Develop | Innovate | Advance

DIA 2015

51ST Annual Meeting

JUNE 14–18 | WASHINGTON, DC

DIAGlobal.org/DIA2015

DIA DEVELOP INNOVATE ADVANCE

PRELIMINARY PROGRAM

It's a Meeting of the Minds

Program Chair

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

Scientist, educator, hospital and global healthcare company executive, Michael Rosenblatt, M.D., is executive vice president and chief medical officer at Merck. He is the company's primary external advocate on medical issues and represents the voice of the patient inside Merck.

Dr. Rosenblatt previously was Dean of Tufts University School of Medicine; the George R. Minot Professor of Medicine at Harvard Medical School; and president of Beth Israel Deaconess Medical Center (BIDMC). He was the Harvard faculty dean and senior vice president for academic programs at BIDMC. He was also director of the Harvard-MIT Division of Health Sciences and Technology. Read More

View 2015 Program Committee

Click Here

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Register today at
DIAGlobal.org/DIA2015

DIA 2015

51ST Annual Meeting

JUNE 14–18 | WASHINGTON, DC

SCHEDULE AT-A-GLANCE

SATURDAY JUNE 13

Registration Hours:

9:00AM-5:00PM	Exhibitor Registration

SUNDAY, JUNE 14

Registration Hours:

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

Schedule:

8:30AM-12:00PM	Half Day Preconference Tutorials*
9:00AM-5:00PM	Full Day Preconference Tutorials*
1:00-4:30PM	Half Day Afternoon Preconference Tutorials*
4:00-5:00PM	DIA 2015 51st Annual Meeting Orientation and Networking

**Space is limited for Preconference Tutorials. Onsite Registration is available, but not guaranteed*

MONDAY, JUNE 15

Registration Hours:

7:00AM-6:00PM	Attendee, Speaker, and Exhibitor Registration

Schedule:

7:30-8:20AM	DIA 2015 51st Annual Meeting Orientation/Networking and Coffee
7:45-8:30AM	Coffee and Breakfast Breads
8:30-10:00AM	Educational Opportunities
8:30-10:00AM	Student Forum
9:30AM–4:30PM	Student Poster Session (Exhibit Hall)
9:30AM-6:00PM	Exhibit Hall Open
10:00-11:00AM	Coffee Break
11:00AM-12:30PM	Educational Opportunities
12:30-2:30PM	Lunch & Exhibit Hall Innovation Theater Presentations
2:30-4:00PM	Plenary Session & Keynote Address
4:00-6:00PM	Opening Reception (Exhibit Hall)

TUESDAY, JUNE 16

Registration Hours:

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

Schedule:

7:15-8:00AM	Coffee and Breakfast Breads
8:00-9:30AM	Educational Opportunities:
9:00AM-4:00PM	Professional Poster Session #1 (Exhibit Hall)
9:00AM-5:00PM	Exhibit Hall Open
9:30-10:30AM	Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30AM-12:00PM	Educational Opportunities
11:30AM-1:30PM	Lunch & Exhibit Hall Innovation Theater Presentations
12:30PM	Student Poster Award Ceremony (DIA Booth #1523)
1:30-3:00PM	Educational Opportunities
1:30-3:30PM	Exhibit Guest Passes
2:30-3:30PM	Refreshment Break & Exhibit Hall Innovation Theater Presentations
3:30-5:00PM	Educational Opportunities

WEDNESDAY, JUNE 17

Registration Hours:

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

Schedule:

7:15-8:00AM	Coffee and Breakfast Breads
8:00-9:30AM	Educational Opportunities
9:00AM-4:00PM	Professional Poster Session #2 (Exhibit Hall)
9:00AM-4:00PM	Exhibit Hall Open
9:30-10:30AM	Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30AM-12:00PM	Educational Opportunities
11:30AM-1:30PM	Lunch & Exhibit Hall Innovation Theater Presentations
1:30-3:00PM	Educational Opportunities
1:30-3:30PM	Exhibit Guest Passes
2:30-3:30PM	Refreshment Break & Exhibit Hall Innovation Theater Presentations
3:30-5:00PM	Educational Opportunities

THURSDAY, JUNE 18

Registration Hours:

8:00-11:00AM	Attendee and Speaker Registration

Schedule:

8:15-9:00AM	Coffee and Breakfast Breads
9:00-10:30AM	Educational Opportunities
10:30-10:45AM	Coffee Break
10:45AM-12:15PM	Educational Opportunities

As of February 24, 2015. Schedule subject to change.

Plan Your Annual Meeting Experience: 20 Tracks and 245+ Educational Offerings.

Track #	Track	Interest Area(s)
Track 01	Clinical Operations	Academic Health Centers/Investigative Sites (AHC/IS), Clinical Research (CR), Clinical Supplies (CS), Manufacturing (MF), Research and Development (RD)
Track 02	Project/Portfolio Management and Strategic Planning	Financing (FI), Project Management (PM), Strategic Planning (SP)
Track 03	Innovative Partnering Models and Outsourcing Strategies	Outsourcing (OS)
Track 04	Preclinical and Translational Development/ Early Phase Clinical Development	Biotechnology (BT), Nonclinical (NC), Pharmacology (PC)
Track 05	Regulation of Product Advertising and Marketing in an Ever-changing World	Advertising and Promotion (AP), Marketing (MA)
Track 06	Medical Communication/Medical Writing, and Medical Science Liaisons	Medical Communications (MC), Medical Science Liaisons (MSL), Medical Writing (MW)
Track 07	Technology/Data/Records and Submissions	Information Technology (IT), eClinical (EC), Clinical Data Management (CDM), Document Management (DM), Study EndPoints/Clinical Outcomes Assessment (SE), Submissions (SUBS), Validation (VA)
Track 08	Regulatory Affairs	Regulatory Affairs (RA)
Track 09	Medical Devices, In Vitro Diagnostics, and Combination Products	Combination Products (CmbP), Medical Devices and Diagnostics (MDD)
Track 10	Public Policy/Health Care Compliance/Law	Public Policy, Health Care Compliance/Law (PPLC)
Track 11	Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice	Good Clinical Practice (GCP), Quality Assurance, Quality Control (QA/QC)
Track 12	Pharmaceutical Quality	Chemistry, Manufacturing and Controls/Good Manufacturing Practices (CMC/GMP)
Track 13	Comparative Effectiveness Research/Global Health Outcomes and Economics	Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine (CEHTAEbM), Pricing and Reimbursement (PR)
Track 14	Clinical Safety and Pharmacovigilance	Clinical Safety and Pharmacovigilance (CP)
Track 15	Statistical Science and Quantitative Thinking	Statistical Science (ST)
Track 16	Professional Development	Professional Education, Training, and Development (PETD)
Track 17	Rare/Orphan Diseases	Rare/Orphan Diseases (ROD), Patient Engagement (PT)
Track 18	Global Regulatory	All
Track 19	Late-breaking Topics	All
Track 20	Innovation Theater	All

Program Highlights

Connect with the key thought leaders conversing on the hottest topics:

21st Century Topics

- 21st Century Cures: Which Are the Most Transformative Provisions and How Do They Accomplish Major Change? - Moving the Role of the CRC and CRA into the 21st Century: Opportunities and Challenges
- Regulation of Combination Products in the 21st Century
- Bringing Clinical Trial Practices into the 21st Century

Advancing R&D Innovations

- Rare Disease Organizations and Industry Players: Collaborating Effectively to Advance R&D for Rare Disease Patients
- Collaborate to Innovate: Exploring a Seconds Market
- Tired of Reinvesting in Old R&D Systems? Several Large Pharmaceutical Companies and Other Leaders are Flipping Paradigms

Audits and Inspections

- How to Prepare for an FDA Inspection
- FDA's International Posts: International Efforts, Regulatory System Strengthening and Inspections
- Office of Pharmaceutical Quality Update
- Pharmacovigilance Inspections: Achieving Compliance in a Global Environment
- Risk-Based Inspections and Compliance

Big Data

- How Pharmaceutical Companies and CROs Are Harnessing Big Data and Cloud Computing to Increase R&D Innovation, Efficiency, and Collaboration
- Engaging Patients and Health Care Professionals Through Social Media and Big Data
- Patient Registries: Design, Development, and Recruitment

Register Online Now

Biosimliars

- Successful Drug Development: Best Practices for Clinical Trial Design, Agency Interactions, and Regulatory Document Writing
- In Vitro and In Vivo Preclinical Testing of Biosimilars: What Have We Learned?
- Global Regulation of Advanced Therapies
- 21st Century Pharmacovigilance: Improving Outcome Traceability for Products Across the Complexity Continuum, From Generics to Biologics and Vaccines

Clinical Trial Design

- Enabling Next Generation Sequencing within Global Clinical Trials
- Direct-to-Patient Strategies That Are Changing the Landscape of Clinical Trials
- Lung-Map: A Future Clinical Trial with a Master Protocol Happening Now and the Value to Patients

Disease Specific

- Using Registries to Support Recruitment in Alzheimer's Disease (AD) Prevention or Delay-of-Onset
- Ebola Virus Disease Case Study: Global Harmonization to Increase Power and Accelerate Outcomes in Clinical Research Data
- Innovative Designs for Cardiovascular Outcome Safety Trials in Type 2 Diabetes

GDUFA/Generics

- Fundamentals of ANDA Submissions and FDA Expectations Under GDUFA
- Does Bioequivalent Always Mean Therapeutically Equivalent? Impact of FDA's Proposed Rule on Generic Labeling
- Statistical Evaluation of Therapeutic Equivalence for Locally-Acting Generic Products

Labeling

- The Impact of the eLabeling Rule on Industry and Stakeholders
- The Role of Labeling in Successful Human Factors Studies
- No More Crying Wolf: FDA Issues Final Rule on Changes to Pregnancy and Lactation Information in Drug Labeling

Patient Engagement

- The Growing Role of the Patient Leading Into PDUFA VI: Negotiations and 2016
- Integrating Patient Engagement with EHR Data and eSource for Better Studies
- Engaging Patients as Partners: Effective Trial Communications to Build Trust and Improve Patient Participation

Personalized Medicines/Targeted Therapy

- Impact of FDA Oversight of Laboratory-Developed Tests Upon Innovation in the Targeted Therapy
- Precision Medicine: Where Is the Technology Taking Us, How Fast and Who Is Driving?
- Leveraging Electronic Health Record Data in Close Collaboration with Health Systems to Accelerate Precision Medicine

Risk-Based Monitoring

- Implementing Risk-Based Monitoring: Best Practices from Pharmaceutical Industries to Contract Research Organizations
- DEVELOP Risk-Based Monitoring Strategies to INNOVATE Study Oversight and ADVANCE Study Execution
- How Risk-Based Monitoring and eSource Methodologies are Impacting Clinical Sites, Patients, Regulators and Sponsors

Vaccines

- Safety in Special Situations: Vaccines, Stem Cells and Beyond
- 21st Century Pharmacovigilance: Improving Outcome Traceability for Products Across the Complexity Continuum, From Generics to Biologics and Vaccines
- Real-World Use of Multi-Criteria Decision Analysis for Benefit-Risk Assessment: Examples and Lessons Learned in the Industrial Setting

Women's Health

- Developing Innovative Approaches to Postmarketing Safety Data Collection in Pregnant Women
- No More Crying Wolf: FDA Issues Final Rule on Changes to Pregnancy and Lactation Information in Drug Labeling

Search the **Online Program** for the complete list of sessions on today's hottest topics!

