Tool Chest

SESSION CHAIRPERSON(S)

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 investigational 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.

Like an effective CEO, a good PM must be action oriented, able to manage financial and operational metrics and be able to connect with people to lead them to completing a trial successfully. Senior management within sponsors and CROs must fully empower the PM and expect accountability just as a CEO answers to a board.

Managing Global Trials: Challenges and Opportunities for Project Managers

Michael J.B. Tansey, MD

Chief Medical Officer, Competitive Drug Development

Project Decision-making Matrix: The PM as Sovereign, President, or Cheerleader

Ron Corey, PhD, MBA, RPh

Senior Director, Clinical and Project Manager, Asubio

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

LEVEL: ■

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.

SESSION 220 RA1 - REGULATORY AFFAIRS, TR

8:00 am-9:30 am

LEVEL: ■

Room A404

Pharmacy credits offered

Fast Track! Accelerated Approval! Priority Review! A Primer in US Regulatory Paths to Approval

SESSION CHAIRPERSON(S)

Cheryl Beal Anderson, PharmD, RAC

Director, US Regulatory Affairs, Eli Lilly and Company

At the end of the session, the learner will be able to explain the various regulatory options that are available to accelerate drug development for serious and life-threatening conditions, such as cancer. Using oncology drug development examples, new regulatory affairs professionals will be able to assess the appropriate use of fast track designation, priority review and accelerated approval. The challenges associated with these regulatory strategies will be highlighted, including considerations for global development programs.

Drug Development Considerations for Accelerated Approval*Colleen Mockbee, RPh*

Associate Director, Regulatory Affairs, Eli Lilly and Company

Accelerated Approval Case Studies: A Closer Look*Sandra R. Karasik, RPh*

Associate Director, Regulatory Affairs, Oncology, AstraZeneca Pharmaceuticals LP

Panelist*Grant A. Williams, MD*

Clinical Development, GlaxoSmithKline

SESSION 221 RA2 - REGULATORY AFFAIRS, MC

8:00 am-9:30 am

LEVEL: ●

Room A405

Pharmacy credits offered

Maximizing the Benefits of Medicines Information through Readability Testing

SESSION CHAIRPERSON(S)

DK Theo Raynor, PhD, MRPPharmS

Professor of Pharmacy Practice, University of Leeds, UK

Mandatory testing of patient leaflets in Europe has increased the focus on accessible and useful consumer medicines information. Also the FDA is focusing on the quality of CMI. This session explores how to harness testing to maximize benefits for patients, industry and regulators.

Where Did Readability Testing Come from and Where is it Going?*DK Theo Raynor, PhD, MRPPharmS*

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

SESSION 222 RD - R&D STRATEGY, PM

8:00 am-9:30 am

LEVEL: ■

Room B305

Drug Development down the Road

SESSION CHAIRPERSON(S)

Keith Ortiz, MBA

VantagePoint Consulting Group

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

SESSION 223 ST - STATISTICS, IT

8:00 am-9:30 am

LEVEL: ●

Room B309

Open-source Statistical Software in Pharmaceutical Research and Development: Validation, Legal Issues, and Regulatory Requirements

SESSION CHAIRPERSON(S)

Gregory R. Warnes

Associate Professor, University of Rochester

This session discusses the use of open-source statistical analysis software in pharmaceutical research and development. This will include a discussion of pros and cons, applicable regulatory requirements, and practical issues in deploying and using such software.

Software and Code Evaluation: Risk-based Approaches to Software Integration*Nicholas J. I. Lewin-Koh, MS*

Statistics and Information Sciences, Eli Lilly and Company

Open-source Software and Pharma Development: Computer Systems Validation and Value*Anthony Rossini*

Novartis Pharma AG, Switzerland

Times R A'changin': FDA Perspectives on Use of Open Source*David M. Petullo, MSc*

Statistician, Center for Veterinary Medicine, FDA

Open-source Software in Pharmaceutical Discovery*Gregory R. Warnes*

Associate Professor, University of Rochester

SESSION 224 TR - TRAINING, GCP

8:00 am-9:30 am

LEVEL: ■

Room B308

Nursing credits offered

Effective Training of Study Site Staff for Better Clinical Trials

SESSION CHAIRPERSON(S)

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

9:30 am-10:00 am

REFRESHMENT BREAK

Building A – Exhibit Hall A Only

Building B – Levels 3 & 4, Meeting Room Corridors

SESSION 225

AD - ADVERTISING, RA

10:00 am-11:30 am

LEVEL: ■

Room A313

Pharmacy credits offered

Enforcement Update from the FDA

SESSION CHAIRPERSON(S)

Wayne L. Pines

President, Regulatory Services and Healthcare, APCO Worldwide Inc.

FDA enforcement actions need to be understood by every regulated company because they reflect FDA's priorities and concerns in regulating advertising and promotion. 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

SESSION 226

BT - BIOTECHNOLOGY, CR

10:00 am-11:30 am

LEVEL: ■

Room B304

CME credits offered

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

SESSION 227

CDM - CLINICAL DATA MANAGEMENT, CR

10:00 am-11:30 am

LEVEL: ■

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 Dimenias, PhD

Clinical Information Strategy Director, AstraZeneca AB, Sweden

SESSION 228

CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA

10:00 am-11:30 am

LEVEL: ■

Room A311

Pharmacy credits offered

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

Chi-wan Chen, PhD

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

CMC Pilot Program: An FDA Perspective #1

Stephen Miller, PhD

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

CMC Pilot Program: An FDA Perspective #2

Christine M. Moore, PhD

Supervisory Chemist, Office of New Drug Quality Assessment, CDER, FDA

SESSION 229

CP1 - CLINICAL SAFETY AND PHARMACOVIGILANCE, RA

10:00 am-11:30 am

LEVEL: ●

Room A302

CME and Pharmacy credits offered

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

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

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

This session will provide an overview of the BPCA and the PREA, and their impact on pediatric research. The clinical issues associated with the pediatric population and the impact these issues have on overall study design and execution will be discussed. Additionally, the use of retrospective data mining as a means of informing prospective pediatric clinical trial design will be shared. Finally, the session will end with a presentation of proven, day-to-day tactics for study success in the pediatric population.

Use of Retrospective Database Analysis in Clinical Trial Planning

John J. Doyle, DrPH

President and Chief Operating Officer, Analytica International

Emerging Clinical Issues in Executing Pediatric Studies

Magali Haas, MD, PhD

Senior Director, CNS, Compound Development Team Leader, Johnson & Johnson Pharmaceutical Development

Operational Strategies for Successful Pediatric Clinical Trials

Karen T. Grossberg

Associate Director, Phase 4 Development, PharmaNet

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

Radical Change in Clinical Development at Wyeth

Ira C. Spector, MBA

Vice President, Clinical Development Operation, Wyeth Research

Radical Change in Clinical Development: An Industry Overview

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	LEVEL: ●
Room B408	<i>CME credits offered</i>
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	LEVEL: ■
Room B403	
Finding Top Performing Sites: A Considered Approach	
SESSION CHAIRPERSON(s)	
Jeffrey S. Painter, MBA	
Independent Consultant	
High-performing investigators are an integral portion of getting your study on-time and on-budget. Numerous studies have validated that about 80% of study subjects come from the top 33% of investigative sites. But how do you find these sites? We will show a practical method to do this.	
Finding Top Performing Sites: New Methods to Consider	
Jeffrey S. Painter, MBA	
Independent Consultant	
Finding Top Performing Sites: New Ideas from Large Pharma	
Mark T. Ridge	
Director, Global Enrollment Planning and Performance, Wyeth Pharmaceuticals	
Finding Top Performing Sites: A View from Industry	
Scott Ballenger, RPh	
President, Trial Acceleration	

SESSION 235	EC - eCLINICAL, CDM
10:00 am-11:30 am	LEVEL: ●
Room A314	<i>CME credits offered</i>
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	
SESSION CHAIRPERSON(s)	
John M. Weiler, MD	
President, CompreWare® Corporation	
This session will be a debate in which the adoption of ePROs for all studies that capture PROs will be considered.	
All Trials that Collect PROs Should Use an Electronic Technology	
Gregory D. Gogates	
Vice President, Quality Management and Regulatory Affairs, CRF Inc	
Not All Trials that Collect PROs Should Use an Electronic Technology	
Mark J. Atkinson, PhD, MEd	
Voluntary Associate Clinical Professor, Department of Family and Preventive Medicine, University of California, San Diego	
Panelists	
Stephen A. Raymond, PhD	
Chief Scientific Officer and Quality Officer, PHT Corporation	
Laurie Beth Burke, MPH, RPh	
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA	
SESSION 236	ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM
10:00 am-11:30 am	LEVEL: ■
Room A412AB	
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. Balcerski, 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 Thriwikramji, 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

Dandapantula 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.

Early-stage Biologics Development**Tina Rarick, PMP**

Global Pharma Development Project Manager, Roche Palo Alto, LLC

Late-stage Biologics Development: Similar Considerations as Small Molecules but Different Challenges**Lawrence G. Vallandigham**

Senior Manager, Project and Portfolio Management, Gilead Sciences, Inc.

Commercial and Life-cycle Development for a Biologic**Laurie Dubrovin, MS, PMP**

Senior Project Manager, Product Portfolio Management, Genentech, Inc.

SESSION 246 PP - PUBLIC POLICY/LAW, MC

10:00 am-11:30 am LEVEL: ●

Room B302 CME credits offered**Personal Health Records in Pharmaceutical Development**

SESSION CHAIRPERSON(S)

William C. Crawford

Center for Biomedical Innovation, Harvard Medical School

Despite the great promise of personal health records, their R&D implications have been largely ignored. This session will explore the opportunities for PHR use in three core pharmaceutical R&D areas: basic population research, clinical trial recruitment, and postmarketing surveillance.

PHRs in Early-stage Research**Ross D. Martin, MD, MHA**

Director, Healthcare Information Convergence, BearingPoint Management & Technology Consultants

The Evolving Role of PHRs in Health Care Transformation**Keith Strier, JD**

Provider Innovation Leader, Deloitte Consulting LLP

PHRs and Postmarket Surveillance**William C. Crawford**

Center for Biomedical Innovation, Harvard Medical School

SESSION 247 RA1 - REGULATORY AFFAIRS, PP

10:00 am-11:30 am LEVEL: ■

Room A405 CME credits offered**Progressive Licensing: The Canadian Regulatory Reform that Reflects a Life Cycle and Benefit/Risk Approach**

SESSION CHAIRPERSON(S)

Agnes V. Klein, MD

Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada

It has been widely recognized that there is a need to re-examine how drugs are regulated to keep pace with the evolution of drug development and regulatory sciences as well as with the current needs of stakeholders and the public. Regulatory agencies have each addressed this gap in the context of their environment. Canada, in turn, has recognized that there is a need to ensure that regulations address the gaps that have been identified. In order to address the gaps appropriately there has emerged a need to modernize and update the existing regulations and rationalize them based on risk management principles and practices founded upon strong scientific evidence.

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 Patent 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, Pharmiceutics 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, Pharmiceutics 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.

Globalization of Industry-sponsored Clinical Trials: Evidence on Recent Trends

Ernst Berndt, PhD

Louis B. Seley Professor of Applied Economics, MIT Sloan School of Management

James E. Taylor

Worldwide Head, Contracts and Outsourcing, Pfizer Global Research & Development

Edward Stephen Seguine, Jr., MBA

Chief Executive Officer, Fast Track Systems, Inc.

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

SESSION 259 CP1 - CLINICAL SAFETY AND PHARMACOVIGILANCE, IMP

2:00 pm-3:30 pm LEVEL: ■

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

SESSION 260 CP2 - CLINICAL SAFETY AND PHARMACOVIGILANCE, CR

2:00 pm-3:30 pm LEVEL: ■

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, FRCPC

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.

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, FRCPC

Director, Drug Safety Research Unit, UK

SESSION 261 CR1 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS

2:00 pm-3:30 pm LEVEL: ■

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

SESSION 262 CR2 - CLINICAL RESEARCH AND DEVELOPMENT, NC

2:00 pm-3:30 pm LEVEL: ■

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 pre-clinical 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 LEVEL: ■

Room B407 CME credits offered**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 LEVEL: ■

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-start targets 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.

