The agenda for Monday, June 14 through Thursday, June 17 is current as of May 11, 2010.
CHAIRPERSON’S MESSAGE

GABY L. DANAN, MD, PhD
sanofi-aventis, France

The future of health care is being debated around the world, and the 46th DIA Annual Meeting provides the perfect venue to cultivate this debate and to exchange knowledge with industry, academia, patient organizations, and regulators worldwide, including representatives from more than 20 global regulatory agencies.

With Washington, DC, serving as the backdrop for this premier event, the US FDA will have its largest representation to date — opening the door for vital discussion about the global concern over the cost-effectiveness, safety, and efficacy of pharmaceuticals and related products. Then, there are the changing industry dynamics we’re all familiar with and the need for increasing the pace and effectiveness of innovation.

This year’s Annual Meeting Program Committee has responded to these concerns and changing dynamics by developing a program that includes tutorials, sessions, panel discussions, regulator town halls, and the world’s most interactive exhibit hall — all designed to facilitate innovation for better health outcomes. The current state of our industry requires that we be more creative, more proactive, and more passionate than ever before. We have a shared responsibility to be facilitators of innovation as we continue to work together to provide everyone with better access to better medicines.

NEW VISION, NEW MISSION, NEW ANNUAL MEETING

"A global forum for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide.”

The 46th DIA Annual Meeting is charting a new course that will reflect DIA’s new vision as “a global forum for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide.” This year, more than ever, the DIA Annual Meeting will:

• Bring together industry professionals and regulatory agencies from all continents
• Facilitate knowledge exchange needed to positively impact innovation and ultimately patient care and outcomes
• Build upon DIA’s traditional breadth and depth of topics running the gamut from preclinical research through postmarketing safety and surveillance.
• Provide an invaluable forum for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products, including discussion of current issues related to new areas such as comparative effectiveness, health outcomes, evidence-based medicine, health technology assessment, and therapeutics.

Best Investment You Can Make to Get the
GREATEST LEARNING AND NETWORKING EXPERIENCE

Five productive days of learning and networking with global industry professionals, academia, and regulatory agencies involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products.
The DIA Annual Meeting attracts leading experts from industry, academia, patient organizations, and regulatory agencies from around the world.

**KNOWLEDGE EXCHANGE**
- 350+ sessions and 20 tutorials
- 1,100 speakers
- 25 hot-topic content areas

**GLOBAL SCOPE**
- 8,000+ attendees from 80 countries
- 20 global regulatory agencies

**FOSTERING INNOVATION**
- 550+ exhibiting companies
- Multidisciplinary networking

Schedule at-a-Glance .................................................. 2
Keynote Speaker ......................................................... 3

**Knowledge Exchange**
- Must-attend Sessions .............................................. 4
- Megatracks ............................................................. 5

**Global Scope**
- Countries Represented ............................................. 6
- University Participation ............................................. 6
- Featured Regulatory Sessions ................................. 7

Network, Network, Network! ................................. 8
Destination DC ......................................................... 9
Program Committee ................................................... 10
General Information .................................................. 12
Continuing Education Information ...................... 13
Tutorials ................................................................. 14
Daily Highlights ......................................................... 22
Meeting Agenda ....................................................... 23

**Fostering Innovation**
- Exhibiting Companies See bookmark
- Benefits of Membership See bookmark
- Hotel Information See bookmark
- Tutorial Pricing Guide See bookmark
- Registration Form See bookmark

“*The DIA Annual Meeting is like having the world of what we do in one venue.*”
## SCHEDULE AT-A-GLANCE

### Saturday, June 12
- **9:00 AM - 5:00 PM**: Exhibitor Registration

### Sunday, June 13

**Registration Hours:**
- **8:00 - 9:00 AM**: Registration for Full-day and Morning Tutorials
- **12:30 - 1:00 PM**: Registration for Afternoon Tutorials
- **8:00 AM - 7:30 PM**: Attendee Registration
- **3:00 - 5:00 PM**: Exhibitor Registration

**Schedule:**
- **8:30 AM - 12:00 PM**: Half-day Morning Tutorials (Optional)
- **9:00 AM - 5:00 PM**: Full-day Tutorials (Optional)
- **1:00 - 4:30 PM**: Half-day Afternoon Tutorials (Optional)
- **3:00 - 5:00 PM**: Student Forum
- **7:00 - 9:00 PM**: Networking Reception (Optional)

### Monday, June 14

**Registration Hours:**
- **7:00 AM - 6:00 PM**: Speaker Registration
- **7:30 AM - 6:00 PM**: Attendee and Exhibitor Registration

**Schedule:**
- **7:30 - 8:15 AM**: Coffee/Breakfast Breads
- **8:30 - 10:00 AM**: Opening Plenary Session
- **9:00 AM - 6:00 PM**: Exhibition Hall Open
- **10:00 - 10:30 AM**: Refreshment Break
- **10:00 AM - 5:00 PM**: Student Poster Session
- **10:30 AM - 12:00 PM**: Concurrent Sessions
- **12:00 - 1:30 PM**: Lunch with Optional Networking Seating
- **1:30 - 3:00 PM**: Concurrent Sessions
- **3:00 - 3:30 PM**: Refreshment Break
- **3:30 - 5:00 PM**: Concurrent Sessions
- **5:00 - 6:00 PM**: Welcome Reception
- **6:15 - 7:15 PM**: CISCRIP Special Event: Voices of Medical Heroes - A Family’s Journey of Hope

### Tuesday, June 15

**Registration Hours:**
- **7:00 AM - 5:30 PM**: Attendee, Speaker, and Exhibitor Registration

**Schedule:**
- **7:15 - 8:00 AM**: Coffee/Breakfast Breads
- **8:00 - 9:30 AM**: Concurrent Sessions
- **9:00 AM - 5:30 PM**: Exhibition Hall Open
- **9:30 - 10:00 AM**: Refreshment Break
- **10:00 - 11:30 AM**: Concurrent Sessions
- **11:30 AM - 1:00 PM**: SIAC Luncheon
- **11:30 AM - 2:00 PM**: Extended Lunch Break with Optional Networking Seating
- **12:00 - 1:30 PM**: Professional Poster Session #1
- **2:00 - 3:30 PM**: Concurrent Sessions

### Wednesday, June 16

**Registration Hours:**
- **7:00 AM - 5:00 PM**: Speaker Registration
- **7:30 AM - 5:00 PM**: Attendee and Exhibitor Registration

**Schedule:**
- **7:30 - 8:15 AM**: Coffee/Breakfast Breads
- **8:30 - 10:00 AM**: Concurrent Sessions
- **9:00 AM - 4:00 PM**: Exhibition Hall Open
- **10:00 - 10:30 AM**: Refreshment Break
- **10:30 AM - 12:00 PM**: Concurrent Sessions
- **12:00 - 1:30 PM**: Lunch with Optional Networking Seating
- **12:00 - 3:00 PM**: Professional Poster Session #2
- **3:00 - 3:30 PM**: Concurrent Sessions
- **3:30 - 5:00 PM**: Refreshment Break
- **5:00 - 6:00 PM**: Welcome Reception

### Thursday, June 17

**Registration Hours:**
- **7:00 - 1:30 PM**: Speaker Registration
- **7:30 - 1:30 PM**: Attendee Registration

**Schedule:**
- **7:30 - 8:15 AM**: Coffee/Breakfast Breads
- **8:30 - 10:00 AM**: Concurrent Sessions
- **10:00 - 10:30 AM**: Refreshment Break
- **10:30 AM - 12:00 PM**: Concurrent Sessions
- **12:00 - 1:30 PM**: Professional Poster Session #2
- **1:30 - 3:00 PM**: Concurrent Sessions
- **3:00 - 3:30 PM**: Refreshment Break
- **3:30 - 5:00 PM**: Concurrent Sessions
- **5:00 - 6:00 PM**: Welcome Reception

### Friday, June 18

**Registration Hours:**
- **7:00 AM - 5:00 PM**: Speaker Registration
- **7:30 AM - 5:00 PM**: Attendee and Exhibitor Registration

**Schedule:**
- **7:30 - 8:15 AM**: Coffee/Breakfast Breads
- **8:30 - 10:00 AM**: Concurrent Sessions
- **10:00 - 10:30 AM**: Refreshment Break
- **10:30 AM - 12:00 PM**: Concurrent Sessions
- **12:00 - 1:30 PM**: Lunch with Optional Networking Seating
- **12:00 - 3:00 PM**: Professional Poster Session #2
- **3:00 - 3:30 PM**: Concurrent Sessions
- **3:30 - 5:00 PM**: Refreshment Break
- **5:00 - 6:00 PM**: Welcome Reception
Dr. Hamburg was unanimously confirmed on May 18, 2009, as the 21st Commissioner of the US Food and Drug Administration. Dr. Hamburg graduated from Harvard Medical School and conducted research on neuroscience and neuropharmacology. As Assistant Director of the National Institute of Allergy and Infectious Diseases, Dr. Hamburg focused on AIDS research.

From 1990 to 1997, while serving as the New York City Deputy Health Commissioner and Health Commissioner, Dr. Hamburg improved services for women and children and initiated novel measures to reduce the spread of HIV and tuberculosis. She also initiated the nation’s first bioterrorism defense program.

Prior to joining the FDA, Dr. Hamburg served as Assistant Secretary for Policy and Evaluation in the Department of Health and Human Services (1997-2001) and Vice President for Biological Programs at the Nuclear Threat Initiative, a public safety foundation.

**SPECIAL TOPICS OF INTEREST**

Practical solutions to and expert discussions on today’s hottest topics including:

- Advanced Therapies
- Best Practices for Sponsors and CROs
- Bioinformatics
- Biosimilars
- Combination Products
- Comparative Effectiveness/Health Technology Assessment
- Corporate Compliance
- Doing More with Less
- Emerging Markets
- Ethics
- Health Care Reform
- Health Information Technology/Electronic Health Records
- Innovation in Technology and Process
- Innovation through Collaboration
- Labeling
- Market Access and Reimbursement
- Medical Devices
- Oncology
- Patient Recruitment/Retention
- Pediatrics
- Personalized Medicine and Companion Diagnostics
- Phase 1
- Risk Management/REMS
- Social Media
- Vaccine Development

**SPECIAL SESSIONS**

**Monday, June 14**

10:30 AM - 12:00 PM  Is Industry Supported Education the Next Taboo? (AD - Mega Track Plenary Session)

10:30 AM - 12:00 PM  Multiregional Clinical Trials: It Takes a Global Village of Expertise (CR/CS - Mega Track Plenary Session)

1:30 - 3:00 PM  Will Electronic Health Records (EHR) Destroy Clinical Research or Transform It? (IT - Mega Track Plenary Session)

**Tuesday, June 15**


4:00 - 5:30 PM  Implications of Health Care Reform for Product Safety and the Pharmaceutical Industry (PP)

**Wednesday, June 16**

10:30 AM - 12:00 PM  Quality-by-design: Linking Quality to Safety and Efficacy — Parts 1 and 2 (CMC/GMP)

1:30 - 3:00 PM  Combination Products: Regulatory and Quality Aspects (CMC/GMP)

**Thursday, June 17**

8:30 - 10:00 AM  Qualifying New Translational Safety Biomarkers for Nonclinical and Early Clinical Development (NC)

10:30 AM - 12:00 PM  Drug Master Files: Regulatory Aspects (CMC/GMP)
MUST-ATTEND SESSIONS

Monday, June 14
8:30 - 10:00 AM
Opening Plenary Session Featuring Keynote Address by Dr. Margaret A. Hamburg

Tuesday, June 15
8:00 - 9:30 AM
Multitrack Plenary Session: Implications of Comparative Effectiveness Research for Health Care Innovation

A high-level panel will present perspectives on what is required to develop and maintain a comparative effectiveness research and health technology assessment program with the end result of better and expedited care for the patient. This session will explore the global experience with comparative effectiveness research and health technology assessment by examining the issues that the global medical community should consider as it strives for a patient-centered and consumer-driven health care marketplace. (EBM)

Keynote:
Jeff Goldsmith, PhD, University of Virginia; President, Health Futures, Inc.

Executive Policy Forum Parts 1 and 2: The New Landscape for Industry-Profession Relations — From Policy to Practice

Thought leaders from government, media, ethics, and academia will discuss industry support of clinical research and medical education and how it has led to intense scrutiny by media and policy makers, debate among ethicists, and attempts at self-regulation by industry, academia, and medical societies. (EXEC)

*Additional panelists to be confirmed.
MEGATRACKS

The 46th DIA Annual Meeting Program Committee has created three megatracks designed to strengthen the presentations and their relevance to the challenges faced by today’s professionals and to promote broader discussion of the topics.

### Advertising/Marketing/Medical Communications Megatrack

Attendees interested in direct-to-consumer (DTC) advertising, business continuity planning, drug information and the Internet, safe use of drugs, and much more, will be interested in attending sessions in these tracks:

- Advertising
- Marketing
- Medical Communications

### Clinical Research Megatrack

If you are interested in global clinical trials, Phase 1, team culture and relationship, portfolio, alliance, risk management, accelerating patient recruitment, Sentinel Network Initiative, outsourcing challenges in emerging regions, CRO and sponsor relationships, and much more, you will be interested in attending sessions in these tracks:

- Academic Health Centers/Investigator Sites
- Clinical Research and Development/Clinical Supplies
- Outsourcing
- Project Management/Finance

### Information Technology Megatrack

Interested in coding, data management standards, FDA’s ODM Pilot Report, SPL indexing, global electronic submissions, eCTDs, SDTM, web-based tools, validation challenges, auditing techniques, and much more? Then you should plan to attend sessions in these tracks:

- Clinical Data Management
- eClinical
- Electronic Regulatory Submissions/Document Management
- Information Technology
- Validation

### Special Blended Session

**Is Industry Supported Education the Next Taboo?** *(AD)*

**Monday, June 14**

10:30 AM - 12:00 PM

**Multiregional Clinical Trials: It Takes a Global Village of Expertise** *(CR/CS)*

**Monday, June 14**

10:30 AM - 12:00 PM

**Will Electronic Health Records (EHR) Destroy Clinical Research or Transform It?** *(IT)*

**Monday, June 14**

1:30 - 3:00 PM
COUNTRIES REPRESENTED

The 46th DIA Annual Meeting provides a unique opportunity to network with and learn from industry, academia, patient organizations, and regulators from around the world, including:

- Australia
- Austria
- Belgium
- Brazil
- Canada
- China
- Denmark
- Finland
- France
- Germany
- Hong Kong
- India
- Ireland
- Israel
- Italy
- Japan
- Macao
- Mexico
- Netherlands
- Republic of Korea
- Singapore
- Sweden
- Switzerland
- Taiwan
- United Kingdom
- United States

UNIVERSITY PARTICIPATION

As of February 1, 2010, the following institutions have confirmed their participation:

- Dartmouth Hitchcock Medical Center
- Institute of Chinese Medical Sciences, University of Macau
- Jadavpur University
- Tufts University
- University Hospitals Case Medical Center
- University of Medicine and Dentistry of New Jersey
- University of Missouri Kansas City School of Medicine
- University of North Carolina - Wilmington
- University of the Sciences in Philadelphia
- KoNECT; Yonsei University
- National Institute for Biological Standards and Control (NIBSC)
- Mayo Clinic
- Seoul National University
- University of Maryland School of Pharmacy
- Dartmouth Medical School
- University of Newcastle
- Oral Health Research Institute, Indiana School of Dentistry
- Memorial Sloan-Kettering Cancer Center
- University of Pennsylvania School of Medicine
- CINECA Inter-University Consortium
- Institute of Medicine/National Academy of Sciences
- University of Liverpool, Alder Hey Children’s NHS Foundation Trust
- Peking University School of Pharmaceutical Sciences
- University of Miami
- Stanford University
- University of Alabama Birmingham
- Hannover Medical School
- University of Reading
FEATURED REGULATORY AGENCY SESSIONS

Monday, June 14
1:30 - 3:00 PM  Center for Devices and Radiological Health (CDRH) Task Force Reports: 510(k) Devices Process Review and New Science in Regulatory Decision Making (page 30)
3:30 - 5:00 PM  State Food and Drug Administration (SFDA) China Update (page 35)

Tuesday, June 15
10:00 - 11:30 AM  European Medicines Agency Town Hall (page 41)
2:00 - 3:30 PM  Pharmaceuticals and Medical Devices Agency (PMDA) Japan Town Meeting (page 46)

Wednesday, June 16
3:30 - 5:00 PM  Center for Biologics Evaluation and Research (CBER) Town Meeting (page 70)

Thursday, June 17
8:30 and 10:30 AM  Center for Drug Evaluation and Research (CDER) Town Hall Parts 1 and 2 (pages 74 and 77)

As of February 1, 2010, the following global regulatory agencies have confirmed their participation as a speaker:

- Agency for Healthcare Research and Quality (AHRQ)
- Center for Drug Evaluation, Taiwan
- EDQM (The European Directorate for the Quality of Medicines and Healthcare)
- European Medicines Agency
- FDA Center for Biologics Evaluation and Research (CBER)
- FDA Center for Devices and Radiological Health (CDRH)
- FDA Center for Drug Evaluation and Research (CDER)
- Federal Institute for Drugs and Medical Devices (BfArM)
- Health Canada
- Indian Ministry of Health & Family Welfare
- Korean Food and Drug Administration
- Medicines Evaluation Board
- Medicines and Healthcare products Regulatory Agency (MHRA)
- National Cancer Institute (NCI)
- National Institutes of Health (NIH)
- Pharmaceuticals and Medical Devices Agency (PMDA) Japan
- State Food and Drug Administration (SFDA) China
- US Department of Justice
- World Health Organization (WHO)
The student and professional poster sessions provide excellent opportunities for the presenters to share their research results to a diverse audience, including professionals from regulatory agencies, pharmaceutical and related industries, and academia worldwide. The posters present scientific developments related to tutorial and session topics and will be displayed in the Exhibit Hall of the Convention Center.

**Student Poster Session**  
Monday, June 14, 10:00 AM – 6:00 PM

**Professional Poster Session**  
Tuesday, June 15, 12:00 – 1:30 PM and Wednesday, June 16, 12:00 – 1:30 PM
DESTINATION DC

Getting to the Walter E. Washington Convention Center

By Train

Amtrak - Amtrak is offering a 10% Amtrak Discount to DIA Annual Meeting attendees. To book your reservation, call Amtrak at +1.800.872.7245 or contact your local travel agent. Please refer to Convention Fare Code X07Z-968 when making your reservation. Convention fares cannot be booked via Internet. Offer is not valid on the Auto Train and Acela service. Offer valid with Sleepers, Business Class or First Class seats with payment of the full applicable accommodation charges. Fare is valid on Amtrak Regional all departures seven days a week, except for holiday blackouts.

By Air

Ronald Reagan National Airport is located in Arlington, Virginia, and is just 4 miles (10 – 15 minutes) from downtown Washington, D.C. For more information on Ronald Reagan Washington National Airport, visit www.metwashairports.com/reagan or call +1.703.417.8000.

Dulles International Airport is located in Dulles, Virginia, and is approximately 26 miles (35 – 45 minutes) from downtown Washington, D.C. For more information on Washington Dulles International Airport, visit www.metwashairports.com/dulles or call +1.703.572.2700.

Baltimore Washington International (BWI) Airport is located in Linthicum, Maryland, and is approximately 32 miles (40 – 50 minutes) from downtown Washington, D.C. For more information on Baltimore/Washington International Airport, visit www.bwiairport.com or call 800-I FLY BWI.

For additional travel information visit www.diahome.org/46thAnnualMeeting and access the Hotel/Travel Information tab.
2010 PROGRAM COMMITTEE

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NautaDutilh N.V., Netherlands

John C. Marlow, MD
Advantastar Communications Inc.

Carl Metzdorff
ACES Health Care, Belgium
Dress Code
The dress code for the 46th DIA Annual Meeting is business casual. Neckties, business suits, or other business attire are acceptable, but not necessary. The Convention Center may be chilly so bring a sweater or jacket; comfortable shoes are a must!

Press Registration Policies and Procedures
DIA welcomes qualified representatives of news organizations to attend The 46th DIA Annual Meeting for the purpose of reporting and publishing/airing articles/stories. DIA reserves the right to screen all requests and refuse the registration of those who are not considered to be qualified. In order to obtain a press pass, applicants must be affiliated with an established media outlet and possess an editorial/reporting title. Publishers, sales representatives and other noneditorial staff will not be granted a press pass. To obtain your press credential contact Joe Krasowski at +1.215.293.5812 or Joe.Krasowski@diahome.org.

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

- **Saturday, June 12**: All times are acceptable
- **Sunday, June 13**: Only after 8:00 PM
- **Monday, June 14**: 7:00 - 8:15 AM and after 6:00 PM
- **Tuesday, June 15**: 7:00 - 8:00 AM and after 5:30 PM
- **Wednesday, June 16**: 7:00 - 8:15 AM and after 5:00 PM
- **Thursday, June 17**: 7:00 - 8:15 AM and after 12:00 PM

To request a DIA Exhibitor-Sponsored Hospitality Event Application Form, contact Lori Risboskin at Lori.Risboskin@diahome.org or +1.215.442.6174.

DIA Career Center
The DIA Career Center will be online to help DIA members at the meeting find new professional employment opportunities and to help companies extend professional opportunities to interested DIA members. Companies will be able to purchase, publish, and receive replies to job postings, and interested DIA members will be able to submit their qualifications for these job postings.

Exhibit Locator
Search an exhibiting company by booth number, company name, or by the services it provides. Exhibit Locator workstations are available near the entrance to the Exhibit Hall.
Overview of Program

The 46th DIA Annual Meeting is the premier event for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products. With 25 content-area tracks, 350 sessions and 20 tutorials, presentations are geared to attendees at all disciplines, work settings, and experience levels. The DIA Annual Meeting, above all others, offers valuable professional cross-functional learning and networking experiences.

Educational Objectives

After completing this activity, the participant should be better able to:

- Compare and contrast the current regional regulatory and public policy environment pertaining to pharmaceuticals and related products
- Discuss the regulatory and economic factors that impact the global biopharmaceutical industry
- Recognize the challenges facing regulatory agencies and industry in research study design and statistical methodology
- Assess the progress toward integrated, state-of-the-art document management systems
- Identify legal, advertising, and marketing issues related to providing product information
- Apply principles of risk assessment and management to development and postmarket phases of new healthcare products
- Summarize issues in safety reporting and data analysis regarding adverse events
- Distinguish regional approaches to integration of evidence-based medicine and comparative effectiveness research into healthcare decision making
- Describe current issues in designing and implementing clinical trials, including patient recruitment, site selection, and management of multiregional clinical trials
- Identify current opportunities and challenges in the area of personalized medicine for disease treatment

Target Audience

This program is designed for individuals in the full continuum of disciplines involved in the development and use of pharmaceuticals and related healthcare products. The program is intended to strengthen participants’ understanding of the value of cross-discipline integration and to foster innovation for better health outcomes.

ACCME

Postgraduate Institute for Medicine

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and the Drug Information Association. PIM is accredited by the ACCME to provide continuing medical education for physicians.

Credit Designation

Postgraduate Institute for Medicine designates this educational activity for a maximum of 19.5 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Nursing Continuing Education

Credit Designation

This educational activity for 19.5 contact hours is provided by Postgraduate Institute for Medicine.

Accreditation Statements

Postgraduate Institute for Medicine is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation.

California Board of Registered Nursing

Postgraduate Institute for Medicine is approved by the California Board of Registered Nursing, Provider Number 13485 for 19.5 contact hours.

Project Management (PMI)

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

This program offers a maximum of 19.5 professional development units (PDUs).

To receive a statement of credit, participants must attend the program and complete the online credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request. Complete details and instructions for accessing My Transcript will be included in the final program.

Disclosure of Conflicts of Interest

Drug Information Association (DIA) and Postgraduate Institute for Medicine (PIM) requires instructors, planners, managers, and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly vetted by DIA and PIM for fair balance, scientific objectivity of studies mentioned in the materials or used as the basis for content, and appropriateness of patient care recommendations.

Americans with Disabilities Act

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.
This tutorial will provide an overview of the regulatory system in China, including the agencies and institutions at the central government and provincial levels, as well as their roles and responsibilities. Various regulations for product registration, clinical trials, and safety reporting will be presented, and the regulatory pathways and strategic considerations for clinical trial and marketing applications will be discussed. A step-by-step roadmap of how to navigate the regulatory system in China for clinical trial approval and product registration will also be discussed. This discussion will include key points to consider, strategies, and tactics.

**Learning Objectives**

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

- Describe the regulatory system in China, including the agencies and institutions and their roles and responsibilities in the regulatory processes for clinical trial and registration approval, as well as safety reporting
- Explain the history and the recent changes in the regulatory system in China and future perspectives
- Describe the regulatory pathways and strategic considerations for successful clinical trial and marketing applications in China
- Navigate the regulatory system in China for clinical trial approval and product registration

**Target Audience**

This tutorial is designed for professionals involved in regulatory affairs, clinical research, pharmacovigilance/drug safety, project management, R&D strategies, and quality assurance and quality control.

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<td>AHC/IS</td>
<td>Academic Health Centers/Investigator Sites</td>
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Unless otherwise disclosed, DIA acknowledges that the statements made by speakers/instructors are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers/instructors and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

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**MORNING HALF-DAY TUTORIALS**

8:30 AM-12:00 PM  Fee: $375.00

**TUTORIAL 20**

**Understanding and Navigating the Regulatory System in China**

**Laurence Huang**

Regulatory Affairs Director
AstraZeneca, China

**Ling Su, PhD**

Vice President, Asia Pacific Research Organization, Wyeth Research, a Pfizer Company, China
TUTORIAL 21 ERS, RA

Structured Product Labeling: Content of Labeling and Drug Establishment Registration and Drug Listing

Lonnie D. Smith
Project Manager, Structured Product Labeling Team, Office of the Center Director, CDER, FDA

The FDA Amendments Act placed into law the requirement for electronic drug establishment registration and drug listing. FDA has adopted the use of extensible markup language (XML) files in a standard SPL format as the standard format for the exchange of drug establishment registration and drug listing information.

The Structured Product Labeling (SPL) is a Health Level Seven markup standard adopted by the FDA as a mechanism to exchange information, such as drug listing, between computer systems to eliminate redundant data collection and improve efficiency. Product data elements include information associated with drug listing, such as the product name, ingredient names and strengths, dosage forms, routes of administration, marketing status, and appearance, as well as information on how the product is packaged for marketing.

At the conclusion of the tutorial, participants will know the basics of the standard and how to create SPL submissions.

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

• Identify information in drug establishment registration, drug listing, and content of labeling SPL submissions to FDA
• Create well formed XML for content of labeling and drug establishment registration and drug listing submissions for human Rx drugs, OTC, and animal drug products

Target Audience
This tutorial is designed for SPL document authors who need to create valid and correct data in SPL format to be submitted to the FDA.

TUTORIAL 22 CR, RA

Fourteen Steps from Research to Development

3.25 AMA PRA Category 1 Credit(s)™

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

There are 14 steps from research to development (R to D) and initiation of phase 3 clinical studies; the majority of time committed to drug development occurs during this period. A discussion of the 14 critical steps from R to D will include identifying ways to streamline the process and interactions with FDA.

With each of the 14 steps used to develop the optimal strategic plan, discussion will address the resources and various approaches to tailoring the plan to a sponsor’s specific product under development and obtaining FDA concurrence with the strategic plan. A smooth progression through the preclinical process into early clinical programs will be presented in this half-day tutorial targeted to familiarize pivotal staff in start-up companies with the required terminology and functions, pharmaceutical/biological companies that have yet to file INDs, and those who want to improve their early development approach.

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

• Identify ways to tailor the development, streamline the process, and interact with FDA
• Explain the specialties and resources needed to develop a product
• Design processes to guide your company smoothly through the progression of research and development

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

TUTORIAL 23 CR, GCP, RA

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

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

This tutorial will review and discuss the legal, regulatory, and practical challenges of (1) FDA enforcement priorities for 2010 and beyond (eg, application integrity policy and GMP/GCP requirements), (2) FDA administrative enforcement weapons and how the Agency uses them (eg, inspections, warning letters, publicity, recalls, and investigator disqualification proceedings), and (3) the civil and criminal penalties for violations (eg, seizure, injunction, criminal prosecution). Included in our focus will be FDA’s renewed commitment to enforcement as articulated in an August 2009 speech by Commissioner Hamburg. We will also address how to handle an FDA enforcement action should you face one, particularly in the wake of an inspection or Warning Letter and the impact of the new initiatives related to responding to 483s and Warning Letters implemented in 2009 following Commissioner’s Hamburg’s pledge to boost enforcement. These interactive discussions will focus on how FDA operates and makes decisions and how to respond effectively, using tactics ranging from negotiation to, when appropriate, litigation.

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

• Discuss FDA’s enforcement priorities for 2010 and beyond
• Describe FDA’s compliance review and decision-making process
• Identify the legal risks and penalties for noncompliance
• Respond appropriately to FDA enforcement
There is no widely accepted definition for portfolio management. It can refer to good decision making at the highest levels or to gathering and reporting data across all projects in the pipeline.

Using the basic elements of Pharmaceutical Project Data (value, cost, risk, and timing tied to the target product profile), we will demonstrate specific portfolio assessments which will highlight gaps and point to actions needed to bring a portfolio into strategic alignment.

An interactive discussion will focus on specific ways to translate company or therapeutic area strategy into actions that improve the portfolio by influencing the development of projects (indications), compounds (with one or more indications), and programs (one or more compounds including backups or secondary compounds). We will also reveal types of analyses that lead to concrete actions geared to help the organization throughout the year as annual R&D budgets change due to unexpected failures, successes, and delays.

**Learning Objectives**

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

- Identify at least three insightful portfolio views valuable for driving discussion within their organizations
- Identify the characteristics of a portfolio management system that would be appropriate for his/her organization
- Recognize how portfolio management can link company strategy to project and program decisions
- Build a tool useful for linking portfolio strategy to monthly project level decisions, within a tight budget environment

**Target Audience**

This tutorial is designed for project and portfolio managers, as well as functional department heads interested in aligning internal decisions to strategy.

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**TUTORIAL 24**

**Utilizing Chemistry, Manufacturing, and Controls in Drug Development**

*Priya Jambhekar*

President

PBS Regulatory Consulting Group Inc.

This tutorial will provide you with the tools to write or assemble CM&C sections of regulatory submissions and other regulatory documents, and adequately prepare you for CM&C meetings with the FDA. Participants will discuss all the CM&C components of INDs and NDAs/CTDs, provide appropriate tools to write or assemble CM&C sections of regulatory submissions and documents, prepare for CM&C meetings with FDA, and navigate through the myriad guidelines and guidance documents.

**Learning Objectives**

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

- Recognize FDA’s regulatory expectations and the regulatory framework
- Outline the CM&C sections of INDs/NDAs/CTDs/DMFs
- Assemble the CM&C sections of INDs and NDAs/CTDs
- Address regulatory documents affected by CM&C

**Target Audience**

This tutorial is designed for regulatory affairs professionals, quality assurance and compliance personnel, and manufacturing personnel.

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**TUTORIAL 25**

**Portfolio Management: The Nuts and Bolts of Aligning Operations with Strategy**

*Jack Kloeber, PhD*

Senior Partner, Kromite

*Homaune A. Razavi, MBP, PhD*

Director, Portfolio Management and Validation Group, Pfizer Inc

The goal of this tutorial is to demonstrate the purpose, strategy, limitations, and analysis of early clinical studies. A contrast of early-versus late-phase clinical trials will be provided. First-in-human studies will be discussed, including limitations of preclinical data, regulations, safety considerations, interpretation of safety signals, patient versus healthy volunteers, and overall strategy. Label information will be used to indicate those portions which are generated from early clinical trials. Flexible protocol design, and the use of DSMBs and biomarkers will be presented. Strategy for supportive clinical pharmacology studies (DDIs, special populations, AME, etc.) and their timing will also be discussed.
Tutorials, Sunday, June 13

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

• Describe the purpose and strategy of early phase clinical studies
• Explain the safety issues and management of participant safety in early phase trials
• Recognize the differences between early- and late-phase clinical trials
• Identify the benefits of a clinical pharmacology strategy for supporting studies

Target Audience
This tutorial is designed for clinical research and development professionals as well as regulatory affairs, clinical operations, and drug safety professionals interested in learning about the benefits and methodology of early clinical studies.

AFTERNOON HALF-DAY TUTORIALS
1:00 PM-4:30 PM Fee: $375.00

TUTORIAL 30 AHC/IS, CR/CS, PD/TR
Developing Standard Operating Procedures (SOPs)

Bernadette Ott
Consultant, Good Clinical Practices/Quality Assurance

One of the best ways to ensure that organizations meet their business and regulatory obligations is to follow standard operating procedures (SOPs). Standard operating procedures are the “procedures” and processes that you use and “operate” under that have been “standardized” to ensure that you do them the same way each time. SOPs are clearly written descriptions of how particular tasks are to be performed. This tutorial will explore what SOPs are, their uses, and how to write them.

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

• Describe what SOPs are and their importance to an organization
• Explain how SOPs will standardize organizational processes, with the goal of functioning consistently and well
• Define various formats for SOPs, as well as the content for each section of the SOP
• Write and/or revise an SOP
• Recognize the importance of training with respect to SOPs
• Implement SOPs in your organization

Target Audience
This tutorial is designed for anyone involved in determining processes and procedures, or writing the associated SOPs, whether at a pharmaceutical company (sponsor, CRO), an investigative site, or an IRB. Although the examples and exercises may be focused primarily on clinical trials, the information related directly to the formulation of SOPs is applicable to many different settings within these organizations.

TUTORIAL 31 RA
Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in the EU

Brenton E. James, FTOPRA
Consultant, Strategic Regulatory Affairs in the European Union, UK

This tutorial will provide an overview of the three regulatory procedures in the European Union – centralized, decentralized and mutual recognition – including details on the review time to approval and opportunities for sponsor/agencies dialogue from scientific advice to granting the Marketing Authorization. It will discuss which procedure is available for NCE including orphan drugs, OTC, and generic products, and examine the business strategic opportunities for each procedure.

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

• Explain the background to the development of the European Union
• Describe the three regulatory procedures for a marketing application in the European Union for NCE, OTC, and generic products
• Identify the business considerations of translations, co-marketing, co-promotion, patents and trademarks

Target Audience
This tutorial is designed for attendees with an interest in European regulatory affairs (regulatory affairs staff, clinical research and development managers, and project managers).

TUTORIAL 32 PD/TR
Leadership: How to Organize and Lead People in Group Work

Michael Laddin, MS, MBA
President, LeaderPoint, LLC

The role of a leader in organizing and leading a group is often misunderstood and, as a consequence, the group may not perform up to expectations, or it may spend a considerable amount of time dealing with dysfunctional group dynamics instead of the work to be accomplished. This tutorial addresses those issues by exploring the types of work groups, how they can be more effective, and how individuals can correct group dynamics and help the group achieve higher levels of performance.
Learning Objectives
At the conclusion of this tutorial, participants should be able to:
• Identify the different types of work group structures and be able to predict the quality of work the group will produce
• Identify and correct dysfunctional group dynamics
• Create and maintain cooperation among team members including cross-functional teams

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

TUTORIAL 34
CP, RA
Hot Topics in Pharmacovigilance in the EU: EudraVigilance Access Policy, International Standardization Work E2B and Identification of Medicinal Products, Signal Detection, Duplicate Management
3.25 AMA PRA Category 1 Credit(s)™

Representative Invited
Business Lead, EudraVigilance and International Standardization in Pharmacovigilance, European Medicines Agency, European Union

Gaby L. Danan, MD, PhD
EU Qualified Person for Pharmacovigilance, sanofi-aventis, France

This tutorial has been prepared to provide attendees with an overview on current hot topics in pharmacovigilance in the EU. The attendees will be offered the opportunity to discuss the latest developments related to the implementation of the new EudraVigilance Access Policy, the finalization of the new international standards related to individual case safety reports (ICSR) and the identification of medicinal products (IDMP), practical approaches in signal detection, and duplicate management in light of recent inspection findings.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
• Describe the latest developments in obtaining access to EudraVigilance
• Identify the main changes related to E2B and the reporting of medicinal product information
• Discuss approaches in signal detection and duplicate management

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

TUTORIAL 33
RA
Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development

Robert R. Fike, MS, PhD
Assistant Vice President, Regulatory Affairs
Japan, Asia Pacific/Latin American Policy and Intelligence, Wyeth Research

Major changes in Japanese pharmaceutical regulations are impacting the development of new drugs in Japan as well as global development programs. This tutorial will describe the major elements of the regulatory system including the Pharmaceuticals and Medical Devices Agency (PMDA), regulatory processes during development (consultations), and J-CTD review.

Several development strategies necessary to meet Japanese requirements for new drug approval will be identified. Postmarket surveillance and pricing reimbursement processes 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:
• Explain the major elements of the Japanese regulatory system
• Describe the regulatory processes during development, registration, and postapproval
• Discuss specific attributes in the Japanese regulatory system and their impact on multinational development strategies

Target Audience
This tutorial is designed for professionals in regulatory affairs, project management, and clinical development who are involved with global development projects involving Japan.

TUTORIAL 35
RA
A Device Primer: 510(k)s, PMAs, IDEs
3.25 AMA PRA Category 1 Credit(s)™

Barry S. Sall
Principal Consultant, PAREXEL International Corporation

Get up to speed on medical device clearances and approvals! This tutorial demystifies FDA’s medical device requirements. We will explain and provide a decision matrix for 510(k)s and PMAs, as well as a matrix to
clarify IDE requirements. Attendees will use that matrix to determine the appropriate pathway for public record/fictional products and explore the strategic implications behind the submission and its indications. We will examine investigational device exemptions, and discuss the role of IRBs and the level of FDA oversight as the trial proceeds.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Distinguish between 510(k)s and PMAs and their strategic advantages
- Describe the scope of IDEs (exempt, nonexempt, SR)
- Explain the nature and type of IRB and sponsor oversight
- Identify and manage major risks

**Target Audience**
This tutorial is designed for regulatory affairs (RA) managers, business development managers and staff; principal investigators, IRB members, clinical research associates (CRAs), academic sites; lawyers, R&D, and those working on combination products, cross-functional medical products and those wishing an introduction to devices.

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**TUTORIAL 36**  
**CR/CS, PP**  
**Designing, Operating and Evaluating Patient Registries**  
3.25 AMA PRA Category 1 Credit(s)™; 3.25 nursing contact hours; 286-000-10-502-L04-P; 3.25 contact hours or .325 CEUs

**Richard Gliklich, MD**  
President, Outcome

**Leanne Larson, MHA**  
Vice President, Strategic Development, Outcome

Physicians, payers, and patients are demanding an increasing amount of real-world evidence surrounding the results of medical products, therapies, and services in larger and more diverse populations. Whether disease-based or product-focused, registries provide real-world data on the safety and effectiveness of a product and/or insight into the natural history of a disease under standard care practices. Even though there is an increased demand for registries to fulfill these real-world data needs, there is still confusion over what a registry is, how it can be used and for what purposes, and what makes them high quality. Better planning and design of registries will enable these tools to be used more successfully in support of regulatory and reimbursement goals.

Unlike randomized clinical trials, there are no consensus standards for how registries should be developed, managed or evaluated. In May 2007, the US Health and Human Services’ Agency for Healthcare Research and Quality released the handbook, “Registries for Evaluating Patient Outcomes: A User’s Guide,” a landmark federal publication providing key information on developing, operating and evaluating patient registries.

In this interactive tutorial, the instructors will discuss practical issues in designing and operating patient registries including: when a registry is an appropriate approach to a requirement or research question; how to design and plan patient registries to address different purposes; operational issues (site recruitment, patient retention, and data management); HIPAA and Common Rule issues; and useful analytic approaches. Instructors will also describe how sponsors should expect registries to be evaluated by decision makers for quality. Registries designed for safety (including REMS), effectiveness, and quality purposes will be used as examples.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Identify key characteristics of registries
- Design and utilize registries for specific goals
- Apply good practice and enhancement recommendations to create a high-quality registry
- Discuss emerging challenges with registries and how they are being addressed

**Target Audience**
This tutorial is designed for regulatory affairs professionals, epidemiologists, drug safety professionals, medical affairs professionals, pharmacovigilance and quality management professionals, and clinical affairs professionals.

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**TUTORIAL 37**  
**AD, CR/CS, MA, MC, RA**  
**Social Media Marketing Accelerator**

**Jonathan Richman, MBA**  
Director of Strategic Planning, Bridge Worldwide

While not new, social media has become the hot topic in pharmaceutical and health care marketing. The recent FDA hearings on use of the social media by the industry have further highlighted the potential of this emerging channel. While many people worldwide have begun using various social media programs, the pharmaceutical and health care industries are still struggling with the best ways to get involved. This tutorial begins by showing some best practice examples of social media from both within and outside the industry. After this introduction, the focus shifts into the effective use of these channels for marketing, consumer interaction, public relations, and scientific study. In just a few short hours, you will have the basic knowledge of what is and what isn’t possible with the newest marketing channel available.

Participants are requested to bring their laptops to view various models on the Internet.

**Learning Objectives**
At the conclusion of this tutorial, participants should be able to:
- Describe the most and least effective social media marketing programs from multiple industries
- Summarize the current social media platforms used by patients and physicians
- Identify the marketing opportunities and challenges for social media
- Discuss both the accepted “etiquette” for participating in social media and applicable DDMAC regulations
- Analyze the current social media efforts of multiple pharmaceutical and health care companies
- Create a “best practice” process for creating and approving social media programs within their organization
Target Audience
This program is designed for individuals involved in marketing, legal, regulatory, public affairs, and advertising executives in the pharmaceutical and biologics industries, plus their consultants and agencies. If you find yourself talking more about social media and its application to your business, you should attend this tutorial.

FULL-DAY TUTORIALS

9:00 AM-5:00 PM  Fee: $650.00

TUTORIAL 40  CR, OS

Advanced CRO-vendor Management: Quality, Performance, and Compliance

Liz Wool, BSN, RN, CCRA, CMT
QD-Quality and Training Solutions, Inc.

Bree Martin
Brianne Martin Consulting, LLC

A recent FDA Sponsor Warning Letter citing “inadequate CRO oversight” (2009) that resulted in nonapproval of an NDA alerts industry to the requirement to manage CROs beyond the receipt of the deliverable and the requirement to implement a prospective set of quality standards, controls, and metrics, especially for outsourced monitoring activities, that are included in the CRO-vendor Management Plan. The quality standards, metrics, and associated controls (CRO-vendor Quality Plan), serve as the critical communication tool to the CRO regarding performance expectations and how deliverables will be evaluated for quality and compliance with regulations and study requirements! Further, this plan outlines for sponsor internal staff/teams a standardized, uniform approach to prospecively, in real-time, evaluate and track CRO performance during a clinical trial. As the regulators state “Sponsors do not delegate accountability for the quality of work transferred to a CRO”, the Sponsor maintains accountability at all times during a clinical trial for the quality and performance of work conducted on their behalf.

This hands-on tutorial utilizes a case study approach, focusing on outsourced site monitoring/site management activities, for participants to practice composing a CRO-vendor management quality plan utilizing proven ISO quality standards. The implementation of the CRO-vendor management quality plan requires modifications to the development of study budgets and CRO-vendor contract terms that will be examined in this tutorial.

PANEL DISCUSSION:
Implementing CRO-vendor Quality Plans – Resources, Budgets and Contracts!
Liz Wool and Bree Martin

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

• Identify the risks and associated risk mitigation strategies for outsourced activities through systematic review of the “CRO-vendor infrastructure” and “personnel” assigned to their study
• Describe and compose the CRO-vendor quality plan that is to be included in the CRO-vendor management plan for each outsourced clinical trial with a focus on outsourced site monitoring/site management activities
• Appraise vendor performance for outsourced activities
• Identify modifications to the development of study budgets and CRO-vendor contract terms

Target Audience
This tutorial is designed for professionals involved in clinical research, clinical operations, outsourcing, regulatory affairs, quality compliance, project managers, contract officers, commercial-medical affairs, sponsors, CROs, ACROs, AROs, NIH, DoD, and VA.

TUTORIAL 41  RA

Regulatory Affairs for Biologics
286-000-10-503-L04-P; 6.5 contact hours or .65 CEUs

Carol H. Danielson, MS, DrPH
President, Regulatory Advantage

In this tutorial, attendees will discuss proven strategies to achieve regulatory compliance for the development of biologics.

What You Will Learn
• Differences between traditional biologics and biotechnology products
• Regulatory needs and requirements for biologics
• Unique aspects in the development of specific biologics such as vaccines and gene therapy
• Differences in how CBER views product development compared to CDER

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

• Discuss specific regulatory requirements for biologics regulated by CBER
• Define expectations of CBER and how they differ from those of CDER
• Identify the unique aspects in the development of specific biologics such as vaccines and gene therapy
• Assess unique characteristics of biologics and why development differs from small molecules
• Compare the differences in regulatory needs and requirements for biologics compared to small molecules

Target Audience
This tutorial is designed for professionals involved in regulatory affairs, quality assurance, and project management.
TUTORIAL 44  CR/CS

Who's Monitoring the Monitor? Explore Trends, Management Techniques and a Reality Check for Sponsors Utilizing CRO- and Alliance-based Site Monitoring

Alicia Pouncey, MEd
Managing Director, Aureus Research Consultants, LLC

Explore trends, management techniques, and a reality check in current site monitoring activities! What’s working; what is not. This tutorial will cover ideas on how we can improve this time-intensive activity through a better understanding of the regulatory requirements and the current environment in clinical operations responsibilities, including interaction and oversight of outsourced monitors. The tutorial will also afford sponsor or contract research organization (CRO) site monitor managers an opportunity to see and discuss current trends regarding site monitoring activity, including new considerations for managing this resource.

Professionals who work with or manage site monitors will learn current trends and new ideas and considerations for site monitoring, including suggestions for improving management techniques.

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

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

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

TUTORIAL 43  CR/CS, ST

Clinical Statistics for Nonstatistician

Michael C. Mosier, PhD
Director, Biostatistics, EMB Statistical Solutions

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

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

- Define the purpose of site monitoring
- Identify sponsor responsibilities relative to site monitoring
- List trends in drug development, clinical operations, and study sites that impact site monitoring
- Compare current resourcing strategies in site monitoring
- Define ICH requirements for site monitoring
- Identify trends in the task of site monitoring
- List common errors made in site monitoring
- Identify trends in FDA warning letters relative to site monitoring
- Identify warning signs of problems with site monitors
- Define industry expectations for documentation of a routine site monitoring visit
- Identify categories to measure site monitor performance
- Discuss the most effective communication methods for site monitors
- Identify best practices in managing site monitors

Target Audience
This tutorial is designed for site monitor managers, project managers, CRA managers, medical monitors, resourcing managers, and sponsors from small- to mid-size pharmaceutical, biotechnology, and device companies.
DAILY HIGHLIGHTS

Monday, June 14

8:30 - 10:30 AM  Opening Plenary Session Featuring Keynote Address by Dr. Margaret A. Hamburg, Commissioner, US FDA
10:00 AM - 6:00 PM  Student Poster Session
10:30 AM - 12:00 PM  Multiregional Clinical Trials—It Takes a Global Village of Expertise
10:30 AM - 12:00 PM  Is Industry Supported Education the Next Taboo?
10:30 AM - 12:00 PM  Will Electronic Health Records (EHR) Destroy Clinical Research or Transform It?
10:30 AM - 12:00 PM  Multiregional Clinical Trials—It Takes a Global Village of Expertise
11:30 AM - 1:00 PM  Special Interest Area Communities (SIAC) Luncheon
11:30 AM - 2:00 PM  Extended Lunch Hours
12:00 - 1:30 PM  Professional Poster Session #1
2:00 - 3:30 PM  Executive Policy Forum: The New Landscape for Industry-Profession Relations—From Policy to Practice Part 2
4:00 - 5:30 PM  Implications of Health Care Reform for Product Safety and the Pharmaceutical Industry

Tuesday, June 15

8:00 - 9:30 AM  Multitrack Plenary Session—Implications of Comparative Effectiveness Research for Health Care Innovation
10:00 AM - 11:30 AM  European Medicines Agency Town Hall
10:00 - 11:30 AM  Project Management Plenary: Evolving Demands in a Changing Industry: Are You Prepared?
10:00 - 11:30 AM  Executive Policy Forum: The New Landscape for Industry-Profession Relations—From Policy to Practice Part 1
11:30 AM - 1:00 PM  Special Interest Area Communities (SIAC) Luncheon
11:30 AM - 2:00 PM  Extended Lunch Hours
12:00 - 1:30 PM  Professional Poster Session #1
2:00 - 3:30 PM  Executive Policy Forum: The New Landscape for Industry-Profession Relations—From Policy to Practice Part 2
2:00 - 3:30 PM  Pharmaceuticals and Medical Devices Agency (PMDA) Town Meeting
4:00 - 5:30 PM  Center for Drug Evaluation and Research (CDER) Compliance Update: Effective Enforcement Strategies
4:00 - 5:30 PM  Implications of Health Care Reform for Product Safety and the Pharmaceutical Industry

Wednesday, June 16

10:30 AM - 12:00 PM  Quality-by-Design: Linking Quality to Safety and Efficacy Part 1
12:00 - 1:30 PM  Professional Poster Session #2
1:30 - 3:00 PM  Quality-by-Design: Linking Quality to Safety and Efficacy Part 2
3:30 - 5:00 PM  Combination Products—Regulatory and Quality Aspects
3:30 - 5:00 PM  Center for Biologics Evaluation and Research (CBER) Town Hall

Thursday, June 17

8:30 - 10:30 AM  Qualifying New Translational Safety Biomarkers for Nonclinical and Early Clinical Development
8:30 and 10:30 AM  CDER Town Hall Parts 1 and 2
10:30 AM - 12:00 PM  Drug Master Files: Regulatory Aspects
The Challenges and Opportunities in Pharmaceutical Research and Development: Focus on Neuroscience
Darryle D. Schoepp
Senior Vice President and Franchise Head, Merck & Co., Inc.

If I Had Only Known
Carol L. Mitchell, MD
Global Medical Information (Men’s Health, Critical Care, Alzheimer’s), Eli Lilly and Company

Panelists
Ling Su, PhD
Senior Vice President and Head, Development Greater China
Novartis Pharmaceuticals Corporation, China

Robin L. Wintersperry, MD
President and CEO, Scientific Advantage LLC

Donna Ellender, PhD
Corporate Regulatory Affairs, sanofi-aventis, France

Sunday, June 13 – Student Forum

3:00 PM-5:00 PM  Room 150A
SESSION CHAIRPERSON(s)
Carol L. Mitchell, MD
Global Medical Information (Men’s Health, Critical Care, Alzheimer’s)
Eli Lilly and Company

Back by popular demand, the Student Forum has been designed to provide information of interest to students and an opportunity for students to provide input to the DIA. In addition to the presentations, representatives from the Professional Education, Training, and Development SIAC will then present “If I had only known…”, an entertaining and informative sketch of essential skills as well as a brief summary of career opportunities in the various fields within the pharmaceutical industry.

Objectives: Describe how innovation in the pharmaceutical industry will influence the nature and complexity of clinical research; Discuss the future needs for personnel in the clinical research enterprise and how they impact hiring trends; Discuss the planned and unplanned experiences which individuals have during their careers which affect the career path.

A Brief History of Student-focused Opportunities and Services at the DIA
Stephen A. Sonstein, PhD, MS
Director, Clinical Research Administration, Eastern Michigan University

More Than Just a Career
Kathryn Troutman
Founder and President, The Resume Place Inc.
Monday, June 14

8:30 AM-10:00 AM  Ballroom ABC, Level Three
Welcome Remarks/Awards Presentation
Jeffrey W. Sherman, MD, FACP
Executive Vice President and Chief Medical Officer, Development and Regulatory Affairs, Horizon Pharma, Inc.
President, DIA

Opening Remarks
Gaby L. Danan, MD, PhD
Senior Director, Global Pharmacovigilance and Epidemiology, sanofi-aventis, France
2010 Annual Meeting Chairperson

Keynote Address
Margaret A. Hamburg, MD
Commissioner, FDA

10:00 AM-10:30 AM  REFRESHMENT BREAK
Exhibit Halls A and B, Lower Level

MONDAY SESSIONS BEGIN

SESSION 101  MEGA TRACK PLENARY
AD - ADVERTISING
MA - MARKETING and MC - MEDICAL COMMUNICATIONS
10:30 AM-12:00 PM  LEVEL: ■
Room 150A  CME and pharmacy credits offered
Is Industry-supported Education the Next Taboo?
SESSION CHAIRPERSON(S)
John F. Kamp, JD, PhD
Executive Director, Coalition for Healthcare Communication

This session will discuss the proposals by the Institute of Medicine, Macey Foundation, Association of American Medical Colleges, and others to reduce or eliminate funding for certified continuing medical education for prescribers of drugs. It will also discuss related matters, including proposals by the ACCME (Accreditation Council for Continuing Medical Education) to change policies and rules for commercial support, proposals by medical societies such as the AMA (American Medical Association), ACC (American College of Cardiology), and the CMSS (Council of Medical Specialty Societies) to restrict commercial involvement in continuing medical education and other activities, and new federal transparency regulations passed as part of health care reform.

SESSION 102  BT - BIOTECHNOLOGY
10:30 AM-12:00 PM  LEVEL: ■
Room 207B  CME and pharmacy credits offered
Hot Topics in Biotechnology
SESSION CHAIRPERSON(S)
Joy A. Cavagnaro, PhD, RAC
President, Access BIO

This session will highlight three important areas in biotechnology: nanotechnology, stem cells, and oligonucleotides.

Translating the Precision of Microelectronics to the Production of Highly Uniform Shape-specific Carriers for Vaccines, Biologics, and Small Molecules
Joseph M. Desimone
William R. Kenan, Jr. Distinguished Professor of Chemistry and Chemical Engineer, University of North Carolina

Highlights from the March 2010 DIA/FDA/Health Canada 3rd Oligonucleotide-based Therapeutics Conference
David H. Schubert
Vice President, Regulatory Affairs and Quality Assurance, Logical Therapeutics Inc.

