The Meeting Agenda in this document was last updated on May 19, 2009.

The 45th DIA Annual Meeting

Better Medicines: Improving Safety with Every Step

June 21-25, 2009

San Diego Convention Center
San Diego, California

PROGRAM CHAIRPERSON

Nancy D. Smith, PhD
Former Director
Office of Training
and Communications
CDER, FDA

DIA®
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NANCY D. SMITH, PhD
Former Director, Office of Training and Communications, CDER, FDA

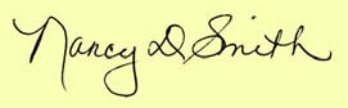
We all share in the responsibility to work together to strengthen the science used in pharmaceutical product development, evaluation, and review. We must find new tools to detect safety issues from preclinical testing through post-marketing and to improve communications about the safe use of medicines to patients, physicians, and other interested parties.

To this end, the 45th DIA Annual Meeting: "Better Medicines: Improving Safety with Every Step," will convene more than 8,900 professionals, including representatives from more than 50 countries. More than 800 exhibiting companies will showcase their products and services in the interactive exhibit hall. A keynote speaker, as well as industry, academic, and regulatory professionals will inspire, motivate, and teach us during the more than 350 sessions and three mega tracks designed to promote broader discussion and fuller understanding of topics related to advertising/marketing/medical communications; clinical research; information technology.

San Diego is an ideal setting for this Annual Meeting. From the shops and restaurants on Coronado Island and the beautiful beaches of Orange County to the famous San Diego Zoo and Sea World, San Diego offers everything to everyone. The city is home to biotechnology companies, big pharmaceutical companies and research institutions. In fact, San Diego is ranked as the top biotech cluster in the US and one of the top 10 most educated cities in the US. Each of these sectors represents the spirit of entrepreneurship and innovation inherent to the region and the industry.

Please join us in beautiful San Diego for what promises to be the most dynamic Annual Meeting in DIA history.

Sincerely,



Nancy D. Smith, PhD
45th Annual Meeting Program Chair

Dr. Nancy Smith is the former Director of the Office of Training and Communications (OTCOM), Center for Drug Evaluation and Research (CDER), US Food and Drug Administration.

She received her PhD in Applied Mathematics and Statistics from the University of Maryland in 1987 and joined the Office of Biostatistics at CDER that year. She served that Office as a Statistical Reviewer, Group Leader, and later Division Director of the Division of Biometrics II. She chaired the Good Review Practices Initiative that developed and implemented CDER's New Reviewer Training curriculum.

Dr. Smith became the Director of the Office of Training and Communications (OTCOM) in 1998. OTCOM coordinates educational resources within CDER, and communication and outreach activities to patients, health professionals, industry, trade press, and the general public. She served on the FDA Task Force that evaluated the system for managing the risks of FDA-approved medical products, and led CDER's effort to expand communication to consumers and health professionals promoting the safe use of medicines.

Dr. Smith served on the Board of the Drug Information Association (DIA) from 2002-2008 and is currently the chair of the DIA Global Training Committee. She is a past-chairman of the Biopharmaceutical Section of the American Statistical Association, and serves on the Board of the National Council for Patient Information and Education (NCPIE).

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2009 Program Committee

♦ ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES
Stanley A. Edlavitch, PhD, MA, University of Missouri-Kansas City, USA
Melvyn Greberman, MD, MS, MPH, FACPM, Public Health Resources, LLC, USA
Ellen R. Kelso, Goodwyn IRB, USA

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

♦ BIOTECHNOLOGY
Joy A. Cavagnaro, PhD, DABT, RAC, Access BIO, USA
Christopher J. Holloway, PhD, ERA Consulting Ltd., UK

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Moheb M. Nasr, PhD, MS, FDA, USA

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Johann Pröve, PhD, Bayer Schering Pharma, Germany

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Ross D. Pettit, MBA, ARIAD Pharmaceuticals, Inc., USA
Shantal Feltham, Stiris Research, Inc., USA

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Nancy P. Smerkanich, Octagon Research Solutions, Inc., USA

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C. Daniel Mullins, PhD, University of Maryland School of Pharmacy, USA

♦ GOOD CLINICAL PRACTICES
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Bruce M. Wagman, MBA, RN, RAC, Covance, Inc., USA

♦ INFORMATION TECHNOLOGY
David P. Fritsche, MBA, Genzyme Corporation, USA
Thomas Quinn, The Hollis Group, Inc., USA

♦ MARKETING
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Jean H. Soul-Lawton, DrPH, GlaxoSmithKline R&D, UK

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♦ NONCLINICAL LABORATORY SAFETY ASSESSMENT
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Frank D. Sistare, PhD, Merck & Co., Inc., USA

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Ian Laws, GlaxoSmithKline Pharmaceuticals, USA
Robert A. Paarlberg, MS, UCB, Inc., USA
Lynne M. Tracey, Procter & Gamble Pharmaceuticals, Inc., USA

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♦ STATISTICS
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Peiling Yang, FDA, USA

♦ TRAINING/PROFESSIONAL DEVELOPMENT
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Monika M. Pietrek, MD, PhD, MS, Germany

♦ VALIDATION
Joanne S. Malia, MS, Purdue Pharma, USA
Frances E. Nolan, MBA, Medidata Solutions Worldwide, USA

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EMEA: Martin Harvey-Allchurch, LLM, European Medicines Agency, EU
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HEALTH CANADA: Agnes V. Klein, MD, DrPH, Health Canada
JAPAN: Tatsuo Kurokawa, PhD, Chiba University, Japan
HOT TOPICS: Stephen E. Wilson, DrPH, CAPT. USPHS, FDA, USA
TUTORIALS & 2010 Program Chair: Gaby L. Danan, MD, PhD, sanofi-aventis, France

"The DIA Annual Meeting Program Committee had the difficult task of reviewing over 1100 submitted abstracts and developing a program of 350 sessions in 25 tracks that will meet the needs and the broad interests of the DIA membership. We are all very grateful for their hard work and dedication, which builds a great foundation for the success of the Annual Meeting in San Diego next June."

– Annual Meeting Program Chair Nancy Smith

Plenary Session Monday, June 22, 8:30-10:00 am

NANCY L. SNYDERMAN, MD

Chief Medical Editor, NBC News

Dr. Nancy Snyderman joined NBC News as the Chief Medical Editor in September 2006. Her reports appear on "Today," "NBC Nightly News with Brian Williams," MSNBC and MSNBC.com. Snyderman has reported on wide-ranging medical topics affecting both men and women and has traveled the world extensively, reporting from many of the world's most troubled areas. She is Associate Professor of Otolaryngology – Head and Neck Surgery at the University of Pennsylvania.

Prior to joining NBC News, Snyderman served as Vice President, Consumer Education for the health care corporation, Johnson & Johnson. There she led the independent educational initiative, Understanding Health, focusing on educating and informing the public about health and medicine. Before that, she served as the medical correspondent for ABC News for 17 years and was a contributor to "20/20," "Primetime," and "Good Morning America." Prior to leaving ABC she was a frequent substitute co-host on "Good Morning America." Committed to patient education, Dr. Snyderman co-founded LLuminari Inc., a Wilmington-based company that provides expert content to Fortune 500 companies on health topics.

Snyderman attended medical school at the University of Nebraska and continued with residencies in Pediatrics and Ear, Nose, and Throat Surgery at the University of Pittsburgh. She joined the surgical staff at the University of Arkansas in 1983 and began her broadcasting career shortly after at KATV, the ABC affiliates in Little Rock, Arkansas.

Snyderman's medical work has been widely published in peer review journals and she is the recipient of numerous research grants from the American Cancer Society, the Kellogg Foundation, and the American Academy of Otolaryngology – Head and Neck Surgery. She has received numerous awards for her broadcasting.

As a "New York Times" best selling author, Dr. Snyderman is the author of four books: *Dr. Nancy Snyderman's Guide to Good Health for Women over Forty, Necessary Journeys, Girl in the Mirror: Mothers and Daughters in the Years of Adolescence, and Medical Myths that Can Kill You and the 101 Truths that Will Save, Extend, and Improve Your Life.* Spring 2009 – *DIET MYTHS THAT KEEP US FATTER and the 101 Truths that Can Save Your Waistline and Perhaps Even Your Life.*

Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape

Monday, June 22, 2009, 3:30-5:00 pm

CHAIRPERSON

NANCY D. SMITH, PhD
2009 Annual Meeting Chairperson
Formerly CDER, FDA

Join industry, regulatory agencies, academia, and patient groups as they share their perspective on how to enhance patient safety in this multi-track plenary session focusing on this year's Annual Meeting program theme: "Better Medicines: Improving Safety with Every Step."

The panelists will focus on each of the pillars of the pharmaceutical landscape and their vision for collaboration in the development of safer medicines to maximize patient safety. With increased awareness on drug safety due to drug withdrawals and the FDAAA Act of 2007, this session will discuss the importance of collaboration among the various groups, what is currently being done, and what needs to happen in the future to ensure that patients get the necessary information to make informed health decisions.

Submit your questions to the panel by the close of business, June 17, 2009 to:

ImprovingSafetywithEveryStepPanel
@diahome.org

Subject: Questions to the Panel

MICHAEL R. COHEN, RPh, MS, DrSc
Institute for Safe Medication Practices

GERALD J. DAL PAN, MD, MPH
Office of Surveillance and Epidemiology, CDER, FDA

KENNETH I. KAITIN, PhD
Tufts University School of Medicine

JEREMIAH MWANGI, MA
International Alliance of Patients' Organizations, UK

NÖEL WATHION, Pharm
European Medicines Agency, European Union

ANNE QUINN YOUNG, MPH
Multiple Myeloma Research Foundation

Annual Meeting Mega Tracks

You have told us that scheduling your time around the more than 350 scheduled sessions can be overwhelming. In response, the Annual Meeting Program Committee has taken extra steps to make your Annual Meeting experience better than ever. The Committee has created three mega tracks that will enhance the quality of the presentations and their relevance to the challenges faced by today's professionals, minimize overlap of similar session topics in different tracks, and promote broader discussion and a fuller understanding of the topics presented.

ADVERTISING/MARKETING/ MEDICAL COMMUNICATIONS MEGA TRACK

NEW for 2009! Attendees interested in direct-to-consumer (DTC) advertising, business continuity planning, drug information and the Internet, and safe use of drugs and much more, will be interested in attending sessions in these tracks:

- **AD**
  Advertising
- **MA**
  Marketing
- **MC**
  Medical Communications

On Monday, June 22, from 10:30 am-12:00 pm, the AD/MA/MC Mega Track will also offer a SPECIAL PLENARY SESSION:

Pharma in the New Age of Transparency

See page 33 for complete session details.

CLINICAL RESEARCH MEGA TRACK

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:

- **AHC/IS**
  Academic Health Centers/ Investigator Sites
- **CR/CS**
  Clinical Research and Development/ Clinical Supplies
- **OS**
  Outsourcing
- **PM/FI**
  Project Management/Finance

INFORMATION TECHNOLOGY MEGA TRACK

Individuals 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, these tracks are for you:

- **CDM**
  Clinical Data Management
- **EC**
  eClinical
- **ERS/DM**
  Electronic Regulatory Submissions/ Document Management
- **IT**
  Information Technology
- **VA**
  Validation

Preconference Tutorials

On Sunday, June 21, DIA is offering more than 30 full- or half-day tutorials designed to increase your knowledge of specific subject areas. The content of many tutorials has been updated, and new topics have been added. Tutorial topics range from professional development to specialized areas within the pharmaceutical industry. A schedule with detailed descriptions of each tutorial's content begins on page 12.

Featured Sessions

- **Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape**
  Monday, June 22, 3:30-5:00 pm
- **Pharma in the New Age of Transparency**
  Monday, June 22, 10:30 am-12:00 pm
- **Meet the Regulators**
  Tuesday, June 23, 2:00-3:30 pm
- **Future Directions of Project Management in the Life Sciences**
  Wednesday, June 24, 1:30-3:00 pm
- **CDER Town Meeting – Parts 1 and 2**
  Thursday, June 25, 8:30-10:00 am and 10:30 am-12:00 pm

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

Hot Topics

Conference participants will benefit from more than 350 sessions in a variety of hot topics, including:

- **Patient Safety**
- **Pharmacovigilance/Risk Management**
- **Patient Enrollment and Retention**
- **Global Clinical Trials**
- **Emerging Markets**
- **Phase 1/Early Development**
- **US FDA's Sentinel Initiative**
- **Lean Six Sigma**
- **Transparency**
- **Biomarkers**
- **The Critical Path Initiative: Five Years Later**
- **Oncology**
- **Pediatrics**
- **Adaptive Trial Design**
- **Pharmacogenomics/ Personalized Medicines**

REGULATORY AGENCIES

As of February 9, participants include representatives from these global regulatory bodies, other agencies, and more …

ANMAT Ministry of Health, Argentina

BfArM, Germany

CBG-MEB, Netherlands

Center for Drug Evaluation, Taiwan

Department of Health and Human Services, US

Department of Veterans Affairs, US

Directorate of Drugs Control, India

EMEA, EU

European Directorate for the Quality of Medicines, France

FDA, US

Health Canada

Korean Food and Drug Administration, Republic of Korea

Medicines Healthcare products Regulatory Agency (MHRA), UK

Ministry for Health, Welfare and Family Affairs, Republic of Korea

Ministry of Health, Vietnam

National Cancer Institute, NIH, US

National Institutes of Health, US

Pharmaceuticals and Medical Devices Agency (PMDA), Japan

SFDA, China

Therapeutic Goods Administration, Australia

WHO, Switzerland

GLOBAL SESSIONS

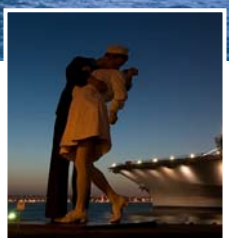
Global drug development is a key focus of the Annual Meeting. This year's event will include more than 350 sessions where issues affecting key regions of the world will be discussed. Representatives from the following countries are currently scheduled to participate.

Argentina	China	Ireland	Netherlands	Switzerland
Australia	Denmark	Israel	Panama	Taiwan
Austria	European Community	Italy	Poland	Turkey
Bangladesh	Finland	Japan	Portugal	United Kingdom
Belgium	France	Kenya	Singapore	United States
Brazil	Germany	Republic of Korea	Spain	Vietnam
Canada	India	Mexico	Sweden	

Networking remains a hallmark of the DIA Annual Meeting **– from the daily continental breakfasts and afternoon refreshment breaks to the more formal Networking Receptions. This year we have expanded some of these opportunities to allow attendees to reap all the benefits of a complete Annual Meeting experience.**

Networking Reception

Join us on Sunday, June 21, 7:00 pm -9:00 pm aboard the historical USS Midway.



The flight deck of the USS Midway, now a floating museum and education center, spans four acres and offers impressive views of San Diego Harbor and the city skyline.

Photos courtesy of San Diego USS Midway Museum

Live the adventure. Honor the legend.

See old friends and make new acquaintances as you take in an unparalleled 360-degree view of San Diego's sparkling skyline and Coronado Bay Bridge.

The USS Midway Museum is the longest-serving US Navy carrier of the 20th century, and today it is the most visited floating naval ship museum in the world. We invite you to join us for what is sure to be a memorable evening where you can inspect the many military aircraft on display, take a tour with a docent, climb onto a flight simulator and feel what it was really like or just watch the sun go down on Mission Bay while enjoying a beverage (hosted soft drinks, beer and wine) and a taste of San Diego cuisine from several different food stations.

The USS Midway is a short stroll along the San Diego waterfront. Shuttle bus service will be available to the reception from the San Diego Convention Center and to each hotel at the conclusion of the event. The ship's flight deck is irregular, so it is recommended that attendees wear flat comfortable shoes. A light jacket is also suggested.

We urge you to preregister for this event as onsite registration cannot be guaranteed. Registration for the Networking Reception only is not available. You must be registered for the meeting as an attendee, speaker, or exhibitor to register for the reception. Your meeting badge, available at the DIA registration desk, will be required for entrance onto the USS Midway.

DIA is pulling out all the stops to make this year's event more comprehensive and enjoyable than ever before. Our networking opportunities and special events offer you something you can't get anywhere else. Don't miss out on a variety of innovative ways to network, relax, and gain insightful knowledge – all in one place!

Refreshment Breaks

Meet with your colleagues each morning, 7:30-8:15 am (7:15-8:00 am on Tuesday) for hot beverages and breakfast breads in the Sails Pavilion of the Convention Center. This will give you an opportunity to network, plan your day and discuss what you've learned. Mid-morning refreshment breaks (hot beverages) and mid-afternoon refreshment breaks (cold beverages) will be available in the Exhibit Hall during the following hours:

- **Monday, June 22**

  7:30 am-8:15 am, Ballroom 20BCD Lobby, Upper Level
  10:00 am-10:30 am, Exhibit Halls B1, B2, C, Ground Level
  3:00 pm-3:30 pm, Exhibit Halls B1, B2, C, Ground Level

- **Tuesday, June 23**

  7:15 am-8:00 am, Sails Pavilion, Upper Level
  9:30 am-10:00 am, Exhibit Halls B1, B2, C, Ground Level
  3:30 pm-4:00 pm, Exhibit Halls B1, B2, C, Ground Level

- **Wednesday, June 24**

  7:30 am-8:15 am, Sails Pavilion, Upper Level
  10:00 am-10:30 am, Exhibit Halls B1, B2, C, Ground Level
  3:00 pm-3:30 pm, Exhibit Halls B1, B2, C, Ground Level

- **Thursday, June 25**

  7:30 am-8:15 am, Sails Pavilion, Upper Level
  10:00 am-10:30 am, Sails Pavilion, Upper Level

Special Luncheon Seating Areas

New this year! There will be a special seating area that will allow you to eat and network with colleagues from your professional discipline.

Extended Luncheon Hours on Tuesday

Again, lunch hours will be extended on Tuesday, 11:30 am-2:00 pm, to allow additional time to network with your colleagues and visit more than 500 exhibiting companies in our Exhibit Hall.

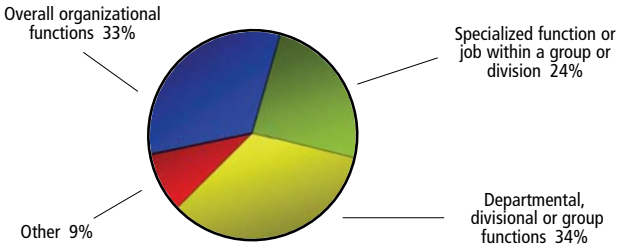
Explore San Diego with Your Colleagues

Sign up for one of our exciting tours. (See page 124 for details.)

Who will you meet this year?

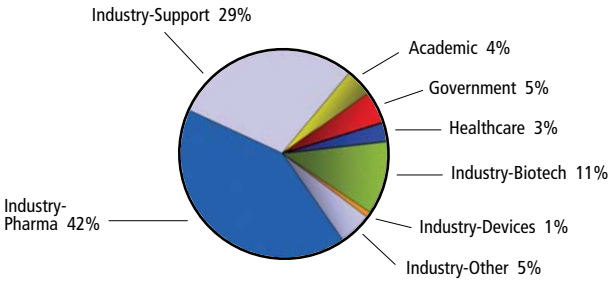
The 2008 DIA Annual Meeting attracted nearly 8,800 attendees, 550 exhibiting companies, and 1,100 speakers. Attendees at the 45th Annual Meeting will benefit from more than 350 sessions and 34 tutorials across 26 content-area tracks, more than 1,000 speakers from regulatory agencies, industry, and academia, and over 550 exhibitors showcasing the industry's latest products and services. The Annual Meeting welcomes attendees from all professional categories, levels of responsibility, and geographic locations – making it the perfect venue for blending multidisciplinary learning with global networking opportunities.

Levels of Responsibility

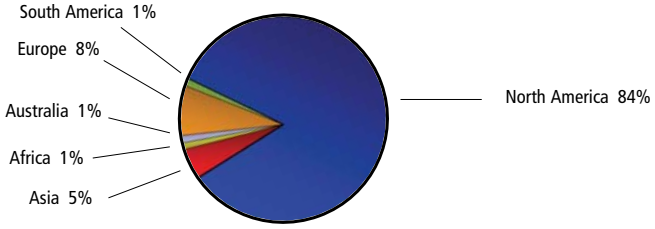


"Beautifully organized with access to the most professional speakers and highest-quality presentations." **2008 Meeting Attendee**

Professional Categories



Geographic Locations



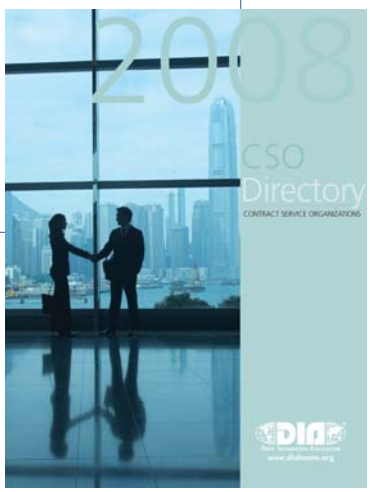
Explore the Benefits of Membership

New DIA Magazine Debuts

In February, DIA members received the first issue of the new publication, the *DIA Global Forum*. In response to member feedback gathered via qualitative and quantitative surveys and Annual Meeting focus groups, the Global Forum will offer a more robust look at regulatory and global updates, practical tips, association news, upcoming DIA events, program notes, and more. All DIA members will receive both digital and hard copies of this new magazine.

Member Benefits

- Monthly publications, delivered digitally and in print, including the *Drug Information Journal,* and the new D*IA Global Forum*
- Exclusive access to our global network of industry professionals
- Global industry eNews
- Discounts on DIA training courses and conferences, including the DIA Annual Meeting and EuroMeeting
- Summaries of regulatory activities from around the world and US FDA drugs and biologics Advisory Committee Meetings sent directly to your inbox
- Career development opportunities
- Access to our online *Membership Directory*
- *Contract Service Organization Directory*
- Participation in the Member Affinity Program
- Continuing Education Credits
- Volunteer opportunities as a speaker, session chair, author, board member, or Special Interest Area Community (SIAC) member
- New Career Center to launch in 2009



Register for the Annual Meeting and enjoy all the benefits of DIA membership . . . for the same price!

You can register as a *NONMEMBER* for $1,405

OR

You can become a *MEMBER AND* register for $1,405

***and* receive at no extra cost ALL THE BENEFITS LISTED ABOVE.**

*Be Sure to Opt in to **DIA Membership***

✓ *To join DIA, check the "**I do want membership"** box under Nonmember Fee on your Annual Meeting registration form.*

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

Destination – San Diego

San Diego, California's second largest city has so much to offer besides incredible weather. The bayside city is perfect for combining business and pleasure with an award-winning downtown Convention Center and a superb array of amenities and attractions as abundant as its year round sunshine. While San Diego is famous for its natural attributes, including 70 miles of pristine beaches, there is no better place to hit the links than on one of its 92 championship golf courses. After a day of DIA Annual Meeting sessions, enjoy an evening in downtown San Diego and the electric Gaslamp Quarter. From suave steakhouses and eclectic ethnic fare, dinner clubs to jazz bars, the over 100 restaurants are all situated within blocks of each other. Be sure to save some time for shopping and comb the specialty boutiques or visit the famous Horton Plaza. The best part: all this is within walking distance from the San Diego Convention Center and DIA room block hotels.

San Diego, California is a popular meeting destination, so make your reservations early!

Getting to San Diego

The **San Diego International Airport,** located three miles northwest of downtown San Diego, is just five minutes away from the Convention Center and 18 major domestic airlines provide daily service to the top 150 markets and bring nearly 17 million visitors to the destination every year.

Driving Directions to San Diego Convention Center

If you are planning to drive to the Convention Center, located at 111 West Harbor Drive, San Diego, CA 92101, please take a look at the driving directions below. On-site parking is available below the Convention Center. Enter the parking garage on Harbor Drive between First Avenue and Fifth Avenue. The parking fee is $8 per vehicle per day during convention center events. Payment is due upon entry with no in and out privileges or overnight parking.

From the Airport: Follow signs to Interstate 5/Downtown. The ramp will put you on Harbor Drive going south. Follow signage to parking entrance.

Driving South on Interstate 5: Take Front Street exit. Continue on Front Street until you reach Harbor Drive, turn left. Follow signage to parking entrance.

Driving North on Interstate 5: Take Cesar Chavez Parkway exit, turn left. Follow Cesar Chavez Parkway to Harbor Drive, turn right. Follow signage to parking entrance.

Driving West on Interstate 8: Take Highway 8 West to 163 South. Follow into city (will turn into 10th Avenue.) Follow 10th Avenue to Market Street, turn right. Take Market Street to Front Street, turn left. Take Front Street to Harbor Drive, turn left. Follow signage to parking entrance.

Driving West on 94: Take 94 West into the city. 94 West will turn into "F" Street. Follow "F" Street to 8th Avenue. Take 8th Avenue to Market Street, turn right. Take Market Street to Front Street, turn left. Take Front Street to Harbor Drive, turn left. Follow signage to parking entrance.

From Coronado: Cross Bay Bridge staying in the right lane. Take the National Avenue exit. Turn left on Cesar Chavez Parkway. Follow Cesar Chavez Parkway to Harbor Drive, turn right. Follow signage to parking entrance.

Getting around San Diego

Taxis and shuttles are abundant and easily accessible from the Center, airport, major hotels and downtown locations. Taxi fares from the airport to the Convention Center range from $10.00 - $12.00 dollars and shuttle service is just a call away.

Taxicab Service

The list below are taxicab companies frequently used by travelers. Call directly to find the taxicab service that best suits your needs.

- Airport Yellow Cab of San Diego – 619-234-6161
- American Cab – 619-234-1111
- Orange Cab – 619-291-3333
- San Diego Cab – 619-226-8294 or 800-368-2947
- USA Cab – 619-231-1144

Shuttle Service

Several shuttle companies with vans and buses are available for hire from the airport. Shuttle service is available at the transportation plazas across from Terminals 1 and 2 and curbside at the Commuter Terminal. At the transportation plaza, a transportation coordinator places visitors with the first available shuttle (unless a particular shuttle is specified).

- Cloud 9 / Super Shuttle – 800-974-8885
  www.cloud9shuttle.com
- Advanced Shuttle – 800-719-3499
  www.advancedshuttle.com/
- Access Shuttle Company – 800-690-9090
  www.accessshuttle.net/
- EZ Ride Shuttle – 800-777-0585 or 619-297-7463
  www.ezrideshuttle.com

San Diego Trolley

MTS Trolley is a light-rail system that operates on three lines (Blue, Orange and Green) throughout San Diego. Two trolley stations are across the street from the Convention Center, providing convenient service around downtown and from the Convention Center to Mission Valley hotels and shopping malls. Route maps and ticket machines are posted at each trolley station. Fares are based on trip distance. Round-trip fares range from $2.50 to $6.00.

Coronado Ferry

A passenger ferry runs regularly across San Diego Bay from downtown's Broadway Pier to Coronado's Ferry Landing. The ferry departs Broadway Pier every hour on the hour from 9:00 am to 9:00 pm. Departures from Coronado are every hour on the half hour from 9:30 am until 9:30 pm. A one-way fare is $3.50 and the trip takes about 10 minutes. Bicycles can be taken across at no charge. For additional information, visit www.sdhe.com.

DIA Complimentary Shuttle Bus

Complimentary shuttle service is provided between the San Diego Convention Center and the DIA room block hotels listed below. A shuttle schedule will be provided to all attendees when checking into all DIA room block hotels. DIA room block hotels not listed below are within walking distance of the Convention Center and will not have shuttle service. See page 127 for complete hotel addresses and room rates.

- Bristol Hotel – 1055 1st Avenue
- Courtyard by Marriott San Diego Downtown – 530 Broadway
- Holiday Inn on the Bay – 1355 North Harbor Drive
- Hampton Inn by Hilton San Diego Downtown – 1531 Pacific Highway
- Ivy Hotel San Diego – 600 F Street
- Resident Inn San Diego Downtown – 1747 Pacific Highway
- The Sofia Hotel – 150 West Broadway
- The US Grant – 326 Broadway
- Westin San Diego – 400 West Broadway
- Westin Gaslamp Quarter – 910 Broadway Circle
- Westgate Hotel – 1055 2nd Avenue

General Information

Dress Code

The dress code for the Annual Meeting is business casual. Neckties, business suits, or other business attire are acceptable, but not necessary. *The Convention Center may be chilly so bring a sweater or jacket, and comfortable shoes are a must!*

Hotel Reservations

See pages 126-127 for the hotel locator map and the hotel reservation form.
Travel Planners is coordinating all reservations, and arrangements for housing must be made through this housing bureau. All hotel reservation forms must be received by May 29, 2009. ***DIA does not process hotel reservations.***

MedDRA® User Group Meeting

MedDRA® User Group will meet on Thursday, June 25 from 12:30 pm to 5:00 pm. The specific location will be included in the final program.

Poster Sessions

The student and professional poster sessions will provide excellent opportunities for the presenters to share their research results with a diverse audience of clinical research professionals. The posters present scientific developments related to topics addressed in meeting tutorials and sessions, and will be displayed in the Sails Pavilion Foyer on the Upper Level of the Convention Center.

Student Poster Session	Monday, June 22, 10:00 am to 6:00 pm
Professional Poster Session	Tuesday, June 23, 9:30 am to 5:30 pm

The chairpersons for the poster sessions are: Lois J. Wagner, PhD, Assistant Professor/Associate Director for Research, Vanderbilt University School of Nursing; Theresa Kane Musser, Vice President, Development Operations, Rigel Pharmaceuticals; Stephen A. Sonstein, PhD, MS, Director, Clinical Research Administration, Eastern Michigan University; Albert I. Wertheimer, PhD, MBA, Professor, Pharmacy, Director, Center for Pharmaceutical Health Research, Temple University.

Press Registration Policies and Procedures

DIA events are attended by a number of international and domestic journalists who represent a variety of well-respected media outlets. DIA welcomes qualified representatives of news organizations to attend these events for the purpose of reporting and publishing/airing articles/stories. Press passes will be given to all who are determined by DIA to be qualified members of the press. 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. Publications and marketing materials may not be distributed at DIA conferences without the express and written permission of DIA. Upon arrival, all media must present a copy of their press credential confirmation letter received from DIA and official press credentials at the DIA event check-in location.

To obtain your press credential confirmation letter, download the Press Pass Request Form from http://www.diahome.org/DIAHome/AboutDIA/Resources/Docs/DIAPressPassFinal.pdf. Return the form to DIA at least one week prior to the event, to Joe Krasowski by email to Joe.Krasowski@diahome.org or by fax to 215-442-6199. If you have any questions, please call Joe Krasowski at 215-293-5812.

Private Social Functions Policy

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

Sunday, June 21	Only after 8:00 pm
Monday, June 22	From 7:00 am-8:15 am and any time after 6:00 pm
Tuesday, June 23	From 7:00 am-8:00 am and any time after 5:30 pm
Wednesday, June 24	From 7:00 am-8:15 am and any time after 5:00 pm
Thursday, June 25	From 7:00 am-8:15 am and any time after 12:00 pm

Contact Lori Risboskin for an DIA Exhibitor-sponsored Hospitality Event Application Form, which is required to book hospitality function space: Lori Risboskin, DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA, tel 215-442-6174, fax 215-293-5941, email Lori.Risboskin@diahome.org.

Reception

DIA will host a reception on Monday, June 22, from 5:00 pm-6:00 pm in Exhibit Halls A-D on the Ground Level of the Convention Center.

Tours

Arrangements Unlimited has organized several tours of the San Diego area on Sunday, June 21 through Wednesday, June 24. Tour descriptions begin on page 124 and the tour order form can be found on page 126.

Continuing Education

Learning Objectives

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

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

Target Audience

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

Continuing Education Credit

Select tutorials and sessions will offer *AMA PRA Category 1 Credit(s)™*, pharmacy contact hours, nursing contact hours, or PMI professional development units. IACET continuing education units are offered for all tutorials and sessions. Credits for tutorials are clearly identified in this program, and the credits for sessions will be indicated in the final program.

Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. This activity has been approved for *AMA PRA Category 1 Credit(s)™.*

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants may earn up to 26 contact hours or 2.6 continuing education units (CEUs) for completing the program and tutorials. 286-000-09-022-L04-P

The Drug Information Association (DIA) has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. DIA is authorized by IACET to offer 2.9 CEUs for this program and tutorials.

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

The Drug Information Association will offer nursing credits for this program in collaboration with Corexcel.

Corexcel is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

PMI

The Drug Information Association has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI). This program offers a maximum of 19.5 professional development units (PDUs).

Tutorials – June 21, 2009

Half-day tutorials (8:30 am-12:00 pm or 1:00 pm-4:30 pm) up to 3.25 *AMA PRA Category 1 Credit(s)™* or 3.25 pharmacy contact hours (.325 CEUs), or .3 IACET CEUs per tutorial

Full-day tutorials (9:00 am-5:00 pm) up to 6.5 *AMA PRA Category 1 Credit(s)™* or 6.5 pharmacy contact hours (.65 CEUs), or .7 IACET CEUs per tutorial

Annual Meeting Sessions

June 22-25, 2009 – Up to 19.5 *AMA PRA Category 1 Credit(s)™* or 19.5 pharmacy contact hours (1.95 CEUs), 286-000-09-022-L04-P; or 2 IACET CEUs (up to 1.5 hours per session)

RAC

Attendance at the 45th DIA Annual Meeting is recognized as an approved RAC educational program.

To Receive a Statement of Credit

If you would like to receive a statement of credit, you must attend the program (and tutorial, if applicable), and complete the online credit request process through **My Transcript at www.diahome.org**. Participants will be able to download a statement of credit upon successful submission of the credit request. **My Transcript** will be available for credit requests on Friday, June 26, 2009.

Disclosure Policy

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

PARTICIPANTS WITH DISABILITIES: *DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Arrangements can be made for sensory-impaired persons who contact the DIA office to indicate their needs at least 15 days prior to the meeting.*

Exhibit Hall Opportunities

Scientific Exhibits On the Ground Level of the Exhibit Hall, nearly 500 vendors will showcase their company's innovations, products, and services to meeting attendees from industry, academia, and regulatory agencies who use these services in the conduct of their professions.

Employment Opportunities The DIA Job Bank will be online to help DIA members at the meeting find new professional employment opportunities, and to help companies extend professional opportunities to interested DIA members. Companies will be able to purchase, publish, and receive replies to job postings, and interested DIA members will be able to submit their qualifications for these job postings. These online workstations will be available in the Sails Pavilion throughout the DIA Annual Meeting.

Exhibit Locator Exhibit Locator workstations, near the entrance to the Exhibit Hall, will find an exhibiting company by booth number, will search by company name or the services it provides, and the "keyword" function will search for terms used in the company description found in the 2009 Exhibitors' Services Summaries.

Questions about the DIA Annual Meeting?

Accounting issues, such as disputes about amount charged for registration, status of membership or inquiries concerning outstanding balances:
Vicki.Adkinson@diahome.org or 215-442-6162
Marilyn.Ginsberg@diahome.org or 215-442-6135
Elizabeth.Espich@diahome.org or 215-293-5802
Jean.Zane@diahome.org or 215-442-6185

Advertising Opportunities, Steve Everly at severly@ki-lipton.com or 267-893-5686

CE (Continuing Education), Marie.Francois@diahome.org or 215-442-6118

Exhibits

Inquiries from exhibiting companies A – L, or inquiries about product locator or company summary book: Jeff.Korn@diahome.org or 215-442-6184

Inquiries from exhibiting companies M – Z, or inquiries about exhibitor mailings and exhibitor kiosk: Shannon Lewis@diahome.org or 215-442-6149

Inquiries about hotel room drops: Eileen.Roth@diahome.org or 215-442-6191

Inquiries about hospitality suites or vendor events: Lori.Risboskin@diahome.org or 215-442-6174

Hotel Reservations

All room reservation inquiries: Travel Planners at 1-800-221-3531 (domestic) / 1-212-532-1660 (international)

Inquiries about hotel reservations for speakers: Susan.Spivak@diahome.org or 215-442-6139

Job Postings/Employment Opportunities

Nontechnical job bank questions: Vicki.Adkinson@diahome.org or 215-442-6162

Technical job bank questions: Madel.Meneses@diahome.org or 215-442-6148

Networking Reception, Colleen.Buckley@diahome.org or 215-442-6108

Poster Sessions, Susan.Spivak@diahome.org or 215-442-6139

Press Passes/Press List/Press Release Program

Joe.Krasowski@diahome.org or 215-293-5812

Registration Status/Registration Fees

Vicki.Adkinson@diahome.org or 215-442-6162
Marilyn.Ginsberg@diahome.org or 215-442-6135
Elizabeth.Espich@diahome.org or 215-293-5802
Jean.Zane@diahome.org or 215-442-6185

Special Interest Area Community (SIAC) Events

Mary.Hildebrandt@diahome.org or 215-442-6151
Michael.McNair@diahome.org or 215-293-5817

Speakers and Session Chairs

Holly.Stevens@diahome.org or 215-442-6123
Maureen.Lamplugh@diahome.org or 215-442-6115

Shuttle Service

Shuttle Service to and from the Convention Center will be available from:

- Bristol Hotel – 1055 1st Avenue
- Courtyard by Marriott San Diego Downtown – 530 Broadway
- Holiday Inn on the Bay – 1355 North Harbor Drive
- Hampton Inn by Hilton San Diego Downtown – 1531 Pacific Highway
- Ivy Hotel San Diego – 600 F Street
- Resident Inn San Diego Downtown – 1747 Pacific Highway
- The Sofia Hotel – 150 West Broadway
- The US Grant – 326 Broadway
- Westin San Diego – 400 West Broadway
- Westin Gaslamp Quarter – 910 Broadway Circle
- Westgate Hotel – 1055 2nd Avenue

All other hotels are within walking distance of the Convention Center.

Inquiries about shuttle service: Lori.Risboskin@diahome.org or 215-442-6174

Student Opportunities

Michael.McNair@diahome.org or 215-293-5817

Tours

All tour inquiries: Arrangements Unlimited at 619-660-5340
Unresolved tour issues: Lori.Risboskin@diahome.org or 215-442-6174

Tutorials, Susan.Spivak@diahome.org or 215-442-6139

TUTORIALS (as of MAY 8, 2009)

Maximize your Annual Meeting experience by attending DIA's preconference tutorials. Tutorials are full- or half-day offerings designed to increase your knowledge of specific subject areas. Most tutorials offer continuing education credit, such as CME, IACET, nursing, and pharmacy, and the applicable credits are indicated within the tutorial description. Complementary tracks are indicated by the track acronym placed to the right of the tutorial title.

Tutorials will take place on Sunday, June 21 prior to the Annual Meeting. The content of many tutorials has been updated, and new topics have been added. Tutorial topics range from professional development to specialized areas within the pharmaceutical industry. DIA may continue to add tutorials to the overall schedule at this year's Annual Meeting, so check www.diahome.org for the latest information.

Track Designations

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

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.

SUNDAY, JUNE 21, 2009 — 8:30 am-12:00 pm

Tutorials #20 through #33 — **Fee $375**

TUTORIAL #20 — **CMC/GMP**

Quality Risk Management: Putting Principles into Practice

Kristin Murray, MS
Senior Manager, Global Regulatory Affairs, Wyeth Pharmaceuticals
Stephen Reich, MS
Risk Management Principal, Wyeth Pharmaceuticals

.3 IACET CEUs

Quality risk management (QRM) is an emerging and increasingly important process within the pharmaceutical industry. This tutorial will allow participants to immerse themselves in a contemporary pharmaceutical case study utilizing the QRM process in order to develop and hone risk management leadership and execution skills. Industry leaders will guide participants through the case study, where the principles of QRM will be turned into practice by focusing on the key aspects of each step outlined in ICH Q9.

The interactive case study will emphasize proper execution and targeted delivery of defined scope statements, specific and justifiable risk assumptions, comprehensive risk identification and assessment, and robust risk control strategies. The tutorial will include guidance and strategies for avoiding common QRM execution pitfalls. Additionally, approaches around effective risk communication, with both internal (management) and external (boards of health) stakeholders, will be shared.

One of the unique benefits afforded by this tutorial will be the opportunity to learn via real-time evaluation of case study results and team performance. Instructors will use case study observations and findings to reinforce core QRM principles and offer effective guidance around factors that influence risk management team performance, including team dynamics, individual behaviors and tendencies, and common technical challenges associated with QRM execution.

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

- Describe how to turn the principles of QRM into practice by exercising a case study
- Recognize how to avoid common pitfalls in the QRM process by focusing on the key aspects of each step outlined in ICH Q9
- Discuss real-time evaluation of case study results and team performance

Target Audience
This tutorial is designed for individuals responsible for leading or participating in risk assessments and risk-based initiatives in the pharmaceutical industry.

A multidisciplinary audience with a basic understanding of ICH Q9 and QRM principles and a desire to hone their QRM leadership, facilitation, and performance skills will benefit from this tutorial.

TUTORIAL #21 **CP**

Qualified Person for Pharmacovigilance: What Do You Need to Know?

Brian D. Edwards, MD, MRCP
Director, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK

.3 IACET CEUs

Recent European legislation such as Volume 9A requires all marketing authorization holders to have one qualified person for pharmacovigilance (QPPV) with responsibility for establishing and maintaining all aspects of the company's global pharmacovigilance system. Although acknowledged to be a vital function, there is little practical guidance on how QPPV responsibilities should best be conducted, while maintaining compliance with regulatory requirements. The jurisdiction of the QPPV stretches to wherever there is an active license for a product authorized in the EU. Thus, the role in many companies has a global impact. During this tutorial we will discuss and advise on current practice to help address issues such as:

- What being qualified means in practice for the QPPV and the organization
- What are appropriate contractual obligations and job descriptions to cover points such as 24-hour availability, workload, personal indemnity, delegation, and adequate back up
- How should QPPV activities be documented to allow for adequate quality assurance and reassurance for inspectors
- How inspectors and regulatory authorities regard the EU QPPV role and expectations for involvement in the entire PV system
- How to make the QPPV role work in practice using examples from both large and small companies, including CROs
- How to optimize interactions between the company as a whole and the QPPV to obtain adequate mutual oversight and support
- What should be QPPV input into postauthorization commitments and risk management plans
- How should the interface between the QPPV and quality function work in practice
- How the QPPV function relates to national nominated individuals for safety

Instructors will also update attendees about whether there should be an appropriate forum to allow QPPVs across the industry to interact and share best practices to the mutual benefit of public health and industry alike.

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

- Explain legal, regulatory and business implications of the QPPV as follows:
  - Define what would be reasonable expectations to have about the QPPV
  - Identify the different approaches taken by other companies
  - Define the expectations of regulators and inspectors

Target Audience
This tutorial is designed for anyone who will be setting up pharmacovigilance operations in Europe or with transatlantic experience in safety such as pharmacovigilance, risk management, quality assurance, qualified persons for pharmacovigilance (QPPV) and deputies, and contract research organizations and consultants.

TUTORIAL #22 **CP**

Active Query, Case Assessment, and Narrative Writing in Pre- and Postmarketing: Working with Clinical Sites, Investigators, and Other Healthcare Professionals to Obtain Quality Safety Data

Stephen A. Goldman, MD, FAPM, DFAPA
Managing Member, Stephen A. Goldman Consulting Services, LLC
Adjunct Assistant Professor of Psychiatry, Uniformed Services University of the Health Sciences
L. Paul Starkey, MD, FAAFP
Executive Director, Medical Affairs - Americas, PRA International

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs; 286-000-09-001-L04-P; 3.25 pharmacy contact hours (.325 CEUs)

Data mining, interactive medical databases, and active surveillance offer promising avenues for enhancing safe use of marketed medical products, and potential utility in premarketing study. However, these techniques are only as good as the quality of adverse event information upon which they depend.

Experienced clinical research and drug safety personnel are critical in the collection of safety information, including serious adverse event reports from clinical trial sites and postmarketing reports from health professionals and consumers. As these provide important clinical data used to evaluate an agent's benefit/risk profile, it is essential that reported safety information be of the highest possible quality.

Intertwined with the question of how to improve the quality of individual case safety reports (ICSRs) is how to ensure optimal case assessment. Knowledge of the underlying disease state being studied or treated, coupled with good understanding of the agent's pharmacological properties and range of clinically relevant adverse effects, is of necessity in performing high-quality case review.

In its 2003 "Safety Reporting Requirements for Human Drug and Biological Products" proposed rule, FDA conceptualized full data sets in both pre- and postmarketing would include a "concise medical narrative of the case," with "active query" entailing a "focused line of questioning" to ascertain "clinically relevant information."

This tutorial will review factors that affect reporting of medical product-associated adverse events, along with interventions to stimulate health professional reporting and foster higher quality reports (eg, targeted questioning) in both premarketing clinical trial and postmarketing pharmacovigilance realms. Further, methods designed to optimally utilize safety data to craft effective case narratives will be reviewed, as will strategies for optimizing interactions with investigators and other trial site personnel.

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

- Discuss interventions designed to garner high-quality adverse event data, including active query and optimal use of clinical expertise
- Illustrate how to craft effective case narratives
- Identify effective strategies for working with clinical trial sites and other health professionals

Target Audience
This tutorial is designed for pharmaceutical and biotechnology professionals involved in postmarketing pharmacovigilance, premarketing clinical safety, clinical research, regulatory affairs, safety data management/analysis, risk management, project management, medical writing, and biostatistics.

TUTORIAL #23 **CP**

Signal Detection Methods for Beginners: Overview and Case Studies

Steve T. Jolley, MA
Principal, SJ Pharma Consulting
William Smedley, MBA
Associate Director, PV Operations, Shire Pharmaceuticals

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs;
286-000-09-002-L04-P; 3.25 pharmacy contact hours (.325 CEUs)

This tutorial will review the application of signal detection and data mining techniques to safety surveillance, and present an overview of strategies and specific situation applications.

Highlights of this tutorial include:

- Recommended approach to signal detection and use of data mining techniques
- Use of visualization tools to enhance signal detection
- Comparison of approaches for a large and a small company

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

- Recognize the basic concepts of data mining and principles of signal detection
- Outline how to apply these techniques within their company
- Discuss the use of data mining to analyze large volumes of adverse event report data

Target Audience
This tutorial is designed for clinical safety professionals involved in pharmacovigilance, pharmacoepidemiology, regulatory affairs, quality assurance, medical product safety assessment, and labeling.

TUTORIAL #24 **CANCELLED** **CR/CS**

Arsenic and Old Lace 3: QT and Beyond

William Wheeler, MD
Global Medical Director, Centralized Cardiac Services,
MDS Pharma Services
J. Rick Turner, PhD, PGCE, MICR
Drug Safety Scholar and Director, Center for the Study of Cardiac Safety, Campbell University School of Pharmacy

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs;
286-000-09-007-L04; 3.25 pharmacy contact hours (.325 CEUs)

CANCELLED

This tutorial will allow an in-depth discussion of the current state-of-the-art Torsade de Pointes (TdP) risk assessment and discussion of ICH Guidance E14 implementation "lessons learned" applied to the prospective assessment of other cardiac safety issues. The knowledge discussed will be utilized in interactive "what if" scenarios.

The discussion of TdP risk assessment will include both standard and novel thorough QT/QTc study designs, oncology QT assessment, recent FDA recommendations, PK/PD analyses, and important factors in determining timing of TQTS. In addition, the use of new techniques and technologies to assess TdP risk such as nontraditional QT parameters and the Telemetry and Holter ECG Warehouse will be discussed.

While clearly important and currently mandated, TdP is a relatively small component of cardiac safety, and many argue that an inordinate number of development resources have been committed to TdP risk. We will discuss how the "lessons learned" from ICH E14 implementation may be applied in the future to non-QT-related cardiac safety issues. The place of cardiac safety within the drug development life cycle will also be discussed. This will include a review of some of the recent major cardiac issues in the media and how to develop an integrated approach to assessing these and other potential future risks as well as developing a benefit:risk profile for cardiac safety.

A programmatic development approach for cardiac safety issues will be advocated. The implication of drug-induced changes in accepted surrogate biomarkers such as cholesterol will be discussed as well as less obvious or well studied effects such as weight gain. The potential benefits of adopting a proactive approach to overall cardiac safety modeled on the ICH E14 approach of employing a "threshold of regulatory concern" to rule out unacceptable cardiac/cardiovascular risks, such as unacceptable blood pressure elevations, will also be discussed.

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

- Discuss integrated approach to QT assessment and cardiac safety throughout the drug development lifecycle
- Describe new technologies and techniques to analyze the risk of proarrhythmia beyond ICH E14
- Discuss application of E14 implementation lessons learned to other areas of cardiac safety

Target Audience
This tutorial is designed for drug safety and clinical development professionals with an emphasis on medical directors, pharmacists, epidemiologists, clinical scientists and others who have at least a moderate knowledge of QT/QTc assessment and cardiac safety.

TUTORIAL #25 **ERS/DM**

Filing INDs as eCTD in the US: Practical Considerations

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

.3 IACET CEUs

This half-day tutorial will focus on the practicalities and processes of creating and maintaining INDs in the eCTD format. Use of guidances and the specifications needed for various types of submissions will be presented, along with common pitfalls and issues.

Practical examples of how to track continuous applications will be discussed; an activity on gathering metadata and case studies will be part of this interactive tutorial. Demonstrations of a pilot eCTD as both IND and NDA will be provided.

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

- Implement practical planning, recognizing the following:
  - Effect on authors of IND sections, specifically around document granularity
  - Importance of tracking documents across functional areas
  - Document mapping from 21 CFR 312 to CTD Modules
- Prepare for eCTD: Identify process change and improvement needs
- Collecting and organizing metadata
  - Recognize the Study tagging file utility
- Define life cycle management
- Describe and discuss cross-dossier referencing [IND to IND; IND to NDA]

Target Audience
This tutorial is designed for regulatory operations and affairs personnel, project managers and functional area contributors to investigational new drug applications.

TUTORIAL #26 **MW**

ISE/ISS: Developing Comprehensive Integrated Summaries of Effectiveness and Safety (ISE/ISS) with the Goal of Transitioning to the Summaries of Clinical Efficacy and Safety (SCE/SCS)

Michael J. Umen, PhD
President, Umen & Co.
David N. Schwartz
Senior Regulatory Strategist and Medical Writer, Umen & Co.

.3 IACET CEUs

This tutorial will focus on how sponsors can most effectively create comprehensive Integrated Summaries of Efficacy and Safety as well as the corresponding Summaries of Clinical Efficacy and Safety (CTD Module 2, Sections 2.7.3 and 2.7.4). The first part of the tutorial will focus on the requirements and guidances that provide the basis for the analyses to be included in these documents. After developing the foundation for these analyses, this tutorial will then focus on examining the relationship between the Module 5 Integrated Summaries and the Module 2 Clinical Summaries. Key insights will be reviewed from the following guidances:

- M4E: The CTD – Efficacy
- Integrated Summary of Effectiveness
- Guidance for Reviewer: Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review
- Integrated Summaries of Effectiveness and Safety: Location within the Common Technical Document

In addition to the guidances, hypothetical and publicly available real-world examples (including FDA Medical Officer Reviews and European Product Assessment Reports) will be shared to highlight how sponsors can develop their Integrated Summaries with the goal of efficiently and effectively transitioning to the Clinical Summaries.

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

- Recognize the scope of analyses necessary in the preparation of a comprehensive ISE and ISS
- Develop an understanding of how to transition from the ISE/ISS to the SCE/SCS
- Develop the skills necessary to prepare these documents in a manner that facilitates reviews by regulatory authorities

Target Audience
This tutorial is designed for professionals in medical writing, regulatory affairs, and medical affairs professionals.

TUTORIAL #27 **NC**

How to Apply Nonclinical Safety Guidelines in Global Drug Development

Klaus Olejniczak, DVM
Scientific Director, Department of Drug Toxicology, BfArM, Germany
Gerd Bode, MD
Consultant and Lecturer, University of Göttingen, Germany

.3 IACET CEUs

The speakers have gained long-term experience as topic leaders in the International Conferences of Harmonization and would like to share their experience with you. All relevant guidelines concerning safety will be addressed, from single dose to carcinogenicity, including safety pharmacology, immunotoxicology, M3, and the common technical document.

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

- Recognize objectives and strategies in toxicology
- Describe improved use of preclinical safety data
- Describe the requirements for safety by agencies

Target Audience
This tutorial is designed for nontoxicologists or beginners in toxicology, regulatory affairs personnel, clinical colleagues, project team leaders, and members.

TUTORIAL #28 **RA**

Fourteen Steps from Research to Development

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

.3 IACET CEUs; 3.25 nursing contact hours

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

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

- 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 #29 **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

.3 IACET CEUs

This tutorial will overview 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 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, project managers).

TUTORIAL #30 **ST**

Basic Concepts in Equivalence/Noninferiority Testing: Issues and Challenges

Tie-Hua Ng, PhD
Lead Mathematical Statistician, CBER, FDA

.3 IACET CEUs

The objective of a noninferiority (NI) trial is to show that the test treatment or the experimental treatment is not inferior to the standard therapy or the active control by a small margin known as the NI margin.

This tutorial will elaborate the rationale of choosing the NI margin as a small fraction of the therapeutic effect of the active control as compared to placebo in testing of the NI hypothesis of the mean difference with a continuous outcome. For testing the NI hypothesis of the mean ratio with a continuous outcome, a similar NI margin on a log scale may be used. This approach may also be applied in testing of the NI hypotheses for survival data based on hazard ratios as well as in the testing of the NI hypothesis with binary endpoints based on the odds ratio. An example in the thrombolytic area will be used for illustrative purposes.

Unlike superiority trials (eg, placebo-control trials), a poorly conducted NI trial (eg, mixing up treatment assignment) would diminish the treatment difference that may exist and hence biases in favor of the test treatment. This is the fundamental issue in the NI trials. The issues of simultaneous tests for NI and superiority will be discussed.

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

- Choose the noninferiority margin for different types of endpoints (e.g., continuous, binary, time to event)
- Recognize the fundamental issue in the noninferiority trials and other related issues

Target Audience
This tutorial is designed for statisticians as well as clinicians who are involved in the design, conduct, and analysis of noninferiority trials.

TUTORIAL #31 **TR/PD**

Leadership: How to Organize and Lead People in Group Work

Michael Laddin, MS, MBA
President, LeaderPoint

.3 IACET CEUs

The role of a leader in organizing and leading a group is often misunderstood and, as a consequence, the group may not perform up to expectations, or it may spend a considerable amount of time in 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 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 #32 **CR/CS, MW, PM/FI**

Best Practices for Development of a Clinical Study Report

Patricia Matone, PhD
President, Scientific Information Services, LLC

.3 IACET CEUs

Examine best practices for preparing integrated clinical study reports for pharmaceutical products. Discussion will focus on the structure and format of a clinical study report, giving special attention to the inclusion and presentation of study-specific information and data.

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

- Describe the structure and format of a clinical study report and its relationship to the study protocol
- Discuss various approaches to handling issues related to report preparation, patient disposition, compliance, and changes to statistical methods
- Explain approaches to effectively structuring the Results, Summary and Discussion, and Synopsis sections

Target Audience
This tutorial is designed for clinical research and development professionals, medical writers, regulatory affairs personnel, biostatisticians, clinical operations professionals.

TUTORIAL #33 **PM/FI**

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

Jack M. Kloeber, Jr., PhD
Senior Partner, Kromite

Homaune A. Razavi, MBA, PhD
Director, Portfolio Management and Validation Group, Pfizer Inc

.3 IACET CEUs

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 three or four 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 program managers, as well as function department heads.

SUNDAY, JUNE 21, 2009 9:00 am-5:00 pm

Tutorials #40 through #46 **Fee $650**

TUTORIAL #40 **CR/CS**

European Regulatory Requirements for the Conduct of Clinical Trials and How to Obtain a CTA

Regina Freunscht
Head, Quality Assurance, Accovion GmbH, Germany

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

The European clinical trial legislation has an impact on clinical trial management, conduct, and adverse event surveillance and reporting, with consequences for sponsors, investigators, ethical committees and regulatory authorities. This full-day interactive tutorial will overview the European legislation affecting clinical trials and provide information on the content of the most important requirements. What's new, and what are its consequences for the conduct of clinical trials? Which documents have to be prepared? Which SOPs might need review? What are the considerations for safety reporting in Europe? Where can I find current and useful further information? Points of discussion will be the clinical trials directive 2001/20/EC and the corresponding detailed guidance on the clinical trial application process, notification of substantial amendments, declaration of end of trial, the ethical committee opinion processes, the EUDRACT and EudraVigilance databases and the reporting of adverse events. Furthermore, relevant content and likely impact of the European data protection directive 95/46/EC, the revised Annex 13 of GMP, the GCP Directive 2005/28/EC and archiving requirements of essential documents, will be discussed. Requirements will be discussed, and an online example of a CTA will be demonstrated, during this tutorial. This will help to understand how to comply with the European CTA regulations and support learning. US FDA requirements will not be addressed.

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

- Recognize the applicable EU regulatory requirements for the conduct of clinical trials in Europe
- Experience the Do's and Don'ts of a CTA
- Better plan and manage your future European clinical trials

Target Audience
This tutorial is designed for any research professional involved in clinical trial programs in Europe. This includes, but is not limited to heads of clinical research departments, project managers, CRAs, trial investigators and CRCs. Furthermore, any person involved in quality assurance (QA) and regulatory affairs will benefit from this tutorial.

TUTORIAL #41 **GCP**

GCPs – Everything You Need to Know and Weren't Afraid to Ask; GCP Similarities and Differences Worldwide; Practical Do's and Don'ts

Munish Mehra, PhD, MSc
Managing Director, Global Drug Development Experts
Shehnaz Kairas Vakhari, MS
Principal Consultant, Theraverity

.7 IACET CEUs

This tutorial will overview ICH E6, FDA GCP requirements, and EU and WHO GCP Guidelines as well as select, country-specific GCPs (eg, India). Understanding differences in GCP requirements across different countries is essential to being able to conduct high-quality trials there which can be used for regulatory submission in the ICH regions of the US, Europe, and Japan. This tutorial will also highlight similarities and differences in GCP requirements in conducting clinical trials under ICH, EU, WHO, and in select countries including the US, India, China, and Russia.

Learning Objectives

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

- Recall an overview of ICH, FDA, EU and WHO GCPs
- Identify GCP requirements to conduct clinical trials in various countries worldwide including India, China, and Russia since these three countries are rapidly becoming some of the most preferred locations for clinical research
- Answer practical GCP FAQs

Target Audience

This tutorial is designed for any individuals who are new to clinical research and want to learn about GCPs, anyone involved with multinational studies who wants to understand the subtle differences in GCPs worldwide, and individuals in project management, regulatory affairs, quality assurance as well as clinical research associates.

TUTORIAL #42 CANCELLED **CP**

Survival Strategies for Successful Pharmacovigilance Inspections in the US, Canada, and EU

Irma Monaco
Associate Director, Medical Affairs, CanReg, Inc., Canada

Patricia A. Moore, MSc
Senior Pharmacovigilance Inspector, Medicines and Healthcare products Regulatory Agency (MHRA), UK

.7 IACET CEUs

CANCELLED

Regulatory agencies around the world have recently increased their efforts to inspect facilities responsible for monitoring product safety. Goals of these pharmacovigilance inspections include determining whether or not safety-related activities adhere to local regulations and time frames, are adequately documented, accurately evaluated, and exhaustively monitored.

Companies can employ several key practices to best prepare for, participate in, and close pharmacovigilance inspections. This tutorial will discuss logistics and trends for inspections in the United States, Canada, and Europe. Regulations, tools, and region-specific topics will be discussed; hands-on activities will give participants the opportunity to prepare for an inspection and assess an inspection report.

Learning Objectives

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

- Prepare and maintain SOPs
- Conduct internal audits
- Identify potential deficiencies
- "Walk through" a pharmacovigilance inspection with various regulatory agencies

Target Audience

This tutorial is designed for safety and pharmacovigilance professionals responsible for ensuring compliance with regulatory agency requirements. The tutorial may also benefit regulatory affairs professionals.

TUTORIAL #43 CANCELLED **TR/PD**

Excelling as a Supervisor or Manager in the Clinical Research Industry

Mary E. Briggs
Senior Vice President, Global Sales and Marketing, CRF Health

.7 IACET CEUs

CANCELLED

This tutorial will provide a clear sense of how to work, lead, and communicate effectively with your team in the clinical trial industry. This entertaining and fast-paced tutorial is ideal for all clinical research managers who want to positively impact their team's performance and work ethic. This tutorial will allow participants to gain the essential skills and knowledge needed to become an effective manager or supervisor in the clinical research industry. Learn practical approaches to communicating, delegating, conflict resolution, and performance enhancement. "Excelling as a Supervisor or Manager in the Clinical Research Industry" is a fast-paced, interactive tutorial that focuses on the number one goal for successful drug development organizations – great managers!

Learning Objectives

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

- Enhance professional presence by reviewing the top three attributes of effective managers and supervisors
- Distinguish between the three primary root causes of performance problems in the clinical research industry
- Communicate and gain compliance by recognizing four primary personality types

Target Audience

This tutorial is designed for clinical research professionals.

TUTORIAL #44 **CR/CS, MC, MW**

Clinical Statistics for Nonstatisticians

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

6.5 AMA PRA Category 1 Credit(s)™; .7 IACET CEUs; 6.5 nursing contact hours; 286-000-09-009-L04-P; 6.5 pharmacy contact hours (.65 CEUs)

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

Learning Objectives

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

- Discuss basic statistical concepts such as variability, confidence intervals, hypothesis testing and p-values
- Compare and contrast various study designs and identify techniques to avoid bias
- Discuss 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 #45 CANCELLED **CR/CS, PM/FI**

Project Management for the Nonproject Manager

Martin D. Hynes, III, PhD
Director, Six Sigma Champion for Product Development,
Eli Lilly and Company

.7 IACET CEUs

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

CANCELLED

Learning Objectives

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

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

Target Audience

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

TUTORIAL #46 CANCELLED **AHC/IS, CR/CS, RA, RD**

Overview of Drug Development

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

.7 IACET CEUs

This tutorial overviews how new pharmaceutical products are identified and developed. The roles and interactions among marketing, clinical R&D, regulatory affairs, and manufacturing will be reviewed. A basic description of the Investigational New Drug Application (IND) will lead to a review of how clinical trials are started, completed, and reported; ethical considerations in conducting clinical research; and filing New Drug Application (NDA) and interactions with the FDA, will also be discussed. The material focuses on developing drugs and biologics under FDA regulations and ICH guidelines.

CANCELLED

Learning Objectives

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

- Recognize the process of discovering and developing new pharmaceutical products
- Describe the activities associated with conducting clinical research and reporting the results and responsibilities of various departments in accomplishing these activities
- Discuss institutional review, informed consent, and financial disclosure
- Develop knowledge about concepts and functions associated with ensuring overall quality of studies
- Describe the organization of the FDA, their authority, and interactions with sponsor companies

Target Audience

This is a "survey" tutorial rather than a "how-to" tutorial. It is intended to describe the "big picture" for personnel seeking to gain a better understanding of how their roles fit into the overall process of pharmaceutical development. It is especially helpful for administrative staff and those from most disciplines who have limited tenure or breadth of experience in the pharmaceutical industry. Although some specific developmental procedures will be reviewed, along with applicable regulations and guidelines, the tutorial provides broad-brush descriptions without in-depth discussion.

SUNDAY, JUNE 21, 2009 1:00 pm-4:30 pm

Tutorials #50 through #62 **Fee $375**

TUTORIAL #50 CANCELLED **CP**

European Interpretation of Product and Company Risk Management

Graeme A. Ladds, III, PhD
Consultant, PharSafer Associates Ltd., UK

.3 IACET CEUs

Signal detection, benefit-risk analysis, risk management, and risk minimization have become the new mantras for both regulatory authorities and pharmaceutical companies alike. Recent legislation and guidances have meant that without demonstrating that such systems are in place, the company will not receive license approval or delayed approval, or if the product is already on the market, not having these systems may result in license suspension until the regulators are satisfied that the company can manage the safety of the product.

CANCELLED

This tutorial has been designed to demonstrate how Europe has implemented its approach to risk management and minimization, while at the same time asking the company to declare that robust safety systems exist for all of its products in the so-called PV plan that must accompany all EU submissions. The tutorial will examine the requirements from the EU template of what needs to be assessed in product-specific risk analyses, together with strategies for supplementing missing safety information or postmarketing commitments to supply such data to the authorities.

Learning Objectives

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

- Define the differences in EU legislation requiring risk management strategies
- Recognize the content of the risk management plan
- Assess the company PV plan required and the role of the EU QP PV

Target Audience

This tutorial is designed for pharmacovigilance and regulatory personnel involved in both license submissions, management of pharmacovigilance systems, clinical safety and postmarketing safety personnel with a view to understanding the information and reporting requirements when implementing a risk management strategy.

TUTORIAL #51 **CP**

How to Prepare a Detailed Description of Pharmacovigilance Systems (DDPS) According to the EU Regulatory Requirements and in Light of Recent Inspection Findings

Gaby L. Danan, PhD
Senior Director, Expert in Pharmacovigilance/Global Pharmacovigilance, sanofi-aventis, France

Sabine Brosch, MSc, PhD
Deputy Head of Sector, Pharmacovigilance and Risk Management, European Medicines Agency, European Union

.3 IACET CEUs

This tutorial will allow attendees to discuss the regulatory requirements with regard to the chapter of Volume 9A on the "Description of Pharmacovigilance Systems for Medicinal Products for Human Use" also referred to as DDPS. It should be supplied with the application dossier and as part of supporting documentation that the applicant should maintain and supply to the competent authorities on request.

Emphasis will be put on the main elements of the DDPS, such as the role and responsibilities of the qualified person responsible for pharmacovigilance (QPPV), an outline of the pharmacovigilance procedures and the pharmacovigilance database(s), methods for updating the DDPS, and points to consider when preparing for inspections.

Learning Objectives

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

- Interpret the potential implications of the requirements on companies' business processes
- Share knowledge on how to prepare DDPS
- Adhere to the requirements of updating a DDPS
- Share knowledge on how to prepare for an inspection in relation to the DDPS and the pharmacovigilance systems

Target Audience

This tutorial is designed for qualified persons responsible for pharmacovigilance, persons in charge in pharmacovigilance systems, experts in regulatory affairs, persons in charge of quality and compliance, and sponsors of clinical trials.

TUTORIAL #52 **CP**

Data Quality Counts from Start to Finish: The Role of MedDRA® in Coding and Analysis of Safety Data

Patricia Mozzicato, MD
Chief Medical Officer, MedDRA® MSSO/Northrop Grumman Corporation

.3 IACET CEUs

When a patient and healthcare provider first discuss a potential adverse event (AE), the quality of information about the AE is significant and carries through to analysis of aggregate data, including product labeling. If data quality is not optimized at that point, even a sophisticated AE coding terminology like MedDRA® cannot improve its quality.

Furthermore, there are challenges in coding poor quality AE data. After a brief review of what MedDRA® is, this tutorial will highlight the challenges and discuss ways to improve initial data quality, tools/methods to optimize MedDRA® coding, and analytical approaches for MedDRA®-coded data that are impacted by data quality.

In clinical trials, investigators provide AE information on standard forms, and those data are transmitted to the sponsor for database entry. Upon data entry, pieces of information about the AE (eg, the event, medical history) are coded using MedDRA®. This involves matching words provided by the investigator ("patient had acute MI") to a coding-level MedDRA® term ("Acute myocardial infarction"). Depending upon the quality of information communicated to the sponsor, MedDRA® coding may or may not be a challenge. This tutorial will highlight examples of varying quality data to demonstrate the MedDRA® coding step. Ways to improve data quality and MedDRA® coding will be discussed.

For marketed products, the sponsor often has less interaction with the reporter; however, there are ways to optimize data quality and make the best choice for coding. Conventions, training, and other approaches, will be discussed.

Over time, a sponsor gathers MedDRA®-coded AE data during clinical trials in the postmarketing phase. These data generally need to be analyzed and communicated to various parties (eg, health authorities). Even at this point, data quality has an impact. The tutorial will also address approaches to aggregate these data to best understand the safety profile of a product.

Learning Objectives

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

- Evaluate the impact of data quality on coding adverse event data using MedDRA®
- Discuss the impact of data quality in analysis of aggregate MedDRA®-coded data
- Identify ways to optimize data quality and to improve MedDRA® coding and analysis

Target Audience

This tutorial is designed for clinical data management personnel, investigators, clinical research associates, safety data assessors, coding personnel, data quality assurance personnel, and other personnel involved in the processing and reporting of AE data.

TUTORIAL #53 **CANCELLED** **RA**

Imaging in Drug Development

Orhan H. Suleiman, MS, PhD
Senior Science Policy Adviser, Office of Oncology Drug Products, Office of New Drugs, CDER, FDA
Paul E. Kinahan, PhD
Professor of Radiology, University of Washington

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

This tutorial will broadly address the FDA Critical Path initiative for drug development, the value of imaging as a research tool, a review of a representative set of imaging modalities, a review of current imaging initiatives across industry, professional organizations, and government agencies, and relevant FDA regulations and guidance. In addition, critical elements necessary to conduct imaging-based drug development trials, and specific pitfalls and problems associated with such imaging trials, will be discussed.

CANCELLED

Learning Objectives

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

- Identify FDA's Critical Path and why many stakeholders value the role imaging can play in drug development
- Recognize FDA regulations and guidance, the many imaging initiatives, different imaging technologies, and critical elements necessary to conduct a good imaging-based trial

Target Audience
This tutorial is designed for individuals responsible for designing and conducting imaging-based clinical trials and individuals who want to learn about essential imaging elements such as the use of imaging phantoms, quality control testing, and clinical image analysis in order to conduct successful imaging based clinical trials.

TUTORIAL #54 **CR/CS**

Planning and Conducting Clinical Trials in Oncology

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

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

Cancer is the leading cause of death in the US for persons 85 years of age and younger. Approximately 1.4 M new cases of invasive cancer are projected to be reported in 2008 (*Jamal et al*, CA, 2008). Total funding for US and worldwide trials in oncology is greater than that for any other therapeutic area. This tutorial has been offered for the past three years. Feedback from previous attendees in this tutorial has been excellent, and feedback/suggestions have been used to further develop this tutorial, according to the needs of the drug development specialist. In 2009, this tutorial will include: a brief introduction to the biology of cancer development, growth, and metastasis; an overall discussion of treatment strategies; in-depth discussion of phase 1 protocol development; in-depth discussion of phase 2-3 protocol development including the potential for accelerated approval for phases 1-3; and a thorough review and critique of recently completed oncology studies.

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

- Recognize the incidence and prevalence of cancer in the US
- Describe tumor growth, metastasis, and transformation processes
- Identify, recall, and apply the essential strategies and unique components of phase 1, 2, and 3 oncology protocols

Target Audience
This tutorial is designed for entry- or intermediate-level drug development professionals who may be involved with protocol development, monitoring, data acquisition or management, statistical analysis, or the clinical site aspects of conducting clinical trials in oncology.

TUTORIAL #55 **GCP**

How to Prepare for an FDA Audit: QA in Clinical Trials

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

.3 IACET CEUs; 286-000-09-021-L04-P; 3.25 pharmacy contact hours (.325 CEUs)

This tutorial will provide information on how to build quality into a clinical trials program. A record number of FDA inspections, both domestic and international, and OHRP audits, have resulted in an increased number of warning letters to Sponsors, Principal Investigators, and IRBs. Using case studies, simulations, and actual findings, participants will be able to describe how to approach clinical trials that fully comply with good clinical practice expectations. Participants will also learn about the considerations for noncompliance and the types of findings in an audit that can lead to regulatory problems. This tutorial will describe the role of the FDA and the preparation of a site for an FDA audit. Presentations will cover the audit from different perspectives and focus on helpful hints and procedural issues regarding what to do in case they are chosen for an FDA audit. There will be a discussion on how to host the audit, how best to prepare for the actual audit, and the do's and don'ts of a successful audit.

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

- Demonstrate how to prepare for and respond to an FDA audit
- Review audit findings and their impact on quality research
- Recognize possible outcomes of an FDA audit

Target Audience
This tutorial is designed for professionals in quality assurance (QA) and clinical staff in companies, pharmaceutical/biological companies that are involved in clinical trials and QA activities for clinical research.

TUTORIAL #56 **MW**

Introduction to the PSUR: Pharmacovigilance and Medical Writing Perspectives

Donald Puccio
Director, Pfizer Inc
Meeghan Sinclair, PhD
Associate Director, Pfizer Inc

.3 IACET CEUs

This tutorial critically examines PSUR content (including PSUR Addendum and Summary Bridging Reports) and process from the pharmacovigilance and medical writing perspectives. It will overview relevant guidance documents (including differences between EU and US requirements) and the role of the qualified person, discuss the limitations of the basic PSUR components (eg, the individual case safety reports, patient exposure data), delineate linkages with the risk management plan, and review the contents of each section, including how the methods of presentation should vary depending on the lifecycle status of the drug and the volume of data to be presented. This tutorial will also discuss topics surrounding the newly implemented EU PSUR Synchronization of Submission scheme, EU Worksharing Project, and the related Assessment Reports. The tutorial will also examine what makes a well written and focused PSUR, including how safety information is collected, processed, and then used to assess benefit-risk. The tutorial will include a "hands-on" portion in which participants will discuss and construct a safety analysis strategy/outline for a medical topic and will review frequently asked questions pertaining to nonsafety and safety sections of a PSUR.

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

- Explain why PSURs are prepared and identify sources of relevant information
- Describe the contents of each section and how these differ according to lifecycle status of the drug and the volume of cases
- Prepare an outline for an analysis of a medical topic

Target Audience
This tutorial is designed for medical writers and pharmacovigilance personnel who are new to PSURs and those with limited experience who might benefit from additional practice in safety evaluation. The tutorial may also benefit regulatory affairs professionals.

TUTORIAL #57 **RA**

A Device Primer: 510(k)s, PMAs, IDEs and Beyond

Josephine Babiarz, Esq.
Director, MS Program in Regulatory Affairs and Health Policy, Massachusetts College of Pharmacy Health Sciences
Barry S. Sall
Principle Consultant, PAREXEL International Corporation

.3 IACET CEUs; 286-000-09-008-L04-P; 3.25 pharmacy contact hours (.325 CEUs)

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.

TUTORIAL #58 CANCELLED **RA**

Practical Approaches and Strategies for Preparing Your EU Pediatric Investigation Plan Application

Gemma Slade
Manager, PAREXEL Consulting, UK

.3 IACET CEUs

This tutorial will focus on the six modules that cover the EU Pediatric Investigation Plan (PIP) Application. Individual modules expand on and address the following topics: 1) Brief overview of the regulation and guidances; 2) First principles; 3) Waivers and deferrals; 4) Nonclinical and CMC; 5) Timelines, deferrals and the PIP life cycle; 6) Tips and tricks for the procedure.

CANCELLED

Learning Objectives

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

- Interpret the EU pediatric regulations and guidelines in order to focus research, analysis, and writing to prepare successful pediatric investigation plans (PIPs).
- Identify good approaches for positioning the PIP (including waivers and deferrals

Target Audience

This tutorial is designed for regulatory affairs professionals with responsibility for overall strategy for compliance with the EU pediatric regulation, or for PIP compliance of one or more development products/marketed drugs; medical writers and researchers involved with structuring, writing and/or researching PIPs.

TUTORIAL #59 **RA**

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

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

.3 IACET CEUs

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 Pharmaceutical and Medical Device 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 involved with global development projects involving Japan.

TUTORIAL #60 **ST**

Constructing Graphical Visualizations of Clinical Trial Data Using the Open Source R Language

Mat Soukup, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

.3 IACET CEUs

Increasing concerns for drug safety and the lengthy drug development process have highlighted the need for efficient, thorough, and transparent statistical data analysis and reporting of clinical studies. The use of compelling statistical graphics can provide transparent representations of the data collected in clinical trials. Such presentations improve the quality of clinical decisions, increase the likelihood of discerning safety signals and efficacy characteristics, and enable more productive communications between the FDA and regulated companies.

R is a language and environment for statistical computing and graphics. R provides a wide variety of statistical (linear and nonlinear modeling, classical statistical tests, time-series analysis, classification and graphical techniques, and is highly extensible. The S language is often the vehicle of choice for research in statistical methodology, and R provides an Open Source route to participation in that activity. The tutorial will include a brief introduction into getting started using the R computing environment, basic syntax of the S language, importing SAS Transport files, and managing data in R. This basic introduction will allow participants with no or little experience with the R computing environment the ability to use R for analyzing and visualizing data gathered in clinical trials. Building on the introduction to the R computing environment, this tutorial focuses on taking advantage of its flexible graphic capabilities for visualizing clinical trial data.

The tutorial will cover basic concepts for constructing and modifying traditional graphs in R, as well as for creating the newer, information-rich, trellis-type displays. Attention is paid to Good Graphic Principles for effectively conveying the information contained in the vast amount of clinical trial data. The tutorial will provide custom-type displays that improve upon traditional displays of clinical trial data such as tables and line listings.

Learning Objectives

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

- Outline basics of the S language and understand its flexible graphic capability
- Extend these concepts to create customized graphs for clinical trial data
- Apply specialized graphical approaches to effectively communicate data gathered in clinical trials

Target Audience

This tutorial is designed for all individuals involved in reporting clinical trial results or involved in developing methods to summarize clinical trial data. Specific interest would be to statisticians, statistical programmers, medical writers, and clinical researchers.

TUTORIAL #61 **CR/CS, PM/FI**

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

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

.3 IACET CEUs

Explore trends, management techniques, and a reality check in current site monitoring activities! What's working; what's 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, attendees 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.

TUTORIAL #62 **AHC/IS, CR/CS, TR/PD**

Developing Standard Operating Procedures (SOPs)

Bernadette Ott
Consultant, Good Clinical Practices/Quality Assurance

.3 IACET CEUs

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 class will explore what SOPs are, their uses, and how to write them.

Learning Objectives

At the conclusion of this tutorial, 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.

Meeting Schedule by Day and Time

Sessions are organized and presented according to the track titles (interest area codes) defined in the chart below. Some sessions may also be of interest to professionals in other specialties or disciplines. For these sessions, the primary interest area code, displayed in bold face type, is followed by the code for a secondary interest area.

Session Level Guide

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

- ● **BASIC Level Content** — Session is appropriate for individuals new to the topic/subject area.
- ■ **Primarily INTERMEDIATE Level Content** — Session is appropriate for individuals who already have a basic understanding of the topic/subject area.
- ◆ **Primarily ADVANCED Level Content** — Session is appropriate for individuals with an in-depth knowledge of the topic/subject area.