Shifting the Study Planning Paradigm: Understanding the Importance of Mid-course Corrections*Peter H. Blake, PhD*

Partner, PrecisTrial LLC

The Site Readiness Index: Combining Data Sets to Operationalize Site Initiation*Matthew Kibby, MBA*

Leader, Global Operations, BBK Worldwide

SESSION 265 EC - eCLINICAL, CDM

2:00 pm-3:30 pm LEVEL: ●

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 LEVEL: ●

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 Fauntleroy*

Director, Electronic Submissions Program, CBER, FDA

Discussion of eCTD Issues

Donovan F. Duggan, II, MBA

Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

Electronic Document Room (EDR) Reengineering

Gary M. Gensinger, MBA

Director, Regulatory Review Support Staff, CDER, 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 269 IS - INVESTIGATOR SITES, GCP

2:00 pm-3:30 pm

LEVEL: ■

Room B303

CME credits offered

Hurricane Katrina: Lessons Learned One Year Later

SESSION CHAIRPERSON(s)

William B. Smith, MD, FACC

Principal Investigator/President, New Orleans Center for Clinical Research

Hurricane Katrina revealed many problems, which affected clinical trials, both in terms of patient safety and data collection. We will outline the major problems with some possible solutions for future catastrophes, either man-made or natural.

Regulatory Perspective

Mary Purucker, MD, PhD

Associate Director, Office of Counterterrorism and Emergency Coordination, CDER, FDA

Industry Perspective

Kathy D. Rolston, RN

Regional Field Operations, Novartis Clinical Operations

Site Perspective

William B. Smith, MD, FACC

Principal Investigator/President, New Orleans Center for Clinical Research

SESSION 270 IT - INFORMATION TECHNOLOGY, CDM

2:00 pm-3:30 pm

LEVEL: ■

Room A305

Issues and Case Studies in Safety Data Migration

SESSION CHAIRPERSON(s)

Uwe P. Trinks, PhD

Chief Information Officer, Sentrax

Pharmaceutical, biotechnology, and medical device manufacturers often face the challenge of migrating data between different dictionaries and clinical or safety systems. Through case studies, this presentation will highlight the critical success factors in performing data migrations.

Drivers and Methods for Data Migration

Brian Perry

Technical Director, Sentrax

Challenges in Electronic Data Migrations in a Systems Upgrade Scenario

Uwe P. Trinks, PhD

Chief Information Officer, Sentrax

Safety Decisions in a Direct Data Mapping Scenario due to Product Acquisition

Eric T. Smith, PharmD

Senior Director, Risk Management & Safety Evaluation, King Pharmaceuticals, Inc.

SESSION 271 MC - MEDICAL COMMUNICATIONS, CR

2:00 pm-3:30 pm

LEVEL: ■

Room B404

Pharmacy credits offered

Sharing Medical Information with Healthcare Professionals Online: Perspectives from Two Pharmaceutical Companies

SESSION CHAIRPERSON(s)

Brian E. Wagner, PharmD

Operations Manager, US Medical Information and Communication Services, Eli Lilly and Company

Representatives from various medical information websites will share insights on how each site was developed and on its intended purpose. They will also provide information on site metrics and highlight some of the biggest challenges to be faced when providing information via a website or electronically.

Review of a Mid-sized Biopharmaceutical Company's HCP Website*Lawrence O'Connor, PhD, MS*

Amgen Inc.

Review of a Large Biopharmaceutical Company's HCP Website*Scott S. Barker, PharmD*

Associate Medical Information Consultant, US Medical Information and Communication Services, US Medical Division, Eli Lilly and Company

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

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**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

SESSION 276 PM1 - PROJECT MANAGEMENT, CP

2:00 pm-3:30 pm

LEVEL: ■

Room B402

Project Management units offered

Risk Management in Clinical Trials

SESSION CHAIRPERSON(s)

Ralph D. White, PhD

Director, PPM&L 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, MBCb, MFPm

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.

SESSION 277 PM2 - PROJECT MANAGEMENT, CR

2:00 pm-3:30 pm

LEVEL: ■

Room B403

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 Mentesana, 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

SESSION 278 PP - PUBLIC POLICY/LAW, RA

2:00 pm-3:30 pm

LEVEL: ■

Room A410

CME credits offered

Product Liability

SESSION CHAIRPERSON(s)

Irene Gerlach, PhD

Novartis Pharma AG, Switzerland

The pharmaceutical industry acts in an increasingly litigious environment. Recent developments in product liability in the EU and the US will be presented. In addition, strategies to reduce potential liability risk will be discussed with a focus on product labeling.

Product Claims, Labeling Risks, and Liability in Europe

Anne Ware

Product Liability Lawyer and Partner, Covington & Burling LLP, UK

Liability Risk Mitigation through a Global Labeling System

Gabriele Braeunlich, PhD

Vice President, Head, Global Labeling and Compliance, Global Regulatory Affairs, Bayer Healthcare AG, Germany

Pharmaceutical Product Liability in the US

Michael S. Labson, JD

Partner, Covington & Burling LLP

SESSION 279 RA1 - REGULATORY AFFAIRS, CR

2:00 pm-3:30 pm

LEVEL: ■

Room A404

Achieving Success in Registration: Avoiding Pitfalls in Drug Development

SESSION CHAIRPERSON(s)

Gopalan Narayanan, MD

Head of Biologicals and Biotechnology Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Potentially useful drugs could fail during application for license due to avoidable problems in development and/or presentation. This session will highlight some key areas for future.

Planning for Success in Phases 2 and 3: Statistical Issues

Robert Hemmings, MS

Statistics Unit Team Leader, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Early Development: Application of Pharmacology

James P. Burns, Jr., PhD, MS, MSc

Senior Vice President, Regulatory Science Worldwide, PharmaNet, Inc.

Pitfall of Process Changes during Biotech Product Development from the CMC Perspective

Christopher J. Holloway, PhD

Group Director, Regulatory Affairs and CSO, ERA Consulting Group, UK

SESSION 280 RA2 - REGULATORY AFFAIRS, TR

2:00 pm-3:30 pm

LEVEL: ●

Room A411

CME credits offered

Good Review Practices in the US and Canada: A Comparison of Attempts to Standardize Product Review Practices among Regulatory Organizations

SESSION CHAIRPERSON(s)

Howard D. Chazin, MD, MBA

Medical Officer, Guidance and Policy Team, Office of New Drugs, CDER, FDA

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 LEVEL: ■

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 LEVEL: ■

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.

Combination Products: Postapproval Challenges from an Industry Perspective

Andrew N. Papas, PhD, MBA, RAC

Associate Director, Wyeth BioPharma

The Global Issue of Expedited Safety Reporting of Drug/Device Combination Products – Case in Point: Pen Injectors

Harold K. Yeager, MS, RAC

Manager, Medical Devices, Worldwide Pharmacovigilance, Eli Lilly and Company

Combination Products: Postapproval Considerations

Patricia Y. Love, MD, MBA

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

SESSION 283 RA5 - REGULATORY AFFAIRS, CR

2:00 pm-3:30 pm LEVEL: ●

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. Mårfält, 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 LEVEL: ■

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

Kimihiko Kasamo, MD

Senior Director, Banyu Pharmaceuticals, Japan

A Sample Size of Each Region and Interpretation of Results

Osamu Komiya

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 investigational 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 responsibil-

ties 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

Young-Jack Lee, PhD

President, LIFECORD STAT-KOREA, Republic of Korea

3:30 pm-4:00 pm

REFRESHMENT BREAK

Building A – Exhibit Hall A Only

Building B – Levels 3 & 4, Meeting Room Corridors

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

Integration of Response Prediction Biomarkers into Clinical Trials in Oncology

Michael E. Burczynski, PhD
Associate Director, Wyeth Research

Regulatory Perspective

Felix W. Frueh, PhD
Associate Director, Genomics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

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.

Developing the AHRQ Handbook: Registries for Evaluating Patient Outcomes – A User's Guide

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 A311

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

SESSION 291

CP - CLINICAL SAFETY AND PHARMACOVIGILANCE, CR

4:00 pm-5:30 pm

LEVEL: ■

Room A302

CME credits offered

Global Approaches to Risk Management Plans and Pharmacovigilance: The View from Japan and Europe

SESSION CHAIRPERSON(S)

E. Stewart Geary, MD

Vice President, Eisai R&D Management Company, Japan

Lyo Inuyama, PhD

Department Manager, Clinical Safety and Pharmacovigilance, GlaxoSmithKline, Japan

This session will describe the status of risk management plans (RMP) globally, including issues arising from implementing RMP in Japan in conjunction with an existing RMP in use in the US or EU.

Japanese Postmarketing Surveillance Systems and Practices

Kaori Nomura

Chief, Safety Information Division, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Global Approaches to Pharmacovigilance from the EU Perspective

Shinya Yamauchi

Deputy Managing Director - Europe, Otsuka Pharmaceutical Europe Limited, France

Pharmacovigilance Activities of Crestor® (Rosuvastatin Calcium) in Japan

Michio Tanaka

Senior Director, Clinical Division, Research & Development, AstraZeneca K.K., Japan

SESSION 292

CR1 - CLINICAL RESEARCH AND DEVELOPMENT, RA

4:00 pm-5:30 pm

LEVEL: ■

Room B407

Clinical Research and Drug Registrations in Developing Countries (BRIC – Brazil, Russia, India, and China)

SESSION CHAIRPERSON(S)

Rominder Singh, PhD

Executive Director, Global Regulatory Affairs, Amgen Inc.

The session aims to provide a detailed analysis of what it takes to conduct clinical trials in China, India, Brazil, Russia, and the CEE countries. This session will provide anecdotal experiences of the multinational pharmaceutical industry executives and review of regulations by government officials.

Clinical Research and Drug Registrations in BRIC: An Overview

Rominder Singh, PhD

Executive Director, Global Regulatory Affairs, Amgen Inc.

Clinical Trials in China

Zili Li, MD, MPH

Director, Clinical Research Operations - Asia Pacific, Merck & Co., Inc., China

Clinical Trials in Russia

Natalie L. Gershman, MD

Chief Executive Officer, Medical Director, Geny Research Group, Inc.

Clinical Trials in India

Brijesh Regal

Chief Executive Officer, Apothecaries Limited India

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 LEVEL: ■

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

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 LEVEL: ●

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

LEVEL: ■

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

LEVEL: ◆

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
SESSION 298 **ERS/DM2 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, RA**

4:00 pm-5:30 pm LEVEL: ■

Room A412AB

Product Information Management (PIM) Is Live in the EU: Update and Experience

SESSION CHAIRPERSON(S)

Andrew P. Marr, PhD

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

PIM is live in the European Centralized Procedure and the first submission for a new product is under review and several pilots are to be run with post-authorization procedures. The session will review the status of PIM, the experience so far and how to prepare for its wider adoption.

Current Status of PIM and Future Direction
Stephen R. Hasler

Vice President, Global Regulatory Operations, GlaxoSmithKline, UK

The First Live PIM Submission: The Applicant's Experience
Andrew P. Marr, PhD

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

The First Live PIM Submission: EMEA and National Competent Authority Experience
Timothy Buxton, LLB

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

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
SESSION 299B **IMP - IMPACT (IMPACT OF MEDICAL PRODUCTS AND THERAPIES), CR**

4:00 pm-5:30 pm

LEVEL: ●

Room B301

CME, Nursing, and Pharmacy credits offered

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 data-sets 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, FRCPC

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. Lapidula, PhD

Regulatory Toxicology, Novartis Pharmaceuticals Corporation

SESSION 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

SESSION 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

SESSION 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.

SESSION 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 *CME and Pharmacy credits offered*

Clinical Trial Registration: Are Registries Useful and User Friendly?

SESSION CHAIRPERSON(s)

Juhana E. Idänpää-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, Clinical.Trials.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 *CME credits offered*

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 View Point 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 Symbax (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 *CME credits offered*

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, FFPMP**

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)

Heng-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

SESSION 299R TR - TRAINING, CR

4:00 pm-5:30 pm

LEVEL: ■

Room B308*Nursing credits offered***Training Investigators and Study Coordinators: Alternatives/Supplements to Investigator Meetings**

SESSION CHAIRPERSON(S)

Robert Zuercher, MA

Senior Manager, Worldwide Medical and Regulatory Affairs, Corporate Planning and Control, Bracco Diagnostics, Inc.

This session will define characteristics of effective investigator/study coordinator training programs, examine the details, pros and cons of various approaches to site staff training, and build some criteria for selecting the most appropriate method(s) for addressing specific needs.