Network with 450+ Exhibiting Companies

Exhibiting Companies Confirmed as of February 10

With virtually every facet of the life sciences industry represented — CROs, technology vendors, research centers, academia, and much more — the Exhibit Hall is one of the busiest places at the meeting.
View Floor Plan

4C Pharma Solutions LLC
Accell Clinical Research
Accenture
Accovion GmbH
ACM Global Central Laboratory
ACRP
Acurian, Inc.
Adaptive Clinical Systems
Advanced Clinical
Aerotek
Alfresco Software, Inc.
Almac
Ancillare, LP
APCER Pharma Solutions, Inc.
Applied Clinical Trials/ Pharmaceutical Executive
ArisGlobal
Artcraft Health
Asia CRO Alliance
Association of Biotechnology Led Enterprises – ABLE
August Research
Axiom Real-Time Metrics Inc.
BARC Global Central Laboratory
Barrington James
BBK Worldwide
Benchmark Research
BioClinica
Biomedical Systems
BioPharm Insight
BioPharma Investigator
BioPoint, Inc
Biorasi
bioskin GmbH
BIOVIA
Blinded Diagnostics
Bracket
CAC EXICARE Corporation
CAHG
Camargo Pharmaceutical Services
Cambridge Healthtech Institute
Canfield Scientific, Inc.
Cardinal Health
Cardiocore
Cardiovascular Imaging Technologies
Catalent
Celerion
Center for Information and Study on Clinical Research Participation (CISCRP)
Chesapeake IRB
Chexx Inc.
Chiba University Hospital
Chiltern International, Inc.
Cincinnati Children's Research Foundation
Citeline Inc.
CITI Program - University of Miami
CitiusTech Inc.
Clariness
ClinDatrix, Inc.
ClinEdge, LLC
Clinical Ink
Clinical Practice Research Datalink (CPRD)
Clinical Reference Laboratory
Clinical Research Advantage
The Clinical Resource Network
Clinlogix
ClinPlus/DZS Clinical Services
ClinTec International Ltd.
Clinverse, Inc.
CluePoints, Inc.
CMIC Holdings Co., Ltd.
Compass IRB
Compass Research, LLC
CompleWare
Comprehend Systems
Continuum Clinical
ConvergeHEALTH by Deloitte
Conversis
CoSign by ARX
Cote Orphan Consulting, LLC
Covance Inc.
CRF Health
CROMSOURCE
CROS NT
CSSi
CTI Clinical Trial & Consulting Services
Cu-Tech, LLC
Cytel Inc.
Data Matrix
DataArt
Datapharm Australia Pty Ltd
DATATRAK International, Inc.
DaVita Clinical Research
DIA
DIA Patient Advocate Fellowship
DITA Exchange
Dohmen Life Science Services
Dr. Ebeling & Assoc. GmbH
DrugDev
DSG, Inc.
d-Wise Technologies
EastHORN Clinical Services in CEE, Ltd.
eClinicalHealth Ltd.
ECLINSO
Elite Research Network, LLC
EMB Statistical Solutions, LLC
Emerson Process Management
endpoint
Enforme Interactive
ENNOV
Entimo AG
ePharmaSolutions
EPS Corporation
ERT
Eurofins
European Medicines Agency

EUROTRIALS
Everest Clinical Research
Exco InTouch
ExL Pharma
Exostar
Experis Clinical Practice
Exponent
EXTEDO, Inc.
Falcon Consulting Group
FDA CDER
FDAnews
Flex Databases
Foresight Group International AG
Formedix Inc.
Frenova Renal Research
Fresenius Medical Care North America
Frontage Labs
Galderma Research & Development, LLC
GenPro International
Global Language Solutions
GlobalCare Clinical Trials, LTD
goBalto, Inc.
GP Strategies
Green Key Resources
Greenphire
Guangzhou KingMed Center for Clinical Laboratory Co. Ltd.
Hangzhou Tigermed Consulting Co., Ltd.
HCL America Inc.
Health Decisions, Inc.
Hummingbird IRB
Hurley Consulting Associates Ltd.
Hurley Write, Inc.
iCardiac Technologies
ICON plc
IDT Australia
ImageIQ, Inc.
Imperial
IMS Health
Inamed GmbH
INC Research
Industry Standard Research
Information Builders, Inc.
Infotehna Inc.
InnovoCommerce LLC
Integrated Clinical Systems, Inc.
Integrated Development Associates Co., Ltd.
IntegReview IRB
INTERLAB GmbH central lab services worldwide
International Dermatology Research, Inc.
Intertek Scientific & Regulatory Consultancy
IntraLinks, Inc.
inVentiv Health Clinical
Investigational Cancer Therapeutics - MD Anderson
IPHARMA / ChemDiv
IQ Pharma S.A.
Jazz Pharmaceuticals Inc.
JMAC Partners
Joulé Clinical Staffing Solutions
KCR
Kelly Scientific Resources
Klein Hersh International
KoNECT
Kuantum CRO and Logistics
LabConnect, LLC
LabCorp Clinical Trials
Lambda Therapeutic Research Inc.
Langland
Life Science Leader
Linical USA
Lionbridge Technologies
Longboat Clinical Ltd.
LORENZ Life Sciences Group
Lovelace Scientific Resources
MakroCare
MASIMO
Massachusetts College of Pharmacy and Health Sciences
MasterControl
MaxisIT Inc.
McGuire Research Institute
Med Fusion
MedDRA MSSO
Medical Vigilance Solutions, Cincinnati Children's
Medidata Solutions, Inc.
MEDIX
MedNet Solutions, Inc.
Medpace Inc.
MedPoint Digital, Inc.
Medrio, Inc.
MedSource
MedTrials
Merge eClinical
MESM Ltd
META Solutions, Inc.
Mission3
MMG
MNX Global Logistics
MonitorForHire.com
Montrium, Inc.
Morningside Translations
Mortara Instrument, Inc.
National Death Index
NCGS Incorporated
NeoGenomics Laboratories
Neuroscience Trials Australia
New Orleans Center for Clinical Research
NextDocs
Nextrials, Inc.
NNIT
Norav Medical
Novella Clinical
November Research Group
Novotech
Ocasa Logistics Solutions
OmniComm Systems, Inc.
Online Business Applications
OpenClinica
Optum
Oracle Corporation
Orlando Clinical Research Center
Otto Trading, Inc.
Palm Beach CRO
Paragon International, Inc.
Paragon Solutions
PAREXEL International
The Patient Recruiting Agency
PatientPoint
PCM TRIALS
Pharma Start
Pharmaceutical eConsulting
Pharmaceutical Packaging Professionals Pty Ltd.
Pharmaceuticals and Medical Devices Agency (PMDA)
PharmApprove
PharmaQuest Ltd
PharmaSeek Companies
PharmaSys, Inc.
PharmaVOICE
Pharm-Olam International Ltd.
Phlexglobal Inc.
PHT Corporation
Pilgrim Quality Solutions
Planet Pharma
PleaseTech Ltd.
Popsi Cube
PPD
PRA Health Sciences
Praxis Communications, LLC
Precision for Medicine

Exhibiting Companies

Continued from Page 7

Premier Research Group
PRL Central Laboratory Services
Projecis, Inc.
PROSAR
ProTrials Research, Inc.
PSKW, LLC
Pyxant Labs Inc
Q2 Business Intelligence
QPS, LLC
Quality and Compliance Consulting, Inc.
Quality Associates, Inc.
Quanticate, Inc.
QuantifiCare
Queensland Clinical Trials Network
Quest Diagnostics
Quintiles
Quorum Review IRB
Randstad Pharma
Real Staffing Group
Regeneron Pharmaceuticals
Regxia Inc.
Research Across America
ReSolution Latin America
Rho, Inc.
RWS Group - Medical Translation Division
Rx Trials Inc.
RxLogix Corporation
SAS Institute Inc.
SAS Institute Inc., JMP Division
Scarritt Group, Inc.
Schlafender Hase GmbH
Schulman Associates IRB
SCI-C
SeaView Research
Sharp Clinical Services
Sidus Biodata
Signix, Inc.
Society for Clinical Research Sites - SCRS
Sonic Clinical Trials
Southern California Research
Southern Star Research
Sparta Systems
Spaulding Clinical Research
Speaking Books
Spectra Clinical Research
SPRI Clinical Trials - Global
Springer
Statistics & Data Corporation (SDC)
Stefanini
Sterling IRB
Stiris Research Inc.
Symbio, LLC
Symphony Clinical Research
Synchrogenix Information Strategies, Inc.
Synowledge
SynteractHCR
Target Health Inc.
Tarius A/S
Tata America International Corporation
Technical Resources International, Inc.
Telerx
Teuteberg Incorporated
TFDA/Center for Drug Evaluation, Taiwan
Theorem Clinical Research
Therapak Corporation
Therapeutics Inc.
Thomson Reuters
ThreeWire, Inc.
TKL Research, Inc.
Total Clinical Trial Management
Total Root Concepts, Inc.
TransPerfect
Trievr, Inc
Trifecta
UBC
Unanet
University of Florida
University of Maryland Online MS in Regulatory Science
University of the Sciences
The Uppsala Monitoring Centre
Valesta Clinical Research Solutions
Veeva Systems, Inc.
Verified Clinical Trials
Veristat, Inc.
Vince & Associates Clinical Research
Viracor-IBT Laboratories
VirtualScopics
Vitalograph, Inc.
Voluntis
WCCT Global
WebbWrites, LLC
Whitsell Innovations, Inc.
Wincere, Inc.
Wingspan Technology Inc.
WIRB-Copernicus Group
Worldwide Clinical Trials
XenoBiotic Laboratories, Inc.
Xerimis Inc.
Y-Prime Inc.
Zigzag Associates Ltd

Interested in Exhibiting? Reserve Your Space Today!
+1.703.631.6200 or
diaexhibits@jspargo.com

Networking

The DIA 2015 51st Annual Meeting attracts the biggest names from the life sciences industry and related sectors with key networking opportunities including:

- DIA Opening Reception
- Annual Meeting Orientation and Networking
- Refreshment Breaks
- Community Luncheon
- Extended Lunch Hours
- Student Poster Session
- Professional Poster Sessions

View Dates and Times

View All Agency Led Presentations

Global Regulatory Presence

The DIA 2015 51st Annual Meeting gives you the unique opportunity to interact with global regulators to share knowledge and discuss key issues in today's hottest topics. 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.

- An Insider's View of Cooperation Between the EMA and CDER/FDA
- An Update From Health Canada
- Asia Town Hall: Asia as a Drug R&D Center in the World
- CBER Town Hall
- CDER Town Hall
- And More!

Patient Advocate Fellowship Program

DIA is working to ensure the voice of the patient is heard globally in every facet of the discovery, development, and life cycle management of pharmaceuticals, biotechnology, and related medical products.

In April, we will be announcing this year's Patient Advocates and opportunities for you to engage with them while in Washington, DC. Stay tuned for details.

View Patient Initiatives

General Information

Click Here

www.ciscrp.org/medhero5K-DC

MEDICAL HEROES APPRECIATION

5K run and walk

CISCRP

THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Medical Heroes Appreciation 5K

Run | Walk | Give

Earlybird registration only $25! Ends May 15

Join us to celebrate study volunteers and honor their gift of participation in clinical research!

Monday, June 15, 2015 • 6:30 to 8:15 AM

At the DIA 2015 51st Annual Meeting

All proceeds will provide education and outreach to patients and their families.

REGISTER NOW

WWW.CISCRP.ORG/MEDHERO5K-DC

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Where to Stay

Travel Planners (now onPeak, part of the GES Global Network) is the official Housing Bureau for the DIA Annual Meeting.

Why Choose an Official DIA Hotel?

We encourage you to understand the importance of selecting an official DIA hotel. To obtain the necessary amount of meeting and exhibit space at the Convention Center and the hotels, DIA must contract a minimum number of guest rooms. If the contractual obligation is not met, DIA will incur significant financial penalties and have difficulty obtaining sufficient meeting space in the future. Conference costs—even attendee and exhibitor fees—could increase. When we are able to maintain a consistent history of hotel rooms sold, we are better positioned to negotiate the lowest hotel rates possible for future DIA meetings.

Travel Discounts

DIA is pleased to provide discounts for your travel plans to Washington, DC. Discounts are available for Amtrak, United Airlines, and Delta Airlines.

Hotel Information | List of Room Block Hotels | Map of DIA Hotels

The Walking Gallery

June 15 | 4:00-6:00PM

For the second year, DIA will be hosting The Walking Gallery, a patient empowerment movement founded by Artist Regina Holliday. During the Opening Reception on Monday, current members of The Walking Gallery are welcome to gather and share their stories. Already A Walking Gallery member? RSVP to Julie.Ho@diahome.org.

Interested in becoming a member of The Walking Gallery? Contact Regina Holliday (via Facebook, Twitter, or Linkedin) prior to the Annual Meeting.

Watch The Walking Gallery of Health Care

We are the Gallery that walks.
We are the Patients that wear our story on our backs.

Continuing Education

The DIA 2015 51st Annual Meeting is the premier event designed for individuals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices, and related medical products. The Annual Meeting is intended to strengthen professionals' understanding of the value of cross-discipline integration and to foster innovation for better health outcomes.

