

# 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

DeorgiaPROGRAM CHAIRPERSONongressAlberto Grignolo, PhDCenterPAREXEL Consulting

### **Program Chairperson**



Alberto Grignolo, PhD

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.

Alberto Grignolo, PhD,

is Corporate Vice Pres-

Manager of the Drug

Development Consult-

past fourteen years he

has been responsible

for PAREXEL's regula-

tory services, including

worldwide drug devel-

opment consulting

ing Practice in PAREXEL Consulting. For the

ident and General

Prior to joining PAREXEL, Dr. Grignolo 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.

He is a past Chairman of the Board of the Regulatory Affairs Professionals Society (RAPS), has been involved in the advancement of the regulatory profession for most of his career and was the recipient of the 1995 Richard E. Greco Professional of the Year from RAPS. He 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, 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, and was an Expert Advisor to the Institute of Medicine's "Committee on Assessing the System for Protecting Human Research Participants" in 2000-2002.

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. choolchildren and mathematicians know that 43 is a "prime number" – one that can only be divided by 1 and by itself. Other than that, the number 43 is not particularly interesting or special. The 43rd wedding anniversary is not even associated with a stone (precious or not). Turning 40 is a major, often traumatic milestone for many people; but turning 43 just makes you glad that you are still a long way from 50!

And so here we are, looking ahead to the 43rd Annual Meeting of DIA. This means that the *first* Annual Meeting was held in 1964. Think about that. Many of us were teenagers then; many who will attend this Annual Meeting had not been born yet. Beatlemania and the Cold War were all the rage. The European Community was 7 years old and had only 6 Member States. The concept of the IND was 2 years old.

Forty-three years later, 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 and nurtured an ever-expanding multinational constituency; has become the must-attend event of the year for so many in our particular world.

Join us in Atlanta! Whether for the first 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 excellence, and have designed a meeting that is timely, topical, and transforming.

Dr. Julie Gerberding, Director of the Atlanta-based Centers for Disease Control (CDC), will deliver the Keynote Address. We will feature nearly 400 regular, plenary, and tutorial sessions with over 1,000 speakers; more than 450 exhibitors will help expand our awareness of services and technologies relevant to the interests of DIA members everywhere. Across 27 tracks, we will map for you such themes as FDA Critical Path, Global Clinical Trials, Personalized Medicine, India, Japan, and China to help you identify the sessions of greatest interest to you. Once again, to facilitate your personal scheduling, we will list all sessions on a website that will allow 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 and the phenomenal DIA staff have collaborated to bring you the best possible Annual Meeting program. The city of Atlanta, home of CNN, the CDC, the world's busiest airport, art, culture, glorious peaches, and innumerable attractions, awaits our arrival with exceptional and warm southern hospitality.

DIA 43rd in Atlanta – a prime number, a prime location! See you there!

Alberto Grignolo 2007 Annual Meeting Program Chairperson

Please monitor <u>www.diahome.org</u> for program updates and online registration.

# 2007 Annual Meeting Program Committee

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### 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?

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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 and one of the largest



Cold Water Quest

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. Onsite registration cannot be guaranteed. Registration for Networking Reception only is not available. You must be registered for the meeting as an attendee, speaker, or exhibitor to register for the Networking 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.

30%

#### The results are in ... the 2006 DIA Annual Meeting attracted:

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

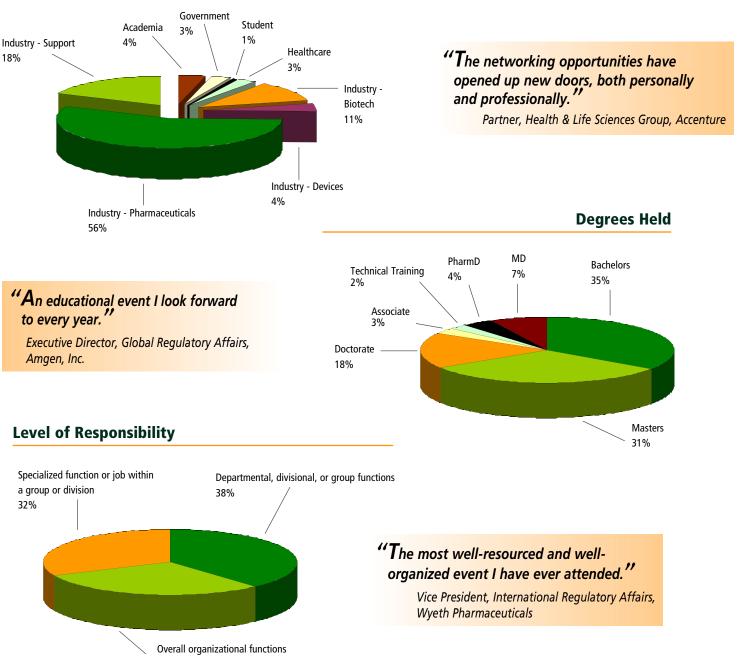
#### Be Sure to Opt in to DIA Membership!

Membership benefits include:

- Discounted Registration Fees
- Members Only Website
- Free Publications
- Access to the DIA Job Bank

To join DIA, check the I do box under Nonmember Fee on your Annual Meeting registration form.

### **Professional Category**



# **Meeting Highlights**

# **New this Year!**

# **MULTITRACK PLENARY**

Tuesday, June 19, 2007 8:00am-9:30am

Session Co-chairpersons

Stanley A. Edlavitch, PhD, MA University of Missouri-Kansas City

Melvyn Greberman, MD, MS, MPH Public Health Resources, LLC

- Academic Health Centers
- Clinical Research and Development
- Clinical Safety and Pharmacovigilance
- Public Policy/Law
- Regulatory Affairs

#### **Drug Safety Reform: Actions and Implications**

In response to growing concerns about health risks associated with approved drugs, the Food and Drug Administration asked the Institute of Medicine to assess and recommend improvements in the US drug safety system. The IOM committee focused its attention on drug review, safety surveillance, and related activities of the FDA Center for Drug Evaluation and Research. In addition, it 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.

### **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).

#### **Continuing Education**

Select tutorials and sessions will offer category 1 credits, pharmacy contact hours, nursing contact hours, and project management PDUs. Credit for tutorials will be clearly identified in the preliminary program mailing in mid-March and credit for sessions will be indicated in the final on-site 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. This activity has been approved for AMA PRA Category 1 Credit(s)<sup>TM</sup>.



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 29.25 contact hours or 2.925 continuing education units (CEUs) for participating in the tutorials and annual meeting sessions.



earn up to 29.25 contact hours or 2.925 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.

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



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

# Call for Abstracts for the Student and Professional Poster Sessions

#### **Poster Session Chairpersons**

Francis B. Palumbo, PhD, JD University of Maryland, School of Pharmacy

Françoise G. Pradel, PhD University of Maryland, School of Pharmacy

Stephen A. Sonstein, PhD, MS Eastern Michigan University

During its 43rd Annual Meeting, the DIA will hold two poster sessions. These sessions are excellent opportunities for attendees to present their research results to a diverse audience of clinical research professionals. All abstracts are peer-reviewed and selected based upon criteria listed below.