A Large Pharma's Experience**Michael A. Pozsgai, MLS**

Global Enrollment Optimization Consultant, Eli Lilly and Company

An Investigator's Experience**Brendan M. Buckley, MD, MSc, DPhil, FRCPI**

Clinical Professor of Medicine and Pharmacology, University College Cork, University of Ireland; Consultant Physician in Endocrinology and Metabolism, Bon Secours Hospital, Ireland; Director, European Centre for Clinical Trials in Rare Diseases; Member, Irish Medicines Board, Ireland

SESSION 299S VA - VALIDATION, IT

4:00 pm-5:30 pm

LEVEL: ■

Room A301**Risk-based Software Validation Techniques**

SESSION CHAIRPERSON(S)

Breffi Martin

Director, CanReg Ltd., Ireland

This session will present some of the latest approaches to software validation.

The New Platform in Computer Validation: Automated Testing**Karen Steenhoudt, MS**

Consultant, Valimation

Software User Acceptance Testing: Approaches for Success**Chuck Harris**

Director, Operations, Clinical Technologies Group, United BioSource Corporation

Benefits and Lessons Learned from Standards and Risk-based Research**Sean Winslow**

Manager, QUMAS

5:30 pm **END OF TUESDAY SESSIONS**5:30 pm-6:30 pm **RECEPTION IN THE EXHIBIT HALL**

Wednesday, June 20

7:30 am-4:00 pm	ATTENDEE REGISTRATION and EXHIBITOR REGISTRATION and SPEAKER REGISTRATION	Introduction and Impact of European Directives <i>Cecil Nick, MS</i> Principal Consultant, PAREXEL Consulting, UK
7:30 am-4:00 pm	Building A/B Registration Hall, International Boulevard, Philips Drive Entrance, GWCC	Process Validation from Phase 1 to 3 Focus on Biotechnology <i>Mark Carver, PhD</i> Chief Scientific Officer, Avecia Biologics Ltd., UK
7:30 am-8:15 am	CONTINENTAL BREAKFAST	Viral Safety Including Recent EU Guidelines on Viral Safety in Clinical Trials <i>Jeri-Ann Boose, PhD</i> Senior Director, Analytical and Viral Clearance Services, BioReliance Corporation
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	<i>Pharmacy credits offered</i>	
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.		
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.		
Lab Units/Normals Management and Maintenance		
Patrick Fredericksen, MBA		
Partner, Fountain Database Design, Inc.		
Confronting Common Challenges in Managing Local Lab Data: A Knowledge-based Approach		
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	<i>CME credits offered</i>	
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

Ethnic Outreach and Inclusion in Clinical Trials and its Impact on the R&D Business, Regulatory and Clinical Development Process in the Pharmaceutical Industry

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 Kram, 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

Where Are All the Standards-based Tools?

Edward Stephen Seguine, Jr., MBA

Chief Executive Officer, Fast Track Systems, Inc.

It's a People Thing: Collaborative eClinical Trials

Michael Schuitevoeder, MS

Director, Team and Technology Ltd., UK

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. Schiemann, 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

GCP Quality Risk Management: The Key Components**Matthias Buente, PhD**

Director, Booz Allen Hamilton AG, Switzerland

GCP Quality Risk Management Case Studies: Drug Safety and Investigational Sites**Peter J. Schiemann, PhD**

Quality Risk Management Project Leader, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

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

CME credits offered

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

Pharmacy credits offered

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.

SESSION 318 MW - MEDICAL/SCIENTIFIC WRITING, CR

8:30 am-10:00 am

LEVEL: ■

Room B405

Overview of Publication Writing

SESSION CHAIRPERSON(S)

Timothy M. Mason, MSc

Senior Scientific Communication Associate, Eli Lilly and Company

The intention of this session is to introduce participants to key elements in publication writing and to engage the participants in a discussion. Topics include an introduction on how to write publications, working with vendors and freelancers, and how publications impact a successful product launch.

How to Write Scientific Publications

Wendy P. Battisti, PhD

Associate Director, Scientific and Medical Publications, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Outsourcing Scientific Publications: Lessons from Bridget Jones

Karen L. Woolley, PhD

Chief Executive Officer, ProScribe Medical Communications, Australia

Scientific Publications and Launch Readiness

Timothy M. Mason, MSc

Senior Scientific Communication Associate, Eli Lilly and Company

SESSION 319 NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT, RA

8:30 am-10:00 am

LEVEL: ■

Room B305

Predictive Safety Testing Consortium

SESSION CHAIRPERSON(S)

William Mattes, PhD

Director, Toxicology, The Critical Path Institute

The first need listed in the FDA's March 2006 critical path opportunities list is that of a process for qualifying new biomarkers of safety and efficacy. This session will discuss the predictive safety testing consortium (PSTC) that was formed to address this very need.

The Predictive Safety Testing Consortium: A Way to Qualified Biomarkers

William Mattes, PhD

Director, Toxicology, The Critical Path Institute

The Predictive Safety Testing Consortium: Challenges and Advantages for Pharmaceutical Companies

Denise Robinson-Gravatt, PhD

Director, Global Technology Development, Pfizer Inc

The Predictive Safety Testing Consortium: Roles and Returns for Regulatory Agencies

Federico Manuel Goodsaid, PhD

Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

SESSION 320 NHP - NATURAL HEALTH PRODUCTS, CR

8:30 am-10:00 am

LEVEL: ■

Room B306 CME and Pharmacy credits offered

Characterizing Variability of Botanical Products: Impact on Scientific Research and Product Development

SESSION CHAIRPERSON(S)

Carmen Tamayo, MD

Director, Research and Development, Flora, Inc.

R&D of botanical drugs derived from traditional herbal medicines requires a multidisciplinary evidence-based approach. To overcome challenges, new research methods should be created. Pros and cons of various approaches and comparative examples from the pharmaceutical industry will be presented.

From Cellular Assays to Clinical Trials: Are We Using the Right Methods to Develop Botanical Drugs?

Carmen Tamayo, MD

Director, Research and Development, Flora, Inc.

Characterization of the Variability in Botanical Materials Used in Scientific Research

Jay Udani, MD

Chief Executive Officer and Medical Director, Medicus Research

Analysis of Natural Health Products: Challenges and Solutions

Mark C. Roman, PhD

President, Tampa Bay Analytical Research, Inc.; AOAC Dietary Supplement Subject Matter Expert

SESSION 321 OS - OUTSOURCING, CR

8:30 am-10:00 am

LEVEL: ■

Room B401

Clinical Trials in China: Opportunity versus Difficulties

SESSION CHAIRPERSON(S)

Mark C. Engel, JD

Chairman, Excel PharmaStudies Inc., China

This session will provide an overview of the drivers that are increasing the number of trials being done in China by an estimated 50% per annum. Practical guidance for dealing with significant obstacles including regulatory, patient enrollment, and informed consent as well as the opportunities such as proof of concept, dual development and large additional indication will be discussed. While some of these drivers are obvious, the session will highlight the aspects that make China unique and often complex. Actual examples will be presented.

An Overview of China Clinical Trials

Mark C. Engel, JD

Chairman, Excel PharmaStudies Inc., China

Clinical Trials in China: Regulatory Quality and Logistics Considerations

Ling Su, PhD

Director, Medical and Pharmaceutical Development, Shanghai Roche Pharmaceuticals, Ltd., China

China Clinical Trials: The BMS Perspective

Cezary Statuch, MD

Executive Medical Director, Greater China, Bristol-Myers Squibb, China

SESSION 322 PM1 - PROJECT MANAGEMENT, CR

8:30 am-10:00 am

LEVEL: ■

Room B402

Project Management units offered

The Evolving Role of Project Management in Drug Development

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.

Learn-and-Confirm Drug Development: An Innovative Approach to Enhancing Productivity

Mark A. Lane, PhD, MS

Director, Project Management, Wyeth Research

Improving Productivity through Timeline Practices

Thomas C. Lange, BSIE

Project Management Consultant, Eli Lilly and Company

Improving Productivity through Resource Planning and Management

Todd Tullis

Manager, Accenture

SESSION 323 PM2 - PROJECT MANAGEMENT, RD

8:30 am-10:00 am

LEVEL: ●

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.

SESSION 324 PP - PUBLIC POLICY/LAW, MA

8:30 am-10:00 am

LEVEL: ■

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

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

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 LEVEL: ■

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

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.

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 LEVEL: ◆

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 330 ST - STATISTICS, EC

8:30 am-10:00 am LEVEL: ■

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 329 RD - R&D STRATEGY, CTM/CS

8:30 am-10:00 am LEVEL: ■

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

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

10:00 am-10:30 am

REFRESHMENT BREAK

Building A – Exhibit Hall A Only

Building B – Levels 3 & 4, Meeting Room Corridors

SESSION 333 AHC - ACADEMIC HEALTH CENTERS, CR

10:30 am-12:00 pm LEVEL: ♦

Room B303*Nursing and Pharmacy credits offered***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

SESSION 335 CDM - CLINICAL DATA MANAGEMENT, EC

10:30 am-12:00 pm LEVEL: ■

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.

SESSION 336 CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA

10:30 am-12:00 pm LEVEL: ■

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

SESSION 337

CP - CLINICAL SAFETY AND PHARMACOVIGILANCE, CDM

10:30 am-12:00 pm

LEVEL: ■

Room A302

CME and Nursing credits offered

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

SESSION 338

CR1 - CLINICAL RESEARCH AND DEVELOPMENT, OS

10:30 am-12:00 pm

LEVEL: ◆

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 LEVEL: ■

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

Actuarial Methods within Pharmacoeconomics and Clinical Trials: Overview*Chris Stehno, MBA, MS*

Senior Manager, Deloitte Consulting

SESSION 340 CR3 - CLINICAL RESEARCH AND DEVELOPMENT, CP

10:30 am-12:00 pm LEVEL: ●

Room B409 CME credits offered

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 research has resulted in proposals to combine the functions between IRB and Data Safety Monitoring Committees (DSMCs). This session will review research in this area with respect to a novel approach of DMC utilization.

THIS SESSION HAS BEEN CANCELLED**The Role of the IRB***Karen 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

SESSION 341 CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, CR

10:30 am-12:00 pm LEVEL: ■

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

SESSION 342 EC - eCLINICAL, CDM

10:30 am-12:00 pm LEVEL: ■

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

SESSION 343 ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, RA

10:30 am-12:00 pm LEVEL: ●

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

SESSION 344 GCP - GOOD CLINICAL PRACTICES, CR

10:30 am-12:00 pm

LEVEL: ■

Room B406AB

Virtual Realities: Quality Considerations when Using Outsource Providers

SESSION CHAIRPERSON(S)

Deborah A. Waltz, MS

Senior Director, R&D Quality, King Pharmaceuticals

Sponsors can wrongly assume ownership of quality responsibility when contracting activities to outside organizations. FDA expectations for the responsibility of assuring GCP compliance and practical steps for sponsors to improve outcomes when working with outsource providers will be discussed.

Developing and Managing a Quality Program in a Virtual Environment

Stanley C. Rogers

Executive Vice President, R&D Quality Assurance, SMHW Associates, LLC

FDA Perspective: Who's Responsible for Quality when Activities Are Outsourced?

Joseph P. Salewski, MS

Deputy Director, Division of Scientific Investigations, CDER, FDA

Implementing a Quality Program

Deborah A. Waltz, MS

Senior Director, R&D Quality, King Pharmaceuticals

SESSION 345 IT1 - INFORMATION TECHNOLOGY, VA

10:30 am-12:00 pm

LEVEL: ■

Room A305

GMP, GLP, GCP ... Why Not GSP – Good Systems Practice?

SESSION CHAIRPERSON(S)

Keith M. Parent, MS

Chief Executive Officer, Court Square Data Group, Inc.

FDA regulations make it difficult for biopharms to improve IT service delivery and maintain compliance. This session will discuss a model for operating in FDA-regulated environments based on ITIL – good systems practice – which enables IT managers to map ITIL to the regulatory regime for compliance.

Implementing ITIL Processes at Small- and Medium-sized Organizations

Rob Michael, MS

Senior Director, IT, Synta Pharmaceuticals Corp.

GMP, GLP ... Why Not GSP?

Keith M. Parent, MS

Chief Executive Officer, Court Square Data Group, Inc.

Identity and Access Management: Why Should You Care?

William Barnes, MS

Identity Services Manager, Pfizer Inc

SESSION 346 IT2 - INFORMATION TECHNOLOGY, VA

10:30 am-12:00 pm

LEVEL: ◆

Room A313

Deploying Life Science IT Using IEEE Methods

SESSION CHAIRPERSON(S)

Thomas Quinn

President, CISSP, The Hollis Group, Inc.

This session presents an overview of IEEE-based prototyping methods, descriptions of case studies (i.e., bespoke code, COTS projects), change control and configuration management of code and documentation from development through test, concluding with labor, schedule, and cost performance summaries.