LEARNING OBJECTIVES

At the conclusion of the DIA 2015 51st Annual Meeting, participants should be able to:

TRACK 01: CLINICAL OPERATIONS

- Identify the important current clinical trial issues and how they can be addressed with innovative solutions
- Discuss methods of reducing costs while maintaining quality in the management of clinical trials using new technologies and efficient best practices
- Describe how to ensure ethical and safe treatment of subjects in the modern trial arena

TRACK 02: PROJECT/PORTFOLIO MANAGEMENT AND STRATEGIC PLANNING

PROJECT MANAGEMENT

- Identify and describe product development/project management practices and project-related finance practices used in the industry and project management practices within regulatory agencies
- Discuss new project management practices and systems used in global product development

PORTFOLIO MANAGEMENT

- Identify and describe 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

- 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, co-development partners, and other organizations

TRACK 04: PRECLINICAL AND TRANSLATIONAL DEVELOPMENT / EARLY PHASE CLINICAL DEVELOPMENT

- Explain some of the latest preclinical technologies and approaches for assessing the safety of pharmaceutical products
- 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

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 LIAISONS

- Identify opportunities to collaborate and meet the expectations of global regulatory authorities, health care professionals, patients, payers, and other customers
- Discuss successful communication channels across Medical Writing, Medical Communications, and Medical Science Liaisons

TRACK 07: TECHNOLOGY/DATA/RECORDS AND SUBMISSIONS

- Discuss best practices for the use of standards, technologies and processes in clinical trials
- Describe novel uses of existing/emerging technologies and processes
- Identify how technical and procedural innovations transform the clinical trial life cycle

TRACK 08: REGULATORY AFFAIRS

- Discuss the latest global regulatory trends and developments that impact the industry, health authorities and other stakeholders

TRACK 09: MEDICAL DEVICES, IN VITRO DIAGNOSTICS, AND COMBINATION PRODUCTS

- Discuss ways to further enhance the abilities of drug companies to meet the regulatory challenges created by innovative drug delivery, companion diagnostics and personalized medicine

TRACK 10: PUBLIC POLICY/HEALTH CARE COMPLIANCE / LAW

- Discuss implications and recommendations raised in current topics in health care compliance, public policy and law

TRACK 11: INNOVATIVE APPROACHES TO ENSURING QUALITY IN CLINICAL TRIALS AND COMPLIANCE TO GOOD CLINICAL PRACTICE (GCP)

- 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 Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

TRACK 13: COMPARATIVE EFFECTIVENESS RESEARCH/GLOBAL HEALTH OUTCOMES AND ECONOMICS

- Describe current issues in measuring and communicating the medical need, health impact, and economic value associated with medical interventions
- Evaluate treatment heterogeneity and CER (methods and applications)

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

- Discuss current information on statistical solutions to issues associated with the evidence and regulatory review of drugs, diagnostics/devices, and biologics
- Examine the role statistical professionals have in raising awareness and providing information in an continuously evolving environment
- Discuss the cross-functional exchange of ideas and problem-solving for statisticians and other stakeholders

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

- Identify the unique challenges, opportunities, and strategies that will help to shape a better future for the successful discovery and development of orphan drugs and novel treatments for rare diseases
- Examine the role of basic, translational, and clinical researchers, drug, device and diagnostics companies, governmental agencies, patient advocacy organizations and patients in novel therapy development
- Recognize the impact of rare/orphan diseases on patient well-being and health care systems

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: LATE-BREAKING TOPICS

- Discuss late breaking hot topics in the pharmaceutical, biotechnology and/or medical device industry

*Select preconference tutorials and program offerings (including sessions, forums, workshops, symposia, TURBO offerings) have been approved for AMA PRA Category 1 Credits™ and will also offer pharmacy or nursing contact hours, or Project Management Institute (PMI) professional development units (PDUs). Continuing education credit information will be clearly identified in the final program with the statement of CME, Pharmacy, Nursing, or PMI PDUs. IACET continuing education units (CEUs) are offered for all program offerings and preconference tutorials. Continuing education credits are **not available** for the Opening Plenary Session on Monday afternoon, Student or Professional Poster Sessions, Innovation Theater, or White Paper Presentations. Learning objectives for each program offering (and preconference tutorial, if applicable) will be shown in all 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 providership of Postgraduate Institute for Medicine (PIM) and the Drug Information Association (DIA). 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 24.5 *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)

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants may earn up to 24.5 contact hours or 2.45 continuing education units (CEUs) for participating in the Annual Meeting program offerings and preconference tutorials.

ACPE Credit Requests MUST BE SUBMITTED by WEDNESDAY, JULY 29, 2015

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor. ***All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity (by Wednesday, July 29, 2015).*** If ACPE credit requests are not submitted within date noted above, the ACPE credit request will not be processed to the CPE Monitor. 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 24.5 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 24.5 contact hours.

Project Management Institute (PMI)

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

Participants may receive up to 10.75 professional development units (PDUs) for attending the Annual Meeting program offerings and preconference tutorials.

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

International Association for Continuing Education and Training (IACET)

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 3.1 CEUs for this program.

CONTINUING LEGAL EDUCATION

For attorneys who would like to receive continuing legal education credits for attending DIA 2015 51st 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.

CE CREDIT ALLOCATION

PRECONFERENCE TUTORIALS – JUNE 14

Half Day Preconference Tutorials:

- 8:30 AM–12:00 PM: Up to: CME 3.25 *AMA PRA Category 1 Credits™*; IACET .3 CEUs; Nursing 3.25 contact hours; Pharmacy 3.25 contact hours or .325 CEUs; 3.25 PMI PDUs
- 1:00 PM–4:30 PM: Up to: CME 3.25 *AMA PRA Category 1 Credits™*; IACET .3 CEUs; Nursing 3.25 contact hours; Pharmacy 3.25 contact hours or .325 CEUs

Full Day Preconference Tutorials:

- 9:00 AM–5:00 PM: Up to: CME 6.5 *AMA PRA Category 1 Credits™*; IACET .7 CEUs; Nursing 6.5 contact hours; Pharmacy 6.5 contact hours or .65 CEUs

ANNUAL MEETING PROGRAM OFFERINGS – JUNE 16-19

Up to CME 18 *AMA PRA Category 1 Credits™*; 2.4 IACET CEUs (.2 IACET CEUs are offered for a 1.5 hour program offering and .1 IACET CEU is offered for a 1 hour TURBO offering); Nursing 18 contact hours; Pharmacy 18 contact hours or 1.8 CEUs; 10.75 PMI PDUs

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

In addition, DIA's Certificate Program units will be available for DIA 2015 51st Annual Meeting preconference tutorials. See specific units that are available for each offering noted in preliminary program book. For more information on DIA's Certificate Program, visit www.DIAGlobal.org/certificateprograms.

Participants will be able to download a statement of credit upon successful submission of the credit request. Complete details and instructions for accessing CE credit will be included in the final program.

DISCLOSURE OF CONFLICTS OF INTEREST

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

DISCLAIMER

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers, agenda, and CE information are subject to change without notice. Recording of any DIA educational material in any type of media is prohibited without prior written consent from DIA.

To view DIA's Grievance Policy, please visit www.DIAGlobal.org/CE.

AMERICANS WITH DISABILITIES ACT

Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

Preconference Tutorials | Sunday, June 14

While you're in Washington, DC, be sure to take advantage of additional educational and networking opportunities before DIA 2015 51st Annual Meeting officially kicks off. Each tutorial is designed to increase your knowledge while allowing for small group interaction. The tutorials listed below are extra-fee events costing $405 for half day or $705 for full day offerings.

Receive $100 off your DIA 2015 51st Annual Meeting registration by registering for two half day tutorials or one full day tutorial. Purchases must be made in the same transaction.

View Full List of Tutorials

Morning Tutorials, Half Day | 8:30am-12:00pm		Tutorial Fee: $405
Tutorial 20:	The Sunshine Act: Understanding the Essentials of Compliance	See page 15 for details.
Tutorial 21:	Leadership: How to Organize and Lead People in a Work Group	See page 15 for details.
Tutorial 22:	Successful Drug Development: Best Practices for Clinical Trial Design, Agency Interactions, and Regulatory Document Writing	See page 16 for details.
Tutorial 23:	How to Prepare for an FDA Inspection	See page 17 for details.
Tutorial 24:	Pharmacogenomics and Companion Diagnostics: The Future of Clinical Trials, New Product Development and the Practice of Medicine	See page 17 for details.
Tutorial 25:	Signal Detection - Identifying and Managing Safety Signals	See page 18 for details.
Afternoon Tutorials, Half Day | 1:00-4:30pm		Tutorial Fee: $405
Tutorial 30:	Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development	See page 19 for details.
Tutorial 31:	Preparing for a US FDA Advisory Committee Meeting	See page 19 for details.
Tutorial 32:	Influencing Culture, Avoiding Bureaucracy, and Encouraging Innovation	See page 20 for details.
Tutorial 33:	Large-Scale Regulatory Functional Outsourcing: Emerging Trends, Challenges, and Decision Criteria	See page 20 for details.
Tutorial 34:	Preparation of Risk Evaluation and Mitigation Strategies Assessment Reports	See page 21 for details.
Tutorial 35:	Ethical Issues in Clinical Trials	See page 22 for details.
Full Day Tutorials | 9:00am-5:00pm		Tutorial Fee: $705
Tutorial 40:	Analysis of Safety Data from Clinical Trials	See page 23 for details.
Tutorial 41:	Quality Oversight of CROs-Clinical Vendors	See page 23 for details.
Tutorial 42:	Fundamentals of ANDA Submissions and FDA Expectations Under GDUFA	See page 24 for details.
Tutorial 43:	Clinical Statistics for Nonstatisticians	See page 25 for details.
Tutorial 44:	Risk Management and Safety Communication Strategies	See page 25 for details.
Tutorial 45:	The Good Pharmacovigiliance Practices in the EU: Global Applications	See page 26 for details.

Maximize your learning while attending the DIA 2015 51st Annual Meeting! Receive $100 off of your meeting registration by registering for two tutorials or one tutorial. Purchases must be made at the same time in order to receive the discount.

MORNING TUTORIALS, HALF DAY

8:30 AM–12:00 PM **FEE: $405**

TUTORIAL 20 Tracks 01, 06 and 10

Related Interest Area(s): PPLC, RA, QA/QC

The Sunshine Act: Understanding the Essentials of Compliance

Continuing Education Credit: CME: 3.25 *AMA PRA Category 1 Credits™;* IACET .3 CEUs; Nursing 3.25 contact hours
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Michael A. Swit Esq
FDA Regulatory Counsel
Illumina

As part of the Affordable Care Act of 2010, the Sunshine Act was enacted. This law is designed to inject greater transparency for the public to understand the relationship between pharmaceutical and medical device companies and the physicians and teaching hospitals that are most likely prescribing their products. The Sunshine Act imposes a duty on "applicable manufacturers" of "covered" drugs and devices to both track and disclose not only payments made to physicians and teaching hospitals in the form of consulting fees, honoraria, etc., but also any other provision of an item or service that has a value to such recipients, including meals, trips, research equipment, etc. And, annually all such payments need to be submitted to a website maintained by the Center for Medicare and Medicaid Services (CMS) for public review. This tutorial will explore in detail the Sunshine Act's requirements, including any potential exemptions, and also the unique way that the Sunshine Act deals with research-related payments, which overlaps in part with the separate provisions in 21 CFR Part 54 that FDA imposes for the disclosure of financial interests held by clinical investigators. The basics of the system and process for submitting the required disclosures to the CMS "Open Payments" database and suggestions on how to implement processes at their companies to ensure compliance with the Act's requirements will be discussed.

Learning Objectives

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

- Discuss how the Sunshine Act is structured
- Identify key definitions that impact duties under the Sunshine Act, including when a product is "covered" so as to potentially render the manufacturer responsible for disclosing payments
- Identify the many different types of payments or provision of other things of value that must be tracked and disclosed under the Sunshine Act

Target Audience

This tutorial is designed for all personnel responsible for ensuring compliance with the Sunshine Act.

TUTORIAL 21 Track 16

Related Interest Area(s): ALL

Leadership: How to Organize and Lead People in a Work Group

Continuing Education Credit: IACET .3 CEUs; PMI 3.25 PDUs, PMI #: 2166-000163
Project Management Certificate Program: 2 Elective Units

Instructor
Michael Laddin
CEO
Leaderpoint

The role of a leader in organizing and leading a group is often misunderstood and, as a consequence, the group may not perform up to expectations, or it may spend a considerable

amount of time dealing with dysfunctional group dynamics instead of the work to be accomplished. This tutorial addresses those issues by exploring the types of work groups, how they can be more effective, and how individuals can correct group dynamics and help the group achieve higher levels of performance.