On **Monday, June 18**, the Student Poster session will take place. On **Tuesday, June 19**, the Professional Poster Session will occur. Eligible students must be defined as being full-time by their educational institution. Medical residents or fellows and postdoctorals are considered students. All other abstracts should be submitted to the Professional Poster Session.

#### **STUDENT POSTER SESSION**

#### Student Poster Session Awards

A total of \$4500 in prize money will be awarded to student winners based on the following criteria:

- Bona fide research project
- Specific objectives and hypothesis
- Analysis of actual data and results
- Clear methods
- Conclusions

#### **PROFESSIONAL POSTER SESSION**

A maximum of 40 abstracts from full-time professionals will be selected for the professional poster presentations to be held on **Tuesday**, **June 19, 2007**. Selected professional poster presenters will be required to pay the applicable meeting registration fee and will be responsible for all other expenses.

More detailed information will be provided upon acceptance.

A maximum of 20 abstracts will be selected for the student poster presentations to be held on **Monday, June 18, 2007.** One listed author for each selected abstract will receive complimentary meeting registration, hotel room, travel expenses and a per diem allowance. Selected student poster presentations will be published in the *DIA Journal.* 



#### All Poster Abstracts are due by FEBRUARY 15, 2007.

All abstracts should pertain to the interest areas represented by the Tracks within the Annual Meeting which are listed below:

Academic Health Centers	
Advertising	
Biotechnology	
Chemistry, Manufacturing and Controls/ Good Manufacturing Practices	
Clinical Data Management	
Clinical Research and Development	
Clinical Safety and Pharmacovigilance	
Clinical Trial Management/Clinical Supplies	
Electronic Regulatory Submissions/ Document Management	
eClinical	
Good Clinical Practices	
Impact of Medical Products and Therapies	
Information Technology	

Investigator Sites Marketing and Sales Medical Communications Medical/Scientific Writing Natural Health Products Nonclinical Laboratory Safety Assessment Outsourcing Project Management/Finance Public Policy/Law Regulatory Affairs R&D Strategy Statistics Training Validation

All abstracts should be submitted online. The deadline for submitting online poster abstracts is February 15, 2007. To submit an abstract for the Student or Professional Poster Session at DIA's 2007 Annual Meeting, please visit the DIA website – http://www.diahome.org. Click on Get Involved at the top right of the screen and Submit Abstract on the left navigation bar and follow the instructions.

#### **GENERAL SUBMISSION REQUIREMENTS**

Please read the following instructions carefully. Abstracts submitted incorrectly will be returned to the author.

- 1. All abstracts must be received through the DIA website by February 15, 2007.
- 2. A student may submit only one abstract.
- 3. Abstracts may not refer to specific brand names.
- Abstracts should follow a structured format including ALL of the following categories: objectives, methods, results and conclusions. Each category is limited to 300 characters.
- Abstracts will be reviewed and authors will be notified of results by March 16, 2007.
- If an abstract is accepted, one author or the author's designee must attend the conference to present the abstract in order to have it listed in the conference program.

Poster boards are four feet high and eight feet wide (4' x 8').

# **Preliminary Session Topics**

Following are the session topics that have been scheduled as of December 12, 2006. Updated information will be included in the preliminary program which will mail in mid-March.

Please monitor www.diahome.org for program updates and online registration.

#### **AD** – Advertising

Enforcement Update from FDA

How Fraud and Abuse Cases are Changing the Corporate Landscape

Direct-to-consumer Update from the FDA

Direct-to-consumer Update from Industry

A Primer on Advertising Regulation

FDA, Fair Balance, and False Claims: Can Companies Distribute New Data and Support CME?

Redefining the Roles of Medical Science Liaisons and Sales Representatives: Separating Science from Marketing

#### **AHC – Academic Health Centers**

*Multitrack Plenary Session* (AHC, CP, CR, PP, RA) Drug Safety Reform: Actions and Implications

Integrating Research and Clinical Care in Academic Health Centers

Global Challenges with Bioethics in IRB's Training

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

Education in Clinical Research/Opportunities in India

Clinical Trials from the Sponsor Viewpoint: Is It a Sprint or a Marathon?

#### **BT – Biotechnology**

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

Process Validation during Clinical Development of Biological Medicinal Products

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

Nonclinical Models for Biotechnology Products Used for Acute Radiation Syndrome

Phase 0/Phase 1: Successful Transition to Clinical Supplies

The "OMICS" Initiative: Leveraging Genomics, Proteomics, and Metabolomics for Diagnostics Development

Transitioning from Stem Cell Research to Commercial Applications

Hot Topics in Biotechnology

Gene Therapy

Biosimilars

#### CDM – Clinical Data Management

Case Studies on Time Critical Data Access Using Phase I EDC Programs

Meeting the Challenges for Data Monitoring Committees

Data Warehousing Concepts for SDTM-compliant Information

Convergence of Healthcare and Life Sciences: Enhancing the Value Chain

Good Registry Practice: Standards, Design, Use, and Valuation of Patient Registries and Methods and Best Practices

Implementing a Comprehensive Lab Data Management Strategy

The Path to the Future: eCDM or No CDM

Overall Data Integrity Plans for Working with Data from Multiple Vendors

Virtual Data Management Models

Clinical Data Management Considerations for Oncology Trials

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

EHR Considerations for Clinical Data Management

#### CMC/GMP – Chemistry, Manufacturing, and Controls/ Good Manufacturing Practices

Update on FDA Initiatives for Postapproval CMC Changes

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

CMC Regulatory Agreement

Lessons Learned from CMC Pilot Program: An FDA Perspective

Implementation of QbD for Biotechnological Products

Update on FDA cGMP Initiatives and Guidances

Lessons Learned from CMC Pilot Program: An Industry Perspective

Role of Multivariate Analysis in QbD Pharmaceutical Development

Challenges in Implementing ICH Q8 & Q9 Guidelines in Global Submission

Updates on ICH Q8 (R) and Q10 Guidelines

#### **CP** – Clinical Safety and Pharmacovigilance

Multitrack Plenary Session (AHC, CP, CR, PP, RA) Drug Safety Reform: Actions and Implications

Adverse Event and Medication Error Coding: Is MedDRA® Up to the Task?