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.

Traditional and Innovative Tools for Evidence-based Medicine (EBM) or Value Proposition Demonstration

Daniel M. Huse, MA

Director, MarketScan Studies, Thomson Healthcare

Inside-out Perspective from an Experienced Health-policy Decision Maker (HPDM) on Needs Assessment

Robert Snediker, RPh

Senior Economic, Clinical and Health Outcomes Scientist, Medical Affairs Department, Centocor, Inc.

SESSION 349 MW - MEDICAL/SCIENTIFIC WRITING, RA

10:30 am-12:00 pm LEVEL: ●

Room B405

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

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

Susan F. Gonsalves, PhD, MBA

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? Overview of Required Postapproval Documents

Julia Cooper, PhD

Senior Director, Worldwide Head of Medical Writing Services, PAREXEL International Ltd., UK

SESSION 350 NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT, CR

10:30 am-12:00 pm LEVEL: ■

Room B305 CME credits offered

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.

Better Prediction of Hepatotoxicity: Industry View

Gerd Bode, MD

Consultant, Germany

The Draft EU Guideline for Hepatotoxicity

Klaus Olejniczak, DVM, FACP

Scientific Director, BfArM, Germany

Hepatotoxicity Working Group of the Critical Path Predictive Safety

Testing Consortium

Holly L. Jordan, DVM, PhD

Director, Clinical Pathology, GlaxoSmithKline

SESSION 351 NHP - NATURAL HEALTH PRODUCTS, CR

10:30 am-12:00 pm LEVEL: ■

Room B306

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

Diabetes mellitus (DM) is one of the most common metabolic disorders in the world. New therapies are still needed to manage this serious and life-threatening clinical condition. Historical use of NHPs may provide evidence of activity against diabetes mellitus. However, the safety and efficacy of these products will need to be validated in appropriate nonclinical and clinical studies. This session will explore scientific and regulatory approaches for NHPs, including the nonclinical testing requirements to support new drug development in the United States. Federal funding for diabetes mellitus through the US National Institutes of Health will also be discussed.

Novel Approaches for the Scientific Validation of Indian Medicinal Plants and Herbs for the Management of Type 2 Diabetes Mellitus

Pradeep Visen, PhD

Research Scientist, Risk Factor Modification Centre, St. Michael's Hospital, University of Toronto, Canada

Conducting Pharmacology-toxicology Studies on Botanical Drugs: IND to NDA

Linda A. Doody, PhD

Senior Director, Clinical Research and Regulatory Affairs, CCS Associates, Inc.

NIH Funding Programs for Diabetes Research

Saul Malozowski, MD, PhD, MBA

Senior Advisor, Endocrine Physiology, NIDDK, National Institutes of Health

SESSION 352 OS - OUTSOURCING, CR

10:30 am-12:00 pm LEVEL: ■

Room B401

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.

Each year, The Avoca Group conducts an industry survey of pharmaceutical companies, biotech companies and service providers focused on the state of clinical outsourcing. Quantitative and qualitative data on a range of topics related to clinical outsourcing is gathered and this data has been presented for the past four years at DIA's Annual Meeting. In this interactive and

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

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

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, MSc**

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.

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, 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**Agnès Saint Raymond, MD, PhD**

Head of Sector, Scientific Advice and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

SESSION 359 ST - STATISTICS, CP

10:30 am-12:00 pm LEVEL: ■

Room B309 CME and Pharmacy credits offered**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

In the wake of recent issues surrounding the safety of marketed pharmaceutical products, new diagnostics and methodologies for detecting and analyzing drug safety signals are needed. This session will cover statistical methods for both premarketing and postmarketing safety assessment. Some of the recommendations mentioned in the FDA's 2005 Guidance for Industry on premarketing risk assessment will be covered under premarketing techniques. For postmarketing, meta-analysis techniques such as exact methods and Bayesian hierarchical modeling will be compared to more traditional approaches. Special attention will be given to the problems associated with rare events. Visual assessment tools will also be covered.

Key Problems in Premarketing Safety Analysis and How to Approach Them**Doris Kolb**

Director of Operations, Medical Affairs, PRA International, Germany

Bayesian Approaches to Combining Rare Event Evidence**Eloise E. Kaizar**

Assistant Professor, Department of Statistics, Ohio State University

Regulatory Challenges to Statistical Safety Analysis**Christopher Holland, MS**

Mathematical Statistician, Quantitative Safety and Pharma Epidemiology Group, Office of Translational Sciences, CDER, FDA

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

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, AAI Pharma, 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

SESSION 370 CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, TR

1:30 pm-3:00 pm

Room B404

Delivering Effective Feedback for Clinical Research Managers

SESSION CHAIRPERSON(S)

Mary E. Briggs, MS

Chief Training Officer, FOCUS, Inc.

Gain essential clinical research management skills to use the feedback formula to better communicate and resolve conflicts. Get your clinical research team to feel a sense of pride in their job and to work more productively.

Removing Emotion from Performance-based Corrective Feedback Sessions

Mary E. Briggs, MS

Chief Training Officer, FOCUS, Inc.

Fundamentals of Delivering Effective Feedback for Managers and Supervisors

Nazma Muhammad-Rosado

Director, Process Management, Standards and Training, Genentech, Inc.

SESSION 371 ERS/DM1 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM

1:30 pm-3:00 pm

LEVEL: ■

Room A314

Content Management

SESSION CHAIRPERSON(S)

Kay Bross, MEd

Senior PKI Specialist, Information Security and Solutions, Procter & Gamble Co.

Initial application of eCTD standards focused on the regulatory aspects of ensuring information segments were in the correct format and submission structure. This session will explore the use of those standards applied to the management of data across the continued product life cycle. Sharing the challenges in understanding this environment and its impact on daily activities of the submission management group focuses attention on the need to move from a reactive environment to proactively planning for change to better manage content into the future.

Introduction

Kay Bross, MEd

Senior PKI Specialist, Information Security and Solutions, Procter & Gamble Co.

Preparing Submission Management (aka Regulatory Operations) for the eWorld

Jean L. Supplee

Group Manager, Submission Management, AstraZeneca

eCTD as an Enabler for the Integrated Management of Drug Information

Don Rosen

Principal, Don Rosen Consulting

SESSION 372 ERS/DM2 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, RA

1:30 pm-3:00 pm

LEVEL: ●

Room A412AB

How Public-private Partnerships Can Facilitate Electronic Regulatory Submissions

SESSION CHAIRPERSON(S)

William A. Rosen, MS

Executive Director, Pfizer Inc

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

SESSION 373 GCP - GOOD CLINICAL PRACTICES, TR

1:30 pm-3:00 pm

LEVEL: ◆

Room B403

Pharmacy credits offered

Successful Implementation of a Quality Management System

SESSION CHAIRPERSON(S)

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 Kisler

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 Kisler**

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

LEVEL: ■

Room B405

CME, Nursing, and Pharmacy credits offered

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.

Narrative Writing of Clinical/Drug Safety Adverse Event Reports

Mark Vieder, RPh

Medical Coding Specialist/AERS-FDA Team Leader, PSI International, Inc.

Preparing Risk Management Plans: Current Best Practices and Practical Considerations

Aparna K. Mohan, MD, PhD

Director, Epidemiology, Benefit Risk Management, Johnson & Johnson Pharmaceutical Medicine and Nutritionals

Writing a Quality PSUR: How to Turn a Sow's Ear into a Silk Purse

Sidney N. Kahn, MD

President, Pharmacovigilance & Risk Management, Inc.

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, HeteroGeneity, 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

which take more time and money to complete. 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. Cioffé, 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

SESSION 383 PP - PUBLIC POLICY/LAW, RA

1:30 pm-3:00 pm

LEVEL: ■

Room A410

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

SESSION CHAIRPERSON(s)

David K. M. Van Passel, LLM

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, LLM

Associate, Covington & Burling LLP, Belgium

SESSION 384 RA1 - REGULATORY AFFAIRS, CR

1:30 pm-3:00 pm

LEVEL: ◆

Room A404

EMEA Guideline on Pharmaceuticals in the Environment (PiE)

SESSION CHAIRPERSON(s)

David J. Cocker, Esq.

Chief Executive Officer, Ecotrac n.v., Belgium

Pharmaceuticals in the Environment (PiE) is a relatively new topic which has attracted regulatory attention. The introduction of a new specific EMEA guideline places a new requirement on pharmaceutical companies to evaluate the environmental impact from exposure to pharmaceutical active ingredients.

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

SESSION 385 RA2 - REGULATORY AFFAIRS, IMP

1:30 pm-3:00 pm

LEVEL: ■

Room A411

CME credits offered

Imaging and Drug Development

SESSION CHAIRPERSON(s)

Orhan H. Suleiman, PhD

Senior Science Policy Adviser, Office of Oncology Drug Products, Office of New Drugs, CDER, FDA

FDA's Critical Path Initiative identifies imaging as a critical drug development tool. This session will provide an overview of a representative set of imaging modalities, computerized tomography (CT), positron emission tomography (PET), and magnetic resonance imaging (MRI), which are having a dramatic impact in medicine today.

Positron Emission Tomography (PET)

Ramsey D. Badawi, PhD

Assistant Professor of Radiology, UCDMC Department of Radiology, University of California - Davis

Computed Tomography (CT)

Dianna D. Cody, PhD

Chief, Radiologic Physics, University of Texas - M.D. Anderson Cancer Center

Magnetic Resonance Imaging (MRI)

Edward F. Jackson, PhD

Professor, University of Texas - M.D. Anderson Cancer Center

SESSION 386 RA3 - REGULATORY AFFAIRS, BT

1:30 pm-3:00 pm

LEVEL: ■

Room A402

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 Feldscheirer, 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

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

SESSION 389

RA6 - REGULATORY AFFAIRS, CP

1:30 pm-3:00 pm

LEVEL: ●

Room A315

Pharmacy credits offered

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 Nutritionals, 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

SESSION 390

ST - STATISTICS, CR

1:30 pm-3:00 pm

LEVEL: ■

Room B309

Nursing and Pharmacy credits offered

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 an 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

3:00 pm-3:30 pm

REFRESHMENT BREAK

Building A – Exhibit Hall A Only

Building B – Levels 3 & 4, Meeting Room Corridors

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, FFPMP**

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

Living without CDMS

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 LEVEL: ■

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 LEVEL: ■

Room A302 CME, Nursing, and Pharmacy credits offered

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

Safety Signal Detection in Clinical Trials: Experience with an Ongoing Study

Linda M. Clayton, PharmD

Manager, Safety Evaluation Risk Management, GlaxoSmithKline

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

SESSION 399B CR3 - CLINICAL RESEARCH AND DEVELOPMENT, RA

3:30 pm-5:00 pm

LEVEL: ■

Room B407

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

SESSION CHAIRPERSON(s)

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

Heng-Der Chern, MD, PharmD, PhD

Executive Director, Center for Drug Evaluation, Taiwan

SESSION 399C CTM/CS - CLINICAL TRIAL MANAGEMENT/CLINICAL SUPPLIES, IS

3:30 pm-5:00 pm

LEVEL: ●

Room B404

Understanding Clinical Trial Volunteer Experiences and Examining Financial Challenges of Investigative Sites

SESSION CHAIRPERSON(s)

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

SESSION 399D ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, CDM

3:30 pm-5:00 pm

LEVEL: ●

Room A412AB

eCTD Life-cycle Management for Authors

SESSION CHAIRPERSON(s)

Nancy P. Smerkanich

Vice President, Regulatory Affairs, Octagon Research Solutions, Inc.

This session will examine the implications of eCTD life-cycle management on the authors of the various technical sections and documents submitted in both US and EU submissions. The focus will be on the quality (chemistry, manufacturing and controls) sections, as well as clinical study reports and regulatory information. The use of the eCTD in submitting and managing all regulatory submission components forces companies to look at the level of documentation, or granularity of the information they provide to FDA in order to leverage the promise of XML. It is the creation of these component documents by the technical authors that both formulates and results in efficient life-cycle management.

Regulatory Document Authoring**Nancy P. Smerkanich**

Vice President, Regulatory Affairs, Octagon Research Solutions, Inc.

Clinical Authoring for eCTD**Michèle A. Gargano, MSc**

Vice President, Clinical Development, Biothera Pharmaceuticals

Authoring CMC/Quality Documents for eCTD**Deanna Murden**

Associate Research Fellow, Pfizer Global Research and Development

SESSION 399E GCP - GOOD CLINICAL PRACTICES, CR

3:30 pm-5:00 pm

LEVEL: ■

Room B406AB

Nursing credits offered

Extreme Informed Consent

SESSION CHAIRPERSON(s)

Darren B. McDaniel, MS

Chief Executive Officer, Managing Officer, Coast IRB, LLC

Informed consent is the single most important aspect in clinical research and a major problem in the conduct of clinical trials. Benefits and pitfalls of the current technologies used, real-life examples, and tangible ways to do informed consent will be presented.

