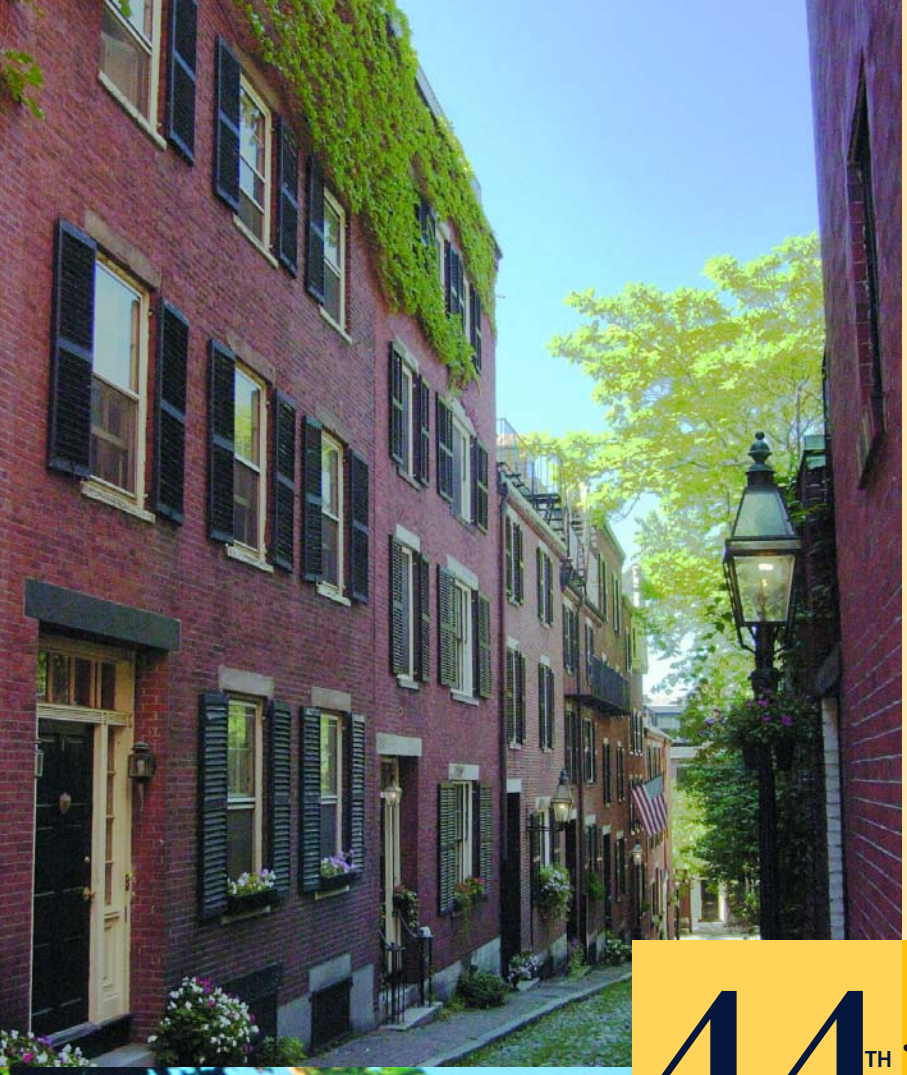

The content in this document was updated on June 13.

***For the most up-to-date information,* CLICK HERE.**

Boston, Massachusetts

44TH *Annual Meeting*

Boston Convention & Exhibition Center

June 22-26, 2008

PROGRAM CHAIRPERSON

Jeffrey W. Sherman, MD, FACP

IDM Pharma, Inc.

Program Chairperson

Jeffrey (Jeff) W. Sherman, MD, FACP,
Chief Medical Officer and Senior Vice President of Research & Development, IDM Pharma, Inc.

Boston – The City of Firsts

As our nation's oldest major city, Boston is home to the first:

- *University*
- *Public school*
- *Public Health Commission*
- *Subway station*
- *Free library*
- *Paid fire and police departments*

Medical Firsts:

- *First time ether was used as an anesthetic during an operation at Massachusetts General Hospital in 1846*
- *First kidney transplant performed in 1954*
- *First pediatric open heart surgery performed at Children's Hospital in 1967*

Before joining IDM Pharma, Jeff was Vice President of Clinical Science at Takeda Global Research and Development. He has also worked as the Chief Medical Officer and Executive Vice President at NeoPharm, Inc. He has also held positions at Searle/Pharmacia Research and Development, including Director, Senior Director, and Executive Director of Clinical Research. There he managed clinical development activities for a variety of therapeutic areas, including infectious diseases, women's health, sleep, and central nervous system. Jeff went on to lead company-wide oncology clinical research as Executive Director, Clinical Research and then oncology medical marketing as Head, Oncology Global Medical Operations. Prior to joining Searle/Pharmacia, Jeff worked at Bristol-Myers Squibb in clinical pharmacology and clinical research.

Jeff received his MD from Rosalind Franklin University/Chicago Medical School. He completed an internship and residency in internal medicine at Northwestern University, where he served as chief medical resident. Additionally, he completed a fellowship in infectious diseases with an interest in immunocompromised patients at the University of California-San Francisco (UCSF) and was a research associate in allergy and immunology at the Howard Hughes Medical Institute at UCSF.

Jeff is an Adjunct Assistant Professor of Medicine at the Northwestern University Feinberg School of Medicine, Diplomat of the National Board of Medical Examiners and American Board of Internal Medicine, and a member of the DIA Board of Directors. He received a DIA Outstanding Service Award in 2001.

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Invitation to DIA's 44th Annual Meeting

June 22-26, 2008 Boston, MA, USA

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Dear Colleague,

Welcome to Boston, a major national and international city of technology, science, and higher education, making it an attractive location for information technology, research and development, and biotechnology companies. Oliver Wendell Holmes called it "The Hub of the Universe." It has also been deemed "The Athens of America." To many it is known as "Beantown." Whatever name you choose, Boston is a unique city that has played a major role in the American experience. More than 90 colleges and universities call the greater Boston area home—a higher concentration than any other part of the world. From distinguished physicians and medical researchers, to world-class athletes and performers, Boston is a host to some of the world's most elite and accomplished people. It is only fitting that DIA has chosen Boston as the site for its 44th Annual Meeting.

Like Boston, the DIA Annual Meeting is rich in history, forward thinking, passionate, and intellectually stimulating; there is something for everyone. The DIA Annual Meeting represents the most significant means for advancing our objectives via our multidisciplinary focus, international reach, and neutral forums. The 44th Annual Meeting will offer innovative ideas, provide answers to new questions, and help the pharmaceutical industry redefine the development, regulation, surveillance, and marketing of pharmaceuticals.

This year's event features keynote addresses by Dennis A. Ausiello, MD, Jackson Professor of Clinical Medicine at Harvard Medical School and Chief of Medicine at Massachusetts General Hospital (MGH), and Kathy Giusti, Founder and Chief Executive Officer, Multiple Myeloma Research Foundation (MMRF) and Multiple Myeloma Research Consortium (MMRC). Dr. Ausiello is a nationally recognized leader in academic medicine who has made significant contributions to epithelial biology, particularly in the areas of membrane protein trafficking, ion channel regulation, and signal transduction. Ms. Giusti is world renowned for her tireless work on behalf of multiple myeloma research.

Conference participants will benefit from nearly 400 sessions across 26 content-area tracks, with more than 1,000 speakers, and over 450 exhibitors showcasing the industry's latest products and services. Networking is also a hallmark of the DIA Annual Meeting—from the daily continental breakfasts and afternoon refreshment breaks to the more formal Networking Receptions.

Your invitation to participate is an invitation to explore the very heart of our work.

See you in Boston!

Jeffrey (Jeff) W. Sherman, MD, FACP
44th Annual Meeting Program Chair

WWW.DIAHOME.ORG

"The meeting far exceeded my expectations. It is THE BEST professional conference I have attended in recent years."

2007 Annual Meeting Attendee

Plenary Session Keynotes

Dennis A. Ausiello, MD, is the Jackson Professor of Clinical Medicine at Harvard Medical School, and Chief of Medicine at Massachusetts General Hospital (MGH). He received his undergraduate degree from Harvard College and his medical degree from the University of Pennsylvania. He has made a substantial contribution to knowledge of epithelial biology in the areas of membrane protein trafficking, ion channel regulation and signal transduction. He has published numerous articles, book chapters, and textbooks and served as the co-editor of *Cecil's Textbook of Medicine*, in its 22nd and 23rd edition.

A nationally recognized leader in academic medicine, Dr. Ausiello was elected to the Institute of Medicine of the National Academy of Science in 1999 and the American Academy of Arts and Sciences in 2003. He has written for the *New York Times*, the *Wall Street Journal*, and the *Boston Globe* on health subjects, including human genetics, clinical trials, and the relationship between the academy and industry.

Dr. Ausiello served as Chief of the MGH Renal Unit and oversaw its development into one of the most sought after research and training programs in the world. As Chief of Medicine at Massachuetts General Hospital, a position he has held since 1996, he leads one of the strongest Departments of Medicine in the country with a clinical, research and education budget exceeding $500 million annually. He is closely involved with the Partners HealthCare System, linking the resources of the Massachusetts - General Hospital, Brigham and Women's Hospital, and Dana-Farber Cancer Institute to provide comprehensive health care. He oversees the training of more than 150 house officers, 500 graduate students and postdoctoral fellows, and dozens of students at Harvard Medical School, many of whom have gone on to careers as physician-scientists. Dr. Ausiello was also Director of the MD/PhD Program at Harvard Medical School and the Massachusetts Institute of Technology until 1999. He served as Chairman of the Executive Committee on Research of the Massachusetts General Hospital where he oversaw a research budget of $350 million annually.

As an internationally recognized scientist, Dr. Ausiello has been the recipient of two MERIT awards from the National Institutes of Health and has served as a council member of the National Institute of Diabetes, Digestive and Kidney Diseases Advisory Council and the National Advisory Council on Aging.

Understanding the need for partnerships between the academy and industry, Dr. Ausiello also serves in a variety of advisory roles beyond his academic affiliations. Dr. Ausiello serves on the Board of Directors of Pfizer, Inc., and MicroCHIPS, a drug-sensing and delivery company. In addition, Dr. Ausiello is also a member of the Scientific Advisory Boards of Promedior, Proventys and Pulmatrix.

Dr. Ausiello is particularly interested in the training of inquisitive physicians and translational investigators, and is the architect and director of the recently implemented Harvard initiative in Patient-Associated Science: Training, Education, Understanding, and Research (PASTEUR) – a novel educational program designed to introduce Harvard medical students and select Harvard undergraduates and graduate students to the excitement, challenges, and opportunities of patient-oriented research and to cultivate the development of the next generation of reflective physician-scientists.

Kathy Giusti, MBA, is the Founder and Chief Executive Officer of the Multiple Myeloma Research Foundation (MMRF) and the Multiple Myeloma Research Consortium (MMRC).

Kathy founded the Multiple Myeloma Research Foundation (MMRF) in 1998, shortly after being diagnosed with multiple myeloma, an incurable blood cancer. The MMRF funds innovative myeloma research and drug discovery. She then founded the Multiple Myeloma Research Consortium (MMRC) in 2004 to enable leading research institutions to work with industry to speed the discovery and development of effective new treatments for myeloma.

Prior to her position at MMRF and MMRC, she served as Executive Director of G.D. Searle & Company's worldwide arthritis franchise. She also worked for Merck & Company and the Gillette Company.

Kathy has been recognized for her work on behalf of multiple myeloma research. She has received the 1998 Healthcare Businesswomen's Association's Woman of the Year Award, the 2001 Harvard Business School Entrepreneurial Award, the 2002 McCarty Cancer Foundation Humanitarian Award, the 2002 Joseph Michaeli Award from the Weill Medical College of Cornell University, the 2005 Harvard Business School Award for Courage and Valor, and the 2006 Partners in Progress Award from the American Society of Clinical Oncology.

Kathy has served on the Institute of Medicine's National Cancer Policy Board and the Cancer Leadership Council. She currently is a member of the Health Research Alliance and serves on the National Cancer Advisory Board (appointed to the position by President Bush) and the Board of Directors for IMS Health. Most recently, Kathy's efforts to advance cancer research and drug development have been featured in the *Wall Street Journal* and on *NBC Nightly News*.

She holds an MBA in general management from the Harvard Business School.

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DIA would like to thank the members of the Boston Host Committee.

Paul A. Bleicher, MD, PhD (Chair), Phase Forward; **Josephine Babiarz, JD,** Massachusetts College of Pharmacy Health Sciences; **David S. Davenport,** Perceptive Informatics, Inc./PAREXEL International, **Kenneth A. Getz, MBA,** CSDD, Tufts University; CISCRP; **Kenneth I. Kaitin, PhD,** CSDD, Tufts University School of Medicine; **Denise DeRenzo Lacey,** Waife & Associates, Inc.; **Alison F. Lawton, PhD,** Genzyme Corporation; **Kristin M. Neff,** MS, Boston Scientific Corporation; **David H. Schubert,** Logical Therapeutics, Inc.

Networking Reception

The Networking Reception, held at the Georgia Aquarium, in conjunction with the 2007 DIA Annual Meeting in Atlanta, Georgia, was attended by more than 1,200 individuals. Comments indicated that the informal reception provided attendees not only exclusive access to the Aquarium, but also a wonderful opportunity to network with their colleagues. This year, in addition to enjoying great food catered by Wolfgang Puck Catering, and a host bar, DIA guests will have exclusive access to the Blue Wing and Green Wing of the Museum of Science.

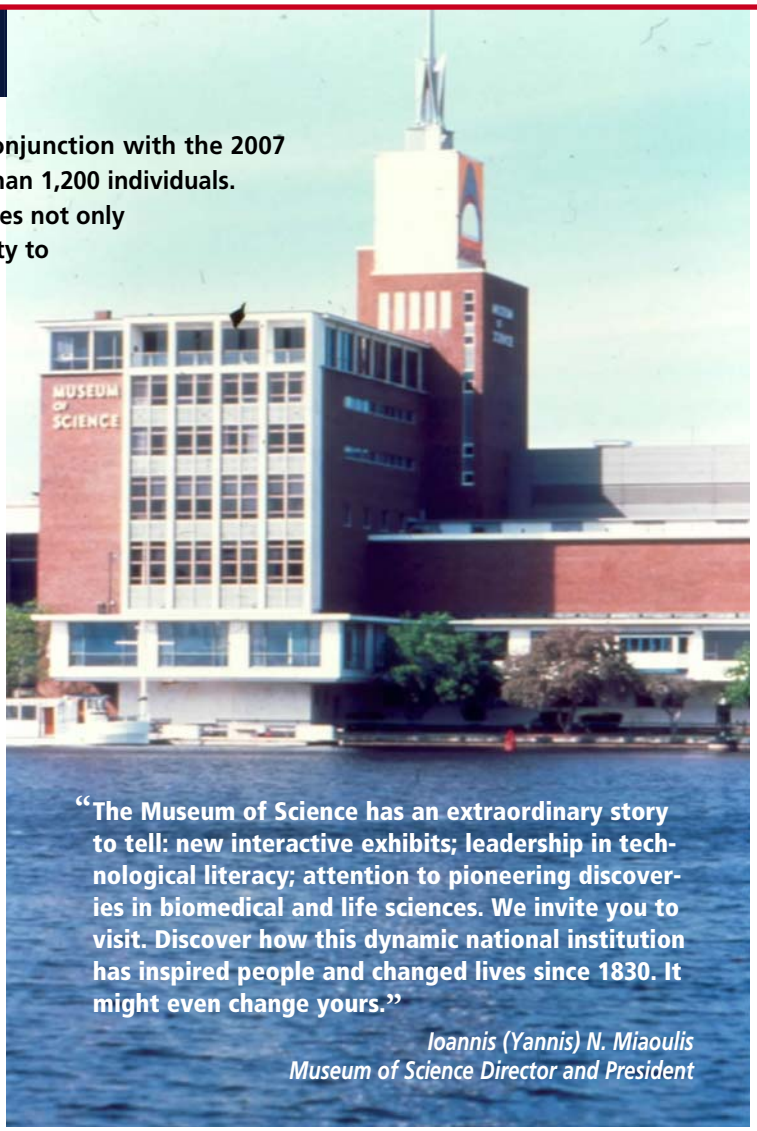
When and Where?

The Networking Reception will take place from 7:00 pm – 9:00 pm on Sunday, June 22, 2008. The Museum is located in Science Park.

About the Museum

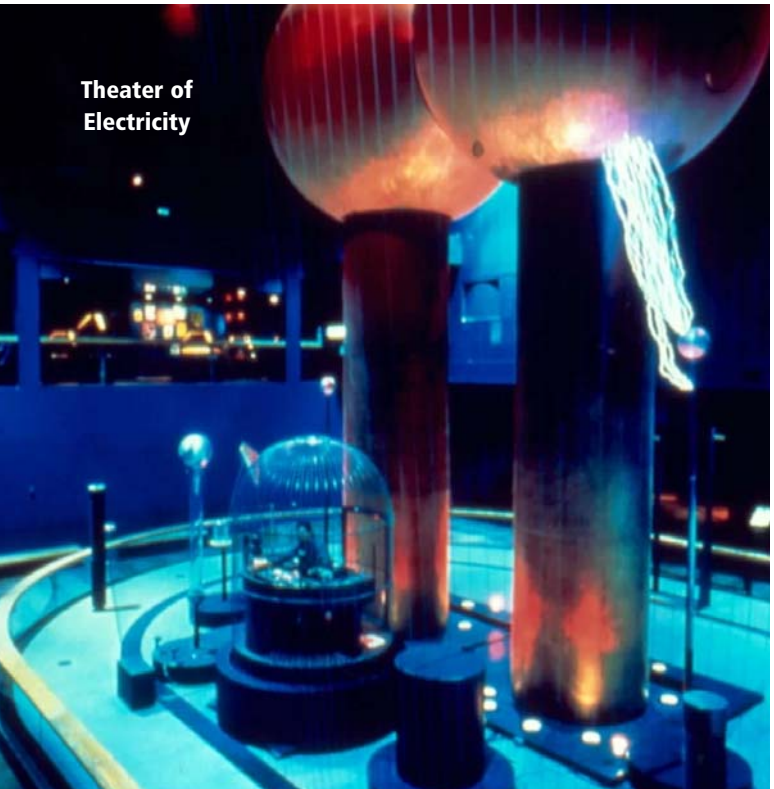
In 1830, six men interested in natural history established the Boston Society of Natural History, an organization through which they could pursue their common scientific interests. Devoted to collecting and studying natural history specimens, the society displayed its collections in numerous temporary facilities until 1864, when it opened the New England Museum of Natural History at the corner of Berkeley and Boylston Streets in Boston's Back Bay. That museum is now known worldwide as the Museum of Science.

After World War II, the society sold the Berkeley Street building, changed its name to the Boston Museum of Science (later, dropping Boston from the name) and negotiated for a 99-year lease with the Metropolitan District Commission for land spanning the Charles River Basin, now known as Science Park. In 1948, the Museum designed and built the first traveling planetarium in New England to promote the development of a new Museum building. The cornerstone for the new Museum was laid at Science Park a year later, and has remained on the cutting edge of science education by developing innovative and interactive exhibits and programs that both entertain and educate. The mission of the Museum of Science, Boston is to stimulate interest in and further understanding of science and technology and their importance for individuals and for society. More than 1.6 million people visit the Museum and its more than 400 interactive exhibits each year.



"The Museum of Science has an extraordinary story to tell: new interactive exhibits; leadership in technological literacy; attention to pioneering discoveries in biomedical and life sciences. We invite you to visit. Discover how this dynamic national institution has inspired people and changed lives since 1830. It might even change yours."

Ioannis (Yannis) N. Miaoulis
Museum of Science Director and President



Theater of Electricity

What is there to do at the Museum of Science on the evening of the Networking Reception?

In addition to the multitude of exhibits in the Blue and Green Wings of the Museum, DIA attendees will also have the opportunity to attend exclusive shows in the following areas of the museum:

Theater of Electricity

Audiences learn about the connections between electric and magnetic forces with this high-voltage presentation. Witness a demonstration of lightning created by the world's largest air-insulated Van de Graaff generator.

Mugar Omni Theater

Museum visitors have scaled the heights of Everest and plunged into the depths of the Amazon rainforest through the unique domed screen of the Mugar Omni Theater. In 1987 the Mugar Omni Theater became the first large-format theater in Boston, and since then more than 15 million visitors have immersed themselves in far-flung adventures through its five-story wraparound screen. Projected onto a five-story-tall domed screen, Omni films wrap audiences in larger-than-life images of flora, fauna, and faraway places. A state-of-the-art digital sound system completes the immersion effect. In New England's only 180° IMAX® Dome theater, you'll find yourself at the center of the action – whether climbing mountains, tracking elusive wildlife, or exploring ancient archaeological secrets. The Mugar Omni Theater has just undergone an exciting renovation, just in time for the theater's 20th anniversary and the DIA 44th Annual Meeting Networking Reception!

Charles Hayden Planetarium

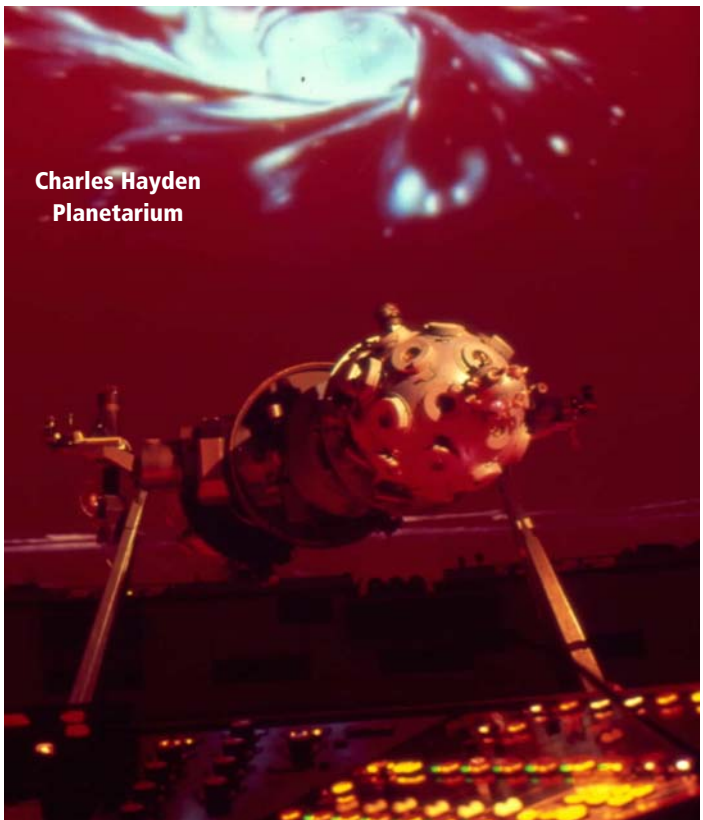
Offering a starry dome and much more, the Charles Hayden Planetarium provides daily departures for outer space. Audiences can glimpse everything from actual images of cosmic phenomena to universes we can still only imagine.

Wright 3-D Theater

The Museum offers film presentations in 3-D with its state-of-the-art digital projection system. Using polarized light rather than traditional red/blue lens filters, the high-definition system offers Museum audiences dramatically crisp images and an exciting presentation format to experience.

Did You Know?

The Blue Wing's Giant Sequoia Tree is over 2,000 years old and was a seedling at the time of Julius Caesar.



Charles Hayden Planetarium

Mugar Omni Theater

What Does it Cost and What is included?

The cost of the Networking Reception is $80.00 per person prior to May 31, 2008 and $95.00 thereafter. The price includes:

- **Shuttle transportation** to and from the Boston Convention and Exhibition Center
- **Exclusive access to the Blue and Green Wings** of the Museum of Science and the above mentioned shows
- **First-class food and beverage** provided by Wolfgang Puck Catering, including four themed reception stations as well as complimentary soft drinks, wine and beer
- **Unlimited networking opportunities!**

Please indicate that you'll be attending the Networking Reception on your meeting registration form. Space is limited and 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 Networking Reception. Your meeting badge, available at the DIA registration desk, will be required for entrance into the Museum of Science.

Annual Meeting Highlights

Maximize Your Time in Boston …

Home to championship sports teams, more than 90 colleges and universities, information technology, research and development, and biotechnology companies, and the 44th DIA Annual Meeting, featuring:

- More than 8,000 attendees
- Over 360 sessions across 26 content areas
- 500+ exhibiting companies
- 40 pre-conference tutorials
- More than 50 representatives from academic institutions around the world

Scheduling your time around the more than 360 sessions offered at the Annual Meeting can be overwhelming. We've taken steps to help you maximize your time in Boston and advance your education about drug development and clinical research throughout the world.

We know you can't attend every session, but …

We still want to bring every session to you. That is why this year, for the first time, all registered Annual Meeting attendees will receive access to ALL available sessions, captured in digital audio with synchronized slides and handouts – a $1,349 value FREE!

- Representatives from these global regulatory bodies, other agencies, and more …

ANMAT Ministry of Health, Argentina
ANVISA, Brazil
CDC, Center for Disease Control and Prevention, US
Center for Drug Evaluation, Taiwan
EMEA, Europe
FDA MOPH, Thailand
Health Canada
Ministry of Health, Vietnam
Ministry of Health & Family Welfare, India
MHLW, Japan
Ministry of Health, Welfare and Sport, Netherlands
PMDA, Japan
SFDA, China
State Institute for Drug Control, Czech Republic
FDA, US
WHO, Switzerland

Exciting Networking Opportunities

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

Emerging Professionals and Students Networking Reception

June 25, 2007, 5:00 pm-6:00 pm

This reception provides the perfect opportunity for students and individuals with six years or less of professional experience to come together during an informal networking reception.

Networking Reception at the Museum of Science

June 22, 2007, 7:00 pm-9:00 pm

This year, in addition to enjoying great food catered by Wolfgang Puck Catering and a host bar, DIA guests will have exclusive access to the Blue and Green Wings of the Boston Museum of Science. See page 4 for full details.

"Networking with exhibitors was truly a valuable experience."
2007 Annual Meeting Attendee

Extended Luncheon Hours

Tuesday, June 24, 11:30 am-2:00 pm

Back by popular demand, expanded luncheon hours on Tuesday will provide additional networking opportunity and allow attendees to reap all the benefits of a complete Annual Meeting experience.

Visit the exhibit hall for an up-close look at the industry's latest and greatest products and services.

Cutting-edge Science Leading to Breakthrough Research

Special Program Features

Hot Topics

Conference participants will benefit from more than 360 sessions in a variety of hot topics, including:

- Adaptive Clinical Designs/Adaptive Methods
- Approval Pathways for Products to Treat Rare Diseases
- Topics related to Biotechnology
- Clinical and Regulatory Considerations for Personalized Medicines
- Combination Device and Therapeutic Products
- Topics related to Critical Path Initiative
- Multinational Clinical Trials including Developing Countries
- Patient Recruitment and Retention
- Topics related to Pediatrics

Megatracks

The Committee has worked to create megatracks that will enhance the quality of the presentations and their relevance to the challenges faced by today's professionals, eliminate overlap of similar session topics in different tracks, and promote broader discussion and a fuller understanding of the topics presented.

Information Technology

If your expertise lies in EDC, data standards, eProcesses, labeling, validation, data management, software development, migration, CDISC, etc., you would be interested in attending sessions in these tracks:

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

Clinical Research

If you're interested in patient recruitment, clinical research, global clinical trials, outsourcing, managing clinical teams, pediatrics, protocol design, clinical trial management, these tracks are for you:

- CR – Clinical Research and Development
- CTM/CS – Clinical Trial Management/Clinical Supplies
- OS – Outsourcing
- PM/FI – Project Management/Finance

Featured Events

Multi-track Plenary Session
The Impact of FDAAA on Drug Safety

Tuesday, June 24, 8:00-9:30 am

Speakers from US and European regulatory agencies, the Reagan Udall Foundation, PhRMA, and other organizations will discuss their goals and experiences with implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and its impact on drug safety. See page 53 for complete session details.

Submit questions to the panel by Friday, June 20 to
FDAAAondrugsafetypanel@diahome.org
Subject: Questions for the Panel

Venture Capital Roundtable: Biotechnology and Pharmaceutical/Health Care IT

Wednesday, June 25 1:30-3:00 pm

Leading venture capitalists from the Boston area will discuss the current state of venture funding in biotechnology, pharmaceutical, and healthcare IT, and look forward to new models of development, funding, and partnerships. See page 92 for complete session details.

CDER Town Meeting Parts 1 and 2

Thursday, June 26 8:30 am and 10:30 am

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. See pages 109 and 113 for complete session details.

Global Sessions

Global drug development is a key focus of the Annual Meeting. This year's event will include more than 100 sessions on issues affecting key regions of the world, including:

- China – 18 sessions
- India – 12 sessions
- Japan – 23 sessions
- Taiwan – 4 sessions
- Vietnam – 1 session
- Latin America– 11 sessions
- Canada – 4 sessions
- Western Europe – 27 sessions
- Eastern Europe – 2 sessions

About the DIA Annual Meeting . . .

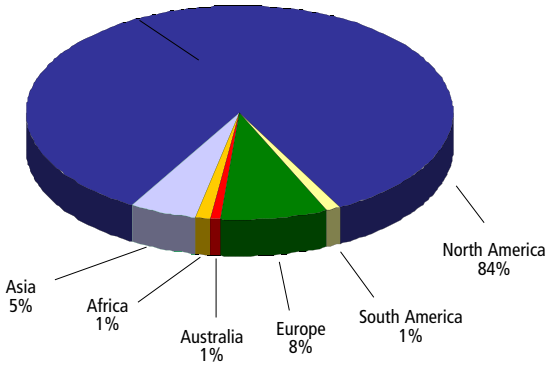
Multidisciplinary Focus, International Reach, Neutral Forum

The 2007 DIA Annual Meeting attracted:

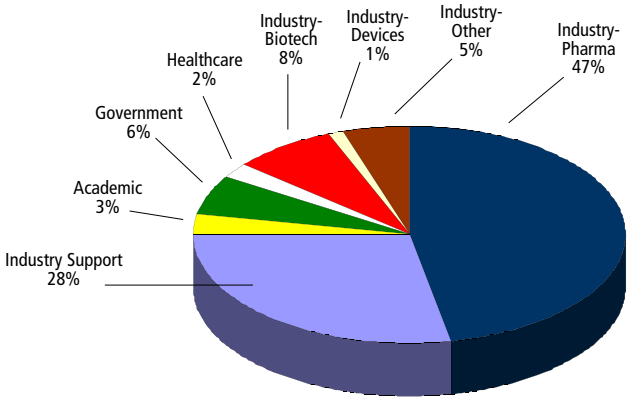
- Nearly 8,000 attendees
- 566 exhibiting companies
- 1,074 speakers

Attendees will benefit from more than 350 sessions and 35 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.

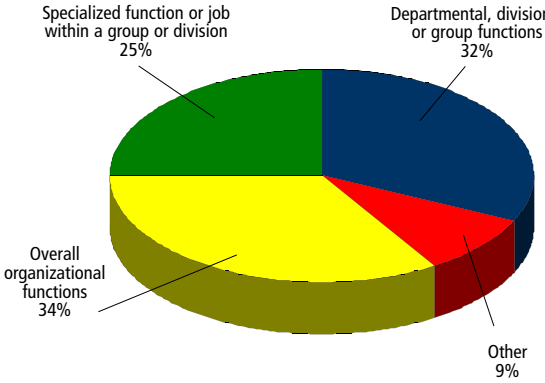
Geographic Locations



Professional Categories



Levels of Responsibility

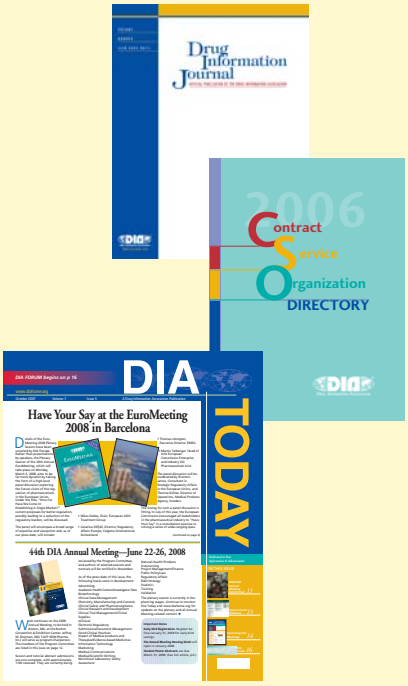


Explore the Benefits of Membership . . .

Register for the Annual Meeting and enjoy all the benefits of DIA membership … *AT NO ADDITIONAL COST!*

Member benefits include:

- Discounted registration fees on all educational offerings
- Free access to *DIA Today*, the Association's official newsletter; the *Drug Information Journal,* a scholarly, international, multidisciplinary, peer-reviewed journal; and the *CSO Directory*, a global database of companies offering products and services for every phase of the clinical trial and drug development process
- Access to the online Membership Directory
- Opportunity to join a Special Interest Area Community where you can share common experiences and knowledge with others in your particular field
- Discounted professional education opportunities with participating institutions
- Internship and employment opportunities with hiring companies
- Resume management services where you can post your resume and be contacted directly by interested companies
- eNewsletter featuring industry and DIA news emailed directly to your inbox



OPT IN TO DIA MEMBERSHIP

To join DIA, be sure to check the "I do want membership" box under the Nonmember fee on your Annual Meeting registration form

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

Getting to Boston

Boston's Logan International Airport, enhanced by a multibillion dollar modernization, is a major national and international gateway with a unique location close to the city – 3 miles northeast of downtown Boston. It takes approximately 10 minutes to get to the Boston Convention and Exhibition Center (BCEC) and approximately 20 minutes to downtown hotels, depending on traffic.

AirTran Airways is offering discounted air travel and unique benefits for DIA meeting attendees. These benefits include:

- A 10% discount on the lowest available AirTran Airways one-way fare,
- No minimum stay length or Saturday night requirement,
- Advance seat assignments at time of booking,
- Confirmed upgrade to Business Class, when available, for passengers booking in the "B" and "Y" fare levels,
- A *one-time waiver* of Change Fee per reservation for any name or itinerary change,
- Attendees have the option of contacting the EventSavers Desk directly or they may book their reservations through their designated travel agency,
- Travel agents must book all EventSavers reservations directly with the EventSavers Desk to receive the 10% discount. Reservations booked through a travel agent General Data System or the Internet *will not* qualify for the 10% discount,
- Attendees may travel three (3) days prior to the event start date and three (3) days after the event close date if they wish to spend any additional time at the event location.

To take advantage of this special program, contact the AirTran Airways EventSavers Desk at 1-866-68EVENT (1-866-683-8368) for reservations. Please provide the Event Savers Coordinator with Event Code: BOS062008 and start saving today!

Amtrak – Boston is an easy train ride away for attendees anywhere in the US. It is part of the Amtrak railroad system serving the Northeast, and connects passengers to the rest of New England, New York City, Washington, Philadelphia, Baltimore, and other cities across the country. Passengers can pick up Amtrak service in Boston at South Station, just minutes from the BCEC and a Back Bay Station close to many of the DIA room block hotels. For more information or ticket purchase, contact www.amtrak.com or 800-872-7245.

Driving – Directions to the Boston Convention and Exhibition Center, 415 Summer Street

From Logan International Airport and Route 1A South: Follow the signs towards I-90 West - Ted Williams Tunnel. Take I-90 West/Ted Williams Tunnel to Exit 25 "South Boston". At the top of the ramp, take a right onto Congress Street. At the end of Congress Street, take a right onto D Street. Take the second right onto Summer Street. The BCEC will be immediately on the left.

From Western Massachusetts via Massachusetts Turnpike: Follow the Massachusetts Turnpike/I-90 East to Exit 25 – "South Boston". At the top of the ramp, bear left. At the first set of lights, take a right onto Congress Street. At the end of Congress Street, take a right onto D Street. Take the second right onto Summer Street. The BCEC will be immediately on the left.

From Points South via I-93 ***(passenger vehicles ONLY):*** Take I-93 North to Exit 20 (immediately after Exit 18). Follow the signs to "I-90 East". Take the "South Boston" exit. At the first set of lights, take a right onto Congress Street. At the end of Congress Street, take a right onto D Street. Take the second right onto Summer Street. The BCEC will be immediately on the left.

From Points South via I-93 ***(commercial vehicles ONLY/Truck Route):*** Take I-93 North to Exit 18 Massachusetts Avenue. At the first set of lights, take a right onto the South Boston Bypass Road. Take a right onto Cypher Street, and then turn left into the BCEC at C Street.

From Points North via I-93: Take I-93 South to Exit 23, "High Street". At the end of the exit ramp, proceed straight onto Purchase Street. Take the first left onto Congress Street. Follow Congress Street for approximately 1.0 mile to the end, and take a right onto D Street. Take the second right onto Summer Street. The BCEC will be immediately on the left.

PARKING – Valet parking ($20) is available via Summer Street. To access valet parking, turn onto East Side Drive and the valet area will be immediately on your right. To self park ($10), drive past valet and continue straight along the side of the building. At the end of the building, make a right and go down the ramp. The South Parking Lot entrance is at the bottom of the ramp on your left.

Getting Around Boston

A variety of transportation options are available from the airport to downtown Boston.

Taxi Service from Logan Airport – Taxis are available at Logan terminals 24 hours a day. All taxis going downtown are charged a metered rate, and all fares are based on the occupancy of one to four passengers per taxi. All fares leaving Logan Airport are charged a $2.25 airport fee, and travel through the harbor tunnels will cost an additional $5.25 toll fee. It is recommended that you ask the taxi driver for a receipt showing the driver's name, the taxi company, the amount paid, and the medallion number. An average cost for taxi service from Logan Airport to the BCEC is $25 and $30 to downtown hotels. There are a total of six cab associations in Boston:

- Boston Cab, 617-536-5010
- Checker Cab, 617-536-7000
- City Cab, 617-536-5100
- ITOA, 617-825-4000
- Metro Cab, 617-782-5500
- Town Taxi, 617-536-5000

Shuttle Bus Service from Logan Airport – The majority of Boston hotels do not provide shuttle service to/from Logan Airport. However, there are several independent companies that conduct regular service between Logan and most hotels. The one-way charge is typically $14–18. For a list of shuttle companies you may go to www.massport.com

Massachusetts Bay Transportation Authority (MBTA) – Better known as "The T", MBTA connects all of Boston and its suburbs by subway, standard rail, bus and commuter boat. The "T" connects the airport with the convention centers and hotels, as well as point-to-point access anywhere in the city. The new Silver Line offers direct public transportation to the new Boston Convention and Exhibition Center from both the airport and downtown Boston via the World Trade Center stop. Take the elevator up to Level 2. Take a left onto World Trade Center Avenue, and the BCEC will be directly in front of you. For more information about the MBTA, please visit www.mbta.com

DIA Complimentary Shuttle Bus – Complimentary shuttle service is provided between the BCEC and the following DIA room block hotels, except for those hotels within walking distance. A shuttle schedule will be provided to all attendees when checking into all DIA room block hotels.

- Boston Marriott Copley Place – 110 Huntington Avenue
- Boston Park Plaza & Towers – 64 Arlington Street
- Hilton Boston Back Bay – 40 Dalton Street
- Sheraton Boston Hotel – 39 Dalton Street
- Westin Copley Place – 10 Huntington Avenue

NOTE!
Please see the bookmark for Hotel Information for the most current list of hotels.

The Westin Boston Waterfront Hotel (425 Summer Street), Renaissance Boston Waterfront Hotel (606 Congress Street), and Seaport Hotel (One Seaport Lane) are within walking distance of the Boston Convention and Exhibition Center.

Boston Convention and Exhibition Center (BCEC)
415 Summer Street, Boston, Massachusetts 02210, USA
Phone 617-954-2000 / www.massconvention.com

Drug Information Association (DIA)
800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA
Phone 215-442-6100 / email dia@diahome.org / www.diahome.org

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 138-139 for the hotel reservation form and the hotel locator map.
The Travel Technology Group (TTG) is coordinating all reservations, and arrangements for housing must be made through this housing bureau. All hotel reservation forms must be received by May 22, 2008. ***DIA does not process hotel reservations.***

MedDRA® User Group Meeting

MedDRA® User Group will meet on Thursday, June 26 from 12:30 pm to 5:00 pm. The specific location will be included in the final program.

Poster Sessions

The student and professional poster sessions will provide excellent opportunities for the presenters to share their research results with a diverse audience of clinical research professionals. The posters present scientific developments related to topics addressed in meeting tutorials and sessions, and will be displayed outside the entrance to Exhibit Hall A on the Exhibit Hall Level of the BCEC.

Student Poster Session	Monday, June 23, 10:00 am to 6:00 pm
Professional Poster Session	Tuesday, June 24, 9:30 am to 5:30 pm

The chairpersons for the poster sessions are Françoise G. Pradel, PhD and Francis B. Palumbo, PhD, JD, both from the University of Maryland School of Pharmacy, along with Stephen A. Sonstein, PhD, MS from Eastern Michigan University.

Press Registration Policies and Procedures

DIA events are attended by a number of international and domestic journalists who represent a variety of well-respected media outlets. DIA welcomes qualified representatives of news organizations to attend these events for the purpose of reporting and publishing/airing articles/stories. Press passes will be given to all who are determined, by DIA and/or its public relations firm, to be qualified members of the press. DIA and/or its public relations firm reserves the right to screen all requests and refuse the registration of those who are not considered to be qualified. In order to obtain a press pass, applicants must be affiliated with an established media outlet and possess an editorial/reporting title. Publishers, sales representatives and other noneditorial staff will not be granted a press pass. Publications and marketing materials may not be distributed at DIA conferences without the express and written permission of DIA. Upon arrival, all media must present a copy of their press credential confirmation letter received from DIA and official press credentials at the DIA event check-in location.

To obtain your press credential confirmation letter, download the Press Pass Request Form from http://www.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 +1-215-442-6199. If you have any questions, please call Joe Krasowski at +1-215-293-5812.

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:

Saturday, June 21	All times are acceptable
Sunday, June 22	Only after 8:00 pm
Monday, June 23	Only after 6:00 pm
Tuesday, June 24	From 7:00 am-8:15 am and any time after 5:30 pm
Wednesday, June 25	From 7:00 am-8:15 am and any time after 5:00 pm
Thursday, June 26	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 +1-215-442-6174, fax +1-215-293-5941, email Lori.Risboskin@diahome.org.

Reception

DIA will host a reception on Monday, June 23, from 5:00 pm-6:00 pm in Exhibit Halls A & B on the Exhibit Hall Level of the BCEC.

Tours

Destination Partners, Inc. has organized several tours of the highlights of Boston on Sunday, June 22 through Wednesday, June 25. Tour descriptions begin on page 140 and the tour order form can be found on page 143.

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. 286-000-08-501-L04

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

SM 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 21-22, 2008 – 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

June 22, 2008 – 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 23-26, 2008 – Up to 19.5 *AMA PRA Category 1 Credit(s)™* or 19.5 pharmacy contact hours (1.95 CEUs), 286-000-08-501-L04; or 2 IACET CEUs (up to 1.5 hours per session)

To Receive a Statement of Credit

If you would like to receive a statement of credit, you must attend the program (and tutorial, if applicable), and complete the online credit request process through **My Transcript at www.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 27, 2008.

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. If you require a scooter or wheelchair, rentals are available by contacting Scootaround Inc. at their toll-free hotline: 888-441-7575. You can also submit a rental inquiry on the web at www.scootaround.com or by fax at +1-204-478-1172.*

Exhibit Hall Opportunities

Scientific Exhibits In the Exhibit Hall on Exhibit Hall Level of the BCEC, 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 Exhibit Hall throughout the DIA Annual Meeting.

Exhibit Locator Exhibit Locator workstations, located in the entrance to the Exhibit Hall, will find an exhibiting company by booth number, will search by company name or the services it provides, and the "keyword" function will search for terms used in the company description found in the 2008 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, Leslie Ringe at lringe@ki-lipton.com or 267-893-5687

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: Erin.Gilliland@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 reservations inquiries: The Travel Technology Group at 1-866-825-6091 (domestic) / 1-312-527-7300 (international)
Inquiries about hotel reservations for speakers: Julie.Ho@diahome.org or 215-442-6179

Job Postings/Employment Opportunities
Non-technical 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.Snyder@diahome.org or 215-442-6108

Poster Sessions, Jessica.Vogt@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 Boston Convention and Exhibition Center will be available from:
- Boston Marriott Copley Place – 110 Huntington Avenue
- Boston Park Plaza & Towers – 64 Arlington Street
- Hilton Boston Back Bay – 40 Dalton Street
- Sheraton Boston Hotel – 39 Dalton Street
- Westin Copley Place – 10 Huntington Avenue

The following hotels are within walking distance of the BCEC:
- Westin Boston Waterfront Hotel – 1425 Summer Street
- Renaissance Boston Waterfront Hotel – 1606 Congress Street
- Seaport Hotel – One Seaport Lane

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: Destination Partners, Inc. at 978-388-3277
Unresolved tour issues: Lori.Risboskin@diahome.org or 215-442-6174

Tutorials, Jessica.Vogt@diahome.org or 215-442-6139

Tutorials (as of MAY 12, 2008)

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

Tutorials will take place on Saturday, June 21 and Sunday, June 22, 2008, 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 Titles and Acronyms

AD	Advertising	EC	eClinical	NC	Nonclinical Laboratory Safety Assessment
AHC/IS	Academic Health Centers/ Investigative Sites	ERS/DM	Electronic Regulatory Submissions/ Document Management	NHP	Natural Health Products
BT	Biotechnology	GCP	Good Clinical Practices	OS	Outsourcing
CDM	Clinical Data Management	IMP/EBM	Impact of Medical Products and Therapies/ Evidence-based Medicines	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 and Sales	RA	Regulatory Affairs
CR	Clinical Research and Development	MC	Medical Communications	RD	R&D Strategy
CTM/CS	Clinical Trial Management/ Clinical Supplies	MW	Medical/Scientific Writing	ST	Statistics
				TR	Training
				VA	Validation

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

■ SATURDAY, JUNE 21, 2008 1:00-4:30 pm

Tutorials #30 through #36 Fee $375

Tutorial #30 has been rescheduled to Sunday, June 22 from 8:30 am-12:00 pm. It will now be tutorial #64.

Tutorial #30 BT, RA

Comparability of Biopharmaceuticals

Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting Group

Tutorial #31 *CP, RA*

A Day in the Life of Adverse Event Reporting for Different Regions

Leyna T. Mulholland, MS, PhD
Director, Global Pharmaceutical Development Regulatory, F. Hoffmann-La Roche AG, Switzerland
Deborah Yaplee, PharmD, RPh
Senior Program Management Officer, Office of Compliance, CDER, FDA

.3 IACET CEUs

With recent changes in requirements for adverse events (AE) reporting among US, EU, and Japan, many pharmaceutical companies face the challenges of effectively coordinating procedures that are compliant with the particular region's guidelines.

This tutorial will provide an overview of regional variations related to AE reporting and regulations. The tutorial will compare similarities and differences of these variations and provide guidance and proper approaches on how to report an AE to a specific region.

This tutorial will offer case studies to participants to familiarize the reporting process in specific regions. This tutorial will help health-care professionals to obtain critical regulatory guidance in order to properly report each AE according to current regulations.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Discuss the requirements for adverse event reporting in the US, EU, and Japan,
- Identify the similarities and major differences between the US, EU, and Japan for adverse event reporting.

Target Audience
This tutorial is designed for health care professionals, medical monitors, clinical research associates, and regulatory professionals.

Tutorial #32 *CR, CTM/CS, RD*

Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People, and Process

Laurie Halloran, MS, CCRA
President and Chief Executive Officer, Halloran Consulting Group

.3 IACET CEUs

What are clinical operations, and why are some of the most successful companies realizing their importance? How does the clinical operations function contribute to the overall success of the organization, and where do we find someone to get it started? Many organizations struggle to determine

how and when to establish this function. Professionals new to the position quickly realize that there is very little available information on how to do their job effectively. This tutorial will explore these questions and challenges and present suggestions on how to get started and where to get help and information.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Describe and explain the role, responsibilities, and activities of a clinical operations management position,
- Identify the competencies for a successful clinical operations manager/director,
- Translate the components and priorities of a clinical operations functional infrastructure into a plan for reorganization within a pharmaceutical company,
- Design a clinical operations plan for a new biopharmaceutical organization.

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

Tutorial #33 *CR, GCP*

How to Prepare for an FDA GCP Audit

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

.3 IACET CEUs; 3.25 nursing contact hours

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 non-compliance and the types of findings in an audit that can lead to regulatory problems.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Prepare for and respond to an FDA audit,
- Assess audit findings and their impact on quality research,
- Build quality into your clinical trials program.

Target Audience
This tutorial is designed for auditors, monitors, clinical research coordinators, principal investigators, project managers and other staff involved in clinical research.

Tutorial #34 *CR, PM/FI, RA*

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

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

.3 IACET CEUs

This tutorial will present an overview of the evolution of the registration procedures for medicinal products (prescription, generics, and consumer health) in the European Union since 1995. It reviews the Centralized, Mutual Recognition, and Decentralized Procedures in detail, and discusses major changes introduced in November 2005. Regulatory strategy as it effects commercial and business arrangements will be described.

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

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

Tutorial #35 *PP, RA*

Abuse Potential and Drug Dependence Assessment: Scientific and Regulatory Guidance in Drug Development

Michael Klein, PhD
Acting Director, Controlled Substance Staff, CDER, FDA
Katherine Bonson, PhD
Pharmacologist, Controlled Substance Staff, Office of the Center Director, CDER, FDA

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs; 3.25 nursing contact hours; 286-000-08-503-L04; 3.25 pharmacy contact hours (.325 CEUs)

This tutorial led by scientists from the Controlled Substance Staff (CSS), Office of the Center Director, CDER, will review the types of studies and data applicable in the abuse potential assessment of new drug applications, the requirements for the characterization of a new drug with potential for abuse, under the FDCA [21 CFR § 314.50 (5) (vii)], as well as the requirements of the CSA [21 USC 811 (f) and 812]. Under the FDCA, the determination of the abuse potential of a drug is considered to be part of the evaluation of its safety and efficacy. Applicable preclinical and clinical studies will be discussed. The definition of abuse potential and the FDA/CDER scientific Guidance and general principles of abuse potential assessment will be presented. Scheduling of drugs under the CSA and criteria for placement of drugs and substances into each of the five schedules will be discussed. At the end of the tutorial, attendees will understand the general scientific and regulatory requirements, and the concept that abuse potential assessment is a composite of a variety of tests.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Discuss the studies, approaches, and methodology in characterizing a drug's potential for abuse, in fulfilling the requirements of the Food, Drug, and Cosmetics Act (FDCA) as well as the Controlled Substances Act (CSA),
- Explain the drug scheduling process, and generally discuss the criteria for a drug's placement in any of the five schedules of the CSA.

Target Audience
This tutorial is designed for representatives of the pharmaceutical industry, clinical research organizations, and academic organizations that are involved in development of drugs that act in the central nervous system and may have an abuse potential.

Tutorial #36 *BT*

Financing of Pharmaceutical and Biotech Startups

Christopher P. Milne, DVM, JD, MPH
Assistant Director, Tufts Center for the Study of Drug Development, Tufts University
Kenneth I. Kaitin, PhD
Director and Associate Professor of Medicine, Tufts Center for the Study of Drug Development, Tufts University

Tutorial #36 has been cancelled.

.3 IACE

This tut examine the landscape for commercial startup companies and opportunities for venture capital and investment funding. Experts from the investment community, as well as startup company CEOs, will provide their perspectives on the economic environment for new pharmaceutical and biopharmaceutical ventures and share their personal experiences.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Describe the economic landscape for startup pharmaceutical and biotechnology companies and the opportunities for venture capital and investment funding,
- Recognize the perspectives of venture capital and investment groups in terms of selecting potential entities for funding.

Target Audience
This tutorial is designed for senior management within the pharmaceutical and biopharmaceutical industry, research academics interested in commercial opportunities in the private sector, and individuals in the VC and investment community interested in biotech and pharma startup investments.

■ SUNDAY, JUNE 22, 2008 9:00 am-5:00 pm

Tutorials #40 through #45 **Fee $650**

Tutorial #40 *CR, GCP, RA*

Regulatory Requirements for the Conduct of Clinical Trials in Europe

Regina Freunscht
Head of Quality Assurance, Accovion GmbH, Germany

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

The European clinical trial legislation has had an impact on clinical trial management, conduct, safety surveillance and reporting, with consequences for sponsors, investigators, ethical committees, and regulatory authorities.

This interactive tutorial will provide an overview of the applicable European legislation and provide practical help for the conduct of clinical trials in Europe. What is new, and what are the consequences for the conduct of clinical trials? Which documents have to be prepared? Which SOPs might need a review? What are the considerations for safety reporting in Europe? Where can I find useful current and further information? Points of discussion will be the clinical trials Directive 2001/20/EC and all corresponding detailed Guidances on the clinical trial application process, notification of substantial amendments, declaration of end of trial, the ethical committee opinion processes, the EUDRACT and EudraVigilance databases, and the reporting of adverse events.

Furthermore, relevant content and likely impact of the European data protection directive 95/46/EC, the revised Annex 13 of GMP, the GCP Directive 2005/28/EC and archiving requirements of essential documents will be discussed. US FDA requirements will not be the subject of this tutorial.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Recognize the applicable regulatory requirements for the conduct of clinical trials in Europe,
- Analyze the impact of these regulations on drug development programs and company SOPs,
- Assess European drug safety reporting requirements from clinical trials,
- Plan, improve, and manage their future clinical trials.

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

Tutorial #41 *CR, MC, MW*

Clinical Statistics for Nonstatisticians

James B. Whitmore, PhD
Senior Director, Biometrics, Gilead Sciences, Inc.

6.5 AMA PRA Category 1 Credit(s)™; .7 IACET CEUs; 6.5 nursing contact hours; 286-000-08-513-L04; 6.5 pharmacy contact hours (.65 CEUs)

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

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Discuss basic statistical concepts such as variability, confidence intervals, hypothesis testing and p-values,
- Compare and contrast various study designs and identify techniques to avoid bias,
- Use basic statistical terminology with ease,
- Discuss information needed for determining sample size.

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

Tutorial #42 *CP, RA, TR*

Principles of Safety Surveillance

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

6.5 AMA PRA Category 1 Credit(s)™; .7 IACET CEUs; 6.5 nursing contact hours; 286-000-08-514-L04; 6.5 pharmacy contact hours (.65 CEUs)

Safety surveillance monitors need to understand the concepts of pharmacovigilance and recognize that risk monitoring and surveillance systems are critical for assessing the risk:benefit ratio of pharmaceutical and biotech products. The identification and management of adverse drug reactions (ADRs) and a competent ADR monitoring system are critical to ensure regulatory compliance when reporting drug safety data, enhancing timely approval of safe and effective new

drugs and to ultimately provide product safety for patients. The tutorial begins by reviewing the fundamentals of ADRs and safety reporting and provides an overview of the regulatory guidelines governing pharmacovigilance.

Participants will learn to formulate a systematic approach for reporting ADRs, which allows for analysis to help identify common trends and potential safety signals. A description of how pharmaceutical companies are implementing electronic submissions of adverse events will also be presented. The MedDRA program will be reviewed and crisis management strategies will be addressed. The course is designed to ensure participants return to their jobs equipped with practical knowledge and skills to manage effective and efficient adverse reporting. This full-day tutorial will deal with the key concepts and elements of safety surveillance.

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

Target Audience
This tutorial is designed for those new to safety surveillance and to update others on current safety, risk management, and regulatory issues in postmarketing surveillance, including safety monitors, physicians, pharmacists, nurses and clinical monitoring, regulatory, quality standards, and quality assurance auditing staffs.

Tutorial #43 *CR, CTM/CS, PM/FI*

Excelling as a Supervisor or Manager in the Clinical Research Industry

Mary E. Briggs
Chief Training Officer, FOCUS, Inc.
Vice President, Global Business Development, Kendle

.7 IACET CEUs

"Excelling as a Supervisor or Manager in the Clinical Research Industry" provides a clear sense of how to work, lead, and communicate effectively with your team in the clinical trial industry. This entertaining and fast-paced tutorial is ideal for all clinical research managers who want to positively impact 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 including verbal and nonverbal communication, professional courtesy, and appearance,
- Distinguish between the three primary root causes of performance problems in the clinical research industry and determine if coaching, counseling, or mentoring is appropriate action,
- Communicate and gain compliance more effectively by recognizing four primary personality types, and quickly adapting to individual differences and preferences,
- Recognize your own individual communication style and differentiate between passive, aggressive, and assertive communication. Participants will review an assertive communication model,
- Diminish on-the-job conflict and confrontation by delivering quick and effective performance feedback. Participants will practice a four-step effective feedback model,
- Delegate more effectively to team members and peers, including steps for subtle management of management.

Target Audience
This tutorial is designed for supervisors and managers in the clinical research industry, including site managers, clinical trial managers, data managers, technical managers, and other supervisors and managers in the drug development industry.

Tutorial #44 *GCP, RA*

Managing Regulatory GCP Inspections

Beat E. Widler, PhD
Global Head of Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science and Director, Good Clinical Practice Program, Office of Science and Health Coordination, Office of the Commissioner, FDA

.7 IACET CEUs

Following up on successful tutorials of past years, we want to provide all those who are exposed to inspections the opportunity to learn how inspections can be successfully prepared, managed, and passed. Two industry representatives will share best practices from their perspective. In the afternoon (second session) inspectors from FDA and EU/EMEA will share their experience. Expectations as well as common findings will be discussed. The tutorial will offer the opportunity for participants to engage in a dialogue with industry and health authority representatives.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Prepare your company for inspections without exposing the organization to inspection paralysis,
- Explain what drives inspections, what matters, and what type of compliance issues they frequently observe.

Target Audience
This tutorial is designed for trial study managers, monitors, auditors, inspectors, QA staff, and clinical site staff.

Tutorial #45 *BT, RA*

Comparability: How to Manage the Impact of Process Change

Cecil Nick, MS
Principal Consultant, PAREXEL Consulting, UK

.7 IACET CEUs

Tutorial #45 has been cancelled.

Biomedicines have one thing in co… signaled out by re… …ufacturing methods can i… …generity, and impurity profiles, and these effects may be difficult to detect, yet can impact safety and efficacy. Therefore, process change needs to be supported by extensive testing, which may require supporting nonclinical and clinical data, and there are cases where process and formulation change have adversely affected safety. CHMP and ICH guidelines on comparability requirements exist, but as biological medicines represent a broad spectrum of products, it is difficult to be prescriptive about the extent of data required to support any particular process change. Therefore, the impact of any change needs to be considered on a case-by-case basis.

The first part of the tutorial will provide guidance on how to construct a compelling and efficient comparability program in accordance with ICH and CHMP guidelines and will highlight potential pitfalls. The technical challenges inherent in establishing a plausible physico-chemical comparability program capable of detecting significant changes will be presented. Delegates will enhance their understanding by participating in interactive case studies in which they will propose comparability strategies for various scenarios.

The second part of the tutorial will explore the value of nonclinical studies in detecting changes in critical product quality parameters. Finally, the tutorial will provide practical guidance on the clinical development strategy and will cover the CHMP guidelines on nonclinical and clinical testing requirements following process change.

Learning Objectives:
At the conclusion of this tutorial, participants should be able to:
- Evaluate the impact of process change,
- Create an efficient and acceptable comparability program.

Target Audience
This tutorial is designed for personnel in regulatory, production, and quality involved with products using rDNA technology.

■ SUNDAY, JUNE 22, 2008 8:30 am-12:00 pm

Tutorials #50 through #63 Fee $375

Tutorial #50 *AHC/IS, BT, CR*

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 1.5 M new cases of invasive cancer were reported in 2006. Total funding for US and worldwide trials in oncology is larger than for any other therapeutic area.

This tutorial will include discussions and presentations on the following topics: an introduction to the biology of cell transformation, tumor growth, and metastasis; screening, diagnosis, and treatment for three of the major cancers; introduction to protocol development for phases 1-3; and discussions regarding the process of accelerated regulatory approval and other issues.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Recognize the incidence and prevalence of cancer in the US and the importance of conducting clinical trials in oncology,
- Explain the tumor growth, metastasis, and transformation processes,
- Identify and recall the essential components of phase 1, 2, and 3 oncology protocols,
- Recognize important clinical issues such as accelerated approval that are relevant to conducting trials in oncology.

Target Audience
This tutorial is designed for entry-level professionals involved with protocol development, monitoring, data management, or clinical site aspects of conducting clinical trials in oncology.

Tutorial #51 *CDM, IT*

A Mapping Primer: The Use of Terminology Standards to Meet Regulatory and Interoperability Requirements

Franklin M. Din, DMD, MA
Informatics Consultant, Apelon
David Sperzel, MD
Senior Informatics Consultant, Apelon

.3 IACET CEUs; 286-000-08-504-L04; 3.25 [illegible]rs (.325 CEUs)

Tutorial #51 has been cancelled.

Th[illegible]ition that standardization of [illegible] knowledge is the key to interoperability. The SPL initiative is an example of the effort to standardize. Since most health-care businesses and institutions have years of data generated and saved in internal systems and millions of dollars invested in internal software systems and processes, it is unlikely that any organization will undertake the cost and effort to recode all existing data with standardized terminologies. The only viable option is to conduct mappings between locally used terms and concepts to nationally recognized standards. This process is commonly called "mapping." Mapping is often seen as simple and straightforward; however, as novices quickly discover, it is a complex process in which a seemingly minor mapping error can propagate throughout and across an enterprise and at the worst, affect patient safety. This tutorial is designed to help avoid these costly errors through an understanding of the complexity, the method, and how to achieve accurate maps. Attendees will also be introduced to more complex mapping issues such as knowledge inferences and cross-mapping to connect disparate biomedical realms, such as bench research and clinical care.

Specifically, we will review
- The idea of concepts, inheritance, hierarchy (and polyhierarchy),
- Different forms of coded terminologies (especially the SPL terminologies) along with advantages and disadvantages,
- The goals of mapping,
- The process of mapping,
- The quality of mapping.

All the didactic information will be interspersed with exercises in mapping. The tools to be used are Apelon's TermWorks, Apelon's DTS, and the CLUE browser for SNOMED CT.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Explain the forms, basic structure, and purpose of coded terminologies,
- Describe the context and nuance in mapping,
- Use mapping and vocabulary server tools,
- Map free text terms to the equivalent coded standard used in SPL.

Target Audience
The tutorial will benefit anyone involved with mapping text to a coded standard terminology used in an SPL-coded data element. Anyone involved with translational research efforts that link basic research with clinical use will also benefit.

Tutorial #52 *CMC/GMP, RA*

Anatomy of Chemistry, Manufacturing and Control: Scientific and Regulatory Expectations of the Office of Generic Drugs

Mike Darj, PhD
Review Chemist, Office of Pharmaceutical Science, CDER, FDA

.3 IACET CEUs; 286-000-08-[illegible] CEUs)

Tutorial #52 has been cancelled.

The Offi[illegible] is inundated with an overwhelming number of Abbreviated New Drug Applications (ANDA) every year. This increasing

number of applications combined with increased review time has created a backlog. One of the main offenders of the increased review time is poor quality applications. The OGD has taken a proactive role in educating the industry at every opportunity available, and by implementing a Question-based Review (QbR) process.

The intention of this tutorial is to teach the attendees the integration of scientific concepts and science-based justifications with the regulatory policies for the preparation of the Chemistry, Manufacturing, and Control (CMC) section of an Abbreviated New Drug Application.

The tutorial will include in-depth discussion of each CMC section, such as: Components and Composition, Raw Material Controls, Manufacturing and Processing, Container/Closure System, Laboratory Controls, and Stability. Attendees will learn what the expectations of the OGD are, and how the regulatory policies, as pertain to each section of CMC, are interpreted.

In conclusion, the objective of OGD's current initiative (QbR) will be delineated with a focus on the utility of the Quality Overall Summary (QOS) section of a QbR application in detail, with a generic example to provide insight on how the QOS portion of the application should be prepared, and how this section should correlate with the main body of the application (CTD Module 3).

Learning Objectives

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

- Discuss how to integrate science with regulatory policy for preparation of chemistry, manufacturing, and control,
- Describe Question-based Review (QbR) – introduction and implementation,
- Explain how to provide justification for proposed specifications set forth in the application.

Target Audience

This tutorial is designed for a regulatory affairs professional who assembles the Chemistry, Manufacturing, and Control section of an Abbreviated New Drug Application.

Tutorial #53 *CP, GCP*

Pharmacovigilance Assessment and Risk Management: Essential Components to Good Pharmacovigilance Practice

Steve T. Jolley
Vice President, Pharmacovigilance, Patni Life Sciences
Carol L. Krueger, BSN, RN
Surveillance Programs Team, Division of Compliance Risk Management and Surveillance, CDER, FDA

.3 IACET CEUs

As pharmaceutical companies face an increasingly complex set of international regulations, demonstrating commitment to good pharmacovigilance practice is essential to drug development and commercialization.

A pharmacovigilance assessment profile monitors and aims to minimize risk. In order to achieve this goal, the assessment captures the requirements of all applicable regulatory bodies, reviews company practices across the product life cycle, inspects detailed documentation on case processing and decisions made, evaluates related information systems, and documents successes, failures and improvements. Assessing the need for formal risk management plans (RMPs) is also recommended during a pharmacovigilance assessment.

Recent regulatory Guidance and initiatives have been issued on the topic by the US Food and Drug Administration, International Conference on Harmonisation, and the European Commission in consultation with the European Agency for the Evaluation of Medicinal Products, Member States and other interested parties. These Guidance documents emphasize the need for proactive pre- and postmarket risk surveillance and the development, implementation, and usage of RMPs as tools to ensure patient safety. Collecting risk information generated during clinical trials, long-term controlled safety studies, and all currently available safety data is imperative. A signaling program and pharmacoepidemiologic assessment will further identify and analyze potential populations at risk. All of this information must be incorporated appropriately into a risk management plan, which may need to be submitted to health authorities at any time during a product's life cycle. Pharmacovigilance assessment and risk management are continuing processes throughout a product's lifetime. A company should be cognizant of updates to existing Guidances and regulations and redefine strategies, as appropriate, to ensure adherence to good pharmacovigilance practice.

Learning Objectives

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

- Discuss the importance of a pharmacovigilance assessment and risk management plans in ensuring good pharmacovigilance practice.

Target Audience

This tutorial is designed for professionals working in pharmacovigilance and drug safety, clinical research, and regulatory affairs.

Tutorial #54 *CP, EC*

Energizing the Drug Safety Practice with the Use of New Media

Sameer Thapar, PharmD, RPh
Director, Safety Surveillance and Pharmacovigilance, Omnicare Clinical Research

3.25 AMA PRA Category 1 C… …ntact hours; 286-000… …CEUs)

Tutorial #54 has been cancelled.

New media is already advancing on the pharmaceutical and health-care audience. There are approximately 113 million Americans relying on the Internet for health information, how to treat common ailments, and even chronic disease management. Physicians are also beginning to rely on the search engines to aid in the diagnosis of rare illnesses. In addition, health content on social media sites such as blogs, podcasts, and social networks is perceived to gather more trust than information disseminated by the pharmaceutical companies, government agencies, and nonprofits. According to Jupiter Research, 80% have used the Internet to connect to others and trust peer-created health information to some degree. Within the pharmaceutical realm, clinical researchers have used online patient recruitment directives, specialized forums, and Internet social communities to attract patients for clinical trials. By employing new media and social media strategies, the researcher not only saves costs, but also has a greater pool of subjects from which to choose.

This tutorial will impart knowledge on the generation of blogs, podcasts, and posts to forums and aid in the dissecting of relevant adverse event and pharmacovigilance information from social media sites such as online communities and networking sites. Several activities will impart valuable proficiencies that are required to navigate the current online realm. Attendees will receive knowledge to create their own new media and demonstrate an understanding of social media. Strategies to overcome regulatory hurdles will also be discussed.

Learning Objectives

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

- Create and implement new media such as blogs, podcasts, and rss feeds for use in adverse event data mining,
- Identify and glean potential signals from social media such as online communities, networks, and forums.

Target Audience

This tutorial is designed for safety and pharmacovigilance professionals who want to understand the realm of new media/social media as it pertains to adverse event practice as well as helping in the potential generation of safety signals.

Tutorial #55 *CP, CR*

Active Query, Case Assessment, and Narrative Writing in Clinical Trials and Postmarketing Pharmacovigilance: Obtaining Quality Data through Clinical Expertise

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
Senior Medical Director, Scientific and Medical Affairs, Head, Medical Monitoring Americas, PRA International, Inc.

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs; 286-000-08-507-L04; 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 studies. 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 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."

In this tutorial, the factors that affect health professional reporting of medical product-associated adverse events will be reviewed, along with interventions designed to both stimulate health professional reporting and foster higher quality reports (eg, educational initiatives, FDA's MedWatch program, targeted questioning) in both premarketing clinical trial and postmarketing pharmacovigilance realms. Further, methods designed to optimally utilize safety data in order to craft effective case narratives will be reviewed.

Learning Objectives

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

- Describe factors affecting adverse event reporting in clinical trials and pharmacovigilance,
- Discuss interventions designed to garner high-quality adverse event data, including active query and optimal use of clinical expertise,
- Create effective case narratives.

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,
- Biostatistics.

Tutorial #56 *CR, CTM/CS*

Clinical Research and Pharmaceutical Registration in India

Surya Chitra, PhD, MBA
Principal Consultant, Savio Health Solutions – US
Venkatraman Sunder
Vice President, Operations, Asian Clinical Trials [illegible] ven Life Sciences Limited – Indi[illegible]

Tutorial #56 has been cancelled.

.3 IACE[illegible] pharmacy contact hours (.325 CEUs)

This tutorial is designed to present a comprehensive overview and analysis of conducting clinical research and the registration processes available for approval of products in India. It reviews the opportunities and challenges in patient recruitment and clinical operations in some of the highest patient population therapeutic categories like cardiology, endocrinology, neurology. and anti-infectives. This tutorial provides discussion on emerging regulatory landscape and a hands-on guidance on how to set up and conduct clinical research in India. It includes strategies developed by the local CRO in obtaining Indian regulatory approvals for clinical trials and drug registration.

Key Topics:

- Cost and value drivers for pharmaceutical development in India,
- Supply chain and clinical operational processes for clinical research,
- CRO infrastructure, analysis, and performance,
- Regulations governing clinical research in India – challenges and opportunities,
- Drug registration of biologics/pharmaceuticals in India,
- Lessons learned by local organizations – dos and don'ts of clinical research in India.

Learning Objectives

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

- Summarize cost and value drivers to make informed decisions about conducting clinical studies in India,
- Discuss the opportunities and challenges in conducting clinical research and share lessons learned about what works and what does not work in India,
- Identify the data management, supply chain, operations, and CRO support in India,
- Discuss the regulatory requirements and processes in India for registration of a pharmaceutical product,
- Explain and discuss emerging government regulations and legal infrastructure in India,
- Prepare and manage set up and conduct of clinical trials in India.

Target Audience

This tutorial is designed for professionals in clinical research and development, clinical supplies, data management, investigator site management, outsourcing management/CROs, project management/biostatistics, medical affairs, R&D and strategic issues, and regulatory affairs.

Tutorial #57 *CTM/CS, GCP, RA*

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

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

.3 IACET CEUs

This tutorial will review and discuss the legal, regulatory, and practical nuances of (1) FDA enforcement priorities for 2008 and beyond (eg, application of data integrity policy and GMP/GCP requirements), (2) FDA administrative enforcement weapons and how the Agency uses them (eg, inspections,

warning letters, publicity, recalls, and investigator disqualification proceedings), and (3) the civil and criminal penalties for violations (eg, seizure, injunction, criminal prosecution). It will also address how to handle an FDA enforcement action should you face one, particularly in the wake of an inspection or warning letter. These interactive discussions will focus on how FDA operates and makes decisions and how to respond effectively, using tactics ranging from negotiation to, when appropriate, litigation.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Discuss FDA's enforcement priorities for 2008 and beyond,
- Describe FDA's compliance review and decision-making process,
- Identify the legal risks and penalties for noncompliance,
- Respond appropriately to FDA enforcement.

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

Tutorial #58 *ERS/DM, IT*

Structured Product Labeling Listing Data Elements

Lonnie D. Smith
Project Manager, Office of the Director, CDER, FDA

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs; 286-000-08-509-L04; 3.25 pharmacy contact hours (.325 CEUs)

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

Manufacturers have been including drug listing data elements with their content of labeling submissions to new drug applications, abbreviated new drug applications, and certain biological license applications to the FDA's Center for Drug Evaluation and Research since October 2005. Drug listing data elements also need to be included in SPL for other labeling submission types such as over-the-counter product monographs.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Recognize the basics of the SPL standard,
- Create well formed XML for listing data elements sections for human drug OTC and human prescription drug labels,
- Identify terminology utilized in SPL submissions to the FDA.

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

Tutorial #59 *CP, MW*

Introduction to the PSUR: Pharmacovigilance and Medical Writing Perspectives

Susan F. Gonsalves, MBA, PhD
Director, Safety and Risk Management, Pfizer Inc
Donald Puccio
Director, Safety and Risk Management, Pfizer Inc

.3 IACET CEUs; 286-000-08-510-L04; 3.25 pharmacy contact hours (.325 CEUs)

This tutorial critically examines PSUR content and process from the pharmacovigilance and medical writing perspectives. It will provide an overview of relevant Guidance documents (including differences between EU and US requirements), discuss the required periodicity for PSURs, the limitations of some of the PSUR components (eg, patient exposure data), and the role of the Qualified Person with respect to the PSUR. The tutorial will also review the contents of each section, including how the methods of presentation may vary depending on the life-cycle status of the drug and the volume of data to be presented, and examine what makes a comprehensive PSUR. The tutorial will include a "hands-on" portion in which participants will plan a safety analysis strategy and, additionally, will construct the outline of a mock PSUR from a list of components.

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 life-cycle status of the drug and the volume of cases,
- Plan a strategy on how to prepare a PSUR.

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 #60 *PM/FI, RD*

Understanding and Managing Uncertainty in Pharmaceutical and Biotech R&D

Randy Dunson, MBA, PMP
President, US Operations, Harpum Consulting Ltd.
Peter Harpum, MSc, MAPM
Director, Harpum Consulting Ltd., UK

.3 IACET CEU

Tutorial #60 has been cancelled.

This high tutorial will give attendees insight and understanding that will enable them to better manage the inherent uncertainty in drug development projects. The format of this tutorial is to mix theory and group exercise sessions, including professionally facilitated discussion between the delegates on learning points from the exercises. The management of uncertainty takes traditional risk management to the next level of effectiveness, by integrating downside risk and upside opportunity into one seamless process. Attendees will be provided with templates they can take back to their workplace and put into use.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Explain the basic theory underlying the management of uncertainty,
- Selectively apply these theoretical concepts to the drug development process,
- Manage an uncertainty management process for a drug development project with confidence.

Target Audience
This tutorial is designed for global product/project directors, drug development functional leaders, program and project managers and support staff, functional project managers and support staff, as well as project management support office managers and staff.

Tutorial #61 *AHC/IS, RA*

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

Josephine C. Babiarz, Esq.
Director, MS Program in Regulatory Affairs and Health Policy, Massachusetts College of Pharmacy and Health Sciences
Barry Sall
Principal Consultant, PAREXEL Consulting

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET 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. Finally, we will review Condition of Approval letters and develop plans to satisfy their postmarketing surveillance requirements, and address the logistical, regulatory, and privacy challenges of COA "registry" trials.

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, etc.),
- Explain the nature and type of IRB and sponsor oversight,
- Develop plans to address the requirements for meeting Condition of Approval letters,
- Identify and manage major risks encountered in the medical device development process.

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

Tutorial #62 *GCP, PM/FI, TR*

Leadership: How to Organize and Lead People in Group Work

Mike Laddin, MS, MBA
President, LeaderPoint

.3 IACET CEUs

The role of a leader in organizing and leading a group is often misunderstood and, as a consequence, the group may not perform up to expectations, or it may spend a considerable amount of time dealing with dysfunctional group dynamics instead of the work to be accomplished.

This tutorial addresses those issues by exploring the types of work groups, how they can be more effective, and how individuals can correct group dynamics and 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,
- Demonstrate an effective response to distracting influences on group work to minimize impact on quality of work.

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

Tutorial #63 *RA, RD*

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 startup companies with the required terminology and functions, pharmaceutical/biological companies that have yet to file INDs, and those who want to improve their early development approach.

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

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

Tutorial #64, originally #30, has been rescheduled from Saturday, June 21 from 1:00-4:30 pm.

Tutorial #64 **BT, RA**

Comparability of Biopharmaceuticals

Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting Group

.3 IACET CEUs; 286-000-08-502-L04; 3.25 pharmacy contact hours (.325 CEUs)

Issues surrounding the complex subject of demonstrating comparability of biological and biotechnological medicinal products from a regulatory perspective will be presented. The impact of manufacturing process changes on product quality, safety, and clinical efficacy will be analyzed. Using case studies, solutions demonstrating comparability of these complex products will be developed.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Identify key aspects of manufacturing processes of biological and biotechnological medicinal products where changes potentially impact product quality, safety, and efficacy,
- Assess the impact of process manufacturing changes from a regulatory perspective.

Target Audience
This tutorial is designed for professionals in biopharmaceutical development, including development managers, research scientists, scientific officers, and regulatory affairs professionals.

■ SUNDAY, JUNE 22, 2008 1:00 pm-4:30 pm

Tutorials #70 through #82 Fee $375

Tutorial #70 *CR, MW, ST*

Analysis of Safety Data from Clinical Trials

Joachim Vollmar, MSc
Executive Consultant, International Clinical Development Consultants, LLC
Jürgen Kübler, PhD
Director, Global Head, Integrated Safety and Health Economics Biostatistics, Novartis Pharma AG, Switzerland

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

This tutorial is a combination of theory, guidelines, practical considerations, and real-life solutions for those working in the clinical development environment (pharmaceutical, biotech industry, or CRO). The aim of this tutorial is to provide a basic understanding of the underlying methodology and the current guidelines on safety data. Aspects of the planning of clinical trials as well as the problems and pitfalls during the analysis of safety data will be presented. The presentations will also include case studies.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Contribute to safety analysis plans,
- Assess statistical safety analysis,
- Identify pitfalls in safety analysis,
- Discuss relevant guidelines and regulatory requirements.

Target Audience
This tutorial is designed for biostatisticians, medical writers, clinical researchers, drug safety specialists, project managers, and investigators.

Tutorial #71 *CP, RA*

Evaluation of Risk Management Programs Using Existing Databases

Annette Stemhagen, DrPh, FISPE
Vice President, Epidemiology and Risk Management, United BioSource Corporation
Mariska F. Kooijmans-Coutinho, MD, PhD
Senior Director, Drug Safety and Risk Management, Biogen Idec

3.25 AMA PRA Category 1 Credit(s)™; .3 IACET CEUs; 3.25 nursing contact hours; 286-000-08-511-L04; 3.25 pharmacy contact hours (.325 CEUs)

A critical component of any risk minimization action plan is defining how success of the plan will be measured. Not only must the evaluation metrics be established a priori, but the methods for evaluation and the data required to complete an evaluation must be determined. This tutorial will provide an overview of risk management evaluation strategies, including surveys, audits, and registries. It will also describe use of epidemiologic and ad hoc databases for evaluation of risk management programs. A final segment will discuss why your marketing department is an untapped resource in evaluation endeavors!

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Discuss the range of evaluation methods that can be used to evaluate risk management interventions,
- Choose the most appropriate evaluation tools for the circumstances.

Target Audience
This tutorial is directed to safety, regulatory, and risk management groups who are actively working in development of risk minimization actions plans (RiskMAPs), risk management programs and their evaluation strategies.

Tutorial #72 *CP, CR*

Effective Drug Safety Systems

Seth Warhaftig
Managing Director, November Research Group
Alan Summer
Senior Director, November Research Group

.3 IACET CEUs

Tutorial #72 has been cancelled.

No[illegible] beyond the core transactional software for processing adverse events and now cover much more functionality including data capture, SAE reconciliation, data transfer, aggregate report management, data analysis, and signal detection. The increased demands due to case volume and regulatory demands have led to companies looking to achieve greater and greater efficiencies via the most effective use of technology. The usage of computerized systems for handling drug safety data is a necessity and the scope of available applications has increased significantly in recent years. This tutorial will examine whether such systems are being used to maximum advantage. The most effective usage of the available software will be discussed.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Explain the complexity of modern safety systems and the challenges of using them effectively,
- Apply approaches for maximizing safety system usage.

Target Audience
This tutorial is designed for drug safety professionals and IT colleagues wishing to gain insights into safety system implementation and usage best practices.

Tutorial #73 *CP, RA*

The Creation and Management of a Worldwide Pharmacovigilance Quality Assurance Unit

Maria C. Koster, PhD
CEO, Vigilex B.V., Netherlands
Joanne Spallone
Executive Director, Clinical Quality Assurance, Novartis Pharmaceuticals Corporation
Jurjen de Jong, PharmD
ISO Lead Auditor and PV Auditor, Vigilex B.V., Netherlands

.3 IACET CEUs

Pharmacovigilance is defined as the activities undertaken to ensure that the administration of medicinal products to humans demonstrates an acceptable balance of benefit-risk at all times during their use, whether in the developmental phase or after authorization. Pharmacovigilance audits are conducted to assess whether these activities are performed in compliance with applicable legislation and guidance for pharmacovigilance and to assure internal consistency, data integrity, and adherence to the company's policies and procedures.

It involves various functions within the organization such as the pharmacovigilance departments, as well as adjacent functions that might potentially be confronted with AEs. Proper routing of AEs is essential to ensure a full overview of all safety information available. In addition, external third parties might be involved and appropriate controls need to be in place to ensure adequate collection and collation. Therefore all departments, partners or contract companies that are involved in any aspect of pharmacovigilance, are eligible for auditing by a pharmacovigilance QA unit.

The frequency and scope of the audits need to reflect the potential risk factors of the organizations, products and sites to be audited. A risk-based audit plan will assist in prioritizing audit activities in the best possible way and therefore be consistent with the organizational goals and available resources. Risk is the combination of the probability of occurrence of harm and the severity of that harm. Standard operating procedures (SOPs) describing the preparation, execution, and reporting of an audit are necessary to ensure consistency thereby facilitating comparison of findings within and between audits performed at various sites and at different points in time. Last, but not least, auditors need to be appropriately qualified to assess the system and proof of such needs to be present.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Discuss the fundamentals of creating a QA unit for pharmacovigilance by learning from previous experiences in building such,
- Manage effective pharmacovigilance audits by creating a risk-based audit plan, SOPs, etc.

Target Audience
The tutorial is designed for QA staff, individuals working in pharmacovigilance/vigilance of medical devices/cosmeticovigilance.

Tutorial #74 *ERS/DM, RA*

Electronic Submission Success

Jay B. Smith
Director, Product Management, Thomson Scientific
Bernadette J. Billet
Product Manager, Thomson Scientific/Li

.3 IACE

Tutorial #74 has been cancelled.

In the l , Guidance on preparation and submission of electronic submissions began to appear, defining acceptable fonts, bookmarks, cross-referencing, pagination, file size, etc. The publishing of electronic paper had become the standard within the life sciences industry. With the introduction of the eCTD specification in 2003, the focus for electronic submissions changed from electronic paper submissions to life-cycle management of documents over the development and marketing phases of pharmaceutical products. The eCTD specification defines the means to create and transfer the electronic submission as well as defining the criteria for acceptance.

The electronic Common Technical Document (eCTD) format is the desired submission format for many regulatory authorities. CDER has mandated that all applications that are submitted electronically must be in the eCTD format starting January 1, 2008. In the European Union, all Member States must be capable of accepting the eCTD format by 2009. In addition, the Regulated Product Submission (RPS) standard is progressing through the approval process at HL7 with significant support from FDA.

In this tutorial, participants will learn what other organizations have done to successfully transition to eCTD and what they are doing to plan for RPS. The tutorial will focus on the importance of standards, process, and technology and the role of each in the transition. Information will be communicated through case studies, exercises, and group discussion.

Learning Objective
At the conclusion of this tutorial, participants should be able to:
- Discuss electronic submission requirements in major regions including eCTD and RPS.

Target Audience
This tutorial is designed for individuals who are responsible for successfully submitting electronic submissions in eCTD or RPS within their organization.

Tutorial #75 *CR, GCP*

GCP Issues in Emerging Regions: India and China

Munish Mehra, PhD, MSc
Managing Director, Global Drug Development Experts
Daniel Liu, PhD
Director, China Development, Medidata Solutions, China

.3 IACET CEUs

This tutorial will highlight the specific requirements of GCP as defined under ICH E6 as well as the FDA's website. These will be compared and contrasted to GCP as required in India and in China.

Learning Objective
At the conclusion of this tutorial, participants should be able to:
- Describe what the ICH GCP requirements are and how they differ from GCP in India and China.

Target Audience
This tutorial is designed for CRAs, QA auditors, PMs and regulatory staff who are involved in conducting global clinical trials with sites in emerging regions.

Tutorial #76 *CR, IMP/EBM*

Training Considerations for Patient-reported Outcomes

Adam Butler
Senior Director, Creative Services, Training and Education, United BioSource Corporation
Anne M. Rentz, MSPH
Research Scientist, The Center for Health ed
Biosource Corp

Tutorial #76 has been cancelled.

3.25 AMA ; .3 IACET CEUs; 3.25 nursing contact hours; 286-000-08-512-L04; 3.25 pharmacy contact hours (.325 CEUs)

Patient-reported outcome (PRO) instruments can be used as effective endpoints in clinical research. The amount and type of evidence required by the FDA to support labeling claims measured by PRO instruments is not different from any other endpoint.

According to the Guidance for Industry Patient-reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, the FDA indicates that increased training for both clinicians and patients will be critical to ensure the effective use and application of PRO assessments. The FDA sug-

gests that study quality can be optimized through standardized instruction for investigators, standardized training and instruction for patients, and standardized interviewer training and training format.

This tutorial will review the impact of this guidance on clinical studies, present a case study on implementing a training program for PRO use in clinical studies, and incorporating results of your training program into your PRO evidence dossier.

Learning Objectives

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

- Discuss the FDA Draft Guidance on PROs and its recommendations for training,
- Discuss a case study on a training scenario for a clinical trial that utilized patient-reported outcomes as primary endpoints,
- Incorporate PRO training and results into your evidence dossier,
- Describe patient-completed versus interviewer-administered outcomes.

Target Audience

This tutorial is designed for research scientists developing new outcomes or incorporating outcomes into a clinical trial. Clinical trial managers supporting studies that utilize interviewer-administered, patient-reported outcomes will also benefit from this tutorial, as well as training managers responsible for programs that include patient-reported outcomes.