Approaches to Quantifying Benefit-risk Assessments: Going Beyond Intuition

Can Risk Communication Be Improved? Pitfalls and Progress

#### **CP** – Clinical Safety and Pharmacovigilance continued CR - Clinical Research and Development continued Clinical Safety Risk Management in Preapproval Drug Development Examining Investigator Meetings Best Practices Data Mining in Pharmacovigilance: Misconceptions and Misunderstanding Factors Influencing the Speed of Clinical Trial Study Completion in Data Mining and Signal Detection Global Development of Cardiovascular Drugs **Detecting Safety Signals in Clinical Trials Global Development of Vaccines** FDA's Quarterly AERS Data Extracts: Availability and Use for Signaling How to Work with Your IRB Global Electronic ADR Exchange: Where Are We Now and What Is Next? Human Phase 0 Microdose Studies: What Will They Deliver? Global Individual Case Safety Reports (ICSRs): Can Quality Data and Improving Success of Psychopharmacological Clinical Trials: A Path to Failure Processing Efficiency Go Hand in Hand? Managing the Placebo Response in Psychiatric Clinical Trials Implementation of Risk Management Plans in Japan Oversight of Research: Data Safety Monitoring Committees (DSMC) -MedDRA® as a Pharmacovigilance Tool: Data Retrieval and Standard A Systems Approach MedDRA<sup>®</sup> Queries (SMQs) Patient Recruitment: Strategic Approaches to Optimize Outcomes Postmarketing Safety Studies and Intensive Event Monitoring Techniques: Pediatric Exclusivity Trials: Lessons Learned from the Field What Have We Learned? Personalized Medicine and Personalized Drug Development: Case Studies **Regulatory Inspections of Industry Pharmacovigilance Operations** and Progress to Date - Parts 1 and 2 **Risk Management for Vaccine Products** Prevention of Fraud and Noncompliance in Clinical Research: What Was Selection and Performance of Safety Database Systems and Is Being Done? Streamlining Adverse Event Case Management Regulatory Reguirements in Late Phase Studies: Do We Really Know What They Are? Use of Disease and Other Registries: Lessons Learned for Use in Risk Management Successful Phase I Clinical Trials Targeted Site Start-up Support Strategy in Clinical Research **CR** – Clinical Research and Development The Business Case for CDISC Standards: Implementation Approaches and Metrics Multitrack Plenary Session (AHC, CP, CR, PP, RA) The Country Study Manager Survey: 2006 Research Data Makes the Case Drug Safety Reform: Actions and Implications for a New Approach A Case Study: Challenges and Suggestions on Patient Recruitment and Update to Radical Change in Clinical Development Retention Using Adaptive Design and Enrichment Designs to Speed Oncology Drug Actuarial Methods within Pharmacoeconomics and Clinical Trials Development Adaptive Trials Case Study in eClinical

Applying Lean and Six Sigma to Eliminate Waste and Streamline Planning and Execution of Clinical Trials

Are Site Monitoring and Data Management a Waste of Time?

Arsenic and Old Lace: How to Avoid a Comedy of Errors when a Thorough QT/QTc Study Cannot Be Performed

Assessing the Impact of Increasing Protocol Complexity on Study Conduct Performance

Biomarker Validation and Qualification for Regulatory Decision Making

Clinical R&D Outsourcing to India: What Do You Outsource to Whom?

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

Common Issues and Solutions for Thorough QT ECG Trial Design

Cost Containment in Clinical Research: What Is Being Done?

Crohn's Disease and Ulcerative Colitis: FDA and EMEA Perspectives

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

Enhancing Patient Compliance in Clinical Trials with eTechnology

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

### CTM/CS – Clinical Trial Management/ Clinical Supplies

The Implementation of a CTMS System and Its Impact

Multinational Clinical Trials in China

Clinical Trials in Asia Pacific: Advantages and Challenges

Understanding Clinical Trial Volunteer Experiences and Examining Financial Changes

The Great Debate: Can Site Performance Be Predicted?

New Techniques for Maximizing Enrollment at Academic Health Centers

Finding Top-performing Sites: A Considered Approach

A Simple Solution for Removing Clinical Supplies as a Rate-limiting Step for the Adaptive Trial Design

Becoming a Sponsor of Choice for Clinical Investigators

Research into the Use of Productive Metrics to Determine Clinical Performance

Identifying and Overcoming Site Initiation Delays in Multinational Clinical Trials

Recruitment of Minority Sites for Clinical Trials

Delivering Effective Feedback for Clinical Research Managers

Improving the Clinical Supply Chain Management Process

#### **EC** – eClinical

The Role of Electronic Data Capture in Adaptive Clinical Trials

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

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

Using CDISC Standards and eClinical Technologies to Improve Patient Safety Monitoring during the Conduct of Clinical Trials

Global Adoption of eClinical Technologies

2012: eClinical Odyssey

The eClinical-eHealth Data Management Environment

#### ERS/DM – Electronic Regulatory Submissions/ Document Management

Document Management Repositories

FDA: eCTD Compliance – Parts 1 and 2

International eCTD

**FDA Standards Initiatives** 

Lifecycle Management

eCTD Standards

FDA Electronic Submission Processing

Labeling (US)

eCTD Case Studies

**Records Management** 

**Document Management** 

Content Management

eCTD for Small Pharma

eIND

Product Information Management (PIM) in Europe

#### FI – Finance

Sustaining Pharmaceutical Development Pipelines

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

#### **GCP** – Good Clinical Practices

Clinical, Logistical and Financial Considerations of Pediatric Research

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

How to Be Prepared for an FDA Audit

Good Clinical Practices (GCPs) and ISO 9000: A Winning Combination

Quality Risk Management in GCP: The Essentials

#### GCP - Good Clinical Practices continued

Working with and Managing Contract Auditors

GCP Town Meeting Session: Quality Systems and the QA Role in Small- and Medium-sized Companies

Virtual Realities: Quality Considerations when Using Outsource Providers

Successful Implementation of a Quality Management System

An Effective SOP Process that Really Works

Conducting Effective CAPA Following an Audit

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

The Additional Challenges of Auditing an Investigational Site Using Electronic Data Capture (EDC)

#### **IMP – Impact of Medical Products and Therapies**

Using Electronic Medical Records for Clinical Research

Data Mining: Perils, Pitfalls and Pragmatism

Integrating the Reimbursement Strategy for a Combination Medical Device into the Clinical Trial Program

Linguistic Validation (aka Translations): The State of the Science

#### **IS – Investigator Sites**

When Sponsors Sue Sites: A Real-life Case History

Investigator Budgets and Reimbursement: The Impact on Patient Enrollment and Retention Objectives

**IRB Site Visits and Audits** 

Feet on the Street: Using Community Outreach to Recruit Study Subjects

Hurricane Katrina: Lessons Learned One Year Later

Emergency Procedures for when a Sponsor Goes Bad

Recruitment and Retention Strategies and Solutions for Visible Minorities into Clinical Trials

#### IT – Information Technology

Leveraging Electronic Health Records in Clinical Research

Protecting Intellectual Property

Clinical Data Warehouse: Approaches and Pitfalls

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

The Move to Structured Content and XML: Patterns and Implications in Life Sciences

Issues and Case Studies in Safety Data Migration

**Deploying Life Science IT Using IEEE Methods** 

Best Practices for Technology Implementation

#### IT – Information Technology continued

Standard Controlled Terminology: A Successful Partnership between CDISC and NCI Enterprise Vocabulary Services

Implementing Biological Sample Management and Biobanking Systems

Next Generation Application Integration Using Web Services

Utilizing Open Source Software in GCP-compliant Environments

The Future of Technology in Clinical Development and Life Sciences

Using Information Visualization to Link Decision-making across a Matrixed Organization

Semantic Web Technologies in Drug Development

Evolving Technologies for Interoperability

#### MA – Marketing and Sales

Maximizing ROI (Return on Information)

Lifestyle-based Analytics: A Revolutionary Marketing Approach

Defining the Value of Pharmaceuticals

#### **MC** – Medical Communications

Standardizing Information Sharing between Medical Information Professionals and Regional Medical Liaisons by Developing Tools to Ensure Compliance and Consistency