SESSION 103  CDM - CLINICAL DATA MANAGEMENT
CDM - CLINICAL DATA MANAGEMENT
10:30 AM-12:00 PM  LEVEL: ■
Room 207B  CME and nursing credits offered
Let’s Speak the Same Language: Experiences with the Use of CDISC-controlled Terminology in Pharmaceutical and Clinical Research
SESSION CHAIRPERSON(S)
Christine Tolk
Director, Terminology, CDISC

This session will consist of presentations on the development and implementation of CDISC-controlled terminology, an overview of development of controlled terminology for the SEND (Standard for Exchange of Non-clinical Data) FDA pilot, and the collaboration that was developed between the SEND Controlled Terminology team, the CDISC Terminology team, and NCI EVS staff, the processes used to develop, review, and finalize code lists. There will be a presentation on the governance and implementation of CDISC terminology and disease-specific standards and terminology.
SESSION 105  CSP - CLINICAL SAFETY AND PHARMACOVIGILANCE
10:30 AM-12:00 PM  LEVEL: ●
Room 143AB  CME, nursing, and pharmacy credits offered

The FDA's Safe Use Initiative
SESSION CHAIRPERSON(S)
Karen Weiss, MD
Associate Director for Medical Affairs, Office of the Center Director, CDER, FDA

This session will be an overview of the sources of risk from medical product use. It will introduce the FDA's Safe Use Initiative that focuses on situations when coordinated efforts between and among FDA and other stakeholders (eg, patient and consumer groups, health care practitioners, pharmacists, health care organizations, other Federal agencies) can reduce preventable harm from medication errors and from misuse, abuse, and self-harm.

Dale Slavin, PhD
Policy Analyst, CDER, FDA

J. Russell Teagarden
Vice President, Clinical Practices and Therapeutics, Medco Health Solutions, Inc.

Jeffrey A. Kelman, MD
Chief Medical Officer, Center for Drug and Health Plan Choice, CMS

SESSION 106  EC - eCLINICAL
10:30 AM-12:00 PM  LEVEL: ●
Room 204BC

Chaos and EDC: What to Avoid if You Possibly Can
SESSION CHAIRPERSON(S)
Ross Rothmeier
Senior Director, Global EDC Solutions, Covance Inc.

This session will share some experiences from people who have been involved with the implementation of products and strategies that did not deliver what was expected. The goal of this session is to provide lessons learned and suggestions for how to avoid some of the mistakes others have made.

Monitoring Mishmash: What to Avoid and How to Optimize Monitoring – Part 1
Catherine Radovich
Director, Clinical Development, QuatRx Pharmaceuticals

Monitoring Mishmash: What to Avoid and How to Optimize Monitoring – Part 2
Penelope K. Manasco, MD, MS
Chief Medical Officer, PharmaVigilant

Successful ePRO Implementation and Use: What the Vendors Won't Tell You
Steve Shevel, MBA
Associate, Waife & Associates, Inc.

SESSION 104  MEGA TRACK PLENARY

CR/CS - CLINICAL RESEARCH AND DEVELOPMENT/ CLINICAL SUPPLIES

AHC/IS - ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES
OS - OUTSOURCING
PM/FI - PROJECT MANAGEMENT/FINANCE
ST - STATISTICS

10:30 AM-12:00 PM  LEVEL: ●
Room 144ABC  CME and nursing credits offered

Multiregional Clinical Trials: It Takes a Global Village of Expertise
SESSION CHAIRPERSON(S)
Bruce Binkowitz, PhD, MSc
Senior Director, Clinical Biostatistics, Merck & Co., Inc.

This session will highlight lessons learned with regard to the design, implementation, summarization, and registration of information on multiregional clinical trials. Panelists will address these different issues and discuss how they are interconnected.

Globalization of Clinical Research: Clinical, Ethical, Regulatory, and Business Considerations
Douglas J. Peddicord, PhD
Executive Director, Association of Clinical Research Organizations

Robert J. Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA

Nancy Meyerson-Hess, MSc
Head, Business Development, Germany and Eastern Europe Harrison Clinical Research Deutschland GmbH, Germany

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

Robert T. O’Neill, PhD
Director, Office of Biostatistics, CDER, FDA

Andy Lee, MA
Senior Vice President, Global Clinical Operations, Genzyme Corporation

Harry Staines, PhD, MSc
Project Statistician, Boehringer-Ingelheim, France

SESSION 104  MEGA TRACK PLENARY

CR/CS - CLINICAL RESEARCH AND DEVELOPMENT/ CLINICAL SUPPLIES

AHC/IS - ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES
OS - OUTSOURCING
PM/FI - PROJECT MANAGEMENT/FINANCE
ST - STATISTICS

10:30 AM-12:00 PM  LEVEL: ●
Room 144ABC  CME and nursing credits offered

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Senior Vice President, Global Clinical Operations, Genzyme Corporation

Harry Staines, PhD, MSc
Project Statistician, Boehringer-Ingelheim, France

Session Specific Data Standards and Terminology:
A Review of Global Projects and Case Studies
Christine Tolk
Director, Terminology, CDISC

Terminology Governance and Implementation: What You Need to Know as a User
Jason Housley
Associate Director, Clinical Data Management, Infrastructure, Shire Plc., UK

Experience with Implementing Controlled Terminology Based on CDISC SDTM as Part of the SEND Project
Margaret Zorn, MBA, MS
Principal Consultant, Liquent, Inc.
**Session 107  ERS/DM 1 - Electronic Regulatory Submissions/Document Management**

10:30 AM-12:00 PM

Room 202A

From EDMS to Collaboration: The Drive Toward Content

**SESSION CHAIRPERSON(S)**

Donald G. Palmer, MA, RAC
Associate Director, Regulatory Systems, Medimmune, LLC

The session will consider the increasing focus of regulatory information management away from final documents and back to the authoring process. It will also suggest that pieces are moving into place for this conservative industry to address content management and that collaborative authoring will drive this change.

Donald G. Palmer, MA, RAC
Associate Director, Regulatory Systems, Medimmune, LLC

Data Is to Metadata as Document Is to?

Joel Finkle
Director, Regulatory Informatics, Image Solutions, Inc. (ISI)

Content Authoring Process: EDMS Collaboration Practical Applications

Jennifer L. Wemstrom
Principal Product Strategist and US Solutions Specialist Lead, CSC Life Sciences

**Session 108  ERS/DM 2 - Electronic Regulatory Submissions/Document Management**

10:30 AM-12:00 PM

Room 202B

Multilingual Labeling in the Context of PIM

**SESSION CHAIRPERSON(S)**

Matthias Heyn, MA
Vice President, Life Science Consulting, SDL International, Belgium

Managing global product information efficiently largely depends on how the central labeling group and the local affiliates organize their interactions. This session discusses how the various methods of local control, local outsourcing, or central outsourcing are best applied and what the imminent risks and benefits of each of the available approaches are. Specifically the role and interaction between central labeling, affiliates, external translation service providers and the regulator are discussed using the example of the European Centralized Procedure (CP) in its electronic submission form (PIM).

Matthias Heyn, MA
Vice President, Life Science Consulting, SDL International, Belgium

Managing PIM Translations Across the Organization

Matthias Heyn, MA
Vice President, Life Science Consulting, SDL International, Belgium

**European Medicines Agency Point of View**

Timothy Buxton
Head of Sector, ICT Development, European Medicines Agency, European Union

**Session 109  GCP - Good Clinical Practices**

10:30 AM-12:00 PM

Room 151A

Virtual Realities: Quality Considerations When Using Outsource Providers

**SESSION CHAIRPERSON(S)**

Deborah A. Waltz, MS, CIP
Senior Director, Scientific Operations Quality, King Pharmaceuticals

Sponsors sometimes wrongly assume that they have delegated ownership of quality responsibilities when they have contracted activities 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.

**Defining Service Quality**

Bruce M. Wagman, MBA, RN, RAC
Vice President, Regulatory Affairs and Quality Assurance Services, Covance Inc.

**Developing Quality Agreements in a GCP Environment**

Cheryl M. McCarthy, CQA, CBA
Manager, Quality Assurance, eClinical Solutions, a Division of Eliassen Group

**Regulatory Compliance Considerations When Outsourcing in a Clinical Trial**

Constance Lewin, MD, MPH
Branch Chief, Office of Compliance, CDER, FDA

**Prospective and Real-time Quality Strategies to Assure Project Success**

Deborah A. Waltz, MS, CIP
Senior Director, Scientific Operations Quality, King Pharmaceuticals

**Session 110  IT - Information Technology**

10:30 AM-12:00 PM

Room 206

CME and nursing credits offered

Building a Next Generation Data Standards Metadata Repository

**SESSION CHAIRPERSON(S)**

Barry R. Cohen, MS
Senior Director, Clinical Data Strategies, Octagon Research Solutions Inc.

A data standards metadata repository is a key to implementation of a standard-based, metadata-driven clinical data life cycle. This session will explore early results from organizations that are building the next generation of such repositories including results, challenges, and lessons learned.

**Leveraging CDISC Metadata to Benefit Your Organization**

David P. Iberon-Hurst
Vice President, Technical Strategy, CDISC, UK

**Roles of a Next Generation Standards Metadata Repository Application**

Barry R. Cohen, MS
Senior Director, Clinical Data Strategies, Octagon Research Solutions Inc.

**Implementing a Next Generation Standards Metadata Repository**

Diane E. Wold, PhD
Director, Data Standards, GlaxoSmithKline
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Basic-level content:primarily intermediate-level content:primarily advanced-level content

Session 115  RA 1 - Regulatory Affairs
10:30 AM-12:00 PM  LEVEL:
Room 146A
International Cooperation Among Regulators, Including the Exchange of Confidential Information
SESSION CHAIRPERSON(S)
Marie A. Dray, MA, MBA
President, International Regulatory Affairs Group LLC
Brenton E. James, FTOPRA
Consultant, Strategic Regulatory Affairs in the European Union, UK
This session will update the audience on cooperation and transparency among regulatory agencies, including the exchanges of confidential information. Senior executive regulators from the FDA, the European Medicines Agency (EMA), and the Japanese PMDA will share perspectives on their confidential arrangements for dialogue about products, processes, and public health issues. This session will also allow time for the audience to ask questions and share feedback with regulators on timely topics of mutual concern.

FDA Point of View
Murray M. Lumpkin, MD
Deputy Commissioner, International Programs, Office of the Commissioner, FDA

European Medicines Agency Point of View
Thomas Lönngren, Pharm, MPharm, MSc
Executive Director, European Medicines Agency, European Union

Pharmaceuticals and Medical Devices Agency Point of View
Tatsuya Kondo, MD, PhD
Chief Executive, PMDA, Japan

Session 116  RA 2 - Regulatory Affairs
10:30 AM-12:00 PM  LEVEL:
Room 150B
Combination Products: Developing an Integrated Regulatory Plan That Works
SESSION CHAIRPERSON(S)
Ann Tunstall, PhD
Managing Consultant, SciLucent LLC
Great progress in providing clarity regarding the review of combination products has been made since the inception of FDA's Office of Combination Products. This session will go beyond the basic presentation of information defining a combination product and describing approval pathways and Center jurisdiction. Participants will gain insight into FDA's thought process in evaluating data to support clinical trials and to support product approval. With this insight, participants will be better able to develop a realistic, integrated product development plan, both for internal planning and for presentation to FDA. In addition, participants will be better prepared to evaluate the impact of an unanticipated review pathway on development plans.

Point of View from the FDA
Patricia Y. Love, MD, MBA
Associate Director, Office of Combination Products, Office of the Commissioner, FDA

Scientific Basis for Clinical and Regulatory Requirements of Drug Fixed Combination Products
Hoss A. Dowlat, Esq., PhD
Vice President, Global Strategy, PAREXEL Consulting, Germany

Nonclinical Testing Strategies for Combination Products
Tracey Zoetis, MS
Consultant, SciLucent, LLC

Session 117  RA 3 - Regulatory Affairs
10:30 AM-12:00 PM  LEVEL:
Room 143C
Regulatory Roundtable on Biosimilar Policies
SESSION CHAIRPERSON(S)
Joseph Scheeren, PharmD
Senior Vice President, Head of Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals, Inc.
This session will explore the challenges of biosimilars in light of recent policy developments in the US, EU, and Asia. Participants will hear from a roundtable of health authorities and industry on how to address biosimilars and the opportunities they see for the future.

Biosimilars in Europe: Experiences and Challenges
Anthony Humphreys
Head of Regulatory, Procedural, and Committee Support, European Medicines Agency, European Union

Biosimilars in Japan: Point of View from the Pharmaceuticals and Medical Devices Agency
Teruyo Arato, PhD
Review Director, Office of Biologics I, PMDA, Japan

Biosimilars in the US: Challenges and the Path Forward
Gillian R. Woollett, MA, DPhil
Chief Scientist, Biologics and Biotechnology, Engel & Novitt LLP

Session 118  RA 4 - Regulatory Affairs
10:30 AM-12:00 PM  LEVEL:
Room 146B
Consideration on Ethnic Differences in Global Drug Development Including Asia Ten Years After ICH E5 Implementation
SESSION CHAIRPERSON(S)
Akio Uemura, PhD
Director, Regulatory Policy, Liaison, and Intelligence, Eli Lilly Japan K.K., Japan
This session is designed to discuss the ethnic difference issues among regions included in global simultaneous development and the appropriate regulatory approach in handling the issue in global NDAs (New Drug Applications). In this session, we will outline the impact of ICH E5 in the past ten
Some Regulatory Experiences in Multiregional Clinical Trials
H.M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Science, CDER, FDA

Pharmaceuticals and Medical Devices Agency Vision of the Future Ethnic Difference in the Handling of Global Regulations
Yasuto Otsubo, MPharm
Reviewer, Office of New Drug II, PMDA, Japan

Proposals to Address the Increased Ethnic Difference: A US Company’s Experience
Patrick J. O’Malley
Senior Director, International Regulatory Affairs, Eli Lilly and Company

Panelist
Yoshiaki Uyama, PhD
Review Director, Office of New Drug III, Leader for PMDA Omics Project, PMDA, Japan

SESSION 119  RA 5 - REGULATORY AFFAIRS
10:30 AM -12:00 PM  LEVEL: ■
Room 146C  CME and pharmacy credits offered

Qualification of Patient-reported Outcome (PRO) Tools to Support Labeling Claims: Development, Evaluation, and a Consortium Approach
SESSION CHAIRPERSON(S)
Laurie Burke, MPH, RPh
Associate Director, Study Endpoints and Label Development, CDER, FDA

Clinical trial endpoints that capture the patient perspective using PRO instruments provide valuable information for regulatory decision making as well as for product labeling. The targeted labeling claims are a critical element in determining the adequacy of the PRO tool as a key efficacy endpoint measure. CDER is in the process of drafting a guidance that will describe the process of how PROs, as well as other drug development tools, can be formally reviewed by CDER to support a specific context of use and purpose in clinical trials. This session will describe the types of evidence the Agency evaluates in review of a PRO tool and will also provide an overview of the proposed qualification review process. An example of a PRO instrument submitted to the Agency for qualification review will be discussed. Finally, an overview of the role of the PRO Consortium in the development of PRO tools for qualification review will be provided.

FDA Evaluation of PRO Measures for Regulatory Qualification to Support Claims
Elektra J. Papadopoulos, MD
Medical Officer, FDA

Development and Documentation of PRO Tools for Regulatory Review
Nancy Kline Leidy, PhD
Senior Vice President, Scientific Affairs, United BioSource Corporation

The Patient-reported Outcomes (PRO) Consortium: A Public-private Partnership Approach
Stephen Joel Coons, PhD, MEd, MSc
Director, PRO Consortium, Critical Path Institute

SESSION 120  RD - R&D STRATEGY
10:30 AM-12:00 PM  LEVEL: ■
Room 154AB  CME and nursing credits offered

Risks and Benefits in Using a Regional Service Providers (RPS) Model When Conducting Global Programs
SESSION CHAIRPERSON(S)
Richard Leach, MBA
Vice President, Business Development, Global Clinical Trials

This session will detail the growth, success, and risk of the regional CRO model in global projects. Through the use of case studies and the interaction of both regional CRO and sponsor presenters, attendees will receive a balanced perspective on the real challenges and benefits of this global model.

Panelists
Kata Mazalin
General Manager, Assign Group, Hungary

Robert John Davis, PharmD
Chief Operating Officer, ResearchPoint

Representative Invited
Vice President, Business Operations, Eagle Pharmaceuticals

12:00 PM-1:30 PM  LUNCHEON
Distribution of lunches 12:00-1:00 pm in Exhibit Hall C, Lower Level. A special seating section will be available for networking with colleagues from your professional interest area.

SESSION 121  AHC/IS - ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES
1:30 PM-3:00 PM  LEVEL: ■
Room 143AB  CME and nursing credits offered

How Investigator Budgets Impact Patient Enrollment and Retention: Improving Processes to Increase Productivity
SESSION CHAIRPERSON(S)
Daniel M. Ulrey, MBA
President and CEO, Midwest Clinical Support, Inc.

This session will address the issues of investigator budgets and how they impact site and investigator performance relating to patient enrollment and retention objectives as well as the profitability of commercial (non-academic) investigative sites. It will also present suggested improvements to the costly processes sponsors and sites use to prepare, initiate, and conduct studies that continue to decrease site performance, which negatively affects sponsor study timelines.

Contract and Budget Negotiations and the Importance of Processes
Nedra S. Rhodes, MA
Lead Contracts Specialist, REGISTRAT-MAPI, Inc.
A Site Perspective: Overcoming Obstacles to Successful Enrollment
Jeffrey M. Adelglass, MD
President and Chief Executive Officer, Research Across America

A View from a Sponsor: Identifying and Rewarding Investigative Sites
Ira C. Spector, MBA
Senior Vice President, Global Development Operations, Allergan, Inc.

**Session 122**
**BT - Biotechnology**
1:30 PM - 3:00 PM
Room 101

Gaining Critical Efficiencies in Biotechnology Drug Development Through Global Regulatory Strategies
**Session Chairperson(s)**
Lois M. Hinman, PhD
Global Head, Early Development and Biologics Oversight and Strategic Projects, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

This session will provide insights into both tactical and strategic considerations for development of biologics in a global environment. It will explore the new thinking by industry on the strategic considerations in planning global development for biologics and identify success factors for first-in-man studies and clinical development of biologics in an international setting. Tactics for obtaining timely scientific advice and building global development strategies will be discussed from perspectives of both industry and regulators.

- **Key Considerations for Global Development Strategies for Biologics**
  - Hoss A. Dowlat, Esq., PhD
    Vice President, Global Strategy, PAREXEL Consulting, Germany

- **Leveraging Emerging Markets as Part of a Global Strategy for Developing Biologics**
  - Mary Ellen Cosenza, PhD, MS, RAC
    Executive Director, Emerging Markets, Amgen Inc.

- **The Changing Environment for Biotechnology Development in Europe**
  - Hans-Georg Eichler, MD, MSc
    Senior Medical Officer, European Medicines Agency, European Union

**Session 123**
**CR/CS 1 - Clinical Research and Development/Clinical Supplies**
1:30 PM - 3:00 PM
Room 152A

A Town Hall Discussion: Who Is Accountable for Site Selection and Patient Recruitment?
**Session Chairperson(s)**
Larry A. Blankstein, PhD
Senior Director, Clinical Research, Genzyme Corporation

With all the meetings and discussion over the past several years on patient recruitment, clinical studies are still not completed on time. This is due to many factors, including protocol design, inadequate site selection, and less-than-spectacular patient recruitment by the site. We are all challenged with completing our clinical trials on time with quality data. To accomplish this we must select high-performing sites. What determines if a site is a high-performing site? How can we determine if a site will meet our expectations to deliver patients and quality data? Who is accountable to ensure success of the clinical site? This session will present ideas on how to approach these challenges and define the various roles and responsibilities for site selection and accelerating the enrollment cycle time.

- **Key Factors in Selecting Sites to Ensure They Meet Your Expectations to Enroll and Retain Patients While Providing Quality Data**
  - Victoria A. Dwyer DiBiaso, MPH, RN
    Director of Study Feasibility and Patient Enrollment, Genzyme Corporation

- **Patient Recruitment Strategy: When Should It Be Developed, What Are the Key Elements, and How Should the Site Be Managed to Meet Your Expectations**
  - James P. Kremidas
    Vice President, Global Head of Patient Recruitment, Quintiles Inc.

**Session 124**
**CR/CS 2 - Clinical Research and Development/Clinical Supplies**
1:30 PM - 3:00 PM
Room 152B

Cracking the Globalization Code: How to Do It Smarter, Faster, Better While Conforming to Evolving Regulatory Framework
**Session Chairperson(s)**
Sondra Pepe
Client Relations Specialist, Medidata Solutions Worldwide

This session will include representatives from three leading pharmaceutical companies with varying approaches to setting up and managing global trials. Each representative will discuss their approach, explaining its benefits and how it makes them smarter, faster and better. They will describe varying approaches such as a centralized approach to plans and budgets which are then negotiated with sites; an approach of using regional intermediaries to manage their trials in each world region; and an outsourcing approach to most of their global trial activity. After introductory descriptions, the panel will take questions from the audience and address the pros and cons of the different approaches. Special attention will be paid to how each method fares with respect to regulatory requirements across the globe.

- **Cracking the Code in Globalization: Choosing the Right CRO**
  - Colleen A. Cook
    Senior Manager, Vendor Management, Mitsubishi Tanabe Pharma Development America Inc.

- **Leveraging Regional Hubs for Global Trials**
  - William Candela, MBA
    Director, Contract and Grants Management, Bristol-Myers Squibb Company

- **Managing Sites for Global Studies**
  - Dex Bilkic
    Manager, Contracts and Budgets, Boehringer Ingelheim, Canada
**SESSION 125**  
**CR/CS 3 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**  
1:30 PM-3:00 PM  
Room 145B  
**Understanding the Benefits and Limitations of Drug Pooling**  
**SESSION CHAIRPERSON(s)**  
Leslie Darling  
Client Development Lead, Almac Clinical Technologies  
The increase in global studies, concurrent and like protocols, and costs of medication, packaging, and shipping are forcing the question to be changed from “should we drug pool?” to “how do we drug pool?” Fortunately, there are several ways to implement and benefit from drug pooling, especially when paired with an interactive voice response/interactive web response (IVR/IWR) system. This session will review the different methods of implementing drug pooling, what is required, and where challenges exist. In addition, approaches to maximize the benefits, regulatory concerns, and the confusion of drug pooling that exists in the industry will be discussed.

**Drug Pooling: Another Step Forward in the Evolution of Clinical Supplies Management**  
Julie Jacobs  
Director, Project Services, Almac Clinical Services  

**Pooling Drug Across Studies: Why Should It Be Done?**  
Carla Reis  
Randomization Specialist, Drug Supply Management, Bristol-Myers Squibb  

**Global Drug Supply: A Pooled Approach**  
Michael Vincent Nest  
Global Investigational Supply Operations, Millennium Pharmaceuticals, Inc.

**SESSION 126**  
**CR/CS 4 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**  
1:30 PM-3:00 PM  
Room 149AB  
**Fiscally Responsible Protocol Development: Minimizing Potholes and Avoiding Sinkholes**  
**SESSION CHAIRPERSON(s)**  
Anne B. Cropp, PharmD  
Executive Director, Pfizer Inc  
This session will focus on several aspects of best practice for protocol development, examine interdependencies of protocol development and the downstream impact (budget, full-time equivalents [FTEs], cycle time) of protocol amendments, and provide tips for avoiding potential sinkholes on the road of protocol development.

**Anticipating and Avoiding Protocol Amendments**  
Kenneth A. Getz, MBA  
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP  

**The Hidden Costs of Protocol Amendments: Money and FTEs**  
Anna L. Hindle, MSc  
Associate Director, Head of Medical Writing Operations, Biogen Idec  

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**SESSION 127**  
**CSP 1 - CLINICAL SAFETY AND PHARMACOVIGILANCE**  
1:30 PM-3:00 PM  
Room 143C  
**FDA Sentinel Initiative: Year 2**  
**SESSION CHAIRPERSON(s)**  
Melissa A. Robb, RN  
Senior Policy Analyst, Office of the Commissioner, FDA  
In May 2008, FDA launched the Sentinel Initiative with the goal of creating a nationwide electronic system for monitoring medical product safety. During the first year of the initiative, eight short-term contracts provided foundational knowledge to inform the building of the Sentinel System.

This session will discuss the latest updates in the second year of the initiative, including two pilots – Mini-Sentinel 1 utilizing private data sources and Mini-Sentinel 2 utilizing federal data sources. These two pilots are being initiated to develop the scientific methods needed to conduct active surveillance on a variety of medical products in a distributed system of automated health care data.

Marcus D. Wilson  
President and CEO, Health Core, Inc.  
Observational Medical Outcomes Partnership  
Thomas Scarnecchia, MS  
Vice President and Chief Technology Officer, Digital Aurora

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**SESSION 128**  
**CSP 2 - CLINICAL SAFETY AND PHARMACOVIGILANCE**  
1:30 PM-3:00 PM  
Room 140B  
**Stretching Boundaries in the Use of Data Mining: Its Role in Risk Management Planning**  
**SESSION CHAIRPERSON(s)**  
William W. Gregory, PhD  
Senior Director, Worldwide Safety Strategy, Pfizer Inc  
Data mining in drug safety has almost exclusively focused on the screening of spontaneous reports for detecting signals of novel adverse events. However, data mining could have value in other applications, including the construction of risk management plans. This session will demonstrate the potential of data mining to enhance patient safety in risk management planning and providing a glimpse into the future of risk management planning.

**Use of a Data Mining Method in Retrospective Screening of Spontaneous Data of Withdrawn Marketed Products**  
Jacinta U. Aniagolu, PhD, MSc  
Director, Pharmacovigilance and Risk Management, Synovate, LLC
**Session 129  MEGA TRACK PLENARY**
**IT - INFORMATION TECHNOLOGY**
CDM - CLINICAL DATA MANAGEMENT
EC - eCLINICAL
ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT
GCP - GOOD CLINICAL PRACTICES
VA - VALIDATION
1:30 PM-3:00 PM  LEVEL: ■
Room 144ABC  CME, nursing, and pharmacy credits offered

**Will Electronic Health Records (EHR) Destroy Clinical Research, or Transform It?**
SESSION CHAIRPERSON(s)
J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality (AHRQ)

CRACK! The first tremors of electronic health records (EHR) have split the foundations of clinical research. The fissures may not seem serious right now, but they could develop into breaks that threaten the very structure of clinical research. Many predict that health care reform will advance the use of EHR, resulting in ever more powerful tremors. Will transformed clinical research processes have the resilience to withstand the shaking?

A diverse panel of experts, who collectively understand clinical research, its underpinnings, and the size and likelihood of future EHR seismic events have been invited to share their views with you. This panel will be led through a discussion of the cracks, fissures, and structural details to identify the areas of clinical research we should be most concerned about in the next two to three years:

- CRACK! Are present protocol design processes ready to use EHR data?
- CRACK! Do we need source data verification of EHR data to maintain cGCP?
- CRACK! Can EHR help health care providers match patients with appropriate clinical trials?
- CRACK! Data must flow between clinical research and EHR, but those systems use different vocabularies – can dictionary management and harmonization help?
- CRACK! Privacy and security are at risk. Is patient ownership of EHR data being respected?
- CRACK! What are the global regulations on use/misuse of data? How is enforcement around the world keeping up?

**European Medicines Agency Point of View**
Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

**FDA Point of View**
Mitra Rocca, MS
Senior Medical Information Specialist, Office of Medical Policy, CDER, FDA

**Panelists**
Felix A. Khin-Maung-Gyi, PharmD, MBA, CIP, RAC
Chief Executive Officer, Chesapeake Research Review Inc.

Ethan M. Basch, MD, MSc
Medical Oncologist, Health Outcomes Group, Memorial Sloan-Kettering Cancer Center

Johann Pröve, PhD
Global Head, Data Management, Bayer Schering Pharma AG, Germany

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**Session 130  MC - MEDICAL COMMUNICATIONS**
1:30 PM-3:00 PM  LEVEL: ●
Room 145A  Pharmacy credits offered

**Pharmaceutical Marketing Primer**
SESSION CHAIRPERSON(s)
Janet L. “Lucy” Rose, MBA
President, Lucy Rose and Associates, LLC

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

- A Primer on Advertising and Promotion
  Kristin Davis, JD
  Deputy Director, Division of Drug Marketing, Advertising and Communications, CDER, FDA

- Pharmaceutical Marketing Principles
  Janet L. “Lucy” Rose, MBA
  President, Lucy Rose and Associates, LLC

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**Session 131  MW - MEDICAL/SCIENTIFIC WRITING**
1:30 PM-3:00 PM  LEVEL: ●
Room 151B

**Document Preparation When You’re Short on Time**
SESSION CHAIRPERSON(s)
Laura Webb, BSN, RN
President, WebbWrites LLC

Written summarization of data will often present the first as well as the most significant impression on reviewers, although it is typically allowed the shortest time to completion in the overall drug development process. Seasoned/experienced writers must continuously identify strategies that allow them to prepare quality documents under severe time constraints. There are many time-saving strategies that can be implemented at the beginning of a project or when warning signs of possible delays become apparent. Some of the areas where preventive action or actual intervention can occur include data analysis, document preparation, and document review.

- Key Performance Indicators for Medical Writing: Fact or Fantasy?
  Michael D. Hoffman, MS
  Senior Director, Medical Writing and Regulatory Operations, United BioSource Corporation

- Statisticians and Writers: Effective Ways to Work Together to Save Time
  Rebecca Drummond, PhD
  Principal Biostatistician, Lundbeck Inc

- So Many Documents, So Little Time
  Laura Webb, BSN, RN
  President, WebbWrites LLC

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**European Medicines Agency Point of View**
Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

**FDA Point of View**
Mitra Rocca, MS
Senior Medical Information Specialist, Office of Medical Policy, CDER, FDA
SESSION 132  NHP - NATURAL HEALTH PRODUCTS
1:30 PM-3:00 PM  LEVEL: ◆  Room 103B  Pharmacy credits offered
New Dimensions in NHP Regulations
SESSION CHAIRPERSON(S)
Werner Knoess
Scientific Director, Head of Department of HMP and CAM, BfArM, Germany
Recently, new concepts have been developed and applied to deal with the quality, safety, and efficacy of natural health products (NHP). Moreover, new analytical techniques and instrumentation have increased the data available for assessment of NHP. The major challenge in the regulation of NHP is to adapt requirements established for all medicinal products and also to consider the particular features of NHP, which are composed of complex mixtures of compounds. The session will review new strategies in Canada, Europe, and China, as well as discuss regulatory experiences to date.

Mitigating Risks to Health in the Premarket, Licensing, and Postmarket Stages of the Product Life Cycle
Maggie Graham
Head, Risk Management Division, Health Canada

The Concept of Well Established Use in the Development of Monographs for Herbal Substances/Preparations in Europe
Werner Knoess
Scientific Director, Head of Department of HMP and CAM, BfArM, Germany

Chinese TCM Regulations
Chun Liu
Section Chief, Division of TCMs and Ethnomedicines, SFDA, China

SESSION 133  OS - OUTSOURCING
1:30 PM-3:00 PM  LEVEL: ◆  Room 151A  CME and nursing credits offered
Strategies for Successful Relationships Between Sponsors and CROs
SESSION CHAIRPERSON(S)
Sheryl L. Storms, MS
Associate Director, CRO Quality Management, sanofi-aventis
As the strategies for partnerships between contract research organizations (CROs) and clinical trial sponsors continue to evolve, one area under increased scrutiny is sponsor oversight. As such, the importance of clear expectations between sponsors and CROs is imperative. This session will focus on the important key factors that sponsors and CROs can use to deliver successful trial outcomes. The session will also address the importance of the sponsor/CRO relationship relative to performance and compliance at the clinical trial team, program team, and company levels; the mechanics of sponsor oversight of CRO monitoring for GCP compliance; the application of periodic reviews to provide continuity for trial oversight; and mitigating risk (case study).

Performance and Compliance at the Clinical Trial Team, Program Team, and Company Levels
Mark E. Lloyd
Expert Clinical Trial Head, Novartis Pharmaceuticals Corporation

SESSION 134  PD/TR - PROFESSIONAL DEVELOPMENT/ TRAINING
1:30 PM-3:00 PM  LEVEL: ◆  Room 103A  CME and nursing credits offered
Social Learning in a Regulated Environment: Can It Work?
SESSION CHAIRPERSON(S)
Josephine Scrofani, MS
Vice President of Training, eClinical Solutions, a Division of Eiilassen Group
In today’s world, social learning is everywhere. You cannot get away from common household terms such as Facebook, LinkedIn, Twitter, wikis, blogs, or even virtual worlds. How does this all work in a regulated environment where compliance is critical? Does it work at all? This session reviews and examines various common social learning technologies and discusses how they may be used successfully in a regulated environment.

Surveying and Leveraging Your Professional Portfolio
Janet F. Zimmerman, MS, RN
Assistant Clinical Professor, Drexel University College of Nursing and Health Professions

How to Organize and Lead People in Group Work
Michael Laddin, MBA, MS
CEO, LeaderPoint, LLC

SESSION 135  PM/FI 1 - PROJECT MANAGEMENT/ FINANCE
1:30 PM-3:00 PM  LEVEL: ◆  Room 147A  PMI PDUs offered
Managing and Developing Business Relationships and Enhancing Partnerships in a Changing Environment
SESSION CHAIRPERSON(S)
Jennifer Charron
Director, Clinical Programs, RPS (ReSearch Pharmaceutical Services, Inc.)
Sponsors and service providers can learn to effectively manage and enhance business relationships and develop partnerships in changing business environments that strengthen communication and sharing of information and result in collaborative, proactive planning, and issue resolution.

What Happens After You Say “I Do”?  
Susan Torchio, BSN, RN  
Associate Director, Clinical Resourcing and Pain, Cephalon Inc.

Jennifer Charron  
Director, Clinical Programs, RPS (ReSearch Pharmaceutical Services, Inc.)
Foundation of Partnership Development Through Project Management Knowledge Areas
Thomas Mayewski
Director, sanofi pasteur
Glynis Archibald, MD, MBA, PMP
Senior Director, Integrated Clinical Programs, RPS (ReSearch Pharmaceutical Services, Inc.)

This interactive session will use case studies to highlight some real-life legal and regulatory issues that affect sponsors, investigators, and IRBs in the conduct of clinical trials. The session will touch upon legal and regulatory issues regarding such things as conflicts of interest, enrolling non-English-speaking subjects and enrollment incentives.

Jeffrey N. Gibbs, JD
Director, Hyman, Phelps & McNamara
John M. Isidor, JD
CEO, Schulman Associates IRB, Inc.

SESSION 138 RA 1 - REGULATORY AFFAIRS
1:30 PM-3:00 PM LEVEL: ♦
Room 146A
Going for BRIC: Accessing Emerging Markets and Japan Before or After US and EU Registration
SESSION CHAIRPERSON(S)
Alberto Grignolo, PhD
Corporate Vice President Global Strategy and Services, PAREXEL Consulting

The pharmaceutical world has turned its attention to emerging markets (eg, BRIC – Brazil, India, Russia, and China, to name a few) because of their current and anticipated high growth rates compared to the American and European markets. Japan has long been the world’s number two pharmaceutical market. Although historically companies have pursued and obtained registration in the US and EU before turning their attention to Japanese registration, the new openness of MHLW (Ministry of Health, Labour and Welfare) is encouraging companies to include Japan in their global drug development plans. This session will illustrate how several companies are approaching Japan and emerging markets today to accelerate drug development and registration in these commercially attractive regions.

Joseph Scheeren, PharmD
Senior Vice President, Head - Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals, Inc.

Emerging in the Emerging Markets
Graham H. Burton, JD, MD, FRCP
Senior Vice President, Regulatory Affairs, Pharmacovigilance and Corporate QA, Celgene Corporation

Evolving Sponsor Strategies and Tactics to Access Emerging Markets
Paul D. Huckle, PhD, MPharm, RPh
Senior Vice President, Global Regulatory Affairs, GlaxoSmithKline

SESSION 139 RA 2 - REGULATORY AFFAIRS
1:30 PM-3:00 PM LEVEL: ♦
Room 146B
Implementing a Life Cycle Management Regulatory Program for Therapeutics in Canada
SESSION CHAIRPERSON(S)
Agnes V. Klein, DrPH, MD
Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada
In Canada, as in two other major regulatory jurisdictions, the US FDA, and the European Medicines Agency, both evolutionary and revolutionary changes are occurring in the way the safety and the efficacy of therapeutics are managed. These changes are reflected in both legal/regulatory and operational considerations that will allow the implementation, in its full implications, of the management of the life cycle of therapeutic products. This session will provide a conceptual overview of life cycle management, from discovery of a product, to marketing, to removal from the market and describe the operational adjustments and processes used to develop this life cycle management concept and describe the many opportunities and some of the challenges to bring together organizational units with diverse mandates that need to collaborate in order to implement successfully the regulatory changes and the operational changes.

**Life Cycle Implementation from the Premarket Point of View**
Agnes V. Klein, DrPH, MD
Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

**Overview of Pharmacovigilance in Canada**
Marc Berthiaume, MD
Director, Marketed Pharmacologicals and Medical Devices Bureau, MHPD, Health Canada

**Challenges and Opportunities in the Safety Surveillance of Drugs Used in the Management of Autoimmune Diseases**
Duc Vu, PhD
Director, Marketed Biologicals, Biotechnology, Natural Health Products, HPD, Health Canada

**SESSION 140 RA 3 - REGULATORY AFFAIRS**
1:30 PM-3:00 PM  
Room 150B

**Center for Devices and Radiological Health Task Force Reports: 510(k) Devices Process Review and New Science in Regulatory Decision Making**

**SESSION CHAIRPERSON(s)**
Jonathan Sackner-Bernstein, MD
Associate Center Director, Postmarketing Operations, Office of the Center Director, CDRH, FDA

CDRH launched two task forces in the fall of 2009. This session will provide the opportunity for top-line components of the individual task force reports to be shared with interested parties.

**Discussants**
Christy L. Foreman
Director, Office of Device Evaluation, CDRH, FDA

Jonathan Sackner-Bernstein, MD
Associate Center Director, Postmarketing Operations, Office of the Center Director, CDRH, FDA

**SESSION 141 RA 4 - REGULATORY AFFAIRS**
1:30 PM-3:00 PM  
Room 150A

**Current Perspectives on the FDA Advisory Committee Process**

**SESSION CHAIRPERSON(s)**
Jonca C. Bull, MD
Vice President, Drug Regulatory Affairs, FDA Liaison Office, Novartis Pharmaceuticals Corporation

This session will provide an overview of the challenges and strategies for effective advisory committee meetings from the perspective of US FDA and industry representatives.

**FDA Advisory Committees: Regulatory Policy Update**
Jill Hartzler Warner, JD
Acting Associate Commissioner for Special Medical Programs, Office of the Commissioner, FDA

**FDA Advisory Committees: Office of New Drugs Perspective**
Robert Justice, MD
Director, Division of Drug Oncology Products, Office of New Drugs, CDER, FDA

**FDA Advisory Committees: Industry Perspective**
Sunita Zalani, PhD, RAC
Executive Director, Global Regulatory Affairs, Amgen Inc.

**SESSION 142 RD - R&D STRATEGY**
1:30 PM-3:00 PM  
Room 154AB

**Improving and Changing R&D Organizations with a Knowledge Management Focus**

**SESSION CHAIRPERSON(s)**
Carlos Augusto C. Sanmarco, Sr., PharmD, MBA
Clinical Operations Manager, Eli Lilly of Brazil Ltd., Brazil

Recognized as the main asset of any organization, intellectual capital is nowadays a constant worry for pharmaceutical companies, CROs, and investigator sites, and must be considered in all steps of an R&D strategy. The information related to R&D companies has been disseminated broadly, but there is no clear guidance for filtering and transforming it into knowledge and a competitive differential. This session will present some forms of knowledge management and considering human, structural, and customer capitals. Some practices currently used by leading companies to accelerate product development that will exemplify methodologies focused on processes, where the knowledge base is crucial, will also be addressed.

**Mining the Clinical Trials Landscape for Competitive Intelligence and R&D Strategy**
Sougato Das, MS
Product Manager, Thomson Reuters

**Accelerating Product Development**
Robert Spector
Principal, Tunnell Consulting

**How Pharmaceutical Companies, CROs, and Investigator Sites Can Improve Intellectual Capital Through Knowledge Management**
Carlos Augusto C. Sanmarco, Sr., PharmD, MBA
Clinical Operations Manager, Eli Lilly of Brazil Ltd., Brazil
**Session 143**

**ST - Statistics**
1:30 PM-3:00 PM  
**Room 140A**
CME, nursing, and pharmacy credits offered

**Noninferiority Studies: Regulatory and Industry Perspectives**

SESSION CHAIRPERSON(S)  
Karen Higgins, PhD  
Mathematical Statistics Team Leader, Office of Translational Science, CDER, FDA

Noninferiority studies are designed to show that one treatment “is not worse than another.” Though often necessary for ethical, scientific, and regulatory reasons, these studies may be difficult to plan and evaluate. The 2007 FDA Amendments Act (FDAAA) required that the Agency produce a guidance to provide scientific advice on the design of these trials. With views from regulatory and industry professionals, this session will describe the clinical and statistical issues that must be considered in planning, conducting, analyzing, and interpreting the noninferiority trials needed for regulatory decision making.

**Panelists**  
Robert T. O’Neill, PhD  
Director, Office of Biostatistics, CDER, FDA  
Kevin J. Carroll, MSc  
Chief Statistician, AstraZeneca, UK

**FDA’s Draft Guidance for Industry on Noninferiority Trials: Why It Is Needed and Key Features**  
Robert T. O’Neill, PhD  
Director, Office of Biostatistics, CDER, FDA

**The FDA Noninferiority Guidance: One Step Forward, or Two Steps Back?**  
Kevin J. Carroll, MSc  
Chief Statistician, AstraZeneca, UK

3:00 PM-3:30 PM  
**REFRESHMENT BREAK**  
Exhibit Halls A and B, Lower Level

**Session 144**

**AHC/IS - Academic Health Centers/Investigator Sites**
3:30 PM-5:00 PM  
**Room 143AB**
CME and pharmacy credits offered

**IRB Qualifications**

SESSION CHAIRPERSON(S)  
William E. Dirkes, MD, MBA  
President, Eagle Research Services

Sponsor/CROs and investigators have a vested interest in ensuring that they are working with an institutional review board (IRB) that functions well. The effectiveness of an IRB depends on three units working together – the process unit (standard operating procedures, operating structure), the board itself (review of the integrity of the study), and the administrative unit (provides regulatory advice and documentation for the board, and provides documentation of the board’s decisions). This session will have a representative from each of the units provide insights on how they internally evaluate the performance of their unit.

**Michael S. Noone**  
Chief Operating Officer, Centurion Clinical Research, LLC

**Session 145**

**BT - Biotechnology**
3:30 PM-5:00 PM  
**Room 101**
CME, nursing, and pharmacy credits offered

**Global Lessons Learned from Development of the Pandemic (H1N1) 2009 Vaccine**

SESSION CHAIRPERSON(S)  
Florence Houn, MD, MPH  
Co-chair, International Network, FDA Alumni Association

Important lessons have been learned by the biotechnology industry and by regulatory authorities regarding the development and licensure of the pandemic (H1N1) 2009 vaccine, particularly in Asia where the first pandemic (H1N1) vaccine was licensed by the Chinese State Food and Drug Administration. Sharing these scientific and regulatory considerations for future pandemic vaccine development will be important for public health. This session will bring together industry and regulators to discuss scientific, regulatory, and other issues related to advancing preparedness for new pandemic influenza vaccine development based on the previous year’s experience with the pandemic (H1N1) 2009 virus.

**Approaches to Licensure of Pandemic Influenza A (H1N1) 2009 Vaccines**  
Sara Gagneten, PhD  
Regulatory Scientist, Office of Vaccines Research and Review, Division of Vaccines and Related Products Applications, CBER, FDA

**Could We Do Better in Preparation of 2009 H1N1 Pandemic Vaccines?**  
Zhiping Ye, PhD  
Regulatory Scientist, Office of Vaccines Research and Review, Division of Vaccines and Related Products Applications, CBER, FDA

**Challenges in the Development of the Pandemic (H1N1) 2009 Vaccine**  
Yong Zou  
Manager, Quality Assurance Department, Sinovac Biotech Ltd., China

**Session 146**

**CDM - Clinical Data Management**
3:30 PM-5:00 PM  
**Room 207B**
Pharmacy credits offered

**Misusing EDC: Bad Examples and How to Fix Them**

SESSION CHAIRPERSON(S)  
Joseph S. Anderson  
Principal Associate, Waife & Associates Inc.

As the use of EDC (electronic data capture) becomes the norm in industry, many companies continue to miss the full benefit of what electronic data capture can offer. This session will move beyond generic observations, such as “We never changed our paper processes,” and will treat specific issues like data quality, data integrity, and data usability in depth.
practices that have had a major negative impact on the use of EDC. Presentations will provide real-life examples from speaker experiences or their own observations that can help session attendees maximize their own EDC operations and avoid repeating the mistakes of others.

**Swallow the EDC Pill, Don't Chew It: Lessons Learned About Electronic Data Capture**
William Gluck, PhD
Director, Clinical Data Management, Gilead Sciences, Inc.

**The Hidden Benefits of EDC: Why We Missed Them and How to Get Them Now**
Joseph S. Anderson
Principal Associate, Waife & Associates Inc.

**Ramping Up EDC Implementation: Turning Pitfalls Into Positives**
Elsie M. Mathews, MPH
Director, Data Operations, Bristol-Myers Squibb

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### Session 147
**CR/CS 1 - Clinical Research and Development/Clinical Supplies**
3:30 PM-5:00 PM
Room 152A

**Is This Trial Enrollable? Defining Recruitment Feasibility**

**SESSION CHAIRPERSON(S)**
Matthew Kibby, MBA
Director, Global Operations, BBK Worldwide, UK

Feasibility. It is on everyone’s lips in the clinical trial industry – study leaders, clinical operations executives, patient recruitment specialists. It is a word widely used but differently defined from company to company and even from individual to individual. This session will focus on one type of feasibility – recruitment feasibility – to help participants understand methods for answering the question, “Is this trial enrolable?”

**Comparing Recruitment Feasibility Methods for Traditional and Emerging Clinical Trial Markets**
Dan McDonald
Vice President, Business Strategy, Excel Life Sciences

**Recruitment Feasibility Components and Tools: Strengths and Limitations**
Martin Lee, MD
Executive Director, Site and Patient Recruitment, PPD, Inc.

**Recruitment Feasibility for Clinical Trials: A Call to Action**
Matthew Kibby, MBA
Director, Global Operations, BBK Worldwide, UK

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### Session 148
**CR/CS 2 - Clinical Research and Development/Clinical Supplies**
3:30 PM-5:00 PM
Room 152B

**Clinical Research in Asia: Beyond Confirmatory Trials**

**SESSION CHAIRPERSON(S)**
Deborah Chee, DrMed, MD
Medical Director, Abbott Korea Ltd., Republic of Korea

Asia has been attracting global clinical research, especially late phases of studies with the region’s large patient population and competitive study cost. This session will focus on challenges in early-phase clinical research and will describe Asia’s infrastructure and strengths in early-phase clinical research by sharing the experience and success cases as a new option.

**New Trend and Challenges in Early-phase Clinical Trial Operation**
Victoria A. Dwyer DiBiaso, MPH, RN
Director of Study Feasibility and Patient Enrollment, Genzyme Corporation

**Early-phase Clinical Trial Experience in Korea**
Yi-Seob Lee, MD, PhD, MBA
Medical and Regulatory Director, Medical Department, GlaxoSmithKline Korea, Republic of Korea

**Infrastructure and Potential for Early-phase Clinical Research in Korea**
Kyung-Sang Yu, MD, PhD, MBA
Professor of Clinical Pharmacology, Seoul National University, Republic of Korea

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### Session 149
**CR/CS 3 - Clinical Research and Development/Clinical Supplies**
3:30 PM-5:00 PM
Room 145B

**Centralized Monitoring: When Does It Make Sense?**

**SESSION CHAIRPERSON(S)**
Ramita Tandon, MPH, MSc
Senior Director, Project Management, Peri-approval Services (PACE), PAREXEL International

Late-stage development studies, ranging from large-phase 3b studies supporting marketing applications to noninterventional postmarketing programs, increasingly require study monitoring procedures that more effectively balance the requirements of the sponsor and the needs of a diverse set of physician investigators. Economies of scale are needed to optimize operations and control study costs. Investigators demand a more efficient use of their time, and sponsor budget limitations have required a revisiting of the traditional formulaic strategies of monitoring as well.

**Adaptive Monitoring**
Michael J. Rosenberg, MD, MPH
President and CEO, Health Decisions Inc.

**The Hidden Benefits of EDC: Why We Missed Them and How to Get Them Now**
Joseph S. Anderson
Principal Associate, Waife & Associates Inc.

**Ramping Up EDC Implementation: Turning Pitfalls Into Positives**
Elsie M. Mathews, MPH
Director, Data Operations, Bristol-Myers Squibb

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### Session 150
**CR/CS 4 - Clinical Research and Development/Clinical Supplies**
3:30 PM-5:00 PM
Room 149AB

**Perspectives of the IRB Process in Phase 1 Studies Conducted in an Academic Setting**

**SESSION CHAIRPERSON(S)**
Vivian L. West, PhD, MBA, RN
Project Leader, Duke Clinical Research Unit

Obtaining Institutional Review Board (IRB) approval to conduct a phase 1 clinical trial presents unique challenges for an academic site conducting the phase 1 study, the pharmaceutical sponsor, and the IRB. This session examines how the three stakeholders approach these unique challenges.
Moderator
Barry Mangum, PharmD
Director, Clinical Pharmacology, Duke University Medical Center

IRB Perspective
Glenn Veit, JD
IRB Chairperson, Copernicus Group IRB

Sponsor Perspective
Anne B. Croppe, PharmD
Executive Director, Pfizer Inc

Session 151  CR/CS 5 - Clinical Research and Development/Clinical Supplies
3:30 PM-5:00 PM  LEVEL:  
Room 146A  CME and nursing credits offered
Clinical Trials: The Race to Study Launch and Speed to Finish
SESSION CHAIRPERSON(S)
Elizabeth A. Moench
President and CEO, MediciGLOBAL Inc.

CROs and pharmaceutical companies are undertaking ways to speed the process of study launch and accelerating patient recruitment through to data lock. Such initiatives involve the global adoption of new processes, technologies, market research analysis, team structure and communications, and more. This session will look at the approaches companies and their task forces are undertaking to accelerate study start to achieve an on time or early study finish.

But, as we focus on the start, let us not forget the end. This session brings together multiple disciplines and players involved in the process of rapid study start and also explores each person’s accountability for successful study conclusion.

Alistair John MacDonald, MS
Executive Vice President, Strategic Development, INC Research, Inc.

Peter A. DiBiaso, MHA
Senior Director, Clinical Planning and Performance, Vertex Pharmaceuticals

Christopher H. Cabell, MD, FACC
Senior Vice President, Access to Patients, Quintiles Transnational Corp.

Session 152  CSP 1 - Clinical Safety and Pharmacovigilance
3:30 PM-5:00 PM  LEVEL:  
Room 143C  CME and nursing credits offered
New Business Models for Postmarketing Surveillance: Beyond ASTER
SESSION CHAIRPERSON(S)
Martin J. Hatlie, JD
CEO, Coalition for Quality and Patient Safety (CQPS) of Chicagoland

New models for postmarketing safety are operating today – and they are not coming from pharmaceutical companies. There are organizations that are finding new sources of safety data and new ways to utilize that data. Will the pharmaceutical industry get involved? Or will they buy safety data the way they buy prescription data? This session will explore

What Can Pharmacovigilance Learn from the Patient Safety Movement?
Martin J. Hatlie, JD
CEO, Coalition for Quality and Patient Safety (CQPS) of Chicagoland

Postmarketing Reporting: New Models, New Challenges
Michael A. Ibara, PharmD
Head of Pharmacovigilance Information Management, Pfizer Inc

Patient-reported Adverse Events: Experience from a Web 2.0 Company
James A. Heywood
Co-founder and Chairman, PatientsLikeMe

Session 153  CSP 2 - Clinical Safety and Pharmacovigilance
3:30 PM-5:00 PM  LEVEL:  
Room 140B  CME and nursing credits offered
Balancing Computational Power and Clinical Prowess in Safety Signal Detection
SESSION CHAIRPERSON(S)
Sally Van Doren, PharmD
President and Chief Executive Officer, BioSoteria, Inc.

The CIOMS (Council for International Organization of Medical Sciences) Working Group VIII has recognized the balance between the use of automated signal detection methods and the need to engage the prepared mind. This session will review the CIOMS VIII recommendations, methods and technology of data mining, and the critical role of good clinical judgment in safety signal detection.

Quantitative Safety Signal Detection and CIOMS VIII Working Group Recommendations
Andrew Bate, PhD, MA
Senior Director, Analytic Team Lead, Epidemiologist, Worldwide Safety Strategy, Pfizer Inc

Safety of Biologics in Cancer Care: Applied Data Mining
Sheila Weiss Smith, PhD, MS, FISPE
Professor, University of Maryland School of Pharmacy
Director, Center for Drug Safety

A New Approach to Aggregate Data Analysis and Signal Detection
Irene Fermont, MD
Vice President, Pharmacovigilance and Risk Management, Advanced Drug Development Services, France
**Session 154**  
EC - eClinical  
3:30 PM-5:00 PM  
Room 204BC

**Standards-based Approach to Creating One Elegant Multisystem Solution**

**Session Chairperson(s)**  
Carl Labb, Jr., MSc  
Manager, New Products and Services, Almac Clinical Technologies

Making that data available during the trial and afterwards presents considerable challenges to sponsors as data streams come from a variety of suppliers and systems, most commonly IVR/IWR (interactive voice response/interative web response), ePRO (electronic patient-reported outcomes), and EDC (electronic data capture). This session offers practical advice managing data integration using CDISC ODM (operational data model) guidelines to assure data quality standards.