Tutorial #77 *MW, RA*

CTD Preparation: Module 2 Clinical Overview and Clinical Summary and Relationship to ISE and ISS

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

.3 IACET CEUs

The Guidance for Industry, M4E: The CTD – Efficacy will be reviewed with particular emphasis on those sections that apply to preparing a Clinical Overview (CTD Module 2, Section 2.5) and a Clinical Summary (CTD Module 2, Section 2.7) for an NDA or BLA. FDA's Clinical Review Template (FDA's MAPP 6010.3) and FDA's reviewer Guidance "Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review" will be analyzed from the perspective of how they can assist sponsors in preparing better Clinical Overviews, Clinical Summaries, ISE documents, and ISS documents. FDA's Guidance on the location of the ISE and ISS within the CTD will also be reviewed. Package inserts, as well as text, tables, and figures excerpted from medical and statistical reviews of approved drugs and biologics will be used as instructional tools.

Learning Objective

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

- Interpret and apply relevant Guidance from ICH and FDA to the writing of an effective Clinical Overview (CTD Module 2, Section 2.5) and an effective Clinical Summary (CTD Module 2, Section 2.7) for an NDA or BLA.

Target Audience

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

Tutorial #78 *CR, CTM/CS, PM/FI*

Project Management for the Nonproject Manager

Robert L. Judd
CEO, Robert Judd Associates (RJA)
Martin D. Hynes, III, PhD
Director, Six Sigma Champion for Product Development, Eli Lilly and Company

.3 IACET CEUs

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

Learning Objectives

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

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

Target Audience

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

Tutorial #79 *RA*

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

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

.3 IACET CEUs

Major changes in the Japanese pharmaceutical regulations are impacting the development of new drugs in Japan 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:

- Identify the major elements of the Japanese regulatory system including the newly created agency,
- Describe the regulatory processes during development, registration, and postapproval safety and pricing in Japan,
- Discuss specific attributes in the Japanese regulatory system and their impact on multinational development strategies.

Target Audience

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

Tutorial #80 *CR, TR*

Working Across Cultures: Asia and the West

Betty R. Kuhnert, PhD, MBA
Executive Director, Global Training Services, PharmaNet
Dean Foster
President, Dean Foster Associates

.3 IACET CEUs

Tutorial #80 has been cancelled.

More and companies are developing drugs in Asian countries, and many Asian companies are doing business in Europe, and in North and South America. However, working across cultures is not always easy, and the opportunities for misunderstandings and gaffs are common even if language is not an issue. This half-day tutorial will provide information and practical exercises that will allow participants to understand how culture influences daily interactions and work practices. For example, while some aspects of culture are very obvious, eg, language or food, other less obvious aspects, such as concepts of politeness, are the ones that may affect working relationships the most. This tutorial will help international co-workers work together, and help companies doing business globally.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Improve cross-cultural interactions and negotiations,
- Overcome cultural obstacles faced by global organizations,
- Build more effective global teams.

Target Audience
This tutorial is designed for those in global organizations with current or future interest in working outside of their own culture, anyone who interacts with someone from another culture, and those who travel to other countries, particularly Asia, and Asians who interact with westerners.

Tutorial #81 *CR, ST*

Adaptive (Flexible) Trial Designs

Gernot Wassmer
Researcher, IMSIE - University of Cologne, Germany
Dr. Martina Elze
ClinResearch GmbH, Germany

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

This tutorial will focus on
- The principle,
- Possible data-dependent changes of design,
- Adaptive designs for dose finding/seamless trials,
- Analysis tools in adaptive designs,
  - Estimation and overall p-values
  - Binary, normal and survival data
- How to plan and analyze an adaptive trial (practical examples),
  - Operational challenges
    - Interim analysis, un-blinding (firewalls), and reporting
    - Data management and data cleaning
    - DMCs and ISCs.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Explain the principles and major areas of application of adaptive trial designs,
- Describe the tools for analyzing adaptive clinical trial designs,
- Discuss the operational challenges for implementing adaptive clinical trial designs.

Target Audience
The tutorial is designed for biostatisticians, medical writers, clinical researchers, regulatory affairs specialists, project managers, and investigators.

Tutorial #82 *CR, 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 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 and what isn't. 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. This tutorial targets those who have clinical operations responsibilities including interaction or oversight of outsourced-site monitors. The tutorial will also afford sponsor or 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 at improving management techniques.

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

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

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 Titles and Acronyms

AD	Advertising	EC	eClinical	NC	Nonclinical Laboratory Safety Assessment
AHC/IS	Academic Health Centers/ Investigative Sites	ERS/DM	Electronic Regulatory Submissions/ Document Management	NHP	Natural Health Products
BT	Biotechnology	GCP	Good Clinical Practices	OS	Outsourcing
CDM	Clinical Data Management	IMP/EBM	Impact of Medical Products and Therapies/ Evidence-based Medicines	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 and Sales	RA	Regulatory Affairs
CR	Clinical Research and Development	MC	Medical Communications	RD	R&D Strategy
CTM/CS	Clinical Trial Management/ Clinical Supplies	MW	Medical/Scientific Writing	ST	Statistics
				TR	Training
				VA	Validation

MONDAY 8:30 am-10:00 am

PLENARY SESSION *All registrants are encouraged to attend.*

Welcome, Award Presentations, Keynote Address — **Grand Ballroom, Level 3, BCEC**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
MONDAY 10:30 am-12:00 pm					
101	FDA Enforcement Update	LEVEL ●	**AD**	RA	**153AB**
102	The Third Annual Session on Investigator Budgets and Reimbursement: The Impact on Patient Enrollment and Retention	LEVEL ■	**AHC/IS**	CR	**104AB**
103	Facilitating the Regulatory Approval of Products for Public Health Emergencies: Emerging Infectious Diseases or Intentional Terrorist Acts	LEVEL ■	**BT**	RA	**105**
104	Clinical Data Optimization	LEVEL ■	**CDM**	CR	**258C**
105	CMC Pilot: Lessons Learned – An FDA Perspective	LEVEL ●	**CMC/GMP**	RA	**154**
106	Case Assessment and Narrative Generation in Pre- and Postmarketing Safety: Clinically-based Active Query Leads to Quality Data	LEVEL ■	**CP**	CR	**156AB**
107	Adaptive Design in Clinical Research	LEVEL ■	**CR 1**	ST	**204AB**
108	Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done?	LEVEL ●	**CR 2**	GCP	**205A**
109	Going "Glocal": The Trend in Global Patient Recruitment and Retention	LEVEL ◆	**CR 3**	AHC/IS	**205B**
110	The Process of Study Feasibility: Three Perspectives, One Common Goal	LEVEL ■	**CR 4**	AHC/IS	**203**
111	Global eCTDs: A Plan for Labeling	LEVEL ●	**ERS/DM 1**	RA	**157C**
112	FDA and CDISC eSubmission Pilots	LEVEL ■	**ERS/DM 2**	EC	**157AB**
113	FDA Amendments Act 2007 (FDAAA) Title 8: Expanded Clinical Trial Registry Data Bank	LEVEL ■	**GCP**	RA	**206AB**
114	SDLC Controls and Project Management Mechanisms to Support IT in Validated Environments	LEVEL ■	**IT 1**	VA	**258A**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
MONDAY	**10:30 am-12:00 pm *continued***				
115	Issues and Case Studies in Safety Data Migration	LEVEL ■	**IT 2**	CDM	**258B**
116	Outsourcing of Clinical Trials to India and Beyond: Developing an Effective Global Outsourcing Team	LEVEL ●	**OS**	CR	**205C**
117	Developing Balanced Matrix and Maturing Product Development Teams	LEVEL ■	**PM/FI 1**	RD	**102AB**
118	Communications Management: The Key to Successful Project Teams	LEVEL ●	**PM/FI 2**	RD	**103**
119	Personalized Medicine: 2008 Update	LEVEL ■	**PP**	RA	**160AB**
120	Women's Health under the FDA Critical Path Initiative	LEVEL ●	**RA 1**	CR	**256**
121	Parallel NDA and Pharmacoeconomical Review for Early Access of Innovative Products	LEVEL ■	**RA 2**	PP	**253B**
122	Regulatory Strategy as a Key Component of the Global Multidisciplinary Drug Development Strategy	LEVEL ■	**RA 3**	RD	**253A**
123	Extraordinary Use New Drugs in Canada: Issues, Initiatives and Challenges	LEVEL ●	**RA 4**	PP	**251**
124	Changing Procedures for Conducting Clinical Trials in Europe	LEVEL ■	**RA 5**	CTM/CS	**252AB**
125	Postmarketing Study Commitments (PMCs): How FDA and Industry Can Effectively Collaborate to Design Better PMCs and Track Them to Completion	LEVEL ■	**RA 6**	CR	**254AB**
126	The European Pediatric Legislation and the Pediatric Committee (PDCO): The First Year of the Implementation	LEVEL ●	**RA 7**	PP	**253C**
127	New Strategies for Successful Licensing Acquisitions	LEVEL ●	**RD**	OS	**104C**
128	Multiregional Clinical Trials: Evaluating the Pros and Cons	LEVEL ●	**ST**	CP,CR,GCP,RA	**259AB**
129	Real Challenges Faced by Leaders of Virtual Teams in Global Pharmaceuticals	LEVEL ■	**TR**	CR	**157AB**
MONDAY	**1:30 pm-3:00 pm**				
130	Direct-to-consumer Statutory Review Program	LEVEL ●	**AD**	RA	**153AB**
131	The Impact of the New Clinical Research Paradigm on Investigational Sites	LEVEL ●	**AHC/IS**	CR	**104AB**
132	Recent Advancement of Novel Biotechnology in the Asia-Pacific Region	LEVEL ■	**BT**	RA	**105**
133	Evolving Role of the Medical Reviewer in Clinical Trials Data Management through the Prism of Growing Industry Expectations and Rising Standards	LEVEL ■	**CDM**	CR	**158C**
134	CMC Pilot Submissions and Lessons Learned: An Industry Perspective	LEVEL ■	**CMC/GMP**	RA	**154**
135	Different Approaches to Spontaneous Reporting: A New Business Model	LEVEL ◆	**CP 1**	ERS/DM	**156AB**
136	Drug-induced Liver Injury (DILI): How Well Do Preclinical and Clinical Studies Predict Hepatotoxicity?	LEVEL ■	**CP 2**	CR	**156C**
137	Improving the Business of Science: How Metrics Can Improve the Pharmaceutical Bottom Line	LEVEL ■	**CR 1**	PM/FI	**203**
138	Subject Recruitment in the US: Is It a Losing Proposition?	LEVEL ●	**CR 2**	CTM/CS	**204AB**
139	Radical Change in Clinical Development: Results from the Changes	LEVEL ◆	**CTM/CS**	CR	**162AB**
140	Replacing Aging EDM Systems: Opportunities and Challenges	LEVEL ■	**ERS/DM 1**	RA	**157C**
141	Pursuing Standards to Enhance eCTD Deliverables	LEVEL ■	**ERS/DM 2**	RA	**257AB**
142	After the Trial is Completed: What, When, Where, and How to Post Trial Results	LEVEL ●	**GCP 1**	PP	**206AB**
143	Navigating the New FDA Part 11 Guidance: Sponsor and Site Perspective	LEVEL ■	**GCP 2**	RA	**208**
144	CDISC SDTM Data Conversion	LEVEL ■	**IT 1**	VA	**258A**
145	How Much Information Technology Do Early Stage Biotechnology Firms Need?	LEVEL ■	**IT 2**	VA	**258B**
146	Outsourcing Strategies and Trial Management in Asia	LEVEL ◆	**OS**	CTM/CS	**205C**
147	Value of Six Sigma to Pharmaceutical Product Discovery and Development	LEVEL ■	**PM/FI 1**	RD	**102AB**
148	Project Manager to Project Leader: Facilitating the Transition	LEVEL ■	**PM/FI 2**	CR	**103**
149	Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials	LEVEL ●	**PP**	RA	**160AB**
150	Facilitating Global Pediatric Drug Development: An Assessment of Recent Experience	LEVEL ●	**RA 1**	CR	**252AB**
151	ICH Global Cooperation Group (GCG) Initiative Update	LEVEL ■	**RA 2**	PP	**253A**
152	Introduction to European Public Assessment Reports (EPARs) and FDA Approval Packages: Finding and Analyzing Unpublished Information about Pivotal Studies	LEVEL ●	**RA 3**	RD	**256**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
MONDAY	**1:30 pm-3:00 pm *continued***				
153	Generic Biologics: Fact or Fiction?	LEVEL ●	**RA 4**	RD	**251**
154	A Standardized Approach to Improving the Quality of the Regulatory Review and Submission: Can Scorecards Increase the Predictability of the Review Process?	LEVEL ■	**RA 5**	RD	**253B**
155	The Current Status within China on GCPs, Computerized Systems Used in Clinical Trials and Data Integrity	LEVEL ●	**RA 6**	GCP	**253C**
156	The EMEA: How to Make the Best of It	LEVEL ●	**RA 7**	PP	**254AB**
157	Go/No Go Decision Making for Global Drug Development Including Japan	LEVEL ■	**RD**	CR	**104C**
158	Genomic (Surrogate) Biomarker in Therapeutic Trials	LEVEL ■	**ST**	CR	**259AB**
159	Developing Academic Program Accreditation Standards for Clinical Research Education Programs	LEVEL ■	**TR**	AHC/IS	**157AB**
	MONDAY 3:30 pm-5:00 pm				
160	Introduction to Pharmaceutical Marketing	LEVEL ●	**AD**	RA	**153AB**
161	Effective Working with Investigative Sites: Essentials for Clinical Trial Conduct in the Emerging World	LEVEL ■	**AHC/IS**	CTM/CS	**104AB**
162	Hot Topics in Biotechnology	LEVEL ■	**BT**	CR	**105**
163	An Honest Look at the eClinical Process: How Biotechnology Can Learn from Best Practices Outside the Industry	LEVEL ■	**CDM**	CR	**258C**
164	CMC Postapproval Management Plan	LEVEL ■	**CMC/GMP**	RA	**154**
165	Electronic AE/ADR Case Reporting Within and Between Regions: Is It Working Well?	LEVEL ◆	**CP 1**	CDM	**156C**
166	The Development Safety Update Report (DSUR): The CIOMS VII Report and the ICH E2F Initiative	LEVEL ■	**CP 2**	RA	**156AB**
167	Personalized Medicine and Its Impact on Drug Development and Commercialization	LEVEL ■	**CR 1**	MA	**205B**
168	The Keys to Establishing Best Practices for Accelerated Study Startup	LEVEL ■	**CR 2**	RD	**204AB**
169	Pediatric Trial Issues from the Global Perspective	LEVEL ■	**CR 3**	CTM/CS	**205A**
170	Patient Enrollment: Underrepresented Populations	LEVEL ●	**CR 4**	CTM/CS	**203**
171	The Realities of Implementing CDISC	LEVEL ●	**EC**	ST	**258B**
172	How Goes It? Electronic Registration and Listing at FDA	LEVEL ●	**ERS/DM 1**	IT	**257AB**
173	The eCTD: Lessons Learned and Practical Experience	LEVEL ■	**ERS/DM 2**	RA	**157C**
174	Are We Doing Too Much? What We Can Learn from Compliance Plans and Audits of WHO Trials Conducted in Developing Countries	LEVEL ■	**GCP**	RA	**206AB**
175	The Implementation of Biological Sample Management and Biobanking Systems	LEVEL ■	**IT**	CDM	**258A**
176	Skills for Medical Writers: Now and in the Future	LEVEL ■	**MW**	TR	**153C**
177	Meeting Clinical Research Challenges in India	LEVEL ■	**OS**	CR	**205C**
178	High Performance Leaders = High Performance Teams	LEVEL ■	**PM/FI 1**	CR	**102AB**
179	Financial Accruals for Clinical Trials: How to Generate without Excruciating Pain	LEVEL ■	**PM/FI 2**	CTM/CS	**103**
180	Civil and Regulatory Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials?	LEVEL ●	**PP**	RA	**160AB**
181	Current Review and Assessment Models for Approval of New Medicines in Emerging Markets: Differences and Similarities across 13 Countries in Latin America, Middle East, Africa, and Southeast Asia	LEVEL ■	**RA 1**	RD	**253B**
182	US-EU Agreement: Administrative Regulatory Simplification – The Next Phase?	LEVEL ●	**RA 2**	PP	**253C**
183	Dispute Resolution with the FDA: Looking for Win-Win Results	LEVEL ■	**RA 3**	RD	**254AB**
184	The Tactical and Practical Side of Quality Systems: How FDA Implementation is Helping Our Customers	LEVEL ■	**RA 4**	CP	**252AB**
185	Proactive Risk Management Planning during Drug Development	LEVEL ■	**RA 5**	RD	**251**
186	Updates in CDE Drug Reviews and GLP Regulations	LEVEL ■	**RA 6**	–	**256**
187	European Innovative Medicines Initiative: Up and Running!	LEVEL ●	**RA 7**	CP	**253A**
188	Public-private Partnership on Clinical Research in the Asia-Pacific Region	LEVEL ■	**RD**	CR	**104C**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
MONDAY	**3:30 pm-5:00 pm *continued***				
189	Selecting the Optimal Sample Size: Initial Realism or Adaptive Re-estimation	LEVEL ■	**ST**	CR	**259AB**
190	Postgraduation in Clinical Research: Brazil	LEVEL ■	**TR**	CR	**157AB**
	TUESDAY 8:00 am-9:30 am				
201	International Promotional Issues	LEVEL ■	**AD**	RA	**153AB**
202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**AHC/IS**	CP,CR,GCP,PP,RA	**210ABC**
203	STARDATE 2013: Visions of the Life of a Data Manager	LEVEL ■	**CDM**	CR	**258C**
202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**CP & CR**	AHC/IS,GCP,PP,RA	**210ABC**
204	Navigating the Bumps in the Road on Partnered Clinical Trials	LEVEL ■	**CR 1**	PM/FI	**205A**
205	Patient Recruitment Strategies and Sites' Perspectives	LEVEL ●	**CR 2**	AHC/IS	**205B**
206	Becoming a Sponsor of Choice for Clinical Investigators	LEVEL ■	**CTM/CS**	CR	**204AB**
207	Applying ePRO in Special Populations	LEVEL ●	**EC**	RD	**258B**
208	IND in eCTD Format: Challenges and Successes	LEVEL ●	**ERS/DM**	CDM	**257AB**
202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**GCP**	AHC/IS,CP,CR, PP,RA	**210ABC**
209	Negotiating IT Contracts: Speeding Up the Process and Finding Common Ground	LEVEL ●	**IT**	OS	**258A**
210	The Lady and the Tiger of Position Choices and Training Keys for Position Success	LEVEL ■	**MC**	TR	**253B**
211	Streamline Your Language Outsourcing	LEVEL ●	**OS**	CDM	**205C**
212	Biomarkers in Drug Development: What a Project Manager Needs to Know and Do to Enhance Project Value	LEVEL ●	**PM/FI 1**	RD	**102AB**
213	Life Science Project Management Is Dead: A New (Old) Model for the Future	LEVEL ■	**PM/FI 2**	RD	**103**
214	Global Communication for Effective Drug Development in Japan: How Westerners Should Communicate with the Japanese for the Best Drug Development in Japan	LEVEL ●	**PM/FI 3**	CR	**105**
215	Doing the Project Planning for Large Multinational Clinical Trials	LEVEL ■	**PM/FI 4**	CTM/CS	**104AB**
216	Incentives and Rewards for Innovation in Pharmaceutical Development	LEVEL ●	**PP**	RA	**160AB**
202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**PP & RA**	AHC/IS,CP,CR,GCP	**210ABC**
217	Applying for Drug Approvals in China: A Mystical Opportunity	LEVEL ●	**RA 1**	RD	**256**
218	Innovative Approval Paths Are Needed for Products that Treat Rare Diseases	LEVEL ●	**RA 2**	RD	**253A**
219	Biotechnology R&D in Developing Countries: A Public-private Partnership between a Cancer Institute, a Brazilian Entrepreneurship, and Health Institutes	LEVEL ◆	**RD**	CR	**162AB**
220	Are You Ready for Adaptive Clinical Development? Examples, Case Studies, Successes – Part 1 of 2	LEVEL ■	**ST**	CTM/CS	**159AB**
221	You're Hired! Strategies for Identifying, Interviewing, and Preparing for a Career in the Pharmaceutical Industry	LEVEL ●	**TR**	CR	**157AB**
	TUESDAY 10:00 am-11:30 am				
222	Medical Science Liaisons Communications	LEVEL ■	**AD**	MC	**153AB**
223	The Impact of FDAAA and Health Information Technology Interoperability Activities on Drug Safety, Implementation of Standards, and Data Stewardship Principles	LEVEL ■	**AHC/IS**	IT	**104AB**
224	Gene Therapy Regulations for EU Clinical Trials: Navigating the Maze	LEVEL ■	**BT**	RA	**105**
225	Building a Strong EDC Foundation through the Power of Partnership	LEVEL ●	**CDM**	EC	**258C**
226	Implementation of Quality by Design: A Global Perspective	LEVEL ■	**CMC/GMP**	RA	**154**
227	Modernization of FDA Postmarket Adverse Event Information Management	LEVEL ■	**CP**	RA	**156AB**
228	The Symbiosis of Clinical Research, Public Health and Patient-consumer Involvement: Reconceptualizing Clinical Trial Research	LEVEL ●	**CR 1**	CTM/CS	**203**
229	Enhancing Patient Adherence in Clinical Trials with eTechnology	LEVEL ●	**CR 2**	EC	**205A**
230	Thirty Ways to Increase Enrollment at Your Site	LEVEL ■	**CR 3**	CTM/CS	**208**
231	Six Sigma: Straightening the Long and Winding Road of Clinical Development	LEVEL ●	**CR 4**	PM/FI	**205B**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
TUESDAY	**10:00 am-11:30 am *continued***				
232	The Implementation of a CTMS System	LEVEL ■	**CTM/CS**	CR	**204AB**
233	CDISC's Healthcare Link Initiatives: An Overview of CDISC Projects, Parallel Activities, and Long-term Implications	LEVEL ■	**EC**	CR	**258B**
234	CDER Electronic Submissions Update	LEVEL ●	**ERS/DM**	CDM	**257AB**
235	Town Meeting: The Very Different Faces of Quality – QA, QC, Validation, Regulatory Affairs, and Compliance	LEVEL ●	**GCP**	RA	**206AB**
236	Business and Technology Considerations for a SaaS Solution in the Life-sciences Industry	LEVEL ●	**IT**	EC	**258A**
237	Evidence-based Medicine: A Practical Approach for the Medical Communications Professional	LEVEL ■	**MC**	TR	**253B**
238	Data Displays to Aid Regulatory Agency Review of Safety Data	LEVEL ■	**MW**	CR	**153C**
239	Regulatory Requirements with NHP: What Is New?	LEVEL ■	**NHP**	RA	**156C**
240	Emerging Dilemma in Japan: Outsourcing for Multinational Trials	LEVEL ■	**OS**	CR	**205C**
241	Organizing for Project Management: Exploring the Value of a Matrix Approach to Project Management in Life Sciences Organizations and Companies	LEVEL ■	**PM/FI 1**	RD	**102AB**
242	Deal Makers and Deal Breakers: What Venture Capital Firms Look for in Drug Development Plans	LEVEL ■	**PM/FI 2**	RD	**103**
243	Off-label Use of Medicinal Products – Part 1 of 2	LEVEL ●	**PP**	RA	**160AB**
244	PMDA Update: PMDA Initiatives and Challenges for Promoting Global Drug Development Including Japan	LEVEL ■	**RA 1**	PP	**253A**
245	Regulatory Strategies in Latin America: New Conquest for Pharmaceutical Companies for Timely Submissions and Project Startups in Mexico and Other Latin American Countries	LEVEL ■	**RA 2**	CTM/CS	**256**
246	EU Variation Regulations Update: Why, What, When, and Authorities' and Industries' Perspectives	LEVEL ■	**RA 3**	BT	**254AB**
247	RAHP Gold: Device Track Masters	LEVEL ◆	**RA 4**	PM/FI	**251**
248	FDA Meetings: Understanding the Process and Maximizing Success	LEVEL ●	**RA 5**	RD	**252AB**
249	SFDA Hot Topic: Efforts to Ensure Drug Quality and Safety	LEVEL ●	**RA 6**	CP	**253C**
250	Postmarketing Commitments and Postapproval Research in the US and International Markets: Evolving Requirements, Efforts to Improve, and Strategies for Fulfillment	LEVEL ■	**RD**	RA	**162AB**
251	Are You Ready for Adaptive Clinical Development? Regulatory Considerations – Part 2 of 2	LEVEL ■	**ST**	CTM/CS	**159AB**
252	Pharmaceutical Medicine in Asia	LEVEL ■	**TR**	CR	**157AB**
	TUESDAY 2:00 pm-3:30 pm				
253	Success at the Crossroads: The Intersection of CDISC Standards with Research Site Processes	LEVEL ■	**AHC/IS**	IT	**104AB**
254	RNA Therapeutics: Bringing the Future of Biological and Medical Innovation to Today	LEVEL ■	**BT**	RA	**105**
255	Metrics Reporting: Challenges, Strategies and Successes	LEVEL ■	**CDM**	CR	**158C**
256	Updates on ICH Q8(R1) and Q10 Guidelines	LEVEL ■	**CMC/GMP**	RA	**154**
257	Pharmacovigilance and Risk Management Plans in Japan Today	LEVEL ■	**CP**	RA	**156AB**
258	Expanded Access Programs: Their Role in Product Development and Keys to Successful Implementation	LEVEL ●	**CR 1**	GCP	**210A**
259	Data-driven Patient Recruitment: Tools for Early Planning and Predictive Management	LEVEL ■	**CR 2**	IT	**205A**
260	Addressing the Adverse Impact of Increasing Protocol Complexity on Study Conduct Performance	LEVEL ●	**CR 3**	RD	**205B**
261	Solving Complex Problems in Clinical Trial Supply Management	LEVEL ■	**CTM/CS**	CR	**204AB**
262	Leveraging Electronic Health Records in Clinical Research	LEVEL ■	**EC**	IT	**158B**
263	FDA: eCTD Compliance – Part 1 of 2	LEVEL ●	**ERS/DM**	CDM	**157AB**
264	Review of Regulatory Agency Inspection Reports	LEVEL ●	**GCP**	RA	**206AB**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
TUESDAY	**2:00 pm-3:30 pm *continued***				
265	Good Practices for Clinical Endpoint (PRO, CRO) and Linguistic Validation: State of the Science	LEVEL ■	**IMP/EBM**	RA	**208**
266	Service-oriented Architecture in R&D	LEVEL ■	**IT**	EC	**258A**
267	Medical Liaison Survey #4: Assessing Tools Used by MLs, Clinical Trial Involvement, and Career Strategies	LEVEL ●	**MC**	IT	**253B**
268	Making the Transition to Writing IND Documents for the eCTD Submission	LEVEL ■	**MW**	RA	**153C**
269	Revisions to ICHM3(R1) in the Areas of Acute Toxicity, Chronic Toxicity, and Developmental Toxicity	LEVEL ■	**NC**	CR	**104C**
270	Challenges with Natural Health Products Research and Development	LEVEL ■	**NHP**	CR	**156C**
271	Lessons Learned: A Global Survey on Outsourcing Practices	LEVEL ■	**OS**	CR	**205C**
272	Utilization of Six Sigma Methodology in Clinical Trial Project Management	LEVEL ■	**PM/FI 1**	CR	**103**
273	Proactive Project Risk Management in Drug Development: The Value of Project Management to the Pharmaceutical Business	LEVEL ■	**PM/FI 2**	CP	**102AB**
274	Off-label Use of Medicinal Products – Part 2 of 2	LEVEL ●	**PP**	RA	**160AB**
275	Asian Cooperation/Collaborations for Promoting Drug Development	LEVEL ■	**RA 1**	PP	**251**
276	Innovative Medicines and the EMEA	LEVEL ■	**RA 2**	BT	**256**
277	Dealing with Potential Genotoxic Impurities (GTIs) Especially in FDC (Fixed-dose Combination) Drug Products for Global Clinical Trials	LEVEL ■	**RA 3**	CMC/GMP	**253A**
278	Foreign Health Authority Inspections of Manufacturing Sites	LEVEL ●	**RA 4**	PP	**252AB**
279	Best Practices for Preparing a Complete NDA that Warrants a Complete Review by FDA	LEVEL ●	**RA 5**	ERS/DM	**254AB**
280	Recent Advances in Adaptive Clinical Trial Designs	LEVEL ◆	**RD**	CR	**162AB**
281	Meta-analysis and the Postapproval Assessment of Safety Based on Accumulating Data from Clinical Trials	LEVEL ■	**ST**	CP	**159AB**
282	Networking for Career Advancement and Change	LEVEL ●	**TR**	MW	**157AB**
283	Systems Development Methodologies and Validation	LEVEL ■	**VA**	IT	**153C**
	TUESDAY 4:00 pm-5:30 pm				
284	Severe Adverse Events in Clinical Trials: A Difficult Issue between Sites and Sponsors	LEVEL ■	**AHC/IS**	PP	**104AB**
285	Current Experiences in Stem Cell Therapies	LEVEL ●	**BT**	NC	**105**
286	Meeting the Challenges of Laboratory Data Management	LEVEL ■	**CDM**	CR	**258C**
287	The Relationship between Biopharmaceutics and Quality by Design	LEVEL ■	**CMC/GMP**	BT	**154**
288	Pharmacovigilance in Latin America	LEVEL ■	**CP 1**	CR	**153AB**
289	OTC Drugs and Nutritional Supplements: The New World of AE/ADR Reporting	LEVEL ■	**CP 2**	NHP	**156AB**
290	Protocol Deviation/Violation/Exception	LEVEL ■	**CR 1**	ST	**205A**
291	Factors Influencing the Speed of Clinical Trial Study Completion	LEVEL ■	**CR 2**	AHC/IS	**205B**
292	Letters from the Front: Experiences with Clinical Trials in Asia and Central America	LEVEL ■	**CR 3**	OS	**203**
293	"E"asing the Management of the Clinical Supply Chain: Drug Accountability, Reconciliation, Returns, and Destruction	LEVEL ■	**CTM/CS**	CR	**204AB**
294	Standards Shock Therapy: Demystifying the Current and Future Roles of CDISC and HL7 Standards for Clinical Research and Regulatory Submissions	LEVEL ◆	**EC**	ERS/DM	**258B**
295	FDA: eCTD Compliance – Part 2 of 2	LEVEL ●	**ERS/DM**	CDM	**257AB**
296	Planning for and Insuring against the Risk Associated with the Conduct of a Clinical Trial Program	LEVEL ■	**GCP**	CR	**206AB**
297	Patient-reported Outcomes (PRO) Claims: Understanding the Scientific and Regulatory Requirements	LEVEL ●	**IMP/EBM**	EC	**208**
298	Utilizing Open-source Software in Clinical Research Environments	LEVEL ■	**IT**	EC	**258A**
299A	Drug Information, Wikipedia, and Google Scholar: Implications for Medical Information	LEVEL ●	**MC**	MW	**253B**
299B	Establishing Standards for Medical Writing	LEVEL ■	**MW**	ERS/DM	**153C**
299C	Pediatric Drug Development	LEVEL ◆	**NC**	CR	**104C**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
TUESDAY	**4:00 pm-5:30 pm *continued***				
299D	Evolving Natural Health Products Market Size and Its Development	LEVEL ●	**NHP**	MA	**156C**
299E	Outsourcing Safety Narrative and AE Management to India	LEVEL ●	**OS**	RA	**205C**
299F	Advanced Portfolio Management Methodologies	LEVEL ◆	**PM/FI 1**	RD	**103**
299G	Intelligent Communication: Empowering Pharmaceutical R&D Project Managers for Success	LEVEL ●	**PM/FI 2**	RD	**102AB**
299H	Legislation, GCP, and Ethical Principles Guiding Clinical Trials in China	LEVEL ■	**PP**	RA	**160AB**
299I	Fifth Update: Outlook for Changes in the Japanese Regulatory and Clinical Development Environment	LEVEL ■	**RA 1**	CR	**256**
299J	Establishment of a Regulatory Function in a Startup Biotechnology/ Pharmaceutical Company	LEVEL ■	**RA 2**	RD	**252AB**
299K	Impact of PDUFA IV Commitments on Review and Evaluation of Trademarks	LEVEL ■	**RA 3**	CP	**253A**
299L	Drug Diagnostic Co-development: Implications for Biomarker Validation and Personalized Medicine	LEVEL ■	**RD**	CR	**162AB**
299M	Novel Statistical Issues from the Regulatory Biostatistician's Viewpoint	LEVEL ■	**ST**	RD	**259AB**
299N	Overview of Drug Development for Emerging Professionals	LEVEL ●	**TR**	CR	**157AB**
299O	Including Risk in Computer Validation	LEVEL ●	**VA**	CP	**253C**
WEDNESDAY	**8:30 am-10:00 am**				
301	Accelerating Research: Integrating Clinical Research with Clinical Care	LEVEL ●	**AHC/IS**	CR	**104AB**
302	Biosimilars/Follow-on Biologics	LEVEL ■	**BT**	RA	**105**
303	Imaging Biomarker Data Management	LEVEL ■	**CDM**	CR	**258C**
304	Quality Risk Management	LEVEL ■	**CMC/GMP**	RA	**154**
305	An Industry-regulatory Survey of Benefit-risk Management Best Practices, Including Case Studies	LEVEL ■	**CP**	CR	**156AB**
306	Conducting Clinical Trials in China: Status and Trends	LEVEL ■	**CR 1**	CTM/CS	**205A**
307	Practical Issues in Industry-sponsored, Investigator-initiated Trials (IITs)	LEVEL ■	**CR 2**	CTM/CS	**205B**
308	Accelerated Recruitment Strategies for Global Megastudies	LEVEL ■	**CTM/CS 1**	CR	**153AB**
309	Electronic Data Capture as a Strategy to Enhance Complete Data Capture, Site Satisfaction, and Participation in Registries and Observational Studies	LEVEL ●	**CTM/CS 2**	CR	**204AB**
310	Anatomy of ePRO Validation	LEVEL ■	**EC**	VA	**258B**
311	eCTD: What It Is, What It Is Not, and What It Might Be	LEVEL ■	**ERS/DM 1**	MW	**256**
312	Transitioning from NDAs to eCTD	LEVEL ●	**ERS/DM 2**	IT	**157AB**
313	Current Status of GCP in China and India	LEVEL ■	**GCP**	CR	**206AB**
314	The Expanding Use of Genomics Studies: Methods, Regulatory Considerations and the Impact on Evidence-based Medicine	LEVEL ●	**IMP/EBM**	CR	**208**
315	Managing Multivendor Projects	LEVEL ●	**IT**	CDM	**258A**
316	Supporting the Business by Building Relationships Beyond Medical Information	LEVEL ■	**MC**	TR	**253B**
317	Efficiency in Medical Writing	LEVEL ■	**MW**	TR	**153C**
318	Experience with Exploratory Clinical Trials and their Nonclinical Support Needed	LEVEL ■	**NC**	RA	**203**
319	Marketing Authorizations in Natural Health Products	LEVEL ●	**NHP**	RA	**156C**
320	The State of Clinical Outsourcing: Results from a 2008 Industry Survey with a Focus on Transforming Business Relationships between Sponsors and CROs – Launching a Program with a Shared Operating Model	LEVEL ■	**OS**	CR	**205C**
321	Best Practices Common to Project and Alliance Management	LEVEL ■	**PM/FI 1**	CR	**102AB**
322	Increasing Productivity by Scope Management and the Impact on PM	LEVEL ■	**PM/FI 2**	CR	**103**
323	BPCA Reauthorized: What's Next?	LEVEL ■	**PP 1**	RA	**160AB**
324	A Progress Report on the Medicare Prescription Drug Benefit: What's Gone Right, What's Gone Wrong	LEVEL ●	**PP 2**	RA	**104C**
325	Introduction of the Improvement Endeavors for Clinical Infrastructure by the Main Organizations in Japan – MHLW, JMA, NHO	LEVEL ●	**RA 1**	CTM/CS	**254AB**

Session Number	Session Title	Difficulty Level	Interest Areas		Room Number
			Primary	Secondary	
WEDNESDAY 8:30 am-10:00 am *continued*					
326	Good Review Practices in the US and Canada: An Update and Discussion of Current Developments	LEVEL ■	**RA 2**	CDM	**253C**
327	EMEA Scientific Advice Evolution and Biomarkers	LEVEL ●	**RA 3**	NC	**253A**
328	Emerging Trends in the Economics of the Pharmaceutical Industry	LEVEL ●	**RD**	PP	**252AB**
329	Obtaining Multiple Endpoint Claims in Product Labels: Issues for Design and Analysis	LEVEL ◆	**ST**	CR	**259AB**
330	Best Practices for Designing and Delivering Training for the Global Deployment of New Technology	LEVEL ■	**TR**	CR	**157AB**
331	Source Systems and Maintaining Data Integrity in Clinical Research	LEVEL ●	**VA**	–	**251**
WEDNESDAY 10:30 am-12:00 pm					
332	Proof-of-concept Clinical Trials and Achieving Enrollment Goals through Centralized Recruitment Tools: It Is More Important than Ever	LEVEL ■	**AHC/IS**	CTM/CS	**104AB**
333	Biotechnology-derived Products and the Immune System: Management of the Effects of the Interaction(s)	LEVEL ◆	**BT**	CR	**105**
334	Tools for Integration of Biomarkers	LEVEL ■	**CDM**	ST	**158C**
335	Establishing and Presenting Design Space	LEVEL ■	**CMC/GMP**	–	**154**
336	Need for the New Risk-benefit Communication Concept Triggered by Regulatory Required Early Signal Notification	LEVEL ■	**CP 1**	RA	**153AB**
337	Impact of Data Mining in Pharmacovigilance: Current and Future	LEVEL ■	**CP 2**	CR	**156AB**
338	Opportunities and Challenges of Globalizing Clinical Research	LEVEL ■	**CR 1**	OS	**205A**
339	Global Oncology Product Development: Strategies for Successful Selection of Patient Populations and Study Endpoints in Early-phase Clinical Development	LEVEL ■	**CR 2**	RD	**205B**
340	Future Advancements in Models and Algorithms for the Optimization of Clinical Trial Recruitment: Using Science to Deliver Superior Business Results	LEVEL ■	**CTM/CS**	ST	**204AB**
341	Detecting Fraud in the Age of Electronic Records	LEVEL ●	**EC**	IT	**158B**
342	FDA Standards Initiatives	LEVEL ●	**ERS/DM**	RA	**157AB**
343	FDA Draft Guidance: Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators/Proactive Solutions for Industry Prior to the Final Guidance	LEVEL ■	**GCP**	CR	**206AB**
344	Evidence from Observational Studies for Evidence-based Medicine	LEVEL ■	**IMP/EBM**	ST	**208**
345	SaaS (Software as a Service): How eSubmissions, eClinical, and Outsourcing Are Creating a Paradigm Shift in Pharmacovigilance	LEVEL ■	**IT**	CP	**258A**
346	Marketing Yourself as a Candidate in a Competitive Clinical Research Job Market	LEVEL ●	**MA**	TR	**104C**
347	Interactions with Drug Information Compendia: On-label, Off-label, Past, Present, and Future	LEVEL ■	**MC**	IMP/EBM	**253B**
348	Patterns and Practices of Clinical Research Document Content Reuse by Pharmaceutical Sponsors	LEVEL ●	**MW**	CR	**153C**
349	High Dose Selection in General Toxicology Studies	LEVEL ■	**NC**	BT	**203**
350	Natural Health Products Quality Control	LEVEL ■	**NHP**	CR	**156C**
351	Outsourcing: Where Is It Now and Where Is It Going?	LEVEL ■	**OS**	CR	**205C**
352	The Next Generation of Project Managers: PMs as CEOs	LEVEL ■	**PM/FI 1**	CR	**103**
353	Identification of Opportunities between CRO and Pharma for Synergistic Application of Lean Six Sigma	LEVEL ■	**PM/FI 2**	RD	**102AB**
354	Drug Counterfeiting: A Public Health Threat, Coordinated Fight and Prevention	LEVEL ■	**PP**	RA	**160AB**
355	The Latest Regulatory Perspective for Pharmacogenomics in Japan	LEVEL ■	**RA 1**	CR	**253A**
356	You Can't Plan Too Early for Your Drug's Final Labeling: Tools that Sponsors Use to Begin with the End in Mind	LEVEL ■	**RA 2**	RD	**253C**
357	After-action: One-year Experience after FDA Guidance on the Target Product Profile	LEVEL ■	**RA 3**	CR	**254AB**
358	EudraCT Latest Developments Including Public Information on Clinical Trials	LEVEL ■	**RA 4**	–	**256**
359	Integrating Market Perspectives into R&D Strategy	LEVEL ■	**RD**	CR	**252AB**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
WEDNESDAY 10:30 am-12:00 pm *continued*					
360	How to Assess Drug Risk when Considering Diversity of Patient Populations and Medical Cultures	LEVEL ■	**ST**	CP	**259AB**
361	Generations in the Workplace: Battlefield or Playground?	LEVEL ●	**TR**	GCP	**157AB**
362	eSources: What Are They and How Do We Deal with Them?	LEVEL ■	**VA**	CDM	**251**
WEDNESDAY 1:30 pm-3:00 pm					
363	Restructuring Protocol Design to Fit the Needs of the Research Subject	LEVEL ■	**AHC/IS**	CR	**104AB**
364	Understanding the Regulation of Advanced Therapy Medicinal Products in Europe	LEVEL ●	**BT 1**	RA	**103**
365	Venture Capital Roundtable: Biotechnology and Pharmaceutical/Health Care IT	LEVEL ■	**BT 2**	PM/FI	**105**
366	Using the Paper as an Easy and Smart Interface to Capture Patients' Data in Digital Format: How the Emerging Technology of Digital Pen and Paper is Bringing New Ideas and Power to EDC in Clinical Studies and in Health-care Projects	LEVEL ■	**CDM**	EC	**258C**
367	Quality-by-design Approaches to Analytical Research and Development	LEVEL ●	**CMC/GMP**	–	**154**
368	Fair Balance in Communication: Addressing the Needs of Prescribers and Patients	LEVEL ■	**CP 1**	MC	**153AB**
369	Data Mining in Pharmacovigilance: Ready for Prime Time?	LEVEL ●	**CP 2**	ST	**156AB**
370	Improving the Quality and Implementation of Medical Imaging in Clinical Trials: Industry/Academia/Government Consortia	LEVEL ■	**CR 1**	–	**205A**
371	Current Challenges and Future Solutions in the Development of Therapeutic Options for Patients with Community-acquired Pneumonia (CAP): Clinical and Regulatory Perspectives	LEVEL ■	**CR 2**	CTM/CS	**205B**
372	Arsenic and Old Lace II: Newer Aspects of QT Study Design, Sample Size, FDA Feedback, and Oncology Considerations	LEVEL ■	**CR 3**	ST	**204AB**
373	Collaborative Clinical Environments for the Public Good	LEVEL ■	**EC**	IT	**258B**
374	International eCTDs: An Update on Regulatory Authority Experience	LEVEL ●	**ERS/DM 1**	CDM	**257AB**
375	Revisiting the Dilemma: Have We Found a Cure for the Ills of Electronic Document Management in the Contemporary Biopharmaceutical Industry? And If So, What Is the Medicine Looking Ahead in 2008 and Beyond?	LEVEL ■	**ERS/DM 2**	CDM	**256**
376	Defining Quality in Clinical Trials	LEVEL ■	**GCP**	CR	**206AB**
377	Semantic Web Applications in Drug R&D	LEVEL ●	**IT**	CP	**258A**
378	Essential Components of Due Diligence	LEVEL ■	**MA**	RD	**104C**
379	Managing Medical Information in a Changing Pharmaceutical Environment	LEVEL ●	**MC**	–	**253B**
380	Regulatory Submission Writing of Safety Narratives	LEVEL ■	**MW**	RA	**153C**
381	Translational Research	LEVEL ■	**NC**	BT	**203**
382	Pharmacovigilance in Natural Health Products	LEVEL ●	**NHP**	CP	**156C**
383	Outsourcing in China: Opportunities and Challenges	LEVEL ●	**OS**	CR	**205C**
384	***Project Management Plenary Session*** Strategic Approaches to Addressing Pharma's R&D Challenges	LEVEL ■	**PM/FI**	RD	**210B**
385	New Paradigms of Drug Regulation	LEVEL ■	**PP**	RA	**160AB**
386	Recent Advancement of Co-development of Medical Devices and Drugs in the Asia-Pacific Region	LEVEL ■	**RA 1**	BT	**253A**
387	Current Status of Regulatory Reform in Canada	LEVEL ■	**RA 2**	PP	**253C**
388	Review of ICH Q5A-Q5E Guidances and Experiences	LEVEL ■	**RA 3**	BT	**254AB**
389	CBER Safety Initiatives	LEVEL ●	**RA 4**	CP	**252AB**
390	Planning, Analysis, and Review of Clinical Trials: Selected Topics	LEVEL ■	**ST**	CR	**259AB**
391	Setting the Standards: Medical Science Liaison Certification	LEVEL ●	**TR**	MC	**157AB**
392	Managing the Scope and Quality of Validation	LEVEL ■	**VA**	IT	**251**
WEDNESDAY 3:30 pm-5:00 pm					
393	PATHWAYS™ in Clinical and Translational Research: Delivering Innovative Education and Training Programs in AHCs	LEVEL ●	**AHC/IS**	TR	**104AB**
394	**SESSION 394 HAS BEEN CANCELLED.** Nanotechnology Task Force: Regulating Nanotechnology Products			LEVEL ◆	**BT**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
WEDNESDAY	**3:30 pm-5:00 pm *continued***				
395	Practical Applications of CDISC SDTM	LEVEL ■	**CDM**	IT	**258C**
396	Real-time Release: Opportunities and Challenges	LEVEL ■	**CMC/GMP**	–	**154**
397	Risk Management and Pharmacovigilance for Opioids	LEVEL ●	**CP 1**	GCP	**153AB**
398	Audits as an Effective Tool for Regulatory Inspections	LEVEL ■	**CP 2**	GCP	**156AB**
399A	Clinical Research and Product Registration in Brazil, Russia, India, China (BRIC), and Other Emerging Regions: An Overview	LEVEL ■	**CR 1**	RA	**205A**
399B	**SESSION 399B HAS BEEN CANCELLED.** What Can Be Learned from Run-in and Extension Periods in Clinical Research?				
399C	Understanding Clinical Trial Volunteer Experiences and Physician Referrals to Clinical Trials	LEVEL ●	**CTM/CS**	CR	**204AB**
399D	Evaluating Current eClinical Technologies and Data Interchange Standards Usage and Experience	LEVEL ●	**EC**	IT	**258B**
399E	Gateway	LEVEL ●	**ERS/DM**	–	**257AB**
399F	Quality without Compromise: Full-cycle Quality Management	LEVEL ■	**GCP**	–	**206AB**
399G	Leveraging Technology to Build an IT Infrastructure for Global Clinical Trials	LEVEL ●	**IT**	CDM	**258A**
399H	From Readability to Language Requirements: Drug Development in a Multicultural Environment	LEVEL ●	**MA**	MC	**104C**
399I	Is Your Medical Information Department Ready for an Avian Influenza Pandemic?	LEVEL ●	**MC**	CR	**253B**
399J	CTD/eCTD Submission-ready Documents and Summaries: Updates and Case Studies	LEVEL ■	**MW**	ERS/DM	**153C**
399K	Consortium Efforts in Safety Biomarker Discovery and Qualification	LEVEL ●	**NC**	CR	**203**
399L	Challenges in Natural Health Products Development in Less Developed Countries	LEVEL ●	**NHP**	CR	**156C**
399M	Creating Partnerships in a World of Gatekeepers	LEVEL ■	**OS**	MW	**205C**
399N	Optimizing Drug Development Practices within the Cross-cultural Environment between Asia and the US	LEVEL ■	**PM/FI 1**	RD	**103**
399O	Enterprise Project Management in Pharmaceutical R&D: The Journey Continues	LEVEL ■	**PM/FI 2**	RD	**102AB**
399P	Patient-driven Clinical Trials	LEVEL ●	**PP**	AHC/IS	**160AB**
399Q	Critical Path Update for 2008	LEVEL ●	**RA 1**	–	**254AB**
399R	Regulatory Requirements for Conducting Clinical Trials in India and China	LEVEL ◆	**RA 2**	CR	**253C**
399S	Public Involvement in the Regulation of Health Products: Methodologies for Assessing and Incorporating Public Input in Regulatory Decision Making	LEVEL ●	**RA 3**	PP	**253A**
399T	Preparing for FDAAA Implementation	LEVEL ■	**RA 4**	CP	**256**
399U	Advancing the Scientific Thinking in Drug Development: The Roles of Statisticians in Industry, Regulatory Agencies, and Academia	LEVEL ■	**ST**	–	**259AB**
399V	Mentoring and Coaching Programs, Getting Started, and Tracking Progress	LEVEL ●	**TR**	–	**157AB**
399W	Outsourcing: Computerized Systems Best Practices for Data Integrity/Quality	LEVEL ●	**VA**	IT	**251**
THURSDAY	**8:30 am-10:00 am**				
401	Global Patient Recruitment and Retention: Identifying and Overcoming Barriers to Accelerate Patient Recruitment and Retention Worldwide	LEVEL ◆	**AHC/IS**	CR	**103**
402	Adding Value to Resource-constrained, Early-stage Biotechnology Product Development from the Regulatory Perspective	LEVEL ■	**BT**	RA	**105**
403	Clinical Trial Data and Coding Processes	LEVEL ■	**CDM**	CP	**256**
404	GMP Updates	LEVEL ●	**CMC/GMP**	–	**253B**
405	MedDRA® Versioning: What Does It Mean to You?	LEVEL ■	**CP**	CDM	**157AB**
406	Industry Insights: Forging Partnerships with NIH-sponsored Clinical Trials and Networks	LEVEL ■	**CR 1**	RD	**102AB**
407	Exploring the Roles of Clinical Research and Medical Affairs in a Contemporary Pharmaceutical Company	LEVEL ■	**CR 2**	PM/FI	**104AB**
408	The Secondary Use of Health-care Data: A Strategy for Merging the Electronic Health Record with Electronic Data Capture	LEVEL ●	**EC**	CR	**205A**
409	eCTD: Life-cycle Management (LCM)	LEVEL ■	**ERS/DM**	IT	**253C**

Session Number	Session Title	Difficulty Level	Interest Areas Primary	Interest Areas Secondary	Room Number
THURSDAY	**8:30 am-10:00 am *continued***				
410	Radical Ideas for Transforming the Informed Consent Process	LEVEL ■	**GCP**	CR	**204AB**
411	Improving Research Site Operational Performance Using Information Technology: Problems, Promise, and Progress	LEVEL ■	**IT**	CR	**205B**
412	Medical Writing in Drug Development: Differences between Japanese Requirements and Those of the US and European Union	LEVEL ●	**MW**	CR	**205C**
413	Harmonization of Requirements for the Preclinical Development of Anticancer Drugs	LEVEL ●	**NC**	BT	**208**
414	Validation Process and Its Impact in Natural Health Products Research and Development	LEVEL ■	**NHP**	VA	**203**
415	Outsourcing, Niche-sourcing, Rural-sourcing, and Offshoring: Saving Time and Money in Clinical Development	LEVEL ■	**OS**	PM/FI	**253A**
416	Illuminate the Dark Side of Clinical Trials Management: Applying Proven Project Management and Process Disciplines to Your Clinical Trial	LEVEL ●	**PM/FI 1**	CTM/CS	**156AB**
417	The Evolving Role of Project and Alliance Managers at Each Stage of Product Development	LEVEL ■	**PM/FI 2**	CR	**154**
418	Using Relationship Management Tools to Improve Project Results	LEVEL ■	**PM/FI 3**	CTM/CS	**251**
419	Product Liability and Drug-induced Injury: Adverse Event Reporting in the US and the Law in Europe	LEVEL ■	**PP**	RA	**104C**
420	CDER Town Meeting – Part 1 of 2	LEVEL ●	**RA 1**	CR	**153AB**
421	Best Practices for Acting as a US Agent	LEVEL ■	**RA 2**	OS	**153C**
422	What Statisticians Need to Know about CDISC	LEVEL ●	**ST**	IT	**206AB**
423	Bringing Online Learning to an Offline Organization	LEVEL ◆	**TR**	PM/FI	**252AB**
424	Regulatory Issues and Opportunities	LEVEL ■	**VA**	RA	**156C**
	THURSDAY 10:30 am-12:00 pm				
425	The Honeymoon's Over: When Sponsors Sue Sites	LEVEL ■	**AHC/IS**	PP	**103**
426	Using Systems Biology to Advance Knowledge-based Drug Development: Case Studies and Progress to Date	LEVEL ■	**BT**	CR	**105**
427	Data Management/CP Interface/SAE Reporting	LEVEL ■	**CDM**	CP	**256**
428	Practical Applications of Standardized MedDRA® Queries	LEVEL ■	**CP**	CDM	**157AB**
429	The Six Risk Areas of Clinical Trial Patient Enrollment	LEVEL ■	**CR 1**	TR	**102AB**
430	Site Relationship Management (SRM) Initiatives for Improving Site Performance	LEVEL ■	**CR 2**	CTM/CS	**104AB**
431	Development and Implementation of Standards for the Structured Representation of Protocols and Trial Design	LEVEL ●	**EC**	CR	**205A**
432	Global Submission Management	LEVEL ●	**ERS/DM**	IT	**253C**
433	Clinical Data Mining/Signal Detection and eAuditing	LEVEL ■	**GCP**	IT	**204AB**
434	Implementing IT Industry Standards at a Large Pharmaceutical: A Case Study	LEVEL ■	**IT**	VA	**205B**
435	Emerging Clinical Documents for Medical Writers	LEVEL ■	**MW**	CR	**205C**
436	Targeted Disease Approach Using Natural Health Products	LEVEL ●	**NHP**	AHC/IS	**203**
437	Outsourcing to India and China: Managing R&D Projects	LEVEL ■	**OS**	PM/FI	**253A**
438	Project Management across Companies and Cultures: Team Creation and Development	LEVEL ■	**PM/FI 1**	CTM/CS	**256AB**
439	The Secret to Achieving Productivity in Clinical Development	LEVEL ●	**PM/FI 2**	CR	**154**
440	Legal Remedies and Drug Approvals during and after the Approval Process in the US and the EU	LEVEL ■	**PP**	RA	**104C**
441	CDER Town Meeting – Part 2 of 2	LEVEL ●	**RA 1**	CR	**153AB**
442	Regulatory Data Protection (Data Exclusivity)	LEVEL ●	**RA 2**	RD	**153C**
443	Update: Pushing the eEnvelope in Statistics for Drug Development	LEVEL ●	**ST**	IT	**206AB**
444	Getting the Message Across: It Is All about the Presentation	LEVEL ●	**TR**	IT	**252AB**
445	Infrastructure, Hardware, Computerized Instrumentation: What Is Needed?	LEVEL ●	**VA**	IT	**156**

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**	FDA Enforcement Update	LEVEL ●	**153AB**
Monday	1:30 pm-3:00 pm	**130**	Direct-to-consumer Statutory Review Program	LEVEL ●	**153AB**
Monday	3:30 pm-5:00 pm	**160**	Introduction to Pharmaceutical Marketing	LEVEL ●	**153AB**
Tuesday	8:00 am-9:30 am	**201**	International Promotional Issues	LEVEL ■	**153AB**
Tuesday	10:00 am-11:30 am	**222**	Medical Science Liaisons Communications	LEVEL ■	**153AB**
AHC/IS	**Academic Health Centers/Investigative Sites**				
Monday	10:30 am-12:00 pm	**102**	The Third Annual Session on Investigator Budgets and Reimbursement: The Impact on Patient Enrollment and Retention	LEVEL ■	**104AB**
Monday	1:30 pm-3:00 pm	**131**	The Impact of the New Clinical Research Paradigm on Investigational Sites	LEVEL ●	**104AB**
Monday	3:30 pm-5:00 pm	**161**	Effective Working with Investigative Sites: Essentials for Clinical Trial Conduct in the Emerging World	LEVEL ■	**104AB**
Tuesday	8:00 am-9:30 am	**202**	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**210ABC**
Tuesday	10:00 am-11:30 am	**223**	The Impact of FDAAA and Health Information Technology Interoperability Activities on Drug Safety, Implementation of Standards, and Data Stewardship Principles	LEVEL ■	**104AB**
Tuesday	2:00 pm-3:30 pm	**253**	Success at the Crossroads: The Intersection of CDISC Standards with Research Site Processes	LEVEL ■	**104AB**
Tuesday	4:00 pm-5:30 pm	**284**	Severe Adverse Events in Clinical Trials: A Difficult Issue between Sites and Sponsors	LEVEL ■	**104AB**
Wednesday	8:30 am-10:00 am	**301**	Accelerating Research: Integrating Clinical Research with Clinical Care	LEVEL ●	**104AB**
Wednesday	10:30 am-12:00 pm	**332**	Proof-of-concept Clinical Trials and Achieving Enrollment Goals through Centralized Recruitment Tools: It Is More Important than Ever	LEVEL ■	**104AB**
Wednesday	1:30 pm-3:00 pm	**363**	Restructuring Protocol Design to Fit the Needs of the Research Subject	LEVEL ■	**104AB**
Wednesday	3:30 pm-5:00 pm	**393**	PATHWAYS™ in Clinical and Translational Research: Delivering Innovative Education and Training Programs in AHCs	LEVEL ●	**104AB**
Thursday	8:30 am-10:00 am	**401**	Global Patient Recruitment and Retention: Identifying and Overcoming Barriers to Accelerate Patient Recruitment and Retention Worldwide	LEVEL ◆	**103**
Thursday	10:30 am-12:00 pm	**425**	The Honeymoon's Over: When Sponsors Sue Sites	LEVEL ■	**103**
BT	**Biotechnology**				
Monday	10:30 am-12:00 pm	**103**	Facilitating the Regulatory Approval of Products for Public Health Emergencies: Emerging Infectious Diseases or Intentional Terrorist Acts	LEVEL ■	**105**
Monday	1:30 pm-3:00 pm	**132**	Recent Advancement of Novel Biotechnology in the Asia-Pacific Region	LEVEL ■	**105**
Monday	3:30 pm-5:00 pm	**162**	Hot Topics in Biotechnology	LEVEL ■	**105**
Tuesday	10:00 am-11:30 am	**224**	Gene Therapy Regulations for EU Clinical Trials: Navigating the Maze	LEVEL ■	**105**
Tuesday	2:00 pm-3:30 pm	**254**	RNA Therapeutics: Bringing the Future of Biological and Medical Innovation to Today	LEVEL ■	**105**
Tuesday	4:00 pm-5:30 pm	**285**	Current Experiences in Stem Cell Therapies	LEVEL ●	**105**
Wednesday	8:30 am-10:00 am	**302**	Biosimilars/Follow-on Biologics	LEVEL ■	**105**
Wednesday	10:30 am-12:00 pm	**333**	Biotechnology-derived Products and the Immune System: Management of the Effects of the Interaction(s)	LEVEL ◆	**105**
Wednesday	1:30 pm-3:00 pm	**364**	Understanding the Regulation of Advanced Therapy Medicinal Products in Europe	LEVEL ●	**103**
Wednesday	1:30 pm-3:00 pm	**365**	Venture Capital Roundtable: Biotechnology and Pharmaceutical/Health Care IT	LEVEL ■	**105**
Wednesday	3:30 pm-5:00 pm	**394**	**SESSION 394 HAS BEEN CANCELLED.** Nanotechnology Task Force: Regulating Nanotechnology Products	LEVEL ◆	

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
BT – Biotechnology ***continued***					
Thursday	8:30 am-10:00 am	**402**	Adding Value to Resource-constrained, Early-stage Biotechnology Product Development from the Regulatory Perspective	LEVEL ■	**105**
Thursday	10:30 am-12:00 pm	**426**	Using Systems Biology to Advance Knowledge-based Drug Development: Case Studies and Progress to Date	LEVEL ■	**105**
CDM	**Clinical Data Management**				
Monday	10:30 am-12:00 pm	**104**	Clinical Data Optimization	LEVEL ■	**258C**
Monday	1:30 pm-3:00 pm	**133**	Evolving Role of the Medical Reviewer in Clinical Trials Data Management through the Prism of Growing Industry Expectations and Rising Standards	LEVEL ■	**158C**
Monday	3:30 pm-5:00 pm	**163**	An Honest Look at the eClinical Process: How Biotechnology Can Learn from Best Practices Outside the Industry	LEVEL ■	**258C**
Tuesday	8:00 am-9:30 am	**203**	STARDATE 2013: Visions of the Life of a Data Manager	LEVEL ■	**258C**
Tuesday	10:00 am-11:30 am	**225**	Building a Strong EDC Foundation through the Power of Partnership	LEVEL ●	**258C**
Tuesday	2:00 pm-3:30 pm	**255**	Metrics Reporting: Challenges, Strategies and Successes	LEVEL ■	**158C**
Tuesday	4:00 pm-5:30 pm	**286**	Meeting the Challenges of Laboratory Data Management	LEVEL ■	**258C**
Wednesday	8:30 am-10:00 am	**303**	Imaging Biomarker Data Management	LEVEL ■	**258C**
Wednesday	10:30 am-12:00 pm	**334**	Tools for Integration of Biomarkers	LEVEL ■	**158C**
Wednesday	1:30 pm-3:00 pm	**366**	Using the Paper as an Easy and Smart Interface to Capture Patients' Data in Digital Format: How the Emerging Technology of Digital Pen and Paper is Bringing New Ideas and Power to EDC in Clinical Studies and in Health-care Projects	LEVEL ■	**258C**
Wednesday	3:30 pm-5:00 pm	**395**	Practical Applications of CDISC SDTM	LEVEL ■	**258C**
Thursday	8:30 am-10:00 am	**403**	Clinical Trial Data and Coding Processes	LEVEL ■	**256**
Thursday	10:30 am-12:00 pm	**427**	Data Management/CP Interface/SAE Reporting	LEVEL ■	**256**
CMC/GMP	**Chemistry, Manufacturing, and Controls/Good Manufacturing Practices**				
Monday	10:30 am-12:00 pm	**105**	CMC Pilot: Lessons Learned – An FDA Perspective	LEVEL ●	**154**
Monday	1:30 pm-3:00 pm	**134**	CMC Pilot Submissions and Lessons Learned: An Industry Perspective	LEVEL ■	**154**
Monday	3:30 pm-5:00 pm	**164**	CMC Postapproval Management Plan	LEVEL ■	**154**
Tuesday	10:00 am-11:30 am	**226**	Implementation of Quality by Design: A Global Perspective	LEVEL ■	**154**
Tuesday	2:00 pm-3:30 pm	**256**	Updates on ICH Q8(R1) and Q10 Guidelines	LEVEL ■	**154**
Tuesday	4:00 pm-5:30 pm	**287**	The Relationship between Biopharmaceutics and Quality by Design	LEVEL ■	**154**
Wednesday	8:30 am-10:00 am	**304**	Quality Risk Management	LEVEL ■	**154**
Wednesday	10:30 am-12:00 pm	**335**	Establishing and Presenting Design Space	LEVEL ■	**154**
Wednesday	1:30 pm-3:00 pm	**367**	Quality-by-design Approaches to Analytical Research and Development	LEVEL ●	**154**
Wednesday	3:30 pm-5:00 pm	**396**	Real-time Release: Opportunities and Challenges	LEVEL ■	**154**
Thursday	8:30 am-10:00 am	**404**	GMP Updates	LEVEL ●	**253B**
CP	**Clinical Safety and Pharmacovigilance**				
Monday	10:30 am-12:00 pm	**106**	Case Assessment and Narrative Generation in Pre- and Postmarketing Safety: Clinically-based Active Query Leads to Quality Data	LEVEL ■	**156AB**
Monday	1:30 pm-3:00 pm	**135**	Different Approaches to Spontaneous Reporting: A New Business Model	LEVEL ◆	**156AB**
Monday	1:30 pm-3:00 pm	**136**	Drug-induced Liver Injury (DILI): How Well Do Preclinical and Clinical Studies Predict Hepatotoxicity?	LEVEL ■	**156C**
Monday	3:30 pm-5:00 pm	**165**	Electronic AE/ADR Case Reporting Within and Between Regions: Is It Working Well?	LEVEL ◆	**156C**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
CP – Clinical Safety and Pharmacovigilance *continued*					
Monday	3:30 pm-5:00 pm	**166**	The Development Safety Update Report (DSUR): The CIOMS VII Report and the ICH E2F Initiative	LEVEL ■	**156AB**
Tuesday	8:00 am-9:30 am	202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**210ABC**
Tuesday	10:00 am-11:30 am	**227**	Modernization of FDA Postmarket Adverse Event Information Management	LEVEL ■	**156AB**
Tuesday	2:00 pm-3:30 pm	**257**	Pharmacovigilance and Risk Management Plans in Japan Today	LEVEL ■	**156AB**
Tuesday	4:00 pm-5:30 pm	**288**	Pharmacovigilance in Latin America	LEVEL ■	**153AB**
Tuesday	4:00 pm-5:30 pm	**289**	OTC Drugs and Nutritional Supplements: The New World of AE/ADR Reporting	LEVEL ■	**156AB**
Wednesday	8:30 am-10:00 am	**305**	An Industry-regulatory Survey of Benefit-risk Management Best Practices, Including Case Studies	LEVEL ■	**156AB**
Wednesday	10:30 am-12:00 pm	**336**	Need for the New Risk-benefit Communication Concept Triggered by Regulatory Required Early Signal Notification	LEVEL ■	**153AB**
Wednesday	10:30 am-12:00 pm	**337**	Impact of Data Mining in Pharmacovigilance: Current and Future and Patients	LEVEL ■	**156AB**
Wednesday	1:30 pm-3:00 pm	**368**	Fair Balance in Communication: Addressing the Needs of Prescribers and Patients	LEVEL ■	**153AB**
Wednesday	1:30 pm-3:00 pm	**369**	Data Mining in Pharmacovigilance: Ready for Prime Time?	LEVEL ●	**156AB**
Wednesday	3:30 pm-5:00 pm	**397**	Risk Management and Pharmacovigilance for Opioids	LEVEL ●	**153AB**
Wednesday	3:30 pm-5:00 pm	**398**	Audits as an Effective Tool for Regulatory Inspections	LEVEL ■	**156AB**
Thursday	8:30 am-10:00 am	**405**	MedDRA® Versioning: What Does It Mean to You?	LEVEL ■	**157AB**
Thursday	10:30 am-12:00 pm	**428**	Practical Applications of Standardized MedDRA® Queries	LEVEL ■	**157AB**
CR	**Clinical Research and Development**				
Monday	10:30 am-12:00 pm	**107**	Adaptive Design in Clinical Research	LEVEL ■	**204AB**
Monday	10:30 am-12:00 pm	**108**	Prevention of Fraud and Noncompliance in Clinical Research: What Was and Is Being Done?	LEVEL ●	**205A**
Monday	10:30 am-12:00 pm	**109**	Going "Glocal": The Trend in Global Patient Recruitment and Retention	LEVEL ◆	**205B**
Monday	10:30 am-12:00 pm	**110**	The Process of Study Feasibility: Three Perspectives, One Common Goal	LEVEL ■	**203**
Monday	1:30 pm-3:00 pm	**137**	Improving the Business of Science: How Metrics Can Improve the Pharmaceutical Bottom Line	LEVEL ■	**203**
Monday	1:30 pm-3:00 pm	**138**	Subject Recruitment in the US: Is It a Losing Proposition?	LEVEL ●	**204AB**
Monday	3:30 pm-5:00 pm	**167**	Personalized Medicine and Its Impact on Drug Development and Commercialization	LEVEL ■	**205B**
Monday	3:30 pm-5:00 pm	**168**	The Keys to Establishing Best Practices for Accelerated Study Startup	LEVEL ■	**204AB**
Monday	3:30 pm-5:00 pm	**169**	Pediatric Trial Issues from the Global Perspective	LEVEL ■	**205A**
Monday	3:30 pm-5:00 pm	**170**	Patient Enrollment: Underrepresented Populations	LEVEL ●	**203**
Tuesday	8:00 am-9:30 am	202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**210ABC**
Tuesday	8:00 am-9:30 am	**204**	Navigating the Bumps in the Road on Partnered Clinical Trials	LEVEL ■	**205A**
Tuesday	8:00 am-9:30 am	**205**	Patient Recruitment Strategies and Sites' Perspectives	LEVEL ●	**205B**
Tuesday	10:00 am-11:30 am	**228**	The Symbiosis of Clinical Research, Public Health and Patient-consumer Involvement: Reconceptualizing Clinical Trial Research	LEVEL ●	**203**
Tuesday	10:00 am-11:30 am	**229**	Enhancing Patient Adherence in Clinical Trials with eTechnology	LEVEL ●	**205A**
Tuesday	10:00 am-11:30 am	**230**	Thirty Ways to Increase Enrollment at Your Site	LEVEL ■	**208**
Tuesday	10:00 am-11:30 am	**231**	Six Sigma: Straightening the Long and Winding Road of Clinical Development	LEVEL ●	**205B**
Tuesday	2:00 pm-3:30 pm	**258**	Expanded Access Programs: Their Role in Product Development and Keys to Successful Implementation	LEVEL ●	**210A**
Tuesday	2:00 pm-3:30 pm	**259**	Data-driven Patient Recruitment: Tools for Early Planning and Predictive Management	LEVEL ■	**205A**
Tuesday	2:00 pm-3:30 pm	**260**	Addressing the Adverse Impact of Increasing Protocol Complexity on Study Conduct Performance	LEVEL ●	**205B**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
CR – Clinical Research and Development *continued*					
Tuesday	4:00 pm-5:30 pm	**290**	Protocol Deviation/Violation/Exception	LEVEL ■	**205A**
Tuesday	4:00 pm-5:30 pm	**291**	Factors Influencing the Speed of Clinical Trial Study Completion	LEVEL ■	**205B**
Tuesday	4:00 pm-5:30 pm	**292**	Letters from the Front: Experiences with Clinical Trials in Asia and Central America	LEVEL ■	**203**
Wednesday	8:30 am-10:00 am	**306**	Conducting Clinical Trials in China: Status and Trends	LEVEL ■	**205A**
Wednesday	8:30 am-10:00 am	**307**	Practical Issues in Industry-sponsored, Investigator-initiated Trials (IITs)	LEVEL ■	**205B**
Wednesday	10:30 am-12:00 pm	**338**	Opportunities and Challenges of Globalizing Clinical Research	LEVEL ■	**205A**
Wednesday	10:30 am-12:00 pm	**339**	Global Oncology Product Development: Strategies for Successful Selection of Patient Populations and Study Endpoints in Early-phase Clinical Development	LEVEL ■	**205B**
Wednesday	1:30 pm-3:00 pm	**370**	Improving the Quality and Implementation of Medical Imaging in Clinical Trials: Industry/Academia/Government Consortia	LEVEL ■	**205A**
Wednesday	1:30 pm-3:00 pm	**371**	Current Challenges and Future Solutions in the Development of Therapeutic Options for Patients with Community-acquired Pneumonia (CAP): Clinical and Regulatory Perspectives	LEVEL ■	**205B**
Wednesday	1:30 pm-3:00 pm	**372**	Arsenic and Old Lace II: Newer Aspects of QT Study Design, Sample Size, FDA Feedback, and Oncology Considerations	LEVEL ■	**204AB**
Wednesday	3:30 pm-5:00 pm	**399A**	Clinical Research and Product Registration in Brazil, Russia, India, China (BRIC), and Other Emerging Regions: An Overview	LEVEL ■	**205A**
Wednesday	3:30 pm-5:00 pm	**399B**	**SESSION HAS BEEN CANCELLED.** What Can Be Learned from Run-in and Extension Periods in Clinical Research?		
Thursday	8:30 am-10:00 am	**406**	Industry Insights: Forging Partnerships with NIH-sponsored Clinical Trials and Networks	LEVEL ■	**102AB**
Thursday	8:30 am-10:00 am	**407**	Exploring the Roles of Clinical Research and Medical Affairs in a Contemporary Pharmaceutical Company	LEVEL ■	**104AB**
Thursday	10:30 am-12:00 pm	**429**	The Six Risk Areas of Clinical Trial Patient Enrollment	LEVEL ■	**102AB**
Thursday	10:30 am-12:00 pm	**430**	Site Relationship Management (SRM) Initiatives for Improving Site Performance	LEVEL ■	**104AB**
CTM/CS	**Clinical Trial Management/Clinical Supplies**				
Monday	1:30 pm-3:00 pm	**139**	Radical Change in Clinical Development: Results from the Changes	LEVEL ◆	**162AB**
Tuesday	8:00 am-9:30 am	**206**	Becoming a Sponsor of Choice for Clinical Investigators	LEVEL ■	**204AB**
Tuesday	10:00 am-11:30 am	**232**	The Implementation of a CTMS System	LEVEL ■	**204AB**
Tuesday	2:00 pm-3:30 pm	**261**	Solving Complex Problems in Clinical Trial Supply Management	LEVEL ■	**204AB**
Tuesday	4:00 pm-5:30 pm	**293**	"E"asing the Management of the Clinical Supply Chain: Drug Accountability, Reconciliation, Returns, and Destruction	LEVEL ■	**204AB**
Wednesday	8:30 am-10:00 am	**308**	Accelerated Recruitment Strategies for Global Megastudies	LEVEL ■	**153AB**
Wednesday	8:30 am-10:00 am	**309**	Electronic Data Capture as a Strategy to Enhance Complete Data Capture, Site Satisfaction, and Participation in Registries and Observational Studies	LEVEL ●	**204AB**
Wednesday	10:30 am-12:00 pm	**340**	Future Advancements in Models and Algorithms for the Optimization of Clinical Trial Recruitment: Using Science to Deliver Superior Business Results	LEVEL ■	**204AB**
Wednesday	3:30 pm-5:00 pm	**399C**	Understanding Clinical Trial Volunteer Experiences and Physician Referrals to Clinical Trials	LEVEL ●	**204AB**
EC	**eClinical**				
Monday	3:30 pm-5:00 pm	**171**	The Realities of Implementing CDISC	LEVEL ●	**258B**
Tuesday	8:00 am-9:30 am	**207**	Applying ePRO in Special Populations	LEVEL ●	**258B**
Tuesday	10:00 am-11:30 am	**233**	CDISC's Healthcare Link Initiatives: An Overview of CDISC Projects, Parallel Activities, and Long-term Implications	LEVEL ■	**258B**
Tuesday	2:00 pm-3:30 pm	**262**	Leveraging Electronic Health Records in Clinical Research	LEVEL ■	**258B**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
EC – eClinical *continued*					
Tuesday	4:00 pm-5:30 pm	**294**	Standards Shock Therapy: Demystifying the Current and Future Roles of CDISC and HL7 Standards for Clinical Research and Regulatory Submissions	LEVEL ◆	**258B**
Wednesday	8:30 am-10:00 am	**310**	Anatomy of ePRO Validation	LEVEL ■	**258B**
Wednesday	10:30 am-12:00 pm	**341**	Detecting Fraud in the Age of Electronic Records	LEVEL ●	**158B**
Wednesday	1:30 pm-3:00 pm	**373**	Collaborative Clinical Environments for the Public Good	LEVEL ■	**158B**
Wednesday	3:30 pm-5:00 pm	**399D**	Evaluating Current eClinical Technologies and Data Interchange Standards Usage and Experience	LEVEL ●	**258B**
Thursday	8:30 am-10:00 am	**408**	The Secondary Use of Health-care Data: A Strategy for Merging the Electronic Health Record with Electronic Data Capture	LEVEL ●	**205A**
Thursday	10:30 am-12:00 pm	**431**	Development and Implementation of Standards for the Structured Representation of Protocols and Trial Design	LEVEL ●	**205A**
ERS/DM	**Electronic Regulatory Submissions/Document Management**				
Monday	10:30 am-12:00 pm	**111**	Global eCTDs: A Plan for Labeling	LEVEL ●	**157C**
Monday	10:30 am-12:00 pm	**112**	FDA and CDISC eSubmission Pilots	LEVEL ■	**157AB**
Monday	1:30 pm-3:00 pm	**140**	Replacing Aging EDM Systems: Opportunities and Challenges	LEVEL ■	**157C**
Monday	1:30 pm-3:00 pm	**141**	Pursuing Standards to Enhance eCTD Deliverables	LEVEL ■	**257AB**
Monday	3:30 pm-5:00 pm	**172**	How Goes It? Electronic Registration and Listing at FDA	LEVEL ●	**257AB**
Monday	3:30 pm-5:00 pm	**173**	The eCTD: Lessons Learned and Practical Experience	LEVEL ■	**157C**
Tuesday	8:00 am-9:30 am	**208**	IND in eCTD Format: Challenges and Successes	LEVEL ●	**257AB**
Tuesday	10:00 am-11:30 am	**234**	CDER Electronic Submissions Update	LEVEL ●	**257AB**
Tuesday	2:00 pm-3:30 pm	**263**	FDA: eCTD Compliance – Part 1 of 2	LEVEL ●	**157AB**
Tuesday	4:00 pm-5:30 pm	**295**	FDA: eCTD Compliance – Part 2 of 2	LEVEL ●	**257AB**
Wednesday	8:30 am-10:00 am	**311**	eCTD: What It Is, What It Is Not, and What It Might Be	LEVEL ■	**256**
Wednesday	8:30 am-10:00 am	**312**	Transitioning from NDAs to eCTD	LEVEL ●	**157AB**
Wednesday	10:30 am-12:00 pm	**342**	FDA Standards Initiatives	LEVEL ●	**157AB**
Wednesday	1:30 pm-3:00 pm	**374**	International eCTDs: An Update on Regulatory Authority Experience	LEVEL ●	**257AB**
Wednesday	1:30 pm-3:00 pm	**375**	Revisiting the Dilemma: Have We Found a Cure for the Ills of Electronic Document Management in the Contemporary Biopharmaceutical Industry? And If So, What Is the Medicine Looking Ahead in 2008 and Beyond?	LEVEL ■	**256**
Wednesday	3:30 pm-5:00 pm	**399E**	Gateway	LEVEL ●	**257AB**
Thursday	8:30 am-10:00 am	**409**	eCTD: Life-cycle Management (LCM)	LEVEL ■	**253C**
Thursday	10:30 am-12:00 pm	**432**	Global Submission Management	LEVEL ●	**253C**
GCP	**Good Clinical Practices**				
Monday	10:30 am-12:00 pm	**113**	FDA Amendments Act 2007 (FDAAA) Title 8: Expanded Clinical Trial Registry Data Bank	LEVEL ■	**206AB**
Monday	1:30 pm-3:00 pm	**142**	After the Trial is Completed: What, When, Where, and How to Post Trial Results	LEVEL ●	**206AB**
Monday	1:30 pm-3:00 pm	**143**	Navigating the New FDA Part 11 Guidance: Sponsor and Site Perspective	LEVEL ■	**208**
Monday	3:30 pm-5:00 pm	**174**	Are We Doing Too Much? What We Can Learn from Compliance Plans and Audits of WHO Trials Conducted in Developing Countries	LEVEL ■	**206AB**
Tuesday	8:00 am-9:30 am	202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**210ABC**
Tuesday	10:00 am-11:30 am	**235**	Town Meeting: The Very Different Faces of Quality – QA, QC, Validation, Regulatory Affairs, and Compliance	LEVEL ●	**206AB**
Tuesday	2:00 pm-3:30 pm	**264**	Review of Regulatory Agency Inspection Reports	LEVEL ●	**206AB**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
GCP – Good Clinical Practices *continued*					
Tuesday	4:00 pm-5:30 pm	**296**	Planning for and Insuring against the Risk Associated with the Conduct of a Clinical Trial Program	LEVEL ■	**206AB**
Wednesday	8:30 am-10:00 am	**313**	Current Status of GCP in China and India	LEVEL ■	**206AB**
Wednesday	10:30 am-12:00 pm	**343**	FDA Draft Guidance: Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators/Proactive Solutions for Industry Prior to the Final Guidance	LEVEL ■	**206AB**
Wednesday	1:30 pm-3:00 pm	**376**	Defining Quality in Clinical Trials	LEVEL ■	**206AB**
Wednesday	3:30 pm-5:00 pm	**399F**	Quality without Compromise: Full-cycle Quality Management	LEVEL ■	**206AB**
Thursday	8:30 am-10:00 am	**410**	Radical Ideas for Transforming the Informed Consent Process	LEVEL ■	**204AB**
Thursday	10:30 am-12:00 pm	**433**	Clinical Data Mining/Signal Detection and eAuditing	LEVEL ■	**204AB**
IMP/EBM	**Impact of Medical Products and Therapies/Evidence-based Medicines**				
Tuesday	2:00 pm-3:30 pm	**265**	Good Practices for Clinical Endpoint (PRO, CRO) and Linguistic Validation: State of the Science	LEVEL ■	**208**
Tuesday	4:00 pm-5:30 pm	**297**	Patient-reported Outcomes (PRO) Claims: Understanding the Scientific and Regulatory Requirements	LEVEL ●	**208**
Wednesday	8:30 am-10:00 am	**314**	The Expanding Use of Genomics Studies: Methods, Regulatory Considerations and the Impact on Evidence-based Medicine	LEVEL ●	**208**
Wednesday	10:30 am-12:00 pm	**344**	Evidence from Observational Studies for Evidence-based Medicine	LEVEL ■	**208**
IT	**Information Technology**				
Monday	10:30 am-12:00 pm	**114**	SDLC Controls and Project Management Mechanisms to Support IT in Validated Environments	LEVEL ■	**258A**
Monday	10:30 am-12:00 pm	**115**	Issues and Case Studies in Safety Data Migration	LEVEL ■	**258B**
Monday	1:30 pm-3:00 pm	**144**	CDISC SDTM Data Conversion	LEVEL ■	**258A**
Monday	1:30 pm-3:00 pm	**145**	How Much Information Technology Do Early Stage Biotechnology Firms Need?	LEVEL ■	**258B**
Monday	3:30 pm-5:00 pm	**175**	The Implementation of Biological Sample Management and Biobanking Systems	LEVEL ■	**258A**
Tuesday	8:00 am-9:30 am	**209**	Negotiating IT Contracts: Speeding Up the Process and Finding Common Ground	LEVEL ●	**258A**
Tuesday	10:00 am-11:30 am	**236**	Business and Technology Considerations for a SaaS Solution in the Life-sciences Industry	LEVEL ●	**258A**
Tuesday	2:00 pm-3:30 pm	**266**	Service-oriented Architecture in R&D	LEVEL ■	**258A**
Tuesday	4:00 pm-5:30 pm	**298**	Utilizing Open-source Software in Clinical Research Environments	LEVEL ■	**258A**
Wednesday	8:30 am-10:00 am	**315**	Managing Multivendor Projects	LEVEL ●	**258A**
Wednesday	10:30 am-12:00 pm	**345**	SaaS (Software as a Service): How eSubmissions, eClinical, and Outsourcing Are Creating a Paradigm Shift in Pharmacovigilance	LEVEL ■	**258A**
Wednesday	1:30 pm-3:00 pm	**377**	Semantic Web Applications in Drug R&D	LEVEL ●	**258A**
Wednesday	3:30 pm-5:00 pm	**399G**	Leveraging Technology to Build an IT Infrastructure for Global Clinical Trials	LEVEL ●	**258A**
Thursday	8:30 am-10:00 am	**411**	Improving Research Site Operational Performance Using Information Technology: Problems, Promise, and Progress	LEVEL ■	**205B**
Thursday	10:30 am-12:00 pm	**434**	Implementing IT Industry Standards at a Large Pharmaceutical: A Case Study	LEVEL ■	**205B**
MA	**Marketing and Sales**				
Wednesday	10:30 am-12:00 pm	**346**	Marketing Yourself as a Candidate in a Competitive Clinical Research Job Market	LEVEL ●	**104C**
Wednesday	1:30 pm-3:00 pm	**378**	Essential Components of Due Diligence	LEVEL ■	**104C**
Wednesday	3:30 pm-5:00 pm	**399H**	From Readability to Language Requirements: Drug Development in a Multicultural Environment	LEVEL ●	**104C**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
MC	**Medical Communications**				
Tuesday	8:00 am-9:30 am	**210**	The Lady and the Tiger of Position Choices and Training Keys for Position Success	LEVEL ■	**253B**
Tuesday	10:00 am-11:30 am	**237**	Evidence-based Medicine: A Practical Approach for the Medical Communications Professional	LEVEL ■	**253B**
Tuesday	2:00 pm-3:30 pm	**267**	Medical Liaison Survey #4: Assessing Tools Used by MLs, Clinical Trial Involvement, and Career Strategies	LEVEL ●	**253B**
Tuesday	4:00 pm-5:30 pm	**299A**	Drug Information, Wikipedia, and Google Scholar: Implications for Medical Information	LEVEL ●	**253B**
Wednesday	8:30 am-10:00 am	**316**	Supporting the Business by Building Relationships Beyond Medical Information	LEVEL ■	**253B**
Wednesday	10:30 am-12:00 pm	**347**	Interactions with Drug Information Compendia: On-label, Off-label, Past, Present, and Future	LEVEL ■	**253B**
Wednesday	1:30 pm-3:00 pm	**379**	Managing Medical Information in a Changing Pharmaceutical Environment	LEVEL ●	**253B**
Wednesday	3:30 pm-5:00 pm	**399I**	Is Your Medical Department Ready for an Avian Influenza Pandemic?	LEVEL ●	**253B**
MW	**Medical/Scientific Writing**				
Monday	3:30 pm-5:00 pm	**176**	Skills for Medical Writers: Now and in the Future	LEVEL ■	**153C**
Tuesday	10:00 am-11:30 am	**238**	Data Displays to Aid Regulatory Agency Review of Safety Data	LEVEL ■	**153C**
Tuesday	2:00 pm-3:30 pm	**268**	Making the Transition to Writing IND Documents for the eCTD Submission	LEVEL ■	**153C**
Tuesday	4:00 pm-5:30 pm	**299B**	Establishing Standards for Medical Writing	LEVEL ■	**153C**
Wednesday	8:30 am-10:00 am	**317**	Efficiency in Medical Writing	LEVEL ■	**153C**
Wednesday	10:30 am-12:00 pm	**348**	Patterns and Practices of Clinical Research Document Content Reuse by Pharmaceutical Sponsors	LEVEL ●	**153C**
Wednesday	1:30 pm-3:00 pm	**380**	Regulatory Submission Writing of Safety Narratives	LEVEL ■	**153C**
Wednesday	3:30 pm-5:00 pm	**399J**	CTD/eCTD Submission-ready Documents and Summaries: Updates and Case Studies	LEVEL ■	**153C**
Thursday	8:30 am-10:00 am	**412**	Medical Writing in Drug Development: Differences between Japanese Requirements and Those of the US and European Union	LEVEL ●	**205C**
Thursday	10:30 am-12:00 pm	**435**	Emerging Clinical Documents for Medical Writers	LEVEL ■	**205C**
NC	**Nonclinical Laboratory Safety Assessment**				
Tuesday	2:00 pm-3:30 pm	**269**	Revisions to ICHM3(R1) in the Areas of Acute Toxicity, Chronic Toxicity, and Developmental Toxicity	LEVEL ■	**104C**
Tuesday	4:00 pm-5:30 pm	**299C**	Pediatric Drug Development	LEVEL ◆	**104C**
Wednesday	8:30 am-10:00 am	**318**	Experience with Exploratory Clinical Trials and their Nonclinical Support Needed	LEVEL ■	**203**
Wednesday	10:30 am-12:00 pm	**349**	High Dose Selection in General Toxicology Studies	LEVEL ■	**203**
Wednesday	1:30 pm-3:00 pm	**381**	Translational Research	LEVEL ■	**203**
Wednesday	3:30 pm-5:00 pm	**399K**	Consortium Efforts in Safety Biomarker Discovery and Qualification	LEVEL ●	**203**
Thursday	8:30 am-10:00 am	**413**	Harmonization of Requirements for the Preclinical Development of Anticancer Drugs	LEVEL ●	**208**
NHP	**Natural Health Products**				
Tuesday	10:00 am-11:30 am	**239**	Regulatory Requirements with NHP: What Is New?	LEVEL ■	**156C**
Tuesday	2:00 pm-3:30 pm	**270**	Challenges with Natural Health Products Research and Development	LEVEL ■	**156C**
Tuesday	4:00 pm-5:30 pm	**299D**	Evolving Natural Health Products Market Size and Its Development	LEVEL ●	**156C**
Wednesday	8:30 am-10:00 am	**319**	Marketing Authorizations in Natural Health Products	LEVEL ●	**156C**
Wednesday	10:30 am-12:00 pm	**350**	Natural Health Products Quality Control	LEVEL ■	**156C**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
NHP – Natural Health Products *continued*					
Wednesday	1:30 pm-3:00 pm	**382**	Pharmacovigilance in Natural Health Products	LEVEL ●	**156C**
Wednesday	3:30 pm-5:00 pm	**399L**	Challenges in Natural Health Products Development in Less Developed Countries	LEVEL ●	**156C**
Thursday	8:30 am-10:00 am	**414**	Validation Process and Its Impact in Natural Health Products Research and Development	LEVEL ■	**203**
Thursday	10:30 am-12:00 pm	**436**	Targeted Disease Approach Using Natural Health Products	LEVEL ●	**203**
OS	**Outsourcing**				
Monday	10:30 am-12:00 pm	**116**	Outsourcing of Clinical Trials to India and Beyond: Developing an Effective Global Outsourcing Team	LEVEL ●	**205C**
Monday	1:30 pm-3:00 pm	**146**	Outsourcing Strategies and Trial Management in Asia	LEVEL ◆	**205C**
Monday	3:30 pm-5:00 pm	**177**	Meeting Clinical Research Challenges in India	LEVEL ■	**205C**
Tuesday	8:00 am-9:30 am	**211**	Streamline Your Language Outsourcing	LEVEL ●	**205C**
Tuesday	10:00 am-11:30 am	**240**	Emerging Dilemma in Japan: Outsourcing for Multinational Trials	LEVEL ■	**205C**
Tuesday	2:00 pm-3:30 pm	**271**	Lessons Learned: A Global Survey on Outsourcing Practices	LEVEL ■	**205C**
Tuesday	4:00 pm-5:30 pm	**299E**	Outsourcing Safety Narrative and AE Management to India	LEVEL ●	**205C**
Wednesday	8:30 am-10:00 am	**320**	The State of Clinical Outsourcing: Results from a 2008 Industry Survey with a Focus on Transforming Business Relationships between Sponsors and CROs – Launching a Program with a Shared Operating Model	LEVEL ■	**205C**
Wednesday	10:30 am-12:00 pm	**351**	Outsourcing: Where Is It Now and Where Is It Going?	LEVEL ■	**205C**
Wednesday	1:30 pm-3:00 pm	**383**	Outsourcing in China: Opportunities and Challenges	LEVEL ●	**205C**
Wednesday	3:30 pm-5:00 pm	**399M**	Creating Partnerships in a World of Gatekeepers	LEVEL ■	**205C**
Thursday	8:30 am-10:00 am	**415**	Outsourcing, Niche-sourcing, Rural-sourcing, and Offshoring: Saving Time and Money in Clinical Development	LEVEL ■	**253A**
Thursday	10:30 am-12:00 pm	**437**	Outsourcing to India and China: Managing R&D Projects	LEVEL ■	**253A**
PM/FI	**Project Management/Finance**				
Monday	10:30 am-12:00 pm	**117**	Developing Balanced Matrix and Maturing Product Development Teams	LEVEL ■	**102AB**
Monday	10:30 am-12:00 pm	**118**	Communications Management: The Key to Successful Project Teams	LEVEL ●	**103**
Monday	1:30 pm-3:00 pm	**147**	Value of Six Sigma to Pharmaceutical Product Discovery and Development	LEVEL ■	**102AB**
Monday	1:30 pm-3:00 pm	**148**	Project Manager to Project Leader: Facilitating the Transition	LEVEL ■	**103**
Monday	3:30 pm-5:00 pm	**178**	High Performance Leaders = High Performance Teams	LEVEL ■	**102AB**
Monday	3:30 pm-5:00 pm	**179**	Financial Accruals for Clinical Trials: How to Generate without Excruciating Pain	LEVEL ■	**103**
Tuesday	8:00 am-9:30 am	**212**	Biomarkers in Drug Development: What a Project Manager Needs to Know and Do to Enhance Project Value	LEVEL ●	**102AB**
Tuesday	8:00 am-9:30 am	**213**	Life Science Project Management Is Dead: A New (Old) Model for the Future	LEVEL ■	**103**
Tuesday	8:00 am-9:30 am	**214**	Global Communication for Effective Drug Development in Japan: How Westerners Should Communicate with the Japanese for the Best Drug Development in Japan	LEVEL ●	**105**
Tuesday	8:00 am-9:30 am	**215**	Doing the Project Planning for Large Multinational Clinical Trials	LEVEL ■	**104AB**
Tuesday	10:00 am-11:30 am	**241**	Organizing for Project Management: Exploring the Value of a Matrix Approach to Project Management in Life Sciences Organizations and Companies	LEVEL ■	**102AB**
Tuesday	10:00 am-11:30 am	**242**	Deal Makers and Deal Breakers: What Venture Capital Firms Look for in Drug Development Plans	LEVEL ■	**103**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
PM/FI – Project Management/Finance ***continued***					
Tuesday	2:00 pm-3:30 pm	**272**	Utilization of Six Sigma Methodology in Clinical Trial Project Management	LEVEL ■	**103**
Tuesday	2:00 pm-3:30 pm	**273**	Proactive Project Risk Management in Drug Development: The Value of Project Management to the Pharmaceutical Business	LEVEL ■	**102AB**
Tuesday	4:00 pm-5:30 pm	**299F**	Advanced Portfolio Management Methodologies	LEVEL ◆	**103**
Tuesday	4:00 pm-5:30 pm	**299G**	Intelligent Communication: Empowering Pharmaceutical R&D Project Managers for Success	LEVEL ●	**102AB**
Wednesday	8:30 am-10:00 am	**321**	Best Practices Common to Project and Alliance Management	LEVEL ■	**102AB**
Wednesday	8:30 am-10:00 am	**322**	Increasing Productivity by Scope Management and the Impact on PM	LEVEL ■	**103**
Wednesday	10:30 am-12:00 pm	**352**	The Next Generation of Project Managers: PMs as CEOs	LEVEL ■	**103**
Wednesday	10:30 am-12:00 pm	**353**	Identification of Opportunities between CRO and Pharma for Synergistic Application of Lean Six Sigma	LEVEL ■	**102AB**
Wednesday	1:30 pm-3:00 pm	**384**	***Project Management Plenary Session*** Strategic Approaches to Addressing Pharma's R&D Challenges	LEVEL ■	**210B**
Wednesday	3:30 pm-5:00 pm	**399N**	Optimizing Drug Development Practices within the Cross-cultural Environment between Asia and the US	LEVEL ■	**103**
Wednesday	3:30 pm-5:00 pm	**399O**	Enterprise Project Management in Pharmaceutical R&D: The Journey Continues	LEVEL ■	**102AB**
Thursday	8:30 am-10:00 am	**416**	Illuminate the Dark Side of Clinical Trials Management: Applying Proven Project Management and Process Disciplines to Your Clinical Trial	LEVEL ●	**156AB**
Thursday	8:30 am-10:00 am	**417**	The Evolving Role of Project and Alliance Managers at Each Stage of Product Development	LEVEL ■	**154**
Thursday	8:30 am-10:00 am	**418**	Using Relationship Management Tools to Improve Project Results	LEVEL ■	**251**
Thursday	10:30 am-12:00 pm	**438**	Project Management across Companies and Cultures: Team Creation and Development	LEVEL ■	**256AB**
Thursday	10:30 am-12:00 pm	**439**	The Secret to Achieving Productivity in Clinical Development	LEVEL ●	**154**
PP	**Public Policy/Law**				
Monday	10:30 am-12:00 pm	**119**	Personalized Medicine: 2008 Update	LEVEL ■	**160AB**
Monday	1:30 pm-3:00 pm	**149**	Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials	LEVEL ●	**160AB**
Monday	3:30 pm-5:00 pm	**180**	Civil and Regulatory Liability from Clinical Trials: What Are the Legal Risks of Clinical Trials?	LEVEL ●	**160AB**
Tuesday	8:00 am-9:30 am	**216**	Incentives and Rewards for Innovation in Pharmaceutical Development	LEVEL ●	**160AB**
Tuesday	8:00 am-9:30 am	202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**210ABC**
Tuesday	10:00 am-11:30 am	**243**	Off-label Use of Medicinal Products – Part 1 of 2	LEVEL ●	**160AB**
Tuesday	2:00 pm-3:30 pm	**274**	Off-label Use of Medicinal Products – Part 2 of 2	LEVEL ●	**160AB**
Tuesday	4:00 pm-5:30 pm	**299H**	Legislation, GCP, and Ethical Principles Guiding Clinical Trials in China	LEVEL ■	**160AB**
Wednesday	8:30 am-10:00 am	**323**	BPCA Reauthorized: What's Next?	LEVEL ■	**160AB**
Wednesday	8:30 am-10:00 am	**324**	A Progress Report on the Medicare Prescription Drug Benefit: What's Gone Right, What's Gone Wrong	LEVEL ●	**104C**
Wednesday	10:30 am-12:00 pm	**354**	Drug Counterfeiting: A Public Health Threat, Coordinated Fight and Prevention	LEVEL ■	**160AB**
Wednesday	1:30 pm-3:00 pm	**385**	New Paradigms of Drug Regulation	LEVEL ■	**160AB**
Wednesday	3:30 pm-5:00 pm	**399P**	Patient-driven Clinical Trials	LEVEL ●	**160AB**
Thursday	8:30 am-10:00 am	**419**	Product Liability and Drug-induced Injury: Adverse Event Reporting in the US and the Law in Europe	LEVEL ■	**104C**
Thursday	10:30 am-12:00 pm	**440**	Legal Remedies and Drug Approvals during and after the Approval Process in the US and the EU	LEVEL ■	**104C**