Extreme Informed Consent**Darren B. McDaniel, MS**

Chief Executive Officer, Managing Officer, Coast IRB, LLC

Adapting Informed Consent: Informed Patient Decisions in Different Cultures**Linda Wolf, MS**

Strategic Consultation, BBK Worldwide

Multimedia to Enhance/Supplement the ICF Process**Susan Brink, DrPH**

President and Chief Executive Officer, ConsentSolutions, Inc.

SESSION 399F IT - INFORMATION TECHNOLOGY, EC

3:30 pm-5:00 pm LEVEL: ■

Room A305

Evolving Technologies for Interoperability

SESSION CHAIRPERSON(s)

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 399G MC - MEDICAL COMMUNICATIONS, TR

3:30 pm-5:00 pm LEVEL: ■

Room B302 *Pharmacy credits offered*

Elevating Scientific Expertise via Formal Assessments

SESSION CHAIRPERSON(s)

Dixie Bibb, MBA, RPh

Medical Liaison Trainer, Eli Lilly and Company

Maintaining scientific excellence is increasingly challenging and requires focusing on learning objectives and training. Effective knowledge assessments evaluate the effectiveness of a training event and provide documentation of individual competency.

Introduction and Overview

Dixie Bibb, MBA, RPh

Medical Liaison Trainer, Eli Lilly and Company

Do You Know It? Can You Do It? Assessing Scientific Knowledge and Performance

Cindy L. Heck, MED

Project Manager/Instructional Designer, C. Heck Instructional Development

A Case Study: Sharing Key Learnings for Successful Training with Assessments

Patricia R. Hogan, BSN

Senior Training Associate, Global Medical, Eli Lilly and Company

SESSION 399H NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT, BT

3:30 pm-5:00 pm

LEVEL: ■

Room B305

Preclinical Safety Assessment of Biopharmaceuticals – Part 2 of 2

SESSION CHAIRPERSON(s)

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 rationale 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

LEVEL: ◆

Room B306 *Pharmacy credits offered*

Follow-on Products: Scientific, Legal, and Regulatory Topics that Impact Chemically Complex and Polymolecular New Drugs

SESSION CHAIRPERSON(s)

Freddie Ann Hoffman, MD

Chief Executive Officer, HeteroGeneity, LLC

Food and Drug Administration has recently approved two complex, polymolecular 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

patenting of natural products, and whether complex products can be copied as generic drugs, this session will provide an overview of obtaining patents for products of nature, the current debate regarding what is the same and what is biosimilar, and how current US law addresses sameness with respect to marketing exclusivity, patent term restoration and similar issues that may impact the development and marketing of NHPs.

Patenting Nature and the Nature of Patenting

Thomas M. Saunders, JD

Partner, Seyfarth Shaw, LLP

Secrets of Nature and the Nature of Secrets: Protecting Intellectual Property Beyond Patents

Freddie Ann Hoffman, MD

Chief Executive Officer, HeteroGeneity, LLC

Impact of US Regulation on Follow-on Natural Health Products

Peter H. Rheinstein, MD, JD, MS

Chief Executive Officer, Severn Health Solutions

SESSION 399J OS - OUTSOURCING, CDM

3:30 pm-5:00 pm

LEVEL: ●

Room B401

Functional Service Providers and the Next Stage of Evolution for Clinical Data Management

SESSION CHAIRPERSON(S)

Jonathan R. Andrus, MS

Vice President, Quality Assurance and Clinical Data Management, Phoenix Data Systems, Inc.

Some pundits have already announced the death of CDM as a profession. This session illustrates the ways that the function has evolved and provides insights on career development as well as new outsourcing choices.

Data Management Mixology

Debra A. Jendrasek

Global Head, EDC Solutions, Chiltern International

Data Management in an Alliance Partnership: Using a CRO to Manage Risk

Tricia Marcy, BSN

Manager, Development Operations, Pfizer Global Research and Development

Douglas Schantz

Senior Director, Development Operations, Pfizer Global Research and Development

Alternatives to Traditional Outsourcing: The FSP Model

Thomas Verish, MS

Senior Director, Development Operations, Pfizer Global Research and Development

Susan Bornstein, MPH

Vice President, Bio-Pharma Consulting, Eliassen Group

SESSION 399K PM1 - PROJECT MANAGEMENT, RD

3:30 pm-5:00 pm

LEVEL: ■

Room B403 Project Management units offered

Project Management as a University Research Tool

SESSION CHAIRPERSON(S)

Cynthia Helplingstine, 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?

Lembit 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

SESSION 399N PP2 - PUBLIC POLICY/LAW, IMP

3:30 pm-5:00 pm

LEVEL: ■

Room A404

Pharmacy credits offered

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, Gruenthal GmbH, Germany

SESSION 399O RA1 - REGULATORY AFFAIRS, RD

3:30 pm-5:00 pm

LEVEL: ■

Room A402

CME credits offered

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.

SESSION 399P RA2 - REGULATORY AFFAIRS, CR

3:30 pm-5:00 pm

LEVEL: ■

Room A405

Compassionate Use Supply of Unlicensed Products in Europe and Beyond

SESSION CHAIRPERSON(S)

Susan M. Sandler

Principal Consultant, PAREXEL Consulting, PAREXEL International, UK

Explores the the maze of regulations and practices on compassionate use of unlicensed medicines within EU member states and other countries. This session will discuss how the EU Commission is attempting to standardize the approach within the EU, with new regulations and evolving guidelines.

Compassionate Use: Challenges for Industry

Finn Mollgaard, MPharm

Vice President, Regulatory Affairs, Novo Nordisk A/S, Denmark

Susan M. Sandler

Principal Consultant, PAREXEL Consulting, PAREXEL International, UK

Francesco Pignatti, MD

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

SESSION 399Q RA3 - REGULATORY AFFAIRS, CR

3:30 pm-5:00 pm

LEVEL: ■

Room A406

Critical Path in Japanese Drug Development Strategy Using Foreign Data

SESSION CHAIRPERSON(S)

Shunsuke Ono, PhD

Associate Professor, University of Tokyo, Japan

The concept of critical path in drug development has been discussed not only in the US but worldwide. Successful global development requires considerations on a regional path. This session will share information about current and future development strategies in Japan from the perspectives of the sponsors, regulators and CROs.

Challenges and Innovations in Asian and Japanese Development Strategies

Hans Peter Goertz

Global Development Liaison Manager, Japan and Emerging Growth Markets, Novartis Pharma K.K., Japan

Role of Ex-Japan Clinical Pharmacology Studies (Ethnobiudging) in Expediting Japanese Drug Development

Stan S. Jhee, PharmD

Vice President, Director of Research, California Clinical Trials, PAREXEL International

Progress in Asian Clinical Development

Hironobu Saito, MPharm

Clinical Group Leader, Asian Development Department, Daiichi-Sankyo Co., Ltd., Japan

SESSION 399R RA4 - REGULATORY AFFAIRS, RD

3:30 pm-5:00 pm

LEVEL: ■

Room A411

CME credits offered

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.

SESSION 399U TR - TRAINING, CR

3:30 pm-5:00 pm

LEVEL: ■

Room B308**Training Enhancements to Support the Evolution of the Monitoring Role**

SESSION CHAIRPERSON(s)

Kristin Ellis

Group President, Kforce Clinical Research

Numerous industry drivers have resulted in a rapid evolution of the clinical research associate's responsibility from traditional source document verification to total site management. This session will focus on understanding the training needs required to support the demands of total site management, new technology, and changes in the industry's regulatory environment. With a greater focus on training, it is essential to understand key metrics to measure its effectiveness.

Panelists**Lisa La Luna**

Vice President, Corporate Business Development, ePharmaSolutions, Inc.

Kristin Ellis

Group President, Kforce Clinical Research

Patricia L. Fisher, BSN, MSc

Compliance and Training Manager, Hoffmann-La Roche, Inc.

SESSION 399V VA - VALIDATION, RA

3:30 pm-5:00 pm

LEVEL: ■

Room A311**Current Regulatory Issues: SOX and Beyond?**

SESSION CHAIRPERSON(s)

Martin Browning, MS

President, EduQuest, Inc.

The global regulatory environment is one that is constantly changing and can result in numerous challenges for the clinical development team in dealing with electronic data integrity, privacy, and technology. This session will discuss some of the recent regulations, changes, and approaches affecting the global trial process. It addresses clinical risk assessment and management, validation compliance of global systems, and presents an approach to system development and management that covers validation and other FDA requirements. Sarbanes-Oxley requirements, as well as other global expectations and requirements for clinical data systems.

Risk Assessment and Management Process: A Case Study of a Clinical Application**Richard M. Siconolfi, MS**

Director, Computer Systems Validation and System Lifecycle Management, Procter & Gamble Pharmaceuticals

Compliance and Validation for Global Systems: Putting the Puzzle Together**Pamela S. Campbell, MBA**

Senior Consultant, BusinessEdge Solutions

A Unified Approach to Global Requirements Development**Martin Browning, MS**

President, EduQuest, Inc.

5:00 pm **END OF WEDNESDAY SESSIONS**5:00 pm-6:00 pm **EMERGING PROFESSIONALS NETWORKING RECEPTION**5:15 pm **CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH MEETING**

Room B301, Building B, Level 3, GWCC

<p>7:30 am-10:30 am ATTENDEE REGISTRATION and SPEAKER REGISTRATION Building A/B Registration Hall, International Boulevard, Philips Drive Entrance, GWCC</p> <p>7:30 am-8:15 am CONTINENTAL BREAKFAST Registration Area Foyer</p> <p>12:30 pm-5:00 pm MedDRA® USER GROUP MEETING Room A410, Building A, Level 4, GWCC</p>	<p>Gene Therapy: Challenges and Hurdles in Planning and Conducting Global Clinical Trials <i>Milan Kovacevic, MD, PhD, MS</i> Vice President, Clinical Operations, GenVec, Inc.</p> <p>Gene Therapy Regulations for EU Clinical Trials: Navigating the Maze <i>Cecil Nick, MS</i> Principal Consultant, PAREXEL Consulting, UK</p> <p>Development of Plasmid-based Vaccines and Therapeutics: Case Studies <i>Alain Rolland, PharmD, PhD</i> Senior Vice President, Product Development, Vical Incorporated</p>
<p>SESSION 401 AHC - ACADEMIC HEALTH CENTERS, TR</p> <p>8:30 am-10:00 am LEVEL: ◆ Room B302</p> <p>Opportunities for Global Clinical Trials in India: Prospects and Challenges</p> <p>SESSION CHAIRPERSON(S) <i>Suresh K. Gupta, DrSc, PhD</i> Dean and Director General, Institute of Clinical Research, India</p> <p>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.</p> <p>FDA GCP Experiences in India</p> <p><i>David A. Lepay, MD, PhD</i> Senior Advisor for Clinical Science; Director, Good Clinical Practice Programs, Office of Science and Health Coordination, Office of the Commissioner, FDA</p> <p>Current Regulatory Environment in India</p> <p><i>Mamidanna Venkateswarlu</i> Drug Controller General, Ministry of Health and Human Welfare, Government of India</p> <p>Capacity Building: Education and Training Opportunities</p> <p><i>Anthony C. Woodman, PhD, MS</i> Professor and Director of Education, Cranfield Health, Cranfield University, UK</p> <p>Challenges in Conducting Clinical Research in India</p> <p><i>Vijai Kumar, MD</i> President and Chief Medical Officer, Excel Life Sciences, Inc.</p> <p>Clinical Trials: Good Review Practices</p> <p><i>Mehul Mehta, PhD</i> Director, Division of Clinical Pharmacology I, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA</p>	<p>SESSION 403 CDM - CLINICAL DATA MANAGEMENT, IT</p> <p>8:30 am-10:00 am LEVEL: ● Room A312</p> <p>EHR Considerations for Clinical Data Management</p> <p>SESSION CHAIRPERSON(S) <i>Anthony J. Costello</i> Vice President, Product Development and Data Services, Nextrials, Inc.</p> <p>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.</p> <p>CDISC/IHE/HIMSS: Demonstrating Healthcare to Clinical Research Interoperability</p> <p><i>Landen C. Bain</i> Healthcare Liaison, CDISC</p> <p>A Tale of Two Markets: Impact of EHR/EDC Integration</p> <p><i>Chris Connor</i> Senior Research Analyst, IDC Health Industry Insights</p> <p>EHR Redefines the Source Document: A Reality Check on Future EHR to EDC Integration</p> <p><i>Anthony J. Costello</i> Vice President, Product Development and Data Services, Nextrials, Inc.</p>
<p>SESSION 402 BT - BIOTECHNOLOGY, CR</p> <p>8:30 am-10:00 am LEVEL: ■ Room B301 CME and Nursing credits offered</p> <p>Gene Therapy: Challenges and Hurdles in Planning and Conducting Global Clinical Trials</p> <p>SESSION CHAIRPERSON(S) <i>Milan Kovacevic, MD, PhD, MS</i> Vice President, Clinical Operations, GenVec, Inc.</p> <p>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.</p>	<p>SESSION 404 CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES, RA</p> <p>8:30 am-10:00 am LEVEL: ■ Room A315</p> <p>cGMPs and Manufacturing Modernization in the 21st Century</p> <p>SESSION CHAIRPERSON(S) <i>Edwin Rivera-Martinez</i> Branch Chief, Office of Compliance, Division of Manufacturing and Product Quality, CDER, FDA</p> <p>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 meeting 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).</p> <p>Update on Guidance, Policy, and International Issues/Inspectional and Drug Quality Trends</p> <p><i>Edwin Rivera-Martinez</i> Branch Chief, Office of Compliance, Division of Manufacturing and Product Quality, CDER, FDA</p>

Update on FDA cGMP Initiatives and Guidances**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 LEVEL: ■

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 LEVEL: ●

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.