Learning Objectives

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

- Identify the different types of work group structures and be able to predict the quality of work the group will produce
- Identify ways to correct dysfunctional group dynamics
- Create and maintain cooperation among team members, including cross-functional teams

Target Audience

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

TUTORIAL 22 — Tracks 01, 06, 08

Related Interest Area(s): RA, MW

Successful Drug Development: Best Practices for Clinical Trial Design, Agency Interactions, and Regulatory Document Writing

Continuing Education Credit: IACET .3 CEUs
Clinical Research Certificate Program: 2 Elective Units
Regulatory Affairs Certificate Program: 2 Elective Units

Instructors

Kathryn Wekselman, PhD, RN
Senior Director, Regulatory and Scientific Affairs
CTI Clinical Trial and Consulting Services

Elaine B. Taylor
Senior Director, Regulatory Strategy, Consulting and Submissions
INC Research

Understanding best practices is critical as you design a clinical program and regulatory strategy for a drug or biologic product. Identifying and obtaining the data actually needed for a product development program is key to the success of the program. Thinking ahead to the marketing application helps a sponsor avoid many of the common mistakes that are made in designing individual clinical trials and overall drug development programs. Even though it may be years before an NDA/BLA/MAA submission, the marketing application is the goal of each development program and should be kept in view throughout the program to avoid pitfalls and delays in submission and product approval.

This tutorial will cover common mistakes and solutions in the areas of drug development planning, clinical study design, statistical analysis planning, regulatory agency interactions, and regulatory document writing. Practic aladvice for each of these areas will be presented, with an emphasis on learning from past examples that illustrate approaches to adopt or to avoid.

Learning Objectives

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

- Identify ways to increase the efficiency and success of product development programs
- Describe key principles for successful regulatory interactions during drug development and marketing application preparation
- Discuss best practices in developing successful clinical trial designs, statistical analysis plans, and regulatory submission documents

Target Audience

This tutorial is designed for professionals with basic knowledge in regulatory affairs, agency submissions, and regulatory medical writing.

TUTORIAL 23 — Track 11

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

How to Prepare for an FDA Inspection

Continuing Education Credit: CME 3.25 *AMA PRA Category 1 Credits™;* IACET .3 CEUs; Nursing 3.25 contact hours
Clinical Research Certificate Program: 2 Elective Units
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Michael R. Hamrell, PhD
President
MORIAH Consultants

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

Learning Objectives

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

- Describe how to prepare for an FDA inspection
- Describe how to respond to an FDA inspection
- Examine audit findings including their impact on quality research
- Discuss possible outcomes of an FDA inspection

Target Audience

This tutorial is designed for QA and clinical staff in companies, pharmaceutical/biological companies that are involved in clinical trials and QA activities for clinical research.

TUTORIAL 24 — Tracks 1, 3 and 9

Related Interest Area(s): CmbP, MDD, RA

Pharmacogenomics and Companion Diagnostics: The Future of Clinical Trials, New Product Development and the Practice of Medicine

Continuing Education Credit: CME 3.25 *AMA PRA Category 1 Credits™*; IACET .3 CEUs; Pharmacy 3.25 contact hours or .325 CEUs (knowledge) 0286-0000-15-501-L04-P; Nursing 3.25 contact hours
Clinical Research Certificate Program: 2 Elective Units
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Michael Drues, PhD
Founder and President
Vascular Sciences

It is often not enough for pharmaceutical companies simply to bring a drug to market. Regulators and insurers are also encouraging companies to develop pharmacogenomic tools such as companion diagnostics to pinpoint which patients are most likely to benefit from a drug, thereby sparing other patients from needless side effects and expense. Pharmacogenomics represents a growing component of medical technology. This tutorial will discuss the way clinical trials are designed and conducted; how it will revolutionize new product development and how it will change the way we practice medicine. This technology can do so much more: pharmacogenomic technology is quickly evolving and the future will look much different than it does today. During this interactive tutorial, participants will be exposed to multiple examples of pharmacogenomic applications currently on the market, under development and on the drawing board.

Learning Objectives

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

- Identify how pharmacogenomic and companion diagnostic technologies are used today
- Discuss current regulatory requirements
- Discuss how to implement current regulatory requirements
- Identify how regulation will change as these emerging technologies evolve
- Describe how pharmacogenomics and companion diagnostics are impacting clinical trial design, new product development, and the practice of medicine

Target Audience

This tutorial is designed for professionals involved with combination products, companion diagnostics, personalized medicine, and pharmacogenomics.

TUTORIAL 25 — Tracks 01, 11

Related Interest Area(s) CP, CR, RD

Signal Detection - Identifying and Managing Safety Signals

Continuing Education Credit: CME 3.25 *AMA PRA Category 1 Credits™;* IACET .3 CEUs; Pharmacy 3.25 contact hours or .325 CEUs (knowledge) 0286-0000-15-506-L04-P; Nursing 3.25; contact hours
Clinical Research Certificate Program: 2 Elective Units
Clinical Safety and Pharmacovigilance Certificate Program: 2 Elective Units

Instructors

Joanna Haas, MD, MSc, FACP, FISPE
Founding Partner
Haas and Partners LLC

David Fram, BA
Vice President Research
Commonwealth Informatics, Inc.

Signal detection is an essential element of the overall risk management process. This tutorial provides a concise review of current methods of drug safety signal detection for marketed products and the role of signal detection within the larger signal and risk management process. Emphasis is on practical pragmatic approaches. Outputs from quantitative signal detection will be the basis for a hands-on exercise and discussion. The tutorial also provides participants with the context to evaluate new research in the field.

Learning Objectives

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

- Identify strengths and limitations of methods for signal detection
- Interpret outputs from automated quantitative signal detection methods (data mining results)
- Discuss how to integrate signal detection methods into the larger signal and risk management process
- Describe emerging methods for signal detection

Target Audience

This tutorial is designed for members of clinical safety and pharmacovigilance organizations who oversee, manage, or perform signal detection activities. The tutorial will also benefit participants who make risk management decisions based on signal detection results.

AFTERNOON TUTORIALS, HALF DAY

1:00–4:30 PM **FEE: $405**

TUTORIAL 30 — Tracks 08, 13

Related Interest Area(s): RA, PR

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

Continuing Education Credit: IACET .3 CEUs
Project Management Certificate Program: 2 Elective Units
Regulatory Affairs Certificate Program: 2 Elective Units

Instructors
Alberto Grignolo, PhD
Corporate Vice President
PAREXEL International

Yoshiaki Uyama, PhD
Director, Division of Epidemiology, Office of Safety I
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Significant changes in Japanese pharmaceutical regulations and procedures are impacting the development of new drugs in Japan as well as global development programs. This tutorial will describe the major drivers of the regulatory system, including the Pharmaceuticals and Medical Devices Agency (PMDA) and Ministry of Health, Labor and Welfare (MHLW), regulatory procedures during drug development (consultations with PMDA and clinical trial notifications), the integration of Japanese drug development with East Asian and global drug development, orphan drug regulation and J-NDA preparation and review. Several development strategies available to address Japanese requirements for new drug approval, as well as selected post-approval requirements, will be discussed.

Learning Objectives

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

- Explain the major elements of the Japanese regulatory system
- Describe the regulatory procedures during development, registration, and post-approval
- Discuss specific attributes of the Japanese regulatory system and their impact on local and global development strategies

Target Audience

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

TUTORIAL 31 — Tracks 01 and 08

Related Interest Area(s): RA, CR

Preparing for a US FDA Advisory Committee Meeting

Continuing Education Credit: IACET .3 CEUs
Clinical Research Certificate Program: 2 Elective Units
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Lisa Peluso
Communications Coach
PharmApprove

What are the critical factors when preparing for an FDA Advisory Committee meeting? Appearing before an FDA Advisory Committee can be one of the most challenging and grueling experiences for any drug, device, or biologic team. In just eight short hours with the FDA Advisory Committee, you not only must thoroughly explain but also defend, in detail, your product in a highly visible, high-stakes public meeting. This tutorial teaches best practices for preparing for an FDA Advisory Committee meeting.

What You Will Learn:

- What is an advisory committee?
- What does an advisory committee "look like"?
- Critical factors for advisory committee preparation
- How to design the most applicable preparation program for your team
- Top ten "best practices" and "must avoids"

Learning Objectives

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

- Identify the critical factors in preparing for a successful Advisory Committee meeting
- Recognize and evaluate those factors that are most applicable to your team
- Design the most effective preparation for your team(s)

Target Audience

This tutorial is designed for professionals in regulatory affairs, clinical research leads, and corporate executives.

TUTORIAL 32 — All Tracks

Related Interest Area(s): All

Influencing Culture, Avoiding Bureaucracy, and Encouraging Innovation

Continuing Education Credit: IACET .3 CEUs;
Project Management Certificate Program: 2 Elective Units

Instructor
Michael Laddin, MBA, MS
CEO
Leaderpoint

This tutorial is designed to help you understand what culture, bureaucracy and innovation really are, and the impact they can have on actual business results — in concrete, clear terms. This requires stripping away the vagueness and assumptions that so commonly surround these topics. The discussion will include three primary components: 1) Understanding and influencing workplace culture and its impact on the results people get while working. Culture can either disrupt people's ability to focus on the work, or it can reinforce and support clarity of focus, but culture is created by those working, not dictated by managers. 2) Avoiding and dealing with workplace bureaucracy, which almost always results from the creation of structure, a necessity as businesses and companies grow. Understanding and managing bureaucracy improves efficiency and economy. 3) Understanding and encouraging workplace innovation, and the direct benefits to efficiency and profitability that innovation brings about. Managers often attempt to drive innovation formally, but these efforts usually fail due to a lack of understanding what really encourages innovation at the work level — where it matters most.

Learning Objectives

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

- Define ways to create focus and direction for people in work groups or project teams
- Identify an applicable set of tools to understand, diagnose and correct dysfunctional culture, bureaucratic inefficiency, and inadequate innovation

Target Audience

This tutorial is designed for designed for managers interested in directly impacting these three areas, generating greater business results through the efforts of others. It is designed for new and experienced managers seeking to understand and address these issues with planned deliberation.

TUTORIAL 33 — Tracks 01, 03 and 08

Related Interest Area(s): RA, PR, OS

Large-Scale Regulatory Functional Outsourcing: Emerging Trends, Challenges, and Decision Criteria

Continuing Education Credit: IACET .3 CEUs
Regulatory Affairs Certificate Program: 2 Elective Units

Instructors
Rick Lilley, PhD
Senior Vice President, Global Regulatory Affairs
Vertex Pharmaceuticals, Inc.

Kimberly Christopher
Senior Director, Head Community and Alliance Management
UCB, Inc.

Paul A. Bridges, PhD, RPh
Corporate Vice President
PAREXEL International, United Kingdom

Katie Connelly
Vice President, Strategic Resourcing & Operations,
PAREXEL International

Thirty years ago, the practice of outsourcing clinical trials was modest and fledgling. Today, as a result of a dramatic evolution of both strategic thinking and operational implementation, clinical outsourcing is well-established and broadly accepted across the pharmaceutical industry and across the globe as a must-have component of clinical R&D. Regulatory tasks have also been outsourced to consultants and CROs during this period of time, not on a grand scale but rather on a transactional project-by-project basis that required deep and substantial scientific and regulatory expertise. On the other hand, regulatory affairs departments have been reluctant to "let go" of large swaths of regulatory work. Variations, supplements, annual reports, and regulatory maintenance tasks have been deemed too sensitive, mission-critical, delicate, or onerous to give out to others. This sentiment is now colliding with economic pressures and the costs of the internal infrastructure required to perform these tasks year after year for scores of countries. Sponsors are reexamining their thinking, in some cases releasing very significant portions of regulatory work to service providers, in others beginning to assess the benefit/cost of keeping all tasks "in-house." As this occurs, it is appropriate to assess the drivers of this change, to understand the opportunities and concerns associated with regulatory outsourcing on a large scale, and to examine the criteria which are or could be used to evaluate service providers prior to selecting them.

Learning Objectives

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

- Identify the new trends in RA outsourcing and product life cycle management
- Discuss ways to reduce internal regulatory infrastructure fixed costs while achieving regulatory milestones
- Identify the concerns of sponsors when considering significant regulatory outsourcing
- Describe the criteria used by sponsors to select/reject RA outsourcingservice providers

Target Audience

This tutorial is designed for those working in regulatory affairs, outsourcing and drug life cycle management.