Meeting Schedule by Interest Area

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
RA	**Regulatory Affairs**				
Monday	10:30 am-12:00 pm	**120**	Women's Health under the FDA Critical Path Initiative	LEVEL ●	**256**
Monday	10:30 am-12:00 pm	**121**	Parallel NDA and Pharmacoeconomical Review for Early Access of Innovative Products	LEVEL ■	**253B**
Monday	10:30 am-12:00 pm	**122**	Regulatory Strategy as a Key Component of the Global Multidisciplinary Drug Development Strategy	LEVEL ■	**253A**
Monday	10:30 am-12:00 pm	**123**	Extraordinary Use New Drugs in Canada: Issues, Initiatives and Challenges	LEVEL ●	**251**
Monday	10:30 am-12:00 pm	**124**	Changing Procedures for Conducting Clinical Trials in Europe	LEVEL ■	**252AB**
Monday	10:30 am-12:00 pm	**125**	Postmarketing Study Commitments (PMCs): How FDA and Industry Can Effectively Collaborate to Design Better PMCs and Track Them to Completion	LEVEL ■	**254AB**
Monday	10:30 am-12:00 pm	**126**	The European Pediatric Legislation and the Pediatric Committee (PDCO): The First Year of the Implementation	LEVEL ●	**253C**
Monday	1:30 pm-3:00 pm	**150**	Facilitating Global Pediatric Drug Development: An Assessment of Recent Experience	LEVEL ●	**252AB**
Monday	1:30 pm-3:00 pm	**151**	ICH Global Cooperation Group (GCG) Initiative Update	LEVEL ■	**253A**
Monday	1:30 pm-3:00 pm	**152**	Introduction to European Public Assessment Reports (EPARs) and FDA Approval Packages: Finding and Analyzing Unpublished Information about Pivotal Studies	LEVEL ●	**256**
Monday	1:30 pm-3:00 pm	**153**	Generic Biologics: Fact or Fiction?	LEVEL ●	**251**
Monday	1:30 pm-3:00 pm	**154**	A Standardized Approach to Improving the Quality of the Regulatory Review and Submission: Can Scorecards Increase the Predictability of the Review Process?	LEVEL ■	**253B**
Monday	1:30 pm-3:00 pm	**155**	The Current Status within China on GCPs, Computerized Systems Used in Clinical Trials and Data Integrity	LEVEL ●	**253C**
Monday	1:30 pm-3:00 pm	**156**	The EMEA: How to Make the Best of It	LEVEL ●	**254AB**
Monday	3:30 pm-5:00 pm	**181**	Current Review and Assessment Models for Approval of New Medicines in Emerging Markets: Differences and Similarities across 13 Countries in Latin America, Middle East, Africa, and Southeast Asia	LEVEL ■	**253B**
Monday	3:30 pm-5:00 pm	**182**	US-EU Agreement: Administrative Regulatory Simplification – The Next Phase?	LEVEL ●	**253C**
Monday	3:30 pm-5:00 pm	**183**	Dispute Resolution with the FDA: Looking for Win-Win Results	LEVEL ■	**254AB**
Monday	3:30 pm-5:00 pm	**184**	The Tactical and Practical Side of Quality Systems: How FDA Implementation is Helping Our Customers	LEVEL ■	**252AB**
Monday	3:30 pm-5:00 pm	**185**	Proactive Risk Management Planning during Drug Development	LEVEL ■	**251**
Monday	3:30 pm-5:00 pm	**186**	Updates in CDE Drug Reviews and GLP Regulations	LEVEL ■	**256**
Monday	3:30 pm-5:00 pm	**187**	European Innovative Medicines Initiative: Up and Running!	LEVEL ●	**253A**
Tuesday	8:00 am-9:30 am	202	***Multitrack Plenary:*** The Impact of FDAAA on Drug Safety	LEVEL ■	**210ABC**
Tuesday	8:00 am-9:30 am	**217**	Applying for Drug Approvals in China: A Mystical Opportunity	LEVEL ●	**256**
Tuesday	8:00 am-9:30 am	**218**	Innovative Approval Paths Are Needed for Products that Treat Rare Diseases	LEVEL ●	**253A**
Tuesday	10:00 am-11:30 am	**244**	PMDA Update: PMDA Initiatives and Challenges for Promoting Global Drug Development Including Japan	LEVEL ■	**253A**
Tuesday	10:00 am-11:30 am	**245**	Regulatory Strategies in Latin America: New Conquest for Pharmaceutical Companies for Timely Submissions and Project Startups in Mexico and Other Latin American Countries	LEVEL ■	**256**
Tuesday	10:00 am-11:30 am	**246**	EU Variation Regulations Update: Why, What, When, and Authorities' and Industries' Perspectives	LEVEL ■	**254AB**
Tuesday	10:00 am-11:30 am	**247**	RAHP Gold: Device Track Masters	LEVEL ◆	**251**
Tuesday	10:00 am-11:30 am	**248**	FDA Meetings: Understanding the Process and Maximizing Success	LEVEL ●	**252AB**
Tuesday	10:00 am-11:30 am	**249**	SFDA Hot Topic: Efforts to Ensure Drug Quality and Safety	LEVEL ●	**253C**
Tuesday	2:00 pm-3:30 pm	**275**	Asian Cooperation/Collaborations for Promoting Drug Development	LEVEL ■	**251**
Tuesday	2:00 pm-3:30 pm	**276**	Innovative Medicines and the EMEA	LEVEL ■	**256**
Tuesday	2:00 pm-3:30 pm	**277**	Dealing with Potential Genotoxic Impurities (GTIs) Especially in FDC (Fixed-dose Combination) Drug Products for Global Clinical Trials	LEVEL ■	**253A**

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
RA – Regulatory Affairs *continued*					
Tuesday	2:00 pm-3:30 pm	**278**	Foreign Health Authority Inspections of Manufacturing Sites	LEVEL ●	**252AB**
Tuesday	2:00 pm-3:30 pm	**279**	Best Practices for Preparing a Complete NDA that Warrants a Complete Review by FDA	LEVEL ●	**254AB**
Tuesday	4:00 pm-5:30 pm	**299I**	Fifth Update: Outlook for Changes in the Japanese Regulatory and Clinical Development Environment	LEVEL ■	**256**
Tuesday	4:00 pm-5:30 pm	**299J**	Establishment of a Regulatory Function in a Startup Biotechnology/ Pharmaceutical Company	LEVEL ■	**252AB**
Tuesday	4:00 pm-5:30 pm	**299K**	Impact of PDUFA IV Commitments on Review and Evaluation of Trademarks	LEVEL ■	**253A**
Wednesday	8:30 am-10:00 am	**325**	Introduction of the Improvement Endeavors for Clinical Infrastructure by the Main Organizations in Japan – MHLW, JMA, NHO	LEVEL ●	**254AB**
Wednesday	8:30 am-10:00 am	**326**	Good Review Practices in the US and Canada: An Update and Discussion of Current Developments	LEVEL ■	**253C**
Wednesday	8:30 am-10:00 am	**327**	EMEA Scientific Advice Evolution and Biomarkers	LEVEL ●	**253A**
Wednesday	10:30 am-12:00 pm	**355**	The Latest Regulatory Perspective for Pharmacogenomics in Japan	LEVEL ■	**253A**
Wednesday	10:30 am-12:00 pm	**356**	You Can't Plan Too Early for Your Drug's Final Labeling: Tools that Sponsors Use to Begin with the End in Mind	LEVEL ■	**253C**
Wednesday	10:30 am-12:00 pm	**357**	After-action: One-year Experience after FDA Guidance on the Target Product Profile	LEVEL ■	**254AB**
Wednesday	10:30 am-12:00 pm	**358**	EudraCT Latest Developments Including Public Information on Clinical Trials	LEVEL ■	**256**
Wednesday	1:30 pm-3:00 pm	**386**	Recent Advancement of Co-development of Medical Devices and Drugs in the Asia-Pacific Region	LEVEL ■	**253A**
Wednesday	1:30 pm-3:00 pm	**387**	Current Status of Regulatory Reform in Canada	LEVEL ■	**253C**
Wednesday	1:30 pm-3:00 pm	**388**	Review of ICH Q5A-Q5E Guidances and Experiences	LEVEL ■	**254AB**
Wednesday	1:30 pm-3:00 pm	**389**	CBER Safety Initiatives	LEVEL ●	**252AB**
Wednesday	3:30 pm-5:00 pm	**399Q**	Critical Path Update for 2008	LEVEL ●	**254AB**
Wednesday	3:30 pm-5:00 pm	**399R**	Regulatory Requirements for Conducting Clinical Trials in India and China	LEVEL ◆	**253C**
Wednesday	3:30 pm-5:00 pm	**399S**	Public Involvement in the Regulation of Health Products: Methodologies for Assessing and Incorporating Public Input in Regulatory Decision Making	LEVEL ●	**253A**
Wednesday	3:30 pm-5:00 pm	**399T**	Preparing for FDAAA Implementation	LEVEL ■	**256**
Thursday	8:30 am-10:00 am	**420**	CDER Town Meeting – Part 1 of 2	LEVEL ●	**153AB**
Thursday	8:30 am-10:00 am	**421**	Best Practices for Acting as a US Agent	LEVEL ■	**153C**
Thursday	10:30 am-12:00 pm	**441**	CDER Town Meeting – Part 2 of 2	LEVEL ●	**153AB**
Thursday	10:30 am-12:00 pm	**442**	Regulatory Data Protection (Data Exclusivity)	LEVEL ●	**153C**
RD	**R&D Strategy**				
Monday	10:30 am-12:00 pm	**127**	New Strategies for Successful Licensing Acquisitions	LEVEL ●	**104C**
Monday	1:30 pm-3:00 pm	**157**	Go/No Go Decision Making for Global Drug Development Including Japan	LEVEL ■	**104C**
Monday	3:30 pm-5:00 pm	**188**	Public-private Partnership on Clinical Research in the Asia-Pacific Region	LEVEL ■	**104C**
Tuesday	8:00 am-9:30 am	**219**	Biotechnology R&D in Developing Countries: A Public-private Partnership between a Cancer Institute, a Brazilian Entrepreneurship, and Health Institutes	LEVEL ◆	**162AB**
Tuesday	10:00 am-11:30 am	**250**	Postmarketing Commitments and Postapproval Research in the US and International Markets: Evolving Requirements, Efforts to Improve, and Strategies for Fulfillment	LEVEL ■	**162AB**
Tuesday	2:00 pm-3:30 pm	**280**	Recent Advances in Adaptive Clinical Trial Designs	LEVEL ◆	**162AB**
Tuesday	4:00 pm-5:30 pm	**299L**	Drug Diagnostic Co-development: Implications for Biomarker Validation and Personalized Medicine	LEVEL ■	**162AB**
Wednesday	8:30 am-10:00 am	**328**	Emerging Trends in the Economics of the Pharmaceutical Industry	LEVEL ●	**252AB**
Wednesday	10:30 am-12:00 pm	**359**	Integrating Market Perspectives into R&D Strategy	LEVEL ■	**252AB**

Meeting Schedule by Interest Area

Day	Time	Session Number	Session Title	Difficulty Level	Room Number
ST	**Statistics**				
Monday	10:30 am-12:00 pm	**128**	Multiregional Clinical Trials: Evaluating the Pros and Cons	LEVEL ●	**259AB**
Monday	1:30 pm-3:00 pm	**158**	Genomic (Surrogate) Biomarker in Therapeutic Trials	LEVEL ■	**259AB**
Monday	3:30 pm-5:00 pm	**189**	Selecting the Optimal Sample Size: Initial Realism or Adaptive Re-estimation	LEVEL ■	**259AB**
Tuesday	8:00 am-9:30 am	**220**	Are You Ready for Adaptive Clinical Development? Examples, Case Studies, Successes – Part 1 of 2	LEVEL ■	**159AB**
Tuesday	10:00 am-11:30 am	**251**	Are You Ready for Adaptive Clinical Development? Regulatory Considerations – Part 2 of 2	LEVEL ■	**159AB**
Tuesday	2:00 pm-3:30 pm	**281**	Meta-analysis and the Postapproval Assessment of Safety Based on Accumulating Data from Clinical Trials	LEVEL ■	**159AB**
Tuesday	4:00 pm-5:30 pm	**299M**	Novel Statistical Issues from the Regulatory Biostatistician's Viewpoint	LEVEL ■	**259AB**
Wednesday	8:30 am-10:00 am	**329**	Obtaining Multiple Endpoint Claims in Product Labels: Issues for Design and Analysis	LEVEL ◆	**259AB**
Wednesday	10:30 am-12:00 pm	**360**	How to Assess Drug Risk when Considering Diversity of Patient Populations and Medical Cultures	LEVEL ■	**259AB**
Wednesday	1:30 pm-3:00 pm	**390**	Planning, Analysis, and Review of Clinical Trials: Selected Topics	LEVEL ■	**259AB**
Wednesday	3:30 pm-5:00 pm	**399U**	Advancing the Scientific Thinking in Drug Development: The Roles of Statisticians in Industry, Regulatory Agencies, and Academia	LEVEL ■	**159AB**
Thursday	8:30 am-10:00 am	**422**	What Statisticians Need to Know about CDISC	LEVEL ●	**206AB**
Thursday	10:30 am-12:00 pm	**443**	Update: Pushing the eEnvelope in Statistics for Drug Development	LEVEL ●	**206AB**
TR	**Training**				
Monday	10:30 am-12:00 pm	**129**	Real Challenges Faced by Leaders of Virtual Teams in Global Pharmaceuticals	LEVEL ■	**157AB**
Monday	1:30 pm-3:00 pm	**159**	Developing Academic Program Accreditation Standards for Clinical Research Education Programs	LEVEL ■	**157AB**
Monday	3:30 pm-5:00 pm	**190**	Postgraduation in Clinical Research: Brazil	LEVEL ■	**157AB**
Tuesday	8:00 am-9:30 am	**221**	You're Hired! Strategies for Identifying, Interviewing, and Preparing for a Career in the Pharmaceutical Industry	LEVEL ●	**157AB**
Tuesday	10:00 am-11:30 am	**252**	Pharmaceutical Medicine in Asia	LEVEL ■	**157AB**
Tuesday	2:00 pm-3:30 pm	**282**	Networking for Career Advancement and Change	LEVEL ●	**157AB**
Tuesday	4:00 pm-5:30 pm	**299N**	Overview of Drug Development for Emerging Professionals	LEVEL ●	**157AB**
Wednesday	8:30 am-10:00 am	**330**	Best Practices for Designing and Delivering Training for the Global Deployment of New Technology	LEVEL ■	**157AB**
Wednesday	10:30 am-12:00 pm	**361**	Generations in the Workplace: Battlefield or Playground?	LEVEL ●	**157AB**
Wednesday	1:30 pm-3:00 pm	**391**	Setting the Standards: Medical Science Liaison Certification	LEVEL ●	**157AB**
Wednesday	3:30 pm-5:00 pm	**399V**	Mentoring and Coaching Programs, Getting Started, and Tracking Progress	LEVEL ●	**157AB**
Thursday	8:30 am-10:00 am	**423**	Bringing Online Learning to an Offline Organization	LEVEL ◆	**252AB**
Thursday	10:30 am-12:00 pm	**444**	Getting the Message Across: It Is All about the Presentation	LEVEL ●	**252AB**
VA	**Validation**				
Tuesday	2:00 pm-3:30 pm	**283**	Systems Development Methodologies and Validation	LEVEL ■	**153C**
Tuesday	4:00 pm-5:30 pm	**299O**	Including Risk in Computer Validation	LEVEL ●	**253C**
Wednesday	8:30 am-10:00 am	**331**	Source Systems and Maintaining Data Integrity in Clinical Research	LEVEL ●	**251**
Wednesday	10:30 am-12:00 pm	**362**	eSources: What Are They and How Do We Deal with Them?	LEVEL ■	**251**
Wednesday	1:30 pm-3:00 pm	**392**	Managing the Scope and Quality of Validation	LEVEL ■	**251**
Wednesday	3:30 pm-5:00 pm	**399W**	Outsourcing: Computerized Systems Best Practices for Data Integrity/Quality	LEVEL ●	**251**
Thursday	8:30 am-10:00 am	**424**	Regulatory Issues and Opportunities	LEVEL ■	**156C**
Thursday	10:30 am-12:00 pm	**445**	Infrastructure, Hardware, Computerized Instrumentation: What Is Needed?	LEVEL ●	**156**

Saturday, June 21 – Monday, June 23

Saturday, June 21

9:00 am-5:00 pm **EXHIBITOR REGISTRATION**
North Lobby, Level 1, BCEC

12:30 pm-1:00 pm **TUTORIAL REGISTRATION**
Registration for Saturday tutorials ONLY
North Lobby, Level 1, BCEC

Sunday, June 22

8:00 am-7:30 pm **EXHIBITOR REGISTRATION**
North Lobby, Level 1, BCEC

8:00 am-9:00 am **TUTORIAL REGISTRATION**
Registration for Sunday morning or full-day tutorials ONLY, North Lobby, Level 1, BCEC

12:30 pm-1:00 pm **TUTORIAL REGISTRATION**
Registration for Sunday afternoon tutorials ONLY
North Lobby, Level 1, BCEC

3:00 pm-5:00 pm *Special Event – DIA Student Forum*

Room 259AB LEVEL: ●

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

The Student Forum has been designed to provide information of interest to students and an opportunity for students to provide input to the DIA. 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 skills essential in the pharmaceutical industry as well as a brief summary of career opportunities in various fields within pharma.

Welcome Remarks
Ronald D. Fitzmartin, PhD, MBA
Vice President, Informatics and Knowledge Management, Daiichi Sankyo Inc.; President, DIA

PRESENTATIONS

The Changing Face of Biopharmaceutical Innovation
Kenneth I. Kaitin, PhD
Director and Associate Professor of Medicine, Tufts University School of Medicine

Trends and Career Opportunities in Clinical Research
Joan A. Chambers
Senior Director, Marketing and Operations, Publications, Cambridge Healthtech Institute

Panel Discussion: If I Had Only Known …
MODERATOR
Carol L. Mitchell, MD, Consultant, Medical Information, Eli Lilly and Company

PANELISTS

Tammy Jeanne Massie, PhD, MS, Mathematical Statistician, Vaccine Evaluation Branch, CBER, FDA

Ingrid Klingmann, MD, President, Pharmaplex, Belgium

Robin L. Winter-Sperry, MD, President and CEO, Scientific Advantage, LLC; MSL Advantage, LLC

Leyna Mulholland, PharmD, PhD, Director, Global Pharma Development Regulatory, Hoffmann-La Roche Inc., Switzerland

3:00 pm-7:30 pm **ATTENDEE REGISTRATION**
North Lobby, Level 1, BCEC

3:00 pm-7:30 pm **SPEAK9ER REGISTRATION**
North Lobby, Level 1, BCEC

4:00 pm-6:00 pm **EXHIBITS OPEN**
Exhibit Halls A & B, Exhibit Level, BCEC

7:00 pm-9:00 pm **NETWORKING RECEPTION**
Museum of Science

Monday, June 23

7:00 am-6:00 pm **SPEAKER REGISTRATION**
North Lobby, Level 1, BCEC

7:30 am-8:15 am **CONTINENTAL BREAKFAST**
Grand Ballroom Foyer, Level 3, BCEC

7:30 am-6:00 pm **ATTENDEE REGISTRATION**
North Lobby, Level 1, BCEC

7:30 am-6:00 pm **EXHIBITOR REGISTRATION**
North Lobby, Level 1, BCEC

8:30 am-10:00 am **PLENARY SESSION** (See next page.)

10:00 am-6:00 pm **STUDENT POSTER SESSION**
North Lobby Entrance to Exhibit Hall, BCEC

10:00 am-6:00 pm **EXHIBITS OPEN**
Exhibit Halls A & B, Exhibit Hall Level, BCEC

5:00 pm-6:00 pm **MONDAY RECEPTION**
Exhibit Halls A & B, Exhibit Hall Level, BCEC

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.

8:30 am-10:00 am **Plenary Session** Grand Ballroom, Level 3, BCEC

Welcome and Awards Presentation

RONALD D. FITZMARTIN, PhD, MBA
Vice President, Informatics
and Knowledge Management
Daiichi Sankyo, Inc.
President, DIA

Keynote Speaker

DENNIS A. AUSIELLO, MD
Jackson Professor of Clinical Medicine,
Harvard University Medical School and
Chief of Medicine, Massachusetts
General Hospital

Opening Remarks

JEFFREY W. SHERMAN, MD, FACP
Chief Medical Officer and Senior Vice
President of Research & Development
IDM Pharma, Inc.
2008 DIA Annual Meeting Chairperson

Keynote Speaker

KATHY GIUSTI, MBA
Founder and Chief Executive Officer,
Multiple Myeloma Research Foundation
(MMRF) and Multiple Myeloma Research
Consortium (MMRC)

10:00 am-10:30 am **REFRESHMENT BREAK – Exhibit Hall**

Monday Sessions

Session 101 AD - Advertising, RA

10:30 am-12:00 pm LEVEL: ●

Room 153AB *Pharmacy credits offered*

FDA Enforcement Update

SESSION CHAIRPERSON(S)

Neal Collins, MD
Senior Medical Director, Global Medical Oncology, Pfizer 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.

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

Enforcement Update CVM
Thomas J. Moskal, DVM
Veterinary Medical Officer, Center for Veterinary Medicine, FDA

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

10:30 am-12:00 pm LEVEL: ■

Room 104AB

The Third Annual Session on Investigator Budgets and Reimbursement: The Impact on Patient Enrollment and Retention

SESSION CHAIRPERSON(S)

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

This session will address the impact of reimbursement and investigator budgets on site and investigator performance relating to patient enrollment and retention objectives as well as the profitability of commercial investigative sites. Many in the industry believe change is required as to how site budgets and reimbursement are determined as well as the acceptance by investigators.

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

A Big Pharma Perspective
Scott P. Jensen, MBA
Manager, Global Clinical Budgeting and Contracting, Eli Lilly and Company

A Multispecialty Site Perspective
Jeffrey M. Adelglass, MD
CEO, Research Across America

Session 103 BT - Biotechnology, RA

10:30 am-12:00 pm LEVEL: ■

Room 105 *CME credits offered*

Facilitating the Regulatory Approval of Products for Public Health Emergencies: Emerging Infectious Diseases or Intentional Terrorist Acts

SESSION CHAIRPERSON(S)

Richard M. Lewis, PhD
Biopharmaceutical Consultant, Access BIO, L.C.

Cynthia L. Kelley, MS
Senior Advisor for Counterterrorism/Medical Countermeasures, Office of the Director, CBER, FDA

Products meant to treat pandemic influenza and intentional acts of terrorism with biological agents can be addressed by similar regulatory approaches which facilitate the availability and expedite the approval of safe and effective products. This session will discuss such mechanisms for products addressing these unique public health emergencies.

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

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

FDA-industry Interaction in Licensure of Counterterror Products
Andrew Storey
Vice President, Quality, Clinical and Regulatory Affairs, Cangene Corporation, Canada

Interaction with FDA: Development of a Pandemic Influenza Vaccine
Rino Rappuoli, PhD
Global Head of Vaccines Research, Novartis Vaccines and Diagnostics, Italy

Session 104 CDM - Clinical Data Management, CR

10:30 am-12:00 pm LEVEL: ■

Room 258C

Clinical Data Optimization

SESSION CHAIRPERSON(S)

David Handelsman
Business Solutions Manager, SAS Institute, Inc.

Although the industry is processing data more efficiently than ever, this operational efficiency does not necessarily translate into optimal efforts in terms of truly improving the process by which new therapies are brought to market. This session will describe how optimized clinical data management processes can change the game with regard to the ultimate goal of bringing safe and effective therapies to market.

Evaluating, Implementing, and Leveraging Standards Technologies
Glen De Vries, PhD
Co-founder and CTO, Medidata Solutions, Inc.

EDC: Faster Horse or Model-T?
Sylva H. Collins, PhD
Vice President, Global Biometrics, Kendle International

Data Management as the Means to Transforming Clinical Trial Business Processes
David Handelsman
Business Solutions Manager, SAS Institute, Inc.

Session 105 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

10:30 am-12:00 pm LEVEL: ●

Room 154

CMC Pilot: Lessons Learned – An FDA Perspective

SESSION CHAIRPERSON(S)

Christine Moore, PhD
Acting Deputy Director, Office of New Drug Quality Assessment, CDER, FDA

This session will discuss the lessons learned from the CMC Pilot Program from the FDA perspective.

FDA Perspective: Part 1
Thomas F. Oliver, PhD
Chemist, Office of Pharmaceutical Science, CDER, FDA

FDA Perspective: Part 2
Terrance Ocheltree, PhD, RPh
Chemist, Office of Pharmaceutical Science, CDER, FDA

Panel Discussion and Q & A Period

Session 106 CP - Clinical Safety and Pharmacovigilance, CR

10:30 am-12:00 pm LEVEL: ■

Room 156AB *CME, Nursing, and Pharmacy credits offered*

Case Assessment and Narrative Generation in Pre- and Postmarketing Safety: Clinically-based Active Query Leads to Quality Data

SESSION CHAIRPERSON(S)

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

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 collecting 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 and providing valuable data for premarketing integrated summaries of safety and postmarketing signaling. The factors that affect health professional reporting of medical product-associated adverse events will be reviewed, along with interventions designed to both stimulate health professional reporting and foster higher quality reports (eg, educational initiatives, FDA's MedWatch program, targeted questioning) in both premarketing clinical trial and postmarketing pharmacovigilance realms. Methods designed to optimally utilize safety data in order to craft effective case narratives will be reviewed, as will the relationship between quality safety data and optimal integrated summaries of safety in marketing applications.

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

Investigating and Crafting the Medical Narrative
L. Paul Starkey, MD, FAAFP
Senior Medical Director, Scientific and Medical Affairs, Head, Medical Monitoring Americas, PRA International, Inc.

Quality Safety Data and the Integrated Summary of Safety
Michael J. Klepper, MD
President, Michael J. Klepper, MD, LLC

Session 107 CR 1 - Clinical Research and Development, ST

10:30 am-12:00 pm LEVEL: ■

Room 204AB *CME credits offered*

Adaptive Design in Clinical Research

SESSION CHAIRPERSON(S)

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

Effective use of adaptive techniques is often limited by poor infrastructure and process change needed to effectively utilize these techniques. This session reviews experience with more than 300 adaptive trials, emphasizing the pragmatic side of adaptive study management.

Adaptive Research in Practice: The Pragmatic Side
Michael J. Rosenberg, MD, MPH
President and CEO, Health Decisions, Inc.

Great Adaptations: A Novel Approach to Clinical Study Design
Graham J. Nicholls, MS
Product Manager, ClinPhone plc, UK

Wrapping It All Up: An Adaptive Example for a Large Global Study
Cyrus R. Mehta, PhD
President, Cytel Software Corporation

Session 108 CR 2 - Clinical Research and Development, GCP

10:30 am-12:00 pm LEVEL: ●

Room 205A *CME and Nursing credits offered*

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 OHRP and discusses new approaches that regulatory agencies, research sponsors, and investigative sites are pursuing to prevent noncompliance and fraud in the future.

FDA Inspection Results and Trends Impacting Noncompliance
Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

Exploring Why Noncompliance Occurs and What Can Be Done about It
Greg Koski, MD, PhD
Associate Professor of Anesthesia, Massachusetts General Hospital, Harvard Medical School

Session 109 CR 3 - Clinical Research and Development, AHC/IS

10:30 am-12:00 pm LEVEL: ◆

Room 205B *Nursing credits offered*

Going "Glocal": The Trend in Global Patient Recruitment and Retention

SESSION CHAIRPERSON(S)

Elizabeth A. Moench
President and CEO, MediciGLOBAL, Inc.

Effective global patient recruitment and retention programs are those that are designed to be "glocal" – programs that combine global reach with local adaptation and customization.

The development and execution of culturally relevant recruitment and retention materials can be costly and time consuming, especially when global studies involve countries on almost every continent. The ethics review process alone can slow the process, and when ethics committees require unique changes, further delays can be envisioned and costs can increase. Through process and technology advances, the world of "glocal" recruitment is emerging and setting new standards of practice.

"Glocalizing" Recruitment and Retention when Time, Quality, and Cost Is of the Essence
Mark E. Lloyd
Senior Manager, International Clinical Trial Management, sanofi-aventis

Economic Model: Issues of Speed, Quality, and Cost
Elizabeth A. Moench
President and CEO, MediciGLOBAL, Inc.

Session 110 CR 4 - Clinical Research and Development, AHC/IS

10:30 am-12:00 pm LEVEL: ■

Room 203

The Process of Study Feasibility: Three Perspectives, One Common Goal

SESSION CHAIRPERSON(S)

Anne-Marie Baughn, MSN, RN
Director, Marketing and Business Development, Rx Trials, Inc.

This session will address the definition of feasibility from the sponsor, CRO, and site perspective. It will also discuss the operational processes, performance metrics, and tools used by each stakeholder to conduct feasibility. Ultimately the common goal is good data, produced by the site, monitored for compliance by the CRO, and compiled/analyzed by the sponsor. A common understanding to each other's needs and processes allows for all stakeholders to come together as better business partners.

Anne-Marie Baughn, MSN, RN
Director, Marketing and Business Development, Rx Trials, Inc.

Kerri M. Mallory, MSc
Site Development Manager, GlaxoSmithKline Biologicals

Kevin Green
Associate Project Director, Beardsworth Consulting Group, Inc.

Session 111 ERS/DM 1 - Electronic Regulatory Submissions/Document Management, RA

10:30 am-12:00 pm LEVEL: ●

Room 157C

Global eCTDs: A Plan for Labeling

SESSION CHAIRPERSON(S)

Robin L. Zumbrunnen
Director, Regulatory Operations, ePublishing and Technical Services, Quintiles, Inc.

Being able to submit regulatory submissions as simultaneously as possible in multiple regions is a critical financial factor for many pharma/bio companies. This session will explore specific strategies and options for global labeling solutions that meet the EU and US labeling requirements.

Timothy Buxton
Head of Sector, Project Management, Communications and Networking Unit, European Medicines Agency, European Union

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

Karsten Krueger
Head of GRO Coordination, Bayer Schering Pharma AG, Germany

Session 112 ERS/DM 2 - Electronic Regulatory Submissions/Document Management, EC

10:30 am-12:00 pm LEVEL: ■

Room 157AB

FDA and CDISC eSubmission Pilots

SESSION CHAIRPERSON(S)

Edward D. Helton, PhD, MA
Chief Scientist, Regulatory and Biomedical Affairs, SAS Institute, Inc.

CDISC has been collaboratively working with the FDA to generate eSubmissions demonstrating the semantic interoperability of the CDISC Data Models (ADaM, SDTM/SEND, ODM, LAB, CRTDDS-Define, etc.). Three new pilots are under development – an initiation regarding integrated safety data, transport of EDC/eCRF data to SDTM using ODM/XML, and the use of the SEND for eSubmission of preclinical safety data. These three pilots, with a brief review of their integrative power and their relationship to HL7, will be the focus of this session.

Overview of FDA and CDISC Regarding eSubmission Pilots Using Both the CDISC Standard and HL7
Edward D. Helton, PhD, MA
Chief Scientist, Regulatory and Biomedical Affairs, SAS Institute, Inc.

CDISC/FDA Integrated Safety Data Pilot
Rebecca D. Kush, PhD
President and CEO, CDISC

FDA/CDISC Pilot for the Use of ODM/xml for the Review of eCRF Data
Armando Oliva, MD
Deputy Director, Bioinformatics, Office of Critical Path Programs, Office of the Commissioner, FDA

Session 113 GCP - Good Clinical Practices, RA

10:30 am-12:00 pm LEVEL: ■

Room 206AB

FDA Amendments Act 2007 (FDAAA) Title 8: Expanded Clinical Trial Registry Data Bank

SESSION CHAIRPERSON(S)

Pamela A. Rose, BSN, RN
Director, Clinical Trial Information Registries R&D, TAP Pharmaceutical Products, Inc.

This session will review the new FDAAA law as it pertains to clinical trial registration and results disclosure. Representatives from the pharmaceutical industry will share their insights and strategies for complying with FDAAA, and FDA and ClinicalTrials.gov staff will review system revisions being made to support FDAAA law.

ClinicalTrials.gov: Expanding the Database to Implement FDAAA
Rebecca Williams, PharmD
Assistant Director, ClinicalTrials.gov, National Library of Medicine

Implementing FDAAA: Challenges and Solutions
Theresa A. Toigo, MBA, RPh
Assistant Commissioner for Special Health Issues, Office of the Commissioner, FDA

PhRMA's Perspective on FDAAA
Alan Goldhammer, PhD
Associate Vice President, Regulatory Affairs, PhRMA

Session 114 IT 1 - Information Technology, VA

10:30 am-12:00 pm LEVEL: ■

Room 258A

SDLC Controls and Project Management Mechanisms to Support IT in Validated Environments

SESSION CHAIRPERSON(S)

Robert D. Hamrick
QA Manager; ASQ CSQE/CSSGB, Agile Technologies, LLC

A standardized and defensible SDLC process can support easier attainment of compliance objectives and improved audit performance for systems within regulated environments. Additionally, a properly selected SDLC model can also dramatically enhance project management practices and tactics to more effectively control the critical aspects of software development, measurement, and validation objectives. This session describes a flexible, publicly available SDLC model with a wide variety of documentation templates that can easily be customized for effective use within validated environments and are easily matched to components of the PMBOK in support of critical project management functions.

SDLC Controls and Project Management Mechanisms: The USDOJ Model from the Software Quality Engineer's Perspective
Robert D. Hamrick
QA Manager; ASQ CSQE/CSSGB, Agile Technologies, LLC

PMBOK vs. SDLC: SDLC Mechanisms and Models – The Project Manager's Perspective
Bryan Foston, PMP
Senior Project Manager, Merck & Co., Inc.

Session 115 IT 2 - Information Technology, CDM

10:30 am-12:00 pm LEVEL: ■

Room 258B

Issues and Case Studies in Safety Data Migration

SESSION CHAIRPERSON(S)

Uwe P. Trinks, PhD
Chief Information Officer, Sentrx

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

Drivers and Methods for Data Migrations
Eric T. Smith, PharmD
Senior Director, Risk Management and Safety Evaluation, King Pharmaceuticals, Inc.

Migrations Using E2B Plus and Direct Data Mapping Due to Product Acquisition
Brian Perry
President and Chief Executive Officer, BKP Technologies, Inc.

Business Cases for Data Migrations in Safety Systems
Uwe P. Trinks, PhD
Chief Information Officer, Sentrx

Session 116 OS - Outsourcing, CR

10:30 am-12:00 pm LEVEL: ●

Room 205C

Outsourcing of Clinical Trials to India and Beyond: Developing an Effective Global Outsourcing Team

SESSION CHAIRPERSON(S)

Sohil A. Khan, MPharm
Lecturer, Manipal University, Shirdi Sai Baba Cancer Hospital and Research Centre, India

This session will describe the practicality of outsourcing clinical trials to Eastern countries, the advantages and limitations. It will also highlight the caution to be followed while involving these destinations for clinical trials with challenges and solutions.

Outsourcing and Offshoring Clinical Research in India
Sohil A. Khan, MPharm
Lecturer, Manipal University, Shirdi Sai Baba Cancer Hospital and Research Centre, India

Functional Outsourcing: Changing the Drug Development Model
Shirish D. Sherlekar, MD
Practice Head, Life Sciences, Tata Consultancy Services, Ltd., India

Building Effective Global Outsourcing Teams
Lorraine Marchand, MA, MBA
Chief Operating Officer, Clinilabs Inc.

Developing and Implementing a Strategic Relationship Outsourcing Model
Rikki Hansen Bouchard, MPA
President and Chief Executive Officer, RH Bouchard & Associates, Inc.

Session 117 PM/FI 1 - Project Management/ Finance, RD

10:30 am-12:00 pm LEVEL: ■

Room 102AB *Project Management units offered*

Developing Balanced Matrix and Maturing Product Development Teams

SESSION CHAIRPERSON(S)

Katya Kovalskaia, MSc, PMP
Associate Director, Product Development, Anthrax Vaccine, Emergent BioSolutions

In this session, we will review approaches to take in identifying and understanding the areas of need for drug development teams within your organization and what project management tools and techniques to apply in resolving them efficiently and effectively.

Small Biotech: Aligning Virtual Product Development Teams
Ailsa Mendez, MBA
Director, Project Governance, Functional Genetics

High-performance Teams: Nurturing Dynamics for Product Development Success
Thomas Hoffman, MD
Principal, PScience Associates

Teams in the Midst of Strategic Growth: Collaborating to Create New Opportunities
Xiaobing Qian, MD, PhD
Director, Translational Medicine Planning, Regeneron Pharmaceuticals, Inc.

Session 118 PM/FI 2 - Project Management/ Finance, RD

10:30 am-12:00 pm LEVEL: ●

Room 103 *Project Management units offered*

Communications Management: The Key to Successful Project Teams

SESSION CHAIRPERSON(S)

Jean A. Yager, PhD
Director, Infectious Diseases, Pfizer Inc

This session will be an interactive audience session designed to enhance audience understanding regarding the importance of managing team communications.

Communications Management: The Key to Successful Project Teams
Jean A. Yager, PhD
Director, Infectious Diseases, Pfizer Inc

Gail H. Sherman
Vice President, Education, PDA

Session 119 PP - Public Policy/Law, RA

10:30 am-12:00 pm LEVEL: ■

Room 160AB *CME and Pharmacy credits offered*

Personalized Medicine: 2008 Update

SESSION CHAIRPERSON(S)

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

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 scientific, legislative, regulatory, ethical, and business issues that continue to underlie this exciting concept and will determine its ultimate viability.

Diagnostic Company's Perspective
Patrick F. Terry
Director, Industry and Government Affairs, Genomic Health, Inc.

Industry Perspective
Richard Deane Hockett, MD
Medical Fellow, Genomic Medicine, Eli Lilly and Company

Human Health Service Perspective
Gregory Downing, DO
Program Director, Personalized Health Care, Department of Health and Human Services (DHHS)

Session 120 RA 1 - Regulatory Affairs, CR

10:30 am-12:00 pm LEVEL: ●

Room 256 *CME credits offered*

Women's Health under the FDA Critical Path Initiative

SESSION CHAIRPERSON(S)

Ameeta Parekh, PhD
R&D Director, Office of Women's Health, Office of the Commissioner, FDA

The Office of Women's Health (OWH) at the FDA has spearheaded several projects involving biomarker development, pharmacogenetics, and bioinformatics under the FDA Critical Path Initiative. The inclusion of both sexes and the evaluation of sex differences are essential in clinical research. Advanced technological and analytical methods offer tools to better define complex biologi-

cal and physicochemical differences and improve disease prevention, diagnosis, and treatment in women and men.

Pregnant Women in Clinical Trials: Should We Change Direction?
Timothee Fraisse, MD, MSc
Research Fellow, University Hospital Geneva, Switzerland

The Difference an X Makes: Sex and the FDA Critical Path
Sherry A. Marts, PhD
Vice President, Scientific Affairs; Executive Director, Society for Women's Health Research; OSSD

FDA Perspective
Ameeta Parekh, PhD
R&D Director, Office of Women's Health, Office of the Commissioner, FDA

Session 121 RA 2 - Regulatory Affairs, PP

10:30 am-12:00 pm LEVEL: ■

Room 253B

Parallel NDA and Pharmacoeconomical Review for Early Access of Innovative Products

SESSION CHAIRPERSON(S)

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

Early access of innovative products to the needed patients is not ended at the time of NDA approval. Drug pricing and reimbursement after pharmacoeconomical evaluation are equally important, especially in countries with national health insurance policies like UK and Taiwan. Many companies will now be building the pharmacoeconomical data requirement into the study design of pivotal trials via regulatory consultation. Parallel NDA and pharmacoeconomical review for innovative products will be illustrated by the innovative approach proposed in UK (MHRA and NICE) and Taiwan (BPA/DOH and CDE).

Role of Outcome Research in the Reimbursement Process of National Health Insurance Agencies
Hong Li, PhD, MPH
Group Leader, Bristol-Myers Squibb Company, Singapore

Promote Public Health via Early Access of Innovative Products with a Cost-effective Approach in Taiwan
Herng-Der Chern, MD, PharmD, PhD
Executive Director, Center for Drug Evaluation, Taiwan

Regulation and Reimbursement: Two Sides of the Same Coin? A Review of How Pharmaceutical Companies are Currently Building HTA Requirements into the Development Process and What Are the Key Issues
Stuart Walker, PhD
Vice President and Founder, CMR International Institute for Regulatory Science, UK

Session 122 RA 3 - Regulatory Affairs, RD

10:30 am-12:00 pm LEVEL: ■

Room 253A

Regulatory Strategy as a Key Component of the Global Multidisciplinary Drug Development Strategy

SESSION CHAIRPERSON(S)

Petra Heyen, Esq., MD, MPH
Business Process Manager, Novartis Vaccines and Diagnostics, Germany

This session describes the RA strategy from an industry perspective as one major component of the overall drug development plan for the entire life cycle, the constituents of an RA strategy, and RA intelligence as the basis for RA strategy. It also highlights the EU regulatory authority perspective: in which cases is the use of a specific submission procedure mandatory, when is it possible, what needs to be considered in the decision-making process?

Regulatory Intelligence as a Foundation for Business Success
Paul A. Bridges
Senior Director, PAREXEL International, UK

Regulatory Affairs Interactions with the Multidisciplinary Global Development Team in an R&D Environment
Petra Heyen, Esq., MD, MPH
Business Process Manager, Novartis Vaccines and Diagnostics, Germany

EU Regulatory Strategy from the Perspective of a Regulatory Authority
Christa Wirthumer-Hoche, PhD
Head, Unit for Marketing Authorization and Life-cycle Management of Medicinal Products, AGES PharmMed, Austria

Session 123 RA 4 - Regulatory Affairs, PP

10:30 am-12:00 pm LEVEL: ●

Room 251

Extraordinary Use New Drugs in Canada: Issues, Initiatives and Challenges

SESSION CHAIRPERSON(S)

Milan Patel
Regulatory Affairs Project Officer, Director, Health Services Operations, Canadian Forces Health Services Group, Canada

Health Canada's Biologics and Genetics Therapies Directorate has taken the lead in developing regulatory amendments to the Food and Drug regulations that will allow Extraordinary Use New Drugs (EUNDs) to be approved with limited clinical safety and efficacy data. The EUND initiative will propose amendments to paragraphs C.08.002 (g) and (h) of the regulations, related to clinical safety and effectiveness, respectively, which restricts Health Canada's ability to approve new drugs only when there is substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended. Issues, initiatives, and challenges that transpire while developing these new regulations, will be addressed.

EUND Regulations: Why Do We Need Them?
Milan Patel
Regulatory Affairs Project Officer, Director, Health Services Operations, Canadian Forces Health Services Group, Canada

Challenges in the Review of New Drugs with Limited Clinical Data
Jim Gallivan, PhD, MSc
Senior Reviewer, Clinical Trials Division, Biologics and Genetics Therapies Directorate, Health Canada

EUND Regulations: What Are They?
Barbara Wong, PhD
Senior Policy Analyst, Policy and Promotion Division, Health Canada

Session 124 RA 5 - Regulatory Affairs, CTM/CS

10:30 am-12:00 pm LEVEL: ■

Room 252AB

Changing Procedures for Conducting Clinical Trials in Europe

SESSION CHAIRPERSON(S)

Brian Davis, MD
Consultant in Clinical Trials, Department of Health, Medicines and Healthcare products Agency (MHRA), UK

The aims of the Clinical Trials Directive (2001/20/EC) are to protect the rights, safety and well being of those participating in clinical trials by standardization of consideration by ethics committees and authorization by competent authorities, good clinical practice (GCP), good manufacturing practice (GMP), and

inspections against internationally accepted standards. Those objectives have been broadly achieved but harmonization across Member States (MS) has not yet been reached particularly in interpreting legislation and Guidance, requirements for notifying amendments, and suspected unexpected serious adverse reactions (SUSARs).

The EU Heads of Medicines Agencies (HMA) established the Clinical Trials Facilitation Group (CTFG) to identify inconsistencies and prioritize them as requiring European Commission advice/guidance, amenable to MS adoption of best practice, or requiring MS legislation changes. In addition, the European Commission through the European Medicines Agency (EMEA) organized a workshop in October 2007 to assess the implementation of the Clinical Trials Directive, its subsidiary legislation and Guidance.

This session will provide an update of CTFG progress and actions resulting from the EMEA conference aimed to resolve identified difficulties. It will include the outcome of surveys of current practice in MS, discussion of best practice especially in notification of amendments, pharmacovigilance and risk management, and proposals to improve the current practice. It will also explain new approaches to evaluating risk in first-in-human studies.

European Industry Experience in Conducting Clinical Trials in the EU
Mats Ericson, PhD
Director, Regulatory Intelligence, Wyeth Research, France

Experience of a US Biotechnology Company in Conducting Clinical Trials in the EU
Andrew A. Wolff, MD, FACC
Chief Medical Officer and Senior Vice President, Clinical Research and Development, Cytogenetics

Changing Procedures for Conducting Clinical Trials in the EU
Chantal Belorgey-Bismut, MD
Head of Clinical Trials and ATU Department, AFSSAPS, France

Session 125 RA 6 - Regulatory Affairs, CR

10:30 am-12:00 pm LEVEL: ■

Room 254AB

Postmarketing Study Commitments (PMCs): How FDA and Industry Can Effectively Collaborate to Design Better PMCs and Track Them to Completion

SESSION CHAIRPERSON(S)

Beth Duvall-Miller
Team Leader, Regulatory Affairs Team, Office of New Drugs, CDER, FDA

In recent years, postmarketing study commitments (PMCs) have been under increased scrutiny because of the perception that many are not initiated and/or completed in a timely manner. This session will provide a brief background on the regulatory history of PMCs and describe ongoing FDA initiatives for improving the decision-making and tracking processes while increasing transparency and efficiency. You will also hear industry's perspective on the causes of PMC delays and how early discussion with the FDA regarding PMC study objectives and design, will increase the likelihood of better outcomes.

Regulatory History of Postmarketing Study Commitments
Cathryn C. Lee, MS
Regulatory Project Manager, Office of New Drugs, CDER, FDA

FDA Process Improvements for PMC Development and Tracking
Susan L. Honig, MD
Medical Reviewer, Guidance and Policy Team, Office of New Drugs, CDER, FDA

An Industry Perspective: How to Enhance Sponsor-FDA Interactions to Develop Meaningful PMCs
Roy J. Baranello, MS
Assistant Vice President, Global Regulatory Policy and Operations, Wyeth Pharmaceuticals

Session 126 RA 7 - Regulatory Affairs, PP

10:30 am-12:00 pm LEVEL: ●

Room 253C *CME credits offered*

The European Pediatric Legislation and the Pediatric Committee (PDCO): The First Year of the Implementation

SESSION CHAIRPERSON(S)

Patrick Le Courtois, MD
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

The European Pediatric Legislation was implemented more than one year ago and the EMEA Pediatric Committee will celebrate its first birthday. The session will review the experience of the Pediatric Committee and its outcome from a procedural, regulatory and scientific point of view. Feedback from industry on challenges for the future will be discussed.

One Year of the Pediatric Committee
Agnès Saint Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

The Scientific Strategy of the Pediatric Committee (PDCO)
Gerard Pons, MD, PhD
Pediatric Committee Member; Head Clinical Pharmacology, University Rene Descartes, France

Industry Point of View
Thomas M. Severin, MD
External Affairs Head Pediatrics, Novartis Pharma AG, Switzerland

Session 127 RD - R&D Strategy, OS

10:30 am-12:00 pm LEVEL: ●

Room 104C

New Strategies for Successful Licensing Acquisitions

SESSION CHAIRPERSON(S)

Peter J. McFarland, IV, PharmD
Postdoctoral Fellow, Forest Research Institute

As pharmaceutical companies struggle to generate strong product pipelines, they must continue to explore alternatives to traditional research and development. Although licensing compounds from external sources is not an innovative concept, the current decline in internal productivity, accompanied by an extremely large number of products facing patent expiration, has further amplified the pharmaceutical industry's reliance on new product acquisitions. This session will discuss the industry's new strategies toward product acquisition, and the importance of executing deals to meet the needs of both the licensee and licensor.

Identifying Licensing Opportunities
Aaron Pelta, MBA
Senior Manager, Corporate Development, Cubist Pharmaceuticals, Inc.

Strategies to Conduct New Product Scientific Assessment (Due Diligence)
Yavuz Selim Silay, MD, CCRP
Associate Director of Clinical Sciences, Clinical and Medical Affairs, KV Pharmaceutical/Ther-Rx Corporation

Business Development/Alliance Management and Finalizing the Deal
Raj Riswadkar
Senior Director, Business Development, KV Pharmaceutical

Session 128 ST - Statistics, CP, CR, GCP, RA

10:30 am-12:00 pm LEVEL: ●

Room 259AB

Multiregional Clinical Trials: Evaluating the Pros and Cons

SESSION CHAIRPERSON(S)

Peiling Yang, PhD
Team Leader, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

More and more clinical trials across multiple regions/countries are being planned and conducted. Although the advantages of such multiregional trials are potentially appealing, there are many challenges to face. This session will summarize the issues and methods that were discussed at the FDA/PhRMA meeting on the "Challenges and Opportunities of Multiregional Clinical Trials" held October 29-30, 2007, in Bethesda, Maryland, and provide an update on subsequent follow-up activities and next steps.

MRCT: Clinical Research Issues and Emerging Solutions
Ekopimo O. Ibia, MD, MPH, FRCP
Director, Regulatory Policy, Merck Research Laboratories

Multiregional Clinical Trials: The Strategic and Operational Challenges of Conducting Global Clinical Trials
Andrew Lee, MA
Vice President, Clinical Study Operations, Pfizer Global R&D

Multiregional Clinical Trials: A Statistical Perspective
H.M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Panelist
Simon Day, PhD
Statistical Expert, Roche Products Ltd., UK

Session 129 TR - Training, CR

10:30 am-12:00 pm LEVEL: ■

Room 157AB

Real Challenges Faced by Leaders of Virtual Teams in Global Pharmaceuticals

SESSION CHAIRPERSON(S)

Sandra Wesley, PhD, MEd
Director, Education and Training, Johnson & Johnson Pharmaceutical Group

This session will provide insight into the obstacles faced by leaders of virtual teams in the pharmaceutical environment. Attendees will hear about specific challenges identified through face-to-face interviews conducted as part of a doctoral study. This will benefit leaders of teams where the members of the teams are not co-located.

Learning and Development Tools Used to Address Challenges Faced by Leaders of Virtual Teams in Global Pharmaceuticals
Andrea G. Procaccino, CCRT, CMT
Senior Director, Learning and Development, Johnson & Johnson Pharmaceutical Research and Development, LLC

Challenges Faced by Leaders of Virtual Teams in Global Pharmaceuticals
Sandra Wesley, PhD, MEd
Director, Education and Training, Johnson & Johnson Pharmaceutical Group

Emerging Technologies for Global Virtual Teams
George Kuebrich
Technology Manager, Centocor, Inc.

12:00 pm-1:30 pm **LUNCHEON – Exhibit Hall C**

Session 130 AD - Advertising, RA

1:30 pm-3:00 pm LEVEL: ●

Room 153AB *Pharmacy credits offered*

Direct-to-consumer Statutory Review Program

SESSION CHAIRPERSON(S)

Kristin I. Davis, JD
Deputy Director, Division of Drug Marketing, Advertising and Communications, Office of Management Programs, CDER, FDA

This session will present an update on direct-to-consumer from a broad perspective and with highlights from FDA professionals who are responsible for policy development and operations in this important topic.

DDMAC Perspective
Kathryn J. Aikin, PhD
Social Science Analyst, DTC Review Group Research Team, Division of Drug Marketing, Advertising and Communications, Office of Management Programs, CDER, FDA

DDMAC Perspective
Marci C. Kiester, PharmD
Leader, DTC Review Group, Division of Drug Marketing, Advertising and Communications, Office of Management Programs, CDER, FDA

Session 131 AHC/IS - Academic Health Centers/ Investigative Sites, CR

1:30 pm-3:00 pm LEVEL: ●

Room 104AB *Nursing credits offered*

The Impact of the New Clinical Research Paradigm on Investigational Sites

SESSION CHAIRPERSON(S)

Ana Filipa Bernardo, MSc
R&D Coordinator in Translational Research Projects, Eurotrials, Scientific Consultants, Portugal

Changes in the clinical research paradigm due to improvements in molecular medicine and the need for more effective approaches in clinical trials design require the upgrade of research sites. Major requirements for enabling the investigational sites for experimental medicine, population-based health research and scale-up of clinical trials, and the framework of Clinical and Translational Research Network in the EU will be discussed.

The Role of ECRIN in the Implementation of the Innovative Medicines Initiative
Jacques Demotes-Mainard
Coordinator, European Clinical Research Infrastructure Network (ECRIN) Programme, INSERM, France

Implementing Functional Biomarker Assays into Clinical Trials: Challenges and Rewards
Andrew Welcher, PhD
Director, Medical Sciences, Amgen Inc.

Translational Aspects of Exploratory Clinical Trials
Beatriz Silva Lima, PharmD, PhD
Professor, Pharmacology, CHMP and SAWP member, SWP Chair, University of Lisbon; INFARMED, Portugal

Session 132 BT - Biotechnology, RA

1:30 pm-3:00 pm LEVEL: ■

Room 105

Recent Advancement of Novel Biotechnology 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 nano-technology has attracted attention among industries as well as in academia. National programs in these countries have supported the interdisciplinary research funding and infrastructure setup. This session will be devoted to the discussion and comparison of recent advances in the development of biotech-nology in the Asia-Pacific region, as well as a comparison of development strategy among these Asian countries.

Emerging Technology and Regulatory Challenges
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Biotechnology: Perspectives in Asian Regional Development
Carlos Linn, MD
Clinical Research Physician, Oncology, Eli Lilly and Company, Hong Kong

New Drug Discovery for Cancer and Protection against a Broad-spectrum Viral Infection
Grace H.W. Wong, PhD
President and Chief Scientific Officer, ActoKine Therapeutics

Session 133 CDM - Clinical Data Management, CR

1:30 pm-3:00 pm LEVEL: ■

Room 158C

Evolving Role of the Medical Reviewer in Clinical Trials Data Management through the Prism of Growing Industry Expectations and Rising Standards

SESSION CHAIRPERSON(S)

Yuri Zaretsky, MD
President, ZM Company, Canada

Even if the position of a medical reviewer (MR) is not new across the industry, its precise role and set of activities in clinical trial data management are still not fully understood. The astonishing progress in medical sciences along with the increasing complexity of the clinical trials has changed the very notion of medical review, and new demands have been laid down. This session will focus on the concept of medical review in the light of growing industry expectations and rising standards and will provide an outlook on the MR as the main connecting link between data managers, pharmacovigilance managers, project managers, and CRAs in clinical data handling. The role of the MR in creating reliable medical data sets will be emphasized as fundamental, and the numerous activities that the MR could be involved in will be further explored. The MR will also be presented in the position of an additional safe-guard for the well-being and safety of the enrolled patients, and further dis-cussion will follow on major concerns and challenges that might be encoun-tered during ongoing and final review. Presentations will be supported by real-life examples based on the experience with the industry.

Bringing Together the Worlds of Medical Affairs and Data Management to Ensure Trial Success
Agnes Nemet, MD
Director, CLINSIG Research Consulting Inc., Canada

Medical Review: The Challenge of Bridging the Gap between Clinical and Data Management Aspects of the Clinical Trial
Yuri Zaretsky, MD
President, ZM Company, Canada

Lessons Learned: Providing Data Management and Statistical Support for Medical Affairs
Janet E. A. McDougall, MS
President and Senior Statistician, McDougall Scientific Ltd (MSL), Canada

Session 134 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

1:30 pm-3:00 pm LEVEL: ■

Room 154

CMC Pilot Submissions and Lessons Learned: An Industry Perspective

SESSION CHAIRPERSON(S)

Karen B. Main, PhD, RPh
Regional Associate Director, UK/US Investigational Products, AstraZeneca

This session will present feedback from current and past industrial participants in the CMC Submission Pilot.

Pilot Submission Experiences
Paul Stott, PhD
Associate Director, Product Development, AstraZeneca

Marc Vanstockem, PhD
Senior Director, Chemistry Pharmaceutical Leader, Johnson & Johnson Pharmaceutical R&D, Belgium

Session 135 CP 1 - Clinical Safety and Pharmacovigilance, ERS/DM

1:30 pm-3:00 pm LEVEL: ◆

Room 156AB

Different Approaches to Spontaneous Reporting: A New Business Model

SESSION CHAIRPERSON(S)

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

The spontaneous reporting system remains the primary source of information regarding potential adverse events associated with pharmaceutical products. Improving the quality of the data received through this system while lowering the burden on the reporter would immediately benefit public safety. The par-ticipants in this session will represent major users of the current system who are working together to test practical applications of standards and technology to improve data quality and facilitate use of the system.

The ASTER Study: Exploring a New Model for Postapproval Reporting
Michael A. Ibara, PharmD
Head of Pharmacovigilance Information Management, Pfizer Inc

ASTER and Spontaneous Reporting: The Not for Profit Service Provider Perspective
Mark E. Vermette
Product Manager, CRIX International

FDA Perspective
Lise R. Stevens
Data Standards Project Manager, Office of Critical Path Programs, CBER, FDA

ASTER and Spontaneous Reporting: The Provider Perspective
Jeffrey A. Linder, MD, MPH, FACP
Assistant Professor of Medicine, Division of General Medicine, Brigham & Women's Hospital and Harvard Medical School

Session 136 CP 2 - Clinical Safety and Pharmacovigilance, CR

1:30 pm-3:00 pm LEVEL: ■

Room 156C *CME credits offered*

Drug-induced Liver Injury (DILI): How Well Do Preclinical and Clinical Studies Predict Hepatotoxicity?

SESSION CHAIRPERSON(S)

Martha E. Carter, PhD, MS, RPh
Associate Clinical Research Scientist, Eli Lilly and Company

The challenge of assessing drug-induced liver injury during preclinical, early-phase, and late-phase clinical studies will be reviewed. This will include the relationship of biomarkers and preclinical data with clinical outcomes. Draft FDA and EMEA regulatory Guidances for the premarketing assessment of hepatotoxicity will be discussed. Innovative studies with the potential for earlier and improved detection of DILI will be explored.

Mechanisms of Idiosyncratic DILI: New Insights from Animal Models
Urs Boelsterli, PhD
Professor and Boehringer Ingelheim Endowed Chair in Mechanistic Toxicology, University of Connecticut School of Pharmacy

Pharmacogenetics of DILI: Pitfalls and Promise in Clinical Development
Beena T. Koshy, PhD, MSc
Pharmacogenetics Consultant, Pharmacogenetics-pharmacovigilance, GlaxoSmithKline

Identifying Idiosyncratic DILI during Drug Development
Arie Regev, MD
Hepatology Consultant, Global Patient Safety, Eli Lilly and Company

Session 137 CR 1 - Clinical Research and Development, PM/FI

1:30 pm-3:00 pm LEVEL: ■

Room 203

Improving the Business of Science: How Metrics Can Improve the Pharmaceutical Bottom Line

SESSION CHAIRPERSON(S)

Eric Lake, MBA
Partner, Pharmica Consulting

This session will discuss why too many companies' metrics initiatives are either unsuccessful or inefficient. The session will interpret metrics approaches from other industries into analogous situations within clinical operations, with an emphasis on financial implications. By helping attendees to recognize that the purpose of any metrics initiative is the same regardless of industry, this session hopes to bring some clarity to a continually muddled part of our industry.

Getting Down to Business: Metrics and the Bottom Line
Eric Lake, MBA
Partner, Pharmica Consulting

Planning Ahead: Reducing Waste and Improving CRA Performance
Carol Seider
Associate Director, Merck & Co., Inc.

Using Metrics to Improve: The Time Is Now
Randy Krauss, PhD
Associate Director, Portfolio Management, Genzyme Corporation

Session 138 CR 2 - Clinical Research and Development, CTM/CS

1:30 pm-3:00 pm LEVEL: ●

Room 204AB *Nursing credits offered*

Subject Recruitment in the US: Is It a Losing Proposition?

SESSION CHAIRPERSON(S)

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

Despite increasing emphasis on site selection, patient outreach and enrollment, US subject participation lags behind expectations while per patient costs are higher relative to other regions of the world. This panel discussion will focus on different tactics that are being used to increase US subject participation in clinical trials, including both technology-based and process-improvement methods. Panelists will answer and discuss several compelling questions on the subject of US subject enrollment, and audience participation will be encouraged.

Matthew Kibby, MBA
Global Operations Leader, BBK Worldwide, UK

David S. Zuckerman, MS
President, Customized Improvement Strategies LLC

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

Session 139 CTM/CS - Clinical Trial Management/ Clinical Supplies, CR

1:30 pm-3:00 pm LEVEL: ◆

Room 162AB

Radical Change in Clinical Development: Results from the Changes

SESSION CHAIRPERSON(S)

Ira C. Spector, MBA
Vice President, Global Development Operation, Wyeth Research

This session will present an update to the 2007 Annual Meeting session on radical change in clinical development. Presentations will address the radical changes in clinical development processes at major pharmaceutical and biotechnology companies.

Update to the 2007 Session on Radical Change in Clinical Development
Peter A. Carberry, MD, MBA
Vice President, Clinical Operations, DPPA and International Development, Genentech, Inc.

Update to the 2007 Session on Radical Change in Clinical Development
Ulo Palm, MD, PhD, MBA
Global Head, Laboratory and Preclinical QA, Exploratory Development, Novartis Pharmaceuticals Corporation

Update to the 2007 Session on Radical Change in Clinical Development
Jose Luis Reynal, MD
Vice President, Central Trial Coordination, Johnson & Johnson Global Clinical Operations

Session 140 ERS/DM 1 - Electronic Regulatory Submissions/Document Management, RA

1:30 pm-3:00 pm LEVEL: ■

Room 157C

Replacing Aging EDM Systems: Opportunities and Challenges

SESSION CHAIRPERSON(S)

Dimitri Stamatiadis, PhD, MBA
Project Leader EDMS, Merck Serono International, Switzerland

Many companies have recently initiated the replacement of their aging EDM systems by state-of-the-art tools that will cover the companies' needs for the next decade. This session will explore the challenges and opportunities of such endeavors in light of the latest improvements and innovations in the field of EDM and electronic submission tools.

Document Management and Workflow that Appeals to Users and IT: A Case Study of the Integrated Collaborative Environment at a Global Biotechnology Company
Rodney Lozano
Vertex Pharmaceuticals Inc.

Planning the Replacement of Several Aging EDM Systems: Challenges and Opportunities
Steve Scribner
Principal Consultant, International Life Science Solutions, Inc.

Document and Records Management from a Regulatory Affairs Perspective
Thomas Altenwerth
Head, Document Management and Archiving, Bayer HealthCare AG, Germany

Session 141 ERS/DM 2 - Electronic Regulatory Submissions/Document Management, RA

1:30 pm-3:00 pm LEVEL: ■

Room 257AB

Pursuing Standards to Enhance eCTD Deliverables

SESSION CHAIRPERSON(S)

Daniel F. Orfe, MS
Associate Director, Merck & Co., Inc.

This session begins with an overview on how sponsors can leverage standards and efficiencies for the production and maintenance of Financial Disclosure, FDA Division of Scientific Investigation, and Administrative Module eCTD components. The Pharmaceutical Research and Manufacturers Association (PhRMA) Electronic Regulatory Submissions (ERS) group has established teams to define standards and identify efficiencies for deliverables provided within the eCTD. These teams have worked with input from the Food and Drug Administration (FDA). The progress from three of these teams will be presented within this session: the Financial Disclosure standardization team, FDA Division of Scientific Investigation deliverable standardization and information access efficiency via the eCTD team, and the eCTD Submissions Administrative Module component delivery efficiencies team.

The session will provide insights into how industry sponsors can leverage the standards and efficiencies these teams have identified for the production and maintenance of their eCTD deliveries. The technical, process, organizational, and regulatory obstacles associated with these standards and approaches will be discussed along with the projected benefits for both industry and the FDA.

FDA Division of Scientific Investigation (DSI): Pursuing Standards to Enhance eCTD Deliverables
Daniel F. Orfe, MS
Associate Director, Merck & Co., Inc.

FDA Submission Efficiencies: Pursuing Standards to Enhance eCTD Deliverables
Terri M. Booth-Genthe, MS
Director II, Global Regulatory Submission Management, Wyeth

FDA Financial Disclosure: Pursuing Standards to Enhance eCTD Deliverables
Maureen J. Lloyd
Senior Director, Medical Business Operations, Pfizer Inc

Session 142 GCP 1 - Good Clinical Practices, PP

1:30 pm-3:00 pm LEVEL: ●

Room 206AB *Nursing credits offered*

After the Trial is Completed: What, When, Where, and How to Post Trial Results

SESSION CHAIRPERSON(S)

Tracy J. Beck, PhD
Global Medical Business Office Consultant, CTR Results Gatekeeper, Eli Lilly and Company

This session will review current law and guidances governing clinical trial results disclosure; what, when, where, and how to post trial results; and how to maintain compliance.

ClinicalTrials.gov Update: Focus on Registration Trends and Results Reporting Requirements
Rebecca Williams, PharmD
Assistant Director, ClinicalTrials.gov, National Library of Medicine

The Use of Adaptive Designs and Clinical Trial Disclosure
Merete Joergensen, MBA, MSc
Project Director, Public Access to Clinical Trials, Novo Nordisk A/S, Denmark

Maintaining Compliance
Barbara Godlew, RN
President and Principal Analyst, The FAIRE Company, LLC

Session 143 GCP 2 - Good Clinical Practices, RA

1:30 pm-3:00 pm LEVEL: ■

Room 208 *Pharmacy credits offered*

Navigating the New FDA Part 11 Guidance: Sponsor and Site Perspective

SESSION CHAIRPERSON(S)

Yvonne P. McCracken, MPH
President and CEO, Carolinas Research Associates

In May 2007 the FDA issued the updated Guidance for Industry Computerized Systems Used in Clinical Investigations (Guidance). This updated Guidance clarifies the scope and applicability of the requirements of the 21 CFR Part 11 regulation (Part 11) pertaining to computerized systems and "records in electronic form that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained, or submitted to the FDA." Among the most important clarifications in the new 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.

Taking the team approach, this session will discuss issues with electronic data collection at investigator sites identified through the site audit process. Both the sponsor and site perspective will be explored in an attempt to identify best practice for maintaining regulatory compliance at investigator sites.

Electronic Data Capture Systems Used by Investigator Sites
Yvonne P. McCracken, MPH
President and CEO, Carolinas Research Associates

Electronic Medical Records Systems Used by Investigator Sites for Source Data Purposes
Blake R. Jensen
Associate Director, Contract QA Services, INC Research, Inc.

Session 144 IT 1 - Information Technology, VA

1:30 pm-3:00 pm LEVEL: ■

Room 258A

CDISC SDTM Data Conversion

SESSION CHAIRPERSON(S)

Hanming Tu, MS
Director, Clinical Information Technology, Octagon Research Solutions, Inc.

With FDA recommendation on the standards, companies will need to convert their clinical and preclinical trials data from various legacy and company standards to the new industry standard SDTM. This session will discuss the many ETL tools explored and how many issues had been encountered in using those tools. Presenters share their experience in implementing and validating ETL tools for converting clinical trials data into submission-ready data based upon the CDISC SDTM. It will also discuss how to use various features in some tools to improve efficiency and share solutions to address some limitations in current tools.

CDISC SDTM Data Conversion Using Oracle Warehouse Builder
Hanming Tu, MS
Director, Clinical Information Technology, Octagon Research Solutions, Inc.

Metadata-driven Technology for Implementing CDISC SDTM
Michael J. Todd, MS
President, Nth Analytics

Using CDISC ODM and XML-based ETL Tools for Converting Clinical Data to SDTM
Claus Lindenau
Head, Business Development, XClinical GmbH, Germany

Using the SAS Metadata Server to Create the Define.xml
Christopher Treglio
Lead Architect, Clinical Information Technology Group, Bayer Corporate Business Services

Session 145 IT 2 - Information Technology, VA

1:30 pm-3:00 pm LEVEL: ■

Room 258B

How Much Information Technology Do Early Stage Biotechnology Firms Need?

SESSION CHAIRPERSON(S)

Keith M. Parent, MS
Chief Executive Officer, Court Square Group

Information technology is often a hidden cost in the drug development life cycle. Yet information technology is becoming an increasingly important part of the drug discovery process. One need only consider FDA's Critical Path Initiative to realize that in the future, informatics will play an increasingly vital role in every phase of drug discovery and development. Unfortunately, many emerging biotechs make costly mistakes when establishing and maintaining IT infrastructure, applications to support processes and data flow in quality management, document management, clinical trials, and adverse event reporting. Emerging biotech firms must determine what IT systems they need today, and how to plan for tomorrow. Some turn to managed services firms, outsourcing the complexity. Others decide to do it in house. Still others choose a hybrid model, outsourcing some while retaining other parts of their IT systems and operations. Whatever path they choose, emerging firms need a cost-effective approach to IT that meets their current needs but can scale as their company grows and matures through the drug development lifecycle.

Assessing the Information Technology Needs of Early and Emerging Life Sciences Companies
Keith M. Parent, MS
Chief Executive Officer, Court Square Group

Evolution of Small Biotechnology to Emerging Biotechnology – Part 1
Kevin Durfee
Director, Information Technology, Ironwood Pharmaceuticals

Evolution of Small Biotechnology to Emerging Biotechnology – Part 2
Robert Michael
Senior Director, Information Technology, Synta Pharmaceuticals

Session 146 OS - Outsourcing, CTM/CS

1:30 pm-3:00 pm LEVEL: ◆

Room 205C

Outsourcing Strategies and Trial Management in Asia

SESSION CHAIRPERSON(S)

James D. Fan, MD
Associate Medical Director, Asia-Pacific Region, ICON Clinical Research Ltd., Singapore

The session will present the analysis of outsourcing strategies in Asia from a CRO's perspective, and will also provide an outline of the roles and responsibilities of the pharmaceutical company and CRO in an outsourcing model, because the outsourcing strategies are needed to create a high-performing sponsor-CRO relationship and to evaluate this relationship by the appropriate performance metrics. Some common lessons from outsourcing pitfalls in Asia will also be shared. With an increasing number of clinical trials being conducted in China, this session will discuss the results of a survey conducted to determine the roles and responsibilities and the key strengths and weaknesses of 229 CRAs in China. This survey was analyzed to provide a snapshot of current CRA-related practices for CROs and biotechnology and pharmaceutical companies intending to conduct clinical trials in China. This session will also share the experience and lessons learned from a state-certified clinical trial site in China.

Building and Sustaining a Successful Outsourcing Strategy between Pharmaceutical Companies and CROs
Raymond S.B. Chua, MD, MBA, MPH, FRCP
Managing Director/Regional Medical Director - Asia Pacific/Oceania/ Middle East, Eisai Clinical Research Singapore Pte Ltd., Singapore

Outsourcing Strategies in Asia from a CRO Perspective
Vijay R. Prabhakar, MD
Medical Director, PharmaNet, Singapore

The Role and Responsibilities of CRAs in China
James D. Fan, MD
Associate Medical Director, Asia-Pacific Region, ICON Clinical Research Ltd., Singapore

Experiences Learned from a Clinical Trial Site in China
Hua Fang Li, MD, PhD
Professor, Psychiatry, Jiaotong University, Shanghai Mental Health Center, China

Session 147 PM/FI 1 - Project Management/ Finance, RD

1:30 pm-3:00 pm LEVEL: ■

Room 102AB *Project Management units offered*

Value of Six Sigma to Pharmaceutical Product Discovery and Development

SESSION CHAIRPERSON(S)

Rebecca A. Vermeulen, RPh
Director, Six Sigma, LRL Medical, Eli Lilly and Company

The intent of this session is to demonstrate how Six Sigma can be applied as an effective tool to improve product development cycle times while reducing cost and maintaining quality. Specific and practical examples of how project management has effectively partnered with early-phase through late-phase drug development to improve efficiency in delivering high-quality medicines to patients.

Application of Six Sigma Methodology
Craig A. Davenport, RPh
Director of Clinical Planning and Execution, Eli Lilly and Company

Application of Six Sigma Methodology: A Functional Example
Louise Doll, MS
Associate Director, Worldwide Clinical Data Management Operations, Merck & Co., Inc.

Applying Lean Six Sigma to Improve Early Drug Development
Alister Thomson, MBA
Director, Strategic Process Optimization, Bristol-Myers Squibb

Session 148 PM/FI 2 - Project Management/ Finance, CR

1:30 pm-3:00 pm LEVEL: ■

Room 103 *Project Management units offered*

Project Manager to Project Leader: Facilitating the Transition

SESSION CHAIRPERSON(S)
Eric M. Towler, PhD, PMP
Associate Project Director, Project Management, Merck & Co., Inc

The purpose of this session is to address the increasing demand that project managers act as project leaders regardless of formal status. The session will provide practical processes which a project manager can implement on both a project level and personal level to help meet these expectations.

Establishing Standard Tools and Processes to Create Opportunities for Demonstrating Accepted Leadership Principles
Jayanthi Reddy, MBA, MS
Associate Project Director, Merck & Co., Inc.

Establishing a Web of Accountability to Ensure Adherence to Accepted Leadership Principles
Jann A. Nielsen, PhD
Senior Director, Project Management, Wyeth Research

Leadership Development: A Personal Experience
Jason C. Bork
Manager, Project Management Excellence, Eli Lilly and Company

Session 149 PP - Public Policy/Law, RA

1:30 pm-3:00 pm LEVEL: ●

Room 160AB *CME, Nursing, and Pharmacy credits offered*

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

SESSION CHAIRPERSON(S)
Mark C. Hegarty, JD
Partner/Attorney, Shook, Hardy & Bacon, LLP

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

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

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

Joan Rachlin, JD, MPH
Executive Director, PRIM&R, Public Responsibility in Medicine and Research

Session 150 RA 1 - Regulatory Affairs, CR

1:30 pm-3:00 pm LEVEL: ●

Room 252AB

Facilitating Global Pediatric Drug Development: An Assessment of Recent Experience

SESSION CHAIRPERSON(S)
William J. Rodriguez, MD, PhD
Science Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

The intent of this session is to provide an overview of changes in the US pediatric legislation and the early implementation of the European pediatric initiative. We will focus on the processes involved in the US-EMEA pediatric cooperative activities and provide some examples of issues that have occurred and approaches used to solve them. This session will describe the US and EMEA's experiences as well as provide industry's perspective on the regulatory issues pertaining to drug development in pediatrics.

Early Experiences in Information between FDA and EMEA in Pediatric Drug Development
M. Dianne Murphy, MD
Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

The Recent Pediatric Regulatory Experience in Europe: EMEA's Regulatory Approach to Pediatric Drug Development
Agnès Saint Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

Pediatric Global Development Coordination Plans: A View from the EU
Angelika Joos, MPharm
Regulatory Policy Europe, Merck Sharp & Dohme (Europe) Inc., Belgium

Pediatric Development and Registration: Perspective from a US Sponsor
David M. Cocchetto, PhD, RPh
Vice President, Antiviral/Antibacterial Regulatory Affairs, GlaxoSmithKline

Session 151 RA 2 - Regulatory Affairs, PP

1:30 pm-3:00 pm LEVEL: ■

Room 253A

ICH Global Cooperation Group (GCG) Initiative Update

SESSION CHAIRPERSON(S)
Yves Juillet, MD, PhD
Senior Advisor, LEEM, France

ICH has a direct influence on drug registration in non-ICH countries. The Global Cooperation Group (GCG) serves as a liaison between ICH and non-ICH Regional Harmonization Initiatives. The current and future role of GCG will be developed as well as its influence on registration of medicinal products in non-ICH countries.

Current and Future Role of ICH GCG
Mike D. Ward
Manager, International Policy Division Bureau, Therapeutic Products Directorate, Health Products and Food Branch, Health Canada

Participation of Regional Harmonisation Initiatives (RHI) in ICH GCG: Influence on Regional Harmonisation and Potential Developments
Yuppadee Javroongrit, PhD
Assistant Director, Drug Control Division, Food and Drug Administration, MOPH, Thailand

ICH GCG Activities: Interest for Industry and New Developments
Kohei Wada, MS
Vice President, General Manager, Asia Development Department, Daiichi Sankyo Co., Ltd., Japan

Session 152 RA 3 - Regulatory Affairs, RD

1:30 pm-3:00 pm LEVEL: ●

Room 256

Introduction to European Public Assessment Reports (EPARs) and FDA Approval Packages: Finding and Analyzing Unpublished Information about Pivotal Studies

SESSION CHAIRPERSON(S)

Amy N. Grant, MS
Director, Regulatory Strategy and Science, ViroPharma Inc.