Andrew Newbigging  
Vice President, Integrations Development, Medidata Solutions  
Worldwide, UK

Sheila C. Rocchio, MBA  
Vice President, Marketing and Product Management, PHT Corporation

Samuel W. Hume, MS  
Director, IS Architecture, AstraZeneca Pharmaceuticals

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**Session 155**  
ERS/DM 1 - Electronic Regulatory Submissions/Document Management  
3:30 PM-5:00 PM  
Room 202A

**Data and Document Due Diligence: What Is Being Done and NOT Done!**

**Session Chairperson(s)**  
Nancy P. Smerkanich  
Vice President, Global Regulatory Affairs, Octagon Research Solutions Inc.

This session will be an introduction to due diligence from different points of view: sponsor, regulator, and vendor. This is not intended to be a legal presentation on due diligence, but rather a primer on how to enhance the process. Speakers will focus on documentation as well as data aspects. Case studies on both successful and unsuccessful procedures will be shared.

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

A Vendor Perspective  
Nancy P. Smerkanich  
Vice President, Global Regulatory Affairs, Octagon Research Solutions Inc.

A Sponsor Perspective  
Owen Jiang, MS  
Senior Clinical Data Manager, PGxHealth™, a Division of Clinical Data

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**Session 156**  
ERS/DM 2 - Electronic Regulatory Submissions/Document Management  
3:30 PM-5:00 PM  
Room 202B

**Electronic Laboratory Notebooks: Perspectives from Three Biopharmaceutical Companies**

**Session Chairperson(s)**  
Cindy Cullen, MSc  
Chief Technology Officer, SAFE-BioPharma Association

Electronic laboratory notebooks (eLNs) are used by lab scientists to record the day’s research. When signed with digital signatures, they become useful evidence in protecting intellectual property. SAFE-BioPharma digital certificates simplify how eLNs are handled and signed. This session will provide an overview of SAFE-BioPharma digital signatures, their use to sign eLNs in the biopharmaceutical industry, and the many efficiencies and cost-saving advantages associated with this use. Speakers will explain how their respective companies are using SAFE-BioPharma digital signatures to sign eLNs and chemistry electronic notebooks in ways unique to each organization.

Life Beyond a Paper Laboratory Notebook  
Jay Stevenson  
R&D, Bristol-Myers Squibb Company

Implementing Digital Signatures in a Scientific Organization  
Anna E. Plappert, MBA, MS, PMP  
Senior Manager, IT Projects, sanofi-aventis

Digital Signatures at Scale: Simplifying the User Experience  
Michael Lavoie, PMP  
Senior Manager, Identity Services, Pfizer Inc

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**Session 157**  
GCP - Good Clinical Practices  
3:30 PM-5:00 PM  
Room 151B

**Computer Systems Compliance: Dealing with Computer Systems, Part 11, and EHR – What You Need to Know**

**Session Chairperson(s)**  
Michael R. Hamrell, PhD, RAC  
President, MORIAH Consultants

The session will cover the obligations for clinical sites and sponsor organizations regarding meeting the requirements for Part 11 and the use of electronic records.

Electronic Records and Part 11: Regulatory Requirements  
Michael R. Hamrell, PhD, RAC  
President, MORIAH Consultants

Electronic Medical Records: Site’s Bane or Blessing  
Yvonne P. McCracken, MPH  
President and CEO, Carolinas Research Associates

Electronic Health Records and Part 11: Friends or Foes?  
Leonard A. Grunbaum, MBA  
Partner, The Practical Solutions Group LLC
### Session 158
**IT1 - Information Technology**
3:30 PM-5:00 PM
Room 206
**Channelling Metadata to Gain Control of the Clinical Trial Process**
**SESSION CHAIRPERSON(S)**
Lisa D. Mulcahy
Pharmaceutical Research Consultant, Mulcahy Consulting, LLC

In theory, the value of metadata is extensive. In practice, capturing metadata is widely challenged by those who have to input the data into a variety of systems for document and data collection, clinical trial management, data transformation, analysis, and reporting. Pharmaceutical companies are facing a significant challenge to adopt and adapt industry metadata standards, governance models for metadata, and how to move forward and gain benefit through the use of metadata in their organization. It is important to establish new methodologies for the integration of both metadata and the platforms which house them so as to allow the automation of flexible high-level cross-platform processes. In turn, through the alignment of technology with processes and the definition of clear metrics based on available metadata, we are able to gain in-depth knowledge and improved control over clinical trial processes.

#### Data Warehouses: An Introduction and Case Study Examination
**Terry D. Hardin**
Senior eTrial Architect, PAREXEL

#### A Knowledge-based Collaborative Model for the Rapid Integration of Platforms, People, and Processes
**Paul Fenton, MBA**
Vice President, Pharmaceutical Processes and Technology, Montrium Inc., Canada

#### Introduction of the Expanded Trial Master File Reference Model
**Lisa D. Mulcahy**
Pharmaceutical Research Consultant, Mulcahy Consulting, LLC

### Session 160
**MC - Medical Communications**
3:30 PM-5:00 PM
Room 145A
**Promotional Challenges Posed by Risk Evaluation and Mitigation Strategies (REMS)**
**SESSION CHAIRPERSON(S)**
Wayne L. Pines
President, Regulatory Services and Health Care, APCO Worldwide Inc.

Risk evaluation and mitigation strategy programs consist largely of communications elements. These elements are regulated by FDA just as promotional materials are. But REMS program also include other elements. This session will address some of the special regulatory considerations applied to REMS programs.

- **FDA Point of View: Challenge of Regulating REMS Communications Elements**
  **Gerald J. Dal Pan, MD, MPH**
  Director, Office of Surveillance and Epidemiology, CDER, FDA

- **Point of View from DDMAC**
  **Thomas W. Abrams, MBA, RPh**
  Director, Division of Drug Marketing, Advertising and Communication (DDMAC), CDER, FDA

### Session 159
**IT2 - Information Technology**
3:30 PM-5:00 PM
Room 207A
**Health Information Interoperability**
**SESSION CHAIRPERSON(S)**
Elliot B. Sloane, PhD, MSEE, CCE, FHIMSS
Research Professor and Director, Health Systems Engineering Program, Drexel University School of Biomedical Engineering, Science and Health Systems

This session will provide an overview of the current US health information interoperability program and its intended improvement of the safety, efficacy, and cost of healthcare. Current DoD (Department of Defense), government sector, and international programs will be discussed and contrasted to our US “Meaningful Use” program for private medicine, and the specific benefits intended for US consumers, patients, hospitals, and clinicians will be presented. Implications and opportunities for the drug industry will be discussed.

- **The Interoperability Value Proposition: Better Health and Wellness for US Consumers Communities**
  **Walter G. Suarez, MD, MPH**
  Director, Health IT Strategy, Kaiser Permanente

**The US Interoperability Framework**
**Representative Invited**
Scientific Director, Office of the National Coordinator, Office of the Secretary, Department of Health and Human Services

**IHE (Integrating the Healthcare Enterprise): Enabling and Promoting Worldwide Interoperability**
**David S. Mendelson, MD**
Co-chair, IHE International, Professor of Radiology, Mt. Sinai Hospital

### Session 161
**MW - Medical/Scientific Writing**
3:30 PM-5:00 PM
Room 102AB
**The Medical Writing Great Debate: Medical Writers SHOULD Be Scientists**
**SESSION CHAIRPERSON(S)**
Karen L. Woolley, PhD
Associate Professor, University of Queensland
CEO, ProScribe Medical Communications, Australia

Should medical writers be scientists? This controversial and topical issue will be hotly debated by respected medical writers. Slides will be banned in favor of passionate, pithy, and persuasive arguments. If you need to hire or contract a medical writer, or you want to be one, you need to attend this session!

- **Affirmative Team Leader**
  **David B. Clemow, PhD**
  Scientific Communications Consultant, Lilly USA, LLC, Eli Lilly and Company

- **Affirmative Team**
  **Michael John Mihm, PhD**
  Manager, Medical Writing and Scientific Communications, i3 Statprobe
With more than half of clinical trials today conducted using electronic data capture (EDC), and more than 50% of trials conducted by CROs, it is increasingly important to understand how CROs and EDC can best work together to maximize benefits for the trial sponsor. This session will include representatives from a clinical research sponsor, a global CRO, and an EDC vendor who will present their perspectives on partnering for success. Attendees will gain a better understanding of the importance of assessing and choosing the right EDC vendor and the value of EDC-CRO alliances; best practices in EDC-CRO alliances, including product capabilities, knowledge transfer, tools and support, along with innovative team approaches to data management; the value of strategically designed partnerships with well aligned roles and teams to streamline and enhance EDC outsourcing processes for sponsors; and clinical data management approaches that are optimized to EDC.

Partnering to innovate and Overcome the Limitations of Conformity and the Path of Least Resistance
Drew Garty
Senior Director, Worldwide eClinical Solutions, PAREXEL International

Sponsor Responsibilities in the Triangle of EDC and Clinical Outsourcing
Ronald S. Waife, MPH
President, Waife & Associates Inc.

A CRO’s Experience in Managing Relationships with eClinical Providers in a Technology Transfer and Software as a Service (SaaS) World
Wayne Walker
Senior Product Manager, Business Solutions, PRA International
**Session 165**  
**PM/FI 1 - Project Management/Finance**  
3:30 PM-5:00 PM  
Room 147A  
**Comprehensive Effectiveness Considerations in Venture Capital Funding Decisions**  
**Session Chairperson(s)**  
Alberto Grignolo, PhD  
Corporate Vice President, Global Strategy and Services, PAREXEL Consulting  
In the past year comparative effectiveness (CE) has emerged as a key focus area in health care reform efforts in the United States, even as it has been a factor in other regions (eg, EU) for years. Emerging biopharmaceutical companies seeking funding from venture capital (VC) firms have heard that at least one VC firm is urging applicants to incorporate CE research in their drug development plans and business plans. This session will include speakers from the VC community and the sponsor community to illustrate the VC preferences with regard to CE (as funding is now becoming more available) and to provide guidance to the audience on how to integrate CE research into successful funding applications.

**Panelists**  
Robert W. Jevon, MBA  
Partner, Boston Millennia Partners  
Gary Patou, MD  
Managing Director, MPM Capital  
Charles A. Stevens  
Vice President, Reimbursement and Market Access Practice, PAREXEL Consulting  

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**Session 166**  
**PM/FI 2 - Project Management/Finance**  
3:30 PM-5:00 PM  
Room 147B  
**Implementing Earned Value Management in Clinical Operations: Case Studies**  
**Session Chairperson(s)**  
Kristin Lucas, PMP  
Senior Director, Clinical Services, ClearTrial, LLC  
As earned value management (EVM) gains wider acceptance for obtaining greater visibility over clinical project status, accruals, and resource demand, implementation questions are also increasing. This session will examine successful EVM implementations across a range of biopharmaceutical companies and review elements that led to their success. This session will also provide further real-world examples and case studies of how biopharmaceutical companies have implemented EVM in their clinical organizations.

**Improving Accrual and Contract Management with Earned Value and SOX Compliance**  
Sally Teeters  
Director, Legal and Business Operations Management, Calistoga Pharmaceuticals, Inc.

**Can EVM Help Align Accruals, Milestones, and CRO Partner Contracts?**  
Todd Georgieff, MBA, RPh  
Functional Excellence Lead, Outsourced Study Management, Genentech, Inc.

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**Session 167**  
**PM/FI 3 - Project Management/Finance**  
3:30 PM-5:00 PM  
Room 146C  
**Right People, Right Place, Right Time: The Holy Grail of a Resource-constrained Industry**  
**Session Chairperson(s)**  
Peter Harpum, MSc  
Managing Director, Harpum Consulting Ltd., UK  
The session will cover the approach used by a big pharmaceutical company in the development of a conceptual model of resource management, turning that model into a vision for the future, and the use of standard project and portfolio management software to automate the processes needed.

**Bespoke Resource Management Maturity Models to Envision Future Capability**  
Peter Harpum, MSc  
Managing Director, Harpum Consulting Ltd., UK  

**Organizational Change Issues when Implementing Low Maturity Resource Management**  
Clay P. Lowry, CPA  
Director, R&D Resource Management, GlaxoSmithKline  

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**Session 168**  
**PP 1 - Public Policy/Law/Corporate Compliance**  
3:30 PM-5:00 PM  
Room 209AB  
**Drug Counterfeiting: New Actions and Initiatives**  
**Session Chairperson(s)**  
Yves Juillet, MD  
Senior Advisor, LEEM, France  
Drug counterfeiting is an increasing public health threat with worrying global consequences. National actions have been taken in the US, and in the EU, but improved cooperation at the international level is key, including the development of the WHO IMPACT initiative. First results have been obtained, but new developments are necessary to succeed, eg, in the fight against illegal Internet pharmacies. This session will discuss how the emerging countries could be more involved in these efforts.

**Supply Chain Security: Home and Abroad**  
Ilisa B.G. Bernstein, JD, PharmD  
Director, Pharmacy Affairs, Office of Policy, Office of the Commissioner, FDA

**New Initiatives of the Council of Europe**  
Sabine Walser, PharmD, MPH, RPh  
Administrative Officer, Council of Europe, EDOM (European Directorate for the Quality of Medicines and Healthcare), France

**Industry Views and Actions**  
Mark Paxton, JD, MS  
Associate Vice President, Regulatory Affairs, PhRMA
**SESSION 169 | PP 2 - PUBLIC POLICY/LAW/ CORPORATE COMPLIANCE**

**3:30 PM-5:00 PM**

**Room 146B**

**CME and pharmacy credits offered**

**Legal Considerations for REMS Design and Implementation**

**SESSION CHAIRPERSON(s)**

David V. Ceryak, JD

Assistant General Counsel, Eli Lilly and Company

Risk evaluation and mitigation strategies (REMS) trigger a number of legal implications that sponsors should consider in connection with design and implementation of these programs. While the FDA has been given broad discretion to implement REMS, the FDA Amendments Act (FDAAA) nonetheless defines some important parameters for the goals of REMS, the types of REMS elements that can be required, and the sponsor’s responsibility for monitoring the practices of third parties (pharmacists, HCPs, and patients). REMS also raise concerns about data privacy, consent, and consistency with the product label. Specific examples of the above points will be discussed as well as the potential complexity of implementing REMS from the perspective of third parties.

- **Statutory Requirements for REMS**
  David V. Ceryak, JD
  Assistant General Counsel, Eli Lilly and Company

- **Impact of REMS on the Health Care System**
  Marcie Bough, PharmD
  Director, Federal Regulatory Affairs, American Pharmacists Association (APhA)

- **REMS Compliance Obligations and Enforcement Risks for Sponsors and Third Parties**
  Erika F. Lietzan, JD, MA
  Partner, Covington & Burling LLP

**SESSION 170 | RA 1 - REGULATORY AFFAIRS**

**3:30 PM-5:00 PM**

**Room 150A**

**CME credits offered**

**Postmarketing Requirements and Commitments (PMRs/ PMCs): A Global Perspective on Their Role in Drug Development**

**SESSION CHAIRPERSON(s)**

Cathryn C. Lee, MSN

Project Management Officer, FDA

Postmarketing studies and clinical trials are an integral phase of drug development and are utilized by drug regulatory authorities worldwide to gather additional information about a product's safety, efficacy, optimal use, quality, stability, or consistency in manufacturing. This session will describe the role of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) in drug development and how they are developed and tracked by the three major drug regulatory authorities: US Food and Drug Administration (FDA), the European Medicines Agency, and the Japanese Ministry of Health, Labour, and Welfare (MHLW).

- **The FDA Perspective**
  Susan L. Honig, MD
  Medical Reviewer, Guidance and Policy Team, Office of New Drugs, CDER, FDA

**SESSION 171 | RA 2 - REGULATORY AFFAIRS**

**3:30 PM-5:00 PM**

**Room 150B**

**CME and pharmacy credits offered**

**Chinese Regulatory Session: Update from the Center for Drug Evaluation**

**SESSION CHAIRPERSON(s)**

Ling Su, PhD

Senior Vice President and Head, Development Greater China, Novartis Pharmaceuticals Corporation, China

Ning Li, MD, PhD

Senior Group Director, Regulatory and Medical Policy, sanofi-aventis, China

This session will present two updates from senior management at the Center for Drug Evaluation (CDE) of the State Food and Drug Administration in China. The first presentation will discuss the initiatives and measures that CDE has taken in the drug review process and practice within CDE to enhance and facilitate regulatory review, such as GRP initiative, sponsor-reviewer communication mechanism, as well as the future perspectives in the context of innovation and globalization. The second presentation will focus on the CMC/quality control in the review of traditional medicines.

- **Recent Developments in Drug Regulatory Review in China**
  Yi Feng
  Director, Evaluation Management and Coordination Department, CDE, SFDA, China

- **Technical Review of Traditional Medicines: Focus on CMC Aspects**
  Jun Hu
  Director of No. 1 Evaluation Department, SFDA, China

**SESSION 172 | RA 3 - REGULATORY AFFAIRS**

**3:30 PM-5:00 PM**

**Room 144ABC**

**CME and pharmacy credits offered**

**FDA and European Medicines Agency Update on Relative Efficacy/Effectiveness**

**SESSION CHAIRPERSON(s)**

Robert J. Temple, MD

Deputy Center Director for Clinical Science, CDER, FDA

Hans-Georg Eichler, MD, MSc

Senior Medical Officer, European Medicines Agency, European Union

This session will discuss how, historically, drug regulatory agencies have considered quality, safety, and efficacy of new drugs, while relative efficacy assessment and cost-effectiveness analyses were a domain of health technology assessment (HTA) bodies. Both technological advances, such as the availability of an increasing number of therapeutic alternatives, and other developments have, in a number of jurisdictions, led to a rising request for...
relative efficacy data to be made available earlier during the drug life span. At the same time, the research-based pharmaceutical industry finds itself confronted with sometimes divergent requirements from regulators and HTA bodies/drug reimbursement agencies.

**European Medicines Agency Perspective**

Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

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**SESSION 173**

**RD - R&D STRATEGY**

3:30 PM-5:00 PM  LEVEL: ■

Room 154AB  Pharmacy credits offered

**Impact of US and EU Pediatric Legislation**

SESSION CHAIRPERSON(s)

Klaus Rose, MD, MS
Principal Consultant, Granzer Regulatory Consulting & Services, Germany

Legislative requirements for pediatric studies in the US and EU present challenges for companies worldwide seeking regulatory approval in those markets. For example, European Medicines Agency expectations for pediatric investigation plans (PIPs) are quite demanding, more than expected based on the US precedent. The impact of US and European Medicine Agency pediatric study requirements and incentives on the business of drug development, regulatory authority workload, and public health will be addressed.

**Impact of Pediatric Legislation on the Pharmaceutical Industry**

Klaus Rose, MD, MS
Principal Consultant, Granzer Regulatory Consulting & Services, Germany

**Impact of Pediatric Legislation on Pediatric Clinical Research Networks**

Rosalind L. Smyth, MD
Head of School of Reproductive and Developmental Medicine, Institute of Child Health, University of Liverpool, Alder Hey Children’s NHS Foundation Trust, UK

**Pediatric Research in Biologics: A Case Study in Psoriasis**

Thorsten Olski, MD
Scientific Administrator, European Medicines Agency, European Union

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**SESSION 174**

**ST - STATISTICS**

3:30 PM-5:00 PM  LEVEL: ◆

Room 140A

**Issues with Missing Data in Confirmatory Clinical Trials: Europe and US Views**

SESSION CHAIRPERSON(s)

David J. Wright, PhD, MS
Senior Statistical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), UK

This session will focus on recent developments in regulatory guidance documents on missing data in Europe and the key issues highlighted in a report of the US National Academy of Sciences National Committee on Statistics on missing data in clinical trials. The session will include talks from US and UK regulators on these documents, and there will be a panel discussion with regulators and industry to explore the implications for how missing data should be handled in future regulatory submissions.

**What Has Changed in the Revised CHMP Missing Data Guideline?**

David J. Wright, PhD, MS
Senior Statistical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), UK

**FDA Perspective**

Thomas Permutt, PhD
Director, Division of Biometrics II, CDER, FDA

**An Assessment of Evolving European and FDA Guidance on Missing Data in Clinical Trials**

Paul Flyer, PhD
Department of Biostatistics, Pacific Northwest Statistical Consulting Inc.

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5:00 PM  END OF MONDAY AFTERNOON SESSIONS

5:00 PM-6:00 PM  RECEPTION IN THE EXHIBIT HALL

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6:15 PM-7:15 PM  **CISCRP SPECIAL EVENT**  Ballroom AB

**Voices of Medical Heroes: A Family’s Journey of Hope**

John Crowley, President and CEO of Amicus Therapeutics

See page 4 for more information.

* This CISCRP event is provided through an unrestricted education grant from Quintiles, Inc.
The Challenges of Developing New Nomenclature for New Biologicals
James S. Robertson, PhD
Principal Scientist; INN Expert Group Vice Chairman and Rapporteur, National Institute for Biological Standards and Control (NIBSC), UK

INNs for mAbs and Glycoprotein Biotherapeutics
Robin Thorpe, PhD
Head, Biotherapeutics Group, National Institute for Biological Standards and Control (NIBSC), UK

USAN and INN
David B. Lewis, PhD, RPh
Pharmaceutical Assessment Lead, Office of Pharmaceutical Science, Office of New Drug Quality and Assessment, CDER, FDA

Session 201  AD - Advertising
8:00 AM-9:30 AM  LEVEL: ★★★
Room 147A
Pharmacy credits offered

FDA Enforcement Update: Regarding Advertising and Promotion
SESSION CHAIRPERSON(S)
Wayne L. Pines
President, Regulatory Services and Health Care, APCO Worldwide Inc.

FDA enforcement actions need to be understood by every regulated company because they reflect FDA's priorities and concerns in regulating advertising and promotion. FDA professionals examine the latest FDA enforcement actions and what they mean in this session.

Enforcement Update from CBER
Ele Y. Ibarra Pratt, MPH, RN
Branch Chief, Advertising and Promotional Labeling Branch, Office of Compliance and Biologics Quality, Division of Case Management, CBER, FDA

Enforcement Update from DDMAC
Thomas W. Abrams, MBA, RPh
Director, Division of Drug Marketing, Advertising and Communication (DDMAC), CDER, FDA

Session 202  BT - Biotechnology
8:00 AM-9:30 AM  LEVEL: ★★★
Room 147B

International Nonproprietary Names (INNs) for Biological Substances: Focus on Monoclonal Antibodies (mAbs) and Gene Therapy Products
SESSION CHAIRPERSON(S)
Raffaella G. Balocco Mattavelli, PharmD, PhD
Manager, International Nonproprietary Name Program, World Health Organization, Switzerland

This session gives an update of the efforts to streamline the process of assigning international nonproprietary names (INNs) to biological and biotechnological substances. It also highlights how transparency and efficiency can be improved in cooperation with the industry applicants and other key parties involved, such as major regulators. The complexities involved in assigning INNs is explained, underlining their importance for the different health sector players, including pharmaceutical industries.
This session will outline FDA expectations for information on manufacturing facilities required to be submitted in NDA (new drug application)/ANDA (abbreviated new drug application) and facility readiness for a preapproval inspection.

**Is Your Product Ready for the Drug Approval Process?**
**Michael Bruckheimer, RPh**
Executive Director, Group Quality Assurance, Novartis Pharmaceuticals Corporation

**Preapproval Inspections Field Perspective**
**Myriam Sosa**
Consumer Safety Officer, Office of Regulatory Affairs, FDA

**Manufacturing Facility Information Needed in the Drug Application**
**Michael Folkendt, MS**
Associate Director for Regulatory Affairs, Office of Pharmaceutical Science, Office of New Drug Quality and Assessment, CDER, FDA

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**SESSION 206 NATURAL HEALTH PRODUCTS**

**8:00 AM-9:30 AM LEVEL: »**

**Room 140A**

**Pharmacy credits offered**

**Safety Perspectives Including Adulteration for Dietary Supplements**

**SESSION CHAIRPERSON(S)**
**Pulok K. Mukherjee, PhD, MPharm, RPh**
Scientist, Central Council for Research in Homoeopathy, Department of AYUSH, Ministry of Health & Family Welfare, Government of India

Drug safety is a rapidly growing area in the pharmaceutical and allied industry. The use of natural health products (NHP) as dietary, nutritional supplements or herbal remedies is going through revolutionary changes, particularly with new initiatives for obtaining regulatory approvals globally, including in the US. This session will focus on World Health Organization (WHO) safety standards and the association of adulteration to the product safety. New FDA regulations on adverse event reporting for dietary supplements will also be addressed.

**Herbal Drug Adulteration by Botanicals Substitute: Their Monitoring and Surveillance for Future Safety**
**Soundararajan Rajan, PhD**
Scientist, Central Council for Research in Homoeopathy, Department of AYUSH, Ministry of Health & Family Welfare, Government of India

**FDA Perspective**
**Robert J. Moore, PhD**
Supervisor, Regulations Implementation Team, Office of Nutrition, Labeling, and Dietary Supplements, CFSAN, FDA

**WHO Activities Relating to Safety and Quality of Herbal Medicines**
**Yukiko Maruyama, MT, RPh**
Scientist, Traditional Medicine, World Health Organization, Switzerland

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**Welcome and Opening of Session**
**Judith L. Glennie, PharmD, MSc**
Director, Strategic Health Technology Assessment (HTA), Medical and Government Affairs, Janssen-Ortho, Inc., Canada
SESSION 207  PD/TF - PROFESSIONAL DEVELOPMENT/Training
8:00 AM-9:30 AM  LEVEL: ■
Room 140B
Coaching Teams in the Matrix Environment
SESSION CHAIRPERSON(S)
Amber Sauer, MEd
Training and Development Manager, Rho, Inc.
A matrix environment can be difficult at times, especially when dealing with team and individual performance issues. This session will help leaders effectively address performance issues and create coaching plans even when they are not the employee’s direct manager.

Coaching the Next Generation of Pharmaceutical Professionals
Morgan L. Seaman
Learning and Development Senior Manager, ResearchPoint

SESSION 208  PM/FI - PROJECT MANAGEMENT/Finance
8:00 AM-9:30 AM  LEVEL: ■
Room 151A
PMI PDUs offered
The Project Manager’s Role in Leading Successful Transitions in the Drug Development Cycle
SESSION CHAIRPERSON(S)
Hema Rupani, MBA, MS, PMP
Senior Project Manager, Amgen Inc.
Project managers and product development teams are confronted with a myriad of key strategic and tactical questions throughout the product development cycle and postlaunch, but especially during transitions between various stages of drug development. Project managers play a crucial role in leading teams and obtaining aligned decisions on strategic questions during the entire development process but especially during the transition periods. Specific skill sets, job knowledge, and competencies are needed of project managers to affect the right decisions at the right time. This session will examine the project manager’s role in successfully leading the team through key transition points in the drug development cycle. Speakers from small and large organizations will share their perspectives using specific examples of skill sets and project management best practices they feel are important to ensure effective transitions between various stages of drug development. The session will also illustrate ways in which project managers can implement project management capabilities and strategic thinking toward effective drug development within their organizations.

Leading Your Project Team into the Clinic: Success Within Large and Small Organizations
Ellen M. Yurek, MS
Director, Project Management, Adamas Pharmaceuticals

Successful Transition from Phase 2 to Phase 3 Drug Development
Sandra J. Zeckel, RPh, PMP
Advisor, Project Management, Eli Lilly and Company

Strategy and Leadership: Phase 3 to Launch Transition Success
Angela Stambaugh, MBA, MS
Global Program Manager, Amgen Inc.

SESSION 209  ST - STATISTICS
8:00 AM-9:30 AM  LEVEL: ■
Room 151B
CME and pharmacy credits offered
Meta-analysis Related to Regulatory Issues: Ruling Out Detrimental Drug Effects on Mortality and Morbidity
SESSION CHAIRPERSON(S)
Andreas Brueckner, MS
Statistician, Bayer Schering Pharma AG, Germany
The cardiovascular safety profile of certain anti-diabetic drugs has been under discussion in the wake of recent publications in major medical journals. In December 2008, the FDA released a new guidance titled “Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes” that makes recommendations about how to demonstrate that a new anti-diabetic therapy to treat type 2 diabetes is not associated with an unacceptable increase in cardiovascular risk. This is an example of a general trend to require more and better safety data and prospectively planned meta-analyses at the time of submission and beyond. Some of the statistical issues include how to plan for and meta-analyze clinical trial data in which many trials may have no events, and how to address multiplicity concerns in such a setting. In this session, we will discuss in detail some of the general issues around analyzing safety data from clinical trials with cumulative meta-analysis methods giving room for academia, industry, as well as regulatory perspectives.

Meta-analysis for Rare Adverse Event Data from Clinical Trials
Brenda Jean Crowe, PhD
Research Advisor, Global Statistical Sciences, Eli Lilly and Company

Evaluating Cardiovascular Risk in Diabetes Clinical Trials: An FDA Statistician’s Perspective
Jon Todd Sahlroot, PhD
Deputy Director and Team Leader, FDA

9:30 AM-10:00 AM  REFRESHERMENT BREAK
Exhibit Halls A and B, Lower Level

SESSION 210  AD - ADVERTISING
10:00 AM-11:30 AM  LEVEL: ■
Room 151A
Pharmacy credits offered
Update on Direct-to-consumer Advertising (DTC)
SESSION CHAIRPERSON(S)
Kristin Davis, JD
Deputy Director, Division of Drug Marketing, Advertising and Communications, CDER, FDA
This session will present an update on direct-to-consumer (DTC) advertising from a broad perspective and with highlights from FDA professionals who are responsible for policy development and operations on this important topic.

DDMAC Direct-to-consumer Update
Sangeeta Vaswani, PharmD
Group Leader, Office of Medical Policy, Division of Drug Marketing, Advertising, and Communications, CDER, FDA
DDMAC Direct-to-consumer Update
Helen W. Sullivan, PhD, MPH
Social Science Analyst, Division of Drug Marketing, Advertising, and Communications, CBER, FDA

CBER Direct-to-consumer Update
Jean Makie, MSc
Regulatory Reviewer, Advertising and Promotional Labeling Branch, CBER, FDA

Session 211  AHC/IS - Academic Health Centers/Investigator Sites
10:00 AM-11:30 AM  LEVEL: ●
Room 140A  CME, nursing, and pharmacy credits offered
Use of Patient-targeted Informatics for Minority Recruitment into Clinical Trials
SESSION CHAIRPERSON(S)
Barbara H. Gladson, PhD, MS
Director, Biopharma Educational Initiative; Professor; University of Medicine and Dentistry of New Jersey

This session promotes understanding of the effects of disparities and diversity on participation in a clinical trial. Underlying factors contributing to these disparities, their influence on health outcomes and participation in clinical trials, will be analyzed. In addition, new approaches to study recruitment will be presented, including patient-targeted informatics, clinical trial alert systems, and web recruiting. These systems will be explained from an effectiveness standpoint as well as from a cost-effectiveness viewpoint. Pilot data plus data collected on an ongoing basis from a five-year project will be presented.

Use of Patient-targeted Informatics to Collect Health Data and Attitudes on Clinical Trials
Andrew N. de la Torre, MD
Associate Professor, Department of Surgery, University of Medicine and Dentistry of New Jersey

An Analysis of Factors Contributing to Disparities in Minority Recruitment
Natalie Dewberry-Moore, MS
Global Trial Optimization, Merck & Co., Inc.

Digital Approaches to Promote Recruitment of Diverse Populations
Brendan O’Neill
Associate Director, Global Trial Optimization, Merck & Co., Inc.

Session 212  BT - Biotechnology
10:00 AM-11:30 AM  LEVEL: ■
Room 101  CME and pharmacy credits offered
Challenges in Bringing Novel Cell-based Therapies from Experimental Studies into Successful Clinical Programs
SESSION CHAIRPERSON(S)
William T. Lee, PhD, RAC
Senior Regulatory Scientist, Cato Research

Exciting progress has been made in the development of cell-based therapeutics, and experimental research has brought forward novel treatment opportunities of allogeneic or autologous cell-based products, in some cases optimized by gene modification. Clinical development is challenging, requiring understanding of controlled manufacturing, relevant nonclinical pharmacology and safety studies, and clinical risk factors. This session will include an overview of the current status from bench to bedside and illustrate the caveats and practical feedback to maximize success.

Introduction to the Development of Cell-based Therapies
William T. Lee, PhD, RAC
Senior Regulatory Scientist, Cato Research

Perspective on Pharm/Tox Assessment for Cell- and Gene-modified Cell Therapy Products
Ying Huang, PhD
Pharmacologist, Office of Cellular, Tissue, and Gene Therapies, CBER, FDA

Regulatory and Clinical Development Aspects for Stem Cell Therapies
Deborah Ladenheim, PhD
Vice President, Regulatory Affairs, Athersys, Inc.

Panelist
Gopalan Narayanan, MD, MRCP, FRCP
Head, Biologicals and Biotechnology Unit, MHRA, UK

Session 213  CDM - Clinical Data Management
10:00 AM-11:30 AM  LEVEL: ■
Room 150B  CME, nursing, and pharmacy credits offered
Electronic Health Records (EHR) and Data Management: What It Means for Us in Clinical Data Management
SESSION CHAIRPERSON(S)
Johann Pröve, PhD
Global Head, Data Management, Bayer Schering Pharma AG, Germany

There is a light on the horizon. The introduction of EDC (electronic data capture) has almost been completed. It is, however, still cumbersome to enter data from one electronic system (electronic health records) in hospitals into another electronic system (EDC). With the harmonization of CDISC and HL7, there is at least an opportunity to bridge these two systems and allow the electronic interfacing of both. Such a change in data management would completely change its processes, which, however, have not been defined yet. This session will shed some light on what can already be done today using EHRs and provide an outlook into the future.

Next Phase of eClinical: Technology Guide to Leverage Electronic Medical Records and eSource Data
Nick Lucas, PhD
Vice President, Data Management, INC Research, Inc., UK

Addressing the Inevitable: The Effect of Government’s Health IT Initiative on Data Management in Clinical Trials and Clinical Research
Charlene L. Dark, MBA
Director, Clinical Data Management, i3 Statprobe

Using EHR Data to Optimize Clinical Trials
Aidan Farrell
Strategic Marketing, GE Healthcare
**SESSION 214**  
**CMC/GMP - Chemistry, Manufacturing, and Controls/Good Manufacturing Practices**  
10:00 AM-11:30 AM  
Room 102AB  
Quality-by-design for Biotechnology  
**SESSION CHAIRPERSON(S):**  
Steven Kozlowski, MD  
Director, Office of Biotechnology Products, CDER, FDA  
Quality-by-design (QbD) approaches offer opportunities for efficient, flexible manufacturing of high-quality pharmaceuticals. QbD can be applied to biotechnology products as well as small molecules. This session will include mock case studies and an FDA pilot program that can facilitate the implementation of QbD for biotechnology products. These strategies will increase the understanding of QbD risk-based approaches for manufacturing development and for the establishment of design spaces for biotechnology products.  

The Promise of QbD and What Will Likely Come True in Practice  
**Anthony R. Mire-Sluis, PhD**  
Executive Director, Global Product Quality, Amgen Inc.  

Experiences in Developing, Communicating, and Implementing QbD  
**Stephen M. Notarnicola, PhD**  
Principal Scientist, Biogen Idec  

Controversy in the Implementation of QbD: Examples of Design Space and Control Strategy Approaches for a mAb Manufacturing Process  
**Jonathan L. Coffman, PhD**  
Principal Engineer II, Drug Substance Development, Pfizer Inc  

**SESSION 215**  
**CR/CS 1 - Clinical Research and Development/Clinical Supplies**  
10:00 AM-11:30 AM  
Room 145A  
Creating an Interactive Connection Between Clinical Strategy and Clinical Operations  
**SESSION CHAIRPERSON(S):**  
Gary Tyson  
Senior Vice President, Clinical Development Practice, Campbell Alliance Group, Inc.  
During this session, clinical development leaders will hear real, practical case studies of clinical strategy and operations plans. They will also learn to understand the importance of building strong and lasting relationships between clinical strategy and clinical operations, and to build a framework to bring back to their organizations regarding how to create and maintain an interactive connection between clinical strategy and clinical operations.  

Gary Tyson  
Senior Vice President, Clinical Development Practice, Campbell Alliance Group, Inc.  

Graeme Currie, PhD  
Vice President, Clinical Operations, Sepracor Inc.  

Lee F. Allen, MD, PhD  
Chief Medical Officer, Senior Vice President, AMAG Pharmaceuticals  

**SESSION 216**  
**CR/CS 2 - Clinical Research and Development/Clinical Supplies**  
10:00 AM-11:30 AM  
Room 140B  
Fostering Global Collaboration Through Adoption of a New Enrollment Planning Culture  
**SESSION CHAIRPERSON(S):**  
Linda Theresa Drumright  
COO, DecisionView, Inc.  
R&D initiatives to drive standardization of the enrollment planning and forecasting process are challenging leaders to change the dynamic of global teams and create a data-driven environment of collaboration and transparency. This session will review the tools available to eliminate manual analysis, create more predictable portfolio planning, and address the challenges of implementing new tools and processes that enable transparency and accountability in the enrollment planning process.  

Driving Standardization in Planning Processes Across an Organization  
**Brian W. Dudt, MBA**  
Director, Performance Analytics and Benchmarking, Pfizer Inc  

IT's Role in Supporting Collaboration and Transparency Within the Business  
**Munther Baara, MS**  
Director, R&D Clinical Business Systems and Processes, Pfizer Inc  

From Instinct to Insight: Delivering Predictable Performance  
**Alex Lancksweert**  
Business Lead, Simplifying Clinical Information Environment, GlaxoSmithKline  

**SESSION 217**  
**CR/CS 3 - Clinical Research and Development/Clinical Supplies**  
10:00 AM-11:30 AM  
Room 145B  
Incorporating Risk Management Strategies into Premarketing Clinical Trials  
**SESSION CHAIRPERSON(S):**  
Annette Stemhagen, DrPH, FISPE  
Senior Vice President, Safety, Epidemiology, Registries and Risk Management, United BioSource Corporation  
With the increasing focus on risk minimization, many pharmaceutical companies are increasingly beginning to develop risk management programs during premarketing clinical trials. This session will discuss risk management strategies that can be used early in the development phase and how to use clinical trials and results to shape risk management programs during commercialization.  

Translating Premarket Risk Assessments into Postmarketing Risk Management Programs  
**Mwango Kashoki, MD, MPH**  
Associate Director, Safety, Office of New Drugs, CDER, FDA  

**Catherine Sigler, PhD, DVM**  
Senior Director, United Biosource Corporation
Tuesday, June 15

**Session 218**
**CR/CS 4 - Clinical Research and Development/Clinical Supplies**

10:00 AM-11:30 AM  
Room 143C  

**Phase 1 Clinical Safety: Subjects and Signals**  
**Session Chairperson(s)**
Royce A. Morrison, MD, MS  
Director, Clinical Strategy, Charles River Clinical Services

Early-phase clinical designs serve increasingly complex objectives – protecting study participants from first single-ascending dose through multiple-ascending dose, enrolling mixed populations, sensitively detecting toxicity signals and distinguishing from background “noise,” and protecting both patients and drugs with good decisions.

**Biologics: Safety from Preclinical to First-in-human**  
Barbara G. Matthews, MD, MPH  
President, BioDirect Inc.

**Biologics: Safety Signal Problems**  
Royce A. Morrison, MD, MS  
Director, Clinical Strategy, Charles River Clinical Services

**Hurdles to FIH Studies, Safety Considerations and Case Study**  
Howard E. Greenberg, MD, MSE, MBA, FCP  
Senior Medical Director, Clinilabs

**Session 219**
**CSP - Clinical Safety and Pharmacovigilance**

10:00 AM-11:30 AM  
Room 146B  

**Risk Management Between the Regulatory Rock (FDA REMS, EU RMP) and the Litigation Hard Place**  
**Session Chairperson(s)**
Uwe P. Trinks, PhD  
Partner, Foresight Group, LLC

The Food and Drug Administration Amendment Act of 1997 (FDAAA) is the most comprehensive revision of the Food Drug and Cosmetic Act ever. Section IX of the act focuses primarily on measures to enhance safety and reduce risks of pharmaceuticals. The European Union’s Volume 9A and its proposed pharmacovigilance (PV) Amendments from 1998 add further requirements for globally acting pharmaceutical companies. An overview of similarities and differences between the risk management approaches (REMS, RMP, RiskMAP) in the US, EU, and Japan as well as their impact will be discussed.

**Global Regulatory Framework for Risk Management**  
Uwe P. Trinks, PhD  
Partner, Foresight Group, LLC

**Risk Management in Small and Midsize Companies**  
Eric T. Smith, PharmD  
Senior Director, Risk Management and Safety Evaluation, King Pharmaceuticals, Inc.

**Risk Management in a Large International Company Setting**  
John Ferguson, DrMed  
Vice President, Global Head of Pharmacovigilance and Medical Safety, Novartis Vaccines and Diagnostics

**Session 220**
**EBM - Evidence-Based Medicines**

10:00 AM-11:30 AM  
Room 149AB  

**PROs: Perspectives from an Oncologist, Regulator, and Patient**  
**Session Chairperson(s)**
Shanthi Ganeshan, PhD  
Director, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

In recent years, cancer care has evolved to reflect a paradigm shift from an immediate life-threatening illness to a more ongoing chronic disease. As a result, there is a growing interest in incorporating patients’ perspectives when measuring and interpreting the clinical benefits of cancer treatments. In oncology, the patient perspective is especially relevant because patients are frequently assessing the trade-off between quantity and quality of life. Patient-reported outcomes (PROs) are now being used in a variety of cancer clinical trials.

This session will address the challenges that an oncologist may face during clinical trials to capture and maintain the integrity of PRO measurements, the regulator’s perspective on the successes and challenges for PRO development in oncology, and the involvement and role of the patient or caregiver in the treatment decision-making process.

**Patient-reported Outcomes in Oncology: From the Clinical Trial to the Clinic and Back Again**  
Lee S. Schwartzberg, MD, FACP  
Clinical Professor, University of Tennessee; Hematology and Oncology, The West Clinic

**Perspective from a Regulator**  
Ethan M. Basch, MD  
Medical Oncologist, Health Outcomes Group, Memorial Sloan-Kettering Cancer Center

**Joanne Buzaglo, PhD**  
Senior Director, Research, Cancer Support Community

**Session 221**
**EC - eClinical**

10:00 AM-11:30 AM  
Room 204BC  

**Parallel Lines Eventually Intersect: Evolution of Technologies in Parallel Industries**  
**Session Chairperson(s)**
David B. Stein  
Senior Director, Product Management, Perceptive Informatics

Integration, standards, interoperability, next generation systems – these terms have long been familiar in several industries. Yet they are relatively new in the biopharmaceutical space. Many sponsors and vendors are now applying lessons learned from other industries to advance the usability of individual systems and, at the same time, to accelerate the overall workflow from source data through to submission. What are these parallel industries and what lessons are being applied from them? We will explore three key sectors to find answers: finance, enterprise resource planning (ERP), and health care.

**What We Learn from the ERP (Enterprise Resource Planning) Industry**  
R. Michael Suttle  
Managing Partner and CEO, Tartini Partners
SESSION 222  ERS/DM 1 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT
10:00 AM-11:30 AM  LEVEL: ▼
Room 202A
FDA Data Standards Initiatives
SESSION CHAIRPERSON(S)
Randy Levin, MD
Director for Health and Regulatory Data Standards, CDER, FDA
This discussion will provide an overview of important FDA data exchange standards initiatives. This overview will include the importance and benefit of the data exchange standard to FDA and industry and an update on the progress of the standard development, adoption, and potential future initiatives.
RPS Update
Patricia N. Garvey, RPh
Senior Policy Analyst, Office of Critical Path Programs, Office of the Commissioner, FDA
CDISC Content to HL7 Standard Update
Jonathan G. Levine, PhD
Senior Scientific Policy Analyst, Office of Critical Path Programs, Office of the Commissioner, FDA
ICSR Update
Lise R. Stevens
Data Standards Project Manager, Office of the Commissioner, FDA

SESSION 223  ERS/DM 2 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT
10:00 AM-11:30 AM  LEVEL: ▼
Room 206
Life Cycle Management of European eCTDs: Centralized, Mutual Recognition, Decentralized, and National Procedures
SESSION CHAIRPERSON(S)
Kate Wilber
Image Solutions, Inc. (ISI), UK
Sponsors submitting in the EU must sort through an alphabet soup of registration procedures, including MRP (mutual recognition procedure), DCP (decentralized procedure), and CP (centralized procedure), to figure out which process best fits product marketing goals. This session uses current guidance, case-study examples and best practice strategies to address the unique business and technical electronic submission challenges faced by companies working under each of these procedure types.
Current and Future Scene for eSubmissions in MRP/DCP
Christa Wirthumer-Hoche, PhD
Deputy Head, AGES PharmMed, Austria
EU Variation Regulation and eCTD: Synergy or Inhibition
Hans Van Bruggen, MSc
Senior Regulatory Affairs Consultant, eCTDconsultancy B.V., Netherlands

SESSION 224  EXEC - EXECUTIVE POLICY FORUM
10:00 AM-11:30 AM  LEVEL: ▼
Room 202B
CME and nursing credits offered
The New Landscape for Industry-profession Relations: From Policy to Practice – Part 1 of 2
SESSION CHAIRPERSON(S)
Arthur L. Caplan, PhD
Emmanuel and Robert Hart Director of the Center for Bioethics and the Sydney D. Caplan Professor of Bioethics, University of Pennsylvania in Philadelphia
Part 2 of this session will take place on Tuesday at 2:00 pm.
Industry support of clinical research and medical education has led to intense scrutiny by media and policy makers, debate among ethicists, and attempts at self regulation by industry, academia, and medical societies. Every aspect of the industry-professional relationship is affected … at all stages of the product life cycle. This session will discuss the policy landscape with leading thought leaders from government, media, ethics, and academia that are driving policy in this arena.
Panelists
Eric G. Campbell, PhD
Associate Professor, Director of Research, Mongan Institute for Health Policy, Massachusetts General Hospital, Harvard Medical School
Murray Kopelow, MD
Chief Executive, Accreditation Council for Continuing Medical Education (ACCME)
Alice Mundy
“The Wall Street Journal”
Nicole Brown
Staff of Senator Herb Kohl, US Senate Special Committee on Aging

SESSION 225  GCP - GOOD CLINICAL PRACTICES
10:00 AM-11:30 AM  LEVEL: ▼
Room 152A
Pharmacy credits offered
FDA and European Medicines Agency Update on GCP Inspections and the Conduct of Clinical Trials
SESSION CHAIRPERSON(S)
Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA
Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union
On September 1, 2009, the FDA and European Medicines Agency launched a bilateral good clinical practices (GCP) initiative designed to ensure that clinical trials submitted in drug marketing applications in the United States and Europe are conducted uniformly, appropriately, and ethically. Products
Regulatory medical writers may find themselves working on a variety of regulatory submission documents such as protocols, clinical study reports (CSRs), or integrated safety summaries for a new drug application (NDA). The speakers in this session will discuss how medical writers and statisticians can work together in the various stages of a clinical study to increase writing efficiency and improve the quality of regulatory submission documents that adhere to regulatory requirements.

Blessed Are the Rule Makers, for They Create Consistency
David D. Morris, PhD
Senior Director of Statistics, WebbWrites LLC

A Medical Writing Essential: Reviewing Statistical Analysis Plans
Anita Frijhoff, PhD
Medical Writer, Premier Research Group

Medical Writing and Statistics Collaborations: A Win-win in Creating Regulatory Submission Efficiencies
Karen Moretti, MS, RAC
Senior Medical Writer, Hoffmann-La Roche Inc.

NIH Research and Development in Botanicals Including Dietary Supplements

ODS Research Portfolio and Program Priorities
Paul Coates, PhD
Director, Office of Dietary Supplements, National Institutes of Health

NCCAM's Botanical Research Portfolio with an Emphasis on Diabetes Mellitus Research
Wendy Weber, ND, PhD, MPH
Program Officer, Division of Extramural Research, NCCAM, National Institutes of Health

NCI's Portfolio of Botanical and Dietary Supplement Research for Cancer and Management of Cancer-related Symptoms and Treatment-related Side Effects
Jeffrey D. White, MD
Director, Office of Cancer Complementary and Alternative Medicine, National Cancer Institute, National Institutes of Health
Session 229  OS - Outsourcing
10:00 AM-11:30 AM  LEVEL: ●
Room 147B
Interactive eProcurement: An Innovative Technology Solution for CROs and Sponsors
SESSION CHAIRPERSON(S)
David N. Slack, PhD
Head of Contracts and Proposals, Quanturate Limited, UK

Electronic procurement (eProcurement) platforms are being increasingly employed in the outsourcing of clinical trials. Electronic tendering can substantially reduce the tasks of distribution, receipt, and tracking of tender submissions to streamline and manage the entire procurement process. This solution offers recognized business benefits, including a reduction in tender cycle time and paper trails, accompanied by a reduction in costs to both buyers and suppliers. Current approaches, however, offer limited interactivity and still rely on traditional proposals and pricing tools.

This session will focus on the successes and limitations of current eProcurement systems from a CRO, sponsor, and technology vendor perspective, and demonstrate an innovative CRO-hosted solution offering an interactive and transparent approach to clinical outsourcing.

Do I buy what eVends?
Mark Wakefield
Head, Clinical Development Operations, Addex Pharma SA, Switzerland

CRO Shopping: Why Can’t Buying Clinical Trial Services Be as Easy as Amazon.com?
Max Leisten, MBA
Market Director, Life Sciences, sciQuest Inc.

eProposals: A Personalized eVending Solution or a Self-service Offering?
David N. Slack, PhD
Head of Contracts and Proposals, Quanturate Limited, UK

Session 230  PD/TR - Professional Development/Training
10:00 AM-11:30 AM  LEVEL: ■
Room 103A  CME credits offered
Effective Multicultural Clinical Staff Training: Embracing the Differences
SESSION CHAIRPERSON(S)
Catherine Van Doren, RN
Executive Director, Global Clinical Operations, GRS Worldwide

This session will address techniques to effectively train multinational clinical staff by recognizing and embracing the diversity of each group to achieve common goals. Learn how to recognize and use cultural differences to maximize the effectiveness of global team training.

Cultural Diversity and Successful Implementation Within a Safety Department: Process Makes Perfect
Mark Vieder, MBA, RPh
Coding Manager, PSI INTERNATIONAL, Inc.

Training Study Sites in Emerging Regions: Effectively Addressing Cultural Differences in Learning Communications
Bill Cooney, MBA
President and CEO, MedPoint Communications

Session 231  PLENARY SESSION
PM/FI - Project Management/Finance
10:00 AM-11:30 AM  LEVEL: ■
Room 146A  PMI PDUs offered
Evolving Demands in a Changing Industry: Are You Prepared?
SESSION CHAIRPERSON(S)
Raymond G. Starrett, MS
Senior Director, Project Management, Targacept Inc.

The biopharmaceutical industry continues to evolve due to increasing business and regulatory pressures. Project management will be called on more and more to provide leadership in helping their organizations to cope with these changes. While the traditional tools and skill sets of project managers (PMs) remain vitally important, sustainable success will require additional capabilities. PMs will need a broader and deeper understanding of drug development, therapeutic area directions, improved tools for managing projects and portfolios, and well honed leadership skills. Effective leadership will require the ability to integrate effectively into areas that transcend the planning and execution of individual projects. The changing environment and pressures require PMs to integrate within many other dimensions including portfolio management, outsourcing, business development, alliance management, novel drug delivery paradigms, personalized medicine, etc. This PM plenary session discusses the key drivers of this evolution, explores the expanded skills that PMs need to address the problems effectively, and offers ideas on how PMs can be prepared for these challenges.

PANELISTS
Kenneth I. Kaitin, PhD
Director, Center for the Study of Drug Development and Professor of Medicine, Tufts University School of Medicine

J. Carmel Egan, PhD
Vice President, Project Management, Eli Lilly and Company

W. Don Gottwald, PhD, CCP, PMP
Core Faculty - Project Management, School of Business and Technology, Capella University

Session 232  PP - Public Policy/Law/Corporate Compliance
10:00 AM-11:30 AM  LEVEL: ■
Room 1544AB
Mock Trial on Pharmaceutical Company Fraud and Abuse Settlements: Having Conviction to Avoid Conviction
SESSION CHAIRPERSON(S)
Sandra A. Milligan, JD, MD
Executive Director, Amgen Inc.

In this session, experienced lawyers will conduct a mock trial involving issues that may arise in lawsuits brought by US state or federal authorities against pharmaceutical companies based on health care false claim allegations. 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. At the conclusion of the mock trial, the lawyers will entertain questions about the mock trial.
Because of its promise to cut the cost of America's health care price tag without cutting the quality, comparative effectiveness (CE) research has been a hot topic for lawmakers, patients, payers, and the public at large. CE aims to assess how different procedures and interventions for a given health condition will make a positive, negative, or no difference on the patient's outcome. Most clinical trials determine how individual therapies compare to doing nothing, but very few studies provide comparisons of two or more therapies, procedures, or interventions. We have very little evidence to help decision making when faced with a range of possibilities under particular circumstances. For years the US has supported an extensive network of independent public and private CE research centers. There are now proposals to harness CE research under a single oversight body and to make CE information broadly available to end users including payers, professionals, and patients alike.

In this session you will gain an understanding of the state of CE research in the US, an overview of how CE research is conducted, and the kinds of health care decisions that are made based on the data.