Importance of Phase 1 Trials**Erin O'Donnell, RN**

Senior Clinical Project Specialist, Schering-Plough Corporation

Erica Elefant, RN, BSN, MSW

Senior Clinical Scientist, Bristol-Myers Squibb Company

Monitoring and Training for Phase 1 Studies**Alicia A. Pouncey, MED**

Managing Director, Aureus Research Consultants, LLC

Phase 1 Trials in Asia: Opportunities and Considerations**Shirley Suresh, MD**

Operations Manager, Clinical Research, SGS Life Science Services, Singapore

SESSION 407 CR2 - CLINICAL RESEARCH AND DEVELOPMENT, CTM/CS

8:30 am-10:00 am

LEVEL: ■

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

LEVEL: ■

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 (RCRM), the FDA Electronic Submission Gateway, and eSubmission developments in ICH.

Progress Report of the HL7 RCRM 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 non-clinical 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

SESSION 413 NHP - NATURAL HEALTH PRODUCTS, RA

8:30 am-10:00 am

LEVEL: ■

Room B306

Asia Strategy on the Research and Development and Regulation for the Modernization of Herbal Medicine

SESSION CHAIRPERSON(S)

Shiouh-Yi Chen, PhD

Senior Officer, Center for Drug Evaluation, Taiwan

This session will share the experience on possible resolution on the quality control, the interaction of botanical drugs with western medicine and the R&D strategy and the approval of the first NDA on botanical drugs in Taiwan.

Regulatory Aspect of CMC Issues on Development of Botanical Drugs*I-Chen Sun, PhD*

Reviewer, Center for Drug Evaluation, Taiwan

Natural Products Significantly Inhibit Five Phase 1 and Phase 2 Hepatic Enzymes*Oliver Yoa-Pu Hu, PhD*

Dean, Research and Development, National Defense Medical Center, Taiwan

Strategy on the Research and Development and Regulation for Herbal Medicine*Shiouh-Yi Chen, PhD*

Senior Officer, Center for Drug Evaluation, Taiwan

SESSION 414 OS - OUTSOURCING, CR

8:30 am-10:00 am

LEVEL: ■

Room B403

Functional Outsourcing: Beyond Data Management

SESSION CHAIRPERSON(S)

Rikki Hansen Bouchard, MPA

President and Chief Executive Officer, RH Bouchard & Associates, Inc.

Functional outsourcing is progressing beyond data management and monitoring to encompass services that are traditionally handled as part of a full service contract or done internally at the sponsor. This session will explore the benefits and drawbacks of this approach.

Functional Outsourcing: Regulatory Document Collection and Processing*Jennifer A. Chow*

Director, NAMG Operations Head, Pfizer Global Research and Development

Outsourcing: Investigator Agreements*Lorenda Dasher, CPA*

Associate Director, Contracts Administration, Novartis Pharmaceuticals Corporation

Functional Outsourcing: Drug Safety Program*Jennifer R. Goodfellow, MS*

Senior Director, Clinical Outsourcing, Sepracor Inc.

Outsourcing: Independent Medical Grant Program*Linda Carlson, PhD, MBA*

Vice President, Medical Operations, EMD Serono, Inc.

SESSION 415 PM - PROJECT MANAGEMENT, GCP

8:30 am-10:00 am

LEVEL: ■

Room B402 *Project Management units offered***Preparing Product Launch Teams Using a War Game Simulation**

SESSION CHAIRPERSON(S)

Rebecca O'Donnell, MBA, MS

Associate Director, Pfizer Inc

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 Thriwikramji, 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

SESSION 416 PP - PUBLIC POLICY/LAW, FI

8:30 am-10:00 am

LEVEL: ●

Room A406

Strategies for Maximizing the Financial Portfolio through Intellectual Property

SESSION CHAIRPERSON(S)

Peter J. Rankin, PhD

Principal, CRA International

Intellectual property represents some of the most significant assets, expenditures, and strategic levers available to life science companies. In this session we will review and assess current litigation affecting the future value of pharmaceutical patents and intellectual property. Strategies will be provided to prevent damages to sales, revenue streams and ultimately consumer confidence. This information is important for pharmaceutical, biotechnology, and professionals from around the world.

Strengthen and Secure Your Global Intellectual Assets*Eric Elting*

Director, Legal Business Development, TransPerfect Translations

Strategies for Maximizing the Value of Intellectual Property*Peter J. Rankin, PhD*

Principal, CRA International

SESSION 417 RA1 - REGULATORY AFFAIRS, CR

8:30 am-10:00 am

LEVEL: ■

Room A411

CDER Town Meeting – Part 1 of 2

SESSION CHAIRPERSON(S)

Nancy D. Smith, PhD

Director, Office of Training and Communications, CDER, FDA

Part 2 of this session will take place on Thursday at 10:30 am.

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

Panelists

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 combine 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 Vandenbende, 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

SESSION CHAIRPERSON(S)

Bryan John Doherty

Director, Global IS Quality and Compliance, AstraZeneca, UK

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

10:00 am-10:30 am

REFRESHMENT BREAK

Building A – Exhibit Hall A Only

Building B – Levels 3 & 4, Meeting Room Corridors

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

SESSION CHAIRPERSON(s)

Melvyn Greberman, 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 AHRQ, 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 insure 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

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 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.

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

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 verbatims, 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 Resironics Company

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

SESSION 428 CR2 - CLINICAL RESEARCH AND DEVELOPMENT, GCP

10:30 am-12:00 pm

Room B309 LEVEL: ■

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

Room B404 LEVEL: ■

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

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

Cheryl 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 LEVEL: ●

Room A412AB

eIND

SESSION CHAIRPERSON(S)

Jeanie 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 LEVEL: ■

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.

Presenting Your Investigational Site's Use of Electronic Data Capture: Best Practices

Earl W. Hulihan, MED

Vice President, Global Regulatory Affairs and Quality Assurance, Medidata Solutions Worldwide

SESSION 432 IT - INFORMATION TECHNOLOGY, EC

10:30 am-12:00 pm

LEVEL: ●

Room A314

Current Advances in eSubmissions: How Digital Signatures Are Transforming Information Exchange

SESSION CHAIRPERSON(S)

Mollie Shields-Uehling

President and Chief Executive Officer, SAFE-BioPharma Association

This session reviews the current state of digital signatures and electronic submissions in the healthcare industry, including costs and limitations of the existing model, from both a regulatory and legal perspective. Additionally, real-world examples of using digital signatures for electronic submissions to regulatory agencies, including the FDA and EMEA, will be addressed from a pharmaceutical company's point of view. Particular attention will be paid to the rapidly progressing future of eSubmissions and the value that digital signatures can deliver to transactions that are critical to streamlining electronic submissions, such as eINDs.

A Tale of Two SAFE Implementations

Colleen P. McMahon

Director, Global Security, Global IT Risk Management, GlaxoSmithKline

Striving for Permanent eRecords: A Pharmaceutical Company Perspective

Kay Bross, MED

Senior PKI Specialist, Information Security and Solutions, Procter & Gamble Co.

Panelist

Gary M. Gensinger, MBA

Director, Regulatory Review Support Staff, CDER, FDA

SESSION 433 NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT, BT

10:30 am-12:00 pm

LEVEL: ■

Room B305

The Utility of Humanized Metabolic Mouse Models in Drug Development

SESSION CHAIRPERSON(S)

Frank D. Sistare, PhD

Executive Director, Safety Assessment, Merck & Co., Inc.

The relevance of using animal models to support drug safety testing in preparation for human trials can be unknowingly limited by unrecognized differences between animals and humans. An area where the integrity of the conduct of such animal safety testing is being challenged, stems from the awareness of differences between humans and animals that could surface as the spectrum of circulating metabolites seen following dosing of certain drug candidates.

Application of Novel Mouse Models Humanized for the CAR and PXR Genes in Drug Metabolism and Safety Studies

Nico Scheer, PhD

Research Group Leader, ADMET/Animal Models, Artemis Pharmaceuticals GmbH, Germany

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

SESSION CHAIRPERSON(S)

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

SESSION CHAIRPERSON(S)

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

Project Management units offered

The Playing Field of Project Management: A Dynamic Investigation of a Team and their Winning Strategy

SESSION CHAIRPERSON(S)

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 dis-sension 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

SESSION CHAIRPERSON(S)

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 LEVEL: ●

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 LEVEL: ■

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

LEVEL: ■

Room B303

CME and Pharmacy credits offered

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, MLIS**

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

LEVEL: ■

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.

12:00 pm **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.

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

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.diahomes.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@diahomes.org

For companies M-Z – Erin Gilliland / Phone +1-215-442-6149 / email Erin.Gilliland@diahomes.org

Exhibiting companies registered as of February 7, 2007

Aagami, Inc.	Atcor Medical, Inc.	CEDRA Corporation
AAIPharma	Averion International Corp.	Center for Drug Evaluation, Taiwan
AbCRO, Inc.	Axiom Real-Time Metrics	Cerner Galt
Abt Associates Inc.	B & C Group	Cetero Research
Accovion	BARC	Charles River Laboratories Clinical Research Services - Northwest Kinetics
ACM-Pivotal Global Central Laboratory	BASI (Bioanalytical Systems, Inc.)	Chesapeake Research Review Inc.
ACR Image Metrix	BattelleCRO	Chiltern International, Inc.
ACRS	Baxa Corporation	Christiana Care Research Institute
Acurian	BBK Worldwide	Cincinnati Children's Research Foundation
Adobe Systems, Inc	Beacon Bioscience	CIRION Clinical Trial Services Inc.
Advanced Biologics, LLC	Beardsworth	City List Co., Inc.
Advanced Biomedical Research, Inc.	Benchmark Research	ClinAudits LLC
Advanced Clinical Services LLC	Bilcare, Inc.	ClinForce, LLC
Advanced Clinical Software	Bio-Imaging Technologies	Clinical DataFax Systems Inc.
Aerotek Scientific	Biomedical Systems	Clinical Financial Services
Allergan, Inc.	Bio-Optronics, Inc.	The Clinical Resource Network
Allphase Clinical Research	BioPharm Insight	Clinical Technology Transfer Group
Almac Clinical Services	bioRASI	Clinical Trial Media
Almac Clinical Technologies	BioResearch Monitors, Inc.	Clinilabs
Amarex Clinical Research	bioskin GmbH	Clinimetrics
American Medical Writers Association	BioStorage Technologies Inc.	Clinlogix LLC
AmeriTrial OTC Research	Biovail Contract Research	ClinPhone Inc.
Amgen Inc.	BRAND INSTITUTE, inc.	Clinsys
Anapharm	C3i, Inc.	ClinTec International Ltd.
APEX International Clinical Research Co., Ltd.	California Clinical Trials	CMAX (a division of IDT Australia Ltd)
Applied Clinical Trials Magazine	Camargo Pharmaceutical Services	CMIC Co., Ltd.
Aptuit Inc.	Cambridge Cognition Ltd.	Coast IRB
Apyx	The Cambridge Group, Ltd.	Cognitive Drug Research
ArisGlobal	Campbell Alliance	Community Research
Arrowhead Electronic Healthcare	Canadian Arthritis Network/Canadian Rheumatology Research Consortium	Compass IRB
ARS, Inc.	CanReg, Inc.	CompleWare® Corporation
ARX (Algorithmic Research)	CANTOX Health Sciences International	Concepts Worldwide
Asian Clinical Trials (Division of Suven Life Sciences Ltd)	Cardinal Health	Constella Group, LLC
Aspire IRB	Cardiocre	Contract Pharma
Assist Technologies	CardioLabs, Inc.	Copernicus Group IRB
AstraZeneca	CCA, Inc.	Cordium Links
Asuragen, Inc.	CDISC	Corporate Translations