Useful unpublished material is available in EPARs and FDA approval packages if you know what you are looking for and how to find it. Although information in EPARs and FDA approval packages is unpublished, it is publicly available once posted by the regulatory agency. The session will provide an overview of the structure and content of EPARs and FDA approval packages including best practices in finding and analyzing key components such as pivotal study information. Examples will include analyses from health authorities, academia, and industry.

A Pragmatic Journey through FDA Approval Packages and Other Key Materials: Researching Drug Studies
Marlene Bobka
Vice President, FOI Services, Inc.

Introduction to European Public Assessment Reports (EPARS) and Researching Drug Studies
Amy N. Grant, MS
Director, Regulatory Strategy and Science, ViroPharma Incorporated

Researching Drug Studies across European Public Assessment Reports (EPARs) and FDA Approval Packages
Linda F. Bowen, MS, RAC
Director, Regulatory Intelligence, US Region, sanofi-aventis

Session 153 RA 4 - Regulatory Affairs, RD

1:30 pm-3:00 pm LEVEL: ●

Room 251

Generic Biologics: Fact or Fiction?

SESSION CHAIRPERSON(S)

Lynda Y. Sutton
Chief Operating Officer, Cato Research

As another year of experience is gained, several biological products have moved past the time for patents to expire. Is there a scientific basis for some biological products to become generic? Significant financial incentives create opposing sides to this issue and thereby potentially inhibit resolution.

Update on Biosimilars in Europe
Sandy M. Eisen, MD, MA
Chief Medical Officer, TEVA Pharmaceuticals Europe, UK

The Next Generation of Biosimilars
Cecil Nick, MS
Principal Consultant, PAREXEL Consulting, UK

Biosimilars from an EU Perspective
Peter J. Richardson, PhD
Scientific Administrator, European Medicines Agency, European Union

Session 154 RA 5 - Regulatory Affairs, RD

1:30 pm-3:00 pm LEVEL: ■

Room 253B

A Standardized Approach to Improving the Quality of the Regulatory Review and Submission: Can Scorecards Increase the Predictability of the Review Process?

SESSION CHAIRPERSON(S)

Professor Stuart Walker, PhD
Vice President and Founder, CMR International Institute for Regulatory Science, UK

Predictable outcomes from the regulatory review are what agencies and companies desire and they are evaluating different ways to improve performance. Increasingly, however, the term quality is being used in discussions of the regulatory process itself. It has been realized that it is not enough to measure regulatory performance solely in terms of timelines and speed of review. The quality of the process, from the construction of the dossier and its content, through the review and ultimately the decision-making process must also be monitored. The use of a scorecard mechanism to collect feedback (in a systematic and harmonized format) on regulatory performance, has been recommended as a way forward. This session will outline the scorecards and their potential utilization as well as having both an agency and companies viewpoint on the potential for this methodology as a fundamental way both companies and agencies can improve the quality of the review and submission.

Review of a Pilot Study to Test the Feasibility of Using a Scorecard to Collect Feedback from Companies and Agencies in a Systematic Format on Both the Regulatory Review and Submission
Neil McAuslane, PhD, MSc
Director, CMR International Institute for Regulatory Science, UK

A Scorecard Methodology to Aid Agencies and Companies to Improve the Regulatory Review and Submission: What Are the Benefits and Potential Outcomes from Utilization of a Scorecard – An Agency Viewpoint
Caroline Vanneste
Project Manager, Good Review Practices, Therapeutic Products Directorate, Health Canada

A Scorecard Methodology to Aid Agencies and Companies to Improve the Regulatory Review and Submission: What Are the Benefits and Potential Outcomes from Utilization of a Scorecard – A Company Viewpoint
Paul D. Huckle, PhD, MPharm, RPh
Senior Vice President, US Regulatory Affairs, GlaxoSmithKline

Session 155 RA 6 - Regulatory Affairs, GCP

1:30 pm-3:00 pm LEVEL: ●

Room 253C

The Current Status within China on GCPs, Computerized Systems Used in Clinical Trials and Data Integrity

SESSION CHAIRPERSON(S)

Earl W. Hulihan, MEd
Corporate Compliance Officer, Vice President, Global RA and QA, Medidata Solutions Worldwide

The global pharmaceutical community has not had the opportunity to hear about the significant partnership between the SFDA and the Chinese medical community in advancing GCP and data integrity. This session will have representation from SFDA, the medical community, and industry. Specific areas discussed will be GCP, training initiatives, and efforts to demonstrate integrity with computerized systems used in their clinical trials and safety management.

GCP Training in China
Cai Cao
Deputy Director-General, Drug Certification Center, SFDA, China

The Current Status within China on Computerized Systems Used in Clinical Trials and Data Integrity
Qing-Shan Zheng, PhD
Director, Center for Drug Clinical Research, Shanghai Traditional Chinese Medicines University, China

Earl W. Hulihan, MEd
Corporate Compliance Officer, Vice President, Global RA and QA, Medidata Solutions Worldwide

Session 156 RA 7 - Regulatory Affairs, PP

1:30 pm-3:00 pm LEVEL: ●

Room 254AB

The EMEA: How to Make the Best of It

SESSION CHAIRPERSON(S)

Patrick Le Courtois, MD
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

The EMEA has in the recent years developed several initiatives and entry points to facilitate regulatory procedures from early development to postmarketing authorizations stages. The session will describe and explore the opportunities offered for liaising with EMEA and having meetings for novel or more classical therapies, for orphan drugs and future advanced therapies, whether you are a big pharma or an SME (small- and medium-size enterprise.)

EMEA: The Most Recent and Future Initiatives for Communicating and Liaising with Industry
Martin Harvey-Allchurch, LLM
Head of Executive Support, Directorate, European Medicines Agency, European Union

The Various Entry Doors of EMEA: How to Get a Meeting for Big Pharmaceutical and Small- and Medium-size Enterprise
Melanie Carr
Scientific Administrator, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

My Best Experiences with the EMEA
Anita Osborne
Director, Regulatory Affairs and Project Management, Rheoscience A/S, Denmark

Session 157 RD - R&D Strategy, CR

1:30 pm-3:00 pm LEVEL: ■

Room 104C

Go/No Go Decision Making for Global Drug Development Including Japan

SESSION CHAIRPERSON(S)

Toshinobu Iwasaki, PhD
General Manager, Shionogi & Co., Ltd., Japan

Shunsuke Ono, PhD
Associate Professor, Pharmaceutical Sciences, University of Tokyo, Japan

Pharmaceutical industries have to carefully scrutinize the medical/social environments, performance of clinical trials, and regulatory requirements for go/no go decision making of the global drug development including Japan. The circumstances surrounding clinical trials in Japan have been drastically changed. The session will introduce the current desirable movement to facilitate global drug development including Japan and the crucial issues for its go/no go decision making from our point of view on the basis of JPMA's survey.

Successful Approach for Global Drug Development: JPMA's Perspective
Tetsuto Nagata
Board Member, Drug Evaluation Committee, Japan Pharmaceuticals Manufacturers Association (JPMA), Japan

Expectations for Global Drug Development from a Reviewer's Point of View
Junko Sato, PhD
Review Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The New Era of Global Simultaneous Development Including Japan
Hiromichi Shirasawa, MD
Executive Director, Head of Regulatory Affairs Department, Pfizer Japan Inc., Japan

Session 158 ST - Statistics, CR

1:30 pm-3:00 pm LEVEL: ■

Room 259AB

Genomic (Surrogate) Biomarker in Therapeutic Trials

SESSION CHAIRPERSON(S)

Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Incorporation of genomic biomarker in designing a well controlled clinical trial can increase statistical power and efficiency in drug development. Utility of genomic biomarker and issues of its use in drug development will be presented.

Regulatory Perspective on Surrogate Markers: Their Role in Drug Development
Aloka G. Chakravarty, PhD
Director, Division of Biometrics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Regulatory Experiences and Statistical Considerations in Utility of Genomic Markers in Cardiovascular and CNS Clinical Trials
H.M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

How to Evaluate Added Value from Bio- and Genetic Markers over the Conventional Clinical Markers for Predicting Clinical Phenotypes?
L.J. Wei
Professor of Biostatistics, Harvard University

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

Session 159 TR - Training, AHC/IS

1:30 pm-3:00 pm LEVEL: ■

Room 157AB *CME and Pharmacy credits offered*

Developing Academic Program Accreditation Standards for Clinical Research Education Programs

SESSION CHAIRPERSON(S)

James L. Parmentier, PhD
Associate Director, Graduate Program in Clinical Investigation, MGH Institute of Health Professions

This session will review past efforts to define the basic components of a clinical research education program, describe the value and the process of academic program accreditation, propose minimal content levels, and discuss outcome measurements by which clinical research education programs might be judged.

Core Competencies for Entry-level Positions in Clinical Research
Stephen A. Sonstein, PhD, MS
Director, Clinical Research Administration, Eastern Michigan University

Standardization of Core Competencies for the Clinical Research Profession
James L. Parmentier, PhD
Associate Director, Graduate Program in Clinical Investigation, MGH Institute of Health Professions

Core Competencies for Principal Investigator Positions in Clinical Research
Carlton A. Hornung, PhD, MPH
Professor, Department of Epidemiology and Public Health, University of Louisville

3:00 pm-3:30 pm **REFRESHMENT BREAK – Exhibit Hall**

Session 160 AD - Advertising, RA

3:30 pm-5:00 pm LEVEL: ●

Room 153AB *Pharmacy credits offered*

Introduction to Pharmaceutical Marketing

SESSION CHAIRPERSON(S)
Janet L. "Lucy" Rose, MBA
Managing Director, Life Sciences, Regulatory, and Capital Markets, Deloitte & Touche, LLP

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 I. Davis, JD
Deputy Director, Division of Drug Marketing, Advertising and Communications, Office of Management Programs, CDER, FDA

Session 161 AHC/IS - Academic Health Centers/ Investigative Sites, CTM/CS

3:30 pm-5:00 pm LEVEL: ■

Room 104AB *Nursing credits offered*

Effective Working with Investigative Sites: Essentials for Clinical Trial Conduct in the Emerging World

SESSION CHAIRPERSON(S)
Nermeen Y. Varawalla, MD, PhD, MBA
Vice President, Investigator Relations, Scientific and Medical Affairs, PRA International, UK

In response to the compelling benefits of including emerging countries in global clinical trials, the demand for experienced investigative sites in these countries is escalating. In these relatively nascent clinical trial environments, investigators are important custodians of data quality and ethical integrity. Hence, nurturing capabilities at investigative sites by continual recruitment of new sites and investigators, site level training and support, and investing in sustainable relationships are key to ensure that emerging countries are able to deliver the promise they hold for global clinical development. The session will draw on the experiences of investigators, academic centers, and sponsors who have attempted to do so and explore ways to further facilitate their efforts.

Importance of Investigative Sites for Successful Clinical Trial Conduct in Emerging Countries
Nermeen Y. Varawalla, MD, PhD, MBA
Vice President, Investigator Relations, Scientific and Medical Affairs, PRA International, UK

Model for Development: INDOX, a Partnership between the University of Oxford and Investigative Sites in India
Raghib Ali, MA, MRCP
Clinical Lecturer in Clinical Pharmacology and General Medicine, University of Oxford, UK

Building Investigative Site Capacity in Emerging Countries: China Experience
Joan C. Millsaps, MSN, RN
Director, RCO International, Bristol-Myers Squibb, China

Session 162 BT - Biotechnology, CR

3:30 pm-5:00 pm LEVEL: ■

Room 105

Hot Topics in Biotechnology

SESSION CHAIRPERSON(S)
Bernard D. King, MD, MBA
CEO, Macnas Consulting International

This session will discuss late-breaking topics important to the development of biotechnology drugs and products.

Algorithm for Cell Bank Characterization
Ralf Dieter Hess, PhD, MSc
Principal Consultant, PAREXEL International, Germany

The OMICS Initiative II: Presentation of Biomarkers to the FDA for Approval
Gordon Vansant, PhD
Director, Biomarker Development, Analytical Services, Althea Technologies, Inc.

Translational Medicine
Bernard D. King, MD, MBA
CEO, Macnas Consulting International

Session 163 CDM - Clinical Data Management, CR

3:30 pm-5:00 pm LEVEL: ■

Room 258C

An Honest Look at the eClinical Process: How Biotechnology Can Learn from Best Practices Outside the Industry

SESSION CHAIRPERSON(S)
Nick Lucas, PhD
Vice President, Global Data Management, INC Research, UK

How much eClinical integration has truly taken place? The eClinical process has been talked about since the late 1990s. However, most organizations are still at the strategy or early implementation stage, and real tangible benefits have yet to be realized. Having an honest discussion about how technologies have been implemented will provide some clarity on how to reach the next level.

The Perfect EDC Implementation Project: Mission Impossible?
Patricia Stone
Consultant, Helios Consulting Services, LLC

EDC: Going, Going, Gone Global – The Changing Role of EDC in Global Trials
Mark Wren, MBA
Director, International eServices Support, Phase Forward, UK

Back to EDC Basics: Things You Need to Know to Maximize Your EDC Potential
Paula M. McHale
Director, EDC Product Management, ClinPhone

Session 164 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

3:30 pm-5:00 pm LEVEL: ■

Room 154

CMC Postapproval Management Plan

SESSION CHAIRPERSON(S)

Moheb M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA

This session will discuss FDA risk-based postapproval regulatory initiatives and will provide an update on the current status of the CMC Postapproval Management Plan (CMC-PMP) from a regulatory and an industry perspective.

Industry Perspective
Leo Lucisano, RPh
Regional Director, North America Postapproval CMC Regulatory Affairs, GlaxoSmithKline

FDA Perspective
Moheb M. Nasr, PhD, MS
Director, Office of New Drug Quality Assessment, CDER, FDA

Panel Discussion and Q & A Period

Session 165 CP 1 - Clinical Safety and Pharmacovigilance, CDM

3:30 pm-5:00 pm LEVEL: ◆

Room 156C

Electronic AE/ADR Case Reporting within and between Regions: Is It Working Well?

SESSION CHAIRPERSON(S)

Teiki Iwaoka, PhD, MS
Director, Drug Safety Outsourcing Planning, CAC Corporation, Japan

Electronic AE/ADR reporting is becoming quite popular in the three ICH regions using ICH E2B(DTD 2.1). However, it does not seem to take place across those regions. This session will focus on the eReporting status and try to uncover the reasons why industries do not want transregional eReporting. The following barriers, and possible solutions, to transregional eReporting will be discussed: regulatory difficulties and differences in E2B population requirement (necessary fields) and possible solutions, commercial safety database insufficiency, gateway difficulties (different specification and certification mechanisms), differences in data collection systems, and difficulties in dictionaries including MedDRA® and Medicinal Product Dictionaries.

Overview of eReporting: Going Well and Almost None
Teiki Iwaoka, PhD, MS
Director, Drug Safety Outsourcing Planning, CAC Corporation, Japan

Industry Perspective: eReporting from EU within and between Regions
Thomas Steinbach, DrMed, MD, PhD, FFPM
Qualified Person for Pharmacovigilance, Senior Director GSSEL, Wyeth Europa Ltd., UK

Industry Perspective: eReporting from Japan within and between Regions
Yoichi Onaka
Banyu Pharmaceutical Co., Ltd., Japan

Future of Global eReporting
Kostas Kidos, MS
Executive Director, MRL IT Regulatory, Merck & Co., Inc.

Session 166 CP 2 - Clinical Safety and Pharmacovigilance, RA

3:30 pm-5:00 pm LEVEL: ■

Room 156AB *CME credits offered*

The Development Safety Update Report (DSUR): The CIOMS VII Report and the ICH E2F Initiative

SESSION CHAIRPERSON(S)

Cindy R. Engle
Director, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline Inc.

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 stakeholders. Equally important 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.

The CIOMS VI and VII Working Groups introduced the concept of an internationally harmonized Development Safety Update Report (DSUR), and provided recommendations and a model DSUR example. An ICH Expert Working Group (EWG) was also convened to develop an ICH Guideline on DSURs. A Step 2 draft Guideline is expected to be published for consultation by the time of the DIA Annual Meeting in June 2008.

This session will summarize the work of the CIOMS VI and VII Working Groups, and provide an update on the work of the ICH E2F EWG, describing the major components of a DSUR and the rationale for their inclusion. Several problematic/controversial issues will be highlighted and the audience will have the opportunity to comment.

Existing Situation: Opportunities for Improvements
Brian Davis, MD
Consultant in Clinical Trials, Department of Health, Medicines and Healthcare products Regulatory Agency (MHRA), UK

General Principles of DSUR: Challenging Topics
Yukiko Watabe, MSc
Group Manager, Drug Safety Evaluation Department, Chugai Pharmaceutical Co., Ltd., Japan

Anticipated Challenges in Implementing DSURs: Beyond the DSUR – Future Possibilities
Linda S. Hostelley
Vice President, Worldwide Product Safety and Quality Assurance, Merck & Co., Inc.

Session 167 CR 1 - Clinical Research and Development, MA

3:30 pm-5:00 pm LEVEL: ■

Room 205B *CME and Pharmacy credits offered*

Personalized Medicine and Its Impact on Drug Development and Commercialization

SESSION CHAIRPERSON(S)

David S. Lester, PhD
Senior Vice President, Strategy and Corporate Development, Gene Express

Personalized medicine is already having an impact on drug development and commercialization; however, there is still confusion and challenges regarding how the pharmaceutical industry will integrate and implement it. This session will provide diverse opinions and insights into what is personalized medicine today, how is it being implemented, and where is it expected to be in the future. The impact of personalized medicine depends on numerous factors including validation, standardization, cost, delivery, and acceptance by the medical community. These will all be discussed and related to impacts on the pharmaceutical industry, in particular drug development and commercialization.

An Overview of the Present State and Future of Personalized Medicine
Wayne A. Rosenkrans, PhD
Scientific and Medical Strategy Director for External Scientific Affairs, Chairperson, Personalized Medicine Coalition, AstraZeneca LP

The Importance of Standardization and Validation in the Delivery of Personalized Medicine: RT–PCR as a Case Study
David S. Lester, PhD
Senior Vice President, Strategy and Corporate Development, Gene Express

Commercialization of Companion Diagnostics: Factors Affecting Test Adoption and Clinical Utility
David M. Johnston, PhD
Vice President and Chief Scientific Officer, Laboratory Corporation of America Holdings

Session 168 CR 2 - Clinical Research and Development, RD

3:30 pm-5:00 pm LEVEL: ■

Room 204AB

The Keys to Establishing Best Practices for Accelerated Study Startup

SESSION CHAIRPERSON(S)

Tim Dietlin, MBA
Vice President, Clinical Development Practice, Campbell Alliance Group, Inc.

The speed of clinical study startup affects the entire timeline of a clinical trial, and the study team has one shot at getting it right. Overall success or failure is typically determined well before startup, during protocol development and startup preparation, so proper planning and management are critical. Also, mistakes at startup will delay the study endpoint and slow patient recruitment. Planning is especially important given the ever increasing complexity of managing the huge range of activities involved in startup including technology requirements, site requirements, and general study management. Given the range of activities involved, there are countless ways to go about study startup. While each company and study has unique requirements, companies can still leverage best practices from both inside and outside their organization to ensure that each study is launched as efficiently as possible.

The Keys to Establishing Best Practices for Accelerated Study Startup
Hassan Movahhed, MS
Vice President, Clinical Development, Elan Biopharmaceuticals

Why Is Effective Startup a Critical Driver in Delivery of Multicountry Clinical Trials?
Javier Revuelta, PharmD, PhD, MBA
Senior Director, European Head of Clinical Operations, MDS Pharma Services, Spain

The Keys to Establishing Best Practices for Accelerated Study Startup
James P. Kremidas
Global Enrollment Optimization, Eli Lilly and Company

Session 169 CR 3 - Clinical Research and Development, CTM/CS

3:30 pm-5:00 pm LEVEL: ■

Room 205A *CME and Nursing credits offered*

Pediatric Trial Issues from the Global Perspective

SESSION CHAIRPERSON(S)

M. Dianne Murphy, MD
Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

The last decade has seen a dramatic increase in government involvement in advocating clinical trials to support development of therapeutic information on products that are being used in the pediatric population. Both the US and Europe now have programs which require and promote pediatric clinical trials for therapeutics. This session will focus on the practical lessons from the perspective of how pediatric trials are different and the issues one needs to address if implementing a pediatric trials program. Speakers from industry, academia, and the FDA will address both scientific and ethical issues that have arisen during pediatric trials.

Practical Experience from Pediatric Trials
Baerbel Fingerhut
Head, Study Operations, Accovion GmbH, Germany

Ethical Issues in International Pediatric Trials
Robert M. Nelson, MD, PhD
Pediatric Ethicist, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

Clinical Issues from the Academic Perspective
Barry Mangum, PharmD
Associate Clinical Professor, Clinical Pharmacology, Department of Pediatrics, Duke Clinical Research Institute

Session 170 CR 4 - Clinical Research and Development, CTM/CS

3:30 pm-5:00 pm LEVEL: ●

Room 203 *Nursing credits offered*

Patient Enrollment: Underrepresented Populations

SESSION CHAIRPERSON(S)

Haleh Sangi-Haghpeykar, PhD
Associate Professor, Department of Obstetrics and Gynecology, Baylor College of Medicine

Certain population groups, including racial and ethnic minorities, women, the poor, rural residents, and the undereducated, encounter special obstacles which reduce their relative rates of participation in clinical trials. However, valid and reliable clinical research requires a subject population representative of the general population. Additionally, many groups have special needs which, if addressed properly, can improve enrollment and retention by these groups. The speakers will discuss the design and strategies of the Eliminating Disparities in Clinical Trials (EDICT) field research project, the importance of ethnic outreach and inclusion in achieving a balanced scientific approach, as well as health and personal issues which influence women's participation in clinical trials and how these may most effectively be addressed by researchers.

Special Populations: Patient Recruitment for Women
David L. Fox
President, CEO, Praxis

Where Are We in 2008 when It Comes to Ethnic Outreach and Inclusion in Clinical Trials and Its Impact on the Pharmaceutical Industry?
David B. Millard
Associate Director, Clinical Protocol Management, Pfizer Inc

Eliminating Disparities in Clinical Trials
Haleh Sangi-Haghpeykar, PhD
Associate Professor, Department of Obstetrics and Gynecology, Baylor College of Medicine

Session 171 EC - eClinical, ST

3:30 pm-5:00 pm LEVEL: ●

Room 258B

The Realities of Implementing CDISC

SESSION CHAIRPERSON(S)

Cathleen F. Barrows, PhD
Associate Director, Statistics and Programming, GlaxoSmithKline

Speakers will describe the production of CDISC-relevant components of a submission (SDTM and analysis datasets and associated metadata), highlighting pros and cons and issues to be considered regarding the approaches used by their companies to incorporate CDISC in existing processes.

Efficiencies in the CDISC Process
Nancy A. Kohl, MBA, MT
President, Quality Data Services, Inc.

From SDTM+ to SDTM
Deborah Bauer, MS
Manager, Statistics, sanofi-aventis

Outsourcing the Implementation of SDTM and ADaM
Susan J. Kenny, PhD
Director, Statistical Programming, Inspire Pharmaceuticals

Session 172 ERS/DM 1 - Electronic Regulatory Submissions/Document Management, IT

3:30 pm-5:00 pm LEVEL: ●

Room 257AB *CME and Pharmacy credits offered*

How Goes It? Electronic Registration and Listing at FDA

SESSION CHAIRPERSON(S)

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

The agency will provide an update on the development and implementation of its electronic registration and listing initiatives, DFRM and eLIST. The session will emphasize the importance of the synergy that public hearings and problem-solving work groups provided to discuss objectives and goals, understand impacts, and work out solutions in implementation of the new rule. These presentations will attempt to provide clarity to those areas in the proposed rule that require the most significant adjustments within the government, industry or both. It will overview the unexpected and expected benefits, which will be carefully studied and documented in a benefits realization strategy. Lessons learned from planning, implementation, and stabilization of the electronic registration module, DFRM (Drug Facility Registration Module) and the electronic listing module (eLIST) will be discussed.

How Goes It? Proposed 21 CFR 207 Rule
John W. Gardner, DrPH, MD
Division Director, Compliance Risk Management and Surveillance, Office of Compliance, CDER, FDA

How Goes It? Drug Facility Registration Module (Electronic Registration)
Lakshmi K. Cherukuri, MA
Public Health Analyst, Office of Compliance, CDER, FDA

How Goes It? eLIST (Electronic Drug Listing)
David E. Mazyck
Consumer Safety Officer, Office of Compliance, CDER, FDA

Session 173 ERS/DM 2 - Electronic Regulatory Submissions/Document Management, RA

3:30 pm-5:00 pm LEVEL: ■

Room 157C

The eCTD: Lessons Learned and Practical Experience

SESSION CHAIRPERSON(S)

Patrick J. Thomas, MS
Associate Director, Regulatory Affairs, Octagon Research Solutions, Inc.

This session will give the audience a good understanding of the process for implementing the eCTD at an organization, whether it is going to be done in house or through a submission vendor. It will cover a number of key components of the eCTD, including regulatory aspects, authoring experience, outsource/insource decisions, and technology considerations.

The eCTD: One Sponsor's Experience with Outsourcing
Michael White
Manager, Regulatory Affairs Document Management (Publishing), Kyowa Pharmaceutical, Inc.

Persuasion Tools and Best Business Tactics for Implementing the eCTD Strategy
Christian A. Buckley, MBA
Associate Director, Regulatory Operations, OSI Pharmaceuticals, Inc.
David Ramroth
Director, Medical Writing, OSI Pharmaceuticals, Inc.

Metadata Management: Are Our Information Systems Ready to Address the Challenge of the eCTD?
Michael Brennan, PhD
ERIS Business Owner, Pharma IT, Centocor, Inc.

Session 174 GCP - Good Clinical Practices, RA

3:30 pm-5:00 pm LEVEL: ■

Room 206AB

Are We Doing Too Much? What We Can Learn from Compliance Plans and Audits of WHO Trials Conducted in Developing Countries

SESSION CHAIRPERSON(S)

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

What matters in a clinical trial is that patients' safety, rights, and integrity are protected. For patients in a trial, this is to be ensured through an effective informed consent process and ongoing risk-benefit assessment by all stakeholders involved. For patients who will benefit from new therapies, data integrity is the key as wrong data can lead to wrong positive or negative conclusions. However, the current approach to clinical trials begs the question of whether formal compliance aspects have taken the precedence over the fundamentals of GCP that is patient protection. In this session, we want to review how this non-negotiable goal can be achieved even under difficult conditions, how cultural circumstances impact compliance aspects, and, most importantly, how a pragmatic view can ensure GCP compliance in a true sense.

Conducting Clinical Trials in Latin America: Focus on Quality and GCP
Silvia Zieher, MD
Director, Clinical Operations; Head, Latin America Resourcing Solutions, MDS Pharma Services, Argentina

The Difference between Compliance and Integrity of a Trial: The Auditor's Experience
Allan Kloeve Johansen, DVM
Head, Pharmaceutical Development Quality Asia Pacific, Roche Products Pty Ltd., Australia

Ensuring Compliance when Conducting Trials in Areas with Limited Research and Clinical Development Infrastructure
Christine Maure, PharmD, MSc
Empowerment Technical Officer, WHO Special Programme for Research and Training in Tropical Diseases, Switzerland

Session 175 IT - Information Technology, CDM

3:30 pm-5:00 pm LEVEL: ■

Room 258A *Pharmacy credits offered*

The Implementation of Biological Sample Management and Biobanking Systems

SESSION CHAIRPERSON(S)

David A. Evans, MS
Chief Information Officer, Octagon Research Solutions, Inc.

This session examines the unique challenges of biospecimen collection and biobanking for life sciences discovery and clinical informatics. Panelists will discuss the design, development, and implementation of biobanking and sample management systems integrated with eClinical study management systems.

Chris Schad
Senior Business Analyst, Mayo Clinic

Biobanking and eClinical Systems
Brian Cass
Director, Clinical Registries, Cerner Corporation

Biobanking Systems: Vendor Selection and Functional Design Requirements
Brian J. Chadwick
Managing Partner, Lookleft Group, LLC

Session 176 MW - Medical/Scientific Writing, TR

3:30 pm-5:00 pm LEVEL: ■

Room 153C

Skills for Medical Writers: Now and in the Future

SESSION CHAIRPERSON(S)

David B. Clemow, PhD
Team Leader, Global Medical Communications, Eli Lilly and Company

This session will examine what the medical writer's job description will look like in the future, examining the skills needed to be successful, as well as the implications of the medical writer's changing job description on matching the best candidate to the job. The role of medical writer as a project manager will be discussed, including what skills and tasks are needed to be successful in this role related to document generation, review, and finalization. Evidence-, eminence-, and experience-based suggestions for improving the diagnosis of medical writing skills in the future will be presented. The role of medical writing tests in staff assessment and hiring practices will be described.

The Metamorphosis of Medical Writing: Defining the Skills Needed to Prosper in the Next Five Years
Rebecca O'Donnell, MBA, MS
Associate Director, Pfizer Inc

The Importance of Solid Project Management in Medical Writing
Neil M. Scheff
Medical Writing Project Manager, Image Solutions, Inc.

Diagnosing Medical Writing Skills: Evidence-, Eminence-, and Experience-based Suggestions
Karen L. Woolley, PhD
Associate Professor, University of Queensland; CEO, ProScribe Medical Communications, Australia

Session 177 OS - Outsourcing, CR

3:30 pm-5:00 pm LEVEL: ■

Room 205C

Meeting Clinical Research Challenges in India

SESSION CHAIRPERSON(S)

Shruti Shukla, MSc
Principal, ICRI Pvt. Ltd., India

Knowing and properly understanding the challenges of clinical research in India will help in proactively strategizing the conduct of the trial. Addressing anticipated challenges will thereby reduce cost and time factors.

Hub-site Model for Patient Recruitment: Benefits and Cost
Rashna Cama, MD
Head, Clinical Operations, IRL Research (P) Ltd., India

Meeting Clinical Research Challenges in India
Shruti Shukla, MSc
Principal, ICRI Pvt. Ltd., India

Meeting Clinical Data Management Challenges in India
Rajiv Prasad, MBA
Assistant Vice President, Life Sciences, Satyam Computer Services

Session 178 PM/FI 1 - Project Management/ Finance, CR

3:30 pm-5:00 pm LEVEL: ■

Room 102AB *Project Management units offered*

High Performance Leaders = High Performance Teams

SESSION CHAIRPERSON(S)

Karole Sutherland
Principal, Sutherland Consulting Group, Canada

Drug development projects frequently miss their targets and it is increasingly difficult to get clinical studies completed on time. Studies are more complex and project teams are geographically distributed, multidisciplinary and multicultural from both an organizational and country perspective. Expectations for project timelines, economies, and quality standards are increasing as organizational structures are changing. Given individual expertise, access to technology and sufficient corporate resources, what role can leadership play in helping trials get conducted faster, more efficiently, and with fewer missteps?

Improving Decision Making for High Performance Results
Michelle A. Littell, MBA, MS
Senior Manager, Clinical Trial Management, Genentech, Inc.

Collaborating for High Performance Results
Natalie Masterton
Clinical Project Manager, Seattle Genetics

Feedback and Acknowledgment for High Performance Results
Beth D. Harper, MBA
President, Clinical Performance Partners, Inc.

Session 179 PM/FI 2 - Project Management/ Finance, CTM/CS

3:30 pm-5:00 pm LEVEL: ■

Room 103 *Project Management units offered*

Financial Accruals for Clinical Trials: How to Generate without Excruciating Pain

SESSION CHAIRPERSON(S)

Chris Chan, MBA
Associate Director, Product Development Finance, Genentech, Inc.

Learn some user-friendly methodologies for generating financial accrued expenses/liabilities for clinical trials, particularly for expenses related to CROs and investigator grants.

Financial Accruals for Clinical Trials: Alternative Viewpoint 1
Jim Shahbazian
FP&A Manager, Development, Exelixis, Inc.

Financial Accruals for Clinical Trials: Alternative Viewpoint 2
Sarah V. Morrone
Director, Clinical Operations, CV Therapeutics, Inc.

Financial Accruals for Clinical Trials: Alternative Viewpoint 3
Chris Chan, MBA
Associate Director, Product Development Finance, Genentech, Inc.

Session 180 PP - Public Policy/Law, RA

3:30 pm-5:00 pm LEVEL: ●

Room 160AB *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 181 RA 1 - Regulatory Affairs, RD

3:30 pm-5:00 pm LEVEL: ■

Room 253B

Current Review and Assessment Models for Approval of New Medicines in Emerging Markets: Differences and Similarities across 13 Countries in Latin America, Middle East, Africa, and Southeast Asia

SESSION CHAIRPERSON(S)

Professor Stuart Walker, PhD
Vice President and Founder, CMR International Institute for Regulatory Science, UK

Pharmaceutical companies are increasingly focusing on global drug development and looking at the rapidly expanding emerging markets in Asia Pacific, Latin America, Africa and the Middle East. The regulatory agencies in these markets are evolving their review process for new medicines but are at different stages of development. The review of new medicines have the same basic components, however, countries differ in their pre-application requirements, the scientific assessment, the use of external experts, the way questions are raised and what is required before authorization can be given. As companies seek to enter into new, expanding markets they need to anticipate differing review practices and avoid unexpected regulatory hurdles. This session will focus on the different assessment models and processes across agencies. It will identify the common factors that promote and impede the efficiency and effectiveness of agencies in the emerging markets, provide an opportunity to discuss and debate the role of evidence of registration from other countries as part of a risk stratification process, and what potential future directions review models could take at both the country and regional levels.

Overview of Similarities and Differences in Models of Regulatory Review and Types of Assessments for New Medicines across 13 Emerging Market Agencies in Latin America, Southeast Asia, Middle East, and Africa
Neil McAuslane, PhD, MSc
Director, CMR International Institute for Regulatory Science, UK

Evidence of Registration in Other Countries – Regional Global Collaboration as Part of an Appropriate Risk-based Review: An Agency Perspective
Lucky Surjadi Slamet, MSc
Deputy for Therapeutic Products, Narcotics, Psychotropic and Addictive Substance Control, National Agency for Drug and Food Control, The Republic of Indonesia

How Could Models and Systems of Regulatory Review Evolve in the Future to Best Utilize Regional and Global Resources and Expertise without Compromising Local Benefit-risk Considerations?
David B. Jefferys, MD, FRCPC
Vice President, Global Regulatory, Eisai Europe Ltd., UK

Session 182 RA 2 - Regulatory Affairs, PP

3:30 pm-5:00 pm LEVEL: ●

Room 253C

US-EU Agreement: Administrative Regulatory Simplification – The Next Phase?

SESSION CHAIRPERSON(S)

Marie A. Dray
President, International Regulatory Affairs Group

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

Since the establishment of the US-EU Confidential Arrangements to Exchange Information in 2004, reports on progress with exchanges of personnel and documents have been provided publicly via DIA Annual Meetings. This session, the fifth in this series, will update the audience, to the extent not limited by confidentiality of sponsors' applications, on the current status of bilateral discussions under this Arrangement. In addition, speakers will present the latest information on the newest US-EU dialogue, being conducted under the auspices of the Transatlantic Economic Integration project, whereby parties are implementing a roadmap for US-EU regulatory cooperation and transparency, to address simplification of regulatory processes.

FDA Perspective
Murray M. Lumpkin, MD
Deputy Commissioner, International and Special Programs, Office of the Commissioner, FDA

EMEA Perspective
Thomas Lönngren, Pharm, MSc
Executive Director, European Medicines Agency, European Union

Industry Perspective
Mathias Hukkelhoven, PhD
Senior Vice President, Head, Global Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

Session 183 RA 3 - Regulatory Affairs, RD

3:30 pm-5:00 pm LEVEL: ■

Room 254AB *CME and Pharmacy credits offered*

Dispute Resolution with the FDA: Looking for Win-Win Results

SESSION CHAIRPERSON(S)

Steven F. Hoff, PhD, RPh
President, Hoff Consulting LLC

This session will provide a clear understanding of the formal dispute resolution process at FDA and how best to utilize that process. Discussion will identify some of the best practices for emerging successfully from the process.

Dispute Resolution: CDER Perspective
Kim Colangelo
Associate Director for Regulatory Affairs, Office of New Drugs, CDER, FDA

Dispute Resolution: CBER Perspective
Howard Balick, JD
Assistant Ombudsman, Office of the Director, CBER, FDA

Dispute Resolution: An Industry Perspective
Kathryn E. Broderick, PharmD, RAC
Associate Director, US Regulatory Affairs, Eli Lilly and Company

Session 184 RA 4 - Regulatory Affairs, CP

3:30 pm-5:00 pm LEVEL: ■

Room 252AB

The Tactical and Practical Side of Quality Systems: How FDA Implementation is Helping Our Customers

SESSION CHAIRPERSON(S)

Lana L. Pauls, MPH
Director, Quality Management Staff, Office of the Center Director, CDER, FDA

The FDA has taken many steps to advocate quality systems for the pharmaceutical industry and implement quality systems throughout the various Centers. CDER is using a quality systems approach for enhancing drug safety, and improving the drug review process. In addition, CVM is using similar, yet different measures to improve its new animal drug review process. The approaches will be outlined along with their impact on both internal and external customers. An industry perspective summarizing the benefits they are experiencing will also be included.

David J. Cummings
Interdisciplinary Scientist, Office of Phamaceutical Science, CDER, FDA

Katherine Weld, PhD
Regulatory Policy Analyst, CVM, FDA

Practical Experience in CDER
Lana L. Pauls, MPH
Director, Quality Management Staff, Office of the Center Director, CDER, FDA

Session 185 RA 5 - Regulatory Affairs, RD

3:30 pm-5:00 pm LEVEL: ■

Room 251

Proactive Risk Management Planning during Drug Development

SESSION CHAIRPERSON(S)

Evelyn M. Rodriguez, MD, MPH, FAAP, FACE, FISPE
Head, Global Pharmacoepidemiology, Bayer HealthCare Pharmaceuticals, Inc.

This session will review the changes in the global regulatory landscape and share lessons learned in the development of risk management plans. The session will demonstrate strategies used in developing proactive RMPs during drug development that are practical, feasible, and pragmatic.

Management of Cardiovascular Risk Potential for a New Oral Contraceptive
Maureen Cronin
Head, Global Medical Affairs, Women's Healthcare, Bayer Schering Pharma AG, Germany

Session 186 RA 6 - Regulatory Affairs

3:30 pm-5:00 pm LEVEL: ■

Room 256

Updates in CDE Drug Reviews and GLP Regulations

SESSION CHAIRPERSON(S)

Yiman Zheng
Vice President, Medical and Regulatory Affairs, Eli Lilly China

Lili Cao
Division Director, China Center for Pharmaceutical International Exchange, SFDA, China

The Center for Drug Evaluation (CDE) is responsible for drug reviews in China. CDE has established technical review process and related guidelines for reviewers to perform drug reviews, and ensure that drugs are safe and effective. With the establishment and implementation of GLP regulations in new drug development in China, the SFDA has gradually requested the GLP compliance in new drug registration in China. The SFDA published the GLP regulation in 1999, and revised it in 2003. In this session, speakers from the SFDA and CDE will provide updates on these two topics.

CDE Review: Process and Technical Guidelines
Lei Zhang, MD
Director, Department of Evaluation II, SFDA, Center for Drug Evaluation, China

GLP Regulations and Status in China
Jin-ju Li
Director, Division of Drug Research Supervision, SFDA, China

Session 187 RA 7 - Regulatory Affairs, CP

3:30 pm-5:00 pm LEVEL: ●

Room 253A

European Innovative Medicines Initiative: Up and Running!

SESSION CHAIRPERSON(S)

Irene Norstedt
Head of Sector, The Innovative Medicines Initiative, European Commission, Belgium

This session will describe the current status of the Innovative Medicines Initiative (IMI), a two billion euro European-scale initiative that will support the development of new knowledge, tools and methods so that better and safer medicines can be made available more quickly.

European Commission Perspective
Irene Norstedt
Head of Sector, The Innovative Medicines Initiative, European Commission, Belgium

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

IMI: An Industry Perspective
Damian O'Connell
Executive Director, Pfizer Ltd., UK

Session 188 RD - R&D Strategy, CR

3:30 pm-5:00 pm LEVEL: ■

Room 104C

Public-private Partnership on Clinical Research 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 infrastructure for clinical trials has become one of the top priorities in Asia with the advance of R&D for biotechnology and medicine. The nations in the Asia-Pacific region such as China, Japan, Korea, and Taiwan have an increasing investment in the establishment of centers of excellence for clinical trials facilitating the development of clinical research. National programs in these countries have supported interdisciplinary research funding and infrastructure setup for clinical research. Public-private partnership in clinical research in the Asia-Pacific region has been adapted as one strategy to facilitate the R&D of biotechnology and medicine. This session is devoted to the discussion and comparison of the recent advancement of these public-private partnerships for clinical research in the Asia-Pacific region. Experts from this region will share their insights on the topic. A comparison of development strategy among these Asian countries will be held in the panel discussion.

The Spirit of Partnership of Public and Private Sectors in APEC
Oliver Yoa-Pu Hu, PhD
Dean, Research and Development, National Defense Medical Center, Taiwan

Public-private Partnership on the Clinical Research in Japan
Yoshikazu Hayashi
Director, Office of Clinical Trial Promotion, Research and Development Division, Ministry of Health, Labour and Welfare (MHLW), Japan

Pooling Public and Private Sector Service Providers: An Australian Model
Mario Pennisi
CEO, Queensland Clinical Trials Network, Australia

Session 189 ST - Statistics, CR

3:30 pm-5:00 pm LEVEL: ■

Room 259AB

Selecting the Optimal Sample Size: Initial Realism or Adaptive Re-estimation

SESSION CHAIRPERSON(S)

Sonja McKinlay, PhD
President, New England Research Institutes, Inc.

Selection of sample sizes for clinical trials and, more recently, for registries, is a major design consideration that greatly affects study duration and/or cost. Until recently, sample size estimation has been an ad hoc iterative process, within cost or recruitment limitations, until a cost-effective solution is reached. This session focuses on available approaches to sample size estimation and assesses their relative advantages in providing more systematic, planned, cost-effective design solutions.

Adaptive Design Pros and Cons
Stuart J. Pocock, PhD, MSc
Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, UK

Simulations for Sample Size Calculations
Sonja McKinlay
President, New England Research Institutes, Inc.

Sample Sizes for Registries
Janet Wittes, PhD
President, Statistics Collaborative, Inc.

Session 190 TR - Training, CR

3:30 pm-5:00 pm LEVEL: ■

Room 157AB

Postgraduation in Clinical Research: Brazil

SESSION CHAIRPERSON(S)

Charles Schmidt, MD, PhD
Director of Operations for Latin America, PRA International, Brazil

A full program for postgraduation in clinical research in Brazil will be discussed, specifically regarding how to implement and conduct it.

Achievements and Hurdles in Development of a Clinical Trial Postgraduation Course: A Brazilian Experience
Pedro Garbes-Netto, MD, MSc
Executive Director, Latin American Group on Clinical Research in Oncology (GLICO), Brazil

The Clinical Research Training Postgraduation Program of Santa Casa Medical School of São Paulo: Can We Replicate It in Other South American Countries?
Charles Schmidt, MD, PhD
Director of Operations for Latin America, PRA International, Brazil

Clinical Research Training Challenges in South America: What Has Been Achieved and What Needs to Be Improved
Margarita T. Eiletz, PhD
Director, Ethics & Excellence Clinical Research Consultants, Argentina

5:00 pm **END OF MONDAY SESSIONS**

5:00 pm-6:00 pm **RECEPTION – Exhibit Hall**

7:00 am-5:30 pm **SPEAKER REGISTRATION**
North Lobby, Level 1, BCEC

7:00 am-5:30 pm **ATTENDEE REGISTRATION**
North Lobby, Level 1, BCEC

7:00 am-5:30 pm **EXHIBITOR REGISTRATION**
North Lobby, Level 1, BCEC

7:15 am-8:00 am **CONTINENTAL BREAKFAST**
North Lobby, Level 1, BCEC

9:00 am-5:30 pm **EXHIBITS OPEN (Extended Luncheon Hours)**
Exhibit Halls A & B, Exhibit Hall Level, BCEC

9:30 am-5:30 pm **PROFESSIONAL POSTER SESSION**
North Lobby Entrance to Exhibit Hall, BCEC

Session 201 AD - Advertising, RA

8:00 am-9:30 am LEVEL: ■

Room 153AB *Pharmacy credits offered*

International Promotional Issues

SESSION CHAIRPERSON(S)

Minnie Baylor-Henry, JD, RPh
Vice President, Global Regulatory Affairs-OTC, McNeil Consumer Healthcare

Today, the promotional environment is global. Activities in the US are influencing the considerations in other parts of the world and vice versa. Promoting through the Internet has dramatically changed how we define borders. In addition, DTC continues to be an issue not just in the US, but also in Europe and Asia. This highly interactive session will examine some of the global policy issues that continue to shape how advertising is regulated today and what the influencing factors will be in the future.

Changing Environment in the EU
Scott D. Myers
Vice President, Regional General Manager, Europe Region I, UCB Pharma S.A., Belgium

Gordon Desveaux, FACP
Executive Vice President and Director of Strategic Planning, Anderson DDB, Canada

Asia Pacific
Wei Ping Li
Director, Regulatory Affairs, Xian Janssen Pharmaceuticals Ltd., China

Session 202 AHC/IS - Academic Health Centers/ Investigative Sites, CP, CR, GCP, PP, RA

8:00 am-9:30 am LEVEL: ■

Room 210ABC

Multitrack Plenary

The Impact of FDAAA on Drug Safety

SESSION CHAIRPERSON(S)

Stanley A. Edlavitch, PhD, MA
Professor, Epidemiology and Director, Graduate Training, School of Medicine, University of Missouri Kansas City

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

On September 27, 2007, President Bush signed the Food and Drug Administration Amendments Act of 2007 (FDAAA) into law. The law includes over 200 provisions and represents a significant addition to FDA authority across the spectrum of products regulated by the agency. Included are the Prescription Drug User Fee Amendments of 2007, the Medical Device User Fee Amendments of 2007, the Pediatric Medical Device Safety and Improvement Act of 2007, the Pediatric Research Equity Act of 2007, and the Best Pharmaceuticals for Children Act of 2007. In addition, FDAAA addresses conflicts of interest and requires the establishment of expanded clinical trial databases by NIH in collaboration with FDA. It also permits FDA to require postapproval studies and clinical trials, risk evaluation and mitigation strategies (REMS) for certain products, and prereview of direct-to-consumer advertisements. The new law also expands the responsibilities of food manufacturers with regard to potential food safety problems and establishes quality standards and recall procedures for pet foods. It also establishes the Reagan-Udall Foundation to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. This session will address the implementation of the drug safety aspects of the FDAAA. Speakers from US and European regulatory agencies, the Reagan-Udall Foundation, PhRMA, and other organizations will discuss their goals and experiences with implementation of this new legislation during its 9 months since passage and whether the legislation will help to meet the important goal of insuring that drugs remain safe throughout their life cycle.

Panelists

RADM Sandra L. Kweder, MD
Rear Admiral, US Public Health Service; Deputy Director, Office of New Drugs, CDER, FDA

Mark B. McClellan, MD, PhD
Director, Engelberg Center for Health Care Reform; Senior Fellow, Economic Studies; Leonard D. Schaeffer Director's Chair in Health Policy, Brookings Institute

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

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

Hugh H. Tilson, DrPH, MD, MPH, FACPM, FISPE
Adjunct Professor, School of Public Health, UNC Public Health Leadership Program, University of North Carolina

Session 203 CDM - Clinical Data Management, CR

8:00 am-9:30 am LEVEL: ■

Room 258C

STARDATE 2013: Visions of the Life of a Data Manager

SESSION CHAIRPERSON(S)

Joseph S. Anderson
Principal Associate, Waife & Associates, Inc.

This session will envision the daily life of a data manager in the year 2013, a mere five years from today. Three sponsor/industry speakers will each present his/her own vision of that future life. The visions will be explicit and concrete, involving all aspects of a data manager's environment: people, roles, trials, tools, and process. Come see your future portrayed in this session and get yourself prepared for STARDATE 2013!

Where No One Has Gone Before: The New Data Manager
Joseph S. Anderson
Principal Associate, Waife & Associates, Inc.

Using Metrics to Picture the Future of the Data Manager
Detlef Nehrdich, MSc
Director, Statistics, Data Management and EDC Project Office, Europe, Abbott GmbH & Co., KG, Germany

Clinical Data Management Prepares for the Future
Paul Clarkson
Director, Clinical Data Management, Genentech, Inc.

CP - Clinical Safety and Pharmacovigilance & CR - Clinical Research and Development, AHC/IS, GCP, PP, RA

8:00 am-9:30 am LEVEL: ■

Room 210ABC

Multitrack Plenary
The Impact of FDAAA on Drug Safety

See **Session 202 – AHC** on page 59 for a complete session description.

Session 204 CR 1 - Clinical Research and Development, PM/FI

8:00 am-9:30 am LEVEL: ■

Room 205A

Navigating the Bumps in the Road on Partnered Clinical Trials

SESSION CHAIRPERSON(S)
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group

In today's drug development paradigm, working collaboratively within partnerships and alliances is a skill that is becoming important for many clinical development management teams. Often the political and cultural environments and usually the standard operating processes are extremely different within the two or more companies that co-exist within these development programs. Defining and aligning a collaborative way of working within the clinical team can be a key factor in the ultimate success of the relationship as well as the development program. This session will look at the relationships in detail, and through the experiences of team members from both large and small companies, we will explore and define best practices for establishing the blended team and executing the program.

Partnerships across the Seas: Execution of US/Japanese Co-development Programs
Gregory E. Dombal
Director of Regulatory Affairs, ArQule

A Tale of Two Companies: Developing and Executing a Successful Joint Clinical Program – The Small Biotech Perspective
Monette M. Cotreau, PhD
Director, Clinical Pharmacology, Clinical Research, AVEO Pharmaceuticals

Session 205 CR 2 - Clinical Research and Development, AHC/IS

8:00 am-9:30 am LEVEL: ●

Room 205B *Nursing credits offered*

Patient Recruitment Strategies and Sites' Perspectives

SESSION CHAIRPERSON(S)
David L. Fox
President, CEO, Praxis

Patient recruitment is a mixture of scientific and creative processes. This session will highlight several case studies to provide a step-by-step analysis of the recruitment campaign, including initial study protocol and feasibility assessment, target audience research demographics, media habits, centralized recruitment strategy, and tactics used to develop an effective communications plan to reach and motivate the patient or caregiver to respond. Key emerging trends and statistics in the digital world and how to integrate these new online strategies into the recruitment campaign will also be presented. From a site's perspective, the latest results of a recent survey of study coordinators reveal their opinions and perceptions on centralized recruitment, external service providers, and site support needed.

Media-buying Strategy for Effective Patient Recruitment Campaigns
David L. Fox
President, CEO, Praxis

Switching On Patient Recruitment with Digital Strategies
John D. McAnulty
Senior Vice President and Partner, Fleishman-Hillard Clinical Trials Division

How Research Sites View Centralized Patient Recruitment and the Companies that Conduct Them
Elizabeth A. Moench
President and CEO, MediciGLOBAL, Inc.

Session 206 CTM/CS - Clinical Trial Management/ Clinical Supplies, CR

8:00 am-9:30 am LEVEL: ■

Room 204AB

Becoming a Sponsor of Choice for Clinical Investigators

SESSION CHAIRPERSON(S)
Gary Tyson
Senior Vice President, Clinical Development Practice, Campbell Alliance Group, Inc.

With so many clinical trials competing for the same patients, a pharmaceutical or biotechnology company must do everything it can to consistently be the sponsor with which sites prefer to work — the sponsor of choice. Being the sponsor of choice involves understanding what investigators value most. This panel of experts will provide delegates with an in-depth understanding of the key factors driving investigator decisions. We will then dive into tactics for identifying a company's strengths and weaknesses in these key areas and developing a robust strategy for improving a company's relationships with the sites and investigators it values most. This session will provide clinical development professionals with the tools required to get ahead in the increasingly competitive race for trial participants.

Becoming a Sponsor of Choice for Clinical Investigators
Gary Tyson
Senior Vice President, Clinical Development Practice, Campbell Alliance Group, Inc.

Alternative Investigator Site Recruitment Strategies
Randall Holzberger, MS
Clinical Research Assistant, Covance

Finding Top Performing Investigators: A Considered Approach
Jeffrey S. Painter, MBA
Associate Vice President, Client Services, etrials

Clinical Study Sites and Sponsor Relationships: Building Stronger Partnerships through Mutual Understanding
Andrew Lee, MA
Vice President, Clinical Study Operations, Pfizer Global R&D

Session 207 EC - eClinical, RD

8:00 am-9:30 am LEVEL: ●

Room 258B *Nursing credits offered*

Applying ePRO in Special Populations

SESSION CHAIRPERSON(S)

Saul Shiffman, PhD
Founder and Chief Science Officer, invivodata, inc.

Electronic methods for collecting patient-reported outcomes (ePRO) data – using platforms such as personal digital assistants, interactive voice response, and others – are being widely applied in clinical trials. However, clinical investigators often have concerns about the applicability of ePRO technologies and methodologies to certain patient populations that are perceived as having special needs or barriers to using ePRO methods. Examples of concerns include low computer literacy among the elderly, severe dysfunction as a result of illness (eg, extreme pain), impaired sensory function (eg, vision and hearing), or motor function (eg, fine motor control) due to age or disease (eg, Parkinson's disease), and low energy and poor performance among populations with depression or other psychiatric conditions. This session will help participants analyze such issues, by presenting research data, case study experience, and a framework for addressing such concerns. Participants will learn how to evaluate the population needs and issues, how to design ePRO solutions to address special needs, how to assess the suitability of the solution to the population, and how to document this process for regulatory review.

Use of eDiary in Elderly Populations
David S. Reasner, PhD
Senior Vice President, Biostatistics, Data Management, and Health Outcomes, Sepracor Inc.

Use of IVRs in Populations with Psychopathology
James Mundt, PhD
Vice President, Research and Development, Healthcare Technology Systems, Inc.

Use of eDiary in Populations with Chronic Pain
Hazel Collie
Global Head, Project Management, Gruenenthal GmbH, Germany

Session 208 ERS/DM - Electronic Regulatory Submissions/Document Management, CDM

8:00 am-9:30 am LEVEL: ●

Room 257AB

IND in eCTD Format: Challenges and Successes

SESSION CHAIRPERSON(S)

Jeanie Kwon
Director, Regulatory Submissions, Image Solutions, Inc.

This session will focus on experiences with the submission of INDs in the eCTD format, starting with the decision process to move from paper to electronic, preparation of granular components, mapping IND documents to the eCTD structure, life-cycle management of the IND in eCTD, and the benefits and challenges of this submission format.

The Process for Our Success: An eCTD IND Case Study
Carol Bailey, MS, RAC
Associate Director, Regulatory Operations, ZymoGenetics, Inc.

IND in eCTD Format: eCTD on a Shoestring
Monte Levinson
Director, Regulatory Operations, ZymoGenetics, Inc.

Case Study: An Outsourced Approach to Our INDs in eCTD Format …
Kristina L. Knights
Senior Manager, Regulatory Affairs, Momenta Pharmaceuticals, Inc.

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

8:00 am-9:30 am LEVEL: ■

Room 210ABC

Multitrack Plenary
The Impact of FDAAA on Drug Safety

See **Session 202 – AHC** on page 59 for a complete session description.

Session 209 IT - Information Technology, OS

8:00 am-9:30 am LEVEL: ●

Room 258A

Negotiating IT Contracts: Speeding Up the Process and Finding Common Ground

SESSION CHAIRPERSON(S)

D. Ari Buchler, JD
Senior Vice President, General Counsel, Phase Forward

Biopharmaceutical companies are actively investing in technology to speed up pharmaceutical and related product development. However, failures in the contracting process are often obstacles that can actually delay or even prevent the technology from getting implemented.

IT contracts in the context of pharmaceutical and related product development come in many shapes, sizes and flavors. These contracts can cover a variety of services, software, hardware or any combination thereof. Vendors and customers bring many competing interests to the negotiating table. These include, for example, a desire for a speedy negotiation, contrasted with a desire to make contracts very detailed and specific. The customer's desire for an offering that meets its own specific requirements is contrasted with a vendor's desire for an offering that can meet the needs of the broadest set of customers as possible. CRO's are also a very important participant in this process, often wearing the hats of both a customer and a vendor at the same time.

This session will provide an overview of the general views that customers, vendors and CRO's bring to the negotiating table. One-sided views will be offered by each side, followed by a discussion of ways in which these gaps are reduced through the negotiating process.

Legal Perspective
Allan Weeks, Esq., JD
Partner, Law Office of Allan Page Weeks

CRO Perspective
Cynthia Grubbs
Vice President, Procurement, PAREXEL International

Session 210 MC - Medical Communications, TR

8:00 am-9:30 am LEVEL: ■

Room 253B *Pharmacy credits offered*

The Lady and the Tiger of Position Choices and Training Keys for Position Success

SESSION CHAIRPERSON(S)

Robin L. Winter-Sperry, MD
President and CEO, Scientific Advantage, LLC; MSL Advantage, LLC

MSLs, medical affairs, and call center associates' success as industry professionals relies on their ability to translate their knowledge into actionable activities and become field-based clinical resources for local thought leaders in health care in their area of expertise. Companies that want to maximize the effectiveness of their MSLs, medical affairs, and call center associates realize they are an enormous investment in terms of their depth of expertise and employment costs. For companies to fully reap the benefits of the investment

in these individuals, proper training, team, and career development is essential. The session will cover the need to evaluate baseline competencies, core skills, and career paths that will not only train them for their position, but allow them to grow and develop within their roles and future positions. This session will focus, with a scientific background, on the many options that are open but adequate and focused training must be tailored to the specific learning needs of this type of audience to maximize success in their roles – scientific background alone is not enough.

Door One: Call Centers on the Front Lines – Specialized Competency-based Training
Cathryn L. Anderson
Senior Medical Affairs Director, Shire Pharmaceuticals

Door Two: Becoming a Medical Science Liaison (MSL) – Specialized Training to Become a Field-based Clinical Resource
Robin L. Winter-Sperry, MD
President and CEO, Scientific Advantage, LLC; MSL Advantage, LLC

Door Three: Skills and Training for the Senior Scientist/Medical Affairs Path
Linda Carlson, PhD, MBA
Vice President, Medical Operations, EMD Serono, Inc.

Session 211 OS - Outsourcing, CDM

8:00 am-9:30 am LEVEL: ●

Room 205C

Streamline Your Language Outsourcing

SESSION CHAIRPERSON(S)
Jessica Eker
Vice President, Global Life Sciences Group, TransPerfect Translations

Because many pharmaceuticals are now made up of hundreds of operating companies that perform clinical trials all over the world, multilingual communication has become vital to conducting business in the industry. Learn why several of the world's major pharmaceutical enterprises choose to consolidate their language outsourcing from as many as hundreds of different providers to just a handful of select language providers.

Best Practices for Centralizing Your Translations
Patrick Hughes
Senior Vice President, Strategic Business Development, Good Products, LLC and Exco InTouch Inc.

The Decision-making Process: A Case Study
Scott W. Dixon
Vice President, Sales and Marketing, Maaguz, LLC

Is Centralization Right for My Organization?
Brooke Christian, MA, MS
Senior Vice President, Global Sales, TransPerfect Translations

Session 212 PM/FI 1 - Project Management/ Finance, RD

8:00 am-9:30 am LEVEL: ●

Room 102AB *Project Management units offered*

Biomarkers in Drug Development: What a Project Manager Needs to Know and Do to Enhance Project Value

SESSION CHAIRPERSON(S)
Siddhartha Roychoudhury, PhD
Associate Director, Project Management and Planning, Centocor R&D

While biomarkers can enhance the value of a drug development program in a variety of ways, for a project manager, they can add significant complexity to project planning, scenario analysis, risk assessment/management, and go/no go recommendations. This session will focus on helping project managers gain a fundamental understanding of biomarkers and identify opportunities and challenges involved in incorporating biomarkers into a drug development program using real-life examples and best practice recommendations.

Biomarkers and Surrogate Endpoints: Definitions, Background, and Validation
Lisa A. Jenkins, PhD
Regulatory Group Leader, Kendle International

Cross-project Biomarker Initiatives in Oncology: Successful Project Management Practices
Sandra J. Zeckel, RPh, PMP
Chief Operating Officer, Oncology Transition Team, Eli Lilly and Company

Managing Complex Biomarker Logistics in a Phase 2 Oncology Trial: 10 Sites, 4 PD Endpoints, 3 Academic Labs
Michael P. Sterba
Project Manager, Rigel, Inc.

Session 213 PM/FI 2 - Project Management/ Finance, RD

8:00 am-9:30 am LEVEL: ■

Room 103 *Project Management units offered*

Life Science Project Management Is Dead: A New (Old) Model for the Future

SESSION CHAIRPERSON(S)
Randy Dunson, MBA, PMP
President, US Operations, Harpum Consulting Ltd.

Where do you think pharmaceutical project management is heading? Is it shifting away from command and control – if you were ever lucky enough to have achieved that level of influence – or getting more deeply established as a core guarantor of value delivery? What do you think is on the radar for pharmaceutical project management of tomorrow? The old co-led (supposedly) line over project model has failed. The time is past for arcane, power-driven arguments for not adopting practices that have been long established and successful in other high technology R&D sectors. Have you heard people in your organization demand to be shown the ROI on implementing project management? The purpose of this session is to explore practices that have been long established and successful in other high technology R&D sectors and how they must be adopted by our sector so that we better understand the strategic direction and impacts we face. Currently, project management practices in our industry vary considerably across sectors, and between (and within) companies. A common paradigm for the industry to follow is way overdue.

The Role of Project Management Using the New Model for the Future
Peter Harpum, MSc
Director, Harpum Consulting Ltd., UK

Value Delivery Using Multidimensional Schedule, Resources, and Quality Trade-offs
Janet S. Lewis, MBA, PMP
Director, Global Project and Portfolio Management, GlaxoSmithKline

Bringing Pharma Project Management Out of the Dark Ages: Example of Risk Management
Jann A. Nielsen, PhD
Senior Director, Project Management, Wyeth Research

Session 214 PM/FI 3 - Project Management/ Finance, CR

8:00 am-9:30 am LEVEL: ●

Room 105 *Project Management units offered*

Global Communication for Effective Drug Development in Japan: How Westerners Should Communicate with the Japanese for the Best Drug Development in Japan

SESSION CHAIRPERSON(S)

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

This session addresses communication between Westerners and Japanese for effective drug development in Japan. This is accomplished by introducing Japanese cultural/custom background and differences on working practice and way of thinking, as well as the regulatory infrastructure in the West and Japan which has been well harmonized over the last few decades.

Effective Communication in Project Management: Experience in the US and Japan
Hideo Yoshida
Director, Project and Resource Management for Japan, Bristol-Myers Squibb Company

Working with Japanese Colleagues: A View from the Western Side
Robert R. Fike, PhD
Assistant Vice President, Regulatory Affairs Japan, Wyeth Research

Effective Global Drug Development Teams: Good Communications Is the Key
Patrick Floody
Executive Director, Development Operations, Pfizer Japan, Inc., Japan

Session 215 PM/FI 4 - Project Management/ Finance, CTM/CS

8:00 am-9:30 am LEVEL: ■

Room 104AB *Project Management units offered*

Doing the Project Planning for Large Multinational Clinical Trials

SESSION CHAIRPERSON(S)

Diego Martin Glancszpigel, MEd
General Manager and Director, PAREXEL, Argentina

Doing the project plan of a global clinical trial program is the most difficult and critical aspect for all project managers. Key elements of a successful planning will be discussed during this session.

Planning the Startup of Multinational Clinical Trials
John A. Jermano, BSN, MPH
Senior Vice President, Clinical Operations, Cogentus Pharmaceuticals, Inc.

Best Practices in the Planning of Global Studies
Dawn F. Eng, BSN, RN
Associate Director, Novartis Pharmaceuticals Corporation

Key Aspects to Be Considered when Planning and Executing Global Clinical Trials
Diego Martin Glancszpigel, MEd
General Manager and Director, PAREXEL, Argentina

Session 216 PP - Public Policy/Law, RA

8:00 am-9:30 am LEVEL: ●

Room 160AB

Incentives and Rewards for Innovation in Pharmaceutical Development

SESSION CHAIRPERSON(S)

Harrie Seeverens, DrMed
Internist, Ministry of Health, Welfare and Sport, Netherlands

In this session, incentives and rewards for innovation in pharmaceutical development will be discussed. The legal framework regarding pediatric medicines in the US and in the European Community will be compared. Patent royalty tax schemes as an incentive will be discussed and a model will be presented to demonstrate the effects a new European law will have on expenditures on medicinal products. This new law, a so-called regulation, will also bring benefits but these may be difficult to quantify. Nevertheless, there will be benefits for children, but parents and attending pediatricians will also feel more confident and/or reassured.

Comparing the US and EC Statutory Conditions for the Pediatric Obligation and Statutory Requirements for the Pediatric Exclusivity
Geneviève Michaux, LLM
Special Counsel, Covington & Burling, Belgium

Experience with Submitting a Pediatric Investigation Plan at the Pediatric Committee/EMEA
Hans-Juergen Kuehnel, DrMed
Medical Director, medac GmbH, Germany

Estimated Expenditures on Medicinal Products Following the Six-months SPC Extension in Europe
Harrie Seeverens, DrMed
Internist, Ministry of Health, Welfare and Sport, Netherlands

PP - Public Policy/Law & RA - Regulatory Affairs, AHC/IS, CP, CR, GCP

8:00 am-9:30 am LEVEL: ■

Room 210ABC

Multitrack Plenary
The Impact of FDAAA on Drug Safety

See **Session 202 – AHC** on page 59 for a complete session description.

Session 217 RA 1 - Regulatory Affairs, RD

8:00 am-9:30 am LEVEL: ●

Room 256

Applying for Drug Approvals in China: A Mystical Opportunity

SESSION CHAIRPERSON(S)

Eileen A. Bedell, MPH
Director, Regulatory Affairs, Genzyme Corporation

Most, if not all, western pharmaceutical companies regard China as an emerging and promising market. However, this regard is often accompanied by the perception that the review by the Chinese authority, the State Food and Drug Administration (SFDA), is time consuming and mystical. This session will try to address these concerns from multiple perspectives – the pragmatic nature of the Chinese culture, the historical and practical reasons for the SFDA regulations, and lessons that professionals in the western pharmaceutical companies learned from submissions in China.

Comparison of Drug Approval Processes by the SFDA and the FDA
Bing Ren, PhD
Principal Associate, Genzyme Corporation

Unique Challenges in Biomarker Development in China
Yiyou Chen, PhD
Chief Scientific Officer, Crown Bioscience Inc.

Practical Guidances on Conducting Clinical Trials in China
Jenny Zhang, MD, MHA
Senior Director, Business Development - US, Tigermed Consulting Ltd.

Session 218 RA 2 - Regulatory Affairs, RD

8:00 am-9:30 am LEVEL: ●

Room 253A

Innovative Approval Paths Are Needed for Products that Treat Rare Diseases

SESSION CHAIRPERSON(S)

Allen E. Cato, MD
CEO, Cato Research

Therapies targeting rare diseases merit special consideration by regulatory agencies. Some diseases are so rare, sporadic or have such limited therapeutic time windows that it is not feasible, or is too costly, to collect the usual volume of clinical data. This session will focus on discussion of innovative potential approval strategies for products targeting rare, sporadic pediatric diseases. The discussion will include the Animal Rule, surrogate endpoints, and their potential applicability to bioterrorism-related products.

Industry-FDA Collaborations that Balance Regulatory and Practical Considerations in the Development of Orphan Products
Ted Murphy, PhD
Vice President, Research and Development, BioMarck Pharmaceuticals, Ltd.

The Proposed Manimal Rule
Allen E. Cato, MD
CEO, Cato Research

Session 219 RD - R&D Strategy, CR

8:00 am-9:30 am LEVEL: ◆

Room 162AB

Biotechnology R&D in Developing Countries: A Public-private Partnership between a Cancer Institute, a Brazilian Entrepreneurship, and Health Institutes

SESSION CHAIRPERSON(S)

Laura Luchini, MD, PhD
Pharmaceutical Medicine Specialist, Brazil

In 2005, a biotechnology company dedicated to the research and development of monoclonal antibodies to be used in the treatment of cancer was founded in Brazil with an innovative model based on partnerships with universities, research institutes and hospitals. Its main scientific partner, a world-renowned cancer research institute, has licensed to the company the intellectual property rights of antibodies with demonstrated potential for use in the treatment of several types of cancer. The company also established an alliance with a local biomedical research institute linked to the State Health Secretariat for monoclonal antibodies production.

The session will address attracting investments for the company's financing from private companies and government grants, as well as identifying and developing the necessary scientific and technological competencies.

Local and International Alliances for Biotechnology Development
Jose Fernando Perez
Recepta Biopharma, Brazil

Private-public Partnerships in Brazil and Biotechnology Development
Laura Luchini, MD, PhD
Pharmaceutical Medicine Specialist, Brazil

Harnessing Global Opportunities for Clinical Discovery
Jonathan C.A. Skipper, PhD
Executive Director, Intellectual Property and Licensing, Ludwig Institute for Cancer Research

Session 220 ST - Statistics, CTM/CS

8:00 am-9:30 am LEVEL: ■

Room 159AB *CME and Pharmacy credits offered*

Are You Ready for Adaptive Clinical Development? Examples, Case Studies, Successes – Part 1 of 2

SESSION CHAIRPERSON(S)

Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

Part 2 of this session will take place on Tuesday at 10:00 am.

Over the last few years, statisticians have developed methodology to use evolving data to modify ongoing clinical trials. Now that the methodology exists, adaptive trials are moving from pilot stage to full production. This session will discuss the steps required throughout clinical operations to prepare and successfully implement these trials.

Successes with Adaptive Designs: One Year Later
W. Tad Archambault, PhD
Principal, Virtu Stat, Ltd.

PhRMA Adaptive Design Working Group: Adaptive Design Best Practices Illustrated through Case Studies
Judith A. Quinlan, MSc
Director, Statistics, Biopharm CEDD, GlaxoSmithKline

A Seamless Phase 2/3 Trial Design Incorporating a Clinical Utility Index and Response Adaptive Randomization
Brenda L. Gaydos, PhD
Research Advisor, Eli Lilly and Company

Session 221 TR - Training, CR

8:00 am-9:30 am LEVEL: ●

Room 157AB

You're Hired! Strategies for Identifying, Interviewing, and Preparing for a Career in the Pharmaceutical Industry

SESSION CHAIRPERSON(S)

Tammy Jeanne Massie, PhD, MS
Mathematical Statistician, Vaccine Evaluation Branch, CBER, FDA

Disappointed with your current position, just finishing school or looking for a career change? These 90 minutes could provide you with the skills and strategies necessary to identify, pursue, and secure a new position in the pharmaceutical industry. In this session, four seasoned speakers will present their perspectives on conducting a successful job search. The main presentation topics will include perspectives on identifying and pursuing career opportunities, resume writing, and interviewing techniques. Specific and detailed advice and suggestions such as effective networking, finding a mentor or career coach to implement a successful job search will also be discussed. Using the information and advice provided in this session, hopefully soon you will hear the phrase, "You're Hired!"

Career Trends and Opportunities for Clinical Research Professionals
Joan A. Chambers
Senior Director of Marketing and Operations, Publications, Cambridge Healthtech Institute

Strategies for Identifying and Pursuing Career Opportunities
Todd Royer
Senior Partner, DiscoveryTech Technical Recruiting

Effective Resumes
Tammy Jeanne Massie, PhD, MS
Mathematical Statistician, Vaccine Evaluation Branch, CBER, FDA

Techniques for a Successful Interview
Thomas H. Parliment, PhD
Consultant-Chemist, Parliment Consulting

9:30 am-10:00 am **REFRESHMENT BREAK – Exhibit Hall**

Session 222 AD - Advertising, MC

10:00 am-11:30 am LEVEL: ■

Room 153AB *Pharmacy credits offered*

Medical Science Liaisons Communications

SESSION CHAIRPERSON(S)

Glenn N. Byrd, MBA, RAC
Director, Regulatory Affairs, MedImmune, Inc.

This session will focus on the roles of the MSL and the sales force, particularly in situations where MSLs and detail representatives are asked to provide off-label information about a drug. The session will discuss the increasing regulatory risk faced by companies, especially in light of recent federal and state investigations of drug company marketing practices under the FDA Act and the False Claims Act. Presentations will discuss the need for clear training of all sales and MSL personnel, the development, implementation of internal procedures, and other internal regulatory controls. Presenters will emphasize both the legal and regulatory constraints as well as practical approaches to compliance within drug companies.

Regulatory Perspective on MSL Communications
Glenn N. Byrd, MBA, RAC
Director, Regulatory Affairs, MedImmune, Inc.

MSLs and Trends in Industry
Robin L. Winter-Sperry, MD
President and CEO, Scientific Advantage, LLC; MSL Advantage, LLC

Dissemination of Off-label Information: The Role of Medical Scientific Liaisons
Peter O. Safir, JD
Partner, Covington & Burling

Session 223 AHC/IS - Academic Health Centers/ Investigative Sites, IT

10:00 am-11:30 am LEVEL: ■

Room 104AB

The Impact of FDAAA and Health Information Technology Interoperability Activities on Drug Safety, Implementation of Standards, and Data Stewardship Principles

SESSION CHAIRPERSON(S)

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

J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality

The FDA Amendments Act of 2007 (FDAAA) requires FDA to move towards an automated standards-based information technology (IT) environment for management of information supporting review of human drug applications throughout the product life cycle. FDA is developing a plan to improve the automation of business processes and maintain information systems that achieve objectives defined in performance goals. After public comment, FDA intends to publish its final IT plan by May 30, 2008. By executive order on April 27, 2004, President Bush established the position of National Coordinator for Health Information Technology to serve as the HHS Secretary's principal advisor on the development, application, and use of health information technology (HIT), and to direct HHS HIT programs and ensure that HIT policy and programs are coordinated with those of relevant executive branch agencies. The National Coordinator is to coordinate outreach and consultation by executive branch agencies with the public and private sectors. In addition, the FDA Bioinformatics Board (Staff Manual Guide SMG 2010.7 effective October 16, 2007) oversees planning and control of FDA bioinformatics activities and is to insure that activities related to its charge are communicated to all parts of the Agency.

The accumulation of health-care data from many sources in the public and private sectors raises concerns about how the data will be safeguarded. The Agency for Healthcare Research and Quality (AHRQ) released a report on national data stewardship in November, 2007. Speakers from FDA, the Office of the National Coordinator for HIT, AHRQ, and other organizations will address current and planned efforts relevant to FDAAA IT goals, national and international efforts to ensure coordination of public and private sector HIT programs, and stewardship issues associated with the use of data by multiple users for regulatory, patient safety, quality, pay for performance, and other purposes.

PDUFA IV Information Technology Plan
Armando Oliva, MD
Deputy Director, Bioinformatics, Office of Critical Path Programs, Office of the Commissioner, FDA

Office of Health IT Adoption Perspective
Karen M. Bell, MD, MMS
Director, Office of Health IT Adoption, Office of the National Coordinator for Health Information Technology, Department of Health and Human Services

Data Stewardship and Related Issues
J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality

Public Health Perspective
Hugh H. Tilson, DrPH, MD, MPH, FACPM, FISPE
Adjunct Professor, School of Public Health, UNC Public Health Leadership Program, University of North Carolina

Questions, Issues, and Solutions
Stanley A. Edlavitch, PhD, MA
Professor, Epidemiology and Director, Graduate Training, School of Medicine, University of Missouri Kansas City

Session 224 BT - Biotechnology, RA

10:00 am-11:30 am LEVEL: ■

Room 105

Gene Therapy Regulations for EU Clinical Trials: Navigating the Maze

SESSION CHAIRPERSON(S)

Cecil Nick, MS
Principal Consultant, PAREXEL Consulting, UK

An array of EU Directives and national legislation has an impact on clinical research of gene therapy. Interpretation of Directives varies between states, even regarding classifications. This session will review requirements for gene therapy trials and how best to facilitate efficient clinical development.

The European Regulatory Landscape for Gene Therapy Clinical Trials
Beate Roder, PharmD, PhD
Senior Consultant, PAREXEL International, Gmbh, Germany

Regulatory Agency Approach to Regulating Gene Therapy Clinical Trials
Gopalan Narayanan, MD
Head, Biologicals and Biotechnology Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

An Innovator's Experience of Gene Therapy Clinical Trials in Europe
Ruth S. Turner
Manager, Regulatory Affairs, Genzyme Corporation

How the EMEA Can Help Facilitate Development of Gene Therapy Products in Europe
Marisa Papaluca-Amati, MD
Deputy Head of Sector, Safety and Efficacy of Medicines, European Medicines Agency, European Union

Session 225 CDM - Clinical Data Management, EC

10:00 am-11:30 am LEVEL: ●

Room 258C

Building a Strong EDC Foundation through the Power of Partnership

SESSION CHAIRPERSON(S)

Mike Davies, PhD
Director, Sales and Global CRO Partnerships, Phase Forward

Drawing on real-world implementations, this session will draw on first-hand EDC deployment and trial experience to identify common EDC implementation challenges and offer valuable implementation advice for addressing them. The speakers will discuss the evolution of their relationships, how the role of EDC within their organizations has both changed and grown over time, and how EDC strategy and services has also been "sized to fit" within this context.

Mike Davies, PhD
Director, Sales and Global CRO Partnerships, Phase Forward

Drew Garty
Senior Director, Worldwide EDC Solutions, PAREXEL

EDC and the Clinical Trial: Changing Clinical Roles and Responsibilities
Anthony M. Cavaliere, MBA
Vice President, Data Management - US, ICON Clinical Research

Session 226 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

10:00 am-11:30 am LEVEL: ■

Room 154

Implementation of Quality by Design: A Global Perspective

SESSION CHAIRPERSON(S)

Haruhiro Okuda, PhD
Director, Division of Organic Chemistry, National Institute of Health Sciences, Ministry of Health, Labour and Welfare (MHLW), Japan

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

This session will present recent approaches for implementing Quality by Design in Europe and Japan. A global perspective on the implementation in these regions will also be discussed by speakers representing both industry and regulators.

Implementation of Quality by Design: Japan Regulator Perspective
Haruhiro Okuda, PhD
Director, Division of Organic Chemistry, National Institute of Health Sciences, Ministry of Health, Labour and Welfare (MHLW), Japan

Implementation of Quality by Design: Japan Industry Perspective
Kimiya Okazaki, PharmD
Director, Global CMC, Pharmaceutical Sciences, Pfizer Japan Inc., Japan

Implementation of Quality by Design: EU Perspective
Blanka Hirschlerova, MSc
Senior Pharmaceutical Assessor, State Institute for Drug Control, Czech Republic

Panel Discussion and Q & A Period

Session 227 CP - Clinical Safety and Pharmacovigilance, RA

10:00 am-11:30 am LEVEL: ■

Room 156AB *CME credits offered*

Modernization of FDA Postmarket Adverse Event Information Management

SESSION CHAIRPERSON(S)

Deborah Sholtes, MS
Director, Business Process Improvement, Office of Surveillance and Epidemiology, 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 information management program.

Modernization of FDA's Drugs and Biologics Adverse Event Information Management
Mary Ross Southworth, PharmD
Safety Evaluator, Division of Drug Risk Evaluation, Office of Surveillance and Epidemiology, CDER, FDA

Modernization of FDA's Devices and Combination Products Adverse Event Information Management
Steven H. Chasin
Supervisory Project Officer, CDRH, FDA

MedWatch Plus: FDA's Unified Portal for Adverse Event and Product Problem Reporting
Don Lipkey
Project Manager, Business Process, Office of the Commissioner, FDA

Session 228 CR 1 - Clinical Research and Development, CTM/CS

10:00 am-11:30 am LEVEL: ●

Room 203

The Symbiosis of Clinical Research, Public Health and Patient-consumer Involvement: Reconceptualizing Clinical Trial Research

SESSION CHAIRPERSON(S)

Vic R. C. Hernandez, DrPH, MPH
Postdoctoral Fellow, School of Public Health, Department of Health and Human Development; Consultant, Harvard University

This session explores the community-based participatory research (CBPR) strategic approach to create a participatory framework between clinical research, public health and the patient/consumer involved in the support and creation of the clinical research process.

What Is Community-based Participatory Research and How Does It Contribute to Reconceptualizing Clinical Trial Research?
Vic R. C. Hernandez, DrPH, MPH
Postdoctoral Fellow, School of Public Health, Department of Health and Human Development; Consultant, Harvard University

Community Advisory Board Purpose, Requirement, and Attachment to Funding: Perspectives from an Emerging Research Center
Gladys Balmas, MD, MPH
Research Coordinator, Peninsula AIDS Research Center

The Role of Patient Organizations in Clinical Trial Research: The European Experience
Nikos Dedes
Chairman of the Board of Directors, European AIDS Treatment Group, Belgium

Session 229 CR 2 - Clinical Research and Development, EC

10:00 am-11:30 am LEVEL: ●

Room 205A *CME and Nursing credits offered*

Enhancing Patient Adherence in Clinical Trials with eTechnology

SESSION CHAIRPERSON(S)

Brenda Jamerson, PharmD
Associate Professor, Clinical Research, Campbell University School of Pharmacy

A range of technologies that may collectively improve compliance in clinical trials, reduce variability, and increase the likelihood of a successful development program is available. Patient-reported outcomes (PROs) are a component of many clinical trials. Electronic technologies to collect PROs are designed to yield higher quality data. This session will focus on eTechnologies (ie, electronic diaries, actigraphy, medication monitoring) that enhance patient medication adherence and protocol compliance.

Leveraging Patient Adherence/Compliance Data to Transform Clinical Development
Craig H. Lipset, MPH
Director, Health Technologies, Pfizer Inc

The Role of eDiaries in Driving and Monitoring Patient Compliance to Clinical Trial Procedures
Jean Paty, PhD, MS
Founder and Senior Vice President, Quality and Regulatory Affairs, invivodata, inc.

Application of Actigraphy-based Monitoring to Identify Patient Compliance in Clinical Trials
Jack E. McKenzie, PhD
Director, Sales and Clinical Affairs, Mini Mitter, a Respironics Company

Assessing Clinical Trial Compliance Using Medication Monitoring Technologies
Brent I. Fox, PharmD, PhD
Assistant to Dean for Educational Technology, Harrison School of Pharmacy, Auburn University

Session 230 CR 3 - Clinical Research and Development, CTM/CS

10:00 am-11:30 am LEVEL: ■

Room 208 *Nursing credits offered*

Thirty Ways to Increase Enrollment at Your Site

SESSION CHAIRPERSON(S)

William J. Flohrs, PharmD
Associate Clinical Research Consultant, Eli Lilly and Company

One of the biggest obstacles that clinical trial sites face is recruiting patients for trials that they have in place. This session will provide specific tools, procedures, and methods to increase enrollment in a clinical trial, regardless of therapeutic area.

Utilizing a Patient Recruitment Firm
Robert Loll
Vice President, New Business Development, Patient interaction® (Pi)

Enrollment Strategies for an In-patient Trial
William J. Flohrs, PharmD
Associate Clinical Research Consultant, Eli Lilly and Company

How to Increase Enrollment in an Outpatient Trial
Abbe Steel
Executive Director, Trial Enhancement Solutions, United BioSource Corporation

Tips to Better Enrollment from a Sponsor's Perspective
Denise Veras, MA
Clinical Trial Manager, Genentech, Inc.

Session 231 CR 4 - Clinical Research and Development, PM/FI

10:00 am-11:30 am LEVEL: ●

Room 205B

Six Sigma: Straightening the Long and Winding Road of Clinical Development

SESSION CHAIRPERSON(S)

Tim G. Strauss, MA
Executive Director, Business Process Improvement, Covance Inc.

Much more than another theoretic overview of how Six Sigma applies to drug development, this session provides three different real-life perspectives on how Six Sigma is being deployed by both development service providers and drug companies. Following a selection of recent case studies, the session participants will take questions and discuss the current and future impact of Six Sigma on clinical development.

Six Sigma: Straightening the Long and Winding Road of Clinical Development
Tim G. Strauss, MA
Executive Director, Business Process Improvement, Covance Inc.

Six Sigma and Clinical Research Operations: Square Peg in Round Hole?
Eric Lake, MBA
Partner, Pharmica Consulting

R&D from a Different Angle: Optimizing Drug Development Processes through Supplier Six Sigma Collaborations
Chandrika Karavadra
Associate Director, Global Pharmaceutical R&D Sourcing, Johnson & Johnson Pharmaceutical Research and Development, LLC

Session 232 CTM/CS - Clinical Trial Management/ Clinical Supplies, CR

10:00 am-11:30 am LEVEL: ■

Room 204AB

The Implementation of a CTMS System

SESSION CHAIRPERSON(S)

Peter Bayer
EDC Coordinator, Lundbeck A/S, Denmark

This session will focus on implementation and rollout of a CTMS system, including technical issues and support, and organization including review of processes. The strategy used for implementation as well as how to identify success criteria will be discussed. It will also cover training and support, specifically eLearning or face-to-face training and organization of support.

Identification and Implementation of a Clinical Trial Management System
Megan Maloney, MS
Clinical Trial Manager, sanofi pasteur

Steps toward Sanity: Migrating to a Single CTMS Platform
Samuel Bryant, MS
Business Systems and Applications Analyst, Averion International Corp.

Real Life with a CTMS: Implementing and Then What?
Dorte Pedersen, RN
Head of Section, Clinical Support, H. Lundbeck A/S, Denmark

Session 233 EC - eClinical, CR

10:00 am-11:30 am LEVEL: ■

Room 258B

CDISC's Healthcare Link Initiatives: An Overview of CDISC Projects, Parallel Activities, and Long-term Implications

SESSION CHAIRPERSON(S)

Landen C. Bain
Health-care Liaison, CDISC

Linking clinical research to health care is a strategic initiative of CDISC and an area of great interest for both the health-care and clinical research industries. This session will provide insight into current work undertaken by CDISC and other organizations, and will forecast the ultimate impact of this work.

CDISC's Healthcare Link Initiatives: The Role of Pharmaceutical Companies
Kraig Kinchen, MD
Director, Electronic Exchange of Healthcare Information, Eli Lilly and Company

EMR Clinical Data Collection: Commercialization Beyond Beta Testing
Andrew Schafer, MBA
Senior Director, Business Planning, Quintiles Transnational Corp.

Wrap Up
Paul Gorup, MBA
Founder, Senior Vice President, Chief of Innovation, Cerner Corporation

Session 234 ERS/DM - Electronic Regulatory Submissions/Document Management, CDM

10:00 am-11:30 am LEVEL: ●

Room 257AB

CDER Electronic Submissions Update

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 along with the development of information management project proposals, which will benefit the consumer and the pharmaceutical industry.

