trifecta™ is the global leader in investigator training.

We’ve designed and developed training for hundreds of clinical trials worldwide.

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  - Empowering investigators in entirely new ways.

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  - Leading global producer of live medical meetings.

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  - Fusing the best of online + live technology.
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Welcome to Boston, and thank you for choosing to attend DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation and Regulatory Science.

The need for innovative therapeutic interventions that meet the health care needs of the world’s changing, aging population, and the corresponding need for regulatory science to advance and keep pace with these innovations, have never been more urgent. Our Program Committee is confident that you will find the educational and networking opportunities that this meeting presents, all carefully developed around the meeting theme, to be quite compelling.

Over the next few days, you will enjoy exhibits, poster programs, sessions, forums, workshops and symposiums that will inform and challenge you. Please take a moment to thank the presenters and exhibitors whose insights encouraged or taught you the most, and consider joining one of DIA’s professional Communities to further your own education — and sharing that expertise at future DIA events.

In the meantime, please accept my own thanks for attending our DIA 2013 49th Annual Meeting. I look forward to working and networking alongside you, to benefit the patients we serve back home.

Sincerely Yours,

Sandra A. Milligan, JD, MD
DIA 2013 49th Annual Meeting Program Chair
### SATURDAY JUNE 22

**Registration Hours:**
9:00 AM–5:00 PM  
Exhibitor Registration

### SUNDAY, JUNE 23

**Registration Hours:**
8:00–9:00 AM  
Registration for Full Day, Morning Preconference Tutorials*
12:30–1:00 PM  
Registration for Afternoon Preconference Tutorials*  
8:00 AM–6:00 PM  
Exhibitor Registration  
3:00–6:00 PM  
Attendee and Speaker Registration

**Schedule:**
8:30 AM–12:00 PM  
Half Day Preconference Tutorials*
9:00 AM–5:00 PM  
Full Day Preconference Tutorials*
1:00–4:30 PM  
Half Day Afternoon Preconference Tutorials*

*Space is limited for Preconference Tutorials, therefore preregistration is strongly recommended. Availability for onsite registration is not guaranteed.

### MONDAY, JUNE 24

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

**Schedule:**
7:30–8:15 AM  
Orientation/Networking and Coffee for DIA 2013 49th Annual Meeting First Timers
7:45–8:30 AM  
Coffee and Breakfast Breads
8:30–10:00 AM  
Opening Plenary Session
9:30 AM–5:30 PM  
Exhibition Hall Open
10:00–11:00 AM  
Coffee Break
10:15–11:45 AM  
Orientation and Coffee for DIA 2013 49th Annual Meeting First Timers
10:00 AM–5:30 PM  
Student Poster Session
11:00 AM–12:30 PM  
Concurrent Educational Opportunities
12:30–2:30 PM  
Lunch
2:30–4:00 PM  
Concurrent Educational Opportunities
4:00–5:30 PM  
Welcome Reception
4:30 PM  
Student Poster Award Ceremony

### TUESDAY, JUNE 25

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

**Schedule:**
7:15–8:00 AM  
Coffee and Breakfast Breads
8:00–9:30 AM  
Concurrent Educational Opportunities
9:00 AM–5:30 PM  
Exhibition Hall Open
9:30–10:15 AM  
Coffee Break
10:15–11:45 AM  
Concurrent Educational Opportunities
10:15–11:45 AM  
Student Forum
11:45 AM–1:45 PM  
Extended Lunch
11:45 AM–4:00 PM  
Professional Poster Session
12:15–1:00 PM  
Innovation Theater Presentation (Exhibit Hall)
1:45–3:15 PM  
Concurrent Educational Opportunities
1:45–3:15 PM  
Exhibit Guest Passes
3:15–4:00 PM  
Refreshment Break
4:00–5:30 PM  
Concurrent Educational Opportunities

### WEDNESDAY, JUNE 26

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

**Schedule:**
7:15–8:00 AM  
Coffee and Breakfast Breads
8:00–9:30 AM  
Concurrent Educational Opportunities
9:00 AM–4:00 PM  
Exhibition Hall Open
9:30–10:15 AM  
Coffee Break
10:15–11:45 AM  
Concurrent Educational Opportunities
11:45 AM–1:45 PM  
Extended Lunch
11:45 AM–4:00 PM  
Professional Poster Session
12:15–1:00 PM  
Innovation Theater Presentation (Exhibit Hall)
1:45–3:15 PM  
Concurrent Educational Opportunities
1:45–3:15 PM  
Exhibit Guest Passes
3:15–4:00 PM  
Refreshment Break
4:00–5:30 PM  
Concurrent Educational Opportunities

### THURSDAY, JUNE 27

**Registration Hours:**
8:00–10:45 AM  
Attendee and Speaker Registration

**Schedule:**
8:15–9:00 AM  
Coffee and Breakfast Breads
9:00–10:30 AM  
Concurrent Educational Opportunities
10:30–10:45 AM  
Coffee Break
10:45 AM–12:15 PM  
Concurrent Educational Opportunities
KEYNOTE SPEAKER

OPENING PLENARY SESSION

Daniel Kraft, MD
Executive Director, FutureMed

Monday, June 24 | 8:30–10:00 AM • Grand Ballroom

Daniel Kraft is a Stanford and Harvard trained physician-scientist, inventor, entrepreneur, and innovator.

Dr. Kraft has over 20 years of experience in clinical practice, biomedical research and healthcare innovation. Daniel chairs the Medicine track for Singularity University and is Executive Director for FutureMed, a program which explores convergent, exponentially developing technologies and their potential in biomedicine and healthcare.

Following undergraduate degrees at Brown and medical school at Stanford, Dr. Kraft was board certified in the Harvard combined Internal Medicine and Pediatrics residency program at the Massachusetts General and Boston Children’s Hospital, and completed Stanford fellowships in hematology/oncology & bone marrow transplantation, and extensive research in stem cell biology and regenerative medicine. He has been published in multiple scientific publications, including Nature and Science.

He has patented medical device, immunology and stem cell related products through faculty positions with Stanford University School of Medicine and as clinical faculty for the pediatric bone marrow transplantation service at UCSF.

Dr. Kraft recently founded IntellMedicine, focused on enabling connected, data driven, and integrated personalized medicine. He is also the inventor of the MarrowMiner, an FDA approved device for the minimally invasive harvest of bone marrow, and founded RegenMed Systems, a company developing technologies to enable adult stem cell based regenerative therapies.

“The Integration of exponentially growing technologies is beginning to empower the patient, enable the doctor, enhance wellness and begin to cure the well before they get sick. In an age where a simple smartphone can be used as a diagnostic tool, I’m excited that DIA invited me to share the significance of leveraging technology to advance health care with such a collaborative community, we will explore how technology will help get the right drug, to the right person, at the right time.”

— Dr. Kraft

MOVIE FEST! ADVANCED TICKETING REQUIRED

Hearing the patient voice, and understanding the patient perspective, are cornerstones of the drug development process. This year’s DIA Annual Meeting presents two film documentaries, shown Tuesday and Wednesday evening, brought to you by the Kauffman Foundation. Wine and light refreshments to be provided.

Seats are limited; Advanced ticketing: First come, first serve.

• To obtain tickets for RARE, please visit the Attendee Registration Desk no later than Monday at 5:00 PM.
• To obtain tickets for HERE.US.NOW, please visit the Attendee Registration Desk no later than Tuesday at 5:00 PM.

Please note that the DIA Courtesy Shuttle will not be available after 7:30 PM.

RARE
Tuesday 5:30–7:30 PM

See session #290 for more information.

HERE.US.NOW.
Wednesday 5:30–7:30 PM

See session #390 for more information.
FEATURED OFFERINGS IN THIS YEAR’S PROGRAM

#135 Cooperation Among Regulators: Impact on Stakeholders
MONDAY | 2:30-4:00 PM
Marie Allison Drake, MA, MBA
President, International Regulatory Affairs
Group LLC
Murray M. Lumpkin, MD, MSc
Commissioner’s Senior Advisor
and Representative for Global
Issues, OC, FDA
Paul Glover, MBA
Assistant Deputy Minister of
the Health Products and Food
Branch, Health Canada
Margaret A. Hamburg, MD
Commissioner, FDA
Guido Rasi, MD
Executive Director
European Medicines Agency
European Union

#204 Making CRO-Sponsor Partnerships Work: Executive Roundtable
TUESDAY | 8:00-9:30 AM
Kenneth I. Kallin, PhD
Professor and Director
Center for the Study of Drug
Development, Tufts University
School of Medicine
Peter A. Carberry, MD, MBA
Senior Vice President
Global Development
Operations, Astellas Pharma
Global Development, inc.
Jamie Macdonald
Chief Executive Officer
INC Research
Claraan Murray
Chief Executive Officer
ICGN Plc
Jonathan B. Zung, PhD
Vice President, Head of Global
Development Operations
Bristol-Myers Squibb Company

#263 Reinventing the R&D Business Model: Heeding the President’s PCAST Report on Innovation
TUESDAY | 1:45-3:15 PM
Kenneth I. Kallin, PhD
Professor and Director
Center for the Study of Drug
Development, Tufts University
School of Medicine
Robert J. Franco, PhD
Principal
PricewaterhouseCoopers LLP
Kenneth A. Getz, MBA
Director of Sponsored
Research, Tufts CSDC
Chaiman, OSCRIP
Tufts University
Tomasz Sabilinski, MD
Founder and CEO
Transparency Life Sciences
Andy Lee, MA
Senior Vice President
Global Clinical Operations
Genzyme Corporation
Bernard Munos, MBA
Founder, InnoThink
Dalvir Gill, PhD
CEO, TransCelerate Biopharma, Inc.

#288 Where Research, Medicine, and Care Converge: A CMO Roundtable Discussion
TUESDAY | 4:00-5:30 PM
Michael Rosenblatt, MD
Executive Vice President &
Chief Medical Officer
Merck & Co., Inc.
Tim Garnett, MD
Chief Medical Director & Senior
Vice President
Eli Lilly and Company
Valentin Fuster, MD, PhD
Physician-in-Chief
Mount Sinai Medical Center
Edmund Pezalla, MD, MPH
National Medical Director
Pharmacy Policy and Strategy
Astra
Richard L. Schilsky, MD
Chief Medical Officer
American Society of Clinical
Oncology

#325 Collaborating to Streamline Drug Development: Are We Making Progress?
WEDNESDAY | 8:00-9:30 AM
Douglas J. Peddicord, PhD
Executive Director
Association of Clinical Research
Organizations
Dalvir Gill, PhD
CEO
TransCelerate Biopharma, Inc.
Patrick Archdeacon
Medical Officer
Office of Medical Policy, CDER
FDA
Christine K. Pehrle, RN
President
Society for Clinical Research Sites
Pamela Tenaerts, MD, MBA
Executive Director, Clinical
Trials Transformation Initiative
(CTTI), Duke Translational
Medicine Institute
#235 Big Data: Impact on Innovation  
Tuesday, June 25 | 10:15-11:45 AM  
A short keynote address will set the groundwork and will be followed by a panel discussion that will examine pharma, safety, and patient perspectives on big data methodology and the need for real-world examples.

Susan Dentzer, MA  
Former Editor-in-Chief  
Health Affairs  
Senior Policy Advisor  
Robert Wood Johnson Foundation

Michael Rosenblatt, MD  
Executive Vice President & Chief Medical Officer  
Merck & Co., Inc.

David W. Bates, MD, MSc  
Senior Vice President for Quality and Safety and Chief Quality Officer  
Brigham and Women’s Hospital

Marc M. Boutin, JD  
Executive Vice President & Chief Operating Officer  
National Health Council

Rachael Fleurence, PhD  
Acting Director, PCORI Methods  
Patient Centered Outcomes Research Institute (PCORI)

ALZHEIMER’S HOT TOPIC SERIES

#336 Advancing Alzheimer’s Innovation: A Call to Action  
Wednesday, June 26 | 10:15-11:45 AM  
Get a visionary perspective on how industry and health authorities are working to help move towards a cure for Alzheimer’s disease. This forum will provide a comprehensive picture of the global impact of this disease and the progress towards earlier detection and meaningful therapeutic intervention.

Meryl Comer  
President  
George and Sharyn Beane Foundation  
Alzheimer’s Initiative

George Vradenburg  
Co-Founder/President  
USAgainst/Alzheimer’s

Peter Neumann, DrSc  
Professor of Medicine  
Director, Center for Evaluation of Value and Risk in Health  
Tufts Medical Center

Reisa A. Sperling, MD  
Director, Professor, Neurology  
Harvard Medical School  
Massachusetts Alzheimer’s Disease Research Center

Rudolph E. Tanzi, PhD  
Head of Genetics and Aging Research Unit  
Professor, Neurology  
Harvard Medical School  
Massachusetts General Hospital

Nicholas A. Kozauer, MD  
Medical Officer  
Office of New Drugs  
CDER, FDA

ADDITIONAL SESSIONS FEATURING ALZHEIMER’S:

#109 Evaluation and Selection of the Optimal Endpoints for Clinical Studies  
Featured presentation: Outcome Measures for Clinical Trials in the Early Stages of Alzheimer’s Disease

#220 Biomarkers for Drug Development: How Are We Dealing with the Challenges?  
Featured presentation: From Animal to Man: Challenges of Biomarkers in Alzheimer’s Research

#330 Innovative Strategies for Evolving Sponsor, CRO and Site Alliances  
Featured presentation: Mobilizing Government, NGOs, and Industry to Prevent Alzheimer’s Disease by 2025

#348 Advancing Alzheimer’s Innovation: Patient Advocacy, Caregiver Support and Health Care System Impact

#372 Advancing Alzheimer’s Innovation: Clinical Development Successes and Challenges
GLOBAL REGULATORY PRESENCE

The Global Regulatory Track is keystone of the DIA 2013 49th Annual Meeting, giving you the rare opportunity to interact with global regulators to share knowledge and discuss key issues in the industry. Attend one of the 13 program offerings listed below and join high-profile officials from a variety of global and regional regulatory agencies to discuss the latest initiatives and challenges faced in the review of drugs, diagnostics/devices, biologics, and more.

MONDAY, JUNE 24

#112 Regulatory Environment in the US: CDRH Panel Discusses What’s on the Horizon
#121 CBER Town Hall
#122 European Town Hall: Implementation of New Safety Legislation and Other Hot Topics
#135 Cooperation Among Regulators: Impact on Stakeholders

TUESDAY, JUNE 25

#223 Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall
#261 Convergence in Regulatory Science Across the Strait
#286 Korea Forum: Introduction to the Korean Ministry of Food and Drug Safety (MFDS) and Government R&D Program

WEDNESDAY, JUNE 26

#323 FDA-Health Canada Regulatory Cooperation Council (RCC) Town Hall
#361 Canadian Approaches to Regulatory Modernization and International Engagement
#386 Challenges for Stable Supply of Drugs and International Cooperation
#387 Latin America Town Hall

THURSDAY, JUNE 27

#417 CDER Town Hall: Part 1 of 2
#431 CDER Town Hall: Part 2 of 2

GOVERNMENTAL AGENCIES as of May 1, 2013

- Agencia Nacional de Medicamentos (ANAMED), Chile
- Agency for Healthcare Research and Quality (AHRQ), US
- Austrian Medicinal and Medical Device Agency (AGES), Austria
- Center for Drug Evaluation (CDE), Taiwan
- Center for Drug Evaluation of CFDA, China
- Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS), Mexico
- European Medicines Agency (EMA), European Union
- Food and Drug Administration (FDA), US
- Health Canada
- Health Sciences Authority, Singapore
- Korean Ministry of Food and Drug Safety (MFDS), Republic of Korea
- Medicines Evaluation Board (MEB), Netherlands
- Ministry of Health, Labour and Welfare (MHLW), Japan
- National Authority of Medicines and Health Products (INFARMED), Portugal
- National Center for Advancing Translational Sciences (NCATS), US
- National Heart, Lung, and Blood Institute (NHLBI), US
- National Institute for Health and Care Excellence (NICE), UK
- National Institutes of Health (NIH), US
- Pharmaceuticals and Medical Devices Agency (PMDA), Japan
- US Attorney’s Office, District of Massachusetts
- US Department of Commerce
**PATIENT FELLOWSHIP PROGRAM**

**ROLE OF PATIENTS IN DRUG DEVELOPMENT**

DIA understands that patients play a key role in the drug development process. Clinical trials help to pinpoint the areas where life sciences professionals need to learn more about scientific and patient innovation. DIA provides the perfect forum for patients to not only network and learn from experts from around the world, but also to participate in the process of bringing safe and effective therapies to market.

Twenty patient representatives, chosen through a competitive process, will have opportunities to develop, strengthen, and support collaborations with policymakers, industry, academia, and health professionals by taking part in all facets of DIA 2013 49th Annual Meeting. The Annual Meeting provides a forum for sharing best practices, stimulating cooperation, and facilitating a two-way dialogue across the entire global health care community.

Visit booth #122 to meet the Patient Fellows and join the conversation about the patient perspective.

**CLASS OF 2013 PATIENT FELLOWSHIP ORGANIZATIONS**
SOLUTION PROVIDER PRESENTATIONS

COMPANY WHITE PAPER SHOWCASE
Learn from the experts in this track called the White Paper Showcase. Selected companies will lead their own Showcase where they will highlight their company expertise and solutions in this year’s program.

MONDAY, JUNE 24
#124 Next Generation Medical Information Call Center
EMC²

TUESDAY, JUNE 25
#224B Moving to a Standards-based, Agile Clinical Development Lifecycle
SOA software

#240B Circulating Tumor Cells (CTCs) as a Biomarker Approach in Oncology
LabCorp CLINICAL TRIALS

#264 Learning to Share—Sharing to Learn: How an Industry Learns to Honor Its Volunteers
S.SAS

#289 Four Ways to Accelerate Clinical Portfolio Strategy
THOMSON REUTERS

INNOVATION THEATER PRESENTATIONS
Location: Exhibit Hall
Take advantage of presentations in the Innovation Theater.

MONDAY, JUNE 24 | 1:00-1:45 PM
Crossing the Threshold — Clinical Portals from a Site Perspective
Developed by:
INTRANET

TUESDAY, JUNE 25 | 12:15-1:00 PM
How Can Technology Change the Way Pharmas Handle Risk? Innovations in Drug Safety and Business Development
Developed by:
CAMBRIDGE SEMANTICS

WEDNESDAY, JUNE 26 | 12:15-1:00 PM
Picture This: Bringing Clinical Data to Life
Developed by:
S.SAS

Additional innovation theater presentations will be announced in the Show Daily and via the DIA Annual Meeting Mobile App.
NETWORKING OPPORTUNITIES

JOIN A DIA COMMUNITY!
Meet colleagues who share your professional interests, experience, and knowledge
- Network with specialists you wouldn’t normally meet
- Stay on the pulse of hot topics and shared learning
- Broad choice of DIA Communities

DIA SCIENTIFIC WORKING GROUPS
Learn about DIA’s newest professional group. Scientific Working Group members have a mutual interest in solving specific problems.
- Bring your expertise to special projects that advance the science of medical product development
- Share knowledge in a neutral, non-competitive environment
Visit the Volunteer Lounge/Get Involved Booth, located in the registration area in the North Lobby, to learn about active projects and how you can join.

VOLUNTEER LOUNGE/GET INVOLVED BOOTH
Stop by the Volunteer Lounge/Get Involved Booth located in the registration area in the North Lobby.
- Learn more about DIA Volunteer Opportunities
- See a demonstration of the DIA Connex tool for global DIA Communities communications

Join a DIA Community Today!

DIA COMMUNITY NETWORKING AREA
Take advantage of the specially designated area for DIA Communities on the Exhibit floor. This special seating area will allow Community members and those who wish to learn about DIA Global Communities to eat and network with colleagues of the same interest. The seating area is located in the rear of the Exhibit Hall (near lunch voucher exchange) and will be available for DIA Community members throughout the conference during Exhibit Hall hours.

TUESDAY DIA COMMUNITY LUNCH
The Tuesday lunch break in the DIA Community Networking Area will include a welcome from DIA Community Leadership Council Chairs and a Speakers Corner with open mic for Community leaders to share best practices and recent developments. This is the best time for new members and members interested in learning about DIA Communities to play Community Bingo and get Community Leaders to sign your Bingo card!

SPEED NETWORKING
The Community Networking Area will host a Speed Networking session that will be open to all Attendees and Exhibitors during the Wednesday lunch break from 11:30-1:45 pm. Speed Networking is fast-paced, so don’t miss this opportunity to get to know at least six new professionals in thirty minutes, build your professional network, and have fun!

TRACK 19 DIA COMMUNITIES SHOWCASE
This year’s DIA Communities Showcase Track will feature content-based offerings developed by our DIA Communities. Each Community Showcase will discuss discipline-specific topics with a global community and share common experiences and knowledge with others in a particular field. Join us in one of the 13 Communities Showcases and begin networking with professionals who share the same responsibilities, disciplines and interests.

This year’s Communities Showcase sessions are:
- Session #123 How Can Translational Medicine Fill the Gaps in Life Sciences Industries?
- Session #145 Defining Clinical Trial Innovation: Challenges and Opportunities for 2013
- Session #224A Using Risk-based Signal Detection Methods to Identify Sites with Potential GCP Problems: Better Than a Crystal Ball
- Session #230A Achieving Innovative Technology Results
- Session #262 First-in-Human Studies: How Much Complexity Is Too Much?
- Session #267 The Evolving Clinical Trial Disclosure Global Landscape
- Session #324 Bringing SPIRIT into Protocols, Structuring Content and Expanding This Work to Noninterventional Postmarketing Protocols
- Session #340 Successful Mentoring Relationships
- Session #362 Clinical Outcome Assessment for Clinical Trials: PROs, CTRs, and Observations
- Session #366 Pharmaceutical Project Management: What’s Really Important and How Can We Do Better?
- Session #368 Herbal-induced Organ Toxicity (HIO): How That May Impact Rx Benefit-Risk
- Session #368 Current Regulatory Landscape Impacting Medical and Scientific Communications
- Session #427 Protocol Deviations: Avoidable Problems or an Unavoidable Risk
FIRST-TIMER ORIENTATION
First time at the DIA Annual Meeting? This year’s program includes two opportunities to learn how to optimize your experience at this year’s event. Bring your business cards to network with fellow Annual Meeting first-timers and learn how to make the most of your experience at the DIA 2013 49th Annual Meeting. Location Room 205.
Monday, June 24 | 7:30–8:15 AM
• (Includes Speed Networking)
Monday, June 24 | 10:15–11:00 AM

REFRESHMENT BREAKS
New This Year! Extended Hours for Lunch and Refreshment Breaks in the Exhibit Hall
Meet with your colleagues to plan your day and discuss what you learned the day before, all while networking with other attendees each morning. Mid-morning and mid-afternoon breaks will also be held in designated areas of the Exhibit Hall.
Extended Refreshment Breaks
• Monday, June 24, 10:00–11:00 AM
• Tuesday, June 25, 9:30–10:15 AM
• Tuesday, June 25, 3:15–4:00 PM
• Wednesday, June 26, 9:30–10:15 AM
• Wednesday, June 26, 3:15–4:00 PM
See schedule At-A-Glance on page 3 for all break times.

LUNCH HOURS IN EXHIBIT HALL
Enjoy extended lunch hours to visit more than 450 exhibiting companies in the Exhibit Hall.
• Monday, 12:30–2:30 PM
• Tuesday–Wednesday, 11:45 AM–1:45 PM

DIA WELCOME RECEPTION
Monday, June 24, 4:00–5:30 PM
We invite you to network with over 7,000 attendees at the DIA Welcome Reception in the Exhibit Hall. See old friends and make new acquaintances, while visiting more than 450 exhibiting companies. While you browse, be sure to use the complimentary beverage coupon which is included in the badge envelope for all non-exhibiting participants.

Reception hosted by DIA with support from Tata Consultancy Services

“The DIA Annual Meeting is an extremely worthwhile opportunity for students to share research and ideas with professionals and students from across the world.”
—DIA 2012 Annual Meeting Student Attendee

STUDENTS
Student attendees are encouraged to attend the DIA 2013 Student Forum: Getting a Job and Developing a Career. This is a great opportunity to network with other students that are attending this year’s DIA Annual Meeting. This forum will be held on Tuesday at 10:15 AM, see session #239 for more information.

Student Networking Area
A dedicated area is located in the rear of the Exhibit Hall (near the lunch voucher exchange) for students to network with meeting attendees and one another, plan their day, meet for lunch, and discuss what they learned the day before.

STUDENT POSTER SESSION
Join us in the Exhibit Hall as we showcase posters by students from around the world. An awards ceremony will be held at 4:30 PM to award the first-, second-, and third-place student poster winners.
Monday, June 24, 10:00 AM–5:30 PM
See page 109 for this year’s student poster presenters.

PROFESSIONAL POSTER SESSION
A selected group of professional poster presenters will share their research results in various topics. There will be two dedicated times with different posters available for view.
Posters will be displayed in the Exhibit Hall.
See page 109 for a listing of this year’s professional poster presenters:
• Session #1: Tuesday, June 25, 11:45 AM–4:00 PM
• Session #2: Wednesday, June 26, 11:45 AM–4:00 PM
PROGRAM COMMITTEE

J. Lynn Bass, PharmD, RPh
Jazz Pharmaceuticals

Nancie CeliMo, DrPH, MPH
CAB Inc.

Michael Follendt, MS
FDA

Nirdosh Jagota, PhD
Genentech, A Member of the Roche Group

Annetta Beauregard, MBA, MS
EMD Serono, Inc.

Anne Cropp, PharmD
Pfizer Inc

Stacey Fung, PharmD
Genentech, A Member of the Roche Group

Janet Jenkins-Showalter
Genentech, A Member of the Roche Group

Larry Blankstein, PhD
Genzyme Corporation
A Sanofi Company

Nancy Dreyer, PhD, MPH FISPE
Quintiles Outcome

Jonathan Haddad, MPH, MT
Shire, A GSK Company

Sheila Lapping
Takeda Global Research & Development Center Inc.

Linda Bowen, MS, RAC
Sanofi

Charles Drucker, MBA
Life Science Marketing

Alan Hochberg
F. Hoffmann-La Roche Ltd.
Switzerland

Jeffrey Litwin, MD
ERT

Joan Buenconsejo, PhD, MPH
FDA

Lauren Edelstein Henry, MEd
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<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gesine Bejeuhr, PhD</td>
<td>vfa Research-Based Pharmaceutical Companies, Germany</td>
</tr>
<tr>
<td>Steve Caffé, MD</td>
<td>MedImmune, the Global Biologics Unit of AstraZeneca</td>
</tr>
<tr>
<td>Nancy Drayer, MPH, PhD, FISPE</td>
<td>Quintiles Outcome</td>
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<tr>
<td>Sergio Guerrero, MD</td>
<td>Accelerum Clinical Research, Mexico</td>
</tr>
<tr>
<td>Truus Janse-de Hoog, PharmD</td>
<td>Medicines Evaluation Board, The Netherlands</td>
</tr>
<tr>
<td>Tatsuo Kurokawa, PhD</td>
<td>Keio University, Japan</td>
</tr>
<tr>
<td>Sandra L. Kweder, MD</td>
<td>FDA</td>
</tr>
</tbody>
</table>

## Michele Livesey, MBA  
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eCliniqua

Health Affairs

CLINICAL TRIALS

Life Science Leader

MM&M

Pharmaceutical Outsourcing™

“The Pink Sheet”

Drug Development & Outsourcing Guide

epc

IPi

International Pharmaceutical Quality

JOURNAL FOR CLINICAL STUDIES

JOURNAL FOR PATIENT COMPLIANCE

MassBio

Massachusetts Life Sciences Center

Pharmaceutical Commerce

Pharmaceutical Executive

PharmaTimes

PharmaVOICE

SmartBrief

touch BRIEFINGS
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NAVIGATE DIA 2013 49TH ANNUAL MEETING FROM YOUR MOBILE DEVICE!

The DIA Annual Meeting app is designed to enhance attendees experience and provide valuable information in one place! Download the FREE app to access a wide range of information, as well as the ability to:

- Manage your Agenda
- Stay in the Know with Event Alerts and Announcements
- Connect and Network with Attendees
- View Exhibiting Companies with their Booth #s
- Plus More...

To download, search for ‘DIA Annual Meeting’ in your device’s app store.

Not able to Access an Apple or Android Product?
Access the Mobile Web version at www.diahome.org/DIA2013mobile.
GETTING AROUND THE CONVENTION CENTER

SIX TIPS TO NAVIGATING THE BCEC

1. Use the two skybridges on Level One to move quickly between the BCEC's east and west sides.
2. The skybridges also offer a bird's eye view of the exhibit floor. Save time by planning your booth visits from above!
3. Meeting rooms are numbered by floor—Level One rooms begin with "1," and Level Two rooms begin with "2."
4. An express elevator to the Grand Ballroom is located in the North Lobby on Level One.
5. Public Safety Stations are located at the Exhibit Level entrance and North Lobby entrance.
6. Guest Service Ambassadors (wearing the red coats) are stationed at each entrance to help you with directions.

Reference your Annual Meeting Pocket Guide for a detailed map.
BY PUBLIC TRANSIT

Massachusetts Bay Transportation Authority (MBTA), better known as “The T,” 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. For more information about the MBTA, please visit www.mbta.com.

BY TAXI

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 International 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 International Airport to the BCEC is $25 and $35 to downtown hotels.

There are seven cab associations in Boston:

- 617TaxiCab Inc — 1+617.829.4222
- Boston Cab Association — 1+617.536.3200
- City Cab Association — 1+617.536.5100
- ITCA Cab Association — 1+617.338.8294
- Metro Cab Association — 1+617.782.3500
- Top Cab — 1+617.266.4800
- Tunnel Taxi — 1+617.567.2700

DIA COURTESY SHUTTLE

The DIA Shuttle arrives and departs from the Northeast Lobby (near room 154) of the BCEC. You must be registered at a DIA room block hotel in order to utilize the DIA Shuttle. A shuttle pass, provided at hotel check-in, must be attached to your name badge as verification that you are staying in a designated DIA hotel. If a shuttle pass was not provided at your hotel check-in, you can stop at the Housing Desk, located in the registration area (North Lobby), and one will be provided to you, after verifying your registration at one of the hotels noted below.

Use of the shuttle pass will be strictly enforced.

The following hotels will be provided with a DIA courtesy shuttle to and from the convention center in the morning and at the conclusion of each day’s events:

- Boston Marriott Copley Place — 110 Huntington Avenue
- Boston Park Plaza — 50 Park Plaza at Arlington Street
- Colonnade Hotel — 120 Huntington Avenue
- Courtyard Boston Downtown — 275 Tremont Street
- DoubleTree Downtown — 821 Washington Street
- Hilton Boston Back Bay — 40 Dalton Street
- Hyatt Regency Boston — One Avenue de Lafayette
- Intercontinental Boston — 510 Atlantic Avenue
- Omni Parker House Hotel — 60 School Street
- Revere Hotel — 200 Stuart Street
- Sheraton Boston — 39 Dalton Street
- Westin Copley Place — 10 Huntington Avenue

The Renaissance Waterfront, Seaport Hotel, and Westin Boston Waterfront are within walking distance of the Boston Convention and Exhibition Center.

AIRPORT SHUTTLE SERVICE

Luggage-friendly service, via Silver Line vehicles to Logan Airport from the BCEC, will be available on Wednesday, June 26 and Thursday, June 27. The cost is $2.50 when boarding, or you can purchase a CharlieCard at the MCCA Transportation Booth, located in the registration area (North Lobby) for $2.00.

The schedule for this service is as follows:

- Wednesday, June 26, 11:30 AM–6:00 PM
- Thursday, June 27, 10:30 AM–1:00 PM
- Location: Southwest Lobby, Level 1 (near room 106)
- Frequency: Every 30 minutes

Boston photography courtesy of
Greater Boston Convention & Visitors Bureau
**ACCESSING PRESENTATIONS**

During the meeting, available PDF versions of the presentations are accessible via DIA’s Live Learning Center to full conference and one-day participants*. Please note that this does not include all of the presentations, but only those that were provided to DIA prior to the start of the Annual Meeting.

Post meeting recordings will be available to full conference and one-day participants* by July 9, 2013. Many recordings will be available within 48 hours of the session. Applicable registrants will be notified by email when all of the recordings are posted and available for viewing. Access to DIA’s Live Learning Center is FREE until September 6, 2013. After this date, access to the Live Learning Center will be available for purchase. Annual Meeting participants can purchase premium access to the recordings for $549 at the meeting by visiting the onsite registration desk. Premium access will allow users to access the presentation recordings until July 9, 2014. Please note that due to their interactivity format, workshops will not be recorded.

*One-day participants will have access to presentation recordings for the day that they attended the meeting.

**BAGGAGE CHECK**

There will be an area of the NE Lobby (near Room 154) reserved for attendees to check their belongings if necessary. The Baggage Check Area will be available at the times listed below:

- **Monday, June 24**
  - 7:00 AM–6:00 PM
- **Tuesday, June 25**
  - 7:00 AM–7:00 PM
- **Wednesday, June 26**
  - 7:00 AM–7:00 PM
- **Thursday, June 27**
  - 8:00 AM–1:00 PM

Note: There will be a $3.00 fee for each bag checked. All items checked must be collected by the close of the Baggage Check Area each day. DIA is not responsible for items left in the Baggage Check Area.

**BUSINESS CENTER**

FedEx is the official business center for the BCEC, providing full service business needs. Their phone number is +1.617.954.2203 and fax number is +1.617.954.2204. The FedEx office retail storefront is located in the NW Corner Prefunction area of the BCEC. Their hours will be as follows:

- **Saturday, June 22**
  - 9:00 AM–5:00 PM
- **Sunday, June 23**
  - 8:00 AM–6:00 PM
- **Monday, June 24**
  - 7:00 AM–6:00 PM
- **Tuesday, June 25**
  - 7:00 AM–6:00 PM
- **Wednesday, June 26**
  - 7:00 AM–7:00 PM
- **Thursday, June 27**
  - 9:00 AM–5:00 PM

**CAREER CENTER**

DIA’s interactive Career Center, located in the corridors near Rooms 101 and 150, is your premier resource for online employment connections! Looking for the perfect fit? The DIA Career Center offers employers targeted access to quality industry professionals, quick and easy job posting, online job activity reports, and access to the National Healthcare Career Network of over 60 top healthcare associations and professional organizations.

Job seekers receive FREE and confidential resume posting, automated weekly email notification of new job listings, and the ability to save jobs for later review.

To find a job or fill a position, visit [www.diahome.org/DIACareerCenter](http://www.diahome.org/DIACareerCenter).

**CYBER CAFÉ, WIFI, AND RECHARGE STATION**

Free wireless internet access will be available to attendees throughout the Boston Convention and Exhibition Center (BCEC). For your convenience, seating has been made available in the meeting corridors as allowed by the BCEC. Simply connect to **DIA 49th Annual**, then launch a browser and you will be authenticated on the wireless system. If you need assistance, please go to the Network Service Desk, located in Exhibitor Services area of the Exhibit Hall. DIA is also providing workstations in the corridors near Rooms 101 and 150 for those who do not have laptop computers, or other devices. Electric recharge stations are also available adjacent to the workstation areas.

**DRESS CODE**

Dress code is business casual. Neckties, business suits, or other business attire are acceptable, but not necessary. The Convention Center may be chilly so bring a sweater or jacket; comfortable shoes are a must!

**EXHIBITOR LOCATOR**

Search for an exhibiting company by company name, keyword, or service. The Exhibitor Locator workstation will be in the registration area (North Lobby).

**FIRST AID CENTER**

First Aid is available for routine health problems and emergency care. The First Aid Center is located in the east side of the North Lobby. In case of emergency dial **2222** from any house phone or **617-954-2222** from your cell phone and provide the location of your emergency.

The convention center will dispatch medical personnel at once. Please do not dial 911. We also urge you to complete the emergency contact information card, included in your badge envelope, and keep it in your badge holder at all times.

**INFORMATION BOOTH**

A DIA Information Booth will be located in the registration area (North Lobby). Should you have any questions throughout the event, please visit the booth for assistance. The Information Booth can also be reached by phone at 617-954-3400, during event hours.

**LUNCH VOUCHER PROGRAM**

In order to provide you with a variety of food options and freedom of choice, a voucher program is being used for DIA’s luncheon service. Your vouchers are included in your badge envelope. Please keep your vouchers in a safe place, as replacement vouchers will not be issued. The voucher is redeemable for up to $15 (inclusive of tax) for food and beverage items, and must be provided at checkout.

Lunch vouchers are not redeemable for cash, and change will not be provided if your purchase is under $15.00. Only one voucher can be used per transaction and they are not transferable. Therefore, each participant will need to pick up his or her own lunch. Vouchers can be used in the Exhibit Hall only, and are valid between the hours of 12:30 PM and 2:30 PM on Monday, and 11:45 AM and 1:45 PM on Tuesday and Wednesday.

In order to expedite your lunch service each day, please reference the lunch voucher flyer included in your registration bag.

**LOST & FOUND**

Misplaced items will be stored at the DIA Information Booth, located in the registration area (North Lobby), until the end of the event. Items remaining at the close of the DIA 49th Annual Meeting will be turned over to the Boston Convention & Exhibition Center (BCEC) Security. At that point, you can contact the BCEC at 617-954-2222 or [http://www.massconversion.com/publicsafety/](http://www.massconversion.com/publicsafety/).

**FIRST DAY**

- **Sunday, June 23**
  - 6:00 PM – 7:30 PM
- **Monday, June 24**
  - 7:00 AM – 4:30 PM
  - **Welcome Reception**
    - 5:00 PM – 7:00 PM
- **Tuesday, June 25**
  - 7:00 AM – 7:00 PM
- **Wednesday, June 26**
  - 7:00 AM – 7:00 PM
- **Thursday, June 27**
  - 7:00 AM – 12:45 PM

**SECOND DAY**

- **Monday, June 24**
  - 12:00 PM – 1:00 PM
  - **Lunch**
  - 1:00 PM – 2:00 PM
  - **Coffee Break**
  - 2:00 PM – 2:15 PM

**THIRD DAY**

- **Tuesday, June 25**
  - 12:00 PM – 1:00 PM
  - **Lunch**
  - 1:00 PM – 2:00 PM
  - **Coffee Break**
  - 2:00 PM – 2:15 PM

**FOURTH DAY**

- **Wednesday, June 26**
  - 12:00 PM – 1:00 PM
  - **Lunch**
  - 1:00 PM – 2:00 PM
  - **Coffee Break**
  - 2:00 PM – 2:15 PM

**FIFTH DAY**

- **Thursday, June 27**
  - 12:00 PM – 2:00 PM
  - **Lunch**
  - 12:00 PM – 1:00 PM
  - **Coffee Break**
  - 1:00 PM – 1:15 PM

**SIXTH DAY**

- **Friday, June 28**
  - 9:00 AM – 4:30 PM
  - **Coffee Break**
  - 11:45 AM – 12:00 PM
  - **Lunch**
  - 12:00 PM – 1:00 PM
  - **Coffee Break**
  - 1:00 PM – 1:15 PM

**SUNDAY**

- 6:30 PM – 8:30 PM
  - **Welcome Reception**

**MONDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**TUESDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**WEDNESDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**THURSDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**FRIDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**SATURDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**SUNDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**MONDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**TUESDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**WEDNESDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**THURSDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**FRIDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**

**SATURDAY**

- 7:30 AM – 9:00 AM
  - **Breakfast Buffet**
MISPLACED YOUR BADGE?

Participants will incur a $25 fee for badge reprints. If you require a badge reprint, please visit the Cashier at Attendee Onsite Registration, located in the North Lobby. Identification will be required.

POSTER SESSIONS

The student and professional poster sessions, located in the Exhibit Hall, provide an excellent opportunity for presenters to share their research results with attendees.

The posters present scientific developments related to the topics addressed in Annual Meeting Tracks:

<table>
<thead>
<tr>
<th>Poster Session</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student Poster Session</td>
<td>Monday, June 24</td>
<td>10:00 AM–5:30 PM</td>
</tr>
<tr>
<td>Professional Poster Session #1</td>
<td>Tuesday, June 25</td>
<td>11:45 AM–4:00 PM</td>
</tr>
<tr>
<td>Professional Poster Session #2</td>
<td>Wednesday, June 26</td>
<td>11:45 AM–4:00 PM</td>
</tr>
</tbody>
</table>

PRIVATE SOCIAL FUNCTIONS POLICY

DIA does not allow any hospitality functions to be held during any Annual Meeting offerings, scheduled Exhibit Hours, or social events. Therefore the hours noted below are the only hours acceptable for hospitality functions:

<table>
<thead>
<tr>
<th>Day</th>
<th>Times Accessible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturday, June 22</td>
<td>All times</td>
</tr>
<tr>
<td>Sunday, June 23</td>
<td>All times</td>
</tr>
<tr>
<td>Monday, June 24</td>
<td>Before 8:30 AM and after 6:00 PM</td>
</tr>
<tr>
<td>Tuesday, June 25</td>
<td>Before 8:00 AM and after 6:00 PM</td>
</tr>
<tr>
<td>Wednesday, June 26</td>
<td>Before 8:00 AM and after 6:00 PM</td>
</tr>
<tr>
<td>Thursday, June 27</td>
<td>Before 9:00 AM and after 12:30 PM</td>
</tr>
</tbody>
</table>

SELECTION OF OFFERINGS

Please note that seating for educational offerings is on a first-come, first-served basis. Attendees should be prepared with an alternate selection in the event that a room is filled to capacity. Selected presentation recordings will be available to full conference and one-day participants by July 9, 2013. Many recordings will be available within 48 hours of the session. See page 22 for the meeting schedule by day and time for more information.

RESTAURANT AND CITY INFORMATION CONCIERGE

The city of Boston is such a food lover’s paradise that you will face just one dilemma: how to choose from so many options? The Greater Boston Convention and Visitors Bureau wants to help you make the most of your dining experience in Boston. To find Boston’s best dining options, stop by the Restaurant and City Information Concierge located in the registration area (North Lobby).
CONTINUING EDUCATION

The DIA 2013 49th Annual Meeting is the premier event for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related products. In an effort to streamline the program and focus on the hottest topics, this year’s program will offer 20+ preconference tutorials and 22 content-area tracks comprising of over 250 educational offerings, with presentations geared to attendees of all disciplines, work settings, and experience levels.

LEARNING OBJECTIVES

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

TRACK 01: CLINICAL OPERATIONS
- Discuss advancing clinical operation innovation through collaboration and process optimization
- Apply operational execution through effective budget management and patient recruitment across different patient groups
- Identify innovative considerations for protocol optimization and risk-based monitoring

TRACK 02: PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING

PROJECT MANAGEMENT
- Describe product management and project-related finance practices used in the product development industry, and project management practices within regulatory agencies
- Discuss new project management practices and systems used in global product development

PORTFOLIO MANAGEMENT
- Examine product development portfolio management practices, portfolio asset strategy decision-making methods, and associated tools
- Discuss new portfolio asset strategy decision-making, management, and portfolio/product prioritization/optimization practices

STRATEGIC PLANNING
- Identify complexities of clinical trial design and development
- Describe approaches to quality design of clinical trials and to building quality risk management into clinical trials from both sponsor and regulatory agency perspectives
- Discuss project and portfolio management practices for strategic planning

TRACK 03: INNOVATIVE PARTNERING MODELS AND OUTSOURCING STRATEGIES
- Identify innovative partnering models and unique outsourcing strategies that are shaping the way in which pharmaceutical and biotechnology companies work with contract research organizations (CROs) and other service providers, academia, codevelopment partners, and other organizations

TRACK 04: NONCLINICAL AND TRANSLATIONAL DEVELOPMENT/EARLY PHASE CLINICAL DEVELOPMENT
- Discuss recent advances in coping with particularly challenging issues that arise in the early phases of novel pharmaceutical development
- Describe current strategies for designing successful early clinical pharmacology and clinical trials
- Identify information needed to facilitate successful early interactions between regulatory agencies and other stakeholders, such as key opinion leaders and patient advocacy groups
- Explain some of the latest nonclinical technologies and approaches for assessing the safety of pharmaceutical products

TRACK 05: REGULATION OF PRODUCT ADVERTISING AND MARKETING IN AN EVER-CHANGING WORLD
- Discuss the current regulatory landscape related to drug advertising and promotion

TRACK 06: MEDICAL COMMUNICATION, MEDICAL WRITING, AND MEDICAL SCIENCE LIAISON
- Identify opportunities to collaborate and meet the expectations of multiple, global regulatory authorities, patients, payers, and other customers

TRACK 07: PROCESSES AND TECHNOLOGIES FOR CLINICAL RESEARCH
- Discuss best practices for technologies and processes in clinical research
- Describe novel uses of existing/emerging technologies and processes
- Identify how technical and procedural innovations transform the clinical trial’s life cycle

TRACK 08: REGULATORY AFFAIRS AND SUBMISSIONS
- Discuss the latest global regulatory trends and developments that impact the industry

TRACK 09: MEDICAL DEVICES, IN VITRO DIAGNOSTICS, AND COMBINATION PRODUCTS
- Discuss updates on changing regulatory practices

TRACK 10: PUBLIC POLICY/HEALTH CARE COMPLIANCE/LAW
- Discuss implications of and recommendations raised in current topics in health care compliance, public policy, and regulatory law

TRACK 11: INNOVATIVE APPROACHES TO ENSURING COMPLIANCE WITH GOOD CLINICAL PRACTICE (GCP) AND QUALITY ASSURANCE (QA)
- Describe innovative approaches being used to manage GCP compliance and ensure quality in the development of new therapeutics in a changing international regulatory landscape

TRACK 12: PHARMACEUTICAL QUALITY
- Explain how to apply fundamental and advanced scientific and regulatory approaches to current and emerging pharmaceutical quality issues, including a strong emphasis on global harmonization efforts within and outside the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

TRACK 13: HEALTH ECONOMICS AND OUTCOMES (HEO)/COMPARATIVE EFFECTIVENESS RESEARCH (CER)/HEALTH TECHNOLOGY ASSESSMENT (HTA)
- Describe current issues in measuring and communicating the medical need, health impact, and economic value associated with medical products

TRACK 14: CLINICAL SAFETY AND PHARMACOVIGILANCE
- Discuss a broad array of concepts and tools (traditional and new) that support participants’ pursuit of excellence in patient safety, for both investigational and marketed health care products

TRACK 15: STATISTICAL SCIENCE AND QUANTITATIVE THINKING
- Identify innovative statistical solutions to issues associated with the evidence and regulatory review of drugs, diagnostics/devices, and biologics
- Describe relevant application of statistical science and quantitative thinking to the development of new therapeutic biologics, drugs, and diagnostics/devices

TRACK 16: PROFESSIONAL DEVELOPMENT
- Discuss ways to foster advancing therapeutic innovation and regulatory science through professional development and educational efforts

TRACK 17: RARE/ORPHAN DISEASES
- Discuss the unique challenges in translating/developing novel treatments for rare/neglected diseases, particularly the importance of knowledge of natural disease progression and patient registries
- Recognize the potential contributions of patients and patient advocacy organizations to effective and efficient novel therapy development

TRACK 18: GLOBAL REGULATORY
- Discuss key initiatives, changes, and challenges of various global regulatory agencies with the review of drugs, diagnostics/devices, and biologics

TRACK 19: COMMUNITIES SHOWCASE
- Discuss discipline-specific topics with a global community and share common experiences and knowledge with others in a particular field

TRACK 20: EXECUTIVE PROGRAM
- Describe the landscape for bioinnovation
- Discuss how companies across the pharmaceutical sector are transforming their R&D business models to meet current and future market demands

TRACK 21: LATE BREAKER
- Discuss late breaking, hot topics in the pharmaceutical, biotechnology and/or medical devices industry

Target Audience
This meeting is designed for individuals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical products and related products. The meeting is intended to strengthen professional understanding of the value of cross-discipline integration and to foster innovation for better health outcomes.

Continuing Education
Select program offerings (including sessions, forums, workshops, symposia) will offer AMA PRA Category 1 Credits™, pharmacy or nursing contact hours, or Project Management Institute (PMI) professional development units (PDUs) and will be clearly identified in the program with the statement of CME, Pharmacy, Nursing, and PMI IACET continuing education units (CEUs) are offered for all program offerings.

Continuing education credits are not available for the plenary session on Monday morning, Innovation Theater, or White Paper presentations. Learning objectives for each program offering will be shown as a slide in the meeting rooms.
ACCREDITATION AND CREDIT DESIGNATION STATEMENTS

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

Credit Designation
The Postgraduate Institute for Medicine designates this live activity for a maximum of 1.5 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Accreditation Council for Pharmacy Education (ACPE)
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 18 contact hours or 1.8 continuing education units (CEUs) for participating in the Annual Meeting program offerings. For a complete list of each ACPE UAN and activity type allocated for the pharmacy-certified program offerings, please refer to pages 130–131.

Information for all ACPE Credit Requests
DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.

American Nurses Credentialing Center (ANCC)
This educational activity for 18 contact hours is provided by PIM. PIM is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

California Board of Registered Nursing
PIM is approved by the California Board of Registered Nursing, Provider Number 13485 for 18 contact hours.

Project Management Institute (PMI)
The Drug Information Association has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI). Participants may receive up to 18 professional development units (PDUs) for attending the Annual Meeting program offerings. PMI #: 2166-00015.

The PMI Registered Education Provider logo is a registered mark of the Project Management Institute, Inc.

International Association for Continuing Education and Training (IACET)
Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102, (703) 506-3275.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer up to 2.4 CEUs for this program.

 Continuing Legal Education
For attorneys who would like to receive continuing legal education credits for attending DIA 2013, 49th Annual Meeting, please complete your state’s application for credit and submit accordingly. If you require additional information to complete your application, please contact Karen Tenaglia at karen.tenaglia@diahome.org for assistance.

TO CALCULATE YOUR CREDITS FROM THE ANNUAL MEETING PROGRAM OFFERINGS

MONDAY THROUGH THURSDAY, JUNE 24–27

All program offerings are 1.5 hours in length. The program offerings that are designated for credit, offer up to:

- 1.5 AMA PRA Category 1 Credits™
- 1.5 pharmacy contact hours
- 1.5 CEUs
- 15 nursing contact hours
- 1.5 PMI PDUs
- 2 IACET CEUs

DIA CERTIFICATE PROGRAMS
Individuals enrolled in DIA Certificate Programs may receive elective units for the designated programs noted below:

- Clinical Research Certificate Program: 12 Elective Units
- Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units
- Project Management Certificate Program: 8 Elective Units
- Regulatory Affairs Certificate Program: 12 Elective Units

For more information on DIA’s Certificate Program, visit www.diahome.org/certificateprograms.

STATEMENT OF CREDIT

Participants who would like to receive continuing education credits for the DIA 2013 49th Annual Meeting must scan their DIA name badge at each program offering to record their attendance and complete each program offering evaluation form. Participants may scan their badges within 45 minutes after the start of each program offering. Attendees who do not scan their badges within the allotted time will not be eligible to receive the available continuing education credits for that program offering.

To request a statement of credit, please go to www.diahome.org, select “Login to My DIA” and you will be prompted for your User ID and Password. Select “My Transcript” (left side bar) and “Credit Request” for each program offering. My Transcript will be available for all DIA 2013 49th Annual Meeting participants to request credit on Tuesday, July 2, 2013.

Keep in mind, to receive continuing education credit you must:

- Scan your DIA name badge at each program offering
- Complete an online evaluation form for each program offering you attend
- Request a statement of credit through My Transcript by visiting www.diahome.org if you experience any difficulties, please contact DIA at mytranscript@diahome.org.

DISCLOSURE OF CONFLICTS OF INTEREST

Postgraduate Institute for Medicine (PIM) and DIA assess conflicts of interest with instructors, planners, managers and other individuals who are in a position to control the content of CME activities. All relevant conflicts of interest that are identified are thoroughly vetted by PIM and DIA for fair balance, scientific objectivity of studies utilized in this activity, and patient care recommendations. PIM and DIA are committed to providing learners with high quality CME activities and related materials that promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.

The faculty members, planners and managers financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interests related to the content of this continuing education activity are noted on pages 122–129.

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This educational activity may contain discussion of published and/or investigational uses of agents that are not indicated by the FDA. PIM and DIA do not recommend the use of any agent outside of the labeled indications.

The opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of PIM or DIA. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

EVALUATION

All program offering evaluations are to be completed online through the DIA Live Learning Center at www.diahome.org/DIA2013LLC. All participant scanned data will be uploaded at the end of each day into the DIA Live Learning Center. If a participant attends multiple program offerings within the same time frame, the last scanned entry will be recorded.

To THANK YOU for your feedback, DIA will conduct multiple drawings from attendees who completed all program offering evaluations for each day of the meeting. Each day, a participant who completed all program offering evaluations will be entered in a drawing to receive a free Premium Upgrade access to DIA’s Live Learning Center. The four winners will receive access to the DIA 2013 49th Annual Meeting content hosted on the Live Learning Center until July 9, 2014.

A GRAND PRIZE drawing winner (1) will receive one free registration to the DIA 2014 50th Annual Meeting, held in San Diego, CA. The five (5) drawing winners will be announced and contacted the week of July 29, 2013.

DISCLAIMER

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patient’s conditions and possible contraindications on dangers in use, review of any applicable manufacturer’s product information, and comparison with recommendations of other authorities.

Recording of any DIA educational material in any type of media is prohibited without prior written consent from DIA.
## TRACKS AND INTEREST AREAS

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## CONTENT LEVEL GUIDE

The difficulty level of each offering has been determined by the Chairperson and is indicated by one of the following symbols. This provides a guide for registrants in their selection of program offerings to attend.

- **Basis Level Content:** Appropriate for individuals new to the topic/subject area.
- **Primarily Intermediate Level Content:** Appropriate for individuals who already have a basic understanding of the topic/subject area.
- **Primarily Advanced Level Content:** Appropriate for individuals with a in-depth knowledge of the topic/subject area.

## DIFFERENT FORMAT FOR DIFFERENT LEARNERS

Each program offering will be delivered in one of the four educational formats noted below.

- **FORUM**
  A 90-minute blended presentation and panel discussion. Forums provide ample opportunity for active participation by panelists and attendees.

- **SESSION**
  A 90-minute presentation delivered lecture-style from the podium. Session chairs will facilitate a formal question and answer period.

- **SYMPOSIUM**
  A 90-minute offering consisting of several shorter presentations such as case studies and presentations from multiple perspectives. Chairs will facilitate a formal question and answer period.

- **WORKSHOP**
  A 90-minute conceptual presentation delivered in an interactive/simulation or role playing format. Workshops feature learning in the form of activities or demonstrations. **Due to their interactive format, workshops will not be recorded.**
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*Due to their interactive format, Workshops will not be recorded.*
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**TUESDAY, JUNE 25  8:00–9:30 AM**

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**TUESDAY, JUNE 25**

10:15–11:40 AM, continued


Track 23 | SPECIAL SESSION | LEVEL: ● not applicable | Exhibit Hall | IT, CP, CR, CDM

**TUESDAY, JUNE 25**

12:15–1:00 PM

**TUESDAY, JUNE 25**

1:45–3:15 PM

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<td>#414</td>
<td>Some Innovative Approaches to Handling Missing Data Problems in Clinical Trials</td>
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<td>LEVEL: CM, IACET, RN</td>
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<td>The Not So Rare Challenge that Faces Rare Disease Development: Demonstrate Value</td>
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<td>#418</td>
<td>CRA's Knowledge and Adaptability Required to Monitor Informed Consent Process in an Evolving Regulatory Environment</td>
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<td>#419</td>
<td>Impact and Interventions Related to FDASIA: Increasing Diversity in Clinical Trials</td>
<td>Track 01B</td>
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<td>Insights into China: Practical Tips for Writing Publication and Regulatory Documents</td>
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<td>Implementing a Paperless Trial for Phase 3: A Biotech's Lessons Learned</td>
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<tr>
<td>#424</td>
<td>What's the Point? Can Point of Care Devices Enhance Clinical Trials?</td>
<td>Track 07B</td>
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*Due to their interactive format, Workshops will not be recorded.*
### DIA 2013 49th Annual Meeting Meeting Schedule

**THURSDAY, JUNE 27 10:45 AM-12:10 PM, continued**

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<td>#431</td>
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*Due to their interactive format, Workshops will not be recorded.*

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### DIA 2014 50th Annual Meeting

**June 15-19, 2014 | San Diego, CA**

Share your expertise with 7,000+ life sciences professionals across all disciplines involved in the discovery, development, and life cycle management of medical products.

**General Call for Abstracts**
- Open: August 1
- Closes: September 9

**Student Posters**
- Open: August 1
- Closes: March 3

**Professional Posters**
- Open: August 1
- Closes: February 10

Visit diahome.org/DIA2014 for more details.
OPENING PLENARY SESSION

Welcome Remarks and Award Presentation
Ling Su, PhD
Strategic Advisor, Life Sciences, Sidley Austin LLP, China

Opening Remarks
Sandra A. Milligan, JD, MD
Vice President, Global Regulatory Therapeutic Area Head
Genentech, Inc., A Member of the Roche Group

Keynote Address
Daniel Kraft, MD
Executive Director, FutureMed

10:00-11:00 AM  COFFEE BREAK

NAVIGATE DIA 2013 49TH ANNUAL MEETING FROM YOUR MOBILE DEVICE!

Download the Annual Meeting Mobile App!

To download, search for ‘DIA Annual Meeting’ in your device’s app store.

Not able to Access an Apple or Android Product? Access the Mobile Web version at www.diahome.org/DIA2013mobile.
#100 Track 01A - Clinical Operations

**Related Interest Area(s): Fl, PM, SP**

**11:00 am–12:30 pm**

**LEVEL: □**

**Room 156C**

**Format: WORKSHOP**

**CME and Nursing and PMI PDUs**

**Shape Your Cost with Hard and Soft Coverage Analysis Trends**

**CHAIRPERSON**

Kelly M. Willenberg, BSN, MBA

Consultant, Kelly Willenberg, LLC

This workshop will assist attendees in the analysis of protocol budget development with a focus on future needs. A coverage analysis will be explored as a way to offset both hard and soft trends within a study project. Tools will be shared.

**Facilitators**

Kelly M. Willenberg, BSN, MBA

Consultant, Kelly Willenberg, LLC

Marianne Parnell, BSN, MBA

Manager, Medical Affairs, Sigma Tau Pharmaceuticals Inc

*Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.*

#101 Track 01B - Clinical Operations

**Related Interest Area(s): CR, FI, SP**

**11:00 am–12:30 pm**

**LEVEL: □**

**Room 205C**

**Format: SYMPOSIUM**

**CME and Nursing**

**Trials, Studies and Programs: Diverse Operational Approaches to Generating Evidence in the Late-phase Environment**

**CHAIRPERSON**

Gary Coward, MSc

Global Head, Patient Safety Services, PAREXEL International, United Kingdom

This symposium will provide attendees with a better appreciation of the different type of operational approaches that can be deployed in the late-phase environment and how the evidence generated can be used to support both product development and dialogue with postmarketing stakeholders. It will be an opportunity to understand the importance of addressing physicians' motivation and why a different operational approach is required, often within a cost-constrained environment.

**Generating Momentum in Post-authorization Studies**

Gary Coward, MSc

Global Head, Patient Safety Services, PAREXEL International, United Kingdom

**Use of Expanded Access Program (EAP) Data to Gain New Insights into Drug Efficacy and Safety**

Heather L. Manna

Senior Manager, Regulatory Affairs, Idis Pharma

**Risk-based Approach to Monitoring in Late-phase Clinical Trials**

Bill Row, MBA, MS, MSc

Director, Clinical Operations, REGISTRAT-MAPI

#102 Track 02A - Project/Portfolio Management and Strategic Planning

**Related Interest Area(s): SP, RD, CR**

**11:00 am–12:30 pm**

**LEVEL: □**

**Room 157C**

**Format: WORKSHOP**

**CME and Nursing**

**Stage Gate Decision-making Workshop, Part 1 of 2**

**CHAIRPERSON**

Courtland R. LaVallee, Jr.

Director, Project Management, Theravance, Inc.

This interactive two-part workshop will help attendees who may be primarily involved in tactical activities understand how a company makes strategic decisions for moving a product forward. After a review of a new drug product, attendees will work in teams to discuss their product’s information and make recommendations for whether and how their product should be advanced through the development pipeline.

Part 1 of this workshop will focus on processes and decisions in Phase 2, while Part 2 will focus on Phase 3 and the decision to file.

Pre-registration is required, and attendees are strongly encouraged to attend both Part 1 and Part 2.

Part 2 will take place on Monday, 2:30-4:00 pm (Session #127).

To secure a seat for this specific Workshop, please email annualmeetingprogram@diahome.org, Subject line: Stage Gate Decision-making Workshop.

*Due to workshop format, seating will be limited. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.*

#103 Track 02B - Project/Portfolio Management and Strategic Planning

**Related Interest Area(s): CR, RD, BT**

**11:00 am–12:30 pm**

**LEVEL: □**

**Room 104C**

**Format: SYMPOSIUM**

**PMI PDUs**

**Portfolio Management Symposium**

**CHAIRPERSON**

Gregg Schneider

Director, R&D Financial Management, Otsuka Pharmaceutical Development & Commercialization, Inc.

This symposium will address adopting an adaptive design strategy at a portfolio level in order to provide significant value to the critical decision-making required to deliver an optimized pipeline of products. We will also look at the substantial challenges faced by generic companies in maximizing the value of their portfolio planning and aligning available and projected resources and strategic goals.