Track Designations

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

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	MONDAY 8:30 am-10:00 am				
	PLENARY SESSION *All registrants are encouraged to attend.* **Welcoming Remarks, Award Presentations, Keynote Address**		**ALL**	**ALL**	**Ballroom 20, Upper Level**
	MONDAY 10:30 am-12:00 pm				
101	*AD/MA/MC Mega Track Plenary Session:* Pharma in the New Age of Transparency	LEVEL ●	**AD**	MA, MC	**30AB**
102	How Investigator Budgets Impact Patient Enrollment and Retention and How to Improve Sponsor/CRO/Site Processes to Increase Productivity	LEVEL ■	**AHC/IS**	CR/CS	**1A**
103	Hot Topics in Biotechnology	LEVEL ●	**BT**	RA	**1B**
104	Getting that Fresh, Clean Feeling: Defining "Clean" Data	LEVEL ■	**CDM**	IT	**11B**
105	The ASTER Pilot One Year Later: Different Approaches to Spontaneous Reporting – A New Business Model	LEVEL ■	**CP**	IT	**33AB**
106	Understanding Clinical Trial Volunteer Experiences and Physician Referral to Clinical Trials	LEVEL ●	**CR/CS 1**	AHC/IS	**5A**
107	Effective Operational Planning for Adaptive Clinical Trials	LEVEL ■	**CR/CS 2**	PM/FI	**3**
108	Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done?	LEVEL ■	**CR/CS 3**	RA	**6C**
109	Improving Safety with Every Step: The Patient Perspective	LEVEL ●	**CR/CS 4**	CP	**6D**
110	FDA's Drug eReg and Listing System: One Year Later	LEVEL ■	**ERS/DM**	RA	**9**
111	Where Are the Goal Posts this Week? An Update on Global Legislation Related to Clinical Trial Disclosure	LEVEL ■	**GCP**	RA	**30CD**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	MONDAY 10:30 am-12:00 pm *continued*				
112	Utilizing and Integrating Open Source Software in Clinical Research Environments	LEVEL ■	**IT**	EC	**15B** MEZZANINE
101	*AD/MA/MC Mega Track Plenary Session:* Pharma in the New Age of Transparency	LEVEL ●	**MA & MC**	AD	**30AB**
113	Medical Writer Competency Model: Understanding Skills, Knowledge, and Behaviors for Use in Hiring, Training, and Evaluating Medical Writers	LEVEL ■	**MW**	OS	**31AB**
114	Sourcing Professionals Are from Mars and Business Development Professionals Are from Venus	LEVEL ■	**OS**	PM/FI	**5B**
115	Using Relationship Management Tools to Improve Project Results	LEVEL ■	**PM/FI 1**	CR/CS	**4**
116	Profiting in the Next Generation Pharmaceutical Industry	LEVEL ■	**PM/FI 2**	CR/CS	**2**
117	Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials	LEVEL ●	**PP**	RA	**32AB**
118	Regulatory Harmonization Initiative in APEC LSIF (Life Science Innovation Forum)	LEVEL ■	**RA 1**	RD	**6E**
119	An Introduction and Discussion of FDAAA, FDA's New Regulatory Authorities	LEVEL ●	**RA 2**	CP	**6F**
120	PDUFA IV Commitments on Review and Evaluation of Trademarks (Proprietary Names) and Update on Pilot Program for Evaluation of Proposed Names	LEVEL ■	**RA 3**	CP	**10**
121	Regulatory Data Protection	LEVEL ◆	**RA 4**	IT	**7A**
122	Proactive FDA Safety Meetings: Anticipating Safety Issues	LEVEL ■	**RA 5**	CP	**8**
123	Establishing Precedence in Regulatory Strategy: The Role of Regulatory Intelligence in the Development Process	LEVEL ■	**RA 6**	RD	**11A**
124	Planning of Drug Safety Evaluation	LEVEL ■	**ST**	CP	**16A** MEZZANINE
125	Training of Investigators and IRB Members in Asia	LEVEL ■	**TR/PD**	AHC/IS	**16B** MEZZANINE
	MONDAY 1:30 pm-3:00 pm				
126	FDA Enforcement Update	LEVEL ●	**AD**	RA	**14A** MEZZANINE
127	Disease Insights: A Truly Global Approach to Accelerating Patient Recruitment and Retention	LEVEL ◆	**AHC/IS**	RD	**1A**
128	Regulatory Methods to Facilitate the Approval of Biological Products to Address Pandemic Influenza	LEVEL ■	**BT**	RA	**1B**
129	CDASH/Standards and the Practical Implications	LEVEL ●	**CDM**	IT	**8**
130	Modernization of FDA Postmarket Adverse Event Information Management	LEVEL ■	**CP 1**	IT	**30AB**
131	Issues and Challenges Associated with the PSUR Process	LEVEL ■	**CP 2**	RA	**33AB**
132	The State of Subject Recruitment in the US: A Town Hall Discussion	LEVEL ■	**CR/CS 1**	AHC/IS	**6C**
133	CTMS Implementation: The Next Steps	LEVEL ■	**CR/CS 2**	AHC/IS	**5B**
134	Informed Country Selection for Multinational Clinical Studies: One Size Does Not Fit All	LEVEL ■	**CR/CS 3**	ST	**6D**
135	Is There Really Such a Thing as a Strategic Partnership?	LEVEL ◆	**CR/CS 4**	GCP	**3**
136	Global Submission Management: Challenges and Opportunities	LEVEL ■	**ERS/DM**	RA	**9**
137	eAudit: Clinical Data Mining and Signal Detection	LEVEL ■	**GCP**	IT	**30CD**
138	Extreme Programming in the Life Sciences	LEVEL ■	**IT**	VA	**15B** MEZZANINE
139	Drug Information and the Internet	LEVEL ●	**MC**	IT	**14B** MEZZANINE
140	IND to CTD in Electronic Format: Strategic Considerations for Life-cycle Maintenance	LEVEL ■	**MW**	ERS/DM	**31AB**
141	Outsourcing Clinical Trials in Latin America: Challenges and Opportunities	LEVEL ■	**OS**	CR/CS	**5A**
142	2008 Benchmark Survey Results: Project Management in the Pharmaceutical Industry	LEVEL ■	**PM/FI 1**	TR/PD	**2**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	MONDAY 1:30 pm-3:00 pm *continued*				
143	Valuing Continuous Process Improvement Projects	LEVEL ■	**PM/FI 2**	RD	**4**
144	Civil and Regulatory Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials?	LEVEL ●	**PP 1**	RA	**32AB**
145	Labeling Risk: Practical Approaches after Wyeth v. Levine	LEVEL ■	**PP 2**	RA	**10**
146	The New "Next Door" in Global Development: When East Goes West or West Goes East	LEVEL ■	**RA 1**	MA	**7A**
147	PMDA Update: PMDA Initiatives and Challenges for Faster Review and Better Life-cycle Management of Drugs	LEVEL ■	**RA 2**	CP	**6E**
148	Best Practices for Interactions between Industry and FDA (Office of New Drugs/ Office of Surveillance and Epidemiology) Considerations during Drug Product Life Cycle on Safety	LEVEL ■	**RA 3**	CP	**6F**
149	Pharmacogenomics in Action: A Practical View of Pharmacogenomic Submissions, FDA Review Process, and Label Revisions	LEVEL ■	**RA 4**	RD	**7B**
150	Integrated Analyses through a Drug's Life Cycle: Plan to Think about Safety	LEVEL ■	**ST**	CP	**16A** MEZZANINE
151	Integrating the Science of Drug Development and Safety into Health-care Professionals' Curriculum	LEVEL ■	**TR/PD**	CP	**16B** MEZZANINE
	MONDAY 3:30 pm-5:00 pm				
152	Office of Inspector General (OIG) Settlements: New Integrity Obligations for Pharmaceutical Companies	LEVEL ●	**AD**	RA	**14A** MEZZANINE
153	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**AHC/IS**	CP,CR/CS, GCP,PP,RA	**6AB**
154	Immunogenicity: Strategies for Testing and Evaluation	LEVEL ■	**BT**	RD	**1B**
155	Metrics and Their Benefits	LEVEL ●	**CDM**	EC	**11B**
153	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**CP, CR/CS**	AHC/IS,GCP PP,RA	**6AB**
156	A La Carte or Prix Fixe: The Right Menu for Clinical Trials Technology	LEVEL ■	**EC**	CDM	**11A**
157	Overcoming Regulatory Diversity to Gain Market Approval in Latin American Regions	LEVEL ■	**ERS/DM**	RA	**9**
153	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**GCP**	AHC/IS,CP, CR/CS,PP,RA	**6AB**
158	Smashing Silos: Bringing Service-oriented Architecture and Data Warehousing to a Pharmaceutical Company Environment	LEVEL ■	**IT**	CDM	**15B** MEZZANINE
159	The Art and Science of Pharmaceutical Project Management: Does a Pharma PM Need to Be a Scientist?	LEVEL ■	**PM/FI 1**	RD	**5B**
160	Improving Accrual and Contract Management with Earned Value Management	LEVEL ◆	**PM/FI 2**	CR/CS	**4**
153	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**PP, RA**	AHC/IS,CP, CR/CS,GCP	**6AB**
161	GCPs in China: Similarities and Differences from ICH GCPs	LEVEL ●	**RA 1**	GCP	**7B**
162	Regulatory Framework in Central and South America	LEVEL ●	**RA 2**	CR/CS	**7A**
163	Asia Pacific: Simultaneous Global Development	LEVEL ■	**RD**	RA	**14B** MEZZANINE
164	Adaptive Designs: New Methods	LEVEL ■	**ST**	CR/CS	**16A** MEZZANINE
165	Agile Training: Thinking like a Cable News Network for High-impact Learning	LEVEL ■	**TR/PD**	RA	**16B** MEZZANINE

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	TUESDAY 8:00 am-9:30 am				
201	Update on Direct-to-consumer Advertising	LEVEL ●	**AD**	RA	**14A** MEZZANINE
202	Health Reform, and FDAAA: Impact on FDA, Industry, Health Professionals, Consumers, Payers, and Other Stakeholders	LEVEL ■	**AHC/IS**	RA	**6C**
203	Countering Bioterrorism: Regulatory Methods Designed to Speed the Availability of Biological Products	LEVEL ■	**BT**	RA	**1B**
204	Future of Data Management/Evolving Role of Data Management	LEVEL ■	**CDM**	OS	**11B**
205	Quality by Design (QbD): Linking Quality to Efficacy – Part 1 of 2	LEVEL ■	**CMC/GMP**	RA	**17A** MEZZANINE
206	Pharmacovigilance Organization Models: How New Regulatory and Business Needs Are Changing the Pharmacovigilance Department, and How to Design an Effective Organization	LEVEL ■	**CP 1**	OS	**33AB**
207	Development Safety Update Report (ICH E2F): Update, Current Status, and Major Provisions	LEVEL ■	**CP 2**	CR/CS	**30AB**
208	Using Performance Metrics to Improve Clinical Trial Performance and Reduce Enrollment Risk	LEVEL ■	**CR/CS 1**	AHC/IS	**1A**
209	Understanding the Complexities of Latin American Borders and Local Regulations to Get the Clinical Trial Material into the Country	LEVEL ●	**CR/CS 2**	OS	**5B**
210	Medical Imaging: Update on PhRMA Consortium Initiatives	LEVEL ●	**CR/CS 3**	CDM	**6D**
211	Beyond the QT Interval: Regulatory Perspective on the Use of Surrogates in Premarket Safety and Risk/Benefit Evaluation	LEVEL ●	**EBM/IMP**	RA	**17B** MEZZANINE
212	Standards in Your Future: How SAFE-BioPharma, IHE, and CDISC Are Collaborating to Improve Safety Reporting	LEVEL ■	**EC**	CP	**15A** MEZZANINE
213	Implementing Global Electronic Submissions: The Company and the Regulators Give their Points of View	LEVEL ■	**ERS/DM**	EC	**9**
214	Corrective Action and Preventive Action Program for Clinical Trial Programs	LEVEL ■	**GCP**	RA	**30CD**
215	Integrated Web-based Tools Supporting the Pharmaceutical Policies of Regulatory Bodies: From Clinical Trial National Registries to the Regulatory eSubmission	LEVEL ●	**IT**	ERS/DM	**15B** MEZZANINE
216	Hot Topics in Publication Writing: Challenges and Solutions	LEVEL ■	**MW**	TR/PD	**31AB**
217	Utilize Standardized CRO Performance Metrics to Drive Appropriate Change: An Industry-wide Effort among Sponsors and CROs to Develop and Implement Standardized CRO Performance Metrics to Improve Clinical Trial Performance	LEVEL ■	**OS**	CR/CS	**5A**
218	Comparing Risk Management Approaches of the US and Japan (Asia): Implications for Global Drug Development	LEVEL ■	**PM/FI 1**	CMC/GMP	**4**
219	Implementing Enterprise-wide Project Management Tools	LEVEL ■	**PM/FI 2**	TR/PD	**2**
220	Transparency: EMEA's Future Policy	LEVEL ●	**PP**	RA	**32AB**
221	FDA Goes Global: Domestic Mission – Global Presence	LEVEL ●	**RA 1**	PP	**6E**
222	Postmarketing Requirements and Commitments (PMRs/PMCs): FDAAA's Impact and How FDA and Industry Are Addressing the Backlog	LEVEL ■	**RA 2**	CP	**6F**
223	Biopharmaceutical Company Regulatory Affairs Functions: Strategies and Structures	LEVEL ■	**RA 3**	RD	**7A**
224	Improving Your Chances of Getting a Drug or Biologic Approved during the First Review Cycle	LEVEL ●	**RA 4**	CR/CS	**8**
225	Development of Oncology Products in the EU and US: Can We Do Better?	LEVEL ■	**RA 5**	RD	**7B**
226	Pediatric Drug Development: A Global Challenge	LEVEL ●	**RD**	–	**14B** MEZZANINE
227	The Next Wave of Adaptive Trials	LEVEL ■	**ST**	RA	**16A** MEZZANINE
228	Get Connected! Expanding Your Business Network	LEVEL ●	**TR/PD**	MA	**16B** MEZZANINE

Session Number	Session Title	Difficulty Level	Interest Areas		Room Number
			Primary	Secondary	
	TUESDAY 10:00 am-11:30 am				
229	Introduction to Pharmaceutical Marketing Primer	LEVEL ●	**AD**	MA	**14A** MEZZANINE
230	The Impact of FDAAA and Health Information Technology on Drug Safety, Standards, and Data Stewardship: 2009 Update and Future Plans	LEVEL ■	**AHC/IS**	IT	**6C**
231	Regulatory Challenges Related to the Development of Second Generation Therapeutic Proteins	LEVEL ■	**BT**	RA	**1B**
232	From Case Report Form to CDISC SDTM: Data Standards	LEVEL ●	**CDM**	IT	**11B**
233	Quality by Design (QbD): Linking Quality to Safety – Part 2 of 2	LEVEL ■	**CMC/GMP**	RA	**17A** MEZZANINE
234	FDA Sentinel Initiative	LEVEL ■	**CP 1**	RA	**30AB**
235	Early Signal Information from the Regulatory Authorities: Implications for the Public and the Need for Risk Benefit Communication to Enhance Understanding	LEVEL ■	**CP 2**	RA	**33AB**
236	Ethical Rewards for Patients in Clinical Studies: A Scientific Approach to Patient Retention	LEVEL ■	**CR/CS 1**	MC	**6D**
237	Building a Clinical Operations Department through Rapid Organizational Growth	LEVEL ◆	**CR/CS 2**	RD	**5B**
238	Is It Truly Informed Consent?	LEVEL ■	**CR/CS 3**	GCP	**1A**
239	Understanding Comparative Effectiveness Research: Policy, Implementation, and Quality	LEVEL ●	**EBM/IMP**	PP	**17B** MEZZANINE
240	Accelerating Site Initiation through a Shared Collaborative Platform	LEVEL ■	**EC**	IT	**15A** MEZZANINE
241	FDA Data Exchange Standards Initiatives	LEVEL ●	**ERS/DM**	IT	**9**
242	The Cost of Compliance: Clinical Trial Registration and Results Disclosure	LEVEL ●	**GCP**	ERS/DM	**30CD**
243	Streamlining Your Clinical Data Environment, End-to-end, Using a Standards-based, Metadata-driven Approach – A Panel Discussion	LEVEL ■	**IT**	CDM	**15B** MEZZANINE
244	The Role of Medical Communications in Developing Risk Management Strategies	LEVEL ■	**MC**	CP	**11A**
245	The Clinical Study Report Revisited: Strategies for Effective Authoring	LEVEL ●	**MW**	CP	**31AB**
246	Training of Investigative Sites in the Latin America Region	LEVEL ■	**OS**	TR/PD	**5A**
247	Project and Alliance Management: Integrating the Roles	LEVEL ■	**PM/FI 1**	TR/PD	**2**
248	Ensuring Strategic Value of Continuous Process Improvement Projects	LEVEL ■	**PM/FI 2**	CR/CS	**4**
249	Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) Report Card	LEVEL ■	**PP**	RA	**32AB**
250	You Can't (b)(2) Careful: Submitting 505(b)(2) Applications	LEVEL ■	**RA 1**	CR/CS	**6E**
251	Update from China's SFDA and CDE	LEVEL ■	**RA 2**	CR/CS	**7B**
252	FDA and EMEA Update on Pediatric Legislation	LEVEL ●	**RA 3**	PP	**7A**
253	European Medicines Agency Town Hall	LEVEL ●	**RA 4**	CR/CS	**8**
254	The Practice of Adaptive Research	LEVEL ■	**RD**	EC	**14B** MEZZANINE
255	What Are the Key Issues in BioPharma Statistics Today and Tomorrow? A Panel Discussion	LEVEL ●	**ST**	EC	**10**
256	Drug Safety Personnel – Qualifications? Further Education? What Are the Basic Requirements and What Is Nice to Have? Where Do Regulators and Industry Find Talent?	LEVEL ■	**TR/PD**	CP	**16B** MEZZANINE
	TUESDAY 2:00 pm-3:30 pm				
257	Biomarkers for Drug Safety and Development: Perspectives from the Institute of Medicine and Industry	LEVEL ●	**AHC/IS**	CR/CS	**6C**
258	Follow-on Biologics: Ensuring Quality, Efficacy, and Safety	LEVEL ■	**BT**	CP	**1B**
259	Metric-based Management and eClinical Trials	LEVEL ■	**CDM**	IT	**11B**
260	CMC Regulatory Development and Updates	LEVEL ●	**CMC/GMP**	–	**17A** MEZZANINE

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	TUESDAY 2:00 pm-3:30 pm *continued*				
261	Pharmacovigilance on a Budget	LEVEL ■	**CP 1**	PM/FI	**30AB**
262	Signal Detection and Data Mining in Pharmacovigilance: Motives, Methods, and Management	LEVEL ■	**CP 2**	ST	**33AB**
263	Meeting the Health Needs of Minorities through Clinical Research: Engaging Minority Investigators and Recruiting Diverse Patient Populations	LEVEL ■	**CR/CS 1**	AHC/IS	**6D**
264	Clinical Supplies Management under Uncertainty	LEVEL ■	**CR/CS 2**	ST	**1A**
265	Creating a Collaborative Environment: Working Together at Monitoring Visits	LEVEL ●	**CR/CS 3**	AHC/IS	**5B**
266	Site Relationship Management (SRM) Initiatives for Improving Site Performance: One Year Later	LEVEL ◆	**CR/CS 4**	AHC/IS	**3**
267	Pharmacoeconomics, Cost Effectiveness, and Outcome Analysis for Personalized Medicine	LEVEL ■	**EBM/IMP**	PP	**17B** MEZZANINE
268	Structured Product Labeling (SPL) Indexing at FDA: Where We Are Today and Towards the Future	LEVEL ■	**EC**	ERS/DM	**15A** MEZZANINE
269	Annual CDER eSubmission Update: The Review Perspective	LEVEL ●	**ERS/DM**	RA	**9**
270	Defining Quality in Clinical Trials (2nd Annual Update)	LEVEL ■	**GCP**	CR/CS	**30CD**
271	Clinical Trial Metadata: Theory into Practice	LEVEL ◆	**IT**	ST	**15B** MEZZANINE
272	Biotechnology Preapproval Communications	LEVEL ●	**MA**	MC	**14A** MEZZANINE
273	Integrated Summaries and Beyond: Be Prepared	LEVEL ■	**MW**	ERS/DM	**31AB**
274	First-in-human Studies	LEVEL ■	**NC**	CR/CS	**10**
275	Regulatory Requirements for Natural Health Products/Herbal Medicinal Products in North America and the EU	LEVEL ●	**NHP**	RA	**11A**
276	Challenges of R&D Outsourcing in Japan: Successful NDA Preparation, and Strategy Planning Area for Global Development	LEVEL ■	**OS**	RD	**8**
277	Deal Makers and Deal Breakers: What Venture Capital Firms Look for in Drug Development Plans and How Applicants Succeed (or Fail) in Winning Funding	LEVEL ■	**PM/FI 1**	RD	**2**
278	Bringing Out the Best in Leaders, Teams, and Relationships	LEVEL ■	**PM/FI 2**	TR/PD	**4**
279	Collaborative for Pharmacist Care Patient Services	LEVEL ●	**PP**	CP	**32AB**
280	*Regulatory Affairs Plenary Session:* Meet the Regulators	LEVEL ●	**RA**	–	**6AB**
281	Drug Regulation in Nigeria and Kenya	LEVEL ●	**RD**	RA	**14B** MEZZANINE
282	Dose-finding Strategies for Early-phase Clinical Trials	LEVEL ■	**ST**	CR/CS	**16A** MEZZANINE
283	Critical Success Strategies for Professional Development	LEVEL ●	**TR/PD**	PM/FI	**16B** MEZZANINE
284	Computerized Systems Used in Clinical Research: Best Practices from Peach – Part 1 of 2	LEVEL ■	**VA**	GCP	**7A**
	TUESDAY 4:00 pm-5:30 pm				
285	Clinical Trial Oversight: Adverse Event Reporting and Handling of Incidental Findings	LEVEL ■	**AHC/IS**	CR/CS	**6C**
286	Adding Value to Early-stage Biotechnology Product Development	LEVEL ■	**BT**	NC	**1B**
287	Site Preferences for EDC: A Comparison of European and North American Perspectives	LEVEL ●	**CDM**	CP	**11B**
288	ICH Implementation Working Group	LEVEL ■	**CMC/GMP**	RA	**17A** MEZZANINE
289	Update on Clinical Safety and Pharmacovigilance in Japan	LEVEL ■	**CP**	RA	**30AB**
290	Adaptive Trial Design: Critical Path at Five Years	LEVEL ■	**CR/CS 1**	RA	**6D**
291	What if ClinOps Ran the EDC Project? Getting the Full Benefit	LEVEL ■	**CR/CS 2**	EC	**1A**
292	First-in-human Trial Designs: How Much is Too Much?	LEVEL ■	**CR/CS 3**	BT	**3**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	TUESDAY 4:00 pm-5:30 pm *continued*				
293	Regulatory Evaluation of Patient-reported Outcome (PRO) Measures Used in Clinical Trials	LEVEL ■	**EBM/IMP**	RA	**17B** MEZZANINE
294	Monitoring of Patient Compliance with eTechnologies	LEVEL ●	**EC**	CR/CS	**15A** MEZZANINE
295	Annual CDER eSubmission Update: The Technical Side	LEVEL ●	**ERS/DM**	IT	**9**
296	Developing Responsible Systems for the Ethical Review of Clinical Trials: A Global Approach Based on Ethical Principles and GCP	LEVEL ■	**GCP**	TR/PD	**30CD**
297	caBIG® Clinical Trials Management System (CTMS): A Standardized, Integrated Approach to Clinical Trials Management – A System Overview and Implementation Case Study	LEVEL ■	**IT**	EC	**15B** MEZZANINE
298	Medical Liaison Survey #5: Reassessment of Medical Liaison Program Demographics and Characteristics, Demonstration of Value, and Assessment of Resource Utilization	LEVEL ●	**MC**	IT	**14A** MEZZANINE
299A	Effective Publication Practices	LEVEL ■	**MW**	RA	**31AB**
299B	Evaluation of the Safety of Pharmaceuticals in the Environment (Water)	LEVEL ■	**NC**	CP	**10**
299C	Marketing and Registration in the EU and US	LEVEL ■	**NHP**	MA	**11A**
299D	Conducting Global Clinical Trials in Emerging Markets	LEVEL ■	**OS**	RA	**5A**
299E	Project and Portfolio Management Insights	LEVEL ■	**PM/FI 1**	RD	**4**
299F	A Search for the Most Effective PM Model in the Pharmaceutical Industry: PMs and PLs – Do We Need Both?	LEVEL ■	**PM/FI 2**	TR/PD	**2**
299G	Drug Counterfeiting International Fight: New Actions Taken in the US and in the World	LEVEL ■	**PP**	RA	**32AB**
299H	Sixth Update: Outlook for Changes in the Japanese Regulatory and Clinical Development Environment	LEVEL ■	**RA 1**	CR/CS	**6E**
299I	Special Protocol Assessments: Industry and FDA Perspectives	LEVEL ●	**RA 2**	CR/CS	**6F**
299J	The Importance of Developing a Comprehensive Regulatory Strategy for Emerging Pharmaceutical Companies	LEVEL ■	**RA 3**	RD	**8**
299K	Changes in the WHO Review of Psychoactive Substances for International Control	LEVEL ●	**RA 4**	PP	**7B**
299L	EMEA and NIH Transatlantic Approach on Pediatric Formulation	LEVEL ■	**RA 5**	CR/CS	**5B**
299M	Critical Decision Factors in the Allocation of Clinical Sites for Global Drug Development	LEVEL ◆	**RD**	AHC/IS	**14B** MEZZANINE
299N	Drug Development and Statistics in Asia: Issues and Challenges	LEVEL ●	**ST**	CR/CS	**16A** MEZZANINE
299O	Organizational Learning in the Web 2.0 Environment	LEVEL ■	**TR/PD**	IT	**16B** MEZZANINE
299P	Computerized Systems Used in Clinical Research: Best Practices from Peach – Part 2 of 2	LEVEL ●	**VA**	GCP	**7A**
	WEDNESDAY 8:30 am-10:00 am				
301	A CRO-sponsor Perspective on the Challenges of Site Selection: Panel Discussion	LEVEL ●	**AHC/IS**	CR/CS	**1A**
302	Managing First-in-man Studies	LEVEL ■	**BT**	RA	**1B**
303	Offshoring/Outsourcing CDM: Will It Last?	LEVEL ■	**CDM**	OS	**11B**
304	Quality by Design (QbD) for Biotechnology Products	LEVEL ■	**CMC/GMP**	BT	**17A** MEZZANINE
305	The EU Risk Management Plan and US Risk Evaluation and Mitigation Strategy (REMS): Company Perspectives and Experience	LEVEL ■	**CP 1**	RA	**33AB**
306	Pharmacovigilance Agreements	LEVEL ■	**CP 2**	PP	**30AB**
307	Understanding ePatients and Engaging Them in Clinical Research	LEVEL ■	**CR/CS 1**	AHC/IS	**6D**
308	Building Quality Research Teams	LEVEL ■	**CR/CS 2**	OS	**5B**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	WEDNESDAY 8:30 am-10:00 am *continued*				
309	The Good, the Bad, and the Surmountable: Overcoming Outsourcing Challenges in Latin America	LEVEL ■	**CR/CS 3**	OS	**3**
310	Update on the FDA's Electronic Case Report Form Submission Operational Data Model (ODM) Pilot	LEVEL ◆	**EC**	IT	**15A** MEZZANINE
311	Minimize the Cost – Maximize the Efficiency: Where Are We Going? What Are the Opportunities?	LEVEL ■	**ERS/DM 1**	–	**9**
312	Life-cycle Management: Where the Real Challenges Are – Module 3, IND, and NDA	LEVEL ■	**ERS/DM 2**	RA	**8**
313	Experience with GCPs Worldwide	LEVEL ■	**GCP 1**	CR/CS	**30CD**
314	Navigating the FDA Part 11 Guidance: Sponsor and Site Perspectives	LEVEL ■	**GCP 2**	AHC/IS	**11A**
315	Clinical Research Repositories as a Collaboration Platform	LEVEL ■	**IT**	EC	**15B** MEZZANINE
316	Safe Use of Drugs – Part 1 of 2: Successfully Communicating with Consumers	LEVEL ●	**MC**	RA	**14A** MEZZANINE
317	Writing for Patients: Communicating Clinical Trial Results	LEVEL ●	**MW**	CR/CS	**31AB**
318	Use and Usefulness of Juvenile Animal Studies in the Development of Pediatric Drugs	LEVEL ◆	**NC**	TR/PD	**10**
319	Harmonization Scope for Natural Health Products Regulatory Requirements	LEVEL ■	**NHP**	RA	**17B** MEZZANINE
320	What Does the Future Hold for CRO-sponsor Relationships? Results from a 2009 Industry Survey with a Focus on How Changes to CRO-sponsor Relationships over the Next Five Years Will Impact Innovation, Cost Savings, and Efficiency	LEVEL ■	**OS**	–	**5A**
321	Six Sigma: How to Leverage a Great Idea in the Complex Reality of Clinical Trials	LEVEL ■	**PM/FI 1**	CR/CS	**2**
322	Influence: Utilizing a Variety of Strategies in Pharmaceutical Drug Development	LEVEL ■	**PM/FI 2**	TR/PD	**4**
323	Personalized Medicine: 2009 Update	LEVEL ■	**PP**	RA	**32AB**
324	Global Simultaneous Development and Asia/Japan: Strategic and Regulatory Issues to Overcome	LEVEL ◆	**RA 1**	RD	**7B**
325	FDA Advisory Committees: New Challenges and Opportunities in the Post-FDAAA Era	LEVEL ■	**RA 2**	RD	**6E**
326	An Introduction to FDA/CDER's Safety First/Safe Use Postmarketing Safety Initiative	LEVEL ●	**RA 3**	CP	**6F**
327	FDA and EMEA Efforts to Harmonize Primary Endpoints	LEVEL ●	**RA 4**	EC	**6C**
328	Transforming the Research Paradigm: 21st Century Models to Unify Discovery Research and Clinical Care	LEVEL ■	**RD**	CR/CS	**14B** MEZZANINE
329	Statistical Issues in Design, Analysis, and Conduct of Thorough QT/QTC Trials	LEVEL ■	**ST**	CR/CS	**16A** MEZZANINE
330	Current Clinical Research Training in Japan	LEVEL ●	**TR/PD**	CR/CS	**16B** MEZZANINE
331	Auditing Risk-based Computer Validation Projects	LEVEL ■	**VA**	CDM	**7A**
	WEDNESDAY 10:30 am-12:00 pm				
332	The Influence of Cultural Diversity and Ethnopharmacology on Recruitment for Clinical Trials	LEVEL ●	**AHC/IS**	TR/PD	**1A**
333	Developing Safe and Effective Biological Medicines: Phase 2 and Beyond	LEVEL ■	**BT**	CR/CS	**1B**
334	Outsourced Data Management: How to Align Performance Expectations	LEVEL ■	**CDM**	OS	**11B**
335	Do Subvisible Particles Contribute to the Immunogenicity of Therapeutic Proteins? Gaps in Risk Evaluation and Mitigation	LEVEL ■	**CMC/GMP**	RA	**17A** MEZZANINE
336	Risk Management Best Practice: Integrating Risk Management Strategies into All Phases of the Product Life Cycle	LEVEL ●	**CP**	CR/CS	**30AB**
337	Can the Government Really Implement Cost-effective and Efficient Clinical Trials?	LEVEL ■	**CR/CS 1**	PM/FI	**3**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	WEDNESDAY 10:30 am-12:00 pm *continued*				
338	Optimizing Clinical Trial Material Supply Planning	LEVEL ■	**CR/CS 2**	CP	**5B**
339	Clinical Automation Systems in Phase 1 Clinical Research	LEVEL ■	**CR/CS 3**	IT	**6D**
340	CDISC Pilots	LEVEL ■	**EC**	ERS/DM	**15A** MEZZANINE
341	The Multilingual Dimension: Best Practices for Addressing Global Content and Global XML	LEVEL ●	**ERS/DM 1**	RA	**8**
342	What's the Meta with this Data? The Shifting Sands of Submission EDMS	LEVEL ■	**ERS/DM 2**	–	**9**
343	Dealing with an FDA Audit: What We Can Learn from Warning Letters and Audits	LEVEL ■	**GCP**	RA	**30CD**
344	Clinical Data Flow and Integration: Three Use Cases from an Information Technology Perspective	LEVEL ■	**IT**	EC	**15B** MEZZANINE
345	Developing Tactical Marketing Strategies from Market Research	LEVEL ●	**MA**	TR/PD	**33AB**
346	Safe Use of Drugs – Part 2 of 2: Communicating Effectively with Health-care Professionals	LEVEL ●	**MC**	RA	**14A** MEZZANINE
347	Changes in International Drug Development: Effects on Common Technical Document Preparation in Japan	LEVEL ■	**MW**	RA	**31AB**
348	New Approaches to Toxicity Testing to Support Pharmaceutical Development – Part 1 of 2: New Endpoints	LEVEL ●	**NC**	RA	**10**
349	Natural Health Products: Current Research and Development	LEVEL ■	**NHP**	RD	**17B** MEZZANINE
350	Faster, Better, Cheaper? Working Outside North America and Western Europe	LEVEL ■	**OS**	AHC/IS	**5A**
351	Virtual Project Teams: Best Practices for Improving Product Development Efficiency	LEVEL ■	**PM/FI 1**	OS	**4**
352	Managing Team Communications Globally	LEVEL ●	**PM/FI 2**	CR/CS	**2**
353	Patient-reported Outcomes Consortium: A Public-private Partnership	LEVEL ●	**PP**	RA	**32AB**
354	Regulatory Strategy in Global Drug Development	LEVEL ■	**RA 1**	CR/CS	**6E**
355	Recent Advancement of Advanced Therapy in the Asian Pacific Region	LEVEL ■	**RA 2**	BT	**7B**
356	Improving Regulatory Outcomes: What Are the Prospective and Retrospective Regulatory Strategies Companies Can Use to Improve the Quality of Development and Review?	LEVEL ■	**RA 3**	RD	**6F**
357	Regulatory Considerations for Subsequent Entry of Biologics in Canada	LEVEL ■	**RA 4**	BT	**7A**
358	Challenges in Developing and Commercializing Personalized Health-care Products	LEVEL ■	**RD**	EBM/IMP	**14B** MEZZANINE
359	Challenges in Noninferiority Studies	LEVEL ■	**ST**	CR/CS	**16A** MEZZANINE
360	Attracting and Training the Best Talent in the 21st Century: The Mix of Generations in the Workplace	LEVEL ●	**TR/PD**	–	**16B** MEZZANINE
361	Town Meeting: Validation Experts Respond to Your Questions and Concerns – OQ, IQ, PQ, and Testing Practices	LEVEL ●	**VA**	EC	**11A**
	WEDNESDAY 1:30 pm-3:00 pm				
362	Increasing Enrollment, Retention, and Compliance through Electronic Patient Payment and Communication Technologies	LEVEL ●	**AHC/IS**	EC	**1A**
363	Opportunities for the Treatment of Rare Diseases	LEVEL ■	**BT**	CR/CS	**1B**
364	WHO Drug Dictionary Utilization	LEVEL ■	**CDM**	CP	**11B**
365	Considerations Applicable to the Drug Development Phase	LEVEL ●	**CMC/GMP**	RA	**17A** MEZZANINE
366	Quantitative Benefit-risk Profile Evaluation Methods: Which to Use?	LEVEL ■	**CP**	RA	**30AB**
367	Clinical Trials and Tribulations: Influences and Challenges of Patient Recruitment and Retention Including Perspectives from Participants, Families, and Research Study Organizers	LEVEL ■	**CR/CS 1**	AHC/IS	**3**
368	Multiregional Clinical Trials	LEVEL ■	**CR/CS 2**	RA	**6C**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	WEDNESDAY 1:30 pm-3:00 pm *continued*				
369	Early-phase Clinical Trials: Confronting the Guinea-pigging Misconception	LEVEL ■	**CR/CS 3**	BT	**6D**
370	The Keys to Establishing Best Practices for Accelerated Study Start-up	LEVEL ■	**CR/CS 4**	GCP	**5B**
371	Views of the CDISC Standards in a Submission	LEVEL ●	**EC**	ERS/DM	**15A** MEZZANINE
372	International eCTDs: An Update on Regulatory Authority Experience	LEVEL ●	**ERS/DM**	IT	**9**
373	Town Meeting: Good Auditing Practices – Internal Audits, External Audits, and the Audit Report	LEVEL ●	**GCP**	VA	**30CD**
374	CDISC SDTM Data Conversion: Reusability and Repeatability	LEVEL ■	**IT**	CDM	**15B** MEZZANINE
375	Furthering the Pharmaceutical Industry's Engagement in Electronic Social Media: A Regulatory Roadmap	LEVEL ■	**MA**	PP	**33AB**
376	Business Continuity Planning within Medical Communications Departments	LEVEL ●	**MC**	MA	**14A** MEZZANINE
377	Authoring CTD/eCTD Submissions: Updates and Case Studies	LEVEL ■	**MW**	ERS/DM	**31AB**
378	New Approaches to Toxicity Testing to Support Pharmaceutical Development – Part 2 of 2: New Models	LEVEL ■	**NC**	CP	**10**
379	Safety before and after Approval of Natural Health Products	LEVEL ■	**NHP**	CP	**17B** MEZZANINE
380	Outsourcing Strategies for Clinical Trial Activities in Central and Latin America	LEVEL ■	**OS**	MC	**5A**
381	*Project Management Plenary Session:* Future Directions of Project Management in the Life Sciences	LEVEL ●	**PM/FI**	CR/CS	**2**
382	Pharmacovigilance and Product Liability	LEVEL ■	**PP**	RA	**32AB**
383	FDA Meetings: Understanding the Process and Maximizing Success	LEVEL ●	**RA 1**	CR/CS	**6E**
384	Connect the Dots: The Map from Labeling Development to Marketing Claim	LEVEL ●	**RA 2**	AD	**7B**
385	US-EU-Japan: Exchange of Information among Regulators from ICH Regions	LEVEL ●	**RA 3**	PP	**6F**
386	Measuring Benefit and Balancing Risk: Strategies for the Benefit-risk Assessment of New Medicines in a Risk-averse Environment	LEVEL ■	**RA 4**	RD	**8**
387	International Cooperation on GMP/GCP Inspections	LEVEL ●	**RA 5**	GCP	**4**
388	Global Clinical Trials: Destination India	LEVEL ●	**RA 6**	CR/CS	**7A**
389	Use of Metrics for R&D Strategizing: Building a Success Matrix	LEVEL ■	**RD**	ST	**14B** MEZZANINE
390	Biomarkers in Oncology Trials	LEVEL ■	**ST**	CR/CS	**16A** MEZZANINE
391	How Do We Train Our Project Managers to Be Leaders Regardless of Formal Status?	LEVEL ■	**TR/PD**	PM/FI	**16B** MEZZANINE
392	Compliance in the Age of Automatic Updates and Virtualization	LEVEL ■	**VA**	IT	**11A**
	WEDNESDAY 3:30 pm-5:00 pm				
393	Nurture the Clinical Trial Leader of Tomorrow	LEVEL ■	**AHC/IS 1**	CR/CS	**1A**
394	Addressing Suicidality in Clinical Trials	LEVEL ■	**AHC/IS 2**	EC	**6C**
395	RNAi Therapeutics: From Concept to Implementation	LEVEL ■	**BT**	NC	**1B**
396	Mega Trials: Planning, Design, Development, Monitoring, and Overall Management	LEVEL ■	**CDM**	EC	**11B**
397	Considerations Applicable to the Drug Manufacturing/Marketing Phase	LEVEL ●	**CMC/GMP**	CP	**17A** MEZZANINE
398	Observational Pharmacovigilance: Analysis Methods and Business Practices across Drug Safety Stakeholders	LEVEL ■	**CP 1**	–	**30AB**
399A	Recent Advancement of Risk Management in the Asian Pacific Region	LEVEL ■	**CP 2**	RA	**33AB**
399B	Improving Patient Recruitment and Retention Planning: Global Perspectives on What Sites Need from Sponsors and CROs	LEVEL ■	**CR/CS 1**	AHC/IS	**3**
399C	Cost Containment: Strategies for Efficient Clinical Research Practices	LEVEL ■	**CR/CS 2**	PM/FI	**6D**
399D	High-impact Quality Protocols	LEVEL ■	**CR/CS 3**	ST	**5B**
399E	Leveraging Electronic Health Records in Clinical Research	LEVEL ■	**EC**	IT	**9**
399F	Creation of Marketing Applications for the ASEAN Region	LEVEL ■	**ERS/DM 1**	RA	**15A** MEZZANINE

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	WEDNESDAY 3:30 pm-5:00 pm *continued*				
399G	Convergence of Data and Document Standards: Where Does CDISC Meet eCTD?	LEVEL ●	**ERS/DM 2**	CDM	**8**
399H	Implementing Effective Quality Risk Management from an Organizational Perspective	LEVEL ■	**GCP**	CP	**30CD**
399I	Empowering the Enterprise with Software as a Service (SaaS)	LEVEL ■	**IT**	OS	**15B** MEZZANINE
399J	New Drug Information Databases at the National Library of Medicine	LEVEL ●	**MC**	TR/PD	**14A** MEZZANINE
399K	Globally Sourced Medical Writing: Windfall or Pitfall?	LEVEL ■	**MW**	CR/CS	**31AB**
399L	Potentially Genotoxic Impurities, Metabolites, and Degradates: The Need for an Integrated Approach to Safety Assessment	LEVEL ●	**NC**	CP	**10**
399M	Current Status and Future Development of Phytomedicines: International Perspective	LEVEL ■	**NHP**	RA	**17B** MEZZANINE
399N	Latin America: Leveraging Regional Strengths while Proactively Ensuring Quality	LEVEL ●	**OS**	CR/CS	**5A**
399O	Integrated Business Modeling: Where Improvements in Productivity Happen by Leveraging Better Forecasting Tools, Techniques, and Processes	LEVEL ■	**PM/FI 1**	IT	**4**
399P	Challenges in Project Management in Front-loading Key Activities for Rapid Drug Development	LEVEL ■	**PM/FI 2**	CR/CS	**2**
399Q	Clinical Trial Registries: Panacea or Pablum?	LEVEL ■	**PP**	CP	**32AB**
399R	Drug Registrations and Clinical Trials in Emerging Pharma Countries and N-11 Countries	LEVEL ■	**RA 1**	CR/CS	**7B**
399S	Asian Regulatory Collaboration Update for Multinational Clinical Trials	LEVEL ■	**RA 2**	RD	**7A**
399T	Good Review Management Practices and Good Communication Practices Leading to Successful NDAs	LEVEL ■	**RA 3**	RD	**6F**
399U	Relative Efficacy/Effectiveness: A New Interface between Drug Regulation and Health Technology Assessment	LEVEL ■	**RA 4**	CP	**6E**
399V	Managing Development Portfolios in a Safety-heightened Environment	LEVEL ◆	**RD**	RA	**14B** MEZZANINE
399W	Issues with Subgroup Analyses in Controlled Clinical Trials	LEVEL ◆	**ST**	–	**16A** MEZZANINE
399X	eLearning and Distance Training	LEVEL ■	**TR/PD**	–	**16B** MEZZANINE
399Y	An International Perspective on the Use of Computerized Systems in Clinical Investigations	LEVEL ●	**VA**	GCP	**11A**
	THURSDAY 8:30 am-10:00 am				
401	Human Subject Protection Programs: Complex Issues for the IRB	LEVEL ■	**AHC/IS**	GCP	**1A**
402	Recent Advancement of Emerging Technology in the Asia Pacific Region	LEVEL ■	**BT**	RA	**1B**
403	Minimizing Data Queries in Clinical Trials	LEVEL ●	**CDM**	CR/CS	**11B**
404	The Role of Excipients and Quality by Design (QbD)	LEVEL ■	**CMC/GMP**	RA	**17A** MEZZANINE
405	Pregnancy Registries: Perspectives on a Unique Risk Management Tool	LEVEL ●	**CP**	RA	**10**
406	Addressing Three Major Challenges in Investigator-initiated Trials: Process, Contracts, and Culture	LEVEL ●	**CR/CS 1**	AHC/IS	**5B**
407	Optimizing the Process of Study Feasibility: Ensuring Better Outcomes for All Stakeholders	LEVEL ■	**CR/CS 2**	AHC/IS	**6D**
408	How Much Do Electronic Diaries Improve the Quality of Clinical Research?	LEVEL ■	**EC**	CR/CS	**15A** MEZZANINE
409	Addressing Document Collaboration Challenges in Drug Development	LEVEL ■	**ERS/DM**	IT	**9**
410	Informed Consent: Promise, Pledge, Contract or Platitude?	LEVEL ■	**GCP**	PP	**8**
411	Implementing Health Informatics Solutions in the Life Sciences Industry	LEVEL ■	**IT**	CDM	**15B** MEZZANINE
412	Pharmacoeconomics and Health Outcomes Primer for the Medical Communications Professional	LEVEL ●	**MC**	MW	**14B** MEZZANINE
413	Pharmacovigilance from the Medical Writer Perspective	LEVEL ●	**MW**	CP	**6E**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
	THURSDAY 8:30 am-10:00 am *continued*				
414	Updating ICH S6 Guidance on Preclinical Safety Evaluation of Biotechnology-derived Pharmaceuticals	LEVEL ■	**NC**	BT	**14A** MEZZANINE
415	Roadmap from Preclinical to Health Claims in Natural Health Products	LEVEL ●	**NHP**	CR/CS	**17B** MEZZANINE
416	Assessing the Security Practices of Business Partners	LEVEL ●	**OS 1**	IT	**5A**
417	Central Laboratory Services in Emerging Markets: Optimizing Results through Laboratory "Glocalization"	LEVEL ■	**OS 2**	CR/CS	**4**
418	Preserving Relationships in the Face of Divergent Project Expectations	LEVEL ●	**PM/FI 1**	CR/CS	**2**
419	Proactive Management of Project Financials: Understand Scope of Work, Cost to Complete, and Scope Change	LEVEL ●	**PM/FI 2**	CR/CS	**3**
420	New Paradigms in Drug Regulation?	LEVEL ■	**PP**	RA	**7A**
421	CDER Town Meeting – Part 1 of 2	LEVEL ●	**RA 1**	CR/CS	**6AB**
422	Efforts Promoting Global Clinical Trials Environment in Korea	LEVEL ■	**RA 2**	CR/CS	**7B**
423	Women in HIV Trials: A Comprehensive Review and Meta-analysis	LEVEL ■	**ST**	EBM/IMP	**16A** MEZZANINE
424	Overview of Drug Development and Career Opportunities for Emerging Professionals	LEVEL ●	**TR/PD**	CR/CS	**16B** MEZZANINE
425	Validation Challenges with Modern System Development Tools and Methodologies	LEVEL ■	**VA**	IT	**11A**
	THURSDAY 10:30 am-12:00 pm				
426	Data Management Challenges within Academic Research Centers	LEVEL ●	**AHC/IS**	CDM	**1A**
427	Preclinical Safety Evaluation of Novel Adjuvants and Vaccines	LEVEL ■	**BT**	NC	**1B**
428	MedDRA® and CTCAE: Two Terminologies and Their Applications	LEVEL ■	**CDM**	CP	**11B**
429	Design Space: Unique Approaches	LEVEL ■	**CMC/GMP**	RA	**17A** MEZZANINE
430	A Registry by Any Other Name	LEVEL ●	**CP**	EBM/IMP	**10**
431	Remote Source Document Verification (SDV): Case Studies in Implementation – The Processes Used and Savings Achieved for Pivotal Phase 2 and 3 Trials	LEVEL ■	**CR/CS 1**	EC	**6D**
432	Investigator Outreach Analysis: Using Performance and Survey Data as Drivers of Investigator Performance	LEVEL ■	**CR/CS 2**	AHC/IS	**5B**
433	Standards Shock Therapy: Monitoring the State of CDISC and HL7 for Clinical Research and Regulatory Submissions	LEVEL ◆	**EC**	ERS/DM	**15A** MEZZANINE
434	Pursuing Standards to Enhance eCTD Deliverables: Pharmaceutical and Research Manufacturer Association Electronic Regulatory Submissions (PhRMA ERS) Group Annual Update	LEVEL ■	**ERS/DM**	RA	**9**
435	Virtual Realities: Quality Considerations when Using Outsource Providers	LEVEL ■	**GCP**	RA	**8**
436	Breaking Boundaries: Making Sense of Your Data through Collaborative Visualization	LEVEL ■	**IT**	CP	**15B** MEZZANINE
437	Targeted Disease Approach Using Natural Health Products	LEVEL ■	**NHP**	CR/CS	**17B** MEZZANINE
438	Go East, Go West: Outsourcing in Asia	LEVEL ■	**OS**	RA	**5A**
439	Global Working Environment Synergy: When an American Team Leader, Japanese Project Manager, and European Team Members Work Together	LEVEL ■	**PM/FI 1**	RD	**3**
440	Improving the Business of Science: Process Improvement and Metrics that Matter	LEVEL ■	**PM/FI 2**	–	**2**
441	Human Research Ethics in an Environment of Global Clinical Trials	LEVEL ■	**PP**	GCP	**7A**
442	CDER Town Meeting – Part 2 of 2	LEVEL ●	**RA 1**	CR/CS	**6AB**
443	Pregnancy and Lactation Labeling: The Past, Present, and Future	LEVEL ●	**RA 2**	CP	**7B**
444	What Statisticians Need to Know about CDISC	LEVEL ■	**ST**	EC	**16A** MEZZANINE
445	Presenting ... YOU! Tips, Tricks, and Advice on Making You and Your Presentations Unforgettable	LEVEL ●	**TR/PD**	–	**16B** MEZZANINE
446	Unique Validation Challenges in the Clinical Area	LEVEL ■	**VA**	GCP	**11A**

Meeting Schedule by Interest Area

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
AD	**Advertising**				
Monday	10:30 am-12:00 pm	**101**	*AD/MA/MC Mega Track Plenary Session:* Pharma in the New Age of Transparency	LEVEL ●	**30AB**
Monday	1:30 pm-3:00 pm	**126**	FDA Enforcement Update	LEVEL ●	**14A** MEZZANINE
Monday	3:30 pm-5:00 pm	**152**	Office of Inspector General (OIG) Settlements: New Integrity Obligations for Pharmaceutical Companies	LEVEL ●	**14A** MEZZANINE
Tuesday	8:00 am-9:30 am	**201**	Update on Direct-to-consumer Advertising	LEVEL ●	**14A** MEZZANINE
Tuesday	10:00 am-11:30 am	**229**	Introduction to Pharmaceutical Marketing Primer	LEVEL ●	**14A** MEZZANINE
AHC/IS	**Academic Health Centers/Investigator Sites**				
Monday	10:30 am-12:00 pm	**102**	How Investigator Budgets Impact Patient Enrollment and Retention and How to Improve Sponsor/CRO/Site Processes to Increase Productivity	LEVEL ■	**1A**
Monday	1:30 pm-3:00 pm	**127**	Disease Insights: A Truly Global Approach to Accelerating Patient Recruitment and Retention	LEVEL ◆	**1A**
Monday	3:30 pm-5:00 pm	**153**	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**6AB**
Tuesday	8:00 am-9:30 am	**202**	Health Reform, and FDAAA: Impact on FDA, Industry, Health Professionals, Consumers, Payers, and Other Stakeholders	LEVEL ■	**6C**
Tuesday	10:00 am-11:30 am	**230**	The Impact of FDAAA and Health Information Technology on Drug Safety, Standards, and Data Stewardship: 2009 Update and Future Plans	LEVEL ■	**6C**
Tuesday	2:00 pm-3:30 pm	**257**	Biomarkers for Drug Safety and Development: Perspectives from the Institute of Medicine and Industry	LEVEL ●	**6C**
Tuesday	4:00 pm-5:30 pm	**285**	Clinical Trial Oversight: Adverse Event Reporting and Handling of Incidental Findings	LEVEL ■	**6C**
Wednesday	8:30 am-10:00 am	**301**	A CRO-sponsor Perspective on the Challenges of Site Selection: Panel Discussion	LEVEL ●	**1A**
Wednesday	10:30 am-12:00 pm	**332**	The Influence of Cultural Diversity and Ethnopharmacology on Recruitment for Clinical Trials	LEVEL ●	**1A**
Wednesday	1:30 pm-3:00 pm	**362**	Increasing Enrollment, Retention, and Compliance through Electronic Patient Payment and Communication Technologies	LEVEL ●	**1A**
Wednesday	3:30 pm-5:00 pm	**393**	Nurture the Clinical Trial Leader of Tomorrow	LEVEL ■	**1A**
Wednesday	3:30 pm-5:00 pm	**394**	Addressing Suicidality in Clinical Trials	LEVEL ■	**6C**
Thursday	8:30 am-10:00 am	**401**	Human Subject Protection Programs: Complex Issues for the IRB	LEVEL ■	**1A**
Thursday	10:30 am-12:00 pm	**426**	Data Management Challenges within Academic Research Centers	LEVEL ●	**1A**
BT	**Biotechnology**				
Monday	10:30 am-12:00 pm	**103**	Hot Topics in Biotechnology	LEVEL ●	**1B**
Monday	1:30 pm-3:00 pm	**128**	Regulatory Methods to Facilitate the Approval of Biological Products to Address Pandemic Influenza	LEVEL ■	**1B**
Monday	3:30 pm-5:00 pm	**154**	Immunogenicity: Strategies for Testing and Evaluation	LEVEL ■	**1B**
Tuesday	8:00 am-9:30 am	**203**	Countering Bioterrorism: Regulatory Methods Designed to Speed the Availability of Biological Products	LEVEL ■	**1B**
Tuesday	10:00 am-11:30 am	**231**	Regulatory Challenges Related to the Development of Second Generation Therapeutic Proteins	LEVEL ■	**1B**
Tuesday	2:00 pm-3:30 pm	**258**	Follow-on Biologics: Ensuring Quality, Efficacy, and Safety	LEVEL ■	**1B**
Tuesday	4:00 pm-5:30 pm	**286**	Adding Value to Early-stage Biotechnology Product Development	LEVEL ■	**1B**
Wednesday	8:30 am-10:00 am	**302**	Managing First-in-man Studies	LEVEL ■	**1B**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
	BT – Biotechnology *continued*				
Wednesday	10:30 am-12:00 pm	**333**	Developing Safe and Effective Biological Medicines: Phase 2 and Beyond	LEVEL ■	**1B**
Wednesday	1:30 pm-3:00 pm	**363**	Opportunities for the Treatment of Rare Diseases	LEVEL ■	**1B**
Wednesday	3:30 pm-5:00 pm	**395**	RNAi Therapeutics: From Concept to Implementation	LEVEL ■	**1B**
Thursday	8:30 am-10:00 am	**402**	Recent Advancement of Emerging Technology in the Asia Pacific Region	LEVEL ■	**1B**
Thursday	10:30 am-12:00 pm	**427**	Preclinical Safety Evaluation of Novel Adjuvants and Vaccines	LEVEL ■	**1B**
CDM	**Clinical Data Management**				
Monday	10:30 am-12:00 pm	**104**	Getting that Fresh, Clean Feeling: Defining "Clean" Data	LEVEL ■	**11B**
Monday	1:30 pm-3:00 pm	**129**	CDASH/Standards and the Practical Implications	LEVEL ●	**8**
Monday	3:30 pm-5:00 pm	**155**	Metrics and Their Benefits	LEVEL ●	**11B**
Tuesday	8:00 am-9:30 am	**204**	Future of Data Management/Evolving Role of Data Management	LEVEL ■	**11B**
Tuesday	10:00 am-11:30 am	**232**	From Case Report Form to CDISC SDTM: Data Standards	LEVEL ●	**11B**
Tuesday	2:00 pm-3:30 pm	**259**	Metric-based Management and eClinical Trials	LEVEL ■	**11B**
Tuesday	4:00 pm-5:30 pm	**287**	Site Preferences for EDC: A Comparison of European and North American Perspectives	LEVEL ●	**11B**
Wednesday	8:30 am-10:00 am	**303**	Offshoring/Outsourcing CDM: Will It Last?	LEVEL ■	**11B**
Wednesday	10:30 am-12:00 pm	**334**	Outsourced Data Management: How to Align Performance Expectations	LEVEL ■	**11B**
Wednesday	1:30 pm-3:00 pm	**364**	WHO Drug Dictionary Utilization	LEVEL ■	**11B**
Wednesday	3:30 pm-5:00 pm	**396**	Mega Trials: Planning, Design, Development, Monitoring, and Overall Management	LEVEL ■	**11B**
Thursday	8:30 am-10:00 am	**403**	Minimizing Data Queries in Clinical Trials	LEVEL ●	**11B**
Thursday	10:30 am-12:00 pm	**428**	MedDRA® and CTCAE: Two Terminologies and Their Applications	LEVEL ■	**11B**
CMC/GMP	**Chemistry, Manufacturing, and Controls/Good Manufacturing Practices**				
Tuesday	8:00 am-9:30 am	**205**	Quality by Design (QbD): Linking Quality to Efficacy – Part 1 of 2	LEVEL ■	**17A** MEZZANINE
Tuesday	10:00 am-11:30 am	**233**	Quality by Design (QbD): Linking Quality to Safety – Part 2 of 2	LEVEL ■	**17A** MEZZANINE
Tuesday	2:00 pm-3:30 pm	**260**	CMC Regulatory Development and Updates	LEVEL ●	**17A** MEZZANINE
Tuesday	4:00 pm-5:30 pm	**288**	ICH Implementation Working Group	LEVEL ■	**17A** MEZZANINE
Wednesday	8:30 am-10:00 am	**304**	Quality by Design (QbD) for Biotechnology Products	LEVEL ■	**17A** MEZZANINE
Wednesday	10:30 am-12:00 pm	**335**	Do Subvisible Particles Contribute to the Immunogenicity of Therapeutic Proteins? Gaps in Risk Evaluation and Mitigation	LEVEL ■	**17A** MEZZANINE
Wednesday	1:30 pm-3:00 pm	**365**	Considerations Applicable to the Drug Development Phase	LEVEL ●	**17A** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**397**	Considerations Applicable to the Drug Manufacturing/Marketing Phase	LEVEL ●	**17A** MEZZANINE
Thursday	8:30 am-10:00 am	**404**	The Role of Excipients and Quality by Design (QbD)	LEVEL ■	**17A** MEZZANINE
Thursday	10:30 am-12:00 pm	**429**	Design Space: Unique Approaches	LEVEL ■	**17A** MEZZANINE
CP	**Clinical Safety and Pharmacovigilance**				
Monday	10:30 am-12:00 pm	**105**	The ASTER Pilot One Year Later: Different Approaches to Spontaneous Reporting – A New Business Model	LEVEL ■	**33AB**
Monday	1:30 pm-3:00 pm	**130**	Modernization of FDA Postmarket Adverse Event Information Management	LEVEL ■	**30AB**
Monday	1:30 pm-3:00 pm	**131**	Issues and Challenges Associated with the PSUR Process	LEVEL ■	**33AB**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
			CP – Clinical Safety and Pharmacovigilance *continued*		
Monday	3:30 pm-5:00 pm	**153**	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**6AB**
Tuesday	8:00 am-9:30 am	**206**	Pharmacovigilance Organization Models: How New Regulatory and Business Needs Are Changing the Pharmacovigilance Department, and How to Design an Effective Organization	LEVEL ■	**33AB**
Tuesday	8:00 am-9:30 am	**207**	Development Safety Update Report (ICH E2F): Update, Current Status, and Major Provisions	LEVEL ■	**30AB**
Tuesday	10:00 am-11:30 am	**234**	FDA Sentinel Initiative	LEVEL ■	**30AB**
Tuesday	10:00 am-11:30 am	**235**	Early Signal Information from the Regulatory Authorities: Implications for the Public and the Need for Risk Benefit Communication to Enhance Understanding	LEVEL ■	**33AB**
Tuesday	2:00 pm-3:30 pm	**261**	Pharmacovigilance on a Budget	LEVEL ■	**30AB**
Tuesday	2:00 pm-3:30 pm	**262**	Signal Detection and Data Mining in Pharmacovigilance: Motives, Methods, and Management	LEVEL ■	**33AB**
Tuesday	4:00 pm-5:30 pm	**289**	Update on Clinical Safety and Pharmacovigilance in Japan	LEVEL ■	**30AB**
Wednesday	8:30 am-10:00 am	**305**	The EU Risk Management Plan and US Risk Evaluation and Mitigation Strategy (REMS): Company Perspectives and Experience	LEVEL ■	**33AB**
Wednesday	8:30 am-10:00 am	**306**	Pharmacovigilance Agreements	LEVEL ■	**30AB**
Wednesday	10:30 am-12:00 pm	**336**	Risk Management Best Practice: Integrating Risk Management Strategies into All Phases of the Product Life Cycle	LEVEL ●	**30AB**
Wednesday	1:30 pm-3:00 pm	**366**	Quantitative Benefit-risk Profile Evaluation Methods: Which to Use?	LEVEL ■	**30AB**
Wednesday	3:30 pm-5:00 pm	**398**	Observational Pharmacovigilance: Analysis Methods and Business Practices across Drug Safety Stakeholders	LEVEL ■	**30AB**
Wednesday	3:30 pm-5:00 pm	**399A**	Recent Advancement of Risk Management in the Asian Pacific Region	LEVEL ■	**33AB**
Thursday	8:30 am-10:00 am	**405**	Pregnancy Registries: Perspectives on a Unique Risk Management Tool	LEVEL ●	**10**
Thursday	10:30 am-12:00 pm	**430**	A Registry by Any Other Name	LEVEL ●	**10**
CR/CS	**Clinical Research and Development/Clinical Supplies**				
Monday	10:30 am-12:00 pm	**106**	Understanding Clinical Trial Volunteer Experiences and Physician Referral to Clinical Trials	LEVEL ●	**5A**
Monday	10:30 am-12:00 pm	**107**	Effective Operational Planning for Adaptive Clinical Trials	LEVEL ■	**3**
Monday	10:30 am-12:00 pm	**108**	Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done?	LEVEL ■	**6C**
Monday	10:30 am-12:00 pm	**109**	Improving Safety with Every Step: The Patient Perspective	LEVEL ●	**6D**
Monday	1:30 pm-3:00 pm	**132**	The State of Subject Recruitment in the US: A Town Hall Discussion	LEVEL ■	**6C**
Monday	1:30 pm-3:00 pm	**133**	CTMS Implementation: The Next Steps	LEVEL ■	**5B**
Monday	1:30 pm-3:00 pm	**134**	Informed Country Selection for Multinational Clinical Studies: One Size Does Not Fit All	LEVEL ■	**6D**
Monday	1:30 pm-3:00 pm	**135**	Is There Really Such a Thing as a Strategic Partnership?	LEVEL ◆	**3**
Monday	3:30 pm-5:00 pm	**153**	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**6AB**
Tuesday	8:00 am-9:30 am	**208**	Using Performance Metrics to Improve Clinical Trial Performance and Reduce Enrollment Risk	LEVEL ■	**1A**
Tuesday	8:00 am-9:30 am	**209**	Understanding the Complexities of Latin American Borders and Local Regulations to Get the Clinical Trial Material into the Country	LEVEL ●	**5B**
Tuesday	8:00 am-9:30 am	**210**	Medical Imaging: Update on PhRMA Consortium Initiatives	LEVEL ●	**6D**
Tuesday	10:00 am-11:30 am	**236**	Ethical Rewards for Patients in Clinical Studies: A Scientific Approach to Patient Retention	LEVEL ■	**6D**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
	CR/CS – Clinical Research and Development/Clinical Supplies *continued*				
Tuesday	10:00 am-11:30 am	**237**	Building a Clinical Operations Department through Rapid Organizational Growth	LEVEL ◆	**5B**
Tuesday	10:00 am-11:30 am	**238**	Is It Truly Informed Consent?	LEVEL ■	**1A**
Tuesday	2:00 pm-3:30 pm	**263**	Meeting the Health Needs of Minorities through Clinical Research: Engaging Minority Investigators and Recruiting Diverse Patient Populations	LEVEL ■	**6D**
Tuesday	2:00 pm-3:30 pm	**264**	Clinical Supplies Management under Uncertainty	LEVEL ■	**1A**
Tuesday	2:00 pm-3:30 pm	**265**	Creating a Collaborative Environment: Working Together at Monitoring Visits	LEVEL ●	**5B**
Tuesday	2:00 pm-3:30 pm	**266**	Site Relationship Management (SRM) Initiatives for Improving Site Performance: One Year Later	LEVEL ◆	**3**
Tuesday	4:00 pm-5:30 pm	**290**	Adaptive Trial Design: Critical Path at Five Years	LEVEL ■	**6D**
Tuesday	4:00 pm-5:30 pm	**291**	What if ClinOps Ran the EDC Project? Getting the Full Benefit	LEVEL ■	**1A**
Tuesday	4:00 pm-5:30 pm	**292**	First-in-human Trial Designs: How Much is Too Much?	LEVEL ■	**3**
Wednesday	8:30 am-10:00 am	**307**	Understanding ePatients and Engaging Them in Clinical Research	LEVEL ■	**6D**
Wednesday	8:30 am-10:00 am	**308**	Building Quality Research Teams	LEVEL ■	**5B**
Wednesday	8:30 am-10:00 am	**309**	The Good, the Bad, and the Surmountable: Overcoming Outsourcing Challenges in Latin America	LEVEL ■	**3**
Wednesday	10:30 am-12:00 pm	**337**	Can the Government Really Implement Cost-effective and Efficient Clinical Trials?	LEVEL ■	**3**
Wednesday	10:30 am-12:00 pm	**338**	Optimizing Clinical Trial Material Supply Planning	LEVEL ■	**5B**
Wednesday	10:30 am-12:00 pm	**339**	Clinical Automation Systems in Phase 1 Clinical Research	LEVEL ■	**6D**
Wednesday	1:30 pm-3:00 pm	**367**	Clinical Trials and Tribulations: Influences and Challenges of Patient Recruitment and Retention Including Perspectives from Participants, Families, and Research Study Organizers	LEVEL ■	**3**
Wednesday	1:30 pm-3:00 pm	**368**	Multiregional Clinical Trials	LEVEL ■	**6C**
Wednesday	1:30 pm-3:00 pm	**369**	Early-phase Clinical Trials: Confronting the Guinea-pigging Misconception	LEVEL ■	**6D**
Wednesday	1:30 pm-3:00 pm	**370**	The Keys to Establishing Best Practices for Accelerated Study Start-up	LEVEL ■	**5B**
Wednesday	3:30 pm-5:00 pm	**399B**	Improving Patient Recruitment and Retention Planning: Global Perspectives on What Sites Need from Sponsors and CROs	LEVEL ■	**3**
Wednesday	3:30 pm-5:00 pm	**399C**	Cost Containment: Strategies for Efficient Clinical Research Practices	LEVEL ■	**6D**
Wednesday	3:30 pm-5:00 pm	**399D**	High-impact Quality Protocols	LEVEL ■	**5B**
Thursday	8:30 am-10:00 am	**406**	Addressing Three Major Challenges in Investigator-initiated Trials: Process, Contracts, and Culture	LEVEL ●	**5B**
Thursday	8:30 am-10:00 am	**407**	Optimizing the Process of Study Feasibility: Ensuring Better Outcomes for All Stakeholders	LEVEL ■	**6D**
Thursday	10:30 am-12:00 pm	**431**	Remote Source Document Verification (SDV): Case Studies in Implementation – The Processes Used and Savings Achieved for Pivotal Phase 2 and 3 Trials	LEVEL ■	**6D**
Thursday	10:30 am-12:00 pm	**432**	Investigator Outreach Analysis: Using Performance and Survey Data as Drivers of Investigator Performance	LEVEL ■	**5B**
EBM/IMP	**Evidence-based Medicines/Impact (Impact of Medical Products and Therapies)**				
Tuesday	8:00 am-9:30 am	**211**	Beyond the QT Interval: Regulatory Perspective on the Use of Surrogates in Premarket Safety and Risk/Benefit Evaluation	LEVEL ●	**17B** MEZZANINE
Tuesday	10:00 am-11:30 am	**239**	Understanding Comparative Effectiveness Research: Policy, Implementation, and Quality	LEVEL ●	**17B** MEZZANINE
Tuesday	2:00 pm-3:30 pm	**267**	Pharmacoeconomics, Cost Effectiveness, and Outcome Analysis for Personalized Medicine	LEVEL ■	**17B** MEZZANINE
Tuesday	4:00 pm-5:30 pm	**293**	Regulatory Evaluation of Patient-reported Outcome (PRO) Measures Used in Clinical Trials	LEVEL ■	**17B** MEZZANINE

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
EC	**eClinical**				
Monday	3:30 pm-5:00 pm	**156**	A La Carte or Prix Fixe: The Right Menu for Clinical Trials Technology	LEVEL ■	**11A**
Tuesday	8:00 am-9:30 am	**212**	Standards in Your Future: How SAFE-BioPharma, IHE, and CDISC Are Collaborating to Improve Safety Reporting	LEVEL ■	**15A** MEZZANINE
Tuesday	10:00 am-11:30 am	**240**	Accelerating Site Initiation through a Shared Collaborative Platform	LEVEL ■	**15A** MEZZANINE
Tuesday	2:00 pm-3:30 pm	**268**	Structured Product Labeling (SPL) Indexing at FDA: Where We Are Today and Towards the Future	LEVEL ■	**15A** MEZZANINE
Tuesday	4:00 pm-5:30 pm	**294**	Monitoring of Patient Compliance with eTechnologies	LEVEL ●	**15A** MEZZANINE
Wednesday	8:30 am-10:00 am	**310**	Update on the FDA's Electronic Case Report Form Submission Operational Data Model (ODM) Pilot	LEVEL ◆	**15A** MEZZANINE
Wednesday	10:30 am-12:00 pm	**340**	CDISC Pilots	LEVEL ■	**15A** MEZZANINE
Wednesday	1:30 pm-3:00 pm	**371**	Views of the CDISC Standards in a Submission	LEVEL ●	**15A** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**399E**	Leveraging Electronic Health Records in Clinical Research	LEVEL ■	**9**
Thursday	8:30 am-10:00 am	**408**	How Much Do Electronic Diaries Improve the Quality of Clinical Research?	LEVEL ■	**15A** MEZZANINE
Thursday	10:30 am-12:00 pm	**433**	Standards Shock Therapy: Monitoring the State of CDISC and HL7 for Clinical Research and Regulatory Submissions	LEVEL ◆	**15A** MEZZANINE
ERS/DM	**Electronic Regulatory Submissions/Document Management**				
Monday	10:30 am-12:00 pm	**110**	FDA's Drug eReg and Listing System: One Year Later	LEVEL ■	**9**
Monday	1:30 pm-3:00 pm	**136**	Global Submission Management: Challenges and Opportunities	LEVEL ■	**9**
Monday	3:30 pm-5:00 pm	**157**	Overcoming Regulatory Diversity to Gain Market Approval in Latin American Regions	LEVEL ■	**9**
Tuesday	8:00 am-9:30 am	**213**	Implementing Global Electronic Submissions: The Company and the Regulators Give their Points of View	LEVEL ■	**9**
Tuesday	10:00 am-11:30 am	**241**	FDA Data Exchange Standards Initiatives	LEVEL ●	**9**
Tuesday	2:00 pm-3:30 pm	**269**	Annual CDER eSubmission Update: The Review Perspective	LEVEL ●	**9**
Tuesday	4:00 pm-5:30 pm	**295**	Annual CDER eSubmission Update: The Technical Side	LEVEL ●	**9**
Wednesday	8:30 am-10:00 am	**311**	Minimize the Cost – Maximize the Efficiency: Where Are We Going? What Are the Opportunities?	LEVEL ■	**9**
Wednesday	8:30 am-10:00 am	**312**	Life-cycle Management: Where the Real Challenges Are – Module 3, IND, and NDA	LEVEL ■	**8**
Wednesday	10:30 am-12:00 pm	**341**	The Multilingual Dimension: Best Practices for Addressing Global Content and Global XML	LEVEL ●	**8**
Wednesday	10:30 am-12:00 pm	**342**	What's the Meta with this Data? The Shifting Sands of Submission EDMS	LEVEL ■	**9**
Wednesday	1:30 pm-3:00 pm	**372**	International eCTDs: An Update on Regulatory Authority Experience	LEVEL ●	**9**
Wednesday	3:30 pm-5:00 pm	**399F**	Creation of Marketing Applications for the ASEAN Region	LEVEL ■	**15A** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**399G**	Convergence of Data and Document Standards: Where Does CDISC Meet eCTD?	LEVEL ●	**8**
Thursday	8:30 am-10:00 am	**409**	Addressing Document Collaboration Challenges in Drug Development	LEVEL ■	**9**
Thursday	10:30 am-12:00 pm	**434**	Pursuing Standards to Enhance eCTD Deliverables: Pharmaceutical and Research Manufacturer Association Electronic Regulatory Submissions (PhRMA ERS) Group Annual Update	LEVEL ■	**9**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
GCP	**Good Clinical Practices**				
Monday	10:30 am-12:00 pm	**111**	Where Are the Goal Posts this Week? An Update on Global Legislation Related to Clinical Trial Disclosure	LEVEL ■	**30CD**
Monday	1:30 pm-3:00 pm	**137**	eAudit: Clinical Data Mining and Signal Detection	LEVEL ■	**30CD**
Monday	3:30 pm-5:00 pm	**153**	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**6AB**
Tuesday	8:00 am-9:30 am	**214**	Corrective Action and Preventive Action Program for Clinical Trial Programs	LEVEL ■	**30CD**
Tuesday	10:00 am-11:30 am	**242**	The Cost of Compliance: Clinical Trial Registration and Results Disclosure	LEVEL ●	**30CD**
Tuesday	2:00 pm-3:30 pm	**270**	Defining Quality in Clinical Trials (2nd Annual Update)	LEVEL ■	**30CD**
Tuesday	4:00 pm-5:30 pm	**296**	Developing Responsible Systems for the Ethical Review of Clinical Trials: A Global Approach Based on Ethical Principles and GCP	LEVEL ■	**30CD**
Wednesday	8:30 am-10:00 am	**313**	Experience with GCPs Worldwide	LEVEL ■	**30CD**
Wednesday	8:30 am-10:00 am	**314**	Navigating the FDA Part 11 Guidance: Sponsor and Site Perspectives	LEVEL ■	**11A**
Wednesday	10:30 am-12:00 pm	**343**	Dealing with an FDA Audit: What We Can Learn from Warning Letters and Audits	LEVEL ■	**30CD**
Wednesday	1:30 pm-3:00 pm	**373**	Town Meeting: Good Auditing Practices – Internal Audits, External Audits, and the Audit Report	LEVEL ●	**30CD**
Wednesday	3:30 pm-5:00 pm	**399H**	Implementing Effective Quality Risk Management from an Organizational Perspective	LEVEL ■	**30CD**
Thursday	8:30 am-10:00 am	**410**	Informed Consent: Promise, Pledge, Contract or Platitude?	LEVEL ■	**8**
Thursday	10:30 am-12:00 pm	**435**	Virtual Realities: Quality Considerations when Using Outsource Providers	LEVEL ■	**8**
IT	**Information Technology**				
Monday	10:30 am-12:00 pm	**112**	Utilizing and Integrating Open Source Software in Clinical Research Environments	LEVEL ■	**15B** MEZZANINE
Monday	1:30 pm-3:00 pm	**138**	Extreme Programming in the Life Sciences	LEVEL ■	**15B** MEZZANINE
Monday	3:30 pm-5:00 pm	**158**	Smashing Silos: Bringing Service-oriented Architecture and Data Warehousing to a Pharmaceutical Company Environment	LEVEL ■	**15B** MEZZANINE
Tuesday	8:00 am-9:30 am	**215**	Integrated Web-based Tools Supporting the Pharmaceutical Policies of Regulatory Bodies: From Clinical Trial National Registries to the Regulatory eSubmission	LEVEL ●	**15B** MEZZANINE
Tuesday	10:00 am-11:30 am	**243**	Streamlining Your Clinical Data Environment, End-to-end, Using a Standards-based, Metadata-driven Approach – A Panel Discussion	LEVEL ■	**15B** MEZZANINE
Tuesday	2:00 pm-3:30 pm	**271**	Clinical Trial Metadata: Theory into Practice	LEVEL ◆	**15B** MEZZANINE
Tuesday	4:00 pm-5:30 pm	**297**	caBIG® Clinical Trials Management System (CTMS): A Standardized, Integrated Approach to Clinical Trials Management – A System Overview and Implementation Case Study	LEVEL ■	**15B** MEZZANINE
Wednesday	8:30 am-10:00 am	**315**	Clinical Research Repositories as a Collaboration Platform	LEVEL ■	**15B** MEZZANINE
Wednesday	10:30 am-12:00 pm	**344**	Clinical Data Flow and Integration: Three Use Cases from an Information Technology Perspective	LEVEL ■	**15B** MEZZANINE
Wednesday	1:30 pm-3:00 pm	**374**	CDISC SDTM Data Conversion: Reusability and Repeatability	LEVEL ■	**15B** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**399I**	Empowering the Enterprise with Software as a Service (SaaS)	LEVEL ■	**15B** MEZZANINE
Thursday	8:30 am-10:00 am	**411**	Implementing Health Informatics Solutions in the Life Sciences Industry	LEVEL ■	**15B** MEZZANINE
Thursday	10:30 am-12:00 pm	**436**	Breaking Boundaries: Making Sense of Your Data through Collaborative Visualization	LEVEL ■	**15B** MEZZANINE