Comparative Effectiveness: Recent History and Future Prospects
Harry P. Selker, MD, MPH
Executive Director, Institute for Clinical Research and Health Policy Studies; Dean, CTSI, Tufts Medical Center

Federal Comparative Effectiveness Research: Current and Future Directions
Carolyn M. Clancy, MD
Director, Agency for Healthcare Research and Quality (AHRQ)

Comparative Effectiveness Research from a Payer Perspective
Richard Justman, MD
National Medical Director, UnitedHealthcare

Session 234  RA 2 - Regulatory Affairs
10:00 AM-11:30 AM  LEVEL: ■
Room 143AB
CME, nursing, and pharmacy credits offered

Comparative Effectiveness Research: Where Is It Headed in the US?
SESSION CHAIRPERSON(S)
Anne E. Trontell, MD, MPH
Senior Advisor, Pharmaceutical Outcomes and Risk Management; Program Director, Centers for Education and Research in Therapeutics, Agency for Healthcare Research and Quality (AHRQ)

The Critical Path Institute and Regulatory Science
Marietta Anthon, PhD
Director of Women's Health, The Critical Path Institute

Perspective from the FDA
Wendy R. Sanhai
Senior Scientific Advisor, Office of the Commissioner, FDA

Session 235  RA 3 - Regulatory Affairs
10:00 AM-11:30 AM  LEVEL: ■
Room 150A

Critical Path Update
SESSION CHAIRPERSON(S)
Leonard V. Sacks, MD
Deputy Director, Office of Critical Path Programs, Office of the Commissioner, FDA

The cost and complexity involved in developing new medical products have escalated to meet the demands for the highest standards of safety and efficacy. To avoid stifling medical product development, several independent stakeholders are grappling with ways to increase the efficiency of medical product development using new science, bioinformatics, and regulations. This session will discuss the various goals, strategies, and initiatives by stakeholders to bring innovation to the process of medical product development. A range of approaches will be presented, including the creation of new collaborative partnerships, the application of new technologies, the development of biomarkers and other tools to personalize medicine and to predict outcome, as well as the application of new bioinformatics tools to aggregate and interrogate data sources. Special challenges presented by rare or neglected diseases, diseases in special populations, and diseases that are inherently difficult to study because of a prolonged natural history or challenging endpoints will be addressed.

The Critical Path Institute and Regulatory Science
Marietta Anthon, PhD
Director of Women's Health, The Critical Path Institute

Perspective from the FDA
Wendy R. Sanhai
Senior Scientific Advisor, Office of the Commissioner, FDA
Global Allocation of Clinical Sites for Oncology Trials
Fabio Thiers, MD, PhD, MSc
Director, Global Clinical Trials Research Program, MIT Center for Biomedical Innovation

Strategies for Start-up Companies with a Focus on Oncology
Representative Invited
Chief Executive Officer, Recepta Biopharma, Brazil

Navigating the European Medicines Agency
Martin Harvey-Allchurch, Esq., LLM
Head of the Office of the Executive Director, European Medicines Agency, European Union

Panelists
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Hilde Boone
Scientific Administrator, Regulatory Affairs, European Medicines Agency, European Union

Emer Cooke, MBA
International Liaison Officer, European Medicines Agency, European Union

Anthony Humphreys
Head of Regulatory, Procedural, and Committee Support, European Medicines Agency, European Union

Strategies for Drug Development in Oncology
SESSION CHAIRPERSON(S)
Gustavo L.F. Kesselring, MD
Director, Clinical Trials Operation, Hospital Alemao Oswaldo Cruz, Brazil

Oncology drugs rank among the top priorities in drug development due to population aging and the efficacy gap that still exists with several cancers. One of the main challenges in clinical research in oncology is that it cannot be undertaken with the number of research sites that are capable of dealing with the complexity of cancer clinical trials and with the number of patients needed to be recruited in all clinical trials. Strategic alliances with start-up companies can bring new molecules to the market faster than traditional drug development companies like big pharma. This session will discuss strategies for any pharmaceutical company whose pipelines include global oncology trials.

Oncology Drug Development: A Global Research Institute Perspective
Linda Pan, PharmD
Senior Manager, Clinical Trials Management, Ludwig Institute for Cancer Research

Making Room at the Health Care Policy Table: The Role of Statisticians
SESSION CHAIRPERSON(S)
Brenda Jean Crowe, PhD
Research Advisor, Global Statistical Sciences, Eli Lilly and Company

As part of the $787 billion economic stimulus bill approved by Congress, $1.1 billion is slated for comparative effectiveness research. The objective is to study the relative efficacy and safety of drugs, devices, surgeries, or other medical interventions. This goal raises important policy questions, namely how is worth quantified, who gets to decide, how will it impact health care access, and how much will it cost? We maintain that statisticians should take an active role in determining health care policy, including providing guidance on establishing weight of evidence for evidence-based decisions, programs to increase statistical literacy related to health care research, and inclusion as members of panels making evidence-based health care policy decisions. This session will discuss these issues, including several national initiatives that will influence and be influenced by statisticians. These include the FDA Amendments Act (FDAAA), Observational Medical Outcomes Partnership (OMOP), the Sentinel Initiative, and the initiative for comparative effectiveness research.

Electronic Medical Data, Public Health Decisions, and Statisticians: An FDA Perspective
Robert T. O’Neill, PhD
Director, Office of Biostatistics, CDER, FDA

The Role of Statistics and Opportunities for Statisticians in Active Drug Safety Surveillance
Patrick Ryan, MS
Manager, Drug Development Sciences, GlaxoSmithKline

Ingram Olkin, PhD
Professor of Statistics and of Education, CHP/PCOR Fellow, Stanford University

Optimizing Quality Management and Controlling Cost Using a Global Delivery Model
SESSION CHAIRPERSON(S)
Arik Gorbam
Associate Vice President, Compliance and Quality Strategies, Patni Life Sciences, Inc.

In this session attendees will learn how global strategies can increase the level of regulatory compliance and simultaneously reduce compliance costs. This session will also describe how to benefit from centralization and harmonization of validation activities and utilize a successful global delivery model.
Colleen Turner, MS
Director, Informatics Quality Assurance, Bristol-Myers Squibb Company

Global Consistency in Compliance with Outsourced IT Services
Blaise Polentes
Associate Director, QA Lead Generation CMC, sanofi-aventis

11:30 AM-2:00 PM  EXTENDED LUNCHEON
Distribution of lunches, 11:30 am-1:30 pm in Exhibit Hall C, Lower Level. A special seating area located in the Exhibit Hall will be available for networking with colleagues from your professional interest area.

SESSION 240  AHC/IS - ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES
2:00 PM-3:30 PM  LEVEL: ■
Room 140A  CME credits offered

Collaborative Approaches to Product Discovery, Development, and Evaluation
SESSION CHAIRPERSON(S)
Melvyn Greberman, FACPM, MPH, MS, MD
President, Public Health Resources, LLC

Many believe that the current drug development paradigm is unsustainable. New approaches leverage IT-enabled connectivity to link researchers and clinicians, and standing online cohorts of consumers and patients willing to participate in research. The new systems increase the liquidity of information to create learning health care systems and capture the benefits of personalized medicine. The Dr. Love Research Foundation and BIG Health Consortium – applying the NCI’s cancer Biomedical Informatics Grid (caBIG) infrastructure – have partnered to mobilize up to one million women in a standing cohort to examine causes, prevention, and treatment of breast cancer. This model can be applied beyond cancer and beyond the US. Other national and international efforts to develop and implement standards and systems for sharing and use of clinical and research information will also be discussed, including those of interest to FDA, other HHS components, IOM, and health reform.

National and International Models for 21st Century Research and Clinical Development
Ken Buetow, PhD
Associate Director for Biomedical Informatics and Information Technology, National Cancer Institute, National Health Institutes

An Army of Women: A Model for Participatory Big Science
Susan Love, MD, MBA, FACS
President, Dr. Susan Love Research Foundation

FDA Data Exchange Standards and Electronic Health Care Initiatives
Randy Levin, MD
Director for Health and Regulatory Data Standards, CDER, FDA

Health Information Uniformity: Essential for Evaluation and Efficiency
J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality

IOM’s Roles in Informatics and Comparative Effectiveness Research
Robert Giffin, PhD, MA
Senior Research Director, Center for Medical Technology Policy

SESSION 241  BT - BIOTECHNOLOGY
2:00 PM-3:30 PM  LEVEL: ■
Room 101  CME and pharmacy credits offered

Gene Therapies: Technology
SESSION CHAIRPERSON(S)
Barrie J. Carter, PhD
President, Carter BioConsulting

Gene therapy began as a gene delivery technology to replace defective genes causing monogenic diseases but expanded rapidly to include cancer and multigenic diseases and infectious disease. The session will review progress in clinical development with several delivery systems including AAV vectors, replicating and nonreplicating retroviral vectors, and virolytic vectors as well as the challenges for production manufacturing and character-ization.

Replicative and Nonreplicative Retroviral Vectors in the Clinic: Horses for Courses
Douglas J. Jolly, PhD
Executive Vice President, Research and Pharmaceutical Development, Tocagen Inc.

Manufacturing and Characterization Challenges for Virus-based Gene Therapy
Peter K. Working, PhD, MSc
President, Working Advisors LLC

Imaging the Spread of Oncolytic Viruses
Paul E. Hallenbeck
Chief Scientific and Medical Officer, NISCO International

SESSION 242  CDM - CLINICAL DATA MANAGEMENT
2:00 PM-3:30 PM  LEVEL: ■
Room 207A

The Future of Data Management
SESSION CHAIRPERSON(S)
Johann Pröve, PhD
Global Head, Data Management, Bayer Schering Pharma AG, Germany

In this session the attendees will get an impression of what it means to peel back the murky veil covering the future and consider how trends in business models and technology will influence the future of clinical data management. This session will look beyond the buzz words and hot topics of today to explore what trends and technology advances are likely to affect clinical management ten years from now.

Peering into the Future of Clinical Data Management
Robert J. Musterer, MBA
President, ER Squared, Inc.

The Evolving Skills of the Data Manager
Susan Bornstein, MPH
Executive Vice President, eClinical Solutions, a Division of Eliassen Group
Change in Scope: Where Is Clinical Data Management Heading?  
Johann Pröve, PhD  
Global Head, Data Management, Bayer Schering Pharma AG, Germany

**SESSION 243**  
**CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES**  
2:00 PM-3:30 PM  
**Room 150B**  
Updates on ICH Quality Topics  
**SESSION CHAIRPERSON(S)**  
Fritz Erni, DrSc  
Consultant, Switzerland  
In this session, the latest activities of the ICH Q8, Q9, Q10 implementation working group will be discussed. Participants will also get an update on the development of the ICH guideline Q11 on the development and manufacture of drug substances (chemical and biotechnological entities).

**ICH Quality Implementation Working Group Update**  
Elaine Morefield, PhD  
Division Director, Division of Premarketing Assessment II, Office of New Drug Quality and Assurance, CDER, FDA

**ICH Guideline on Development and Manufacture of Drug Substances**  
Brian Withers  
Director, CMC Global Pharmaceutical Regulatory Affairs, Abbott Laboratories, UK

**SESSION 244**  
**CR/CS 1 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**  
2:00 PM-3:30 PM  
**Room 145A**  
Recognizing the Potential of the Site  
**SESSION CHAIRPERSON(S)**  
Anna E. McBride, BSN, MBA  
President, McBride Consulting  
This session will look at techniques and tools for designing recruitment plans that can be effectively customized for individual sites, including benchmarks and initiation tactics. Case studies of successful sites and what differentiates their success, and the associated metrics from site, sponsor, and CRO perspectives will also be presented.

**Meeting Enrollment Goals in a Competitive Environment: Development, Implementation and Monitoring of Site Patient Recruitment and Enrollment Plans**  
Jacqueline M. Zarro, PhD, MA  
Vice President, Clinical Project Management - US, Premier Research Group

**Successful Site Characteristics: How to Partner with CROs and Pharma for Success**  
Kerry L. Gorman  
Manager, Program Development Nononcology, Sarah Cannon Research Institute

**What Makes a Site Successful from a Sponsor Perspective**  
Richard Robinson  
Assistant Director, Internal Medicine, Metabolism, and Diabetes Group, sanofi-aventis

**SESSION 245**  
**CR/CS 2 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**  
2:00 PM-3:30 PM  
**Room 145B**  
The Ripple Effect in Clinical Trials  
**SESSION CHAIRPERSON(S)**  
Erica Elefant, BSN, MA, RN  
Senior Clinical Scientist, Bristol-Myers Squibb Company  
This session will examine key changes that may occur at the site and sponsor levels in response to a single protocol change. General change management concepts and the application of a change management approach at the study project level will be reviewed. The development of teams that can adapt to and implement protocol and/or project modifications proficiently will be discussed.

**A Small Change? The Big Picture**  
Cynthia L. Yones, RN  
Associate Director, Cardiovascular Operations Portfolio Lead, Bristol-Myers Squibb Company

**Effective Teams in the Face of Change**  
Rhonda Ehmann, BSN, RN  
Study Delivery Leader, AstraZeneca Pharmaceuticals

**Protocol Change: Site Implications**  
Selena Farrar, MPH, RN  
Clinical Operations Manager, PAREXEL

**SESSION 246**  
**CR/CS 3 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**  
2:00 PM-3:30 PM  
**Room 140B**  
Clinical Projects: Faster and Smarter? It’s All in the Planning!  
**SESSION CHAIRPERSON(S)**  
John Shillingford, PhD  
Vice President, Clinical Operations, Averion International Corp., Germany  
The global financial crisis has required the pharmaceutical and device industries to review costs even more closely to conserve assets in a difficult economic environment. This, coupled with an ongoing requirement to reduce R&D times, now demands advanced and complex planning in drug development projects and with more projects needing to be run globally. This inevitably means that the global project manager with the core team need to make crucial decisions on where to place projects and acutely aware that they will need to work with teams operating in diverse countries with differing cultural sensitivities. This session will include global project managers who will discuss and provide hard data to illustrate their own experiences and explain how they meet such challenges.

**Metrics and Planning: The Basis of Project Strategy**  
John Shillingford, PhD  
Vice President, Clinical Operations, Averion International Corp., Germany
Global Study Experiences: Lessons from Observing Regional Variations
Alek Safarian, MBA, RPh
CEO, Novotech (Australia) Pty Ltd., Australia

Challenges of Global Clinical Trial Management, Company Culture, Country Culture, and Team Culture
Giedrius Gaudieusis, MD, PhD
Clinical Research Senior Manager, Vifor Pharma, Switzerland

Understanding CMS’ Value Equation
Larry A. Oday
Partner, Vinson & Elkins, LLP

Session 249 EC - eClinical
2:00 PM-3:30 PM LEVEL:
Room 204BC
Standards Shock Therapy: Monitoring the State of CDISC and HL7 Standards for Clinical Research and Regulatory Submissions
SESSION CHAIRPERSON(S)
Wayne R. Kubick, MBA
Senior Vice President, Phase Forward Lincoln Safety Group
This session will help companies understand when to use CDISC and HL7 standards for representing clinical data for various use cases now and in the future, focusing on the CDISC Content to HL7 Message initiative in particular.

The CDISC View of Clinical Data Submission Standards
David P. Iberson-Hurst
Vice President, Technical Strategy, CDISC, UK

The FDA View of Clinical Data Submission Standards
Armando Oliva, MD
President, Avilo Consulting, LLC

The Current State and Importance of HL7 CDISC Content Standards
Jason Rock
Chief Technology Officer, GlobalSubmit Inc.

Session 250 ERS/DM - Electronic Regulatory Submissions/Document Management
2:00 PM-3:30 PM LEVEL:
Room 144ABC
CDER eSubmission Update: The Review Perspective
SESSION CHAIRPERSON(S)
Mark A. Gray
Director, Division of Regulatory Review Support, Office of Business Process Support, CDER, FDA
CDER is continuing to streamline processes and procedures to further facilitate the review of electronic submissions. These changes include the conversion from traditional electronic submissions to eCTD (electronic common technical document) along with the development of information management project proposals, which will benefit the consumer and the pharmaceutical industry. This session addresses the review aspects and concerns of this process, and delivers CDER’s current perspective on these issues.

Virginia R. Ventura
Team Leader, eSST, Office of Business Informatics, CDER, FDA

Sarah Connelly, MD
Medical Officer, Office of New Drugs, CDER, FDA

A CMC Reviewer’s Perspective on the Quality Overall Summary and Module 3
Arthur B. Shaw, PhD
Review Chemist and DMF Expert, Office of New Drug Quality and Assessment, CDER, FDA
Room 202B
issues identified. Current thinking and developments in the FDA and the European Medicines Agency, together with practical examples of the new approaches, will provide a further update on progress made during the last year on emerging regulatory guidelines from industry, medical societies, clinical researchers, and providers which are intended to restore and maintain public confidence.

Panelists
Karen L. Hackett, FACHE, CAE
CEO, American Academy of Orthopaedic Surgeons
Paul T. Kim, JD
Partner, Foley Hoag LLP
Kay Holcombe, MS
Senior Policy Advisor, Government Relations, Genzyme Corporation
Kenneth I. Kaitin, PhD
Director, Center for the Study of Drug Development and Professor of Medicine, Tufts University School of Medicine
Rita F. Redberg, MD, MSc, FACC, FAHA
Director, Women’s Cardiovascular Services, UCSF
Professor of Medicine, UCSF Medical Center

Session 253 IT - INFORMATION TECHNOLOGY
LEVEL: ●
Room 143AB
CME and pharmacy credits offered

Health Information Technology (HIT) and Personalized Medicine: The Knowledge-driven Health Care Transformation
SESSION CHAIRPERSON(s)
Brett Jason Davis
Senior Director, Personalized Healthcare, Oracle Health Sciences

Much of the dialogue around personalized medicine focuses on the scientific and biotechnology breakthroughs we have witnessed in recent years, as well as the ethical, regulatory, and reimbursement challenges facing organizations commercializing these breakthroughs. We have seen great strides in the molecular understanding of disease, resulting in many new diagnostics, therapeutics, and treatment regimens impacting quality of life for many. This session will focus on the essential role health care information technology will need to play to achieve the vision of personalized health care. Specifically, it will explore the market and regulatory factors driving this imperative including the HITECH legislation, pay for performance, and comparative effectiveness research (CER).

Informatics to Support Translational Research
J. Richard Landis, PhD
Professor, Biostatistics and Statistics, Director, Biostatistics Unit, University of Pennsylvania School of Medicine

Changing Role of Clinical Trials to Support Molecular Diagnostics
Mara Aspinall, MBA
President and CEO, On-Q-ity

Health Care IT: Enabling Personalized Medicine from Development to the Clinic
Michael N. Cantor, MD
Director, Healthcare Informatics, Pfizer Inc

Session 254 MC - MEDICAL COMMUNICATIONS
LEVEL: ●
Room 151A
CME and nursing credits offered

Medical Communications Roles at Scientific Medical Meetings
SESSION CHAIRPERSON(s)
Stacey M. Fung, PharmD
Senior Manager, Medical Communications, Genentech, Inc.

This session will present the various roles and responsibilities of medical communications groups, headquarter- and field-based, to support scientific medical meetings. A review of available regulatory/legal guidance for this function, processes for training and maintaining the safe harbor within a scientific/medical/clinical affairs booth, and best practices will be presented. Additional discussion will include how to partner with commercial colleagues to manage expectations and identify potential opportunities, role in development and review of booth materials, and coordinating medical support activities.
Supporting a Scientific Medical Meeting with a Joint Venture Partner: Challenges and Successes from a Medical Information Perspective
Rebecca Falcone, PharmD
Senior Manager, CV/Thrombosis Medical Information, sanofi-aventis

Prior to, During, and Post Congress
Jimmy Black, PharmD
Senior Director, Medical Development, Amylin Pharmaceuticals, Inc.

William Lai, III, PharmD, MBA
Senior Manager, Global Clinical and Medical Affairs, Baxter Healthcare

SESSION 255  MW - MEDICAL/SCIENTIFIC WRITING
2:00 PM-3:30 PM  LEVEL: ●
Room 152B

Topic-based Content: Is the New Paradigm for Authoring Regulatory Submissions a Modern Miracle or a Frankenstein?
SESSION CHAIRPERSON(S)
Nancy R. Katz, PhD
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.

In this session, three presenters who are members of the EDM Reference Model team, and two who are members of the pharmaceutical content subcommittee of the Organization for the Advancement of Structured Information Standards (OASIS) will explore the impact of a topic-based content authoring paradigm, including the Darwin Information Typing Architecture (DITA) standard, on regulatory submissions.

Nancy R. Katz, PhD
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.

Michelle Herrera Foster, PhD
Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

James M. Averback, MS
Partner, Life Science Integration Partners

SESSION 256  NHP - NATURAL HEALTH PRODUCTS
2:00 PM-3:30 PM  LEVEL: ●
Room 103B

Turning Wine into Medication: Moving Natural Dietary Ingredients into the Drug Route
SESSION CHAIRPERSON(S)
Freddie Ann Hoffman, MD
CEO, HeteroGenenity LLC

This session will provide an overview of what may be required to develop a dietary supplement ingredient as a new drug in the United States.

Managing Expectations: How Can Natural Dietary Ingredients Be Drugs?
Freddie Ann Hoffman, MD
CEO, HeteroGenenity LLC

Design and Implementation of Clinical Trials with Dietary Supplements Aimed at the US Drug Route
Jay Udani, MD
CEO and Medical Director, Medicus Research

Upgrading the Dietary Supplement Manufacturing Process to Meet Drug cGMPs
Ira Peine
President, Magid-Haffner Associates, Inc.

SESSION 257  OS - OUTSOURCING
2:00 PM-3:30 PM  LEVEL: ●
Room 147B

The State of Clinical Outsourcing
SESSION CHAIRPERSON(S)
Denise A. Calaprice-Whitty, PhD, MS
Executive Director, The Avoca Group Inc.

This session will explore clinical service providers’ and sponsors’ perceptions of how provider-sponsor relationships have changed in the last year and will continue to change over the next five years. Data from the 2010 State of Clinical Outsourcing Survey will be shared.

Mitchell A. Katz, PhD
Vice President, Global Clinical Operation and Data Management, Eisai Inc.

Adrian Otte, MD, FFPM
Vice President, Global Development Operations, Amgen Inc.

Badhri N. Srinivasan, MS
Vice President, BPM and Advanced Analytics, Quintiles, Inc.

SESSION 258  PD/TR - PROFESSIONAL DEVELOPMENT/TRAINING
2:00 PM-3:30 PM  LEVEL: ■
Room 103A

Learning, Survival, Success, and Career Development
SESSION CHAIRPERSON(S)
Betty R. Kuhnert, PhD, MBA
Executive Director, Training Services, PharmaNet Development Group, Inc.

This session will help you identify and avoid characteristics (eg, derailers, career stallers, or stoppers) that you or others may unknowingly exhibit. Often feedback from others is required to recognize subtle derailers, but you do not have to learn from painful career mistakes if you can avoid making them in the first place. It will help you adapt to reduced resources. It will help you survive the slow-down and be prepared for job loss.

You Don’t Have to Learn from Your Career Mistakes: You Can Avoid Making Them in the First Place
Betty R. Kuhnert, PhD, MBA
Executive Director, Training Services, PharmaNet Development Group, Inc.

Surviving in Times of Scarcity: Adapting to Reduced Resources
Cathryn L. Anderson
Sepracor Inc.

Surviving the Slow Down
Chanie Schwartz
President, A Vested Interest Wealth Management
## Session 259  PM/FI 1 - Project Management/Finance

2:00 PM - 3:30 PM  LEVEL: ■  Room 206  PMDUs offered

**Effective Project Team Management: Dealing with Diversity within Asia**

**Session Chairperson(s)**

Atsushi Tsukamoto, MSc, PMP  
Manager, Group I, Global Project Management Department, R&D Division, Daiichi Sankyo Co., Ltd., Japan

Being able to successfully lead increasingly diverse project teams is an important skill for any project manager to possess. In this session, a specialist in intercultural communication/diversity management and project manager in industry will discuss potential friction points within the team, especially when members come from cultures which exhibit similar behaviors, such as Asians (e.g., Korea and Japan), that are sometimes difficult to recognize. The discussion will be useful for project managers who manage multicultural project teams.

- **Project Management in the New Paradigm: Global Clinical Development in Asia**  
  Joanne J. Chen, PhD  
  Vice President, Fountain Medical Development

- **Dealing with Diversity within Asia**  
  Robert A. Hilke, MA  
  Senior Consultant, INTEC Japan K. K., Japan

- **Effective Communication and Diversity Management in Pharmaceutical Global Project Management**  
  Atsushi Tsukamoto, MSc, PMP  
  Manager, Group I, Global Project Management Department, R&D Division, Daiichi Sankyo Co., Ltd., Japan

## Session 260  PM/FI 2 - Project Management/Finance

2:00 PM - 3:30 PM  LEVEL: ■  Room 143C  CME credits and PMI PDUs offered

**Conflict Resolution: How to Manage Conflict on Alliance Teams**

**Session Chairperson(s)**

Ailsa Mendez, MBA  
Director, Project Governance, Functional Genetics

Success on drug development teams, especially alliance teams, does not rely solely on the attributes of the licensed asset. Rather, more often than not, success lies in the ability of alliance teams to work together collaboratively and effectively even in the face of disagreement on program strategy or project execution. Alliances falter, fail, and do not deliver on the goals set forth for them during the negotiation stage, primarily because teams are not provided an effective environment by which their ideas can be heard and challenged constructively, to afford a better outcome for both partners than what was envisioned by one side alone. This session will discuss how to set up a collaborative environment on alliance teams and assist team leaders in looking out for early warning signs of destructive behavior.

- **Critical Problem-solving Skills for Alliance Professionals**  
  David Chapnick  
  Senior Consultant, Vantage Partners LLC

## Session 261  PM/FI 3 - Project Management/Finance

2:00 PM - 3:30 PM  LEVEL: ■  Room 207B  PMI PDUs offered

**Project Termination: The Good, the Sad, and the Plan**

**Session Chairperson(s)**

Sandra J. Zeckel, RPh, PMP  
Advisor, Project Management, Eli Lilly and Company

Drug development projects are often difficult to terminate. Team members and management champions can see opportunities for further evaluation even in the face of disappointing data. It is the role of the project manager to remain objective and to ensure the project has clear critical success factors to continue in development. Once the decision is made to discontinue development, a termination plan will provide a clear communication as to what work needs to be completed, as well as the budget and timeline for doing so. A communication plan is important to gain alignment across the organization. The project manager also needs to understand the emotional commitment of team members and project sponsors. These feelings need to be addressed to successfully close the project. This session will discuss and provide information to help project managers successfully terminate projects.

- **Making the Decision to Terminate the Project**  
  John David Cornpropst  
  Director, Program Management, Janssen Alzheimer Immunotherapies

- **Elements of a Good Termination Plan**  
  Matthew Bunn, PharmD  
  Project Manager, Bristol-Myers Squibb Company

- **Identifying Personal Project Commitment and Providing Closure**  
  Sandra J. Zeckel, RPh, PMP  
  Advisor, Project Management, Eli Lilly and Company

## Session 262  PP - Public Policy/Law/Corporate Compliance

2:00 PM - 3:30 PM  LEVEL: ■  Room 154AB  CME and pharmacy credits offered

**Drug Product Liability in the United States and the European Union**

**Session Chairperson(s)**

Klara Dalmay, JD, MSc  
Manager, Global Regulatory Affairs, Quintiles GmbH, Germany

The session provides an overview of the drug product liability rules and also strategies for management of the associated risks in the United States and the European Union. The impact of the EU law on the EU member states’ national legislations will also be discussed.

- **Managing Product Liability Risks in the EU**  
  Gizzy Klink, JD  
  Senior Associate, NautaDutilh N.V., Netherlands

- **Tips for Product Liability Risk Minimization and Pharmacovigilance in the US**  
  Linda Pissott Reig, JD  
  Principal, Porzio Bromberg & Newman

- **Drug Liability Rules in the European Union**  
  Klara Dalmay, JD, MSc  
  Manager, Global Regulatory Affairs, Quintiles GmbH, Germany
SESSION 263  RA 1 - REGULATORY AFFAIRS
2:00 PM-3:30 PM  LEVEL: ●
Room 147A
Current Challenges in Development of Novel Vaccines
SESSION CHAIRPERSON(S)
Taryn Rogalski-Salter, PhD
Global Head of Regulatory Affairs, Novartis Vaccines & Diagnostics, Inc.
Lydia A. Falk, PhD
Assistant Vice President, Worldwide Regulatory Strategy, Vaccines, Pfizer Inc
This session will discuss approaches to development of novel vaccines from basic research through advanced clinical development. Special focus will be directed to regulatory challenges for vaccines requiring rapid development and approval such as required for the licensure of pandemic influenza vaccines, developing alternative licensure pathways using novel antigens, and regulatory considerations in the development of therapeutic vaccines.

FDA Point of View
Marion F. Gruber, PhD
Deputy Director, Office of Vaccine Research and Review, CBER, FDA

Challenges on the Path to Approval
Manon Cox, PhD, MBA
President and Chief Executive Officer, Protein Sciences Corporation

Challenges to the Development of a Broadly Protective Neisseria Meningitidis Serogroup B Vaccine
Kathrin U. Jansen, PhD
Senior Vice President, Vaccine Research and Early Development, Pfizer Inc

SESSION 264  RA 2 - REGULATORY AFFAIRS
2:00 PM-3:30 PM  LEVEL: ●
Room 146A
Regulatory Data Protection
SESSION CHAIRPERSON(S)
Nadja Heimonen, MSc
Senior Manager, Regulatory Affairs, Orion Corporation, Finland
This session will present the latest information for regulatory data protection in major countries outside the EU and US. The different regulatory approaches to secure proprietary data and ensure market exclusivity offered by health authorities in various countries will be presented and discussed. Real cases will be illustrated, and the benefits and controversies associated with data protection will be analyzed by speakers.

Regulatory Data Protection (RDP) and Market Exclusivity Standards in a Global Context
Nadja Heimonen, MSc
Senior Manager, Regulatory Affairs, Orion Corporation, Finland

Latest News on Regulatory Data Protection in the EU
Martine Zimmermann, PharmD
Director, Pharmaceutical Affairs, Europe/Middle East/Africa, Alexion Europe, France

Regulatory Data Protection (RDP) and Case Examples Related to the US, EU, Japan, and Canada
James T. Rawls, PharmD
Senior Director, Regulatory Affairs and Document Services, Dainippon Sumitomo Pharma America Inc.

SESSION 265  RA 3 - REGULATORY AFFAIRS
2:00 PM-3:30 PM  LEVEL: ●
Room 146C
Pharmaceuticals and Medical Devices Agency Town Meeting
SESSION CHAIRPERSON(S)
Kyoichi Tadano, PhD
Director, Division of Planning and Coordination, PMDA, Japan
The Pharmaceuticals and Medical Devices Agency (PMDA) has developed many initiatives to facilitate regulatory procedures and scientific dialogue from early development to postmarketing authorization stages. The session offers the opportunity to interact directly with a panel of PMDA senior staff that represent almost all services within the Agency, including reviews/consultations, postmarketing safety measures, GCP/GMP inspections, international programs, future scientific issues, procedural and regulatory issues. Following short introductory presentations, the majority of the session will offer the opportunity for the audience to pose questions to the panel.

Questions may be submitted in advance, please email 2010 program@diahome.org using this subject line: Questions for PMDA Town Hall.

The Future Direction of the PMDA
Tatsuya Kondo, MD, PhD
Chief Executive, PMDA, Japan

Panelists
Mitsuo Saito, PhD
Director, Review Management Division, Office of Review Management, PMDA, Japan
Nobuo Uemura
International Liaison Officer, PMDA, Japan
Yoshiaki Uyama, PhD
Review Director, Office of New Drug III, Leader for PMDA Omics Project, PMDA, Japan
Chieko Ishiguro, MPH
Office of Safety I, PMDA, Japan
Yuki Ando, MSc
Principal Reviewer for Biostatistics, PMDA, Japan
Shingou Sakurai, PhD
Director, GMP Inspection/GMP Audit, Office of Compliance and Standards, PMDA, Japan

SESSION 266  RA 4 - REGULATORY AFFAIRS
2:00 PM-3:30 PM  LEVEL: ●
Room 150A
FDA and European Medicines Agency Update on Pediatric Legislation
SESSION CHAIRPERSON(S)
Dianne Murphy, MD
Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA
Agnès Saint-Raymond, MD
Head of Human Medicines Special Areas, European Medicines Agency, European Union
This session will provide an update on recent developments in the interactions between FDA and the European Medicines Agency on pediatric medicines. Specific examples and broad issues with different approaches and regulatory efforts to address them will be presented.
Global Pediatric Trials: Update on EMA and FDA Exchanges  
Jean Temeck, MD  
Lead Medical Officer, Office of Pediatric Therapeutics, Office of Compliance, FDA  

European Medicines Agency Perspective  
Agnès Saint-Raymond, MD  
Head of Human Medicines Special Areas, European Medicines Agency, European Union  
Panelist  
Junko Sato, PhD  
Director for Risk Management, Office of Safety II, PMDA, Japan  

Learning Appropriate Dose Regimen for Later-phase Drug Development: Case Study  
Frank Bretz, PhD  
Global Head, Statistical Methodology, Novartis Pharma AG, Switzerland  
Panelists  
David J. Wright, PhD, MS  
Senior Statistical Assessor, MHRA, UK  
Susan C. Todd, PhD, MSc  
Reader in Medical Statistics, University of Reading, UK  
Anthony G. Durmowicz, MD  
Medical Officer, Office of New Drugs, CDER, FDA  

Confirmatory Evidence of Selected Dose via Two-stage Adaptive Design Consideration: Case Study  
Frank Xiaoyin Fan, PhD  
Associate Director, Scientific Staff, Merck Research Laboratories  
Panelists  
H.M. James Hung, PhD  
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDE, FDA  
Brenda L. Gaydos, PhD  
Senior Research Advisor, Eli Lilly and Company  
Mark K. Walton, MD, PhD  
Associate Director, Office of Translational Sciences, CDE, FDA  

SESSION 267  RD - R&D STRATEGY  
2:00 PM-3:30 PM  LEVEL: ★  Room 151B  CME credits offered  
The Path Toward Mini-clini’s: An Innovative Approach to R&D Effectiveness  
SESSION CHAIRPERSON(S)  
Keith Ortiz, MBA  
World Class R&D  
Mini-clini’s are small, 6- to 12-patient clinical studies at pharmacologically active doses. A mini-clini capability sets the stage for the use of humans in research – allowing human clinical trial results to be the common touchstone for all evidence claims. They offer a chance to revolutionize pharmaceutical R&D operations, using early human clinical trial results to determine the direction of research, from exploratory discovery through to ready-for-phase 3. This session will address the many useful aspects of mini-clini’s and their impact on research, clinical, and ultimately commercial success.  

New Options for Exploratory INDs: Why Aren’t They Being Used?  
David Jacobson-Kram, PhD  
Associate Director for Pharmacology and Toxicology, Office of New Drugs, CDE, FDA  

Improving the Probability of Technical Success of Novel Targeted Therapeutics  
Jamie Dananberg, MD  
Executive Director, Clinical Pharmacology, Eli Lilly and Company  

Toward Mini-clini’s: Exploratory INDs and CTAs  
Representative Invited  
Vice President, Clinical Pharmacology, Merck & Co., Inc.  

SESSION 268  ST - STATISTICS  
2:00 PM-3:30 PM  LEVEL: ★  Room 102AB  CME, nursing, and pharmacy credits offered  
Adaptive Design Clinical Trials – Part 1 of 2: Practical Experiences from Case Studies  
SESSION CHAIRPERSON(S)  
Sue-Jane Wang, PhD, MA, MS  
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, CDE, FDA  

Part 2 of this session will take place on Tuesday at 4:00 pm.  
This session will feature two completed case studies, one aimed for learning an appropriate dose regimen for later phase drug development, and one aimed for confirmatory evidence of selected dose via two-stage adaptive design consideration. The speakers and panelists will address the principles and utilities of adaptive design clinical trials in the exploratory domain versus the confirmatory domain.  

SESSION 269  VA - VALIDATION  
2:00 PM-3:30 PM  LEVEL: ●  Room 209AB  CME and nursing credits offered  
Computerized Systems Used in Clinical Research: Best Practices from PEACH  
SESSION CHAIRPERSON(S)  
Richard M. Siconolfi, MS  
Section Manager (Director), Computer Validation Services, Procter & Gamble Company  
This session will focus on “Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts” (a.k.a. PEACH Initiative), an event hosted by DIA with participants from around the world and for which a publication should be released in 2010. This session will provide an introductory overview of the DIA publication, which is the result of input from over 100 industry professionals and regulators from around the world, as well as the chapters on data integrity, data quality, risk, security, and data collection.  

Integrations and Interfaces: Angels and Daemons  
Richard M. Siconolfi, MS  
Section Manager (Director), Computer Validation Services, Procter & Gamble Company  

Stakeholders: The Good, the Bad, and the Missing  
Joanne S. Malia, MS, MSc  
Associate Director, Medical Research Process Management, Purdue Pharma  

Data Quality and Data Integrity: Where No One Has Gone Before  
Richard L. Chamberlain, PhD, MS  
President, ECS Inc.
**SESSION 270**
**AHC/IS 1 - ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES**

4:00 PM-5:30 PM
Room 140A
Pharmacy credits offered

**Operationalizing ACPU Standards in an Evolving Early-phase Environment**

**SESSION CHAIRPERSON(S)**
Donna W. Dorozinsky, MSN, RN
President, DWD & Associates

This session presents the most recently issued Association of Clinical Pharmacology Units (ACPU) standards for operations of a clinical pharmacology unit. It focuses on safety, administrative operations, study management, and data collection as they relate to these standards. A panel of phase 1 experts will discuss the challenges of implementing these standards in the evolving phase 1 environment.

**ACPU Study Management Standards**
Howard E. Greenberg, MD, MSE, MBA, FCP
Senior Medical Director, Clinilabs

**ACPU Operational Standards**
Michael Turik, MD
Medical Fellow, Exploratory and Program Phase Medical, LRL, Eli Lilly and Company

**ACPU Safety Standards**
Charles H. Pierce, MD, PhD
Medical Director, CTI Clinical Trial and Consulting Services

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**SESSION 271**
**AHC/IS 2 - ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES**

4:00 PM-5:30 PM
Room 140B

**CRO and Sponsor Perspectives on the Challenges of Site Selection: Panel Discussion**

**SESSION CHAIRPERSON(S)**
Joan A. Chambers
Senior Director of Marketing and Operations, Publications, Cambridge Healthtech Institute

The principal investigator landscape is changing and posing several threats to sponsors and CROs, thus making the site selection process very challenging. This panel session provides invaluable investigative site staff insights shared by a sponsor and CRO representative on their strategies and processes employed in site identification/assessment/selection for clinical research projects.

**Richard Robinson**
Assistant Director, Internal Medicine, Metabolism, and Diabetes Group, sanofi-aventis

**James P. Kremidas**
Vice President, Global Head of Patient Recruitment, Quintiles Inc.
Panelists
Vikas Gulati
Associate Director, Vertex Pharmaceuticals Inc.

Gary J. Thompson, MS
Director, Data Sciences and Solutions, Eli Lilly and Company

Chris Connor
Founder and Principal Analyst, eClinicalGuru.Com

**Session 274**  
**CMC/GMP - Chemistry, Manufacturing, and Controls/Good Manufacturing Practices**  
4:00 PM-5:30 PM  
**Room 150B**  
**GMP for API: Global Perspectives on API (Active Pharmaceutical Ingredients) Quality – Collaborations on Inspections**  
*SESSION CHAIRPERSON(S):*
Fergus Sweeney, PhD  
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

Carmelo Rosa  
Team Leader, International Compliance Team, Office of Compliance, CDER, FDA

This session will outline the way competent authorities deal with the issues of the quality of API (Active Pharmaceutical Ingredients) nationally and internationally and how collaboration can be an effective help to adequately protect the patient against potentially harmful and even deadly APIs.

**FDA Point of View**
Edwin Rivera Martinez  
Acting Associate Director, Drug Quality Assurance, Office of Compliance, CDER, FDA

**European Medicines Agency Point of View**
Olivier Gross, PhD  
European Medicines Agency, European Union

**Global Perspectives on API Quality: Indian Scenario**
Gurudatta G. Gayatri, MBA, MSc  
Director and Chief Operating Officer, Semler Research Centre Pvt., Ltd., India

**Session 275**  
**CR/CS 1 - Clinical Research and Development/ Clinical Supplies**  
4:00 PM-5:30 PM  
**Room 145A**  
**When Senior Management Says “Prove It!”: Can You Articulate Patient Recruitment ROI?**  
*SESSION CHAIRPERSON(S):*
Richard Malcolm, PhD  
Chief Executive Officer, Acurian, Inc.

The session will help trial managers, patient recruitment specialists, and outsourcing personnel evaluate and budget patient recruitment fees, and will illustrate how this can be a very cost-effective spend (investment) through offsetting savings in personnel and trial costs, and can enable large financial returns through speeding time to market.

Brendan O’Neill  
Associate Director, Global Trial Optimization, Merck & Co., Inc.

**Session 276**  
**CR/CS 2 - Clinical Research and Development/ Clinical Supplies**  
4:00 PM-5:30 PM  
**Room 145B**  
**Global Trials on a Budget: How Small to Mid-size Companies Can Get Quality Data**  
*SESSION CHAIRPERSON(S):*
Shantal Feltham  
President and CEO, Stiris Research Inc., Canada

Just as the necessity to run trials globally becomes more prevalent, sponsors are also being charged with doing more with less. In this new regime, resourcing issues, operational planning challenges, cost containment constraints, and milestones must continue to be met – all without compromising the quality of information and data.

**Panelists**
Shantal Feltham  
President and CEO, Stiris Research Inc., Canada

John M. Illingworth  
Managing Director, Clinical Development and Support Services Ltd., UK

Renee Elaine Moore, PhD  
President, Global Operations, Progenitor International Research, Germany

**Session 277**  
**CR/CS 3 - Clinical Research and Development/ Clinical Supplies**  
4:00 PM-5:30 PM  
**Room 146A**  
**Adaptive Trials: Too Complicated for Little Return?**  
*SESSION CHAIRPERSON(S):*
Bill Byrom, PhD  
Senior Director of Product Strategy, Perceptive Informatics, UK

In this session, we will consider three themes to dispel the myth that adaptive designs are too complicated for little return. First, we will consider the statistical design and how to assess, compare, and select different designs. We will illustrate this by considering a simple single interim analysis design in comparison to a Bayesian approach, with specific reference to dose finding. Second, we will consider the practical aspects of implementing adaptive designs from a clinical operations perspective. We will evaluate the use of activity-based planning models to simplify the prediction and management of resource and budget for adaptive clinical trials. Finally, we will explore how planning and forecasting of clinical supplies can be simplified and packaging optimized in adaptive dose finding studies. We will discuss how clinical trials technology can be used to ease the implementation of adaptive studies, and consider some of the common pitfalls in their implementation. Throughout the session, we will draw from case studies and practical experience.
Benefits of Simple Adaptive Designs
Nitin R. Patel, PhD, MBA
Chairman, Chief Technology Officer, and Co-founder, Cytel, Inc.

Accurate Budgeting/Forecasting for Adaptive Clinical Trials: Not an Oxymoron
Molly Blake-Michaels, MS
Director, Clinical Sciences, ClearTrial, LLC

Simplifying Supplies Forecasting and Study Implementation Using Clinical Trial Technologies
Bill Byrom, PhD
Senior Director of Product Strategy, Perceptive Informatics, UK

European Medicines Agency Perspective
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

US Perspective
James V. Scanlon
Deputy Assistant Secretary, Office of Science and Data Policy, Department of Health and Human Services

Patient Perspective
Representative Invited
President, US Hereditary Angioedema Association

Academic Perspective
Gary R. Cutter, PhD
Professor of Biostatistics, University of Alabama at Birmingham School of Public Health

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**Session 278**

**CSP - Clinical Safety and Pharmacovigilance**

**4:00 PM-5:30 PM**

**Room 146B**

**CME, nursing, and pharmacy credits offered**

**REMS Evaluations: What Have We Learned?**

**SESSION CHAIRPERSON(S)**

Kelly D. Davis, MD
Vice President, Safety, Epidemiology, and Risk Management, United BioSource Corporation

A critical component of any risk evaluation and mitigation strategy (REMS) is defining how the success of the plan will be measured. This session will provide an overview of possible REMS evaluation methodologies, and give specific examples of several REMS evaluation plans that have been utilized for program assessments.

**Development of the REMS Assessment Plan**

Kelly D. Davis, MD
Vice President, Safety, Epidemiology, and Risk Management, United BioSource Corporation

**REMS KAB Survey Design: Did the Patients and HCPs Get the Message?**

Kala L. Paul, MD, MS
President, The Corvallis Group LLC

**FDA’s Perspective on the First Round of REMS Evaluation Results**

Mary Willy, PhD
Senior Risk Management Analyst, Team Leader, CDER, FDA

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**Session 279**

**EBM - Evidence-based Medicines**

**4:00 PM-5:30 PM**

**Room 149AB**

**Data-focused Collaborations: Challenges and Opportunities**

**SESSION CHAIRPERSON(S)**

Jessica J. Federer, MPH
Global Advocacy, Bayer Health Care, Germany

This session will provide an overview of the policy developments incentivizing data-driven collaborations in the US and EU. Participants will hear examples of collaborations involving industry, academia, etc., to improve comparative effectiveness, pharmacoepidemiology and pharmacovigilance research. The session will also highlight some key challenges and opportunities from these collaborations.

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**Session 280**

**EC - eClinical**

**4:00 PM-5:30 PM**

**Room 204BC**

**CME, nursing, and pharmacy credits offered**

**EHRs and Clinical Research: Update from the HL7 Working Team and the New ANSI Standard**

**SESSION CHAIRPERSON(S)**

Harry J. Fisher
President, Health ResearchTx LLC

Electronic health records (EHRs) will revolutionize pharmaceutical R&D in ways that will benefit patients, drug developers, regulatory bodies, and public health. Any organization considering major strategic or financial investments in the above areas must understand the risk and reward of EHRs prior to making any long-term commitments.

This session will focus on the progress of the HL7 EHRCR (electronic health records for clinical research) Working Group, and the convergence of EHRs and clinical research.

**Clinical Research and EHRs in the US Navy**

Wayman Wendell Cheatham, MS
Special Assistant to the Surgeon General for Medical Research, Department of the Navy, Bureau of Medicine and Surgery

**The New ANSI Standard and Practical Considerations for EHRs and Clinical Research**

Mitra Rocca, MS
Senior Medical Information Specialist, Office of Medical Policy, CDER, FDA

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**Session 281**

**ERS/DM - Electronic Regulatory Submissions/Document Management**

**4:00 PM-5:30 PM**

**Room 202A**

**CDER eSubmission Update: The Future State**

**SESSION CHAIRPERSON(S)**

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

CDER is continuing to streamline processes and procedures to further facilitate the review of electronic submissions and lead the effort towards standardization. These changes have included the conversion from tra-
The session is a case study showing the identification of a need by a series of departments from different viewpoints. A clinical representative will present on the actual identified improvement and the rationale for improving the system and modifying existing practices. A representative from quality will explain the task from a quality perspective and the necessity of building solid requirements necessary for delivery. A technology representative will then present the technology solution provided and how a fusion of technology and process created a better quality system in the collection of documents in a rapid manner. An end summary will wrap up how the goals were achieved, how the quality system was improved as a result of the implementation, and present metrics on the collection of documents and associated error control.

**Challenges of Document Processing in Rapid Start-up Studies**

Bill Row, MBA, MS  
Director, Clinical Operations North America, REGISTRAT-MAPI, Inc

**Developing a Quality Process for Document Handling**

Pamela Campbell, MBA  
Senior Practice Consultant, EMC Consulting

**Fusing Quality and Process Using Technology: A Project Case Study**

Andrew A. Smith  
Director, Information Technology, REGISTRAT-MAPI, Inc.
**SESSION 285**  
**MW - MEDICAL/SCIENTIFIC WRITING**  
4:00 PM-5:30 PM  
**LEVEL:** ⚫  
**Room 152B**  
**Clinical Study Report Appendices: For Better or Worse**  
**SESSION CHAIRPERSON(S)**  
Mary Stewart, MSc  
Divisional Director, Medical Documentation and Literature, H. Lundbeck A/S, Denmark

Ever since the clinical study report (CSR) guideline (ICH E3) was finalized in the mid-1990s, many of us have, for better or worse, come up with our own interpretation of what the guideline authors actually intended for us to append to our CSRs. The advent of the CTD guideline (ICH M4E) added to the challenge as some of the appendices (patient listings and case report forms) required by ICH E3 acquired a new home outside the CSRs. The advent of the eCTD meant that some of the creative solutions to the appendix challenge had become obsolete – the homes we had created for some documents had suddenly disappeared. This session will provide a brief historical perspective for the CSR appendices, the current initiatives for the CSR appendices, examples of how different companies deal with the CSR appendix dilemma, and then open a panel discussion with input and questions from the audience.

Helle Gawrylewski, MA  
Director, Medical Writing, Johnson & Johnson Pharmaceutical R&D LLC

Christopher J. Preston, PhD  
International Documentation Manager, F. Hoffmann-La Roche Ltd., Switzerland

**SESSION 286**  
**NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT**  
4:00 PM-5:30 PM  
**LEVEL:** ⚫  
**Room 103B**  
**CME credits offered**  
**The Interplay between Nonclinical Studies and Pharmacovigilance Activities: Mitochondrial Toxicity as an Example**  
**SESSION CHAIRPERSON(S)**  
Abigail C. Jacobs, PhD  
Associate Director, Pharmacology/Toxicology, Office of New Drugs Immediate Office, CDER, FDA

Data mining the FDA Adverse Event Reporting System (AERS) pharmacovigilance database can generate hypotheses about the mechanisms of drug-induced toxicity. Postmarketing evaluations of drugs associated with a specific adverse event may uncover a pattern or common mechanism that warrants further nonclinical testing of a drug or drug class. The drugs most commonly associated with the terms hemorrhagic or necrotizing pancreatitis were analyzed for common actions. A PubMed search of the drugs notes that the associated drugs adversely affect mitochondrial function by inhibiting enzymes in the Krebs Cycle or disrupting electron transport. The results of the AERS data mining and PubMed searches on mitochondrial toxicity will be presented, as well as a review of mechanisms of drug-induced mitochondrial toxicity focusing upon the drugs associated with necrotizing pancreatitis, a brief overview of emerging treatments for mitochondrial toxicity, and industry's approach to testing for mitochondrial toxicity.

The Results of the AERS Data Mining and PubMed Searches on Mitochondrial Toxicity of Drugs  
Keith K. Burkhart, DrMed  
Senior Advisor, Medical Toxicology, CDER, FDA

**SESSION 287**  
**OS - OUTSOURCING**  
4:00 PM-5:30 PM  
**LEVEL:** ●  
**Room 147B**  
**Proven Methods for Reducing Change Orders and Accurately Assessing Their Impact**  
**SESSION CHAIRPERSON(S)**  
Melinda K. Davis  
Director, Clinical Services, ClearTrial, LLC

The management of change orders continues to be time consuming and costly. This session will identify proven strategies for reducing the number of change orders as well as the time to generate, negotiate, and approve them. Representatives from sponsors and CROs will share their unique challenges, as well as successful case studies.

Brenda Gibson  
Associate Director, Clinical Operations, Proacta, Inc.

Peter A. DiBiaso, MHA  
Senior Director, Clinical Planning and Performance, Vertex Pharmaceuticals

David G. DeMarco, MS  
Senior Director, Global Key Accounts, Kendle International

**SESSION 288**  
**PD/TR - PROFESSIONAL DEVELOPMENT/TRAINING**  
4:00 PM-5:30 PM  
**LEVEL:** ●  
**Room 103A**  
**How to Use Web 2.0 in Training Programs**  
**SESSION CHAIRPERSON(S)**  
Danny A. Benau, PhD  
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia

We are bombarded daily with messages telling us to use the Web 2.0 as a tool in training. Unfortunately, these messages are not clear about what parts of Web 2.0 are useful as training tools, and, even worse, they do not include instructions on how to actually use Web 2.0 technology to create and deploy training materials. This session will show step-by-step methods for creating and using Web 2.0 training materials. Included will be a demonstration of using YouTube in training and going beyond simple skit-based training sessions, embedding interactive material in PowerPoint, and other step-by-step methods as allowed by the presenting technology of the meeting.

Danny A. Benau, PhD  
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia
Designing Training for Web 2.0: Social Media Meets Social Learning Theory
Pamela Loughner, PhD, MEd
President, Loughner and Associates Inc.

SESSION 289  PM/FI 1 - PROJECT MANAGEMENT/FINANCE
4:00 PM-5:30 PM  LEVEL: ★
Room 147A  PMI PDUs offered
The Role of the Project Manager in the Implementation of Quality by Design
SESSION CHAIRPERSON(S)
Martin D. Hynes, III, PhD
Senior Director, Six Sigma Champion, Research & Development, Eli Lilly and Company
One of the more significant changes driven by the FDA in recent memory, in terms of drug development, is the concept of quality by design (QbD). The basic principle behind QbD is to design quality into the product during the development period. The new QbD approach focuses on critical quality attributes related to chemistry, formulation, and process design. Under QbD, manufacturers will depend on a risk-based approach, linking attributes and process to product performance, safety, and efficacy. This session will focus on the role of the drug development project manager in the implementation of QbD principles.

Value of CMC Project Management
Mukund “Mike” Yelvigi, MS
Senior Director, CMC Therapeutic Area Management, Pfizer Inc

What is Quality by Design: Why Is It an Important Element in Drug Development?
Don Henry
Consumer Safety Officer, Office of Pharmaceutical Sciences, CDER, FDA

Role of the CMC Project Manager in Quality by Design
Mark A. Kryah, PMP
Advisor, CMC Project Management, Eli Lilly and Company

SESSION 290  PM/FI 2 - PROJECT MANAGEMENT/FINANCE
4:00 PM-5:30 PM  LEVEL: ★
Room 150A  CME credits and PMI PDUs offered
Adapting Project Risk Mitigation and Prevention Tools in Real-life Trials
SESSION CHAIRPERSON(S)
Jill Johnston
Executive Director, Operational Strategy and Planning, Covance Inc.
This session discusses real-life examples of how implementing sophisticated risk management tools such as FMEA (failure modes and effects analysis) can prevent study-associated risks, help improve sponsor/CRO communication, and more effectively manage risk expectations across the entire study life cycle.