**Adopting an Adaptive Design Strategy to Manage Portfolio Risk and Value**

Sarah Arbe-Barnes, PhD

Senior Vice President, Translational Sciences, Aptiv Solutions, United Kingdom

**Portfolio Optimization for a Generic Drug Company**

Vladimir Shnaydman, PhD

President, ORBee Consulting
**#104 Track 03A – Innovative Partnering Models and Outsourcing Strategies**  
Related Interest Area(s): CR, SP  
11:00 AM-12:30 PM  
Level: ■  
Format: FORUM  
Room 104AB  
CME, Nursing and PMI PDUs  
**The State of Clinical Outsourcing: Managing Risk in Outsourced Clinical Trials**  
**Chairperson**  
Denise A. Calaprice-Whitty, PhD, MS  
Executive Director, The Avoca Group Inc.  
Data from 2013 State of Clinical Outsourcing research focused on risk management will be shared. A panel of industry experts will provide their perspective on the data and their predictions of future trends.  
**Panelists**  
Alistair John MacDonald, MS  
Chief Operating Officer, INC Research  
Mitchell A. Katz, PhD  
Executive Director, Medical Research Operations, Purdue Pharma LP  
Andy Lee, MA  
Senior Vice President, Global Clinical Operations, Genzyme Corporation, A Sanofi Company  

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**#105 Track 03B – Innovative Partnering Models and Outsourcing Strategies**  
Related Interest Area(s): IT, CR  
11:00 AM-12:15 PM  
Level: ●  
Format: FORUM  
Room 206AB  
CME and Nursing  
**Innovative Partnerships for mHealth**  
**Chairperson**  
Nancy Carter-Foster, MS  
Senior Advisor, US Department of Commerce  
This forum highlights the opportunities of mHealth in leveling the playing field in global health, and the need to broaden partnerships among all stakeholders to overcome the challenges to its long-term sustainability.  
**Panelists**  
Robert B. McCray  
President and Chief Executive Officer, Wireless-Life Sciences Alliance  
Mathew Taylor  
Senior ICT Strategist and Architect, Intel, Inc.  
Cortney Nicolato  
Vice President for Healthcare Strategies, Get Real Health  
Paula Guy  
Chief Executive Officer, Georgia Partnership for TeleHealth, Inc.  

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**#106 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development**  
Related Interest Area(s): CR, NC, RD  
11:00 AM-12:30 PM  
Level: ■  
Format: SYMPOSIUM  
Room 105  
CME and Nursing  
**Global Symposium**  
Barry Mangum, PharmD  
Director, Clinical Pharmacology, Duke University Medical Center  
This symposium will examine innovations in drug development in China and Latin America as well as the impact of regional cooperation on global development in the Asia Pacific region.  
**Would China Be Ready for First-in-human Study in Global R&D Strategy?**  
Jack Xu, MD, MS  
Senior Vice President, Shanghai Clinical Research Center (SCRC), China  
**Impacts to Global Development from Paradigm Shifts of Regional Cooperation of Translational Researches in the Asia Pacific Region**  
Chih-Hwa Wallace Lin, PhD  
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan  
**Early Development of New Drugs in Latin America**  
Joao Massud, MD  
CEO, Trials Consulting, Brazil  

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**#107 Track 06 – Medical Communication, Medical Writing and Medical Science Liaison**  
Related Interest Area(s): MW, SUBS, RA  
11:00 AM-12:30 PM  
Level: ●  
Format: FORUM  
Room 204AB  
**Finessing Scientifically Accurate, Comprehensible, Compliant, Clinically-focused Module 2 Summaries of an eCTD-based Submission**  
**Chairperson**  
Nancy R. Katz, PhD  
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.  
This forum features three speakers who will provide expert and proven strategies that enable scientifically accurate, on time, on budget eCTD-based submissions.  
**Memorable and Compelling Writing for eCTD Documents**  
Meredith E.S. Brown-Tuttle, RAC  
Regulatory Affairs, Regulatorium  
**The Well-Oiled Team: Playing Your Position from SAS Output Through Quality Assurance Audit to Create Reviewer-ready Regulatory Documents**  
Nancy R. Katz, PhD  
President and Principal Medical Writing Consultant, Illyria Consulting Group, Inc.  
Stephen B. Shrewsbury, MD, FFPM  
Chief Medical Officer, Aquinox Pharmaceuticals Inc., Canada
#108 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): CDM, CR, RA

11:00 am–12:30 pm  LEVEL: ■  FORMAT: FORUM
Room 251  CME and Nursing

Managing Data at Arms’ Length: China
CHAIRPERSON
Ralph Douglas Harkins, Sr., PhD
Senior Statistical Consultant and Project Manager, RDH Statistical Consulting Service

This forum will focus on CFDA-approved sites, data generation and reporting, electronic data capture, and the role of clinical research coordinators, clinical research associates, and other data management professionals in Chinese clinical trials.

CFDA Regulatory Processes
Ivan Yu Zhai, MD, MBA
CEO, GCP CMIC ClinPlus CRO/SMO, Ltd., China

Data Monitoring at Arms’ Length
Ethel Kagan, RN
President, Innovations Clinical Research, LLC

Drug Safety Monitoring at Arms’ Length
Barton L. Cobert, MD, FACP
President, BLCMD Associates, LLC

#109 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): SE, CR, RD

11:00 am–12:30 pm  LEVEL: ■  FORMAT: SESSION
Room 252AB  CME, Pharmacy and Nursing

Evaluation and Selection of the Optimal Endpoints for Clinical Studies
CHAIRPERSON
Freda W. Cooner, PhD
Mathematical Statistician, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

An endpoint for measuring the disease severity and treatment comparison is not always readily definable. We will discuss why it is important to select true patients and properly quantify treatment effects in considering endpoints.

Patient Reported Outcomes as Endpoints for Clinical Studies
Debra G. Silberg, MD, PhD
Senior Director, Clinical Medicine, Shire Specialty Pharmaceuticals

Evaluation and Selection of Endpoints for Ulcerative Colitis
Anil Rajpal, MD, MPH
Medical Team Leader, Division of Gastroenterology and Inborn Errors Products, Office of New Drugs, CDER, FDA

Outcome Measures for Clinical Trials in the Early Stages of Alzheimer’s Disease
Nandini Raghavan, PhD, MSc
Associate Director, Biostatistics & Programming, Global Development Organization, Janssen Research & Development, LLC

#110 Track 08A – Regulatory Affairs and Submissions

Related Interest Area(s): RA, CR

11:00 am–12:30 pm  LEVEL: ■  FORMAT: SESSION
Room 253A  CME, Pharmacy and Nursing

Pediatric Drug Development: A New Paradigm Under FDASIA
CHAIRPERSON
Rosemary M. Addy
Supervisory Consumer Safety Officer, Office of New Drugs, CDER, FDA

With the passage of the Food and Drug Administration Safety and Information Act (FDASIA), pediatric drug development has taken another step forward. This session will review the impact of this new paradigm on pediatric drug development.

Using FDASIA to Move Forward with Pediatric Drug Development
Rosemary M. Addy
Supervisory Consumer Safety Officer, Office of New Drugs, CDER, FDA

Does FDASIA Change the Global Strategy for Pediatric Drug Development?
James Lindsay Cobbs, RPh
Associate Director, US Regulatory Affairs, Johnson & Johnson PRD LLC

Global Pediatric Development Programs: Are We There Yet?
Chin Koerner, MS
Executive Director, Regulatory Policy, Novartis Pharmaceuticals Corporation

EU Perspective
Paolo Tomasi, MD, PhD
Head of Paediatric Medicines, European Medicines Agency, European Union

#111 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): CR, CS, PPLCC

11:00 am–12:30 pm  LEVEL: ■  FORMAT: SESSION
Room 253B  CME and Nursing

Is There a Disagreement? We Can Help - Dispute Resolution between Industry and US/EU Regulators
CHAIRPERSON
Virginia L. Behr
Ombudsman, Office of Executive Programs, CDER, FDA

Sometimes conflict happens between those in regulated industry and the regulators and can arise at any time in the drug or biologic life cycle. Regulators from FDA and EMA will discuss practical ways to seek resolution.

The CDER/CBER Formal Dispute Resolution: Appeals Above the Division Level
Amy Bertha
Regulatory Health Project Manager, Office of New Drugs, CDER, FDA

EMA Perspective
Emer Cooke, MBA
Head of International and European Cooperation, European Medicines Agency, European Union

Is There a Disagreement? We Can Help
Sheryl L. Lard Whiteford, PhD
Associate Director for Quality Assurance, Ombudsman, CBER, FDA
#112 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

**Related Interest Area(s): RA**

11:00 AM–12:30 PM  LEVEL:  Format: FORUM

Room 253C  CME and Nursing

**Regulatory Environment in the US: CDRH Panel Discusses What’s on the Horizon**

**CHAIRPERSON**

Janet Jenkins-Showalter
Senior Regulatory Group Director, Regulatory Policy and Intelligence, Genentech, A Member of the Roche Group

Following the recent passage of the MDUFA, there will be many challenges ahead to implement the new legislation. This forum will focus on understanding the way forward and the key initiatives for CDRH in the post-user fee reauthorization era. CDRH Senior Staff will discuss their priorities and challenges and provide their perspective on areas that are expected to be the focus of external stakeholders.

**Panelists**

Jeffrey Shuren, JD, MD
Director, CDRH, FDA

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

Alberto Gutierrez, PhD
Director, Office of In Vitro Diagnostic Device Evaluation and Safety, CDRH, FDA

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#113 Track 10 – Public Policy/Health Care Compliance/Law

**Related Interest Area(s): CR, RA, IS**

11:00 AM–12:30 PM  LEVEL:  Format: WORKSHOP

Room 153AB  CME, Pharmacy and Nursing

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

**CHAIRPERSON**

Mark C. Hegarty, Esq, JD
Partner/Attorney, Shook, Hardy & Bacon L.L.P.

In this workshop, 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 its conclusion, the lawyers will entertain questions about the mock trial.

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#114 Track 11A – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)

**Related Interest Area(s): QA/QC, CP, OS**

11:00 AM–12:30 PM  LEVEL:  Format: SESSION

Room 154

**Vendor Management Using Quality by Design and Risk Management Strategies**

**CHAIRPERSON**

Sherri A. Hubby
Director, US Quality Assurance, Premier Research Group

Quality by Design quality system concepts (ICH Q8, Q9, and Q10) long used by the pharmaceutical industry and risk management tools will be presented from an industry and regulatory perspective on how to effectively select, manage, and overcome obstacles when outsourcing resources to run clinical trials to ensure that contracted services fulfill client, regulatory, and business expectations. Examples will be shown on how risk management models may be applied to conduct market analysis so that vendors may be ranked for consideration for clinical trials. A helpful checklist will be presented on how to conduct effective assessments and management of vendors. Examples will be provided on how to develop and implement vendor quality management plans which must contain specific elements to capture on each vendor to assure that vendors are appropriately ranked, assessed, and managed. The future of new outsourcing models will also be described. Pharmaceutical representatives and regulators will compare and contrast different approaches to selecting the best vendors and areas of concern/ top findings from audits.

The Advantages of Creating a Vendor Quality Management Plan
Suzanne M. Fink
Senior Project Lead, Clinical Data Management, RPS, Inc.

Applying Quality by Design and Risk Management Strategies for Selecting Vendors to Perform Trials in Emerging Markets
Sherri A. Hubby
Director, US Quality Assurance, Premier Research Group

Third Party Vendor Comprehensive Approach
Kimberly Washburn
Director, Quality Assurance, Quintiles Transnational Corp.

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#115 Track 11B – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)

**Related Interest Area(s): GCP, CP, CR**

11:00 AM–12:30 PM  LEVEL:  Format: SESSION

Room 156AB  CME and Nursing

**Practical Considerations for GCP Audits in a Risk-based Environment**

**CHAIRPERSON**

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

A program for audits is an integral means for meeting regulatory expectations for clinical quality. This session will discuss the advent of risk-based approach to monitoring and inspections which means that sponsors should be employing risk-based audits to assess quality.

Auditing in Today’s Changing Environment
Walter Townsend
Director, Quality Assurance, DATATRAK
Conducting GCP Audits Using a Risk-based Model
Michael R. Hamrell, PhD, RAC
President, MORIAH Consultants

Critical Aspects of CAPA and Root Cause Analysis
Liz Wool, BSN, RN
President and Chief Executive Officer, GD-Quality and Training Solutions Inc.

#116 Track 12 - Pharmaceutical Quality
Related Interest Area(s): RA, MF
11:00 am-12:30 pm LEVEL: ■ FORMAT: SESSION
Room 153C CME and Nursing
Chemistry, Manufacturing and Controls (CMC) Regulatory Landscape in Emerging Markets
Chairperson
Thirunellai G. Venkateshwaran, PhD
Director Pharma Technical Regulatory, Genentech, A Member of the Roche Group

This session will discuss the challenges observed due to the changing regulations in emerging markets.

Clinical Trial Application in China
Chi-Wan Chen, PhD
Executive Director, Global CMC, Global Research & Development, Pfizer Inc

An Industry Perspective of the Approval Process in Russia
Rebecca E. Komas, MS
Director, CMC Advocacy, GlaxoSmithKline

Latin America: Emerging Regulations — Are They a Challenge or an Opportunity?
Nirdosh K. Jagota, PhD
Vice President and Global Head - Small Molecules, Genentech, A Member of the Roche Group

#117 Track 14A - Clinical Safety and Pharmacovigilance
Related Interest Area(s): CDM
11:00 am-12:30 pm LEVEL: ■ FORMAT: SESSION
Room 152 CME and Nursing
Narrative Medicine and Pharmacovigilance
Chairperson
Michael A. Ibara, PharmD
Head of Business Development Coordination & Innovation, WW Safety Reg Operations, Pfizer Inc

In recent years, pharmacovigilance has emphasized the collection and submission of tabular data. Using ideas from narrative medicine, we can re-focus on the patient’s story to better understand adverse drug reactions and benefit-risk balance.

What in the World is Narrative Medicine?
Jesus Rivera, MSc
Senior Learning Manager, Bristol-Myers Squibb Company

Case Study for How the Narrative Improves Clinical Quality
Allison D. Salke, MBA
COO, Tombolo, Inc.

#118 Track 14B - Clinical Safety and Pharmacovigilance
Related Interest Area(s): SUBS, DM
11:00 am-12:30 pm LEVEL: ■ FORMAT: SESSION
Room 157AB CME, Pharmacy and Nursing
Electronic Health Records (EHRs) in Signal Detection and Evaluation
Chairperson
Preciosa M. Coloma, MD, PhD, MSc, RPh
Researcher, Erasmus University Medical Center, Netherlands

Safety-related warnings and market withdrawals of prominent drugs in recent years have fueled efforts to explore other data sources and develop new methodologies in order to offset the limitations of existing safety signal detection systems. One of the important resources proposed as having enormous potential for proactive surveillance are electronic health records (EHRs). There are various initiatives that have been launched worldwide to investigate the secondary use of EHRs for this purpose. In this session, we will give an update on these ongoing initiatives.

Separating the Big Fish from the Small Fry: Strategies for Evaluation and Triage of Potential Signals Identified from EHR
Preciosa M. Coloma, MD, PhD, MSc, RPh
Researcher, Erasmus University Medical Center, Netherlands

Can Electronic Health Care Records be Exploited for Drug Safety Signal Detection? Lessons Learned From the EU-Adverse Drug Reactions (ADR) Project
Gianluca Trifiro, MD, PhD
Assistant Professor, Dept of Clinical and Experimental Medicine and Pharmacology, University of Messina, Italy

#119 Track 15 - Statistical Science and Quantitative Thinking
Related Interest Area(s): CR, RA, PM
11:00 am-12:30 pm LEVEL: ■ FORMAT: FORUM
Room 254AB CME and Nursing
Hot Topics in Statistics: Working Together Effectively to Transform Our Science
Chairperson
Stephen E. Wilson, DrPH, CAPT, USPHS
Director, Division of Biometrics III, Office of Translational Science, CDER, FDA

On February 24, 2010, FDA launched its Advancing Regulatory Science Initiative to transform the way medical products are developed, evaluated, and manufactured. This Regulatory Science is defined as “the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.” This science needs to be a team effort, requiring integrated/applied thought and effort from all of the players—the professionals associated with the discovery, development and review of new drugs, biologics and devices. Statisticians need to know and think about this new science, constantly defining and applying rigorous quantitative thinking in making the decisions to discover, move forward and regulate new products. It’s bigger than all of us in industry, government and academia, and it needs to be collaborative and strategic. This forum will describe the challenges and opportunities associated with making this happen.

FDA Perspective
Robert T. O'Neill, PhD
Senior Statistical Advisor, Office of Translational Sciences, CDER, FDA

Advisory Committee Perspective
Representative Invited
Chair, Mathematics and Statistics Department, Boston University
Monday, June 24

#120 Track 16 – Professional Development
Related Interest Area(s): PETD
11:00 AM-12:30 PM LEVEL: ● FORMAT: SYMPOSIUM
Room 103 CME and Nursing
Challenges and Solutions for Professional Development and Training of Clinical/Nonclinical Staff
CHAIRPERSON
Nancy P. Smerkanich
Program Specialist/Doctoral Candidate, University of Southern California
This symposium is relevant for professionals whose training may not have prepared them to work in a drug development or health care environment and/or did not receive enough hands-on training to perform effectively. Our presenters will address topics such as getting on-the-job training for persons with non-health care backgrounds, formal training for clinical research professionals, as well as how organizations in Japan are developing training programs for young professionals.

Serving Drug Development and Health Care Organizations with Personnel Who Have No Health Care Experience
Badri Rengarajan, MD
Medical Director, Archimedes Inc.

Are New Clinical Research Professionals Well Trained for the Front Line?
Eduardo F. Motti, MD
Owner, Trials & Training Consult, Brazil

Young Professionals with New Ideas Accelerate the Transformation of the Pharmaceutical Industry
Junichi Nishino, MPharm, RPh
Group Head, Novartis Pharma K.K., Japan

#121 Track 18A – Global Regulatory
Related Interest Area(s): RA, CR
11:00 AM-12:30 PM LEVEL: ● FORMAT: FORUM
Room 151B CME and Nursing
CBER Town Hall
CHAIRPERSON
Karen Midthun, MD
Director, Center for Biologics Evaluation and Research, FDA
This forum will provide an overview of CBER’s current work on ongoing initiatives, guidances, and regulations.

Panelist
Robert A. Yetter, PhD
Associate Director for Review Management, Office of the Director, CBER, FDA

#122 Track 18B – Global Regulatory
Related Interest Area(s): CP, RA, CR
11:00 AM-12:30 PM LEVEL: ■ FORMAT: FORUM
Room 257AB CME and Nursing
European Town Hall: Implementation of New Safety Legislation and Other Hot Topics
CHAIRPERSON
Guido Rasi, MD
Executive Director, European Medicines Agency, European Union
The new pharmacovigilance legislation came into force in July 2012. The new Pharmacovigilance Risk Assessment Committee (PRAC) started work in July 2012. The focus in this forum will be on the first experiences with the new PRAC and how the PRAC interacts with the different EU committees (such as the CHMP and CMDh.) The new legislation has increased the transparency on early announcements of safety referrals and publication of agendas and minutes of different scientific committees. Also new is the possibility for a public hearing. What has been the response from the patients and general public to this increase in transparency? Regarding benefit-risk assessment pre- and postlicensing, does the new legislation provide better tools to generate data to assess benefit-risk of new medicines on an ongoing basis?

Panelists
Christa Wirthumer-Hoche, PhD
Deputy Head, Austrian Medicinal and Medical Device Agency (AGES), Austria

Aginus A. W. Kalis, MD
Executive Director, Medicines Evaluation Board, Netherlands

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

#123 Track 19 – Communities Showcase
Related Interest Area(s): CR, NC, RD
11:00 AM-12:30 PM LEVEL: ◆ FORMAT: FORUM
Room 102AB CME and Nursing
How Can Translational Medicine Fill the Gaps in Life Sciences Industries?
CHAIRPERSON
Aamir Shahzad, MD
President, European Society For Translational Medicine (EUSTM), Austria
The panel in this forum will highlight examples of how translational medicine has been applied and what it can contribute to the life sciences industry.

This forum has been developed by the Translational Medicine Community.

Panelists
Michael N. Liebman, PhD
Managing Director, IPQ Analytics

Anastasia M. Christianson, PhD
Senior Director, R&D Information, AstraZeneca

Nicholas John Sarlis, MD, PhD
Vice President and Head, Medical Affairs, Experimental Station, Incyte Corporation
#124 Track 22 - White Paper Showcase

Related Interest Area(s): MC, MSL, IT

11:00 AM-12:30 PM  LEVEL: ●  FORMAT: SESSION
Room 203

Next Generation Medical Information Call Center

Chairperson:
Charles M. Kalfaian
Director, Global Services Health Sciences, EMC Corporation

This session will discuss best practices for building a next generation medical information call center that expediently and efficiently delivers medical information on a global scale. We will discuss how advanced technology can enable and enhance critical patient and provider relationships.

Brought to you by EMC.

*Attendee badges scanned for this White Paper Showcase will be shared with the company hosting this offering. If you prefer not to have your badge scanned, please inform the ISK staff member.

12:30-2:30 PM  EXTENDED LUNCH

#125 Track 01A - Clinical Operations

Related Interest Area(s): IS, CR, SP

2:30-4:00 PM  LEVEL: ●  FORMAT: FORUM
Room 205A  CME and Nursing

Implementing Performance Metrics: How Investigator Sites Can Pave the Way for Running Successful Clinical Trials

Chairperson:
Christine K. Pierre, RN
President, Society for Clinical Research Sites

This forum will explore new approaches and performance metrics being developed and adopted by sites to improve the execution of their clinical trials.

Panelists
Christine K. Pierre, RN
President, Society for Clinical Research Sites

Christopher J. Hoyle, MBA
Executive Director, Elite Research Network

#126 Track 01B - Clinical Operations

Related Interest Area(s): CR, IS, RD

2:30-4:00 PM  LEVEL: ■  FORMAT: SYMPOSIUM
Room 206AB  CME and Nursing

Global Clinical Trials: The Role of Emerging Markets

Chairperson:
Nancy Meyerson-Hess, MSc
Compound Development and Branding, Gruenenthal, Germany

Today’s drug development relies on global clinical trials which include emerging markets. The symposium will address performance, best practices, strategies and challenges of undertaking global clinical trials. The speakers will provide examples from global clinical trials with a focus on reducing risks, optimizing strategy to improve site enrollment and overall performance, and experience from the Clinical Trial Consortium in the Asia Pacific region.

Reducing the Risks of Integrating Emerging Regions in Global Clinical Trials

Nancy Meyerson-Hess, MSc
Compound Development and Branding, Gruenenthal, Germany

Establishment of a Clinical Trial Consortium in the Asia Pacific Region

Guei-Jen Sheih, PhD
Director, Clinical Group, National Research Program For Biopharmaceuticals, Taiwan

Clinical Trials in Emerging Markets: Trends and Experience Study Highlights

Linda Martin, MBA
Principal and Founder, KMR Group Inc.

#127 Track 02A - Project/Portfolio Management and Strategic Planning

Related Interest Area(s): SP, RD, CR

2:30-4:00 PM  LEVEL: ■  FORMAT: WORKSHOP
Room 157C  CME and Nursing

Stage Gate Decision-making Workshop, Part 2 of 2

Chairperson:
Courtland R. LaVallee, Jr.
Director, Project Management, Theravance, Inc.

This interactive two-part workshop will help attendees who may be primarily involved in tactical activities understand how a company makes strategic decisions for moving a product forward. After a review of a new drug product, attendees will work in teams to discuss their product’s information and make recommendations for whether and how their product should be advanced through the development pipeline.

Part 1 of this workshop will focus on processes and decisions in Phase 2, while Part 2 will focus on Phase 3 and the decision to file.

Pre-registration is required, and attendees are strongly encouraged to attend both Part 1 and Part 2.

Part 1 will take place on Monday, 11:00-12:30 PM (Session #102).

To secure a seat for this specific Workshop, please email annualmeetingprogram@diahome.org.
Subject line: Stage Gate Decision-making Workshop.

*Due to workshop format, seating will be limited. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.
Bridging the Gap Between Strategy and Execution

**Chairperson**
Akhil Agrawal, PhD, PMP
Associate Director, Merck Research Laboratories

This symposium will explore ways to bridge the gap between strategy and execution. The importance of an effective link between strategy and execution, or simply “Strategy=Execution,” is also becoming increasingly important in the pharmaceutical and biotechnology industry due to the increasing pressure on costs and timelines. Moreover, it can help ensure innovation occurs not only during discovery of new products, but also during strategic planning and execution. This symposium will highlight a few case studies and will share real life best practices and lessons learned.

**Role of Project Managers in Improving the Effectiveness of Global Product Development**
Akhil Agrawal, PhD, PMP
Associate Director, Merck Research Laboratories

**Strategy and Operations: Mutually Exclusive or Delicate Balancing Act?**
Jaime Baldner
Manager, Clinical Data Management, Genentech, A Member of the Roche Group

**Strategic Implementation of Clinical Trials**
Raymond G. Starrett, MS
Senior Director, Project Management Operations, Ikaria, Inc.

#129  **Track 03 – Innovative Partnering Models and Outsourcing Strategies**

**Chairperson**
Tracy Tsuetaki, MBA, MS
Group President, Life Sciences, OptumInsight

This forum will present examples of regulatory outsourcing partnerships and discuss trends in this area. A panel of experts will provide their interpretation of data from results of a global regulatory outsourcing survey and share best practices.

**Survey of Regulatory Outsourcing Trends**
Tracy Tsuetaki, MBA, MS
Group President, Life Sciences, OptumInsight

**Regulatory Offshoring, Nearshoring and Homeshoring: Is It Smartsourcing?**
Pamela M. Williamson, MBA, RAC, FRAPS
Senior Vice President, Global Head, Regulatory Affairs and Compliance, Genzyme Corporation, A Sanofi Company

**Maximizing Value of Outsourcing**
Andrew Storey
Head, Regulatory Affairs Area and Affiliate Strategy, US/Canada, AbbVie

#130  **Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development**

**Chairperson**
Celine Adessi, PhD
Senior Clinical Safety Scientist, F. Hoffmann-La Roche, Switzerland

The human health risk assessment and management plan in early clinical phase is based on a weight of evidences approach, integrating knowledge of the therapeutic agent from in vivo animal toxicity studies, mechanism of action, and class effect. This session will cover some of the needs and potential limitations of this translational approach with a particular focus on the interpretation of toxicity testing. Topics will address the dilemma for industries for the clinical development of drug-induced non-monitorable toxicity, focusing on vasculitis; cover the supportive information generated from nonclinical assessment of blood pressure changes, reviewing current challenges, new technologies, and translation to human; and discuss the importance of nonclinical juvenile animal guidance in pediatric drug development, sharing real-world experience.

**Introduction**
Celine Adessi, PhD
Senior Clinical Safety Scientist, F. Hoffmann-La Roche, Switzerland

**Nonclinical Assessment of Blood Pressure Changes: Challenges, New Technologies and Translation to Human**
Andrea Greiter-Wilke, DVM, PhD
Head, Safety Pharmacology, F. Hoffmann-La Roche AG, Switzerland

**Juvenile Animal Studies and Pediatric Drug Development: Systematic or Case-by-case?**
Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

Management and Oversight of Outsourcing Services for Patient Safety and Medical Information
Sean Darcy, BSN, RN
Senior Director, Global Patient Safety and Global Medical Information, Vertex Pharmaceuticals

#131  **Track 07A – Processes and Technologies for Clinical Research**

**Chairperson**
Denise Derenzo Lacey, MA, MS
Principal Consultant, Halloran Consulting Group

In this session, we will explore best practices for making the transition from a paper to electronic trial master file (TMF), from the different perspectives of an eTMF vendor, a clinical operations sponsor, and an electronic document management system manager.
#132 TRACK 07B – PROCESSES AND TECHNOLOGIES FOR CLINICAL RESEARCH

Related Interest Area(s): CDM, CR, DM

2:30–4:00 pm  LEVEL: ●  FORMAT: SESSION

Room 252AB  CME, Pharmacy and Nursing

CDISC SHARE: A Promising Approach to Therapeutic Area Standards Development

CHAIRPERSON
Julie Evans
Senior Director, Technical Services, CDISC

This session provides an orientation to the thinking behind the CDISC SHARE project metadata library and how this method can support computable semantic interoperability (CSI), regulatory requirements and therapeutic area standards development.

Information Requirements for Data Standards
Julie Evans
Senior Director, Technical Services, CDISC

The New Model-based Standards Development Process
Diane E. Wold, PhD
Director, Data Standards, GlaxoSmithKline

Practical Electronic Data Standards From the New Process
David Peter Iberson-Hurst
CEO, Assero, United Kingdom

#133 TRACK 08A – REGULATORY AFFAIRS AND SUBMISSIONS

Related Interest Area(s): RD, PPLCC, ROD

2:30–4:00 pm  LEVEL: ■  FORMAT: FORUM

Room 253A  CME and Nursing

Roundtable on Personalized Therapy Innovation in Rare Disease: Focus on Public Policy

CHAIRPERSON
Jeffrey N. Stuart, PhD, RAC
Director, Regulatory Affairs, Novartis Pharmaceuticals Corporation

Orphan product developers face unique challenges that multiply when combined with the need for co-registered diagnostic devices. This forum will discuss the latest policy trends impacting personalized orphan products and patient access.

Regulatory Landscape for the Acceptance of Novel Clinical Study Designs in Rare Diseases
Federico Manuel Good said, PhD
Vice President, Strategic Regulatory Intelligence, Vertex Pharmaceuticals

Economic Disincentives and Incentives of Personalized Therapy and Possible Policy Responses
Mark Trusheim
Executive in Residence and Visiting Scientist, Massachusetts Institute of Technology, Sloan School of Management

NORD Perspective
Diane D. Edquist Dorman
Vice President, Public Policy, National Organization For Rare Disorders (NORD)

#134 TRACK 08B – REGULATORY AFFAIRS AND SUBMISSIONS

Related Interest Area(s): CR, BT, NC

2:30–4:00 pm  LEVEL: ■  FORMAT: SESSION

Room 253B  CME and Nursing

Navigating the Regulatory Pathway for Advanced Therapy Medicinal Products (ATMPs) and Combined ATMPs

CHAIRPERSON
Mark J. Hope
Global Head of Neuroscience and Cardiovascular-Metabolism, Regulatory Affairs, F. Hoffmann-La Roche Ltd., Switzerland

This session will discuss a first analysis and achievements of regulations and legislation for Advanced Therapy Medicinal Products (ATMPs), which are defined as gene therapy and somatic cell therapy medicinal products and tissue-engineered products.

Clinical Trials: The Regulatory Requirements for Combined Advanced Therapy Medicinal Products
Sunita Prem Ahir, PhD, MSc, RAC
Regulatory Affairs Manager, D-Target SA, A Premier Research Company, Switzerland

Preapproval Advice: How Can EMA Support and Recent Experience with the Regulation for Advanced Therapy Medicinal Products
Spiros Vamvakas, MD
Head of Scientific Advice, Human Medicines Special Areas, European Medicines Agency, European Union

Current Status of Cell Therapies From a Regulatory Perspective
Agnes V. Klein, DrPH, MD
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

#135 TRACK 10A – PUBLIC POLICY/ HEALTH CARE COMPLIANCE/ LAW

Related Interest Area(s): RA

2:30–4:00 pm  LEVEL: ■  FORMAT: SESSION

Room 254AB  CME, Pharmacy and Nursing

Cooperation Among Regulators: Impact on Stakeholders

CHAIRPERSON
Marie Allison Dray, MA, MBA
President, International Regulatory Affairs Group LLC
Murray M. Lumpkin, MD, MSc
Commissioner’s Senior Advisor and Representative for Global Issues, Office of the Commissioner, FDA

In this session, the audience will hear views from the leaders of three of the most influential drug regulatory agencies — The Health Products and Food Branch of Health Canada, the European Medicines Agency and the US FDA — on important issues.

FDA Point of View
Margaret A. Hamburg, MD
Commissioner, FDA
### #136 Track 10B – Public Policy/ Health Care Compliance/Law
#### Related Interest Area(s): IS, CR, RA

**Room 153AB**
**CME, Pharmacy and Nursing**

**Legal Jeopardy from the Conduct of Clinical Trials**

**CHAIRPERSON**
Mark C. Hegarty, Esq, JD
Partner/Attorney, Shook, Hardy & Bacon L.L.P.

This forum will address a wide range of regulatory and legal issues governing modern clinical research. Using a well known game show format, experts will compete to show their knowledge of the elements of informed consent, IRB requirements, FDA regulations, the history of clinical investigations and other key topics. The audience will also participate in the game show format.

**Panelists**
- John M. Isidor, JD
  CEO, Human Subject Protection Consulting, LLC
- Jeffrey N. Gibbs, JD
  Director, Hyman Phelps & McNamara, PC
- Kate Gallin Heffernan
  Founder, KGH Advisors LLC
- David Forster, JD, MA
  Vice President, Office of Compliance, Western Institutional Review Board
- Marc B. Wilenzick, Esq, JD
  Consultant, Core Risks, Ltd

**#137 Track 11A – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)**

**Room 156AB**
**CME and Nursing**

**Quality Risk Management: An Old Hat?**

**CHAIRPERSON**
Beat E. Widler, PhD
Managing Partner, Widler & Schiemann AG, Switzerland

A risk-based approach to quality management in clinical trials is the obvious solution. However, many sponsors of clinical trials have attempted it and failed. This session will show the essentials and examples of a successful implementation.

**QRM: Connecting the Operational Dots**
Beat E. Widler, PhD
Managing Partner, Widler & Schiemann AG, Switzerland

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**#138 Track 11B – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)**

**Room 156C**
**CME and Nursing**

**Effectiveness Checks in the Clinical Research Setting**

**CHAIRPERSON**
Cassandra Kennedy
Senior Vice President, Global Quality Assurance, Quintiles Inc.

A closed-loop Corrective and Preventative Action (CAPA) process inclusive of effectiveness checks is central to a company’s quality system. So we dare ask — why is this CAPA element not as clearly defined or employed in the clinical research/GCP space of our industry?

**Facilitators**
- Kevin J. Wilson
  Root Cause Analysis and CAPA Quality Consultant, ASQ Certified SixSigma, Eli Lilly and Company (via Rockwell Automation)
- Michael R. Hamrell, PhD, RAC
  President, MORIAH Consultants

**#139 Track 12 – Pharmaceutical Quality**

**Room 153C**
**CME and Nursing**

**Update on Submission and GMP Expectations for Part 3 Combination Products**

**CHAIRPERSON**
Michael Folkendt, MS
Associate Director for Regulatory Affairs, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

This session will provide an update on both the submission and GMP requirements for part 3 combination products as well as the current review process. Speakers will be from the FDA Office of Combination Products, CDRH and CDER.

**Combination Products: Regulation and Guidance Updates**
- Patricia Y. Love, MD, MBA
  Deputy Director, Office of Combination Products, Office of the Commissioner, FDA
**Perspectives Regarding the Jan FR Notice on GMPs for Part 3**  
Combination Products and Practical Recommendations: Information Expected in the Submission and Where to Put it in the eCTD Application  
Carl Fischer, PhD  
Chief, General Hospital Devices Branch, Office of Compliance, CDRH, FDA

**Industry Perspective**  
Suzanne Kiani, MSc  
Associate Director, CMC Regulatory, MedImmune

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**#140 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)**  
Related Interest Area(s): ST, CR  
2:30–4:00 pm  
LEVEL:  
FORMAT: SESSION  
Room 151B  
CME, Pharmacy and Nursing  
Using Epidemiologic Methods to Advance Comparative Effectiveness Research  
CHAIRPERSON  
Nancy A. Dreyer, PhD, MPH, FISPE  
Senior Vice President, Global Chief of Scientific Affairs, Quintiles Outcome  
The strengths and limitations of observational studies of comparative effectiveness research will be presented, along with a discussion of epidemiologic methods, resources, and a validated scale for assessing observational study quality.

**Science Beyond the Randomized Trial**  
Kenneth J. Rothman, DrPH, FISPE  
Distinguished Fellow, RTI Health Solutions

**GRACE Checklist for Observational Studies of Comparative Effectiveness Research**  
Nancy A. Dreyer, PhD, MPH, FISPE  
Senior Vice President, Global Chief of Scientific Affairs, Quintiles Outcome

**(How) Can Regulators Support CER?**  
Hans-Georg Eichler, MD, MSc  
Senior Medical Officer, European Medicines Agency, European Union

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**#141 Track 14A – Clinical Safety and Pharmacovigilance**  
Related Interest Area(s): RA  
2:30–4:00 pm  
LEVEL:  
FORMAT: SESSION  
Room 157AB  
CME and Nursing  
The New Standards for the Identification of Medicinal Products and Individual Case Safety Reporting Applied in Pharmacovigilance  
CHAIRPERSON  
Sabine Brosch, PharmD, PhD  
Business Lead, EudraVigilance and International Standardisation in PhV, European Medicines Agency, European Union

The development of the international standards arising from the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human use topics MS, Identification of Medicinal Products (IDMP) and E2B(R3), Data Elements for the Transmission of Individual Case Safety Reports, are close to finalization and implementation. In this session, attendees will hear about the status of the two related projects from an EMA and FDA perspective and the industry response to this work.

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**#142 Track 14B – Clinical Safety and Pharmacovigilance**  
Related Interest Area(s): CR, RA, RD  
2:30–4:00 pm  
LEVEL:  
FORMAT: SESSION  
Room 152  
CME, Pharmacy and Nursing  
Characterizing Drug Shortages and Their Causes: Anticipating Future Trends  
CHAIRPERSON  
Kenneth A. Getz, MBA  
Director of Sponsored Research, Tufts CSDD; Chairman, CISCRP, Tufts University

The incidence and scale of drug shortages have both increased markedly during the past several years. As a result, regulatory agencies, drug manufacturers, and policy makers have been focusing more attention on understanding drug shortages and mitigating associated risk. This session includes information on a 2012 study capturing robust descriptive and detailed data on the incidence of, and longitudinal trends in, drug shortages and where and why they occur. This session will also discuss the anticipated increase in the incidence of drug shortages under the rising proportion of biosimilars in the market and the impact of other forecasted drug development and commercialization trends.

**Pharmacovigilance in the Age of Biosimilars: Effectively Tracking Biologic Drug Outcomes Today and Tomorrow**  
Richard Dolinar, MD  
Chairman, Alliance For Safe Biologic Medicines

**Drug Shortages: An Industry Perspective**  
David Gaugh, RPh  
Senior Vice President for Sciences and Regulatory Affairs, Generic Pharmaceutical Association (GPhA)

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**#143 Track 15 – Statistical Science and Quantitative Thinking**  
Related Interest Area(s): RA, CR  
2:30–4:00 pm  
LEVEL:  
FORMAT: SESSION  
Room 257AB  
CME and Nursing  
Key Multiplicity Issues in Clinical Trials  
CHAIRPERSON  
Alex Dmitrienko, PhD  
Executive Director, Center for Statistics in Drug Development, Quintiles Inc.

This session will discuss key multiplicity issues arising in confirmatory clinical trials, including commonly used statistical methods, regulatory considerations presented in the draft FDA multiplicity guidance and case studies.

**Multiple Endpoints in Clinical Trials: A Regulatory Perspective**  
Mohammad Huque, PhD  
Director, Division of Biometrics IV, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

**Key Multiplicity Issues in Clinical Drug Development**  
Ralph B. D’Agostino, Sr., PhD, MA  
Chair, Mathematics and Statistics Department, Boston University
Analysis of Clinical Trials with Multiple Objectives
Alex Dmitrienko, PhD
Executive Director, Center for Statistics in Drug Development,
Quintiles Inc.

#144 Track 16 - Professional Development
Related Interest Area(s): CR, RA
2:30–4:00 pm LEVEL: ● FORMAT: FORUM
Room 103
The Secret of Stellar Careers: Serendipity plus Planning = Success
CHAIRPERSON
Sandra A. Wiejowski, PharmD, RPh
Senior Director, Global Medical Review, Abbott Laboratories
Most successful professionals will speak to the importance of intentional career planning along their journeys. A career plan should, however, be flexible enough to allow an individual to capitalize on unexpected opportunities or serendipitous moments. Sometimes the unplanned can provide for amazing experiences. You just never know! This forum, comprised of leaders from academia, the pharmaceutical industry and the consulting world, will draw upon their personal experiences and own serendipitous moments to provide advice on professional development.
Panelists
Jay Liebowitz, DrSc
Orland Endowed Chair in Management and Technology, University of Maryland University College
Ursula Jorch, MEd, MSc
President, Jorch Consulting, Inc., Canada
Lynn King
Assistant Vice President, Clinical Operations, Rho, Inc.

#145 Track 19 – Communities Showcase
Related Interest Area(s): CR, RD
2:30–4:00 pm LEVEL: ● FORMAT: FORUM
Room 204AB CME and Nursing
Defining Clinical Trial Innovation: Challenges and Opportunities for 2013
CHAIRPERSON
Susan K. Nunchuck, PhD, MSN
Senior Clinical Research Associate, Actelion Clinical Research
Innovation to improve global health and meet unmet medical needs has challenges and opportunities. Given the regulated and increasingly resource-constrained R&D environment, are there opportunities for innovation to ensure a sustainable future? Panelists will debate and discuss the issues in this interactive forum.
This forum has been developed by the Clinical Research Community.
Panelists
Craig H. Lipset
Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc
Andreas Koester, MD, PhD
Vice President, Clinical Trial Innovation, External Alliances, Janssen Pharmaceutical Companies of Johnson & Johnson
Jeffrey S. Kasher, PhD
Vice President, Clinical Trial: Materials, Implementation and Transformation, Eli Lilly and Company

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TUESDAY, JUNE 25

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

Schedule:
7:15-8:00 AM Coffee and Breakfast Breads
8:00-9:30 AM Concurrent Educational Opportunities
9:00 AM-5:30 PM Exhibition Hall Open
9:30-10:15 AM Coffee Break
10:15-11:45 AM Concurrent Educational Opportunities
10:15-11:45 AM Student Forum
11:45 AM-1:45 PM Extended Lunch
11:45 AM-4:00 PM Professional Poster Session
12:15-1:00 PM Innovation Theater Presentation (Exhibit Hall)
1:45-3:15 PM Concurrent Educational Opportunities
1:45-3:15 PM Exhibit Guest Passes
3:15-4:00 PM Refreshment Break
4:00-5:30 PM Concurrent Educational Opportunities

#200 Track 01A – CLINICAL OPERATIONS
Related Interest Area(s): IS, FI, PM
8:00-9:30 AM LEVEL: ■ FORMAT: SESSION
Room 205B CME, Nursing and PMI PDUs
Is This Trial Worth It? A Panel Discussion for Sites and Project Managers
CHAIRPERSON
Rodney William Butt, MBA, MSc
Director, Project Management & Quality Systems, Nutrasource, Canada

Financial pressures are increasing at both the sponsor level and the site level. The implementation of sophisticated models and the introduction of Fair Market Value make study evaluation and discussions more challenging for sites and sponsors.

Investigator Site Perspective
Adam Chasse, MHA
Chief Operating Officer, RxTrials, Inc.

CRO Project Manager Perspective
Andrew Townshend
Vice President, Alliance Development, INC Research

Grant Planning: It’s Harder than You Think
Jessica Dolfi, MS
Senior Business Consultant II, Medidata Solutions Worldwide

#201 Track 01B – CLINICAL OPERATIONS
Related Interest Area(s): CR, RD, IS
8:00-9:30 AM LEVEL: ● FORMAT: FORUM
Room 205C CME, Pharmacy and Nursing
Leveraging In-Pharmacy Education to Improve Patient Comprehension and Access to Clinical Trials
CHAIRPERSON
Kenneth A. Getz, MBA
Director of Sponsored Research, Tufts CSDD; Chairman, CISCRP, Tufts University

Pharmacists are an untapped resource to educate the public about clinical research. A panel reports on a new study suggesting that clinical research education efforts in the community pharmacy can support clinical trial patient recruitment.

The Impact of In-Pharmacy Education on Patients’ Knowledge and Attitudes about Clinical Trials
Kenneth A. Getz, MBA
Director of Sponsored Research, Tufts CSDD; Chairman, CISCRP, Tufts University

Case Study: Proactive Patient Engagement Through Community Pharmacists
Carrie Hurwitz, MBA
Director, Corporate Strategy and Business Development, McKesson

#202 Track 02A – PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING
Related Interest Area(s): PM, PETD
8:00-9:30 AM LEVEL: ◆ FORMAT: FORUM
Room 104C PMI PDUs
Careers Beyond Project and Portfolio Management: A Panel Discussion
CHAIRPERSON
Leigh Shultz, PhD, PMP
Executive Director, Global Project Management, Merck & Co., Inc.

In a panel discussion, former project managers (PMs) who have moved on to executive roles in other areas will share their personal career stories and insights regarding how the project management experience lead to success in other roles outside project/portfolio management.

Panelists
Sandra A. Morris, PhD, PMP
Vice President, Strategy Realization, Johnson & Johnson World Headquarters

Mike Myers
Senior Director, Eli Lilly and Company

Vera Wolowodiuk, PhD
Vice President, Product Development, Nora Therapeutics

#203 Track 02B – PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING
Related Interest Area(s): FI, CR, OS
8:00-9:30 AM LEVEL: ◆ FORMAT: SESSION
Room 203 CME and Nursing
The Financial, Resource and Planning Challenges of Incorporation of Mandatory Language into Protocols
CHAIRPERSON
Anne B. Cropp, PharmD
Executive Director, Pfizer Inc

This session will focus on assessing the impact of implementing legislation-required changes to protocols, lessons learned, and points for consideration to help prepare your organization for future similar challenges.

Lessons Learned from Recent Implementation of Legislation-Required Safety Language into Protocols: Cost, People, Planning
Anne B. Cropp, PharmD
Executive Director, Pfizer Inc
Use of Virtual Population Simulation to Improve Protocol Design and Amendment Management
Badri Rengarajan, MD
Medical Director, Archimedes Inc.

Benchmarking the Clinical Budget and Outsourcing Processes
Stella Stergiopoulos
Project Manager, Tufts Center for the Study of Drug Development

Eliminating the E14 TQT: It is Not If, but When
Charles Benson, MD, PhD
Medical Fellow, Eli Lilly and Company

Assessing Cardiac Repolarization Without the E14 TQT
Jay W. Mason, MD
Professor of Medicine; Chief Medical Officer, Spaulding Clinical Research, University of Utah

New Measures to Differentiate Between Malign and Benign QT Prolongation
David Strauss, MD, PhD
Medical Officer, Office of Science and Engineering Laboratories, CDRH, FDA

#204 Track 03 – Innovative Partnering Models and Outsourcing Strategies
Related Interest Area(s): SP
8:00–9:30 am  LEVEL: ◆  FORMAT: FORUM
Room 104AB  PMI PDUs
Making CRO-Sponsor Partnerships Work: Executive Roundtable
CHAIRPERSON
Kenneth I. Kaitin, PhD
Professor and Director, Center for the Study of Drug Development, Tufts University School of Medicine

For the past several years, CROs and pharma companies have been forming strategic partnerships designed to improve quality and efficiency in the drug development process. But how strategic are they really? Where are the biggest gains being made? What are some of the pitfalls to avoid? Learn from senior thought leaders in the CRO and pharma industries who have broken new ground in the relationships between sponsors and CROs. These executives will share information on structure, governance, metrics and results.

Panelists
Jamie Macdonald
Chief Executive Officer, INC Research

Ciaran Murray
Chief Executive Officer, ICON Plc, Ireland

Peter A. Carberry, MD, MBA
Senior Vice President, Global Development Operations, Astellas Pharma Global Development, Inc.

Jonathan B. Zung, PhD
Vice President, Head of Global Development Operations, Bristol-Myers Squibb Company

#205 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development
Related Interest Area(s): CR, CP, BT
8:00–9:30 am  LEVEL: ■  FORMAT: SESSION
Room 105  CME, Pharmacy and Nursing
The Thorough QT Study: Isn’t There a Better Way to Do This?
CHAIRPERSON
Jay W. Mason, MD
Professor of Medicine; Chief Medical Officer, Spaulding Clinical Research, University of Utah

QT studies are required for drug approval but are expensive and inappropriately scheduled. A better repolarization assessment can be achieved earlier and at lower cost and risk to subjects as compared to the ICH E-14 thorough QT study approach. This session will review efforts now underway to revise the process for assessing repolarization and related arrhythmia risk during drug development.

The Regulatory Writing Game Show
CHAIRPERSON
Jessie Wolfe Galson, PhD
Director, Regulatory Writing, Amgen Inc.

It’s time to play THE REGULATORY WRITING GAME SHOW! Test your knowledge of regulatory documents, from the mundane to the exotic. The format will emphasize group participation and sharing of experience.

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

Clifton D. Chunn
Senior Director, Global Medical Writing, Allergan Inc.
#208 Track 06B – Medical Communication, Medical Writing and Medical Science Liaison

8:00–9:30 AM LEVEL: ■ FORMAT: SYMPOSIUM

Room 204AB

Innovation and Evolution Within the Medical Science Liaison Role

CHAIRPERSON
J. Lynn Bass, PharmD, RPh
Director, Medical Scientists, Jazz Pharmaceuticals

The pharmaceutical industry is composed of diverse constituents who, as a whole, result in a unique, overall industry composite. Since the inaugural team of Medical Science Liaisons (MSL) was deployed, the role and function of the individual MSL has evolved and pivoted in numerous directions. Modern day MSLs continue to evolve and represent the crucial link between the academic and investigator community with the pharmaceutical manufacturer. In this symposium, we will explore how an experienced MSL continues to develop professionally; the evolution, innovation, and challenges of the MSL’s use of technology in their roles; and the future role of the MSL in educational activities.

Recommendations for Developing and Implementing a Training Road Map for a Medical Science Liaison Team

Jane W. Springer, BSN, RN
Principal Specialist, Medical Relations and Information, Amylin Pharmaceuticals, LLC

Growing the Grand Canyon: Is Regulation or Strangulation Creating a Gap in Medical Information and Education in the US?

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

Beam Me Up Scottie: The Role of Technology in the Success of the MSL Role

Craig J. Klinger, RPh
Consultant, Medical Liaison Operations - Trainer, Eli Lilly and Company

#209 Track 07A – Processes and Technologies for Clinical Research

8:00–9:30 AM LEVEL: ■ FORMAT: FORUM

Room 251

Development of a New Patient-reported Outcome (PRO) Measure for Depression: Progress and Results from the PRO Consortium

CHAIRPERSON
Stephen Joel Coons, PhD, MEd, MSc
Executive Director, PRO Consortium, Critical Path Institute

Gain an understanding of the research conducted by the PRO Consortium’s Depression Working Group to develop a new patient-reported outcome (PRO) measure for depression which is intended for use as an endpoint to support medical product labeling.

Panelists

Steven I. Blum
Director, Health Economics, Forest Research Institute

Elektra Johanna Papadopoulos, DrMed, MPH
Medical Officer, Office of New Drugs, CDER, FDA

Mona L. Martin, MPA, RN
Executive Director, Research Scientist, Health Research Associates Inc.

#210 Track 07B – Processes and Technologies for Clinical Research

8:00–9:30 AM LEVEL: ■ FORMAT: SESSION

Room 252AB

Data from Everyone: Using Smartphones and the Internet to Connect with Subjects

CHAIRPERSON
Anne M. Zielinski, MBA
Global Lead, Patient Cloud, Medidata Solutions Worldwide

The rapid proliferation of mobile communications and the high penetration of the internet in the developed world provide opportunities to collect data from subjects. This session will explore these opportunities and their real-world application.

Sponsor Considerations for Alternate Methods of eCOA Collection

Kenneth Grice
Associate Director, ePRO Operations, Global Electronic Data Capture, Bayer Healthcare Pharmaceuticals

Teaming for eCOA Success

Gregg Jewett, MBA
Global Procurement Leader, AstraZeneca

Scientific and Regulatory Aspects of Current and Future eCOA Collection Methods

Willie Muehlhausen, DVM
Vice President, eCOA and Innovation, ICON Late Phase and Outcomes Research, Ireland

#211 Track 08A – Regulatory Affairs and Submissions

8:00–9:30 AM LEVEL: ■ FORMAT: FORUM

Room 253A

Expediting Drug Development and Review for Serious Conditions

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

This forum will provide clarity about FDA’s expedited drug development and review programs and ways in which the EMA enables drug development. It will emphasize the importance of expediting drug development to address the critical need for new therapies to treat serious or life-threatening diseases that lack therapeutic alternatives.

From Gatekeepers to Enablers: How Drug Regulators Respond to a Challenging and Changing Environment

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

A Pharma Company Perspective on Expedited Development Pathways

Robert Metcalf, PhD
Vice President, Global Regulatory Affairs - US, Eli Lilly and Company

Panelist

Jeff Allen, PhD
Executive Director, Friends of Cancer Research
#212 Track 08B – Regulatory Affairs and Submissions

Related Interest Area(s): CR

8:00–9:30 am

A Regulatory Perspective of Biosimilars in Emerging Markets

CHAIRPERSON

Linda F. Bowen, MS, RAC
Head of US Regulatory Policy and Intelligence, Sanofi

With a number of innovator biologicals going off patent, biosimilars present a promising opportunity and a high market potential. However, unlike small molecules, which have known chemical structures, structure activity relationships and well-defined chemical synthesis processes, biosimilars are complex proteins requiring multistep multifaceted manufacturing processes. Hence the development of biosimilars presents unique and complex challenges which need to be strategically planned.

As pharmaceutical business interests spread to Latin America and the Asia Pacific regions, understanding aspects of the regulatory environment in those regions became a critical success factor. This session will provide high-level insight into the regulatory framework for biosimilar product development in key Latin America and Asia Pacific markets. There will be a discussion of a practical case study involving different marketed biosimilar developments in those regions.

Biosimilar Regulatory Environment in the Asia Pacific Region

Sonica Sachdeva Batra, DrMed
Director, Medical and Scientific Affairs, Jubilant Clinsys Ltd., India

Biosimilar Regulatory Environment in Latin America

Oliver Cox, MSc
Consultant, PAREXEL International, United Kingdom

#213 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): RA

8:00–9:30 am

Room 253C

Postmarket Surveillance Issues for Medical Devices

CHAIRPERSON

Kirsten H. Paulson
Senior Officer, Medical Device Initiative, The Pew Charitable Trusts

FDA’s CDRH released a draft National Postmarket Strategy in September 2012, outlining major areas of focus for the postmarket program. This session will look at the scope of the strategy document and status, provide an overview of the Postapproval Study program and look in detail at one of the pillars of the new strategy—medical device registries.

A Global Perspective on Strengthening the Postmarket Surveillance for Medical Devices

Colin R.W. Hayward, FFPM
Vice President, Medical Affairs, Premier Research Group, United Kingdom

Panelist

Kirsten H. Paulson
Senior Officer, Medical Device Initiative, The Pew Charitable Trusts

#214 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): CR, RA, IS

8:00–9:30 am

Room 157C

Ethical Issues in Clinical Trials

CHAIRPERSON

Art Gertel, MS
Vice President, Strategic Regulatory Consulting and Medical Writing, TFS International

This workshop will provide an overview of the various ethical considerations associated with conducting clinical trials, including the history of ethical principles: Nuremberg Conventions, Declaration of Helsinki, The Belmont Report and ICH. Topics will include obtaining ethics committee and regulatory authority clearance, subject informed consent, investigator conflict-of-interest, issues of fraud, authorship, and ensuring subject safety and well-being. In addition, consideration will be given to conducting studies in emerging economy populations where fair distribution of risks and benefits come into play. It will become evident, through case examples, that these issues are not always black-and-white, and that the situation in which these issues are considered result in many shades of gray.

This workshop will also be offered on Wednesday, June 26, at 4:00 pm (#377).

*Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

#215 Track 11 – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)

Related Interest Area(s): GCP, RA

8:00–9:30 am

Room 156AB

GCP and Inspection Readiness

CHAIRPERSON

Marta Haley Fields, MBA
Senior Director, Compliance and Quality Systems, Seattle Genetics, Inc.

While strict compliance with good clinical practice is the best preparation for a regulatory inspection, even the most compliant sponsors and clinical sites view the possibility of an inspection with fear and trepidation. Having a toolkit for managing inspections can go a long way to reducing those concerns. The FDA and EMA have different inspectional approaches and a toolkit for managing inspections can go a long way to reducing those concerns. The FDA and EMA have different inspectional approaches and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

#220 Track 20 – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)

Related Interest Area(s): GCP, RA

8:00–9:30 am

Room 156AB

GCP and Inspection Readiness

CHAIRPERSON

Marta Haley Fields, MBA
Senior Director, Compliance and Quality Systems, Seattle Genetics, Inc.

While strict compliance with good clinical practice is the best preparation for a regulatory inspection, even the most compliant sponsors and clinical sites view the possibility of an inspection with fear and trepidation. Having a toolkit for managing inspections can go a long way to reducing those concerns. The FDA and EMA have different inspectional approaches and require different means of preparation.

This session will explore those differences and propose alternative methods to approach each experience.

A Comparison of FDA and EMA GCP Inspections

Marta Haley Fields, MBA
Senior Director, Compliance and Quality Systems, Seattle Genetics, Inc.

PAI: Beginning with the End in Mind

Donna W. Dorozinsky, MSN, RN
President, DWD & Associates, Inc.

The Relentless Pursuit of ‘All Available Data’: European Inspections Post Good Pharmacovigilance Practices (GVP) Implementation

David William Fryrear, MSc
Head, GCP Operations & Pharmacovigilance Compliance, R&D Quality Assurance, AbbVie, Inc.
#216  TRACK 12 – PHARMACEUTICAL QUALITY

Related Interest Area(s): RA, CR, PT

8:00–9:30 AM  LEVEL: ◆  Format: SESSION
Room 153C  CME, Pharmacy and Nursing

Developing and Embracing a Culture of Quality in the Pharmaceutical Industry

CHAIRPERSON
Mary Oates, PhD
Vice President, Global Quality Operations and EHS, Pfizer Inc

Reliable availability of quality medicines requires more than following the rules laid down by regulators. Today’s complex, global environment demands that all participants in the supply chain adopt a culture of quality, a culture in which every employee understands and embraces their responsibility for delivering quality outcomes that benefit patients. This focus on quality outcomes must exist across the product life cycle, including product and process development, clinical trials, regulatory submissions and commercial manufacturing. The session will define the characteristics of a quality culture across a range of firms and functions, describe how to assess existing culture and achieve the desired state and outline the benefits for patients, regulators and the pharmaceutical industry.

FD A Point of View on Culture of Quality
Christine M. V. Moore, PhD
Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

Quantifying Quality Culture at an API CMO
Guy Villax
Chief Executive Officer, Hovione, Portugal

Developing and Embracing a Culture of Quality Beyond the Manufacturing Environment
David A. Tainsh, PhD, RPh
Chief Product Quality Officer, Governance, Ethics and Assurance, GlaxoSmithKline, United Kingdom

#217  TRACK 13 – HEALTH ECONOMICS AND OUTCOMES (HEO)/COMPARATIVE EFFECTIVENESS RESEARCH (CER)/HEALTH TECHNOLOGY ASSESSMENT (HTA)

Related Interest Area(s): PR, CR, PT

8:00–9:30 AM  LEVEL: ●  Format: SESSION
Room 151B  CME, Pharmacy and Nursing

Payer Collaborations with Pharma: Real-world Evidence to Improve Patient Outcomes and Influence the Pipeline

CHAIRPERSON
Christopher M. Marrone, PharmD
Outcomes Liaison, Eli Lilly and Company

This session will focus on the objectives and outcomes of payer/pharmaceutical real-world evidence collaborations. Speakers will include pharmaceutical representatives and payers sharing their goals, vision, and experiences of their collaborations.

Collaborations Overview and the Pharma Perspective
James Darnett, PharmD, MS
Senior Director, Real World Data and Analytics, Pfizer Inc

The Payer Perspective: National Managed Care Experience
Stephen Chick
Vice President, Competitive Health Insights, A Humana Company

#218  TRACK 14A – CLINICAL SAFETY AND PHARMACOVIGILANCE

Related Interest Area(s): RA, IT, MC

8:00–9:30 AM  LEVEL: ◆  Format: SESSION
Room 152  CME, Pharmacy and Nursing

Social Media, Mobile Applications and Patient Support Programs: Challenges and Solutions for Handling Drug Safety Information

CHAIRPERSON
Arpad Simon, MD
Site Head, Drug Safety, Global Development Safety Evaluation Center, Mitsubishi Tanabe Pharma Development America

Social media, mobile applications and patient support programs are becoming integral parts of the pharmaceutical and biotech industries. However, they also present unique operational and strategic challenges. This session will discuss pharmacovigilance implications including adverse event handling and risk mitigation solutions from the regulatory and drug safety point of view. Through case examples, experts will demonstrate how to best utilize these new technologies and procedures in order to meet expectations from regulators and from patients.

Pharmacovigilance Approaches to Patient Support Programs and Digital Media
Arpad Simon, MD
Site Head, Drug Safety, Global Development Safety Evaluation Center, Mitsubishi Tanabe Pharma Development America

Leveraging Mobile Telecommunications Technology for Vaccine Safety Surveillance
Preciosa M. Coloma, MD, PhD, MSc, RPh
Researcher, Erasmus University Medical Center, Netherlands

Use of Relational Modeling as a Means to Conduct Pharmacovigilance Using Spontaneous Patient Communications on the Internet
James Sawyer, DrMed
CEO, Prism Ideas Ltd, United Kingdom

#219  TRACK 14B – CLINICAL SAFETY AND PHARMACOVIGILANCE

Related Interest Area(s): CR, ST

8:00–9:30 AM  LEVEL: ◆  Format: FORUM
Room 153AB  CME and Nursing

Aligning Statistical Science and Regulatory Practices for Expedited Safety Reporting

CHAIRPERSON
Judith M. Kramer, MD, MS
Professor of Medicine, Duke University Medical Center, Duke Translational Medicine Institute

Recommendations are presented from projects of the Clinical Trials Transformation Initiative (CTTI) exploring expedited safety reporting for clinical trials conducted under an IND (Investigational New Drug) and for aligning regulatory practices for expedited safety reporting with statistical science and patient expectations.
The Direction of Rare Disease Research
Marshall Summar, MD
Chief, Genetics and Metabolism, Children’s National Medical Center

Place of Value to Patients in Drug Development for Rare Diseases
Russell Teagarden
Senior Vice President, Medical and Scientific Affairs, National Organization For Rare Disorders (NORD)
Tuesday, June 25

#223 Track 18 – Global Regulatory
Related Interest Area(s): RA, CR
8:00–9:30 AM LEVEL: ■ Format: FORUM
Room 254AB CME and Nursing
Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall
CHAIRPERSON
Nobumasa Nakashima
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PMDA will explain and answer questions from the audience about Japanese regulation, PMDA’s current situation, activities and future initiatives for faster and more efficient review to cope with medical products using advanced science technology.