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
MA	**Marketing**				
Monday	10:30 am-12:00 pm	**101**	*AD/MA/MC Mega Track Plenary Session:* Pharma in the New Age of Transparency	LEVEL ●	**30AB**
Tuesday	2:00 pm-3:30 pm	**272**	Biotechnology Preapproval Communications	LEVEL ●	**14A** MEZZANINE
Wednesday	10:30 am-12:00 pm	**345**	Developing Tactical Marketing Strategies from Market Research	LEVEL ●	**33AB**
Wednesday	1:30 pm-3:00 pm	**375**	Furthering the Pharmaceutical Industry's Engagement in Electronic Social Media: A Regulatory Roadmap	LEVEL ■	**33AB**
MC	**Medical Communications**				
Monday	10:30 am-12:00 pm	**101**	*AD/MA/MC Mega Track Plenary Session:* Pharma in the New Age of Transparency	LEVEL ●	**30AB**
Monday	1:30 pm-3:00 pm	**139**	Drug Information and the Internet	LEVEL ●	**14B** MEZZANINE
Tuesday	10:00 am-11:30 am	**244**	The Role of Medical Communications in Developing Risk Management Strategies	LEVEL ■	**11A**
Tuesday	4:00 pm-5:30 pm	**298**	Medical Liaison Survey #5: Reassessment of Medical Liaison Program Demographics and Characteristics, Demonstration of Value, and Assessment of Resource Utilization	LEVEL ●	**14A** MEZZANINE
Wednesday	8:30 am-10:00 am	**316**	Safe Use of Drugs – Part 1 of 2: Successfully Communicating with Consumers	LEVEL ●	**14A** MEZZANINE
Wednesday	10:30 am-12:00 pm	**346**	Safe Use of Drugs – Part 2 of 2: Communicating Effectively with Health-care Professionals	LEVEL ●	**14A** MEZZANINE
Wednesday	1:30 pm-3:00 pm	**376**	Business Continuity Planning within Medical Communications Departments	LEVEL ●	**14A** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**399J**	New Drug Information Databases at the National Library of Medicine	LEVEL ●	**14A** MEZZANINE
Thursday	8:30 am-10:00 am	**412**	Pharmacoeconomics and Health Outcomes Primer for the Medical Communications Professional	LEVEL ●	**14B** MEZZANINE
MW	**Medical/Scientific Writing**				
Monday	10:30 am-12:00 pm	**113**	Medical Writer Competency Model: Understanding Skills, Knowledge, and Behaviors for Use in Hiring, Training, and Evaluating Medical Writers	LEVEL ■	**31AB**
Monday	1:30 pm-3:00 pm	**140**	IND to CTD in Electronic Format: Strategic Considerations for Life-cycle Maintenance	LEVEL ■	**31AB**
Tuesday	8:00 am-9:30 am	**216**	Hot Topics in Publication Writing: Challenges and Solutions	LEVEL ■	**31AB**
Tuesday	10:00 am-11:30 am	**245**	The Clinical Study Report Revisited: Strategies for Effective Authoring	LEVEL ●	**31AB**
Tuesday	2:00 pm-3:30 pm	**273**	Integrated Summaries and Beyond: Be Prepared	LEVEL ■	**31AB**
Tuesday	4:00 pm-5:30 pm	**299A**	Effective Publication Practices	LEVEL ■	**31AB**
Wednesday	8:30 am-10:00 am	**317**	Writing for Patients: Communicating Clinical Trial Results	LEVEL ●	**31AB**
Wednesday	10:30 am-12:00 pm	**347**	Changes in International Drug Development: Effects on Common Technical Document Preparation in Japan	LEVEL ■	**31AB**
Wednesday	1:30 pm-3:00 pm	**377**	Authoring CTD/eCTD Submissions: Updates and Case Studies	LEVEL ■	**31AB**
Wednesday	3:30 pm-5:00 pm	**399K**	Globally Sourced Medical Writing: Windfall or Pitfall?	LEVEL ■	**31AB**
Thursday	8:30 am-10:00 am	**413**	Pharmacovigilance from the Medical Writer Perspective	LEVEL ●	**6E**
NC	**Nonclinical Laboratory Safety Assessment**				
Tuesday	2:00 pm-3:30 pm	**274**	First-in-human Studies	LEVEL ■	**10**
Tuesday	4:00 pm-5:30 pm	**299B**	Evaluation of the Safety of Pharmaceuticals in the Environment (Water)	LEVEL ■	**10**
Wednesday	8:30 am-10:00 am	**318**	Use and Usefulness of Juvenile Animal Studies in the Development of Pediatric Drugs	LEVEL ◆	**10**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
	NC – Nonclinical Laboratory Safety Assessment *continued*				
Wednesday	10:30 am-12:00 pm	**348**	New Approaches to Toxicity Testing to Support Pharmaceutical Development – Part 1 of 2: New Endpoints	LEVEL ●	**10**
Wednesday	1:30 pm-3:00 pm	**378**	New Approaches to Toxicity Testing to Support Pharmaceutical Development – Part 2 of 2: New Models	LEVEL ■	**10**
Wednesday	3:30 pm-5:00 pm	**399L**	Potentially Genotoxic Impurities, Metabolites, and Degradates: The Need for an Integrated Approach to Safety Assessment	LEVEL ●	**10**
Thursday	8:30 am-10:00 am	**414**	Updating ICH S6 Guidance on Preclinical Safety Evaluation of Biotechnology-derived Pharmaceuticals	LEVEL ■	**14A** MEZZANINE
NHP	**Natural Health Products**				
Tuesday	2:00 pm-3:30 pm	**275**	Regulatory Requirements for Natural Health Products/Herbal Medicinal Products in North America and the EU	LEVEL ●	**11A**
Tuesday	4:00 pm-5:30 pm	**299C**	Marketing and Registration in the EU and US	LEVEL ■	**11A**
Wednesday	8:30 am-10:00 am	**319**	Harmonization Scope for Natural Health Products Regulatory Requirements	LEVEL ■	**17B** MEZZANINE
Wednesday	10:30 am-12:00 pm	**349**	Natural Health Products: Current Research and Development	LEVEL ■	**17B** MEZZANINE
Wednesday	1:30 pm-3:00 pm	**379**	Safety before and after Approval of Natural Health Products	LEVEL ■	**17B** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**399M**	Current Status and Future Development of Phytomedicines: International Perspective	LEVEL ■	**17B** MEZZANINE
Thursday	8:30 am-10:00 am	**415**	Roadmap from Preclinical to Health Claims in Natural Health Products	LEVEL ■	**17B** MEZZANINE
Thursday	10:30 am-12:00 pm	**437**	Targeted Disease Approach Using Natural Health Products	LEVEL ■	**17B** MEZZANINE
OS	**Outsourcing**				
Monday	10:30 am-12:00 pm	**114**	Sourcing Professionals Are from Mars and Business Development Professionals Are from Venus	LEVEL ■	**5B**
Monday	1:30 pm-3:00 pm	**141**	Outsourcing Clinical Trials in Latin America: Challenges and Opportunities	LEVEL ■	**5A**
Tuesday	8:00 am-9:30 am	**217**	Utilize Standardized CRO Performance Metrics to Drive Appropriate Change: An Industry-wide Effort among Sponsors and CROs to Develop and Implement Standardized CRO Performance Metrics to Improve Clinical Trial Performance	LEVEL ■	**5A**
Tuesday	10:00 am-11:30 am	**246**	Training of Investigative Sites in the Latin America Region	LEVEL ■	**5A**
Tuesday	2:00 pm-3:30 pm	**276**	Challenges of R&D Outsourcing in Japan: Successful NDA Preparation, and Strategy Planning Area for Global Development	LEVEL ■	**8**
Tuesday	4:00 pm-5:30 pm	**299D**	Conducting Global Clinical Trials in Emerging Markets	LEVEL ■	**5A**
Wednesday	8:30 am-10:00 am	**320**	What Does the Future Hold for CRO-sponsor Relationships? Results from a 2009 Industry Survey with a Focus on How Changes to CRO-sponsor Relationships over the Next Five Years Will Impact Innovation, Cost Savings, and Efficiency	LEVEL ■	**5A**
Wednesday	10:30 am-12:00 pm	**350**	Faster, Better, Cheaper? Working Outside North America and Western Europe	LEVEL ■	**5A**
Wednesday	1:30 pm-3:00 pm	**380**	Outsourcing Strategies for Clinical Trial Activities in Central and Latin America	LEVEL ■	**5A**
Wednesday	3:30 pm-5:00 pm	**399N**	Latin America: Leveraging Regional Strengths while Proactively Ensuring Quality	LEVEL ●	**5A**
Thursday	8:30 am-10:00 am	**416**	Assessing the Security Practices of Business Partners	LEVEL ●	**5A**
Thursday	8:30 am-10:00 am	**417**	Central Laboratory Services in Emerging Markets: Optimizing Results through Laboratory "Glocalization"	LEVEL ■	**4**
Thursday	10:30 am-12:00 pm	**438**	Go East, Go West: Outsourcing in Asia	LEVEL ■	**5A**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
PM/FI	**Project Management/Finance**				
Monday	10:30 am-12:00 pm	**115**	Using Relationship Management Tools to Improve Project Results	LEVEL ■	**4**
Monday	10:30 am-12:00 pm	**116**	Profiting in the Next Generation Pharmaceutical Industry	LEVEL ■	**2**
Monday	1:30 pm-3:00 pm	**142**	2008 Benchmark Survey Results: Project Management in the Pharmaceutical Industry	LEVEL ■	**2**
Monday	1:30 pm-3:00 pm	**143**	Valuing Continuous Process Improvement Projects	LEVEL ■	**4**
Monday	3:30 pm-5:00 pm	**159**	The Art and Science of Pharmaceutical Project Management: Does a Pharma PM Need to Be a Scientist?	LEVEL ■	**5B**
Monday	3:30 pm-5:00 pm	**160**	Improving Accrual and Contract Management with Earned Value Management	LEVEL ◆	**4**
Tuesday	8:00 am-9:30 am	**218**	Comparing Risk Management Approaches of the US and Japan (Asia): Implications for Global Drug Development	LEVEL ■	**4**
Tuesday	8:00 am-9:30 am	**219**	Implementing Enterprise-wide Project Management Tools	LEVEL ■	**2**
Tuesday	10:00 am-11:30 am	**247**	Project and Alliance Management: Integrating the Roles	LEVEL ■	**2**
Tuesday	10:00 am-11:30 am	**248**	Ensuring Strategic Value of Continuous Process Improvement Projects	LEVEL ■	**4**
Tuesday	2:00 pm-3:30 pm	**277**	Deal Makers and Deal Breakers: What Venture Capital Firms Look for in Drug Development Plans and How Applicants Succeed (or Fail) in Winning Funding	LEVEL ■	**2**
Tuesday	2:00 pm-3:30 pm	**278**	Bringing Out the Best in Leaders, Teams, and Relationships	LEVEL ■	**4**
Tuesday	4:00 pm-5:30 pm	**299E**	Project and Portfolio Management Insights	LEVEL ■	**4**
Tuesday	4:00 pm-5:30 pm	**299F**	A Search for the Most Effective PM Model in the Pharmaceutical Industry: PMs and PLs – Do We Need Both?	LEVEL ■	**2**
Wednesday	8:30 am-10:00 am	**321**	Six Sigma: How to Leverage a Great Idea in the Complex Reality of Clinical Trials	LEVEL ■	**2**
Wednesday	8:30 am-10:00 am	**322**	Influence: Utilizing a Variety of Strategies in Pharmaceutical Drug Development	LEVEL ■	**4**
Wednesday	10:30 am-12:00 pm	**351**	Virtual Project Teams: Best Practices for Improving Product Development Efficiency	LEVEL ■	**4**
Wednesday	10:30 am-12:00 pm	**352**	Managing Team Communications Globally	LEVEL ●	**2**
Wednesday	1:30 pm-3:00 pm	**381**	*Project Management Plenary Session:* Future Directions of Project Management in the Life Sciences	LEVEL ●	**2**
Wednesday	3:30 pm-5:00 pm	**399O**	Integrated Business Modeling: Where Improvements in Productivity Happen by Leveraging Better Forecasting Tools, Techniques, and Processes	LEVEL ■	**4**
Wednesday	3:30 pm-5:00 pm	**399P**	Challenges in Project Management in Front-loading Key Activities for Rapid Drug Development	LEVEL ■	**2**
Thursday	8:30 am-10:00 am	**418**	Preserving Relationships in the Face of Divergent Project Expectations	LEVEL ●	**2**
Thursday	8:30 am-10:00 am	**419**	Proactive Management of Project Financials: Understand Scope of Work, Cost to Complete, and Scope Change	LEVEL ●	**3**
Thursday	10:30 am-12:00 pm	**439**	Global Working Environment Synergy: When an American Team Leader, Japanese Project Manager, and European Team Members Work Together	LEVEL ■	**3**
Thursday	10:30 am-12:00 pm	**440**	Improving the Business of Science: Process Improvement and Metrics that Matter	LEVEL ■	**2**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
PP	**Public Policy/Law**				
Monday	10:30 am-12:00 pm	**117**	Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials	LEVEL ●	**32AB**
Monday	1:30 pm-3:00 pm	**144**	Civil and Regulatory Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials?	LEVEL ●	**32AB**
Monday	1:30 pm-3:00 pm	**145**	Labeling Risk: Practical Approaches after Wyeth v. Levine	LEVEL ■	**10**
Monday	3:30 pm-5:00 pm	**153**	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**6AB**
Tuesday	8:00 am-9:30 am	**220**	Transparency: EMEA's Future Policy	LEVEL ●	**32AB**
Tuesday	10:00 am-11:30 am	**249**	Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) Report Card	LEVEL ■	**32AB**
Tuesday	2:00 pm-3:30 pm	**279**	Collaborative for Pharmacist Care Patient Services	LEVEL ●	**32AB**
Tuesday	4:00 pm-5:30 pm	**299G**	Drug Counterfeiting International Fight: New Actions Taken in the US and in the World	LEVEL ■	**32AB**
Wednesday	8:30 am-10:00 am	**323**	Personalized Medicine: 2009 Update	LEVEL ■	**32AB**
Wednesday	10:30 am-12:00 pm	**353**	Patient-reported Outcomes Consortium: A Public-private Partnership	LEVEL ●	**32AB**
Wednesday	1:30 pm-3:00 pm	**382**	Pharmacovigilance and Product Liability	LEVEL ■	**32AB**
Wednesday	3:30 pm-5:00 pm	**399Q**	Clinical Trial Registries: Panacea or Pablum?	LEVEL ■	**32AB**
Thursday	8:30 am-10:00 am	**420**	New Paradigms in Drug Regulation?	LEVEL ■	**7A**
Thursday	10:30 am-12:00 pm	**441**	Human Research Ethics in an Environment of Global Clinical Trials	LEVEL ■	**7A**
RA	**Regulatory Affairs**				
Monday	10:30 am-12:00 pm	**118**	Regulatory Harmonization Initiative in APEC LSIF (Life Science Innovation Forum)	LEVEL ■	**6E**
Monday	10:30 am-12:00 pm	**119**	An Introduction and Discussion of FDAAA, FDA's New Regulatory Authorities	LEVEL ●	**6F**
Monday	10:30 am-12:00 pm	**120**	PDUFA IV Commitments on Review and Evaluation of Trademarks (Proprietary Names) and Update on Pilot Program for Evaluation of Proposed Names	LEVEL ■	**10**
Monday	10:30 am-12:00 pm	**121**	Regulatory Data Protection	LEVEL ◆	**7A**
Monday	10:30 am-12:00 pm	**122**	Proactive FDA Safety Meetings: Anticipating Safety Issues	LEVEL ■	**8**
Monday	10:30 am-12:00 pm	**123**	Establishing Precedence in Regulatory Strategy: The Role of Regulatory Intelligence in the Development Process	LEVEL ■	**11A**
Monday	1:30 pm-3:00 pm	**146**	The New "Next Door" in Global Development: When East Goes West or West Goes East	LEVEL ■	**7A**
Monday	1:30 pm-3:00 pm	**147**	PMDA Update: PMDA Initiatives and Challenges for Faster Review and Better Life-cycle Management of Drugs	LEVEL ■	**6E**
Monday	1:30 pm-3:00 pm	**148**	Best Practices for Interactions between Industry and FDA (Office of New Drugs/Office of Surveillance and Epidemiology) Considerations during Drug Product Life Cycle on Safety	LEVEL ■	**6F**
Monday	1:30 pm-3:00 pm	**149**	Pharmacogenomics in Action: A Practical View of Pharmacogenomic Submissions, FDA Review Process, and Label Revisions	LEVEL ■	**7B**
Monday	3:30 pm-5:00 pm	**153**	*Multitrack Plenary Session:* Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape	LEVEL ●	**6AB**
Monday	3:30 pm-5:00 pm	**161**	GCPs in China: Similarities and Differences from ICH GCPs	LEVEL ●	**7B**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
	RA – Regulatory Affairs *continued*				
Monday	3:30 pm-5:00 pm	**162**	Regulatory Framework in Central and South America	LEVEL ●	**7A**
Tuesday	8:00 am-9:30 am	**221**	FDA Goes Global: Domestic Mission – Global Presence	LEVEL ●	**6E**
Tuesday	8:00 am-9:30 am	**222**	Postmarketing Requirements and Commitments (PMRs/PMCs): FDAAA's Impact and How FDA and Industry Are Addressing the Backlog	LEVEL ■	**6F**
Tuesday	8:00 am-9:30 am	**223**	Biopharmaceutical Company Regulatory Affairs Functions: Strategies and Structures	LEVEL ■	**7A**
Tuesday	8:00 am-9:30 am	**224**	Improving Your Chances of Getting a Drug or Biologic Approved during the First Review Cycle	LEVEL ●	**8**
Tuesday	8:00 am-9:30 am	**225**	Development of Oncology Products in the EU and US: Can We Do Better?	LEVEL ■	**7B**
Tuesday	10:00 am-11:30 am	**250**	You Can't (b)(2) Careful: Submitting 505(b)(2) Applications	LEVEL ■	**6E**
Tuesday	10:00 am-11:30 am	**251**	Update from China's SFDA and CDE	LEVEL ■	**7B**
Tuesday	10:00 am-11:30 am	**252**	FDA and EMEA Update on Pediatric Legislation	LEVEL ●	**7A**
Tuesday	10:00 am-11:30 am	**253**	European Medicines Agency Town Hall	LEVEL ●	**8**
Tuesday	2:00 pm-3:30 pm	**280**	*Regulatory Affairs Plenary Session:* Meet the Regulators	LEVEL ●	**6AB**
Tuesday	4:00 pm-5:30 pm	**299H**	Sixth Update: Outlook for Changes in the Japanese Regulatory and Clinical Development Environment	LEVEL ■	**6E**
Tuesday	4:00 pm-5:30 pm	**299I**	Special Protocol Assessments: Industry and FDA Perspectives	LEVEL ●	**6F**
Tuesday	4:00 pm-5:30 pm	**299J**	The Importance of Developing a Comprehensive Regulatory Strategy for Emerging Pharmaceutical Companies	LEVEL ■	**8**
Tuesday	4:00 pm-5:30 pm	**299K**	Changes in the WHO Review of Psychoactive Substances for International Control	LEVEL ●	**7B**
Tuesday	4:00 pm-5:30 pm	**299L**	EMEA and NIH Transatlantic Approach on Pediatric Formulation	LEVEL ■	**5B**
Wednesday	8:30 am-10:00 am	**324**	Global Simultaneous Development and Asia/Japan: Strategic and Regulatory Issues to Overcome	LEVEL ◆	**7B**
Wednesday	8:30 am-10:00 am	**325**	FDA Advisory Committees: New Challenges and Opportunities in the Post-FDAAA Era	LEVEL ■	**6E**
Wednesday	8:30 am-10:00 am	**326**	An Introduction to FDA/CDER's Safety First/Safe Use Postmarketing Safety Initiative	LEVEL ●	**6F**
Wednesday	8:30 am-10:00 am	**327**	FDA and EMEA Efforts to Harmonize Primary Endpoints	LEVEL ●	**6C**
Wednesday	10:30 am-12:00 pm	**354**	Regulatory Strategy in Global Drug Development	LEVEL ■	**6E**
Wednesday	10:30 am-12:00 pm	**355**	Recent Advancement of Advanced Therapy in the Asian Pacific Region	LEVEL ■	**7B**
Wednesday	10:30 am-12:00 pm	**356**	Improving Regulatory Outcomes: What Are the Prospective and Retrospective Regulatory Strategies Companies Can Use to Improve the Quality of Development and Review?	LEVEL ■	**6F**
Wednesday	10:30 am-12:00 pm	**357**	Regulatory Considerations for Subsequent Entry of Biologics in Canada	LEVEL ■	**7A**
Wednesday	1:30 pm-3:00 pm	**383**	FDA Meetings: Understanding the Process and Maximizing Success	LEVEL ●	**6E**
Wednesday	1:30 pm-3:00 pm	**384**	Connect the Dots: The Map from Labeling Development to Marketing Claim	LEVEL ●	**7B**
Wednesday	1:30 pm-3:00 pm	**385**	US-EU-Japan: Exchange of Information among Regulators from ICH Regions	LEVEL ●	**6F**
Wednesday	1:30 pm-3:00 pm	**386**	Measuring Benefit and Balancing Risk: Strategies for the Benefit-risk Assessment of New Medicines in a Risk-averse Environment	LEVEL ■	**8**
Wednesday	1:30 pm-3:00 pm	**387**	International Cooperation on GMP/GCP Inspections	LEVEL ●	**4**
Wednesday	1:30 pm-3:00 pm	**388**	Global Clinical Trials: Destination India	LEVEL ●	**7A**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
	RA – Regulatory Affairs *continued*				
Wednesday	3:30 pm-5:00 pm	**399R**	Drug Registrations and Clinical Trials in Emerging Pharma Countries and N-11 Countries	LEVEL ■	**7B**
Wednesday	3:30 pm-5:00 pm	**399S**	Asian Regulatory Collaboration Update for Multinational Clinical Trials	LEVEL ■	**7A**
Wednesday	3:30 pm-5:00 pm	**399T**	Good Review Management Practices and Good Communication Practices Leading to Successful NDAs	LEVEL ■	**6F**
Wednesday	3:30 pm-5:00 pm	**399U**	Relative Efficacy/Effectiveness: A New Interface between Drug Regulation and Health Technology Assessment	LEVEL ■	**6E**
Thursday	8:30 am-10:00 am	**421**	CDER Town Meeting – Part 1 of 2	LEVEL ●	**6AB**
Thursday	8:30 am-10:00 am	**422**	Efforts Promoting Global Clinical Trials Environment in Korea	LEVEL ■	**7B**
Thursday	10:30 am-12:00 pm	**442**	CDER Town Meeting – Part 2 of 2	LEVEL ●	**6AB**
Thursday	10:30 am-12:00 pm	**443**	Pregnancy and Lactation Labeling: The Past, Present, and Future	LEVEL ●	**7B**
RD	**R&D Strategy**				
Monday	3:30 pm-5:00 pm	**163**	Asia Pacific: Simultaneous Global Development	LEVEL ■	**14B** MEZZANINE
Tuesday	8:00 am-9:30 am	**226**	Pediatric Drug Development: A Global Challenge	LEVEL ●	**14B** MEZZANINE
Tuesday	10:00 am-11:30 am	**254**	The Practice of Adaptive Research	LEVEL ■	**14B** MEZZANINE
Tuesday	2:00 pm-3:30 pm	**281**	Drug Regulation in Nigeria and Kenya	LEVEL ●	**14B** MEZZANINE
Tuesday	4:00 pm-5:30 pm	**299M**	Critical Decision Factors in the Allocation of Clinical Sites for Global Drug Development	LEVEL ◆	**14B** MEZZANINE
Wednesday	8:30 am-10:00 am	**328**	Transforming the Research Paradigm: 21st Century Models to Unify Discovery Research and Clinical Care	LEVEL ■	**14B** MEZZANINE
Wednesday	10:30 am-12:00 pm	**358**	Challenges in Developing and Commercializing Personalized Health-care Products	LEVEL ■	**14B** MEZZANINE
Wednesday	1:30 pm-3:00 pm	**389**	Use of Metrics for R&D Strategizing: Building a Success Matrix	LEVEL ■	**14B** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**399V**	Managing Development Portfolios in a Safety-heightened Environment	LEVEL ◆	**14B** MEZZANINE
ST	**Statistics**				
Monday	10:30 am-12:00 pm	**124**	Planning of Drug Safety Evaluation	LEVEL ■	**16A** MEZZANINE
Monday	1:30 pm-3:00 pm	**150**	Integrated Analyses through a Drug's Life Cycle: Plan to Think about Safety	LEVEL ■	**16A** MEZZANINE
Monday	3:30 pm-5:00 pm	**164**	Adaptive Designs: New Methods	LEVEL ■	**16A** MEZZANINE
Tuesday	8:00 am-9:30 am	**227**	The Next Wave of Adaptive Trials	LEVEL ■	**16A** MEZZANINE
Tuesday	10:00 am-11:30 am	**255**	What Are the Key Issues in BioPharma Statistics Today and Tomorrow? A Panel Discussion	LEVEL ●	**10**
Tuesday	2:00 pm-3:30 pm	**282**	Dose-finding Strategies for Early-phase Clinical Trials	LEVEL ■	**16A** MEZZANINE
Tuesday	4:00 pm-5:30 pm	**299N**	Drug Development and Statistics in Asia: Issues and Challenges	LEVEL ●	**16A** MEZZANINE
Wednesday	8:30 am-10:00 am	**329**	Statistical Issues in Design, Analysis, and Conduct of Thorough QT/QTC Trials	LEVEL ■	**16A** MEZZANINE
Wednesday	10:30 am-12:00 pm	**359**	Challenges in Noninferiority Studies	LEVEL ■	**16A** MEZZANINE
Wednesday	1:30 pm-3:00 pm	**390**	Biomarkers in Oncology Trials	LEVEL ■	**16A** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**399W**	Issues with Subgroup Analyses in Controlled Clinical Trials	LEVEL ◆	**16A** MEZZANINE
Thursday	8:30 am-10:00 am	**423**	Women in HIV Trials: A Comprehensive Review and Meta-analysis	LEVEL ■	**16A** MEZZANINE
Thursday	10:30 am-12:00 pm	**444**	What Statisticians Need to Know about CDISC	LEVEL ■	**16A** MEZZANINE

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
TR/PD	**Training/Professional Development**				
Monday	10:30 am-12:00 pm	**125**	Training of Investigators and IRB Members in Asia	LEVEL ■	**16B** MEZZANINE
Monday	1:30 pm-3:00 pm	**151**	Integrating the Science of Drug Development and Safety into Health-care Professionals' Curriculum	LEVEL ■	**16B** MEZZANINE
Monday	3:30 pm-5:00 pm	**165**	Agile Training: Thinking like a Cable News Network for High-impact Learning	LEVEL ■	**16B** MEZZANINE
Tuesday	8:00 am-9:30 am	**228**	Get Connected! Expanding Your Business Network	LEVEL ●	**16B** MEZZANINE
Tuesday	10:00 am-11:30 am	**256**	Drug Safety Personnel – Qualifications? Further Education? What Are the Basic Requirements and What Is Nice to Have? Where Do Regulators and Industry Find Talent?	LEVEL ■	**16B** MEZZANINE
Tuesday	2:00 pm-3:30 pm	**283**	Critical Success Strategies for Professional Development	LEVEL ●	**16B** MEZZANINE
Tuesday	4:00 pm-5:30 pm	**299O**	Organizational Learning in the Web 2.0 Environment	LEVEL ■	**16B** MEZZANINE
Wednesday	8:30 am-10:00 am	**330**	Current Clinical Research Training in Japan	LEVEL ●	**16B** MEZZANINE
Wednesday	10:30 am-12:00 pm	**360**	Attracting and Training the Best Talent in the 21st Century: The Mix of Generations in the Workplace	LEVEL ●	**16B** MEZZANINE
Wednesday	1:30 pm-3:00 pm	**391**	How Do We Train Our Project Managers to Be Leaders Regardless of Formal Status?	LEVEL ■	**16B** MEZZANINE
Wednesday	3:30 pm-5:00 pm	**399X**	eLearning and Distance Training	LEVEL ■	**16B** MEZZANINE
Thursday	8:30 am-10:00 am	**424**	Overview of Drug Development and Career Opportunities for Emerging Professionals	LEVEL ●	**16B** MEZZANINE
Thursday	10:30 am-12:00 pm	**445**	Presenting ... YOU! Tips, Tricks, and Advice on Making You and Your Presentations Unforgettable	LEVEL ●	**16B** MEZZANINE
VA	**Validation**				
Tuesday	2:00 pm-3:30 pm	**284**	Computerized Systems Used in Clinical Research: Best Practices from Peach – Part 1 of 2	LEVEL ■	**7A**
Tuesday	4:00 pm-5:30 pm	**299P**	Computerized Systems Used in Clinical Research: Best Practices from Peach – Part 2 of 2	LEVEL ●	**7A**
Wednesday	8:30 am-10:00 am	**331**	Auditing Risk-based Computer Validation Projects	LEVEL ■	**7A**
Wednesday	10:30 am-12:00 pm	**361**	Town Meeting: Validation Experts Respond to Your Questions and Concerns – OQ, IQ, PQ, and Testing Practices	LEVEL ●	**11A**
Wednesday	1:30 pm-3:00 pm	**392**	Compliance in the Age of Automatic Updates and Virtualization	LEVEL ■	**11A**
Wednesday	3:30 pm-5:00 pm	**399Y**	An International Perspective on the Use of Computerized Systems in Clinical Investigations	LEVEL ●	**11A**
Thursday	8:30 am-10:00 am	**425**	Validation Challenges with Modern System Development Tools and Methodologies	LEVEL ■	**11A**
Thursday	10:30 am-12:00 pm	**446**	Unique Validation Challenges in the Clinical Area	LEVEL ■	**11A**

Saturday, June 20

9:00 am-5:00 pm **EXHIBITOR REGISTRATION**
Exhibit Hall B1 Lobby, Ground Level

Sunday, June 21

8:00 am-7:30 pm **EXHIBITOR REGISTRATION**
Exhibit Hall B1 Lobby, Ground Level

8:00 am-9:00 am **TUTORIAL REGISTRATION**
Registration for Sunday morning or full-day tutorials ONLY, Sails Pavilion, Upper Level

12:30 pm-1:00 pm **TUTORIAL REGISTRATION**
Registration for Sunday afternoon tutorials ONLY
Sails Pavilion, Upper Level

3:00 pm-7:30 pm **ATTENDEE REGISTRATION**
Sails Pavilion, Upper Level

3:00 pm-7:30 pm **SPEAKER REGISTRATION**
Sails Pavilion, Upper Level

7:00 pm-9:00 pm **NETWORKING RECEPTION**
USS Midway Museum

Special Event

DIA Student Forum

3:00 pm-5:00 pm LEVEL: ●
Room 1B

FORUM CHAIR: ***Stephen A. Sonstein, PhD, MS***
Director, Clinical Research Administration, Eastern Michigan University

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 .

Introduction
Stephen A. Sonstein, PhD, MS
Director, Clinical Research Administration, Eastern Michigan University
President, DIA

Welcome Remarks
Marie A. Dray, MBA
President, International Regulatory Affairs Group LLC
President, DIA

Careers in the FDA
Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biostatistics III, CDER, FDA

Creating an Effective Resume
Tammie J. Massie, PhD, MS
Mathematical Statistician, Vaccine Evaluation Branch, CBER, FDA

Panel Discussion: If I Had Only Known …

Carol L. Mitchell, MD
Coordinator of Virtual Team Coordinators - Global Brand Development Medical Information, Eli Lilly and Company

Beat E. Widler, PhD
Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche AG, Switzerland

Bela S. Denes, MD, FACS
Senior Director, Clinical Research and Development, Spectrum Pharmaceuticals

Sheldon M. Schuster, PhD
President, Keck Graduate Institute of Applied Life Sciences

Monday, June 22

7:00 am-6:00 pm **SPEAKER REGISTRATION**
Sails Pavilion, Upper Level

7:30 am-8:15 am **MORNING REFRESHMENTS**
Ballroom 20 Lobby, Upper Level

7:30 am-6:00 pm **ATTENDEE REGISTRATION**
Sails Pavilion, Upper Level

7:30 am-6:00 pm **EXHIBITOR REGISTRATION**
Exhibit Hall B1 Lobby, Ground Level

8:30 am-10:00 am **PLENARY SESSION**
Ballroom 20, Upper Level

10:00 am-6:00 pm **STUDENT POSTER SESSION**
Sails Pavilion Lobby, Upper Level

9:00 am-6:00 pm **EXHIBITS OPEN**
Exhibit Halls A-C, Ground Level

5:00 pm-6:00 pm **OPENING RECEPTION**
Exhibit Halls A-C, Ground Level

8:30 am-10:00 am **Monday Plenary Session**
Ballroom 20, Upper Level

Welcoming Remarks and Awards Presentation

MARIE A. DRAY, MBA
President, International Regulatory Affairs Group LLC
President, DIA

Opening Remarks

NANCY D. SMITH, PhD
Former Director, Office of Training and Communications, CDER, FDA
2009 DIA Annual Meeting Chairperson

Keynote Speaker

NANCY L. SNYDERMAN, MD
Chief Medical Editor
NBC News

10:00 am-10:30 am **REFRESHMENT BREAK**
Exhibit Halls B1, B2, C, Ground Level
(See SDCC Map for exact locations.)

Session Level Guide

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

- ● **Basic Level Content:** Session is appropriate for individuals new to the topic/subject area.
- ■ **Primarily Intermediate Level Content:** Session is appropriate for individuals who already have a basic understanding of the topic/subject area.
- ◆ **Primarily Advanced Level Content:** Session is appropriate for individuals with an in-depth knowledge of the topic/subject area.

Sessions Begin

Session 101 AD - Advertising, MA, MC

10:30 am-12:00 pm LEVEL: ●

Room 30AB

AD/MA/MC Mega Track Plenary Session: Pharma in the New Age of Transparency

SESSION CHAIRPERSON(S)

Wayne L. Pines
President, Regulatory Services and Health Care, APCO Worldwide Inc.

John F. Kamp, JD, PhD
Executive Director, Coalition for Healthcare Communication

Calls for transparency in goverment and private industry are leading to new laws and policies that include the biopharmaceutical industries. Whether by state and federal statutes or through settlements in enforcement cases, the relationships between the biopharmaceutical and device industries and the prescribers of their products are increasingly transparent to the public, the press, and public policy makers. Three experts in health-care policy will discuss how this public scrutiny will impact the industry and public policy as the nation debates major changes in health-care delivery.

Cole Palmer Werble, MA
Senior Executive Editor, FDC/Windhover

Allan Coukell
Director, The Pew Charitable Trusts, Pew Prescription Project

Session 102 AHC/IS - Academic Health Centers/ Investigator Sites, CR/CS

10:30 am-12:00 pm LEVEL: ■

Room 1A

How Investigator Budgets Impact Patient Enrollment and Retention and How to Improve Sponsor/CRO/Site Processes to Increase Productivity

SESSION CHAIRPERSON(S)

Daniel M. Ulrey, MBA
President and CEO, Midwest Clinical Support, Inc.

This session will address investigator contracts and 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: Perspectives from the Parties
Nedra S. Rhodes, MA
Senior Paralegal, REGISTRAT, Inc.

Roadblocks to Successful Enrollment: The Top 10 Ways to Impede the Independent Research Site
Jeffrey M. Adelglass, MD
President and Founder, Research Across America

Sites Are Clients
Daniel M. Ulrey, MBA
President and CEO, Midwest Clinical Support, Inc.

Session 103 BT - Biotechnology, RA

10:30 am-12:00 pm LEVEL: ●

Room 1B *CME, Nursing, and Pharmacy credits offered*

Hot Topics in Biotechnology

SESSION CHAIRPERSON(S)

Joy A. Cavagnaro, PhD, DABT, RAC
President, Access BIO

Biopharmaceuticals continue to increase in their complexity in conjunction with an evolving regulatory environment. Over the next decade many analysts have predicted that biopharmaceuticals will account for a large part of the pharmaceutical industry growth. This session will highlight three important areas to help ensure successful development, including considerations for designing less immunogenic therapeutic proteins, practical advice on how best to approach the FDA for guidance early in development, and finally a case study will be presented in response to a new FDA regulatory authority to show how best to evaluate and mitigate risk following approval of a novel biopharmaceutical.

Fixing Immunogenicity: New Methods
Annie De Groot, MD
CEO and CSO, EpiVax; Director of BioInformatics Center, University of Rhode Island

Pre-IND Meetings: When Are They Worthwhile?
A. Seth Pauker, PhD, MPH
Independent Consultant, Biopharmstrategies

N-plate (Romiplostim NEXUS Program): Practical Experience with REMS for a Biopharmaceutical Agent
Rekha Garg, MD
Executive Director, Risk Intervention Strategy and Communication, Amgen Inc.

Session 104 CDM - Clinical Data Management, IT

10:30 am-12:00 pm LEVEL: ■

Room 11B

Getting that Fresh, Clean Feeling: Defining "Clean" Data

SESSION CHAIRPERSON(S)

Denise DeRenzo Lacey, MA, MS
Director, Business Operations, Vertex Pharmaceuticals Incorporated

You're cleaning your data in preparation for database lock. How do you know when you're done? In this session, we will explore methods that different companies are using to plan, execute, and complete data cleaning activities. Topics of discussion include the following: the paradigm shift in data acquisition that has redefined the concept of "database lock"; the use of data cleaning plans, and the challenges involved in planning for study closeout while study start-up activities are in full force; innovative methods being used industry-wide to bring the same sort of statistical rigor to data cleaning activities as is brought to bear on data analysis; and tracking pre-lock steps.

Database(s) Lock
Denise DeRenzo Lacey, MA, MS
Director, Business Operations, Vertex Pharmaceuticals Incorporated

Clean Database Faster: Tackling Queries with a Consultant-guided Plan
Teresa Ancukiewicz, MA
Senior Manager, Boston Scientific Corporation

Anomalous Data Surveillance
Eric Yow, MS
Senior Statistician, Duke Clinical Research Institute

Session 105 CP - Clinical Safety and Pharmacovigilance, IT

10:30 am-12:00 pm LEVEL: ■

Room 33AB

The ASTER Pilot One Year Later: Different Approaches to Spontaneous Reporting – A New Business Model

SESSION CHAIRPERSON(S)

Michael A. Ibara, PharmD
Head of Pharmacovigilance Information Management, Pfizer Inc

This session will include a moderator from the biopharmaceutical industry and three speakers who are users of the spontaneous reporting system – a practicing clinician, a not-for-profit organization representative, and a regulator. Data from the completed pilot will be presented and discussed. Conclusions from the pilot and implications for spontaneous reporting will be considered.

FDA Perspective
Lise R. Stevens
Data Standards Project Manager, Office of the Commissioner, FDA

Academic Perspective
Atif Zafar, MD
Clinical Professor, Indiana University School of Medicine; Investigator, Riegenstief Institute

Not-for-profit Perspective
Landen C. Bain
Health-care Liaison, CDISC

Session 106 CR/CS 1 - Clinical Research and Development/Clinical Supplies, AHC/IS

10:30 am-12:00 pm LEVEL: ●

Room 5A *CME credits offered*

Understanding Clinical Trial Volunteer Experiences and Physician Referrals to Clinical Trials

SESSION CHAIRPERSON(S)

Mary Jo Lamberti, PhD, MA
Director, Market Research, CenterWatch

Results of two recent surveys: one survey examines patients' clinical trial experences, and the second survey looks at physicians' reasons for referring or not referring patients into a clinical trial will be presented. The patient volunteer survey will examine data from nearly 1,000 patients who have recently completed a phase 1-3b clinical trial and will be compared with data collected from past surveys conducted from 2004-2008. This study examines overall perceptions about the study volunteer experience, their decision to participate in a study, and whether or not they would participate in a future study. The physician referral survey will analyze data from nearly 1,000 physicians and looks at the top disease areas to which physicians refer patients; factors that would increase a physician's comfort level with or motivation to refer patients into trials, and whether or not physicians have received any formal training on conducting clinical trials. Results from prior CenterWatch physician surveys (2005 and 2007) will be compared. The results of the

patient and physician surveys will shed light on patients' experiences in trials across all disease states and will clarify the reasons why physicians may not be willing to refer patients into trials. These results can contribute to greater awareness within the industry as well as within the medical community.

Understanding Physician Referrals to Clinical Trials
Mary Jo Lamberti, PhD, MA
Director, Market Research, CenterWatch

Results of a Survey of Study Volunteers
Paul Dewberry
Senior Research Analyst, CenterWatch

Session 107 CR/CS 2 - Clinical Research and Development/Clinical Supplies, PM/FI

10:30 am-12:00 pm LEVEL: ■

Room 3

Effective Operational Planning for Adaptive Clinical Trials

SESSION CHAIRPERSON(S)

Molly Blake-Michaels, MS
Director, Clinical Services, ClearTrial LLC

Adaptive clinical trials pose additional and unique challenges to trial operational planning. This session will examine these challenges, provide practical design guidelines that improve the success of this approach, and look at adaptive trial case studies from an operational planning perspective.

Effective Operational Planning for Adaptive Clinical Trials
Michael Krams, MD
Vice President, Adaptive Trials and Applied Program Strategies, Wyeth Research

Implementing Adaptive Clinical Trials
Tom Parke
Head of Clinical Trials Solutions, Tessella Support Services, UK

Optimizing Adaptive Trial Designs: Methodology and Impact on Supplies
Graham J. Nicholls, MS
Associate Director, Client Account Management, Perceptive Informatics, UK

Session 108 CR/CS 3 - Clinical Research and Development/Clinical Supplies, RA

10:30 am-12:00 pm LEVEL: ■

Room 6C

Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done?

SESSION CHAIRPERSON(S)

Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

The incidence of noncompliant and fraudulent activity by institutions and investigative sites continues to rise. Recent regulatory changes in disclosure and privacy have the potential to drive higher levels of noncompliance. This session reviews recent and historical inspection audit reports issued by FDA and the Office of Human Research Protections and discusses new approaches that regulatory agencies, research sponsors, and investigative sites are pursuing to prevent noncompliance and fraud in the future.

Review and Discussion of CDER Inspection Results
Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Why Fraud and Noncompliance Are Occurring
Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

Fraud and Noncompliance: What Can Be Done about It?
Michael Koren, PhD
CEO and Medical Director, Jacksonville Center for Clinical Research

Session 109 CR/CS 4 - Clinical Research and Development/Clinical Supplies, CP

10:30 am-12:00 pm LEVEL: ●

Room 6D *CME, Nursing, and Pharmacy credits offered*

Improving Safety with Every Step: The Patient Perspective

SESSION CHAIRPERSON(S)

Nancy D. Smith, PhD
Former Director, Office of Training and Communications, CDER, FDA

There is no shortage of information about drug safety – some of this information is credible, some not so credible because it is presented from a biased perspective. With this increased emphasis on drug safety, making information available is not enough. This special session will focus on innovative and novel approaches to educate patients and optimal ways to present information to patients so that they use their medicines for the greatest benefit with the least risk. Representatives from international and national patient groups and academia will discuss the latest research in this area and present new programs for patient education and outreach, including programs developed cooperatively with the pharmaceutical industry and other organizations.

Panelists

Jeremiah Mwangi, MA
Senior Policy Officer, International Alliance of Patients' Organizations, UK

Anne Quinn Young, MPH
Program Director, Multiple Myeloma Research Foundation

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

Session 110 ERS/DM - Electronic Regulatory Submissions/Document Management, RA

10:30 am-12:00 pm LEVEL: ■

Room 9

FDA's Drug eReg and Listing System: One Year Later

SESSION CHAIRPERSON(S)

Middleton "John" Coburn, MBA, MPharm
Leader, Drug Registration and Listing, Office of Compliance, CDER, FDA

A twelve-month pilot study began on July 11, 2008 when the FDA announced the availability of its eReg and Listing system. The pilot will run through May 31, 2009 when paper applications 2656 and 2657 will no longer be accepted. Drug establishments may voluntarily register and list electronically until May 31, 2009, at which time use of the eSystem will become mandatory.

DRLS Transition to eLIST
Middleton "John" Coburn, MBA, MPharm
Leader, Drug Registration and Listing, Office of Compliance, CDER, FDA

Operational Issues Related to Transition
David E. Mazyck
Project Manager, eDRLS Operations, Office of Compliance, CDER, FDA

Session 111 GCP - Good Clinical Practices, RA

10:30 am-12:00 pm LEVEL: ■

Room 30CD

Where Are the Goal Posts this Week? An Update on Global Legislation Related to Clinical Trial Disclosure

SESSION CHAIRPERSON(S)

Jacqueline A. Sayers, PhD, MBA
Quality Projects Manager, Pharma Development Quality, Roche Products Ltd., UK

The clinical trial registry and results database arena has seen multiple changes and new entrants in recent years, resulting in a complex and often confusing landscape of laws, recommendations, and guidelines. This session will provide a global overview of current legislation and anticipated future developments.

Public Disclosure Requirements in the US: Federal and State Legislation
Tracy J. Beck, PhD
Associate Medical Business Office Consultant, CTR Results Gatekeeper, Eli Lilly and Company

Public Disclosure Requirements in Europe: EudraCT and Associated Regulations
Fergus Sweeney, PhD
Head of Inspections Sector, European Medicines Agency, European Union

Deja Vu: Posting a Global Study Again and Again and Again? An Overview of Disclosure Requirements in the Rest of the World
John C. McKenney
President, SEC Associates Inc.

Session 112 IT - Information Technology, EC

10:30 am-12:00 pm LEVEL: ■

Room 15B MEZZ.

Utilizing and Integrating Open Source Software in Clinical Research Environments

SESSION CHAIRPERSON(S)

Cal Collins
CEO, Akaza Research

We will explore how open source, standards-based software can improve flexibility, interoperability, and cost in clinical trials. We will discuss the unique advantages and challenges in developing and using open source software, and review open source technologies used in clinical trials. A number of examples will be used as case studies to examine the benefits and challenges of OSS. Topics will include: OSS licensing, using industry standards (caBIG, CDISC, BRIDG), and community experience to integrate open source technologies, GCP-compliance for a distributed, collaborative development process, meeting 21 CFR Part 11 requirements with OSS – from system level time-stamp synchronization to application support for electronic signatures, finding, evaluating, and supporting OSS technology for clinical trials.

Implementing Open Source EDC
Mark M. Paul, MBA
CEO, StatWorks Inc.

Using Open Source Software in the Clinical Trials Environment
Adam Bruehl
PharPoint Research, Inc.

Session 101 MA - Marketing and MC - Medical Communications, AD

10:30 am-12:00 pm LEVEL: ●

Room 30AB

AD/MA/MC Mega Track Plenary Session: Pharma in the New Age of Transparency

See **AD** on page 38 for a complete session description.

Session 113 MW - Medical/Scientific Writing, OS

10:30 am-12:00 pm LEVEL: ■

Room 31AB *CME credits offered*

Medical Writer Competency Model: Understanding Skills, Knowledge, and Behaviors for Use in Hiring, Training, and Evaluating Medical Writers

SESSION CHAIRPERSON(S)

David B. Clemow, PhD
Scientific Communications Consultant, Lilly USA, LLC, Eli Lilly and Company

This session will examine the development of a medical writer competency model for both regulatory and publication writers. The model will be presented, along with details of how it was developed and information on how to access an online copy. The model provides the competencies and associated knowledge, skills, and behaviors believed by industry experts to be needed to succeed as a medical writer in the pharmaceutical industry. Competencies encompassing the diverse skills of a medical writer professional will be outlined and include scientific expertise, leadership, and influence, project management, communication expertise, and relationship management.

Input into the model was gained from leaders in the medical writer profession from the United States, European Union, Japan, Australia, and other regions. Input was included from small and big pharma, as well as CROs, niche vendors, and freelancers that provide medical writing services. The competency model may be a time- and cost-effective way for candidates, recruitment consultants, new managers, human resource staff, and even experienced medical writers to gain a better understanding of what it currently takes to succeed as a pharmaceutical medical writer. How the model can be used to hire and train medical writers will be discussed. The competency model may be a valuable tool for hiring, developing, and subsequently evaluating medical writing staff as they grow in their careers. How the model can be used for staff performance management will also be discussed. Moreover, an example of the development of a training course will be presented.

Medical Writer Competency Model: Development and Content (Skills, Knowledge, Behavior)
David B. Clemow, PhD
Scientific Communications Consultant, Lilly USA, LLC, Eli Lilly and Company

Medical Writer Competency Model: Use in Hiring, Training, and Performance Management
Karen L. Woolley, PhD
CEO, ProScribe Medical Communications; Associate Professor, University of Queensland, Australia

Editorial Training for Medical Writers: A Stitch in Time
Dawn Pirozzi Maxemow
Senior Medical Editor, Forest Research Institute, Inc.

Session 114 OS - Outsourcing, PM/FI

10:30 am-12:00 pm LEVEL: ■

Room 5B

Sourcing Professionals Are from Mars and Business Development Professionals Are from Venus

SESSION CHAIRPERSON(S)

Mary E. Briggs, MS
Senior Vice President, Global Sales and Marketing, CRF Health

Join this session for a lively and revealing discussion that shares many insights on the "behind the scenes" decision-making process during the sourcing selection process. Varying perspectives on the pursuit and award of clinical trial business will be delivered in a fast and fun format.

David John Parker
Director, Clinical Outsourcing, AstraZeneca Pharmaceuticals LP

Gregg Jewett, MBA
Senior Manager, Global Strategic Sourcing, Schering-Plough

Debi Maloney
Vice President, Corporate Accounts, CRF Inc.

Michelle Gause
Global Strategic Sourcing Manager, Bayer HealthCare, LLC

Cyndi Brooks, BSN
Director, Global Sales, Phase 1/Cardiac Safety, Quintiles, Inc.

Kimberly Martinez
Director, Business Development, ICON Clinical Research

Session 115 PM/FI 1 - Project Management/ Finance, CR/CS

10:30 am-12:00 pm LEVEL: ■

Room 4 *Project Management units offered*

Using Relationship Management Tools to Improve Project Results

SESSION CHAIRPERSON(S)

Karean L. Eissler, MS, PMP
President, InsightRx Consulting LLC

This session explores both prevention and treatment for project teams with respect to managing these critical and often overlooked dimensions of your project. Learn how relationship and communication management tools such as facilitation, mediation, and communication planning can be leveraged at various stages of the project to improve project results.

Building Collaborative Team Relationships
Joanne Godman
Director, Clinical Training and Communication, Shire Pharmaceuticals

Business Impact of Effective (and Ineffective) Relationship Management Deployment
Julia Lloyd-Parks, MS
Senior Director, Daiichi Sankyo Development Ltd., UK

Managing High Performance Project Teams
Jacqueline M. Zarro, PhD, MA
Vice President, Clinical Project Management - US, Premier Research Group

Session 116 PM/FI 2 - Project Management/ Finance, CR/CS

10:30 am-12:00 pm LEVEL: ■

Room 2 *Project Management units offered*

Profiting in the Next Generation Pharmaceutical Industry

SESSION CHAIRPERSON(S)

Joseph Pekny, PhD
Professor of Chemical Engineering, Purdue University

The ongoing revolution in the life sciences is creating a number of challenges and opportunities for the development of next generation pharmaceuticals. This session will provide an overview of this revolution and discuss its impact on the development of the next generation pharmaceuticals.

The Implication of Continuing Life Science Advances on the Pharmaceutical Industry and Portfolio/Pipeline Management
Joseph Pekny, PhD
Professor of Chemical Engineering, Purdue University

Innovation at a CRO: A Strategic Management Platform to Enhance Overall Value of a Client's Portfolio
Krish Ghosh, PhD, MBA
Vice President, Global Resource Management, Covance, Inc.

Maximize Patient Value and Revenue: A Strategy to Manage Parenteral Product Life Cycle
Colleen K. Dixon, MS, PMP
PMO Manager, Eli Lilly and Company

Session 117 PP - Public Policy/Law, RA

10:30 am-12:00 pm LEVEL: ●

Room 32AB *CME, Nursing, and Pharmacy credits offered*

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

SESSION CHAIRPERSON(S)

Mark C. Hegarty, JD
Partner/Attorney, Shook Hardy & Bacon LLP

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

Nicholas P. Mizell, JD
Associate, Shook Hardy & Bacon LLP

John M. Isidor, JD
CEO, Schulman Associates IRB, Inc.

Bernard L. Hertzman, MD
Director, Clinical Research, The Urology Group

Session 118 RA 1 - Regulatory Affairs, RD

10:30 am-12:00 pm LEVEL: ■

Room 6E

Regulatory Harmonization Initiative in APEC LSIF (Life Science Innovation Forum)

SESSION CHAIRPERSON(S)

Herng-Der Chern, MD, PharmD, PhD
Executive Director, Center for Drug Evaluation, Taiwan

With the rapidly growing pharmaceutical market and patient/talent pool, Asia has been viewed as one of the priority regions for targeting global simultaneous development (GSD) for new drugs. However, Asia is a diverse and heterogeneous region in terms of politics or economics, experience in new drug development, and capacity resources of its regulatory agencies. Many regional regulatory harmonization initiatives have been proposed to serve different purposes. These efforts harmonize among members within the initiatives in one way but may duplicate functions in other initiatives if not coordinated appropriately.

APEC LSIF was proposed by President Bush and endorsed by the APEC Leaders to promote Life Science Innovation in 2002. Regulatory harmonization facilitates the development and early access to innovative products by patients. The non-binding recommendation from the annual meeting will be later endorsed by the region's ministers and leaders as an important strategy. "Partnership in Harmonization" instead of "Mutual Recognition" is the key theme for APEC. In August, 2008, the Peru APEC LSIF VI annual meeting concluded with three recommendations: 1) LSIF recommends that ministers and leaders endorse and support the establishment of the APEC Harmonization Centre proposed by Korea; 2) LSIF supports the proposed feasibility study of the exchange between economies of evaluation reports proposed by Taiwan; and 3) LSIF agrees to establish a Regulatory Steering Committee within the LSIF structure proposed by Canada. These recommendations were welcomed by the GSD group of the industry as an important platform to coordinate all the different existing regional regulatory harmonization initiatives. The session will include key drivers in the region to update the challenges to progress of these action plans.

Regulatory Steering Committee within the APEC LSIF Structure
Mike D. Ward
Manager, International Programs Division, Health Canada

Industry Efforts on Simultaneous Global Development
Mark Paxton, JD, MS
Associate Vice President, International Regulatory Affairs, PhRMA

Regulatory Harmonization Initiative in APEC LSIF (Life Science Innovation Forum)
Herng-Der Chern, MD, PharmD, PhD
Executive Director, Center for Drug Evaluation, Taiwan

Session 119 RA 2 - Regulatory Affairs, CP

10:30 am-12:00 pm LEVEL: ●

Room 6F *Pharmacy credits offered*

An Introduction and Discussion of FDAAA, FDA's New Regulatory Authorities

SESSION CHAIRPERSON(S)

Howard D. Chazin, MD, MBA
Medical Officer, Guidance and Policy Team, Office of New Drugs, Immediate Office, CDER, FDA

With the passage of Title IX, Subtitle A, section 901 of the Food and Drug Administration Amendments Act on September 27, 2007, the US FDA was given new regulatory authorities by Congress to help strengthen FDA's ability to develop, modify, and track postmarketing safety issues related to drug products. These new authorities include the ability to require of sponsors: 1) postmarketing studies or trials, 2) risk evaluation and mitigation strategies, and 3) safety labeling changes under new time frames and enforcement. This session will illustrate, describe, and discuss these new authorities from the US FDA point of view.

FDAAA Title IX: Implementation One Year Later
Andrea C. Masciale, JD
Senior Director, Regulatory Affairs, Johnson & Johnson

FDA Perspective
Jane A. Axelrad, JD
Associate Director for Policy, Office of Regulatory Policy, FDA

Session 120 RA 3 - Regulatory Affairs, CP

10:30 am-12:00 pm LEVEL: ■

Room 10

PDUFA IV Commitments on Review and Evaluation of Trademarks (Proprietary Names) and Update on Pilot Program for Evaluation of Proposed Names

SESSION CHAIRPERSON(S)

Linda S. Carter
Senior Director, Johnson & Johnson

Under PDUFA IV, FDA committed to performance goals for the review of trademarks and also committed to develop and implement a pilot program that will enable pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and submit the data generated from these evaluations to FDA for review. FDA has held a technical meeting on the pilot program, and published a draft concept paper requesting comments on the draft. FDA plans to finalize the concept paper at the end of 2008. This session will provide an update on the PDUFA commitments, review the final concept paper, and provide details on implementation of the pilot program. The session will also include industry perspectives on the fiscal year 2009 performance goals and the pilot program.

FDA Perspective
Carol Holquist, RPh
Director, Division of Medication Errors and Technical Support, Office of Surveillance and Epidemiology, CDER, FDA
Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

Safety Evaluation Techniques under PDUFA IV
Jerry Phillips, RPh
President and CEO, Drug Safety Institute

Industry Perspective on PDUFA IV Commitments: Problems, Progress, Promise
Robert E. Lee, Jr., JD, MS
Assistant General Patent Counsel, Eli Lilly and Company

Session 121 RA 4 - Regulatory Affairs, IT

10:30 am-12:00 pm LEVEL: ◆

Room 7A

Regulatory Data Protection

SESSION CHAIRPERSON(S)

Martine Zimmermann-Laugel, PharmD
Head of Department, Regulatory Intelligence and Policy, Lundbeck SAS, France

This session will present the latest information on regulatory data protection. The different regulatory options to secure R&D offered by various health authorities across the globe will be presented and discussed. Speakers will expose real cases and analyze the benefits of data protection as well as associated controversies.

Data Protection: Benefit and Controversies – An Industry Point of View
Nadja Heimonen, MPharm
Manager, Regulatory Affairs, Orion Pharma, Finland

Data Protection: Available Options across the Globe and Presentation of Real Cases
James T. Rawls, PharmD
Senior Director, Regulatory Affairs and Clinical Drug Safety, Dainippon Sumitomo Pharma America Inc.

Session 122 RA 5 - Regulatory Affairs, CP

10:30 am-12:00 pm LEVEL: ■

Room 8 *CME and Pharmacy credits offered*

Proactive FDA Safety Meetings: Anticipating Safety Issues

SESSION CHAIRPERSON(S)

Gerald A. Faich, MD, MPH
Senior Vice President, Epidemiology and Risk Management, United BioSource Corporation

In this session, participants will learn how to prepare for a proactive FDA safety meeting and read all safety data from clinical trials. Additionally, methods to anticipate safety issues and gather more data on potential safety issues will also be discussed.

Planning and Preparing for FDA Safety Meetings Pre- and Postapproval
Paul Stang, PhD
Senior Director, Epidemiology, Johnson & Johnson Pharmaceutical R&D LLC

Meetings in the New Area of Regulation: Examples
Linda J. Scarazzini, MD
Assistant Vice President, Risk Management, sanofi-aventis

FDA Perspective
Sandra L. Kweder, MD
Deputy Director, Office of New Drugs, CDER, FDA

Session 123 RA 6 - Regulatory Affairs, RD

10:30 am-12:00 pm LEVEL: ■

Room 11A

Establishing Precedence in Regulatory Strategy: The Role of Regulatory Intelligence in the Development Process

SESSION CHAIRPERSON(S)

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

Regulatory strategy is one of the main drivers behind successful drug development and life-cycle management plans. It is an ever-evolving process, defined by scientific, regulatory, and legislative parameters that can and do change over the life cycle of a product. This session will assess the available regulatory intelligence tools, define the strategic process, and identify sources of precedence through case studies. To conclude the session, a stepwise regulatory strategy will be developed, based on preselected topics and questions, involving interaction between the panelists and the audience.

The Tools of Regulatory Intelligence: Where to Start when Developing Regulatory Strategy or Answering a Question
Meredith E.S. Brown-Tuttle, RAC
Director, Regulatory Affairs, APT Pharmaceuticals, Inc.

Strategic Analyses and Interpretation: Regulatory Intelligence for Decision Making
Amy N. Grant, MS
Director, Regulatory Strategy and Science, ViroPharma, Inc.

Precedent and its Significance in Developing Regulatory Strategy
Linda F. Bowen, MS, RAC
Director, Regulatory Intelligence, US Region, sanofi-aventis

Session 124 ST - Statistics, CP

10:30 am-12:00 pm LEVEL: ■

Room 16A MEZZ.

Planning of Drug Safety Evaluation

SESSION CHAIRPERSON(S)

Brenda Jean Crowe, PhD
Principal Research Scientist, Global Statistical Sciences, Eli Lilly and Company

A drug safety conference was held October 14-15, 2008, in Arlington, VA, that stimulated discussion among FDA and industry participants for proactive planning of a safety evaluation. At that conference, many topics were discussed, such as challenges and opportunities to improve premarketing safety planning, evaluation, and reporting as well as planning for effective meta-analysis. This session will summarize the issues and insights that were discussed at the conference and provide an update on subsequent follow-up activities and next steps.

Points to Consider when Planning a Drug Safety Evaluation
Joachim Vollmar, MSc
Executive Consultant, International Clinical Development Consultants, LLC

A Future State of Quantitative Safety Evaluation in a Regulatory Setting
C. George Rochester, PhD, RAC
Acting Director, Division of Biometrics VII, CDER, FDA

Summarizing Safety Data for Risk Management Plans
Andreas Brueckner, MS
Statistician, Bayer Schering Pharma AG, Germany

Session 125 TR/PD - Training/Professional Development, AHC/IS

10:30 am-12:00 pm LEVEL: ■

Room 16B MEZZ.

Training of Investigators and IRB Members in Asia

SESSION CHAIRPERSON(S)

Jean-Paul M.F. Deslypere, MD, PhD
Business Development Manager, Life Sciences - Asia Pacific, SGS Life Sciences Services, Singapore

Audits by the FDA of investigators and IRB members in Asia have clearly demonstrated that most of the deviations observed are linked to a lack of training and experience. Since the number of clinical trials is increasing in Asia, it is therefore important that the proper systems are in place to ensure full compliance with ICH/GCP. Hence, comprehensive training programs need to be put in place specifically targeted to the Asian environment followed by a proper accreditation system. The session will describe a first attempt for establishing such systems in Asia.

Clinical Staff Training in China
Sandra S. Garrett, PhD
Executive Chairman, Global Research Services LLC

GCP Compliance and Talent Management in China
Jenny Zhang, MD, MHA
Senior Director, Business Development - US, Tigermed Consulting Ltd.

Training of Investigators and IRB Members in South Asia
Kiran Vithaldas Marthak, MD
Director, Veeda Clinical Research (P) Ltd., India

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

Exhibit Hall D, Ground Level

A special seating section will be available for networking with colleagues from your professional interest area. *(See SDCC Map for exact location.)*

Session 126 AD - Advertising, RA

1:30 pm-3:00 pm LEVEL: ●

Room 14A MEZZ.

FDA Enforcement Update

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

Enforcement Update 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

Session 127 AHC/IS - Academic Health Centers/ Investigator Sites, RD

1:30 pm-3:00 pm LEVEL: ◆

Room 1A *CME and Nursing credits offered*

Disease Insights: A Truly Global Approach to Accelerating Patient Recruitment and Retention

SESSION CHAIRPERSON(S)

Janet Jones, PhD
Senior Director, Patient Recruitment and Feasibility, ICON Clinical Research, France

A deep understanding of the global patient population is essential for recruitment success. In practice, this involves ensuring that the study patient population matches the clinical protocol through robust and targeted feasibility and site selection. But what happens when we have made our country choices? This session examines the challenges, culture, and recruitment methodologies encountered when conducting global studies. It will examine global infectious disease studies, which are especially prevalent in poorer countries, and the disease and recruitment landscape in different regions such as sub-Saharan Africa and India. It will also look at how we need to reach out to and communicate with patients in different ethnic settings and the specific challenges of recruiting rare and difficult-to-find patient populations.

Infectious Disease Insights to Global Patient Recruitment
Janet Jones, PhD
Senior Director, Patient Recruitment and Feasibility, ICON Clinical Research, France

Global Patient Communication
Kate Spencer
Patient Recruitment Business Director, Langland, UK

Approach to Patient Recruitment for Rare Diseases and Small Patient Populations
Sarb Shergill, PhD
Senior Director, Clinical Research, Genzyme Corporation

Session 128 BT - Biotechnology, RA

1:30 pm-3:00 pm LEVEL: ■

Room 1B *CME, Nursing, and Pharmacy credits offered*

Regulatory Methods to Facilitate the Approval of Biological Products to Address Pandemic Influenza

SESSION CHAIRPERSON(S)

Richard M. Lewis, PhD
CEO, Access BIO

The session will incorporate descriptions of novel regulatory mechanisms for vaccine approval with a discussion of successful applications for pandemic influenza.

Overview of Progress on Approval of Pandemic Influenza Vaccines
Richard M. Lewis, PhD
CEO, Access BIO

Pandemic Influenza Vaccine Development: FDA Perspective
Jean L. Hu-Primmer, MS
Program Manager, Pandemic and Emerging Threat Preparedness, Office of the Director, CBER, FDA

Influenza Pandemic and EMEA Influenza Crisis Management Plan
John Purves, Esq., PhD
Head of Sector, Quality of Medicines, European Medicines Agency, European Union

Development of Adjuvanted Pandemic Vaccines to Support the US National Stockpile
Ozzie Berger
Senior Director and Head, Influenza Vaccines, US Regulatory Affairs, Biologicals, GlaxoSmithKline

Session 129 CDM - Clinical Data Management, IT

1:30 pm-3:00 pm LEVEL: ●

Room 8

CDASH/Standards and the Practical Implications

SESSION CHAIRPERSON(S)

Teresa Ancukiewicz, MA
Senior Manager, Boston Scientific Corporation

This session will bring audience members up to date on two complementary projects, NCI's Cancer Biomedical Informatics Grid (caBIG™) and CRF Harmonization and Standardization project (CDASH). Data standards ownership, maintenance, and enforcement will be discussed. Specific factors that should be considered when developing a standards strategy will be examined.

CDASH Projects: Development Experience
Rhonda Facile
CDASH Project Director, CDISC

The NCI-caBIG™: Development Experience
Dianne M. Reeves, MSN
Associate Director, Biomedical Data Standards, National Cancer Institute, National Institutes of Health

Standards Governance: Managing the Implementation of Enterprise-wide Data Standards
David A. Evans, MS
Chief Information Officer, Octagon Research Solutions Inc.

Strategies for Implementing Data Standards
Kit Howard, MS
Principal and Owner, Kestrel Consultants, Inc.

Session 130 CP 1 - Clinical Safety and Pharmacovigilance, IT

1:30 pm-3:00 pm LEVEL: ■

Room 30AB *CME, Nursing, and Pharmacy credits offered*

Modernization of FDA Postmarket Adverse Event Information Management

SESSION CHAIRPERSON(S)

Deborah Sholtes, MS
Project Director, CDER, FDA

With FDA's efforts to consolidate electronic reporting and information management, the postmarket product review offices across FDA have progressed towards realization of the next generation information technology system for adverse event reporting, review, and analysis. This session will detail FDA's modernized adverse event program.

MedWatch Plus Implementation
Toni Piazza Hepp, PharmD
Director, Review Management Staff, Office of Surveillance and Epidemiology, CDER, FDA

FAERS Release 1: Drugs and Biologics
Deborah Yaplee
Senior Program Management Officer, Office of the Director, CBER, FDA

FAERS Release 2: Center for Devices and Radiological Health
Terrie Reed, MS
Policy Analyst, Patient Safety Staff, Office of Surveillance and Biometrics, CDRH, FDA

Session 131 CP 2 - Clinical Safety and Pharmacovigilance, RA

1:30 pm-3:00 pm LEVEL: ■

Room 33AB

Issues and Challenges Associated with the PSUR Process

SESSION CHAIRPERSON(S)

Robert Bader, PharmD
Senior Director, Product Safety Services, Covance Inc.

In this session, representatives from two global pharmaceutical companies will describe how they have implemented the PSUR guidelines with a focus on what methods they use to capture, evaluate, and present the safety data. In addition, an introduction will focus on the PSUR process and how to improve safety data evaluation and compliance via internal processes and behaviors.

PSUR from a Small Pharmaceutical Company Perspective
Camelia Dumitrescu, MD, MPH
Director, Drug Safety, Actelion Pharmaceutical United States, Inc.

PSUR Writing: Current Process and the Future
Ursula Maria Schmidt Ott, MD
International Drug Safety Manager, Bayer Schering Pharma AG, Germany

Using the Human Factor to Improve PSUR Quality and Compliance
Brian D. Edwards, MD, MRCP
Director, Pharmacovigilance and Drug Safety, NDA Regulatory Science, Ltd., UK

Session 132 CR/CS 1 - Clinical Research and Development/Clinical Supplies, AHC/IS

1:30 pm-3:00 pm LEVEL: ■

Room 6C

The State of Subject Recruitment in the US: A Town Hall Discussion

SESSION CHAIRPERSON(S)

Jane E. Myles, MS
Associate Director, Clinical Trial Management, Genentech, Inc.

US subject participation lags behind expectations despite increasing information availability about clinical trials via media, advocacy outreach, federal clinical trials registries, and increasing spending on recruitment tactics. What is the reason for this gap, and how can it be addressed in the US to drive faster trial completion? Is there a gap between expectations and reality, or is there a strategic flaw in our approach? Participants in this session will get to offer their perspectives about the reasons behind the US subject recruitment gap. Panel members will offer their expert opinions on both underlying causes and successful strategies to address these issues to increase US subject participation in clinical trials. Key themes will include discussions of who is accountable for recruitment, the key factors causing enrollment challenges, and the content/utility of recruitment plans. Our intent is to poll audience members in real time for their opinions, followed by responses from the expert panel.

Please bring your cell phones to this session. We will use them for real-time data collection.

Panelists

Kate Booth
Account Manager, BBK Worldwide

Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

Beth D. Harper, MBA
President, Clinical Performance Partners, Inc.

Monica Anne DeYoung
Medical Assistant, Affiliated Research Institute

Session 133 CR/CS 2 - Clinical Research and Development/Clinical Supplies, AHC/IS

1:30 pm-3:00 pm LEVEL: ■

Room 5B

CTMS Implementation: The Next Steps

SESSION CHAIRPERSON(S)

Peter Bayer
Study Process and Training Manager, H. Lundbeck A/S, Denmark

This session will review the requirements for the implementation of a clinical trial management system (CTMS) and the steps taken to implement and deploy the system. At the end of the session, the participant should be able to identify the phases of the implementation process, the resource needs, and the strategies to overcome the challenges of implementing and deploying a CTMS within the clinical environment.

Configure, Customize, or Stay Vanilla? Best Practices in Implementing a Highly Configurable CTMS Solution
Rachel Yang, DrMed, PhD
Director, Product Strategy, Oracle Corporation, Switzerland

Business Process Analysis Enables CTMS Definition and Selection Process
Susan Butler, PMP
Managing Partner, ResultsWorks LLC

CTMS: Connecting Systems – Getting the Overview
Peter Bayer
Study Process and Training Manager, H. Lundbeck A/S, Denmark

Session 134 CR/CS 3 - Clinical Research and Development/Clinical Supplies, ST

1:30 pm-3:00 pm LEVEL: ■

Room 6D

Informed Country Selection for Multinational Clinical Studies: One Size Does Not Fit All

SESSION CHAIRPERSON(S)

Matthew Kibby, MBA
Director, Global Operations, BBK Worldwide

Each country's health-care system, treatment and referral patterns, patient and physician attitudes, demographic and disease prevalence data, and other variables affect patient recruitment. This session illustrates how to evaluate these recruitment drivers and how to gauge different countries' recruitment potential for the same case study protocol.

Global Clinical Development: Can Country Selection Be Optimized?
Jane A. Sharples, PhD, MBA
General Manager, CMR International, UK

When Management Asks for the Impossible: A Country Selection Case Study
Joseph Kim, MEd
Manager, Global Trial Optimization, Merck & Co., Inc.

The Matrix Has You: A New Research and Data-driven Approach to Country Selection
Matthew Kibby, MBA
Director, Global Operations, BBK Worldwide

Session 135 CR/CS 4 - Clinical Research and Development/Clinical Supplies, GCP

1:30 pm-3:00 pm LEVEL: ◆

Room 3

Is There Really Such a Thing as a Strategic Partnership?

SESSION CHAIRPERSON(S)

Christine K. Pierre, RN
President and CEO, RxTrials Inc.

This session discusses the structure and strategic role of collaboration models that sponsors and investigative sites are entering into, to combat rising development costs and cycle times. Representatives from pharmaceutical companies, CROs, sites, and academic centers will discuss specific models that have been established and how they were implemented.

Christine K. Pierre, RN
President and CEO, RxTrials Inc.

Adam Chasse
Senior Director; Head, US Prime Sites, Quintiles Inc.

Peter A. DiBiaso, MHA
Senior Clinical Operations Director, Shire Pharmaceuticals

Session 136 ERS/DM - Electronic Regulatory Submissions/Document Management, RA

1:30 pm-3:00 pm LEVEL: ■

Room 9

Global Submission Management: Challenges and Opportunities

SESSION CHAIRPERSON(S)

Dominique E. Lagrave, PharmD, MSc
Director, Regulatory Operations and Innovation, Novo Nordisk, Inc.

The session will review the concept of global submission management in the light of the further globalization of our work environment. We will review how industry can leverage current resources to better support affiliates' needs, how it provides better traceability on what was submitted where, and discuss how we shorten the time from first to last submission around the world. Technologies, processes, and organizations exist today to support this vision. We will review what it would take to aim at this vision with a practical approach discussed through case studies.

Regional eCTD Recycling: How to Reduce, Rework, and Reuse Submission Components and Tools across Global Dossiers
Meredith Purcell
Associate Director, Global Regulatory Affairs Publishing, Allergan Inc.

Comparison of Regulatory Filing Requirements
Sarah Powell
Executive Director, Regulatory Strategies, Thomson Reuters Ltd.

Consolidated Information Management and a Head Start with eCTD
Matthew J. Neal, MA
Director, Global Regulatory Affairs and Safety, Amgen Inc.

Session 137 GCP - Good Clinical Practices, IT

1:30 pm-3:00 pm LEVEL: ■

Room 30CD *Pharmacy credits offered*

eAudit: Clinical Data Mining and Signal Detection

SESSION CHAIRPERSON(S)

C. Grant Simmons, MS
Global Head, CQA Operations, Novartis Pharmaceuticals Corporation

The session will provide updates to the systems and concepts of eAudit, signal detection and risk- or knowledge-based QA. In addition, new developments in the field will be discussed. Presenters will show system updates and provide anecdotes of successes with these approaches. Some new concepts will also be presented, such as the importance of the feedback loop in refining the risk measurements in your system, and expanding access beyond the borders of the QA group, certainly to clinical research and monitoring functions, but potentially to health authorities, as well. There will be a discussion of the pros and cons of such expansion of QA tools.

Keeping Clinical Monitors on Their Toes: The Role of a Quality Compliance Manager in Assuring Audit Preparedness
Denicia Hernandez
Assistant Director, RPS (ReSearch Pharmaceutical Services, Inc)

Risk Assessment of Clinical Trial Centers in Practice
Peter J. Schiemann, PhD
Quality Risk Management Project Leader, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Session 138 IT - Information Technology, VA

1:30 pm-3:00 pm LEVEL: ■

Room 15B MEZZ.

Extreme Programming in the Life Sciences

SESSION CHAIRPERSON(S)

Thomas Quinn
President, CISSP, The Hollis Group Inc.

This session is a presentation of two case studies of bespoke-code development of a clinical data system that used eXtreme Programming (XP) development methods.

Agile Software Development and Regulated Clinical Research: Friend or Foe? Can Agile Methods Improve Software Development and Validation and Satisfy Regulatory Requirements?
Andrew Newbigging
Vice President, Integrations Development, Medidata Solutions Worldwide, UK

Quality Assurance Perspective on XP in a Regulated Industry
Andrea Bradbury
Vice President, Compliance and Quality, Clarix Products Group, Phase Forward

Session 139 MC - Medical Communications, IT

1:30 pm-3:00 pm LEVEL: ●

Room 14B MEZZ.

Drug Information and the Internet

SESSION CHAIRPERSON(S)

Evelyn R. Hermes-DeSantis, PharmD
Director of Drug Information, Rutgers University

This session will update participants in Wikipedia and newer medical information sites such as Medipedia. In addition, participants will learn how to critically evaluate websites and identify "good" medical information sites.

Update on Medical Information on Internet Websites: Review of Content
JiHyun Lee Miller, PharmD
Associate Medical Information Consultant, Global Medical Information, Eli Lilly and Company

Websites for Risk Management: Collection and Dissemination
Heather A. Schiappacasse, PharmD, MBA
Director, Risk Management, sanofi-aventis

Evaluating Medical Websites: The Good, the Bad, the Indifferent and How to Tell Them Apart
Evelyn R. Hermes-DeSantis, PharmD
Director of Drug Information, Rutgers University

Session 140 MW - Medical/Scientific Writing, ERS/DM

1:30 pm-3:00 pm LEVEL: ■

Room 31AB

IND to CTD in Electronic Format: Strategic Considerations for Life-cycle Maintenance

SESSION CHAIRPERSON(S)

Sandra J. Hecker, RAC
US Agent; Regulatory Consultant, Hecker & Associates, LLC

Strategic submission and maintenance of an IND in eCTD format requires detailed knowledge of: 1) the extent and type of data submitted with the IND, 2) IND to NDA content evolution (life cycle), and 3) how IND amendment electronic files are managed and accessed at FDA. This session will describe lessons learned from submission of multiple eCTD INDs to CBER and CDER, effective sponsor-publisher working relationships, and best practices for placement of submission content, beginning with the filing of the IND.

Submitting INDs in eCTD Format: Looking Forward
Michael Brennan, PhD
ERIS Business Owner, Pharma R&D IM, Centocor Inc.

Managing CMC Content in an eCTD IND
Kenny Seaver, MS
Manager, Regulatory Affairs, Solvay Pharmaceuticals

Deciding Placement for IND Foreign Clinical Data to Facilitate Strategic Life-cycle Maintenance
Sandra J. Hecker, RAC
US Agent; Regulatory Consultant, Hecker & Associates, LLC

Session 141 OS - Outsourcing, CR/CS

1:30 pm-3:00 pm LEVEL: ■

Room 5A

Outsourcing Clinical Trials in Latin America: Challenges and Opportunities

SESSION CHAIRPERSON(S)

Silvia Zieher, MD
Director, Head of Clinical Operations Latin America, Global Clinical Development, MDS Pharma Services, Argentina

Latin America is becoming increasingly attractive as a research region. There has been a large increase in clinical trials in Latin America filed to an IND over the past few years, and the general clinical research environment in Latin America has developed rapidly. The proportion of sponsor outsourcing clinical trials is also increasing. The challenges and opportunities for conducting clinical trials in Latin America must be taken into account when outsourcing studies in Latin America.

Regulatory Framework: What Should Be Taken into Consideration when Outsourcing Clinical Trials in Latin America?
Wanda Dobrzanski-Nisiewicz, MD
General Manager, i3 Research, Argentina

Vendor Selection and Interaction with Industry in Latin America
Cory Gutterman, MPH
Associate Director, Outsourcing, Abbott Laboratories

Strategies for Patient Recruitment and Retention in Latin America: A CRO Perspective
Pablo A. Hammerschmidt, MBA, MSc
Regional Director, Clinical Operations/Latin America, ICON Clinical Research, Argentina

Session 142 PM/FI 1 - Project Management/ Finance, TR/PD

1:30 pm-3:00 pm LEVEL: ■

Room 2 *Project Management units offered*

2008 Benchmark Survey Results: Project Management in the Pharmaceutical Industry

SESSION CHAIRPERSON(S)

Ellis Wilson, MBA, MS
Senior Director, Project Coordination, AstraZeneca Pharmaceuticals LP

This session highlights 2008 benchmark survey data on project management (PM) practices within the pharmaceutical industry. The 2008 survey is the fourth in a series of surveys conducted over the last decade by the Pharmaceutical Specific Interest Group of the Project Management Institute. The effective application of project management principles contributes significantly to successful biopharmaceutical drug development, business viability, and ultimately improved health care.

2008 benchmark survey data from the pharmaceutical industry area includes details on project managers' academic preparation, ongoing training activities, project management experiences and pharmaceutical industry experience to establish a preparation and experience baseline. Considerable detail is captured regarding project management's place within the organizational structure, including utilization of a Project Management Office (PMO). Other areas of analysis include the longevity of the project management organization, size (FTEs) of the PM function, and reporting structures. Baseline information on geography allows the identification of similarities and differences in project management practices across geographic boundaries. Benchmarking information on the practice of project management in the pharmaceutical milieu includes an examination of responsibilities, scope of work, software tools and knowledge areas. Priority rankings on project management knowledge areas will be outlined and compared with responses from earlier surveys. This session also provides insights into the recruitment and retention of project managers within the industry, including compensation package averages. This combination of longitudinal research findings on the practice of project management and the characteristics of project managers practicing within the pharmaceutical industry serves to provide the most comprehensive picture to date of pharmaceutical project management.

Project Management in the Biopharmaceutical Industry: Survey Background and Overview
Kristen Lee Dougherty, MBA, PMP
Franchise and Portfolio Manager, Business and Research Integration, Merck & Co., Inc.

Project Management in Life Sciences: 2008 Benchmarking Survey Results
Jann A. Nielsen, PhD
Senior Director, Project Management, Wyeth Research

Project Management across the Decade
Ellis Wilson, MBA, MS
Senior Director, Project Coordination, AstraZeneca Pharmaceuticals LP

Session 143 PM/FI 2 - Project Management/ Finance, RD

1:30 pm-3:00 pm LEVEL: ■

Room 4 *Project Management units offered*

Valuing Continuous Process Improvement Projects

SESSION CHAIRPERSON(S)

David T. Asher, MBA
Chief Executive Officer, Asher Associates Inc.

Continuous Process Improvement and/or Lean Six Sigma projects are vital to the continued success in achieving business objectives. A true measure of success is seen in each project's valuation as it relates to specific business requirements.

Six Sigma Projects Designed to Reduce the Cost and Cycle Time of Cross-functional New Drug Development
Gregory Z. Pendell, MBB
Executive Director, Business Process Improvement, MDS Pharma Services

Six Sigma Projects to Increase Revenue
Martin D. Hynes, III, PhD
Director, Six Sigma Champion, Research & Development, Eli Lilly and Company

Session 144 PP 1 - Public Policy/Law, RA

1:30 pm-3:00 pm LEVEL: ●

Room 32AB *CME and Pharmacy credits offered*

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

SESSION CHAIRPERSON(S)

Mark C. Hegarty, JD
Partner/Attorney, Shook Hardy & Bacon LLP

This 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.

John M. Isidor, JD
CEO, Schulman Associates IRB, Inc.

Ernest D. Prentice, PhD
Associate Vice Chancellor, University of Nebraska Medical Center

Session 145 PP 2 - Public Policy/Law, RA

1:30 pm-3:00 pm LEVEL: ■

Room 10

Labeling Risk: Practical Approaches after Wyeth v. Levine

SESSION CHAIRPERSON(S)

Patrick C. O'Brien, JD, PharmD
Partner, Burke O'Neil, LLC

In March 2009, the Supreme Court held in Wyeth v. Levine that pharmaceutical companies are not necessarily shielded from failure-to-warn product liability lawsuits in state courts when the US FDA has determined that approved labeling appropriately explains risk information. This session will explore practical approaches pharmaceutical companies should consider when disseminating risk information to minimize failure-to-warn liability and to maximize the possibility such liability is preempted.

John B. Moriarty, Jr., JD
Senior Vice President, Law, Elan Pharmaceuticals

Sandra A. Milligan, JD, MD
Executive Director, Amgen Inc.

Mary K. Pendergast, Esq., JD, LLM
President, Pendergast Consulting

Session 146 RA 1 - Regulatory Affairs, MA

1:30 pm-3:00 pm LEVEL: ■

Room 7A

The New "Next Door" in Global Development: When East Goes West or West Goes East

SESSION CHAIRPERSON(S)

Carolyn D. Finkle, MSc
Vice President, Global Product Development Strategy, PAREXEL International

Many biotechnology and pharmaceutical companies are considering expanding into global markets with their products. Patent clocks tick, pressure rises from generics, and access to new large patient populations compels. Historically, eastern drug companies have focused on the local market for the development and marketing of their products and have shied away from the perceived difficult FDA and EMEA. Similarly, western pharmaceutical and biotechnology companies have focused on the US and Europe for their initial marketing applications and only much later on the Asia Pacific region.

Today the global market is the new "next door." Developed and emerging Asia companies are considering conducting the required studies for entry into the US and Western Europe. Western companies recognize that the Japanese pharma market is the second largest market and are beginning to understand the need to synchronize or integrate drug development in Japan with US/EU development to reduce the historic time lag for entry into the Japanese market. By 2010, China is anticipated to be the fifth largest drug market in the world, a very large and complex market that differs in many aspects from those in the west. With these global markets opening, companies should be encouraged to consider integrated global development earlier in their product development programs as part of a global development strategy, eg, inclusion of subjects of certain ethnic origin in their clinical trials and inclusion of additional endpoints in their nonclinical studies to satisfy reviewers outside of the FDA and EMEA. Representatives will share their views on harmonized and unique aspects of global product development.

Global Product Development: What Are the Regulatory Considerations when East Heads West and West Heads East (and South)?
Carolyn D. Finkle, MSc
Vice President, Global Product Development Strategy, PAREXEL International

What Japan Found: Its Priority and Strategy
Tatsuo Kurokawa, PhD
Professor, Chiba University, Japan

US Regulatory Considerations for Global Oncology Trials
Grant Williams, MD
President, Williams Cancer Drug Consulting, LLC

Session 147 RA 2 - Regulatory Affairs, CP

1:30 pm-3:00 pm LEVEL: ■

Room 6E

PMDA Update: PMDA Initiatives and Challenges for Faster Review and Better Life-cycle Management of Drugs

SESSION CHAIRPERSON(S)

Yoshiaki Uyama, PhD
Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

In this session, PMDA will explain the current PMDA/Japanese drug regulatory environment and present the PMDA perspectives for faster review and better life-cycle management of drugs.

PMDA Contribution to Better Regulation for Providing Effective and Safe Drugs to Patients
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PMDA Initiatives for Faster Review and Better Life-cycle Management of Drugs
Haruo Akagawa, MPharm
Associate Center Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 148 RA 3 - Regulatory Affairs, CP

1:30 pm-3:00 pm LEVEL: ■

Room 6F *Pharmacy credits offered*

Best Practices for Interactions between Industry and FDA (Office of New Drugs/Office of Surveillance and Epidemiology) Considerations during Drug Product Life Cycle on Safety

SESSION CHAIRPERSON(S)

Susan Boynton, Grad Dip Law, MJ (Health Law)
Executive Director, Therapeutic Area Head, Global Regulatory Affairs, Amgen Inc.

The 2008 OND/OSE Memorandum of Agreement assists FDA in the implementation of the Safety First Initiative and FDAAA provisions. It presents opportunities to develop best principles and practices for industry/FDA interactions for management of safety considerations in drug development. Industry welcomes an opportunity to participate in this initiative and to discuss the best principles and practices during this session.

Office of New Drugs (OND) Perspective
Sandra L. Kweder, MD
Deputy Director, Office of New Drugs, CDER, FDA

Office of Surveillance and Epidemiology (OSE) Perspective
Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

Industry Perspective
John R. Cutt, PhD
Vice President, US DRA; Franchise Head, Immunology and Infectious Diseases (IID), Novartis Pharmaceuticals Corporation

Session 149 RA 4 - Regulatory Affairs, RD

1:30 pm-3:00 pm LEVEL: ■

Room 7B *Pharmacy credits offered*

Pharmacogenomics in Action: A Practical View of Pharmacogenomic Submissions, FDA Review Process, and Label Revisions

SESSION CHAIRPERSON(S)

Peter Morrow, MSc
Manager, US Regulatory Affairs, Eli Lilly and Company

This session will inform the audience of real experiences with pharmacogenomic (PGx) data submissions – one example from an NDA data submission and one from a postapproval data submission that significantly changed the label. An FDA representative will give an overview from the regulator's perspective, and a representative from a sponsor organization will describe its experience with filing genetic data in association with an NDA. All stages of the process will be followed, from planning through execution. Great emphasis has been placed on protecting against possible re-identification of trial subjects. To complement the sponsor's view, the FDA's perspective on the handling of genetic datasets within the Agency, IPRG-review division interactions, and the role of the NCTR will be presented. A sponsor representative will also review experience with postmarketing label revision.

The prescribing information for a marketed product was recently updated to include information about an increased risk of hypersensitivity reactions in a genetically identified subgroup. Pretherapy genetic screening can identify patients at risk and thereby improve patient safety. This session will present information on the initial identification of the marker through retrospective analyses and the verification of the marker's clinical utility in a prospective clinical trial. Outcomes from prospective screening and avoidance of the product on the incidence of hypersensitivity reactions will be summarized. This label change may serve as a model for safety-related genetic biomarker labeling changes. Finally, a sponsor representative will discuss how it came to recognize the need for conducting the study, the study design, sampling, data submissions, and the negotiations with FDA on the label.

Themes from Current Pharmacogenomic Regulatory Guidance: Lessons for the Future
Jane Mitchell, PhD, RAC
Associate Director, Regulatory Services, CanReg, Inc., Canada

Guiding the Clinician with Novel Biomarkers: Label Revisions Using Abacavir Pharmacogenetics (PGt) as an Example
Linda C. Surh, MD, PhD, FRCPC
Director, Centers of Excellence in Drug Discovery, Global Regulatory Affairs, Neurosciences and Pharmacogenetics, GlaxoSmithKline, UK

FDA Perspective
Federico Manuel Goodsaid, PhD
Associate Director, Operations in Genomics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

Session 150 ST - Statistics, CP

1:30 pm-3:00 pm LEVEL: ■

Room 16A MEZZ.

Integrated Analyses through a Drug's Life Cycle: Plan to Think about Safety

SESSION CHAIRPERSON(S)

Andreas Brueckner, MS
Statistician, Bayer Schering Pharma AG, Germany

The enormous amount of safety data collected throughout a drug's life cycle offers opportunities and challenges for safety data analysis and pharmacovigilance. This session will provide an opportunity to have a more in-depth discussion of integrated analyses in the context of safety assessment through several case studies. We will provide examples from analysis created during the submission process, as part of ongoing risk-management activities and for postapproval commitments, discussing problems and pitfalls as well as solutions.

Integrated Analysis: Challenges and Solutions
Sophie Hannah Louise Collingborn, MSc
Epidemiologist, PRA International, Germany

Long-term Safety: Managing Challenges of Data and Interpretation
Melanie Poulin-Costello, MSc
Senior Manager, Biostatistics, Amgen Canada

Meta-analyses for Safety Issues in a Regulatory Setting
Chris Holland, MS
Director, Biostatistics, Macrogenics Inc.

Session 151 TR/PD - Training/Professional Development, CP

1:30 pm-3:00 pm LEVEL: ■

Room 16B MEZZ.

Integrating the Science of Drug Development and Safety into Health-care Professionals' Curriculum

SESSION CHAIRPERSON(S)

Heidi C. Marchand, PharmD
Healthprofessional Outreach, Office of Special Health Issues, Office of the Commissioner, FDA

FDAAA will bring forth new resources, systems, and processes towards managing a product's life cycle. Emergence of a science of safety will expand the health-care practitioner's role. This session reviews the FDA's plans for working collaboratively with the health-care community to begin work on enhancing the pharmacy professional's curriculum and other potential health-care curricula.

Developing a Preclinical Safety Course for the USC Master's in Regulatory Science Program
Mary Ellen Cosenza, PhD, MS, RAC
Executive Director, Regulatory Affairs, Amgen Inc.

Working with Academia to Promote Graduate Courses in Drug Development and Safety
Jonathon M. Parker, MS, RPh
Senior Director, Worldwide Regulatory Affairs, Pfizer Inc

Overview of Project Evaluating the Science of Safety in Colleges of Pharmacy
David A. Holdford, PhD, MS, RPh
Associate Professor of Pharmacy, Virginia Commonwealth University

3:00 pm-3:30 pm **REFRESHMENT BREAK**
Exhibit Halls B1, B2, C, Ground Level
(See SDCC Map for exact locations.)

Session 152 AD - Advertising, RA

3:30 pm-5:00 pm LEVEL: ●

Room 14A MEZZ.

Office of Inspector General (OIG) Settlements: New Integrity Obligations for Pharmaceutical Companies

SESSION CHAIRPERSON(S)

David E. Matyas, JD
Member of the Firm, Health Care and Life Sciences Practice, Epstein Becker & Green, P.C.