Risk-based Monitoring: Mitigation Strategies and Process Control
Holger Liebig
Senior Director, Project Management, PAREXEL International, Belgium

CHALLENGES TO PROPER RISK MITIGATION AND CONTINGENCY PLANNING IN REAL-LIFE TRIALS
Tom Giannaris
Manager of Study Management, Global Monitoring and Study Management, Bayer Healthcare Pharmaceuticals, Canada
Effective Management of Risk: Cost, Benefits, and Adaptation in Clinical Trials
Jill Johnston
Executive Director, Operational Strategy and Planning, Covance Inc.

SESSION 291  PP - PUBLIC POLICY/LAW/CORPORATE COMPLIANCE
4:00 PM-5:30 PM  LEVEL: ★
Room 144ABC  CME and pharmacy credits offered
Implications of Health Care Reform for Product Safety and the Pharmaceutical Industry
SESSION CHAIRPERSON(S)
Stanley A. Edlavitch, PhD, MA
Professor, Epidemiology, University of Missouri Kansas City, School of Medicine
Health reform is one of the top administration priorities for 2010. This session addresses the impact of health reform legislation on drug safety and quality of care. Speakers will discuss how the pharmaceutical industry and FDA implementation of recent safety reform legislation (FDAAA 2007) will be affected.

The Impact of New Comparative Effectiveness Requirements
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA

Industry Perspective
Paul R. Eisenberg, MD, MPH, FACP
Senior Vice President, Global Regulatory Affairs and Safety, Amgen Inc.

Patient Perspectives
Ellen V. Sigal, PhD
Founder and Chairperson, Friends of Cancer Research

The Evolving FDA Policy Landscape: A Work in Progress
Robert Giffin, PhD, MA
Senior Research Director, Center for Medical Technology Policy

SESSION 292  RA 1 - REGULATORY AFFAIRS
4:00 PM-5:30 PM  LEVEL: ★
Room 143AB  Pharmacy credits offered
CDER Compliance Update: Effective Enforcement Strategies
SESSION CHAIRPERSON(S)
Deborah Autor, JD
Director, Office of Compliance, CDER, FDA
This session provides a venue for a focused discussion on effective enforcement strategies specific to drug products. The session is designed to promote feedback and input from the audience on those enforcement strategies in place, proposed, or newly implemented – what works best and how to improve the enforcement process.
This session will provide an update on the regulatory environment in Japan including the regulatory review process and performance, and how these impact on clinical development. The metrics and outcome for the prior assessment PMDA consultation system, which was newly introduced in 2009 will be presented. This session will also address the future perspectives for clinical development and regulatory strategy with a global development program in Japan.

**Perspective on Development Strategy and Regulatory Environment in Japan**
Yoshihiko Ono, RPh
Director, Pfizer Japan Inc., Japan

**Clinical Development and Review Times of New Drugs in Japan: 2010 Update**
Taro Ishibashi, MS, RPh
Research Fellow, Office of Pharmaceutical Industry Research, Japan Pharmaceutical Manufacturers Association, Japan

**Recent Challenges of PMDA for Promoting New Drug Developments**
Yoshiko Komuro, PhD
Reviewer, Office of New Drug III, PMDA, Japan

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**Overview of the Office of Compliance Effective Enforcement Strategies**
Deborah Autor, JD
Director, Office of Compliance, CDER, FDA

Michael Levy, Jr., JD
Director, Division of New Drugs and Labeling Compliance, Office of Compliance, CDER, FDA

Teddi Elaine Lopez, MA
Branch Chief, Domestic Case Management Branch, Office of Compliance, CDER, FDA

Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Gregg Claycamp, PhD, MS
Director, Division of Compliance Risk Management and Surveillance, CDER, FDA

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**Session 293 RA 2 - Regulatory Affairs**
4:00 PM-5:30 PM
Room 143C
CME credits offered

**Global Pediatric Drug Development: All About Communication**
SESSION CHAIRPERSON(S)
Gesine Bejeuhr, PharmD
Senior Manager, Regulatory Affairs/Quality, vfa Research-Based Pharmaceutical Companies, Germany

Globalized pediatric drug development has become a necessity rather than an option for international-acting companies. Practical examples will illustrate how both companies and regulators could enhance their communication to better address the requirements of the US and the European legislation. This session will highlight the opportunities for cooperation between industry, academia, and regulators in Europe, the US, and worldwide and will discuss how communication between all stakeholders could be facilitated and improved.

**FDA Point of View**
Melissa S. Tassinari, PhD
Staff Fellow, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

**IFPMA Pediatric Task Force Point of View**
Emma L. Du Four, MBA
Director, Regulatory Intelligence and Policy, Abbott Laboratories, UK

**Industry Point of View**
Sharon N. Olmstead
Head, US Regulatory Policy, Merck & Co., Inc.

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**Session 294 RA 3 - Regulatory Affairs**
4:00 PM-5:30 PM
Room 154AB
Nursing credits offered

**Outlook for Changes in the Japanese Regulatory and Clinical Development Environment**
SESSION CHAIRPERSON(S)
Yoshihiko Ono, RPh
Director, Pfizer Japan Inc., Japan

Ian Hunt
Vice President, AZRA, CUGI, AstraZeneca Pharmaceuticals, LP
SESSION 296  RD - R&D STRATEGY
4:00 PM-5:30 PM  LEVEL: ■
Room 151B
Pharmaceutical Patent Valuation: Novel Models and Applications in Industry
SESSION CHAIRPERSON(S)
Yuanjia Hu, PhD, MS
Research Fellow, Institute of Chinese Medical Sciences, University of Macau, Macao
This session will introduce the emerging drug patent valuation market, identify predictors of pharmaceutical patent value, and present existing and novel models to valuate the value of pharmaceutical patents and their application perspectives in the industry, including patent/patent portfolio valuation, patent licensing, pipeline drug valuation, R&D performance/innovation output assessment, and firm valuation based on core patents.

Pharmaceutical Patent Valuation: A Litigation (Disputed) Model
Albert Wai-Kit Chan, JD, PhD
Managing Partner, Law Offices of Albert Wai-Kit Chan, PLLC

Evaluation of Health Care Enterprises in Strategic Investment
Minchuan Wang, PhD
Research Scholar, International Research Center for Medicinal Administration, Peking University, School of Pharmaceutical Sciences, China

Patent Value Benchmarking: Statistical Value Perspectives from an Intellectual Capital Merchant Bank
Jonathan Barney, JD
Managing Director, Ocean Tomo LLC

SESSION 297  ST - STATISTICS
4:00 PM-5:30 PM  LEVEL: ■
Room 102AB  CME and pharmacy credits offered
Adaptive Design Clinical Trials – Part 2 of 2: Guidance for Industry
SESSION CHAIRPERSON(S)
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, CDER, FDA
Part 1 of this session will take place on Tuesday at 2:00 pm.
This session will present US regulatory clinical and statistical perspectives in light of the available draft guidance on adaptive design clinical trials. Design principles for exploratory adaptive trials versus confirmatory adaptive trials will be discussed.

Statistical Perspective
Robert T. O’Neill, PhD
Director, Office of Biostatistics, CDER, FDA

SESSION 298  VA - VALIDATION
4:00 PM-5:30 PM  LEVEL: ■
Room 209AB
Using Agile Practices on Validated Solutions
SESSION CHAIRPERSON(S)
Michael Vogel, MS
Agile Practice Lead, EMC Consulting
This session will describe appropriate ways to use agile software development practices on validated projects. Topics for focus are core agile practices, extensions needed for validated projects, building quality in versus attempting to test it in, applicable types of projects, and business user experience on agile projects.

Maintaining a Validated, Agile Developed System
Patricia Sukovich
IT Development Manager, MedAvante

Experience and Challenges Using Agile for Validated Product Development
Andrew Newbigging
Vice President, Integrations Development, Medidata Solutions Worldwide, UK

Agile and Validation: Working Together
Michael Vogel, MS
Agile Practice Lead, EMC Consulting

5:30 PM  END OF TUESDAY SESSIONS
Investigators Needed! Why Clinical Research Should Be Part of Your Practice

SESSION 302  
8:30 AM-10:00 AM  
Room 140A
  
Investigators Needed! Why Clinical Research Should Be Part of Your Practice
  
SESSION CHAIRPERSON(S)
  
John L. Lewis, MA
Vice President of Public Affairs, Association of Clinical Research Organizations (ACRO)

Currently, less than 4% of US physicians participate in clinical trials, and the number of investigators has declined annually since 2001. Why? Based on fresh research, this session examines the myths and facts around being an investigator so physicians can make better informed decisions.

Investigators Needed! 

Kevin Olson
President, Industry Standard Research

Panelists
Thomas W. Littlejohn, III, MD, CPI, FAAFP
President and Executive Medical Director, PMG Research

David M. Knepper, MS, MBA
Executive Director, Clinical Research, PharmaNet

Session 304
Electronic Data Capture in Phase 1: Do the Pros Outweigh the Cons?

SESSION 304  
8:30 AM-10:00 AM  
Room 206
  
Electronic Data Capture in Phase 1: Do the Pros Outweigh the Cons?
  
SESSION CHAIRPERSON(S)
  
Anne M. Zielinski, MBA
Vice President, Alliances, Medidata Solutions Worldwide

Phase 1 trials are sometimes viewed as inappropriate for EDC. This session explores that perspective, from the viewpoints of both phase 1 units and organizations sponsoring and conducting phase 1 trials. The goal of the session is to provide participants with pros and cons for this argument, based in real-world experience, and to promote informed decision making on the use of EDC in phase 1 trials.
EDC in Phase 1 Trials: A CRO Perspective
Brock Heinz
Systems Integration Engineer, Spaulding Clinical

Susan Bornstein, MPH
Executive Vice President, eClinical Solutions, a Division of Eliassen Group

Anthony W. Tolcher, MD
Director, Clinical Research, South Texas Accelerated Research Therapeutics (START)

A CRO Perspective on Study Feasibility
Lars-Olof Eriksson, PhD
PAREXEL Consulting

A Sponsor’s Perspective on Study Feasibility
Otis Johnson, MPA
Manager, Global Trial Optimization (GTO), Clinical Research Operations, Merck & Co., Inc.

Site’s Perspective for Feasibility Assessments
Geralyn Pumper, RN
Mayo Clinic

**SESSION 305**  **CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES**
8:30 AM-10:00 AM  LEVEL: ■
Room 145A
Pharmacy credits offered

Challenges in the implementation of Quality-by-design Across the Pharmaceutical Industry
SESSION CHAIRPERSON(S)
Moheb M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA

This session will discuss progress and challenges of implementing quality-by-design (QbD) initiative among different industry sectors and regulatory authorities.

State of QbD Implementation: Adoption, Successes, and Challenges
Ted Fuhr, MBA
Consultant, McKinsey & Company

QbD Moving Forward: Opportunities and Challenges
Helen N. Winkle
Director, Office of Pharmaceutical Science, CDER, FDA

Implementing QbD in FDA’s GMP Program
Vibhakar Shah, PhD
Senior Policy Advisor, Office of Compliance, Division of Manufacturing and Product Quality, CDER, FDA

**SESSION 306**  **CR/CS 1 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**
8:30 AM-10:00 AM  LEVEL: ■
Room 149AB

No More Questionnaires! Rethinking the Study Feasibility Assessment Process to Ensure Successful Implementation
SESSION CHAIRPERSON(S)
Beth D. Harper, MBA
Chief Clinical Officer, Centerphase Solutions

The traditional approach to feasibility assessment, using questionnaires, results in the typical site enrollment performance whereby <10% of the sites enroll the number of patients predicted in the feasibility assessment. This level of performance is simply not sustainable. This session will explore various perspectives, approaches, and case studies for rethinking the currently flawed feasibility assessment process. Hear how our panelists (representing sites and sponsors) have transformed their processes for more predictable and successful results.

**SESSION 307**  **CR/CS 2 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**
8:30 AM-10:00 AM  LEVEL: ■
Room 150B
CME, nursing, and pharmacy credits offered

Clinical Trials in the Age of Personalized Cancer Medicine: The Evolution of a More Efficient, Patient-focused Clinical Research System
SESSION CHAIRPERSON(S)
Eric Lynam, MS
Vice President, Business Development, Pharmatech Oncology, Inc.

With over 850 new compounds in development for the treatment of cancer and only three percent of adult oncology patients entering clinical trials, under-enrollment of oncology clinical trials is a serious problem. Traditional site-based clinical trial methods are inadequate for the development of cancer treatments in the era of personalized medicine. This session will present the rationale and data for a patient-focused model with an emphasis on the challenges of trials in a highly regulated, administratively oriented, and financially restrictive environment.

Protecting Patient Rights and Regulatory Compliance in a Patient-directed Clinical Research System
Matthew R. Baker
President and CEO, Compass IRB LLC

Clinical Trials in Oncology: Re-examining the Site-based Research Paradigm
Jeffrey Vacirca, MD
Clinical Director of Research, North Shore Hematology Oncology Associates

**SESSION 308**  **CR/CS 3 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**
8:30 AM-10:00 AM  LEVEL: ■
Room 151A
CME credits offered

Solving the Clinical Supplies Challenges for Adaptive Trials
SESSION CHAIRPERSON(S)
Gerald Finken, MS, RPh
CEO, Clinical Supplies Management

Adaptive by design and adaptive randomization methods allow companies to perform clinical studies faster and cheaper. However, clinical supplies tend to pose a challenge. This session features methods that detail how companies may approach clinical supply issues associated with adaptive trials. Complicating factors including limited investigational drug product (IDP) and short period of use will also be addressed.
Impact of On-demand Packaging and Labeling for Adaptive Trials
Gerald Finken, MS, RPh
CEO, Clinical Supplies Management

The Key Role of Simulation in Planning and Implementing Clinical Supplies for Adaptive Trials
Nitin R. Patel, PhD, MBA
Chairman, Chief Technology Officer, and Co-founder, Cytel, Inc.

Drug Supply Management for Adaptive Trials
Nancy Burnham, MA
Associate Director, GlaxoSmithKline

SESSION 309  CR/CS 4 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES
8:30 AM-10:00 AM  LEVEL:  ■
Room 151B  CME credits offered
How Many Clinical Trial Managers Does It Take to Manage a Trial?
SESSION CHAIRPERSON(S)
Jeanne M. Green, BSN, MSc
Director, Clinical Operations, ExecuPharm, Inc.

Projecting resource demand is an art and a science. Companies that manage resource allocation against demand with accuracy will preserve budgets, increase productivity, and create efficiency. Both large and small pharmaceutical and biotechnology companies are finding it increasingly difficult to stretch dollars and resources. This session will focus on CTM resourcing models currently in use, factors that go into development of algorithms, challenges with implementation, and future trends.

Resourcing CTMs: A Mid-size Pharmaceutical Perspective
Carrie L. Melvin, BSN
Director, Clinical Operations, Millenium: The Takeda Oncology Company

Resourcing CTMs: A Large-size Pharmaceutical Perspective
Heather A. Meyers, MS
Associate Director, Pfizer Inc

Resourcing CTMs: A Small-size Pharmaceutical Perspective
Lisa Robarge, MBA
Director, Clinical Development, Achillion Pharmaceuticals, Inc.

SESSION 310  CSP 1 - CLINICAL SAFETY AND PHARMACOVIGILANCE
8:30 AM-10:00 AM  LEVEL:  ■
Room 145B  CME credits offered
Pharmaceutical Packages and New Safety Legislation in the EU
SESSION CHAIRPERSON(S)
William W. Gregory, PhD
Senior Director, Safety and Risk Management, Pfizer Inc

Significant changes in pharmacovigilance requirements are expected in the European Union aimed at improving patient protection through better safety monitoring. This session will go through the essential pieces of the so-called pharmaceutical package, a set of new legislation and guidance aimed at reforming the regulation of the drug industry in the EU.

Industry View on Proposed Changes to EU Pharmacovigilance Legislation
Barry Arnold, MD
EU Qualified Person for Pharmacovigilance, AstraZeneca, UK

A New Era for Pharmacovigilance in EU: Regulatory Perspective
June Raine, MSc, MD
Director, Division of Vigilance Risk Management of Medicines and Chair of the Pharmacovigilance Working Party, MHRA, UK

SESSION 311  CSP 2 - CLINICAL SAFETY AND PHARMACOVIGILANCE
8:30 AM-10:00 AM  LEVEL:
Room 143C  CME, nursing, and pharmacy credits offered
Can a Risk Management Program Save a Product from Withdrawal?
SESSION CHAIRPERSON(S)
Gerald A. Faich, MD, MPH
Senior Vice President, SERRM, United BioSource Corporation

Product safety can be improved by implementing a risk management program. Risk management programs can mitigate the risks of a product and make sure that only those people who will benefit most are able to use them. Risk management programs have helped bring products back to the market after they have been withdrawn for safety concerns. This session will explore how risk management programs can save products from withdrawal.

The Tysabri Experience
Representative Invited
Vice President, Global Head, Drug Safety and Risk Management, Biogen Idec

Inhaled Insulin
Anders H. Boss, MD, FFPM
Chief Medical Officer, MannKind Corporation

FDA Point of View
Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

SESSION 312  EC - eCLINICAL
8:30 AM-10:00 AM  LEVEL:  ■
Room 204BC  CME and nursing credits offered
Electronic Source Documents: Removing the Paper Burden from Sites and Sponsors
SESSION CHAIRPERSON(S)
Edward Stephen Seguine, Jr., MBA
President, Clinical Ink

This session will present the unique views/experiences of a site, data monitor, and CRO as they have implemented technology and adopted new business practices to capture source documents electronically. The presenters will focus on how the patient and study coordinators are affected both during the visit as well as in managing the patient data at the site, how source data verification and site monitoring visits are impacted, and how data management, reporting, and performance are improved.
Informed Consent: Promise, Pledge, Contract, or Platitude?
Michael A. Swit, JD
Vice President, The Weinberg Group Inc.

SESSION 315  IT - INFORMATION TECHNOLOGY
8:30 AM-10:00 AM  LEVEL: ●
Room 202B
Life Sciences Cybercrime: A Law Enforcement Perspective
SESSION CHAIRPERSON(S)
Thomas Quinn
President, CISSP, The Hollis Group Inc.

What do you do if the worst case IT scenario happens to you and your team has been the victim of a cybercrime? This session will teach you what to do, what will happen during the investigation and prosecution processes, and inform you of the successes federal law enforcement has had in assisting organizations in similar situations.

Special Considerations in Life Science Criminal Investigations
Glenn Watson, MA
Special Agent, Senior Operations Manager, Cybercrime, Office of Criminal Investigations, FDA

Prosecuting Life Science Research and Operations Cases
P. Michael Cunningham, Esq., JD, LLM
Assistant U.S. Attorney, U.S. Department of Justice

Investigating Life Science Cyber Crimes
Representative Invited
Supervisory Special Agent, Washington Field Office, Cyber Squad

SESSION 316  MW - MEDICAL/SCIENTIFIC WRITING
8:30 AM-10:00 AM  LEVEL: ●
Room 152B
CME and nursing credits offered

Reporting Safety Data in FDA Marketing Applications: Is There a Change in FDA Expectations?
SESSION CHAIRPERSON(S)
Peggy M. Boe, RN
Senior Director, Regulatory Writing, Image Solutions, Inc. (ISI)

In this session, speakers will address questions raised by the discovery that some sponsors have started submitting CIOMS reports in the marketing application, appending the CIOMS reports to the clinical study reports in lieu of writing traditional narratives from the final clinical database.

Safety Report Considerations in Clinical Trials: What to Do and What Not to Do
Sandra J. Hecker, RAC
US Agent, Regulatory Consultant, Hecker & Associates, LLC

Best Practices in Clinical Study Report Narrative Generation
Peggy M. Boe, RN
Senior Director, Regulatory Writing, Image Solutions, Inc. (ISI)

The FDA’s Clinical Reviewer’s Perspective on CSR Safety Narratives
Howard Chazin, MD, MBA
Medical Officer, Office of New Drugs Immediate Office, Guidance and Policy Team, CDER, FDA
**Session 317**  
**NC - Nonclinical Laboratory Safety Assessment**  
8:30 AM-10:00 AM  
Room 103A  
LEVEL:  
CME credits offered  

**Preclinical and Clinical Development of Anticancer Pharmaceuticals**  
**Session Chairperson(s):** Klaus Olejniczak, DVM, FACP  
Scientific Director, Department of Drug Toxicology, BfArM, Germany  
The ICH S9 guideline on Nonclinical Development of Anticancer Pharmaceuticals will be presented and information will be given to assist in the design of an appropriate program of preclinical and clinical studies for the development of anticancer drugs.

**The ICH S9 Guideline for Nonclinical Evaluation of Anticancer Pharmaceuticals**  
Gerd Bode, MD, PhD  
Consultant, Germany  

**Industry Perspective**  
Daniel M. Lapadula, PhD  
Global Head, Toxicology, Novartis Pharmaceuticals Corporation  

**Phase 0 Trials for Anticancer Pharmaceuticals**  
James Doroshow, DrMed, FACP  
Director, Division of Cancer Treatment and Diagnosis; Senior Investigator, National Cancer Institute, National Institutes of Health

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**Session 318**  
**OS - Outsourcing**  
8:30 AM-10:00 AM  
Room 147B  
CME and nursing credits offered  

**It's Not Just a Project, It's a Relationship: The Site’s Perspective**  
**Session Chairperson(s):** Mike Menta, MBA  
Senior Practice Executive, Campbell Alliance Group, Inc  
As in any healthy relationship, clinical study sponsors and sites need to take a proactive and collaborative approach to establish and manage their relationship in order for it to flourish. It is important that both sponsors and sites define and understand what is most important to each party. This session will provide attendees with the tools to support clinical development professionals as they work to forge effective and lasting relationships between sponsors, sites, and CROs. Attendees will gain an understanding of the key factors driving investigator decisions, strategies for identifying a company’s needs and abilities in these key areas, and approaches for developing a robust strategy for improving a sponsor’s relationships with the sites and investigators it values most for outsourced and in-sourced studies.

**Amanda Wright**  
Director of Development, PMG Research, Inc.

**Mairead Kehoe-Whistance**  
Executive Director, Clinical Operations, Celgene Corporation

**Melissa Holbrook, MSN**  
Senior Director, Site Management; Head, North America Partner Sites, Quintiles

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**Session 319**  
**PD/TR - Professional Development/Training**  
8:30 AM-10:00 AM  
Room 103B  
CME, nursing, and pharmacy credits offered  

**An Overview of Drug Development for Emerging Professionals**  
**Session Chairperson(s):** Kavita Johal, PharmD  
Assistant Director, Global Regulatory Affairs, Bayer Healthcare Pharmaceuticals, Inc.  
This session will provide the target audience of emerging professionals (less than 6 years’ experience) with a basic understanding of the drug development process. It will outline the stages of drug development, how the various functional areas on a development team collaborate to bring a drug from discovery to approval, and postapproval life cycle management.

**Overview of Drug Development**  
Kavita Johal, PharmD  
Assistant Director, Global Regulatory Affairs, Bayer Healthcare Pharmaceuticals, Inc.  

**Career Opportunities for Emerging Professionals and Planning for the Future**  
Joan A. Chambers  
Senior Director of Marketing and Operations, Publications, Cambridge Healthtech Institute  

**A Brief Overview of Clinical Trials**  
Jun Kawashima, MD, MDiv  
Senior Medical Monitor, Pharmacovigilance Officer, Pharm-Olam International  

**Medical Product Development Moves Beyond “The Patient Is Waiting”**  
James E. Valentine, MSc  
Program Analyst, Office of Special Health Issues, Office of the Commissioner, FDA

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**Session 320**  
**PM/FI 1 - Project Management/Finance**  
8:30 AM-10:00 AM  
Room 140B  
PMI PDUs offered  

**Addressing the Biopharmaceutical Industry’s Leadership Challenges**  
**Session Chairperson(s):** Robin G. Foldesy, PhD  
Vice President, Project Management, PRA International  
The success or failure of a cross-functional team most often rests with the skill of the team leader. The most critical factors in effective leadership will be presented in this session. Key topics to be discussed include essential core competencies, the importance of soft as well as hard skills, and the common mistakes of new team leaders.

**Identifying and Developing Effective Leaders**  
Robin G. Foldesy, PhD  
Vice President, Project Management, PRA International
Designing an Innovative Organization: The Influence of Organizational Structure and Behavior on Leadership Development
Richard J. Heaslip, PhD
President, Programmatic Sciences

Alternative Future Drug Development Leadership Models and the Implications for the Core Competencies Needed
Peter Harpum, MSc
Managing Director, Harpum Consulting Ltd., UK

European Medicines Agency Perspectives
Ana Rodriguez, PhD
Head of Clinical and Nonclinical Compliance, European Medicines Agency, European Union

ClinicalTrials.gov Perspective
Rebecca Williams, PharmD
Assistant Director, ClinicalTrials.gov; Lister National Center for Biomedical Communication, National Library of Medicine

Research Perspective: The Role of Clinical Trial Register Information
Joseph S. Ross, MD, MS
Assistant Professor, Department of Geriatrics and Palliative Medicine, Mount Sinai School of Medicine

Panelist
Nicholas C. Ide, MS
Chief Architect, ClinicalTrials.gov, National Library of Medicine, National Institutes of Health

Session 323  RA 1 - REGULATORY AFFAIRS
8:30 AM-10:00 AM  LEVEL:
Room 147A  CME credits offered
Behind the Curtain with a Multinational Pharmaceutical Company for Pediatric Drug Development
SESSION CHAIRPERSON(S)
Chin Koerner, MS
Executive Director, Regulatory Policy, Novartis Pharmaceuticals Corporation

This session will discuss the inner workings of how companies are structured to carry out pediatric development, test pediatric formulations, design and implement clinical trials, and think globally while acting locally.

The Nuts and Bolts: A Sponsor’s Framework for Putting Together the Pediatric Plan
Megan Zoschg, PharmD
Group Director, Regulatory Affairs, Hoffman-La Roche Inc.

Building a Pediatric Development Research Program
Samuel D. Maldonado, MD, MPH
Vice President and Head, Pediatric Drug Development Center of Excellence, Johnson & Johnson Pharmaceutical Research and Development, LLC

Implementation Challenges of a Pediatric Research Program
Ronald Portman, MD
Group Director, Bristol-Myers Squibb Company

Lisa L. Mathis, MD
Associate Director, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
**SESSION 324**  
**RA 2 - REGULATORY AFFAIRS**  
8:30 AM-10:00 AM  
Room 146C  
CME and pharmacy credits offered  
**Evolution of Risk Evaluation and Mitigation Strategies (REMS)**  
**SESSION CHAIRPERSON(s)**  
Rekha Garg, MD  
Executive Director, Global Regulatory Affairs and Safety, Amgen Inc.  
This session will address the best practices, challenges, and unresolved issues based on substantially more experience over the past two years. Key aspects of REMS to be presented are safety registries, assessment of comprehension or knowledge of medication guide, patterns of prescribing and use, and REMS process and procedures.

REMS: Key Challenges  
Rekha Garg, MD  
Executive Director, Global Regulatory Affairs and Safety, Amgen Inc.

Key REMS Learnings from FDA Perspective  
Claudia B. Karwoski, PharmD  
Team Leader, Risk Management Team, Office of Surveillance and Epidemiology, CDER, FDA

REMS: Key Learnings 2007-2010, Key Questions 2010-?  
Nayan Acharya, MD, MRCP  
Senior Director, Risk Management and Pharmacoepidemiology, Global Patient Safety, Eli Lilly and Company

**SESSION 325**  
**RA 3 - REGULATORY AFFAIRS**  
8:30 AM-10:00 AM  
Room 146B  
**GRMPs and 21st Century Review Process: Are We Making Progress?**  
**SESSION CHAIRPERSON(s)**  
Daniel Brum, PharmD, MBA, RAC  
Senior Regulatory Project Manager, Division of Cardiovascular Renal Products, CDER, FDA  
A discussion of marketing application review and approval cannot be held without using the phrases “GRMP,” “complete application,” or “application quality.” CDER continues to phase in its 21st Century Review Process to implement GRMPs (Good Review Manufacturing Practices). This session will debrief an application that was reviewed under this process and share the lessons learned from both industry and review staff.

CDER 21st Century Review  
Daniel Brum, PharmD, MBA, RAC  
Senior Regulatory Project Manager, Division of Cardiovascular Renal Products, CDER, FDA

Implementing the 21st Century Review: An Early Case Study from an Industry Perspective  
Susan Boynton  
Executive Director, Therapeutic Area Head, Global Regulatory Affairs, Amgen Inc.

Panelists  
Rafel (Dwaine) Rieves, MD  
Director, Division of Medical Imaging and Hematology Products, Office of New Drugs, CDER, FDA

**SESSION 326**  
**RA 4 - REGULATORY AFFAIRS**  
8:30 AM-10:00 AM  
Room 144ABC  
CME and pharmacy credits offered  
**FDAAA Required Safety Labeling: The Why, How, and When**  
**SESSION CHAIRPERSON(s)**  
Joyce Korvick  
Deputy Director, Division of Gastrointestinal Products, Office of New Drugs, CDER, FDA  
The FDA Amendment Act provides for required safety labeling changes. A description of this section of the Act and required timelines, as well as application of the Act and challenges in class labeling, will be discussed from FDA and industry perspectives.

Safety Labeling Changes Under Food and Drug Administration Amendments Act 2007  
Larissa Lapteva, MD, MHS  
Deputy Director for Safety, Division of Anesthesia, Analgesia, and Rheumatology Products, Office of Evaluation 2, Office of New Drugs, CDER, FDA

Industry Point of View  
John R. Cutt, PhD  
Vice President, US DRA Franchise Head, Immunology and Infectious Diseases (IID), Novartis Pharmaceuticals Corporation

Safety Regulatory Project Manager’s Perspective  
Martin E. Kaufman, DPM, MBA  
Safety Regulatory Project Manager, Office of New Drugs, Division of Reproductive and Urologic Products, CDER, FDA

**SESSION 327**  
**RD - R&D STRATEGY**  
8:30 AM-10:00 AM  
Room 143AB  
**Global Market Access and Reimbursement Strategies**  
**SESSION CHAIRPERSON(s)**  
Rick Morton, PhD  
Senior Director, PAREXEL International, UK  
This session will explore existing challenges and opportunities in developing a global market access (MA) strategy given evolving relationships between regulatory and reimbursement agencies. This session will also explore research for reimbursement and gaining traction between MA with R&D workflows to support aligned thinking and focus on securing patient access to new technologies.

The Evolving Interface Between Regulatory and Reimbursement Agencies  
Mel D. Walker, PhD, RPh  
Director, Global Integrated Payer Strategy, GlaxoSmithKline, UK

Research for Reimbursement  
Representative Invited  
Senior Research Fellow, Center for the Study of Drug Development, Tufts University
Cloud Computing and Compliance with FISMA
Joel Junker, MBA, MS
Vice President, Systems Security Division, DSD Laboratories, Inc.

International Cloud Computing Issues and Recommendations
Neil O. McClennan, MS
Principal Consultant, VeriScientia Inc.

How to Select a Cloud Computing Provider
Glenn D. Watt, MS
Vice President, Information Security and Privacy, Medidata Solutions Worldwide

8:30 AM - 10:00 AM
Room 209AB
CME and pharmacy credits offered

Modeling and Simulation in Clinical Development: Beyond Trial Design and Exploratory Analyses

Jose C. Pinheiro, PhD
Senior Director, Biostatistics, Johnson & Johnson Pharmaceuticals Research & Development, LLC

Modeling and simulation (M&S) approaches are well established and accepted in the “learn” phase of drug development, as well as in the design of complex studies, such as adaptive designs. However, model-based primary analyses in pivotal trials remain controversial, mostly because of the stronger assumptions, often not easily testable, required for their validity. This session will discuss the potential role of M&S approaches in providing primary evidence of efficacy and/or safety in confirmatory trials. Concerns with model evaluation and validation (including regulatory) will be discussed, and potential strategies for addressing them will be described and illustrated. The focus of the session will be on establishing a constructive dialog toward better understanding of the value and limitations of M&S in the context of confirmatory studies.

Modeling and Simulation in Clinical Development: A Regulatory Perspective
H.M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Quantitative Decision Making in Clinical Development: Industry Perspective
Marc Pfister, MD
Executive Director, Discovery Medicine and Clinical Pharmacology, Head of S&M&S R&D, Bristol-Myers Squibb Company

Yaning Wang, PhD
Associate Director for Science, FDA

Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, CDER, FDA

10:00 AM - 10:30 AM
Refreshment Break

10:30 AM - 12:00 PM
Room 101
CME credits offered

Progress Towards a US Regulatory Pathway for Follow-on Biologics

Bruce P. Babbitt, PhD
Principal Consultant, PAREXEL Consulting

Given the current intense focus on the creation of a regulatory pathway supporting the development of biosimilars in the US, it has become very important for global developers of these products to ensure that their preclinical and clinical development plans are flexibility-designed such that they are able to satisfy both (likely) US and ex-US (primarily European) regulatory requirements. In particular, when meeting with US regulators in the absence of a follow-on biologics (FOB) pathway or subsequent clear-cut product specific guidances, FOB developers need to understand...
what additional product characterization and nonclinical/clinical testing is needed above and beyond what is planned to satisfy primarily European biosimilar development regulations. This session will address the diverse challenges and issues related to the design and performance of a global biosimilar development program which optimally integrates both US and ex-US requirements.

**Biosimilars: Navigating the Uncharted Waters**
David Rosen, JD, RPh  
Partner, Foley & Lardner, LLP

**Key Challenges in Global Development of Biosimilar Products**
Islah Ahmed, MD  
Global Medical Director, Drug Development, Hospira Inc.

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**SESSION 332  CDM - CLINICAL DATA MANAGEMENT**
10:30 AM-12:00 PM  LEVEL: ★
Room 206  Pharmacy credits offered

**What Deliverable? Importance of Close Collaboration Between Data Management and Other Functions**
SESSION CHAIRPERSON(S)
Carol Matthews  
Senior Director, Clinical Programming, United Biosource Corporation

This session will illustrate how close collaboration between data management and other functions is crucial in achieving good results in the most efficient way. Particularly, advantages of working with biostatistics will be discussed. Specific examples of reports used in cleaning the data will be provided, and the need to understand the roles and needs of other functions will be explored.

**Statistical Programmers: What They Do and How They Can Help**
Carol Matthews  
Senior Director, Clinical Programming, United BioSource Corporation

**Study Quality Metrics: Helping to Manage Studies Across Functions**
Michele Jenkins, BSN, RN  
Project Manager, Clinical Operations, Morphotek, Inc.

**Preparing for Interim Analyses: Cross-collaboration Between Clinical, Data Management, and Statistics**
Michele Houghton, RN  
Global Senior Director, Clinical Operations, Taiho Pharma USA, Inc.

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**SESSION 333  CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES**
10:30 AM-12:00 PM  LEVEL: ★
Room 146A  CME and pharmacy credits offered

**Quality-by-design: Linking Quality to Safety and Efficacy – Part 1 of 2**
SESSION CHAIRPERSON(S)
Janet Woodcock, MD  
Director, Center for Drug Evaluation and Research, FDA

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

This session will discuss quality-by-design (QbD), which is a systematic approach to pharmaceutical development and product cycle management beginning with predefined performance objectives and emphasizing enhanced product and process understanding, based on sound science and quality risk management. A QbD approach typically begins with determining the desired clinical performance requirements prior to product development. Fundamental understanding of the linkage between quality, safety and efficacy is essential to establishing a well-designed product with clinically relevant product specifications.

**Quality-by-design: Challenges and Opportunities**
Janet Woodcock, MD  
Director, Center for Drug Evaluation and Research, FDA

**Role of Biopharmaceuticals and Clinical Pharmacology in Drug Development**
James F. McLeod, MD  
Vice President, Experimental Medicine, Merck Research Laboratories

**Establishing Links Between Quality and Safety: What Are the Possibilities?**
Peter K. Honig, MD, MPH  
Managing Director, Peter Honig Regulatory and Medical Advisors, LLC  
PhRMA Representative to ICH Steering Committee and GCG Co-Chair

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**SESSION 334  CR/CS 1 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES**
10:30 AM-12:00 PM  LEVEL: ★
Room 150A  CME and nursing credits offered

**New and Evolving Patient Recruitment and Retention Practices**
SESSION CHAIRPERSON(S)
Kenneth A. Getz, MBA  
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

This session explores a variety of new initiatives that sponsors have implemented to improve patient recruitment and retention effectiveness. From the establishment of patient recruitment specialists and centralized recruitment functions to the use of Web 2.0 solutions (eg, social networking) and public outreach and education, this session explores various initiatives, their impact and shortcomings, and ways that they can be improved in the future.

**Leveraging Online Social Media for Patient Recruitment and Retention**
Bonnie A. Brescia  
Founding Principal, BBK Worldwide

**Advocacy Groups and Other Opportunities to Partner with Patient Communities**
Carmen R. Gonzalez, JD  
Manager, Strategy and Communications, Healthcare Communications Group

**Centralized Recruitment and Other Practices Enhancing Investigator Site Effectiveness**
James P. Kremidas  
Vice President, Global Head of Patient Recruitment, Quintiles Inc.
**Session 335**  
**CR/CS 2 - Clinical Research and Development/Clinical Supplies**  
10:30 AM-12:00 PM  
Room 151A

The Added Value of Including Emerging Markets in Global Clinical Trials  
**Session Chairperson(s):** Renee Elaine Moore, PhD

Navigating drug development in the emerging markets can seem challenging. With a multitude of cultural differences, diverse regulatory processes, and a variety of local medical practices, there is a clear need to develop a road map to reach successful completion of a quality clinical trial. This session will examine the reasons for choosing a specific emerging country for global clinical trials, challenges that should be foreseen in the planning stages of clinical trials in the emerging markets, including ethical considerations, intellectual property protection, understanding the human factor of risk taking to better understand cultural differences encountered in clinical trials in the various emerging market regions, regulatory considerations across multiple countries when planning a placebo-controlled trial in emerging markets, and solutions to effectively arrive at the successful completion of the global clinical trial. Regions examined are Asia (India, China, South East Asia, and Japan), South Africa, and Latin America.

**Opportunities for Successful Clinical Trial Conduction in the Emerging Markets**  
Renee Elaine Moore, PhD  
President, Global Operations, Progenitor International Research, Germany

**India: An Emerging Destination for Clinical Research**  
Suresh Kumar Gupta, DrSc, PhD  
Director General, IRL Research P Ltd., India

**Regulatory Trends in Global Clinical Trials**  
Ekopimo O. Ibia, MD, MPH, FRCP  
Director, Global Medical and Regulatory Policy, Merck & Co., Inc.

**Session 336**  
**CR/CS 3 - Clinical Research and Development/Clinical Supplies**  
10:30 AM-12:00 PM  
Room 151B

Communication to Bridge the Gap Between Regulations and Feasible Trials  
**Session Chairperson(s):** M. Renee Simar, PhD

This session will aid development teams in mapping pediatric program strategies that satisfy company goals and comply with regulatory requirements. Representative case studies will be presented to demonstrate the value of ongoing communication among stakeholders and how requirements impact resources, budgets, and study outcomes. Perspectives on how to incorporate these practical issues into pediatric clinical development plans and regulatory strategy will be presented by representatives from pharmaceutical companies and pediatric trial consultants.

**Early Planning to Ensure Success in Pediatric Programs**  
Andrew E. Mulberg, MD  
Senior Director, Internal Medicine, Established Products, Johnson and Johnson Pharmaceutical Research and Development

**Session 337**  
**CR/CS 4 - Clinical Research and Development/Clinical Supplies**  
10:30 AM-12:00 PM  
Room 149AB

Investigator-initiated Trials (IIT): State of the Industry and the Need for Global Standards and Metrics  
**Session Chairperson(s):** Michael T. Cullen, MD, MBA

Investigator-initiated trials (IITs) are an instrumental part of the life cycle of any drug/biologics/device. They bring innovation and new treatment options to products and patients. Learn how industry-led initiatives address global standards/best practices, metrics, compliance, and regulatory needs relative to this growing area.

**Current Global IIT Environment/Successful IIT Process**  
Michael Montgomery, MD  
President, IISRA, Centocor Ortho Biotech, Inc.

**When Is an IIT Program Successful? Measurements and Milestones**  
Susan Malecha, PharmD, MBA  
Senior Director, BioOncology Medical Science Liaisons, Genentech, Inc.

**Practical Issues in IISR: Examining Different US and European Approaches for Structuring IISR from Clinical and Regulatory Perspectives**  
Ran Frenkel, RPh  
CEO, Pharma Focus Israel

**Industry-led Initiatives Promoting Standards and Best Practices in the US**  
Karen Bartels, MBA, RN  
Executive Director, IISRA, AstraZeneca Pharmaceuticals LP

**Session 338**  
**CSP - Clinical Safety and Pharmacovigilance**  
10:30 AM-12:00 PM  
Room 145B

Clarifying Blinded and Unblinded Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting in US and Europe  
**Session Chairperson(s):** Nina Piskareva, MD

Blinded and unblinded reporting of SUSARs is one of the most complicated components for regulatory compliance. It becomes an even more arduous task when conducting global studies with country-specific ethics and regulatory requirements. Sponsors need to know when, how, and who is required to submit blinded and unblinded SUSARs. This session will
provide clarification on blinded versus unblinded specific requirements. In addition, new ways of handling secure submission of unblinded information to the principal investigator will be presented.

**Challenges of Reporting SUSARs for Blinded and Unblinded Studies in the USA and Europe**

Nina Piskareva, MD
Executive Director, Drug Safety and Pharmacovigilance, INC Research, Inc.

**Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting in Europe**

Vincent Yeung, PhD, MBA, RPh
GCP Operations Manager, Inspection, Enforcement, and Standards Division, MHRA, UK

**Implementation of a Web Portal for Posting and Distribution of IND/SUSAR Safety Updates**

Mary Ellen Thompson, BSN
Director, Clinical Operations, Celgene Corporation

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**SESSION 339**

**EC - eCLINICAL**

10:30 AM-12:00 PM  
Room 204BC  
CME and pharmacy credits offered

**eInformed Consent: Putting the Pieces Together**

**SESSION CHAIRPERSON(S)**

Susan Brink, DrPH  
President and CEO, ConsentSolutions, Inc.

This session will explore making a decision to use eConsenting, the steps to electronic consent usage with special emphasis on assessment of FDA guidelines for consent, interaction with Institutional Review Boards and their relationship to electronic consenting, and eConsenting interaction with eTrial management, and data capture facilities.

**eConsent: The Perfect Solution?**

Melissa Mau, MS  
Director, Clinical Research Core, Oral Health Research Institute, Indiana School of Dentistry

**FDA Point of View**

Jonathan S. Helfgott, MS  
Consumer Safety Officer, CDRH, FDA

**Considerations Regarding IRB Review of Electronic Consents**

Linda M. Coleman, Esq., JD  
Director, Regulatory Affairs, Quorum Review IRB

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**SESSION 340**

**ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT**

10:30 AM-12:00 PM  
Room 201  
CME and pharmacy credits offered

**Data Submissions to CDER: Getting It Right**

**SESSION CHAIRPERSON(S)**

Karen Higgins, PhD  
Mathematical Statistics Team Leader, Office of Translational Sciences, CDER, FDA

The Center for Drug Evaluation and Research (CDER) is pushing hard to assure that all NDAs (New Drug Applications) and BLAs (Biologic License Applications) receive a “21st Century Review” – this means that submissions are complete and fully reviewable on day 1 of the PDUFA calendar. This session will describe the Center’s efforts to get it right – to assure sponsors that the data they submit will be accepted and reviewable.

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**SESSION 341**

**GCP - GOOD CLINICAL PRACTICES**

10:30 AM-12:00 PM  
Room 152A  
CME and pharmacy credits offered

**Communication Dilemmas Among Clinical Sites, Sponsors, and Institutional Review Boards (IRBs): A Case of Regulatory Confusion or Confused Interpretations?**

**SESSION CHAIRPERSON(S)**

Felix A. Khin-Maung-Gyi, PharmD, MBA, CIP, RAC  
Chief Executive Officer, Chesapeake Research Review Inc.

The recent issuance of an FDA guidance regarding reporting requirements to institutional review boards (IRBs) may have added to rather than clarified the uncertainty of “who is responsible for what” in order to remain in regulatory compliance. Furthermore, recent high-profile events have raised sensitivities about the IRB’s role in vetting qualified clinical investigators. In this session, we will examine why IRBs, sponsors, and clinical investigators sometimes have different views of which and how adverse events and protocol deviations need to be reported under the current guidance. What does the current guidance outlining the clinical investigator’s (CI) responsibilities really state? What can the CI appropriately delegate to the staff/subinvestigator? Who is responsible for selecting the IRB? What are the responsibilities of the IRB in determining the qualifications of the CI? These questions will be addressed in an open forum with experts presenting the sponsor, IRB, and CI viewpoints.

**How Do IRBs Assess Investigator Qualifications and Compliance?**

Terri P. Kelly, RN, MSQA, CQA  
President and Principal GCP Compliance Auditor and Trainer, Achieve Quality, Inc.

**Dilemmas Reporting Serious Adverse Events (SAEs): Should We Sacrifice All Efficiencies or Specifically Accentuate Expedience?**

Lin Rhea, CCRC  
GCP Compliance Consultant, LMR Research Solution Inc.

**Informed Consent Process: Divergent Sponsor, Clinical Site, and IRB Perspectives**

Stephen Schwartz  
Manager, Clinical Trials, Reckitt Benckiser Pharmaceuticals
Wednesday, June 16

**SESSION 342**  
**IT 1 - INFORMATION TECHNOLOGY**  
10:30 AM-12:00 PM  
LEVEL: ☺

Room 202B

**Bringing Hosting, SaaS, and Cloud Computing to Clinical Research and Development**

**SESSION CHAIRPERSON(S)**

David Handelsman  
Business Solutions Manager, SAS Institute Inc.

Emerging implementation methodologies such as software-as-a-service (SaaS), cloud computing, and hosted offerings are changing the landscape in how new technologies are procured and deployed. This session will describe the differences between each of these approaches and cite examples of real-world deployments for clinical research processes.

- **Cloud Computing in Clinical Trials**
  Eudoro van der Biest, MS  
  Director, Information Services, LabConnect LLC

- **Taking Drug Discovery and Development by Storm: The Cancer Knowledge Cloud**
  Ken Buetow, PhD  
  Associate Director for Biomedical Informatics and Information Technology, National Cancer Institute, National Institutes of Health

- **Clouds, SaaS and Hosting: Definitions, Implications, and Opportunities**
  David Handelsman  
  Business Solutions Manager, SAS Institute Inc.

**SESSION 343**  
**IT 2 - INFORMATION TECHNOLOGY**  
10:30 AM-12:00 PM  
LEVEL: ☮

Room 144ABC

**The Opportunities and Challenges of Biomedical Informatics in the New Global Pharmaceutical Model**

**SESSION CHAIRPERSON(S)**

Ronald D. Fitzmartin, PhD, MBA  
Senior Principal Consultant, Decision Analytics, LLC

This interactive panel session will focus on the transformational capability of biomedical informatics to change the way we do clinical R&D and deliver health care from our current slow, costly, and error-prone methods to a future cost-effective, timely, and targeted approach. The panelists will include leaders from the FDA, pharmaceutical industry, health care, and technology providers. The session chair, following opening remarks by each panelist, will lead the panel and audience through a discussion of the challenges and opportunities of predictive analytics and standards in designing more modern clinical trials and more efficient aggregation, access, analysis, and reporting of disparate clinical and health care data.

- **Food and Drug Administration Point of View**
  Theresa M. Mullin, PhD  
  Associate Director, Office of Planning and Informatics, CDER, FDA

- **Panelists**
  Jason Burke, MA  
  Global Director, Health and Life Sciences R&D, SAS Institute

  Martin D. Leach, PhD  
  Executive Director, Basic Research and Biomarker IT, Merck & Co., Inc.

  John Cuddeback, MD, PhD  
  Chief Medical Informatics Officer, Anceta, AMGA's Collaborative Data Warehouse

**SESSION 344**  
**MC - MEDICAL COMMUNICATIONS**  
10:30 AM-12:00 PM  
LEVEL: ☮

Room 209AB

**Industry Support of Continuing Medical Education (CME): To Continue or Not – That is the Question!**

**SESSION CHAIRPERSON(S)**

Julie Brideau, PharmD, RPh  
Manager, Deloitte & Touche, LLP

The pharmaceutical, biologic, and medical device industries are significant financial supporters of continuing medical education (CME). Their support continues to be a hot topic, receiving increasing media and congressional attention. Both sides of this debate will be presented and discussed, as well as the alternative options currently under consideration for industry support.

- **Michele M. Garvin, JD, PhD**  
  Partner, Ropes & Gray LLP

- **John F. Kamp, JD, PhD**  
  Executive Director, Coalition for Healthcare Communication

- **Hilary Schmidt**  
  Associate Vice President, Medical Education, Medical Communication, sanofi-aventis

**SESSION 345**  
**MW - MEDICAL/SCIENTIFIC WRITING**  
10:30 AM-12:00 PM  
LEVEL: ☮

Room 152B

**INDs with a Global Focus**

**SESSION CHAIRPERSON(S)**

Sandra J. Hecker, RAC  
US Agent; Regulatory Consultant, Hecker & Associates, LLC

This session will examine medical writing project manager best practices to organize a complex document development program for clinical trial applications submitted to the US and other regions, efficiently, by reuse of components where possible and consideration of unique documents required by specific regions. Handling paper as well as electronic CTAs for the same product will also be discussed. Case studies will illustrate how to work globally and efficiently.

- **Medical Writing Challenges for Global Yet Harmonized CTA Submissions**
  Sandra J. Hecker, RAC  
  US Agent; Regulatory Consultant, Hecker & Associates, LLC

- **Investigational New Drug (IND) Applications: A Case Study of Document Development from the Medical Writing Perspective**
  Marilyn Ingram, BSN  
  Manager, Global Medical Writing, Premier Research Group Limited

- **Scientific Advice and Successful EU Clinical Trial Applications**
  Irene Gander-Meisterernst, DrSc  
  Consultant, Regulatory Strategies, Germany
**Session 346  NC - Nonclinical Laboratory Safety Assessment**

10:30 AM-12:00 PM  LEVEL:  
Room 103A  CME and nursing credits offered

**Preclinical Safety Evaluation of Oligonucleotide-based Therapies**

**SESSION CHAIRPERSON(s)**
S. Leigh Verbois, PhD  
Supervisory Pharmacologist, Division of Drug Oncology Products, CDER, FDA

This session will highlight the distinct product attributes for oligonucleotide-based therapies and their impact on the design of preclinical safety evaluation programs. In particular, the progress in five areas of preclinical assessment will be summarized; these areas include immunomodulatory effects, exaggerated pharmacology, off-target effects, genetic toxicity, and inhalation toxicity. Each area is being discussed by subcommittees of the Oligonucleotide Safety Working Group, which is an informal group of industry and regulatory professionals addressing safety issues associated with oligonucleotide-based therapeutics.

*Exaggerated Pharmacology of Oligonucleotides*
Joy A. Cavagnaro, PhD, RAC  
President, Access BIO

*Genetic Toxicity Testing of Oligonucleotides*
Cindy L. Berman, PhD  
Independent Consultant

**Session 347  OS - Outsourcing**

10:30 AM-12:00 PM  LEVEL:  
Room 147B

**Offshore, Re-shore or Right-shore: Risks and Opportunities in the Emerging Markets, with a Focus on India**

**SESSION CHAIRPERSON(s)**
Antal K. Hajos, PhD  
Managing Director and CEO Europe, Ecron Acunova GmbH, Germany

The stable and continuous trend to utilize the advantages of emerging markets such as India as an offshoring location to optimize costs and delivery over recent years is well recognized. Additional cost pressures on industry and the need to further lower fixed costs augment this trend; yet, not all initiatives taken by pharmaceutical companies and CROs seem to be fully successful. This session will critically evaluate the risks and opportunities of offshoring versus nearshoring models, the need for coordination and communication alignment, and aspects of project, service, and vendor selection. Overall strategic models for utilizing geographies will be discussed from both a pharmaceutical and a CRO perspective.

*Re-shore: A CRO Perspective*
Antal K. Hajos, PhD  
Managing Director and CEO Europe, Ecron Acunova GmbH, Germany

*Offshore: A Consultancy Perspective*
Rajiv Amarnath Pillai  
Senior Manager, Ernst & Young, India

David Freschi  
Global Category Manager, Development Strategic Sourcing, Novartis Pharmaceuticals Corporation

**Session 348  PD/TR - Professional Development/Training**

10:30 AM-12:00 PM  LEVEL:  
Room 103B  CME, nursing, and pharmacy credits offered

**Pediatric Drug Safety: Using Evidence in Real-time Treatment Decisions**

**SESSION CHAIRPERSON(s)**
Ann McMahon, MD, MS  
Acting Director, Division of Pharmacovigilance II, Office of Surveillance and Epidemiology, CDER, FDA

This session will explore the best methods for keeping informed regarding pediatric drug safety. The discussion will include strengths and weaknesses of available data on pediatric pharmacovigilance, including passive surveillance systems and clinical trials, and use of package inserts and other FDA resources in this setting.

*In Search of Pediatric Information: Where Is It?*
Dianne Murphy, MD  
Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

*Finding the Appropriate Benefit-risk Balance in Pediatric Pharmacotherapy*
Samuel D. Maldonado, MD, MPH  
Vice President and Head, Pediatric Drug Development/Center of Excellence, Johnson & Johnson Pharmaceutical Research and Development, LLC

*Role of Spontaneous Reporting in the Evaluation of Pediatric Drug Safety*
Ann McMahon, MD, MS  
Acting Director, Division of Pharmacovigilance II, Office of Surveillance and Epidemiology, CDER, FDA

**Session 349  PM/FI 1 - Project Management/Finance**

10:30 AM-12:00 PM  LEVEL:  
Room 140B  PMI PDUs offered

**Using Web 2.0 Technologies to Enhance PMO Effectiveness**

**SESSION CHAIRPERSON(s)**
Dana DiFerdinando, MS  
Senior Director, Information Technology, Arena Pharmaceuticals, Inc.

Web 2.0 technologies are being used to improve the effectiveness and efficiency of program management offices (PMOs) and improve enterprise collaboration. Learn how these tools can add value to portfolio management, improve management processes, and enhance partner communications.

