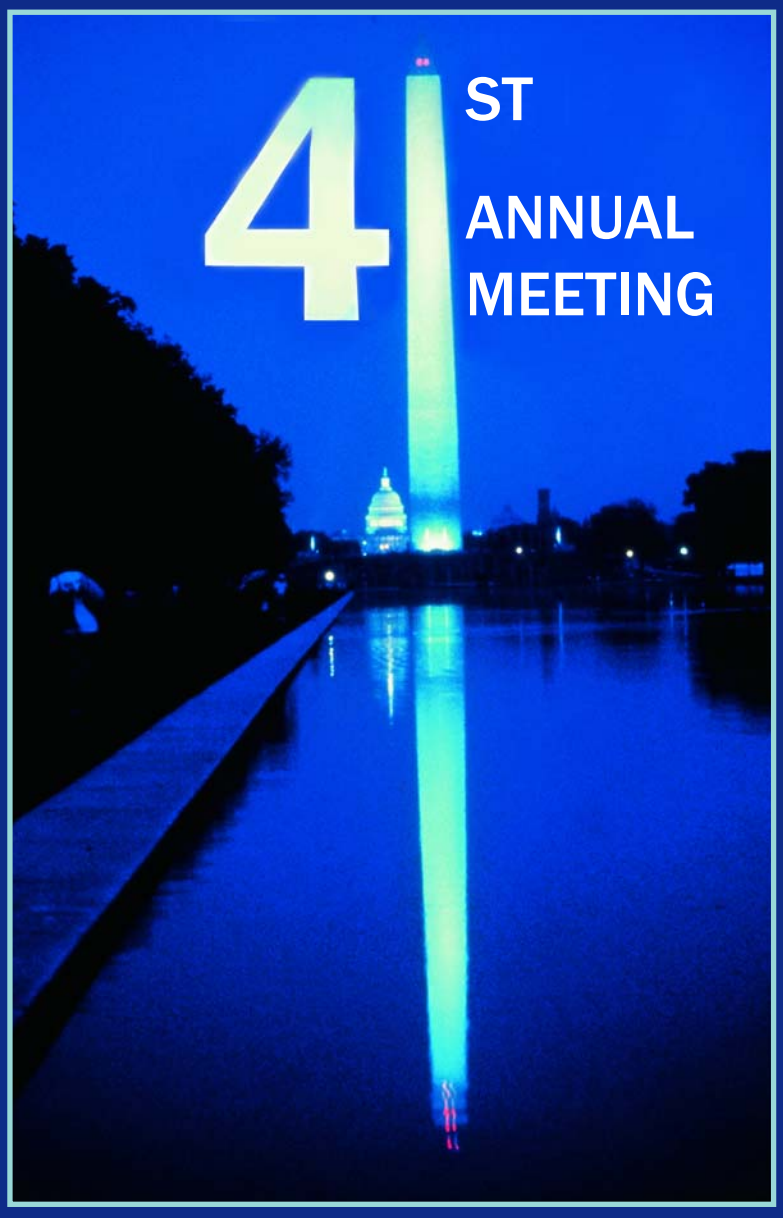
DRUG INFORMATION ASSOCIATION

# JUNE 26-30, 2005 | WASHINGTON, DC




WASHINGTON CONVENTION CENTER

PROGRAM CHAIRPERSON

Ronald D. Fitzmartin, PhD, MBA

Daiichi Medical Research, Inc.

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## Chairpersons' Message


**Ronald D. Fitzmartin, PhD, MBA**
Vice President
Global Technical Services
Daiichi Medical Research, Inc.


The DIA Annual Meeting is "the event to attend" each year by biotechnology, pharmaceutical and regulatory professionals. There is no other industry meeting of its kind that can rival the breadth and depth of experience that this meeting delivers. With over 20 content-area tracks and 300 sessions, the presentations are geared to all experience levels of attendees, from R&D and regulatory leaders to professionals in specific functional areas. The DIA Annual Meeting, above all others, offers valuable professional cross-functional learning and networking experiences.

The DIA Program Committee has developed an operational action plan with the primary goal to maintain and enhance the overall quality of the tutorials, meeting tracks, sessions, and presentations. We have developed and have begun to deliver training to track and session chairs on procedures and processes for enhancing the overall meeting experience of the attendee. We have developed and will implement session content difficulty levels. These levels will be assigned by the session chairs and will provide the attendee with a guide as to whether the session content is basic, intermediate or advanced. The levels will better assist the attendees in the selection of sessions to attend and thereby facilitate a more efficient use of their time at the meeting. We will link the tutorials to various tracks and sessions by noting which sessions complement the tutorial topic areas. There will be a number of plenary sessions that focus on special topics that range from health policy and international regulatory issues to the FDA's Critical Path Initiative. Dr. Bernadine Healy will be the first woman to deliver a DIA keynote address at the opening plenary.

The DIA Annual Meeting has one of the largest venues in the industry for exhibitors. Virtually every facet of the biopharmaceutical industry and related fields is represented by an exhibitor offering services or products in this extraordinary exhibit hall marketplace. From CROs, technology vendors to site research centers, academia and much more, the DIA Annual Exhibit Hall is one of the busiest places during the meeting. If someone wants to have a "one stop shopping" experience to see it all in one place, at one time – this is the meeting.

There is only one meeting that offers a total integrated experience of tutorials, posters, session-based learning with professional networking and exhibitor marketplace – ***the DIA Annual Meeting***.

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**Ron Fitzmartin, PhD, MBA,** is Vice President, Global Technical Services at Daiichi Medical Research, Inc., with global responsibility for biostatistics, data management, pharmacokinetics, bioanalysis, medical writing, and informatics. Previously, Ron was Group Executive Director, Biostatistics and Data Operations at Purdue Pharma L.P. At Purdue Pharma, Ron served as head of biostatistics and clinical data management, head of clinical information technology, and worldwide head of clinical data operations. Ron worked as a statistician and technologist in government, industry, and academia. These included: META Solutions, Inc., US Bureau of the Census, US Department of the Navy, and the University of Maryland, College Park. Ron received an MS in Statistics from Southern Connecticut State University, a PhD in Measurement and Statistics from the University of Maryland, College Park, and an MBA from the University of New Haven.

## Keynote Speaker


**Bernadine Healy, MD**
Adviser on Bioterrorism and
Weapons of Mass Destruction
Preparedness, US White House


Bernadine Healy, MD, currently serves as an adviser on bioterrorism and weapons of mass destruction preparedness to the US White House. Prior to this position she served for two years as president and chief executive officer of the American Red Cross.

Dr. Healy previously served as the Dean of the College of Medicine and Public Health and Professor of Medicine at Ohio State University. She is a past director of the National Institutes of Health, where she conceived and initiated the NIH Women's Health Initiative, a $625 million effort to study the causes, prevention, and cures of diseases that affect women at midlife and beyond – the largest clinical research study ever.

Before her NIH appointment, Dr. Healy chaired the Research Institute of the Cleveland Clinic Foundation, directing the research programs of nine departments, more than doubling the size of the Institute and expanding it into newly built research facilities. Dr. Bernadine Healy will be the first woman to deliver a DIA keynote address at the opening plenary session.

# Don't miss the sessions on these exciting new topics!

## A New Era of Transparency in Clinical Research: The Evolution, Impact, and Future of Clinical Trial Registers and Registries

**Monday, June 27, 10:30 AM - 12:00 PM**
**CLINICAL RESEARCH AND DEVELOPMENT TRACK**

SESSION CHAIRPERSON

***Craig A. Metz, PhD,*** Vice President, CEDD Regulatory Affairs, GlaxoSmithKline

This session will explore the seminal issues that led to the public outcry for transparency in the clinical research process and resulted in the evolution of the various clinical trial result registers currently supported by PhRMA and a number of its member pharmaceutical companies. The session will also address the expansion of the ClinicalTrials.gov National Library of Medicine database beyond the original mandate described in FDAMA 113. Presentations will be made regarding the development and experience to date with these databases, as well as procedures being developed to verify compliance with posting requirements. Panel discussants will include individual representatives from key stakeholder groups such as the US Congress/government agencies, American Medical Association, International Committee of Medical Journal Editors, World Health Organization, PhRMA, the US Food and Drug Administration, and the European Medicines Agency.

❖ **The ClinicalTrials.gov team will be available in Exhibit Hall A, lower level of the Washington Convention Center, on Monday and Tuesday, June 27 and 28 to answer any questions you may have about the Protocol Registration System (PRS) or about entering trials in ClinicalTrials.gov.**

*Presenters*

***Arthur L. Caplan, PhD,*** Professor of Bioethics, University of Pennsylvania

***Deborah A. Zarin, MD,*** Director, ClinicalTrials.gov, National Library of Medicine; Assistant Director, Clinical Research Projects, National Institutes of Health

***Alan Goldhammer, PhD,*** Associate Vice President, Regulatory Affairs, PhRMA

***Frank W. Rockhold, PhD,*** Senior Vice President, Biomedical Data Sciences, GlaxoSmithKline

***David McAvoy, MSES, JD,*** Director, Office of Scientific and Regulatory Policy, Global Regulatory Affairs, Eli Lilly and Company

*Panelists*

***Representative Invited,*** CDER, FDA

***Francis P. Crawley, PhD,*** Secretary General and Ethics Officer, European Forum for Good Clinical Practice, Belgium

## *Plenary Session* Critical Path: Are We at the Fork in the Road?

**Monday, June 27, 1:30 PM - 3:00 PM**
**CLINICAL RESEARCH AND DEVELOPMENT/REGULATORY AFFAIRS TRACKS**

SESSION CHAIRPERSONS

***Stephen E. Wilson, DrPH, Capt. USPHS,*** Deputy Director, Division of Biometrics II, CDER, FDA

***Ronald D. Fitzmartin, PhD, MBA,*** Vice President, Global Technical Services, Daiichi Medical Research, Inc.

The FDA has published a report entitled *"Innovation or Stagnation – Challenge and Opportunity on the Critical Path to New Medical Products"* (March 2004, available at http://fda.gov). The "Critical Path" report identifies the need for unprecedented improvement in the drug development process so that it is more efficient, predictable, and innovative, and less costly. The opportunities for dramatic change fall into three major dimensions and are identified as: *assessing safety, demonstrating medical utility, and industrialization.* This moderated plenary will have FDA and industry leaders engaged in an interactive Q & A panel session to address the goals, accomplishments to date and future of the Critical Path initiative.

*Moderator*

***Debbie Henderson,*** Director, Office of Executive Programs, CDER, FDA

*Panelists*

***Lawrence J. Lesko, PhD,*** Director, Office of Clinical Pharmacology and Biopharmaceutical Science, CDER, FDA

***Janet Woodcock, MD,*** Acting Deputy Commissioner of Operations, FDA

***Robert J. Temple, MD,*** Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

***Douglas C. Throckmorton, MD,*** Director, Division of Cardio-Renal Drug Products, CDER, FDA

***Steven J. Miller, PhD,*** Vice President, Regulatory Affairs, AstraZeneca

***Sean Harper, MD,*** Vice President, Medical Sciences, Amgen Inc.

## *Two-part Session* Medicines and Healthcare: Rebuilding the Trust, Reshaping the Future

**Tuesday, June 28, 8:30 AM - 10:00 AM and 10:30 AM - 12:00 PM**
**PUBLIC POLICY TRACK**

SESSION CHAIRPERSONS

***Raymond G. Starrett, MLS,*** Project Manager, GlaxoSmithKline

***Jean Yager, PhD,*** Director, Department of Methods and Training, Global Project Management, Pfizer Inc

The pharmaceutical industry is facing an unprecedented challenge to restore public confidence in the contribution of pharmaceuticals to healthcare and the value of new drug innovation. Without this confidence, the very fabric of the pharmaceutical and biotech industries and the future of new drug innovation are at risk. The potential long-term impact on patient welfare is enormous. In this session, panelists representing industry, regulatory authorities, academia, policy makers, media and patients will discuss some of the key issues affecting public perception of the industry. A moderator will guide the panelists through constructive discussion.

*Moderator*

***Kenneth I. Kaitin, PhD,*** Director, Tufts Center for the Study of Drug Development, Tufts University

*Panelists*

***Billy Tauzin, JD,*** President and CEO, Pharmaceutical Research and Manufacturers of America, (PhRMA)

***Scott Gottlieb, MD,*** Resident Fellow, American Enterprise Institute for Public Policy Research

***Robert J. Temple, MD,*** Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

***Patient Group Representative Invited***

***Member of the Press Invited***

# Annual Meeting Program Committee

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### DOCUMENT MANAGEMENT/eSUBMISSIONS
**Mary L. Collins,** Image Solutions, Inc., USA

### eCLINICAL
**Charles Jaffe, MD, PhD,** SAIC, USA

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**William R. Hahn,** Shaw Science Partners, USA

### MEDICAL COMMUNICATIONS
**Timothy E. Poe, PharmD,** GlaxoSmithKline Inc., USA

### MEDICAL/SCIENTIFIC WRITING
**Cathy Stein-Izsak, PhD,** Daiichi Asubio Pharmaceuticals, Inc., USA

**Virginia I. Watson,** Cardinal Health, UK

### NATURAL HEALTH PRODUCTS
**Hubertus Cranz, PhD, PharmD, MS,** AESGP, Belgium

**Floyd E. Leaders, PhD,** Botanical Enterprises, Inc., USA

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**James F. McCormack, PhD,** FDA, USA

**Per Spindler, DVM, MSc, MBIRA,** University of Copenhagen, Denmark

### OUTSOURCING
**James P. Burns, PhD,** PharmaNet, USA

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**Michele C. Livesey,** Barrier Therapeutics, USA

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**Peter H. Rheinstein, MD, JD, MS,** Severn Health Solutions, USA

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**Leyna T. Mulholland, PhD, PharmD,** Merck & Co., Inc., USA

**Patricia L. DeSantis,** Johnson & Johnson PRD, USA

### R&D STRATEGY
**Kenneth I Kaitin, PhD,** Tufts Center for the Study of Drug Development, Tufts University, USA

### STATISTICS
**Robert T. O'Neill, PhD,** FDA, USA

**Joachim Vollmar, PhD, MSc,** Executive Consultant, USA

### TRAINING
**Betty R. Kuhnert, PhD, MBA,** Wyeth Research, USA

### VALIDATION
**Earl W. Hulihan, MEd,** META Solutions, Inc., USA

# Tutorials

**For a schedule of tutorials by title only, see page 101 (pdf page 103).**

Get the most out of this year's annual event with DIA's preconference tutorials designed to broaden your knowledge in specialized subject areas. Most tutorials will offer continuing education credit including CME, IACET, pharmacy, and nursing.

**NEW THIS YEAR!**

Some tutorials are linked to various tracks, listed below, and specific sessions that complement the tutorial topic area. As of February 11, 2005, these are the tutorials being offered. Please continue to monitor **www.diahome.org** for tutorial updates and online registration. ***Space is limited so register early!***

**TRACK TITLES**

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

## *Saturday Afternoon Tutorials* June 25, 1:00 PM - 4:30 PM

12:00 PM - 1:00 PM **TUTORIAL REGISTRATION** Registration for **Saturday tutorials ONLY;** East Registration Area, Convention Center, Mount Vernon Place Entrance

### #30 Active-controlled Noninferiority/Equivalence Trials: Methods and Practice (ST)

*286-000-05-502-L04; 3.25 contact hours (.325 CEUs); .3 IACET CEUs*

***Irving K. Hwang, PhD***
Adjunct Professor/President, University of Medicine and Dentistry of New Jersey/Irving Consulting Group

In this tutorial, the methods and practice for the active-controlled noninferiority/ equivalence trials will be addressed. Critical definitions such as: assay sensitivity (AS), historical evidence of sensitivity-to-drug effects (HESDE), appropriate trial conduct (ATC), and constancy assumption (CA), will be discussed. Key notions of prespecification of a fixed margin and preservation of a fraction of active control effect for noninferiority trials will be specifically delineated, as well as a sample size comparison among these trial designs. In addition, switching objectives between superiority and noninferiority, and important issues in design and analysis of noninferiority trials will be further reiterated. Though this intermediate-level tutorial emphasizes concept and practical matters, prior knowledge and experience in clinical dug development in regulatory settings is required.

**Learning Objectives**

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

- Describe the fundamentals of superiority vs. noninferiority/equivalence trials
- Comprehend the know-how of design and analysis of active-controlled noninferiority/equivalence trials

**Target Audience**

This tutorial is designed for clinical project teams in drug development, specifically project team leaders, biostatisticians, clinicians, and SAS programmers. Regulatory liaisons, project managers, and marketing directors would also benefit from this tutorial.

### #31 Advanced Auditing of Clinical Research Systems for Validation (CR, VA)

*.3 IACET CEUs*

***Earl W. Hulihan, MEd***
Vice President, Regulatory Consulting, META Solutions, Inc.
***Joanne Malia, MS, MS***
Senior Manager, Medical Research Quality Management, Purdue Pharma L.P.

This tutorial explores how to identify and audit the various components of a clinical research system. Using the brief overview and discussion of international regulations relating to clinical research systems as a basis, the attendees will develop an understanding of what international regulators are looking for in regulated clinical systems. Various real-life clinical systems will be discussed during the practical portion of the tutorial.

These will allow the attendee to leave the tutorial with a good understanding of what should always be present in a quality clinical system and what some of the typical "breaking" points might be. A discussion of audit tools/aids followed by the initial creation of samples will be held to allow the attendee to have a solid understanding and platform on which to build and audit in this area.

**Learning Objectives**

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

- Define all the components of a clinical research system
- Identify common "breakdown" areas within clinical systems
- Recognize what international regulators are looking for in regulated systems
- Develop audit tools and aids to use in auditing of clinical research systems

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

### #32 Please note that this tutorial has been CANCELLED
### Contract Management: A Review of Industry Best Practices (OS, CR, FI)

*.3 IACET CEUs*

***Tiffany Sizemore Cherry, JD, MBA,*** Principal, Kontrax Consulting Services

This tutorial is intended for procurement, outsourcing and finance managers and other biotech/pharmaceutical industry professionals responsible for the management or leadership of clinical contracts. You will learn the fundamentals of contract management and how they can be applied to best meet the needs of projects. The tutorial will include presentations, and [illegible] pharmaceutical industry setting. You will take away an understanding of basic contract legalese, advanced finance principles in developing, interpreting and negotiating budgets, and contract management skills that can be immediately put to use in your work.

CANCELLED

**Key Topics**

- Initiating, planning, executing, and applying contracts
- Risk assessment, finance management
- Key legal terms and conditions

**Learning Objectives**

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

- Describe the contract management process – initiating, planning, executing, controlling and applying the contract and best practices
- Recognize contract legalese, when and how it should be applied
- Assess risk of financial error in contracts
- Apply tools and techniques to the part of the drug development process that you are engaged in within your organization
- Discuss sensitivities to working within a matrix organization and contract team

**Target Audience:** This tutorial will be of interest to new contract managers, experienced contract managers who are new to the biotech/pharmaceutical industry, clinical or other industry professionals who are responsible for managing contracts and procurement including CRAs, outsourcing and finance team members who wish to gain a deeper understanding of contract management processes.

## #33 Developing Author Templates for Submission Documents (DM)

*.3 IACET CEUs*

***Robin Zumbrunnen***
Associate Director, Document Management Technologies, Quintiles, Inc.

This tutorial will discuss how to develop authoring templates in MS Word for several electronic regulatory submission types including eCTD and electronic study reports to meet study tagging file specifications, and will include suggestions for authoring macros that will enable authors to more easily meet the guidance requirements in their documents.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Recognize what authors need for efficient authoring versus how the final submission document must appear
- Design, train and use author templates to achieve both goals

**Target Audience**
This tutorial is designed for regulatory or support personnel who are responsible for developing authoring templates for regulatory submissions.

❋ *Receive additional information about this topic by attending the Monday, June 27, 10:30 AM-12:00 PM DM Track session entitled "A Standards-based Approach for Authoring through Distribution."*

## #34 Clinical Trial Performance and Risk Analysis: Using the Earned Value Method (PM, FI)

*.3 IACET CEUs*

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

Earned Value Analysis measures the performance of projects or parts thereof. It integrates scope, cost and schedule and provides variances, key performance indicators and forecasts over cost and schedule. EVA allows for retrospective analyses and thus deriving the past performance. This may feed general performance monitoring systems for benchmarking and management of overall productivity. Prospective analysis of a running project reveals current performance and forecasts of time and money for completion. If these results are critical, methods from risk management may be applied. A concept for an Earned Value Management approach will be outlined.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Perform Earned Value Analysis (EVA) on clinical trials and other tasks during drug development
- Discuss how to model progress of a clinical trial for prospective analysis
- Distinguish between prospective (risk focused) and retrospective performance analysis
- Set up the infrastructure for input data to EVA

**Target Audience**
This tutorial is designed for project managers; executives from benchmarking, performance and risk management; and managers of clinical trials.

## #35 Identifying, Recruiting and Training Multiple Research Naïve Physicians for Participation in Simplified Clinical Trials (IS, CR)

*.3 IACET CEUs*

***Charles Laudadio, MD, MBA***
Director, Medical Affairs, McNeil Consumer & Specialty Pharmaceuticals, Inc.
***Cynthia Verst-Brasch, PharmD, MS***
Vice President, Late Phase, Kendle International, Inc.

Simplified trials conducted at a private physician's office or clinic can provide valuable insights into medical practice in a real world setting. Primary care physicians are willing to share their knowledge and expertise in this setting, but recruiting and training them to participate in a clinical trial can be a challenge. Barriers of time, overwork, claims forms, and disinterest have to be overcome before they are willing to participate. This tutorial will explore the operational challenges and solutions of simplified trial management through a case study approach.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Recognize the challenges of recruiting research naïve physicians to enroll patients into a simplified clinical trial
- Prepare training and materials that enable a primary care physician to successfully participate in a simplified clinical trial

**Target Audience**
This tutorial is designed for project managers, CRAs, site recruitment vendors, CROs, physicians, and study coordinators.

## #36 New Challenges to IRBs, Sponsors, and Investigators (IS, PP)

*3.25 category 1 credits; 286-000-05-503-L04; 3.25 contact hours (.325 CEUs); 3.9 nursing contact hours; .3 IACET CEUs*

***Paul W. Goebel, Jr., CIP***
Vice President, Chesapeake Research Review, Inc.
***Jill C. Alvarez, JD, LIM in Taxation***
Partner, Epstein, Becker, and Green

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

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Compare/contrast litigation-based and regulation-based penalties of noncompliance
- Identify the common causes of action cited in law suits filed by research subjects
- Recognize the FDA enforcement process for noncompliance
- Identify the first steps to take in reorganizing your procedures to assure best practices are always observed

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

❋ *Receive additional information about this topic by attending the Monday, June 27, 1:30-3:00 PM IS Track session entitled "I Am OK, I Am Indemnified! What Does This REALLY Mean?"*

## #37 European Regulatory Affairs: Current Regulatory Procedures and New Medicines Legislation Effective November 2005 (RA)

*.3 IACET CEUs*

***Brenton E. James, FBIRA***
Consultant in Strategic Regulatory Affairs in the European Union
***Rolf Bass, MD***
Resident Twinning Advisor (PHARE), Head of Department, URPL (Polish Authority), Poland; BfArM, (German Authority), Germany

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

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Explain the development of the European Union
- Evaluate both Centralized and Mutual Recognition Procedures
- Analyze the key business reasons for choosing the optional route
- Describe the impact of changes in the New Medicines Legislation

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

## #38 Statistical Analysis Plan Made Easy (ST)

*.3 IACET CEUs*

***Kazem Kazempour, PhD***
Acting Director Biometrics, Amarex Clinical Research

***Sally Breisch, MS***
Vice President, Amarex Clinical Research

This tutorial will discuss the value of having a SAP at the beginning of a trial, in relation to regulatory affairs, science, and ethics; and understanding the different parts of a SAP and the relative importance of those parts.

**Learning Objectives**

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

- Recognize the importance of having a statistical analysis plan (SAP) drafted before the start of a clinical trial from the perspectives of good science, regulatory affairs, and ethics.
- Describe subjective vs. objective parts of an SAP
- Describe the different components of an SAP
- Identify optional parts of an SAP

**Target Audience**

This tutorial is designed for beginner through advanced statisticians, investigators, project managers, medical writers, regulatory affairs staff, and CRAs.

## *Also available* Saturday, June 25, 1:00 PM - 5:30 PM

### Certified Clinical Investigator Examination Review Course (CR, IS)

*4.25 category 1 credits; 286-000-05-012-L04; 4.25 contact hours (.425 CEUs)*

As regulatory agencies, institutions, and research sponsors are setting stricter guidelines with regard to investigator training, this half-day Certified Clinical Investigator examination review course provides an in-depth review of the roles and responsibilities of the clinical investigator and others involved in clinical trials, the regulations and guidelines that govern clinical trials, and the practices that ensure effective and efficient study conduct.

**Target Audience** This Certified Clinical Investigator examination review course is designed to prepare physicians, pharmacists, physician assistants, nurse practitioners, and research scientists for the Certified Clinical Investigator examination.

**Learning Objectives** At the conclusion of this course, participants should be able to: differentiate the roles and responsibilities of the clinical investigator, sub-investigator, study staff, IRB, and sponsor; describe the regulations and guidelines applicable to conducting safe and effective clinical trials; successfully prepare a site to conduct a clinical trial including study design, patient recruitment, and protocol development; use appropriate methods to ensure compliance, subject safety, and protocol adherence.

**Online registration is available for the CCI Examination Review Course at http://www.diahome.org/docs/Events/events_search_detail.cfm?EventID=05410**

### *Two Offerings!* Certified Clinical Investigator Examination

**Sunday, June 26, 9:00 AM - 12:00 PM and 2:00 PM - 5:00 PM**

***This examination is three hours in length and is administered by DIA Certification, Inc. It consists of 150 randomized multiple-choice questions, designed to objectively assess and measure professional knowledge of the materials covered in the Core Content for Certification Handbook.***

For general information on the Certified Clinical Investigator Program, or specific information about qualifications for taking the examination, other examination dates, group discounts, or training opportunities, please contact Kia Gray at kia.gray@diahome.org.

**Online registration is not available for the CCI examination. You must submit an application found at http://www.diahome.org/content/Events/Clinical_Investigator_Guide_Application.pdf.**

## *Sunday, Full-day Tutorials* June 26, 9:00 AM - 5:00 PM

8:00 AM - 9:00 AM **TUTORIAL REGISTRATION** Registration for **Sunday, full-day or morning tutorials ONLY;** East Registration Area, Convention Center, Mount Vernon Place Entrance

## #40 Clinical Statistics for Nonstatisticians (CR)

*6.5 category 1 credits; 286-000-05-504-L04; 6.5 contact hours (.65 CEUs); 7.8 nursing contact hours; .7 IACET CEUs*

***Michael C. Mosier, PhD***
Director, Biostatistics, EMB Statistical Solutions, LLC
***James Whitmore, PhD***
Director, Statistics, Programming and Data Management, Berlex, Inc.

This tutorial is intended to introduce basic statistical concepts that are fundamental to clinical research, and is designed for individuals with some exposure to statistics (either through course work, or on the job experience), that is equivalent to an introductory statistics course. While a few formulae are included for individuals who are interested in computational details, the overall emphasis of the tutorial is on the application of the statistical concepts to clinical investigation.

**Learning Objectives**

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

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

**Target Audience**

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

## #41 Computer Validation from A to Z: Practical Reality for User Acceptance of GXP Systems (IT, VA)

*.7 IACET CEUs*

***Teri Stokes, MT (ASCP), MS, PhD***
Director, GXP International
***Richard Chamberlain, MS, PhD***
President, ECS, Inc.

This busy day provides an immersion learning experience in the reality of computer validation. Participants will be actively involved in working group discussions, case study analysis, and a hands-on test experience to illustrate concepts given in interactive presentations. Come prepared to analyze, open to reality-based discussions, and ready for fun while you work. We will cover computer validation from A to Z!

For hands-on testing, attendees should bring the following: laptop with a USB port and MS EXCEL (98 or higher) to test a spreadsheet and laptop powerpack. Without the laptop you can still participate as a witness or recorder of the testing.

**Learning Objectives**

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

- Describe the essential regulatory requirements for computerized system validation (CSV)
- Compare and contrast the content and focus of IQ, OQ, and PQ system validation packages and define the roles and responsibilities needed for each package
- Analyze the need for and difference between Validation Plan and Test Plan and their respective summary reports
- Identify the key elements for auditable test documentation and experience formal testing practices by executing a test script

**Target Audience**

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

*Receive additional information about this topic by attending the Monday, June 27, 10:30 AM-12:00 PM VA Track session entitled "General Validation Issues."*

## #42 Data Mining, Data Flow Modeling, Data Warehousing, and Knowledge Management (CDM)

*.7 IACET CEUs*

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

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

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Categorize and assess data mining tools
- Apply data mining algorithms
- Perform data mining tasks
- Construct and analyze process models

**Target Audience**
This tutorial is designed for data analysts, data and knowledge managers, data flow experts, clinicians interested in modern data analysis tools, biotech experts, professionals involved in data mining and data warehousing projects, and pharmaceutical industry experts interested in getting more value from the data.

❋ *Receive additional information about this topic by attending the Wednesday, June 29, 8:30-10:00 AM CP Track session entitled "Data Mining and Signal Detection: Where Are We?"*

## #43 Design and Statistical Analysis of Bioequivalence Studies (ST)

*6.5 category 1 credits; 286-000-05-505-L04; 6.5 contact hours (.65 CEUs); .7 IACET CEUs*

***Scott D. Patterson, MSc, PhD***
Director, Statistical Sciences, GlaxoSmithKline
***Byron Jones, PhD***
Senior Director, Development Operations, Pfizer Inc

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

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Design and analyze bioequivalence trials
- Discuss their history and place within drug development

**Target Audience**
This tutorial is designed for clinical pharmacologists, pharmacokineticists, physicians, nursing staff, and statisticians in the pharmaceutical industry, universities, and international regulatory agencies. Regulators interested in this topic would also benefit from this tutorial.

## #44 Pharmacokinetics and Pharmacodynamics: A Gentle Introduction (CR)

*6.5 category 1 credits; 286-000-05-506-L04; 6.5 contact hours (.65 CEUs); 7.8 nursing contact hours; .7 IACET CEUs*

***Michael J. Fossler, PharmD, PhD, FCP***
Principal Clinical Pharmacokineticist, GlaxoSmithKline

Pharmacokinetic/pharmacodynamic modeling (PK/PD) is assuming an increasingly important role in the drug development process. Go/no-go, dosing regimen, and study design decisions are now made using PK/PD information. However, for the pharmaceutical professional not specifically trained in this area, the terminology and mathematics can be a bit overwhelming. In this full-day tutorial, the morning session will be devoted to explaining the basics of PK/PD using familiar terms and as little math as possible. The afternoon will be spent reviewing some special topics (building on the morning session), including population PK/PD modeling and clinical trials simulation, in order to provide the regulatory professional with a conceptual grasp of this important field.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Define the following pharmacokinetics concepts:
  - Clearance; volume of distribution; half-life; relative and absolute bioavailability; steady state; population pharmacokinetics/pharmacodynamics; clinical trials simulation
- Explain the difference between one compartment and two compartment PK models
- Define the following pharmacodynamics concepts:
  - Emax; EC50; direct and indirect response models
- Explain (in a general way) how simulation is used in contemporary drug development

**Target Audience**
This tutorial is designed for clinical research and regulatory affairs professionals, physicians, nurses, CRO personnel, or anyone working in the pharmaceutical industry desiring some additional information about pharmacokinetics and pharmacodynamics.

## #45 Principles of Safety Surveillance (CP)

*6.5 category 1 credits; 286-000-05-507-L04; 6.5 contact hours (.65 CEUs); 7.8 nursing contact hours; .7 IACET CEUs*

***Stanley B. Garbus, MD, MPH***
Chief Medical Officer, Sentrx
***Brandt Rowles, PhD***
Vice President, Pharmacovigilance and Risk Management, Sentrx

Current FDA requirements mandate that the pharmaceutical industry maintain a competent adverse drug reaction monitoring system. Recognizing changing regulatory guidelines for monitoring reporting compliance, as well as understanding the risk implications of suspected adverse events, has become more critical with recent product recalls. Understanding the processes of pharmacovigilance and the changing regulations will assist pharmaceutical personnel in providing critical safety services.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Define key elements and definitions of safety surveillance
- Implement methods for risk monitoring and surveillance systems to capture and process suspected adverse drug reactions
- Ensure compliance when reporting adverse events to regulatory authorities
- Recognize value of utilizing web-based pharmacovigilance

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

## #46 Techniques for Applying Risk Management Principles to Computer System Validation (IMP, VA)

*.7 IACET CEUs*

***Frances E. Nolan, MBA***
Vice President, Taratec Development Corporation
***Arik Gorban***
Vice President, Taratec Development Corporation

Utilizing different case studies, this tutorial will demonstrate techniques for applying risk management principles to computer system validation (CSV) at each stage of the system life cycle (SLC), including planning and definition (vendor assessment/vendor selection; user requirements specification); system design specification and design reviews; code development, review and testing, commissioning and qualification; ongoing operation (maintaining the validated state); and decommissioning/retirement.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Identify the components and benefits of risk-based compliance management
- Describe how risk-based compliance management differs from:

  - Traditional system life cycle (SLC) and computer system validation (CSV) planning and execution
  - Medical device risk analysis approaches that focus on individual system functions and determine testing requirements
  - GxP applicability and 21 CFR Part 11 gap analysis
  - System criticality categorization
- Apply risk management principles to the development, implementation and validation of computer systems in a regulated environment

**Target Audience**
This tutorial is designed for individuals who have experience planning and executing system life cycle (SLC) and computer system validation (CSV) processes in a regulated environment, but do not necessarily have experience and expertise with techniques to formally apply risk management principles to such processes.

## #47 Update on the European Clinical Trial Legislation (CR, RA)

*.7 IACET CEUs*

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

The new European clinical trial legislation has an impact on clinical trial management, conduct, surveillance, and reporting, with consequences for sponsors, investigators, ethical committees and regulatory authorities. The directive has been enforced since 2001 and enhanced upon by nine detailed guidance documents. Five of these detailed guidelines have been finalized and required implementation by May 2004 by each European Member State to comply with the European legislation. This interactive tutorial will provide an overview of the European legislation affecting clinical trials and provide information on the contents of each document: What is new, and what are the consequences for the conduct of clinical trials? Points of discussion will be the Clinical Trials Directive 2001/20/EC and the corresponding detailed guidance on the clinical trial application process, notification of substantial amendments, declaration of end of trial, the ethical committee opinion processes, the EUDRACT and EudraVigilance databases, and the reporting of adverse events. Furthermore, the impact of the European Data Protection Directive 95/46/EC, the retention times of essential documents (as of directive 2003/63) and the revised Annex 13 of GMP on clinical trial practices will be discussed.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Describe the legal environment for clinical trials in Europe
- Identify the new requirements arising from this legislation
- Identify responsibilities and relevant documents for day-to-day business
- Carefully plan clinical trials in order to meet regulatory milestones and submit valid applications and documents to competent authorities, ethical committees, investigators and clinical trial subjects

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

❋ *Receive additional information about this topic by attending the Wednesday, June 29, 10:30 AM-12:00 PM RA7 Track session entitled "Regulation of Clinical Research in the EU: Impact of the Clinical Trials' Directive" and Wednesday, June 29, 3:30-5:00 PM RA4 Track session entitled "Clinical Trials Directive: EU Remains Attractive for Clinical Research."*

## *Sunday Morning Tutorials* June 26, 8:30 AM - 12:00 PM

8:00 AM - 9:00 AM **TUTORIAL REGISTRATION** Registration for **Sunday, full-day or morning tutorials ONLY;** East Registration Area, Convention Center, Mount Vernon Place Entrance

## #50 Overview of the 21 CFR 11 Regulations and Guidance: What Has Changed and What Is Now Required? (IT)

*.3 IACET CEUs*

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

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

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Discuss and analyze the scope and application of the 21 CFR 11 regulations
- Interpret the changes in FDA guidance and expectations
- Formulate a realistic and justified position for their company's 21 CFR 11 plans and standards

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

❋ *Receive additional information about this topic by attending the Thursday, June 30, 10:30 AM-12:00 PM RA3 Track session entitled "21 CFR Part 11 and Electronic Source Documentation Requirements for Investigators."*

## #51 Case Studies on Signal Detection and Investigation (CP)

*3.25 category 1 credits; 286-000-05-508-L04; 3.25 contact hours (.325 CEUs); .3 IACET CEUs*

***Monika Pietrek, MD, PhD, MSc***
Senior Vice President, Global Medical and Safety Services
PRA International, Germany

***Robert C. Nelson, PhD, FISPE***
Consultant, RCN Associates, Inc.

***Rosalind Coulson***
Consultant in Pharmacovigilance Information Management
PRA International, Germany

Safety signals may arise from various sources during development and postlaunch of a drug, device or vaccine. This tutorial uses case studies of different safety signals and explains how signals and safety issues are distinguished and evaluated, how risks can be quantified and which data sources for investigation are available.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Describe signal identification and assess the impact of a potential safety concern
- Classify different methods of investigations
- Describe the strengths and limitations of available data sources for investigations
- Interpret findings

**Target Audience**
This tutorial is designed for physicians and pharmacists in clinical research and drug safety, statisticians, clinical scientists, drug safety associates, clinical data coordinators in the pharmaceutical and CRO industries, academia and regulatory agencies.

## #52 Best Practices When Using MedDRA® (CP, CDM)

*.3 IACET CEUs*

***JoAnn Medbery, RN***
Manager, Dictionary Management, Johnson & Johnson Pharmaceutical Research & Development, L.L.C

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

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Recognize "MedDRA's® Best Practices"
- Analyze the need for establishment of "MedDRA's® Best Practices" within their environment

- Describe at least two "MedDRA® Best Practices" and how they could be implemented within your organization

**Target Audience**

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

❋ *Receive additional information about this topic by attending the Thursday, June 30, 8:30-10:00 AM CP Track session entitled "The Use of Multilanguage MedDRA® in a Global Environment."*

## #53 Critical Issues and Important Considerations for Outsource Contracting (OS, PP)

*.3 IACET CEUs*

***Daniel J. O'Connor***
Assistant Vice President, Legal, ImClone Systems Incorporated
President, CEO, Milestone Research, Inc.

This tutorial will cover important issues and considerations for: (1) sponsor/CRO contracts; (2) sponsor/consultant contracts; and (3) sponsor/CRO/investigator/site contracts. The tutorial will explain, in non-legalese, the legal and operational considerations for preparing and then managing these types of contracts. Participants in this tutorial will learn how to approach and negotiate difficult contractual issues, including: (1) the respective obligations of the parties to the contracts, e.g., sponsor/CRO; (2) clearly establishing the project costs vs. change orders; (3) payment schedule: fee-for-service vs. milestones; (4) insurance; (5) term and termination provisions; (6) confidentiality; (7) ownership of inventions and other intellectual property; (8) publication; (9) limitation of liability; (10) indemnification; (11) exclusive assignment of study personnel; (12) regulatory compliance; inspections, warranties; and (13) delays. Each topic will be illustrated, analyzed and discussed utilizing sample contract language.

**Learning Objectives**

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

- Identify and describe the important legal and operational issues regarding certain outsourcing contracts
- Design appropriate outsourcing contracts which will address the issues

**Target Audience**

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

❋ *Receive additional information about this topic by attending the Tuesday, June 28, 8:30-10:00 AM OS Track session entitled "Are the Pharmaceutical Industry's New Initiatives for Managing Outsourcing Producing Better Results?"*

## #54 Compliance-driven Risk Detection: A New Approach within Drug Safety (CP)

*3.25 category 1 credits; 286-000-05-509-L04; 3.25 contact hours (.325 CEUs); .3 IACET CEUs*

***Pradip K. Paul, MBBS, MS***
Director, Global Medical Safety Surveillance, Berlex Pharmaceuticals, Inc.
***Carol L. Krueger, RN***
Consumer Safety Officer, Division of Compliance, Risk Management, and Surveillance, CDER, FDA

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

**Learning Objectives**

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

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

**Target Audience**

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

## #55 Dealing Effectively with Cultural Differences for Clinical Trial Professionals (CR, TR)

*3.25 category 1 credits; 286-000-05-510-L04; 3.25 contact hours (.325 CEUs); 3.9 nursing contact hours; .3 IACET CEUs*

***Mary E. Briggs***
President and Chief Training Officer, FOCUS, Inc.

One of the biggest challenges in the clinical trial industry is managing global work teams. Differing cultures, working practices and mannerisms often lead to miscommunication and conflict. Drug development organizations that are able to integrate many ways of thinking have seen an increase in productivity of their global teams. This tutorial addresses how to bridge the differences with multi-national teams in the clinical trial industry. We will explore North America, Western and Eastern Europe and Asia.

**Learning Objectives**

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

- Practice skills to build rapport with colleagues and customers from different cultures
- Practice a process to gently address behaviors, attitudes and norms that do not promote an inclusive work environment
- Discuss cultural etiquette traditions and customs for the clinical trial business in Asia, countries in Eastern and Western Europe and North America
- Recognize the stereotypical behaviors that break down our ability to function effectively in global work teams

**Target Audience**

This tutorial is designed for clinical trial professionals who wish to work more effectively with colleagues and clients from other cultures.

## #56 *Please note that this is now Tutorial #84 being offered on Sunday, 1:00 pm - 4:30 pm (effective 4-7-05)*

## EU Regulatory Requirements: Pharmacovigilance in the Pre- and Postmarketing Phase and the EudraVigilance Database (CP, RA)

## #57 Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People and Process (CR)

*.3 IACET CEUs*

***Laurie Halloran, MS***
President, Halloran Consulting Group, Inc.

What is clinical operations and why are some of the most successful companies realizing the importance of it? How does the clinical operations function contribute to the overall success of the organization? Who is successfully establishing or running clinical operations? Many organizations find themselves struggling to determine how and when to establish the function. Professionals new to the position quickly realize there's very little information out there to learn how to do their job effectively. A thorough overview of the functions and responsibilities of clinical operations will be followed by comprehensive exploration of the processes, tools, and technologies to enhance the department's output and value to the organization.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Describe and explain the role, responsibilities and activities of a clinical operations management position
- Identify the competencies for a successful clinical operations manager/ director
- Discuss major technologies that manage and improve clinical operations functions
- Plan for use of tools to project and maximize clinical trial resources and efficiencies

**Target Audience**
This tutorial is designed for executives considering the establishment of clinical operations to improve their development organizations, as well as seasoned clinical research professionals who are considering or have recently made a change into clinical operations positions.

## #58 Leadership: How to Organize and Lead People in Group Work (TR)

*.3 IACET CEUs*

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

The role of a manager in organizing and leading a group is often misunderstood and, as a consequence, the group may not perform up to expectations or may spend a considerable amount of time dealing with dysfunctional group dynamics instead of the work to be accomplished. This tutorial addresses those issues by exploring the different types of work groups, how they can be more effective, and how individuals can correct group dynamics and help the group achieve higher levels of performance.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Identify and correct dysfunctional group dynamics
- Create and maintain cooperation among team members
- Respond to distracting influences on group work to minimize impact on quality of work

**Target Audience**
This tutorial is designed for individuals who must manage group activities on a permanent or project basis, and individuals to whom project managers report. In addition, those who must work on teams but are not in charge of the teams can learn how to exert influence over group behavior. Past participants of the DIA Leadership Experience will also find this an excellent review as well as an opportunity to cover new materials.

## #59 Preparation of Integrated Clinical and Statistical Reports for Individual Studies (MW, CR)

*3.9 nursing contact hours; .3 IACET CEUs*

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

This tutorial will focus on the activities of the clinical team, interaction with supporting disciplines, and documents needed for report preparation. The ICH guideline for report structure and content will be reviewed and samples of key tables will be discussed. Participants are encouraged to play an active role in the tutorial by asking questions, exchanging ideas, and addressing problem areas of report generation. This tutorial will: 1) provide an understanding of how a study report fits into overall product development; 2) explore the process of preparing a clinical study report; and 3) discuss ways to improve the writing and review process.

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

**Target Audience**
This tutorial is designed for clinical research professionals with less than two years of experience in preparing integrated study reports, individuals in related disciplines (data management, statistics, clinical research associates, etc.), and managers or supervisors interested in an overview of the reporting process.

## #60 Basic Audit Preparation: What You Should Know About Being Audited (VA, GCP)

*.3 IACET CEUs*

***Ken O'Brien***
Associate Director, Process Quality Management, Perceptive Informatics, Inc.
***James H. Graffam, MS***
Manager, Software Quality Management, Perceptive Informatics, Inc.

Lack of training and preparation is a significant contribution to the fear, apprehension, and stress often associated with being audited. This half-day tutorial is designed to instruct potential auditees in the fine art of preparing for and responding during audits. Three main areas of focus will be covered: preparing for the audit, auditee responsibilities, and auditor techniques.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Approach an audit with new-found confidence and recognize how a well prepared auditee will affect the outcome of the audit in a positive manner
- Create a process to support a client audit
- Apply learnings to internal training programs at their company

**Target Audience:** This tutorial is designed for auditees of any level.

❋ *Receive additional information about this topic by attending the Monday, June 27, 10:30 AM-12:00 PM GCP Track session entitled "Managing Regulatory Inspections."*

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

*.3 IACET CEUs*

***Robert Fike, MS, PhD,*** Assistant Vice President, Regulatory Affairs Japan, Wyeth Research Division of Wyeth
***J.D. Rafizadeh-Kabe, MD, JD, RAC,*** Associate Director, Global Regulatory Strategy, Bristol-Myers Squibb Pharmaceutical Research Institute

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

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Identify the major elements of the Japanese regulatory system including the newly created agency
- Describe the regulatory processes during development, registration, and post approval safety and pricing in Japan
- Recognize specific attributes in the Japanese regulatory system and their impact on multinational development strategies

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

## #62 Please note that this tutorial has been CANCELLED
## Trust, Relationships and the Negotiation Process

*.3 IACET CEUs*

***Ira G. Asherman,*** Consultant, Asherman Associates
***Barry Sagotsky, MBA,*** Consultant, Magnolia Lane Consulting

Through the use of lecture, small group discussion and practice negotiations the participants will explore the impact of trust on the negotiation process. The participants will explore the importance of trust when negotiating with co-workers, vendors and agency personnel. Emphasis will be placed on identifying the steps they can take to

CANCELLED

enhance relationships where trust has been compromised.

**Learning Objectives**

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

- Describe the importance of trust to negotiation success
- List the factors critical to building trust
- Identify the steps to follow when trust is not present
- Describe the six step successful negotiator process

**Target Audience**

This tutorial is designed for clinical research staff, regulatory liaison staff, and anyone who is faced with seeking help from others.

## *Sunday Afternoon Tutorials* June 26, 1:00 PM - 4:30 PM

12:30 PM - 1:00 PM **TUTORIAL REGISTRATION** Registration for **Sunday, afternoon tutorials ONLY;** East Registration Area, Convention Center, Mount Vernon Place Entrance

### #70 Auditing the Vendor: Keys to Making It Work Before and After the Audit (OS, CR)

*.3 IACET CEUs*

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

This tutorial is intended to provide the participant with information he/she can use to effectively select, audit, and manage vendors. The management of vendors, after the initial selection, is one of the most important aspects of the vendor-sponsor relationship. Audits are a snapshot in time, and as such, vendors must be continuously evaluated and expectations must be clearly defined to avoid potential misinterpretation and misunderstanding.

**Learning Objectives**

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

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

**Target Audience**

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

### #71 Introduction to Capacity Management, Tools and Techniques (PM)

*.3 IACET CEUs*

***Paul Bunch***
Manager, Capacity Planning and Management, Eli Lilly and Company

***Joseph F. Pekny, PhD***
Professor, School of Chemical Engineering, Purdue University

This tutorial will provide a basic understanding of the theory and practice of capacity management as it applies to an R&D setting. Several examples of practical application will also be reviewed. Ample time for hands-on Q&A will be provided.

**Learning Objectives**

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

- Operate with a basic understanding of capacity management
- Apply the basic concepts in an R&D setting
- Recognize how to optimize project resources using a variety of capacity management tools and techniques that lead to improved project and portfolio performance

**Target Audience**

This tutorial is designed for project managers, line managers, and functional managers in the pharmaceutical and biotechnical industry.

❋ *Receive additional information about this topic by attending the Monday, June 27, 3:30-5:00 PM PM1 Track session entitled "Enterprise Project Management and Capacity Management: An Interactive Session."*

### #72 CTD Preparation: Module 2 Clinical Overview and Clinical Summary (MW, RA, ST)

*.3 IACET CEUs*

***Michael J. Umen, PhD***
President, Michael Umen & Co., Inc.

***Mary Vanderhoof, MS***
Senior Medical Writer, Michael Umen & Co., Inc.

The Guidance for Industry, M4E: The CTD – Efficacy will be reviewed with particular emphasis on those sections that apply to preparing a Clinical Overview (CTD Module 2, Section 2.5) and a Clinical Summary (CTD Module 2, Section 2.7) for an NDA or BLA. FDA's Clinical Review Template (FDA's MAPP 6010.3) will be analyzed from the perspective of how it can assist sponsors in preparing better Clinical Overviews and Clinical Summaries. Package inserts of approved products will be analyzed for the kinds of supporting tables, figures and analyses that could be expected to be found in the corresponding CTD Clinical Summaries and/or in various reports of data from more than one study (e.g., ISE, ISS, etc.) which might be placed in CTD Module 5, Section 5.3.5.3. Sample tables and figures excerpted from medical and statistical reviews of approved drugs and biologics will be used as instructional tools.

**Learning Objectives**

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

- Interpret and apply the Guidance for Industry, M4E: The CTD – Efficacy, to the writing of an effective Clinical Overview (CTD Module 2, Section 2.5) and an effective Clinical Summary (CTD Module 2, Section 2.7) for an NDA or BLA
- Use FDA's Clinical Review Template as a guide to writing an effective Clinical Overview (CTD Module 2, Section 2.5) and an effective Clinical Summary (CTD Module 2, Section 2.7) for an NDA or BLA
- Determine when a stand alone ISE may be useful in addition to a Summary of Clinical Efficacy (Module 2, Section 2.7.3)
- Determine when a stand alone ISS may be useful in addition to a Summary of Clinical Safety (Module 2, Section 2.7.4)

**Target Audience**

This tutorial is designed for medical writers, pharmaceutical physicians, biostatisticians, clinical pharmacologists, and regulatory affairs professionals.

### #73 Effective, Legal Rx Drug Promotion for the Year 2005: A Regulatory Primer (MA, RA)

*3.25 category 1 credits; 286-000-05-511-L04; 3.25 contact hours (.325 CEUs); 3 IACET CEUs*

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

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

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

**Learning Objectives**

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

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

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

## #74 Effective Presentation Skills for Clinical Trial Professionals (CR, TR)

*286-000-05-512-L04; 3.25 contact hours (.325 CEUs); 3.9 nursing contact hours; .3 IACET CEUs*

***Mary E. Briggs***
President and Chief Training Officer, FOCUS, Inc.

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

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Apply presentation fundamentals (preparation, delivery and style) to future business/clinical talks
- Build confidence with personal presentation style
- Recognize and manage symptoms of performance anxiety
- Gain credibility as a speaker in the clinical trial industry

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

## #75 Please note that this tutorial has been CANCELLED
## Writing Effective Emails for a Multinational Audience (TR)

*.3 IACET CEUs*

***Bill Whelan, BS,*** Program Facilitator, LinguaCall
***Jennifer Thompson, BA,*** President, LinguaCall

This tutorial provides examples, illustrations and interactions that permit participants to explore their style and content for improvement. By learning cues from cultural research, participants are able to adjust their written expressions to reflect greater sensitivity for their audience while focusing on the essential elements of the message. The goal is to produce a document that achieves a shared sense of understanding that lessens the chance of misunderstandings and escalations.

CANCELLED

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Discuss the practical background and techniques in crafting "emails" for a multinational audience
- Recognize the value of mastering core cross-cultural skills and how to use that knowledge to improve the content of worldwide "emails"
- Describe cultural differences and similarities
- Identify the principles of effective "email" business writing and improve meaning when communicating with a culturally diverse audience

**Target Audience**
This tutorial is designed for people who wish to improve the quality of their multinational business emails while acquiring cross-cultural communications training. It would also be beneficial for administrators and middle management executives.

## #76 Ensuring the Integrity of Electronic Records and Signatures: An Internal Controls Approach (CR, IT, GCP)

*3.9 nursing contact hours; .3 IACET CEUs*

***Leonard A. Grunbaum, MBA***
President, META Solutions, Inc.

This tutorial will answer the following question: what internal controls must an organization employ, as part of the business infrastructure, to help ensure the integrity of electronic records and signatures in the most effective and efficient manner? It will (1) define and describe the concept of internal controls, (2) provide a detailed description of the pertinent internal controls, and (3) relate the internal controls to the requirements of 21 CFR Part 11 and applicable predicate regulations.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Describe the control environment that is conducive to compliant and efficient automated clinical trials operations
- Identify the pertinent internal controls
- Relate the internal controls to requirements of applicable regulations

**Target Audience**
This tutorial is designed for those responsible for various aspects of clinical trial operations, including the trials themselves (how data integrity can be maximized), systems development (what requirements should a system be designed to meet), IT operations (what controls must exist to protect pertinent corporate assets), and quality assurance (what disciplines must be brought to the table to help ensure quality).

## #77 FDA Enforcement: What You Need to Know to Avoid or Respond to the FDA (RA, GCP)

*3.25 category 1 credits; 286-000-05-513-L04; 3.25 contact hours (.325 CEUs); .3 IACET CEUs*

***Michael A. Swit, JD***
Vice President, Life Sciences, THE WEINBERG GROUP INC.

This tutorial will review and discuss the legal, regulatory and practical nuances of 1) FDA enforcement priorities for 2005 and beyond (e.g., application of data integrity policy and good clinical practice requirements), 2) FDA administrative enforcement weapons and how the Agency uses them (e.g., inspections, warning letters, publicity, recalls, and investigator disqualification proceedings), and 3) the civil and criminal penalties for GCP violations (e.g., seizure, injunction, criminal prosecution). The tutorial will also address how to handle an FDA enforcement action should you face one, particularly in the wake of an inspection or warning letter at a clinical site or of a sponsor. These interactive discussions will focus on how FDA operates and makes decisions; how to respond effectively, using tactics ranging from negotiation to, when appropriate, litigation.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Discuss FDA's enforcement priorities for 2005 and beyond
- Describe FDA's compliance review and decision making process
- Recognize the legal risks and penalties for noncompliance
- Respond appropriately to FDA enforcement actions with regard to sponsor records in clinical studies as well as inspections at the clinical site

**Target Audience**
This tutorial is designed for personnel at sponsor and clinical sites, and investigators and CROs that have responsibility for ensuring compliance with FDA's Good Clinical Practice ("GCP") requirements, regardless of whether in a supervisory or direct role.

## #78 Fourteen Steps from Research to Development (RD, RA)

*3.9 nursing contact hours; .3 IACET CEUs*

***Judi Weissinger, PhD***
President and CEO, Weissinger Solutions, Inc.
***Michael R. Hamrell, PhD, RAC***
President, MORIAH Consultants

There are 14 steps from research to development (R to D) and initiation of phase 3 clinical studies; the majority of time committed to drug development occurs during this period. A discussion of the 14 critical steps from R to D will include identifying ways to streamline the process and interactions with FDA. With each of the 14 steps used to develop the optimal strategic plan, discussion will address the resources and various approaches to tailoring the plan to a sponsor's specific product under development and obtaining FDA concurrence with the strategic plan. A smooth progression through the preclinical process into early clinical programs will be presented in this half-day tutorial targeted to familiarize pivotal staff in start-up companies with the terminology and functions required, to pharmaceutical/biological companies that have yet to file INDs, and to those who want to improve their early development approach.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Recognize the terminology and process involved in product development
- Identify ways to tailor the development, streamline the process and interact with FDA for unique products
- Explain the specialties and resources needed to develop a product
- Guide your company smoothly through the progression of research and development through the preclinical process into early clinical programs

**Target Audience**
This tutorial is designed for pivotal staff in start up companies, pharmaceutical/biological companies that have yet to file INDs, and all personnel that want to broaden their knowledge of product development.

## #79 Investigator Site and Monitor Training to Improve Data Quality and Optimize MedDRA® Coding (IS)

*.3 IACET CEUs*

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

One of the most significant aspects of MedDRA implementation is training of organization personnel. Training of coding personnel about the size, structure and specificity of MedDRA is necessary to achieve accurate and meaningful data for subsequent analysis; however, both the encoding and analysis of MedDRA-coded data are highly dependent on the initial quality of the data received from reporters, including investigators. This tutorial will focus on how the quality of initial data impacts MedDRA coding and analysis and will describe training strategies to optimize the quality of reported data from investigators.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Describe how the quality of initial data from investigators impacts MedDRA coding and subsequent data analysis
- Define the role of MedDRA training for investigators, CRAs and CROs in the effort to improve data quality

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

## #80 Please note that this tutorial has been CANCELLED
## Quantitative Clinical Imaging in Clinical Trials: Operational and Statistical Issues (ST)

***James M. Dancy, MBA***
Vice President, Operations, dKb Technologies
***Robert J. Buck, PhD***
Statistician, Pfizer Inc

This tutorial will describe the strategic use of clinical imaging for quantitative biomarkers, and will explain common imaging modalities (CT, MRI, PET, fMRI). The operational data capture process from 'machine format' to sponsor database will be described. Statistical study design and analysis issues will be discussed, including variance sources and approaches to control variance.

CANCELLED

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Communicate the purpose and clinical use of common imaging modalities (CT, PET, MRI, and fMRI) that are being used as quantitative endpoints in clinical trials
- Demonstrate the data management and data monitoring process for imaging data collection in a clinical trial – regardless of imaging modality
- Describe the statistical analysis factors relevant to study design and analysis
- Explain existing industry use of imaging biomarkers in the drug development decision process as well as regulatory submission process

**Target Audience**
This tutorial is designed for individuals involved in the implementation of clinical trials with a significant imaging based endpoint. The focus is on operational roles such as data management, study monitoring, regulatory, clinicians, and statisticians.

## #81 Evidence-based Medicine Throughout the Clinical Drug Development Process (CP)

*3.25 category 1 credits; .3 IACET CEUs*

***Matthew W. Reynolds, PhD***
Senior Director, Risk Management and Safety Services, MetaWorks, Inc.
***Susan D. Ross, MD***
Chief Scientific Officer and Co-founder, MetaWorks, Inc.

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

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

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

## #82 The Building Blocks for Patient Recruitment and Retention (IS, CR, BT)

*.3 IACET CEUs*

***Elizabeth A. Moench***
President, MediciGroup® Inc.
***Lisa Fell***
Vice President, Recruitment Operations, MediciGroup® Inc.

When today's patient recruitment processes are riddled with inefficiencies that slow, sideline and sometimes stop clinical trials, and more than three-quarters of all clinical trials fail to meet their recruitment deadlines, steps to streamline processes, accelerate patient recruitment and improve the margin of study success are critical. This tutorial will address the following themes:
- *Recruitment Feasibility:* Practical, realistic case study examples in clinical trial recruitment. Participants will collaborate to forecast, analyze and set performance markers, identify hidden pitfalls and solutions for clinical trial recruitment.
- *Recruitment Strategy Design:* Realistic development of recruitment programs to recruit different patient populations assessing different media methods and cost per acquisition analysis. This module incorporates case-studies based on historical data and published articles.
- *Recruitment Performance Metrics:* Cost and performance management are key to tracking progress and monitoring recruitment timelines.
- *Site Accountability for Recruitment:* Setting achievable timelines, performance parameters and fostering study commitment. Using realistic case study examples, strategic options are reviewed within an IRB framework.
- *Return on Investment for Retention:* Retention programs are not necessary for every study. Determining which studies will require implementing such programs early rather than watchful waiting requires evaluating study costs and potential overruns versus the value of time and potentially data.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Identify realistic recruitment forecasts and budgets to avoid future budget creep
- Determine the critical steps to recruitment strategy design
- Discuss which metrics to collect, to track recruitment effectiveness and where to direct ongoing investment
- Motivate sites to deliver on recruitment milestones

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

*Receive additional information about this topic by attending the Tuesday, June 28, 8:30-10:00 AM CTM Track session entitled "Strategies for Achieving Recruitment Goals in Pediatric Trials" and the Tuesday, June 28, 3:30-5:00 PM CR1 Track session entitled "Town Meeting on Patient Enrollment: What DO We Know? What Can We Do?"*

## #83 Structured Product Labeling (CR, IT, RA)

*.3 IACET CEUs*

***Steven Gitterman, MD, PhD***
Deputy Director, Director of Special Pathogens and Immunologic Drug Products, CDER, FDA

***Lisa Stockbridge, PhD, MS***
Regulatory Reviewer, Office of Information Management, CDER, FDA

***Kristofer Spahr***
Associate Director, Regulatory and Labeling Applications, Wyeth

This tutorial will be an overview of FDA implementation of the Structured Product Labeling (SPL). Topics will include the current status of SPL at FDA and implementation timelines, the content and development of an SPL document, the mechanism for submission of SPL to FDA, and FDA/sponsor interactions regarding SPL submissions.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Describe the basic structure of an SPL document
- Discuss the timelines for submission of SPL to FDA
- Recognize the coding and data elements used in SPL
- Explain the mechanism for submitting SPL To FDA

**Target Audience**
This tutorial is designed for industry personnel involved in the development and submission of labeling to FDA. Aspects of the tutorial will be relevant to clinical, regulatory, and information technology personnel.

## #84 *Please note that this was formerly Tutorial #56, offered on Sunday from 8:30 am - 12:00 pm (effective 4-7-05)*

## EU Regulatory Requirements: Pharmacovigilance in the Pre- and Postmarketing Phase and the EudraVigilance Database (CP, RA)

*.3 IACET CEUs*

***Sabine Brosch, MSc, PhD***
Deputy Head of Sector, EMEA, European Medicines Agency, EU

***Gaby L. Danan, MD, PhD***
Head, Pharmacovigilance and Epidemiology Department, sanofi-aventis, France

This tutorial will focus on the new regulatory framework that has been put in place in the EU to strengthen the conduct of pharmacovigilance throughout the lifecycle of medicinal products. Aspects that will be addressed are:
- Responsibilities of the sponsor in the collection, verification and presentation of adverse reaction reports arising from clinical trials conducted in the EU
- Responsibilities of the qualified person for pharmacovigilance and the notification of adverse reactions occurring either in the Community or in a third country for marketed products
- Mandatory electronic reporting (save in exceptional circumstances) of adverse reactions by November 2005 independent of the authorization procedure of the medicinal products in the EU
- The main functionalities of the EudraVigilance database, which is one of the pillars of the EU Risk Management Strategy and methodologies for the effective detection of potential safety signals
- Access by healthcare professionals, marketing authorization holders and the public to the EudraVigilance database, taking into account personal data protection
- Pharmacovigilance inspections to monitor the implementation of the obligations of marketing authorization holders by the European Medicines Agency (EMEA) and competent authorities.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Describe the new regulatory environment with regard to adverse reaction management during clinical trials and the postauthorization phase including the mandated electronic reporting in the EU coming into force in November 2005
- Recognize the main system components of EudraVigilance including access to adverse reaction data by pharmaceutical industry, sponsors of clinical trials, healthcare professionals and patients
- Discuss the pharmacovigilance inspections process

**Target Audience**
This tutorial is designed for drug safety and pharmacovigilance managers and personnel, regulatory affairs professionals, clinical trial sponsors and all personnel who need to understand the impact of the new Community legislation related to the day-to-day pharmacovigilance activities in the EU.