FDA Perspective
Donovan F. Duggan, II, MBA
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

IT PDUFA: FDA Perspective
Joseph Montgomery
Lead IT Specialist, Office of the Commissioner, FDA

Session 235 GCP - Good Clinical Practices, RA

10:00 am-11:30 am LEVEL: ●

Room 206AB

Town Meeting: The Very Different Faces of Quality – QA, QC, Validation, Regulatory Affairs, and Compliance

SESSION CHAIRPERSON(S)

Teri E. Stokes, PhD, MS, MT
Director, GXP International

Defining the roles and responsibilities of quality functions in an organization can be a confusing process, and yet there are distinctly different disciplines to be covered. This Town Meeting session will use an experienced panel to set the scene for audience discussion to explore the many ways in which organizations large and small go about addressing these different quality roles.

Introduction on Validation and Compliance
Teri E. Stokes, PhD, MS, MT
Director, GXP International

Defining Quality Roles: QA, QC, and Regulatory Affairs
Bruce M. Wagman, MBA, RN, RAC
Vice President, Regulatory Affairs and Quality Assurance Services, Covance Inc.

Big Pharma Challenges and Success with Quality Practices
Melvyn R. Rapprecht, MSc
Global Head, Clinical Quality Assurance, F. Hoffmann-La Roche, Ltd., Switzerland

Small Pharma Use of Technology for Quality Systems
Virginia Viau
Director, Quality Systems, Altus Pharmaceuticals Inc.

Session 236 IT - Information Technology, EC

10:00 am-11:30 am LEVEL: ●

Room 258A

Business and Technology Considerations for a SaaS Solution in the Life-sciences Industry

SESSION CHAIRPERSON(S)

John Shipway
Industry Technical Architect, SAS Institute, Inc.

Within the life-sciences industry, numerous business and technology factors are converging to provide an environment that is fostering the rapid adoption of Software as a Service (SaaS), also known as the Application Service Provider (ASP) model. In a business climate that is focused on reducing operational costs, outsourcing, and improving time to market, enterprises have an unprecedented need to share information globally and collaborate on business and scientific processes. This session will give a background of the SaaS model within the life-sciences industry, discuss the benefits, risks, and mitigation strategies from both a technical and business viewpoint.

Business and Technology Considerations for a SaaS Solution in the Life-sciences Industry
Alistair John MacDonald, MS
Vice President, Data Services, INC Research, Inc.

Business and Technology Considerations for a SaaS Solution in the Life-sciences Industry
James L. Bland, MBA
Executive Director, CRIX International

Not Our Ancestor's Internet: Factors Affecting SaaS Enterprise Solution Performance
Chris Decker, MS
Clinical Practice Director, d-Wise Technologies, Inc.

Session 237 MC - Medical Communications, TR

10:00 am-11:30 am LEVEL: ■

Room 253B *CME and Pharmacy credits offered*

Evidence-based Medicine: A Practical Approach for the Medical Communications Professional

SESSION CHAIRPERSON(S)

Christopher M. Marrone, PharmD
Senior Outcomes Liaison, Cardiovascular, Eli Lilly and Company

This educational session will provide the medical communications professional with a practical approach for applying evidence-based medicine (EBM) principles. In addition to providing an EBM process which can be applied immediately by the medical communications professional, use of this process will be described for assisting with drug information practices within the pharmaceutical industry, including evaluating literature, writing medical documents, answering health-care professionals' questions and assessing evidence-based clinical guidelines.

Practical EBM Process for the Clinician and Applying the Process to Making Individual Patient and Populations Drug Therapy Decisions
Patrick J. Bryant, PharmD
Director, Drug Information Center; Clinical Associate Professor, Pharmacy Practice, University of Missouri-Kansas City

EBM Principles Applied to Drug Utilization and Formulary Discussion
Michael J. Steinberg, PharmD
Medical Outcomes Specialist, Global Medical Division, Pfizer Inc

Session 238 MW - Medical/Scientific Writing, CR

10:00 am-11:30 am LEVEL: ■

Room 153C

Data Displays to Aid Regulatory Agency Review of Safety Data

SESSION CHAIRPERSON(S)

Susan C. Sisk, PhD
Principal, SFP Consulting, LLC

Intelligent use of tabular and graphic displays in the analysis of trial data creates efficiencies in interpreting and communicating clinical information. The aim of this session is to share lessons learned with respect to appropriate display of safety data to expedite document preparation and review. Special emphasis will be placed on graphic presentation of data, including identifying opportunities for using graphs and a primer on interpreting different graphical displays of clinical data. Detailed suggestions on how to design specific displays for ease of use by writers and reviewers will also be presented.

Use of Displays for the Review of Safety Data from a Medical Officer's Viewpoint
Howard D. Chazin, MD, MBA
Acting Associate Director for Safety, Office of New Drugs, CDER, FDA

Statistical Graphics for Safety Data Analysis, Review and Reporting
Michael O'Connell, PhD
Director, Life Sciences, Insightful Corporation

Use of Displays for the Review of Safety Data from a Statistician's Viewpoint
Mat Soukup, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Session 239 NHP - Natural Health Products, RA

10:00 am-11:30 am LEVEL: ■

Room 156C

Regulatory Requirements with NHP: What Is New?

SESSION CHAIRPERSON(S)

Jinhui Dou, PhD
Botanical Review Team, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA

New developments in regulatory approaches for natural health products in various parts of the world will be presented. In addition, the session will address their implications in product development and maintenance.

NHP Submissions to the FDA: What One Should Know
Jinhui Dou, PhD
Botanical Review Team, Office of New Drugs, Office of Drug Evaluation I, CDER, FDA

Herbal Medicinal Products Committee Work at EMEA: Results Update
Heribert Pittner, MD
Member of the EMEA Herbal Medicinal Products Committee (HMPC); Chair of the HMPC Working Party on Community Lists and Monographs (MLWP), AGES PharmMed, Austria

Good Manufacturing Practices for Dietary Supplements: New Requirements that Affect Manufacturers, Consumers, and Health-care Professionals
Hiren D. Patel, PharmD
Postdoctoral Fellow, Regulatory Affairs, St. John's University College of Allied Health Professions/Forest Research Institute

Session 240 OS - Outsourcing, CR

10:00 am-11:30 am LEVEL: ■

Room 205C

Emerging Dilemma in Japan: Outsourcing for Multinational Trials

SESSION CHAIRPERSON(S)

Chris R. Albani, MBA
Managing Director, Pharmaceutical Industry Lead, Pittiglio, Rabin, Todd & McGrath, Japan

As global multinational trials become a standard part of clinical development in Japan, new approaches for effectively using CROs to support these trials are needed.

Outsourcing in Asia from the Perspective of a Japan-based CRO
Keiko Oishi, MS
Senior Managing Director, CMIC Co., Ltd., Japan

Outsourcing Global Clinical Trials in Japan
Elaine A. Hawkings
Senior Director, Clinical Operations Japan, Bristol-Myers K.K., Japan

Outsourcing Trends in Japan and Asia
Chris R. Albani, MBA
Managing Director, Pharmaceutical Industry Lead, Pittiglio, Rabin, Todd & McGrath, Japan

Session 241 PM/FI 1 - Project Management/ Finance, RD

10:00 am-11:30 am LEVEL: ■

Room 102AB *Project Management units offered*

Organizing for Project Management: Exploring the Value of a Matrix Approach to Project Management in Life Sciences Organizations and Companies

SESSION CHAIRPERSON(S)

Robert Lund Judd, III, MS
Chief Executive Officer, RJA Management Consulting and Training

This session will focus on how organizations and companies are structured, how the structure impacts project management, and the advantages and disadvantages. This session will explore functional to projectized, with a variety of matrix structures in between. Examples of organizations and companies that provide insight to organizing for success will be presented.

Translational Research Acceleration: Changing How Research Moves from the Bench to the Bedside
Mark Kelley, PhD
Academic ITRAC Program Leader, Indiana University Cancer Center

Organizing for Success in a Nonprofit Pharmaceutical Company
Susan E. Wilson, PhD
Senior Program Director, Institute for OneWorld Health

Chorus: A Model for Global Early-phase Development
Rosie S. Jones, RPh
Clinical Module Manager, Eli Lilly and Company

Session 242 PM/FI 2 - Project Management/ Finance, RD

10:00 am-11:30 am LEVEL: ■

Room 103 *Project Management units offered*

Deal Makers and Deal Breakers: What Venture Capital Firms Look for in Drug Development Plans

SESSION CHAIRPERSON(S)

Alberto Grignolo, PhD
Corporate Vice President and General Manager, Drug Development Consulting Practice, PAREXEL Consulting

Venture capital 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. This session will feature representatives from the venture capital 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.

Panel Discussion

Ed Mascioli, MD
Venture Partner, MPM Capital

Robert W. Jevon, MBA
Partner, Boston Millennia Partners

C. Richard Lyttle, PhD
President and CEO, Radius Health, Inc.

Session 243 PP - Public Policy/Law, RA

10:00 am-11:30 am LEVEL: ●

Room 160AB *CME and Pharmacy credits offered*

Off-label Use of Medicinal Products – Part 1 of 2

SESSION CHAIRPERSON(S)

John A. Lisman, LLM, MPharm
Attorney, NautaDutilh N.V., Netherlands

Part 2 of this session will take place on Tuesday at 2:00 pm.

This session will introduce the concept of off-label use and its implications in the context of various regulatory, policy, and legal issues.

Off-label Use from a Legal Perspective
John A. Lisman, LLM, MPharm
Attorney, NautaDutilh N.V., Netherlands

Policy Developments of Off-label Use
Josee M.M. Hansen, PharmD
Chief Inspector, Dutch Health Care Inspectorate, Netherlands

Frits Lekkerkerker, DrMed
Member of Advisory Board, Medicines Evaluation Board, Netherlands

Session 244 RA 1 - Regulatory Affairs, PP

10:00 am-11:30 am LEVEL: ■

Room 253A

PMDA Update: PMDA Initiatives and Challenges for Promoting Global Drug Development Including Japan

SESSION CHAIRPERSON(S)

Kyoichi Tadano, PhD
Director, International Affairs Division, Office of Planning and Coordination, 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 successful global drug development including Japan.

Overview and Perspective of PMDA Activities
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Challenges to Promote Global Drug Development including Japan
Satoshi Toyoshima, PhD
Executive Director and Director, Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Major Ongoing Projects to Provide Effective and Safe Drugs Quickly to Patients
Yoshiaki Uyama, PhD
Review Director, Office of New Drugs III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 245 RA 2 - Regulatory Affairs, CTM/CS

10:00 am-11:30 am LEVEL: ■

Room 256

Regulatory Strategies in Latin America: New Conquest for Pharmaceutical Companies for Timely Submissions and Project Startups in Mexico and Other Latin American Countries

SESSION CHAIRPERSON(S)

Marlene Llopiz-Aviles, MD, MBA, MPH
Regional Director for Latin America, Venn Life Sciences Clinical Research de Mexico, S.A. de C.V., Mexico

Pharmaceutical companies and partnering contract research organizations (CROs) have recently paid closer attention to promoting and conducting international and global clinical trials in Latin America. One of their main concerns is the timely fashion and quality of regulatory matters related to their studies to bring new drugs to market. Timely submissions and project startups are often difficult tasks due to the complexity of the documentation required and delays in their delivery in each Latin American country versus differences with other continents. However, the variety and availability of naive patients, adequate research sites, well experienced principal investigators, in addition to large patient populations and huge sales markets, makes Latin America a perfect choice for global clinical trial conduction and pharmaceutical marketing sales terrain.

What We Can Learn from the Brazilian Experience with Study Regulatory Approvals
Sonia Mansoldo Dainesi, MD, MBA
Medical Director, Boehringer Ingelheim, Brazil

Regulatory Affairs in Argentina, Chile and Peru: New Highlights on Submission Strategies
Pablo Marcelo Viard, MD
Clinical Trials Manager, Bristol-Myers Squibb, Argentina

Session 246 RA 3 - Regulatory Affairs, BT

10:00 am-11:30 am LEVEL: ■

Room 254AB

EU Variation Regulations Update: Why, What, When, and Authorities' and Industries' Perspectives

SESSION CHAIRPERSON(S)

Merete Schmiegelow, MPharm, MSc
Director, Regulatory Intelligence, Novo Nordisk A/S, Denmark

What are the problems in the current EU variation regulation system? What has the EU Commission proposed to change? What is the position of the EMEA, the national authorities, and industries on the proposed changes?

Why – What – When?
Merete Schmiegelow, MPharm, MSc
Director, Regulatory Intelligence, Novo Nordisk A/S, Denmark

Perspective from a National Agency and the CMD(h)
Peter Bachmann
Senior Expert, European Drug Regulatory Affairs and German Member of the CMD(h), Federal Institute for Drugs and Medical Devices, (BfArM), Germany

Perspective from the European Medicines Agency
Emer Cooke, MBA, MSc
Head of Sector, Inspections, European Medicines Agency, European Union

Perspective from the Biotechnology Industries (EuropaBio)
Merete Schmiegelow, MPharm, MSc
Director, Regulatory Intelligence, Novo Nordisk A/S, Denmark

Session 247 RA 4 - Regulatory Affairs, PM/FI

10:00 am-11:30 am LEVEL: ◆

Room 251

RAHP Gold: Device Track Masters

SESSION CHAIRPERSON(S)

Josephine Babiarz, JD
Director, MS Program in Regulatory Affairs and Health Policy, Massachusetts College of Pharmacy Health Sciences

This session consists of three presentations on advanced device regulatory topics from the Masters of Science degree program in regulatory affairs and health policy at Massachusetts College of Pharmacy and Health Sciences: comparison of approval processes for drugs and implantable devices for the same indication. Are the risks and agency standards the same?; the current standards used by FDA in 510(k) clearances and the impact of court decisions on the agency's thinking, and what can be expected from the GAO 510(k) study mandated by the Sept. 2007 amendments to the Food, Drug and Cosmetic Act; the barriers to spontaneous reporting of device events and the impact on manufacturer reporting and patient safety issues.

Same Indication, Same Risk?
Kevin Stevens, MS
Senior Regulatory Affairs Associate, C.R. Bard, Inc.

Substantial Equivalence in 510(k)s: Interpretations and Pitfalls
James M. Flaherty, Jr., JD, RAC
Attorney, Foley Hoag LLP

Issues with the Spontaneous Reporting System and MedSun Improvements
Melissa Anne Ostuni, MS
Senior Medical Research Associate, Boston Scientific

Session 248 RA 5 - Regulatory Affairs, RD

10:00 am-11:30 am LEVEL: ●

Room 252AB

FDA Meetings: Understanding the Process and Maximizing Success

SESSION CHAIRPERSON(S)

Jonca C. Bull, MD
Regulatory Policy and Strategy/Product Operations, DC Policy and Liaisons Office, Genentech, Inc.

The session will describe the complex issues involved in key FDA meetings including discussions of the regulations sponsor preparation, FDA perspective, and best practices from both sponsor and FDA perspectives. The discussion will include review of relevant guidances and up-to-date information on evolving CDER operational policies for meetings.

General Process and Best Practices for EOP2 and Pre-NDA Meetings
Michelle Wilson, PhD, MS
Senior Regulatory Specialist, Kendle International

Industry Perspective on Meetings with FDA
Patricia L. DeSantis
Vice President, Global Regulatory Affairs, Johnson and Johnson Pharmaceuticals Group

FDA Perspective on Milestone Meetings with Industry
Enid M. Galliers
Chief, Project Management, Division of Metabolism and Endocrinology Products, Office of New Drugs, CDER, FDA

Session 249 RA 6 - Regulatory Affairs, CP

10:00 am-11:30 am LEVEL: ●

Room 253C

SFDA Hot Topic: Efforts to Ensure Drug Quality and Safety

SESSION CHAIRPERSON(S)

Ling Su, PhD
Vice President, Clinical Research and Development, Asia Pacific, Wyeth Pharmaceutical Co., Ltd., China

Lili Cao
Division Director, China Center for Pharmaceutical International Exchange, SFDA, China

In this session, speakers from various departments of the State Food and Drug Administration (SFDA) of China will present the current situation and activities in market compliance and adverse drug reaction monitoring in China. The information presented will help the audience understand the SFDA's efforts to ensure quality and safety of pharmaceutical products.

Market Supervision in China
Xu Chen
Director, Division of Supervision on Distribution Licensing, SFDA, China

Reporting and Monitoring of Drug Adverse Reactions in China
Yixin Chen
Division Director, National Center for ADR Monitoring, SFDA, China

Session 250 RD - R&D Strategy, RA

10:00 am-11:30 am LEVEL: ■

Room 162AB

Postmarketing Commitments and Postapproval Research in the US and International Markets: Evolving Requirements, Efforts to Improve, and Strategies for Fulfillment

SESSION CHAIRPERSON(S)

Belinda J. Schluchter, PhD, RAC
Operations Manager, US Regulatory Affairs, Eli Lilly and Company

This session will address evolving requirements for postmarketing commitments (PMCs) in the US, including new FDA authorities under FDAAA to require, monitor, and enforce PMCs; reporting on the status and results of PMCs; and the impact of the predicted increase of user-fee resources available for postmarketing issues. An assessment of the utility of the data generated by PMC studies will be presented. In addition, the legal framework and practical implications of postapproval studies in Europe will be provided. Results of a comparison of postapproval research in Europe, Japan, and the US conducted by Tufts Center for the Study of Drug Development will also be discussed.

US Perspective: Postmarketing Commitments
Thomas H. Hassall, MS
Senior Director, Regulatory Intelligence, Abbott Laboratories

Postapproval Studies in Europe: Legal Framework and Practical Implications
Ian Laws, PhD
Vice President, Regulatory Affairs - Europe, GlaxoSmithKline Pharmaceuticals, UK

Comparison of Postapproval Research Required by the FDA, EMEA, and MHLW
Laura B. Faden, MPH
Senior Research Analyst, Tufts Center for the Study of Drug Development, Tufts University

Session 251 ST - Statistics, CTM/CS

10:00 am-11:30 am LEVEL: ■

Room 159AB *CME and Pharmacy credits offered*

Are You Ready for Adaptive Clinical Development? Regulatory Considerations – Part 2 of 2

SESSION CHAIRPERSON(S)

Bruce Binkowitz, PhD, MA
Senior Director, Late Development Statistics, Merck Research Laboratories

Part 1 of this session will take place on Tuesday at 8:00 am.

Over the last few years, statisticians have developed methodology to use evolving data to modify ongoing clinical trials. Now that the methodology exists, adaptive trials are moving from pilot stage to full production. This session will discuss the steps required throughout clinical operations to prepare and successfully implement these trials.

Bayesian Utility in Adaptive Designs
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Putting the "Pre" Back in Pre-specify: Planning Clinical Trial Design and Analyses in Today's Regulatory Environment
Bruce Binkowitz, PhD, MA
Senior Director, Late Development Statistics, Merck Research Laboratories

Session 252 TR - Training, CR

10:00 am-11:30 am LEVEL: ■

Room 157AB

Pharmaceutical Medicine in Asia

SESSION CHAIRPERSON(S)

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

Over the last 10 years, as Asia became an attractive region for pharmaceutical clinical development, many institutes and programs for the training of clinical research personnel were set up. These programs mainly addressed the needs of operational personnel and comprised elements of drug development as well as the various GXPs.

More recently, centers and institutions for pharmaceutical R&D for the local development of pharmaceutical and biological products have been set up in various Asian countries. With the rapid growth of the industry, many physicians are seeking career opportunities in the pharmaceutical industry. To meet the growing need and to maximize efficiency, these professionals require comprehensive understanding of the integrated process of global drug development, combined with customer focus and management skills. New technologies and methodologies further increase the requirement for professional, in-depth training into the various aspects required for sound decision making.

Pharmaceutical medicine has been recognized in Europe as a medical subspeciality for the past 30 years, but is relatively new in Asia. This session will look at some Asian countries that have successfully launched the program as a medical subspecialty, and will include the challenges in introducing it in the local environment and how these were overcome.

Thirty Years of Pharmaceutical Medicine in Japan
Kyoko Imamura, MD, PhD, DrMedSci
Vice President, Medical Affairs, Janssen Pharmaceutical K.K., Japan

Starting Up Pharmaceutical Medicine in China
Frank Fan, DrMed
Medical Director, Abbott China

Pharmaceutical Medicine in Japan: Regulatory Perspective
Tetsuya Tanimoto, MD
Reviewer, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

11:30 am-2:00 pm **EXTENDED LUNCHEON HOURS – Exhibit Hall C**

Session 253 AHC/IS - Academic Health Centers/ Investigative Sites, IT

2:00 pm-3:30 pm LEVEL: ■

Room 104AB

Success at the Crossroads: The Intersection of CDISC Standards with Research Site Processes

SESSION CHAIRPERSON(S)

Bron Witt Kisler
Director, Terminology and Strategic Alliances, CDISC

This session will provide an overview and detailed explanation of standards activities pertinent to investigative research sites and the benefits that can be derived. CDISC is leading an FDA "Critical Path Opportunity" project to define standards for data collection known as CDASH. This work is being aligned with CDISC controlled terminology standards for regulatory submissions that is currently in production and referenced in an FDA Federal Register notice, dated December 2006. FDA standards activities will also be highlighted as they

relate to CDISC, data collection, submission and the PDUFA IV Information Technology Plan.

CDASH: Background, Charter, Status, and Focus 2008
Rhonda Facile
CDASH Project Director, CDISC

Brief Survey of Domains
Paul Bukowiec, MS
Director, Statistical Programming, Millennium Pharmaceuticals, Inc.

Terminology and How It Relates to CDISC Standards
Mary Lenzen, MS
Principal Consultant, Octagon Research Solutions, Inc.

FDA Perspectives
Armando Oliva, MD
Deputy Director, Bioinformatics, Office of Critical Path Programs, Office of the Commissioner, FDA

Session 254 BT - Biotechnology, RA

2:00 pm-3:30 pm LEVEL: ■

Room 105

RNA Therapeutics: Bringing the Future of Biological and Medical Innovation to Today

SESSION CHAIRPERSON(S)

James B. Crawford
Scientist, PharmaSys, Inc.

This session will provide an introduction to RNA therapeutics – what the term means, the different methods/concepts presently used, how they are engineered, and how they are delivered – and their potential for treatment of many disease states.

James B. Crawford
Scientist, PharmaSys, Inc.

James G. Patton
Professor, Biological Sciences, Vanderbilt University

Jared A. Gollob, MD
Senior Director, Clinical Research, Alnylam Pharmaceuticals

Session 255 CDM - Clinical Data Management, CR

2:00 pm-3:30 pm LEVEL: ■

Room 158C

Metrics Reporting: Challenges, Strategies and Successes

SESSION CHAIRPERSON(S)

Patrick Fredericksen, MBA
Partner, Fountain Database Design, Inc.

Developing meaningful metrics is a challenge. A comprehensive metrics approach will address the needs of senior management, provide a useful tool for data management, and be tailored to work with the individual makeup of the company.

Metrics: You Want Them – Go Get Them
Patrick Fredericksen, MBA
Partner, Fountain Database Design, Inc.

Developing Meaningful Metrics with EDC: Useful vs. Meaningless Metrics
Johann Pröve, PhD
Global Head, Data Management, Bayer Schering Pharma, Germany

Metrics Strategy for a Growing Pharma: A Case Study
Laurie S. Callen
Senior Technical Manager, Clinical Data Management, Synta Pharmaceuticals Corp.

Session 256 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

2:00 pm-3:30 pm LEVEL: ■

Room 154

Updates on ICH Q8(R1) and Q10 Guidelines

SESSION CHAIRPERSON(S)

Charles P. Hoiberg, PhD
Executive Director, Pfizer Inc

This session will present updates regarding two Step 2 ICH Quality Guidelines. ICH Q8(R1) is concerned with pharmaceutical development and ICH Q10 is concerned with pharmaceutical quality system.

ICH Q8(R1)
Brian Withers
Director, CMC Global Pharmaceutical Regulatory Affairs, Abbott Laboratories, UK

ICH Q10
Diana Amador
Director of Investigations, Office of Regulatory Affairs, FDA

Panelist
Charles P. Hoiberg, PhD
Executive Director, Pfizer Inc

Panel Discussion and Q & A Period

Session 257 CP - Clinical Safety and Pharmacovigilance, RA

2:00 pm-3:30 pm LEVEL: ■

Room 156AB *CME credits offered*

Pharmacovigilance and Risk Management Plans in Japan Today

SESSION CHAIRPERSON(S)

E. Stewart Geary, MD
Vice President, Eisai Co., Ltd., Japan

We will provide a general update on pharmacovigilance, risk communication, and the implementation and interpretation of risk management plans in Japan, including the implementation of the ICH E2E Guidance, and Japanese equivalent examples of risk minimization plans and risk management activities. The session will also describe some of the practices and expectations for communicating new safety updates of the package insert by medical representatives in Japan.

Risk Communication in Japan
Hiroko Koyama, RPh
Training and Planning Coordinator, Society of Japanese Pharmacopoeia, Japan

Risk Management Plans and Review of the J-NDA
Kaoru Misawa
Director, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

The All Cases Surveillance in Japan
Jinshu Cho
Senior Manager, Wyeth, Japan

MHLW Policy on Drug Safety
Tatsuo Kurokawa, PhD
Councilor for Pharmaceutical Affairs, Ministry of Health, Labour and Welfare (MHLW), Japan

Session 258 CR 1 - Clinical Research and Development, GCP

2:00 pm-3:30 pm LEVEL: ●

Room 210A

Expanded Access Programs: Their Role in Product Development and Keys to Successful Implementation

SESSION CHAIRPERSON(S)

Scott Cooley
Executive Director, Phase 3b/4 Product Management, Quintiles, Inc.

Expanded access programs are known by many names throughout the research community. They are identified differently depending on individual countries and have varying regulations which cover their implementation. Common to all, however, is the need to craft a message that appeals to each of the stakeholders. The very conduct of the program itself may refine that message over time. Keys to successfully implementing an expanded access program will be to establish a sound regulatory strategy, develop a clean and simple protocol, set up a scientific advisory group, simple investigator registration, simple subject registration, set up a strong just-in-time training program, keep the monitoring strategy simple, provide a data management platform that is flexible in design, and constantly assess the site burden at the investigative site level. Each of these will be addressed in this interactive presentation.

Just-in-time Training: Key Success Factor for a Successful EAP
Jennifer Lansink
Founder and President, Total Root Concepts, Inc.

Expanded Access Programs: Strategy, Messaging and Stakeholders
Scott Cooley
Executive Director, Phase 3b/4 Product Management, Quintiles, Inc.

Conducting Expanded Access Programs in a Global Environment
Hilde Vanaken, PhD, MSc
Associate Director, Global Clinical Research, Tibotec, Belgium

Patient Community Perspectives and Expectations for Expanded Access Programs
Bob Huff, MA
Antiretroviral Project Director, Treatment Action Group (TAG)

Session 259 CR 2 - Clinical Research and Development, IT

2:00 pm-3:30 pm LEVEL: ■

Room 205A *Nursing credits offered*

Data-driven Patient Recruitment: Tools for Early Planning and Predictive Management

SESSION CHAIRPERSON(S)

Joshua Schultz, MS
Vice President, Clinical Research Services, PAREXEL International

With patient recruitment now one of the biggest challenges facing the biopharmaceutical industry, the ability to utilize tools for more accurate last-patient-in (LPI) predictions is becoming a critical component to any successful program. When incorporated early enough, predictive tools can relieve the patient recruitment bottleneck, helping sponsors reduce costs involved in bringing new products to market faster.

This session will focus on the results of a major analysis of over 50,000 investigators and 500 trials, which identifies the major drivers of recruitment and structural factors (such as staggered study startup) that impact the vast majority of trials but are rarely incorporated into planning.

Attendees will take away new approaches to identify potential high performing investigators, use tools to better plan for recruitment based upon known factors, incorporate contingency-based escalation into recruitment planning, and establish organizationally integrated groups that drive recruitment with minimal loss between silos.

The Closed Loop Approach Using Electronic Medical Records
Brendan O'Neill
Associate Director, Patient Recruitment Specialists, Merck & Co., Inc.

Multivariate Scenario Planning: A Case Study
Ulrika Sullivan, MBA
Clinical Project Manager, AstraZeneca

Approaches to Data-driven Site Selection and LPI Planning
Joshua Schultz, MS
Vice President, Clinical Research Services, PAREXEL International

Session 260 CR 3 - Clinical Research and Development, RD

2:00 pm-3:30 pm LEVEL: ●

Room 205B *CME credits offered*

Addressing the Adverse Impact of Increasing Protocol Complexity on Study Conduct Performance

SESSION CHAIRPERSON(S)

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

Since 1997, protocol complexity and the work effort required to implement protocols have increased substantially. A recent Tufts Center study demonstrates that protocol design and work effort trends adversely impact study conduct efficiency, budgets, and recruitment and retention effectiveness. This session looks at specific strategies and practices that sponsor companies are implementing to optimize protocol design and improve study conduct performance.

Assessing the Impact of Rising Protocol Complexity on Study Conduct Performance
Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

Evaluating Internal Protocol Design Processes
Anne B. Cropp, PharmD
Executive Director, Pfizer Global Research & Development

Optimizing Efficiency through Protocol Design Improvements
Edward Stephen Seguine, Jr., MBA
General Manager, Trial Planning, Medidata Solutions Worldwide

Session 261 CTM/CS - Clinical Trial Management/ Clinical Supplies, CR

2:00 pm-3:30 pm LEVEL: ■

Room 204AB

Solving Complex Problems in Clinical Trial Supply Management

SESSION CHAIRPERSON(S)

Bill Byrom, PhD
Vice President, Product Strategy, ClinPhone Group Ltd., UK

Technology solutions have been valuable in simplifying the logistics and supply management for complex study designs. This session will explore the use of technology to solve particularly complex problems. The use of sham algorithms in maintaining treatment blinding where doses are adjusted based on (unblinding) response endpoint data such as coagulation times in warfarin studies will be discussed. We will also consider practical solutions in complex titration designs, and examine advanced approaches to situations where medication is in short supply.

Estimating Medication Requirements for Adaptive Trial Designs
Bill Byrom, PhD
Vice President, Product Strategy, ClinPhone Group Ltd., UK

Maintaining the Study Blind in Studies where Dose Is Titrated by Clinical Endpoint
Allison Brown
Senior Manager, IVRS Central Management Group, Celgene

Solving Practical Challenges in Complex Titration Designs
Wendi E. Carroll, PharmD
Director, Global Clinical Study Management, Amgen Inc.

Session 262 EC - eClinical, IT

2:00 pm-3:30 pm LEVEL: ■

Room 158B *CME, Nursing, and Pharmacy credits offered*

Leveraging Electronic Health Records in Clinical Research

SESSION CHAIRPERSON(S)

Michael J. Barrett, JD
Managing Partner, Critical Mass Consulting

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 moderator and audience members will provide questions for the panelists.

Panelists

John D. Halamka, MD, MS
Chief Information Officer, Harvard Medical School

Demetris Zambas
Associate Director, GCDM, Schering-Plough Research Institute

Jane Griffin, RPh
Director, Cerner Corporation

Paul A. Bleicher, MD, PhD
Chairman and Founder, Phase Forward

Landen C. Bain
Health-care Liaison, CDISC

Session 263 ERS/DM - Electronic Regulatory Submissions/Document Management, CDM

2:00 pm-3:30 pm LEVEL: ●

Room 157AB

FDA: eCTD Compliance – Part 1 of 2

SESSION CHAIRPERSON(S)

Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

Part 2 of this session will take place on Tuesday at 4:00 pm.

This session is Part 1 of Guidance-compliant eCTDs and will provide an overview of FDA's eCTD Guidance.

Module 1
David Roeder, MS
Associate Director for Regulatory Affairs, Office of Antimicrobial Products, Office of New Drugs, CDER, FDA

Module 2
Donovan F. Duggan, II, MBA
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

Module 3
Norman R. Schmuff, PhD
Branch Chief, Division of Pre-Marketing Assessment II, Office of Pharmaceutical Science, CDER, FDA

Modules 4 and 5
Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

Session 264 GCP - Good Clinical Practices, RA

2:00 pm-3:30 pm LEVEL: ●

Room 206AB

Review of Regulatory Agency Inspection Reports

SESSION CHAIRPERSON(S)

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

For those managing clinical trials, inspections are nothing new. However, what we have been observing over the past few years is a change in the inspections landscape. Only a few years ago, FDA was one of the few health authorities that systematically conducted inspections on clinical trials and pharmacovigilance systems. This has changed. In Europe, with the implementation of the EU Clinical Directive, strong inspectorates have been established across the Member States, and countries in other regions are following suit. This change highlights the need for a more harmonized approach to inspections. In this session, we will hear from inspectors and an industry representative, respectively, how inspections are planned and targeted by health authorities, and what sponsors from industry or academia can learn from past inspection experience.

Clinical Investigators: A Recipe for Success?
Michael Marcarelli, PharmD, MS
Director, Division of Bioresearch Monitoring, CDRH, FDA

GCP Inspections: EMEA Perspective
Fergus Sweeney, PhD
Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, European Medicines Agency, European Union

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

Session 265 IMP/EBM - Impact (Impact of Medical Products and Therapies)/ Evidence-based Medicines, RA

2:00 pm-3:30 pm LEVEL: ■

Room 208 *Pharmacy credits offered*

Good Practices for Clinical Endpoint (PRO, CRO) and Linguistic Validation: State of the Science

SESSION CHAIRPERSON(S)

Sonya L. Eremenco, MA
ePRO Manager, United BioSource Corporation

Increasingly, researchers are confronted with how to administer the same patient- and clinician-reported outcomes assessment in different countries while retaining equivalent meaning across languages. While the FDA Draft Guidance focuses primarily on patient-reported outcomes (PRO), FDA has publicly indicated that clinician-reported outcomes (CROs) will be held to the same rigorous standards as those applied to PROs and other clinical endpoints. The Guidance also emphasizes the importance of qualitative methods for instrument development along with quantitative methods for the purposes of validating these instruments. These developments raise the stakes for outcomes researchers, study leaders, statisticians, and data managers who must balance efficacy claims for approval and the collection of appropriate data for

paying authorities. This session will present the state of the science for validation of patient-reported outcomes, clinician-assessed outcomes, and translations, including regulatory and sponsor perspectives.

Qualitative Approaches to Linguistic Validation of PROs and CROs
Sonya L. Eremenco, MA
ePRO Manager, United BioSource Corporation

Quantitative Validation of PROs and CROs
James Pierce, PhD, MPH, MS
ePRO Partnering Manager, ClinPhone Inc.

Industry Perspective on Clinical Endpoint Validation Issues
Ingela Karin Wiklund, PhD
Director, Patient-reported Outcomes, GlaxoSmithKline, UK

FDA Perspective
Laurie Beth Burke, MPH, RPh, CAPT. USPHS
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

Session 266 IT - Information Technology, EC

2:00 pm-3:30 pm LEVEL: ■

Room 258A

Service-oriented Architecture in R&D

SESSION CHAIRPERSON(S)

Stuart Henderson, MBA
Life Sciences R&D Leader, Global Business Services, IBM Corporation

The power behind SOA is the ability to share services through system-to-system interactions that help support end-to-end processes, automate process steps, remove redundancy, use messaging and alerts to trigger essential people-powered workflow, and enable new capabilities. When a company adds new applications and retires old ones, SOA can help facilitate the transition and migration. Over time, services may be modified, shared and recombined to streamline activities across yet more applications. This approach allows companies to more efficiently automate regulated and compliance-driven activities – freeing people to perform higher-level activities, and providing an integrated business view to authorized staff across departments and organizations.

Jason Bronfeld
Executive Director, Pharmaceutical Development Informatics, Bristol-Myers Squibb

Session 267 MC - Medical Communications, IT

2:00 pm-3:30 pm LEVEL: ●

Room 253B *Pharmacy credits offered*

Medical Liaison Survey #4: Assessing Tools Used by MLs, Clinical Trial Involvement, and Career Strategies

SESSION CHAIRPERSON(S)

Craig J. Klinger, RPh
Senior Medical Liaison Consultant, Eli Lilly and Company

This session will review results for a survey that was conducted to identify tools used by field-based MLs (virtual office), and how MLs are involved in clinical trials from phase 1 through phase 4. In addition we will review survey results of career strategies for the ML role.

Technology and Tools Used by MLs
Craig J. Klinger, RPh
Senior Medical Liaison Consultant, Eli Lilly and Company

Clinical Trial Involvement
J. Lynn Bass, PharmD
Senior Regional Medical Liaison, Scientific Affairs, Amgen Inc.

Career Strategies
Christopher M. Marrone, PharmD
Senior Outcomes Liaison, Cardiovascular, Eli Lilly and Company

Session 268 MW - Medical/Scientific Writing, RA

2:00 pm-3:30 pm LEVEL: ■

Room 153C

Making the Transition to Writing IND Documents for the eCTD Submission

SESSION CHAIRPERSON(S)

Peggy M. Boe, RN
Senior Director, Medical Writing, Image Solutions, Inc.

The FDA is strongly encouraging that companies submit Investigational New Drug (IND) applications in the electronic Common Technical Document (eCTD) format rather than as paper. In fact, if submitting to the Center for Drug Evaluation and Research (CDER), as of January 1, 2008, companies either have to submit all paper or all electronic. However, change is always difficult, and making the transition to submitting the IND as an eCTD is especially difficult when all of your corporate processes were developed for paper submissions; there is a lot to consider. This session will focus on only three of the many considerations. A speaker from the pharmaceutical industry will share the experience of trying to decide when and how to make the transition to an electronic submission, from the point of view of a company that typically does not take a product beyond proof of concept. A second speaker will explain how at least one submission document (the Investigator Brochure) can be used as a virtual tool for building final marketing application material from the IND. Finally, an FDA speaker will explain how submitting amendments and updates to an IND in eCTD format can make the IND process easier in the long run for either your company or an out-licensed partner hoping to eventually submit an eCTD marketing application.

Best Practices for Submitting Amendments and Updates to an IND in eCTD Format
Sean Patrick McNiff
Manager, Regulatory Operations, Vertex Pharmaceuticals

Timing is Everything: Deciding when to Transition Your INDs from Paper to eCTD
Cassandra K. MacArthur, MS
Owner and Primary Consultant, International and Quality, CMAC, LLC

Using the Investigator Brochure from the IND on, as a Virtual Document to Facilitate the Final CTD
Peggy M. Boe, RN
Senior Director, Medical Writing, Image Solutions, Inc.

Session 269 NC - Nonclinical Laboratory Safety Assessment, CR

2:00 pm-3:30 pm LEVEL: ■

Room 104C *CME credits offered*

Revisions to ICHM3(R1) in the Areas of Acute Toxicity, Chronic Toxicity, and Developmental Toxicity

SESSION CHAIRPERSON(S)

Klaus Olejniczak, DVM, FACP
Scientific Director, Department of Drug Toxicology, Federal Institute for Drugs and Medical Devices, (BfArM), Germany

Standard acute (single dose) and repeated toxicity studies in animals are usually conducted prior to first-in-man studies in line with the ICH Guideline M3 (R). Exploratory clinical trials in humans may be initiated with less, or different, nonclinical support than is generally required for traditional clinical studies and, therefore, the estimation of the clinical starting (and maximal)

dose may differ. Inclusion of women of childbearing potential in clinical trials may be acceptable without nonclinical developmental toxicology studies in certain circumstances. The criteria for starting doses for the various exploratory clinical trial designs and the circumstances for inclusion of women of childbearing potential in clinical trials are discussed in this session.

This session is aimed at anyone who comes into contact with nonclinical (toxicological) data in relation to clinical development. Furthermore, this session identifies the needs of acute toxicity studies, repeated toxicity studies, and reproduction toxicity studies in early drug development based on the revised ICH Guideline M3.

Could We Skip the Conventional Acute Toxicity Studies?
Klaus Olejniczak, DVM, FACP
Scientific Director, Department of Drug Toxicology, Federal Institute for Drugs and Medical Devices, (BfArM), Germany

Chronic Toxicology Studies
Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs, CDER, FDA

Development Toxicology Studies
Joseph J. DeGeorge, PhD
Vice President, Safety Assessment, Merck & Co., Inc.

Session 270 NHP - Natural Health Products, CR

2:00 pm-3:30 pm LEVEL: ■

Room 156C *CME and Pharmacy credits offered*

Challenges with Natural Health Products Research and Development

SESSION CHAIRPERSON(S)
Christelle Anquez-Traxler, PharmD
Regulatory and Scientific Affairs Manager, AESGP, Belgium

In order to acquire market authorization of natural health products, the demand for knowledge of clinical trials is expanding. This session will focus on the challenges one may encounter in such endeavors in the paradigm of research and development.

New Challenges Concerning TCM Drug Development
James D. Fan, MD
Associate Medical Director, Asia-Pacific Region, ICON Clinical Research Ltd., Singapore

Can NHP Rhyme with Innovation?
Christelle Anquez-Traxler, PharmD
Regulatory and Scientific Affairs Manager, AESGP, Belgium

Clinical Trials of Fixed-dose Combined Phytochemical Formulation of Casicum Annum
Pratim Banerji, MBA
Chief Executive Officer, Ulysses Pharmaceuticals Pvt. Ltd., India

Session 271 OS - Outsourcing, CR

2:00 pm-3:30 pm LEVEL: ■

Room 205C

Lessons Learned: A Global Survey on Outsourcing Practices

SESSION CHAIRPERSON(S)
John R. Vogel, PhD
Drug Development Consultant, John R. Vogel Associates, Inc.

This audience participation session focuses on the results of a global "lessons learned" survey of sponsor and provider views on outsourcing practices that was recently conducted with the DIA membership. The results of the survey will be presented, and the panelists and audience will discuss how these results suggest ways to better design and manage outsourced projects.

Larry A. Blankstein, PhD
Senior Director, Clinical Research, Genzyme Corporation

Ronny K. Schnel, MA
Executive Director, Business Development and Client Services, Criterium, Inc.

John R. Vogel, PhD
Drug Development Consultant, John R. Vogel Associates, Inc.

Session 272 PM/FI 1 - Project Management/ Finance, CR

2:00 pm-3:30 pm LEVEL: ■

Room 103 *Project Management units offered*

Utilization of Six Sigma Methodology in Clinical Trial Project Management

SESSION CHAIRPERSON(S)
Peter H. Blake, PhD
President, PrecisTrial LLC

The pharmaceutical industry faces increasing pressure to reduce clinical trial timelines. Six Sigma methodology offers the opportunity to systematically define, measure, analyze, improve, and control the processes that drive drug development cycle times. Six Sigma and similar methodologies enables us to reduce process variability and continuously improve process cycle times in a structured, systematic, and sustainable way. This session will report on the methods, challenges, and benefits of applying Six Sigma to clinical trial processes. The speakers will address the effectiveness of Six Sigma techniques in the management and control of clinical trial processes.

Utilization of Six Sigma Methodology in Patient Enrollment Management
Peter H. Blake, PhD
President, PrecisTrial LLC

Creating a Sustainable Breakthrough in Drug Development Performance: A Case Study
Rene Sluijter
Director, Global Clinical Services, Solvay Pharmaceuticals B.V., Netherlands

Actively Managing Human Factors to Create a Sustainable Breakthrough in the Drug Development Process
Jeff Powell
Managing Director, Critical Business Solutions

Session 273 PM/FI 2 - Project Management/ Finance, CP

2:00 pm-3:30 pm LEVEL: ■

Room 102AB *Project Management units offered*

Proactive Project Risk Management in Drug Development: The Value of Project Management to the Pharmaceutical Business

SESSION CHAIRPERSON(S)
Leigh Shultz, PhD, PMP
Associate Project Director, Merck & Co., Inc.

Effective management of risk in pharmaceutical projects can reduce scope creep, decrease or contain project costs, and prevent delays in bringing products to market. Using a disciplined approach toward risk throughout the life of a pharmaceutical project enables the project manager to focus on execution of strategy and leadership of the project team. Examples of risk management tools from the industry will be discussed by presenters experienced in their practical application.

Proactive Project Risk Management in Drug Development: The Value of Project Management to the Pharmaceutical Business
Leigh Shultz, PhD, PMP
Associate Project Director, Merck & Co., Inc.

Risky Business: Navigating the Uncertainties in Drug Development Programs
Nita Ichhpurani, PMP
Director, Program Management, Development and Regulatory Services, MDS Pharma Services, Canada

Proactive Risk Management for New Product Development: Managing Risks for Pharmaceuticals, Medical Devices, and Biologics
Monique McRipley Ollie, PhD, MS
Director, Strategic Planning, Johnson & Johnson Pharmaceutical Services
Debra Hyde, PMP
Associate Director, Global Project Management, Schering-Plough

Session 274 PP - Public Policy/Law, RA

2:00 pm-3:30 pm LEVEL: ●

Room 160AB *CME and Pharmacy credits offered*

Off-label Use of Medicinal Products – Part 2 of 2

SESSION CHAIRPERSON(S)
John A. Lisman, LLM, MPharm
Attorney, NautaDutilh N.V., Netherlands

Part 1 of this session will take place on Tuesday at 10:00 am.

This session together with Part 1, will provide insight into the complex regulatory, legal, and policy aspects of off-label use.

Off-label Promotion in the US and the EU
Shane H. Freedman, JD
Counsel, Patton Boggs LLP

Off-label Use from the Perspective of Responsibilities of Health-care Professionals and Learned Societies
Albert I. Wertheimer, PharmD, MBA
Professor, Pharmacy; Director, Center for Pharmaceutical Health Research, Temple University

Session 275 RA 1 - Regulatory Affairs, PP

2:00 pm-3:30 pm LEVEL: ■

Room 251

Asian Cooperation/Collaborations for Promoting Drug Development

SESSION CHAIRPERSON(S)
Yoshiaki Uyama, PhD
Review Director, Office of New Drugs III, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

This session focuses on Asian cooperation/collaboration activities among regulatory agencies and industries for promoting drug development.

Asian Regulatory Cooperation/Collaborations for Promoting Drug Development
Kyoichi Tadano, PhD
Director, International Affairs Division, Office of Planning and Coordination, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Collaborative Activities of Japanese Pharmaceutical Companies in Asia to Facilitate Drug Development
Hironobu Saito, PhD
Director, Clinical Development Group, Asian Development Department, Daiichi Sankyo Co., Ltd., Japan

Challenges of Drug Development Including Asia and Japan: A US-based Multinational Company Point of View
Cathy Ann Vlahos, MBA
Manager, Project Management, Lilly Research Laboratory, Eli Lilly and Company

Session 276 RA 2 - Regulatory Affairs, BT

2:00 pm-3:30 pm LEVEL: ■

Room 256

Innovative Medicines and the EMEA

SESSION CHAIRPERSON(S)
Cecil Nick, MS
Principal Consultant, PAREXEL Consulting, UK

In the EU, regulatory professionals need to wrestle with a spectrum of opinions, cultures and approaches. But this plurality of views can be harnessed to optimize clinical development and regulatory strategy. The EMEA are well aware of the importance of innovative drug development and one of the goals of their long-term strategy is to foster research and innovation uptake in the development of pharmaceuticals and are therefore focusing much effort in this area. This session investigates how best to interact with the EMEA to maximize the value of scientific advice and the potential within the EU for applying new approaches such as adaptive trial designs, use of biomarkers, and the potential for accelerated and conditional approval. The best way to share information with the regulators will be discussed as will the need for well documented justifications of the company's position. The additional support available to small and medium enterprises, and those developing orphan drugs, pediatric medicines, and advanced therapy medicinal products will be considered. Once ready for submission, there will be the need to choose between the centralized and decentralized procedures and the pros and cons for this will be considered.

Working with the EMEA
Agnès Saint Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

Optimizing the Global Program for Europe
David B. Jefferys, MD, FRCPC
Vice President, Global Regulatory, Eisai Europe Ltd., UK

Strategizing for Success in the EU
Cecil Nick, MS
Principal Consultant, PAREXEL Consulting, UK

Session 277 RA 3 - Regulatory Affairs, CMC/GMP

2:00 pm-3:30 pm LEVEL: ■

Room 253A

Dealing with Potential Genotoxic Impurities (GTIs) Especially in FDC (Fixed-dose Combination) Drug Products for Global Clinical Trials

SESSION CHAIRPERSON(S)
Nancy Bower, MSc
Associate Director, Regulatory Biosafety, sanofi-aventis

This session presents requirements for potential GTIs for fixed-dose combination products including case studies involving toxicology evaluation, process, analytical development and regulatory issues.

Requirements for Potential GTIs for Fixed-dose Combination Products: Industry Perspective
Nancy Bower, MSc
Associate Director, Regulatory Biosafety, sanofi-aventis

EU Perspective
David R. Jones, MS, RAC
Expert Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Agency (MHRA), UK

FDA Perspective
Timothy J. McGovern, PhD, MS
Supervisory Pharmacologist, Office of New Drugs, CDER, FDA

Session 278 RA 4 - Regulatory Affairs, PP

2:00 pm-3:30 pm LEVEL: ●

Room 252AB

Foreign Health Authority Inspections of Manufacturing Sites

SESSION CHAIRPERSON(S)
Virginia Beakes-Read, Esq., BSN, JD
Director, Regulatory Policy Liaison, Genentech, Inc.

This session will describe the dramatic increase over the last few years in the numbers of GMP inspections by health authorities inspecting manufacturing facilities outside of their own borders. Panel members will explore concerns related to those inspections, including the threat to manufacturers' intellectual property and the heavy financial and resource burdens for both industry and regulators. These burdens and threats are balanced against the value to the GMP state of the facilities and quality of the products, and thus to public health. US and international protections related to intellectual property, as well as the role and concerns of the foreign health authorities, will be presented.

FDA Perspective
Murray M. Lumpkin, MD
Deputy Commissioner, International and Special Programs, Office of the Commissioner, FDA

The Burden of Duplicative cGMP Inspections
John O'Connor, PhD
Senior Director, Corporate Inspection Management, Genentech, Inc.

EMEA Perspective
Emer Cooke, MBA, MSc
Head of Sector, Inspections, European Medicines Agency, European Union

Session 279 RA 5 - Regulatory Affairs, ERS/DM

2:00 pm-3:30 pm LEVEL: ●

Room 254AB

Best Practices for Preparing a Complete NDA that Warrants a Complete Review by FDA

SESSION CHAIRPERSON(S)
John R. Cutt, PhD
Vice President, US Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

Achieving a formula for successful NDA submissions will be discussed. What are the common errors and how do you avoid them? The filing and successful approval of an NDA is a win-win scenario for patients, FDA and the sponsor. Important life-altering and lifesaving drugs need to be made available to patients using efficient processes for drug development, review and approval. The construction of a complete NDA does not begin at a tracking meeting or when individual reports are being written. Building a strong foundation early in development is critical to success. During construction [of the drug] the level and quality of communication between the architect, the engineers, and the building inspectors, the quality of the building materials used, and the actions taken to remediate deficiencies can result in either a solid home, or a building collapse. A successful NDA submission includes best practices over the life cycle of a drug – the development of a Target Product Profile (TPP), clinical studies to support the TPP, transparent communications during interactions, a first-cycle NDA approval and beyond. The session will explore the following topics: the importance of key milestone meetings – pre-IND, end of phase 2 and pre-NDA/BLA meetings, need to be more effectively utilized to further enhance the probability of first cycle approvals; submission of a complete application is essential. The FDA will speak to reasons why an NDA may be considered incomplete. Are there missing pieces, is the quality not there, or are critical issues not addressed properly?; how implementation of Good Review Management Principles (GRMP) can facilitate first-cycle reviews, improve sponsor and FDA efficiencies, and enhance the quality of the overall regulatory review process.

Enhancing the Probability of First Cycle Approvals
Gregory T. Brophy, PhD
Director, US Regulatory Affairs, Eli Lilly and Company

GRMP Experiences and Proposals for the Future
Taryn Rogalski-Salter, PhD
Vice President, Global Head Regulatory CMC, Novartis Pharmaceuticals Corporation

FDA Perspective
RADM Sandra L. Kweder, MD
Rear Admiral, US Public Health Service; Deputy Director, Office of New Drugs, CDER, FDA

Session 280 RD - R&D Strategy, CR

2:00 pm-3:30 pm LEVEL: ◆

Room 162AB *CME credits offered*

Recent Advances in Adaptive Clinical Trial Designs

SESSION CHAIRPERSON(S)
Lisa A. Jenkins, PhD
Regulatory Group Leader, Kendle International

Adaptive clinical trials hold promise for increasing the probability of success by using more efficient trial designs. Despite criticisms that adaptive trials are more vulnerable to bias and results from such trials may be difficult to interpret, continued advances in research and methodology may be paving the way for mainstream use of adaptive trials from group sequential designs to the most complex Bayesian response-adaptive patient randomization.

Experience with Adaptive Dose-ranging Studies in Learn
Michael Krams, MD
Assistant Vice President, Adaptive Trials, Clinical Development, Wyeth Pharmaceuticals

A Simple and Easy Strategy for Implementing Adaptive Designs in Clinical Development
Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

Regulatory Perspective of the Utility of Adaptive Designs in Early versus Late-phase Drug Development
Sue-Jane Wang, PhD, MA, MS
Associate Director, Adaptive Design and Pharmacogenomics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Session 281 ST - Statistics, CP

2:00 pm-3:30 pm LEVEL: ■

Room 159AB

Meta-analysis and the Postapproval Assessment of Safety Based on Accumulating Data from Clinical Trials

SESSION CHAIRPERSON(S)
Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

Often, following the initial approval of a new therapeutic drug or biologic, additional randomized trials using the product might be conducted to explore new indications/labeling claims, better describe the product's use or, perhaps, for comparison to other drugs/biologics. These postapproval trials provide a source of accumulating data that can be used to better assess safety, potentially contributing to our knowledge of the overall benefit-risk profile of the drug.

As the adverse events of interest might be relatively rare, it is often the practice to combine the results from a number of studies using meta-analysis. However, meta-analyses of these growing databases are not straightforward. It is well known that it can be tough work to do these analyses – to decide on which studies to include, how to characterize the events, how to combine data/results, how to do the analyses, etc. Is there a signal? What is the signal? Is there a cause for concern?

Recent experience, such as the controversy and media excitement surrounding the publication of a meta-analysis conducted using published results to assess the increased cardiac risk of rosiglitazone (Avandia), have illustrated how important it is for statisticians, epidemiologists, and clinical researchers to collaborate closely in thinking about the most scientific methods to assess these accumulating data.

The Evolving Role of Meta-analysis in Evaluating Postmarketing Safety Issues: Where Have We Been and Where Are We Headed?
Judy Racoosin, MD, MPH
Senior Safety Policy Advisor, Safety Policy and Communication Staff, Office of the Center Director, CDER, FDA

Meta-analysis of Dichotomous Events Including the Special Issues in Analyzing Rare Events: The Advantages and Pitfalls
Arlene S. Swern, PhD
Associate Director, MCD, Merck Research Laboratories

FDA Avandia Meta-analysis: Challenges and Choices
Joy D. Mele, MS
Statistician, Division of Biometrics II, CDER, FDA

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

Session 282 TR - Training, MW

2:00 pm-3:30 pm LEVEL: ●

Room 157AB

Networking for Career Advancement and Change

SESSION CHAIRPERSON(S)

Danny A. Benau, PhD
Associate Professor, Biomedical Writing, University of the Sciences in Philadelphia

Networking is one of the keys to successful career development and career change. The dynamics of virtual networking have changed dramatically over the last three years. Online networking for career enhancement has grown out of online social networking. LinkedIn™ and Ryze™ have replaced the more socially oriented MySpace™ and Facebook™ as career-oriented online communities. How can individuals use these to enhance their career paths? Person-to-person networking remains a critical skill in career enhancement. How does one overcome the natural reluctance to interact with strangers and distant acquaintances in order to achieve career goals? How can virtual and personal networking be combined? This session will explore the above questions.

Online Networking
Danny A. Benau, PhD
Associate Professor, Biomedical Writing, University of the Sciences in Philadelphia

Networking Strategies of Biomedical Writers
David Reilly, MS
Medical Writer/Copywriter

Creating and Using Your Personal Brand for Networking
Bill Brown
Senior Managing Director, International Center for Executive Options, Drake Beam Morin Inc
Barbara Sullivan, BSN
Director, Business Development, Drake Beam Morin Inc

Session 283 VA - Validation, IT

2:00 pm-3:30 pm LEVEL: ■

Room 153C

Systems Development Methodologies and Validation

SESSION CHAIRPERSON(S)

Teri E. Stokes, PhD, MS, MT
Director, GXP International

This session will discuss the emergence of agile software development methods, the common characteristics and disciplines of agile methods, and how to harmonize agile methods with validation practices. Practical case experience will be included. Validation documentation and activities should take significantly different paths when supporting in-house development operations as opposed to COTS systems. This session describes these variations (with detailed real-world case studies supporting the underlying concepts) and discusses how and why they fit together with both the GAMP 5 updates and international regulatory objectives.

Validation in an Agile Software Development Environment
Gregg Yost, PhD
Vice President, Engineering, GulfStream Bioinformatics

Differentiation of Validation and Quality Management Strategies Supporting Bespoke versus Commercial Software Systems
Robert D. Hamrick
QA Manager; ASQ CSQE/CSSGB, Agile Technologies, LLC

3:30 pm-4:00 pm **REFRESHMENT BREAK – Exhibit Hall**

Session 284 AHC/IS - Academic Health Centers/ Investigative Sites, PP

4:00 pm-5:30 pm LEVEL: ■

Room 104AB

Severe Adverse Events in Clinical Trials: A Difficult Issue between Sites and Sponsors

SESSION CHAIRPERSON(S)

Gustavo L.F. Kesselring, MD
Director, Clinical Trials Operation, Hospital Alemao Oswaldo Cruz, Brazil

This session will present how one of the top leaders in academic health centers (AHCs) in the US negotiates with sponsors' serious adverse event (SAE) coverage (liability, medical assistance, and hospitalization costs) before a clinical trial starts, how pharmaceutical sponsors and CROs are negotiating with AHC and with for-profit sites' SAE coverage, and how this issue has been treated in emerging countries for clinical trials where personal medical insurance is scarce and not universal (eg, Latin America).

SAE Coverage in Clinical Trials: Sponsors' Responsibilities
Dagoberto de Castro Brandao, MD
Scientific Board, LARAMARA, Brazil

SAE Coverage in Clinical Trials in Latin America
Claudia Mano Senise
Medical Director, PRA International, Brazil

The Negotiation of Subject Injury and Indemnification Terms in Clinical Trial Agreements: An Academic Institution's Perspective
Mary E. Melloni, JD, MBA, RN
Contracts Negotiator, Dana-Farber Cancer Institute

Session 285 BT - Biotechnology, NC

4:00 pm-5:30 pm LEVEL: ●

Room 105 *Nursing credits offered*

Current Experiences in Stem Cell Therapies

SESSION CHAIRPERSON(S)

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

Mahendra Rao, PhD
Vice President, Research, Invitrogen Corporation

Over 500 companies are currently involved in cell therapy technology and approximately 120 of these are involved in stem cell therapies. Cell-based products present similarities as well as complex issues not encountered with traditional biologicals. Mesenchymal stem cells are being used in a series of clinical trials as allogeneic and autologous cells, while embryonic stem cells have been targeted as allogeneic cells for neurological disease. Despite this progress, several issues of CMS manufacture, lot release, and potency assays still need to be finalized. Speakers from both industry and academia with experience in cellular therapy will discuss their experience in submitting INDs as well as designing manufacturing protocols and release criteria.

CMC Manufacturing Issues in Stem Cell Development
Linda L. Kelley, PhD
Associate Professor, Medicine; Director, Cell Therapy Facility, University of Utah

Embryonic Stem Cell Scale-up and Manufacturing
Jane S. Lebkowski, PhD
Senior Vice President, Regenerative Medicine, Geron Corporation

Session 286 CDM - Clinical Data Management, CR

4:00 pm-5:30 pm LEVEL: ■

Room 258C

Meeting the Challenges of Laboratory Data Management

SESSION CHAIRPERSON(S)

Laurie S. Callen
Senior Technical Manager, Clinical Data Management, Synta Pharmaceuticals Corp.

Case studies will be presented that deal with the complexities and challenges of working with laboratory data. Careful consideration of all the factors impacting lab data will lead to efficient maintenance, analysis, and submission.

EDC and Laboratory Data: Opportunities and Challenges
Keith L. Howells
Vice President, Development, Medidata Solutions, Inc.

The View of Data Management from the Central Laboratory
John Raker
Global Director, Clinical Data Management, Covance Central Laboratory Service

Lab Units/Normals Management and Maintenance
Patrick Fredericksen, MBA
Partner, Fountain Database Design, Inc.

Session 287 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, BT

4:00 pm-5:30 pm LEVEL: ■

Room 154 *CME credits offered*

The Relationship between Biopharmaceutics and Quality by Design

SESSION CHAIRPERSON(S)

Richard T. Lostritto, PhD
Director, Division of Pre-Marketing Assessment III and Manufacturing Science (DPAMS). Office of Pharmaceutical Science, Office of New Drug Quality Assessment, CDER, FDA

This session will discuss the role of biopharmaceutics in characterizing in vitro and in vivo drug product performance and demonstrate its value in achieving the clinically desired drug release/dissolution specifications. Serving as a link between the product and the patient/consumer, biopharmaceutics can facilitate leveraging information gained on material attributes and process parameters and in vivo drug product performance to design and ultimately, develop quality products within the target range of parameters.

Arzu Selen, PhD
Associate Director, Biopharmaceutics, Office of Pharmaceutical Science, Office of New Drug Quality Assessment, CDER, FDA

Panel Discussion and Q & A Period

Session 288 CP 1 - Clinical Safety and Pharmacovigilance, CR

4:00 pm-5:30 pm LEVEL: ■

Room 153AB *CME credits offered*

Pharmacovigilance in Latin America

SESSION CHAIRPERSON(S)

Sergio Guerrero, MD
Director, OCA Hospital/Monterrey International Research Center, Mexico

This session will provide current developments related to pharmacovigilance and describe the most recent relevant regulatory aspects in the Latin American region.

Pharmacovigilance in Argentina
Analia Cristina Perez, MS
Director, Medical Evaluations, ANMAT Ministry of Health, Argentina

Pharmacovigilance in Mexico and Central America
Everardo Vazquez, MPharm
Compliance and Clinical Trials Administration Manager, Mexico and Central America, Wyeth S.A. de C.V., Mexico

Pharmacovigilance in Brazil
Murilo Freitas Dias, MSc
Pharmacovigilance Manager, ANVISA, Brazil

Session 289 CP 2 - Clinical Safety and Pharmacovigilance, NHP

4:00 pm-5:30 pm LEVEL: ■

Room 156AB *CME and Nursing credits offered*

OTC Drugs and Nutritional Supplements: The New World of AE/ADR Reporting

SESSION CHAIRPERSON(S)

Jarilyn Dupont, JD
Director, Regulatory Policy, Office of Policy, Planning, and Preparedness, Office of the Commissioner, FDA

The session will provide an overview of the Dietary Supplement and Nonprescription Drug and Consumer Protection Act, Public Law 109-462, which became effective December 22, 2007, and the implementation of the law from the federal regulatory perspective and private industry's perspective. Existing guidances issued by the FDA will be addressed as well as future plans for implementation including comments and concerns relating to the guidances. Technical requirements for filing adverse event reports through the FDA's MedWatch system and future plans for electronic receipt of all reports will be covered. The industry's implementation efforts and the expected impact on its business practices and consumers will be discussed. Other issues of interest will be covered including: the differences in the adverse event report filing requirements for dietary supplements and over-the-counter (non-prescription) drugs and prescription drugs; the potential use of adverse event reports, and the interaction of this law with other laws and regulations on dietary supplements and OTC drugs. A summary of the FDA's experience with the first five months of receiving mandatory adverse event reports for dietary supplements will be discussed. A third-party reporter perspective on issues faced by both OTC drug and dietary supplement manufacturers will be presented including challenges in documenting, categorizing, and interpreting spontaneously reported adverse event data and communicating the reporting experience to the public, regulators, and health professionals.

Dietary Supplement and Nonprescription Drug Consumer Protection Act: Dietary Supplements Update
Vasilios H. Frankos, PhD, MS
Director, Division of Dietary Supplements, CFSAN, FDA

Challenges and Opportunities in Collecting, Documenting, Interpreting and Reporting Spontaneously Reported AE's
Richard Kingston, PharmD
President, Regulatory and Scientific Affairs, SafetyCall™ International; Clinical Professor of Pharmacy and Toxicology, University of Minnesota

Session 290 CR 1 - Clinical Research and Development, ST

4:00 pm-5:30 pm LEVEL: ■

Room 205A

Protocol Deviation/Violation/Exception

SESSION CHAIRPERSON(S)
Eliezer Katz, DrMed
Senior Medical Director, CTI Clinical Trial and Consulting Services

Principal investigators in clinical trials are expected to adhere to the study protocol. Instances of "Protocol Not Followed" (PNF) are not addressed in the CFR or other regulatory rules. The various terms used to describe PNF (violation, deviation, and exception) are open to different interpretations by the parties involved. This session aims to achieve a consensus on a definition of PNF that should be used across clinical trials.

Protocol Deviation/Violation/Exception: How Are They Defined? Why Are They Important? How Should They Be Managed?
Eliezer Katz, DrMed
Senior Medical Director, CTI Clinical Trial and Consulting Services

Introducing a Proactive Approach to Predict and Prevent Clinical Trial Protocol Violations
Pamela H. Atwell
Director, Operational Strategy and Planning, Covance Inc.

Pharmaceutical Company Perspective on Protocol Deviation/Violation/Exception
Patrick M. Nealon, MBA
Senior Director, Clinical Research, Genzyme Corporation

FDA Perspective
Joseph P. Salewski, MS
Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA

Session 291 CR 2 - Clinical Research and Development, AHC/IS

4:00 pm-5:30 pm LEVEL: ■

Room 205B *CME credits offered*

Factors Influencing the Speed of Clinical Trial Study Completion

SESSION CHAIRPERSON(S)
Harold E. Glass, PhD, MSc
Professor, Health Policy, University of the Sciences in Philadelphia

Building on the second results presentation at the 2007 Annual Meeting, this session concentrates on the descriptive quantitative variables which distinguish better performing sites from poorer performing sites.

The Profiles of Successful Sites
Harold E. Glass, PhD, MSc
Professor, Health Policy, University of the Sciences in Philadelphia

Research into the Use of Predictive Metrics to Determine Clinical Performance
Ira C. Spector, MBA
Vice President, Global Development Operation, Wyeth Research

Accurately Predicting Actual Enrollment Per Site: A New Model
Malcolm C. Bohm, MSc
President, SDI trialytics LLC

Session 292 CR 3 - Clinical Research and Development, OS

4:00 pm-5:30 pm LEVEL: ■

Room 203

Letters from the Front: Experiences with Clinical Trials in Asia and Central America

SESSION CHAIRPERSON(S)
Munish Mehra, PhD
Managing Director, Global Drug Development Experts

Asia and Central America are rapidly becoming preferred regions to conduct clinical trials. This session will bring together speakers who have been involved in the recent conduct of phase 2 and 3 studies in Asia (specifically in India and China) and Central America and share their practical examples of what the benefits were, what challenges they faced, and how they overcame them.

Meeting Challenges in Clinical Research in Asia Pacific
Christophe Tournerie, DrMed
Executive Director, PharmaNet, Singapore

A Recent Experience with a Rescue Trial in Guatemala
Benjamin Torun, MD, PhD
President, Director General, CIDAL, Guatemala

From Rescue to Pivotal Trials: The Changing Landscape of Clinical Research in India
Syed Mubarak Naqvi, MD
Vice President, Operations, CliniRx Research Pvt. Ltd., India

Session 293 CTM/CS - Clinical Trial Management/ Clinical Supplies, CR

4:00 pm-5:30 pm LEVEL: ■

Room 204AB

"E"asing the Management of the Clinical Supply Chain: Drug Accountability, Reconciliation, Returns, and Destruction

SESSION CHAIRPERSON(S)

Chuck Harris
Director, Operations, Clinical Technologies Group, United Biosource Corporation

The final and most pivotal step in the supply chain process is drug accountability, reconciliation, return, and destruction. As next generation technologies are being implemented throughout clinical studies, electronic solutions are replacing paper in the drug accountability process in order to streamline the process and eliminate inaccurate data.

Clinical Supply Chain Management
Karen M. Diaz
Associate Director, Clinical Supplies Operations, Daiichi Sankyo

Session 294 EC - eClinical, ERS/DM

4:00 pm-5:30 pm LEVEL: ◆

Room 258B

Standards Shock Therapy: Demystifying the Current and Future Roles of CDISC and HL7 Standards for Clinical Research and Regulatory Submissions

SESSION CHAIRPERSON(S)

Wayne R. Kubick, MBA
Senior Vice President, Phase Forward/Lincoln Technologies, Inc.

This session will help companies understand when to use CDISC and HL7 standards for representing clinical data for various use cases now and in the future.

RPS Case Study
Jason Rock
Chief Information Officer, GlobalSubmit, Inc.

RCRIM Overview
Edward D. Helton, PhD, MA
Chief Scientist, Regulatory and Biomedical Affairs, SAS Institute, Inc.

eDCI Case Study
Donald Kacher
Senior Principal Applications Engineer, Oracle Corporation

FDA Perspective
Armando Oliva, MD
Deputy Director, Bioinformatics, Office of Critical Path Programs, Office of the Commissioner, FDA

Session 295 ERS/DM - Electronic Regulatory Submissions/Document Management, CDM

4:00 pm-5:30 pm LEVEL: ●

Room 257AB

FDA: eCTD Compliance – Part 2 of 2

SESSION CHAIRPERSON(S)

Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

Part 1 of this session will take place on Tuesday at 2:00 pm.

This session is part 2 of Guidance-compliant eCTDs and will provide an overview of FDA's eCTD Guidance.

Module 1
David Roeder, MS
Associate Director for Regulatory Affairs, Office of Antimicrobial Products, Office of New Drugs, CDER, FDA

Module 2
Donovan F. Duggan, II, MBA
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

Module 3
Norman R. Schmuff, PhD
Branch Chief, Division of Pre-Marketing Assessment II, Office of Pharmaceutical Science, CDER, FDA

Modules 4 and 5
Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

Session 296 GCP - Good Clinical Practices, CR

4:00 pm-5:30 pm LEVEL: ■

Room 206AB *Nursing and Pharmacy credits offered*

Planning for and Insuring against the Risk Associated with the Conduct of a Clinical Trial Program

SESSION CHAIRPERSON(S)

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

This session will focus on the current regulatory requirements of risk management and insurance planning for trials. The risk management cycle of risk planning, identification, analysis, response, monitoring, and control will be defined for the audience through the use of a case study of an actual project. The insurance presentation will describe the effect of the insurance placement cost, efficiency, and quality and will focus on clinical trials performed in Europe and Asia.

Clinical Trial Insurance Considerations
Bradley M. John
Vice President, Chubb Life Sciences

Evaluating and Managing the Risk in a Clinical Trial
Sergei Varshavsky, MD, PhD
Chief Executive Officer, Evidence Clinical & Pharmaceutical Research

Session 297 IMP/EBM - Impact (Impact of Medical Products and Therapies)/ Evidence-based Medicines, EC

4:00 pm-5:30 pm LEVEL: ●

Room 208 *Nursing and Pharmacy credits offered*

Patient-reported Outcomes (PRO) Claims: Understanding the Scientific and Regulatory Requirements

SESSION CHAIRPERSON(S)

Josephine M. Norquist, MS
PRO Specialist, Merck & Co., Inc.

The FDA PRO Guidance on PROs has provided a framework for the regulatory review of proposed patient-reported outcome (PRO) label claims. PRO label claims must be supported by substantive scientific evidence and must be precise in the communication of the benefits to the physician and patient. Therefore, the PRO instrument must be conceptually sound, psychometrically valid, and properly matched to the labeling claim. Furthermore, the design of the trial and the analysis plan must be scientifically sound and must also be designed to support the specific labeling claim. This session will review the scientific and regulatory requirements for obtaining PRO label claims. In addition, case examples will be used to illustrate various pitfalls in making sure that PROs, trial design, and analysis plan all support the specific labeling claim.

Overview of FDA Guidance, Conceptual Framework and Endpoint Model
Josephine M. Norquist, MS
PRO Specialist, Merck & Co., Inc.

Issues Arising in Developing Claims Based on PROs from the Sponsor and Vendor Perspectives
William R. Lenderking, PhD
Senior Research Scientist, United Biosource Corporation

Using Multisponsored Collaborative Studies to Improve PRO Research for FDA Submissions
Jane A. Scott, PhD, MA
Research Director, Mapi Values, UK

Regulatory Perspective and Closing Remarks
Laurie Beth Burke, MPH, RPh, CAPT. USPHS
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

Panel Discussion: Examples Linking Labeling Claims to PROs

Session 298 IT - Information Technology, EC

4:00 pm-5:30 pm LEVEL: ■

Room 258A

Utilizing Open Source Software in Clinical Research Environments

SESSION CHAIRPERSON(S)

Cal Collins
CEO, Akaza Research

This session will explore how open, standards-based software can address challenges of flexibility, interoperability, and cost in clinical trials. The panelists will discuss the unique advantages and challenges in developing and using open source software, and review open source technologies used in the clinical trials.

Validation and Quality Concepts in Open Source Clinical Software: Not an Oxymoron
Brian Shoemaker, PhD
Principal Consultant, ShoeBar Associates

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

The Use of Open Source Software in a Clinical Trials Environment
Darin Morley
Director, Application Development, PharPoint Research, Inc.

Session 299A MC - Medical Communications, MW

4:00 pm-5:30 pm LEVEL: ●

Room 253B

Drug Information, Wikipedia, and Google Scholar: Implications for Medical Information

SESSION CHAIRPERSON(S)

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

Web-based medical resources abound, ranging from Google Scholar to Wikipedia. Google Scholar, launched in 2004, searches for scholarly publications; however, search results are influenced by availability and accessibility of the information. Wikipedia was launched January 2001 and has become one of the largest web-based reference websites. Entries in Wikipedia can be generated and changed, often anonymously, by anyone with internet access. The development of WikiScanner in August 2007 has made it easy to identify the network from which changes to Wikipedia entries were made and has revealed self-serving edits made from networks belonging to corporations. Also in August 2007, RxWiki was launched as a web-based reference powered by pharmacists. What is the role of the medical information specialist with regards to drug information on Wikipedia or other internet sites? Do pharmaceutical company medical information personnel have an obligation to monitor drug information on the web for accuracy and balance, as product experts with a health-care background? What are the legal and regulatory implications of editing drug information on nonpeer-reviewed websites like Wikipedia?

Google Scholar: A New Way of Searching for Information
Evelyn R. Hermes-DeSantis, PharmD
Director of Drug Information, Rutgers University

Drug Information on the Web: Implications for Medical Information Specialists
Susanne Lee, PharmD
Senior Global Medical Information Associate - Neuroscience, Eli Lilly and Company

Wikipedia and RxWiki: A Fast Way of Accessing Information
Nesreen El-Toukhy, PharmD
Senior Medical Information Specialist, sanofi-aventis

Session 299B MW - Medical/Scientific Writing, ERS/DM

4:00 pm-5:30 pm LEVEL: ■

Room 153C *CME and Pharmacy credits offered*

Establishing Standards for Medical Writing

SESSION CHAIRPERSON(S)

Art Gertel, MS
Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.

As regulatory processes and documents become more global, there is, by necessity, growing need for standards. These better ensure that across the industry and across geographic regions, the representation of clinical data becomes uniform. This should expedite the preparation and review of the regulatory documentation. The panel will review standards that have emerged during the current phase of globalization, focusing on CDISC, ICH, publication, reporting, posting, authorship, nomenclature, and electronic filing Guidance.

The eCTD Conformable Document and its Impact on Medical Writing
Olaf Schoepke, PhD
Managing Director, Extedo Ltd., UK

Standards as We Know Them: Medical Writers in Lock Step?
Mary Stewart
Director, Medical Writing, H. Lundbeck A/S, Denmark

Session 299C NC - Nonclinical Laboratory Safety Assessment, CR

4:00 pm-5:30 pm LEVEL: ◆

Room 104C *CME credits offered*

Pediatric Drug Development

SESSION CHAIRPERSON(S)

Beatriz Silva Lima, PharmD, PhD
Professor, Pharmacology, CHMP and SAWP member, SWP Chair, University of Lisbon; INFARMED, Portugal

The session intends to update discussions on nonclinical studies for pediatric drugs, the use of juvenile animals, and the views of authorities and industry on the usefulness and compatibility of the existing guidelines in Europe and the US.

One European Experience with Juvenile Animal Studies
Beatriz Silva Lima, PharmD, PhD
Professor, Pharmacology, CHMP and SAWP member, SWP Chair, University of Lisbon; INFARMED, Portugal

FDA Experience on the Request for Juvenile Animal Studies and Guideline Management
Karen L. Davis Bruno, PhD
Supervisory Pharmacologist, Office of New Drugs, CDER, FDA

Comparative Request for Juvenile Animal Studies in the EU and the US: Industry Experience
Mark E. Hurtt, PhD
Head, Global Developmental and Reproductive Toxicology, Pfizer Inc

Session 299D NHP - Natural Health Products, MA

4:00 pm-5:30 pm LEVEL: ●

Room 156C *CME and Pharmacy credits offered*

Evolving Natural Health Products Market Size and Its Development

SESSION CHAIRPERSON(S)
Bernd Eberwein
Executive Director, BAH, Germany

In order to become a part of the huge evolving market for natural health products, one needs to know the current data. In this session, worldwide market data will be presented. The session will also take an extensive look into cosmeceuticals to address the value of this important segment of the market.

Worldwide Market Aspects on NHP
Bernd Eberwein
Executive Director, BAH, Germany

The Regulatory System for Herbal Medicinals in the EU: An Overview
Werner Knoess
Head of Department for Herbal Medicines, Homeopathics and Anthroposophics, Federal Institute for Drugs and Medical Devices, (BfArM), Germany

Cosmeceuticals: Marketing Topical Products without Making Licensable Medicinal Claims in Europe
Peter M. Lassoff, PharmD
Vice President, Europe, PAREXEL Consulting, UK

Session 299E OS - Outsourcing, RA

4:00 pm-5:30 pm LEVEL: ●

Room 205C

Outsourcing Safety Narrative and AE Management to India

SESSION CHAIRPERSON(S)
Rajiv Prasad, MBA
Assistant Vice President, Life Sciences, Satyam Computer Services

This session will identify the key steps in outsourcing routine drug safety narrative writing and adverse event management to health-care professionals in India, in order to free up time for safety surveillance and signal detection.

Session Overview: Outsourcing Safety Narrative and AE Management to Indian Health-care Professionals
Rajiv Prasad, MBA
Assistant Vice President, Life Sciences, Satyam Computer Services

Identify the Key Steps in Outsourcing Routine Drug Safety Narrative Writing, Adverse Event Management, Reporting and Litigation Medical Documentation Support to Health-care Professionals in India
Pradip Advani
Global Head, Business Operations, Nipuna Services Ltd., India

Supporting AE Case Processing and Aggregate Report Authoring from India
Dinesh S. Thakur, MS
President and CEO, Sciformix Corporation

Session 299F PM/FI 1 - Project Management/ Finance, RD

4:00 pm-5:30 pm LEVEL: ◆

Room 103 *Project Management units offered*

Advanced Portfolio Management Methodologies

SESSION CHAIRPERSON(S)
J. Mark Horn, MA
Independent Consultant

This session will present state-of-the-art methodologies for maximizing portfolio value, achieving balance, aligning to strategy, and integrating resource planning. Novel analytical methodologies and portfolio process design strategies will be presented and the use of portfolio management within the pharmaceutical industry will be presented within an historical context. The session level will be advanced and the objective will be to offer attendees actionable alternatives to current practices.

Optimization of R&D Investments for Portfolio Planning and Resource Allocation for Biopharmaceutical Companies
Vladimir Shnaydman, PhD
President, ORBee Consulting

Option Space Mapping
Christian Elze
Senior Partner, Catenion, Germany

Multiobjective Analysis
Jeffrey S. Handen, PhD
Director, R&D Portfolio Management, Merck & Co., Inc.

Session 299G PM/FI 2 - Project Management/ Finance, RD

4:00 pm-5:30 pm LEVEL: ●

Room 102AB *Project Management units offered*

Intelligent Communication: Empowering Pharmaceutical R&D Project Managers for Success

SESSION CHAIRPERSON(S)
Paul S. Hara, PMP
Senior Director, Program Management, MDS Pharma Services

Effective communication is an important tool for pharmaceutical project managers. Having an understanding of emotional intelligence, communication tools and styles aids the project manager in leading successful drug development project teams.

The Project Manager's Guide to Successful Communication in Large Pharma Matrix Organizations
Melanie Ebojo, MBA
Senior Project Manager, Genentech, Inc.

The Value of Flexible Communication in a Small Company
Mary Ann A. Lumiqued, PMP
Senior Manager, Program Management, Anesiva, Inc.

The Importance of Effective Communication in Harnessing the Potential of a True Collaborative Partnership
James M. Huebner, MS
Associate Director, Project Management, RPS, Inc.

Session 299H PP - Public Policy/Law, RA

4:00 pm-5:30 pm LEVEL: ■

Room 160AB

Legislation, GCP, and Ethical Principles Guiding Clinical Trials in China

SESSION CHAIRPERSON(S)

Juhana E. Idänpään-Heikkilä, MD, PhD
Senior Adviser, CIOMS c/o WHO, Finland

China is an increasingly popular location for clinical trials because many leading multinational pharmaceutical companies have moved their clinical research there. National legislation, good clinical practice (GCP) and ethical principles guiding clinical research are under development. The session will review progress made, detail challenges, and provide suggested solutions for investigators and sponsors.

Guiding Principles for Scientific and Ethical Conduct of Clinical Trials in China
Qiu Renzong, PhD
President, Ethics Committee; Professor, Center for Bioethics, Chinese Academy of Social Sciences, China

FDA GCP: Expectations and Experience in China
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science and Director, Good Clinical Practice Program, Office of Science and Health Coordination, Office of the Commissioner, FDA

Session 299I RA 1 - Regulatory Affairs, CR

4:00 pm-5:30 pm LEVEL: ■

Room 256

Fifth Update: Outlook for Changes in the Japanese Regulatory and Clinical Development Environment

SESSION CHAIRPERSON(S)

Hiroshi Matsumori, MS
Executive Director, Regulatory Affairs, PGRD, Tokyo Laboratories, Pfizer Japan Inc., Japan

Robert R. Fike, 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 the future perspective for clinical development and regulatory strategy with a global development program in Japan.

PMDA's Challenges to Reduce the Drug Lag
Kazuhiko Mori, MS
Associate Center Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Challenges for the Pharmaceutical Industry to Realize Simultaneous Global Development and Registration in Japan
Yoshihiko Ono, RPh
Director, Regulatory Policy and Intelligence, Pfizer Japan Inc., Japan

Trend in Review and Clinical Times for New Drugs in Japan
Kuniaki Yasuda
Research Fellow, Office of Pharmaceutical Industry Research, Japan Pharmaceutical Manufacturers Association (JPMA), Japan

Session 299J RA 2 - Regulatory Affairs, RD

4:00 pm-5:30 pm LEVEL: ■

Room 252AB

Establishment of a Regulatory Function in a Startup Biotechnology/Pharmaceutical Company

SESSION CHAIRPERSON(S)

Harriette Nadler, PhD
Vice President, Regulatory Affairs, DDJ Global Pharma LLC

This session is for small biotechnology/pharmaceutical companies who are planning to establish or have recently established a regulatory function. The session will cover the potential roles and skills required for the regulatory head as a multitasking, and often multidisciplinary professional, and provide practical approaches to effectively facilitate regulatory project management, outsourcing, internal product development communications, and benefit the company with tools, eg, eCTD INDs, user-friendly regulatory archives, and submission planning as well as content management, and vendor management from a quality and regulatory perspective.

Paradigm for Success: Alignment of Corporate Goals and Regulatory Experience
Mary Zimmerman
Senior Vice President, Regulatory Affairs and Quality, Cerexa Inc.

Value-added Regulatory Operations
Harriette Nadler, PhD
Vice President, Regulatory Affairs, DDJ Global Pharma LLC

Demystifying the Regulatory Role in Outsourcing Product Development
Howard R. Hubbell, PhD
President, Hubbell Consulting, LLC

Session 299K RA 3 - Regulatory Affairs, CP

4:00 pm-5:30 pm LEVEL: ■

Room 253A

Impact of PDUFA IV Commitments on Review and Evaluation of Trademarks

SESSION CHAIRPERSON(S)

Linda S. Carter
Senior Director, Johnson & Johnson

Approval of the trademark (proprietary name) of a drug or biologic product is an important regulatory and marketing step for manufacturers in the review process for a New Drug Application or Biologics Licensing Application. Currently, 35 to 40% of trademarks submitted to FDA for review by Division of Medical Errors and Technical Support (DMETS), CDER's Office of Surveillance and Epidemiology (OSE) have been rejected. In addition, there have been no metrics for the review of trademarks. This session will discuss the PDUFA IV commitments and how they will be implemented by FDA and industry.

FDA Perspective
Lana L. Pauls, MPH
Director, Quality Management Staff, Office of the Center Director, CDER, FDA

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

Role of Medication Safety in Trademark Naming Practices
Robert E. Lee, Jr., JD, MS
Assistant General Patent Counsel, Eli Lilly and Company

Session 299L RD - R&D Strategy, CR

4:00 pm-5:30 pm LEVEL: ■

Room 162AB *CME credits offered*

Drug Diagnostic Co-development: Implications for Biomarker Validation and Personalized Medicine

SESSION CHAIRPERSON(S)

Jonca C. Bull, MD
Regulatory Policy and Strategy/Product Operations, Genentech, Inc.

This session will provide an overview of current regulatory and scientific issues impacting drug and diagnostic co-development. The implications for biomarker validation and personalized medicine will also be examined.

Regulatory Considerations Related to Biomarker Qualification
Lawrence J. Lesko, PhD
Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA

Drug Diagnostic Codevelopment: Current Policy Considerations
M.J. Finley Austin, PhD
Director, US External Science Policy, F. Hoffmann-La Roche, Inc.

An Industry Perspective on Drug Diagnostic Codevelopment
Bernard Fine, MD, PhD
Associate Group Director, Genentech, Inc.

Session 299M ST - Statistics, RD

4:00 pm-5:30 pm LEVEL: ■

Room 259AB

Novel Statistical Issues from the Regulatory Biostatistician's Viewpoint

SESSION CHAIRPERSON(S)

Tohru Uwoi, PhD
Registered IT Consultant/Executive Director, Data Science, EPS International Co., Ltd., Japan

Globalization of the data acquisition, the necessity for faster drug development, and utilization of innovative biological technology are resourcing new statistical issues. Examples of the issues are global trial designing and analyses methodology, adaptive design/sample size re-estimation, design and analyses of early stage clinical trials, etc. The speakers will give their views on emerging issues.