*Increasing the Visibility of Enterprise Projects for Enhanced Decision Making*
Albert Oriol, MBA, MHA  
Chief Information Officer, Rady Children’s Hospital and Health Center

*Collaboration Tools for Managing Enterprise Programs*
Janet Firestein  
Managing Partner, Life Sciences, Clarkston Consulting.

*Maximizing Research Partnerships with Collaboration Tools*
Terri A. Roberson, MBA  
Senior Director, Operations, Global External Research & Development, Eli Lilly and Company
**SESSION 350**  | **PM/FI 2 - PROJECT MANAGEMENT/ FINANCE**  
10:30 AM-12:00 PM  
Room 154AB  
*The Changing Drug Development Environment: Effect on the Biopharmaceutical Project Manager*

**SESSION CHAIRPERSON(S)**: Michael J. Gaskell, PhD, PMP  
Global Program Manager, Program Management and Strategic Operations, Amgen Inc.

There are many factors which are contributing to the changing way drugs are developed. These include the unsustainable rising cost of healthcare coupled with an increased global health care demand, the decreasing return on investment from the pharma R&D pipeline, and the emergence of personalized medicine in partnership with targeted drug development. This session will examine some of the predictions of how the drug development process will continue to evolve from the project management viewpoint and use examples of drug/diagnostic co-development programs to illustrate the roles played by the project manager.

- **Effective Project Management: The Key to Effective and Efficient Projects in Today’s Environment**  
  Jean A. Yager, PhD  
  Executive Director, Project Management Consulting, BioPharm People

- **The Role of the Project Manager During the Development of Vectibix and the K-ras Biomarker**  
  Catherine A. Allen  
  Director, Program Management and Strategic Operations, Amgen Inc.

**SESSION 351**  | **PM/FI 3 - PROJECT MANAGEMENT/ FINANCE**  
10:30 AM-12:00 PM  
Room 140A  
*Financial Accruals for Clinical Trials: Basic Concepts and Effective Accrual Models*

**SESSION CHAIRPERSON(S)**: Chris Chan, MBA  
Senior Director, Clinical Finance, Fibrogen, Inc.

Clinical development and project management personnel are often required to assist their respective finance departments in generating financial accruals (ie, estimating incurred expenses) for clinical trials. However, for biopharmaceutical companies of all sizes, this task is often a challenging one. This session is intended to evolve from the project management viewpoint and use examples of drug/diagnostic co-development programs to illustrate the roles played by the project manager.

- **Accurately Managing Accruals in Clinical Trial Accounting**  
  Michael Bruns, MBA  
  Chief Financial Officer, ClearTrial, LLC

- **Effective Methodologies for Clinical Trial Financial Accruals**  
  (Large Company)  
  Michelle E. Polowski, MBA, MS  
  Associate Director, Business Operations, Genentech, Inc.

- **Effective Methodologies for Clinical Trial Financial Accruals**  
  (Small Company)  
  Chris Chan, MBA  
  Senior Director, Clinical Finance, Fibrogen, Inc.

**SESSION 352**  | **PP - PUBLIC POLICY/LAW/CORPORATE COMPLIANCE**  
10:30 AM-12:00 PM  
Room 102AB  
*Off-label Drug Use on Both Sides of the Atlantic*

**SESSION CHAIRPERSON(S)**: John A. Lisman, LLM, MPharm  
Lawyer, Lisman Legal Life Sciences B.V., Netherlands

Off-label promotion of drugs and devices is currently a hot topic: huge amounts of money are paid as a penalty for promoting a product beyond its authorization. But off-label use is a necessity in medical practice in those cases where off-label treatment is better than any authorized treatment. This session will look at the discrepancies between the neatly regulated uses of a product and the actual use that is made of these products. Furthermore, legislation and case law with respect to off-label use in the EU and in the US are being presented.

- **Off-label Use in the US**  
  Albert I. Wertheimer, PharmD, MBA  
  Professor, Pharmacy; Director, Center for Pharmaceutical Health Research, Temple University

- **Reasons for Off-label Use**  
  John A. Lisman, LLM, MPharm  
  Lawyer, Lisman Legal Life Sciences B.V., Netherlands

- **Panel Discussion: Off-label Drug Use**  
  Randall S. Stafford, MD, PhD  
  Associate Professor of Medicine, Prevention Research Center, Stanford University

**SESSION 353**  | **RA 1 - REGULATORY AFFAIRS**  
10:30 AM-12:00 PM  
Room 147A  
*Acceptability of Foreign Clinical Data for Registration of New Medicines*

**SESSION CHAIRPERSON(S)**: Neil McAuslane, PhD, MSc  
Director, CMR International Institute for Regulatory Science, UK

This session will focus on what is the current experience of using foreign clinical data for registration of new medicines and what the scientific principles are that should be at the forefront with regard to its acceptability.

- **What Are the Key Regulatory Principles That Will Give Confidence to Regulators for Acceptance of Foreign Clinical Data to Be Used as Pivotal in the Assessment of New Medicines for Approval?**  
  Murray M. Lumpkin, MD  
  Deputy Commissioner, International Programs, Office of the Commissioner, FDA

- **Pharmaceuticals and Medical Devices Agency Point of View**  
  Yoshiaki Uyama, PhD  
  Commissioner, FDA

- **Ethnic Factors, E5 Guideline and Acceptability of Foreign Data: What Is the Company Experience and Perspective for the Future?**  
  Paul D. Huckle, PhD, MPharm, RPh  
  Senior Vice President, Global Regulatory Affairs, GlaxoSmithKline
The Principles of Good Review Management Practices and Risk Evaluation and Mitigation Strategies (REMS)

SESSION CHAIRPERSON(S)
John R. Cullt, PhD
Vice President, US DRA Franchise Head, Immunology and Infectious Diseases (IID), Novartis Pharmaceuticals Corporation

Industry and FDA representatives will discuss good review management principles applied to REMS (Risk Evaluation and Mitigation Strategies). Lessons learned and REMS case studies will be shared.

Best Practices for REMS: An Industry Perspective
Jean A. Wright, DVM
Regulatory Manager, US Regulatory Affairs, Eli Lilly and Company

Lessons Learned on REMS: A Perspective on Stakeholder Implementation
Susan Boynton
Executive Director, Therapeutic Area Head, Global Regulatory Affairs, Amgen Inc.

REMS: FDA Perspective
Mwango Kashoki, MD, MPH
Associate Director, Safety, Office of New Drugs, CDER, FDA

Panelist
Suzanne B. Robottom, PharmD
Team Leader, Division of Risk Management, Office of Surveillance and Epidemiology, CDER, FDA

Negotiating Regulatory Hurdles in Vaccine and Adjuvant Development and Licensure

SESSION CHAIRPERSON(S)
Judith S. Atkins, PhD
Principal Consultant, PAREXEL Consulting, Canada

This session will discuss the regulatory requirements for development and approval of vaccines with or without adjuvants. Special focus will be directed to vaccines incorporating novel adjuvants. Understanding how the regulators view vaccines and adjuvants, and what they are looking for in terms of pivotal information for safety and effectiveness, can help speed successful development and access to patients in need. Development histories of failed vaccines will be presented, as well as the secret to the success of others. A “lessons learned” will also be presented.

Vaccines and Adjuvants: What Can We Learn from the Past?
Judith S. Atkins, PhD
Principal Consultant, PAREXEL Consulting, Canada

Hurdles in Vaccine Development
Nancy Kirschebaum, PhD
Senior Consultant, PAREXEL Consulting

Addressing the Challenges of Developing a Novel Adjuvant as a Technology Platform: Iscomatrix® Adjuvant Case Study
Jillian K. Bennet, MSc, MPH
Vice President, CSL Limited, Australia

The Regulatory History of Licensing of Cervarix
Cynthia A. d’Ambrosio, PhD
Director, GlaxoSmithKline

Modernizing Regulatory Pathways in Personalized Medicine: Update on the Latest Initiatives to Stimulate Drug-diagnostic Co-development and Overcome Dual Registration Barriers

SESSION CHAIRPERSON(S)
Jeffrey N. Stuart, PhD, RAC
Associate Director, Regulatory Affairs, Novartis Oncology

The attraction of personalized medicine is grounded in the need for more informative, rapid clinical trials and enhanced health outcomes. For example, using a diagnostic test to identify likely responders to a given drug may reduce the number of subjects needed to demonstrate a favorable risk-benefit profile. However, to date, only a few drugs have been successfully developed and registered with a companion diagnostic.

With initiatives spanning multiple centers, FDA is aiming to streamline regulatory pathways for personalized medicine. This session will investigate the potential benefits and unique regulatory hurdles for co-development and registration of a drug and companion diagnostic, the current international regulatory environment for pursuing co-development, and the challenges facing regulators in jointly evaluating a drug and companion diagnostic. With regulators and industry aligned, the promise of personalized medicine can be more fully realized.

Myths and Truths About Regulatory Requirements for Co-development of Drug-diagnostic Pairs
Elizabeth A. Mansfield, PhD
Director, Personalized Medicine, Office of In Vitro Diagnostic Evaluation and Research, CDRH, FDA

Food and Drug Administration Guidance for Industry on Drug-diagnostic Co-development
Vicki L. Seyfert-Margolis, PhD
Senior Advisor, Science Innovation and Policy, Office of the Commissioner, FDA

Considerations for Companion Diagnostic Assays in the Development of Targeted Therapies
Jon Askaa, DVM, PhD
Chief Executive Officer, Medical Prognosis Institute A/S, Denmark

Personalized Medicine: Are We There Yet?

SESSION CHAIRPERSON(S)
Georgia Mitsi, PhD, MBA, MSc
Senior Research Associate, United BioSource Corporation

“The right drug or treatment for the right patient at the right time.” This session will address many questions. Did what began as a promise of a major medical breakthrough manage to be part of the everyday medical practice? People still expect that personalized medicine will affect the traditional way of thinking about clinical care and health care services. Some may argue that it will increase the quality of care while it reduces health care costs, whereas others argue that personalized medicine is associated with more diagnostic tests and therefore additional costs (eg, R&D, test validation). Who has the right side of the story? Assuming that technological advancements continue in the right direction, is the existing framework ready to support this approach? Is there a certain plan, accepted from
all the health-related parties, physicians, scientists, payers, government, regulatory bodies, pharmaceutical companies, diagnostic companies, and patients to address specific challenges like scientific, economic, legal/ethical, and operational? What is the future of personalized medicine, since only a handful of genetic tests have managed to enter successfully into the market after quite some time? Is there a future for additional diagnostic tests or will the only platform for continuous development be along with drug development?

Personalized Medicine: Food and Drug Administration Perspective
Francis Kalush, PhD
Network Leader, Diagnostics and Personalized Medicine, FDA

Will Personalized Medicine Manage to Be Part of the Everyday Medical Practice?
Walter G. Bradley, DrMed, MD, MA
Professor and Chairman Emeritus, Department of Neurology, University of Miami

Industry’s Challenges and Action Plans
Mark E. Curran, PhD
Senior Director, Immunology Biomarkers, Centocor R&D Inc.

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**Session 359**

**ST - Statistics**

1:30 PM-3:00 PM
Room 140A

**Responding to FDA/OHRP Training Requirements for Investigators and Institutions**

**Session Chairperson(s)**
Erika Stevens, MA
Director of Clinical Trials Office, Dartmouth Hitchcock Medical Center

The FDA and Office for Human Research Protections (OHRP) expect that investigational site staff receive training to ensure they are qualified (e.g., competent) to perform their assigned duties in clinical research. This session will present the FDA and OHRP expectations, as highlighted in FDA warning letters and guidance documents, as well as OHRP determination letters. FDA has communicated this via investigator warning letters since 2006, and OHRP has communicated this in a proposed regulation. An academic institution case study will be presented for the audience to learn an implementation methodology and for benchmarking to current regulatory agency standards.

**Responding to FDA Training Requirements for Investigators and Institutions**
Liz Wool, BSN, RN
President and Chief Executive Officer, QD-Quality and Training Solutions Inc.

**Training Considerations for Complying with 45 CFR Part 46**
Freda E. Yoder, MA
Human Subjects Protections Analyst, Office of Human Research Protections, US Department of Health and Human Services

**An Academic Case Study**
Erika Stevens, MA
Director of Clinical Trials Office, Dartmouth Hitchcock Medical Center

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**Session 360**

**BT - Biotechnology**

1:30 PM-3:00 PM
Room 101

**Recent Advancement of Follow-on Biologics in Asian Pacific Region**

**Session Chairperson(s)**
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

The development of follow-on biologics has attracted attention among industries as well as academia in Asia. This session will be devoted to the discussion and comparison of recent advances in the development of follow-on biologics in the Asia-Pacific region. Industry and regulatory experts will share insights on the topic as well as discuss a comparison of development strategies.

**Overview of Follow-on Biologics in the Region**
Duu-Gong Wu, PhD
Executive Director, Consulting Division, Pharmanet Development Group, Inc.

**Opportunity and Challenges: Regulatory Pathway for Follow-on Biologics in Asia**
Meir-Chyun Tzou, PhD
Director, Division of Drugs and New Biotechnology Products, Food and Drug Administration, Department of Health, Taiwan
Global Development of Follow-on Biologics: Implications for Asia Pacific Region
Lois M. Hinman, PhD
Global Head, Biologics Oversight and Strategic Projects, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation
Panelist
Oliver Yoa-Pu Hu, PhD
FAAPS Distinguished Professor, School of Pharmacy, National Defense Medical Center, Taiwan

SESSION 361 CDM - CLINICAL DATA MANAGEMENT
1:30 PM-3:00 PM LEVEL: ■
Room 206
CME credits offered
How Do We Prepare for Database Lock? Readiness of Sites, CROs, and Sponsors
SESSION CHAIRPERSON(S)
Heather E. Fahs
Project Manager, Covance Inc.
On-time database lock is essential, as it is the culmination of weeks, months, or even years of data collection. To meet database lock timelines, it is essential that sites, CROs, and sponsors know their roles and responsibilities leading up to database lock. By assessing the site’s perspective on their role in meeting database lock and reviewing effective preparation by the CRO/sponsor, this session will discuss various ways to maximize site engagement leading up to an on-time database lock.
Leadership Challenges of a Successful Data Management Staff Lift from a Pharmaceutical Company to a Data Services CRO and the Culture Change from “Vendor” to “Strategic Partner”
Sandy Imboden
Director, Strategic Alliances, Data Management, i3 Statprobe
Four Steps to Bridge the Specifications Gap: How Technical and Clinical Staff Can Find a Common Language
Jeff Sonas
Owner, Sonas Consulting

SESSION 362 CMC/GMP - CHEMISTRY, MANUFACTURING, AND CONTROLS/GOOD MANUFACTURING PRACTICES
1:30 PM-3:00 PM LEVEL: ■
Room 146A
CME and pharmacy credits offered
Quality-by-design: Linking Quality to Safety and Efficacy – Part 2 of 2
SESSION CHAIRPERSON(S)
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA
Part 1 of this session will take place on Wednesday at 10:30 am.
This session will discuss quality-by-design (QbD), which is a systematic approach to pharmaceutical development and product life cycle management beginning with predefined performance objectives and emphasizing enhanced product and process understanding, based on sound science and quality risk management. A QbD approach typically begins with determining the desired clinical performance requirements prior to product development. Fundamental understanding of the linkage between quality, safety, and efficacy is essential to establishing a well designed product with clinically relevant product specifications.

SESSION 363 CR/CS 1 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES
1:30 PM-3:00 PM LEVEL: ◆
Room 150A
Site Relationship Management (SRM) Initiatives for Improving Site Performance
SESSION CHAIRPERSON(S)
Richard Robinson
Assistant Director, Internal Medicine, Metabolism, and Diabetes Group, sanofi-aventis
This group of site management experts previously provided their vision of where site relationship management (SRM) was heading and described specific initiatives that their organizations were implementing. This session will highlight the various SRM programs that each sponsor is undertaking and provide practical insights as to the challenges, opportunities, and progress they have achieved over the past year. Participants will hear case studies and have a chance to ask questions of these experts representing pharmaceutical companies, a CRO, and industry.
Understanding and Improving Sponsor/Site Relationships
Cheryl K. Fiedler, PharmD
Executive Director, Study Strategy and Planning, Bristol-Myers Squibb
Working in Collaboration with Investigator Sites to Enhance Their Ability to Enroll Patients and Streamline Operations
James P. Kremidas
Vice President, Global Head of Patient Recruitment, Quintiles Inc.
Re-engaging Relationships with Academic Medical Centers
Beth D. Harper, MBA
Chief Clinical Officer, Centerphase Solutions

SESSION 364 CR/CS 2 - CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES
1:30 PM-3:00 PM LEVEL: ◆
Room 151A
CME and nursing credits offered
Stretching the Clinical Dollar in Challenging Financial Times
SESSION CHAIRPERSON(S)
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group Inc.
A wealth of operational data has accumulated over the last ten years of eClinical trials. This session shows how metrics can establish credible expectations for subject and site performance during the design of clinical studies, and can help in managing subject and site compliance during trials.

Metrics to Manage Subject and Site Performance During Trials
Jill V. Platko, PhD
Scientific Advisor, PHT Corporation

Collecting Useful Data: A Guide to Using eClinical Metrics for Managing Studies and Sites
Thamar Draper, MSc
Senior Director, Product Strategy, Omnicomm Systems

Use of eDiary Impact on Study Design and Conduct: Experience from Asthma Trials
Åsa C. Carlsheimer
Clinical Information Science Director, AstraZeneca R&D Lund, Sweden

In turbulent times, it seems that containing costs becomes just one more challenge to hard-working teams engaged in difficult, high-pressure, high-stakes work; however, in many companies the funding well is drying up. This session will look at this topic from several biopharmaceutical companies’ perspectives to address the issue creatively without deep cuts to the organization’s head count.

The Relentless Pursuit of Clinical Operations Efficiencies in Clinical Development
Scot Harper, PhD
Chief Executive Officer, Novartis Clinical Operations, Inc.

Managing Global Trials for Maximum Value
Gene Williams, MBA
Chairman, TMI

How Multiple Companies Stretch Clinical Dollars
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group Inc.
**Session 369**  
**ERS/DM 1 - Electronic Regulatory Submissions/Document Management**  
1:30 PM-3:00 PM  
Room 202A  
**FDA’s Electronic Registration and Listing System: After One Year**  
SESSION CHAIRPERSON(S)  
Middleton “John” Coburn, MBA, MPHarm  
FDA Senior Advisor, FDA  

FDA regulations require all firms that market drug products in the United States to register and list those products. This session will provide an overview of the electronic drug registration and listing system (eDRLS), and presenters will share their experience, objectively and subjectively, one year after converting to electronic from the paper system.

- **Electronic Registration and Listing: New Challenges**  
  David E. Mazyck  
  Consumer Safety Officer, eDRLS Operations, Office of Compliance, CDER, FDA  
- **Transition to eDRLS: Highlights and Lessons Learned**  
  Leyla Rahjou-Esfandiary, PharmD  
  Pharmacist, Office of Compliance, CDER, FDA

**Session 370**  
**ERS/DM 2 - Electronic Regulatory Submissions/Document Management**  
1:30 PM-3:00 PM  
Room 201  
**Experiences with Outsource Partnering for eCTD Production**  
SESSION CHAIRPERSON(S)  
Daniel F. Orfe, MS  
President and CEO, Regulatory eSubmissions, LLC  

The life science industry is turning to specialized resources to meet the business needs of their organizations. A key area for the use of skilled partners is in the compilation of regulatory documents into electronic submission (ie, eCTD) assembled for delivery to the regulatory authorities worldwide. This session will discuss opportunities for leveraging eCTD partners from the perspective of a large pharmaceutical company, an emerging pharmaceutical company, and a clinical research organization (CRO).
Smashing Silos: Using Data Governance to Cultivate Value

SESSION CHAIRPERSON(S)
Paulette V. Roper, MS
Senior Manager, eSolutions, Allergan Inc.

Replacing information silos with an enterprise data architecture enables full integration of information assets and provides future growth readiness. These changes decrease costs by removing the need to develop point-to-point system integrations, provide capabilities for future IT projects, and positively impact project timelines and costs. Realizing these benefits requires diligent governance. Implementing data governance is an essential complement to architecture and data warehousing efforts. The legacy of silos, independent cultures, and the perceived magnitude of work involved in fully implementing data governance prevents many companies from realizing these benefits.

In this session, we will provide details regarding experiences shaping data governance within pharmaceutical companies. We will present case studies describing how data governance took shape, what the framework included, the outcomes, and the learnings.

If Data is King, Then Data Governance is Critical: The Structure and Mission of a Data Council
Thomas C. Grundstrom, MA
Vice President, Global Data Solutions, Quintiles Transnational Corp.

Data Governance: Can the King Be Governed?
Beth Everett, PhD
Associate Vice President, Enterprise Information Management, SAIC

Living with Data Governance: Where Do the Benefits Outweigh the Costs?
James Farrelly
Director, Clinical Application Development, Pfizer Inc

Smashing Silos: Using Data Governance to Cultivate Value

SESSION 374  MW - MEDICAL/SCIENTIFIC WRITING
1:30 PM-3:00 PM  LEVEL: ◆
Room 152B

Authoring CTD/eCTD Submissions: Experience from FDA and Industry
SESSION CHAIRPERSON(S)
Michelle Herrera Foster, PhD
Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

This session will present common technical document (CTD) and electronic CTD (eCTD) authoring updates and case studies. This session will describe writing clinical/nonclinical and chemistry, manufacturing, and control (CMC) sections, focusing on effective processes for writing and reviewing eCTD-ready documents, including content reuse. In addition, we will present results of a survey of FDA eCTD reviewer comments, summarizing reviewability considerations.

Getting It Right the First Time: An Introduction to Document Authoring Best Practices for eCTD Submissions
Shannon P. Strom
Associate Director, Regulatory Affairs, Pearl Therapeutics

Authoring to Help FDA’s Review
Sarah Connelly, MD
Medical Officer, Office of New Drugs, CDER, FDA

Effective CMC Document Preparation Process for Global New Product Registration
Laura P. O’Brien, PhD
Senior Principal Scientist, Boehringer Ingelheim Pharmaceuticals, Inc.

Therapy Compliance: Good Practice in Any Practice

SESSION CHAIRPERSON(S)
Willem Th. Kort, PhD
Owner, Last of the Free Spirits B.V., Netherlands

Gain a better understanding of the benefits that therapy compliance and adherence strategies for medication use can bring. This still relatively underdeveloped area will be regarded from different perspectives (health care insurance, pharmaceutical/biotech industry, government, CROs, academia, patients, politics, and payers) whereby focus will be on the current status, the future opportunities, and the technological evolution that will allow all these changes to take place.

Trias Medica: The Triumvariate of Pharma, Insurance, and Regulatory to Enhance Therapy Compliance
Representative Invited
Brand Leader, Cardiovascular, AstraZeneca, Netherlands

The Compliance Factory in Day-to-day Practice: A Vision for Community Pharmacists
Isabelle Arnet, PharmD, DrPhil
Senior Scientist, Department of Pharmaceutical Care, University of Basel, Switzerland

GLP and GCP: Perspectives from US and China

SESSION CHAIRPERSON(S)
Florence Houn, MD, MPH
Co-chair, International Network, FDA Alumni Association

As clinical and nonclinical investigations increase in China, multinational global biotechnology and pharmaceutical companies benefit from understanding the US and Chinese requirements for good clinical practices (GCP) and good laboratory practices (GLP) in China. This session will bring together industry and US and Chinese regulators to discuss scientific, regulatory, and other issues related to compliance with standards for both regulatory agencies.

US GCP Requirements for Global Trials
Jean Mulinde, MD
Acting Team Lead, Good Clinical Practices Team 2, FDA

US GLP Regulations Facing Globalization Challenges
Dalin Dylan Yao, MD, PhD
Pharmacologist/GLP Expert, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Chinese GCP and GLP Requirements
Jinju Li
Director, Division of Drug Research Supervision, SFDA, China
SESSION 376  OS 1 - OUTSOURCING
1:30 PM-3:00 PM  LEVEL: ●
Room 147B
Strategic Partnerships: Models, Best Practices, and Measuring Success
SESSION CHAIRPERSON(S)
Simon Higginbotham
Senior Vice President and Chief Marketing Officer, Kendle
Clinical research organizations (CROs) and their biopharmaceutical customers have entered a new generation of outsourcing relationships focused around innovation and collaboration to drive efficiency and value across the drug development life cycle. CROs today are not just a helping hand but a helping brain. This session will focus on the evolution of strategic partnerships, the types of partnership models and the advantages of each, best practices of successful partnerships, and how to measure partnership success.

Best Practices in Managing Service-provider Relationships
Roberto Vaccaro, MBA
Director, R&D Global Strategic Sourcing, Amgen Inc.

Tracking the Evolution and Adoption of Integrated Sponsor-CRO Alliance Relationships
Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRR

Building a Strategic Partnership: A Road Less Traveled
Debbie Profit, MS
Associate Director, Clinical Operations, Global Clinical Development, Otsuka Pharmaceutical Development and Commercialization, Inc.

SESSION 377  OS 2 - OUTSOURCING
1:30 PM-3:00 PM  LEVEL: ▲
Room 149AB
Moving from a Fully Integrated Pharmaceutical Company to a Fully Integrated Pharmaceutical Network
SESSION CHAIRPERSON(S)
Steve J. Rosenberg, MSC
Senior Vice President, Phase Forward
Under the traditional fully integrated pharmaceutical company (FIPCO) model, a pharmaceutical company owns almost every aspect of development, manufacturing, and marketing and bears all the financial risk of bringing a drug to market. This model had success in the past, but new industry pressures and the continuing trend of globalizing drug development efforts have caused some organizations to re-evaluate the effectiveness of this strategy. The speakers will describe an evolving business model, FIPNet, that is gaining traction and how it can move more drugs through development pipelines, quicker and cheaper than the FIPCO strategy.

Dermot Kenny
Vice President, Data Management, ICON Clinical Research, Ireland

Paula Brown Stafford, MPH
Executive Vice President, Integrated Clinical Services, Quintiles

Katherine J. Vandebelt
Senior Director, Data Sciences and Solutions, Eli Lilly and Company

Gregg Dearhammer
President, i3 Statprobe

SESSION 378  PD/TR - PROFESSIONAL DEVELOPMENT/TRAINING
1:30 PM-3:00 PM  LEVEL: ■
Room 103B
A Career Survival Primer: Using Networks to Thrive Professionally
SESSION CHAIRPERSON(S)
Jane E. Myles, MS
Global Patient Recruitment Specialist, Genentech, Inc.
Merger and acquisition (M&A) has been a key trend in the pharmaceutical/biotechnology industry in 2009, with three large deals reached in the first half of the year. The M&A process can absorb a tremendous amount of energy for employees, even if they are not in key decision-making senior management roles. This session will focus on three approaches to networking during M&A and throughout a career: using online networking tools to develop and maintain relationships while clarifying your skills to others; developing and leveraging internal networks to drive opportunity and commitment; and partnering with external recruiters to clarify career goals and opportunities while sharing your skillset with a broader network.
This session will use online media and tools to allow audience participation. Bring your smart phones and be ready to text or surf the web!

Networking for Career Advancement and Successfully Working with a Professional Recruiter
Bridgid Nelson
Executive Recruiter, Liberty Consulting Group

Networking: Why, How, When, Where
Christopher H. Matheus, MBA
Senior Director, Sales, ICON Clinical Research

SESSION 379  PM/FI 1 - PROJECT MANAGEMENT/FINANCE
1:30 PM-3:00 PM  LEVEL: ■
Room 140B
The Role and Importance of Decision Analytics in Project and Portfolio Management
SESSION CHAIRPERSON(S)
Eric M. Towler, PhD, PMP
Director, Global Project Management and Leadership, Daiichi Sankyo Inc.
Protracted declines in productivity of new drug development require the project manager to more actively manage the triple constraints (scope/time/cost) and deliver projects that are capable of sustaining pipelines that continue to be depleted by high attrition and, on many occasions, questionable quality. Toward this end, the project manager must utilize more effective and expedient processes, methods, and tools which transcend those that have been used both routinely and successfully for many decades. Nowhere is this truer than in scope management, where a variety of decision support techniques have been used to efficiently enable smart decisions and focus project teams on their objectives. This session will review the use of decision analytics as a holistic discipline to increase productivity at both the project team and portfolio level.

The Role and Importance of Decision Analytics in Early-stage R&D
Matt Hendricks, MS
Senior Consultant, Centerline Partners
The Role and Importance of Decision Analytics in Clinical Development
Sabine Bernotat-Danielowski, PhD, MBA
Vice President, Decision Analysis, Daiichi Sankyo Pharma Development

The Role and Importance of Decision Analytics in Portfolio Management
Richard Bayney, PhD, MBA
President and Founder, Project & Portfolio Value Creation

Session 380 PM/FI 2 - Project Management/Finance
1:30 PM-3:00 PM
Room 154AB
PMI PDUs offered
Crossing International and Functional Boundaries: Successfully Implementing an Enterprise Project Management System in a Global Clinical Research Organization
SESSION CHAIRPERSON(S)
Gail Batson Fowler, FACP
Vice President, ICON Clinical Research
Criteria for successful implementation of an enterprise project management system in a global CRO will be reviewed. Presenters from resourcing and finance, IT, and project management will provide metrics data, case histories, and lessons learned from pre- and postlaunch activities. Communication and measurement strategies will be emphasized.

Maximizing Efficiencies in Project Management and Monitoring Through a Centralized Resourcing Model
Cindi Stout
Director, CTM Resourcing, Premier Research Group Limited

Session 381 PP - Public Policy/Law/Corporate Compliance
1:30 PM-3:00 PM
Room 102AB
CME, nursing, and pharmacy credits offered
Risk Managing Your Clinical Trial Process Against Liability Claims
SESSION CHAIRPERSON(S)
Kevin Quinley, MA
Vice President, Risk Services, Berklely Life Sciences, LLC
Drug companies can face significant legal liabilities and financial drain from claims arising from test subjects. This session will discuss some of the liability risks from the clinical trial process, and risk management strategies and techniques to mitigate these uncertainties.

Planning and Insuring Against Risk Associated with the Conduct of a Clinical Trial Program
Bruce Wagman, MBA, RN, RAC
Vice President, Regulatory Affairs and Quality Assurance Services, Covance Inc.

Best Practices in Clinical Trial Compliance
Jill Anderson, JD
Of Counsel, Moses & Singer LLP

Defending and Preventing Tort Liability Claims from Clinical Trial Adverse Events
Walter (Pete) Swayze, III, JD
Managing Partner, Segal McCambridge Singer & Mahoney, Ltd.

Session 382 RA 1 - Regulatory Affairs
1:30 PM-3:00 PM
Room 147A
CME credits offered
Clinical Trial Environment in the EU: Time for Changes
SESSION CHAIRPERSON(S)
Martine Zimmermann, PharmD
Director, Pharmaceutical Affairs, Europe/Middle East/Africa, Alexion Europe, France
The session will review the current regulatory environment for clinical trials in the EU in force since implementation of Directive 2001/20. The impact on development strategies for SMEs (small and medium enterprises) or small biotechnology companies will be illustrated by real case examples. The panel representing various stakeholders in the EU will discuss their proposed solutions that ultimately will benefit the quality, quantity, and effectiveness of clinical research.

Current Challenges of the EU Clinical Trial Directive: The View from a Biotechnology Company
Stephane Wilzius, MSc
Director of Clinical Operations, Europe/Middle East/Asia, Alexion Pharma International, Switzerland

Proposed Solutions to Improve the Clinical Trial Environment in the EU
Beat E. Widler, PhD
Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Revision of the Clinical Trial Directive and the View from the Academic Network ECRIN
Christine Kubiak, PharmD, PhD
ECRIN Executive Manager; INSERM, Institut Thématique Santé Publique, France

Session 383 RA 2 - Regulatory Affairs
1:30 PM-3:00 PM
Room 146C
CME credits offered
Behind the Curtain with the Pediatric Review Committee
SESSION CHAIRPERSON(S)
Lisa L. Mathis, MD
Associate Director, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
Sections 4 and 5 of FDAAA require an internal review committee to provide high-level oversight of the activities conducted under the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). This panel session, comprised of actual Pediatric Review Committee (PeRC) members, will provide insight to how the PeRC operates and what goes into decisions and recommendations made by the committee.

Panelists
Hari Cheryl Sachs, MD
Lead Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
Rosemary M. Addy, MS
Regulatory Project Manager, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

Melissa S. Tassinari, PhD
Staff Fellow, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

SESSION 384  RA 3 - REGULATORY AFFAIRS
1:30 PM-3:00 PM  LEVEL:
Room 143AB
PDUFA Reauthorization: Where Do We Go from Here?
SESSION CHAIRPERSON(S)
Roy J. Baranello, MS
Regulatory Affairs Consultant

Following the reauthorization of PDUFA in conjunction with the FDA Amendments Act in 2007, we are now near the midpoint before the PDUFA program will once again be up for reauthorization in 2012. The goals of this session are to reflect on what were the intended objectives of the PDUFA legislation, identify progress as well as the constraints toward meeting the objectives and performance goals, and provide an outlook on the next round of reauthorization (ie, where have we been, where are we now, where are we heading). Speakers, including an FDA representative, will discuss these issues and share their perspectives on what the PDUFA program has accomplished, identifying both the successes and the impediments to achieving the desired goals, and provide a forward-looking view on potential issues to be addressed when PDUFA is up for reauthorization again in 2012.

FDA's View on PDUFA: Progress and Challenges
Theresa M. Mullin, PhD
Associate Director, Office of Planning and Informatics, CDER, FDA

Assessment of PDUFA: The Promise and the Reality
Kenneth I. Kaitin, PhD
Director, Center for the Study of Drug Development and Professor of Medicine, Tufts University School of Medicine

PDUFA: A Perspective from Industry
Kay Holcombe, MS
Senior Policy Advisor, Government Relations, Genzyme Corporation

SESSION 385  RA 4 - REGULATORY AFFAIRS
1:30 PM-3:00 PM  LEVEL:
Room 146B
Regulatory Harmonization and Cooperation Initiatives: What Will Success Look Like?
SESSION CHAIRPERSON(S)
Romi Singh, PhD
Executive Director, Global Regulatory Affairs and Safety, Amgen Inc.

This session will provide an overview of regulatory harmonization and cooperation efforts and highlight the barriers to mutual recognition on a regional and global basis. There will be discussion on how a major industry-regulatory authority initiative such as Simultaneous Global Development could lead to reduced regulatory barriers and good review practices. There will be evaluation of how the erstwhile European-based pharmaceutical evaluation report (PER)-like alliance could do away with bureaucratic requirements, avoiding unnecessary duplication of effort in the review of product applications, faster approvals, and improved patient access to novel drugs. Finally, there will be discussion of various regional initiatives that involve partnerships rather than full mutual recognition of approvals, highlighting a need to account for differences in local conditions and ethnic differences.

Opportunities and Challenges in Simultaneous Global Development
Peter K. Honig, MD, MPH
Managing Director, Peter Honig Regulatory and Medical Advisors, LLC; PhRMA Representative to ICH Steering Committee and GCG Co-Chair

Why Recent APEC Developments Matter: Promoting a More Effective Approach to Regulatory Harmonization and Cooperation
Mike D. Ward
Manager, International Programs Division, Health Canada

Good Regulatory Practices and Partnership on APEC LSIF
Herng-Der Chern, MD, PhD
Executive Director, Center for Drug Evaluation, Taiwan
**SESSION 387**  
**VA - Validation**  
1:30 PM-3:00 PM  
Room 209AB

**Validation Challenge of eClinical When EHR/EMR Is Integrated**

**SESSION CHAIRPERSON(S)**  
James Huang, PhD  
Consultant, JP Technology and Compliance

This session provides a comprehensive review of challenges, opportunities, impacts, available technical solutions, and case studies of validation of integration between EMR/EHR and eClinical to achieve maximum efficiency and data quality.

- **How Are Pharmaceutical and Health Care Industries Collaborating to Improve Electronic Clinical Trial Data Collection and Security**  
Rich Furr  
Head, Global Regulatory Affairs and Chief Compliance Officer, SAFE-BioPharma Association

- **EMR/EHR Integration and Validation Using a Health Care Information Bus**  
George Wu, PhD  
CEO, Doublebridge Technologies Inc.

- **Use of EMR in Clinical Trials: Operational Considerations**  
Laura Araujo, MEd  
Senior Consultant, Halloran Consulting Group Inc.

**REFRESHMENT BREAK**  
3:00 PM-3:30 PM  
Exhibit Halls A and B, Lower Level

**SESSION 388**  
**AHC/IS - Academic Health Centers/Investigator Sites**  
3:30 PM-5:00 PM  
Room 140A

**Quality and Performance in Clinical Research: Establishing a Quality Management System for Success**

**SESSION CHAIRPERSON(S)**  
Carol Fedor, ND, RN  
Clinical Research Manager, Center for Clinical Research and Technology, University Hospitals Case Medical Center

This session will review quality management principles, their applicability to clinical research, and outline the components of a clinical research site-institution quality management program. A case study will review methods and approaches of an academic health center that has implemented a clinical research quality management program.

- **Quality Management Systems: The Foundation for Human Subject Protection**  
Liz Wool, BSN, RN  
President and Chief Executive Officer, QD-Quality and Training Solutions Inc.

- **Quality Management Systems for Human Subjects Protection: Case Study**  
Christina Eberhart  
President and CEO, PhaseCare

**SESSION 389**  
**BT - Biotechnology**  
3:30 PM-5:00 PM  
Room 101

**Immunogenicity Assessment for Therapeutic Proteins**

**SESSION CHAIRPERSON(S)**  
Ronald L. Wange, PhD  
Pharmacologist, Office of New Drugs, CDER, FDA

Enzyme-linked immunosorbent assay (ELISA) and radioimmunoassay (RIA) based techniques, which are widely used and accepted, will be described in the use of addressing non-neutralizing and neutralizing antibodies to therapeutic drugs (ADA). Assays to detect neutralizing antibodies can be cell based. Designer cell-based assays will be introduced, which simultaneously will serve as potency assays in the characterization of drug and in lot release.

- **Immunogenicity Assays for Therapeutic Antibodies**  
Ralf Dieter Hess, PhD, MSc  
Principal Consultant, PAREXEL International, Germany

- **Methodologies for Immunogenicity Assessment**  
Steven J. Swanson, PhD  
Executive Director, Medical Sciences, Clinical Immunology Department, Amgen Inc.

- **FDA’s “Guidance for Industry: Assay Development for Immunogenicity Testing of Therapeutic Proteins” Representative Invited**  
Acting Associate Chief, Laboratory of Immunology, Developmental Therapeutics Program, CDER, FDA

**SESSION 390**  
**CDM - Clinical Data Management**  
3:30 PM-5:00 PM  
Room 206

**CDASH Standard CRFs: Everyone’s a Winner**

**SESSION CHAIRPERSON(S)**  
Rhonda Facile  
CDASH Project Director, CDISC

This session will begin by introducing the CDASH project, background, scope, process, and how it fits with other CDISC standards. Each of the following presentations will present different perspectives that benefit from the use of CDASH Standard case report forms.

- **CDASH from the CRO Perspective**  
Dawn Marie Kaminski  
EDC Product Manager, Octagon Research Solutions Inc.

- **CDASH from the Operational Data Modeling Team (ODM) and Controlled Terminology Perspective**  
Gary G. Walker  
Associate Director, Enterprise Data Standards, Quintiles

- **CDASH from the NCI caBIG Perspective**  
Dianne M. Reeves, MSN  
Associate Director, Biomedical Data Standards, National Cancer Institute, National Institutes of Health
**Session 391**  
**CMC/GMP - Chemistry, Manufacturing, and Controls/Good Manufacturing Practices**  
3:30 PM-5:00 PM  
Room 146A  
**Combination Products: Regulatory and Quality Aspects**  
**Session Chairperson(s):** Christine Moore, PhD  
Acting Deputy Director, Office of New Drug Quality Assessment, CDER, FDA  
Combination products range from simple prefilled syringes to more complex products like drug-eluting stents and antibody-drug conjugates. These products are regulated by multiple FDA offices and centers, which raises regulatory, policy, and review management challenges. This session will discuss some of the regulatory and quality considerations for submission of combination products. It will provide an overview of the regulations and procedures for combination products, including assignment of the Center and Office with primary jurisdiction for premarketing review and regulation. Quality considerations for complex combination products will also be addressed including product development, product characterization, and manufacturing and process controls.

- **Drug-device Combination Products: Quality Considerations from an FDA Perspective**  
  Kasturi Srinivasachar, PhD  
  Pharmaceutical Assessment Lead Chemist, Office of Pharmaceutical Science, Office of New Drug Quality and Assessment, CDER, FDA  

- **Antibody Drug Conjugates: Development of Regulatory Submissions**  
  Elsie C. Webber, PhD  
  Manager, Pfizer Inc  

- **Current Regulatory Jurisdiction, Procedures, and Considerations**  
  Michael Folkendt, MS  
  Associate Director for Regulatory Affairs, Office of Pharmaceutical Science, Office of New Drug Quality and Assessment, CDER, FDA

**Session 392**  
**CR/CS 1 - Clinical Research and Development/Clinical Supplies**  
3:30 PM-5:00 PM  
Room 150A  
**Patient Recruitment in a Technological Era**  
**Session Chairperson(s):** Richard J. Mayewski  
Global Trial Optimization Specialist, Merck & Co., Inc.  
This session will discuss current trends in recruitment and retention focusing on the technological aspects available to both sites and sponsors. Combining the perspectives of both vendor and sponsor, attendees will be able to gain insight into how some of these tactics/strategies work and what it may take for your group to implement these new practices. Equally, this session will provide metrics on standard recruitment practices versus new technology-assisted practices.

- **Patient Recruitment 2.0: Making the Case for Technological Adoption**  
  Joseph Kim, MBA, MEd  
  Director, Site Feasibility and Patient Recruitment, ePharmaSolutions

**Session 393**  
**CR/CS 2 - Clinical Research and Development/Clinical Supplies**  
3:30 PM-5:00 PM  
Room 151A  
**Assessing and Measuring Performance in Clinical Research**  
**Session Chairperson(s):** Catherine Crane, MBA, RN  
Associate Vice President, sanofi-aventis  
Conducting clinical trials to ensure safety, data validity, and GCP compliance while meeting performance targets and controlling cost remains a significant challenge for R&D in the pharmaceutical industry. This session will provide examples of how these challenges are addressed by using a more cost-effective approach to achieve a performance-driven quality outcome. In addition, the use of signal detection methods to identify and mitigate potential risk, ongoing and adaptive performance management using predictive modeling, and embedding expected compliance outcomes into behavioral practices up front are some of the areas to be discussed with examples provided.

**Session 394**  
**CR/CS 3 - Clinical Research and Development/Clinical Supplies**  
3:30 PM-5:00 PM  
Room 151B  
**Increasing Importance of Independent Data and Safety Monitoring in Clinical Research**  
**Session Chairperson(s):** Charles H. Pierce, MD, PhD  
Medical Director, CTI Clinical Trial and Consulting Services  
Formal data monitoring committees (DMCs) are increasingly used in clinical trials sponsored by the pharmaceutical industry. With the introduction of new therapeutics in critically ill patient populations, the role of independent DMCs to ensure patient safety in multicenter global clinical studies is
of critical importance. Selecting appropriately qualified clinical expertise, guaranteeing independence, and implementing processes to maintain confidentiality to avoid biasing the trial, are important challenges. This session will address how to define standards and processes so that the DMC can perform its functions in a timely and objective manner.

**Why Are DMCs Important in Clinical Research: Setting the Stage and Defining the Problem**
Eliezer Katz, DrMed, MD
Vice President, Medical Affairs, CTI Clinical Trial and Consulting Services

**A Statistician’s Role and Perspective on Running Effective DMC Meetings**
Ramesh N. Amatya, PhD
Director, BioStatistics, Kendle International Inc.

**Sponsor Perspectives on the Optimal Establishment and Functioning of DMCs**
Paul P. Gallo, PhD
Biometrical Fellow, Novartis Pharmaceuticals Corporation

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**SESSION 395**

**CSP 1 - CLINICAL SAFETY AND PHARMACOVIGILANCE**

3:30 PM-5:00 PM
Room 145B

CME, nursing, and pharmacy credits offered

**Data Gathering and Communication Tools to Improve Safe and Effective Use of Drugs During Pregnancy and Lactation**

SESSION CHAIRPERSON(S)
Tammie Howard, BSN, MSN, RN
Regulatory Reviewer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

This session will focus on gathering data on medicine use during pregnancy and lactation through pregnancy registries, clinical lactation studies, pharmacokinetic studies, clinical trials, and database studies. How FDA legislation, guidance, and rulemaking work together to facilitate data collection and communication to better inform prescribers and patient care will also be addressed.

**Drug Information Needs for Pregnant Women**
Richardae Araojo, PharmD
Reviewer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

**Drug Safety Information for Lactating Women and Human Milk Fed Infants**
Jeanine Best, MSN, RN
Clinical Analyst, Office of New Drugs, CDER, FDA

**Synthesizing and Communicating Available Data on Drug Use During Pregnancy and Lactation**
Leyla Sahin, MD
Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA
Karen B. Feibus, MD
Medical Team Leader, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

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**SESSION 397**

**EC - eCLINICAL**

3:30 PM-5:00 PM
Room 204BC

CME credits offered

**Innovations in Combining Patient-reported Outcomes with Physiologic Measurements to Leverage Real-time Access to Data**

SESSION CHAIRPERSON(S)
Christina Curry, MSc
Marketing Specialist, PHT Corporation

Clinical trial endpoints can involve patient collection of physiologic and patient-reported outcome data. These data can be collected and transmitted remotely due to technological advances. This session addresses opportunities and challenges of parallel biometric-PRO data collection in clinical trials for empirical evidence of product value.

**Innovations in Physiologic and Patient-reported Data Capture**
Sonya L. Emerenoco, MA
ePRO Manager, United BioSource Corporation

**Innovations in Oncology Symptom Data Capture: PROs versus ClinROs**
Ethan M. Basch, MD
Medical Oncologist, Health Outcomes Group, Memorial Sloan-Kettering Cancer Center

**Innovations in Cognitive Testing: Using ePRO to Assess Drug Effect**
Christina Curry, MSc
Marketing Specialist, PHT Corporation
SESSION 398  ERS/DM 1 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT

3:30 PM-5:00 PM  LEVEL: ●
Room 202A  Pharmacy credits offered


Mollie Shields-Uehling
President and CEO, SAFE-BioPharma Association

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

European Medicines Agency Point of View
Timothy Buxton
Head of Sector, ICT Development, European Medicines Agency, European Union

Enabling Fully Electronic Global Business and Regulatory Processes Through Digital Signatures
Peter Loupos, MS
Vice President, Prospective and Strategic Initiatives, sanofi-aventis

SESSION 399A  ERS/DM 2 - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT

3:30 PM-5:00 PM  LEVEL: ●
Room 201

The EDM Reference Model: Current Use and Future Plans
SESSION CHAIRPERSON(S)
James M. Averback, MS
Partner, Life Science Integration Partners

The electronic document management system (EDM) forms the foundation of a pharmaceutical company’s assembly line for regulatory submission documentation. As technology and documentation business processes have matured, companies have recognized increasing business value in EDM systems which are more easily implemented and are lower in cost to maintain and operate. This session will present a brief on the current state, implementations and future plans for the model’s extension. In addition, during the panel discussion, representatives will talk about their company’s experiences in implementing EDM systems and the impact of the reference model.

Large Pharma’s Experience of a Standardized EDM Model
Dimitri Stamatiadis, PhD, MBA
Project Director, Merck-Serono, Switzerland

Industry Experience with Implementing the EDM Reference Model
Steve Scribner
Managing Consultant, International Life Science Solutions

SESSION 399B  GCP - GOOD CLINICAL PRACTICES

3:30 PM-5:00 PM  LEVEL: ●
Room 152A

Quality Assurance Methods to Ensure Compliance in Global Biorepository Operations
SESSION CHAIRPERSON(S)
Jennifer Benner
Director of Global Quality Assurance, BioStorage Technologies

As clinical trials evolve and expand to a worldwide scale, rigorous controls and restrictions have been set in place that, if not adhered to correctly, can result in costly fines and timely audits that can delay the launch of a new product. Moreover, regulatory agencies are conducting complex and multifaceted analyses of clinical investigators and sponsors to validate clinical trials data. Therefore, the session will highlight quality assurance methods that pharmaceutical companies can take to mitigate risk and ensure compliance of global biorepository operations.

Quality Assurance Methods to Ensure Compliance in Global Biorepository Operations
Jennifer Benner
Director of Global Quality Assurance, BioStorage Technologies

Maintenance of High-quality Samples from Collection through Final Disposition
Anita J. Pascarella-Hallett
Director, Clinical Diagnostic Services, Eli Lilly and Company

Handling of Biological Samples to Ensure Analytical Data Integrity in Clinical Trials
Douglas E. King, MS
Director, Business Development, Division of Pharma, DCL Medical Laboratories

SESSION 399C  IT 1 - INFORMATION TECHNOLOGY

3:30 PM-5:00 PM  LEVEL: ●
Room 202B

Clinical Development Applications and Databases Integration Programs Update
SESSION CHAIRPERSON(S)
Rajiv Prasad, MBA
Assistant Vice President, Life Sciences, Mahindra Satyam BPO Ltd.

This session will evaluate the efforts of an industry sponsor, systems providers, and systems integrators to integrate disparate clinical development applications into an end-to-end, seamless, integrated platform with database and application interactivity with archival for ease of access, analysis, and reporting. This platform is integrated with CDISC-compatible eCTD submissions systems. The data archival is by molecule stage and the phase of development available for query analysis and reporting for future decision making. All roles will be affected by these improvements, and the session will address the changes that will impact attendees and their organizations. Design your own clinical integration program and participate in discussions with the presenters and other attendees to explore solutions that industry is seeking.

A Systems Integrator’s Perspective
Rajiv Prasad, MBA
Assistant Vice President, Life Sciences, Mahindra Satyam BPO Ltd.

A Systems Provider’s Perspective
Gregory Jones
Chief Technology Officer, Oracle Health Sciences
**SESSION 399D**  **IT 2 - INFORMATION TECHNOLOGY**  
3:30 PM-5:00 PM  
LEVEL: ●  
Room 207B  
Service-oriented and Event-driven Architectures: Modern Architectural Patterns in a Complex Enterprise  
SESSION CHAIRPERSON(S)  
Douglas M. Doedens, MS  
Senior Director, Integration and Standards, Oracle Corporation Health Sciences Global Business Unit  
This session will educate business users on the key advantages of implementing a service-oriented and event-oriented architecture within a pharmaceutical company’s enterprise.  

*It’s Not the Application, but the Integrations Among Them, That Matters*  
Jaydev Thakkar, MS, PMP  
Principal Architect, IS Enterprise Architecture, Amgen Inc.  

*Applying Service- and Event-driven Architecture to Enable the Business of Clinical Development*  
David Pasirstein, MS  
Director, Business Architecture, Global Clinical Trial Operations, MRL IT, Merck & Co., Inc.  

**SESSION 399E**  **MC - MEDICAL COMMUNICATIONS**  
3:30 PM-5:00 PM  
LEVEL: ●  
Room 143C  
The Patient Perspective  
SESSION CHAIRPERSON(S)  
Nancy D. Smith, PhD  
Former Director, Office of Training and Communications, CDER, FDA  
There is a wealth of information about the risks and benefits of medicines available to patients. However, much of it is written in a way that makes it almost incomprehensible to anyone without a background in health care. Also, some of the information is biased and/or misleading. This session will focus on the needs of patients and how we can all work together to better serve these needs. The session will present several success stories from industry and patient advocacy groups. These will be discussed from both a regulatory and an academic perspective. Emphasis will be on ways we can all work together to improve patient education and provide better information to everyone.  

*Drug Information and the Patient Perspective*  
Nancy D. Smith, PhD  
Former Director, Office of Training and Communications, CDER, FDA  

*Involving Patients: An FDA Perspective*  
Theresa A. Toigo, MBA, RPh  
Director, Special Health Issues, Office of the Commissioner, FDA  

*Patient Advocacy Group Perspective*  
Jeff Allen, PhD  
Executive Director, Friends of Cancer Research  

**SESSION 399F**  **MW - MEDICAL/SCIENTIFIC WRITING**  
3:30 PM-5:00 PM  
LEVEL: ■  
Room 152B  
Global Strategies in Medical Writing: A Perspective from Asia  
SESSION CHAIRPERSON(S)  
Leyna Mulholland, PharmD, PhD  
Director, Global Regulatory Affairs, Hoffmann-La Roche Inc., Japan  
Global clinical trials for the international release of a drug are costly and lengthy, yet the potential to streamline processes does exist. The development in Asia follows US or EU’s approach and Asia does not start its development until the proof of concepts is well established in the US or EU. With the increase in development in Asia, there is a great need for proactive study design and plans, which can maximize the use of global documents that could cover Asia. This session examines the development and implementation of a global development model and discusses different options to consider from a medical writing perspective in Asia.  

*CTD: Does One Size Fit All?*  
Jo Vibe Tolshave, MSc  
Medical Writer, Specialist, H. Lundbeck A/S, Denmark  

*How to Be Successful in Global Medical Writing: Japan Perspective*  
Yuko Kojima, RPh  
Senior Manager, Japan Medical Communications, Eli Lilly Japan K.K., Japan  

**SESSION 399G**  **NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT**  
3:30 PM-5:00 PM  
LEVEL: ■  
Room 103A  
Update and Experience with ICH M3R2  
SESSION CHAIRPERSON(S)  
Abigail C. Jacobs, PhD  
Associate Director, Pharmacology/Toxicology, Office of New Drugs Immediate Office, CDER, FDA  
Major revisions were incorporated into ICH M3R2, which was finalized in June 2009. Changes were made to existing sections, and new sections were added. These included sections on acute toxicity studies, limit dose in toxicity studies, duration of repeat dose studies for non-rodents, estimation of the first dose in human, exploratory clinical studies: limited clinical studies with nonclinical testing program directed only to support those early exploratory approaches, and reproduction toxicity studies. New material was included on timing for special studies, such as disproportionate metabolite studies, toxicity studies to support clinical trials in pediatric populations, immunotoxicity studies, phototoxicity studies, nonclinical abuse liability studies, and fixed combination drug nonclinical studies.  