*Receive additional information about this topic by attending the Monday, June 27, 3:30-5:00 PM CP Track session entitled "Electronic Submissions of ICSRs."*

# Tutorial Pricing *(effective 5-4-05)*

Tutorials will take place on Saturday, June 25 and Sunday, June 26, 2005, prior to the Annual Meeting. ***Many tutorials have been updated with new content, and new topics have been added.*** Topics range from professional development to specialized areas within the pharmaceutical industry. Continuing medical, pharmacy, and nursing education credits and IACET continuing education units will be available for various tutorials. DIA will continue to add tutorials to the overall schedule at this year's Annual Meeting. Tracks that complement the tutorial topic area are indicated by the track acronym in parentheses. See page 5 for acronym definitions and tutorial overviews. Please continue to monitor **www.diahome.org** for tutorial updates and online registration. ***Space is limited so register early!***

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

## Saturday Afternoon Tutorials

*Tutorial Fee:* **$350**

**June 25, 2005 1:00 PM - 4:30 PM**

#30 Active-controlled Noninferiority/Equivalence Trials: Methods and Practice (ST)

#31 Advanced Auditing of Clinical Research Systems for Validation (CR, VA)

#32 **This tutorial has been CANCELLED:** Contract Management: A Review of Industry Best Practices (OS, CR, FI)

#33 Developing Author Templates for Submission Documents (DM)

#34 Clinical Trial Performance and Risk Analysis: Using the Earned Value Method (PM, FI)

#35 Identifying, Recruiting and Training Multiple Research Naïve Physicians for Participation in Simplified Clinical Trials (IS, CR)

#36 New Challenges to IRBs, Sponsors, and Investigators (IS, PP)

#37 European Regulatory Affairs: Current Regulatory Procedures and New Medicines Legislation Effective November 2005 (RA)

#38 Statistical Analysis Plan Made Easy (ST)

***Also available*** – Certified Clinical Investigator Review Course (CR, IS)
*Course Fee:* **Members $250/Nonmembers $300**

## Sunday Full-day Tutorials

*Tutorial Fee:* **$500**

**June 26, 2005 9:00 AM - 5:00 PM**

#40 Clinical Statistics for Nonstatisticians (CR)

#41 Computer Validation from A to Z: Practical Reality for User Acceptance of GXP Systems (IT, VA)

#42 Data Mining, Data Flow Modeling, Data Warehousing, and Knowledge Management (CDM)

#43 Design and Statistical Analysis of Bioequivalence Studies (ST)

#44 Pharmacokinetics and Pharmacodynamics: A Gentle Introduction (CR)

#45 Principles of Safety Surveillance (CP)

#46 Techniques for Applying Risk Management Principles to Computer System Validation (IMP, VA)

#47 Update on the European Clinical Trial Legislation (CR, RA)

## Sunday Morning Tutorials

*Tutorial Fee:* **$350**

**June 26, 2005 8:30 AM - 12:00 PM**

#50 Overview of the 21 CFR 11 Regulations and Guidance: What Has Changed and What Is Now Required? (IT)

#51 Case Studies on Signal Detection and Investigation (CP)

#52 Best Practices When Using MedDRA® (CP, CDM)

#53 Critical Issues and Important Considerations for Outsource Contracting (OS, PP)

#54 Compliance-driven Risk Detection: A New Approach within Drug Safety (CP)

#55 Dealing Effectively with Cultural Differences for Clinical Trial Professionals (CR, TR)

#56 *(now #84)* **This tutorial is now being offered as Tutorial #84 on Sunday, 1:00 pm - 4:30 pm**

#57 Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People and Process (CR)

#58 Leadership: How to Organize and Lead People in Group Work (TR)

#59 Preparation of Integrated Clinical and Statistical Reports for Individual Studies (MW, CR)

#60 Basic Audit Preparation: What You Should Know About Being Audited (VA, GCP)

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

#62 **This tutorial has been CANCELLED:** Trust, Relationships, and the Negotiation Process

## Sunday Afternoon Tutorials

*Tutorial Fee:* **$350**

**June 26, 2005 1:00 PM - 4:30 PM**

#70 Auditing the Vendor: Keys to Making It Work Before and After the Audit (OS, CR)

#71 Introduction to Capacity Management, Tools and Techniques (PM)

#72 CTD Preparation: Module 2 Clinical Overview and Clinical Summary (MW, RA, ST)

#73 Effective, Legal Rx Drug Promotion for the Year 2005: A Regulatory Primer (MA, RA)

#74 Effective Presentation Skills for Clinical Trial Professionals (CR, TR)

#75 **This tutorial has been CANCELLED:** Writing Effective Emails for a Multinational Audience (TR)

#76 Ensuring the Integrity of Electronic Records and Signatures: An Internal Controls Approach (CR, IT, GCP)

#77 FDA Enforcement: What You Need to Know to Avoid or Respond to the FDA (RA, GCP)

#78 Fourteen Steps from Research to Development (RD, RA)

#79 Investigator Site and Monitor Training to Improve Data Quality and Optimize MedDRA® Coding (IS)

#80 **This tutorial has been CANCELLED:** Quantitative Clinical Imaging in Clinical Trials: Operational and Statistical Issues

#81 Evidence-based Medicine Throughout the Clinical Drug Development Process (CP)

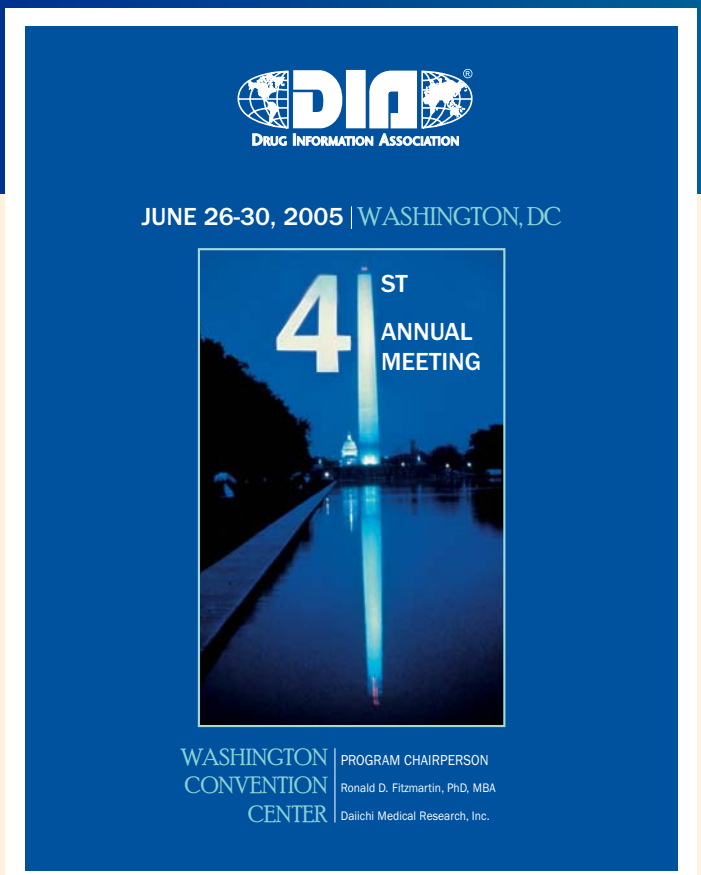
#82 The Building Blocks for Patient Recruitment and Retention (IS, CR, BT)

#83 Structured Product Labeling (CR, IT, RA)

#84 *(formerly #56)* **EU Regulatory Requirements: Pharmacovigilance in the Pre- and Postmarketing Phase and the EudraVigilance Database (CP, RA)**

***Also available*** – **TWO OFFERINGS!** *Please see page 7 for details.*
Certified Clinical Investigator Examination
Sunday, June 26, 9:00 am-12:00 pm and 2:00 pm-5:00 pm

*Please indicate the tutorials you plan to attend on the registration form, page 102.*




**To view the most current information about sessions and scheduling online, please click on the links below.**

**Monday, June 27**

**Tuesday, June 28**

**Wednesday, June 29**

**Thursday, June 30**

# Conference Schedule by Day and Time

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

## Level of Difficulty

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

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

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

| Session Number | Session Title | Difficulty Level | Interest Areas: Primary | Interest Areas: Associated | Room Number |
|---|---|---|---|---|---|
| | **MONDAY 8:30 AM - 10:00 AM** | | | | |
| | **PLENARY SESSION**<br>Welcome, Award Presentations, Keynote Address | | **ALL** | ALL | **Ballroom ABC 3rd Floor Conv. Center** |
| | **MONDAY 10:30 AM - 12:00 PM** | | | | |
| | Drug Advertising and Promotion: A Regulatory Primer | LEVEL ● | **AD** | MA, RA | **202B** |
| | Pharmaceutical Quality Assessment: The New CMC Review Paradigm | LEVEL ■ | **CMC** | RA | **150B** |
| | The Application of Good Pharmacovigilance Practices | LEVEL ■ | **CP** | CR, PP, RA | **207A** |
| | Real Life Safety and Efficacy of Levitra® (REALISE): Operational Aspects of a Postmarketing Surveillance Study | LEVEL ● | **CR1** | CP | **145A** |
| | Human Phase 0 (Microdosing) Studies: Regulatory and Scientific Aspects | LEVEL ■ | **CR2** | RA | **145B** |
| | Is the Analgesic Drug Development Pipeline Drying Up? | LEVEL ■ | **CR3** | — | **147A** |
| | A New Era of Transparency in Clinical Research: The Evolution, Impact, and Future of Clinical Trial Registers and Registries | LEVEL ● | **CR4** | RA | **144ABC** |
| | Clinical Trial Offices: Boon or Boondoggle? | LEVEL ● | **CTM** | AHC, IS | **140B** |
| | A Standards-based Approach for Authoring Through Distribution | LEVEL ● | **DM** | — | **206** |
| | Tools Sponsors Need to Implement Industry-wide Data Standards | LEVEL ● | **eCLIN** | CR, RA | **207B** |
| | The Red Team Review: Avoiding Study Delays and Expenses from the Outset | LEVEL ● | **FI** | CR | **140A** |
| | Managing Regulatory Inspections | LEVEL ● | **GCP** | RA | **202A** |
| | Compliance and Clinical Trials Finance | LEVEL ● | **IS** | CR, FI | **101** |
| | PDUFA and Information Technology | LEVEL ■ | **IT** | RA | **204BC** |
| | CTD: Practical Solutions for Mixed Applications, Herbals and Biologics | LEVEL ● | **MW** | RA | **102AB** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| | **MONDAY 10:30 AM - 12:00 PM *continued*** | | | | |
| | Biological Markers: Validations and Points to Consider | LEVEL ● | **NC** | — | **103B** |
| | Examining Use of Best Practices in CRO Outsourcing | LEVEL ■ | **OS** | CR, FI | **150A** |
| | Fostering Innovation, Efficiency, and Effectiveness on Project Teams | LEVEL ■ | **PM1** | — | **143AB** |
| | Drug Development Teams: Heavyweights versus Lightweights – What Is the Score? | LEVEL ● | **PM2** | — | **143C** |
| | Immunogenicity of Biotechnology-derived Medicinal Products and Biosimilars/ Follow-on Biologics: Regulatory Update and Recommendations | LEVEL ■ | **RA1** | BT | **151B** |
| | Registering Drugs for Pediatric Use | LEVEL ■ | **RA2** | CR | **152A** |
| | Regulations of Botanical Drugs in the US | LEVEL ● | **RA3** | NHP | **152B** |
| | FDA Initiative's Influence on Approval and Scale-up of Biotechnology Products | LEVEL ■ | **RA4** | BT, CMC | **146B** |
| | Generic Applications in the EU after Review 2001 | LEVEL ● | **RA5** | — | **154AB** |
| | When to Specify the Statistical Analysis | LEVEL ■ | **ST** | — | **201** |
| | Effectively Managing the Challenges of Global Training | LEVEL ■ | **TR** | GCP | **151A** |
| | General Validation Issues | LEVEL ■ | **VA** | — | **209AB** |
| | **MONDAY 1:30 PM - 3:00 PM** | | | | |
| | Update on FDA Enforcement of Promotional Activities | LEVEL ■ | **AD** | MA, RA | **202B** |
| | ICH Quality Guidances: Q8, Q9, and Q10 | LEVEL ■ | **CMC** | RA | **150B** |
| | Regulatory Inspections of Company Pharmacovigilance Departments | LEVEL ● | **CP** | RA | **207A** |
| | **PLENARY SESSION** Critical Path: Are We at the Fork in the Road? | LEVEL ■ | **CR/RA** | RD | **Ballroom ABC** |
| | Clinical Supply Management | LEVEL ■ | **CS** | CR | **143C** |
| | Emerging World Clinical Development: Learning from Each Other | LEVEL ■ | **CTM** | — | **140B** |
| | FDA Data Standards Initiatives | LEVEL ● | **DM** | RA | **206** |
| | Clinical Data Interchange Standards (CDISC), from Protocol Through Submission | LEVEL ■ | **eCLIN** | — | **207B** |
| | Outsourcing in Europe: Guidance to US Companies | LEVEL ■ | **FI** | OS | **140A** |
| | GCP Audits and Inspections: Determination of What Is, and What Is Not, Investigational Site Staff Misconduct | LEVEL ■ | **GCP** | AHC, IS | **202A** |
| | I Am OK, I Am Indemnified! What Does This REALLY Mean? | LEVEL ● | **IS** | AHC, CR | **101** |
| | EDC Vendor Selection: Do We Really Need a Pool? | LEVEL ● | **IT** | eCLIN | **204BC** |
| | ICH CTD Guidelines and Current Status of Implementation in DMFs, INDs, NDAs, BLAs and ANDAs | LEVEL ■ | **MW** | RA | **102AB** |
| | The In Vitro Clastogen Conundrum | LEVEL ■ | **NC** | RA | **103B** |
| | Evaluating Natural Health Products in Patients with Serious and Life-threatening Conditions | LEVEL ● | **NHP** | CR | **154AB** |
| | A Look at Today's Drug Development Outsourcing Practices: Successes, Failings, and Ways to Improve Them – Part 1 of 2 | LEVEL ■ | **OS1** | RD | **147B** |
| | Functional Outsourcing: How Are Different Project Management Models Being Applied? | LEVEL ■ | **OS2** | CR | **150A** |
| | Resource Management: Key Success Factors and Lessons Learned | LEVEL ● | **PM1** | — | **143AB** |
| | eXtreme Project Management: How to Succeed in the Face of Volatility | LEVEL ■ | **PM2** | — | **145A** |
| | Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials | LEVEL ● | **PP** | CR | **103A** |
| | Monitoring and Managing a Changing Investigative Site Landscape | LEVEL ● | **RD** | AHC, CR, IS | **149AB** |
| | Analyze as You Randomize? | LEVEL ■ | **ST** | — | **201** |
| | Pros and Cons of Web-based Training in a Global Research and Development Setting | LEVEL ● | **TR** | — | **151A** |
| | Current Regulatory Issues | LEVEL ● | **VA** | IT, RA | **209AB** |

## Conference Schedule by Day and Time

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Interest Areas Associated | Room Number |
|---|---|---|---|---|---|
| | **MONDAY 3:30 PM - 5:00 PM** | | | | |
| | The OIG/US Attorney/Attorney General Update: Where They've Been, Where They Are, and Where They're Going | LEVEL ■ | **AD** | MA, RA | **202B** |
| | ICH Quality Guidance: Q5E | LEVEL ■ | **CMC** | RA | **150B** |
| | Electronic Submission of ICSRs | LEVEL ■ | **CP** | eClin, RA | **207A** |
| | Global Pediatric Trials | LEVEL ● | **CR1** | RA | **145A** |
| | Monitoring of Clinical Endpoint Trials | LEVEL ● | **CR2** | ST | **145B** |
| | How to Get Reliable Results from Feasibility Studies: Factors and Metrics | LEVEL ■ | **CR3** | — | **147A** |
| | The Clinical, Technical, and Regulatory Validation of Novel Surrogate Endpoints | LEVEL ■ | **CR4** | RA | **147B** |
| | A Key to Success in Bringing a Product to Market Is Proper Protocol Design | LEVEL ■ | **CR5** | RA | **146A** |
| | Handling the Tough Logistical Issues in Clinical Supplies | LEVEL ■ | **CS** | RA | **143C** |
| | A Comprehensive Analysis of Factors Influencing the Length and Corresponding Cost | LEVEL ◆ | **CTM** | FI | **140B** |
| | Submission Standards (CDISC, etc.) | LEVEL ● | **DM** | RA | **206** |
| | The National Health Information Network (NHIN): Changing the Role of Biopharma in Clinical Research | LEVEL ● | **eCLIN** | CR | **207B** |
| | Impact of SOX Act on R&D Costs of the Pharmaceutical Industry | LEVEL ● | **FI** | RD | **140A** |
| | The Rising Cost of Quality: Is It Making a Difference? | LEVEL ■ | **GCP** | CR, RA | **202A** |
| | Designing and Executing Studies that Meet Patient Needs | LEVEL ■ | **IS** | CR | **101** |
| | The Ease of Paper, the Speed of Electronics: The Next Generation of Data Collection | LEVEL ■ | **IT** | eCLIN, IS | **204BC** |
| | Pharmaceutical Excipient Development: A Preclinical Challenge | LEVEL ■ | **NC** | CMC, RA | **103B** |
| | A Look at Today's Drug Development Outsourcing Practices: Successes, Failings, and Ways to Improve Them – Part 2 of 2 | LEVEL ■ | **OS** | RD | **150A** |
| | Enterprise Project Management and Capacity Management: An Interactive Session | LEVEL ■ | **PM1** | — | **144ABC** |
| | Go/No Go Decisions | LEVEL ◆ | **PM2** | RD | **143AB** |
| | Clinical Trials: Legal and Regulatory Jeopardy | LEVEL ■ | **PP** | CR, RA | **103A** |
| | The New Europe for Pharmaceuticals: From Research and Development to Marketing Authorization and Marketing | LEVEL ■ | **RA1** | RD | **151A** |
| | PMDA and Related Drug Safety Activities | LEVEL ● | **RA2** | CP, CR, RD | **152A** |
| | Making International Nonproprietary Names (INNs) User-friendly | LEVEL ■ | **RA3** | PP | **152B** |
| | Trial Design and the Study Data Tabulation Model | LEVEL ■ | **RA4** | CR | **154AB** |
| | Risk/Management Throughout Product Development: Clarifying Requirements and Managing Expectations | LEVEL ■ | **RA5** | CP | **151B** |
| | Electronic Management of Drug Information and Labeling | LEVEL ● | **RA6** | — | **146B** |
| | Medical Affairs for Biotechnology/Pharmaceutical Start-ups: Strategies for Launch (Research and Medical Communications) | LEVEL ■ | **RD** | BT, PM | **149AB** |
| | Multiregional Trial: Global and Japanese View in Biostatistics | LEVEL ■ | **ST** | CR | **201** |
| | Training and Clinical Research in the 21st Century: You Can Get Your Drug to Market Faster! | LEVEL ■ | **TR** | CR | **146C** |
| | Validation in the Real World: Global System and Revalidation Approaches | LEVEL ■ | **VA** | — | **209AB** |
| | **TUESDAY 8:30 AM - 10:00 AM** | | | | |
| | Support for CME: How Difficult? How Dangerous? | LEVEL ■ | **AD** | MA, PP, TR | **202B** |
| | Validation of Immunogenicity Testing Methods | LEVEL ● | **BT** | NC, VA | **154AB** |
| | Electronic Source in Clinical Trials | LEVEL ● | **CDM** | eCLIN, IS | **204BC** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Interest Areas Associated | Room Number |
|---|---|---|---|---|---|
| | **TUESDAY 8:30 AM - 10:00 AM *continued*** | | | | |
| | FDA Drug Substance and Drug Product Guidances | LEVEL ■ | **CMC** | RA | **147A** |
| | Risk Minimization Through Risk Communication: The Impact of New Regulatory Developments in Safety Labeling | LEVEL ■ | **CP** | CR, RA | **207A** |
| | Conjugated Vaccines | LEVEL ■ | **CR1** | BT, RA | **145B** |
| | Cardiovascular Safety and QT Assessment | LEVEL ■ | **CR2** | CP | **146A** |
| | Future Trends in Clinical Supplies | LEVEL ■ | **CS** | CTM | **149AB** |
| | Strategies for Achieving Recruitment Goals in Pediatric Trials | LEVEL ■ | **CTM** | CR | **140B** |
| | eCTD: Lifecycle Management | LEVEL ■ | **DM** | RA | **206** |
| | Electronic Patient-reported Outcomes (ePRO) 2005: A Town Meeting | LEVEL ● | **eCLIN** | CR, RA | **145A** |
| | Establish and Maintain a CAPA System | LEVEL ■ | **GCP** | — | **202A** |
| | Revolutionizing the Role of Quality Assurance | LEVEL ■ | **IS** | AHC | **101** |
| | Testing Security in a Regulated Environment: The What, When, and Where | LEVEL ◆ | **IT1** | — | **152A** |
| | Distributed Systems in Clinical Data Management | LEVEL ● | **IT2** | CDM, eCLIN | **146B** |
| | The Role of Medical Communications Departments in Risk Management Programs | LEVEL ● | **MC** | CP | **209AB** |
| | Document Reviews: Bridge to Quality or Roadblock to Completion? | LEVEL ● | **MW** | — | **102AB** |
| | Extrapolating Nonclinical Animal Data to the Clinic | LEVEL ■ | **NC** | RA | **103B** |
| | Regulatory Requirements versus Financial Benefit: Justifying Natural Health Products from a Private Sector Perspective | LEVEL ■ | **NHP** | RA, RD | **140A** |
| | Are Changes in Pharmaceutical Outsourcing Meeting the Needs of Investors, Sponsors, and Vendors? | LEVEL ■ | **OS** | FI | **150A** |
| | Maintaining the Talent Pipeline: Options for Identifying, Training, and Developing Pharmaceutical Project Managers | LEVEL ● | **PM1** | — | **143AB** |
| | Lead, Follow, or Get Out of the Way! | LEVEL ■ | **PM2** | — | **143C** |
| | Medicines and Healthcare: Rebuilding the Trust – Reshaping the Future – Part 1 of 2 | LEVEL ● | **PP** | RA, RD | **144ABC** |
| | New Horizons for the EMEA: Priorities for 2005-2006 | LEVEL ■ | **RA1** | — | **146C** |
| | Implementation of the August 30 WTO Decision: Access to Medicines | LEVEL ● | **RA2** | — | **151B** |
| | Global Development: Focus on Asia | LEVEL ■ | **RA3** | RD | **151A** |
| | CBER Update | LEVEL ● | **RA4** | — | **152B** |
| | Workload Management and Performance Monitoring | LEVEL ■ | **RD** | FI, OS | **150B** |
| | Statisticians and Standards: Emerging Tools and Processes for Faster, Cleaner Results from Clinic to Submission | LEVEL ● | **ST** | RA | **201** |
| | Investigative Site Readiness | LEVEL ● | **TR** | CR, IS | **207B** |
| | Validation Methodology II | LEVEL ● | **VA** | — | **147B** |
| | **TUESDAY 10:30 AM - 12:00 PM** | | | | |
| | DTC Update | LEVEL ■ | **AD** | MA, RA | **202B** |
| | Current Challenges in the Development of Cell-based Therapies | LEVEL ■ | **BT** | RA, RD | **154AB** |
| | An Introduction to SNOMED CT®: Comprehensive Terminology for eMedical Records | LEVEL ● | **CDM** | CP | **204BC** |
| | Open Forum: Ask CMC Questions on the Latest Hot Topics to Agency and Industry Experts | LEVEL ■ | **CMC** | RA | **147A** |
| | Risk Minimization Action Plans | LEVEL ■ | **CP** | RA | **207A** |
| | Safer, Better, More Appropriate: Clinical Trial Design for Pediatric Drug Labels | LEVEL ● | **CR1** | RA | **145B** |
| | What Patient Recruitment Methods Work Best for Women and Minorities? | LEVEL ● | **CR2** | IS | **145A** |
| | Alternative Country Selection | LEVEL ■ | **CR3** | — | **149AB** |
| | Understanding How to Design a Better Placebo-controlled Trial | LEVEL ● | **CR4** | — | **147B** |

## Conference Schedule by Day and Time

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Interest Areas Associated | Room Number |
|---|---|---|---|---|---|
| | **TUESDAY 10:30 AM - 12:00 PM *continued*** | | | | |
| | Innovative, Objective, Data-based Approach to Trial Planning and Implementation | LEVEL ● | CTM | — | 140B |
| | eCTD: Case Studies | LEVEL ● | DM | RA | 206 |
| | Town Hall Forum on Current GCP Issues | LEVEL ■ | GCP | RA | 202A |
| | Successful Selection of an ePRO Technology Provider | LEVEL ■ | IMP | eCLIN, OS | 152A |
| | Accelerating Subject Enrollment: A Handbook for Sites and Sponsors | LEVEL ■ | IS | CR, CTM | 101 |
| | Lightweight Integration for Clinical Trial Operations | LEVEL ■ | IT | CTM | 146B |
| | Integrating Field Medical Liaisons with Clinical Drug Development | LEVEL ■ | MC | CR | 209AB |
| | Post Red Apple Conference Update | LEVEL ■ | NC/VA | RA | 103B |
| | The New Legislative Environment for Herbal Products in Europe | LEVEL ■ | NHP | RA | 102AB |
| | Exploring Both Sides of the Perfect CRO/Pharmaceutical Partnership | LEVEL ■ | OS | PM | 150A |
| | Risk Management | LEVEL ■ | PM1 | RD | 143AB |
| | Alliance Management: From Partner Selection to Joint Program Teams | LEVEL ■ | PM2 | BT, RD | 143C |
| | Medicines and Healthcare: Rebuilding the Trust – Reshaping the Future – Part 2 of 2 | LEVEL ● | PP | RA, RD | 144ABC |
| | New Pharmaceutical Legislation – Part 1 of 3: Tools for Quick Access to Medicines | LEVEL ■ | RA1 | — | 146C |
| | Self-medication and OTCs | LEVEL ● | RA2 | CP, MC | 151B |
| | Public Clinical Trials Data: Preparing for the Registry | LEVEL ● | RA3 | CR | 151A |
| | Labeling and Drug Development: Product Information and Company Core Data Sheet | LEVEL ● | RA4 | — | 152B |
| | SPL Is Coming ... Will You Be Ready? | LEVEL ● | RA5 | IT | 146A |
| | Update from China | LEVEL ■ | RA6 | — | 140A |
| | Managing the Discovery-development Transition | LEVEL ■ | RD | PM | 150B |
| | Design and Analyses Issues in Prevention Trials | LEVEL ● | ST | CR | 201 |
| | The Career Trends and Challenges for Clinical Research Professionals | LEVEL ■ | TR | CR | 207B |
| | **TUESDAY 1:30 PM - 3:00 PM** | | | | |
| | Clinical Database Registries | LEVEL ■ | AD | CR, RA | 202B |
| | Hot Topics in Biotechnology | LEVEL ■ | BT | CMC, RD | 154AB |
| | A Discreet Professional Discipline: What Initiated the Evolution/Revolution of Clinical Data Management | LEVEL ● | CDM | — | 204BC |
| | Quality by Design | LEVEL ■ | CMC | RA | 147A |
| | Regulatory Changes in EU Pharmacovigilance | LEVEL ■ | CP | RA | 207A |
| | Innovative Recruitment and Retention Techniques in Europe | LEVEL ● | CR1 | — | 149AB |
| | Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done? | LEVEL ● | CR2 | PP | 145A |
| | Managing Late Phase in the Global Environment | LEVEL ■ | CR3 | RA, RD | 145B |
| | Drug Supply Doesn't Always Have to Be Rate Limiting in Clinical Development | LEVEL ■ | CR4 | CS | 147B |
| | FDA Labeling Update: Target Product Profile | LEVEL ● | CR5 | — | 146A |
| | Achieving Win/Win Results for Sponsors and Sites: Metrics and Budgeting Practices that Encourage Partnership and Performance | LEVEL ■ | CTM | FI, PM | 140B |
| | eCTDs: Regional Progress and Lessons Learned from the Regulatory Authority Perspective | LEVEL ● | DM | RA | 206 |
| | Clinical Development for Drug-device Combination Products | LEVEL ■ | GCP | CR, RA | 202A |
| | Effective Operation of Clinical Research Units | LEVEL ■ | IS | AHC | 101 |
| | Integrating Multivendor Clinical Trial Systems | LEVEL ● | IT1 | OS | 152A |
| | PhRMA IMPACC's Strategic View of the Future of Healthcare IT and Associated Implications for the Biopharmaceutical Industry | LEVEL ■ | IT2 | — | 146B |
| | Survey of Medical Liaison Practices Across the Pharmaceutical Industry | LEVEL ● | MC | MA | 209AB |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| | **TUESDAY 1:30 PM - 3:00 PM *continued*** | | | | |
| | Medical Writing and Biostatistics: A Significant Interaction | LEVEL ● | MW | ST | 102AB |
| | Update on the Use of Juvenile Animals for Safety Assessment of Pediatric Drugs | LEVEL ■ | NC | CR, RA | 103B |
| | High-tech Outsourcing: Computerizing the Selection Process | LEVEL ■ | OS | — | 150A |
| | PLENARY SESSION Transforming the Product Development Lifecycle: Where Are the Opportunities and What Happens if We Don't Start Changing the Way Drugs Are Developed? | LEVEL ● | PM | CR, PP, RA, RD | 143AB |
| | Publication and Availability of Clinical Trial Results: Ethical, Public Health, Confidentiality, Commercial and Other Critical Issues – A Panel Discussion | LEVEL ■ | PP | CR, RA | 144ABC |
| | New Pharmaceutical Legislation – Part 2 of 3: Decentralized Procedure and Mutual Recognition Procedure | LEVEL ■ | RA1 | — | 146C |
| | Regulatory Impact in Drug Development of Integrating Toxicogenomics into Nonclinical Development | LEVEL ● | RA2 | CR, NC | 151B |
| | Drug Importation: At What Cost? | LEVEL ● | RA3 | PP | 151A |
| | CDER Hot Topics | LEVEL ■ | RA4 | — | 152B |
| | Clinical Trials in China: Progress and Future Perspective | LEVEL ■ | RA5 | — | 140A |
| | Increase in Expected Net Present Value Through Design Modifications | LEVEL ◆ | RD | — | 150B |
| | Genomic Statistical Approaches for the Use and Validation of Genomic Biomarker Information | LEVEL ● | ST | CR | 201 |
| | Status of Study Nurse Qualification in Europe and the US | LEVEL ● | TR | IS | 207B |
| | **TUESDAY 3:30 PM - 5:00 PM** | | | | |
| | Getting the Claims You Want | LEVEL ■ | AD | MA, RA | 202B |
| | The State of Biopharmaceuticals: Where the Jobs Are | LEVEL ● | BT | TR | 154AB |
| | Multiple Inputs/Multiple Destinations: How Project Management Can Help | LEVEL ■ | CDM | PM | 204BC |
| | Challenges and Opportunities in Setting Specifications | LEVEL ■ | CMC | RA | 147A |
| | FDA Office of Drug Safety: Update on Regulatory Initiatives | LEVEL ● | CP | PP, RA | 207A |
| | Town Meeting on Patient Enrollment: What Do We Know? What Can We Do? | LEVEL ■ | CR1 | IS | 146A |
| | Applying Medical Imaging in Cardiovascular Drug Development | LEVEL ◆ | CR2 | — | 145A |
| | Integrated Placebo Database: An Idea Whose Time Has Come | LEVEL ● | CR3 | RA | 145B |
| | Emerging Regulatory Trends in Human Research Protection: Accrediting Institutions and the Use of Data Monitoring Committees | LEVEL ■ | CR4 | PP, RA | 147B |
| | Multicenter Trials Done in Phase I Clinical Research Units | LEVEL ● | CR5 | — | 149AB |
| | Evaluation, Implementation, and Integration of a Clinical Trials Management System | LEVEL ● | CTM | — | 140B |
| | eINDs | LEVEL ● | DM | RA | 206 |
| | Training in QA Issues According to GCP | LEVEL ● | GCP | TR | 202A |
| | The Site Is the Client | LEVEL ■ | IS | CR, OS | 101 |
| | Building Reliable, Secure IT Infrastructures in the Pharma Industry | LEVEL ● | IT | — | 146B |
| | Developing Risk Communications: The ABCs of Health Literacy | LEVEL ● | MC | CR, RA | 209AB |
| | Adding Value: The Role of Technical Editors in Cross-functional Document Development Teams of Biopharmaceutical Organizations | LEVEL ● | MW | — | 102AB |
| | Can Single Dose Toxicity Study Support First Dose in Humans? | LEVEL ■ | NC | CR, RA | 103B |
| | Controlling the Quality of Natural Health Products | LEVEL ■ | NHP | CMC | 140A |
| | Does Consolidation Among Outsourcing Firms Matter? | LEVEL ● | OS | — | 150A |
| | Sources of Failure in Drug Development Projects | LEVEL ■ | PM1 | RD | 143AB |
| | Working Remotely: Project Management Challenges with Virtual Teams | LEVEL ● | PM2 | — | 143C |
| | Pharmaceutical Product Liability in Drug Development and Regulation | LEVEL ■ | PP | RA | 103A |

## Conference Schedule by Day and Time

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| | **TUESDAY 3:30 PM - 5:00 PM *continued*** | | | | |
| | New Pharmaceutical Legislation – Part 3 of 3: Other Practical Aspects | LEVEL ■ | **RA1** | — | **146C** |
| | Comparison of Alternatives for Transferring Personal Data Outside the EU | LEVEL ■ | **RA2** | — | **151B** |
| | Effective Switching from Prescription to Over-the-counter Status: Role in Product Life Cycle Development | LEVEL ■ | **RA3** | MA | **152A** |
| | Progress and Challenges with Combination Product Development | LEVEL ● | **RA4** | CR | **152B** |
| | The Target Product Profile Practical Implementation: FDA and Sponsor Perspective | LEVEL ● | **RA5** | CR | **151A** |
| | How Can Statistics Contribute to Pharmacovigilance? | LEVEL ■ | **ST** | CP | **201** |
| | Clinical Research Is a Contact Sport | LEVEL ● | **TR** | CR | **207B** |
| | **WEDNESDAY 8:30 AM - 10:00 AM** | | | | |
| | Human Subject Protection: Organization and Training of IRBs and Clinical Sites | LEVEL ■ | **AHC** | CR, IS | **103B** |
| | Integrating Pharmacogenetics in Clinical R&D: From Data Acquisition to Data Management and Exchange | LEVEL ■ | **BT** | CR | **154AB** |
| | Data Management and the Globalization of the Japanese Clinical Trial Industry | LEVEL ■ | **CDM** | — | **202B** |
| | Updates on FDA GMP Initiatives and Guidances | LEVEL ■ | **CMC** | RA | **147A** |
| | The CIOMS VI Project on Managing Clinical Trial Safety | LEVEL ■ | **CP** | RA | **207A** |
| | The Secret Code for Efficient Clinical Research | LEVEL ■ | **CR1** | — | **140B** |
| | Clinical and Regulatory Update on Imaging in Oncology Trials | LEVEL ■ | **CR2** | RA | **145A** |
| | Experiences with the New Ethics Committee Systems in Europe | LEVEL ■ | **CR3** | RA | **145B** |
| | How to Establish and Successfully Run Data Monitoring Committees | LEVEL ● | **CR4** | — | **146A** |
| | Differing Viewpoints? An In-depth Look at Patients' Experiences in Clinical Trials versus Media Coverage of the Clinical Trials Industry and Its Impact on Public Perception and Patient Participation Rates | LEVEL ■ | **CTM** | CR, PP | **101** |
| | Managing the Living Global Dossier | LEVEL ■ | **DM** | RA | **206** |
| | Virtual Realities: Quality Considerations when Using Contract Organizations | LEVEL ■ | **GCP** | OS | **202A** |
| | Web Services: The Glue for a Fractured Infrastructure | LEVEL ● | **IT** | — | **146B** |
| | Value Optimization of Medical Products Reflecting Development and Marketing Strategies | LEVEL ● | **MA** | RD | **204BC** |
| | Field-based Medical Involvement Beyond Scientific Thought Leaders: Reaching Out to Help Healthcare Decision Makers | LEVEL ■ | **MC** | MA | **209AB** |
| | Discovering and Reporting Safety Issues in Clinical Trial Data | LEVEL ● | **MW** | CR | **102AB** |
| | Avoiding Regulatory Blunders in Promoting Natural Health Products | LEVEL ● | **NHP** | AD, RA | **140A** |
| | The CRO Response to Emerging Drug Development Trends Using New Technology and Best Business Practices | LEVEL ■ | **OS** | RD | **150A** |
| | Does Breaking Up Have to Be Hard to Do? Dissolving Partnerships, Changing CROs | LEVEL ● | **PM1** | OS | **143C** |
| | Critical Chain Project Management in Pharmaceuticals Development | LEVEL ● | **PM2** | — | **143AB** |
| | The European Situation on Pediatrics within a Global Environment | LEVEL ■ | **RA1** | CR | **152A** |
| | Lessons Learned from Hormone Therapy: WHI Experience | LEVEL ■ | **RA2** | CR | **151B** |
| | Case Studies in Risk Management | LEVEL ● | **RA3** | CP, CR | **146C** |
| | Is Data Privacy Possible? A 360° View | LEVEL ■ | **RA4** | CR | **151A** |
| | The Effect of Japanese Pharmaceutical Affairs Law's Revision and PMDA's Activities on Pharmaceutical Industries | LEVEL ■ | **RA5** | RD | **152B** |
| | Don't Sweat SOX: Implementing Reporting for Sarbanes-Oxley (SOX) | LEVEL ● | **RA6** | FI | **147B** |
| | Implementing Clinical Modeling and Simulation: A Practical Guide | LEVEL ● | **RD** | CR | **150B** |
| | Randomization | LEVEL ■ | **ST** | CR | **201** |
| | Facilitation Magic: Conjuring Up Extraordinary Results in Teams and Groups | LEVEL ■ | **TR** | PM | **207B** |
| | Current International Regulatory Issues | LEVEL ■ | **VA** | RA | **103A** |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| | **WEDNESDAY 10:30 AM - 12:00 PM** | | | | |
| | Clinical Trials from the Pharmaceutical Company (Sponsor) Viewpoint | LEVEL ● | AHC | CR, IS | 103B |
| | ECGs on First, EDCs on Second, and CROs on Third: Creating Teamwork Between Clinical Service Providers | LEVEL ● | BT | CR, OS | 154AB |
| | Advancing Data Quality in the 21st Century | LEVEL ■ | CDM | RA | 202B |
| | Combination Products: Challenges and Opportunities | LEVEL ■ | CMC | RA | 147A |
| | Data Mining and Signal Detection: Where Are We? | LEVEL ■ | CP | RA | 207A |
| | Integrating Pharmacogenomics into Clinical Trials | LEVEL ■ | CR1 | — | 146A |
| | GCP Compliance Considerations for Drugs, Devices and Biologics, and Combination Products | LEVEL ● | CR2 | GCP | 145A |
| | How to Navigate the NIH for Grants and Contracts | LEVEL ● | CR3 | AHC | 145B |
| | Clinical Trials: More Sensible Arrangements for Dealing with Serious Adverse Events | LEVEL ● | CTM | CR | 101 |
| | eCTD: The Impact on the Organization | LEVEL ● | DM | RA | 206 |
| | Training Late-phase Investigators: GCP Still Matters! | LEVEL ■ | GCP | TR | 202A |
| | Use of Drug Utilization Data for Risk Assessment and Risk Management | LEVEL ● | IMP | CP, RA | 149AB |
| | Industry Standards and Web Services: Are We Ready for an Industry Architecture? | LEVEL ■ | IT | — | 146B |
| | Salud! Reaching Foreign-born Patients in the US Market | LEVEL ● | MA | — | 204BC |
| | Thinking Outside the Medicine Box: Creative Ways of Getting Health Information to Consumers | LEVEL ● | MC | MA | 209AB |
| | Clinical Trial Registry: Build It and They Will Come? | LEVEL ● | MW | CR | 102AB |
| | Strategies for Improving Botanical Medicine Acceptance in a Conventional Medical Setting | LEVEL ● | NHP | CR | 140A |
| | Functional Partnerships: A New, Robust Model for Pharmaceutical Industry-CRO Contracting | LEVEL ■ | OS | — | 150A |
| | Strategic Planning for Drug Development Projects | LEVEL ■ | PM1 | — | 143AB |
| | Are Portfolio Management Processes Really Working in Dealing with Current Issues within the Pharmaceutical Industry? | LEVEL ■ | PM2 | — | 143C |
| | Impact of Significant Payments of Other Sorts (SPOOS) on Clinical Research | LEVEL ■ | PP | CR, FI | 103A |
| | Voluntary Pharmacogenetics Data Submissions 1 Year Later | LEVEL ● | RA1 | — | 147B |
| | Reporting and Assessing Inclusion of Subpopulations in Clinical Trials | LEVEL ● | RA2 | CR | 151B |
| | The Radioactive Drug Research Committee: Academic Research or Drug Development Tool? | LEVEL ● | RA3 | CR | 151A |
| | Pediatric Medicine: New Challenge in Japan | LEVEL ● | RA4 | CR | 152A |
| | Current Issues with 505(B)(2) Applications | LEVEL ■ | RA5 | — | 152B |
| | Regulation of Clinical Research in the EU: Impact of the Clinical Trials Directive | LEVEL ◆ | RA6 | CR | 146C |
| | Innovation or Stagnation: When the Obvious Choice Is Also the More Difficult Choice | LEVEL ■ | RD | — | 150B |
| | Analysis of Responder Data | LEVEL ■ | ST | — | 201 |
| | Training and Development of New and Experienced CRAs | LEVEL ● | TR | CR | 207B |
| | **WEDNESDAY 1:30 PM - 3:00 PM** | | | | |
| | Financial Checks and Balances: Making Sure You're Getting What You Negotiate | LEVEL ■ | AHC | IS | 103B |
| | Current Process for Follow-on Proteins in Europe: The Biosimilars Products | LEVEL ■ | BT | RA | 154AB |
| | Experiences with MedDRA® Translations | LEVEL ■ | CDM | — | 202B |
| | IND CMC Issues | LEVEL ■ | CMC | RA | 147A |
| | COX-2 Inhibitors: Where Are We in 2005? | LEVEL ■ | CP | CR | 207A |
| | Global Expanded Access Program: The Ins and Outs | LEVEL ● | CR1 | RD | 140B |

## Conference Schedule by Day and Time

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| | **WEDNESDAY 1:30 PM - 3:00 PM *continued*** | | | | |
| | Generic Biologics: Fact or Fiction? | LEVEL ■ | CR2 | BT, RA | 145A |
| | Development of New Antibiotics | LEVEL ■ | CR3 | RA | 146A |
| | Imaging of Alzheimer's and Other Neurodegenerative Diseases: Role in Clinical Trials | LEVEL ● | CR4 | RA | 145B |
| | Why Would You Want to Do a Registry? | LEVEL ● | CTM | CR | 101 |
| | Guidance-compliant eCTDs – Part 1 of 2 | LEVEL ● | DM | RA | 206 |
| | Planning for Electronic Data Quality in Clinical Trials | LEVEL ■ | GCP | eCLIN, CR | 202A |
| | Update on FDA's Draft Guidance on Patient-reported Outcomes | LEVEL ■ | IMP | CR, RA | 149AB |
| | Advancing Patient Recruitment with Technology and Metrics | LEVEL ■ | IT | CTM | 146B |
| | Moving to Higher Levels of Launch Excellence | LEVEL ■ | MA | — | 204BC |
| | Outsourcing Medical Communications Services | LEVEL ■ | MC | OS | 209AB |
| | Nonclinical Regulatory Writing | LEVEL ■ | MW | NC, RA | 102AB |
| | Botanical Drug Development: It Starts at the Beginning – Control of the Plant | LEVEL ■ | NHP | — | 140A |
| | The State of Clinical Outsourcing: Industry Practices and Perceptions | LEVEL ■ | OS | CR | 150A |
| | Who Reads the Development Plan Anyway! | LEVEL ● | PM1 | — | 143AB |
| | Project Management's Role in the Pharmaceutical Industry of the Future | LEVEL ■ | PM2 | — | 143C |
| | Formulary Decisions in the US and UK | LEVEL ● | PP | IMP | 103A |
| | US-EU Agreement to Exchange Scientific Advice: A Status Report | LEVEL ■ | RA1 | — | 146C |
| | Outlook for Changes in Japanese Regulatory and Clinical Development Environment – Part 1 of 2 | LEVEL ■ | RA2 | CR | 152A |
| | Development of Oncology Products in the US and EU: More Stagnation than Innovation? | LEVEL ■ | RA3 | CR | 151A |
| | Scientific Advice in Europe: State of the Art | LEVEL ■ | RA4 | — | 151B |
| | Managing Communications with Regulatory Agencies in Global Decentralized Matrix Organizations | LEVEL ■ | RA5 | — | 147B |
| | CDER Hot Topics | LEVEL ■ | RA6 | — | 152B |
| | Intercompany Auditing Agreement as Part of Strategic Risk Management | LEVEL ◆ | RD | — | 150B |
| | Statistical Considerations in the Evaluation of Red Blood Cell Products | LEVEL ● | ST | CR, RA | 201 |
| | **WEDNESDAY 3:30 PM - 5:00 PM** | | | | |
| | The Right to Publish: A Sword of Many Blades | LEVEL ● | AHC | CR, MW | 103B |
| | Use of Toxicogenomics for Drug Candidate Selection, Rescuing and Biomarker Discovery | LEVEL ● | BT | RD | 154AB |
| | Data Management Models for Multicenter and Multinational Clinical Trials: Case Histories | LEVEL ■ | CDM | — | 202B |
| | Follow-on Biotechnology/Biological Products – Part 1 of 2 | LEVEL ■ | CMC | RA | 147A |
| | Unblinding: Need to Know Basis? | LEVEL ■ | CP | CR | 207A |
| | Conducting Clinical Trials in Erectile Dysfunction (ED) | LEVEL ● | CR1 | — | 145B |
| | Application of Critical Path Principles to the Development of Drugs for Menopausal Symptom Therapy After the Women's Health Initiative | LEVEL ■ | CR2 | RA | 145A |
| | Incorporating Formal Economic Analysis in Evaluating Trial, Development, and Portfolio Strategies | LEVEL ● | CR3 | RD | 140B |
| | New Expectations for Drug Development: Lessons Learned from the COX-2 Inhibitors | LEVEL ■ | CR4 | — | 146A |
| | Skating to Where the Puck Is Going: Understanding Tomorrow's Challenges in Oncology Drug Development and Creating Infrastructure to Pave the Way | LEVEL ■ | CR5 | — | 143C |
| | Sometimes It Takes Two or More to Tango: Managing Trials in a Global Collaboration | LEVEL ■ | CTM | BT, RD | 101 |
| | Guidance-compliant eCTDs – Part 2 of 2 | LEVEL ● | DM | RA | 206 |

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Associated | Room Number |
|---|---|---|---|---|---|
| | **WEDNESDAY 3:30 PM - 5:00 PM *continued*** | | | | |
| | Preparing for and Surviving an FDA Inspection: US and International Perspectives from Industry and Regulators | LEVEL ● | GCP | RA | 202A |
| | IT Services: Delivering High Value in the New Pharmaceutical Environment | LEVEL ● | IT | — | 146B |
| | Discovering and Meeting Customer Expectations of Medical Communications | LEVEL ● | MC | — | 209AB |
| | Exploring Natural Health Products: Promotion and International Coordination | LEVEL ■ | NHP | — | 140A |
| | Calculation Comparison of Pharma Internal Costs and Outsourced CRO Costs | LEVEL ● | OS | CR | 150A |
| | Ten Things You Never Thought I Would Say (About Leading Teams) | LEVEL ■ | PM1 | — | 149AB |
| | A Community Response to the Critical Path | LEVEL ● | PP | RA, RD | 103A |
| | Use of Color Coding/Branding on Pharmaceutical Product Labels, Labeling, and Packaging | LEVEL ● | RA1 | — | 146C |
| | Outlook for Changes in Japanese Regulatory and Clinical Development Environment – Part 2 of 2 | LEVEL ■ | RA2 | CR | 152A |
| | Clinical Trials Directive: EU Remains Attractive for Clinical Research | LEVEL ■ | RA3 | CR | 151A |
| | Various Roles and Implementation Techniques of Quality Systems in a Regulatory Agency | LEVEL ● | RA4 | — | 151B |
| | Research in Developing Drug Interactions and Dose Adjustments Model and Terminology Assessment for Drug Labeling | LEVEL ● | RA5 | — | 147B |
| | Developing Medications in Ethnically Diverse Populations | LEVEL ■ | RD | CR | 150B |
| | Clinical Data to Information to Knowledge | LEVEL ● | ST | — | 201 |
| | Training Approaches for MedDRA® | LEVEL ■ | TR | CR | 207B |
| | **THURSDAY 8:30 AM - 10:00 AM** | | | | |
| | Remote Management of Rural Diabetic Patients Using a Web-based Monitoring Device | LEVEL ● | AHC | CR | 103B |
| | Viral Safety: Impact of Advances in Technology | LEVEL ◆ | BT | — | 154AB |
| | Clinical Data Management: An Integral Part of the Drug Development Process | LEVEL ● | CDM | RA | 103A |
| | Follow-on Biotechnology/Biological Products – Part 2 of 2 | LEVEL ■ | CMC | BT, RA | 209AB |
| | The Use of Multilanguage MedDRA® in a Global Environment | LEVEL ■ | CP | — | 145B |
| | What Sponsors and CROs Need to Know About Accreditation | LEVEL ■ | CR1 | — | 140B |
| | Integrated Clinical Development | LEVEL ■ | CR2 | RA | 145A |
| | Burnout, Workload, and Job Satisfaction in Clinical Trial Coordinators | LEVEL ■ | CTM | — | 101 |
| | Compliance Portals: The Gateway to eSubmissions | LEVEL ● | DM | RA | 152A |
| | FIREBIRD: Implementing an Electronic Global Investigator Registry | LEVEL ● | IT | CR | 146B |
| | The CDISC Operational Data Model (ODM): It's Not Just Data Exchange! | LEVEL ■ | IT/CDM | eCLIN | 149AB |
| | Assessing Value-based Performance in the Eyes of Our Customers (Thought Leaders) | LEVEL ■ | MC | MA | 201 |
| | The Future of Medical Writing | LEVEL ■ | MW | — | 102AB |
| | Nonclinical Testing Strategies to Support Clinical Trials | LEVEL ■ | NC | CR, RA | 147B |
| | Chinese Herbal Medicines Development | LEVEL ● | NHP | — | 140A |
| | Capturing Drivers of Outsourcing Growth and Quantifying Outsourcing Value | LEVEL ● | OS | RD | 150A |
| | Cross-cultural Challenges in Multinational Pharmaceutical Companies: Differences in Communication and Decision-making Practices Between Japan and the West | LEVEL ■ | PM1 | — | 143C |
| | Approaches to Reducing Risk and Improving Success in R&D Project Management | LEVEL ● | PM2 | — | 143AB |
| | Recent and Pending Case Law in the EU | LEVEL ● | PP | RA | 150B |
| | CDER Town Meeting – Part 1 of 2 | LEVEL ● | RA1 | — | 146A |
| | How to Avoid Trademark-related Delays of NDA Approvals: The FASLODEX Experience | LEVEL ■ | RA2 | PP | 151B |
| | DSMBs from an IRB Perspective | LEVEL ● | RA3 | CR | 151A |

## Conference Schedule by Day and Time

| Session Number | Session Title | Difficulty Level | Interest Areas Primary | Interest Areas Associated | Room Number |
|---|---|---|---|---|---|
| | **THURSDAY 8:30 AM - 10:00 AM *continued*** | | | | |
| | European Clinical Trials Directive Implementation: An Actual Status | LEVEL ■ | **RA4** | CR | **144ABC** |
| | Prescription Drug Labeling: Implementation of FDA's New Regulation for the Content and Format of the USPI and an Update on the Status of the USPI Guidance Documents | LEVEL ■ | **RA5** | — | **152B** |
| | Statistical Considerations in Human Drug Abuse Potential Studies | LEVEL ● | **ST** | — | **146C** |
| | Did the Training Do What It Was Supposed to Do? Evaluating the Employee and the Training Program | LEVEL ■ | **TR** | — | **147A** |
| | **THURSDAY 10:30 AM - 12:00 PM** | | | | |
| | Regulatory Obligations of an IND Sponsor-investigator | LEVEL ■ | **AHC** | IS, RA | **103B** |
| | Overcoming Hurdles to Develop Clinically Validated Standardized, Quantitative, Quality Controlled, Next Generation, Multigene Expression Biomarker Assays Suitable for Clinical Trials | LEVEL ■ | **BT** | CR | **154AB** |
| | Evidence-based Medicine: Evaluating the Data from Outcome-based Clinical Trials | LEVEL ■ | **CDM** | IMP | **103A** |
| | Analyses Using MedDRA®-coded Data | LEVEL ■ | **CP** | — | **145B** |
| | Clinical Studies in Psychiatry: New Variations on the Placebo Response | LEVEL ◆ | **CR1** | — | **140B** |
| | Patient Safety: Ethics, Pharmaceuticals for Children, and Human Research Protections | LEVEL ■ | **CR2** | — | **145A** |
| | Patient Insights from the Frontlines of Medical Communication | LEVEL ■ | **CTM** | MC | **101** |
| | Structured Product Labeling (SPL): Requirements, Challenges, and Best Practices | LEVEL ● | **DM** | RA | **152A** |
| | Risk Management Focus in Clinical QA | LEVEL ● | **GCP** | — | **149AB** |
| | The Use and Impact of Patient-level Electronic Data in Healthcare Decision Making | LEVEL ● | **IMP/CP** | eCLIN | **152B** |
| | Assessing Global Adoption of Electronic Data Collection Technologies | LEVEL ■ | **IT/CDM** | — | **146B** |
| | Re-engineering Document Preparation: Setting the Stage for Study Tagging Files | LEVEL ■ | **MW** | DM | **102AB** |
| | Immunotoxicity Testing of Human Pharmaceuticals | LEVEL ■ | **NC** | RA | **147B** |
| | Regulatory Issues in the Development of Heterogeneous Products: Town Hall Meeting with the FDA CDER Botanical Review Team and Center for Biologics | LEVEL ● | **NHP** | RA | **151B** |
| | The Real World of Outsourcing: Outsourcing Fact and Fiction | LEVEL ● | **OS** | IT | **150A** |
| | Drug Development Projects: A Vehicle for Organizational Learning | LEVEL ■ | **PM1** | — | **143C** |
| | Increased Productivity Through Effective Resource Management | LEVEL ■ | **PM2** | — | **143AB** |
| | FDAMA Part 113: ClinicalTrials.gov – Where Are We Now? | LEVEL ■ | **PP** | RA | **150B** |
| | CDER Town Meeting – Part 2 of 2 | LEVEL ● | **RA1** | — | **146A** |
| | 21 CFR Part 11 and Electronic Source Documentation Requirements for Investigators | LEVEL ■ | **RA3** | eCLIN, IS | **151A** |
| | Clinical Trials in Latin America: A Review of the Regulatory Framework | LEVEL ■ | **RA4** | — | **144ABC** |
| | Global Development Program and Data Quality | LEVEL ◆ | **ST** | — | **146C** |
| | Communication Tools/Practices that Work | LEVEL ● | **TR** | — | **147A** |

# ATTENDEE REGISTRATION FORM

**Attendees may register online at www.diahome.org**

**Online registration is *NOT* available to speakers or exhibitors. The appropriate registration forms will be included with the exhibitor or speaker packet.**

## 41ST ANNUAL MEETING ID #05001 June 26-30, 2005, Washington, DC, 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 20, 2005, will be included in the Advance Registration Attendee List.**

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All cancellations must be in writing and received at the DIA office by 5:00 PM on June 10, 2005. Registrants who do not cancel by June 10, 2005 and do not attend will be responsible for the full applicable fee. **Registrants are responsible for canceling their own airline and hotel reservations.** You may transfer your registration to a colleague at any time, but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. **Substitute registrants will be responsible for nonmember fee, if applicable.**

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**TUTORIALS** See pages 5-15 for tutorial descriptions and page 101 for tutorial pricing. Space is limited and preregistration is encouraged. Please indicate the ID number and fee for each tutorial you plan to attend.

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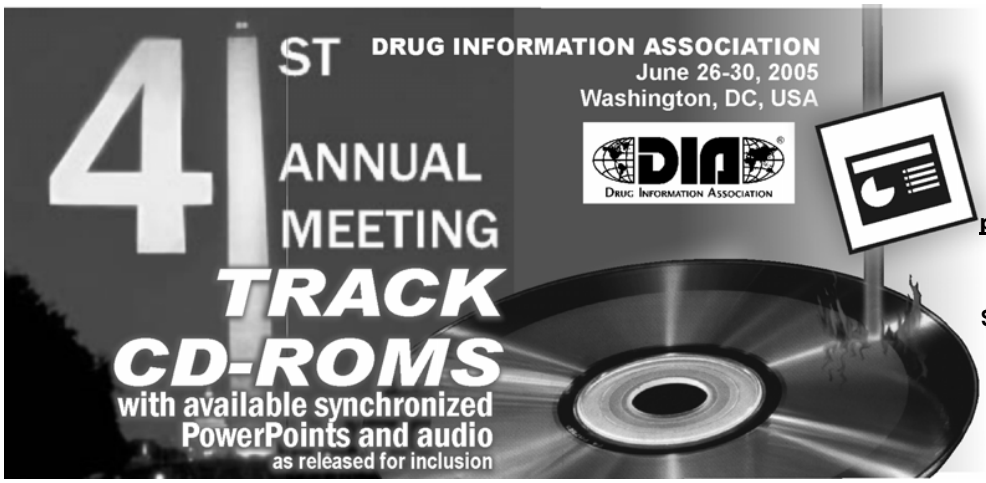


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- ❑130...**eClinical/Good Clinical Practices Track** - 17 sessions
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- ❑150...**Impact of Medical Products and Therapies/Public Policy/Law Tracks** – 15 sessions
- ❑160...**Information Technology Track** – 16 sessions
- ❑170...**Medical Communications and Medical/Scientific Writing Tracks** – 19 sessions
- ❑180...**Natural Health Products Track** – 10 sessions
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- ❑240...**Regulatory Track 3** – 12 sessions
- ❑250...**Regulatory Track 4** – 12 sessions
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9. Names of all occupants of room
10. Address to which confirmation is to be sent
11. Daytime telephone number
12. Fax number (if you would like a confirmation faxed)

**DEPOSIT** A one-night room deposit, **plus 14.5% tax** is required for **all** reservations. The deposit amount is payable by credit card (online only), check (if you are paying by check, all funds must be in US dollars, drawn on a US bank) or money order.
**No reservation will be processed without a deposit.**

**CREDIT CARD** Your credit card will be used as a guarantee and will not be charged immediately. Most major credit cards are accepted (VISA, MasterCard, American Express, Discover). You will not receive a confirmation from each hotel. Each hotel will honor the housing bureau acknowledgement.

**CHECKS** Your deposit check should be made out to DIA 2005/WCTC Housing and mailed to DIA 2005/WCTC Housing, 901 7th Street, NW, Washington, DC 20001 *Attn: Housing*. **No checks will be accepted after June 3, 2005.**

**CHANGES/CANCELLATIONS/REFUNDS** **Prior to June 3, 2005,** all changes and cancellations should be made directly with the DIA Housing Bureau. **After June 3, 2005,** changes and cancellations should be made directly with the hotel. Cancellation policy is as follows:
**Cancellations made after May 20, 2005, will be charged a processing fee of $150.00.**
**Cancellations made within 72 hours of arrival will be charged the first night's room and tax by the hotel.**

***Please complete the following information and submit to DIA/WCTC prior to June 3, 2005.***

Name _____

Company/Institution _____

Address _____

Tel _____ Fax _____ email _____

**HOTEL INFORMATION** Choice of hotel will be honored based on availability. If your choices are not available, we will select another hotel based on (check one): ☐ lowest rate ☐ distance to the meeting (prefer to be closer to the event)

**HOTEL SELECTION** Please list in order of preference.

1. _____ Arrival Date _____ Departure Date _____
2. _____ ☐ Smoking ☐ Nonsmoking
3. _____ ☐ Single ☐ Double ☐ Triple ☐ Quad

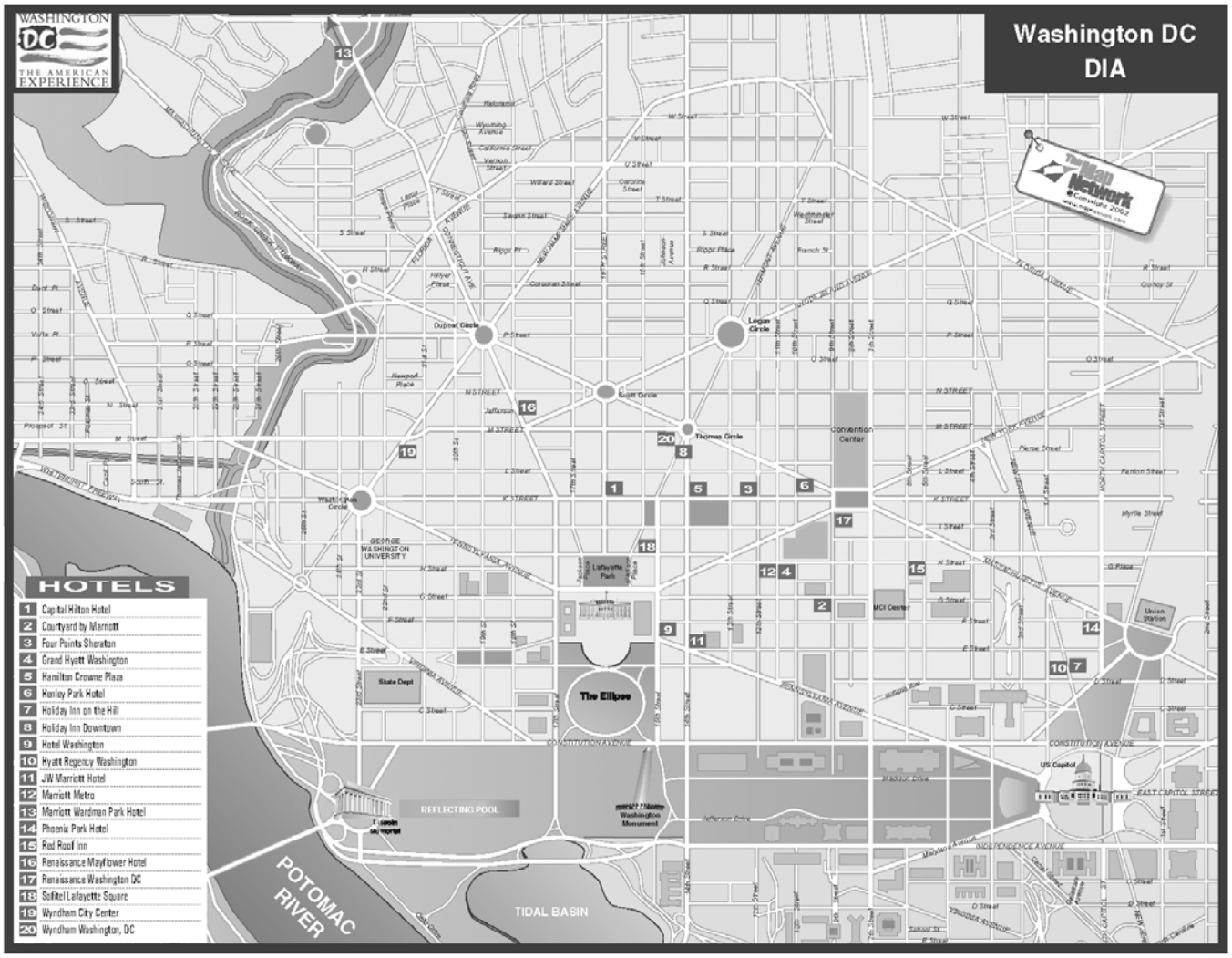
**SPECIAL NEEDS** *(attach a note if you need more room)* _____

Sharing with the following person(s) _____

**PAYMENT INFORMATION** ☐ Visa ☐ MasterCard ☐ Discover ☐ AMEX ☐ Other _____

Credit Card # _____ Expiration Date _____

Signature _____




| Hotel | Address | Single Rate | Double Rate | Distance to Conv. Center | Distance to Metro Stop | Shuttle Offered |
|---|---|---|---|---|---|---|
| 1 Capital Hilton Hotel | 16th & K Streets, NW | $208 | $228 | 8 blocks | 2 blocks | Yes |
| 2 Courtyard by Marriott Conv. Center | 900 F Street, NW | $195 | $195 | 4 blocks | 3 blocks | Yes |
| 3 Four Points Sheraton | 1201 K Street, NW | $189 | $189 | 3 blocks | 3 blocks | No |
| 4 Grand Hyatt Washington | 1000 H Street, NW | $232 | $232 | 3 blocks | At hotel | Yes |
| 5 Hamilton Crowne Plaza | 14th & K Streets, NW | $199 | $199 | 5 blocks | 1 block | Yes |
| 6 Henley Park Hotel | 926 Massachusetts Ave., NW | $195 | $195 | 1 block | At Cnv. Ctr. | No |
| 7 Holiday Inn on Capitol Hill | 415 New Jersey Ave., NW | $199 | $209 | 10 blocks | 2 blocks | Yes |
| 8 Holiday Inn Downtown | 1155 14th Street, NW | $199 | $209 | 5 blocks | 3 blocks | Yes |
| 9 Hotel Washington | 515 Pennsylvania Ave. | $190 | $190 | 8 blocks | 2½ blocks | Yes |
| 10 Hyatt Regency Washington | 400 New Jersey Ave., NW | $217 | $217 | 10 blocks | 2 blocks | Yes |
| 11 JW Marriott Hotel | 1331 Pennsylvania Ave., NW | $228 | $228 | 8 blocks | At hotel | Yes |
| 12 Marriott Metro | 775 12th Street, NW | $205 | $216 | 4 blocks | ½ block | Yes |
| 13 Marriott Wardman Park Hotel | 2660 Woodley Rd., NW | $205 | $205 | 30 blocks | ½ block | No |
| 14 Phoenix Park Hotel | 520 North Capitol Street, NW | $189 | $219 | 11 blocks | 1 block | Yes |
| 15 Red Roof Inn | 500 H Street, NW | $115 | $115 | 4 blocks | 2 blocks | Yes |
| 16 Renaissance Mayflower Hotel | 1127 Connecticut Ave., NW | $210 | $210 | 10 blocks | 2 blocks | Yes |
| 17 Renaissance Washington DC | 999 9th Street, NW | $213 | $224 | 1 block | At Cnv. Ctr. | No |
| 18 Sofitel Lafayette Square | 806 15th Street, NW | $209 | $209 | 8 blocks | 2 blocks | Yes |
| 19 Wyndham City Center | 1143 New Hampshire Ave., NW | $169 | $189 | 17 blocks | 3 blocks | Yes |
| 20 Wyndham Washington, DC | 1400 M Street, NW | $169 | $189 | 6 blocks | 3 blocks | Yes |

**HOTEL RESERVATIONS AND MEETING REGISTRATION**

**All hotel reservations are being handled by the DIA HOUSING BUREAU in Washington, DC.**

Early registration is advised in order to ensure space in one of the participating hotels. The published rates will continue until June 3, 2005. After June 3, 2005, room rates cannot be guaranteed. To ensure that your registration is completed properly, it is imperative that you submit each of the two forms to the proper location:

**Hotel Reservations**

See page 106 for reservation instructions. **All housing questions should be directed to the DIA Housing Bureau in Washington, DC.**

By mail: DIA 2005/WCTC Housing, 901 7th Street, NW, Washington, DC 20001, USA *Attn: Housing*

By fax: +1-506-433-3033

By email: kristen@washington.org

**Meeting Registration**

The **ONLY** form that should be returned to DIA in Horsham is the attendee registration form on page 102. Register online at **www.diahome.org** or return the form to Drug Information Association, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA, Fax +1-215-442-6199.

## Important Points

**TRACK CD-ROMS** Audio CDs for individual sessions will not be available this year. True multimedia recreations of the sessions are available on track CD-ROMS to fully registered attendees. See page 103 for pre-ordering instructions. Recording of DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA. Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of DIA.

**DRESS CODE** The dress code for the Annual Meeting is business casual. Slacks and casual dresses are encouraged for wear throughout the meeting. Neckties, business suits, or other business attire are acceptable, but not necessary. *Comfortable shoes are a must!*

**MEDDRA® USER GROUP MEETING** MedDRA® User Group will meet at the conclusion of the Annual Meeting on Thursday, June 30 from 12:30 PM to 4:30 PM. The specific location will be included in the final program.

**NETWORKING DINNER** The networking dinner, on Sunday, June 26 at 6:30 PM at the Renaissance Washington, DC Hotel, will provide attendees with just the right atmosphere for informal conversation with old friends and new acquaintances. The fee for the networking dinner is $70.00**.**

**PLEASE NOTE** Attendance at the networking dinner is limited; reservations must be confirmed; purchase on site cannot be guaranteed.

*Cancellation Policy for Networking Dinner only:* If received in writing on or before June 10, 2005, a full refund will be given. Please collect your badge and dinner tickets on June 26 at the DIA registration desk.

**POSTER SESSIONS** An area has been set aside to provide certain attendees with an opportunity to exhibit scientific developments associated with the pharmaceutical development and registration process. The chairpersons for the poster sessions are Françoise G. Pradel, PhD, and Francis B. Palumbo, PhD, JD, both from the University of Maryland School of Pharmacy. The **Students' Poster Session** will take place on Monday, June 27 from 10:00 AM to 6:00 PM in the entrance to Exhibit Hall A on the Lower Level of the Convention Center. The **Professionals' Poster Session** will take place on Tuesday, June 28 from 9:00 AM to 5:30 PM in the same location.

**PRESS REGISTRATION** Only individuals who are working for and representing a recognized news organization may register as press. Preregistration for press badges is strongly suggested as on-site registration is also subject to approval. To obtain a press badge, you must present identification certifying that you are a working member of the print, broadcast or online (writers working for web-based media) media. Acceptable identification includes press credentials or a business card. All freelancers must present a letter of assignment. DIA has the right to inspect the credentials of anyone registering as press and reserves the right to refuse to register any individual as press. Be advised that based on space requirements, DIA reserves the right to limit the number of on-site press badges issued.

An application for a press pass is available for download from the preliminary program posted on **www.diahome.org.** Return this form by fax to Andrea Pawlowski of Tattar Richards-DBC Public Relations at +1-215-957-1297.

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

**RECEPTIONS** DIA will host one reception on Monday, June 27 from 5:00 PM to 6:00 PM, in the Exhibit Hall.

**SCIENTIFIC EXHIBITS** There will be approximately 500 companies exhibiting in Washington, DC. The exhibit area will also serve as the site of coffee breaks, luncheons, and the Poster Sessions on Monday, June 27, and Tuesday, June 28.

## Transportation

### *Save through Area Pricing and Discount Fees*

**UNITED AIRLINES** To obtain schedule information and the best fares, call United Airlines's Specialized Meeting Reservations Center at 1-800-521-4041. **Make sure you refer to Meeting ID Number 571AK.** Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

**US AIRWAYS** US Airways' Group and Meeting Reservations staff can assist you in obtaining flight, fare and availability information toll-free at +1-877-874-7687. **Be sure to refer to Gold File Number 22633254.**

**AMTRAK** *Discount pricing available!*

Amtrak offers a 10% discount off the lowest available fare to Washington, DC between June 22 and July 3, 2005. Travel dates are approved three days prior to the convention start date and three days following the last day of the meeting. To book your reservation call Amtrak at **+1 (800) 872-7245** or contact your local travel agent. Conventions cannot be booked via Internet. **Please be sure to refer to Convention Fares Code X20G-936** when making your reservation. This offer is not valid on Auto Train. Fare is valid on Metroliner and Acela service for all departures seven days a week, except for holiday blackouts. Offer valid with Sleepers, Business Class or First Class seats with payment of the full applicable accommodation charges.

**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.

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

# Continuing Education

### Learning Objectives

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

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

### Target Audience

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

### Continuing Education

Select tutorials and sessions will offer category 1 credits, pharmacy contact hours, and nursing contact hours. Credits for tutorials are clearly identified in this program, and the credits for sessions will be indicated in the final program.

### Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 29.25 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants may earn up to 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.

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

### Tutorials

Full-day tutorials (9:00 AM - 5:00 PM) – up to 6.5 category 1 credits or contact hours (.65 CEUs), or .7 IACET CEUs per tutorial

Half-day tutorials (8:30 AM - 12:00 PM or 1:00 PM - 4:30 PM) – up to 3.25 category 1 credits or contact hours (.325 CEUs), or .3 IACET CEUs per tutorial

### Annual Meeting Sessions

June 26-30, 2005 – 286-000-05-501-L04; up to 19.5 category 1 credits or contact hours (1.95 CEUs), or 2 IACET CEUs (up to 1.5 hours per session)

### Nursing

The Drug Information Association will offer nursing credits for various tutorials and sessions in collaboration with Corexcel. Corexcel is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

### PMI

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

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If you would like to receive a statement of credit, you must attend the program (and tutorial, if applicable), and return the credit request form to the DIA. Statements of credit will be issued within 10 weeks of receipt of this form.

### Disclosure Policy

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

# Exhibit Hall Opportunities

NEW!

### DIA eLearning Demo, Contest, and Giveaway

***Win an iPod!***

**The Demo:** Experience an exclusive DIA eLearning module first hand at one of our computer stations and chat with our design team about this and other offerings.

**The Contest:** Test your new knowledge with interactive games based on content from the module and get your name up on the leader board – ***each day's highest scorer wins a $50 gift certificate!***

**The Giveaway:** Stop by, see all that DIA eLearning has to offer, and enter to win an iPod at the drawing on Wednesday, June 29!

**Scientific Exhibits** There will be approximately 500 companies exhibiting in Exhibit Halls A, B and C, located on the Lower Level of the Convention Center. This area also serves as the site of coffee breaks and luncheons as well as the Poster Sessions on June 27 and 28.

**Employment Opportunities** In an effort to be more technologically driven, DIA is providing employment opportunities electronically. Participants will also have the ability to post positions on this system throughout the meeting.

**Exhibit Locator** Visitors to the Exhibit Hall will be able to easily obtain a company's booth number by searching electronically for exhibiting companies using the workstations located in the entrance to Exhibit Hall A. They will be able to search by company name, by their services provided, or, using the keyword search engine, for any term used in the company description found in the 2005 Exhibitors' Services Summaries.

## CONTACT INFORMATION

**Drug Information Association**
**http://www.diahome.org**
800 Enterprise Road, Suite 200
Horsham, PA 19044-3595, USA
*Tel* +1-215-442-6100
*Fax* +1-215-442-6199
*email* dia@diahome.org

**Washington, DC Convention Center**
**http://www.dcconvention.com**
801 Mount Vernon Place, NW
Washington, DC 20001, USA
*Tel* +1 202-249-3000
800-368-9000
*Fax* +1 202-249-3533

# *THE* Networking Event in the Pharmaceutical Industry

DIA's 41st Annual Meeting provides a perfect forum for attendees and speakers to network and evaluate approximately 500 exhibiting companies. Meet with a wide range of companies to learn about new offerings and technologies, all in one event. From CROs and technology vendors to site research centers, academia, and much more, the DIA Annual Exhibit Hall is one of the busiest places during the meeting. Visitors to the Exhibit Hall will be able to easily obtain a company's booth number by searching electronically for exhibiting companies using the workstations conveniently located in the Exhibit Hall.

## *TOP REASONS WHY PEOPLE ATTEND DIA'S ANNUAL MEETING*

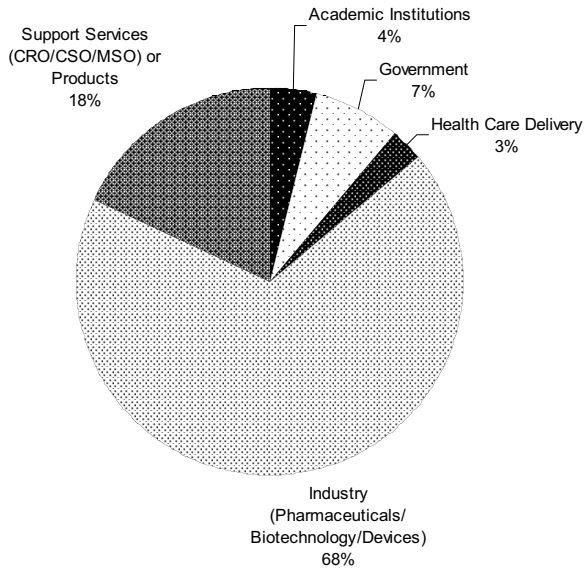
- **Networking opportunities**
- **Quality and value of information and speaker presentations**
- **Relevance of content to their profession**
- **Timeliness of topics**
- **Breadth and depth of topics**

***Limited space is still available.***

**Visit www.diahome.org for an application form.**

Exhibiting companies, as of February 25, 2005, are listed below.

### Audience Profile of DIA's 2004 Annual Meeting




AAHRPP
AAI Development Services
Abt Associates Inc.
Accelovance
Accovion Inc.
ACM Medical Laboratory
ADAllen Pharma Ltd.
AdClin
Adobe Systems, Inc.
Advanced Biologics, LLC
Advanced Biomedical Research, Inc.
Advanced Clinical Services
Advanced Clinical Software
Aerotek Scientific
Affymetrix
ALMEDICA
Amarillo Center for Clinical Research, Ltd.
American Medical Writers Association
American Pharmaceutical Review/American Pharmaceutical Outsourcing
AmeriTrial OTC Research
AMG IT Systems
Amgen Inc.
APEX International
Applied Clinical Trials Magazine
Appligent, Inc.
Apyx, Inc.
Aris Global, LLC
ARS, Inc.
Aspire IRB
Assist Technologies
AstraZeneca
Astrolabe Analytica, Inc.
Atlantic Institute of Clinical Research
Averion Inc.
AXIS Healthcare Communications LLC
B & C Group
BARC - The Central Laboratory
BASi (Bioanalytical Systems, Inc.)
Baxa Corporation
BBK Healthcare, Inc.
Beacon Bioscience, Inc.
Beardsworth
Benchmark Research
BioCor
BioExecutive International
Bio-Imaging Technologies, Inc.
Biomedical Research Institute of America
Biomedical Systems
BioResearch Monitors, Inc.
bioskin GmbH
Biospace, Inc.
Biotechnical Services, Inc.