This session will describe the recent Department of Health and Human Services Office of the Inspector General (OIG) settlements involving the pharmaceutical industry. As part of those settlements, the pharmaceutical companies usually execute a corporate integrity agreement (CIAs) with the OIG. These CIAs include a wide range of contractual integrity obligations for the company to comply with over what is usually a five-year period. Pharmaceutical professionals are then trained on the terms of the CIAs likely to affect their positions. Pharmaceutical companies are also required to retain an independent review organization (IRO) to review certain systems and transactions related to these high-risk areas. One particular high-risk area of integrity focus has been government price reporting. Other particular high-risk areas include monitoring for off-label promotional activities or financial relationships with health-care prescribers. This session will highlight some of the newest integrity obligations in the CIAs with pharmaceutical companies. These integrity obligations often serve as guidance for what is recommended so that a company's voluntary corporate compliance program is effective, even in the absence of a CIA.

David E. Matyas, JD
Member of the Firm, Health Care and Life Sciences Practice, Epstein Becker & Green, P.C.

Thomas A. Gregory, MBA
Partner, Fraud Investigation and Dispute Services, Ernst & Young LLP

Session 153 AHC/IS - Academic Health Centers/ Investigator Sites, CP, CR/CS, GCP, PP, RA

3:30 pm-5:00 pm LEVEL: ●

Room 6AB

Multitrack Plenary Session
Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape

See **CP** on page 52, for a complete session description.

Session 154 BT - Biotechnology, RD

3:30 pm-5:00 pm LEVEL: ■

Room 1B *CME, Nursing, and Pharmacy credits offered*

Immunogenicity: Strategies for Testing and Evaluation

SESSION CHAIRPERSON(S)

Steven J. Swanson, PhD
Executive Director, Medical Sciences, Clinical Immunology Department, Amgen Inc.

Immunogenicity assessment for therapeutic proteins is an area of increasing concern. Sponsors must have a thorough understanding of a protein's immunogenicity in order to respond to regulatory agencies' concerns. With an increasing number of testing platforms available, it is important to develop an appropriate testing strategy. This session will describe the development of a risk-based approach to immunogenicity testing. Some of the topics discussed include the types of assays that can be utilized in a testing strategy, how those assays can be developed to provide meaningful data on the immunogenicity of a protein therapeutic, how results of immunogenicity tests should be interpreted, and when more sophisticated testing is warranted.

Successful Design of the Strategy for Immunogenicity Assays
Ralf Dieter Hess, PhD, MSc
Principal Consultant, PAREXEL International, Germany

Developing a Risk-based Approach for Immunogenicity Assessment
Steven J. Swanson, PhD
Executive Director, Medical Sciences, Clinical Immunology Department, Amgen Inc.

Session 155 CDM - Clinical Data Management, EC

3:30 pm-5:00 pm LEVEL: ●

Room 11B

Metrics and Their Benefits

SESSION CHAIRPERSON(S)

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

Metrics are and remain key to process improvements. In this session, the speakers will share their ways of looking at available data in order to change processes for the better. One area to be looked at is EDC and the metric data available in EDC, potentially helping organizations to take a closer look at the suitability of their processes. A second aspect to be presented is the use of metrics as the basis for resource planning, team productivity, and the development of training plans. Finally, the medical review metrics for clinical trials, a topic that has been viewed as a niche area with respect to metrics, will be scrutinized.

EDC Front to Back: Streamline Processes End to End for True Operational Benefit
Ross Rothmeier
Senior Director, EDC Portfolio, Covance Inc.

Promoting Teamwork and Communication through Metric Reporting
Greg Matts, MA
Assistant Manager, Satellite Data Operations, RPS (ReSearch Pharmaceutical Services, Inc)

Performance Metrics in Medical Review: Challenges and Limitations
Yuri Zaretsky, MD
President, ZM Company, Canada

Session 153 CP - Clinical Safety and Pharmacovigilance, AHC/IS, CR/CS, GCP, PP, RA

3:30 pm-5:00 pm LEVEL: ●

Room 6AB

Multitrack Plenary Session

Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape

SESSION CHAIRPERSON(S)

Nancy D. Smith, PhD
Former Director, Office of Training and Communications, CDER, FDA

Join industry, regulatory agencies, academia, and patient groups as they share their perspective on how to enhance patient safety in this multitrack plenary session focusing on this year's Annual Meeting program theme, "Better Medicines: Improving Safety with Every Step."

This multitrack plenary session will focus on each of the pillars of the pharmaceutical landscape and their vision for collaboration in the development of safer medicines to maximize patient safety. With increased awareness of drug safety due to drug withdrawals and the FDAAA Act of 2007, this session will discuss the importance of collaboration among the various groups, what is currently being done, and what needs to happen in the future to ensure that patients get the necessary information to make informed health decisions.

Panelists

Michael R. Cohen, DrSc, RPh, MS
President, Institute for Safe Medication Practices

Andrzej Czarnecki, MD, PhD, DSc, FFPM, FISPE
Director, Deputy Qualified Person for Pharmacovigilance, Global Patient Safety, Eli Lilly and Company Ltd., UK

Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

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

Jeremiah Mwangi, MA
Senior Policy Officer, International Alliance of Patients' Organizations, UK

Noël Wathion, Pharm
Head of Unit, Postauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

Anne Quinn Young, MPH
Program Director, Multiple Myeloma Research Foundation

Session 153 CR/CS - Clinical Research and Development/Clinical Supplies, AHC/IS, CP, GCP, PP, RA

3:30 pm-5:00 pm LEVEL: ●

Room 6AB

Multitrack Plenary Session

Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape

See **CP** above, for a complete session description.

Session 156 EC - eClinical, CDM

3:30 pm-5:00 pm LEVEL: ■

Room 11A

A La Carte or Prix Fixe: The Right Menu for Clinical Trials Technology

SESSION CHAIRPERSON(S)

Anne M. Zielinski, MBA
Vice President, Alliances, Medidata Solutions Worldwide

An increasing number of clinical trials employ multiple technologies. Whether to use technologies from an integrated suite or to use technologies from various providers is a question that must be answered – but what is the right answer? Well, it depends. This session explores the options available, the strengths and weaknesses and nuances of each approach. Users of technologies will provide their opinions based on their real-world experience with using a number of integrated technologies so that attendees can make informed decisions.

The Technology Divide: Evaluation of CRO eClinical Strategies as Impacted by the Level of Sponsor System Prescriptiveness
Drew Garty
Senior Director, Worldwide EDC Solutions, PAREXEL International

A Sponsor Perspective on Clinical Trial Technology Sourcing (Build or Buy? Multiple or Single Vendor?): Implications with External Partners
Nathaniel C. Blevins, MS
Global Drug Development IS, Senior Clinical Business Relationship Manager, AstraZeneca Pharmaceuticals LP

Technology Evolved: How to Leverage Your Clinical Data from Global Library Standards and EDC to CDR
Susan Bornstein, MPH
Executive Vice President, eClinical Solutions, a Division of Eliassen Group

Session 157 ERS/DM - Electronic Regulatory Submissions/Document Management, RA

3:30 pm-5:00 pm LEVEL: ■

Room 9

Overcoming Regulatory Diversity to Gain Market Approval in Latin American Regions

SESSION CHAIRPERSON(S)

Michelle A. Perez
Manager, Regulatory Consulting/Professional Services, Image Solutions Inc. (ISI)

The growing Latin American marketplace offers significant opportunities for life science companies able to overcome the challenges of diverse regulatory systems and requirements. This session uses real-life examples to illustrate best-practice strategies to gaining regulatory approval in this emerging region.

The Diversity of Regulatory Systems and the Evolving Requirements in Latin America
Analia Cristina Perez, MS
Director, Medical Evaluations, ANMAT Ministry of Health, Argentina

Effective Collaboration and Communication Strategies for Successfully Submitting CTDs in Latin America
Robert J. Russell, MS
President, RJR Consulting, Inc.

Navigating the Latin American CTD Landscape by Identifying Structural Efficiences
Robin L. Zumbrunnen
Director, Regulatory Operations, ePublishing and Technical Services, Quintiles, Inc.

Session 153 GCP - Good Clinical Practices, AHC/IS, CP, CR/CS, PP, RA

3:30 pm-5:00 pm LEVEL: ●

Room 6AB

Multitrack Plenary Session

Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape

See **CP** on page 52, for a complete session description.

Session 158 IT - Information Technology, CDM

3:30 pm-5:00 pm LEVEL: ■

Room 15B MEZZ. *Pharmacy credits offered*

Smashing Silos: Bringing Service-oriented Architecture and Data Warehousing to a Pharmaceutical Company Environment

SESSION CHAIRPERSON(S)

Paulette V. Roper, MS
Senior Manager, eSolutions, Allergan Inc.

Over time, R&D information systems have grown within functional areas. Some of these well established systems serve R&D functions such as clinical trial management, clinical data collection and management, clinical data analysis, and regulatory submission. These disparate systems that serve specific R&D functions create information silos between departments and functions. Creating individual connections between these applications is difficult because the number of connections increases quadratically with the number of applications. To become more productive and agile, pharmaceutical companies must move away from this silo-operating model. We must move to a fluid-operating model of sharing data between different information systems. We should also develop single-source information architecture, and single-source reporting, and comprehensive security models that protect our intellectual property as well as provide necessary access. These models can help us to become more agile in our R&D operations, provide efficiency in planning, increase governance, and reduce the time lag between completion of clinical studies and NDA submission. This session will focus on the architectural concepts relating to realizing a service-oriented architecture environment across the R&D enterprise. The experiences of different companies in their endeavors to implement this approach will be described.

Modern Architectural Patterns to Support a Changing Safety and Risk Management Ecosystem
Douglas M. Doedens, MS
Senior Vice President, Engineering, Relsys International

Infrastructure to Enable Business Process Optimization
Beth Everett, PhD
Associate Vice President, Enterprise Information Management, SAIC

Integrating Technology Solutions with Business Processes
Paulette V. Roper, MS
Senior Manager, eSolutions, Allergan Inc.

Session 159 PM/FI 1 - Project Management/ Finance, RD

3:30 pm-5:00 pm LEVEL: ■

Room 5B *Project Management units offered*

The Art and Science of Pharmaceutical Project Management: Does a Pharma PM Need to Be a Scientist?

SESSION CHAIRPERSON(S)

Leigh Shultz, PhD, PMP
Associate Project Director, Merck & Co., Inc.

This session will review current practices across the pharmaceutical industry with respect to requiring scientific backgrounds for project managers. Two opposing viewpoints will then be presented in a pro/con debate on whether the pharmaceutical PM must be a scientist first to be effective.

Overview of Current Practices: Scientists as PMs
Nita Ichhpurani, PMP
Director, Drug Development, Development and Regulatory Services, MDS Pharma Services, Canada

A PM is a PM: No Scientific Degree is Required to Be a Pharma PM
Jayna Rose, PhD, PMP
Director, Global Program Manager, Amgen Inc.

A Degree in Science Makes a Better Pharma PM
Claudia G. Harrington, MBA, MS, PMP
Senior Project Coordinator, Bayer Diabetes Care

Session 160 PM/FI 2 - Project Management/ Finance, CR/CS

3:30 pm-5:00 pm LEVEL: ◆

Room 4 *Project Management units offered*

Improving Accrual and Contract Management with Earned Value Management

SESSION CHAIRPERSON(S)

Kristin Lucas, PMP
Senior Director, Clinical Services, ClearTrial LLC

Earned value management (EVM) is rapidly gaining favor as a tool to gain greater control over clinical development costs, payments, and accruals. This session will explore the underpinnings of EVM, its clinical applications, and guidelines for implementing EVM in your organization.

Alan Stowe, MBA
Associate Director, Financial Planning and Analysis, Facet Biotechnology, Inc.

Jack Lawler
Director, Clinical Operations, Cephalon Inc.

Sally Teeters
Senior Manager, Contract and Outsourcing Management, Calistoga Pharmaceuticals

Session 153 PP - Public Policy/Law and RA - Regulatory Affairs, AHC/IS, CP, CR/CS, GCP

3:30 pm-5:00 pm LEVEL: ●

Room 6AB

Multitrack Plenary Session

Improving Safety with Every Step: Pillars of the Pharmaceutical Landscape

See **CP** on page 52, for a complete session description.

Session 161 RA 1 - Regulatory Affairs, GCP

3:30 pm-5:00 pm LEVEL: ●

Room 7B

GCPs in China: Similarities and Differences from ICH GCPs

SESSION CHAIRPERSON(S)

Earl W. Hulihan, MEd
Corporate Compliance Officer, Senior Vice President, Regulatory Compliance, Medidata Solutions Worldwide

With the rapid increase in the conduct of clinical trials in emerging markets, the importance of knowing specific GCP requirements in these regions and ensuring adherence to these practices is essential. India and China are rapidly becoming two of the most preferred countries for conducting phase 2 and 3 clinical trials. This session will bring together speakers who have been involved in the recent conduct of phase 2 and 3 studies in various emerging markets and share their practical examples of exactly what needs to be done to ensure GCP compliance. GCP similarities and differences will be highlighted between ICH, US, EU, and these countries.

The Strategy of Streamlining Chinese Clinical Studies with International GCP Standards
Cai Cao, PharmD
Deputy Director-General, Drug Certification Center, SFDA, China

Regulatory Concerns on Clinical Studies of Herbal Medicines in China
Haitang Xie, PhD
Director, Anhui Provincial Center of Drug Clinical Evaluation, Yijishan Hospital, China

Session 162 RA 2 - Regulatory Affairs, CR/CS

3:30 pm-5:00 pm LEVEL: ●

Room 7A

Regulatory Framework in Central and South America

SESSION CHAIRPERSON(S)

Miguel-Angel Salcedo, MBA
Vice President, Clinical Operations, Europe and Africa, AAIPharma, Spain

Central America and South America are relevant regions when executing clinical trials. Because there is a lack of harmonization from a clinical trials standpoint, legislation is completely different from country to country, and there is a clear need for local knowledge and expertise to meet global timelines. In conclusion, the global clinical development contribution of countries within Central and South America will definitely be higher in the coming years, and it is necessary to become familiar with and understand the regulatory framework in this area.

Description of Clinical Development Activities in Central and South America: Average Start-up Timelines in Central and South America – Projections for the Region
Miguel-Angel Salcedo, MBA
Vice President, Clinical Operations, Europe and Africa, AAIPharma, Spain

Regulatory Framework in Colombia and Venezuela: Timeline Comparation with Reference Countries in the Area (Argentina and Brazil) – Current Contribution and Projections for the Future
Renee Elaine Moore, PhD
President, Global Operations, Progenitor International Research, Germany

Regulatory Framework in Guatemala, Costa Rica, Panama and Dominican Republic: Timeline Comparation with Reference Country in the Area (Mexico) – Current Contribution and Projections for the Future
Eulises Franco, MD
Director, Clinical Operations, ICON Clinical Research, Mexico

Session 163 RD - R&D Strategy, RA

3:30 pm-5:00 pm LEVEL: ■

Room 14B MEZZ.

Asia Pacific: Simultaneous Global Development

SESSION CHAIRPERSON(S)

Chin Koerner, MS
Executive Director, Regulatory Policy, Novartis Pharmaceuticals Corporation

Ulrich Taglieber, MD
Chair, Simultaneous Global Development Committee, PhRMA

Traditionally, global development included the United States, Europe, and sometimes Japan. With recent pharmaceutical growth trends in the Asia Pacific region, there are compelling reasons to move into these growth markets sooner. Meanwhile, there is heightened interest by Asian governments to stimulate multinational investment into local pharmaceutical economies. The time is right for industry and governments to work together to identify key opportunities for and barriers to enable drug development to the region. In this session, we will highlight regulatory and scientific barriers that need to be addressed to build an updated drug development infrastructure in the Asia Pacific region. China will serve as a case study where local and multinational industries and US and Chinese governments have worked collaboratively to help advance international standards.

The Business Case for and the Barriers against Simultaneous Global Drug Development
Jerry Stewart, JD, MS, RPh
Global Regulatory Affairs Strategist-Asia Pacific/Latin America, Wyeth Pharmaceuticals

Drug Development in China: A Case Study
Wen Chang, PhD
Head of Regulatory Intelligence and Advocacy, Asia Pacific Region, Global DRA, Novartis Pharmaceuticals Corporation

Global Harmonization Efforts beyond ICH
Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Director for International Programs, CDER, FDA

Session 164 ST - Statistics, CR/CS

3:30 pm-5:00 pm LEVEL: ■

Room 16A MEZZ. *Pharmacy credits offered*

Adaptive Designs: New Methods

SESSION CHAIRPERSON(S)

Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

Adaptive trials have emerged as a major opportunity to improve the efficiency of the clinical development process. Many companies have begun broader use of adaptive trials for both dose response and for phase 2/phase 3. The wider use of these trials has been accompanied by the use of novel statistical methods and operations. This session will present new innovative methods and logistical operations with examples. There will also be a discussion of the impact of adaptive clinical trials when used throughout the entire drug development process.

Prediction Intervals and Decision Making for Adaptive Trials
L. J. Wei, PhD
Professor of Biostatistics, Harvard University

The Financial Case for Adaptive Drug Development
Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

Using Software to Simplify the Design of Adaptive Trials
S. Krishna Padmanabhan, PhD
Senior Principal Statistician, Wyeth Research

Session 165 TR/PD - Training/Professional Development, RA

3:30 pm-5:00 pm LEVEL: ■

Room 16B MEZZ.

Agile Training: Thinking like a Cable News Network for High-impact Learning

SESSION CHAIRPERSON(S)

Karen M. Soskin, MLS
Director, Quality Systems and Training, Abbott Laboratories

This session will build the business case for agile training, similar to operating a cable news network, in the biopharmaceutical industry. Learn why you need to think like a video journalist, plot like a board game creator, and inquire like a sensitive late night host. The five keys to creativity and production for agile training events will be described and examples will be detailed. Psychological angles will be explored. This session offers a point of view and tools to get started economically and pragmatically. Our overarching intent is to stimulate thinking on agile, smart training as an instrument of business change reflecting today's world.

What Do Video Journalists and Television Show Producers Know about Engaging and Sustaining Our Attention? How Can We Utilize These Techniques in Our Training Programs?
Joan Harley, BSN, RN
Training Consultant and eLearning Developer, Training Extension, a Division of Pastor Consulting, Inc

Motivating People in Clinical Research Study Teams to Change: Ideas and Strategies to Promote Quality Work and Enhance Performance
Elizabeth Gail Brenner, MSW
Associate, Waife & Associates, Inc.

5:00 pm **END OF MONDAY SESSIONS**

5:00-6:00 pm **OPENING RECEPTION**
Exhibit Halls A-C, Ground Level

Notes

7:00 am-5:30 pm **SPEAKER REGISTRATION**
Sails Pavilion, Upper Level

7:00 am-5:30 pm **ATTENDEE REGISTRATION**
Sails Pavilion, Upper Level

7:00 am-5:30 pm **EXHIBITOR REGISTRATION**
Exhibit Hall B1 Lobby, Ground Level

7:15 am-8:00 am **MORNING REFRESHMENTS**
Sails Pavilion, Upper Level

9:00 am-5:30 pm **EXHIBITS OPEN**
Exhibit Halls A-C, Ground Level

9:30 am-5:30 pm **PROFESSIONAL POSTER SESSION**
Sails Pavilion Lobby, Upper Level

Session 201 AD - Advertising, RA

8:00 am-9:30 am LEVEL: ●

Room 14A MEZZ.

Update on Direct-to-consumer Advertising

SESSION CHAIRPERSON(S)

Kristin Davis, JD
Deputy Director, Division of Drug Marketing, Advertising and Communication, Office of Management Programs, CDER, FDA

This session will present an update on direct-to-consumer advertising from a broad perspective and with highlights from FDA professionals who are responsible for policy development and operations in this important topic.

Direct-to-consumer FDAAA Update
Kristin Davis, JD
Deputy Director, Division of Drug Marketing, Advertising and Communication, Office of Management Programs, CDER, FDA

Direct-to-consumer Promotion: DDMAC Update
Sangeeta Vaswani, PharmD
Group Leader, Office of Medical Policy, Division of Drug Marketing, Advertising and Communication, Office of Management Programs, CDER, FDA

Direct-to-consumer Research Update
Amie C. O'Donoghue, PhD
Social Science Analyst, Division of Drug Marketing, Advertising and Communication, Office of Management Programs, CDER, FDA

Session 202 AHC/IS - Academic Health Centers/ Investigator Sites, RA

8:00 am-9:30 am LEVEL: ■

Room 6C

Health Reform, and FDAAA: Impact on FDA, Industry, Health Professionals, Consumers, Payers, and Other Stakeholders

SESSION CHAIRPERSON(S)

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

Stanley A. Edlavitch, PhD, MA, FACE
Professor, Epidemiology and Director, Graduate Training, School of Medicine, University of Missouri Kansas City

President Obama campaigned on a health reform platform that includes making health insurance affordable and accessible to all, lowering health-care costs, and promoting public health. This session will provide a six-month progress update on health reform and implementation of the FDAAA. Speakers will provide perspectives on the opportunities and challenges for diverse stakeholders.

Public-private Sector Collaboration to Facilitate Health Reform
J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information and Technology, Office of the Director, Agency for Healthcare Research and Quality, HHS

Perspectives on Drug Development and Safety
Robert Giffin, PhD, MA
Director, Forum on Drug Discovery, Development, and Translation, Institute of Medicine/National Academy of Sciences

FDA Perspective
Malcolm J. Bertoni, MS
Assistant Commissioner for Planning, Office of the Commissioner, FDA

Session 203 BT - Biotechnology, RA

8:00 am-9:30 am LEVEL: ■

Room 1B

Countering Bioterrorism: Regulatory Methods Designed to Speed the Availability of Biological Products

SESSION CHAIRPERSON(S)

Cynthia L. Kelley, MS
Senior Advisor for Counterterrorism/Medical Countermeasures, Office of the Director, CBER, FDA

The national strategic plan to address bioterrorism includes the development of drug products. The FDA has promulgated guidance and implemented methods to facilitate interaction with biologics sponsors who sponsor the development of counterterrorist therapeutic products.

Regulatory Mechanisms to Facilitate the Development of and Access to Medical Countermeasures
Cynthia L. Kelley, MS
Senior Advisor for Counterterrorism/Medical Countermeasures, Office of the Director, CBER, FDA

Lessons Learned from Attempting to Navigate the Path to Medical Countermeasure Licensing
Alan Liss, PhD
Deputy Director, Regulatory and Quality Affairs, BARDA/ASPR, Department of Health and Human Services

Industry Perspective and Experience in Delivering Four Medical Countermeasures into the Strategic National Stockpile
Andrew Storey
Vice President, Quality, Clinical and Regulatory Affairs, Cangene Corporation, Canada

Session 204 CDM - Clinical Data Management, OS

8:00 am-9:30 am LEVEL: ■

Room 11B

Future of Data Management/Evolving Role of Data Management

SESSION CHAIRPERSON(S)

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

Clinical data management has been around for many decades, however, recently transitioned through major changes. The move from paper-based studies to EDC changed the skill requirements substantially. Off-shoring and outsourcing became a threat to the traditional CDM organizations, with sev-

eral companies moving their data management activities to either CROs or to India-based service organizations. This session will address some of the trends in industry, the changing environment and also provide thoughts on how internal CDM can add value to overall drug development.

What a Partnership Means for Data Management
Andrew Schafer, MBA
Senior Director, Strategic Resourcing, Quintiles Transnational Corp.

Redefining Data Management's Role in EDC
Michael Burton
Director, eClinical Solutions, Omnicare Clinical Research

Keeping Data Management in House: How and Why?
Johann Pröve, PhD
Global Head, Data Management, Bayer Schering Pharma AG, Germany

Session 205 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

8:00 am-9:30 am LEVEL: ■

Room 17A MEZZ.

Quality by Design (QbD): Linking Quality to Efficacy – *Part 1 of 2*

SESSION CHAIRPERSON(S)

Janet Woodcock, MD
Director, CDER, FDA

Part 2 of this session will take place on Tuesday at 10:00 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.

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

QbD Linkage to Efficacy
Badrul Chowdhury, MD, PhD
Director, Division of Pulmonary and Allergy Drug Products, Office of New Drugs, CDER, FDA

Panel Discussion and Q&A
Janet Woodcock, MD
Director, CDER, FDA

Session 206 CP 1 - Clinical Safety and Pharmacovigilance, OS

8:00 am-9:30 am LEVEL: ■

Room 33AB *Pharmacy credits offered*

Pharmacovigilance Organization Models: How New Regulatory and Business Needs Are Changing the Pharmacovigilance Department, and How to Design an Effective Organization

SESSION CHAIRPERSON(S)

Axel Hagel
Practice Manager, Intrasphere Technologies, Inc., Canada

Companies continuously evaluate their safety vision, but often neglect the organizational structure in order to support the vision and instead develop band-aid solutions yielding a suboptimal design. This session will examine a methodology for developing an optimal organizational structure that can withstand major business changes. Various organizational structures will be presented with their associated strengths and weaknesses factoring in the ever-changing regulatory and business reality.

Pharmacovigilance Organization Models: How New Regulatory Needs Are Changing the PV Department, and How to Design an Effective Organization
Axel Hagel
Practice Manager, Intrasphere Technologies, Inc., Canada

Enabling Strategic Roadmaps: How Effective Organization Design Enables Global Pharmacovigilance Transformation
Sanket Agrawal, MBA
Executive Director, Global Regulatory Affairs and Safety, Amgen Inc.

Real-life Example of Planning a Reorganization from a Pharmaceutical Company Perspective
Jill E. Robinson, MBA, RPh
Vice President, Global Pharmacovigilance Operations, Wyeth Research

Session 207 CP 2 - Clinical Safety and Pharmacovigilance, CR/CS

8:00 am-9:30 am LEVEL: ■

Room 30AB

Development Safety Update Report (ICH E2F): Update, Current Status, and Major Provisions

SESSION CHAIRPERSON(S)

Cindy R. Engle
Director, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

The collection, monitoring, and regulatory reporting of safety information on clinical trial subjects is an essential part of conducting clinical trials. Regulations and guidance specify the responsibilities and reporting requirements for sponsors, investigators, and their institutions. Most of these focus on the expedited reporting of individual case safety reports, with the ICH E2A Guideline generally considered the standard for defining the content and timing of information that must be sent to the various stakeholders. Equally important, however, is the periodic review and evaluation of the evolving safety information, which is crucial to the ongoing assessment of risk during clinical development of an investigational drug.

Recognizing the need for an internationally harmonized periodic report for investigational compounds, similar to the Periodic Safety Update Report for marketed products, the CIOMS VI and VII Working Groups introduced the concept of an internationally harmonized Development Safety Update Report (DSUR), and provided recommendations regarding general principles behind a DSUR, as well as model DSUR examples. Following on from the work of the CIOMS Working Groups, an ICH Expert Working Group (EWG) was convened to develop an ICH Guideline on DSURs. A Step 2 draft Guideline was published for consultation and comment in June 2008, and it is expected that a final Guideline (Step 4) will be available by the time of the DIA Annual Meeting in June 2009.

This session will provide an update on the work of the ICH E2F EWG, and will also describe the major components of a DSUR and the rationale for their inclusion. Discussion will focus on the major components of the DSUR, those that generated considerable comment during the consultation period, and those that are most changed from the draft Guideline. Draft examples of model DSUR reports will also be provided. Several of the more problematic/controversial issues will be highlighted.

Key Sections of the DSUR Guideline: Part 1
Ellis Unger, MD
Deputy Director, Division of Cardiovascular and Renal Products, CDER, FDA

Key Sections of the DSUR Guideline: Part 2
Yukiko Watabe, MSc, RPh
Group Manager, Drug Safety Evaluation Department, Chugai Pharmaceutical Co., Ltd., Japan

Implications for Implementation
Valerie E. Simmons, MD, FFPM
EU QPPV Executive, Global Patient Safety, Eli Lilly and Company Ltd., UK

Session 208 CR/CS 1 - Clinical Research and Development/Clinical Supplies, AHC/IS

8:00 am-9:30 am LEVEL: ■

Room 1A

Using Performance Metrics to Improve Clinical Trial Performance and Reduce Enrollment Risk

SESSION CHAIRPERSON(S)

Anna E. McBride, BSN, MBA
Director, Strategic Development, MMG

In this session, we will look at new approaches for improving clinical trial cycle time and enrollment through measurement, prevention, and systematic improvement. We will look at measures and techniques that can help pinpoint performance, enrollment risk, and management of expectations, avoid those problems, and help sites perform more effectively and efficiently.

Developing a Risk Management Plan and Associated Metrics to Ensure Successful Protocol
Graeme Currie, PhD
Vice President, Clinical Operations, Sepracor Inc.

Advance Actions to Ensure that You Have the Best Protocol and Sites
David S. Zuckerman, MS
President, Customized Improvement Strategies LLC

Metrics Monitoring and Contingency Planning to Optimize Enrollment
Anna E. McBride, BSN, MBA
Director, Strategic Development, MMG

Session 209 CR/CS 2 - Clinical Research and Development/Clinical Supplies, OS

8:00 am-9:30 am LEVEL: ●

Room 5B

Understanding the Complexities of Latin American Borders and Local Regulations to Get the Clinical Trial Material into the Country

SESSION CHAIRPERSON(S)

Claudina Mariel Berciano, RPh
Director of Clinical Logistics Services, Latin America, PAREXEL International, Argentina

The expansion of clinical trials into new regions offers a solution to the failure to recruit patients on time, but this approach has some difficulties. This session will provide a brief overview of some of the logistical and regulatory challenges involved in performing clinical trials in Latin America as well as possible approaches to mitigate their effects on the project initiation. The six major markets – Brazil, Mexico, Argentina, Chile, Peru, and Colombia – have experienced a substantial increase in clinical trials. New countries such as Ecuador, Panama, and Costa Rica are currently being included in some clinical trials. Emerging countries offer access to large patient populations, the majority of which are treatment-naïve and have a rapid patient enrollment in clinical trials. However, it is important to take other factors into consideration when planning a clinical trial in Latin America. Clinical trial logistics in this region is a key area of concern, especially getting the drug to patients.

Regulatory Aspects of CTM Import into Latin American Countries
Carolina Dias Rato, RPh
Regulatory Affairs Manager, i3 Latin America, Argentina

Understanding Latin American Borders
Jorge Mezzadra
Managing Director, USA, EU and Asia, OCASA

Strategies to Mitigate Import and Project Initiation Delays in Latin American Countries
Claudina Mariel Berciano, RPh
Director of Clinical Logistics Services, Latin America, PAREXEL International, Argentina

Session 210 CR/CS 3 - Clinical Research and Development/Clinical Supplies, CDM

8:00 am-9:30 am LEVEL: ●

Room 6D *Pharmacy credits offered*

Medical Imaging: Update on PhRMA Consortium Initiatives

SESSION CHAIRPERSON(S)

Craig H. Lipset, MPH
Director, Molecular Medicine, Pfizer Inc.

While the opportunities for using medical imaging in clinical trials have grown substantially over the past decade, challenges have remained to limit consistent success. A PhRMA imaging group was created to identify and address these challenges, with membership extended to include other stakeholders including imaging CROs, academic groups, and government entities. Through collaboration across stakeholders, the group has worked to address pre-competitive areas of significant impact to those responsible for the appropriate use of medical imaging in clinical development.

Making the Metrics Meaningful: How Sponsors and Core Imaging Labs Can Work Together to Drive Continuous Process Improvement
Karen Connor, MS
Senior Director, Perceptive Informatics

Update on Consortium for Improving Web-based Image Transfer
Craig H. Lipset, MPH
Director, Molecular Medicine, Pfizer Inc.

Session 211 EBM/IMP - Evidence-based Medicines/Impact (Impact of Medical Products and Therapies), RA

8:00 am-9:30 am LEVEL: ●

Room 17B MEZZ.

Beyond the QT Interval: Regulatory Perspective on the Use of Surrogates in Premarket Safety and Risk/Benefit Evaluation

SESSION CHAIRPERSON(S)

Robert Fiorentino, MD, MPH
Medical Officer, Office of New Drugs, CDER, FDA

The development of the thorough QT study offers insight into one mechanism by which evidence-based clinical data have been incorporated into the premarket evaluation of safety. Beyond prolongation of the QT interval, could there be other surrogates associated with adverse clinical outcomes that can be used to better assess benefit/risk in drug development? Scientific reviewers at the FDA will discuss recent efforts to model the effects that small, drug-induced increases in blood pressure may have on cardiovascular risk for chronically taken drug products. An industry speaker will discuss practical issues of BP evaluation (ABPM) and working group consensus opinions.

Alterations in Blood Pressure and Cardiovascular Outcomes
Robert Fiorentino, MD, MPH
Medical Officer, Office of New Drugs, CDER, FDA

Lessons Learned from Thorough QT and Simulation of CV Outcomes Using Available BP Data
Rajanikanth Madabushi, PhD
Pharmacometrics Reviewer, CDER, FDA

Practical Considerations and Building Consensus
Jeffrey Heilbraun, MS
Senior Director, Business Development, Medifacts International

Session 212 EC - eClinical, CP

8:00 am-9:30 am LEVEL: ■

Room 15A MEZZ.

Standards in Your Future: How SAFE-BioPharma, IHE, and CDISC Are Collaborating to Improve Safety Reporting

SESSION CHAIRPERSON(S)

Rich Furr
Head, Global Regulatory Affairs and Chief Compliance Officer, SAFE-BioPharma Association

Three industry standards organizations are collaborating to improve global clinical trial electronic data collection and safety reporting. Representatives from these groups – CDISC, IHE, and SAFE-BioPharma Association – will describe their collaboration around their respective standards to develop an approach in which Individual Case Safety Reports are electronically generated and submitted to the FDA. This convergence of technology is an early step in achieving other clinical systems improvements including faster safety trend analysis, data mining, and moving data from electronic health records to archived and digitally signed electronic case report forms and to individual case safety reports.

The Opportunity for Digital Signature in the Retrieve Form for Data-capture Workflow
Landen C. Bain
Health-care Liaison, CDISC

Interoperability in Safety Reporting
Lori Reed-Fourquet, MS, MSc
Consultant, e-HealthSign, LLC

Rich Furr
Head, Global Regulatory Affairs and Chief Compliance Officer, SAFE-BioPharma Association

Session 213 ERS/DM - Electronic Regulatory Submissions/Document Management, EC

8:00 am-9:30 am LEVEL: ■

Room 9

Implementing Global Electronic Submissions: The Company and the Regulators Give their Points of View

SESSION CHAIRPERSON(S)

Mollie Shields-Uehling
President and CEO, SAFE-BioPharma Association

Safety is enhanced with faster and more accurate reporting, a goal of fully electronic submissions. eSubmissions are being made possible with the use of the SAFE-BioPharma digital signature standard. The session will report on the growing use of the SAFE-BioPharma standard, a large pharmaceutical company's initiative to make simultaneous electronic submissions to both the FDA and to EMEA, and a regulator's perspective on the move to all-electronic receipt and review.

FDA Perspective on the Advance to Fully Electronic Submissions
Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

EMEA Perspective on the Advance to Fully Electronic Submissions
Timothy Buxton
Head of Sector, Project Management, Communications, and Networking Unit, European Medicines Agency, European Union

Industry Perspective on the Advance to Fully Electronic Submissions
Teresa Brunone, MS
Assistant Director, Global Regulatory Operations, GlaxoSmithKline

Session 214 GCP - Good Clinical Practices, RA

8:00 am-9:30 am LEVEL: ■

Room 30CD *Pharmacy credits offered*

Corrective Action and Preventive Action Program for Clinical Trial Programs

SESSION CHAIRPERSON(S)

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

To assure the veracity and the scientific value of the clinical research data identified in the package insert is to adhere to Good Clinical Practices regulations and guidance, protocols, using sound medical practice to obtain the data. The sponsor has to develop clinical and project management systems and standard operating procedures to ensure that all personnel involved in clinical research are producing high-quality data. Developing and using a Corrective And Preventive Action Program (CAPA) is one quality assurance program that can be used to evaluate and correct problems that may have occurred in a sponsor's clinical program.

Implementing a Corrective and Preventive Action (CAPA) Program in a Clinical Quality System: A CRO's Perspective
Richard E. Shannahan, Jr.
Senior Quality Assurance Auditor, ICON Development Solutions

Beyond the Audit Report: A Means for Improving the Organization's Quality Management System through Classifying, Measuring, Compiling, and Trending Audit Results
Kathleen Magliere Zajd
Senior Vice President, Regulatory Operations/Compliance, Prologue Research International, Inc.

Integration of Q9 Quality Risk Management into Industry and Regulatory Operations when Conducting GCP Regulatory Inspections and Audits and Implementing Effective CAPAs
Sherri A. Hubby
Director, US Quality Assurance, Premier Research Group

Session 215 IT - Information Technology, ERS/DM

8:00 am-9:30 am LEVEL: ●

Room 15B MEZZ. *Pharmacy credits offered*

Integrated Web-based Tools Supporting the Pharmaceutical Policies of Regulatory Bodies: From Clinical Trial National Registries to the Regulatory eSubmission

SESSION CHAIRPERSON(S)

Marisa De Rosa, PharmD, PhD
Head of Systems and Services for Health Department (SISS), CINECA Inter-University Consortium, Italy

Advanced web-based systems for supporting large and complex organizations can improve and simplify the management of all the processes across the pharmaceutical domain, from early stages of clinical research through monitoring and postmarketing surveillance. From the perspective of regulatory bodies, the availability of an integrated and unified IT infrastructure is becoming of paramount importance in order to guarantee the definition, planning, implementation, and tracking of pharmaceutical policies. The introduction of IT systems, when properly engineered, can lead to the simplification of drug registration procedures, to the tracking of pharmaceutical expenditure, and to the dissemination of independent information, by supplying the availability of centralized repositories of all the information (data and documents) updated in real-time.

This session will provide an outline on how the use of such IT platforms, in Italy and in other countries, can bring an improved efficiency and transparency of the scientific evaluation process and a deeper collaboration among all the actors involved in the regulatory process, while ensuring accountability in regulatory decision making.

ePlatform: An FDA Perspective
Armando Oliva, MD
Deputy Director, Bioinformatics, Office of Critical Path Programs, Office of the Commissioner, FDA

MHRA Perspective
Alison Davis
Director, Information Management Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Perspective from Austria
Christa Wirthumer-Hoche, PhD
Head of Institute, Deputy Head of PharmMed, AGES PharmMed, Austria

Session 216 MW - Medical/Scientific Writing, TR/PD

8:00 am-9:30 am LEVEL: ■

Room 31AB *CME and Pharmacy credits offered*

Hot Topics in Publication Writing: Challenges and Solutions

SESSION CHAIRPERSON(S)

Karen L. Woolley, PhD
CEO, ProScribe Medical Communications; Associate Professor, University of Queensland, Australia

This session will identify, and provide solutions for, a number of publication writing challenges. Experienced medical writers will provide practical suggestions to help attendees understand how to: 1) ensure new medical writers are aware of (the most) relevant international publication writing guidelines; 2) enhance authors' chances of publication success, particularly for authors who have English as a second language; 3) use research and practical tools to help medical writing employees or contractors stand up to scrutiny by senior management, authors, medical journal editors, and the media.

Guidelines, Guidelines Everywhere: Which Guidelines Do Medical Writers Need to Know when Working on Publications?
Noëlle Holten Pind
Clinical Reporting, Global Development, Novo Nordisk A/S, Denmark

English Isn't Necessarily the Biggest Issue: Effective Ways to Help 'English as Second Language' Authors to Publish
Yuko Kojima
Manager, Japan Medical Communications, Japan Clinical Research, Eli Lilly Japan K.K., Japan

Round Up the Usual Suspects? Evidence and Practical Tools to Help Medical Writers (and Sponsors) Stand Up to Scrutiny
Karen L. Woolley, PhD
CEO, ProScribe Medical Communications; Associate Professor, University of Queensland, Australia

Session 217 OS - Outsourcing, CR/CS

8:00 am-9:30 am LEVEL: ■

Room 5A

Utilize Standardized CRO Performance Metrics to Drive Appropriate Change: An Industry-wide Effort among Sponsors and CROs to Develop and Implement Standardized CRO Performance Metrics to Improve Clinical Trial Performance

SESSION CHAIRPERSON(S)

Cory Gutterman, MPH
Associate Director, Outsourcing, Abbott Laboratories

Learn about an industry-wide effort to develop and implement standardized CRO performance metrics to improve clinical trial performance. Today's drug development industry is under increased pressure to improve its research and development performance/strategies by reducing drug development times and costs, while at the same time increasing productivity and maintaining quality. The utilization of standardized performance metrics by the drug development industry to reduce clinical development times and to improve clinical trial deliverables is essential to its success. In 2006, a group of biotechnology, pharmaceutical, and service provider organizations formed a not-for-profit organization, the Metrics Champion Consortium (MCC), where member organizations work collaboratively to develop and implement standardized performance metrics aimed at improving the efficiency and effectiveness of managing and tracking resources needed to successfully run clinical trials. A review of those metrics will be provided in this session.

Collaborative Efforts to Establish Industry Metrics
Guy Mascaro
President, Metrics Champion Consortium

Process for Development of Clinical Trial Performance Metrics
Cory Gutterman, MPH
Associate Director, Outsourcing, Abbott Laboratories

Clinical Trial Performance Metrics: Development of the Beta Version
April Davis, MA
Senior Director, eClinical Technology Services, Perceptive Informatics

Session 218 PM/FI 1 - Project Management/ Finance, CMC/GMP

8:00 am-9:30 am LEVEL: ■

Room 4 *Project Management units offered*

Comparing Risk Management Approaches of the US and Japan (Asia): Implications for Global Drug Development

SESSION CHAIRPERSON(S)

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

Effective risk management in pharmaceutical projects can prevent delays, reduce scope creep, and decrease or contain development costs. However, different approaches and risk tolerance styles can lead to different risk management plans for the same potential event. Recognizing that tolerance for risk can vary between different companies and regions within the same country, this session will explore similarities and differences between US- and Japan-based styles of risk management, and will identify ways to develop harmonized risk plans for cross-cultural global development projects.

Japanese Perspective on Risk Management
Yuko Kawakita, RPh
Project Manager, Global Project Management, Daiichi Sankyo, Japan

US Perspectives on Risk Management
Mark A. Kryah, PMP
CMC Project Manager, Eli Lilly and Company

Developing Harmonized Risk Management Plans
Blythe Anderson, MS
Project Manager, Merck & Co., Inc.

Session 219 PM/FI 2 - Project Management/ Finance, TR/PD

8:00 am-9:30 am LEVEL: ■

Room 2 *Project Management units offered*

Implementing Enterprise-wide Project Management Tools

SESSION CHAIRPERSON(S)

Matthew J. Kiernan, MBA
Partner, Pharmica Consulting

Implementing enterprise-wide project management tools has been a trend in the pharmaceutical industry over the last five years, but have they changed the project manager role? This session will explore each area of project management, discuss lessons learned, and best practices for implementation.

The Evolution of the Project Manager Role in a World of Enterprise PM Tools
Jodi Hayes, MBA
Senior Project Manager, Wyeth Pharmaceuticals

Enhancing R&D Project, Portfolio, and Resource Decisions with Enterprise PM Applications
Gregory Bayer, MBA
Group Director, R&D Resource Management

The SPEAR Tool: An Objective Clinical Resource Utilization Model Driven by Functional Productivity and Projected Patient Enrollment
Grant Morgan, PhD
Senior Global Project Manager, Allergan Inc.

Session 220 PP - Public Policy/Law

8:00 am-9:30 am LEVEL: ●

Room 32AB

Transparency: EMEA's Future Policy

SESSION CHAIRPERSON(S)

Noël Wathion, Pharm
Head of Unit, Postauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

One of the European Medicines Agency's priorities for 2009 is to further increase transparency and provide for more openness in its activities. This session will discuss what the Agency is currently working on for the development of an EMEA transparency policy that will be released for public consultation later in 2009.

Panelists

Martin Harvey-Allchurch, Esq., LLM
Head of Executive Support, European Medicines Agency, European Union

Vincenzo Salvatore, II, JD, PhD
Head of Legal Sector, European Medicines Agency, European Union

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

Session 221 RA 1 - Regulatory Affairs, PP

8:00 am-9:30 am LEVEL: ●

Room 6E

FDA Goes Global: Domestic Mission – Global Presence

SESSION CHAIRPERSON(S)

Patricia L. DeSantis
Vice President, Global Regulatory Affairs, Johnson & Johnson Pharmaceuticals Group

The US FDA will station technical staff, as well as inspectors, in China to establish on-site cooperation and to scrutinize exports to the world's largest economy, responding to concerns over the safety of China-produced food, toys, and pharmaceutical ingredients. Recruiting has begun for inspectors in India as well. In this session you will learn why it is important to station FDA offices abroad and the goals and status of the offices.

Regulatory Changes in the Greater China Region
Linda Zhao, PhD
President and CEO, Draco Healthcare Consulting LLC

FDA Perspective
Murray M. Lumpkin, MD, MSc
Deputy Commissioner, International and Special Programs, Office of the Commissioner, FDA

Session 222 RA 2 - Regulatory Affairs, CP

8:00 am-9:30 am LEVEL: ■

Room 6F

Postmarketing Requirements and Commitments (PMRs/ PMCs): FDAAA's Impact and How FDA and Industry Are Addressing the Backlog

SESSION CHAIRPERSON(S)

Beth Duvall-Miller
Team Leader, Regulatory Affairs Team, Office of New Drugs, CDER, FDA

The Food and Drug Administration Amendments Act of 2007 provided FDA with additional authority to require certain postmarketing safety studies and clinical trials. This session will describe the impact of FDAAA on developing and tracking PMRs/PMCs and how both FDA and industry are addressing the backlog of PMRs/PMCs.

PMR/PMC Tracking and FDAAA Backlog Review: Progress and Future Strategies
Cathryn C. Lee, MS
Regulatory Project Manager, Office of New Drugs, CDER, FDA

Postmarketing Expectations and Requirements in the FDAAA Era: A Large Pharma's Experience
David Altarac, MD, MPA
Vice President, Merck & Co., Inc.

FDAAA's Impact on PMRs/PMCs: FDA's New Policies and Procedures
Susan L. Honig, MD
Medical Reviewer, Guidance and Policy Team, Office of New Drugs, CDER, FDA

Session 223 RA 3 - Regulatory Affairs, RD

8:00 am-9:30 am LEVEL: ■

Room 7A *Pharmacy credits offered*

Biopharmaceutical Company Regulatory Affairs Functions: Strategies and Structures

SESSION CHAIRPERSON(S)

Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

This session looks at regulatory affairs functions within biopharmaceutical companies and the strategies and tactics being employed to handle changing global workload and regulatory requirements. Tufts CSDD will present the results of a study conducted in 2008 and early 2009 to benchmark the regulatory affairs functions. Representatives from major pharmaceutical and biotechnology companies will also discuss their direct experiences, challenges, and vision for their organizations' global regulatory affairs functions.

Overview of the Evolving Regulatory Affairs Function
Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

A Pharma Perspective: Experiences, Challenges, and Response
Joseph C. Scheeren, PharmD
Senior Vice President, Head, Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals

A Pharma Perspective: Experiences, Challenges, and Response
Steven J. Miller, PhD
Vice President, Regulatory Affairs, Johnson & Johnson Pharmaceutical R&D LLC

Session 224 RA 4 - Regulatory Affairs, CR/CS

8:00 am-9:30 am LEVEL: ●

Room 8

Improving Your Chances of Getting a Drug or Biologic Approved during the First Review Cycle

SESSION CHAIRPERSON(S)

Daniel Brum, PharmD, MBA, RAC
Senior Regulatory Management, Division of Cardiovascular and Renal Products, CDER, FDA

Beginning in 2008, CDER and CBER officially implemented the Good Review Management Principles and Practices (GRMPs), also known as the 21st Century Review Process. The GRMPs build upon FDA's current best practices and incorporate goals for review management improvements. This session will include highlights from a report entitled "Independent Evaluation of FDA's First Cycle Review Performance," points for sponsors to consider prior to submitting drug applications, and examples of setbacks incurred during the drug review process.

How to Avoid Setbacks in the Drug Approval Process: Part 1 – Presubmission
Vada A. Perkins, BSN, MSc, RN
Regulatory Program Management Officer, Office of the Director, CBER, FDA

How to Avoid Setbacks in the Drug Approval Process: Part 2 –- Postsubmission
Edward Fromm, RPh, RAC
Supervisory Consumer Safety Officer, Office of New Drugs, CDER, FDA

Enhancing the Probability of First Cycle Approvals
Pamela Smeder-Douglas, MBA
Senior Associate, Booz Allen Hamilton

Session 225 RA 5 - Regulatory Affairs, RD

8:00 am-9:30 am LEVEL: ■

Room 7B

Development of Oncology Products in the EU and US: Can We Do Better?

SESSION CHAIRPERSON(S)

Ionel Mitrica, PhD, RAC
Director, Clinical Development, Oncology, GlaxoSmithKline

As has become apparent in recent years in both the EU and the US, the scientific advances of the last decade have not necessarily been quickly converted into medical advances – ie, innovative pharmaceutical products. This trend applies to the field of oncology too, and happens despite continuous increases in the funding available for medical research in the field. This session will attempt a comparative review of regulatory experience, current tools/procedures, and future plans for facilitating the development of oncology products in the EU and US regulatory regions.

Development of Oncology Products in the EU and US: EMEA Views
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Development of Oncology Products in the EU and US: Views from Academia
Bradley J. Monk, MD, FACOG, FACS
Associate Professor and Director of Research, Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Chao Family Comprehensive Cancer Care, University of California Irvine Medical Center

Development of Oncology Products in the EU and US: FDA Views
Robert Justice, MD
Director, Office of Oncology Drug Products, CDER, FDA

Session 226 RD - R&D Strategy

8:00 am-9:30 am LEVEL: ●

Room 14B MEZZ.

Pediatric Drug Development: A Global Challenge

SESSION CHAIRPERSON(S)

Klaus Rose, MD, MS
Head, Pediatrics, F. Hoffmann-La Roche Ltd., Switzerland

US and EU legislation now require the inclusion of children in drug development with a different mixture of voluntary incentives and mandatory requirements. In the EU, a Pediatric Investigation Plan (PIP) is now required at the end of phase 1, while the FDA approach is more flexible depending of the severity of the targeted disease. The regulatory authorities of the US, EU, and Japan confer on pediatrics on a regular basis. Furthermore, at the end of 2007 the World Health Organization initiated a campaign to make medicines child size, focusing on childhood diseases of developing countries. In response, the pharmaceutical industry's global representation, IFPMA, has established a pediatric task force. Pediatric requirements have an increasing impact on the drug development process and confront companies with continuously increasing requests from regulators on epidemiology, preclinical and clinical safety, pharmacovigilance, clinical testing, and postmarketing surveillance, to name a few. The session will map out the challenges with speakers who represent the pharmaceutical industry, regulatory authorities, and further stakeholders. The panel discussion will contribute to draft tentative solutions to the main challenges.

Pediatric Drug Development: Update on Europe and the WHO Global Pediatric Campaign
Klaus Rose, MD, MS
Head, Pediatrics, F. Hoffmann-La Roche Ltd., Switzerland

US Pediatric Legislation and Stimulation of Pediatric Research: Challenges and Opportunities
Samuel D. Maldonado, MD, MPH
Vice President and Head, Pediatric Drug Development/Center of Excellence, Johnson & Johnson Pharmaceutical R&D LLC

Learnings from US Pediatric Legislation and Global Collaboration of FDA with Other Regulatory Authorities
William J. Rodriguez, MD, PhD
Science Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

EU Pediatric Regulation: Update and Challenges
Agnès Saint-Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization of Medicines for Human Use Unit, European Medicines Agency, European Union

Session 227 ST - Statistics, RA

8:00 am-9:30 am LEVEL: ■

Room 16A MEZZ. *Pharmacy credits offered*

The Next Wave of Adaptive Trials

SESSION CHAIRPERSON(S)

Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

For several years, we have heard about the tremendous interest and potential of adaptive clinical trials. Many companies have already been designing and implementing these trials. Now that the initial phase of implementation of these trials is well underway, some companies are planning the next wave of adaptive trials. We will discuss the future of adaptive clinical development from the perspective of both the pharmaceutical industry and regulatory agencies. This session will present examples of ongoing adaptive clinical trials as well as discuss the future directions for adaptive clinical development. We will also discuss the global planning of clinical development programs from early phase 1 through submission. Additionally, the use of adaptive trials in product portfolio planning and decision making will be reviewed.

Panel Discussion

Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics/Pharmacogenetics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Session 228 TR/PD - Training/Professional Development, MA

8:00 am-9:30 am LEVEL: ●

Room 16B MEZZ.

Get Connected! Expanding Your Business Network

SESSION CHAIRPERSON(S)

Janet F. Zimmerman, MS, RN
Associate Director, Clinical Research Group, Drexel University College of Medicine

Business networking is an essential marketing skill for the 21st century. Presenters will explain the difference between face-to-face and online networking and how these connections can be used to identify business opportunities. Emphasis will be on describing proven methods for developing or expanding a professional network locally and globally.

Networking for Career Success
Christopher H. Matheus, MBA
Senior Director, Sales, ICON Clinical Research

Setting Up Your Networking Toolbox
Janet F. Zimmerman, MS, RN
Associate Director, Clinical Research Group, Drexel University College of Medicine

9:30 am-10:00 am **REFRESHMENT BREAK**
Exhibit Halls B1, B2, C, Ground Level
(See SDCC Map for exact locations.)

Session 229 AD - Advertising, MA

10:00 am-11:30 am LEVEL: ●

Room 14A MEZZ.

Introduction to Pharmaceutical Marketing Primer

SESSION CHAIRPERSON(S)

Janet L. "Lucy" Rose, MBA, PA
President, Lucy Rose and Associates, LLC

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

FDA Perspective
Kristin Davis, JD
Deputy Director, Division of Drug Marketing, Advertising and Communications, CDER, FDA

Session 230 AHC/IS - Academic Health Centers/ Investigator Sites, IT

10:00 am-11:30 am LEVEL: ■

Room 6C

The Impact of FDAAA and Health Information Technology on Drug Safety, Standards, and Data Stewardship: 2009 Update and Future Plans

SESSION CHAIRPERSON(S)

J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality

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

With a new administration and HHS leadership, health information technology will enable many FDA, AHRQ, and ONC initiatives. Seasoned speakers from these three organizations will describe the anticipated changes health information technology brought about through the innovative policies and strategies of the new president. FDAAA of 2007 calls for active postmarket safety surveillance and analysis. Section 905 of FDAAA calls for the HHS Secretary to develop methods to access disparate data sources and establish a postmarket risk identification and analysis system to analyze health-care data from multiple sources. The law sets a data access goal of 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. FDA has launched the Sentinel Initiative to monitor medical product safety.

Beginning August 2006, Presidential Executive Order 13410 requires federal agencies to use Presidential Interoperability Standards (PIS), for new health information systems and major upgrades. Any starting place must include the

PIS and their data elements. The AHRQ speaker describes health data standards, PIS and a public-domain tool (USHIK) for accessing the data elements and their characteristics (metadata). This tool supports not only PIS implementations but also AHRQ's Patient Safety program and harmonization across patient safety event reporting systems. The Office of the National Coordinator (ONC) for Health IT has led the nation's work in developing interoperability standards, proving their use in 10 specific Nationwide Health Information Network (NHIN) information exchange projects. The ONC speaker brings his experience at ONC to inform us about the most recent developments in the federal government's lead Health IT office in the areas of privacy and confidentiality, health data standards, NHIN, and the new National eHealth Collaborative.

National Interoperability Standards, Their Data Elements, and Patient Safety
J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality

Initiatives and Coordination of Health Information Technology
Charles P. Friedman, PhD, FACMI
Deputy National Coordinator, Office of the Secretary, ONC, Health and Human Services

New Initiatives in Health Information Technology for Advancing Patient Safety
Malcolm J. Bertoni, MS
Assistant Commissioner for Planning, Office of the Commissioner, FDA

Session 231 BT - Biotechnology, RA

10:00 am-11:30 am LEVEL: ■

Room 1B *Pharmacy credits offered*

Regulatory Challenges Related to the Development of Second Generation Therapeutic Proteins

SESSION CHAIRPERSON(S)

Bruce P. Babbitt, PhD
Principal Consultant, PAREXEL Consulting

To address perceived deficiencies in the safety and/or efficacy profiles of various approved therapeutic proteins, many biopharmaceutical companies are currently developing second generation versions of well established classes of biologics, such as EPO, G/M-CSF, IFN, etc. From a regulatory science standpoint, the biggest challenge for developers of these second generation biologics is the need to simultaneously demonstrate: a) comparability to the key (desirable) characteristics of the approved product, b) support for the added benefit of the altered domain(s) of the molecule (ie, the enhanced safety or efficacy engineered into the protein), and c) the overall safety of the newly modified biological entity. Speakers from both the biopharmaceutical industry and the FDA/EMEA will present their strategies and recommendations for addressing the issues and challenges involved in the development of second generation biologics.

Rising to the Challenges in the Clinical Development of Second Generation Biologics
Cecil Nick, MS
Vice President, Biotechnology, PAREXEL Consulting, UK

EMEA Perspective
John Purves, Esq., PhD
Head of Sector, Quality of Medicines, European Medicines Agency, European Union

FDA Perspective
Steven Kozlowski, MD
Director, Office of Biotechnology Products, CDER, FDA

Session 232 CDM - Clinical Data Management, IT

10:00 am-11:30 am LEVEL: ●

Room 11B

From Case Report Form to CDISC SDTM: Data Standards

SESSION CHAIRPERSON(S)

Ingo Beinlich, MD, MS
Partner, Cidar Health Care

This session will review the data flow from capture to submission in the light of CDISC standards for submission and interchange. The session will review case report form design considerations that will ease the creation of CDISC SDTM data sets for submission. In particular, CDASH domains will be reviewed to see how they may facilitate the creation of SDTM data sets. The session will review the design of SDTM domains for efficacy data with special coverage of custom domain design with the SDTM framework and show implementation examples from CRF to submission for cardiovascular and oncology domains covering custom findings, interventions, and events domains. Finally, the session will review data flowing from patient diaries, ePRO and EDC solutions, and review the CDISC eSource Data Interchange work with special emphasis on integrating data from multiple sources and addressing regulatory hurdles along the way.

Data Concepts and Data Elements for Efficacy
Ingo Beinlich, MD, MS
Partner, Cidar Health Care

Updated Look at eSource Data: Current Definitions and Fundamental Working Practices
Nick Lucas, PhD
Vice President, Data Management, INC Research, UK

From Case Report Form to CDISC SDTM
Alastair Clewlow
Product Strategy Director, Clinical Data Management, Oracle Corporation, Denmark

Session 233 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

10:00 am-11:30 am LEVEL: ■

Room 17A MEZZ.

Quality by Design (QbD): Linking Quality to Safety – *Part 2 of 2*

SESSION CHAIRPERSON(S)

Janet Woodcock, MD
Director, CDER, FDA

Part 1 of this session will take place on Tuesday at 8:00 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.

FDA Perspective
Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

Academic Perspective
Ram Sasisekharan, PhD
Professor, Biological Engineering, Massachusetts Institute of Technology

Panel Discussion and Q & A

Session 234 CP 1 - Clinical Safety and Pharmacovigilance, RA

10:00 am-11:30 am LEVEL: ■

Room 30AB *CME, Nursing, and Pharmacy credits offered*

FDA Sentinel Initiative

SESSION CHAIRPERSON(S)

Melissa A. Robb, RN
Senior Policy Analyst, Office of the Commissioner, FDA

On May 22, 2008, FDA launched the Sentinel Initiative with the goal of creating a nationwide electronic system for monitoring medical product safety. In the meantime, a number of related activities have been under way. FDA has met with a variety of potential stakeholders and solicited eight short-term contracts. A series of collaborative pilot projects have been launched involving the public and private sectors. Findings from the contracts and early results from select pilots will be presented.

Sentinel-related Activities in CDER
Judy Anne Staffa, PhD, MS, RPh, FACP
Associate Director for Regulatory Research, Office of Surveillance and Epidemiology, CDER, FDA

Vaccine Safety in CBER
Hector Izurieta, MD, MPH
Chief, Analytic Epidemiology Branch, Office of Biostatistics and Epidemiology, CBER, FDA

The Observational Medical Outcomes Partnership: Research Goals and Objectives
Paul Stang, PhD
Senior Director, Epidemiology, Johnson & Johnson Pharmaceutical R&D LLC

Session 235 CP 2 - Clinical Safety and Pharmacovigilance, RA

10:00 am-11:30 am LEVEL: ■

Room 33AB *CME, Nursing, and Pharmacy credits offered*

Early Signal Information from the Regulatory Authorities: Implications for the Public and the Need for Risk Benefit Communication to Enhance Understanding

SESSION CHAIRPERSON(S)

Andrzej Czarnecki, MD, PhD, DSc, FFPM, FISPE
Director, Deputy Qualified Person for Pharmacovigilance, Global Patient Safety, Eli Lilly and Company Ltd., UK

The wide use of Automatic Signal Detection on large databases delivers a substantial number of adverse event terms depicted by disproportionality. The FDAAA requires that such information is made public on their website. The EU law also requires prompt notification of any newly identified signals. Discussion is needed on how such information is handled by the stakeholders, ie, regulators and industry and what impact it will have on the public/patients.

Implications of Early Signal Communication
Carmen R. Bozic, MD
Vice President, Global Head, Drug Safety and Risk Management, Biogen Idec

FDAAA Section 921: Internet Posting of Potential Safety Signals
Toni Piazza Hepp, PharmD
Director, Review Management Staff, Office of Surveillance and Epidemiology, CDER, FDA

Impact of Early Information on Risk
Andrzej Czarnecki, MD, PhD, DSc, FFPM, FISPE
Director, Deputy Qualified Person for Pharmacovigilance, Global Patient Safety, Eli Lilly and Company Ltd., UK

Session 236 CR/CS 1 - Clinical Research and Development/Clinical Supplies, MC

10:00 am-11:30 am LEVEL: ■

Room 6D *Pharmacy credits offered*

Ethical Rewards for Patients in Clinical Studies: A Scientific Approach to Patient Retention

SESSION CHAIRPERSON(S)

Karen Rumrill
Director, Client Operations, BBK Worldwide

The relationship between patient and study staff is the overwhelming reason participants remain enrolled and compliant. This presentation provides a framework for assessing patients' flight risk, and outlines specific elements of an effective patient retention program, including appropriate giveaways in the context of the newly revised PhRMA Code.

Balancing Revised PhRMA Marketing Code with Patient Recruitment and Retention
Tammy S. Ice
Director of Patient Recruitment and Investigator Services, INC Research

Principle-based Decision Making: How IRBs Decide
Felix A. Gyi, PharmD, MBA
Chief Executive Officer, Chesapeake Research Review Inc.

Commitment Counts: Creating a Retention Program to Engage Patients and Investigators
Karen Rumrill
Director, Client Operations, BBK Worldwide

Session 237 CR/CS 2 - Clinical Research and Development/Clinical Supplies, RD

10:00 am-11:30 am LEVEL: ◆

Room 5B

Building a Clinical Operations Department through Rapid Organizational Growth

SESSION CHAIRPERSON(S)

Brianne Martin
Director, Clinical Operations, Exelixis

Rapid growth within a small clinical operations organization as it transitions from one to two compounds to multiple compounds can be challenging. This session will provide guidance and experience around how to plan for rapid growth within an organization.

Doing More with Less in Clinical Development
Gary Tyson
Senior Vice President, Clinical Development Practice, Campbell Alliance Inc.

Forming Partnerships Early
Robert G. Heard, PhD
Vice President, Project Delivery, PRA International

Leading into the Future
Judy Batlin
Vice President of Organizational Learning and Development, Onyx Pharmaceuticals

Session 238 CR/CS 3 - Clinical Research and Development/Clinical Supplies, GCP

10:00 am-11:30 am LEVEL: ■

Room 1A

Is It Truly Informed Consent?

SESSION CHAIRPERSON(S)

Emily Walker, MBA
Associate Director, Global Trial Manager, Global Clinical Operations, Johnson & Johnson Pharmaceutical R&D LLC

As protocol complexity increases, our informed consents are also becoming longer and more complex. We have a responsibility to ensure study participants truly understand the risks and potential benefits to them for participating in a study and what is expected of them. But are we truly successful in helping them understand this information? This session will share the results of a study that examined the information transfer of a novel protocol template. We will demonstrate what is understood, as well as the proven things that can be done to improve comprehension. We will also introduce the concept of standardizing risk language within the informed consent. We will show how utilizing a systematic approach will not only ensure consistency of information, but also ensure patients are consistently provided the latest risk information available. Lastly, as clinical research increases in emerging regions, such as India, we are faced with unique issues in the informed consent process. We will take a closer look at some of these challenges in India. We will identify the social and cultural challenges that exist and discuss potential solutions to address and overcome these issues.

Informed Consent? A Test Market Exercise
Emily Walker, MBA
Associate Director, Global Trial Manager, Global Clinical Operations, Johnson & Johnson Pharmaceutical R&D LLC

Standardizing the Risk Language of the Informed Consent
Lisa D. Mulcahy
Independent Pharmaceutical Research Consultant

Challenges to Informed Consent in India
Rajiv Prasad, MBA
Assistant Vice President, Life Sciences, Satyam BOP Ltd.

Session 239 EBM/IMP - Evidence-based Medicines/Impact (Impact of Medical Products and Therapies), PP

10:00 am-11:30 am LEVEL: ●

Room 17B MEZZ. *CME credits offered*

Understanding Comparative Effectiveness Research: Policy, Implementation, and Quality

SESSION CHAIRPERSON(S)

Craig A. Hunter, MPP, PGDP
Senior Manager, Science Policy; United BioSource Corporation

The American Reinvestment and Recovery Act ushered in a new age of comparative effectiveness research (CER). The panel will explore the policy drivers, approaches, and implications; implementation issues and examples; and the need for best practices and standards in performing and evaluating CE research, including consensus efforts such as GRACE.

Positioning the Policy Environment to Ensure CER Evidence Matters
Craig A. Hunter, MPP, PGDP
Senior Manager, Science Policy; United BioSource Corporation

Quality, Standards, and GRACE in Observational CE Research
William B. Saunders, PhD, MPH
Director of Epidemiology, Outcome

Session 240 EC - eClinical, IT

10:00 am-11:30 am LEVEL: ■

Room 15A MEZZ.

Accelerating Site Initiation through a Shared Collaborative Platform

SESSION CHAIRPERSON(S)

Mark E. Vermette
Product Manager, CRIX International

Administrative processes associated with site identification, selection, and initiation have long been recognized as major hurdles in completing clinical trials in a timely fashion. New technologies and approaches make it possible to standardize and streamline these processes. This session will explore how a shared collaborative platform, leveraging emerging Internet and security technologies, streamlines the site initiation process for both sponsors and sites.

Panelists

John Speakman, MS
Associate Director for Clinical Trials Products and Programs, National Cancer Institute, National Institutes of Health

Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

Session 241 ERS/DM - Electronic Regulatory Submissions/Document Management, IT

10:00 am-11:30 am LEVEL: ●

Room 9 *Pharmacy credits offered*

FDA Data Exchange Standards Initiatives

SESSION CHAIRPERSON(S)

Jason Rock
Chief Technology Officer, GlobalSubmit Inc.

This session will provide an overview of important FDA data exchange standards initiatives. The overview will include the importance and benefit of the data exchange standard to FDA and industry, an update on the progress of the standard development, adoption, and potential future initiatives.

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 Director, CDER, FDA

Individual Case Study Reports (ICSR) Update: Joint Initiative ICH ISO
Lise R. Stevens
Data Standards Project Manager, Office of the Commissioner, FDA

Regulated Product Submission Status
Peggy R. Leizear
Program Analyst, Office of the Commissioner, OPPL/OPL/PS, FDA

Session 242 GCP - Good Clinical Practices, ERS/DM

10:00 am-11:30 am LEVEL: ●

Room 30CD

The Cost of Compliance: Clinical Trial Registration and Results Disclosure

SESSION CHAIRPERSON(S)

Thomas Wicks, MBA
Practice Manager, Intrasphere Technologies, Inc.

Evolving clinical trial registration and results disclosure requirements are significantly increasing the workload of clinical operations and medical affairs departments. This session presents real-world approaches to the clinical trial registration and results disclosure process, which include the tasks and common workflows required to comply with the various disclosure regulations, the emerging standards for describing the disclosure data, and the ideal set of high-level requirements for a technology solution. The session will close with a summary of an industry survey designed to capture the actual compliance work effort, providing an industry benchmark that can be used in establishing the necessary level of investment in the disclosure process, and provides the data to develop a business case for investing in additional FTEs or supporting technology.

Harmonizing Clinical Trial Transparency: An Update on the HL7 CTR&R Project
Tracy J. Beck, PhD
Associate Medical Business Office Consultant, CTR Results Gatekeeper, Eli Lilly and Company

Automating Clinical Trial Disclosure: Ideal Requirements for a Technology Solution
Monica Mehta, MBA
Director, Regulatory Affairs, Genzyme Corporation

Clinical Trial Disclosure in Practice: The Tasks and Workflows Required to Comply with Disclosure Regulation
Volker Mludek, MD, MSc
CTPI and IB Management, Bayer Schering Pharma AG, Germany

Session 243 IT - Information Technology, CDM

10:00 am-11:30 am LEVEL: ■

Room 15B MEZZ.

Streamlining Your Clinical Data Environment, End-to-end, Using a Standards-based, Metadata-driven Approach – A Panel Discussion

SESSION CHAIRPERSON(S)

Sue Dubman, MA
Senior Director, Standards and Architecture, Genzyme Corporation

This session will present a panel discussion with senior leaders in the biopharmaceutical industry on how their companies are reinventing their clinical development processes, organization, and technology using a standards-based, metadata-driven approach to managing clinical data end-to-end, across the entire clinical data life cycle, from trial planning through regulatory submission and beyond.

Initial Steps to Develop an End-to-end, Standards-based, Metadata-driven Clinical Data Life Cycle
Barry R. Cohen, MS
Senior Director, Clinical Data Strategies, Octagon Research Solutions Inc.

Metadata: The Foundation for Our Clinical Data Communications
Stephen Ruberg, PhD
Senior Director, Medical Information Sciences, Eli Lilly and Company

Reinventing Clinical Data Life-cycle Processes
David Christie
Executive Director, Information Systems, Development Phase of R&D, Amgen Inc.

Session 244 MC - Medical Communications, CP

10:00 am-11:30 am LEVEL: ■

Room 11A *Pharmacy credits offered*

The Role of Medical Communications in Developing Risk Management Strategies

SESSION CHAIRPERSON(S)

Wynter J. Balcerski, PharmD
Manager, Cardiovascular/Thrombosis, US Medical Information Services, sanofi-aventis

Risk management in pharmaceutical companies has continued to evolve over recent years, especially in response to the FDA Amendments Act of 2007 and associated risk management guidance documents issued in 2005. It is important for those in medical communication roles to understand these new developments and how they can contribute to the creation and implementation of a risk management strategy. In this session, we will present an overview of the recent changes as well as examples of how medical communication departments can participate in the development of communication plans as part of a risk management strategy. In addition, a specific case study implemented at a pharmaceutical company will be reviewed.

Role of Medical Communications in Risk Management: Key Takeaways
Wynter J. Balcerski, PharmD
Manager, Cardiovascular/Thrombosis, US Medical Information Services, sanofi-aventis

FDAAA and REMS 101
Annette Stemhagen, DrPH, FISPE
Vice President, Epidemiology and Risk Management, United BioSource Corporation

Contemporary Issues in Risk Communication
Patrick K. Brady, PharmD
Manager, Global Medical, Regulatory, and Safety Policy, Eli Lilly and Company

Session 245 MW - Medical/Scientific Writing, CP

10:00 am-11:30 am LEVEL: ●

Room 31AB *CME credits offered*

The Clinical Study Report Revisited: Strategies for Effective Authoring

SESSION CHAIRPERSON(S)

Christopher J. Preston, PhD
International Documentation Manager, F. Hoffmann-La Roche Ltd., Switzerland

This session will discuss the elements necessary to more effectively write clinical study reports which meet today's requirements for greater speed while maintaining quality. Topics covered in this session will enable the writer to better frontload the process for increased efficiency, prepare a high-quality first draft which is fit for purpose, and how to build in and assess the quality of a clinical study report.

Medical Writing and the Parallel Processing Approach®
Anita Frijhoff, PhD
Medical Writer, Premier Research Group

The Clinical Study Report Revisited: Writing a High-quality First Draft
Pamela Lindroos, PhD
Senior Director, Medical Writing, WebbWrites, LLC

The Clinical Study Report: Metrics and Continuous Improvement
Janet K. Stoltenborg, MS
Senior Director, Scientific Communications, AstraZeneca Pharmaceuticals LP

Session 246 OS - Outsourcing, TR/PD

10:00 am-11:30 am LEVEL: ■

Room 5A

Training of Investigative Sites in the Latin America Region

SESSION CHAIRPERSON(S)

Adriana Janeri, RPh
Lead Clinical Research Associate, RPS (ReSearch Pharmaceutical Services, Inc), Brazil

Considering the high number of clinical research sites in Latin America, it is necessary to create an effective and ongoing training model. This interactive session describes the goals, advantages, challenges, methodology, and application of a model training program for research sites in Brazil.

Training of Investigative Sites in the Latin America Region
Adriana Janeri, RPh
Lead Clinical Research Associate, RPS (ReSearch Pharmaceutical Services, Inc), Brazil

The Investigative Site Perspective: Goals, Expectations, and Results
Thais Oliveira, MPH, RN
Research Coordinator, Instituto Estadual de Hematologia Arthur Cavalcanti (Hemorio), Brazil

Session 247 PM/FI 1 - Project Management/ Finance, TR/PD

10:00 am-11:30 am LEVEL: ■

Room 2 *Project Management units offered*

Project and Alliance Management: Integrating the Roles

SESSION CHAIRPERSON(S)

Ailsa Mendez, MBA
Director, Project Governance, Functional Genetics

Drug development will continue to grow through partnerships, joint ventures, and licensing opportunities. While most biopharmaceutical companies have established PMOs or professionally staffed project management departments, there remains a gap with regard to integrating alliance management in all phases of drug development. This session will focus on the following: a) demonstrate the value of alliance management in assessing the asset and potential partner; b) illustrate how alliance managers can assist their project management colleagues with improving the effectiveness of joint project teams and navigate through their partner organizations to assess continued strategic and operational alignment; and c) illustrate ways in which to implement alliance capabilities within your organization.

Integrating Alliance Management and Business Development in the Partnering Process
Andrew S. Eibling, MBA
Alliance Manager, Office of Alliance Management, Eli Lilly and Company

Collaborative Relationships: Alliance and Project Managers on Joint Project Teams
Ailsa Mendez, MBA
Director, Project Governance, Functional Genetics

How to Develop an Alliance Capability within Your Organization
David Chapnick
Senior Consultant, Vantage Partners

Session 248 PM/FI 2 - Project Management/ Finance, CR/CS

10:00 am-11:30 am LEVEL: ■

Room 4 *Project Management units offered*

Ensuring Strategic Value of Continuous Process Improvement Projects

SESSION CHAIRPERSON(S)

Rebecca A. Vermeulen, RPh
Director, LRL/Medical Six Sigma, Eli Lilly and Company

Alignment of strategy to execution is critical to the success of any Continuous Process Improvement or Lean Six Sigma program. Without proper alignment of improvement activities to business objectives, the results will reflect wasted resources being spent on issues which are not important to achieving business objectives. The intent of this session is to discuss how to work with business leadership to identify potential projects that will enable strategic objectives and bring significant return in productivity savings.

Embracing Lean and Six Sigma in Pharma
Karean L. Eissler, MS, PMP
President, InsightRx Consulting LLC

How Strategic Business Management Can Contribute to Control Clinical Research Processes
Carlos Augusto Candiotti Sanmarco, PharmD, MBA
Clinical Operations Manager, Eli Lilly of Brazil Ltd., Brazil

Continuous Transformation: Creating Value in a Strategic Partnership
Sumit Vohra, MBA, MS
Senior Consultant, Enterprise Transformation Unit, Quintiles Transnational Corp.

Session 249 PP - Public Policy/Law, RA

10:00 am-11:30 am LEVEL: ■

Room 32AB

Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) Report Card

SESSION CHAIRPERSON(S)

Chin Koerner, MS
Executive Director, Regulatory Policy, Novartis Pharmaceuticals Corporation

Even after a decade of pediatric policy and incentives, pediatric research continues to be a challenge in the United States. This panel will discuss why this is so and what can be done. Our experts will cover research barriers and efforts to remove these barriers, policy answers needed to help inform towards better pediatric research policies, and an update on the implementation of Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) as enacted in FDA Amendments Act (FDAAA).

FDAAA Implementation: Industry Perspective
Sharon N. Olmstead
Vice President, Regulatory Policy and Intelligence, Schering-Plough

FDAAA Implementation: FDA Perspective
Lisa L. Mathis, MD
Associate Director, Pediatric and Maternal Health, Office of New Drugs, CDER, FDA

The Unanswered Questions: Looking Ahead to 2012
Christopher P. Milne, DVM, JD, MPH
Associate Director, Tufts Center for the Study of Drug Development, Tufts University

Barriers to Pediatric Research in the US
Steven Hirschfeld, MD, PhD, CAPT. USPHS
Associate Director for Clinical Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health

Session 250 RA 1 - Regulatory Affairs, CR/CS

10:00 am-11:30 am LEVEL: ■

Room 6E

You Can't (b)(2) Careful: Submitting 505(b)(2) Applications

SESSION CHAIRPERSON(S)

Kim M. Quaintance
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

Approval of New Drug Applications submitted through the 505(b)(2) pathway can often involve complicated regulatory requirements. This session will provide an opportunity to hear how FDA is managing the regulatory requirements for these applications, and will provide tips for avoiding common obstacles.

The 505(b)(2) Pathway: Overview and Common Issues Related to Regulatory Requirements
Janice L. Weiner, JD, MPH
Regulatory Counsel, Office of Regulatory Policy, CDER, FDA

Managing and Tracking 505(b)(2) Applications: FDA Procedures
Beth Duvall-Miller
Team Leader, Regulatory Affairs Team, Office of New Drugs, CDER, FDA

Challenges and Things to Remember for OTC Products
Leah A. Christi, PhD
Associate Director, Regulatory Affairs, Office of Nonprescription Products, CDER, FDA

Session 251 RA 2 - Regulatory Affairs, CR/CS

10:00 am-11:30 am LEVEL: ■

Room 7B

Update from China's SFDA and CDE

SESSION CHAIRPERSON(S)

Lili Cao
Division Director, China Center for Pharmaceutical International Exchange, SFDA, China

Ling Su, PhD
Vice President, Clinical Research and Development, Asia Pacific, Wyeth Pharmaceutical Co., Ltd., China

Speakers from the State Food and Drug Administration (SFDA) and Center for Drug Evaluation (CDE) will discuss the new regulations of the New Drug Special Approval Procedure. They will also describe measures that the CDE has been taking to enhance transparency and accessibility to information at CDE by both the sponsor and the public. The session will also provide an update from the Drug Registration Department of the SFDA

New Drug Special Approval Procedure and Accessibility to Information at the CDE
Peipei Zhang
Deputy Director General, Center for Drug Evaluation, SFDA, China

New Drug Special Approval Procedure and Accessibility to Information at the CDE
Jiangping Dong
Department Director, Center for Drug Evaluation, SFDA, China

SFDA and Drug Registration Update
Xiaoqiang Xu, PhD
Section Chief, Department of Drug Registration, SFDA, China

Session 252 RA 3 - Regulatory Affairs, PP

10:00 am-11:30 am LEVEL: ●

Room 7A

FDA and EMEA Update on Pediatric Legislation

SESSION CHAIRPERSON(S)

Agnès Saint-Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use Unit, European Medicines Agency, European Union

This session will provide an update on the recent developments in both regions and the interaction between FDA and EMEA on pediatric medicines. The perspective of industry based on experience with both regulatory agencies will be presented.

FDA Perspective
Jean Temeck, MD
Lead Medical Officer, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

EMEA Perspective
Agnès Saint-Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use Unit, European Medicines Agency, European Union

Session 253 RA 4 - Regulatory Affairs, CR/CS

10:00 am-11:30 am LEVEL: ●

Room 8

European Medicines Agency Town Hall

SESSION CHAIRPERSON(S)

Noël Wathion, Pharm
Head of Unit, Postauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

The European Medicines Agency has developed initiatives and entry points 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 EMEA staffers representing almost all disciplines within the Agency, including pharmacovigilance, GCP and GMP, inspections, international issues, future scientific issues, procedural and regulatory issues, electronic submission. Following short introductory presentations, the majority of the session will offer the opportunity for the audience to pose questions to the panel.

Questions may also be submitted in advance; please email 2009program@diahome.org using this subject line: *Questions for European Medicines Agency Town Hall.*

Sabine Brosch, PharmD, PhD
Deputy Head of Sector, Pharmacovigilance and Risk Management, European Medicines Agency, European Union

Timothy Buxton
Head of Sector, Project Management, Communications and Networking Unit, European Medicines Agency, European Union

David J. Cockburn, Esq.
Principal Scientific Administrator, Inspections Sector, European Medicines Agency, European Union

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

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

Martin Harvey-Allchurch, Esq., LLM
Head of Executive Support, European Medicines Agency, European Union

Vincenzo Salvatore, II, JD, PhD
Head of Legal Sector, European Medicines Agency, European Union

Fergus Sweeney, PhD
Head of Inspections Sector, European Medicines Agency, European Union

Session 254 RD - R&D Strategy, EC

10:00 am-11:30 am LEVEL: ■

Room 14B MEZZ.

The Practice of Adaptive Research

SESSION CHAIRPERSON(S)

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

This session focuses on the pragmatic aspects of conducting adaptive research, including design and operational components, technology platform required, and implications for internal decision making.

Operational Adaptations: Running Tighter, Faster Studies
Mike Ford, MBA
Head of Data Management, Health Decisions Inc.

Drug Supply in Adaptive Studies
Michael Krams, MD
Vice President, Adaptive Trials and Applied Program Strategies, Wyeth Research

Statistical Issues
Roger J. Lewis, MD, PhD
Professor of Medicine, Department of Emergency Medicine, Harbor UCLA Medical Center

Financial Benefits of Adaptive
Michael Rosenberg, MD, MPH
President and CEO, Health Decisions Inc.

Session 255 ST - Statistics, EC

10:00 am-11:30 am LEVEL: ●

Room 10

What Are the Key Issues in BioPharma Statistics Today and Tomorrow? A Panel Discussion

SESSION CHAIRPERSON(S)

Susan P. Duke, MS
Associate Director, Biostatistics Development Partners, GlaxoSmithKline

This panel has a breadth and depth of perspective on the role of statistics/statistical programming in today's biopharmaceutical environment. The panelists will cover what they believe to be the key issues for statisticians today and tomorrow.

Panelists

Alan Hopkins, PhD
Senior Director, Biometrics, Theravance Inc.