Panelists
Tatsuya Kondo, MD, PhD
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Takao Yamori, PhD
Director of Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
Kazuhiko Mori, MS
Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

#224B Track 22 – White Paper Showcase
Related Interest Area(s): CR, IT, CDM
8:00–9:30 AM LEVEL: ● Format: SESSION
Room 154
Moving to a Standards-based, Agile Clinical Development Lifecycle
This Whitepaper Showcase will describe a new agile approach to the clinical development lifecycle that maximizes reuse of clinical content and examines how SOA Software’s Semantics Manager facilitates the creation, management, and use of data standards and operational metadata in the context of this approach.
Brought to you by SOA Software.

**Attendee badges scanned for this White Paper Showcase will be shared with the company hosting this offering. If you prefer to not have your badge scanned, please inform the DIA staff member.

Chairperson
Julie Smiley, MS
Director, Product Management, SOA Software

9:30–10:15 AM COFFEE BREAK

#225 Track 01A – Clinical Operations
Related Interest Area(s): FI, CR
10:15–11:45 AM LEVEL: ■ Format: WORKSHOP
Room 156C CME, Nursing and PMI PDUs
Domestic and Global Trends in Clinical Trial Budgeting
CHAIRPERSON
Frank J. Cattie
Vice President, Trial Planning Solutions, Medidata Solutions Worldwide

This workshop will equip attendees with current cost insights enabling them to produce more effective trial budgets. Through the use of both domestic and region-specific trends, attendees will gain a deeper understanding of the trial cost landscape.

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Facilitator
Jessica Dolfi, MS
Senior Business Consultant II, Medidata Solutions Worldwide

Join the 27,000+ members on LinkedIn
#226 Track 01B – Clinical Operations

Related Interest Area(s): IS, PT, CR

10:15–11:45 AM LEVEL: ◆ FORMAT: SESSION

Room 205C

CME, Pharmacy and Nursing

Optimizing Trial Feasibility by Leveraging Electronic Health Record (EHR) Data and Engaging Investigators and Patient Advocacy Groups

CHAIRPERSON
Lisa Palladino Kim, MS
Global Trial Optimization Specialist, Inventiv Health Clinical

This session will provide proven solutions to optimize clinical trial feasibility in an innovative, collaborative and dynamic partnership with researchers, patients and service providers that will include innovation, controversy, and best practices.

Innovative Approach to Clinical Trial Feasibility
Lisa Palladino Kim, MS
Global Trial Optimization Specialist, Inventiv Health Clinical

Effective Use of Electronic Health Record (EHR) Data to Test Recruitment Feasibility
Sam Holliday, MBA
Vice President, PrimeRESEARCH, Greenway Medical Technologies

Patient Advocacy and Industry Collaboration
Marion Schwartz
Director of Advocacy, Cholangiocarcinoma Foundation

#227 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, SP

10:15–11:45 AM LEVEL: ◆ FORMAT: SESSION

Room 104C

CME and Nursing

Effective Diverse Team Collaboration and Management for Drug Development: Key Commonalities and Differences among Korea, China and Japan

CHAIRPERSON
Atsushi Tsukamoto, MSc, PMP
Director, Global Project Management, Daiichi Sankyo Co., Ltd., Japan

Growing opportunities for drug development in Asian countries have drawn attention to those countries from the West, and also from other Asian countries. Although some of the traditional cultural styles are considered to be shared within Asia (i.e., Confucian rather than Socratic), other aspects, such as historical background, values and business styles, are very different among Korea, China and Japan. In this session, we will introduce typical pitfalls when working with Asian countries, especially in drug development, together with a framework to understand the commonalities and differences, in order to help the attendees with effective and efficient management of diverse Asian teams.

Effective Collaboration in Pharmaceutical R&D in Asia
Atsushi Tsukamoto, MSc, PMP
Director, Global Project Management, Daiichi Sankyo Co., Ltd., Japan

East Asian Perspectives on Working with Global Teams (Part I)
Robert A. Hilke, MA
CEO, Hilke Communications Corporation, Japan

East Asian Perspectives on Working with Global Teams (Part II)
Gareth Julian Monteath, MBA, MS
Program Director, Link Global Solution Inc., Japan

#228 Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RA, SUBS

10:15–11:45 AM LEVEL: ◆ FORMAT: SESSION

Room 104AB

CME and Nursing

Developing and Maintaining Sponsor/CRO Partnership Regulatory Submissions Processes: Challenges and Successes

CHAIRPERSON
Bill Leslie
Executive Director, Global Regulatory Submissions, Covance Inc.

Over four years ago, Merck selected Covance and PAREXEL as alliance partners. Representatives from each company will speak to challenges faced in building relationships leading to successful processes and enabling quality regulatory submissions.

Sponsor/CRO Partnership Regulatory Submissions Processes: Sponsor Perspective
Denise Booker, MS
Associate Director and Relationship Manager, Merck & Co., Inc.

Sponsor/CRO Partnership Regulatory Submissions Processes: CRO Perspective
Ulrike Behr, MSc
Director, Regulatory Affairs, PAREXEL International GmbH, Germany

#229 Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): SP

10:15–11:45 AM LEVEL: ◆ FORMAT: FORUM

Room 103

CME, Nursing and PMI PDUs

Change Order Panel Discussion and Brainstorming Session: Can We Be More Efficient?

CHAIRPERSON
Owen N. Charles, MBA, RN
Manager, Outsourcing Management, Bristol-Myers Squibb Company

This forum will explore the current state of scope change in outsourcing: the pain points, magnitude of resource and cost-saving opportunities, strategic partnerships and recent solutions utilized. Participants will be encouraged to help us brainstorm.

Contractual and Financial Structures
Moisha Platto
Vice President, Global Proposals and Finance, PRA International

Central Laboratory Change Order Management
Jennifer Henry-Smith, MBA
Vice President, PrimeRESEARCH, Greenway Medical Technologies

How Different Cost Structures Affect Change Orders
David Gillogly, MBA
Senior Director, Clinical Outsourcing, Otsuka Pharmaceutical Development & Commercialization, Inc.
#230 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development
Related Interest Area(s): CR, NC, IT

10:15-11:45 AM  LEVEL: ■  FORMAT: SESSION
Room 105  CME and Nursing

Measuring the Impact of Subject Dual Enrollment on Study Data Validity and a Web-based Tool to Avoid Simultaneous Participation in Multiple Concurrent Clinical Trials
CHAIRPERSON
Darran Boyer, MBA
President, clinicalRSVP

This session will evaluate methods used by researchers to measure the impact of subject dual enrollment on clinical trial study data. We will explore the scientific and economic impact of dual subject enrollment to the clinical research industry. We will also discuss steps taken by industry to mitigate subject dual enrollment and explore methods to overcome key challenges.

An Analysis of Continental Registration for Early Phase Clinical Research Volunteers
Mary L. Westrick, PhD
Vice President, US Phase 1, Quintiles Inc.

Evaluating Need for a Uniform European Registration System for Volunteer Participation
Annick Peremans
General Manager, Phase 1 Unit, Research Centre Aalst, Belgium

#231 Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World
Related Interest Area(s): AP, RA

10:15-11:45 AM  LEVEL: ■  FORMAT: FORUM
Room 102AB  CME, Pharmacy and Nursing

FDA Enforcement Update: Advertising and Promotion
CHAIRPERSON
Wayne L. Pines
President, Regulatory Services and Healthcare, APCO Worldwide Inc.

FDA enforcement actions and policy guidances need to be understood by every company because they reflect FDA’s priorities and concerns in regulating advertising and promotion. In this forum, an FDA professional and a representative from industry will examine the latest agency enforcement actions and policies and what they mean.

CDER Perspective
Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, CDER, FDA

Industry Perspective
Pamela M. Williamson, MBA, RAC
Senior Vice President, Global Head, Regulatory Affairs and Compliance, Genzyme Corporation, A Sanofi Company

#232 Track 06 – Medical Communication, Medical Writing and Medical Science Liaison
Related Interest Area(s): MW, RA

10:15-11:45 AM  LEVEL: ■  FORMAT: FORUM
Room 204AB  CME and Nursing

Preparation of Clinical Study Reports and Summary Documents: Maximize Efficiency and Minimize Redundancy
CHAIRPERSON
Pamela Lindroos, PhD
Senior Director, Medical Writing, WebbWrites, LLC

This forum will discuss how the preparation of high-quality clinical study reports (CSRs) and summary documents for a New Drug Application (NDA) may be achieved by preparation of shell documents, adherence to guidance documents, avoidance of redundancy within and across documents, and structured authoring.

Writing Clinical Documents for Regulatory Submissions
Pamela Lindroos, PhD
Senior Director, Medical Writing, WebbWrites, LLC

Structured Authoring: Driving Improved Efficiency, Quality and Costs
Kristina Brannstrom, PhD
Director and Regional Head, Global Medical Writing and Document Publishing, Quintiles Inc.

Medical Review of Clinical Documents for Regulatory Submissions
Helen Colquhoun, MD, FFPM
Senior Vice President, CROMSOURCE

#233 Track 08 – Regulatory Affairs and Submissions
Related Interest Area(s): CP, CR, IS

10:15-11:45 AM  LEVEL: ■  FORMAT: FORUM
Room 253A  CME, Pharmacy and Nursing

The Aging Population: Approaches to Ensure Safety and Efficacy
CHAIRPERSON
Francesca Cerreta, PharmD, MPharm, MS
Scientific Administrator, European Medicines Agency, European Union

People older than 75 are the fastest growing population segment and are major users of medication, and yet are highly underrepresented in clinical trials. FDA, EMA and PMDA representatives will discuss potential innovative therapeutic, research and regulatory approaches.

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

Drug Development for Older Population in Japan: Current Status and Challenges
Yasuko Asahina, PhD
Researcher, Office of Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Industry Point of View
Susanna Del Signore, MD
Associate Vice President, Global Regulatory Affairs, Sanofi, France
**#234 Track 12 – Pharmaceutical Quality**

**Related Interest Area(s):** SUBS, RA

**10:15–11:45 AM**  
**Room 153C**  
**Format: SESSION**  
**CME, Pharmacy and Nursing**

**Strategies for the Development and Registration of Antibody Drug Conjugates**

**CHAIRPERSON**  
Sarah C. Pope Mikinski, PhD  
Acting Director, Division 1, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

The session will provide an overview of the current status of antibody drug conjugate development and regulations. The challenges associated with the regulatory submission (format and content) and the technical issues will also be discussed.

- **Gaining Enhanced Product and Process Understanding During ADC Development: Challenges and Opportunities**  
  Fred Jacobson  
  Principal Scientist and T-DMI Technical Team Leader, Genentech, A Member of the Roche Group

- **Aspects to Consider in Defining the Control Strategies for the Small Molecule Components of Antibody Drug Conjugates**  
  Nathan Ihle, PhD  
  Executive Director, Process Chemistry and Analytical Biochemistry, Seattle Genetics, Inc.

**#235 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)**

**Related Interest Area(s):** CP, QA/QC, CDM

**10:15–11:45 AM**  
**Room 210ABC**  
**Format: FORUM**  
**CME, Pharmacy and Nursing**

**Big Data: Impact on Innovation**

**CHAIRPERSON**  
Susan Dentzer, MA  
Former Editor-in-Chief, Health Affairs; Senior Policy Advisor, Robert Wood Johnson Foundation

With the greater use of electronic data, access to real-world data on patients, payers and the health system is exploding, bringing with it many opportunities to shape drug development, commercialization and access. Many significant initiatives with broad impact have been undertaken to shape how these types of data are being used to guide decision-making. How are these data being used to support safety and effectiveness? Does this information impact the payer landscape? What are the gaps and limitations? What are the standards, if any, available to guide good practice?

A short keynote address will set the groundwork and will be followed by a panel discussion that will examine pharma, safety, and patient perspectives on big data methodology and the need for real-world examples.

- **Keynote**  
  Michael Rosenblatt, MD  
  Executive Vice President and Chief Medical Officer, Merck & Co., Inc.

- **Panelists**  
  Marc M. Boutin, Esq, JD  
  Executive Vice President and Chief Operating Officer, National Health Council

- **David W. Bates, MD, MSc**  
  Senior Vice President for Quality and Safety, Chief Quality Officer, Brigham and Women’s Hospital

**#236 Track 14 – Clinical Safety and Pharmacovigilance**

**Related Interest Area(s):** IT, EC

**10:15–11:45 AM**  
**Room 153AB**  
**Format: SESSION**  
**CME and Nursing**

**EU Update: PROTECT and EnCePP**

**CHAIRPERSON**  
Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP  
EMA Risk Management Development and Scientific Lead, European Medicines Agency, European Union

This session will discuss The Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) which aims to develop and validate innovative methods for benefit-risk (BR) assessment of medicine and describe the ongoing PROTECT study of signal detection in electronic health records, and in particular its development of strategies to strengthen or refute potential safety signals emerging from routine surveillance of longitudinal observational databases. We will also discuss the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (EnCePP) aimed at further strengthening post-authorization monitoring of medicines by facilitating the conduct of studies focusing on safety and on benefit-risk.

- **Benefit-risk Integration and Representation: Results From PROTECT**  
  Diana Hughes  
  Vice President, Worldwide Safety, Pfizer Inc

- **Triage Strategies for Screening Longitudinal Observational Databases**  
  Niklas Noren, PhD  
  Chief Science Officer, Uppsala Monitoring Centre (UMC), Sweden

- **ENCePP: Strengthening Methodology, Transparency and Independence**  
  Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP  
  EMA Risk Management Development and Scientific Lead, European Medicines Agency, European Union

**#237 Track 15 – Statistical Science and Quantitative Thinking**

**Related Interest Area(s):** RA, CDM, CR

**10:15–11:45 AM**  
**Room 157AB**  
**Format: SESSION**  
**CME and Nursing**

**Statistical Considerations When Developing Antibacterial Treatments**

**CHAIRPERSON**  
Rima Izem, PhD  
Mathematical Statistician, Office of Translational Science, CDER, FDA

The traditional regulatory requirement when assessing a new agent is often for two adequate and well controlled Phase III trials which control the type I error rate at 2.5% (one-sided) per trial. Such a requirement is a challenge for some antibacterial agents due to issues of feasibility, particularly for infections due to uncommon pathogens or treatments with a narrow spectrum of activity. As a result, there has been discussion regarding the use of differing amounts of clinical data to support approval in areas with large unmet medical need and limited feasibility.

This session will cover experiences working in this challenging area and will consider how to use the totality of evidence from a range of sources.
the methodological considerations when interpreting such data, and the application of methods improving the precision of estimates of efficacy in the setting of uncommon pathogens along with design features to enable a more feasible development program while controlling the false-positive risk and ensuring there is sufficient evidence of drug effect.

Statistical Considerations When Feasibility of Traditionally Sized Trials is an Issue
Aaron L. Dane, MS
Biometrics & Information Sciences Infection Head, AstraZeneca, United Kingdom

FDA Perspective
Daniel B. Rubin
Statistician, Office of Translational Science, CDER, FDA

Challenges in Design and Analyses of Antibacterial Trials in the Face of Resistance
Scott Evans, PhD
Senior Research Scientist, Harvard University School of Public Health

Soft Skills and Interviewing
Kelleen Flaherty, MS
Assistant Professor, University of the Sciences In Philadelphia

Finding a Mentor to Guide your Career
Amy N. Grant, MS
Director, Global Regulatory Strategy & Science, ViroPharma

Incorporated Using Fellowships and Internships to Start Your Career
Justin Balint, PharmD
Post-Doctoral Fellow, Oncology Advocacy and Policy, Rutgers, The State University of New Jersey

#240A Track 19 – Communities Showcase

Achieving Innovative Technology Results
CHAIRPERSON
James O’Keefe
Director, Clinical & Regulatory Optimization, Paragon Solutions, Inc.

This session will discuss reducing business risk when using Software as a Service (SaaS) and leveraging cloud technology as part of your company’s clinical architecture.

This session has been developed by the Information Technology Community.

When and How to Leverage Cloud Technology Into Your Clinical Architecture
James O’Keefe
Director, Clinical & Regulatory Optimization, Paragon Solutions, Inc.

Reducing Business Risk While Remaining Compliant With SaaS Solutions
Jim Schweitzer, MBA
Director, Commercial Technology Services, Vision Point Systems

#240B Track 22: White Paper Showcase

Circulating Tumor Cells (CTCs) as a Biomarker Approach in Oncology
Circulating tumor cells (CTCs) are rare in healthy individuals and patients with nonmalignant diseases; however, they are present in patients with various metastatic carcinomas. Some clinical studies indicate the number of CTCs present in the patient is an indicator of progression-free and overall survival for cancer patients. Therefore, evaluating CTCs can assist physicians to monitor and predict cancer progression for those with metastatic cancer.

This White Paper Showcase is brought to you by LabCorp Clinical Trials.

Kenneth J. Pennline, PhD
Vice President and Global Head, Cytometry Services, LabCorp Clinical Trials

**Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

#239 Track 16B – Professional Development

DIA 2013 Student Forum: Getting a Job and Developing a Career
CHAIRPERSON
Danny A. Benau, PhD
Director, Biomedical Writing Programs, University of the Sciences in Philadelphia

Previous Student Forums and sessions in the Professional Development Track have concentrated on ways to get noticed and getting one’s foot in the door on the way to getting a job. These have included discussions on networking skills, capabilities charting, prospect selecting, and common and less common job opportunities. This year’s forum will continue the topic of getting a job with presentations on soft skills, interviewing and using internships and fellowships to launch your career. An additional topic — finding a mentor — will introduce the theme of going from finding a job to developing a career. A good mentor can guide you with priceless tacit knowledge that otherwise could take years to find.

**Attendee badges scanned for this White Paper Showcase will be shared with the company hosting this offering. If you prefer to not have your badge scanned, please inform the DIA staff member.

Kenneth J. Pennline, PhD
Vice President and Global Head, Cytometry Services, LabCorp Clinical Trials
can, of course, use these metrics to focus activities to improve on whatever is being measured.

This symposium will focus on clinical trial management, with the speakers describing how metrics have been defined, implemented and used within their organizations. This will include how to focus on the right metrics and not be overwhelmed by measuring everything, how to assess industry benchmarks and incorporate them into your organization, and ensure that best practice for the implementation and display of metrics is applied.

The Art and Science of Data: How to Ensure the Story Hidden within Clinical Study Conduct Data Is Revealed
Nikki Dowiman, PhD
Product Director, Perceptive Informatics, United Kingdom

Fed Up with Tracking Pointless Metrics? Learn How to Select and Use Metrics that Work
Keith Dorriscott
Director, Operations Management - Process Improvement and Metrics, INC Research, United Kingdom

Installing Clinical Trial Metrics to Drive Operations, Governance and Client Satisfaction
Russell F. Boyd, PhD, PMP
Executive Director, Head of Project Management (Americas), Covance Inc.

**#243 Track 02A – Project/Portfolio Management and Strategic Planning**

1:45-3:15 PM  LEVEL:  Format: SESSION
Room 204C  Pharmacy

Regulatory, Clinical, and Quality Challenges in Contracting and Due Diligence: The Forgotten Keys to Biopharma Transactions
CHAIRPERSON
Michael A. Swit, Esq, JD
Special Counsel, Duane Morris, LLP

This session will provide drug professionals with a deeper understanding of the key regulatory, clinical or quality issues that must be reviewed in buying a biopharmaceutical product or company and how to address those concerns in the due diligence phase.

Navigating Potential Regulatory Land Mines in Due Diligence
Laurie A. Halloran, BSN, MS
President and Chief Executive Officer, Halloran Consulting Group

**#244 Track 02B – Project/Portfolio Management and Strategic Planning**

1:45-3:15 PM  LEVEL:  Format: FORUM
Room 253A  CME and Nursing

Approaches to Quality Risk Management: Understanding What Matters
CHAIRPERSON
Martin Landray, PhD, FRCP
Reader in Epidemiology, Clinical Trial Service Unit, University of Oxford, United Kingdom

This forum will review the Clinical Trials Transformation Initiative’s (CTTI) potential methods to apply principles of Quality by Design and quality risk management to the scientific and operational design of clinical trials.
What Are the Key Drivers for Quality?  
Martin Landray, PhD, FRCP  
Reader in Epidemiology, Clinical Trial Service Unit, University of Oxford, United Kingdom

Quality Risk Assessment and Quality by Design: Principles Not Jargon  
Briggs W. Morrison, MD  
Head, Global Medicines Department, AstraZeneca

Regulatory Requirement for Ensuring Quality: A US Perspective  
Ann Meeker-O’Connell, MS  
Director, Division of GCP Compliance (Acting), Office of Scientific Investigations, Office of Compliance, CDER, FDA

#245 Track 03A – Innovative Partnering Models and Outsourcing Strategies  
Related Interest Area(s): PM, CR  
1:45–3:15 PM  
LEVEL: ■  
Room 104AB  
CME, Nursing and PMI PDUs

Pharma, Academia and CRO Preferred Partnerships: Why Collaboration Makes a Better Global Trial  
CHAIRPERSON  
Mary Ann Sellers, MSN  
Senior Project Leader, Duke Clinical Research Institute

This session will describe successful strategies used by a multi-partner collaboration to manage challenges encountered in an ongoing “megatrial.” The team will share structural and operational models that have been used to drive novel solutions.

Why Collaboration Makes a Better Global Trial: An Academic Perspective  
Michelle Masterson  
Project Manager, Diabetes Trials Unit, Oxford University, United Kingdom

Why Collaboration Makes a Better Global Trial: A Sponsor Perspective  
Joe Zimmerman, MBA  
Senior Director, R&D Business Operations, Amylin Pharmaceuticals, Inc.

Why Collaboration Makes a Better Global Trial: A CRO Perspective  
Sara Tullberg, PhD  
Senior Project Leader, PAREXEL International, United Kingdom

#246 Track 03B – Innovative Partnering Models and Outsourcing Strategies  
Related Interest Area(s): RA, MC  
1:45–3:15 PM  
LEVEL: ◆  
Room 103  
CME, Pharmacy and Nursing

FDA Collaborations Broaden the Reach of Health Care Messages to Effectively Communicate with the Public  
CHAIRPERSON  
Anna M. Fine, PharmD, MS  
Director, Health Professional Liaison Program, Office of the Commissioner, FDA

This session will provide an understanding of FDA’s innovative collaborative programs to extend the reach of communication from the agency to inform and educate the public about potential risks associated with use of regulated products.

A New Vision: Leveraged Opportunities to Improve Public Health  
Michael Duenas  
Chief Public Health Officer, American Optometric Association

Innovation in Collaboration: Lessons from Public-Private Partnerships  
Amy Nadel  
Executive Director, Professional Relationships, Medscape

#247 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development  
Related Interest Area(s): NC, CR, RA  
1:45–3:15 PM  
LEVEL: ■  
Room 156C  
CME, Pharmacy and Nursing

Human Abuse Liability Testing in CNS Drug Development  
CHAIRPERSON  
Lynn Roy Webster, MD  
Medical Director, CRI Lifetree

This workshop will address clinical aspects of conducting human abuse liability studies. It will provide insight on FDA’s Draft Decision Tree on Assessment of Abuse Potential and the appropriate methodology for assessment of abuse liability potential.

What You Must Know Before Conducting a Human Abuse Liability Study  
Lynn Roy Webster, MD  
Medical Director, CRI Lifetree

Cause for Discrimination: Importance of the Discrimination Phase in Human Abuse Liability Studies  
Jack Henningfield, PhD  
Vice President, Research, Health Policy, and Abuse Liability, Pinney Associates

Decisions, Decisions: How the FDA Decides Whether or Not to Require a HAL Study  
Robert A. Medve, MD  
Chief Medical Officer, Nektar Therapeutics

#248 Track 05 – Regulation of Product Advertising and Marketing in an Ever-Changing World  
Related Interest Area(s): RA, RD, MC  
1:45–3:15 PM  
LEVEL: ■  
Room 102AB  
CME and Nursing

Drug Development for Commercial Success  
CHAIRPERSON  
Michele L. Sharp, PharmD  
Senior Director, Global Regulatory Affairs - US, Eli Lilly and Company

Many companies make development plans based on the shortest path to filing a marketing application. This may mean doing the minimum number of trials required to gain approval and designing trials to maximize the probability of gaining a positive clinical outcome. This panel will describe and discuss an alternative approach. By understanding the promotional claims necessary for successful commercialization before pivotal trials are initiated and by involving all the relevant regulatory disciplines in designing
a development program, the probability of commercial success can be maximized.

Panelists
Darshna Patel
Director, Global Regulatory Affairs and Safety; Pipeline Product Labeling, Amgen Inc.

Lynette Hopkinson
Senior Director, Commercial Regulatory Affairs, Eisai Inc.

#249 TRACK 06 – MEDICAL COMMUNICATION, MEDICAL WRITING AND MEDICAL SCIENCE LIASON

Related Interest Area(s): MW, CP, RA

1:45–3:15 PM  LEVEL: ■  FORMAT: SESSION

Room 204AB

The New European Pharmacovigilance Legislation: Guiding Medical Writers Through the Risks and Benefits

CHAIRPERSON
Julia Cooper, PhD
Senior Director, Worldwide Head of Medical Writing Services, PAREXEL International Ltd., United Kingdom

This session reviews practical experience of the new European Union pharmacovigilance legislation as it relates to medical writers preparing periodic safety update reports, risk management plans and documents for postauthorization safety studies.

Julia Cooper, PhD
Senior Director, Worldwide Head of Medical Writing Services, PAREXEL International Ltd., United Kingdom

Three Reports — One Story: Managing the DSUR, PBRER and the RMP
Sven Schirp
Head of Global Pharmacovigilance Writing, Boehringer Ingelheim Pharma Gmbh & Co. KG, Germany

Navigating Module VIII: Post Authorization Safety Studies
Swapu Banerjee, MD, MBA, MSc, FRCP
Deputy Managing Director, Pope Woodhead & Associates Ltd, United Kingdom

#250 TRACK 07A – PROCESSES AND TECHNOLOGIES FOR CLINICAL RESEARCH

Related Interest Area(s): VA, IT

1:45–3:15 PM  LEVEL: ■  FORMAT: FORUM

Room 251

Innovative Computerized System Validation and Auditing

CHAIRPERSON
Frances E. Nolan, MBA
Vice President, Quality and Regulatory Affairs, Medidata Solutions Worldwide

Panel participants and attendees will discuss how suppliers, users and regulators can leverage more modern and innovative techniques for developing, validating and deploying solutions.

Panelists
Ron Fitzmartin, PhD, MBA
Senior Advisor, Office of Planning and Informatics, CDER, FDA

Eric Staib, MBA, MSc
Senior Director, IT Quality Systems, RPS, Inc.

Tam D. Woodrum, JD, MS
Executive, Software, GE Healthcare

#251 TRACK 07B – PROCESSES AND TECHNOLOGIES FOR CLINICAL RESEARCH

Related Interest Area(s): CDM, IT, EC

1:45–3:15 PM  LEVEL: ■  FORMAT: SESSION

Room 252AB

Changing View of Electronic Data Capture (EDC) and Implications for Data Quality

CHAIRPERSON
Laurie S. Callen
Senior Manager, Clinical Data Management, Tesaro Biosciences

This session will provide actual examples of using the smartphone for clinical data collection and experiences with the quality of the data. It will also provide insight into the benefits and risks in relying on the Smartphone as an EDC instrument.

Clinical Trial Data Capture: Mobile Technology Moves it From the Clinic to the Subject
Scott Brand, PhD
Principal Scientist, Global Data and Bioinformatics, QPS LLC

Putting the “e”asy in ePRO: Generating Mobile Patient Reported Outcomes Apps Using EDC Design Tools and CDISC Operational Data Model (ODM)
Cal Collins
CEO, OpenClinica

New Strategies for Conducting Research Using New Technologies
Benjamin B. Brodey, MD, MPH
CEO, TeleSage, Inc.

#252 TRACK 08A – REGULATORY AFFAIRS AND SUBMISSIONS

Related Interest Area(s): SUBS, IT, CDM

1:45–3:15 PM  LEVEL: ●  FORMAT: SESSION

Room 206AB

Electronic Submissions in PDUFA V

CHAIRPERSON
Nancy D. Smith, PhD
Adjunct Professor at Temple University, FDA Alumni Association

CDER will present an update and report on PDUFA performance goals and requirements related to electronic submissions. These include the requirement of electronic submissions and development of clinical and nonclinical terminology standards.

CDER Perspective
Mary Ann Slack
Deputy Director, Office of Planning and Informatics, CDER, FDA

PDUFA V Electronic Submission Requirements: eCTD Update
Mark A. Gray
Director, Division of Data Management Services and Solutions, Office of Business Informatics, CDER, FDA

CDER Perspective
Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, Office of Translational Science, CDER, FDA
**#253 Track 08B — Regulatory Affairs and Submissions**

**Related Interest Area(s): CP**

1:45–3:15 PM  
Room 257AB  
CME and Nursing

**Implementing an Internationally Acceptable Framework for the Benefit-risk Assessment of Medicines: How Close Are We to This?**

**CHAIRPERSON**  
Stuart Walker, PhD  
Founder, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

Major changes of benefit-risk methodologies have been undertaken by agencies and companies which have enabled the development of an overarching eight step framework. This session will bring together the various stakeholders to review progress.

- **Benefit-risk Framework Study: Can This Improve Regulatory Decision Making?**  
  James Leong, MPPharm  
  Regulatory Specialist, Health Sciences Authority, Singapore

- **PDUFA V Implementation Plan for a Structured Approach to Benefit-risk Assessment**  
  Nate C. Blevins, MS  
  Director, Global Regulatory Affairs and Patient Safety, AstraZeneca Pharmaceuticals LP

- **Quantitative Benefit-risk Assessment: Where Are We Now, Why the Resistance and Where Are We Going?**  
  Lawrence Phillips, PhD  
  Emeritus Professor of Decision Sciences, Department of Management, London School of Economics, United Kingdom

**#254 Track 08C — Regulatory Affairs and Submissions**

**Related Interest Area(s): CR, MW, PT**

1:45–3:15 PM  
Room 254AB  
CME and Nursing

**US and EU Regulatory Update of Clinical Trial Disclosure**

**CHAIRPERSON**  
Barbara Godlew, RN  
President, The FAIRE Company, LLC

This session focuses on US and EU requirements for clinical trial disclosure, including results reporting. Information obtained during this session applies to regulatory, clinical operations, medical writing, patient advocacy and other areas.

- **Mission Possible: Creating a Trial Quality Profile**  
  Penelope K. Manasco, MD, MS  
  CEO, MANA Consulting

- **Like a Fine Wine, Risk-based Monitoring Approaches Take Time**  
  Kathleen Goin, MS  
  Associate Director, Clinical and Data Operations, Endo Pharmaceuticals Inc.

- **New Monitoring Approaches: Evolution or Revolution?**  
  Sherri A. Hubby  
  Director, US Quality Assurance, Premier Research Group

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**#255 Track 09 — Medical Devices, In Vitro Diagnostics, and Combination Products**

**Related Interest Area(s): RA**

1:45–3:15 PM  
Room 253C  
CME and Nursing

**Co-development of Targeted Therapies and Companion Diagnostics: Identifying Regulatory Strategies to Overcome Challenges**

**CHAIRPERSON**  
Janet Jenkins-Showalter  
Senior Regulatory Group Director, Regulatory Policy and Intelligence, Genentech, A Member of the Roche Group

FDA released a draft guidance in July 2011 that outlined the basics on developing targeted therapies and companion diagnostics, but it left many questions unanswered. This session will discuss potential approaches to address these remaining questions.

- **Panelists**  
  Jeff Allen, PhD  
  Executive Director, Friends of Cancer Research

  Erling Thor Donnelly, PhD, RAC  
  Manager, Worldwide Regulatory Strategy, Pfizer Inc

  Shayesteh Fuerst-Ladani, MBA, MS  
  Director, SFL Regulatory Affairs & Scientific Communication, Switzerland

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**#256 Track 11 — Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)**

**Related Interest Area(s): GCP, IS, CP**

1:45–3:15 PM  
Room 156AB  
CME and Nursing

**GCP Risk-based Monitoring**

**CHAIRPERSON**  
Kathleen Goin, MS  
Associate Director, Clinical and Data Operations, Endo Pharmaceuticals Inc.

This symposium will discuss the impact of the FDA “Guidance for Industry Oversight of Clinical Investigations,” explore how a study team implemented some risk-based strategies and examine various strategies to implement risk-based monitoring strategies to enhance site and monitor performance in the conduct of clinical trials.

- **Mission Possible: Creating a Trial Quality Profile**  
  Penelope K. Manasco, MD, MS  
  CEO, MANA Consulting

- **Like a Fine Wine, Risk-based Monitoring Approaches Take Time**  
  Kathleen Goin, MS  
  Associate Director, Clinical and Data Operations, Endo Pharmaceuticals Inc.

- **New Monitoring Approaches: Evolution or Revolution?**  
  Sherri A. Hubby  
  Director, US Quality Assurance, Premier Research Group
### #257 Track 14A – Clinical Safety and Pharmacovigilance

**Related Interest Area(s):** RA, GCP

**1:45–3:15 PM**  
**LEVEL:**  
**Room 152**

**Quality Assurance for Signal Detection Programs**
**CHAIRPERSON**
Elizabeth E. Garrard, PharmD, RPh  
Specialist Leader, Deloitte Consulting L.L.P.

New EU legislation requires quality assurance of critical safety processes, including signal detection. This forum will offer the chance to discuss how best to measure compliance, effectiveness, and efficiency of a signal detection program.

**Quality Assurance and Quality Management Measures With Respect to Signal Detection and Signal Management: A Priority in the EU Pharmaceutical Legislation and Guidance**
Kerstin Geldmeyer-Hilt, PhD  
Quality Manager, Pharmacovigilance, Dr. Ebeling & Association GmbH, Germany

**EU Perspective**
Representative Invited  
Director, NDA Group, United Kingdom

**Industry Point of View**
George N. Pajovich, RPh  
Head of Safety Risk Research, Pfizer Inc

### #258 Track 14B – Clinical Safety and Pharmacovigilance

**Related Interest Area(s):** CR, RA

**1:45–3:15 PM**  
**LEVEL:**  
**Room 153AB**

**Periodic Reporting in Drug Safety: From Safety Updates to Continuous Signal Monitoring and Benefit-risk Evaluations**
**CHAIRPERSON**
Reingart Bordel, DrSc, MS  
Senior Pharmacovigilance Manager, Dr. Ebeling & Assoc. GmbH, Germany

The session will present the new structure of periodic safety update reports (PSURs)/periodic benefit-risk evaluation reports (PBRERs) according to the good pharmacovigilance practices (GVP)/ICH E2C(R2) guidance. Requirements and challenges for PSUR/PBRERs are outlined. Interference with RMPs and DSURs as well as practical advice for compilation is given. Examples for signal identification and risk evaluations are provided.

**The Challenges of the New PSUR/PBRER Guidance and Strategies for Efficient Implementation**
Steve Jolley, MA  
Principal, SJ Pharma Consulting

**The New PSUR/PBRER: Template and Synergistic Workflows for the Continuous Benefit-risk Assessment During the Life Cycle of a Product**
Reingart Bordel, DrSc, MS  
Senior Pharmacovigilance Manager, Dr. Ebeling & Assoc. GmbH, Germany

**PSUR/PBRER Submission Strategies and Special Requirements in the EU and the US**
Sandra J. Hecker, RAC  
US Agent; Regulatory Consultant, Hecker & Associates, LLC

### #259 Track 15 – Statistical Science and Quantitative Thinking

**Related Interest Area(s):** CR, RD

**1:45–3:15 PM**  
**LEVEL:**  
**Room 157AB**

**Looking Closer into the Utility of Adaptive Approaches**
**CHAIRPERSON**
Sue-Jane Wang, PhD, MA, MS  
Associate Director, Adaptive Design & Pharmacogenomics, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

This symposium will discuss the advantages and disadvantages of a few methodologies that are directly related to implementation of adaptive designed trials. A weighted average approach on the type I error and type II error will be introduced and will be compared with the standard approach where type I error is fixed and type II error is to be minimized. As for randomization, a hybrid randomization algorithm will be presented, which will be contrasted with conventional randomization to illustrate the pros and cons among the algorithms. Finally, adaptive dose finding designs including penalized D-optimal design, CRM design and Bayesian adaptive designs will be compared. In addition, the tradeoff between the desire to maximize information and various constraints will be discussed while gaining information under ethical/cost constraints in adaptive dose finding studies.

**Optimal Choice of the Type I Error Rate in Drug Development**
Andrew Peter Grieve, DrSc, PhD, MSc  
Senior Vice President Clinical Trial Methodology, Aptiv Solutions, Germany

**Gaining Information under Ethical/Cost Constraints in Dose Finding Studies**
Valeri Fedorov, DrSc, PhD  
Vice President, Quintiles Inc.

**A Hybrid Randomization Algorithm Offering the Best of Minimization, Dynamic and Permuted Block Randomization Methods**
Jonathan (Yoni) D. Lebowitsch  
Product Manager, Medidata Solutions Worldwide

### #260 Track 17 – Rare/Orphan Diseases

**Related Interest Area(s):** CR, RD, RA

**1:45–3:15 PM**  
**LEVEL:**  
**Room 153C**

**Is There a Recipe for Successful Implementation of Registries for Rare Diseases?**
**CHAIRPERSON**
Martine Zimmermann, PharmD  
Executive Director, Global Regulatory Affairs, Alexion Pharma International Sàrl, Switzerland

This session will describe how registries can support development of new drug for rare diseases, how they can contribute to regulatory approval, and decisions on access to orphan medicinal products.

**Public-private Partnerships for Registries: Challenges and Solutions**
Samantha Parker, MBA  
Director of External Affairs and Rare Disease Partnerships, Orphan Europe, France

**Urea Cycle Disorders as a Model of Rare Disease Registries**
Marshall Summar, MD  
Chief, Genetics and Metabolism, Children’s National Medical Center
First-in-Human at the Clinical Front Line
William B. Smith, MD
President & Principle Investigator, New Orleans Center For Clinical Research

The Polarized Perspectives of the Sponsor for Phase 1
Stacie J. Bell, PhD
Director, Clinical and Translational Research, Questcor Pharmaceuticals

#261 Track 18 - Global Regulatory
Related Interest Area(s): RA, CR, CP
1:45–3:15 PM  LEVEL: ●  FORMAT: FORUM
Room 253B  CME and Nursing
Convergence in Regulatory Science Across the Strait
CHAIRPERSON
Ning Li, MD, PhD
Vice President, GRA Head, Medical Policy, Asia, Sanofi, China

In this forum, representatives from the Center of Drug Evaluation from mainland China and the Center for Drug Evaluation from Taiwan will share their views and experience in Good Review Practice (GRP) and IND review. This will form the basis for the discussion of collaboration opportunities and areas of convergence in regulatory science in the two centers.

Moderator
Ling Su, PhD
Strategic Advisor, Life Sciences, Sidley Austin LLP, China

Point of View from China CDE
Yi Feng
Office of Evaluation Management and Communication, Center for Drug Evaluation of CFDA, China

Representative Invited
Deputy Office Director, Office of New Drug Pharmaceutical Science, Center for Drug Evaluation of CFDA, China

Point of View from Taiwan CDE
Hsin-Jung Lee, MD
Reviewer, Division of New Drugs, Center for Drug Evaluation, Taiwan

Mey Wang, PhD
Reviewer, Division of New Drugs, Center for Drug Evaluation, Taiwan

#262 Track 19 - Communities Showcase
Related Interest Area(s): PC, NC
1:45–3:15 PM  LEVEL: ■  FORMAT: SESSION
Room 105  CME and Nursing
First-in-Human Studies: How Much Complexity Is Too Much?
CHAIRPERSON
Royce A. Morrison, MD, MS
Executive Vice-Chair, Quorum Review, Inc.

On the first-in-human (FIH) fast track, what defines “just right” design? Join us to hear experience of sponsor development teams, CROs, investigators and regulatory agencies, and best practice guidance on appropriate limits for FIH study complexity.

This session has been developed by the Clinical Pharmacology Community.

The IRB: Regulatory Protection
Royce A. Morrison, MD, MS
Executive Vice-Chair, Quorum Review, Inc.

The CRO: Avoiding “Too Much” in First-in-Human
Mary L. Westrick, PhD
Vice President, US Phase I, Quintiles Inc.

First-in-Human at the Clinical Front Line
William B. Smith, MD
President & Principle Investigator, New Orleans Center For Clinical Research

The Polarized Perspectives of the Sponsor for Phase 1
Stacie J. Bell, PhD
Director, Clinical and Translational Research, Questcor Pharmaceuticals

#263 Track 20 - Executive Program
Related Interest Area(s): CR, RA, RD
1:45–3:15 PM  LEVEL: ◆  FORMAT: FORUM
Room 205A  CME and Nursing
Reinventing the R&D Business Model: Heeding the President’s PCAST Report on Innovation
CHAIRPERSON
Kenneth I. Kaitin, PhD
Professor and Director, Center for the Study of Drug Development, Tufts University School of Medicine

The landscape for bioinnovation is changing. This session, hosted by the Tufts Center for the Study of Drug Development (CSDD), will examine how companies across the pharma sector are transforming their R&D business models to meet current and future market demands. This senior-level session represents the cross-functional issues that embrace not just R&D, but preclinical, clinical, regulatory, operations, portfolio management and marketing — all aspects of business development. An executive-level panel will lead this interactive session, which will cover topics including:

• What are the greatest market challenges facing the industry today?
• In what ways are companies adjusting their R&D business models to meet those challenges?
• How has the focus on precision and targeted therapies altered the business model?
• What role do partnerships, alliances and collaborations play in the new bioinnovation landscape?
• How can government further support innovation within the pharma sector?

Moderator
Kenneth A. Getz, MBA
Director of Sponsored Research, Tufts CSDD; Chairman, CISCRP, Tufts University

Panelists
Robert J. Franco, PhD
Principal, PricewaterhouseCoopers LLP

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

Bernard Munos, MBA
Founder, InnoThink

Tomasz Sablinski, MD
Founder and CEO, Transparency Life Sciences

Dalvir Gill, PhD
CEO, TransCelerate Biopharma Inc
Learning to Share-Sharing To Learn: How an Industry Learns to Honor Its Volunteers

Panelists
Matt Gross
Director, Health Care and Life Sciences Global Practice, SAS Institute Inc.
Angela L. Lightfoot
Director, OnDemand Health and Life Sciences Consulting, SAS Institute Inc.
Joel Beetsch
Vice President, Patient Advocacy Group, Celgene Corporation

Brought to you by SAS.

Using Site Metrics to Enhance Site Performance
Scott R. Martin, JD, MA
Principal, KMR Group Inc.

A Case Study: Strategies for Optimizing Site Selection
Elizabeth Desrosiers, MS, PMP
Director, Global Trial Management, Merck Research Laboratories

New Approaches to Site Feasibility
Douglas A. Swain, RPh
Senior Functional Manager, Northeast Region, Genentech, A Member of the Roche Group

Generating Evidence for a NICE Technology Appraisal
Leeza Osipenko, PhD, MSc
Senior Scientific Advisor, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), United Kingdom

When Lab Scientists Meet Economic Payors: A Market Access Professional’s Dilemma When You Come to Us Too Late
Chia Wen Lee
Head, Emerging Markets Access, Biogen Idec

Facilitating Global Program Convergence for Optimized Registration and Market Access
Libbie Mansell
President, White Oak Biopharma Solutions

Ensuring data integrity and patient safety has been interpreted as 100% source document verification (SDV) and onsite monitoring. The 2011 FDA Perspective

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#268 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): IS, FL, CR

4:00–5:30 pm  LEVEL: ■  FORMAT: SESSION

Room 104AB  CME and Nursing

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

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

A panel of executives from a major Pharmaceutical company, a major CRO and a large investigative site will present their processes for site identification and selection and how to better obtain Fair Market Value for site budgets.

Investigator Sites Challenged with Securing Grants and Increased Protocol Complexity
Joan A. Chambers
Chief Operating Officer, CenterWatch, Inc.

Innovative Tools and Strategies to Optimize Site Selection and Performance
Suresh Kannan, MBA
Vice President, Product Development, Clinical Trial Optimization Solutions, IMS Health

#269 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): NC, CP, CR

4:00–5:30 pm  LEVEL: ●  FORMAT: SESSION

Room 105  CME and Nursing

Optimizing the Transition from Preclinical to Clinical Research

CHAIRPERSON
Stella Stergiopoulos
Project Manager, Tufts Center for the Study of Drug Development

This session will highlight strategies for transitioning from nonclinical to early phase drug discovery most efficiently. The first presentation will discuss current industry processes and perceived costs in preclinical and early phase drug development. The second presentation will focus on risk mitigation in early phase studies, while the third presentation will focus on strategies for bridging the gap between preclinical and clinical development.

Characterizing the Development Pathway from Preclinical through Early Clinical Drug Development
Stella Stergiopoulos
Project Manager, Tufts Center for the Study of Drug Development

Translational Value of Early Target-based Safety Assessment and Associated Risk Mitigation
Laszlo Urban, MD, PhD
Head, Preclinical Safety Profiling, Novartis Institutes for Biomedical Research

Opportunities for Achieving Higher Levels of Efficiency in Preclinical Research
Simone Braggio
Director, Drug Design and Discovery, Aptuit, Italy

#270 Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

Related Interest Area(s): MC, MA, RA

4:00–5:30 pm  LEVEL: ■  FORMAT: SESSION

Room 102AB  CME and Nursing

Product Communications in the Preapproval Phase

CHAIRPERSON
Mark Gaydos
Vice President, US Regulatory Affairs Marketed Products, Sanofi

This session will focus on the types of information a company might consider communicating about its research efforts, pipeline products and corresponding development programs. Select topics include: What, how, and to whom can companies communicate about research efforts and pipeline products while avoiding allegations of preapproval or off-label promotion? What and when can a company proactively communicate about planned and ongoing clinical trials? What are the parameters a company should observe when developing a preapproval disease awareness campaign? What are the pros and cons of a “coming soon” campaign?

Enforcement Action Summary
Mark Gaydos
Vice President, US Regulatory Affairs Marketed Products, Sanofi

Emerging Communication Channels in Preapproval Communication: Does the Medium Matter?
Dennis Lawrence Nosco, PhD, RAC
Senior Director, Global Labeling, Regulatory Affairs, Mallinckrodt, The Pharmaceuticals Business of Covidien

Impact of Caronia on Preapproval Communications
Alan R. Bennett, JD
Managing Partner, DC Office, Ropes & Gray

#271 Track 06 – Medical Communication, Medical Writing and Medical Science Liaison

Related Interest Area(s): MW, RA, PM

4:00–5:30 pm  LEVEL: ■  FORMAT: SYMPOSIUM

Room 204AB  CME and Nursing

Protocol Trends and Strategies for Quality

CHAIRPERSON
Linda Fossati Wood, MPH, RN
President, MedWrite, Inc.

This symposium will discuss current trends in protocol characteristics and explore a variety of strategies for development of a successful protocol. Clinical protocols have become increasingly complex in the past decade and, consequently, initiatives have been developed to improve efficiency and quality and reduce the impact of amendments through protocol design. The advantages gained by engaging a medical writer in the review of study documents initiated by other departments such as the case report forms and the statistical analysis plan will be discussed.

Protocol Quality Tools: New Approaches to an Old Problem
Anne B. Cropp, PharmD
Executive Director, Pfizer Inc

Assessing the Impact of Regulatory and Scientific Pressures on Protocol Design
Kenneth A. Getz, MBA
Director of Sponsored Research, Tufts CSD; Chairman, CISCPR, Tufts University
#274 Track 08A – REGULATORY AFFAIRS AND SUBMISSIONS

4:00–5:30 pm  LEVEL:  ◆  FORMAT:  SESSION

Room 254AB  CME, Pharmacy and Nursing

Labeling and Patient Medical Information (PMI)

CHAIRPERSON
Lynette Hopkinson
Senior Director, Commercial Regulatory Affairs, Eisai Inc.

Currently three documents serve to communicate patient product information, the Patient Package Insert (PPI), Medication Guide, and Consumer Medication Information (CMI). None are deemed optimal as a ‘One Document Solution.’ Over the past 20 years FDA has collaborated with multiple healthcare stakeholders to explore how to effectively communicate the most useful prescription medication information to patients. This session will discuss two pilot projects that were conducted with one-page Patient Medical Information (PMI) samples to determine, amongst other objectives, patient comprehension and patient preferences for format, content and method of receipt.

Evaluation of Two Novel Formats Versus the Current CMI
Julie Aker, MT
President & CEO, Concentrics Research LLC

The PMI Operational Pilot Experience
Paul R. Wilson, MA
Vice President, Catalina Health

Patient Perspective: What Do Patients Want/Need?
Marc M. Boutin, Esq, JD
Executive Vice President and Chief Operating Officer, National Health Council

#275 Track 08B – REGULATORY AFFAIRS AND SUBMISSIONS

4:00–5:30 pm  LEVEL:  ●  FORMAT:  SESSION

Room 253B  CME and Nursing

Bringing the Views of “Payer Regulators” into Product Development to Align Label Outcomes and Safety with Patient Access

CHAIRPERSON
Charles A. Stevens, JD, MBA
Vice President and General Manager, PAREXEL Consulting

This session will discuss how data requirements of payer regulators post-approval can be different than the needs of regulators working on product approval. Developing market facing data during development can impact product label, patient access and overall product success.

Panelists
Marc B. Samuels, JD, MPH
Managing Partner, HillCo HEALTH

Brian Carey, JD
Partner, Life Sciences and Health Care, Foley Hoag LLP
#276 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

Related Interest Area(s): CR, RD, ST

4:00–5:30 pm  LEVEL: ◆  FORMAT: SESSION

Room 253C  CME and Nursing

Diagnostic Biomarker Verification and Validation: A Cost-efficient, Speed to Market Adaptive Design Clinical Trial Model

CHAIRPERSON
Alan J. Touch
Consultant

Through proactive protocol design and targeted clinical trial operational models, the sample collection process for all in vitro diagnostics (IVDs) can be managed in increments that allow for development of the diagnostic and/or allow for decisions to be made at any time regarding the viability or robustness of the diagnostic and the need for more development work or to finalize the diagnostic sensitivity and specificity desired as well as the establishment of the intended use. This session will address biostatistical models, proper site selection, and data management tools to be used for central and onsite monitoring, and sample collection processing and handling procedures to reduce induced error. The session will cover models which should be used for diagnostic, predictive and companion diagnostics, and human factors studies.

Clinical Trial Models for IVD Sample Collection and Human Factors Studies
Alan J. Touch
Consultant

A Data Collection Strategy to Improve the Effectiveness and Speed of the Companion Diagnostic and Therapeutic Product Co-Development Process
Cari DeLoa
Principal Data Manager, Genentech, A Member of the Roche Group

Future Outlooks for Imaging Clinical Trials in Latin America
Joao Massud, MD
CEO, Trials Consulting, Brazil

#277 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA, PT

4:00–5:30 pm  LEVEL: ■  FORMAT: FORUM

Room 253A  CME, Pharmacy and Nursing

Breakthrough Therapy: One Candle on the Birthday Cake — Are Innovators Enjoying Sweet Success or Is the Pathway Not Baked Yet?

CHAIRPERSON
Nancy Bradish Myers, Esq, JD
President, Catalyst Healthcare Consulting, Inc

What has been accomplished in the first year of Breakthrough Therapy? This forum will explore experiences, lessons learned and how these lessons could inform new regulatory changes intended to spur innovation.

Patient Advocacy Perspective on Breakthrough Therapy at One Year
Jeff Allen, PhD
Executive Director, Friends of Cancer Research

#278 Track 11 – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)

Related Interest Area(s): RA, CR

4:00–5:30 pm  LEVEL: ■  FORMAT: SESSION

Room 156AB  CME and Nursing

GCPs in Emerging Countries

CHAIRPERSON
Fred Feldstein, JD
Senior Director, Head of GCP/GLP/PV QA, Primary Care and Consumer BUs, Pfizer Inc

This session will discuss how increased globalization of clinical development and continued advancement in the clinical trial environment, standard of care, and regulations has brought challenges to successfully execute studies with quality and cost-effectiveness in emerging markets. It is important to evaluate cultural attributes, local health care regulations, site/vendor capabilities, and identify the critical quality factors up-front to ensure a high quality trial that will withstand regulatory scrutiny.

Simultaneous Global Clinical Trials and Coordinated Conformation to GCP Compliance in the Asia Pacific Region
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

GCP Compliance in the Asia Pacific Region
Chih-Hwa Wallace Lin, PhD
Director, Division of Resource Development, Center for Drug Evaluation, Taiwan

Panelists
Roan Martin
Senior Director and Head of Research Regulatory Compliance (RRC), PAREXEL International

Representative Invited
Clinical Reviewer, New Medicine Application and Regulation of Biological Product, Dirección General de Medicamentos Insumos y Drogas (DIGEMID), Peru

#279 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA

4:00–5:30 pm  LEVEL: ■  FORMAT: SESSION

Room 153C

Lessons Learned from the EMA-FDA Quality by Design (QbD) Pilot

CHAIRPERSON
Evdokia Korakianiti, PhD, MSc
Head of Chemicals Section, Quality of Medicines, European Medicines Agency, European Union

This session will present the EMA-FDA quality by design pilot. The presentations will describe the two review pathways available under the pilot, i.e. parallel assessment and consultative advice. The purpose of the pilot, the application process and the review procedures will be described. The key lessons learned from the applications received so far will be discussed.
There will also be a panel discussion with the speakers and some industry representatives that have participated in the pilot.

**Update from the EMA-FDA GbD Pilot: Consultative Advice**
Elaine Morefield, PhD
Deputy Office Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Chemistry, CDER, FDA

**Update from the EMA-FDA GbD Pilot Parallel Assessment**
Evdokia Korakianiti, PhD, MSc
Head of Chemicals Section, Quality of Medicines, European Medicines Agency, European Union

**Industry Experience**
Antoinette Paone, MBA, MSc
Senior Director, Global CMC Regulatory Affairs Strategy, Vertex Pharmaceuticals

**Industry Experience**
John Groskoph, MBA
Senior Director, Global CMC, Pfizer Inc

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**#280 Track 13 – HEALTH ECONOMICS AND OUTCOMES (HEO)/COMPARATIVE EFFECTIVENESS RESEARCH (CER)/HEALTH TECHNOLOGY ASSESSMENT (HTA)**

**Related Interest Area(s): CR, CDMeCl, IT**

**4:00–5:30 pm**

**LEVEL:** 

**FORMAT:** SESSION

**Room 151B**

**CME, Pharmacy and Nursing**

**Session Title:** Utilizing Electronic Medical Records as an Innovative Methodology for Evaluating Therapeutic Effectiveness

**Chairperson:**

Ryan Gifford, MBA
Senior Manager, Business Development, CTI Clinical Trial and Consulting Services

**Clinical trials are considered the gold standard for determining the efficacy of a therapeutic but operate in an idealized patient setting, only measuring efficacy in restrictive populations. As such, they may not provide a true indication of effectiveness within a diversified target population. Data retrieved from electronic medical records (EMRs) allow for the examination of health care utilization patterns and associated outcomes in a real-world setting. This unique data collection approach will provide new insights on therapeutic efficacy in restrictive populations. As such, they may not provide a true indication of effectiveness within an idealized patient setting, only measuring efficacy in restrictive populations.**

**Related Topics:**
- Are Electronic Medical Records (EMR) Presenting a New Opportunity for Outcome Assessments of Therapeutics in the Postapproval Phase?
- Clinical trial data describe the observations from a clinical trial, and standardized analysis (Analysis Data Model [ADaM]) data are created to use the information from a study — both are critical elements in the submission and review of regulated drugs and biologics. We need to describe, discuss and solve the problems associated with many important analysis data issues/opportunities: Therapeutic area analysis data standards, refuse-to-file considerations, and the EMA’s unprecedented call for the submission and secondary use of “raw data.” This session will provide an overview of important issues associated with the development, application, submission and review of analysis data.

**Speakers:**

- Eliezir Katz, DrMed, MD
  Senior Director, Transplantation, Medicines Development Group, Pfizer Specialty Care

- Dorry Segev, MD
  Associate Professor of Surgery, Division of Transplantation, Dept of Surgery, Johns Hopkins University School of Medicine

- William Irish, PhD, MSc
  Vice President, Outcomes Research and Biostatistics, CTI Clinical Trial and Consulting Services

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**#281 Track 14 – CLINICAL SAFETY AND PHARMACOVIGILANCE**

**Related Interest Area(s): RA**

**4:00–5:30 pm**

**LEVEL:** 

**FORMAT:** SESSION

**Room 153AB**

**CME and Nursing**

**Session Title:** Risk Management in the US, EU and Japan: The Challenges of Diversity

**Chairperson:**

Nancy A. Dreyer, PhD, MPH, FISPE
Senior Vice President, Global Chief of Scientific Affairs, Quintiles Outcome Experience

**Panelists:**

- **FDA Point of View**
  Gerald J. Dal Pan, MD
  Director, Office of Surveillance and Epidemiology, CDER, FDA

- **EU Point of View**
  Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
  EMA Risk Management Development and Scientific Lead, European Medicines Agency, European Union

- **Risk Management in Japan**
  Stewart Geary, MD
  Vice President, Chief Medical Officer, Director, Corporate Medical Affairs HQ, Eisai Co., Ltd., Japan

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**#282 Track 15 – STATISTICAL SCIENCE AND QUANTITATIVE THINKING**

**Related Interest Area(s): CR, RA, CDM**

**4:00–5:30 pm**

**LEVEL:** 

**FORMAT:** SESSION

**Room 157AB**

**CME and Nursing**

**Session Title:** Analysis Data Standards: Developing, Applying, Submitting and Reviewing

**Chairperson:**

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, Office of Translational Science, CDER, FDA

**Panelists:**

- **Clinical Trial Data: Open For All? Recent Developments at EMA**
  Frank Pétavy
  Biostatistician, Human Medicines Development and Evaluation, European Medicines Agency, European Union

- **ISAP and ADaM Datasets: Keys to Developing Integrated Safety Analyses**
  James Zuazo
  Senior Biostatistician, MMS Holdings Inc.
ADaM Double-Header: ADaM Therapeutic Area Standards and Considerations for Ensuring the Successful Submission and Review of ADaM Data
Dana J. Soloff, MS
Senior Director, Standards and Architecture, Genzyme Corporation, A Sanofi Company

#283 Track 16A – Professional Development
Related Interest Area(s): CR, RA, PT
4:00–5:30 pm LEVEL: ● FORMAT: SESSION
Room 103 CME and Nursing
So You Want to Foster Innovation: A Neuroscience Primer on How Creative Ideas Arise from the Brain
CHAIRPERSON
C. Latham Mitchell, MD
Managing Principal, Erudita Biotechnical LLC
“So much talent. So little creativity.” Be you manager or frontliner, has this thought crossed your mind? Those interested in finding out how to tap the innovator in oneself or others won’t want to miss this thought-provoking and informed session.
Creativity, Leadership and Your Brain
Kanchna Ramachandran, PhD
Postdoctoral Fellow, Department of Psychiatry, University of Iowa Hospitals and Clinics
Creativity: Causes and Consequences
Tad Waddington, PhD
CEO, Lasting Contribution ? LLC

#284 Track 16B – Professional Development
Related Interest Area(s): PT, CR, RA
4:00–5:30 pm LEVEL: ■ FORMAT: WORKSHOP
Room 157C
Advanced Presentation Skills
CHAIRPERSON
Lauren Edelstein Henry, MEd
Principal Operational Specialist, Janssen Pharmaceutical Companies of Johnson & Johnson
This workshop will delve deeper into issues encountered when presenting. Topics include making the most of presenting remotely, analyzing your audience to create better presentations and how to present to senior management.
This workshop will also be offered on Tuesday, June 25, at 10:15 AM (#238).

**Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

#285 Track 17 – Rare/Orphan Diseases
Related Interest Area(s): CR, PT, RA
4:00–5:30 pm LEVEL: ■ FORMAT: SYMPOSIUM
Room 154 CME and Nursing
Development for Rare Disease Treatments
CHAIRPERSON
Jurgen Venitz, MD, PhD
Professor, Pharmaceuticals, Virginia Commonwealth University
This symposium will review various aspects of therapy development for rare (orphan) diseases. The difficulties and trade-offs in developing a comprehensive patient registry to assess natural disease progression and treatment effects will be highlighted using pemphigoid as a case example. The role and limitations of (observational) natural history studies instead of/or in addition to placebo-controlled clinical trials within the framework of drug development and approval for enzyme replacement therapies will be discussed. Finally, a case study will be presented where a pharmaceutical company was able to successfully reach out to the community of tuberous sclerosis complex patients in order to help with orphan drug development.

Planting a Seed: Initiating a Patient Registry in an Ultra-orphan Disease — The Case of Pemphigus and Pemphigoid
Badri Rengarajan, MD
Medical Director, Archimedes Inc.
Are Natural History Studies Helpful to Foster Development of New Drugs for Rare Diseases?
Martine Zimmermann, PharmD
Executive Director, Global Regulatory Affairs, Alexion Pharma International Sàrl, Switzerland
Reaching a Rare Disease Community Eager for Treatment Options
Brian Loew
CEO, Inspire

#286 Track 18 – Global Regulatory
Related Interest Area(s): RA, CR, CP
4:00–5:30 pm LEVEL: ■ FORMAT: FORUM
Room 257AB CME and Nursing
Korea Forum: Introduction to the Korean Ministry of Food and Drug Safety (MFDS) and Government R&D Program
CHAIRPERSON
Yi-Seob Lee, MD, MBA
Executive Member, Korea National Enterprise for Clinical Trials (KoNECT), Korea, Republic of
The Korean Ministry of Food and Drug Safety (MFDS) (formerly the KFDA) has evolved rapidly as one of the leading regulatory agencies in Asia, and the Korean government is initiating several R&D program to promote clinical development. This forum will discuss the current regulatory system and practices from the MFDS and government R&D program.