Biotrial International
Biovail Contract Research
Booz Allen Hamilton
Borgess Health Alliance
Brecon Pharmaceuticals
BusinessEdge Solutions
California Clinical Trials
Cambridge Group, Ltd., The
Cambridge Regulatory Services Ltd.
Canadian Rheumatology Research Consortium
CanReg Inc.
Cardinal Health
Cardiocore
CardioDynamics
CareStat, Inc.
Carpermor, SA de CV
CCA, Inc.
CCRI
CDISC
CEDRA Clinical Research
Center for Drug Evaluation
CenteRXperts
CentraLabS Clinical Research
Certus International, Inc.
Charterhouse Clinical Research & EPA EURO PHARMA
Children's Hospital of Orange County
Chiltern International, Inc.
Christiana Care Research Institute
CIF-BIOTEC
Cincinnati Children's Research Foundation
Cirion Clinical Trial Services Inc.
City List
Clarix
Clarkston Consulting
ClickFind, Inc.
Clin Axys DBA Clinical Systems, Inc.
ClinAudits LLC
ClinForce, Inc.
Clinical Business Solutions
Clinical DataFax Systems, Inc
Clinical Financial Services
Clinical Network Services
Clinical Research Atlanta
Clinical Research Center at Tampa General Hospital
Clinical Research Networks (CRNets)
Clinical Resource Network, The
Clinical Trial Media
Clinical Trial Services
Clinical Trials & Epidemiology Research Unit
Clinical Trials Services, Inc.
Clinilabs
ClinLogic
ClinPhone, Inc.
Clintrak Pharmaceutical Services
Cmax Pty Ltd.
CMIC Co., Ltd.
CNS Vital Signs
Coast IRB, LLC
Cognitive Drug Research
Cogtest plc
Colortrieve Record Systems, Inc.
Community Research
Comprehensive NeuroScience, Inc.
Concepts Worldwide
Constella Clinical Informatics, Inc.
Contract Pharma
Copernicus Group IRB
Covance Inc.
CRF Inc
CRL.Medinet
CSA Associates, LLC
CSS Informatics
CTMS, Inc.
Cu-Tech, LLC
CYA Technologies, Inc.
D. Anderson & Company
Data Capture International
Data Communique International
DataCeutics, Inc.
Datafarm, Inc.
DataForm Software
DataLabs, Inc.
Datapharm Australia Pty Ltd.
DATATRAK International
Datatrial
DaVita Clinical Research
DCL Medical Laboratories
DDS Medicines Research Ltd.
Degge Group, Ltd., The
Dendrite International
Designing Events
DGP export Ltd.
DIA
Diamond Medical Group
Dimensional HealthCare
DOCS International
Document Control Systems, Inc.
Drexel University College of Medicine
Drug Safety Alliance
DrugLogic Inc.
DSG (Document Solutions Group, Inc.)
Duke Clinical Research Institute
DxS Limited
Dynarand
DZS Software Solutions, Inc.
ECRON
Edinger Medical Group & Research Center
Elsevier
EMC/Documentum
EMEA
Endpoint Research
Engel Publishing

Enterprise Ireland
Envision Pharma, Inc.
ePharmaLearning, Inc.
ERBI
eResearchTechnology, Inc.
Esoterix
Essential CRO/AmericasDoctor, Inc.
eStudySite
etrials Worldwide
Eurotrials
EXAKT Technologies, Inc.
Examination Management Services, Inc.
Excel PharmaStudies, Inc.
Fast Track Systems
FDA/CBER
FDA/CDER
FDAnews
F-D-C Reports, Inc.
First Consulting Group
Fisher Clinical Services
Fleishman-Hillard Clinical Trials Division
Fleury Diagnostics
Focus Bio-Inova, Inc.
FOI Services, Inc.
Food and Drug Law Institute
ForeignExchange Translations
Forest Laboratories, Inc.
Formedix Ltd.
Fulcrum Pharma Developments, Inc.
Galt
Gene Logic Inc.
Gentiae Clinical Research
Geny Research Corp.
George Washington University Medical Center
GFI Research Center
Glemser Technologies Corporation
Global Languages & Cultures, Inc.
Global Medical Institutes, LLC
GPA International
GroupNet
Harris Interactive
Harrison Clinical
Hawaii Clinical Research Center
HCL Technologies
Health Decisions
Healthcare Communications Group
HealthCore
Hillicon TrainingCampuses
HungaroTrial
Hurley Consulting Associates Ltd.
i3 Research
i3 Statprobe
IBIC Clinical Research Center
IBIS
IBM Corporation
ICON Clinical Research
ICTI
iD Globe
Image Solutions, Inc.
iMedRIS Data Corp.
IMFORM International Clinical Research
IMIC - Mexican Institute of Clinical Research
Impact Clinical Trials
Imperial Graphics, Inc.
IMRO TRAMARKO International
INC Research
InfoMedics, Inc.
Innovative Print & Media Group
Innovus Research Inc.
Inprint USA
Integic Corporation
Integrated Clinical Systems, Inc.
Integrated Development Associates Co., Ltd.
IntegReview, Inc. Ethical Review Board
Integrex
Integrium
Intermountain Clinical Research
International Dermatology Research
Interspond, LLC
IntraLinks, Inc.
Inveresk Research Group, Inc.
invivodata
Iowa Clinical Research Corporation
IVRAS
J&S Studies, Inc.
Jeiven Pharmaceutical Consulting, Inc.
Johnson & Johnson Professional Recruiting
Joule Clinical Solutions
Kcentrix Software
Kelly Scientific Resources
Kendle International
Keris, Inc.
Kforce Clinical Research Staffing
Klein Management Systems
LabConnect, LLC
LabCorp
Laboratorio Hidalgo
LabWare, Inc.
LatinTrials
LEADPHARMA
Leake
Lernia Training Solutions
LifeTree Technology
Liquent
Logos Technologies Ltd.
LORENZ Life Sciences Group
Lovelace Scientific Resources
M+BIOLAW
MAJARO InfoSystems
Marken Time Critical Express
Mayne Pathology
Mayo Clinical Trial Services

McCarthy Consultant Services Inc.
McElroy Translation Company
McGuire Research Institute, Inc.
McKesson BioServices
MDS Pharma Services
MedDRA® MSSO
MedFocus, LLC
Medical Staffing Network
MediciGroup Inc.
Medidata Solutions
Medifacts International
Medpace, Inc.
MedPoint Communications, Inc.
MedQualis
MedSource
Medstat
MEDTOX Laboratories
MedTrials, Inc.
MedXview, Inc.
Merck & Co., Inc.
META Solutions, Inc.
MetaWorks, Inc.
MHRA
Microsoft Corporation
Microsystems
Mid*Lands IRB
Midwest Research Specialists
MonitorForHire.com
Monitoring Force USA, Inc.
Mortara Instrument
MSOURCE
National Death Index, NCHS, CDC
Neeman Medical International
Ness Technologies
New England Institutional Review Board
New Horizons Clinical Research
New Orleans Center for Clinical Research
Nextrials, Inc.
Northwest Clinical Research Center
Northwest Kinetics, Inc.
NOTOX BV
Novotech
NUCRO-TECHNICS
Ocasa Inc.
Octagon Research Solutions
Odyssey Research Services
Omnicare Clinical Research
Omnicia, Inc.
OmniComm Systems, Inc.
On Assignment Clinical Research
Open Text Corporation
Optimed Research
Oracle Corporation
ORIAM
Origin Pharmaceutical Services Ltd.
Orlando Clinical Research Center
Outcome
Ovation Research Group
Pacific Biometrics, Inc.
Pacific Data Designs
Paragon Biomedical
PDP Courier Services Ltd.
Pediatric Clinical Trials International
PeerView, Inc.
Penn Pharmaceutical Services Ltd.
PerMedics, Inc.
Pfizer Global Research and Development
Pharmaceutical C-Trials, Inc.
Pharmaceutical Executive Magazine
Pharmaceutical Information Associates, Ltd.
Pharmaceutical Research Network
Pharmaceutical Research Plus, Inc.
Pharmaceutical Resource Corp.
Pharmafile Ltd.
PharmaLinkFHI
PharmaNet
PharmaSeek, LLC
PharmaSys, Inc.
PharmaTech Solutions, Inc.
PharmaVOICE
PharmData, Inc.
Pharm-Olam International
PharmSource
Phase Forward
Phoenix Data Systems, Inc.
Phoenix Pharma Central Services (S) Pte Ltd.
Phoenix Software International
Phoenix Translations
PHRP
PHT Corporation
(Pi) Patient interaction
PII
PJB Publications
Placemart Personnel Service
PLANISWARE USA Inc.
PPD, Inc.
PRA International
PRACS Institute, Ltd.
PreAnalytix
Precept Life Sciences
Premier Research, a Division of CRC Development Ltd.
PRL Central Laboratory Services
ProGene Biomedical/IBT Reference Laboratory
Prologue Research
Promedica International
Prometrika
Protech Pharmaservices Corporation
ProTrials Research, Inc.
PRTM Management Consultants
PSI International, Inc.
PSI Pharma Support Intl
Quality & Compliance Consulting, Inc.

Quality Associates, Inc.
Quality Data Services, Inc.
Quantum Research
Quest Diagnostics
Quest Pharmaceutical Services
Quintiles
QUMAS
Quorum Review IRB
Radiant Research
RadPharm
RCRC IRB
Recruitech International
Regional Clinical Research
REGISTRAT, Inc.
Relsys International, Inc.
Research Across America
Research Dynamics
Research Investigator's Source
Research Solutions, LLC
Rho, Inc.
Richmond Pharmacology
Romar Consulting
RPS, Inc.
RWD Technologies, Inc.
Rx Trials, Inc.
RxCCI - Regulatory/Clinical Consultants, Inc.
SAFE - BioPharma
SAS Institute
Schulman Associates IRB, Inc.
Science Applications International Corp.
SCIREX Corporation
Sentrx
SFBC International
SGS Life Science Services
SH3 Inc.
Sierra Scientific Software, Inc.
Simpson Healthcare Executives
Siris Pharmaceutical Services
Site Support Institute Co., Ltd.
SleepMed, Inc.
Smith Hanley
SNOMED International
Society of Quality Assurance
Source4
Spacelabs Medical Data
Spectra Clinical Research
Spotfire
SRG Woolf Group, Inc.
Standard Register
STATKING Consulting, Inc.
Stelex
Sterling Research Group, Ltd.
Strata
SunTech Medical, Inc.
Symbiance, Inc.
SYMFO
SYNARC, Inc.
Synchron Research Services
Synteract, Inc.
Tablus, Inc.
Tandem Labs
Taratec
Target Health Inc.
Target Research Associates
Technical Resources International, Inc.
Therapak Corporation
Thesaurus Information and Strategies, Inc.
ThinSpring
Thomson Center for Clinical Research Practice
Thomson CenterWatch
Thomson PDR
Thywill LatAm Solutions
TKL Research, Inc.
TNT
TransPerfect Translations
TRC Clinical
Trial Management Group Inc.
TrialsNet
Trident Clinical Research Pty Ltd.
Trio Clinical Research, LLC
UBC
UK Clinical Research Organization
UMC Products & Services, The
Uniform Data System for Medical Rehabilitation
University Clinical Research, Inc.
University of California, San Diego
University of Florida
University of Medicine & Dentistry of New Jersey
University of Vermont
VA Cooperative Studies Program
Veritas Research, Inc.
VIASYS Healthcare Clinical Services
ViPS Biomedical Services, Inc.
Vitalograph Ltd
VivoMetrics Inc.
Volt Life Sciences
Waban Software
Wellspring Pharmaceutical
West Coast Clinical Trials
Winchester Business Systems
Winnertech Consulting
Woodley Equipment Company Ltd.
World Class International
World Courier Inc.
WorldCare Clinical, Inc.
Wyeth
Xenobiotic Laboratories, Inc.
XERIMIS Inc.
XTrials Research Services
Yoh Scientific
Yourway Transport Inc.
Zenosis Ltd.

# EXHIBITOR REGISTRATION FORM

**Online registration is NOT available for exhibitors.**

**Exhibitors should return this form to the attention of the Exhibits Department at DIA.**

## 41ST ANNUAL MEETING ID #05001 June 26-29, 2005, Washington, DC, USA

If registering for tutorials or the networking dinner and paying by credit card, return this completed form to DIA by fax to **+1-215-442-6199** or by mail to 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA. If paying by check, follow instructions under Payment Methods below.

**All registrations received at the DIA office in Horsham, PA, USA, by 5:00 PM on May 20, 2005, will be included in the Advance Registration Attendee List.**

Each 10' x 10' booth includes one (1) complimentary full-meeting registration and three (3) exhibit booth personnel registrations. Please fill out a separate form for each exhibitor registrant. To expedite your registration, please check the appropriate category:

❑ COMPLIMENTARY FULL-MEETING REGISTRATION ❑ EXHIBIT BOOTH PERSONNEL

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

**PAYMENT METHODS Please check payment method:**

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association, Inc., PO Box 827192, Philadelphia, PA, USA 19182-7192. Please include a copy of this registration form to facilitate identification of attendee.

❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to the currency conversion rate at the time of the charge.

❑ VISA ❑ MC ❑ AMEX Expiration Date _____

Card # _____

Signature _____

❑ **BANK TRANSFER** in the currency of your choice to: PNC Bank, 1600 Market Street, Philadelphia, PA 19103, USA. DIA Account # 8606072742. ABA # 031000053. SWIFT-CODE # PNCCUS33. Your name and company, as well as the above Meeting I.D. Number, must be included on the transfer document to ensure payment to your account.

**CANCELLATION POLICY**

All cancellations must be in writing and received at the DIA office by 5:00 PM on June 10, 2005. Registrants who do not cancel by June 10, 2005 and do not attend will be responsible for the full applicable fee. **Registrants are responsible for canceling their own airline and hotel reservations.** You may transfer your registration to a colleague at any time, but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. **Substitute registrants will be responsible for nonmember fee, if applicable.**

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel, or other costs incurred by registrants. Speakers and program agenda are subject to change. **Cancellations received in writing on or before June 10, 2005, 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 DINNER CANCELLATION

On or before June 10, 2005 = Full Refund

TUTORIAL CANCELLATION

On or before June 10, 2005 – Registration fee paid minus $50 = Refund Amount

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

**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.***

**CERTIFIED CLINICAL INVESTIGATOR REVIEW COURSE #05410** See website for details.
MEMBER US $ 250 ❑ NONMEMBER US $ 300 ❑

**CERTIFIED CLINICAL INVESTIGATOR EXAMINATION** See website for registration information.

**ONE-DAY ONLY REGISTRATION FEE** will be available closer to the meeting date at a cost of $505 for members and $680 for nonmembers.

**TUTORIALS** See the website for the tutorial schedule. Space is limited and preregistration is encouraged. Please indicate the ID number and fee for each tutorial you plan to attend.

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____ Tutorial Subtotal _____

**NETWORKING DINNER** Sunday, June 26, 6:30 pm. US $ 70 ❑

**PREREGISTRATION FEES** Attendees will be required to produce their confirmation letter. 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 17, 2005. An email address must be included below for confirmation process.**

| MEMBER EARLY-BIRD OPPORTUNITY<br>Available on nondiscount member fee only. | On or before JAN 31* | After JAN 31 |
|---|---|---|
| Member Fee | US $ 950 ❑ | US $1050 ❑ |
| Join DIA now to qualify for the early-bird member fee! www.diahome.org/docs/Membership | | US $ 130 ❑ |

*To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/ academia/nonprofit members.

**Nonmember Fee** US $1180 ❑

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 $ 625 ❑ | US $ 755 ❑ |

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

MEETING REGISTRATION FEE US $ _____

TUTORIAL REGISTRATION FEE US $ _____

NETWORKING DINNER FEE US $ _____

**TOTAL PAYMENT DUE US $ _____**

Last Name First Name MI

Degrees DIA PIN # (optional) ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Mailing Address

City State Zip/Postal Code Country

Telephone # Fax #

email **(email address is required for confirmation)**

# Registration Form for TUTORIALS & NETWORKING DINNER *ONLY*

***Can't attend the entire Annual Meeting?*** **Register for weekend Tutorials**

***Already registered for the Annual Meeting?*** **Add on the Networking Dinner or Tutorials**

**41ST ANNUAL MEETING ID #05001 June 26-30, 2005 Washington, DC, USA**

**Return this form by MAIL or FAX ONLY** DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595 ● Fax +1-215-442-6199

**PLEASE CHECK IF:** ❑ You are already registered for the meeting but wish to add Tutorials or the Networking Dinner to your registration.
❑ You do not wish to register for the meeting but would like to register for a Tutorial(s) or the Networking Dinner.

*Please PRINT or TYPE in the space below.*

Last Name _____ First Name _____ MI _____

Degrees _____ DIA PIN # (optional) _____ ❑ Dr. ❑ Mr. ❑ Ms.

Job Title _____

Company _____

Mailing Address _____ Please indicate if this is your ❑ Home Address or ❑ Office Address

City _____ State _____ Zip/Postal Code _____ Country _____

Telephone # _____ Fax # _____

email **(email address is required for confirmation)** _____

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

**PLEASE NOTE: This page must be completed and submitted for each person registering for the Networking Dinner or Tutorials.**

❑ **YES, I am registered for the meeting and I would like to add the Networking Dinner and/or the following Tutorials to my registration.**

❑ **NO, I do not wish to register for the meeting but I would like to register for the Networking Dinner and/or the following Tutorials.**

**Networking Dinner** **$70.00** ❑

**Tutorials** Please indicate all applicable Tutorial Number(s) and fee(s).

Tutorial #_____ Fee $ _____

Tutorial #_____ Fee $ _____

Tutorial #_____ Fee $ _____

**Total Tutorial Fee Due** $ _____

**TOTAL PAYMENT DUE** $ _____

## PAYMENT METHODS

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❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199.
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❑ VISA ❑ MC ❑ AMEX Exp. Date _____

Card # _____

Signature _____

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**Join DIA now to qualify for the member fee, save and receive all the benefits of membership for a full year!** **$130.00** ❑

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**TUTORIAL CANCELLATION:** On or before June 10, 2005 – Registration fee paid minus $50 = Refund Amount

# *Press Pass Request Form*

**REGISTRATION POLICIES AND PROCEDURES**

The Drug Information Association's (DIA) events are attended by a number of international and domestic journalists who represent a variety of well-respected media outlets. DIA welcomes qualified representatives of news organizations to attend these events for the purpose of reporting and publishing articles.

Press passes will be given to all who qualify as members of the press. The DIA reserves the right to screen all requests and refuse the registration of those who do not qualify. In order to obtain a press pass, applicants must be affiliated with an established media outlet and posses an editorial title. Publishers, sales representatives and other non-editorial staff will not be granted a press pass. Publications and marketing materials may not be distributed at DIA conferences. Upon arrival, all media must present confirmation letters, press credentials and/or a letter of assignment from the media outlet at the check-in location.

Please fill out this form and fax it to Andrea Pawlowski of Tattar Richards-DBC Public Relations at 215.957.1297. If you have any questions, please call Andrea at 215-957-0300.

**Course Code for DIA Event:** _____
**(The five-digit number that appears near the event's title on DIA's Web site.)**

**Title of DIA Event:** _____

**Date of DIA Event:** _____

**Name:** _____

**Job Title:** _____

**Media Outlet:** _____

**Address:** _____

**City/State/Zip:** _____

**Telephone Number:** _____

**Email:** _____

**Confirmed Registration:** Written confirmation is forwarded via email within five (5) business days upon receipt. Email apawlowski@dbcommunications.net if you have not received confirmation within seven (7) business days from submittal of registration.

**Deadline:** Registration should be received at least two weeks before the conference. Registrations received after the deadline and on-site registrations will be accepted upon space availability. For space availability, contact apawlowski@dbcommunications.net.

**Meeting Cancellation:** DIA reserves the right to cancel any conference at its sole discretion, whereupon all registration fees will be refunded. DIA will not be responsible for airfare penalties or other costs incurred due to a cancellation.

**Agenda/Speakers:** Subject to change without notice. Check www.diahome.org for updates.

**Resources:** Conference agendas will be provided to news representatives. At the respective speaker's discretion, printed speaker handouts (not including reference CD-ROMs) will be available to the press at no extra cost. They may be quoted, but not reproduced in whole or in part without explicit permission from DIA. They are provided as a helpful resource to news reporters and may not be redistributed or sold.

**Recording:** Recording at sessions is allowed for the purpose of taking notes. Permission is needed in advance if the intention is to broadcast any taped session, in full or in part. Videotaping is prohibited.

Please help DIA maintain a thorough archive of press coverage by providing DIA with a clipping, e-copy or URL of articles developed from information presented at conferences.
Mail clippings to:

Andrea Pawlowski
Tattar Richards—DBC, Suite 100
655 Business Center Drive
Horsham, PA 19044

Fax: 215-957-1297

Email: apawlowski@dbcommunications.net

*By signing my name below, I am verifying that I have read and agree to the policies and procedures above and that the information I have provided is correct. Further, I am granting permission to the DIA to publish any articles that I produce about the above meeting in *DIA Today.*

**Signature:** _____

# Saturday, June 25 - Monday, June 27 *(some speaker changes will occur before the event.)*

## Saturday, June 25

12:00 PM - 1:00 PM **TUTORIAL REGISTRATION**
Registration for Saturday tutorials ONLY
East Registration Area, Convention Center
Mount Vernon Place Entrance

12:00 PM - 5:00 PM **EXHIBITOR REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

1:00 PM - 5:30 PM **CERTIFIED CLINICAL INVESTIGATOR REVIEW COURSE**
Renaissance Washington, DC Hotel

## Sunday, June 26

8:00 AM - 9:00 AM **TUTORIAL REGISTRATION**
Registration for Sunday morning or full-day tutorials ONLY
East Registration Area, Convention Center
Mount Vernon Place Entrance

8:00 AM - 6:30 PM **EXHIBITOR REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

9:00 AM - 12:00 PM **CERTIFIED CLINICAL INVESTIGATOR EXAMINATION**
Renaissance Washington, DC Hotel

12:30 PM - 1:00 PM **TUTORIAL REGISTRATION**
Registration for Sunday afternoon tutorials ONLY
East Registration Area, Convention Center
Mount Vernon Place Entrance

2:00 PM - 5:00 PM **CERTIFIED CLINICAL INVESTIGATOR EXAMINATION**
Renaissance Washington, DC Hotel

3:00 PM - 6:30 PM **ATTENDEE REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

3:00 PM - 6:30 PM **SPEAKER REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

4:00 PM - 6:00 PM **EXHIBITS OPEN**
Exhibit Hall A, B and C, Lower Level, Convention Center

6:30 PM - 8:30 PM **NETWORKING DINNER**
Grand Ballroom, Renaissance Washington, DC Hotel

## Monday, June 27

7:30 AM - 6:00 PM **ATTENDEE REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 6:00 PM **EXHIBITOR REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 6:00 PM **SPEAKER REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 8:15 AM **CONTINENTAL BREAKFAST**
Ballroom Foyer, 3rd Floor, Convention Center

10:00 AM - 6:00 PM **STUDENTS' POSTER SESSION**
Exhibit Hall A Entrance, Lower Level, Convention Center

10:00 AM - 6:00 PM **EXHIBITS OPEN**
Exhibit Hall A, B & C, Lower Level, Convention Center

5:00 PM - 6:00 PM **MONDAY RECEPTION**
Exhibit Hall A, B & C, Lower Level, Convention Center

8:30 AM - 10:00 AM

## Plenary Session

Ballroom ABC, 3rd Floor, Convention Center

### Welcome and Awards Presentation

***THERESA K. MUSSER***
Senior Director
Project Management and
Clinical Operations
Rigel Pharmaceuticals
*Acting President, DIA*

### Opening Remarks

***RONALD D. FITZMARTIN, PHD, MBA***
Vice President
Global Technical Services
Daiichi Medical Research, Inc.
*2005 DIA Annual Meeting Chairperson*

### Keynote Address

***BERNADINE HEALY, MD***
Medical and Health Columnist, *US News & World Report*; Former Head, National Institutes of Health and the American Red Cross

10:00 AM - 10:30 AM **REFRESHMENT BREAK**
**Exhibit Halls ABC, Lower Level**
**Convention Center**

## Session 101 AD - Advertising, MA, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 202B** *Pharmacy credits offered*

### Drug Advertising and Promotion: A Regulatory Primer

SESSION CHAIRPERSON

***Glenn N. Byrd, MBA, RAC***
Chief, Advertising and Promotional Labeling Branch, CBER, FDA

Drug advertising and promotion is a hot topic in today's environment. Direct-to-consumer (DTC) advertising, First Amendment issues, FDA compliance, and off-label promotion are all "in the news."

Who should attend: Regulatory, legal, public relations, marketing, and management staffs of pharmaceutical, veterinary medicine, biologics, and medical device companies, as well as consultants to these companies with less than 2-3 years of experience in the areas of advertising, public relations, legal issues, and marketing communications.

***Jean-Ah Kang, PharmD***
Senior Regulatory Affairs Consultant, Science Applications International Corporation (SAIC)

***Lesley R. Frank, MSFS, PhD, JD***
Acting Group Leader, Professional Review Group II, Division of Drug Marketing, Advertising, and Communications, CDER, FDA

***Ann Karen Henry, PharmD***
Director, Regulatory Affairs, Biogen Idec

## Session 102 CMC - Chemistry, Manufacturing, and Controls, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 150B**

### Pharmaceutical Quality Assessment: The New CMC Review Paradigm

SESSION CHAIRPERSON

***Moheb M. Nasr, PhD***
Director, Office of New Drug Chemistry, CDER, FDA

This session will discuss the FDA Office of New Drug Chemistry's (ONDC) implementation of a new quality assessment system and concurrent reorganization. ONDC is establishing a modern, risk-based pharmaceutical quality assessment system consistent with the FDA's initiative concerning modernization of the regulation of pharmaceutical manufacturing and product quality (Pharmaceutical Current Good Manufacturing Practices for the 21st Century: A Risk-based Approach). The new system encompasses several initiatives whose objectives are to allow rapid introduction of new technologies into pharmaceutical manufacturing and expedite review of applications without compromising the high quality of drugs in the United States. Major features will be examined including emphasis on quality by design in the evaluation of critical aspects of pharmaceutical quality attributes, dedicated premarketing and postmarketing divisions, a strong focus in manufacturing science, integration of review and inspection functions, and improved usage of modern statistical methodologies. Industry perspectives and concerns with implementation will also be discussed.

**FDA Perspectives**
***Moheb M. Nasr, PhD***
Director, Office of New Drug Chemistry, CDER, FDA

**Industry Perspective**
***Jeffrey J. Blumenstein, PhD***
Group Director, Regulatory, CMC and Quality Assurance, Pfizer Inc

**Panel Discussion/Q&A Period**

## Session 103 CP - Clinical Safety and Pharmacovigilance, CR, PP, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 207A** *CME credits offered*

### The Application of Good Pharmacovigilance Practices

SESSION CHAIRPERSONS

***Robert C. Nelson, PhD, MBA***
President, RCN Associates, Inc.

***Penelope Przekop, MSQA, CQM***
Director, Global Quality Management, Johnson & Johnson Pharmaceuticals Group

This session will consist of topics that address how the application of good pharmacovigilance practices and managment of pharmacovigilance processes using business metrics can improve long-term results such as: accuracy of benefit risk assessment, compliance, individual adverse event quality, aggregate report quality, and minimization of tort liability.

**Johnson & Johnson Pharmacovigilance Quality and Compliance System**
***Penelope Przekop, MSQA, CQM***
Associate Director, Global Quality Management, Johnson & Johnson Pharmaceutical Research and Development, LLC

**On the Proper Handling and Assessment of Spontaneous Reports**
***Robert C. Nelson, PhD, MBA***
President, RCN Associates, Inc.

**Issues in the Adoption and Implementation of Pharmacovigilance Data Mining**
***Michael D. Blum, MD, MPH***
Assistant Vice President, Wyeth Pharmaceuticals

## Session 104 CR1 - Clinical Research and Development, CP

10:30 AM - 12:00 PM LEVEL = ●

**Room 145A** *CME and Pharmacy credits offered*

### Real Life Safety and Efficacy of Levitra® (REALISE): Operational Aspects of a Postmarketing Surveillance Study

SESSION CHAIRPERSON

***Dawn Bradway, PhD***
Associate Director, Medical Science, US Phase IV Grants and Studies, Bayer HealthCare, Pharmaceuticals

The REALISE study was initiated to collect data on safety and patient acceptance of erectile dysfunction (ED) treatment with Levitra® under daily life conditions and included 30,000 subjects in the United States.

**REALISE: From Concept to Study Start**
***Dawn Bradway, PhD***
Associate Director, Medical Science, US Phase IV Grants and Studies, Bayer HealthCare, Pharmaceuticals

**REALISE: Study Execution**
***Dawn Bradway, PhD***
Associate Director, Medical Science, US Phase IV Grants and Studies, Bayer HealthCare, Pharmaceuticals

**REALISE: Overview from the CRO Perspective and Comparison with Other Phase IV Studies**
***Jill Conner, MSM***
Director, Project Management, Late Stage Group, UBC

## Session 105 CR2 - Clinical Research and Development, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 145B** *CME credits offered*

### Human Phase 0 (Microdosing) Studies: Regulatory and Scientific Aspects

SESSION CHAIRPERSON

***R. Colin Garner, PhD, DSc, FRCPath***
Chief Executive Officer, Xceleron Ltd., UK

The earlier introduction of drug candidates into humans is a prerequisite for improving attrition rates in clinical development. Ultrasensitive big physics instruments such as accelerator mass spectrometry (AMS) and positron emission tomography (PET) have allowed a new concept known as human microdosing to be developed. These screening human ADME studies allow smarter candidate selection prior to committing large resources to full-scale Phase I studies.

**Human Phase 0 (Microdosing) Studies: Scientific Aspects**
***R. Colin Garner, PhD, DSc, FRCPath***
Chief Executive Officer, Xceleron Ltd., UK

**New Drug Initiatives: Something Old and Something New**
***Orhan Suleiman, MS, PhD, FAAPM***
Senior Science Policy Advisor, CDER, FDA

**Human Phase 0 Studies: Practical Examples Using Renin Inhibitors**
***J. Chris Jensen, PhD***
Director, Pharmacology, Speedel Experimenta AG, Switzerland

## Session 106 CR3 - Clinical Research and Development

10:30 AM - 12:00 PM LEVEL = ■

**Room 147A** *CME and Pharmacy credits offered*

### The Critical Path for Analgesic Drug Development

SESSION CHAIRPERSON

***Raymond A. Dionne, DDS, PhD***
Chief, Pain and Neurosensory Mechanisms Branch, NIDCR, National Institutes of Health

The intent of the workshop is to address the dichotomy between the unmet need for analgesic drugs that improve upon the two drug classes (opioids, aspirin-like drugs) that are still predominantly used to treat acute and chronic pain and the opportunities created by increasing understanding of the molecular-genetic mechanisms of pain and analgesia. The workshop will examine the factors that influence analgesic drug development from differing perspectives to identify opportunities for improvements in the critical path for analgesic drug development.

**The FDA Critical Path Initiative**
***Janet Woodcock, MD***
Acting Deputy Commissioner of Operations, FDA

**Clinical Analgesic Drug Trials: Targets, Research Strategies and Individualizing Outcome Measures**
***Raymond A. Dionne, DDS, PhD***
Chief, Pain and Neurosensory Mechanisms Branch, NIDCR, National Institutes of Health

**The Optimal Model for Evaluating Acute Pain Drugs**
***Steven A. Cooper, DMD, PhD***
Senior Vice President, Global Clinical and Medical Affairs, Wyeth Consumer Healthcare

**Development of Opioids for Analgesic Indications**
***William K. Sietsema, PhD***
Vice President, Clinical and Regulatory Strategic Planning, Kendle

## Session 107 CR4 - Clinical Research and Development, RA

10:30 AM - 12:00 PM LEVEL = ●

**Ballroom A**
**3rd Floor** *CME, Nursing, and Pharmacy credits offered*

### A New Era of Transparency in Clinical Research: The Evolution, Impact, and Future of Clinical Trial Registers and Registries

SESSION CHAIRPERSON

***Craig A. Metz, PhD***
Vice President, CEDD Regulatory Affairs, GlaxoSmithKline

This session will explore the seminal issues that led to the public outcry for transparency in the clinical research process and resulted in the evolution of the various clinical trial result registers currently supported by PhRMA and a number of its member pharmaceutical companies. The session will also address the expansion of the ClinicalTrials.gov National Library of Medicine database beyond the original mandate described in FDAMA 113. Presentations will be made regarding the development of and experience to date with these databases, as well as procedures being developed to verify compliance with posting requirements. Presentations will be made by representatives from key stakeholder groups including the National Institutes of Health, academia, PhRMA, and individual pharmaceutical companies.

**The Case for Transparency in Clinical Research: A Journey Just Begun**
***Arthur L. Caplan, PhD***
Professor of Bioethics, University of Pennsylvania

**The Origin and Evolution of ClinicalTrials.gov**
***Deborah A. Zarin, MD***
Director, ClinicalTrials.gov, National Library of Medicine
Assistant Director, Clinical Research Projects, National Institutes of Health

**Clinical Trial Register Case Study 1: The PhRMA Experience**
***Alan Goldhammer, PhD***
Associate Vice President, Regulatory Affairs, PhRMA

**Clinical Trial Register Case Study 2: The GSK Experience**
***Frank W. Rockhold, PhD***
Senior Vice President, Biomedical Data Sciences, GlaxoSmithKline

**Evaluating Compliance**
***David McAvoy, MSES, JD***
Director, Office of Scientific and Regulatory Policy, Global Regulatory Affairs, Eli Lilly and Company

## Session 108 CTM - Clinical Trial Management, AHC, IS

10:30 AM - 12:00 PM LEVEL = ●

**Room 140B**

### Clinical Trial Offices: Boon or Boondoggle?

SESSION CHAIRPERSON

***John F. Bender, PharmD***
Vice President, Clinical Research, Favrille, Inc.

Many research institutions are setting up clinical trial offices (CTOs) to handle the process of implementing clinical trials at their institutions. We will explore the pros and cons of CTOs and let you help decide if CTOs are a boon to clinical research or the latest boondoggle.

***Susan K. Langley***
Manager, Clinical Projects, Favrille, Inc.

***Laurie Smith***
Director of Research, Rush University Medical Center

## Session 109 DM - Document Management/ eSubmissions

10:30 AM - 12:00 PM LEVEL = ●

**Room 206**

### A Standards-based Approach for Authoring Through Distribution

SESSION CHAIRPERSON

***Christopher M. Lee, MS, MPA***
Director, Pfizer Inc

This session will present an overview of advantages to migrating from unstructured to structured authoring within a standards-based infrastructure.

**Authoring and Distribution of Content: A Standards-based Approach**
***Anthony N. Brown***
Associate Director, Pfizer Inc

**Achieving Competitive Advantage Through XML Technology**
***Joe E. Jenkins***
Marketing Director, Life Sciences, Arbortext, Inc.

## Session 110 eCLIN - eClinical, CR, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 207B**

### Tools Sponsors Need to Implement Industry-wide Data Standards

SESSION CHAIRPERSON

***Susan P. Duke, MS***
Assistant Director, Novel Opportunity Assessment, GlaxoSmithKline

Now that the Study Data Tabulation Model (SDTM) is part of FDA guidance and the Analysis Data Model (ADaM) is close behind, it is a good time to consider next steps for industry-wide technical solutions. A discussion among more than 50 representatives from sponsors, vendors, CROs, FDA, and others was held in October 2004 to elucidate the needs of pharma. This session will highlight the tools prioritized from this discussion and relevant progress made since that time.

**Plug and Play Tools: Why and How Industry-wide Clinical Data Standards Can Make the Difference**
***Susan P. Duke, MS***
Assistant Director, Novel Opportunity Assessment, GlaxoSmithKline

**Statistical Computing Environments: What It Is, Why It's Hot**
***Alan Hopkins, PhD***
President, PharmaStat LLC

**Tools Wish List: Protocol Authoring, ODM Connectors, Standards Management, and a Standard Investigator Interface**
***Diane E. Wold, PhD***
Director, Data Standards Development and Management, GlaxoSmithKline

## Session 111 FI - Finance, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 140A**

### The Red Team Review: Avoiding Study Delays and Expenses from the Outset

SESSION CHAIRPERSON

***Christopher T. Speh, MA, MBA***
Independent Consultant

Many clinical studies are doomed to encounter costly delays simply because bid specifications on which proposals are based do not meet expectations of management or reflect the needs of the protocol. The Red Team Review uses knowledgable, but disinterested, personnel within the sponsor's own environment to assure that the bid spec "maps" back to the outsourcing requirement. In so doing, sponsors can avoid costly time delays and unnecessary study expenses.

**The CRO Perspective**
***Linda M. Orovitz***
Director, Contracts and Resource Management, Constella Clinical Informatics

**The Third-Party Perspective**
***Lani M. Hashimoto-Little***
Vice President, Recruitment Services, PharmaTech Solutions, Inc.

**The Sponsor Perspective**
***Rhonda L. Caudill, Esq.***
Senior Purchasing Manager, Global R&D Clinical Sourcing, The Procter & Gamble Pharmaceuticals Company

## Session 112 GCP - Good Clinical Practices, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 202A** *Nursing and Pharmacy credits offered*

### Managing Regulatory Inspections

SESSION CHAIRPERSON

***David B. Barr***
Vice President, Pharmaceutical Services, AAC Consulting Group, Inc.

FDA and other regulatory agencies perform inspections of sponsors-monitors, clinical investigators, IRBs, clinical supply manufacturing sites and other associated sites as part of their approval process for new drugs, as well as for many other programmatic reasons. Knowing how to manage these inspections effectively can dramatically decrease the chances of compliance problems with the regulatory agencies, shorten the inspection time, and help assure successful results from these inspections.

***Matthew T. Thomas, MD***
Pharmacologist, Office of Medical Policy, Division of Scientific Investigations, CDER, FDA

***David B. Barr***
Vice President, Pharmaceutical Services, AAC Consulting Group, Inc.

***M. Scott Harris, MD, MS, FACP***
Clinical Professor of Medicine, University of Wisconsin Medical School
President, Middleburg Consultants

## Session 113 IS - Investigator Sites, CR, FI

10:30 AM - 12:00 PM LEVEL = ●

**Room 101** *CME credits offered*

### Compliance and Clinical Trials Finance

SESSION CHAIRPERSON

***Harriett Singer, MS***
Instructor, Baylor College of Medicine

This session will discuss compliance risks in clinical trial finances and suggest approaches and some best practice models to ameliorate these risks. This session will discuss information of interest to beginners through experienced study personnel, and may represent a new perspective on financial risks in clinical research.

**Compliance and Risk**
***Angela Fornataro McMahill, JD, CCP, CCRA***
Director, Central Clinical Trials Office and Research Compliance, University of California-San Diego Health Sciences

**Where Finance and Compliance Intersect**
***Harriett Singer, MS***
Instructor, Baylor College of Medicine

**Coordination Issues**
***Germaine Luyckx, CCRC***
Clinical Program Manager, Scripps Research Institute

## Session 114 IT - Information Technology, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 204BC**

### PDUFA and Information Technology

SESSION CHAIRPERSON

***Thomas Scarnecchia, MS***
Vice President, Corporate Informatics, Millennium Pharmaceuticals, Inc.

PDUFA III established a series of information technology goals for the FDA and industry. These goals cover aspects of IT organization, infrastructure, governance, common systems, and technology to enable electronic submissions. Members of PhRMA's Information Management Policy and Affairs Coordinating Committee (IMPACC) and FDA will lead a series of discussions covering the activities and accomplishments related to these goals and the implications for the industry. The session will also provide a preview of the themes under consideration for setting IT goals for PDUFA IV.

**PDUFA III Information Technology Goals and Status**
***Mark A. Gray***
PDUFA IT Program Manager, Gateway Project Officer, Office of the Commissioner, FDA

**IMPACC Strategic Agenda**
***Dennis X. Murray***
North American Regional Head, Lifecycle and Licensing Information Management, Hoffmann-La Roche Pharmaceuticals

**Themes Under Consideration for PDUFA IV IT Goals**
***Thomas Scarnecchia, MS***
Vice President, Corporate Informatics, Millennium Pharmaceuticals, Inc.

## Session 115 MW - Medical/Scientific Writing, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 102AB**

### CTD: Practical Solutions for Mixed Applications, Herbals and Biologics

SESSION CHAIRPERSON

***Leonardo C.I. Ebeling, PhD, MD***
General Manager, Dr. Ebeling & Assoc. GmbH, Germany

Practical problems and solutions in preparing the CTD modules 2.4 to 2.7 for applications with both original and bibliographical data and with respect to the concept of (essentially) similar products will be presented and discussed.

**CTD: Practical Problems for Mixed Applications of Pharmaceutical Drugs**
***Leonardo C.I. Ebeling, PhD, MD***
General Manager, Dr. Ebeling & Assoc. GmbH, Germany

**CTD: Practical Problems for Herbal Medicinal Products and the Reference to Bibliographical Literature/Documentation**
***Burt H. Kroes***
Senior Assessor for Quality, Department for the Assessment of Herbal and Homeopathic Medicinal Products, Medicines Evaluation Board, Netherlands

**CTD: Practical Problems for Biologics and the Concept of Comparability/Similarity**
***William D. Schwieterman, MD***
Founder, Tekgenics, Inc., Biopharm Consultants

## Session 116 NC - Nonclinical Laboratory Safety

10:30 AM - 12:00 PM LEVEL = ●

**Room 103B** *CME credits offered*

### Biological Markers: Validations and Points to Consider

SESSION CHAIRPERSON

***Philip R. Oldfield, DPhil, MSc***
Scientific Director, Charles River Laboratories - CTBR, Canada

Verification that a biomarker assay is specific for its intended purpose poses a formidable challenge. Biological markers are endogenous molecules present at some baseline concentration in the biological matrix of interest. It would be of interest from a regulatory point of view to consider the methods validation, and subsequent determination of biomarkers and their interpretation. Real case examples will be described with a number of points to consider.

**Validation of Analytical Methods for the Determination of Biomarkers**
***Ralph McDade, PhD***
Strategic Development Officer, Rules-Based Medicine Inc.

**Validation of a Biomarker Model**
***Aurore Varela, DVM, IPSAV, MSc***
Research Scientist, Charles River Laboratories - CTBR, Canada

**Biomarkers: Regulatory Aspects**
***Douglas C. Throckmorton, MD***
Director, Division of Cardio-Renal Drug Products, CDER, FDA

## Session 117 OS - Outsourcing, CR, FI

10:30 AM - 12:00 PM LEVEL = ■

**Room 150A**

### Examining Use of Best Practices in CRO Outsourcing

SESSION CHAIRPERSON

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

CenterWatch has collected metrics on sponsor outsourcing practices for two consecutive years. We will explore the following: the most common metrics that sponsors use; any changes that are occurring in outsourcing practices; and current approaches to best practices. The data provided will benefit companies in implementing more effective outsourcing strategies and tactics and will examine trends in the data over a two-year time period.

**Vendor and Outsourcing Data Examining Best Practices Among Sponsor Companies**
***Mary Jo Lamberti, PhD***
Senior Manager, Market Intelligence, Thomson CenterWatch

**CRO Perspective on Best Practices in Sponsor Outsourcing**
***Joseph Bedford, PhD***
Associate Director, Global Market Research, Covance

**Creating an Effective Outsourcing Network**
***Dennis J. LaCroix, JD***
Director and Senior Counsel, Genzyme Corporation

## Session 118 PM1 - Project Management

10:30 AM - 12:00 PM LEVEL = ■

**Room 143AB** *Project Management Institute credits offered*

### Fostering Innovation, Efficiency, and Effectiveness on Project Teams

SESSION CHAIRPERSON

***Cindy Faulkner, MS***
Associate Director, Regulatory Project Management, AstraZeneca

Doing more with less, being more efficient and effective, and tapping the full creative power of teams can be difficult, especially in large, matrix-structured organizations. This session will explore the factors that can stifle or promote a team's ability to be more innovative. A practical example of a unique program designed to drive creativity, efficiency, and effectiveness will be presented, along with suggestions to consider in designing a program to meet your own organization's needs.

**A Case Study of an Innovation Initiative in Regulatory Project Management**
***Cindy Faulkner, MS***
Associate Director, Regulatory Project Management, AstraZeneca

**A Framework for Improving Innovation**
***Jean M. Egmon, EdD, MA***
President, Third Angle, Inc.; Director, Center for Learning and Organizational Change, Northwestern University

**Collaboration Across Domains to Improve Care of the Critically Ill**
***Alvin Lever***
Executive Vice President and Chief Executive Officer, American College of Chest Physicians

## Session 119 PM2 - Project Management

10:30 AM - 12:00 PM LEVEL = ●

**Room 143C** *Project Management Institute credits offered*

### Drug Development Teams: Heavyweights versus Lightweights – What Is the Score?

SESSION CHAIRPERSON

***Martin D. Hynes, III, PhD***
Director, Quality and Operations, Pharmaceutical Product Research and Development, Eli Lilly and Company

This session will be a review of the processes companies utilize to establish team structures within the pharmaceutical industry and the results obtained using these methods.

**Introduction: Team Constructs**
***Martin D. Hynes, III, PhD***
Director, Quality and Operations, Pharmaceutical Product Research and Development, Eli Lilly and Company

**Heavyweight Teams: A Retrospective**
***Russell L. Barton, MS***
Director, Project Management Procedure Teams, Eli Lilly and Company

**Lightweight Teams to Heavyweight and Back Again**
***Carol S. Meyer***
Senior Director, Project Planning and Management, Takeda Pharmaceutical Company

**Panel Discussion**

## Session 120 RA1 - Regulatory Affairs, BT

10:30 AM - 12:00 PM LEVEL = ■

**Room 146B** *CME credits offered*

### Immunogenicity of Biotechnology-derived Medicinal Products and Biosimilars/Follow-on Biologics: Regulatory Update and Recommendations

SESSION CHAIRPERSON

***Iman Barilero, PhD, PharmD***
Associate Director, European Regulatory Affairs, Global Regulatory Affairs and Quality Assurance, Johnson & Johnson Pharmaceutical Research and Development, LLC, UK

All experts from regulatory agencies (EMEA/CHMP, FDA), industry, and academia have stressed the need for a proactive and integrated approach to prediction, detection and management of harmful immunogenic properties of biotech-derived proteins. The prediction of risk of immunogenicity is based on previous experience, nature of the active substance, impurities accompanying the active substance and formulation of the final product (excipients, aggregates, etc.), route of administration, dosing regimen, and target patient population. The assessment of immune response in recipients requires an optimal antibody testing strategy, characterization of the observed immune response, as well as evaluation of the correlation between antibodies and clinical findings during phase III. If the risk is regarded high (considering above mentioned risk factors), a special risk management program should be proposed and will be required post-marketing by both FDA and the EMEA.

This session will provide with a regulatory update and experience sharing from the EMEA/CHMP and FDA on the current and future guidances for the assessment of immunogenicity for biotechnology-derived medicinal products and biosimilars/follow-on biologics, as a part of the overall guidance to assess the application of biosimilars/follow-on biologics. This session will also be an opportunity to share industry experience and provide best practices in managing immunogenic response and risk management plan for biotechnology-derived medicinal products throughout product life cycle.

**Regulatory Update and Experience from the EMEA/CHMP on the Assessment of Immunogenicity**
***Jean-Hughes Trouvin, PhD***
Chairman of CHMP Biotechnology Working Group; Director, AFSSAPS, France

**Regulatory Update from the FDA: Scientific Evaluation and Recommendations for the Assessment of Immunogenicity**
***Susan L. Kirshner, PhD***
Biologist, CDER, FDA

**Industry Experience: Monitoring Changes in Immunogenicity of Biologics Following Manufacturing Changes Through Risk Management and Post-marketing Surveillance**
***Adrian P. Thomas, MD***
Vice President, Benefit Risk Management, Johnson & Johnson Pharmaceutical Research and Development, LLC

## Session 121 RA2 - Regulatory Affairs, CR

10:30 AM - 12:00 PM LEVEL = ■

**Room 152A** *CME and Pharmacy credits offered*

### Registering Drugs for Pediatric Use

SESSION CHAIRPERSON

***Anne Tomalin***
Chief Executive Officer, CanReg Inc., Canada

This session will focus on the development of drugs for pediatric use, including a discussion of research difficulties involved in preclinical and clinical development of pediatric drugs. Incentive programs in various countries will be

discussed, including programs that exist to encourage pediatric research outside of the national departments of health. Guidelines and Expert Advisory Committees focused on pediatric review of drug products will also be reviewed.

**Regulatory Framework for Pediatric Drug Development and Registration in the US**
***Shirley Murphy, MD***
Director, Division of Pediatric Drug Development, FDA

**European Pediatric Initiative**
***Agnès Saint-Raymond, MD, PhD***
Head of Sector, Orphan Drugs and Scientific Advice; Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

**Challenges in Pediatric Research**
***Stuart M. MacLeod, MD***
Children's and Women's Health Centre of BCACB, Canada

## Session 122 RA3 - Regulatory Affairs, NHP

10:30 AM - 12:00 PM LEVEL = ●

**Room 152B** *CME and Pharmacy credits offered*

### Regulations of Botanical Drugs in the US

SESSION CHAIRPERSON

***Faraneh Attarchi, PhD, RAC***
Director, Regulatory and Technical Services, Quintiles Inc.

Botanical products have been used for centuries in many parts of the world for their medical properties. These products are widely used in the United States as dietary supplements, but the focus of this session is their use and regulations as drugs.

This session will provide information on FDA guidance for conducting investigations and marketing botanical products as drugs in the United States. A member of the Botanical Review Team from the Center for Drug Evaluation and Research (CDER) will highlight the current submission trends and important points to consider for applicants.

***Faraneh Attarchi, PhD, RAC***
Director, Regulatory and Technical Services, Quintiles Inc.

***Leslie A. Vaccari, RAC***
Regulatory Project Manager, CDER, FDA

## Session 123 RA4 - Regulatory Affairs, BT, CMC

10:30 AM - 12:00 PM LEVEL = ■

**Room 151B**

### FDA Initiative's Influence on Approval and Scale-up of Biotechnology Products

SESSION CHAIRPERSON

***Andrea Chamblee, JD***
Manager, Regulatory Affairs, Cambrex BioScience Walkersville Inc.

Scale-up raises a myriad of issues and questions for any manufacturer, and additional ones for manufacturers of biotechnology. It is unclear how FDA's modernization programs will be implemented by center officials and at the reviewer level in order for sponsors to realize the benefits. Also, the modernization program is centered in CDER; it is unclear whether biotechnology products in CBER, or even those now in CDER, will be treated as other drugs under PAT.

**FDA's PAT Initiative**
***Michael VanDerWerf***
Senior Regulatory Affairs Scientist, SAIC

**FDA Initiatives and CMC Review and Approval**
***Ajaz S. Hussain, PhD***
Deputy Director, Office of Pharmaceutical Science, CDER, FDA

**FDA Initiatives and Biologics/Biotechnology Scale-up: Impediment or Opportunity?**
***Nita Upendra Patel, PhD***
Vice President, Regulatory Affairs, GenVec, Inc.

## Session 124 RA5 - Regulatory Affairs

10:30 AM - 12:00 PM LEVEL = ●

**Room 154AB**

### Generic Applications in the EU after Review 2001

SESSION CHAIRPERSON

***John A. Lisman, MPharm, LLM***
Policy Advisor, Medicines Evaluation Board, Netherlands

Review 2001 provides for some important changes with respect to generic applications. These changes are discussed in the context of ECJ case law and the practice of generic authorization in the EU.

**Data Exclusivity after Review 2001**
***John A. Lisman, MPharm, LLM***
Policy Advisor, Medicines Evaluation Board, Netherlands

**Generics after Review 2001: Position of the Generic Industry**
***Beata Stepniewska, MS***
Pharmacist, Regulatory Affairs and EU Accession, European Generic Medicines Association, Belgium

**Generics after Review 2001: Position of the Innovative Industry**
***Christine-Lise Julou, PharmD***
Manager, Scientific and Regulatory Affairs, EFPIA, Belgium

## Session 125 ST - Statistics

10:30 AM - 12:00 PM LEVEL = ■

**Room 201** *CME credits offered*

### When to Specify the Statistical Analysis

SESSION CHAIRPERSON

***Simon Day, PhD***
Statistics Unit Manager and Scientific Advice Coordinator, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

The speakers will discuss the advantages and disadvantages of specifying the detailed statistical analysis for a study very early or very late. We will discuss how much detail can be left to (or changed in) the blind review of the analysis plan.

**Prespecifying Details of the Statistical Analysis: What, Where, When, and Why?**
***Robert Hemmings, MSc***
Senior Statistical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**To Be (Late) or Not to Be (Late): What's the Reason?**
***Jorgen Seldrup, PhD***
Development Director, Quintiles, France

**Statistical Analysis Plans: An FDA Reviewer's Perspective**
***J. Todd Sahlroot, PhD***
Statistics Team Leader, CDER, FDA

## Session 126 TR - Training, GCP

10:30 AM - 12:00 PM LEVEL = ■

**Room 151A**

### Effectively Managing the Challenges of Global Training

SESSION CHAIRPERSON
***Janet F. Zimmerman, MS, RN***
Senior Director, Training Services, PharmaNet

When planning worldwide training, what operational or resource issues need to be addressed? How do trainers balance delivering global company policies and procedures with local office or affiliate practices and customs? During this session, speakers from sponsor and contract research organizations will present case studies from their global training programs. The emphasis will be on explaining the challenges encountered in implementing worldwide training and how they were effectively managed.

**Case Study 1: Global SOP Training**
***Liz Wool***
Clinical Research Trainer, SCIOS, Inc.

**Case Study 2: Global Introductory Course in Clinical Development**
***Sibylle Roth, MA***
Manager, International Training, ALTANA Pharma, Germany

**Case Study 3: Global Monitor Training**
***Bruce A. Edelman, MS***
Senior Training Associate, Eli Lilly and Company

## Session 127 VA - Validation

10:30 AM - 12:00 PM LEVEL = ■

**Room 209AB**

### General Validation Issues

SESSION CHAIRPERSON
***Martin Browning, MS***
President, EduQuest Inc.

The lack of understanding, the myth, and the reality of validation are explored. A mechanism for determining the degree of validation and an approach to validation are presented.

**When is Enough, Enough?**
***Martin Browning, MS***
President, EduQuest Inc.

**An Ethical Approach to Validation**
***K. T. Oxford***
Director, META Solutions, Inc.

12:00 PM - 1:30 PM **LUNCHEON**

**Lunches will be distributed from 12:00 PM to 1:00 PM in Exhibit Hall C, Lower Level, Convention Center**

## Session 128 AD - Advertising, MA, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 202B** *Pharmacy credits offered*

### Update on FDA Enforcement of Promotional Activities

SESSION CHAIRPERSON
***Wayne L. Pines***
President, Regulatory Services and Healthcare, APCO Worldwide

FDA's active enforcement of promotion regulations provides insight into how the agency regards certain promotional activities. This session will provide a review of the latest enforcement actions by DDMAC and APLB and the practices that the agency is concerned about.

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

**Update from APLB**
***Glenn N. Byrd, MBA, RAC***
Chief, Advertising and Promotional Labeling Branch, CBER, FDA

## Session 129 CMC - Chemistry, Manufacturing, and Controls, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 150B**

### ICH Quality Guidances: Q8, Q9, and Q10

SESSION CHAIRPERSON
***Robert G. Baum, PhD***
Executive Director, Pfizer Global R&D

Updates on three quality guidelines being developed by the International Committee on Harmonization Working Groups will be presented. ICH Q8 on Pharmaceutical Development, ICH Q9 on CMC Risk Management, and ICH Q10 on Quality System Life Cycle Management will be discussed from industry's and the Agency's perspectives.

**Industry Perspective**
***Robert G. Baum, PhD***
Executive Director, Pfizer Global R&D

**FDA Perspective**
***Norman R. Schmuff, PhD***
Deputy Director, Division of New Chemistry III, CDER, FDA

**Panel Discussion/Q&A Period**

## Session 130 CP - Clinical Safety and Pharmacovigilance, RA

1:30 PM - 3:00 PM LEVEL = ●

**Room 207A** *CME credits offered*

### Regulatory Inspections of Company Pharmacovigilance Departments

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

An international pharmacovigilance program expert, an FDA CDER compliance officer, and a field investigator will discuss their experiences with postmarketing adverse drug event (PADE) reporting inspectional programs and provide guidance on preparing for PADE inspections. They will discuss common deficiencies found during PADE inspections, and review strategies to enhance regulatory compliance and pharmacovigilance capabilities.

***Helen Politis-Norton***
Director, UK & Ireland, Vigilex Ltd., The Innovation Centre, UK

***Carl Anderson***
QA Auditor and Consultant

## Session 131 CR/RA - Clinical Research and Development/Regulatory Affairs, RD

1:30 PM - 3:00 PM LEVEL = ■

**Ballroom AB, 3rd Floor**

### PLENARY SESSION
### Critical Path: Are We at the Fork in the Road?

SESSION CHAIRPERSONS

***Ronald D. Fitzmartin, PhD, MBA***
Vice President, Global Technical Services, Daiichi Medical Research, Inc.

***Stephen E. Wilson, DrPH, Capt. USPHS***
Deputy Director, Division of Biometrics II, CDER, FDA

The FDA has published a report entitled *"Innovation or Stagnation – Challenge and Opportunity on the Critical Path to New Medical Products"* (March 2004, available at http://fda.gov). The "Critical Path" report identifies the need for unprecedented improvement in the drug development process so that it is more efficient, predictable, and innovative, and less costly. The opportunities for dramatic change fall into three major dimensions and are identified as: *assessing safety, demonstrating medical utility, and industrialization.*

This moderated plenary will have FDA and industry leaders engaged in an interactive Q & A panel session to address the goals, accomplishments to date and future of the Critical Path initiative.

*Moderator*

***Debbie Henderson***
Director, Office of Executive Programs, CDER, FDA

*Panelists*

***Lawrence J. Lesko, PhD***
Director, Office of Clinical Pharmacology and Biopharmaceutical Science, CDER, FDA

***Janet Woodcock, MD***
Acting Deputy Commissioner of Operations, FDA

***Robert J. Temple, MD***
Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

***Douglas C. Throckmorton, MD***
Director, Division of Cardio-Renal Drug Products, CDER, FDA

***Steven J. Miller, PhD***
Vice President, Regulatory Affairs, AstraZeneca

***Sean Harper, MD***
Vice President, Medical Sciences, Amgen Inc.

## Session 132 CS - Clinical Supplies, CR

1:30 PM - 3:00 PM LEVEL = ■

**Room 143C** *Pharmacy credits offered*

### Clinical Supply Management

SESSION CHAIRPERSON

***Douglas Meyer, MBA, RPh***
Senior Vice President, Pharmaceutical Science, InfoPro Solutions

The entire clinical supply chain is usually not visible to clinicians, except when there is a supply problem. This session provides a comprehensive picture of the diverse clinical supply service providers: CROs, IVRS vendors, distributors, clinical packagers, and clinical sites. Topics include forecasting models, resupply models, and automated data exchange among these providers.

**Mastering the Extended Clinical Supply Chain**
***Douglas Meyer, MBA, RPh***
Senior Vice President, Pharmaceutical Science, InfoPro Solutions

**Integration Between Clinical Supply Management and IVR/EDC Systems**
***Tom O'Connell***
Vice President, Operations, DynaRand, LLC

**IVRS Systems and Other Technologies to Manage Limited Drug Supply**
***Jean-Remy Behaeghel, MS***
Director, IVRS, Perceptive Informatics, Inc.

## Session 133 CTM - Clinical Trial Management

1:30 PM - 3:00 PM LEVEL = ■

**Room 140B** *CME credits offered*

### Emerging World Clinical Development: Learning from Each Other

SESSION CHAIRPERSON

***Nermeen Varawalla, PhD, MD, MBA***
Vice President, Business Development International, PRA International, UK

Emerging countries represent compelling opportunities for cost-effective patient recruitment. However, sponsors have concerns related to data quality and nascent regulatory and ethics processes. Because of a similarity between the individual emerging countries and their varying degrees of advancement on the clinical development "learning curve," there is a valuable opportunity for them to share experiences and jointly develop solutions to the challenges they face. This session will do just this.

***Cezary Statuch, PhD***
Executive Director, Regional Clinical Operations - International, Global Development Operations, Bristol-Myers Squibb

***Andy Lee, MA***
Senior Director, Pfizer Global Research and Development

***William D. Schwieterman, MD***
Founder, Tekgenics, Inc., Biopharm Consultants

## Session 134 DM - Document Management/ eSubmissions, RA

1:30 PM - 3:00 PM LEVEL = ●

**Room 206**

### FDA Data Standards Initiatives – Part 1 of 2

SESSION CHAIRPERSON

***Randy Levin, MD***
Director, Office of Information Management, CDER, FDA

*Part 2 of this session is being held on Monday at 3:30 PM.*

FDA is actively pursuing data standards designed to streamline and expedite the regulatory review process. This session will focus on the need for data standards, current FDA data standardization initiatives, the impact on the review process, and the anticipated benefits of these initiatives.

**Stability Data and CDISC**
***Randy Levin, MD***
Director, Office of Information Management, CDER, FDA

**SPL**
***Steven Gitterman, MD, PhD***
Deputy Director, Director of Special Pathogens and Immunologic Drug Products, CDER, FDA

**Update on the Health Level Seven Individual Case Safety Report Standard**
***Lise Stevens-Hawkins***
Consumer Safety Officer, Office of Biostatistics and Epidemiology, Division of Epidemiology, CBER, FDA

## Session 135 eCLIN - eClinical

1:30 PM - 3:00 PM LEVEL = ■

**Room 207B** *CME credits offered*

### Clinical Data Interchange Standards (CDISC), from Protocol Through Submission

SESSION CHAIRPERSON
***Rebecca D. Kush, PhD***
President, CDISC

CDISC, the Clinical Data Interchange Standards Consortium, has made significant progress in the past year. Independently and through collaborations with Health Level 7 (HL7), NCI, and FDA, standards developed to facilitate the exchange of clinical trial information now span the realm from protocols through electronic submissions and are beginning to link clinical research with clinical care.

This session will include information on the business case for standards and global adoption of the CDISC standards; an update on CDISC progress over the past year, including progress towards harmonization of the CDISC standards with the HL7 Reference Information Model; and implementation experiences with the CDISC standards, including submissions to FDA.

**Global Adoption of CDISC Standards and a Business Case for Standards**
***Edward Helton, PhD***
Chief Strategist, Regulatory and Biomedical Affairs, SAS Institute

**The Business Cases for CDISC Standards**
***Carol Rozwell***
Vice President and Research Director, Life Sciences Industry Research, Gartner Group

**FDA Experiences with CDISC Standards**
***Armando Oliva, MD***
Associate Director for Policy, Office of New Drugs, CDER, FDA

## Session 136 FI - Finance, OS

1:30 PM - 3:00 PM LEVEL = ■

**Room 140A**

### Outsourcing in Europe: Guidance to US Companies

SESSION CHAIRPERSON
***Francisco Harrison, MD***
Chairman, Harrison Clinical Research GmbH, Germany

Europe is a crucial market for pharmaceuticals and product development. With the expansion of the European Union, the complexity of the European clinical trials performance requires a deep understanding of the advantages and disadvantages of this market as a whole and as individual countries.

**Europe: Expectations and Reality**
***Lesley J. Groves, PhD***
Senior Director, Clinical Operations, Santarus, Inc.

**Why and When to Go to Europe**
***Barbara J. Geiger, RN***
President and Clinical Director, Clinical Research Management Services, Inc.

**The Reality of Collaborating with US Companies**
***Nancy Meyerson-Hess, MPhil***
Director, Clinical Operations, Harrison Clinical Research GmbH, Germany

## Session 137 GCP - Good Clinical Practices, AHC, IS

1:30 PM - 3:00 PM LEVEL = ■

**Room 202A** *CME, Nursing, and Pharmacy credits offered*

### GCP Audits and Inspections: Determination of What Is, and What Is Not, Investigational Site Staff Misconduct

SESSION CHAIRPERSON
***Vernette J. Molloy, MBA, RN***
Vice President, GCPA, Inc.

This session will explore advanced auditing and instances of misconduct discovery; discussion will include determinants of what constitutes misconduct and will identify ways to mitigate charges of misconduct.

**Misconduct: A GCP Auditor's Perspective**
***Douglas R. Mackintosh, DrPH, MBA***
President, GCPA, Inc.

**GCP Inspections: Investigational Site Misconduct from the FDA Perspective**
***Leslie Ball, MD***
Branch Chief, Medical Officer, CDER, FDA

**Misconduct: A Regulatory Attorney's Perspective**
***Michael D. Petty, JD, MPH***
Partner, Ropes and Gray

## Session 138 IS - Investigator Sites, AHC, CR

1:30 PM - 3:00 PM LEVEL = ●

**Room 101** *CME credits offered*

### I Am OK, I Am Indemnified! What Does This REALLY Mean?

SESSION CHAIRPERSON
***Nadina C. Jose, MD, CPI***
President and CEO, Research Strategies, Inc.

Is there a real understanding of what it means to be "indemnified"? Does one truly know what coverage is received when a subject suffers a serious adverse event that is determined to have been caused by the study product? Sponsor-CRO-site perspectives will be presented in addressing the issues surrounding "indemnification."

**Issues in Site Indemnification: The CRO Perspective**
***Arthur Gertel, PhD, MS***
Vice President, Clinical Services, Regulatory and Medical Writing, Beardsworth Consulting Group, Inc.

**Managing Risks in Clinical Trials**
***J. Andrew Lemons, JD***
Attorney at Law, Alston & Bird LLP

**Issues in Indemnification**
***Nadina C. Jose, MD, CPI***
President and CEO, Research Strategies, Inc.

## Session 139 IT - Information Technology, eClin

1:30 PM - 3:00 PM LEVEL = ●

**Room 204BC**

### EDC Vendor Selection: Do We Really Need a Pool?

SESSION CHAIRPERSON

***Kimberly Tiefenbach***
Director, Clinical Services and Support, OmniComm Systems Inc.

With all of the electronic data capture vendors out there, both large and small, determining which vendor will be the best fit for your company can be a daunting task. The importance of knowing not only what the different vendors have to offer but also what your internal needs are will be stressed. A pharmaceutical company and a CRO will discuss the process they used to choose an EDC vendor.

**One CRO's Criteria and Process in Selecting an EDC Vendor**
***Lloyd J. Baroody, MBA***
Chief Executive Officer, Target Research Associates

**Selecting an EDC Vendor from the Pharmaceutical Perspective**
***Mark J. Holdbrook***
Director, Data Management and Biostatistics, Santen, Inc.

## Session 140 MW - Medical/Scientific Writing, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 102AB**

### ICH CTD Guidelines and Current Status of Implementation in DMFs, INDs, NDAs, BLAs and ANDAs

SESSION CHAIRPERSON

***Justina A. Molzon, JD, MPharm***
Associate Director for International Programs, CDER, FDA

Globalization of the pharmaceutical industry has created the need to harmonize recommendations for the development of new pharmaceuticals as well as regulatory requirements. To address this need, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was created in 1990. ICH has generated over 50 harmonized guidelines on the information to be submitted to ICH regulatory authorities for pharmaceuticals. The next logical step was to arrange the information in a common format for submission, and ICH has established the Common Technical Document (CTD). The concept of the CTD has been extended from the NDA to DMFs, INDS, BLAs, and ANDAs. CDER staff will discuss implementation and review aspects of this extension to various submission formats.

**ICH CTD Guidelines Implementation and Current Status**
***Justina A. Molzon, JD, MPharm***
Associate Director for International Programs, CDER, FDA

**e-CTD Use in CDER Submissions**
***Gary Gensinger***
Director, Review Technology Staff, Office of Information Management, CDER, FDA

**CTD and e-CTD: A Reviewer's Perspective**
***Mark R. Seggel, PhD***
Chemist, CDER, FDA

## Session 141 NC - Nonclinical Laboratory Safety, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 103B**

### The In Vitro Clastogen Conundrum

SESSION CHAIRPERSON

***Carl L. Alden, MD, DVM***
Vice President, Drug Safety Evaluation, Millennium Pharmaceuticals, Inc.

Since 26% of the drugs in the PDR are in vitro clastogens across therapeutic indications, the predictiveness (for in vivo genotoxicity) of this assay has been questioned. However, the in vitro clastogen assessment is required in drug development. The finding of a molecule that is an in vitro clastogen but that is an in vivo clastogen negative and Ames negative molecule represents a common situation in drug development necessitating additional testing prior to repeat dosing in humans. The current regulatory guidance in this situation as well as strategies to reduce the high false positive rate will be the focus of discussion.

**Evolution in Regulatory Guidance for Ames Negative, In Vivo Micronucleus Negative but In Vitro Clastogen Drug Candidates**
***David Jacobson-Kram, PhD, DABT***
Associate Director for Pharmacology and Toxicology, Office of New Drugs, CDER, FDA

**Strategies for Reducing the High False Positive Rate in In Vitro Clastogen Testing**
***Maik Schuler, PhD***
Senior Principal Scientist, Pfizer Inc

## Session 142 NHP - Natural Health Products, CR

1:30 PM - 3:00 PM LEVEL = ■

**Room 154AB** *CME and Pharmacy credits offered*

### Evaluating Natural Health Products in Patients with Serious and Life-threatening Conditions

SESSION CHAIRPERSONS

***Freddie Ann Hoffman, MD***
Chief Executive Officer, HeteroGeneity, LLC

***Shaw T. Chen, MD, PhD***
Team Leader, Botanical Review Team, Associate Director, Office of Drug Evaluation V, CDER, FDA

Although Natural Health Products (NHPs) are being sold in the United States as "foods" (including dietary supplements), many NHPs are now being evaluated for their potential as drugs. This session will examine clinical trials assessing NHPs for serious and life-threatening conditions. A discussion of the selection of starting dose, use of prior history of human use, protocol design, and the filing of an Investigational New Drug Application and New Drug Application with the US Food and Drug Administration will be discussed.

**A Phase I/II Study of the Botanical Drug (PHY906) Plus Capecitabine Advanced in Unresectable Hepatocellular Carcinoma**
***Robert Tilton, PhD***
Vice President, Science and Technology, Phytoceutica, Inc.

**Treatment for Hypertriglyceridemia: The Approval of a Heterogeneous "New" Drug**
***Robert A. Shalwitz, MD***
Executive Director, Clinical Development, Reliant Pharmaceuticals, Inc.

**Role of the National Center for Complementary Medicine (NCCAM) in Developing Natural Health Products as Drugs: Scientific Requirements for NIH Funding and Funding Programs**
***Johnathan (Josh) Berman, MD, PhD, FAAP***
Director, Office of Clinical and Regulatory Affairs, National Center for Complementary and Alternative Medicine, National Institutes of Health

## Session 143 OS1 - Outsourcing, RD

1:30 PM - 3:00 PM LEVEL = ■

**Room 147B**

### A Look at Today's Drug Development Outsourcing Practices: Successes, Failings, and Ways to Improve Them – Part 1 of 2

SESSION CHAIRPERSON

***John R. Vogel, PhD***
Drug Development Consultant, John R. Vogel Associates, Inc.

*Part 2 of this session is being held on Monday at 3:30 PM.*

This two-part session will begin with a presentation and discussion of the results of a recent comprehensive survey on sponsor views of the effectiveness of clinical drug development outsourcing. The second part of the session will focus on identifying practical approaches to ensuring successful outsourcing.

***David Ginsberg, DO***
Chief Medical Officer and Senior Vice President, Omnicare Clinical Research

***James Kirwin***
Assistant Vice President, Clinical Development, Wyeth Research

## Session 144 OS2 - Outsourcing, CR

1:30 PM - 3:00 PM LEVEL = ■

**Room 150A**

### Functional Outsourcing: How are Different Project Management Models Being Applied?

SESSION CHAIRPERSON

***Barbara J. Birch***
Alliance Business Director, i3 Statprobe

Over the past several years, sponsors have focused on functional outsourcing to expand the capacity of internal teams while retaining close control of clinical development projects. Can functional outsourcing be successful without project management? How can PM processes be streamlined? Where are the sponsor's greatest opportunities for cost savings? This session will address these questions and examine alternative approaches to project management in a functional alliance relationship.

***Cynthia R. Rutgers, MS***
Associate Director, Business Operations, Valeant Pharmaceuticals International

***David P. Facklam, MS***
Senior Director, Clinical Research, Astellas Pharma, Inc.

***Mark A. Sanders, MBA***
Director, Site Lead - New London, Contracts and Outsourcing, Pfizer Inc

## Session 145 PM1 - Project Management

1:30 PM - 3:00 PM LEVEL = ●

**Room 143AB** *Project Management Institute credits offered*

### Resource Management: Key Success Factors and Lessons Learned

SESSION CHAIRPERSON

***Michael Deagle, MBA***
Principal, PRTM

The scarcity of blockbuster launches combined with the expiration of existing patents is forcing many drug discovery and development companies to re-examine how to gain the most from their limited resources. Improving R&D productivity through optimized resource management is emerging as a critical core competency to accelerate time to market and maximize portfolio value. This session will highlight for participants resource management approaches and lessons learned within big pharma on key areas such as adapting to scale, integrating planning and control processes and methods for estimating demand.