*Introduction*  
Abigail C. Jacobs, PhD  
Associate Director, Pharmacology/Toxicology, Office of New Drugs Immediate Office, CDER, FDA  

*An Industry Perspective*  
Joseph J. DeGeorge, PhD  
Vice President, Global Safety Assessment, Merck & Co., Inc.  

*An EU Perspective*  
David R. Jones, MS  
Expert Pharmacotoxicologist, MHRA, UK
SESSION 399H  OS - OUTSOURCING
3:30 PM-5:00 PM  LEVEL: ■
Room 147B
Resource Management in a Virtual Model: Effective and Efficient Spending
SESSION CHAIRPERSON(S)
Gregory E. Dombal
Managing Partner, Halloran Consulting Group Inc.

Virtual development models offer the promise of bringing the right expertise to bear on a project at the right time with minimal company infrastructure. When effective, this model can offer an extremely cost-effective approach to ensure efficient progress through the development cycle. However, if poorly executed, virtual development can be derailed by exorbitant outsource and consultant costs. A thorough and detailed understanding of how to plan for and integrate the use of a variety of external sources is essential for the program leader in a virtual development setting. This session will explore methods that have been successfully employed to ensure effective and efficient spending in virtual models.

Vendor Management: Keeping Many Vendors on the Same Timeline
April A. Dovholuk
Clinical Research Manager, Clinical Operations, Millenium Pharmaceuticals

The Right Resources at the Right Time: Building a Virtual Team
Robert Gallato
Chief Business Officer, Alnara Pharmaceuticals

SESSION 399I  PD/TR - PROFESSIONAL DEVELOPMENT/ TRAINING
3:30 PM-5:00 PM  LEVEL: ■
Room 103B
Training and Education of Pharmaceutical Physicians: Experiences from Different Regions
SESSION CHAIRPERSON(S)
Jean-Paul M.F. Deslypere, MD, PhD
CEO, Aesculape Pte Ltd., Singapore

The session will provide information about the current efforts to train and certify pharmaceutical physicians in the US and elsewhere. It will highlight the different possibilities for training and the role of professional organizations in organizing this. In addition, it will more specifically focus on the various approaches which are taken in the different continents. This session will also review the details of an Innovative Medicines Initiative in the EU and compare it with the situation in the US, Latin America, and Asia.

Training and Education of Pharmaceutical Physicians: Experiences from Latin America
Joao Massud, MD
Executive Officer, Newco Trials Pesquisa Clinica, Ltda., Brazil

Emerging Needs in Pharmaceutical Medicine Education: Is Harmonization Possible?
Honorio Silva, DrMed
President, Inter American Foundation for Clinical Research

Continuing Professional Training and Career Development of Pharmaceutical Physicians: Case Studies in China
Representative Invited
Medical Director, Wyeth Ltd., Hong Kong

SESSION 399J  PM/FI 1 - PROJECT MANAGEMENT/ FINANCE
3:30 PM-5:00 PM  LEVEL: ■
Room 140B
What Makes a Project Manager Effective?
SESSION CHAIRPERSON(S)
Leigh Shultz, PhD, PMP
Associate Project Director, Merck & Co., Inc.

What defines effective project management in the pharmaceutical industry, given that more than nine out of ten R&D projects fail? Effective project managers are defined both by what they do and how they do it. This session will examine what truly great project managers do and what combination of skills they have that sets them apart from their peers.

Survey Results: What Do the Data Say?
Jayna Rose, PhD, PMP
Director, Global Program Manager, Amgen Inc.

Large Pharma Perspective
Leigh Shultz, PhD, PMP
Project Leader, Bone and Pain, Merck & Co., Inc.

Effective Project Management: A CRO Perspective
Nita Ichhpurani, PMP
Director, Drug Development, Development and Regulatory Services, MDS Pharma Services, Canada

SESSION 399K  PM/FI 2 - PROJECT MANAGEMENT/ FINANCE
3:30 PM-5:00 PM  LEVEL: ■
Room 154AB
Six Sigma in Drug Development: The Good, the Bad, and the Ugly Experiences in Deployment
SESSION CHAIRPERSON(S)
Michael A. Walega, MSc
Six Sigma Master Black Belt, Covance

While the drug development industry is clearly not yet saturated in Six Sigma, the language and strategic importance of process excellence continue to grow and are already fairly common across a broad variety of organizations globally. Join us as we take a critical look at the accumulating reality and the lessons learned leveraging Six Sigma to optimize the complex process that is clinical trial conduct. The session addresses the experiences with Six Sigma deployment from complementary strategic and real-life practical perspectives. We will explore and expose lessons learned from various deployment models, share specific project case studies, and discuss the applicability of the methodology itself to our highly variable and complex industry.

Panelists
Daniel G. Rudmann, DVM, PhD
Group Leader, Molecular Pathology and Imaging, Certified Lean/ Six Sigma Black Belt, Lilly Research Laboratories

Debbie Profi t, MS
Associate Director, Clinical Operations, Global Clinical Development, Otsuka Pharmaceutical Development & Commercialization, Inc.
**SESSION 399L  PP - PUBLIC POLICY/LAW/CORPORATE COMPLIANCE**

3:30 PM-5:00 PM  
Room 102AB  
CME, nursing, and pharmacy credits offered

**Influences of the Changing Drug Development Environment**

SESSION CHAIRPERSON(s)

John A. Lisman, LLM, MPH  
Lawyer, Lisman Legal Life Sciences B.V., Netherlands

This session will look into the environment in which decisions are made with respect to development of new medicinal drugs. Expected climate change and policies developed to prevent detrimental consequences have, as in many other areas, their impact on drug development. The environment for the development of new medicines is also changing with respect to the involvement of academia and private companies and their interaction. Finally, there is the influence of politics and policies that prefer to develop medicinal products for large wealthy populations, rather than for tropical diseases or rare conditions. This leads to an allocation of R&D investments in areas where adequate medicines are already available and leave many medical needs unmet. This session discusses the incentives and disincentives for innovation in the pharmaceutical field.

- **Impact of Climate Change on Pharma**  
  Breffni Martin  
  Director, Regintel Ltd., Ireland

- **Changing the Research Paradigm**  
  Regina Awe, MS  
  Society for Independence in Research

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**SESSION 399N  RA 2 - REGULATORY AFFAIRS**

3:30 PM-5:00 PM  
Room 146C  
CME and pharmacy credits offered

**21st Century Genomics Reviews at the US FDA**

SESSION CHAIRPERSON(S)

Federico Manuel Goodsaid, PhD  
Associate Director, Operations in Genomics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

This session will show how the Genomics Group at the FDA has integrated reviews of genomic data within regulatory reviews of investigatory new drugs (INDs), new drug applications (NDAs), and biologic license applications (BLAs). This session will show how novel tools have led to the analysis, interpretation, and conclusions from genomic data in regulatory reviews.

- **Pharmacogenetics, Regulatory Science, and the Advancement of Personalized Health**  
  Issam Zineh, PharmD, MPH  
  Associate Director of Genomics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

- **The Path from Scoping to Integrated Review for Genomic Data**  
  Michael Pacanowski  
  Clinical Pharmacologist, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

- **Relabeling Drugs with Genomic Information for Improved Risk/Benefit**  
  Shashi Amur, PhD  
  Senior Genomics Reviewer, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

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**SESSION 399M  RA 1 - REGULATORY AFFAIRS**

3:30 PM-5:00 PM  
Room 147A  
CME and pharmacy credits offered

**Regulatory Implications of the Final Rules for Expanded Access**

SESSION CHAIRPERSON(s)

Libbbie J. Mansell, PhD, MBA  
President, White Oak BioPharma Solutions

This session will examine key elements of “Expanded Access to Investigational Drugs for Treatment Use” and “Charging for Investigational Drugs under an Investigational New Drug Application” final rules. A distinguished panel representing the FDA, product development, and patient advocacy will share their perspectives on the effects of the final rules.

- **FDA Point of View on Two New Final Rules**  
  Robert J. Temple, MD  
  Deputy Center Director for Clinical Science, CDER, FDA

- **Industry Perspective on Expanded Access New Rules**  
  Denise E. Williams, MD  
  Executive Director, US Clinical Development and Medical Affairs, Novartis Pharmaceuticals Corporation

- **FDA’s “New” Treatment Use Regulations: A Missed Opportunity**  
  Steve Walker  
  Co-founder, Abigail Alliance

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**SESSION 399O  RA 3 - REGULATORY AFFAIRS**

3:30 PM-5:00 PM  
Room 150B  
Center for Biologics Evaluation and Research Town Meeting

SESSION CHAIRPERSON(S)

Robert A. Yetter, PhD  
Associate Director for Review Management, Office of the Director, CBER, FDA

This session will provide an overview of CBER’s current work on ongoing initiatives, guidelines, and regulations.

- **SPL (Structured Product Labeling) Update**  
  Vada A. Perkins, BSN, MSc, RN  
  Regulatory Program Management Officer, Office of the Director, CBER, FDA

- **CDISC SDTM (Study Data Tabulation Model)**  
  Amy Mallia, MT, PMP  
  Review Management, Office of the Director, CBER, FDA
**Wednesday, June 16**

### Session 399R - ST - Statistics
3:30 PM - 5:00 PM
Room 145A
CME and nursing credits offered

**Randomization Issues in Multicenter Trials**

**Session Chairperson(s)**
- Gerd Rosenkranz, PhD
  - Scientific Officer, Biostatistics, Novartis Pharma AG, Switzerland
- Olga M. Kuznetsova, PhD
  - Director, Scientific Staff, Merck & Co., Inc.

A widespread use of an interactive voice response system (IVRS) brings forward a variety of randomization techniques that provide balance in treatment assignments in multicenter trials while limiting the amount of drug supplies shipped to the sites. These techniques and their analytical implications will be discussed at the session.

- **Randomization Techniques in Multicenter Trials: From Static to Dynamic**
  - Olga M. Kuznetsova, PhD
    - Director, Scientific Staff, Merck & Co., Inc.
- **The Impact of Randomization on Data Analysis**
  - Gerd Rosenkranz, PhD
    - Scientific Officer, Biostatistics, Novartis Pharma AG, Switzerland
- **Randomization in Clinical Trials: A Regulatory Perspective**
  - H.M. James Hung, PhD
    - Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

### Session 399S - VA - Validation
3:30 PM - 5:00 PM
Room 209AB

**Clinical Software Validation in the Cloud (SaaS)**

**Session Chairperson(s)**
- J. Peter Armerding
  - President, Integrated Clinical Solutions, Inc.

Clinical software implementation in the cloud using Software as a Service (SaaS) technology presents obstacles or challenges to traditional software validation practices. This session will explore ways to overcome these obstacles and benefit from the implementation disciplines of the SaaS environments as they have evolved in today’s marketplace.

- **Building on the Virtual Physical Environment with Installation Records, IQ, and OQ in the Cloud**
  - J. Peter Armerding
    - President, Integrated Clinical Solutions, Inc.
- **Validating Clinical Applications in the Cloud**
  - Charles L. Lankford
    - CEO, PharmaSys Inc.
- **Qualifying the Virtual Physical Environment for Cloud Deployed Clinical Systems**
  - Deepak Singh, PhD, MS
    - Business Development Manager, Amazon EC2, Amazon Web Services

5:00 PM

**END OF WEDNESDAY SESSIONS**
Session 401  AHC/IS - Academic Health Centers/Investigator Sites
8:30 AM-10:00 AM
Room 145A
CME and nursing credits offered
Investigative Sites and CROs: Working Together Toward One Common Goal
Session Chairperson(s)
Bill Gallagher, MA
Director, Project Management, RPS (ReSearch Pharmaceutical Services, Inc)
Although working toward one common goal, the development of effective and safe therapies for patients, CROs, and investigative sites may find themselves at odds with each other. This session will examine the working relationships between CROs and sites as well as present ways in which to strengthen that relationship.

Sponsor/CRO – Site: The Perils of Proximity
Susan Maino Vetuschi, BSN
Owner, M & W Clinical Research Consulting, LLC
A Dynamic Industry: The Importance of Defining Key Stakeholder Expectations in the Face of Change
Michael J. Hill
Project Manager, Registries and Observational Studies, Covance Periapproval Services
Three's Company: The Relationship Between Sponsor, CRO, and Investigative Sites
Bill Gallagher, MA
Director, Project Management, RPS (ReSearch Pharmaceutical Services, Inc)

Session 402  BT - Biotechnology
8:30 AM-10:00 AM
Room 103A
CME and pharmacy credits offered
Next Generation Biologics: De-immunization and Tolerance Induction
Session Chairperson(s)
Annie De Groot, MD
CEO, EpiVax
Immunogenicity may impact the safety and/or efficacy of biologics. The contribution of T cells to clinical immunogenicity is now broadly accepted. Preclinical efforts are therefore directed towards screening for T cell epitopes. Experts participating in this session will describe the latest immunogenicity screening approaches. In addition, two of the presentations will describe the importance of natural regulatory T cell epitopes and the induction of “tolerance” to protein therapeutics, a true paradigm shift for protein therapeutics.

Session 403  CDM - Clinical Data Management
8:30 AM-10:00 AM
Level: ■
Room 151A
Pharmacy credits offered
Clinical Database Audits: Past, Present, and Future
Session Chairperson(s)
Kit Howard, MS
Principal and Owner, Kestrel Consultants, Inc.
Database audits have been a staple of the clinical data manager’s quality arsenal for decades, and they persist even in the face of persistent nagging questions about their validity and usefulness. These questions are even more relevant now that adoption of EDC (electronic data capture), ePRO (electronic patient-reported outcome) and other electronic data capture media is accelerating. This session will explore what these audits hope to achieve, what they really tell us about the data, and what the regulators expect from such an audit. It will also discuss appropriate designs for audits in electronic data capture environments.

Understanding Database Audits: What Do They Really Tell Us?
Kit Howard, MS
Principal and Owner, Kestrel Consultants, Inc.
Deciding How to Audit in Paper and EDC Trials
Jonathan R. Andrus, MS
Vice President, Data and Study Operations, BioClinica, Inc.
Defining and Measuring Errors in Database Audits
Reza Rostami, MBA, RAC
Assistant Director, Quality Assurance and Regulatory Compliance, Duke Clinical Research Institute

Session 404  CMC/GMP - Chemistry, Manufacturing, and Controls/Good Manufacturing Practices
8:30 AM-10:00 AM
Level: ■
Room 145B
Supply Chain Security
Session Chairperson(s)
Joseph C. Famulare
Head of External Relations and Collaboration, Genentech, a Member of the Roche Group
Highlighted by the heparin crisis, many challenges have been faced in securing quality ingredients and components in recent years. Proposals for new legislation and guidance from regulators and approaches used by industry that incorporate scientific and risk-based approaches utilizing a pharmaceutical quality system (PQS) have been advanced to mitigate threats. This session will discuss current industry and regulator PQS approaches to help mitigate supply chain risks.
Session 405  CR/CS - Clinical Research and Development/Clinical Supplies
8:30 AM-10:00 AM  Room 146B
CME and nursing credits offered
The Mechanics of Virtual, Global Communication: Executive Perspectives
SESSION CHAIRPERSON(S)
Clareece West
Vice President, Global Business Development, Paragon Biomedical, Inc.
This session will provide insights and tools needed to build effective communications between new vendors (CROs) and sponsors. Presentations will address key areas in the clinical research industry, including executive leadership, operations, regulatory, business development, and marketing. The session will also focus on how to build structurally sound communications processes and systems.

It's Not Just About Time Zones: The Challenges of Working in Multicultural Remote Teams
Vanessa Cooke, RN
Global Head, Strategic Sourcing R&D Services, Bayer Healthcare, UK

How to Meet the Challenges of Working with Virtual Teams to Meet Common Goals
Catherine Van Doren, RN
Executive Director, Global Clinical Operations, GRS Worldwide

Beyond the Horizon: Fundamental Techniques to Optimize Global Communication in a Virtual Environment
Linda G. Strause, PhD
Executive Director, Global Oncology Operations, Vical Incorporated

Session 406  CSP - Clinical Safety and Pharmacovigilance
8:30 AM-10:00 AM  Room 143C
CME credits offered
From Paper Pushing to Insights: Designing a Global, Cross-functional Pharmacovigilance Solution that Focuses on Vigilance
SESSION CHAIRPERSON(S)
Nina Stuccio, DO
Executive Medical Director, Global Regulatory Affairs and Safety Operations, Amgen Inc.
This session presents the design and deployment of a global pharmacovigilance solution that not only encompasses the core pillars of safety data management, signal detection, analysis, and regulatory compliance, but also fully integrates clinical data and processes including sites and investigators in a seamless, electronic information flow. By minimizing paper flow and implementing a single global model across the enterprise, this solution enables the safety organization to shift focus towards analysis and insights, away from transactional activities.

Enabling a Safety Organization to Focus on Data Analysis and Signal Detection through Integrated Safety Systems and Data Management Tools
Nina Stuccio, DO
Executive Medical Director, Global Regulatory Affairs and Safety Operations, Amgen Inc.

Implementing a Commercial Safety System in a Global Environment to Support the New Era of Safety
Leann Fieldstad, PharmD
Global Head, Compliance, Safety Risk Management, Hoffmann-La Roche Inc.

Integrated Systems and Organizational Strategies Ensure End-to-end Pharmacovigilance
Ann O’Brien, MBA, MPH
Director, Case Management Group, GlaxoSmithKline
The Pharmaceutical and Research Manufacturer Association’s Electronic Regulatory Submissions (PhRMA ERS) group presents their annual progress report on the hottest key subteams involved in the pursuit of standards to facilitate efficient and effective electronic regulatory submissions. This session will provide a quick status update of the subteams since 2009 and then review the status of at least two completely new hot topics.

**EASE-ing Your Way into Electronic Promotion and Advertising**
Daniel P. Clark  
Senior Manager, Regulatory Innovation, Novo Nordisk, Inc.

**Regulated Product Submission (RPS): Building a Better eCTD**
Robert F. Birmingham  
Director, Global Regulatory Policy and Intelligence, Johnson & Johnson Pharmaceutical R&D LLC

**How to Get Some R and R into Your Clinical Trials**
Scott A. Getzin  
Consultant, Data Sciences, Eli Lilly and Company

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**SESSION 410  IT - INFORMATION TECHNOLOGY**
8:30 AM-10:00 AM  LEVEL: 
Room 152B

**Utilizing and Integrating Open Source Software in Clinical Research Environments**
Cal Collins  
CEO, Akaza Research

Open source software (OSS) can enhance flexibility, interoperability, and cost in clinical trials. Using case studies, we will explore advantages and challenges of OSS, specifically finding, evaluating, and supporting OSS technology, 21 CFR Part 11 and GCP compliance, and measuring cost and ROI (return on investment).

R. Mark Adams, PhD  
Project Manager, NCI’s Cancer Biomedical Informatics Grid; Principal, Booz Allen Hamilton

Case Study: Leveraging an Open Source EDC System  
Mark M. Paul, MBA  
CEO, StatWorks Inc.

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**SESSION 411  MA - MARKETING**
8:30 AM-10:00 AM  LEVEL:  
Room 140A  
CME, nursing, and pharmacy credits offered

**Beyond Compliance: Self-regulation and Initiatives to Ensure Ethical Business Practices**

**SESSION CHAIRPERSON(S)**
Russell Williams  
President, Rx&D Canada; IFPMA CCN Vice Chair, Canada

The pharmaceutical industry, represented by the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), is fully committed to the promotion and support of ethical practices. To achieve this, IFPMA is increasingly engaging in code awareness and outreach activities as well as collaboration and partnership with external stakeholders. The pharmaceutical industry has undertaken multiple initiatives to ensure ethical business practice and is involved in rigorous self-regulation processes. Patient safety is at the heart of compliance, self-regulation, and efforts to ensure ethical business practices, and this session will address these issues and initiatives.

**The New PhRMA Code, FDA Promotion, and US Legislation**
Jeffrey K. Francer, JD, MPA  
Assistant General Counsel, PhRMA

**The Mexican Transparency Agreement: Best Practices in All Stakeholders Alignment**
Juan Francisco Millan Soberanes  
Secretary and Executive Director, CETIFARMA, Mexico

**The Global R&D Biopharmaceutical Industry and Ethics**
Russell Williams  
President, Rx&D Canada; IFPMA CCN Vice Chair, Canada

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**SESSION 412  MW - MEDICAL/SCIENTIFIC WRITING**
8:30 AM-10:00 AM  LEVEL:  
Room 147B  
CME and nursing credits offered

**Effective Publication Practices**

**SESSION CHAIRPERSON(S)**
Art Gertel, MS  
Vice President, Strategic Regulatory Consulting, Medical Writing, and QA, Beardsworth Consulting Group Inc.

The panel will present different perspectives on adapting to evolving publication and disclosure standards that require authors and publishers to react more quickly, with greater depth of information, and to comply with heightened expectations of disclosure and adherence to strict standards.
Qualifying New Translational Safety Biomarkers for Nonclinical and Early Clinical Development

**SESSION 413**
**NC - NONCLINICAL LABORATORY SAFETY ASSESSMENT**

8:30 AM-10:00 AM
Room 103B

Qualifying New Translational Safety Biomarkers for Nonclinical and Early Clinical Development

**SESSION CHAIRPERSON(S)**
Eric Thompson
Assistant Director, Predictive Safety Training Consortium, Critical Path Institute

Both regulatory agencies and the drug development industry recognize the opportunities for new safety biomarkers to enhance drug development success. Consortia such as the Critical Path Institute’s Predictive Safety Testing Consortium have been created as a resource sharing precompetitive mechanism to generate the evidentiary standards that are needed to advance the qualification and acceptance of these biomarkers through a formal and transparent interface with worldwide regulatory agencies. Great strides have been made in 2009 and 2010 to expand the experimental basis for advancing mutual understanding of the performance characteristics of new safety biomarkers of drug-induced injuries to kidney, liver, and skeletal muscle. In the course of the experimentation and subsequent data sharing and data evaluation, critical issues have surfaced between industry and regulatory agencies that must be resolved for future efforts to succeed at a reasonable pace. The data that support the novel utility of these emerging new safety biomarkers, the issues that have surfaced, the different viewpoints and resolutions achieved, and the processes that have evolved for qualifying new safety biomarkers will be shared and discussed.

- **C-Path’s Predictive Safety Testing Consortium: Progress in Developing Evidentiary Standards and Regulatory Processes for Evaluating and Adopting New Safety Biomarkers**
  - **Eric Thompson**
    Assistant Director, Predictive Safety Training Consortium, Critical Path Institute
  - **Mark K. Walton, MD, PhD**
    Associate Director, Office of Translational Sciences, CDER, FDA
  - **Hans-Georg Eichler, MD, MSc**
    Senior Medical Officer, European Medicines Agency, European Union

**SESSION 414**
**OS - OUTSOURCING**

8:30 AM-10:00 AM
Room 147A

Clinical Trials in the Fast Lane: Is There a Speed Limit on the Road to Excellence?

**SESSION CHAIRPERSON(S)**
David Lucey
Director, Clinical Operations, ExecuPharm, Inc.

Speed of drug development continues to be the ultimate defense against rising clinical research costs, and regulatory and economic pressure. The fastest drug developers are known to utilize CROs at a high rate, and collaborate with specialized providers for their development operations. The greatest opportunities for increased speed and efficiency are found in the conduct/management of clinical trials. But how do you get faster, and better, at the same time? How do you accelerate operational processes, yet maintain - or even heighten - the level of quality? In this session, learn how to implement a “pedal to the metal” strategy for clinical trial management; leave no stone unturned using key performance indicators (KPIs), resulting in increased compliance and reduced vulnerability.

- **Making Metrics Work for the People Doing the Work**
  - **Steven P. Sweeney**
    Director, Head of Clinical Operations, Infinity Pharmaceuticals
- **Speed and Quality: Two Case Studies**
  - **Charles Ingram Romano**
    Director, Global Clinical Operations and Government Affairs, Peachtree Bioresearch Solutions

**SESSION 415**
**PD/TR - PROFESSIONAL DEVELOPMENT/TRAINING**

8:30 AM-10:00 AM
Room 140B

Help Your Trainers Become Internal Training Consultants

**SESSION CHAIRPERSON(S)**
Jill Huentelman, MBA
President, Lernia Training Solutions

Trainers are increasingly asked to manage, coordinate, and impart training skills to people who are experts in subject matter. As a result, trainers have a variety of areas to focus on and numerous clients to satisfy. This session will explore the best practices of training consulting and provide strategies to help trainers become internal training consultants.

- **Expanding Pharmacovigilance Training Beyond SOPs Without Blowing Your Budget**
  - **Michelle N. Fiewell**
    Vice President, eLearning and Informatics, BioSoteria, Inc.
- **How Quality Training Increases Safety in Clinical Trials**
  - **Esther Maria Daemen**
    Global Manager, Training and Development, Kendle International Inc., Belgium
- **Training Strategies to Increase System Adoption**
  - **Hajime Arnold**
    Senior Manager, Worldwide Clinical Solutions, Abbott Vascular

**SESSION 416**
**PM/FI 1 - PROJECT MANAGEMENT/FINANCE**

8:30 AM-10:00 AM
Room 150A

Effective Pharmaceutical Project Management Team Leadership

**SESSION CHAIRPERSON(S)**
Matthew J. Kiernan, MBA
Partner, Pharmica Consulting
Effective teams are critical to the success of pharmaceutical and biotechnology companies. But how effective are the teams you work with? Or do you understand how to gauge the effectiveness of a team? Using case studies from pharmaceutical companies, this session will discuss a framework for describing what constitutes effective teams in the pharmaceutical industry and the role of a leader, such as a project manager.

What Makes an Effective Team: Perspective from a Project Manager
Debra E. Oister, PMP
Project Manager, Global Project and Portfolio Management, GlaxoSmithKline

Effective Leadership from Global Project Leader Perspective
Akihisa Mori, PhD
Vice President, Project Product Management, Kyowa Hakko Kirin Pharma, Inc

Thursday, June 17

Session 417  PM/FI 2 - Project Management/Finance
8:30 AM-10:00 AM  LEVEL: ●
Room 150B  PMI PDUs offered
Seven Steps to Project Performance Metrics that Matter
SESSION CHAIRPERSON(S)
Colleen K. Dixon, MS, PMP
PMO Manager, Baxter BioPharma Solutions
In this session, we will discuss how to develop metrics to help drive performance across R&D from the distinct viewpoints of clinical, manufacturing, and an overall strategic level. Key topics include: selecting the right metrics; a step-wise process for developing the metrics system; making your system lean and sustainable; and avoiding common pitfalls. Through specific examples, practical tips, and the framework of seven essential steps, we will show you how to build a metrics system that helps you lead your projects.

Manufacturing Metrics
Reuben Vandeventer
Operations Analyst, Baxter BioPharma Solutions

Customer Experience Metrics
Alice D. Susemichel, PMP
Director, US Diabetes Medical Affairs, Eli Lilly and Company

R&D-level Metrics: Experiences in Developing and Implementing a Performance Measurement Framework
Mary Moore, MTPW
Associate Director, R&D Strategy and Analytics, Bristol-Myers Squibb Company

Session 418  PP - Public Policy/Law/Corporate Compliance
8:30 AM-10:00 AM  LEVEL: ●
Room 149AB  Pharmacy credits offered
Incentives, Disincentives, and Market Powers: New Medicines for the World
SESSION CHAIRPERSON(S)
Lembit Rägo, MD, PhD
Coordinator, Quality Assurance and Safety, Medicines, Policy, and Standards, World Health Organization, Switzerland

The session will look into the future of available treatments. The current paradigm in drug development is the model of free market and return on investment. An important role is played by intellectual property rights and financing on the expectation of future profits. Would it be useful if new strategies are implemented, leading to exactly those medicines the world needs?

Intellectual Protection, Patent, and Choices in Drug Development
John A. Lisman, LLM, MPharm
Lawyer, Lisman Legal Life Sciences B.V., Netherlands

Neglected Diseases: Priority Medicines
Lembit Rägo, MD, PhD
Coordinator, Quality Assurance and Safety, Medicines, Policy, and Standards, World Health Organization, Switzerland

Orphans, Children, and Public Health Priorities
Regina Awe, MS
Society for Independence in Research

Session 419  RA 1 - Regulatory Affairs
8:30 AM-10:00 AM  LEVEL: ●
Room 144ABC  CME credits offered
CDER Town Meeting – Part 1 of 2
SESSION CHAIRPERSON(S)
Nancy D. Smith, PhD
Former Director, Office of Training and Communications, CDER, FDA

Part 2 of this session will take place on Thursday at 10:30 am. The Senior Leadership Team of CDER will be invited to participate in this session. The topics that will be discussed will depend on the audience and on areas that are of current importance within the CDER community.

Deborah Autor, JD
Director, Office of Compliance, CDER, FDA

ShaAvhree Y. Buckman, MD, PhD
Director, Office of Translational Sciences, CDER, FDA

Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

John K. Jenkins, MD
Director, Office of New Drugs, CDER, FDA

Sandra L. Kweder, MD
Deputy Director, Office of New Drugs, CDER, FDA

Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Director for International Programs, Office of the Center Director, CDER, FDA

Robert J. Temple, MD
Deputy Center Director for Clinical Sciences, CDER, FDA

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research, FDA
SESSION 420  RA 2 - REGULATORY AFFAIRS
8:30 AM-10:00 AM  LEVEL: ■
Room 143AB
Update on Orphan Drugs in the US, EU, and Japan
SESSION CHAIRPERSON(S)
Noriaki Murao  
Representative, Merz Pharmaceuticals Gmbh, Japan

This session addresses the current status and forthcoming activities relating to orphan drugs in the US, EU, and Japan. Orphan drug development is obviously essential to these regions, but the provisions in place for drugs included for rare diseases are often passed over. There is a harmony in the regulatory requirements; however, there are still some differences and challenges in these three regions. The session will present information relevant to planning their development and commercialization strategy.

European Medicines Agency Point of View on Orphan Drugs  
Agnès Saint-Raymond, MD  
Head of Human Medicines Special Areas, European Medicines Agency, European Union

US Orphan Products: Current Considerations  
Drusilla L. Scott, PhD, RAC  
Vice President, Regulatory Affairs, Cempra Pharmaceuticals

Development of Orphan Drugs in Japan  
Keiko Ebihara, RPh  
Director, Regulatory Policy Group, Public and Industry Policy Office, Banyu Pharmaceutical Co. Ltd., Japan

Pharmaceuticals and Medical Devices Agency Point of View on Orphan Drugs  
Mitsuo Saito, PhD  
Director, Review Management Division, Office of Review Management, PMDA, Japan

SESSION 421  ST - STATISTICS
8:30 AM-10:00 AM  LEVEL: ■
Room 146A
CDISC Update for Statisticians
SESSION CHAIRPERSON(S)
Cathleen F. Barrows, PhD  
Director, Biostatistics and Programming, Neurosciences MDC, GlaxoSmithKline

What is the practical impact of the CDISC ADaM standard on statisticians? The first presentation in this session will provide an update on ADaM, describing what it means to follow the standards given in the Analysis Data Model (ADaM) document (version 2.1) and the ADaM Implementation Guide (version 1.0), as well as discussing the documents currently being worked on by the ADaM team and presenting next steps for ADaM. The second presentation will present a case study from industry in implementing ADaM. The speaker will describe what it means to implement ADaM from a real-world perspective, discussing issues to be considered in embedding ADaM as a standard within a pharmaceutical company. The third presentation will provide a CDER reviewer’s perspective on working with ADaM datasets outlining both the advantages to the reviewer as well as some of the challenges, highlighting the potential impact of establishing ADaM as a standard.

ADaM: What Now?  
Michael Nessly, MS  
Director, TA Head Biostatistics for Neurosciences, Shire Specialty Pharmaceuticals

SESSION 422  VA - VALIDATION
8:30 AM-10:00 AM  LEVEL: ■
Room 154AB  CME and nursing credits offered
An International Perspective on the Use of Computerized Systems
SESSION CHAIRPERSON(S)
Patricia Beers Block  
Vice President, Strategic Regulatory Initiative, Medidata Solutions Worldwide

This session will offer attendees the opportunity to learn more about the regulations and policies that govern clinical investigations conducted in the US, the EU, and Asia-Pacific regions when these investigations utilize electronic data capture and electronic signatures.

FDA Point of View  
Joseph P. Salewski, MS  
Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

EU Regulatory Point of View for eSource Documents  
Ana Rodriguez, PhD  
Head of Clinical and Nonclinical Compliance, European Medicines Agency, European Union

SESSION 423  AHC/IS - ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES
10:30 AM-12:00 PM  LEVEL: ■
Room 145A  CME credits offered
Capacity-building Initiatives in Emerging Markets: Is Principal Investigator Training the Answer?  
SESSION CHAIRPERSON(S)
Anupama Ramkumar, MD  
Director, Arkus CTSS, India

With more clinical trials being run at new locations in new countries because of the attractiveness of high recruitment potential, the comfort of a CRO/sponsor with an already known site is causing many sites in such countries to be running more trials than they can probably handle. Busy principal investigator (PI), inadequate site staff, and lack of proper training may not reveal any short-term consequences but surely have a potential to escalate in major issues of noncompliance and patient safety. This session will take a look at some of these issues and discuss the idea that a paradigm shift in thinking among sponsors and CROs is necessary, and that it means doing more than just training the PI and site staff during trial-related meetings or interactions. This session will take a look at capacity-building initiatives, when to begin, current trends, gap analysis, and offer some solutions to this vital issue.
This session will focus on the evolution of existing standards, Medical Dictionary for Regulatory Activities (MedDRA) and the Individual Case Safety Report (ICSR), and the development of a new standard, Identification of Medicinal Products (IDMP).

**The Next Generation of the ICH ICSR: Design, Impacts, and Opportunities**

**Andrew P. Marr, PhD**

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

**International Standardization of Identification of Medicinal Products (IDMP, ICH M5): Current Status and Next Steps**

**Sabine Brosch, PharmD, PhD**

Scientific Administrator, Pharmacovigilance and Risk Management, European Medicines Agency, European Union

**MedDRA® Versioning: Best Practices**

**JoAnn Medbery, BSN, RN**

Director, BRM Dictionary Management Systems, Johnson & Johnson

**Benefit Risk Management**

**SESSION 426**

**CMC/GMP - Chemistry, Manufacturing, and Controls/Good Manufacturing Practices**

**10:30 AM-12:00 PM LEVEL: »**

**Room 145B**

**Drug Master Files: Regulatory Aspects**

**SESSION CHAIRPERSON(S)**

**Elaine Morefield, PhD**

Division Director, Division of Premarketing Assessment II, Office of New Drug Quality and Assessment, CDER, FDA

This session will explore the regulatory aspects of drug master files and certificates of suitability from a US FDA, EDQM (The European Directorate for the Quality of Medicines and HealthCare), and industry perspective. The expectations for submission content and the advantages and disadvantages of using drug master files will be discussed.

**Drug Master Files: An FDA Perspective**

**Arthur B. Shaw, PhD**

Review Chemist and DMF Expert, Office of New Drug Quality and Assessment, DPA1, CDER, FDA

**The API Quality Documentation in European Marketing Authorization Dossiers: Active Substance Master Files and Certificates of Suitability**

**Susanne Keitel, DrSc, RPh**

Director, EDQM (The European Directorate for the Quality of Medicines and HealthCare), France

**Industry Perspective on the Use of US Drug Master Files, EU Active Substance Master File (ASMF) and Certificates of Suitability (CEP) for Drug Substances**

**Wendy Mavroudakis, Esq., JD**

Senior Director, Global Regulatory Affairs, Johnson & Johnson Pharmaceutical Research and Development, LLC
**Session 427**  
**CR/CS - Clinical Research and Development/Clincial Supplies**  
10:30 AM-12:00 PM  
Room 146B  
CME and pharmacy credits offered  

**Impact of Productivity Transformation Initiatives on Clinical Site Monitoring Processes**  
**Session Chairperson(s):** Warren H. Pence  
Associate Director, US Regional Monitoring, Bristol-Myers Squibb Company  

This session will explore how clinical site monitoring processes have changed as a result of productivity transformational initiatives from various perspectives. Many productivity changes have resulted due to implementation of new technology tools to facilitate the monitoring process. Process changes include reduced source data verification, reduced drug accountability, remote monitoring, the result of using electronic tools such as electronic data capture (EDC), EDC via electronic source, and database viewing tools, ie, I-Review. In addition, the potential risks will be examined along with how companies have approached methods to mitigate this potential risk.

**Implementation of Productivity Initiatives for Site Monitoring Efficiencies at a Mid-sized Pharmaceutical Company**  
Brett Wilson  
Associate Director, Clinical Site Monitoring, Bristol-Myers Squibb Canada  

**Leveraging Technology to Drive Site Monitoring Productivity**  
Debra Tatton, MA  
Senior Director, Clinical Project Operations, PAREXEL International  

**Driving Improvement in the Effectiveness of Clinical Site Monitoring**  
Lorraine Waring  
Senior Director, Site Monitoring Process Owner, Pfizer Inc

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**Session 428**  
**CSP - Clinical Safety and Pharmacovigilance**  
10:30 AM-12:00 PM  
Room 146C  
CME credits offered  

**Due Diligence and In-licensing Opportunities with a Pharmacovigilance/Safety Perspective**  
**Session Chairperson(s):** Mariette Boerstoel-Streefland, MD, MBA, MS  
Chief Safety Officer, Vice President, Global Drug Safety, Forest Laboratories Inc.  

The due diligence process is used by pharmaceutical companies looking to commit investment in third parties who have developed a therapeutic solution to a disease state. Companies, which are often more agile than large pharma now develop molecules which they intend to license to other partners to continue development to marketing approval. Because stakes are now so much higher, past due diligence which reviewed efficacy and marketing potential is no longer sufficient. Safety is now pivotal to drug approval and thus the process for pharmacovigilance review requires additional analysis and calculation of benefit/risk, which involves many specialties within drug development. This session intends to examine the role of pharmacovigilance from the perspective of the reviewer and the host.

**Safety Due Digilence from the Sponsor’s Point of View: Preclinical Perspective**  
Lewis B. Kinter, PhD  
Senior Director, Regulatory Toxicology, Global Safety Assessment, AstraZeneca Pharmaceuticals LLP

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**Session 429**  
**EC - eClinical**  
10:30 AM-12:00 PM  
Room 151B  

**CDISC Pilots: Implementing Real-world Pilot Projects to Gain a Better Understanding of Industry and Regulatory Needs**  
**Session Chairperson(s):** Chris Decker, MS  
Director, Life Sciences, d-Wise Technologies, Inc.  

One of the main objectives within the CDISC technical roadmap released in 2008 was to conduct pilots to gain a better understanding of the needs of regulators and industry. Based on this objective, a number of pilot projects have either been completed or are ongoing. This session will provide an overview of three ongoing pilots involving collaboration between CDISC and the FDA with the goal of obtaining efficiencies from the use of data standards.

The CDISC/FDA Integrated Data Pilot: A Case Study in Implementing CDISC Standards to Support an Integrated Review  
Steven Hirschfeld, MD, CAPT. USPHS  
Associate Director for Clinical Research, National Institutes of Health, NICHD

Overview of the CDISC SHARE Initiative and Pilot  
David P. Iberson-Hurst  
Vice President, Technical Strategy, CDISC, UK

Overview and Update of the FDA/CDER SEND Pilot  
Lou Ann Kramer  
Consultant, Eli Lilly and Company

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**Session 430**  
**ERS/DM - Electronic Regulatory Submissions/Document Management**  
10:30 AM-12:00 PM  
Room 152A  

**Global Submission Management: Improving Efficiencies in Working with Non-ICH Regions**  
**Session Chairperson(s):** Dominique E. Lagrave, PharmD, MSc  
Senior Director, Regulatory Operations and Innovation, Novo Nordisk Inc.  

The session will provide details on global submission management and its challenges and opportunities with a specific emphasis on non-ICH countries/regions. The presenters will provide industry case studies and as a panel will provide expert opinions on how to leverage current technologies to better support emerging markets and strategic affiliates. The new trends in submissions management, foreseen benefits, and challenges will be discussed.

Regional Comparison of Regulatory Filing Requirements  
Brooke Castleberry, MS  
Senior Manager, Regulatory Strategies, Lixiquent

Orchestrating Publishing Resources and Source Documents for Global Submissions  
Meredith Sewell  
Associate Director, Global Regulatory Affairs Publishing, Allergan Inc.

Consolidated Information Management for Global Submissions  
Matthew J. Neal, MA  
Director, Global Regulatory Affairs and Safety, Amgen Inc.
Global Perspectives on Conducting Quality Clinical Trials

SESSION CHAIRPERSON(S)
Jan Holladay Pierre, MPH
Principal Consultant, Quintiles

This session will identify the rationale behind the development of precision monitoring and auditing strategies to improve the clinical trial process. The FDA has also been improving its follow-up of violative inspections and working to identify alternative methods to select clinical investigator sites for inspection, such as risk-based approaches and using statistical evaluations to identify sites of interest. An in-depth review of regulatory trends in GCP compliance from both the European and US perspective will be explored.

Effective Monitoring and Auditing Tools for Quality Clinical Trials
Jan Holladay Pierre, MPH
Principal Consultant, Quintiles

European Regulatory Perspective on Quality Clinical Trials
Regina Freunscht
Director, Accovion GmbH, Germany

US Regulatory Trends in GCP Compliance
Tejashri Purohit-Sheth, MD
Branch Chief, GCP2, FDA

Achieving Cost-effective Scalability in the Clinical Environment Through Cloud Computing

SESSION CHAIRPERSON(S)
Leslie Bihari, Jr.
President, Eclipse Professionals Services, LLC

The latest Internet technologies have permanently blurred the traditional boundaries between clients and servers, paving the way for a slurry of new abstract acronyms such as SaaS, PaaS and IaaS – and terminology such as “cloud computing.” Some have dismissed these terms simply because they describe technological capabilities that predate coining the terms that describe them. Although it is true that from a technological perspective the concepts behind cloud computing have existed for many years, the delivery of these services has very much changed – and therein lie the benefits. The value of cloud computing is that it delivers existing technologies in a scalable, flexible, cost-effective, utilitarian manner that increases productivity, reliability, and regulatory compliance and transparency. This session seeks to demonstrate the advantages of strategies that make up cloud computing with real world application in the clinical environment.

The Use of Paperless-oriented IT Tools to Enhance the Transparency in Medicines Regulatory Agencies
Maurizio Ortali, MBA, MSc, PMP
CINECA Inter-University Consortium, Italy

Data Integration, Document Dematerialization and eSubmission in Clinical Research Workflow
Luca Dematte, PhD
CINECA Inter-University Consortium, Italy

Online Health Information: The Rise of Health 2.0 and Its Impact on Consumer Ability to Obtain Quality Health Information

SESSION CHAIRPERSON(S)
Morgan Sperry, PharmD
Assistant Director, Drug Information Center, Clinical Assistant Professor, University of Missouri Kansas City

Consumer health information has become increasingly accessible on the Internet. While this can be empowering for patients, it can be a very dangerous practice. Little is being done to educate consumers about the dangers of obtaining health content via the Internet. A great opportunity exists for industry to become actively involved with this issue.

Consumer Health Information and Contemporary Practice
Morgan Sperry, PharmD
Assistant Director, Drug Information Center, Clinical Assistant Professor, University of Missouri Kansas City

Improving the Consumer’s Use of Online Health Information: Potential Roles for Health Care Providers and Industry
Meghan Williams, PharmD
Drug Information Fellow, School of Pharmacy, University of Missouri Kansas City

Industry Partnering with Consumers to Deliver Better Patient Outcomes
Michele L. Steele, MA
eChannel Advisor USMD MIS, Eli Lilly and Company

GLP Study Sponsors, Monitors, and Contract Research Organizations: Planning for Success

SESSION CHAIRPERSON(S)
Joe Cwiertniewicz
Principal, Quality and Regulatory Compliance

Successful partnering between nonclinical research sponsors and contract research organizations is essential in meeting regulatory requirements. The panel will share their experience in developing clear understanding and effective relationships that lead to successful regulatory submissions.

GLP Success from a Sponsor’s Perspective
Walter Bee, DrSc, MS
Vice President, Preclinical Development, Halozyme Therapeutics, Inc.

GLP Success from a Regulatory Submissions Perspective
George Shopp, PhD
Consultant, Shopp Nonclinical Consulting LLC

GLP Success by Designing in Quality
Joe Cwiertniewicz
Principal, Quality and Regulatory Compliance
Thursday, June 17

**SESSION 435**  
**OS - OUTSOURCING**  
10:30 AM-12:00 PM  
Room 147A  
Managing Strategic Partnering Relationships in R&D  
**SESSION CHAIRPERSON(S)**  
Joseph Bedford, PhD  
Director, Marketing, Almac Clinical Technologies  
This session will educate professionals from biopharmaceutical companies, CROs, and other organizations about trends and practices relating to strategic outsourcing. A panel of R&D professionals will offer practical, real-world examples regarding why and how biopharmaceutical companies are selecting strategic partners, and advice on how to best manage such relationships.

**Panelists**  
Thomas Privette  
Vice President, Strategic Partnering, Covance, Inc.

Adrienne R. Takacs, PhD  
Senior Advisor, Alliance Executive, Lilly Research Laboratories Operations, Lilly Research Laboratories

Roberto Vaccaro, MBA  
Director, R&D Global Strategic Sourcing, Amgen, Inc.

Scott J. Mahoney, MBA  
Director, PRTM Management Consultants

**SESSION 436**  
**PD/TR - PROFESSIONAL DEVELOPMENT/TRAINING**  
10:30 AM-12:00 PM  
Room 140B  
CME and nursing credits offered  
Cultural Awareness in a Global Workplace  
**SESSION CHAIRPERSON(S)**  
Lauren Edelstein-Henry, MEd  
Principal Operations Specialist, Johnson & Johnson Pharmaceutical Research and Development, LLC  
Most pharmaceutical companies are now global, whether they have offices throughout the world or work with a vendor from another country. While globalization is a fact of corporate life, training on cultural differences resulting from globalization is slow to happen. This session will help participants learn basic cultural considerations when dealing with day-to-day business.

**Dealing Effectively with Cultural Difference for Clinical Research Professionals**  
Mary E. Briggs, MS  
Vice President of Global Sales and Marketing, CRF Health

**Making Differences Work: Tools and Best Practices for Boosting Employee Engagement in a Diverse Culture**  
Theresa Hummel-Krallinger  
Director, Organizational Development and Training, Almac Group

**Befriend, Not Offend: Cultural Considerations for Presentation Skills**  
Lauren Edelstein-Henry, MEd  
Principal Operations Specialist, Johnson & Johnson Pharmaceutical Research and Development, LLC

**SESSION 437**  
**PM/FI - PROJECT MANAGEMENT/FINANCE**  
10:30 AM-12:00 PM  
Room 150A  
CME and nursing credits, and PMI PDUs offered  
The Honeymoon Is Over: Is Your Project Team Like a Marriage Made in Heaven (or Somewhere Else)?  
**Marriage Counseling for the Project Team**  
**SESSION CHAIRPERSON(S)**  
Karen L. Eissler, MS, PMP  
President, InsightRx Consulting LLC  
How are relationships in business and in projects like a marriage? There are a few basic needs present in all relationships. What is different is what party plays which role fulfilling what needs, and in what priority. There are also habits that if not dealt with can wreak havoc on marriages as well as teams. This session explores concepts from marriage counseling, translating them to team concepts and ideas you may try with your team relationships.

**Team Needs: A Sponsor Perspective**  
Jodi Hayes, MBA  
Senior Project Manager, Wyeth Pharmaceuticals

**Team Needs: A CRO Perspective**  
Bari Kowal, MS  
Senior Director, Clinical Operations, ICON Clinical Research

**SESSION 438**  
**PP - PUBLIC POLICY/LAW/CORPORATE COMPLIANCE**  
10:30 AM-12:00 PM  
Room 149AB  
Building an Effective Compliance Program in Health Care Products R&D  
**SESSION CHAIRPERSON(S)**  
Michael P. Swiatocha, MS  
Practice Leader, R&D Compliance and Bioresearch Monitoring Services, Quintiles Consulting  
Pharmaceutical and medical device companies have been highly scrutinized by enforcement agencies for almost two decades. The primary areas of focus have been sales and marketing activities. This interactive session will provide the participants with a background on enforcement activity, a roadmap for applying the seven elements of an effective compliance program in R&D, and a process for identifying and mitigating regulatory compliance and reputational risks.

**Panelists**  
Seth B. Whitelaw, JD, LLM  
Compliance Officer, Global R&D, GlaxoSmithKline

Richard Reed  
Director, Ethics and Compliance, ImClone Systems, a Wholly-owned Subsidiary of Eli Lilly and Company

**SESSION 439**  
**RA 1 - REGULATORY AFFAIRS**  
10:30 AM-12:00 PM  
Room 144ABC  
CME credits offered  
CDER Town Meeting – Part 2 of 2  
**SESSION CHAIRPERSON(S)**  
Nancy D. Smith, PhD  
Former Director, Office of Training and Communications, CDER, FDA  
Part 1 of this session will take place on Thursday at 8:30 am.
In this session, the speakers will present a new environment that allows for collaborative development of specialized analytical tools based on the wiki concept. The use of wiki will allow a community of users (e.g., the regulatory agency, academia, and industry) to create, edit, and potentially validate program codes that can be used in the entire life cycle of drug development. Each speaker will present the efforts being done within their organization, and will give their perspective on how to utilize such an environment to invoke user participation from within and outside their respective organizations.

**Collaborative Development of Analytical Tools: Streamlining Analysis of Clinical Trial Data**
Mat Soukup, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

**CTSpedia: A Collaborative Working Environment**
Mary Banach, PhD, MPH
Analyst, University of California-Davis

**DIA Statistics SIAC Activities**
Jerald Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories; Chairperson, DIA Statistics SIAC

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

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**Session 440  RA 2 - Regulatory Affairs**
10:30 AM-12:00 PM  LEVEL: ■
Room 143C  CME credits offered

**Regulating Advanced Therapies**
SESSION CHAIRPERSON(s)
Victoria English, MS
Editor, MedNous, UK

This session will review the new regulatory pathway in Europe for advanced therapy medicinal products, with reference to parallel guidance in the US, with the aim of helping companies understand the new requirements. The session will also examine some of the products approved thus far.

**ATMP Regulation: A New Dawn Over Europe**
Duncan MacKay
Director, Regulatory Affairs Europe Biosurgery, Genzyme Corporation, UK

**Point of View from the European Medicines Agency**
Anthony Humphreys
Head of Regulatory, Procedural, and Committee Support, European Medicines Agency, European Union

**Regulation of Cell and Gene Therapies: The View from the FDA**
Steven Oh, PhD
Office of Cellular, Tissue, and Gene Therapies, Division of Cellular and Gene Therapies, CBER, FDA

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**Session 441  ST - Statistics**
10:30 AM-12:00 PM  LEVEL: ●
Room 146A  CME and nursing credits offered

**Collaborative Environments for Statistical Methodology Development: The Wiki Way**
SESSION CHAIRPERSON(s)
Joan K. Buenconsejo, PhD, MPH
Mathematical Statistician, Office of Translational Sciences, CDER, FDA
## EXHIBITING COMPANIES  (registered as of April 1, 2010)

The 46th DIA Annual Meeting features one of the industry’s largest exhibit halls, where companies from around the world can showcase their products and services to more than 8,000 attendees involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products.

*Limited exhibit space is still available.* Visit [www.diahome.org](http://www.diahome.org) or contact one of the Exhibit Associates.