European Attitudes toward Methodological and Regulatory Advances
Simon Day, PhD
Statistical Expert, Roche Products Ltd., UK

How to Make More Effective and Safer Drugs/Devices Available to the Public Faster: PMDA Statisticians' Perspective
Yuki Ando, MSc
Principal Reviewer for Biostatistics, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Biostatistical Initiatives in CDER: An Update
Robert T. O'Neill, PhD
Director, Office of Biostatistics, CDER, FDA

Session 299N TR - Training, CR

4:00 pm-5:30 pm LEVEL: ●

Room 157AB *Pharmacy credits offered*

Overview of Drug Development for Emerging Professionals

SESSION CHAIRPERSON(S)

Kavita K. Johal, PharmD
Manager, Regulatory Affairs, Otsuka Pharmaceutical Development & Commercialization, Inc.

This session will provide the target audience of emerging professionals (less than 6 years experience) with a basic understanding of the drug development process. It will outline the stages of drug development, how the various functional areas on a development team collaborate to bring a drug from discovery to approval, and postapproval life-cycle management.

Global Regulatory Affairs in Drug Development and Product Life Cycle Management
Yasmin de Faria Krim, PharmD
Manager, CMC Regulatory Affairs, Johnson & Johnson, Belgium

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
Manager, Medical Affairs, ENDO Pharmaceuticals

Session 299O VA - Validation, CP

4:00 pm-5:30 pm LEVEL: ●

Room 253C

Including Risk in Computer Validation

SESSION CHAIRPERSON(S)

Richard L. Chamberlain, PhD, MS
President, ECS, Inc.

This session will present the important aspects of risk management as they apply to computer systems validation and will present some examples.

Risk and Regulation
Representative Invited

What Risk Management Is?
Richard M. Siconolfi, MS
Director, Computer Systems Validation and System Life-cycle Management, Procter & Gamble Pharmaceuticals

Keeping Up with the Joneses Through Risk Management
Cynthia Senerchia, MS, RN
Senior Manager, Quality and Regulatory Compliance, Phase Forward

5:30 pm **END OF TUESDAY SESSIONS**

Wednesday, June 25

7:00 am-4:00 pm **SPEAKER REGISTRATION**
North Lobby, Level 1, BCEC

7:30 am-8:15 am **CONTINENTAL BREAKFAST**
North Lobby, Level 1, BCEC

7:30 am-4:00 pm **ATTENDEE REGISTRATION**
North Lobby, Level 1, BCEC

7:30 am-4:00 pm **EXHIBITOR REGISTRATION**
North Lobby, Level 1, BCEC

9:00 am-2:30 pm **EXHIBITS OPEN**
Exhibit Halls A & B, Exhibit Hall Level, BCEC

5:00 pm-6:00 pm **EMERGING PROFESSIONALS AND STUDENTS NETWORKING RECEPTION**
Grand Ballroom Lobby, Level 3, BCEC

5:15 pm **CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH MEETING**
Room 103, Level 1, BCEC

Session 301 AHC/IS - Academic Health Centers/ Investigative Sites, CR

8:30 am-10:00 am LEVEL: ●

Room 104AB *Nursing credits offered*

Accelerating Research: Integrating Clinical Research with Clinical Care

SESSION CHAIRPERSON(S)

Michael Nourie, MBA
President and Chief Technology Officer, Accelere, Inc.

Today's academic clinical research environment faces new challenges: competing for NIH funding for increasingly complex studies, evolving and changing environment around translational medicine, finding and enrolling patients given complex inclusion/exclusion criteria and complex timing constraints (ie, acute conditions), maintaining patient confidentiality in accordance with HIPAA guidelines while conducting research, and integrating care and research activities on the hospital floor.

This panel will focus on the proven strategies and implementations that radically improve the process of how clinical studies can be planned and conducted within an academic medical setting. The panel will focus specifically on evolving study design, investigator screening, real-time patient screening and recruitment, and research workflow in parallel with quality care.

Decision Support Challenges and Solutions
Stephen K. Woody
Chief Information Officer, Duke Clinical Research Institute

Changing Roles and Responsibilities in Drug Safety: What Is Coming and How Can You Prepare?
Richard C. Dart, MD, PhD
Professor, Surgery, Medicine and Pharmacy, University of Colorado; Director, Rocky Mountain Poison and Drug Center

Accelerating Research: Integrating Clinical Research with Clinical Care
Michael Nourie, MBA
President and Chief Technology Officer, Accelere, Inc.

Session 302 BT - Biotechnology, RA

8:30 am-10:00 am LEVEL: ■

Room 105

Biosimilars/Follow-on Biologics

SESSION CHAIRPERSON(S)

Bruce P. Babbitt, PhD
Principal Consultant, PAREXEL Consulting

Follow-on biologics (FOBs) are second and subsequent versions of biologics that are independently developed and approved after an original version. There remain many complex technical, legal, and regulatory issues associated with the development of FOBs. Speakers in this session will focus on five highly specific scientific/technical aspects of the development of FOBs.

Unique Aspects of the Development of Follow-on Biologics Products
Bruce P. Babbitt, PhD
Principal Consultant, PAREXEL Consulting

Biosimilars: EU Experiences in Regulation
Paul Kuiken
General Manager, Pharmalink Consulting

Possible Regulatory Expectations for FOBs/Biogenerics/Biosimilars
Theresa L. Gerrard, PhD
President, TLG Consulting, Inc.

EU Experiences of Demonstrating Comparability for Biosimilars
Peter Richardson, PhD
Scientific Administrator, Quality of Medicines Sector, European Medicines Agency, European Union

How a Small Manufacturer Views the Evolving FOB Landscape (Development Risks/Legislative Risks)
Glen Kelley, PhD
Vice President, Regulatory Affairs, Insmed, Inc.

Session 303 CDM - Clinical Data Management, CR

8:30 am-10:00 am LEVEL: ■

Room 258C

Imaging Biomarker Data Management

SESSION CHAIRPERSON(S)

Michael Hehenberger, DrSc, PhD
Solutions Executive, Global Life Sciences/Pharma, IBM

This session will discuss the concept of biomarkers and use of clinical biomarkers to increase biopharmaceutical R&D productivity, focusing on the role of imaging as a biomarker for therapeutic drug development, in particular for cancer, neuroscience, and cardiovascular disease. The session will also address IT challenges associated with imaging data management across pharmaceutical companies, CROs, and clinical investigator sites, and how to develop a working solution.

The Impact of Imaging Technologies on Cancer Drug Discovery
Haren Rupani, MD
Global Head, Oncology Imaging, Novartis Pharmaceuticals Corporation

Integration of Imaging into Therapeutic Drug Development
P. David Mozley, MD
Senior Director, Imaging, Merck Research Laboratories

Qualification and Validation of Imaging Biomarkers
George Q. Mills, MD, MBA
Vice President, Medical Imaging Consulting, Perceptive Informatics/PAREXEL

Session 304 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices, RA

8:30 am-10:00 am LEVEL: ■

Room 154

Quality Risk Management

SESSION CHAIRPERSON(S)

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

Case studies and examples of the application of quality risk management as related to the pharmaceutical development process and drug substance facilities will be discussed.

ORM Overview and Case Studies in Biopharmaceutical Drug Substance Facilities
Kristin Murray, MS
Senior Manager, Global Regulatory Affairs, Wyeth Pharmaceuticals
Steve Reich, MS
Risk Management Principal, Wyeth Pharmaceuticals

Risk Management in the Pharmaceutical Development Process
Alton D. Johnson, PhD, RPh
Vice President, Global Manufacturing Services, Marketed Products Support, Pfizer Inc

Panel Discussion and Q & A Period

Session 305 CP - Clinical Safety and Pharmacovigilance, CR

Room 156AB

8:30 am-10:00 am LEVEL: ■

An Industry-regulatory Survey of Benefit-risk Management Best Practices, Including Case Studies

SESSION CHAIRPERSON(S)

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

The results of a benefit-risk management global industry/regulatory survey will be presented. Information provided will enable companies to assess their position and learn from the shared experience, trends, and emerging methods that will assist with benefit-risk management strategies. Specific case studies described by leading industry and regulatory experts will be presented.

Industry and Regulatory Survey of Benefit-risk Management Best Practices
Jennifer Markey
Vice President, Pharmaceuticals, Intrasphere Technologies, Inc., UK

Case Study
John Ferguson, MD
Vice President, Global Head of Pharmacovigilance and Medical Safety, Novartis Vaccines and Diagnostics

Session 306 CR 1 - Clinical Research and Development, CTM/CS

8:30 am-10:00 am LEVEL: ■

Room 205A

Conducting Clinical Trials in China: Status and Trends

SESSION CHAIRPERSON(S)

QingAn Jiao, MD, MS
Director, Clinical Operations, Head of Resourcing Solutions, Asia, MDS Pharma Services, China

China is one of the emerging markets for the conduct of clinical trials and is now playing a more important role in global drug development. Both multinational pharmaceutical companies and global contract research organizations (CROs) are actively conducting global clinical trials in China in compliance with ICH GCP guidelines. This session will cover topics pertaining to conducting clinical trials in China, as well as discuss a summary of a survey conducted in China that showed a significant increase in the number of global trials conducted there by the global pharmaceutical industry, the current level of using CROs in clinical trials, and perspectives from the global pharmaceutical industry on outsourcing more clinical trials in China during the next few years.

Effective and Efficient Interactions: Investigator, Sponsor, and CRO in China
Paul Dai, DrMed
Head, ICRO, Beijing Novartis Pharma Ltd., China

Clinical Trials Grant Status in China: A Survey Report
Frank Fan, DrMed
Medical Director, Abbott China

Outsourcing Clinical Trials in China
QingAn Jiao, MD, MS
Director, Clinical Operations, Head of Resourcing Solutions, Asia, MDS Pharma Services, China

Session 307 CR 2 - Clinical Research and Development, CTM/CS

8:30 am-10:00 am LEVEL: ■

Room 205B

Practical Issues in Industry-sponsored, Investigator-initiated Trials (IITs)

SESSION CHAIRPERSON(S)

Ran Frenkel, RPh
CEO, Pharma Focus Israel

The trend towards industry-sponsored global multicenter investigator-initiated trials (IIT) increases significantly and reaches the operational and regulatory complexities of pivotal studies. The use of IITs needs to be carefully planned by the sponsor, establishing centralized IIT management resources, analyzing conventional tactics, evaluating best practices, challenges, and pitfalls.

Challenges in Investigator-initiated Studies in India
Vijai Kumar, MD
President and Chief Medical Officer, Excel Life Sciences, Inc.

Establishing an IIT Department: Flexible Approaches for Success in a Highly Structured Environment
Ornah T. Dolberg, MD
Senior Medical Manager, IITs, H. Lundbeck A/S, Denmark

Lessons from the FREEDOM Trial: A Large International Multicenter, Multidisciplinary IIT
Michael E. Farkouh, MD, MSc, FACC
Director, Cardiovascular Clinical Trials, The Mount Sinai Medical Center

Session 308 CTM/CS 1 - Clinical Trial Management/Clinical Supplies, CR

8:30 am-10:00 am LEVEL: ■

Room 153AB

Accelerated Recruitment Strategies for Global Megastudies

SESSION CHAIRPERSON(S)

Ken Faulkner, PhD
Vice President, Scientific Services, Synarc Inc.

Concerns regarding drug safety, as well as stricter IRB regulations, have made patient recruitment and retention increasingly difficult for clinical studies. On the other hand, the FDA and other regulatory agencies are requiring longer and larger studies to gain market approval for new compounds. A session devoted to these issues, and strategies to overcome these challenges, is timely for all attendees involved in clinical research. The goals of this session are to highlight the patient recruitment challenges encountered when conducting global megastudies, and to provide alternative strategies to overcome these challenges.

Recruitment Challenges and Strategies: The Sponsor Perspective
Catherine Stehman-Breen, MD, MSc
Vice President, Bone Therapeutic Area, Amgen Inc.

Optimizing Global Recruitment: Adapting to Change
James P. Kremidas
Global Enrollment Optimization, Eli Lilly and Company

Recruitment Challenges and Strategies: The Clinical Perspective
Hans-Detlev Stahl
Founding CEO, Clinpharm International, Germany

Session 309 CTM/CS 2 - Clinical Trial Management/Clinical Supplies, CR

8:30 am-10:00 am LEVEL: ●

Room 204AB

Electronic Data Capture as a Strategy to Enhance Complete Data Capture, Site Satisfaction, and Participation in Registries and Observational Studies

SESSION CHAIRPERSON(S)

Eunice Franklin-Becker, MPH
Project Manager, Registries and Observational Studies, Covance Periapproval Services

In this session, speakers representing CRO, investigative site, and electronic data capture (EDC) design perspectives will discuss site preferences for features of EDC systems and approaches to using EDC that can maximize site recruitment, retention and complete data capture. Considerations based on real program experience and feedback from sites with experience using EDC platforms across different programs will be discussed.

Leveraging EDC to Maximize Site Satisfaction, Data Quality, and Overall Participation in Registries
Jim Primerano, MBA
Senior Director, Portfolio Management, Medidata Solutions Worldwide

EDC as a Strategy to Enhance Complete Data Capture, Site Satisfaction, and Participation in Registries and Observational Studies
Eunice Franklin-Becker, MPH
Project Manager, Registries and Observational Studies, Covance Periapproval Services

Site Perspectives: Real-world Experience with EDC
Cheryl Moore
Clinical Research Coordinator, Georgia Cancer Specialists

Session 310 EC - eClinical, VA

8:30 am-10:00 am LEVEL: ■

Room 258B *CME and Nursing credits offered*

Anatomy of ePRO Validation

SESSION CHAIRPERSON(S)

Keith W. Wenzel
Product Director, ePRO, ClinPhone Inc.

More than 95 new medical entities with a labeling claim based on patient reported outcomes (PRO) data have been approved by the FDA and EMEA since 1995. PRO data is increasingly being collected electronically (ePRO). Systems validation remains an essential component of validation for any study; however, psychometric validation (or evaluation of measurement properties) is an increasingly relevant topic, especially for those using ePRO. This session is sponsored by the DIA's new Patient Reported Outcomes SIAC and is intended to educate and inform the clinical scientist and regulatory communities about the latest best practices in validation. Attendees will be exposed to study designs used to validate instruments that are delivered electronically. In addition, the state of the art for system validation will be presented by a well respected provider of electronic data collection solutions. Finally, the Food and Drug Administration will offer their perspective both on systems and psychometric validations and the most relevant guidelines and regulations that apply to PROs and ePRO.

Psychometric Validation for Electronic Patient Reported Outcomes
Jean Paty, PhD, MS
Founder and Senior Vice President, Quality and Regulatory Affairs, invivodata inc.

Systems Validation for Electronic Patient Reported Outcomes
John M. Weiler, MD
President, CompleWare Corporation

The Regulatory View of ePRO Validation
Laurie Beth Burke, MPH, RPh, CAPT. USPHS
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

Session 311 ERS/DM 1 - Electronic Regulatory Submissions/Document Management, MW

8:30 am-10:00 am LEVEL: ■

Room 256

eCTD: What It Is, What It Is Not, and What It Might Be

SESSION CHAIRPERSON(S)

Kenneth R. VanLuvanee
President and CEO, Apyx Inc.

This session will discuss commonalities and disagreements among even seasoned eCTD professionals, related to implementing eCTD within an organization. The session discusses broader implications of eCTD, such as its document management implications, authoring impact, and the influence of metadata, all from multiple points of perspective.

John Aitken, PhD
Managing Director, West Coast Operations, Octagon Research Solutions, Inc.

Kenneth R. VanLuvanee
President and CEO, Apyx Inc.

Session 312 ERS/DM 2 - Electronic Regulatory Submissions/Document Management, IT

8:30 am-10:00 am LEVEL: ●

Room 157AB

Transitioning from NDAs to eCTD

SESSION CHAIRPERSON(S)

Laura J. Sherman, MBA
Vice President, Enterprise Publishing Solutions, Impact Systems Inc.

Is your organization still submitting paper submissions to the FDA? While the transition from paper to electronic may seem to be a daunting task, this strategic shift can be an effective enabler to gain enterprise efficiencies. This session will focus on examining approaches to address business process changes and organizational challenges such as the new tools, new technology, and infrastructure support. The benefits and advantages of the eCTD format and the standardization of regulatory submission documents will be explored. Industry case studies and supporting data, including both subjective and quantitative, will examine compelling reasons to make the switch to eCTD to improve return on investment and the life-cycle management of your electronic records.

Case Study: eCTD and Business Process Impacts
Joseph R. Baldari
Manager, Document Formats and Standards, Forest Research Institute

eNDA in eCTD Format
William J. Qubeck, IV, MBA
Director, Global Regulatory Operations, Stiefel Laboratories, Inc.

Case Study: Strategy and eCTD Reasons Why to Transition
Matthew J. Neal, MA
Director, Global Regulatory Affairs and Safety, Amgen Inc.

Session 313 GCP - Good Clinical Practices, CR

8:30 am-10:00 am LEVEL: ■

Room 206AB

Current Status of GCP in China and India

SESSION CHAIRPERSON(S)

Munish Mehra, PhD
Managing Director, Global Drug Development Experts

With the rapid increase in the conduct of clinical trials in emerging markets, the importance of knowing specific GCP requirements and ensuring adherence 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.

Indian GCP: The Trials and Tribulations of a Developing Country
Arun D. Bhatt, MD
President, Clininvent Research Pvt. Ltd., India

GCPs in China: Similarities and Differences from ICH GCPs
Daniel Liu, PhD
Director, China Development, Medidata Solutions, China

GCP and Other Current Initiatives in Clinical Research in India
Shehnaz Kairas Vakharia, MS, MRQA
Consultant, QA and Training, India

Session 314 IMP/EBM - Impact (Impact of Medical Products and Therapies)/Evidence-based Medicines, CR

8:30 am-10:00 am LEVEL: ●

Room 208 *CME and Pharmacy credits offered*

The Expanding Use of Genomics Studies: Methods, Regulatory Considerations and the Impact on Evidence-based Medicine

SESSION CHAIRPERSON(S)

Nayan Nanavati, MS, MT
Vice President, Peri Approval Clinical Excellence Americas, PAREXEL International

The inclusion of genomics studies in clinical development plans is increasing dramatically. Genomics protocol structure, regulatory considerations, impact to timelines, cost implications, and methodologies available to protect patient privacy will be explored. The role of genomics data on evidence-based medicine will be debated.

Ramita Tandon
Director, Project Management, Peri-approval Services (PACE), PAREXEL International

Lynn Condreay, PhD
Pharmacogenetics, GlaxoSmithKline

Session 315 IT - Information Technology, CDM

8:30 am-10:00 am LEVEL: ●

Room 258A

Managing Multivendor Projects

SESSION CHAIRPERSON(S)

Ralph Bagley
Director, Information Services, Abt Associates Clinical Trials

Technology projects often require multivendor arrangements to meet the growing business and technical requirements for providing clinical intelligence. However, involving multiple vendors significantly increases the challenges and risks of implementing a successful IT project. This session identifies successful approaches and tactics for planning, communicating, staffing, and support in a multivendor environment.

Effective Communication Tactics
Steven P. Schmidt
Chief Information Officer (CIO), Vertex Pharmaceuticals

Planning Validation Approaches
Sean M. McNiff
Director, Database Programming Services, Genzyme Corporation

Successful Negotiation Tactics
Jennifer R. Goodfellow, MS
Senior Director, Clinical Outsourcing, Sepracor, Inc.

Session 316 MC - Medical Communications, TR

8:30 am-10:00 am LEVEL: ■

Room 253B *Pharmacy credits offered*

Supporting the Business by Building Relationships Beyond Medical Information

SESSION CHAIRPERSON(S)

Kristin R. Reilly, PharmD
Manager, Medical Information, Psychiatry, Ortho McNeil Janssen Scientific Affairs, LLC

The value of medical information in the pharmaceutical industry is continually increasing. Building relationships beyond medical information and identifying opportunities for partnership throughout the business are essential in today's environment. This session will describe unique ways medical information professionals can expand communication and relationships across the business. The session will provide insights into medical information interactions with medical information centers, cross-functional medical groups during development of promotional materials, and medical field colleagues. Each discussion will be facilitated to identify new opportunities and discuss other strategies to improve relationships.

Medical Communication with One Voice: Bridging the Gap between Medical Information Services and Field-based Medical Teams
Anjali Sharma, PharmD
Manager, Regional Scientific Services, Allergan

Improving Communication, Education, and Fostering Relationships between a Medical Information Center (MIC) and a Therapeutic Area
Marybeth Toscano, PharmD, RPh
Manager, Oncology/Urology Medical Information Services, sanofi-aventis

The Value of Developing Cross-functional Medical Alignment to Support the Promotional Review Process
Thomas Malieckal, PharmD
Associate Director, Medical Information, Bristol-Myers Squibb

Session 317 MW - Medical/Scientific Writing, TR

8:30 am-10:00 am LEVEL: ■

Room 153C *CME and Pharmacy credits offered*

Efficiency in Medical Writing

SESSION CHAIRPERSON(S)

Tess Gilbert
Clinical Development Associate, Eli Lilly and Company

How can we work smarter, not harder? We ask ourselves this question often as we assess our current processes and seek to continually improve them. In this session, you'll learn about new techniques and efficient practices that will help you accomplish quality results with fewer resources. Topics include patient narrative generation, medical editing, and strategic document review.

Implementation of a Novel Process for Patient Narrative Generation
Tess Gilbert
Clinical Development Associate, Eli Lilly and Company

Enhancing Strategic Document Review Practices
Gregory P. Cuppan, MA
Managing Principal, McCulley/Cuppan LLC

Medical Editing: How It Can Benefit You
Marc J. Stern
Assistant Director, Document Formats and Standards, Forest Research Institute

Session 318 NC - Nonclinical Laboratory Safety Assessment, RA

8:30 am-10:00 am LEVEL: ■

Room 203

Experience with Exploratory Clinical Trials and their Nonclinical Support Needed

SESSION CHAIRPERSON(S)

Per Spindler, DVM, MBA, MSc
Head, Director, BioLogue, University of Copenhagen, Denmark

The success of drug candidates that enter clinical development is not improving, and if anything is decreasing below the 10% level. As a result, in addition to better nonclinical screening paradigms, there is an increasing regulatory and industry awareness of the value of early clinical data in providing information for better compound and target selection. Since the FDA first published its Guidance on Exploratory IND, efforts by the EMEA and other national governments have been proposed that facilitate more early clinical data being collected prior to entering full development paradigms. These approaches have the intent of safely yielding better clinical development candidate selection with lower resource use. This session will discuss the proposed and available early development options and the industry and regulatory experience to date.

New Exploratory Study Opportunities under the ICH Process
Joseph J. DeGeorge, PhD
Vice President, Safety Assessment, Merck & Co., Inc.

Industry Experiences with Exploratory Approaches for First-in-Man Studies
William T. Robinson, PhD
Consultant, Novartis Pharmaceuticals Corporation

An EU Regulator's Experiences with Exploratory Approaches for First-in-Man Studies
David R. Jones, MSc, RAC
Expert Scientific Officer, Pharmacotoxicologist, Medicines and Healthcare products Agency (MHRA), UK

Session 319 NHP - Natural Health Products, RA

8:30 am-10:00 am LEVEL: ●

Room 156C

Marketing Authorizations in Natural Health Products

SESSION CHAIRPERSON(S)

Werner Knoess
Head of Department for Herbal Medicines, Homeopathics and Anthroposophics, Federal Institute for Drugs and Medical Devices, (BfArM), Germany

Individual marketing authorizations and traditional registrations for NHP will be discussed. The session will also discuss how to avoid failures in receiving the market authorizations. Herbal medicinal products are medicines falling under the normal regulatory rules, but present important special aspects.

Implementation of the Directive on Traditional Medicinal Products and Its Impact on the System of Marketing Authorization and Registration: View of a Competent Authority
Werner Knoess
Head of Department for Herbal Medicines, Homeopathics and Anthroposophics, Federal Institute for Drugs and Medical Devices, (BfArM), Germany

Individual Marketing Authorizations and Traditional Registrations for Herbal Medicinal Products from the View of an Applicant
Rainer Kolkmann
Managing Director, Diapharm Regulatory Services GmbH, Germany

Session 320 OS - Outsourcing, CR

8:30 am-10:00 am LEVEL: ■

Room 205C

The State of Clinical Outsourcing: Results from a 2008 Industry Survey with a Focus on Transforming Business Relationships between Sponsors and CROs – Launching a Program with a Shared Operating Model

SESSION CHAIRPERSON(S)

Patricia Leuchten
President, The Avoca Group, Inc.

Each year, an industry survey of pharmaceutical companies, biotechnology companies, and service providers focused on the state of clinical outsourcing is conducted. Quantitative and qualitative data on a range of topics related to clinical outsourcing are gathered, and these data have been presented for the past five years at DIA's Annual Meeting. In the 2008 survey, the specific topics of delivering results, setting expectations and launching a program with a "shared operating model" will be explored. Data from previous years clearly indicate that both pharmaceutical companies and their clinical service providers associate project and relationship issues with a lack of clarity around expectations. Repeatedly, "mismatched expectations" has emerged as the primary source of conflict in such relationships. When sponsor personnel do not think through their expectations at project start, the end result is often that expectations are not met. Sponsors often admit that they do not take the time to consider, clearly document, and review expectations, in many cases assuming that service organizations know what is expected. CROs state that sponsors often do not communicate specific expectations during the RFP stage and during the project kick-off meeting, making it difficult to determine exactly what is expected of them. Sponsors state that CROs are not proactive about gathering the information they need at the launch of a project. In this interactive and provocative session, quantitative and qualitative data regarding current practices, challenges, and opportunities in the topic areas will be presented. Case studies and best practice processes for both pharmaceutical companies and CROs will be presented.

John W. Hubbard, PhD
President ICON US, ICON Clinical Research

Stephen Cutler, MBA
Senior Vice President, Northeast Region, Quintiles, Inc.

Janet Zebleckes
Director, AstraZeneca

Solomon Babani, MBA
Director, Outsourcing and Vendor Management, Celtic Pharma Development Services

Session 321 PM/FI 1 - Project Management/ Finance, CR

8:30 am-10:00 am LEVEL: ■

Room 102AB *Project Management units offered*

Best Practices Common to Project and Alliance Management

SESSION CHAIRPERSON(S)

David J. Fontana, PhD, PMP
Vice President, Portfolio and Project Management, ZymoGenetics, Inc.

This session will relate the practical experiences and lessons learned for activities common to alliance management and project management. Possible topics that will be covered include program planning and tracking, collaboration and teamwork dynamics, accountability, negotiation, and effectiveness metrics. The session will focus on the practical aspects of cross-functional and cross-company interactions. The session format will include key topics each having a brief introduction followed by perspectives from both alliance management and project management. The session will close with audience discussion.

Rajendra Mohabir, PhD
Site Head, Pharma Development Project Management (PDP), Roche Pharmaceuticals

David J. Fontana, PhD, PMP
Vice President, Portfolio and Project Management, ZymoGenetics, Inc.

Jeremy Ahouse, PhD
Senior Alliance Manager, ImmunoGen, Inc.

Session 322 PM/FI 2 - Project Management/ Finance, CR

8:30 am-10:00 am LEVEL: ■

Room 103 *Project Management units offered*

Increasing Productivity by Scope Management and the Impact on PM

SESSION CHAIRPERSON(S)

Samina Kanwar, PhD, PMP
Associate Director, Project Management, Merck & Co., Inc.

In today's competitive environment, clear definition and management of "scope" for drug development projects is critical to the success of the industry's pipeline. Proactive and innovative scope management in research and development provides an opportunity to enhance productivity across the pharmaceutical industry. Careful scope management can enable alignment of critical activities, resources, methodologies, processes, and procedures around project priorities and complexities. This session will focus on how management of project scope is a key component of managing a project within pharmaceutical research and development; effective management of all activities within a project or program leads to optimal use of resources and increased probability of success, increasing productivity and return on investment.

Learn/Confirm and Project Management: What Have We Learned?
Mark A. Lane, PhD, MS
Director, Project Management, Wyeth Research

Leveraging Technology and Processes to Manage Scope with a Globally Distributed Team
Terri A. Roberson, MBA
Manager, Clinical Operations and Portfolio Administration, Chorus, Eli Lilly and Company

Driving Customer Value into Product Development and Life-cycle Management
Peter DeVilbiss
Senior Director, Merck & Co., Inc.

Session 323 PP 1 - Public Policy/Law, RA

8:30 am-10:00 am LEVEL: ■

Room 160AB

BPCA Reauthorized: What's Next?

SESSION CHAIRPERSON(S)

Chin C. Koerner, MS
Executive Director, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

FDAAA reauthorized BPCA (and PREA) for another five years. As a public policy that advocates more pediatric research this has been a success model which other regions, including Europe, have copied. Companies are now challenged to work globally while acting locally to be compliant with the EU legislation and FDAAA. Moreover, FDA and the EMEA are working together to assess company proposals to determine how best to meet the needs of the pediatric community. In this session what is new under BPCA and PREA will be reviewed, an update will be given on the implementation of the EU legislation, and the collaboration on pediatric efforts between FDA and EMEA will be shared.

Overview of BPCA and PREA as Reauthorized Under FDAAA
Sharon N. Olmstead
Vice President, Regulatory Policy and Intelligence, Schering-Plough

After FDAAA and the EU Pediatric Regulation: Considerations for Developing a Written Request
Melissa S. Tassinari, PhD
Senior Director, Strategic Policy Management, Worldwide Regulatory Policy and Intelligence, Pfizer Inc

Reauthorized PREA and BPCA Implementation
Lisa L. Mathis, MD
Medical Team Leader, Pediatric and Maternal Health, Office of New Drugs, CDER, FDA

Session 324 PP 2 - Public Policy/Law, RA

8:30 am-10:00 am LEVEL: ●

Room 104C

A Progress Report on the Medicare Prescription Drug Benefit: What's Gone Right, What's Gone Wrong

SESSION CHAIRPERSON(S)

Joshua P. Cohen, PhD
Senior Research Fellow, Tufts University

In January 2006 the Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) was implemented. The centerpiece of the MMA is the Medicare Part D drug benefit, managed by PDPs and MAs. Plans have been given unprecedented authority to design and implement formularies to promote clinically appropriate prescribing, while containing growth in prescription drug spending. Formulary design has a significant impact on Medicare beneficiary access to pharmaceuticals. In this session, three experts on formulary management will provide a progress report on the Medicare drug benefit. First we will present an overview of the drug benefit. Second, our session will examine beneficiary satisfaction with the Medicare drug benefit. Third, we will present research findings on coverage of psychotropic medications deemed medically necessary in CMS guidance.

Customer Satisfaction with Medicare Part D
Jim Dougherty
Executive Director, Health Insurance, J.D. Power and Associates

How Commercial Plans Are Managing Psychopharmaceutical Costs and the Implications for Medicare Coverage
Dominic Hodgkin, PhD
Associate Professor, The Heller School, Brandeis University

Medicare Part D Formularies: How They Impact Patient Access as Well as the Biopharmaceutical Industry
Julie Donohue, PhD
Assistant Professor of Health Policy and Management, University of Pittsburgh

Session 325 RA 1 - Regulatory Affairs, CTM/CS

8:30 am-10:00 am LEVEL: ●

Room 254AB

Introduction of the Improvement Endeavors for Clinical Infrastructure by the Main Organizations in Japan – MHLW, JMA, NHO

SESSION CHAIRPERSON(S)

Takatoshi Sato
Professor, Yokohama City University; Executive Director of New Projects, HALD, Inc., Japan

This session will focus on how three main organizations in Japan – Ministry of Health, Labour and Welfare, Japan Medical Association and National Hospital Organization – try to improve the clinical study infrastructure.

MHLW's Initiatives and Regulatory Policy for Future Drug Development in Japan
Yoshikazu Hayashi
Director, Office of Clinical Trial Promotion, Research and Development Division, Ministry of Health, Labour and Welfare (MHLW), Japan

National Hospitals' Initiatives for Clinical Study in Japan
Suminobu Ito
Director, Clinical Research Division, Department of Medical Service, National Hospital Organization Headquarters, Japan

Industries' Perspectives for Future Drug Development in Japan
Noriaki Murao, MS
Representative, Japan Representative Office, Merz Pharmaceuticals GmbH, Japan

Session 326 RA 2 - Regulatory Affairs, CDM

8:30 am-10:00 am LEVEL: ■

Room 253C

Good Review Practices in the US and Canada: An Update and Discussion of Current Developments

SESSION CHAIRPERSON(S)

Howard D. Chazin, MD, MBA
Acting Associate Director for Safety, Office of New Drugs, CDER, FDA

Both the US FDA's Center for Drug Evaluation and Research and Health Canada are independently developing Good Review Practices (GRPs) in order to standardize and promote best practices among their respective review staffs for product reviews. Each independent regulatory organization's attempts to develop GRPs are unique but share similar general fundamental values and processes and are a logical extension of the harmonization efforts of ICH. This session will discuss, update, compare, and contrast the development of GRPs at both the US FDA/CDER and Health Canada and how they advance review science.

Good Review Practices in the United States: An Update
Howard D. Chazin, MD, MBA
Acting Associate Director for Safety, Office of New Drugs, CDER, FDA

An Historical Perspective of Good Review Practices
Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Director for International Programs, CDER, FDA

Good Review Practices at Health Canada: An Update
Caroline Vanneste
Project Manager, Good Review Practices, Therapeutic Products Directorate, Health Canada

Session 327 RA 3 - Regulatory Affairs, NC

8:30 am-10:00 am LEVEL: ●

Room 253A

EMEA Scientific Advice Evolution and Biomarkers

SESSION CHAIRPERSON(S)

Patrick Le Courtois, MD
Head of Unit, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

The EMEA and its Scientific Committee, the CHMP, has further developed the Scientific Advice Procedure where more novel products, novel targets or novel methodologies are considered for normal and for conditional approvals. The session will review the recent development of the Scientific Advice Procedure and the recently made public proposal for qualification for biomarkers and novel methodologies.

How to Get the Best Out of the EMEA Scientific Advice Procedure
Jan Regnstrom, MD
Scientific Administrator, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

The New EMEA Procedure for Qualifications of Biomarkers and Novel Methodologies
Marisa Papaluca-Amati, MD
Deputy Head of Sector, Safety and Efficacy of Medicines, European Medicines Agency, European Union

Biomarker Qualification in Europe: Industry Expectations
Solange Rohou, MD
Director, Regulatory Affairs, AstraZeneca, UK

Session 328 RD - R&D Strategy, PP

8:30 am-10:00 am LEVEL: ●

Room 252AB

Emerging Trends in the Economics of the Pharmaceutical Industry

SESSION CHAIRPERSON(S)

Joseph A. DiMasi, PhD
Director, Economic Analysis, Tufts University

This session will examine data on development times, success rates, development costs, and market dynamics for pharmaceuticals. The implications of industry practices and public policies for R&D productivity and the incentives to innovate will be examined.

Drug Development and the Changing Landscape of Patent Law
Robert Silverman, JD, PhD
Vice President and General Counsel, Concert Pharmaceuticals, Inc.

Trends in Drug Development and Regulatory Approval Metrics
Joseph A. DiMasi, PhD
Director, Economic Analysis, Tufts University

The Future Environment for Pharmaceuticals, Public Policy, and Economics
Richard Manning, PhD
Senior Director, Corporate Policy, Pfizer Inc

Session 329 ST - Statistics, CR

8:30 am-10:00 am LEVEL: ◆

Room 259AB

Obtaining Multiple Endpoint Claims in Product Labels: Issues for Design and Analysis

SESSION CHAIRPERSON(S)

Pilar C. Lim, PhD
Senior Director, Johnson & Johnson Pharmaceutical Research and Development, LLC

Current regulations from health authorities mandate that for inclusion in product labels, claims based on primary and secondary endpoints require prospective designs and analyses addressing the multiplicity. Procedures will be discussed for use in dose-response clinical trials to control the type I error across families of primary and secondary endpoints.

General Stepwise Gatekeeping Procedures
Ajit Tamhane, PhD, MS
Professor and Chairman, Industrial Engineering and Management Sciences Department, Northwestern University, Weinberg College of Arts and Sciences

A Parallel Gatekeeping Procedure for Dose-response Clinical Trials with Multiple Endpoints
Pilar C. Lim, PhD
Senior Director, Johnson & Johnson Pharmaceutical Research and Development, LLC

Statistical Considerations in Handling Multiple Endpoints
H.M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Session 330 TR - Training, CR

8:30 am-10:00 am LEVEL: ■

Room 157AB

Best Practices for Designing and Delivering Training for the Global Deployment of New Technology

SESSION CHAIRPERSON(S)

Yvonne Moores
Head, Programming, Quanticate, UK

A large number of factors need to be taken into account when creating a training strategy that will result in the successful design and delivery of training that supports the global deployment of new technology. This endeavor is further complicated when the training must be designed in parallel with the development of the technology. This session describes the theory behind the design, delivery, and project management of training for the global deployment of analysis and reporting technology to numerous global sites. Key factors that need to be considered are reviewed, as well as features of the strategy and project management plan that need to be in place.

Best Practices for Designing and Delivering Training for the Global Deployment of New Technology
Yvonne Moores
Head, Programming, Quanticate, UK

To "e" or Not to "e": The Benefits and Limitations of eLearning
Pamela Loughner, PhD, MEd
President, Loughner and Associates, Inc.

Effective Technical Contribution to Training Material: Who, How, What, When, and Why
Mark Holland
Programming Group Manager, AstraZeneca, UK

Session 331 VA - Validation

8:30 am-10:00 am LEVEL: ●

Room 251

Source Systems and Maintaining Data Integrity in Clinical Research

SESSION CHAIRPERSON(S)

Barton L. Cobert, MD, FACP, FACG, FFPM
Vice President, Global Regulatory Initiatives and Pharmacovigilance, Medidata Solutions Worldwide

Today's clinical research environment has moved electronic due to the basic need to get products out of research, approved and marketed more quickly. However, this new reliance on computerized systems has raised some issues that are not fundamentally different than those with the paper world. This session will focus on two of those: source and maintaining data integrity.

Ensuring Integrity of Data in Electronic Data Capture Systems
Sourav (Neil) Banerjee
Quality Assurance Manager, Validation, ICON Clinical Research

Clinical Research and Electronic Data Capture: A Site's Perspective
Nelson P. Kopyt, DO, MD, FACP
Director, Research, Northeast Clinical Research Center

Source Data: eRecords versus Paper Records
Stanley C. Rogers
Executive Vice President, R&D Quality Assurance, SMHW Associates, LLC

10:00 am-10:30 am **REFRESHMENT BREAK – Exhibit Hall**

Session 332 AHC/IS - Academic Health Centers/ Investigative Sites, CTM/CS

10:30 am-12:00 pm LEVEL: ■

Room 104AB

Proof-of-concept Clinical Trials and Achieving Enrollment Goals through Centralized Recruitment Tools: It Is More Important than Ever

SESSION CHAIRPERSON(S)

Timothy LaCroix, MBA
Vice President/Engagement Partner, PRA International

Academic health centers frequently serve as investigative sites for proof-of-concept or phase 2 studies due to their unique access to patients. Due to the growing challenges in meeting increasingly difficult enrollment targets and the need for patient populations to be more homogeneous, AHCs need to evaluate centralized patient recruitment tools to ensure meeting enrollment goals and finding the right patients. This session will explore when it is appropriate for AHCs to consider such tools, and how these may best be budgeted. A specific case study will be shared.

The APPLE Experience: Recruiting Patients with a Challenging Disease in an Important POC Study
Laura Schanberg, MD
Associate Professor and Co-chief, Pediatric Rheumatology, Duke University Medical Center

POC Patient Recruitment: The Patient Comes First
Diane Simmons
President and CEO, Center for Information and Study on Clinical Research Participation (CISCRP)

Patient Recruitment Trends and Considerations
Timothy LaCroix, MBA
Vice President/Engagement Partner, PRA International

Session 333 BT - Biotechnology, CR

10:30 am-12:00 pm LEVEL: ◆

Room 105

Biotechnology-derived Products and the Immune System: Management of the Effects of the Interaction(s)

SESSION CHAIRPERSON(S)

Gopalan Narayanan, MD
Head, Biologicals and Biotechnology Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

The relationship between a biological/biotechnology product and the immune system could be in either direction. The effect of the immune system on the product could vary from minimal to profound, at worst producing autoimmunity to endogenous protein. These will need to be thoroughly evaluated. Conversely, biotechnology-derived therapeutic products could affect the immune system through stimulation or suppression. These tend to be more specific to certain types of products.

Evaluation of Immunomodulatory Agents
Stephen Poole, PhD
Parenterals Section Leader, Biotherapeutics Group, National Institute for Biological Standards and Controls (NIBSC), UK

Clinical Aspects
Gopalan Narayanan, MD
Head, Biologicals and Biotechnology Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

The Detection and Characterization of Immunogenicity: The Testing and Interpretation
Steven J. Swanson, PhD
Executive Director, Clinical Immunology, Amgen Inc.

Session 334 CDM - Clinical Data Management, ST

10:30 am-12:00 pm LEVEL: ■

Room 158C

Tools for Integration of Biomarkers

SESSION CHAIRPERSON(S)

Federico Manuel Goodsaid, PhD
Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

There is a very real gap between biomarker data and its accurate application in drug development. This gap is a hurdle for the application of new biomarkers in drug development. Software tools developed by the pharmaceutical industry and the FDA have been developed to accurately map the application of new biomarkers to several nonclinical and clinical steps in drug development.

Novel FDA and Pharmaceutical Industry Software Tools for the Integration of Biomarker Data in Clinical Studies
Federico Manuel Goodsaid, PhD
Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

Finding Opportunities for Pharmacogenetics (PG) in Clinical Development
Aiden Flynn, PhD, MSc
Director, Discovery Biometrics, GlaxoSmithKline, UK

FDA Pharmacogenomic Clinical Study Design (PCSD) Tool for Late Phase 2 and Phase 3 Drug Development
Michael C. Palmer, MS
President, Adaptive Pharmacogenomics, LLC

Session 335 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices

10:30 am-12:00 pm LEVEL: ■

Room 154

Establishing and Presenting Design Space

SESSION CHAIRPERSON(S)

Christine Moore, PhD
Branch Chief, Office of Pharmaceutical Science, Office of New Drug Quality Assessment, CDER, FDA

John Lepore, PhD
Senior Director, Chemical Process Development and Commercialization, Merck & Co., Inc.

Methodologies involved in establishing a design space for pharmaceutical manufacturing and strategies for including design space information in a quality-by-design submission will be discussed.

A Risk-based, Systematic, Science-based Approach to Development of a Drug Substance Process
Nicole Brown
Global Pharmaceutical Commercialization, Merck & Co., Inc.

FDA Perspective
Christine Moore, PhD
Acting Deputy Director, Office of New Drug Quality Assessment, CDER, FDA

Panel Discussion and Q & A Period

Session 336 CP 1 - Clinical Safety and Pharmacovigilance, RA

10:30 am-12:00 pm LEVEL: ■

Room 153AB

Need for the New Risk-benefit Communication Concept Triggered by Regulatory Required Early Signal Notification

SESSION CHAIRPERSON(S)

Andrzej Czarnecki, DrSc, MD, PhD
Director, Deputy Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

Automatic signal detection (ASD) developed significantly in the last decade and is widely used by industry and regulatory authorities. EU law requires prompt notification of any new identified signals/risks. Discussion needs to take place at which point a disproportionality detected event should be notified and how the causality and risk benefit (RB) should be assessed so as to not affect patients' treatment, prevent false alarms, and in extreme, prevent potential litigation.

Early Risk Communication
Paul J. Seligman, MD, MPH, CAPT. USPHS
Associate Director, Safety Policy and Communication, CDER, FDA

Elizabeth J. Swain, RPh
Director, OCMO Operations and R&D Policy, GlaxoSmithKline, UK

Early Signal Disclosure
Andrzej Czarnecki, DrSc, MD, PhD
Director, Deputy Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

Session 337 CP 2 - Clinical Safety and Pharmacovigilance, CR

10:30 am-12:00 pm LEVEL: ■

Room 156AB *CME, Nursing, and Pharmacy credits offered*

Impact of Data Mining in Pharmacovigilance: Current and Future

SESSION CHAIRPERSON(S)

Eric C. Brinsfield, MS
Global Director, Health and Life Sciences, SAS Professional Services, SAS Institute, Inc.

The session will discuss the advantages and disadvantages of investing in data mining for pharmacovigilance. The session will cover past experience, current efforts, and future potential, including what has changed in the safety analysis space that makes data mining more viable and rewarding now than it has been in the past.

Speculations on the Problem
John C. M. Wise, MA
Senior Director, Informatics, Daiichi Sankyo, UK

A Decision Matrix for Selecting Analytic and Data Mining Methods for Pharmacovigilance
Eric C. Brinsfield, MS
Global Director, Health and Life Sciences, SAS Professional Services, SAS Institute, Inc.

Data Mining in Spontaneous versus Active Surveillance Databases: Past, Present, Near Future
Vitali Pool, DrMed
Surveillance and Epidemiology, Global Patient Safety, Eli Lilly and Company

Making Sense of Pharmacovigilance Data: The Limits of Meta-analysis
Steve Gardner, PhD
Senior Consultant, BioLauncher Ltd., UK

Session 338 CR 1 - Clinical Research and Development, OS

10:30 am-12:00 pm LEVEL: ■

Room 205A

Opportunities and Challenges of Globalizing Clinical Research

SESSION CHAIRPERSON(S)

Coreen Oei, PhD
Vice President, Clinical Pharmacology and Discovery Medicine, GlaxoSmithKline

There is an increased trend by major pharmaceutical companies to move clinical testing to Asia, Latin America, and Eastern Europe in an attempt to cut costs and speed up the time it takes to conduct drug trials. Many of these emerging countries offer a vast and inexpensive talent pool, fast-growing R&D capabilities and resources, and a huge treatment-naive patient population. However, most of the offshored clinical activities are confined mainly to the late-phase (phase 3) arena. Following the trend of increased offshoring of late-phase clinical research in nontraditional countries, are there advantages for pharmaceutical companies to globalize the early-phase clinical studies? This session will examine the complexities of conducting international trials with a focus on early-phase clinical development, biotechnology product development, and oncology clinical research in these emerging areas.

Complexities of Conducting International Clinical Trials
Lynn B. Sutton, MSN, RN
Strategic Operational Development Liaison, RPS, Inc.

Early-phase Clinical Research in Emerging Countries: A Large Pharma Company
Coreen Oei, PhD
Vice President, Clinical Pharmacology and Discovery Medicine, GlaxoSmithKline

Adding Value to Early-stage Biotechnology Product Development
Matthias Grossmann, MD, PhD
Vice President and Principal Consultant, Clinical Pharmacology, PAREXEL International GmbH, Germany

Oncological Clinical Research in Emerging Regions
Miguel Angel Salcedo, MBA
Vice President, Clinical Operations, Europe and Africa, AAIPharma, Spain

Session 339 CR 2 - Clinical Research and Development, RD

10:30 am-12:00 pm LEVEL: ■

Room 205B

Global Oncology Product Development: Strategies for Successful Selection of Patient Populations and Study Endpoints in Early-phase Clinical Development

SESSION CHAIRPERSON(S)

Marga Oortgiesen, PhD
Director, Integrated Drug Development, Cato Research, Ltd.

Options for early-phase protocol designs, such as the definition of the patient population and appropriate endpoints to determine proof of concept will be evaluated to optimize the chances for success in pivotal oncology studies. In addition, emerging strategies for pivotal study design will be discussed.

Selection of Patient Populations in Phase 1-2 Studies for Broad-targeted Cancer Drugs
Carolyn Sidor, MD, MBA
Vice President and Chief Medical Officer, EntreMed Inc.

Participation by Clinical Investigators on Early-phase Study Designs
J. Paul Eder, MD
Associate Professor, Harvard Medical School; Clinical Director, Experimental Therapeutics, Dana-Farber Cancer Institute

Maximize the Clinical Oncology Program by Selection of Biomarkers and Pharmacodynamic Endpoints
Marga Oortgiesen, PhD
Director, Integrated Drug Development, Cato Research, Ltd.

Session 340 CTM/CS - Clinical Trial Management/Clinical Supplies, ST

10:30 am-12:00 pm LEVEL: ■

Room 204AB

Future Advancements in Models and Algorithms for the Optimization of Clinical Trial Recruitment: Using Science to Deliver Superior Business Results

SESSION CHAIRPERSON(S)

Cosimo Spera, PhD
Director, Advanced Mathematics, DecisionView, Inc.

For more than 20 years, academic researchers and practitioners have studied patient recruitment in clinical trials. While a variety of models and algorithms have been presented and discussed at a theoretical level, real world implementations have lacked success mostly because of the complexity of the proposed models and algorithms and the difficulty in gathering the data required at the right time. In this session we will show how to overcome these challenges. Our panel of experts will include world-renowned scholars in the field from both academia and industry.

Adaptive Clinical Trials
Valerii V. Fedorov, PhD
Group Director, Research Statistics Unit, GlaxoSmithKline Pharmaceuticals

Recruitment Models in Clinical Trials
Vladimir V. Anisimov, DrSc, PhD
Director, Research Statistics Unit, GlaxoSmithKline, UK

Delivering Superior Results to Optimize Clinical Trial Processes: From Modeling to Implementation to Customers' Satisfaction
Cosimo Spera, PhD
Director, Advanced Mathematics, DecisionView, Inc.

Session 341 EC - eClinical, IT

10:30 am-12:00 pm LEVEL: ●

Room 158B *Nursing credits offered*

Detecting Fraud in the Age of Electronic Records

SESSION CHAIRPERSON(S)

Stephen A. Raymond, PhD
Chief Scientific Officer and Quality Officer, PHT Corporation

We have passed the dawning of the electronic age in clinical research trials, and now have experience with the changed risk and incidence of fraud in comparison to paper methods. This session conveys that experience and also explores the clinical and business impact of fraud today.

eSource and Sources of Fraudulent Data
Stephen A. Raymond, PhD
Chief Scientific Officer and Quality Officer, PHT Corporation

Integrity of Clinical Trial Records in the Electronic Age: FDA Perspective
Patricia Beers Block
Consumer Safety Officer, Office of the Commissioner, FDA

Industry Experience with Integrity of Electronic Records in Clinical Research
Cynthia Senerchia, MS, RN
Senior Manager, Quality and Regulatory Compliance, Phase Forward

Session 342 ERS/DM - Electronic Regulatory Submissions/Document Management, RA

10:30 am-12:00 pm LEVEL: ●

Room 157AB

FDA Standards Initiatives

SESSION CHAIRPERSON(S)

Gary G. Walker
Associate Director, Programming Standards, Global Data Management, Quintiles Transnational Corp.

This session will provide an overview of important FDA data exchange standards initiatives. This overview will include the importance and benefit of the data exchange standard to FDA and industry, an update on the progress of the standard development, adoption, and potential future initiatives.

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

Individual Case Safety Reporting (ICSR)
Lise R. Stevens
Data Standards Project Manager, Office of Critical Path Programs, CBER, FDA

Regulated Product Submission (RPS) Standard
Peggy R. Leizear
Program Analyst, Office of the Commissioner, OPPL/OPL/PS, FDA

Session 343 GCP - Good Clinical Practices, CR

10:30 am-12:00 pm LEVEL: ■

Room 206AB *Nursing and Pharmacy credits offered*

FDA Draft Guidance: Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators/Proactive Solutions for Industry Prior to the Final Guidance

SESSION CHAIRPERSON(S)

Liz Wool
President and CEO, QD-Quality and Training Solutions, Inc.

The emergence of this FDA Draft Guidance in May, 2007 and its short public comments period (July, 2007) indicates the FDAs commitment to finalizing this Guidance for investigators. However, this Guidance document significantly impacts sponsors and CRO methods, standards, and SOPs for study management of drug, medical devices, and biologic clinical trial investigators. This, in turn, impacts the clinical QA department as well as they support the business

in their role. This session will outline the impacted business standards, practices, processes, and SOPs as well as the methods for informing, educating, and training staff to the Guidance document contents, standards for investigators in clinical research, and sponsor/CRO responsibilities.

Overview of the FDA Guidance Document
John A. Coundouris, PhD
Director, Quality Compliance, Tercica

Clinical Research Sites: Responsibilities and Methods for Implementation of Guidance Document
Ellen L. Hoverson
Manager, Hepatology Research, Department of Transplant, California Pacific Medical Center

Institutional Review Boards: Methods and Standards for Implementation of Guidance Document
Felix A. Gyi, PharmD, MBA
Chief Executive Officer, Chesapeake Research Review, Inc.

Sponsors/CRO: Best Practices, Standards, and Solutions for Investigator/Site Assessments and Study Oversight
Liz Wool
President and CEO, QD-Quality and Training Solutions, Inc.

Session 344 IMP/EBM - Impact (Impact of Medical Products and Therapies)/Evidence-based Medicines, ST

10:30 am-12:00 pm LEVEL: ■

Room 208 *CME and Pharmacy credits offered*

Evidence from Observational Studies for Evidence-based Medicine

SESSION CHAIRPERSON(S)
Thomas Goss, PharmD
Vice President, Outcomes and Observational Studies, Covance Inc.

There is a growing need for real-world data on the use of medical products and therapies to monitor ongoing safety and to document product value. This session will address how observational data is used in developing evidence for decision makers. Speakers will focus on the purpose, design, and use of data from large simple trials, registries (including pregnancy registries), and other observational designs that can be used to meet these needs. Speakers will use case studies and highlight strengths and limitations of observational data, and discuss best practices to enhance the rigor of observational studies.

The Role of Observational Studies in Demonstrating Product Value and Benchmarking Product Safety
Thomas Goss, PharmD
Vice President, Outcomes and Observational Studies, Covance Inc.

Lessons from Observational Studies of Pregnancy: Registries and Databases
Annette Stemhagen, DrPH, FISPE
Vice President, Epidemiology and Risk Management, United Biosource Corporation

Generating Evidence for Comparative Effectiveness through Observational Studies and Trials
Richard Gliklich, MD
President and CEO, Outcome Sciences, Inc. dba Outcome

Session 345 IT - Information Technology, CP

10:30 am-12:00 pm LEVEL: ■

Room 258A

SaaS (Software as a Service): How eSubmissions, eClinical, and Outsourcing Are Creating a Paradigm Shift in Pharmacovigilance

SESSION CHAIRPERSON(S)
Sanket Agrawal, MBA
Chief Strategy Officer, Relsys International, Inc.

SaaS (Software as a Service) has brought significant time and cost advantages to many application verticals and industries, such as CRM, and even clinical trials. The intersection of open data standards in PV (E2b, eSubs), success of eClinical technologies, and outsourcing trends have all combined to create an opportunity to introduce SaaS for PV. This session will present case studies to outline current offerings, technology trends, and how PV departments will be able to leverage SaaS to go beyond just outsourcing.

New Pharmacovigilance Business Models: Making the Best Operational Choices for the Right Reasons, with the Support of Information Technology
Wendy P. Stephenson, MD, MPH, MS
President, Wendy Stephenson & Associates LLC

Opportunities Offered by the Combination of SaaS and BPO for Transformation of PV Operations: Industry-leading Case Studies from 2007 and Strategies that Will Mark 2008 as the Turning Point in PV Operational Excellence
Eric Sandor
Partner, Accenture, UK

Best Practice Pharmacovigilance SaaS and Services Framework for Small- and Mid-sized Pharmaceutical Companies: Models, Benefits, and Considerations
Uwe P. Trinks, PhD
Chief Information Officer, Sentrx

Session 346 MA - Marketing, TR

10:30 am-12:00 pm LEVEL: ●

Room 104C *Pharmacy credits offered*

Marketing Yourself as a Candidate in a Competitive Clinical Research Job Market

SESSION CHAIRPERSON(S)
Bill Neese, MBA
Director, Global Recruitment, Kendle International

The session is intended to educate attendees on the current status of the clinical research job market by informing them of the current challenges/practices of candidates who are attempting to market themselves to a clinical research organization.

Marketing Yourself as a Candidate in a Competitive Clinical Research Job Market
Bill Neese, MBA
Director, Global Recruitment, Kendle International

Session 347 MC - Medical Communications, IMP/EBM

10:30 am-12:00 pm LEVEL: ■

Room 253B *CME, Nursing, and Pharmacy credits offered*

Interactions with Drug Information Compendia: On-label, Off-label, Past, Present, and Future

SESSION CHAIRPERSON(S)

Laura Opincar, PharmD
Senior Medical Information Associate, Eli Lilly and Company

Health-care professionals rely on drug information compendia for both on- and off-label information, as well as treatment guidelines established by health care organizations for an application of the evidence base on the appropriate (safe and effective) use of medication for clinical decision making. This session will provide background on the off-label use of medications, specifically relating to compendia including: which compendia are recognized by CMS, how a medically accepted indication for off-label use is determined, how CMS assesses which compendia will be recognized, and how the inclusion of an off-label use in CMS-recognized compendia affects patient care. New developments in the process for submitting information to compendia, as well as new developments at CMS regarding the inclusion of new compendia will be discussed. The role of a pharmaceutical company's medical information department in interacting with compendia for both on- and off-label uses will be described. In addition, a case study of the timeliness of updates to compendia for on-label information and labeling changes will be presented.

On-label Information Communications with Drug Information Compendia
Laura Opincar, PharmD
Senior Medical Information Associate, Eli Lilly and Company

Patient Access to Treatment Options: Current State and New Developments
Christian Downs, JD, MHA
Executive Director, Association of Community Cancer Centers

Compendia Submissions for Off-label Information: An Industry and Historical Perspective
Christine Wyble, PharmD
Director, Oncology/Urology Medical Information Services, sanofi-aventis

Session 348 MW - Medical/Scientific Writing, CR

10:30 am-12:00 pm LEVEL: ●

Room 153C

Patterns and Practices of Clinical Research Document Content Reuse by Pharmaceutical Sponsors

SESSION CHAIRPERSON(S)

Fredric Cohen, MD
President, Pharma Growth Strategies, LLC

Systematic reuse of regulatory document content could reduce development time, while preserving or enhancing document quality. Knowing current practices of content reuse will help determine where to intervene with enabling technologies and the value such intervention could be expected to yield.

Reuse of Text and Information from Clinical Protocols
Edward Stephen Seguine, Jr., MBA
General Manager, Trial Planning, Medidata Solutions Worldwide

Reuse of Text and Information from Core and Local Labeling
A. Leander Fontaine, DrMed
President, Pharmiceutics LLC

Content Sources and Mechanisms of Reuse in Clinical CTD Documents
Patricia Valencia, PharmD, RPh
Associate Director, Pfizer Inc

Session 349 NC - Nonclinical Laboratory Safety Assessment, BT

10:30 am-12:00 pm LEVEL: ■

Room 203 *CME credits offered*

High Dose Selection in General Toxicology Studies

SESSION CHAIRPERSON(S)

Abigail C. Jacobs, PhD
Associate Director, Pharmacology/Toxicology, Office of New Drugs, CDER, FDA

Nonclinical studies are conducted to support clinical studies and use of a pharmaceutical in humans. Often toxicology studies are conducted to include a high dose that is characterized as identifying dose-limiting toxicity (ie, identification of a maximum tolerated dose [MTD]), regardless of exposure margins projected to the clinical exposure. This approach is repeated throughout the preclinical development testing. The questions that often arise are: How is the MTD defined? Need it be re-identified throughout the testing duration? What is the value of this endpoint in supporting clinical development? There is a wide diversity of opinion on the appropriateness of continuously assessing for an MTD and whether studies at some multiple of the human exposure in animals, rather than an MTD, could sufficiently assure safety in humans, particularly if the dose-limiting toxicity that has been identified can be monitored in clinical studies. This is a critical issue that encompasses scientific and ethical, both human and nonhuman, considerations.

Addressing Animal Welfare Regulations in Toxicology Study Design
Jodie Kulpa-Eddy, DVM
Staff Veterinarian, APHIS, Animal Care, US Department of Agriculture

FDA Perspective
Todd Bourcier, PhD
Team Leader, Division of Metabolic and Endocrine Products, Office of New Drugs, CDER, FDA

Industry Perspective
Michael A. Dorato, PhD
Executive Director, Toxicology, Eli Lilly and Company

Panelist

Joseph J. DeGeorge, PhD
Vice President, Safety Assessment, Merck & Co., Inc.

Session 350 NHP - Natural Health Products, CR

10:30 am-12:00 pm LEVEL: ■

Room 156C

Natural Health Products Quality Control

SESSION CHAIRPERSON(S)

I-Chen Sun, PhD
Reviewer, Center for Drug Evaluation, Taiwan

Quality control is one of the most vital segments in the entire research and development program of natural health products. Discussion will focus on the perspective from a regulator and the expectation from the sponsor or the manufacturer to avoid rejection in marketing authorizations. An industry or academic perspective in developing quality control with botanicals will also be discussed.

Building Quality for Botanical Drugs: A Regulatory Perspective
I-Chen Sun, PhD
Reviewer, Center for Drug Evaluation, Taiwan

Quality Control of Multicomponent Botanicals
Mahabir P. Gupta, PhD
Director, CIFLORPAN and Research Professor of Pharmacognosy, University of Panama

A Comprehensive Approach to Botanical Quality Control: A Case Study of PHY906
Robert Tilton, PhD
Vice President, Science and Technology, Phytoceutica, Inc.

Session 351 OS - Outsourcing, CR

10:30 am-12:00 pm LEVEL: ■

Room 205C

Outsourcing: Where Is It Now and Where Is It Going?

SESSION CHAIRPERSON(S)

Harold E. Glass, PhD, MSc
Professor, Health Policy, University of the Sciences in Philadelphia

The University of the Sciences in Philadelphia (USP) conducted an in-person and web-based survey of sponsor pharmaceutical companies and CROs on their thoughts and perceptions on clinical outsourcing. Over 400 people from 100 companies took part in the study. The session will highlight the findings as well as the management and training implications of the findings.

How Do CROs and Sponsor Companies View Each Other?
Harold E. Glass, PhD, MSc
Professor, Health Policy, University of the Sciences in Philadelphia

Outsourcing: Where Is It Going?
David W. Gillogly, MBA
Senior Director, Outsourcing and Alliance Management, Daiichi Sankyo Pharma Development

CRO Selection Criteria
Jim Laughlin
Vice President, TTC, LLC

Session 352 PM/FI 1 - Project Management/ Finance, CR

10:30 am-12:00 pm LEVEL: ■

Room 103 *Project Management units offered*

The Next Generation of Project Managers: PMs as CEOs

SESSION CHAIRPERSON(S)

Munish Mehra, PhD
Managing Director, Global Drug Development Experts

Project managers are the key individuals who lead project teams to ensure clinical trials are conducted well and per aggressive timelines. Their skills include strong leadership which inspires team members as they lead by example. A strong knowledge of conducting trials, a level of humility, respect, and recognizing each team member's role while focusing each individual on "getting things done" is what the new generation of PMs are able to do.

Preparing Project Managers to Lead
Ron Corey, PhD, MBA, RPh
Executive Director, Clinical and Project Management, Asubio Pharmaceuticals

Critical Chain PM: Improving Reliable Delivery and Accelerating Timelines
Jason C. Bork
Manager, Project Management Excellence, Eli Lilly and Company

The Effective Project Manager's Toolkit
Munish Mehra, PhD
Managing Director, Global Drug Development Experts

Session 353 PM/FI 2 - Project Management/ Finance, RD

10:30 am-12:00 pm LEVEL: ■

Room 102AB *Project Management units offered*

Identification of Opportunities between CRO and Pharma for Synergistic Application of Lean Six Sigma

SESSION CHAIRPERSON(S)

Michel Roy, MSc
Director, Program Management, MDS Pharma Services, Canada

Historically, Lean Six Sigma has been used in the manufacturing industry with great success. Recently the same techniques are being applied in the service industry. In fact, contract research organizations (CROs) and the pharmaceutical industry are utilizing the Lean Six Sigma (LSS) methodology in order to meet the voice of the customer and improve operational efficiencies. While both CROs and the pharmaceutical industry have respectively implemented LSS, neither have undertaken the challenge of creating synergistic partnerships in order to address common issues. The pharmaceutical industry has become a very competitive environment. The main objective for a pharmaceutical or biotechnology company is to bring their drugs to market as rapidly and as cost effectively as possible. In order to meet this constant market pressure, some CROs and pharmaceutical companies have started to deploy Lean Six Sigma methodology within their organizations. This methodology has been demonstrated to be very helpful in reducing cost, cycle and lead time and incurring fewer errors in the drug development process. The next level of maturity for Lean Six Sigma within both CRO and pharmaceutical companies is the development of partnered projects focused on combined successes in delivering shorter cycle times.

Implementing Lean Six Sigma Methodology in a Contract Research Organization (CRO)
Michel Roy, MSc
Director, Program Management, MDS Pharma Services, Canada

Examples of Clinical Lean Six Sigma Project Portfolio within the Pharmaceutical Industry
Trafford Clarke, PhD
Executive Director, Six Sigma, Eli Lilly and Company

Using Lean Six Sigma to Promote Synergy and Partnership Development
David T. Asher, MBA
Chief Executive Officer, Asher Associates, Inc.

Session 354 PP - Public Policy/Law, RA

10:30 am-12:00 pm LEVEL: ■

Room 160AB *Nursing credits offered*

Drug Counterfeiting: A Public Health Threat, Coordinated Fight and Prevention

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 fighting fiercely. The FDA has developed and implemented a proactive policy. 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.

Industry-coordinated Actions with other Stakeholders: The Example of Good Distribution Practices
Yves Juillet, MD, PhD
Senior Advisor, LEEM, France

IMPACT: The WHO Initiative – Coordination of Actions Involving All Stakeholders
Valerio Reggi
Coordinator, Medicines Regulatory Support, World Health Organization, Switzerland

Anti-counterfeiting Activity in the US
C. Michelle Limoli, PharmD
International Policy Analyst, Office of International Programs, Office of the Commissioner, FDA

Session 355 RA 1 - Regulatory Affairs, CR

10:30 am-12:00 pm LEVEL: ■

Room 253A

The Latest Regulatory Perspective for Pharmacogenomics in Japan

SESSION CHAIRPERSON(S)
Yasuhiko Imai, MSc
Manager, Clinical Pharmacology, Early Development, Bristol-Myers K.K., Japan

First, we would like to introduce the current status of Japan PGx guidelines which has been drafted by MHLW on the basis of a concept paper document discussed among MHLW, PMDA, and JPMA. These documents will involve all pharmacogenomic issues in clinical trials conducted on the basis of GCP standards and ethics standards. Second, we would like to see how and what pharmacogenomic data was integrated from clinical research and development in Japan. If available, our experiences in genomic data submission may make a difference to the regulatory review process for them. Third, we would like to consider how we should qualify pharmacogenomic biomarkers for the patient's benefit, which will lead to a reliable personalized therapy in the near future.

How Should PGx Biomarkers Be Available in Clinical Trials?
Yasuhiko Imai, MSc
Manager, Clinical Pharmacology, Early Development, Bristol-Myers K.K., Japan

PMDA Perspective
Akihiro Ishiguro, MSc
Drug Safety Division, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

A Molecular-epidemiological Study for Discovery of a Novel Drug Target for Parkinson's Disease
Takeo Kato, MD, PhD
Professor and Chairman, DNHMED, Department of Internal Medicine and Therapeutics, Yamagata University School of Medicine, Japan

Session 356 RA 2 - Regulatory Affairs, RD

10:30 am-12:00 pm LEVEL: ■

Room 253C *CME and Pharmacy credits offered*

You Can't Plan Too Early for Your Drug's Final Labeling: Tools that Sponsors Use to Begin with the End in Mind

SESSION CHAIRPERSON(S)
Michael Robert Langley, DVM, MBA, RAC
Associate Director, Regulatory Affairs, Eli Lilly and Company

Sponsors use a variety of tools to help guide the drug development process. These tools have various names, such as 'Draft Launch Label' or 'Target Drug Development Tool'. Some sponsors use the Target Product Profile (TPP) as an internal planning tool. But all these tools are used to provide drug development teams with a means to conduct thoughtful, structured planning, early in the drug development process, for the statements desired on the eventual global label. Drug development teams need to consider in a disciplined manner the efficacy, safety, health outcomes, formulation, and other aspects of the final product and the product label very early in the development process. Such planning allows teams to conduct the right studies, both preclinical and clinical, to allow for successful drug approval and launch while at the same time making the most efficient use of scarce development resources. This session will discuss examples of the internal planning tools used by sponsors, as well as how they interact with, and complement, the use of the TPP. A case study exploring the issues in developing a Draft Launch Label for a specific product will be discussed. The session will contain practical advice, from the speakers' own experience, on the development and use of such planning tools.

The ''Label as Driver'' Concept and Use of the ''Draft Launch Label'' Tool to Drive Drug Development Plans
Michael Robert Langley, DVM, MBA, RAC
Associate Director, Regulatory Affairs, Eli Lilly and Company

The TPP: A Tool to Meet Both FDA and Sponsor's Needs
Ingrid Stahl Bryzinski, MS, RPh
Director, Strategic Global Labeling, Abbott Laboratories

Globalization of Labels: Impacts Pre- and Postapproval
Barbara Kolb, RAC
Senior Director, Global Regulatory Affairs, Johnson & Johnson Pharmaceutical Research and Development, LLC.

Session 357 RA 3 - Regulatory Affairs, CR

10:30 am-12:00 pm LEVEL: ■

Room 254AB

After-action: One-year Experience after FDA Guidance on the Target Product Profile

SESSION CHAIRPERSON(S)
Cheryl Beal Anderson, PharmD, RAC
Director, US Regulatory Affairs, Eli Lilly and Company

The Target Product Profile (TPP) is an FDA, PhRMA endorsed initiative to increase efficiency between FDA and sponsors and expedite drug development. The FDA issued its Draft Guidance in March 2007. A TPP is a nonbinding document that sponsors voluntarily submit to the FDA to facilitate discussion of the strategic intent and labeling goals of a clinical drug development program. The objective of this session is to provide an update on the impact of TPP from a PhRMA and FDA perspective when meeting with the FDA since the issuance of the FDA Draft Guidance document.

The PhRMA Perspective on TPP One Year Later: How Has Generating the TPP Changed at Drugs Rx, Inc.?
Teresa P. Dowling, PharmD
Director, Promotional Regulatory Affairs, AstraZeneca

The PhRMA Perspective on TPP One Year Later: How Have FDA Meetings Changed?
Daniel R. Brady, PhD, MA, RAC
Associate Director, US Regulatory Affairs, Eli Lilly and Company

The FDA Perspective on TPP One Year Later: How Have FDA Meetings Changed?
Laurie Beth Burke, MPH, RPh, CAPT. USPHS
Director, Study Endpoints and Labeling Development Team, Office of New Drugs, CDER, FDA

Session 358 RA 4 - Regulatory Affairs

10:30 am-12:00 pm LEVEL: ■

Room 256

EudraCT Latest Developments Including Public Information on Clinical Trials

SESSION CHAIRPERSON(S)

Fergus Sweeney, PhD
Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, European Medicines Agency, European Union

The current developments of the EudraCT system, and related guidelines will be presented and discussed. In particular the session will address the implementation of the EU legislation relating to the public of information on clinical trials, and on their results.

EMEA Perspective
Agnès Saint Raymond, MD
Head of Sector, Scientific Advice, Pediatrics and Orphan Drugs, Preauthorization Evaluation of Medicines for Human Use, European Medicines Agency, European Union

Brian Davis, MD
Consultant in Clinical Trials, Department of Health, Medicines and Healthcare products Agency (MHRA), UK

Detlef Niese, MD
Head, External Affairs, Clinical Development & Medical Affairs, Novartis Pharma AG, Switzerland

Session 359 RD - R&D Strategy, CR

10:30 am-12:00 pm LEVEL: ■

Room 252AB

Integrating Market Perspectives into R&D Strategy

SESSION CHAIRPERSON(S)

Schumarry Chao, MD, MBA
School of Medicine and School of Pharmacy; President, PMAC, University of Southern California

In the US private health-care system, market stakeholders are evolving in how they define and seek value. At the same time, clinicians are continually seeking value based on the best interests of their patients. Other stakeholders also have a keen eye for value, namely financial market investors. This session will provide various stakeholder perspectives of value and discuss their market implications. It will further describe innovative models which are being developed and applied in the R&D process to optimize product value. Examples help manufacturers in considering stakeholder input on trial design throughout the R&D process, definition of trial and study endpoints, points of differentiation as seen from multiple outside stakeholders, perspectives on market potential such as likely size of target population for access, likely reimbursement and pricing, and likely controls for access.

Market Assessment of Value for Coverage and Reimbursement
Schumarry Chao, MD, MBA
School of Medicine and School of Pharmacy; President, PMAC, University of Southern California

Trends of Integrating Stakeholder Perspectives into R&D Strategy and Development Cycle
Stephen Teller
Managing Director, Co-founder, Parallax Life Sciences Consulting

Window to the Future of Drug Value Assessment
Sonya J. Lewis, RPh, MBA
Pharmacy Director, BCBS of Colorado/Nevada; Adjunct Professor/Lecturer, University of Colorado School of Pharmacy, Denver School of Nursing

Session 360 ST - Statistics, CP

10:30 am-12:00 pm LEVEL: ■

Room 259AB *Pharmacy credits offered*

How to Assess Drug Risk when Considering Diversity of Patient Populations and Medical Cultures

SESSION CHAIRPERSON(S)

Joachim Vollmar, MSc
Executive Consultant, International Clinical Development Consultants, LLC

Jürgen Kübler, PhD
Global Head, Integrated Safety and Health Economics Biostatistics, Novartis Pharma AG, Switzerland

This session will investigate the differences in medical terminology and coding practice, differences in special medical expertise of investigators, and cultural differences on reporting of adverse events in clinical trials. Case studies will be presented from clinical development programs where these aspects were explored. Examples for differences in medical terminology and their potential impact on coding will be given.

Implications for risk assessment will be discussed both for the reporting of individual clinical studies, especially for multiregional trials, and for the Summary of Clinical Safety. Search strategies to identify adverse events of special interest and for case adjudications will be considered, and the impact on the use and interpretation of background/placebo incidence rates will be discussed. A panel discussion will include the industry as well as the regulatory view.

Introduction
Joachim Vollmar, MSc
Executive Consultant, International Clinical Development Consultants, LLC

My Liver, My Heart: Country-specific Reporting of Adverse Events
Andreas Brueckner
Statistician, Bayer Healthcare AG, Germany

Safety Assessments: Diversity of Risk Factors
Irina Baeumer, MD, PharmD, PhD
Senior Director, ICON Clinical Research, Germany

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

Session 361 TR - Training, GCP

10:30 am-12:00 pm LEVEL: ●

Room 157AB

Generations in the Workplace: Battlefield or Playground?

SESSION CHAIRPERSON(S)

Barbara C. Van Der Schalie, MS
Clinical Trials Manager, SAIC-Frederick, Inc.

One of the most critical elements of a successful training event is appropriateness of the training for the specific audience. This session will focus on addressing various aspects of an extremely diverse workplace training audience. Learning style preferences, generational differences and cultural diversity as they influence instructional design and training delivery will be discussed. Knowing their audience will allow trainers to maximize their training effectiveness and increase their return on investment.

Learning Style Diversity
Betty R. Kuhnert, PhD, MBA
Executive Director, Training Services, PharmaNet

Generations in the Workplace: Battlefield or Playground?
Barbara C. Van Der Schalie, MS
Clinical Trials Manager, SAIC-Frederick, Inc.

Cultural Implications on Training
Joanne W. Cochran, MEd
Principal, JWC Training Associates

Session 362 VA - Validation, CDM

10:30 am-12:00 pm LEVEL: ■

Room 251

eSources: What Are They and How Do We Deal with Them?

SESSION CHAIRPERSON(S)

Joanne S. Malia, MS, MSc
Associate Director, Medical Research Process Management, Purdue Pharma

This session will present three different types of eSource records typically found in clinical research. In each case the source record will be defined. Additionally, the discussion will continue with best practices and validation topics which lead to protecting and preserving data quality and integrity.

Clinical Lab Considerations
Stacy Kirn Barker, MT
Project Manager, LabConnect LLC

Electronic Patient Diaries: Validation in an Unsupervised Setting
Brian Tiplady
Senior Clinical Scientist, invivodata, inc., UK

Electronic Medical Records: A Fully Integrated System at the VA
Deborah Sullivan
VA Medical Center - IRM
Benita Constantino, MT
IT Specialist, VA Medical Center - IRM

12:00 pm-1:30 pm **LUNCHEON – Exhibit Hall C**

Session 363 AHC/IS - Academic Health Centers/ Investigative Sites, CR

1:30 pm-3:00 pm LEVEL: ■

Room 104AB

Restructuring Protocol Design to Fit the Needs of the Research Subject

SESSION CHAIRPERSON(S)

Erin J. Iturriaga, RN, CCRC
Nurse Consultant/Project Officer, National Institutes of Health

It is important to rethink inclusion/exclusion criteria in order to meet the needs of the research subject, especially when dealing with sensitive therapeutic areas. You can use the information learned from previous studies in order to avoid the same obstacles in participant recruitment for future trials.

The Challenge of Recruitment and Retention in a Vulnerable Study Population
Pamela Normandin, MSN, RN
Clinical Nurse Specialist, Office of Research, Iowa Lutheran Hospital

Retaining Vulnerable Populations through Motivational Interviewing
Suzanne Plumb, SAC, CRP
Project Specialist, University of Utah, VA Salt Lake City Healthcare System

Restructuring Protocol Design to Fit the Needs of the Research Subject
Erin J. Iturriaga, RN, CCRC
Nurse Consultant/Project Officer, National Institutes of Health

Session 364 BT 1 - Biotechnology, RA

1:30 pm-3:00 pm LEVEL: ●

Room 103

Understanding the Regulation of Advanced Therapy Medicinal Products in Europe

SESSION CHAIRPERSON(S)

Ralf Dieter Hess, PhD, MSc
Principal Consultant, PAREXEL International, Germany

This session will provide information on the new regulations on advanced therapy medicinal products (ATMP) to be implemented in the European Member States. ATMP offers new opportunities for the treatment of diseases and dysfunction of the human body. Its core objective is to create a single legal framework for three kinds of advanced therapies, such as gene therapy, somatic cell therapy, and tissue engineering. ATMP regulations will provide quality and safety rules for the donation, testing, processing, preservation, storage, and distribution of human cells and tissue.

Introduction to the New Regulations on Advanced Therapy Medicinal Products
Ralf Dieter Hess, PhD, MSc
Principal Consultant, PAREXEL International, Germany

Understanding the Regulation of Advanced Therapy Medicinal Products in Europe
Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting, Ltd., UK

Session 365 BT 2 - Biotechnology, PM/FI

1:30 pm-3:00 pm LEVEL: ■

Room 105

Venture Capital Roundtable: Biotechnology and Pharmaceutical/Health Care IT

SESSION CHAIRPERSON(S)

Paul A. Bleicher, MD, PhD
Chairman and Founder, Phase Forward

Venture-funded biotechnology companies have been an important source of new drugs and biologics for 20 years. Similarly, venture-funded pharmaceutical IT/services and health-care IT/services companies have begun to change the landscape in these industries. This session will feature leading venture capitalists from the Boston area, looking back, discussing the current state of venture funding in these areas, and looking forward to new models of development, funding, and partnerships. The session will have brief presentations by each of the panelists and will focus on discussions and questions from a moderator and the audience.

Panelists

Teo Forcht Dagi, MD
Partner, HLM Venture Partners

Jean-François Formela, MD, MBA
Partner, Atlas Venture Boston

Jonathan Fleming, MPA
Managing General Partner, Oxford Bioscience Partners

Michael Greeley, MBA
General Partner, Flybridge Capital Partners

Session 366 CDM - Clinical Data Management, EC

1:30 pm-3:00 pm LEVEL: ■

Room 258C *CME credits offered*

Using the Paper as an Easy and Smart Interface to Capture Patients' Data in Digital Format: How the Emerging Technology of Digital Pen and Paper is Bringing New Ideas and Power to EDC in Clinical Studies and in Health-care Projects

SESSION CHAIRPERSON(S)

Massimo Raineri, PhD
Head of System Development - Biometry, Actelion, Italy

The emerging technology of digital pen and paper is combining the power of electronics with the easy use of a pen, turning the paper into a smart interface which can capture patients' data and transform it into digital format. The digital pen and paper (DPP) technology is now a reality in the collection of clinical data, and it fits perfectly with the electronic data capture trend, adding the benefit of an easy and natural approach from the end-user perspective. DPP has been used by different pharmaceutical companies and CROs to collect case report form data in phase 2, 3, and 4 multinational clinical trials. DPP has also been used to streamline the workflow in long-term care health projects. Founded on real-life experiences, the impact of this new technology on the different aspects of the organization of work and of the collection and processing of data are presented and discussed.

Use of Digital Pen in International Clinical Trials: Experience and Perspectives
Brigitte Picandet, FACP
Project Director, Servier, France

On-time Quality Improvement in Long-term Care: Health IT and Workflow Redesign Improve Clinical Outcomes (Pressure Ulcer Prevention and Healing)
Siobhan Sharkey, MBA
Managing Director, Health Management Strategies, Inc.

Pros and Cons with Digital Pen and Paper in Healthcare Data Capture
Petter Ericsson
Chief Science Officer, Anoto Group AB, Sweden

Session 367 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices

1:30 pm-3:00 pm LEVEL: ●

Room 154

Quality-by-design Approaches to Analytical Research and Development

SESSION CHAIRPERSON(S)

Moheb M. Nasr, PhD, MS
Director, Office of Pharmaceutical Science, Office of New Drug Quality Assessment, CDER, FDA

Mary Oates, PhD
Vice President, Quality Operations, Pfizer Global Manufacturing, Pfizer Inc

This session will focus on QbD approaches to analytical research and development.

Industry Perspective
Mary Oates, PhD
Vice President, Quality Operations, Pfizer Global Manufacturing, Pfizer Inc

FDA Perspective
Moheb M. Nasr, PhD, MS
Director, Office of Pharmaceutical Science, Office of New Drug Quality Assessment, CDER, FDA

European Perspective
Fritz Erni, DrSc
Head Technical Liaison, Group Quality Operations, Novartis Pharma AG, Switzerland

Panel Discussion and Q & A Period

Session 368 CP 1 - Clinical Safety and Pharmacovigilance, MC

1:30 pm-3:00 pm LEVEL: ■

Room 153AB *CME and Nursing credits offered*

Fair Balance in Communication: Addressing the Needs of Prescribers and Patients

SESSION CHAIRPERSON(S)

Stephen F. Hobbiger, FFPM, FRCP
Vice President, Neurosciences, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline, UK

This session will explore the problems and opportunities for fair and balanced communication on the safety of medicines. The limitations of doing this solely via the labeling process will be discussed with actual data, and the experience of using alternatives to the "Dear Healthcare Provider" letter will be described. A case study describing the Health Care Notification Network (HCNN) will be included to illustrate the potential for new methods of communicating safety information to both prescribers and patients.

Communicating on the Safety of Medicines: Issues and Opportunities
Saad A.W. Shakir, MD, FRCPC
Director, Drug Safety Research Unit, UK

Implementing Label Changes: The Results of an Industry Survey – How Long Does It Take?
Oliver Steck, MBA
Senior Managing Consultant, WCI

HCNN: A Case Study in Improving Safety Communication
Edward Fotsch, MD
Chief Executive Officer, Medem Inc

Session 369 CP 2 - Clinical Safety and Pharmacovigilance, ST

1:30 pm-3:00 pm LEVEL: ●

Room 156AB *CME and Nursing credits offered*

Data Mining in Pharmacovigilance: Ready for Prime Time?

SESSION CHAIRPERSON(S)

Manfred Hauben, MD, MPH
Medical Director, Risk Management Strategy, Pfizer Inc

With increasing experience, data mining of spontaneous adverse event (AE) reports is becoming accepted as a credible tool in the pharmacovigilance toolkit. Speakers in this session will report on recent research that has clarified the capabilities, limitations, and practical details of safety data mining. These presentations are intended to help the audience understand how data-mining results can contribute to their own decision-making processes in drug safety.

MedDRA®, Masking, and Modeling: Studies of Factors which Affect Safety Data Mining Performance
Victor V. Gogolak, MA
President, DrugLogic, Inc.

Understanding Behavior of Data Mining Algorithms: Some Surprises
Alan M. Hochberg
Vice President, Research, ProSanos Corporation

Signal Detection with Proportional Reporting Rates (PRR) Compared with Established Pharmacovigilance Procedures
Jim Slattery, Esq., MSc
Scientific Administrator, Pharmacovigilance and Postauthorization Safety and Efficacy of Medicines Sector, Postauthorization Evaluation of Medicines for Human Use Unit, European Medicines Agency, European Union

Session 370 CR 1 - Clinical Research and Development

1:30 pm-3:00 pm LEVEL: ■

Room 205A *CME credits offered*

Improving the Quality and Implementation of Medical Imaging in Clinical Trials: Industry/Academia/Government Consortia

SESSION CHAIRPERSON(S)
Craig H. Lipset, MPH
Director, Health Technologies, Pfizer Inc

As the use of medical imaging in clinical development has continued to expand, challenges in applying imaging technology have become more transparent. As described in the FDA's Critical Path Opportunities List, harmonization and standardization of imaging bring the opportunity to improve the quality – from acquisition and analysis through reporting and management. This session will review the critical components in imaging-based trials, and identify and discuss the different consortia currently addressing the use of imaging in clinical development.

An inventory of consortia initiatives will be mapped in order to recognize the scope, overlap, and potential gaps among current programs. Specific initiatives will be featured, including the PhRMA/FDA/DIA collaboration to standardize image review charters, and the Metrics Champion Consortium (MCC) to develop standardized metrics for clinical trial imaging. The session will emphasize the potential impact of consortia activities on successful drug development programs, and seek to provide tangible value for those actively incorporating imaging in clinical trials.

Improving the Quality of Medical Imaging in Clinical Trials through Industry/Academia/Government Consortia
Craig H. Lipset, MPH
Director, Health Technologies, Pfizer Inc

Imaging in Drug Development
Orhan H. Suleiman, PhD
Senior Science Policy Adviser, Office of Oncology Drug Products, Office of New Drugs, CDER, FDA

Session 371 CR 2 - Clinical Research and Development, CTM/CS

1:30 pm-3:00 pm LEVEL: ■

Room 205B *CME credits offered*

Current Challenges and Future Solutions in the Development of Therapeutic Options for Patients with Community-acquired Pneumonia (CAP): Clinical and Regulatory Perspectives

SESSION CHAIRPERSON(S)
Joseph R. Assenzo, PhD
Executive Director, Education, The Critical Path Institute

This session will discuss the syndrome of community-acquired pneumonia (CAP), what it is, issues in clinical trials, and how it fits into the review of an antimicrobial; current perspectives on opportunities and gaps in the clinical, radiological, and microbiological approach to diagnosis; and innovative approaches to CAP drug evaluation, including biomarkers, clinical evaluations for diagnosis and endpoints, and issues with novel study designs.