**Portfolio and Resource Management: Adapting to Scale**
***Michael D. Taylor, PhD***
Senior Vice President, Global Project Management, Pfizer Global Research & Development

**Integrating the Planning and Control Processes**
***Leah Goldbroch, MBA***
Director, Global Project Management, Abbott Laboratories

**Developing a Standard and Validated Approach to Estimating Resource Demand**
***Linda Martin, MBA***
Principal, KMR Group, Inc.

## Session 146 PM2 - Project Management

1:30 PM - 3:00 PM LEVEL = ■

**Room 145A** *Project Management Institute credits offered*

### eXtreme Project Management: How to Succeed in the Face of Volatility

SESSION CHAIRPERSON

***Doug DeCarlo***
Principal, The Doug DeCarlo Group

Agility, not rigidity, is the key to success on extreme projects. This often requires that we break the rules and abandon the rigor and regimentation of traditional project management. Our panel will share experiences along a number of dimensions critical to delivering value in the face of change and uncertainty.

**The eXtreme Project Management Framework**
***Doug DeCarlo***
Principal, The Doug DeCarlo Group

**An Immunomodulatory Oligonucleotide: The Race to the Clinic**
***J. Michael Grindel, PhD***
President, EPD Pharma Solutions LLC

**An Immunomodulatory Oligonucleotide: The Race to the Clinic**
***Timothy M. Sullivan, PhD***
Vice President, Development, Hybridon, Inc.

## Session 147 PP - Public Policy/Law, CR

1:30 PM - 3:00 PM LEVEL = ●

**Room 103A** *CME, Nursing, and Pharmacy credits offered*

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

SESSION CHAIRPERSON

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

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

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

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

## Session 148 RD - R&D Strategy, AHC, CR, IS

1:30 PM - 3:00 PM LEVEL = ●

**Room 149AB** *Nursing credits offered*

### Monitoring and Managing a Changing Investigative Site Landscape

SESSION CHAIRPERSON

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

This session reviews and discusses the structure and longitudinal changes in the investigative site market. Representatives from the Tufts Center for the Study of Drug Development and the University of the Sciences in Philadelphia will present original research on the changing investigative site market and offer insights into ways that sponsors can more effectively and efficiently manage their investigative sites.

**A Look at the Changing Structure of the PI Landscape**
***Kenneth A. Getz, MS, MBA***
Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

**R&D Trends and Their Impact on the Study Conduct Market**
***Christopher P. Milne, DVM, MPH, JD***
Assistant Director, Tufts Center for the Study of Drug Development, Tufts University

**Implications of a Changing PI Landscape on Site Selection and Site Management**
***Harold E. Glass, PhD***
Professor and Director, Graduate Program in Pharmaceutical Business, University of the Sciences in Philadelphia

## Session 149 ST - Statistics

1:30 PM - 3:00 PM LEVEL = ■

**Room 201** *CME credits offered*

### Analyze as You Randomize?

SESSION CHAIRPERSON

***Michael P. O'Kelly, PhD, MA***
Statistical Consultant, Quintiles Ireland Ltd., Ireland

"Analyze as you randomize" is a principle of Fisher's which almost all statisticians feel they must follow. The history of the principle is explained and practical responses to it, from strict adherence to loose approximation, are described and argued for. Practical examples of where the issue arises include baseline adaptive randomization, and dose-escalation trials where a control is pooled across a number of separately randomized cohorts.

**A Regulatory Perspective on Adaptive Randomization**
***H. M. James Hung, PhD***
Team Leader and Acting Deputy Director, Division of Biometrics I, Office of Biostatistics, CDER, FDA

**Role of Randomization in Early Phase II Trials**
***Ad Theeuwes***
Project Statistician, CNS, Solvay Pharmaceuticals, Netherlands

**Biased Coin Randomization: When Can a Nominal Analysis of Covariance Be Appropriate?**
***James W. Frane, PhD***
Statistical Consultant

## Session 150 TR - Training

1:30 PM - 3:00 PM LEVEL = ●

**Room 151A**

### Pros and Cons of Web-based Training in a Global Research and Development Setting

SESSION CHAIRPERSON

***Michael van der Burght, MD, MBA***
Director, Department of Planning and Administration, Clinical R&D, Ferring Pharmaceuticals A/S, Denmark

Web-based training represents a great opportunity within the area of global training. The speakers will share experiences after introducing this tool into an academic R&D setting. The steps involved in introducing web-based training will be provided.

**Assessing if You Should Use Web-based Training**
***Kimberly N.M. Andrews, MEd***
Performance Consulting Manager, PPD Development

**Delivering Content Using Web-based Training: To Whom?**
***Bo Maach-Moller, MS***
Clinical Operations Manager, Nordic Area, Eli Lilly and Company, Denmark

**How to Implement Web-based Training**
***Michael van der Burght, MD, MBA***
Director, Department of Planning and Administration, Clinical R&D, Ferring Pharmaceuticals A/S, Denmark

## Session 151 VA - Validation, IT, RA

1:30 PM - 3:00 PM LEVEL = ●

**Room 209AB**

### Current Regulatory Issues

SESSION CHAIRPERSON

***Harry C. Huss, MS***
Manager, Quality Auditing Services, Stelex, Inc.

This session will address three topics that generate a great deal of discussion within the pharmaceutical industry. First, risk assessment strategies and management related to computer system validation have been employed unofficially for a long time, but recent guidelines issued by FDA have called for documented and justified risk assessments related to computer system controls. Second, the cost/benefit of computer system validation has long been a controversial topic, especially when discussed between company management and quality assurance. Finally, with modern pharmaceutical companies operating routinely on a global basis, the issue of regulatory requirements of authorities outside the US can be confusing. By addressing these topics, the session will provide a broad range of information that all pharmaceutical professionals with computer system control responsibilities should find interesting and useful.

**Risk Assessment and Management Specific to Computer Validation**
***Leonard A. Grunbaum, MBA***
Partner, The Practical Solutions Group, LLC

**Cost/Benefit of Validation**
***Breffni K. Martin***
Company Director, RegIntel Ltd., Ireland

**International Regulations on Quality Systems and Risk Affecting Manufacturing and Validation: Current and Future Initiatives**
***Louis A. Angelucci, III***
Vice President, AAC Consulting Group, Inc.

3:00 PM - 3:30 PM **REFRESHMENT BREAK**

**Exhibit Halls ABC, Lower Level**
**Convention Center**

## Session 152 AD - Advertising, MA, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 202B** *Pharmacy credits offered*

### The OIG/US Attorney/Attorney General Update: Where They've Been, Where They Are, and Where They're Going

SESSION CHAIRPERSON

***Norman A. Drezin, RPh, JD***
President, Drezin Consultants, LLC

The OIG Compliance Program Guidance, the PhRMA Code on Interactions with Healthcare Professionals, and the enforcement posture of federal and state law enforcement agencies have significantly changed the concerns and compliance issues involved with the marketing of prescription drugs.

This session will examine the concerns of agencies other than FDA over the last ten years – from their initial concerns through lessons learned from the cases they've pursued, to where they are going tomorrow. It will examine the interests of federal and state law enforcement agencies in the marketing practices of the prescription drug, biologic, and medical device industries, and provide an understanding of why the authorities select or pursue certain cases, the types of conduct that concern these agencies, and what their concerns are for the future.

***Thomas Kanwit, JD***
Assistant US Attorney, US Attorney's Office

***T. Reed Stephens, JD***
Partner, Sonnenschein Nath & Rosenthal LLP

## Session 153 CMC - Chemistry, Manufacturing, and Controls, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 150B**

### ICH Quality Guidance: Q5E

SESSION CHAIRPERSON

***Keith Webber, PhD***
Acting Director, Office of Biotechnology Products, CDER, FDA

The ability to make changes to a pharmaceutical manufacturing process is critical to ensuring the availability of drugs of the highest quality and affordability. The ICH Q5E document provides for a harmonized set of principles to assess the impact of manufacturing changes on biotechnology drug products to ensure that there has been no adverse impact on quality, safety, or efficacy. This session will provide an overview of the ICH Q5E document and will explore aspects of its utilization.

**Industry Perspective**
***Anthony S. Lubiniecki, ScD***
Vice President, Technology Transfer and Project Planning, Centocor

**FDA Perspective**
***Barry Cherney, PhD***
Deputy Director, Division of Therapeutic Proteins, Office of Biotechnology Products, CDER, FDA

**Panel Discussion/Q&A Period**

## Session 154 CP - Clinical Safety and Pharmacovigilance, eClin, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 207A**

### Electronic Submission of ICSRs

SESSION CHAIRPERSONS

***William W. Gregory, PhD***
Director, Regulatory Affairs, Pfizer Inc

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

Technical and regulatory hurdles for electronic transmission of Individual Case Safety Reports (ICSRs) by companies to regulatory authorities have been overcome in the three ICH regions. Indeed, paperless submission of expedited ICSRs to the FDA, EMEA, MHLW, and other national authorities is now a reality, and other business partners are actively engaged. The scope now includes reports from both clinical trial and spontaneous sources. In November 2005 new regulation in Europe will impact products approved under the Central Authorisation Procedure, Mutual Recognition Procedure, and National Authorisation Procedure. Electronic trading of ICSRs requires careful integration of the ICH E2B(M), M2, and M1 (MedDRA®) standards, which are interdependent. In this session, the current status of electronic case reporting in Europe, Japan, and the US will be discussed from the perspectives of regulators

and industry, with the focus on the situation in the US and Europe. Summary statements from each region and a public update from the ICH E2B(M) and M5 Working Groups will be followed by a panel discussion.

**Electronic Case Reporting: Bird's Eye View of the Terrain**
***William W. Gregory, PhD***
Director, Regulatory Affairs, Pfizer Inc

**Status of Electronic Case Reporting in the US and the AERS Database**
***Roger A. Goetsch, PharmD***
Director, Regulatory Affairs, Office of Drug Safety, CDER, FDA

**Status of EudraVigilance and Related Electronic Reporting with All Stakeholders**
***Sabine Brosch, MSc, PhD***
Deputy Head of Sector, Pharmacovigilance, EMEA, EU

**Industry Perspectives on Electronic Case Reporting with Multiple Trading Partners**
***Kostas Kidos, MSc***
Senior Director, Regulatory Services, Merck & Company, Inc.

**Panel Discussion**
***Michael A. Ibara, PharmD***
Director, Information Resources, Worldwide Safety, Pfizer Inc

## Session 155 CR1 - Clinical Research and Development, RA

3:30 PM - 5:00 PM LEVEL = ●

**Room 145A** *Nursing and Pharmacy credits offered*

### Global Pediatric Trials

SESSION CHAIRPERSON

***Daniel Brasseur, MD, PhD***
Chairman of CHMP at EMEA, EU; Ministry of Public Health, Belgium

This session will address the New European Pediatric Regulation within the global context of drug development, most particularly in the US. The Pediatric Regulation will be described and its impact assessed from a global industry viewpoint.

**European Situation**
***Daniel Brasseur, MD, PhD***
Chairman of CHMP at EMEA, EU; Ministry of Public Health, Belgium

**Pediatric Regulation**
***Magali Lecomte-Bekkaï, PharmD, MS***
Director, Regulatory Information - IDRAC, Thomson Scientific, France

**EMEA Activities in Preparation of the Pediatric Regulation**
***Agnès Saint-Raymond, MD, PhD***
Head of Sector, Orphan Drugs and Scientific Advice; Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

## Session 156 CR2 - Clinical Research and Development, ST

3:30 PM - 5:00 PM LEVEL = ●

**Room 145B** *Pharmacy credits offered*

### Monitoring of Clinical Endpoint Trials

SESSION CHAIRPERSON

***Nacer E. Abrouk, PhD***
Director, Department of Statistics and Data Management, ALZA Corporation

The design, execution, analysis and interpretation of large endpoint trials have many challenges. Interim monitoring of data pertinent to safety and efficacy can be an intricate process involving several committees with differing discipline affiliations. This session will provide an indispensable discussion of the challenges encountered, and some best practices recommendations.

**Overview of Clinical Endpoint Trials**
***Nacer E. Abrouk, PhD***
Director, Department of Statistics and Data Management, ALZA Corporation

**Overview of Product Safety Assessment Strategies**
***Noel Mohberg, PhD***
Consultant/Advisor

## Session 157 CR3 - Clinical Research and Development

3:30 PM - 5:00 PM LEVEL = ■

**Room 147A** *Pharmacy credits offered*

### How to Get Reliable Results from Feasibility Studies: Factors and Metrics

SESSION CHAIRPERSON

***Didier Saur, MD***
European Medical Director, MDS Pharma Services, France

Feasibility studies have the potential to provide powerful results, but are exposed to serious inherent pitfalls, which should be controlled, to obtain confident results. This session will present the methodological considerations (what are the factors impacting on results and their interactions), and provide some quality metrics, which will allow us to determine the "confidence interval" of the results.

**Feasibility Studies: What Is It? What Are the Stakes? What Are the Challenges?**
***Simon Larkin, PhD***
Vice President, Drug Development, Europe, Kyowa Hakko Ltd., UK

**Factors Impacting the Feasibility Results**
***Gernot Wagner, MD***
Senior Consultant, Corporate External Services, Merck KgaA, Germany

**How to Assess the Quality of the Feasibility Study**
***Didier Saur, MD***
European Medical Director, MDS Pharma Services, France

## Session 158 CR4 - Clinical Research and Development, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 147B** *CME and Pharmacy credits offered*

### The Clinical, Technical, and Regulatory Validation of Novel Surrogate Endpoints

SESSION CHAIRPERSON

***David S. Lester, PhD***
Senior Director, Pfizer Inc

The opportunity to leverage novel surrogate endpoints to improve decision making in a clinical development program has been recognized, but significant confusion and inconsistency remain in establishing criteria for validation. This session will address the major issues for validation of a surrogate endpoint and standards for achieving a claim of validation.

**A Pharmaceutical Industry Perspective of Validation in Bioimaging Clinical Trials**
***David S. Lester, PhD***
Senior Director, Pfizer Inc

**A Regulatory Perspective on the Validation of Surrogate Endpoints**
***Lawrence J. Lesko, PhD***
Director, Office of Clinical Pharmacology and Biopharmaceutical Science, CDER, FDA

**The Technical Validation of Surrogate Endpoints for Clinical Development**
***Craig H. Lipset, MPH***
Senior Program Director, Oncology, Compound Therapeutics, Inc.

## Session 159 CR5 - Clinical Research and Development, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 146A** *Pharmacy credits offered*

### A Key to Success in Bringing a Product to Market Is Proper Protocol Design

SESSION CHAIRPERSON

***Lynda Y. Sutton***
Chief Operating Officer and Chief Regulatory Officer, Cato Research, Ltd.

Success in bringing a drug to market depends on factors that must be addressed long before initiating clinical trials. One such factor is proper protocol design. A good protocol depends on specific, carefully conceived objectives. Without clear objectives, the chance for success is at risk.

**Avoid the Landmines: Concentrate on the Right Objectives**
***Allen Cato, MD, PhD***
President, Cato Research, Ltd.

**Examples of Where Protocol Design Became a Critical Factor in the Success or Failure of a Product**
***Robert J. Temple, MD***
Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

**Human Performance Factor Analysis to Predict and Mitigate Protocol Violations**
***Lawrence A. Meinert, MD, MPH***
Vice President, Medical and Scientific Affairs, Covance, Inc.

## Session 160 CS - Clinical Supplies, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 143C**

### Handling the Tough Logistical Issues in Clinical Supplies

SESSION CHAIRPERSON

***David F. Bernstein, PhD***
Vice President, Pharmaceutical Science and Regulatory Compliance, Cato Research West

One of the more challenging aspects of the clinical supply process is the determination of expiry dating (retest date, use-by date) for investigational products when there is little or no prior data available. A common approach is to monitor the stability of investigational products concurrently with their clinical use to ensure that the drug products continue to meet their quality attributes and specifications. However, the EU requirement for investigational products to bear an expiry date on the actual supplies poses a difficult challenge when an originally short expiry date needs to be extended. In this case, a relabeling procedure is required and poses potential procedural, regulatory, and documentation issues. This session will also include a look at the unique challenges of transport and use of investigational products in Eastern Europe and Russia.

**Automated Tools for Drug Expiry Management and Reconciliation**
***David B. Sundin, MS, MBA, MPH***
Director, Client Services, Dynarand, LLC

**Clinical Trial Material Issues in Eastern Europe and Russia**
***Sergei Varshavsky, PhD, MD***
Evidence Clinical and Pharmaceutical Research

**Global Regulatory Requirements for Expiry Dates**
***David F. Bernstein, PhD***
Vice President, Pharmaceutical Science and Regulatory Compliance, Cato Research West

## Session 161 CTM - Clinical Trial Management, FI

3:30 PM - 5:00 PM LEVEL = ◆

**Room 140B** *CME credits offered*

### A Comprehensive Analysis of Factors Influencing the Length and Corresponding Cost

SESSION CHAIRPERSON

***Harold E. Glass, PhD***
Professor and Director, Graduate Program in Pharmaceutical Business, University of the Sciences in Philadelphia

This session will address the issue of why some phase III clinical trials are completed more quickly and efficiently than others, and the financial consequences of these variations. The results of our research will be determined by thoroughly analyzing in-field clinical data provided by 10 major pharmaceutical companies, in addition to extensive interviews conducted with representatives of those companies.

***Harold E. Glass, PhD***
Professor and Director, Graduate Program in Pharmaceutical Business, University of the Sciences in Philadelphia

***Jeffrey J. DiFrancesco, MS, ME***
Managing Director, Jeffrey Group Inc.

***Mark Travers, PhD***
Vice President, Global Trial Coordination for Global Clinical Operations, Johnson & Johnson Pharmaceutical Research and Development, LLC

## Session 162 DM - Document Management/ eSubmissions, RA

3:30 PM - 5:00 PM LEVEL = ●

**Room 206**

### Data Standards Initiatives – Part 2 of 2

SESSION CHAIRPERSON

***Gary G. Walker***
Senior Document Management Advisor, Electronic Regulatory Submissions, Regulatory and Technical Services, Quintiles, Inc.

*Part 1 of this session is being held on Monday at 1:30 PM.*

Clinical Data Interchange Standards Consortium (CDISC) and Health Level 7 (HL7) have been at the lead in creating standards for data interchange and submissions. FDA has been collaborative in creating these standards and has pointed to them as the standards to use when submitting data. This presentation will provide an update on the current state of these initiatives and their impact on the submission and review of datasets.

**The Case Report Tabulation Data Definition Specification (CRTDDS) (Alias "Define.XML"): The What and Why**
***William J. Qubeck, MBA, MS***
Electronic Submission Data Group Leader, Pfizer Inc

**Standard for Exchange of Nonclinical Data (SEND)**
***Thomas Papoian, PhD, DABT***
Senior Pharmacologist, Cardio-renal Drug Products, CDER, FDA

**Case Study: Perspectives on Implementing the FDA Digital ECG Initiative**
***Brian Hoffman***
Director, ECG/IVR Services, Quintiles, Inc.
***Randy Spaulding***
Vice President, Clinical Research, Mortara Instrument

## Session 163 eCLIN - eClinical, CR

3:30 PM - 5:00 PM LEVEL = ●

**Room 207B**

### The National Health Information Network (NHIN): Changing the Role of Biopharma in Clinical Research

SESSION CHAIRPERSON
***Charles Jaffe, MD, PhD***
Vice President, Life Sciences, SAIC

The United States has embarked on an ambitious 10-year plan to computerize healthcare. This will require the seamless integration of systems and the exchange of interoperable data. The biopharmaceutical industry will benefit from the development of standards to achieve this end, as well as from the integration of clinical research into the healthcare continuum.

**Evolution of the Regional Health Information Organization with the NHIN**
***William A. Yasnoff, MD, PhD***
Managing Partner, NHII Advisors

**Implications of Connecting the Cancer Bioinformatics Grid (caBIG) to the NHIN**
***Sue Dubman, MA***
NCICB Director, Applications, National Cancer Institute, Center for Bioinformatics, National Institutes of Health

**Global Trial Bank: Connecting Clinical Research to Clinical Care**
***Don E. Detmer, MD, MA***
President and CEO, American Medical Informatics Association

## Session 164 FI - Finance, RD

3:30 PM - 5:00 PM LEVEL = ●

**Room 140A**

### Impact of SOX Act on R&D Costs of the Pharmaceutical Industry

SESSION CHAIRPERSON
***Joseph Curran, CPA***
Senior Advisor, Relevante, Inc.

Operational and financial risks have greatly increased due to the competition among pharmaceutical companies to bring products to market faster. The Sarbanes-Oxley Act (SOX Act) has legislated a control regime whereby companies need to ensure that an internal control mechanism is established and that management attests to its effectiveness. Among the various risks, risks arising out of R&D cost management need to be constantly monitored and evaluated.

**Impact of SOX Act on R&D Costs of the Pharmaceutical Industry**
***Fred Kaplan, CPA, CBM***
Director, Financial Consulting, Relevante, Inc.

***Robert Rausch, MBA***
Consultant (formerly Senior Vice President - Finance, AstraZeneca)

## Session 165 GCP - Good Clinical Practices, CR, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 202A**

### The Rising Cost of Quality: Is It Making a Difference?

SESSION CHAIRPERSON
***Gregory M. Hockel, PhD, MBA***
Senior Vice President, Regulatory Affairs, PharmaNet

There has been a steady, worldwide increase in the quality assurance effort relating to good clinical practice (GCP). Has the effort paid off? Are subjects/patients safer? Are fewer drugs being withdrawn from the market for safety reasons? Is the adoption of a more "risk-based" approach for adherence to GCP appropriate? These and other questions will be discussed by panelists representing both industry (US and Europe) and US/European regulatory authorities.

**Today's Quality Assurance Mantra: More Is Never Enough**
***Gregory M. Hockel, PhD, MBA***
Senior Vice President, Regulatory Affairs, PharmaNet

**Did the Increase of Clinical Trial Requirements Improve Quality and Enhance Patients' Safety?**
***Regina Freunscht***
Head, Quality Assurance, Accovion GmbH, Germany

**Quality Assurance: Investment in the Future**
***Donald W. Ashbrook, PhD, RAC***
Chief Executive Officer, GPA International

## Session 166 IS - Investigator Sites, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 101** *CME, Nursing, and Pharmacy credits offered*

### Designing and Executing Studies that Meet Patient Needs

SESSION CHAIRPERSON
***Burt P. Koonsvitsky, PhD***
Director, Strategic Development, UBC

This session will explore how to scrutinize a study design to ensure that patients' needs are adequately addressed and how to assess the feasibility of conducting the study at a site. Some examples of successful and unsuccessful studies will be examined.

**Sponsor Perspective**
***Julie Prejean Weikel, RN, OCN***
Clinical Trials Coordinator, Texas Cancer Care

**CRO Perspective**
***Kathryn Hutchinson, MSc***
Managing Director, AMS - Advanced Medical Services - Europe, UK

**Site Perspective**
***Terri Gaffney***
Associate Director, Clinical Operations, Procter & Gamble Pharmaceuticals, Inc.

## Session 167 IT - Information Technology, eClin, IS

3:30 PM - 5:00 PM LEVEL = ■

**Room 204BC**

### The Ease of Paper, the Speed of Electronics: The Next Generation of Data Collection

SESSION CHAIRPERSON
***Michael J. Rosenberg, MD, MPH***
President and CEO, Health Decisions, Inc.

Adoption of technology for data collection has been slowed in part by user issues at clinical sites. A new method of data entry that combines the ease of traditional paper with electronic capture and transmission through a special pen with an optical sensor will be demonstrated and compared with other data collection options.

**Strengths and Limitations of Different Methods of Data Collection**
***Rick Farris***
Chief Technology Officer, Health Decisions, Inc.

**New Technology in the Regulated Environment**
***Lisa A. Olson***
Principal Compliance Consultant, SEC Associates, Inc.

**Data Collection from the User Perspective**
***David Archer, MD***
Professor, Obstetrics-Gynecology, Eastern Virginia Medical School

## Session 168 NC - Nonclinical Laboratory Safety, CMC, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 103B**

### Pharmaceutical Excipient Development: A Preclinical Challenge

SESSION CHAIRPERSON

***Paul Baldrick, PhD***
Head, Regulatory Affairs, Covance Laboratories Europe, UK

The development of excipient materials for use in drug formulations represents a growing area of interest (and of invested time and cost) for pharmaceutical companies. Development has been fueled by the increasing need for more sophisticated excipients and/or new uses for established ones. A key consideration is, "How safe is the material?" Answering such a question is vital, especially since pharmaceutical excipients can no longer be regarded as totally inert/inactive substances within the formulation of pharmacologically active drugs. Thus, evaluation for potential toxicity is vital, and the proposed session will examine the safety evaluation process for excipients (new, "essentially" new, and established) from a preclinical perspective and will show that the role of the toxicologist is indeed a challenging one.

**Preclinical Development of Excipients: Getting It Right!**
***Paul Baldrick, PhD***
Head, Regulatory Affairs, Covance Laboratories Europe, UK

**Regulatory Experiences with Excipients**
***David R. Jones, MSc***
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**Halt the Catch-22 Need for Innovating New Excipients**
***Ashok V. Katdare, PhD***
Vice President, R&D Laboratories, Morton Grove Pharmaceuticals, Inc.

## Session 169 OS - Outsourcing, RD

3:30 PM - 5:00 PM LEVEL = ■

**Room 150A**

### A Look at Today's Drug Development Outsourcing Practices: Successes, Failings, and Ways to Improve Them – Part 2 of 2

SESSION CHAIRPERSON

***John R. Vogel, PhD***
Drug Development Consultant, John R. Vogel Associates, Inc.

*Part 1 of this session is being held on Monday at 1:30 PM.*

This two-part session will begin with a presentation and discussion of the results of a recent comprehensive survey on sponsor views of the effectiveness of clinical drug development outsourcing. The second part of the session will focus on identifying practical approaches to ensuring successful outsourcing.

***David Ginsberg, DO***
Chief Medical Officer and Senior Vice President, Omnicare Clinical Research

***James Kirwin***
Assistant Vice President, Clinical Development, Wyeth Research

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

## Session 170 PM1 - Project Management

3:30 PM - 5:00 PM LEVEL = ■

**Room 144ABC** *Project Management Institute credits offered*

### Enterprise Project Management and Capacity Management: An Interactive Session

SESSION CHAIRPERSON

***Raymond G. Starrett, MLS***
Project Manager, GlaxoSmithKline

Participants will engage in a roundtable, interactive working session to explore the state of the art of enterprise PM and capacity management within the biopharm industries.

***Martin D. Hynes, III, PhD, MS***
Director, Quality and Operations, Pharmaceutical Product Research and Development, Eli Lilly and Company

***Randal J. Ofensend, MBA***
Associate Director, Clinical IT&S, Cephalon

## Session 171 PM2 - Project Management, RD

3:30 PM - 5:00 PM LEVEL = ◆

**Room 143AB** *Project Management Institute credits offered*

### Go/No Go Decisions

SESSION CHAIRPERSON

***Rajendra Mohabir, PhD***
Therapeutic Area Head, Oncology, R&D Project Management, Amgen Inc.

This session will discuss factors that need to be considered when Go/No Go decisions are made during drug development. Wherever possible, case study examples will be provided without disclosure of proprietary information.

**Decision Making Around Lead Product Candidates and Back-up/ Follow-on Molecules**
***Lewis K. Lee, MS, SM***
Director, Planning and Portfolio Management, Amgen Inc.

**The Team's Role in GNG Decisions: Helping Management Actually Make One**
***Joseph A. Carlino, PhD, MS***
Former Senior Director, Biopharmaceuticals Development Management, Chiron Corporation

## Session 172 PP - Public Policy/Law, CR, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 103A** *CME, Nursing, and Pharmacy credits offered*

### Clinical Trials: Legal and Regulatory Jeopardy

SESSION CHAIRPERSON

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

This session will include presentations on current legal and regulatory issues that affect sponsors, investigators, and IRBs in the conduct of clinical trials. This session will also feature preselected members of the audience playing a game utilizing a very popular television game show format. The questions will primarily be limited to legal and regulatory issues. It will be a lot of fun and the winner will be awarded a fabulous (but modest) prize.

***John M. Isidor, JD***
Chief Executive Officer, Schulman Associates IRB, Inc.

***Jeffrey N. Gibbs, JD***
Director, Hyman Phelps & McNamara, P.C.

## Session 173 RA1 - Regulatory Affairs, RD

3:30 PM - 5:00 PM LEVEL = ■

**Room 151A**

### The New Europe for Pharmaceuticals: From Research and Development to Marketing Authorization and Marketing

SESSION CHAIRPERSON

***Rolf Bass, MD***
Resident, Twinning Advisor (PHARE), Head of Department, URPL (Polish Authority), Poland; BfArM (German Authority), Germany

The new Europe for Pharmaceuticals is arriving everywhere. Companies from Central and Eastern Europe are as keenly interested to authorize and market their products (usually generics) in Western Europe – and beyond, as are Western companies to do so in Central and Eastern Europe – and beyond.

Whereas the EU system of European Commission, EMEA and national competent authorities have agreed with trade associations the conditions to be fulfilled for their products "to go East," no such arrangements have become available so far "to go West." Questions and problems span from manufacturing authorizations and GMP inspections to update of marketing authorizations of Central/Eastern locally marketed products before they would fulfill the EU-acquis communautaire, which is the precondition for any such pharmaceutical traveling westwards.

In such scenarios, economically driven decisions have to be taken including performance of studies and where, understanding market needs and opportunities, and outsourcing of which steps outside the originator country.

These issues and questions will be addressed from the viewpoint of a regulator (Austria), the European Generic Medicines Association (EGA), and a clinical CRO operating throughout Europe. Missing links will be introduced and filled in from the chair, who currently serves as Advisor to the Polish Ministry of Health.

**Does West (East) Outsource (and Why) from East (West)? Special Aspects: European Trade Association (Namely Generics)**
***Beata Stepniewska, MS***
Pharmacist, Regulatory Affairs and EU Accession, European Generic Medicines Association, Belgium

**Does West (East) Outsource (and Why) from East (West)? Special Aspects: Clinical Trials Conditions in Europe**
***Veronique Larsimont, PhD***
Director, Clinical Operations, IMFORM GmbH, International Clinical Research, Germany

**Does West (East) Outsource (and Why) from East (West)? Special Aspects: European Regulator Viewpoint and Pharmaceutical Quality Documentation**
***Rolf Bass, MD***
Resident, Twinning Advisor (PHARE), Head of Department, URPL (Polish Authority), Poland; BfArM (German Authority), Germany

## Session 174 RA2 - Regulatory Affairs, CP, CR, RD

3:30 PM - 5:00 PM LEVEL = ●

**Room 152A**

### PMDA and Related Drug Safety Activities

SESSION CHAIRPERSON

***Deborah Yaplee***
US FDA Mansfield Fellow, In Residence at MHLW, Tokyo, FDA

On April 1, 2004, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) began conducting NDA reviews for the Ministry of Health Labour and Welfare. This session will be used to provide an overview and update on the PMDA's overview and an update on its postmarketing drug safety activities after its first year.

***Kaori Nomura***
Principal Official for Electronic Data Submissions, Office of Safety, Safety Information Division, PMDA, Japan

***Hiroko Koyama***
Senior Leader, Drug Safety Evaluation Department, Chugai Pharmaceutical Company, Ltd., Japan

***Jennifer Driscoll, MS***
Pharmacovigilance Officer, Banyu Pharmaceutical Company, Ltd., a Subsidiary of Merck & Co., Inc., Japan

## Session 175 RA3 - Regulatory Affairs, PP

3:30 PM - 5:00 PM LEVEL = ■

**Room 152B**

### Making International Nonproprietary Names (INNs) User-friendly

SESSION CHAIRPERSON

***Raffaella G. Balocco-Mattavelli, PhD, PharmD***
Responsible Officer, INN Programme, World Health Organization, Switzerland

This session focuses on efforts to streamline the process of assigning International Nonproprietary Names. It also highlights how transparency and efficiency can be improved in cooperation with the applicants and other involved parties such as regulators.

**The Industry Perspective**
***Robert E. Lee, Jr.***
Assistant General to Patent Counsel, Patents-therapeutic Areas Department, Eli Lilly and Company
Pharmacopoeia Expert

**The FDA Perspective**
***David Lewis, PhD***
Review Chemist, Office of New Drug Chemistry, CDER, FDA

**The National and European Perspective**
***Noël Wathion, Pharm***
Head of Unit, Postauthorization Evaluation of Medicines for Human Use, EMEA, EU

## Session 176 RA4 - Regulatory Affairs, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 154AB**

### Trial Design and the Study Data Tabulation Model

SESSION CHAIRPERSON

***Diane E. Wold, PhD***
Director, Data Standards Development and Management, GlaxoSmithKline

The Study Data Tabulation Model (SDTM) is now referenced as specification in FDA guidance. It includes the Trial Design Model, a completely new kind of data for submission. This session explains what the Trial Design Model is, how it can be implemented, and how it relates to the larger problem of representing the protocol in machine-readable form.

**The Trial Design Model as Part of a Structured Protocol Representation**
***Cara Willoughby, MA***
Co-chair, Protocol Representation Group; Associate Consultant, Scientific Communications-Regulatory, Eli Lilly and Company

**Introduction to the Trial Design Model**
***Diane E. Wold, PhD***
Director, Data Standards Development and Management, GlaxoSmithKline

**Implementation of the Trial Design Model**
***Sherry G. Green***
Director, Statistical Programming, Quintiles, Inc.

## Session 177 RA5 - Regulatory Affairs, CP

3:30 PM - 5:00 PM LEVEL = ■

**Room 151B** *CME and Pharmacy credits offered*

### Risk/Management Throughout Product Development: Clarifying the Requirements and Managing Expectations

SESSION CHAIRPERSON

***Carrol Marcus, MSc***
Vice President, Europe, Drug Development Consulting Practice, PAREXEL Consulting, UK

The session explores the current thinking in industry and the regulatory authorities about risk management strategies, how these can be built into drug development programs and how such a program impacts the development process.

***Valerie E. Simmons, MD***
Advisor and EU Qualified Person for Pharmacovigilance, Eli Lilly and Company, UK

***Geoff J. Barton***
Director, Regulatory Policy and Intelligence, Europe, GlaxoSmithKline, UK

***Dr. June Raine***
Group Manager, Medicines and Healthcare products Regulatory Agency (MHRA), UK

*Discussant*

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

## Session 178 RA6 - Regulatory Affairs

3:30 PM - 5:00 PM LEVEL = ●

**Room 146B**

### Electronic Management of Drug Information and Labeling

SESSION CHAIRPERSON

***Lisa Stockbridge, PhD, MS***
Regulatory Reviewer, Office of Information Management, CDER, FDA

To improve patient healthcare through better health information management, the FDA is moving toward the electronic management and standardization of drug information and labeling. Uniform standards for drug labeling and listing are fundamental to this goal. FDA, working with Health Level 7, has developed Structured Product Labeling (SPL) as a standard format for exchanging labeling information among computer systems. The Substance Registration System has been developed to generate and store unique, unambiguous identifiers for substances in FDA-regulated drug products. JANUS is a database modeled after the CDISC Study Data Tabulation (SDTM). The SDTM standardizes the submission of the results of clinical trials-demographics, raw data from case report forms, and derived data.

**FDA's Structured Product Labeling Program Update**
***Lisa Stockbridge, PhD***
Regulatory Reviewer, Office of Information Management, CDER, FDA

**FDA's Substance Registration System**
***Jonathan Cook, MS***
Operation Research Analyst, Office of Pharmaceutical Science, CDER, FDA

**FDA's JANUS Data Warehouse**
***Norman Stockbridge, MD, PhD***
Acting Director, Division of Cardio-Renal Drug Products, CDER, FDA

## Session 179 RD - R&D Strategy, BT, PM

3:30 PM - 5:00 PM LEVEL = ■

**Room 149AB**

### Medical Affairs for Biotechnology/Pharmaceutical Start-ups: Strategies for Launch (Research and Medical Communications)

SESSION CHAIRPERSON

***Ronald P. Evens, PharmD, FCCP***
Clinical Professor, University of Florida; President, MAPS 4 Biotec, Inc.

For a first product launch by a start-up company, the medical affairs unit plays both a strategic and operational role, with both external and internal audiences. At a start-up, resources are limited, and the science and marketing divisions need bridging for optimal periapproval strategy. A strategy and plan for medical affairs must be integrated with corporate, product, and research strategies. Strategic analyses are needed, roadblocks should be anticipated, and compliance with new government regulations can be a significant demand. Many further needs exist that require research data and medical support, and outsourcing versus company staffing versus corporate alliances is another strategic consideration. This session will address strategies and related staffing, goals, timelines, and action plans for the medical affairs unit involved in a product launch for research and medical communications.

**Strategic and Program Overview for Medical Affairs at a Start-up Company: What to Do, Why, How, When, and by Whom?**
***Ronald P. Evens, PharmD, FCCP***
Clinical Professor, University of Florida; President, MAPS 4 Biotec, Inc.

**Product Experiences and Communications: Strategies and Programs**
***Mario F. Sylvestri, PhD, PharmD***
Senior Director, Regulatory and Medical Information, Amylin Pharmaceuticals, Inc.

**Postmarketing Studies: Challenges – Strategies – Planning – Programs**
***Stanfell Boone, MD, MBA***
Associate Director, Amgen Inc.

## Session 180 ST - Statistics, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 201** *CME credits offered*

### Multiregional Trial: Global and Japanese View in Biostatistics

SESSION CHAIRPERSON

***Tohru Uwoi, PhD***
Division Manager, ICH Intelligence, Medical Support Business Unit, Bellsystem24, Inc., Japan

Global development and simultaneous worldwide launching has been a hot issue for several years. Due to the ICH E5 guideline, one approach to global submission became possible, but the E5 approach may result in delayed submission in some countries, especially Japan. With the experiences of bridging strategies, regulators and industries became aware of the effectiveness of the prospective bridging approach. Even with the prospective approach, delay problems in some regions are not solved because of the asymmetric nature of the bridging. This session is devoted to the alternative approach of multiregional trials taking into account the utilization of non-ICH region trials.

**Development Strategy with Multiregional Trials**
***Kimihiro Kasamo, MD, PhD***
Deputy Head, Clinical Development Institute, Senior Director, Safety Information and Vigilance, Banyu Pharmaceutical Co., Ltd., Japan

**Statistical Considerations on Design and Evaluation in Multiregional Trials**
***Toshiyuki Sato, PhD***
Assistant Manager, Biostatistics and Pharmacokinetics Group, Data and Biostatistics Center, R&D Division, Daiichi Pharmaceutical Co., Ltd., Japan

**Statistical and Regulatory Issues in Multiregional Trials**
***Simon Day, PhD***
Statistics Unit Manager and Scientific Advice Coordinator, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

*Discussant*
***Robert T. O'Neill, PhD***
Director, Office of Biostatistics, CDER, FDA

## Session 181 TR - Training, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 146C**

### Training and Clinical Research in the 21st Century: You Can Get Your Drug to Market Faster!

SESSION CHAIRPERSON

***Jennifer Lansink***
Founder and CEO, TRC Clinical, Inc.

In this highly interactive discussion, we will investigate how accelerated learning techniques, when applied effectively to a training environment, can positively impact sponsor-to-site communication and increase the amount of information retained by site personnel. This hands-on session requires participants to interact with their peers and apply newly learned techniques. This session also includes a review of the industry's leading online technology and distance learning principles. Get more from every site interaction!

***Jennifer Lansink***
Founder and CEO, TRC Clinical, Inc.

***Jeffrey D. Goldford***
Founding Partner, The Iris Group

***Bernice Kuca, MS***
Director of Clinical Operations, Oscient Pharmaceuticals

***Olivia Woodard***
Independent Consultant

## Session 182 VA - Validation

3:30 PM - 5:00 PM LEVEL = ■

**Room 209AB**

### Validation in the Real World: Global System and Revalidation Approaches

SESSION CHAIRPERSON

***Joanne S. Malia, MS, MS***
Assistant Director, Medical Research Quality Management, Purdue Pharma L.P.

This session will discuss some of the more challenging validation situations in today's global pharmaceutical environment. These include, but are not limited to, implementation of global systems to benefit both business and regulatory compliance concerns and the revalidation of systems currently existing in a validated state. The session will provide a mixture of points to consider as well as examples from real-life experiences.

**Case Study: Challenges in Implementing a Global SDLC Process**
***Marian M. Mutch, MSc***
Manager, Global IT Quality Systems, Europe, Covance Laboratories Ltd., UK

**Managing the Validation Challenges Associated with Global Systems Implementation**
***Kate Townsend, MS***
Solutions Partner, Validation and Compliance, BusinessEdge Solutions

**Revalidation Triggers**
***Gregory D. Gogates***
Vice President, Quality Management and Regulatory Affairs, CRF, Inc.

5:00 PM **END OF MONDAY SESSIONS**

7:30 AM - 5:30 PM **ATTENDEE REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 5:30 PM **EXHIBITOR REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 5:30 PM **SPEAKER REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 8:15 AM **CONTINENTAL BREAKFAST**
Meeting Rooms 145-147, Concourse
Convention Center

9:00 AM - 5:30 PM **PROFESSIONALS' POSTER SESSION**
Exhibit Hall A Entrance, Lower Level, Convention Center

9:00 AM - 5:30 PM **EXHIBITS OPEN**
Exhibit Hall A, B & C, Lower Level, Convention Center

5:00 PM - 6:30 PM **CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH MEETING**
Meeting Room 103B, Convention Center

## Session 201 AD - Advertising, MA, PP, TR

8:30 AM - 10:00 AM LEVEL = ■

**Room 202B**

### Support for CME: How Difficult? How Dangerous?

SESSION CHAIRPERSON

***David G. Adams, JD***
Partner, Venable LLP

This session will explore the challenges facing the pharmaceutical industry with regard to commercial support of CME. The panel will discuss the standards that have been set by the medical profession and implemented through the ACCME for accredited educational programs. It will also address the broader landscape of potential legal liability associated with support for CME and will consider how compliance with ACCME's Standards for Commercial Support may provide protection from actions brought by state and federal authorities, as well as by whistle-blowers.

**Overview of the Professional and Regulatory Environment**
***David G. Adams, JD***
Partner, Venable LLP

**ACCME Standards for Commercial Support: A Strategic Asset for CME Providers**
***Murray Kopelow, MD, MS, FRCPC***
Chief Executive, Accreditation Council for Continuing Medical Education (ACCME)

**Industry as a Stakeholder in CME and the Integrity of CME**
***Marc B. Wilenzick, JD***
Senior Corporate Counsel, Pfizer Inc

## Session 202 BT - Biotechnology, NC, VA

8:30 AM - 10:00 AM LEVEL = ●

**Room 154AB** *CME credits offered*

### Validation of Immunogenicity Testing Methods

SESSION CHAIRPERSON

***Lynne LeSauteur, PhD***
Scientific Director, Charles River Laboratories - CTBR, Canada

Immunogenicity testing is required for peptide and protein-based therapeutics, because of the likelihood that these agents will elicit an immune response and the fact that antibody generation may effect the therapeutics, pharmacokinetics/pharmocodynamics, safety and efficacy profiles. The assessment of immunogenicity requires validated assays to detect, isotype, and characterize the antibody response.

**Development and Validation of Cell-based Assays for the Detection of Antidrug Neutralizing Antibodies to Biological Therapeutics**
***Shalini Gupta, PhD***
Associate Director, Amgen Inc.

## Session 203 CDM - Clinical Data Management, eClin, IS

8:30 AM - 10:00 AM LEVEL = ●

**Room 204BC** *CME and Pharmacy credits offered*

### Electronic Source in Clinical Trials

SESSION CHAIRPERSON

***Xander Baroque, CCRC***
Clinical Research Professional, Children's Hospital Central California

Clinical research coordinators, monitors, investigators, and other research staff are encouraged to attend this session on the issues of electronic data capture, monitoring, and signatures. We will discuss topics from a coordinator and research department perspective. New regulations address electronic signatures; however, there is much more occurring in the real clinical world.

**Electronic Source in Clinical Trials: A Site Perspective**
***Lauro Roberto, MD***
Associate Director, Pulmonology; Physician, Children's Hospital Central California

**Electronic Source in Clinical Trials: A Site Perspective**
***Xander Baroque, CCRC***
Clinical Research Professional, Children's Hospital Central California

## Session 204 CMC - Chemistry, Manufacturing, and Controls, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 147A** *CME credits offered*

### Updates on CDER CMC Guidances

SESSION CHAIRPERSON

***Dhiren N. Shah, PhD***
Director, US DRA-CMC, sanofi-aventis

In this session, the current status and technical issues associated with CDER CMC guidances from a regulatory as well as an industry perspective will be discussed.

**FDA Perspective**
***Guirag K. Poochikian, PhD, FACP***
Associate Director for Regulatory Science, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, FDA

**Industry Perspective**
***Richard Poska, MS***
Director, Regulatory Affairs, Abbott Laboratories

**Panel Discussion/Q&A Period**

## Session 205 CP - Clinical Safety and Pharmacovigilance, CR, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 207A** *CME, Nursing, and Pharmacy credits offered*

### Risk Minimization Through Risk Communication: The Impact of New Regulatory Developments in Safety Labeling

SESSION CHAIRPERSONS

***Stephen A. Goldman, MD, FAPM, FAPA***
Managing Member, Stephen A. Goldman Consulting Services, L.L.C
***Sidney N. Kahn, MD, PhD***
President, Pharmacovigilance & Risk Management Inc.

Risk minimization through risk communication is a major public health aspect whose effectiveness has come under increasing regulatory and public scrutiny. As health professional medical product labeling is considered a major tool for communicating safety information to prescribers, this session will discuss how proposed revisions to US FDA labeling regulations/guidances, possible changes in the EU Summary of Product Characteristics (SPC) guidelines on safety information presentation, and the use of MedDRA® may have significant effects on pharmacovigilance and risk communication. Methods for assessing the effectiveness and impact of such public health actions as health professional notifications, focused educational efforts, and practice guidelines will be reviewed.

**Minimizing Medical Product Risk Through Effective Public Health Communication Methods**
***Stephen A. Goldman, MD, FAPM, FAPA***
Managing Member, Stephen A. Goldman Consulting Services, L.L.C

**Medical and Regulatory Implications of Using MedDRA® for Analysis and Communication of Risk**
***Sidney N. Kahn, MD, PhD***
President, Pharmacovigilance & Risk Management Inc.

**An Updated Comparison of Safety-related Information in US and EU Health Professional Pharmaceutical Labels**
***A. Leander Fontaine, MD, PhD***
President, Pharmiceutics, LLC

## Session 206 CR1 - Clinical Research and Development, BT, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 145B** *CME and Pharmacy credits offered*

### Conjugated Vaccines

SESSION CHAIRPERSON

***Anne-Marie P. Georges, PharmD***
Consultant, AMQuid Pharma, Belgium

This session will present a review and an overview of new conjugate vaccines and related issues.

*Panelist*
***Daniel Brasseur, MD, PhD***
Chairman of CHMP at EMEA, EU; Ministry of Public Health, Belgium

**New Meningitis Vaccines and Correlate for Protection: The Challenge**
***Johan Van Hoof, MD***
Chiron Vaccines, Belgium

**Staphylococcus Aureus Vaccine**
***Henrik Rasmussen, MD, PhD***
Senior Vice President, Clinical Research, Medical and Regulatory Affairs, and Project Management, Nabi Biopharmaceuticals

**Interference Between Antigens in Conjugate Vaccines**
***Bernard Fritzell***
Vice President, Scientific and Medical Affairs, Wyeth France

## Session 207 CR2 - Clinical Research and Development, CP

8:30 AM - 10:00 AM LEVEL = ■

**Room 146A** *CME, Nursing, and Pharmacy credits offered*

### Cardiovascular Safety and QT Assessment

SESSION CHAIRPERSON

***Lawrence Z. Satin, MD***
Chief Medical Officer, Cardiocore Lab

QT interval assessment and cardiovascular safety have become synonymous in the drug development process. Although regulatory guidance continues to evolve, challenges once thought to be daunting now have clear and poignant solutions.

**Meeting the Challenges of ECG Acquisition**
***Justin L. Mortara, PhD***
Vice President, Sales and Marketing, Mortara Instruments, Inc.

**Meeting the Challenges of QT Assessment**
***Lawrence Z. Satin, MD***
Chief Medical Officer, Cardiocore Lab

**Meeting the Challenges of Trial Design and Analysis**
***Eugene R. Heyman, PhD***
Statistical Consultant

## Session 208 CS - Clinical Supplies, CTM

8:30 AM - 10:00 AM LEVEL = ■

**Room 149AB** *Pharmacy credits offered*

### Future Trends in Clinical Supplies

SESSION CHAIRPERSON

***Frank J. Tiano, RPh***
President, Clinical Supplies Consulting Services

With the current emphasis on implementing effective demand management, speed in responding to clinical protocol requirements, patient-specific therapies, and providing ultimate flexibility, the 21st century clinical supply function is much different from its predecessors. Visionary clinical supply units incorporate proactive management strategies, real-time packaging and labeling strategies, and innovative technology solutions to streamline the drug supply management process.

**The Future of Clinical Supplies**
***Angus J. McCulloch***
Principal, World Class International

**Real-time Packaging and Labeling Strategies**
***Brian Moe, PharmD***
Vice President, CSM-Rx, CSM

**WebEZ™: An Innovative Solution to the Drug Supply Management Challenge**
***Donna Christopher***
Vice President of Operations, Clinical Trial Services

## Session 209 CTM - Clinical Trial Management, CR

8:30 AM - 10:00 AM LEVEL = ■

**Room 140B** *Nursing credits offered*

### Strategies for Achieving Recruitment Goals in Pediatric Trials

SESSION CHAIRPERSON

***Kate Didio, RN, MBA***
Director, Clinical Monitoring Management, Sepracor, Inc.

Meeting timelines for recruitment in pediatric clinical trials is always a challenge. Sepracor completed enrollment for a pediatric asthma study one month ahead of schedule. This session will take a detailed look at the recruitment strategies utilized by Sepracor for accelerated enrollment.

**Identifying Key Enrollment Challenges in a Study Design**
***Kate Didio, RN, MBA***
Director, Clinical Monitoring Management, Sepracor, Inc.

**Best Practices in Recruiting Pediatric Patients**
***Jeannine L. Heinemann***
Project Manager, Essential

**Ensuring Successful Implementation of Recruitment Strategies Across a Multicenter Study to Achieve Project Success**
***Stacy Weil, MS, RDH***
Associate Director, Clinical Operations, PPD Development

## Session 210 DM - Document Management/ eSubmissions, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 206** *Pharmacy credits offered*

### eCTD: Lifecycle Management

SESSION CHAIRPERSON

***Daniel F. Orfe, MS***
Associate Director, Worldwide Regulatory Operations, Merck & Co., Inc.

This session will deal with the various implementation and process obstacles faced by sponsors in addressing the lifecycle management aspect of the eCTD. Additionally, discussions and specifics of the rewards resulting from adoption of the eCTD will be covered within the presentations.

**eCTD Lifecycle Management: Challenges and Benefits**
***Michael J. Mellott, MS***
Associate Director, Merck & Co., Inc.

**Managing the eSubmission Lifecycle**
***Gary G. Walker***
Senior Document Management Advisor, Electronic Regulatory Submissions, Regulatory and Technical Services, Quintiles, Inc.

## Session 211 eCLIN - eClinical, CR, RA

8:30 AM - 10:00 AM LEVEL = ●

**Room 145A** *CME credits offered*

### Electronic Patient-reported Outcomes (ePRO) 2005: A Town Meeting

SESSION CHAIRPERSON

***John M. Weiler, MD***
President, CompleWare® Corporation

This session will consider regulatory issues in the use of ePRO. What's new about PRO guidance from the FDA? How can sponsors, vendors, and sites be compliant with the regulations?

**The Sponsor's Perspective**
***Jay Pearson, PhD***
Senior Director, Scientific Staff, Epidemiology Department, Merck Research Laboratories

**The Regulator's Perspective**
***Joseph P. Salewski***
Chief, Bioresearch Monitoring Branch, CBER, FDA

**The Vendor's Perspective**
***Valdo Arnera, MD***
General Manager, Europe, PHT Corporation, Switzerland

## Session 212 GCP - Good Clinical Practices

8:30 AM - 10:00 AM LEVEL = ■

**Room 202A**

### Establish and Maintain a CAPA System

SESSION CHAIRPERSON

***Bruce M. Wagman, MBA, RN***
Vice President, US Regulatory Affairs and Global Clinical Quality Assurance, Omnicare Clinical Research

Three quality assurance professionals who have established and maintain a CAPA system within their respective companies will discuss how they operated within their business environment. This session will include one cGMP director and two GCP directors to highlight the differences between cGMP and GCP.

***CAPA – Definitions for Compliance Standards (Part 1);***
***CAPA for Drug Manufacturers (Part 2)***
***Raymond Regimbal, PhD***
Director, Regulatory Compliance, Genta Incorporated

***CAPA in Clinical Research***
***J. Michael Sobczyk***
Director, BMRA Compliance, Genzyme

## Session 213 IS - Investigator Sites, AHC

8:30 AM - 10:00 AM LEVEL = ■

**Room 101** *CME credits offered*

### Revolutionizing the Role of Quality Assurance

SESSION CHAIRPERSON

***Patricia Brown, PhD, MSN, RN***
Director, CNS Healthcare

This session will provide an overview of how a structured approach to quality assurance can impact a research site.

**A Multifaceted Look at Quality**
***Kelly J. Abernathy***
Section Head, Clinical Operations and Regulatory Affairs, Lineberry Research Associates

**Making the Intangible, Tangible**
***Melissa Parsloe***
Psychology and Criminal Justice Graduate Student

**Revolutionizing the Role of Quality Assurance**
***Patricia Brown, PhD, MSN, RN***
Director, CNS Healthcare

## Session 214 IT1 - Information Technology

8:30 AM - 10:00 AM LEVEL = ◆

**Room 152A**

### Testing Security in a Regulated Environment: The What, When, and Where

SESSION CHAIRPERSON

***Kim R. Truett, MS***
Senior Clinical Programmer (Independent)

This section will focus on the need for security tests, what goes into a thorough security test, and how the OSSTMM helps facilitate this need.

**The Myth of Data Security: Putting a $100,000 Fence Around a $50 Horse**
***Peter V. Herzog***
Managing Director, Institute for Security and Open Methodologies (ISECOM), Spain

**Balancing Security and Operability: How to Keep a Secure Environment Without Reducing Business Efficiency**
***Kim R. Truett, MS***
Senior Clinical Programmer (Independent)

## Session 215 IT2 - Information Technology, CDM, eClin

8:30 AM - 10:00 AM LEVEL = ●

**Room 146B**

### Distributed Systems in Clinical Data Management

SESSION CHAIRPERSON

***Jeffrey C. Phillips, MA***
Director, Application Development, Medifacts International

Now that high-speed Internet access is more the rule than the exception, clinical trial data processing can be distributed; sites can enter and clean their own data via electronic data capture; laboratory data can be transmitted directly to databases; and staff all over the world can work on a study database at the same time. Distributed systems are already widely in use for electronic/remote data capture and high-volume processing of lab and imaging data. The advantages of this processing model are obvious. However, systems that are distributed widely and grant access to users outside central facilities carry special burdens: they must be friendly enough for less-trained users in the field, they must be secure enough to handle clinical data in the security-hostile Internet environment, they must perform consistently even when their operating conditions cannot be fully controlled, and they must be very robust, with a high degree of reliability and "up-time."

This session discusses some of the technical issues that surround the use of distributed systems for clinical data management, including security, database design, user interfaces, and fault tolerance. Attendees should come away with a greater appreciation of what it takes to move data collection, management and analysis "out from the center."

**Truly Web-based Systems for Clinical Data Management**
***Jeffrey C. Phillips, MA***
Director, Application Development, Medifacts International

**Challenges of Managing Distributed Systems to Support Remote Medical Image Review**
***Howard W. Foster, MS***
Vice President and Chief Technology Officer, Perceptive Informatics, Inc.

**Training Considerations for a Clinical Study Using Distributed Remote Data Capture**
***Steven C. Rifkin, PhD***
Chief Application Expert, BioPharm Systems, Inc.

## Session 216 MC - Medical Communications, CP

8:30 AM - 10:00 AM LEVEL = ●

**Room 209AB** *CME and Pharmacy credits offered*

### The Role of Medical Communications Departments in Risk Management Programs

SESSION CHAIRPERSON

***Monica Kwarcinski, PharmD***
Senior Director, Medical Services, Purdue Pharma L.P.

Risk management programs are an emerging regulatory issue whereby the FDA expects pharmaceutical companies to propose plans that proactively manage the risks in relation to the benefit for their products. Elements of an RMP include training, education, signal detection, and interventions. The medical communications department within a pharmaceutical company can play a significant role in RMPs.

**Brief Overview of Risk Management Programs: Their Similarities and Differences**
***Anne E. Trontell, MD, MPH***
Deputy Director, Office of Drug Safety, CDER, FDA

**The Role of the Medical Communications Department in a Modified-release Opioid Risk Management Program**
***J. David Haddox, DDS, MD***
Vice President, Risk Management and Health Policy, Purdue Pharma L.P.

**The Role of Medical Information in the Plenaxis® User Safety (PLUS™) Program: A Subpart H-approved Product with a Restricted Distribution Risk Management Program**
***Camille Motta, PhD, MS***
Senior Manager, Medical Information, Praecis Pharmaceuticals Incorporated

**The Role of Medical Information in the Clozaril National Registry Risk Management Program**
***Richard F. Eschle, PharmD***
Director, Neuroscience Medical Information and Communication, Novartis Pharmaceuticals Corporation

## Session 217 MW - Medical/Scientific Writing

8:30 AM - 10:00 AM LEVEL = ●

**Room 102AB**

### Document Reviews: Bridge to Quality or Roadblock to Completion?

SESSION CHAIRPERSON

***Linda Kelly***
Senior Scientific Communication Associate, Eli Lilly and Company

Reviews are an integral part of the document development process on cross-functional teams, but they can sometimes become a roadblock to timely document completion. This session will differentiate among various types of document reviews and identify the goals of each type. Specific, practical strategies for improving the value and efficiency of document reviews will be discussed.

**Effective Document Review Practices**
***Linda Kelly***
Senior Scientific Communication Associate, Eli Lilly and Company

**Managing the Art and Science of Team Reviews**
***Gregory P. Cuppan, MA***
Managing Principal, McCulley Cuppan LLC

**Document Review Challenges: Case Studies**
***Helle-Mai Gawrylewski, MA***
Director, Medical Writing and Medical Knowledge Management, Johnson & Johnson Pharmaceutical Research and Development, LLC

## Session 218 NC - Nonclinical Laboratory Safety, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 103B**

### Extrapolating Nonclinical Animal Data to the Clinic

SESSION CHAIRPERSON

***David R. Jones, MSc***
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

High attrition rates in early clinical trials continues to be a challenge to the pharmaceutical industry. The session will look at some of the problems and recent strategies employed to improve success rates.

**A Regulatory Viewpoint on the Challenges of Extrapolating Preclinical Data to a Safe Starting Dose in Clinical Trials in Man**
***David R. Jones, MSc***
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**Interpretation of Preclinical Data to Support Clinical Trials in Man**
***Paul Baldrick, PhD***
Head, Regulatory Affairs, Covance Laboratories Europe, UK

**Interspecies Extrapolation of ADME Data to Support First Dose in Man Studies**
***Doris Weilert, PhD***
Research Scientist, PK/PD, Clinical Pharmacology, Quintiles, Inc.

## Session 219 NHP - Natural Health Products, RA, RD

8:30 AM - 10:00 AM LEVEL = ■

**Room 140A**

### Regulatory Requirements versus Financial Benefit: Justifying Natural Health Products from a Private Sector Perspective

SESSION CHAIRPERSON

***Floyd E. Leaders, Jr., PhD***
Chairman and CEO, Botanical Enterprises, Inc.

Three interdependent and critical considerations must be evaluated when a private sector enterprise commits the resources necessary to develop a natural health product for treatment of serious and/or life-threatening medical conditions: 1) the safety and efficacy (benefit to risk ratio) of the product; 2) the size and viability of the intended market, and 3) the ability to recoup the significant financial cost of obtaining regulatory approval. This session will explore these three considerations within the context of the Guidance for Industry for Botanical Drugs that was published in June of 2004.

**Regulatory Requirements versus Financial Benefit: Justifying Natural Health Products from a Private Sector Perspective**
***Leonard P. Smith, MBA***
President, NUTRAssociates, Inc.

**Developing a Successful "Cutting Edge" Botanical Drug Business Strategy**
***Thomas M. Hnat***
CEO, CuraPharm, Inc.

**Safety and Efficacy: Can Previous Human Experience Realistically Be Used to Reduce the Financial Risk of Botanical Drug Development?**
***Floyd E. Leaders, Jr., PhD***
Chairman and CEO, Botanical Enterprises, Inc.

## Session 220 OS - Outsourcing, FI

8:30 AM - 10:00 AM LEVEL = ■

**Room 150A**

### Are Changes in Pharmaceutical Outsourcing Meeting the Needs of Investors, Sponsors, and Vendors?

SESSION CHAIRPERSON

***Mark A. Hovde, MBA***
President, Hovde Associates LLC

As the pharmaceutical industry's reliance on CROs has grown, methods for managing the outsourcing process have evolved from no formal outsourcing management to sophisticated online auctions managed by professional contracting groups. Has the evolution improved financial or project operational results? Will the new methods lead to better alignment or more discord among the stated goals and strategies of pharmaceutical development management, leading CROs, and investors?

**Overview: Changes in Pharmaceutical Outsourcing**
***Mark A. Hovde, MBA***
President, Hovde Associates LLC

**Investor's Perspective: Are the Changes Meeting Investor Needs?**
***Michael A. Martorelli, MBA***
Research Partner, Fairmount Partners

**Vendor's Perspective: Are the Changes Helping Vendors to Better Meet Sponsor Needs?**
***Tracy Blumenfeld, MBA***
Chief Executive Officer, RapidTrials

## Session 221 PM1 - Project Management

8:30 AM - 10:00 AM LEVEL = ●

**Room 143AB** *Project Management Institute credits offered*

### Maintaining the Talent Pipeline: Options for Identifying, Training, and Developing Pharmaceutical Project Managers

SESSION CHAIRPERSONS

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

***Kathleen J. Warner, PhD, MS***
Vice President, Research and Development Practice, Taratec Development Corporation

Recruiting, training, and developing project managers remains a key challenge for the pharmaceutical industry. There is no single training or certification program that has been identified as the gold standard, and as a result we have seen a plethora of choices evolve. This session provides some guidance on how to not only find the people with the right potential, but also how to train and develop them and provide enough career options to keep them motivated.

**Training Priorities for Project Managers in Life Sciences**
***Kathleen J. Warner, PhD, MS***
Vice President, Research and Development Practice, Taratec Development Corporation

***Naomi Clark-Turner, PhD***
Director, Operations, Project Management and Portfolio Planning, Centocor, Inc.

## Session 222 PM2 - Project Management

8:30 AM - 10:00 AM LEVEL = ■

**Room 143C** *Project Management Institute credits offered*

### Lead, Follow, or Get Out of the Way!

SESSION CHAIRPERSON

***Robin G. Foldesy, PhD***
Vice President, Project Management, Wyeth Research

Every successful team is greater than the sum of its parts. It's no coincidence that great teams are led by great leaders. Through the use of case studies from seasoned project management professionals, this session will discuss the characteristics of effective leaders and the successful teams they lead.

**Lead, Follow, or Get Out of the Way!**
***Robin G. Foldesy, PhD***
Vice President, Project Management, Wyeth Research

**Leadership, Decision Making, and Credibility, and the Critical Links Between Them**
***Martin Reeves***
Vice President, Strategic Planning, Cephalon, Inc.

**Roll Up Your Sleeves: Welcome to Biotech Project Management**
***Elizabeth P. Eberhardt***
Project Leader, ViroPharma Incorporated

## Session 223 PP - Public Policy/Law, RA, RD

8:30 AM - 10:00 AM LEVEL = ●

**Room 144ABC** *Pharmacy credits offered*

### Medicines and Healthcare: Rebuilding the Trust – Reshaping the Future – Part 1 of 2

SESSION CHAIRPERSONS

***Raymond G. Starrett, MLS***
Project Manager, GlaxoSmithKline

***Jean Yager, PhD***
Director, Department of Methods and Training, Global Project Management, Pfizer Inc

*Part 2 of this session will be held on Tuesday at 10:30 AM.*

The pharmaceutical industry is facing an unprecedented challenge to restore public confidence in the contribution of pharmaceuticals to healthcare and the value of new drug innovation. Without this confidence, the very fabric of the pharmaceutical and biotech industries and the future of new drug innovation are at risk. The potential long-term impact on patient welfare is enormous.

In this session, panelists representing industry, regulatory authorities, academia, policy makers, media and patients will discuss some of the key issues affecting public perception of the industry. A moderator will guide the panelists through constructive discussion.

*Moderator*
***Kenneth I. Kaitin, PhD***
Director, Tufts Center for the Study of Drug Development, Tufts University

*Panelists*
***Billy Tauzin, JD***
President and CEO, Pharmaceutical Research and Manufacturers of America, (PhRMA)

***Scott Gottlieb, MD***
Resident Fellow, American Enterprise Institute for Public Policy Research

***Robert J. Temple, MD***
Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

***Joanne Silberner***
Health Policy Correspondent, National Public Radio (NPR)

## Session 224 RA1 - Regulatory Affairs

8:30 AM - 10:00 AM LEVEL = ■

**Room 146C**

### New Horizons for the EMEA: Priorities for 2005-2006

SESSION CHAIRPERSON

***Thomas Lönngren, MPharm***
Executive Director, EMEA, EU

The new pharmaceutical legislation in the European Union goes into effect in 2005. Various new legislative tools will be made available to the EMEA and pharmaceutical industry as of November 2005. In addition, the EMEA published its strategy paper for the next years, "The EMEA Road Map to 2010: Preparing the Ground for the Future." It sets out the various initiatives the EMEA will undertake over the next few years in a range of fields, including research and innovation, safety of medicines and transparency and communication.

***Thomas Lönngren, MPharm***
Executive Director, EMEA, EU

***Patrick Le Courtois, MD***
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

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

## Session 225 RA2 - Regulatory Affairs

8:30 AM - 10:00 AM LEVEL = ●

**Room 151B** *CME credits offered*

### Implementation of the August 30, 2003 WTO Decision: Access to Medicines

SESSION CHAIRPERSON

***Karolyn S. Lui, MSc***
Associate Director, Policy Bureau, Therapeutics Products Directorate, Health Canada

The WTO decision of August 2003 waived certain compulsory licensing obligations to facilitate affordable access to medicines, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics in

developing countries with no or insufficient domestic manufacturing capability. This session will present the background of the WTO agreement as well as how Canada and different countries have responded within this context.

**Canada's Implementation of the WTO Decision**
***Karolyn S. Lui, MSc***
Associate Director, Policy Bureau, Therapeutics Products Directorate, Health Canada

**The European Union's Implementation of the WTO Decision**
***Béatrice Kressmann***
Director, European and International Affairs, LEEM (Pharmaceutical Industry Association in France)

## Session 226 RA3 - Regulatory Affairs, RD

8:30 AM - 10:00 AM LEVEL = ■

**Room 151A**

### Global Development: Focus on Asia

SESSION CHAIRPERSON
***Eric W. Lewis, MD***
Director, Clinical Pharmacology, GlaxoSmithKline

As Asia continues to grow economically and to develop into a center of global research and discovery, greater demands will be placed on the global pharmaceutical industry for development in this region. The incorporation of Asia into global development programs can lead to important contributions in the creation of "well-characterized" clinical data packages.

**Can Asia Pacific Be the Place for Global Clinical Development?**
***Xiaogang (XG) Wang, MD***
Director, Business Development, ICON Clinical Research, Japan

***Masahiro Takeuchi, MD***
Professor, Center for Clinical Pharmacy and Clinical Services, Kitasato University Graduate School, Japan

## Session 227 RA4 - Regulatory Affairs

8:30 AM - 10:00 AM LEVEL = ●

**Room 152B**

### CBER Update

SESSION CHAIRPERSON
***Jesse L. Goodman, MD, MPH***
Director, Center for Biologics Evaluation and Research, FDA

This session will provide a CBER management overview of important issues. CBER initiatives regarding regulation, review processes, research, and/or safety will be summarized and current issues impacting CBER's mission will be discussed.

**An Overall Center Update**
***Jesse L. Goodman, MD, MPH***
Director, Center for Biologics Evaluation and Research, FDA

**Regulations/Policy Update**
***Diane Maloney, Esq.***
Associate Director for Policy, CBER, FDA

**Review Management Update**
***Robert A. Yetter, PhD***
Associate Director for Review Management, Office of the Director, CBER, FDA

## Session 228 RD - R&D Strategy, FI, OS

8:30 AM - 10:00 AM LEVEL = ■

**Room 150B**

### Workload Management and Performance Monitoring

SESSION CHAIRPERSON
***Wolfgang Seifert, PhD, MD***
Senior Advisor, Drug Development, Schering AG, Germany

Outsourcing may be selected for various reasons. This session outlines specific performance properties of outsourced work, analyzes the relationship of total cost for in-house and outsourced work, and describes how to get to a cost-optimal workload balance. Earned value analysis as a performance evaluation method tracks the outsourced work and the progress of the total work.

**The Role of Outsourcing Over the Clinical Development Phases**
***Cyndy E. Lumley, PhD***
Executive Vice President, Corporate Affairs, CMR International Ltd., UK

**How to Manage Workload Using a Cost Analysis Model**
***Hermann Kulmann, PhD***
Head, Biometry - Europe, Schering AG, Germany

**Monitoring External and Internal Performance with Earned Value Analysis**
***Wolfgang Seifert, PhD, MD***
Senior Advisor, Drug Development, Schering AG, Germany

## Session 229 ST - Statistics, RA

8:30 AM - 10:00 AM LEVEL = ●

**Room 201**

### Statisticians and Standards: Emerging Tools and Processes for Faster, Cleaner Results from Clinic to Submission

SESSION CHAIRPERSON
***Russell Helms, PhD, MS***
Assistant Director, Biostatistics, Rho, Inc.

Statisticians have an important role in the ever-increasing drive to speed the drug development process. In this session, speakers will discuss ways statistician involvement with new standards and tools can lead to better and faster results.

**Implementation of Clinical Reporting Using CDISC Study Data Tabulation Model**
***Steve Light***
Principal Consultant, DataCeutics, Inc.

**The Statistician's Role in Data Review**
***Beth Fetterman, MS***
Director, Clinical Reporting, PharmaLink FHI, Inc.

**Programming and Analysis Specifications: A Detailed SAP Tool**
***Tara Maddala, PhD***
Manager, Biostatistics, Clinmetrics Research Associates, Inc.

## Session 230 TR - Training, CR, IS

8:30 AM - 10:00 AM LEVEL = ●

**Room 207B** *CME, Nursing, and Pharmacy credits offered*

### Investigative Site Readiness

SESSION CHAIRPERSON

***Nadina C. Jose, MD, CPI***
President and CEO, Research Strategies, Inc.

Increased enrollment delays, inadequate documentation, and protocol violations are common causes for increased expenditures in clinical research. Rather than having a delayed response to these issues, research sites must be able to go home from an investigator meeting, feeling pumped up and ready to begin the study, knowing they not only understand the protocol, but that they also are fully equipped with the right tools to be able to troubleshoot along the way.