### For companies **A through L**
- **Jeff Korn**    /    Phone: +1.215.442.6184   /  email: Jeff.Korn@diahome.org

### For companies **M through Z**
- **Shannon Lewis**    /    Phone: +1.215.442.6149   /  email: Shannon.Lewis@diahome.org

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Exhibiting Companies registered as of April 1, 2010

Investigator Support Services
invivodata
IRB Company
IRB Services
ISI
Italian Medicines Agency
J&S Studies, Inc.
JANIX
Johnson & Johnson
Joule Clinical Staffing Solutions
Judge Group
Kansas Bioscience Authority
Kansas City University of Medicine & Biosciences
Karmic Labs Pvt. Ltd.
Kayentis
Kendle
Kforce Clinical Research
Kika Clinical Solutions
Klein Hersh International
KoNECT
LabConnect, LLC
Laboratorio Hidalgo
Lernia Training Solutions
Lifetree Clinical Research
Lionbridge Life Sciences
Lippincott Williams & Wilkins - WKH
Liquent
Logos Technologies Inc.
LORENZ Life Sciences Group
Lovelace Scientific Resources
Mahindra Satyam
MAJARO InfoSystems, Inc.
MakroCare
Malvern Consulting Group, Inc.
Marken
MaxisIT Inc.
McGuire Research Institute
MedAvante, Inc.
MedDRA MSSO
MedFocus, LLC
Medical Research Network Ltd.
Medidata Solutions Worldwide
Medifacts International, Inc.
MedNet Solutions, Inc.
Medpace
MedPoint Communications, Inc.
MedQIA
MedSource
MEDTOX Laboratories
MedTrials, Inc.
Merge eClinical, A Division of Merge Healthcare
META Solutions, Inc.
Metroplex Clinical Research Center
Microsoft Corporation
Microsystems
Mid*Lands IRB
MMG, Inc.
MNX Global LifeSciences Logistics
Monitorforhire.com
Mortara Instrument, Inc.
MPI Research
National Death Index
New England Institutional Review Board
New Orleans Center for Clinical Research
NewCardio, Inc.
NextDocs
Nexttrials, Inc.
Norwich Clinical Research Associates
Novella Clinical
Novotech
nSpire Health, Inc.
OCASA Logistics Solutions
OCT
Octagon Research Solutions, Inc.
Odyssey Research
Omnicare Clinical Research
OmniComm Systems, Inc.
Omnilingua Worldwide, LLC
On Assignment Clinical Research
Online Business Applications
Oracle Systems Corporation
Oracle Systems Corporation
Orlando Clinical Research Center
Outcome
Oxford Outcomes Ltd.
Pacific Biomarkers, Inc.
Pacific Bridge Medical
Palm Beach CRO
Paragon Biomedical Inc
PAREXEL International
The Patient Recruiting Agency
PDR Network, LLC
Pegasystems Inc.
Penn Pharma
Perceptive Informatics
Pharm-Olam International
Pharmaceutical Executive
Pharmaceuticals and Medical Devices Agency (PMDA)
PharmaNet Development Group, Inc.
PharmaSeek, LLC
PharmaSys, Inc.
PharmaVigilant
PharmaVOICE
Phase Forward
Philips Respironics
Phlexglobal Limited
PHT
Pierrel Research USA
Playaway
PleaseTech Ltd.
PPD
Exhibiting Companies registered as of April 1, 2010

PRA International
Precept Life Sciences
Premier Research Group
PRL Central Laboratory Services
Progressive Impressions International
Proherant
Prologue - The Oncology CRO
PROMETRIKA, LLC
PROSAR
ProTrials Research, Inc.
PSI
PSI International, Inc.
QPharma
QPS LLC
Qualitix Clinical Research Co., Ltd.
Quality and Compliance Consulting, Inc.
Quality Associates, Inc.
Quanticate Inc.
Queensland Clinical Trials Network
Quest Diagnostics Clinical Trials
Quintiles
Qumas
Quorum Review IRB
Radiant Research, Inc
RadPharm, Inc.
Reed Technology
REGISTRAT-MAPI
Research Across America
ResearchPoint
Rho, Inc.
Roche
Rose Clinical Research
RPS, Inc.
Rx Trials Inc.
S-Clinica
Saf-t-Pak, Inc.
SAS Institute
Schlafender Hase GmbH
Schulman Associates IRB
Sciformix Corporation
SDL
Sentrx
SGS Life Science Services
SIRO ClinpharmUSA
Small Planet Meetings
Smith Hanley Consulting Group
SNBL-CPC
Sonic Clinical Trials
Southern Star Clinical Research
Sparta Systems, Inc.
Spectra Clinical Research
Springfire Lab Network
SRA Global Clinical Development
Stat-Tech Services, LLC
STATKING Consulting, Inc.

StatWorks, Inc.
SterlingBio
Sticares InterACT
Stiris Research Inc.
Strata Companies
Streck, Inc.
Symbio, LLC
Symfo
Synchron Research Services Pvt. Ltd.
Synergy Research Group, LLC
Synteract Inc
Target Health Inc.
Tarius A/S
TecHorizon S.r.l.
TechTeam Global
TFS Trial Form Support
Therapak Corporation
Thomson Reuters
TKL Research, Inc.
Total Root Concepts, Inc.
TrainingCampus.com
Transenda International LLC
TransPerfect Translations
Triangle Biostatistics
Trident Clinical Research
Trifecta Multimedical
Trio Clinical Research
TTCLlc
UHCT Alliance
United BioSource Corporation
University of Florida Center for Clinical Trials Research
University of Iowa Pharmaceuticals
University of the Sciences in Philadelphia
the Uppsala Monitoring Centre
VA Cooperative Studies Program
Velos Inc
Verdacom
Veristat, Inc.
Vince and Associates Clinical Research
Virtify, Inc.
Virtual Clinical Solutions
VirtualScopics Inc.
Vitalograph
WCI Consulting Limited
WebbWrites, LLC
WebtrialZ by APT
WebWise Learning, Inc.
West Coast Clinical Trials
WIRB
Woodley Equipment Company
World Courier
Worldwide Clinical Research Inc.
Worldwide Clinical Trials
XClinical GmbH
Xerimis Inc.
Almac provides world-class, integrated research, development and manufacturing services to the pharmaceutical and biotechnology sectors.

**Almac Clinical Technologies** specializes in technology and service solutions that increase the quality and efficiency of the clinical trial process. Our core suite of integrated technologies includes Interactive Voice and Web Response (IXRS™) for patient tracking, randomization and inventory management, our reporting platform, our electronic phone and web-based patient diary solution (ePRO), as well as statistical services. Our facilities are located in Yardley (PA, USA), San Francisco (CA, USA), and Craigavon (UK).

**Almac Clinical Services** is globally focused on the provision of solutions for clinical trial supplies, with sites based in Audubon (PA, USA), Durham (NC) and Craigavon (UK). Almac Clinical Services has evolved from a contract packaging company to a full Clinical supplies management organization. We provide a truly global service for blinding, packaging, labeling, distribution and analysis of clinical trial supplies.

Almac is defined by exceptional customer service. Our organizational stability, innovation and global reach combined with our highly experienced staff ensures our unique positioning within the market. Our robust quality systems and flexible approach ensure that all our clients achieve their trial start dates as efficiently and effectively as possible.

We also understand that our clients are different. From large pharmaceutical organizations to smaller virtual and biotech companies, we must ensure that we are able to match the different needs from different clients, but delivering a consistent level of exceptional client service.

We put our clients at the heart of everything we do.

**Services**

Our clinical technology solutions:
- IVRS/IWRS
- IVR Express
- ePRO (Electronic Patient Reported Outcomes)
- Biostatistical Services
- Adaptive Trial Design
- Data Integration
- Clinical Hotline
- Web Drug Reconciliation

Our clinical trial supply solutions:
- Clinical trial supplies management
- Comparator sourcing
- Over-encapsulation
- Packaging (blistering, bottling, carding)
- Labeling of clinical supplies
- Global distribution and depot network
- QP release and analytical services
- Returns, accountability and destruction

**Contact Almac:**
1040 Stony Hill Road, Suite 200, Yardley, PA 19067 / Phone: 267-685-4284 / Fax: 267-685-4262
email: info@www.almacgroup.com / web: www.almacgroup.com
Cardiac Safety and ePRO Solutions

Based in Philadelphia, PA, ERT is a provider of technology and services to the pharmaceutical, biotechnology and medical device industries. The Company is a market leader in providing centralized core-diagnostic electrocardiographic (ECG) technology and services to evaluate cardiac safety in clinical development. A suite of ePRO Solutions™ complements the product portfolio providing sponsors and users with a simple technology interface which enables engagement of the patient and accurate data capture in a timely manner. This phone based system drives a Complete Patient Experience - from Recruiting and Screening subjects, capturing Assessments and Diaries right through to safety assessment by monitoring for Suicidality ideation and behavior.

Centralized Cardiac Safety 2.0 – The Enhanced Digital Collection, Analysis and Distribution of Cardiac Safety Data

- Centralized Cardiac Safety 2.0 provides global BioPharma sponsors and users with leading technology and services resulting in better science, significantly lower costs and the most convenience
- EXPERT 2®, ERT’s market leading analysis and data management platform, is at the heart of ERT’s new, innovative approach to cardiac safety, providing scalable capacity and flexible workflow processing in a secure and validated environment
- Flexible capacity and throughput will support the entire range of studies from single center to global, multi-center trials
- Full cardiac safety capabilities ranging from digital collection and analysis to paper processing including rescue projects for all clinical trial phases
- ERT is an industry thought leader with experts available to consult on medical and regulatory issues related to cardiac safety study design, data evaluation and reporting
- Industry leaders for Thorough QTc/ECG Trials (TQT/TET), having completed significantly more than any other core lab
- ERT provides best-in-class 12-Lead Digital ECG devices for standard cardiac safety or Holter collection with our inventory of validated devices
- Global experience spanning 6 continents currently supporting concurrently over 700 studies and 25,000 sites
- Global, 24/7 customer care, logistics and site support with comprehensive translation capabilities
- SOP-driven, cross-functional Project Assurance methodology encompasses planning, set-up, monitoring and close out activities. My Study Portal provides sponsors with on-demand data access in a secure web platform to resolve queries, manage supplies, and access reports
- ERT is experienced in partnerships across the clinical services spectrum with many worldwide providers including a significant presence in Japan

www.ert.com/ecg

ePRO Solutions™ – Simple, Powerful Technology Driving The Complete Patient Experience

- A telephone based system that makes the collection of critical Patient Reported Outcomes simple, immediate and cost effective
- Quick implementation of recruiting tools and patient diaries without expensive training and logistics
- Access to over 60 clinical assessments, providing unsurpassed reliability and reproducibility without the bias, training and expense of human raters
- A cutting edge solution to the FDA’s suicidality monitoring directive; the eC-SSRS can be quickly added to any trial

The Complete Patient Experience:

- Accelerated Recruitment
- Consistent Screening
- Unbiased Assessments
- Compliant Diaries
- Improved Retention
- Increased Compliance
- Real-time Safety Monitoring
- Suicidality Monitoring

www.ert.com/epro
Eurofins Medinet is a global organization fully focused and dedicated to providing standardized, high quality global central laboratory services to support all phases of clinical trials. With over 20 years of experience and scientific accomplishment, our laboratory testing portfolio has become one of the widest available in the biopharmaceutical industry and offers the synergy of integrated safety assessment, exploratory biomarkers, end point biomarkers, biomarker development, PK/PD, therapeutic drug monitoring, proteomics, metabolomics, immunogenicity testing, genomic testing and a full range of services to support anti-infective drug development.

Eurofins Medinet supports its customers with 6 wholly-owned and harmonized laboratory facilities located in

- **Europe**: Breda (Netherlands), Paris (France)
- **North America**: Washington DC (USA), Denver (USA), and
- **Asia**: Singapore and Shanghai (China).

When required we extend our global coverage through standardized partners, e.g. in Japan, India, South Africa and Latin America.

Eurofins Medinet is committed to providing the highest quality services, accurate, timely results capturing the planned completion date, and expert advice from our highly qualified team of experienced scientists. As data integrity is of paramount importance, we continually monitor both data quality and our laboratory operations to ensure that the highest standards are maintained:

- Full package of safety and efficacy parameter
- Standardized instruments and analytical methods enable the use of global reference intervals
- Integration of Bioanalytical, Genomic and Anti-Infective Services in one project
- Global standard operating procedures
- Accreditations, certifications and endorsements for a wide range of regulatory requirements such as: CAP, CLIA, ISO15189, ISO17025 and GLP
- Global coverage to minimize sample transportation and logistics
- Single point of contact at Project & Data Management
- Open and pro-active communication
- Dedicated to investigator sites
- Logistics support and courier management
- Global LIMS system
- Real time online access to global database

**Contact Eurofins Medinet**

Contact Person: Eloy del Toro
14100 Park Meadow Drive, Chantilly, VA 20151, United States
Phone: +1.866.324.8691/+1.703.480.2500 / Fax: +1.703.480.2670
email: info@eurofinsmedinet.com / Web: [www.eurofinsmedinet.com](http://www.eurofinsmedinet.com)
IntegReview Ethical Review Board

Applying ethics and integrity to human research while accelerating the IRB process through Internet technology, IntegReview provides the highest level of customer service while providing flexibility to meet the specific needs of each client. IntegReview provides unsurpassed ethical review services from diversified, experienced, knowledgeable board members as well as consultants while acting as an advocate for research study participants. The IRB process is accelerated without compromising accuracy or the protection of the rights and welfare of research study participants.

IntegReview has a proven track record of providing ethical review of research in a timely manner. Committee members and staff are highly trained and readily available to provide personalized, responsive, knowledgeable service.

Clients have 24/7 instant access to study documents via the Internet within twenty-four to forty-eight hours of board review. This real-time communication system is password protected and encrypted for security.

IntegReview’s success continues to grow by word-of-mouth endorsement from pharmaceutical and medical device companies, contract research organizations, and study sites. All committees are registered with the Office for Human Research Protections (OHRP).

FDA, pharmaceutical companies, contract research organizations, as well as AAHRPP perform regular inspections of our processes. An FDA inspection in July 2009 resulted in no findings.

CERTIFICATION: Staff and board members have earned certifications, such as Certified IRB Professional (CIP), Certified Clinical Research Professional (CCRP) and Certified IRB Manager (CIM).

ACCRREDITATION: IntegReview is proud to have earned full accreditation from the Association for the Accreditation of Human Research Protection Programs in 2007.

MISSION STATEMENT
IntegReview is committed to protecting the rights and welfare of human subjects participating in research by:

➤ Striving to go above and beyond federal regulations
➤ Ensuring research is ethical and safe
➤ Providing education for all parties involved in research

IntegReview is committed to maintaining superior customer service without compromising ethical values by:

➤ Providing rapid, quality service
➤ Assisting clients with ethical compliance
➤ Demonstrating respect
➤ Offering flexibility

SERVICES:

➤ Review of Phase I-IV drug studies, medical device studies, behavioral science studies
➤ Single and multiple investigator review
➤ Unscheduled meetings, as requested
➤ Multiple weekly board meetings
➤ Personalized attention to client needs
➤ Forty-eight hour turnaround
➤ Instant access to study documents via Internet
➤ Downloadable forms and e-submissions
➤ Presence at investigator meetings
➤ Translations
➤ Competitive fees

HOW OUR CLIENTS BENEFIT

• Drug can be shipped to sites faster
• Real-time Internet access to study documents
• Internet website access to downloadable forms
• Sample informed consent written below

Let IntegReview be your choice in IRB services for your next research study.

Contact IntegReview:
Melissa Meyer, 3001 South Lamar Boulevard, Suite 210, Austin, TX 78704, United States
Phone: +1.512.326.3001 / Fax: +1.512.326.3446
email: Mmeyer@integreview.com / Web: www.integreview.com
Medpace, Inc.

Areas of Expertise

• Cardiology  • Metabolism  • Oncology  • Nephrology  • CNS

Medpace is a leading global full-service research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled the industry’s most experienced and therapeutically focused teams to execute at every level of the company’s operations, providing complete and seamless drug development services. In June 2009 Medpace was rated as the best CRO by US Investigators in the 2009 CenterWatch Site Survey.

Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost-effective path to drug development – from program planning and execution to product approval.

With more than 1,000 employees and clinical trial experience in over 40 countries, Medpace has the global reach and capability to conduct studies and navigate regulatory requirements worldwide. Medpace provides Phase I-IV clinical trial management and data services, centralized laboratory services, a core ECG laboratory, bioanalytical laboratory services, and imaging services.

The Medpace Family of Companies:

**Medpace Clinical Pharmacology** is a state-of-the-art facility, focuses on Phase I and Iia confined / controlled pharmacokinetic / pharmacodynamic studies utilizing special patient populations and healthy volunteers with first-in-human capability.

The Medpace CPU, a 65-bed research facility, provides a full range of clinical research services including clinical protocol design and development, pharmacokinetic, drug development consulting, project management, data management, statistics, and medical writing.

**Medpace Reference Laboratories** is a fully owned central laboratory with locations in Cincinnati, US; Leuven, Belgium; Beijing, China; and Mumbai, India. MRL expertise includes coagulation, cardiovascular diseases, oncology, lipids, diabetes, and other metabolic diseases.

MRL offers clients analytical support during all stages of the drug development process, with more than 76,000 square feet dedicated to laboratory operations and specimen storage. Preparation, packaging, and delivery of all supplies and materials necessary for specimen collection are also managed within the laboratory facilities.

**Medpace Bioanalytical Laboratories** provides complete bioanalytical services in all stages of drug development leveraging state-of-the-art instrumentation, techniques, and facilities with experience in a broad range of analytical support. Working in a Good Laboratory Practice (GLP) compliant setting, the MBL provides method transfer, development, validation, and analysis of preclinical and clinical biological samples.

**Imagepace** Provides centralized imaging core laboratory management and reading services utilizing advanced imaging technologies to seamlessly integrate imaging studies into the complex structure of a clinical trial. The Imagepace team brings clinical trial experience and discipline to the management of imaging processes to ensure that imaging study results are valid, controlled, and easily integrated into overall clinical trial study results.

Products and Services

• Medical Expertise  • Regulatory Affairs  • Safety/Pharmacovigilance  • Clinical Operations  • Data Management
• Biostatistics  • Quality Assurance  • Medical Writing  • Cardiac Safety  • Central Laboratory
• Bioanalytical  • Clinical Pharmacology  • Imaging Management and Reading  • Interactive Voice Response System  • Business Contact:

Contact Medpace, Inc.:
August Troendle, MD, President and CEO, 4620 Wesley Avenue, Cincinnati, OH 45212, United States
Phone: 513-579-9911 / Fax: 513-579-0444

Business Contact:
Catherine Soldano, Executive Director, Business Development / Phone: 513-579-9911 / c.soldano1@medpace.com

Website: www.medpace.com
PharmaNet Development Group

PharmaNet Development Group, Inc., a global, drug development services company, provides expertise to the pharmaceutical, biotechnology, generic drug, and medical device industries. PharmaNet companies offer clinical development solutions including consulting services, Phase I clinical studies, bioequivalency and pharmacodynamic studies, bioanalytical services, and Phase II, III, and IV clinical development programs. With global resources and expertise in a wide variety of therapeutic areas, PharmaNet is a recognized leader in outsourced clinical development.

Consulting
PharmaNet’s consulting professionals include former senior-level FDA officials and other international regulatory experts who offer comprehensive early- and late-stage consulting services for small and large molecule therapeutics, vaccines, blood products, cell and gene therapies and medical devices in a wide range of disciplines, including: international regulatory affairs; scientific and medical affairs; quality; risk management; chemistry, manufacturing and controls; as well as biopharmaceutical investor interests. They have deep experience in tackling unique product development and marketing challenges and are particularly adept at helping clients transition into new therapeutic disciplines, product lines and markets.

Phase I
For more than a decade, PharmaNet has been providing a comprehensive range of clinical development services for early stage programs, including Phase I/bioequivalence, regulatory affairs and bioanalytical laboratory analyses through its clinics in Canada. Our modern, well-designed and spacious clinics have a 400-bed capacity, 35+ physicians and 300+ staff to support your clinical development program.

Phase II–IV
Through our global network of offices and field-based staff in North America, Latin America, Europe, Asia, and Australia, PharmaNet facilitates investigator site selection, timely patient recruitment and the efficient conduct of complex clinical trials in Phases II-IV. Our dedicated teams conduct studies and registries in virtually all therapeutic areas, with specialized resources in oncology, neurosciences, cardiovascular disease, infectious diseases, nephrology, dermatology, ophthalmology, pediatrics and women’s health. Our professionals can design and execute studies that meet the highest standards of scientific integrity and regulatory compliance while meeting the sponsor’s commercial objectives. We have the capability and resources to implement programs of any scale.

Bioanalytical
Global bioanalytical services in support of drug discovery and clinical studies are offered through PharmaNet’s two GLP-compliant labs. Housed in approximately 44,000 ft. of modern laboratory space equipped with robotics and LIMS, we have a staff of 170+ thoroughly trained scientists. In addition to having 1000+ validated assays, we offer a full range of analytical support services, including preclinical, bioavailability and drug-metabolism studies, bioequivalence studies, clinical study-compliance samples, drug-interaction studies, and drug discovery and dose-escalating studies. They also have specialized expertise in tissue analysis in support of drug disposition studies, small molecule and peptide quantitation using LC-MS/MS, endogenous validated biomarker quantitation using GC-MS/MS, and immunogenicity testing for biologics.

Clinical Technology Solutions
PharmaNet offers PharmaSoft®, a suite of integral applications including CDMS, CTMS, IVRS/IWRS and other web-based products specifically designed to support clinical development activities by facilitating the collection, management and reporting of clinical trial information. Its data management staff also works with all major clinical trial management systems, including those from Phase Forward, Medidata and Oracle.

For comprehensive Phase I–IV services in clinical development, consulting, bioanalysis, and information technology, choose PharmaNet, for experience you can trust.

Visit PharmaNet Development Group at the 46th Annual DIA Meeting at Booth #445.

Contact us for more information:
504 Carnegie Center
Princeton, NJ 08540
Phone: 609-951-6800
**PharSafer® Associates Ltd**

**Your preferred choice for Safety Provider**

**PharSafer® Associates Ltd** is a niche CRO specialising in Global Clinical and Post Marketing Safety as well as Medical Services.

**PharSafer®** was founded 8 years ago and has grown every year offering all types of Pharma (Innovator; Biotech; Advanced Therapy (stem cell); Generic; OTC; Herbal; Medical Devices) Companies specialist services in all aspects of Safety (Pharmacovigilance). Our client base is National and multi-National and extends from top 10 Pharma to first to market Companies.

**PharSafer®** clients are based in the USA, Canada, Europe, and SE Asia and have provided world-wide post-marketing safety activities including the role of the **EU QP for Pharmacovigilance** for clients and hosted Regulatory Inspections on site at our offices for both GCP and Pharmacovigilance in order to demonstrate Regulatory compliance to the legislation as part of routine assessments.

**PharSafer®** clinical activities include safety monitoring for Phase I – IV Studies including Risk Management activities as conditions of licence approval and Marketing Studies safety assessments. The trials are conducted globally and our knowledge of the various safety reporting rules and periodic submissions means that we keep our clients compliant for Safety.

**PharSafer®** staff are trained in all aspects of Pharmacovigilance and Medical Services and have helped Companies with many Projects as well as full out-sourcing including:

- Due diligence; Regulatory Inspection readiness; safety database implementations; PSUR/Periodic writing;
- Auditing (GCP and Pharmacovigilance); DSMB support; Clinical Annual Safety writing; signal detection and Benefit-Risk analysis; Promotional item review; production of Medical Services FAQs; Device vigilance reporting;
- Core Safety writing; Production of ISS and Risk Management documents; writing sections 1.8.1 & 1.8.2 of the CTD;
- SOP writing; production of the DDPS; and corrective activities following a Regulatory Inspection.

The **PharSafer®** team are either Safety Physicians; Pharmacists; scientists and have many years of experience in the area of Global Pharmacovigilance and Medical Services. **PharSafer®** is committed to training and all staff undergo rigorous induction training and on-going internal and external development training to better serve our clients. Also, **PharSafer®** through its sister Company **SaPhar** conducts Safety training multi-nationally for Companies from Introductory to Advanced level Pharmacovigilance courses to bespoke client requested training courses.

The Company founder is Graeme Ladds whose last industry role was Global Head of Drug Safety & EU QP for Pharmacovigilance for a multi-national innovator Pharma Company and has 20 years of experience in this field. Graeme is actively involved at **PharSafer®** with all clients and day to day operational activities.

**PharSafer®** has a Quality Management System to ensure accurate and reputable documentation is produced and submitted and we constantly look at ways to improve our service to clients and have stream-lined, cost efficient processes.

**PharSafer®** sticks to what it does best - Pharmacovigilance and Medical Services. However, we are acutely aware that clients will have other needs too, e.g. Regulatory; Marketing etc... and so **PharSafer®** has strategic partners in many other disciplines to help you.

We look forward to hearing from you and we can be contacted on

enquiries@pharsafer.com or graemeladds@pharsafer.com

and more information is available on our website www.pharsafer.com
Quorum Review IRB

When Performance Matters.

Quorum Review is an independent ethics review board that is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Quorum was founded in 1992 by a small group of individuals with a wealth of experience in clinical research human participant protection. Quorum’s founders believed an IRB could strive to protect human participants without giving up a focus on customer service.

See why research organizations choose Quorum:

- **AAHRPP accredited:** The Association for the Accreditation of Human Research Protection Programs accredits high-quality human research protection programs to promote excellent, ethically sound research. AAHRPP accreditation means that Quorum has demonstrated a commitment to high standards of patient protection and regulatory compliance.

- **Quality and accuracy at all times:** Quorum conducts a thorough quality check on all outgoing documents, to ensure that sites receive high quality approval documents that are free of errors.

- **Prompt turnaround:** We guarantee a 24-hour turnaround on eligible site submissions (from submission to document posting). And with a prompt amendment review cycle, plus expedited translation services, you’ll gain efficiencies when it matters most.

- **Secure access to an on-line electronic portal:** The OnQ™ portal is a powerful information hub providing sponsors, CROs and investigators immediate access to all Board correspondence, site start-up status as well as on-line submission capabilities.

- **Single point of contact:** At Quorum, there’s no need to guess about who to call for assistance. Quorum assigns one Quorum representative to each study, and that person will serve as the single point of contact for the life of the study.

- **Canadian and US Review:** Quorum has one of the few ethics review boards accredited to review studies in both the United States and Canada*. Quorum can manage and coordinate submissions from either side of the 38th parallel using a single point of contact per study.

  *Certain provincial restrictions that apply to most other central REBs in Canada also apply to Quorum Review.

- **Streamlined process for working with institutions:** Quorum has worked with researchers from hundreds of institutions and we offer the same prompt turnaround times to our institutional researchers as we offer to our other researchers.

- **Experience as diverse as your needs:** Our board has a deep knowledge and understanding of a broad range of therapeutic areas as well as medical devices, nutraceuticals, cosmetic products and social and behavioral research.

- **Timely and accurate review of Phase I investigational drugs:** Quorum offers a dedicated Phase I team that is specially trained in the unique needs of Phase I studies. We offer flexibility and faster timelines in our Phase I processes.

- **Simplified process for Qualified Minimal Risk studies:** With a streamlined submission process, aggressive volume pricing for large studies and rapid study start-up processes, we’re ideally prepared to support minimal risk research.

To learn more about Quorum, call our Client Relations Department at 206-448-4082 or visit our website at [www.quorumreview.com](http://www.quorumreview.com).
Sticares InterACT

Sticares InterACT is a European academic CRO, headquartered in the Netherlands, operating globally and providing full service for clinical research projects of pharmaceutical and biotechnology companies. We have a long tradition in conducting phases II to IV cardiovascular and metabolic clinical research. Sticares InterACT can manage trials with over 1000 sites and over 10,000 patients. We are present in 24 European countries including the CEE.

We offer a comprehensive package of clinical services. Quality Assurance and Quality Control is an integral part of all our services; all applicable rules and regulations, including the ones derived from the ICH-Good Clinical Practice (GCP) and Pharmacovigilance guidelines are embedded.

Clinical Trial Management is the core of our services and we also have a large, all MD, medical division. Our MDs have years of clinical experience, real knowledge of medical aspects of drug safety and regulatory requirements and have extensive experience in medical review.

We pride ourselves that more than a third of our staff have a medical degree and more than half a life science degree. Sticares InterACT has an annual staff turnover of less than 10%. Sticares InterACT was established in 1981 by our CEO, Professor W.J. Remme.

Scientific Advisory Board
The Scientific Advisory Board of Sticares InterACT consists of outstanding cardiologists Professor of Medicine and Cardiology Robert S. Rosenson, MD, PhD, FACC, FAHA, of the Mount Sinai Hospital in New York, for atherosclerosis and lipids, Professor of Cardiology Hani N. Sabbah, MD, PhD, FACC, FAHA, of the Henry Ford hospital in Detroit for cardiac remodelling, heart failure, myocardial infarction and our CEO Professor of Cardiology W.J. Remme, MD, PhD, FACC, FAHA, FESC, for heart failure.

Sticares InterACT & Partners in GlobalACT
Sticares InterACT’s global reach is guaranteed by GlobalACT, our strategic alliance with partner organizations in North America, South Africa and Australasia. For a global trial we act as one CRO. Our partner in the US is Integrium with offices on the West Coast and on the East Coast and an office located in South Africa. Our partner covering Australasia is George Clinical, the CRO of The George Institute located in Sydney. George Clinical was the leading CRO in the largest trial on diabetes ever conducted, the ADVANCE study.

Partnership with Cardialysis
Sticares InterACT starts a partnership with Cardialysis, an internationally recognized catalyst in cardiology in general, and coronary stent trials in particular.

Cardialysis has an excellent reputation as supplier of expertise and services in studies in Cardiology. Close collaboration of Sticares InterACT and Cardialysis with knowledgeable opinion leaders allows us to design and run high-quality, fast-recruiting, and cost-effective trials.

Landmark Trials
Sticares InterACT successfully managed several multinational landmark endpoint trials such as EUROPA (12000 subjects), HYVET (3850 subjects), BEAUTIFUL (10000 subjects), PREAMI (1200 subjects) and SHIFT (6550 subjects). Sticares InterACT has 3 decades of clinical trial expertise and was involved in more than 181 clinical trials in angina, acute coronary syndrome, arrhythmias, MI, acute and chronic heart failure, hypertension, metabolic syndrome, diabetes, hyperlipidemia, and atherosclerosis.

Contact Sticares InterACT:
Jan A. de Witt, Chief Business Officer, j.dewitt@sticares.org, cell: +31 6 5200 5367
Mark P. op ten Berg, Account Manager Business Development, m.optenberg@sticares.org, cell: +31 6 464 333 98
Ronald W. Stapel, Director, Contracts and Proposals, r.stapel@sticares.org, cell: +31 6 5089 1133
P.O. Box 882, 3160 AB Rhoon, The Netherlands, Europe
Phone: +31 10 48 55 177 / Fax: +31 10 50 10 733
Website: www.sticaresinteract.com
Thomson Reuters

INFORMATION FOR FAST, ACCURATE, AND CONFIDENT
REGULATORY DECISIONS

Visit us at booth 1845/1847 for hands-on product demonstrations.

Stay fully up to date with the ever-changing requirements of governments and regulatory authorities around the world with IDRAC®. Only IDRAC has the global reach, depth of analysis, and local expertise to keep you informed of every regulation that could affect your product.

With IDRAC you can count on updated reliable, impartial knowledge, that's backed up by accurate, expert analysis and the world’s finest customer support.

As the largest single repository of regulatory reference, knowledge and expertise available, IDRAC houses a unique collection of regulatory documents, continuously updated regulatory summaries, and exclusive regulatory intelligence reports. The complete suite contains more than 80,000 critical documents going back to 1885.

COMPARE GLOBAL REGULATORY REQUIREMENTS QUICKLY AND SIMPLY

NEW! The IDRAC Global Module is an access point for users who work with more than one IDRAC country module. The Global Module provides content, regulatory expertise, and dynamic tables to aid comparisons between the regulatory requirements in multiple countries and regions.

Don’t miss our latest key solutions at DIA Annual 2010:

• IDRAC: Strategic intelligence to stay informed on the ever-changing regulatory environment
• PROUS SCIENCE INTEGRITY® and BIOMARKERcenter®: Timely, trusted integrated biological, chemical, pharmacological, and biomarker information
• THOMSON PHARMA®: Complete pharmaceutical solution for the drug discovery and development pipeline

To learn more now, visit go.thomsonreuters.com/request_info

Contact Thomson Reuters:
3501 Spring Garden Street, 4th Floor
Philadelphia, PA 19130
Phone: 215-386-0100
DIA holds more than 100 meetings, workshops, and conferences annually around the world, most of which offer exhibit opportunities that provide the perfect opportunity for attendees to meet with companies and learn about the latest technologies. Exhibit programs range from a handful of tabletop exhibitors to a large exhibit hall. You select the best setting to showcase your products or services and meet with key decision makers. Space for the 2010 Annual Meeting in Washington, DC, is still available.

**Looking for High Visibility in an Intimate Setting?**

DIA’s Tabletop Exhibit Program offers a unique opportunity to market your products and services to a global audience. Tabletop exhibits are strategically positioned in high traffic areas to help you maximize your exposure to meeting attendees.

Visit [www.diahome.org](http://www.diahome.org) and click on “Exhibits” for available exhibiting opportunities.

**Contact Information:**

exhibits@diahome.org
+1-215-442-6100
HOTEL INFORMATION

PLEASE NOTE: Travel Planners is the exclusive housing provider for the 46th Annual Meeting. It has been brought to DIA’s attention that unauthorized third-party providers are contacting DIA Annual Meeting attendees to book their hotel reservations. These providers may require reservations to be fully prepaid, are nonrefundable and may be subject to steep cancellation and change fees. Should you choose to book with any provider other than Travel Planners, DIA will not be able to assist you with any issues you may encounter with the terms of a third-party agreement.

Travel Planners is coordinating all reservations for DIA, and arrangements for housing must be made through them and NOT with the hotel directly. For best availability, please book prior to May 21, 2010. After this date, rooms will be available on a space-available basis until the start of the meeting. DIA does not process hotel reservations.

- **ONLINE**
  Log on to [www.diahome.org](http://www.diahome.org), double click on the Annual Meeting icon and click on the Hotel Information tab. Here you will find details for making your reservation online.

- **BY PHONE**
  1.800.221.3531 (domestic) / 1.212.532.1660 (international)
  Please have all of the information below ready.

  - Name of convention: DIA Annual Meeting, June 13-17, 2010
  - 1st, 2nd, 3rd choice of hotel
  - Arrival/departure dates
  - Number of rooms requested
  - Type of room (single, double/triple/quad)
  - Number of group and persons in your party
  - Credit card type, account number, expiration
  - Names of all room occupants
  - Daytime phone and fax numbers
  - eMail address to which confirmation will be sent
  - Mailing address

**CREDIT CARD:** Your credit card will be used as a guarantee but will not be charged immediately. The hotel may charge the deposit to your credit card on or around May 21, 2010 when they receive the reservations for processing from Travel Planners. Most major credit cards are accepted.

**CHANGES/CANCELLATIONS:** Until June 9, 2010, all changes and cancellations should be made directly online with Travel Planners.

**CANCELLATION POLICY:** Please refer to your confirmation information for specific details about the hotel’s cancellation policy.

If a guest does not arrive by their scheduled arrival date, the full reservation will be cancelled by the hotel and any applicable deposit or charges will be assessed.

---

<table>
<thead>
<tr>
<th>Event Hotels</th>
<th>Address</th>
<th>Single Room Rates* starting at</th>
<th>Distance to Convention Center</th>
<th>Shuttle Offered†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Capital Hilton DC</td>
<td>1001 16th Street NW</td>
<td>$289</td>
<td>8 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>2 Comfort Inn Convention Center Downtown</td>
<td>1201 13th Street NW</td>
<td>$179</td>
<td>4 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>3 Donovan House - a Thompson Hotel</td>
<td>1155 14th Street NW</td>
<td>$239</td>
<td>5 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>4 Doubletree Hotel DC</td>
<td>1515 Rhode Island Avenue NW</td>
<td>$199</td>
<td>8 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>5 Embassy Suites DC Convention Center</td>
<td>900 10th Street NW</td>
<td>$259</td>
<td>2 blocks</td>
<td>No</td>
</tr>
<tr>
<td>6 Four Points Downtown by Sheraton</td>
<td>1201 K Street NW</td>
<td>$259</td>
<td>3 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>7 Grand Hyatt Washington</td>
<td>1000 H Street NW</td>
<td>$289</td>
<td>3 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>8 Hamilton Crowne Plaza</td>
<td>1001 14th Street NW</td>
<td>$265</td>
<td>5 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>9 Hampton Inn Washington, DC Convention Center</td>
<td>901 6th Street, NW</td>
<td>$289</td>
<td>2 blocks</td>
<td>No</td>
</tr>
<tr>
<td>10 Hilton Garden Inn DC Downtown</td>
<td>815 14th Street NW</td>
<td>$249</td>
<td>7 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>11 Hyatt Regency on Capitol Hill</td>
<td>400 New Jersey Avenue NW</td>
<td>$270</td>
<td>10 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>12 JW Marriott</td>
<td>1231 Pennsylvania Ave NW</td>
<td>$279</td>
<td>11 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>13 Liaison Capitol Hill, an Affinia Hotel</td>
<td>415 New Jersey Avenue NW</td>
<td>$249</td>
<td>10 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>14 Madison DC, a Loews Hotel</td>
<td>1177 Fifteenth Street NW</td>
<td>$235</td>
<td>6 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>15 Marriott Metro Center</td>
<td>775 12th Street NW</td>
<td>$270</td>
<td>5 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>16 Morrison-Clark Inn</td>
<td>1015 L Street NW</td>
<td>$211</td>
<td>2 blocks</td>
<td>No</td>
</tr>
<tr>
<td>17 Phoenix Park</td>
<td>520 North Capitol Street NW</td>
<td>$269</td>
<td>11 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>18 Renaissance Mayflower</td>
<td>1127 Connecticut Avenue NW</td>
<td>$285</td>
<td>8 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>19 Renaissance DC</td>
<td>999 9th Street NW</td>
<td>$270</td>
<td>1 block</td>
<td>No</td>
</tr>
<tr>
<td>20 Sofitel Lafayette Square</td>
<td>806 15th Street NW</td>
<td>$269</td>
<td>9 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>21 Washington Plaza Hotel</td>
<td>10 Thomas Circle NW</td>
<td>$209</td>
<td>5 blocks</td>
<td>Yes</td>
</tr>
<tr>
<td>22 Westin Washington, DC City Center</td>
<td>1400 M Street NW</td>
<td>$249</td>
<td>7 blocks</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Hotel rates do not include current tax of 14.5% or applicable surcharges; subject to change.
†Shuttle service will be provided in the morning and afternoon only. Mid-day service will not be available.
The tutorials being offered as of February 12, 2010 are listed below. Please continue to monitor [www.diahome.org](http://www.diahome.org) for tutorial updates and online registration. **Space is limited so register early!**

### Sunday, June 13, 8:30 AM-12:00 PM
**Morning Half-day Tutorials**

<table>
<thead>
<tr>
<th>Fee: $375.00</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interest Areas</strong></td>
</tr>
<tr>
<td>#20 Understanding and Navigating the Regulatory System in China</td>
</tr>
<tr>
<td>#21 Structured Product Labeling: Content of Labeling and Drug Establishment Registration and Drug Listing</td>
</tr>
<tr>
<td>#22 Fourteen Steps from Research to Development</td>
</tr>
<tr>
<td>#23 FDA Enforcement: Understanding the Agency’s Authority, How Violations Occur, How to Prevent Them, and How to Respond If Violations Do Occur</td>
</tr>
<tr>
<td>#24 Utilizing Chemistry, Manufacturing, and Controls in Drug Development</td>
</tr>
<tr>
<td>#25 Portfolio Management: The Nuts and Bolts of Aligning Operations with Strategy</td>
</tr>
<tr>
<td>#26 Early Clinical Studies: An Overview</td>
</tr>
</tbody>
</table>

### Sunday, June 13, 1:00 PM-4:30 PM
**Afternoon Half-day Tutorials continued**

<table>
<thead>
<tr>
<th>Interest Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>#33 Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development</td>
</tr>
<tr>
<td>#34 Hot Topics in Pharmacovigilance in the EU: EudraVigilance Access Policy, International Standardization Work E2B and Identification of Medicinal Products, Signal Detection, Duplicate Management</td>
</tr>
<tr>
<td>#35 A Device Primer: 510(k)s, PMAs, IDEs</td>
</tr>
<tr>
<td>#36 Designing, Operating, and Evaluating Patient Registries</td>
</tr>
<tr>
<td>#37 Social Media Marketing Accelerator</td>
</tr>
</tbody>
</table>

### Sunday, June 13, 9:00 AM-5:00 PM
**Full-day Tutorials**

<table>
<thead>
<tr>
<th>Fee: $650.00</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interest Areas</strong></td>
</tr>
<tr>
<td>#40 Advanced CRO-vendor Management: Quality, Performance, and Compliance</td>
</tr>
<tr>
<td>#41 Regulatory Affairs for Biologics</td>
</tr>
<tr>
<td>#42 How to Prepare for a Safety Inspection</td>
</tr>
<tr>
<td>#43 Clinical Statistics for Nonstatisticians</td>
</tr>
<tr>
<td>#44 Who’s Monitoring the Monitor: Explore Trends, Management Techniques and a Reality Check for Sponsors Utilizing CRO- and Alliance-based Site Monitoring</td>
</tr>
</tbody>
</table>

Please indicate the tutorials you plan to attend on the registration form on the next page.
The rates on this registration form are applicable after May 28, 2010.

Attendee Registration Form
DIA 46th Annual Meeting  ID 10001
June 13-17, 2010, Washington, D.C.

Each paying attendee registering for any portion of this event must complete and submit this page.

PAYMENT OPTIONS
Register online at www.diahome.org or check payment method below.

☐ CREDIT CARD  Complete this form and fax to +1.215.442.6199 or mail to Drug Information Association, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA. Non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa  ☐ MC  ☐ AMEX  Exp. Date __________________________

Card # __________________________

Name (printed) __________________________

Signature __________________________

CANCELLATION POLICY: All cancellations must be received in writing at DIA’s office by 5:00 pm, May 28, 2010.

If you do not cancel by May 28, 2010 and do not attend, you are responsible for the full applicable fee. Registrants are responsible for cancelling their 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.

Refunds for cancellations received in writing on or before May 28, 2010 will be:

- Full Meeting: Government/Nonprofit/Academia = Registration fee paid minus $100 = Refund Amount
- All Others – Registration fee paid minus $200 = Refund Amount
- Networking Reception: On or before May 28, 2010 = Full Refund
- Tutorial: On or before May 28, 2010 – Registration fee paid minus $75 = Refund Amount
- One-day Registration: NO REFUNDS

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

Photography Policy: By attending the DIA 46th Annual Meeting, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by the DIA in promotional materials, publications, and website and waive any and all rights including, but not limited to, compensation or ownership.

Attendees may register online at www.diahome.org.

ONLINE REGISTRATION IS NOT AVAILABLE TO SPEAKERS OR EXHIBITORS.

All registrations received at the DIA office in Horsham, PA, USA by 5:00 pm on May 7, 2010 were included in the Advance Registration Attendee List.

FREE ACCESS TO ALL THE ANNUAL MEETING CONTENT!

Attendees paying the full registration fee will receive access to ALL available post-meeting audio synchronized PowerPoint presentations. To view a sample of this product, go to www.diahome.org and click on the Annual Meeting icon.

Full-meeting Registration (attendance of 2 or more days) includes admission to all sessions, exhibits, coffee breaks, luncheons, and receptions, excluding Sunday Networking Reception. If DIA cannot verify your membership, you will be charged the nonmember fee. All fees are in US dollars.

Tutorials Registration for tutorials only is not available. You must be a paid attendee, speaker, or exhibitor to register for tutorials. See pages 14-21 for tutorial details and page 96 for an at-a-glance tutorial schedule and pricing guide. Space is limited and preregistration is encouraged. Please indicate the ID # and fee for tutorials you plan to attend.

1. Tutorial # ________ Fee ________
2. Tutorial # ________ Fee ________
   TUTORIAL SUBTOTAL ________

Preregistration Fees
A surcharge of $150 has been included in the registration fees for ALL registrations received after May 28, 2010 (does not apply to one-day registrations). An email address must be included below for confirmation process.

MEMBER FEE  US $1440  ☐

Join DIA now to save on future meetings and to enjoy the benefits of membership for one year! www.diahome.org

NONMEMBER FEE  US $1580  ☐

Nonmember fee includes a one-year membership option. Please indicate preference.

☐ I DO want DIA membership  ☐ I DO NOT want DIA membership

DISCOUNT FEES

<table>
<thead>
<tr>
<th>Membership Type</th>
<th>Member Fee</th>
<th>Nonmember Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government (Full-time)**</td>
<td>US $570</td>
<td>US $710</td>
</tr>
<tr>
<td>Charitable Nonprofit/Academia (Full-time)**</td>
<td>US $965</td>
<td>US $1105</td>
</tr>
</tbody>
</table>

**If paying a nonmember fee, please check preferred membership option above.

Includes access to post-meeting presentations.

ONE-DAY FEES†

You must indicate which day you plan to attend.

- Monday, June 14  ☐ Tuesday, June 15  ☐ Wednesday, June 16  ☐ Thursday, June 17  ☐

†One-day attendees will receive access to post-meeting presentations for that one day only.

If paying a nonmember fee, please check preferred membership option above.

NETWORKING RECEPTION

Registration for the Networking Reception ONLY is not available. You must be registered for the full meeting to attend.

After May 14, 2010

US $85  ☐

TOTAL PAYMENT DUE  US $

Include all applicable fees: meeting, tutorials, networking reception.

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<tr>
<th>Last/Family Name</th>
<th>First Name</th>
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<tr>
<th>Job Title</th>
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<th>Rating Address</th>
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<tr>
<th>City</th>
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ADD Tutorials and/or Networking Reception TO YOUR EXISTING REGISTRATION

46th ANNUAL MEETING | ID #10001
June 13-17, 2010    Washington, DC, USA

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

This page must be completed and submitted for each person attending any portion of this event. Please fax to +1.215.442.6199.

<table>
<thead>
<tr>
<th>REGISTRATION FEES</th>
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<tbody>
<tr>
<td>❑ YES, I am registered for the meeting and I would like to add the Networking Reception and/or the following Tutorials to my registration. I am registered as:</td>
</tr>
<tr>
<td>❑ Attendee ❑ Speaker ❑ Track Chair</td>
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<tr>
<td>❑ Session Chair ❑ Exhibitor (Full Meeting or Booth Personnel)</td>
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</table>

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<thead>
<tr>
<th>TUTORIALS</th>
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</thead>
<tbody>
<tr>
<td>You must be registered for the Annual Meeting before registering for tutorials. Tutorials ONLY are not available.</td>
</tr>
<tr>
<td>See pages 10-11 in the online brochure for tutorial information and fees. Space is limited and preregistration is encouraged. Please indicate the I.D.# and fee for each tutorial you plan to attend:</td>
</tr>
<tr>
<td>❑ Tutorial # ______ Fee ________</td>
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<tr>
<td>❑ Tutorial # ______ Fee ________</td>
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<tr>
<td>TUTORIAL SUBTOTAL __________________</td>
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<thead>
<tr>
<th>NETWORKING RECEPTION</th>
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<tbody>
<tr>
<td>You must be registered for the Annual Meeting before registering for the Networking Reception. Networking Reception ONLY is not available.</td>
</tr>
<tr>
<td>On or before MAY 14, 2010 After MAY 14, 2010</td>
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<tr>
<td>US $75 ☐ US $85 ☐</td>
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<td>TOTAL PAYMENT DUE US $________</td>
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<tr>
<th>CANCELLATION POLICY</th>
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<tr>
<td>All cancellations must be received in writing at DIA’s office by 5:00 PM, May 28, 2010.</td>
</tr>
<tr>
<td>If you do not cancel by May 28, 2010 and do not attend, you are responsible for the full applicable fee. Registrants are responsible for cancelling their 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.</td>
</tr>
<tr>
<td>Refunds for cancellations received in writing on or before May 28, 2010 will be:</td>
</tr>
<tr>
<td>❑ FULL MEETING: Government/Nonprofit/Academia - Registration fee paid minus $100 = Refund Amount</td>
</tr>
<tr>
<td>❑ NETWORKING RECEPTION: On or before MAY 28, 2010 = Full Refund</td>
</tr>
<tr>
<td>❑ TUTORIAL: On or before May 28, 2010 - Registration fee paid minus $75 = Refund Amount</td>
</tr>
<tr>
<td>❑ ONE-DAY REGISTRATION: NO REFUNDS</td>
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<tr>
<th>REGISTRANT’S INFORMATION</th>
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<tbody>
<tr>
<td>Last/Family Name</td>
</tr>
<tr>
<td>Degrees</td>
</tr>
<tr>
<td>Job Title</td>
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<tr>
<td>Mailing Address</td>
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<tr>
<td>City State Zip/Postal Code Country</td>
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<tr>
<td>Email (email address is required for confirmation)</td>
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<tr>
<td>Telephone # Fax #</td>
</tr>
</tbody>
</table>

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.

PAYMENT METHODS

Please check your payment method.

❑ CREDIT CARD Complete this form and fax to +1.215.442.6199 or mail to:
DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA. Non-US credit card payment will be subject to the currency conversion rate at the time of charge.

❑ VISA ☐ MC ☐ AMEX Exp. Date ________________ |

Card # __________ Signature __________________ |

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

❑ BANK TRANSFER Upon completion of registration, DIA sends an email to the address on the form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name, company, and Meeting ID #10001 must be included on the transfer document to ensure payment to your account.
EXHIBIT PERSONNEL REGISTRATION FORM
Online registration is not available to exhibit personnel.

46th ANNUAL MEETING | ID #10001
June 13-17, 2010 Washington, DC, USA

Completed forms should be faxed to +1.215.442.6199

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

Once you have utilized the four (4) badges provided per each 10’ x 10’ booth, any additional personnel must register as an attendee (NOT as an exhibitor).
Log on to www.diahome.org and download the ATTENDEE Registration Form, complete and return it as per the instructions on the form.

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

Payment is required ONLY if also registering for Tutorials or the Networking Reception. Please check payment method:
- CREDIT CARD Complete this form and fax to +1.215.442.6199 or mail to:
DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA. Non-US credit card payment will be subject to the currency conversion rate at the time of charge.
- VISACARD AMEXMC Exp. Date
Card # ____________________________
Signature ____________________________

- CHECK drawn on a US bank payable to and mailed along with this form to:
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CANCELLATION POLICY: All cancellations must be received in writing at DIA’s office by 5:00 PM, May 28, 2010. If you do not cancel by May 28, 2010 and do not attend, you are responsible for the full applicable fee. Registrants are responsible for cancelling their 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.

Refunds for cancellations received in writing on or before May 28, 2010 will be:
- NETWORKING RECEPTION: On or before May 28, 2010 = Full Refund
- TUTORIAL: On or before May 28, 2010 = Registration fee paid minus $75 = Refund Amount

Full-Meeting Registration (attendance of 2 or more days) includes admission to all sessions, exhibits, coffee breaks, luncheons and receptions, excluding Sunday Networking Reception.

Tutorials Titles and fees on pages 10-11 of the online brochure. Space is limited; preregistration encouraged. Please indicate the ID # and fee for tutorials you plan to attend.

Join DIA Now . . . SAVE on future meeting registration fees . . .
Enjoy the benefits of membership for one year!
www.diahome.org

Networking Reception Only is not available.

Total Payment Due $ ____________

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

Last/First Name
Dr.  Mr.  Ms.

Degrees
Job Title
Company

Mailing Address
City State Zip/Postal Code Country

Email (email address is required for confirmation)

Telephone #  Fax #
**FUNKY FESTIVALS**
Get fired up for a culture-packed getaway. Stroll hip and historic neighborhoods, see a collection of eclectic art, music and happenings at the annual Artomatic festival and discover the spoken word poetry scene (and the chili half-smokes) on U Street.

- Groove to jazz legends at the annual DC Jazz Festival (June 1-3)
- Discover talent in 10 minutes at the Source Festival (June 12-July 3)
- Discover why DC is referred to as “Docu-Wood” during SILVERDOCS Film festival (June 13-19)

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**ALL ACCESS PASS TO DC**

| YOUR GUIDE TO FREE & AFFORDABLE FUN |

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**OUTDOOR ESCAPES**
Let DC fuel your passion for the great outdoors by heading to the river. Learn to sail at the Washington Sailing Marina or rent a kayak from Jack’s Boathouse, Fletcher’s Boathouse or Thompson Boat Center for a daytime adventure.

- Take in the Tidal Basin near the Jefferson Memorial on paddle boats
- Navigate the nation’s capital by bike through Bike-the-Sites or by Segway with City Segway Tours and Seeg in the City
- Relax with afternoon tea at the stunning Hillwood Museum and Gardens

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**FOODIE FINDS**
DC’s dining scene sizzles from José Andrés’ Penn Quarter hotspots to low-cost local favorites like Busboys & Poets and Ben’s Chili Bowl. For more foodie fun, view the White House’s own vegetable garden or learn about garden-fresh seasonings at the National Arboretum’s National Herb Garden.

- Check out all of DC’s dining hot spots at washington.org/dinins
- Take a tour of Julia Child’s kitchen at the National Museum of American History
- Taste what’s fresh and local at historic and lively Eastern Market on Capitol Hill

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**DC welcomes DIA attendees** with an all access pass to dozens of free attractions, festivals, performances and concerts year-round. Learn more at washington.org or by calling 1-800-422-8644.
46th DIA Annual Meeting Live Learning Center
Free with Full Meeting Registration!

THE SOLUTION IS THE DIA LIVE LEARNING CENTER!

Access meeting content on digital media – WHENEVER you want it – captured live and available to you online via the DIA Live Learning Center! View the sessions online (as released for inclusion), captured as true multimedia re-creations with audio synchronized presentations, and much more. You can even download the sessions in MP3 format to your iPod or MP3 player for portable listening! Listen to a motivating, informative session you may have missed. This is an excellent training tool and informational resource for missed sessions. DIA Live Learning Center is available to full meeting registrants for a period of 6 months – and will not be made available to non-registrants. You must register for the meeting to get this value.

46th Annual Meeting presentations and handouts are just a click away.

The DIA Learning Center is your online portal to educational content from the 46th Annual Meeting. You can access audio recordings of the sessions presented at the Annual Meeting synchronized with the presentation slides.

The DIA Live Learning Center is your one-stop location to manage everything about the sessions at the DIA 46th Annual Meeting.
Premier Event for Professionals Involved in the Discovery, Development, and Life Cycle Management of Pharmaceuticals, Medical Devices, and Related Products

Five Productive Days of Learning and Networking with Global Regulatory, Academia, and Industry Professionals!

The DIA Annual Meeting is the premier event for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products. There is no other industry meeting of its kind that can rival the breadth and depth of experience that this meeting delivers. With 25 content-area tracks, 350 sessions and 20 tutorials, presentations are geared to attendees from all disciplines, work settings, and experience levels. The DIA Annual Meeting, above all others, offers valuable professional cross-functional learning and networking experiences.

HIGHLIGHTS

- 8,000+ professionals from 80 countries who work in all areas of discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products
- 20+ global regulatory agencies
- 350+ sessions in 25 content-area tracks
- 20 pre-conference tutorials
- 550+ exhibiting companies

ABOUT THE DRUG INFORMATION ASSOCIATION

The Drug Information Association (DIA) is a neutral, global, professional, member-driven association of nearly 18,000 biotechnology, pharmaceutical, academic, and regulatory professionals. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies, and services to improve health and well being worldwide. Headquarters are in Horsham, PA, USA, with offices in Basel, Switzerland; Tokyo, Japan; Mumbai, India; and Beijing, China.

“The best investment you can make to get the broadest learning and networking experience.”