Medical Liaison Survey #3: Assessing Practice Trends across the Pharmaceutical Industry

Approach, Design and Development of Medical Science Liaison Portal

Elevating Scientific Expertise via Formal Assessments

Health Education: Teaching Consumers about the Safe Use of Medicines

Establishing Principles to Support Co-marketed Products between Two Medical Information Departments: One Company's Perspective

Sharing Medical Information Online: Weighing the Risks versus Benefits

#### MW – Medical/Scientific Writing

Providing Data Displays to Support Communication of Safety Information

The HL7/CDISC Glossary: Mapping the R&D Process with a Common Vocabulary

The Evolving Role of the Investigator Brochure in Global Submissions

**CTD Summaries as Key Reviewer Tools** 

Submitting an IND in eCTD Format: Lessons Learned

Overview of Publication Writing: Maximizing Partnerships

The "Other Documents" that Medical Writers Impact

Writing for Patients

Efficient Authoring Using Contractors

Medical Writing for Risk Management and Pharmacovigilance

#### NC – Nonclinical Laboratory Safety Assessment

Adverse Effects of Anti-cancer Drugs: A Problem of the Past

Drug-induced Liver Toxicity

Nonclinical Development of Nanopharmaceuticals: How Much is Covered by Existing Guidance?

Safety Assessment of Biotechnology-derived Medical Products – Parts 1 and 2  $\,$ 

Humanized Models

**Changing Paradigm of Carcinogenicity Testing** 

Predictive Safety Testing Consortium

#### NHP – Natural Health Products

Validating Botanicals for the Management of Diabetes Mellitus

"Next Generation" Natural Health Products: Protecting Intellectual Property of Complex and Polymolecular Drugs

Phytomedicine Development in Latin America: Interphase between Science and Development

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

Challenges and Solutions in the Evaluation of Traditional Chinese Medicine (TCM)

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

Impact of Quality and CMC on the Development and Use of Botanicals and Other Natural Health Products

International Initiatives for Natural Health Products

**Global Regulation of Botanical Products** 

#### **OS – Outsourcing**

Lessons Learned: A Non-confrontational Technique to Improve Sponsorprovider Team Performance – Parts 1 and 2

A Case Study of a Successful Functional Service Provider (FSP) Relationship: Outsourcing Site Contracts

Benefits and Challenges of Implementing Standards in Outsourced Studies

Transforming Five New Clinical Development Strategies into Real Results – and What We Can Learn from the Industries that Have Done It

Improving CRO Negotiations to Accelerate Time to Market

**Outsourcing Clinical Trial Logistics** 

India: An Emerging Clinical Research Destination – Challenges and Advantages

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

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

#### **OS** – Outsourcing continued

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

Functional Outsourcing: Beyond Data Management

R&D Outsourcing in Japan: Successes and Challenges

Outsourcing Clinical Trials in China: Opportunities vs. Difficulties

#### PM – Project Management

Who Is This Jack-of-all-trades: The Pharmaceutical R&D Project Manager?

Evolving Operational Models in the Pharmaceutical Industry: Project Management Perspective

Applying Six Sigma Methodology

Getting Started with Portfolio Management

PMs as Project CEOs and the Effective Project Managers Tool Chest

Ending the Isolation of Project Management in Drug Development

Value of Project Management Function in Drug Development in Japan

The Evolving Role of Project Management in Drug Development

Integrated US/Japan Effective Team Management

The Methodology of Process Metrics in Leading an Organization to Success

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

Creating Dynamic Product Development Teams

Development of an Integrated Molecule and Nonmolecule Forecast

eStrategy: Preparing Product Launch Teams Using a War Game Simulation

Case Studies of Critical Chain Project Management in the Pharmaceutical Industry

Project Management as a University Research Tool

#### **PP – Public Policy/Law**

#### Multitrack Plenary Session (AHC, CP, CR, PP, RA)

Drug Safety Reform: Actions and Implications

Off-label Promotion and Physician Liability

Personalized Medicine: A Perspective Beyond Science

Personal Health Records in Pharmaceutical Development

Strategies for Maximizing the Financial Portfolio through Intellectual Property

New Paradigms of Drug Regulation

**Product Liability** 

Clinical Trial Registration: Are Registries Useful and User Friendly?

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

Civil and Criminal Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials?

**BPCA** Report Card

Legal Remedies and Drug Approvals: During and after the Approval Process in the US and the  $\ensuremath{\mathsf{EU}}$ 

#### RA – Regulatory Affairs

Multitrack Plenary Session (AHC, CP, CR, PP, RA) Drug Safety Reform: Actions and Implications

Added Therapeutic Value: How to Communicate It

Avoidable Pitfalls in Drug Development

Best Practices for Addressing Pharmaceutical Multilingual XML Requirements

Best Practices in Preparing for and Participating in a Pre-IND Meeting

**Biosimilars in Europe** 

Challenges for Global Labeling: New FDA and European Requirements

4th Update: US-EU Agreement Regarding Exchange of Information among Regulators

Clinical Development of Oncology Drugs in Japan

Clinical Trial Disclosure: Getting Ready for the Regulations

CMC Challenges and Considerations for Clinical Trial and Marketing Applications in China

Combination Products - Parts 1 and 2

Compassionate Use Programs in the EU

Five-year Update on Regulatory Intelligence Utilization by Industry: 2002 to 2007 and Three Industry Examples of RegIntel Programs

Critical Path in Japanese Drug Development Strategy Using Foreign Data

Critical Path: Biomarker from Concept to Action

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

Achieving a Global Trademark

Drug Development in Japan: Drug Development Models to Ensure Acceptance of Preclinical Data Requirements as Part of Global Drug Development

Effective Milestone Meetings with FDA

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

FDA Guidances: How to Make Comments Count

FDA's Drug Establishment Registration and Drug Product Listing System

Fixed-dose Combination Products: Registration Strategies and Case Studies

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

Good Review Management Practices (GRMPs)

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

Highlights Data Elements (HLDEs): One Year's Experience with Computerprocessable Highlights for US Prescribing Information

Imaging in Drug Development

dly? Good Review M

#### **RA** – Regulatory Affairs continued

#### ST – Statistics

Implications of Patient-reported Outcomes Guidance on Electronically Collected (ePRO) Data

Maximizing the Benefits of Medicines Information through Readability Testing

Nanomedicine: The Way Forward

New Directions and Innovations in Canadian Drug Regulations: The Canadian Approach to Draw a Critical Path to Better Drug Regulations and Development

**Optimizing EU Regulatory Strategy** 

Outlook for Changes in Japanese Regulatory and Clinical Development Environment

Partnership in Regulatory Harmonization: Revival of Pharmaceutical Evaluation Report (PER) Scheme in Asia

Pharmaceuticals in the Environment

Phase III: Are You Studying the Right Dose?