Exhibiting Companies (registered as of February 7, 2007)

Covance Inc.	Fisher Clinical Services	Klein Management Systems
CRF Inc.	Fleury SA	KMI Diagnostics, Inc.
Criterium, Inc.	FOI Services, Inc.	LabConnect, LLC
CRL.Medinet	Forest Laboratories, Inc.	Laboratorio Hidalgo
CTI Clinical Trial & Consulting Services	Formedix Ltd.	Lernia Training Solutions
CTMS, Inc.	Formosa Biomedical Technology Corp.	Lifecord Stat-Korea Co., Ltd.
Cu-Tech, LLC	Fraunhofer Institute of Toxicology and Experimental Medicine (ITEM)	Lionbridge
Cytel Inc.	Future Science Group	Logos Technologies Ltd.
D. Anderson & Company	Galderma Research & Development	LORENZ Life Sciences Group
Data Systems Analysts	GB Pharma Services & Consulting s.r.l.	Los Angeles Biomedical Research Institute
DataCeutics, Inc.	Gentiae Clinical Research	Lovelace Scientific Resources
Datafarm, Inc.	Gentris Corporation	LSUHSC-Shreveport
DATATRAK International	Geny Research Group, Inc.	Maaguzi, LLC
Datatrial	Genzyme	MAJARO InfoSystems
DaVita Clinical Research	Glemser Technologies	Makro Technologies
Delta Pharma, Inc.	Global Languages & Cultures, Inc.	MasterControl, Inc.
Dendrite Clinical Solutions	Global Lifescience Solutions, LLC	Mayo Clinical Trial Services
Diabetes & Glandular Disease Research Associates	Green Mountain Logic, Inc.	McElroy Translation Company
Doublebridge Technologies, Inc.	GroupNet	McGuire Research Institute, Inc.
Drexel University Online	Harrison Clinical Research	MD Events Limited
Drug Safety Alliance, Inc.	Hawaii Clinical Research Center	MDS Pharma Services
DrugLogic Inc.	Health Decisions	MedDRA® MSSO
DSG, Inc.	Health Industry Insights	MedFocus, LLC
DUCK FLATS Pharma, LLC	Healthcare Communications Group	Medica Sur - CIFBIOTEC
Duke Clinical Research Institute	Hibernia College	Medical Graphics
DZS Software Solutions, Inc.	Howard M. Proskin & Associates, Inc.	The Medical Letter
ECLA	i3 Research	Medical Staffing Network
ECRON	i4i	Medidata Solutions
Edgewater Technology	IBT Reference Laboratory	Medifacts International
Elite Research Network, LLC	ICON Clinical Research	MedNet Solutions
Encore Research Group, LLC	iGATE Clinical Research International	Medpace, Inc.
Encorium	Image Solutions, Inc.	MedSignals
Endpoint Research	iMedRIS Data Corporation	MedSource
Engel Publishing Partners	IMIC - Mexican Institute of Clinical Research	MEDTOX Laboratories
entimo AG	Impact Clinical Trials	MedTrials, Inc.
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EPS Co., Ltd.	IMRO TRAMARKO	META Solutions, Inc.
eResearchTechnology, Inc.	INC Research	MetaClin Research Inc
Esoterix Clinical Trials Services, Inc.	Inclinix	MIC Medical Corp.
Essential Group, Inc.	Innovative Print & Media Group	Microsoft Corporation
EtQ, Inc.	Institute of Clinical Research India	Microsystems
etrials Worldwide	Integrated Clinical Systems, Inc.	Mid*Lands IRB
Eurofins Medinet, Inc.	Integrated Development Associates Co., Ltd.	MMG
European Medicines Agency (EMEA)	IntegReview Ethical Review Board	Monitorforhire.com
Eurotrials Scientific Consultants	Integrium - Integrex	Monitoring Force Group
Examination Management Services, Inc.	International Dermatology Research	Mortara Instrument, Inc.
Excel Life Sciences	Intralinks, Inc.	MPI Research
Excel PharmaStudies, Inc.	invivodata	MSOURCE Medical Development
Fast Track Systems	iProcess Inc	National Center for Health Statistics
Fast4wD Ogilvy	IRL (Pvt) Ltd	National Institute of Allergy and Infectious Disease
Favorite Healthcare Staffing	J&S Studies, Inc.	NDA Regulatory Science Ltd.
FDA/CDER	Johnson & Johnson Family of Companies	NERI - New England Research Institutes
FDAnews	Joulé Clinical Staffing Solutions	New Orleans Center for Clinical Research
Ferraris Respiratory	Kendle	Next Generation Clinical Research
First Consulting Group	Kforce Clinical Research Staffing	NextDocs Corporation

Northrop Grumman	Queensland Clinical Trials Network	Synarc, Inc.
Novotech	Quest Diagnostics	Synteract Inc
OCASA Logistics Solutions	Quintiles	TAKE Solutions Inc.
Octagon Research Solutions	QUMAS	Tandem Labs
Omnicare Clinical Research	Quorum Review IRB	Taratec
Omnicia, Inc.	Radiant Research	Target Health Inc.
OmniComm Systems, Inc.	RadPharm	Tarius A/S
On Assignment Clinical Research	RCRC IRB	TGen Drug Development Services
Open Text Corporation	RCT - Global	Therapak Corporation
Organon USA	Real Regulatory Ltd.	Thermo Scientific
Outcome	Recruitech International	ThesIS (Thesaurus Information and Strategies, Inc.)
Pacific Biometrics, Inc.	Reed Technology	ThinSpring
Pacific Data Designs	Regional Clinical Research	Thomson Healthcare
Paragon Biomedical, Inc.	REGISTRAT, Inc.	Thomson Scientific
PAREXEL International	Regulatory Presentation Management	TKL Research, Inc.
Patheon Inc.	Reliance Clinical Research Services	TNT Express
Patient Interaction (Pi)	Relsys International, Inc.	Total Root Concepts, Inc.
The Patient Recruiting Agency	Reprints Desk	Transenda
PDP Courier Services Ltd	Research Across America	TransPerfect
Penn Pharmaceutical Services Ltd.	Research Solutions, LLC	Trial Management Group Inc.
Perceptive Connection, LLC	Research Testing Laboratories	Trialstat Corporation
Perceptive Informatics, Inc	ResearchPoint Inc.	Trident Clinical Research Pty Ltd.
Pharmaceutical C-Trials, Inc.	Respironics	Triligent International
Pharmaceutical Executive Magazine	Rho, Inc.	Trio Clinical Research, LLC
Pharmaceutical Institute	Roche	TTC, LLC
PharmaInteractive	RPS, Inc.	UK Clinical Research Organization
PharmaLinkFHI	RTI Health Solutions	United BioSource Corporation
PharmaNet	RWD Technologies, Inc.	University Clinical Research Deland
Pharmascan	Rx Trials Inc.	University of California San Diego
PharmaSys, Inc.	SAIC - Frederick	University of Florida Center for Clinical Trials Research
PharmaVOICE	Sancilio & Company, Inc.	University of Rochester Medical Center
Pharm-Olam International	sanofi-aventis	Uppsala Monitoring Centre
Pharsight Corporation	SAS Institute	Velos Inc
Phase Forward	Satyam Computer Services	Veritas Medicine
Phoenix Data Systems, Inc.	Schlafender Hase GmbH	VIASYS Healthcare
Phoenix Software International	Schulman Associates Institutional Review Board, Inc.	Virtify, Inc.
Phoenix Translations	SCRIP	VirtualScopics Inc.
PHT Corporation	Sentrax	Vitalograph Ltd.
PII	SGS Life Science Services	Volt Life Sciences
Pinnacle Trials, Inc.	Sharp Corporation	Waban Software
Placemart Personnel Service	SIRO Clinpharm Pvt Ltd	WebbWrites, LLC
PleaseTech Ltd.	Smith Hanley Consulting Group LLC	WebWise Learning, Inc.
PPD, Inc.	SNBL Clinical Pharmacology Center	Wellspring Pharmaceutical
PRA International	SNOMED International	Wiley Pharmafile
Premier Research Group plc	Source4	Wolters Kluwer Health
PRL Central Laboratory Services	Spacelabs Healthcare	Woodley Equipment Company Ltd.
Prologue Research	Sparta Systems, Inc.	Working Words Inc.
Promedica Health System	Spectra Clinical Research	World Courier Inc.
PROMETRIKA, LLC	SRG Woolf Group, Inc.	WorldCare Clinical Inc
ProSanos Corporation	St. Joseph Hospital	Worldwide Translations Inc
PROSAR	Statistical Solutions	Xceleron Inc
ProTrials Research, Inc.	STATKING Consulting, Inc.	XERIMIS Inc.
PSI Pharma Support Intl	Stiris Research Inc.	
Quality & Compliance Consulting, Inc.	Strata	
Quality Associates, Inc.	SYMFO	
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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.



www.diahome.org

Tutorial Pricing Guide

The tutorials being offered as of April 7, 2007, are listed below. Please continue to monitor www.diahomed.org for tutorial updates and online registration.
Space is limited so register early!

Saturday, June 16, 2007	1:00-4:30 pm	Sunday, June 17, 2007	1:00-4:30 pm
Tutorials #30 through #35	Fee \$375	Tutorials #70 through #87	Fee \$375
#30 Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People, and Process	<i>CR, CTM/CS, RD</i>	#70 FDA Enforcement: Understanding the Agency's Authority, How Violations Occur, How to Prevent Them, and How to Respond If Violations Do Occur	<i>CTM/CS, GCP, RA</i>
#31 Leadership: How to Organize and Lead People in Group Work	<i>GCP, PM, TR</i>	#71 Evaluation of Risk Management Programs Using Existing Databases	<i>CP, RA</i>
#33 The Investigator's Brochure: Best Practices for Writing and Updating	<i>CR, MW, RA</i>	#72 Regulations, Guidance, Dockets, Specifications and Manual of Policies and Procedures (MAPPs): A Primer for Pharmaceutical Professionals	<i>CR, PM, RA</i>
#34 Project Management for the Nonproject Manager	<i>CR, CTM/CS, PM</i>	#73 Analysis of Safety Data from Clinical Trials	<i>CR, MW, ST</i>
#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	<i>CR, PM, RA</i>	#74 GCP, Clinical Trial Safety, and Pharmacovigilance Compliance: How Global Pharmaceutical Companies Can Cope in Interesting Times	<i>CP, CR, GCP, RA</i>
 		#75 Planning and Conducting Clinical Trials in Oncology	<i>BT, CR, IS</i>
 		#76 The CRA Role for GCP Compliance with Electronic Data Capture (EDC)	<i>EC, GCP, IS</i>
Sunday, June 17, 2007	9:00 am-5:00 pm	#77 Collecting Abuse Liability Data During CNS Drug Development	<i>CR, RA, RD</i>
Tutorials #40 through #45	Fee \$650	#78 Development of Stem Cells-based Therapeutics, including Human Embryonic Stem Cells, from Proof of Concept to Clinical Trials	<i>CR, PM</i>
#40 Clinical Statistics for Nonstatisticians	<i>CR, MC, MW</i>	#79 The Expanding Role of Clinical Site Monitors	<i>CTM/CS, GCP, IS</i>
#41 European Regulatory Requirements for the Conduct of Clinical Trials	<i>CR, GCP, RA</i>	#80 Randomization and Trial Supply Management Using IVR: A Tutorial for Study Teams	<i>CR, CTM/CS</i>
#42 Pharmacokinetics and Pharmacodynamics: A Gentle Introduction	<i>CR</i>	#81 Pharmacogenomics as a Tool to Accelerate Drug Development	<i>CR, RA, RD</i>
#43 Principles of Safety Surveillance	<i>CP, RA, TR</i>	#82 Introduction to Biomedical and Health Informatics	<i>CR, IS, MW, PM</i>
#44 Developing Realistic Drug Development Project Plans	<i>CR, CTM/CS, PM</i>	#83 Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in EU	<i>CR, PM, RA</i>
#45 Excelling as a Supervisor or Manager in the Clinical Research Industry	<i>CR, CTM/CS, PM</i>	#84 Pediatric Clinical Trials: The Way Forward	<i>CR, RA, TR</i>
 		#85 The Changing Landscape of Pharmaceutical Product Launches	<i>CR, MC, RA</i>
 		#86 The CDISC Standard: Four Models Working in Harmony	<i>CDM, CR, IT</i>
Sunday, June 17, 2007	8:30 am-12:00 pm		
Tutorials #50 through #59	Fee \$375		
#50 Pharmacovigilance Audit	<i>CP, GCP, RA</i>		
#51 Fourteen Steps from Research to Development	<i>RA, RD</i>		
#52 Preparation of Integrated Clinical and Statistical Reports for Individual Studies	<i>CR, MW, RA</i>		
#53 Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development	<i>RA</i>		
#54 A Compliance-driven Nonstatistical Risk Detection Process in Drug Safety	<i>CP, CR, RA</i>		
#55 Alcohol-drug Interaction Studies: Understanding the Regulatory Requirements and Study Design Issues	<i>CR, RA, RD</i>		
#56 Market Access for Prescription Drugs and Biologics in Canada	<i>RA</i>		
#57 eClinical: Optimizing the Clinical Trial Process	<i>CDM, CR, EC, PM</i>		
#58 Producing Structured Product Labeling (SPL): XML and Data Elements	<i>CP, EC, IT</i>		
#59 Best Practices Using MedDRA®	<i>CDM, CP</i>		

Please indicate the tutorials you plan to attend on the registration form on page 118.