TUTORIAL 34 **Tracks 09 and 14**

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

Preparation of Risk Evaluation and Mitigation Strategies Assessment Reports

Continuing Education Credit: CME 3.25 *AMA PRA Category 1 Credits™;* IACET .3 CEUs; Pharmacy 3.25 contact hours or .325 CEUs (knowledge) 0286-0000-15-502-L04-P; Nursing 3.25 contact hours
Clinical Research Certificate Program: 2 Elective Units
Clinical Safety and Pharmacovigilance Certificate Program: 2 Elective Units

Instructors

Catherine Sigler, DVM, MPH, PhD
Senior Director, Safety, Epidemiology, Registries and Risk Management
UBC: An Express Scripts Company

Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management
UBC: AN Express Scripts Company

Matthew A. Lee, PharmD
Director, Regulatory Affairs
Marathon Pharmaceuticals, LLC

Risk evaluation and mitigation strategies (REMS) vary from simple to complex. Particularly for the complex Elements to Assure Safe Use (ETASU) REMS, data in the form of a REMS assessment report may greatly challenge team members as many may be new to the process. Creation of a REMS assessment report requires a high-functioning, coordinated and cooperative team (whether done all in-house or including vendors). During this tutorial, participants will discuss, and learn by role playing, key functional areas — data management, project writing, medical writing, pharmacovigilance, drug safety, epidemiology, and regulatory affairs with an emphasis on providing a timely, high-quality deliverable. Time will be spent on refinement of the project plan, development of the table of contents, and how to coordinate disparate sections such as knowledge survey reports and adherence metrics. Discussion will also focus on topics such as the content of the REMS assessment as dictated by the REMS and REMS approval letter, determination of data cut-off dates, working with vendors, what to include in the report regarding survey design issues such as comprehension testing, special concerns for shared REMS, and FDA input and timing.

Learning Objectives

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

- Describe the key milestones needed to create a REMS assessment report
- Identify who and how to engage in the multidisciplinary team required to create the report
- Discuss the type of sections included in various types of REMS assessment reports

Target Audience

This tutorial is designed for professionals involved in clinical safety and pharmacovigilance.

TUTORIAL 35 Tracks 01, 08 and 11

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

Ethical Issues in Clinical Trials

Continuing Education Credit: CME 3.25 *AMA PRA Category 1 Credits™;* IACET .3 CEUs; Nursing 3.25 contact hours
Clinical Research Certificate Program: 2 Elective Units
Regulatory Affairs Certificate Program: 2 Elective Units

Instructor
Art Gertel, PhD
President & Principal Consultant
MedSciCom, LLC

This tutorial will provide an overview of the various ethical considerations associated with conducting clinical trials, including the history of ethical principles — Nuremburg 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.

Learning Objectives

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

- Discuss the foundations of ethics
- Explain how ethical decisions may be influenced by context and experience
- Discuss the viewpoint of the clinical study subject in educating clinical study site staff as to ethical considerations

Target Audience

This tutorial is designed for pharmaceutical company clinical operations staff; clinical trial site investigators and study coordinators; ethicists; regulators and regulatory affairs staff.

FULL DAY TUTORIALS

9:00 AM–5:00 PM **FEE: $705**

TUTORIAL 40 Tracks 14 and 15

Related Interest Area(s): ST, CR, CP, RA

Analysis of Safety Data from Clinical Trials

Continuing Education Credit: CME 6.5 *AMA PRA Category 1 Credits™;* IACET .7 CEUs; Pharmacy 6.5 contact hours or .65 CEUs (application) 0286-0000-15-503-L04-P; Nursing 6.5 contact hours
Clinical Research Certificate Program: 4 Elective Units
Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units
Project Management Certificate Program: 4 Elective Units

Instructors

Jürgen Kübler, PhD
Global Head
Quantitative Safety Sciences
CSL Behring GmbH, Germany

Joachim Vollmar
Executive Consultant
International Clinical Development Consultants LLC

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

Learning Objectives

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

- Discuss how to utilize guidelines and regulatory requirements for clinical trials
- Describe ways to contribute to safety analysis plans
- Discuss the statistical safety analysis process and pitfalls that could occur
- Identify impact of benefit-risk assessment in safety data

Target Audience

This tutorial is designed for regulatory affairs professionals, drug safety specialists, biostatisticians, medical writers, clinical researchers, project managers, and investigators.

TUTORIAL 41 Tracks 01, 03 and 11

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

Quality Oversight of CROs-Clinical Vendors

Continuing Education Credit: IACET .7 CEUs
Clinical Research Certificate Program: 4 Elective Units
Project Management Certificate Program: 4 Elective Units

Instructors

Jennifer J. Poulakos, PhD
Director, Development Quality Assurance
Agensys, Inc

Liz Wool, BSN, RN, CCRA, CMT
President and CEO
Q-D Quality and Training Solutions Inc.

Joan Versaggi, BS, MBA
Principal
QPM Solutions, LLC

FDA and EMA communicate at industry conferences, FDA-CTTI meetings, and regulatory agency public meetings. Sponsors and CRO-vendors who are transferred the responsibilities for trial conduct must have in place a vendor management-oversight program and methods, as well as a quality management system and risk management framework for the execution of clinical trials. Building upon this framework and benchmarking to ISO-9001: 2008, Quality Management Systems, this tutorial describes quality oversight of vendors, with the focus on quality management systems, risks associated with outsourcing and

approaches for early identification of risks to support adequate oversight, quality attributes, and performance monitoring.

Learning Objectives

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

- Discuss quality management systems principles and methods, and the criticality for early risk identification with a CRO clinical vendor in order to execute adequate vendor oversight
- Identify two key elements of an internal communication plan for vendor oversight that supports both business and team successes
- Identify two metrics for utilization when outsourcing a clinical trial to a vendor

Target Audience

This tutorial is designed for professionals involved in clinical research, clinical operations, outsourcing, regulatory affairs, quality compliance, project management and commercial-medical affairs. Sponsors, CROs, ACROs, AROs, as well as personnel from the NIH, DoD, and VA will also find this tutorial valuable.

TUTORIAL 42 Track 8

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

Fundamentals of ANDA Submissions and FDA Expectations Under GDUFA

Continuing Education Credit: CME 6.5 *AMA PRA Category 1 Credits™;* IACET .7 CEUs; Nursing 6.5 contact hours
Clinical Research Certificate Program: 4 Elective Units
Project Management Certificate Program: 4 Elective Units
Regulatory Affairs Certificate Program: 4 Elective Units

Instructor
Carol H. Danielson, DrPh, MS, RAC
President
Regulatory Advantage, LLC

There have been significant changes in FDA expectations of Abbreviated New Drug Applications (ANDAs) since the passage of the Generic Drug User Fee Act (GDUFA) in 2012. In this tutorial participants will learn about FDA regulations and expectations for the content, submission, and review of ANDAs and the importance of regulatory strategy in the age of GDUFA. The ANDA format and technical submission requirements, FDA expectations, fees, timelines under GDUFA, and the nuances of ANDA strategy for the regulatory professional including patent certification, and exclusivity periods will be discussed. The tutorial will also focus on suitability petitions and the 505 (b)(2) NDA as a strategy option. Course Level: Beginner/Intermediate

What you will Learn

- Fundamentals of the Abbreviated New Drug Application (ANDA)
- Preparation
- Content
- Strategy
- Submission expectations and content under GDUFA
- Chemistry, manufacturing and controls
- Bioequivalence
- Drug master files
- Fees and FDA review timelines under GDUFA
- Overview of therapeutic ratings, patent certification, 180-day exclusivity
- What is a suitability petition and when to submit one
- When does a “generic-like” drug become a 505 (b)(2) NDA

Learning Objectives

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

- Explain the importance of regulatory strategy for an ANDA
- Recognize content and format requirements for ANDAs
- Discuss patent certifications, exclusivity, and therapeutic ratings
- State ANDA review timelines and FDA expectations under GDUFA
- Discuss suitability petitions and when to submit
- Recognize when an application requires a 505 (b)(2)

Target Audience

This tutorial is designed for regulatory affairs professionals new to the ANDA, professionals in quality assurance, quality control, or manufacturing, and project managers.

TUTORIAL 43 — Tracks 01 and 15

Related Interest Area(s): CR, ST, MC/MW

Clinical Statistics for Nonstatisticians

Continuing Education Credit: CME 6.5 *AMA PRA Category 1 Credits™;* IACET .7 CEUs; Pharmacy 6.5 contact hours or .65 CEUs (knowledge) 0286-0000-15-504-L04-P; Nursing 6.5 contact hours
Clinical Research Certificate Program: 4 Core Units

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

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

Learning Objectives

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

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

Target Audience

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

TUTORIAL 44 — Tracks 08 and 14

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

Risk Management and Safety Communication Strategies

Continuing Education Credit: CME 6.5 *AMA PRA Category 1 Credits™;* IACET .7 CEUs; Pharmacy 6.5 contact hours or .65 CEUs (knowledge) 0286-0000-15-505-L04-P; Nursing 6.5 contact hours
Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units
Regulatory Affairs Certificate Program: 4 Elective Units

Instructor
Nancy D. Smith, PhD
Adjunct Professor
Temple University, FDA Alumni

Risk Communication is increasingly important to everyone involved in our health care system, especially the patients whose lives we strive to improve. This tutorial will look at current initiatives and new strategies to advance the safe use of drugs. The current status and future of Risk Evaluation and Mitigation Strategies (REMS) in the US will be discussed, and compared with Risk Management Plans in Europe and Japan.

What You Will Learn:

- Current state of risk communication in the United States
- New strategies to improve understanding of drug safety concerns among health care providers and to promote better communication to patients
- The development of Risk Evaluation and Mitigation Strategies (REMS) in the US
- How US REMS with Risk Management Plans compare with those of Europe and Japan
- The importance of good communication during a crisis situation

Learning Objectives

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

- Describe current risk communication strategies
- Discuss the development of REMS in the US
- Explain new methods to improve the proper use of medicines to maximize patient benefit and minimize risk
- Discuss the future of drug safety and risk communication especially during a crisis situation

Target Audience

This tutorial is designed for professionals who work in clinical safety and pharmacovigilance, regulatory affairs, medical writing, and marketing and communications.

TUTORIAL 45 **Tracks 14, 07 and 08**

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

The Good Pharmacovigiliance Practices in the EU: Global Applications

Continuing Education Credit: CME 6.5 *AMA PRA Category 1 Credits™;* IACET .7 CEUs; Nursing 6.5 contact hours
Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units
Regulatory Affairs Certificate Program: 4 Elective Units

Instructors

Representative Invited
Monitoring and Incident Management
Pharmacovigilance Department
European Medicines Agency (EMA), European Union

Saad A.W. Shakir, MD, FFPM, FISPE, FRCP
Director
Drug Safety Research Unit
United Kingdom

Steve Jolley, MA
CEO
SJ Pharma Consulting, LLC

The objective of this tutorial is to provide a platform, which allows us to address frequently asked questions and recent updates/ developments in relation to the EU guidelines on good pharmacovigilance practices taking into account their global application and focusing on the following interest areas:

- Overview of the latest developments in the area of pharmacovigilance in the EU including related IT systems
- Management and reporting of adverse reactions and signal management
- Updates of GVP Module VI
- The new EU E2B(R3) ICSR Implementation Guide
- New process for marketing authorization holders regarding the monitoring of medical literature and entry of relevant information into the EudraVigilance database by the EMA
- Updates to the EudraVigilance Access Policy

Learning Objectives

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

- Describe recent developments on EU Good Pharmacovigilance Practices guidance
- Examine principles for new literature monitoring and the revised EudraVigilance Access Policy
- Discuss FAQs in signal management
- Identify important aspects in preparing risk management plans and conducting post-authorization safety studies
- Describe key principles for pharmacovigilance audits and inspections

Target Audience

This tutorial is designed for professionals who work in the following areas: clinical safety and pharmacovigilance, regulatory affairs, risk management, and quality & compliance.