Overview of Drug Regulation and Clinical Trials
Tae Kyun Nam, MPH
Deputy Director, Korean Ministry of Food and Drug Safety (MFDS), Korea, Republic of
Regulatory Framework for Biosimilar Products in Korea
Jeewon Joung, PhD
Deputy Director, Korean Ministry of Food and Drug Safety (MFDS), Korea, Republic of Government’s R&D Investment Program
Kyung-Sang Yu, MD, PhD, MBA
Associate Professor, Clinical Pharmacology, Seoul National University College of Medicine, Korea, Republic of
#287 Track 19 – Communities Showcase

Related Interest Area(s): CR, RA

4:00–5:30 PM LEVEL: ■ FORMAT: SESSION

Room 205B

The Evolving Clinical Trial Disclosure Global Landscape

CHAIRPERSON
Sarah Doyle Larson
Associate Director, Clinical Operations, Biogen Idec

This session will present the current disclosure landscape, identify important global developments, discuss the potential impact that increased disclosure will have on clinical research, and identify how best to prepare for the future.

This session has been developed by the Clinical Trial Disclosure Community.

Panelists
Rebecca H. Li, PhD
Executive Director, Multi-Regional Clinical Trial (MRCT) Center at Harvard

Jacqueline Cole, MS
Oncology Clinical Operations Portfolio Management, NA Clinical Operations, Eli Lilly and Company

#288 Track 20 – Executive Program

Related Interest Area(s): CR, RA, SP

4:00–5:30 PM LEVEL: ■ FORMAT: FORUM

Room 205A

CME and Nursing

Where Research, Medicine and Care Converge: A CMO Roundtable Discussion

CHAIRPERSON
Michael Rosenblatt, MD
Executive Vice President and Chief Medical Officer, Merck & Co., Inc.

Patients today confront challenges that reach far beyond the diagnosis itself, such as what information to believe, understanding that information, and how to apply it to achieve better health. Today's chief medical officers reside squarely at the intersection of innovation, patient advocacy, safety and well being, and communication, and play a unique role in their respective organizations. This panel of chief medical officers will discuss their responsibilities to patients and in improving health care in an evolving landscape.

Panelists
Tim Garnett, MD
Chief Medical Director and Senior Vice President, Eli Lilly and Company

Edmund Pezalla, MD, MPH
National Medical Director, Pharmacy Policy and Strategy, Aetna

Richard L. Schilsky, MD
Chief Medical Officer, American Society of Clinical Oncology

Valentin Fuster, MD, PhD
Physician-in-Chief, Mount Sinai Medical Center

#289 Track 22 – White Paper Showcase

Related Interest Area(s): CR, CDM, IT

4:00–5:30 PM LEVEL: ● FORMAT: SESSION

Room 203

Four Ways to Accelerate Clinical Portfolio Strategy

CHAIRPERSON
Larissa Comis-Tis, MA
Director, Product Strategy, Clinical Solutions, Thomson Reuters

This white paper presentation addresses several practical problems with regard to clinical development and research, and it identifies practical real-world solutions that have been built and implemented in a large biopharmaceutical organization. This includes, among other things, identifying the elements necessary to turn the overwhelming amount of data being created and consumed by the industry into actionable insight that can be used to make successful decisions in a way that is replicable and understandable throughout the organization of a large biopharmaceutical company.

Brought to you by Thomson Reuters.

**Attendee badges scanned for this White Paper Showcase will be shared with the company hosting this offering. If you prefer to not have your badge scanned, please inform the DIA staff member.

#290 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, RA

5:30–7:30 PM

Movie Documentary: RARE

CHAIRPERSON
Karen E. Jaffe, MBA, MS, MSc, RAC
Regulatory Research, Alfred Mann Institute

RARE tells the story of Donna Appell, an extraordinary mother, in a race against time to get a clinical trial going to treat her daughter’s rare genetic disease; the heartbreak when her daughter Ashley, whose disease is advancing with her age, is excluded from the trial; a surprising love story when Ashley falls in love with an earnest young man who also has Hermansky Pudlak Syndrome; and the intimate, intricate relationship between a research scientist and the patients to whom he inevitably becomes emotionally attached. Along the way, the film profiles the extraordinarily joyful, funny, resilient, and loving group of people who have HPS—blind, albino, and suffering from terrible chronic lung and stomach disease, they nonetheless remind us of the importance of love, hope, and community in the face of adversity.

Seats are limited: Advanced ticketing: First come, first serve.

To obtain tickets to screen RARE, please visit the Attendee Registration Desk no later than Monday at 5:00 PM. **Please note that the DIA Courtesy Shuttle will not be available.

5:30 PM

END OF TUESDAY OFFERINGS
### #300 Track 01A – CLINICAL OPERATIONS

**Related Interest Area(s): CR, ST, SUBs**

**Room 205C**  
**Format:** SESSION  

**Clinical Trial Design for Optimal Patient Recruitment and Retention**  
**Chairperson:** William W. Gwinn, Jr., MBA  
Vice President, Clinical Informatics Solutions, OptumInsight

This session will bring together representatives from health information, sponsor, pharmaceutical manufacturing and academic organizations to show how to use medical statistics for better planning and faster clinical trials. We will cover national tools and best practices for using data.

**Patient Recruitment Using Electronic Medical Records**  
**Pete Fronte, MBA**  
President, Altura

**Sources for Conducting Indication and Study Level Feasibilities and Tactics for Site Identification and Patient Enrollment**  
**Sarah Luijters, PMP**  
Director, Study Feasibility and Patient Recruitment, Forest Research Institute

**Using Patient Records at the Site Level for Clinical Trials**  
**Damon Michaels**  
Director, Clinical Trials Research, Vanderbilt University Medical Center

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### #301 Track 01B – CLINICAL OPERATIONS

**Related Interest Area(s): IS, CR, RD**

**Room 206AB**  
**Format:** SYMPOSIUM  

**Understanding Operational Feasibility:**  
A Discussion of Current Methodologies, Primary Research Limitations and Opportunities  
**Chairperson:** Nicole Turner, MBA  
Associate Director, Global Feasibility, Quintiles Inc.

This symposium will discuss the four pillars that support a comprehensive operational feasibility assessment for clinical trial planning from a CRO and sponsor perspective: Internal/proprietary data analysis, commercial/publicly available data analysis, primary investigator and patient research, and industry expert input/guidance. In addition, we will provide details regarding the limitations of primary investigator research at early stages of clinical planning, including a specific quantitative analysis of investigator estimates at the feasibility stage versus actual enrollment performance during study participation. Finally, we will discuss areas of opportunity for leveraging the value of investigator input and provide specific examples of how this has been done successfully from a sponsor perspective.

**Investigator Enrollment Estimates: An Assessment of Accuracy in Comparison to Actual Enrollment Performance**  
**Nicole Turner, MBA**  
Associate Director, Global Feasibility, Quintiles Inc.

**Innovative Approach to Clinical Trial Feasibility Through an Investigator Consultation Network**  
**Lisa Palladino Kim, MS**  
Global Trial Optimization Specialist, Inventiv Health Clinical

**Establishing the Four Pillars of Data-driven Feasibility: Best Practices and Tools for Patient Recruitment Planning**  
**Travis D. Caudill**  
Director, Feasibility & Site Identification, INC Research

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### #302 Track 02A – PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING

**Related Interest Area(s): CR, FI, RD**

**Room 104C**  
**Format:** SESSION  

**Cost Management for Global Drug Development Projects**  
**Chairperson:** Mark A. Kryah  
Advisor, Pharmaceutical Project Management, Eli Lilly and Company

What are the key aspects in developing and managing budgets for drug development projects? How are changes handled? These questions and others, as well as the role of the project manager in cost management, will be explored.

**Fiscal Oversight in Clinical Operations Improves Financial Forecasting in an Early Development Portfolio**  
**Mick O’Quigley, MBA**  
Program Group Leader, Genentech, A Member of the Roche Group

**Role of the Project Manager in Cost Management**  
**Carolyn K. O’Leary, MBA, PMP**  
Associate Director, Global Project Management, Merck & Co., Inc.

**R&D Cost Planning, Management and Control Processes in the Pharmaceutical Industry**  
**Frank P. DePaoli**  
Director, Pharmaceutical/Life Sciences R&D, PricewaterhouseCoopers LLP
**Wednesday, June 26**

### #303 Track 02B – Project/Portfolio Management and Strategic Planning

**Related Interest Area(s): CR, CP**

8:00–9:30 AM  
**LEVEL:**  
**FORMAT:** SESSION

Room 205B  
**CME and Nursing**

**Stop Moving the Goalposts: A Life Cycle Approach to Risk-based Quality Management in Clinical Development**

**CHAIRPERSON**

Barbara Leishman, MA  
External Business Alliance Leader, F. Hoffmann-La Roche Ltd., Switzerland

This session will highlight the value of a product life cycle approach to prospective quality optimization, as opposed to a study-by-study approach, and provide real life experience in the risk-based design and management of a product life cycle.

**Integrated QRM Across the Clinical Development Life Cycle**  
Kenneth J. Sprenger, MD  
Executive Director, Medicine Team Leader, Pfizer Inc

**Regulatory Life Cycle Management: A Risk-based Approach**  
Mary Christian, PharmD  
Executive Director, Mature Products and Geographic Optimization, Bristol-Myers Squibb Company

**Planning and Managing the Safety Life Cycle of a Product: A Risk-based Approach to Quality**  
Barbara Leishman, MA  
External Business Alliance Leader, F. Hoffmann-La Roche Ltd., Switzerland

### #304 Track 03A – Innovative Partnering Models and Outsourcing Strategies

**Related Interest Area(s): CR, RD, RA**

8:00–9:30 AM  
**LEVEL:**  
**FORMAT:** FORUM

Room 102AB

**Evolving to Functional Service Providers (FSP): Successfully Transforming Existing Partnerships into FSP Relationships**

**CHAIRPERSON**

Andrew Townshend  
Vice President, Alliance Development, INC Research

As expertise continues to transfer from pharma to CROs, how can the industry continue to drive improvement and innovation? One approach is the evolution of functional service provider (FSP) relationships. This forum brings together experts to discuss their successful approaches.

**Panelist**

Peter A. Carberry, MD, MBA  
Senior Vice President, Global Development Operations, Astellas Pharma Global Development, Inc.

### #305 Track 03B – Innovative Partnering Models and Outsourcing Strategies

**Related Interest Area(s): SP, CR, IT**

8:00–9:30 AM  
**LEVEL:**  
**FORMAT:** SESSION

Room 104AB

**Unique Nonprofit-Industry Partnerships to Develop and Disseminate Technology**

**CHAIRPERSON**

Badri Rengarajan, MD  
Medical Director, Archimedes Inc.

There are several barriers to developing and disseminating technology, including small scale of producer, lack of complete patient population data, and unfavorable economics/governance. Nonprofit-industry partnerships can help overcome these barriers. This session will present three examples highlighting unique aspects of the collaborations: A foundation's $16 million funding effort to disseminate technology for simulating virtual patient populations, the Merck-Regenstrief Institute partnership and the co-development and dissemination of technology to support real-world evidence-based research and health care innovation, and a university's direct investment in creating its own startups.

**Unique Foundation-Industry Partnership to Disseminate Novel Virtual Population Simulation Technology**  
Brian Quinn, PhD  
Team Director and Senior Program Officer, Robert Wood Johnson Foundation

**Merck-Regenstrief Partnership: An Academic-Pharmaceutical Company Partnership**  
Patrick Michael Loerch, PhD  
Director, Health Informatics, Merck & Co., Inc.

**A University’s Direct Investment in Creating Its Own Startups**  
Ralph Lin, PhD  
Global Strategy and Corporate Development Officer, Shin Nippon Biomedical Laboratories, Japan

### #306 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

**Related Interest Area(s): NC, CR, RD**

8:00–9:30 AM  
**LEVEL:**  
**FORMAT:** SESSION

Room 105  
**CME, Pharmacy and Nursing**

**Molecular Imaging: Utilizing It as an Effective Drug Development Tool**

**CHAIRPERSON**

Todd E. Peterson  
Director, Nuclear Imaging; Associate Professor, Radiology and Radiological Sciences, Vanderbilt University

Molecular imaging (MI) can assist in the development of new drugs. It can provide MI biomarkers that can be utilized in trials as endpoints for clinical outcomes. In this session, we will discuss the development of MI biomarkers and their use in drug development.

**Development of Molecular Imaging Probes**

Jonathan McConathy, MD, PhD  
Assistant Professor of Radiology, Department of Radiology, Washington University

**In Vivo Preclinical Molecular Imaging in Therapeutic Drug Development**

Todd E. Peterson  
Director, Nuclear Imaging; Associate Professor, Radiology and Radiological Sciences, Vanderbilt University
As companies and our industry evolve, it is imperative for communications to effectively connect the internal drivers of scientific and medical content, Medical Science Liaisons, Medical Communications, and Medical Writing to meet customer needs. Best practices for working cross-functionally and an overview of tools for measuring success will be discussed. This session will discuss how each of these functional areas contributes to the overall scientific interface with both customers and health care professionals.

**Design and Implementation of Molecular Imaging Endpoints in Multicenter Therapeutic Drug Trials**

Jeffrey T. Yap, PhD
Senior Diagnostic Physicist, Dana-Farber Cancer Institute

**Tethering the Channels of Scientific and Medical Content**

J. Lynn Bass, PharmD, RPh
Director, Medical Scientists, Jazz Pharmaceuticals

Scientific communications are integral in channeling the activities within the clinical, medical, regulatory and other functional areas of pharmaceutical companies to ensure the safe and effective utilization of medications. As the internal drivers of scientific and medical content, Medical Science Liaisons, Medical Communications, and Medical Writing functions are being utilized to guide these communication channels and are responsible for the scientific interface with both customers and health care professionals. As companies and our industry evolve, it is imperative for communications from each of these functions be streamlined and coordinated. This session will discuss how each of these functional areas contributes to the overall scientific communications strategy in their unique modes. Best practices for working cross-functionally and an overview of tools for measuring success will be discussed.

**Medical and Scientific Content**

Jennifer Kern Sliwa, PharmD, RPh
Director, CNS Medical Information, Janssen Scientific Affairs, LLC

James Stephen Dodge, PharmD, MBA
Executive Director, Diabetes Field Medical Affairs, Novo Nordisk

**Medical Writing Contribution to Medical Communication Designed to Meet Customer Needs**

David B. Clemow, PhD
Senior Clinical Research Scientist, Eli Lilly and Company

**Enhancing Regulatory Science and Expediting Drug Development: eClinical and eHealth Tools**

Ron Fitzmartin, PhD, MBA
Senior Advisor, Office of Planning and Informatics, CDER, FDA

This session will be an interactive FDA panel focused on eClinical and eHealth tools and guidance to enhance regulatory science and expedite drug development. The audience will actively participate throughout the session.

**Panelists**

Leonard V. Sacks, MD
Associate Director for Clinical Methodology, Office of Medical Policy, CDER, FDA

Mitra Rocca, MS
Senior Medical Informatician, Office of Translational Science, CDER, FDA

Jonathan S. Helfgott, MSc
Operations Research Analyst, Office of Scientific Investigations, Office of Compliance, CDER, FDA

**FDASIA: Impact of New Legislative Provisions on Innovative Drug Development**

Janet Jenkins-Showalter
Senior Regulatory Group Director, Regulatory Policy and Intelligence, Genentech, A Member of the Roche Group

The Food and Drug Administration Safety and Innovation Act (FDASIA) was implemented on October 1, 2012. This session will discuss how regulatory professionals need to understand the terms of the FDASIA provisions and the impact they have on the drug and device development and review process, and effectively assess FDA’s progress thus far.

**Panelists**

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

BIO Point of View
Andrew Emmett, MPH
Managing Director, Science and Regulatory Affairs, The Biotechnology Industry Organization (BIO)
**NORD Point of View**
Diane D. Edquist Dorman  
Vice President, Public Policy, National Organization For Rare Disorders (NORD)

**#311 Track 08B – Regulatory Affairs and Submissions**  
Related Interest Area(s): OS, SUBS  
8:00-9:30 AM  
LEVEL: ●  
FORMAT: SESSION  
Room 253B  

**Regulatory Operations: Types and Industry Trends of Outsourcing the Life Cycle Management of Your Electronic Submissions**  
CHAIRPERSON  
Janel Demeter  
Manager, Regulatory Operations, Accenture LLP  

This session will focus on the value proposition of outsourcing the life cycle management of your eSubmission documents. It will harness expertise and best practices based on hands-on knowledge, past problems solved, and developing a strategic approach to the submission process to prevent issues before they happen. This session will include a case study focused on applying the large pharma models to small pharma companies and include details of a specific client engagement and lessons learned. It will also illustrate best practices, and perceived barriers and solutions based on experience. Discussions will also focus on what you should expect out of your strategic outsourcing partnership.

Is Outsourcing Right for You? Outsourcing Trends Focusing on Small to Midsize Pharmaceutical Companies  
Janel Demeter  
Manager, Regulatory Operations, Accenture LLP  

Outsourcing Full Electronic Submission Services for Initial Applications and Life Cycle Maintenance  
Sunita Reddy Nalla, MS  
Associate Director, Regulatory Operations, Aveo Pharmaceuticals, Inc.  

Outsourcing: Transitioning Document Support Activities to an Offshoring Model  
Aaron Miller  
Alliance Manager, Labeling & Submissions Management, Janssen Research & Development, LLC

**#312 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products**  
Related Interest Area(s): RA  
8:00-9:30 AM  
LEVEL: ■  
FORMAT: SESSION  
Room 253C  

**How to Convert a New Device (PMA) into an Old (510(k)) Device: The De Novo 510(k)**  
CHAIRPERSON  
Michael A. Swit, Esq, JD  
Special Counsel, Duane Morris, LLP  

Under the 1976 Device Amendments, new technology that is not substantially equivalent to a marketed device is automatically put in Class III. This session reviews how to get that class switched to a less risky, less expensive regulatory path.

Overview of the De Novo Process  
Michael A. Swit, Esq, JD  
Special Counsel, Duane Morris, LLP

**#313 Track 10 – Public Policy/Health Care Compliance/Law**  
Related Interest Area(s): RA, CR, FI  
8:00-9:30 AM  
LEVEL: ■  
FORMAT: SESSION  
Room 154  

**Using Legislation to Advance Regulatory Science: “I’m Just a Bill...”**  
CHAIRPERSON  
Karen E. Jaffe, MBA, MS, MSc, RAC  
Regulatory Research, Alfred Mann Institute  

Several legislations have been introduced calling for regulatory reform for the drug approval process. FDA is under pressure from industry to enable a regulatory framework for translational medicine but at the same time preserve the public health. This session will discuss impacts to the pharmaceutical industry and investment community as well as the patient community.

Panelists  
Juergen Froehlich, MD, MBA, FFPM  
Vice President, Global Regulatory Affairs, Vertex Pharmaceuticals  

Marc M. Boutin, Esq, JD  
Executive Vice President and Chief Operating Officer, National Health Council  

Steven Walker  
Co-founder, Abigail Alliance  

Carla Mann Woods  
CEO and Founder, Fight to Live

**#314 Track 11 – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)**  
Related Interest Area(s): GCP, RA, CR  
8:00-9:30 AM  
LEVEL: ■  
FORMAT: SESSION  
Room 156AB  

**How Will Risk-adapted Clinical Trials Be Inspected?**  
CHAIRPERSON  
John Poland, PhD  
Senior Director, Regulatory Policy and Compliance, Covance Clinical Development Services, United Kingdom  

The particular challenges posed by GCP inspection of a risk-adapted clinical trial, and how they may be addressed, will be analyzed and discussed in terms of regulatory agency expectations and practical examples.

FDA Point of View  
Ann Meeker-O’Connell, MS  
Director, Division of GCP Compliance (Acting), Office of Scientific Investigations, Office of Compliance, CDER, FDA  

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

Industry Point of View  
Mike Sobczyk, MSc  
Senior Director, Regulatory Compliance, Gilead Sciences, Inc.
**#315 Track 12A – Pharmaceutical Quality**

**Related Interest Area(s): RA, CR**

8:00–9:30 AM  LEVEL: ●  FORMAT: WORKSHOP

Room 156C  CME and Nursing

**How to Prepare for Meetings, Both Internal and with the FDA**

**CHAIRPERSON**

Antoinette Paone, MBA, MSc
Senior Director, Global CMC Regulatory Affairs Strategy, Vertex Pharmaceuticals

Meetings with the FDA are an important and essential tool for industry sponsors to identify and discuss critical review issues. This workshop will present a thoughtful and organized approach to meeting preparation that fosters Industry and Agency collaboration and assists in achieving meeting goals.

**Facilitators**

Bink Garrison
President, Bink, Inc.

Stephanie Krogmeier, PhD, RPh
Director, Global CMC Regulatory Affairs Strategy, Vertex Pharmaceuticals

**#314 Track 12B – Pharmaceutical Quality**

**Related Interest Area(s): RA, CP, CMC**

8:00–9:30 AM  LEVEL:  FORMAT: FORUM

Room 153C  CME and Nursing

**Current Developments in the Automated NDA Field Alert Reporting Project**

**CHAIRPERSON**

Mark W. Browning, Esq, JD
Consumer Safety Officer, Office of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

This session will discuss the phase 1 pilot for development of an automated form used to submit data from the manufacturer to the Office of Regulatory Affairs and Office of Manufacturing and Product Quality.

**New ORA/CDER Field Alert Reporting Initiative**

Karen E. D’Orazio
Pre-Approval Manager, Office of Regulatory Affairs, FDA

**Electronic NDA Field Alert Reports: Industry Perspective**

Hitesh A. Patel
Product Manager, Pharma Technical Regulatory, Hoffmann-La Roche Inc.

**NEW ORA/CDER Field Alert Reporting Initiative**

Mark W. Browning, Esq, JD
Consumer Safety Officer, Office of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

**#317 Track 13 – Health Economics and Outcomes**

**(HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)**

**Related Interest Area(s): CR, PR, PT**

8:00–9:30 AM  LEVEL:  FORMAT: SESSION

Room 151B  CME, Pharmacy and Nursing

**The Environment for Health Care Decision-making: Collecting, Using and Understanding Comparative Effectiveness Research**

**CHAIRPERSON**

Kimberly Westrich, MA
Director, Health Services Research, National Pharmaceutical Council

This session will provide an overview of how stakeholders view the environment for health care decision-making, an in-depth look at how payers view and use comparative effectiveness research (CER) studies for these decisions, and an innovative way to collect patient data needed for these CER studies.

**Monitoring Changes in the Environment for Health Care Decision-making**

Kimberly Westrich, MA
Director, Health Services Research, National Pharmaceutical Council

**Translating CER into Medical Payment Policy: Views from Public and Private Payers**

Joel S. Weissman, PhD
Associate Professor, Health Policy, Harvard Medical School

**Working Directly with Patients to Collect HEO/CER Data Using Innovative Hybrid Observational Research Models**

John Reites, Jr.
Director, Operations, Quintiles Inc.
Chemical Structure in Pharmacovigilance: Molecular Predictors of Drug-induced Harm
Niklas Noren, PhD
Chief Science Officer, Uppsala Monitoring Centre (UMC), Sweden

#319 Track 14B – Clinical Safety and Pharmacovigilance

Pharmacovigilance Update for Japan, Developing Asia and Latin America

8:00–9:30 am LEVEL: ■ FORMAT: SESSION
Room 153AB CME and Nursing

Stewart Geary, MD
Vice President, Chief Medical Officer, Director, Corporate Medical Affairs HQ, Eisai Co., Ltd., Japan

In spite of ICH activities, there are tremendous gaps between Japanese and western (US and Europe) pharmacovigilance practices. Recent implementation of EU GVP module made this gap evident. Pharmacovigilance systems, procedures, even the concept, are so different, which makes Eastern companies safety information and practices with western companies. From ICSR technical submission to regulations, there are differences which the companies cannot overcome or harmonize. In this session, the differences are compared in respect of pharmacovigilance systems, SOPs, internal audits, risk management, and finally regulatory inspections. Pharmacovigilance regulations continue to evolve rapidly in the developing Asian and Latin American countries. Increasingly these countries require not only that local adverse reaction reports are expedited but that adverse reactions from foreign countries are reported along expedited timelines during clinical development and postmarketing. There is also growing interest in risk management plans (RMP) and an interest in RMPs that companies have submitted to regulatory authorities elsewhere in the world.

This session will review the current status of pharmacovigilance and provide suggestions on how to meet reporting requirements and working with licensing partners and affiliated companies in Japan and the developing world in Asia and Latin America.

Gaps between East and West: Pharmacovigilance Practice and Concept
Teiki Iwaoka, PhD, MS
Executive Consultant, Director of Drug Safety Outsourcing Planning, CAC EXICARE Corporation, Japan

Pharmacovigilance Regulations and Risk Management Plans in Developing Asia
Stewart Geary, MD
Vice President, Chief Medical Officer, Director, Corporate Medical Affairs HQ, Eisai Co., Ltd., Japan

Pharmacovigilance in Latin America
Sheila Przybysz
Safety Manager, Allergan Pharmaceuticals Ltd, Brazil

#320 Track 15 – Statistical Science and Quantitative Thinking

Quantitative Benefit-risk in the Current Regulatory Environment and the Implications for Clinical Statisticians

8:00–9:30 am LEVEL: ■ FORMAT: SESSION
Room 157AB CME and Nursing

Susun P. Duke, MS
Manager, Benefit/Risk Evaluation, Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline

Benefit-risk in clinical development is increasingly important to statisticians, as interest from regulators in more formal methods increases. We will describe decision science and statistical approaches, and what more statisticians can do in this area.

An Example of Benefit-risk Analysis Applying the BRAT Framework
Conny Berlin, MS
Global Head, Quantitative Safety Function, Novartis Pharma AG, Switzerland

A Regulator’s View of Quantitative Benefit-risk Analysis
Jonathan D. Norton, PhD
Mathematical Statistician, Division of Biometrics V, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Benefit-risk Evaluation: Concepts and Methods
Scott Evans, PhD
Senior Research Scientist, Harvard University School of Public Health

#321 Track 16 – Professional Development

How Economic and Technological Change Can Affect Professional Expectations: Case Studies in Succeeding in the Midst of Change

8:00–9:30 am LEVEL: ■ FORMAT: SESSION
Room 103 CME and Nursing

Elizabeth Lincoln, MA
Worldwide Director, Human Resources, DIA

When external pressures create a need for new professional standards, they also create opportunities for entirely new definitions of individual roles and institutional competencies. This often requires more than just training people on new skills; it requires wholesale transformation of professions, professional standards and even organizational culture. This session will present two cases where this type of professional (re)definition occurred in response to growing pressures to provide new skills and standards in given professions. We will look at the elements that support sustained professional development and culture change that are definable and repeatable in all organizations.

Patron-driven Acquisition Is Here to Stay: How Libraries Can Benefit
Ryan Jones, MBA
Senior Director, Business Development, Pubget

Personnel and Clinical Site Certification and Academic Program Accreditation: Ensuring Quality for Clinical Research
Stephen A. Sonstein, PhD, MS
Director, Clinical Research Administration Program, Eastern Michigan University
Models for Genomic Research Success: Empowering Patient-Researcher Relationships and the Emerging Role of Crowd Sourcing in Rare Disease Research

Chairperson
Jimmy Lin, MD, PhD
CEO, Rare Genomics Institute

This session will provide a review of successful genomic studies that have been driven by strong patient-investigator relationships, and the recent role of social media and crowd sourcing in rare disease studies. It will include a case study of the identification of the first genetic causal mechanism for postural orthostatic tachycardia syndrome (POTS) due to an altered norepinephrine transporter reuptake process. Recent advances in genome sequencing technology, coupled with the rise of social media, have opened new models for research funding for rare disease. The role of nonprofit organizations in connecting genomic researchers, patients, and internet-based funders, as well as success stories from this new model, will be discussed.

The Power of Large-scale Genomic Approaches for the Diagnosis of Rare Diseases
Daniel P. Smith
President, National Dysautonomia Research Foundation

Patient-Researcher Interactions
Jan Teller
Science Officer, Dystonia Medical Research Foundation

New Mechanisms for Researching Rare Disorders
Jimmy Lin, MD, PhD
CEO, Rare Genomics Institute

The Power of Large-scale Genomic Approaches for the Diagnosis of Rare Diseases
Daniel MacArthur, PhD
Group Leader, Analytic and Translational Genetics Unit, Massachusetts General Hospital

Collaborating to Streamline Drug Development: Are We Making Progress?

Chairperson
Douglas J. Peddicord, PhD
Executive Director, Association of Clinical Research Organizations

Ever since 2004 when the FDA released its “Critical Path” white paper, there has been broad agreement that the drug development enterprise needs “new tools to get fundamentally better answers about how the safety and effectiveness of new products can be demonstrated, in faster time frames, with more certainty, and at lower costs.” Over nearly a decade, a number of academic-industry/public-private collaboratives that aim to transform or accelerate clinical trial processes and product development have been convened. In this forum, leaders of TransCelerate Biopharma Inc (TransCelerate) and the Clinical Trials Transformation Initiative (CTTI) will provide a status report on current projects, with additional perspectives provided by representatives of the FDA, the Association of Clinical Organizations (ACRO), and the Society for Clinical Research Sites (SCRS).
Panelists
Dalvir Gill, PhD
CEO, TransCelerate Biopharma Inc

Pamela Tenaerts, MD, MBA
Executive Director, Clinical Trials Transformation Initiative (CTTI), Duke Translational Medicine Institute

Patrick Archdeacon
Medical Officer, Office of Medical Policy, CDER, FDA

Christine K. Pierre, RN
President, Society for Clinical Research Sites

9:30–10:15 AM  COFFEE BREAK

#326 Track 01A – CLINICAL OPERATIONS
Related Interest Area(s): CR, IS, SUB
10:15–11:45 AM  LEVEL: ■  FORM: SYMPOSIUM
Room 205C  CME and Nursing
Driven by Data: More Effective Strategies to Reach Your Patient Recruitment Goals
CHAIRPERSON
Julie Parmelee
Director, Patient Recruitment, Quintiles Transnational Corp.
Finding and enrolling the right patients is the most critical factor in completing a clinical trial on time. In an industry focused on data, how can you gain insights and leverage new data sources to craft more effective patient recruitment strategies? This symposium discusses the use of investigator experience, clinical data and Electronic Medical Records (EMR) in developing a recruitment program that is targeted to the specific needs of your protocol and can efficiently deliver on your study goals.

One Global Plan Does Not Fit All: Investigators’ Perspectives on the Most Effective Patient Recruitment Approaches
Julie Parmelee
Director, Patient Recruitment, Quintiles Transnational Corp.

Using Alert-driven Patient Recruitment to Accelerate Clinical Research
Daniel Carnese, MS
CEO, KDH Systems

Applying Mathematical Algorithms to Individual Electronic Medical Records to Identify Subjects for Clinical Trials
Don Morris, PhD
Vice President, Scientific Products and Technology, Archimedes Inc.

#327 Track 01B – CLINICAL OPERATIONS
Related Interest Area(s): IS, CR
10:15–11:45 AM  LEVEL: ■  FORM: SYMPOSIUM
Room 205B  CME and Nursing
Study Startup Symposium
CHAIRPERSON
Mary Jo Lamberti, PhD, MA
Senior Project Manager, Tufts Center for the Study of Drug Development, Tufts University
This symposium will examine key metrics within the clinical trial initiation process, and the first presentation will present the results of aggregate company data. Data from studies completed during 2008-2011 were analyzed across study and site level. A second presentation will examine those strategies and approaches that drive efficiencies during study startup including protocol review, targeted site identification and streamlined regulatory document collection. The third presentation will examine various solutions to conduct efficient investigator meetings.

Benchmarking the Study Startup Process
Mary Jo Lamberti, PhD, MA
Senior Project Manager, Tufts Center for the Study of Drug Development, Tufts University

Moving Investigator Meetings into the 21st Century
Leslie (Mi Ok) Chong, MA
Senior Clinical Program Leader, Genentech, A Member of the Roche Group

Insights to Accelerate Your Clinical Trial: How Proactive Planning in Study Startup Drives Efficiencies in Drug Development
Shyla VanReenen
Senior Manager, Clinical Operations, Synteract, Inc.

#328 Track 01C – CLINICAL OPERATIONS
Related Interest Area(s): CP, CR, IS
10:15–11:45 AM  LEVEL: ■  FORM: SYMPOSIUM
Room 206AB  CME and Nursing
Meeting the Operational Challenges of Risk-based Monitoring: Investigator and Sponsor Perspectives
CHAIRPERSON
Donna W. Dorozinsky, MSN, RN
President, DWD & Associates, Inc.
This symposium will explore the changing regulatory landscape and novel approaches to risk-based monitoring. Risk-based monitoring puts new demands on the both the sponsor and investigator site. This symposium will offer solutions to meeting some of the many operational challenges of risk-based monitoring. It will also examine the impact of this guidance on the site from both the site perspective and the site monitoring perspective. It will also provide useful tips for successful site management and the identification of high quality sites that are prepared to thrive in this changing regulatory environment.

Preparing the Investigator Site for Risk-based Monitoring
Donna W. Dorozinsky, MSN, RN
President, DWD & Associates, Inc.

Risk-based Monitoring: The New Regulatory Landscape and Conjectures on the Future of Clinical Trial Execution
Amanda Julie Sax, RN
Senior Director, Integrated Processes and Technologies, Quintiles Transnational Corp.

Central Statistical Monitoring in Action
François Torche
CEO, Cluepoints
#329 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PETD, PM

10:15–11:45 AM LEVEL: ● Format: FORUM

Room 104C

So You Want to Be a Project Manager: How to Find Your Way to a Challenging and Rewarding Career

CHAIRPERSON

Karla Childers, MS
Associate Director, Project Management, Merck Research Laboratories

Participants will gain insight into changing careers into project management (PM) from individuals currently employed in the field. Basic PM concepts and helpful hints on résumé building and training/networking will also be discussed.

Panelists

Nita Ichhpurani, PMP
Director, Drug Development, Celerion, Canada

Kristen Snipes
Senior Project Manager, Rho, Inc.

Jim L. Vandergriff, II
Pharmaceutical Project Management, Eli Lilly and Company

#330 Track 03a – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): SP, CR, IS

10:15–11:45 AM LEVEL: ■ Format: SESSION

Room 102AB

Innovative Strategies for Evolving Sponsor, CRO and Site Alliances

CHAIRPERSON

Mick O’Quigley, MBA
Program Group Leader, Genentech, A Member of the Roche Group

The session will outline three perspectives on delivering improved outcomes using integrated alliance methodologies: the sponsor perspective on implementing a portfolio oversight committee to improve partnership alignment, integrated resourcing, early partnering and process improvements on an outsourced portfolio; the CRO perspective on building an integrated business unit by investing in the partnership; and the investigative site network perspective on bridging communication between site, CRO and sponsor.

Panelists

Strategies for Evolving a Sponsor/CRO Alliance to the Next Level: A Sponsor Perspective
Mick O’Quigley, MBA
Program Group Leader, Genentech, A Member of the Roche Group

Strategies for Integrating a Sponsor/CRO Alliance into a CRO Business Model
Michael Henning, BSN, MBA
Director, Project Management, PPD

Lisa Marks
Director, Business Development, PharmaSeek

#331 Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, RD, CP

10:15–11:45 AM LEVEL: ■ Format: FORUM

Room 104AB

Project Data Sphere: Clinical Trial Data-sharing in Cancer to Accelerate Innovation and Enhance Patient Health

CHAIRPERSON

Angela L. Lightfoot
Director, OnDemand Health and Life Sciences Consulting, SAS Institute Inc.

Project Data Sphere is a cancer data-sharing collaboration supported by over 30 pharmaceutical companies, academic institutes, and advocacy organizations with one goal: To safely and openly share clinical trial data to advance our understanding of cancer therapy.

Panelists

Planting Oak Trees, Not Acorns
Ronit Simantov, MD
Senior Director, US Medical Affairs, Oncology, Pfizer Inc

Project Data Sphere: A Revolution in Cancer Research
Joel Beetsch
Vice President, Patient Advocacy Group, Celgene Corporation

#332 Track 04 – Nonclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): NC, PC, RD

10:15–11:45 AM LEVEL: ■ Format: SESSION

Room 105

Pharmacometrics: Implications and Impact in Preclinical to Early Phase Clinical Development

CHAIRPERSON

Royce A. Morrison, MD, MS
Executive Vice-Chair, Quorum Review, Inc.

Increasingly, sponsors’ and regulators’ decisions in drug programs are being driven by pharmacometric methods. Early phase trials will change to give the right range of data for physiologically- and pharmacologically-based modeling and simulations.

Panelists

Pharmacometrics Drives Drug Approval and Labeling Decisions
Jogarao V. Gobburu, PhD, MBA
Professor, School of Pharmacy and School of Medicine, University of Maryland

Pharmacometrics Impacts Drug Development Decisions:
Big Pharma Experience
Sriram Krishnaswami
Director, Clinical Pharmacology, Specialty Care Business Unit, Pfizer Inc

Opportunities to Take Advantage of Pharmacometrics
Royce A. Morrison, MD, MS
Executive Vice-Chair, Quorum Review, Inc.
#334 Track 07A – Processes and Technologies for Clinical Research

10:15–11:45 AM LEVEL: ■ Format: SYMPOSIUM
Room 251 CME and Nursing

EDC Insights: Before, During, and After

**CHAIRPERSON**

Maryanne C. Nicosia, MS
Director, Clinical Data Management, Neurcrine Biosciences Inc.

This symposium will provide multiple perspectives on selecting, implementing, and getting the most out of an EDC system. Insight will be provided on the factors to consider and the critical questions to ask in order to choose the best EDC platform for an organization or clinical study. Attendees will also learn to determine which EDC-related challenges can be fixed through process re-engineering and change management, which issues truly necessitate switching to a new system, and the challenges and costs associated with moving to a new system. Finally, attendees will hear about current trends for using alternative EDC solutions in postmarketing studies.

**Sessions**

- **Love the One You’re With: The High Costs of Switching EDC Platforms and How to Get the Most Out of Your Current One**
  Kent Mahoney, MBA
  Director, Soltex Consulting LLP

- **Electronic Data Capture: The Importance and Impact of Selecting the Optimum EDC Platform for Your Clinical Program**
  Toby Odenheim, MBA
  Director, IT Services, SynteractHCR, Inc.
Research and Development: Searching for a Cure
Rudolph E. Tanzi, PhD
Head, Genetics and Aging Research Unit; Professor, Neurology, Harvard Medical School, Massachusetts General Hospital

Mobilizing Government, NGOs, and Industry to Prevent Alzheimer’s Disease by 2025
George Vradenburg
Co-Founder/President, USAgainstAlzheimer’s

#337 Track 08B – Regulatory Affairs and Submissions
Related Interest Area(s): CR, PM
10:15–11:45 AM LEVEL: ■ FORMAT: FORUM
Room 253A CME and Nursing
A Comparison of Study Startup Regulations and Timelines in Several Major Emerging Markets and the Decision Process for Selection
CHAIRPERSON
David Passov, MBA
Senior Vice President, Eastern Europe, ClinStar, A PRA Company

The panel will explore conventional definitions of emerging markets; critique advantages and challenges of conducting trials in these markets; and examine study startup regulations/timelines and the decision-making process for entering these markets.

Panelists
Ori Ben-Yehuda, MD, FACC
Vice President, Clinical Research, Gilead Sciences, Inc.
Robert A. Baughman, PharmD, PhD
Senior Vice President, Clinical Sciences, MannKind Corporation
Nancy Widener, MS
Executive Director, Clinical Science and Operations, Bristol-Myers Squibb Company

#338 Track 10 – Public Policy/ Health Care Compliance/Law
Related Interest Area(s): RA, CR
10:15–11:45 AM LEVEL: ■ FORMAT: FORUM
Room 154 CME, Pharmacy and Nursing
Enforcement Trends and Public Policy: Lessons Learned and Practices to Follow
CHAIRPERSON
Barry A. Berger, JD, MBA
Professor of Regulatory Affairs, Temple University

In the context of recent compliance and enforcement trends, this forum will ask and answer such questions as: Should FDA and other government agencies place more of a priority on criminal enforcement? How has the Park doctrine and the Responsible Corporate Officer doctrine evolved, and is this good public policy? What is the significance of recent False Claims and Whistleblower lawsuits? What is the significance of the Foreign Corrupt Practices Act on our global industry? And, what can we learn from past government actions, and how should what we learn impact our future practices?

Panelists
Adolfo R. Garcia, JD
Partner, K&L Gates LLP
Susan G. Winkler
Assistant US Attorney, US Attorney’s Office, District of Massachusetts

#339 Track 12 – Pharmaceutical Quality
Related Interest Area(s): CMC, CP, RD
10:15–11:45 AM LEVEL: ■ FORMAT: FORUM
Room 153AB CME, Pharmacy and Nursing
Drug Shortages: Causes, Current State and Path Forward
CHAIRPERSON
Marta E. Wosinska, PhD
Director for Economics Staff, Office of Planning and Analysis, CDER, FDA

This forum will discuss the history and current state of drug shortages. It will primarily focus on the drivers and consequences of manufacturing quality problems for sterile injectable products.

Economic and Technological Drivers of Sterile Injectable Drug Shortages
Marta E. Wosinska, PhD
Director for Economics Staff, Office of Planning and Analysis, CDER, FDA

Availability of Medicinal Products in the EU
Christa Wirthumer-Hoche, PhD
Deputy Head, Austrian Medicinal and Medical Device Agency (AGES), Austria

Current Trends in Drug Shortages
Erin Fox, PharmD
Director, Drug Information Service, University of Utah Hospitals and Clinics

#340 Track 16 – Professional Development
Related Interest Area(s): PETD
10:15–11:45 AM LEVEL: ■ FORMAT: WORKSHOP
Room 156C CME and Nursing
Successful Mentoring Relationships
CHAIRPERSON
Yasmin de Faria Krim, PharmD, MSc
Manager, Global CMC Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium

This workshop will discuss and brainstorm with potential mentors and mentees on the critical skills of mentors and mentees for successful mentoring relationships, and getting the best out of it.

This workshop has been developed by the Emerging Professionals Community.

“Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

Facilitators
Sandra A. Wiejowski, PharmD, RPh
Senior Director, Global Medical Review, Abbott Laboratories
Susan Morris, MEd
Director, Ment Systems
12:15-1:00 PM  LEVEL: ●
SAS Innovation Theater
Related Interest Area(s): CDM, VA, IT, CP, CER
See the map located on the back of the
Exhibitors tab for location.

Picture This: Bringing Clinical Data to Life
Ready to visually explore data across your research programs — and fast? Within seconds you can understand your data like never before. You’ll gain rapid insights into medication safety profiles, health outcomes, operations forecasts and more. Attend this exciting presentation to see firsthand how SAS® Visual Analytics can bring your research data to life and create picture perfect views for better, faster decision making across your organization.

11:45 AM-1:45 PM  EXTENDED LUNCH

11:45 AM-4:00 PM  PROFESSIONAL POSTER SESSION #2 (EXHIBIT HALL)

#341 TRACK 01 - CLINICAL OPERATIONS
Related Interest Area(s): IT, CDM, CEHTAEbM
1:45-3:15 PM  LEVEL: ■  FORMAT: SYMPOSIUM
Room 205C  CME and Nursing
Using Big Data to Design Smarter Studies
CHAIRPERSON
Jane E. Myles, MS
Global Head, Recruitment Strategy, Genentech, A Member of the Roche Group

It is challenging to design cost-effective trials that can be executed on time, collect just the data that is needed, fit the available patient populations and are attractive to patients. New data sources and methods are now available, along with more sophisticated analytics to understand and make decisions to build smarter studies. Accessing these data streams is new; applying the rigor and structure needed to use the data to drive meaningful study design decisions is even newer and more challenging. Join us to hear examples of how this has been done.

Smart Patients Build Smart Protocols: Putting the Patient’s Voice into Your Design
Jane E. Myles, MS
Global Head, Recruitment Strategy, Genentech, A Member of the Roche Group

Innovative Solutions to Program Design: Using a Computer-assisted Design Platform to Drive Quality in Design
Rick Sax, DrMed, FACP
Vice President, Integrated Clinical Services, Quintiles Transnational Corp.

Optimizing Study Design for Efficient Trial Execution
Igor Gery Altman
Product Manager, Medidata Solutions Worldwide

Using the Right Tool for the Right Job: Methods for Gaining Patient Input into Protocol Design
James P. Kremidas
Consultant

#342 TRACK 02A - PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING
Related Interest Area(s): PM, RD
1:45-3:15 PM  LEVEL: ●  FORMAT: SESSION
Room 104C  CME, Nursing and PMI PDUs
Using Competence Models to Drive High Quality Drug Project Management
CHAIRPERSON
Peter Harpum, PhD, MSc
Managing Director, Harpum Consulting Ltd., United Kingdom

Research consistently shows that effective behavior predicates project success, whereas process compliance does not. This session presents a case study of the use of a tailored project management competence framework in a mid-sized pharma.

Practical/Operational Applications of Project Manager Competency Models
Douglas W. Call, PhD, PMP
Consultant, Call & Warwick Project Partners, LLC

Theoretical and Practical Implications of Competency Models in Drug Project Management
Peter Harpum, PhD, MSc
Managing Director, Harpum Consulting Ltd., United Kingdom

#343 TRACK 02B - PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING
Related Interest Area(s): RD, CP, RA
1:45-3:15 PM  LEVEL: ●  FORMAT: FORUM
Room 104AB  CME, Pharmacy and Nursing
Challenges and Strategic Approaches to Biosimilar Development
CHAIRPERSON
Jayanthi Reddy, MBA, MS, PMP
Director and Biologics Pipeline Leader, Global Project Management, Merck & Co., Inc.

This session will focus on understanding the strategic questions companies are facing when developing biosimilars and the drug development approaches that are being adopted. Case studies will be provided followed by an open forum discussion.

CMC Challenges to Biosimilar Development
Steve Farrand, PhD, MSc
Vice President and Head Bioprocess Development, Merck Research Laboratories

Clinical Challenges and Strategic Approaches to Biosimilar Development
Andrew J. Rankin
Vice President, Biopharmaceuticals, Prescient Life Sciences

Nonclinical Challenges to Biosimilar Development
David Shen, PhD
Vice President, Global Head of Biologics Development, Global R&D, Teva Pharmaceuticals
**#344 Track 03 – Innovative Partnering Models and Outsourcing Strategies**

**Related Interest Area(s): RD, OS, PM**

**1:45–3:15 pm**  
**Room 102AB**  
**CME, Nursing and PMI PDUs**

**Towards an Effective Virtual R&D Team for Faster Accessing of the East Asian Market**

**CHAIRPERSON**  
Deborah Chee, MD, PhD, MBA  
Medical Director, AbbVie Korea Ltd., Korea, Republic of

Strategic use of a “virtual” R&D team model could benefit companies that have limited capabilities in East Asian markets — including Japan, China, Korea and Taiwan — to minimize the drug lag and to maximize product value in these markets.

**Program Management: Striving for Productive Conversations, Team Chemistry and a Drive for Results**

Philip Bonasia, PhD  
Executive Director and Head, Chemistry and Pharmaceutical Sciences, Sunovion Pharmaceuticals Inc.

**Drug Lag, Regulatory Innovation and the Role of the Academic Center in East Asia**

Howard Lee, MD, PhD  
Professor, Department of Clinical Pharmacology and Therapeutics, Seoul National University Hospital, Korea, Republic of

**Challenges and Successes of Virtual R&D Teams for East Asia**

Chris Bruenger, MD  
President and CEO, IDEC Inc., Japan

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**#345 Track 06 – Medical Communication, Medical Writing and Medical Science Liaison**

**Related Interest Area(s): MC, CP, MA**

**1:45–3:15 pm**  
**Room 204AB**  
**CME and Nursing**

**Recent Corporate Integrity Agreements: Impact on Industry-sponsored Publications and Medical Communications Activities**

**CHAIRPERSON**  
Monica A. Kwarcinski, PharmD  
Executive Director, Medical Services, Purdue Pharma LP

Pharmaceutical industry compliance obligations have increased dramatically over the last several years. In light of this, it is critical that companies have policies and procedures that address industry-sponsored publications activities as well as documenting and responding to medical inquiries. This session will provide an overview of recent corporate integrity agreements with a focus on industry-sponsored publication and medical communications obligations. Additionally the speakers will discuss what policies, procedures, and programs companies should consider implementing to help mitigate risk in the area of industry-sponsored publications and medical communications activities.

**Government Enforcement Regarding Medical and Scientific Communications**

Kristin Graham Koehler, JD  
Partner, Sidley Austin LLP

**Corporate Integrity Agreements: What They Say About Publications, Publication Planning, Transparency and ICMJE**

Frank J. Rodino  
President and Founder, Churchill Outcomes Research, LLC

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**What Policies and Procedures Medical Communications Department Should Have In Place Based On Recent Corporate Integrity Agreements**

Monica A. Kwarcinski, PharmD  
Executive Director, Medical Services, Purdue Pharma LP

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**#346 Track 07A – Processes and Technologies for Clinical Research**

**Related Interest Area(s): IT, RA, CR**

**1:45–3:15 pm**  
**Room 252AB**  
**CME, Pharmacy and Nursing**

**Coalition for Accelerating Standards and Therapies (CFAST): The Ultimate Drug Development Drivers**

**CHAIRPERSON**  
Rebecca D. Kush, PhD  
President and CEO, CDISC

The Coalition for Accelerating Standards and Therapies (CFAST) was formed by the Clinical Data Interchange Standards Consortium (CDISC) and the Critical Path Institute (C-Path) “to accelerate clinical research and medical product development by creating and maintaining data standard, tools and methods for conducting research in therapeutic areas that are important to public health.” CFAST was officially launched in October 2012. This session will focus on CFAST activities, specifically the development of data standards and the implementation of these standards to accelerate the development and review of new therapies and to enhance the information that can be obtained from streamlining the sharing, aggregation and analysis of clinical research data. CFAST is working with FDA, TransCelerate, the Innovative Medicines Initiative (IMI), ACRES, other partners and countless volunteers in this endeavor.

**Panelists**

David C. Jordan, PhD, MSc  
Leader, Data Standards Project, TransCelerate Biopharma Inc.

Brian Harvey, MD  
Vice President, US Regulatory Strategy, Pfizer Inc

Ron Fitzmartin, PhD, MBA  
Senior Advisor, Office of Planning and Informatics, CDER, FDA

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**#347 Track 07B – Processes and Technologies for Clinical Research**

**Related Interest Area(s): VA, IT, RA**

**1:45–3:15 pm**  
**Room 251**  
**CME and Nursing**

**Cloud Technology for Decision Makers: What’s Real and How to Validate It**

**CHAIRPERSON**  
Teri E. Stokes, PhD, MS, MT  
Director, GXP International

The goal of this session is to help people make practical, informed decisions based on what cloud technology options exist today and how to assess their pros and cons for productivity and regulatory compliance in clinical trials. It is important to use this technology in a responsible way, and speakers will share their experience with system validation and data validation in the cloud. The presentations will identify and discuss the key factors and concepts required to make defensible decisions about using cloud technology for regulated purposes.
What is Cloud Technology and How Does it Work?
Chris R. Dagdigian
Co-Founder and Principal Consultant, BioTeam, Inc.

How Do We Validate The Use of Cloud Technology?
Charles L. Lankford
CEO, PharmaSys, Inc.

How Do We Validate Data in The Cloud?
Julia Zhang, PhD
Associate Director, Sanofi

#349 Track 08B – Regulatory Affairs and Submissions
Related Interest Area(s): PT, CR
1:45–3:15 PM LEVEL: ● FORMAT: SESSION
Room 254AB
FDASIA Patient Provisions: One Year Later
CHAIRPERSON
James E. Valentine
Program Analyst, Office of Health and Constituent Affairs, OC, FDA

The Future of Personalized Medicine is Dependent Upon the Development of Rational Reimbursement and Coverage Policies. These Policies Must Reflect the Real Value Companion Diagnostics Play in Targeting Important Breakthrough Medical Therapies to Ensure that Patients Are Receiving the Therapy Most Suited to Their Specific Condition.

This session will discuss the following key elements that are critical to ensuring appropriate decisions are taken reflecting the market-based value and importance of diagnostics in patient health and well-being: Working with payers on coverage policies to support appropriate adoption and use of the co-developed diagnostic; working with payers on coding and billing policies to distinguish co-developed diagnostics from tests analyzing the same or similar biomarkers, but which have not been validated or labeled specifically for use with the therapeutic; outreach to customers and treating physicians to explain

The Patient Perspective
Marc M. Boutin, Esq, JD
Executive Vice President and Chief Operating Officer, National Health Council

#350 Track 08C – Regulatory Affairs and Submissions
Related Interest Area(s): SUBS, OS
1:45–3:15 PM LEVEL: ■ FORMAT: SESSION
Room 253B
eSubmission Outsourcing and Mergers and Acquisitions: Now This Is An Intriguing Equation
CHAIRPERSON
Daniel F. Orfe, MS
Associate Director, Global Regulatory Operations-Technology, Standards, Vendor Mgmt, Teva Pharmaceuticals USA, Inc

This session will explore the approach taken by three life science companies for leveraging eSubmission outsourcing. The specific challenges and opportunities for outsourcing resulting from ongoing mergers and acquisitions will be examined.

Daniel F. Orfe, MS
Associate Director, Global Regulatory Operations-Technology, Standards, Vendor Mgmt, Teva Pharmaceuticals USA, Inc

Submission Outsourcing: Stop Working For it, Make it Work For You
Karen Towns
Senior Director and Global Head, Publishing and Product License Support, Pfizer Inc

In/Out Sourcing: Risks and Benefits of a Hybrid Sourcing Model
Cortney A. Gilbert, MBA, MS
Associate Director, Global Regulatory Operations, Merck & Co., Inc.

#351 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products
Related Interest Area(s): PR, MDD
1:45–3:15 PM LEVEL: ■ FORMAT: SESSION
Room 253C
Developing Effective Policy Strategies for Coverage and Reimbursement of Companion Diagnostics
CHAIRPERSON
Paul Shelfes, JD, MS
Director for Diagnostics and Personalized Medicine Policy, Biotechnology Industry Organization (BIO)

The Future of Personalized Medicine is Dependent Upon the Development of Rational Reimbursement and Coverage Policies. These Policies Must Reflect the Real Value Companion Diagnostics Play in Targeting Important Breakthrough Medical Therapies to Ensure that Patients Are Receiving the Therapy Most Suited to Their Specific Condition.

This session will discuss the following key elements that are critical to ensuring appropriate decisions are taken reflecting the market-based value and importance of diagnostics in patient health and well-being: Working with payers on coverage policies to support appropriate adoption and use of the co-developed diagnostic; working with payers on coding and billing policies to distinguish co-developed diagnostics from tests analyzing the same or similar biomarkers, but which have not been validated or labeled specifically for use with the therapeutic; outreach to customers and treating physicians to explain.
test-specific coverage and payment policies; plus a case study to illustrate the importance of managing expectations and negotiations with payers/price-setters.

Panelist
Representative Invited
Health Advances

#352 Track 10 – Public Policy/ Health Care Compliance/ Law
Related Interest Area(s): MDD, CR, RA
1:45–3:15 pm LEVEL: ■ Format: FORUM
Room 154 CME, Pharmacy and Nursing
The Science of Compliance
CHAIRPERSON
Patrick C. O’Brien, JD, PharmD
Vice President, Chief Legal Officer, Shire Regenerative Medicine, Inc.
This forum will discuss how we should be implementing compliance controls in our industry and discuss Codes of Conduct, and the fact that every corporate integrity agreement negotiated between a pharmaceutical or device company and the Office of Inspector General lays out requirements in a way that is probably less likely to be effective than could be.

Panelists
Francesca Gino, PhD
Associate Professor, Negotiation, Organization, and Markets Unit, Harvard University Business School
Mary Patrice Brown, JD
Partner, White Collar Defense and Corporate Investigations Practice, O’Melveny & Myers LLP

#353 Track 11 – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)
Related Interest Area(s): CP, GCP, RA
1:45–3:15 pm LEVEL: ■ Format: SESSION
Room 156AB CME and Nursing
FDA/EMA/WHO Collaboration and Cooperation on Good Clinical Practice (GCP), Bioequivalence (BE) and Pharmacovigilance (PV) Inspections
CHAIRPERSON
Cynthia Kleppinger, MD
Senior Medical Officer, Office of Scientific Investigations, CDER, FDA
This session will provide updates about the FDA's international collaborative inspection initiatives with the EMA and cooperative exchanges with the WHO. Included will be discussions of the FDA-EMA GCP initiative, the new BE initiative and information exchange regarding pharmacovigilance.

FDA Point of View
Cynthia Kleppinger, MD
Senior Medical Officer, Office of Scientific Investigations, CDER, FDA

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

WHO Point of View
Lembit Rago
Coordinator for Quality Assurance and Safety for Medicines, World Health Organization (WHO), Switzerland

#354 Track 12 – Pharmaceutical Quality
Related Interest Area(s): CMC, RA
1:45–3:15 pm LEVEL: ■ Format: FORUM
Room 153C CME, Pharmacy and Nursing
Implementation of Quality by Design: Progress, Challenges and Opportunities - Industry Perspective
CHAIRPERSON
Moheb M. Nasr, PhD, MS
Vice President, Regulatory CMC Strategy, GlaxoSmithKline
Three industry speakers, representing different segments of the pharma industry, will share their perspectives on Quality by Design (QbD) implementation progress. Presentations will outline different implementation approaches supplemented by case studies.

Implementing QbD at a Major Pharmaceutical Company: Tales from the Road
Michael Thien, DrSc
Senior Vice President, Global Science, Technology and Commercialization, Merck & Co., Inc.

Lessons Learned From Implementing QbD for Two Novel Pharmaceutical Products: Progress Towards Global Regulatory Alignment
Patricia N. Hurter, PhD, MS
Senior Vice President, Product Development, Vertex Pharmaceuticals

Lessons Learned From Two Case Studies in the FDA QbD Pilot for Biotech Products
Lynne Krummen
Vice President, Technical Regulatory, Biologics, Genentech, A Member of the Roche Group

#355 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)
Related Interest Area(s): PR, CR, RA
1:45–3:15 pm LEVEL: ■ Format: SESSION
Room 151B CME, Pharmacy and Nursing
The 2012 US Payer Landscape: Results from a Survey of Medical and Pharmacy Directors on Comparative Effectiveness Research
CHAIRPERSON
Richard Alan Brook, MBA, MS
Head, Retrospective Analysis, The Jestarx Group
This session will present the findings from an online survey of medical and pharmacy directors of US health plans, insurers, and pharmacy benefit managers (PBMs) that covered how comparative effectiveness research (CER) and evidence-based medicine (EBM) results are incorporated into a Pharmacy and Therapeutics (P&T) Committee’s decision-making process. The speakers will also provide a pharma and a US health plan perspective on partnering with health plans and payers to develop and disseminate EBM and CER information, challenges with communicating these results, and strategies to address these challenges.

Medical and Pharmacy Directors’ Views on CER and EBM
Richard Alan Brook, MBA, MS
Head, Retrospective Analysis, The Jestarx Group

A Pharmaceutical Company’s Perspective on CER and EBM
Krithika Rajagopalan, PhD, MS
Vice President, Health Economics & Outcomes Research, Sunovion Pharmaceuticals Inc.
Making CER and EBM Results Actionable: The Perspective of an Independent Evidence Review Organization
Dan Ollendorf, MPH
Chief Review Officer, Institute for Clinical and Economic Review

#356 Track 14 – Clinical Safety and Pharmacovigilance
Related Interest Area(s): ST, IT

1:45–3:15 pm LEVEL: ◆ FORMAT: WORKSHOP
Room 157C
CME and Nursing

An Interactive Course on Likelihood Ratio Test-based Method for Signal Detection
CHAIRPERSON
Ram Tiwari, PhD
Associate Director, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

This workshop will provide an overview of the likelihood ratio test-based signal detection method for FDA’s Adverse Event Reporting System (AERS) database. It will also include a demonstration via the presentation of the likelihood ratio test (LRT) tool to certain drugs or adverse events.

*Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

Facilitators
Lan Huang, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Ted J. Guo, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

#357 Track 15 – Statistical Science and Quantitative Thinking
Related Interest Area(s): CR, RD

1:45–3:15 pm LEVEL: ◆ FORMAT: SESSION
Room 157AB
CME and Nursing

Clinical Trial Simulations and Modeling
CHAIRPERSON
David A. Amato, PhD
Vice President, Biometrics and Data Management, Vertex Pharmaceuticals

Regulatory agencies are not only now recognizing the use of clinical trial simulation in the drug development process as an effective trial design and outcome prediction tool, but are actively collaborating with biopharmaceutical clinical trialists in an effort to make available new and promising drugs to patients sooner. This transformative and collaborative way of developing new therapies has the potential to enable timely knowledge-based decision making and translate into more high-value therapies through increased development efficiencies. This session will explore some of the potential benefits of clinical trial simulation practices throughout the drug development process with expert speakers from the biopharmaceutical industry.

Experiences with Using Clinical Trial Simulation and Modeling at the Program Level
Nitin R. Patel, PhD, MBA
Founder, Chairman and Chief Technology Officer, Cytel Inc.

#358 Track 16A – Professional Development
Related Interest Area(s): CR

1:45–3:15 pm LEVEL: ◆ FORMAT: SYMPOSIUM
Room 103
CME and Nursing

Transition from Subject Matter Expert (SME) to Subject Matter Educator Extraordinaire (SMEE)!
CHAIRPERSON
Kristina R. Barkhouser
President, Excelen Performance, Inc.

As companies are being asked to do more with less, it is critical that organizations take a fresh approach to transforming the role of experienced personnel within the company to meet ever present learning and development needs. This symposium will equip subject matter experts (SMEs), as well as those looking to leverage this expertise in their organizations, with the tools and process to ensure successful use of internal expertise, knowledge and resources. There is no doubt that an SME can be a great training resource; and with proper preparation, management and transition, an internal expert can become an educator extraordinaire!