Dana J. Soloff, MS
Director, Statistical Programming, Biomedical Operations, Genzyme Corporation

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

Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

Don Rosen
Principal, Don Rosen Consulting

Session 256 TR/PD - Training/Professional Development, CP

10:00 am-11:30 am LEVEL: ■

Room 16B MEZZ.

Drug Safety Personnel – Qualifications? Further Education? What Are the Basic Requirements and What Is Nice to Have? Where Do Regulators and Industry Find Talent?

SESSION CHAIRPERSON(S)

Monika M. Pietrek, MD, PhD, MSc
Pietrek Associates GmbH, Germany

The steep increase in workload and enhanced risk management requirements have triggered a great demand for qualified drug safety personnel; however, no international curriculum of drug safety qualification and training exists. This session will focus on the future needs and opportunities for drug safety staff, describe a drug safety training program, and provide recommendations for successful recruitment.

The Changing Role of a Pharmacovigilance Scientist: A Regulator's View
Mick Foy
Group Manager, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Drug Safety Personnel: Trends in Industry
James Nickas, PharmD
Senior Director - Development, Head of Drug Safety, Genentech, Inc.

Drug Safety Training and Education: Proposed Actions
Monika M. Pietrek, MD, PhD, MSc
Pietrek Associates GmbH, Germany

11:30 am-2:00 pm **EXTENDED LUNCHEON HOURS**
Exhibit Hall D, Ground Level
A special seating section will be available for networking with colleagues from your professional interest area. *(See SDCC Map for exact location.)*

Session 257 AHC/IS - Academic Health Centers/Investigator Sites, CR/CS

2:00 pm-3:30 pm LEVEL: ●

Room 6C

Biomarkers for Drug Safety and Development: Perspectives from the Institute of Medicine and Industry

SESSION CHAIRPERSON(S)

Ellen R. Kelso
Chief Executive Officer/Managing Member, Goodwyn IRB

Robert Giffin, PhD, MA
Director, Forum on Drug Discovery, Development, and Translation, Institute of Medicine/National Academy of Sciences

The average cost to develop a new drug is now estimated to be $1.3 billion, including $424 million for preclinical development, and $848 million for clinical development. For each successful drug, however, there are many more that fail during development and after substantial investments have already been made. The main reasons for failure include safety issues and lack of demonstrated efficacy. The ability to predict success earlier in development is essential to increasing the efficiency of the drug development process, and earlier prediction of safety and efficacy will reduce the number of serious adverse reactions that occur once a product is available for wide-spread public use.

Recent advancements in biomedical and genomic knowledge are creating new technologies for drug discovery and development. As a result of these technologies – including high throughput screening, genomics, proteomics, metabolomics, biomarker imaging, and in silico analysis – drug development is becoming increasingly reliant upon molecular and genetic screening, resulting in earlier understanding of the viability of new compounds. In this session, we will review and discuss the outcomes of the October 2008 Institute of Medicine Forum workshop which examined the current state of the art for accessing and accelerating development of toxicity biomarkers early in development. Industry speakers will discuss how pharmaceutical and biopharmaceuticals are using biomarkers to bolster research productivity and enhance pharmacovigilance. We will also consider methods to collect the large numbers of human biological samples required to confirm biomarker relevance and measures necessary to protect individual donors' privacy.

Industry-sponsored Pharmacogenomic/Biomarker Studies
Amelia Wall Warner, PharmD, RPh
Associate Director, Schering-Plough

Biomarkers for Drug Safety: Report from the IOM Meeting
Alistair Wood, MB ChB
Managing Director, Symphony Capital LLC

Lessons Learned and Challenges Ahead
Paul B. Watkins, MD
Director, General Clinical Research Center; Professor, Medicine and Pharmacotherapy, University of North Carolina

Session 258 BT - Biotechnology, CP

2:00 pm-3:30 pm LEVEL: ■

Room 1B

Follow-on Biologics: Ensuring Quality, Efficacy, and Safety

SESSION CHAIRPERSON(S)

Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting Ltd., UK

Follow-on biologics (FOBs) remain highly topical. In Europe, several similar biological medicinal products (or biosimilars), have now been approved and are finding their way onto the market. Examples will be used to illustrate success stories and failures and the practical difficulties associated with the development of these products. Requirements for quality, efficacy, and safety of an FOB will be discussed in terms of different jurisdictions, and the evolving legislation and regulatory developments in the US will also be considered.

Complex Drugs
J. Michael Nicholas, PhD
Senior Director, Strategic Regulatory Affairs and Postmarketing Labeling/Compliance, Teva Neuroscience

MHRA Perspective
Gopalan Narayanan, MD
Head, Biologicals and Biotechnology Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Experience to Date with Similar Biological Medicinal Products (Biosimilars) in Europe: Successes and Failures
Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting Ltd., UK

Session 259 CDM - Clinical Data Management, IT

2:00 pm-3:30 pm LEVEL: ■

Room 11B

Metric-based Management and eClinical Trials

SESSION CHAIRPERSON(S)

Glen De Vries
President, Medidata Solutions Worldwide

Existing techniques in metrics-based and benchmark-based management of clinical trials (including both trial planning and execution) will be reviewed, including case studies. Then future potential metrics and metric-based management techniques will be examined from the perspective of opportunities to optimize site activities, monitoring, and data management. Both management techniques and underlying infrastructure requirements will be outlined in current and future scenarios.

eClinical Platform: A Foundation for Better Decisions
Jim Rizzi, PhD
Senior Director, Computational Technologies, Array BioPharma

Truly Efficient EDC/CDM: The Solution in a Large Pharmaceutical Company
Andrew Worley
Assistant Vice President, R&D Clinical Business Systems and Processes, Wyeth Pharmaceuticals

Metrics-based Management and eClinical Trials
Glen De Vries
President, Medidata Solutions Worldwide

Session 260 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices

2:00 pm-3:30 pm LEVEL: ●

Room 17A MEZZ.

CMC Regulatory Development and Updates

SESSION CHAIRPERSON(S)

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

This session will identify recent regulatory issues and challenges, provide an update on FDA CMC guidances, and discuss QbD implementation progress.

FDA Perspective
Christine Moore, PhD
Acting Deputy Director, Office of New Drug Quality Assessment, CDER, FDA

Regulatory Challenges and Landscape for the Future
Nirdosh Jagota, PhD
Vice President, Global Regulatory Affairs, CMC and Conformance, Wyeth Pharmaceuticals

Panel Discussion and Q&A
Moheb M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA

Session 261 CP 1 - Clinical Safety and Pharmacovigilance, PM/FI

2:00 pm-3:30 pm LEVEL: ■

Room 30AB

Pharmacovigilance on a Budget

SESSION CHAIRPERSON(S)

Catherine C. Stokes, MS
President and CEO, Drug Safety Alliance

Drug safety is a critical and vital function necessary to protect the public health. Although much is talked about and written regarding what is needed and how to do it, little is available on the cost/benefit analyses and budgeting for the drug safety function. This session will examine how to approach the issue and how to prepare a plan to perform excellent drug safety within a reasonable cost structure. Physicians, nurses, pharmacists, regulators, and others will understand where costing issues arise for the industry, vendors, and health-care professionals.

How to Implement a Risk-based Approach for Pharmacovigilance Processes
Andrew R. Rut, DrMed, MD
Vice President, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline, UK

Financial Implications for Drug Safety and Pharmacovigilance: What is Required and What is Nice to Have in a Global World
Barton L. Cobert, MD, FACP, FFPM
President, BLCMD Associates LLC

Drug Safety and Pharmacovigilance Strategies: Case Studies
Elizabeth E. Garrard, PharmD
Chief Safety Officer, Drug Safety Alliance

Session 262 CP 2 - Clinical Safety and Pharmacovigilance, ST

2:00 pm-3:30 pm LEVEL: ■

Room 33AB *CME, Nursing, and Pharmacy credits offered*

Signal Detection and Data Mining in Pharmacovigilance: Motives, Methods, and Management

SESSION CHAIRPERSON(S)

Eric C. Brinsfield, MS
Director, Professional Services, Global Health and Life Sciences, SAS Institute Inc.

The first part of the session will focus on the motives for signal detection, the impact of FDAAA on the use of signal detection, and the responsibility of sponsor companies when signals are identified. The session will then review the different methods of signal detection and data mining and identify when each technique should be used. We will discuss how to incorporate all appropriate methods into a well designed risk management plan. To wrap up the session, we will address recommended methods for investigating signals to confirm or reject their validity. Throughout the session, examples will be provided wherever possible to illustrate different techniques and the pros and cons of each.

Impact of FDAAA and Sponsor Responsibility
John C. M. Wise, MA
Head of Informatics, Daiichi Sankyo Development Ltd., UK

Bayesian Methods, Data Sources, FDRs
A. Lawrence Gould, PhD
Senior Director, Scientific Staff, Merck Research Laboratories

Challenges in Data Mining Health-care Information
Matthew D. Rotelli, PhD, MS, MSc
Head, Clinical Statistics, Global Patient Safety and Global Patient Outcomes, Eli Lilly and Company

Session 263 CR/CS 1 - Clinical Research and Development/Clinical Supplies, AHC/IS

2:00 pm-3:30 pm LEVEL: ■

Room 6D *CME and Nursing credits offered*

Meeting the Health Needs of Minorities through Clinical Research: Engaging Minority Investigators and Recruiting Diverse Patient Populations

SESSION CHAIRPERSON(S)

Melynda Geurts, MS
Chief Operating Officer, D. L. Anderson International Inc.

Every year the US population demographics change significantly. Statistics show that by the year 2050, the majority of the US population will be made up of minorities (ie, Hispanics, African-Americans, Asians, etc.). This significant trend has led pharmaceutical and biotechnology companies to research and develop medications that not only target a specific disease indication but specific ethnic groups. This evolution within the clinical research industry will cause sponsors to evaluate and modify their business model and practices. From the clinical operations perspective, more sponsor companies will begin targeting community-based research centers and will be in need of obtaining this information from their CRO partners. In terms of patient recruitment, providers will need to realign their modalities of education and outreach. Targeting ethnic populations within the community will be a primary factor within a recruitment plan. This session examines the current state of minority participation in clinical research and strategies for improving minority awareness and involvement.

Strategies for Increasing the Ethnic Diversity in Clinical Drug Trials
Owen Garrick, MD, MBA
Chief Operating Officer, HOV Research

Who Are They and Why Include Them in Clinical Trial Research?
E. Francis Jones
President/CEO, Innovative Clinical Concepts LLC

Myths and Realities Regarding the Participation of Minorities in Clinical Trials
Alfonso Alanis, MD
Chairman and Chief Executive Officer, Anaclim, LLC

Session 264 CR/CS 2 - Clinical Research and Development/Clinical Supplies, ST

2:00 pm-3:30 pm LEVEL: ■

Room 1A

Clinical Supplies Management under Uncertainty

SESSION CHAIRPERSON(S)

Srinivas Karri, MSc
Principal Sales Consultant, Oracle Corporation, UK

How can we manage the need to conduct clinical trials flexibly, using adaptive design methodologies while at the same time reconciling with available clinical supply? This session will explore the uncertainties with clinical demand drivers and how they have a disproportionate impact on the timely conduct of clinical trials. Forecasting methods that aid clinical supply chain planning and execution will be presented. Additionally, a framework for making strategic and operational decisions across the clinical supply chain using a service-oriented architecture will be presented.

Utilizing Real-time IVRS/IWRS Data to Improve Planning Clinical Supplies and Safety of Patients Participating in Clinical Research
Mitchell S. Horoho
Senior CT Materials Management Associate, Eli Lilly and Company

IVR and EDC Technology Convergence for the Benefit of Clinical Supply Management
Frank Maxwell
Practice Manager (Life Sciences), Business & Decisions, Ireland

Clinical Supplies Management under Uncertainty
Srinivas Karri, MSc
Principal Sales Consultant, Oracle Corporation, UK

Session 265 CR/CS 3 - Clinical Research and Development/Clinical Supplies, AHC/IS

2:00 pm-3:30 pm LEVEL: ●

Room 5B

Creating a Collaborative Environment: Working Together at Monitoring Visits

SESSION CHAIRPERSON(S)

Angela Ricci, MSc
Senior Clinical Research Associate, Abbott Vascular

This session will explore the state of the industry from an investigational site and clinical monitor's perspective based upon a comprehensive survey administered to a global network. Along with asking for detailed demographic information, the questionnaires queried clinical sites on attributes they value in a clinical monitor and recommendations for improvement. Clinical monitors were queried on the expectations and increasing responsibilities placed on them by the sponsor, their perceived success factors in a clinical study both at the sponsor and investigative site level, and their experiences with currently available EDC technology. We will also suggest ways in which enhanced clinical monitor training and the possible reassignment of some duties to more appropriate professionals might improve clinical trial performance. Survey results will provide a basis for a discussion of investigational site and clinical monitors' preferences, as well as recommendations for improvement.

Clinical Research Associate (CRA) Impact on Site Productivity
April A. Lewis
Associate Director of Operations, RapidTrials

Clinical Research Coordinator (CRC) Perspective of a Quality Monitoring Visit
Carol Opalek, MSN, BSN, RN
Clinical Research Associate, Abbott Vascular

A Survey of Clinical Monitors on the State of the Industry
Scott D. Freeman, MBA
President, MonitorForHire.com

Session 266 CR/CS 4 - Clinical Research and Development/Clinical Supplies, AHC/IS

2:00 pm-3:30 pm LEVEL: ◆

Room 3

Site Relationship Management (SRM) Initiatives for Improving Site Performance: One Year Later

SESSION CHAIRPERSON(S)

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

This group of site management experts had provided their vision a year ago of where site relationship management (SRM) was heading and described specific initiatives that their organizations were implementing. This session will provide an update one year later of the initiatives that have been implemented – their successes, lessons learned, and benefit analysis. Participants will hear case studies and have a chance to ask questions of these experts from two major pharmaceutical companies, a leading CRO, and an industry expert.

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 - Global Access to Patients

The Clinical Trials Participation Equation (CTPQ)
Beth D. Harper, MBA
President, Clinical Performance Partners Inc.

Becoming a Sponsor of Choice
Gretchen Goller, MA
Patient Recruitment and Compliance Strategist, sanofi-aventis

Session 267 EBM/IMP - Evidence-based Medicines/Impact (Impact of Medical Products and Therapies), PP

2:00 pm-3:30 pm LEVEL: ■

Room 17B MEZZ. *CME credits offered*

Pharmacoeconomics, Cost Effectiveness, and Outcome Analysis for Personalized Medicine

SESSION CHAIRPERSON(S)

Patrick F. Terry
President and CEO, Technic Solutions, LLC

Policy and evidence evaluation in the US by Medicare, third-party payers, and technology assessment groups are poised for dramatic changes in relation to innovative therapeutics and diagnostics products. Changing expectations and informational requirements by evaluators and regulators will require manufacturers to develop, compile, present, and compare/contrast evidence of cost effectiveness and demonstrated utility before positive coverage and pricing decisions are made. Cost-effectiveness analysis will shift from being an academic curiosity to an essential tool for health-care decision making.

Pharmacoeconomics, Cost Effectiveness, and Outcome Analysis
John Hornberger, MD
Principal/Founder, CEDAR Associates LLC

Commercial Considerations for Pharmacoeconomics, Cost Effectiveness, and Product Development
Patrick F. Terry
President and CEO, Technic Solutions, LLC

Clinical Construction of Pharmacoeconomics, Effectiveness, and Outcome Evidence
Kevin A. Schulman, MD, MBA
Professor of Medicine, School of Medicine and Fuqua School of Business, Duke University

Session 268 EC - eClinical, ERS/DM

2:00 pm-3:30 pm LEVEL: ■

Room 15A MEZZ.

Structured Product Labeling (SPL) Indexing at FDA: Where We Are Today and Towards the Future

SESSION CHAIRPERSON(S)

Laurie Burke, MPH, RPh
Director, Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

Structured Product Labeling (SPL) enables the addition of indexing elements to FDA-approved labeling for use in Clinical Decision Support. The VHA maintains the NDF-RT system that FDA identifies as the pharmacologic class data standard for labeling. Structured Product Labeling (SPL) indexed labeling is publicly available at the NLM. These indexed labeling files can be a useful resource to the health-care industry.

SPL Indexing at FDA: Pharmacologic Class and Beyond
Laurie Burke, MPH, RPh
Director, Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

National Library of Medicine's Daily Med: Clinical Decision Support to Enhance Patient Care
Stuart J. Nelson, MD
Head, Medical Subject Headings, National Library of Medicine

Veteran's Health Administration's National Drug File Reference Terminology (NDF-RT)
Michael J. Lincoln, MD
Associate Professor, Medicine and Medical Informatics, University of Utah; Chief Terminologist, Department of Veterans Affairs

Session 269 ERS/DM - Electronic Regulatory Submissions/Document Management, RA

2:00 pm-3:30 pm LEVEL: ●

Room 9

Annual CDER eSubmission Update: The Review Perspective

SESSION CHAIRPERSON(S)

Virginia R. Ventura
Team Leader, eSST, 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 those issues.

eSubmissions: A Clinical Reviewer's Perspective
Christine P. Nguyen, MD
Medical Officer, Office of New Drugs, Division of Reproductive and Urologic Products, CDER, FDA

The Properly Formatted eCTD: Examples and Practical Advice
Constance Robinson Kuiperi, PMP, RAC
Regulatory Information Specialist, Office of Business Process Support, Division of Regulatory Review Support, CDER, FDA

Chemistry Reviewer's Perspective of the eCTD
Mark Seggel
Chemist, Office of Pharmaceutical Science, Office of New Drug Quality Assessment, CDER, FDA

Session 270 GCP - Good Clinical Practices, CR/CS

2:00 pm-3:30 pm LEVEL: ■

Room 30CD *CME credits offered*

Defining Quality in Clinical Trials (2nd Annual Update)

SESSION CHAIRPERSON(S)

John Poland, PhD
Senior Director, Regulatory Policy, Covance Inc., UK

The need for new approaches to defining quality in clinical trials was introduced by the FDA and EMEA at a DIA-sponsored conference in May 2007. It was noted that quality in clinical trials is a much broader concept than implied solely by the historical focus on subject well-being and the accuracy and consistency of data, and the aim was to initiate discussion on new approaches to ensure that modern concepts of quality adequately reflect the needs of the current clinical trial environment. This session will provide a further update on progress towards developing these new approaches. Current thinking and developments in the FDA and EMEA will be explained, and the implications for the sponsors of clinical trials will be analyzed and discussed.

Defining Quality in Clinical Trials: An Update from the FDA
Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Defining Quality in Clinical Trials: An Industry View
J. Michael Sobczyk, MSc
Director, Corporate Quality Assurance, Genzyme Corporation

Defining Quality in Clinical Trials: An Update from EMEA
Fergus Sweeney, PhD
Head of Inspections Sector, European Medicines Agency, European Union

Session 271 IT - Information Technology, ST

2:00 pm-3:30 pm LEVEL: ◆

Room 15B MEZZ.

Clinical Trial Metadata: Theory into Practice

SESSION CHAIRPERSON(S)

Joel Hoffman, PhD, MA
Senior Director, Waban Software, Switzerland

In recent years, we have seen an increasingly robust connection between the information electronically collected for defining a protocol and the use of that information in electronic data capture systems. The sharing of this metadata between protocol and EDC systems is already starting to be offered by vendors and is being used by biopharmaceutical companies in trials. Companies are also beginning to use metadata in the analysis and reporting process. A set of constructs can be used to categorize, understand, and clearly differentiate metadata from the data it is describing. A system that integrates metadata from the SAP and uses it for downstream processes will be described. Using a variety of processes and techniques, companies are recording the mapping and transformation used to structure data into SDTM structures and into ADaM structures. These applications are helpful in knitting together the set of tables, listing, and graphs needed for a submission, but fall short in providing traceability between specification and output and between data collected and data reported.

This session will also report on a pilot system used to process the integration of SAP metadata with the submission output. The collection of transaction-based metadata makes full traceability possible. The session will also focus on the use of common metadata across functional areas. We will describe how metadata collected for a clinical trial is the data that is required by these functional areas. A system that can collect, store, and report metadata associated with ongoing processes and how this metadata can be used to better manage clinical development will be described.

Perspective of Analysis and Reporting
Jon Roth, MBA
H. Lundbeck A/S, Sweden

Perspective of Operational Data and Clinical Trial Management
Jacob Kobber Petersen
Head of Section, Application Management, H. Lundbeck A/S, Denmark

Session 272 MA - Marketing, MC

2:00 pm-3:30 pm LEVEL: ●

Room 14A MEZZ.

Biotechnology Preapproval Communications

SESSION CHAIRPERSON(S)

William R. Hahn, Jr.
President, Science Branding Communications

Led by industry marketing and regulatory professionals, this session will present examples of disease state, science education, and clinical data communications that are considered relevant and acceptable within today's regulatory environment. The session will include a discussion of the latest policies from FDA that affect preapproval communications, examples of preapproval communications that may be considered promotional, and examples of preapproval communications that fall into the classification of Scientific Exchange.

Janet L. "Lucy" Rose, MBA, PA
President, Lucy Rose and Associates, LLC

Joe Young
Principal, Young & Associates

Session 273 MW - Medical/Scientific Writing, ERS/DM

2:00 pm-3:30 pm LEVEL: ■

Room 31AB *Pharmacy credits offered*

Integrated Summaries and Beyond: Be Prepared

SESSION CHAIRPERSON(S)

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

The speakers will describe strategies that enable efficient creation of high-quality, integrated summaries (ISSs and ISEs) and other eCTD-compliant documents.

Preparing Medical Writers to Create Effective Content for the Common Technical Document
Mark Goldschlag, MBA, RN
Senior Medical Writer, Image Solutions Inc. (ISI)

Tales from the Crypt: The Hidden Text Behind Drafting an Integrated Summary of Safety
Rebecca Ann Luffman
Senior Director, Clinical Writing, WebbWrites LLC

FDA Perspective on the Integrated Summary of Effectiveness (ISE)
Howard D. Chazin, MD, MBA
Medical Officer, Guidance and Policy Team, Office of New Drugs Immediate Office, CDER, FDA

Session 274 NC - Nonclinical Laboratory Safety Assessment, CR/CS

2:00 pm-3:30 pm LEVEL: ■

Room 10

First-in-human Studies

SESSION CHAIRPERSON(S)

David R. Jones, MS, RAC
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

It is recognized that in some cases insight on human physiology/pharmacology, knowledge of drug candidate characteristics, and therapeutic target relevance to disease are benefited by earlier access to human data. Streamlined early exploratory approaches can accomplish this end. Exploratory clinical studies (ECS) are those intended to be conducted early in phase 1, involve limited human exposure, have no therapeutic or diagnostic intent, and are not intended to examine maximum tolerated dose. They can be used to investigate a variety of parameters such as pharmacokinetics, pharmacodynamics, and other biomarkers, which could include PET receptor binding and displacement.

First-in-human Study Designs: Proof-of-concept with Safety in Mind
Graham K. Wood, PhD
Senior Scientific Liaison, Business Development, Cetero Research, Canada

First-in-human Studies: An EU Regulatory Perspective
David R. Jones, MS, RAC
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Nonclinical Support for First-in-human Clinical Trials
Paul Baldrick, PhD
Head of Department, Pharmaceutical Regulatory Affairs, Covance Laboratories Ltd., UK

Session 275 NHP - Natural Health Products, RA

2:00 pm-3:30 pm LEVEL: ●

Room 11A *Pharmacy credits offered*

Regulatory Requirements for Natural Health Products/ Herbal Medicinal Products in North America and the EU

SESSION CHAIRPERSON(S)

Jinhui Dou, PhD
Botanical Review Team, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA

In the United States, FDA regulates botanical/herbal health products as food, dietary supplements, or drugs, among others, according to their intended use. Premarketing approval for drugs by the FDA must be based on well controlled clinical trials, while no such requirement applies to dietary supplements, which can only be marketed for structure-function, not drug, claims. With the publication of the FDA's "Guidance for Industry-Botanical Drug Products" and the first approval of a botanical new drug application (NDA), the growing interest in developing botanical drugs continues. Updates of the botanical drug submissions in the US and discussion on some of the challenging issues, such as quality control and clinical trial designs, that sponsors may encounter during late-stage drug development, will also be included.

In the European Union, authorizations/registrations for herbal medicinal products can be obtained according to the following regulatory procedures: 1) full authorizations: a full documentation on quality, nonclinical, and clinical issues has to be submitted by the applicant; 2) authorizations according to well established use: the results of preclinical tests or clinical trials are not required if it can be demonstrated that the active substances of the medicinal product

have been in well established medicinal use within the European Community for at least 10 years, with recognized efficacy and an acceptable level of safety; 3) registrations as traditional herbal medicinal products which have to fulfill the following criteria: the indications must be suitable for prescription-free use; the product must have a specified strength and posology; only for oral, external and/or inhalation preparations; 30 years in medicinal use (including at least 15 years within the European Community); the product must not be harmful, and efficacy is plausible on the basis of long-standing use.

US Perspective
Jinhui Dou, PhD
Botanical Review Team, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA

EU Perspective
Werner Knoess, PharmD
Scientific Director, Head of Department of HMP and CAM, BfArM, Germany

Canadian Perspective
Nancy Richards
Senior Executive Director, Natural Health Products Directorate, Bureau of Product Review and Assessment, Health Canada

Session 276 OS - Outsourcing, RD

2:00 pm-3:30 pm LEVEL: ■

Room 8

Challenges of R&D Outsourcing in Japan: Successful NDA Preparation, and Strategy Planning Area for Global Development

SESSION CHAIRPERSON(S)

Keiko Ebihara, RPh
Director, Regulatory Policy Group, Public and Industry Policy Office, Banyu Pharmaceutical Co., Ltd., Japan

This session will describe new challenges and approaches of the R&D outsourcing, especially New Drug Application (NDA) preparation and strategy planning in Japan with other countries. Case studies provided by global industry and outsourcing companies will show models as Functional OS could accelerate the R&D, cost effectively.

Can Strategy Development for Clinical Studies Be Outsourced to Japanese CROs?
Keiko Oishi, MS
Senior Managing Director, International and New Business Development, CMIC Co., Ltd., Japan

Regulatory Outsourcing at a Pharmaceutical Company
Akikazu Yoshikawa, PhD
Director, Japan Regulatory Affairs, Eli Lilly Japan K.K., Japan

Junko Sato, PhD
Review Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 277 PM/FI 1 - Project Management/ Finance, RD

2:00 pm-3:30 pm LEVEL: ■

Room 2 *Project Management units offered*

Deal Makers and Deal Breakers: What Venture Capital Firms Look for in Drug Development Plans and How Applicants Succeed (or Fail) in Winning Funding

SESSION CHAIRPERSON(S)

Alberto Grignolo, PhD
Corporate Vice President, Global Strategy and Services, PAREXEL Consulting

Venture capital (VC) firms are presented with myriad drug development investment opportunities every year and must sift through them looking for the high-return potentials. While many factors determine their final decision, one of them is the innovator's thinking behind the drug development plan, and how well the plan is likely to deliver on its promise – a sound mix of sensible drug development planning and effective project management. This session will feature speakers from the VC community who will share their insights, experiences and recommendations for emerging companies who are looking for funding and who wish to target their drug development plans for success – often defined as a timely and realistic exit strategy (eg, IPO or pharma buy-out).

Gary Patou, MD
Managing Director, MPM Capital

C. Richard Lyttle, PhD
President and CEO, Radius Health Inc.

Robert W. Jevon, MBA
Partner, Boston Millenia Partners

Session 278 PM/FI 2 - Project Management/ Finance, TR/PD

2:00 pm-3:30 pm LEVEL: ■

Room 4 *Project Management units offered*

Bringing Out the Best in Leaders, Teams, and Relationships

SESSION CHAIRPERSON(S)

Karole Sutherland
Principal, Sutherland Consulting Group, Canada

What do drug development teams need, beyond technical expertise and adequate resources, to achieve project goals? What behaviors and competencies ensure teams get results that matter? The goal of this session is to examine how focusing on key nontechnical competencies can bring out the best in project teams. Emphasis will be placed on team, leadership, and relationship behaviors that are often either overlooked or underappreciated when assessing the factors essential for successful team performance. Practical techniques as well as insights gained from decades of experience in drug development will be presented with a focus on ideas and solutions which can be easily implemented to bring out the best in teams.

Bringing Out the Best in Teams
Karole Sutherland
Principal, Sutherland Consulting Group, Canada

Bringing Out the Best in Leaders
Allison McCormick, Esq.
Vice President, Global Project Management and Logistics, Paragon Biomedical

Bringing Out the Best in Working Relationships
Natalie Masterton
Clinical Project Manager, Seattle Genetics

Session 279 PP - Public Policy/Law, CP

2:00 pm-3:30 pm LEVEL: ●

Room 32AB *Pharmacy credits offered*

Collaborative for Pharmacist Care Patient Services

SESSION CHAIRPERSON(S)

Eleanor M. Vogt, PhD, RPh
Health Sciences Clinical Professor of Pharmacy, University of California San Francisco

The Northern California Pharmacists Care Collaborative involves pharmaceutical companies, community pharmacies, payers (insurers, employers, and unions), and researchers to provide quality patient care. The goal of this ses-

sion is to introduce a unique, replicable, clinical, and cost-effective program for chronic care management that is a model for value-based health benefit design and has proven to be a win/win for all the collaborative partners.

Managing Diabetes with Improved Outcomes and Reduced Costs: A Case Study from The Northern California Collaborative
R. William Soller, PhD
Professor; Executive Director, Center for Consumer Self Care, School of Pharmacy, University of California San Francisco

Driving Value for Stakeholders
Timothy McCarthy, MBA
Employer National Account Manager, sanofi-aventis

Prevention and Wellness in the Chronic Care Model
Liz Helms
Chair, California Chronic Care Coalition

Session 280 RA - Regulatory Affairs

2:00 pm-3:30 pm LEVEL: ●

Room 6AB

Regulatory Affairs Plenary Session
Meet the Regulators

SESSION CHAIRPERSON(S)

Nancy D. Smith, PhD
Former Director, Office of Training and Communications, CDER, FDA

This session will provide the opportunity to hear directly from leaders of regulatory agencies in Europe and the United States. The panel will address regulatory issues facing the medical products communities of these two areas. Topics will be solicited in advance of the session and presented to the panel for discussion.

Annual Meeting attendees are welcome to send questions to the panel. Please email *2009program@diahome.org,* subject line: Questions for Meet the Regulators session.

Panelists

Janet Woodcock, MD
Director, CDER, FDA

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

Robert A. Yetter, PhD
Associate Director for Review Management, Office of the Director, CBER, FDA

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

Session 281 RD - R&D Strategy, RA

2:00 pm-3:30 pm LEVEL: ●

Room 14B MEZZ.

Drug Regulation in Nigeria and Kenya

SESSION CHAIRPERSON(S)

Susanna Dodgson, PhD
Editor-in-chief, *Medical Journal of Therapeutics Africa (MJoTA)*

Kenya and Nigeria have laws regulating drugs and devices: preclinical and nonclinical testing, clinical trials, marketing, formulating, and compounding. The laws regulating drugs and devices in each country plus international laws in different markets shape the availability of drugs in these countries and affect the health of individual humans. Nigeria prohibits the manufacture and import of unregistered products under the Drugs and Related Products (Registration, etc.) Decree No. 19 of 1993 as amended by Decree No. 20 of 1999, and Kenya's Industrial Property Act of 2001. These laws, patents, and the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) have hindered the rapid development of pharmaceutical industry in Kenya and Nigeria and ensured that the branded and generic pharmaceutical therapies available in both countries are mostly imported from Asia, Europe, and the United States.

Traditional Medicines to Drugs in Kenya
Ndu David Ifudu, PhD
Dean, Faculty of Pharmacy, University of Lagos, Africa

Marketing Drugs in Kenya and East Africa
John J. Kilama, PhD
President, Global Bioscience Development Institute

Marketing Drugs in Nigeria
Echeazu Ogu, PhD, MSc, RAC
Independent Consultant and President, BonScience Inc.

Session 282 ST - Statistics, CR/CS

2:00 pm-3:30 pm LEVEL: ■

Room 16A MEZZ.

Dose-finding Strategies for Early-phase Clinical Trials

SESSION CHAIRPERSON(S)

Yeh-Fong Chen, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

The success of a confirmatory clinical trial depends on the correct selection of a dose for the experimental drug. Nowadays, more and more drug sponsors choose to use some modeling strategies to determine the dose, but it is a challenge to pick a useful dose-response model. Design approaches, frequentist or Bayesian, that incorporate more statistical tools may offer improved solution compared to a fixed design approach. In this session, some successful dose-finding approaches will be presented, and the potential utilities will be explored.

Adaptive Designs in Early Exploratory Trials
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics/Pharmacogenetics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Simulation Study to Evaluate Performance of Several Adaptive Designs for Dose-ranging Studies
Inna T. Perevozskaya, PhD, MS
Director, Statistical Research and Applications, Wyeth Research

Model-based Dose Finding
Carl-Fredrik Burman, PhD
Statistical Science Director, AstraZeneca R&D, Sweden

Session 283 TR/PD - Training/Professional Development, PM/FI

2:00 pm-3:30 pm LEVEL: ●

Room 16B MEZZ.

Critical Success Strategies for Professional Development

SESSION CHAIRPERSON(S)

Betty R. Kuhnert, PhD, MBA
Executive Director, Training Services, PharmaNet Development Group, Inc.

Transitions to new positions are common today due to downsizing, outsourcing, reorganization, etc. However, employees get little guidance on successfully navigating these transitions. Consequently, people at all levels may inadvertently fail. This session addresses transition issues and provides strategies for success, describes how to create and implement short-term and long-term career development plans, utilize mentors and networks, and provides tips for working remotely.

So You Have a New Job, Now What? Tactics for Surviving a Job Transition
Betty R. Kuhnert, PhD, MBA
Executive Director, Training Services, PharmaNet Development Group, Inc.

Reach for the Sky: Strategies for Effective Professional Growth and Development
Tammy J. Massie, PhD, MS
Mathematical Statistician, Office of Biostatistics and Epidemiology, Vaccines Evaluation Branch, CBER, FDA

Common Career Conundrums: Solving Those Frustrations
Florence Houn, MD, MPH
Vice President, Regulatory Policy and Strategy, Celgene Corporation

Session 284 VA - Validation, GCP

2:00 pm-3:30 pm LEVEL: ■

Room 7A

Computerized Systems Used in Clinical Research: Best Practices from Peach – *Part 1 of 2*

SESSION CHAIRPERSON(S)

Earl W. Hulihan, MEd
Corporate Compliance Officer, Senior Vice President, Regulatory Compliance, Medidata Solutions Worldwide

Part 2 of this session will take place on Tuesday at 4:00 pm.

This session will present Part 1 of a two-part forum for "Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts," an event hosted by DIA with participants from around the world. Computerized systems and electronic data management have been embedded into clinical research at a rapid pace, in all kinds of applications. Sometimes this progress seems hardly noticed. Many of the users of these computerized systems in clinical research environments are aware of the importance for data quality and data integrity for their patients. However, they often underestimate the impact that the use of electronic applications, use of computerized systems, and transmission of patient data to remote sites may bring to the quality and integrity of data they have on patient safety.

This initiative is intended to set a benchmark regarding requirements for computerized systems used in clinical research, at the time that awareness for this need is gradually increasing. It is simultaneously intended to support the many users struggling to implement validation processes into clinical research, stimulating innovation in the clinical research environment, and promoting drug development. Proper validation and use of computerized systems will help ensure the safety of patients and the credibility of the clinical research data. After an introductory overview of the anticipated DIA publication – a result of over 100 industry professionals and regulators from around the world – presentations will be made from the chapters on "Data Integrity" and "Data Quality." Part 2 will provide presentations from the chapters on "Risk," "Security," and "Data Collection."

An Overview of the Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts Manual
Earl W. Hulihan, MEd
Corporate Compliance Officer, Senior Vice President, Regulatory Compliance, Medidata Solutions Worldwide

Highlights from the Chapter on Data Integrity
Rolf Peter Banholzer, PhD
Global Head, CQA Computerized System Services, Novartis Pharma AG, Switzerland

Highlights from the Chapter on Data Quality
Silvia Zieher, MD
Director, Head of Clinical Operations Latin America, Global Clinical Development, MDS Pharma Services, Argentina

3:30 pm-4:00 pm **REFRESHMENT BREAK**
Exhibit Halls B1, B2, C, Ground Level
(See SDCC Map for exact locations.)

Session 285 AHC/IS - Academic Health Centers/ Investigator Sites, CR/CS

4:00 pm-5:30 pm LEVEL: ■

Room 6C *Nursing credits offered*

Clinical Trial Oversight: Adverse Event Reporting and Handling of Incidental Findings

SESSION CHAIRPERSON(S)

Ellen R. Kelso
Chief Executive Officer/Managing Member, Goodwyn IRB

This session is about unanticipated risk and adverse event reporting during the conduct of a clinical trial. What should be reported to whom, the management of those reports, and the actual responsibilities of those receiving them are some of the most misunderstood aspects of clinical trial administration. A key to protecting research subjects is monitoring the actual safety of ongoing research trials. Adverse event reports are central to this process. IRBs receive adverse event reports from investigators and sponsors but do not carry the responsibility for the safety monitoring of a research study. In effect the IRB's role comprises much more: assuring the appropriateness of the research, its design, and that measures are in place for subject protections. It is not necessary for the IRB to undertake data monitoring. It is, however, the IRB's responsibility to ensure that this function is carried out by an appropriate group, and that that group reports to the IRB on an appropriate schedule.

In support of this notion, the FDA and OHRP have each published guidelines that are intended to streamline the adverse event reporting process. These guidances assign responsibility to the sponsors' and/or a data safety monitoring boards (DSMB) to triage all adverse event reports and report them to the IRB. The broader responsibility of the IRB to monitor unanticipated problems that occur during the course of the research is reflected in these recommendations. The accreditation standards set by the Association for Accreditation of Human Research Protection Programs (AAHRPP) for reporting and IRB evaluation of unanticipated risks provide further support to researchers and IRBs, and support placement of the right responsibilities with the right expertise and assigned functions. This session includes consideration of how incidental findings should be managed in human subjects research and the issues to be considered in reporting and disclosing such findings.

Accreditation Standards for Management of Reports of Unanticipated Risks and Adverse Events
Marjorie A. Speers, PhD
Executive Director, Association for Accreditation of Human Research Protection Programs (AAHRPP)

Reviewing and Reporting Unanticipated Problems and Adverse Events: OHRP's Perspective
Michael Carome, MD
Associate Director, Regulatory Affairs, Office for Human Research Protections, Department of Health and Human Services

Adverse Event Reporting to IRBs: Sponsor, Investigators, and IRBs Working Together
Kevin A. Prohaska, DO, MD, MPH
Medical Officer, Office of Compliance, CDER, FDA

Session 286 BT - Biotechnology, NC

4:00 pm-5:30 pm LEVEL: ■

Room 1B

Adding Value to Early-stage Biotechnology Product Development

SESSION CHAIRPERSON(S)

Peter D. Beattie, LLM, MA
Trade Commissioner to the Americas, Queeensland Trade Office for the Americas, Australia

This session will provide practical advice on maximizing the potential of an early-stage development program from the regulatory perspective. We will focus on themes of orphan designation, optimizing agency interactions and the importance of regulatory intelligence, and innovative regulatory strategies. We will also provide advice on due diligence processes for product in- or out-licensing as well as address the all-important issues of intellectual property and the patent portfolio.

Opportunities for Rapid Entry into Early-stage Clinical Trials for Biologics in Australia
Mario Pennisi, MSc
Chief Executive Officer, Queensland Clinical Trials Network, Inc., Australia

Australia: An Interesting Alternative for Conducting First-in-man Clinical Studies on Novel Biopharmaceutical Products
Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting, Ltd., UK

Biological Products Regulation in Japan
Masatoshi Narita
Associate Executive Director, Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 287 CDM - Clinical Data Management, CP

4:00 pm-5:30 pm LEVEL: ●

Room 11B

Site Preferences for EDC: A Comparison of European and North American Perspectives

SESSION CHAIRPERSON(S)

Eunice Franklin-Becker, MPH
Project Manager, Registries and Observational Studies, Covance Periapproval Services

In this session, we will discuss factors to consider when selecting and/or designing EDC systems for use on North American and European studies and site preferences for EDC system features and use. We will present data based on real-world experience and site feedback based on participation in multiple studies across several EDC platforms.

Site Preferences for EDC: A Comparison of North American and European Sites
Eunice Franklin-Becker, MPH
Project Manager, Registries and Observational Studies, Covance Periapproval Services

Practical Implications of EDC Onsite: A CRA's Rating
Elke Jahn, MSc
Group Manager, Clinical Research and Medical Information, Berlin-Chemie AG Menarini, Germany

Session 288 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

4:00 pm-5:30 pm LEVEL: ■

Room 17A MEZZ.

ICH Implementation Working Group

SESSION CHAIRPERSON(S)

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

An ICH Implementation Working Group (IWG) was formed to ensure the globally consistent implementation of recent ICH guidelines on pharmaceutical development (Q8 and Q8[R1]), quality risk management (Q9), and pharmaceutical quality system (Q10). During this session, speakers from industry and regulatory agencies will discuss the ongoing activities of the IWG as well as some of the regional hurdles to achieving successful implementation of these new ICH guidelines.

Industry Perspective
Swroop Sahota, PhD, MBA
Vice President, Global Quality Services, Schering-Plough

FDA Perspective
Elaine Morefield, PhD
Division Director, Division of Premarketing Assessment II, Office of New Drug Quality Assessment, CDER, FDA

Implementation of ICH Q8, Q9, and Q10: EMEA Perspective
David J. Cockburn, Esq.
Principal Scientific Administrator, Inspections Sector, European Medicines Agency, European Union

Panel Discussion and Q&A

Session 289 CP - Clinical Safety and Pharmacovigilance, RA

4:00 pm-5:30 pm LEVEL: ■

Room 30AB

Update on Clinical Safety and Pharmacovigilance in Japan

SESSION CHAIRPERSON(S)

E. Stewart Geary, MD
Vice President, Eisai Co., Ltd., Japan

In April 2009, Japan adopted new regulations for reporting adverse reactions during clinical development and for a six-monthly periodic safety report during clinical development. These new regulations and other developments in pharmacovigilance in Japan will be presented. In addition, recommendations on Constituting the Drug Regulatory Authority to Prevent Relapses of Drug-induced Injury will be addressed.

Drug Safety Policy: Constituting the Drug Regulatory Authority to Prevent Relapses of Drug-induced Injury
Kaoru Misawa, MS
Director, Office of Safety, Pharmaceuticals and Medical Devices (PMDA), Japan

Update on Pharmacovigilance in Japan
E. Stewart Geary, MD
Vice President, Eisai Co., Ltd., Japan

New Japanese Regulation for Periodic Six-monthly Report during Clinical Development
Hiroyuki Ohshima, MSc
Group Manager, Development DRA Group 2; JPMA, Clinical Evaluation Department, Nippon Boehringer Ingelheim Co., Ltd., Japan

Session 290 CR/CS 1 - Clinical Research and Development/Clinical Supplies, RA

4:00 pm-5:30 pm LEVEL: ■

Room 6D

Adaptive Trial Design: Critical Path at Five Years

SESSION CHAIRPERSON(S)

Lynne Fahey McGrath, PhD, MPH
NA Head, Drug Regulatory Affairs, Oncology, Novartis Pharmaceuticals Corporation

In 2004, the Critical Path Initiative was developed to address the growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, more affordable, and safe medical products for patients. The Critical Path Initiative proposed the development of a toolkit which would contain powerful new scientific and technical methods, including new clinical evaluation techniques to improve the efficiency and effectiveness of the clinical trial process, including trial design, endpoints, and analyses. In the 2006 Critical Path Opportunities List, the Adaptive Trial Design was specifically proposed. Several questions about this design were asked at this time: When can extra trial arms be dropped? When can an early marker be used to choose which treatment to carry forward or to choose a subset for analysis? When is it valid to modify randomization based on results, for example, in a combined phase 2/3 cancer trial? When is it valid and under what situations can one stage or phase of a study be combined with the second stage or phase? With the Critical Path Initiative now 5 years old, it seems timely to examine the experience with these adaptive designs in oncology and determine if the original questions can now be addressed. What new questions, statistical issues, and logistical issues have arisen since the original proposal and adoption of adaptive trial design? What impact have these designs had on regulatory decision making?

Evolution of Adaptive Trial Design: Problems and Solutions
Michael Krams, MD
Vice President, Adaptive Trials and Applied Program Strategies, Wyeth Research

Optimizing Adaptive Trial Designs for Registration
Judith A. Quinlan, MSc
Vice President, Adaptive Clinical Trials, Cytel Inc.

Adaptive Design Clinical Trials: How Can We Do Better?
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics/Pharmacogenetics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Session 291 CR/CS 2 - Clinical Research and Development/Clinical Supplies, EC

4:00 pm-5:30 pm LEVEL: ■

Room 1A

What if ClinOps Ran the EDC Project? Getting the Full Benefit

SESSION CHAIRPERSON(S)

Joseph S. Anderson
Principal Associate, Waife & Associates Inc.

EDC has reached the big time in clinical research. Acceptance is nearly universal, adoption rates are climbing, and no one wants to do a paper trial anymore. At the same time, the practice of EDC continues to be dominated by IT and CDM groups across the industry, while clinical operations professionals feel either ignored or imposed on by the EDC tasks required of them.

This session addresses this remaining frontier in EDC adoption: the full use, benefit, and even control of the EDC process by clinical operations. This session will address how the current processes might be different if optimized from a ClinOps perspective, how other processes might be included if process responsibility was centered within ClinOps, and how the EDC tools themselves might develop if a proper focus was placed on the main users of any EDC tool, ie, site personnel and ClinOps regional monitors.

This interactive session will also look at the topic both from the perspective of clinical operations management and from the viewpoint of ClinOps personnel who actually use the EDC systems.

What if Clinical Ran the EDC Project? An Ambitious Perspective
Kathryn Real King, MA
Senior Director, Clinical Program Management, Abbott Laboratories

Clinical Running EDC? Completing the Half that's Missing
Joseph S. Anderson
Principal Associate, Waife & Associates Inc.

Session 292 CR/CS 3 - Clinical Research and Development/Clinical Supplies, BT

4:00 pm-5:30 pm LEVEL: ■

Room 3

First-in-human Trial Designs: How Much is Too Much?

SESSION CHAIRPERSON(S)

Mary L. Westrick, PhD
Global Vice President and General Manager, Clinical Pharmacology, Covance Inc.

First-in-human (FIH) trial designs in healthy adult volunteers have become increasingly complex in recent years. Typical protocols now combine the Single Ascending Dose (SAD), Multiple Ascending Dose (MAD), Food Effect and Probe designs into one overarching study. Perspectives from the sponsor, IRB, and clinical research unit will be presented with respect to the objectives and concerns of these study designs.

Strategies in Phase 1 Clinical Research: The Next Decade
Elizabeth Allen, PhD
Director of Scientific Affairs and Deputy Unit Head, Quintiles, G.D.R.U. Limited, UK

Phase 1 Study Design: Red Flags, Insights, and Solutions from the Board Room
Kim Lerner
Chair, Independent Investigational Review Board, Inc.

Session 293 EBM/IMP - Evidence-based Medicines/ Impact (Impact of Medical Products and Therapies), RA

4:00 pm-5:30 pm LEVEL: ■

Room 17B MEZZ.

Regulatory Evaluation of Patient-reported Outcome (PRO) Measures Used in Clinical Trials

SESSION CHAIRPERSON(S)

Laurie Burke, MPH, RPh
Director, Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

PRO instruments are increasingly used in clinical trials. The proposed labeling claims determine the adequacy of PRO measures and endpoints. This session will describe how FDA evaluates the development process, content validity, and other measurement properties of a PRO instrument.

Regulatory Overview of PRO Measurement
Laurie Burke, MPH, RPh
Director, Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

PRO Review Highlights
Ann Marie Trentacosti, MD
Endpoint Reviewer, Study Endpoints and Labeling, CDER, FDA

Why It Is Important to Establish Content Validity: The EXACT-PRO Model
Nancy Kline Leidy, PhD
Senior Vice President, Scientific Affairs, United BioSource Corporation

Session 294 EC - eClinical, CR/CS

4:00 pm-5:30 pm LEVEL: ●

Room 15A MEZZ.

Monitoring of Patient Compliance with eTechnologies

SESSION CHAIRPERSON(S)

Brenda Jamerson, PharmD
Associate Professor, Clinical Research, Campbell University School of Pharmacy

Understanding the degree of patient compliance with drug or protocol requirements is important to properly interpret data from clinical trials. Electronic technologies for data collection can objectively capture data, which may result in lowering patient burden and providing a method to unobtrusively monitor compliance with protocol requirements. This session will focus on applications of various electronic technologies (eg, electronic diaries, medication monitoring, accelerometry) which can be used to objectively collect data to evaluate and monitor patient compliance.

Leveraging Patient Adherence and Compliance Data to Transform Clinical Development
Craig H. Lipset, MPH
Director, Molecular Medicine, Pfizer Inc.

Physiological Measures and Adherence in Clinical Trials
Jack E. McKenzie, PhD, MSc
Director of Clinical Affairs, Phillips Respironics

Session 295 ERS/DM - Electronic Regulatory Submissions/Document Management, IT

4:00 pm-5:30 pm LEVEL: ●

Room 9

Annual CDER eSubmission Update: The Technical Side

SESSION CHAIRPERSON(S)

Gary M. Gensinger, MBA
Deputy Director, 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 technical aspects and concerns of this process, and delivers CDER's current perspective on those issues.

CDER's Computational Science Center
Theresa M. Mullin, PhD
Associate Director for the Office of Planning and Informatics, CDER, FDA

Regulated Products Submission Update
Mark A. Gray
Director, Division of Regulatory Review Support, Office of Business Process Support, CDER, FDA

PDUFA IV IT Plan Review and Update
Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

Session 296 GCP - Good Clinical Practices, TR/PD

4:00 pm-5:30 pm LEVEL: ■

Room 30CD *Nursing and Pharmacy credits offered*

Developing Responsible Systems for the Ethical Review of Clinical Trials: A Global Approach Based on Ethical Principles and GCP

SESSION CHAIRPERSON(S)

Francis P. Crawley, MA, FFPM
Executive Director, Good Clinical Practice Alliance - Europe & SIDCER, Belgium

This session examines the ethical principles and GCP standards for the development of systematic approaches to ethical review for improving human subjects protections and promoting responsible research. Ethical review practices globally are increasingly defined by national practices that involve cooperation between ethics committees as well as increased accountability. This session examines how Institutional Review Boards/Independent Ethics Committees can respond to changes in international guidelines and develop systematically to demonstrate responsible approaches to ethics in research and to provide public assurance that ethical review is meeting society's expectations. It looks at the 2008 revision of the Declaration of Helsinki as well as new developments in good clinical practice and how these affect ethical review practices and the education of members of ethics committees internationally.

The 2008 Revised Declaration of Helsinki and Its Impact on Institutional Review Boards/Ethics Committees: Global Concerns
Francis P. Crawley, MA, FFPM
Executive Director, Good Clinical Practice Alliance - Europe & SIDCER, Belgium

Preparing Ethical Review Committees for Public Accountability: Ethical Principles and Education
Juntra Karbwang, MD, DrMed, PhD
Clinical Coordinator, WHO, Switzerland

The Implementation of GCP for International Non-IND Studies at the FDA: Approaches for Institutional Review Boards and Ethics Committees
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science, Science and Health Coordination, Office of the Commissioner, FDA

Meeting the Challenges of Ethical Principles and Ethics Committees in China: A Sponsor's Approach
Ling Su, PhD
Vice President, Clinical Research and Development, Asia Pacific, Wyeth Pharmaceutical Co., Ltd., China

Session 297 IT - Information Technology, EC

4:00 pm-5:30 pm LEVEL: ■

Room 15B MEZZ.

caBIG® Clinical Trials Management System (CTMS): A Standardized, Integrated Approach to Clinical Trials Management – A System Overview and Implementation Case Study

SESSION CHAIRPERSON(S)

William T. Dyer, Jr.
Principal Consultant, Pyramed Research Corporation

The caBIG® Clinical Trials Management System is a comprehensive set of modular, interoperable, and standards-based tools designed to meet diverse clinical trials management needs. The vision of caBIG® is a virtual network of interconnected data, individuals, and organizations whose goal is to redefine how research is conducted, care is provided, and patients/participants interact with the biomedical research enterprise. This session will also describe how an early adopter of the caBIG® CTMS applications has creatively implemented the caBIG® CTMS tools and customized its environment to achieve further interoperability with some of its existing clinical trials tools.

caBIG® Overview
John Speakman, MS
Associate Director for Clinical Trials Products and Programs, National Cancer Institute, National Institutes of Health

caBIG® Clinical Trial Suite Demonstration
William T. Dyer, Jr.
Principal Consultant, Pyramed Research Corporation

caBIG® Clinical Trial Suites Adopter Implementation Overview
Troy Walls
Project Manager, Department of Information Technology, University of Arkansas

Session 298 MC - Medical Communications, IT

4:00 pm-5:30 pm LEVEL: ●

Room 14A MEZZ. *Pharmacy credits offered*

Medical Liaison Survey #5: Reassessment of Medical Liaison Program Demographics and Characteristics, Demonstration of Value, and Assessment of Resource Utilization

SESSION CHAIRPERSON(S)

Craig J. Klinger, RPh
Senior Medical Liaison Consultant, Eli Lilly and Company

During this session, survey results of medical liaison practices will be presented in an attempt to evaluate trends over the past several years. Updated information on medical liaison program characteristics and demographics will be shared, along with information on how ML value is demonstrated to business partners. New data will be presented on resources used by medical liaisons to obtain and communicate scientific information.

Survey Review: Part 1
Christopher M. Marrone, PharmD
Senior Outcomes Liaison, Eli Lilly and Company

Survey Review: Part 2
J. Lynn Bass, PharmD
Senior Regional Medical Liaison, Scientific Affairs, Amgen Inc.

Survey Review: Part 3
Craig J. Klinger, RPh
Senior Medical Liaison Consultant, Eli Lilly and Company

Session 299A MW - Medical/Scientific Writing, RA

4:00 pm-5:30 pm LEVEL: ■

Room 31AB *CME credits offered*

Effective Publication Practices

SESSION CHAIRPERSON(S)

Art Gertel, MS
Vice President, Strategic Regulatory Consulting, Medical Writing and Quality Assurance, Beardsworth Consulting Group Inc.

The need to provide timely and informative publications has become more difficult in a world of on-demand information, electronic media, and greater regulatory oversight and scrutiny. The authors and publishers must now react more quickly, with greater depth of information, and comply with expectations of disclosure and adherence to strict standards. No longer is information disseminated strictly according to schedules dictated by the printing press and peer-review processes. Online and real-time are becoming the norm and stakeholders in the health-care arena (prescribers, journalists, regulators, care providers, and, most importantly, patients) want more information on demand. The panel will present different perspectives on adhering to standards and maximizing the efficiency of the publication process, and will suggest some strategies for effective publication planning and execution practices.

A Best-practices Approach to Compliant Publication Planning
Henry W. Singer
Managing Director, Publication Connexion

Strategic Publication Planning throughout the Drug Development Life Cycle
Kristine L. Healey, PharmD, RPh
Team Leader, Global Medical Communications, Eli Lilly and Company

Defensive Publication Strategies: Medical Writer as "First Responder"
Art Gertel, MS
Vice President, Strategic Regulatory Consulting, Medical Writing and Quality Assurance, Beardsworth Consulting Group Inc.

Session 299B NC - Nonclinical Laboratory Safety Assessment, CP

4:00 pm-5:30 pm LEVEL: ■

Room 10

Evaluation of the Safety of Pharmaceuticals in the Environment (Water)

SESSION CHAIRPERSON(S)

Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs, Immediate Office, CDER, FDA

A number of pharmaceuticals have been reported at low levels in surface and drinking water. Although these levels are not thought to cause harm to humans, a data-based assessment is needed. The EPA is responsible for deciding what ADIs (acceptable daily intake) in water are appropriate. Whereas the FDA has both animal and human detailed data available to it, the EPA has only studies in animals or what is in the open literature. The EPA approach (with reference doses and uncertainty factors), the PhRMA approach (the PhATE model), and the FDA perspective will be presented.

An EPA Regulatory Perspective on Risk Assessment for Pharmaceuticals in Water
Elizabeth A. Doyle, PhD
Chief, HRAB-HECD-OW, US Environmental Protection Agency

An Industry Perspective: The PhATE Model and ADIs
Frank Mastrocco, MS
Director, Environmental Toxicology, Pfizer Inc.

An FDA Perspective: Considerations of ADIs
Raanan A. Bloom, PhD
Senior Environmental Officer, CDER, FDA

Panelist
Klaus Olejniczak, DVM, FACP
Scientific Director, Department of Drug Toxicology, BfArM, Germany

Session 299C NHP - Natural Health Products, MA

4:00 pm-5:30 pm LEVEL: ■

Room 11A

Marketing and Registration in the EU and US

SESSION CHAIRPERSON(S)

Christelle Anquez-Traxler, PharmD
Regulatory and Scientific Affairs Manager, AESGP, Belgium

Natural health products are gaining more importance in both the EU and the US. In both regions, two different systems of product authorizations have been developed. In this session, we will learn how the same goal – marketing safe and effective products – is achieved in both regions.

Herbal Medicines, Botanical Drugs: The Next Generation of INDs and NDAs
Nadina C. Jose, MD
Associate Dean, School of Clinical Research, American University for Health

Marketing of Herbal Products to Health-care Practitioners in the US and Europe
Donald J. Brown, ND
Vice President, Medical and Educational Affairs, Schwabe North America

The Story of Successful Registrations of Herbal Medicinal Products in the EU
Rainer Kolkmann, DrSc, PharmD
Managing Director, Diapharm Regulatory Services GmbH, Germany

Session 299D OS - Outsourcing, RA

4:00 pm-5:30 pm LEVEL: ■

Room 5A

Conducting Global Clinical Trials in Emerging Markets

SESSION CHAIRPERSON(S)

Dan Weng, MD, PhD
President, Rest of World, ICON Clinical Research

Turkey, China, Taiwan, and India are poised to provide new markets for the clinical trial industry, and some big pharma and CROs are ready to enter those markets. This session will present the analysis of outsourcing strategies in the new markets and describe the regulatory environment in those markets including RA organization structure, regulatory framework, review process and timeline for IND/NDA, clinical trial environment (eg, IRB, GCP, investigator training), and clinical trial status (academic, local, and global). This session will include a case study from a CRO, describing how they continually strive to keep ahead of ever-increasing market demands. An onshore/offshore model for pharmacovigilance outsourcing in India will be analyzed. Since the Chinese government finances research on how to improve clinical trial standards in response to market demands, we will describe the research on this government project and share the experiences and lessons learned from a state-certified clinical trial site in China. This session will provide a snapshot of sites for CROs, biotechnology, and pharmaceutical companies intending to run clinical trials in those countries.

New Models in Pharmacovigilance Outsourcing Strategy in India: Case Study
Dan Weng, MD, PhD
President, Rest of World, ICON Clinical Research

Emerging Trends of Clinical Trials in Taiwan
Helen Chiang, PhD
Director, Managing Director of Taiwan Branch, CMIC Asia-Pacific Pte. Ltd., Taiwan

The Regulatory Environment and Current Status of Clinical Trials in Turkey
Serdar Asenaoktar, DrMed
Administrative Director, Kuantum CRO Ltd., Turkey

The Role and Experiences of a State-certified Site in China
Prof. Yimin Mao, MD
Professor of Gastroenterology, RenJi Hospital of Shanghai JiaoTong University School of Medicine; Chief Executive Officer, State Institute for Drug Clinical Research of Renji Hospital, China

Session 299E PM/FI 1 - Project Management/ Finance, RD

4:00 pm-5:30 pm LEVEL: ■

Room 4 *Project Management units offered*

Project and Portfolio Management Insights

SESSION CHAIRPERSON(S)

Matthew J. Kiernan, MBA
Partner, Pharmica Consulting

This session will present tools, processes, and recent innovative ideas on how to improve project, resource, and portfolio management capabilities.

Connecting Project Management with Portfolio Planning
Matthew J. Kiernan, MBA
Partner, Pharmica Consulting

Optimization of Capacity Planning, Resource Allocation and Scheduling for Portfolio of Clinical Trials
Vladimir Shnaydman, PhD
President, ORBee Consulting

Managing Risk and Value in a Discovery Portfolio
James M. Samanen, PhD
President, James Samanen Consulting

Session 299F PM/FI 2 - Project Management/ Finance, TR/PD

4:00 pm-5:30 pm LEVEL: ■

Room 2 *Project Management units offered*

A Search for the Most Effective PM Model in the Pharmaceutical Industry: PMs and PLs – Do We Need Both?

SESSION CHAIRPERSON(S)

Catherine K. Ohura, MS, PMP
Senior Manager, Project Product Management Department, Kyowa Hakko Kirin Pharma Inc.

Why does the pharmaceutical industry often divide the roles of project managers (PMs) and project leaders (PLs), unlike other industries? PM models in nonpharmaceutical industries use one individual as the PM of a given project. In many pharmaceutical organizations, PMs and PLs work on a given project as a pair. Perhaps there is a good explanation for this unique model. Roles between PMs and PLs will be defined and presented using examples of milestones that occur in drug development. At the end of the session, we should be able to determine if this model is the most effective PM model in the pharmaceutical industry. Once the ideal model is determined, pharmaceutical organizations could move toward it by defining roles and responsibilities between the two roles.

Project Team Structures: One Size Does Not Fit All
Julie G. Bukar, MBA
Managing Director, JGB BioPharma Consulting Inc.

Should Project Managers Lead Drug Development Teams?
Linette J. Edison, MBA, PMP
Senior Project Manager, Genentech, Inc.

The Role of the Project Leader in the Pharmaceutical Industry
Jann A. Nielsen, PhD
Senior Director, Project Management, Wyeth Research

Session 299G PP - Public Policy/Law, RA

4:00 pm-5:30 pm LEVEL: ■

Room 32AB *Nursing credits offered*

Drug Counterfeiting International Fight: New Actions Taken in the US and in the World

SESSION CHAIRPERSON(S)

Yves Juillet, MD, PhD
Senior Advisor, LEEM, France

Drug counterfeiting is a clear public health threat that health authorities as well as industry are trying to limit. FDA has developed and implemented a proactive policy, and the EU is developing new regulations. WHO has taken a very important initiative IMPACT (International Medicinal Products Anti-counterfeiting Task Force) including all stakeholders. Different actions have already been defined. Industry has developed a proactive attitude and participates directly in the different task forces. First results are now tangible.

Current Status and Anticounterfeiting Activity in the US
C. Michelle Limoli, PharmD
Director, EU Harmonization and Trade Staff International Programs, Office of the Commissioner, FDA

Counterfeiting in the EU: Trends and Initiatives
John A. Lisman, LLM, MPharm
Lawyer, NautaDutilh N.V., Netherlands

International Actions, WHO IMPACT Update, and New Activities
Yves Juillet, MD, PhD
Senior Advisor, LEEM, France

Session 299H RA 1 - Regulatory Affairs, CR/CS

4:00 pm-5:30 pm LEVEL: ■

Room 6E

Sixth Update: Outlook for Changes in the Japanese Regulatory and Clinical Development Environment

SESSION CHAIRPERSON(S)

Yoshihiko Ono, RPh
Director, Regulatory Policy and Intelligence, Pfizer Japan Inc., Japan

Robert R. Fike, II, PhD
Assistant Vice President, Regulatory Affairs Japan, Wyeth Research

This session will provide an update on the regulatory environment in Japan, including the regulatory review process and performance, and how these impact clinical development. This session will also address future perspectives for clinical development and regulatory strategy with a global development program in Japan.

Perspective on Global Development Strategy in Japan
Yoshihiko Ono, RPh
Director, Regulatory Policy and Intelligence, Pfizer Japan Inc., Japan

Trends in Clinical Development and Review Times for New Drugs in Japan: 2009 Update
Taro Ishibashi, MS, RPh
Research Fellow, Office of Pharmaceutical Industry Research, Japan Pharmaceutical Manufacturers Association, Japan

Junko Sato, PhD
Review Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 299I RA 2 - Regulatory Affairs, CR/CS

4:00 pm-5:30 pm LEVEL: ●

Room 6F

Special Protocol Assessments: Industry and FDA Perspectives

SESSION CHAIRPERSON(S)

Michael E. Pierce, MBA
Director, Policy, Intelligence and Education, US Regulatory Affairs/R&D, GlaxoSmithKline

The Special Protocol Assessment process was incorporated into the 1997 reauthorization of the Prescription Drug User Fee Act. This session will explore the evolution of this process over the ensuing years, provide an understanding of the metrics associated with SPA reviews, and recommend best practices to facilitate this critical drug development agreement.

Special Protocol Assessments: Guidance and Process
Craig A. Metz, PhD
Vice President, CEDD US Regulatory Affairs, GlaxoSmithKline

Special Protocol Assessments: FDA Perspective
Kim M. Quaintance
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

Special Protocol Assessments: Industry Perspective
Anthony P. Waclawski, PhD
Vice President, Regulatory Sciences, Bristol-Myers Squibb

Session 299J RA 3 - Regulatory Affairs, RD

4:00 pm-5:30 pm LEVEL: ■

Room 8

The Importance of Developing a Comprehensive Regulatory Strategy for Emerging Pharmaceutical Companies

SESSION CHAIRPERSON(S)

Mark A. Ammann, PharmD
Vice President, Regulatory Affairs, United BioSource Corporation

Emerging pharmaceutical companies are often not fully aware or do not fully value the importance of strategic regulatory guidance. Such guidance can provide a crucial framework for the overall development plan of their asset, whether the goal is to establish initial proof of efficacy and out-license the product, seek a partner, or to fully develop and market the compound. Starting well before clinical trials are initiated, companies need to understand both the regulatory landscape (ie, guidelines, important stakeholders, emerging policies) and relevant precedents. This facilitates assembly of a total picture of the scope of preclinical, technical, and clinical testing that will likely be required for registration. In so doing, they can carefully evaluate potential hurdles and create a plan to address them. An important tool in this process is a prospectively prepared regulatory strategy document that answers key development questions such as: Is there a precedent for the indication and key claims being sought? Are any accelerated regulatory pathways applicable? Are there opportunities for expanded market exclusivity? In this session, we will explore what a regulatory strategy document should contain, with an explanation of why these elements are crucial to success for emerging companies.

Benefits and Components of a Regulatory Strategy
Mark A. Ammann, PharmD
Vice President, Regulatory Affairs, United BioSource Corporation

Implementation of Regulatory Strategy Model, including Roles and Responsibilities
James T. Rawls, PharmD
Senior Director, Regulatory Affairs and Clinical Drug Safety, Dainippon Sumitomo Pharma America Inc.

Session 299K RA 4 - Regulatory Affairs, PP

4:00 pm-5:30 pm LEVEL: ●

Room 7B *Pharmacy credits offered*

Changes in the WHO Review of Psychoactive Substances for International Control

SESSION CHAIRPERSON(S)

Edgar H. Adams, DrSc, MS
Executive Director, Epidemiology, Covance Inc.

The scheduling of drugs by the WHO can have a profound effect on medical care. Two major initiatives are underway – one is to increase the transparency of the scheduling process, and the second is a program to increase access to controlled medications.

Overview of WHO Review Process Related to Domestic and International Scheduling: The Need for Increased Transparency
James R. Phelps, JD
Attorney at Law, Hyman Phelps & McNamara pc

Increasing the Transparency of the ECDD Review and Improving Access to Needed Medications
Willem K. Scholten, PharmD, MPA
Technical Officer, WHO, Switzerland

Session 299L RA 5 - Regulatory Affairs, CR/CS

4:00 pm-5:30 pm LEVEL: ■

Room 5B

EMEA and NIH Transatlantic Approach on Pediatric Formulation

SESSION CHAIRPERSON(S)

Agnès Saint-Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use Unit, European Medicines Agency, European Union

This session will review the recent developments in pediatric formulation in the EU and the US following the new regulatory requirements. What is the current knowledge and where are the gaps?

The EU Pediatric Formulation Initiative
Tony Nunn
Assistant Care Group Director, Clinical Support Services/Director of Pharmacy, Alder Hey Children's NHS Foundation Trust, UK

The NIH Initiative on Pediatric Formulations
Donald R. Mattison, MD
Branch Chief, OPPB, National Institute of Child Health and Human Development, National Institutes of Health

Session 299M RD - R&D Strategy, AHC/IS

4:00 pm-5:30 pm LEVEL: ◆

Room 14B MEZZ.

Critical Decision Factors in the Allocation of Clinical Sites for Global Drug Development

SESSION CHAIRPERSON(S)

Gustavo L.F. Kesselring, MD
Director, Clinical Trials Operation, Hospital Alemao Oswaldo Cruz, Brazil

In the last decade, we have seen a shift in the number of clinical trials (CTs) related to drug development from the US and Western Europe to other regions. Global drug development is now a complex activity that takes into account many factors in selecting sites/countries to participate in this process. These decisions take into account the number of potential patients/site/country, local costs, and how quickly a clinical trial can be started. A presentation from a major pharmaceutical company will show a comparison between countries and will analyze how countries are chosen for global drug development. An analysis from an international site management organization perspective will focus on how a regulatory/ethical review process and local costs affect this start-up, and what impact they can have on the decision-making process. Finally, a group from MIT-Harvard has recently published an in-depth study on where global CTs are going. These results will be shown and will challenge the audience to think about whether global drug development is going where it should.

How to Allocate Countries/Sites in Global Drug Development: A Sponsor Perspective
Elaine Rahal Rodas Messias, MD, MBA
Country Medical Director, Bristol-Myers Squibb, Brazil

How Global SMOs Allocate Clinical Sites in Multinational Trials
Jean-Claude Provost, MD
Senior Vice President, Head of Clinical Research Centres Division, CCBR-SYNARC, Denmark

Trends in the Globalization of Clinical Trials
Fabio Thiers, MD, PhD
Co-director of Strategic Global Trials Research Program, MIT Center for Biomedical Innovation

Session 299N ST - Statistics, CR/CS

4:00 pm-5:30 pm LEVEL: ●

Room 16A MEZZ.

Drug Development and Statistics in Asia: Issues and Challenges

SESSION CHAIRPERSON(S)

Peiling Yang, PhD
Team Leader, Office of Biostatistics, CDER, FDA

Globalization of clinical research is a 21st century reality. Increasing numbers of clinical studies intended to support drug registration are being conducted throughout Asia. Government research institutes, regulatory agencies, sponsors, universities, and CROs are expanding in-country capabilities to address scientific/statistical issues associated with the planning, conduct, interpretation, and reporting of studies. Biostatisticians in China, Japan, and Taiwan are taking on increasingly important roles in assuring that scientific research efforts aimed at the commercialization of new medical products (drugs, biologics, and devices) are successful and provide evidence for regulatory approval decisions. What are the roles of these statisticians? Where are they employed? Are there a sufficient number of statisticians? How are they trained? How do statisticians from government, sponsors, universities, and CROs work with one another? What are the particular statistical issues and challenges, both current and emerging, faced by statisticians in identifying

and solving the problems associated with regulatory decision-making processes regarding the safety and efficacy of new products that may be common among or unique to these countries, including, for example, the interpretation of global trials, the analysis of multiple studies, and the evidentiary extrapolation results from bridging studies? This session will describe and discuss the current "State of Statistics" in these important Pacific Rim countries.

Global Drug Development in Taiwan
Chin-Fu Hsiao, PhD
Associate Investigator, National Health Research Institutes, Taiwan

Drug Evaluation and Biostatistics in Japan
Tohru Uwoi, PhD
Invited Professor, Osaka University, Japan

Biostatistics in China: Education and Application
William Wubao Wang, PhD
Associate Director, Scientific Staff, Merck, Sharp & Dohme (China) Ltd., China

Panelist
H. M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Session 299O TR/PD - Training/Professional Development, IT

4:00 pm-5:30 pm LEVEL: ■

Room 16B MEZZ.

Organizational Learning in the Web 2.0 Environment

SESSION CHAIRPERSON(S)

Danny A. Benau, PhD
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia

Learning and training are related, but different, activities. This session will explore the possibilities for enhancing learning strategies and organizational information delivery to achieve deeper understanding and longer retention of content needed by industry personnel. The use of Web 2.0 methods and delivery systems helps knowledge transmission to current members of the industry and also anticipates the knowledge reception needs of the coming generation of workers in the therapy development and marketing fields.

Learning Organization 2.0: How to Evolve in Today's Learning Environment
Richard Wood, MS
Associate Director, Global Training, INC Research

Learning 2.0: Could It, Should It, Will It?
James Robert Wetzel, MS
Director of Strategic Account Services, MedPoint Communications

What Have I Learned from YouTube and Other Web 2.0 Technologies?
Joan Harley, BSN, RN
Training Consultant and eLearning Developer, Training Extension, a Division of Pastor Consulting, Inc

Session 299P VA - Validation, GCP

4:00 pm-5:30 pm LEVEL: ●

Room 7A

Computerized Systems Used in Clinical Research: Best Practices from Peach – *Part 2 of 2*

SESSION CHAIRPERSON(S)

Patricia Beers Block
Expert Consumer Safety Officer, Office of the Commissioner, FDA

Part 1 of this session will take place on Tuesday at 2:00 pm.

This session will present Part 2 of a two-part forum "Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts," an event hosted by DIA with participants from around the world. Computerized systems and electronic data management have been embedded into clinical research at a rapid pace, in all kinds of applications. Sometimes this progress seems hardly noticed. Many of the users of these computerized systems in clinical research environments are aware of the importance for data quality and data integrity for their patients. However, they often underestimate the impact that the use of electronic applications, use of computerized systems, and transmission of patient data to remote sites may bring to the quality and integrity of data they have on patient safety.

This initiative is intended to set a benchmark regarding requirements for computerized systems used in clinical research, at the time that awareness for this need is gradually increasing. It is simultaneously intended to support the many users struggling to implement validation processes into clinical research, stimulating innovation in the clinical research environment, and promoting drug development. Proper validation and use of computerized systems will help ensure the safety of patients and the credibility of the clinical research data. After an introductory overview of the anticipated DIA publication – a result of over 100 industry professionals and regulators from around the world – presentations will be made from the chapters on "Risk," "Security," and "Data Collection."

Highlights from the Chapter on Risk
Bradley D. Wong
Senior Manager, IS Compliance, Allergan, Inc.

Highlights from the Chapter on Security
Glenn D. Watts, MS
Vice President, Global Information Security and Privacy, Medidata Solutions Worldwide

Highlights from the Chapter on Data Collection
Jean Paty, PhD, MS
Founder and Senior Vice President, Scientific, Quality, and Regulatory Affairs, invivodata inc.

5:30 pm **END OF TUESDAY SESSIONS**

Notes

7:00 am-4:30 pm **SPEAKER REGISTRATION**
Sails Pavilion, Upper Level

7:30 am-8:15 am **MORNING REFRESHMENTS**
Sails Pavilion, Upper Level

7:30 am-4:30 pm **ATTENDEE REGISTRATION**
Sails Pavilion, Upper Level

7:30 am-4:30 pm **EXHIBITOR REGISTRATION**
Exhibit Hall B1 Lobby, Ground Level

9:00 am-4:00 pm **EXHIBITS OPEN**
Exhibit Halls A-C, Ground Level

Session 301 AHC/IS - Academic Health Centers/ Investigator Sites, CR/CS

8:30 am-10:00 am LEVEL: ●

Room 1A

A CRO-sponsor Perspective 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 (PI) landscape is changing and posing several threats to research sponsors. To date, several articles have been published stating a shortfall of PIs will occur; one article references the Tufts Center's recent study revealing that the total number of FDA-regulated US PIs declined 11% from 2001 to 2003, while the number of investigators abroad increased by 8% during the same period. As the total number of clinical projects has dropped since 2001 and with the changing PI landscape, CROs and pharmaceutical companies that rely on investigative sites to conduct their clinical trials are challenged with the site selection process. This session provides investigative site staff with invaluable insights presented by a CRO and pharmaceutical representative on the site selection challenges, their strategies, and processes.

Panel Discussion
Gretchen Goller, MA
Patient Recruitment and Compliance Strategist, sanofi-aventis

James P. Kremidas
Vice President, Global Head of Patient Recruitment, Quintiles - Global Access to Patients

Philippa J. Brydon, MSc
Global Enrollment Optimization Consultant, Eli Lilly Australia Pty Ltd., Australia

Beth D. Harper, MBA
President, Clinical Performance Partners Inc.

Session 302 BT - Biotechnology, RA

8:30 am-10:00 am LEVEL: ■

Room 1B

Managing First-in-man Studies

SESSION CHAIRPERSON(S)

Victoria English, MS
Editor, *MedNous*, UK

This session will look at how companies have used a new European guideline to plan their first-in-man studies. Reference will be made to the relevant ICH and FDA guidelines. It will explore the special risks associated with testing novel biologic products in man for the first time.

European Guideline on First-in-man Trials
David R. Jones, MS, RAC
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Managing First-in-Man Trials: The View from the FDA
Cynthia Kleppinger, MD
Medical Officer, Division of Scientific Investigations, Office of Compliance, CDER, FDA

A Biotechnology Company's Experience with First-in-man Trials
Michael Vincent, MD, PhD
Executive Director, Medical Sciences, Amgen Inc.

Session 303 CDM - Clinical Data Management, OS

8:30 am-10:00 am LEVEL: ■

Room 11B

Offshoring/Outsourcing CDM: Will It Last?

SESSION CHAIRPERSON(S)

Joseph S. Anderson
Principal Associate, Waife & Associates Inc.

More and more companies are replacing traditional CDM operations with other models of providing data management services. Some sponsors are creating virtual organizations by making nontraditional use of CROs, while others are looking for DM services from new entities entering this space as functional service providers. In addition, some are looking to transfer their own, current CDM staff into new, on-site business entities. All of these new models have significant impact on the value proposition of clinical data management, the role of data handling in clinical trial execution, and the career path of thousands of data management professionals.

This session will address the various types of models being used, the advantages and disadvantages of each model, the impact of these models on the career development of data management professionals, and the future of these models in terms of viability and their ability to meet sponsors' needs long-term, from multiple perspectives. It will address the perceived advantages of the models to the sponsor and discuss the challenges the sponsor has in making the new models work. It will also look at the topic from the service provider's angle, paying attention to the way in which flexibility, efficiency, and quality could be brought together to meet the sponsors' needs. Finally, ideas on how a professional data manager can follow this industry trend and incorporate that trend into his/her own career planning will also be presented.

Functional, Full Service, Onshore, Offshore: The End or the Beginning of the Journey?
Robert Goodwin, MBA, MSc
Executive Director, Pfizer Inc

Adjusting Clinical Operations to Achieve Optimized Outsourcing
Henrik Nakskov, MSc
Manager, Novo Nordisk A/S, Denmark

The Trajectory of Offshoring: Where Does it Land?
Joseph S. Anderson
Principal Associate, Waife & Associates Inc.

Session 304 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, BT

8:30 am-10:00 am LEVEL: ■

Room 17A MEZZ.

Quality by Design (QbD) for Biotechnology Products

SESSION CHAIRPERSON(S)

Steven Kozlowski, MD
Director, Office of Biotechnology Products, CDER, FDA

Wassim Nashabeh, PhD
Director, CMC Regulatory Affairs, Genentech, Inc.

In order to implement Quality-by-design manufacturing, critical quality attributes need to be defined. For complex products, with many quality attributes, defining criticality can be a significant challenge. Application of risk-based assessments and scientific studies to increase product knowledge can facilitate the definition of critical quality attributes for complex products.

Critical Quality Attributes for Monoclonal Antibodies
Ronald Taticek, PhD
Director, Regulatory CMC, Genentech, Inc.

Approaches to Understanding the Importance of Quality Attributes
Mark A. Schenerman
Vice President, Analytical Biochemistry, MedImmune

Panel Discussion and Q&A

Session 305 CP 1 - Clinical Safety and Pharmacovigilance, RA

8:30 am-10:00 am LEVEL: ■

Room 33AB *Pharmacy credits offered*

The EU Risk Management Plan and US Risk Evaluation and Mitigation Strategy (REMS): Company Perspectives and Experience

SESSION CHAIRPERSON(S)

Terry Crowley, MS, RN
Director, Drug Safety, CV Therapeutics Inc.

The art and science of pharmacovigilance continues to evolve and mature, as evidenced by the European Medicines Agency (EMEA) requirement requiring the submission of an EU Risk Management Plan (EU-RMP) for many centralized Marketing Authorization Applications, and for other instances, and the more recent legislation, the Food and Drug Administration Amendments Act of 2007 (FDAAA), including the introduction of the Risk Evaluation and Mitigation Strategy (REMS). Navigating through the regulations can be formidable, yet understanding the context, rationale, and infrastructure of the EU-RMP and REMS allows industry professionals to develop these documents with greater understanding and confidence. This session will identify key components of the EU-RMP and REMS and appraise the similarities and differences between the documents. Attendees will be able to organize scientific and medical data and information into appropriate templates for development of an EU-RMP and REMS.

REMS: A Year Later, Real-world Experience
Edgar H. Adams, DrSc, MS
Executive Director, Epidemiology, Covance Inc.

Development and Implementation of an EU-RMP: Perspectives from a Global Pharmaceutical Company
Karen Naim, PhD, MSc
Director, Postmarketing Safety Expert, Pain Products, Benefit Risk Management, Johnson & Johnson Pharmaceutical R&D LLC

REMS and EU-RMP: Comparison of Requirements with Practical Examples
Rachael L. DiSantostefano, PhD, MS
Associate Director, Epidemiology, GlaxoSmithKline

Session 306 CP 2 - Clinical Safety and Pharmacovigilance, PP

8:30 am-10:00 am LEVEL: ■

Room 30AB *Pharmacy credits offered*

Pharmacovigilance Agreements

SESSION CHAIRPERSON(S)

Bruce A. Donzanti, PhD
Senior Director, Business Support Global Pharmacovigilance and Epidemiology, Cephalon Inc.

Pharmacovigilance agreements have become a critical component in monitoring third-party relationships with regard to safety reporting requirements. This session will describe the current structure and use of such agreements and the associated issues to be cognizant of when such partnerships are formed.

Contracts and Agreements: A View from the EU
Patricia A. Moore, MSc
Senior Pharmacovigilance Inspector, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Particular Challenges of Third-party Safety Collaborations
Kathleen F. Sullivan, MPH
Director, Pharmacovigilance Alliance Management, Johnson & Johnson Pharmaceutical R&D LLC

Differing Pharmacovigilance Definitions and Standards: An Adverse Event by Any Other Name
Jonathan Wagner, JD
Associate, Sidley Austin LLP

Session 307 CR/CS 1 - Clinical Research and Development/Clinical Supplies, AHC/IS

8:30 am-10:00 am LEVEL: ■

Room 6D

Understanding ePatients and Engaging Them in Clinical Research

SESSION CHAIRPERSON(S)

Bonnie A. Brescia
Founding Principal, BBK Worldwide

Today's empowered patients seek information on their diagnosis and treatment options using the Internet, giving rise to a new breed of health consumer known as the ePatient. This session will discuss the ePatient in the context of clinical trial participation and will present strategies for partnering with this population to optimize enrollment.