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- Drug Safety Regulatory Requirements
- Premarketing Clinical Trial Safety
- Postmarketing Safety Management
- Basics of Signal Detection and Pharmacoepidemiology
- Safety Audits and Inspections

MEETING SCHEDULE BY DAY AND TIME

DIA 2015 51ST ANNUAL MEETING TRACKS AND INTEREST AREAS

Track #	Track Title	Interest Area
Track 01	Clinical Operations	Academic Health Centers/Investigative Sites (AHC/IS), Clinical Research (CR), Clinical Supplies (CS), Manufacturing (MF), Research and Development (RD)
Track 02	Project/Portfolio Management and Strategic Planning	Financing (FI), Project Management (PM), Strategic Planning (SP)
Track 03	Innovative Partnering Models and Outsourcing Strategies	Outsourcing (OS)
Track 04	Preclinical and Translational Development/ Early Phase Clinical Development	Biotechnology (BT), Nonclinical (NC), Pharmacology (PC)
Track 05	Regulation of Product Advertising and Marketing in an Ever-changing World	Advertising and Promotion (AP), Marketing (MA)
Track 06	Medical Communication/Medical Writing and Medical Science Liaisons	Medical Communications (MC), Medical Science Liaisons (MSL), Medical Writing (MW)
Track 07	Technology/Data/Records and Submissions	Information Technology (IT), eClinical (EC), Clinical Data Management (CDM), Document Management (DM),Study EndPoints/Clinical Outcomes Assessment (SE), Submissions (SUBS),Validation (VA)
Track 08	Regulatory Affairs	Regulatory Affairs (RA)
Track 09	Medical Devices/In Vitro Diagnostics, and Combination Products	Combination Products (CmbP), Medical Devices and Diagnostics (MDD)
Track 10	Public Policy/Health Care Compliance/Law	Public Policy, Health Care Compliance/Law (PPLC)
Track 11	Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice	Good Clinical Practice (GCP), Quality Assurance, Quality Control (QA/QC)
Track 12	Pharmaceutical Quality	Chemistry, Manufacturing and Controls/Good Manufacturing Practices (CMC/GMP)
Track 13	Comparative Effectiveness Research/Global Health Outcomes and Economics	Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine (CEHTAEbM), Pricing and Reimbursement (PR)
Track 14	Clinical Safety and Pharmacovigilance	Clinical Safety and Pharmacovigilance (CP)
Track 15	Statistical Science and Quantitative Thinking	Statistical Science (ST)
Track 16	Professional Development	Professional Education, Training, and Development (PETD)
Track 17	Rare/Orphan Diseases	Rare/Orphan Diseases (ROD), Patient Engagement (PT)
Track 18	Global Regulatory	ALL
Track 19	Late-breaking Topics	ALL
Track 20	Innovation Theater	ALL

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CONTENT LEVEL GUIDE

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

- ● **Basic 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 an in-depth knowledge of the topic/subject area.

DIFFERENT FORMAT FOR DIFFERENT LEARNERS

FORUM
A 60-minute (called TURBO Offering) or 90-minute blended presentation and panel discussion.

SESSION
A 60-minute (called TURBO Offering) or 90-minute presentation delivered lecture-style from the podium.

SYMPOSIUM
A blend of three 20-minute presentations.

WORKSHOP
A 90-minute conceptual presentation delivered in an interactive/simulation or role playing format.

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
MONDAY, JUNE 15 8:30–10:00 AM				
Track 01A	Patient-Centricity: Buzzword or Method to Improve Operational Efficiency? ▲ **TURBO offering ends 9:30 AM**	SESSION	LEVEL: ■	PT, FI
Track 01B	Next Generation Feasibility: How to Predict the Unpredictable and Plan for Success	SYMPOSIUM	LEVEL: ■	CR, RD
Track 02	Project Management of Adaptive Trials: Infrastructure and Methodology	FORUM	LEVEL: ■	PM, CR
Track 03	Adventures in Strategic Planning: Is the Functional Service Provider Model Dead? ▲ **TURBO offering ends 9:30 AM**	FORUM	LEVEL: ■	SP
Track 04	In Vitro and In Vivo Preclinical Testing of Biosimilars: What Have We Learned?	SESSION	LEVEL: ■	NC, RA
Track 06	Communicating Pharmaceutical Risks and Benefits: Why Is It So Hard and How Can We Do Better?	FORUM	LEVEL: ■	MC
Track 07A	How Pharmaceutical Companies and CROs Are Harnessing Big Data and Cloud Computing to Increase R&D Innovation, Efficiency, and Collaboration	SESSION	LEVEL: ■	EC, IT, RD
Track 07B	How Sponsors Are Solving the Unique Data Collection Challenges of Late-Stage Studies	SESSION	LEVEL: ■	EC, IT
Track 08	Forward Progress Through Collaboration: Internal and External to the FDA	FORUM	LEVEL: ■	CR
Track 09	Enabling Next Generation Sequencing within Global Clinical Trials	SESSION	LEVEL: ■	MDD, CR, RA
Track 10	The Growing Role of the Patient Leading Into PDUFA VI: Negotiations and 2016	FORUM	LEVEL: ■	RA, PT

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 11	Clinical Quality Management Systems in the New Millennium	SESSION	LEVEL: ■	CR
Track 12	Comprehensive Control Strategy: Building Confidence in Quality	FORUM	LEVEL: ■	CMC/GMP
Track 14	Risk Management Plans Ten Years On: Where are We Now and Where Are We Going?	SESSION	LEVEL: ■	RA
Track 16	DIA 2015 Student Forum: Job Hunter's Toolkit — Some Things Change, Some Stay the Same	FORUM	LEVEL: ■	PETD
Track 18	An Update From Health Canada	FORUM	LEVEL: ■	RA, CR
Track 19A	The Emerging Role of Medical Affairs in Biopharmaceutical Organizations: Challenges and Opportunities	FORUM	LEVEL: ■	SP
Track 19B	Ebola Virus Disease Case Study: Global Harmonization to Increase Power and Accelerate Outcomes in Clinical Research Data	FORUM	LEVEL: ●	CR
MONDAY, JUNE 15 11:00 AM–12:30 PM				
Track 01A	Pediatric Clinical Trials: Learning from Patients, Parents, and Investigative Sites	SESSION	LEVEL: ●	CR, AHC/IS
Track 01B	The Clinical Trials Transformation Initiative Data Monitoring Committee Project: Findings and Next Steps	SESSION	LEVEL: ●	CR, PM
Track 02A	Codevelopment of a Drug in the Pharmaceutical Industry: Is It Ever Fun?	FORUM	LEVEL: ■	SP, RD
Track 02B	How to Achieve Value of Operational Transformation: It Requires Innovation, Process Excellence, and Adoption	WORKSHOP	LEVEL: ◆	CR, PETD
Track 03	What Contract Research Organizations Value in a Partner: Results of a Perception Survey ▲ **TURBO offering ends 12:00 PM**	SESSION	LEVEL: ●	CR, RD
Track 04	Next Generation Nanomedicines and Nanosimilars: Regulators' Perspective ▲ **TURBO offering ends 12:00 PM**	SESSION	LEVEL: ■	BT, RA
Track 06	Engaging Patients and Health Care Professionals Through Social Media and Big Data Systems	SYMPOSIUM	LEVEL: ■	MC, PETD, RA
Track 07A	Integrating Patient Engagement with EHR Data and eSource for Better Studies ▲ **TURBO offering ends 12:00 PM**	SESSION	LEVEL: ■	EC, PT
Track 07B	Evolving Your Regulatory Information Management Strategy to Meet the Changing Business Environment ▲ **TURBO offering ends 12:00 PM**	SESSION	LEVEL: ■	SUBS, RA
Track 08	Global Drug Development in China: Opportunities and Challenges for Innovation	FORUM	LEVEL: ●	CR, RD

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Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 10	New Pandemics: Lessons Learned from the Ebola Regulatory Experience — How Will We Be More Nimble Next Time?	FORUM	LEVEL: ■	RA
Track 11	Clinical Quality by Design: From Theory to Practice	SESSION	LEVEL: ■	CR
Track 12	Reducing Drug Shortages	SESSION	LEVEL: ■	RA
Track 14	REMS Integration into the Health Care System: Three Perspectives in an Evolving Environment	FORUM	LEVEL: ■	RA
Track 15	Statistical Evaluation of Therapeutic Equivalence for Locally-Acting Generic Products	SESSION	LEVEL: ■	ST
Track 16	The What, Why and How of Coaching and Its Application in the Work Place	WORKSHOP	LEVEL: ●	PETD
Track 17	Facilitating Rare Disease Patient Participation in Clinical Trials	SYMPOSIUM	LEVEL: ●	CR, PETD
Track 18	International Regulatory Convergence: Collaboration, Cooperation and Global Governance	FORUM	LEVEL: ●	RA

MONDAY, JUNE 15 2:30–4:00 PM

Plenary Session & Keynote Address — FORUM — ALL

Welcome Remarks

Per Spindler, DVM, MBA, MSc
Director Biopeople, University of Copenhagen, Denmark; DIA President and Chair, Board of Directors

Michael Rosenblatt, MD
2015 Program Chair; Executive Vice President and Chief Medical Officer Merck & Co., Inc.

Keynote Address

To be Announced!

TUESDAY, JUNE 16 8:00–9:30 AM

Track 01A	The Development of Patient Power: From Consumer to Active Participant!	SESSION	LEVEL: ●	PT
Track 01B	The Role of Innovation in Clinical Trial Advocacy: Developing and Executing Patient-Centered Strategies and Partnerships Throughout the Continuum	FORUM	LEVEL: ■	CR, PT
Track 02	The Art and Science of Portfolio Management	FORUM	LEVEL: ■	PM
Track 03A	Centralized Ethics: How a Unique Partnership Between a CRO and an IRB Is Changing the Regulatory and Ethics Review Process ▲ **TURBO offering ends 9:00 AM**	SESSION	LEVEL: ■	RA, PM

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 03B	A Biopharmaceutical Company/Services Provider Partnership: Value to Both Companies and Progress to Date ▲ **TURBO offering ends 9:00 AM**	SESSION	LEVEL: ■	OS, CR
Track 04	Regulatory Examination of Nonclinical Testing Requirements and Juvenile Animal Studies	SYMPOSIUM	LEVEL: ■	NC, RA
Track 05	Prescription Drug Marketing Regulatory Primer	WORKSHOP	LEVEL: ●	RA
Track 06	New Approaches to Submission Components	SYMPOSIUM	LEVEL: ■	MW, CR
Track 07A	Implementing Risk-Based Monitoring	SYMPOSIUM	LEVEL: ■	CDM, CR
Track 07B	International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP): Will Your Company Be Ready by 2016?	SESSION	LEVEL: ■	CDM, IT
Track 08A	Can We Talk? Alternative Strategies for Communicating with FDA	SESSION	LEVEL: ■	CR, PETD
Track 08B	Global Regulation of Advanced Therapies	SESSION	LEVEL: ■	CR
Track 10	Pediatric Therapeutic Development: From Policy to Portfolios to Patients	FORUM	LEVEL: ■	RA
Track 11	FDA GCP Compliance and Enforcement Updates	SESSION	LEVEL: ■	EC, CR, RA
Track 12	Learning By Doing: Regulatory Applications for Breakthrough Therapies ▲ **TURBO offering ends 9:00 AM**	SESSION	LEVEL: ■	CMC/GMP
Track 13A	Remember That? Choosing Recall Intervals for Patient-Reported Outcome Measures	SESSION	LEVEL: ■	SE, RA
Track 13B	Emerging Practices in Product Commercialization Planning: How Cross Collaboration Is Redefining Product Development Planning	SYMPOSIUM	LEVEL: ■	PR
Track 14A	Social Media: Opportunities and Challenges in Pharmacovigilance and Clinical Research	SESSION	LEVEL: ■	CR
Track 14B	Safety in Special Situations: Vaccines, Stem Cells and Beyond	SESSION	LEVEL: ■	BT, CmbP
Track 15	New Challenges for a Data Monitoring Committee	SESSION	LEVEL: ■	CR, ST
Track 16	Moving the Role of the CRC and CRA into the 21st Century: Opportunities and Challenges ▲ **TURBO offering ends 9:00 AM**	SESSION	LEVEL: ■	CR, PETD
Track 17	How to Succeed in Orphan Drug Regulatory Affairs ▲ **TURBO offering ends 9:00 AM**	SESSION	LEVEL: ■	RA
Track 18	PMDA Town Hall	FORUM	LEVEL: ■	RA, CP