Transition from Subject Matter Expert (SME) to Subject Matter Educator Extraordinaire (SMEE)!
Kristina R. Barkhouser
President, Excelen Performance, Inc.

Improving eLearning in Clinical Research: Is Anyone Tired of Clicking “Next”?
James Robert Wetzel, MS
Principal Consultant, Pharmica Consulting

How to Be Innovative and Break Through the Glass Ceiling
Stacy Surensky
Principal, Sustained Cultural Integration

#359 Track 16B – Professional Development
Related Interest Area(s): P&T

1:45–3:15 pm LEVEL: ◆ FORMAT: WORKSHOP
Room 156C

Submitting an Abstract for the DIA 2014 50th Annual Meeting
CHAIRPERSON
Julie Ho
Manager, Annual Meeting Content Development, DIA

Join members of the DIA 2014 50th Annual Meeting Program Committee and the DIA Annual Meeting Team for tips and helpful hints as you submit an abstract for next year’s Annual Meeting.

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**#360 Track 17 – Rare/Orphan Diseases**  
Related Interest Area(s): CR, BT, PT  
1:45–3:15 PM  
LEVEL: ■  
FORMAT: SESSION  
Room 205B  
CME and Nursing  
Rising to the Challenge of Developing Novel Orphan Medicines for the Global Market  
CHAIRPERSON  
Cecil J. Nick, MS  
FTOPRA, Vice President (Technical), PAREXEL Consulting, United Kingdom  

One in ten people could be affected by a rare disease; for many there is no treatment, yet modern technology could resolve this. This session investigates the opportunities available to facilitate successful global development of novel orphan medicines.

**Rare and Orphaned Disease Drug Products: Convergence of Scientific and Regulatory Paths Leading to Successful Approval**  
John Ziegler, MD  
Medical Director, Premier Research Group  

**European Perspective**  
Spiros Vamvakas, MD  
Head of Scientific Advice, Human Medicines Special Areas, European Medicines Agency, European Union  

**Regulatory Perspective**  
Representative Invited  
FDA  

**#361 Track 18 – Global Regulatory**  
Related Interest Area(s): RA, CR  
1:45–3:15 PM  
LEVEL: ■  
FORMAT: SESSION  
Room 203  
CME and Nursing  
Canadian Approaches to Regulatory Modernization and International Engagement  
CHAIRPERSON  
Agnes V. Klein, DrPH, MD  
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada  

After several attempts at a major modernization via the Food and Drugs Act, it was decided in Health Canada to use the regulatory pathway to bring the regulations up to date without modifying the Food and Drugs Act itself. To that end, a new set of regulations for orphan drugs are being drafted. The approach that is used is novel, different, and unique as the regulatory framework; the needed guideline and the operational elements are being developed simultaneously and are informed by each other. In addition, the regulations will be a complete self-standing set which is intended to be a model for drug life cycle management. Health Canada has also adopted a number of postmarket ICH guidelines. Regulatory amendments are being drafted to allow Health Canada to request safety information on an ongoing basis from sponsors. In addition, in order to harmonize requirements, Health Canada has decided to consider the new PBRER as the format and content sufficient to fulfill Canadian requirements.

This session will also provide an overview of new developments on the clinical trial front with new directives, internationally, as well as the intended establishment of educational networks and networks of excellence that will facilitate global drug development.

**International Collaborations in Clinical Trials**  
Agnes V. Klein, DrPH, MD  
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada  

**#362 Track 19 – Communities Showcase**  
Related Interest Area(s): CR, OS  
1:45–3:15 PM  
LEVEL: ■  
FORMAT: SESSION  
Room 205A  
CME, Pharmacy and Nursing  
Clinical Outcome Assessment for Clinical Trials: PROs, ClinROs, and ObsROs  
CHAIRPERSON  
Melynn Greberman, MD, MS, MPH, FACPM  
President, Public Health Resources  

This session will discuss the use of patient-reported outcomes (PROs), clinician-reported outcomes (ClinROs), and observer-reported outcomes (ObsROs) to assess treatment benefits in clinical trials, and collaborative ventures that support scientific, regulatory, and clinical applications in the US and other countries. This session has been developed by the Clinical Research Community.

**Current Challenges for Clinical Research in Our Rapidly Changing Health System**  
J. Michael Fitzmaurice, PhD, FACMI  
Senior Science Advisor for Information Technology, Office of the Director, Agency for Healthcare Research and Quality (AHRQ)  

**The Challenge of Collecting Reliable Patient Outcome Data**  
Stanley A. Edlavitch, PhD, MA, FACE  
Professor, Epidemiology, School of Medicine; Center for Behavioral Medicine, University of Missouri Kansas City  

**Clinical Outcome Assessments: Use in Clinical Trials to Demonstrate Treatment Benefit**  
Elektra Johanna Papadopoulos, DrMed, MPH  
Medical Officer, Office of New Drugs, CDER, FDA  

**#363 Track 21 – Late Breaker**  
Related Interest Area(s): CP, CR, RA  
1:45–3:15 PM  
LEVEL: ■  
FORMAT: SESSION  
Room 206AB  
CME and Nursing  
TransCelerate’s Collaborative Approach to Risk-based Monitoring: The Methodology  
CHAIRPERSON  
Craig A. Wozniak  
Head, Americas Clinical Operations, GlaxoSmithKline  

TransCelerate BioPharma Inc. (TransCelerate) developed a methodology for monitoring that shifts monitoring processes from an excessive concentration on source data verification to comprehensive risk-driven monitoring. This philosophical shift in monitoring processes employs centralized and offsite mechanisms to identify and monitor important study parameters holistically and uses adaptive onsite monitoring to further support subject safety and data quality.
TransCelerate: Overview of Organization and Risk-based Monitoring Methodology  
Craig A. Wozniak  
Head, Americas Clinical Operations, GlaxoSmithKline  
Pilot Implementation: Practical Experience to Date  
Michael B. Luker  
Eli Lilly and Company  

#364 Track 01A – CLINICAL OPERATIONS  
4:00–5:30 pm  
LEVEL: ■  
FORMAT: SYMPOSIUM  
Room 206AB  
CME and Nursing  

Innovative Ways of Working with Patients to Make Clinical Research More Productive, Less Costly and Less Burdensome for the Patient  
CHAIRPERSON  
Elisa F. Cascade, MBA  
Vice President, Corporate Development, DrugDev.org  
The purpose of this patient-centric symposium is to describe how patients are an important driver of innovation for clinical research. In addition to describing issues from the patient perspective, we will discuss activities that can be implemented to achieve time and cost efficiencies without sacrificing study quality. Such activities include, but are not limited to, patient protocol assessments, supplemental patient recruitment, patient retention support, alternative site clinical visits and long-term data collection post-study.  

Patient Perspective on Increasing the Quality and Efficiency of Clinical Trials  
Bray Patrick-Lake, MS  
Director of Stakeholder Engagement, Clinical Trials Transformation Initiative (CTTI)  

Methods for Working with Patients to Make Research More Efficient  
Elisa F. Cascade, MBA  
Vice President, Corporate Development, DrugDev.org  

Bringing the Study to the Patient  
Nicki M. Norris, CPA, MBA  
CEO, Symphony Clinical Research  

#365 Track 01B – CLINICAL OPERATIONS  
4:00–5:30 pm  
LEVEL: ■  
FORMAT: SYMPOSIUM  
Room 205C  
CME and Nursing  

Overcoming Unique Challenges of Pediatric Studies  
CHAIRPERSON  
Kathryn Elaine Bohannon  
Principal Strategist, Pediatrics, INC Research  
As a result of significant legislative efforts within the United States and European Union, pharmaceutical companies must address the pediatric population during the drug development process, and, when applicable, design and conduct pediatric trials in the appropriate pediatric age groups. Given the involvement of pediatric patients and their parents/guardians in the research study process, the special needs and considerations of the vulnerable patient population, and the crucial focus on ensuring safety and well-being of the pediatric study participants, conducting a pediatric research study most certainly involves unique challenges. This symposium will explore unique challenges, present insights, and offer best practices associated with pediatric trial recruitment, retention and blood sample collection.  

Best Practices for Recruitment and Retention of Pediatric Patients for Clinical Trials  
Kathryn Elaine Bohannon  
Principal Strategist, Pediatrics, INC Research  

Recruiting for Pediatric Trials: How to Communicate with Parents and Improve Enrollment into Clinical Trials  
Neil Weisman  
Executive Vice President and General Manager, Blue Chip Patient Recruitment  

Pediatric Studies: Limited Blood Volume in Children Requires New Approaches in Sample Collection and Handling  
Hermann Schulz, DrMed  
CEO, INTERLAB Central Lab Services - Worldwide GmbH, Germany  

#366 Track 02A – PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING  
4:00–5:30 pm  
LEVEL: ◆  
FORMAT: SESSION  
Room 104C  
PMI PDUs  

Pharmaceutical Project Management: What’s Really Important and How Can We Do Better?  
CHAIRPERSON  
John Z. Sun, PhD, MBA, PMP  
Novartis Pharmaceuticals Corporation  
Project management (PM) plays an important role in pharma and biotech companies, but what can we do to further improve, particularly in today’s environment? Come and hear the critical findings from a panel of PM practitioners and experts.  
This session has been developed by the Project Management Community.  

Managing Complex Product Development Projects  
Peter Harpum, PhD, MSc  
Managing Director, Harpum Consulting Ltd., United Kingdom  

The Five Core Qualities of Authentic Leaders  
Robin G. Foldesy, PhD  
Vice President, Strategic Drug Development, Quintiles Transnational Corp.  

Meeting the Challenges of Managing Teams and Alliances  
Mary Lou Bell  
Head, Portfolio and Program Management, Nimbus Discovery  

#367 Track 02B – PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING  
4:00–5:30 pm  
LEVEL: ■  
FORMAT: FORUM  
Room 203  
CME and Nursing  

Pharmacometric Methods: Essential for Optimal Drug Development Strategy  
CHAIRPERSON  
Royce A. Morrison, MD, MS  
Executive Vice-Chair, Quorum Review, Inc.  
This session will explore the definition of pharmacometrics, its key role in strategy, program planning, study design, labeling and regulatory decision-making, and its rapidly developed implementation by regulatory agencies.
Clinical Implications of Population Pharmacokinetics of rFIXFc in Management of Hemophilia B
Haiyan Jiang, PhD
Senior Director, Preclinical and Clinical Research (Hemophilia), Biogen Idec

Seeing into the Future: The Prasugrel Story of Pharmacometric Support for Dose Adjustments in Higher-risk Subgroups
David S. Small, PhD
Research Advisor, Global Pharmacokinetics/Pharmacodynamics, Eli Lilly and Company

Impact of Pharmacometrics on Pediatric Drug Development
Amit Roy, PhD
Group Director, Clinical Pharmacology and Pharmacometrics Research & Development, Bristol-Myers Squibb Company

#368 Track 03 – Innovative Partnering Models and Outsourcing Strategies

4:00–5:30 PM LEVEL: ■ FORMAT: SYMPOSIUM
Room 102AB CME, Nursing and PMI PDUs

Partnering and Outsourcing Challenges in India: The New Paradigm Shifts
CHAIRPERSON
Anupama Ramkumar, MD
Director, Arkus Clinical Trial Support Solutions, India

This symposium will address the paradigm shifts now occurring with the partnering and outsourcing models in India as a result of the evolution of local and global regulatory, scientific and business needs related to the clinical development of drugs and biosimilars. We will discuss case studies and lessons learned from conducting trials in India with a focus on biosimilars, as well as the realities of the shifting center of the pharmaceutical world and the implications for implementing various strategies both in outsourcing as well as in-licensing and other partnering models.

Clinical Trials in Biosimilars or Follow-on Biologics: Outsourcing Strategies and Challenges
Anupama Ramkumar, MD
Director, Arkus Clinical Trial Support Solutions, India

Global Licensing and Co-development Models: Innovative Route to Faster Commercialization
Nidhi Saxena, MBA
Founder and CEO, Karmic Lifesciences, Inc., India

Insourcing to India: The Real Politics of Building a Dynamic partnership between US and Hyderabad Regulatory Professionals
Raffy H. Chilingerian, DMH, MS, BBA
Senior Regulatory Manager, Novartis Pharmaceuticals Corporation

#369 Track 06 – Medical Communication, Medical Writing and Medical Science Liaison

4:00–5:30 PM LEVEL: ■ FORMAT: SYMPOSIUM
Room 204AB CME, Pharmacy and Nursing

Learnings from Safety Communications Across the Industry: Patients and EMA, REMS and FDA, Physicians and Medical Information Groups
CHAIRPERSON
Stacey M. Fung, PharmD
Associate Director, Medical Communications, Genentech, A Member of the Roche Group

This symposium will include three presentations reviewing learnings from various safety communications initiatives. A five year experience from the EMA, experience from the FDA of incorporating safety reports to package labeling, and findings from a survey of physicians’ familiarity with REMS and medical information safety responsibilities will be discussed.

Patient Involvement in Preparation of the EMA Information on Medicines: Five Year Experience at the EMA
Martin Harvey-Ailchur, Esq, LLM
Head of Communications, European Medicines Agency, European Union

MedWatch from Spontaneous Report to FDA Alert and Beyond: An Overview of Incorporating Safety Information into Practice
Heidi C. Marchand, PharmD
Assistant Commissioner for Special Health Issues, Office of the Commissioner, FDA

Physician Familiarity with REMS and Role of Medical Information in Safe and Effective Use of Pharmaceutical Products
Inessa Volonueva, PharmD, MS, RPh
Associate Director, Medical Information, Janssen Scientific Affairs, LLC

#370 Track 07A – Processes and Technologies for Clinical Research

4:00–5:30 PM LEVEL: ■ FORMAT: WORKSHOP
Room 157C CME and Nursing

Clinical Trial Visit of the Future: Leveraging Emerging Technologies to Crack the Patient Recruitment Challenge
CHAIRPERSON
Komathi Stem
Senior Director, Product Development, Innovation Lead, Genentech, A Member of the Roche Group

This workshop will simulate a future clinical trial visit using emerging technologies followed by an expert panel of regulators, industry leaders, and technology developers discussing the opportunities and challenges.

*Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, 12A will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

Panelists
Tomasz Sablinski, MD
Founder and CEO, Transparency Life Sciences

Lorenzo Rossaro, MD, FACP
Chief, Division of Gastroenterology and Hepatology, University of California Davis School of Medicine

Room capacities, and they are strictly enforced. Once all seats are occupied, 12A will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.
Wednesday, June 26

#371 Track 07B – Processes and Technologies for Clinical Research

**Related Interest Area(s):** CDM, PM, CR  
4:00–5:30 pm  
LEVEL: ■  
ROOM 252AB  
**Format:** SESSION

**Data Standards Strategy**  
**Chairperson**  
Stephen E. Wilson, DrPH, CAPT, USPHS  
Director, Division of Biometrics III, Office of Translational Science, CDER, FDA

Study data standards are a critical factor in improving the overall effectiveness and efficiency of the regulatory review process. This session will provide an overview of FDA’s commitment to the use of open, consensus-based data standards that will facilitate the efficient review of regulatory submissions. The discussion will include topics on the data standards strategy, data governance structure and planned guidances. In addition, the session will discuss data standards issues and tools from the reviewer’s perspective. Lastly, an industry perspective on data standards will be provided.

- **FDA Perspective on Data Standards**  
  Ron Fitzmartin, PhD, MBA  
  Senior Advisor, Office of Planning and Informatics, CDER, FDA

- **CDISC Perspective on Data Standards**  
  Representative Invited  
  Vice President, Strategic Initiatives, CDISC

- **FDA’s Efforts on the Health Care Side Related to data Standards**  
  Mitra Rocca, MS  
  Senior Medical Informatician, Office of Translational Science, CDER, FDA

- **Industry Perspective on Data Standards**  
  Michael J. Brennan, PhD  
  Director, Informatics, Johnson & Johnson Pharmaceutical Research & Development, LLC

#372 Track 08A – Regulatory Affairs and Submissions

**Related Interest Area(s):** CR, RD, BT  
4:00–5:30 pm  
LEVEL: ■  
ROOM 254AB  
**Format:** FORUM

**Advancing Alzheimer’s Innovation: Clinical Development Successes and Challenges**  
**Chairperson**  
Andrew Satlin  
Senior Vice President, Eisai Inc.

Drug discovery is hard. In fact, approximately, only 11% of new drugs that enter clinical trials make it to the US market. For central nervous system (CNS) drugs, which includes Alzheimer’s, this rate is even lower — only about 8%. The most troubling trend is the rate of failure for Alzheimer’s drugs in Phase 3, the final step of the drug development process before regulatory submission.

This session will discuss innovative approaches to clinical trial design, and the use of companion diagnostic testing and biomarkers, to improve the success of clinical trials in Alzheimer’s disease and mild cognitive impairment.

- **Bayesian Adaptive Trial Design: A New Approach for Phase 2 Clinical Trials in Alzheimer’s Disease**  
  Andrew Satlin  
  Senior Vice President, Eisai Inc.

- **Current Landscape of Alzheimer’s Clinical Trials: Lessons From the Recent Failures in Phase 3**  
  Reisa A. Sperling, MD  
  Director, Professor, Neurology, Harvard Medical School, Brigham and Women’s Hospital and Massachusetts General Hospital

- **Advancement of Diagnostics for Patient Stratification in Alzheimer’s Disease Drug Trials**  
  Johan Luthman, MD  
  Vice President, Neuroscience and Ophthalmology R&D for Franchise Integrator, Merck & Co., Inc.

#373 Track 08B – Regulatory Affairs and Submissions

**Related Interest Area(s):** SUBS, IT, RD  
4:00–5:30 pm  
LEVEL: ■  
ROOM 253B  
**Format:** SESSION

**Electronic Regulatory Submission (ERS) Development and the Impact on the Sponsor’s Organization: Retooling R&D for ERS**  
**Chairperson**  
Peter M. Lassoff, PharmD  
Vice President and Head of Global Regulatory Affairs, Quintiles Inc., United Kingdom

This session will assist pharmaceutical companies in reorganizing their R&D departments to fit the requirements of electronic regulatory submission development. This will speed up the writing and submission of eCTDs and other electronic submissions leading to faster time to market.

- **Stories From The Frontline: Lessons Learned from Electronic Submissions in R&D**  
  Peter M. Lassoff, PharmD  
  Vice President and Head of Global Regulatory Affairs, Quintiles Inc., United Kingdom

- **Electronic Submissions in R&D**  
  Anita Michelle Coleman  
  Dossier Technical Lead, Sanofi

- **Global Dossier Production: Around the World**  
  Jeffrey S. Morrison, MS  
  Director, Global Regulatory Operations, GlaxoSmithKline

#374 Track 08C – Regulatory Affairs and Submissions

**Related Interest Area(s):** CR  
4:00–5:30 pm  
LEVEL: ■  
ROOM 253A  
**Format:** SESSION

**Global Pediatric Development: Next Steps**  
**Chairperson**  
Chin Koerner, MS  
Executive Director, Regulatory Policy, Novartis Pharmaceuticals Corporation

With the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) and the permanent reauthorization of the Pediatric Research Equity Act (PREA) and Best Pharmaceuticals for...
Children Act (BPCA), the promise of earlier and meaningful interactions with FDA regarding pediatric drug development is now a reality. This, coupled with the EU Pediatric Legislation that provides for a required and predictable process for pediatric discussions with EMA, sets the stage for global pediatric development programs that can align with needs of children and address concerns of the FDA and EMA.

In this session, we will explore initiatives that each FDA and EMA oversee to advance pediatric research. We will also explore those initiatives the Health Authorities are undertaking together to better advance unmet and under-served needs of children. Updates on monthly cluster calls, joint FDA/EMA pediatric program review, the EMA five year report, and use of MedDRA® to help identify additional pediatric studies needed will be just some of the topics to be discussed.

Cluster Activities Including Joint Review Pilot and Other Harmonization Initiatives
Dianne Murphy, MD
Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

EU Update: The Five Year Report and Streamlining Pediatric Investigation Plan Processes
Paolo Tomasi, MD, PhD
Head of Paediatric Medicines, European Medicines Agency, European Union

A Bridge From Here to There
Janet Jenkins-Showalter
Senior Regulatory Group Director, Regulatory Policy and Intelligence, Genentech, A Member of the Roche Group

Industry Perspective
Representative Invited
Head, Pediatric & Maternal Health Policy, Novartis Pharmaceuticals Corporation

#375 Track 09 – Medical Devices, In Vitro Diagnostics, and Combination Products

4:00–5:30 pm
Room 253C

Global Development of Novel Combination Products: Regulatory and Clinical Case Studies from Biotech and Pharma Sponsors

Chairperson:
Kevin B. Johnson, PhD, MBA
Global Head, Regulatory Affairs, Novella Clinical

This forum will present targeted, real-world case studies from biotechnology and pharmaceutical sponsors as well as a CRO on the development of novel combination products with a particular focus on global regulatory strategy and implementation.

- Human Factors Evaluations Throughout Combination Product Development Optimizes Performance and Streamlines Regulatory Review
  Cynthia Joan Nolte, PhD
  Director, Medical Device Regulatory Services, Aptiv Solutions

- Good Manufacturing Practices and Postapproval Changes for Combination Products
  Suzanne M. O’Shea, JD
  Counsel, Faegre Baker Daniels

- FDA’s Evolving Standards on Product Classification and Interpretation of the Effect of Chemical Action

Representative Invited
Partner, Head, FDA Practice, McDermott Will and Emery

#376 Track 10A – Public Policy/Health Care Compliance/Law

4:00–5:30 pm
Room 154

Meeting the Challenges of Health Care Disparities and Clinical Trial Requirements in the Global Environment

Chairperson:
Florence Houn, MD, MPH, FACP
FDA Alumni Association; Celgene

This session will identify expectations of industry for INDs and marketing applications regarding racial and ethnic enrollment into clinical trials, demographic analyses, and FDASIA requirements on FDA. It will also discuss policy implications for global development, health disparities, and meaningful inclusion of demographic subgroups (sex, race, ethnicity, age) and current Office of Minority Health initiatives in collaboration and advancing regulatory science.

The Challenge of the Generalizability of Clinical Data and Demographic Subgroups
Jonca C. Bull, MD
Director, Office of Minority Health, Office of the Commissioner, FDA

Regulatory Review Considerations for Demographic Subgroups: Representativeness and Interpretability of Results
Lisa M. LaVange, PhD
Director, Office of Biostatistics, Office of Translational Science, CDER, FDA

Leveraging Industry’s Global Clinical Trials to Reduce Health Disparities Via Data Generation and Capacity Building
Lisa Egbuonu-Davis, MD, MBA, MPH
Co-Founder, Director, ROI Squared LLC, ROI Squared LLC

#377 Track 10B – Public Policy/Health Care Compliance/Law

4:00–5:30 pm
Room 156C

Ethical Issues in Clinical Trials

Chairperson:
Art Gertel, MS
Vice President, Strategic Regulatory Consulting and Medical Writing, TFS International

This workshop will provide an overview of the various ethical considerations associated with conducting clinical trials, including the history of ethical principles — Nuremberg Conventions, Declaration of Helsinki, The Belmont Report, and ICH. Topics will include obtaining ethics committee and regulatory authority clearance, subject informed consent, investigator conflict-of-interest, issues of fraud, authorship, and ensuring subject safety and well-being. In addition, consideration will be given to conducting studies in emerging economy populations where fair distribution of risks and benefits come into play. It will become evident, through case examples, that these issues are not always black-and-white, and that the situation in which these issues are considered result in many shades of gray.
This workshop will also be offered on Tuesday, June 25, at 8:00 AM (#214).

*Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

### #378 Track 11 – Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)

**Related Interest Area(s): QA/QC, CR**

**4:00–5:30 PM**

**Room 156AB**

**LEVEL: [CME and Nursing]**

**FORMAT: FORUM**

**Chairperson**

**Denise A. Calaprice-Whitty, PhD, MS**
Executive Director, The Avoca Group Inc.

This forum will explore industry best practices and the variability in industry approaches to quality management. Data from the 2012 Quality Consortium Assessment research will be shared. A panel of industry experts and representatives from the FDA and EMA will provide their perspectives.

**Panelists**

**Jennifer G. Marsh**
Senior Director, Global Medical Quality, Eli Lilly and Company

**Coleen M. Glessner**
Vice President, Clinical Trial Processes and Quality, Pfizer Inc.

**Ann Meeker-O’Connell, MS**
Director, Division of GCP Compliance (Acting), Office of Scientific Investigations, Office of Compliance, CDER, FDA

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

**Cassandra Kennedy**
Senior Vice President, Global Quality Assurance, Quintiles Inc.

### #379 Track 12 – Pharmaceutical Quality

**Related Interest Area(s): CMC, RA**

**4:00–5:30 PM**

**Room 153C**

**LEVEL: [CME, Pharmacy and Nursing]**

**FORMAT: SESSION**

**Chairperson**

**Christine M. V. Moore, PhD**
Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

This session will focus on the implementation of Quality by Design (QbD) in FDA’s Center for Drug Evaluation (CDER). Opportunities will be discussed for application of QbD approaches to support continuous improvement and assurance of product quality.

**Panelists**

**Sarah C. Pope Miksinski, PhD**
Acting Director, Division 1, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

### #380 Track 13 – Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)

**Related Interest Area(s): CR, PR, CP, CR, GCP, QA/QC**

**4:00–5:30 PM**

**Room 151B**

**LEVEL: [CME and Nursing]**

**FORMAT: SYMPOSIUM**

**Chairperson**

**Larry Liberti, MS, RPh, RAC**
Director, Centre For Innovation In Regulatory Science (CIRS)

A health technology assessment (HTA) is used to inform reimbursement decisions. However, because approaches are diverse, opportunities to share scientific information and best practices should be explored. This symposium aims to identify the process available to assess the value of medicines in real-world practice.

**Panelists**

**Robyn R. Lim, PhD**
Senior Science Advisor, Office of Legislative and Regulatory Modernization, HPFB, Health Canada

An updated version of the Patient Decision Aid, a tool which will have undergone preliminary field testing with regional Canadian patient focus groups, will be presented, and this will be followed by open discussion. The
session will: 1) raise awareness across the decision-making health community about recent drug regulatory science innovations driving a patient-focused approach; and 2) be a springboard to trigger further engineering of applications for these trends for use across the community.

Patient Perspective
Linda Wilhelm
Consumer Advisory Council, Canadian Arthritis Network, Canada

Patient Perspective
Louise Binder
Patient Advocate, International Community of Women Living With HIV/AIDS, Canada

Challenges Related to Noninferiority Tests: An Overview
Liang Yuh, PhD
Vice President, Quantitative Sciences, Endo Health Solutions

Noninferiority Margin Determination Using Dirichlet Process and Power Priors
Ram Tiwari, PhD
Associate Director, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Practical Experiences with Design and Analysis of Noninferiority Clinical Trials in Infectious Diseases
Ulysses A. Diva, PhD
Principal Statistician, Bioinformatics and Information Sciences, AstraZeneca

#382 Track 14B – Clinical Safety and Pharmacovigilance
Related Interest Area(s): CR, CP
4:00–5:30 pm
Room 152
CME and Nursing

Herbal-induced Liver Injury (HILI): How That May Impact Rx Benefit-Risk
CHAIRPERSON
Pradip K. Paul, MD, MS
Consultant, Strategic Pharmacovigilance and Risk Management

Natural health products (NHP) safety plays an important role in the possible risk assessment of a compound under development or a product in the market. This important noise can be reduced, and recalibration of internal evaluation processes is needed.

This session has been developed by the Natural Health Products (NHP) Community.

Herbal Induced Liver Injury (HILI); Epidemiology and Regulation of the Use of Herbs
Leonard B. Seeff, MD
Consultant in Hepatology, The Hill Group

Herbal-Induced Liver Injury (HILI): Overview
Victor J. Navarro, MD
Chair, Hepatology, Einstein Medical Center

Rx Benefit-risk May be Impacted by Herbal-induced Organ Injury
Pradip K. Paul, MD, MS
Consultant, Strategic Pharmacovigilance and Risk Management

#383 Track 15 – Statistical Science and Quantitative Thinking
Related Interest Area(s): CR, RA
4:00–5:30 pm
Room 157AB
CME and Nursing

Noninferiority Trials in Drug Development: Clinical, Statistical and Regulatory Perspectives
CHAIRPERSON
Surya P. Chitra, PhD, MBA
Director, Biostatistics, Endo Health Solutions

Increasing trends in conducting noninferiority trials in drug development will continue as more drugs are approved. Although this trend will make interpretation of trial results more challenging, it can provide opportunities for new outcomes for patients.

#384 Track 16 – Professional Development
Related Interest Area(s): PT, CR, CP
4:00–5:30 pm
Room 103
CME, Pharmacy and Nursing

Ensuring Patient-centered Care: Partnering with Patient Advocacy
CHAIRPERSON
Vicki Breitbart
Director, Health Advocacy Program, Sarah Lawrence College

Focusing on patient-centered care, these experts promise an up-to-date discussion of the essential role of patient advocates and why the demand for their skills is increasing in research, hospital, community, industry and policy making settings.

Collaborating Through Volunteer Patient Advocacy
Stephen Pew, PhD
Professor, Bethel University

Panelists
Barbara Winrich, MA, CCRP
Senior Clinical Research Program Manager, Massachusetts General Hospital

Karleen R. Habin, MSN, RN
Nursing Supervisor, Clinical Research Program Breast Oncology, Massachusetts General Hospital

#385 Track 17 – Rare/Orphan Diseases
Related Interest Area(s): CR, RA, RD
4:00–5:30 pm
Room 205B
CME and Nursing

Rescuing and Repurposing Drugs: Challenges and Opportunities
CHAIRPERSON
Cindy Luxhoj Hahn
President and CEO, Alagille Syndrome Alliance

Drug rescue and repurposing presents an opportunity to spur the drug development process by building upon previous research and development efforts. However, this strategy also has challenges, particularly related to treatments for rare/orphan diseases.

A Case Study
Ciara Kennedy, PhD, MBA, MSc
Vice President, Operations, Lumena Pharmaceuticals
Regulatory Challenges of Rescue and Repurposing
Larissa Lapteva
Medical Officer, Rare Diseases Program, Office of New Drugs, CDER, FDA

Catalyzing Innovation at the National Center for Advancing Translational Sciences
John C. McKew, PhD
Acting Director, Division of Preclinical Innovation, National Center for Advancing Translational Sciences

#386 Track 18A – Global Regulatory
Related Interest Area(s): CMC, CR, RA
4:00–5:30 pm
LEVEL: ■
FORMAT: SESSION
Room 257AB
CME, Pharmacy and Nursing

Challenges for Stable Supply of Drugs and International Cooperation
CHAIRPERSON
Nobumasa Nakashima
Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

FDA, EMA and PMDA representatives will explain the current issues and measures against drug shortages in the rapid globalization of supply chains. They will also suggest a cooperative scheme among regulatory authorities and industries to secure a stable supply of drugs.

FDA Perspective
Justina A. Molzon, JD, MPharm, CAPT. USPHS
Associate Center Director for International Programs, CDER, FDA

EMA Perspective
Emer Cooke, MBA
Head of International and European Cooperation, European Medicines Agency, European Union

Japan Perspective
Naoyuki Yasuda
International Planning Director, Pharmaceutical Affairs, Minister’s Secretariat, Ministry of Health, Labour and Welfare (MHLW), Japan

#387 Track 18B – Global Regulatory
Related Interest Area(s): RA, CR, BT
4:00–5:30 pm
LEVEL: ■
FORMAT: FORUM
Room 251
CME and Nursing

Latin America Town Hall
CHAIRPERSON
Alejandro Bermudez-del-Villar, MA
Project Coordinator, Latin America and Global Program Development, DIA

This forum will provide an overview of the evolution of biotechnological product regulations from Latin American regulatory personnel and a discussion on how these regulations are modeled after and differ from European (EMA) and US (FDA) regulations.

Panelists
Helen Rosenbluth, PhD
Head, Licensing Department, Instituto de Salud Publica de Chile (ISPCH), Agencia Nacional de Medicamentos (ANAMED), Chile

Representative Invited
Comisionado de Autorización Sanitaria, Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS), Mexico

#388 Track 19 – Communities Showcase
Related Interest Area(s): MC, RA
4:00–5:30 pm
LEVEL: ■
FORMAT: SESSION
Room 205A
CME, Pharmacy and Nursing

Current Regulatory Landscape Impacting Medical and Scientific Communications
CHAIRPERSON
Mary K. Sendi, PharmD
Director and Team Lead, Medical Information, Pfizer Inc

This session will address how FDA regulatory guidance documents affect the pharmaceutical industry, impacting how externally-facing medical functions communicate medical and scientific information to health care professionals and consumers.

This session has been developed by the Medical Communications Community.

Panelists
Melissa L. Hams, PharmD
Executive Director, US Medical Information, Bristol-Myers Squibb Company

Stuart Sowder, JD
Vice President, External Medical Communications, Pfizer Inc

Jeffrey K. Francer, JD, MPA
Assistant General Counsel, PhRMA

#389 Track 21 – Late Breaker
Related Interest Area(s): CR, GCP, QA/QC
4:00–5:30 pm
LEVEL: ●
FORMAT: SESSION
Room 104AB
CME and Nursing

Collaborative Approach for Site Qualification and Training Efficiencies
CHAIRPERSON
Megan Schaeffer
Director, Oncology R&D Quality Management, GlaxoSmithKline

This session will discuss efforts to create efficiencies as it relates to GCP training and site qualification.

Panelists
Megan Schaeffer
Director, Oncology R&D Quality Management, GlaxoSmithKline

Helen Rosenbluth, PhD
Head, Licensing Department, Instituto de Salud Publica de Chile (ISPCH), Agencia Nacional de Medicamentos (ANAMED), Chile

Representative Invited
Comisionado de Autorización Sanitaria, Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS), Mexico
#390 TRACK 17 - RARE/ORPHAN DISEASES

5:30-7:30 pm


CHAIRPERSON

Lesa Mitchell
CEO, Marion Kauffman Foundation

Hearing the patient voice, and understanding the patient perspective, are cornerstones of the drug development process. This year’s DIA Annual Meeting presents Here.Us.Now, a movie documentary on Wednesday evening. Wine and light refreshments will be available. An expert panel discussion will follow after the movie showing.

Here.Us.Now. is directed by Emmy award-winning filmmaker Rudy Poe, and is a story of three realities in the United States today. First, the patient advocate’s role in driving changes in policy and popular sentiment—we saw this in the AIDS movement and hope for the same in pediatric and rare diseases. Second, the Myelin Repair Foundation, Michael J. Fox Foundation, Army of Women are depicted and are pursuing models of patient-driven R&D partnerships with academic and private sector scientists. These models, which are intent on utilizing a patient focus to accelerate research outcomes while also driving policy changes through their unique funding models, have grown significantly and are achieving critical outcomes. Last but not least, this documentary underscores the story of the Hempels, who represent a patient/parent-conducted R&D model. The intent of this documentary is to underscore the need for accelerating the alternative pathways from new discoveries to curing patients.

Seats are limited: Advanced ticketing: First come, first serve.

To obtain tickets to screen HERE.US.NOW, please visit the Attendee Registration Desk no later than Tuesday at 5:00 pm. **Please note that the DIA Courtesy Shuttle will not be available.

END OF WEDNESDAY OFFERINGS

5:30-7:30 pm

CONSORTIUM OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH

Room 203

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#401 Track 01A – Clinical Operations

**Parents as Partners: Engaging Caregivers for Pediatric Trials**

**Chairperson:**
Donald Sickler
Group Account Supervisor, CAHG

This session will present best practices for engaging parents in clinical trials from both a centralized (sponsor) and localized (site) perspective. Market research results and case studies on innovative engagement strategies will be shared.

- **Enrollment in Pediatric Clinical Trials for Orphan Indications:**
  Changing Challenges into Opportunities
  Tristen Moors, MSc
  Associate Director, Clinical Operations, Hyperion Therapeutics

- **Overcoming Patient Recruitment Challenges at a Busy Pediatric Practice:**
  Ann L. Edmunds, MD, PharmD
  Principal Investigator, Omaha Ear, Nose and Throat Clinic, P.C.

#401 Track 01B – Clinical Operations

**Hot Topics in Clinical Supplies**

**Chairperson:**
Chuck Harris
Director, Product Development, Endpoint Clinical, Inc.

This symposium will address a number of current clinical supplies topics, including managing the ever-growing costly needs of large-scale investigator-initiated studies (IIS)/investigator-initiated trials (IIT)/investigator-sponsored trials (IST) program management, mitigating risk in your interactive response technology (IRT) system’s automated supply chain configuration, and an update on methods for maintaining regulatory compliance with continuously evolving import/export processes. Through a combination of instruction and case studies, our panel will surface recent developments in these areas that impact a broad spectrum of clinical operations stakeholders.

- **Supply Pooling: Lessons Learned for Making It Work in Your IIS/IIT Trials:**
  Chuck Harris
  Director, Product Development, Endpoint Clinical, Inc.

Managing Drug Supply via an Interactive Response Technology (IRT) System

Karen McNamara, MBA
Senior Manager, Clinical Supply, Infinity Pharmaceuticals, Inc.

Enhancing the Security and Regulatory Compliance of Investigational Drug and Study Material Supply to International Sites

Andrey Gurachevsky
Senior Technical Logistics Coordinator, PAREXEL International, Germany

#402 Track 02 – Project/Portfolio Management and Strategic Planning

**Orphan Drug Development Strategy by Big and Medium/Small Pharmaceutical Industries**

**Chairperson:**
Noriaki Murao, MS
Representative, NM Consulting, Japan

This session will address considerations for planning the development and commercialization strategy of orphan drugs by large as well as small companies.

- **Perspective on Orphan Drug Development: From the Industry Viewpoint:**
  Yoshihiko Ono, RPh
  Executive Director, Head of Regulatory Affairs, Japan Development, MSD K.K., Japan

- **Evolution of a Biotech from Startup to Mid Cap: Making the Orphan Disease Strategy Happen:**
  Kenneth N. Hitchner, MA
  Vice President, Development Sciences Project Management, BioMarin Pharmaceutical Inc.

- **Value and Specificity of Rare Diseases Business Model: Is the Pursuit of This Societal Priority Sustainable?**
  Michael C. Diem, MD
  Director and Head of Business Development, GSK Rare Diseases, GlaxoSmithKline

#403 Track 03 – Innovative Partnering Models and Outsourcing Strategies

**Strategic Partnerships: Emerging Models and Their Impact on Drug Development**

**Chairperson:**
Neil Ferguson
Executive Vice President, Business Development, INC Research

Strategic partnerships are gaining significant traction in the Sponsor-CRO relationship. This forum brings together experts to discuss both macro trends and individual companies’ approaches to success.

- **Panelists:**
  - David D. Lilley
    Non Executive Board Director, SFJ Pharmaceuticals Inc.
  - Mitchell A. Katz, PhD
    Executive Director, Medical Research Operations, Purdue Pharma LP
#404 Track 06 – Medical Communication, Medical Writing and Medical Science Liaison

Related Interest Area(s): MC, MDD, RA

9:00-10:30 AM  LEVEL: ●  FORMAT: SESSION
Room 104AB  CME and Nursing

Key Learnings from the Approval and Launch of a 505(b)(2) Product from a Medical Communications Perspective

CHAIRPERSON
Tamar S. Yarkoni, PharmD, RPh
Manager, Medical Information, Sanofi

This session will discuss the concept of a 505(b)(2) application. It will be compared/contrasted to a New Drug Application (NDA) for a pharmaceutical product. The responsibilities of preparing for, launching and supporting various types of medical products including drugs and devices after approval via 505(b)(2) application will be discussed.

There are unique opportunities and challenges associated with supporting devices, vaccines and diagnostic tools in the pharmaceutical industry; these will be described and general examples will be provided.

Introduction to 505(b)(2) Approved Products: How are They Different From Other Approved Products? How Do I Prepare for a Product Launch?
Tamar S. Yarkoni, PharmD, RPh
Manager, Medical Information, Sanofi

Case Studies From Contact Centers Launching 505(b)(2) Approved Products
David Bowers, PharmD
Director, Medical Communications, PPD

#405 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): DM, IT, CDM

9:00-10:30 AM  LEVEL: ■  FORMAT: SESSION
Room 252AB  CME and Nursing

edM From Three Sponsors

CHAIRPERSON
Bhanu Bahl, PhD, MA, PMP
Director, Clinical and Translational Science Center, Harvard University

Document management systems have been in use by the biotechnology/pharmaceutical industry for decades. Early efforts focused on a central repository approach using first generation technology; this was costly, failure-prone and limited in scope. Sponsors have gained new perspectives through these experiences and intensified efforts to implement advanced content management platforms to increase efficiency, expand and educate new users and address global business/regulatory challenges. This session will explore methods and use cases for how sponsors are revitalizing their content management strategies and platforms to address enterprise needs and how they are gaining new ground and reaping larger benefits.

Best Practices and Change Management Challenges for Implementing a Structured Content Management System
Mitzi S. Allred
Assistant Director, R&D Technical Information, Mgmt Clinical Sciences, Sanofi

EDM: A Case Study
Michael J. Brennan, PhD
Director, Informatics, Johnson & Johnson Pharmaceutical Research & Development, LLC

Implementation of an Electronic Document Management Process for a Global Sponsor
Bryan Christopher Souder
Associate Director, Project Management, Merck & Co., Inc.

#406 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): IT, RA

9:00-10:30 AM  LEVEL: ■  FORMAT: SESSION
Room 253A  CME and Nursing

Changing Landscape of IT in the Pharmaceutical Industry

CHAIRPERSON
Pamela Campbell, MBA
Senior Consultant, EMC Corporation

Join us for a look at current and future computing innovations that will impact how health and life sciences gather, store and share information.

The MURDOCK Study: Informatics as a Cornerstone for Understanding the Molecular Underpinnings of Chronic Diseases
Douglas Wixted, MS
Informatics Project Leader, Duke Translational Medicine Institute

Managing Big Data to Accelerate Personalized Medicine
Representative Invited
Oracle Corporation Health Sciences

#407 Track 08 – Regulatory Affairs and Submissions

Related Interest Area(s): SUBS, CR

9:00-10:30 AM  LEVEL: ■  FORMAT: WORKSHOP
Room 156C  CME and Nursing

NDA Submission Strategy for New Chemical Entity (NCE) Products in Asia Pacific Countries to Reduce Drug Lag

CHAIRPERSON
Shun Jin, MBA
Associate Director, Regulatory Affairs, Asia, Takeda Development Center, Singapore

This workshop will introduce the regulatory hurdles and strategy for a New Drug Application (NDA) submission in the Asia Pacific region. Presentations, together with interactive case studies, will help the audience understand how to reduce regulatory risk and drug lag with proper NDA strategy.

∗Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

Regulatory Challenge for NDA Submissions in China
Ning Li, MD, PhD
Vice President, GRA Head, Medical Policy, Asia, Sanofi, China
The complex network of health product research, development, manufacturing and commercial distribution continues to expand globally. Different regulatory requirements must be taken into account when dealing with international development. The focus of this symposium will be to elaborate on the varying regulatory requirements with respect to the following:

- Specific EU rules for innovative therapies, the differences with US regulatory requirements and some clues on how to build a development plan that can support an international development; the current Chinese regulatory environment, challenges on clinical trial design, and on site and patient management; and recent efforts in the developing world (including sub-Saharan Africa) aimed at regulatory capacity as well as streamlining and strengthening regulatory processes for the regulation of medicines globally.

**EU Regulatory Requirements for Innovative Drug/Delivery System Combination Products: Comparison with US Requirements**

Anne Dupraz-Poiseau
Director, Voisin Consulting Life Sciences, France

**The Challenges for Designing and Conducting Clinical Trials for Medical Devices in China**

Charlie Chen, PhD
Vice President, GCP Clinplus, China

**Medical Devices and In Vitro Diagnostics: Capacity Building for Effective Regulation in Developing Countries**

Ekopimo O. Ibia, MD, MPH, FRCP
Director and US Regulatory Policy Lead, Global Regulatory Strategy, Policy, and Safety; FDA Alumni Association International Network; Merck & Co., Inc.

The collection and use of eSource clinical data is rapidly becoming the standard medium for clinical research. Regulatory authorities have been increasingly more vocal of their support for the use of eSource clinical data, a fact that may be helping in the continued adoption of eSource and electronic data capture in general during the conduct and assessment of clinical research.

This symposium will introduce risk-based approaches when electronic data are intended to serve as the source of clinical data. Additionally, we will discuss how monitors and data managers can work together when developing and implementing a risk-based monitoring program. A final topic is the assessment of electronic health record systems that will be the repository of eSource data.

**A Common Tool for Investigator Site eSource (EHRS) Readiness Assessment**

Catherine Celingant, MA
Senior Director, Medical Business Operations, Medical Strategy and Operations, Millennium: The Takeda Oncology Company

**eSource and Risk-Based Monitoring: Impact on Sites, Data Management and Regulatory Compliance**

Edward Stephen Seguine, Jr., MBA
CEO, Clinical Ink

**Is It Time to Change the Clinical Trial Monitoring Paradigm? Results From a Phase 3 Clinical Trial Using EDC Fully Integrated With the eClinical Trial Record for Real-time Data Entry (eSource), Together with Risk-based Monitoring**

Jules T. Mitchell, PhD, MBA
President, Target Health Inc.


**Provider Perspective**
Troy Trygstad, PhD, MBA
Vice President, Pharmacy Programs, Community Care of North Carolina

**Industry Perspective**
Alan Menius
Senior Director, Medical Analytics, GlaxoSmithKline

### #412 Track 14A – Clinical Safety and Pharmacovigilance

9:00–10:30 AM  LEVEL:  Format: WORKSHOP
Room 157C  CME and Nursing

**Coding with Confidence**
CHAIRPERSON
Judy E. Harrison, MD
Senior Medical Officer, MedDRA® MSSO

This workshop will provide an overview of coding safety data with MedDRA®. Participants will apply the key principles of the MedDRA® Term Selection: Points to Consider* document by engaging in practical coding exercises in an interactive format.

*Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Boston Convention and Exhibition Center (BCEC) has stringent regulations on maximum room capacities, and they are strictly enforced. Once all seats are occupied, DIA will be required to close the workshop, and no more participants will be admitted. Interested attendees are encouraged to arrive at workshops early in order to ensure seating. Please note, as a workshop with interactivity, this event will not be recorded.

**Practical Experience Applying Coding Principles and Conventions**
Jean D. Cole, PharmD
Associate Director, Drug Safety and Public Health, Gilead Sciences, Inc.

### #413 Track 14B – Clinical Safety and Pharmacovigilance

9:00–10:30 AM  LEVEL:  Format: SESSION
Room 153AB  CME, Pharmacy and Nursing

**Tracking Misuse and Abuse of Marketed Products: Is Pharma Doing All that It Can?**
CHAIRPERSON
Mitch Miller, PharmD
Director, Publications and Medical Writing, Drug Safety Alliance, Inc.

This session will discuss if pharmaceutical companies are doing all that they can to ensure accurate communication of the risks involved in misuse of certain medications, and if they are appropriately tracking all adverse event reports received as a result of product misuse. This session will focus on the best practices involved in monitoring, tracking and reporting off-label use and misuse of pharmaceutical products.

**Faster, Higher, Stronger: The Biopharmaceutical Industry’s Collaboration Against Doping Abuse of Medicines in Sport**
Barbara Leishman, MA
External Business Alliance Leader, F. Hoffmann-La Roche Ltd., Switzerland

**Data Sources for Monitoring Usage of Drug Products and Supporting Safety and REMS Evaluations**
Juliane Mills
Senior Project Manager, United BioSource Corporation

### #414 Track 15 – Statistical Science and Quantitative Thinking

9:00–10:30 AM  LEVEL:  Format: WORKSHOP
Room 157AB  CME and Nursing

**Some Innovative Approaches to Handling Missing Data Problems in Clinical Trials**
CHAIRPERSON
Peiling Yang, PhD
Team Lead, Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

In this session, innovative alternative designs will be proposed that may be applicable to trials in certain disease areas to mitigate missing data problems. With regard to sophisticated analyses, such as multiple imputation and pattern mixture model, which require simulating data sets to impute missing values, an illustration will be given as to how to pre-specify the computer algorithms and capture simulated data values in ADaM to enhance the traceability and reproducibility.

**Design Consideration to Drop Out Problem in Psychiatric Trials**
Jinglin Zhong, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

**Academic Perspective**
Sonia Davis, DrPH
Director of the Collaborative Studies Coordinating Center, Department of Biostatistics, University of North Carolina

**Pre-specified, Traceable and Reproducible Multiple Imputation and Pattern Mixture Models Using ADaM and Define.XML**
Mat D. Davis, MS
Project Statistician, Theorem Clinical Research

### #415 Track 16 – Professional Development

9:00–10:30 AM  LEVEL:  Format: SYMPOSIUM
Room 251  CME and Nursing

**Mobile Learning and Social Media Symposium**
CHAIRPERSON
Pamela Loughner, PhD, MEd
President, Loughner and Associates Inc.

The use of mobile devices is expected to increase exponentially in the next few years. By 2016, it is estimated that there will be more than 2.1 billion mobile devices, nearly a twenty-fold increase from 2010. Mobile learning and social media are two ways to tap into the mobile revolution. Mobile learning can be used in a variety of ways to deliver both formal and informal learning and performance support. Social media supports the transmission of user-generated content and has become a powerful source of information. This symposium explores the use of both mobile learning and social media. The use of mobile learning is explored at a strategic level, with the intent to help attendees determine how to best implement mobile learning in their organizations, while the exploration of the use of social media is hands on. The social media platform that will be examined is Twitter, specifically how to use Twitter to improve your job search and to improve your conference experience.
Learning on the Go: Making the Most of Mobile Learning Technologies
Pamela Loughner, PhD, MEd
President, Loughner and Associates Inc.

Tweet Your Way to a New Job: Leveraging Twitter for Networking
Tracy A. England, MBA
Vice President, Marketing, OpenQ

Live Tweeting a Conference: Setting Personal and Professional Ground Rules
Robin Whitsell
President, Whitsell Innovations, Inc.

#416 Track 17 – Rare/Orphan Diseases
Related Interest Area(s): CEHTAebM, CR
9:00–10:30 am LEVEL: ● FORMAT: SESSION
Room 154 CME and Nursing

The Not So Rare Challenge that Faces Rare Disease Development: Demonstrate Value
CHAIRPERSON
Charles A. Stevens, JD, MBA
Vice President and General Manager, PAREXEL Consulting

Increased development of orphan products has changed how payer regulators view rare diseases. Rare disorders can now have several products FDA indicated for use; this requires that developers demonstrate the value of these rare disease products.

Panelists
Paul T. Kim, JD
Partner, Foley Hoag LLP

Jim Long
Co-Founder and Principal, BioSolutia

#417 Track 18 – Global Regulatory
Related Interest Area(s): RA, CR, CP
9:00–10:30 am LEVEL: ● FORMAT: FORUM
Room 210B CME and Nursing

CDER Town Hall: Part 1 of 2
CHAIRPERSON
Nancy D. Smith, PhD
Adjunct Professor at Temple University, FDA Alumni Association

This forum is a roundtable discussion with CDER leadership. Topics to be discussed will depend on the interests of the audience. Panel members will discuss and update regulatory changes and the current hot topics at CDER.

Part 2 of this forum will take place Thursday, June 27 at 10:45 am

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

John K. Jenkins, MD
Director, Office of New Drugs, CDER, FDA

Justina A. Molzon, JD, MPharm, CAPT, USPHS
Associate Center Director for International Programs, CDER, FDA

Robert T. O’Neill, PhD
Senior Statistical Advisor, Office of Translational Sciences, CDER, FDA

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

10:30–10:45 am COFFEE BREAK

#418 Track 01A – Clinical Operations
Related Interest Area(s): CR, RA
10:45 am–12:15 pm LEVEL: ■ FORMAT: SESSION
Room 151B CME and Nursing

CRA’s Knowledge and Adaptability Required to Monitor Informed Consent Process in an Evolving Regulatory Environment
CHAIRPERSON
Maria del Pilar Torres
Clinical Research Manager, RPS Colombia LTDA, Colombia

The evolving regulatory environment in clinical trials challenges clinical research associates (CRAs) to efficiently monitor the Informed Consent process. Today most countries have incorporated ICH guidelines into their regulations, GCP is the global standard for clinical research, and some countries are drafting stricter regulations (for example, Guatemala and Costa Rica). CRAs must be aware of all the local regulations requirements when monitoring informed consents in different countries in Latin America. Due to the evolving regulations, the continuous review, training and search for any updates to the ICH Guidelines and local regulations are needed for the team.

Informed Consent: Promise, Pledge, Contract or Platitude?
Michael A. Swit, Esq, JD
Special Counsel, Duane Morris, LLP

#419 Track 01B – Clinical Operations
Related Interest Area(s): RA, CR
10:45 am–12:15 pm LEVEL: ● FORMAT: SYMPOSIUM
Room 153AB CME and Nursing

Impact and Interventions Related to FDASIA: Increasing Diversity in Clinical Trials
CHAIRPERSON
Brenda Jamerson, PharmD
Associate Professor, Clinical Research, Campbell University College of Pharmacy and Health Sciences

This symposium will provide an overview of the FDA Safety and Innovation Act (FDASIA) addressing the challenges and strategies related to increasing minority enrollment in clinical trials and the strategies that may facilitate comprehension of Informed Consent.

Strategies to Improve Informed Consent to Enhance Comprehension and Recruitment of Ethnically Diverse Populations
Brenda Jamerson, PharmD
Associate Professor, Clinical Research, Campbell University College of Pharmacy and Health Sciences

Understanding the Food and Drug Administration Safety and Innovation Act (FDASIA) and How It Will Impact Minority Recruitment
Almenia K. Garvey, MSc
Senior Clinical Feasibility Leader, PAREXEL International

Sociological Trends Affecting Minority Participation in US Clinical Trials
Rebecca Lynn Budd
Managing Director, Navita Clinical Strategy Group
#420 Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): CR, MA, RD

10:45 AM–12:15 PM

LEVEL: ◆

Format: SESSION

Room 152

CME and Nursing

The Importance of Country Selection in Clinical Study Design

CHAIRPERSON

Joan M. Meyer

Executive Director, Operational Strategy and Planning, Covance Inc.

The importance of country selection as part of the overall clinical trial strategy will be discussed. The impact of country selection on patient recruitment and retention programs and how it impacts a company’s marketing plans will be considered.

Panelists

Jeffrey S. Handen, PhD

Vice President, Clinical Solutions, Medidata Solutions Worldwide

#421 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): SP, OS

10:45 AM–12:15 PM

LEVEL: ■

Format: SESSION

Room 153C

CME, Nursing and PMI PDUs

Transforming Relationships to Adapt to Evolving Organizational Strategic Goals

CHAIRPERSON

Alison Holland

Executive Director, Alliance Leader, Covance Inc., United Kingdom

A big pharma-CRO partnership was established in 2004. Over the years environmental, organizational and strategic shifts have required readjustment for the partnership to remain fit for purpose and value added, as this session will explore.

Panelists

Tim Steven

Global Alliance Leader, Scientific Sourcing, Roche Products Ltd., United Kingdom

Ruth Fullerton, PhD

CRO Key Service Area Manager, Roche Products Ltd., United Kingdom

#423 Track 07A – Processes and Technologies for Clinical Research

Related Interest Area(s): EC, BT, IT

10:45 AM–12:15 PM

LEVEL: ■

Format: SESSION

Room 252AB

CME and Nursing

Implementing a Paperless Trial for Phase 3: A Biotech’s Lessons Learned

CHAIRPERSON

Mary R. Flack

Vice President, Clinical Research, NanoBio Corporation

This session will discuss how a small biotech implemented a paperless trial for a phase 3 trial using electronic source, eTMF, IVR, and a reporting tool to “integrate” all the data.

Panelists

Sukhwant Khanuja, PhD

Impact of Home-based PRO on Clinical Trial Database Architecture

Sukhwan Khanuja, PhD

President and CEO, Carematix / Blipcare Inc

The session will discuss how point of care (POC) devices for clinical application may enhance the clinical trial enterprise. Clinical trials serve as a venue for testing and validating emerging or existing POC devices for successful application and commercialization of these technologies.

Impact of Home-based PRO on Clinical Trial Database Architecture

Sukhwan Khanuja, PhD

President and CEO, Carematix / Blipcare Inc

Point of Care Technology on Clinical Cardiovascular Trials

Anu Rao, MD

Medical Officer, Division of Cardiovascular Services, National Heart, Lung, and Blood Institute (NHLBI)

Point of Care Technology Adoption: A Researcher Turned Patient’s Point of View

Sue Dubman, MA

Senior Director, Global Biomedical Informatics, Sanofi

#422 Track 06 – Medical Communication, Medical Writing and Medical Science Liaison

Related Interest Area(s): MW, RA

10:45 AM–12:15 PM

LEVEL: ■

Format: SESSION

Room 156AB

CME and Nursing

Insights into China: Practical Tips for Writing Publication and Regulatory Documents

CHAIRPERSON

Julie A. Ely, PhD

Senior Medical Writer, Proscribe Medical Communications, Australia

If you think China is far away, think again! Attend this session to gain eight practical tips to help you when (not if) the opportunity arises to prepare regulatory and publication documents with your Chinese colleagues and authors.

Panelists

Joan M. Meyer

Executive Director, Operational Strategy and Planning, Covance Inc.

Alison Holland

Executive Director, Alliance Leader, Covance Inc., United Kingdom

Penelope K. Manasco, MD, MS

CEO, MANA Consulting

Insights into China: Perspectives of a Medical Journal Editor

Leslie Citrome, MD, MPH

Clinical Professor of Psychiatry and Behavioral Sciences, New York Medical College

Working Successfully as a Medical Writer in China: Practical Tips and Effective Communication with the CFDA

Julie A. Ely, PhD

Senior Medical Writer, Proscribe Medical Communications, Australia

#424 Track 07B – Processes and Technologies for Clinical Research

Related Interest Area(s): VA, IT

10:45 AM–12:15 PM

LEVEL: ■

Format: SESSION

Room 253A

CME and Nursing

What’s the Point? Can Point of Care Devices Enhance Clinical Trials?

CHAIRPERSON

Erin Iturriaga, RN

Clinical Trials Specialist, National Heart, Lung, and Blood Institute (NHLBI)

The session will discuss how point of care (POC) devices for clinical application may enhance the clinical trial enterprise. Clinical trials serve as a venue for testing and validating emerging or existing POC devices for successful application and commercialization of these technologies.

Panelists

Penelope K. Manasco, MD, MS

CEO, MANA Consulting

Sukhwant Khanuja, PhD

Impact of Home-based PRO on Clinical Trial Database Architecture

Sukhwan Khanuja, PhD

President and CEO, Carematix / Blipcare Inc

Point of Care Technology on Clinical Cardiovascular Trials

Anu Rao, MD

Medical Officer, Division of Cardiovascular Services, National Heart, Lung, and Blood Institute (NHLBI)

Point of Care Technology Adoption: A Researcher Turned Patient’s Point of View

Sue Dubman, MA

Senior Director, Global Biomedical Informatics, Sanofi
Emerging Electronic Tools in Cardiovascular Outcomes Studies

**CHAIRPERSON**
Jonathan Plehn, DrMed, FACC
Vice President, Global Therapeutic Lead, Cardiovascular/Metabolic Unit, Covance Inc.

The costs of performing large cardiovascular outcomes trials is prohibitive and constraining to development of new molecular entities. We will describe novel electronic techniques that can add to trial rigor and efficiency while reducing costs.

**CV Endpoint Management: From Identification to Adjudication**
Steffan Ekman, MPharm, MSc, RPh
Senior Clinical Scientist, F. Hoffmann-La Roche AG, Switzerland

**Mobile Patient Engagement in Cardiovascular Outcomes: A Two Way Process**
Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

**Applications and Efficiencies of Research Portals in Cardiovascular Outcomes Trials**
Rob Saiter, MS
Managing Director, Life Sciences Practice, Accenture LLP

Certificate of Pharmaceutical Product (CPPs): How Can the Process for Obtaining from and Submitting to Health Authorities Be Made More Efficient? Moving from Ribbons and Wax to Electronic Solutions

**CHAIRPERSON**
Fraser McKillop Stodart
Senior Director, Global Regulatory Affairs, Emerging Markets, Eisai Limited, United Kingdom

Most emerging market health authorities require a CPP when a marketing application is submitted. The process and timelines for requesting and accepting CPPs can cause significant delays in the execution of regulatory strategy, authority assessment and ultimately provision of new medicines to patients.

**Panelists**
Lembit Rago
Coordinator for Quality Assurance and Safety for Medicines, World Health Organization (WHO), Switzerland

Jalene W.W. Poh, RPh
Director (Ag), Therapeutic Products Branch, Health Sciences Authority, Singapore

Marianne Vogt
Manager, Regulatory Operations (EUCOC), Abbott GmbH & Co. KG, Germany

Protocol Deviations: Avoidable Problems or an Unavoidable Risk

**CHAIRPERSON**
Leslie M. Sam
Director, Global Quality Systems, Eli Lilly and Company

There is no consistent terminology or methods to categorize and report protocol deviations. The Good Clinical Practice Quality Assurance (GCP-QA) Community collaborated with industry experts and is working on a paper that will be submitted to a peer reviewed journal for publication. This interactive workshop will share findings and seek your input.

**Facilitators**
Maryrose Petrizzo, MS
Manager, Clinical Services- Vendor Management, Allergan Inc.

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

Off-target Blood Pressure Changes and Evaluation in Drug Development: Safety, Clinical and Regulatory Considerations

**CHAIRPERSON**
Jeffrey Heilbraun, MS
Director Strategic Development, Bioclinica Inc

There has been an increased focus on changes in blood pressure (BP) related to cardiac safety from a regulatory perspective. This session will provide insight into the “off-target” BP response of drugs outside of cardiovascular drugs from a development and regulatory perspective.