**Launching Clinical Trials in a Multisite Hospital Setting**
***David M. Vulcano, MBA, LCSW, CIP***
Director, Clinical Trials, Ardent Health Services

**Stress: Getting It or Giving It?**
***Ronny K. Schnel, MS***
Executive Director, Business Development and Client Services, Criterium

**Investigative Site Readiness**
***Nadina C. Jose, MD, CPI***
President and CEO, Research Strategies, Inc.

## Session 231 VA - Validation

8:30 AM - 10:00 AM LEVEL = ●

**Room 147B**

### Validation Methodology

SESSION CHAIRPERSON

***Earl W. Hulihan, MEd***
Senior Vice President, Regulatory Consulting Services, META Solutions, Inc.

This session will focus on today's clinical trial technology and which steps must be taken to ensure overall accuracy and reliability of data. Reviewing three areas of focus [electronic data capture systems, electronic databases (specifically viewed from the high risk perspective of a safety database), and software development] this session will provide insight and clarification on the measures required for data integrity and reliability.

**Life Beyond the Release of Clinical Trial Electronic Data**
***Jean A. Paty, PhD, MS***
Chief Quality Officer, invivodata

**Validation and Impact Analysis of a Safety Database**
***Earl W. Hulihan, MEd***
Senior Vice President, Regulatory Consulting Services, META Solutions, Inc.

## Special Event

8:30 AM - 12:00 PM

**Room 204A**

### Student Forum

FORUM CHAIRPERSON

***Stephen A. Sonstein, PhD***
Coordinator, Clinical Research Administration, Eastern Michigan University

The Student Forum has been designed to provide information of interest to students and an opportunity to provide input to the DIA. The agenda for the Student Forum is as follows:

*Continental Breakfast for Students (8:30 AM – 9:00 AM)*

**Perspectives on the Future Workforce for the Clinical Research Enterprise**
***Kenneth A. Getz, MS, MBA***
Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

**Education and Training Opportunities in Clinical Research**
***Stephen A. Sonstein, PhD***
Coordinator, Clinical Research Administration, Eastern Michigan University

*Refreshment Break (10:30 AM – 10:45 AM)*

**A Career in Clinical Research**
***Theresa K. Musser***
Senior Director, Project Management and Clinical Operations, Rigel Pharmaceuticals; Acting President, DIA

**Roundtable/Panel Discussion**

- Employment in the pharmaceutical and biotechnology industries
- Need for suitable education
- Role of students in the DIA

*Student Forum concludes at 12:00 PM.*

10:00 AM - 10:30 AM **REFRESHMENT BREAK**

**Exhibit Halls ABC, Lower Level**
**Convention Center**

## Session 232 AD - Advertising, MA, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 202B** *CME and Pharmacy credits offered*

### DTC Update

SESSION CHAIRPERSON

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

This session will explore the current environment surrounding DTC promotion in the US, including the possible impact of recent drug safety and regulatory concerns. Additionally, the panel will address the issues and concerns regarding global DTC promotion and the likelihood of expanded promotion.

*Panelists*

***Melissa M. Moncavage, MPH***
Leader, DTC Review Group, Office of Medical Policy, Division of Drug Marketing, Advertising and Communications, CDER, FDA

***Kathryn J. Aikin, PhD***
Social Science Analyst, Office of Medical Policy, Division of Drug Marketing, Advertising and Communications, CDER, FDA

***Minnie Baylor-Henry, RPh, JD***
Vice President, Medical and Regulatory Affairs, Johnson & Johnson Pharmaceutical Research and Development, LLC

## Session 233 BT - Biotechnology, RA, RD

10:30 AM - 12:00 PM LEVEL = ■

**Room 154AB** *CME credits offered*

### Current Challenges in the Development of Cell-based Therapies

SESSION CHAIRPERSON

***Darin Weber, PhD***
Senior Consultant, The Biologics Consulting Group, LLC

This session will highlight some of the unique challenges facing developers of cell-based therapies including those related to CMC, preclinical development, and clinical trials. Information resources identifying current FDA thinking in this field, as well as specific strategies for working with the review staff at the FDA, will be described.

**FDA Perspective on Current Challenges in the Development of Cell-based Therapies**
***Kimberly A. Benton***
Supervisory Microbiologist, Office of Cellular, Tissue and Gene Therapies, CBER, FDA

**Experiences in Exploring the FDA Regulatory Path for a Novel Cell-scaffold Combination Product**
***Timothy A. Bertram, DVM, PhD***
Vice President, Preclinical Science and Technology, Tengion, Incorporated

**Essential Tools and Strategies for Overcoming Developmental Challenges for Cell-based Products**
***Darin Weber, PhD***
Senior Consultant, The Biologics Consulting Group, LLC

## Session 234 CDM - Clinical Data Management, CP

10:30 AM - 12:00 PM LEVEL = ●

**Room 204BC** *CME and Pharmacy credits offered*

### An Introduction to SNOMED CT®: Comprehensive Terminology for eMedical Records

SESSION CHAIRPERSON

***Doris McGinness***
Terminology Manager, Pharmacy, SNOMED International

SNOMED CT® is a comprehensive controlled terminology with over 350,000 concepts that spans all medical specialties and has been recommended as the standard for the electronic health record for the US. The core content is current, dynamic and organized in multiple hierarchies with relationships that capture complex concepts describing diagnoses, complications, therapy, and outcomes. This overview of SNOMED will emphasize the scope, its hierarchical structure, pharmaceuticals, and adverse events.

**An Introduction to SNOMED CT® (Systemized Nomenclature of Medicine Clinical Terms): Comprehensive Terminology for Electronic Medical Records**
***Doris McGinness***
Terminology Manager, Pharmacy, SNOMED International

**SNOMED CT® Terminology and the United Kingdom's National Health Service**
***Paul Frosdick, MRPharmS, MBA***
Senior Clinical Pharmacist, National Programme for Information Technology (NPfIT) Design Authority, National Health Service, UK

**SNOMED CT® Terminology and Kaiser Permanente**
***James Shalaby, PharmD***
Manager, Convergent Medical Terminology, Kaiser Permanente Information Technology

## Session 235 CMC - Chemistry, Manufacturing, and Controls, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 147A**

### Open Forum: Ask CMC Questions on the Latest Hot Topics to the Agency and Industry Experts

SESSION CHAIRPERSON

***Dhiren N. Shah, PhD***
Director, US DRA-CMC, sanofi-aventis

This session will provide attendees with the opportunity to ask questions of our team of experts from industry and the Agency on preselected topics. These topics include: genotoxic impurities, starting material in the manufacture of drug substances, tangible benefits of application of PAT to drug substances and drug products, specification process, first-time approvals, and comparability protocols.

*Panelists*

***Moheb M. Nasr, PhD***
Director, Office of New Drug Chemistry, CDER, FDA

***Chi-wan Chen, PhD***
Deputy Director, Office of New Drug Chemistry, CDER, FDA

***Charles P. Hoiberg, PhD***
Executive Director, Pfizer Inc

***Richard Poska, MS***
Director, Regulatory Affairs, Abbott Laboratories

***Frank O. Holcombe, Jr., PhD***
Associate Director for Chemistry, Office of Generic Drugs, CDER, FDA

## Session 236 CP - Clinical Safety and Pharmacovigilance, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 207A** *CME and Pharmacy credits offered*

### Risk Minimization Action Plans

SESSION CHAIRPERSON

***Annette Stemhagen, DrPh, FISPE***
Vice President, Strategic Development Services, Covance Periapproval Services, Inc.

The FDA final guidance on risk management includes strategies for pre- and postmarketing risk management, and the development of Risk Management Action Plans (RiskMAPs). This session will review key components of risk management: assessment, intervention, communication, and evaluation, and describe both pre- and postmarketing approaches to each of these components.

**Strategies for Designing Risk Management Programs**
***Annette Stemhagen, DrPh, FISPE***
Vice President, Strategic Development Services, Covance Periapproval Services, Inc.

**Risk Management: Practical implications for Pharmaceutical Manufacturers**
***Mary Ellen Turner, MD, MPH***
Vice President, Global Safety Surveillance and Epidemiology, Wyeth Pharmaceuticals

**Evaluation of Risk Minimization Action Plans (RiskMAPs)**
***Matthew W. Reynolds, PhD, MS***
Senior Director, Risk Management and Safety Services, MetaWorks, Inc.

## Session 237 CR1 - Clinical Research and Development, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 145B** *CME, Nursing, and Pharmacy credits offered*

### Safer, Better, More Appropriate: Clinical Trial Design for Pediatric Drug Labels

SESSION CHAIRPERSON

***William Rodriguez, MD, PhD***
Science Director for Pediatrics, CDER, FDA

Off-label use of drugs in pediatrics remains a national and international problem. Congress has mandated the study of drugs in pediatrics, and this legislation provides for the study of both on-patent and off-patent drugs in the pediatric population. This session is designed to delineate the current legislation, to identify partnership opportunities, and to provide information on the design of pediatric clinical trials in order to obtain safety, efficacy, and pharmacokinetic data for pediatric drug labeling.

**Regulatory Issues in Pediatric Drug Development**
***Lisa L. Mathis***
Commander, USPHS, Medical Team Leader, Division of Pediatric Drug Development, Office of Counter-terrorism and Pediatric Drug Development, CDER, FDA

**Creative Clinical Trial Design for Pediatric Drug Development**
***Susan McCune, MD, MA***
Medical Officer, CDER, FDA

**Global Partnerships for Improved Clinical Trials**
***Karen L. Ball***
President and CEO, The Sturge-Weber Foundation

**Pediatric Clinical Trial Designs: Varied Paths to the Top of the Mountain**
***David M. Cocchetto, PhD***
Vice President, Antiviral/Antibacterial Regulatory Affairs, GlaxoSmithKline

## Session 238 CR2 - Clinical Research and Development, IS

10:30 AM - 12:00 PM LEVEL = ●

**Room 145A**

### What Patient Recruitment Methods Work Best for Women and Minorities?

SESSION CHAIRPERSON

***William W. Gwinn, Jr., MBA***
Director, Clinical Trial Solutions, Medstat Inc.

This session is a joint presentation by Medstat, Matthews Media Group, and an independent researcher. It will review clinical trial participation by women and minorities, with broader supplemental views by age and by lifestyle segmentation groups. The session will also present initial survey findings, as well as a proposal for a research study to assess the effectiveness of community-based recruitment, population-based "sampling" methods, and the use of call centers and the Internet. It will also have advertising examples.

**Overview and New Survey Results by Demographic and Lifestyle Segments**
***William W. Gwinn, Jr., MBA***
Director, Clinical Trial Solutions, Medstat Inc.

**Communication Strategies and Techniques**
***Nancy A. Mulligan***
Vice President, Matthews Media Group

**A Proposal for a Research Study: Patient Recruitment Methods in Clinical Trials Involving Women and Minorities**
***Michelle D. Burton, MSHS, CCRP***
Clinical Research Associate, TAP Pharmaceutical Products, Inc./MedFocus LLC

## Session 239 CR3 - Clinical Research and Development

10:30 AM - 12:00 PM LEVEL = ■

**Room 149AB**

### Alternative Country Selection

SESSION CHAIRPERSON

***Alan Wood, PhD, MPharm***
General Manager, Clinical Development Services, Covance Clinical and Periapproval Services, UK

An interactive panel discussion with representatives from India, Latin America, and Eastern Europe offering insight into the practical opportunities and challenges with clinical trial enrollment and management in their respective regions.

**Central and Eastern Europe: Maximizing Success Through Rapid Patient Recruitment and Quality Data**
***Malgorzata Szerszeniewska, MD***
Director, Strategic Development, CEE, Covance (Polska) Poland

**India and Clinical Development: Some Myths and Facts**
***Rupesh V. Patki, PhD, MPharm***
Manager, Clinical Operations, Siro Clinpharm, India

**Latin America: Do's and Don'ts in Clinical Trials**
***Sergio Guerrero, MD***
Vice President/Chief Operating Officer, Mexican Institute of Clinical Research, Mexico

## Session 240 CR4 - Clinical Research and Development

10:30 AM - 12:00 PM LEVEL = ●

**Room 147B** *CME and Pharmacy credits offered*

### Understanding How to Design a Better Placebo-controlled Trial

SESSION CHAIRPERSON

***Arlene S. Swern, PhD***
Associate Director, Merck Research Laboratories

Many factors contribute to and affect the order of magnitude of the placebo response. Some of these factors may be minimized, and some may not. The intent of this session is to discuss the factors that contribute to the placebo response and to examine what may be done in the design of a trial to minimize the placebo effect.

**Strategies for Minimizing the Placebo Response**
***Arlene S. Swern, PhD***
Associate Director, Merck Research Laboratories

**Baseline Elevation Subterfuge, Meddlesome Measurement, and Other Factors that Affect Subjective Responses in Clinical Trials**
***Bernard P. Schachtel, MD***
Lecturer, Department of Epidemiology and Public Health, Yale University School of Medicine; Medical Director, Schachtel Research Center

**Understanding and Modeling Placebo Effects in Clinical Trials**
***Mani Y. Lakshminarayanan, PhD***
Director/Statistical Scientist, Pfizer Inc

## Session 241 CTM - Clinical Trial Management

10:30 AM - 12:00 PM LEVEL = ●

**Room 140B** *Pharmacy credits offered*

### Innovative, Objective, Data-based Approach to Trial Planning and Implementation

SESSION CHAIRPERSON

***Rajiv Prasad, MBA***
President, Clindata International, LLC

This session deals with innovative, integrated, patient-level longitudinal data-based approaches to clinical trial planning and implementation. The use of predictive enrollment for refining protocol inclusion/exclusion criteria, site location and selection and patient recruitment, including the patient's own pharmacists, web-based and IVRS patient screening methods for rapid enrollment, will be discussed.

**ROI on Innovations in Data-based Approaches to Trial Planning and Design**
***Mark A. Hovde, MBA***
President, Hovde Associates LLC

**Process for Evaluating Longitudinal Databases for Site Selection**
***Nancy J. Dynes, MBA***
Data Steward, Global Enrollment Optimization, Eli Lilly and Company

**Improving Site Selection Through the Utilization of Innovative Data Sources**
***Matthew J. Wallach, MBA***
Chief Marketing Officer, Health Market Science, Inc.

## Session 242 DM - Document Management/ eSubmissions, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 206** *Pharmacy credits offered*

### eCTD: Case Studies

SESSION CHAIRPERSON

***Alison W. Buno***
Site Lead, Pfizer Global Research and Development

This basic level session will present real-life experience submitting eCTDs in the US and Europe. Hear how others have worked through challenges and various scenarios to successfully create valid eCTD submissions in the US, Europe, and simultaneously to more than one region.

**Practical Experience on Participating in the FDA eCTD Pilot Program**
***Kenneth R. VanLuvanee***
President and CEO, Apyx, Inc.

**Simultaneous eCTD Assembly**
***Justin DiFebbo***
Wyeth Research

**Submitting an eCTD in Europe**
***Tracy L. Baldwin***
Associate Director, Pfizer Inc, UK

## Session 243 GCP - Good Clinical Practices, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 202A** *Nursing credits offered*

### Town Hall Forum on Current GCP Issues

SESSION CHAIRPERSONS

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

***Beat E. Widler, PhD***
Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

As the role of the different parties in clinical research has changed, the types of tasks delegated to third parties has increased. This change has prompted the need for more oversight of the quality of the work conducted. This session will discuss the importance of assessing the quality and performance of vendors and staff as part of your overall quality assurance program in clinical research. Understanding these issues can help to minimize the risk and reduce the exposure for the sponsor and the clinical investigator. This session will discuss recent trends in the inspection of clinical studies.

***David A. Lepay, PhD, MD***
Senior Advisor for Clinical Science and Director, Good Clinical Practices Programs, OSHC, Office of the Commissioner, FDA

***Fergus L. Sweeney, PhD***
Principal Administrator, Inspections Unit, EMEA, EU

***Jean Saint-Pierre***
Coordinator, Good Clinical Practices, National Coordination Center, Inspectorate; Health Products and Food Branch, Health Canada

## Session 244 IMP - Impact, eClin, OS

10:30 AM - 12:00 PM LEVEL = ■

**Room 152A**

### Successful Selection of an ePRO Technology Provider

SESSION CHAIRPERSON

***Jennifer Aquino***
Vice President, Voice and Data Systems, Perceptive Informatics, Inc.

This session will focus on the key aspects of the process of selecting suppliers to collect patient self-report data. The focus will be on the need for technology – which ones?; ePRO choices available; establishing the selection criteria; running the selection; the results/reality; and the future shape of the market.

**ePRO Selection**
***Christopher Pitcherella, MBA***
Clinical Outsourcing Manager, AstraZeneca LP

**ePRO Implementation**
***Daryl S. Kershner***
Manager, BDS Business Planning and Development, GlaxoSmithKline

**ePRO: Fitting the Pieces Together**
***Paula McHale***
Director, EDC Solutions, PAREXEL International

## Session 245 IS - Investigator Sites, CR, CTM

10:30 AM - 12:00 PM LEVEL = ■

**Room 101** *CME credits offered*

### Accelerating Subject Enrollment: A Handbook for Sites and Sponsors

SESSION CHAIRPERSON

***Louis C. Kirby, MD***
Medical Director and Founder, Pivotal Research Centers

This session identifies barriers to timely enrollment and makes specific recommendations for improvement. Sponsors can do a better job of site identification, allocation of resources, budgeting, and preplanning with sites for a successful recruitment campaign. Customization of site interactions, learning from sites, and fostering the individual site strengths can make a world of difference in accelerating enrollment. Sites can discover new and powerful techniques to increase the efficiency of their recruitment efforts and work closely with sponsors to make their capabilities known.

This session will clearly and specifically discuss the real-world approaches to reducing recruitment delays in ways that both sponsors and sites can take home and employ tomorrow. Dr. Kirby will be the sole speaker to present the material in detail not easily achieved by multispeaker sessions.

***Louis C. Kirby, MD***
Medical Director and Founder, Pivotal Research Centers

## Session 246 IT - Information Technology, CTM

10:30 AM - 12:00 PM LEVEL = ■

**Room 146B**

### Lightweight Integration for Clinical Trial Operations

SESSION CHAIRPERSONS

***William Crawford***
President, Crawford Life Sciences

***Jean-Remy Behaeghel***
Director, IVRS, Perceptive Informatics, Inc.

A panel will discuss the challenges of integrating operations systems with trial management and reporting applications, and provide a report on the development of L2M2, an XML-based secure data model and messaging layer for the conduct of a clinical trial, linking CTMS, IVRS, supply management and other systems on an ad-hoc, trial-by-trial basis.

**L2M2: Protocol and Data Model for Lightweight Integration of Clinical Trial Operations**
***William Crawford***
President, Crawford Life Sciences

**Making the Case for Lightweight Clinical Trial Operations Integration Protocol: An In-depth Look at the Clinical Trial Information System**
***Jean-Remy Behaeghel***
Director, IVRS, Perceptive Informatics, Inc.

## Session 247 MC - Medical Communications, CR

10:30 AM - 12:00 PM LEVEL = ■

**Room 209AB**

### Integrating Field Medical Liaisons with Clinical Drug Development

SESSION CHAIRPERSON

***Ellis H. Wilson, MS, MSA***
Study Delivery Director, Neuroscience, AstraZeneca Pharmaceuticals

Field medical liaison professionals are in a special position to contribute significantly to clinical drug development on numerous levels. This session is underpinned by the experience of three well-organized field medical liaison initiatives and is focused on outlining both the potential contributions to drug development programs and the obstacles that must be overcome in order to leverage this important resource.

**Capturing and Integrating Field Input to Clinical Development Plans**
***Michael M. Januszeski, PhD***
Associate Director, Medical Affairs, Centocor, Inc.

**Influencing the Direction of Research Based on Medical Liaison Input**
***Rashmi Yadav-Marya, MPH***
Neuroscience Medical Liaison, Eli Lilly Pharmaceuticals

**Are We There Yet? Optimizing Field Liaison Contributions to Development**
***Ellis H. Wilson, MS, MSA***
Study Delivery Director, Neuroscience, AstraZeneca Pharmaceuticals

## Session 248 NC/VA - Nonclinical Laboratory Safety/Validation, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 103B**

### Post Red Apple Conference Update

SESSION CHAIRPERSON

***Earl W. Hulihan, MEd***
Senior Vice President, Regulatory Consulting Services, META Solutions, Inc.

In 1987 the Office of Regulatory Affairs and the National Center for Toxicological Research (NCTR) of the Food and Drug Administration and NCTR Associated Universities, Inc., conducted a workshop on computerized systems used in nonclinical laboratories. The workshop was conducted at the Red Apple Conference Center in Heber Springs, Arkansas. Over sixty persons, representing government, industry, and academia were chosen to participate in the workshop. The purpose of the workshop was to develop a reference document on computer automation in toxicology laboratories that would describe effective means for ensuring the quality of computerized systems. In 1988 the product of the conference was published as "Computerized Data Systems for Nonclinical Safety Assessment: Current Concepts and Quality Assurance." The document became an industry standard for assuring the quality of computerized systems and many of its principles are applicable today. This session will review the reasons for the Red Apple Conference and provide an overview of the resulting document. Presentations will discuss the impact of the document on the regulated industry, its relevance to today's regulated environment, and plans for revisiting the Red Apple Conference.

***James F. McCormack, PhD***
Vice President, Regulatory Affairs and Compliance, Charles River Laboratories - CTBR

***Martin Browning, MS***
President, EduQuest, Inc.

***Karen Raskasky***
President, Raskasky Group

## Session 249 NHP - Natural Health Products, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 102AB**

### The New Legislative Environment for Herbal Products in Europe

SESSION CHAIRPERSON

***Hubertus Cranz, PhD***
Director General, Association of the European Self-medication Industry (AESGP), Belgium

This session will review legislation and assessment in relation to herbal medicines in Europe.

**Impact of the New Directive on Traditional Herbal Medicines**
***Riccardo Sciabica, PharmD, MS***
Senior Editor - IDRAC, Thomson Scientific, France

**Scientific Evaluation of Medicinal Plants**
***Heribert Pittner, MD***
Vice Chair, EMEA Committee of Herbal Medicinal Products, Bundesministerium für Gesundheit und Frausen, Austria

**Industry Expectations**
***Hubertus Cranz, PhD***
Director General, Association of the European Self-medication Industry (AESGP), Belgium

## Session 250 OS - Outsourcing, PM

10:30 AM - 12:00 PM LEVEL = ■

**Room 150A**

### Exploring Both Sides of the Perfect CRO/Pharmaceutical Partnership

SESSION CHAIRPERSON

***Patricia A. Mosher***
Senior Director, Clinical Infectious Disease Research, PharmaNet

Managing the relationship and activities between a CRO and a pharmaceutical company is challenging. Expectations, competencies and staffing must be balanced with timelines, flexibility, and resources. The success of a project, i.e., meeting deliverables on time, is contingent on the strength of the team, specific tools used to achieve milestones, and how well the team works together to complete tasks.

**Exploring Both Sides of the Perfect CRO/Pharmaceutical Partnership**
***Bryce D. Bartruff, PhD, MBA, RN***
Manager, Clinical Infectious Disease Research, PharmaNet

**Exploring Both Sides of the Perfect CRO/Pharmaceutical Partnership**
***Audrey Rossow***
Senior Project Manager, PAREXEL MMS, Patient and Clinical Communications

## Session 251 PM1 - Project Management, RD

10:30 AM - 12:00 PM LEVEL = ■

**Room 143AB** *Project Management Institute credits offered*

### Risk Management

SESSION CHAIRPERSON

***Jane M. Bainbridge, MSc***
Vice President, Project Management, Celgene Corporation

Understanding risk is the first step towards realizing the ways to manage and reduce risk in order to tip the risk/reward ratio toward increased value. This session will address the following: portfolio risk, risk in invention/candidate selection, and project risk.

**Portfolio Risk Management: The Practical Issues**
***Stephen W. Allport, Cbiol, MIBiol, DMS, DipM, MCIM, MCMI***
Managing Director, SWA Consulting, UK

**From Invention to Development: Reducing the Risk of Starting Projects that Fail**
***Allen C. Sarapu, PhD***
President, Value-Added Drug Development, LLC

**Practical Approach to Project Risk Management**
***Leah Goldbroch, MBA***
Director, Global Project Management, Abbott Laboratories

## Session 252 PM2 - Project Management, BT, RD

10:30 AM - 12:00 PM LEVEL = ■

**Room 143C** *Project Management Institute credits offered*

### Alliance Management: From Partner Selection to Joint Program Teams

SESSION CHAIRPERSON

***Julie G. Bukar, MBA, RD***
Principal, JGB BioPharma Consulting

Corporate alliances are an excellent way for companies to join forces on a program or research area, such that goals are achieved faster than they could be by either company individually. However, partner selection and alliance management are key to success. This session will focus on both of these aspects in relation to achieving productive corporate alliances.

**Strategic Alliances with Big Pharma**
***Kelly L. Longo, MA, MBA***
Associate Director, Strategic Alliances, Pfizer Inc

**Creating a Good Alliance: Hints in Strategy, Valuation, Negotiation and Contracts**
***Linda M. Pullan, PhD***
Vice President, Business Development, Kosan Biosciences

**How to Run an Effective Alliance**
***Cynthia Perettie, MS, MBA***
Senior Director, Product Planning, Genentech, Inc.

## Session 253 PP - Public Policy/Law, RA, RD

10:30 AM - 12:00 PM LEVEL = ●

**Room 144ABC** *Pharmacy credits offered*

### Medicines and Healthcare: Rebuilding the Trust – Reshaping the Future – Part 2 of 2

SESSION CHAIRPERSONS

***Raymond G. Starrett, MLS***
Project Manager, GlaxoSmithKline

***Jean Yager, PhD***
Director, Department of Methods and Training, Global Project Management, Pfizer Inc

*Part 1 of this session will be held on Tuesday at 8:30 AM.*

The pharmaceutical industry is facing an unprecedented challenge to restore public confidence in the contribution of pharmaceuticals to healthcare and the value of new drug innovation. Without this confidence, the very fabric of the pharmaceutical and biotech industries and the future of new drug innovation are at risk. The potential long-term impact on patient welfare is enormous.

In this session, panelists representing industry, regulatory authorities, academia, policy makers, media and patients will discuss some of the key issues affecting public perception of the industry. A moderator will guide the panelists through constructive discussion.

*Moderator*
***Kenneth I. Kaitin, PhD***
Director, Tufts Center for the Study of Drug Development, Tufts University

*Panelists*
***Billy Tauzin, JD***
President and CEO, Pharmaceutical Research and Manufacturers of America, (PhRMA)

***Scott Gottlieb, MD***
Resident Fellow, American Enterprise Institute for Public Policy Research

***Robert J. Temple, MD***
Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

***Joanne Silberner***
Health Policy Correspondent, National Public Radio (NPR)

## Session 254 RA1 - Regulatory Affairs

10:30 AM - 12:00 PM LEVEL = ■

**Room 146C** *CME credits offered*

### New Pharmaceutical Legislation – Part 1 of 3: Tools for Quick Access to Medicines

SESSION CHAIRPERSONS

***Yves M. Juillet, MD, PhD***
Senior Advisor, LEEM (Pharmaceutical Industry Association in France)

***Patrick Le Courtois, MD***
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

*Part 2 of this session will be held on Tuesday at 1:30 PM; Part 3 will be held on Tuesday at 3:30 PM.*

Within the scope of the New Pharmaceutical Legislation, which will enter into force in the 25 Member Sates of the European Union in October-November 2005, more focus will be placed on the procedures under the responsibility of the European Medicines Agency (EMEA). In particular, any product in oncology, diabetes, HIV or in neurodegenerative diseases will have to follow the centralized procedure, as the compulsory registration route. This will be extended to other therapeutic areas in the future. It is therefore important to understand the strategic and practical issues relating to these important changes, such as faster access to new innovative medicines on one side, and issues relating to assessment, availability of scientific expertise, or postauthorization procedures and systems like pharmacovigilance. In this respect, two sessions are proposed addressing the tools for quick access to medicines, as well as other practical aspects, with intervention from the key stakeholders, i.e. EMEA, CHMP and industry.

**NML Implementation in EU and at the EMEA**
***Francesco Pignatti***
Scientific Administrator, EMEA, EU

**NML Implementation: Industry Views**
***Christine-Lise Julou, PharmD***
Manager, Scientific and Regulatory Affairs, EFPIA, Belgium

**NML Implementation in EU Member States**
***John A. Lisman, MPharm, LLM***
Policy Advisor, Medicines Evaluation Board, Netherlands

*Panelist*
***Eric Abadie, MD, MBA***
Vice Chairman, CHMP, EMEA, EU; AFSSAPS, France

## Session 255 RA2 - Regulatory Affairs, CP, MC

10:30 AM - 12:00 PM LEVEL = ●

**Room 151B** *CME and Nursing credits offered*

### Self-medication and OTCs

SESSION CHAIRPERSON

***Mohammed Razdar Khan***
Director, Synergex Consulting, Canada

Concurrent use of multiple OTC formulations by consumers is putting them at the risk of inadvertent overdosing, and not infrequently, with serious consequences. It is perhaps time that we gave serious thought to assessing the adequacy of product labeling and consumer education needs.

**Self-medication and OTCs: Perspective on the Canadian OTC Market**
***Mohammed Razdar Khan***
Director, Synergex Consulting, Canada

**Consumer Health Product Safety: A US Perspective, with a Focus on Botanicals and Other Natural Products**
***Freddie Ann Hoffman, MD***
Chief Executive Officer, HeteroGeneity, LLC

**Self-medication Risks of OTC Drugs and Herbal Products: Special Focus on Sensitive Populations**
***Harpal S. Buttar, DVM, PhD, MSc***
Senior Scientist and Adjunct Professor, Therapeutic Products Directorate, Health Canada

## Session 256 RA3 - Regulatory Affairs, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 151A** *CME, Nursing, and Pharmacy credits offered*

### Public Clinical Trials Data: Preparing for the Registry

SESSION CHAIRPERSON

***Lee H. Evans***
Director, Strategic Planning and Portfolio Management, Clinical and Regulatory Information Services, Merck & Co., Inc.

This session addresses the latest information from industry, legal challenges from state and federal governments, and the potential impact on regulatory strategies related to public clinical trials data. These issues are considered within the context of a logical technology framework for the aggregation, staging, and transmittal of data points for inclusion in a registry.

**Merck's Approaches to Publication and Registration of Clinical Trials**
***Laurence J. Hirsch, MD***
Executive Director, Medical Communications, Merck Research Laboratories

**Regulatory Risks, Operational Considerations, and Overall Impact of Public Clinical Trial Registries**
***Annetta C. Beauregard, MBA, MS***
Regulatory Consultant, Office of Scientific and Regulatory Policy, Global Regulatory Affairs, Eli Lilly and Company

**Issues in Reporting Results of Clinical Trials**
***Deborah A. Zarin, MD***
Director, ClinicalTrials.gov, National Library of Medicine
Assistant Director, Clinical Research Projects, National institutes of Health

## Session 257 RA4 - Regulatory Affairs

10:30 AM - 12:00 PM LEVEL = ●

**Room 152B**

### Labeling and Drug Development: Product Information and Company Core Data Sheet

SESSION CHAIRPERSON

***Concettina I. Cordaro, MD***
Head, Central Product Information-Group Regulatory Affairs, Bracco Imaging S.p.A., Italy

Labeling is region-specific. However, the generation and use of CORE prescribing information can ensure consistent information throughout regions. Understanding format and content of the regional labeling requirements in the USA, EU, Japan, and Canada will facilitate devising and updating the company core data sheet, as an effective global tool for reaching consistency.

**US, European, Canadian, and Japanese Package Inserts and Linkage to the Company Core Data Sheet**
***Diana E. Fordyce, PhD, RAC***
Senior Regulatory Affairs Scientist, Cato Research, Ltd.

**Compiling the Efficacy Part of the European, USA, and Japanese Prescribing Information**
***Concettina I. Cordaro, MD***
Head, Central Product Information-Group Regulatory Affairs, Bracco Imaging S.p.A., Italy

**Link Between the CCDS/CCSI and the Approved Prescribing Information**
***Joseph Kappel***
Head, Global Product Information and Marketed Products, Novartis Pharma AG, Switzerland

## Session 258 RA5 - Regulatory Affairs, IT

10:30 AM - 12:00 PM LEVEL = ●

**Room 146A**

### Structured Clinical Trial Protocol

SESSION CHAIRPERSON
***Joe E. Jenkins***
Marketing Director, Life Sciences, Arbortext, Inc.

Structured Clinical Trial Protocol (SCTP) is an evolving XML-based initiative to define a standard representation for the content and structure of clinical trial protocol information. The initiative is being driven through a team consisting of industry, agency, and software representatives. Attendees of this session will learn about the SCTP initiative, the role XML will play, and the benefits organizations can achieve when using structured content.

**Overview of the Structured Clinical Trial Protocol Initiative**
***Joe E. Jenkins***
Marketing Director, Life Sciences, Arbortext, Inc.

**Business Implications of SCTP: Is Your Organization Ready?**
***Vivian Bruner, MS***
Team Leader, Scientific Communications, Eli Lilly and Company

## Session 259 RA6 - Regulatory Affairs

10:30 AM - 12:00 PM LEVEL = ■

**Room 140A** *CME credits offered*

### Update from China

SESSION CHAIRPERSONS
***Wenzhuang Cao***
Director General, Department of Drug Registration, State Food and Drug Administration, China
***Ling Su, PhD***
Medical and International Pharma Development Director, Shanghai Roche Pharmaceuticals Ltd., China

In this session, speakers from the Chinese regulatory agency, State Food and Drug Administration, will discuss recent developments in regulatory policies and regulations in China, with a focus on drug registration and clinical trial areas.

**Overview of Drug Registration in China**
***Wenzhuang Cao***
Director General, Department of Drug Registration, State Food and Drug Administration, China

**Review and Approval of Clinical Trials in China**
***Jianhua Ding***
Deputy Director, Division of Pharmaceuticals, Department of Drug Registration, State Food and Drug Administration, China

## Session 260 RD - R&D Strategy, PM

10:30 AM - 12:00 PM LEVEL = ■

**Room 150B**

### Managing the Discovery-development Transition

SESSION CHAIRPERSON
***Thomas Senderovitz, MD***
Vice President, Experimental Medicine, Ferring Pharmaceuticals A/S, Denmark

This session will provide an overview of a way to manage the research/discovery/early development process and a discussion focusing on the importance of the corporate culture rather than only on technologies.

**Why Is It Important to Focus on Discovery-development Transition?**
***Thomas Senderovitz, MD***
Vice President, Experimental Medicine, Ferring Pharmaceuticals A/S, Denmark

**Transition of Molecules from R to D in a Project-centric Organization**
***Lars Guldbaek Karlsen***
Senior Vice President, Product Development, Novo Nordisk A/S, Denmark

**Critical Path Initiative: Importance in the Discovery-development Transition**
***Shiew-Mei Huang, PhD, FCP***
Deputy Director for Science, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA

## Session 261 ST - Statistics, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 201** *CME credits offered*

### Design and Analyses Issues in Prevention Trials

SESSION CHAIRPERSON
***Mohamed Al Osh, PhD, MS***
Biostatistics Team Leader, CDER, FDA

This session considers some of the issues that arise in prevention trials across different clinical areas. Among these issues are selection of the patient population, low incident rates and their impact on study power, long study duration and the use of surrogate endpoints, and multiple and composite endpoints.

**Study Design Issues in Prevention Trials**
***Kathleen S. Fritsch, PhD***
Division of Biometrics III, Office of Biostatistics, CDER, FDA
***Mohamed Al Osh, PhD, MS***
Biostatistics Team Leader, CDER, FDA

**Preventing Alzheimer's Disease: The PREADVISE Experience**
***Richard J. Kryscio, PhD***
Professor, Saunders-Brown Center on Aging, University of Kentucky

**Piggyback Large Prevention Trials for Cancer Biomarker Discovery and Evaluation**
***Ziding Feng, PhD***
Member/Professor of Biostatistics, Division of Public Health Science, Fred Hutchinson Cancer Research Center

## Session 262 TR - Training, CR

10:30 AM - 12:00 PM LEVEL = ■

**Room 207B**

### The Career Trends and Challenges for Clinical Research Professionals

SESSION CHAIRPERSON

***Joan A. Kroll-Chambers***
Director of Strategic Marketing and Development, Tufts Center for the Study of Drug Development, Tufts University

Since 1998, trends and challenges have been tracked within the clinical trials employment market. This session provides a detailed review and discussion of the trends surrounding clinical research positions and the evolution of responsibilities and skill sets required to perform these positions. This session will offer a first-hand look at three positions from three different professionals in the roles of a CRA, regulatory/QA, and CRC and how their roles and responsibilities have evolved because of the changing R&D paradigm and market pressures.

**A Look at Industry Trends Impacting Clinical Research Positions**
***Joan A. Kroll-Chambers***
Director of Strategic Marketing and Development, Tufts Center for the Study of Drug Development, Tufts University

**Personal Perspectives Discussed on How Roles and Responsibilities Have Evolved in Response to Industry Changes**
***Laurie Halloran, MS***
President, Halloran Consulting Group, Inc.

**Personal Perspectives Discussed on How Roles and Responsibilities Have Evolved in Response to Industry Changes**
***Cindy Baxter***
Therapeutic Director, AmericasDoctor, Inc.

12:00 PM - 1:30 PM **LUNCHEON**

**Lunches will be distributed from 12:00 PM to 1:00 PM in Exhibit Hall C, Lower Level, Convention Center**

## Session 263 AD - Advertising, CR, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 202B** *CME and Pharmacy credits offered*

### Clinical Database Registries

SESSION CHAIRPERSON

***Minnie Baylor-Henry, RPh, JD***
Vice President, Medical and Regulatory Affairs, Johnson & Johnson Pharmaceutical Research and Development, LLC

Clinical trial registries demonstrate the pharmaceutical companies' commitment to providing healthcare professionals and patients worldwide with meaningful information about the science behind the products. It is working towards a goal of transparency. This session will discuss a number of issues including:

- Can a global company have only one clinical trials registry?
- How do we decide what studies to post on this registry?
- Can the studies contain the conclusions of the clinical trial or just the data?
- Are these sites promotional? Do you need the package insert? For which country?
- What is the time commitment for posting the study data for a marketed product?
- What should the industry be doing for investigational drug clinical trials?

***Kathleen Meriwether, JD***
Assistant US Attorney

***Thomas E. Costa, JD***
Vice President, International Policy and Government Affairs, Bristol-Myers Squibb

## Session 264 BT - Biotechnology, CMC, RD

1:30 PM - 3:00 PM LEVEL = ■

**Room 154AB** *CME credits offered*

### Hot Topics in Biotechnology

SESSION CHAIRPERSONS

***George F. Steinfels, PhD, MBA***
President, Genomic Strategies

***Barney King, MD, MBA***
President, Macnas Consulting International

This session will focus on the latest important topics in the field of biotechnology. Topics to be considered in the session will include changes in GMPs and their impact on biotechnology processes, the impact of recent California initiatives in the area of stem cell research, and the latest regulatory and clinical topics.

**New cGMP Initiative and Impact on Biotechnology Products**
***Barney King, MD, MBA***
President, Macnas Consulting International

**Stem Cell Initiatives**
***Judi Weissinger, PhD***
President and CEO, Weissinger Solutions, Inc.

## Session 265 CDM - Clinical Data Management

1:30 PM - 3:00 PM LEVEL = ●

**Room 204BC**

### A Discreet Professional Discipline: What Initiated the Evolution/Revolution of Clinical Data Management

SESSION CHAIRPERSON

***C. Michael Bailey***
Project Manager, Biotechnical Services, Inc.

This session addresses how the discreet profession of clinical data management developed, as well as emerging needs during the discipline's evolution.

**A Brief History of Clinical Data Management**
***C. Michael Bailey***
Project Manager, Biotechnical Services, Inc.

**The New CDM: EDC's Impact on the Role of the Clinical Data Manager**
***William Gluck, PhD***
Director, Clinical Data Management, Gilead Sciences, Inc.

**What Is Next for Clinical Data Management**
***Donald F. Fortin, MD***
President and CEO, Versagenics

## Session 266 CMC - Chemistry, Manufacturing, and Controls, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 147A**

### Quality by Design

SESSION CHAIRPERSON

***Ajaz S. Hussain, PhD***
Deputy Director, Office of Pharmaceutical Science, CDER, FDA

It is well recognized that quality cannot be tested into a product and that it has to be built in by design. Use of the phrase "quality by design," or QbD in the pharmaceutical context, raises many responses such as "It is a great concept, but can we afford it?" and "How does one achieve and demonstrate QbD?" This suggests a lack of clear understanding of this concept, when it essentially has been the foundation of current regulations. This session will elaborate on this concept and describe how we are currently achieving or falling short of achieving QbD, seek to describe the minimal level of QbD that is necessary, and describe how a higher level of QbD may be leveraged to provide regulatory flexibility for continuous improvement.

**An FDA Perspective**
***Ajaz S. Hussain, PhD***
Deputy Director, Office of Pharmaceutical Science, CDER, FDA

**An Industry Perspective**
***Robert A. Reed, PhD***
Senior Director, Pharmaceutical Analysis and Control, Merck Research Laboratories

**Panel Discussion/Q&A Period**

## Session 267 CP - Clinical Safety and Pharmacovigilance, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 207A**

### Regulatory Changes in EU Pharmacovigilance

SESSION CHAIRPERSONS

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

In this session, the following aspects will be presented and discussed:

- The impact of the new Community legislation on the EU pharmacovigilance activities with the main focus on new risk management and minimization activities, the reinforced EMEA coordination role in the pharmacovigilance networking model, and strengthening the partnership with competent authorities in the Member States in the EU.
- The EMEA Roadmap to 2010 and EMEA's vision on postauthorization activities focusing on a proactive conduct of pharmacovigilance, throughout the lifecycle of a medicinal product in order to further strengthen public health in an enlarged EU.
- Collaboration between EMEA and FDA in the area of pharmacovigilance.

***Panos Tsintis***
Head of Sector for Pharmacovigilance and Postauthorization and Efficacy, EMEA, EU

***Ingemar Persson***
CHMP, EMEA, EU

***Gaby L. Danan, MD, PhD***
Head, Pharmacovigilance and Epidemiology Department, sanofi-aventis, France

## Session 268 CR1 - Clinical Research and Development

1:30 PM - 3:00 PM LEVEL = ●

**Room 149AB**

### Innovative Recruitment and Retention Techniques in Europe

SESSION CHAIRPERSON

***Emma Sergeant, RN***
President, Fast4wD Ogilvy, UK

This session will provide a deeper understanding of the use of innovative techniques for patient recruitment and retention in Europe and how to incorporate these techniques into clinical study plans. It will provide insight into the challenges of ethical approval of these types of programs across Europe's culturally diverse populations and give guidance on how to make allowances for these challenges in both planning and rescue situations.

**Accelerated Patient Recruitment: Practical Approaches for US and European Trials**
***Bill Byrom, PhD***
Product Development Director, ClinPhone, Inc., UK

**Competitive Recruitment in Global Multicenter Trials: Different Perspectives**
***Laura Luchini, PhD, MD***
Executive Director, Eurotrials Brazil Consultores Científicos, Brazil

**Optimizing Patient Recruitment in Central and Eastern Europe**
***Suzanne Pozsonyi, MPH***
Senior Director, Account Management, PAREXEL International, Netherlands

## Session 269 CR2 - Clinical Research and Development, PP

1:30 PM - 3:00 PM LEVEL = ●

**Room 145A** *CME and Nursing credits offered*

### Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done?

SESSION CHAIRPERSON

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

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

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

**An Examination of Why Fraud and Noncompliance Occurs**
***Paul W. Goebel, Jr., CIP***
President and Founder, Paul W. Goebel Consulting, Inc.

**Preventing Fraud and Noncompliance**
***Gary L. Chadwick, PharmD, MPH***
Executive Director, Office of Human Subject Protection, University of Rochester

## Session 270 CR3 - Clinical Research and Development, RA, RD

1:30 PM - 3:00 PM LEVEL = ■

**Room 145B**

### Managing Late Phase in the Global Environment

SESSION CHAIRPERSON

***Carol A. Collins, PhD, MBA***
Corporate Vice President, Clinical Research Services, PAREXEL, UK

There are strong directional forces driving internationalization of late phase clinical research in Europe and a trend towards more global programs. This paper examines the unique issues and major challenges of running these large-scale studies; meeting the needs of both strategic and local medico-marketing divisions, as well as physicians, patients and regulatory authorities.

**The Changing Paradigm of Late-phase Research**
***Carol A. Collins, PhD, MBA***
Corporate Vice President, Clinical Research Services, PAREXEL, UK

**Managing through the Global Environment**
***Nayan Nanavati, MS***
President and Chief Operating Officer, Suven Life Sciences

**Maximizing Returns on Late-phase Studies**
***Jeffrey P. Trotter, MS***
President, Ovation Research Group

## Session 271 CR4 - Clinical Research and Development, CS

1:30 PM - 3:00 PM LEVEL = ■

**Room 147B**

### Drug Supply Doesn't Always Have to Be Rate Limiting in Clinical Development

SESSION CHAIRPERSON

***David F. Bernstein, PhD***
Vice President, Pharmaceutical Science and Regulatory Compliance, Cato Research West

The procurement of CTM (clinical supply materials; IMP = investigational medicinal product in the EU) is often perceived as rate limiting to the initiation of clinical research programs. This session provides pro-active suggestions to identify likely rate-limiting steps and how they can be circumvented. The presentations are from the perspectives of a clinical research physician, a clinical research consultant, and a clinical supply manufacturing and packaging coordinator.

**Clinical Supplies or Clinical Surprise**
***Sam L. Teichman, MD, FACC, FACP***
Principal, WinPharm Associates

**Essential CTM for Busy Research Professionals**
***Harold D. Doshan, PhD***
President, Pharmaconsult Associates

**Clinical Research Is from Venus; Clinical Supplies Are from Mars**
***David F. Bernstein, PhD***
Vice President, Pharmaceutical Science and Regulatory Compliance, Cato Research West

## Session 272 CR5 - Clinical Research and Development

1:30 PM - 3:00 PM LEVEL = ●

**Room 146A** *Pharmacy credits offered*

### FDA Labeling Update: Target Product Profile

SESSION CHAIRPERSON

***Jeanne M. Delasko, RN, MS***
Label Initiatives Specialist, Study Endpoints and Label Development, Office of New Drugs, CDER, FDA

This session provides an update/overview of the role and utility of a target product profile (TPP) in the drug development process in terms of product labeling goals. A description of what TPP is, what it is not, and use of a TPP at meetings between the sponsor and FDA will be discussed in addition to the benefits and challenges of using a TPP.

**TPP: An FDA Update**
***Jeanne M. Delasko, RN, MS***
Label Initiatives Specialist, Study Endpoints and Label Development, Office of New Drugs, CDER, FDA

**TPP: The Benefits and Challenges**
***Sharon N. Olmstead***
Vice President, Regulatory Liaison and Policy, Global Regulatory Affairs, Schering-Plough Research Institute

**TPP: An Industry Perspective**
***Linda S. Carter***
Senior Director, Regulatory Affairs, Johnson & Johnson Pharmaceutical Research and Development, LLC

## Session 273 CTM - Clinical Trial Management, FI, PM

1:30 PM - 3:00 PM LEVEL = ■

**Room 140B**

### Achieving Win/Win Results for Sponsors and Sites: Metrics and Budgeting Practices that Encourage Partnership and Performance

SESSION CHAIRPERSONS

***Linda Martin, MBA***
Principal, KMR Group, Inc.
***Cathy A. White***
Global Chief Executive Officer, Neeman Medical International

As sponsors continue to focus on efficiencies, targeting time reductions as great as 50%, there is a critical need to support participating sites with accurate up-front expectations, patient recruitment techniques, systems to accurately estimate study costs, and metrics that serve as navigational tools to assure that both the sponsor and the site can establish a partnership that achieves a shared success.

**Developing Study Budgets that Achieve Results for Sponsor, CRO, and Site**
***Cathy A. White***
Global Chief Executive Officer, Neeman Medical International

**Setting Standards on Metrics to Manage and Drive Performance at Clinical Sites**
***Scott Martin, MA, JD***
Principal, KMR Group, Inc.

**Effective Site Selection and Management: A Sponsor Perspective**
***James P. Kremidas***
Global Enrollment Optimization, Eli Lilly and Company

## Session 274 DM - Document Management/ eSubmissions, RA

1:30 PM - 3:00 PM LEVEL = ●

**Room 206**

### eCTDs: Regional Progress and Lessons Learned from the Regulatory Authority Perspective

SESSION CHAIRPERSON

***Mary L. Collins***
Director, Regulatory Affairs, Image Solutions, Inc.

This session will provide the regulatory authority perspective on progress achieved and lessons learned as the number of eCTD submissions and our experience continues to grow. Topics will include authority readiness, initiatives to support eCTD review and evaluation, and regional specific challenges and opportunities.

**eCTD: US Perspective**
***Gary Gensinger***
Director, Review Technology Staff, Office of Information Management, CDER, FDA

**eCTD: EU Perspective**
***Timothy Buxton, LLB***
Head of Sector, Project Management, EMEA, EU

**eCTD: Japan's Perspective**
***Hitoshi Matsui***
Executive Consultant, CAC Corporation, Japan

## Session 275 GCP - Good Clinical Practices, CR, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 202A**

### Clinical Development for Drug-device Combination Products

SESSION CHAIRPERSON

***Charma Konnor, RPh, RAC***
Senior Consultant/Manager, Phoenix Regulatory Association, Ltd.

There are an increasing number of products being developed that are regulated as combination products. This can raise questions about the role of GCP expectations for drug-device products and how to best achieve a quality clinical study that meets the differing regulatory requirements. Questions also arise concerning the FDA's review of such products.

**Drug versus Device Clinical Trials, and Now the Combination!**
***Charma Konnor, RPh, RAC***
Senior Consultant/Manager, Phoenix Regulatory Associates, Ltd.

**GCP Compliance Considerations for Drugs and Biologics**
***Michael R. Hamrell, PhD, RAC***
President, MORIAH Consultants

**Clinical Trials for Combination Products: An FDA Perspective**
***Ashley B. Boam***
Supervisory Biomedical Engineer, CDRH, FDA

## Session 276 IS - Investigator Sites, AHC

1:30 PM - 3:00 PM LEVEL = ■

**Room 101** *CME credits offered*

### Effective Operation of Clinical Research Units

SESSION CHAIRPERSON

***Gary L. Steinman, MSEE***
Chief Executive Officer, Medexetech; President, GLS & Associates

This presentation will describe approaches to examining the operational productivity of clinical research sites that encompass safety, quality, and timeliness as well as money. Some common problems encountered at typical clinical sites will be discussed, and some potential solutions will be offered.

**Principles and Practices**
***Gary L. Steinman, MSEE***
Chief Executive Officer, Medexetech; President, GLS & Associates

**Site Perspective and Experience**
***Antoni A. Piergies, MD, MSEE***
Unit Director; Vice President, Clinical Pharmacology, PAREXEL International

## Session 277 IT1 - Information Technology, OS

1:30 PM - 3:00 PM LEVEL = ●

**Room 152A**

### Integrating Multivendor Clinical Trial Systems

SESSION CHAIRPERSON

***Joseph J. Donaghy, Jr., MS***
Technical Project Manager, PharmalinkFHI

Clinical trials amass data from multiple sources such as clinical data management systems, central labs, safety databases, and trial management systems. This session will focus on approaches to integrating multiple electronic clinical trial data. Approaches and techniques that provide validated integration systems for re-use from trial to trial will be discussed.

**An Integrated Approach to Clinical Data Warehousing**
***Glen De Vries, PhD***
Chief Technology Officer, Medidata Solutions, Inc.

**Clinical Data Management Systems' Database Structure versus Reporting Systems' Database Structure**
***Robert B. Stephens***
Software Developer, Integrated Clinical Systems, Inc.

**Creating Specifications to Auto-generate Data Files, FDA Listings, and Interactive Reporting Systems Input from EDC Systems**
***Joseph J. Donaghy, Jr., MS***
Technical Project Manager, PharmalinkFHI

## Session 278 IT2 - Information Technology

1:30 PM - 3:00 PM LEVEL = ■

**Room 146B**

### PhRMA IMPACC's Strategic View of the Future of Healthcare IT and Associated Implications for the Biopharmaceutical Industry

SESSION CHAIRPERSON

***Diana McKenzie***
Senior Director, Development Information Systems, Amgen Inc.

In this session, the leadership of PhRMA's Information Management Policy and Affairs Coordinating Committee will present their strategic view of the biopharmaceutical landscape from the perspective of the broader healthcare system and related e-health initiatives. The session will include an overview of advances in the area of e-prescribing, electronic health records and the establishment of regional health organizations and will address potential implications to policy, information standards, industry level IT infrastructure and biopharmaceutical operating models. A panel discussion will cover the key elements of the strategy and how it relates to other significant IT strategies emerging across the regulatory and health care landscape.

**A Strategic View of eHealth and the Biopharmaceutical Industry: Commercial Perspective**
***Mike Curnyn***
Senior Director, Commercial IS, AstraZeneca PLC

**A Strategic View of eHealth and the Biopharmaceutical Industry: R&D Perspective**
***Albert W. Kellenbenz, MS, MBA***
Vice President, Research Information Services, Wyeth Pharmaceuticals

*Panelists*
***Shawn E. Ramer, PhD***
Vice President, Informatics, Bristol-Myers Squibb

***Thomas Scarnecchia, MS***
Vice President, Corporate Informatics, Millennium Pharmaceuticals, Inc.

## Session 279 MC - Medical Communications, MA

1:30 PM - 3:00 PM LEVEL = ●

**Room 209AB** *CME and Pharmacy credits offered*

### Survey of Medical Liaison Practices Across the Pharmaceutical Industry

SESSION CHAIRPERSON
***Christopher Marrone, PharmD***
Medical Liaison Consultant, Eli Lilly and Company

Roles and responsibilities of persons in field-based medical liaison positions may differ across the pharmaceutical industry. In an effort to assess trends in the area of medical liaisons, a survey was administered to medical liaison management across the industry.

**Medical Liaison Survey Overview**
***Christopher Marrone, PharmD***
Medical Liaison Consultant, Eli Lilly and Company

**Medical Liaison Survey Results: Part 1 of 2**
***J. Lynn Bass, PharmD***
Regional Medical Liaison II, Amgen Inc.

**Medical Liaison Survey Results: Part 2 of 2**
***Craig J. Klinger, RPh***
Medical Liaison Consultant, Eli Lilly and Company

## Session 280 MW - Medical/Scientific Writing, ST

1:30 PM - 3:00 PM LEVEL = ●

**Room 102AB**

### Medical Writing and Biostatistics: A Significant Interaction

SESSION CHAIRPERSON
***Kerry Gordon, PhD***
Director, Biostatistics and Medical Writing (UK), Quintiles Ltd., UK

This session will explore the importance of the biostatistician and the medical writer as members of the core project team. In particular, key interactions between biostatisticians and medical writers will be discussed.

**Numbers and Words: Positive Collaborations Improve Regulatory Submissions**
***MaryAnn Foote, PhD, MS***
Director, Global Regulatory Writing, Amgen Inc.

**Partnering with Biostatisticians**
***Mike W. Colopy, PhD***
Biostatistician, GlaxoSmithKline

**Medical Writing Review of Statistical Analysis Plans**
***Kerry Gordon, PhD***
Director, Biostatistics and Medical Writing (UK), Quintiles Ltd., UK

## Session 281 NC - Nonclinical Laboratory Safety, CR, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 103B**

### Update on the Use of Juvenile Animals for Safety Assessment of Pediatric Drugs

SESSION CHAIRPERSON
***Beatriz Silva Lima, PhD***
Professor and Faculty, University of Lisboa and National Institute of Pharmacy and Medicines (INFARMED), Portugal

The use of juvenile animals in the context of safety assessment of pediatric drugs will be discussed in line with the currently available guidance in the US and in preparation in the EU. The experience gained from the more recent assessment and advisory procedures will be presented and discussed by regulators and industry.

**Regulatory Initiatives in Europe: The Guideline on the Need for Nonclinical Testing of Human Pharmaceuticals in Juvenile Animals**
***Beatriz Silva Lima, PhD***
Professor and Faculty, University of Lisboa and National Institute of Pharmacy and Medicines (INFARMED), Portugal

**The US FDA Perspective and Experience**
***Karen Davis-Bruno, PhD***
Pharmacologist, Division of Metabolic and Endocrine Drug Products, Office of New Drugs, CDER, FDA

**The European Experience on Assessing and Requesting Studies in Juvenile Animals: Examples from Centralized Applications and Scientific Advice**
***Bert Haenen, PhD***
Senior Assessor, National Institute of Public Health & Environment, Netherlands

**Ongoing Industry Experience on Safety Studies in Juvenile Animals**
***Mark E. Hurtt, PhD***
World Wide Safety Sciences, Pfizer Global Research and Development

## Session 282 OS - Outsourcing

1:30 PM - 3:00 PM LEVEL = ■

**Room 150A**

### High-tech Outsourcing: Computerizing the Selection Process

SESSION CHAIRPERSON
***Rikki Hansen Bouchard, MPA***
President and CEO, RH Bouchard & Associates, Inc.

Sponsor companies have been investigating new methods for selecting service providers. Amgen's Strategic Sourcing and Procurement organization has taken this to a new level by mandating the use of an on-line tool and electronic sourcing process for the selection of all providers. In 2004, Amgen launched an initiative to select prequalified CRO service providers using this tool. This session will explore the tool, its benefits, drawbacks, and how the providers reacted to its use.

**Panel Discussion – Interactive Discussion of eSourcing: A Case Study**

***Ann G. Kilrain***
Senior Manager, Strategic Sourcing and Procurement, Amgen Inc.

***David F. Fenske***
Senior Director, Contracts and Proposals, ICON Clinical Research

## Session 283 PM - Project Management, CR, PP, RA, RD

1:30 PM - 3:00 PM LEVEL = ■

**Room 143AB** *Project Management Institute credits offered*

### PLENARY SESSION
### Transforming the Product Development Lifecycle: Where Are the Opportunities and What Happens if We Don't Start Changing the Way Drugs Are Developed?

SESSION CHAIRPERSONS

***Michele C. Livesey***
Head, Project Management, Barrier Therapeutics

***Martin D. Hynes, III, PhD***
Director, Quality and Operations, Pharmaceutical Product Research and Development, Eli Lilly and Company

Current challenges within the pharmaceutical industry include increased R&D spending with a reduction of the new chemical entities that make it to approval. Obviously, this is a formula which cannot be sustained. What happens if our industry continues in this manner? What can be gleaned from other industries and past experiences in order to transform how business is being done today? What can be done to transform the industry and what role does the project manager play in helping companies succeed?

In this session, we will explore through case studies what it takes to transform an industry and what happens when companies don't evolve. Additionally, current practices which are making a difference will be explored.

***Kenneth I. Kaitin, PhD***
Director, Tufts Center for the Study of Drug Development, Tufts University

**Project Management's Role in the Transformation of the Pharmaceutical Industry**
***Robin G. Foldesy, PhD***
Vice President, Project Management, Wyeth Research

## Session 284 PP - Public Policy/Law, CR, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 144ABC** *CME and Pharmacy credits offered*

### Publication and Availability of Clinical Trial Results: Ethical, Public Health, Confidentiality, Commercial and Other Critical Issues – A Panel Discussion

SESSION CHAIRPERSON

***Juhana E. Idänpään-Heikkilä, MD***
Secretary General, Council for International Organizations of Medical Sciences (CIOMS), c/o World Health Organization, Switzerland

Requests that the results of clinical trials be made publicly available are increasing. The session will discuss the challenging role of investigators, ethics committees, drug regulators, and industrial sponsors of clinical trials in facilitating the increased transparency of clinical trials.

*Panelists*

***Greg Koski, MD, PhD***
Associate Professor of Anesthesia, Massachusetts General Hospital Partners Healthcare System

***Marcia Angell, MD***
Former Editor, *New England Journal of Medicine*; Senior Lecturer on Social Medicine, Harvard Medical School

***Bert A. Spilker, MD, PhD***
President, Bert Spilker and Associates

***Robert J. Temple, MD***
Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

## Session 285 RA1 - Regulatory Affairs

1:30 PM - 3:00 PM LEVEL = ■

**Room 146C** *CME credits offered*

### New Pharmaceutical Legislation – Part 2 of 3: Decentralized Procedure and Mutual Recognition Procedure

SESSION CHAIRPERSONS

***Truus Janse-de-Hoog, PharmD***
Coordinator, Mutual Recognition Procedures; Medicines Evaluation Board, Netherlands

***Anu Tummavuori-Liemann***
EU Enlargement Coordinator, F. Hoffmann-La Roche Ltd., Switzerland

*Part 1 of this session will be held on Tuesday at 10:30 AM; Part 3 will be held on Tuesday at 3:30 PM.*

In this session, the most important changes in Mutual Recognition Procedures will be highlighted. The view from MRFG/national authorities and industry expectations will be presented.

**Overview of Changes in Mutual Recognition Procedure after Implementation of New Legislation**
***Truus Janse-de-Hoog, PharmD***
Coordinator, Mutual Recognition Procedures, Medicines Evaluation Board, Netherlands

**The New Decentralized Procedure**
***Peter Bachmann***
Head of Unit, Mutual Recognition Procedures, Federal Institute for Drugs and Medical Devices, (BfArM), Germany

**Industry View on the New Decentralized Procedure**
***Nicole Dillier***
Head, EU Regulatory Intelligence, Novartis Pharma AG, Switzerland

## Session 286 RA2 - Regulatory Affairs, CR, NC

1:30 PM - 3:00 PM LEVEL = ●

**Room 151B**

### Regulatory Impact in Drug Development of Integrating Toxicogenomics into Nonclinical Development

SESSION CHAIRPERSON

***Sydney A. Gilman, PhD***
Vice President, Regulatory Affairs, Gene Logic Inc.

Toxicogenomics and pharmacogenomics offer the possibility of influencing nonclinical and clinical information for pharma, CROs, regulatory authorities, and domestic and international organizations in the strategic planning in drug development. This session will discuss the regulatory impact of genomics on the drug development program and ways that the impact may lead to streamlining the pathway to approval.

**Ongoing FDA Activities in Pharmacogenomics and Biomarker Validation**
***Gualberto Ruaño, MD, PhD***
President and CEO, Genomas

**Pharmaceutical Industry View on the Impact of Genomics on Drug Safety**
***Rakesh Dixit, PhD, DABT***
Section Head, Toxicokinetics and Biomarker Laboratories, Merck & Co., Inc.

**Attenuation of Ventricular Remodeling Associated with Heart Failure in an Animal Model: Use of Microarray Data in Support of a Hypothetical Drug Submission**
***Thomas Papoian, PhD, DABT***
Senior Pharmacologist, Cardio-renal Drug Products, CDER, FDA

## Session 287 RA3 - Regulatory Affairs, PP

1:30 PM - 3:00 PM LEVEL = ●

**Room 151A** *Pharmacy credits offered*

### Drug Importation: At What Cost?

SESSION CHAIRPERSON

***Amjad Iqbal, PharmD***
Postdoctoral Fellow - Regulatory Affairs, St. John's University

The issue of drug importation is one that directly and indirectly affects nearly every aspect of healthcare and has far-reaching economic and clinical implications. The decisions that are made today regarding the importation of drugs have the potential to compromise the integrity of our drug supply chain. Discussing this topic from a variety of perspectives will provide insight into this issue.

**The Springfield Success Story: A Model for America**
***Michael J. Albano, MS, MPA, DH***
President, Michael Albano & Associates

***Douglas B. Farquhar***
Principal, Hyman, Phelps & McNamara, PC

## Session 288 RA4 - Regulatory Affairs

1:30 PM - 3:00 PM LEVEL = ■

**Room 152B**

### CDER Hot Topics – Part 1 of 2: FDA Risk Minimization Guidances

SESSION CHAIRPERSON

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

*Part 2 of this session will be held on Wednesday at 1:30 PM.*

On March 24, 2005, FDA released three final drug safety guidances – "Premarketing Risk Assessment," "Development and Use of Risk Minimization Action Plans," and "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment." This session will describe the scope and key issues in the three guidances and will discuss drug safety considerations for all stages of clinical development of medical products.

**Premarketing Risk Assessment**
***Robert J. Meyer, MD***
Director, Office of Drug Evaluation II, CDER, FDA

**Development and Use of Risk Minimization Action Plans**
***Anne E. Trontell, MD, MPH***
Deputy Director, Office of Drug Safety, CDER, FDA

**Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment**
***Julie G. Beitz, MD***
Deputy Director, Office of Drug Evaluation III, CDER, FDA

## Session 289 RA5 - Regulatory Affairs

1:30 PM - 3:00 PM LEVEL = ■

**Room 140A**

### Clinical Trials in China: Progress and Future Perspective

SESSION CHAIRPERSONS

***Jianhua Ding***
Deputy Director, Division of Pharmaceuticals, Department of Drug Registration, State Food and Drug Administration, China

***Edmund Tsuei, PhD***
Head, Pharmaceutical Development Operations - Asia, Roche Products Pty Ltd., Australia

In this session, speakers from the regulatory agency and the industry will discuss recent activities in regulation and supervision of clinical trials, as well as the experience of conducting multinational trials, in China.

**Implementation of GCP in China**
***Cai Cao***
Assistant Committee Director and Division Director, Certification Committee of Drugs, State Food and Drug Administration, China

**Experience of Multinational Clinical Trials in China**
***Ling Su, PhD***
Medical and International Pharma Development Director, Shanghai Roche Pharmaceuticals Ltd., China

**Global Drug Clinical Development in China: An Industry Perspective**
***James Cai***
Vice President, Research and Development, AstraZeneca Pharmaceutical Co. Ltd., China

## Session 290 RD - R&D Strategy

1:30 PM - 3:00 PM LEVEL = ◆

**Room 150B**

### Increase in Expected Net Present Value Through Design Modifications

SESSION CHAIRPERSON

***Jonathan R. Smith, PhD, MSc***
Executive Director, Strategic Development, Biostatistics, Quintiles, Inc.

The presentations within this session will identify and discuss areas where large gains in expected net present value (NPV) can be obtained through particular design modifications to a drug development program. Examples covered will include: (a) running more than two phase III trials in parallel; (b) conducting a more definitive dose-ranging trial; and (c) incorporating certain recently developed adaptive designs within the program.

***Carl-Fredrik Burman, PhD***
Statistical and Mathematical Science, AstraZeneca R&D, Sweden

**Moving Statistics Beyond the Individual Clinical Trial: Using Simple Decision Science to Optimize a Clinical Development Plan**
***Steven A. Julious, PhD***
Senior Lecturer, Medical Statistics Unit, Institute of General Practice and Community Care, University of Sheffield Community Sciences Centre, Northern General Hospital, UK

***Jonathan R. Smith, PhD, MSc***
Executive Director, Strategic Development, Biostatistics, Quintiles, Inc.

## Session 291 ST - Statistics, CR

1:30 PM - 3:00 PM LEVEL = ●

**Room 201** *CME and Pharmacy credits offered*

### Genomic Statistical Approaches for the Use and Validation of Genomic Biomarker Information

SESSION CHAIRPERSONS

***Sue Jane Wang, PhD, MA, MS***
Expert Mathematical Statistician, US FDA Intercenter Pharmacogenomics and Pharmacogenetics Initiative WG, Office of Biostatistics, OPaSS, CDER, FDA

***Lutz Edler, PhD***
Head, Biostatistics Unit, German Cancer Research Center, Germany

Quantitative information from genotyping patients and identifying genes that are differentially expressed in various situations is becoming routinely integrated into clinical trials for new and better treatment. The identification of new biomarkers for novel therapeutic targets requires efficient statistical use of functional genomic data. This session will cover statistical design and analysis methods for the development of diagnostic and/or therapeutic pharmacogenomic products.

**Statistical Designs for Validating High-dimensional Pharmacogenomic Signatures in Drug Development**
***Richard M. Simon, DSc***
Chief, Biometric Research Branch, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

**Statistical Methods for Proteomic Biomarker Data**
***Dr. Francoise Seillier-Moiseiwitsch***
Director, Biostatistics and Bioinformatics Shared Resource Lombardi Cancer Center, Georgetown University Medical Center

*Discussants*
***Sue Jane Wang, PhD, MA, MS***
Expert Mathematical Statistician, US FDA Intercenter Pharmacogenomics and Pharmacogenetics Initiative WG, Office of Biostatistics, OPaSS, CDER, FDA

***Lutz Edler, PhD***
Head, Biostatistics Unit, German Cancer Research Center, Germany

## Session 292 TR - Training, IS

1:30 PM - 3:00 PM LEVEL = ●

**Room 207B** *CME, Nursing, and Pharmacy credits offered*

### Status of Study Nurse Qualification in Europe and the US

SESSION CHAIRPERSON
***Wolfgang Seifert, MD, PhD***
Senior Advisor, Drug Development, Schering AG, Germany

Requirements from academia and industry for study nurses will be presented, and the approaches in different countries will be shown.

**Education Programs for Study Nurses in European Countries**
***Kerstin Breithaupt-Groegler, MD***
Clinical Pharmacologist, KBR Clinical Pharmacology Services, Germany

**Study Nurse Training Courses in the US**
***Beth D. Harper, MBA***
Senior Vice President, Global Operations, D. Anderson & Company

**What Industry, CRO and Academia Require from Their Clinical Trial Staff**
***Karen Kragt, MSc***
Manager, International Business, DOCS International, The Netherlands

3:00 PM - 3:30 PM **REFRESHMENT BREAK**
**Exhibit Halls ABC, Lower Level**
**Convention Center**

## Session 293 AD - Advertising, MA, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 202B** *Pharmacy credits offered*

### Getting the Claims You Want

SESSION CHAIRPERSON
***Teresa P. Dowling, PharmD***
Director, Promotional Regulatory Affairs, AstraZeneca

The development of claims occurs in various stages throughout a product's life cycle. Getting the claims that you want for your product requires the integration of input from the marketing, clinical development, regulatory affairs, and legal departments within the company and negotiations with the regulatory agency.

**Introduction**
***Teresa P. Dowling, PharmD***
Director, Promotional Regulatory Affairs, AstraZeneca

***Nancy Kline Leidy, PhD***
President and CEO, MEDTAP Institute at UBC

**The Label and the Claims: Managing Expectations**
***Christine Duffy Smith***
Director, Promotional Regulatory Affairs, Oncology, AstraZeneca

## Session 294 BT - Biotechnology, TR

3:30 PM - 5:00 PM LEVEL = ●

**Room 154AB**

### The State of Biopharmaceuticals: Where the Jobs Are

SESSION CHAIRPERSON
***Mark D. Dibner, PhD, MBA***
President, BioAbility, LLC

This session will provide an overview of the biopharmaceutical industry as it stands today and where it is going, with insights on employment needs and opportunities from the point of view of an HR expert and president of a search firm, and a HR director of Human Genome Sciences, a major biotech or pharmaceutical company. There will be discussions on industry needs, valuable skill sets, as well as how to best sell yourself and secure a job. An overview of the biopharmaceutical industry as it now stands and issues facing the industry, including those that lead to new job formation, will also be presented.

**The Biopharmaceutical Industry Today and Tomorrow, and New Job Opportunities**
***Mark D. Dibner, PhD, MBA***
President, BioAbility, LLC

**Managing Your Career: Landing the Right Job in Biopharmaceuticals**
***David G. Jensen, FACP***
Managing Director, CTI Executive Search, a unit of CareerTrax Inc.

## Session 295 CDM - Clinical Data Management, PM

3:30 PM - 5:00 PM LEVEL = ■

**Room 204BC**

### Multiple Inputs/Multiple Destinations: How Project Management Can Help

SESSION CHAIRPERSON
***Harry J. Fisher***
President, PQ Consulting

This session will highlight the challenges and solutions from the new data management paradigm of "multiple inputs/multiple destinations." The role of project management will be explored as an enabler, facilitator, and driver of the various DM components.