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Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
TUESDAY, JUNE 16 10:30 AM–12:00 PM				
Track 01	How Pharmaceutical Companies Can Engage Responsibly with Patients Online	FORUM	LEVEL: ■	PT
Track 02A	Better Team Performance in Drug Development: Effective Relationship Building Across Cultures, Especially the West and Asia	FORUM	LEVEL: ●	PETD
Track 02B	Recent Trends in Facilitating Decision Making in Drug Development	FORUM	LEVEL: ◆	RD, PM
Track 03	Taking the Pulse of Outsourcing Relationship Structures and Their Impact ▲ **TURBO offering ends 11:30 AM**	SESSION	LEVEL: ■	OS, CS
Track 04	Navigating Complex Biological and Regulatory Pathways to Bring Novel Gene and Cell Therapies to the Clinic	SESSION	LEVEL: ■	NC, RA
Track 05	FDA Enforcement Update: Advertising and Promotion	FORUM	LEVEL: ■	RA
Track 06	Efficient Authoring of Submission Documents ▲ **TURBO offering ends 11:30 AM**	SYMPOSIUM	LEVEL: ●	MW
Track 07A	FDA Study Data Technical Conformance Guide (Part 1 of 2): An Overview	SESSION	LEVEL: ■	CDM, RA
Track 07B	How to Trust Data from Wearable Devices Used in Clinical Trials	SESSION	LEVEL: ●	VA, CR, MDD
Track 08A	Good Regulatory Practice (GRP): A Regulatory Affairs Quality System for the 21st Century	SESSION	LEVEL: ■	OS, CR
Track 08B	The State of Pediatric Research in the United States	SESSION	LEVEL: ■	CR
Track 09	Impact of FDA Oversight of Laboratory-Developed Tests Upon Innovation in the Targeted Therapy Setting	FORUM	LEVEL: ■	RA, MDD
Track 11	Risk-Based Quality Management in Clinical Trials: From the Vision to Its Regulation and Implementation	SESSION	LEVEL: ■	CR, RA
Track 12	Office of Pharmaceutical Quality Update	FORUM	LEVEL: ■	RA
Track 13	Breakthrough Medicines or Affordable Health Care: Do We Have to Choose?	FORUM	LEVEL: ■	RD, PR, CR
Track 14	21st Century Pharmacovigilance: Improving Outcome Traceability for Products Across the Complexity Continuum, From Generics to Biologics and Vaccines	FORUM	LEVEL: ■	PETD
Track 15	The Impact of Adaptive and Bayesian Approaches to Improving the Efficiency of Clinical Trial Design and Analysis	FORUM	LEVEL: ●	CR
Track 16	Networking: It's Not What You Know, But Who You Know!	WORKSHOP	LEVEL: ●	PETD

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 17	Rare Disease Organizations and Industry Players: Collaborating Effectively to Advance R&D for Rare Disease Patients	SESSION	LEVEL: ■	RD, CR
Track 18	FDA's International Posts: International Efforts, Regulatory System Strengthening and Inspections	FORUM	LEVEL: ■	RA, CR
Track 19A	Using Registries to Support Recruitment in Alzheimer's Disease (AD) Prevention or Delay-of-Onset Studies	SESSION	LEVEL: ●	CR
Track 19B	Regulation of Combination Products in the 21st Century	FORUM	LEVEL: ■	CmbP
TUESDAY, JUNE 16 1:00–1:30 PM				
Track 20	Veeva Innovation Theater: 2015 Paperless Trial Master File (TMF) Survey: Trends and Insights	SPECIAL SESSION	LEVEL: ■	IT, MW, SUBS
TUESDAY, JUNE 16 1:30–3:30 PM				
Track 01A	Engaging Patients as Partners: Effective Trial Communications to Build Trust and Improve Patient Participation	FORUM	LEVEL: ●	PT, MC
Track 01B	Implementing Risk-Based Monitoring: Best Practices from Pharmaceutical Industries to Contract Research Organizations	SESSION	LEVEL: ■	CR
Track 02	Life Cycle and Portfolio Management: Regulatory Agency and Pharmaceutical Company Approaches	SESSION	LEVEL: ●	PM, CP
Track 03	Collaborate to Innovate: Exploring a Seconds Market ▲ **TURBO offering ends 2:30 PM**	SESSION	LEVEL: ■	RD
Track 05	Essential Approaches to Promotional Review of Mobile Health Apps: Technology That is Here to Stay and Evolving Fast	SESSION	LEVEL: ■	IT, MA, AP
Track 06	Tool is a Good Four-Letter Word	SYMPOSIUM	LEVEL: ■	MW, IT, SUBS
Track 07A	Developing Online Communities: Perspectives for Site and Patient Engagement ▲ **TURBO offering ends 2:30 PM**	SYMPOSIUM	LEVEL: ■	EC, PT
Track 07B	FDA Study Data Technical Conformance Guide (Part 2 of 2): An Interactive Q&A Session	FORUM	LEVEL: ■	CDM, SUBS
Track 08	Transatlantic Collaboration on Pediatric Study Plan (PIP)/Pediatric Investigation Plan (PSP): Recent Experience	SESSION	LEVEL: ■	RA, SUBS
Track 09	Success from Bench to Launch: Challenges and Opportunities with Development of Companion Diagnostics	SESSION	LEVEL: ■	MDD

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Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 10	The Challenges and Opportunities of Digital Health Care: What Does the Future Hold?	FORUM	LEVEL: ■	MDD
Track 11	Roadmap to Measuring Clinical Trial Quality	SESSION	LEVEL: ■	CR
Track 12	Continuous Improvement and Innovation ▲ **TURBO offering ends 2:30 PM**	FORUM	LEVEL: ■	MF, CM
TUESDAY, JUNE 16 3:30–5:00 PM				
Track 01A	Bringing Clinical Trial Practices into the 21st Century	SYMPOSIUM	LEVEL: ■	CR
Track 01B	Pediatric Clinical Trials: One Size Does Not Fit All	SESSION	LEVEL: ●	CR, PM
Track 02A	A Critical Examination of the Strengths and Weaknesses of Different Project Management Models	FORUM	LEVEL: ◆	PM, PETD
Track 02B	How Biomarkers Can Be Leveraged to Improve Return on Investment in Drug Development	FORUM	LEVEL: ◆	CR, MDD
Track 03A	Incorporating a VAT Tax Strategy Into Your Global Investigator Payment Plan ▲ **TURBO offering ends 4:30 PM**	FORUM	LEVEL: ■	FI, CR
Track 03B	Getting More Out of Outsourcing Agreements: Value Additions Through Synergies and Process Optimization ▲ **TURBO offering ends 4:30 PM**	SESSION	LEVEL: ■	PM
Track 04	Striking a Balance Between Ethical Treatment and Impact on Nonclinical Safety and Animal Rule Efficacy Study Interpretation When Using Prophylactic or Supportive Care	SESSION	LEVEL: ■	NC, RA
Track 05	The Free Exchange of Truthful and Non-Misleading Medical Information	FORUM	LEVEL: ■	MC, RA, PPLC
Track 06	Leadership and Process in Medical Writing	SYMPOSIUM	LEVEL: ■	MW, PETD
Track 07A	How Risk-Based Monitoring and eSource Methodologies are Impacting Clinical Sites, Patients, Regulators and Sponsors	SYMPOSIUM	LEVEL: ■	EC, CR, RA
Track 07B	Data and Evaluation Needed for Robust Evidence: Regulators' Challenges	SESSION	LEVEL: ■	CDM, RA
Track 08A	Getting the Most Out of Scientific Advice in the US and EU	SESSION	LEVEL: ■	CR
Track 08B	Optimizing Patient Labeling: A Panel Discussion Between Industry, Academia, and Prescribers	FORUM	LEVEL: ■	PT, MC, AP
Track 09	Continuing Growth in Combination Products: More Products, More Questions — Perspectives from FDA and Industry	SESSION	LEVEL: ■	CmbP, RA, PPLCC
Track 10	Progress Report on Emerging Nations and Regulatory Capacity Building	SESSION	LEVEL: ■	RA

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 11	Managing Protocol Deviations: Applying the Protocol Deviations Working Group SOP for Handling Protocol Deviations in Clinical Trials	WORKSHOP	LEVEL: ■	GCP, CR
Track 12	Risk-Based Regulatory Review	SESSION	LEVEL: ■	QC, CMC/ GMP
Track 13	Innovative Approaches to Patient Registries for Evaluating Outcomes	FORUM	LEVEL: ■	SE, IT, CR
Track 14A	Translating New Knowledge from Regulatory Science into Postmarketing Safety Practice	FORUM	LEVEL: ■	RA
Track 14B	Has the New Format PSUR/PBRER Achieved What Was Originally Intended?	SESSION	LEVEL: ■	RA
Track 15	Predictive Subgroup Methodologies and Molecular Basket Designs	SESSION	LEVEL: ■	CR
Track 16	Conflict Resolution: Helping Teams Manage Through Conflict	WORKSHOP	LEVEL: ●	PETD
Track 17	Pediatric Drug Development ▲ **TURBO offering ends 4:30 PM**	SESSION	LEVEL: ■	CR, RA
Track 18	CDRH Town Hall	FORUM	LEVEL: ■	MDD, CmbP
Track 19	European Medicines Agency Scientific Guidance on Postauthorization Efficacy Studies	SESSION	LEVEL: ●	RD

WEDNESDAY, JUNE 17 8:00–9:30 AM

Track 01A	Leveraging Diverse Patient Insights	SYMPOSIUM	LEVEL: ■	PT, CR
Track 01B	Patient Registries: Design, Development, and Recruitment	WORKSHOP	LEVEL: ●	PT, CR
Track 02	Keys to Managing a Successful Regulatory Strategy and Submission	FORUM	LEVEL: ■	RA, SUBS
Track 03A	How to Make a Strategic Partnership Model Work at the Country/Site Level in Asia Pacific and Insight from a Regulatory Inspector ▲ **TURBO offering ends 9:00 AM**	SESSION	LEVEL: ■	CR, SP
Track 03B	Transforming Industry Through Centralization of Key Business Practices: A Focus on Prequalification of Niche Suppliers	FORUM	LEVEL: ■	OS, IT
Track 04	Innovative Approaches to Predictive Clinical Safety and Signal Detection Utilizing Clinical Pharmacology Concepts	SESSION	LEVEL: ■	PC, CP
Track 06	Returning Results to Study Participants: Health Literacy and Effective Language	SESSION	LEVEL: ■	MC, RA
Track 07A	CDISC SHARE Repository: Laying the Tracks and Building the Stations for this New Metadata Train ▲ **TURBO offering ends 9:00 AM**	SESSION	LEVEL: ■	CDM

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 07B	Mapping the Future for Trial Master File	SESSION	LEVEL: ■	DM, CR
Track 08A	Recent Experiences with Adaptive Licensing and Facilitated Regulatory Pathways	FORUM	LEVEL: ■	CR
Track 08B	Update: FDA's CDER Progress to Adapting Standardized Data to Select Clinical Sites for Inspection ▲ **TURBO offering ends 9:00 AM**	SESSION	LEVEL: ■	SUBS, CR
Track 10	21st Century Cures: Which Are the Most Transformative Provisions and How Do They Accomplish Major Change?	FORUM	LEVEL: ■	RA
Track 11	Changes in Regulations That May Impact How Inspections are Conducted: Regulatory Perspectives	SESSION	LEVEL: ■	RA
Track 12	Challenges in Managing Global Regulatory Divergence	FORUM	LEVEL: ■	CMC/GMP, RA
Track 13	Real-World Use of Multi-Criteria Decision Analysis for Benefit-Risk Assessment: Examples and Lessons Learned in the Industrial Setting	SESSION	LEVEL: ■	CEHTAEbM
Track 14	Pharmacovigilance Concerns with the Use of Experimental Medicines for Ebola and Enterovirus B-68	SESSION	LEVEL: ■	RA, CR
Track 15	Benefit-Risk Assessment of Medicines: Three Perspectives on Current Methodologies and the Statistician's Role in Implementation	SESSION	LEVEL: ●	ST
Track 17	Rare Diseases and Subgroups Defined by Tumor Evolution: Common Themes and Challenges	SESSION	LEVEL: ■	CR, BT
Track 19	The Impact of the eLabeling Rule on Industry and Stakeholders	FORUM	LEVEL: ■	RA
WEDNESDAY, JUNE 17 9:45–10:15 AM				
Track 20	SAS Institute Inc., JMP Division Innovation Theater: Benefit and Risk Signal Detection in Clinical Trials	SPECIAL SESSION	LEVEL: ■	CP, CR
WEDNESDAY, JUNE 17 10:30–12:00 PM				
Track 01A	Direct-to-Patient Strategies That Are Changing the Landscape of Clinical Trials	WORKSHOP	LEVEL: ■	CR
Track 01B	Putting It All Together: A Shared, Comprehensive, Integrated Global System for Clinical Research	FORUM	LEVEL: ◆	CR, PM
Track 02A	Incremental Innovation: How to Strategically and Practically Move Innovative Ideas into Action Within Your Company and Research Programs ▲ **TURBO offering ends 11:30 AM**	SESSION	LEVEL: ■	SP, CR, RD
Track 02B	Best Practices for Successfully Managing Clinical and Pharmaceutical Projects ▲ **TURBO offering ends 11:30 AM**	SESSION	LEVEL: ■	FI, CR