**Panelists**
Mary Jane Geiger
Vice President, Clinical Development, Relypsa, Inc

Fergus Sweeney, PhD
Head of Sector, Compliance and Inspection, European Medicines Agency, European Union
Thursday, June 27

#429 Track 15 – Statistical Science and Quantitative Thinking

## Related Interest Area(s): CEHTAEbM, CP, CR

10:45 AM–12:15 PM LEVEL: ■ FORMAT: SESSION Room 157AB CME, Pharmacy and Nursing

**Bayesian Methods in Medical Product Development and Comparative Effectiveness**

**CHAIRPERSON**

David Ohlssen, PhD
Senior Expert Methodologist, Novartis Pharmaceuticals Corporation

This session will discuss the importance of Bayesian methods in medical product development. We will also highlight the recent efforts of the Bayesian DIA working group.

- **An Overview of the Bayesian DIA Working Group**
  Karen Lynn Price
  Research Advisor, Eli Lilly and Company

- **Hierarchical Bayesian Methods for Combining Efficacy and Safety in Multiple Treatment Comparisons**
  Bradley P. Carlin, PhD, MS
  Professor and Head of Biostatistics, University of Minnesota

- **Panelist**
  Lisa M. LaVange, PhD
  Director, Office of Biostatistics, Office of Translational Science, CDER, FDA

#430 Track 16 – Professional Development

## Related Interest Area(s): PM, CR

10:45 AM–12:15 PM LEVEL: ■ FORMAT: SYMPOSIUM Room 251 CME and Nursing

**Cultural Awareness and Collaboration**

**CHAIRPERSON**

Gary M. Bufferd
Associate Director, Corporate Training and Employee Engagement, RPS, Inc.

With the globalization of clinical drug and device trials, cultural awareness and collaboration, as well as the ability to effectively manage organizational change, have become key components to any successful product development program. Thus, in order to optimize communication and productivity, global team leaders and members should possess certain qualities, skills, and “cultural intelligence,” as well as an awareness of change management principles. This symposium will highlight specific cultural and change management issues by discussing conceptual principles, best practices and relevant case studies.

- **Global Virtual Teams: Benefits, Challenges, and Best Practices for Effective Cross-Cultural Collaboration**
  Gary M. Bufferd
  Associate Director, Corporate Training and Employee Engagement, RPS, Inc.

- **Organizational Change Management: Toolbox for Innovation and Collaboration**
  Diane Cooney
  Principal, Perceive Media Group LLC

- **Cultural Awareness and Fluency as Vital Skills to Successfully Perform in the International Clinical Research Community**
  Heike Schoen, MBA, MSc
  Managing Director, LUMIS International, Germany

12:15 PM ANNUAL MEETING ADJOURNED

12:30–5:00PM MedDRA® User Group Meeting Room 102AB

#431 Track 18 – Global Regulatory

## Related Interest Area(s): RA, CR, CP

10:45 AM–12:15 PM LEVEL: ■ FORMAT: FORUM Room 210B CME and Nursing

**CDER Town Hall: Part 2 of 2**

**CHAIRPERSON**

Nancy D. Smith, PhD
Adjunct Professor at Temple University, FDA Alumni Association

This is a roundtable discussion with CDER leadership. Topics to be discussed will depend on the interests of the audience. Panel members will discuss and update regulatory changes and the current hot topics at CDER.

Part 1 of this forum will take place Thursday, June 27 at 9:00 AM

- **Panelist**
  Gerald J. Dal Pan, MD
  Director, Office of Surveillance and Epidemiology, CDER, FDA

  John K. Jenkins, MD
  Director, Office of New Drugs, CDER, FDA

  Justina A. Molzon, JD, MPharm, CAPT. USPHS
  Associate Center Director for International Programs, CDER, FDA

  Christine M. V. Moore, PhD
  Acting Director, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

  Robert T. O’Neill, PhD
  Senior Statistical Advisor, Office of Translational Sciences, CDER, FDA

  Robert J. Temple, MD
  Deputy Center Director for Clinical Science, CDER, FDA
DIA would like to take this opportunity to thank all of the preconference tutorial instructors who were involved in the Sunday, June 23 program.

TUT 20 Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development
Alvaro Grignolo, PhD
Corporate Vice President, Global Strategy
PAREXEL Consulting

TUT 21 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, JD
Special Counsel
Duane Morris LLP

TUT 22 Global Reimbursement Systems: A Market Access Perspective
John Brennick, MPA
Director, Worldwide Market Access
Janssen Global Services, LLC

TUT 23 A Device Primer: 510(k)s, PMAs, IDEs
Barry S. Sall, RAC
Principal Consultant
PAREXEL Consulting

TUT 24 Designing, Operating and Evaluating Patient Registries
Richard Gliklich, MD
President
Quintiles Outcome

TUT 25 Leadership: How to Organize and Lead People in Group Work
Michael Laddin, MBA, MS
CEO
LeaderPoint

TUT 26 Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development
Aamir Shahzad
President
European Society For Translational Medicine (EUSTM), Austria

TUT 27 Understanding Comparative Effectiveness Research (CER) in the Biopharmaceutical Industry
Nancie E. Celini, DrPH, MPH
Chief Learning Consultant
CAB, Inc.

TUT 28 Fourteen Steps from Research to Development
Michael R. Hamrell, PhD, RAC
President
MORAIH Consultants

TUT 29 Investigative Site Boot Camp: Innovative Solutions to your Operational Challenges
Christopher J. Hoyle, MBA
Executive Director
Elite Research Network

TUT 30 Analysis of Safety Data from Clinical Trials
Joachim Vollmar, MSc
Executive Consultant
International Clinical Development Consultants, LLC

TUT 31 Highlights of the New Pharmacovigilance Legislation in the EU-Key Points to be Taken into Account for Successful Implementation and Lessons Learned
Sabine Brosch, PharmD, PhD
Business Lead
EudraVigilance and International Standardisation in PhV
European Medicines Agency, European Union

TUT 32 Understanding Translational Medicine: Benefits and Innovative Approaches
Aamir Shahzad
President
European Society For Translational Medicine (EUSTM), Austria

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Sabine Brosch, PharmD, PhD
Business Lead
EudraVigilance and International Standardisation in PhV
European Medicines Agency, European Union

TUT 50 Understanding and Navigating the Regulatory System in China
Laurence Bin Huang, MS
Executive Director, Regulatory Affairs
AstraZeneca Pharmaceuticals Co. Ltd., China

TUT 51 Quality Oversight of CROs – Clinical Vendors
Liz Wool, BSN, RN, CCRA, CMT
President and CEO
QD-Quality and Training Solutions, Inc.

TUT 52 Regulatory Affairs for Biologics
Carol H. Danielson, DrPH, MS
President
Regulatory Advantage

TUT 53 Clinical Statistics for Nonstatisticians
Michael C. Mosier, PhD
Director, Biostatistics
EMB Statistical Solutions, LLC

TUT 54 The Art of Writing a Clinical Overview
Patricia A. Matone, PhD
President
Scientific Information Services, LLC

TUT 55 Overview of Drug Development
George H. D’Addamio, PhD
President
PharmConsult, Inc.

TUT 56 Risk Communications
Nancy D. Smith, PhD
FDA Alumni
Adjunct Professor, Temple University

TUT 57 Preparing for a US FDA Advisory Committee Meeting
Pete Taft
President
Taft and Partners

Catherine Angell Sohn, PharmD, CLP
Dean’s Professor; President, Sohn Health Strategies LLC
University of the Sciences

Karen Hough
Founder and CEO
ImprovEdge, LLC

Laurie F. Smaldone, MD
President
PharmApprove

Taft and Partners
President
FDA Alumni
Adjunct Professor, Temple University

Laurie F. Smaldone, MD
President
PharmApprove
### Student Poster Session
**Monday, June 24, 10:00 AM–5:30 PM**
*Award Ceremony at 4:30 PM*

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<td>Harshavardhan Narendra Sant, Seth G.S. Medical College and K.E.M. Hospital, India</td>
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<td>Shuai Xu, MSc, Harvard Medical School</td>
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<td>Elizabeth Olubukola Adeniran, BSN, MSc, RN, University of Liverpool/ Laureate, United Kingdom</td>
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<td>M 04</td>
<td>A Cost Analysis of Skeletal Related Events Among Elderly Men with Stage IV Metastatic (M1) Prostate Cancer</td>
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<td>Jinani Charmila Jayasekera, MA, University of Maryland</td>
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<td>Receipt of ACE Inhibitors or ARBs among Medicare Beneficiaries with Diabetes and Hypertension</td>
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<td>Satya Surbhi, MS, University of Tennessee</td>
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<td>Jia Wang, MPH, Yale University</td>
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<td>Peter Yamoah, RPh, Komfo Anokye Teaching Hospital, Ghana</td>
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<td>Shi Yin, MSc, University of Macau, Macao</td>
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### Professional Poster Session #1
**Tuesday, June 25, 11:45 AM–4:00 PM**

| T 01 | Toward a New Regulatory Paradigm for Lipid Emulsions for Parenteral Nutrition                           |
|      | Edward Tabor, MD, Fresenius Kabi                                                                       |
| T 02 | Recruitment Metrics From Together RA: A Study in Rheumatoid Arthritis Patients to Evaluate Feasibility of Direct-to-Patient Research Approach |
|      | Elisa F. Cascade, MBA, Quintiles Transnational Corp                                                    |

<p>| T 03 | Site-level Quality Assurance Outcome: Identification of Sponsor-provided Source Documents With Greatest Prevalence of Errors |
|      | Patrick Clay, PharmD, University of North Texas Health Science Center College of Pharmacy              |
| T 04 | Potential Differences in Subjects From Physician Recruitment Versus Centralized Recruitment Campaigns in a Clinical Trial |
|      | Raymond Panas, PhD, Shay Consulting, LLC &amp; George Washington University                                 |</p>
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<td>EMB Statistical Solutions, LLC.</td>
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<td>Wendy Ye, MD, MPH</td>
<td>Novartis-Alcon Labs</td>
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<td>Kay Friel</td>
<td>Ontario Institute for Cancer Research, Canada</td>
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<td>Thomas Schindler</td>
<td>Boehringer Ingelheim Pharma GmbH &amp; Co.KG, Germany</td>
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<td>Risk-based Centralized Monitoring of Clinical Trials: A Statistical Approach</td>
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<td>Mukta Tripathi, MS</td>
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<td>Patricia Brown, PhD</td>
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<td>Quintiles Transnational, India</td>
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<td>Pelin Tanyeri, MD</td>
<td>Sakarya University Medical Faculty, Turkey</td>
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<td>What Are the Attributes That Companies Believe Would Help Agencies to Make Quality Regulatory Review Decisions?</td>
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<td>Larry Liberti, MS, RPh, RAC</td>
<td>Centre For Innovation In Regulatory Science (CIRS)</td>
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<td>Karen Bossert, PhD, RPh</td>
<td>Lyophilization Technology, Inc.</td>
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<td>Jannette Karl, MBA, PMP</td>
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<td>Antonio Ferrari, MD</td>
<td>Chiesi Farmaceutici S.P.A., Italy</td>
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<td>Quintiles East Asia Pte Ltd., Singapore</td>
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<td>Kelly Lyn Traverso</td>
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<td>Andy MacKelfresh</td>
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<td>Ankita Modi, PhD</td>
<td>Merck &amp; Co., Inc.</td>
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<td>Ranjana LNU</td>
<td>Cognizant Technology Solutions Corporation</td>
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### Professional Poster Session #2
**Wednesday, June 26, 11:45 AM–4:00 PM**

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<td>Suwanna Lakshmi Jetti</td>
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<td>Andrew Dropsey, MSc</td>
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<td>Cardiabase, France</td>
<td>John Reites, Jr.</td>
<td>Quintiles, Inc.</td>
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<td>Brazilian National Cancer Institute – INCA, Brazil</td>
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<td>Amgen Inc.</td>
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<td>Katherine Saunders, MS</td>
<td>CORRONA</td>
<td>Diane Carpenter</td>
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<td>Korea Institute of Drug Safety and Risk Management, Korea, Republic of</td>
<td>Arun Krishna, PhD</td>
<td>Merck &amp; Co., Inc.</td>
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<td>Julia Brain, PhD</td>
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<td>Hye Lynn Choi</td>
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</table>
DIA Awards recognize significant individual or group accomplishments in the discovery, development or life cycle management of pharmaceutical, devices, or related products, and/or acknowledge significant volunteer contributions in the advancement of DIA’s mission and vision.

DIA PRESIDENT’S AWARD FOR OUTSTANDING ACHIEVEMENT IN WORLD HEALTH

This award recognizes the significant, innovative contributions of an individual, group of individuals, or organization to the improvement of world health.

EURORDIS
Yann Le Cam, MBA
Chief Executive Officer
France

National Organization For Rare Disorders (NORD)
Peter L. Saltonstall
President and CEO

FOUNDERS’ SERVICE AWARD

The Founders’ Service Award is named after the group of 30 professionals who founded the DIA in 1964 with a fundamental value that the Association is member driven and fueled by the pharmaceutical industry’s need for a neutral forum. It recognizes those individuals who have contributed to the advancement of the mission, vision and values of the DIA and fostered its growth and development through their dedicated and sustained volunteerism.

Francoise Augier de Cremiers, PharmD
FDC Consulting
France

OUTSTANDING SERVICE AWARD

The DIA Outstanding Service Award is given to recognize those individuals who consistently, through their volunteer efforts, made contributions to the DIA mission and vision over the past several years. These individuals have exceeded expectations in their volunteer activities with DIA.

James Xue Jun Cai, MD
Senior Vice President, Clinical Development
Roche
China

Nandkumar K. Chodankar, PhD
CEO
Excel Industries Limited
India

David B. Clemow, PhD
Senior Clinical Research Scientist
Eli Lilly and Company

Joao Massud Filho, MD
CEO
Trials Consulting
Brazil

DISTINGUISHED CAREER AWARD

The Distinguished Career Award recognizes and honors an individual with a distinguished career in the discovery, development, regulation, surveillance, or marketing of pharmaceuticals or related products. The recipient of this award has shown extraordinary service and dedication to the advancement of healthcare through career contributions to pharmaceutical and related industries that benefit industry, government and the patient.

Freda Lewis-Hall, MD, FAPA
Chief Medical Officer and Senior Vice President
Pfizer Inc

Odette Morin, MD
Director, Regulatory & Scientific Affairs
IFPMA (NGO)
Switzerland
The DIA Honorary Fellows Program is an honorary recognition of long-time volunteers and highly engaged members for their significant contributions to DIA, its members and the health care community. This is one of DIA’s highest honors and designation to recognize individuals who have made a significant impact on the Association through exemplary volunteer service and leadership.
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No Relationship or Conflicts of Interest (Nothing to Disclose)

Thomas Abrams  Bradley Carlin  Keith Dorricott  David Gillogly
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Following are the disclosures received by press time, May 3, 2013. Disclosure statements received after this date will be listed on the Addendum that is included in the meeting materials distributed on site.

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### Speaker Disclosure Statements

**Disclosure Statements (as of May 3, 2013), continued**

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<td>Inessa Volonueva</td>
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The following PIM planners and managers, Laura Excell, ND, NP, MS, MA, LPC, NCC; Trace Hutchison, PharmD; Samantha Mattiucci, PharmD, CCMEP; and Jan Schultz, RN, MSN, CCMEP; hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months.

The following DIA planners and managers, Jennifer Andree-Webb; Susan Cantrell; Julie Ho; Melissa Matta; Holly Stevens; Karen (Wetzel) Tenaglia and Joanne Wallace, hereby state that they or their spouse/life partner do not have any financial relationships or relationships to products or devices with any commercial interest related to the content of this activity of any amount during the past 12 months. The DIA planner and manager, Maureen Lamplugh, has disclosed that she is a stock shareholder of Express Scripts, and Merck & Co., Inc.

The following DIA Pharmacy Committee members have disclosed the following: Alan F. Boyd, RPh, stock shareholder of CNS Vital Signs, LLC; David M. Cocchetto, PhD, RPh, stock shareholder of GlaxoSmithKline, Teva; Teresa P. Dowling, PharmD, stock shareholder of AstraZeneca, Bristol-Myers Squibb, Merck & Co., Inc., and Vertex Pharmaceuticals; Truus Janse-de Hoog, PharmD, MSc, no financial relationships; Monica A. Kwarcinski, PharmD, employee of Purdue Pharma LP; Karin Mueller, PharmD, RPh, MBA, stock shareholder of AstraZeneca; J. Christopher Prue, MBA, RPh, no financial relationships.

The following project management professional reviewers have disclosed the following: Thomas R. Dunson, MBA, PMP, no financial relationships; Jayna Rose, PhD, PMP, employee of Amgen; Leigh Shultz, PhD, PMP, stock shareholder and employee of Merck & Co., Inc.
# UNIVERSAL ACTIVITY NUMBERS

Below is a list of the pharmacy designated Universal Activity Numbers (UAN) and type of activity that is applicable for the following program offerings:

## MONDAY, JUNE 24, 2013

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<td>109</td>
<td>Evaluation and Selection of the Optimal Endpoints for Clinical Studies</td>
<td>0286-0000-I3-523-L04-P</td>
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<td>Pediatric Drug Development: A New Paradigm Under FDASIA</td>
<td>0286-0000-I3-528-L04-P</td>
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<td>113</td>
<td>Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials</td>
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<td>118</td>
<td>Electronic Health Records (EHRs) in Signal Detection and Evaluation</td>
<td>0286-0000-I3-563-L04-P</td>
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<td>Translational Aspects from Preclinical Animal Toxicology Studies to Early Human Health Risk Assessment: Needs and Limitations</td>
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<td>CDISC SHARE: A Promising Approach to Therapeutic Area Standards Development</td>
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ABL, Inc.  
Contact: Andrew Arrage  
Email: info@ablinc.com  
Website: www.ablinc.com  

Advanced BioScience Laboratories, Inc. (ABL) is a biomedical contract research and manufacturing organization dedicated to advancing the development of therapeutics, vaccines and other biologic products. ABL has extensive experience working with government and academic entities as well as commercial bio/pharmaceutical companies. Our services include research, product design, assay development, preclinical in vivo models, immunological testing, and Phase I/II cGMP biologics manufacturing.

Acceleirum Research  
Contact: Sergio Guerrero  
Phone: 210-834-0782  

Accelevance  
Contact: Garrett Smith  
Email: information@accelevance.com  
Website: www.accelevance.com  

Accelovance is an award-winning, forward-thinking clinical services provider who implements patient-centric study solutions. We accelerate enrollment rates, ensure critical timelines are met and delivery quality data. Fixed price budgets, guarantees and shared risk relationships are examples of our vested interest. How can flexible CRO services, six wholly-owned dedicated research centers, patient recruitment/retention solutions and clinical call center services best support your next study?

Accenture  
Contact: Kristen Casey  
Email: kristen.casey@accenture.com  
Website: www.octagonresearch.com  

Accenture’s Life Science is dedicated to helping companies rethink, reshape or restructure their businesses to deliver better health outcomes. We provide consulting, outsourcing and technology around the globe in all strategic and functional areas—with a strong focus on R&D. Accenture’s Life Sciences practice connects more than 10,000 skilled professionals in over 50 countries who are personally committed to helping our clients deliver better health outcomes for people around the world.

AccuNet, Inc.  
Contact: Michael Milligan  
Email: mmilligan@acconet.com  
Website: www.peoplereadyacconet.com  

AccuNet works with CROs to deliver a complete accounting and project management solution that reduces the costs of operations and regulatory compliance while continuously improving business performance. Our solution encompasses the key system capabilities necessary to meet these demands and challenges, including Investigator Fee Processing, Pass-Through Expense Processing, Study Management, Business Management, and Sales and Business Development.

ACM Global Central Lab  
Contact: Mark Engelhart, Chief Commercial Officer  
Phone: 585-429-1990  
Email: mengelhart@acmcentral.com  
Website: www.acmglobalcentral.com  

ACM Global Central Lab offers a powerful combination of robust global capabilities, operational and scientific expertise, and unsurpassed service. Our dedicated scientific and operational management teams function as an extension of our clients’ clinical teams to develop and execute the optimal strategies to deliver the best possible outcomes for their clinical development programs.

ACR Image Metrix  
Contact: Donald Rosen, MD  
Email: info@acrimagemetrix.com  
Website: www.acrimagemetrix.com  

We are a full-service imaging Contract Research Organization (CRO) that helps optimize the power of imaging studies across all phases of drug trials (I – IV) and in medical device/software evaluations. We integrate the appropriate imaging technologies, modalities and clinical design techniques into imaging clinical trials while delivering the highest data integrity.

Acurian, Inc.  
Contact: Kirk McPoyle  
Email: kirk.mcpoyle@acurian.com  
Website: www.acurian.com  

Acurian is a global leader of clinical trial patient enrollment and retention solutions. We increase enrollment performance of sites; we identify, contact, prescreen and refer people in the local area, but unknown to a research site. As a result, sponsors complete enrollment faster and more cost-efficiently without adding sites or extending timelines. And with our patient engagement solutions, your sites will more successfully retain patients at a fraction of the cost of replacing lost patients.

ADI CRO Pvt. Ltd.  
Contact: Maneet Singh  
Email: maneet@adicro.com  
Website: www.adicro.com  

An ADI Group Company, ADI CRO has its expertise in managing data, developing tools & effective training mechanism for Clinical Trials. We are a unique blend of 80+ Medical Professionals and 100+ IT Professionals. Our expertise: 1. Create end to end training on Study Design for Patients/CRAs/Pis. Our team of Clinical Trial Experts and animators create elearning modules tailored to your needs. 2. Develop Data Conversion/Capturing tools 3. Data Management 4. EDC 5. Statistical Analysis and Medical Writing.

Adicon Clinical Laboratory Inc.  
Contact: Freyja Cheng  
Email: info@adicon.com.cn  
Website: www.adicon.com  

ADICON Clinical Trial Center leading full-service central lab for clinical trials in China, conducts activities to support new pharmaceutical developments including clinical trials and CRO (contract research organization) business. The company's comprehensive support for clinical trials contributes to realizing rapid and high quality pharmaceutical development.

Advanced Clinical  
Contact: Julie Heneghan  
Email: jheneghan@advancedclinical.com  
Website: www.advancedclinical.com  

Advanced Clinical is a full-service CRO with flexible FSP and talent management solutions that works in all areas of clinical development including preclinical development, translational medicine, and Phases 1-4. Our flexible solutions are offered through multiple outsourcing models designed meet each specific client's needs.

Aerotek  
Contact: Allyson Curran  
Email: acurrann@aerotek.com  
Website: www.aerotek.com  

Aerotek is the #1 U.S. provider of clinical and scientific staffing and provides the highest level of service through our customized recruiting solutions. By understanding your industry, our specialized recruiters are aware of hiring trends and know how to identify the necessary skills for each position.
Algorithme Pharma
Contact: Catherine Konidas
Email: contact@algopharm.com
Website: www.algopharm.com
Algorithme Pharma is an early stage clinical CRO with a full service offering, from study design to study conduct, PK analysis and bioanalysis (preclinical to Phase IV). Along with our sister company, Simbec Research in the UK, we have been servicing international pharmaceutical, biotechnology and generic drug companies for over 35 years.

Allergan, Inc.
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Phone: 770-880-3570

Aptiv Solutions
Contact: Laura Saklad
Email: info@aptivsolutions.com
Website: www.aptivsolutions.com
Aptiv Solutions is a global biopharmaceutical and medical device development company that provides a portfolio of innovative services including adaptive trials, translational sciences, regulatory services, pharmacovigilance, clinical resourcing and the operational support of a global clinical research organization. Aptiv Solutions is the only CRO to offer design, simulation and execution of adaptive clinical trials.

Aquila Solutions, LLC
Contact: Joshua Boutwell
Email: jboutwell@aquilasolutions.us
Website: www.aquilasolutions.us
Aquila provides expert eCTD publishing support. We help with both in-sourcing and out-sourcing support. We will strengthen your publishing group or take your publishing project and complete it at quickly and easily. Check out our eCTD Timeline calculator! We can help you plan your development project.

American Medical Writers Association
Contact: Shari Rager
Email: srager@amwa.org
Website: www.amwa.org
The American Medical Writers Association (AMWA), founded in 1940, is the leading professional organization for writers, editors, and other communicators of medical information. The association offers a highly regarded continuing education and certificate program; an annual conference; professional networking and listserves; job services, including Jobs Online and a Freelance Directory; member discount opportunities; and the AMWA Journal, an indexed, peer-reviewed publication.

Aptiv Solutions
Contact: Laura Saklad
Email: info@aptivsolutions.com
Website: www.aptivsolutions.com
Aptiv Solutions is a global biopharmaceutical and medical device development company that provides a portfolio of innovative services including adaptive trials, translational sciences, regulatory services, pharmacovigilance, clinical resourcing and the operational support of a global clinical research organization. Aptiv Solutions is the only CRO to offer design, simulation and execution of adaptive clinical trials.

ArisGlobal
Contact: David Liff
Email: info@arisglobal.com
Website: www.arisglobal.com
ArisGlobal is the leading provider of integrated solutions for pharmacovigilance & safety, regulatory affairs, clinical research, and quality & compliance for medical inquiries. Life science companies using ArisGlobal’s solutions can better build and maintain the trust they need with their customers, medical practitioners and regulatory bodies around the world.

Arithmos
Contact: Mike Breen
Email: info@arithmostech.com
Website: www.arithmostech.com
ARITHMOS provides IT products and services to different industries but with a special focus on making the conduct of clinical trials faster and more efficient for Pharmaceutical, Biotech and Medical Device companies as well as CROs. The company provides products for ePRO, EDC, CTMS, Pharmacovigilance, eLearning, Data Visualisation and Project Governance. Services include data integration, computer system validation, hosting and HelpDesk.

Asaman, Inc.
Contact: Marie Vrakking
Email: mail@asaman.com
Website: www.asaman.com
We are a fully licensed specialty pharmaceutical distributor. For over 19 years we have focused on serving the needs of the pharmaceutical and scientific communities in sourcing products and quality comparator drugs for clinical trials. We serve the needs of clients both domestically and internationally. Our mission is to be a reliable partner dedicated to providing the right solutions tailored to meet your specific needs, on time and on budget.
<table>
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<tr>
<td><strong>Asia CRO Alliance</strong></td>
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<tr>
<td>Contact: Sung Ho Cho</td>
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<tr>
<td>Email: <a href="mailto:info@asiacroalliance.com">info@asiacroalliance.com</a></td>
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The Asia CRO Alliance aims to provide clinical trials support to small and medium-sized pharma, biotech, medical device companies as well as multinational CROs. This innovative partnership was created to meet the demand for more options for conducting Asian clinical trials. Through its strong presence in Asia, the Asia CRO Alliance believes that it can help serve the demand by providing flexibility in its services and local expertise while working closely with sponsors and multinational CROs.

| **August Research** | **Booth: 121** |
| Contact: Liz Leff |
| Email: lleff@augustresearch.com |
| Website: www.augustresearch.com |

August Research is an American-owned niche CRO working exclusively in Central and Eastern Europe. August Research has offices in Bulgaria, Croatia, Poland, Romania and Serbia, with office-based clinical staff and Project Managers. In addition, we operate in Czech Republic, Hungary, and Slovakia with our women-owned CRO partners. With more than 12 years of clinical trials experience in the region, the August Research team combines deep local expertise and American-style customer service.

| **Author-it Software Corporation** | **Booth: 1559** |
| Contact: Chris Helgeson |
| Email: sales@author-it.com |
| Website: www.author-it.com |

Author-it is a world leader in Cloud-based component authoring for applications such as Medical Device User Documentation, Medical Communications, SOPs and Labeling. Component authoring breaks content into reusable chunks for assembly into multiple publications delivered via print and/or web. This speeds time to market, guarantees quality and standards, enhances transparency, reduces writing and review time, improves search, cuts translation costs and enables collaboration across multiple teams.

| **Axiom Real-Time Metrics Inc.** | **Booth: 413** |
| Contact: Andrew Schachter |
| Email: andrews@axiommetrics.com |
| Website: www.axiommetrics.com |

Primary Focus: Small to Medium Biotech and Pharma --- Axiom delivers easy-to-use, powerful and cost-effective EDC/Data Management solutions and services wrapped around your study needs and with cost effective pricing. We deliver a broad range of powerful and intuitive enterprise functionality/modules built around the needs of small to medium biotech, pharma and CROs. Key features include EDC, DM, randomization, integrated AE/SAE Safety Database and real-time project and clinical data reporting.

| **Axis Group LLC** | **Booth: 1732** |
| Contact: Oleksandr Kovaliukh |
| Email: ovk@axis-group.com.ua |
| Website: axis-group.com.ua |

Axis Group is clinical trials services provider in bio/pharmaceutical R&D sector. The company offers complete CRO services for phase I-IV clinical trials: since budget development thru management and monitoring to study closure. We operate locally in Ukraine with own office and on regional level in Central/Eastern Europe region via our partnering network. Our experience together with capabilities allow to execute trials successfully in various indications.

| **BARC Global Central Laboratory** | **Booth: 559** |
| Contact: Kenneth Kim |
| Email: kkim@barcusa.com |
| Website: www.barclab.com |

BARC Global Central Laboratory was founded over 25 years ago with the mission to provide services that meet the highest quality of standards, at highly competitive prices. With laboratories in the Americas, Europe, South Africa, Australia, China, Japan, and Singapore, BARC’s global reach can meet all phase I-IV study needs from routine to esoteric testing. We pride ourselves in the development of strong sponsor relationships by offering consistency, accuracy, and exceptional project management.

| **Barrington James** | **Booth: 1358** |
| Contact: Pippa Wilson |
| Email: pwilson@barringtonjames.com |
| Website: www.barringtonjames.com |

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| **BBK Worldwide** | **Booth: 307** |
| Contact: Joan F. Bachenheimer and Bonnie A. Brescia, Founding Principals |
| Phone: 617-630-4477 |
| Email: info@bbkworldwide.com |
| Website: www.bbkworldwide.com |

Founded in 1983, BBK Worldwide is the recognized global leader in patient recruitment. Through its partner companies, TCN Technologies and Agency320, BBK offers sophisticated technology, creative, and media services. BBK meets accreditation standards of the Women’s Business Enterprise National Council and is certified as a Safe Harbor company.

| **Beaufort, LLC** | **Booth: 1916** |
| Contact: John Wilson |
| Email: jwilson@beaufortcro.com |
| Website: www.beaufortcro.com |

Beaufort is a leading provider of strategic resourcing services for the Life Sciences Industry. Our recruiting and staffing services provide qualified clinical research personnel for Phase I-IV clinical trials. Beaufort Quality Oversight is an independent CRO assessment service that helps assure the integrity of global clinical trials.

| **Beckloff Associates, Inc.** | **Booth: 432** |
| Contact: Christopher Kavlick |
| Email: info@beckloff.com |
| Website: www.cardinal.com/us/en/beckloff |

Founded in 1976, Beckloff Associates, Inc. assists companies with worldwide development of pharmaceutical, biotechnology, and medical device products through regulatory and product development planning, regulatory authority interaction, regulatory documentation preparation, regulatory publishing (eCTD or paper), and compliance programs.
for sites, hospitals, SMOs, CROs and sponsors. Bio-Optronics offers its industry leading CTMS software, Clinical Conductor, in workflow and integration and a focus on unparalleled customer service. Since 1985, Bio-Optronics has demonstrated leadership in innovation, expertise thus enhancing quality, productivity and patient and staff satisfaction. Since 1985, Bio-Optronics has demonstrated leadership in innovation, expertise in workflow and integration and a focus on unparalleled customer service. Bio-Optronics offers its industry leading CTMS software, Clinical Conductor, for sites, hospitals, SMOs, CROs and sponsors.

Bio-Optronics, Inc.
Contact: Sergio Armani
Email: sales@bio-optronics.com
Website: www.bio-optronics.com
Bio-Optronics, Inc. is a software and services provider specialized in solutions to help healthcare professionals manage and optimize workflow, thus enhancing quality, productivity and patient and staff satisfaction. Since 1985, Bio-Optronics has demonstrated leadership in innovation, expertise in workflow and integration and a focus on unparalleled customer service. Bio-Optronics offers its industry leading CTMS software, Clinical Conductor, for sites, hospitals, SMOs, CROs and sponsors.

BioPharm Insight
Contact: Holly Burke
Website: www.biopharminsight.com
BioPharm Insight is your definitive guide to the global biopharma community, combining an online business intelligence system of comprehensive market analytics and key industry contacts with an independent investigative journalism news service. As part of the Financial Times Group, BioPharm Insight is also an acclaimed independent journalist team with a proven track record of breaking forward-looking and competitive business intelligence 6-12 months ahead of mainstream press.

bioskin GmbH
Contact: Betsy Hughes-Formella, PhD
Email: info@bioskin.de
Website: www.bioskin.de
Founded in 1992, bioskin® is a unique and valuable partner in dermatology research services. With state-of-the-art facilities at its headquarters in Hamburg, and its site in the center of Berlin, bioskin® has experience in innovative study designs, in-house Phase I safety & Proof-of-Concept studies, and global multi-center Phase II-IV trials.

Blinded Diagnostics
Contact: Paul Savuto
Email: paul.savuto@blindeddiagnostics.com
Website: www.blindeddiagnostics.com
Blinded Diagnostics is a contract service organization providing same day lab test results for global clinical trials. We offer over 100 test analytes on accurate and proven point of care diagnostics systems. To see the test menu visit www.pointofcaresearch.com or for more information on our services go to www.blindeddiagnostics.com.

Blue Chip Patient Recruitment
Contact: Ken Shore
Email: kshore@bluechipww.com
Website: www.bcpatientrecruitment.com
Blue Chip Patient Recruitment is the only fully-integrated patient recruitment agency in the industry. Our mission is simple: accelerating enrollment for clinical trials. Our success is rooted in our scientific, fact-based approach to patient recruitment. For over 20 years, we have accelerated enrollment for over 600 clinical trials across 52 diseases. In the last 3 years alone we have helped our sponsor and CRO partners reduce enrollment timelines by an average of 9 months per engagement.

Blue Sky Broadcast
Contact: Jim Bohlen
Email: jbohlen@blueskybroadcast.com
Website: www.blueskybroadcast.com
Blue Sky Broadcast specializes in delivering virtual meetings and web based training for life sciences programs. Our state of the art webcasting platforms and Learning Portals combined with our attentive, hands on project management has made us a respected leader in the industry.

Bracket Global
Contact: Jen Burstedt
Email: info@bracketglobal.com
Website: www.bracketglobal.com
Bracket is a specialty services provider dedicated to helping pharmaceutical sponsors and contract research organizations achieve greater certainty and accurate outcomes in their clinical trials by seamlessly leveraging science, technology and operational excellence. Products and services include IVRS/ IWRS; ePRO (via smartphone, web, phone); Rater Training & Certification; Scale Management; CDR System (computerized cognitive testing); Concordant Rater Station; VERIFIED; and In-Study Ratings Reliability.
Brand Institute
Contact: Joseph Doerfler
Website: www.brandinstitute.com

Brand Institute is a premier international branding agency that partners with healthcare, pharmaceutical and consumer companies to develop brand names. In operation since 1993, Brand Institute offers a comprehensive list of branding services including brand strategy/architecture, name development, market research, regulatory, and visual identity solutions. With regional offices strategically located, we offer the highest level of in-house expertise.

C3i, Inc.
Contact: Dave Hanaman
Email: sales@c3i-inc.com
Website: www.c3i-inc.com

From its integrated operation centers in North America, Europe, India and China, C3i helps life science companies conduct more efficient global clinical trials. C3i’s portfolio of end-to-end technology services for EDC, IR/IT, CTMS, ePRO applications and investigator portals includes: end-user training, 24x7 multi-lingual service desk, mobile device support, application hosting.

Cactus Communications
Contact: Gary Groesbeck
Email: gary.groesbeck@cactusmed.com
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CAHG
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Email: clinicaltrials@cahg.com
Website: www.cahtrialstrials.com

CAHG is a full-service patient recruitment organization, with a unique emphasis on patient insight and evidence-based strategic thinking. We provide clinical trial enrollment support services as well as specialized clinical trial consulting.

Camargo Pharmaceutical Services
Contact: Jenna Heithoff
Email: jenna@scorrmarketing.com
Website: www.camargopharma.com

Camargo Pharmaceutical Services is an end-to-end drug development service provider specializing in the 505(b)(2) approval pathway. Camargo works with companies to develop comprehensive programs, managing every facet of the plan from formulating and testing the drug product, to conducting clinical studies and FDA application submissions. Connect with Camargo on the President’s blog www.camargoblog.com or visit www.camargopharma.com for more information.

Cambridge Healthtech Media Group
Contact: Bethany Gray
Email: chi@healthtech.com
Website: www.bio-itworld.com

Cambridge Healthtech Institute (CHI) is the preeminent life science network for leading researchers and business experts from top pharmaceutical, biotech and academic organizations. CHI’s portfolio of products includes Cambridge Healthtech Institute Conferences, Insight Pharma Reports, Cambridge Marketing Consultants, Barnett Educational Services, Cambridge Meeting Planners and Cambridge Healthtech’s Media Group, which includes numerous e-newsletters as well as Bio-IT World magazine.

Cambridge Semantics
Contact: Lee Feigenbaum
Website: www.cambridge semantics.com

Cardiac Safety Research Consortium
Contact: Valarie Morrow
Email: cardiasafety@mc.duke.edu
Website: www.cardiac-safety.org

The Cardiac Safety Research Consortium (CSRC) was launched in 2006 through a MOU with Duke University to support research into the evaluation of cardiac safety of medical products. CSRC supports research by engaging stakeholders from industry, academia, and government to share data and expertise. Outputs of the CSRC include research projects taking advantage of waveforms released from the FDA ECG warehouse, “Think Tank Incubator” programs, and consensus white papers.

Cardiocore
Contact: Veronica Palacios
Email: sales@cardiocore.com
Website: www.cardiocore.com

Cardiocore and its parent company, CardioNet, are world’s largest cardiac analytics organization, offering centralized electrocardiography (ECG), Holter monitoring, cardiac event monitoring (CEM), mobile cardiac telemetry (MCOT), blood pressure monitoring (ABPM), echocardiography (ECHO), protocol development and statistical analysis for Phase I-IV clinical trials.

Cardiovascular Imaging Technologies
Contact: Staci Courter, MA CCRP
Email: info@catalent.com
Website: www.cardiovascular imagingtechnologies.com

Cardiovascular Imaging Technologies is recognized world-wide for performing and providing support for quality cardiovascular imaging clinical and research objectives, and providing expertise, products, and support for industry and end-users of cardiovascular imaging technologies with primary focuses on SPECT, PET, CT and MR.

Catalent Pharma Solutions
Contact: Kerrie Levy
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Tailored solutions from a global leader. With more than 25 years of clinical trial supply experience, we have the resources and expertise to deliver cost effective and time sensitive solutions around the world. Whether you are seeking standalone support or a comprehensive package, we have the right solution for you.

Catholic Health Initiatives Institute for Research and Innovation
Contact: Damon Hostin
Email: damonhostin@catholichealthinit.org
Website: www.catholichealthinit.org

CHI’s emerging National Clinical Research network. Being one of the largest providers of healthcare in the US, Catholic Health Initiatives recognizes that access to advances in medicine is key to care and part of CHI’s mission to provide quality and access to our communities. The CHI Center for Clinical Research’s revolutionary network model utilizes central management of multiple trials across CHI sites using standardized procedures, policies, IT/CTMS, and biospecimen collection structures.
CDISC
Contact: Andrea Vadakin
Email: info@cdisc.org
Website: www.cdisc.org
CDISC is a 501(c)(3) global non-profit charitable organization, with over 300 member organizations across the clinical research and healthcare arenas. Through the efforts of volunteers around the globe, CDISC catalyzes productive collaboration to develop freely available, industry-wide clinical research data standards. The CDISC Vision is to inform patient care and safety through higher quality medical research.

Cenduit, LLC
Contact: Rebecca Galloway
Email: info@cenduit.com
Website: www.cenduit.com
Cenduit provides interactive response technology (IRT) - driven services for clinical trials around the world. Cenduit’s IRT solutions deliver optimized clinical supply chain management and facilitate precise control over patient randomization and drug administration to enable more efficient, compliant trials. With expert personnel located around the globe, Cenduit’s unprecedented level of support currently covers more than 16,000 sites in more than 100 countries.

CenterWatch
Contact: Amy Fontaine
Email: amy.fontaine@centerwatch.com
Website: www.centerwatch.com
Founded in 1994, CenterWatch is a trusted source and global destination of clinical trials information for both professionals and patients. CenterWatch provides a wide variety of information services including study leads for investigative sites; business development leads for service providers; career opportunity resources; clinical trial listings; advertising and promotional opportunities; and proprietary market research on the global clinical trials industry.

Cerner Corporation
Contact: Caitlin Phillips
Email: www.cerner.com
Cerner, a global leader in healthcare information technology, is solving healthcare’s many challenges by connecting the right people with the right information at the right time. With more than 30 years of experience and our partnerships at more than 9300 client sites worldwide, we are now focusing on improving healthcare by leveraging technology, data and expertise to improve research – Healthcare improves when Research improves.

CFS Clinical
Contact: Kevin Williams
Email: info@cfsclinical.com
Website: www.cfsclinical.com
CFS Clinical is a specialty provider focused on the business and financial management of clinical trials. The company offers a blend of contract, regulatory, and investigator grant payment services which operate in unison to accelerate cycle times, manage compliance and risk, and stimulate investigator relationships. With our people, processes and technology we provide high quality, cost effective solutions that address critical study startup and financial issues affecting clinical trials.

Chesapeake IRB
Contact: Lauri Carlile
Email: info@irbinfo.com
Website: www.chesapeakeirb.com
Chesapeake IRB has been providing central independent IRB services since 1993. Chesapeake IRB earned AAHRPP accreditation in 2004 and was reaccredited a second time in June 2010. Chesapeake IRB offers a 21 CFR Part 11 compliant, electronic IRB platform (CIRBI) which streamlines protocol submissions and decreases investigator review turnaround times resulting in faster subject enrollments.

Chexx Inc.
Contact: Peter Sampson
Email: info@chexxinc.com
Website: www.chexxinc.com
Chexx Inc. offers a better way to send stipend payments to clinical trial patients around the world. We issue local currency incentive payments to trial participants in over 70 countries. Chexx Inc. checks, bank transfers and prepaid cards are easy to order, quickly delivered, and appreciated by beneficiaries everywhere.

Chiba University
Contact: Hideki Hanaoka
Email: info@irbinfo.com
Phone: 81-467-237-435

Chiltern International, Inc.
Contact: Susan Ojanen
Email: susan.ojanen@chiltern.com
Website: www.chiltern.com
Chiltern is a leading, full service, global Contract Research Organization with extensive experience in the management of Phase I-IV clinical trials across a broad range of therapeutic areas and contract staffing solutions. Chiltern has conducted trials in more than 40 countries and employs more than 1,500 people globally. Chiltern prides itself as a development partner that offers flexibility, responsiveness and quality delivery. Further information is available at: www.chiltern.com.

Cincinnati Children's Research Foundation
Contact: Mark Schuller
Email: mark.schuller@cchmc.org
Website: www.cincinnatichildrens.org/clinical-trials-office
Cincinnati Children's is a pediatric academic medical center and clinical research test site conducting Phase I-IV (all major therapeutic areas) and select adult Phase I-IV studies. AAHRPP accredited, it has more than 2100 active IRB approved protocols annually, more than 1100 investigators, 300 GCP trained study coordinators and more than 80 years of pediatric research experience. Contact our full-service Clinical Trials Office to place and conduct your next study.
ClinAudits can serve as your virtual QA unit or preferred vendor. Specializing in pharmaceuticals, medical devices, biotechnology, biologicals, and gene and biologics industries; specifically GCP, GMP, and GLP. Since 1994, ClinAudits has provided QA and regulatory compliance services and a profound understanding of the clinical research industry.

Website: www.clinaudits.com

Clariness has a thorough understanding of international clinical trial recruitment, study feasibility, patient surveys and site management. With more than 700 trials, we run the unique, international patient portal ClinLife®, working in 33 countries and 24 languages, with experience in more than 14,029 patients across 182 vaccine studies exceeding enrollment by 148%!

Email: michael.stadler@clariness.com
Website: www.clin-edge.com
Contact: John Giammona

Clinical Research Advantage (CRA) has provided experienced research sites to the pharmaceutical and CRO industry through its partnerships with independent physician investigators in community based settings since 1992. CRA is the largest Integrated Site Network in the industry with 38 sites in 7 states having conducted 1900+ studies in diverse therapeutic areas and ages. CRA places an emphasis on vaccines and has enrolled 14,029 patients across 182 vaccine studies exceeding enrollment by 148%!

Website: www.spgcrn.com
Email: corvin@crastudies.com
Contact: Casey Orvin

CRN is an innovative and dynamic clinical contractor and project resourcing provider. We support Sponsors/CROs with Clinical Professionals, Data Management, SAS, Biostatistics, Pharmacovigilance, and Project Teams. Our solutions provide significant cost savings with an emphasis on quality and service delivery. If you are seeking clinical/data professionals or rewarding opportunities CRN sets the standard.

Website: www.spgcrn.com
Email: diannucci@crnspg.com
Contact: David Iannucci
<table>
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<tr>
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<td>Clinical Site Services</td>
<td>637</td>
<td>Charlie Speno, 443-308-5804</td>
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<td>726</td>
<td>Cara Brant, 916-242-6466</td>
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<td>1343</td>
<td>Leslie Eisenberg, 800-887-0639-906</td>
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<td>JeanMarie Markham, 215-855-9054</td>
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<td>Bob Borysko and Greg Ambra, 732-764-6969</td>
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<td>2000</td>
<td>Jeff Rogers, 919-746-7676</td>
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<td>Clintec International Ltd.</td>
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<td>313</td>
<td>Marie-Laure Dyck, 617-576-2005</td>
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<td>Cmed Group Ltd</td>
<td>858</td>
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Clinical Site Services (CSS) is a GlobalSite Performance Company. Our services focus on managing the clinical trial patient enrolment process & supporting sites to maximize their performance in meeting or exceeding patient accrual timelines. We have proven that setup sites for success is best achieved by investing our efforts in developing site-specific enrolment strategies which minimizes costs, timelines and maximizes the site's enrollment potential.

Clinical Trial Media is a global patient recruitment and retention company specializing in outreach, call center, tracking and support services to successfully complete studies on time and under budget. CTM has randomized subjects for thousands of clinical research studies across a wide variety of therapeutic areas since 1995.

ClinicalConnection offers e-patient recruitment to sponsors, CROs, SMOs and investigator sites. With a quarter of a million visitors each month, ClinicalConnection is the most visited non-government website for clinical trial searches and patient referrals. Services include: customized trial listings and patient referral options, PatientEdge™ database recruitment, branded recruitment and site support websites, online advertising, and industry career listings.

Clinicallingua Translation Services see Imperial

Clinlogix is a full service, multi-therapeutic Clinical Research Service Organization that provides expert outsourcing on a functional basis — globally. We offer customized, metric-driven, essential services such as Project management, Safety, Monitoring, Data management, Vendor management and Investigator Site identification and Management. Clinlogix delivers support with highly experienced and therapeutically aligned professionals on a flexible and scalable global platform.

DZS has been providing software and services supporting clinical trials to the life sciences industry since 1996. 65+ organizations currently depend on our clinical solutions for CDI, Coding, Trial Management and Statistical Reporting through ClinPlus software and our clinical services division.

ClinPlus/DZS Clinical Services
Bob Borysko and Greg Ambra
Email: bborysko@clinplus.com
Website: www.clinplus.com

ClinStar, LLC
Erin King
Email: erin.king@clinstar.com
Website: www.clinstar.com

ClinStar is a Western managed CRO with local operations in Russia and Eastern Europe. We have 13 years of experience in Phase I-IV clinical trials across multiple therapeutic areas. Unlike many global CROs, we offer a substantial local presence across all areas of operations, providing us with unique local knowledge and personal relationships that benefit your clinical trial.

Clinverse, Inc.
Jeff Rogers
Email: jrogers@clinverse.com
Website: www.clinverse.com

Clinverse, Inc. is a global technology and financial services company that delivers highly secure, cloud-based financial management and payment solutions for the clinical trials industry. Used by leading BioPharma companies, Clinverse has developed, ClinPay® FLS, a fully-configurable, game-changing SaaS-based platform which manages tens of millions of dollars in financial transactions for thousands of Global sites while supporting payments in 140 different currencies.

Clintec is a niche CRO with registered offices in over 40 countries worldwide. One of our key USPs is our presence in the Middle East and North Africa (MENA), ClinTec has over 8 years of experience in MENA, with offices based in Dubai Health Care City (UAE), Cairo (Egypt) and Beirut (Lebanon). To date ClinTec has worked in 11 countries in the MENA region including Turkey and Saudi Arabia; in various numerous therapeutics and studies ranging from I-IV.

ClinicalConnection offers e-patient recruitment to sponsors, CROs, SMOs and investigator sites. With a quarter of a million visitors each month, ClinicalConnection is the most visited non-government website for clinical trial searches and patient referrals. Services include: customized trial listings and patient referral options, PatientEdge™ database recruitment, branded recruitment and site support websites, online advertising, and industry career listings.

Cmed Group is an innovative clinical trials services and advanced software provider which includes two divisions: Cmed Clinical Services, a full-service CRO specialized in the design and delivery of pre-phase III traditional and innovative clinical studies, and Cmed Technology, an eClinical technology provider. Central to our business is Timeaas, a cloud-based eClinical platform that supports Study Design through Reporting.
CMIC HOLDINGS Co., Ltd.
Contact: Aya Sasada
Phone: 81-35-745-7033
Website: www.cmic-holdings.co.jp/e
CMIC — Your Strategic Partner to Lead You into the Asian Market CMIC is a one-stop gateway to the Asian market supporting pharmaceutical, biotechnology and medical device companies. Our quality services include pre-clinical and clinical research management, site management, manufacturing, sales/marketing, and consulting services which will be tailored to fit your unique specifications.

Cognitive Research Corporation
Contact: Stephen Horohonich
Phone: 727-897-9000
Website: www.cogres.com
Cognitive Research Corporation (CRC) is a full-service CRO specializing in CNS product development for pharmaceutical, nutraceutical, food/beverage, and biotechnology companies. In addition to our CRO services, CRC offers state-of-the-art computerized cognitive testing and driving simulation to assess the therapeutic effectiveness or side effects of drugs, medicinal foods, and food/beverage products on cognition, memory, mood, perceptual-motor functioning and driving performance, respectively.

Cognizant
Contact: Rohit Wadhwa
Phone: 201-801-0233
Website: www.cognizant.com
Cognizant’s Life Science Practice partners today with 27 of the top 30 global pharmaceutical/biotech organizations in addition to serving the medical devices, CRO and life sciences product companies. Cognizant is a leading provider of IT, consulting, and BPO services, dedicated to helping the world’s leading companies build stronger businesses.

Compass IRB
Contact: Wil Stewart
Phone: 919-593-1357
Website: www.compassirb.com
Compass IRB is a Central IRB located in Mesa, Arizona with full AAHRPP accreditation. Compass IRB is dedicated to outstanding customer service and the protection of human subjects. Compass IRB utilizes a customized online system “THE ANCHOR™” for online submissions and real time 24/7 tracking of all IRB documents.

CompleWare
Contact: Stacy Sanderson
Phone: 319-626-8888
Website: www.compleware.com
Complete Data. Complete Trials. CompleWare. Complete trials rely on complete data. Anything less won’t do. That’s why CompleWare pairs comprehensive eClinical software with integrated service solutions to see your clinical trial through from concept to completion. Our solutions can be fitted to fulfill whatever your trial demands, all with a supreme level of precision. CompleWare is your all-in-one-and-done clinical trial partner.

Compliance Insight
Contact: Julie Waltz Gerlach, B.S.N., M.P.H., C.I.P.
Phone: 513-860-3512-305
Website: www.compliance-insight1.com
Compliance Insight specializes in Regulatory and Quality Assurance consulting and training for pharmaceutical, nutraceutical, medical device, chemical, and bio-technology companies in North America, Europe and Asia.

Consent Solutions, Inc.
Contact: Susan Brink, DrPH
Phone: 202-497-9633
Website: www.consent solutions.com
Consent Solutions Inc. is a developer of electronic systems for informed consent for clinical trials. The flagship product, SecureConsent, enables trial candidates to review consent documents that can include embedded multimedia education and quizzes as well and other features. Handwritten digital signatures conclude the initial consenting process, which is subsequently supported through detailed tracking, a facilitated re-consent process and state-of-the-art integration with external systems.

Contract Pharma
Contact: Damaris Kopec
Phone: 201-825-2552
Website: www.contractpharma.com
Contract Pharma is the magazine and website designed specifically for outsourcing decision-makers. From drug discovery to contract manufacturing, Contract Pharma covers the world of contract services. The annual Contract Pharma conference will be held September 19 &20th at the Hyatt in New Brunswick, NJ. Stop by our booth for a free subscription and chance to win a free conference pass.

Conversis
Contact: Briana McCrory
Phone: 44-018-692-5583-1
Website: www.conversisglobal.com
Conversis is a leading provider of globalisation, internationalisation, localisation and translation services. We do business in more than 50 countries worldwide and work in over 70 languages. Other services offered: software localisation, multilingual desktop publishing, quality control & testing, interpreting, bespoke project management, content analysis & globalisation consulting and international marketing services. We love what we do and we hire translation experts who share our passion.

CORE (Centers of Research Excellence)
Contact: Andrew Kimball
Phone: 469-854-0294
Website: www.coresitenetwork.com
CORE (Centers of Research Excellence) is a revolutionary network of independent yet integrated research sites with broad therapeutic experience and geographic reach. Standardized recruitment, retention, quality, training and site operations combined with CORE’s “One Voice” communication model offer unmatched financial efficiencies. Contact us today about making Centers for Research Excellence the CORE of your next program.
Corporate Translations
Contact: Ted Gawlicki
Email: sales@corptransvinc.com
Website: www.corptransvinc.com

Corporate Translations is an ISO9001:2008 and EN15038 certified and trusted provider of translation and linguistic validation solutions to the world's top life science companies. Our proven methodology and expertise in this highly regulated industry make us well qualified to translate and format documents throughout the entire lifecycle of a drug.

Court Square Group, Inc.
Contact: Keith Parent, CEO
Email: sales@courtsquaregroup.com
Website: www.courtsquaregroup.com

CSG is a professional consultancy specializing in the needs of FDA regulated companies, including IT planning, network, security and project management. CSG has expertise in business process optimization, auditing and quality (including validation), clinical data services, application development, and provides secure cloud based hosted and managed systems.

Covance Inc.
Contact: Sarah Wilde
Email: covance.inc@covance.com
Website: www.covance.com

Covance is one of the world's largest and most comprehensive drug development services companies with more than 11,000 employees in 60 countries. Through its discovery, nonclinical, clinical and commercialization services, Covance has helped pharmaceutical and biotech companies develop one-third of all prescription medicines in the market today.

Covigilant
Contact: Ken Nordeen
Email: kenneth.nordeen@covigilant.com
Website: www.covigilant.com

We provide a full-service, validated, hosted Argus Safety environment, complete with safety monitoring dashboard, global regulatory reporting rules, custom PBRER and DSUR reports, custom E2B mappings, custom E2B edit checks, auto-case narrative generation, auto-letter generation, dynamic workflow and many other enhancements resulting from over 10 years experience configuring and managing Argus Safety systems. We offer the highest level of quality and compliance while reducing cost of ownership.

CPRD, The Clinical Practice Research Datalink
Contact: Maggie Massam
Email: maggie.massam@cprd.com
Website: www.cprd.com/home/

CPRD delivers major efficiencies to the clinical trials process via new digital platforms that enable fast access to large national data sets. Services include near real time feasibility, protocol optimisation and patient and site recruitment. Visit us to find out how a National Healthcare System approach can deliver a step change in clinical research.

CRA Assessments
Contact: Gerald DeWolfe
Email: gerald.dewolfe@craassessments.com
Website: www.craassessments.com

CRA Assessments can deliver a step change in clinical research. Visit us to find out how a National Healthcare System approach platforms that enable fast access to large national data sets. Services CPRD delivers major efficiencies to the clinical trials process via new digital delivery. FIM to PoC with Thorough QT, Special Patient Groups -hepatic -renal, -post menopausal and complex endpoint study specialities. CRS Clinical Research Services means competence in Clinical Development with its Human Pharmacology Infrastructure of 186 bed in 3 units, GLP-certified Bioanalytics, GMP-certified Pharmacy, Project Management, Monitoring, Biostatistics, Datamanagement, Medical Writing and Non-interventional studies.

CRF Health
Contact: Heather Bilinski
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CRF Health delivers electronic Clinical Outcome Assessments (eCOA) solutions for global clinical trials. Since 2000, CRF Health has initiated more than 400 clinical trials in over 70 countries and more than 150 regional languages; all while delivering the industry’s highest patient compliance, data accuracy and unmatched patient and site acceptance.

CRI Lifetree
Contact: Larry Brownstein
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Website: www.crilifetree.com

CRI Lifetree is a leader in early stage research with expertise in pain, abuse liability, psychiatry, neurology and diabetes. CRI Lifetree offers a range of Phase I-IV services to meet the requirements of complex clinical trials and conducts inpatient and outpatient trials in Philadelphia, New Jersey and Salt Lake City.

CROSMOUNTO
Contact: Margherita Mosconi
Email: margherita.mosconi@cromsource.com
Website: www.cromsource.com

CROS NT is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialized in clinical development and staffing solutions. CROSMOUNTO is unique. We guarantee trials will be delivered on time and to the contract price (our End-to-End Guarantee).

CROS NT Srl
Contact: Mary Wieder
Email: mary.wieder@crosnt.com
Website: www.crosnt.com

CROS NT is an international CRO specialized in clinical data services. Founded in 1992, CROS NT has completed over 800 studies and remains focused on biometrics services including clinical data management, biostatistics (analysis and programming), pharmacovigilance, medical writing and life science technology. CROS NT can also offer expert consultancy services on trial design, CDISC standards, DSMB review and regulatory submissions.

CRI Lifetree
Contact: Hannu Rautanen
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Website: www.crowncro.com

Crown CRO provides you a market access to Europe, with new level of reliability, flexibility and cost effective. Our Clinical and Regulative operations work smoothly with high attention to your needs by providing you professional services in all phases of clinical development in Europe and wide range of regulatory consulting in global level to complete your drug development team when and where needed.

CRI Lifetree
Contact: David Surjo
Email: david.surjo@crs-group.de
Website: www.crs-group.de

CRI Lifetree is an international CRO specialized in clinical data services. Founded in 1992, CRI Lifetree has completed over 800 studies and remains focused on biometrics services including clinical data management, biostatistics (analysis and programming), pharmacovigilance, medical writing and life science technology. CRI Lifetree can also offer expert consultancy services on trial design, CDISC standards, DSMB review and regulatory submissions.

CRI Lifetree
Contact: Sarah Wilde
Email: covance.inc@covance.com
Website: www.covance.com

Covance is one of the world’s largest and most comprehensive drug development services companies with more than 11,000 employees in 60 countries. Through its discovery, nonclinical, clinical and commercialization services, Covance has helped pharmaceutical and biotech companies develop one-third of all prescription medicines in the market today.

Covigilant
Contact: Ken Nordeen
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We provide a full-service, validated, hosted Argus Safety environment, complete with safety monitoring dashboard, global regulatory reporting rules, custom PBRER and DSUR reports, custom E2B mappings, custom E2B edit checks, auto-case narrative generation, auto-letter generation, dynamic workflow and many other enhancements resulting from over 10 years experience configuring and managing Argus Safety systems. We offer the highest level of quality and compliance while reducing cost of ownership.

CPRD, The Clinical Practice Research Datalink
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Email: maggie.massam@cprd.com
Website: www.cprd.com/home/

CPRD delivers major efficiencies to the clinical trials process via new digital platforms that enable fast access to large national data sets. Services include near real time feasibility, protocol optimisation and patient and site recruitment. Visit us to find out how a National Healthcare System approach can deliver a step change in clinical research.

CRA Assessments
Contact: Gerald DeWolfe
Email: gerald.dewolfe@craassessments.com
Website: www.craassessments.com

CRA Assessments can deliver a step change in clinical research. Visit us to find out how a National Healthcare System approach platforms that enable fast access to large national data sets. Services CPRD delivers major efficiencies to the clinical trials process via new digital delivery. FIM to PoC with Thorough QT, Special Patient Groups -hepatic -renal, -post menopausal and complex endpoint study specialities. CRS Clinical Research Services means competence in Clinical Development with its Human Pharmacology Infrastructure of 186 bed in 3 units, GLP-certified Bioanalytics, GMP-certified Pharmacy, Project Management, Monitoring, Biostatistics, Datamanagement, Medical Writing and Non-interventional studies.
CAROLINA.

DATATRAK Consulting Services™ group assists clients in conducting Phase I-IV drug product, cloud-based clinical research platform, DATATRAK’s Clinical and services for the clinical trials industry. Using the DATATRAK ONE™ multi-
timelines, thus bringing pharmaceutical products to market

Cu-Tech, LLC
Contact: Kathleen Ashenfelter or Anna Majeranowski
Email: kashenfelter@cu-tech.com
Website: www.cu-tech.com

Cu-Tech, LLC is a full-service CRO, celebrating two decades of premier service to the pharmaceutical industry, specializing in Dermatology clinical trials management, conduct, and monitoring. Cu-Tech professionals offer a complete array of services and consultation to the client from the inception to completion of a project. We maintain an extensive database of the finest dermatologists in North America and abroad. Our clients can attest to our personal hands-on approach.

Cytei Inc.
Contact: Mike Weitz
Phone: 617-661-2011
Website: www.cytei.com

At Cytei, we use science and technology to change how clinical trials are designed and conducted because it improves success rates. Pioneers in adaptive designs, all 25 leading biopharmaceutical companies rely on us when planning and implementing their trials.

DAC Patient Recruitment Services see Imperial

DataForm Software
Contact: Rodney Elliott
Phone: 973-882-8835
Website: www.dataformsoftware.com

DataForm Software develops and delivers R&D Program Management solutions that fully integrate team management, financial planning, project management, and analysis and reporting. These solutions measurably reduce administrative cost, improve resource utilization and expedite development timelines, thus bringing pharmaceutical products to market faster, helping people and contributing bottom line benefits.