PMDA Challenges for Global Drug Development including Japan

Postmarketing Commitments: Operational Issues and Public Perceptions

Prescription Drug Labeling: FDA's New Regulation for the Content and Format of the USPI – One Year Later

Quality Submissions Begin with Quality Deliverables

Running Clinical Trials in Argentina and Mexico

Scientific Advice in the EU

Site Selection Risk Models for FDA Inspections and Theoretical Considerations

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

The Evolution of Risk Management Plans

**US/EU Risk Management Initiatives** 

New Pediatric Legislations in the EU

Practical Implementation of EU Pediatric Legislations

#### **RD** – **R&D** Strategy

Mapping the Clinical Investigator Landscape

Experimenting with Clinical R&D Management Metrics Using the Latest Computer Technology

Drug Development Down the Road

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

Emerging Trends in the Economics of New Drug Development

Japan Challenges to Global Simultaneous Drug Development: Adapting Japanese Environments to Worldwide Drug Development

Rainmaker for the Biopharmaceutical Industries in the Emerging Markets

Improvement in Japan's Clinical Trial Environment: A Sponsor Company Perspective

Graphical Analysis of Clinical Safety and Efficacy Data

Design and Analysis Issues in Analgesic Trials

Early Successes with Adaptive Designs

Statistical Analysis with Missing Data

Statistical Computing Environments: Part B – Setting Forth Requirements

Adaptive Methods in Phase II Proof-of-concept Trials in Practice

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

CDISC and Statisticians: Implications and Implementations

Strategies for Ethnic Comparison in Global Cooperative Clinical Trials

Statistical Methodologies for Safety Assessments

Statistics in Drug Safety and Health Economics and Outcomes Research: Anything in Common?

#### TR – Training

Searching PubMed®: Trade Secrets from Three 4-Star Medical Library Scientists

Training Investigators and Study Coordinators: Alternatives/Supplements to Investigator Meetings

eClinical Meets eLearning: Theory to Practice to Best Practice

Rapid Development/Rapid Delivery of eLearning Solutions to External Clinical Trial Personnel

Self-guided Mentoring Program Administered by Training

Podcasting, Interactive Simulations and "On Demand" Web Assistants: Delivering Your Courses via the Latest Technologies

A Blended Learning Approach to Establishing a Global Standards and Practices Program for Clinical Study Documentation

Practical Models for Training Clinical Research Monitors

Effective Training of Study Site Staff for Better Clinical Trials

Networking as a Personal Disaster Preparation Plan: Helping You Stay Up when the Sizing is Down

Pre-hire Assessment and Mapped Training Curriculum to Speed On-boarding Process

Getting the Message Across: It's All about the Presentation

MedDRA® Training: A Mentor-protégé Approach

Bringing Global Staff to Headquarters for Training

#### **VA – Validation**

#### CSV Fundamentals

Extraordinary Opportunities: Issues with Regulated Computerized Systems and How to Meet Them

Validation Quality and Costs: It's All about Risk

Assessing and Auditing Clinical Computerized Systems

Red Apple II

Current Regulatory Issues: SOX and Beyond?

Measurement of Quality without the Pain

# Confirmed Tutorials (as of January 8, 2007)

DIA's preconference tutorials, scheduled for June 16-17, 2007, are designed to broaden your knowledge in specialized subject areas related to the pharmaceutical industry. Medical, pharmacy, nursing, project management, and IACET continuing education units will be available for various tutorials. As of December 12, 2006, the following tutorials are being offered.

Continue to monitor www.diahome.org for tutorial updates and online registration. Space is limited so REGISTER EARLY!

Half Day • Saturday, June 16, 2007 1:00 pm-4:30 pm

\$375

**#30 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

**#31 Leadership: How to Organize and Lead People in Group Work Mike Laddin, MS, MBA** President, LeaderPoint

#32 This tutorial was rescheduled as of January 8 to #87 on Sunday, June 17, 2007, 1:00 pm-4:30 pm. New Release of EU Regulatory Requirements: Pharmacovigilance in the Pre- and Postmarketing Phase and eReporting

**#33** The Investigator's Brochure: Best Practices for Writing and Updating Peggy M. Boe, RN Director, Professional Services and Medical Writing, Image Solutions, Inc.

#34 Project Management for the Nonproject Manager Martin D. Hynes, III, PhD, MS Director of PR&D Operations, Eli Lilly and Company Robert L. Judd Director, Program Management, Kosan Biosciences, Inc.

#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

P.K. Tandon, PhD Vice President, BioMedical Operations, Genzyme Corporation Marisa Bacchi Director, Serono International

Full Day • Sunday, June 17, 2007 9:00 am-5:00 pm

\$650

**#40 Clinical Statistics for Nonstatisticians Rafe Donahue, PhD** Research Associate Professor, Vanderbilt University Medical Center

#41 European Regulatory Requirements for the Conduct of Clinical Trials Regina Freunscht Head of Quality Assurance, Accovion, GmbH, Germany

**#42** Pharmacokinetics and Pharmacodynamics: A Gentle Introduction Michael J. Fossler, PharmD, PhD, FCP Director, GlaxoSmithKline

#43 Principles of Safety Surveillance
Stanley B. Garbus, MD, MPH
Chief Medical Officer, Sentrx
Ralph E. Bobo, MD
Executive Vice President, Pharmacovigilance Practice, Medical Safety Officer, Sentrx

#44 Developing Realistic Drug Project Plans
 Peter Harpum, MSc, MAPM
 Director, Life Science Practice Leader, Harpum Consulting, UK
 Randy Dunson, MBA, PMP
 Principal of Equinox Consulting, LLC

#45 Excelling as a Supervisor or Manager in the Clinical Research Industry Mary E. Briggs Chief Training Officer, Focus Inc.

#### Half Day • Sunday, June 17, 2007 8:30 am-12:00 pm \$375

**#50 Pharmacovigilance Audit** Steve Jolley Vice President, Pharmacovigilance, Taratec Development Corporation Doreen Lechner, PhD Senior Vice President, Quality Assurance, Sentrx

**#51 Fourteen Steps from Research to Development** Judi Weissinger, PhD President and CEO, Weissinger Solutions, Inc. Michael R. Hamrell, PhD President, MORIAH Consultants

**#52** Preparation of Integrated Clinical and Statistical Reports for Individual Studies George D'Addamio, PhD President, PharmaConsult, Inc.

#53 Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development
Robert Fike, MS, PhD
Assistant Vice President, Regulatory Affairs Japan, Wyeth Research Division of Wyeth
#54 A Compliance-driven Nonstatistical Risk Detection Process in Drug Safety
Pradip K. Paul, MBBS, MS
Head, CME Group, Global Pharmacovigilance and Epidemiology, sanofi-aventis Pharmaceuticals, Inc.
#55 Alashal Drug Interaction Studies: Understanding the Devulatory

#55 Alcohol-Drug Interaction Studies: Understanding the Regulatory Requirements and Study Design Issues Beatrice Setnik, PhD Research Scientist, Ventana Clinical Research Corporation #56 Market Access for Prescription Drugs and Biologics in Canada Anne M. Tomalin, RAC

President, CanReg Inc., Canada

**#57 eClinical: Optimizing the Clinical Trial Process David P. Iberson-Hurst** Chief Executive Officer, Assero Limited, UK **Rebecca D. Kush, PhD** President, CDISC

#### Please indicate which tutorials you plan to attend and the total tutorial payment due on the registration form on the back cover.