Strategies for Partnering with ePatients to Promote Clinical Study Participation
Bonnie A. Brescia
Founding Principal, BBK Worldwide

Oncology Online: Opening Communication between Cancer Patients and Researchers
Elly J. Cohen, PhD
Program Director, BreastCancerTrials.org, Center of Excellence Breast Cancer Care, University of California San Francisco

The Patient's Role in Advancing Medical Science, before and after the Internet
James Heywood
Co-founder, Chairman, PatientsLikeMe

Session 308 CR/CS 2 - Clinical Research and Development/Clinical Supplies, OS

8:30 am-10:00 am LEVEL: ■

Room 5B *Pharmacy credits offered*

Building Quality Research Teams

SESSION CHAIRPERSON(S)

Kim Palli
Clinical Research Manager, RPS (ReSearch Pharmaceutical Services, Inc)

This session will address how pharmaceutical companies and their outsourcing vendors can collaborate to identify, hire, and retain quality team members. Through an understanding of a sponsor's culture and transparency, outsourcing companies are better able to identify resources which are the right fit for a sponsor company and, in doing so, positively impact long-term retention, projects completing on-time/on-budget, and reduce recurring training costs often associated with high turnover. A discussion will include the unique challenges and strategies of small- and mid-sized organizations operating with more limited resources to train and orient their team resources. The session will include a discussion of the use of RACI (Responsible, Accountable, Consulted, and Informed) and process maps within a biopharmaceutical company and how quality can be measured on programs that are resourced internally, externally, or with a combination of resources.

Training and Development Strategies for Small- to Mid-size Sponsor Organizations
Bonnie Miller, MSN
President and CEO, BMQCR, Bonnie Miller Quality Clinical Research Consulting

Developing and Using RACI, Process Maps, and Process Manual in Outsourced/Insourced Clinical Trials
Diana Chen, MSc
Senior Manager, Clinical Trial Management, Genentech, Inc.

Sponsor and Outsourcing Vendor Collaboration: It's All about the Relationship!
Rosemary Watson Bramigk, BSN, RN
Clinical Research Manager, RPS (ReSearch Pharmaceutical Services, Inc)

Session 309 CR/CS 3 - Clinical Research and Development/Clinical Supplies, OS

8:30 am-10:00 am LEVEL: ■

Room 3

The Good, the Bad, and the Surmountable: Overcoming Outsourcing Challenges in Latin America

SESSION CHAIRPERSON(S)

Lynn B. Sutton, MSN, RN
Strategic Operations Liaison, RPS (ReSearch Pharmaceutical Services, Inc)

Latin America provides treatment-naive patients in medical centers with competent, eager, qualified investigators and established regulatory systems at comparable cost. This session will discuss the challenges that require forward thinking and strategic planning to optimize timely study start and execution.

Enhancing Relationships in Team Dynamics: Working Cross Culturally
Karole Sutherland
Principal, Sutherland Consulting Group, Canada

Conducting Clinical Trials in Latin America: Understanding the Regulatory, Cultural, and Logistical Differences between Clinical Research in the US and Latin America
Inna Kassatkina
President, Global Language Solutions

Session 310 EC - eClinical, IT

8:30 am-10:00 am LEVEL: ◆

Room 15A MEZZ.

Update on the FDA's Electronic Case Report Form Submission Operational Data Model (ODM) Pilot

SESSION CHAIRPERSON(S)

Sally Cassells, MS
Vice President, Phase Forward Lincoln Safety Group

This session will provide an update on the role of CDISC XML technology at the FDA and NIH. Representatives from CDISC, NCI, and industry will share their vision of how the use of XML for data transmissions will look in 2009, 2010, and beyond. Attendees will learn about the FDA and NIH goals for piloting XML clinical data message use, and gather information from both sponsors and third-party data providers who have participated in the FDA pilot program.

CDISC XML for NCI Clinical Trials
Charles Mead, MD
Senior Director, Healthcare and Life Sciences Strategy, Booz Allen Hamilton

CDISC XML Technology in an HL7 Framework
David P. Iberson-Hurst
Vice President, Technical Strategy, CDISC, UK

Deploying XML Technology at the FDA
Sally Cassells, MS
Vice President, Phase Forward Lincoln Safety Group

Session 311 ERS/DM 1 - Electronic Regulatory Submissions/Document Management

8:30 am-10:00 am LEVEL: ■

Room 9

Minimize the Cost – Maximize the Efficiency: Where Are We Going? What Are the Opportunities?

SESSION CHAIRPERSON(S)

Nancie E. Celini, MPH
President, CAB Inc.

For several decades, the biopharmaceutical industry has been attempting to exploit information, and few could argue it has been easy or cost-effective. An open, community-driven dialogue must continue regarding the concept of managing information and developing broad, industry-based standards and services that would allow any entity access to a shared regulatory-compliant system.

Document Management in the Clouds
Allen E. Jones, MS
Director, Global Regulatory Operations, GlaxoSmithKline

Industry under Siege? Key Pressures Shaping Information Management
John J. Oidtman
Vice President, Worldwide Regulatory Operations and Worldwide Regulatory Strategy, Established Products, Pfizer Inc

Technology Trends in Drug Development: It's All about Collaboration
John C. M. Wise, MA
Head of Informatics, Daiichi Sankyo Development Ltd., UK

Session 312 ERS/DM 2 - Electronic Regulatory Submissions/Document Management, RA

8:30 am-10:00 am LEVEL: ■

Room 8

Life-cycle Management: Where the Real Challenges Are – Module 3, IND, and NDA

SESSION CHAIRPERSON(S)

Nancy P. Smerkanich
Vice President, Regulatory Affairs, Octagon Research Solutions Inc.

This session will address the complexities of eCTD life-cycle management specific to Module 3 (Quality/Chemistry, Manufacturing and Controls) as well as sections of the eCTD IND and NDA that can be especially challenging. Speakers will share real dossier examples and the ways that they dealt with them either technically or by adapting their authoring processes.

NDA eCTD Challenges: Sharing Five+ Years of Experience through Case Studies
Justin D. DiFebbo
Senior Manager, Global Regulatory Affairs, Wyeth Pharmaceuticals

Transitioning and Maintaining the IND as eCTD: A Case Study
John Aitken, PhD
Director, Regulatory Operations, Gilead Sciences

Life-cycle Challenges of M3: Chemistry, Manufacturing, and Controls
Deanna Murden
President and CEO, ePharmaCMC, LLC

Session 313 GCP 1 - Good Clinical Practices, CR/CS

8:30 am-10:00 am LEVEL: ■

Room 30CD *Pharmacy credits offered*

Experience with GCPs Worldwide

SESSION CHAIRPERSON(S)

Munish Mehra, PhD
Managing Director, Global Drug Development Experts

With the rapid increase in the conduct of clinical trials globally, it is important to know the level of adherence to GCPs. This session will bring together speakers who have experience with conducting or overseeing clinical trials globally. The session will share quality of clinical trials and results from GCP inspections in the US, Europe, India, China, and other countries.

Experience with FDA Inspections Worldwide and Commonly Occurring GCP Violations
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science, Science and Health Coordination, Office of the Commissioner, FDA

EMEA's Experience with GCP Inspections in Europe and Elsewhere and Commonly Occurring GCP Violations
Fergus Sweeney, PhD
Head of Inspections Sector, European Medicines Agency, European Union

The Quality of Clinical Trials in China
Jenny Zhang, MD, MHA
Senior Director, Business Development - US, Tigermed Consulting Ltd.

Session 314 GCP 2 - Good Clinical Practices, AHC/IS

8:30 am-10:00 am LEVEL: ■

Room 11A *Pharmacy credits offered*

Navigating the FDA Part 11 Guidance: Sponsor and Site Perspectives

SESSION CHAIRPERSON(S)

Yvonne P. McCracken, MPH
President and CEO, Carolinas Research Associates

Among the most important clarifications in the FDA Guidance is the applicability of Part 11 to source data collected at investigator sites participating in clinical investigations, when that data is collected in electronic format. This session will identify the issues of electronic data from both the sponsor and site perspectives, suggesting solutions that have practical applications.

Electronic Medical Records Systems Used for Source Data Purposes
Blake Jensen
Director, Quality Assurance, INC Research

Electronic Data Capture Systems Used by Investigator Sites
Yvonne P. McCracken, MPH
President and CEO, Carolinas Research Associates

Session 315 IT - Information Technology, EC

8:30 am-10:00 am LEVEL: ■

Room 15B MEZZ.

Clinical Research Repositories as a Collaboration Platform

SESSION CHAIRPERSON(S)

Tim Rochford
Chief Technical Officer, Phase Forward

This session will discuss how research repositories not only house data, but also form the foundation for collaboration that is essential to the research enterprise. Panelists will discuss how clinical research repositories could facilitate discourse between bedside and bench within translational research.

eCollaboration: Challenges in Delivering Internet Collaboration Capabilities
Laszlo Vasko, MS
Senior Business Relation Manager, AstraZeneca Pharmaceuticals LP

Translational Research and Clinical Trial Failure Analysis
Joseph Duncan
CEO and Chairman, Teranode

Session 316 MC - Medical Communications, RA

8:30 am-10:00 am LEVEL: ●

Room 14A MEZZ. *CME and Pharmacy credits offered*

Safe Use of Drugs – *Part 1 of 2:* Successfully Communicating with Consumers

SESSION CHAIRPERSON(S)

Julie Anne Zawisza, MA
Director, Office of Communications, CDER, FDA

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

This session will include an interactive discussion about current communication approaches and discuss their advantages and disadvantages. We will discuss innovative approaches to improve communication with consumers by use of partnerships.

Peter J. Pitts
President, Center for Medicine in the Public Interest

Ray Kerins
Vice President, Head of Media Relations and Public Relations, Pfizer Inc

Session 317 MW - Medical/Scientific Writing, CR/CS

8:30 am-10:00 am LEVEL: ●

Room 31AB *CME, Nursing, and Pharmacy credits offered*

Writing for Patients: Communicating Clinical Trial Results

SESSION CHAIRPERSON(S)

Virginia I. Watson, RPh
Director, Clinical Operations and Medical Writing, Catalent Pharma Solutions, UK

Do patients receive appropriate information on the results of clinical trials in which they have participated or in therapeutic areas of interest or concern? A number of factors, which can affect patient interpretation and morale, should be taken into consideration. This session will examine the needs of the patient, the extent to which these are currently met, and ways in which this can be improved.

The Complexities of Communicating Results Back to Study Participants
Jean H. Soul-Lawton, PhD
Global Medical Writing Director, Respiratory MDC, GlaxoSmithKline R&D, UK

Effective Communication: Clinical Trial Disclosure and its Impact on Medical Writers
Barbara Godlew, RN
President and Principal Analyst, The FAIRE Company, LLC

Effective Communication: The Patient Perspective
Elda Railey
Co-founder, Research Advocacy Network

Session 318 NC - Nonclinical Laboratory Safety Assessment, TR/PD

8:30 am-10:00 am LEVEL: ◆

Room 10

Use and Usefulness of Juvenile Animal Studies in the Development of Pediatric Drugs

SESSION CHAIRPERSON(S)

Beatriz Silva Lima, PharmD, PhD
CHMP and SAWP Member, SWP Chair; Professor, Pharmacology, University of Lisbon, Portugal

Increasing experience with the use of juvenile animals in the development of pediatric drugs may either increase or decrease any differences in US and EU approaches in this area. There will be a discussion highlighting case examples on whether juvenile animal studies are needed. The views from regulators (EU and US) and industry, including some case examples, will also be addressed.

FDA Perspective
Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs Immediate Office, CDER, FDA

Industry Perspective
Mark E. Hurtt, PhD
Head, Global Developmental and Reproductive Toxicology, Pfizer Inc

Juvenile Animal Studies in the Context of Pediatric Investigation Plans in Europe
Beatriz Silva Lima, PharmD, PhD
CHMP and SAWP Member, SWP Chair; Professor, Pharmacology, University of Lisbon, Portugal

Session 319 NHP - Natural Health Products, RA

8:30 am-10:00 am LEVEL: ■

Room 17B MEZZ. *Pharmacy credits offered*

Harmonization Scope for Natural Health Products Regulatory Requirements

SESSION CHAIRPERSON(S)

Werner Knoess, PharmD
Scientific Director, Head of Department of HMP and CAM, BfArM, Germany

Worldwide medicinal plants are playing an important role in health care. Even terminology is not uniquely defined; common terms are "natural health products," "herbal medicines," (traditional) "herbal medicinal products," or simply "botanicals." The use of natural health products is based on different traditions as well as on availability of competing medicinal products. The development of regulatory environments for natural health products in different regions created a broad spectrum of approaches for suitable regulation of such products. Global trade with natural health products and popularity of traditional therapeutic systems are constantly growing. Consequently, there is a need for comparison of regulatory approaches and for harmonization of regulatory requirements. This session will provide insight on regulation of natural health products in North America, Asia, and Europe.

Harmonization of Regulatory Requirements of Natural Products for Ensuring Quality, Safety, and Efficacy
Subhash C. Mandal, PhD
Inspector of Drugs, Directorate of Drugs Control, India

Canadian Regulatory Framework for Complex Natural Health Products
Nancy Richards, MPA
Senior Executive Director, Natural Health Products Directorate, Bureau of Product Review and Assessment, Health Canada

Translating Tradition into Modern Medicines: The Approach of the National Competent Authority in Germany
Werner Knoess, PharmD
Scientific Director, Head of Department of HMP and CAM, BfArM, Germany

Session 320 OS - Outsourcing

8:30 am-10:00 am LEVEL: ■

Room 5A

What Does the Future Hold for CRO-sponsor Relationships? Results from a 2009 Industry Survey with a Focus on How Changes to CRO-sponsor Relationships over the Next Five Years Will Impact Innovation, Cost Savings, and Efficiency

SESSION CHAIRPERSON(S)
Denise A. Calaprice-Whitty, PhD
Senior Director, The Avoca Group

This session will explore CROs' and sponsors' expectations for how CRO-sponsor relationships and CRO operations will change over the next five years. Data from a 2009 State of Clinical Outsourcing Survey will be shared.

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

Mitchell A. Katz, PharmD, PhD
Vice President, Global Clinical Operations, Eisai Medical Research Inc.

Badhri N. Srinivasan, MS
Vice President, Enterprise Transformation Unit, Quintiles Inc.

Session 321 PM/FI 1 - Project Management/ Finance, CR/CS

8:30 am-10:00 am LEVEL: ■

Room 2 *Project Management units offered*

Six Sigma: How to Leverage a Great Idea in the Complex Reality of Clinical Trials

SESSION CHAIRPERSON(S)
Tim G. Strauss, MA
Executive Director, Business Process Improvement, Covance Inc.

Reinforce your knowledge of Six Sigma with rea-life examples of how it can help optimize the clinical trials process.

Six Sigma: How to Leverage a Great Idea in the Complex Reality of Clinical Trials
Tim G. Strauss, MA
Executive Director, Business Process Improvement, Covance Inc.

Strategic Business Management Associated with Lean Six Sigma Philosophy in Clinical Research: How to Apply New Management Skills to Transform the Area in a Business Unit
Carlos Augusto Candiotti Sanmarco, PharmD, MBA
Clinical Operations Manager, Eli Lilly of Brazil Ltd., Brazil

Utilizing the Concepts of Six Sigma in a Strategic Partnership Selection Process
Anthony J. Carita
Director, Clinical Outsourcing, Otsuka Pharmaceutical Development & Commercialization

Session 322 PM/FI 2 - Project Management/ Finance, TR/PD

8:30 am-10:00 am LEVEL: ■

Room 4 *Project Management units offered*

Influence: Utilizing a Variety of Strategies in Pharmaceutical Drug Development

SESSION CHAIRPERSON(S)
Paul S. Hara, PMP
Senior Director, Program Management, MDS Pharma Services

Influence is an important tool for pharmaceutical project managers. A project manager's ability to influence the team is often the primary tool available to provide direction for a project. Influence is more than verbal persuasion. It also requires utilizing a blend of other sources of influence to effectively match the diverse circumstances we encounter. This session will explore the other sources of influence that can empower a project manager to be an effective influencer.

How the New Kid on the Block Can Sway the Organization!
Mary Ann A. Lumiqued, PMP
Associate Director, Project Management, OXiGENE, Inc.

Applying Influence Strategies to CRO/Vendor Management
James M. Huebner, MS
Associate Director, Early Development, RPS (ReSearch Pharmaceutical Services, Inc)

You Have More Power than You Think! Influence and Stakeholder Management
Melanie Ebojo, MBA, PMP
Senior Project Manager, Genentech, Inc.

Session 323 PP - Public Policy/Law, RA

8:30 am-10:00 am LEVEL: ■

Room 32AB

Personalized Medicine: 2009 Update

SESSION CHAIRPERSON(S)
Bryan Dechairo
Senior Director, Development Head, Personalized Medicine, Medco Health Solutions, Inc.

Personalized medicine has been identified as a public health policy priority by the US government and has inspired a number of debates and initiatives that intersect with the continuing evolution of the scientific evidence and tools required to make it a reality. This session will provide a broad update of the issues that continue to underlie this exciting concept and will determine its ultimate viability.

FDA Perspective
Lawrence J. Lesko, PhD
Director, Office of Clinical Pharmacology and Biopharmaceutics, Office of Translational Sciences, CDER, FDA

Pharmaceutical's Pipeline in Personalized Medicine
Richard Deane Hockett, MD
Consultant

Tools of the Trade in Personalized Medicine
Patrick F. Terry
President and CEO, Technic Solutions, LLC

Session 324 RA 1 - Regulatory Affairs, RD

8:30 am-10:00 am LEVEL: ◆

Room 7B

Global Simultaneous Development and Asia/Japan: Strategic and Regulatory Issues to Overcome

SESSION CHAIRPERSON(S)

Akio Uemura, PhD
Director, Regulatory Policy, Liaison and Intelligence, Eli Lilly Japan K.K., Japan

This session provides an overview of global simultaneous development, particularly focused on the inclusion of Asia and Japan as additional regions to the EU and the US. In the past, most Asian countries were included in global clinical trials by default, and the regulations relevant to registration by the use of the global studies, or the implementation of such studies were much simpler than they are now. As Japan accumulated its scientific considerations and experiences about ethnic differences between Japanese and Western populations after the implementation of ICH E5 guideline, Asian countries are influenced by Japanese agencies, and are trying to increase their interventions in global drug development plans conducted by Western multinational companies. In the past several years, Japanese regulatory agencies have tried to develop more active relationships with other Asian agencies to establish a new landscape in Asian drug development regulations. Now that many multinational companies make it a default plan to have Asian countries and Japan as part of global simultaneous development, what are the unresolved strategic/regulatory issues? What still prevents those companies from having global simultaneous development strategy as a default archetype?

In this session, we will discuss the default global development model by looking at regions, specifically US, EU, or Japan, and discuss potential strategic/regulatory issues based on their case studies. We will then discuss countermeasures for those issues by region to further promote global simultaneous drug development including these exciting and growing regions.

Asia Contribution for Global Study
Hironobu Saito, PhD
Director, Clinical Development Group, Asian Development Department, Daiichi Sankyo Co., Ltd., Japan

Simultaneous Global Development and the Importance of the Asian Area: An EU-based Company's Point of View
Jeannie W. Hou, MD
Director, Medical Science, AstraZeneca Pharmaceutical Co. Ltd., China

Global Development Strategy: Inclusion of Asia and Japan – A US-based Company's Viewpoint
Patrick J. O'Malley
Director, Intercontinental Regulatory Affairs, Eli Lilly and Company

Panelist
Yoshiaki Uyama, PhD
Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 325 RA 2 - Regulatory Affairs, RD

8:30 am-10:00 am LEVEL: ■

Room 6E *Pharmacy credits offered*

FDA Advisory Committees: New Challenges and Opportunities in the Post-FDAAA Era

SESSION CHAIRPERSON(S)

Jonca C. Bull, MD
Vice President, Drug Regulatory Affairs; FDA Liaison Office, US Medical and Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

This session will provide an overview of the FDA Advisory Committee process and its regulatory framework and offer differing viewpoints on current issues impacting the advisory committee process.

Best Practices for a Successful FDA Advisory Committee Meeting
Sunita Zalani, PhD, RAC
Executive Director, Global Regulatory Affairs, Amgen Inc.

Office of the Commissioner's Perspective
William McConagha
Senior Advisor, OPPL, Office of the Commissioner, FDA

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

Session 326 RA 3 - Regulatory Affairs, CP

8:30 am-10:00 am LEVEL: ●

Room 6F *Pharmacy credits offered*

An Introduction to FDA/CDER's Safety First/Safe Use Postmarketing Safety Initiative

SESSION CHAIRPERSON(S)

Howard D. Chazin, MD, MBA
Medical Officer, Guidance and Policy Team, Office of New Drugs Immediate Office, CDER, FDA

As part of FDA's response to the IOM and GAO reports, FDA strengthened its efforts to achieve seamless, effective, efficient management of postmarketing safety issues. This was initiated by delineating roles and responsibilities with CDER's Office of New Drugs and Office of Surveillance and Epidemiology, establishing standard procedures throughout CDER for management of postmarketing safety issues and improving and formalizing procedures for communication and collaboration within CDER. The first phase of this program, Safety First, focuses on the internal FDA/CDER processes, roles, and responsibilities. FDA/CDER plans to expand this effort as "Safe Use" through the utilization of public/private partnerships and assessment of safety information from large postmarketing safety databases. This session will instruct attendees on the basics of FDA/CDER's evolving postmarketing safety efforts.

Safety First: OSE Perspective
Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

Safety First: OND Perspective
Mwango Kashoki, MD, MPH
Associate Director for Safety, Office of New Drugs, CDER, FDA

Session 327 RA 4 - Regulatory Affairs, EC

8:30 am-10:00 am LEVEL: ●

Room 6C *Pharmacy credits offered*

FDA and EMEA Efforts to Harmonize Primary Endpoints

SESSION CHAIRPERSON(S)

Laurie Burke, MPH, RPh
Director, Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

Challenges to instrument development and clinical trial design include meeting the objectives of multiple regulatory authorities. This session will review some of those challenges specific to primary and key secondary endpoints and describe how FDA and EMEA will address some of these issues in an effort to harmonize study endpoint regulatory policy.

EMEA Point of View
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

EMEA Endpoints Review Perspective
Olivier Chassany, MD, PhD
Medical Head, Clinical Research and Development Department, Public Assistance - Hospital of Paris, France

Session 328 RD - R&D Strategy, CR/CS

8:30 am-10:00 am LEVEL: ■

Room 14B MEZZ.

Transforming the Research Paradigm: 21st Century Models to Unify Discovery Research and Clinical Care

SESSION CHAIRPERSON(S)

Kenneth H. Buetow, PhD
Director, Center for Biomedical Informatics and Information Technology, National Cancer Institute, National Health Institutes

Advances in biomedicine allow researchers and clinicians to address disease on the fundamental, molecular level and tailor treatments to a patient's individual genetic makeup, creating a powerful movement among patients to harness their own clinical and genomic data to support research. This session discusses the pathway to connect genomics-based discovery research with clinical care, in order to accelerate identification of biomarkers, conduct more efficient patient recruitment for clinical trials, improve clinical trials outcomes through targeted patient selection, speed delivery of new therapies to market, and reduce R&D costs.

Kenneth H. Buetow, PhD
Director, Center for Biomedical Informatics and Information Technology, National Cancer Institute, National Health Institutes

Dietrich Stephan, PhD
Co-founder and Chief Science Officer, Navigenics

Session 329 ST - Statistics, CR/CS

8:30 am-10:00 am LEVEL: ■

Room 16A MEZZ.

Statistical Issues in Design, Analysis, and Conduct of Thorough QT/QTC Trials

SESSION CHAIRPERSON(S)

Venkat Sethuraman, PhD, MS
Senior Associate Director, Novartis Pharmaceuticals Corporation

This session will discuss statistical issues in the assessment of QT/QTc prolongation from early- and late-stage clinical development studies, address the sample size relating to the primary hypotheses, address the exposure-QT modeling strategies in early development and TQT studies, and compare three types of baseline methods (time-matched, time-averaged, and pre-dose averaged baseline) widely used in the TQT studies to derive change from baseline in QTc. The impact of baseline values on the guidance recommended largest time-matched analyses will be explored using simulations, and the impact on Type I error and power for both crossover and parallel group designs will also be presented.

Assay Sensitivity in Thorough QTc Studies
Joanne Zhang, PhD, MS
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Sample Size Calculation for Thorough QT/QTc Study
Zhaoling Meng, PhD
Manager, Biostatistics and Programming, sanofi-aventis

Exposure-response Modeling in Thorough QT/QTc Study
Balakrishna S. Hosmane, PhD
Director, Statistical Consulting Services; Associate Professor, Northern Illinois University

Session 330 TR/PD - Training/Professional Development, CR/CS

8:30 am-10:00 am LEVEL: ●

Room 16B MEZZ.

Current Clinical Research Training in Japan

SESSION CHAIRPERSON(S)

Tetsuya Tanimoto, MD
Reviewer, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Changes in legislation have encouraged Japanese participation in global clinical research as well as the acceleration of clinical development in Japan. The trend for increasing international clinical research requires intensified training and education programs for staff members of pharmaceutical companies and investigators in Japan. This session will describe the different approaches Japanese companies and global pharmaceutical companies take for clinical research training.

Overview of Current Regulatory Requirements for Clinical Development
Tetsuya Tanimoto, MD
Reviewer, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Update on Clinical Research in Japan
Ichiro Nakaoka
General Manager, Japan Development Center, Pharmaceutical Division, Takeda Pharmaceutical Co., Ltd., Japan

Current Training System in a Japanese Pharmaceutical Company
Hiroyuki Taruno
Director, R&D Operations Department, R&D Division, Daiichi Sankyo Co., Ltd., Japan

Professional Education and Training in a Global Pharmaceutical Company in Japan
Hiroyuki Aoki, MPharm
Manager, Medical Writing Group, Regulatory Affairs Department 2, GlaxoSmithKline K.K., Japan

Session 331 VA - Validation, CDM

8:30 am-10:00 am LEVEL: ■

Room 7A

Auditing Risk-based Computer Validation Projects

SESSION CHAIRPERSON(S)

Breffni Martin
Director, CanReg Europe Ltd., Ireland

The session will cover risk assessment applied to computer validation in the context of clinical research. It will describe current best practice, regulatory basis, and audit findings. The session will provide an auditor's perspective, industry perspective, and the perspective of anex-FDA consultant.

Regulatory Bodies Are Auditing Investigator Sites, Sponsors, and CROs More than Ever: Are You Ready for Inspection?
Angela M. Berns
Global Vendor Manager, Clinical Quality Assurance, UCB, Inc.

Auditing for Integrity, Reliability, and Trustworthiness of Clinical Research Records
Stewart Crumpler, MPH
Principal Consultant, Quintiles Consulting

FDA Perspective: Auditing Risk-based Computer Validation Projects
Robert D. Tollefsen
Consumer Safety Officer, National Expert-Computers, Office of Regulatory Affairs, FDA

10:00 am-10:30 am **REFRESHMENT BREAK**
Exhibit Halls B1, B2, C, Ground Level
(See SDCC Map for exact locations.)

Session 332 AHC/IS - Academic Health Centers/ Investigator Sites, TR/PD

10:30 am-12:00 pm LEVEL: ●

Room 1A

The Influence of Cultural Diversity and Ethnopharmacology on Recruitment for Clinical Trials

SESSION CHAIRPERSON(S)

Barbara H. Gladson, PhD
Professor, University of Medicine and Dentistry of New Jersey

This session promotes understanding of the effects of disparities and diversity in clinical trials and pharmacological management in global populations. The session will also present information on a web-based course that describes issues related to recruitment and retention of individuals of diverse backgrounds. Underlying factors contributing to these disparities, their influence on health outcomes, and participation in clinical trials are analyzed using evidence-based data. Cultural values and customs regarding health care and diversity in learning styles will be reviewed. In addition, some global regulations influencing the recruitment strategy will be introduced. Attendees will formulate strategies to minimize the effects of disparities.

Ethnopharmacology: Ethnic, Racial, and Cultural Attitudes and their Influence on Clinical Trial Recruitment, Retention, and Compliance
Rita Musanti, PhD, MSN
Assistant Professor, Oncology, Clinical Trials, University of Medicine and Dentistry of New Jersey

Accessing Health Literacy and Learning Styles among Different Cultures and their Influence on Recruitment for Clinical Trials
Natalie Dewberry-Moore, MS
Recruitment Specialist, Merck & Co., Inc.

Recruiting Strategies
Ira C. Spector, MBA
Vice President, Global Development Operations, Wyeth Research

Session 333 BT - Biotechnology, CR/CS

10:30 am-12:00 pm LEVEL: ■

Room 1B

Developing Safe and Effective Biological Medicines: Phase 2 and Beyond

SESSION CHAIRPERSON(S)

Robert M. Miller, MD, FFPM
Chief Medical Officer, Fulcrum Pharma PLC, UK

One way of establishing the utility of a novel biological is to perform a large phase 2 study confirming positive results with similar size or possibly smaller phase 3. This is generally not an option for most biological companies, and ways need to be found to establish the dosing regimen and proof of concept with smaller numbers of patients. To do this, consideration has to be given to the mode of action and patient population that may benefit from treatment. Niche indications may provide a more reliable proof of concept with small numbers of patients than more common conditions and could establish whether there is any point in taking an agent forward to phase 3 and beyond.

The purpose of this session will be to establish: 1) how phase 2 dosing and proof of concept could best be realized; 2) how the phase 2 dosing and efficacy findings can be taken onto pivotal phase 3 studies and potential marketing; 3) the types of study(ies) that would best achieve the development and commercial goals; and 4) the regulatory environment to facilitate this process is fundamental to efficiency and will round off the clinical rationale for development options.

Proof of Concept in Biologics Development: Failure is Not an Option
Robert M. Miller, MD, FFPM
Chief Medical Officer, Fulcrum Pharma PLC, UK

Rising to the Challenges of Confirmatory and Safety Trials in the Development of New Biologicals
Cecil Nick, MS
Vice President, Biotechnology, PAREXEL Consulting, UK

Biological Medicines: Can the Rules of the Game Change?
Gopalan Narayanan, MD
Head, Biologicals and Biotechnology Unit, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Session 334 CDM - Clinical Data Management, OS

10:30 am-12:00 pm LEVEL: ■

Room 11B

Outsourced Data Management: How to Align Performance Expectations

SESSION CHAIRPERSON(S)

Mark C. Anderson
Senior Director, Clinical Data Management, Covance Inc.

It's not uncommon to see data management included in the clinical development outsourcing process only once this process is well underway or nearly complete. However, this tactical approach to data management outsourcing opens the door for performance expectations to diverge once the trial is underway, as initial expectations were never made transparent and fully aligned. This session explores the challenges and strategies involved in successful data management outsourcing between sponsor companies and CROs. This session will provide specific areas and actionable, pragmatic approaches to consider, including case studies measuring the impact of these approaches on the sponsor's business success.

Long-term Data Management Outsourcing: Can Companies Find Better Ways to Outsource Large Studies in Data Management?
Dorothy B. Dorotheo
Director, Clinical Data Management, InterMune Inc.

Clinical Data Standards: How a Partnership Outsourced Model Could Improve Data Management Project and Data Quality Performance
Richard Burlingame, MBA
Associate Director, Merck & Co., Inc.

Outsourced Data Management: How to Better Align Performance Expectations with External Service Providers
Mark C. Anderson
Senior Director, Clinical Data Management, Covance Inc.

Session 335 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

10:30 am-12:00 pm LEVEL: ■

Room 17A MEZZ.

Do Subvisible Particles Contribute to the Immunogenicity of Therapeutic Proteins? Gaps in Risk Evaluation and Mitigation

SESSION CHAIRPERSON(S)

Jack Ragheb, MD, PhD
Principal Investigator, Laboratory of Immunology, Office of Biotechnology Products, Office of Pharmaceutical Science, Division of Therapeutic Proteins, CDER, FDA

This session will describe the potential impact that enhanced immunogenicity, due to large protein aggregates produced during the manufacturing of therapeutic protein products, has on a product's safety and efficacy profile. The factors affecting this risk, case studies of the occurrence of these aggregates during the manufacturing process, and the methods that can be useful in evaluating and controlling the associated risk will also be discussed.

Homogeneous and Heterogeneous Protein Aggregates: Relationship with Immunogenicity?
Theodore W. Randolph, PhD
Gillespie Professor, Center for Pharmaceutical Biotechnology, University of Colorado at Boulder

Immunogenicity Risk Prediction: Current Tools and Potential Applications
Theresa J. Goletz, PhD
Director, Medical Sciences, Clinical Immunology Site Head, Amgen Inc.

Session 336 CP - Clinical Safety and Pharmacovigilance, CR/CS

10:30 am-12:00 pm LEVEL: ●

Room 30AB *Pharmacy credits offered*

Risk Management Best Practice: Integrating Risk Management Strategies into All Phases of the Product Life Cycle

SESSION CHAIRPERSON(S)

Uwe Maennl, MD, PhD, MBA
Vice President, Global Head, Pharmacovigilance, Drug Safety and Medical Affairs, Quintiles (QTHV), UK

With greater emphasis on RiskMAPs in Europe and REMS in the US, pharmaceutical companies must evolve their standard processes to incorporate risk management at all phases of the product life cycle. Understanding best practices for risk benefit readiness will be critical to successfully evolve the drug development process.

Risk Management: Getting It Off the Ground during Clinical Trials
Annette Stemhagen, DrPH, FISPE
Vice President, Epidemiology and Risk Management, United BioSource Corporation

Corporate and Operational Prerequisites that Need to Be Met in Order to Deliver Effective Risk Management Strategies
Jill E. Robinson, MBA, RPh
Vice President, Global PV Operations, Wyeth Pharmaceuticals

Next Generation Pharmacovigilance: Challenges and Opportunities
Amrit Ray, MD, MBA
Vice President, Global Pharmacovigilance and Epidemiology-Medical Safety, Bristol-Myers Squibb

Session 337 CR/CS 1 - Clinical Research and Development/Clinical Supplies, PM/FI

10:30 am-12:00 pm LEVEL: ■

Room 3

Can the Government Really Implement Cost-effective and Efficient Clinical Trials?

SESSION CHAIRPERSON(S)

Erin J. Iturriaga, RN
Nurse Consultant/Project Officer, National Institutes of Health

Data from project management timelines will show that clinical trials implemented through government funding mechanisms are cost-effective and efficient. The government is able to maneuver through the various government agencies and tap into some of the best scientific leaders in the field to collaborate with academic institutions and industry partners. The government has access to experts in the field not only in the sciences, but also in information technology such as data-sharing capabilities and innovative ideas shared for various projects.

Role of VA-affiliated Nonprofit Corporations in Management of Industry-funded Research
David E. Johnson, PhD
Deputy Associate Chief of Staff for Research and Development, Research Services, VA Medical Center

Doing More with Less: The Impact of Public-private Partnerships on Innovation in Pharma R&D
Michael Hehenberger, DrSc, PhD
Solutions Executive, Global Life Sciences/Pharma, IBM

Implementing Cost-effective and Efficient Clinical Trials through the Government (NIH)
Steven R. Oversby, BSN, PhD, RN
Health Scientist Administrator, National Institute on Drug Abuse, National Institutes of Health

Session 338 CR/CS 2 - Clinical Research and Development/Clinical Supplies, CP

10:30 am-12:00 pm LEVEL: ■

Room 5B

Optimizing Clinical Trial Material Supply Planning

SESSION CHAIRPERSON(S)

Sonja E. Davis
Team Leader, Six Sigma, Eli Lilly and Company

Robust clinical trial supply planning is essential to patient safety and the smooth execution of clinical research. In this session, we will explore development of a supply plan, impact of packaging design decisions, and assessment of supply chain risks. The use of fundamental elements of the study protocol and key information from study team members along with standard and advanced methods of forecasting supply needs will be discussed. Additionally, across the industry, there is an increased awareness of the impact of packaging design on patient compliance and safety. We will consider innovative packaging technologies available to address these needs.

Optimizing Clinical Trial Material Supply Planning
Lori Bottom
Clinical Trial Project Manager, Eli Lilly and Company

Strategies to Reduce the Risk of Comparator Drug Sourcing
Mark Anthony Ware
Director, Clinical Trial Services, IDIS Ltd., UK

Session 339 CR/CS 3 - Clinical Research and Development/Clinical Supplies, IT

10:30 am-12:00 pm LEVEL: ■

Room 6D

Clinical Automation Systems in Phase 1 Clinical Research

SESSION CHAIRPERSON(S)

Barry Mangum, PharmD
Associate Clinical Professor, Clinical Pharmacology, Department of Pediatrics, Duke Clinical Research Institute

Clinical automation systems in phase 1 clinical research are now evolving so that patient safety can better be assessed in real time. It is hoped that through the seamless integration of EKG data into the electronic data capture (EDC) that drug safety can also be assessed. This session will present the first seamless EKG data interface.

Enhancing the Safety and Efficiency of Early-phase Research through Automated Systems
Vivian L. West, PhD, RN, MBA
Project Leader, Duke Clinical Research Unit

Integrating Electronic Data Capture into a Phase 1 Unit
Giles Wilson
Business and Operations Director, Logos Technologies Ltd., UK

Improving the Acquisition of Digital ECGs in Phase 1 Trials
Mark Mentzer
Vice President, Clinical Research, Mortara Instrument Inc.

Session 340 EC - eClinical, ERS/DM

10:30 am-12:00 pm LEVEL: ■

Room 15A MEZZ.

CDISC Pilots

SESSION CHAIRPERSON(S)

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

This session will bring attendees up-to-date information on two pilot projects being run by CDISC in conjunction with the FDA: 1) the Integrated Safety Data pilot examining the use of the SDTM (Study Data Tabulation Model) and Analysis Data Model (ADaM) standards for integrating data for regulatory submission and 2) a pilot looking at the use of the SEND (Standard for Exchange of Nonclinical Data) standard for the submission of preclinical data.

The CDISC/FDA Integrated Data Pilot
Chris Decker, MS
Life Sciences Director, d-Wise Technologies Inc.

The Standard for Exchange of Nonclinical Data (SEND) Pilot
Lou Ann Kramer
Team Leader, Eli Lilly and Company

FDA Perspective: The Standard for Exchange of Nonclinical Data (SEND) Pilot
Lilliam Rosario, PhD
Associate Director, Nonclinical Data Standards, Office of the Commissioner, FDA

Session 341 ERS/DM 1 - Electronic Regulatory Submissions/Document Management, RA

10:30 am-12:00 pm LEVEL: ●

Room 8

The Multilingual Dimension: Best Practices for Addressing Global Content and Global XML

SESSION CHAIRPERSON(S)

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

The pharmaceutical industry is driven by government bodies, by market demand, and not least by good ethical communication practices to supply information in local languages. Local clinical trial documentation, local drug safety information, and local product information are mandated by governments. End users expect consistent responses for off-label information in their native tongue. Narratives in local language explain today's drug safety procedures. European product information alone consists of 96% of text written in a language other than English. Any global pharmaceutical company today coordinates 50+ local language versions of all critical information. And, only a fraction of what would be considered useful in a local context is actually supplied by today's businesses. Multilingual content therefore is increasingly recognized as critical-path elements when it comes to regulatory, clinical trial, medical information, or drug safety procedures.

This session looks at best practices and technologies (XML authoring, component management, translation process, and quality management) needed to address systematic multilingual content delivery. This session will focus on examining real-world examples of best practices for managing multilingual content for today's pharmaceuticals, using the European Medicines Agency (EMEA) Central Procedure (CP) and Product Information Management (PIM) system as a backdrop.

EMEA Perspectives
Timothy Buxton
Head of Sector, Project Management, Communications and Networking Unit, European Medicines Agency, European Union

Translation and the Critical Path to Centralized Product Labeling in the European Union
Raun S. Kupiec, MS
Senior Director, Regulatory Affairs, Genzyme Europe, Netherlands

Content Management for Labeling: Translation Management, SPL, and PIM – Lessons Learned from an Implementation of XML across US and Europe
Bernie Coney, MA
Senior Regulatory Specialist, Regulatory Operations, Wyeth Research

Session 342 ERS/DM 2 - Electronic Regulatory Submissions/Document Management

10:30 am-12:00 pm LEVEL: ■

Room 9 *Pharmacy credits offered*

What's the Meta with this Data? The Shifting Sands of Submission EDMS

SESSION CHAIRPERSON(S)

Donald G. Palmer, MA
Associate Director, Regulatory Systems, MedImmune

This session will consider the changing EDM market. We will use an industry survey to identify trends as the marketplace shifts toward content and collaboration; we will also consider and address the need for metadata-driven systems in submission management and processing. We will review the DIA Cross-SIAC EDM Reference Model and the continually increasing importance of metadata for describing, structuring, and processing submission content. The focus of the session will be on submission documents and processing.

Is it Time for Radical Change? Benchmark of Emerging Technologies and Approaches for Collaboration and Document Management
Steve Scribner
Managing Consultant, International Life Sciences Solutions, Inc.

Views of Metadata and MetaViews of Data: The Power of EDMS Systems
Donald G. Palmer, MA
Associate Director, Regulatory Systems, MedImmune

Ask Not What You Can Do for the Metadata: Ask What the Metadata Can Do for You
Ole Rom Andersen
Director and Co-founder, Content Technologies ApS, Denmark

Session 343 GCP - Good Clinical Practices, RA

10:30 am-12:00 pm LEVEL: ■

Room 30CD *Nursing credits offered*

Dealing with an FDA Audit: What We Can Learn from Warning Letters and Audits

SESSION CHAIRPERSON(S)

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

This session will cover the audit from different perspectives and focus on helpful hints and procedural issues regarding what to do in case you are chosen for an FDA audit. There will be a discussion on how to host the audit and how best to prepare for the actual audit. The audience will learn some of the do's and don'ts of a successful audit from actual case examples and inspections.

FDA Audits and What We Can Learn
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

Serious and Continuing Noncompliance: How IRBs and Sponsors Can Work Together to Manage Noncompliant Sites and Protect Human Subjects
Deborah A. Waltz, MS
Senior Director, Scientific Operations Quality, King Pharmaceuticals

Prepare and Pass Audit by Learning from Auditors: Trends, Practical Tips of Managing Audit and Compliance
James Huang, PhD
Director, Quality Assurance and Regulatory Compliance, Almac Clinical Technologies

Session 344 IT - Information Technology, EC

10:30 am-12:00 pm LEVEL: ■

Room 15B MEZZ.

Clinical Data Flow and Integration: Three Use Cases from an Information Technology Perspective

SESSION CHAIRPERSON(S)

Susan P. Duke, MS
Associate Director, Biostatistics Development Partners, GlaxoSmithKline

With the adoption of electronic data capture and maturation of industry data standards, biopharma companies are considering new architectures to streamline data flow and strategies for their implementation. This session describes the motivations and plans from several biopharma companies from an information technology perspective.

Clinical Data Flow: Contrasting and Comparing Approaches
Robert E. Vermeulen
Enterprise Architect, R&D IT, GlaxoSmithKline

Clinical Data Management in a Fully Integrated Pharmaceutical Network
Rocky Turner
Information Consultant, Eli Lilly and Company

Metadata-driven Enterprise Data Management: A Case Study
Sue Dubman, MA
Senior Director, Standards and Architecture, Genzyme Corporation

Session 345 MA - Marketing, TR/PD

10:30 am-12:00 pm LEVEL: ●

Room 33AB

Developing Tactical Marketing Strategies from Market Research

SESSION CHAIRPERSON(S)

Elizabeth Malson, MBA, MS
Senior Product Manager, Assay Life Cycle Management, Ventana Medical Systems, Inc.

This session will provide an overview of fundamental market research tools used to develop tactical marketing strategies. Customer segments, promotional messaging, and sales force effectiveness can be identified and refined through primary and secondary market research.

Effectively Leveraging Insights from Market Research
Reid Bengard
Owner, Aquest Research

Building a Strategic Marketing Plan
Elizabeth Malson, MBA, MS
Senior Product Manager, Assay Life Cycle Management, Ventana Medical Systems, Inc.

Utilizing Market Research and Brand Strategy as a Field Representative
Jarrod C. Hamilton, MBA
Senior Manager, CMG Partners, LLC

Session 346 MC - Medical Communications, RA

10:30 am-12:00 pm LEVEL: ●

Room 14A MEZZ. *CME and Pharmacy credits offered*

Safe Use of Drugs – *Part 2 of 2:* Communicating Effectively with Health-care Professionals

SESSION CHAIRPERSON(S)

Steven Osborne, MD
Executive Director, Drug Safety Oversight Board, CDER, FDA

Part 1 of this session will take place on Wednesday at 8:30 am.

We will discuss the tools that FDA uses to communicate with health-care professionals. An external panel will discuss the pros and cons of FDA's current approaches.

Norman S. Marks, MD, MHA
Medical Director, MedWatch Program, Office of Scientific and Medical Programs, Office of the Commissioner, FDA

Joyce A. Generali, MS, RPh
Director, Drug Information Center, Kansas University Medical Center

Session 347 MW - Medical/Scientific Writing, RA

10:30 am-12:00 pm LEVEL: ■

Room 31AB

Changes in International Drug Development: Effects on Common Technical Document Preparation in Japan

SESSION CHAIRPERSON(S)

Satomi Ando, MS
Head, Document Operations in Clinical Development Division, Novartis Pharma K.K., Japan

The Common Technical Document (CTD) for New Drug Applications (NDAs) varies in content and structure, depending on the strategy of drug development and regulatory submittal. In Japan, the development strategy has evolved from full Japanese development to a bridging strategy which extrapolates foreign data to Japanese patients, and now to simultaneous multinational development. In this session, the different types of CTD for submission to the Japanese drug evaluation agency (PMDA) will be described. We will discuss how to prepare each type of CTD and how medical writers can take the lead in making all types of Japanese NDAs successful. The most recent approach is simultaneous multinational drug development, which is believed to be more efficient because it can greatly shorten the times to submission and approval. This strategy is also thought to reduce the drug lag problem (marketing approval in some countries before that in Japan), which is currently an important regulatory concern in Japan. One key factor for successful simultaneous submissions is efficient CTD preparation using medical writers to facilitate good cross-national and cross-functional collaboration.

This session will describe the challenge of simultaneous submissions to the Japanese, US, and EU regulatory agencies, using an oncology product as an example. It will also examine the topics to address and method of presentation in those sections of the CTD in which Japanese and non-Japanese data are needed under a bridging strategy or mutinational simultaneous development. From the regulatory perspective, a review officer will provide input on how the Japanese Agency views different types of CTDs and what aspects the PMDA considers important in every type of CTD.

What Reviewers Expect from the Submission Documents for IND Scientific Advice and NDA Review: Development Strategy Could also Change Reviewers' Perspective for Submission Documents
Katsuhiko Ichimaru, MS
Principal Reviewer, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Is Writing a CTD Dependent or Independent of Development Strategy?
Hiroko Terano
Manager, Medical Writing Group, Clinical Development Division, Novo Nordisk Pharma Ltd., Japan

A Multiregional Simultaneous Submission: Toward a Truly Common Technical Document
Cheryl S. Ingram
Senior Scientific Communications Associate, Global Medical Communications, Eli Lilly and Company

Session 348 NC - Nonclinical Laboratory Safety Assessment, RA

10:30 am-12:00 pm LEVEL: ●

Room 10 *Pharmacy credits offered*

New Approaches to Toxicity Testing to Support Pharmaceutical Development – *Part 1 of 2:* New Endpoints

SESSION CHAIRPERSON(S)

Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs, Immediate Office, CDER, FDA

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

Current practices for nonclinical safety evaluations of drug candidates in the development pipeline have remained essentially unchanged for decades despite advances in technologies to support drug discovery, biological understanding of drug action, and the modern practice of human medicine. We continue to rely heavily on tedious microscopic histological tissue sample evaluations and weakly informative biomarkers from a sequential series of progressively longer animal studies designed to identify human safety concerns based on target organ effects seen at intolerable dose levels of test agents. In this session, industry and regulatory perspectives will be presented on the advances being made to implement whole animal imaging technologies and improved accessible biomarkers into animal toxicology testing that could easily translate to bridge clinical testing. The challenges, expectations, and potential impact of noninvasive imaging approaches and improved accessible biomarkers on reducing especially nonrodent animal testing numbers, and overall resource burdens and testing timelines while maintaining protection of clinical trial safety, will be discussed.

Imaging
Thomas Monticello, DVM, PhD
Worldwide Executive Director, Department of Safety Assessment, Merck & Co., Inc.

Biomarkers
Jeffrey W. Lawrence, PhD
Director, Biochemical Toxicology and Safety Biomarkers, Amgen Inc.

A Regulatory Perspective on Imaging Methods and Biomarkers
Beatriz Silva Lima, PharmD, PhD
CHMP and SAWP Member, SWP Chair; Professor, Pharmacology, University of Lisbon, Portugal

Session 349 NHP - Natural Health Products, RD

10:30 am-12:00 pm LEVEL: ■

Room 17B MEZZ. *Pharmacy credits offered*

Natural Health Products: Current Research and Development

SESSION CHAIRPERSON(S)

Christelle Anquez-Traxler, PharmD
Regulatory and Scientific Affairs Manager, AESGP, Belgium

The session will focus on concrete experience of R&D on traditional (herbal) medicines in Asia. The role of public programs or incentives (such as the one launched by the Committee on Chinese Medicine and Pharmacy) in stimulating research on phytomedicines will also be considered. Challenges encountered in the development of natural health products using top-notch scientific standards and how to best address them will also be discussed.

Capabilities and Strategy for the Development of Traditional Medicines in Asia
Jean-Paul M.F. Deslypere, MD, PhD
Business Development Manager, Life Sciences - Asia Pacific, SGS Life Sciences Services, Singapore

Plan of Establishing Comprehensive Chinese Medicine Clinical Trial Centers in Educational Hospitals (2001-2006) Research Accomplishment Analysis and Evaluation
Lin Chi-Yang, MS
Committee on Chinese Medicine and Pharmacy, Taiwan

Good Clinical Practices and Quality in Developing Natural Health Products: What Must Be Done and What Must Be Avoided
Firoz Nilam, MS
President, Nilam Pharmaceutical Consulting Inc.

Session 350 OS - Outsourcing, AHC/IS

10:30 am-12:00 pm LEVEL: ■

Room 5A

Faster, Better, Cheaper? Working Outside North America and Western Europe

SESSION CHAIRPERSON(S)

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

CROs, investigators, and research institutions outside North America and Western Europe have been promoting access to patients, shortened enrollment timelines, and reduced cost of working in emerging countries. This session explores whether the reality has measured up to the marketing, exploring the experiences, challenges, and successes of companies that have worked in these environments both locally (in a specific region or country) and as part of larger global trials.

Working Outside North America and Western Europe
Anthony J. Carita
Director, Clinical Outsourcing, Otsuka Pharmaceutical Development & Commercialization

Working Outside North America
Eric L. Hurden, PhD, MSc
Associate Director, Global Clinical Operations, Biogen Idec, UK

Working beyond North America
Graeme Currie, PhD
Vice President, Clinical Operations, Sepracor Inc.

Session 351 PM/FI 1 - Project Management/ Finance, OS

10:30 am-12:00 pm LEVEL: ■

Room 4 *Project Management units offered*

Virtual Project Teams: Best Practices for Improving Product Development Efficiency

SESSION CHAIRPERSON(S)

Libbie J. Mansell, PhD, MBA
President, White Oak BioPharma Solutions, LLC

The need to improve product development efficiency makes implementation of virtual teams very attractive to pharmaceutical, biologic, and medical device companies. This session will provide attendees with constructive approaches to using the virtual project team paradigm to its best advantage. Speakers with expertise in a range of development disciplines, including pharmacovigilance/safety, CMC, and clinical research functions, will discuss obstacles and challenges frequently encountered by the virtual team. Real-life examples will be presented along with lessons learned and possible alternative solutions. Speakers will address issues from the perspective of company personnel, external consultants and partners, and geographically dispersed team members.

Inside Productive Virtual Teams
Douglas Cowart, PharmD
Executive Director, Therapeutic Development Consultants LLC

Using a Virtual Model Effectively in Pharma
Libbie J. Mansell, PhD, MBA
President, White Oak BioPharma Solutions, LLC

Building Virtual Biotechs for Foundations and Institutions
Jeff Shrager, PhD
Chief Technology Officer, CollabRx

Session 352 PM/FI 2 - Project Management/ Finance, CR/CS

10:30 am-12:00 pm LEVEL: ●

Room 2 *Project Management units offered*

Managing Team Communications Globally

SESSION CHAIRPERSON(S)

Jean A. Yager, PhD
Director, Infectious Diseases, Pfizer Inc.

Biopharmaceutical industries (pharma, biotech, medical device, CROs, etc.) have gone global, and teams are often composed of individuals from different regions of the world who participate via a variety of electronic communications venues. As a result, the diversity of team members has greatly increased in terms of culture, native language, and regional perspectives. Project team member participation is facilitated via global communications technology. However, is communication effective? Continuous rapid advances in global communication technologies have enabled almost instantaneous distribution of information worldwide 24/7. Myriads of communications assail team members and executive management daily, often producing information overload

and in some cases causing confusion. A structured and planned approach to team communications is the key to effective team communications. Electronic tools, if applied appropriately, may facilitate communications and understanding. Assuring critical information is delivered to those who need it in a manner that will best enable their understanding is a key role of project leaders and project managers.

Collaborative Tool for Global Clinical Project Management
Hal J. Bredbenner
Director, Applications Development Group, SRA Global Clinical Development LLC

Facilitating Communications within a Global Project Team: Practical Tips
Jacqueline M. Zarro, PhD, MS
Vice President, Clinical Project Management - US, Premier Research Group

Communicating across Cultures
Gail H. Sherman
Senior Vice President, Strategic Development, FinTel Communications, LLC

Session 353 PP - Public Policy/Law, RA

10:30 am-12:00 pm LEVEL: ●

Room 32AB

Patient-reported Outcomes Consortium: A Public-private Partnership

SESSION CHAIRPERSON(S)

Joseph R. Assenzo, PhD
Executive Director, Education, The Critical Path Institute

Patient-reported outcomes (PRO) instruments provide information concerning the patient's perspective of an intervention or therapy on one or more aspects of the patient's health status. PRO instrument development is expensive and time consuming because of the extensive qualitative research and validation testing process. It is unlikely that any one entity will possess all the necessary expertise and resources to accomplish the work needed to design, evaluate, and qualify an accurate PRO instrument in an expeditious manner. Further, FDA's advisory role in instrument development is resource intensive and must be duplicated across multiple sponsors who may be developing treatments in the same disease area. To facilitate the development of PRO instruments for use in clinical trials designed to evaluate the safety and effectiveness of medical products, the Food and Drug Administration (FDA) and the Critical Path Institute developed an overarching framework for collaboration with pharmaceutical, biotechnology, device and diagnostic companies, academia, vendors, and other governmental agencies to leverage resources and expertise toward mutually beneficial goals and in the interest of public health.

This session will describe the main objectives of the PRO Consortium and its research program, consortium membership, consortium management, roles and responsibilities of consortium members, selection of PRO instruments for development, and current status of the consortium.

FDA Interest and Perspective on Benefits of the Consortium
Laurie Burke, MPH, RPh
Director, Study Endpoints and Labeling, Office of New Drugs, CDER, FDA

Summary and Highlights of the Coordinating Committee Kickoff Meeting
Priti Jhingran, PhD
Director, US Health Outcomes, GlaxoSmithKline

Background and Rational for the Creation of a Consortium from the PhRMA Perspective
Jean-Louis Saillot, MD
Vice President, Global Project Management, Immunology, Schering-Plough

Session 354 RA 1 - Regulatory Affairs, CR/CS

10:30 am-12:00 pm LEVEL: ■

Room 6E

Regulatory Strategy in Global Drug Development

SESSION CHAIRPERSON(S)

Iman Barilero, PhD
Divisional Director, Regulatory Development Strategy, R&D, H. Lundbeck A/S, Denmark

Pharmaceutical companies are taking strategic decision to globally develop new compounds for both EU and US markets. This requires agreement on global clinical development plan, disease understanding and unmet medical need in both regions to support regulatory approval. Regulatory requirements and precedents in approving new drugs in both regions play a pivotal role in designing optimal global clinical development and regulatory strategy. Alignment between FDA and EMEA on one clinical development plan would support a global approach for drug development and regulatory approval and would minimize needs for further clinical studies. Furthermore, global approach to risk mitigation and risk management is increasingly becoming an integrated part of global drug development and regulatory process to ensure patient safety. Collaboration between FDA and EMEA during drug development of new medicines and postmarketing is taking place to support regulatory approval in both regions and protect public health. The session will provide an opportunity to address the challenges and considerations in establishing successful regulatory strategy for global drug development in view of facilitating regulatory approval. This will include industry experience as well as points of view and experience of the health authorities in US (FDA) and EU (EMEA/CHMP) with examples of interactions between the two agencies such as during scientific advice and communication during drug evaluation and postmarketing.

Interaction between EMEA and FDA during Drug Development: Scientific Advice
Bruno Flamion, MD, PhD
Chair, Scientific Advice Working Party, CHMP; Professor, Clinical Pharmacology, University of Namur, Belgium

Collaboration between EMEA and FDA during Drug Evaluation Case Study: Oncology Drugs
Lawrence J. Lesko, PhD
Director, Office of Clinical Pharmacology and Biopharmaceutics, Office of Translational Sciences, CDER, FDA

Benefit-risk Assessment Postmarketing with Case Study
Deborah Szafir
Head, Safety Risk Management Strategy, Roche, France

Session 355 RA 2 - Regulatory Affairs, BT

10:30 am-12:00 pm LEVEL: ■

Room 7B

Recent Advancement of Advanced Therapy in the Asian Pacific Region

SESSION CHAIRPERSON(S)

Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Advanced therapy such as cell/gene therapy has become one of the focal points with the advance of biotechnology and medicine. The nations in the Asian Pacific region such as China, Japan, Korea, and Taiwan have increasing investment in this emerging technology. This led to a trend of regulatory con-

sideration of advanced therapy in early stages during development of novel treatment of diseases. National programs in these countries have supported interdisciplinary research funding and infrastructure set-up. This session will be devoted to the discussion and comparison of recent advancement of advanced therapy in the Asian Pacific region.

Regulatory Perspectives on Advanced Therapy
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Advanced Therapy: Industry Point of View
Alexander Kuta, PhD
Group Vice President, Regulatory Affairs, Genzyme Corporation

Recent Advancement of Advanced Therapy in Japan
Mayumi Shikano, PhD
Office Director, Office of Biologics II, Pharmaceuticals and Medical Devices (PMDA), Japan

Advanced Therapies: Industry Point of View
Thomas G. Evans, MD
Vice President, Global Head of Infectious Diseases, TS-Shanghai, Novartis Institutes for BioMedical Research, Inc.

Session 356 RA 3 - Regulatory Affairs, RD

10:30 am-12:00 pm LEVEL: ■

Room 6F

Improving Regulatory Outcomes: What Are the Prospective and Retrospective Regulatory Strategies Companies Can Use to Improve the Quality of Development and Review?

SESSION CHAIRPERSON(S)

Neil McAuslane, PhD, MSc
Director, CMR International Institute for Regulatory Science, UK

Pharmaceutical research is a high-risk business, but the regulatory approval system should be predictable and risk free for medicines developed in accordance with current guidelines. One of the challenges faced by companies is that, in the 12-14 years that it takes to bring a new product to market, the regulatory goalposts may have moved to keep pace with scientific progress. In this complex global regulatory environment, a comprehensive regulatory strategy is a vital component of the overall drug development plan. In a recent pharma industry survey, over 60% of regulatory professionals polled did not think their function had a high enough profile within their company. What does it take to make a business impact in regulatory affairs and demonstrate its value both in the short term and long run?

There are two main areas in which companies can focus to improve the regulatory outcome. One is prospectively, by ensuring that they have a clear view of the appropriate regulatory activities and strategies embedded into the development process, and the other is retrospective in terms of learning why and when new drug applications do not achieve companies' expectation from the review process, and what were the main reasons. Seeking scientific advice and discussion during development with agencies at predefined milestones are common process and procedures. However as the regulatory environment changes, how should companies and agencies best manage scientific progress over the time taken to develop a new product so that development work is not deficient at the time of submission? It has also been realized that it is not enough to measure regulatory performance solely in terms of timelines and speed of review. This session will concentrate on how to improve regulatory outcomes from both a prospective viewpoint in terms of what can be done during development and from a retrospective position in terms of what companies and agencies can learn from the review and submission.

How Integrating Regulatory Strategy into Development Today is Critical to Achieving Business Success
Heather Cook, PhD
Head of Department, Regulatory Development Projects, H. Lundbeck A/S, Denmark

Facilitating Feedback on the Submission and Review between Companies and Agencies: Can This Increase the Predictability of the Review Process?
Neil McAuslane, PhD, MSc
Director, CMR International Institute for Regulatory Science, UK

How Can Agencies Help Companies Prospectively and Retrospectively Improve the Quality of their Development and Submission?
Leonie Hunt, MD, MBA
Head, Office of Prescription Medicines, Therapeutic Goods Administration, Australia

Session 357 RA 4 - Regulatory Affairs, BT

10:30 am-12:00 pm LEVEL: ■

Room 7A

Regulatory Considerations for Subsequent Entry of Biologics in Canada

SESSION CHAIRPERSON(S)

Agnes V. Klein, DrPH, MD
Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Product, Biologics and Genetic Therapies Directorate, HPFB, Health Canada

In Canada, most recently, the regulatory agency for Biological Products, the Biologics and Genetic Therapies Directorate, has started to tackle the issue of regulating these products. There are a number of important considerations that have entered into the development of regulations allowing the eventual marketing of these Subsequent Entry Biologics or SEBs.

A Canadian Regulatory Perspective on Biosimilars: Nonclinical and Clinical Requirements
Agnes V. Klein, DrPH, MD
Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Product, Biologics and Genetic Therapies Directorate, HPFB, Health Canada

A Canadian Regulatory Perspective on Biosimilars: Demonstrating Comparability and Other Product Quality-related Issues
Anthony Ridgway, PhD
Senior Regulatory Scientist, Office of the Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Health Canada

A Canadian Regulatory Perspective on Biosimilars: Policy and Regulatory Framework
Kwasi Nyarko, PhD
Unit Manager, Special Projects, Policy and Promotion Division, Health Canada

Session 358 RD - R&D Strategy, EBM/IMP

10:30 am-12:00 pm LEVEL: ■

Room 14B MEZZ.

Challenges in Developing and Commercializing Personalized Health-care Products

SESSION CHAIRPERSON(S)

Duncan McHale, MD, PhD, MRCP
Medical Director, Personalized Healthcare, AstraZeneca Pharmaceuticals LP, UK

Personalized health care can be defined as the application of a diagnostic test or platform to improve the benefit/risk ratio of the drug. Many companies are now moving towards developing more personalized therapies in an effort to demonstrate clear differentiation from competitor products. Despite the theoretical advantages of this approach, there are few examples currently being used in clinical practice. This session will use real examples to highlight some of the challenges with this strategy and how they have been successfully addressed by companies and regulators.

Challenges in Developing and Commercializing Personalized Healthcare Products: Clinical Aspects
Kaushikkumar Shastri, MD
Medical Officer, Office of Oncology Drug Products, Division of Biologic Oncology Products, CDER, FDA

Challenges of Companion Diagnostics Development for HIV Tropism Testing
Hakan Sakul, PhD, MS
Senior Director and Global Head of Diagnostics, Molecular Medicine Group, Pfizer Global R&D

Investigating the Utility of KRAS as a Biomarker for Anti-EGFR Therapy
Scott D. Patterson, PhD
Executive Director, Medical Sciences, Amgen Inc.

Session 359 ST - Statistics, CR/CS

10:30 am-12:00 pm LEVEL: ■

Room 16A MEZZ.

Challenges in Noninferiority Studies

SESSION CHAIRPERSON(S)
Pilar C. Lim, PhD
Senior Director, Johnson & Johnson Pharmaceutical R&D LLC

This session focuses on practical insights into designs and analyses for noninferiority studies by considering in detail several case studies. These case studies will illustrate the challenges that have been encountered in the design, execution, and analysis of noninferiority studies.

Noninferiority Tests under Heterogeneous Treatment Effects
Pilar C. Lim, PhD
Senior Director, Johnson & Johnson Pharmaceutical R&D LLC

Noninferiority Trials: What We Have Learned and What We Still Need to Solve
Ralph B. D'Agostino, Sr., PhD, MA
Chair, Mathematics and Statistics Department; Professor of Mathematics and Statistics and Public Health, Boston University

Multiplicity Issues when Testing Noninferiority and Superiority Objectives Involving Primary and Key Secondary Endpoints
H. M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Session 360 TR/PD - Training/Professional Development

10:30 am-12:00 pm LEVEL: ●

Room 16B MEZZ.

Attracting and Training the Best Talent in the 21st Century: The Mix of Generations in the Workplace

SESSION CHAIRPERSON(S)
Richard Wood, MS
Associate Director, Global Training, INC Research

It is no secret that we are in a talent war. It is more important than ever to create a compelling reason for talented people to not only work for your organization, but to be fully engaged there. The key is engaging this talent. In this session, we will learn from several companies the best practices that have been used to attract and retain talented employees and improve employee engagement. We will identify different generations in your workplace and learn tips on ensuring the best ways to motivate, train, and engage these employees.

Creating Workplaces Where People Want to Work
Theresa Hummel-Krallinger
Director, Organizational Development and Training, Almac Clinical Technologies

Training a Virtual and Multigenerational Workforce
Richard Wood, MS
Associate Director, Global Training, INC Research

Session 361 VA - Validation, EC

10:30 am-12:00 pm LEVEL: ●

Room 11A

Town Meeting: Validation Experts Respond to Your Questions and Concerns – OQ, IQ, PQ, and Testing Practices

SESSION CHAIRPERSON(S)
Teri E. Stokes, PhD, MS, MT
Director, GXP International

This session will use an experienced panel to set the scene for audience discussions to explore the many ways in which attendees have struggled with all phases of computer validation. The expert panel will respond to audience questions with their experience of what works well and not so well in different system settings.

Audible Testing
Teri E. Stokes, PhD, MS, MT
Director, GXP International

IQ and PQ for Commercial GCP Systems
Brian Shoemaker, PhD
Principal Consultant, ShoeBar Associates

OQ for In-house Software
Richard L. Chamberlain, PhD, MS
President, ECS Inc.

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

Exhibit Hall D, Ground Level
A special seating section will be available for networking with colleagues from your professional interest area. *(See SDCC Map for exact location.)*

Session 362 AHC/IS - Academic Health Centers/ Investigator Sites, EC

1:30 pm-3:00 pm LEVEL: ●

Room 1A

Increasing Enrollment, Retention, and Compliance through Electronic Patient Payment and Communication Technologies

SESSION CHAIRPERSON(S)

Samuel J. Whitaker
CEO, GreenPhire Inc.

This session will review current strategies to drive enrollment, retention and compliance and will explore the effects of new technology-driven strategies. New technologies will be discussed and examined using a case study.

Effect of Mobile Communication Strategies on Enrollment, Retention, and Compliance
Tim Davis
Co-founder, Exco InTouch, UK

Coupling Electronic Payment and Communication Strategies to Increase Retention and Enrollment Rates
Scott H. Connor
Vice President, Marketing, Acurian Inc.

Effectively Integrating Electronic Communication Strategies into the Trial Environment
Joseph Kim, MEd
Manager, Global Trial Optimization, Merck & Co., Inc.

Session 363 BT - Biotechnology, CR/CS

1:30 pm-3:00 pm LEVEL: ■

Room 1B *CME credits offered*

Opportunities for the Treatment of Rare Diseases

SESSION CHAIRPERSON(S)

Agnès Saint-Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use Unit, European Medicines Agency, European Union

Gene and cell therapy products are at the forefront of the new therapeutic approaches for hitherto unmet clinical needs. Quality requirements are a prerequisite for safety of these products, and an aim of this session is to introduce examples to illustrate how a product-specific paradigm needs to be developed for the quality attributes of such a product. Key CMC concerns will be addressed from the concept stage through preclinical and clinical development to approval. The approach in this session will be international, comparing requirements in the US, the EU, and elsewhere.

GRNOPC1: A Human Embryonic Stem Cell-derived Product, in a Phase 1 Trial in Patients with Neurologically Complete, Subacute, Spinal Cord Injury
Alice M. Varga, MA, MS
Vice President, Regulatory Affairs/Quality Systems, Geron Corporation

FDA Incentives for Developing Products for Rare Diseases
Mathew T. Thomas, MD
Health Science Administrator, Office of Orphan Products Development, Office of Science and Health Coordination, Office of the Commissioner, FDA

EMEA Perspective
Agnès Saint-Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use Unit, European Medicines Agency, European Union

Session 364 CDM - Clinical Data Management, CP

1:30 pm-3:00 pm LEVEL: ■

Room 11B

WHO Drug Dictionary Utilization

SESSION CHAIRPERSON(S)

Branislav Bradic, MD
Manager, Drug Safety Surveillance, PSI INTERNATIONAL, Inc.

This session presents the best practices and common challenges in applying the WHO Drug Dictionaries in coding of concomitant medications, and later in the analysis processes. The session starts with an overview of the WHO Drug Dictionaries, followed by one organization's specific approach to WHO-DD implementation, and ends with a presentation of the UMC perspective.

WHO Drug Dictionary Overview
Mark Vieder, MBA, RPh, PMP
Manager, AERPS-FDA Coding/QC/QA, PSI INTERNATIONAL, Inc.

Organization's Specific Approach to WHO Drug Dictionary Utilization
Christianne Minkiewitz
Global Safety Manager, Amgen Inc.

Vigibase Data Mining
Niklas Noren, PhD, MS
Senior Statistician, Uppsala Monitoring Centre/WHO, Sweden

Session 365 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

1:30 pm-3:00 pm LEVEL: ●

Room 17A MEZZ.

Considerations Applicable to the Drug Development Phase

SESSION CHAIRPERSON(S)

Steven Wolfgang, PhD
Chemist, Office of Compliance, Division of Manufacturing and Product Quality, CDER, FDA

How well a drug manufacturer ultimately assures patient safety is determined at various stages of the product life cycle. Thus, quality management is a continual process, spanning the entire product life cycle starting with product development. This session aims to point out the ways in which patient safety is positively affected by the approaches taken during the drug development phase and address challenges to assurance of patient safety associated with the current trend toward globalized drug manufacturing.

Good Manufacturing Practices during the IND Phase
Monica E. Caphart, MS
Consumer Safety Officer, Office of Compliance, Division of Manufacturing and Product Quality, CDER, FDA

Managing Quality of Outsourced Products and Services
Kenneth Drost, MS
Executive Director, Quality, Amgen Inc.

Session 366 CP - Clinical Safety and Pharmacovigilance, RA

1:30 pm-3:00 pm LEVEL: ■

Room 30AB

Quantitative Benefit-risk Profile Evaluation Methods: Which to Use?

SESSION CHAIRPERSON(S)

William C. Maier, PhD, MPH
Director, MAPI-EPI, UK

The importance of an in-depth understanding of the benefit-risk profile medication to aid in making decisions about the public health value of a medicine has been emphasized in guidance documents by both the FDA and the EMEA. Currently, benefit-risk profile estimation is based primarily on a qualitative assessment of available information on products. However, assessment may be improved through the additional application of methods which quantitatively compare the benefits and risks of different medications. This session will review the strengths and limitations of different methods to quantitatively determine the benefit-risk profile of a medication.

Quantitative Methods for Benefit-risk Characterization
Brian A. Millen, PhD, MS
Principal Research Scientist, Eli Lilly and Company

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

Session 367 CR/CS 1 - Clinical Research and Development/Clinical Supplies, AHC/IS

1:30 pm-3:00 pm LEVEL: ■

Room 3 *Pharmacy credits offered*

Clinical Trials and Tribulations: Influences and Challenges of Patient Recruitment and Retention Including Perspectives from Participants, Families, and Research Study Organizers

SESSION CHAIRPERSON(S)

Tammy J. Massie, PhD, MS
Mathematical Statistician, Office of Biostatistics and Epidemiology, Vaccine Evaluation Branch, CBER, FDA

A bit disappointed in not meeting recruitment goals or experiencing excessive dropouts in your clinical studies? These 90 minutes could provide you with some hints, tips, and techniques to successfully recruit and retain subjects in your clinical studies. The primary goal of this session is to identify successful strategies to maximize recruitment and retention of subjects while minimizing missing values and loss to follow-up in clinical studies. The speakers will discuss various aspects of organizing and implementing a successful clinical study, including an amusing and humorous presentation on several clinical study experiences from a participant's perspective, how participating in a clinical study can effect family members, and observations from the sponsor perspective on how feasibility and planning can improve recruitment and retention. This session will assist those who create and implement clinical studies to improve how clinical studies are executed in the future.

Patient Recruitment and Retention: Perspective from a Patient Patient
Tammy J. Massie, PhD, MS
Mathematical Statistician, Office of Biostatistics and Epidemiology, Vaccine Evaluation Branch, CBER, FDA

Patient Recruitment and Retention: Tips and Techniques of Effective Strategies
Katherine Valentine
Senior Manager, Clinical Trial Management, Genentech, Inc.

Session 368 CR/CS 2 - Clinical Research and Development/Clinical Supplies, RA

1:30 pm-3:00 pm LEVEL: ■

Room 6C *CME and Nursing credits offered*

Multiregional Clinical Trials

SESSION CHAIRPERSON(S)

Ekopimo O. Ibia, MD, MPH, FRCP
Director, Global Medical and Regulatory Policy, Merck Research Laboratories

The conduct of multiregional clinical trials (MRCT) to generate acceptable data for regulatory decision making presents significant challenges for industry and regulators. Such challenges must be effectively addressed. This session builds on the discussions at the FDA/PhRMA meeting on the "Challenges and Opportunities of Multiregional Clinical Trials" held in October 2007 in Maryland with updates on ongoing efforts by the PhRMA MRCT Working Group and others.

Lessons Learned from Doing Large Multinational Clinical Trials
Diego Martin Glancszpigel, MBA
Vice President, Latin America, PAREXEL, Argentina

The Challenges of Data Quality and Standardization in Multiregional Clinical Trials (MRCTs)
Andrew Lee, MA
Vice President, Clinical Project Management and Clinical Quality Management, Pfizer Global R&D

Data Quality in MRCT: A Regulatory Perspective on Issues
H. M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Session 369 CR/CS 3 - Clinical Research and Development/Clinical Supplies, BT

1:30 pm-3:00 pm LEVEL: ■

Room 6D *CME, Nursing, and Pharmacy credits offered*

Early-phase Clinical Trials: Confronting the Guinea-pigging Misconception

SESSION CHAIRPERSON(S)

Jack Corman
President, IRB Services, Canada

Thousands of compounds from generics, biosimilars, and novel drugs and biologic agents await early-phase (phase 1) testing in humans. Highly publicized tragic events in a time when the entire industry is under siege for alleged wrongdoing have attracted substantial criticism of the industry, much of which is unfounded. This session will review steps taken by regulators, sponsors, CROs, and IRBs to ensure safety and fair treatment of subjects in these trials to dispel perceptions of guinea-pigging promulgated by not always well- or fully informed industry critics and the media.

The Regulator's Role and Perspective
Agnes V. Klein, DrPH, MD
Director, Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutic Product, Biologics and Genetic Therapies Directorate, HPFB, Health Canada

Study Design and the CRO/Clinic Role and Perspective
Edward M. Sellers, MD, PhD, FRCPC
General Manager, Kendle Early Stage, Kendle International Inc., Canada

The Clinic Staff Perspective and Role of the Sponsor Monitor
Valerie Willetts, BSN, RN
President and CEO, ASKA Research, a Division of Valerie Willetts & Associates Inc., Canada

Session 370 CR/CS 4 - Clinical Research and Development/Clinical Supplies, GCP

1:30 pm-3:00 pm LEVEL: ■

Room 5B

The Keys to Establishing Best Practices for Accelerated Study Start-up

SESSION CHAIRPERSON(S)

Tim Dietlin, MBA
Vice President, Clinical Development Practice, Campbell Alliance Inc.

The speed of clinical study start-up affects the entire timeline of a clinical trial, and the study team has one shot at getting it right. Mistakes at start-up can slow patient recruitment and lengthen the time to study completion. Overall success or failure is typically determined well before start-up – during protocol development and start-up preparation – so proper planning and management are critical. There are a wide range of activities involved in study start-up, and there are numerous ways to go about it. Even though each organization and study have unique requirements, companies can still leverage some key best practices to ensure that each study is launched as efficiently as possible.

A Discussion of Best Practices in Study Startup
Tim Dietlin, MBA
Vice President, Clinical Development Practice, Campbell Alliance Inc.

The Importance of Cross-functional Processes in Effective Study Startup
Kelly R. Vaillant
Vice President, Clinical Operations, Ambit Biosciences Company

Site Activation: How to Get beyond the Classic Pitfalls
Heather Almonte, MBA, RAC
Senior Manager, Site Activation Services, Covance Inc.

Session 371 EC - eClinical, ERS/DM

1:30 pm-3:00 pm LEVEL: ●

Room 15A MEZZ.

Views of the CDISC Standards in a Submission

SESSION CHAIRPERSON(S)

Cathleen F. Barrows, PhD
Statistics and Programming, Neurosciences MDC, GlaxoSmithKline

This session will present three views of CDISC-relevant components of a submission (SDTM datasets, analysis datasets, metadata, Define), including aspects that are of particular benefit to FDA statistical reviewers. The first view will focus on what a company should consider when planning a CDISC-compliant submission that will include legacy studies. Management of meta-data, ways to maintain a solid relationship between SDTM and ADaM, and developing a plan for the content of the ISS and ISE will be considered. The second view will focus on specific aspects of the submission and how it all gets pulled together into a cohesive whole. Views of the metadata and how metadata is incorporated in the submission will be discussed. The third view will be from the perspective of a reviewer using the submission to evaluate a new drug and will include the reviewer's views of why using the CDISC standards is important and what impact they have on the review of a submission.

Beginning with the Old and the End in Mind: Planning for a CDISC-compliant Submission in Advance
Dana J. Soloff, MS
Director, Statistical Programming, Biomedical Operations, Genzyme Corporation

A CDISC-compliant Submission: An SDTM - ADaM Implementation Case Study
Stephen Hamburg
Senior Programmer/Analyst, Biometrics, Omnicare Clinical Research

An FDA Reviewer's Perspective on What Makes a CDISC-adherent Submission Special
Mat Soukup, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Session 372 ERS/DM - Electronic Regulatory Submissions/Document Management, IT

1:30 pm-3:00 pm LEVEL: ●

Room 9

International eCTDs: An Update on Regulatory Authority Experience

SESSION CHAIRPERSON(S)

Mary L. Collins
Senior Director, Regulatory and Industry Relations, Image Solutions Inc. (ISI)

Regulatory authority representatives will provide an overview, status of acceptance, review, and approval of electronic regulatory submissions in this session. Topics will include accepted electronic submission formats, experience to date, and the challenges and opportunities that are recognized as we progress towards a global electronic environment.

FDA Perspective
Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

EMEA Perspective
Timothy Buxton
Head of Sector, Project Management, Communications and Networking Unit, European Medicines Agency, European Union

EU Update
Rob de Haan, PhD
Deputy Director, CBG-MEB, Netherlands

Session 373 GCP - Good Clinical Practices, VA

1:30 pm-3:00 pm LEVEL: ●

Room 30CD

Town Meeting: Good Auditing Practices – Internal Audits, External Audits, and the Audit Report

SESSION CHAIRPERSON(S)

Teri E. Stokes, PhD, MS, MT
Director, GXP International

This session will use an experienced panel to set the scene for audience discussion to explore the many ways in which GCP QA audits are performed and hosted. The panel will discuss what works well and not so well in different audit settings.

Conducting GCP QA Audits Both Internal and External to a Pharma Company in Europe and as an Independent Consultant: Successes and Challenges
Lisbeth Tofte Hemmingsen, DDS
Director, Drug Safety International, Denmark

Conducting QA Audits of Computerized Systems to GCP, ePRO, and Part 11 Requirements for Pharma Companies, CROs, and Systems Suppliers: Successes and Challenges
Teri E. Stokes, PhD, MS, MT
Director, GXP International

Managing the QA Audit Process for GCP Compliance: Successes and Challenges
Michael Owings
Vice President, Quality and Regulatory Compliance, Phase Forward

Session 374 IT - Information Technology, CDM

1:30 pm-3:00 pm LEVEL: ■

Room 15B MEZZ.

CDISC SDTM Data Conversion: Reusability and Repeatability

SESSION CHAIRPERSON(S)

Hanming Tu, MS
Director, Clinical Information Technology, Octagon Research Solutions Inc.

This session will discuss CDISC SDTM data model, the process of analyzing, mapping, and transforming raw data sets into SDTM data sets, and how to improve efficiency of data conversion through building reusable programs in different languages and repeatable processes in different types of studies. The methods used to verify the compliance of the final SDTM data sets will also be discussed in this session.

Building Reusability and Repeatability in SDTM Data Conversion through Oracle Warehouse Builder
Hanming Tu, MS
Director, Clinical Information Technology, Octagon Research Solutions Inc.

Benefits of CDISC XML-based Metadata for SDTM Transformation
Claus Lindenau, PhD
Head, Business Development, XClinical GmbH, Germany

SDTM Mapping: Current Technology and Future Directions
Michael J. Todd, MS
President, Nth Analytics

Session 375 MA - Marketing, PP

1:30 pm-3:00 pm LEVEL: ■

Room 33AB

Furthering the Pharmaceutical Industry's Engagement in Electronic Social Media: A Regulatory Roadmap

SESSION CHAIRPERSON(S)

Mark Gaydos
Senior Director, US Regulatory Affairs Marketed Products, sanofi-aventis

This session will focus on understanding and overcoming the regulatory hurdles that have limited the pharmaceutical industry's engagement in online social media. Consumers and physicians increasingly seek health information online, yet industry has yet to fully engage them in this space. Learn how it can be done within current regulations.

DDMAC Perspective on Social Media
Jean-Ah Kang, PharmD
Special Assistant to the Director, Office of Medical Policy, Division of Drug Marketing, Advertising and Communication (DDMAC), CDER, FDA

Social Media and Adverse Event Reporting
Barbara Rullo, MD
Vice President, Drug Safety, sanofi-aventis

Industry Regulatory Considerations for Social Media Participation
Leah Palmer, PharmD
Executive Director, Regulatory Affairs, Amgen Inc.

Session 376 MC - Medical Communications, MA

1:30 pm-3:00 pm LEVEL: ●

Room 14A MEZZ.