Serving Its Members and the Industry for More than 40 Years

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



FREE PUBLICATIONS

- *Drug Information Journal*
- *DIA Today/Forum*
- *CSO Directory*

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

Discover the Benefits of DIA Membership at www.diahome.org

Worldwide Headquarters: 800 Enterprise Road Suite 200 Horsham, PA 19044, USA
Tel. +1 215 442 6100 Fax. +1 215 442 6199 email: dia@diahome.org www.diahome.org

Hotel Reservation Instructions

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

First Name (please print)

Last Name

Middle Initial

Company/Institution

Address

City

State

Tel

HOTEL INFORMATION

Arrival Date _____ Departure Date _____

Smoking* Nonsmoking* 1 Bed* 2 Beds*

*This is a request only.

Single Double Triple Quad

2. _____

3. _____

Departure Date _____

SPECIAL NEEDS (attach a note if you need more room) _____

Sharing with the following person(s) 1. _____ 2. _____

3. _____ 4. _____

PAYMENT INFORMATION Visa MasterCard Discover AMEX Diners Other _____

Credit Card # _____ Expiration Date _____

Name on Card _____ Signature _____

Attendees should make hotel reservations early to guarantee rates and availability.

Hotel Locator Map



Reproduced with permission of the Atlanta Convention and Visitors Bureau | (404) 521-6600 | www.atlanta.net

Hotel rates include a nominal \$5 fee to help defray venue costs.

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.

Hotel	Address	Telephone Number Fax Number	Distance to Congress Center	Shuttle Offered
# 1 Atlanta Marriott Marquis	265 Peachtree Center Avenue	T +1-404-521-0000 F +1-404-586-6299	8 blocks	Yes
# 2 Embassy Suites Hotel Atlanta Centennial Olympic Park	267 Marietta Street	T +1-404-223-2300 F +1-404-223-0925	Across the street from Congress Center	No
# 3 Hilton Atlanta & Towers	255 Courtland Street NE	T +1-404-659-2000 F +1-404-221-6368	9 blocks	Yes
# 4 Hyatt Regency Atlanta	265 Peachtree Street, NE	T +1-404-577-1234 F +1-404-588-4137	7 blocks	Yes
# 5 Omni Hotel @ CNN	100 CNN Center	T +1-404-659-0000 F +1-404-525-5050	Across the street from Congress Center	No
# 6 Westin Peachtree Plaza	210 Peachtree Street, NW	T +1-404-659-1400 F +1-404-589-7424	6 blocks	Yes
# 7 Amerisuites Downtown	330 Peachtree Street, NE	F +1-404-577-1980 T +1-404-688-3706	9 blocks	Yes
# 8 Days Inn	300 Spring Street	T +1-404-523-1144 F +1-404-522-1694	5 blocks	Yes
# 9 Holiday Inn Atlanta Downtown	101 Andrew Young International Boulevard	T +1-404-524-5555 F +1-404-221-0702	3 blocks	Yes
#10 Sheraton Atlanta	165 Courtland Street	T +1-404-659-6500 F +1-404-524-1259	9 blocks	Yes

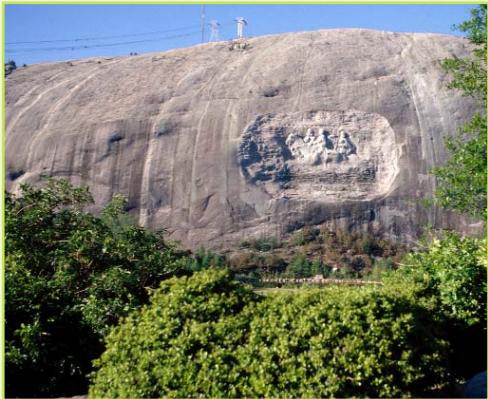
Optional Tours

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.diahomes.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

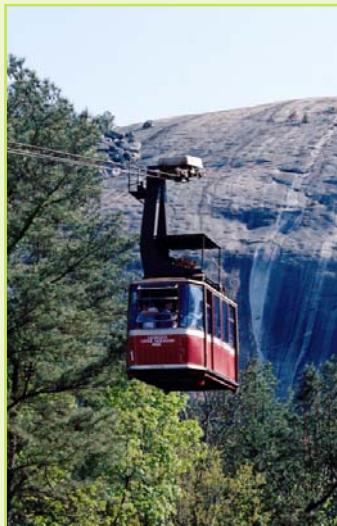


Guests are in for a treat as they visit the "Eighth Wonder of the World" – Stone Mountain Park. Formed over 300 million years ago, the giant granite rock rises 1,683 feet above sea level and covers 583 acres.

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.



Optional Tours continued

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 city's 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.

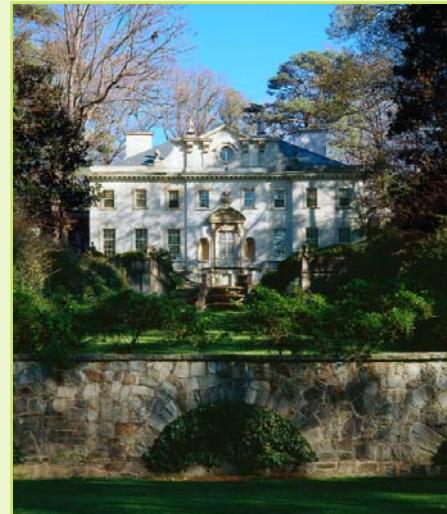


Photo Credit for CDC Building: James Gathany

All other photos courtesy of the Atlanta Convention and Visitors Bureau

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:

PRA Destination Management Atlanta, by **Monday, May 14, 2007**. No refunds will be given for tickets after Monday, **May 14, 2007**.

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.*

Date/Time	Tour Title	Price per Person	Number of Persons	Amount Due per Tour
Sunday, June 17				
11:00 am-5:00 pm	Stone Mountain Park	\$ 72.00	x _____	= \$ _____
1:00 pm-5:00 pm	A Thirst for Atlanta	\$ 49.00	x _____	= \$ _____
Monday, June 18				
THIS TOUR IS CANCELLED	Nobelists of Georgia			
5:30 pm to 10:00 pm	Welcome to Tara	\$ 82.00	x _____	= \$ _____
Tuesday, June 19				
THIS TOUR IS CANCELLED	From Page to Stage			
THIS TOUR IS CLOSED	Visit the CDC		x _____	= \$ _____
Wednesday, June 20				
THIS TOUR IS CANCELLED	Buckhead Homes and History			
1:00 pm to 4:00 pm	Visit the CDC	\$ 39.00	x _____	= \$ _____
			TOTAL # of TICKETS	TOTAL AMOUNT DUE
			_____	= \$ _____

Registrant's Name (please print) _____

Address _____

City _____ State _____ Zip/Postal Code _____ Country _____

Daytime Phone # _____ Fax # _____

eMail _____

PAYMENT (please check one):

Credit Card Type: Visa MasterCard American Express Check (payable to PRA Destination Management Atlanta, drawn on U.S. Bank only)

Card # _____ Expiration Date _____

Name on Card (please print) _____

Authorized Signature _____ V Code _____

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

ATTENDEES MAY REGISTER ONLINE AT WWW.DIAHOME.ORG | ONLINE REGISTRATION IS *NOT* AVAILABLE TO SPEAKERS OR EXHIBITORS.

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** **AMEX** Exp. Date _____

Card # _____

Signature _____

CHECK drawn on a US bank payable to and mailed along with this form to:

Drug Information Association, Inc., 800 Enterprise Road, Suite 200, Horsham, PA, USA 19044-3595. Please include a copy of this registration form to facilitate identification of attendee.

CANCELLATION POLICY

All cancellations must be in writing and be received at the DIA office by 5:00 PM on 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.

FULL-MEETING REGISTRATION (attendance of 2 or more days) includes admission to all scientific sessions, exhibits, coffee breaks, luncheons and receptions. *If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. All fees are in US dollars.*

TUTORIALS See bookmarks for tutorial descriptions and pricing guide. Space is limited and preregistration is encouraged. Please indicate the I.D# and fee for each tutorial you plan to attend.

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____ Tutorial Subtotal _____

PREREGISTRATION FEES

A surcharge of \$150 has been included in the registration fees for ALL registrations received after JUNE 8, 2007 (does not apply to one-day registrations).

Member Fee US \$ 1300

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

Nonmember Fee US \$ 1430

A one-year membership to DIA is available to those paying a NONMEMBER meeting registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I do I do NOT want to be a DIA member

Discount Fees **MEMBER** **NONMEMBER***

Government (Full-time) US \$ 450 US \$ 580

Charitable Nonprofit/Academia (Full-time) US \$ 825 US \$ 955

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

ONE-DAY REGISTRATION FEES **MEMBER** **NONMEMBER**

You must indicate which day you will attend. US \$ 690 US \$ 820

Monday, June 18 Tuesday, June 19 Wednesday, June 20 Thursday, June 21

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

NETWORKING RECEPTION (Must be registered for meeting in order to attend) US \$ 70

Networking Reception Only is not available.

Applicable Meeting Registration Fee US \$ _____

Tutorial Registration Fee US \$ _____

Networking Reception Fee US \$ _____

TOTAL PAYMENT DUE US \$ _____

PARTICIPANTS WITH DISABILITIES DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Arrangements can be made for sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

Last Name _____ First Name _____ MI _____

Degrees _____ Dr. Mr. Ms.

Job Title _____

Company _____

Mailing Address _____

City _____ State _____ Zip/Postal Code _____ Country _____

Telephone # _____ Fax # _____ email (*email address is required for confirmation*) _____

EXHIBIT PERSONNEL REGISTRATION FORM

Online registration is *not* available to exhibit personnel.

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

Once you have utilized the four (4) badges provided per each 10' x 10' booth, any additional personnel must register as an attendee (not as an exhibitor).

Log on to www.diahome.org and download the ATTENDEE Registration Form, complete and return it as per the instructions on the form.

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

PAYMENT METHODS: Check payment method:

CREDIT CARD number may be faxed to: +1-215-442-6199.

You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to the currency conversion rate at the time of the charge.

VISA MC AMEX Exp. Date _____

Card # _____

Signature _____

CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association, Inc., PO Box 95000-1240, Philadelphia, PA, USA 19195-1240. Please include a copy of this registration form to facilitate identification of attendee.

BANK TRANSFER When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Meeting I.D. #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.**

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

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)

Registration for Networking Reception Only is not available.

US \$ 70

TOTAL PAYMENT DUE US \$ _____

PARTICIPANTS WITH DISABILITIES DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Arrangements can be made for sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

Last Name _____ First Name _____ MI _____

Degrees _____ Dr. Mr. Ms.

Job Title _____

Company _____

Mailing Address _____

City _____ State _____ Zip/Postal Code _____ Country _____

Telephone # _____ Fax # _____ email (email address is required for confirmation)



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