**The Methodology of Process Metrics in Leading an Organization to Success**
***David A. Evans, MS***
Executive Vice President and Chief Technical Officer, First Genetic Trust

## Session 296 CMC - Chemistry, Manufacturing, and Controls, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 147A**

### Challenges and Opportunities in Setting Specifications

SESSION CHAIRPERSON

***Charles P. Hoiberg, PhD***
Executive Director, Pfizer Inc

The FDA and the pharmaceutical industry have been exploring new approaches for setting specifications for process controls, the drug substance and the drug product given the "desired state" that is being advocated. The "desired state" at the PQRI Workshop encompassed the objectives that the product quality and performance should be achieved and assured by design of effective and efficient manufacturing processes; that the product specification should be based on the mechanistic understanding of how formulation and process factors impact product performance; and that the manufacturers have the ability to effect continuous improvement. These concepts will be discussed.

**An Innovator Industry Perspective**
***Charles P. Hoiberg, PhD***
Executive Director, Pfizer Inc

**FDA Perspective**
***Chi-wan Chen, PhD***
Deputy Director, Division of New Drug Chemistry III, CDER, FDA

**Panel Discussion/Q&A Period**

## Session 297 CP - Clinical Safety and Pharmacovigilance, PP, RA

3:30 PM - 5:00 PM LEVEL = ●

**Room 207A** *CME, Nursing, and Pharmacy credits offered*

### FDA Office of Drug Safety: Update on Regulatory Initiatives

SESSION CHAIRPERSON

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

This will be a panel discussion with Office of Drug Safety senior management to discuss recent regulatory initiatives relating to drug safety, including a discussion of high profile risk management programs, advisory committee deliberations, and other issues relating to reducing medical error.

**Current Safety Topics of Interest**
***Paul J. Seligman, MD, MPH***
Director, Office of Pharmacoepidemiology and Statistical Science, CDER, FDA

**Isotretinoin Update**
***Anne E. Trontell, MD, MPH***
Deputy Director, Office of Drug Safety, CDER, FDA

**Antidepressant Use in Children**
***Andrew D. Mosholder, MD***
Medical Officer, CDER, FDA

## Session 298 CR1 - Clinical Research and Development, IS

3:30 PM - 5:00 PM LEVEL = ■

**Room 146A** *Nursing credits offered*

### Town Meeting on Patient Enrollment: What Do We Know? What Can We Do?

SESSION CHAIRPERSON

***Mark A. Hovde, MBA***
President, Hovde Associates LLC

Most managers of clinical trials recognize the crucial importance of timely patient enrollment. This interactive meeting will review tactics for managing several major causes of poor enrollment, including excessively restrictive enrollment criteria, inadequate patient referrals, insufficient site capacity, and deficient physician motivation.

**Recruitment, Retention, and Patient Preference**
***Audrey Rossow***
Senior Project Manager, PAREXEL MMS, Patient and Clinical Communications

**Predicting Enrollment**
***James P. Kremidas***
Global Enrollment Optimization and Innovation, Eli Lilly and Company

**Options for Enrollment Acceleration**
***Mark Eisenach, MBA***
Chief Executive Officer, Acurian, Inc.

## Session 299A CR2 - Clinical Research and Development

3:30 PM - 5:00 PM LEVEL = ◆

**Room 145A** *CME and Pharmacy credits offered*

### Applying Medical Imaging in Cardiovascular Drug Development

SESSION CHAIRPERSON

***Philip T. Sager, MD, FACC, FAHA***
Senior Director, Cardiac Research, Medical Science Director, AstraZeneca LP

According to a recent survey there are 123 new medicines in development for cardiovascular disease, which is recognized as the leading cause of death in the United States. Medical imaging techniques can play a critical role in the development of these new medicines, but there is a range of available modalities with varying strengths.

**Regulatory and Core Imaging Laboratory Issues**
***Philip T. Sager, MD, FACC, FAHA***
Senior Director, Cardiac Research, Medical Science Director, AstraZeneca LP

**Vascular Imaging for Drug Development**
***Bradley T. Wyman, PhD***
Manager, Worldwide Clinical Platforms, Pfizer Global Research and Development

**The Role of Cardiac Imaging in Clinical Trials**
***Neil Weissman, MD***
Director, Cardiac Ultrasound and Ultrasound Core Laboratories, Washington Hospital Center

## Session 299B CR3 - Clinical Research and Development, RA

3:30 PM - 5:00 PM LEVEL = ●

**Room 145B**

### Integrated Placebo Database: An Idea Whose Time Has Come

SESSION CHAIRPERSON

***Ronald J. Innerfield, MD***
Senior Medical Director, Medical and Scientific Affairs, PharmaNet

There is a wealth of information that we obtain in our clinical research that may not be put to the best possible use. One example of this is the plethora of cross-sectional information obtained from studies of placebo groups in any disease process. The clinical research community could rectify this situation by contributing resources and information to establish a database of this information across all disease spectra.

**Adventures with a Placebo Database I**
***John R. Senior, MD***
Medical Officer, Office of Pharmacoepidemiology and Statistical Science, CDER, FDA

**Adventures with a Placebo Database II**
***Robert Tipping, MD***
Director, Department of Clinical Research, Merck Research Laboratories

**Integrated Placebo Database: Hows, Whys, and Wherefores**
***Ronald J. Innerfield, MD***
Senior Medical Director, Medical and Scientific Affairs, PharmaNet

## Session 299C CR4 - Clinical Research and Development, PP, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 147B** *CME, Nursing, and Pharmacy credits offered*

### Emerging Regulatory Trends in Human Research Protection: Accrediting Institutions and the Use of Data Monitoring Committees

SESSION CHAIRPERSON

***Esther Emard***
Chief Executive Officer, Partnership for Human Research Protection; Chief Operating Officer, NCQA

This session will focus on addressing the various approaches of the comprehensive recommendations coming out of federal agencies. The session is informative and explores future potential collaborations and innovations in HRP programs.

This session will address the various regulatory strategies designed to enhance patient protection. Faculty will review current guidance surrounding the use of Data Monitoring Committees and will outline current efforts in clinical trial patient safety. The session will also focus on identifying how accreditation activities support compliance with and go beyond regulations. The presentation will conclude with faculty offering their perspectives on how best to move forward using available tools to both optimally protect human subjects and to meet the emerging regulatory standards.

***Jonathan Seltzer, MD, MA, MBA***
Director, Clinical Research, Main Line Health Heart Center

***Margaret VanAmringe***
Public Policy Support, PHRP; Vice President, External Affairs, Joint Commission on Accreditation of Healthcare Organizations

***Eileen Hilton, MD***
President and Chief Executive Officer, Biomedical Research Alliance of New York

## Session 299D CR5 - Clinical Research and Development

3:30 PM - 5:00 PM LEVEL = ●

**Room 149AB** *Pharmacy credits offered*

### Multicenter Trials Done in Phase I Clinical Research Units

SESSION CHAIRPERSON

***Stephan de la Motte, MD***
Chief Medical Officer, Harrison Clinical Research, Germany

Clinical research units can be utilized for large multicenter trials which can substantially facilitate the performance of difficult or complex trials. Specific logistical aspects, types of studies and patient populations, advantages, and limitations will be presented in this session.

**Global Lipid-lowering Phase III Trial in Phase I Units: Experiences of the Sponsor**
***Graham Price***
European Clinical Development Director, Takeda Europe R&D Centre, Ltd., UK

**Global Lipid-lowering Phase III Trial in Phase I Units: Experiences of the CRO**
***Monika Pietrek, MD, PhD, MSc***
Senior Vice President, Global Medical and Safety Services, PRA International GmbH, Germany

**Global Lipid-lowering Phase III Trial in Phase I Units: Experiences of the Phase I Unit**
***Stephan de la Motte, MD***
Chief Medical Officer, Harrison Clinical Research, Germany

## Session 299E CTM - Clinical Trial Management

3:30 PM - 5:00 PM LEVEL = ●

**Room 140B**

### Evaluation, Implementation, and Integration of a Clinical Trials Management System

SESSION CHAIRPERSON

***Andrew D. Linegang***
Systems Manager, Procter & Gamble Company

As clinical operations evolve, it is possible for numerous tools and databases to be developed to meet study planning and tracking requirements. Companies may find these tools to be highly disconnected, independent, and labor-intensive leading to duplication of data and difficulty analyzing the information that is captured, especially across projects and therapeutic areas. Clinical trial management systems offer an opportunity to address these problem areas.

In this session, we will discuss aspects of the selection and implementation process, including some evaluation strategies. We will also share a perspective on the challenges involved in implementing a clinical trial management system. And finally we will provide some insight on how to manage the change to your organization and gain acceptance for the trials management system.

**Evaluation, Implementation, and Integration of a Clinical Trials Management System**
***Andrew D. Linegang***
Systems Manager, Procter & Gamble Company

**Implementation of a CTMS at MedImmune**
***Laura Sandler, MPH***
Clinical Systems Analyst, MedImmune

**Successful Campaign Message for Standardizing the Management of Clinical Trials**
***Magaly Woolard***
Associate Director, Research Planning and Integration, Merck & Co., Inc.

## Session 299F DM - Document Management/ eSubmissions, RA

3:30 PM - 5:00 PM LEVEL = ●

**Room 206**

### Building, Submitting, and Maintaining an Electronic IND in eCTD Format

SESSION CHAIRPERSON

***Robin L. Zumbrunnen***

Associate Director, Regulatory Operations, Quintiles, Inc.

When the FDA's draft guidance for submitting CTD submissions electronically was published in 2003, it opened the door for electronic INDs to be submitted to CDER and CBER in eCTD (XML backbone) format. This session will explore the benefits of filing eINDs electronically using this format, as well as how to organize for, prepare, submit, and maintain these INDs electronically.

**eIND – Past, Present, and Future: The Transition from Paper to eIND in the eCTD Format**

***Christopher R. Patterson***

Senior Consultant, Life Sciences, IBM Global Services

**The IND: A Makeover Story**

***Lynne B. Miller***

Regulatory eSubmissions Team Leader, EPIX Pharmaceuticals

***Jeanie Kwon***

Associate Director, eDocument Services, Image Solutions, Inc.

**Making the Move to eCTD**

***Matthew J. Neal, MA***

Manager, Regulatory Affairs, Amgen, Inc.

## Session 299G GCP - Good Clinical Practices, TR

3:30 PM - 5:00 PM LEVEL = ●

**Room 202A**

### Training in QA Issues According to GCP

SESSION CHAIRPERSON

***Hans F. Poland, ScD***

Head, Corporate Clinical Quality Assurance, Schering AG, Germany

This session deals with ongoing training necessities in quality issues for personnel working in the area of clinical development. Current needs and training approaches under different views and for different groups will be presented.

**Who, How, and When to Refresh GCP Understanding**

***Hans F. Poland, ScD***

Head, Corporate Clinical Quality Assurance, Schering AG, Germany

**Use of GCP Audit Results in GCP Training of Sponsor Personnel and Investigators**

***Ursula Streicher-Saied***

Vice President, Head Global Medical Quality Management, Bayer HealthCare AG, Germany

**QA's Contribution to Ongoing GCP Training**

***Alexander Both, MS***

Associate Director, Corporate Clinical Quality Assurance, Berlex

## Session 299H IS - Investigator Sites, CR, OS

3:30 PM - 5:00 PM LEVEL = ■

**Room 101**

### The Site Is the Client

SESSION CHAIRPERSON

***Daniel M. Ulrey, MBA***

President and Chief Executive Officer, Midwest Clinical Support, Inc.

This session will present current, as well as innovative, clinical research processes designed to improve both sponsor and site productivity and decrease sponsors' cost of clinical trials while increasing the total revenue reimbursed to sites. The widely held view by many sponsors and CROs that sites and their patients are commodities continues to result in poor productivity for all parties. The speakers will present many of the major site complaints about sponsors and CROs, as well as major complaints by sponsors and CROs about sites. The speakers will also present how they are addressing these complaints in an attempt to improve both sponsor and site productivity by viewing each other as mutual clients. Audience participation will be welcome.

**A Site Perspective**

***Daniel M. Ulrey, MBA***

President and Chief Executive Officer, Midwest Clinical Support, Inc.

**A CRO Perspective**

***Leslie M. Cate, MS***

Vice President, Patient/Site Management Services, Quintiles, Inc.

**A Sponsor Perspective**

***Peter A. DiBiaso, MPH***

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

## Session 299I IT - Information Technology

3:30 PM - 5:00 PM LEVEL = ●

**Room 146B**

### Building Reliable, Secure IT Infrastructures in the Pharma Industry

SESSION CHAIRPERSON

***Munish Mehra, PhD, MSc***

Chief Information Officer, Medifacts International

This presentation shares our experience in building a reliable, scalable, and secure IT infrastructure. The initiative initially started as an effort to ensure 21 CFR 11 compliance and provide access to locations worldwide but eventually resulted in our recognizing its benefit beyond the regulatory requirement.

**A Roadmap to Successful Post-merger IT Integration: The Journey to Day 1**

***Gareth D. Creasey***

Director, Research Informatics, Pfizer Inc

**A Risk-based Approach to Infrastructure Validation**

***Laura Araujo***

Senior Director, Quality and Support Services, Perceptive Informatics, Inc.

**Use Cases as a Backbone for Requirements and Validation**

***Spencer Dillard***

Partner, Conscientia, Inc.

## Session 299J MC - Medical Communications, CR, RA

3:30 PM - 5:00 PM LEVEL = ●

**Room 209AB** *CME, Nursing, and Pharmacy credits offered*

### Developing Risk Communications: The ABCs of Health Literacy

SESSION CHAIRPERSON

***Nancy M. Ostrove, PhD***
Senior Risk Communication Advisor, Office of Planning, Office of the Commissioner, FDA

Written materials are a primary method of communicating risk to patients and healthcare providers. The FDA communicates risk to patients through review of written materials such as Patient Package Inserts and Medication Guides. Fundamental to the success of these risk communications is the use of principles that provide information in an efficient and effective manner to facilitate understanding and use; therefore, the FDA is acknowledging the usefulness of health literacy in the development of information for patients. The purpose of this session is to discuss the importance of health literacy in developing written risk communication materials.

**Risk Information: What Do Patients Understand and Remember?**
***Ruth S. Day, PhD***
Director, Medical Cognition Laboratory, Duke University

**Health Literacy**
***Cynthia Baur, PhD***
Senior Health Communication and eHealth Advisor, Office of Disease Prevention and Health Promotion, US Department of Health and Human Services

**Industry Perspective: Incorporating Learnings from Patients in Risk Communication**
***Kala L. Paul, MD***
President, The Corvallis Group LLC

**FDA Risk Communication Initiatives**
***Toni Piazza-Hepp, PharmD***
Deputy Director, Division of Surveillance, Research and Communication Support, Office of Drug Safety, CDER, FDA

## Session 299K MW - Medical/Scientific Writing

3:30 PM - 5:00 PM LEVEL = ●

**Room 102AB**

### Adding Value: The Role of Technical Editors in Cross-functional Document Development Teams of Biopharmaceutical Organizations

SESSION CHAIRPERSON

***Lori Thomae, MA***
President, LAB Communications, Inc.

This session examines the expanding role of technical editors in the cross-functional document development teams of biopharmaceutical organizations. Specialists from technical writing, medical writing, and regulatory affairs will discuss how technical editors support standardization initiatives, troubleshoot technical issues of electronic submissions, ensure regulatory compliance, and expedite the document review process.

**Development of Report Writing and Review Processes from a Regulatory Affairs Perspective**
***Mark A. De Rosch, PhD***
Director, Regulatory Affairs, Vertex Pharmaceuticals Incorporated

**Templating: Practical Tips from a Publisher's Perspective**
***Stacy Tegan***
Regulatory Business Analyst, Apyx Inc.

## Session 299L NC - Nonclinical Laboratory Safety, CR, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 103B**

### Can Single Dose Toxicity Study Support First Dose in Humans?

SESSION CHAIRPERSONS

***Klaus Olejniczak, DVM, FACP***
Preclinical Assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany

***Per Spindler, DVM***
Head of BioLogue®, University of Copenhagen, Denmark

The state of the nation for the use and the nonuse of single dose toxicity studies to support initial clinical trials will be discussed. Scientific progress, industry needs and trends, and regulatory positions will also be covered.

**US Industry Perspective**
***Joseph J. DeGeorge, PhD***
Vice President, Safety Assessment, Merck & Co., Inc.

**European Industry Perspective**
***Gerd Bode, MD***
Head, Pathology and Toxicology, ALTANA Pharma AG, Germany

**Regulatory Perspective**
***David R. Jones, MSc***
Principal Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

## Session 299M NHP - Natural Health Products, CMC

3:30 PM - 5:00 PM LEVEL = ■

**Room 140A**

### Controlling the Quality of Natural Health Products

SESSION CHAIRPERSON

***Willem K. Scholten, PharmD, MPA, MSc***
Head, Office of Medicinal Cannabis, Ministry of Health, Welfare and Sport, Netherlands

Both FDA and WHO issued documents that recognize the standardization of cultivation and primary processing recently. WHO did this in its good agricultural and collecting practices (GACP, 2003) and FDA in its guidance for industry, botanical drug products (June 2004). GXP has come to stand for good agricultural (and collecting) practices, good manufacturing practices, good laboratory practices, and good clinical practices. But the trick is to turn the "X" into excellence.

**Natural Health Products on the Guided Path**
***Anna Marie C. McSorley***
Senior Manager, Quality Assurance, i3 Research

**Evaluation Problems Arising from Different Compendial Requirements for Plant Materials**
***Urszula Krawczyk, PharmD, MPharm***
National Institute of Public Health, Poland

**Standardization of Herbal Starting Materials: It Can Be Done**
***Willem K. Scholten, PharmD, MPA***
Head, Office of Medicinal Cannabis, Ministry of Health, Welfare and Sport, Netherlands

## Session 299N OS - Outsourcing

3:30 PM - 5:00 PM LEVEL = ●

**Room 150A**

### Does Consolidation Among Outsourcing Firms Matter?

SESSION CHAIRPERSON

***Michael A. Martorelli, MBA***
Research Partner, Fairmount Partners

Consolidation certainly matters to all employees of outsourcing firms, as well as to study coordinators and medical directors dealing with those providers. But does it matter to the efficiency or effectiveness of the drug development process, or the success of the drug development industry?

**Impact of Consolidation in Other Industries**
***George A. Laszlo, MS***
Director, Life Sciences, CSC Global Health Solutions

**Views from a Sponsor**
***Barry A. Sachais, PhD***
Vice President, Clinical Development, Neuromed

## Session 299O PM1 - Project Management, RD

3:30 PM - 5:00 PM LEVEL = ■

**Room 143AB** *Project Management Institute credits offered*

### Sources of Failure in Drug Development Projects

SESSION CHAIRPERSON

***Peter H. Blake, PhD***
Managing Partner, Pharmaceutical Performance Institute

The absence of one or more of four critical processes is identified as the reason drug development projects fail to meet schedule goals 85% of the time. These are: 1) process basics, 2) team development and support, 3) risk management, and 4) schedule validation and management. By using this framework as a lens for identifying what's missing in a drug development program, one can pinpoint and make changes that will have maximum impact on improving drug development results.

**Sources of Failure in Drug Development Projects**
***Peter H. Blake, PhD***
Managing Partner, Pharmaceutical Performance Institute

**Sources of Failure: Risk and Schedule Design and Management**
***David J. Hulett, PhD***
President, Hulett and Associates, LLC

**Sources of Failure: Work Environment Management**
***Brian P. Reger, MBA***
President, Brighton Consulting Group

## Session 299P PM2 - Project Management

3:30 PM - 5:00 PM LEVEL = ●

**Room 143C** *Project Management Institute credits offered*

### Working Remotely: Project Management Challenges with Virtual Teams

SESSION CHAIRPERSON

***Kathleen C. Greer, PMP***
Vice President, Professional Services, DataCeutics, Inc.

This presentation will show evidence that working remotely with a strong project management methodology will improve customer satisfaction and reduce time to complete deliverables. It will also give samples of materials needed to project manage successfully.

**Working Remotely: Project Management Challenge – But Does It Improve Customer Satisfaction?**
***Curtis Wolf***
Lead Consultant, DataCeutics, Inc.

**Human Collaboration and Virtual Teams: Project Management Implications**
***Jonathan Gardner, MA***
Head of the Behavioural Change Management Practice, The Chalfont Project, Ltd., UK

**Project Management Skill Center as Remote Team**
***Ralf Eulentrop, MS***
Head, Global Project Management, Merck KGaA, Germany

## Session 299Q PP - Public Policy/Law, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 103A** *Pharmacy credits offered*

### Pharmaceutical Product Liability in Drug Development and Regulation

SESSION CHAIRPERSON

***Sandy M. Eisen, MD, MA, FRCS, Dip Pharm Med***
Vice President, Clinical, PAREXEL Consulting, UK

Pharmaceutical product liability is an increasingly important concern for both companies and regulators. This session aims to survey the topic of product liability in relation to pharmaceutical products covering both the EU and the US perspective. The session will include risk management and defensive approaches that may be appropriate for many companies, as well as examples taken from cases in the public domain. The focus will be on liability issues during product development and the role of the regulators in this area.

**Product Liability for the Drug Regulator**
***Peter Feldschreiber, MD, LLB(Hons), FFPM, RCP***
Senior Medical Assessor and Special Litigation Coordinator, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**Liability Issues in Drug and Clinical Trial Regulation: US and Europe**
***Anne Ware, LLB***
Product Liability Lawyer and Partner, Covington and Burling, UK

**The Emergence of Pharmaceutical and Medical Product Liability Litigation in Europe**
***Grant H. Castle, PhD***
Associate, Covington and Burling, UK

## Session 299R RA1 - Regulatory Affairs

3:30 PM - 5:00 PM LEVEL = ■

**Room 146C** *CME credits offered*

### New Pharmaceutical Legislation – Part 3 of 3: Other Practical Aspects

SESSION CHAIRPERSONS

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

***Jacques C. Mascaro, PhD***
Director, European Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

*Part 1 of this session will be held on Tuesday at 10:30 AM; Part 2 will be held on Tuesday at 1:30 PM.*

Within the scope of the New Pharmaceutical Legislation, which will enter into force in the 25 Member Sates of the European Union in October-November 2005, more focus will be placed on the procedures under the responsibility of the European Medicines Agency (EMEA). In particular, any product in oncology, diabetes, HIV or in neurodegenerative diseases will have to follow the centralized procedure, as the compulsory registration route. This will be extended to other therapeutic areas in the future. It is therefore important to understand the strategic and practical issues relating to these important changes, such as faster access to new innovative medicines on one side, and issues relating to assessment, availability of scientific expertise, or postauthorization procedures and systems like pharmacovigilance. In this respect, two sessions are proposed addressing the tools for quick access to medicines, as well as other practical aspects, with intervention from the key stakeholders, i.e. EMEA, CHMP and industry.

**EMEA Point of View**
***Panos Tsintis***
Head of Sector for Pharmacovigilance and Postauthorization and Efficacy, EMEA, EU

**CHMP Point of View**
***Daniel Brasseur, MD, PhD***
Chairman of CHMP at EMEA, EU; Ministry of Public Health, Belgium

**Industry Point of View**
***Michael J. Doherty***
Global Head, Regulatory Affairs, F. Hoffmann-La Roche, Ltd., Switzerland

*Panelist*
***Eric Abadie, MD, MBA***
Vice Chairman, CHMP, EMEA, EU; AFSSAPS, France

## Session 299S RA2 - Regulatory Affairs

3:30 PM - 5:00 PM LEVEL = ■

**Room 151B** *CME credits offered*

### Comparison of Alternatives for Transferring Personal Data Outside the EU

SESSION CHAIRPERSON
***Judith E. Beach, PhD, JD***
Vice President and Senior Associate General Counsel for Regulatory Affairs; Chief Privacy Officer and Coordinator, Government Affairs, Quintiles Transnational Corporation

In this session, the various permissible alternatives for transferring personal data outside the European Union (EU) will be discussed in detail. The pros and cons of several alternatives will be compared including Data Transfer Agreements (Model Contracts), Informed Consents, Binding Corporate Rules, and Certification to the US Department of Commerce Safe Harbor (for US entities). Additionally, differences among national laws and court interpretations and recent enforcement actions will be presented.

**Legal Issues and Practical Considerations in Using Informed Consents and Data Transfer Agreements to Satisfy the EU Data Protection Directive for Exporting Personal Data Outside the EU**
***Nancy Strehlow, JD***
Special Counsel for Health Law and Policy Affairs, Quintiles Transnational Corp.

**US-EU Safe Harbor and Binding Corporate Rules Deemed as Adequate Level of Protection Under the EU Data Protection Directive for Transfer of Personal Data Outside the EU**
***Judith E. Beach, PhD, JD***
Vice President and Senior Associate General Counsel for Regulatory Affairs; Chief Privacy Officer and Coordinator, Government Affairs, Quintiles Transnational Corporation

**Transfer of Personal Data Outside the EU: A European Perspective**
***Ulrich Wuermeling, JD, LLM***
Partner, Latham & Watkins, L.L.P., Germany

## Session 299T RA3 - Regulatory Affairs, MA

3:30 PM - 5:00 PM LEVEL = ■

**Room 152A** *CME and Pharmacy credits offered*

### Effective Switching from Prescription to Over-the-counter Status: Role in Product Life Cycle Development

SESSION CHAIRPERSON
***Neil Edwards***
Director, Drug Development Consulting Practice, PAREXEL Consulting, UK

The pressure on innovator companies to maximize the return on their commercial investment is ever increasing. At the same time, governmental pressures to control healthcare costs give rise to a regulatory environment that is receptive to proposals for innovative switches of medicines from prescription control to OTC status. These two complementary pressures mean that there is increasing opportunity for innovator companies to consider the potential for legal reclassification of their compounds as a central element of their product life cycle planning.

Topics to be covered include development of an effective pan-European and US switch strategy, case study presentations from companies on successful POM to OTC switches, an agency perspective on issues encountered in assessment of OTC switch applications and proposals on how to optimize data presentation in OTC switch applications, and US Time and Event Application/OTC monograph procedure – potential to use OTC marketing experience gained outside the US to leverage US OTC approval.

**Development of an Effective Pan-European OTC Switch Strategy, Including UK Experiences with Simvastatin**
***Cheryl J. Hall, FIMLS, FTOPRA***
Senior Director, Regulatory Affairs Europe, McNeil Ltd., UK

**FDA Perspective on OTC Switching**
***Curtis Rosebraugh, MD, MPH***
Deputy Director, Office of New Drugs, Office of Drug Evaluation V, CDER, FDA

**Successful OTC Switches in the US: Industry Perspective**
***Edwin L. Hemwall, PhD***
Vice President, Global Regulatory and Scientific Affairs, Merck Research Laboratories

## Session 299U RA4 - Regulatory Affairs, CR

3:30 PM - 5:00 PM LEVEL = ●

**Room 152B** *CME and Pharmacy credits offered*

### Progress and Challenges with Combination Product Development

SESSION CHAIRPERSON
***Andrea C. Masciale, JD***
Associate Director, Global Regulatory Affairs and Quality Assurance, Johnson & Johnson Pharmaceutical Research and Development, LLC

This session will provide you with highlights of progress made in the OCP, lessons learned from case studies, and areas that still need to be resolved, and possible next steps.

**The Role of and Current News Regarding the Office of Combination Products**
***Mark D. Kramer, MS***
Director, Office of Combination Products, Office of the Commissioner, FDA

**Case Study on a Drug/Device Combination Using Iontophoresis (with CDER as the Lead)**
***George Baskinger***
Manager, Quality Management and Regulatory Compliance, Vyteris

## Session 299V RA5 - Regulatory Affairs, CR

3:30 PM - 5:00 PM LEVEL = ●

**Room 151A**

### The Target Product Profile Practical Implementation: FDA and Sponsor Perspective

SESSION CHAIRPERSON

***Cheryl Beal Anderson, PharmD, RAC***
Director, US Regulatory Affairs, Eli Lilly and Company

The target product profile (TPP) is an FDA-PhRMA endorsed initiative to increase efficiency between FDA and sponsors and expedite drug development. A TPP is a nonbinding document that sponsors voluntarily submit to the FDA to facilitate discussion of the strategic intent and labeling goals of a clinical drug development program. The objective of this session is to provide practical advice by FDA and PhRMA companies on developing and using a TPP.

**TPP: An FDA Perspective**
***Laurie Beth Burke, RPh, MPH***
Director, Study Endpoints and Label Development, Office of New Drugs, CDER, FDA

**TPP Implementation: Considerations for FDA Interactions**
***Peter J. DiRoma***
Director, Worldwide Regulatory Affairs, Pfizer Global R&D

**TPP Implementation: Considerations for Pharmaceutical Companies**
***David M. Cocchetto, PhD***
Vice President, Antiviral/Antibacterial Regulatory Affairs, GlaxoSmithKline

## Session 299W ST - Statistics, CP

3:30 PM - 5:00 PM LEVEL = ●

**Room 201** *CME credits offered*

### How Can Statistics Contribute to Pharmacovigilance?

SESSION CHAIRPERSON

***Jürgen Kübler, PhD***
Director, Global Statistical Science, Bayer HealthCare AG, Germany

ICH E5 on Good Clinical Practice is widely regarded as the guideline that establishes the role of statisticians in drug development. As of today, the application of statistical methods in the pharmaceutical industry has mainly been devoted to planning and analysis of clinical trials. Surprisingly, statisticians are a rare species in other areas of drug development. There is also an obvious desire for more sophisticated statistical approaches in these areas. As an example, we explore the field of statistical safety. In this session we will explore different fields of application and demonstrate the broad methodological spectrum in this field. Finally, we will touch on the development of new statistical methods.

**Missing Data in Safety Evaluation: Analyses and Issues**
***Satish C. Misra, PhD***
Mathematical Statistician, CDER, FDA

**Discovery of Medication Errors in a Vaccine Safety Database Using Data Mining**
***Vitali Pool, MD***
Medical Epidemiologist, Immunization Safety Branch, Centers for Disease Control and Prevention

**Sample Size Estimation in Postmarketing Safety Studies with Incorporation of External Data**
***Yu-Te Wu, PhD, MPH***
Yale University

## Session 299X TR - Training, CR

3:30 PM - 5:00 PM LEVEL = ●

**Room 207B**

### Clinical Research Is a Contact Sport

SESSION CHAIRPERSON

***Mary E. Briggs***
President and Chief Training Officer, FOCUS, Inc.

Let's face it - confused dialogue, virtual teams, and failure to ask for clarification can create peril for clinical trial professionals. Using a football metaphor, this session combines humor and drama to help clinical trial professionals turn frustrating communications into successful exchanges. This is a great all-purpose communication session that explores ways to "connect" with CRAs, site professionals, patients, and co-workers.

***Nadina C. Jose, MD***
President and CEO, Research Strategies, Inc.

***Mary E. Briggs***
President and Chief Training Officer, FOCUS, Inc.

5:00 PM **END OF TUESDAY SESSIONS**

5:00 PM - 6:30 PM **CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH MEETING**
Meeting Room 103B, Convention Center

7:30 AM - 3:30 PM **ATTENDEE REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 3:30 PM **EXHIBITOR REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 3:30 PM **SPEAKER REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 8:15 AM **CONTINENTAL BREAKFAST**
Meeting Rooms 145-147, Concourse
Convention Center

9:00 AM - 3:30 PM **EXHIBITS OPEN**
Exhibit Halls A, B & C, Lower Level,
Convention Center

## Session 301 AHC - Academic Health Centers, CR, IS

8:30 AM - 10:00 AM LEVEL = ■

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

### Human Subject Protection: Organization and Training of IRBs and Clinical Sites

SESSION CHAIRPERSON

***Shirley Suresh, MD***
Head, Quality Assurance, Clinical Trials and Epidemiology Research Unit, Singapore

Human subject protection is a basic requirement of clinical research. With the rapid advancement in biomedical research, the issues faced by IRBs and the clinical profession in addressing and overseeing clinical research are becoming more complex. IRBs and clinical sites are being reorganized to streamline their processes to improve efficiency and to meet regulatory requirements. Training of IRB members and clinical investigators is an essential component that is being addressed. This session will highlight the organization and training programs of IRBs and investigative sites to meet regulatory requirements in three Asian countries.

**Working and Training of IRBs and Investigative Sites in China**
***Yishi Li, MD***
Director, Center of Clinical Pharmacology, Fu Wai Hospital and Cardiovascular Institute, CAMS and PUMC, China

**Transforming the Ethical Review Process**
***Jieun Shyard Wong, MBBS***
Director, Clinical Programs, Professional Policy and Planning/Research and Development Office, National Healthcare Group, Singapore

**Quality Improvement and Assurance for Ethical Review Mechanism in India**
***Vasantha Muthuswamy, MD, DGO, FAIBMS***
Senior Deputy Director General and Chief, Division of Basic Medical Sciences, Indian Council of Medical Research, India

## Session 302 BT - Biotechnology, CR

8:30 AM - 10:00 AM LEVEL = ■

**Room 154AB** *CME credits offered*

### Integrating Pharmacogenetics in Clinical R&D: From Data Acquisition to Data Management and Exchange

SESSION CHAIRPERSONS

***Lee H. Evans***
Director, Strategic Planning and Portfolio Management, Clinical and Regulatory Information Services, Merck & Co., Inc.

***Athanasios Zavras, DMD, MS, DrMedS***
Senior Scientist, Pharmacogenetics, Ingenix Research

The primary aim of this session is: a) to identify distinct phases in the life cycle of a drug where pharmacogenetic research can provide value; b) to provide practical advice about different PGx study designs and some of the scientific, economic or logistical issues involved; and c) to discuss methods and present examples of how the combination of pharmacogenomic and traditional clinical data can be properly resolved through the use of biomedical data exchanges.

**The Science and Practice of Applied Pharmacogenomics**
***Athanasios Zavras, DMD, MS, DrMedS***
Senior Scientist, Pharmacogenetics, Ingenix Research

**Genetic and Molecular Pharmacoepidemiology**
***Stephen E. Kimmel, MD, MS***
Associate Professor, University of Pennsylvania School of Medicine

**Pharmacogenomics and Clinical Data: Bridging the Chasm**
***Lee H. Evans***
Director, Strategic Planning and Portfolio Management, Clinical and Regulatory Information Services, Merck & Co., Inc.

## Session 303 CDM - Clinical Data Management

8:30 AM - 10:00 AM LEVEL = ■

**Room 202B**

### Data Management and the Globalization of the Japanese Clinical Trial Industry

SESSION CHAIRPERSON

***Cliona O'Donovan***
Director, Data Services, Quintiles Pty Ltd., Australia

This session will be an exploration of the globalization of the Japanese clinical trial industry on current practices in data management. ICH subscribers are USA, Europe and Japan. We will explore some of the success factors to consider in the data management of multinational studies that include sites in and outside of Japan.

**Working with Japanese Investigative Sites**
***Julie Olszewski***
Data Management Expert, Banyu Pharmaceutical Co. Ltd., Japan

**Data Management and the Globalization of the Japanese Clinical Trial Industry**
***Tetsunari Kihira, PhD***
Senior Reviewer, Office of New Drugs Evaluation III, Pharmaceuticals and Medical Devices Agency (PMDA), MHLW, Japan

**A Swiss View of Japanese CTDs Based on Trials in Japan, Australia, America, and Europe**
***David W. Warne, PhD, MSc***
Associate Director, Biostatistics, Serono International, Switzerland

## Session 304 CMC - Chemistry, Manufacturing, and Controls, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 147A**

### Updates on FDA GMP Initiatives and Guidances

SESSION CHAIRPERSON

***Joseph C. Famulare***
Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

This session will focus on advancements and developments in the CGMP Compliance and Inspection Programs that are advancing since the final announcement of the CGMP initiative in September 2004. Key areas of discussion will be process validation and the recent revision of the 1987 Process Validation Guidance coming as a draft guidance, furthering the update on FDA's Compliance Policy Guide which was published on March 17, 2004, updating the preapproval Inspection Compliance Program, additional enhancements of the risk-based site selection program, among other areas. Developments in forming the Pharmaceutical Inspectorate, incorporating product specialists on inspections, and updates on the status of Part 11 will also be discussed, illustrating technical advancements and the input of science in the CGMP programs.

**Update on Compliance CGMP Initiatives: Upcoming PAI Program Changes, Integration across Quality Regulation – Review, Inspection, Compliance, Progress on the Pharmaceutical Inspectorate**
***Joseph C. Famulare***
Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

**Continuous Improvement under Modern Quality Systems and CGMPs**
***Richard L. Friedman, MS***
Consumer Safety Officer, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

**Role of the Annual Review and the Life-cycle Approach to Validation**
***Grace E. McNally***
Consumer Safety Officer, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

**Panel Discussion/Q&A Period**

## Session 305 CP - Clinical Safety and Pharmacovigilance, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 207A** *CME, Nursing, and Pharmacy credits offered*

### The CIOMS VI Project on Managing Clinical Trial Safety

SESSION CHAIRPERSON

***Arnold J. Gordon, PhD***
Pharmaceutical Consultant

The CIOMS VI Working Group has developed principles and proposals for the collection, evaluation, and reporting of safety information obtained during clinical trials to all appropriate stakeholders. Included are new considerations on ethics, terminology and definitions, recommendations on statistical approaches, and a systematic approach to risk management and pharmacovigilance, especially for a drug development program. A summary of the key proposals, some of which represent departures from current regulations, will be presented.

**The Scope and Objectives of CIOMS VI**
***Arnold J. Gordon, PhD***
Pharmaceutical Consultant

**Proposals and Recommendations from CIOMS VI: An Industry Perspective**
***Wendy P. Stephenson, MD, MS, MPH***
Principal, Wendy Stephenson & Associates LLC

**Proposals and Recommendations from CIOMS VI: A Regulatory Perspective**
***Gottfried Kreutz, MD***
Director and Professor; Head, Department of Clinical Pharmacology, BfArM, Germany

*Panelist*
***Gerald J. Dal Pan, MD, MHS***
Director, Division of Surveillance, Research and Communication Support, Office of Drug Safety, CDER, FDA

## Session 306 CR1 - Clinical Research and Development

8:30 AM - 10:00 AM LEVEL = ■

**Room 140B**

### The Secret Code for Efficient Clinical Research

SESSION CHAIRPERSON

***Norman M. Goldfarb, MBA, CRCPA***
Managing Partner, First Clinical Research, Inc.
Chairman, MAGI, the Model Agreement Group Initiative

Existing coding systems can be used to improve communication between sponsors and sites and the efficiency of clinical research. For example, physicians use CPT procedure codes and ICD-9 diagnostic codes for clinical reimbursement. Sponsors can use these same codes to unambiguously communicate eligibility criteria and study procedures to investigators. Two new coding systems will be presented: Clinical Research Terminology (CRT) codes specify study activities that are not covered by CPT codes. Protocol Deviation and Violation (PDV) codes differentiate between deviations, violations and other errors. These and other coding systems that will be described facilitate the collection and use of metrics. Metrics are the foundation of systematic performance and process improvement. "You can't manage what you can't measure." (This session is not about billing third-party payors.)

**The Secret Code for Efficient Clinical Research**
***Norman M. Goldfarb, MBA, CRCPA***
Managing Partner, First Clinical Research, Inc.
Chairman, MAGI, the Model Agreement Group Initiative

**Metrics for Effective Site Selection**
***Melissa Hutchens***
Consultant, KMR Group, Inc.

**Metrics for Effective Site Management and Process Improvement**
***Alan S. Taggart, MS***
Principal, Life Sciences Business Group, Pittiglio Rabin Todd & McGrath

## Session 307 CR2 - Clinical Research and Development, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 145A** *CME and Pharmacy credits offered*

### Clinical and Regulatory Update on Imaging in Oncology Trials

SESSION CHAIRPERSON

***Richard Jacobs, MD***
Vice President and Chief Medical Officer, Perceptive Informatics, Inc.

This session provides an update on a very well attended session from the 2004 annual meeting. Key updates will include new guidance from FDA now being made final and publicly available, outcomes of FDA workshops on cancer trial endpoints, and ongoing initiatives on imaging in oncology drug development from NCI and FDA.

**Understanding the Current Status of Regulatory Initiatives Pertaining to Imaging in Oncology Drug Development**
***Jerry M. Collins, PhD***
Director, Division of Clinical Pharmacology Research, CDER, FDA

**Understanding New Clinical Developments in Applying Imaging Endpoints in Oncology Trials: Part 1**
***Giles L. Boland, MD***
Vice Chair, Department of Radiology, Massachusetts General Hospital

**Understanding New Clinical Developments in Applying Imaging Endpoints in Oncology Trials: Part 2**
***Lawrence H. Schwartz, MD***
Director of Magnetic Resonance Imaging, Memorial Sloan Kettering Cancer Center

## Session 308 CR3 - Clinical Research and Development, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 145B**

### Experiences with the New Ethics Committee Systems in Europe

SESSION CHAIRPERSON

***Ingrid Klingmann, MD***
President, Pharmaplex bvba, Belgium

The Clinical Trials Directive has enforced the implementation of new ethics committee systems, including new roles and responsibilities of ethics committees in different European countries. First experiences are now available. This session will provide an opportunity to understand the challenges and solutions in different European countries.

**The Variety of Ethics Committee Systems in Europe: An Introduction**
***Ingrid Klingmann, MD***
President, Pharmaplex bvba, Belgium

**The German System of Ethics Committees Under the EU-based Regulations**
***Elmar Doppelfeld, MD***
Chairman of the Permanent Working Group, Research Ethics Committees in Germany

**Impact of the EU Clinical Trials Directive on the Ethics Committee Systems in Hungary and Other CEE Countries**
***Prof. Tamás L. Paál, PhD, MA***
Director General, National Institute of Pharmacy, Hungarian Health Authority, Hungary

## Session 309 CR4 - Clinical Research and Development

8:30 AM - 10:00 AM LEVEL = ●

**Room 146A**

### How to Establish and Successfully Run Data Monitoring Committees

SESSION CHAIRPERSON

***Doris Kolb***
Director, Data Pooling and Analysis Center, PRA International, Germany

Various national and internal guidelines are available for data monitoring committees (DMC). However, practical experience shows limited operational implementation. To successfully set up and conduct a data monitoring committee, the DMC charter clearly needs to define roles and responsibilities of all involved parties as well as the associated processes.

**Planning and Development of Charters for Data Monitoring Committees**
***Doris Kolb***
Director, Data Pooling and Analysis Center, PRA International, Germany

**Statistical Considerations for Data Monitoring Committees**
***Lisa M. LaVange, PhD***
Vice President, Biostatistics and Data Management, Inspire Pharmaceuticals

**Data Monitoring Committees from the Regulatory Perspective**
***Susan S. Ellenberg, PhD***
Professor of Biostatistics, Associate Dean for Clinical Research, University of Pennsylvania School of Medicine

## Session 310 CTM - Clinical Trial Management, CR, PP

8:30 AM - 10:00 AM LEVEL = ■

**Room 101** *CME credits offered*

### Differing Viewpoints? An In-depth Look at Patients' Experiences in Clinical Trials versus Media Coverage of the Clinical Trials Industry and Its Impact on Public Perception and Patient Participation Rates

SESSION CHAIRPERSON

***Daniel McDonald***
Vice President, Thomson CenterWatch

This session will examine and compare the findings from two Thomson CenterWatch studies conducted in late 2004/early 2005 that shed light on the factors affecting public perception, participation and retention levels, and level of care. The first study looks at media coverage of the clinical trials industry. The second study looks at the experiences of patients who have actually participated in a clinical trial. Findings of both studies will be presented and discussed. The results will help industry professionals understand the attributes that shape public perception of clinical research, the impact upon participation levels and areas of misinterpretation.

**Examining Media Coverage of the Clinical Trials Industry and Its Impact on Public Perception and Patient Participation Rates**
***Daniel McDonald***
Vice President, Thomson CenterWatch

**Understanding Clinical Trial Volunteer Experiences**
***Mary Jo Lamberti, PhD***
Senior Manager, Market Intelligence, Thomson CenterWatch

## Session 311 DM - Document Management/ eSubmissions, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 206**

### Managing the Living Global Dossier

SESSION CHAIRPERSON

***Teresa Torello-Lincoln***
Submission Project Lead, AstraZeneca

Explore the concept of creating a Dossier Management Center of Excellence (DMCE). The DMCE provides concentrated knowledge and expertise dedicated to growing and managing a Living Global Dossier. The Living Global Dossier is implemented at the beginning of a project to support strategy around document and module reuse. Incorporation of people, content, regulatory knowledge, project management, document management, and technology are essential to the success of the DMCE and to the drug program that is supported by the DMCE.

**Cultivating a Global Dossier Group**
***Teresa Torello-Lincoln***
Submission Project Lead, AstraZeneca

**Planting the Seeds for a Successful Global Dossier**
***Michelle A. McGuinness, MS***
Director, Solution Business Development, Octagon Research Solutions, Inc.

**Propagation and Maintenance of Your Living Global Dossier**
***John W. Kiser***
Associate Director, Abbott Laboratories

## Session 312 GCP - Good Clinical Practices, OS

8:30 AM - 10:00 AM LEVEL = ■

**Room 202A**

### Virtual Realities: Quality Considerations when Using Contract Organizations

SESSION CHAIRPERSON

***Deborah A. Waltz, MS, CIP***
Senior Director, R&D Quality, King Pharmaceuticals Research and Development

Sponsors sometimes wrongly assume that quality assurance is less of a concern or responsibility when they have contracted responsibilities to outside organizations. This session will provide information on FDA expectations for the responsibility of assuring GCP compliance as well as practical steps that can be implemented by sponsor organizations to improve quality outcomes when working with outsource providers.

**Quality and Compliance in a Virtual Environment: Enforcement Trends and Expectations**
***Joseph P. Salewski***
Chief, Bioresearch Monitoring Branch, CBER, FDA

**Selecting CROs: What to Look for, What to Run from**
***Erin H. Krohl, MS, MPH***
President, EHKrohl Consulting, Inc.

**Strategies for Optimizing Quality when Using CROs**
***Deborah A. Waltz, MS, CIP***
Senior Director, R&D Quality, King Pharmaceuticals Research and Development

## Session 313 IT - Information Technology

8:30 AM - 10:00 AM LEVEL = ●

**Room 146B**

### Web Services: The Glue for a Fractured Infrastructure

SESSION CHAIRPERSON

***James Langford, MBA, MS***
President, DataLabs, Inc.

Clinical development uses many different systems that frequently do not communicate, creating an inefficient process for drug development. The use of web services and CDISC now provides a powerful tool for stitching together these systems in a way that provides significant cost and time savings.

**The Technology and Value of Web Services and an Open Architecture**
***Jason A. Burke, MA***
Life Sciences Industry Strategist, Microsoft Corporation

**The Value and Use of Web Services in a Global CRO**
***John F. Morgan***
Senior Vice President, Information Technology, United Biosource Corporation (UBC)

**How to Use Web Services and CDISC ODM to Connect Disparate Systems**
***Richard Gleeson***
Vice President, Enterprise Solutions, DataLabs, Inc.

## Session 314 MA - Marketing and Sales, RD

8:30 AM - 10:00 AM LEVEL = ●

**Room 204BC**

### Value Optimization of Medical Products Reflecting Development and Marketing Strategies

SESSION CHAIRPERSON

***Toshio Nagae***
President, CMIC MPSS Company, Ltd., Japan

Who are decision makers and what are the critical factors to determine value of medical products? Product attributes, price, and promotion (3P) would be major factors reflecting development/marketing strategies and implementations. This session will highlight alternative strategies leading to different commercial value for your best decision making.

**Optimizing the Profiles of the Emerging Pharmaceutical Pipeline**
***François Kerendi, MBA***
Senior Director, Commercial Development, Global Business Operations, Schering-Plough Corporation

**A Successful Product Launch: Commercial Evaluation and Prelaunch Marketing to Maximize Value**
***Robert S. Livesay, MBA***
Senior Director, New Products Commercialization, Thrombosis/Cardiology, sanofi-aventis

**Value Optimization of Medical Products Reflecting Development and Marketing Strategies**
***Malcolm Lloyd, MD***
Commercial Team Leader, Surgery Business, The Medicine Company

## Session 315 MC - Medical Communications, MA

8:30 AM - 10:00 AM LEVEL = ■

**Room 209AB** *CME and Pharmacy credits offered*

### Field-based Medical Involvement Beyond Scientific Thought Leaders: Reaching Out to Help Healthcare Decision Makers

SESSION CHAIRPERSON

***Keith L. Steward, MD, MBA***
Vice President, Medical Education, Medical Affairs RBU, sanofi-aventis Pharmaceuticals

Decisions impacting patient healthcare and the value of pharmaceutical treatment options have continued to evolve over time. This requires medical personnel within the pharmaceutical industry to demonstrate considerable flexibility in meeting the needs of customers that directly impact healthcare. Field-based medical personnel are uniquely positioned to meet these needs and their specific role in the process will be addressed.

**The Scientific Interface between Field Medical Organizations and Managed Health Care Organizations**
***Eric M. Hillson, PhD, MBA, RPh***
Director, Economic, Clinical and Health Outcome (ECHO) Scientist Group, Medical Affairs Department, Centocor, Inc.

## Session 316 MW - Medical/Scientific Writing, CR

8:30 AM - 10:00 AM LEVEL = ●

**Room 102AB**

### Discovering and Reporting Safety Issues in Clinical Trial Data

SESSION CHAIRPERSON

***Margaret Boe, RN***
Director, Medical Writing, Image Solutions, Inc.

Accurate interpretation of safety research data is imperative for those in decision-making positions. Medical writers must have a broad-based knowledge of current trends in safety issues to understand which data should be discussed in clinical study reports, and to thoroughly interpret safety data to assist sponsors with discovering pertinent trends in their data. Likewise, regulatory agency reviewers must have a means of rapidly compiling and reviewing the safety data.

This session will present three areas of concern and interest to medical writers and others who are responsible for reviewing, interpreting, and/or reporting clinical trial safety data. The first speaker will present an overview of the concerns regarding drug products that affect electrocardiogram QT intervals. The second speaker will discuss some of the electronic tools currently being used or considered for use at CDER to facilitate and expedite their safety data reviews. The third speaker will present issues and best practices for writing patient safety narratives for global submissions.

**QTc Intervals: Why the Fuss?**
***Margaret Boe, RN***
Director, Medical Writing, Image Solutions, Inc.

**Premarketing Safety Assessment: Data Standards and the Safety Review Guidance**
***Armando Oliva, MD***
Associate Director for Policy, Office of New Drugs, CDER, FDA

**The Art of Writing Safety Narratives**
***Sandra J. Hecker, RAC***
President, Hecker and Associates, LLC

## Session 317 NHP - Natural Health Products, AD, RA

8:30 AM - 10:00 AM LEVEL = ●

**Room 140A**

### Postcards from the Edge: Avoiding Regulatory Blunders in Promoting Natural Health Products

SESSION CHAIRPERSON

***Enid Doggett***
Director, Communications Department, American Federation of Government Employees, AFL-CIO

Knowing where the line is drawn between dietary supplement and "disease" claims can be difficult for those who are marketing natural health products (NHPs). In the US, products are regulated by their "intended use." "Intended use" is defined by the label and the labeling claims made on the product. This session will explore the regulatory criteria for making food, dietary supplement and drug claims for naturally-derived products, which can be regulated in more than one category. Making a selection between these different routes to market, along with other factors determines what you can say about the product.

**What You Say Is What You Are: The Food-drug Paradox for Natural Health Products**
***Freddie Ann Hoffman, MD***
Chief Executive Officer, HeteroGeneity, LLC

**Basic Principles of Drug Advertising: How Do They Apply to Natural Health Products**
***Peter H. Rheinstein, MD, JD, MS***
President, Severn Health Solutions

**How the Federal Trade Commission Can Help You – the Manufacturer of Natural Health Products**
***Daniel Kaufman, JD***
Staff Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission

## Session 318 OS - Outsourcing, RD

8:30 AM - 10:00 AM LEVEL = ■

**Room 150A**

### The CRO Response to Emerging Drug Development Trends Using New Technology and Best Business Practices

SESSION CHAIRPERSON

***Mark Levine, MBA***
Director of Business Development, Averion Inc.

Contract research organizations are integrating new technologies and business practices to meet the demand for accelerated drug approval timelines. This session will discuss the latest trends in this area.

**Using Technology to Streamline Clinical Trials**
***Michael O. Regentz***
Managing Director, Winchester Business Systems, Inc.

**Managing Day-to-day Operations: Getting Your Hands Dirty**
***Christine B. Philput, PhD, MS***
Chief Clinical Officer, Averion Inc.

**Implementing Technology: Easier Said than Done**
***William Jacobson, PhD***
Director Project Management, Wyeth Research

## Session 319 PM1 - Project Management, OS

8:30 AM - 10:00 AM LEVEL = ●

**Room 143C** *Project Management Institute credits offered*

### Does Breaking Up Have to Be Hard to Do? Dissolving Partnerships, Changing CROs

SESSION CHAIRPERSON

***Carolyn H. Kruse, MSc***
President, Kruse Consulting Group, Inc.

This session will discuss practical means for "changing horses in the middle of the development and marketing stream." Speakers with experience in keeping projects on track while companies dissolved or changed codevelopment agreements and/or switching CROs will discuss some of the pitfalls.

**Opening Remarks**
***Carolyn H. Kruse, MSc***
President, Kruse Consulting Group, Inc.

**Regulatory Perspectives on Contracts and Partnership: Your Contract as a Prenuptial Agreement**
***Nadine M. Qashu Lim, MS***
Consultant, SNK Associates

**What to Do if Your Horse Won't Move in the Middle of the Stream**
***Roberta L. Schneider, MD, FACEP***
President, Tudox Consulting, Inc.

## Session 320 PM2 - Project Management

8:30 AM - 10:00 AM LEVEL = ●

**Room 143AB** *Project Management Institute credits offered*

### Critical Chain Project Management in Pharmaceuticals Development

SESSION CHAIRPERSON

***Michelle R. Smith***
Senior Project Manager, Procter & Gamble Pharmaceuticals

Critical Chain Project Management (CCPM) is based on the Theory of Constraints (TOC). It utilizes aggressive durations and buffers to decrease project cycle time. When integrated across a portfolio of projects, CCPM leads to improved resource management and increased business productivity.

**Theory of Constraints**
***Lawrence P. Leach, MME, PMP***
President, Advanced Projects, Inc.

**Flow-based Management of Pharmaceutical R&D: Increasing Speed Throughput and Reducing Risks**
***Jaideep Srivastav***
Director, Implementations, Realization

**CCPM Experiences in Pharmaceuticals R&D**
***Bernard L. Rosato***
Section Head, Global Project Management and Planning, Procter & Gamble Pharmaceuticals

## Session 321 RA1 - Regulatory Affairs, CR

8:30 AM - 10:00 AM LEVEL = ■

**Room 152A** *CME credits offered*

### The European Situation on Pediatrics within a Global Environment

SESSION CHAIRPERSONS

***Françoise de Crémiers, PharmD, MS, ML***
Vice President, Worldwide Regulatory Affairs-Europe, Wyeth Research, France

***Daniel Brasseur, MD, PhD***
Chairman of CHMP at EMEA, EU; Ministry of Public Health, Belgium

This session will address the New European Pediatric Regulation within the global context of drug development, most particularly in the US. The pediatric regulation will be described and its impact assessed from a global industry viewpoint.

**European Situation**
***Daniel Brasseur, MD, PhD***
Chairman of CHMP at EMEA, EU; Ministry of Public Health, Belgium

**US Industry Viewpoint**
***Richard M. Tresley, MD, PhD***
Johnson & Johnson Pharmaceutical Research and Development, LLC

**EU Industry Viewpoint**
***Françoise de Crémiers, PharmD, MS, ML***
Vice President, Worldwide Regulatory Affairs-Europe, Wyeth Research, France

## Session 322 RA2 - Regulatory Affairs, CR

8:30 AM - 10:00 AM LEVEL = ■

**Room 151B** *CME credits offered*

### Lessons Learned from Hormone Therapy: WHI Experience

SESSION CHAIRPERSON

***Joseph S. Sonk, PhD***
Vice President, US Regulatory Affairs, Berlex, Inc.

New medical information about a drug can have a profound effect on the messages sent to healthcare providers and patients alike. The publication of the WHI trial results affected the view of hormone therapy and its perceived risks and benefits. This session will review the processes employed to integrate the new information into product labeling.

***Barbara Alving, MD, MACP***
Deputy Director, National Heart, Lung, and Blood Institute, National Institutes of Health

***Tara Parker-Pope***
Medical/Health Columnist, *The Wall Street Journal*

***Daniel Shames, MD***
Director, Division of Reproductive and Urologic Drug Products, CDER, FDA

## Session 323 RA3 - Regulatory Affairs, CP, CR

8:30 AM - 10:00 AM LEVEL = ●

**Room 146C** *CME, Nursing, and Pharmacy credits offered*

### Case Studies in Risk Management

SESSION CHAIRPERSON

***Walter E. Chalkley, MA***
Associate Editor, IDRAC, Thomson Scientific

To assist sponsors in risk management activities, in May 2004 the FDA published three interrelated risk management draft guidances. Case studies will be presented on different phases of risk management, including clinical development and postmarketing activities.

**Identifying and Communicating Risks During Clinical Trials**
***Helen McFarland, PharmD***
Pharmacy Clinical Specialist, Oncology Investigational Drug Service, Johns Hopkins Oncology Center

**Postmarketing Pharmacovigilance and Risk Management**
***Deborah S. Kirby, MD***
Vice President, Risk Management Site Head, Safety and Risk Management, Worldwide Development, Groton/New London, Pfizer Inc

## Session 324 RA4 - Regulatory Affairs, CR

8:30 AM - 10:00 AM LEVEL = ■

**Room 151A** *CME credits offered*

### Is Data Privacy Possible? A 360° View

SESSION CHAIRPERSON

***Michael Owings***
Vice President, Quality and Regulatory Compliance, Phase Forward

This session will survey the subject of data privacy and patient protection from three very diverse perspectives – technology, healthcare, and the European regulatory environment.

**Patient Confidentiality and Privacy in European Clinical Trials: The Background to the Development of European Guidelines**
***Francis P. Crawley, PhD***
Secretary General and Ethics Officer, European Forum for Good Clinical Practice, Belgium

**Privacy, Confidentiality and Human Subject Protections**
***Marjorie A. Speers, PhD***
Executive Director, Association for the Accreditation of Human Research Protection Programs, Inc.® (AAHRPP®)

**EDC and the HIPAA Security Rule**
***Michael Owings***
Vice President, Quality and Regulatory Compliance, Phase Forward

## Session 325 RA5 - Regulatory Affairs, RD

8:30 AM - 10:00 AM LEVEL = ■

**Room 152B**

### The Effect of Japanese Pharmaceutical Affairs Law's Revision and PMDA's Activities on Pharmaceutical Industries

SESSION CHAIRPERSONS

***Tamaki Fushimi, MS***
Director, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), MHLW, Japan

This session will provide updated information on implementation of the recently revised PAL and activities of newly established PMDA. It will also provide discussions about the effects of PAL revision and PMDA's establishment on pharmaceutical industries.

**Review Activities of the PMDA/MHLW**
***Kazuhiko Mori, MS***
Director, Office of New Drugs Evaluation I, Pharmaceuticals and Medical Devices Agency (PMDA), MHLW, Japan

**Vigilance Activities of the PMDA/MHLW**
***Tamaki Fushimi, MS***
Director, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), MHLW, Japan

## Session 326 RA6 - Regulatory Affairs, FI

8:30 AM - 10:00 AM LEVEL = ●

**Room 147B**

### Don't Sweat SOX: Implementing Reporting for Sarbanes-Oxley (SOX)

SESSION CHAIRPERSON

***Christine Oh, PharmD, RPh***
Regulatory Compliance Manager, AstraZeneca Pharmaceuticals LP

The Sarbanes-Oxley Act calls for the CEO and CFO to certify the accuracy of their company's financial results, internal controls over financial reporting, and disclosure controls. This session will highlight the importance of the Sarbanes-Oxley Act and its impact on the regulatory affairs department both locally and globally. It will consist of brief presentations and a panel discussion.

***Scott Cunningham, JD***
Associate, Covington & Burling

***Ann Booth-Barbarin***
Senior Counsel, AstraZeneca

## Session 327 RD - R&D Strategy, CR

8:30 AM - 10:00 AM LEVEL = ●

**Room 150B**

### Implementing Clinical Modeling and Simulation: A Practical Guide

SESSION CHAIRPERSON

***Helena U. Enahoro, PhD, MSc***
Senior Consultant, IBM Business Consulting Services

This session presents the issues and challenges to making modeling and simulation relevant in the decision-making processes in an organization and discusses the possible organizational structures to support the use of modeling and simulation in decision making.

**Modeling and Simulation in Clinical Development**
***Kevin H. Dykstra, PhD***
Senior Scientist, Pharsight Corporation

**Organizing for Modeling and Simulation**
***Helena U. Enahoro, PhD, MSc***
Senior Consultant, IBM Business Consulting Services

**Integration of Modeling and Simulation into the Pharmaceutical Industry Environment: Successes and Challenges**
***William E. Pullman, PhD, MB, FRACB***
Senior Vice President, sanofi-aventis

## Session 328 ST - Statistics, CR

8:30 AM - 10:00 AM LEVEL = ■

**Room 201** *CME credits offered*

### Randomization

SESSION CHAIRPERSON

***Scott A. Hamilton, PhD, MS***
Clinical Assistant Professor, Stanford University Medical Center; President, Dynarand, LLC

Several novel methods of randomization for clinical trials will be presented and discussed.

**Assess Pros and Cons for Using Rerandomization Designs for Clinical Studies**
***Cornelia Dunger-Baldauf, PhD***
Senior Biostatistician, Novartis Pharma AG, Switzerland

**A List-based/Dynamic Hybrid Model for Two-stage Randomization**
***David B. Sundin, MS, MBA, MPH***
Director, Client Services, Dynarand, LLC

## Session 329 TR - Training, PM

8:30 AM - 10:00 AM LEVEL = ■

**Room 207B**

### Facilitation Magic: Conjuring Up Extraordinary Results in Teams and Groups

SESSION CHAIRPERSON

***Barry Sagotsky, MBA***
Managing Director, Magnolia Lane Consulting

Whether you have to plan for and facilitate a team meeting, kickoff, lessons learned, training session, or other meeting requiring involvement, open discussion, and decision making, the skills demonstrated and practiced in this session will provide a solid foundation for getting the results you want. Topics include preparation, giving instructions, managing discussions, managing personalities and conflict involving participants, and building and deepening relationships and trust. As the title implies, the session will utilize magic effects to demonstrate principles and techniques and involve participants. This is a participative learning experience.

**Facilitation Magic: Conjuring Up Extraordinary Results in Teams and Groups**
***Barry Sagotsky, MBA***
Managing Director, Magnolia Lane Consulting

***Ira Spector, MBA***
Vice President, Clinical Trial Operations; Vice Chief of Operations, Wyeth Research

## Session 330 VA - Validation, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 103A**

### Current International Regulatory Issues

SESSION CHAIRPERSON

***Teri E. Stokes, MT (ASCP), MS, PhD***
Director, GXP International

In this session, speakers will share their views on the practical aspects of deploying validated systems in the regulated environments of Europe and Japan. Speakers have many years of experience in industry actually working to validate systems in their respective regions. They have also faced the challenge of working with North American colleagues who might see the world differently. This session provides the opportunity to see computer validation from a non-US perspective.

**Implementing and Maintaining Global Validated Clinical Trial Systems in Europe**
***Jan W. Kesteloot***
Associate Director, Computer System Validation, Johnson & Johnson Pharmaceutical Research and Development, LLC, Belgium

**Computerized System Regulatory Requirements in Japan: Practical Approach to Preparing Global Validation Policy and Standards**
***Hitoshi Matsui***
Executive Consultant, CAC Corporation, Japan

10:00 AM - 10:30 AM **REFRESHMENT BREAK**

**Exhibit Halls ABC, Lower Level**
**Convention Center**

## Session 331 AHC - Academic Health Centers, CR, IS

10:30 AM - 12:00 PM LEVEL = ●

**Room 103B**

### Clinical Trials from the Pharmaceutical Company (Sponsor) Viewpoint

SESSION CHAIRPERSON

***Scott B. H. Davis***
Sponsored Programs Administrator, Office of Research Administration, University of Oklahoma Health Sciences Center

This discussion will cover clinical trials from the beginning to the end of contract signing. Why do both parties want everything signed yesterday?

**Clinical Trial Agreements: The Sponsor Perspective**
***Stacie S. Switzer, JD***
Counsel, Takeda Pharmaceuticals North America, Inc.

**Clinical Trial Agreements: Academic Health Center's Perspective**
***Scott B. H. Davis***
Sponsored Programs Administrator, Office of Research Administration, University of Oklahoma Health Sciences Center

## Session 332 BT - Biotechnology, CR, OS

10:30 AM - 12:00 PM LEVEL = ●

**Room 154AB**

### ECGs on First, EDCs on Second, and CROs on Third: Creating Teamwork Between Clinical Service Providers

SESSION CHAIRPERSON

***Bruce L. Maloff, PhD***
Vice President, Business Development Services, Invitrogen

Biotechnology companies rely on an array of different research service companies for clinical trials. Service providers may excel at their individual skills, but few address their ability to orchestrate trials with other vendors. Their ability to play well together can accelerate a study and minimize management cost to the sponsor. This session defines the performance metrics needed to win as a team.

**Taking Partnerships to the Next Level**
***Barbara J. Birch***
Alliance Business Director, i3 Statprobe

**Taking Partnerships to the Next Level**
***Cynthia R. Rutgers, MS***
Manager, Medical Affairs Outsourcing, Amgen Inc.

**Maximizing the Efficiency of Centralized Electronic Data Management Services in Clinical Trials**
***Gary K. Zammit, PhD***
President and CEO, CliniLabs

## Session 333 CDM - Clinical Data Management, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 202B** *CME credits offered*

### Advancing Data Quality in the 21st Century

SESSION CHAIRPERSON

***Kit A. Howard, MPh***
Principal, Kestrel Consulting, Inc.

Tremendous effort goes into creating high quality data, and in the end we do not know how to assess the quality because we lack the right tools. In 1999, the Institute of Medicine, working with the FDA, conducted a meeting that produced a report outlining the current state of data quality research. This session will summarize advances in data quality since the IOM report, present a roadmap for researching the issues raised, and discuss the perspectives of the FDA and of clinical practice in achieving data quality.

**Defining Data Quality: The FDA Perspective**
***Janet Woodcock, MD***
Acting Deputy Commissioner of Operations, FDA

**Defining Data Quality in Medical Practice**
***Paul V. Miles, MD***
Director of Quality, American Board of Pediatrics

**Achieving Data Quality: The Role of DQRI**
***Kaye H. Fendt, MPH***
Adjunct Associate Professor, School of Medicine, UNC-Chapel Hill; Director, Data Quality Research Institute

## Session 334 CMC - Chemistry, Manufacturing, and Controls, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 147A** *CME and Pharmacy credits offered*

### Combination Products: Challenges and Opportunities

SESSION CHAIRPERSON

***John E. Simmons, PhD***
Director, Division of New Drug Chemistry, CDER, FDA

Combination products have experienced steady growth over the past decade. The number of products that must be evaluated by two (or more) centers has grown to the point where the Office of Combination Products was established at the Commissioner's level to deal with jurisdictional issues and facilitate the process. Drug-device, drug-biologic, and biologic-device combinations present many challenges as well as opportunities for the future of therapy. The primary mode of action of the combination product must be established, and the

primary center for review must be decided early in the process, so that the Agency can bring the most qualified and appropriate review staff together to evaluate and approve the product. Inspection issues must also be weighed, as each center operates under different inspection regulations.

The Agency strives to bring the appropriate disciplines together as early into the process as possible to allow sufficient time for in-depth evaluation, communications with the applicant, and schedule appropriate facilities evaluations.

Drug eluting stents will serve as an example of how the Agency successfully deals with issues and resolves disputes. Speakers representing a cross-section of centers will present perspectives and observations.

**FDA Perspective**
***John E. Simmons, PhD***
Director, Division of New Drug Chemistry, CDER, FDA

**Industry Perspective**
***Chris Cramer, MBA, MS***
Consultant, Manager, PRTM

**Panel Discussion/Q&A Period**

***Kasturi Srinivasachar, PhD***
Chemistry Team Leader, Division of Cardio-renal Drug Products, CDER; Consultant for Stents Reviews, CDRH, FDA

***Steven R. Koepke, PhD***
President, SRK Consulting, LLC

## Session 335 CP - Clinical Safety and Pharmacovigilance, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 207A** *CME and Pharmacy credits offered*

### Data Mining and Signal Detection: Where Are We?

SESSION CHAIRPERSON

***Manfred Hauben, MD, MPh***
Medical Director, Risk Management Strategy, Pfizer Inc

Computational, computer-assisted signal detection algorithms, also known as data mining algorithms (DMAs), have received considerable attention as potentially attractive options for assisting expert safety reviewers responsible for screening large volumes of aggregate postmarketing safety data (SRS) in search of drug-event associations that may warrant further investigation ("signals.")

Most experience to date has involved application of DMAs to SRS data. Residual questions remain about this particular mode of application, but researchers are now exploring whether the relevant database environments and queries in data mining may be extended to additional applications in drug safety, pharmacovigilance, and pharmacoepidemiology.

This session will use recent experience with both SRS data and emerging applications to update pharmacovigilance specialists and pharmacoepidemiologists on the state-of-the-art of data mining in drug safety and pharmacovigilance.

**Data Mining to Enhance Vaccine Safety**
***Robert Ball, MD***
Chief, Vaccine Safety Branch, CBER, FDA

**Data Mining: To Shrink or Not to Shrink**
***Charles Gerrits, PhD, PharmD, MS***
Schering Plough Corporation

**Recent Improvements in Data Mining at the UMC**
***Andrew Bate, PhD***
Program Leader, Signal Research Methodology, Uppsala Monitoring Centre, Sweden

## Session 336 CR1 - Clinical Research and Development

10:30 AM - 12:00 PM LEVEL = ■

**Room 146A** *CME and Pharmacy credits offered*

### Integrating Pharmacogenomics into Clinical Trials

SESSION CHAIRPERSON

***David M. Weinreich, MD, MBA***
Vice President, Clinical Affairs, Gene Logic, Inc.

Pharmacogenomics offers the possibility of providing a wealth of information to aid in decision making regarding clinical development of a drug. These include identifying the MOA of a drug, patient stratification to improve development success rates, and identifying markets or submarkets for development of a compound. This session will discuss the integration of pharmacogenomics into clinical drug development while minimizing risk to and alteration of the underlying drug development plan.

**Expression Profiling in Clinical Pharmacogenomic Studies**
***Michael E. Burczynski, PhD***
Principal Research Scientist II, Molecular Profiling and Biomarker Discovery, Biological Technologies, Wyeth Research

**Applications of Genomics to Biomarker Discovery for Research & Development**
***Harsukh Parmar, MD***
Executive Director, Global Discovery Medicine, Respiratory and Inflammation Area, AstraZeneca R&D, UK

## Session 337 CR2 - Clinical Research and Development, GCP

10:30 AM - 12:00 PM LEVEL = ●

**Room 145A**

### GCP Compliance Considerations for Drugs, Devices and Biologics, and Combination Products

SESSION CHAIRPERSON

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

There are an increasing number of products being developed that are regulated as combination products. This can raise questions about the role of GCP expectations for the different products and how to best achieve a quality clinical study that meets the differing regulatory requirements.