#58 Producing Structured Product Labeling (SPL): XML and Data Elements Kate Hamilton Consultant, Alschuler Associates, LLC FDA Representative Invited

#59 Best Practices Using MedDRA® JoAnn Medbery, RN Director, Dictionary Management Systems, Johnson & Johnson

#### Half Day • Sunday, June 17, 2007 1:00 pm-4:30 pm \$375

**#70 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.

#71 Evaluation of Risk Management Programs Using Existing Databases Annette Stemhagen, DrPh, FISPE

Vice President, Epidemiology and Risk Management, United BioSource Corporation

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

**Representative Invited** Division of Biometrics III, CDER, FDA

#### **#73 Analysis of Safety Data from Clinical Trials**

Joachim Vollmar, MSc International Clinical Development Consultants, LLC Jürgen Kübler, PhD Director, Global Head PRO, Novartis Pharma AG, Switzerland

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

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

President, LNL Clinical Research Consulting

#### #75 Planning and Conducting Clinical Trials in Oncology Ronald Harning, PhD

Director of Clinical Research, Teijin America, Inc.

**#76** The CRA Role for Compliance with Electronic Data Capture (EDC) Teri Stokes, MS, MT (ASCP), PhD Director, <u>GXP</u> International

# #77 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

**#78 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. #79 The Expanding Role of Clinical Site Monitors
Ken Light, MS
Solutions Partner, BusinessEdge Solutions, Inc.
Geoff Garabedian
Solutions Partner, BusinessEdge Solutions, Inc.
#80 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

#81 Pharmacogenomics as a Tool to Accelerate Drug Development William Lee Regulatory Scientist, Cato Research Michael P. Murphy, MSc President and CEO, Gentris Corporation

#82 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 #83 Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in the EU

Brenton James, FTOPRA

Consultant in Strategic Regulatory Affairs in the European Union

### #84 Pediatric Clinical Trials

Barry Mangum, PharmD Faculty Pediatrics, Duke Clinical Research Institute (DCRI) Danny Benjamin, MD, PhD Faculty Pediatrics, Duke Clinical Research Institute (DCRI)

**#85** The Changing Landscape of Pharmaceutical Product Launches Courtney Rowell, MS, MBA Managed Care Executive, Myriad Genetic Laboratories, Inc.

William R. Hahn Vice President, Marketing and Business Development, Shaw Science Partners, Inc.

#### #86 The CDISC Standard: Four Models Working in Harmony

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

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

### **#87** This tutorial was rescheduled on January 8 from #32 on Saturday, June

16, 2007, 1:00-4:30pm. New Release of EU Regulatory Requirements:

#### Pharmacovigilance in the Pre- and Postmarketing Phase and eReporting Representative Invited

Pharmacovigilance and Postauthorization Safety and Efficacy, EMEA, EU Gaby L. Danan, MD, PhD

Expert, Global Pharmacovigilance and Epidemiology, sanofi-aventis, France

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# Exhibiting Companies (as of December 12, 2006) Exhibit space is still available.

AAIPharma Accovion ACM-Pivotal Global Central Laboratory ACRS Acurian Adobe Systems, Inc. Advanced Biologics, LLC Advanced Biomedical Research, Inc. Advanced Clinical Services LLC Advanced Clinical Software Aerotek Scientific Allphase Clinical Research Almac Clinical Services Almac Clinical Technologies Amarex Clinical Research American Medical Writers Association AmeriTrial OTC Research Amgen Inc. Anapharm APEX International Clinical Research Co., Ltd. **Applied Clinical Trials Magazine** Aptuit Inc. ArisGlobal ARS, Inc. ARX (Algorithmic Research) Asian Clinical Trials (Division of Suven Life Sciences Ltd) Assist Technologies Asuragen, Inc. Atcor Medical, Inc. Averion International Corp. **Axiom Real-Time Metrics** B & C Group BARC BASi (Bioanalytical Systems, Inc.) **BattelleCRO** Baxa Corporation **BBK Worldwide Beacon Bioscience** Beardsworth **Benchmark Research** Bilcare, Inc. BioCor **Bio-Imaging Technologies Biomedical Systems Biopharm Insight** BioResearch Monitors, Inc. bioskin GmbH BioStorage Technologies Inc. **Biovail Contract Research** California Clinical Trials **Camargo Pharmaceutical Services** The Cambridge Group, Ltd. Campbell Alliance Canadian Arthritis Network/Canadian Rheumatology Research Consortium CanReg, Inc. **CANTOX Heath Sciences International** Cardinal Health

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#### Call 215-442-6100 and ask for the Exhibits Department or go to the Exhibitor's Corner at www.diahome.org

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# **Hotel Reservation Instructions**

The Atlanta Housing Bureau will open for reservations on JANUARY 15, 2007.

The Atlanta Housing Bureau is coordinating all reservations, and arrangements for housing must be made through this housing bureau and not with the hotel directly. All housing reservation forms must be received by May 15, 2007. DIA DOES NOT PROCESS HOTEL RESERVATIONS. Attendees can make hotel reservations by any of the following methods:

**ONLINE RESERVATIONS** Log on to www.diahome.org, double click the Annual Meeting icon, and go to Housing Bureau Reservations, now open. *Please have your credit card, arrival and departure information ready.* 

#### **BY FAX** 506-433-3033 (domestic and international)

Please print or type all information to ensure accuracy. Complete each part below in detail for correct and rapid processing. For multiple rooms, this form may be duplicated. Confirmations will be sent to the individual listed below, **by email if provided.** 

**BY PHONE** 866-413-5150 (domestic) / 506-637-0311 (international) Please have all of the information that is requested on this form ready along with a credit card number and expiration date for the \$150.00+ room deposit.

BY MAIL Fill out this form completely and mail to DIA/Atlanta Housing Bureau, 233 Peachtree Street NE, Suite 100, Atlanta, Georgia 30303, USA

**MAKING RESERVATIONS** Please have the following information available if reserving by phone: • Name of convention: DIA Annual Meeting • 1st, 2nd and 3rd choice of hotel • Arrival/departure dates • Number of rooms requested • Type of room (single/double, etc.) • Number of persons in party • Arrival time • Credit card type, account number and expiration date • Names of all occupants of room • Daytime telephone number • Fax number • eMail address to which confirmation will be sent

**DEPOSIT** All hotels require a room deposit, **plus 15% tax**, of **\$150.00** for a standard room, **\$300.00** for a one-bedroom suite, and **\$450.00** for a two-bedroom suite. The deposit amount is payable by credit card, or by check in US dollars, drawn on a US bank (by mail only). *No wire transfers or purchase orders will be accepted.* No reservation will be processed without a deposit.

**CREDIT CARD** Your credit card will be used as a guarantee but will not be charged immediately. The hotel may charge the deposit to your credit card after **May 15, 2007** when they receive the reservations for processing. Most major credit cards (VISA, Master-Card, American Express, Discover, Diners) are accepted. Each hotel will honor the Housing Bureau acknowledgement.