History of Outcomes Research in Pneumonia and its Relationship to Past Clinical Trials and Drug Development
Joshua Metlay, MD
Associate Professor of Medicine and Epidemiology, University of Pennsylvania School of Medicine

Current Regulatory Perspective for Drug Development
Katherine A. Laessig, MD
Deputy Director, Division of Anti-infective and Ophthalmology Products, Office of New Drugs, CDER, FDA

Future Directions in Clinical Research in Community-acquired Pneumonia
John H. Powers, MD, FACP
Assistant Professor of Medicine, George Washington School of Medicine

Session 372 CR 3 - Clinical Research and Development, ST

1:30 pm-3:00 pm LEVEL: ■

Room 204AB *CME and Pharmacy credits offered*

Arsenic and Old Lace II: Newer Aspects of QT Study Design, Sample Size, FDA Feedback, and Oncology Considerations

SESSION CHAIRPERSON(S)
William Wheeler, MD
Global Medical Director, MDS Pharma Services Centralized Cardiac Services

The clinical assessment of the proarrhythmic potential of nonantiarrhythmic compounds is continuing to evolve. Potential exceptions to the guidelines outlined in ICH E14 are being encountered as more compounds are developed. Decisions involved in when, and if, to do a thorough QT/QTc study or perform an alternative design are becoming more complex. The program will build upon and provide an update to the 2007 session where alternatives to a standard thorough QT/QTc study were discussed for the development of oncology compounds. FDA feedback from various study designs will be analyzed. Sample size considerations and assay sensitivity issues will be discussed. There will be analyses of those factors that go into designing QT assessment for biologics or compounds with limited systemic bioavailability.

QT Evaluation in Oncology Drug Development
John K. Finkle, MD
Director, Cardiovascular Therapeutic Area, GCSP, GlaxoSmithKline

Common Issues and Solutions for Thorough QT ECG Trial Design
Jeffrey S. Litwin, MD
Chief Medical Officer, eResearch Technology, Inc.

Sample Size and Assay Sensitivity in QT Studies
Joanne Zhang, PhD, MS
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Arsenic and Old Lace – The Sequel: Other Design Considerations
William Wheeler, MD
Global Medical Director, MDS Pharma Services Centralized Cardiac Services

Session 373 EC - eClinical, IT

1:30 pm-3:00 pm LEVEL: ■

Room 158B

Collaborative Clinical Environments for the Public Good

SESSION CHAIRPERSON(S)

James L. Bland, MBA
Executive Director, CRIX International

Disparate repositories and multiple technological formats and standards add unnecessary layers of complexity to the clinical research process, thus impeding new medical therapies from ever reaching patients. Attendees of this session will learn how a common ePlatform, where all parties involved in clinical research can share information easily, solves this critical problem.

James L. Bland, MBA
Executive Director, CRIX International

Harry J. Fisher
General Manager, Global Life Sciences, Northrop Grumman

Session 374 ERS/DM 1 - Electronic Regulatory Submissions/Document Management, CDM

1:30 pm-3:00 pm LEVEL: ●

Room 257AB

International eCTDs: An Update on Regulatory Authority Experience

SESSION CHAIRPERSON(S)

Mary L. Collins
Director, Regulatory and Industry Relations, Image Solutions, Inc.

Regulatory authority representatives from the three ICH regions will provide an overview, status of acceptance, review and approval of electronic 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.

US Electronic Submission Update
Gary M. Gensinger, MBA
Deputy Director, Office of Business Process Support, CDER, FDA

EMEA, EU Electronic Submission Update
Timothy Buxton, LLB
Head of Sector, Project Management, Communications and Networking Unit, European Medicines Agency, European Union

Japan Electronic Submission Update
Kiyohito Nakai, PhD
Japanese Regulator, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 375 ERS/DM 2 - Electronic Regulatory Submissions/Document Management, CDM

1:30 pm-3:00 pm LEVEL: ■

Room 256

Revisiting the Dilemma: Have We Found a Cure for the Ills of Electronic Document Management in the Contemporary Biopharmaceutical Industry? And If So, What Is the Medicine Looking Ahead in 2008 and Beyond?

SESSION CHAIRPERSON(S)

Nancie E. Celini, MPH
President, CAB, Inc.

For several decades, the biopharmaceutical industry has been attempting to exploit electronic document management systems (EDMS) and few could argue it has been easy or cost effective. An open, community-driven dialog must continue regarding the concept of an externally hosted, standards-based EDMS service that would allow any entity access to a shared regulatory-compliant system.

The speakers will examine the current state of enterprise EDMS including the challenges that lie ahead, recent developments and some history that are helping current and future concepts evolve. Current standards such as RPS, PIM, and SPL, among others, exploit XML and are driving "traditional" document management toward content management. This will require more sophisticated techniques to manage and implement these systems that will rely more heavily on appropriate description and attribution. Additionally, broad collaboration requirements mean a move to better partnering capabilities and streamlined information exchange. The group will lead a dialog about how we can better develop the next generation and capabilities efficiently and successfully. The interactive panel session will include cross-industry representatives and will address audience questions.

Emerging Opportunities in the BioPharma Industry: Why Does That Require Document Management
John J. Oidtman
Vice President, Worldwide Regulatory Operations, Pfizer Inc

A Technological Perspective
John C. M. Wise, MA
Senior Director, Informatics, Daiichi Sankyo, UK

These Better Keep You Awake at Night …
Allen E. Jones, MS
Director, Global Regulatory Operations, GlaxoSmithKline

Session 376 GCP - Good Clinical Practices, CR

1:30 pm-3:00 pm LEVEL: ■

Room 206AB *Nursing and Pharmacy credits offered*

Defining Quality in Clinical Trials

SESSION CHAIRPERSON(S)

John Poland, PhD
Senior Director, Regulatory Policy, Late Stage Development Services, Covance, Inc., UK

In May 2007, the DIA and FDA held a conference on Defining and Implementing Quality in Clinical Investigations from Design to Completion. The aim was to initiate discussion on new approaches to quality in clinical trials in order to ensure that modern concepts of quality adequately reflect the needs of the current clinical trial environment. The need to pursue modernization of the clinical research enterprise by improving the efficiency of the clinical trial process by building quality into each step of the process and using a risk-based approach to variation was emphasized by the FDA. At the same time, it was noted that quality in clinical trials is a much broader concept than implied solely by the current focus on subject safety and the accuracy and consistency of data. The EMEA's GCP Inspectors Working Group also has these topics under continuous review and participated in the conference. In this session, speakers from both the FDA and EMEA will describe progress since the May 2007 conference and explain current thinking within the agencies, and the implications for the sponsors of clinical trials will be highlighted and discussed.

Defining Quality in Clinical Trials: A View from the EMEA
Fergus Sweeney, PhD
Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, European Medicines Agency, European Union

Defining Quality in Clinical Trials: A View 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
Director, Corporate Quality Assurance, Genzyme Corporation

Session 377 IT - Information Technology, CP

1:30 pm-3:00 pm LEVEL: ●

Room 258A

Semantic Web Applications in Drug R&D

SESSION CHAIRPERSON(S)

Eric Neumann, PhD
Director; Co-Chair, Clinical Semantics Group; W3C HCLS

Semantic web-based applications in drug R&D are increasing, and cover a wide range of functional areas. In addition, new applications are being identified in clinical and regulatory areas that could demonstrate even bigger impact of semantic standards. This session will describe some current applications within companies, as well as some activities published through the W3C's Health Care and Life Sciences Interest Group. Functional areas that will be discussed include chemical development, safety information, clinical trials data management, and pharmacovigilance.

Potential Impact of Semantic Web on Translational Medicine
Eric Neumann, PhD
Director; Co-Chair, Clinical Semantics Group; W3C HCLS

Semantic Web and Applied Integrated Knowledge
Ted Slater, PhD
Associate Director, Pfizer Inc

Session 378 MA - Marketing, RD

1:30 pm-3:00 pm LEVEL: ■

Room 104C

Essential Components of Due Diligence

SESSION CHAIRPERSON(S)

Joel I. Falk, MBA
Executive Vice President, The Weinberg Group Inc.

The key components of due diligence essential to making informed and profitable acquisition decisions will be the focus of this session. Pitfalls to avoid and synergies to seek will be highlighted. This session will provide you with the practical knowledge and tools to assess products or company acquisition potential.

Intellectual Property Considerations in FDA: Regulated Transactions
Marta E. Gross, JD
Partner, Goodwin Procter

Asher Rubin
Partner, Hogan & Hartson LLP

Regulatory Aspects of Due Diligence
Joel I. Falk, MBA
Executive Vice President, The Weinberg Group Inc.

Session 379 MC - Medical Communications

1:30 pm-3:00 pm LEVEL: ●

Room 253B *Pharmacy credits offered*

Managing Medical Information in a Changing Pharmaceutical Environment

SESSION CHAIRPERSON(S)

Donna H. Savulich, PharmD
Director, Medical Information, sanofi-aventis

The current environment in the pharmaceutical industry has presented challenges for medical communication professionals as they adapt to change and strive to remain flexible and innovative. We will discuss strategies for managing a medical communications department in a changing environment utilizing new technologies and past experiences to reach customers, streamlining and outsourcing functions to improve efficiency, and best practices for managing office and field-based staff.

Strategies for Managing a Medical Information Contact Center in a Cost-conscious Environment
Barbara M. Bonetti, PharmD
Director, Medical Customer Interface, Pfizer Inc

Best Practices in Managing the Outsourced Medical Information Partner
Pamela H. Cates, RPh
Director, Operations, Professional Contact Center, PPD, Inc.

The Human Side of Change Management
Marietta Stalcup
Manager, Oncology and Women's Health Medical Liaisons, Eli Lilly and Company

Session 380 MW - Medical/Scientific Writing, RA

1:30 pm-3:00 pm LEVEL: ■

Room 153C

Regulatory Submission Writing of Safety Narratives

SESSION CHAIRPERSON(S)

Karen Johnstone, RN
Associate Director, Drug Safety, RPS, Inc.

Safety narratives for a CSR/ISS are a vital component of the risk assessment associated with a marketing authorization application submitted to any regulatory authority. The narrative writing process is multidisciplinary, encompassing clinical, data management, safety, medical writing, and programming. This session will address how best to work across all of these areas and meet aggressive timelines with a quality deliverable. The perspective of a safety reviewer will also be presented.

Narrative Writing of Clinical and Postmarketing Adverse Event Reports
Mark Vieder, MBA, RPh
Manager, Medical Safety, Regeneron Pharmaceuticals, Inc.

The Multidisciplinary and Global Aspect of Narrative Writing
Julie E. McCusker, RPh
Lead Safety Associate, RPS, Inc.

Key Considerations from a Drug Safety Perspective in Drafting Narratives for a CSR
Michelle J. Dardeno, RPh, RAC
Associate Director, Pharmacovigilance and Medical Information, Genzyme Corporation

Session 381 NC - Nonclinical Laboratory Safety Assessment, BT

1:30 pm-3:00 pm LEVEL: ■

Room 203

Translational Research

SESSION CHAIRPERSON(S)

David B. Carlson, PhD
Toxicologist, Division of Metabolism and Endocrinology Products, CDER, FDA

Type 2 diabetes and obesity rates have climbed recently, and controlling the diseases has become a public health priority. While the health consequences of diabetes and obesity are well known, understanding the disease etiology

and providing effective therapies have proved challenging. With diabetes, the mechanisms of poor glucose control are well known but understanding the mechanisms of disease progression and controlling hyperglycemia-related morbidity are vexing. Obesity, by contrast, seems to have a complex, poorly understood etiology and far reaching health effects on multiple organ systems and systemic metabolism. The complexities of these two prevalent diseases provide good case-case studies to discuss the challenges in modeling disease and predicting safety and efficacy in preclinical animal models. One particular case study will discuss the challenges and successes with glucokinase activation, a promising therapeutic target under development for the treatment of type 2 diabetes mellitus. Glucokinase activators have the potential to provide potent, prolonged blood glucose control in diabetic individuals, but neither euglycemic nor diabetic animal models alone are ideal for pharmacology and toxicology studies. This session is intended to address the challenges of toxicity assessment in nonclinical development and the resulting regulatory decisions that affect clinical development of glucokinase activators and other new drugs.

Regulatory Challenges in Preclinical Development: Obesity, Diabetes, and Beyond
David B. Carlson, PhD
Toxicologist, Division of Metabolism and Endocrinology Products, CDER, FDA

Preclinical Disease Models: Challenges and Success Stories
Brendan Leighton, PhD
Principal Scientist, AstraZeneca, UK

Preclinical Safety Assessment: Understanding Mechanism-based Toxicities of Glucokinase Activators
Thomas D. Steele, PhD
Senior Research Leader and Head, Science and Strategy, Nonclinical Safety, Hoffmann-La Roche, Inc.

Session 382 NHP - Natural Health Products, CP

1:30 pm-3:00 pm LEVEL: ●

Room 156C

Pharmacovigilance in Natural Health Products

SESSION CHAIRPERSON(S)

Pradip K. Paul, MS
Head, Case Medical Evaluation Group, Global Pharmacovigilance and Epidemiology, sanofi-aventis

NHP pharmacovigilance is an evolving field where the potential toxicity of an natural health product may be learned. A toxicity may be prevented starting from the field up to the bedside if the process can be understood. The session will also discuss an excellent example of a nutritional compound that may protect adverse reactions to the widely used traditional medicine acetaminophen. In addition, the session will discuss the new European rule EudraLex.

Promoting Safe Natural Health Products from Field to Bedside with International Coordination
Pulok K. Mukherjee, PhD, MPharm, RPh
Director, School of Natural Product Studies, Department of Pharmaceutical Technology, Jadavpur University, India

Medical Assessments and Safety Evaluations for Herbal or Borderline Medicinal Products and Medical Devices
Leonardo C.I. Ebeling, MD, PhD
General Manager, Ebeling and Associates GmbH, Germany

The Use of Nutritionals as a Protection against Adverse Reactions: Acetaminophen – A Case Study of the Use of Methionine in Formulation
Raymond Tumarkin
Medical Scientific Information Analysis Consultant

Session 383 OS - Outsourcing, CR

1:30 pm-3:00 pm LEVEL: ●

Room 205C

Outsourcing in China: Opportunities and Challenges

SESSION CHAIRPERSON(S)

Simon Wang, MBA, MSc
Manager, PAREXEL APEX International Co., Ltd., China

Outsourcing is a trend for pharmaceutical companies to enter the emerging markets. This session illustrates the opportunities of outsourcing in China and the pitfalls most western pharmaceutical companies misunderstand. After this session, all pharmaceutical companies will be able to develop their own outsourcing strategies based on their size, scope, and project needs.

Outsource a Clinical Trial to China: Challenges and Advantages
Tailiang Xie, PhD
Statistician/Founder, Brightech International

Training: From Scratch to Production
JauRuey Huang, MA
Senior Manager, Johnson & Johnson Pharmaceutical Research and Development, LLC

Outsourcing in China: Decision Models and Case Study
Simon Wang, MBA, MSc
Manager, PAREXEL APEX International Co., Ltd., China

Session 384 PM/FI - Project Management/Finance, RD

1:30 pm-3:00 pm LEVEL: ■

Room 210B *Project Management units offered*

Project Management Plenary Session
Strategic Approaches to Addressing Pharma's R&D Challenges

SESSION CHAIRPERSON(S)

Robin G. Foldesy, PhD
Vice President, Project Management, Wyeth Research

The pharmaceutical industry is in a crisis. The business model that served it well for decades has become irrelevant. Higher regulatory hurdles, skyrocketing development costs, a challenging reimbursement environment, and aggressive attacks on intellectual property by generic companies have combined to stem the revenue streams for companies at a time when they can least afford to reduce their support for R&D. The initial reaction to slash expenses by terminating projects and reducing staff may be appropriate in the short term. However, it does not address the fundamental issues over the long term, and without the appropriate analytical tools, it can be misguided. Regardless of their size, companies can improve their chances of long-term success by creating a rational strategy for sustained growth, along with a plan and the analytical tools to implement and adhere to the strategy. This plenary session will describe the processes and benefits of taking a strategic approach to drug development in the current environment, along with examples demonstrating the consequences of failing to do so.

The Increasing Importance of Rational R&D Investments
Robin G. Foldesy, PhD
Vice President, Project Management, Wyeth Research

Staying Strategic when Tactics Tempt: Effective Approaches for Communicating and Addressing Pharma's R&D Challenges
Richard Sonnenblick
CEO, Enrich Consulting

Session 385 PP - Public Policy/Law, RA

1:30 pm-3:00 pm LEVEL: ■

Room 160AB

New Paradigms of Drug Regulation

SESSION CHAIRPERSON(S)

John A. Lisman, LLM, MPharm
Attorney, NautaDutilh N.V., Netherlands

In recent years the crisis in drug development and regulation has cast shadows on the pharmaceutical industry and drug regulators. In spite of attention for the emerging issues, lack of trust, differences of opinion between stakeholders, etc., no initiatives for fundamental changes have been taken. This session will focus on three issues – agenda setting for the industry's development pipeline, transparency versus confidentiality, and pharmaceutical sector and society.

Pharmaceutical Industry in a Global Environment
Lembit Rägo, MD, PhD
Coordinator, Quality Assurance and Safety: Medicines, Policy and Standards, World Health Organization, Switzerland

New Paradigms of Drug Regulation
John A. Lisman, LLM, MPharm
Attorney, NautaDutilh N.V., Netherlands

Transparency and Credibility in Drug Regulation
Frits Lekkerkerker, DrMed
Member of Advisory Board, Medicines Evaluation Board, Netherlands

Session 386 RA 1 - Regulatory Affairs, BT

1:30 pm-3:00 pm LEVEL: ■

Room 253A

Recent Advancement of Co-development of Medical Devices and Drugs in the Asia-Pacific Region

SESSION CHAIRPERSON(S)

Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

The co-development of drugs and devices has become one of the focal points in the advancement of biotechnology and medicine. The nations in the Asia-Pacific region such as China, Japan, Korea, and Taiwan have increasing investment in medical devices such as IVD. This led to a trend of consideration of co-development of devices and drugs in early stages during development of novel products or administrative technology such as nanotechnology. National programs in these countries have supported interdisciplinary research funding and infrastructure setup. This session will be devoted to the discussion and comparison of recent advancement of the co-development of devices and drugs in the Asia-Pacific region. The impact on regulatory affairs would be included if required.

Existing and Emerging Regulatory Considerations in Co-development of Drugs and Devices
Lois M. Hinman, PhD
Executive Director, BD&L, Global Regulatory Affairs, Novartis Pharmaceuticals Corporation

Co-development of Devices and Drugs in Taiwan
Li-Ling Liu
Deputy Director-General, Bureau of Pharmaceutical Affairs, Department of Health, Taiwan

Pharmacogenomics CRO Service: Drug Reposition Program and Molecular Diagnosis Products
Ellson Y. Chen, PhD
President and CEO, Vita Genomics, Inc., Taiwan

Session 387 RA 2 - Regulatory Affairs, PP

1:30 pm-3:00 pm LEVEL: ■

Room 253C

Current Status of Regulatory Reform in Canada

SESSION CHAIRPERSON(S)

Agnes V. Klein, MD
Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada

Modernization of the therapeutic products regulatory framework in Canada has been ongoing and has gathered additional momentum in recent months. New legislation is being developed and new regulatory instruments are being considered with added scientific depth that will naturally result in raising the bar for quality of the data and benefit-risk assessments across the entire life cycle of regulated products.

In the process of modernizing Canada's framework for regulating therapeutic products, the approach to development of policy has been recognized as novel. This session will provide an overview of the current status of this modernization project, aimed at establishing the benefits and risks of products from the legal, policy, and scientific perspectives. The hope is that these new and novel approaches will serve Canada well in areas of scientific/regulatory foresight. It is Canada's way to ensure the continued health of therapeutics development, assessment, and regulation while stimulating scientific development.

Robyn Lim, PhD
Scientific Advisor, Health Canada

David K. Lee
Director, Office of Patented Medicines Liaison, Therapeutic Products Directorate, Health Canada

Session 388 RA 3 - Regulatory Affairs, BT

1:30 pm-3:00 pm LEVEL: ■

Room 254AB

Review of ICH Q5A-Q5E Guidances and Experiences

SESSION CHAIRPERSON(S)

Nellie W. Forwood, MS, RAC
Regulatory Writer, Six Sigma Master Black Belt, Research Pharmaceutical Services, RPS, Inc.

This session will begin with an overview of the five ICH Quality Guidances available. It will then provide the audience with an opportunity to learn the direction other experienced biotechnology scientists have taken when addressing quality issues unique to their product, as well as how the Guidances helped or hindered resolution. The audience will gain a perspective from industry leaders through interactive discussions.

Q5A and Q5B
Stephen J. Rochelle, MS
President, Rochelle & Associates Inc

Q5C and Q5D
Steven I. Engel, PharmD, PhD, MS

Experiences with ICH Guidance Q5E, Comparability of Biotechnology/ Biological Products Subject to Changes in Their Manufacturing Process
Nellie W. Forwood, MS, RAC
Regulatory Writer, Six Sigma Master Black Belt, Research Pharmaceutical Services, RPS, Inc.

Session 389 RA 4 - Regulatory Affairs, CP

1:30 pm-3:00 pm LEVEL: ●

Room 252AB

CBER Safety Initiatives

SESSION CHAIRPERSON(S)

Robert P. Wise, MD, MPH, FACPM, FISPE
Chief, Therapeutics and Blood Safety Branch, Division of Epidemiology, Office of Biostatistics and Epidemiology, CBER, FDA

Assuring safety of biological products is an essential element in the mission of the Center for Biologics Evaluation and Research (CBER). CBER uses multiple approaches to ensure product safety, including postmarketing surveillance and interdisciplinary safety teams. CBER staff will provide an overview of CBER's postmarketing surveillance activities along with information about CBER's different interdisciplinary safety teams and their objectives.

Safety Surveillance for Licensed Biological Products at FDA's Center for Biologics Evaluation and Research
Robert P. Wise, MD, MPH, FACPM, FISPE
Chief, Therapeutics and Blood Safety Branch, Division of Epidemiology, Office of Biostatistics and Epidemiology, CBER, FDA

Tissue Safety Team
Ruth Solomon, MD
Tissue Safety Team Chair; Director, Division of Human Tissues, Office of Cellular, Tissue, and Gene Therapies, CBER, FDA

Blood Safety Team
Jonathan C. Goldsmith, MD
Blood Safety Team Chair; Deputy Director, Office of Blood Research and Review, CBER, FDA

Vaccine Safety Team
Carmen M. Collazo, PhD
Vaccine Safety Team Regulatory Project Officer; Microbiologist, Office of Vaccines Research and Review, CBER, FDA

Session 390 ST - Statistics, CR

1:30 pm-3:00 pm LEVEL: ■

Room 259AB *CME and Pharmacy credits offered*

Planning, Analysis, and Review of Clinical Trials: Selected Topics

SESSION CHAIRPERSON(S)

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

Statisticians working for industry and for the FDA want clinical trials to succeed – that is, provide the convincing, scientific evidence needed to approve new drugs and biologics. To accomplish this goal, we must assure ourselves that confirmatory trials are well planned and based on good science. However, clinical trials are big, complicated, sometimes messy, always expensive experiments. Making our jobs even tougher, the science and methods of clinical trials are continuously changing – we are always pushing for more information, developing new instruments and endpoints, and trying to learn more about the real effects that drugs and biologics have on people.

Results from most of the trials we analyze are potentially biased by unknown and unknowable missing data phenomena; yet we still need to weigh the evidence, often making decisions in spite of the potential effects of missing data. This session will offer some strategies for avoiding, or dealing with, missing data in the analysis.

With the release of the draft FDA Guidance on "Patient-reported Outcome [PRO] Measures: Use in Medical Product Development to Support Labeling Claims," the Agency stressed the need for sponsors, working with review divisions, to describe and pre-specify the PRO instruments and the validation process. This session will also describe and recommend appropriate statistical approaches for the planning and analysis of PRO validation studies.

We will also learn more about the role of the CDER statistical reviewer who answers questions on all statistical scientific and regulatory issues, as they collaborate with industry in the development of protocols and assess the evidence based on trial data and reported results.

Practical Preventive and Corrective Approaches for Dealing with Missing Data
Abdul J. Sankoh, PhD
Senior Director and Head, Biometrics, Vertex Pharmaceuticals

Validation of Modified PRO Instruments: The State of the Statistical Science
Damian John McEntegart, MS
Vice President, Statistics and Product Support Services, Clinphone Group, Limited, UK

Evaluating Study Protocols and Clinical Trial Results: A Statistical Reviewer's Perspective
Joan K. Buenconsejo, PhD, MPH, MS
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Session 391 TR - Training, MC

1:30 pm-3:00 pm LEVEL: ●

Room 157AB

Setting the Standards: Medical Science Liaison Certification

SESSION CHAIRPERSON(S)

Robin L. Winter-Sperry, MD
President and CEO, Scientific Advantage, LLC; MSL Advantage, LLC

As the role of the Medical Science Liaison (MSL) continues to evolve within the pharmaceutical, biotechnology, and device health-care industry, there is an increasing need to begin to set standards. The purpose of this session is to discuss how to create an effective certification program that takes into account core competency requirements, industry standards, and best practices and develops a baseline competency for MSLs that transcends companies. It will also be used as a foundation building block for career path development in this area.

MSL Certification: An Unmet Need
Robin L. Winter-Sperry, MD
President and CEO, Scientific Advantage, LLC; MSL Advantage, LLC

Certification: An Academic Approach
Susanna J. Dodgson, PhD
Director, Graduate Programs in Biomedical Writing, Professor, Biomedical Writing, University of the Sciences in Philadelphia

Compliance and Regulations: Education and Risk Reduction
Linda Carlson, PhD, MBA
Vice President, Medical Operations, EMD Serono, Inc.

Providing Career Paths and Role Definition
Joanne Marie Vanak, MSN, RN
Senior Field Director, Medical Affairs, Centocor Biotech, LLC

Session 392 VA - Validation, IT

1:30 pm-3:00 pm LEVEL: ■

Room 251

Managing the Scope and Quality of Validation

SESSION CHAIRPERSON(S)

Breffni Martin
Director, CanReg Ltd., Ireland

The first presentation in this session will describe how involving the end user makes it possible to drive the software development and validation process with greater efficiency, produce an end result that better meets user requirements, and save time and money in the process. The second presentation will address a similar objective but in terms of vendor software validation. This is the third in a popular series of sessions covering this general area.

Collaborating with End Users to Drive the Process and Reduce Development Time
Joanne S. Malia, MS, MSc
Associate Director, Medical Research Process Management, Purdue Pharma

Vendor Software Validation is Practical and Achievable
Rita Geiger, MBA
CEO/President, InfoStrength Inc.

An Auditor's Perspective: Being Prepared for Sponsor Audits and Regulatory Inspections and Ensuring Compliance with 21 CFR Part 11
Angela M. Berns
Global Vendor Manager, Clinical Quality Assurance, UCB Group, Inc.

3:00 pm-3:30 pm **REFRESHMENT BREAK – North Lobby, Level 1**

Session 393 AHC/IS - Academic Health Centers/ Investigative Sites, TR

3:30 pm-5:00 pm LEVEL: ●

Room 104AB *CME credits offered*

PATHWAYS™ in Clinical and Translational Research: Delivering Innovative Education and Training Programs in AHCs

SESSION CHAIRPERSON(S)

Paula Carney, PhD
Director, Education and Training – Clinical Research Professionals, NUCATS, Northwestern University

Current growth in clinical and translational research efforts has heightened the need for a competent clinical research workforce. Rapid industry growth presents a challenge for academic health centers (AHCs) who strive to maintain compliance through education and training across hospitals, medical schools, community-affiliated physicians, and ancillary facilities. This session will provide an overview of the challenges and considerations for AHCs in developing multidimensional training, including location, cost, and role-specific training needs. In addition, results from a case study documented by Northwestern University Clinical and Translational Sciences (NUCATS) Institute will be shared to define successful approaches to learning management system selection and implementation to meeting clinical research training needs of these audiences by academic health centers. Finally, the presentation will address various types of online education and training and provide best practices and examples to highlight outcomes of online education delivery for decentralized clinical research staff.

Assessing Need for Innovative Delivery of Education and Training Programs in a University Setting
Paula Carney, PhD
Director, Education and Training – Clinical Research Professionals, NUCATS, Northwestern University

Strategies for Delivering Education and Training at Community Sites
Peri Todd
Director, Clinical Research, DuPage Medical Group

Selecting Appropriate Learning Technologies
Jennifer S. DeVries, MA
President and Chief Solutions Architect, BlueStreak Learning

Session 394 BT - Biotechnology, RA

3:30 pm-5:00 pm LEVEL: ◆

Room 105

Nanotechnology Task Force: Regulating Nanotechnology Products

SESSION CHAIRPERSON(S)

George Q. Mills, MD, MBA
Vice President, Medical Imaging Consulting, Perceptive Informatics/PAREXEL

In 2006, the FDA initiated a Nanotechnology Task Force at the request of

Session 394 HAS BEEN CANCELLED.

This session analyzes the impact of this report on regulations related to nanotechnology products, including biological effects and interactions of nanoscale materials.

FDA's Exploratory IND Guidance: Transitioning Nanotechnology Drugs/Biologics
George Q. Mills, MD, MBA
Vice President, Medical Imaging Consulting, Perceptive Informatics/PAREXEL

Translational Issues in Nanomedicine Development and Early Clinical Trials
Alexander J.B. McEwan, MD
Division Director, Oncologic Imaging, Department of Oncology, University of Alberta, Canada

Session 395 CDM - Clinical Data Management, IT

3:30 pm-5:00 pm LEVEL: ■

Room 258C

Practical Applications of CDISC SDTM

SESSION CHAIRPERSON(S)

Glenn A. Ritz, MS
Associate Technical Director, Statistical Programming, Millennium Pharmaceuticals, Inc.

This session will help participants understand various practical applications of the CDISC SDTM standard. There will be discussions on approaches to building a Clinical Data Warehouse using SDTM standards, the impact of SDTM standards on running clinical trials, and using controlled terminology in the SDTM domains.

Data Warehousing Concepts for SDTM-compliant Information
David A. Evans, MS
Chief Information Officer, Octagon Research Solutions, Inc.

CDISC SDTM Implementation Process
Michael J. Todd, MS
President, Nth Analytics

Controlled Terminology in CDISC-SDTM
Kevin King, MS
Lead Statistical Programmer, Biostatistics, Millennium Pharmaceuticals, Inc.

Session 396 CMC/GMP - Chemistry, Manufacturing and Controls/Good Manufacturing Practices

3:30 pm-5:00 pm LEVEL: ■

Room 154

Real-time Release: Opportunities and Challenges

SESSION CHAIRPERSON(S)

Nirdosh Jagota, PhD
Assistant Vice President, Global Regulatory Affairs, CMC and Conformance, Wyeth Pharmaceuticals

The session will include discussion on strategies and challenges in implementing real-time release (RTR). A statistical approach for setting specification for RTR will be presented. Some learnings and experience will be shared from case studies.

Statistical Considerations for Developing Specifications for Real-time Release
Lori Pfahler, MS
Associate Director, Merck & Co., Inc.

Real-time Release (RTR) Implementation: Challenges and Opportunities
Stephen Simmons, PhD
Vice President, Pharmaceutical New Products Quality and Quality by Design, Wyeth Pharmaceuticals

Real-time Release: A Case Study
Staffan Folestad
Senior Principal Scientist, AstraZeneca R&D, Sweden

Panel Discussion and Q & A Period

Session 397 CP 1 - Clinical Safety and Pharmacovigilance, GCP

3:30 pm-5:00 pm LEVEL: ●

Room 153AB *CME and Nursing credits offered*

Risk Management and Pharmacovigilance for Opioids

SESSION CHAIRPERSON(S)
Edgar H. Adams, DrSc, MS
Executive Director, Epidemiology, Covance Inc.

Unlike many other drugs, manufacturers of opioids must be concerned about the abuse and diversion of their products to abusing populations. These concerns impact drug approval as well as the specific requirements for pharmacovigilance. In addition, smaller firms developing drugs for restricted indications in smaller markets face cost pressures such that a comprehensive phase 4 commitment or extensive RiskMAP can make a product uneconomical to develop. In such settings the firms cannot rely on a multimillion dollar RiskMAP to manage the risks of their products, but must instead select strategies with a high ratio of risk reduction to cost and build them into their development plans.

In this session, two representatives from pharma companies and the director of the RADARS system will discuss how their companies have employed standard RiskMAP tools to mitigate risk, the challenges faced by small companies in meeting their public health and patient protection goals, and how approaches such as the RADARS system provide pharmacovigilance data on diversion and abuse.

Risk Management Considerations for Small Pharmaceutical Companies
Curtis Wright, IV, MD, MPH
Vice President, Clinical and Medical Affairs, Star Scientific

Pharmacovigilance and RADARS
Richard C. Dart, MD, PhD
Professor, Surgery, Medicine, and Pharmacy, University of Colorado; Director, Rocky Mountain Poison and Drug Center

Risk Management Approaches for Opioids and Other Controlled Substances
Sidney H. Schnoll, MD, PhD
Vice President, Pinney Associates, Inc.

Session 398 CP 2 - Clinical Safety and Pharmacovigilance, GCP

3:30 pm-5:00 pm LEVEL: ■

Room 156AB

Audits as an Effective Tool for Regulatory Inspections

SESSION CHAIRPERSON(S)
Maria C. Koster, PharmD
CEO, Vigilex B.V., Netherlands

Compliance by pharmaceutical and medical device companies is nowadays inextricably bound up with the conduct of audits, both internal and by third parties. Legal requirements and expectations of competent authorities for such audits have evolved rapidly over the past four to five years, and the lack of a global QA PV department is a frequent finding during inspections these days. The implementation of a global PV QA structure that meets expectations is frequently a large challenge for a variety of reasons. Examples of this will be provided, as well as coping strategies.

Experience to Date in the Three Regions
Maria C. Koster, PharmD
CEO, Vigilex B.V., Netherlands

Approaches and Challenges for Big Pharma Companies
Joanne Spallone
Global Head, Audit; Executive Director, Clinical Quality Assurance, Novartis Pharmaceuticals Corporation

Audits as a Building Tool for a Sound PV System
Hedva Voliovitch, MD, PhD
Vice President, Global Drug Safety and Pharmacovigilance, Teva Pharmaceutical Industries Ltd., Israel

Session 399A CR 1 - Clinical Research and Development, RA

3:30 pm-5:00 pm LEVEL: ■

Room 205A *Nursing credits offered*

Clinical Research and Product Registration in Brazil, Russia, India, China (BRIC), and Other Emerging Regions: An Overview

SESSION CHAIRPERSON(S)
Rominder Singh, PhD
Executive Director, Global Regulatory Affairs, Amgen Inc.

It is estimated that nearly 30% of all clinical trials are now being conducted globally, with a rapidly increasing proportion being conducted in developing countries. The presenters in this session will discuss the climate for conducting clinical trials in these regions, how to avoid pitfalls, the quality of clinical trial work in emerging countries, and filing IPs with foreign data.

Statistics and data will be presented on each of these major regions, with a focus on Russia and Eastern Europe. In addition to exploring where the emerging markets will take us in 2008 and beyond, the data will also explore the FDA's and local regulatory authorities' attitudes and perceptions towards clinical research in these areas.

Clinical Research and Product Registration in Brazil, Russia, India, China (BRIC), and Other Emerging Regions: An Overview
Rominder Singh, PhD
Executive Director, Global Regulatory Affairs, Amgen Inc.

Identifying and Mitigating Risks to Intellectual Property in Emerging Markets
Gregory E. Kalbaugh, Esq., JD, LLM
Director and Counsel, US Chamber of Commerce - India Business Council

The Advantages and Disadvantages of Clinical Trials in Russia and Eastern Europe
Paul L. Loveday, JD
CEO, ClinStar LLC

Session 399B CR 2 - Clinical Research and Development, CP

3:30 pm-5:00 pm LEVEL: ■

Room 205B

What Can Be Learned from Run-in and Extension Periods in Clinical Research?

SESSION CHAIRPERSON(S)

Timothee Fraisse, MD, MSc
Research Fellow, University Hospital Geneva, Switzerland

Session 399B HAS BEEN CANCELLED.

information about the treatments, and if so, what needs to be assessed and reported when planning such add-on periods.

Methodological Pitfalls in Setting and Analyzing an Extension Period
Jean Pierre Boissel
University Claude Bernard, France

European Regulatory Acceptance of Extended Clinical Trials
Jean-Marc Husson, MD, FACP
Co-director, European Diploma in Pharmaceutical Medicine, Eudipharm, France

Session 399C CTM/CS - Clinical Trial Management/ Clinical Supplies, CR

3:30 pm-5:00 pm LEVEL: ●

Room 204AB *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

CenterWatch will present the results of two surveys: one survey examines patients' clinical trial experiences and the second survey looks at physicians' reasons for referring or not referring patients into a clinical trial. The patient volunteer survey examines data from over 1,000 patients who have recently completed a phase 1-3b clinical trial and will be compared with data collected from surveys conducted in 2004, 2005, and 2006. 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 analyzes data from over 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. The results of these surveys will shed light on patients' experiences of having participated in trials across all disease states and will clarify those 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.

Reasons Physicians Do or Do Not Refer Patients into Clinical Trials
Mary Jo Lamberti, PhD, MA
Director, Market Research, CenterWatch

Influences and Challenges of Patient Recruitment and Retention: Perspectives from Participants, Families, and Research Study Organizers
Tammy Jeanne Massie, PhD, MS
Mathematical Statistician, Vaccine Evaluation Branch, CBER, FDA

Understanding Clinical Trial Volunteer Experiences
Paul Dewberry
Research Analyst, CenterWatch

Session 399D EC - eClinical, IT

3:30 pm-5:00 pm LEVEL: ●

Room 258B

Evaluating Current eClinical Technologies and Data Interchange Standards Usage and Experience

SESSION CHAIRPERSON(S)

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

This session reviews the results of original research recently completed by the Tufts Center for the Study of Drug Development focusing on global adoption of eClinical technology solutions and data interchange standards. Results of this study will be discussed and compared with the results of adoption studies conducted in the past. Presenters will also discuss strategies and practices now being implemented by sponsor companies to facilitate and leverage the benefits of eClinical technology and standards usage. Challenges to adoption and integration will also be discussed.

Review of Tufts CSDD 2007 Study on eCT Solutions and Standards Adoption
Kenneth A. Getz, MBA
Senior Research Fellow, Center for the Study of Drug Development, Tufts University; Chairman, CISCRP

Current Sponsor and CRO Adoption Needs
Frank T. Newby
Chief Operating Officer, CDISC

Current Investigative Site Adoption Needs
Christine K. Pierre, RN
President and CEO, Rx Trials Inc.

Session 399E ERS/DM - Electronic Regulatory Submissions/Document Management

3:30 pm-5:00 pm LEVEL: ●

Room 257AB

Gateway

SESSION CHAIRPERSON(S)

Michael Blanchard Fauntleroy
Director, Electronic Submissions Program, CBER, FDA

The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions which enables the secure submission of regulatory information for review. This session will focus on the "The Electronic Submissions Gateway" and include metrics on the current usage and future directions. The presenters will review the procedure for companies who wish to participate and use the Gateway, discuss tips for efficient use, and what the process is at FDA once submissions are sent via the Electronic Submissions Gateway.

Update on the Electronic Secure Gateway (ESG)
Michael Blanchard Fauntleroy
Director, Electronic Submissions Program, CBER, FDA

FDA Opinion
Representative Invited
FDA

Industry Perspective
Representative Invited

Session 399F GCP - Good Clinical Practices

3:30 pm-5:00 pm LEVEL: ■

Room 206AB *Pharmacy credits offered*

Quality without Compromise: Full-cycle Quality Management

SESSION CHAIRPERSON(S)

Steven Steinbrueck, MPH
President, Stonebridge GCP Consulting Inc.

This session will address the essential components of a robust quality management system (QMS) within the complex clinical research environment. Using the principles of ISO 9001:2000 as a model, the first presentation will describe the implementation of a QMS in a clinical research environment. This will be followed by an examination of essential resource management considerations, with emphasis on the requisite competency and learning components of a QMS. The final presentation will focus on how to execute one of the QMS steps by providing a framework for both the development and implementation of standard operating procedures (SOP) intended to provide quality products or services.

Knowing the System: Quality Management According to ISO 9001:2000
Antje Dahlen, PhD
Quality Assurance Manager, Harrison Clinical Research, Germany

Process Approach to Resource Management
Malaika Miller Simmons
Policy Development Officer, Contractor, Henry M. Jackson Foundation

SOPs as a Framework for a Quality Management System
Elizabeth E. Bodi, MS
Associate, Halloran Consulting Group

Session 399G IT - Information Technology, CDM

3:30 pm-5:00 pm LEVEL: ●

Room 258A

Leveraging Technology to Build an IT Infrastructure for Global Clinical Trials

SESSION CHAIRPERSON(S)

Rich Deyermond
Vice President, Global Customer Care, Phase Forward

Implementing or expanding an EDC initiative for high volumes of trial data requires an IT infrastructure that meets high standards for performance and reliability. With careful advance planning and through the use of the latest technologies, organizations can help to ensure that data is accessible when needed and will meet even the most stringent auditing requirements. This session will provide attendees with an overview of what's needed to ensure your infrastructure – arguably one of the most vital components of clinical data collection and analysis – can support the demand of your global clinical trial.

Network Performance Optimization: Challenges Around Geographically Dispersed Users, Bandwidth, and Network Latency
Neil Cohen
Senior Product Marketing Manager, Akamai

Scaling EDC Solutions to Meet the Needs of Large-scale Global Trials
Ian Sparks
Business Consultant, EDC Solutions Group, PAREXEL International, UK

Hosting and Provisioning of Managed Service Operations to Support Global Clinical Trials
Rich Deyermond
Vice President, Global Customer Care, Phase Forward

Session 399H MA - Marketing, MC

3:30 pm-5:00 pm LEVEL: ●

Room 104C

From Readability to Language Requirements: Drug Development in a Multicultural Environment

SESSION CHAIRPERSON(S)

Inna Kassatkina
President, Global Language Solutions

Compelling opportunities exist for drug developers and clinical researchers to boost value through strategic investments in cultural competency, health literacy, disease education initiatives, and grassroots partnerships. According to the latest US census numbers (Sept. 2007), among the 20 largest metro areas, more than half of all people over age five speak a language other than English at home (ie, 53.4% in Los Angeles). In order for pharmaceutical companies to reach multicultural communities, they must understand the unique differences between specific cultures, and how to incorporate these differences into their primary communications. This session will identify the major considerations that must be made when communicating a message to a multicultural audience. It will address topics including cultural sensitivity, translation processes, and legal components related to translating materials into other languages.

From Readability to Language Requirements: Drug Development in a Multicultural Environment
Inna Kassatkina
President, Global Language Solutions

Kelly Andress
Manager, Business Development, Alliance Healthcare Information, Inc.

Session 399I MC - Medical Communications, CR

3:30 pm-5:00 pm LEVEL: ●

Room 253B *CME and Pharmacy credits offered*

Is Your Medical Information Department Ready for an Avian Influenza Pandemic?

SESSION CHAIRPERSON(S)

Mona Gandhi, PharmD
Product Knowledge Manager, Roche

New cases of H5N1 avian influenza are being identified every week, yet many still minimize the seriousness of the situation. A recent survey of 24 industry-based medical information departments has shown that many are not adequately prepared for an avian flu pandemic – only 25% of respondents have a strategic plan of action in place and an additional 25% have no intentions of developing one. The purpose of this session is to show how medical information departments are prepared to handle communications during an avian influenza pandemic. In conclusion, this session will serve as a starting point for industry-based medical information departments to develop a preparedness plan for an avian flu pandemic.

Pandemic Planning at GSK: GSK Response Center
Michael David Barnes, RPh
Manager, GSK Response Center Medical Operations, GlaxoSmithKline

Pandemic Planning at Roche: Medical Information Department
Deborah Breidt Kapucuoglu, MSN, RN
Manager, Professional Product Information, Roche

CDC Perspective
Martin Meltzer, PhD, MS
Senior Health Economist and Distinguished Consultant, Coordinating Center for Infectious Diseases, National Center for Preparedness, Detection, and Control of Infectious Diseases, Division of Emerging Infection and Surveillance Services, Centers for Disease Control (CDC)

Session 399J MW - Medical/Scientific Writing, ERS/DM

3:30 pm-5:00 pm LEVEL: ■

Room 153C

CTD/eCTD Submission-ready Documents and Summaries: Updates and Case Studies

SESSION CHAIRPERSON(S)

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

This session will present regulatory updates and trends in writing submission-ready documents and summaries for the CTD and eCTD, and will present case studies of recent eCTD submissions. The presentations will address writing the ISS and clinical summaries and will also present tips for medical/technical writers to transition to the eCTD; this will cover granularity, eCTD specifications relevant to authoring, level of detail, using eCTD templates, writing CTD summaries, and effective processes for writing and reviewing eCTD-ready documents in Modules 1-5.

Putting the ''Common'' Back in the CTD: Writing One Clinical Overview for the US and EU Health Authorities
Frank C. Hubbard, PhD
Acting Associate Director, Medical Communications and Document Management, AstraZeneca

How Statisticians Help Medical Writers in Preparation of the ISE, ISS, and CTD Summaries
Pamela Lindroos, PhD
Director, Medical Writing, WebbWrites

Transitioning to the eCTD: Modules 1-5
Michelle Herrera Foster, PhD
Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

Session 399K NC - Nonclinical Laboratory Safety Assessment, CR

3:30 pm-5:00 pm LEVEL: ●

Room 203

Consortium Efforts in Safety Biomarker Discovery and Qualification

SESSION CHAIRPERSON(S)

William Mattes, PhD
Director, Toxicology, The Critical Path Institute

Safety testing in pharmaceutical drug development begins early as nonclinical studies and continues into clinical trials. A presupposition of this process is that drug-induced injury can be detected at all stages, using a variety of assays. Unfortunately many such injuries detected in nonclinical studies are not easily monitored in clinical studies, while in other cases the nonclinical correlate of the clinical injury is not clear. Therefore, new biomarkers of safety are desirable that can be applied in all stages of drug development to sensitively detect and monitor the potential for drug-induced injury. Consortia are the ideal forums for efficient discovery and qualification of safety biomarkers, providing the critical mass of expertise, experience, and resources for developing comprehensive datasets. However, new biomarkers have full impact when they are accepted by regulatory bodies as applicable to studies conducted to support the registration of new medicines and treatments. Thus, a regulatory process for approving the qualification of new biomarkers is equally important. This session will review two Consortium efforts (e.g. Predictive Safety Testing Consortium and ILSI HESI) and their progress, and will provide a review of both FDA and EMEA experience in the biomarker qualification review process.

The Role of Consortia and the Predictive Safety Testing Consortium
William Mattes, PhD
Director, Toxicology, The Critical Path Institute

Bridging Biomarker Evaluation through the HESI Collaborative Structure
Syril D. Pettit, MS
Senior Scientific Program Manager, Health and Environmental Sciences Institute

Results from the First Year of Biomarker Qualification at the EMEA
Marisa Papaluca-Amati, MD
Deputy Head of Sector, Safety and Efficacy of Medicines, European Medicines Agency, European Union

Results from the First Year of Biomarker Qualification at the FDA
Federico Manuel Goodsaid, PhD
Senior Staff Scientist, Genomics Group, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

Session 399L NHP - Natural Health Products, CR

3:30 pm-5:00 pm LEVEL: ●

Room 156C

Challenges in Natural Health Products Development in Less Developed Countries

SESSION CHAIRPERSON(S)

Mahabir P. Gupta, PhD
Director, CIFLORPAN and Research Professor of Pharmacognosy, University of Panama

The less developed or developing countries suffer from various limitations in knowledge and resources. In this session, attendees will learn what the current system is for developing NHP, and what improvements are possible to safeguard better quality products to meet international standards. Perspectives and challenges developing natural health products in Chile will also be addressed. In addition, the session will examine the development requirements for Unani and Ayurvedic in a small country like Bangladesh.

WHO Activities in the Field of Traditional Medicine
Yukiko Maruyama
Scientist, Traditional Medicine, World Health Organization, Switzerland

Prospects and Challenges of Herbal Medicines in Bangladesh: Focus on Requirements for the Manufacture of Unani versus Ayurvedic
Mohammad Rafiqul Islam
Director, Marketing and Sales, Acme Laboratories Ltd., Bangladesh

Current Situation and Perspectives of Development of Phytopharmaceuticals in Latin America: Case of Chile
Ximena Polanco
General Manager, Laboratorios Ximena Polanco, Chile
Maria Eugenia Letelier
Professor, Department of Pharmaceutical Chemistry and Toxicology, University of Chile

Session 399M OS - Outsourcing, MW

3:30 pm-5:00 pm LEVEL: ■

Room 205C

Creating Partnerships in a World of Gatekeepers

SESSION CHAIRPERSON(S)

Art Gertel, MS
Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.

The success or failure of any project often turns on how effectively a true partnership was established. Too often there is not equal investment among stakeholders. This results in unequal distribution of responsibility, accountability, and ownership. A model of success represents partnership among service providers and clients. A panel of experts will represent different perspectives across a number of outsourcing models in the pharmaceutical industry. They will address differences among the models, how to overcome perceived obstacles to partnership, and how to develop approaches to best ensure success for all parties.

Changing the Culture: Outsourcing Is Not All that Bad
Clifton D. Chunn
Director, Global Medical Writing Projects, Allergan, Inc.

Running the Big Pharma Gauntlet: A View from Inside the Maze
Rhonda D. Sprague
Team Leader, GMC Business Office, Eli Lilly and Company

CRO Perspective
Art Gertel, MS
Vice President, Clinical Services, Regulatory, and Medical Writing, Beardsworth Consulting Group, Inc.

Session 399N PM/FI 1 - Project Management/ Finance, RD

3:30 pm-5:00 pm LEVEL: ■

Room 103 *Project Management units offered*

Optimizing Drug Development Practices within the Cross-cultural Environment between Asia and the US

SESSION CHAIRPERSON(S)

Atsushi Tsukamoto, MSc, PMP
Global Project Manager, Daiichi Sankyo Co., Ltd., Japan

As Asian countries, including China, India, Korea and Japan, continue to expand their contribution to global pharmaceutical development, effective collaboration with those countries is increasingly essential for the industry. This session will examine the key challenges and pitfalls that commonly occur when Americans and other Westerners work with Asians, and provide practical suggestions and solutions. The session will also discuss strategic and operational considerations for product development (regulatory, clinical, and CMC), including potential benefits and risks of these efforts, especially in China.

Improving the Relationships and Performance for a US-Asia Joint Team
Marshall Hewitt, MS
President, Global Alignment

Considerations for Product Development in China, India and Other Asian Countries
Mark A. Kryah, PMP
CMC Project Manager, Eli Lilly and Company

Managing Global Trials in China and the US: Commonalities and Differences
Ming Lu
Director, China Operations, ICON Clinical Research Pte. Ltd., China

Session 399O PM/FI 2 - Project Management/ Finance, RD

3:30 pm-5:00 pm LEVEL: ■

Room 102AB *Project Management units offered*

Enterprise Project Management in Pharmaceutical R&D: The Journey Continues

SESSION CHAIRPERSON(S)

Randal J. Ofensend, MBA
Vice President, Product Development and Integration, ePharmaSolutions

This session will provide an update regarding the state of enterprise project management (EPM) within pharmaceutical R&D, followed by presentations from three different organizations regarding their projects to implement EPM over time. The update will address the current state of EPM within pharmaceutical R&D: What are the trends, challenges, and future directions? Speakers will present case studies regarding their EPM implementation projects: what has been done, what are the challenges, what are the lessons learned, and what are the next steps. This session will be of interest to anyone involved in pharmaceutical R&D project management processes, systems or organization, including schedule, resource, cost, and portfolio management. This session will provide insight into EPM that can be applied to small pharmaceutical companies, biotechnology companies, and CROs.

A Project-centric Approach to EPM Implementation in Pharma: A Paced, Project-by-project Approach to Implementation
Jan R. Nichols
Vice President, Project and Portfolio Management Capabilities, GlaxoSmithKline, UK

Implementation of Enterprise Resource and Project Management within a Biotechnology Organization
Sean Gharpurey, MBA, MS
Senior Director, Development Planning and Performance Analysis, Genentech, Inc.

Implementation of EPM within a CRO Organization
Jean Bolte, BSN, MSN
Director, Project Office, Duke Clinical Research Institute

Session 399P PP - Public Policy/Law, AHC/IS

3:30 pm-5:00 pm LEVEL: ●

Room 160AB *Nursing and Pharmacy credits offered*

Patient-driven Clinical Trials

SESSION CHAIRPERSON(S)

William C. Crawford, MBA
Informatics Services Group General Manager, Children's Hospital Informatics Program

New technologies have rapidly increased the amount of information gathered on and by patients during the normal course of clinical care. This session focuses on engaging patients in clinical research through the patient-driven clinical trial, which focuses on efficient use of patient-controlled health-care data for research, and on improved communication with patients through personal health records and other media. The session will look at real research examples from the Harvard Medical School, as well as existing platforms for patient-controlled health-care data and research.

Genomics, Health Information Altruists, and Patient-driven Trials
Isaac Kohane
Lawrence J. Henderson Associate Professor of Pediatrics and HST, Harvard Medical School

The Challenges of Personal Genomics
Mark Boguski, MD, PhD
Center for Biomedical Informatics, Harvard Medical School

Session 399Q RA 1 - Regulatory Affairs

3:30 pm-5:00 pm LEVEL: ●

Room 254AB

Critical Path Update for 2008

SESSION CHAIRPERSON(S)

ShaAvhrée Y. Buckman, MD, PhD
Acting Director, Office of Translational Sciences, CDER, FDA

In March 2004, FDA first announced the Critical Path Initiative which had as its focus identifying additional mechanisms through applied scientific studies to develop better methods and new technologies that may improve the product development process. Since that time, a number of efforts have launched to leverage collaborations to modernize development of new genomic, imaging, statistical, methodological, analytical, and informatics tools, with the ultimate goal of reducing the uncertainty about product performance throughout the medical product life cycle. The goal of this session is to provide a progress update on specific activities undertaken in support of the Critical Path Initiative and provide key areas of focus for future efforts.

Serious Adverse Event Consortium (SAEC) Effort
Daniel K. Burns
Senior Vice President, Pharmacogenetics, GlaxoSmithKline

FDA Perspective
ShaAvhrée Y. Buckman, MD, PhD
Acting Director, Office of Translational Sciences, CDER, FDA

Garry A. Neil, MD
Corporate Vice President, Corporate Office of Science and Technology (COSAT), Johnson & Johnson

Session 399R RA 2 - Regulatory Affairs, CR

3:30 pm-5:00 pm LEVEL: ◆

Room 253C

Regulatory Requirements for Conducting Clinical Trials in India and China

SESSION CHAIRPERSON(S)

Munish Mehra, PhD
Managing Director, Global Drug Development Experts

India and China are rapidly becoming the most preferred countries to conduct 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 these countries and share their practical examples of exactly what needs to be done to obtain regulatory approval to conduct trials.

FDA Perspective
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science and Director, Good Clinical Practice Program, Office of Science and Health Coordination, Office of the Commissioner, FDA

Schedule Y and Indian GCP Requirements
Munish Mehra, PhD
Managing Director, Global Drug Development Experts

Session 399S RA 3 - Regulatory Affairs, PP

3:30 pm-5:00 pm LEVEL: ●

Room 253A

Public Involvement in the Regulation of Health Products: Methodologies for Assessing and Incorporating Public Input in Regulatory Decision Making

SESSION CHAIRPERSON(S)

Tyler Lacombe
A/Manager, Policy Planning and Analysis, Office of Consumer and Public Involvement, Health Products and Food Branch, Health Canada

The focus of this session is a specific aspect of the modernization of drug regulation in North America: the involvement of the public in quality regulatory decision making, thereby fostering a more transparent and accountable system for regulating health products. The session will address two specific cases. The first is a Policy on Public Input launched in 2007 by Health Canada's Health Products and Food Branch, and the development of tools and Guidance to assist in the policy's implementation. The second is the approach taken by the US Food and Drug Administration (FDA) to encourage patient/public involvement in regulatory decision-making processes, and to incorporate the patient perspectives in the drug review and approval process.

The session will conclude with a facilitated discussion regarding the assessment of information gathered through public input activities against appropriate standards of reliability and relevance, and how public input evidence can be incorporated in regulatory decision making.

FDA Perspective
Richard Klein
Public Health Specialist, Office of Special Health Issues, Office of the Commissioner, FDA

Mavis Jones, PhD
Postdoctoral Fellow, Department of Bioethics, Dalhousie University, Canada

Session 399T RA 4 - Regulatory Affairs, CP

3:30 pm-5:00 pm LEVEL: ■

Room 256

Preparing for FDAAA Implementation

SESSION CHAIRPERSON(S)

Chin C. Koerner, MS
Executive Director, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

With the passage of FDAAA, there is now even more focus on postapproval safety. Even as FDA was given more authority, FDA and companies are working together to understand how best to interpret and implement the law in the area of the Science of Safety, risk communication in labeling, postapproval studies, and Risk Evaluation and Mitigation Strategies (REMS). This session will highlight the FDAAA safety provisions, FDA's recent post approval safety practices, and the impact of FDAAA on the future of drug development and the pharmaceutical industry.

Overview of FDAAA Safety Provisions
Scott M. Lassman, JD, MA
Partner, Regulatory and Government Affairs; Co-chair, FDA Practice Group, WilmerHale

Review of Recent Postapproval Safety Experiences
Christopher P. Milne, DVM, JD, MPH
Associate Director, Tufts Center for the Study of Drug Development, Tufts University

Preparing for the New Age of Safety: An Industry Perspective
Eslie H. Dennis, MD
Executive Medical Director, Novartis Pharmaceuticals Corporation

Session 399U ST - Statistics

3:30 pm-5:00 pm LEVEL: ■

Room 159AB

Advancing the Scientific Thinking in Drug Development: The Roles of Statisticians in Industry, Regulatory Agencies, and Academia

SESSION CHAIRPERSON(S)

Yeh-Fong Chen, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

To bring safe and effective drugs to the market successfully, the pharmaceutical industry, regulatory agencies, and academia need to work together closely. For a statistician, it is important to keep abreast of the latest developments in regulatory sciences in order to make important contributions to the drug development process. In addition to learning about newly developed methodologies, it is also beneficial to collaborate in identifying issues and working towards mutually acceptable statistical solutions to our problems. All three parties need to be devoted to these efforts. Although the issues might be similar, statisticians from industry, regulatory agencies and academia, all have their own methods, motivations and agendas in focusing on new problems that are emerging as we work to improve the drug development process. If all three parties can work together on common problems, it will certainly speed the development and acceptance of new statistical methodologies and the science of drug development. For achieving this goal, the first step is to learn the agenda that each party has and the challenges that we are currently facing. There are many problems for us to work on together. It is critical for us to know what useful information is available. In this session, we will have speakers from industry, FDA and academia describe their approaches to new problems and their experience with some practical examples. The needs and suggestions for improvements to the current drug development process will also be discussed. The focus will be on identifying problems, developing methods and coming to a mutual understanding of what is acceptable practice.

Drug Development: The Role of the Academic Statistician from Phase 2 to Phase 4
Ralph B. D'Agostino, PhD, MA
Chair, Mathematics and Statistics Department; Professor of Mathematics/Statistics and Public Health, Boston University

Handling Uncertainty in HIV Endpoint Selection and Other Endpoint Issues
Fraser Smith, PhD
Mathematical Statistician, Division of Biometrics IV, CDER, FDA

Optimality and Flexibility in Clinical Trial Design
Gordon Lan, PhD
Senior Director/Statistics Fellow, Johnson & Johnson

Session 399V TR - Training

3:30 pm-5:00 pm LEVEL: ●

Room 157AB

Mentoring and Coaching Programs, Getting Started, and Tracking Progress

SESSION CHAIRPERSON(S)

Julia A. Dillon, PharmD
Account Leader, Global Medical Communications, Eli Lilly and Company

Mentoring programs can vary in structure from mentee/mentor pair assignments to mentee-driven, self-guided relationships. Learning professionals can apply various models to develop a mentoring program. Program evaluation methods will also be discussed.

Mentoring Programs, Getting Started, and Tracking Progress
Julia A. Dillon, PharmD
Account Leader, Global Medical Communications, Eli Lilly and Company

Mentoring, Coaching, and Career Development
Danny A. Benau, PhD
Associate Professor, Biomedical Writing, University of the Sciences in Philadelphia

Mentoring Success: Training New Mentors
Patricia Wallenstein
Senior Curriculum Trainer, PRA International

Session 399W VA - Validation, IT

3:30 pm-5:00 pm LEVEL: ●

Room 251

Outsourcing: Computerized Systems Best Practices for Data Integrity/Quality

SESSION CHAIRPERSON(S)

Martin Browning, MS
President, EduQuest, Inc.

As companies seek ways to reduce costs and supplement internal resources with external expertise, compliance and quality must be considered. This session will cover best practices for outsourcing of computerized systems, programming and related services: best practices for outsourcing, regulatory expectations, questions to ask, issues to explore before you sign the contract, self-protection, a framework for assessment and selection, "extreme outsourcing" outsourcing and staying in compliance – GXPs for the virtual biotechnology company

Outsourcing and Staying in Compliance: GXPs for the "Virtual" Biotechnology Company
Robert C. Blanks, MS, RAC
Vice President, Quality/Compliance, Idenix Pharmaceuticals

Louis Bravos
Principal, CausePoint Consulting

Martin Browning, MS
President, EduQuest, Inc.

5:00 pm **END OF WEDNESDAY SESSIONS**

5:00 pm-6:00 pm **EMERGING PROFESSIONALS AND STUDENTS NETWORKING RECEPTION**
Grand Ballroom Lobby, Level 3, BCEC

5:15 pm **CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH MEETING**
Room 103, Level 1, BCEC

7:00 am-10:30 am **SPEAKER REGISTRATION**
North Lobby, Level 1, BCEC

7:30 am-8:15 am **CONTINENTAL BREAKFAST**
North Lobby, Level 1, BCEC

7:30 am-10:30 am **ATTENDEE REGISTRATION**
North Lobby, Level 1, BCEC

12:30 pm-5:00 pm **MEDDRA® USER GROUP MEETING**
Room 210A, Level 2, BCEC

SESSION 401 AHC/IS - ACADEMIC HEALTH CENTERS/ INVESTIGATIVE SITES, CR

8:30 am-10:00 am LEVEL: ◆

Room 103 *Pharmacy credits offered*

Global Patient Recruitment and Retention: Identifying and Overcoming Barriers to Accelerate Patient Recruitment and Retention Worldwide

SESSION CHAIRPERSON(S)

Janet Jones, PhD
Director, Feasibility and Patient Recruitment, Kendle, UK

In a global study, good feasibility, appropriate site selection, and proper planning are critical to patient recruitment success. Adopting patient-centric approaches from initial planning to study end will maximize patient involvement, provided they form part of a strong operational plan. This presentation evaluates challenges, compares the recruitment methodologies that have been used in several key geographic regions, and provides insights into how to develop a successful global recruitment and retention plan.

Successfully Recruiting Niche Populations for Clinical Trials: God, Money, and Me – The Influence of Religion, Economics, and Ethnicity on Recruitment Strategies Targeting a Specific Population
Patrick G. Clay, PharmD
Director, Dybedal Clinical Research Center, Kansas City University of Medicine and Biosciences

Patients, Perception, and Protocols
Kate Spencer
Patient Recruitment Business Director, Langland, UK

Global Patient Recruitment and Retention: Identifying and Overcoming Barriers to Accelerate Patient Recruitment and Retention Worldwide
Janet Jones, PhD
Director, Feasibility and Patient Recruitment, Kendle, UK

SESSION 402 BT - BIOTECHNOLOGY, RA

8:30 am-10:00 am LEVEL: ■

Room 105

Adding Value to Resource-constrained, Early-stage Biotechnology Product Development from the Regulatory Perspective

SESSION CHAIRPERSON(S)

Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting Group, UK

The primary goal of most smaller biotechnology companies is to develop a product to a stage where additional funding can be attracted or partnering becomes feasible. Therefore, the focus of the company should be to add as much value as possible to the project during early development, within the constraints of available resources. Value is partly based on the achievement of regulatory milestones. This session will provide practical advice towards maximizing the potential of development program from the regulatory perspective. The topics to be covered include orphan designation, optimizing agency interactions, the importance of regulatory intelligence, and innovative regulatory strategies.

Adding Value towards Licensing Out or Partnering an Innovative Biotechnology Product from the Regulatory Perspective
Richard A. Wolfe, PhD
Director/Team Leader, Biopharma Operations, Pfizer Global Manufacturing

The Small Biotechnology Company Perspective
Christopher J. Holloway, PhD
Group Director, Regulatory Affairs and CSO, ERA Consulting Ltd., UK

SESSION 403 CDM - CLINICAL DATA MANAGEMENT, CP

8:30 am-10:00 am LEVEL: ■

Room 256 *Nursing credits offered*

Clinical Trial Data and Coding Processes

SESSION CHAIRPERSON(S)

Sonja Brajovic, MD
Medical Manager, PSI International, Inc.

This session focuses on clinical trial adverse event data coding. Presented are current models for implementing standards and achieving coding quality and consistency utilizing the Medical Dictionary for Regulatory Activities (MedDRA®) and also the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE). A brief overview of the adverse event verbatim pathway is followed by a presentation on one organization's experience in managing the quality of clinical trial coding in a fully outsourced model. Next is a presentation exploring another organization's experience in implementing a centralized, internal coding model. Both focus on MedDRA® terminology. The final presentation focuses on NCI oncology adverse event data and coding standards utilizing CTCAE terminology and the MedDRA® bridge.

Adverse Event Verbatim Pathway: An Overview
Sonja Brajovic, MD
Medical Manager, PSI International, Inc.

Quality Management in Outsourced Clinical Data Coding
Linda Amato-Smith
Associate Director, Dictionary Services, Pfizer Inc

Coding Quality and Consistency: Centralized Coding Approach
Martina Viell
Head, Medical Coding Operations, Bayer Vital GmbH, Germany

Oncology Adverse Event Data, CTCAE Terminology and MedDRA®
Ann Setser, BSN, MEd
Nurse Consultant, Office of Associate Director, Cancer Therapy Evaluation Program, National Cancer Institute

Panelist
Judy E. Harrison, MD
Medical Officer, MedDRA® MSSO

SESSION 404 CMC/GMP - CHEMISTRY, MANUFACTURING AND CONTROLS/GOOD MANUFACTURING PRACTICES

8:30 am-10:00 am LEVEL: ●

Room 253B

GMP Updates

SESSION CHAIRPERSON(S)

Monica E. Caphart, MS
Consumer Safety Officer, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

This session will cover diverse topics including ingredient safety, recalls and a Q10 update.

Theory and Application of Risk-based Prioritization for GMP Surveillance Inspections
Gregg Claycamp, PhD, MS
Director, Division of Compliance Risk Management and Surveillance, Office of Compliance, CDER, FDA

Panelist
Monica E. Caphart, MS
Consumer Safety Officer, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

Session 405 CP - Clinical Safety and Pharmacovigilance, CDM

8:30 am-10:00 am LEVEL: ■

Room 157AB *CME credits offered*

MedDRA® Versioning: What Does It Mean to You?

SESSION CHAIRPERSON(S)

Patrick Revelle
Director, MedDRA® MSSO, Northrop Grumman

MedDRA® versioning as a general topic is not new. What is new is the idea of better synchronization of MedDRA® updates between industry and regulators and between industry partners. The second component of this session is focused on identifying what is meant by each organization when upversioning MedDRA®. The concept is that each organization would identify what is done to their existing data when the new version of MedDRA® is loaded (eg, no changes to significant changes) utilizing a scale with defined levels of upgrade.

Do You Version? We Version!
JoAnn Medbery, BSN, RN
Director, Dictionary Management, Johnson & Johnson

MedDRA® Versioning Proposals
Patrick Revelle
Director, MedDRA® MSSO, Northrop Grumman

Aversion to Version
David A. Pherson, PhD
Associate Director, Central Coding Operations, Genzyme Corporation

Session 406 CR 1 - Clinical Research and Development, RD

8:30 am-10:00 am LEVEL: ■

Room 102AB

Industry Insights: Forging Partnerships with NIH-sponsored Clinical Trials and Networks

SESSION CHAIRPERSON(S)

Rebecca H. Li, PhD
Vice President, Clinical Research, New England Research Institutes, Inc.

This session will offer perspectives from the public and private sectors on the valuable corporate opportunities and the advantages to both the private sector and NIH that are offered by partnerships on NIH-sponsored trials. Companies looking to explore new ways to broaden the scope of their research and tap into a valuable public data resource will benefit from these partnerships. Case studies involving device, biomarker, and drug manufacturers will be presented to show how this pathway has been used to further corporate research and development efforts.

Perspectives on Identifying Opportunities for Industry to Partner with NIH
Rebecca H. Li, PhD
Vice President, Clinical Research, New England Research Institutes, Inc.

NHLBI Perspectives on Collaborations and Partnerships with Industry
Michael Domanski, MD
Branch Chief, Atherothrombosis and Coronary Artery Disease, National Heart, Lung, and Blood Institute (NHLBI)

Experience Working within an NHLBI Cardiac Trial
Dean Winter, PhD
Vice President, Scientific and Clinical Affairs, AtCor Medical, Inc.

Session 407 CR 2 - Clinical Research and Development, PM/FI

8:30 am-10:00 am LEVEL: ■

Room 104AB

Exploring the Roles of Clinical Research and Medical Affairs in a Contemporary Pharmaceutical Company

SESSION CHAIRPERSON(S)

Frank E. Plonski, RN
Clinical Project Leader, sanofi-aventis

In the pharmaceutical industry there is a wide variety of medical and scientific roles. This session will focus on exploring the roles of clinical research and medical affairs within a contemporary pharmaceutical company with regard to the life-cycle management of products, with an additional focus then being placed on the potential of collaborations between the two areas. The collaboration between medical affairs and clinical research professionals looks to utilize innovative methods to capitalize on existing synergies between the two groups to build better relationships, as well as enhance the quality of the conduct of clinical trials. Examples of this collaboration will include team models used for successful identification of new investigators, support models for existing investigators, accurate and thorough trial feasibility, and modes to facilitate communication between the two groups.

Collaborating for Success in Clinical Trials: A Collaboration Model between Clinical Research and Medical Affairs to Enhance Clinical Trial Conduct and Investigator Relationships
Frank E. Plonski, RN
Clinical Project Leader, sanofi-aventis

Medical Affairs of a Contemporary Pharmaceutical Company: An Organization and Functional Model
Andrei Pikalov, MD, PhD
Senior Director, Medical Affairs, Otsuka America Pharmaceuticals, Inc.

Clinical Operations and Medical Affairs: A Partnership for Patient Accrual and Retention
Ross D. Pettit, MBA
Vice President, Clinical Operations, ARIAD Pharmaceuticals, Inc.

Session 408 EC - eClinical, CR

8:30 am-10:00 am LEVEL: ●

Room 205A

The Secondary Use of Health-care Data: A Strategy for Merging the Electronic Health Record with Electronic Data Capture

SESSION CHAIRPERSON(S)

Charles Jaffe, MD, PhD, FACMI
CEO, Health Level 7, Inc.

Regulated clinical research has been hampered by prolonged execution times and increasing costs. A myriad of data from patient care is available to reverse these trends, while improving the efficiency of research execution and the quality of research data. Advances in technology and standards have provided new opportunities to drive this process. Policy changes at both a regulatory and operational level are needed to enable these advances.

Connecting Patient Care and Research: Critical Requirements for Standardizing Data
Charles Jaffe, MD, PhD, FACMI
CEO, Health Level 7, Inc.

Connecting Two Worlds: Electronic Health Record Systems and Clinical Research
Miguel A. Valenzuela, MA
Head of Enterprise Systems QRM, Roche Products Ltd., UK

Connecting Two Worlds: Electronic Health Record Systems and Clinical Research – HIMSS 2008 Interoperability Update
Linda King, MT
Data Management Team Leader, Eli Lilly and Company

Session 409 ERS/DM - Electronic Regulatory Submissions/Document Management, IT

8:30 am-10:00 am LEVEL: ■

Room 253C

eCTD: Life-cycle Management (LCM)

SESSION CHAIRPERSON(S)

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

The electronic common technical document (eCTD) presents a new approach to both document and dossier life cycle. Inherent in this process are challenges involving both document authoring and sponsor decision making. This session will introduce the challenges of LCM, present common errors and present efficiencies that can be gained when creating eCTD-ready documents.

eCTD Errors: Avoidance, Corrections, and Recovery
Patricia Sichort
Regulatory Document Specialist, Wyeth Pharmaceuticals

How Do Submission-ready Documents Boost eCTD and Product Life-cycle Quality?
Olaf Schoepke, PhD
Managing Director, Extedo Ltd., UK

eCTD Life-cycle Management: Challenges and Opportunities
Nancy P. Smerkanich
Vice President, Regulatory Affairs, Octagon Research Solutions, Inc.

Session 410 GCP - Good Clinical Practices, CR

8:30 am-10:00 am LEVEL: ■

Room 204AB

Radical Ideas for Transforming the Informed Consent Process

SESSION CHAIRPERSON(S)

Susan Brink, DrPH
President and CEO, ConsentSolutions, Inc.

How do we know if the informed consent process is successful? What are the elements that make up "the process behind the process"? This session will take a fresh look at four key elements that sponsors can impact to improve the patient experience and overall success rate of informed decision making – information design, delivery of information, candidate processing of information, and ensuring comprehension. Ideas for improving the consent process for the candidate and the clinical staff will be presented in each area.

Extreme Ideas for Ensuring Candidate Comprehension and Autonomous Decision Making
Darren B. McDaniel, MS
CEO, Managing Officer, Coast IRB, LLC

Multinational Informed Consent: Addressing the Cultural Context
Linda Wolf, MS
Emerging Markets and Services, BBK Worldwide

Building a Better Informed Consent Process through a Better Informed Consent Document
Matthew R. Baker
President and CEO, Compass IRB, LLC

Session 411 IT - Information Technology, CR

8:30 am-10:00 am LEVEL: ■

Room 205B

Improving Research Site Operational Performance Using Information Technology: Problems, Promise, and Progress

SESSION CHAIRPERSON(S)

Michael Koren, MD
CEO and Medical Director, Jacksonville Center for Clinical Research

IT implementation concepts will be discussed in this lively session of investigators, study managers, and vendors who will explore barriers to and possible future benefits of technological solutions for research practices. The distinguished panel will demonstrate IT tools that enhance site selection, study startup, and operational performance.

Advanced Web Project Management Tools Supporting the Conduction of Clinical Trials in Cooperative Groups
Marisa De Rosa, PharmD, PhD
Head of Systems and Services for Health Department (SISS), CINECA Inter-University Consortium, Italy

Session 412 MW - Medical/Scientific Writing, CR

8:30 am-10:00 am LEVEL: ●

Room 205C

Medical Writing in Drug Development: Differences between Japanese Requirements and Those of the US and European Union

SESSION CHAIRPERSON(S)

Satomi Ando, MS
Head, Document Operation Department, Development Division, Novartis Pharma K.K., Japan

This session provides a review of the current role and responsibilities of medical writing in the Japanese pharmaceutical industry. It also addresses how key regulatory documents are prepared in collaboration with other regions (US, EU) in a foreign-affiliated pharmaceutical company in Japan and also provides the Japanese-specific needs for the key regulatory documents, in terms of content, quality, and importance.

Global Simultaneous Submission: Overcoming the Challenges – A Japan Perspective
Yuko Kojima, RPh
Manager, Japan Medical Communications, Eli Lilly Japan K.K., Japan

CTD and IB Preparation: A Dilemmma between Globalization and Local Requirements
Hiroko Terano
Manager, Medical Writing Group, Novo Nordisk Pharma Ltd., Japan

Expectations for Medical Writing from a Reviewer's Point of View in Japan
Tetsuya Tanimoto, MD
Reviewer, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Session 413 NC - Nonclinical Laboratory Safety Assessment, BT

8:30 am-10:00 am LEVEL: ●

Room 208

Harmonization of Requirements for the Preclinical Development of Anticancer Drugs

SESSION CHAIRPERSON(S)

Jon Daniels, PhD
Vice President and Senior Toxicologist, Intrinsik Health Sciences Inc., Canada

The preclinical development of oncology drugs is not harmonized globally. Recently, ICH began working on a new Guidance, "Preclinical Guideline on Oncology Therapeutic Development" (ICH S9). This session will review current requirements for the nonclinical safety evaluation of novel anticancer agents and describe this important ICH initiative.

Common Mechanism-based Adverse Events Associated with Chemotherapy in Survivors
Lee Silverman, DVM, PhD
Senior Scientist II, Millennium Pharmaceuticals, Inc.

FDA Perspective
John Leighton, PhD
Associate Director for Pharmacology, Office of Oncology Drug Products, Office of New Drugs, FDA

Daniel M. Lapadula, PhD
Safety Profiling and Assessment, Novartis Pharmaceuticals Corporation

Session 414 NHP - Natural Health Products, VA

8:30 am-10:00 am LEVEL: ■

Room 203

Validation Process and Its Impact in Natural Health Products Research and Development

SESSION CHAIRPERSON(S)

Carmen Tamayo, MD
Director, Research and Development, Flora, Inc.

The validation process within the research and development paradigm is a critical entity. This session is designed to discuss issues surrounding the validation process and its impact scientifically, as well as economically. Multidisciplinary evidence-based approaches will be presented.

Bioassays and CMC Approaches
Carmen Tamayo, MD
Director, Research and Development, Flora, Inc.

Research on Herbal Medicinal Products: Scientific and Economic Perspectives
Werner Busse
Director, International Division, Dr. Willmar Schwabe Pharmaceuticals, Germany

Natural Health Product Development: Concept Development, Evidence, and Finished Goods
Joel J. Gagnier, ND, MSc
Senior Science Officer, Jamieson Laboratories Limited, Canada

Session 415 OS - Outsourcing, PM/FI

8:30 am-10:00 am LEVEL: ■

Room 253A

Outsourcing, Niche-sourcing, Rural-sourcing, and Offshoring: Saving Time and Money in Clinical Development

SESSION CHAIRPERSON(S)

Jeremy Jokinen, MS
Director of Statistics and Data Management, STATKING Consulting

Alternatives to single-CRO outsourcing will be compared and contrasted. Through a case study, the presenters will examine alternatives often considered to save time and money, including niche-sourcing, offshoring, and rural-sourcing. A checklist for niche-sourcing readiness will be presented.

Niche-sourcing of a Phase 3 Clinical Trial: A Case Study
Michelle Caillouette
Clinical Trial Manager, Genentech, Inc.

Niche-sourcing for a Startup Device Company Running a Pivotal Clinical Trial
Roland K. Winger
Vice President, Clinical and Product Development, Ash Access Technology, Inc.

Factors Associated with Successful Niche-sourcing and Offshoring
Roderick L. Lashley
Vice President, Statistical Programming and Data Management, STATKING Consulting Inc.

Session 416 PM/FI 1 - Project Management/ Finance, CTM/CS

8:30 am-10:00 am LEVEL: ●

Room 156AB *Project Management units offered*

Illuminate the Dark Side of Clinical Trials Management: Applying Proven Project Management and Process Disciplines to Your Clinical Trial

SESSION CHAIRPERSON(S)

Jeffrey A. Kueffer, MBA, PMP
Executive Director, Operations Management, INC Research, Inc.

This session will give examples of how proven management and process disciplines from other industries can be applied to clinical trials, such as SEI's Capability Maturity Model, Six Sigma, Project Management Institute's PMBOK, and TQM. This session will focus on how to configure best practices across these various models to meet the unique needs of clinical trials management.

PMP Methodology and Tools for Management of Clinical Studies
Niki Valavanis, PMP
Program Manager, MDS Pharma Services, Canada

Cornerstones of Effective Project Management
Johanna Schenk, DrMed, MD, FFPM
Senior Partner and Managing Director, PharmaProjekthaus GmbH & Co. KG, Germany

Project Management Best Practices for Use in Study Startup
Jeffrey A. Kueffer, MBA, PMP
Executive Director, Operations Management, INC Research, Inc.

Session 417 PM/FI 2 - Project Management/ Finance, CR

8:30 am-10:00 am LEVEL: ■

Room 154 *Project Management units offered*

The Evolving Role of Project and Alliance Managers at Each Stage of Product Development

SESSION CHAIRPERSON(S)

Ailsa Mendez, MBA
Director, Project Governance, Functional Genetics

Alliances and partnerships are frequently being formed between biotechnology and pharmaceutical companies, and there is a growing need for alliance management professionals to manage these complex collaborations and programs. In this session, we will discuss the complexity of the project/alliance manager role at three major stages in drug development – early research collaborations, clinical development, and commercialization.

Start of a Long Journey: Focus on Science in Early-stage Alliance Programs
Katya Kovalskaia, MSc, PMP
Associate Director, Product Development, Anthrax Vaccine, Emergent BioSolutions

Joint Clinical Development: Complexity of Project/Alliance Manager Role
Martine Zimmermann-Laugel, PharmD
Head of Department, Presubmission Division, Worldwide Regulatory Affairs, Science Union (Servier), France

The Alliance at Product Launch: Market Strategies and Life-cycle Management
Laurie Dubrovin, MS, PMP
Senior Project Manager, Product Portfolio Management, Genentech, Inc.

Session 418 PM/FI 3 - Project Management/ Finance, CTM/CS

8:30 am-10:00 am LEVEL: ■

Room 251 *Project Management units offered*

Using Relationship Management Tools to Improve Project Results

SESSION CHAIRPERSON(S)

Karean L. Eissler, MS, PMP
Managing Leader, InsightRx Consulting LLC

This session explores 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.

How to Build Collaborative Team Relationships
Ruth Dubinsky, MS
President, Clarity Consulting, Inc.

The Power of Conflict: Strategies to Surface and Reframe Bumps in the Road
Angela Balduzzi
Director, Organization Development, GlaxoSmithKline

Business Impact of Effective (and Ineffective) Relationship Management Deployment
David W. Gillogly, MBA
Senior Director, Outsourcing and Alliance Management, Daiichi Sankyo Pharma Development

Session 419 PP - Public Policy/Law, RA

8:30 am-10:00 am LEVEL: ■

Room 104C *CME and Nursing credits offered*

Product Liability and Drug-induced Injury: Adverse Event Reporting in the US and the Law in Europe

SESSION CHAIRPERSON(S)

Peter Feldschreiber, JD, MD, FFPM
Senior Medical Assessor and Special Litigation Coordinator, Medicines and Healthcare products Agency (MHRA), UK

This session will review the law on product liability and consumer protection against drug induced injury in Europe together with an examination of the way that adverse event reporting of potential drug induced damage is evolving in the United States. The session will review the product liability directive which imposes strict liability on producers of medicinal products, together with the policies behind the legislation, its application by European courts, the concept of a defective medicinal product, and the evaluation of causation on the basis of reported adverse events by the regulator and the court. We will also discuss the role of warnings in patient information literature and marketing/promotional platforms as regards liability in Europe. In comparison, US lawyers and IRB experts will explore the regulatory environment for the categorization and reporting of adverse events to the FDA and the consequent risks of litigation as regards regulatory compliance and in tort. In particular this part of the session will explore the FDA's draft Guidance on requirements for reporting unanticipated problems, where the responsibility for analysis and reporting shifts from the clinical investigator to the sponsor. This will include a discussion of measures needed to be put in place and the strategic planning to reduce and mitigate/manage litigation and regulatory risk associated with these changes in reporting responsibilities.

Reducing Regulatory and Litigation Risks Associated with Adverse Event Reporting
Ann Begley, BSN, JD
Partner, Kirkpatrick & Lockhart Preston Gates Ellis LLP

Adverse Event Reporting as it Pertains to the IRB
Cami E. Gearhart, JD
CEO, Quorum Review, Inc.

Paul Schmidt, JD
Partner, Intellectual Property, Pharmaceutical Litigation and Investigations, Covington & Burling, LLP

Session 420 RA 1 - Regulatory Affairs, CR

8:30 am-10:00 am LEVEL: ●

Room 153AB

CDER Town Meeting – Part 1 of 2

SESSION CHAIRPERSON(S)

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

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

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

Lawrence J. Lesko, PhD
Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA

RADM Sandra L. Kweder, MD
Rear Admiral, US Public Health Service; Deputy Director, Office of New Drugs, CDER, FDA

Paul J. Seligman, MD, MPH, CAPT. USPHS
Associate Director, Safety Policy and Communication, CDER, FDA

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

Session 421 RA 2 - Regulatory Affairs, OS

8:30 am-10:00 am LEVEL: ■

Room 153C

Best Practices for Acting as a US Agent

SESSION CHAIRPERSON(S)

Victoria C. Gunto, PhD, RAC
Director, Regulatory Affairs, Senior Regulatory Scientist, Cato Research

What does it mean to be a US agent for a medicinal product in development? The lack of specific guidance on this topic has resulted in significant variability in expectations and quality of services provided by those undertaking the role

of US agent. This session will discuss best practices for US agents including risk management and case studies.

Being a US Agent: Practical Aspects and Case Studies
Sandra J. Hecker, RAC
President, Hecker and Associates LLC

Being a US Agent: Responsibilities, Qualification and Consideration of Risk (or Risk Management)
Victoria C. Gunto, PhD, RAC
Director, Regulatory Affairs, Senior Regulatory Scientist, Cato Research

FDA Perspective
Anne R. Pariser, MD
Medical Reviewer, Office of New Drugs, Office of Drug Evaluation III, CDER, FDA

Session 422 ST - Statistics, IT

8:30 am-10:00 am LEVEL: ●

Room 206AB *Pharmacy credits offered*

What Statisticians Need to Know about CDISC

SESSION CHAIRPERSON(S)

Cathleen F. Barrows, PhD
Associate Director, Statistics and Programming, GlaxoSmithKline

CDISC has an impact on many of the issues and decisions that statisticians encounter. This session will focus on key aspects of the statistician's work affected by the CDISC standards, such as creating analysis datasets and associated metadata following the precepts of the Analysis Data Model (ADaM).

SDTM and ADaM: Maintaining Harmony in a Submission
Musa Nereko
Associate Director, Statistical Programming, Shire Pharmaceuticals

What CDISC Standards Do to and for Statisticians
Russell W. Helms, PhD
Chief Technology Officer, Rho, Inc.

Introducing the CDISC Analysis Data Model (ADaM) Implementation Guide
John Troxell
Senior Statistical Programming Analyst, Merck & Co., Inc.

Session 423 TR - Training, PM/FI

8:30 am-10:00 am LEVEL: ◆

Room 252AB

Bringing Online Learning to an Offline Organization

SESSION CHAIRPERSON(S)

Janet F. Zimmerman, MS, RN
Independent Consultant

Online learning options are now standard for a global workforce. However, bringing online learning to an offline organization that is accustomed to a traditional model of instructor-led, classroom-based training can be a bumpy process. Using case studies, presenters will discuss their experiences implementing online learning, including the challenges they encountered and how they were managed.

Web-based Training for Clinical Trial Staff: A GxP Case Study
Susan Giddens
Senior Instructional Designer, GeneEd

Training via Podcasts
Joan Harley, BSN, RN
Training Consultant and eLearning Developer, Training Extension, Division of Pastor Consulting, Inc.