**General GCP Compliance for Drugs and Biologics**
***Michael R. Hamrell, PhD, RAC***
President, MORIAH Consultants

**Clinical Issues and Regulatory Strategy for Combination Products in the EU**
***Sandy M. Eisen, MD, FRCPC, MA, MBA***
Vice President, Clinical, PAREXEL International Corporation, UK

**Clinical and Regulatory Strategy in the Development of Combination Products**
***Michael Gross, PhD, RAC***
Vice President, Regulatory Affairs, QLT Inc., Canada

## Session 338 CR3 - Clinical Research and Development, AHC

10:30 AM - 12:00 PM LEVEL = ●

**Room 145B**

### How to Navigate the NIH for Grants and Contracts

SESSION CHAIRPERSON

***Anne Zajicek, MD, PharmD***
Pediatric Medical Officer, National Institute of Child Health and Human Development, National Institutes of Health

Knowledge of the NIH funding mechanisms is crucial for academic success. This session will explain in detail how to find out about grant opportunities and contract solicitations, how to submit grants and respond to contract solicitations, and how to obtain further information from the NIH in these areas.

**Government Grants: Where to Look, How to Apply**
***Anne Zajicek, MD, PharmD***
Pediatric Medical Officer, National Institute of Child Health and Human Development, National Institutes of Health

**Government Contracts: The Other Funding Frontier**
***Perdita Taylor-Zapata, MD***
Pediatric Medical Officer, National Institute of Child Health and Human Development, National Institutes of Health

**Making a Living in the World of Grants**
***Marianne Garland, MB, ChB***
Neonatology Attending, Columbia University, Physicians and Surgeons

## Session 339 CTM - Clinical Trial Management, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 101** *CME, Nursing, and Pharmacy credits offered*

### Clinical Trials: More Sensible Arrangements for Dealing with Serious Adverse Events

SESSION CHAIRPERSON

***Richard O. Day, AM, MD, FRACP***
Clinical Pharmacologist and Rheumatologist, University of New South Wales, St. Vincent's Hospital, Australia

Investigators, IRBs, clinical trial auditors, CROs, and sponsors are increasingly distracted by an exponential increase in paperwork involved in dealing with serious adverse event (SAEs) reports. CIOMS VI is attempting to reintroduce some balance to the system of dealing with these. This might better reflect the purpose of communicating about SAEs to investigators and IRBs – to enhance the safety of clinical trials. There is a concern that the SAE "system" has lost sight of this purpose.

***Richard O. Day, AM, MD, FRACP***
Clinical Pharmacologist and Rheumatologist, University of New South Wales, St. Vincent's Hospital, Australia

***Vish S. Watkins, MD***
Project Leader, Program Phase and Pharmacovigilance, Global Product Safety, Oncology/Infectious Diseases Therapeutic Area, Eli Lilly and Company

***Yvonne Ditoro, RN, MBA***
Senior Director, Global Safety, Surveillance and Epidemiology, Wyeth

## Session 340 DM - Document Management/ eSubmissions, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 206** *Pharmacy credits offered*

### eCTD: The Impact on the Organization

SESSION CHAIRPERSON

***Betsy A. Fallen, RN***
Manager, Worldwide Regulatory Coordination, Merck & Co., Inc.

In this session, you will learn how to prepare for the migration to electronic publishing of the CTD format for worldwide paper and electronic eCTD dossiers and components. You will be presented with an overview of the process of revising the authoring and publishing procedures to support the CTD format. The evolution of CTD/eCTD has, for the first time, initiated harmonization of dossier format across ICH regions. Simultaneously, the trend in industry has been toward globalization and centralization, developing more effective and efficient operations. With the implementation of eCTD, specialized views of the data for various reviewers have become important. Those who inspect clinical trial sites have a different need than medical and statistical reviewers. Facilitating this access has been focused on by regulators and industry and has resulted in application of the proposed processes.

**Developing CTD/eCTD Formatted Submissions and Submission Components**
***Carol M. Stretch***
Senior Manager, Clinical Information and Technology (CITy), Novo Nordisk Inc.

**Industry Changes and Their Impact on Submission Management**
***Jean L. Supplee***
Associate Director, Dossier Management, AstraZeneca LP

**Implementation of eCTD Initiative by Collaboration**
***Daniel F. Orfe, MS***
Associate Director, Worldwide Regulatory Operations, Merck & Co., Inc.

## Session 341 GCP - Good Clinical Practices, TR

10:30 AM - 12:00 PM LEVEL = ■

**Room 202A** *CME credits offered*

### Training Late-phase Investigators: GCP Still Matters!

SESSION CHAIRPERSON

***Alicia Pouncey, MEd***
Managing Director, Aureus Research Consultants, LLC

Late-phase clinical trials are growing at an unprecedented rate. This session will discuss the unique differences between early- and late-phase trials and emphasize the importance of training this group of investigators and sites in GCP. A case study will also be presented.

**Late-phase Investigator Training: The Critical Components**
***Alicia Pouncey, MEd***
Managing Director, Aureus Research Consultants, LLC

**Incorporating Investigator Training into Your Late-phase Trial: A Sponsor's Perspective**
***Victor M. Montalvo-Lugo***
Manager, Medical Research, Global Medical Affairs, Amgen Inc.

## Session 342 IMP - Impact, CP, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 149AB** *CME and Pharmacy credits offered*

### Use of Drug Utilization Data for Risk Assessment and Risk Management

SESSION CHAIRPERSON

***Laura Governale, PharmD, MBA***
Drug Utilization Specialist Team Leader, Office of Drug Safety, CDER, FDA

This session will present an overview of current drug utilization resources available to FDA, and examples of their use in assessing and managing risks associated with drug products.

**Managing Risks Through Limited Distribution**
***Laura Governale, PharmD, MBA***
Drug Utilization Specialist Team Leader, Office of Drug Safety, CDER, FDA

**Duration of Therapy as a Risk Management Tool**
***David Moeny, USPHS, RPh***
Drug Data Utilization Specialist, Office of Drug Safety, Division of Surveillance, Research and Communication Support, CDER, FDA

**Nuances of Claims Data and Its Impact on Risk Assessment**
***Aaron B. Mendelsohn, PhD, MPH***
Epidemiologist, Office of Drug Safety, Division of Surveillance, Research and Communication Support, CDER, FDA

## Session 343 IT - Information Technology

10:30 AM - 12:00 PM LEVEL = ■

**Room 146B**

### Industry Standards and Web Services: Are We Ready for an Industry Architecture?

SESSION CHAIRPERSON

***Jason A. Burke, MA***
Life Sciences Industry Strategist, Microsoft Corporation

The advancement of information and technology standards within and beyond the life sciences industry currently provides for a simple flow of clinical and operational data between systems and organizations. But can the industry effectively define and implement electronic business processes that leverage these standards? We will examine how several organizations have explored this, and the implications for developing broader industry architecture(s) to support electronic business in healthcare.

**The Pharmaceutical Perspective**
***Martin H. Brodbeck, MS***
Director, Pfizer Global Pharmaceuticals

**The Technology Perspective**
***Sandy Sharma***
Vice President, Technology and Strategy, Immedient

**The Services Perspective**
***Ashif Jiwani***
Capgemini

## Session 344 MA - Marketing and Sales

10:30 AM - 12:00 PM LEVEL = ●

**Room 204BC**

### Salud! Reaching Foreign-born Patients in the US Market

SESSION CHAIRPERSON

***Mary F. Stober, MBA***
President, Global Project Resources, LLC

Immigration patterns are changing the ethnic makeup of the patient and provider populations in the US, presenting powerful new marketing needs and opportunities. This session will study ethnic marketing campaigns, with industry practitioners presenting strategies and tactics for market preparation, market research, and program implementation.

**Patients and Providers in the US: An Overview of Diverse Needs**
***Mary F. Stober, MBA***
President, Global Project Resources, LLC

**Pharmaceutical Marketing to Diverse Communities: Solutions for Translation Success**
***Inna Kassatkina***
President, Global Language Solutions

**Salud es Vida - Enterate! Improving Health Through Targeted Multimedia**
***Jorge Daboub***
Univision TV Group

## Session 345 MC - Medical Communications, MA

10:30 AM - 12:00 PM LEVEL = ●

**Room 209AB** *CME, Nursing, and Pharmacy credits offered*

### Thinking Outside the Medicine Box: Creative Ways of Getting Health Information to Consumers

SESSION CHAIRPERSON

***John A. Friel, JD***
Deputy Director, Office of Training and Communications, CDER, FDA

FDA's Center for Drug Evaluation and Research has recognized the need to educate consumers on the safe and effective use of medicines. The session will focus on message development, dissemination, and evaluation of several FDA consumer education campaigns.

**CDER Public Information Campaigns**
***Ellen Shapiro***
Director, Division of Public Affairs, Office of Training and Communications, CDER, FDA

**The California Health Communication Partnership**
***R. William Soller, PhD***
Executive Director, Center for Consumer Self Care, University of California-San Francisco School of Pharmacy

**Educational Programs of the Peter Lamy Center**
***Nicole Brandt, PharmD***
Director, Clinical and Educational Programs, University of Maryland School of Pharmacy

## Session 346 MW - Medical/Scientific Writing, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 102AB**

### Clinical Trial Registry: Build It and They Will Come?

SESSION CHAIRPERSON

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

In September 2004, a statement from the International Committee of Medical Journal Editors (ICJME) was published in *JAMA* (15 Sept, 2004), to suggest a clinical trial registry for posting negative clinical trial information. Included was a policy statement to the effect that member journals would not publish submitted manuscripts unless critical clinical protocol information was published on a publicly accessible website. Subsequently, there have been bills introduced in

Congress to propose a "Fair Access to Clinical Trials Act." PhRMA has come out with guidance to its members and individual pharmaceutical companies have established their own websites. Existing registries (clinicaltrials.gov and the NCI PDQ registry) address some aspects. Decisions will be made with respect to type and complexity of information, timing, audience, proprietary concerns, maintenance of the database, funding, and oversight. This may have a significant effect on the medical writer, given the need to prepare documentation to fulfill these obligations. The panel will review case histories and lessons learned in the construction of current registries, and implications of the proposed registry will also be addressed.

**Building the Registry: Lilly's Experience**
***Annetta C. Beauregard, MS, MBA***
Regulatory Consultant, Office of Scientific and Regulatory Policy, Global Regulatory Affairs, Eli Lilly and Company

**NCI's PDQ Clinical Trials Registry as a Model: Successes and Challenges**
***Lakshmi M. Grama, MA, MLS***
Technical Information Specialist/PDQ Database Project Manager, Cancer Information Products and Systems, National Cancer Institute, National Institutes of Health

**The FDA Perspective**
***Patricia C. Delaney***
Associate Director, Cancer Liaison Program, Office of Special Health Issues, Office of the Commissioner, CDER, FDA

## Session 347 NHP - Natural Health Products, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 140A**

### Strategies for Improving Botanical Medicine Acceptance in a Conventional Medical Setting

SESSION CHAIRPERSON

***Daniel Labriola, ND***
Naturopathic Consultant, State of Washington Department of Health

This session addresses the issues affecting the acceptance of botanical medicine in a conventional medical setting as well as strategies for improvement. The importance of evidence-based protocols will be addressed with attention to presenting data with formats and controls that have meaning for conventional providers.

**Clinical Trials Database: Prejudice or Full Disclosure?**
***Anna Marie C. McSorley***
Senior Manager, Quality Assurance, i3 Research

**Efficacy Testing to Prove a Claim for a Multiple Ingredient NHP**
***Mark T. Goldberg, PhD***
Principal, GlobalTox International Consultants, Canada

**Strategies for Improving Botanical Medicine Acceptance in a Conventional Medical Setting**
***Daniel Labriola, ND***
Naturopathic Consultant, State of Washington Department of Health

## Session 348 OS - Outsourcing

10:30 AM - 12:00 PM LEVEL = ■

**Room 150A**

### Functional Partnerships: A New, Robust Model for Pharmaceutical Industry-CRO Contracting

SESSION CHAIRPERSON

***James R. Schnieders, MS***
Vice President, Astellas Pharma, Inc.

Pharmas and CROs are constantly searching for new and more effective ways to work together. Full-service outsourcing partnerships, preferred providers and other models have been tried with mixed success. Astellas Pharma Inc. has examined all of these models, as well as unique approaches such as the Wyeth-Accenture partnership, and has derived a new and comprehensive approach to pharma-CRO partnering.

The functional partnership model is a comprehensive function-by-function model that is being implemented across multiple functions within Astellas R&D in the US. It balances the pharma's need for long-term staffing stability and quality with the CRO's need for long-term financial stability. It accounts for the functional strengths of each partner CRO and uses a comprehensive governance structure to make sure that all parties benefit from the relationship.

In this session, we will look at functional partnerships from both a pharma and CRO perspective and discuss the practical aspects of implementing functional partnerships across an entire organization.

**Functional Partnerships: A New Outsourcing Approach**
***David S. Zuckerman, MS***
President, Customized Improvement Strategies, LLC

**Implementing Functional Partnerships Across a Pharmaceutical Industry R&D Organization**
***James R. Schnieders, MS***
Vice President, Astellas Pharma, Inc.

**Making Functional Partnerships Work for a CRO**
***Lee Spurgin, PhD***
Vice President, Clinimetrics

## Session 349 PM1 - Project Management

10:30 AM - 12:00 PM LEVEL = ■

**Room 143AB** *Project Management Institute credits offered*

### Strategic Planning for Drug Development Projects

SESSION CHAIRPERSON

***David J. Fontana, PhD, PMP***
Head, Project Management and Regulatory Affairs, Archemix Corporation

Operational effectiveness and strategy are both critical to high project performance, which is the goal of any project management effort. This session will explore strategy development and scenario planning at the project level. Best practices in setting strategy, trade-offs, and option planning as applied to drug development, will be highlighted.

**A Framework for Project Strategy Planning: What's Important and When?**
***David J. Fontana, PhD, PMP***
Head, Project Management and Regulatory Affairs, Archemix Corporation

**Scenario and Option Planning: Critical Practices**
***Scott J. Mahoney, MBA***
Director, PRTM

## Session 350 PM2 - Project Management

10:30 AM - 12:00 PM LEVEL = ■

**Room 143C** *Project Management Institute credits offered*

### Are Portfolio Management Processes Really Working in Dealing with Current Issues within the Pharmaceutical Industry?

SESSION CHAIRPERSON

***Krish Ghosh, PhD***
Director, Portfolio Planning and Information, Wyeth Research

Managing and prioritizing projects in a pharmaceutical company pipeline portfolio is getting harder and harder, mostly due to immense challenges that the industry is currently facing. R&D productivity, which is a good indicator of the company/industry performance, is declining. Productivity is mostly influenced by the number of project starts, development cycle times, success rates, development costs, and value. Understanding the root causes of the current trends and high variability in these factors is key to improved portfolio management and decision making. Drawing on the experiences of the experts in the industry, this session will discuss current portfolio management processes, its major drawbacks, and the vision of the future of the portfolio management.

***Richard J. Heaslip, PhD***
Vice President, Project and Portfolio Management, Wyeth Research

***Krish Ghosh, PhD***
Director, Portfolio Planning and Information, Wyeth Research

## Session 351 PP - Public Policy/Law, CR, FI

10:30 AM - 12:00 PM LEVEL = ■

**Room 103A**

### Impact of Significant Payments of Other Sorts (SPOOS) on Clinical Research

SESSION CHAIRPERSON

***Michael A. Swit, JD***
Vice President, Life Sciences, THE WEINBERG GROUP

Disclosure of financial interests of investigators continues to be a key issue for the clinical research community. This session will examine both how significant payments of other sorts (SPOOS) can create the appearance — or reality — of bias for the clinical investigator and how to deal with such situations both before — and after – they arise.

***Michael A. Swit, JD***
Vice President, Life Sciences, THE WEINBERG GROUP

***Linda Strause, PhD***
Executive Director, Site Development, CancerVax Corporation

## Session 352 RA1 - Regulatory Affairs

10:30 AM - 12:00 PM LEVEL = ●

**Room 147B** *CME credits offered*

### Voluntary Pharmacogenetics Data Submissions 1 Year Later

SESSION CHAIRPERSON

***Barbara Kolb***
Director, Global Regulatory Affairs and Quality Assurance, Johnson & Johnson Pharmaceutical Research and Development, LLC

Pharmacogenomics holds the promise of individualizing medicine. To enhance the Agency's understanding of scientific issues associated with this field, FDA issued a guidance requesting sponsors to voluntarily submit pharmacogenomic data, when such data are not required to be submitted to an IND, NDA, or BLA. FDA and industry perspectives on the first year of experience with such submissions, called Voluntary Genomic Data Submissions (VGDS), will be explored in this session.

***Felix W. Frueh, PhD***
Associate Director for Genomics, CDER, FDA

***Richard Deane Hockett, MD***
Senior Clinical Research Physician, Eli Lilly and Company

*Panelists*

***Mark L. Watson, MD***
Therapeutic Area Director, GlaxoSmithKline

***Brian B. Spear, PhD***
Director, Pharmacogenetics, Abbott Laboratories

## Session 353 RA2 - Regulatory Affairs, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 151B** *Nursing and Pharmacy credits offered*

### Reporting and Assessing Inclusion of Subpopulations in Clinical Trials

SESSION CHAIRPERSON

***Katherine A. Hollinger, DVM, MPH, DACVPM***
Senior Supervisory Health Promotions Officer, Office of Women's Health, Office of the Commissioner, FDA

This session will review the history of the FDA's policy on gender inclusion and assessments of subpopulation inclusion in clinical trials. An overview of the FDA's assessments of subpopulation inclusion in clinical trials will be presented.

**HHS Policy on Inclusion and History**
***Katherine A. Hollinger, DVM, MPH, DACVPM***
Senior Supervisory Health Promotions Officer, Office of Women's Health, Office of the Commissioner, FDA

**Review of 2002 IND Submissions and Inclusion and Exclusion Criteria**
***Ellen E. Pinnow, MS***
Fellow, Office of Women's Health, Office of the Commissioner, FDA

**Representing and Identifying Patient Populations in the CDISC SDTM Model**
***Wayne R. Kubick, MBA***
Vice President, Lincoln Technologies, Inc.

**Differences in Subpopulation Risk: Should it Affect Trial Design?**
***Jonathan G. Levine***
ORISE Fellow, FDA

## Session 354 RA3 - Regulatory Affairs, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 151A**

### The Radioactive Drug Research Committee: Academic Research or Drug Development Tool?

SESSION CHAIRPERSON

***Orhan Suleiman, PhD, MS, FAAPM***
Senior Science Policy Advisor, CDER, FDA

In the United States, clinical research using radiolabeled drugs can be conducted without an FDA Investigational New Drug (IND) application under the authority of an FDA Radioactive Drug Research Committee (RDRC). This FDA program, promulgated in 1975, is very similar to microdosing, a recent drug development initiative championed in Europe. A review of RDRC requirements will be presented, along with their relationship to FDA's Critical Path initiative, microdosing, and imaging.

**The University of Pittsburgh Experience with the Radioactive Drug Research Committee**
***Dennis P. Swanson, RPh, MS, BCNP***
Director, Research Conduct and Compliance Office, University of Pittsburgh Medical Center

**Drug Research Initiatives: The Critical Path, Exploratory IND and Microdosing**
***Jerry M. Collins, PhD***
Director, Division of Clinical Pharmacology Research, CDER, FDA

**The Radioactive Drug Research Committee: 1975 and Today**
***Steven M. Larson, MD***
Chief, Nuclear Medicine Service, Weill Medical College of Cornell University, Memorial Sloan-Kettering Cancer Center

## Session 355 RA4 - Regulatory Affairs, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 152A** *CME credits offered*

### Pediatric Medicine: New Challenge in Japan

SESSION CHAIRPERSON

***Toshinobu Iwasaki, PharmD***
Manager, Pharmaceutical Affairs Division, Shionogi & Co., Ltd., Japan

Japan will take action to approve over 100 unauthorized medicines for pediatric patients for the next five years. Japanese industries, pediatric academia, and regulatory authorities will collaborate to establish the way to conduct rational pediatric trials. This session will demonstrate how each organization handles off-label use and facilitates pediatric studies.

**Update on Japanese Pediatric Action in Drug Evaluation**
***Junko Sato, PhD***
Principal Reviewer, Office of New Drug I, Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency, Japan

**Development of a Clinical Research Framework for Medicines for Children in Japan**
***Hidefumi Nakamura, MD, PhD***
Director, Division of Clinical Research, National Center for Child Health and Development, Japan

**Regulatory Innovations for Pediatric Medicines in Japan: Pharmaceutical Industrial Aspect**
***Yoshitaka Ike***
Manager, Medical Regulatory Affairs, Otsuka Pharmaceutical Co., Ltd., Japan

## Session 356 RA5 - Regulatory Affairs

10:30 AM - 12:00 PM LEVEL = ■

**Room 152B**

### Current Issues with 505(B)(2) Applications

SESSION CHAIRPERSON

***J. Christopher Prue, RPh, MBA***
Senior Director, Regulatory Affairs, Purdue Pharma L.P.

There are many factors to consider in deciding between a 505(b)(1) and 505(b)(2) application. This topic is an important consideration in the development strategy for a new product involving an active ingredient that has been previously approved. The session will approach this issue from the regulatory and legal perspectives.

**Legal Perspectives with 505(b)(2) Applications**
***Kelly N. Reeves, JD***
Attorney, King and Spalding LLP

**Current Issues with 505(b)(2) Applications**
***J. Christopher Prue, RPh, MBA***
Senior Director, Regulatory Affairs, Purdue Pharma L.P.

## Session 357 RA6 - Regulatory Affairs, CR

10:30 AM - 12:00 PM LEVEL = ◆

**Room 146C** *CME credits offered*

### Regulation of Clinical Research in the EU: Impact of the Clinical Trials Directive

SESSION CHAIRPERSON

***Carolyn L. Hynes, PhD***
Regulatory Affairs Manager, Johnson & Johnson Pharmaceutical Research and Development, LLC, UK

This session highlights some of the practical experiences of companies with conducting research in Europe under the Clinical Trials Directive, which has now been in force for one year. It also reviews the experiences of the EMEA in developing the EudraCT database of European clinical trials and of the Commission in developing guidance documents to facilitate the harmonized implementation of the Directive throughout the Community.

**Industry Experiences with Conducting Clinical Trials in Europe Under the Directive**
***Carolyn L. Hynes, PhD***
Regulatory Affairs Manager, Johnson & Johnson Pharmaceutical Research and Development, LLC, UK

**Development of the EudraCT Database: Experiences to Date and Future Plans**
***Fergus L. Sweeney, PhD***
Principal Administrator, Inspections Unit, EMEA, EU

**Harmonization of the European Procedures for Clinical Trials: Where Do We Stand Today?**
***Birka Lehmann, MD***
Pharmaceutical Unit, European Commission, Belgium

## Session 358 RD - R&D Strategy

10:30 AM - 12:00 PM LEVEL = ■

**Room 150B**

### Innovation or Stagnation: When the Obvious Choice Is Also the More Difficult Choice

SESSION CHAIRPERSON

***David Handelsman***
Lead Strategist, Clinical R&D, SAS

The need to accelerate the development and application of new medical technologies is well known, and grows increasingly urgent. This session will feature speakers who are utilizing innovative methodologies in the marketplace, and shortening the critical path for new medical products.

**Risk and Reward: Implementing New Technologies for the Life Sciences**
***David Handelsman***
Lead Strategist, Clinical R&D, SAS

**Maximizing the Value Proposition of EDC Through Proper Workflow**
***Jeffrey A. Green, PharmD***
President and Chief Executive Officer, DATATRAK International, Inc.

**Unifying Data Management, Statistical Analysis and Document Management Using a Collaborative Environment**
***Steven Kramer***
Program Director, Clinical Informatics, Regeneron Pharmaceuticals, Inc.

## Session 359 ST - Statistics

10:30 AM - 12:00 PM LEVEL = ■

**Room 201** *CME credits offered*

### Analysis of Responder Data

SESSION CHAIRPERSON

***Chih Stan Lin, PhD***
Statistical Team Leader, Office of Biostatistics, CDER, FDA

In clinical trials, the treatment response outcome often has been dichotomized into success or failure, response or nonresponse, cure or no cure, etc. When the data are analyzed, the outcome variable is often treated as a Bernoulli variable, regardless of the distribution of the original response variable. Recent research accommodates the distribution information, and sensitivity evaluation of the dichotomization proved to be an improvement to the naïve analysis.

**Compare Responder Rates Without Data Dichotomization**
***Yi Tsong, PhD***
Mathematical Statistician, CDER, FDA

**Odds Ratio for a Continuous Outcome Variable**
***Barry Kurt Moser, PhD***
Deputy Director, CALGB Center, Duke University Medical Center

*Discussant*
***Gary G. Koch, PhD***
Professor, Biostatistics, University of North Carolina

## Session 360 TR - Training, CR

10:30 AM - 12:00 PM LEVEL = ●

**Room 207B**

### Training and Development of New and Experienced CRAs

SESSION CHAIRPERSON

***Michelle L. Pearsall, CCRA***
Associate Director, Staff Training and Development, Inveresk

The presentation and discussion will revolve around methods of training new CRAs to the clinical research industry and methods of developing experienced CRAs. The focus will include the technical materials to be covered in new CRA training as well as the soft skills required to handle the CRA's responsibilities. The presentation will also include innovative ways to provide continuing education and development to experienced CRAs.

**Training and Development of the New CRA**
***Michelle L. Pearsall, CCRA***
Associate Director, Staff Training and Development, Inveresk

**CRA Leader: Advancing Your Career to the Next Level**
***Louis Grue, RN, CCRA***
CPCRA Research Unit Manager, Social and Scientific Systems

**Building the Effective Study Team**
***Sara M. Brandon***
Chief Financial Officer, Carolinas Research Associates, Inc.

12:00 PM - 1:30 PM **LUNCHEON**

**Lunches will be distributed from 12:00 PM to 1:00 PM in Exhibit Hall C, Lower Level, Convention Center**

## Session 361 AHC - Academic Health Centers, IS

1:30 PM - 3:00 PM LEVEL = ■

**Room 103B**

### Financial Checks and Balances: Making Sure You're Getting What You Negotiate

SESSION CHAIRPERSON

***James Wynn***
Director of Business Development, Clinical Financial Services, Inc.

Every academic health center is concerned about negotiating the best agreement with the best budget, but how does it know if it's really getting paid the correct amount? Because of the complexity of different agreements, errors are more likely to occur in the clinical trials industry than in most others. We will explore this issue and discuss some accounting techniques that can be applied to assure that all research dollars are accounted for, paid in a timely manner and paid in full ... and why it's important.

**Life Cycle of Clinical Trials: A Financial Perspective**
***Richard Hlenski, MBA***
Director, Finance and Strategic Planning, Columbia University Medical Center-NY Presbyterian Hospital

**Financial Performance from the Clinical Site Perspective**
***James R. Kilgore, PhD***
President and Chief Executive Officer, Clinical Research Consultants, Inc.

## Session 362 BT - Biotechnology, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 154AB**

### Current Process for Follow-on Proteins in Europe: The Biosimilars Products

SESSION CHAIRPERSONS

***Louis-Christian Clauss, PharmD, MBA, MPharm***
Director, Regulatory Affairs, Global NPD Biologics, Baxter, France

***Jacques C. Mascaro, PhD***
Director, European Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

Learn the latest development and understand the situation regarding follow-on proteins in Europe – the biosimilars – what is happening and what should be done from the point of view of the innovator company, the competitors, and the authorities.

**Biosimilars in Europe: The Point of View of the Innovator Company**
***Jacques C. Mascaro, PhD***
Director, European Regulatory Affairs and Liaison, F. Hoffmann-La Roche Ltd., Switzerland

**Case Studies in Comparability of Biological Medicinal Products: Consequences for Products Claimed to Be Similar to Another One Already Marketed**
***Chris J. Holloway, PhD***
Group Director, Regulatory Affairs, ERA Consulting Group, Germany

**Biosimilars in Europe: The Regulatory Authorities' Point of View**
***Maria-Sol Ruiz***
Head, Biotechnology Unit, Spanish Medicines Agency, Spain

## Session 363 CDM - Clinical Data Management

1:30 PM - 3:00 PM LEVEL = ■

**Room 202B** *CME and Nursing credits offered*

### Experiences with MedDRA® Translations

SESSION CHAIRPERSON

***Anna Zhao-Wong, PhD, MD***
Medical Review Officer, Northrop Grumman Corporation

MedDRA in Japanese (MedDRA/J) has been available for six years. MedDRA non-English EU language translations have been released for three years. It is time to exchange experiences and discuss lessons learned among regulators and pharmaceutical companies concerning the use of non-English MedDRA.

**Working with MedDRA in Various Languages**
***Nancy H. Woo, PhD***
Principal, Woo Consulting

**Japanese Translation of MedDRA**
***Tomoko Maeda***
Manager, MedDRA Support and Maintenance, Quintiles Transnational Japan K.K., Japan

**Working with MedDRA in Europe**
***Philippe Thouvay, MD***
Head, EU Pharmacovigilance, Amgen Inc., UK

## Session 364 CMC - Chemistry, Manufacturing, and Controls, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 147A**

### IND CMC Issues

SESSION CHAIRPERSON

***Charles P. Hoiberg, PhD***
Executive Director, Pfizer Inc

Updates and perspectives on FDA guidelines currently under development will be presented, along with a discussion on best approaches for meeting with the Agency and on what the desired content of submission should be at various phases of the IND.

**FDA Perspective**
***Guirag K. Poochikian, PhD, FACP***
Associate Director for Regulatory Science, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, FDA

**Industry Perspective**
***Leslie Bloom, PhD***
Director, Global R&D, Pfizer Inc

**Panel Discussion/Q&A Period**

## Session 365 CP - Clinical Safety and Pharmacovigilance, CR

1:30 PM - 3:00 PM LEVEL = ■

**Room 207A** *CME and Pharmacy credits offered*

### COX-2 Inhibitors: Where Are We in 2005?

SESSION CHAIRPERSON

***Richard O. Day, AM, MD, FRACP***
Clinical Pharmacologist and Rheumatologist, University of New South Wales, St. Vincent's Hospital, Australia

The future of the COX-2 inhibitors is uncertain in the light of the withdrawal of VIOXX and the finding of a risk of thrombosis with Celebrex and Bextra. Questions are now also being raised on the cardiovascular risks of traditional NSAIDs (e.g., naproxen). The clinical, commercial, and political consequences for the medicines industry and its regulation are immense, and the drug development landscape, especially for new COX-2 candidates, will alter substantially. This session will chart the history of the development and marketing of the COX-2 inhibitors from the perspective of the quality of the science, data, and decisions that underpinned the highs and lows of the COX-2 saga. Was the reliance on event-driven, randomized, blinded, and controlled trials with sufficient power misplaced? For drugs with emerging safety questions, has the time come to undertake sequential meta-analyses on trial data as they become available? How can we resolve concerns about bias and inadequate rigor of postmarketing, epidemiologic studies in comparison to large-scale randomized controlled trials? Do we know the risk factors for thrombotic events, and if so, was there a better, faster way to resolve uncertainties concerning the relative risk in different patients taking these drugs? These important questions will be addressed.

***Richard O. Day, AM, MD, FRACP***
Clinical Pharmacologist and Rheumatologist, University of New South Wales, St. Vincent's Hospital, Australia

***Daniel E. Furst, MD***
Professor, Rheumatology, University of California at Los Angeles

## Session 366 CR1 - Clinical Research and Development, RD

1:30 PM - 3:00 PM LEVEL = ●

**Room 140B** *Pharmacy credits offered*

### Global Expanded Access Program: The Ins and Outs

SESSION CHAIRPERSON

***Robert V. Riccio, PhD***
Vice President, Periapproval Services, PAREXEL International

The benefit of expanded access for a patient who is running out of hope is clear, but what about pharmaceutical companies? What is the benefit to them?

*Panelists*

***Kenneth Watters, MD***
Vice President, Clinical Development and Regulatory Affairs, Europe, Celgene Europe Limited, UK

***Wayne Dankner, MD***
Senior Medical Director, PAREXEL International

***Hua Dupre, MD***
Director, Clinical R&D, Tibotec BVBH (a J&J Company), Belgium

***Richard Pazdur, MD***
Director, Division of Oncology Drug Products, CDER, FDA

## Session 367 CR2 - Clinical Research and Development, BT, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 145A**

### Generic Biologics: Fact or Fiction?

SESSION CHAIRPERSON

***Allen Cato, PhD, MD***
President, Cato Research, Ltd.

As another year of experience is gained, several biological products have moved past the time for patents to expire. Is there a scientific basis for some biological products to become generic? Significant financial incentives create opposing sides to this issue and thereby potentially inhibit resolution.

**The Evolving Landscape for Follow-on Biologics in the US and Biosimilar Products in the EU**
***David G. Shoemaker, PhD***
Vice President, Regulatory Affairs and Project Management, Cato Research, Ltd.

**Considerations of the Scope of Preclinical Safety Programs for a Follow-on Biologic**
***Joy A. Cavagnaro, PhD***
President, Access BIO

**Navigation Studies in the Uncertain Seas of Follow-on Biologics**
***Janet M. McNicholas, PhD***
Partner, McAndrews, Held & Malloy

## Session 369 CR4 - Clinical Research and Development, RA

1:30 PM - 3:00 PM LEVEL = ●

**Room 145B** *CME and Pharmacy credits offered*

### Imaging of Alzheimer's and Other Neurodegenerative Diseases: Role in Clinical Trials

SESSION CHAIRPERSON

***Michael W. Weiner, MD***
Director, Magnetic Resonance Unit, San Francisco VAMC, University of California, San Francisco

This session focuses on use of MRI (to a lesser extent PET) imaging to monitor disease progression and determine treatment effects in Alzheimer's trials and potentially in other neurodegenerative diseases. Speakers will present an academic, industry, and FDA perspective.

**Use of Imaging in Clinical Trials of Alzheimer's Disease: The NIA Alzheimer's Disease Neuroimaging Initiative**
***Michael W. Weiner, MD***
Director, Magnetic Resonance Unit, San Francisco VAMC, University of California, San Francisco

**Imaging to Optimize CNS Drug Discovery**
***Richard Hargreaves, PhD***
Vice President, Imaging, Merck & Co., Inc.

**FDA Perspective on the Use of Imaging to Determine Treatment Effects in Alzheimer's Disease Clinical Trials**
***Russell G. Katz, MD***
Director, Division of Neuropharmacologic Drug Products, Office of New Drugs, CDER, FDA

## Session 370 CTM - Clinical Trial Management, CR

1:30 PM - 3:00 PM LEVEL = ●

**Room 101** *CME credits offered*

### Why Would You Want to Do a Registry?

SESSION CHAIRPERSON

***Elizabeth Fraulo, RN***
Project Leader, Duke Clinical Research Institute

Randomized clinical trials are often slow, always expensive and labor-intensive, and occasionally do not answer the question they were designed to answer. Registries, on the other hand, are less expensive, faster, and less encumbered by paperwork. This session will address registries as an option from the perspective of the FDA, a site coordinator, and a sponsor.

**Why a Registry? An Academic Healthcare Organization's Point of View**
***Amy L. Kessenich***
Administrative Director, Heart Center, Duke Medical Center

**Registries: Current FDA Perspectives**
***Allen Brinker, MD***
Lead Medical Officer, Epidemiology, Office of Drug Safety, Division of Drug Risk Evaluation, CDER, FDA

**Real World Data – Real World Impact**
***Michael Moye***
Senior Marketing Manager, Millennium Pharmaceuticals, Inc.

## Session 371 DM - Document Management/ eSubmissions, RA

1:30 PM - 3:00 PM LEVEL = ●

**Room 206** *Pharmacy credits offered*

### Guidance-compliant eCTDs – Part 1 of 2

SESSION CHAIRPERSON

***Gary Gensinger***
Director, Review Technology Staff, Office of Information Management, CDER, FDA

*Part 2 of this session will be held on Wednesday, at 3:30 PM.*

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

***Gary Gensinger***
Director, Review Technology Staff, Office of Information Management, CDER, FDA

***Norman R. Schmuff, PhD***
Deputy Director, Division of New Chemistry III, CDER, FDA

***Stephen E. Wilson, DrPH, Capt. USPHS***
Deputy Director, Division of Biometrics II, CDER, FDA

***Armando Oliva, MD***
Associate Director for Policy, Office of New Drugs, CDER, FDA

***Bronwyn E. Collier, RN***
Associate Director of Regulatory Affairs, CDER, FDA

***Kenneth Edmunds***
IT Specialist, CDER, FDA

## Session 372 GCP - Good Clinical Practices, eClin, CR

1:30 PM - 3:00 PM LEVEL = ■

**Room 202A**

### Planning for Electronic Data Quality in Clinical Trials

SESSION CHAIRPERSON

***Teri E. Stokes, MT (ASCP), MS, PhD***
Director, GXP International

Source data in clinical trials is quickly moving to electronic status. The US Health Information Technology initiative is driving towards a national electronic medical record (EMR). Protocol teams must integrate measures for electronic data quality into their design and planning process for GCP trials going forward, and this session discusses a practical approach.

**Compliance and Process Issues in ePatient Data Collection and eSource Documentation Solutions for Clinical Studies: The Sponsor Perspective**
***Pamela A. Rose, RN-FNP***
Director, Research Quality Assurance, TAP Pharmaceuticals

**Integrating Electronic Data Quality at the Study Site: The Site View**
***Yvonne P. McCracken, DH, CCRC, MPH***
Chief Executive Officer, Carolinas Research Associates

**Managing the Quality of eData Technology in Clinical Studies: The Technology View**
***Teri E. Stokes, MT (ASCP), MS, PhD***
Director, GXP International

## Session 373 IMP - Impact, CR, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 149AB** *CME, Nursing, and Pharmacy credits offered*

### Update on FDA's Draft Guidance on Patient-reported Outcomes

SESSION CHAIRPERSON

***Jane A. Scott, PhD, MA***
Endpoint Reviewer, Office of New Drugs, IO/SEALD, CDER, FDA

FDA invited comments on a draft guidance for industry regarding Patient-reported Outcome (PROs) Measures: Use in Medical Product Development to Support Claims. This session will provide a summary of the issues addressed in the draft guidance and an overview of the comments received to date.

**Comments on the Draft PRO Guidance: The Role of PROs in Medical Product Development**
***Margaret L. Rothman, PhD***
Executive Director, HE&PP, PGSM, Johnson & Johnson Pharmaceutical Services, LLC

**Comments on the Draft PRO Guidance: Development and Validation of PROs for Clinical Trials**
***Donald L. Patrick, PhD, MSPH***
Professor and Director, Social and Behavioral Sciences Program, School of Public Health and Community Medicine, University of Washington

**Comments on the Draft PRO Guidance: Implementation and Analysis of PROs in Clinical Trials**
***Jeffrey A. Sloan, PhD***
Professor of Biostatistics, Professor of Oncology, Mayo Clinic

## Session 374 IT - Information Technology, CTM

1:30 PM - 3:00 PM LEVEL = ■

**Room 146B**

### Advancing Patient Recruitment with Technology and Metrics

SESSION CHAIRPERSON

***David Fox***
President and CEO, Praxis

The purpose of the presentation is to demonstrate the efficiencies gained in time, money, and knowledge by applying technological advances to patient recruitment for clinical trials. Increasing demands on study coordinators' time, as well as rising drug development costs, necessitate the implementation of measures to improve, yet simplify, the patient recruitment process. Applying technological advances to the patient recruitment process is the most efficient way of accomplishing this, while providing additional benefits to sites and sponsors alike.

**Using Technology and Metrics to Select Investigators and Identify Site Locations**
***William W. Gwinn, Jr., MBA***
Director, Clinical Trial Solutions, Medstat Inc.

**Using Technology and Metrics: A Sponsor's Perspective**
***Frederick K. Lovelace, Jr.***
Associate Manager, Pfizer Inc

**Using Technology and Metrics: A Site's Perspective**
***Kenneth R. Thomas***
Clinical Research Coordinator, Rx R&D

## Session 375 MA - Marketing and Sales

1:30 PM - 3:00 PM LEVEL = ■

**Room 204BC**

### Moving to Higher Levels of Launch Excellence

SESSION CHAIRPERSON

***Leo G. Dodds, MBA***
Solution Partner, BusinessEdge Solutions

A major goal of pharmaceutical companies is the acceleration of new product commercialization and excellence in the execution of product launch processes. In today's competitive, cost-conscious environment, there must be efficiency and effectiveness throughout launch preparation. This session will cover the prerequisites of launch success and describe the linkage to responsibilities and processes. Also, a case study will be discussed with a focus on key determining factors for operations.

**Launch Mobilization: Experiences and Lessons Learned**
***Raymond J. Suehnholz, MBA***
Vice President, New Business Development, North American Pharmaceutical Centers of Excellence, Division of Ortho-McNeil, Johnson & Johnson

**Excellence in Medical Education: A Key to Launch Success**
***Roseann Peluso Nguyen, PharmD***
Director, Medical Education, Janssen Medical Affairs, L.L.C.

**Tracking and Communicating Progress: A Foundation for Teamwork**
***Leo G. Dodds, MBA***
Solution Partner, BusinessEdge Solutions

## Session 376 MC - Medical Communications, OS

1:30 PM - 3:00 PM LEVEL = ■

**Room 209AB**

### Outsourcing Medical Communications Services

SESSION CHAIRPERSON

***Stacey M. Fung, PharmD***
Senior Medical Communications Scientist, Genentech, Inc.

The decision to outsource projects or operational services involves a number of considerations. The use of vendors may have potential cost-savings and may increase the opportunities for department staff. The presentations will discuss making the initial assessment and decision to outsource, what can be outsourced, identifying potential vendors, the selection process, and developing working SOPs. Training and maintenance considerations will also be reviewed. Other issues will include how to sell this option to management, ensure quality service and products, and essential "must-haves" when making agreements.

**Basics of Outsourcing Partnerships**
***Stacey M. Fung, PharmD***
Senior Medical Communications Scientist, Genentech, Inc.

**Maintaining Quality Outsourced Professional Services**
***Mario F. Sylvestri, PharmD, PhD***
Senior Director, Regulatory and Medical Information, Amylin Pharmaceuticals, Inc.

**Expectations of Relationships for All Stakeholders for Field-based Outsourcing**
***Joyce Morrell***
Managing Director, Ventiv Pharma Services

## Session 377 MW - Medical/Scientific Writing, NC, RA

1:30 PM - 3:00 PM LEVEL = ■

**Room 102AB**

### Nonclinical Regulatory Writing

SESSION CHAIRPERSON

***Linda Fossati Wood, RN, MPH***
President, MedWrite, Inc.

High-quality documentation of nonclinical testing is essential to support product registration. Allocation of writing services to nonclinical scientists is often insufficient, as few medical writers are familiar with the components of nonclinical research and the regulatory documents that govern it. This session will serve as a review of the regulatory environment surrounding this fascinating area of product development, will describe the good laboratory practice (GLP) report, and will discuss the application of techniques used in clinical writing to generate the GLP report.

**Regulatory Guidance for Nonclinical Documents**
***Theresa A. Thompson-Hoffman, PhD***
Medical Writer, Image Solutions, Inc.

**Good Laboratory Practice Nonclinical Study Reports: Essential Elements**
***James F. McCormack, PhD***
Vice President, Regulatory Affairs and Compliance, Charles River Laboratories - CTBR

**Applying Techniques Used in Clinical Study Reports to Nonclinical Study Reports**
***Linda Fossati Wood, RN, MPH***
President, MedWrite, Inc.

## Session 378 NHP - Natural Health Products

1:30 PM - 3:00 PM LEVEL = ■

**Room 140A**

### Botanical Drug Development: It Starts at the Beginning – Control of the Plant

SESSION CHAIRPERSON

***Edward M. Croom, Jr., PhD***
Chief Executive Officer, Croomia

In developing a botanical as an ethical drug, one of the key attributes of a natural product that must be addressed early in the process is establishing batch-to-batch consistency. This level of control begins at the beginning, with the genetic make-up of the plant, where and how the plant is grown, and how it is handled during the growing period and during harvesting. This session will explore current guidances that address "good agricultural practices," and real-life examples of how these principles are being addressed in the manufacture of botanical drug products.

**Good Agricultural and Collection Practices for the Production of Botanical Drugs**
***Edward M. Croom, Jr., PhD***
Chief Executive Officer, Croomia

**Phytoneering: Research of Plant-based Medicines – from the Seed, to Cultivation, to Clinical Efficacy**
***Michael A. Popp, PhD***
Chief Executive Officer, Bionorica AG, Germany

**Controlling the Plant through Hydroponics**
***Ilya Raskin, PhD***
Professor, Rutgers University

## Session 379 OS - Outsourcing, CR

1:30 PM - 3:00 PM LEVEL = ■

**Room 150A**

### The State of Clinical Outsourcing: Industry Practices and Perceptions

SESSION CHAIRPERSON

***Patricia Leuchten***
President, The Avoca Group

This session will present quantitative and qualitative data based on industry research and focused on the state of clinical outsourcing. Information presented will include current practices for purchasing clinical services and industry perceptions about what constitutes a "best practice," problems and challenges with current approaches, opportunities that exist for achieving cost savings without sacrificing high quality and projected trends for the future.

**Panel Discussion**

***R. Adrian Otte, MB, FFPM***
Senior Vice President, Worldwide Business Operations, Pfizer Inc

***Paula Brown Stafford, MPH***
Executive Vice President, Client and Site Operations for Clinical Development Services Americas, Quintiles Transnational Corporation

***Cynthia J. Kearney***
Vice President, Global R&D Pharmaceutical Sourcing, Johnson & Johnson Pharmaceutical Research and Development, LLC

## Session 380 PM1 - Project Management

1:30 PM - 3:00 PM LEVEL = ●

**Room 143AB** *Project Management Institute credits offered*

### Who Reads the Development Plan Anyway!

SESSION CHAIRPERSON

***Pauline A. Goldsmith, MS***
President, Goldsmith Consulting

Getting frustrated spending hours, even days, updating your development plans? Wonder why you are doing this if no one ever reads it? Tired of hearing scathing remarks from management, who do not understand the need for a plan, never mind look at it? Join us for a lively discussion with representatives from R&D, new product planning-marketing and strategic planning-business development. You will be surprised who wants to read your development plan.

***Peter Elliott, PhD***
Executive Vice President, Product Development, Combinatorx Inc.

***James Reilly, MSc***
Director, New Product Marketing, ZLB Behring LLC

***Pauline A. Goldsmith, MSc***
President, Goldsmith Consulting

## Session 381 PM2 - Project Management

1:30 PM - 3:00 PM LEVEL = ■

**Room 143C** *Project Management Institute credits offered*

### Project Management's Role in the Pharmaceutical Industry of the Future

SESSION CHAIRPERSON

***Richard J. Heaslip, PhD***
Vice President, Project and Portfolio Management, Wyeth Research

This session will focus on two challenges facing project management professionals as we define our new role in the pharmaceutical industry of the future, the establishment of new expectations and competency models for project management performance within the R&D environment, and the definition of an emerging role for project management as leaders of operational and strategic planning within the pharmaceutical industry.

**Aligning Your Organization for Project Management Success**
***Jan J. Malek, MBA***
PA Consulting Group

**Role of the Project Manager in a Complex Environment: Aligning Expectations, Deliverables, Skills, and Core Competencies**
***Laurie H. May, MPH***
Director, Product Portfolio Management, Genentech, Inc.

**Preparing for Change in the Pharmaceutical Industry: The New Skills Required for Project Management Professionals**
***Richard J. Heaslip, PhD***
Vice President, Project and Portfolio Management, Wyeth Research

## Session 382 PP - Public Policy/Law, IMP

1:30 PM - 3:00 PM LEVEL = ●

**Room 103A**

### Formulary Decisions in the US and UK

SESSION CHAIRPERSON

***Joshua P. Cohen, PhD***
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University

This session will draw comparisons between the US and UK with respect to the decision-making process underlying drug reimbursement and pharmaceutical care management. In the US, there is no standardized approach to drug reimbursement, formulary design, and pharmaceutical care management. Private and public payers use different therapeutic classification systems to devise formularies, cover different sets of FDA-approved drugs, and apply a variety of clinical practice guidelines aimed at improving the (cost) effectiveness of pharmaceutical care. In the UK, there is one predominant payer, the National Health Service, and one list of MHRA-approved medicines that British healthcare providers may prescribe from, the British National Formulary. Moreover, there is one organization, the National Institute for Clinical Excellence, responsible for providing national guidance on treatments and care for those using the NHS. NICE's mandate is to develop authoritative guidance on the clinical- and cost-effectiveness of (pharmaceutical) care.

**The Impact of Clinical Programs on Formulary Compliance**
***Mark Rubino***
Chief Pharmacy Officer, Aetna, Inc.

**NICE Impact on Drug Reimbursement Decisions**
***Peter Littlejohns***
Chief Clinical Officer, National Institute of Clinical Excellence, UK

**US-UK Comparison of Pharmacoeconomic Assessments of 70 Recently Approved High-cost, High-impact Drugs**
***Joshua P. Cohen, PhD***
Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University

## Session 383 RA1 - Regulatory Affairs

1:30 PM - 3:00 PM LEVEL = ■

**Room 144ABC**

### US-EU Agreement to Exchange Scientific Advice: A Status Report

SESSION CHAIRPERSONS

***Marie A. Dray, MBA***
Executive Director, Global Regulatory Policy, Merck Sharp & Dohme (Europe), Inc., Belgium

***Brenton E. James, FBIRA***
Consultant, UK

In September 2003, the FDA and the European Commission/EMEA signed a wide-ranging agreement to share information on a large number of regulatory topics. Other agreements or Memoranda of Understanding (MOUs) have been established for similar purposes between other regulatory authorities. In this session, speakers will provide greater details on the practical aspects of implementation of these agreements.

*Panelists*

***Steven K. Galson, MD, MPH***
Acting Director, CDER, FDA

***Thomas Lönngren, MPharm***
Executive Director, EMEA, EU

***Jesse L. Goodman, MD, MPH***
Director, Center for Biologics Evaluation and Research, FDA

***Mathias Hukkelhoven, PhD***
Senior Vice President, Global Head, Regulatory Affairs, Novartis Pharmaceuticals

## Session 384 RA2 - Regulatory Affairs, CR

1:30 PM - 3:00 PM LEVEL = ■

**Room 152A**

### Outlook for Changes in Japanese Regulatory and Clinical Development Environment – Part 1 of 2

SESSION CHAIRPERSONS

***Jean-David Rafizadeh-Kabe, MD, JD, MS***
Associate Director, Global Regulatory Strategy, Bristol-Myers Squibb Pharmaceutical Research Institute

***Noriaki Murao, MS***
Representative Director, Schwarz Pharma Japan

*Part 2 of this session will be held on Wednesday at 3:30 PM.*

This session will provide an update on the regulatory environment in Japan, including the regulatory review process and performance, implementation of ICH guidelines and CTD, and the ways they impact on clinical development. The session will also address the future perspectives for clinical development and regulatory strategy with global development programs in Japan.

**Current Environment of Clinical Study in Japan**
***Tetsuto Nagata***
Chairperson, Clinical Evaluation Subcommittee, Drug Evaluation Committee, JPMA, Japan

**Regulatory Review Performance in Japan**
***Shunsuke Ono, PhD***
Reviewer, Pharmaceutical and Medical Devices Agency (PMDA), MHLW, Japan

**Companies' Perspective on the PMDA**
***Orie Asaka, PhD***
Research Fellow, Office of Pharmaceutical Industry Research, Japan; Pharmaceutical Manufacturers Association (JPMA), Japan

## Session 385 RA3 - Regulatory Affairs, CR

1:30 PM - 3:00 PM LEVEL = ■

**Room 151A** *CME and Pharmacy credits offered*

### Development of Oncology Products in the US and EU: More Stagnation than Innovation?

SESSION CHAIRPERSON

***Ionel Mitrica, PhD, MS***
Senior Scientist, Cato Research, Ltd.

It is increasingly apparent that the scientific advances of the last decade are not quickly converted into innovative pharmaceutical products. This trend applies to the field of oncology too, and happens despite continuous increases in the funding available for medical research in the field. This session will attempt a comparative review of regulatory experience, current tools/procedures, and future plans for facilitating the development of oncology products in the US and EU regulatory regions.

***Ramzi N. Dagher, MD***
Lead Medical Officer, CDER, FDA

***Michele D. Bronson, PhD, RAC***
Director, Regulatory Affairs Oncology, Chiron Corporation

***Francesco Pignatti***
Scientific Administrator, EMEA, EU

## Session 386 RA5 - Regulatory Affairs

1:30 PM - 3:00 PM LEVEL = ■

**Room 147B**

### Managing Communications with Regulatory Agencies in Global Decentralized Matrix Organizations

SESSION CHAIRPERSON

***Robert Butz, PhD***
Vice President, Global Regulatory Affairs, MDS Pharma Services

Many pharmaceutical companies, and most global CROs, operate as decentralized matrix organizations to accommodate variations in national laws, clinical practices, and cultures around the world. Within this type of organizational structure, there remains the need to establish practical operating standards for the management of communications with the various national regulatory agencies. Such communications may more frequently involve clinical operations physicians, study directors, statisticians, and QA auditors than regulatory affairs staff, and the degree of formality with which such communications occur may vary considerably. In addition to corporate SOPs, effectively managing these interactions requires an ongoing program of training, monitoring, documentation, and communication. This session will discuss best-practice approaches to successfully address this complex challenge.

**Managing Regulatory Communications within a Phase I Clinical and Bioanalytical CRO**
***Heimo W. Scheer, PhD***
Vice President, North American Regulatory Affairs, MDS Pharma Services

**Balancing Local and Global Regulatory Communications in Multinational Pharmaceutical Companies and CROs**
***M. Lynn Pritchard, PhD***
King Pharmaceuticals Research & Development, Inc.

**Interpreting FDA Communicated Expectations and Developing an Appropriate Corporate Response**
***James P. Burns, PhD***
Senior Vice President, Regulatory Consulting Worldwide, PharmaNet

## Session 387 RA6 - Regulatory Affairs

1:30 PM - 3:00 PM LEVEL = ■

**Room 152B**

### CDER Hot Topics – Part 2 of 2: FDA Drug Safety Initiative

SESSION CHAIRPERSON

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

*Part 1 of this session will be held on Tuesday at 1:30 PM.*

The FDA's drug safety initiative is a comprehensive program to address the safety of medical products. This session will provide an overview of the initiative, and will discuss various steps announced in the past few months to address the issues.

***Several representatives from CDER, FDA will participate as discussants in this session.***

## Session 388 RD - R&D Strategy

1:30 PM - 3:00 PM LEVEL = ◆

**Room 150B**

### Intercompany Auditing Agreement as Part of Strategic Risk Management

SESSION CHAIRPERSON

***Brian B. O'Neill, PhD***
Global Head, CQA External Alliances, F. Hoffmann-La Roche AG, Switzerland

There is scope for sponsor companies to maximize efficiencies and avoid or reduce duplication of effort related to risk management of R&D by cooperating strategically in the planning of vendor audits of mutual interest and sharing the reports of such audits. There are also advantages for vendors who may hope to reduce the number of similar audits to which they are subjected by pharmaceutical sponsor companies. The results of a pilot study set up as proof of concept are presented.

**Pharma Development Quality Management of Third-party Service Providers**
***Timothy J. Highman, MS***
Associate Director, Worldwide Development Quality Assurance, Pfizer Global Research and Development

**Intercompany Auditing Agreement as Part of Strategic Risk Management**
***Brian B. O'Neill, PhD***
Global Head, CQA External Alliances, F. Hoffmann-La Roche AG, Switzerland

**A Central Laboratories View on Sharing Audit Findings with Collaborating Sponsor Companies**
***Linda Yare, MSc***
Global Head of Sales, CentraLabS Clinical Research, Inc.

## Session 389 ST - Statistics, CR, RA

1:30 PM - 3:00 PM LEVEL = ●

**Room 201** *CME and Pharmacy credits offered*

### Statistical Considerations in the Evaluation of Red Blood Cell Products

SESSION CHAIRPERSON

***Tie-Hua Ng, PhD***
Lead Mathematical Statistician, CBER, FDA

This session discusses the FDA's requirements for autologous 24-hour post-transfusion in vivo survival studies in the evaluation of RBC products. Sample size calculation and statistical power consideration will be given.

**Evaluation of RBC Products**
***Ping He, MD***
Medical Officer, CBER, FDA

**FDA Requirements for *in vivo* Survival Studies**
***Tie-Hua Ng, PhD***
Lead Mathematical Statistician, CBER, FDA

**Statistical Considerations**
***Jessica Kim, PhD***
Mathematical Statistician, CBER, FDA

**Sample Size Calculation and Statistical Power Consideration**
***Paul Hshieh, PhD***
Mathematical Statistician, CBER, FDA

3:00 PM - 3:30 PM **REFRESHMENT BREAK**

**Exhibit Halls ABC, Lower Level**
**Convention Center**

## Session 390 AHC - Academic Health Centers, CR, MW

3:30 PM - 5:00 PM LEVEL = ●

**Room 103B** *CME credits offered*

### The Right to Publish: A Sword of Many Blades

SESSION CHAIRPERSON

***Patricia K. Hodgson***
Director of Communications, DCRI Communications

The right to publish is a contractual clause required by academic research organizations. It is a source of considerable controversy, and there are numerous viewpoints among the players in the issue. During this interactive session, those players will provide their perspectives on the right to publish.

**I'm in Academic Research: Why Does This Matter to Me?**
***David R. Holmes, Jr., MD***
Consultant, Internal Medicine and Cardiology, Mayo Clinic and Foundation

**I Sponsor Clinical Research: How Does This Affect Me?**
***Laurence J. Hirsch, MD***
Executive Director, Medical Communications, Merck Research Laboratories

**I'm a Journal Editor: How Does This Affect What I Publish?**
***Hal Sox, MD***
Editor-in-Chief, *Annals of Internal Medicine*

## Session 391 BT - Biotechnology, RD

3:30 PM - 5:00 PM LEVEL = ●

**Room 154AB** *CME and Pharmacy credits offered*

### Use of Toxicogenomics for Drug Candidate Selection, Rescuing and Biomarker Discovery

SESSION CHAIRPERSON

***Donna Mendrick, PhD***
Vice President, Toxicogenomics, Gene Logic, Inc.

The cost of developing successful drugs continues to rise, thus putting additional pressure for early selection of the most promising candidates and for understanding the mechanism of toxicity should it be discovered later in the pipeline. Toxicogenomics is proving to be an important addition to the pharmaceutical toolbox. In this session, the potential of toxicogenomics in compound toxicity prediction, mechanism of toxicity, and biomarker discovery will be explored.

**Use of Toxicogenomics to Predict Nephrotoxicity**
***Cindy Afshari, PhD, DABT***
Associate Director, Toxicology, Amgen Inc.

**Investigating Drug-related Toxic Mechanisms Using Genomics**
***Peter G. Lord, PhD***
Director, Mechanistic Toxicology, Johnson & Johnson Pharmaceutical Research and Development, LLC

**Use of Genomics to Identify and "In Silico" Validate Biomarkers of Toxicity**
***Donna Mendrick, PhD***
Vice President, Toxicogenomics, Gene Logic, Inc.

## Session 392 CDM - Clinical Data Management

3:30 PM - 5:00 PM LEVEL = ■

**Room 202B**

### Data Management Models for Multicenter and Multinational Clinical Trials: Case Histories

SESSION CHAIRPERSON

***Stefano Marini, MD***
General Manager, Dimensione Ricerca s.r.l., Italy

This session will present the different views and experiences on the use of electronic means in data collection for clinical trials, with representatives from the Ministry of Health, industry, and a CRO.

**From EDC to Clinical Trials: Twenty Years of Experience Using Internet in the Management of Clinical Trials and Epidemiological Registries**
***Marisa De Rosa, PhD***
Head, Systems and Services for Health Department (SISS), CINECA - Consorzio Interuniversitario; Member, Clinical Trials Committee of AIFA, Italian National Medicines Agency, Ministry of Health, Italy

**Some Experiences in Implementing Electronic Data Capture for Clinical Development**
***Tommy Pedersen, MSc***
Director, Clinical Data Operations, Lundbeck SA, France

## Session 393 CMC - Chemistry, Manufacturing, and Controls, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 147A**

### Follow-on Biotechnology/Biological Products

SESSION CHAIRPERSON

***Keith Webber, PhD***
Acting Director, Office of Biotechnology Products, CDER, FDA

As protein manufacturing technologies and analytical methodologies have advanced, the potential for one manufacturer to produce its own version of another manufacturer's protein product is on the horizon. However, given the wide variety of types of biotechnology products currently on the market, it may be expected that some products will be more challenging than others. This session will explore the scientific factors that may need to be considered when assessing the similarity of these types of products.

**FDA Perspective**
***Steven Kozlowski, MD***
Medical Officer, Office of Biotechnology Products, Office of Pharmaceutical Science, CDER, FDA

**Industry Perspective**
***Dr. Martina Weise***
Head, Section on Endocrinology and Diabetes, BfArM, Germany

**Panel Discussion/Q&A Period**

## Session 394 CP - Clinical Safety and Pharmacovigilance, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 207A** *CME credits offered*

### Unblinding: Need to Know Basis?

SESSION CHAIRPERSON

***L. Paul Starkey, MD, FAAFP***
Senior Medical Director, Global Medical and Safety Services Americas, PRA International

Unblinding during a clinical trial can be used in emergent medical situations to protect a patient, but more often unblinding occurs because of a regulatory requirement. Jurisdictional regulations with regard to unblinding are often very different, and sometimes very vague. This session will explore these differences and requirements.

**Unblinding: What's the Problem?**
***Andrzej Czarnecki, MD, PhD, MSc***
Medical Fellow, Associate Medical Director, Global Product Safety, Oncology, Eli Lilly and Company, Ltd., UK

**What Are Decision Trees for?**
***David I. Goldsmith, MD, FISPE***
President, Senior Consultant, Goldsmith Pharmacovigilance and Systems

## Session 395 CR1 - Clinical Research and Development

3:30 PM - 5:00 PM LEVEL = ●

**Room 145B** *CME and Pharmacy credits offered*

### Conducting Clinical Trials in Erectile Dysfunction (ED)

SESSION CHAIRPERSON

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

Erectile dysfunction (ED) is a therapeutic area of immense scientific and pharmacologic interest. The treatment of ED may be approached from both the peripheral vasculature and the central nervous system, using a variety of pharmacologic agents or medical devices. However, the clinical development of drugs for the treatment of ED follows a very specific path. This seminar is designed to discuss the etiology of ED, issues in study design, clinical development plans, and clinical site management.

**The Etiology of Erectile Dysfunction**
***Ronald Harning, PhD***
Executive Director, Clinical Affairs, Palatin Technologies, Inc.

**Protocol Development for Erectile Dysfunction**
***Lisa E. Diamond, PhD***
Associate Director, Clinical Development, Palatin Technologies, Inc.

**Clinical Site Issues in Erectile Dysfunction Trials**
***Michael S. Willett, PharmD***
President and Chief Executive Officer, Advanced Biomedical Research, Inc.

## Session 396 CR2 - Clinical Research and Development, RA

3:30 PM - 5:00 PM LEVEL = ■

**Room 144ABC** *CME and Pharmacy credits offered*

### Application of Critical Path Principles to the Development of Drugs for Menopausal Symptom Therapy After the Women's Health Initiative

SESSION CHAIRPERSON

***Daniel Shames, MD***
Director, Division of Reproductive and Urologic Drug Products, CDER, FDA

Publication of results from the Women's Health Initiative over the last several years has caused confusion and anxiety for all stakeholders in the area of menopausal symptom therapy (MST). The Division of Reproductive and Urologic Drug Products is applying 'critical path" principles to the clinical evaluation of drugs for MST. The results of these initiatives will be guidance to sponsors regarding more efficient development of therapies with optimal modes and regimens of administration.

**Vasomotor Symptom Modeling**
***Stephan Ortiz, RPh, PhD***
Clinical Pharmacologist, CDER, FDA

**Alternative Methods for Assessing Endometrial Protection**
***Gerald D. Willett, MD***
Medical Officer, Division of Reproductive and Urologic Drug Products, CDER, FDA

**Construction of Critical Paths for Development of Drugs for Menopausal Symptom Therapy**
***Daniel Shames, MD***
Director, Division of Reproductive and Urologic Drug Products, CDER, FDA

## Session 397 CR3 - Clinical Research and Development, RD

3:30 PM - 5:00 PM LEVEL = ●

**Room 140B** *Pharmacy credits offered*

### Incorporating Formal Economic Analysis in Evaluating Trial, Development, and Portfolio Strategies

SESSION CHAIRPERSON

***Christy Chuang-Stein, PhD***
Senior Director, Pfizer Inc

Economic analysis with an emphasis on the net present value (NPV) has been increasingly used in portfolio evaluations. In this session, we will demonstrate that in addition to portfolio evaluations, such analysis is equally relevant when assessing different development strategies. We will also show that such considerations have a role in adaptive designs when a sponsor is facing the trade-off between the desire for a high statistical power and the need to maximize the expected NPV.

**Incorporating Formal Economic Analysis into Clinical Ttrial Design**
***Cyrus R. Mehta, PhD***
Cytel Software Corporation

**Option Values of Two-stage Adaptive Designs: A Financial Benefit-risk Evaluation**
***Qing Liu, PhD***
Statistical Science, Johnson & Johnson Pharmaceutical Research and Development, LLC

**The Use of Economic Valuations in R&D Portfolio Management**
***Jay Andersen, PhD***
Decision Sciences, Eli Lilly and Company

## Session 398 CR4 - Clinical Research and Development

3:30 PM - 5:00 PM LEVEL = ■

**Room 146A** *CME and Pharmacy credits offered*

### New Expectations for Drug Development: Lessons Learned from the COX-2 Inhibitors

SESSION CHAIRPERSONS

***Arnold J. Gordon, PhD***
Pharmaceutical Consultant

This session will feature regulators and industry professionals discussing new expectations for drug development in the aftermath of COX-2 inhibitor safety concerns.

***John K. Jenkins, MD***
Director, Office of New Drugs, CDER, FDA

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

## Session 399A CR5 - Clinical Research and Development

3:30 PM - 5:00 PM LEVEL = ■

**Room 143C**

### Skating to Where the Puck Is Going: Understanding Tomorrow's Challenges in Oncology Drug Development and Creating Infrastructure to Pave the Way

SESSION CHAIRPERSON

***Kim McDonald-Taylor, MSc***
Vice President, Operations, Endpoint Research, Canada

Over the past decade, oncology drug development has become increasingly competitive and global in scope. Companies developing oncology drugs now face tremendous competition for study subjects as well as market opportunity. This session will address the international landscape for oncology drug development and examine specific initiatives designed to address challenges.

**Current Opportunities and Challenges in Oncology Drug Development**
***Kim McDonald-Taylor, MSc***
Vice President, Operations, Endpoint Research, Canada

**The Globalization of the Oncology Drug Development: The Case of Central and Eastern Europe**
***Miroslav Reljanovic, MD***
Chief Executive Officer and President, Ergomed Group, Frankfurt Biotechnology Innovation Center, Germany

**Infrastructure Programs to Support Oncology Clinical Trials**
***Robert A. Phillips, PhD***
President and Chief Executive Officer, Ontario Cancer Research Network, Canada

**Accessing National Oncology Networks**
***William T. McGivney, PhD***
Chief Executive Officer, National Comprehensive Cancer Network

## Session 399B CTM - Clinical Trial Management, BT, RD

3:30 PM - 5:00 PM LEVEL = ■

**Room 101** *Nursing credits offered*

### Sometimes It Takes Two or More to Tango: Managing Trials in a Global Collaboration

SESSION CHAIRPERSON

***Angela Carroll, MLS***
Manager, Clinical Affairs, Genentech, Inc.

More pharmaceutical and biotechnology companies are forming partnerships in the development of new drug products. The focus of this session is to review best practices in managing and conducting clinical trials within global sponsor collaborations. While there are many efficiencies afforded through collaborations, there are also differences which should be anticipated and addressed prior to beginning a clinical trial.

**Multisponsor Collaborations in Global Drug Development**
***Steve D. Thorne, PhD***
Operations Project Leader, Roche Products Limited, UK

**Preparing for a Global Collaboration**
***Victor K. Chan***
Senior Clinical Trials Manager, Biogen IDEC

**Lessons Learned from a Global Collaboration**
***Angela Carroll, MLS***
Manager, Clinical Affairs, Genentech, Inc.

## Session 399C DM - Document Management/ eSubmissions, RA

3:30 PM - 5:00 PM LEVEL = ●

**Room 206** *Pharmacy credits offered*

### Guidance-compliant eCTDs – Part 2 of 2

SESSION CHAIRPERSON

***Gary Gensinger***
Director, Review Technology Staff, Office of Information Management, CDER, FDA

*Part 1 of this session will be held on Wednesday at 1:30 PM.*

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

***Gary Gensinger***
Director, Review Technology Staff, Office of Information Management, CDER, FDA

***Bronwyn E. Collier, RN***
Associate Director of Regulatory Affairs, CDER, FDA

***Armando Oliva, MD***
Associate Director for Policy, Office of New Drugs, CDER, FDA

***Norman R. Schmuff, PhD***
Deputy Director, Division of New Chemistry III, CDER, FDA

***Kenneth Edmunds***
IT Specialist, CDER, FDA

***Stephen E. Wilson, DrPH, Capt. USPHS***
Deputy Director, Division of Biometrics II, CDER, FDA

## Session 399D GCP - Good Clinical Practices, RA

3:30 PM - 5:00 PM LEVEL = ●

**Room 202A** *CME, Nursing, and Pharmacy credits offered*

### Preparing for and Surviving an FDA Inspection: US and International Perspectives from Industry and Regulators

SESSION CHAIRPERSON

***Donald W. Ashbrook, PhD, RAC***
Chief Executive Officer, GPA International

This session will address strategies for preparation to survive FDA/regulator inspections in the US or abroad. Industry and FDA/regulator perspectives will be presented. International and US inspection findings trends will be discussed. An interactive discussion will take place on what the FDA expects to see from an audit perspective.

**Preparing for an FDA Inspection of International Studies: An Industry Perspective**
***Donald W. Ashbrook, PhD, RAC***
Chief Executive Officer, GPA International

**Preparing for an FDA Inspection: What Everyone Wants to Know**
***Sherri A. Hubby***
Associate Director, Clinical Quality Assurance, North America, PPD Development

**US and International FDA Inspections: Current Focus, Findings and Concerns**
***Joseph P. Salewski***
Chief, Bioresearch Monitoring Branch, CBER, FDA

## Session 399E IT - Information Technology

3:30 PM - 5:00 PM LEVEL = ●

**Room 146B**

### IT Services: Delivering High Value in the New Pharmaceutical Environment

SESSION CHAIRPERSON

***Samuel Goldman***
Co-founder and Chief Technology Officer, Intrasphere Technologies, Inc.

IT services are critical to pharmaceutical companies' ability to deliver new medicines to patients. Yet, the "taken for granted" nature of infrastructure and critical applications often makes them "visible" only when there is a problem. The resulting perception among users and executives is that IT does not provide high value. This session will describe approaches used by pharmaceutical companies to counter these perceptions by delivering high-value services and aligning IT with corporate goals.

**Imitate, then Innovate: A Holistic Look at Automation**
***Thomas P. Haskell***
Vice President, Pharmaceutical Solutions, Idea Integration

**Experts without Borders: How Technology Can Overcome Geography in Global Drug Development Teams**
***Mark H. Bradshaw, PhD***
Managing Director, GCP MB, Inc.

***Samuel Goldman***
Co-founder and Chief Technology Officer, Intrasphere Technologies, Inc.

## Session 399F MC - Medical Communications

3:30 PM - 5:00 PM LEVEL = ●

**Room 209AB** *CME and Pharmacy credits offered*

### Discovering and Meeting Customer Expectations of Medical Communications

SESSION CHAIRPERSON

***Nina Barchha, PharmD***
Senior Medical Information Associate, Eli Lilly and Company

This session will present both qualitative and quantitative market research that medical communications groups have conducted to obtain feedback from customers on satisfaction and expectations of their services and/or medical responses. Feedback and customer preferences will be shared from different perspectives and improvements that have been made and standards that have been set based on customer feedback will be described.