DATATRAK International, Inc.
Contact: Lisa Pahl
Phone: 979-393-9025
Email: lisa.pahl@datatrak.net
Website: www.datatrak.net

DATATRAK is the leader of unified eClinical® technologies and related services for the clinical trials industry. Using the DATATRAK ONE™ multi-

DATATRAK ONE™ multi-product, cloud-based clinical research platform, DATATRAK’s Clinical and Consulting Services™ group assists clients in conducting Phase I-IV drug and device studies in multiple languages throughout the world. DATATRAK has offices located in Cleveland, Ohio; Bryan, Texas; and Cary (RTP), North Carolina.

DaVita Clinical Research
Contact: Sharon Parker
Email: sharon.parker@daVita.com
Website: www.davitaclinicalresearch.com

DaVita Clinical Research uses its extensive database and real-world healthcare experience to assist pharmaceutical and medical device companies in the design, recruitment and completion of retrospective, prospective pragmatic and clinical trials. DCR’s scientific and clinical expertise spans the lifecycle of product development with more than 150 client companies. DCR is focused on providing world-class research in both complex/specialty populations and therapeutic areas, and especially in CKD and ESRD populations.

Datatrial Limited
Contact: Julie Wright
Email: julie.wright@datatrial.com
Website: www.datatrial.com

Datatrial is an oncology-focused boutique clinical data organization that provides the reliability of a big company, but the personalized service and flexibility of a more nimble provider. We design your study with insight, innovation and expertise, backed by comprehensive bio-statistical and consulting services. With more than a decade of experience and offices in both Europe and the U.S., we bridge the huge gap between the promise of clinical outsourcing and the way you want results delivered.

Deloitte.
Contact: Lindsey Sloan
Email: l Sloan@deloitte.com
Website: www.deloitte.com/lifesciences

Deloitte helps life sciences organizations pursue growth opportunities and grapple with multiple scientific, business and regulatory challenges. Our extensive industry experience, advanced analytics capabilities, data stakeholders, and relevant content bring the “right” insights to our clients, solving their toughest issues. Learn how our solutions can help you in booth #1219.

DIA
Contact: Courtney Ingram
Email: dia@diahome.org
Website: www.diahome.org

DIA provides professionals at all levels and across all disciplines within the pharmaceutical, biotechnology, and medical device industries with access to knowledge resources and professional development opportunities to advance therapeutic innovation.

DIA Patient Fellowship Program
Contact: Donna Mayer
Email: donna.mayer@diahome.org
Website: www.diahome.org/DIA2013patients

Patient organizations are key stakeholders in helping DIA achieve its mission and vision. Through the Patient Fellowship Program, DIA is working to ensure that the “voice of the patient” is heard globally in every facet of the life cycle management of pharmaceuticals, medical devices, and related health care products. Stop by our booth to meet with 20 patient fellows and learn more about the DIA Patient Fellowship program.
DiagnoSearch Life Sciences  
Contact: Corey Fowler  
Email: corey.fowler@diagnosearch.com  
Website: www.diagnosearch.com

DiagnoSearch is a full service CRO headquartered in Mumbai, India offering Clinical Operations in U.S., India, Mexico, S. Korea, Philippines, Thailand and Malaysia. DiagnoSearch has over 17 years of Phase I-IV experience across a broad therapeutic spectrum, having supported 151+ clinical trials, passed 190+ CQA audits with 135 professionals across Clinical Operations, Data Management, Biostatistics, CAP Accredited Central Laboratory, Pharmacovigilance & Consulting.

DOCS  
Contact: Stephen Cottrell  
Email: stephen.cottrell@docsglobal.com  
Website: www.docsglobal.com

DOCS, as a leading provider of global resourcing solutions has a broad geographic footprint. Our expertise includes FSP, Contract Placement, Permanent Placement and Executive Search. Recent acquisitions have added scale to resource across the full development spectrum enhancing DOCS existing value proposition to provide resourcing excellence.

Dohmen Safety  
Contact: Les Williams  
Email: contact@biosoteria.com  
Website: www.dohmensafety.com

Dohmen Safety is the premier medical communications, call center and pharmacovigilance service provider to pharmaceutical and medical device companies, offering global pre- and post-approval services, award-winning educational programs, and unmatched experience to maximize the benefit-risk profile of your products and protect your patients.

DoubleBridge Technologies, Inc.  
Contact: Jimmy Chen  
Email: rosetta@doublebridge.com  
Website: www.rosettaectd.com

Established in 1997, DoubleBridge Technologies provides software and IT services to life sciences industry and regulatory agencies. Trusted by 9 of the world’s top 20 life sciences companies, our ROSETTA suite of software offers enterprise-wide, holistic views and management of your company’s regulatory information. Visit www.doublebridge.com/rosetta for details.

Dr. Ebeling & Assoc. GmbH  
Contact: Dr. Leonardo Ebeling  
Email: info@ebeling-assoc.com  
Website: www.ebeling-assoc.com

Headquartered in Hamburg, Germany, Dr. Ebeling & Assoc. GmbH is a CSO with experience in regulatory and quality and compliance consulting as well as in project and data management, providing a wide range of services in the area of GCP and pharmacovigilance for the pharmaceutical, biotech, generic drug and medical device industry. If you need an EU-QPPV or EU Legal Representative - we have the experience to support you!

Drug Safety Alliance, Inc.  
Contact: Catherine Crompton  
Email: lcarr@drugsofally.com  
Website: www.drugsafetyalliance.com

Drug Safety Alliance, a United Drug Company (DSA), is a global leader in pharmacovigilance and medical information services. DSA, as part of United Drug, is uniquely focused on providing both full-service and augmentation services for drug safety and medical information. With locations in over 23 countries, DSA provides a seamless solution for every step from initial call intake and medical communication through comprehensive pharmacovigilance and worldwide safety reporting.

DS InPharmatics  
Contact: Pamela Savoy  
Email: psavoy@dsinpharmatics.com  
Website: www.DSinPharmatics.com

DS InPharmatics is a CMC focused consulting firm providing drug development and regulatory expertise to emerging pharmaceutical and biotech companies. Our exceptional value begins with our multidisciplinary teams of manufacturing, quality, and regulatory affairs specialists. Our consultants combine in-depth product development knowledge with risk-based submission authoring and regulatory strategies for all product phases and dosage forms.

DSG, Inc.  
Contact: Jack Minster  
Email: jminster@dsg-us.com  
Website: www.dsg-us.com

DSG, Inc. celebrates over 20 years of supporting clinical trial data collection and management with a fully integrated suite of innovative technology solutions. These include industry award-winning full service Electronic Data Capture and Tech/Knowledge Transfer; specialized Clinical Data Management services; IWRs; Safety Reporting; Patient Profiles; ePRO; Clinical Trial Management Systems; on-demand CDISC SAS exporting; and digital on-demand Case Report Form publishing management software.

DUCK FLATS Pharma  
Contact: Pam Lazor  
Email: info@dfpharma.com  
Website: www.dfpharma.com

DUCK FLTAS Pharma is an expert consulting and contract firm specializing in clinical pharmacology, nonclinical development and translational medicine. Pharmacology/Toxicology/ADME studies and analyses, PK & PK/PD analyses and POP PK modeling, Statistics, Phase 1 & 2 clinical pharmacology trials, including pediatric and oncology studies, regulatory consulting; solid record of successful White Papers, IND and NDA/CTD submissions.

d-Wise Technologies  
Contact: Keith Ward  
Email: kward@d-wise.com  
Website: www.d-wise.com

At d-Wise, we believe the key to lasting success in this changing global business environment is innovation — the actual application of new ideas to improve your organization's efficiency, effectiveness, and overall competitive advantage. Innovation requires moving beyond the data to find creative answers to problems no one else can solve allowing your organization to achieve its potential as a leader in today's economy. Our service and consulting solutions help clients optimize data and systems.

EastHORN Clinical Services in CEE, Ltd.  
Contact: Leonard Gold  
Email: 908-317-2846  
Website: www.easthorn.com

EastHORN Clinical Services in CEE is a full-service CRO that offers high-value Phases I through IV clinical trial capabilities in Central and Eastern Europe. EastHORN consistently achieves the last-patient-out milestone within the proposed budget and schedule. We are the ideal regionally-focused CRO.
eClinical Solutions
Contact: Bob Arnesen
Email: barnesen@eclincialsol.com
Website: www.eclincialsol.com

eClinical Solutions seamlessly orchestrates clinical technology and expertise to accelerate the clinical development process. We provide a spectrum of customized data management services including EDC, Clinical Reporting, Data Standardization and eLLUMINATE, an innovative Clinical Data Repository with advanced visualization and analytical capabilities. Through experience and innovation we allow organizations to manage and proactively make decisions regarding clinical trials and programs.

ECLINSO
Contact: Cathy Hlinka
Email: cathy.hlinka@eclinso.com
Website: www.eclinso.com

ECLINSO is an innovative provider of Clinical Technology solutions and support services to enhance the conduct of clinical trials. Its Trialforce™ platform is easy to deploy, accessible and scalable. Using a subscription based service that saves time and cost in study deployment Trialforce™ delivers Electronic Data Capture and Data Management, Electronic Document Management, Regulatory Solutions and Services, 24 Hour Support Services and Professional and Consulting Services.

Ecron Acunova
Contact: Dorothea Hackstein
Email: dorothea.hackstein@ecronacunova.com
Website: www.ecronacunova.com

Ecron Acunova (EA) is an expert CRO with 26 years of track record. EA offers full-service clinical research including clinical operations, project management, data management, biostatistics, pharmacovigilance, PK/PD services and central lab to pharma, biotech, medical device, nutrition and diagnostic companies. EA covers 19 European as well as 9 South Asian & SEA countries. EA operates each region as a priority market with European HQ in Frankfurt, Asian HQ in Bangalore, and US HQ at Princeton.

Elite Research Network
Contact: Christopher Hoyle
Email: choyle@elteresearchnetwork.com
Website: www.elteresearchnetwork.com

Founded in 2004, Elite Research Network is a group of independently owned investigator sites which conduct clinical studies in all therapeutic areas and phases, including Phase I. We have earned a reputation for quick study start up time lines, high enrollment and providing our clients with quality data. Our sites utilize central IRBs.

Elsevier Business Intelligence
Contact: Ken May
Email: K.May@elsevier.com
Website: www.ElsevierBI.com

Elsevier Business Intelligence provides business intelligence on regulatory, business and reimbursement issues that are vital to the healthcare industry. Products include publications, conferences, e-learning, databases and reports. EBI places biopharma and medical device professionals, and those who focus on these industries, at the forefront of knowledge.

EMB Statistical Solutions, LLC
Contact: Brenda Bishop
Email: BBISHOP@EMBSTATS.COM
Website: www.EMBStats.com

EMB is a CRO specializing in the Data Management and Statistical Analysis/Reporting of clinical research data. EMB was formed in 2000 with a dedicated team of senior level associates each with over 15 years of industry experience and a proven track record of success. EMB is associate owned, has had ZERO turnover, and is “Powered by Experience”.

EMC
Contact: Lauren McDonnell
Website: www.emc.com

EMC Corporation is a global leader in enabling businesses and service providers to transform their operations and deliver IT as a service. Fundamental to this transformation is cloud computing. Through innovative products and services, EMC accelerates the journey to cloud computing, helping IT departments to store, manage, protect and analyze their most valuable asset — information — in a more agile, trusted and cost-efficient way.

Emerson Process Management
Contact: Gail Hiebner
Website: www.emersonprocess.com/systems

Emerson Process Management (EPM) is a leading process management (BPM) systems provider with a single focus: delivering cost effective, best-of-breed, off the shelf, highly configurable, user friendly solutions to our clients. The wide array of offerings from EPM allows our clients to build a complete solution that best meets their requirements and eliminates the need for multiple vendors.

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eClinical Solutions seamlessly orchestrates clinical technology and expertise to accelerate the clinical development process. We provide a spectrum of customized data management services including EDC, Clinical Reporting, Data Standardization and eLLUMINATE, an innovative Clinical Data Repository with advanced visualization and analytical capabilities. Through experience and innovation we allow organizations to manage and proactively make decisions regarding clinical trials and programs.

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Ecron Acunova (EA) is an expert CRO with 26 years of track record. EA offers full-service clinical research including clinical operations, project management, data management, biostatistics, pharmacovigilance, PK/PD services and central lab to pharma, biotech, medical device, nutrition and diagnostic companies. EA covers 19 European as well as 9 South Asian & SEA countries. EA operates each region as a priority market with European HQ in Frankfurt, Asian HQ in Bangalore, and US HQ at Princeton.

Elite Research Network
Contact: Christopher Hoyle
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Founded in 2004, Elite Research Network is a group of independently owned investigator sites which conduct clinical studies in all therapeutic areas and phases, including Phase I. We have earned a reputation for quick study start up time lines, high enrollment and providing our clients with quality data. Our sites utilize central IRBs.

Elsevier Business Intelligence
Contact: Ken May
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Website: www.ElsevierBI.com

Elsevier Business Intelligence provides business intelligence on regulatory, business and reimbursement issues that are vital to the healthcare industry. Products include publications, conferences, e-learning, databases and reports. EBI places biopharma and medical device professionals, and those who focus on these industries, at the forefront of knowledge.

EMB Statistical Solutions, LLC
Contact: Brenda Bishop
Email: BBISHOP@EMBSTATS.COM
Website: www.EMBStats.com

EMB is a CRO specializing in the Data Management and Statistical Analysis/Reporting of clinical research data. EMB was formed in 2000 with a dedicated team of senior level associates each with over 15 years of industry experience and a proven track record of success. EMB is associate owned, has had ZERO turnover, and is “Powered by Experience”.

EMC
Contact: Lauren McDonnell
Website: www.emc.com

EMC Corporation is a global leader in enabling businesses and service providers to transform their operations and deliver IT as a service. Fundamental to this transformation is cloud computing. Through innovative products and services, EMC accelerates the journey to cloud computing, helping IT departments to store, manage, protect and analyze their most valuable asset — information — in a more agile, trusted and cost-efficient way.

Emerson Process Management
Contact: Gail Hiebner
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Emerson Process Management (EPM) is a leading process management (BPM) systems provider with a single focus: delivering cost effective, best-of-breed, off the shelf, highly configurable, user friendly solutions to our clients. The wide array of offerings from EPM allows our clients to build a complete solution that best meets their requirements and eliminates the need for multiple vendors.
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Entimo is a product oriented life sciences and regulatory informatics company. It delivers high-quality IT products, custom solutions and services which shorten the drug research and development processes of the pharmaceutical industry. Entimo uses current IT standards, methods and tools to create and deliver regulatory compliant and cost saving products as well as professional services that cover the customers' needs in the pre-clinical and clinical development areas.

### ePharmaSolutions
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ePharmaSolutions is a leading provider of eClinical solutions to the life sciences industry servicing over 300,000 clinical researchers in 130 countries. ePharmaSolutions' fully integrated Clinical Trial Portal, User Management, and eTMF solutions can be configured in minutes and externalized to study team and sites with single credential access to 15 of the leading eClinical applications.

### EPS Corporation
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EPS Corporation is a full-service CRO with Headquarters in Japan, 22 offices in 7 countries, and operations in Japan, China, and Southeast Asia. EPS provides R&D support to pharmaceutical, biotech, medical device companies, and CROs. EPS also provides SMO, IT, Professional Support Call Center, and Contract Sales Organization services in Asia Pacific.

### ERT
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ERT, a global technology-driven provider of health outcomes research solutions & services supporting biopharma & medical device organizations to achieve their new medical product development & commercialization objectives. ERT harnesses leading technology coupled with reliable processes & scientific expertise to collect, analyze & report on clinical trial data to support the determination of health outcomes critical to the approval, labeling & reimbursement of pharmaceutical & medical products.

### European Medicines Agency
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The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by member states for the evaluation, supervision, and pharmacovigilance of medicinal products.

### EUROTRIALS
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Eurotrials is a private independent company founded in 1995 in Lisbon, Portugal, providing CRO services in R&D and general consulting in the Health sector in Europe and Latin America. Eurotrials is in Brazil since 2001 and opened offices in Argentina and Chile in 2011. We are small enough to care and big enough to deliver!

### Evado eClinical
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Evado eClinical is a cloud-based user friendly Australian designed and developed EDC and CTMS for Phase 1, 2 trials and post market surveillance trials and studies. Patent Pending Evado eClinical is suitable for pharma, device, research and CAM studies and trials. Evado Registry is simple to configure for complex disease and specialist registries. EVADO* will be launching exciting new products at DIA 2013.

### Evaluate
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Evaluate is the trusted source for life science market intelligence and analysis and exclusive consensus forecasts to 2018. We proudly support sector companies, financial institutions, consultancies and service providers. Our services are EvaluatePharma, EvaluateClinical and EvaluateMedTech. Our editorial arm, EP Vantage, leverages our content to cut through the noise, giving you daily opinion and insights. Evaluate is committed to deliver the highest quality content and make it highly valuable.

### Everest Clinical Research
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Everest Clinical Research Services Inc. is a CRO providing biostatistics, data management, medical writing, IWRS, and other services to pharmaceutical, biotechnology, and medical devices companies worldwide. We provide quality, customer-focus, and flexibility, working with many of the most advanced drugs in development today. Welcome to our corporate website www.ecrscorp.com.

### Exco InTouch
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Exco InTouch is the leading provider of mobile and digital patient engagement solutions to support Clinical, Late Phase and mHealth programs. Using a combination of regulatory compliant software and services, Exco InTouch solutions provide simple, secure and non-intrusive channels of communication that facilitate the collection of quality data, ensuring successful study outcomes for Sponsors, Clinical Research Organisations, Sites and Patients.

### ExecuPharm, Inc.
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- **Website:** www.execupharm.com

ExecuPharm (EP) is an experienced contract research organization and outsourcing company. Our core management team has extensive clinical operations experience from the sponsor side and can provide global services for all or specific functions within your clinical programs. EP provides access to a pre-screened talent pool, outstanding training, responsive management, and a commitment to reduce your operational challenges. ExecuPharm is WBENC certified.
Pharmacovigilance, Risk Management Planning, Adverse Event Planning, management processes. Feith can assist in streamlining your processes for even your most challenging production, governance, and business.

Feith's comprehensive BridgeLogiQ platform is easily tailored to meet leading software and innovative Business Process Management requirements of clinical research. This platform supports a seamless exchange of ECG data from investigator sites to a centralized location including the export of FDA-HL7 data.

Foresight Group, LLC
Contact: Joe Salamon
Email: dia@foresightgroup.com
Website: www.foresightgroup.com
Foresight Group is a global professional services company focused exclusively on drug safety and surveillance and risk management services and solutions. We specialize in PV process design and optimization, drug safety database implementation and hosting, reporting, signal detection, risk management and inspection readiness and response.

Formedix Inc.
Contact: Louise Hopper
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Website: www.formedix.com
Our clinical trial automation software, the Formedix Origin and Transform suite, coupled with consultancy services enables you to remove manual, expensive, inefficient and labor intensive tasks from study set-up, EDC build, validation and submission publication processes. In facts, across every area of your end-to-end clinical trial, the time and cost savings we deliver speak for themselves and continue to do so time and time again... YOUR CLINICAL TRIALS AUTOMATED. EVERYWHERE.

Galderma Research & Development, LLC
Contact: Dia Flanagan, MS, RN, CCRC
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Galderma is a global company founded in 1981 committed to delivering innovative medical solutions to meet the dermatological needs of people throughout their lifetime while serving healthcare professionals around the world. The company has 31 wholly-owned affiliates with a worldwide network of distributors and more than 4,000 employees. Galderma’s extensive product portfolio is available in 70 countries and treats a range of dermatological conditions.

ExL Pharma
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ExL Pharma, a division of ExL Events, Inc., develops innovative, educational forums that serve the pharmaceutical and allied healthcare communities in the United States, Europe, and Latin America. Our primary market sectors include: Pharmaceuticals • Biopharmaceuticals • Biotechnology • Contract Research Organizations • Medical Devices • Academic Research Institutions

EXTEDO, Inc.
Contact: Ellie Stone
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EXTEDO is the key software and service solutions provider in the field of Regulatory Information Management. The complete EXTEDOsuite covers: Product Registration Planning & Tracking, Submission Management, Pharmacovigilance Management and Document Management. Today, EXTEDO serves more than 700 customers in 60 countries and more than 25 Regulatory Authorities worldwide. Please visit us at www.extedo.com.

Fresenius Medical Care-Clinical Studies Group
Contact: Brigid Flanagan, MS, RN, CCRC
Email: research@fmc-na.com
Website: www.fmcna.com
Fresenius Medical Care's Clinical Studies team offers a wide range of services to meet complex, diverse needs in the ESRD or CKD research arena. The team plays a leading role in managing and coordinating research services in our 2100+ dialysis facilities and CKD partners in all aspects of study implementation.

FACIT.org and FACITrans
Contact: Lauren Lent
Website: www.facit.org
FACIT.org publishes domestic and international regulatory, legislative and business news and information for the pharmaceutical and biotechnology industry. The site is a valuable resource for regulatory compliance professionals. The FACITrans e-newsletter provides industry professionals with a quick overview of FDA, EMA and other regulatory news, including links to the relevant documents.

FDAnews
Contact: Nelly Valentin
Email: nelly.valentin@fda.gov
Website: www.fdanews.com
FDAnews publishes domestic and international regulatory, legislative and business news and information for executives in industries regulated by the U.S. Food and Drug Administration. Pharmaceutical and medical device professionals rely on FDAnews’ print and electronic newsletters, books, management reports and conferences to stay in compliance with international standards and FDA’s complex and ever-changing regulations to get their products to market faster and boost profits.

Feith Systems and Software, Inc.
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Email: mitch@feith.com
Website: www.feith.com
For over three decades, Feith Systems has been developing class-leading software and innovative Business Process Management solutions for the pharmaceutical, commercial and government markets. Feith’s comprehensive BridgeLogiQ platform is easily tailored to meet even your most challenging production, governance, and business management processes. Feith can assist in streamlining your processes for Pharmacovigilance, Risk Management Planning, Adverse Event Planning, and any other critical process.
Global Language Solutions
Contact: Inna Kassatkina
Email: info@globallanguages.com
Website: www.globallanguages.com
Global Language Solutions (GLS) is an ISO 9001:2008 and EN 15038 certified translation and interpreting company specializing in pharmaceutical and clinical research translations in over 100 languages. Our regulatory experts and medical linguists have the knowledge that regulated industries demand plus extensive experience translating protocols, ICFs, labels, patient-reported outcomes (PROs), clinical trial agreements, websites, IVR/IWR & EDC applications. GLS is a certified WBE founded in 1994.

GlobalCare Clinical Trials, LTD
Contact: Gail Adinamis
Email: gadinamis@globcarect.com
Website: www.globcarect.com
GlobalCare conducts study visits (eg. blood draws, drug admin) at patients’ homes or other convenient locations via its global network of traveling clinicians to facilitate trials in a variety of indications and all phases and age groups. Globalcare’s patient-centric approach provides faster patient recruitment and better compliance/retention.

goBalto, Inc.
Contact: Charley Bratton
Email: charley@gobalto.com
Website: www.gobalto.com
goBalto develops next-generation, cloud-based solutions that simplify how clinical trials are conducted in the pharmaceutical, biotechnology, and medical device industries. Our flagship product, Tracker, is a purpose-built software-as-a-service clinical research tool. It enables clinical trial sponsors and research organizations to track and collaborate on operational data in a transparent, regulatory-compliant, and user-friendly way.

GP Strategies
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Website: www.gpstrategies.rwd.com
GP Strategies is a global provider of human and operational performance improvement solutions in the Life Sciences industry. Through our medical authoring, case management and response fulfillment solution, infoMaestro, our clients can deliver timely, consistent, customized, and compliant responses from around the globe.

Green Key Resources
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Website: www.greenkeypharma.com
Green Key Resources is one of the fastest growing professional recruitment firms offering a complete portfolio of staffing solutions, including temporary and contract staffing, executive search, and payroll services to leading Pharmaceutical, Biotechnology, Medical Device, and CRO companies nationwide.

Greenphire
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Greenphire is the industry’s leading provider of clinical payment technology, designed to change the way research professionals work. We leverage our proprietary workflow automation and advanced webâ€œ based payment technologies to help our clients improve operational efficiency, reduce costs, mitigate regulatory risks, increase subject retention and compliance, and produce quantifiable results that improve clinical operations and strategic planning.

Greenway Medical Technologies
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Hangzhou Tigermed Consulting Co., Ltd.
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Hangzhou Tigermed Consulting Co., Ltd is a leading CRO in China dedicated to provide professional full clinical trial services. Since inception in 2004, Tigermed has been committed to accelerating medical product development with costs efficiency and quality. Headquartered in Hangzhou, Tigermed operates 9 subsidiaries, 42 offices across China and 2 overseas offices in Hong Kong and USA. For more information about Tigermed, please visit www.tigermed.net.

HealthCarePoint
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Celebrating 25 years, Hurley Consulting is an international consulting company recognized for its high level of regulatory expertise and excellent quality in preparing documentation and submissions. We offer clients a broad range of unique consulting expertise together with comprehensive contract research services and submission services including eCTD and CDISC. Other services range from nonclinical, clinical assessments, regulatory strategy, document preparation and compilation.

HighPoint Solutions
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HighPoint Solutions solves the toughest IT challenges facing companies in the highly regulated life sciences and healthcare industries by providing our clients with practical IT strategies and solution implementations and giving them direct access to the people and technology that get things done. Since 2000, our 400+ consultants have provided business consulting and technology solutions that continue to deliver business value and competitive advantage to more than 140 clients nationwide.

iCardiac Technologies
Contact: Sasha Latypova
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iCardiac Technologies, Inc. is a technologically-differentiated cardiac core lab providing the industry’s most sophisticated ICH E14 compliant cardiac safety assessment methodologies for clinical studies, supported by scientific expertise, project management, worldwide site and equipment logistics, customer support and regulatory data submission.
ICON plc
Contact: Vanessa Byrne
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Website: www.iconplc.com
ICON plc is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. We specialise in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. With our global footprint and expertise and our commitment to excellence, we can help clients maximize the effectiveness of their R&D activities, with a focus on reducing fixed costs.

IDDI
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IDDI eClinical and Biostatistical Services for phase I-IV clinical trials since 1991. Trial Design - Randomization - Data Management - Biostatistics - Medical Writing. IDDI is as a major service provider in the design, collection, analysis and reporting of clinical research data combining expert methodology in Biostatistics (incl. Biomarkers validation and Support to IDMCs) with integrated technology (IWRS and coding integrated to EDC). IDDI has contributed to 15 EMA/FDA market approvals.

Imperial
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Introducing the industry’s first truly vertically integrated Clinical Research Support Organization. Comprised of DAC Patient Recruitment Services, ClinicaLingua Translation Services, and Imperial Graphics, the Imperial family of companies delivers the strength of 3 life science organizations through one point of contact. We have serviced Sponsors and CRO’s alike for 60+ combined years. We invite you to experience what it’s like to have our family working for you.

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IMS Health
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IMS Health is a leading provider of information, services and technology for the healthcare industry around the world. The company draws on its global technology infrastructure and unique combination of in-depth, sophisticated analytics, on-shore/off-shore commercial services, and software platforms to help clients better understand the performance and value of medicines. With more than 55 years of industry experience, IMS serves leading decision makers across the entire healthcare ecosystem.

Infotehna Inc.
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INFOTEHNA is a leading provider of integral compliance and regulatory content management solutions for the life sciences industry. INFOTEHNA's solutions cover content and process management across the entire product lifecycle and beyond organizational boundaries. They help users tackle challenges in R&D, Clinical Trials, RA, Pharmacovigilance, QA/ QC, Manufacturing and Submissions. They are ready to be validated and deployed without expensive customization and offer the best TCO in the market.

Infuserve America
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Website: www.infuserveamerica.com
Infuserve America provides central pharmacy support and coordination for all size clinical trials anywhere in the United States. We have honed our processes to be the most efficient and effective, and can customize to any trial’s needs. We have the all the advantages of a large, state of the art facility while maintaining the small-town feel of a corner pharmacy, providing exceptional customer service, customization, quality and follow through.
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Website: www.innopharma.it

Description: INNOPHARMA, a CRO founded in 1995, has the people, resources, culture to respond to pharma and biotech clients’ toughest drug development challenges. We are a Company with the capability and expertise to conduct clinical trials on either a local or international basis. Our Int. branches enable us to manage clinical projects across all of Europe. Services: Study Feasibility, Sites Recruitment, Project Mgmt., Patient Recruitment, Trial Monitoring, eCRF, CSR, EDC, IVRS, Med. Writing, QA.

IntegReview IRB  
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IntegReview IRB is AAHRPP accredited, provides daily meetings, including Canadian and Latin American review, expedited site review, thorough, prompt, experienced and available staff/committee members, along with consulting, e-submissions and real-time web portal access to documents within 1–2 days of board review. We maintain high standards of quality, ethical integrity and regard for human safety while being responsive and flexible to customer needs for prompt, professional services.

International Dermatology Research, Inc.  
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International Dermatology Research, Inc. is a research Site specializing in dermatology. Headquartered in Miami, Florida it provides state-of-the-art facilities, a highly qualified staff and 9 additional sites in Latin America. Over the past 20 years IDR has gained excellent recognition for conducting successful Phase II, III and IV studies.

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Intertek Cantox is a leading international scientific and regulatory consulting firm. With diverse and in-depth experience in pharmaceutical development, our resourceful and innovative team in the Pharmaceutical and Healthcare Group consists of regulatory affairs professionals, board-certified toxicologists, and scientific writers.

IntraLinks, Inc.  
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IntraLinks (NYSE: IL) empowers global companies to share content and collaborate with business partners without losing control over information. Through the IntraLinks platform, companies, partners, and third parties can share and work together on the most sensitive documents while maintaining compliance with policies that mitigate corporate and regulatory risk. IntraLinks has more than 15 years of experience, and a track record of enabling high-stakes transactions and business collaborations.

inVentiv Health Clinical  
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inVentiv Health Clinical, formerly PharmaNet/i3, is a leading provider of global drug development services to pharmaceutical, biotechnology, generic drug, and medical device companies. With 7,000 employees in more than 36 countries, inVentiv Health Clinical offers therapeutically specialized capabilities for all phases of clinical development, bioanalytical services, and strategic resourcing.

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IRB Services is a well established & respected central IRB, since 1993. Physical Boards in Florida, Ontario, and Quebec, we provide TRUE North America-wide service with local expertise. Human Research Protection, excellence in service, quality, and efficiency are at the core of our mission. Multiple weekly meetings, ultra-fast turnaround times & dedicated service teams provide Real Reviews... In Real Time, second to none.

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The Italian Medicines Agency (AIFA) is the national competent authority for: Marketing authorisation of medicinal products; Pharmacovigilance; Clinical trials; Inspections of products and manufacturing process; Independent information; and Price and Reimbursement.

JANIX CRO  
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Kelly Services specializes in clinical research solutions and has years of experience as a strategic partner to help your business reach critical goals. We build custom workforce plans as well as project-based solutions, including a synchronized approach to outsourced clinical trial management, helping you save money and increase speed to market.

Websitewww.kellyservices.us/science
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At Joule Clinical Staffing you could say the right match is in our DNA. For more than 20 years we’ve connected pharmaceutical, biotech, clinical research and medical device firms to professionals nationwide. Our specialized experience and network enable us to provide the most qualified clinical research, regulatory and drug safety specialists. Recognized for superior service, Joule provides complete solutions including contract, temporary, project and direct hire. The Right Match is in our DNA.

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The Kansas Bioscience Authority was created by the state to accelerate growth in the bioscience sector. KBA investments encourage private capital investments in Kansas bioscience companies. The KBA is a partner in BioResearch Central, home to more than 90 contract research organizations who employ more than 9,000 experts in all aspects of drug and device development.

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Kinetigen, Inc., formerly known as ClinPharm Consulting, continues to impact the pharmaceutical industry as the leading consulting firm focused on clinical pharmacology and pharmacokinetics. Kinetigen gives pharmaceutical companies and CROs rare access to a hands-on team of leading clinical pharmacology and PK professionals experienced in a multitude of therapeutic areas and using leading PK analysis software.

Contact: Mark Diamond, MBA
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KoNECT manages regional clinical trial centers, operates clinical trials training academies and provides clinical trial technology development services including all clinical monitorization activities as well as IMP/materials importation, storage, distribution, returns and destruction arrangements. Both of our facilities are inspected and approved by the Turkish Ministry of Health. We are your eye on clinical research in Turkey.

Contact: Julie Lee
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Kuantum is a leading provider of CRO and Clinical Supplies Management Services for the life science industry in Turkey and in the region. We offer a comprehensive set of cGCP and cGDP compliant services including all clinical monitorization activities as well as IMP/materials importation, storage, distribution, returns and destruction arrangements. Both of our facilities are inspected and approved by the Turkish Ministry of Health. We are your eye on clinical research in Turkey.

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Email: mehtap.asenaoktar@kuantum-cro.com
Website: www.kuantum-cro.com

Kubo Recruitment focuses on sourcing talent for the Life Sciences sector by identifying only the best fit available. This is only possible through close working relationships and a level of service second to none. Our areas of focus are clinical research, clinical data management, statistics and programming, pharmacovigilance, medical affairs, clinical monitoring and IT while our services cover Contract & Interim, Executive Search and Contingent Recruitment.

Contact: Danielle Nubani
Email: danielle.nubani@jazzpharma.com
Website: www.eusapharma.com

Joule Clinical Staffing Solutions Booth: 534
Phone: 800-382-0382

Website: www.jouleclinical.com

The Judge Group Booth: 648
Phone: 752-346-9100

Contact: Marissa Carnevale
Email: mcarnevale@judge.com
Website: www.judge.com

Looking for a new Career? The Judge Group has been recruiting Scientific & Clinical Professionals to work in the nation’s leading Pharmaceutical & Biotech companies since 1970. Whether you’re looking for a permanent or contract position, you can be sure Judge will work with you every step of the way to ensure your next career move is the right one!

Kansas Bioscience Authority Booth: 1353
Phone: 913-397-8300

Contact: Thomas F. Krol, PharmD, CLP
Email: krol@kansasbioauthority.org
Website: www.bioresearchcentral.com

The Kansas Bioscience Authority was created by the state to accelerate growth in the bioscience sector. KBA investments encourage private capital investments in Kansas bioscience companies. The KBA is a partner in BioResearch Central, home to more than 90 contract research organizations who employ more than 9,000 experts in all aspects of drug and device development.

Kayentis Booth: 1357
Phone: +33(0)169182540

Contact: Sophie Switalski
Email: sswitelski@kayentis.com
Website: www.kayentis.com

Kayentis www.kayentis.com, the leader in digital pen and paper solutions, provides the optimal paper-based e-data capture solutions for clinical trials. It offers the easiest and most reliable data collection method for both patients and physicians (pen & paper), resulting in the highest quality captured data. Kayentis solutions are based on Anoto Digital Pen & Paper technology; Kayentis is one of the leading world partners of Anoto, and is certified Anoto Platinum Partner.

Contact: Amanda Wahl
Email: jcsinfo@jouleinc.com
Website: www.jouleclinical.com

Kuborecruitment specializes in clinical research solutions and has years of experience as a strategic partner to help your business reach critical goals. We build custom workforce plans as well as project-based solutions, including a synchronized approach to outsourced clinical trial management, helping you save money and increase speed to market.

Contact: Rachel Keay
Email: info@kuborecruitment.com
Website: www.kuborecruitment.com

Kuo Recruitment Booth: 608
Phone: +44 (0) 1908487586

Contact: Joanne Hilton
Website: www.kinapse.com

Kinapse provides expert consulting and outsourcing services to the life sciences industry. We collaborate with our clients to innovate for exceptional results. We develop actionable recommendations and innovative solutions which are implemented successfully. We are one global business with expert teams of over 300 professionals worldwide. Our deeply held values and operational processes drive our teams to ensure excellent client service on all our engagements. We are KINAPSE. Come and meet us.

Contact: Mark Lanfear
Email: mark.lanfear@kellyservices.com
Website: www.kellyservices.us/science

Kelly Services specializes in clinical research solutions and has years of experience as a strategic partner to help your business reach critical goals. We build custom workforce plans as well as project-based solutions, including a synchronized approach to outsourced clinical trial management, helping you save money and increase speed to market.

Contact: Marissa Carnevale
Email: mcarnevale@judge.com
Website: www.judge.com

Looking for a new Career? The Judge Group has been recruiting Scientific & Clinical Professionals to work in the nation’s leading Pharmaceutical & Biotech companies since 1970. Whether you’re looking for a permanent or contract position, you can be sure Judge will work with you every step of the way to ensure your next career move is the right one!

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Phone: 913-397-8300

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Email: krol@kansasbioauthority.org
Website: www.bioresearchcentral.com

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Kayentis Booth: 1357
Phone: +33(0)169182540

Contact: Sophie Switalski
Email: sswitelski@kayentis.com
Website: www.kayentis.com

Kayentis www.kayentis.com, the leader in digital pen and paper solutions, provides the optimal paper-based e-data capture solutions for clinical trials. It offers the easiest and most reliable data collection method for both patients and physicians (pen & paper), resulting in the highest quality captured data. Kayentis solutions are based on Anoto Digital Pen & Paper technology; Kayentis is one of the leading world partners of Anoto, and is certified Anoto Platinum Partner.

Contact: Thomas F. Krol, PharmD, CLP
Email: krol@kansasbioauthority.org
Website: www.bioresearchcentral.com

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KCR Booth: 2047
Phone: 443-203-1847

Contact: Jenny O'Neill

KCR specializes in clinical research solutions and has years of experience as a strategic partner to help your business reach critical goals. We build custom workforce plans as well as project-based solutions, including a synchronized approach to outsourced clinical trial management, helping you save money and increase speed to market.

Contact: Jenny O'Neill
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<thead>
<tr>
<th>Company</th>
<th>Booth</th>
<th>Contact</th>
<th>Phone</th>
<th>Website</th>
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<tr>
<td>LabConnect, LLC</td>
<td>616</td>
<td>Dan Knabb</td>
<td>206-322-4680</td>
<td><a href="http://www.labconnectllc.com">www.labconnectllc.com</a></td>
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<tr>
<td>LabCorp Clinical Trials</td>
<td>1451</td>
<td>Josh Goldsmith, PhD</td>
<td>877-788-8861</td>
<td>labcorp.com/clinicaltrials</td>
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<tr>
<td>Lambda Therapeutic Research Inc.</td>
<td>1847</td>
<td>Cathy Lopez</td>
<td>95-492-956-27</td>
<td><a href="http://www.lambda-cro.com">www.lambda-cro.com</a></td>
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<tr>
<td>Liaison Healthcare Informatics</td>
<td>1858</td>
<td>Shannon Vance</td>
<td>770-442-4046</td>
<td><a href="http://www.liaisonhealthcare.com">www.liaisonhealthcare.com</a></td>
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<tr>
<td>Life Science Leader</td>
<td>1541</td>
<td>Sean Hoffman</td>
<td>724-940-7555</td>
<td><a href="http://www.lifescienceleader.com">www.lifescienceleader.com</a></td>
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<td>Lionbridge Life Sciences</td>
<td>2005</td>
<td>Tiana Pignone</td>
<td>978-964-4886</td>
<td><a href="http://www.lionbridgefsciences.com">www.lionbridgefsciences.com</a></td>
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<tr>
<td>LIQUENT, A PAREXEL Company</td>
<td>953</td>
<td>Chris Braun</td>
<td>215-328-4397</td>
<td><a href="http://www.liquent.com">www.liquent.com</a></td>
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<td>Logos Technologies Inc.</td>
<td>1251</td>
<td>Giles Wilson</td>
<td>44-845-838-5900</td>
<td>logostechnologies.com</td>
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<td>Lambda Therapeutic Research</td>
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<td>Edward Trappler</td>
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<td>lyotechnology.com</td>
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<td>MakroCare</td>
<td>754</td>
<td>John Harte</td>
<td>508-373-2935</td>
<td>makrocare.com</td>
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<td>LIQUENT, A PAREXEL Company, the leading provider of</td>
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<td>efficient &amp; innovative laboratory testing services for</td>
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<td>clinical trials programs.</td>
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<td>LabCorp Clinical Trials supports pharmaceutical</td>
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<td>companies globally with efficient &amp; innovative</td>
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<td>laboratory services to support all aspects of</td>
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<td>centralized testing at wholly owned central labs in</td>
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<td>Belgium, China, Singapore, and the U.S. – including</td>
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<td>Phase I-IV trials, esoteric testing, biomarker</td>
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<td>development and validation, new method development,</td>
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<td>and companion diagnostics.</td>
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<td>Liaison Healthcare is a global data integration</td>
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<td>and management company providing unique, scalable</td>
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<td>and high-value solutions to securely move, transform,</td>
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<td>harmonize and manage complex data for Life Science</td>
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<td>organizations. Utilizing Liaison's customized cloud-</td>
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<td>based solutions, Life Science organizations will</td>
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<td>realize an increase in overall operational efficiencies,</td>
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<td>leading to faster time-to-market. For more information,</td>
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<td>visit <a href="http://www.liaisonhealthcare.com">www.liaisonhealthcare.com</a> or call 877.336.5163.</td>
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<td>Life Science Leader strives to be an essential</td>
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<td>business tool for Life Science executives. The</td>
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<td>editorial is designed to provide readers with content</td>
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<td>pertaining to the life cycle of Life Science products</td>
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<td>and services. Our goal is to provide information</td>
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<td>that helps high-level industry personnel improve</td>
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<td>profits and overcome hurdles within the industry.</td>
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<td>Lionbridge Life Sciences is the leading provider of</td>
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<td>language services to medical device developers,</td>
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<td>pharmaceutical and biotechnology companies, and CROs.</td>
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<td>Specialize in high-quality translation, linguistic</td>
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<td>validation, and interpretation services in 150+</td>
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<td>languages. Lionbridge Life Sciences clients benefit</td>
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<td>from our highly specialized network of medically</td>
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<td>trained linguists, operating in over 40 full-service</td>
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<td>solution centers across 26 countries.</td>
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Mapi
Contact: Karin Andersson
Email: contactus@mapigroup.com
Website: www.mapigroup.com

Mapi is a leading global organization, offering evaluation and support of therapeutic strategies. With offices worldwide, Mapi provides high quality and efficient operations to help our clients secure product approvals and reimbursement, as well as addressing post-marketing requirements and late phase needs, meeting the needs of patients, physicians, regulatory authorities and health care technology purchasers. Mapi offers a complete spectrum of Real World services.

MASIMO
Contact: Scott Baldwin
Email: sbaldwin@masimo.com
Website: www.masimo.com

Masimo is a global medical technology company that develops and manufactures innovative noninvasive technologies, medical devices and sensors that may enable earlier detection and treatment of potentially life-threatening conditions—offers numerous award-winning patient monitoring solutions, including Masimo SET®, Masimo rainbow SET® noninvasive and continuous hemoglobin (SpHb®), acoustic respiration rate (RRa™), Masimo SafetyNet™, and SEDLine® (EEG-based) Brain Function Monitors.

Massachusetts College of Pharmacy and Health Sciences
Contact: Brian Barlone
Email: bbarlone@mcphs.edu
Website: www.mcphs.edu

Massachusetts College of Pharmacy and Health Sciences (MCPHS) offers exciting opportunities for those interested a graduate education in health care. To accommodate unique personal and professional schedules, students can enroll in programs as full-time or part-time studies at either our Boston Campus or Online Campus.

Massachusetts Life Sciences Center
Contact: Angus McQuilken
Email: angus.mcquilken@masslifesciences.com
Website: www.masslifesciences.com

Massachusetts Life Sciences Center is the public-private partnership of Massachusetts life sciences companies, investors, universities, research institutes, hospitals, and government agencies. The Center promotes collaboration and innovation to improve healthcare for patients in clinical trials; taking the trial to the patient above 95%.

Medidata Solutions
Contact: Craig Strauss
Email: contact@mdsol.com
Website: www.mdsol.com

Medidata Solutions is the leading global provider of cloud-based clinical development solutions that enhance the efficiency of customers' clinical trials. Medidata’s advanced platform lowers the total cost of clinical development by optimizing clinical trials from concept to conclusion.

MaxisIT Inc.
Contact: Maulik Shah
Email: mshah@maxisit.com
Website: www.maxisit.com

MaxisIT offers integrated data, analytics and regulatory content management platform CTRenaissance® as managed hosting and software-as-a-service, which empowers pharmaceuticals, life sciences and academic organizations with web-based and scalable environment to design, manage, monitor clinical trials as well as analyze and submit data on-demand in most efficient manner. A unique and successful blend of clinical trial software and services in compliance to regulatory and industry data standards.

McGuire Research Institute
Contact: Robert Dresch
Email: robert.dresch@va.gov
Website: www.research.va.gov

McGuire Research Institute (MRI) was established in 1989 and conducts Phase 1-4 clinical trials. MRI is affiliated with the Richmond VA Medical Center and has a 35,000 patient panel. IRB meets weekly, AAHRPP accredited human research protection program. Special expertise in diabetes, lipids, Hep C, Crohn's, colitis, interventional cardiology, electrophysiology, DVT, Parkinson's, spinal cord injury, traumatic brain injury.

MedDRA MSSO
Contact: Char Guy
Email: mssorequest@meddrasso.com
Website: www.meddrasso.com

MedDRA is a clinically validated terminology used for encoding adverse events for the biopharmaceutical industry and regulators. The MSSO maintains MedDRA and provides support services (e.g., training, data conversion, consulting).

Medical Research Network Ltd.
Contact: Stuart Redding
Email: stuart.redding@themrn.co.uk
Website: www.themrn.co.uk

Established in 2006, the MRN is the world’s leading provider of home healthcare for patients in clinical trials; taking the trial to the patient makes participation more convenient and appealing for the patients and boosts recruitment rates considerably (from 60% upwards). This ease of participation also significantly improves patient retention, consistently above 95%.

MedNet Solutions Worldwide
Contact: Craig Strauss
Email: contact@mednetstudy.com
Website: www.mednetstudy.com

MedNet is a leading eClinical technology solutions company specializing in electronic data capture (EDC) and clinical study management systems. Since 2001, MedNet’s web-based solutions have successfully supported research initiatives worldwide. Visit our booth to see iMedNet EDC...an affordable solution that allows sponsors and CROs to quickly and easily build their own studies.
Medpace Inc.
Contact: Jennifer Hammonds
Email: j.hammonds@medpace.com
Website: www.medpace.com
Medpace Inc., is a leading global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. Medpace has assembled the industry’s most experienced and therapeutically focused teams to execute at every level of the company’s operations, providing complete and seamless drug/device development services in over 45 countries.

MedPoint Digital, Inc.
Contact: William Cooney
Email: bill.cooney@medpt.com
Website: www.medpt.com
MedPoint Digital develops specialty eClinical platforms for investigator and study start-up portals, site training centers, virtual meetings and remote monitor visits. We support digital solutions for site databases, feasibility surveys, study documents, eStudy Binders, secure site communications, issues escalation, patient visit guides, single sign-on, and consolidated study metrics. All systems are ICH/GCP and FDA 21 CFR Part 11 compliant, modular, scalable, interoperable and audit-ready.

Medsight Solutions
Contact: Sharad Prakash
Email: info@medsight.com
Website: www.medsight.com
Medsight Solutions is a life sciences solutions and professional services company with specialties in Clinical trial optimization, Benefit-risk assessment and Compliance monitoring. Medsight delivers advanced cloud analytics platform that enables informed decision making through systematic process of data discovery, prioritization, evaluation and communication.

MedSource
Contact: Eric Lund
Email: eric@medsource.com
Website: www.medsource.com
MedSource, a therapeutically focused CRO, specializes in providing support for the most complex clinical trials. Be it a challenging therapeutic area or a sophisticated trial design, our highly experienced team always exceeds expectations. By focusing on our core service offerings, MedSource provides quality results and client satisfaction.

MedTrials
Contact: Jamie Edwards
Email: j.edwards@medtrials.com
Website: www.medtrials.com
MedTrials is a full-service CRO specialized in providing project specific clinical trial management solutions. We are committed to exceptional service and high quality results throughout all phases of clinical development. MedTrials is a WBENC-certified, women-owned business, and is positioned to meet your supplier diversity needs.

Merge eClinical
Contact: Larissa Amoroso
Email: larissa.amoroso@merge.com
Website: www.merge.com/eClinical
Merge eClinical provides clinical trial capabilities that can be mixed and matched to build a solid foundation for each trial environment. With unsurpassed ease-of-use, one consistent experience, and critical tools available anywhere, anytime, Merge eClinical makes the process of managing clinical trials faster, easier, and more efficient for investigative research sites, study sponsors, and CROs.

META Solutions, Inc.
Contact: David Pfennig
Email: kim.nitahara@metasol.com
Website: www.metasol.com
META Solutions, Inc. is a regulatory compliance consultancy with 25 years of experience assisting over 300 biopharmaceutical and related service companies in managing their regulatory compliance risk by assessing non-compliance and developing and implementing practical solutions with expert guidance and training. Our core expertise includes GxP auditing, computer validation remediation and consulting, data management, and monitoring services.

Microsoft Corporation
Contact: Jason Wilson
Email: v-jawi@microsoft.com
Website: www.microsoft.com/lifesciences
Life sciences organizations are under pressure to meet regulatory requirements and reduce the time it takes to develop drugs and take them to market. Microsoft and partners have developed cost-effective solutions that enable organizations to streamline processes that improve productivity and deliver information whenever and wherever it is needed.

Microsystems
Contact: John McClure
Email: johnm@microsystems.com
Website: www.microsystems.com
Microsystems offers DocXtools, a collection of document assessment, cleanup and problem-solving tools that helps medical writers, submission authors and QC/Compliance departments prevent document problems and produce high-quality Word documents more quickly. Pharmaceutical companies rely on DocXtools to ensure conformity with house styles and FDA/EMA guidelines prior to eCTD submissions.

Mission3
Contact: Chris Joslin
Email: cjoslin@mission3.com
Website: www.mission3.com
Mission3 provides integrated solutions for Life Science companies and is unique in the breadth of its solutions, the integration of its technology, and the flexibility of its cloud-based models. Mission3 was first to the cloud with regulatory document management for Life Sciences helping companies that want reliable, easy-to-use, and quick-to-implement solutions that meet all of their regulatory needs including compliance with eCTD and CFR 21 Part 11.

Mitsubishi Chemical Medience Corporation
Contact: Etsuko Noda
Email: noda.etsuko@mm.medience.co.jp
Website: www.medience.co.jp
Mitsubishi Chemical Medience Corporation offers consistent drug development services from pre-clinical to clinical trials in the medical and chemical fields. We provide services based on our vast experience and advanced technologies as a comprehensive clinical testing center in Japan. By collaborating with affiliated laboratories, we can offer services not only in Japan but also in Europe, the United States and Asia. We strongly support global expansion of collaborative clinical trials.
MMG
Contact: Angelica Carter
Email: acarter@mmgct.com
Website: www.mmgct.com
MMG is a full-service global health communications group specializing in patient recruitment. Our mission: to improve healthy behaviors through public health awareness campaigns and to help advance science by accelerating participation in clinical trials. As part of the Omnicom Group and Ketchum we reach 71 countries in 700 locations. We are privileged to be the patient recruitment group for the NCI's 150+ intramural clinical research studies. MMG - Advancing Health. Accelerating Recruitment.

MMRG
Contact: Peter Joshua
Email: peter.joshua@mmr-g.com
Website: www.mmr-g.com
Throughout a product’s lifecycle there are times when advice and support from external experts and opinion leaders is needed. MMRG helps life science companies find the right people, with the required mix of skills and experience, for particular activities, wherever in the world they're needed.

MMS Holdings Inc.
Contact: Don McLean
Email: dmclean@mms Holdings.com
Website: www.mms Holdings.com
MMS is a niche CRO that focuses on regulatory submission support for pharma. Our strong industry experience and scientific approach makes us a valuable partner in creating compelling regulatory submissions. Our clients span from top 10 pharma to virtual biotech’s, and we support each one with the same standard of excellence. Our core service areas include Data Management, Biostats, Clinical Programming, Medical/Regulatory Writing, PV, Trial Disclosure and Oncology Data Abstraction.

MonitorForHire.com
Contact: Scott Freedman
Email: scott.freedman@monitorforhire.com
Website: www.monitorforhire.com
Clinical trial sponsors should be able to locate independent clinical trial monitors anywhere in the world, fast. MonitorForHire.com is a patented web based resourcing tool with nearly 5,000 registered and pre-qualified monitors in 60 countries including the US, Europe, Asia & MENA. For more information contact us at: +1 (610) 862 0909 (US) or +44 (0)20 8832 1205 (UK & Europe).

Montrium, Inc.
Contact: Jeff Shuran
Email: jshuran@montrium.com
Website: www.montrium.com
Montrium is a GxP consulting group focused on providing technological solutions to the life sciences industry. Montrium is unique in that it provides an integrated set of pre-configured SharePoint based workspaces for records, quality, systems and clinical process management, as well as consulting services for systems strategy, implementation and validation. Montrium Workspaces can be used in our validated SharePoint cloud 'Montrium Connect' or within your existing SharePoint environment.

Mortara Instrument, Inc.
Contact: Tiffany Wisniewski
Email: tiffany.wisniewski@mortara.com
Website: www.mortara.com
Mortara Instrument is a recognized technology leader in the world of ECG. Mortara's global headquarters is located in Milwaukee, Wisconsin with operations in Australia, Germany, Italy, the Netherlands, and the United Kingdom. The complete line of ECG products includes electrocardiographs, stress exercise systems, Holter systems, data warehousing solutions, and cardiology monitoring systems.

MTZ US Clinical Research/ Cambridge Biomedical
Contact: Sharon Ault
Email: info01@musatechnology.com
Website: www.musatechnology.com
MUSA is a service provider with specific expertise in the Life Sciences industry. Where GxP meets Technology, MUSA’s strategic compliance planning, scientific application support, Laboratory Services Program and Validated Cloud services fill the gap between traditional service providers and the business requirements of the BioPharma and Medical Devices industries.

myClin
Contact: James Denmark
Email: james.denmark@myclin.com
Website: www.myclin.com
Study Sites, Sponsors, Service Providers - CONNECTED! myClin provides a secure online social collaboration platform for clinical research teams to use in phase I-IV clinical trials, patient registries and device trials. Use myClin to conduct site feasibility, share documents, facilitate site initiation, answer questions, provide training, centralize operational information and communicate with your entire clinical trial community.

Myoderm
Contact: Michael Cohen
Email: sales@myoderm.com
Website: www.myoderm.com
Myoderm is a leading service provider for global procurement of commercial pharmaceuticals including drugs utilized for comparator, rescue, adjunctive or concomitant therapy. We utilize our experience, knowledge, supplier and manufacturer network to provide clients with critical information and accurate delivery of product. In addition, Myoderm can act as the Central Rx for direct to clinical site distribution as an alternative to local site sourcing.

NCGS Incorporated
Contact: Angie Carnicom
Website: www.ncgs.com
Neuroscience Trials Australia
Contact: Tina Soulis
Email: athina.soulis@unimelb.edu.au
Website: www.neurotrialsaustralia.com
Neuroscience Trials Australia is a not-for-profit contract research organization specializing in neuroscience clinical research. We work on global or local projects. As a wholly owned subsidiary of The Florey Institute of Neuroscience and Mental Health, our staff has global management expertise in all phases of clinical research including studies sponsored by pharmaceutical and device companies, the biotechnology industry and granting bodies.
New England IRB
Contact: Carolyn Newman
Phone: 617-243-3924
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Website: www.neirb.com

New England IRB (NEIRB), now celebrating 25 years as an independent IRB providing ethical review of research involving human subjects, including phase I - IV single and multi-site studies. NEIRB offers: • Review across North America • Free Protocol Consultation • One-week Protocol Review • 24-Hour Site Review • Full AAHRPP Accreditation • In good standing with FDA (2011 inspection).

New Orleans Center for Clinical Research
Contact: Jeff Gary
Phone: 865-305-9100
Email: jgary@noccr.com
Website: www.noccr.com

NOCCR / VRG is an academic hospital based research company. We conduct research in a wide range of medical specialties for the pharmaceutical, biotechnical and device industries. NOCCR Knoxville is primarily a 52 bed Phase I unit, well suited for conducting first-in-human trials. VRG and NOCCR New Orleans are primarily focused on conducting later phase studies.

NextDocs
Contact: Margaret Mottolo
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Email: mmottolo@nextdocs.com
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NextDocs is the worldwide leader in providing Microsoft SharePoint-based compliance solutions to life sciences organizations. It enables businesses in regulated industries to achieve compliance with FDA and other agencies while automating processes, improving efficiency and dramatically reducing costs.

NextPharma Technologies
Contact: Matthew Wilder
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Email: matthew.wilder@nextpharma.com
Website: www.nextpharma.com

NextPharma is a CDMO that provides services ranging from development to clinical trials services to commercial manufacturing. NextPharma specializes in solid dosage forms, liquids and semi solids. NextPharma has special containment expertise for both hormone and Cephalosporin. Your “right sized” partner for formulation development, clinical batch manufacture, scale-up and process validation, analytical and microbiological services as well as pediatric medicinal products.

NextTrials, Inc.
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Phone: 925-415-8942
Email: Mskinner@nexttrials.com
Website: www.nexttrials.com

NextTrials is an award-winning innovative leader in software solutions for clinical research. Prism®, Nexttrials’ clinical trial management software, brings together clinical trial management, EDC and EHR integration in a single package enabling clinical researchers to derive more value from their data, accelerate time to market and lower costs.

NNIT
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NNIT is one of Europe's leading consultancies in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry’s strictest requirements for quality. For over a decade, we have applied the latest advances in technology to make our clients' software, business processes and communication more effective.

Norwich Pharmaceuticals
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Norwich is a recognized leader in full-service contract pharmaceutical development and manufacturing. As a single-source provider, Norwich offers customers greater flexibility, resources, and speed that result in a streamlined progression from product development to scale-up and commercial manufacturing through clinical services.

Nova Language Services Ltd.
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NOVA is a full service translation provider of multilingual language services to the CRO/Regulatory affairs sectors in Europe. From clinical trial protocols to marketing authorisation dossiers, we will fulfil all your translation requirements with expertise, accuracy and reliability in all European languages. NOVA is ISO 9001:2008 and UNE EN 15038 certified. Nova has been included in the top ten translation providers in Southern Europe by Common sense advisory group.

Novella Clinical
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Novella Clinical, Inc. is a full service contract research organization with dual headquarters in Research Triangle Park, N.C and Stevenage, England. For more than a decade, Novella has served as an active partner to the oncology, biopharma and medical device industries. As the first global eCRO, Novella integrates deep clinical expertise with industry-leading technologies and a proven approach to support, streamline and expertly resource the entire product development process.

November Research Group
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November Research Group is a professional services firm that provides a complete spectrum of software and services to pharmacovigilance organizations. We have extensive experience in the implementation and production support for the Argus Safety Suite. Our flagship software tools are designed to work seamlessly with both Argus Safety and AERS: PRIMO for streamlined intake, review and triage of adverse events, product complaints; and WebReports for true ad hoc reporting in English and Japanese.

Novotech
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Internationally recognized as the leading Australian CRO, Novotech is a full service clinical CRO with operations in Australia and across the Asia Pacific. Together with our strategic partners on six continents, we assist biotechnology and pharmaceutical companies bring new products to market by offering a full range of ICH compliant clinical services from first human exposure through to completion of Phase III trials.
nSpire Health, Inc.  
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nSpire Health offers Centralized Spirometry, Pulmonary Diagnostics, Challenge Testing, eDiary, and Data Management for Phase I-IV Clinical Trials including Asthma, COPD, and inhaled therapeutics. We have provided services to over 225 trials in the past 10 years and global support to over 5,000 investigational sites in more than 50 countries. Our quality review team has reviewed more than 1 million PFT’s. Our experience includes clinical trials as large as 500 sites spanning 34 countries.

Ocaso Logistics Solutions  
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With over 30 years of experience developing Logistics Solutions worldwide, OCASA’s Bio-Pharmaceutical logistic service offers tailor made solutions for the Pharma industry including export, import, distribution, fulfillment, and temperature controlled warehousing for: Diagnostic Specimens, Medication/Vaccines, Experimental Drugs, Controlled Substances, Dangerous Goods, and Medical Supplies.

OCT Group LLC  
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Website: www.oct-clinicaltrials.com

OCT’s clinical data management team is using the advanced clinical data management CDISC ODM standards-compliant software to ensure auditable GCP quality results. OCT’s DM services include: Paper and web-based trials; EDC in full compliance with CFR 21 part 11; Blind and independent double data entry; Computer-generated DCFs; Coding terms using MedDRA, WHO adverse events and medications, or client’s custom dictionary; Capabilities for import, export, and interchange of clinical data with other systems.

OmniComm Systems, Inc.  
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OmniComm Systems, Inc. is dedicated to helping the world’s pharmaceutical, biotechnology, CROs, research and medical device organizations maximize the value of their clinical research investments through the use of innovative and progressive technologies. Our Electronic Data Capture (EDC) and eClinical technologies have been used in over 3,000 clinical trials around the globe. Please visit us at booth 230 for a demonstration of our EDC, Phase I Automation, or one of our other eClinical solutions.

Online Business Applications  
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Online Business Applications provides advanced software solutions for the Pharmaceutical, Biotechnology, and Medical Device industries in the areas of Medical Communications and Drug Safety. We utilize proven leading-edge technologies, anticipate our clients’ needs, and deliver solutions that exceed expectations.

OpenClinica  
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OpenClinica is an open source clinical trials software solution for electronic data capture and clinical data management. It has been successfully used in thousands of clinical trials across some very diverse settings in all phases of clinical trials. OpenClinica offers 2 editions: Community and Enterprise. Visit us at www.openclinica.com.