Essentials for Implementing Online Learning
Janet F. Zimmerman, MS, RN
Independent Consultant

Session 424 VA - Validation, RA

8:30 am-10:00 am LEVEL: ■

Room 156C

Regulatory Issues and Opportunities

SESSION CHAIRPERSON(S)

Stephan Bachmann
Associate Director, Merck Research Laboratories

This session will explore the latest Guidances from FDA and EMEA surrounding the use of electronic source data and computerized systems in clinical trials. It will describe the major challenges and expectations identified in the EMEA Draft Reflection Paper on Expectations for Electronic Source Documents and FDA's Guidance for Computerized Systems Used in Clinical Investigations. It will highlight key points and offer current interpretations and clarification of those points.

FDA Guidance for Computerized Systems Used in Clinical Investigations
Patricia Beers Block
Consumer Safety Officer, Office of the Commissioner, FDA

Draft Reflection Paper on Expectations for Electronic Source Documents
Fergus Sweeney, PhD
Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, European Medicines Agency, European Union

Roundtable Discussion
Stephan Bachmann
Associate Director, Merck Research Laboratories

10:00 am-10:30 am **REFRESHMENT BREAK – North Lobby, Level 1, BCEC**

Session 425 AHC/IS - Academic Health Centers/ Investigative Sites, PP

10:30 am-12:00 pm LEVEL: ■

Room 103

The Honeymoon's Over: When Sponsors Sue Sites

SESSION CHAIRPERSON(S)

J. Andrew Lemons, JD
Of Counsel, Health Law Group, Baker Donelson

Follow the events surrounding an actual clinical research study that resulted in the sponsor suing the research site and a lawsuit that is still being litigated. One issue of particular interest in the industry is whether the sponsor is entitled to obtain lost profits from the site as a result of the site's acts and omissions related to the study. Equally important, however, is the fact that the clinical trial agreement, which is often largely overlooked during the earliest stages in the research process, takes center stage in the litigation. Therefore, this case serves as a useful reminder to sponsors and sites alike of the importance of careful contracting at the front end. Interwoven during our presentation will be practical guidance for appropriate contracting.

The Honeymoon's Over: When Sponsors Sue Sites
J. Andrew Lemons, JD
Of Counsel, Health Law Group, Baker Donelson

The Honeymoon's Over: When Sponsors Sue Sites
David M. Vulcano, MBA, MS, RAC
Assistant Vice President, Clinical Research, Hospital Corporation of America (HCA)

Session 426 BT - Biotechnology, CR

10:30 am-12:00 pm LEVEL: ■

Room 105

Using Systems Biology to Advance Knowledge-based Drug Development: Case Studies and Progress to Date

SESSION CHAIRPERSON(S)

Alan S. Louie, PhD
Research Director, Health Industry Insights, an IDC Company

The shift towards knowledge-based drug development is becoming increasingly important as pharmaceutical companies seek to become more efficient and productive. This shift has manifested itself in the form of increased efforts in computational biology, systems biology, and translational medicine initiatives within the industry. This session will focus on an overview of progress to date and case studies highlighting specific efforts to use systems biology-based solutions to accelerate drug development.

Systems Biology: Success Stories
Bruce Gomes, PhD
Head of Mathematical Modeling, Systems Biology Group, Pfizer Global Research and Development

Systems Biology Leads to the Development of MM-121, a Human Monoclonal Antibody ErbB3 Antagonist
Bridget Schoeberl, PhD
Associate Director, Computational Biology, Merrimack Pharmaceuticals, Inc.

Using Causal Network Modeling to Define Drug Mechanisms and Disease Biomarkers
Keith O. Elliston, PhD
President and CEO, Genstruct, Inc.

Session 427 CDM - Clinical Data Management, CP

10:30 am-12:00 pm LEVEL: ■

Room 256 *Pharmacy credits offered*

Data Management/CP Interface/SAE Reporting

SESSION CHAIRPERSON(S)

Mariette Boerstoel-Streefland, MD, MBA, MS
Executive Director, Pharmacovigilance/Risk Management, Forest Research Institute, Forest Laboratories, Inc.

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

This session will explore ways of breaking the artificial barriers between PV case management in one silo and data management in the other by thinking in terms of integrated safety data management. During this session the three speakers will each provide their perspective on and experience with the interface between clinical data management and drug safety. Adequate reporting of serious adverse events from clinical trials typically requires entry and processing in a safety database separate from the clinical trial database. This poses issues for reconciliation of similar information between the two databases and two departments. This session will go into the question if there are better ways to interface methods and/or systems that reduce the resources that can go into full traditional reconciliation.

EDC in Japan from a PV Perspective: Is There a Political or Cultural Divide?
Shinya Yamauchi
Deputy Managing Director - Europe, Otsuka Pharmaceutical Europe Limited, France

Integrating the Safety Database with EDC: Potential Advantages and Challenges
Edward A. Kelly, MD
Vice President, Global Pharmacovigilance, Strategic Research and Safety, Quintiles

Digital Healthcare and Future Vision for Safety Data Reconciliation
William W. Gregory, PhD
Senior Director, Safety and Risk Management, Pfizer Inc

Session 428 CP - Clinical Safety and Pharmacovigilance, CDM

10:30 am-12:00 pm LEVEL: ■

Room 157AB *CME credits offered*

Practical Applications of Standardized MedDRA® Queries

SESSION CHAIRPERSON(S)

Judy E. Harrison, MD
Medical Officer, MedDRA® MSSO

Standardized MedDRA® Queries (SMQs) are a tool to assist in retrieval of cases from a MedDRA®-coded database. This session will focus on the practical use of SMQs for signal detection from both regulatory and industry perspectives. Examples of multidisciplinary approaches taken by physicians, statisticians, and programmers in the application of SMQs will also be presented.

FDA Experience with Use of SMQs
Charles K. Cooper, MD
Medical Officer, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Practical Applications of SMQs in an Industry Pharmacovigilance Group
Bobbie Michaelis
Senior Director, Global Pharmacovigilance Operations, Wyeth Research

EU Perspective
Jim Slattery, Esq., MSc
Scientific Administrator, Pharmacovigilance and Postauthorization Safety and Efficacy of Medicines Sector, Postauthorization Evaluation of Medicines for Human Use Unit, European Medicines Agency, European Union

Session 429 CR 1 - Clinical Research and Development, TR

10:30 am-12:00 pm LEVEL: ■

Room 102AB *Nursing credits offered*

The Six Risk Areas of Clinical Trial Patient Enrollment

SESSION CHAIRPERSON(S)

Jaime Cohen
Managing Director, TCN e-Systems, LLC

Clinical research professionals may not realize that, while different protocols present unique recruitment challenges, the source of delayed or failed enrollment can be boiled down to six risk areas. This session will reveal, define, and provide real-world context for all six risk areas of clinical trial patient enrollment and offer information and solutions every sponsor should know before embarking on their next clinical study.

Data-driven Country and Site Selection
James P. Kremidas
Global Enrollment Optimization, Eli Lilly and Company

Creating Culturally Effective Recruitment Materials
Fernando Arias
Principal, Gonzales, Arias and Partners, Spain

An Ounce of Prevention: Creating a Risk Response Strategy for Patient Enrollment
Jaime Cohen
Managing Director, TCN e-Systems, LLC

Session 430 CR 2 - Clinical Research and

DEVELOPMENT, CTM/CS

10:30 am-12:00 pm LEVEL: ■

Room 104AB

Site Relationship Management (SRM) Initiatives for Improving Site Performance

SESSION CHAIRPERSON(S)

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

In January 2008, a seminal article on site relationship management, "Improving Site Performance through Intentional Relationship Building," was published. This article described the history, objectives, and current state of affairs with regard to industry initiatives aimed at improving sponsor-site relationships. This session will feature one CRO and two sponsor representatives, highlighting their site relationship management initiatives, and provide an update on their progress with the SRM programs over the past year.

New Global Approaches to Increase Patient Recruitment through Site Relationships
Jane Eisner, RPh
Senior Vice President, Global Access to Patients, Quintiles, UK

Improving Site Performance through an Introspective Look at Our Own Performance: A Pharmaceutical Company Perspective
Mark T. Ridge, MBA
Director, Global Enrollment Planning and Performance, Wyeth Pharmaceuticals

Becoming a Sponsor of Choice: Operation Cupid Initiative
Gretchen Goller
Recruitment and Retention Specialist, sanofi-aventis

SESSION 431 EC - ECLINICAL, CR

10:30 am-12:00 pm LEVEL: ●

Room 205A

Development and Implementation of Standards for the Structured Representation of Protocols and Trial Design

SESSION CHAIRPERSON(S)

Diane E. Wold, PhD
Director, Data Standards, GlaxoSmithKline

Structured representation of the clinical trial protocol has been a crucible for CDISC and HL7 standards for use in clinical research and healthcare. The BRIDG model, an abstract information model of the world of protocol-driven research, is being used to ensure that the standards and messages that are developed have a semantically sound foundation and will be mutually compatible. Models, standards, and messages for important parts of the protocol are in development, and are already being implemented in a variety of settings.

The Structured Protocol Representation Express: Get on Board and Realize the Benefits
Joel Hoffman, PhD
Senior Director, Insightful AG, Switzerland

Overview: CDISC/HL7 Protocol Representation
Lisa Chatterjee, MS
Vice President, Healthcare Data Standards, Digital Infuzion, Inc.

Overview: Academic Health Center Perspective
Warren A. Kibbe, PhD
Director of Bioinformatics, The Robert H. Lurie Comprehensive Cancer Center, Northwestern University

Overview: CDISC/HL7 Protocol Representation Group – BRIDG Model
Peter Abramowitsch, MA
Vice President, Development, Trial Planning, Medidata Solutions Worldwide

Overview: Providing Services to Institutes within NIH
Scott Brand, PhD
Director, IT, KAI Research, Inc.

SESSION 432 ERS/DM - ELECTRONIC REGULATORY SUBMISSIONS/DOCUMENT MANAGEMENT, IT

10:30 am-12:00 pm LEVEL: ●

Room 253C

Global Submission Management

SESSION CHAIRPERSON(S)

Mickey Baldachin, MS
Senior Developer, Merck & Co., Inc.

Case studies of the experiences of managing submissions at three major pharmaceutical companies will be presented.

Global Submission Management: Key Factors for Success
Mickey Baldachin, MS
Senior Developer, Merck & Co., Inc.
Amanda Keller, MA
Senior Process Consultant, Octagon Research Solutions, Inc., UK

Submission of an eCTD in Japan
Deborah S. Bruner, MBA
Associate Director, Global Regulatory Operations, Wyeth
Valerie A. Mackner, MS
Senior Manager, Global Regulatory Operations, Wyeth

Successful Case Studies from a Large Pharmaceutical Company in Implementing an eCTD Tool and a New Global, Cross-functional Approach to Building eCTD Submissions
David S. Ross, MBA
GEL Templates and Publishing Manager, AstraZeneca
Karen Elizabeth Brutnell
Principal Document Management Specialist, AstraZeneca, UK

SESSION 433 GCP - GOOD CLINICAL PRACTICES, IT

10:30 am-12:00 pm LEVEL: ■

Room 204AB *CME credits offered*

Clinical Data Mining/Signal Detection and eAuditing

SESSION CHAIRPERSON(S)

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

The session will present case studies of implementation of eAuditing programs and systems. One case presented will be a system which identifies signals (outliers, trends, patterns, and clusters). Based on criteria set by the users, these signals are watched by the system and the user is notified that there are signals which require review and possible action.

How to Improve Your Clinical Processes through Risk Analysis
Peter J. Schiemann, PhD
Quality Risk Management Project Leader, Clinical Quality Assurance, F. Hoffmann-La Roche Ltd., Switzerland

Taking Advantage of Timely, Harmonized Clinical Data to Improve Clinical Safety Analytics and Clinical Operational Processes
Kalyan Gopalakrishnan
Executive Vice President, Strategic Planning, TAKE Solutions Inc.

Identifying Signals in Clinical Data for a Risk-based QA Program
C. Grant Simmons, MS
Head, CQA Operations, Novartis Pharmaceuticals Corporation

Session 434 IT - Information Technology, VA

10:30 am-12:00 pm LEVEL: ■

Room 205B *Pharmacy credits offered*

Implementing IT Industry Standards at a Large Pharmaceutical: A Case Study

SESSION CHAIRPERSON(S)

Pamela Campbell, MBA
Senior Consultant, BusinessEdge Solutions

This session will provide a case study of a large pharmaceutical company's successful implementation of a service-oriented IT organization in a regulated environment. The speakers will discuss goals, service-oriented organization in a regulated environment, the transformation approach, using a maturity model, results to date, and lessons learned.

A Pharmaceutical Company's New IT Operating Model: A Case Study
Joseph T. Solfaro
Senior Director, Merck & Co., Inc.

Implementing a Pharmaceutical Company's IT Operating Model
Timothy Rehac
Solutions Partner, BusinessEdge Solutions

Session 435 MW - Medical/Scientific Writing, CR

10:30 am-12:00 pm LEVEL: ■

Room 205C *CME and Pharmacy credits offered*

Emerging Clinical Documents for Medical Writers

SESSION CHAIRPERSON(S)

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

The role of the medical writer in the pharmaceutical industry is expanding, and they are being asked to take on a whole array of new document types which need to be written and submitted to regulatory agencies in support of an NDA/MAA. This session will focus on the content and writing of three such documents: pediatric investigation plans, risk management plans, and annual safety reports.

An Overview of Risk Management Plans
Susan L. DiMaggio
Associate Director, Pfizer Inc

Annual Safety Reports for Writers: Why, When, and How
Kerry L. Johnson, MS
Senior Medical Writer, Stiefel Laboratories Inc.

Pediatric Investigation Plans: Mere Child's Play?
Thomas Gerster, PhD
Site Head, Regulatory Documentation, Pharma Development Regulatory Affairs - PDRD, F. Hoffmann-La Roche Ltd., Switzerland

Session 436 NHP - Natural Health Products, AHC/IS

10:30 am-12:00 pm LEVEL: ●

Room 203

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. Three products either already in the market or under clinical development in the therapeutic areas of metabolism-endocrinology and oncology will discussed in depth.

Scientific Validation of Botanicals in the Management of Diabetes Mellitus
Pradeep Visen, PhD
Research Scientist, Risk Factor Modification Centre, St. Michael's Hospital, University of Toronto, Canada

Nutraceuticals: Impact on the Management of Obesity
Waqar H. Bhatti, Esq., PhD, MS, RPh
Professor, College of Pharmacy, Butler University

Oncology: Research and Development of New Oncological Compound from an Herbal
Dagoberto de Castro Brandao, MD
Scientific Board, LARAMARA, Brazil

Session 437 OS - Outsourcing, PM/FI

10:30 am-12:00 pm LEVEL: ■

Room 253A

Outsourcing to India and China: Managing R&D Projects

SESSION CHAIRPERSON(S)

Surya P. Chitra, PhD, MBA
President and Principal Consultant, Savio Group Inc. - Health Solutions

With escalating costs, declining R&D productivity and numerous regulatory challenges, the industry is rapidly shifting its R&D operations to India and China, mainly to reduce the costs, time, and risk involved in R&D. Currently, about 20 to 30% of the total global clinical trials are outsourced to developing countries. Access to specialized skills in both countries and long work hours creates an underlying basis for their competitive advantage. In addition to rapid recruitment of patients, better project management from the start reduces development risks. Despite these benefits, there has been a relatively low level of utilization of the opportunities in both countries due to various concerns with respect to quality and infrastructure. This session will provide the true experiences with conducting clinical studies and practical challenges in doing business in India and China. These experiences will be shared by local experts from India, China, and US organizations.

Successful Management of Drug Development in China
Michael Chen
President, TCM Groups, Inc.

Experiences in Conducting Clinical Trials in India: A CRO Perspective
Hameed Allaudeen
Vice President, Clinical Research and Regulatory Affairs, Asian Clinical Trials

Conducting Global Trials in China and India: Lessons Learned
Joan Shen, MD, PhD, MS
Medical Director, CNS Division, Wyeth Medical Research

Session 438 PM/FI 1 - Project Management/Finance, CTM/CS

10:30 am-12:00 pm LEVEL: ■

Room 256AB *Project Management units offered*

Project Management across Companies and Cultures: Team Creation and Development

SESSION CHAIRPERSON(S)

John Shillingford, PhD

President, Averion Europe GmbH, Germany

The requirement to reduce R&D times now is such that more and more projects need to be run globally. This inevitably means that the global project manager has to work with teams from other companies operating in diverse countries with differing cultural sensitivities. This session will be given by global project managers talking of their own experiences as to how they meet such challenges.

The Global Study: The CRO Management Option
John Shillingford, PhD
President, Averion Europe GmbH, Germany

The Global Drug Development Program: Experiences from a Major Pharmaceutical Company
Niekol Weissbach
Project Director, Novartis Pharma AG, Switzerland

Cultural, Language, and Process Issues: Experiences across Europe
Anton Mamin
Regional Director, Hesperion Russia, Averion International Corporation, Russian Federation

Session 439 PM/FI 2 - Project Management/Finance, CR

10:30 am-12:00 pm LEVEL: ●

Room 154 *Project Management units offered*

The Secret to Achieving Productivity in Clinical Development

SESSION CHAIRPERSON(S)

Edward Stephen Seguine, Jr., MBA
General Manager, Trial Planning, Medidata Solutions Worldwide

Every clinical organization is being forced to do more, with less, faster, and with higher quality. Countless initiatives with catchy slogans promise to improve productivity in clinical development, but the reality is that truly productive gains are illusory. There are really only three levers that senior management can control to deliver productivity improvements – people, process, and technology. The pharmaceutical industry has historically focused on people and process with little regard to leveraging technology to improve operational metrics. This session will look at the risk/return of investment in each of these three areas to determine how lasting productivity can be achieved.

When Will Clinical Outsourcing Mature?
Anthony J. Carita
Director, Clinical Outsourcing, Otsuka Pharmaceutical Development & Commercialization

Technology as a Means to Achieving Productivity in Clinical Development
Steven J. Olsen, MS
Principal, SJO Consulting, LLC

Session 440 PP - Public Policy/Law, RA

10:30 am-12:00 pm LEVEL: ■

Room 104C

Legal Remedies and Drug Approvals during and after the Approval Process in the US and the EU

SESSION CHAIRPERSON(S)

Geneviève Michaux, LLM
Special Counsel, Covington & Burling, Belgium

This session will provide an overview of the most important procedural guarantees and legal remedies that are available during and after a drug approval process. Whether any lessons can be learned from the experience in the US and the EU will also be addressed.

Legal Remedies and Drug Approvals during and after the Approval Process in the US and the EU
Jeffrey Senger, JD
Deputy Chief Counsel, Office of the Commissioner, Office of Chief Counsel, FDA

Session 441 RA 1 - Regulatory Affairs, CR

10:30 am-12:00 pm LEVEL: ●

Room 153AB

CDER Town Meeting – Part 2 of 2

SESSION CHAIRPERSON(S)

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

Part 1 of this session will take place on Thursday at 8:30 am.

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

Lawrence J. Lesko, PhD
Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA

RADM Sandra L. Kweder, MD
Rear Admiral, US Public Health Service; Deputy Director, Office of New Drugs, CDER, FDA

Paul J. Seligman, MD, MPH, CAPT. USPHS
Associate Director, Safety Policy and Communication, CDER, FDA

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

Session 442 RA 2 - Regulatory Affairs, RD

10:30 am-12:00 pm LEVEL: ●

Room 153C

Regulatory Data Protection (Data Exclusivity)

SESSION CHAIRPERSON(S)

Martine Zimmermann-Laugel, PharmD
Head of Department, Presubmission Division, Worldwide Regulatory Affairs, Science Union (Servier), France

Regulatory data exclusivity (data protection) is now available in many countries but the means for obtaining and parameters related to data protection are as diverse as the countries themselves. Obtaining such protection allows sponsors to maximize the value of their investments in innovative medicines so it is often sought but may not be well understood from an international perspective. This session will present an international comparison of different regulatory options to obtain data protection for new drugs. Speakers will present real-case examples and analyze the various options, benefits and challenges in obtaining protection.

Data Protection: Illustration with Recent Real Cases
James T. Rawls, PharmD
Global Program Regulatory Director, Novartis Pharmaceuticals Corporation

Session 443 ST - Statistics, IT

10:30 am-12:00 pm LEVEL: ●

Room 206AB *Pharmacy credits offered*

Update: Pushing the eEnvelope in Statistics for Drug Development

SESSION CHAIRPERSON(S)

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

We need to be thinking about how statisticians, both in industry and at regulatory agencies, will work most efficiently and effectively in the 21st century – in an environment that is dominated and facilitated by new sources of data, advancing technology and scientific computing capabilities. Open-source statistical software and tools such as "R" continue to penetrate pharmaceutical R&D. In this session, we will update the efforts to address the pros and cons of open-source software including the hidden costs.

Although many biostatistics departments have transformed their operations, there is very little that is comprehensive or that provides end-to-end transparency, reproducibility, traceability, and complete and accurate documentation. We will examine how the establishment of Scientific Computing Environments (SCEs) is important to statisticians through the description of a case study that describes one company's implementation of an SCE software solution.

Motivated by a desire to respond to the 2007 FDA Science Board report, "FDA Science and Mission at Risk," and with the anticipated infusion of resources from PDUFA IV, regulators, including statisticians, are moving to establish a scientific computational capability that will address the needs of a truly modern regulatory agency capable of contributing to the goals of Critical Path and the needs for efficient and effective review of new drugs and biologics. We will discuss these important eEfforts and how they might affect our future roles and interactions from a reviewer's perspective.

Case in Point: The Point of an SCE and a Case Study, or Alice v. Billy the Kid – How the Metadata Wonderland Trumps the Wild, Wild Legacy System
Daniel Boisvert
Principal Programmer Analyst, Genzyme Corporation
Dana J. Soloff, MS
Director, Statistical Programming, Biomedical Operations, Genzyme Corporation

Open-source Statistical Software in Pharmaceutical Research and Development: Validation, Legal Issues, and Regulatory Requirements
Gregory R. Warnes
Associate Professor, Statistics and Computational Biology, University of Rochester

Statistical Computing: Moving towards the Future – A Reviewer's Perspective
Mat Soukop, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Session 444 TR - Training, IT

10:30 am-12:00 pm LEVEL: ●

Room 252AB

Getting the Message Across: It Is All about the Presentation

SESSION CHAIRPERSON(S)

Theresa Hummel-Krallinger
Director, Training and Organizational Development, Almac Clinical Technologies

You do not have to be a motivational speaker to deliver an effective, engaging presentation! Attend this session for some great tips and demonstrations of tools and tricks that will add value and punch to your training or presentations. You will receive advice on how to make the best use of the presentation software, MS PowerPoint. You will learn simple speaking techniques to engage your audience. You will also get an overview of several web-based tools that make quizzes and surveys a snap – even for the non-techies.

Wow Your Audience with Technology: Tools to Engage, Inspire, and Entertain
Theresa Hummel-Krallinger
Director, Training and Organizational Development, Almac Clinical Technologies

PowerPoint Presentations that Pop! Proper Design = Powerful Presentations
Lauren Edelstein-Henry, MEd
Lead Process Support Specialist, Centocor R&D Inc.

Wisdom from the Trenches: Pitfalls to Avoid, Value to Include
Donna Walsh
President, RedShoes Solutions

Session 445 VA - Validation, IT

10:30 am-12:00 pm LEVEL: ●

Room 156

Infrastructure, Hardware, Computerized Instrumentation: What Is Needed?

SESSION CHAIRPERSON(S)

Martin Browning, MS
President, EduQuest, Inc.

The world is becoming more dependent on computers and software, and regulators expect sponsors and investigators to have qualified their equipment and supporting software. What does this mean and what is expected? This session will discuss regulatory expectations for the foundation pieces of IT: regulatory expectations, qualification and validation – which and when?, system use, risk, and requirements, quality system for infrastructure, documentation and management.

Dan Mihai, MBA, MS
Managing Consultant, Prius Medical Systems LLC

Martin Browning, MS
President, EduQuest, Inc.

12:00 pm **END OF THURSDAY SESSIONS**

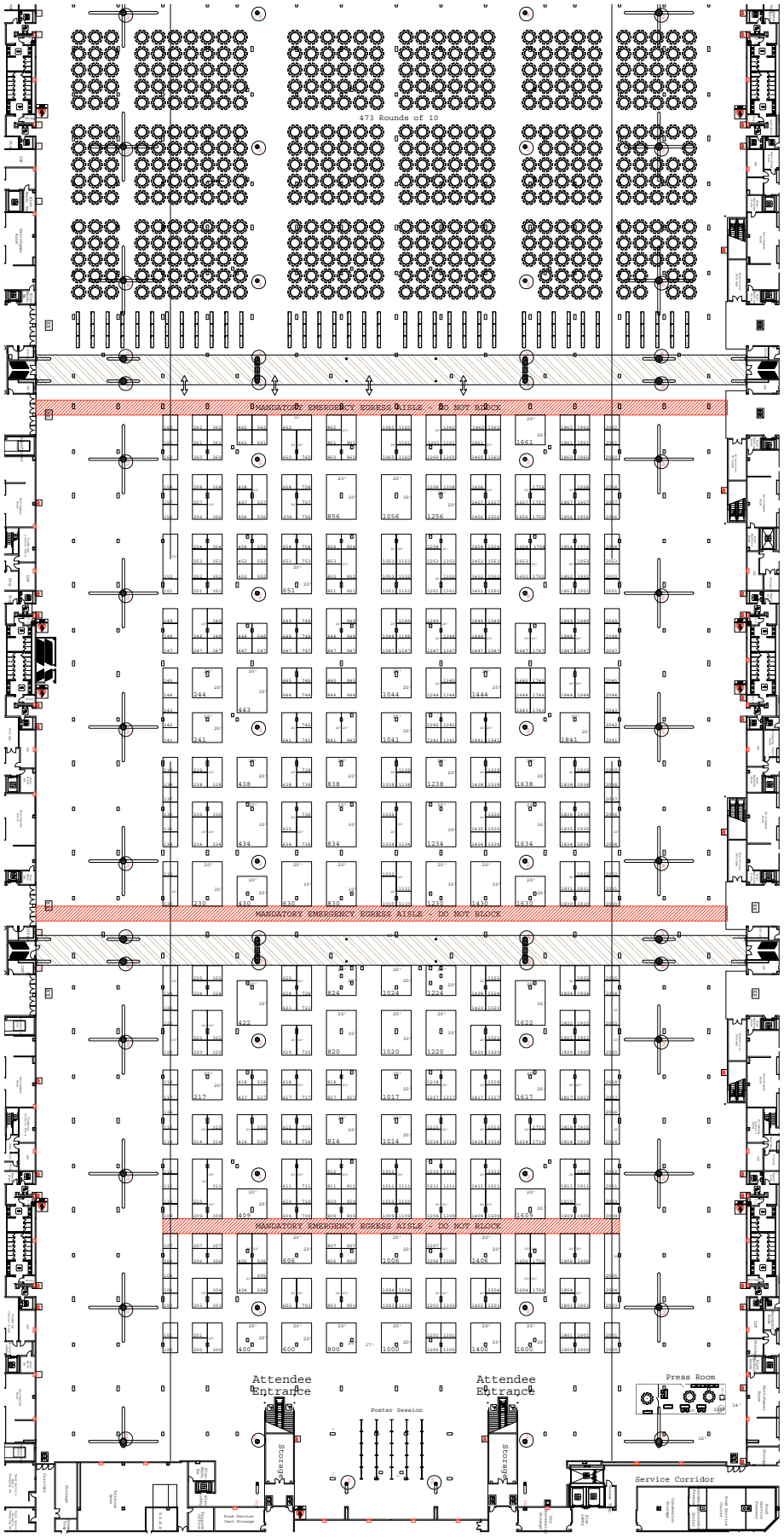
ANNUAL MEETING ADJOURNED

12:30 pm-5:00 pm **MedDRA® USER GROUP MEETING**
Room 210A, Level 2, BCEC

Exhibiting Companies

Exhibit Hall Floor Plan

Boston Convention & Exhibition Center, Level 0 – Halls A, B & C



Summaries of Exhibitors' Services

AAIPharma Inc.

Booth 1860

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Booth 111

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Booth 1557

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Booth 1806

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Booth 239

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Advanced Diagnostic Laboratories at National Jewish Medical & Research Center

Booth 1835

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Fax: 303-270-2125

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Allphase Clinical Research — Booth 354

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Telephone: 415-506-6700
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BioMarin (Nasdaq: BMRN) develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions including three approved products, NAGLAZYME for MPS VI, ALDURAZYME for MPS I, and KUVAN for PKU, and multiple clinical and preclinical product candidates including 6R-BH4 and PEG-PAL. Headquarters: San Francisco Bay Area.

Biomedical Systems — Booth 651

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Fax: 314-576-1664

Biomedical Systems is a global provider of centralized diagnostic services for Cardiac Safety, Respiratory and Imaging services for clinical trials. BMS works with over 11,000 clinical sites in 75 countries around the world. Corporate headquarters is based in St. Louis, MO with a EU Headquarters in Brussels, Belgium and an office in Tokyo, Japan.

BioPharm Insight — Booth 1458

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Telephone: 781-702-6938
Fax: 781-762-9400

BioPharm Insight provides daily intelligence on pharmaceutical, biotech, and medical device companies and their R&D activities, including clinical trials, company and drug profiles, pharmaceutical sales projections, licensing deals, and forward-looking Pharmawire coverage.

BioResearch Monitors, Inc. — Booth 306

Contact: Paul Gittelson
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Website: QA4GCP.com
Telephone: 315-696-8139
Fax: 315-696-8722

BioResearch Monitors, Inc. provides independent Quality Assurance audits and regulatory compliance consulting services related to FDA's Good Clinical Practice (GCP) regulations and associated multinational standards for the conduct of clinical and nonclinical Research and Development of pharmaceutical and biomedical products (GCP, GLP, GMP).

bioskin GmbH — Booth 414

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bioskin, a wholly-owned subsidiary of Dow Pharmaceutical Sciences, Inc., is a full-service CRO specialized in dermatology, offering clinical trials Phase 1-4. Unique capabilities include early-stage Proof-of-Concept studies and advanced bioengineering methods.

BioSoteria — Booth 134

Contact: Michelle Flewell
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Website: www.biosoteria.com
Telephone: 650-616-4151
Fax: 925-281-6087

BioSoteria, Inc., a drug safety consulting company based in California, offers clients in pharmaceutical/biotech and healthcare industries our expertise and services throughout the product lifecycle: clinical safety, postmarketing pharmacovigilance, risk management, & innovative drug safety educational/training programs.

BioStorage Technologies — Booth 1811

Contact: Ann Whitfield
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Website: www.biostorage.com
Telephone: 317-390-1866
Fax: 317-390-1868

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Biotec Services International — Booth 2031

Contact: Dr Matthew Lakelin
E-mail: enquires@biotec-uk.com
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Biotrin International — Booth 252

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Biotrin International develops, manufactures and promotes propriety biomarker assays. Biotrin's biomarkers have known origins and enable toxic or other effects to be localised to precise cell groups or tissues. The Biotrin Acute Kidney Injury panel enables renal injury to be detected well in advance of changes in serum parameters.

Bioval Contract Research — Booth 1451

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Bostwick Laboratories, Inc. — Booth 1644

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Website: www.bostwicklaboratories.com
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Fax: 804-545-9760

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Brand Institute, inc. — Booth 2042

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BRANY/RBS — Booth 654

Brecon Pharmaceuticals — Booth 1815

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Brecon Pharmaceuticals is a leading provider of clinical trials supplies packaging and worldwide logistics services. Based in the EU, Brecon Pharmaceuticals is well placed to assist with the importation of supplies through use of considerable QP expertise and a purpose-built analytical laboratory.

BT Global Services — Booth 160

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BT Global Services has extensive experience working with global pharmaceutical organizations across the industry We offer enterprise communications and integrated IT services and solutions to the majority of the top 25 global pharmaceutical companies.

BusinessEdge Solutions, an EMC consulting practice

Booth 1012

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Telephone: 732-828-3200
Fax: 732-839-3600

BusinessEdge Solutions, an EMC consulting practice, offers strategy, process optimization, and information management services to clients in the Life Sciences industry. Leveraging our industry vertical thought leadership and consulting, BusinessEdge drives competitive advantage for clients and reduces the time, cost, and risk of delivering results.

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Booth 945

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Booth 2044

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The Cambridge Group Ltd was founded in 1976. We have steadily grown into one of the leading recruitment firms in the pharmaceutical industry today that specializes in permanent placements and contract staffing.

Cancer Research And Biostatistics

Booth 115

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Canon Communications Pharmaceutical Media Group

Booth 1536

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Canon Communications Pharmaceutical Media Group, publisher of Med Ad News, R&D Directions, and PharmaLive.com, disseminates original, thought-provoking content providing busy pharmaceutical executives with insight into trends and events that will affect their business as well as the industry.

CanReg Inc.

Booth 1925

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CanReg is a company dedicated exclusively to regulatory affairs consulting for the pharmaceutical, biotechnology and medical device industries. More than 100 in-house consultants and staff serve clients in the United States, Canada and Europe. CanReg is a one-stop global regulatory solution for companies at all stages of development.

Cardinal Health Research Services (formerly VIASYS Clinical Services)

Booth 1430

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Fax: 714-919-3361

Cardinal Health Research Services, formerly VIASYS Clinical Services, is now an integral part of Cardinal Health. Research Services is a global market leader in providing innovative hardware and software technologies and services (centralized Spirometry, ECG and ePRO) to pharmaceutical and biotechnology companies in all phases of clinical trials.

Cardiocore

Booth 1614

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Booth 852

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Booth 157

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Catalent Pharma Solutions is one of the leading providers of advanced dose form and packaging technologies as well as development, manufacturing and packaging services for pharmaceutical, biotechnology and consumer healthcare companies in nearly 100 countries. Formerly known as Cardinal Health Pharmaceutical Technologies and Services (PTS).

CDISC

Booth 1004

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Fax: 919-489-4850

CDISC is a non-profit Standards Development Organization whose mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. The CDISC standards are freely available on the CDISC website (www.cdisc.org).

Cedra Corporation — Booth 443

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Center for Drug Evaluation and Research — Booth 909

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The FDA's Center for Drug Evaluation and Research (CDER) makes sure that safe and effective drugs are available to improve the health of the American people. CDER ensures that prescription and over-the-counter drugs, both brand name and generic work correctly and that the health benefits outweigh the known risks.

Center for Drug Evaluation, Taiwan — Booth 911

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CDE is a regulatory agency sponsored by Health, Taiwan since 1998 to review investigational new drug, new drug application, investigational device exemption and premarket approval, health technology assessment, draft guidelines, provide consultation and improve regulatory science.

CenterWatch — Booth 1706

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CenterWatch is a trusted source and global destination for clinical trials information for both professionals and patients. A Boston-based publishing and information services company, providing proprietary data and information about clinical trials through a variety of newsletters, books, databases and information services.

Cerner Corporation — Booth 1234

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Certus International — Booth 1362

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Cetero Research — Booth 1600

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Website: www.cetero.com
Telephone: 877-7-CETERO
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Charles River Clinical Services — Booth 1131

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Fax: 253-593-5181

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Chemic Laboratories, Inc. — Booth 253

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Chemic Laboratories, Inc. is a contract chemistry organization, FDA registered and DEA licensed, servicing the pharmaceutical, biotech, medical device, veterinary medicine, and specialty chemicals industries.Chemic also offers a line of high-purity excipients, manufactured through proprietary methodology.

Chesapeake Research Review, Inc. — Booth 1311

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Chiltern — Booth 724

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Chiltern is a global CRO with experience running and staffing international Phase I to Phase IV clinical trials. Chiltern has 20 offices across the United States, Europe and in India. Chiltern's services include: Early Phase, Global Clinical Development, Late Phase, Biometrics, Medical and Regulatory Affairs and Resourcing Solutions.

ChosenSecurity, Inc. — Booth 2051

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ChosenSecurity is the leading provider of On-Demand PKI (public key infrastructure) security services in the world, enabling a wide range of PKI-enabled security services for enterprise authentication, secure e-mail and digital signatures. ChosenSecurity is a true leader of certification service providers at the forefront of identity management.

Christiana Care Research Institute — Booth 1441

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Christiana Care Research Institute is a multi specialty research site conducting phase I through phase IV research. Over 3000 protocols implemented. Experienced Principal Investigators and Coordinators are dedicated to each clinical trial.

Cincinnati Children's Research Foundation — Booth 809

Contact: Mark Schuller
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Telephone: 513-636-0314
Fax: 513-636-0168

Cincinnati Children's is a pediatric Phase I-IV (all major therapeutic areas) and a select adult Phase I-IV (vaccine and cancer) clinical study site. It is the second highest recipient of NIH research grant funding among comprehensive pediatric centers. Cincinnati Children's is AAHRPP accredited and has more than 75 years of research experience.

CIRION Clinial Trial Services Inc. — Booth 952

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Website: www.cirion.com
Telephone: 866-688-2474
Fax: 450-902-3060

CIRION offers Contract Research and Central Laboratory services including safety and specialized testing, project and logistical management, research and development and assay validation for clinical studies worldwide. Our team is committed to quality assurance exceeding industry standards to ensure reliable results and uncompromised service.

City List Co, Inc. — Booth 1130

Contact: Dan Peltier
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Contact: Kenji Uematsu
E-mail: info@cityofkobe.org

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Clarix — Booth 151

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Telephone: 610-964-9604
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Fax: 949-502-6062

ClinAssure is a full-service CRO in Irvine, California, specializing in clinical research contract services for Phase I-IV clinical trials in a variety of therapeutic areas. Our corporate culture encourages mutual respect, leadership, professional development and above all – integrity, resulting in a growing dynamic and positive environment.

ClinAudits, LLC — Booth 1556

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ClinAudits provides domestic and international quality assurance auditing to the pharmaceutical/biotech industries. We have a US based team. We offer investigator site, CROs, Central Lab, CTS, CSR, AE audit, Phase I, CVS, Mock-FDA, GMP/GLP audits.

Clinesian — Booth 2056

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Fax: 732-875-0841

Clinesian is a boutique CRO offering a broad range of services to the Sponsors for Phase I-IV trials including project management, clinical and medical monitoring, data management, biostatistics, report writing and QA. Clinesian has offices in California, New Jersey, India and the Ukraine and employs more than 50 people worldwide.

ClinForce, LLC — Booth 300

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Clinical Business Solutions, Inc. — Booth 1715

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Fax: 901-435-4696

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Clinical Conductor Enterprises — Booth 457

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Telephone: 877-279-8377
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Clinical Network Services (CNS) Pty Ltd — Booth 518

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Clinical Research Advantage — Booth 954

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Website: www.crastudies.com
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Clinical Resource Network — Booth 2017

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The Clinical Resource Network — Booth 944

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Clinical Technology Transfer Group — Booth 1161

Contact: Kate Duffy Mazan
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Website: www.cttg-law.com
Telephone: 703-734-0484
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The Clinical Technology Transfer Group (CTTG) is a law firm providing access to legal and regulatory expertise on the conduct of clinical trials, and is a resource for outsourcing the negotiation of Clinical Trial related contracts. Through an alliance with M+BIOLAW we provide clients seamless access to the same services on a global basis.

Clinical Trial Media — Booth 1525

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Clinilabs, Inc. — Booth 1238

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Website: www.clinilabs.com

Clinilabs, Inc. is a specialty contract research organization that provides a full portfolio of services to pharmaceutical, biotechnology, and medical device companies involved in the development of CNS and cardiovascular therapeutics. The Company also provides early phase services in a wider range of therapeutic areas at its Phase I facility.

Clinimetrics — Booth 638

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Clinimetrics is a full-service contract research organization (CRO) that provides a complete array of global clinical research services with a focus on the development needs of the biotechnology and early stage pharmaceutical and medical device industries. Clinimetrics is celebrating 20 years of service in 2008.

ClinPhone — Booth 217

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CLINSIGHT Corp. — Booth 448

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Clinsys Clinical Research — Booth 1041

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Clinsys is a therapeutically focused CRO that provides services in support of Phase I-IV drug and device development, including project, site and data management; clinical monitoring; scientific and medical support; investigator and patient recruitment; biostatistics; drug safety; quality assurance; regulatory affairs; and medical writing.

ClinTec International — Booth 2020

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Full service Global CRO which provides clinical research support services to the pharmaceutical, biotechnology and medical device industry and assist in their product development efforts.

Clintrak Clinical Labeling Services, LLC — Booth 110

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Booth 734

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Contact: Robert Bilgrad
E-mail: ndi@cdc.gov
Website: www.cdc.gov/nchs/ndi.htm
Telephone: 301-458-4444
Fax: 404-929-2823

The National Death Index (NDI) assists researchers in determining whether subjects have died and provides the states and dates of death, death certificate numbers and causes of death.

National Institute of Allergy and Infectious Diseases — Booth 1552

Contact: Hillary Franzen
E-mail: hfranzen@air.org
Website: www.niaid.nih.gov
Telephone: 202-403-5458
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NERI - New England Research Institutes, Inc. — Booth 1341

Contact: Dawn M. Porthouse, MA
E-mail: dporthouse@neriscience.com
Website: www.neriscience.com
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New Orleans Center for Clinical Research — Booth 1504

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Contact: Eduardo Hussey
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OCT Group LLC — Booth 220

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E-mail: jlifshitz@phonescreen.com
Website: www.phonescreen.com
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Contact: Sheila Rocchio
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Website: www.phtcorp.com
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Contact: Steve King
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Website: www.pharm-int.com
Telephone: 410-584-0001
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Contact: David Cornwell
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PPD — Booth 814

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Telephone: 919-456-4847
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PRA International — Booth 830

Contact: Frank Hijek
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Website: www.prainternational.com
Telephone: 919-786-8200
Fax: 919-786-8201

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Premier Research Group plc — Booth 1617

Contact: Jessica Barag
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Website: www.premier-research.com
Telephone: 215-282-5500
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PRL Central Laboratory Services — Booth 1435

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ProMedica Laboratories — Booth 456

Contact: Carla Dunsmoor, MT(ASCP) CCRP
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Telephone: 419-824-1227
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PROMETRIKA, LLC — Booth 101

Contact: Christopher Gallant
E-mail: cgallant@prometrika.com
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Telephone: 617-868-2020
Fax: 617-868-2122

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ProSanos Corporation / Phimap — Booth 1453

Contact: Jonathan Morris
E-mail: info@prosanos.com
Website: www.prosanos.com
Telephone: 717-635-2140

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PROSAR — Booth 418

Contact: Mike Bieniek
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Website: www.prosardrugsafety.com
Telephone: 651-917-6116
Fax: 651-641-0341

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ProTrials Research, Inc. — Booth 1417

Contact: Mark Andrews
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Telephone: 650-846-9186
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Contact: Jennifer Buchanan
E-mail: buchanan@prosof.com
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Telephone: 650-592-9100
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PSI INTERNATIONAL, Inc. — Booth 1562

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Quality and Compliance Consulting, Inc. — Booth 1003

Contact: Jason Bertram
E-mail: qc2@qc2.com
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Quality Associates, Inc (QAI) — Booth 2003

Contact: Lora Martin
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Quality Associates, Inc (QAI) was established in 1986 to provide quality assurance and regulatory services to the pharmaceutical and agrochemical industries. A corollary service offering was the archiving of scientific records. Today QAI maintains a broad client base. Contact us at www.qualityassociatesinc.com or 410.884.9100.

QualityMetric Incorporated — Booth 461

Contact: Sheila Hetu
E-mail: shetu@qualitymetric.com
Website: www.QualityMetric.com
Telephone: 800-572-9394
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Fax: 401-334-8801

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Quanticate Inc — Booths 660, 662

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Queensland Clinical Trials Network Inc. — Booth 517

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Quest Diagnostics Clinical Trials — Booth 201

Contact: Business Development
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Website: www.questcentrallab.com
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Quest Diagnostics Clinical Trials consists of 600 employees dedicated to central laboratory services for Phase II - IV clinical trials. Laboratories are located in the US, UK and India. Additionally, Clinical Trials operates a project management office in Wavre, Belgium and affiliate laboratories in Singapore, Melbourne and Shanghai.

Quintiles — Booth 1406

Contact: John Nicosia
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Website: www.quintiles.com

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Contact: Matthew Eberhart
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Quintiles Drug Safety — Booth 1604

Contact: John Nicosia
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Contact: Lynne Murray
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E-mail: info@qumas.com
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Quorum Review, Inc. — Booth 1822

Contact: Suzanne McCaffrey
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E-mail: smccaffrey@quorumreview.com
Website: www.quorumreview.com

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Contact: Cindy Bratton
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REGISTRAT, Inc — Booth 1256

Contact: Carolyn Maki
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E-mail: cmaki@registrat.com
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Regulatory Compliance Initiatives, Inc — Booth 562

Contact: Dr. James E Carter
E-mail: kimdavis@regulatorycomp.com

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Regulatory Presentation Management — Booth 1758

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Contact: John Loucks
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Research Across America — Booth 1803

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Website: www.researchacrossamerica.com
Telephone: 281-579-1938
Fax: 281-646-8750

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ResearchPoint — Booth 1414

Contact: Tonya Taylor
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Telephone: 512-343-1092
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The RPM Report — Booth 352

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Booth 1909

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Booth 1551

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Booth 1411

Contact: Mike Blume
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Website: www.spacelabshealthcare.com
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Booth 1521

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Booth 620

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Booth 347

Contact: Jeff Welch
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Telephone: 919-812-0329
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Booth 760

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Booth 1900

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Booth 304

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Booth 2041

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Contact: Carol Yuhasz
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WellSpring is a full-service provider of contract manufacturing and packaging solutions for finished non-sterile liquid, solid and semi-solid dosage forms. We provide clinical manufacturing, labelling, packaging and distribution solutions to support your clinical trials. Our facility has been successfully inspected by Health Canada and the FDA.

West Coast Clinical Trials, LLC — Booth 224

Contact: Yves Grenon
E-mail: yvesg@wctrials.com
Website: www.wctrials.com
Telephone: 714-252-0700
Fax: 714-252-0799

West Coast Clinical Trials (WCCT) is a specialized Early Stage Clinical CRO. Located in Cypress, CA, WCCT specializes in Renal Impaired, Ethno-Bridging studies, such as Japanese Bridging, Healthy Volunteers, and Platelet Aggregometry. WCCT also has expertise in Allergy, Asthma, Post-Menopausal, Cholesterol, Diabetes, and upper respiratory studies.

Wiley-Blackwell — Booth 225

Contact: Katy Reeves
E-mail: corporatesales@wiley.co.uk
Website: www.inpharm.com
Telephone: +44 1243 772010

Publisher of Pharmafile, the key resource for people who need to source specialist suppliers of goods and services within the pharmaceutical and related industries. Pharmafile contains details of thousands of pharmaceutical, biotech, diagnostic, medical devices and animal healthcare sites. For more information visit www.inpharm.com.

Winchester Business Systems, Inc. — Booth 1862

Contact: Mike Regentz
E-mail: Mike_Regentz@wbsnet.com
Website: www.wbsnet.com
Telephone: 781-503-0200
Fax: 781-503-0207

Winchester's Protocol Manager is a CTMS that serves as the Enterprise Resource Planning (ERP) system for your clinical operations. Plan, execute, manage, and report on all aspects of a trial including investigator contracts, payment cycles, and clinical supplies. Interface with EDC, IVRS, ePRO, AEs, and finance.

Wolters Kluwer Health — Booth 717

Contact: Bhavna Tailor
E-mail: bhavna.tailor@wolterskluwer.com
Telephone: +44 0-1829 77 2798
Fax: +44 0-1829 77 0330

Wolters Kluwer Health is a leading provider of information for professionals in drug development and therapy in the pharmaceutical industry and academia. Major brands include the Adis journals and Newsletters and the Adis drug development and clinical trials databases Adis R&D Insight and Adis Clinical Trials Insight.

Woodley Equipment Company Ltd — Booth 514

Contact: Customer Service Team
E-mail: sales@woodleyequipment.com
Website: www.woodleyequipment.com
Telephone: +44 0-8456 777 001
Fax: +44 0-8456 777 002

Medical and laboratory equipment rental specialists – centrifuges, refrigeration, ECG, Point Of Care. View the Clinispin Horizon range: small, low cost swing-out centrifuges, for hire/purchase. We source and supply any equipment. USA office opening THIS YEAR! Come to booth 514 for more information and to see the wide range of equipment available.

World Courier, Inc. — Booth 1017

Contact: Tina E Brooks
E-mail: tbrooks@worldcourier.com
Website: www.worldcourier.com
Telephone: 800-357-1712
Fax: 212-590-7008

World Courier has set the standard for speed, reliability and personalized service for shippers demanding schedules, 24 hours a day, 365 days a year.

WorldCare Clinical, LLC — Booth 325

Contact: Vanessa Conde
E-mail: vconde@wcclinical.com
Website: www.wcclinical.com
Telephone: 617-583-1601
Fax: 617-583-1602

Central imaging CRO, WorldCare Clinical, provides comprehensive imaging services for clinical trials in the biopharmaceutical and medical device industries. WCC provides therapeutic knowledge, modality expertise and innovative technology harmonizing the entire trial process and speeding the discovery and delivery of new therapeutic treatments.

Worldwide Clinical Research — Booth 1034

Contact: Clareece West
E-mail: cwest@wwcr-cro.com
Website: www.wwcr-cro.com
Telephone: 913-681-3078
Fax: 913-663-2290

Over the past 7 years, WWCR has emerged as one of the industry's trusted CROs. WWCR employs highly experienced teams with global access. Clients use our services year after year, which is the best compliment we get as a service organization. Our current employee turnover rate is <10%, while our "project to project" repeat customer rate is >87%.

Worldwide Translations, Inc. — Booth 1930

Contact: Frank Blaha
E-mail: fblaha@cox.net
Website: www.wwtranslations.com
Telephone: 702-897-8841

Worldclass supplier of translation to the pharmaceutical industries. Certified technical translation services, with professional project management, to assure timely, superior and accurate translation, at a competitive price. All translators have industry experience in the related technical field. ISO 9001:2000 registered and certified.

X Factor Advertising — Booth 658

Contact: Mike Lakey
E-mail: mlakey@xfactoradvertising.com
Website: www.xfactoradvertising.com
Telephone: 503-235-6249
Fax: 503-235-6572

X FACTOR is an innovative, full-service advertising agency that specializes in patient recruitment, retention and tracking services to assist the clinical trial industry. Develop/implement creative and media strategies that recruit more patients for less money. High-quality In-house production, personalized site contact, NO REFERRAL LEFT BEHIND system.

Xceleron Inc — Booth 554

Contact: Lisa Stockdale
E-mail: lisa.stockdale@xceleron.com
Website: www.xceleron.com
Telephone: 240-361-1900
Fax: 240-361-1901

Xceleron adds value to drug development pipelines through optimization of Exploratory Clinical Development programs. We aim to reduce the risk of clinical failure and improve candidate selection. Our services include Phase Zero/Human Microdosing, META-ID™ and IV-PK, we are able to obtain human specific ADME data earlier than ever before.

XClinical GmbH — Booth 1523

Contact: Dr. Claus Lindenau
E-mail: cl@xclinical.com
Website: www.xclinical.com
Telephone: +49 89 452277-5200
Fax: +49 89 452277-5900

XClinical is an innovative EDC-CDM system vendor offering a CDISC based product suite covering the full clinical data life cycle. XClinical's EDC/DDE system MARVIN provides an easy, flexible and state-of-the-art tool for all kind of clinical trials.

XERIMIS INC. — Booth 1030

Contact: Evan Wohl, R.Ph.
E-mail: Evan.Wohl@Xerimis.com
Website: www.XERIMIS.com
Telephone: 856-727-9940
Fax: 856-727-9942

GLOBAL CLINICAL PACKAGING SERVICES for pharmaceutical / biotech firms and CRO's of all sizes. Customized Primary and Secondary Clinical Packaging - Project Management - Monitoring and Distribution Services - Returns and Accountability Services. DEA Schedule III-V Capabilities. Quality and customer service is our primary focus. YOUR PROJECT-YOUR TIMELINE.

XTrials Research Services — Booth 2022

Contact: Mike Loftus
E-mail: mloftus@xtrials.com
Website: www.xtrials.com
Telephone: 732-805-3434
Fax: 732-805-3387

XTrials Research Services differs from EDC companies in that we are not a software company, but rather a full-spectrum CRO services provider. Instead of having to find a CRO to work with a particular EDC package you like, XTrials provides one-stop-shopping for World Class EDC software, expert ClinOps and DM support services.

Yoh Clinical — Booth 1938

Contact: Mike Gamble
E-mail: michael.gamble@yoh.com
Website: yohclinical.com

Yoh Clinical is a leading provider of talent and outsourcing services with expertise in clinical operations including regional monitoring and project management. With 374 million USD in annual sales, Yoh provides long- and short-term temporary and direct placement of clinical talent to customers nationwide. For more information, visit yohclinical.com.

Tutorial Pricing Guide

The tutorials being offered as of MAY 12, 2008, are listed below. Please continue to monitor www.diahome.org for tutorial updates and online registration.
Space is limited so register early!

Saturday, June 21, 2008 1:00-4:30 pm
Tutorials #30 through #36 Fee $375

Tutorial #30 has been rescheduled to #64, taking place on Sunday, June 22 from 8:30 am-12:00 pm.

#30 Comparability of Biopharmaceuticals *BT, RA*

#31 A Day in the Life of Adverse Event Reporting for Different Regions *CP, RA*

#32 Getting Your Clinical Operations on the Right Track: Strategy, Knowledge, People, and Process *CR, CTM/CS, RD*

#33 How to Prepare for an FDA GCP Audit *CR, GCP*

#34 Regulatory Affairs in the European Union: An Overview of Registration Procedures for Medicinal Products in EU *CR, PM/FI, RA*

#35 Abuse Potential and Drug Dependence Assessment: Scientific and Regulatory Guidance in Drug Development *PP, RA*

#36 Financing of Pharmaceutical and Biotech Startups *BT*

Tutorial #36 has been cancelled.

Sunday, June 22, 2008 9:00 am-5:00 pm
Tutorials #40 through #45 Fee $650

#40 Regulatory Requirements for the Conduct of Clinical Trials in Europe *CR, GCP, RA*

#41 Clinical Statistics for Nonstatisticians *CR, MC, MW*

#42 Principles of Safety Surveillance *CP, RA, TR*

#43 Excelling as a Supervisor or Manager in the Clinical Research Industry *CR, CTM/CS, PM/FI*

#44 Managing Regulatory GCP Inspections *GCP, RA*

#45 Comparability: How to Manage the Impact of Process Change

Tutorial #45 has been cancelled.

Sunday, June 22, 2008 8:30 am-12:00 pm
Tutorials #50 through #63 Fee $375

#50 Planning and Conducting Clinical Trials in Oncology *AHC/IS, BT, CR*

#51 A Mapping Primer: The Use of Terminology Standards to Meet Regulatory and Interoperability Requirer **Tutorial #51 has been cancelled.**

#52 Anatomy of Chemistry, Manufacturing and Control: Scientific and Regulatory Expectations of t **Tutorial #52 has been cancelled.**

#53 Pharmacovigilance Assessment and Risk Management: Essential Components to Good Pharmacovigilance Practice *CP, GCP*

#54 Energizing the Drug Safety Practice with the Use of New Media

Tutorial #54 has been cancelled.

#55 Active Query, Case Assessment, and Narrative Writing in Clinical Trials and Postmarketing Pharmacovigilance: Obtaining Quality Data through Clinical Expertise *CP, CR*

#56 Clinical Research and Pharmaceutical Registration in India

Tutorial #56 has been cancelled.

#57 FDA Enforcement: Understanding the Agency's Authority, How Violations Occur, How to Prevent Them, and How to Respond If Violations Do Occur *CTM/CS, GCP, RA*

#58 Structured Product Labeling Listing Data Elements *ERS/DM, IT*

#59 Introduction to the PSUR: Pharmacovigilance and Medical Writing Perspectives *CP, MW*

#60 Understanding and Managing Uncertainty in Pharmaceutical and Biotech

Tutorial #60 has been cancelled.

#61 A Device Primer: IDEs, 510(k)s, PMAs, and Beyond *AHC/IS, RA*

#62 Leadership: How to Organize and Lead People in Group Work *GCP, PM/FI, TR*

#63 Fourteen Steps from Research to Development *RA, RD*

Tutorial #64 was originally scheduled as #30, on Saturday, June 21 from 1:00-4:30 pm.

#64 Comparability of Biopharmaceuticals *BT, RA*

Sunday, June 22, 2008 1:00-4:30 pm
Tutorials #70 through #82 Fee $375

#70 Analysis of Safety Data from Clinical Trials *CR, MW, ST*

#71 Evaluation of Risk Management Programs Using Existing Databases *CP, RA*

#72 Effective Drug Safety Systems *CP, CR*

Tutorial #72 has been cancelled.

#73 The Creation and Management of a Worldwide Pharmacovigilance Quality Assurance Unit *CP, RA*

#74 Electronic Submission Success *ERS/DM, RA*

Tutorial #74 has been cancelled.

#75 GCP Issues in Emerging Regions: India and China *CR, GCP*

#76 Training Considerations for Patient-reported Outcomes

Tutorial #76 has been cancelled.

#77 CTD Preparation: Module 2 Clinical Overview and Clinical Summary and Relationship to ISE and ISS *MW, RA*

#78 Project Management for the Nonproject Manager *CR, CTM/CS, PM/FI*

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

#80 Working Across Cultures: Asia and the West *CR, TR*

Tutorial #80 has been cancelled.

#81 Adaptive (Flexible) Trial Designs *CR, ST*

#82 Who's Monitoring the Monitor? Explore Trends, Management Techniques, and a Reality Check for Sponsors Utilizing CRO- and Alliance-based Site Monitoring *CR, PM/FI*

Please indicate the tutorials you plan to attend on the registration form on page 143.

Hotel Reservations Instructions

The Travel Technology Group (TTG) is coordinating all reservations, and arrangements for housing must be made through them and not with the hotel directly. Housing reservation forms must be received by **May 22, 2008.** **DIA DOES NOT PROCESS HOTEL RESERVATIONS.** Methods for making hotel reservations are:

- **ONLINE** To make your reservations online, log on to **www.diahome.org**, double click the Annual Meeting icon, and go to Hotel Information. *Please have your credit card, arrival and departure information ready.*
- **BY FAX** **1-312-329-9513 (domestic and international)** Please print or type all information to ensure accuracy. Complete each part of the form for correct and rapid processing. For multiple rooms, you may duplicate the form. Confirmations will be sent to the individual listed, **by email if provided.**
- **BY PHONE** **1-866-825-6091 (domestic) / 1-312-527-7300 (international)** Please have all of the information that is requested on the form ready along with a credit card number and expiration date for the room deposit.
- **BY MAIL** Complete each part of the form and mail to: **Travel Technology Group**, 110 West Hubbard Street, Chicago, IL 60610, USA

RESERVATIONS BY PHONE Please have the following information ready: • Name of convention – DIA Annual Meeting • 1st, 2nd, 3rd choice of hotel • Arrival/departure dates • Number of rooms requested • Type of room (single/double/triple/quad) • Number of persons in your party • Arrival time • Credit card type, account number, expiration date • Names of all room occupants • Daytime phone number • Fax number • eMail address to which confirmation will be sent • **Requests for suites must be sent to Lori.Risboskin@diahome.org**

DEPOSIT A one-night room deposit, **plus 12.45% tax**, is required for all reservations. The deposit amount is payable by credit card, or by check in US dollars, drawn on a US bank (by mail only). ***No wire transfers or purchase orders will be accepted. No reservation will be processed without a deposit.***

CREDIT CARD Your credit card will be used as a guarantee but will not be charged immediately. The hotel may charge the deposit to your credit card after **May 23, 2008** when they receive the reservations for processing from TTG. Most major credit cards are accepted. Each hotel will honor the TTG acknowledgement.

CHECKS Your deposit check must be made payable to **Travel Technology Group** in US funds drawn on a US bank and mailed to 110 West Hubbard Street, Chicago, IL 60610, USA. **No checks will be accepted after May 22, 2008.**

CHANGES/CANCELLATIONS/REFUNDS **Until May 22, 2008,** all changes and cancellations should be made directly with TTG by phone, fax, mail, or by email to **dia@ttgonline.com. Data will be transferred to the hotels on May 23 and changes/cancellations/reservations will NOT be accepted from May 23 through May 25. Beginning May 26, 2008,** changes and cancellations should be made directly with the confirming hotel. Cancellation policy is as follows:

- **Cancellations made on May 1, 2008, or earlier,** will receive a full refund. If deposit was paid by check, a $25.00 processing fee will be deducted.
- **Cancellations made after May 1, 2008,** will forfeit the full room and tax deposit.
- **If a guest does not arrive by their scheduled arrival date,** the full reservation will be cancelled by the hotel and the deposit will be forfeited.

Hotel Locator Map

Reproduced with permission of the Travel Technology Group and the Boston Convention and Exhibition Center

You must be a DIA member, a confirmed Annual Meeting registrant, and have booked your registration through the Travel Technology Group. Drawing will be held May 28.

Win a $500 Visa Gift Card!

Complete the following information and submit to Travel Technology Group by May 22, 2008.

First Name (please print) _____ Last Name _____ Middle Initial _____

Company/Institution _____

Address _____ City _____ State _____ Zip/Postal Code _____ Country _____

Tel _____ Fax _____

email _____

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

HOTEL SELECTION Please list in order of preference.

1. _____ Arrival Date _____ Departure Date _____
2. _____ ❑ Smoking* ❑ Nonsmoking* ❑ 1 Bed* ❑ 2 Beds*
3. _____ ❑ Single ❑ Double ❑ Triple ❑ Quad

**This is a request only.*

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

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

3. _____ 4. _____

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

Credit Card # _____ Expiration Date _____

Name on Card (please print) _____ Signature _____

Event Hotels

**Rates do not include current tax of 12.45% or applicable surcharges; subject to change. Hotel rates include a nominal $5 fee to help defray venue costs.*

Hotel Name and Address	Room Rates* Single	Double	Triple	Quad	Distance to Convention Center	Shuttle Offered
Co-headquarters Hotels						
1 Westin Boston Waterfront Hotel 425 Summer Street	$235	$255	$295	$335	Connecting to BCEC	No
2 Boston Marriott Copley Place 110 Huntington Avenue	$241	$241	$261	$281	2.3 Miles	Yes
3 Boston Park Plaza & Towers 64 Arlington Street	$190	$210	$250	$290	1.4 Miles	Yes
4 Hilton Boston Back Bay 40 Dalton Street	$242	$242	$262	$282	2.5 Miles	Yes
5 Renaissance Boston Waterfront Hotel 606 Congress Street	$249	$269	$289	$309	5 Blocks	No
6 Seaport Hotel One Seaport Lane	$242	$242	$267	$292	2 Blocks	No
7 Sheraton Boston Hotel 39 Dalton Street	$224	$244	$284	$324	2.5 Miles	Yes
8 Westin Copley Place 10 Huntington Avenue	$246	$266	$306	$346	2.2 Miles	Yes
9 Colonnade Hotel 120 Huntington Avenue	$245	$245	–	–	2.4 Miles	Yes
10 Hyatt Regency Boston One Avenue de Lafayette	$259	$259	$284	–	1.1 Miles	Yes
11 Doubletree Boston Downtown 821 Washington Street	$239	$239	–	–	1.3 Miles	Yes
12 Hampton Inn & Suites Boston Crosstown Center *(** Shuttle service will be provided by the hotel, NOT by DIA.)* 811 Massachusetts Avenue	$180	$180	–	–	2.5 miles	**Yes
13 Hilton Boston Logan Airport *(** Shuttle service will be provided by the hotel, NOT by DIA.)* One Hotel Drive	$249	$249	$269	$289	3.2 miles	**Yes
14 *New Hotel!* **The Langham Boston** 250 Franklin Street	$259	$259	$289	$319	1.2 Miles	Yes
15 *New Hotel!* **InterContinental Boston** 510 Atlantic Avenue	$269	$269	–	–	1.1 Miles	Yes
16 *New Hotel!* **Hyatt Harborside** *(** Shuttle service will be provided by the hotel, NOT by DIA.)* 101 Harborside Drive	$249	$249	$274	$299	3.1 Miles	**Yes
17 *New Hotel!* **Embassy Suites Boston at Logan** *(** Shuttle service will be provided by the hotel, NOT by DIA.)* 207 Porter Street	$249	$249	$–	$–	2.7 Miles	**Yes

Optional Tours

These activities provide an opportunity to enjoy the Boston area. Use the registration form on page 143, or you can CLICK HERE to register online. All tours depart from and return to the Boston Convention and Exhibition Center (BCEC) and will take place rain or shine.

TREASURES OF NEWPORT — Sunday, June 22 • 9am-5pm • $82 per person


Photographer © Jxpfeer/Dreamstime.com

The 19th century was the era of romanticism in America, inspiring a creative burst of innovation in architecture and décor. In Newport, picturesque mansions, cottages and shingled villas reflected a way of life devoted to nature and summers by the sea. Writers, artists, statesmen and pillars of industry made Newport their home and filled their houses with treasures from around the world. Discover the magic at Newport's grandest estates remaining from the Gilded Age. Your tour includes private tours of The Breakers and Marble House.

Marble House was built between 1888 and 1892 for Mr. and Mrs. William K. Vanderbilt as a summerhouse – or "cottage" as Newporters called them – in remembrance of the modest houses of the early 19th century. But Marble House was much more; it was a social and architectural landmark that set the pace for Newport's subsequent transformation from a quiet summer colony of wooden houses to the legendary resort of opulent stone palaces. The Breakers is the grandest of Newport's summer "cottages" and a symbol of the Vanderbilt family's social and financial preeminence in turn-of-the-century America. In 1893, Commodore Cornelius Vanderbilt's grandson, Cornelius Vanderbilt III, commissioned architect Richard Morris Hunt and an international team of craftsmen and artisans to create a 70-room, Italian Renaissance-style palazzo inspired by the 16th century palaces of Genoa and Turin.

The Vanderbilt's had seven children. Their youngest daughter, Gladys, inherited the house on her mother's death in 1934. An ardent supporter of The Preservation Society of Newport County, she opened The Breakers in 1948 to raise funds for the Society. In 1972, the Preservation Society purchased the house from her heirs. Today, the house is designated a National Historic Landmark. Lunch will be on your own at your choice of one of the many downtown waterfront restaurants with spectacular views of Newport's famous harbor.

Includes executive motor coach transportation; professional tour guide; all admissions, taxes, and gratuities.
***Note:** This tour involves considerable walking; sensible footwear recommended. Not suitable for children under 5 years.*

THE FREEDOM TRAIL
Sunday, June 22 • 1pm-4pm • $40 per person


Photographer: Chee-Ony Leong/Big Stock Photo

Your comfortable motor coach transports you to beautiful Boston Common to begin your walk back in time on the Freedom Trail! From here, your guide leads you on a 90-minute walking tour back to colonial times on the city's esteemed Freedom Trail, ending at Faneuil Hall.

Boston's 2 ½-mile walk through history follows the red brick road to 16 historic sites: Boston Common, The Massachusetts State House, Park Street Church, Granary Burying Ground, King's Chapel, Ben Franklin's statue, Old South Meeting House, Old Corner Bookstore, Old State House, Boston Massacre Site, Faneuil Hall, Paul Revere House, Old North Church, Copps Hill Burying Ground, USS Constitution and Bunker Hill Monument.

Your tour will continue through the Quincy Market area to Boston's famous Faneuil Hall, where statesmen, orators and the public have gathered for two centuries to discuss and debate the freedoms we all share. Nibble in Quincy Market's massive food hall or peruse the maze of shops before boarding your coach back the hotel.

Includes executive motor coach transportation; professional tour guide; all admissions, taxes, and gratuities. ***Note:*** *This tour is mostly walking, sometimes on cobblestone streets; sensible footwear recommended. Not suitable for children under 5 years.*

THE BOSTON POPS
Sunday, June 22 • 7:30pm-9:30pm • $62.40 per person

Year after year, the Boston Pops remain one of the most popular orchestras in America, continuing its tradition of producing the best in music for its audience while often featuring exciting guest stars of stage, screen, and performance halls. Through concerts, tours, radio, TV and an endless series of record albums, this versatile ensemble brings classical music, marches, and contemporary pop to millions of listeners!


Photographer: Stu Rosner

Over the past 70 years, the orchestra's trio of accomplished conductors – Arthur Fiedler, John Williams, and Keith Lockhart – have made the Boston Pops a household name!

All seats are located in the first balcony section – center.

Transportation is not included; the Boston Convention and Exhibition Center is a short taxi ride from this event. Includes all admissions, taxes, gratuities.

OLD TOWN TROLLEY

Monday, June 23 • 3:30pm-5:30pm • $35 per person

Photographer: Anthony Berenyi/Big Stock Photo

All aboard! Don't miss this tremendously popular, narrated city tour filled with fun, facts and history. See Boston on an open-air trolley while taking in the following sites: New England Aquarium/Faneuil Hall Marketplace; Historic North End/Paul Revere House; USS Constitution/ Charlestown Navy Yard; TD Banknorth Garden/North Station; Old State House/ Quincy Market Boston Common/Trolley Stop Store; Massachusetts State House/ Boston Welcome Center; Cambridge/ M.I.T/Harvard; Charles Street Meeting House/Antique Row; Back Bay/Mapparium at Mary Baker Eddy Library; Prudential Skywalk Observatory/Shops at Prudential Center; Boston Marriott Copley Hotel; Copley Square/Newbury Street; Hard Rock Cafe; Theatre District/Chinatown.

Includes authentic trolley transportation; professional driver/guide; DPI host; all admissions, taxes, and gratuities. ***Note:*** *This tour involves minimal walking. Suitable for children.*

BOSTON RED SOX V. ARIZONA DIAMONDBACKS

Monday, June 23 • 7:05pm • $89 per person
Tuesday, June 24 • 7:05pm • $89 per person

Photographer: Elena Milevska © Dreamstime.com

The World Champion Boston Red Sox host the Arizona Diamondbacks at 7:05 pm. "Taking in a game" at one of America's most beloved stadiums, Fenway Park, which just happens to be home to the World Champions is an experience never to be forgotten! Don't miss out on this opportunity. A limited number of tickets are available.

All tickets are center field bleacher seats.

Transportation is not included; the Boston Convention and Exhibition Center is a short taxi ride from this event. GET THERE EARLY!

BEHIND THE SCENES AT FENWAY PARK EXPERIENCE!

Tuesday, June 24 • 10am-12pm • $54 per person

Guests will enjoy this behind-the-scenes tour of Boston's famous Fenway Park! No other professional baseball park captures the spirit and triggers emotion like Fenway Park. Named for the famous "Fens" area of Boston where it stands, Fenway Park has been a Boston landmark since 1912, a standing monument to America's favorite pastime. From Pesky's Pole to the Greet Monster, Fenway's mystique continues to grow with each generation of fans.

Come experience Fenway Park up close and personal. This is the park where the Babe pitched, The Kid hit, Yaz dazzled and Manny and Ortiz still thrill young fans today. Soak up the rich baseball history; hear the echoes of the past.

Photographer: Christopher Penter/Big Stock Photo

Close your eyes and let your imagination wander. You just may be able to hear the crack of the bat as Ted Williams hits the longest measured homerun in Fenway's 94-year history deep into right field on June 9, 1946 – an amazing 502 feet from home plate!!!

Bring your camera and your imagination!

Includes executive motor coach transportation; professional tour guide; all admissions, taxes, and gratuities. This tour has a fair amount of walking. Great fun for all ages!

BIKE BOSTON'S NEIGHBORHOODS

Monday, June 23 • 1pm-3pm • $60 per person

Photographer: Elena Elisseeva/Big Stock Photo

This is our original Boston Tour. From the BCEC, we pedal down the length of the Back Bay, observing the transformation of architectural styles, admiring and learning the merits of the people honored in our city's statues and recounting the history that made this neighborhood one of the most prestigious in Boston. Next, roll on to the Back Bay Fens, featuring the Victory Garden allotments, the Keller Rose Garden, the Museum of Fine Arts and the palazzo-inspired Isabella Stewart Gardner Museum. Boston University and Fenway Park – the oldest ballpark in major league baseball and home of the Boston Red Sox – are visible as we cover a portion of the 17-mile Dr. Paul Dudley White bicycle path on our way to the Charles River Esplanade. We cross the river for a peek at the Massachusetts Institute of Technology (MIT), drinking in the panoramic view of Boston. Stopping at the Hatch Memorial Shell pavilion, where the Boston Pops Orchestra traditionally play for Boston's 4th of July celebration, we recall the popular festivities of music, fireworks and a patient audience of thousands!

Next we pedal on to the quaint, quiet, historical neighborhood of Beacon Hill. From the antique shops on Charles Street to the cobblestones of Acorn Street, Beacon Hill is loaded with charm and character. This off-the-beaten-path bike tour visits sites bypassed by the Freedom Trail. Six to nine flat and easy miles; mostly parks and bike paths. Suitable for all levels of cyclists.

Includes professional tour guide and dispatcher; bike and helmet rental; all admissions, taxes, and gratuities.
Note: *Entire tour is on bicycle. Wear comfortable shoes and clothing. Not suitable for children without supervision.*

QUACK-QUACK!! BOSTON DUCK TOUR

Tuesday, June 24 • 1pm-3pm • $46 per person

Truly Boston's most unique tour experience is on our famous Ducks! These beautiful, multicolored, World War II amphibious vehicles navigate the streets of Boston as well as the currents of our Charles River. Your duck traverses past historic sites including the State House, Boston Common, Government Center, fashionable Newbury Street and so much more! Then, it's into the Charles River you go for breathtaking views of the Boston and Cambridge Skylines – unique vistas you can't get anywhere else! Then land back on the banks of the river and return to the BCEC via the streets of Boston.

Each conDUCKtor is a unique character in costume, bringing to you Boston's history laced with lore and legends. But don't underestimate their knowledge. These characters take their historical wisdom very seriously and welcome your challenges!

Fun for all ages! This tour never lets you down! Quack! Quack!!

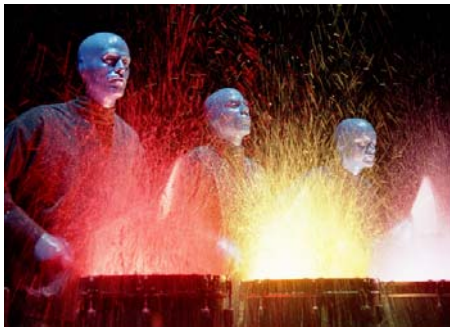
Includes special VIP pick-up and drop-off at the Boston Convention and Exhibition Center; professional dispatcher; all admissions, taxes, gratuities. ***Note:*** *This tour involves no walking. Wear practical clothing; you will likely get splashed in the river.*

BLUE MAN GROUP

Tuesday, June 24 **The Tuesday performance has been cancelled**

Wednesday, June 25 • 8pm-9:45pm • $49.20 per person

Blue Man Group is best known for its wildly popular theatrical shows and concerts that combine music, comedy and multimedia theatrics to produce a totally unique form of entertainment. Centered on a trio of bald, mute performers who present themselves in blue grease paint and black clothing, Blue Man Group's quirky, theatrical acts incorporate rock music, odd props, audience participation, sophisticated lighting and large amounts of toilet paper.



Photographer: Ken Howard © BMP

All seats are located in the "poncho section" in the front rows, where patrons are provided with plastic ponchos in order to protect them from various food, substances, paints, and so on which get thrown, ejected, or sprayed from the stage. The blissful party atmosphere created has become the trademark of a Blue Man Group experience!

Transportation is not included; the Boston Convention and Exhibition Center is a short taxi ride from this event. Includes all admissions, taxes, gratuities. ***Note:*** *Wear practical clothing as all seats are in the "poncho section" in the front rows.*

HARVARD UNIVERSITY AND JOHN F. KENNEDY PRESIDENTIAL LIBRARY AND MUSEUM

Wednesday, June 25 • 12:30pm-4:30pm • $49 per person

Photographer: Jorge Salcedo/Big Stock Photo

Come stroll through Harvard University as your guide points out the historic architecture of the oldest university in the country. John F. Kennedy lived and studied here in his younger years. Visit the burial ground of Harvard's first eight presidents.

You'll have free time to browse the unique shops, boutiques and bookstores of Harvard Square before heading off to Dorchester to tour the impressive John F. Kennedy Library.

Photographer: Ted Holt/Big Stock Photo

With its collection of personal mementos and gifts that John F. Kennedy received during his presidency as well as historical artifacts, informative displays and unique films, you will find yourself reliving the time during the Kennedy presidential campaign, the Kennedy and Nixon debates, the Kennedy presidency and the Cuban missile crisis.

Includes executive motor coach transportation; professional tour guide; all admissions, taxes, and gratuities.
Note: *This tour involves considerable walking; sensible footwear recommended. Not suitable for children under 5 years.:*

All tours are based on a minimum number of guests. If the minimum guest requirements are not met, the tour will be cancelled and guests will receive a full refund. The registration deadline is Monday, May 26, 2008. All requests for refunds must be received prior to this date. No refunds will be accepted after this date. **Please return this form, with check attached, or credit card information completed** (US funds only) to: Destination Partners, Inc., Attn: Burton L. Hartford, by **Monday, May 26, 2008**.

Make checks payable to:

Destination Partners, Inc.
111 Main Street, Suite 3, Amesbury, MA 01913, USA • Phone (978) 388-3277 • Fax (978) 388-3118

Participants with Disabilities: All tours are accessible to persons with disabilities. Arrangements can be made if requested by May 26, 2008. Contact Destination Partners, Inc. to indicate your needs.

TOUR TICKET PICK-UP: Tour Desk in the BCEC registration area.

Please indicate the number of tickets for each activity.

Date/Time	Tour Title	Price per Person		Number of Persons		Amount Due per Tour
Sunday, June 22						
9am-5pm	Treasures of Newport	$82.00	x	_____	=	$ _____
1pm-4pm	The Freedom Trail	$40.00	x	_____	=	$ _____
7:30pm-9:30pm	The Boston Pops *(first balcony section - center)*	$62.40	x	_____	=	$ _____
Monday, June 23						
1pm-3pm	Bike Boston's Neighborhoods	$60.00	x	_____	=	$ _____
3:30pm-5:30pm	Old Town Trolley	$35.00	x	_____	=	$ _____
7:05pm	Boston Red Sox v. Arizona Diamondbacks	$89.00	x	_____	=	$ _____
Tuesday, June 24						
10am-12pm	Behind the Scenes at Fenway Park Experience	$54.00	x	_____	=	$ _____
1pm-3pm	Quack-Quack!! Boston Duck	$46.00	x	_____	=	$ _____
7:05pm	Boston Red Sox v. Arizona Diamondbacks	$89.00	x	_____	=	$ _____
8pm-9:45pm	Blue Man Group *(poncho section - front)*	***The Tuesday performance has been cancelled.***				
Wednesday, June 25						
12:30pm-4:30pm	Harvard University & John F. Kennedy Presidential Library and Museum	$49.00	x	_____	=	$ _____
8pm-9:45pm	Blue Man Group *(poncho section - front)*	$49.20	x	_____	=	$ _____
				Total # Tickets		**Total Amount Due**
				_____		$ _____

Registrant's Name (please print)

Address

City State Zip/Postal Code Country

Daytime Phone # Fax #

eMail

PAYMENT (please check one): Credit Card Type: ❑ Visa ❑ MasterCard ❑ American Express ❑ Check (payable to Destination Partners, Inc., drawn on US Bank only)

Name on Card (please print) Credit Card # Expiration Date

Authorized Signature V Code

WAIVER

Enclosed are funds in the amount of $_____ as full payment for the Tour Program. I understand that this is nonrefundable after **May 26, 2008**, unless the minimum number of participants required to operate the tour is not met. Neither **Destination Partners, Inc.**, nor **DIA** is responsible for lost or damaged articles, traffic delays, accidents, strikes, riots, war, governmental action or regulation, acts of God, or other causes over which the parties have no control. In the event any or all of the Tours are canceled because of reasons beyond the parties' control, neither party shall incur any liability or obligation, and Destination Partners, Inc., shall refund all deposits to participants. I further represent that I (and/or my children) am (are) in proper physical condition to participate in all requested activities and waive all claims for myself, my heirs, and assigns against Boston, DIA and all event sponsors and their representatives, successors, and assigns for any injury or illness which may result from my (or my children's) participation.

Signature of participant Date

Completed Forms may be FAXED to (978) 388-3118 or follow the instructions on page 140 to register for tours online.

ATTENDEE REGISTRATION FORM

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

44TH ANNUAL MEETING ID #08001 June 22-26, 2008, Boston, MA, USA

This registration form is for use by paying **ATTENDEES ONLY.** If paying by credit card, complete and mail this form to DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA or fax to +1-215-442-6199. If paying by check, see Payment Methods below.

All registrations received at the DIA office in Horsham, PA, USA by 5:00 PM on May 16, 2008 will be included in the Advance Registration Attendee List.

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

PAYMENT METHODS **REGISTER ONLINE AT www.diahome.org or please check payment method:**

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

❑ VISA ❑ MC ❑ AMEX Exp. Date _____

Card # _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, 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** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Meeting I.D. #08001 must be included on the transfer document to ensure payment to your account.

CANCELLATION POLICY

All cancellations must be in writing and be received at the DIA office by 5:00 PM on June 6, 2008. Registrants who do not cancel by June 6, 2008 and do not attend will be responsible for the full applicable fee. **Registrants are responsible for cancelling their own airline and hotel reservations.** You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. **Substitute registrants will be responsible for nonmember fee, if applicable.**

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants. Speakers and program agenda are subject to change. **Cancellations received in writing on or before June 6, 2008 will be processed as follows:**

FULL MEETING CANCELLATION
Government/Nonprofit/Academia – Registration fee paid minus $100 = Refund Amount
All Others – Registration fee paid minus $200 = Refund Amount

NETWORKING RECEPTION CANCELLATION
On or before June 6, 2008 = Full Refund

TUTORIAL CANCELLATION
On or before June 6, 2008 – Registration fee paid minus $75 = Refund Amount

ONE-DAY REGISTRATION
There will be NO REFUNDS given for cancellations of one-day registrations or one-day no shows.

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

FULL-MEETING REGISTRATION (attendance of 2 or more days) includes admission to all 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 pages 12-24 for tutorial descriptions and page 137 for an at-a-glance tutorial schedule/pricing guide. 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 # _____ Fee _____

TUTORIAL SUBTOTAL _____

PREREGISTRATION FEES ***A surcharge of $150 will apply to all registrations received after June 13, 2008*** (does not apply to one-day registrations). Your confirmation letter is required to avoid the $150 surcharge. For sufficient time to process your registration, and ensure receipt of a confirmation letter, your completed registration form and payment must be received by **June 13, 2008. An email address must be included below for confirmation process.**

MEMBER FEE** **US $1200** ❑

Join DIA now to save on future meetings and enjoy the benefits of membership for one year! www.diahome.org **US $130** ❑

NONMEMBER FEE** **US $1330** ❑

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

I do ❑ I do NOT ❑ want to be a DIA member

DISCOUNT FEES	MEMBER	NONMEMBER*
Government (Full-time)**	US $330 ❑	US $460 ❑
Charitable Nonprofit/Academia (Full-time)**	US $725 ❑	US $855 ❑

*If paying a nonmember fee, please check one box above, indicating whether you want membership.
**Includes access to post-meeting presentations.

ONE-DAY REGISTRATION FEES You must indicate which day you plan to attend.	MEMBER US $690 ❑	NONMEMBER* US $820 ❑

Monday, June 23 ❑ Tuesday, June 24 ❑ Wednesday, June 25 ❑ Thursday, June 26 ❑

*If paying a nonmember fee, please check one box above, indicating whether you want membership.
(One-day registration fee does not include access to post-meeting presentations.)

NETWORKING RECEPTION Must be registered for the full meeting to attend. Networking Reception Only is not available.	On or before MAY 31, 2008 US $80 ❑	After MAY 31, 2008 US $95 ❑

TOTAL PAYMENT DUE * **US $** _____

*Include all applicable fees: meeting, tutorials, networking reception.

Last/Family Name First Name MI

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Mailing Address

City State Zip/Postal Code Country

Telephone # Fax #

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

ADD TUTORIALS and/or NETWORKING RECEPTION to an Existing Meeting Registration

DRUG INFORMATION ASSOCIATION

44TH ANNUAL MEETING ID #08001

June 22-26, 2008, Boston, MA, 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.

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

PAYMENT METHODS – Please check payment method:

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

❑ VISA ❑ MC ❑ AMEX Exp. Date _____

Card # _____

Signature _____

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

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Meeting I.D. #08001 must be included on the transfer document to ensure payment to your account.

CANCELLATION POLICY

All cancellations must be in writing and be received at the DIA office by 5:00 PM on June 6, 2008. Registrants who do not cancel by June 6, 2008 and do not attend will be responsible for the full applicable fee. **Registrants are responsible for cancelling their own airline and hotel reservations.** You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. **Substitute registrants will be responsible for nonmember fee, if applicable.**

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants. Speakers and program agenda are subject to change. **Cancellations received in writing on or before June 6, 2008 will be processed as follows:**

FULL MEETING CANCELLATION
Government/Nonprofit/Academia – Registration fee paid minus $100 = Refund Amount
All Others – Registration fee paid minus $200 = Refund Amount

NETWORKING RECEPTION CANCELLATION
On or before June 6, 2008 = Full Refund

TUTORIAL CANCELLATION
On or before June 6, 2008 – Registration fee paid minus $75 = Refund Amount

ONE-DAY REGISTRATION
There will be NO REFUNDS given for cancellations of one-day registrations or one-day no shows.

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

❑ **YES,** I am registered for the meeting and I would like to add the Networking Reception and/or the following Tutorials to my registration. I am registered as:
❑ 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 13-14 in the online brochure for tutorial prices and schedule. Space is limited and pre-registration is encouraged. Please indicate the I.D. # and fee for each tutorial you plan to attend.

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____

Tutorial # _____ Fee _____ Tutorial Subtotal _____

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

NETWORKING RECEPTION

	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 $80 ❑	US $95 ❑

TOTAL PAYMENT DUE US $ _____

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

Last Name First Name MI

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Mailing Address

City State Zip/Postal Code Country

Telephone # Fax #

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

EXHIBIT PERSONNEL REGISTRATION FORM

Online registration is *not* available to exhibit personnel.

DIA
Drug Information Association

44TH ANNUAL MEETING ID #08001

June 22-26, 2008, Boston, MA, 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 16, 2008 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** number may be faxed to: +1-215-442-6199.
You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to the currency conversion rate at the time of the charge.

❑ VISA ❑ MC ❑ AMEX Exp. Date _____

Card # _____

Signature _____

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TUTORIAL CANCELLATION
On or before June 6, 2008 – Registration fee paid minus $75 = Refund Amount

FULL-MEETING REGISTRATION: (Attendance of 2 or more days) includes admission to all scientific sessions, exhibits, coffee breaks, luncheons and receptions ***(excluding the Sunday Networking Reception).***

TUTORIALS: See pages 12-24 for tutorial descriptions and page 137 for an at-a-glance tutorial schedule/pricing guide. 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 # _____ Fee _____ Tutorial Subtotal _____

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

NETWORKING RECEPTION	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 $80 ❑	US $95 ❑

TOTAL PAYMENT DUE US $ _____

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Last Name First Name MI

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Mailing Address

City State Zip/Postal Code Country

Telephone # Fax #

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