**CHECKS** Your deposit check must be made payable to **DIA/Atlanta Housing Bureau** in US funds drawn on a US bank and mailed to DIA/Atlanta Housing Bureau, at the address above. **No checks will be accepted after May 15, 2007.** 

CHANGES/CANCELLATIONS/REFUNDS Up until May 15, 2007, all changes and cancellations should be made directly with the DIA/Atlanta Housing Bureau via phone, fax, mail, or email to housing@atlanta.net. Data will be transferred to the hotels between May 16 and May 25 and changes/cancellations/reservations will NOT be accepted during this time. Beginning May 25, 2007, changes and cancellations should be made directly with the confirming hotel. Cancellation policy is as follows:

**Cancellations made on May 7, 2007, or earlier**, will receive a full refund. If deposit was paid by check, a \$25.00 processing fee will be deducted.

Cancellations made after May 7, 2007, will forfeit the full \$150+ deposit.

Also, should a guest not arrive by their scheduled arrival date, the full reservation will be cancelled by the hotel and the \$150+ deposit will be forfeited.

Please complete the following information and submit to DIA/Atlanta Housing Bureau by May 15, 2007.

First Name (please print)	.ast Name		Middle Initial
Company/Institution			
Address City	State	Zip/Postal Code	Country
Tel Fax		email	
HOTEL INFORMATION       Choice of hotel will be honored based on availability.         □       lowest rate       □       distance to the meeting (prefer	•		r hotel based on (check one):
HOTEL SELECTION Please list in order of preference.			
1	Arrival Date		Departure Date
2	Smoking*	Nonsmoking* 1 E	
3	🗆 Single	Double     Triple	*This is a request only.
SPECIAL NEEDS (attach a note if you need more room)			
Sharing with the following person(s) <u>1.</u>	2.		
3.	4.		
PAYMENT INFORMATION   Visa MasterCard Discover A	MEX 🗆 Diners 🗆 Ot	her	
Credit Card #	_ Expiration Date		
Name on Card	_ Signature		

# **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.

#1 Atlanta Marriott Marquis	#2 Embassy Suites Hotel Atlanta Centennial Olympic Park	#3 Hilton Atlanta & Towers	#4 Hyatt Regency Atlanta	#5 Omni Hotel @ CNN	#6 Westin Peachtree Plaza
Address 265 Peachtree Center Avenue	Address 267 Marietta Street	Address 255 Courtland Street NE	Address 265 Peachtree Street, NE	Address 100 CNN Center	Address 210 Peachtree Street, NW
Room Rates \$174 Single \$184 Double \$194 Triple \$204 Quad	<b>Room Rates</b> \$189 Single \$189 Double	Room Rates \$149 Single \$149 Double	Room Rates \$179 Single \$179 Double	Room Rates \$179 Single \$179 Double \$204 Triple \$204 Quad	Room Rates \$169 Single \$189 Double \$209 Triple \$229 Quad
Distance to Convention Center 8 blocks	Distance to Convention Center Across the street from Convention Center	Distance to Convention Center 9 blocks	Distance to Convention Center 7 blocks	Distance to Convention Center Across the street from Convention Center	Distance to Convention Center 6 blocks
Shuttle Offered Yes	Shuttle Offered No	Shuttle Offered Yes	Shuttle Offered Yes	Shuttle Offered No	Shuttle Offered Yes

# **Optional Tours**

These activities provide an opportunity to enjoy the Atlanta area. A registration form follows on page 23, or you can register online. Log on to www.diahome.org, click the Annual Meeting icon, click the Networking Opportunities tab at the top of the screen, and select Tours. **The Atlanta Housing Bureau will open for reservations on JANUARY 15**, **2007.** 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**

Monday, June 18, 2007 • 1:00 pm-5:00 pm \$39.00 per person



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

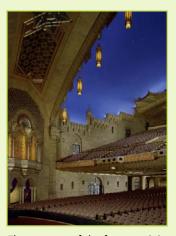


As guests step into the grounds of Stately Oaks Plantation located in Jonesboro, Georgia, they almost believe that it's 1863 and they are back in the days of Rhett and Scarlett. Stately Oaks has a history as expansive and magnificent as its rooms. The home, built in 1839 is the epitome of Southern history 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

Tuesday, June 19, 2007 • 9:30 am-1:30 pm \$53.00 per person



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 apart-



ment in this home. Margaret Mitchell's apartment is the only interior space of the restored house that is preserved as an apartment with all furnishings of the period. Architectural features include the famous leaded glass window out of which Margaret looked while writing.

#### **VISIT THE CDC**

This tour will be offered on both Tuesday and Wednesday. Be sure to select the desired day on the registration form.

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**

Wednesday, June 20, 2007 • 9:30 am-1:30 pm \$47.00 per person

Buckhead has a reputation as Atlanta's most affluent and elegant district. But its name preserves the legacy of its frontier beginnings, when hunting in the virgin forests was the main local enterprise. Now Buckhead is the jewel of Atlanta, an area of gracious homes, elegant hotels, shopping centers and some of the cities best restaurants.

A drive along West Paces Ferry Road provides a view of the most exclusive homes in Atlanta. The first stop is Georgia's elegant Governor's Mansion, a stunning example of Classical Revival architecture. After a short drive, guests arrive at the Atlanta History Center which features a museum housing memorabilia from Atlanta's past. The exhibits are open for guests to experience the Civil War, Georgia's Native Americans, the legendary Atlanta golfer Bobby Jones, and the newest exhibit on the 1996 Centennial Olympic Games held in Atlanta.

After walking the beautiful grounds of the History Center, guests visit The Swan House, a former private home, built for Edward Inman and his wife in 1929. The Swan motif appears in every room of this 1920s masterpiece and the home sits on beautiful gardens.

In comparison, the Tullie Smith Farm, an Atlanta "plantation plainstyle" 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.

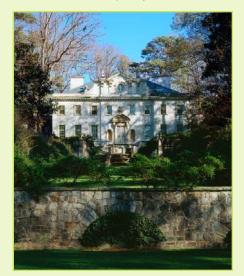


Photo Credit for CDC Building: James Gathany All other photos courtesy of the Atlanta Convention and Visitors Bureau

# **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, 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	х	=	= \$
1:00 pm-5:00 pm	A Thirst for Atlanta	\$ 49.00	х	=	= \$
Monday, June 18					
1:00 pm to 5:00 pm	Nobelists of Georgia	\$ 39.00	х	=	= \$
5:30 pm to 10:00 pm	Welcome to Tara	\$ 82.00	х	=	= \$
Tuesday, June 19					
9:30 am to 1:30 pm	From Page to Stage	\$ 53.00	х	=	= \$
1:00 pm to 4:00 pm	Visit the CDC	\$ 39.00	х	=	= \$
Wednesday, June 20					
9:30 am to 1:30 pm	Buckhead Homes and History	\$ 47.00	х	=	= \$
1:00 pm to 4:00 pm	Visit the CDC	\$ 39.00	х	=	= \$
				TOTAL # of TICKETS	TOTAL AMOUNT DUE
				=	= \$
Registrant's Name (please print)					
Address					
City	State	Zip/Postal Co	ode	Country _	
Daytime Phone #		Fax#			
eMail					
PAYMENT (please check one): Credit Card Type: D Visa D	MasterCard 🔲 American Express 🔲	Check (payable to Pl	RA Dest	tination Management Atlanta	a, drawn on U.S. Bank only)
Card #	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 20 to register for tours online. The Atlanta Housing Bureau will open for reservations on JANUARY 15, 2007.