Business Continuity Planning within Medical Communications Departments

SESSION CHAIRPERSON(S)

Stacey M. Fung, PharmD
Senior Manager, Medical Communications, Genentech, Inc.

This session will review the key areas to consider when developing a business continuity plan for a medical communications department. Specific examples will be described to develop a business continuity plan and which groups or individuals need to be involved. Lastly, a discussion regarding how to train the department on the business continuity plan will take place.

Business Continuity Planning: Pandemics and "People" Disasters
Robert P. Baker, PharmD
Director, Professional Product Information (PPI), Roche

Business Continuity Planning: Disaster Recovery and Infrastructure Considerations
Mai Tran
Manager, MC Business Systems, Genentech, Inc.

Business Continuity Planning Considerations
Denise A. Dixon
Vice President, Marketing, WRB Communications

Session 377 MW - Medical/Scientific Writing, ERS/DM

1:30 pm-3:00 pm LEVEL: ■

Room 31AB

Authoring CTD/eCTD Submissions: Updates and Case Studies

SESSION CHAIRPERSON(S)

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

This session will present updates and case studies in writing documents for the CTD and eCTD. The presentations will address writing clinical, nonclinical, and chemistry, manufacturing, and control (CMC) sections, focusing on: 1) reviewability, 2) content reuse, 3) granularity and life-cycle management, and 4) effective processes for writing and reviewing eCTD-ready documents.

Global Clinical eCTD Submission Case Studies
David H. Brown, MA, MSc
Associate Director, Medical Communications Science, AstraZeneca Pharmaceuticals LP

Global CMC eCTD Submission Case Studies
Michelle Herrera Foster, PhD
Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

Reviewability Standards for eCTD Content
Peggy Boe, RN
Senior Director, Regulatory Content Services, Image Solutions, Inc.

Panel Discussion and Q&A

Discussant:
Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Director for International Programs, CDER, FDA

Session 378 NC - Nonclinical Laboratory Safety Assessment, CP

1:30 pm-3:00 pm LEVEL: ■

Room 10 *Pharmacy credits offered*

New Approaches to Toxicity Testing to Support Pharmaceutical Development – *Part 2 of 2:* New Models

SESSION CHAIRPERSON(S)

Joseph J. DeGeorge, PhD
Vice President, Safety Assessment, Merck & Co., Inc.

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

This session continues the theme of new approaches to animal toxicology testing to support the safe conduct of clinical trials with the focus on new model systems. Two areas of pharmaceutical safety testing that have seen significant modification over the past decade are new models of cardiac safety pharmacology testing and new models of carcinogenicity testing. Despite the advances made in evaluating the potential of new agents to significantly alter human cardiac electrophysiology, there remain ambiguities in test evaluation and interpretation that are driving additional innovative approaches to early screening. The development and utility of the zebrafish model for screening human QT prolongation potential will be discussed. Evaluations of test compound carcinogenicity potential have seen the introduction of transgenic mouse models over the past decad, but the two-year rat study remains a necessary component. Recent analyses of the predictivity of chronic rat study data for the outcome of the two-year rat carcinogenicity indicates that a large fraction of two-year rat studies might be avoided if chronic rodent studies show no preneoplastic signals, and other criteria are carefully considered. There will also be a panel discussion to debate the presentations of the two linked sessions and weigh the virtues, concerns, and likelihood of the proposed new endpoints and model systems gaining regulatory approval and industry acceptance.

Zebrafish Cardiotoxicity Screening in an Automated Platform Shows High Reproducibility and Good Correlation with Results Observed in Humans
Arantza Muriana, PharmD, MPharm
R&D Management Director, Biobide S.L, Spain

Predictivity of Chronic Toxicity Data for Potential Carcinogenic Risk
Joseph J. DeGeorge, PhD
Vice President, Safety Assessment, Merck & Co., Inc.

Thomas Monticello, DVM, PhD
Worldwide Executive Director, Department of Safety Assessment, Merck & Co., Inc.

Session 379 NHP - Natural Health Products, CP

1:30 pm-3:00 pm LEVEL: ■

Room 17B MEZZ. *Pharmacy credits offered*

Safety before and after Approval of Natural Health Products

SESSION CHAIRPERSON(S)

Pradip K. Paul, MS
Head, Case Medical Evaluation Group/Global Pharmacovigilance and Epidemiology, sanofi-aventis

Drug safety is a rapidly growing area in the pharmaceutical and allied industries. The use of natural health products (NHP) as a dietary or nutritional supplement or herbal remedy is going through revolutionary changes, particularly with new initiatives for obtaining regulatory approvals globally, including the US. This session will focus on safety aspects pre- and postproduct approvals. We will discuss the requirements, monitoring, and best practices of pharmacovigilance. The session will also focus on possible links of drug safety to efficacy and quality.

Evaluating and Monitoring the Safety of Dietary Supplements
Dandapantula N. Sarma, PhD, RPh
Senior Scientist, United States Pharmacopeia

Medical Assessments and Safety Evaluations for Herbal or Borderline Medicinal Products and Medical Devices
Leonardo Ebeling, DrMed, MD, PhD
General Manager, Ebeling and Associates GmbH-Diapharm Partner, Germany

Testing for Safety and Efficacy: Nutritional Supplements and Herbal Remedies
Tom D. Davis, PharmD
Director, Legacy Pharma Research

Session 380 OS - Outsourcing, MC

1:30 pm-3:00 pm LEVEL: ■

Room 5A

Outsourcing Strategies for Clinical Trial Activities in Central and Latin America

SESSION CHAIRPERSON(S)

Peter D. Feldman, PhD
Scientific Communications Consultant, Eli Lilly and Company

This session will discuss the strategic outsourcing of clinical trial activities to Central America, as well as the benefits and challenges of outsourcing to these areas, with an emphasis on medical writing services. Key to successful outsourcing partnerships are relationship building, clear mutual expectations, and open communication. Successful vendors provide cost-effective resources that meet the constantly changing and complex business demands of the pharmaceutical industry. Ultimately, one of the primary benefits of strategic outsourcing, cost reduction, will be realized. Unique perspectives and lessons learned, drawing from successful Central American outsourcing partnerships, will be shared.

Strategic Outsourcing of Clinical Trial Publications between Pharma and Central America: The Client Perspective
Peter D. Feldman, PhD
Scientific Communications Consultant, Eli Lilly and Company

Strategic Outsourcing of Clinical Trial Publications between Pharma and Central America: A Vendor Perspective
Goy E. Navas, PhD
CEO and CSO, PRIMO Scientific Corporation, Panama

Session 381 PM/FI - Project Management/ Finance, CR/CS

1:30 pm-3:00 pm LEVEL: ●

Room 2 *Project Management units offered*

Project Management Plenary Session
Future Directions of Project Management in the Life Sciences

SESSION CHAIRPERSON(S)

Sandra J. Zeckel, RPh, PMP
COO, Oncology Transition Team, Eli Lilly and Company

There are many challenges confronting the life sciences industry today. High-quality management of research and development is critical to the future of the entire industry. While the cost of drug research continues to increase and regulatory requirements become more stringent, the health-care system can no longer pay for the resulting increase in cost. Project management must play a central role as this industry transforms to meet these challenges. Based on the results of a survey recently completed to investigate best project management practices in R&D drug development, a perspective will be provided on how project management can meet these challenges, and provide huge competitive advantage to companies willing to embrace the cultural and process changes required.

Jann A. Nielsen, PhD
Senior Director, Project Management, Wyeth Research

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

Jean A. Yager, PhD
Director, Clinical Development and Medical Affairs, Pfizer Inc

Session 382 PP - Public Policy/Law, RA

1:30 pm-3:00 pm LEVEL: ■

Room 32AB

Pharmacovigilance and Product Liability

SESSION CHAIRPERSON(S)

John A. Lisman, LLM, MPharm
Lawyer, NautaDutilh N.V., Netherlands

Safety is the most important aspect of any drug marketed, everywhere in the world. Adverse events and the way they are reported to the authorities are not only important from a regulatory point of view, but are also an important aspect of judicial assessments related to (product) liability. Interestingly, both pharmacovigilance and the influence adverse event reports could have on legal claims have been regulated differently in the US and the EU. This session will compare the regulatory systems dealing with adverse event reporting, as well as the consequences regulatory decisions could have for litigation, both in the EU and in the US.

US Perspective: AE Reporting Requirements
Ann Begley, BSN, JD
Partner, K&L Gates, LLP

Impact of Pharmacovigilance in US Litigation
Paul W. Schmidt, JD
Partner, Pharmaceutical Litigation and Investigations, Covington & Burling LLP

EU Perspective: ADR Reporting and Litigation
Stijn Franken, LLM
Partner, NautaDutilh N.V., Netherlands

Session 383 RA 1 - Regulatory Affairs, CR/CS

1:30 pm-3:00 pm LEVEL: ●

Room 6E *Pharmacy credits offered*

FDA Meetings: Understanding the Process and Maximizing Success

SESSION CHAIRPERSON(S)

Andrea C. Masciale, JD
Senior Director, Regulatory Affairs, Johnson & Johnson Pharmaceuticals Group

This session will describe the complex issues involved in key FDA meetings, including discussions of the 312 and 314 regulations, current guidance and up-to-date information on evolving CDER operational policies for meetings.

The Pre-IND Meeting: Understanding the Worth and Optimizing the Value
LaVonne L. Lang, DrPH, MPH, RN
Senior Director, Regulatory Affairs, United BioSource Corporation

FDA Perspective on Optimizing Meetings
Leah A. Christi, PhD
Associate Director, Regulatory Affairs, Office of Nonprescription Products, CDER, FDA

Session 384 RA 2 - Regulatory Affairs, AD

1:30 pm-3:00 pm LEVEL: ●

Room 7B

Connect the Dots: The Map from Labeling Development to Marketing Claim

SESSION CHAIRPERSON(S)

Tracie A. Parker, MS
Director, Regulatory Affairs, RPS (ReSearch Pharmaceutical Services, Inc)

This session will describe the evolution and application of drug advertising regulation and will discuss the challenges involved with developing a target product label focusing on claims contained in the product labeling that are then used in product advertising and promotional pieces.

The Evolution of Drug Advertising Regulation
Tracie A. Parker, MS
Director, Regulatory Affairs, RPS (ReSearch Pharmaceutical Services, Inc)

Target Label Development
Pamela Swiggard, MS
Director, Project Management, Endo Pharmaceuticals

Application of Drug Product Advertising Regulations
Franklin Vairinhos, PhD
Director, Regulatory Affairs, Cephalon Inc.

Session 385 RA 3 - Regulatory Affairs, PP

1:30 pm-3:00 pm LEVEL: ●

Room 6F

US-EU-Japan: Exchange of Information among Regulators from ICH Regions

SESSION CHAIRPERSON(S)

Marie A. Dray, MBA
President, International Regulatory Affairs Group LLC

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

An update on the exchange of regulatory and public health information among regulators from ICH regions – US FDA, European EMEA, and Japanese PMDA. Although this session has been an annual event including dialogue between senior regulators of the US FDA and European Medicines Agency, this year's conversation will include a representative from the Japanese PMDA.

Perspective from the FDA
Murray M. Lumpkin, MD
Deputy Commissioner, International and Special Programs, Office of the Commissioner, FDA

Perspective from the EMEA
Thomas Lönngren, Pharm, MSc
Executive Director, European Medicines Agency, European Union

Perspective from the PMDA
Akira Kawahara, MS
Senior Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 386 RA 4 - Regulatory Affairs, RD

1:30 pm-3:00 pm LEVEL: ■

Room 8

Measuring Benefit and Balancing Risk: Strategies for the Benefit-risk Assessment of New Medicines in a Risk-averse Environment

SESSION CHAIRPERSON(S)

Stuart Walker, PhD
Founder, CMR International Institute for Regulatory Science, UK

Measuring the benefits and risks of medicines is the underlying theme whenever the development, review, and regulation of new medicines are discussed. Over the last five years the environment for developing new medicines has become increasingly risk averse. Agencies and companies are each developing their own viewpoint on what are appropriate frameworks for assessing benefit-risk. There is a need to encourage an environment in which a more balanced view of risks and benefits is taken. Important progress has been made in the methods used to assess benefit-risk in the development and review of new medicines, but there is a great deal yet to be achieved.

In this session, the views of companies and agencies on a framework for benefit-risk will be presented as well as the current status from an agency and company perspective on the current activity in developing a benefit-risk framework, what value parameters are being utilized, how the information can be used to manage risk, and how can agencies and companies share best practice will be explored.

Current Approaches and the Way Forward for Developing a Benefit-risk Framework: An Industry Perspective
Patrizia Cavazzoni, MD
Group Medical Director, Surveillance and Epidemiology, Eli Lilly and Company

Recent Initiatives within the FDA for Development of a Benefit-risk Framework for the Review of Medicines
Theresa M. Mullin, PhD
Associate Director, Office of Planning and Informatics, CDER, FDA

Recent Initiatives within the CHMP for Development of a Benefit-risk Framework for the Review of Medicines
Bruno Flamion, MD, PhD
Chair, Scientific Advice Working Party, CHMP; Professor, Clinical Pharmacology, University of Namur, Belgium

Session 387 RA 5 - Regulatory Affairs, GCP

1:30 pm-3:00 pm LEVEL: ●

Room 4

International Cooperation on GMP/GCP Inspections

SESSION CHAIRPERSON(S)

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

FDA and EMEA have embarked on several collaborative projects in the inspections area. A pilot project on inspections of APIs was launched in 2008, and a pilot project on joint GMP inspections of finished products has also been initiated; one such inspection has already taken place. Discussions on greater collaboration on GCP inspections are also ongoing. In this session you will learn about the status of these initiatives and the rationale behind increasing transatlantic collaboration in this area.

FDA Perspective
Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

EMEA Perspective
Fergus Sweeney, PhD
Head of Inspections Sector, European Medicines Agency, European Union

Industry Case Study
Georges L. France, PharmD
Vice President, Quality and Compliance Europe, EFPIA Topic Leader ICH Quality, IWG, Wyeth Europa Limited, UK

Panelist
David J. Cockburn
Principal Scientific Administrator, Inspections Sector, European Medicines Agency, European Union

Session 388 RA 6 - Regulatory Affairs, CR/CS

1:30 pm-3:00 pm LEVEL: ●

Room 7A

Global Clinical Trials: Destination India

SESSION CHAIRPERSON(S)

Vijay Kumar Topa, MSc
Advisor to the Secretary General, Federation of Indian Chambers of Commerce and Industry (FICCI), India

This session will provide a broad update and the evolving changes and recent advancements in addressing the scientific, regulatory, and ethical issues of clinical trials in India. It will also address some of the practical experiences of clinical trial conduct in India and how the Indian clinical research industry is coming together with academia and the government through public-private partnerships to address the growing demands of global drug development needs in India. The session will draw on the experiences of industry, academic centers, and the government in meeting these demands and explore ways to further facilitate their efforts.

Advantage India: Pharmaceutical Innovation Hub and Clinical Trials
Devendra Chaudhary
Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

Clinical Research and Trials in India: Prospects and Challenges
T. S. Rao
Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India

Vasudeo Ginde, MD
Chief Executive Officer, DiagnoSearch Life Sciences Pvt Ltd., India

Session 389 RD - R&D Strategy, ST

1:30 pm-3:00 pm LEVEL: ■

Room 14B MEZZ.

Use of Metrics for R&D Strategizing: Building a Success Matrix

SESSION CHAIRPERSON(S)

Christopher P. Milne, DVM, JD, MPH
Associate Director, Tufts Center for the Study of Drug Development, Tufts University

The R&D environment is changing, and so are the metrics. There are not only new metrics, but new ways of using them.

The Big Picture: Trends in New Drug Development and Regulatory Approval Macrometrics
Joseph A. DiMasi, PhD
Director, Economic Analysis, Tufts University

Portfolio Decision-making: Building Predictability into the Development of New Medicines
Jane A. Sharples, PhD, MBA
General Manager, CMR International, UK

Using Metrics to Understand the Downstream Execution Effects of Upstream Clinical Design Decision
Edward Stephen Seguine, Jr., MBA
President, Gordian Technology

Session 390 ST - Statistics, CR/CS

1:30 pm-3:00 pm LEVEL: ■

Room 16A MEZZ. *CME credits offered*

Biomarkers in Oncology Trials

SESSION CHAIRPERSON(S)

Aloka G. Chakravarty, PhD
Director, Division of Biometrics V, CDER, FDA

The use of biomarkers in oncology trials can improve efficiency of a drug development program. Issues related to the use of biomarkers and practical insights gained from oncology trials will be discussed with practical case examples.

Biomarkers in Oncology: A Regulatory Perspective
Rajeshwari Sridhara, PhD
Deputy Director, Office of Biostatistics, CBER, FDA

Clinical Considerations for a Biomarker in Oncology Drugs
Kaushikkumar Shastri, MD
Medical Officer, Office of Oncology Drug Products, Division of Biologic Oncology Products, CDER, FDA

Biomarkers: Focused Statistical Analysis Plans for Co-development of Drugs and Diagnostics
Richard M. Simon, DrSc, PhD
Chief, Biometric Research Branch, National Cancer Institute, National Institutes of Health

Panelist
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics/Pharmacogenetics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Session 391 TR/PD - Training/Professional Development, PM/FI

1:30 pm-3:00 pm LEVEL: ■

Room 16B MEZZ.

How Do We Train Our Project Managers to Be Leaders Regardless of Formal Status?

SESSION CHAIRPERSON(S)

Eric M. Towler, PhD, PMP
Director, Global Project Management and Leadership, Daiichi Sankyo Inc.

This session will discuss the importance of leadership on a project team, how to recognize potential leaders and how to train them for future roles. An open discussion will follow.

Installation of a Leadership Training Program for Project Managers/ Leaders
Jonathan B. Zung, PhD
Vice President, Bristol-Myers Squibb

Recognizing the Potential Leaders
Sean Morgan-Jones. Esq., MBA
Director, PharmaTimes, UK

Factor to Consider in Designing a Leadership Program
Jennie R. Platt
Director, Training, RPS (ReSearch Pharmaceutical Services, Inc)

Session 392 VA - Validation, IT

1:30 pm-3:00 pm LEVEL: ■

Room 11A

Compliance in the Age of Automatic Updates and Virtualization

SESSION CHAIRPERSON(S)

Pamela Campbell, MBA
Senior Consultant, EMC Consulting

With the propagation of desktops, mobile devices, automatic updates, and virtualization information technology is no longer able to map an application to a box. This session examines how pharmaceutical companies and CROs meet the challenge of maintaining control and compliance in this complex environment.

Managing Desktop Change at a Large CRO
Pamela Campbell, MBA
Senior Consultant, EMC Consulting

Change Management within the Client Environment
Skip Garrison
Quality Assurance, Informatics, Forest Laboratories Inc.

Regulatory Compliance in a Virtual Environment
Martin Browning, MA, MS
President, EduQuest, Inc.

3:00 pm-3:30 pm **REFRESHMENT BREAK**
Exhibit Halls B1, B2, C, Ground Level
(See SDCC Map for exact locations.)

Session 393 AHC/IS 1 - Academic Health Centers/ Investigator Sites, CR/CS

3:30 pm-5:00 pm LEVEL: ■

Room 1A

Nurture the Clinical Trial Leader of Tomorrow

SESSION CHAIRPERSON(S)

Herng-Der Chern, MD, PharmD, PhD
Executive Director, Center for Drug Evaluation, Taiwan

A well-designed and well-performed pivotal trial is a cornerstone in fulfilling the regulatory requirements of efficacy and safety for new drug approval. Many physicians can do a good GCP quality trial, but not many can design or lead a clinical trial team. To address this, many academic centers and drug industries have identified the need for a proactive design program to nurture the clinical trial leaders of tomorrow. For example, the government of Taiwan has set up four Centers of Excellence for clinical trials in medical centers. Many promising young physicians choosing clinical research as their career can apply for fellowship training in the prestigious clinical trial facilities, with their time and salary protected. A concept of a virtual clinical trial academy was proposed by the National Taiwan University Hospital.

In cooperation with experienced high-caliber speakers from industry, academia, and the local regulatory agency, promising young physicians will be trained in a series of practical and inspirational small group workshops. Topics will include how to interact with others in the international investigator meeting, how to write PI-initiated clinical trial protocol, the concept of new drug development from the perspective of industry, and hands-on experience in the IRB review for IND. Six physicians were trained in a three-month fellowship in the Center for Drug Evaluation in Taiwan with hands-on experience in IND reviewing under the supervision of senior clinical reviewers. These long-term investments in human resources have been well reflected in the NIH clinical trial registry. Other than Australia, Taiwan has championed in the number of PI-initiated clinical trials in Asia. We will review similar approaches in countries such as the US, Japan, and Korea.

Clinical Trial Leadership in Global Drug Development
H. M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Nurture the Clinical Trial Leaders of Tomorrow: Viewpoint from an Academic Medical Center
Wing-Kai Chan, DrMed
Director, National Clinical Trial and Research Center, National Taiwan University Hospital, Taiwan

Strategic National Program in Nurturing the Clinical Trial Leaders in Asia
Herng-Der Chern, MD, PharmD, PhD
Executive Director, Center for Drug Evaluation, Taiwan

Session 394 AHC/IS 2 - Academic Health Centers/ Investigator Sites, EC

3:30 pm-5:00 pm LEVEL: ■

Room 6C

Addressing Suicidality in Clinical Trials

SESSION CHAIRPERSON(S)

John H. Greist, MD
Director, Healthcare Technology Systems Inc.

Topics to be covered in this session include: 1) FDA safety concerns and regulatory requirements regarding suicidality assessments, 2) the Columbia Suicide Severity Rating Scale (C-SSRS) and Columbia Classification Algorithm of Suicide Assessment (C-CASA), 3) computer-automated suicide assessment systems for monitoring patients participating in clinical trials, and 4) research experiences in using such automated systems in federally funded studies such as the Sequenced Treatment Alternatives to Relieve Depression (STAR*D).

CNS at FDA: FDA Safety Concerns and Regulatory Requirements
Gwen L. Zornberg, DrSc, MD, MS
Team Leader, Division of Psychiatry Products, Office of New Drugs, CDER, FDA

Clinical Skills and Training for Accurately Assessing Suicidality
Kelly Posner, PhD
Associate Clinical Professor, Columbia University

Lessons from Research: Automated Telephone Assessments of Suicide in Patients – STAR*D and Other Experiences
James Mundt, PhD
Vice President, Research and Development, Healthcare Technology Systems Inc.

Session 395 BT - Biotechnology, NC

3:30 pm-5:00 pm LEVEL: ■

Room 1B

RNAi Therapeutics: From Concept to Implementation

SESSION CHAIRPERSON(S)

Dmitry Samarsky, PhD
Vice President, Technology Development, RXi Pharmaceuticals

RNAi is a naturally occurring phenomenon where short double-stranded RNA molecules interfere with the expression of targeted genes. RNAi technology takes advantage of this phenomenon and potentially allows it to effectively interfere with particular genes within living cells. RNAi offers a novel approach to the drug development process because RNAi compounds can potentially be designed to target any one of the thousands of human genes. The specificity of RNAi is achieved by an intrinsic biological mechanism based on designing the sequence of an RNAi compound to match the sequence of the targeted gene. The specificity of RNAi may be sufficient to permit therapeutic targeting of only a single gene and, importantly, may even selectively destroy expression from a single abnormal copy of a gene while preserving expression from a normal copy (allele-specific targeting).

Oligonucleotide Therapeutics: Antisense, RNAi and Beyond
Arthur M. Krieg, MD
CSO, Research Technology Center, Pfizer Inc

Locked Nucleic Acids (LNA): Delivering on the Promise of RNAi Therapy
Henrik Ørum, PhD
Vice President and CSO, Santaris Pharma A/S, Denmark

Development of the Novel RNAi Therapeutic Platform and Programs
Dmitry Samarsky, PhD
Vice President, Technology Development, RXi Pharmaceuticals

Session 396 CDM - Clinical Data Management, EC

3:30 pm-5:00 pm LEVEL: ■

Room 11B

Mega Trials: Planning, Design, Development, Monitoring, and Overall Management

SESSION CHAIRPERSON(S)

Patrick J. Burns, MHA, MS
Project Manager, Phase Forward

Pharmaceutical companies are experiencing a rise in the number of mega trials – global studies with sites numbering in the tens of thousands and subjects in the hundreds of thousands. Speakers will impart first-hand experiences with the considerations for deployment of these mega trials and the challenges of monitoring, reporting, change management, and ongoing administration.

Selina Sibbald, RN
Director, Global EDC, Quintiles, Inc., UK

Thurman Hamlet, MBA
Business Consultant, Worldwide EDC Solutions Group, PAREXEL International

Session 397 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, CP

3:30 pm-5:00 pm LEVEL: ●

Room 17A MEZZ.

Considerations Applicable to the Drug Manufacturing/ Marketing Phase

SESSION CHAIRPERSON(S)

Steven Wolfgang, PhD
Chemist, Office of Compliance, Division of Manufacturing and Product Quality, CDER, FDA

How well a drug manufacturer ultimately assures patient safety is determined at various stages of the product life cycle. Thus, quality management is a continual process, spanning the entire product life cycle starting with product development. This session aims to point out the ways in which patient safety is positively affected by the approaches taken during the manufacturing/ marketing phase and address challenges to assurance of patient safety associated with the current trend toward globalized drug manufacturing.

Postmarketing Assessment: Making the Connection between Product Quality and Patient Safety
Jason Woo, MD
Associate Director, Medical and Scientific Affairs, Office of Compliance, CDER, FDA

Root Cause Analysis of Drug Recalls
Karen Hirshfield, RPh
Director, Regulatory, Office of Compliance, CDER, FDA

International Cooperation on Inspections
David J. Cockburn, Esq.
Principal Scientific Administrator, Inspections Sector, European Medicines Agency, European Union

Session 398 CP 1 - Clinical Safety and Pharmacovigilance

3:30 pm-5:00 pm LEVEL: ■

Room 30AB *CME and Nursing credits offered*

Observational Pharmacovigilance: Analysis Methods and Business Practices across Drug Safety Stakeholders

SESSION CHAIRPERSON(S)

Patrick Ryan, MS
Statistical and Quantitative Sciences, GlaxoSmithKline

Electronic health records and insurance claims databases offer the potential to explore the utilization and effects of medicines within large populations. In the context of pharmacovigilance, observational data can contribute to the preponderance of the evidence used to enable the timely identification and evaluation of potential safety concerns of marketed pharmaceutical products. This session will explore various stakeholder perspectives on applying observational data to supplement current pharmacovigilance activities.

MHRA Perspective
John Parkinson, Esq., PhD
Director, General Practice Research Database Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Incorporating Observational Data into Everyday Pharmacovigilance Practices
Gregory E. Powell, PharmD, MBA
Manager, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Using Observational Data within a Managed Care Setting for Drug Safety Purposes
T. Craig Cheetham, PharmD, MS
Pharmacist, Pharmacy Analytical Service, Kaiser Permanente

Session 399A CP 2 - Clinical Safety and Pharmacovigilance, RA

3:30 pm-5:00 pm LEVEL: ■

Room 33AB

Recent Advancement of Risk Management in the Asian Pacific Region

SESSION CHAIRPERSON(S)

Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Risk management has become one of the focal points with the advance of biotechnology and medicine. The nations in the Asian Pacific region such as China, Japan, Korea, and Taiwan have increasingly paid attention to this emerging issue in addition to the existing measures such as a drug relief fund. This also led to a trend in regulatory consideration of ADR reporting and related risk management measures in early stages during development of novel medicine. This session will be devoted to the discussion and comparison of recent advancement of risk management in the Asian Pacific region.

Overview of Risk Management Scheme in Taiwan
Li-Ling Liu
Deputy Director-General, Bureau of Pharmaceutical Affairs, Department of Health, Taiwan

Incorporation of Risk Management in the Australian Review Process
Leonie Hunt, MD, MBA
Head, Office of Prescription Medicines, Therapeutic Goods Administration, Australia

Recent Advancement of Risk Management in Japan
Junko Sato, PhD
Review Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The Development and Implementation of a Core Risk Management Plan
Judith M. Sills, PharmD
Vice President, Medical Safety Operations, Novartis Pharmaceuticals Corporation

Session 399B CR/CS 1 - Clinical Research and Development/Clinical Supplies, AHC/IS

3:30 pm-5:00 pm LEVEL: ■

Room 3 *Nursing credits offered*

Improving Patient Recruitment and Retention Planning: Global Perspectives on What Sites Need from Sponsors and CROs

SESSION CHAIRPERSON(S)

Beth D. Harper, MBA
President, Clinical Performance Partners Inc.

Each year the biopharmaceutical industry invests more and more in patient recruitment services to overcome the chronic enrollment delays that plague the clinical trials process. Sponsors, CROs, and recruitment vendors all struggle with finding the most cost-effective and efficient way to support sites in their recruitment efforts. The globalization of trials and the fact that one size does not fit all when it comes to patient recruitment and retention support further compounds the challenge.

This session will present the results of a large voice-of-the-customer survey that highlights perspectives from investigators and research coordinators in over 30 countries. Their unique yet practical requests and priorities provide a great opportunity for sponsors and CROs to enhance their upfront recruitment and retention planning discussions and activities. Bridging the gap between site needs and current practices will ensure more successful and effective implementation of patient recruitment and retention support programs.

Results of a Global Site Survey and the CRO Perspective
Janet Jones, PhD
Senior Director, Patient Recruitment and Feasibility, ICON Clinical Research, France

Site Perspective: What Sites Need for Successful Recruitment Planning
Lisa M. Pazdur, BSN
Nurse Practitioner, Study Coordinator, Medical Specialists Clinical Research Center

Sponsor Perspective: Supporting Global Sites through Multiple Approaches
Peter A. DiBiaso, MHA
Senior Clinical Operations Director, Shire Pharmaceuticals

Session 399C CR/CS 2 - Clinical Research and Development/Clinical Supplies, PM/FI

3:30 pm-5:00 pm LEVEL: ■

Room 6D

Cost Containment: Strategies for Efficient Clinical Research Practices

SESSION CHAIRPERSON(S)

Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group Inc.

In turbulent times, it seems that containing costs sometimes becomes just one more imagined insult to hard-working teams engaged in difficult, high-pressure, high-stakes work; however, the deep well has seemed to dry up, and it is now one more hurdle on the drug development highway. This session will look at this topic from several perspectives to offer insights into how multiple companies have addressed the issue without radical changes such as layoffs and divestitures.

Cost Containment Strategies Utilized throughout the Industry
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group Inc.

Implementing Site Management Strategies to Maximize Efficiencies and Reduce Total Trial Costs
Eric L. Eisenstein, PhD
Assistant Professor in Medicine, Duke Clinical Research Institute

Effective Contingency Planning to Improve Outcomes and Minimize Costs
David F. Fenske
Global Head of Outsourcing and Clinical Trial Budget Management, Novartis Oncology

Session 399D CR/CS 3 - Clinical Research and Development/Clinical Supplies, ST

3:30 pm-5:00 pm LEVEL: ■

Room 5B *Pharmacy credits offered*

High-impact Quality Protocols

SESSION CHAIRPERSON(S)

Anne B. Cropp, PharmD
Executive Director, Global Research and Development, Pfizer Inc

This session will focus on several aspects of high-performance protocol design. All protocols need to balance a multitude of demands: scientific questions, regulatory requirements, ethics committees, operational delivery, and commercial drivers. How is protocol quality defined and how much is poor site performance a reflection of inadequate protocol design? This session will also examine the downstream impact of protocol amendments.

Protocol Development: Three Keys to Faster, Better Protocols
Gary Tyson
Senior Vice President, Clinical Development Practice, Campbell Alliance Inc.

High Performance Protocol Design
Anne B. Cropp, PharmD
Executive Director, Global Research and Development, Pfizer Inc

The Downstream Impact of Suboptimal Protocols
Edward Stephen Seguine, Jr., MBA
President, Gordian Technology

Session 399E EC - eClinical, IT

3:30 pm-5:00 pm LEVEL: ■

Room 9

Leveraging Electronic Health Records in Clinical Research

SESSION CHAIRPERSON(S)

Landen C. Bain
Health-care Liaison, CDISC

The role of electronic health records (EHR) in clinical research is currently an area of great interest. This session will be a panel discussing the potential role for EHR in clinical research. Aside from a brief introductory presentation, the panel will consist of an in-depth conversation with experts representing the various stakeholders in combining EHR and clinical research. The audience members will have an opportunity to ask questions of the panelists.

Electronic Health Records and Clinical Research: The Time Is Now
Linda King, MT
Data Sciences and Solutions Team Leader, Eli Lilly and Company

Panelists

Charles Jaffe, MD, PhD, FACMI
CEO, Health Level 7 Inc.

Jason Colquitt
Director, Clinical Development, Greenway Medical Technologies

Tim Rochford
Chief Technical Officer, Phase Forward

Michael A. Ibara, PharmD
Head of Pharmacovigilance Information Management, Pfizer Inc

Session 399F ERS/DM 1 - Electronic Regulatory Submissions/Document Management, RA

3:30 pm-5:00 pm LEVEL: ■

Room 15A MEZZ.

Creation of Marketing Applications for the ASEAN Region

SESSION CHAIRPERSON(S)

Joseph McDonnell, IV, MBA, MS
Associate Director, Merck & Co., Inc.

ASEAN regulatory authorities have mandated the use of a standard format for all regulatory marketing applications (ACTD) that differs significantly from the established ICH Common Technical Document (CTD) format used for regulatory submission in the rest of the world. While this guidance does not necessitate the creation of new content, it does require extensive reformatting of the existing CTD components. Thus, in the absence of a centralized and automated process, the new regulation could result in the need for additional capital resources or expensive outsourcing. Innovative internal improvements can eliminate the need to do either.

Creation of Marketing Applications for the ASEAN Region
Michelle R. Ponpipom, MPH
Associate Director, Regulatory Affairs, Merck & Co., Inc.

ASEAN CTD Implementation: Challenges and Successes
Alice Bongiovanni Wisniewski, MBA
Associate Director, Clinical Trial Application and Submission Coordination, Johnson & Johnson Pharmaceutical R&D LLC

David Holzwarth, MBA
Global Dossier Leader, Johnson & Johnson Pharmaceutical R&D LLC

Session 399G ERS/DM 2 - Electronic Regulatory Submissions/Document Management, CDM

3:30 pm-5:00 pm LEVEL: ●

Room 8

Convergence of Data and Document Standards: Where Does CDISC Meet eCTD?

SESSION CHAIRPERSON(S)

Gary G. Walker
Associate Director, Enterprise Data Standards, Quintiles Transnational Corp.

In the US, the eCTD is the submission format for not just the research conclusions justifying marketing your product for an indication. It also contains the data supporting your results. This session will explore the standards the FDA has pointed to in its specifications for data submissions and how CDISC is working with the Agency and industry to streamline the collection, reporting, and use of the data that is the result of the research, and the basis for claims made from the research.

CDISC Submission Standards and Future Direction
David P. Iberson-Hurst
Vice President, Technical Strategy, CDISC, UK

Validation and Uses of Standardized Submission Data: Evolving Perspectives
Wayne R. Kubick, MBA
Senior Vice President, Phase Forward Lincoln Safety Group

Closing the Loop: Bringing Health-care Data into Clinical Research
Gary G. Walker
Associate Director, Enterprise Data Standards, Quintiles Transnational Corp.

Session 399H GCP - Good Clinical Practices, CP

3:30 pm-5:00 pm LEVEL: ■

Room 30CD *CME and Nursing credits offered*

Implementing Effective Quality Risk Management from an Organizational Perspective

SESSION CHAIRPERSON(S)

Sharon Wyatt Moore, MD, MBA, MPH
Global Head, Quality Assurance, Chiltern

Companies need systems that will facilitate quality improvement in a cost-effective manner. This session will discuss what constitutes an effective quality management system, risk tools, and risk management plans. Practical approaches will be discussed on both organizational and project levels.

Designing an Effective Quality Management System
Sharon Wyatt Moore, MD, MBA, MPH
Global Head, Quality Assurance, Chiltern

Sponsor/Service Provider Collaboration in Quality Risk Management
Brian B. O'Neill, PhD
Head, CQA Management, External Alliances, F. Hoffmann-La Roche Ltd., Switzerland

Developing a Study-specific Risk Management Plan
Judy M. Atkins, PharmD
President and CEO, Compliance Resources, LLC

Session 399I IT - Information Technology, OS

3:30 pm-5:00 pm LEVEL: ■

Room 15B MEZZ.

Empowering the Enterprise with Software as a Service (SaaS)

SESSION CHAIRPERSON(S)

Leslie Bihari, Jr.
President, MPower Software Inc.

Software as a Service (SaaS) provides pharmaceutical, device and biotechnology companies an approach for rapid technological implementations without the need to assemble very specialized teams in the new technologies. Instead, sponsor business teams focus on what they do best, leaving management of software to the experts. Discover more about SaaS and its impact on companies in this session and learn how to assemble a plan for SaaS implementation.

SaaS in a Global Life Sciences Marketplace: A Software Vendor's Perspective
John Shipway
Industry Solutions Architect, SAS Institute Inc.

Pharmacovigilance Business Process Outsourcing in a SaaS Environment
Gurunathan Venkat, PMP
Associate Director, Aris Global LLC

Session 399J MC - Medical Communications, TR/PD

3:30 pm-5:00 pm LEVEL: ●

Room 14A MEZZ. *CME and Nursing credits offered*

New Drug Information Databases at the National Library of Medicine

SESSION CHAIRPERSON(S)

James E. Knoben, PharmD, MPH
Consultant, National Library of Medicine, Kelly Services

The session will provide information for drug information specialists and clinical practitioners on five new drug information databases at the National Library of Medicine: DailyMed, Drug Imaging Database, Drug Information Portal, LactMed (Drugs and Lactation Database), and LiverTox (drug-induced liver toxicity).

The National Library of Medicine (NLM) Drug Information Portal and DailyMed Database
Diane M. Howden
Chemist, National Library of Medicine

The Drugs and Lactation (LactMed) Database
Philip O. Anderson, PharmD
Health Sciences Clinical Professor, Skaggs School of Pharmacy, University of California San Diego

The LiverTox (Drug-induced Liver Injury) Database and Drug Imaging Database
James E. Knoben, PharmD, MPH
Consultant, National Library of Medicine, Kelly Services

Session 399K MW - Medical/Scientific Writing, CR/CS

3:30 pm-5:00 pm LEVEL: ■

Room 31AB *Pharmacy credits offered*

Globally Sourced Medical Writing: Windfall or Pitfall?

SESSION CHAIRPERSON(S)

Carolyn L. Smith-Barrett, PhD
Global Head, Regulatory Medical Writing, Johnson & Johnson Pharmaceutical R&D LLC

Off-shoring research activities have become attractive for the pharmaceutical industry, looking to explore efficiencies and cost-effective approaches. Regulatory medical writing has been growing as a candidate for off-shore partnerships. Success or failure depends on how the partnership was established and nurtured. Experts with different perspectives on resource models and these partnerships will share their experience, how to overcome perceived obstacles, what can go wrong, and how to develop next practices to best maintain successful offshore operations.

Establishing and Nurturing the Medical Writing Partnership for Success
Nimita Limaye, PhD
Vice President, Clinical Data Management and Medical Writing, SIRO Clinpharm Pvt. Ltd., India

Strategic Decisions Related to Global Sourcing of Medical Writing
Karen P. Heraty
Strategic Clinical Sourcing Consultant, Eli Lilly and Company

Globally Sourced Medical Writing Case Studies Using Professionals and Technology
Rajiv Prasad, MBA
Assistant Vice President, Life Sciences, Satyam BPO Ltd.

Session 399L NC - Nonclinical Laboratory Safety Assessment, CP

3:30 pm-5:00 pm LEVEL: ●

Room 10

Potentially Genotoxic Impurities, Metabolites, and Degradates: The Need for an Integrated Approach to Safety Assessment

SESSION CHAIRPERSON(S)

Sheila M. Galloway, PhD
Executive Director, Genetic and Cellular Toxicology, Merck Research Laboratories

In pharmaceutical development, assessment of potential for genotoxicity based on chemical structural analyses and/or on genotoxicity testing is done for multiple reasons: preclinical safety testing of drug, impurities or degradates, and testing of production materials to support occupational health or transport of materials. Quite often, synthetic intermediates or drug degradates are also drug metabolites. New regulatory guidelines address assessment and control of genotoxic impurities; other guidelines address safety testing of metabolites. An integrated approach is needed to qualification and safety assessment of impurities, degradates, and metabolites. This session aims to bring together representatives of regulatory agencies and the pharmaceutical industry to develop such a strategy.

Companies encounter differing regulatory requests for testing metabolites for genotoxicity. Issues include whether structural alerts are part of the trigger for testing, lack of a consistent definition of a disproportionate human metabolite, and the concern that if a human metabolite is synthesized and tested in a biological assay, it is further metabolized, confounding interpretation of the relevance of the results to people. Topics for discussion include the concept that qualification of potentially genotoxic metabolites occurs in genotoxicity testing of the parent drug with S-9. While such testing of the parent can be sufficient to support patient safety, how is this reconciled with the need to test the intermediate itself, even if it is a metabolite, at high, regulatory concentrations to support occupational health in manufacturing, and transport of materials? There is mixed regulatory feedback on whether a PGI that is a metabolite has to be controlled in the drug to meet the TTC, the threshold of toxicological concern. Also, when is it appropriate to use a limited top dose in the Ames test (eg, 250 µg/plate) for testing intermediates/metabolites?

Safety Assessment of Impurities and Metabolites in Drug Development
Sheila M. Galloway, PhD
Executive Director, Genetic and Cellular Toxicology, Merck Research Laboratories

Safety Assessment of Impurities and Metabolites in Drug Development: European Perspective
Peter Kasper, PhD
Scientific Director, BfArM, Germany

Safety Assessment of Impurities and Metabolites in Drug Development: FDA Perspective
Abigail C. Jacobs, PhD
Associate Director, Pharmacology and Toxicology, Office of New Drugs, Immediate Office, CDER, FDA

Session 399M NHP - Natural Health Products, RA

3:30 pm-5:00 pm LEVEL: ■

Room 17B MEZZ.

Current Status and Future Development of Phytomedicines: International Perspective

SESSION CHAIRPERSON(S)

Mahabir P. Gupta, PhD
Director, CIFLORPAN and Research Professor of Pharmacognosy, University of Panama

This session will showcase the challenges in the introduction of high-quality, clinically evaluated phytomedicines developed locally in Brazil. In addition, the requirements for the development of Ayurvedic and Unani medicines from Bangladesh will be presented. Finally, the regulatory status of Traditional, Alternative and Complementary Medicine (TACM) in Latin America and development and implementing clinical trials for botanical drugs will be provided.

Regulatory Status of Traditional, Alternative, and Complementary Medicine in Latin America
Mahabir P. Gupta, PhD
Director, CIFLORPAN and Research Professor of Pharmacognosy, University of Panama

Development and Implementation of Clinical Trials of Botanical Drugs
Daniel J. Labriola, ND
Medical Director, Northwest Natural Health-Specialty Care Clinic

Requirements and Challenges for Development of Ayurvedic and Unani Medicine in Bangladesh
Mohammad Rafiqul Islam, MS
Director, Marketing and Sales, Acme Laboratories Ltd., Bangladesh

Session 399N OS - Outsourcing, CR/CS

3:30 pm-5:00 pm LEVEL: ●

Room 5A

Latin America: Leveraging Regional Strengths while Proactively Ensuring Quality

SESSION CHAIRPERSON(S)

Katie Margules, PharmD, MSc
Senior Director, Latin America, Covance Inc., Mexico

This session will provide a clear vision of the status of clinical research in Latin America by discussing the advantages the region offers as well as the shortcomings and challenges encountered in the region and by describing how clinical research will develop in the region in near future.

Clinical Research and Innovation in Latin America to Protect and Advance the World's Health Challenges and Opportunities
Salomon Stavchansky, PhD
Alcon Centennial Professor of Pharmaceutics, University of Texas at Austin

Investigator Sites in Latin America: Success Creates Challenges
Juan-Pablo Guzman, MD
Senior Director, Global Clinical Development, UCB Pharma

Latin America: Leveraging Regional Strengths while Proactively Ensuring Quality
Katie Margules, PharmD, MSc
Senior Director, Latin America, Covance Inc., Mexico

Session 399O PM/FI 1 - Project Management/ Finance, IT

3:30 pm-5:00 pm LEVEL: ■

Room 4 *Project Management units offered*

Integrated Business Modeling: Where Improvements in Productivity Happen by Leveraging Better Forecasting Tools, Techniques, and Processes

SESSION CHAIRPERSON(S)

Jim L. Vandergriff, II
Project Management Consultant, Eli Lilly and Company

In this challenging drug development environment, pharmaceutical companies must find ways to be more productive by leveraging effective portfolio management approaches and efficient forecasting methodologies. Complex matrix organizations have unique challenges in that stakeholders, end-users, and organizational leadership may have different expectations and needs for resource and dollar information. Budget and/or project managers (BM/PM) must often find that delicate balance within those competing business needs to establish common language, processes, and tools. Inherent variability in clinical trial execution and associated workflow creates additional uncertainty and makes accurate forecasting even more difficult. To account for common variations in the portfolio (eg, probability of technical success) and execution of clinical trial (eg, patient enrollment) a BM/PM must leverage best practices in budget forecasting and resource optimization. These efforts to effectively integrate business data facilitate trial and portfolio execution, enable gover-

nance bodies to make better trade-off decisions, and maximize opportunities. They also help operations groups better understand the internal and external resource needs to support the drug development portfolio. Therefore, a BM/PM can play a key role in an organization by enhancing its ability to address these challenges.

Budgeting and Forecasting for Clinical Trials: Pitfalls and How to Overcome Them
Chris Chan, MBA
Associate Director, Product Development Finance, Genentech, Inc.

Resource Optimization: Protecting Throughput in the Face of High Variation
Kevin Doyle, PMP
Director, Resource Analytics, Merck & Co., Inc.

Leveraging Modeling Tools in Clinical Resource Planning
Karin L. Daun
Manager, Data Science Solutions, Eli Lilly and Company

Session 399P PM/FI 2 - Project Management/ Finance, CR/CS

3:30 pm-5:00 pm LEVEL: ■

Room 2 *Project Management units offered*

Challenges in Project Management in Front-loading Key Activities for Rapid Drug Development

SESSION CHAIRPERSON(S)

Michael W.J. Wang, PhD, MBA
Global Project Manager, Hoffmann-La Roche Inc.

Front-loading of resources is activating resources at risk prior to go/no-go decisions to ensure rapid drug development in case of a possible go decision. In early-stage drug development projects from preclinical to clinical stages, there are often front-loading key activities in research, formulation, preclinical, clinical, and financial areas. Appropriate front-loading depends on a detailed planning and team management that will ensure rapid deployment of resources when needed. This session will highlight some of the risks and benefits of front-loading key activities associated with functions involved in early-stage drug development. Practical approaches will be offered to ensure seamless transition and progression of the project for moving from preclinical into completion of proof-of-concept studies.

Preclinical Aspects of Front-loading
Jennifer May
Project Manager/Senior Training Specialist, ZymoGenetics

CMC: To Spend or Not to Spend, That Is the Question
John David Cornpropst
Director, Program Management, Facet Biotechnology, Inc.

Clinical Aspects of Front-loading
Julie G. Bukar, MBA
Managing Director, JGB BioPharma Consulting Inc.

Session 399Q PP - Public Policy/Law, CP

3:30 pm-5:00 pm LEVEL: ■

Room 32AB

Clinical Trial Registries: Panacea or Pablum?

SESSION CHAIRPERSON(S)

Michael A. Swit, JD
Vice President, The Weinberg Group Inc.

Since FDAMA in 1997, the use of clinical trial registries has evolved from an attempt to allow patients greater access to experimental therapies to a solution to allegations of buried adverse clinical trial results. This session explores the evolving demand for registries, the requirements of federal, state, and international authorities – especially the US after the enactment of the 2007 FDAAA registry and results database provisions – and their legal and practical challenges.

Clinical Trials Disclosure: Are We Meeting the Target Audiences?
Gesine Bejeuhr, PharmD, PhD
VFA German Association of Research-Based Pharm Co., Germany

Clinical Trials Disclosure: Critical Legal Issues
Linda A. Malek, Esq., JD
Partner, Moses & Singer LLP

Session 399R RA 1 - Regulatory Affairs, CR/CS

3:30 pm-5:00 pm LEVEL: ■

Room 7B

Drug Registrations and Clinical Trials in Emerging Pharma Countries and N-11 Countries

SESSION CHAIRPERSON(S)

Romi Singh, PhD
Executive Director, Global Regulatory Affairs and Safety, Amgen Inc.

The session will feature speakers who are experts on regulatory affairs and clinical trials in the emerging pharma countries (Brazil, Russia, India, China, Korea, Turkey, Mexico) and some of the the N-11 countries (eg, Bangladesh, Egypt, Indonesia, Iran, Mexico, Nigeria, Pakistan, Philippines, South Korea, Turkey, and Vietnam). The first presentation will feature the definition of emerging countries and the N-11 countries and their importance to the pharmaceutical companies as favorable destinations for new markets, patients, and talent. The emerging regulatory landscape of these countries will also be presented.

The second presentation will address current trends in clinical trials in emerging countries and how and why these countries offer value to pharmaceutical companies. Challenges and opportunities of conducting clinical trials in those countries will be discussed. The third presentation will provide a high-level overview of the drug registration process in these emerging countries and some of the challenges associated with drug registrations, timelines, and CPP requirements, highlighting some variations from ICH requirements.

Regulatory Landscape in Emerging and N-11 Countries: An Overview
Romi Singh, PhD
Executive Director, Global Regulatory Affairs and Safety, Amgen Inc.

Clinical Trials in Emerging and N-11 Countries: An Overview
Fabio Thiers, MD, PhD
Co-director of Strategic Global Trials Research Program, MIT Center for Biomedical Innovation

Drug Registrations in Emerging and N-11 Countries: An Overview
Stuart Walker, PhD
Founder, CMR International Institute for Regulatory Science, UK

Session 399S RA 2 - Regulatory Affairs, RD

3:30 pm-5:00 pm LEVEL: ■

Room 7A

Asian Regulatory Collaboration Update for Multinational Clinical Trials

SESSION CHAIRPERSON(S)

Hironobu Saito, PhD
Director, Clinical Development Group, Asian Development Department, Daiichi Sankyo Co., Ltd., Japan

This session will provide a high-level understanding of major advantages and challenges encountered from managing these studies in Asian countries and will also share an in-depth country-level knowledge in how to properly plan for future new drug development in this region.

Asian Regulatory Cooperation and Collaboration for Promoting Drug Development
Yoshiaki Uyama, PhD
Review Director, Office of New Drug III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Global Development Strategy from a Chinese Point of View
Ling Su, PhD
Vice President, Clinical Research and Development, Asia Pacific, Wyeth Pharmaceutical Co., Ltd., China

Asian Development Strategy from a Japanese Sponsor's Point of View
Tetsuomi Takano, RPh
Director, Head of Asian Project Management, Asian Development, Astellas Pharma Inc., Japan

Session 399T RA 3 - Regulatory Affairs, RD

3:30 pm-5:00 pm LEVEL: ■

Room 6F

Good Review Management Practices and Good Communication Practices Leading to Successful NDAs

SESSION CHAIRPERSON(S)

John R. Cutt, PhD
Vice President, US DRA; Franchise Head, Immunology and Infectious Diseases (IID), Novartis Pharmaceuticals Corporation

Industry and FDA representatives will discuss Good Review Management Practices that contribute to first cycle approvals. Lessons learned and examples of what constitutes complete and incomplete NDAs will be shared.

FDA Perspective
Sandra L. Kweder, MD
Deputy Director, Office of New Drugs, CDER, FDA

PhRMA Survey on Good Review Management Practices
Taryn Rogalski-Salter, PhD
Global Head of Regulatory Affairs, Novartis Vaccines & Diagnostics, Inc.

Industry Perspective on Good Review Management Practices
Thomas H. Hassall, MS
Senior Director, Regulatory Intelligence, Abbott Laboratories

Session 399U RA 4 - Regulatory Affairs, CP

3:30 pm-5:00 pm LEVEL: ■

Room 6E

Relative Efficacy/Effectiveness: A New Interface between Drug Regulation and Health Technology Assessment

SESSION CHAIRPERSON(S)

Thomas Lönngren, Pharm, MSc
Executive Director, European Medicines Agency, European Union

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 Health Technology Assessment (HTA) bodies/drug reimbursement agencies.

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

Determining Value: Science and Price
Guido Rasi, DrMed
Chief Executive, Agenzia Italiana del Farmaco, Italy

Relative Efficacy: FDA and CMS Experience
Scott Gottlieb, MD
Resident Fellow and Practicing Physician, American Enterprise Institute

Relative Efficacy: Industry Experience
Robert B. Clark, MS
Vice President, Worldwide Regulatory Strategy, Pfizer Inc

Session 399V RD - R&D Strategy, RA

3:30 pm-5:00 pm LEVEL: ◆

Room 14B MEZZ.

Managing Development Portfolios in a Safety-heightened Environment

SESSION CHAIRPERSON(S)

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

As a result of recent product withdrawals and increasing public awareness, pharmaceutical portfolio management is changing. Portfolio management is beginning to place more emphasis on evaluating the expected risk/benefit ratio in various patient populations. Since most new molecular entities have potential for treating more than one disease, companies are more often selecting for initial development diseases which have a greater tolerability for potential risks.

Introduction to Portfolio Management
William K. Sietsema, PhD
Vice President, US Regulatory Consulting and Submissions, Kendle International Inc.

Selection of Drug Indications in a Risk-conscious Environment
Marilyn A. Metcalf, PhD
Director, Quant and Decision Sciences, GlaxoSmithKline

Pipeline and Portfolio Planning
Yan Zhang, PhD
Director of Pipeline and Portfolio Planning, Genentech, Inc.

Portfolio and Pipeline Planning for Medical Devices
Rajendra V. Deshpande, PhD
Executive Director, Clinical Affairs, Ethicon Endo-Surgery

Session 399W ST - Statistics

3:30 pm-5:00 pm LEVEL: ◆

Room 16A MEZZ.

Issues with Subgroup Analyses in Controlled Clinical Trials

SESSION CHAIRPERSON(S)

Abdul J. Sankoh, PhD
Senior Director and Head, Biometrics, Vertex Pharmaceuticals Incorporated

With the current Congressional mandate requiring the FDA to come up with guidelines on how to deal with perennial issues like multiplicity, subgroup analysis, missing data, etc., in controlled clinical trials, the FDA and DIA held a joint workshop on these three topics in April 2008. The aim of this session is to continue the dialogue that was started in one of these topics - subgroup analysis.

Some Statistical Considerations for Confirmatory Subgroup Analysis
Mohammad Huque, PhD
Director, Division of Biometrics IV, Office of Biostatistics, CDER, FDA

The Role of Retrospective Subgroup Analyses in Developing Tailored Therapies
Walter W. Offen, PhD, MS
Senior Research Fellow, Global Statistical Services, Eli Lilly and Company

Analyzing and Reporting Subgroup Analyses: What to Consider and What to Avoid
Ralph B. D'Agostino, Sr., PhD, MA
Chair, Mathematics and Statistics Department; Professor of Mathematics and Statistics and Public Health, Boston University

Session 399X TR/PD - Training/Professional Development

3:30 pm-5:00 pm LEVEL: ■

Room 16B MEZZ.

eLearning and Distance Training

SESSION CHAIRPERSON(S)

Danny A. Benau, PhD
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia

Training and learning are related but different activities. This session will explore the delivery of information to different training audiences by using online delivery systems. Training is a combination of background knowledge delivery coupled with just-in-time information for critical projects. Distance delivery of training materials must be adequately structured to assure that vital information is received by all members of the target teams rather than just transmitting general directions to team leaders. While Web 2.0 methods are part of many means of training, content delivery methods also include webinars, podcasts, and videoconferencing. The key to distance training is motivating the trainees to absorb content quickly and accurately.

An Overview of Challenges and Strategies to Make Remote Investigator Training a Reality
Yvonne Albright, MSN, RN
Project Manager, Covance Periapproval Services

Next Generation eLearning for the Next Generation Workforce
Pamela Loughner, PhD, MEd
President, Loughner and Associates Inc.

Motivating Your Distant Learners
Jill M. Huentelman, MBA
Owner, Lernia Training Solutions

Session 399Y VA - Validation, GCP

3:30 pm-5:00 pm LEVEL: ●

Room 11A

An International Perspective on the Use of Computerized Systems in Clinical Investigations

SESSION CHAIRPERSON(S)

Patricia Beers Block
Expert Consumer Safety Officer, Office of the Commissioner, FDA

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 Latin America when these investigations utilize electronic data capture and electronic signatures.

Perspective from the US
Patricia Beers Block
Expert Consumer Safety Officer, Office of the Commissioner, FDA

A Practical Approach to the Use of Computerized Systems in Clinical Investigations: FDA Requirements and Expectations
Jonathan S. Helfgott, MS
Consumer Safety Officer, CDRH, FDA

Perspective from the EMEA
Fergus Sweeney, PhD
Head of Inspections Sector, European Medicines Agency, European Union

Perspective from Latin America
Silvia Zieher, MD
Director, Head of Clinical Operations Latin America, Global Clinical Development, MDS Pharma Services, Argentina

5:00 pm **END OF WEDNESDAY SESSIONS**

Notes

Notes

7:00 am-10:30 am **SPEAKER REGISTRATION**
Sails Pavilion, Upper Level

7:30 am-8:15 am **MORNING REFRESHMENTS**
Sails Pavilion, Upper Level

7:30 am-10:30 am **ATTENDEE REGISTRATION**
Sails Pavilion, Upper Level

12:30 pm-5:00 pm **MEDDRA® USER GROUP MEETING**
Room 6C

SESSION 401 AHC/IS - ACADEMIC HEALTH CENTERS/ INVESTIGATOR SITES, GCP

8:30 am-10:00 am LEVEL: ■

Room 1A

Human Subject Protection Programs: Complex Issues for the IRB

SESSION CHAIRPERSON(S)

Paul Papagni, JD
Executive Director, Clinical Research, University of Texas M. D. Anderson Cancer Center

This session will address institutional, investigator, and IRB responsibilities when investigators conduct investigator-initiated studies requiring the holding of an IND/IDE. Investigator-initiated studies are encouraged due to the positive recognition generated for the reputation of the institution and investigators. However, the financial and regulatory burdens of these studies are often understated. Additionally, conducting these studies as multicenter or multinational collaborations increases both the cost and the risk. This session will include the challenges of conducting multicenter studies while serving as the lead investigator responsible for data quality monitoring, regulatory compliance, and data and safety monitoring. These challenges further include performance site assessment, investigator selection and training, recruitment, and ethical concerns relating to conducting research outside the US.

IRB and Site Relationships: Smooth Sailing or Perfect Storm
Felix A. Gyi, PharmD, MBA
Chief Executive Officer, Chesapeake Research Review Inc.

Centralized IND Sponsorship at Academic Medical Centers
Chicquita Hatten, BSN, MSN, RN
Manager, Research Education and Regulatory Management, University of Texas M. D. Anderson Cancer Center

SESSION 402 BT - BIOTECHNOLOGY, RA

8:30 am-10:00 am LEVEL: ■

Room 1B

Recent Advancement of Emerging Technology in the Asia Pacific Region

SESSION CHAIRPERSON(S)

Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

The development of novel products or administrative technology such as nanotechnology has attracted attention among industries as well as academia. National programs in Asia Pacific countries have supported the interdisciplinary research funding and infrastructure set-up. This session will be devoted to the discussion and comparison of recent advancement of the development of emerging biotechnology such as nanotechnology in the Asia Pacific region. The comparison of development strategy among these Asian countries will be held in the panel discussion.

Emerging Technology: Regulatory Viewpoints in Asia Pacific
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Drug Interaction of Herbal and Western Medicines
Oliver Yoa-Pu Hu, PhD
Dean, Research and Development, National Defense Medical Center, Taiwan

The Opportunity and the Challenge for Clinical Trial Execution in Asia
Catherine Lee, MPharm
Regional Director, Clinical Research Asia, Pfizer Inc, Taiwan

SESSION 403 CDM - CLINICAL DATA MANAGEMENT, CR/CS

8:30 am-10:00 am LEVEL: ●

Room 11B

Minimizing Data Queries in Clinical Trials

SESSION CHAIRPERSON(S)

Kit Howard, MS
Principal and Owner, Kestrel Consultants, Inc.

Generating and resolving data queries in clinical trials represent significant cost in terms of both time and money, and reducing the number of queries has become a major focus in recent years. Achieving this goal requires a deep understanding of why queries are generated in the first place, and of the relationship between queries and data quality. This session will challenge attendees to rethink their assumptions of what data quality really means in light of the Institutes of Medicine definition of data quality: data are of high quality when they are fit for the uses to which they will be put. The talks will present three ways in which this understanding can be translated into practical strategies for reducing data queries. The first will discuss a method for site/monitor/data management collaboration that reduces queries by increasing communication and understanding between these roles. The second will discuss the role of electronic data capture in reducing queries and how EDC can optimize data quality in other ways. Finally, the role of data standards in reducing queries will be examined. The combination of these three elements can decrease the number of queries required without compromising data quality.

How to Stop Drowning in Data Queries By Collaborating across Roles
Kit Howard, MS
Principal and Owner, Kestrel Consultants, Inc.

Using Electronic Clinical Tools to Improve Data Quality
Jonathan R. Andrus, MS
Vice President, Data and Study Operations, Phoenix Data Systems Inc.

Eliminating Queries by Using Data Standards
Melissa Binz, MS
Director, Central Standards Group, Wyeth Pharmaceuticals

Session 404 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

8:30 am-10:00 am LEVEL: ■

Room 17A MEZZ.

The Role of Excipients and Quality by Design (QbD)

SESSION CHAIRPERSON(S)

Janeen Skutnik
Quality and Regulatory Policy, Global Regulatory CMC, Pfizer Inc, UK

This session will focus on the role of excipients in Quality by Design. We will explore concepts such as flexible formulations, excipient variability and considerations for QbD, excipient functionality and the role of pharmacopoeias. We will focus on considerations for the formulation of the future, driving towards flexibility and excipient variability.

FDA Perspective on the Role of Excipients in Quality by Design
Terrance W. Ocheltree, PhD, RPh
Pharmaceutical Assessment Lead, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

EDQM Perspective on the Role of Pharmacopoeias in Quality by Design
Susanne Keitel, DrSc, PharmD, RPh
Director, European Directorate for the Quality of Medicines, France

Flexible Formulations, Excipient Functionality and Future Considerations for Formulations and Excipients
Brian A. C. Carlin, PhD, RPh
Director, Open Innovation, FMC Biopolymer

Session 405 CP - Clinical Safety and Pharmacovigilance, RA

8:30 am-10:00 am LEVEL: ●

Room 10 *CME and Nursing credits offered*

Pregnancy Registries: Perspectives on a Unique Risk Management Tool

SESSION CHAIRPERSON(S)

Deborah Covington, DrPH, MS
Senior Director, Global Late Phase, Kendle International Inc.

This session will review the utility of pregnancy registries as a risk management tool and the challenges involved in their conduct. The information presented will illustrate their usefulness in assessing the benefit-risk profile of drugs in pregnancy throughout the drug life cycle. Speakers from industry and the FDA will lead the discussion.

Methodologies Employed in Conducting Pregnancy Exposure Registries
Laura F. McKain, MD
Medical Director, Registries and Epidemiology, Late Phase, Kendle International Inc.

Pharmaceutical Sponsor Perspective on Conducting a Global Pregnancy Registry
Dawn F. Eng, BSN, RN
Associate Director, Global Medical Affairs-Oncology, Novartis Pharmaceuticals Corporation

Pregnancy Exposure Registries: New Developments at FDA
Susan K. Cummins, MD, MPH
Senior Science Advisor, Office of New Drugs, Immediate Office, Pediatric and Maternal Health Staff, CDER, FDA

Session 406 CR/CS 1 - Clinical Research and Development/Clinical Supplies, AHC/IS

8:30 am-10:00 am LEVEL: ●

Room 5B

Addressing Three Major Challenges in Investigator-initiated Trials: Process, Contracts, and Culture

SESSION CHAIRPERSON(S)

Cathryn L. Anderson
Sepracor Inc.

Investigator-initiated trials (IITs) represent an important opportunity for companies to support innovative and important research projects. Supporting IITs, however, can present numerous organizational, operational, and ideological challenges. This session addresses each of these challenges and presents case studies as examples of issue management.

Avoiding Potential Cultural Misunderstandings and Conflicts by Creating Global Standards for IITs
Ran Frenkel, RPh
CEO, Pharma Focus Israel

Development and Implementation of a Global IST (IIT) Process
Joseph P. Kerkering, MBA
Associate Medical Affairs Director, Shire Pharmaceuticals

IIT Contracts: Establishing Agreements that Balance Company and Investigator Interests Globally
Cathryn L. Anderson
Sepracor Inc.

Session 407 CR/CS 2 - Clinical Research and Development/Clinical Supplies, AHC/IS

8:30 am-10:00 am LEVEL: ■

Room 6D *Pharmacy credits offered*

Optimizing the Process of Study Feasibility: Ensuring Better Outcomes for All Stakeholders

SESSION CHAIRPERSON(S)

Anne-Marie Baughn, MSN, RN
Director, Marketing and Business Development, RxTrials Inc

This session will address study feasibility as a process. This process is a critical component to all stakeholders of the clinical research team; however, each stakeholder utilizes very different operational processes, tools, criteria, and objectives when performing study feasibility. Ultimately, the common goal for all stakeholders is good data – produced at the site, monitored for compliance by the CRO, and compiled/analyzed by the sponsor. A common understanding of each other's process, identifying challenges, and recommending strategies for change, will allow all stakeholders to work towards optimizing the study feasibility process, ensuring better outcomes. This session will focus on the strategies needed for improvement in the study feasibility process, ensuring better outcomes for all.

Sponsor Perspective
Maria Trudette Madison, DrSc
Director of Clinical Operations, Enanta Pharmaceuticals, Inc.

CRO Perspective
Donna E. Beardsworth, MA
Founder, Chief Delivery Officer, Beardsworth Consulting Group Inc.

Site Perspective
Anne-Marie Baughn, MSN, RN
Director, Marketing and Business Development, RxTrials, Inc.

Session 408 EC - eClinical, CR/CS

8:30 am-10:00 am LEVEL: ■

Room 15A MEZZ.

How Much Do Electronic Diaries Improve the Quality of Clinical Research?

SESSION CHAIRPERSON(S)

Valdo Arnera, MD
General Manager, Europe, PHT Corporation, Switzerland

The use of electronic patient diaries in clinical trials where data are collected from patients, typically at their homes, and transferred to a central server where data are available for review has been increasing over the last ten years. While the number of clinical studies having used such data collection methods may soon reach a thousand, the real benefits of such tools remains unknown to a vast majority of clinical trial professionals. What are the advantages of e over paper, how can those benefits be quantified, and why are there still regulatory hurdles preventing total adoption of such tools in every clinical trial will be the questions this session addresses.

The Site Point of View
Tammy Ernst
Study Coordinator, Allergy, Asthma & Clinical Research Center

The Sponsor Point of View
David Templeton
Manager, Clinical Operations and IT, Asthmatx Inc.

The Regulatory Point of View
Patricia Beers Block
Expert Consumer Safety Officer, Office of the Commissioner, FDA

Session 409 ERS/DM - Electronic Regulatory Submissions/Document Management, IT

8:30 am-10:00 am LEVEL: ■

Room 9

Addressing Document Collaboration Challenges in Drug Development

SESSION CHAIRPERSON(S)

Edsel David, MA
Senior Director, Knowledge Management, Daiichi Sankyo Inc.

eCollaboration allows global, web-based, cross-functional, and enterprise-wide collaboration so organizations can process documents faster and more effectively. This session provides an overview of the latest in collaboration tools, reviews key challenges and lessons learned in implementing an eCollaboration system, and identifies strategies for implementing a global eCollaboration solution. This session will also explore global collaboration strategies on key clinical and regulatory submission documents.

Emerging Technology Trends: True Document Collaboration
Jennifer L. Wemstrom
Regulatory Solution Director, CSC Life Sciences

eCollaboration and Potential Benefits to CMC
Deanna Murden
President and CEO, ePharmaCMC, LLC

eCollaboration on Key Drug Development Documents
Edsel David, MA
Senior Director, Knowledge Management, Daiichi Sankyo Inc.

Session 410 GCP - Good Clinical Practices, PP

8:30 am-10:00 am LEVEL: ■

Room 8 *CME and Nursing credits offered*

Informed Consent: Promise, Pledge, Contract, or Platitude?

SESSION CHAIRPERSON(S)

Michael A. Swit, JD
Vice President, The Weinberg Group Inc.

Informed consent is the lynchpin of good clinical practice. If done right, it helps maximize subject safety. If done wrong, the downstream consequences can run the gamut from subject injury or death to liability – civil or criminal – on an array of the parties involved in the research effort. This session will review the key challenges in the consent process for drug research professionals.

Standardization of the ICF Risk Language: A Challenge and a Process
Patricia Ann Moore
Director, Global R&D Quality Assurance, Johnson & Johnson Pharmaceuticals Research & Development

Informed Consent: Key Considerations in Implementing at the Site
Linda G. Strause, PhD
Executive Director, Global Oncology Operations, Vical Incorporated

Session 411 IT - Information Technology, CDM

8:30 am-10:00 am LEVEL: ■

Room 15B MEZZ. *CME, Nursing, and Pharmacy credits offered*

Implementing Health Informatics Solutions in the Life Sciences Industry

SESSION CHAIRPERSON(S)

Donald L. Griffin, II, MBA, MS
Director, Health Informatics Technology, Computer Sciences Corporation

The life sciences industry, and the health-care industry as a whole, are under increasing pressure to convert data from all available sources into actionable knowledge on how to improve quality, safety, and effectiveness while reducing cost. However, the fragmented nature of health care, and, consequently, of the data generated by its major players, providers, payors, life sciences companies, and government organizations, make cross-source informatics challenging to implement. Most of these challenges are surmountable with the proper technology solution architecture, although not without considerable work, most notably in the terminology/ontology domain. This work will be required, though, to continue to demonstrate the value of health-care products and services to those who bear the costs.

Considerations in Building Informatics Solution Architectures that Support Multiple Data Sources and Standards
Donald L. Griffin, II, MBA, MS
Director, Health Informatics Technology, Computer Sciences Corporation

Terminology/Ontology Issues in Creating Searchable Data Repositories
James J. Cimino, MD
Chief, Laboratory for Informatics Development, Clinical Center, National Institutes of Health

The Role of Informatics in Enhancing Our Understanding of Medicines
Patrick Ryan, MS
Statistical and Quantitative Sciences, GlaxoSmithKline

Session 412 MC - Medical Communications, MW

8:30 am-10:00 am LEVEL: ●

Room 14B MEZZ. *Pharmacy credits offered*

Pharmacoeconomics and Health Outcomes Primer for the Medical Communications Professional

SESSION CHAIRPERSON(S)

Christopher M. Marrone, PharmD
Senior Outcomes Liaison, Eli Lilly and Company

Pharmacoeconomics and health outcomes can be important components of the regulatory and formulary decision-making process. The field has grown rapidly, and recent research from the Tufts Center for the Study of Drug Development suggests the demand for industry-led pharmacoconomic research is likely to continue to grow substantially. This session will provide the audience with a high-level overview of these important concepts, as well as an introduction to pharmacoeconomic and health outcomes career opportunities within the pharmaceutical industry.

Overview and Application of Pharmacoeconomics and Health Outcomes
Jeffrey McCombs, PhD
Associate Professor and Director of Graduate Studies, University of Southern California

Health Outcomes Career Opportunities within the Pharmaceutical Industry
Christopher M. Marrone, PharmD
Senior Outcomes Liaison, Eli Lilly and Company

Session 413 MW - Medical/Scientific Writing, CP

8:30 am-10:00 am LEVEL: ●

Room 6E *CME and Pharmacy credits offered*

Pharmacovigilance from the Medical Writer Perspective

SESSION CHAIRPERSON(S)

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

Pharmacovigilance is increasingly considered to encompass the entire drug development lifecycle. Companies need to proactively consider the risks and benefits of their drug in the preapproval phase. Once a drug is on the market, the company is under obligation to continue to monitor the risk and benefits of its product. The tools used for safety monitoring must present the data in a clear and concise manner to ensure that the risk-benefit profile is properly assessed. Increased scrutiny of the analysis and presentation of pharmacovigilance data by all stakeholders, and the impact of these data on the public health in managing product risks, call for inclusion of the medical writer skill set in the teams responsible for these documents. At the same time, the volume of data and demands for transparency are increasing. Business constraints are also driving both authors and consumers of pharmacovigilance documents to become more efficient in their preparation and evaluation of benefits and risks. The potential for a single document to satisfy regulatory requirements in multiple regulatory jurisdictions, as well as a means of sharing key safety information with regulators in all regions, has created opportunities to produce more concise documents with improved presentation of relevant medical concepts. In this session, we will illustrate how the skills that medical writers already possess, such as the ability to present data clearly and concisely, analytical skills, and management of the document preparation and review process, can be used to improve quality and efficiency in generation of pharmacovigilance documents. Specific document types will be discussed from the perspective of the medical writer in a pharma company, as well as the medical writer working in a CRO.

All Drugs, New and Old: Transformational Medical Writing Applied to the Periodic Safety Update Report (PSUR)
Kay Oluwole, DVM, MA
Director, Pfizer Inc

Risk Management Plans and REMS: Practical Advice and Pitfalls
Cheryl A. Ward, MA
Director, Regulatory Medical Writing, Johnson & Johnson Pharmaceutical R&D LLC

Preparing Pharmacovigilance Documents in a CRO
Julia Cooper, PhD
Senior Director, Worldwide Head of Medical Writing Services, PAREXEL International Ltd., UK

Session 414 NC - Nonclinical Laboratory Safety Assessment, BT

8:30 am-10:00 am LEVEL: ■

Room 14A MEZZ.

Updating ICH S6 Guidance on Preclinical Safety Evaluation of Biotechnology-derived Pharmaceuticals

SESSION CHAIRPERSON(S)

Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs, Immediate Office, CDER, FDA

All parties to ICH agreed that updating of ICH S6 was needed and that an addendum would be the best way to address the issues. The topics needing updating were identified as: a) species selection, b) study design, c) reproductive/developmental toxicity, d) carcinogenicity, and e) immunogenicity. Getting consensus is a challenging and ongoing process, as some of the issues are difficult to resolve. Scientists from industry and regulatory agencies will provide an update of the current status of ICH deliberations and highlight areas where continued dialogue and/or data are needed for reaching consensus.

An Introduction to the Topics in ICH S6 Addressed in the Addendum: A European Regulatory Perspective
Beatriz Silva Lima, PharmD, PhD
CHMP and SAWP Member, SWP Chair; Professor, Pharmacology, University of Lisbon, Portugal

Highlighting the Contrasting Viewpoints of Selected Issues under Discussion: A US Regulatory Perspective
Anne M. Pilaro, PhD
Supervisory Toxicologist, Office of New Drugs, Office of Oncology Drug Products, Division of Biologic Drug Products, CDER, FDA

Panel Discussion
Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs, Immediate Office, CDER, FDA

Session 415 NHP - Natural Health Products

8:30 am-10:00 am LEVEL: ●

Room 17B MEZZ.

Roadmap from Preclinical to Health Claims in Natural Health Products

SESSION CHAIRPERSON(S)

Daniel J. Labriola, ND
Medical Director, Northwest Natural Health-Specialty Care Clinic

This session will focus on a variety of interesting topics related to natural health products. We will discuss how an initial concept can be generated and can offer the preclinical foundation of a natural health product. Once the

foundation is developed, then the natural health product needs to move through its designated pathways of establishing the efficacy without sacrificing quality. Of course, pre- and postapproval safety is a huge paradigm especially for the consumer. Finally, we will cover health claims in depth.

Cost-effective Strategies for Establishing New Botanical Drug Health Claims
Daniel J. Labriola, ND
Medical Director, Northwest Natural Health-Specialty Care Clinic

NHPs: Navigating through the Safety, Quality, and Efficacy Maze
Mohammed Razdar Khan
Director, Synergex Consulting, Canada

Plant Sources and Possible Medical Uses of Abscisic Acid, a Plant Hormone
Raymond Tumarkin, MA
Library Researcher

Session 416 OS 1 - Outsourcing, IT

8:30 am-10:00 am LEVEL: ●

Room 5A

Assessing the Security Practices of Business Partners

SESSION CHAIRPERSON(S)

Peter Hesse
President, Gemini Security Solutions

In today's global marketplace, pharmaceutical industry organizations outsource many business processes to external business partners to improve efficiency and reduce costs. Since the pharmaceutical industry is so heavily regulated by policies such as HIPAA, SOX, and 21 CFR Part 11, how can an organization tell if a business partner's security practices are sufficient to meet their regulatory needs? If a business partner is responsible for a breach of your customer data which requires disclosure, what is the cost to your business in money, productivity, and lost reputation? This session will educate attendees on effective techniques for assessing the security practices of a business partner, and help attendees understand ways to manage the risk associated with working with external business partners.

Understanding the Risk Posed by Business Partners
Peter Hesse
President, Gemini Security Solutions

Streamlining the Security Assessment Process
Justin Bovee, MS
Manager, Worldwide Information Security, Johnson & Johnson

Establishing Partner Agreement Frameworks
Terence Zagar, MS
Program Manager/Technologist, Northrop Grumman

Session 417 OS 2 - Outsourcing, CR/CS

8:30 am-10:00 am LEVEL: ■

Room 4

Central Laboratory Services in Emerging Markets: Optimizing Results through Laboratory "Glocalization"

SESSION CHAIRPERSON(S)

Jeffrey K. Mayhew
Chief Operating Officer, LabConnect LLC

The provision of central laboratory services in emerging markets presents unique challenges. Regionally based laboratory service providers offer an alternative approach through a combination of harmonization and local logistics support.

Concepts of Harmonization
Francisco Leao, Jr., MD
Independent Consultant, Brazil

Optimizing Results: Logistic Support
Shilpa S. Puthran, MD
Head, Clinical Research, Metropolis Health Services, Ltd., India

Laboratory Reference Values
Janusz P. Kabata, MD, PhD, MBA
Director, European Operations and Medical Director, CRN Europe, Poland

Session 418 PM/FI 1 - Project Management/ Finance, CR/CS

8:30 am-10:00 am LEVEL: ●

Room 2 *Project Management units offered*

Preserving Relationships in the Face of Divergent Project Expectations

SESSION CHAIRPERSON(S)

Michael J. Hill
Project Manager, Covance Periapproval Services

Managing divergent project expectations is a challenge that is often faced by project managers at CROs and sponsor companies. The session will address best practices for project planning that ensure consistent expectations and strategies for addressing divergent expectations and improving working relationships.

Fostering an Effective Project Management Culture: A Psychosocial Perspective
Bill Gallagher, MA
Director, Clinical Research, RPS (ReSearch Pharmaceutical Services, Inc)

Managing Expectations and Preserving Relationships: A Case Study
Michael J. Hill
Project Manager, Covance Periapproval Services

CRO versus Sponsor: Can This Marriage Be Saved? or "You Can't Shake Hands with a Clenched Fist" (Indira Gandhi) – The Project Manager's Role in Team Dynamics and Conflict Resolution
Susan Maino Vetuschi, BSN
Owner, M & W Clinical Research Consulting, LLC

Session 419 PM/FI 2 - Project Management/ Finance, CR/CS

8:30 am-10:00 am LEVEL: ●

Room 3 *Project Management units offered*

Proactive Management of Project Financials: Understand Scope of Work, Cost to Complete, and Scope Change

SESSION CHAIRPERSON(S)

Ann Flandermeyer, BSN, PhD, MSN, RN
Senior Director, Project Management and Clinical Operations, North America, Covance Inc.

Effective management of project financials is absolutely integral to successful project management. This session combines industry and CRO viewpoints and best practice on how to build a budget, analyze spending, proactively identify change orders, identify strategies to work within the budget, and identify options for effectively controlling the budget.

How to Write a Contract and Budget to Avoid Future Scope Changes
Lois B. Rosenberger, PhD, MS
President, LBR Regulatory and Clinical Consulting Services

How to Clearly Define the Task Matrix and Track Cost to Complete
Amy Larrison, MS
Senior Manager, Clinical Project Management, Targanta Therapeutics

Session 420 PP - Public Policy/Law, RA

8:30 am-10:00 am LEVEL: ■

Room 7A *Pharmacy credits offered*

New Paradigms in Drug Regulation?

SESSION CHAIRPERSON(S)

John A. Lisman, LLM, MPharm
Lawyer, NautaDutilh N.V., Netherlands

The pharmaceutical industry, as well as the world's regulatory authorities, struggle with their image and with the ethical grounds of their actions. The innovation that used to improve public health seems to be decreasing. The regulatory requirements are very demanding and continue to increase, yet do not seem to deliver safety for the users. In spite of efforts to harmonize regulations for new medicines, cooperation between different regulatory authorities globally has developed little and disharmonies occur, for example the case of biosimilars. Industry does not deliver the medicines necessary to meet unmet medical needs, both in the developed and the developing world. This session will focus on high-level, global issues, which ask for innovative solutions to ensure innovation in the pharmaceutical industry and improvement of public health as a result thereof. The topics to be discussed are: orphan drugs, neglected diseases, medicines for children, and public health and innovation.

Neglected Diseases and the World's Orphans: What Are the World's Unmet Medical Needs and How Can These Needs Be Addressed?
Lembit Rägo, MD, PhD
Coordinator, Quality Assurance and Safety: Medicines, Policy and Standards, WHO, Switzerland

Better Use of the Knowledge of Registration Authorities in Optimizing Pharmacotherapy
John A. Lisman, LLM, MPharm
Lawyer, NautaDutilh N.V., Netherlands

Orphan Drug Designation and Market Exclusivity: Its Relevance and Evolving Role in Today's Business and Regulatory Environment
Soraya Madani, PhD
Director, FDA Liaison and Policy Office, Novartis Pharmaceuticals Corporation

Session 421 RA 1 - Regulatory Affairs, CR/CS

8:30 am-10:00 am LEVEL: ●

Room 6AB

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.

One of the many DIA Annual Meeting program highlights is the CDER Town Meeting, Parts 1 and 2. Join leaders from the US FDA's Center for Drug Evaluation and Research in this interactive session where members of the audience may submit questions to this highly distinguished panel of senior leaders. Topics to be discussed will be determined by the interests of the audience.

Questions may also be submitted in advance; please email *2009program@diahome.org* using the subject line: Questions for CDER Town Meeting.

Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

Sandra L. Kweder, MD
Deputy Director, Office of New Drugs, CDER, FDA

Justina A. Molzon, JD, MPharm
Associate Director for International Programs, CDER, FDA

Theresa M. Mullin, PhD
Associate Director for Planning and Informatics, Office of the Director, CDER, FDA

Julie Anne Zawisza, MA
Director, Office of Communications, CDER, FDA

Session 422 RA 2 - Regulatory Affairs, CR/CS

8:30 am-10:00 am LEVEL: ■

Room 7B

Efforts Promoting Global Clinical Trials Environment in Korea

SESSION CHAIRPERSON(S)

Sang-Goo Shin, DrMed, MD
President, KoNECT, Republic of Korea

This session will review the Korean drug development environment, which has changed significantly since 2000, including government initiation and regulatory globalization efforts. Based on the review of this progress, the competiveness of the Korean market will be discussed from an industry point of view.

Overview of Clinical Trials in Korea and Regulatory Changes for Global Competitiveness
Seong Ho Kim, RPh
Director, Clinical Trial Management Division, Korean Food and Drug Administration, Republic of Korea

New MIHWFA Initiatives: KoNECT, Enhancing Clinical Trial Infrastructure in Korea
Ho Young Maeng
Director, Ministry for Health, Welfare and Family Affairs, Republic of Korea

Global Drug Development in Korea: Opportunities and Challenges from an Industry Perspective
Edmund S. Tsuei, PhD, MSc
Regional Head, Pharma Development Operations, Asia-Pacific-Africa, Roche Products Pty. Ltd., Australia

Session 423 ST - Statistics, EBM/IMP

8:30 am-10:00 am LEVEL: ■

Room 16A MEZZ.

Women in HIV Trials: A Comprehensive Review and Meta-analysis

SESSION CHAIRPERSON(S)

Guoxing (Greg) Soon, PhD
Lead Mathematical Statistician, CDER, FDA

HIV-infected women represent a growing proportion of all HIV infections, yet historically the clinical trials have enrolled fewer women. Safety and efficacy of HIV treatments in women often has to be inferred from the overall clinical trial results. This session will shed light on this issue through a summary and meta-analysis of historical trials.

Women in HIV Trials: History and the Current State
Kimberly A. Struble, PharmD
Medical Team Leader, Office of New Drugs, CDER, FDA

Women in HIV Trials: A Meta-analysis
Min Min, PhD
Mathematical Statistician, CDER, FDA

Discussion
Dawn Averitt Bridge
Founder and Chair, The Well Project

Session 424 TR/PD - Training/Professional Development, CR/CS

8:30 am-10:00 am LEVEL: ●

Room 16B MEZZ.

Overview of Drug Development and Career Opportunities for Emerging Professionals

SESSION CHAIRPERSON(S)

Kavita Johal, PharmD
Assistant Director, Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals

This session will provide the target audience of emerging professionals (less than six 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. This session will also review employment strategies implemented by hiring authorities and how they have evolved in response to industry market changes. In addition, a look at the various career opportunities available for emerging professionals will be discussed.

Global Regulatory Affairs in Drug Development and Product Life Cycle Management
Kavita Johal, PharmD
Assistant Director, Global Regulatory Affairs, Bayer HealthCare Pharmaceuticals

The Purpose, Design, and Conduct of Clinical Trials
Jun Kawashima, MD
Senior Director, Medical Affairs and Safety, AAIPharma

Post Drug Approval: Initiatives and Strategies
William Lai, PharmD, RPh
Senior Manager, Global Clinical and Medical Affairs, Baxter Bioscience, Baxter Healthcare Corporation

Employment Strategies and Career Opportunities for Clinical Research Professionals
Joan A. Chambers
Senior Director of Marketing and Operations, Publications, Cambridge Healthtech Institute

Session 425 VA - Validation, IT

8:30 am-10:00 am LEVEL: ■

Room 11A

Validation Challenges with Modern System Development Tools and Methodologies

SESSION CHAIRPERSON(S)

Frances E. Nolan, MBA
Vice President, Quality Assurance, Medidata Solutions Worldwide

Modern system development tools and methodologies offer new opportunities to create improved (higher quality, more functionality) software products in a more timely manner. However, these tools present validation challenges as a result of their very nature, such as fewer deliverables, less documentation, and lack of a defined sequence. Agile development methods (eg, eXtreme Programming [XP], Scrum) offer several advantages over the traditional Waterfall approach, such as the ability to adapt to the unpredictability of requirements and changing customer needs. But the lack of mandating defined, approved requirements up-front can make quality professionals and regulators very uncomfortable. Open Source software permits users to use, change, and improve such software, and to redistribute it in modified or unmodified form. Although there are economic and enterprising advantages to the use of Open Source software, the lack of defined ownership, accountability, and responsibility may call into question the long-term viability of such technology. This session will discuss how to employ Agile Development methods, as well as other modern tools and technology (Open Source, Automated Testing Tools) in a manner that doesn't jeopardize an organization's compliance standing.

Techniques and Tools for Validating Open Source Software
Wyetta Palmby, MS
Consultant, Pharmasys, Inc.

Agile Life Science Project: A Customer Experience
Amir ElFar
Vice President, Information Technology, MedAvante, Inc.

Agile Life Science Project: Practices Required for Success
Michael Vogel, MS
Agile Practice Lead, EMC Consulting

10:00 am-10:30 am **REFRESHMENT BREAK**
Sails Pavilion, Upper Level

Session 426 AHC/IS - Academic Health Centers/ Investigator Sites, CDM

10:30 am-12:00 pm LEVEL: ●

Room 1A

Data Management Challenges within Academic Research Centers

SESSION CHAIRPERSON(S)

John B. Nevy
Consultant, John B. Nevy Independent Consulting

Many academic research centers have begun to develop centralized data management centers in response to increased interest from regulatory, funding, and ethical oversight bodies. While such centers offer numerous advantages for institutions and investigators, they often continue to struggle to meet their missions. This session will bring together data management leaders from various academic institutions to discuss the issues that they face.

The Challenges of Clinical Data Management within an Academic Research Center
John B. Nevy
Consultant, John B. Nevy Independent Consulting

Developing Data Coordination and Data Management at a Children's Hospital Medical Center
Jimmy Thomas Efird, PhD
Associate Professor, Center for Health of Vulnerable Populations, School of Nursing, University of North Carolina at Greensboro

Development of a Research Information System at a Children's Medical Center
Robert McCarter, DrSc
Director, Biostatistics and Informatics Unit, Children's National Medical Center

Session 427 BT - Biotechnology, NC

10:30 am-12:00 pm LEVEL: ■

Room 1B

Preclinical Safety Evaluation of Novel Adjuvants and Vaccines

SESSION CHAIRPERSON(S)

Peter T. Thomas, PhD
Senior Program Manager, Early Development, Covance Laboratories, Inc.

In this session we will review and discuss key regulatory and scientific issues that affect the development of vaccine adjuvants. An introductory presentation providing general background on vaccine development and the use of adjuvants will be followed by a panel discussion.

Preclinical Safety Evaluation of Novel Adjuvants and Vaccines: Introduction
Peter T. Thomas, PhD
Senior Program Manager, Early Development, Covance Laboratories, Inc.

Regulatory Considerations in the Preclinical Safety Assessment of Novel Adjuvants and Preventive Vaccines
Marion F. Gruber, PhD
Deputy Director (Acting) Office of Vaccine Research and Review, CBER, FDA

Concepts in the Nonclinical Safety Assessment of Adjuvants and Adjuvanted Preventive Vaccines Using MF59 as an Example
Deborah L. Novicki, PhD
Global Head, Toxicology, Novartis Vaccines & Diagnostics, Inc.

Nonclinical Safety Assessment of a Vaccine Containing a Novel Adjuvant
Brian J. Ledwith, PhD, MBA
Executive Director, Safety Assessment, Merck Research Laboratories

Session 428 CDM - Clinical Data Management, CP

10:30 am-12:00 pm LEVEL: ■

Room 11B

MedDRA® and CTCAE: Two Terminologies and Their Applications

SESSION CHAIRPERSON(S)

Ann Setser, BSN, MEd
Nurse Consultant, Center for Bioinformatic Technology and Training, National Cancer Institute, National Institutes of Health

This session will provide an update on the status of the Common Terminology Criteria for Adverse Events (CTCAE) revision project and will describe participation of the oncology community, industry, and regulators. The potential impact of Common Terminology Criteria for Adverse Events (CTCAE) revision will also be discussed as well as plans for ongoing Common Terminology Criteria for Adverse Events (CTCAE) governance, maintenance, and MedDRA® compliance. This session discusses the important role that medical coding plays in clinical data management and pharmacovigilance by demonstrating the intricacies and implications involved in assigning the correct code. It explores the challenges imposed by terminology dictionaries and data quality issues on the coding function, as well as how people and organizations have dealt with them.

NCI, Common Terminology Criteria for Adverse Events Revision Project and MedDRA® Compliance
Ann Setser, BSN, MEd
Nurse Consultant, Center for Bioinformatic Technology and Training, National Cancer Institute, National Institutes of Health

Interpreting a Clinician's Verbatim: The Art and Science of Coding in Clinical Trials Using MedDRA®
Marie Lou Munson, MD, MPH
Director, Global Pharmacovigilance and Risk Management, Elan Pharmaceuticals

MedDRA® Integration in the CTCAE Revision Project
Judy E. Harrison, MD
Medical Officer, MedDRA® MSSO

Session 429 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

10:30 am-12:00 pm LEVEL: ■

Room 17A MEZZ.

Design Space: Unique Approaches

SESSION CHAIRPERSON(S)

Richard P. Poska, RPh
Director, Global Pharmaceutical Regulatory Affairs, Abbott Laboratories

Current definitions and concepts will be reviewed as well as approaches that can be taken to clearly communicate the content to the review chemist. We will focus on considerations for the evolution of design space in the future, driving towards leveraging flexibility postapproval.

The NDA CMC Information Transfer Process
Richard P. Poska, RPh
Director, Global Pharmaceutical Regulatory Affairs, Abbott Laboratories

Developments in the Role of Design Space
Fritz Erni, DrSc
Head Technical Liaison, Group Quality Operations, Novartis Pharma AG, Switzerland

The FDA Perspective
Elaine Morefield, PhD
Division Director, Division of Premarketing Assessment II, Office of New Drug Quality Assessment, CDER, FDA

Session 430 CP - Clinical Safety and Pharmacovigilance, EBM/IMP

10:30 am-12:00 pm LEVEL: ●

Room 10

A Registry by Any Other Name

SESSION CHAIRPERSON(S)

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

There is a lack of consensus as to exactly what constitutes a registry. This session will explore similarities and differences between large, streamlined studies, epidemiologic cohort studies, and disease and exposure registries, with examples of the various designs and their rationales.

Risk Mitigation Using Registries
Flora Sandra Siami, MPH
Director, Regulatory Affairs, New England Research Institutes Inc.

Session 431 CR/CS 1 - Clinical Research and Development/Clinical Supplies, EC

10:30 am-12:00 pm LEVEL: ■

Room 6D

Remote Source Document Verification (SDV): Case Studies in Implementation – The Processes Used and Savings Achieved for Pivotal Phase 2 and 3 Trials

SESSION CHAIRPERSON(S)

Penelope K. Manasco, MD, MS
Chief Medical Officer, PharmaVigilant

This session will provide case studies of the implementation of remote source document verification (SDV) for pivotal phase 2 and 3 trials. The presenters will explain the process and deliver the metrics from their unique point of view: sponsors, process implementation, and technology solution provider. The session will provide real data on the metrics and the processes that were successful for this implementation.

Implementation of rSDV for a Phase 3 Study: Benefits and Lessons Learned
Catherine Radovich
Director, Clinical Development, QuatRx Pharmaceuticals

Implementation of rSDV: Process Issues to Optimize Benefits
Achim Reeb, MSc
Managing Partner, PROsys LLC

Implementation of RSD: Implementation and Budget Metrics across Studies
Penelope K. Manasco, MD, MS
Chief Medical Officer, PharmaVigilant

Session 432 CR/CS 2 - Clinical Research and Development/Clinical Supplies, AHC/IS

10:30 am-12:00 pm LEVEL: ■

Room 5B

Investigator Outreach Analysis: Using Performance and Survey Data as Drivers of Investigator Performance

SESSION CHAIRPERSON(S)

Joshua Schultz, MS
Vice President, Clinical Research Services, PAREXEL International

Effective investigators and efficient site selection are among the most critical factors to ensure the success of any clinical trial. Site selection can become a hurdle in designing a clinical trial, and numerous factors must be considered before a site can be chosen. This session will show how using historical investigator performance and self-reported survey data in tandem to select investigators allows for much better performance (fewer investigators or faster achievement of timelines). The first stage of this approach is to collect historical performance data from within the organization. This can involve developing clear descriptions of the type of data required, pulling historical data from previous trials, exchanging data across departmental borders, and cleaning data obtained. While aspects will be unique to each company, some are common across organizations. A case study will be presented of how performance data for 25,000 investigators was collected from IVRS, data management, CTMS, and project manager spreadsheets across four continents.

The second aspect of selecting sites that are most likely to be high performing involves collecting self-reported information from the sites. This requires selecting possible predictive values such as experience or capabilities, implementing a global web-based survey tool to request the selected parameters, contacting investigators to collect data, and collating the data. A case study of a major 40,000-site outreach effort will be presented with response rates by country and general results. Upon collecting both historical data and self-reported data, a process of analysis that brings these together is required. Upon identifying the relevant factors that drive performance, a tool and process must be created that allows this data to be applied to an ever changing list of investigators – across indications and regions. Descriptions of how this can be done will be presented and discussed.

Predicting PI Performance: An Academic/Industry Collaboration
Alex Lancksweert
Director, Business Performance Analytics, GlaxoSmithKline

Selecting Sites: The Sponsor Perspective
Jeff Zucker, MA
Manager, Patient Recruitment Specialist, Clinical Research Operations, Merck & Co., Inc.

Session 433 EC - eClinical, ERS/DM

10:30 am-12:00 pm LEVEL: ◆

Room 15A MEZZ.

Standards Shock Therapy: Monitoring the State of CDISC and HL7 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 (with a particular emphasis on the CDISC content to message project) for representing clinical data for various use cases now and in the future.

The CDISC View of Goals of the CDISC-HL7 Relationship and Projects
David P. Iberson-Hurst
Vice President, Technical Strategy, CDISC

The CDISC-HL7 Project: An FDA Perspective
Armando Oliva, MD
Deputy Director, Bioinformatics, Office of Critical Path Programs, Office of the Commissioner, FDA

Case Study: CDISC HL7 Message
Jason Rock
Chief Technology Officer, GlobalSubmit Inc.

Session 434 ERS/DM - Electronic Regulatory Submissions/Document Management, RA

10:30 am-12:00 pm LEVEL: ■

Room 9

Pursuing Standards to Enhance eCTD Deliverables: Pharmaceutical and Research Manufacturer Association Electronic Regulatory Submissions (PhRMA ERS) Group Annual Update

SESSION CHAIRPERSON(S)

Daniel F. Orfe, MS
Vice President, Global Regulatory Submission Services, Datafarm, Inc.

At the 2008 Annual DIA meeting the Pharmaceutical and Research Manufacturer Association's Electronic Regulatory Submissions (PhRMA ERS) group provided their first annual update on the progress of several key sub-teams involved in the pursuit of standards to facilitate efficient and effective eCTD submission deliveries. This session will provide a status update on two of the teams and a status on another hot-topic PhRMA ERS sub-team also involved with the establishment of eCTD submission efficiencies. An overview on how sponsors can leverage standards and efficiencies for the production and maintenance of Administrative Module eCTD components and Financial Disclosure components will be provided. The technical, process, organizational, and regulatory challenges and benefits associated with these initiatives will be presented.

FDA Division of Drug Marketing, Advertising, and Communications (DDMAC): Pursuing Standards to Enhance eCTD Deliverables
Felicia A. Feldman, BSN
Senior Director, Worldwide Regulatory Operations, Pfizer Inc

FDA Submission Efficiencies: Pursuing Standards to Enhance eCTD Deliverables
Valerie A. Mackner, MS
Senior Manager, Global Regulatory Operations, Wyeth Pharmaceuticals

FDA Financial Disclosure: Pursuing Standards to Enhance eCTD Deliverables
Patricia A. Miller, RN
Manager, Merck & Co., Inc.

Session 435 GCP - Good Clinical Practices, RA

10:30 am-12:00 pm LEVEL: ■

Room 8

Virtual Realities: Quality Considerations when Using Outsource Providers

SESSION CHAIRPERSON(S)

Deborah A. Waltz, MS
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 of FDA expectations for the responsibility of assuring GCP compliance as well as practical steps that can be implemented.

FDA Overview
Cynthia Kleppinger, MD
Medical Officer, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Risk-based Approach to Implementing a Comprehensive GCP Program
Deborah A. Waltz, MS
Senior Director, Scientific Operations Quality, King Pharmaceuticals

Transfer of Obligations Doesn't Mean Transfer of Accountability
Celine M. Clive, MBA
President, Polaris Compliance Consultants, Inc.

Session 436 IT - Information Technology, CP

10:30 am-12:00 pm LEVEL: ■

Room 15B MEZZ.

Breaking Boundaries: Making Sense of Your Data through Collaborative Visualization

SESSION CHAIRPERSON(S)

Robert Gordon, MSc
Biostatistician, Centocor Inc.

Significant research has proven that teams will produce better results than individuals in most situations. It is increasingly more important to be able to rapidly and effectively examine data collectively to communicate the team's decisions. Programs allowing the user to drill down through the datasets without disturbing the integrity of the data represent the cutting edge of data analysis. The ability to work interactively with the data during presentations or meetings only enhances the analysis. This session introduces the user to the process of combining disparate data into an aggregate form and analyzing the data through the use of visualization tools. The advanced capabilities of modern tools enables the user to efficiently create high-powered graphics with drill down capabilities. Decision support and collaborative visualization systems can give teams topsight into their projects and the ability to intuitively and more easily analyze data, allowing earlier detection of problems and more cost-effective solutions. We will explore the steps necessary to develop an interactive, visual environment, allowing the user to effectively drill through graphics with embedded data. During the process, output can be created to manage the evaluation of the data. This session will provide examples of how interactive clinical trials data visualization systems can encourage team awareness and improve management decision making. Facing the existing or impending deluge of data, management teams need these tools and processes that offer rapid, intuitive data exploration and relegate nonvalue-added querying and data administration tasks. Attendees will also participate in the process of drilling through aggregate drug safety data to create a customized case series. The end result will be custom graphics and spreadsheets representing the identified cases of interest.

Increased Team Effectiveness through Information Visualization: An Interactive Environment
Terek Peterson, MBA
Director, Clinical Programming, Octagon Research Solutions Inc.

Using Data Visualization in the Clinical Pharmacovigilance Safety Review Process: A Case Study
Robert Gordon, MSc
Biostatistician, Centocor Inc.

Visualization and Decision Support for Clinical Trial Management
Jason Neiss, MBA, MS
Product Manager, Life Sciences, General Dynamics C4 Systems - Viz

Session 437 NHP - Natural Health Products, CR/CS

10:30 am-12:00 pm LEVEL: ■

Room 17B MEZZ.

Targeted Disease Approach Using Natural Health Products

SESSION CHAIRPERSON(S)

Dagoberto de Castro Brandao, MD
Scientific Board, LARAMARA, Brazil

This session will address the scope of botanical or herbal products targeted for specific diseases such as malaria, diabetes, and cancer.

Natural Health Products in Malaria
Sukanta Aich, DrMed
Consultant Physician, Mount Diagnostic Centre, Bangladesh

Clinical Trials of Natural Health Products in the Management of Type 2 Diabetes Mellitus
Pradeep Visen, PhD
Research Scientist, Risk Factor Modification Centre, St. Michael's Hospital, University of Toronto, Canada

Research and Development of a New Oncological Compound from an Herbal
Dagoberto de Castro Brandao, MD
Scientific Board, LARAMARA, Brazil

Session 438 OS - Outsourcing, RA

10:30 am-12:00 pm LEVEL: ■

Room 5A

Go East, Go West: Outsourcing in Asia

SESSION CHAIRPERSON(S)

Nancy Meyerson-Hess, MSc
Senior Vice President, Project Management International, Omnicare Clinical Research GmbH & Co. KG, Germany

The session will focus on the operational, financial, regulatory, and cultural aspects of undertaking clinical studies in Asia. The positive side of outsourcing in Asia will be presented along with the challenges.

How to Integrate China into International Trials Starting from Protocol Involvement
Yan Wu, MD
Medical and Clinical Development Director, Biogen Idec SRO Inc., China

Strategies for Global Trials: Asia Pacific
Jennifer Carothers, DrSc, PhD, MBA
Associate Director, Clinical Project Management, Ortho-McNeil Janssen Pharmaceuticals, Inc.

A Passage to India Clinical Trials
Jonathan Guerriero, MBA
Director, Product Development, Radius Health Inc.

Session 439 PM/FI 1 - Project Management/ Finance, RD

10:30 am-12:00 pm LEVEL: ■

Room 3 *Project Management units offered*

Global Working Environment Synergy: When an American Team Leader, Japanese Project Manager, and European Team Members Work Together

SESSION CHAIRPERSON(S)

Atsushi Tsukamoto, MSc, PMP
Global Project Manager, Daiichi Sankyo Co., Ltd., Japan

Leadership plays a critical role to manage a multicultural team, and the effective style depends on various factors, such as team culture. This session will review typical challenges, issues, and synergies in a multicultural team related to leadership and management styles. Participants will learn the importance of the styles for better performance.

Big Ears versus Large Antennae: When West and East Work Together
Fred Senatore, MD, PhD, FACC
Executive Director, Clinical Research and Safety, Therapeutic Area Head, Mitsubishi Pharma America, Inc., Japan

Global Project Management: Beyond American, European, and Japanese Project Management
Atsushi Tsukamoto, MSc, PMP
Global Project Manager, Daiichi Sankyo Co., Ltd., Japan

Leading Diverse Teams: Understanding Culturally Informed View of Work Responsibilities
Robert A. Hilke, MA
Senior Consultant, INTEC Japan K.K., Japan

Session 440 PM/FI 2 - Project Management/ Finance

10:30 am-12:00 pm LEVEL: ■

Room 2 *Project Management units offered*

Improving the Business of Science: Process Improvement and Metrics that Matter

SESSION CHAIRPERSON(S)

Eric Lake, MBA
Partner, Pharmica Consulting

This session will discuss why too many companies' process improvement project portfolios are overstuffed and/or do not yield sufficient results. The session will focus on the right questions to ask when considering potential improvement projects and what metrics should be paired alongside them to properly measure success. In addition, the session will go over the basic building blocks needed to put together a compelling business case to justify moving forward with such a project. By helping attendees recognize the key drivers in project selection and prioritization, this session hopes to reduce the number of special projects while improving their impact.

Improving the Business of Science: Metrics that Matter
Eric Lake, MBA
Partner, Pharmica Consulting

Study Startup Process: A Case Study
Sophie Visonneau, PhD
Senior Director, Global Clinical Operations, Biogen Idec

The Use of Metrics between Sponsors and Service Providers to Jointly Improve Clinical Trial Cost, Quality, and Efficiency: The MCC Initiative
Guy Mascaro
President, Metrics Champion Consortium

Session 441 PP - Public Policy/Law, GCP

10:30 am-12:00 pm LEVEL: ■

Room 7A

Human Research Ethics in an Environment of Global Clinical Trials

SESSION CHAIRPERSON(S)

Rafael Duncan Escandon, PhD, MPH, MS
Senior Director, Clinical Operations, Cytokinetics Inc

Globalization of clinical trials, particularly to developing countries, has experienced explosive growth in the past decade. With this growth comes many challenges, perhaps the greatest of which are ethical ones. This session explores the long-term commitments sponsors must be willing to make to trial participants and investigators to conduct clinical research in the developing world.

Global Health Initiatives: Forging Partnerships that Work!
Libbie J. Mansell, PhD, MBA
President, White Oak BioPharma Solutions, LLC

Evolving Landscape of Clinical Trials and Ethics in India
Mohanish Anand, PhD, MS, MSc
Head, Clinical Research, Pfizer Limited, India

Session 442 RA 1 - Regulatory Affairs, CR/CS

10:30 am-12:00 pm LEVEL: ●

Room 6AB

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.

One of the many DIA Annual Meeting program highlights is the CDER Town Meeting, Parts 1 and 2. Join leaders from the US FDA's Center for Drug Evaluation and Research in this interactive session where members of the audience may submit questions to this highly distinguished panel of senior leaders. Topics to be discussed will be determined by the interests of the audience.

Questions may also be submitted in advance; please email *2009program@diahome.org* using the subject line: Questions for CDER Town Meeting.

Gerald J. Dal Pan, MD, MPH
Director, Office of Surveillance and Epidemiology, CDER, FDA

Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

Sandra L. Kweder, MD
Deputy Director, Office of New Drugs, CDER, FDA

Justina A. Molzon, JD, MPharm
Associate Director for International Programs, CDER, FDA

Theresa M. Mullin, PhD
Associate Director for Planning and Informatics, Office of the Director, CDER, FDA

Julie Anne Zawisza, MA
Director, Office of Communications, CDER, FDA

Session 443 RA 2 - Regulatory Affairs, CP

10:30 am-12:00 pm LEVEL: ●

Room 7B

Pregnancy and Lactation Labeling: The Past, Present, and Future

SESSION CHAIRPERSON(S)

Richardae Araojo, PharmD
Regulatory Reviewer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

On May 29, 2008, the FDA published the proposed Pregnancy and Lactation Labeling Rule. The proposed Rule will amend current regulations on the format and content of the Pregnancy, Labor and Delivery, and Nursing Mothers subsections of labeling. This session will describe how the proposed rule will impact labeling.

Historical Overview of Pregnancy and Lactation Labeling
Leyla Sahin, MD
Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

Major Elements of the Proposed Rule for Pregnancy and Lactation Labeling
Richardae Araojo, PharmD
Regulatory Reviewer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

Summary of Major Comments on the Proposed Rule for Pregnancy and Lactation Labeling
Tammie Howard, BSN, MSN, RN
Regulatory Reviewer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

Session 444 ST - Statistics, EC

10:30 am-12:00 pm LEVEL: ■

Room 16A MEZZ.

What Statisticians Need to Know about CDISC

SESSION CHAIRPERSON(S)

Cathleen F. Barrows, PhD
Statistics and Programming, Neurosciences MDC, GlaxoSmithKline

A key contribution made by statisticians in producing a CDISC-adherent submission is the design of analysis datasets and associated metadata. The CDISC Analysis Data Model (ADaM) is intended to provide a framework that enables reviewers to have a clear understanding of the analysis datasets and analysis results provided in a submission. Speakers will highlight key aspects and advantages of implementing ADaM, including the ADaM Implementation Guide and the use of the ADaM basic structure, the use of the ADaM AE model, and what it means to incorporate traceability and transparency.

The ADaM Basic Data Structure
John Troxell, MS
Associate Director, Scientific Programming, Merck & Co., Inc.

Beyond the ADaM Basic Data Structure: ADSL and ADAE as Special Purpose Analysis Datasets
Shantha S. Rao, PhD
Senior Manager, Biostatistics, sanofi-aventis

Traceability and Transparency: Essential Components in an eSubmission
Stephen E. Wilson, DrPH
Director, Division of Biometrics III, CDER, FDA

Session 445 TR/PD - Training/Professional Development

10:30 am-12:00 pm LEVEL: ●

Room 16B MEZZ.

Presenting ... YOU! Tips, Tricks, and Advice on Making You and Your Presentations Unforgettable

SESSION CHAIRPERSON(S)

Lauren Edelstein-Henry, MEd
Lead Process Support Specialist, Johnson & Johnson

Create and deliver more effective and enjoyable PowerPoint presentations.

PowerPoint Presentations that Pop! Proper Design = Powerful Presentations
Lauren Edelstein-Henry, MEd
Lead Process Support Specialist, Johnson & Johnson

Freedom of Speech: Public Speaking Skills that Make People Listen
Donna Walsh
President, RedShoes Solutions

D'oh! Stupid Things Speakers Do to Sabotage Success
Theresa Hummel-Krallinger
Director, Organizational Development and Training, Almac Clinical Technologies

Session 446 VA - Validation, GCP

10:30 am-12:00 pm LEVEL: ■

Room 11A

Unique Validation Challenges in the Clinical Area

SESSION CHAIRPERSON(S)

Richard L. Chamberlain, PhD, MS
President, ECS Inc.

Many of the computer systems being implemented in the clinical research area try to take advantage of new technologies that use the Internet for processing data, handheld computers for collecting patient data, and information systems that try to take advantage of data already collected, and so on. These new technologies sometimes raise difficult questions that become part of the problems when validating these systems for use. The speakers will raise some of these issues and where possible at least discuss some of the alternatives and the pros and cons of each.

Validation Challenges Using PDAs for PRO
Jean Paty, PhD, MS
Founder and Senior Vice President, Scientific, Quality, and Regulatory Affairs, invivodata inc

12:00 pm **END OF THURSDAY SESSIONS**
ANNUAL MEETING ADJOURNED

12:30 pm-5:00 pm **MedDRA® USER GROUP MEETING**
Room 6C

Exhibiting Companies

AAIPharma	Booth 445
Abingdon Life Sciences, Inc.	Booth 2034
Abroms & May Associates LLC	Booth 2239
Accelovance	Booth 745
Accovion GmbH	Booth 2017
ACM Global Central Laboratory	Booth 726
ACORN CRO	Booth 2039
ACR Image Metrix	Booth 212
ACRONET Corporation	Booth 1040
Acurian	Booth 1633
Adlib Software	Booth 2241
Adobe Systems	Booth 2348
Advanced Biomedical Research – see Frontage	Booth 1339
Advanced Clinical Research Institute	Booth 316
Aerotek Scientific, LLC	Booth 1607
Akaza Research	Booth 2230
Akos Ltd	Booth 2043
Alamo Medical Research	Booth 1723
Algorithme Pharma Inc.	Booth 632
ALMAC	Booth 1301
Ambry Genetics	Booth 2047
AmeRuss Clinical Trials	Booth 1747
Ann Arbor Bio Research, LLC	Booth 1450
Apothecaries Private Limited	Booth 1721
Applied Clinical Trials	Booth 1835
Aptuit, Inc	Booth 1606
Apyx, Inc.	Booth 1423
Archimedes, Inc.	Booth 2105
Argutus Medical	Booth 2214
Aris Global LLC	Booth 521
Ashuren Health Sciences	Booth 2126
Asian Clinical Trials	Booth 1838
ASKA Research	Booth 1326
ASKLEP Inc.	Booth 1335
Aspire IRB	Booth 314
The Association of Clinical Research Organizations (ACRO)	Booth 1934
Astellas US LLC	Booth 1646
Asuragen, Inc.	Booth 1932
Atlantic Research Group	Booth 2103
Averion International Corp.	Booth 845
Avrio Biopharmaceuticals	Booth 844
Axiom Real-Time Metrics, Inc.	Booth 139
Azopharma Product Development Group	Booth 1421
BARC Global Central Laboratory	Booth 1903
BBK Worldwide	Booth 1221
Beardsworth, a full-service CRO	Booth 300
Beckloff Associates, Inc.	Booth 220
Bilcare Global Clinical Supplies	Booth 500
Bio-Imaging Technologies, Inc. – see BioClinica Inc.	Booth 315
Bio-Optronics, Inc	Booth 1647
BioClinica Inc.	Booth 315
BioKinetic Europe Ltd	Booth 1306
Biomedical Systems	Booth 539
BioPharm Insight	Booth 544
BioPhase Solutions	Booth 2151
BioPier Inc.	Booth 129
BioResearch Monitors, Inc.	Booth 1613
Bioserve Clinical Research (P) Ltd	Booth 646
bioskin GmbH	Booth 1503
BioSoteria	Booth 1439
BioStorage Technologies	Booth 1821
Biotec Services International Limited	Booth 1233
Bostwick Scientific, a Division of Bostwick Laboratories	Booth 2141
Brand Institute, inc.	Booth 1743
Brecon Pharmaceuticals Ltd	Booth 2147
C3i Inc	Booth 1830
Camargo Pharmaceutical Services	Booth 207
The Cambridge Group Ltd	Booth 734
Canon Communications Pharmaceutical Media Group	Booth 415
CanReg Inc	Booth 2101
Cardinal Health Research Services	Booth 833
Cardiocore	Booth 1601
CardioDynamics	Booth 951
Catalent	Booth 1349
CDISC	Booth 1915
CEDRA Corporation	Booth 2031
Center for Drug Evaluation, Taiwan	Booth 907
CenterWatch	Booth 324
Centrical	Booth 846
Cerner LifeSciences	Booth 1931
Cetero Research	Booth 1001

Charles River Clinical Services	Booth 1731
Chesapeake Research Review, Inc.	Booth 2143
Chiltern	Booth 203
Christiana Care Research Institute	Booth 1925
Cincinnati Children's Research Foundation	Booth 1317
CIRION Clinical Trial Services Inc.	Booth 2107
ClearTrial	Booth 2224
ClinAudits, LLC	Booth 2030
ClinDatrix, Inc.	Booth 1222
ClinForce, LLC	Booth 1201
Clinical Financial Services	Booth 547
Clinical Network Services	Booth 1327
Clinical Reference Laboratory	Booth 1725
Clinical Research Advantage	Booth 1434
Clinical Research Centre	Booth 2142
Clinical Resource Network	Booth 1046
The Clinical Resource Network	Booth 201
Clinical Site Services	Booth 2123
The Clinical Trial Company Ltd.	Booth 2021
Clinical Trial Media	Booth 1017
Clinilabs Inc.	Booth 715
Clinimetrics	Booth 1345
clinIT AG	Booth 1147
Clinlogix, LLC	Booth 1940
ClinOps	Booth 627
ClinPhone – see Perceptive Informatics	Booth 1707
ClinResearch GmbH, Addplan GmbH	Booth 332
Clinsys Clinical Research	Booth 101
ClinTec International	Booth 225
CMAX, a Division of IDT Australia Limited	Booth 1604
CMIC	Booths 1824, 1825
CMM Global	Booth 2120
Cognizant Technology Solutions	Booth 211
Community Research	Booth 1333
Compass IRB	Booth 1220
Compliance Implementation Services	Booth 2242
COMSYS Life Sciences	Booth 312
Concepts Worldwide, Inc.	Booth 629
Contact Canada	Booth 1631
Contract Pharma	Booth 1346
Copernicus Group IRB	Booths 1847, 1930
Corporate Translations	Booth 2222
Court Square Group	Booth 1050
Covance Inc.	Booth 1515
CPR Pharma Services	Booth 2216
CRF Health	Booth 1007
CRID Pharma	Booth 1923
CROM Srl	Booth 2220
Crown CRO Oy	Booth 607
CSC	Booth 939
CSM	Booth 2149
CTI Clinical Trial and Consulting Services	Booth 1331
Cu-Tech, LLC	Booth 1322
Cytel Inc.	Booth 2025
DataCeutics, Inc	Booth 1409
Datafarm Inc.	Booth 1900
Datapharm Australia	Booth 1820
DATATRAK International	Booth 1525
Datatrial, Limited	Booth 603
DaVita Clinical Research	Booth 516
Delta Pharma	Booth 1832
Distributed Compliance Solutions LLC	Booth 1051
Drug Safety Alliance, Inc.	Booth 1815
DrugLogic, Inc.	Booth 120
DSG, Inc.	Booth 501
DUCK FLATS Pharma	Booth 1142
Duke Clinical Research Institute	Booth 915
DZS Software Solutions, Inc.	Booth 1024
EBSCO Publishing	Booth 2140
eCast Corporation – CT Select	Booth 1338
eClinical Solutions, A Division of Eliassen Group	Booth 1209
ECRFPlus, Inc.	Booth 117
ECRON ACUNOVA	Booth 1516
Edinger Medical Group and Research Center	Booth 2223
Elite Research Institute	Booth 2225
Elite Research Network	Booth 1817
Elsevier	Booth 529
EMB Statistical Solutions, LLC	Booth 125
ENNOV/CLINSIGHT	Booth 2135
Entimo AG	Booth 1128
ePharmaSolutions	Booth 1712
EPS Co., Ltd.	Booth 2338
ERT	Booth 507
Esoterix Clinical Trials	Booth 1006
Essential Group, Inc.	Booth 704

etrials Worldwide, Inc.	Booth 1321
Eurofins Medinet	Booth 1002
European Medicines Agency (EMEA)	Booth 903
Eurotrials	Booth 1926
Excel Life Sciences Inc	Booth 1227
Excel PharmaStudies Inc	Booth 239
Exco InTouch	Booth 1039
ExecuPharm, Inc	Booth 1538
EXTEDO, Inc	Booth 2346
Falcon Consulting Group, LLC	Booth 2133
Fast4wD Ogilvy	Booth 1746
FDA Center for Drug Evaluation & Research	Booth 901
Federation of Indian Chambers of Commerce & Industry	Booth 611
FGK Clinical Research GmbH	Booth 702
Fleury Medicine and Health	Booth 1416
Foresight Group LLC	Booth 747
Formedix	Booth 2032
Frontage	Booth 1339
Galderma Research & Development, Inc.	Booth 1013
General Dynamics C4S	Booth 224
The Geneva Foundation	Booth 113
Global Language Solutions	Booth 231
Global Languages & Cultures, Inc.	Booth 1948
Global Research Services, LLC	Booth 2227
GlobalSubmit, Inc.	Booth 923
Good Products LLC	Booth 1043
Goodwyn IRB	Booth 1427
greenphire	Booth 1846
Greenway Medical Technologies	Booth 2015
GroupNet Research Sites	Booth 310
GVK Biosciences Private Limited	Booth 611
Harrison Clinical Research	Booth 1330
Hawaii Clinical Research Center	Booth 2235
Health Decisions	Booth 1447
Health Market Science	Booth 100
Health Products and Food Branch, Health Canada	Booth 913
Healthcare Communications Group	Booth 1313
HungaroTrial CRO	Booth 1546
Hurley Consulting Associates, LTD	Booth 1732
i3	Booth 107
i4i Inc.	Booth 121
IBERICA USA, Inc.	Booth 106
ICON plc	Booth 1307
ICRI Global Research	Booth 1831
Idem Translations, Inc.	Booth 1231
IDIS	Booth 235
IMIC – Mexican Institute of Clinical Research	Booth 230
Impact Clinical Trials	Booth 1340
Imperial Clinical Research Services, Inc.	Booth 1500
Inamed Research GmbH & Co. KG	Booth 2326
INC Research	Booth 645
Inclinix, Inc.	Booth 1430
Indegene Pharmaceutical Solutions, Inc.	Booth 251
IndiPharm Inc	Booth 514
Integrated Clinical Systems, Inc	Booth 221
IntegReview Ethical Review Board	Booth 1508
Integrium	Booth 407
International Dermatology Research, Inc.	Booth 2026
Intrasphere Technologies	Booth 927
inVentiv Clinical Solutions	Booth 621
Investigative Clinical Research	Booth 1151
Investigator Support Services	Booth 1121
invivodata, inc.	Booth 1706
IRB Services	Booth 1316
IRBCo	Booth 1645
ISI	Booth 851
Italian Early Phase Studies Network	Booth 1841
Italian Medicines Agency	Booth 1014
IXICO Ltd.	Booth 244
J&S Studies, Inc.	Booth 1529
JANIX	Booth 2202
Jean Brown Research	Booth 2306
Johnson & Johnson	Booth 216
Joulé Clinical Staffing Solutions	Booth 1444
Kansas Bioscience Authority	Booth 1412
Kayentis	Booth 943
Kelly Scientific Resources	Booth 1845
Kendle	Booth 439
Kforce Clinical Research	Booth 1801
KGK Synergize Inc.	Booth 240
Kika Clinical Solutions	Booth 1247
Kinapse, Inc.	Booth 2238
Klein Management Systems	Booth 1602
KoNECT	Booth 1012

LabConnect, LLC	Booth 2131
Laboratorio Hidalgo	Booth 2023
Lernia Training Solutions	Booth 630
Lifetree Clinical Research	Booth 2115
Lionbridge	Booth 730
Logos Technologies	Booth 1401
LORENZ Life Sciences Group	Booth 304
Lotus Labs Pvt. Ltd.	Booth 1514
Lovelace Scientific Resources, Inc.	Booth 2005
M2S, Inc.	Booth 1004
Maaguzi	Booth 1114
MAJARO InfoSystems, Inc.	Booth 1038
MakroCare	Booth 2240
Malvern Consulting Group	Booth 2150
Marken Ltd.	Booth 1025
Massachusetts College of Pharmacy and Health Sciences	Booth 1641
MaxisIT Inc.	Booth 1140
McElroy Translation	Booth 1342
McGuire Research Institute	Booth 1138
MDS Pharma Services	Booth 721
MedAvante, Inc.	Booth 1822
MedDRA® MSSO	Booth 1921
MedFocus LLC	Booth 720
MEDGRAPHICS Clinical Research	Booth 1225
Medical Research Network Ltd	Booth 2302
Medidata Solutions Worldwide	Booth 701
Medifacts International	Booth 2125
MedNet Solutions	Booth 431
Medpace	Booth 2122
MedPoint Communications, Inc.	Booth 751
MedQIA	Booth 2148
MedSource	Booth 1415
MEDTOX Laboratories, Inc.	Booth 1912
MedTrials, Inc.	Booth 2114
MedXview Inc.	Booth 1451
MESM Ltd.	Booth 246
META Solutions Inc.	Booth 635
MetaClin Research, Inc.	Booth 1639
Metastorm Inc.	Booth 1540
Metropolitan Research Associates	Booth 1600
Mi-Co	Booth 2213
Microsoft Corporation	Booth 931
Microsystems	Booth 1446
Mid*Lands IRB	Booth 1241
Millennium Pharmaceuticals	Booth 2138
Missouri Biotechnology Association	Booth 1246
MMG	Booth 1624
MNX Global LifeSciences Logistics	Booth 1924
Monitorforhire.com	Booth 601
Moonbay Technology	Booth 2041
Mortara Instrument	Booth 234
MPI Research	Booth 2112
MSOURCE Medical Development	Booth 2300
National Death Index	Booth 2104
National Taiwan University, National Clinical Trial and Research Center	Booth 909
NeoGenomics Clinical Trial Services	Booth 1848
New England IRB	Booth 1015
New England Research Institutes, Inc. (NERI)	Booth 1507
New Orleans Center for Clinical Research	Booth 2233
NewCardio, Inc.	Booth 238
NextDocs	Booth 1033
Nextrials, Inc.	Booth 1302
Northrop Grumman Corporation	Booth 1545
Novotech	Booth 1332
nSpire Health, Inc.	Booth 1425
NSW Clinical Trials Business Development Centre	Booth 1615
OBS Medical	Booth 1649
OCASA Logistics Solutions	Booth 2332
Octagon Research Solutions, Inc.	Booth 513
Odyssey Research	Booth 644
Omnicare Clinical Research	Booth 639
Omnicia Inc.	Booth 1730
OmniComm Systems, Inc.	Booth 245
On Assignment Clinical Research	Booth 2247
Online Business Applications, Inc.	Booth 2102
Open Text Corporation	Booth 2024
Opus Regulatory, Inc.	Booth 1839
Oracle	Booth 421
Orlando Clinical Research Center	Booth 1308
Outcome	Booth 1504
Oxford Outcomes Ltd	Booth 2221
Pacific Biometrics, Inc.	Booth 2121
Pacific Data Designs – see ClinOps	Booth 627
Palm Beach CRO	Booth 2139

Paragon Biomedical, Inc.	Booth 839
Paragon International, Inc.	Booth 215
PAREXEL International	Booth 1701
Patheon	Booth 1414
The Patient Recruiting Agency	Booth 1739
Penn Pharma	Booth 1020
Perceptive Informatics	Booth 1707
Pharm-Olam International	Booth 1738
Pharmaceutical Executive	Booth 1833
Pharmaceuticals and Medical Devices Agency (PMDA)	Booth 905
PharmaLinkFHI	Booth 2314
PharmaNet Development Group Inc.	Booths 320, 321
PharmaSeek	Booth 510
PharmaSys Inc	Booth 1112
PharmaTimes	Booth 1123
PharmaVigilant Inc.	Booth 2205
PharmaVOICE	Booth 1300
Phase Forward	Booth 729
Philips Respironics	Booth 2113
Phoenix Data Designs – see BioClinica Inc.	Booth 315
Phoenix Software International	Booth 512
PHT Corporation	Booths 1124, 1125
PII – Pharmaceutics International, Inc.	Booth 1314
Placemart Personnel Service	Booth 2212
PleaseTech Ltd	Booth 1916
PPD	Booth 546
PRA International	Booth 811
Precept Life Sciences, LLC	Booth 2342
Precision Trials, LLC	Booth 545
Premier Research Group Ltd.	Booth 827
PRL Central Laboratory Services	Booth 2001
Profil Institute for Clinical Research	Booth 2231
Prologue – The Oncology CRO	Booth 1935
PROMETRIKA, LLC	Booth 1551
ProSanos Corporation	Booth 222
PROSAR	Booth 1520
ProTrials Research, Inc.	Booth 1215
PSI	Booth 2201
PSI International, Inc.	Booth 2330
QPharma	Booth 949
QPS LLC	Booth 1122
Quality and Compliance Consulting, Inc.	Booth 1000
Quality Associates, Inc.	Booth 1914
QualityMetric Incorporated	Booth 1106
Quanticate	Booth 2204
Queensland Clinical Trials Network Inc. (QCTN)	Booth 1329
Quest Diagnostics Clinical Trials	Booth 504
Quintiles	Booth 329
QUMAS	Booth 2002
Quorum Review IRB	Booth 227
Radiant Research, Inc.	Booth 1904
RadPharm Inc	Booth 1312
RCRC Independent Review Board	Booth 1441
Recruitech International	Booth 411
Reed Technology	Booth 2334
REGISTRAT – MAPI, Inc.	Booth 1521
Reliance Clinical Research Services	Booth 611
Relsys International, Inc.	Booth 1621
Research & Development RA SA	Booth 947
Research Across America	Booth 2013
ResearchPoint	Booth 1626
Rho, Inc	Booth 1905
Roche	Booth 217
RPS, Inc.	Booths 1713, 1714
The RRI Group of Companies	Booth 1849
Rx Trials, Inc	Booth 925
S-Clinica	Booth 1049
sanofi-aventis	Booth 102
SAS Institute Inc.	Booth 301
Schlafender Hase GmbH	Booth 1942
Schulman Associates IRB, Inc.	Booth 1908
SDL	Booth 2243
SEC Associates, Inc.	Booth 1512
Sensitech Inc.	Booth 1432
Sentrx	Booth 2232
SGS Life Science Services	Booth 1115
SIRO ClinPharmUSA	Booth 2246
Sitrof Technologies, Inc.	Booth 108
Small Planet Meetings Ltd	Booth 1047
Smart Trials CRO	Booth 110
Smith Hanley Consulting Group	Booth 722
SNBL-CPC	Booth 401
Sonic Clinical Trials	Booth 116
SpaceLabs Healthcare Clinical Trial Services	Booth 1205

Sparta Systems, Inc.	Booth 1901
speakTECH	Booth 1549
Spectra Clinical Research	Booth 1805
SRA International	Booth 2020
SRG Woolf Group	Booth 2007
Stat-Tech Services, LLC	Booth 2146
STATKING Consulting, Inc.	Booth 2200
StatWorks, Inc.	Booth 2100
SterlingBio	Booth 1748
Sticares InterACT bv	Booth 1749
Stiris Research Inc.	Booth 1809
Strata	Booth 921
Streck, Inc.	Booth 2106
Super Religare Laboratories Limited	Booth 2250
Symbio LLC	Booth 1644
Synchron Research Services Private Limited	Booth 611
Synergy Research Centers	Booth 228
Synteract	Booth 700
Systems Technology, Inc.	Booth 1745
t+ Clinical	Booth 2312
TAKE Solutions Inc.	Booth 2251
Tandem Labs	Booth 1008
Target Health Inc.	Booth 2322
Tarius A/S	Booth 213
TechTeam Global	Booth 2209
Teradata	Booth 1348
TFS Trial Form Support	Booth 1148
TGen Drug Development Services (TD2)	Booth 2308
Therapak Corporation	Booth 1524
ThesIS (Thesaurus Information and Strategies, Inc.)	Booth 1239
Thompson Publishing Group	Booth 1548
Thomson Reuters	Booth 821
TIBCO Spotfire	Booth 2051
TKL Research, Inc.	Booth 1413
TNT Express	Booth 1742
Total IRB	Booth 1550
Total Root Concepts, Inc.	Booth 1048
TranSenda International, LLC	Booth 1027
TransPerfect, Inc.	Booth 1431
Trial Management Group Inc	Booth 1320
Trident Clinical Research	Booth 1617
Trio Clinical Research	Booth 2004
TTC,llc	Booth 2215
United BioSource Corporation	Booth 1101
University Clinical Research DeLand, LLC	Booth 1213
University of Florida, Center for Clinical Trials Research	Booth 417
The University of Iowa Pharmaceuticals	Booth 330
University of Rochester – Clinical Materials Services Unit	Booth 533
University of Rochester – URMC LABS	Booth 535
University of the Sciences in Philadelphia, College of Graduate Studies	Booth 1448
the Uppsala Monitoirng Centre	Booth 1224
VA Cooperative Studies Program	Booth 1522
Veeda Oncology	Booth 1405
Velos, Inc.	Booth 1840
Veridex, LLC	Booth 2249
Veristat, Inc.	Booth 628
Vince & Associates Clinical Research	Booth 1243
Virtify Inc	Booth 403
Virtual Clinical Solutions, Inc.	Booth 1643
VirtualScopics, Inc.	Booth 631
VisualShare, Inc.	Booth 322
Vitalograph	Booth 1813
Waban Software	Booth 2000
WCI Consulting Limited	Booth 1938
WebbWrites, LLC	Booth 1235
WebtrialZ by APT	Booth 2049
WebWise Learning, Inc.	Booth 232
West Coast Clinical Trials, LLC	Booth 2108
Wiley-Blackwell	Booth 1428
Wolters Kluwer Health	Booth 1842
Wolters Kluwer Health – Lippincott Williams & Wilkins	Booth 1946
Woodley Equipment Company Ltd	Booth 1120
World Courier, Inc.	Booth 1533
WorldCare Clinical, LLC	Booth 1501
Worldwide Clinical Research	Booth 1920
XClinical GmbH	Booth 1426
XERIMIS INC.	Booth 1021
XTrials Research	Booth 1146

Almac

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 integrated suite of technologies includes Interactive Voice and Web Response (IXRS™) for patient tracking, randomization and inventory management, iTrial EDC™ for on-line only and on-line / off-line electronic data capture, and iDiary, our electronic phone and web-based patient diary solution. 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)
- EDC (Electronic Data Capture)
- Biostatistical Services
- Adaptive Trial Design
- Data Integration
- Clinical Hotline
- Web Drug Reconciliation

Our clinical trial supply solutions:

- Clinical trial supplies management
- Web-based randomization via WebEZ™
- 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**

BioSoteria, Inc.

BioSoteria, a drug safety consulting company with headquarters in San Bruno, California, provides high quality drug safety consultant services and innovative educational programs to the biopharmaceutical and healthcare community.

SAFETY CONSULTING SERVICES

We offer a **wide range of safety consulting services:**

- ✓ Premarketing clinical safety and postmarketing pharmacovigilance
- ✓ Therapeutic risk management, including REMS and RMP
- ✓ Safety regulation compliance assessment and inspection preparedness
- ✓ Safety department infrastructure and SOP development
- ✓ Safety signal detection and analyses
- ✓ Labeling and Core Data Sheets
- ✓ NDA, BLA, and MAA safety medical writing and analysis

TRAINING AND EDUCATION

BioSoteria has recently launched ***eLadder™ Safety***, a first-of-its-kind, multimedia eLearning training course series in drug safety and pharmacovigilance. Courses in BioSoteria's engaging, online ***eLadder™ Safety*** eLearning Program are:

- ✓ **The only commercially available online *curriculum* in drug safety**
- ✓ **Developed by an experienced multidisciplinary team** of subject-matter experts, eLearning instructional designers, graphic designers, animators, programmers, and learning management/curriculum specialists
- ✓ **Comprehensive, content-rich,** and **truly multimedia**
- ✓ **Self-paced, engaging,** and **easy to navigate**
- ✓ Conveniently **available immediately** through the Internet
- ✓ Available **off-the-shelf** for rapid-deployment drug safety training
- ✓ **AICC/SCORM-compliant** and ready to run on a corporation's Learning Management System (LMS) or on BioSoteria's hosted LMS solution

***eLadder™ Safety* Core Series:**

- ✓ Course 1: Drug and Device Development and Regulation
- ✓ Course 2: Clinical Safety Surveillance
- ✓ Course 3: Postmarketing Pharmacovigilance
- ✓ Course 4: Premarket Annual Safety Reports
- ✓ Course 5: Postmarket Periodic Safety Reports
- ✓ Course 6: MedDRA and WHODRUG Coding

Courses on the following **Advanced Topics** also in development:

- ✓ Safety Signal Detection and Risk Assessment
- ✓ Product Safety Labeling and Core Safety Information
- ✓ Drug Safety Data Management
- ✓ Therapeutic Risk Management
- ✓ Introduction to Pharmacoepidemiology
- ✓ Compliance and Regulatory Inspections

Together, the core series and advanced courses of the ***eLadder™ Safety*** curriculum form a cohesive training program with one course building on another, thereby offering the learner continuity in their study of drug safety and a comprehensive program built on a solid instructional design to produce measurable performance results.

For more information about **BioSoteria** consulting services or our ***eLadder™ Safety*** training course series, please visit our website at www.biosoteria.com and contact us at 1.866.660.5553 or email contact@biosoteria.com.

CEDRA Corporation

CEDRA Corporation offers a full range of Phase I-IV clinical research and bioanalytical services as well as specialized studies to determine the effects of dose, formulation, dosing regimen, drug interactions, genotype, gender, and other factors on pharmacokinetics. We provide expert advice on everything from protocol development to regulatory submission.

Clinical Site Services

CEDRA operates two state-of-the-art clinical sites in Austin and San Antonio, Texas with a capacity of over 300 beds and the flexibility to conduct 1-patient to 200-patient studies – carefully supervised by full-time physicians and staff. On-site clinical laboratory, medical technologists and pharmacists are also available for each client's laboratory and pharmaceutical needs.

Additional Clinical Development Services

To complete our full clinical package, we offer protocol design, QA services, statistical/pharmacokinetic analysis (WinNonlin & SAS), project management and report writing. When your trials require a global reach, CEDRA works through our parent corporation, Worldwide Clinical Trials (WCT), a leading provider of international contract clinical research services. With WCT, we can provide protocol design, database management, clinical monitoring and drug development strategies.

Pharmacokinetic Services

We offer the services you need, including pharmacokinetic and pharmacokinetic/pharmacodynamic modeling; bioequivalence and bioavailability testing; and clinical and preclinical pharmacokinetics/toxicokinetics.

Bioanalytical Services

At the backbone of our analytical capabilities is experience stretching back to 1990 and a library of more than 1300 validated methods. Our laboratories are fully GLP-compliant, and are committed to quality and accuracy, even on high-volume, fast turnaround projects. With extensive use of laboratory automation and numerous LC-MS/MS instruments dedicated to sample analysis, CEDRA can analyze approximately 50,000 samples per month to help meet your deadlines.

Immunoassay Services

Our Ligand Binding Assay (LBA) Laboratory complements our small molecule bioanalysis, pharmacokinetic modeling, and clinical trial management services. The ligand binding technique allows us to support biological therapeutic, preclinical and clinical pharmacokinetic programs, as well as biomarker and immunogenicity studies.

In the end, the difference between CEDRA Corporation and many CROs comes down to one of commitment. At CEDRA, we are committed to thorough study design, meticulous execution and painstaking reporting; we are committed to high-efficiency methods and processes that ensure accurate results, on time, every time. Our commitment to our clients enables us to provide a fully customizable package using any combination of the services CEDRA offers – the type of commitment that builds long-term relationships based on trust and consistent performance.

Contact CEDRA Corporation

8609 Cross Park Drive, Austin, TX 78754, Tel: 512-834-7766, Fax: 512-834-1165
email: info@cedracorp.com / web: www.cedracorp.com

CEDRA's Contract Research Services: Our Commitment to Our Client.

CT Renaissance™

An Agile Perspective

REAL-TIME HARMONIZATION OF COMPOSITE CLINICAL TRIALS

The existing Clinical Trial Software landscape suffers from a glaring lack of a single, holistic software solution that provides the requisite end-to-end functionality. Instead, each of the existing software in the industry provides point solutions with limited and often overlapping functionalities with no clear integration roadmap. Not only do these modules have no clear guidelines for reuse and interoperability – they lead to a proliferation of technology stacks and hence negatively impact infrastructure costs.

With the advent of CDISC based standardization and a strong need for interoperability, it becomes imperative that clinical trial software applications communicate in real-time in a harmonized fashion. The solutions – integrate and orchestrate via point-to-point interfaces or **ONE ENTERPRISE-SCALE SOFTWARE SUITE** that provides end-to-end functionalities and also facilitates deliverables generation with the required interoperability, reusability, and scalability.

CT Renaissance™, enterprise-class completely integrated and automated software suite for clinical trials, offers the most efficient, web-based software solutions that involve no IT footprint at the point of use and captures all the regulatory requirements are available at the most competitive investment that guarantees return.

As simple as using a web-based email account, this software-as-a-service oriented, internet solution helps MaxisIT's small to large customers worldwide manage their clinical trials and produce clinical deliverables ranging from protocol to eCTD – anytime, anywhere, on-demand. All the functional processes are integrated and automated based on industry standards, reusable meta-data and parameter driven processes. These services oriented web-based software solutions provide the means to accommodate multiple trials and global user-base in parallel, role-based, secured and collaborative work-environment.

CT Renaissance™ helps realize significant time and cost savings through standardized, streamlined and reusable infrastructure requiring minimum user intervention. It facilitates real-time monitoring of clinical trials enabling faster competitive business decisions with the help of its built-in business process monitoring and reporting system.

With the help of *CT Renaissance*™, our customers are able to focus on core research, constantly innovate and scale-up, make faster deliverables and smarter business decisions. *CT Renaissance*™ gives our customers *"The power to grow"*.

CT Renaissance™ **Software Solutions**

Available as an independent software solution and as an integral part of *CT Renaissance*™

1. **Clinical Trial Business Process Manager:** Management of *Trial* | *Site* | *Drug Inventory* | *Finance* | *Enterprise*
2. **Patient Randomization**
3. **Samples Size Determination**
4. **Collaborative Document Writing, Reviewing and Tracking:** Standardized yet customizable templates of Protocol | SAP | CSR | SOPs | Investigator Brochure | CRF | Other Medical writing
5. **Clinical Data Management:** Medical Coding | SDTM Validation | Data Mapping | DEFINE.xml
6. **Clinical Data Analysis and Reports Development:** Utilizing web-based wizard driven interfaces, automated batch and/or real-time production of:
   a. Pre-clinical safety reports
   b. Interim analysis and reporting
   c. Clinical data viewing and ad-hoc reporting
   d. Clinical efficacy and safety analysis and reports
   e. Patient profiles
   f. Non-clinical reports
   g. Progress monitoring Reports
7. **Enterprise Repository:** Electronic *Documents* | *Content* | *Metadata* Management
8. **Electronic Submission:** eCTD, RPS, Multi-Region
9. **Structured Product Labeling:** Support to SPL 4.0
10. **Business Process Engine:** Clinical Trial Business Process Designer, Process Integrator and business rules definition in a web-based environment
11. **Integration Adapters**

VISIT MAXISIT INC. AT 45TH DIA ANNUAL MEETING AT BOOTH # 1140

Contact our product specialist for more information: MaxisIT, Inc. 203 Main Street, Metuchen, NJ 08840,
Ph. (877) MAXISIT (629-4748) Toll free | Ph. 732-494-2005 ext.101 Direct | Fax. 732-875-0884
Email. ctrenaissance@maxisit.com | Web. www.maxisit.com

ICON

ICON plc is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. The company specializes in the strategic development, management and analysis of programs that support clinical development – from compound selection to Phase I-IV clinical studies. ICON has the operational flexibility to prvide development services on a stand-alone basis or as part of a full-service solution. With headquarters in Dublin, Ireland, ICON currently has over 6,800 employees, operating from 71 locations in 38 countries.

ICON's extensive full-service portfolio spans the entire lifecycle of product development, can be adapted to suit small local trials or large global programs and is offered by the following ICON divisions:

- **ICON Clinical Research**: phase IIb – IV clinical trial management, medical and safety services, biostatistics, data management and late phase services.
- **ICON Development Solutions:** strategy and delivery of early drug development, non-clinical development, early-phase research, bioanalytical, pharmacokinetics, pharmacodynamics, modeling and simulation and regulatory affairs.
- **ICON Central Laboratories:** global central laboratory services dedicated exclusively to Clinical Trials.
- **ICON Medical Imaging:** imaging solutions for all modalities and therapeutic areas, full-service solutions for diagnostic imaging products, clinical endpoint committee management.
- **ICON Contracting Solutions:** specialty contract and permanent staffing services dedicated to the pharmaceutical and biotech industries.

Industry Awards

- **North American CRO Business Development Strategy Leadership Award**
  Frost & Sullivan, Best Practice Awards, Jan 2009
- **Clinical Research Company of the Year 2008**
  Pharmatimes, Clinical Research Awards, Jan 2009
- **Leading CRO for International Project Execution**
  Lehman Brothers Equity Research, R&D Managers Survey 2007
- **Sponsors' Favorite CRO to Work With**
  Thomson Centerwatch/William Blair, Sponsor Survey 2007
- **North American Pharma & Biotech Service Provider of the Year**
  Frost & Sullivan, Best Practice Awards 2007

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Email: info@iconplc.com

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Fax: +1 215 699 6288
Email: info@iconplc.com

Website: www.iconplc.com

inVentiv Clinical

inVentiv Clinical: Built to FIT

Early in the history of inVentiv Clinical, we made a decision that would have a profound impact on our company. We decided to build our business through a customer-centric approach. Our orientation would be to the needs and behaviors of our customers rather than internal drivers determined by short-term business trends. This has allowed us to nimbly meet customer requirements as they change, provide services and frameworks to be flexible and solve problems. It is a simple formula that explains how we're built to **"FIT"**:

Flexibility around customer needs, with
Infrastructure, Intelligence, and Integrity to
Tailor solutions that accelerate results

So whether you need comprehensive clinical development solutions, a dedicated team of professionals working without the constraints of co-employment, or a few specialized contractors for an upcoming project, we can help effectively manage your resources, drive costs down, and accelerate results.

The Scale to FIT Diverse Needs
Our company has grown to provide far more than traditional clinical outsourcing, allowing pharmaceutical, biotechnology, and medical device companies the greatest control and flexibility through unmatched access to high quality clinical resources.

- More than 25 years of experience from over 700 projects in all major therapeutic areas
- More than 300 clinical research professionals
- 65 professional recruiters
- More than 1,200 contractors
- 13 offices in the US, India, Europe and Latin America
- More than 190 pharmaceutical, biotech and medical device clients

Clinical Development Solutions
A range of clinical development services, from full-service clinical trial management to functionally-based services, including protocol and CRF design, project management, clinical monitoring, data management, biostatistics and programming, regulatory consulting/liaison, medical writing and pharmacovigilance.

Strategic Resource Groups
Custom-built teams for access to longer term relationships with research-critical personnel to maintain headcount flexibility and organizational knowledge while avoiding co-employment issues.

inSourcing Solutions
Industry-leading contract and permanent recruitment services to help you manage your resources throughout shifting needs.

At inVentiv Clinical, we understand the increased regulatory and price pressures faced by the biopharmaceutical industry today. That's why we offer comprehensive and flexible services to fit your specific clinical development needs. As a division of inVentiv Health (NASDAQ: VTIV), we have the unique ability to leverage the expertise of more than 5700 employees from clinical to communications and commercialization to build cutting edge solutions, such as efficient patient recruitment strategies and new technology applications.

As a strategic partner, we are nimble enough to change with you, helping you develop the best plan to tackle your resource and development needs at each stage.

> "*At inVentiv Clinical Solutions, we are committed to providing superior research services tailored to support our clients' clinical development pipelines. We have accomplished excellence through our unique ability to fit our people, process, and systems around customer needs.*"
>
> — Mike Hlinak, Chief Executive Officer, inVentiv Clinical

Contact inVentiv Clinical:
16225 Park Ten Place, Suite 200, Houston, TX 77084 / Phone: 866-707-9567 / **www.inventivclinical.com**

Hotel Reservation Instructions

Travel Planners is coordinating all reservations, and arrangements for housing must be made through them and **NOT** with the hotel directly. Reservations must be received by **May 29, 2009.** **DIA DOES NOT PROCESS HOTEL RESERVATIONS.**

Methods for making hotel reservations are:

- **ONLINE** **CLICK HERE** to access Instant Confirmations, Local Map, City Information, Detailed Hotel Descriptions, and more. Please have your credit card, arrival and departure information ready.
- **BY PHONE** **1-800-221-3531 (domestic) / 1-212-532-1660 (international)**
  Please have all of the information ready along with a credit card number and expiration date.

RESERVATIONS BY PHONE Please have the following information ready:

- Name of convention:
  DIA Annual Meeting, June 21-25, 2009
- 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
- Arrival time
- Credit card type, account number, expiration
- Names of all room occupants
- Daytime phone number
- Fax number
- eMail address to which confirmation will be sent
- Mailing address

Hotel Locator Map

Reproduced with permission of Travel Planners, Inc.

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 15, 2009 when they receive the reservations for processing from Travel Planners. Most major credit cards are accepted. Each hotel will honor the Travel Planners acknowledgement.

CHANGES/CANCELLATIONS

Until June 15, 2009, all changes and cancellations should be made directly online with Travel Planners.

Cancellation policy is as follows:
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.

Win a $500 Visa Gift Card!

YOU MUST
1) Be a DIA member
2) Be a confirmed Annual Meeting registrant
3) Have booked your reservation through Travel Planners

The drawing will be held on June 21, 2009.

Event Hotels

		Address	Single Room Rates* starting at	Distance to Convention Center	Shuttle Offered
BH	**Bristol Hotel**	1055 1st Avenue	$189.00	.7 Miles	Yes
CT	**Courtyard by Marriott San Diego Downtown**	530 Broadway	$189.00	.7 Miles	Yes
ES	**Embassy Suites - San Diego Bay Downtown**	601 Pacific Highway	$269.00	.44 Miles	No
HB	**Holiday Inn on the Bay**	1355 North Harbor Drive	~~$222.00~~ *New Rate!* $145.00	1.3 Miles	Yes
HG	**Hilton San Diego - Gaslamp Quarter**	401 K Street	$244.00	.1 Mile (approximately)	No
HH	**Hampton Inn by Hilton San Diego Downtown**	1531 Pacific Highway	$179.00	1.3 Miles	Yes
HO	**Horton Grand Hotel**	311 Island Avenue	$189.00	.3 Miles	No
HR	**Hard Rock Hotel San Diego**	207 Fifth Avenue	$265.00	.1 Mile (approximately)	No
HS	**Hilton San Diego - Bayfront**	1 Park Boulevard	$269.00	.1 Mile (approximately)	No
IH	**Ivy Hotel San Diego**	600 F Street	$239.00	.5 Miles	Yes
MG	**Manchester Grand Hyatt**	One Market Place	$238.00	.4 Miles	No
OM	**Omni San Diego Hotel**	675 L Street	$260.00	.1 Mile (approximately)	No
RI	**Residence Inn San Diego Downtown**	1747 Pacific Highway	$199.00	1.6 Miles	Yes
SF	**The Sofia Hotel**	150 West Broadway	$170.00	.7 Miles	Yes
SG	**San Diego Marriott Gaslamp Quarter**	660 K Street	$282.00	.3 Miles	No
SM	**San Diego Marriott Hotel & Marina**	333 West Harbor Drive	$246.00	.1 Mile (approximately)	No
SO	**Hotel Solamar**	435 6th Avenue	$219.00	.4 Miles	No
US	**The US Grant**	326 Broadway	$249.00	.7 Miles	Yes
WE	**Westin San Diego**	400 West Broadway	~~$229.00~~ *New Rate!* $189.00*	.7 Miles	Yes
		**The new room rate now includes complimentary Internet access and airport shuttle service!*			
WG	**Westin Gaslamp Quarter**	910 Broadway Circle	$249.00	.6 Miles	Yes
WH	**Westgate Hotel**	1055 2nd Avenue	~~$243.00~~ *New Rate!* $219.00	.7 Miles	Yes

**Hotel rates do not include current tax of 12.5% or applicable surcharges; subject to change.*

Tour Information

Tours are no longer available through DIA.

However there will be a local hospitality desk available during DIA event hours, located outside Exhibit Hall B2 of the San Diego Convention Center, that can assist with local attractions.

Hike Torrey Pines State Reserve and Kayak La Jolla Cove

Tuesday, June 23 12:30 pm-5:30 pm $156.00

Torrey Pines State Reserve, a majestic wilderness in an increasingly urban area, is the home of our nation's rarest pine tree - *Pinus torreyana*. The park also preserves the last salt marshes and waterfowl refuges in Southern California. The reserve features high broken cliffs overlooking the ocean, 8 miles of picturesque trails, a rich plant community, and a lagoon that is vital to migrating seabirds. Hikers will also enjoy the pueblo-style structure that now houses the visitor center, which offers guided nature walks and exhibits on local wildlife, flowers, and geology. Hike where the sea has risen and fallen over the past million years and experience the Reserve's many views combining wind bent trees, abstract sandstone formations, wildflowers, and the sea below. Next, you will be awed by the beauty and splendor as you kayak through the scenic La Jolla Cove Ecological Reserve. You may encounter sea lions and harbor seals or, on a calm afternoon, you may even get to kayak into the caves located up and down the coast and visit the kelp forest that spans this area.

Includes transportation; customized, narrated tour en route; two-hour nature walk through Torrey Pines State Reserve; two-hour guided kayak tour at La Jolla Cove; all equipment provided (helmet, life vest, kayak); all taxes, gratuities and service fees.

Birch Aquarium Tour, Salk Institute Architecture Tour, Free Time in La Jolla

Tuesday, June 23 12:30 pm-5:30 pm $56.00

Birch Aquarium: The Birch Aquarium at Scripps is one of the largest oceanographic museums in the country. Set above the sea on the cliffs of Torrey Pines, it offers outstanding views of the Pacific Ocean and an interactive discovery and learning experience. Tour the Hall of Fish, the Hall of Oceanography, and then venture outside to the tide pool and learn about, touch, and feel mammals that thrive in a simulated tide pool.

Salk Institute: Louis Kahn's Salk Institute for Biological Studies is viewed as elegantly detailed, with abstracted modern shapes combined with a formal symmetry. The original buildings of the Salk Institute were designated as an historical landmark in 1991 and the Institute received the American Institute of Architects Twenty-five Year Award in 1992. The structure consists of two symmetric buildings with a stream of water flowing in the middle of a courtyard that separates the two. Explore the geometric architecture of the Salk Institute and tour one of the interior galleries hung with modern works of art.

La Jolla: Your tour concludes with free time to enjoy the panorama of green palms, turquoise sky and amethyst sea, white domes and red-tiled roofs adorned with bougainvillea. Or you can shop and enjoy the galleries.

Includes transportation; customized, narrated tour en route; tour of the Birch Aquarium; Salk Institute architecture tour; free time in La Jolla; all taxes, gratuities and service fees.

Sailing on San Diego Bay

Wednesday, June 24 1:00 pm-5:00 pm $147.00

Warm sunshine, calm water, a heady ocean breeze, and boats full of happy guests are excellent ingredients for a successful San Diego experience. Our best captains will gather tour groups at their respective boats and go over the chart of the bay and train at the dock for 10 minutes before taking the group out on the bay. While mastering sailing techniques, you will enjoy such sites as aircraft carriers, submarines, beautiful hotels, the famous Coronado Bay Bridge, and the breathtaking San Diego skyline. Join us for a relaxing and invigorating activity surrounded by the sites and sounds of the most beautiful harbors of the world!

Includes transportation; customized, narrated tour en route; six-person sailing yachts; snack and beverage baskets; all taxes, gratuities and service fees.

Tutorial Schedule/Pricing Guide

The tutorials being offered as of February 10, 2009, are listed below. Please continue to monitor www.diahome.org for tutorial updates and online registration.
Space is limited so register early!

■ SUNDAY, JUNE 21, 2009 — 8:30 am-12:00 pm

Tutorials #20 through #33 — **Fee $375**

#20	Quality Risk Management: Putting Principles into Practice	*CMC/GMP*
#21	Qualified Person for Pharmacovigilance: What Do You Need to Know?	*CP*
#22	Active Query, Case Assessment, and Narrative Writing in Pre- and Postmarketing: Working with Clinical Sites, Investigators, and Other Healthcare Professionals to Obtain Quality Safety Data	*CP*
#23	Signal Detection Methods for Beginners: Overview and Case Studies	*CP*
#24	Arsenic and Old Lace 3: QT and Beyond	**CANCELLED**
#25	Filing INDs as eCTD in the US: Practical Considerations	*ERS/DM*
#26	ISE/ISS: Developing Comprehensive Integrated Summaries of Effectiveness and Safety (ISE/ISS) with the Goal of Transitioning to the Summaries of Clinical Efficacy and Safety (SCE/SCS)	*MW*
#27	How to Apply Nonclinical Safety Guidelines in Global Drug Development	*NC*
#28	Fourteen Steps from Research to Development	*RA*
#29	Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in the EU	*RA*
#30	Basic Concepts in Equivalence/Noninferiority Testing: Issues and Challenges	*ST*
#31	Leadership: How to Organize and Lead People in Group Work	*TR/PD*
#32	Best Practices for Development of a Clinical Study Report	*CR/CS, MW, PM/FI*
#33	Portfolio Management: The Nuts and Bolts of Aligning Operations with Strategy	*PM/FI*

■ SUNDAY, JUNE 21, 2009 — 9:00 am-5:00 pm

Tutorials #40 through #46 — **Fee $650**

#40	European Regulatory Requirements for the Conduct of Clinical Trials and How to Obtain a CTA	*CR/CS*
#41	GCPs – Everything You Need to Know and Weren't Afraid to Ask; GCP Similarities and Differences Worldwide; Practical Do's and Don'ts	*GCP*
#42	Survival Strategies for Successful Pharmacovigilance Inspections in the US, Canada, and EU	**CANCELLED**
#43	Excelling as a Supervisor or Manager in the Clinical Research Industry	**CANCELLED**
#44	Clinical Statistics for Nonstatisticians	*CR/CS, MC, MW*
#45	Project Management for the Nonproject Manager	**CANCELLED**
#46	Developing New Drugs: An Eagle's Perspective (former title: Overview of Drug Development)	**CANCELLED**

■ SUNDAY, JUNE 21, 2009 — 1:00 pm-4:30 pm

Tutorials #50 through #62 — **Fee $375**

#50	European Interpretation of Product and Company Risk Management	**CANCELLED**
#51	How to Prepare a Detailed Description of Pharmacovigilance Systems (DDPS) According to the EU Regulatory Requirements and in Light of Recent Inspection Findings	*CP*
#52	Data Quality Counts from Start to Finish: The Role of MedDRA® in Coding and Analysis of Safety Data	*CP*
#53	Imaging in Drug Development	**CANCELLED**
#54	Planning and Conducting Clinical Trials in Oncology	*CR/CS*
#55	How to Prepare for an FDA Audit: QA in Clinical Trials	*GCP*
#56	Introduction to the PSUR: Pharmacovigilance and Medical Writing Perspectives	*MW*
#57	A Device Primer: 510(k)s, PMAs, IDEs and Beyond	*RA*
#58	Practical Approaches and Strategies for Preparing Your EU Pediatric Investigation Plan Application	**CANCELLED**
#59	Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development	*RA*
#60	Constructing Graphical Visualizations of Clinical Trial Data Using the Open Source R Language	*ST*
#61	Who's Monitoring the Monitor? Explore Trends, Management Techniques and a Reality-Check for Sponsors Utilizing CRO- and Alliance-based Site Monitoring	*CR/CS, PM/FI*
#62	Developing Standard Operating Procedures (SOPs)	*AHC/IS, CR/CS, TR/PD*

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

ATTENDEE REGISTRATION FORM

Applicable AFTER JUNE 12, 2009

45th ANNUAL MEETING ID #09001
June 21-25, 2009, San Diego, CA, USA

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

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

***FREE* Access to ALL the Annual Meeting Content!!**
As part of your registration fee, you will receive access to ALL available sessions, captured in digital audio with synchronized slides. To view a sample of this product, go to www.diahome.org and click on the Annual Meeting icon.

PAYMENT METHOD **Register Online www.diahome.org**

***This registration form is for use by paying* ATTENDEES ONLY.**

❑ CREDIT CARD

Complete this form and fax to 215-442-6199.

You may prefer to pay by check since 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 _____

CANCELLATION POLICY: All cancellations must be received in writing at DIA's office by 5:00 PM, June 5, 2009. **If you do not cancel by June 5, 2009 and do not attend, you are responsible for the full applicable fee. Registrants are responsible for cancelling their airline & 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 June 5, 2009 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 June 5, 2009 = Full Refund
- **TUTORIAL:** On or before June 5, 2009 – Registration fee paid minus $75 = Refund Amount
- **ONE-DAY REGISTRATION:** NO REFUNDS

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

FULL-MEETING REGISTRATION (attendance of 2 or more days) includes admission to all 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 See bookmarks in the online pdf for tutorial descriptions and for an at-a-glance tutorial schedule/pricing guide. Space is limited; preregistration encouraged. Please indicate the ID # and fee for tutorials you plan to attend.

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____ **TUTORIAL SUBTOTAL** _____

PREREGISTRATION FEES

A surcharge of $150 has been included in the registration fees for ALL registrations received after June 12, 2009 (does not apply to one-day registrations).

MEMBER FEE **US $1,425 ❑**

Join DIA now to save on future meetings and to enjoy the benefits of membership for one year! **www.diahome.org** **US $130 ❑**

NONMEMBER FEE** **US $1,555 ❑**

Nonmember fee includes a one-year membership option. Please indicate your preference.

❑ I **DO** want to be a DIA member ❑ I **DO NOT** want to be a DIA member

DISCOUNT FEES	**MEMBER**	**NONMEMBER***
Government (Full-time)**	**US $555 ❑**	**US $685 ❑**
Charitable Nonprofit/Academia (Full-time)**	**US $950 ❑**	**US $1,080 ❑**

*If paying a nonmember fee, please check preferred membership option above.
**Includes access to post-meeting presentations (see page 2).

ONE-DAY FEES**	**MEMBER**	**NONMEMBER***
You must indicate which day you plan to attend.	**US $750 ❑**	**US $880 ❑**

❑ **Monday, June 22** ❑ **Tuesday, June 23** ❑ **Wednesday, June 24** ❑ **Thursday, June 25**

*If paying a nonmember fee, please check preferred membership option above.
**One-day registration does NOT include access to post-meeting presentations (see page 2).

NETWORKING RECEPTION **After MAY 31, 2009**

US $85 ❑

You must be registered for the meeting to attend. Registration for the NETWORKING RECEPTION ONLY *is not available.*

Applicable Meeting Fee US $ _____

Tutorial Registration Fee US $ _____

Networking Reception Fee US $ _____

TOTAL PAYMENT DUE US $ _____

Last/Family Name First Name MI

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title Company

Mailing Address

City State Zip/Postal Code Country

email

Telephone # Fax #

ADD TUTORIALS and/or NETWORKING RECEPTION to an Existing Meeting Registration

45th Annual Meeting ID #09001 June 21-25, 2009 San Diego, CA, 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, or by someone who wishes to register for Tutorials only.

PLEASE NOTE: This page must be completed and submitted for each person attending any portion of this event. Please fax to +1-215-442-6199.

REGISTRATION FEES

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

❑ Attendee ❑ Speaker ❑ Track Chair
❑ Session Chair ❑ Exhibitor (Full Meeting or Booth Personnel)

❑ **NO,** I do not wish to register for the meeting, but I would like to register for the following Tutorials.

TUTORIALS See pages 10-11 in the online brochure for tutorial schedule, descriptions and fees. Space is limited; preregistration is encouraged. Please indicate the I.D.# and fee for each tutorial you plan to attend.

- Tutorial # _____ Fee _____
- Tutorial # _____ Fee _____

TUTORIAL SUBTOTAL _____

JOIN DIA now ... SAVE on future meeting registration fees ...
ENJOY the benefits of membership for one year!
www.diahome.org **US $130** ❑

NETWORKING RECEPTION

	On or before MAY 31, 2008	After MAY 31, 2008
Must be registered for the full meeting to attend.		
Networking Reception Only is not available.	US $75 ❑	US $85 ❑

TOTAL PAYMENT DUE * **US $**_____

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

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 #09001 must be included on the transfer document to ensure payment to your account.

CANCELLATION POLICY

All cancellations must be received in writing at DIA's office by 5:00 PM, June 5, 2009. If you do not cancel by June 5, 2009 and do not attend, you are responsible for the full applicable fee. **Registrants are responsible for cancelling their airline & 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 June 5, 2009 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 June 5, 2009 = Full Refund
- **TUTORIAL:** On or before June 5, 2009 – Registration fee paid minus $75 = Refund Amount
- **ONE-DAY REGISTRATION:** NO REFUNDS

REGISTRANT'S INFORMATION

Last/Family Name _____ First Name _____ MI _____

Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

Job Title _____ Company _____

Mailing Address _____

City _____ State _____ Zip/Postal Code _____ Country _____

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

Telephone # _____ Fax # _____

EXHIBIT PERSONNEL REGISTRATION FORM

Online registration is *not* available to exhibit personnel.

DIA Drug Information Association

45TH ANNUAL MEETING ID #09001 June 21-25, 2009, San Diego, CA, USA

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

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

All registrations received at the DIA office in Horsham, PA, USA by 5:00 PM on May 15, 2009 will be included in the Advance Registration Attendee List.

Each 10' x 10' booth includes: **one (1) complimentary full-meeting registration and three (3) exhibit booth personnel registrations.**

Please fill out a separate form for each exhibitor registrant.

To expedite your registration, please check the appropriate category:

❑ COMPLIMENTARY FULL-MEETING REGISTRATION ❑ EXHIBIT BOOTH PERSONNEL

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

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

PLEASE NOTE:

1) **This page must be completed and submitted for each person attending any portion of this event.**
2) **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.

❑ 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 #09001 must be included on the transfer document to ensure payment to your account.

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Refunds for cancellations received in writing on or before June 5, 2009 will be:

- **NETWORKING RECEPTION:** On or before June 5, 2009 = Full Refund
- **TUTORIAL:** On or before June 5, 2009 – 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.

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____ **TUTORIAL SUBTOTAL** _____

Join DIA now to qualify for all the benefits of membership for one year! **www.diahome.org** **US $130** ❑

NETWORKING RECEPTION

Must be registered for the full meeting to attend.
Registration for the Networking Reception only is not available.

On or before MAY 31, 2009	After MAY 31, 2009
US $75 ❑	US $85 ❑

TOTAL PAYMENT DUE US $ _____

Include all applicable fees: meeting, tutorials, networking reception.

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

Last Name First Name MI

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Mailing Address

City State Zip/Postal Code Country

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

Telephone # Fax #