Oracle Corporation  
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OCRC is a cutting edge independent Phase I - IV custom-built 35,000 sq. ft. research site. Designed specifically for Phase 1 clinical trials, OCRC includes 110 in-house volunteer beds, dual lead digital telemetry, CCTV security system, and cardkey access. A special treatment/observation area has 12 hospital beds (6 used for onsite Hemodialysis studies). OCRC is specialized in Phase I trials with an emphasis in PK, QTc, and SAD/MAD studies in healthy, hepatic, hemodialysis, renal populations.

PA Consulting Group  
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PA Consulting Group provides clinical services that meet the highest quality standards with appropriate client timelines. PBCRO manages the entire clinical trial process from site selection, investigator meetings, monitoring, IRB submissions, regulatory affairs, data management, statistical analysis and final reports for Phase I - III trials throughout the USA.
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Paragon Solutions  Booth: 1658
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Paragon Solutions is an advisory consulting and systems integration firm that focuses on clinical and regulatory operations collaboration, document management, and information insight and governance. We partner with clients to define and deliver optimal business outcomes by applying proven methodologies, technology frameworks and best practices to successfully blend people, process and technology.

PAREXEL International  Booth: 215
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An innovative leader for more than 30 years, PAREXEL understands clinical trial management from end-to-end of the product maturation cycle: clinical development, integrated technologies, regulatory affairs, market access and commercialization services. We complement your capabilities with our global reach, strategic insight, deep scientific knowledge, and tactical expertise—providing support and guidance to secure strategic advantage and succeed in the biopharmaceutical marketplace.

Path-Tec  Booth: 2012
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Patient Point  Booth: 826
Contact: Noel Khirsukhani  Phone: 888-479-5600
Email: LearnMore@PatientPoint.com
Website: www.PatientPoint.com

PatientPoint® is the leader and innovator of patient engagement solutions at the point of care, including award-winning patient education programs and care coordination platform. The PatientPoint Care Coordination Platform is prevalidated by the National Committee for Quality Assurance (NCQA) for 2011 patient-centered medical home (PCMH) criteria. Learn more at www.patientpoint.com.

The Patient Recruiting Agency  Booth: 345
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Email: lance@tprausa.com
Website: www.patientrecruiting.com

TPRA’s data-driven IN-HOUSE SOLUTIONS include: creative production, patient/physician outreach, site selection plus website & call prescreening. Now with RADIUS365™, TPRA’s online platform to track & manage all response, referral, randomization & retention activities in real-time, TPRA is the Leader In Successful PATIENT RECRUITING & RETENTION.

PCC A  Booth: 113
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PCCA helps pharmacists and prescribers create personalized medicine that makes a difference in patients’ lives. We are the complete resource for the independent compounding pharmacist, providing high-quality products, education and support. “Lives depend on a job well done.” For PCCA, it’s not just a saying, but the way we approach Quality. Our members have access to over 4,640 active & non-active chemicals - more than any other compounding pharmacy supplier.

PC M TRIALS  Booth: 1730
Contact: Julie Church-Thomas/Rick Heth  Phone: 888-976-2676
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Perceptive Informatics®, an industry-leading eClinical solutions provider, delivering leading technologies such as medical imaging, RTSM, EDC, CTMS, ePRO which are all part of our Perceptive MyTrials Framework - a single place to plan, design and conduct clinical trials, delivering a seamless user experience across clinical trial applications.

Pharma Start  Booth: 341
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Website: www.pharma-start.com

Pharma Start is a functional outsourcing firm focused on the pharmaceutical, biotechnology, and devices industries. We combine our functional outsourcing delivery model with in-house expertise in scientific and medical research to offer a single, reliable bridge into the drug development realm. Our services include preclinical assessment (translational modeling), early phase clinical development, and regulatory submission/approval and life cycle management.

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Pharmaceutical eConsulting (PeC) is the emerging leader in electronic submissions services for the global life sciences industry. PeC has customers spanning from small to large pharmaceutical companies to developing bio-tech. Our core mission is to support marketing filing efforts (eCTD, Nees or Paper submission) to the Regulatory Authorities (FDA, EMA, Health Canada, Rest of World). PeC is headquartered in Copenhagen with offices in Boston and London.
Pharmaceuticals and Medical Devices Agency (PMDA)

Contact: Hiroshi Kato
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The Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency that reviews applications for marketing approval of pharmaceuticals and medical devices, monitors product safety, and provides financial relief to people suffering from adverse drug reactions, in collaboration with the Ministry of Health, Labour and Welfare.

Pharmalink Consulting Inc.

Contact: Stephen Loughrey
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Pharmalink Consulting is the #1 choice for global Regulatory Affairs consulting. We support our clients in 115 countries across all sectors incl. Pharmaceuticals, Biotech, Consumer, Devices & Generics. We are Regulatory Affairs specialists and can resource any project regardless of size or timescale. From filing submissions to management of compliance issues and post-licensing activities, we supply the market intelligence and expertise to match any Regulatory Affairs need anywhere in the world.

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PharmaSeek

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PharmaVigilant

Contact: Meghan Morrissey
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Email: mmorrissey@pharmavigilant.com
Website: www.pharmavigilant.com

PharmaVigilant is an eClinical company founded to provide broader solutions to streamline the clinical trial process for biopharmaceutical companies. Its full suite of SaaS solutions automate the collection, management and analysis of clinical trial data: EDC (InSpire EDC), Data Warehousing (I-Warehouse), eTMF (I-Vault eTMF), Remote Monitoring (I-Vault rSDV), Study Building (I-Builder), Automated Site Payments (PaySite), Study Administration (InSpire Control Center), and Data Entry (I-Monitor).

PharmaVOICE

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Website: www.pharmavoice.com

PharmaVOICE magazine provides readers with insightful and thought-provoking commentary about the challenges and trends impacting the life-sciences industry in a multiple-perspective format through articles covering a range of issues from molecule through market. PharmaVOICE’s more than 29,000 BPA-qualified subscribers are also kept abreast of the latest trends and information through additional media resources, including WebLinx Interactive WebSeminars, Podcasts, Videocasts, and White Papers.

Pharm-Olam International Ltd.

Contact: Mark Eberhardt
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Email: mark.eberhardt@pharm-olam.com
Website: www.pharm-olam.com

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Contact: Kristen Boatman
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Website: www.pilgrimsoftware.com

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Planet Pharma
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Planet Pharma was founded by a seasoned group of professionals with over 25 years of Clinical and Scientific staffing and FSP experience. Planet Pharma provides experienced staff across numerous therapeutic and functional areas for all phases of the clinical trial process. Our service offerings include: Contract / Contract-to-Hire, Permanent Placement, FSP / Outsourcing Solutions, and PayRolling.

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POPSICUBE
Booth: 238
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<td>PrimeVigilance is dedicated to compliant and cost-effective pharmacovigilance and Medical Information solutions. PrimeVigilance sits between large CROs who focus on clinical trial delivery and small service providers who lack the critical mass, expertise or international presence needed for reliable scientific and safety services.</td>
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<td><strong>PRL Central Laboratory Services</strong></td>
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<td>Website: <a href="http://www.prlwecare.com">www.prlwecare.com</a></td>
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<td>PRL Central Laboratory Services one of the best kept secrets in the business, a great value with incredible service. We specialize in comprehensive diagnostic testing, with a focus on protocol requirements. We serve all phases of clinical research on a global basis, providing each client with accurate study set-up, timely results delivery and validated data management.</td>
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<td><strong>Projecis, Inc.</strong></td>
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<td>Contact: Diane Alvarado</td>
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<td>Website: <a href="http://www.biotech.com">www.biotech.com</a></td>
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<td>PSC Biotech Corporation is a global, employee owned, life sciences consultancy that performs projects and staff augmentation in the following disciplines: Engineering, Information Technology, Technical Services, Validation, Compliance, Regulatory Submissions, Clinical, Project Management and Quality Assurance. PSC Biotech, incorporated in 1996, has been performing projects globally for over 15 years.</td>
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<td>Website: <a href="http://www.pskw.com">www.pskw.com</a></td>
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<td>PSKW's core business is creating co-pay assistance programs that are extremely popular with physicians and patients. In addition, we have leveraged our relationships with banking partners, our payment processor, and our card program manager to create an efficient payment platform for all segments of the life sciences marketplace. This platform allows us to offer our ATM, debit, and Visa debit engines to firms in market research, patient reimbursement, loyalty programming, and clinical research.</td>
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<td><strong>QPS, LLC</strong></td>
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<td>Founded by Dr. Ben Chien in 1995, QPS has Bioanalysis and Preclinical testing and Clinical Research facilities at its Newark, DE headquarters, in Groningen, Netherlands and in Taipei, Taiwan. Early-phase clinical facilities are located in Springfield, MO, Taipei, Taiwan, and Groningen, Netherlands. Business development offices are maintained in the US, Europe, and Asia.</td>
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<td><strong>Quality and Compliance Consulting, Inc.</strong></td>
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<td>Q2C provides worldwide audit and consulting services, including: GCP, GLP, and cGMP Audits; Bioanalytical Laboratory Audits; Clinical Pathology Laboratory Audits; Sponsor, CRO, and Vendor Audits; Computerized System Validation Audits; Standard Operating Procedures Review and Preparation; GCP, GLP, QA, and SOP Training; and Consulting.</td>
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Quintiles is the world's largest provider of biopharmaceutical development and commercial outsourcing services with a network of 27,000+ employees conducting business in nearly 100 countries. We have helped develop or commercialize all of the top-50, best-selling drugs on the market. Quintiles has a staff of 15 auditors, all with various scientific experience. QAI also maintains a GLP compliant archive (vaulted).

Quest Diagnostics Clinical Trials provides laboratory solutions by harnessing the power of the entire Quest Diagnostics organization, including unsurpassed global central laboratory and biomarker services, diagnostics & esoteric testing, and research & development innovation, combined with one of the world's largest clinical laboratory, a single global database, and unparalleled scientific and logistics expertise.

Quorum Review is an independent ethics review board that is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Our primary focus is to safeguard the rights and well-being of research participants. We provide sponsors, CROs, institutions, and sites with reliable, responsive service that ensures efficient study start-up and management.

Quanticate offers an extensive suite of Biometric Solutions that standardize the collection, analysis, and reporting of clinical trial data. As the largest fully dedicated clinical biometrics company we utilize top industry talent and leading technology to ensure our customers bring their drugs to market more quickly than ever before.

Radcore Labs offers complete IMAGING CORE LAB services for your study, today. With highly trained and board certified sub-specialty imaging experts, RadCore Labs brings diagnostic, molecular and therapeutic expertise in all facets of drug, pharmaceutical, biotechnology and medical device clinical trials. We assist in imaging design, development of standard operating procedures, quality management, regulatory compliance, and image archiving throughout the entire study period and beyond.

Randstad Pharma matches professionals with career opportunities at the world’s leading biopharma and life science companies for more than 20 years. Our candidates are matched at organizations that will fully utilize their expertise while advancing the candidates skills and career aspirations. Our staffing services encompass specific areas of Clinical Research & Development, including Clinical Operations, Pharmacovigilance, Medical Writing, Clinical IT, Biometrics, Regulatory Affairs and more.

Rapport International specializes in foreign language translation services for the pharmaceutical, medical and healthcare industries. Understanding needs, surpassing expectations and clarifying the translation process has been our goal since 1987. We work with many of the same clients that helped us start. Free quotes and project consulting.
Real Staffing Group  
**Booth: 156**

Contact: Ben Muwoki  
Email: b.muwoki@realstaffing.com  
Website: www.realstaffing.com

Real is a global leader in the provision of pharmaceutical, biotechnology and medical devices staffing services. We are one of the world’s most extensive pharma, biotech and medical devices recruiters and have one of the largest networks of specialist recruiters globally. Our premise is a simple one: by recognising talent and valuing relationships we are able to consistently deliver local, global and industry expertise which in turn ensures success time after time.

Reed Technology  
**Booth: 649**

Contact: Mark Bayer  
Email: mbayer@reedtech.com  
Website: www.ReedTech.com

Reed Technology is a leading provider of SPL solutions to the Pharmaceutical industry, providing a comprehensive portfolio of services including SPL conversion and e-submissions, SPL XML composition and printing services for print- and web-ready promotional materials, content lifecycle management, and labeling consulting to over 600 customers.

Research Across America  
**Booth: 1649**

Contact: Kelly Walker  
Email: kwalker@raasites.com  
Website: www.researchacrossamerica.com

Research Across America is an Independent Site Network-ISN (Non-SMO) that manages and conducts Phase I thru Phase IV and Post marketing trials utilizing their 7 regional multi-specialty sites located in Dallas, TX, El Paso, TX, Houston TX, Suburban Houston-Katy, TX, New York, NY, Santa Ana, CA, Reading/Lancaster, PA, and most having Satellite Sites in their surrounding areas. The physicians affiliated with Research Across America have conducted over 1800 clinical trials since 1989.

ReSearch Pharmaceutical Services  
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Contact: Sean Quinn  
Email: info@rpsweb.com  
Website: www.rpsweb.com

RPS, The Next Generation CRO, provides comprehensive global Phase I-IV clinical development solutions to the Pharmaceutical, Biotechnology, Medical Device and Diagnostic industries. By combining an experienced clinical research operations infrastructure with the industry’s largest resourcing engines, RPS is uniquely positioned to offer our Customers a broad spectrum of outsourcing solutions. With more than 4000 employees, RPS operates in 64 countries across the globe.

Research Presentation Strategies Inc.  
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Contact: Robert Befus  
Email: info@r-pstrat.com  
Website: www.r-pstrat.com

Research Presentation Strategies Inc. provides expertise for the preparation of both regulatory and scientific presentations. We offer unique, industry leading solutions to regulatory and medical affairs customers in the pharmaceutical and medical device industries.

ReSolution Latin America  
**Booth: 1849**

Contact: Eric Johansson, Ph.D.  
Email: eric.johansson@resolutioncrs.com  
Website: www.resolutioncrs.com

ReSolution Latin America is a CRO/clinical consultancy company completely focussed on clinical development in Latin America and we specialize in providing clinical research solutions for development companies that are interested in Latin America for their clinical development programs. We provide the opportunity to work with a credible regional CRO provider that is able to successfully deliver clinical research conducted in Latin America to international quality standards and expectations.

Rho, Inc.  
**Booth: 1606**

Contact: Joan Parks  
Email: joan_parks@rhoworld.com  
Website: www.rhoworld.com

Rho is a full service CRO dedicated to enhancing the quality and speed of its customers’ clinical trials through the highest levels of performance, accuracy, and scientific integrity. Rho contributes to the success of pharmaceutical, medical device, and biotechnology studies in a range of therapeutic areas.

The ROMaN Project, Inc.  
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Contact: Bruce C. Ross  
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Contact: Jennifer Soronen  
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Rx Sample Solutions  
**Booth: 1620**

Contact: Brian Horan  
Email: brianhoran@rxsamplesolutions.com  
Website: www.rxsamplesolutions.com

Rx Sample Solutions specializes in the development and implementation of customized programs for clinical study medicine, devices and ancillary supplies to be dispensed to study subjects through their own retail pharmacies by using a Clinical Study Prescription Card™. Along with customized programs, we specialize in robust web-based reporting metrics designed to track study participants based upon a client’s needs.

Rx Trials Inc.  
**Booth: 1332**

Contact: Anne-Marie Baughn, RN MSN  
Email: anne-marie.baughn@rxtrialsinc.com  
Website: www.rxtrialsinc.com

RxTrials is an elite Investigative Site Network (ISN), training, and consulting firm. Our network is comprised of private physician practices and clinics that have successfully completed over 1000 trials in the past two decades. Our consulting division provides guidance to sites, sponsors, and CROs to ensure efficient, high-quality study delivery. In addition, we bring more than a decade of training solutions to sites. Events include The Site Solutions Summit, workshops, and webinars.
RxLogix Corporation  
Contact: Shalini Modi  
Email: shalini.modi@rxlogix.com  
Website: www.rxlogix.com

RxLogix is the foremost provider of business and technology solutions and services for Drug Safety and Pharmacovigilance. Our experienced team of experts offer consulting and strategic software solutions. We bring best practices across all areas of drug safety. RxLogix Solutions have been developed by the leading experts on the Oracle Argus Safety suite and Drug Safety.

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Contact: Phil Turner  
Email: phil.turner@samarindrms.com  
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Samarind is an award winning software vendor in the global Regulatory Information Management arena, and a leading provider of xEVMPD software - with a roadmap to ISO IDMP for 2015. Samarind RMS is an innovative ‘unified’ regulatory information management database with integrated submissions tracking, xEVMPD, eCTD and EDMS tools, superbly flexible reporting facilities and excellent security. The system is available as an on-premise solution or as a software-as-a-service (SaaS) model.

SAS Institute Inc.  
Contact: Janet Forbes  
Email: janet.forbes@sas.com  
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Contact: Tracy Torrez  
Email: tracy.torrez@scarritt.com  
Website: www.scarrittgroup.com

Scarritt Group is global meeting & logistics planning company specializing in the implementation & execution of meetings for clinical related studies. Our collective 200 years of experience in hotel and logistics management allow us to anticipate potential challenges and offer the best possible meeting experience at the lowest possible price.

Schlafender Hase GmbH  
Contact: Frank Hessler  
Email: dia2013@sh-p.de  
Website: www.text-verification.com

The Text Verification Tool (TVT) developed by Schlafender Hase GmbH is the global standard solution in computer-driven proofreading. It helps global pharmaceutical leaders save time, money, improve quality, avoid embarrassment and legal costs that can result from avoidable mistakes. Designed to support all standard file types, including XML.

Schulman Associates IRB  
Contact: Kristina Vohland  
Email: businessdevelopment@sairb.com  
Website: www.sairb.com

In 2013, Schulman Associates IRB celebrates 30 years of protecting human research subjects in the US and Canada. Our comprehensive suite of IRB review services includes dedicated review capabilities for all phases of research. Schulman is AAHRPP accredited and has an unparalleled clean audit history with FDA. We are committed to providing high quality, rigorous IRB reviews via streamlined processes, customized technology solutions and responsive customer service.

SDL  
Contact: Liz Grotzke  
Email: liz.grotzke@www.sdl.com

SDL enables global businesses to enrich their customers’ experience through the entire customer journey. SDL’s technology and services help brands to predict what their customers want and engage with them across multiple languages, cultures, channels and devices. SDL has over 1,500 enterprise customers, 400 partners and a global infrastructure of 70 offices in 38 countries. 42 out of the top 50 brands work with SDL. For more information, visit www.sdl.com.

Sentrx  
Contact: Michael O’Gorman  
Email: michael.ogorman@sentrx.com  
Website: www.sentrx.com

Sentrx, a leading provider of technology-enabled solutions and services for global drug safety, aims to help pharmaceutical, biotechnology, medical device, and consumer health companies document the safety profile of their products during clinical development and post-approval, enabling them to minimize risks & maximize benefits. Sentrx delivers a unique combination of highly skilled medical experts, exclusive technology, and best practices in drug safety monitoring. For info. Call 972-812-7575.

Seoul National University Hospital Clinical Trials Center  
Contact: Howard Lee  
Email: en.ctc.snuh.org

The Global Center of Excellence in Early Clinical Trials at Seoul National University Hospital (GREATS) is one of the two centers chosen by the Korean government in November 2012. GREATS is led by Prof. Yung-Jue Bang, a world-renowned medical oncologist, who has advised many global phamas and CROs. Oncology and clinical pharmacology are the two leading programs. Also, GREATS has many world-class investigators in cardiovascular diseases, endocrinology, gastroenterology, and rheumatology.

SFL Regulatory Affairs & Scientific Communication GmbH  
Contact: Faiz Kermani  
Email: sfl-services.com

SFL combines expertise in Regulatory Affairs, Public Affairs, Legal Services and Medical Communication and thus can offer a wide range of services related to practically all lifecycle stages of your product. Depending on the complexity of a project, we offer single services or a customized service package drawing from our broad expertise. SFL also provides specialized training courses where participants can benefit from the team’s cross-functional expertise.
SGS Life Science Services  
Contact: Ronald Baker  
Email: mckenzie.landgraf@sgs.com  
Website: www.sgs.com/cro  
SGS Life Science Services has 35 years of experience as a global contract service organization providing integrated solutions from Phase I-IV clinical trials, bioanalytical and QC testing, and protein characterization. Our clinical research services include clinical pharmacology trials, late phase monitoring and management, biometrics and pharmacovigilance. With more than 1,300 employees and 2,000 clinical trials performed, SGS serves the pharmaceutical, biotech and medical device industries.

Sharp Clinical Services  
Contact: Sandy Richwalski  
Email: USInfo@sharpclinical.com  
Website: www.sharpclinical.com  
Sharp Clinical Services IVRS/IWRS provides a sophisticated method of optimizing & managing clinical trials through dynamic resupply algorithms, data integration with eCRF, labs & real-time study data access. Our Management Team provides guidance and advice on packaging design and distribution as well as randomization scheme and visit schedule. We optimize your clinical trial experience with the foresight to include all study requirements before “GO LIVE” reducing out of scope and change control.

Sharp Corporation  
Contact: Bob Macadangdang  
Email: bob.mac@sharpcorporation.com  
Website: www.sharpcorporation.com  
Sharp, a United Drug Company is a world class healthcare contract packager serving the Rx, OTC, nutritional, animal health, clinical trials and biotechnology markets. We offer full range of design services and are recognized for delivering reliable, cost-effective packaging solutions in blister packaging, bottling, carded blisters, vial labeling, pouching and more. Our dedicated project management teams serve customers from concept to shipping your product on time.

Sidus BioData  
Contact: Lisa Ackerson  
Email: lackerson@sidusdata.com  
Website: www.sidusbiodata.com  
Sidus BioData provides secure, compliant data hosting solutions for the Life Sciences/Medical Device and Health IT industries. Sidus BioData is committed to the highest level of quality in the management, security, integrity and availability of regulated data. In addition, Sidus’ culture of compliance ensures all regulatory goals are met with our premium service offerings.

Sitrof Technologies, Inc.  
Contact: Bryan Reynolds  
Email: sales@sitrof.com  
Website: www.sitrof.com  
Sitrof provides premier IT and document management solutions that enable top Life Sciences companies to improve efficiency and mitigate risk. Backed by decades of industry knowledge and world-class partnerships, the process harmonization, collaboration and compliance experts at Sitrof have saved millions of dollars and countless time for hundreds of leading firms.

Small Planet Events  
Contact: Stacey Powles  
Email: stacey.powles@smallplanetevents.com  
Website: www.smallplanetevents.com  
Small Planet organizes and delivers meetings worldwide for the pharmaceutical industry. We create programs, write content, train speakers and manage logistics. We aim to help you maximize the valuable opportunities created by face to face contact, and we contribute to your site productivity, patient recruitment and a successful trial outcome.

SNBL Cardiac Safety Evaluation Center  
Contact: Robert Phillips  
Email: robert@cpc-jp.com  
Website: www.cpc-global.jp  
SNBL Cardiac Safety Evaluation Center (CSEC) offers a unique, comprehensive approach to drug development by integrating SNBL’s preclinical, bio-analytical and clinical capabilities. CSEC utilizes customizable algorithms, which enables early detection of cardiovascular toxicity in new chemical entities. The strategy of integrating all levels of drug development into a “One-Stop” service provides sponsors with efficient and accelerated contract research services.

Society for Clinical Research Sites - SCRS  
Contact: Christine Pierre  
Email: christine.pierre@myscrs.org  
Website: www.myscrs.org  
The Society for Clinical Research Sites (SRCS) was founded in 2012 in response to the growing need for a trade organization to represent the global voice and community of research sites within the clinical research enterprise. The goals of the Society include providing sites with resources, mentorship, and new ideas through a membership organization dedicated only to research sites.

Sonic Clinical Trials  
Contact: Paullette Azar-Tannous  
Email: pazar@sonicclinicaltrials.com  
Website: www.sonicclinicaltrials.com.au  
Sonic Clinical Trials is a wholly owned subsidiary of Sonic Healthcare Limited; one of the world’s largest medical diagnostic companies. Sonic Clinical Trials is a dedicated central laboratory supporting all phases of clinical trials and ensuring the highest regulatory compliance. All studies are managed locally whilst following best global practices. Services Offered: Central Laboratory Services: Protocol Management, Data Management, Blood Collection, Logistics and Laboratory Services.

Source Group LLC.  
Contact: Monique Carter  
Email: info@southernstarresearch.com  
Website: www.SouthernStarResearch.com  
Southern Star Research is a leading Australian CRO, dedicated to providing an exceptional quality of personalised service. Expertise covers Ph I-IV trials in Pharmaceutical, Medical Device & Biotechnology projects. Services incl; Project Management, Monitoring, In-house staff placement, Patient Recruitment, Local safety reporting, Medical Monitoring & local study sponsorship. Staff are located across Australia & New Zealand, with a focus on providing high quality & cost effective services.
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Spectra Clinical Research
Contact: Charles Keyes
Email: charles.keyes@fmc-na.com
Website: www.spectraclinicalresearch.com
As a global provider of central laboratory services, Spectra Clinical Research pairs the capacity and technology of a large corporation with the flexibility and responsiveness of a small specialty laboratory to support diverse clinical trials of all sizes. We focus on meeting your unique research needs and delivering timely, reliable results.

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Statistical Solutions
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Statistics & Data Corporation (SDC)
Contact: Jim Townsend
Email: jtownsend@sdcclinical.com
Website: www.sdcclinical.com
Statistics & Data Corporation (SDC) is a specialized Contract Research Organization (CRO) focused exclusively on delivering biostatistics, clinical data management, and EDC services to pharmaceutical, biotechnology, and medical device companies as well as CRO partners. SDC is committed to providing innovative services with experienced teams that take ownership of your needs and provide positive engagement in your project. SDC has successfully supported clients on 100+ studies since 2005.

Symbio, LLC
Contact: Betsey Zbyszynski
Email: bzbyszynski@symbioresearch.com
Website: www.symbioresearch.com
Symbio is a full-service CRO. Since 2002, we have been successfully managing Phase I-IV clinical trials. By partnering with our Sponsors, we are involved with strategic planning throughout the entire product development cycle. Therapeutic areas include dermatology, ophthalmology, women's health and internal medicine.

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Sterling IRB
Contact: Kathye Richards
Email: kathye.richards@sterlingirb.com
Website: www.sterlingirb.com
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Sylogent
Contact: Jack Yeager
Email: solutions@sylogent.com
Website: www.sylogent.com

Symphony Clinical Research
Contact: Nicki Norris
Email: nnorris@clinicalresource.net
Website: www.clinicalresource.net
Exhibitor Directory

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Target Health Inc. is a New York City-based eCRO with staff dedicated to all aspects of Regulatory Affairs and Strategic Planning, Chemistry Manufacturing and Controls, Clinical Research, Biostatistics, Data Management and Medical Writing. Target Health has developed innovative web-based software that provides a transparent paperless environment and significant productivity edge.

TAKE Life Sciences
Contact: Mike Lewis
Phone: 609-720-1002-230
Website: www.takesolutions.com
Email: contact@takesolutions.com
TAKE is a global business & technology solutions company with domain excellence in Life Sciences & offers IP-based software and extensive knowledge-based solutions to enable efficient clinical, regulatory, safety and commercialization processes. TAKE has been recognized as a leader by IDC’s MarketScape Worldwide Life Sciences R&D IT Outsourcing for 2011. Present in 8 countries TAKE is CMMI Level 5, PCMM Level 3 certified. 150+ Fortune-1000 customers. Gold Partners of Microsoft, Oracle & SAP BO.

TAKE Solutions
Contact: Mike Lewis
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SynteractHCR
Contact: Trisha Vonder Reith
Phone: 760-268-8028
Website: www.synteracthcr.com
SynteractHCR is a full-service CRO with a successful track record supporting biotech, medical device and pharma companies in Phases I-IV clinical trials. With our “Shared Work – Shared Vision” philosophy we provide customized services collaboratively and cost effectively, ensuring on-time delivery of quality data. We deliver trials internationally in 16 countries, offering expertise across many therapeutic areas.

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Contact: Eva L. Petersen
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Technical Resources International, Inc.
Contact: Jane Helmick
Phone: 301-897-7107
Email: jhelmick@tech-res.com
Website: www.tech-res.com
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TechHorizon S.r.l.
Contact: Silvio Severini
Phone: 39-045-822-2888
Website: www.techhorizon.com
TechHorizon are technology experts supplying the biopharmaceutical and medical device industries with advanced solutions and services. As a subsidiary of CROMSOURCE, an International CRO, TechHorizon combines technical expertise with a deep understanding of clinical research processes to deliver innovative and customized technology solutions which seamlessly integrate to support all aspects of clinical development.

TechSol
Contact: Vivek Pokhare
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Website: www.techsolcorp.com
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Development, management and control of clinical trials. Techtrials is a company distinguished by its high technology, speed, customizations, high standard services and low operational costs. It aims to be an agile company, bringing new approaches in terms of client services and cost effectiveness to your clinical development project. Techtrials was created to serve a select group of clients who wants performance, costs control and smooth working conditions.

**Teradata**
Contact: Monica Smith  
Phone: 937-445-5993  
Website: www.teradata.com

Teradata is the world’s leading analytic data solutions company focused on integrated data warehousing, big data analytics, and business applications. We have built our leadership position in business intelligence from a powerful portfolio designed to solve business problems for companies of all sizes. Teradata gives leaders the confidence to think boldly and act decisively in pursuit of the best decisions possible.

**TFDA / Center for Drug Evaluation, Taiwan**
Contact: Frank Liu  
Phone: 886-2-81706000  
Email: ccliu308@cede.org.tw  
Website: www.cde.org.tw

Taiwan Food and Drug Administration (TFDA) and, Center for Drug Evaluation regulatory agencies, review investigational new drug, new drug application, generic drug applications, bridging study evaluation, drug master file, BA/BE protocol and reports, dissolution reports, IDE, investigational device exemption, pre-market approval, evaluate PMA, and provide health technology assessment, consultation and regulatory science on the regulation of medicinal products.

**TFS International**
Contact: Hani Zaki  
Phone: 908-788-1729  
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Website: www.tfscro.com

TFS International is one of the largest privately owned CROs headquartered in Sweden and operating across Europe, the USA and Japan. TFS led studies in 150 indications, including numerous orphan drug indications; and has processed over 310,000 subjects in more than 1,300 clinical trials. TFS operates through four business verticals: TFS-Explore™, TFS-Develop™, TFS-People™ and TFS-Academy™. Information about TFS is available through www.tfscro.com.

**Theorem Clinical Research**
Contact: Shawn Clary  
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Website: www.theoremcclinical.com

Theorem Clinical Research is one of the industry’s leading full-service, contract research organizations (CRO). A global organization with 1,000+ employees located throughout 27 countries, Theorem Clinical Research provides core CRO services for Phases I-IV, but with niche business units in the areas of technical services, medical devices and pharmacetics with speed, flexibility and attention to detail to drive a high-quality performance.

**Therapak Corporation**
Contact: Arbi Harootoonian  
Phone: 626-357-5900-254  
Email: info@therapak.com  
Website: www.therapak.com

Therapak is the global leader in providing 3rd party kit assembly and distribution services to pharmaceutical and laboratory organizations. Therapak’s menu of services include assembly of lab convenience kits for collection of samples, temperature sensitive shipping systems, requisition and label printing and ancillary supply distribution direct to sites on a global basis. Therapak is a cGMP compliant organization with facilities in the US, UK and Singapore.

**Therapeutics Inc.**
Contact: Bryan Macy  
Phone: 858-571-1800  
Email: opportunities@therapeuticsinc.com  
Website: www.therapeuticsinc.com/about_us

Therapeutics, Inc. is The Dermatology CRO with unparalleled dermatology expertise & decades of experience. A full service CRO with numerous product approvals, TI designs and executes Ph 1-4 multicenter trials in acne, psoriasis, dermatitis, rosacea, alopecia, tissue fillers, inflammation, & all pediatric/adult derm categories. We help with strategy, clinical development, trial management, & life cycle management: concept, design, project planning & management, regulatory review & registration.

**Thomson Reuters**
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Thomson Reuters Life Sciences supports R&D productivity across the Pharma lifecycle with respected and comprehensive intelligence solutions. Offering unbiased scientific, competitive, regulatory, and generics information, analytics, and expertise for your organization, Thomson Reuters Life Sciences empowers and enables effective, evidence-based decision-making at every stage from discovery to launch and beyond.

**ThreeWire, Inc.**
Contact: Bruce Gould  
Phone: 952-852-5557  
Email: bgould@threewire.com  
Website: www.threewire.com

ThreeWire is a global patient recruitment, enrollment and management provider focused on accelerating patient recruitment and enrollment for the medical device, pharmaceutical, and biotech industries. We utilize a proven, flexible, systematic approach with predictable and measurable outcome-based strategies backed by performance-based pricing. Our customized recruitment programs provide value-based solutions, including real-time tracking and reporting, across North America and Europe.

**TIBCO Software**
Contact: Ben McGraw  
Phone: 703-208-3915  
Email: bmcgraw@tibco.com  
Website: spotfire.tibco.com

From early stage discovery to clinical development to marketing and sales force optimization, Spotfire helps the world’s leading pharmaceutical, medical device, and biotech companies discover new therapeutics, develop their pipeline of assets, launch their drugs to the market, and align marketing and sales campaigns.
TKL Research, Inc.
Contact: Reid Tripp
Email: rtripp@tklresearch.com
Website: www.tklresearch.com
Driving Enrollment, Accelerating Timelines. TKL Research, Inc. is a full-service, Global CRO providing comprehensive trial management for Phase 1-4 studies across multiple therapeutic areas. We also offer an inpatient Phase 1 facility and specialized outpatient research clinics. Since 1944, we continue to deliver the highest level of services to Pharmaceutical and Biotech companies.

Total Root Concepts, Inc.
Contact: Jennifer Lansink
Email: jlansink@totalrootconcepts.com
Website: www.totalrootconcepts.com
Total Root Concepts is a training and communication company providing site solutions for more effective program delivery: Pre-, During, and Post-Investigator Meeting. This includes: Face-to-Face Investigator Meetings, Online Investigator Meetings, Regional Update and Recruitment Boost Meetings, Site Rejuvenation Meetings, Study-Specific Portals with eLearning Modules, & DVD creation. Total Root Concepts creates a more powerful, tailored message to drive BETTER site recruitment and enrollment!

TransPerfect
Contact: Ryan Simper
Email: rsimper@transperfect.com
Website: www.transperfect.com
TransPerfect leads the way in life sciences translation services and solutions. Our next-generation approach centers around innovation, combining cutting-edge workflow technologies with the industry’s only quality management system fully certified to EN 15038:2006 and ISO 9001:2008. When it comes to clinical development, we speak your language.

TrialScope
Contact: Bill Schnell
Email: bill@trialscopeinc.com
Website: www.trialscopeinc.com
Software as a service (SAAS) hosting software for sponsors, clinical trial management and participants. For use in global project management, providing operational trial visibility, workflow, performance, document library, task management and business intelligence to manage all aspects of clinical trials.

TrialNetworks
Contact: Cameron Snider
Email: info@trialnetworks.com
Website: www.trialnetworks.com
TrialNetworks is a technology company with a cloud-based platform that boosts clinical site engagement leading to improved recruitment, retention, training and workflow. We have a wide variety of applications that we bring to each trial ranging from practical efficiency tools (e.g. sharing documents, providing training, various online trackers, visit guide) to features designed to increase site motivation (email updates, leaderboards, badging) to novel tools for maximizing time on study drug.

Trifecta
Contact: Deborah Novick
Email: sales@trifectaclinical.com
Website: www.trifectaclinical.com
Trifecta has extensive experience training clinical research sites and optimizing site start-up and conduct. Trifecta’s minimally disruptive solutions fit within, or can improve upon, existing Sponsor/CRO processes. Their use allows clients to immediately realize significant cost savings and reduce time lines. Trifecta provides innovation, globalization and execution for projects of any size.

UBC
Contact: Krista Huck
Email: info@ubc.com
Website: www.ubc.com
UBC unites unsurpassed experience in generating real-world evidence of product safety, value, and effectiveness, with the strength of its parent company, Express Scripts, the nation’s largest healthcare company. UBC brings together renowned epidemiology, risk management and periapproval experts with leading-edge technologies, enabling customized solutions that support an optimized regulatory pathway while maximizing product position in a competitive market.

UC Health Clinical Research
Contact: Wendy Newman
Email: wendy.newman@ucphysicians.com
Website: www.uchealth.com
UC Health is a partnership of the University of Cincinnati, one of the nation’s top public research universities, University of Cincinnati Medical Center, a “Best” hospital as ranked by U.S. News and World Report, and University of Cincinnati Physicians, the region’s largest network of specialists. UC Health also includes West Chester Hospital, the Drake Center, and Lindner Center of Hope. Our clinicians conduct industry, investigator-initiated and NIH sponsored clinical studies (Phase I - IV).

University of Florida Online MS in Pharmaceutical Outcomes & Policy
Contact: Heather Steingraber
Website: onlinepop.pharmacy.ufl.edu
The University of Florida Online MS in Pharmaceutical Outcomes & Policy is designed for working professionals to expand their career options. Tailor your degree to fit your goals. Choose from: Applied Pharmacoeconomics, Patient Safety & Medication Risk Management, Drug Regulatory Affairs, Pharmacy Regulation & Policy, and more.

University of Iowa Pharmaceuticals
Contact: Randy Yeates
Email: randhall-yeates@uiowa.edu
Website: uip.pharmacy.uiowa.edu
University of Iowa Pharmaceuticals (UIP) is an FDA-registered contract pharmaceutical manufacturing and analytical testing facility. UIP services include clinical supply manufacturing, small scale commercial manufacturing, analytical method development and validation, routine quality control analysis, and stability studies. UIP is capable of handling controlled substances and potent and cytotoxic compounds.

University of Utah Clinical Research Services
Contact: Jaci Skidmore
Email: jaci.skidmore@hsc.utah.edu
Website: medicine.utah.edu/pediatrics/cro
The University of Utah Clinical Research Center was established with a mission to provide clinical investigators and sponsors with comprehensive support services, research tools, personnel and facilities to conduct clinical research studies. Our experience includes working with special populations including neonatal, pediatric, adolescent, young adult, pregnant and geriatric participants including diverse populations from ethnic minorities to geographically distant groups.
The Uppsala Monitoring Centre  
Booth: 1807  
Contact: Mats Persson  
Phone: 46-186-560-60  
Email: sales@umc-products.com  
Website: www.umc-products.com  
A non-profit foundation and WHO Collaborating Centre, managing the technical and scientific operations of the WHO Medicines Safety Programme. To be able to perform effective data management and signal detection, Uppsala Monitoring Centre (UMC) also manages VigilBase™, the WHO Drug Dictionaries and WHO-ART with their related tools and services.

Valesta Clinical Research Solutions  
Contact: Carolyn Benslimane  
Phone: 866-445-2465  
Email: info@us.valesta.com  
Website: www.valesta.com  
Valesta Clinical Research Solutions is a proven industry leader in placing skilled clinical research professionals at all career levels in project-based, contract-to-hire, and direct hire opportunities, both locally and globally. We have a long track record of making successful job matches in specialized areas, including clinical data, clinical monitoring, medical writing, biometrics, and regulatory affairs.

Veeva Systems, Inc.  
Booth: 1557  
Contact: Brittany Machion  
Phone: 925-452-6500  
Email: brittany.machion@veevasystems.com  
Website: www.veevasystems.com  
Veeva Systems is the leader in cloud-based business solutions for the global life sciences industry. Veeva Vault is our suite of business process-specific content management applications, which spans every major part of a life sciences company – from R&D to clinical trials to manufacturing, medical communications and marketing. Committed to innovation, product excellence and customer success, Veeva has over 150 customers, ranging from the largest pharmaceutical companies to emerging biotechs.

Verified Clinical Trials  
Booth: 326  
Contact: Mitchell Efros  
Phone: 516-998-7499  
Email: DrEfros@verifiedclinicaltrials.com  
Website: www.verifiedclinicaltrials.com  
Verified Clinical Trials is a clinical trials database registry designed to prevent dual enrollment and improve safety and data quality in clinical trials. VCT has built in visit and dosing reminders, novel recruitment modules, and adverse event monitoring to reduce fines and penalties from governmental agencies. VCT has many functions that enhance the trial experience and safety while reducing liabilities in many arenas. VCT is partnered with many of the world’s largest research companies.

Veristat, Inc.  
Booth: 1255  
Contact: Bryan Adams  
Phone: 508-429-7340  
Email: info@veristat.com  
Website: www.veristat.com  
Veristat, a clinical research organization and CDISC Solution Provider, provides strategic consulting, biostatistics, SAS programming, medical writing, and clinical data management services to life science companies. In addition, Veristat supports regulatory submissions through the preparation of integrated summary documents and submission-ready CDISC data. Based on over 15 years of experience, Veristat provides flexible, innovative, and science-focused services customized to our clients’ needs.

Viracor-IBT Laboratories  
Booth: 741  
Contact: Dawn Denny  
Phone: 816-347-0113  
Email: dawn.denny@ViracorIBT.com  
Website: www.viracoribt.com  
Viracor-IBT provides clinical trial testing services and large molecule/biologic biomarker support for phase I-IV trials. We are a CAP/CLIA and NY state accredited laboratory with nearly 30 years of experience in molecular testing, immune response monitoring, vaccine safety and efficacy assessment, allergy and hypersensitivity testing. To learn more visit www.viracoribt.com.

Virifi, Inc.  
Booth: 1647  
Contact: Deeksha Taneja  
Phone: 617-301-8723  
Email: www.virifi.com  
Virifi is the market leader in Structured Content Management software solutions for life sciences. Organizations rely on Virifi solutions to reduce time-to-market, risk & costs by managing and automating the complex regulatory compliance and content exchange requirements throughout the product life cycle. Virifi’s easy-to-use software suite is the industry’s only solution to provide a secure, collaborative, web-based environment for managing regulated content throughout the entire continuum.

VirtualScopics  
Booth: 737  
Contact: Chris Gilman  
Phone: 585-249-6231  
Email: Chris_Gilman@virtualscopics.com  
Website: www.virtualscopics.com  
VirtualScopics is a leading imaging core lab providing central reads and quantitative imaging solutions for drug and medical device clinical trials. Therapeutic area expertise includes: oncology, musculoskeletal, neurology, cardiovascular and medical devices utilizing MRI, PET, CT, Ultrasound, DEXA, Bone Scans and X-Ray imaging modalities.

Vitalograph, Inc.  
Booth: 303  
Contact: John Buchholz  
Phone: 913-720-3212  
Email: john.buchholz@vitalograph.com  
Website: www.vitalograph.com  
Vitalograph is a leading manufacturer of cardio-respiratory testing devices used in physician clinics and in pharmaceutical clinical development. In 2013, Vitalograph celebrate a 50 year history of producing high quality medical instrumentation for diagnosing and monitoring cardio-respiratory diseases. Vitalograph also provide integrated solutions to collect, centralize and report site generated and patient reported outcomes for clinical trials. Vitalograph, your Respiratory Partner for 50 years.

Wake Research Associates  
Booth: 1708  
Contact: Earl Seltzer  
Phone: 919-781-2514  
Email: eseltzer@wakeresearch.com  
Website: www.wakeresearch.com  
Wake Research Associates is an independent multi-center clinical research group designed to work closely with and meet the needs of the pharmaceutical industry and CROs in the conduct of Phase I-IV trials. We are known for effectively combining strategic patient recruitment and retention with high quality clinical research procedures. Our approach is uncompromising - each study conducted at our site is carefully planned and executed according to regulations and guidelines with superior quality.

WCCT Global  
Booth: 1543  
Contact: Christopher Theo  
Phone: 714-553-8176  
Email: Christopher.Theo@wcct.com  
Website: www.wcctglobal.com  
WCCT Global is an early phase drug development clinical CRO that partners with domestic and foreign innovator companies who need regulatory and strategic development support from First-in-Man through the Proof of Concept stage. We also specialize in special patient population phase I studies that require complex study designs and procedures.
WCI Consulting Limited
Contact: Kate Derham
Email: kate.derham@wcigroup.com
Website: www.wcigroup.com

Founded in 1986, WCI is the leading life science consulting practice focused on Patient Safety, Medical Affairs, Benefit and Safety Risk Management, Quality and Compliance, Labelling, and Medical Governance. We have worked with over 50 pharmaceutical, biotechnology, consumer health, medical device, and dietary supplement organisations; helping to implement solutions which simplify what you do to assure compliance and boost performance.

WebbWrites, LLC
Contact: Laura A. Webb-Murrah
Email: webb@webbwrites.com
Website: www.webbwrites.com

Extensive experience in regulatory document preparation, ability to provide a full range of statistical services, and provision of superior products due to continuity of personnel, flexibility to work onsite with clients, unsurpassed customer service, & capacity to meet aggressive timelines. WebbWrites has prepared > 81 NDAs in 15 years.

Whittell Innovations, Inc.
Contact: Natalie Becker
Email: info@whittellinnovations.com
Website: www.whittellinnovations.com

Whittell Innovations, Inc. is a medical and scientific writing company with expertise in providing regulatory and safety writing solutions for all aspects of pharmaceutical development and chemistry, manufacturing, and controls. We have an extensive set of offerings that includes authoring documents for all phases of clinical development from pre-clinical to post-market. Whether your needs include IBs, DSURs, or patient education materials, WI is your partner for all of your writing needs.

Wingspan Technology Inc.
Contact: Meghan McKeown
Email: mmckeown@wingspan.com
Website: www.wingspan.com

Wingspan Technology, Inc, the leading provider of Documentum to SharePoint integration software, is the maker of the DocWay products and Wingspan eTMF. Founded in 1996, Wingspan provides innovative technology solutions and offers in-depth industry knowledge and experience to companies in life sciences and pharmaceutical industries.

WIRB-Copernicus Group
Contact: Cara Deieso
Email: cdeieso@wcgirb.com
Website: www.wcgirb.com

The WIRB-Copernicus Group is the world’s largest provider of regulatory and ethical review services for human research, bringing more expertise to the industry than any other ethical solutions provider. The WIRB-Copernicus Group is comprised of Western IRB and Copernicus Group IRB, the nation’s leading independent institutional review boards, as well as IRBNet, the top institutional research compliance software solution. For more information, please visit us at www.wcgirb.com.

Woodley Equipment Company
Contact: Candy Hazard
Email: enquiries@woodleyequipment.com
Website: www.woodleyequipment.com

Woodley Equipment Company is a specialist global supplier of medical and laboratory equipment to the Clinical Trials Industry. Woodley has over 20 years experience of providing a full service from initial enquiry to global delivery and collection of equipment from multiple sites, technical support, servicing, calibration and training options.

World Courier, Inc.
Contact: Tim Redmond
Email: tredmond@worldcourier.com
Website: www.worldcourier.com

With over 150 offices in 51 countries – all ISO 9001 certified- World Courier has the network, trained personnel and resources to manage the most demanding research project, biologic, or pharmaceutical shipment.

Worldwide Clinical Trials
Contact: Enrico de Leon, Jr, BS
Email: sales@wwctrials.com
Website: www.wwctrials.com

Worldwide Clinical Trials is ready to be a vital part of your drug development program, from preclinical and bioanalytical analysis to late-phase (Phase I–IV) clinical trials by combining modern clinical research and state-of-the-art bioanalytical work with a direct link to our Worldwide Clinical Trials global sites.

WoundMatrix, Inc.
Contact: Paul Geary
Website: www.woundmatrix.com


WriteResult LLC
Contact: Peter Oudheusden
Email: info@writeresult.com
Website: www.writeresult.com

Experience true innovation in ePRO as WriteResult introduces myPROpad. WriteResult has been solving the challenges of clinical research for over 20 years, and thousands of patients have used our global ePRO solutions. myPROpad transforms standard and custom questionnaires into touch-friendly iPad screens that are intuitive for patients and fit neatly into site workflow. Visit us to get YOUR hands on the newest member of the WriteResult family.

XenoBiotic Laboratories, Inc.
Contact: Dennis Heller
Email: dheller@xbi.com
Website: www.XBL.com

XenoBiotic Laboratories, Inc. is a leading contract laboratory specializing in non-clinical ADME, PK/TK, in vitro/vivo drug metabolism, human radiolabel studies, bioanalytical method development/validation and clinical sample analysis. XBL is FDA and USDA registered and located near Princeton, NJ and XBL-China is located in Nanjing. Both sites are AAALAC accredited.

Xerimis Inc.
Contact: Kevin Clover, Business Development Executive
Email: kevin.clover@XERIMIS.com
Website: www.XERIMIS.com

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Y-Prime LLC
Contact: Matt Cocking
Email: mcocking@y-prime.com
Website: www.yprime.com
Y-Prime LLC is a premier eClinical products and consulting company that leverages groundbreaking platform technology and systems intelligence to provide novel, personalized decision making solutions to life sciences companies. Since 2006, Y-Prime has developed a robust franchise of enterprise, clinical and operations solutions that offer the potential to dramatically accelerate time to market while significantly reducing costs.

ZigZag Associates LTD
Contact: Julie Beal
Website: www.zigzag.eu.com
ZigZag Associates Ltd is a Quality Assurance ("QA") consultancy company based in the UK, who can provide a team of highly experienced QA professionals to support you. Whether you need ad hoc support, a more regular commitment through outsourcing, or an experienced team to partner with on audit programs, we can offer you a flexible, pragmatic and responsive global service tailored to suit your requirements. We specialise in audits, inspection readiness, Quality Management Systems and training.

Zinc Ahead, Inc.
Contact: Hamish Miller
Website: www.zinc-ahead.com
Developed and refined over the course of more than a decade, Zinc MAPS is the world’s leading promotional compliance solution specifically for the life science industry. Our solution makes the approval and sharing of promotional materials quick and easy while driving compliance, quality and efficiency into the processes. With clients in over 100 countries, Zinc Ahead is the world’s leading provider of promotional compliance solutions designed specifically for the life science industry.

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ICON
nextdocs
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>3500A</td>
<td>FDA form for mandatory reporting of adverse events</td>
</tr>
<tr>
<td>ADE</td>
<td>adverse drug event</td>
</tr>
<tr>
<td>ADR</td>
<td>adverse drug report or adverse drug reaction</td>
</tr>
<tr>
<td>AE</td>
<td>adverse event</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Quality and Research</td>
</tr>
<tr>
<td>ANDA</td>
<td>abbreviated new drug application</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
</tr>
<tr>
<td>BA/BE</td>
<td>bioavailability/bioequivalence</td>
</tr>
<tr>
<td>BB IND</td>
<td>biological investigational new drug</td>
</tr>
<tr>
<td>BCE</td>
<td>beneficial clinical event</td>
</tr>
<tr>
<td>BDPA</td>
<td>Bureau of Drug Policy and Administration (China)</td>
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<tr>
<td>BDS</td>
<td>Bureau of Drug Surveillance (Canada)</td>
</tr>
<tr>
<td>BISTIC</td>
<td>Biomedical Information Science and Technology Initiative Consortium (NIH)</td>
</tr>
<tr>
<td>BLA</td>
<td>biologics license application</td>
</tr>
<tr>
<td>BPA</td>
<td>Bureau of Pharmaceutical Assessment (Canada)</td>
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<tr>
<td>CDASH</td>
<td>Clinical Data Acquisition Standards Harmonization</td>
</tr>
<tr>
<td>CDDI</td>
<td>Collaboration for Drug Development Improvement</td>
</tr>
<tr>
<td>CDISC</td>
<td>Clinical Data Interchange Standards Consortium</td>
</tr>
<tr>
<td>CDM</td>
<td>clinical data management</td>
</tr>
<tr>
<td>CEN</td>
<td>Comité Européen de Normalisation (European Committee for Standardization)</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>cGMP</td>
<td>current good manufacturing practice</td>
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<tr>
<td>CLIA</td>
<td>Clinical Laboratory Improvement Amendments of 1988</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare and Medicaid Services</td>
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<tr>
<td>CPMP</td>
<td>Committee for Proprietary Medicinal Products (EMEA)</td>
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<tr>
<td>CRA</td>
<td>clinical research associate</td>
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<tr>
<td>CRADA</td>
<td>cooperative research and development agreement</td>
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<tr>
<td>CRF</td>
<td>case report form</td>
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<tr>
<td>CRIX</td>
<td>Clinical Research Information Exchange (FDA and NCI)</td>
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<tr>
<td>CRO</td>
<td>contract research organization</td>
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<tr>
<td>CSA</td>
<td>clinical study agreement</td>
</tr>
<tr>
<td>CSDD</td>
<td>Center for the Study of Drug Development (Tufts University)</td>
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<tr>
<td>CSM</td>
<td>Committee on Safety of Medicines (UK)</td>
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<tr>
<td>CSR</td>
<td>clinical study report</td>
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<tr>
<td>CTA</td>
<td>clinical trial application</td>
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<tr>
<td>CTD</td>
<td>common technical document</td>
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<tr>
<td>CTMS</td>
<td>Clinical Trial Management System</td>
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<td>CTTI</td>
<td>Clinical Trials Transformation Initiative</td>
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<tr>
<td>DSMB</td>
<td>Data Safety Monitoring Board</td>
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<tr>
<td>DTC</td>
<td>direct-to-consumer</td>
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<tr>
<td>DTP</td>
<td>direct-to-patient</td>
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<tr>
<td>DUR</td>
<td>drug utilization review</td>
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<tr>
<td>EAB</td>
<td>Ethics Advisory Board</td>
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<tr>
<td>eCTD</td>
<td>electronic common technical document</td>
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<tr>
<td>EDMS</td>
<td>Electronic Document Management System</td>
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<tr>
<td>EDQM</td>
<td>European Directorate for the Quality of Medicines</td>
</tr>
<tr>
<td>eIND</td>
<td>electronic investigational new drug application</td>
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<tr>
<td>EMEA (EMA)</td>
<td>European Medicines Agency (formerly European Medicines Evaluation Agency)</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Records</td>
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<tr>
<td>EMR</td>
<td>Electronic Medical records</td>
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<tr>
<td>ERB</td>
<td>Ethics Review Board</td>
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<tr>
<td>ERS</td>
<td>electronic regulatory submission</td>
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<tr>
<td>eSubs</td>
<td>electronic submissions</td>
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<tr>
<td>FDASIA</td>
<td>The Food and Drug Administration Safety and Innovation Act</td>
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<tr>
<td>FIH</td>
<td>first-in-human [clinical trials]</td>
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<tr>
<td>FPE</td>
<td>First Patient Enrolled</td>
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<td>FPI</td>
<td>First Patient In</td>
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<tr>
<td>GAAP</td>
<td>Greater Access to Affordable Pharmaceuticals Act of 2003</td>
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<tr>
<td>GCP</td>
<td>good clinical practice</td>
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<td>GLP</td>
<td>good laboratory practice</td>
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<td>GMP</td>
<td>good manufacturing practice</td>
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<td>GRP</td>
<td>good review practice</td>
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<tr>
<td>GSP</td>
<td>Good Statistics Practice</td>
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<tr>
<td>HPB</td>
<td>Health Protection Board (Canada)</td>
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<tr>
<td>IC</td>
<td>informed consent</td>
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<tr>
<td>ICD-9-CM</td>
<td>International Classification of Diseases, Ninth Revision, Clinical Modification</td>
</tr>
<tr>
<td>ICH</td>
<td>International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)</td>
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<tr>
<td>ICSR</td>
<td>Individual Case Safety Reports</td>
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<tr>
<td>IDE</td>
<td>investigational device exemption</td>
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<tr>
<td>IND</td>
<td>investigational new drug</td>
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<tr>
<td>IRB</td>
<td>Investigational Review Board</td>
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<tr>
<td>IRS</td>
<td>Incident Reporting System</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<tr>
<td>LOAEL</td>
<td>Lowest Observed Adverse Effect Level</td>
</tr>
<tr>
<td>LPE</td>
<td>Last Person Enrolled</td>
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<tr>
<td>LPI</td>
<td>Last person In</td>
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<tr>
<td>LPLV</td>
<td>Last Patient Last Visit</td>
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<tr>
<td>MCA</td>
<td>Medicines Control Agency (part of MHRA)</td>
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<tr>
<td>MedDRA</td>
<td>Medical Dictionary for Regulatory Activities</td>
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<tr>
<td>MEDIARIS</td>
<td>Medical Literature Analysis and Retrieval System (NLM)</td>
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<tr>
<td>MedSuN</td>
<td>Medical Product Safety Network</td>
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<tr>
<td>MHLW</td>
<td>Ministry of Health, Labor and Welfare (Japan)</td>
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<td>MPA</td>
<td>Medical Products Agency (Sweden)</td>
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<tr>
<td>NAF</td>
<td>notice of adverse findings</td>
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<tr>
<td>NAI</td>
<td>no action indicated</td>
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<tr>
<td>NAS</td>
<td>new active substance</td>
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<tr>
<td>NC</td>
<td>non-clinical (phase, studies)</td>
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<tr>
<td>NCE</td>
<td>new chemical entity</td>
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<tr>
<td>NME</td>
<td>new medical entity</td>
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<tr>
<td>NCS</td>
<td>not clinically significant</td>
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<tr>
<td>NDA</td>
<td>new drug application</td>
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<tr>
<td>NDE</td>
<td>new drug evaluation</td>
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<tr>
<td>NDS</td>
<td>New Drug Submission (Canada)</td>
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<tr>
<td>OAI</td>
<td>official action indicated</td>
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<tr>
<td>ODM</td>
<td>operational data model (CDISC)</td>
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<tr>
<td>PAB</td>
<td>Pharmaceutical Affairs Bureau (Japan)</td>
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<td>PAHO</td>
<td>Pan American Health Organization (WHO)</td>
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<td>PD</td>
<td>pharmacodynamics</td>
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<td>PDR</td>
<td>Physician’s Desk Reference</td>
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<td>PDUFA</td>
<td>Prescription Drug User Fee Act</td>
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<tr>
<td>PI</td>
<td>principal investigator</td>
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<tr>
<td>PIP</td>
<td>Pediatric Investigational Plan</td>
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<tr>
<td>PPI</td>
<td>patient package insert</td>
</tr>
</tbody>
</table>
The following are divisions and offices within the US Food and Drug Administration, FDA

**CBER — Center for Biologics Evaluation and Research (FDA)**
- OBE: Office of Biostatistics and Epidemiology
- OBRR: Office of Blood Research and Review
- OCBQ: Office of Compliance and Biologics Quality
- OCD: Office of the Center Director
- OCOD: Office of Communication, Outreach and Development
- OCTGT: Office of Cellular, Tissue and Gene Therapies
- OM: Office of Management
- OVRR: Office of Vaccines Research and Review

**CDER — Center for Drug Evaluation and Research Organization (FDA)**
- OAP: Office of Antimicrobial Products
- OB: Office of Biostatistics
- OBI: Office of Business Informatics
- OBP: Office of Biotechnology Products
- OC: Office of Compliance
- OC: Office of Communications
- OCD: Office of the Center Director
- OCP: Office of Clinical Pharmacology
- OCTEC: Office of Counter-Terrorism and Emergency Coordination
- ODE I: Office of Drug Evaluation I
- ODE II: Office of Drug Evaluation II
- ODE III: Office of Drug Evaluation III
- ODE IV: Office of Drug Evaluation IV
- ODSIR: Office of Drug Security, Integrity, and Recalls
- OEP: Office of Executive Programs
- OGD: Office of Generic Drugs
- OHOP: Office of Hematology Oncology Products
- OM: Office of Management
- OMEPRM: Office of Medication Error and Prevention and Risk Management
- OMP: Office of Medical Policy
- OMPI: Office of Medical Policy Initiatives
- OMPQ: Office of Manufacturing and Product Quality
- OND: Office of New Drugs
- ONDQA: Office of New Drug Quality Assessment
- OPA: Office of Planning and Analysis
- OPDP: Office of Prescription Drug Promotion
- OPE: Office of Pharmacovigilance and Epidemiology
- OPI: Office of Planning and Informatics
- OPS: Office of Pharmaceutical Science
- ORP: Office of Regulatory Policy

**CDRH — Center for Devices and Radiological Health, FDA**
- OSE: Office of Surveillance and Epidemiology
- OSI: Office of Scientific Investigations
- OTR: Office of Testing and Research
- OTS: Office of Translational Sciences
- OUDLC: Office of Unapproved Drugs and Labeling Compliance

**CDRH — Center for Devices and Radiological Health, FDA**
- OC: Office of Compliance
- OCD: Office of the Center Director
- OCERP: Office of Communication, Education, and Radiation Programs
- ODE: Office of Device Evaluation
- OIVDDES: Office of In Vitro Diagnostic Device Evaluation and Safety
- OMO: Office of Management Operations
- OSB: Office of Surveillance and Biometrics
- OSEL: Office of Science and Engineering Laboratories

**OCE — Office of the Commissioner, FDA**
- OCET: Office of Counter-Terrorism and Emerging Threats
- OCM: Office of Crisis Management
- OCS: Office of the Chief Scientist
- OEA: Office of External Affairs
- OL: Office of Legislation
- OMH: Office of Minority Health
- OPP: Office of Policy and Planning
- ORSI: Office of Regulatory Science and Innovation
- OSI: Office of Scientific Integrity
- OSPI: Office of Scientific Professional Development
- OWH: Office of Women's Health

**OGROP — Office of Global Regulatory Operations and Policy, FDA**
- OIP: Office of International Programs

**OMPT — Office of Medical Products and Tobacco, FDA**
- OCP: Office of Combination Products
- OOPD: Office of Orphan Products Development
- OPT: Office of Pediatric Therapeutics
- OSMP: Office of Special Medical Programs

**ORAH — Office of Regulatory Affairs, FDA**
- OCI: Office of Criminal Investigations
- OE: Office of Enforcement
- ORM: Office of Resource Management
- ORO: Office of Regional Operations

**WHO-ART**
- World Health Organisation Adverse Reaction Terminology

**SNOMED-RT**
- Systematized Nomenclature of Medicine Reference Terminology

**SPAC**
- State Pharmaceutical Administration of China

**SUD**
- sudden unexpected death — or — single-use device

**TBP**
- therapeutic biologic product

**TE**
- therapeutic equivalence

**TIND**
- treatment investigational new drug

**TMO**
- trial management organization

**USP**
- U.S. Pharmacopeia

**VAERS**
- Vaccine Adverse Event Reporting System

**VAI**
- voluntary action indicated

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