# ATTENDEE REGISTRATION FORM

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

#### 43<sup>RD</sup> 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:

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.

U VISA	🗆 мс	AMEX	Exp. Date	
Card #				
Signaturo				

- 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 19195-1240, USA. 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 reserva-tions.** 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	$\label{eq:Government/Nonprofit/Academia - Registration fee paid minus \$100 = Refund Amount \\ \mbox{All Others - Registration fee paid minus \$200 = Refund Amount}$
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.

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. 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.

 ${\tt ONE-DAY}$  ONLY REGISTRATION FEE  $\,$  Will be available closer to the meeting date at a cost of \$690 for members and \$820 for nonmembers.

 $\label{eq:turber} \begin{array}{ll} \textbf{TUTORIALS} & \text{See pages 14-15 for the tutorial schedule. Space is limited and preregistration is encouraged. Please indicate the I.D# and fee for each tutorial you plan to attend. \end{array}$ 

Tutorial #	 Fee	
Tutorial #	 Fee	

Tutorial # Fee

PREREGISTRATION FEES A surcharge of \$150 will apply to all registrations received after June 8, 2007. (does not apply to one-day registrations). Attendees will be required to produce their confirmation letter to avoid the \$150 surcharge. To ensure that your registration is processed and sufficient time is allowed for receipt of confirmation letter, a completed registration form and payment must be received by the preregistration deadline of June 8, 2007. An email address must be included below for confirmation process.

Tutorial Subtotal

Member Fee	US \$1150 🗆
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 \$1280 🗆

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 \$ 300 🗖	US\$ 430 🗆		
Charitable Nonprofit/Academia (Full-time)	US \$ 675 🗖	US \$ 805 🗆		
*If paying a nonmember fee, please check one box above, indicating whether you want membership.				

The paying a nonmember ree, please check one box above, indicating whether you want membership.

NETWORKING RECEPTION (Must be registered for meeting in order to attend) Networking Reception Only is not available.		
	Applicable Meeting Registration Fee	US \$
	Tutorial Registration Fee	US \$
	Networking Reception Fee	US \$
	TOTAL PAYMENT DUE	US \$

First Name		МІ
		□ Dr. □ Mr. □ Ms.
State	Zip/Postal Code	Country
Fax #	email (email address	is required for confirmation)
	State	State Zip/Postal Code



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

### Add TUTORIALS and/or NETWORKING RECEPTION to an Existing Meeting Registration



43<sup>RD</sup> ANNUAL MEETING ID #07001

June 17-21, 2007, Atlanta, GA, USA

#### PAYMENT METHODS: Please check payment method:

□ CREDIT CARD number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to

It is a second se

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 reserva-tions.** 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 CANCELLATION

 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.

This registration form should be used by attendees, speakers, track and session chairs, or exhibitors who wish to add Tutorials or the Networking Reception to an existing meeting registration, or by someone who wishes to register for Tutorials only.

If paying by credit card, mail this completed form to DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA or fax to +1-215-442-6199. If paying by check, follow instructions under Payment Methods.

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

YES, I am registered for the meeting and I would like to add the Networking Reception and/or the following Tutorials to my registration. I am registered as:				
Ξ.	Attendee Session Chair	_	Speaker Exhibit Personnel	Track Chair
	I do not wish to repowing Tutorials.	giste	er for the meeting, b	ut I would like to register for the

#### TUTORIALS

See pages 14-15 in the online brochure for tutorial prices and schedule. Space is limited and preregistration is encouraged. Please indicate the I.D. # and fee for each tutorial you plan to attend.

Tutorial #	Fee	
Tutorial #	Fee	
Tutorial #	Fee	Tutorial Subtotal

Join DIA now to save on future meeting registration fees and					
to enjoy the benefits of membership for a full year!	www.diahome.org	US \$ 130 🖵			

NETWORKING RECEPTION (Must be registered for meeting in order to attend) US \$70 Registration for Networking Reception Only is not available.

TOTAL PAYME	NT DUE	
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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.

Telephone #	Fax #	email (email address is re	equired for confirmation)
City	State	Zip/Postal Code	Country
Mailing Address			
Company			
Job Title			
Degrees			Dr. D Mr. Ms.
Last Name	First Name		MI

# **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.

#### 43<sup>RD</sup> 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.

Please fill out a separate form for each exhibitor registrant. To expedite your registration, please check the appropriate category:		
To expedite your registration, please check the appropriate category:	Log on to www.diahome.org and download the	
	ATTENDEE Registration Form,	
COMPLIMENTARY FULL-MEETING REGISTRATION	complete and return it as per the instructions on the form.	
PLEASE NOTE: This page must be completed and submitted for each person	FULL-MEETING REGISTRATION	
attending any portion of this event.	(attendance of 2 or more days) includes admission to all scientific sessions, exhibits, coffee	
PAYMENT METHODS: Check payment method:	breaks, luncheons and receptions.	
<ul> <li>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.</li> <li>VISA A MC AMEX Exp. Date</li></ul>	<b>ONE-DAY ONLY REGISTRATION FEE</b> Will be available closer to the meeting date at a cost of \$690 for members and \$820 for nonmembers.	
Card #	TUTORIALS	
Signature	See pages 14-15 in the online brochure for the tutorial schedule and prices. Space is limited and	
□ 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.	preregistration is encouraged. Please indicate the I.D. # and fee for each tutorial you plan to atten Tutorial # Fee	
<b>BANK TRANSFER</b> When DIA completes your registration, an email will be sent to the address on the	Tutorial # Fee	
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.	Tutorial #         Fee         Tutorial Subtotal	
	Join DIA now to qualify for the member fee and to enjoy the	
<b>CANCELLATION POLICY</b> 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	benefits of membership for a full year! www.diahome.org US \$ 130 🗆	
will be responsible for the full applicable fee. <b>Registrants are responsible for cancelling their own air- line and hotel reservations.</b> You may transfer your registration to a colleague at any time but member- ship is not transferable. Please notify DIA of any such substitutions as soon as possible. <b>Substitute</b> <b>registrants will be responsible for nonmember fee, if applicable.</b>	NETWORKING RECEPTION (Must be registered for meeting in order to attend) US \$70 Registration for Networking Reception Only is not available.	
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. <b>Cancellations received in writing on or before June 1, 2007 will be processed as follows.</b>	TOTAL PAYMENT DUE US \$	
NETWORKING RECEPTION CANCELLATION PARTICIPANTS WITH DISABILITIES DIA meeting facilities and overnight accommodati persons with disabilities. Arrangements can be made for sensory-impaired persons with disabilities. Arrangements can be made for sensory-impaired persons with disabilities.		
TUTORIAL CANCELLATION On or before June 1, 2007 - Registration fee paid minus \$75 = Refund Amount	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 confirm	ation)