**Assessing Customer Needs Via an Internet-based Survey**
***Stacey M. Fung, PharmD***
Senior Medical Communications Scientist, Genentech, Inc.

**What Do Customers Really Want from Industry-based Drug Information Services?**
***Robert P. Baker, PharmD***
Director, Professional Product Information, Roche Laboratories, Inc.

**Improvement of Medical Letter Quality Based on Results of Market Research**
***Helen M. Hochstetler, PharmD***
Senior Medical Information Associate, Eli Lilly and Company

## Session 399G NHP - Natural Health Products

3:30 PM - 5:00 PM LEVEL = ■

**Room 140A**

### Exploring Natural Health Products: Promotion and International Coordination

SESSION CHAIRPERSON

***Pulok K. Mukherjee, PhD, MPharm, RPh, FIC***
Director, School of Natural Product Studies, Jadavpur University, India

For the promotion and development of botanicals, quality, validated processes of manufacturing, customer awareness, and postmarketing surveillance are major criteria to rationalize their use. Regulations and promotional aspects for NHP vary from country to country and this makes it difficult to maintain uniform standards for NHP. This session will highlight various aspects of promotion and development of NHP for their regulation and control with international coordination.

**Present Status of Natural Products Research and Development in Latin America: Experience of CYTED Program**
***Mahabir P. Gupta, PhD***
International Coordinator, Iberoamerican Program for Science and Technology for Development CYTED, University of Panama, Panama

**The LatinPharma Project**
***Diana Flores***
Visiting Professor, Scientific University of South Lima; WTO Consultant, LatinPharma Project, International Trade Centre UNCTAD, Peru

**Exploring Indian Systems of Medicine (ISM) Drugs for Their Assessment and Evaluation**
***Pulok K. Mukherjee, PhD, MPharm, RPh, FIC***
Director, School of Natural Product Studies, Jadavpur University, India

## Session 399H OS - Outsourcing, CR

3:30 PM - 5:00 PM LEVEL = ●

**Room 150A**

### Calculation Comparison of Pharma Internal Costs and Outsourced CRO Costs

SESSION CHAIRPERSON

***Maria Fernández Freire, MD***
Director, Thywill LatAm Solutions, Argentina

It is very common to hear from sponsors that CROs double or triple the costs compared to doing the tasks internally. Usually the calculation is "We just pay our employees their salaries." An adequate comparison could make cooperation between sponsors and external providers more profitable.

**Cost Benefit Assessment for Outsourcing Clinical Trial Services**
***John A. Gilly, PhD***
President, North American Division, Premier Research Group PLC

**CRO Monitoring Costs Versus Internal Costs**
***Peter A. Lyn***
Project Liaison Manager, Novartis Oncology

**Comparing CRO and Cost Estimates: The Truth Behind the Clinical Development Program Budget**
***Barbara J. Geiger, RN***
President and Clinical Director, Clinical Research Management Services, Inc.

## Session 399I PM1 - Project Management

3:30 PM - 5:00 PM LEVEL = ■

**Room 149AB** *Project Management Institute credits offered*

### Ten Things You Never Thought I Would Say (About Leading Teams)

SESSION CHAIRPERSON

***Jeffrey Antos***
President, Beacon Hill Technologies, Inc.

This provocative session provides unconventional wisdom for leading project teams to success. Project leadership tools are described, demonstrated, and experienced in this hands-on workshop. After an overview presentation, participants will form small groups to learn and use team leadership methods.

***Jeffrey Antos***
President, Beacon Hill Technologies, Inc.

## Session 399J PP - Public Policy/Law, RA, RD

3:30 PM - 5:00 PM LEVEL = ●

**Room 103A**

### A Community Response to the Critical Path

SESSION CHAIRPERSON

***Raymond L. Woosley, MD, PhD***
President, The C-Path Institute

The FDA's Critical Path Initiative calls for partnerships between the FDA, academia and commercial sector. C-Path is a nonprofit organization created to host this type of partnership. The research and educational programs of C-Path designed to speed the development of safe medications will be presented.

**The C-Path Institute: A Partnership to Advance the Development of Medicines**
***Raymond L. Woosley, MD, PhD***
President, The C-Path Institute

**Innovations in Drug Development from Disciplines Other than Biosciences**
***Walter Moos***
Vice President, Biosciences, SRI International

**FDA Partnerships in the Critical Path Initiative**
***Janet Woodcock, MD***
Acting Deputy Commissioner of Operations, FDA

## Session 399K RA1 - Regulatory Affairs

3:30 PM - 5:00 PM LEVEL = ●

**Room 146C**

### Use of Color Coding/Branding on Pharmaceutical Product Labels, Labeling, and Packaging

SESSION CHAIRPERSON

***Carol Holquist, RPh***
Director, Division of Medication Errors and Technical Support, CDER, FDA

Color coding is the systematic application of color or colors to a label, package, or container to help classify and identify drug products. However, there is very limited research to demonstrate that color coding is an effective tool in reducing medication errors. In fact, it has been suggested that the use of color coding may actually contribute to medication errors, including ophthalmic, dental, and insulin products.

***Wiley A. Chambers, MD***
Deputy Director, Division of Anti-inflammatory, Analgesic and Opthalmologic Drug Products, CDER, FDA

***Carol Holquist, RPh***
Director, Division of Medication Errors and Technical Support, CDER, FDA

***Mary C. Gross***
Policy Analyst, Office of Drug Safety, CDER, FDA

## Session 399L RA2 - Regulatory Affairs, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 152A**

### Outlook for Changes in Japanese Regulatory and Clinical Development Environment – Part 2 of 2

SESSION CHAIRPERSONS

***Hiroshi Matsumori, MS***
Global Regulatory Leader, PGRD La Jolla, Pfizer Japan Inc., Japan

***Robert R. Fike, PhD***
Assistant Vice President, Regulatory Affairs Japan, Wyeth Pharmaceuticals

*Part 1 of this session will be held on Wednesday at 1:30 PM.*

This session will provide an update on the regulatory environment in Japan, including the regulatory review process and performance, implementation of ICH guidelines and CTD, and their impacts on clinical development. The session will also address the future perspectives for clinical development and regulatory strategy with global development programs in Japan.

**The Next Stage of Global Development (Postbridging Strategy in Japan)**
***Kazuhiko Mori, MS***
Director, Office of New Drugs Evaluation I, Pharmaceuticals and Medical Devices Agency, Japan

**Experience of Global Study by the Company in Japan: Experience 1**
***Kaoru Ishiyama***
Clinical Planning, Clinical Support, Clinical Development, Scientific Affairs, Sanofi-Aventis Group, Aventis Pharma Ltd., Japan

**Experience of Global Study by the Company in Japan: Experience 2**
***Yoshihiko Ono***
Senior Manager, Regulatory Policy and Intelligence, PGRD Tokyo Laboratories, Pfizer Japan Inc., Japan

## Session 399M RA3 - Regulatory Affairs, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 151A** *CME and Nursing credits offered*

### Clinical Trials Directive: EU Remains Attractive for Clinical Research

SESSION CHAIRPERSON

***Barbara Schnurr, PhD***
Chief Quality Assurance Manager, Harrison Clinical Research GmbH, Germany

This session will discuss the background, key content, and legal implications of the EU Clinical Trials Directive as well as its implementation status in some key EU Member States. The impact of the changes and the resulting opportunities will be reviewed.

**Basic Principles of the Clinical Trials Directive**
***Barbara Schnurr, PhD***
Chief Quality Assurance Manager, Harrison Clinical Research GmbH, Germany

**Implementation of the CT Directive into National Legislation Overview of the Situation of the Most Important EU Member States**
***Benedikt Van Nieuwenhove, PhD***
General Manager, European Centre for Clinical Research Training, Belgium

**Advantages and Disadvantages of Performing Clinical Studies in the EU from the US Perspective**
***Jules T. Mitchel, PhD, MBA***
President, Target Health Inc.

## Session 399N RA4 - Regulatory Affairs

3:30 PM - 5:00 PM LEVEL = ●

**Room 151B**

### Various Roles and Implementation Techniques of Quality Systems in a Regulatory Agency

SESSION CHAIRPERSON

***Lana L. Pauls, MPH***
Director, Quality Assurance Staff, CDER, FDA

The intent of this session is to help individuals understand how using a QS approach as an approach for accomplishing their daily activities can actually facilitate their work, make it more effective, and thus more efficient. Several types of QS approaches will be discussed, as well as implementation processes in different industries.

***Lana L. Pauls, MPH***
Director, Quality Assurance Staff, CDER, FDA

***Patricia Maroney-Benassi, PhD***
Consumer Safety Officer, DHHS, Office of Regulatory Affairs, FDA

***Diann Sims***
Environmental Scientist, US Environmental Protection Agency

## Session 399O RA5 - Regulatory Affairs

3:30 PM - 5:00 PM LEVEL = ●

**Room 147B**

### Research in Developing Drug Interactions and Dose Adjustments Model and Terminology Assessment for Drug Labeling

SESSION CHAIRPERSON

***Katherine A. Hollinger, DVM, MPH, DACVPM***
Senior Supervisory Health Promotions Officer, Office of Women's Health, Office of the Commissioner, FDA

Representation of the content of a package insert (also known as the Comprehensive Prescribing Information or the drug label) in computer applications representing machine readable/processable label information has been difficult because of the complexity of the information found in many labels. As part of an effort to make clinically relevant label content more accessible to computer applications, the FDA is researching the development of a computable representation of label content that will enhance digital clinical applications, specifically for drug interactions and dose adjustments, particularly for better management of subpopulation differences in product safety and effectiveness.

**Terminology Analysis for the Drug Labeling Conceptual Model**
***John S. Carter, MBA***
Director, Consulting Services, Apelon, Inc.

***Katherine A. Hollinger, DVM, MPH, DACVPM***
Senior Supervisory Health Promotions Officer, Office of Women's Health, Office of the Commissioner, FDA

**SPL and Drug Labeling**
***Sandra L. Boyer***
Independent Consultant, Australia

## Session 399P RA6 - Regulatory Affairs

3:30 PM - 5:00 PM LEVEL = ■

**Room 152B**

### Scientific Advice in Europe: State of the Art

SESSION CHAIRPERSON

***Gopalan Narayanan, MD, FRCP, MFPM***
Medical Assessor, Biologicals and Biotechnology Unit, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Advice on drug development is increasingly being sought by companies engaged in manufacturing through to development and marketing of pharmaceutical/biotechnology medicinal products. This session will discuss some of the current procedure(s), the experience gained, how to use the procedure(s) to get maximum value and the future direction in the European Union.

**Experience of a Member State: United Kingdom**
***Ian Hudson, MD, MRCP***
Director, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**Past, Present, and Future: EMEA's Position**
***Agnès Saint-Raymond, MD, PhD***
Head of Sector, Orphan Drugs and Scientific Advice; Preauthorization Evaluation of Medicines for Human Use, EMEA, EU

**View from the Industry**
***Paul Huckle, PhD***
Senior Vice President, European and International Regulatory Affairs, GlaxoSmithKline R&D, UK

## Session 399Q RD - R&D Strategy, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 150B** *CME and Pharmacy credits offered*

### Developing Medications in Ethnically Diverse Populations

SESSION CHAIRPERSON
***Eric W. Lewis, MD***
Director, Clinical Pharmacology, GlaxoSmithKline

This session will focus on the various scientific and logistic aspects of the development of a product for a global regulatory marketplace. Type 2 diabetes has been selected as a model disease, largely because of the well-established primary endpoints and the medical importance of this disease.

**Clinical Pharmacology and Drug Development in Populations of Diverse Ethnicity**
***Annette S. Gross, PhD***
Director, Ethnopharmacology, Clinical Pharmacology and Discovery Medicine, GlaxoSmithKline, Australia

***Edmund Lee, MD***
Professor, Pharmacology Department, National University of Singapore

## Session 399R ST - Statistics

3:30 PM - 5:00 PM LEVEL = ●

**Room 201** *CME and Pharmacy credits offered*

### Clinical Data to Information to Knowledge

SESSION CHAIRPERSONS
***Douglas M. Okamoto, PhD***
Senior Director, Biostatistics, Clinimetrics Research Associates, Inc.
***Yin Yin, PhD***
Director, Statistics Data Sciences, MV CEDD Leader, GlaxoSmithKline

The purpose of this session is to evaluate the clinical development process from a statistical perspective. In the past ten years, electronic data capture at the front end and electronic filing at the back end have transformed the way we collect our clinical data and submit our new drug and biologic license applications to the regulatory authorities. Biopharmaceutical industry standards are emerging for clinical data management and electronic submissions, but what about the rest of the data-to-information-to-knowledge paradigm? Biostatisticians have a leadership role to play from clinical trial design to interpretation of safety and effectiveness data for decision-making before and after product approval.

**Quantitative Issues and Statisticians' Role in the Clinical Development Plan**
***Yin Yin, PhD***
Director, Statistics Data Sciences, MV CEDD Leader, GlaxoSmithKline

**On the Generation and Ownership of Alpha in Medical Studies**
***Vance W. Berger, PhD***
Mathematical Statistician, National Cancer Institute, National Institutes of Health

**Food for Thought: Statistical Thinking, Strategic Thinking, Systems Thinking**
***Douglas M. Okamoto, PhD***
Senior Director, Biostatistics, Clinimetrics Research Associates, Inc.

*Discussant*
***Ralph Harkins, PhD***
Vice President, Biometrics, Otsuka Maryland Research Institute

## Session 399S TR - Training, CR

3:30 PM - 5:00 PM LEVEL = ■

**Room 207B**

### Training Approaches for MedDRA®

SESSION CHAIRPERSON
***Patricia Mozzicato, MD***
Medical Officer USA, Northrop Grumman/MedDRA MSSO

One of the most significant aspects of MedDRA implementation is training of personnel involved in a variety of organizational functions. Organizations that have been the most successful in MedDRA implementation have incorporated training of personnel as a cornerstone of their overall implementation strategy. This session will focus on lessons learned from organizations that have faced the challenge of MedDRA training.

**MedDRA Training: A Mentor-protégé Approach and Skill Maintenance Program**
***Sonja Brajovic, MD***
Medical Coding Manager, PSI International, Inc.

**Enlightenment Yields Acceptance**
***JoAnn Medbery***
Manager, Dictionary Management, Johnson & Johnson

5:00 PM **END OF WEDNESDAY SESSIONS**

7:30 AM - 10:30 AM **ATTENDEE REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 10:30 AM **SPEAKER REGISTRATION**
East Registration Area, Convention Center
Mount Vernon Place Entrance

7:30 AM - 8:15 AM **CONTINENTAL BREAKFAST**
Meeting Rooms 145-147, Concourse
Convention Center

12:30 PM - 4:30 PM **MEDDRA® USER GROUP MEETING**
Meeting Room 140A, Concourse
Convention Center

## SESSION 401 AHC - ACADEMIC HEALTH CENTERS, CR

8:30 AM - 10:00 AM LEVEL = ●

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

### Remote Management of Rural Diabetic Patients Using a Web-based Monitoring Device

SESSION CHAIRPERSON

***Bonne Farberow***
Project Manager, Division of Cardiology, University of Pennsylvania

Diabetes is a complex, chronic, and challenging disease. The risk of death among people with diabetes is about two times, and healthcare costs are three times, that of people without diabetes. Sequelae of poorly-managed diabetes mellitus (DM) include cardiovascular disease, renal failure, blindness, and amputation, with increased hospitalization and decreased quality of life. The intensity of provider knowledge, system resources, patient adherence, and patient self-care required to manage diabetes is a challenge for healthcare practitioners and patients alike. This challenge is amplified in rural and frontier areas, where access to care may be severely limited. Strategies will be presented to overcome these barriers in frontier and rural areas by integrating several Internet-based technologies with skilled nursing care to facilitate patients' adherence to diabetes self-care regimens and to provide remote monitoring, care management, and comprehensive oversight.

**Focused Disease Management in the Medically Frail Diabetic**
***David Chess, MD***
President and Chief Executive Officer, Enhanced Care Initiatives

**Use of a Medication Adherence and Electronic Patient Diary Device to Monitor Diabetic Patients and Improve Patient Drug Safety**
***Bruce A. Kehr, MD***
Chairman and Chief Executive Officer, InforMedix, Inc.

**Digitally Monitored Objective and Subjective Data and Automated Feedback for Remote and Self-management of Patients with Diabetes**
***John K. Holland***
President and Chief Executive Officer, LifeLink Monitoring

## SESSION 402 BT - BIOTECHNOLOGY

8:30 AM - 10:00 AM LEVEL = ◆

**Room 154AB** *CME and Pharmacy credits offered*

### Viral Safety: Impact of Advances in Technology

SESSION CHAIRPERSON

***Cecil Nick, MSc***
FTOPRA Director, PAREXEL Consulting, UK

Emerging viral threats have always been a concern. The introduction of advanced therapies such as gene and cell therapy and of new manufacturing methods employing human cells and transgenic animals spotlights viral safety as an area for ever-increasing focus. This session will examine the threats from viruses and how these can be countered by progress in the methodology for testing starting materials and for in-process viral clearance.

**An Introduction to Advanced Viral Clearance Technologies and Meeting the Demands for Production of Advanced Therapeutic Products**
***Cecil Nick, MSc***
FTOPRA Director, PAREXEL Consulting, UK

**Risks Associated with Advanced Therapy and Need for New Viral Clearance Technology**
***Philip Minor, PhD***
Head, Department of Virology, National Institute for Biological Standards and Control, UK

**The Importance of New Viral Clearance Technologies in Meeting Regulatory Demands: Now and in the Future**
***Jeri-Ann Boose, PhD***
Senior Director, Analytical and Viral Clearance Services, BioReliance Corporation

## SESSION 403 CDM - CLINICAL DATA MANAGEMENT, RA

8:30 AM - 10:00 AM LEVEL = ●

**Room 103A**

### Clinical Data Management: An Integral Part of the Drug Development Process

SESSION CHAIRPERSON

***Linda S. King, MT***
Team Leader, Global Clinical Data Management, Eli Lilly and Company

Electronic data capture and patient-reported outcomes, multiple data platforms, ancillary data, data standards application, comprehensive data review and submission strategies ... the world of data management is becoming more complex, and the role of the data manager is ever-expanding and key in the drug development process. Throughout the process, the partnership with statistics, the clinical team and regulatory ensures a well-defined data strategy leading to a high-quality submission.

**Key Role of Data Managers in an Optimized Study Development Process**
***Linda S. King, MT***
Team Leader, Global Clinical Data Management, Eli Lilly and Company

**The Data Manager's Role in an Organization with Distributed Study and Project Teams**
***Claudia M. Lehmann***
Head, Clinical Data Management, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

**The Regulatory Submission Process and the Key Role Data Managers Can Play**
***Donna R. Park, MA***
Associate Director, Clinical Data Management and Regulatory Operations, Procter & Gamble Pharmaceuticals

## Session 405 CP - Clinical Safety and Pharmacovigilance

8:30 AM - 10:00 AM LEVEL = ■

**Room 145B**

### The Use of Multilanguage MedDRA® in a Global Environment

SESSION CHAIRPERSON

***Carla Hagelberg, PhD, MSc***
Director, Innometrica Ltd., UK

Global pharmaceutical companies need to ensure that the translation of clinical, safety, and product information data from international studies is done to the highest standard and consistency, so that the underlying meaning of the data is not compromised. With the availability of sophisticated technologies and the introduction of multilanguage versions of MedDRA®, the whole process of translation can be significantly improved.

**A Multilingual Data Management and Coding Environment: Technical and Functional Requirements**
***Robbert P. Van Manen, MSc***
Worldwide Technical Director, Phase Forward

**MedDRA® Hierarchy and Translation: Impact on the Reporting of Safety Data**
***Nancy H. Woo, PhD***
Principal, Woo Consulting

**Use of MedDRA® in a Multilanguage Environment to Analyze and Report Safety Data**
***E. Stewart Geary, MD***
Director, Medical Regulatory Affairs and Pharmacovigilance, Eisai Co., Ltd., Japan

## Session 406 CR1 - Clinical Research and Development

8:30 AM - 10:00 AM LEVEL = ■

**Room 140B**

### What Sponsors and CROs Need to Know About Accreditation

SESSION CHAIRPERSON

***Marjorie A. Speers, PhD***
Executive Director, Association for the Accreditation of Human Research Protection Programs

As the number of accredited organizations within the clinical research enterprise increases, both sponsors and CROs need to be more fully aware of the impact of accreditation on those research entities with which they work, as well as on their own organization. Sponsors and CROs should have an understanding of the whats, whys, and hows of accreditation.

**Efficient and Effective Human Research Protections and Risk Management Oversight**
***Matthew D. Whalen, PhD***
Co-founder and Chief Development Officer, Chesapeake Research Review, Inc.

**Perspectives from CROs**
***Courtney Gray Haupt***
Senior Associate, Government Relations and Special Projects, Association of Clinical Research Organizations (ACRO)

**Perspectives from Sponsors**
***Michael J. Werner, JD***
Chief of Policy, Biotechnology Industry Organization

## Session 407 CR2 - Clinical Research and Development, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 145A**

### Integrated Clinical Development

SESSION CHAIRPERSON

***Ira Spector, MBA***
Vice President, Clinical Trial Operations; Vice Chief of Operations, Wyeth Research

This session will publicly unveil the newly integrated clinical development organization at Wyeth Research, which combines clinical R&D, global medical affairs, vaccines and experimental development operations into one cohesive group. Very few, if any, large pharmaceutical companies have adopted this approach. Wyeth will explain the rationale for this major change and the vision for this new approach to conducting clinical research.

***Ira Spector, MBA***
Vice President, Clinical Trial Operations; Vice Chief of Operations, Wyeth Research

***Peter Carberry, MD***
Vice President, Clinical Operations, Genentech, Inc.

***R. Adrian Otte, MB, FFPM***
Senior Vice President, Worldwide Business Operations, Pfizer Inc

## Session 408 CTM - Clinical Trial Management

8:30 AM - 10:00 AM LEVEL = ■

**Room 101** *Nursing credits offered*

### Burnout, Workload, and Job Satisfaction in Clinical Trial Coordinators

SESSION CHAIRPERSON

***Clement Gwede, PhD, MPH, RN***
Assistant Professor, Moffitt Cancer Center, University of South Florida

A large number of clinical trial coordinators (CTCs) work in emotionally and psychologically challenging settings at investigative sites. Yet there is a dearth of literature on the prevalence of burnout, work overload, and job-related distress among CTCs. This presentation explores issues and patterns of burnout, workload, and professional satisfaction among CTCs.

**Burnout and Job Satisfaction in Clinical Trial Coordinators**
***Clement Gwede, PhD, MPH, RN***
Assistant Professor, Moffitt Cancer Center, University of South Florida

**Workload Issues for Clinical Trial Coordinators**
***Kathie Roche, RN, CCRP***
Manager, Clinical Trials and Epidemiology, Toronto Sunnybrook Regional Cancer Center, Canada

## Session 409 DM - Document Management/ eSubmissions, RA

8:30 AM - 10:00 AM LEVEL = ●

**Room 152A**

### Compliance Portals: The Gateway to eSubmissions

SESSION CHAIRPERSON

***Kevin O'Leary***

President, QUMAS, Ireland

This session will focus on creating e-submissions in a web-based electronic content management system. The discussion will focus on Part 11 as it relates to the eCTD. Along with speakers from Microsoft and a representative from industry, we will cover content creation from remote locations, review and approval of the content, and assembly into a final CTD or eCTD.

**Compliance Portals: The Gateway to eSubmissions**
***Warren Perry***
Product Manager, QUMAS

**Information-driven Applications: Using Web Services to Improve Submissions and Compliance**
***Jason A. Burke, MA***
Life Sciences Industry Strategist, Microsoft Corporation

## Session 410 IT - Information Technology, CR

8:30 AM - 10:00 AM LEVEL = ●

**Room 146B**

### FIREBIRD: Implementing an Electronic Global Investigator Registry

SESSION CHAIRPERSON

***William A. Rosen, MS***

Executive Director, Worldwide Regulatory Affairs, SRMS, Pfizer Inc

The National Cancer Institute has advanced a pilot project known as FIREBIRD. FIREBIRD will be a collaborative effort among industry, government, and academia to establish a more cost-efficient flow of high-quality clinical research data to regulatory authorities. It will instantiate a trusted hosting service that will provide a sustainable, secure infrastructure for electronic submissions. The pilot will focus on the development of an electronic global investigator registry.

**Towards a Shared Clinical Infrastructure**
***Sue Dubman, MA***
NCICB Director, Applications, National Cancer Institute, Center for Bioinformatics, National Institutes of Health

**FIREBIRD: Moving Concepts to Reality**
***Kamal Narang, MS***
Project Manager, Mission Phoenix/FIREBIRD, CTIS, Inc.

**SAFE (Secure Access for Everyone): An Update on Progress**
***Gary W. Secrest, MS***
Director, Worldwide Information Security, Johnson & Johnson

## Session 411 IT/CDM - Information Technology/ Clinical Data Management, eClin

8:30 AM - 10:00 AM LEVEL = ■

**Room 149AB**

### The CDISC Operational Data Model (ODM): It's Not Just Data Exchange!

SESSION CHAIRPERSON

***David Iberson-Hurst***

Chief Executive Officer, Assero Limited, UK

CDISC was designed to provide a vendor-neutral, platform-independent means of exchanging and archiving electronic clinical data. However, the inherent power within the model has been leveraged to extend the scope of application of the model. This session presents a number of use cases that demonstrate the power and flexibility of the ODM and the roles that the model can perform within the clinical trial enterprise from data acquisition through submission to data archive.

**The ODM: From Protocol to Submission**
***Mark L. Wheeldon***
Chief Executive Officer, Formedix, UK

**The ODM and Electronic Submission**
***William J. Qubeck, MBA, MS***
Electronic Submission Data Group Leader, Pfizer Inc

**The ODM: Easing the Regulatory Burden?**
***David Iberson-Hurst***
Chief Executive Officer, Assero Limited, UK

## Session 412 MC - Medical Communications, MA

8:30 AM - 10:00 AM LEVEL = ■

**Room 202B**

### Assessing Value-based Performance in the Eyes of Our Customers (Thought Leaders)

SESSION CHAIRPERSON

***Machelle Manuel, PhD***

Director, Medical and Scientific Affairs Field Operations, Sankyo Pharma, Inc.

Establishing value for field-based medical programs with key internal stakeholders can be a challenge given the intent of the positions in building relationships with thought leaders and supporting their needs for medical information. This session will discuss how value for field-based medical programs is assessed across the industry and innovative approaches for assessing value through external customer feedback.

**Evaluating the Impact of Medical Liaisons: The Customer's Voice**
***Brian E. Wagner, PharmD***
Operations Manager, US Medical Information and Communication Services, US Medical, Eli Lilly and Company

**Assessing the Value of Your FBMP Through the Eyes of Your Customer**
***Beth A. Price***
Executive Vice President, Science Oriented Solutions (SOS)

## Session 413 MW - Medical/Scientific Writing

8:30 AM - 10:00 AM LEVEL = ■

**Room 102AB**

### The Future of Medical Writing

SESSION CHAIRPERSON

***Susanna J. Dodgson, PhD***
Director, Graduate Biomedical Writing Program, University of the Sciences in Philadelphia

Drug development, and thus the environment of medical writers, is a highly dynamic area. Drug development processes, the regulatory environment, and the industry itself are constantly evolving. This session will discuss the impact of changes in these areas on medical writing as a profession. Furthermore, future skill requirements will be examined.

**Chances and Challenges: Outlook on the Future Environment of Medical Writers**
***Dan Benau, PhD***
Medical Writing Consultant, Emerald Swift, LLC

**Laying the Ground: How to Prepare for Future Requirements**
***Susanna J. Dodgson, PhD***
Director, Graduate Biomedical Writing Program, University of the Sciences in Philadelphia

*Panelists*

***Réginald Hulhoven, MD, PhD, FFPM***
Senior Medical Advisor, Clinical Pharmacology/Experimental Medicine, UCB, Belgium

***Virginia I. Watson***
Director, Clinical Writing, Cardinal Health, UK

## Session 414 NC - Nonclinical Laboratory Safety, CR, RA

8:30 AM - 10:00 AM LEVEL = ■

**Room 147B**

### Nonclinical Testing Strategies to Support Clinical Trials

SESSION CHAIRPERSONS

***Per Spindler, DVM***
Head of BioLogue®, University of Copenhagen, Denmark

***Klaus Olejniczak, DVM, FACP***
Preclinical Assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Planned topics for this session include the following: stage gate systems, decision trees, and bottleneck analysis; importance of making a strategy, handling uncertainty; strategic integration with other scientific disciplines, screening IND, trap-doors from too hasty early development, nonclinical strategy after initiation of clinical trials – a life after death?, assessment of US and EU possibilities – a global vision; use of regulatory scientific advice procedures as part of strategy, model systems and new models to facilitate nonclinical assessment.

**Nonclinical Testing Strategy I**
***Herman Van Cauteren, DVM***
Tibotec BVBA, Belgium

**Nonclinical Testing Strategy II**
***Per Spindler, DVM, MSc***
Head of Biologue®, University of Copenhagen, Denmark

**The Regulatory System: Providing Directions and Facilitation**
***Klaus Olejniczak, DVM, FACP***
Preclinical Assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany

## Session 415 NHP - Natural Health Products

8:30 AM - 10:00 AM LEVEL = ●

**Room 140A**

### Chinese Herbal Medicines Development

SESSION CHAIRPERSON

***Carmen Tamayo, MD***
Research and Development Consultant, Canada

Natural health product development is an evolving area of research around the world. Researchers in Canada and in other countries strive to be more rigorous and to be taken seriously. As part of evidence-based medicine it is essential to recognize both how NHP research is similar to, and how it differs from conventional drug research. Traditional philosophies and traditional health practices often differ significantly from conventional medicine. It has been widely recognized that the variety and complexity of traditional herbal medicines must be recognized and considered in any development program.

Several challenges to traditional Chinese medicine (TCM) research have been identified in the literature and modifications and adjustments to conventional methods have been developed. However, there are still major gaps with respect to evaluating safety and efficacy of whole healing systems such as TCM. In this session information about current international initiatives and collaborations between TCM practitioners, manufacturers, researchers and regulators will be presented.

Individual contributions will emphasize practical approaches to good agricultural practices of Chinese herbal medicines, preclinical and clinical evaluation and protocol and data management used in the evaluation of promising Chinese herbal medicines. In addition, the speakers will address the continuum of thought that is involved in an evidence-based approach to TCM research and implementation.

**Challenges in Product Development Involving Chinese Medicinal Herbs: A Canadian-Chinese Perspective**
***Edmund M.K. Lui, PhD***
Associate Professor, Department of Physiology and Pharmacology, University of Western Ontario, Canada

**A Case Study of Good Agriculture Practice (GAP): Challenges and Solutions in Manufacturing Chinese Herbal Medicines in China**
***Zhuohan Hu, PhD***
CEO/CSO, Research Institute for Liver Diseases; Professor, School of Pharmacy, Fudan University, China

**Methodological Issues in Studying Herbs**
***Adriane Fugh-Berman, MD***
Associate Professor, Department of Physiology and Biophysics, School of Medicine, Georgetown University

## Session 416 OS - Outsourcing, RD

8:30 AM - 10:00 AM LEVEL = ●

**Room 150A**

### Capturing Drivers of Outsourcing Growth and Quantifying Outsourcing Value

SESSION CHAIRPERSON

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

This session explores metrics that capture key operating and economic factors that have driven the increased use of outsourcing during the past decade. In addition, a quantitative assessment of the impact and value of outsourcing in drug development will be reviewed and discussed.

**R&D Trends Driving Past and Projected Changes in the Clinical Outsourcing Market**
***Kenneth I. Kaitin, PhD***
Director, Tufts Center for the Study of Drug Development
Tufts University

**Overview of CRO Marketplace and Its Changing Operating Environment**
***Douglas Peddicord, PhD***
Legislative Director, Association of Clinical Research Organizations

**A Look at New Research Quantifying the Impact of Outsourcing**
***Kenneth A. Getz, MS, MBA***
Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

## Session 417 PM1 - Project Management

8:30 AM - 10:00 AM LEVEL = ■

**Room 143C** *Project Management Institute credits offered*

### Cross-cultural Challenges in Multinational Pharmaceutical Companies: Differences in Communication and Decision-making Practices Between Japan and the West

SESSION CHAIRPERSON

***Atsushi Tsukamoto, MSc***
Project Manager, Sankyo Pharma Development

The session will begin with an overview of cross-cultural communication issues in the global context, followed by presentations about challenges and lessons learned about the role of cross-cultural differences in business practices and expectations among global drug development team members, from the perspective of a western and a Japanese pharmaceutical company, respectively.

**Dimensions of Cross-cultural Communication Among Nationals of US, Europe, and Japan**
***Bhaskar Pant, MS***
Managing Director, World Learning for Business

**West-Japan Integration: From a US Parent Company Perspective**
***Craig A. Davenport, RPh***
Managing Director and Director of Drug Development, Eli Lilly Japan KK, Japan

**West-Japan Integration: From a US Subsidiary of a Japanese Parent Company Perspective**
***Atsushi Tsukamoto, MSc***
Project Manager, Sankyo Pharma Development

## Session 418 PM2 - Project Management

8:30 AM - 10:00 AM LEVEL = ●

**Room 143AB** *Project Management Institute credits offered*

### Approaches to Reducing Risk and Improving Success in R&D Project Management

SESSION CHAIRPERSON

***Jeffrey S. Handen, PhD***
Associate Director, Business Performance Improvement, Merck Research Laboratories

It is more important than ever to manage the risks associated with drug discovery and development across the entire portfolio, to identify those candidates at highest risk as early as possible and to concentrate scarce resources on addressing those risks. Drug development success can then be better predicted by understanding the risks associated with a particular compound/project at each step of the discovery and development life cycle.

**Minimizing Risk during Outsourcing and Off-shore Clinical Development**
***Michael M. Rossi, PhD***
Medical Monitor, Medifacts International Consultants LLC

**The Project Management Office as a Tool for Risk Management in Pharmaceutical R&D Projects**
***Jay J. Armstrong, MS***
Director - Project Management, Benefit Risk Management, Johnson & Johnson Pharmaceutical Research and Development, LLC

**Reducing Risk in R&D from an IT Perspective**
***Janet L. Gagnon, PhD***
Associate Director, Development IT, Novartis Pharmaceuticals

## Session 419 PP - Public Policy/Law, RA

8:30 AM - 10:00 AM LEVEL = ●

**Room 150B**

### Recent and Pending Case Law in the EU

SESSION CHAIRPERSON

***John A. Lisman, MPharm, LLM***
Policy Advisor, Medicines Evaluation Board, Netherlands

The legal framework for marketing authorizations and for parallel import within the EU is evolving rapidly. Without a good understanding of rulings of the ECJ and the CFI, interpretation of the EU legislation is not possible. This session gives an update on the most important actual issues.

**Introduction of the Legal System in the European Union**
***John A. Lisman, MPharm, LLM***
Policy Advisor, Medicines Evaluation Board, Netherlands

**Case Law in the EU: Focus on Data Exclusivity and Generic Applications**
***Carla Schoonderbeek, JD***
NautaDutilh N.V., Netherlands

**Case Law in the EU: Focus on Parallel Import, Harmonization, and Other Issues**
***David Van Passel, JD***
Covington & Burling, Belgium

## Session 420 RA1 - Regulatory Affairs

8:30 AM - 10:00 AM LEVEL = ●

**Room 146A**

### CDER Town Meeting – Part 1 of 2

SESSION CHAIRPERSON

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

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

*Panelists*

***Randy Levin, MD***
Director, Office of Information Management, CDER, FDA

***Robert J. Temple, MD***
Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

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

***John K. Jenkins, MD***
Director, Office of New Drugs, CDER, FDA

***Steven K. Galson, MD, MPH***
Acting Director, CDER, FDA

## Session 421 RA2 - Regulatory Affairs, PP

8:30 AM - 10:00 AM LEVEL = ■

**Room 151B**

### How to Avoid Trademark-related Delays of NDA Approvals: The FASLODEX Experience

SESSION CHAIRPERSON

***Kathleen R. Gans-Brangs, PhD, MS***
Director, Regulatory Affairs, AstraZeneca Pharmaceuticals LP

During NDA review consults by the Division of Medication Error and Technical Support (DMETS) of proposed labeling, packaging and trademarks, theoretical risks of confusion between trademarks are often identified along with improvements in labeling and packaging that may avoid medication errors. As a result of this consult, approximately 30% of submitted trademarks are identified as being at risk of theoretical confusion between trademarks. This session will present information on the evolution and current status of FDA postmarketing commitments in medication error reporting, a case study of the completed FASLODEX 2-year postmarketing medication error commitment, and a closer look at the role of trademarks in medication error reporting to determine when they are the cause and when they are simply the code.

**Role of Postmarketing Commitments for Medication Error**
***Thomas G. "Jerry" Phillips, RPh***
President, Drug Safety Institute

**How to Avoid Trademark-related Delays of NDA Approvals: The FASLODEX Experience**
***Kathleen R. Gans-Brangs, PhD, MS***
Director, Regulatory Affairs, AstraZeneca Pharmaceuticals LP

**Are Trademarks the Causes or the Codes in Medication Errors?**
***George Di Domizio, JD***
President, Gemini Trademark Services

## Session 422 RA3 - Regulatory Affairs, CR

8:30 AM - 10:00 AM LEVEL = ●

**Room 151A** *CME, Nursing, and Pharmacy credits offered*

### DSMBs from an IRB Perspective

SESSION CHAIRPERSON

***Nora M. Cavazos, MD, CIP***
Director, DSM Services, Western Institutional Review Board

DSMBs and similar committees play an important role in the protection of human subjects. The roles and interactions of IRBs and DSMBs ought to be discussed to avoid duplication of functions in the continuing review of research and to support the implementation of DSMB recommendations. The session will present the views of IRB professionals, regulators, and industry sponsors.

***Gary L. Chadwick, PharmD, MPH, CIP***
Executive Director, Office of Human Subject Protection, University of Rochester

***Andreas Sashegyi, PhD***
Research Scientist, Statistics, Eli Lilly and Company

## Session 423 RA4 - Regulatory Affairs, CR

8:30 AM - 10:00 AM LEVEL = ■

**Room 144ABC**

### European Clinical Trials Directive Implementation: An Actual Status

SESSION CHAIRPERSON

***Miguel-Angel Salcedo, PharmD, MBA***
Managing Director, MDS Pharma Services, Spain

Each Member State should include in its local legislation a new European Clinical Trials Directive 2001/20/CE. For example, in Spain, the Spanish Drug Agency worked and agreed with all actors involved in the clinical research arena to launch the Royal Decree 223/2004. From the industry point of view, a major concern to set up new clinical studies is how swift a country can recruit the first patient. Reducing the timeframe from protocol finalization to FPI is an important metric to pay attention to, when making decisions about the best countries to participate in a global, pan-European or local pivotal clinical study. European Clinical Trials Directive 2001/20/EC simplifies IRB's approval process and guarantees a timeframe to obtain an answer (positive or negative) in each Member State. Within 60 days a multisite clinical study protocol has to be approved or denied for the IRB in each participant country. Some European Members have already implemented the European Directive and is applicable assuming that all clinical study protocols will be reviewed within 60 days after clinical study protocol submissions. Is Europe achieving the European Directive goals from a timelines point of view? Actual industry experience will illustrate the current situation.

**How the Implementation of the European Directive Has Impacted a Spanish Pharmaceutical Company Working Through Europe**
***Xavier Luria, MD***
Medical Director, Almirall Prodesfarma, Spain

**Impact of the Directive on Industry and Suggestions for Future Improvements**
***Carolyn L. Hynes, PhD***
Regulatory Affairs Manager, Johnson & Johnson Pharmaceutical Research and Development, LLC, UK

**Implementation of the EU GCP Directive: A Scandinavian Perspective**
***Alistair Bone***
Director of Quality Assurance and Training, TFS Trial Form Support, Sweden

**Perspective in Eastern Europe**
***Prof. Jozef Glasa, MD, PhD***
Chairman, Central Ethics Committee, Ministry of Health, Slovak Republic

## Session 424 RA5 - Regulatory Affairs

8:30 AM - 10:00 AM LEVEL = ■

**Room 152B** *CME and Pharmacy credits offered*

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

SESSION CHAIRPERSONS

***Steven W. Bass, PhD***
Director, Global Labeling and Promotion Compliance, Global Regulatory Sciences, Bristol-Myers Squibb

***Melody L. Eble, PharmD***
Director, Regulatory Affairs, Global Regulatory Information, Johnson & Johnson Pharmaceutical Research and Development, LLC

One of the FDA's recent major initiatives was its proposal to revise the format and content of the USPI, issued as a proposed regulation on December 22, 2000. This new format is intended to make important information available in a clear, consistent and readable manner. The FDA believes that this new user-friendly format also has the potential to help reduce errors in drug prescribing. This session will review the new regulation, the time frame for implementation of the "new format" and will discuss the major changes from the Current Regulations for the content and format of the US Package Insert (CFR 201.56 and CFR 201.57). The session will also provide a forum to discuss both the FDA's and industry's questions and expectations regarding its implementation.

In addition, the industry and FDA panel will answer questions regarding draft (i.e, adverse reactions, clinical studies section) and proposed guidance documents to support various sections of the package insert. We will also discuss the implication of the new format on the Content of Labeling (FDA e-Labeling Final Rule of December 11, 2003), on the PhRMA Paperless Labeling Initiative and on its use in Direct-to-consumer Brief Summaries.

This new format is a major change to the way we have been delivering safety and efficacy information to healthcare providers and to the patient. This should be a fascinating and interactive session.

**Background and Overview**
***Steven W. Bass, PhD***
Director, Global Labeling and Promotion Compliance, Global Regulatory Sciences, Bristol-Myers Squibb

**Presentation of the Final Rule: Overview, Expectations and Implications**

## Session 425 ST - Statistics

8:30 AM - 10:00 AM LEVEL = ●

**Room 146C** *CME credits offered*

### Statistical Considerations in Human Drug Abuse Potential Studies

SESSION CHAIRPERSON

***Yi Tsong, PhD***
Mathematical Statistician, CDER, FDA

Data from relevant preclinical studies, clinical safety-efficacy trials, and human pharmacology studies are needed for FDA review and are necessary for evaluation of the abuse potential of new chemical entities. Such data are included in the new drug applications (NDAs) and frequently provide the basis for drug scheduling decisions. Several aspects of the human pharmacology drug abuse potential studies are unique with regard to design and analysis. Subject population, inclusion and exclusion criteria, dosing regimen, selection of positive controls, outcome measures and timing of measurements, pharmacokinetics of the drug, reliability of scales, and statistical approaches are important to interpretation of results. Regarding statistical considerations, these trials are often designed with Latin Square with multiple treatments (test and positive control of different dose levels) and placebo. Appropriate length of washout period becomes crucial in design and analysis. This session will address such issues as selection of response variables and study designs.

**The Objectives of a Drug Abuse Potential Human Laboratory Study.**
***Michael Klein, PhD***
Pharmacologist, Controlled Substance Staff, CDER, FDA

**The Clinical and Statistical Considerations in Clinical Trial Design, Planning and Analysis from the Consultant Point of View**
***Donald R. Jasinski, MD***
Professor, Department of Medicine; Chief, Center for Chemical Dependency, Johns Hopkins Universitiy

**Statistical Considerations in Design and Analysis of Drug Abuse Clinical Trial**
***Ling Chen, PhD***
Mathematical Statistician, Quantitative Methods Research Staff, Office of Biostatistics, CDER, FDA

*Discussant*
***Deborah B. Leiderman, MD, MA***
Director, Controlled Substance Staff, Office of the Center Director, CDER, FDA

## Session 426 TR - Training

8:30 AM - 10:00 AM LEVEL = ■

**Room 147A**

### Did the Training Do What It Was Supposed to Do? Evaluating the Employee and the Training Program

SESSION CHAIRPERSON

***Kimberly N.M. Andrews, MEd***
Performance Consulting Manager, PPD Development

The presentations within this session will address the most commonly recognized model for evaluating training, evaluating the individual training participant's comprehension of the content covered within the program, and evaluating the transfer of the training to the job or the on-the-job behavioral change based on the training program.

**Evaluating the Effectiveness of Training**
***Claudia Lappin, JD, MS***
Associate Training Consultant, Eli Lilly and Company

**Did the Employee Learn the Content of the Training Program? How to Create and Use a Level 2 Evaluation**
***Melissa O. Ockert, MS***
Program Director, Clinical Trials Research Associate Programs, Durham Tech Community College

**Did the Employees Transfer the Training to Their Behavior on the Job? How to Create and Use a Level 3 Evaluation**
***Kimberly N.M. Andrews, M Ed***
Performance Consulting Manager, PPD Development

10:00 AM - 10:30 AM **REFRESHMENT BREAK**

**Meeting Rooms 145-147, Concourse Convention Center**

## Session 427 AHC - Academic Health Centers, IS, RA

10:30 AM - 12:00 PM LEVEL = ■

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

### Regulatory Obligations of an IND Sponsor-investigator

SESSION CHAIRPERSON

***Harvey M. Arbit, PharmD, MBA***
Director, IND/IDE Assistance Program, University of Minnesota

A clinical researcher who files an IND application becomes the sponsor of that IND as well as the investigator. The FDA regulations at 21 CFR 312 Subpart D specify the responsibilities of sponsors and investigators that must be followed to be in compliance. These obligations will be presented from three perspectives: FDA, academia, and legal.

**IND Sponsor-investigator Obligations from an FDA Perspective**
***Patricia A. Holobaugh, MS***
Consumer Safety Officer, CBER, FDA

**IND Sponsor-investigator Obligations from an AHC Perspective**
***Harvey M. Arbit, PharmD, MBA***
Director, IND/IDE Assistance Program, University of Minnesota

**IND Sponsor-investigator Obligations from a Legal Perspective**
***David B. Clissold, JD, MA***
Attorney, Hyman, Phelps & McNamara, P.C.

## Session 428 BT - Biotechnology, CR

10:30 AM - 12:00 PM LEVEL = ■

**Room 154AB** *Pharmacy credits offered*

### Overcoming Hurdles to Develop Clinically Validated Standardized, Quantitative, Quality Controlled, Next Generation, Multigene Expression Biomarker Assays Suitable for Clinical Trials

SESSION CHAIRPERSON

***Terry Osborn, PhD, MBA***
President and CEO, Gene Express, Inc.

Pharmacogenomics is clearly an area of great promise, but how do we turn tomorrow's promise into today's reality? This session addresses some of the fundamental questions and regulatory hurdles that need to be addressed in the development of clinically validated and successful multigene expression assays for biomarkers for use in clinical trials. A comparison of three different cancer tissues analyzed with different quantitative gene expression methods. Biomarker assays to diagnose lung cancer and to evaluate a multigene set in normal subjects will be described.

**Review of FDA Guidance for Pharmacogenomic Biomarker Data Submission Relative to Strengths and Weaknesses of Gene Expression Measurement Technologies**
***James C. Willey, MD***
Professor of Medicine and Pathology, Medical College of Ohio

**Comparison of a Five-gene Biomarker in Three Different Cancer Tumor Tissues with Different Quantitative Gene Expression Methods to Meet Reproducibility, Robustness, and the Other Characteristics of the New FDA Pharmacogenomic Biomarker Guidance**
***Richard Deane Hockett, MD***
Senior Clinical Research Physician, Eli Lilly and Company

## Session 429 CDM - Clinical Data Management, IMP

10:30 AM - 12:00 PM LEVEL = ■

**Room 103A** *CME credits offered*

### Evidence-based Medicine: Evaluating the Data from Outcome-based Clinical Trials

SESSION CHAIRPERSON

***Marguerite Fisher, RN, MSN***
Team Leader, Data Management, Eli Lilly and Company

This session will explore the nature of outcome-based clinical trials, how clinical endpoints are managed and used to evaluate whether a clinical trial's objectives have been met, and the current regulatory environment surrounding outcome-based clinical trials and the use of DMCs/CECs. Perspectives on this trend will be provided from the view of the sponsor, the members of the adjudication board, and the Data Analysis Group (DAG).

**Design and Operational Features for Trials with Clinical Events as the Primary Study Endpoints**
***Andreas Sashegyi, PhD***
Research Scientist, Statistics, Eli Lilly and Company

**Developing a Safety Profile for the Data Monitoring Committee when Clinical Events Are the Primary Study Endpoints**
***Patrick D. O'Meara, PhD***
President, Pat O'Meara Associates, Inc.

## Session 430 CP - Clinical Safety and Pharmacovigilance

10:30 AM - 12:00 PM LEVEL = ■

**Room 145B** *CME credits offered*

### Analyses Using MedDRA®-coded Data

SESSION CHAIRPERSON

***Patricia Mozzicato, MD***
Medical Officer USA, Northrop Grumman/MedDRA MSSO

During MedDRA® implementation, most organizations initially put great emphasis on the "input" aspects of MedDRA usage, i.e., the encoding of information such as adverse events, medical histories, etc. At some point, these organizations are faced with having to analyze this encoded data in some fashion. The focus of this session will be on postretrieval steps such as tabular presentation of data, use of primary versus secondary system organ classes (SOCs), and statistical considerations.

**Good Data Retrieval Practices: What Does the PtC Document Contribute?**
***Reinhard Fescharek, MD***
Head of Medicine, Bayer Healthcare AG, Germany

***Panos Tsintis***
Head of Sector for Pharmacovigilance and Postauthorization and Efficacy, EMEA, EU

**MedDRA's Characteristics and Their Impact on Retrieval and Presentation of Coded Data**
***Patricia Mozzicato, MD***
Medical Officer USA, Northrop Grumman/MedDRA MSSO

## Session 431 CR1 - Clinical Research and Development

10:30 AM - 12:00 PM LEVEL = ◆

**Room 140B** *CME and Pharmacy credits offered*

### Clinical Studies in Psychiatry: New Variations on the Placebo Response

SESSION CHAIRPERSON

***Ellis H. Wilson, MS, MSA***
Study Delivery Director, Neuroscience, AstraZeneca Pharmaceuticals

There is consensus that placebos will remain an important part of clinical research. The frequency of statistically significant placebo response rates in some clinical trials, particularly in psychiatry, is a subject of substantial concern across the drug development community. This session is designed to review the conventional wisdom surrounding the placebo response and to provide details on new theories, approaches, and technologies designed to identify and mitigate this effect.

**The Influence of Clinical Trial Design Features and Patient Characteristics on Placebo Response and the Outcome of Antidepressant Trials**
***Charles G. Lineberry, PhD***
CEO, Lineberry Research Associates, LLC

**Impact of Factors Associated with Clinician Ratings on Placebo Response and Signal Detection**
***Kenneth Kobak, PhD***
Vice President, Research, MedAvante, Inc.

**Placebo Response in Depression Studies: Lessons from a Large Depression Database**
***Richard A. Entsuah, PhD***
Senior Director, Wyeth Research

## Session 432 CR2 - Clinical Research and Development

10:30 AM - 12:00 PM LEVEL = ■

**Room 145A** *CME, Nursing, and Pharmacy credits offered*

### Patient Safety: Ethics, Pharmaceuticals for Children, and Human Research Protections

SESSION CHAIRPERSON

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

This session will address patient safety research issues of importance to government, healthcare providers and consumers, researchers, and industry. They include ethical and other issues relevant to clinical research, public-private sector collaborative efforts to improve the safety and effectiveness of drugs for pediatric use, and federal human subject protection regulations. Undertaking human research without the requisite oversight can create regulatory, legal, and ethical hazards, and it is important to determine whether or not proposed projects should be considered research subject to IRB approval. Since drugs are frequently prescribed for children even though they have not been tested in them, there is concern about adverse effects in pediatric age groups that are not anticipated from adult studies. To address such concerns, NIH is working closely with FDA and other public and private sector organizations to implement the Best Pharmaceuticals for Children Act. In addition, the Institute of Medicine issued a report on Ethical Conduct of Clinical Research Involving Children in 2004 recommending clarification of the definitions that appear in 45 CFR Part 46 Subpart D: Additional DHHS Protections for Children Involved as Subjects in Research. In response to this recommendation, the Secretary's Advisory Committee on Human Research Protections (SACHRP) has developed guidance to aid in the interpretation of the requirements of Subpart D. The guidance that SACHRP has proposed will be discussed in this session.

**Medical, Ethical, and Economic Issues that Impact the Development and Use of Pharmaceuticals for Children**
***Stanley A. Edlavitch, PhD, MA***
Professor of Epidemiology and Director, Epidemiology Research, University of Missouri at Kansas City School of Medicine

**Implementation of the Best Pharmaceuticals for Children Act: Public and Private Sector Collaboration**
***Donald R. Mattison, MD, MS***
Senior Advisor to the Directors of the National Institute of Child Health and Human Development and the Center for Research for Mothers and Children, NIH, HHS

**Research Involving Children: Emerging Human Protection Issues**
***Judith Brooks, MS, RN, CIP***
Public Health Analyst, Division of Education and Development, Office for Human Research Protections, HHS

## Session 433 CTM - Clinical Trial Management, MC

10:30 AM - 12:00 PM LEVEL = ■

**Room 101** *CME, Nursing, and Pharmacy credits offered*

### Patient Insights from the Frontlines of Medical Communications

SESSION CHAIRPERSON

***Sarah Ebner, MBA, MPH***
Director, Business Development, Phone Screen

Critical insights and trends related to patient habits, demographics, medications, call scripts, therapeutic areas, and cultural barriers are meticulously documented every day by skilled professionals who are on the front lines of medical communications. This session will cover key findings and tips derived from direct contact with hundreds of thousands of patients and providers representing more than 50 disease states.

**The Call Center Perspective**
***Jim Ringstad***
Senior Project Manager, Phone Screen

**The Research Site Perspective**
***Pamela Kivitz-Keenan***
Director, Patient Recruitment, Altoona Center for Clinical Research

**The Advocacy Group Perspective**
***Julie Totten, MBA***
President and Founder, Families for Depression Awareness

## Session 434 DM - Document Management/ eSubmissions, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 152A**

### Structured Product Labeling (SPL): Requirements, Challenges, and Best Practices

SESSION CHAIRPERSON

***Andrew Glemser***
Chief Technology Officer, Glemser Technologies Corporation

Regulatory authorities around the world are requiring product labeling documents to be submitted in XML format, such as SPL and PIM. Join us at this session to understand the regulatory requirements of XML-based product labeling, discuss issues and challenges, review implementation options, define a document and data migration strategy, review an implementation roadmap, and discuss best practices.

**An Overview of SPL, the Regulatory Requirements and Implication Timeframe, and Future Plans for SPL**
***Steven Gitterman, MD, PhD***
Deputy Director, Director of Special Pathogens and Immunologic Drug Products, CDER, FDA

**The Current Environment, Challenges, and Approach to Addressing SPL and PIM**
***Kristofer J. Spahr***
Associate Director, Regulatory and Labeling Applications, Wyeth Pharmaceuticals

**Improving Business and Public Health Through Open Standards**
***Thomas Moore, MPA***
Vice President, Document Management Practice, Intrasphere Technologies, Inc.

## Session 435 GCP - Good Clinical Practices

10:30 AM - 12:00 PM LEVEL = ●

**Room 149AB** *Nursing credits offered*

### Risk Management Focus in Clinical QA

SESSION CHAIRPERSON

***Mary Kay Denham, MS***
Director, Worldwide Regulatory Compliance - GCP, Bristol-Myers Squibb PRI

The clinical research environment has become less predictable in recent years, with an increase in high-risk areas which include vulnerable populations, complaints, higher-risk protocols and products. QA professionals need to take a more risk-based approach in conducting audits, internal reviews, and training. This session will focus on the different aspects of how to prioritize critical issues to enhance performance.

**Managing Risks in Clinical Investigator Audit Strategy**
***Mary Kay Denham, MS***
Director, Worldwide Regulatory Compliance - GCP, Bristol-Myers Squibb PRI

**Risk-based Approach to Vendor Audits: Why, When, How, and What?**
***Richard M. Siconolfi, MS***
Director, Computer Systems Validation and System Lifecycle, Procter & Gamble Pharmaceuticals, Inc.

**Protocol Complexity as a Factor in Clinical Compliance Risk: Case Studies**
***Marta H. Fields, MBA***
Associate Director, Global Head, Therapeutic Area Quality Leaders, Clinical Quality Assurance, Amgen Inc.

## Session 436 IMP/CP - Impact/Clinical Safety and Pharmacovigilance, eClin

10:30 AM - 12:00 PM LEVEL = ●

**Room 152B** *CME and Pharmacy credits offered*

### The Use and Impact of Patient-level Electronic Data in Healthcare Decision Making

SESSION CHAIRPERSON

***Robert M. A. Thwaites, MA, MCom***
Director, Healthcare Information Factory, GlaxoSmithKline Research and Development, UK

Following a brief introduction covering the development and extent of the use of patient-level electronic data in healthcare decision making, the speakers will provide examples of the growing value of these data in decisions across different types of healthcare organizations.

**The Impact of Patient-level Data on Decision Making in an Integrated Healthcare Organization**
***K. James Ehlen, MD***
Halleland Health Consulting

**The Impact of Patient-level Data on Decision Making in a Pharmaceutical Company**
***Robert M. A. Thwaites, MA, MCom***
Director, Healthcare Information Factory, GlaxoSmithKline Research and Development, UK

## Session 437 IT/CDM - Information Technology/ Clinical Data Management

10:30 AM - 12:00 PM LEVEL = ■

**Room 146B**

### Assessing Global Adoption of Electronic Data Collection Technologies

SESSION CHAIRPERSON

***Rebecca D. Kush, PhD***
President, CDISC

The use of and attitudes towards new electronic data collection technologies and data interchange standards were explored in 2002 and 2003 through two major global research projects. A subsequent project, conducted by CDISC and completed in 2004, explored the issues raised in the preceding efforts, specifically to update the adoption and attitudes around technologies that collect case report form data (eCRF) and those that collect patient-reported outcomes (ePRO) and to assess the adoption of standards in more depth. This research project was sponsored by 16 pharmaceutical companies, CROs, and technology providers and was supported by nonprofit organizations to reach users of these new technologies and standards for their opinions. Key findings, trends and comparisons will be presented with a goal of assisting companies in their implementation of new technologies and standards.

**Global Industry Adoption of Data Interchange Standards**
***Frank T. Newby***
Vice President, Education and Member Relations, CDISC

**Adoption of New Technologies by Trial Sponsors and Technology Providers**
***David Iberson-Hurst***
Chief Executive Officer, Assero Limited, UK

**Adoption of New Technologies by Investigative Sites**
***Kenneth A. Getz, MS, MBA***
Research Fellow, Tufts Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

## Session 438 MW - Medical/Scientific Writing, DM

10:30 AM - 12:00 PM LEVEL = ■

**Room 102AB**

### Re-engineering Document Preparation: Setting the Stage for Study Tagging Files

SESSION CHAIRPERSON

***Victoria E. Seidenberger***
Director, Document Quality and Technology, Wyeth Research

This session will review the implementation of study tagging files which has implications for the way industry plans and prepares documents and for adjustments to electronic publishing processes.

**Building an eCTD: A Model in Cross-functional Area Cooperation**
***Ryan R. Claringbold***
Global Dossier Leader, Johnson & Johnson Pharmaceutical Research and Development, LLC

**Impact of the STF Format on Document Preparation**
***Susan Nielsen, PhD***
Associate Director, Clinical Writing and Resource Management, Wyeth Research

**Study Tagging Files: The Outsourcing Perspective**
***Christina M. Rogers, PhD***
Director, Medical Writing, ReSearch Pharmaceutical Services, Inc.

## Session 439 NC - Nonclinical Laboratory Safety, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 147B**

### Immunotoxicity Testing of Human Pharmaceuticals

SESSION CHAIRPERSON

***Jan Willem Van der Laan, PhD***
Head, Preclinical Assessment Group of the Medicines Evaluation Board, National Institute for Public Health and the Environment, Netherlands

In November 2004, the ICH agreed upon a Step 2 document on Immunotoxicity Testing of Human Pharmaceuticals. The main issue is the cause-for-concern approach that is now adopted by all parties. Two speakers will present their views on this process. A third speaker will highlight the pathological aspects of the issue.

**The ICH Step 2 Immunotoxicity Testing from a European Regulatory Perspective**
***Jan Willem Van der Laan, PhD***
Head, Preclinical Assessment Group of the Medicines Evaluation Board, National Institute for Public Health and the Environment, Netherlands

**The ICH Step 2 Immunotoxicity Testing from an Industrial Perspective**
***Stephen K. Durham***
Executive Director, Pharmaceutical Research Institute

## Session 440 NHP - Natural Health Products, RA

10:30 AM - 12:00 PM LEVEL = ●

**Room 151B**

### Regulatory Issues in the Development of Heterogeneous Products: Town Hall Meeting with the FDA CDER Botanical Review Team and Center for Biologics

SESSION CHAIRPERSONS

***Shaw T. Chen, MD, PhD***
Team Leader, Botanical Review Team, Associate Director, Office of Drug Evaluation V, CDER, FDA

***Julienne M. Vaillancourt, MPH, RPh***
Regulatory Reviewer, Project Manager, CBER, FDA

Probiotics are live, bacterial preparations often marketed as dietary supplements and considered to have beneficial health effects. However, when used to treat or prevent disease, they are biological products, specifically live biotherapeutic products, and subject to pertinent regulatory requirements. This session will present the regulatory issues and challenges faced in the development of probiotics and other live biotherapeutic products for clinical indications and use within the US.

**Regulation of Probiotics and Other Live Biotherapeutic Products as Biologics**
***Julienne M. Vaillancourt, MPH, RPh***
Regulatory Reviewer, Project Manager, CBER, FDA

**Status Report from the Botanical Review Team, FDA Center for Drug Evaluation and Research**
***One of the participants from FDA will present.***

**FDA Town Hall on Natural Health Products: Question & Answer Panel Regarding Heterogeneous Drug Development**

*Discussants*

***Jinhui Dou, PhD***
Pharmacologist, Botanical Reviewer, Office of Drug Evaluation V, CDER, FDA

***Leslie A. Vaccari, RAC***
Regulatory Project Manager, CDER, FDA

## Session 441 OS - Outsourcing, IT

10:30 AM - 12:00 PM LEVEL = ●

**Room 150A**

### The Real World of Outsourcing: Outsourcing Fact and Fiction

SESSION CHAIRPERSON

***Paul Hodge***
Vice President, Practice Manager (Pharmaceuticals), Intrasphere Technologies, Inc.

Pressures in the pharma industry are forcing organizations to drive down their IT project costs, while increasing value and reducing project timeframes. In recent years, part of the solution to these seemingly irreconcilable priorities has been to deploy global delivery models. Using a real-world case study, involving outsourced IT services to a large pharma company, this session will offer a unique opportunity to explore the lessons learned on the road to establishing an off-shore IT model.

**An Introduction to the Real World of Outsourcing**
***Vivek Agrawal***
Country Manager, Intrasphere Information Technologies Pvt, Ltd., India

**International Best Practices**
***Dr. Chetan Tamhankar***
General Manager, SIRO Clinpharm Pvt Ltd., India

## Session 442 PM1 - Project Management

10:30 AM - 12:00 PM LEVEL = ■

**Room 143C** *Project Management Institute credits offered*

### Drug Development Projects: A Vehicle for Organizational Learning

SESSION CHAIRPERSON

***Jonas Roth, PhD, MSc***
Head, Knowledge Management and Communications, AstraZeneca R&D, Sweden

This session will present innovative approaches to managing project knowledge and how drug development projects can be the focal point for individual, team, and organizational learning to create business value. Practical examples and tools will be given, as well as provocative evidence that challenges existing theories about how individuals, teams, and organizations learn.

**Project Work Is About Creating New Knowledge**
***David Williamson***
Wenell Management, Sweden

**A Practical Method for Knowledge-sharing Between Projects**
***Lena Berg, MSc***
Director, AstraZeneca Research and Development, Sweden

**Projects: The Vehicle for Organizational Learning**
***Jonas Roth, PhD, MSc***
Head, Knowledge Management and Communications, AstraZeneca R&D, Sweden

## Session 443 PM2 - Project Management

10:30 AM - 12:00 PM LEVEL = ■

**Room 143AB** *Project Management Institute credits offered*

### Increased Productivity Through Effective Resource Management

SESSION CHAIRPERSON

***Scott J. Mahoney, MBA***
Director, PRTM

This session will explore how effective resource management practices can contribute to increased productivity at both the strategic and tactical levels. Additionally, industry case studies will explore varying approaches organizations are employing to avoid common resource management pitfalls.

**Practical Application of Resource Management: Diary of a Journey**
***Chris Clement, PhD***
Director/Head, Project Office, Millennium Pharmaceuticals, Inc.

**Capacity Management: Delivering the "Holy Grail" of Resource Management**
***Patrick A. Grogan, MBA***
Senior Director, Global Project Management, Pfizer Inc

**Resource Management in an Ever-changing Portfolio**
***Colleen K. Dixon***
Project Management Consultant, Eli Lilly and Company

## Session 444 PP - Public Policy/Law, RA

10:30 AM - 12:00 PM LEVEL = ■

**Room 150B** *CME credits offered*

### FDAMA Part 113: ClinicalTrials.gov – Where Are We Now?

SESSION CHAIRPERSON

***Maureen Morgan, MS***
Associate Director, Regulatory Affairs, AstraZeneca Pharmaceuticals LP

In this session, you will hear from a major pharmaceutical company that has developed a best-practice approach for both the decision making and the process of posting clinical trials to this website.

This session will also review FDA's compliance report for the year 2002 and will provide new information regarding compliance for the year 2004 for one disease state. In addition, the patient advocacy community's position on the usefulness of the ClinicalTrials.gov data base will be discussed.

**ClinicalTrials.gov: FDA's Perspective**
***Theresa A. Toigo, RPh, MBA***
Assistant Commissioner for Special Health Issues, Office of the Commissioner, FDA

**ClinicalTrials.gov: An Industry Perspective**
***Michelle Folz, RN, MSN***
Manager, US Regulatory Affairs Operations, Eli Lilly and Company

**ClinicalTrials.gov: The Patient Advocate Perspective**
***Jane Reese-Coulbourne, MS, ChE***
Staff, ALCASE (Alliance for Lung Cancer)

## Session 445 RA1 - Regulatory Affairs

10:30 AM - 12:00 PM LEVEL = ●

**Room 146A**

### CDER Town Meeting – Part 2 of 2

SESSION CHAIRPERSON

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

*Part 1 of this session will be held on Thursday at 8:30 AM.*

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

***Randy Levin, MD***
Director, Office of Information Management, CDER, FDA

***Robert J. Temple, MD***
Director, Office of Medical Policy and Office of Drug Evaluation, CDER, FDA

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

***John K. Jenkins, MD***
Director, Office of New Drugs, CDER, FDA

***Steven K. Galson, MD, MPH***
Acting Director, CDER, FDA

## Session 446 RA3 - Regulatory Affairs, eClin, IS

10:30 AM - 12:00 PM LEVEL = ■

**Room 151A** *CME credits offered*

### 21 CFR Part 11 and Electronic Medical Records Used as Investigational Source Documents

SESSION CHAIRPERSON

***David M. Knepper, MS***
Executive Director, Clinical Research, PharmaNet

21 CFR Part 11 draft guidance documents have been published and then withdrawn. Questions regarding the application of these regulations to electronic medical records systems at investigational sites remain, and industry has adopted widely varying policies for electronic source documentation requirements and controls. This session will explore the challenges surrounding the application of Part 11 requirements to investigational sites and discuss solutions that are both legal and practical.

**Academic Health Centers and FDA Electronic Records Regulations: Do the 21 CFR 11 Requirements Apply to Me?**
***Gregg J. Fromell, MD***
Executive Director, Office of Human Research, University of Pennsylvania, School of Medicine

**Meeting Existing Investigator Data Integrity Requirements in the New Electronic Environment: Is Part 11 Redundant?**
***David M. Knepper, MS***
Executive Director, Clinical Research, PharmaNet

## Session 447 RA4 - Regulatory Affairs

10:30 AM - 12:00 PM LEVEL = ■

**Room 144ABC** *CME credits offered*

### Clinical Trials in Latin America: A Review of the Regulatory Framework

SESSION CHAIRPERSON

***Manuel Fresno, MBA***
Managing Director, Latin America, MDS Pharma Services, Argentina

Latin America has recently become one of the most active regions for clinical trials in the world. The regulatory environment of Latin America has improved over the last few years and increasingly operates in accordance with international standards and guidelines. This session will present a review of the approval process across the main countries in Latin America.

**Regulatory Framework for Clinical Trials in Argentina**
***Graciela C. Racaro***
Regional Clinical Development Liaison, Latin America, Serono International S.A., Argentina

**Regulatory Framework for Clinical Trials in Brazil**
***Eduardo Motti, MD***
Clinical Research Manager, Schering AG, Brazil

**Regulatory Framework for Clinical Trials in Mexico**
***Sergio Guerrero, MD***
Vice President/Chief Operating Officer, Mexican Institute of Clinical Research, Mexico

## Session 448 ST - Statistics

10:30 AM - 12:00 PM LEVEL = ◆

**Room 146C**

### Global Development Program and Data Quality from the Japanese Point of View

SESSION CHAIRPERSONS

***Shunsuke Ono, PhD***
Reviewer, Pharmaceutical and Medical Devices Agency (PMDA), MHLW, Japan
***Takatoshi Sato, PhD***
President, Hyclips K.K., Japan

The objective of this session is to understand the issues of global development from the perspective of Japanese pharmaceutical industry representatives and authorities of the US, EU, and Japan. We need to learn how the concepts of these authorities differ, and about the practical circumstances of clinical study from a data quality point of view.

**The Concept of Global Development and Data Quality from the Japanese Authorities' Point of View**
***Shunsuke Ono, PhD***
Reviewer, Pharmaceutical and Medical Devices Agency (PMDA), MHLW, Japan

**Global Development Programs in Eisai Co., Ltd.**
***E. Stewart Geary, MD***
Director, Medical Regulatory Affairs and Pharmacovigilance, Eisai Co., Ltd., Japan

**Global Development Programs and Data Quality in Sankyo Co., Ltd.**
***Hironobu Saito, MBA***
Manager, Clinical Development Department, Sankyo Co., Ltd., Japan

**Panel Discussion**

## Session 449 TR - Training

10:30 AM - 12:00 PM LEVEL = ●

**Room 147A**

### Communication Tools/Practices that Work

SESSION CHAIRPERSON

***Debra A. Jendrasek, MBA***
Manager, US EDC Solutions, Chiltern international

Change is ongoing in today's work environment. For most of us, this requires us to accomplish more work in less time. When communication goes astray, productivity is impacted. Good communication and influence skills can help us be more effective in getting our work done with and through others more efficiently. In this session, we will discuss communication tools that organizations have found to be most effective in keeping their monitoring staff, investigators, and vendors focused, on task and apprised of the best practices in clinical trials.

**Electronic Performance Enhancement Tools for the Pharmaceutical Industry**
***Joan E. Pastor***
Clinical Research Training Consultant, Pastor Consulting, Inc.

**Project Success: Focus on the Fundamentals**
***Jessica A. Whittaker***
Senior Consultant, Glemser Technologies Corporation

**Best Practice: Rapid Application Prototyping to Align Business Units around Enterprise Project Management**
***Gus Cicala, MS***
President and Chief Executive Officer, Project Assistants, Inc.

12:00 PM **END OF THURSDAY SESSIONS**

12:00 PM **ANNUAL MEETING ADJOURNED**

12:30 PM - 4:30 PM **MedDRA® MSSO USER GROUP MEETING**
Meeting Room 140A, Concourse, Convention Center