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 03	Emerging and Mid-Sized Biopharmaceutical Companies Building Successful CRO Relationships: Overcoming the Challenges by Applying Alliance Management Principles and Technology	SESSION	LEVEL: ◆	CR, IT
Track 04	Implications of Clinical Test Result and ECG Variability on the Design, Conduct, and Interpretation of Early Phase Clinical Studies	SESSION	LEVEL: ■	PC, CR
Track 06	How Collective Insights of Medical Affairs Customer-Facing Teams Work to Inform Strategy	SESSION	LEVEL: ■	MC
Track 07A	Electronic Standardized Data in Regulatory Submissions	SESSION	LEVEL: ■	CDM, SUBS
Track 07B	Digitization of Clinical Trials: Check the Pulse on Bringing Benefits to Patients	SYMPOSIUM	LEVEL: ■	EC, PT, IT
Track 08A	Medicine Development and Authorization: A Patient-Centered Approach	SESSION	LEVEL: ■	PT
Track 08B	Opening the Door to Data Transparency: What's the Verdict?	SESSION	LEVEL: ■	PT, CR
Track 09	The Role of Labeling in Successful Human Factors Studies	FORUM	LEVEL: ■	RA, PT
Track 10	Precision Medicine: Where Is the Technology Taking Us, How Fast and Who Is Driving?	FORUM	LEVEL: ■	RA, CR
Track 11	Good Clinical Practice and Pharmacovigilance Issue Management and CAPA Effectiveness	SESSION	LEVEL: ■	CP
Track 12	How Can International Guidances Enable Global Regulatory Convergence?	SESSION	LEVEL: ■	RA, QC
Track 13A	FDA Sentinel Initiative	SESSION	LEVEL: ■	CEHTAEbM
Track 13B	Best Evidence Generation: Regulatory Perspectives ▲ **TURBO offering ends 11:30 AM**	SESSION	LEVEL: ■	RA
Track 14A	Integrated Cardiac Safety	SESSION	LEVEL: ■	CR
Track 14B	Pharmacovigilance Inspections: Achieving Compliance in a Global Environment	SESSION	LEVEL: ■	RA
Track 15	The Role of the Clinical Statistician in Understanding and Using ADaM Data Standards	FORUM	LEVEL: ■	CR, ST
Track 16A	Conducting Courageous Conversations as a Strategy to Work with Difficult People	WORKSHOP	LEVEL: ■	PETD
Track 16B	DEVELOP Excellent Presentations to INNOVATE the Way You Communicate Information and ADVANCE Your Career	WORKSHOP	LEVEL: ■	CR, RA, PETD
Track 17	Orphan Drug Development Challenges: Case Studies	SYMPOSIUM	LEVEL: ■	CR

The content noted on this page was made available to DIA as of January 28.

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
WEDNESDAY, JUNE 17 12:00–12:30 PM				
Track 20	SAS Innovation Theater: Accelerate Value-Based Drug Development With Analytics	SPECIAL SESSION	LEVEL: ■	IT, RD
WEDNESDAY, JUNE 17 1:30–3:00 PM				
Track 01A	Cardiac Safety Considerations in Pediatric Drug Development	SESSION	LEVEL: ■	CR, CP
Track 01B	Is Facebook Hurting Your Trial? Social Media and the Introduction of Bias in Clinical Studies	SESSION	LEVEL: ■	CR
Track 02A	Project Management in Context: Reflections on the Project Manager Role from Other High-Risk Industries	SESSION	LEVEL: ■	PETD
Track 02B	Issue Resolution in Clinical Partnerships	FORUM	LEVEL: ■	CR
Track 03	The Voice of the Sites: Collaborating to Build a Site Partnership Model to Enable Study Start-Up	FORUM	LEVEL: ■	CR
Track 04	Effective Discovery, Development and Use of Biomarkers in Early Drug Development	SYMPOSIUM	LEVEL: ■	NC, CR
Track 06	Globalization of Field Medical Science Liaison: How to Take it to the Next Level	SESSION	LEVEL: ■	MSL
Track 07A	Searching for the Gold Nuggets: Text Analysis in Clinical Data	SESSION	LEVEL: ■	IT, CDM, SE
Track 07B	Frontier Issues in Electronic Information Integrity Today	SYMPOSIUM	LEVEL: ■	VA, IT
Track 08A	Expediting Drug Development through FDA's Breakthrough Therapy Designation	SESSION	LEVEL: ■	CR, PPLC
Track 08B	Does Bioequivalent Always Mean Therapeutically Equivalent? Impact of FDA's Proposed Rule on Generic Labeling ▲ **TURBO offering ends 2:30 PM**	SESSION	LEVEL: ●	AP
Track 09	Global Clinical Trials ▲ **TURBO offering ends 2:30 PM**	SESSION	LEVEL: ■	MDD, CR, CP
Track 10	The Challenges, Solutions and Right To Try Surrounding Expanded Access	FORUM	LEVEL: ■	CR, RA
Track 11	Using Data Analytics to Detect Quality Issues	SESSION	LEVEL: ■	CR
Track 12	Risk-Based Inspections and Compliance	FORUM	LEVEL: ■	CP
Track 13	Patient-Centered Outcomes Research: Pragmatic Clinical Trials	FORUM	LEVEL: ●	CR
Track 14A	A Proactive and Systematic Approach to Managing Product Risk Across the Life Cycle	SESSION	LEVEL: ■	RD
Track 14B	Measuring the Impact of Regulatory Pharmacovigilance in Europe and the United States	SESSION	LEVEL: ■	RA
Track 15	Big and MultiStream Data for Drug Evaluation: The Promise and Cautions	FORUM	LEVEL: ■	CP, CR

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 16	Using Games and Play to Create an Innovative Learning Experience	WORKSHOP	LEVEL: ●	PETD
Track 17	A Global Update on Orphan Drugs	SYMPOSIUM	LEVEL: ■	RA
Track 18	CBER Town Hall: Innovation and Public Health Response	FORUM	LEVEL: ■	RA
Track 19A	No More Crying Wolf: FDA Issues Final Rule on Changes to Pregnancy and Lactation Information in Drug Labeling	SESSION	LEVEL: ■	RA
Track 19B	TransCelerate Collaboration: Harmonization Efforts to Find Solutions to Critical Industry Challanges	SESSION	LEVEL: ●	CR
WEDNESDAY, JUNE 17 3:30–5:00 PM				
Track 01A	Best Practices for Effective Engagement with Patient Groups Around Clinical Trials	FORUM	LEVEL: ●	PT, CR
Track 01B	How to Best Optimize Site/Country Selection Based on Online Feasibility Tools and Global Regulatory Approval Timelines	SYMPOSIUM	LEVEL: ■	RD, CR
Track 02	Pediatric Product Development in the 21st Century: Developing Research Networks to Get the Job Done	FORUM	LEVEL: ■	RD, PPLCC
Track 03	Outing Innovation: How Partnerships Help (and Hinder) the Movement Toward Novel Approaches to Clinical Development	FORUM	LEVEL: ■	OS, CR
Track 06	Accountable Care Organizations and Integrated Health Care	SESSION	LEVEL: ■	CEHTAEbM, MC, MSL
Track 07A	CFAST Initiative: Potential to Dramatically Increase ROI and Reduce Timelines in the Conduct of Clinical Trials	SESSION	LEVEL: ●	CDM
Track 07B	The Critical Role of Document Management Supporting Submissions: Regulatory Operations, IT and Vendor Perspectives ▲ **TURBO offering ends 4:30 PM**	SESSION	LEVEL: ■	SUBS, RA, IT
Track 08	Dynamic Changes in Regulatory Landscape in Asia: Regulations for Global Drug Development	SESSION	LEVEL: ■	CR, RD
Track 09	Enhanced Collaborative Strategies: FDA and Device Makers Focusing on Improved Device Clearance Processes	SESSION	LEVEL: ●	RA, MDD
Track 10	Enforcement Update and Trends From a Global Perspective	FORUM	LEVEL: ■	RA
Track 11	Adapting Risk Management Principles to Non-Traditional R&D Settings	SESSION	LEVEL: ●	RD, BT, CR
Track 12	Knowledge Management for the Product Life Cycle	SESSION	LEVEL: ■	RA, MF, PM

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Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 13	Making Evidence at Launch More Real-World: Pragmatic Trials, Current Developments and Operational Challenges	WORKSHOP	LEVEL: ■	CR
Track 14A	Developing Innovative Approaches to Postmarketing Safety Data Collection in Pregnant Women	SESSION	LEVEL: ■	RA, CR
Track 14B	CIOMS IX: Practical Approaches to Risk Minimization and Its Evaluation	SESSION	LEVEL: ■	RA
Track 15	Statistical Support of Risk-Based Monitoring	SESSION	LEVEL: ■	CR, ST
Track 16	Abstract and Article Publication Opportunities with DIA	WORKSHOP	LEVEL: ●	ALL
Track 17	Rare Diseases: Patients, Caregivers and Advocates as Equal Partners in Clinical Trial Process ▲ **TURBO offering ends 4:30 PM**	FORUM	LEVEL: ■	PETD, CR
Track 18A	Asia Town Hall: Asia as a Drug R&D Center in the World	SESSION	LEVEL: ■	RA, RD
Track 18B	The State of Informatics at CDER, CBER and CDRH	FORUM	LEVEL: ■	IT, SUBS, CDM

THURSDAY, JUNE 18 9:00–10:30 AM

Track 01A	Lung-Map: A Future Clinical Trial with a Master Protocol Happening Now and the Value to Patients ▲ **TURBO offering ends 10:00 AM**	SESSION	LEVEL: ■	PT, CR
Track 01B	The Ultimate in Patient-Centered Trials: Bringing Study Visits into the Home ▲ **TURBO offering ends 10:00 AM**	SESSION	LEVEL: ■	PT, CR
Track 02	Survey Results: How Project Managers Leverage Tools and Techniques	WORKSHOP	LEVEL: ■	CR, RD
Track 03	Innovations in Strategic Alliances and Overcoming Obstacles	SYMPOSIUM	LEVEL: ■	CR, PM
Track 07A	Tired of Reinvesting in Old R&D Systems? Several Large Pharmaceutical Companies and Other Leaders are Flipping Paradigms	FORUM	LEVEL: ●	IT, RD
Track 07B	Bring Your Own Device (BYOD) Approaches to the Collection of Electronic Patient-Reported Outcome Data in Clinical Trials	SESSION	LEVEL: ■	SE
Track 08	Accidental Drugs: A Historical Look at How Certain Drugs Came to Market and Policy Pathway Opportunities	SESSION	LEVEL: ■	PPLC
Track 14	Novel Data Sources and Tools for Pharmacovigilance	SESSION	LEVEL: ■	EC, IT
Track 15	Innovative Designs for Cardiovascular Outcome Safety Trials in Type 2 Diabetes	SESSION	LEVEL: ■	CR, ST

Track #	Title of Offering	Type of Format	Level of Difficulty	Interest Area(s)
Track 16	AHA Moments: Breakthrough Thinking Leading to Deeply Satisfying Career Changes ▲ **TURBO offering ends 10:00 AM**	FORUM	LEVEL: ■	PETD
Track 18	An Insider's View of Cooperation Between the EMA and CDER/FDA	FORUM	LEVEL: ■	RA
Track 19	Mobile Health, Telemedicine, and Remote Sensors in Clinical Investigations: A New Era in Clinical Trial Design?	FORUM	LEVEL: ●	EC
THURSDAY, JUNE 18 10:45 AM–12:15 PM				
Track 01	DEVELOP Risk-Based Monitoring Strategies to INNOVATE Study Oversight and ADVANCE Study Execution	FORUM	LEVEL: ■	CR, RD
Track 02	A Systematic Approach to Study Start-Up ▲ **TURBO offering ends 11:45 AM**	SESSION	LEVEL: ■	SP, CR
Track 03	Just the Facts: A Model for Evaluating the ROI of Outsourcing Investigator Payments	FORUM	LEVEL: ■	OS, FI, AHC/IS
Track 07	mHealth / mClinical and Clinical Trials: A Candid Discussion on Opportunities and Risks	SESSION	LEVEL: ■	EC, CR, RA
Track 08	Global Developments in the Regulation of Biological Therapeutics	SESSION	LEVEL: ■	CR, BT
Track 14	The Future of Pharmacovigilance Operations	FORUM	LEVEL: ■	IT, PM
Track 16	Making Technology a Key Component of Your Learning Strategy ▲ **TURBO offering ends 11:45 AM**	SESSION	LEVEL: ■	IT, PETD
Track 18	CDER Town Hall	FORUM	LEVEL: ■	RA, CR
Track 19	Leveraging Electronic Health Record Data in Close Collaboration with Health Systems to Accelerate Precision Medicine ▲ **TURBO offering ends 11:45 AM**	FORUM	LEVEL: ■	CEHTAEbM

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The content noted on this page was made available to DIA as of January 28.

The following agenda details were made available to DIA on January 28. Speaker names identified as "Invited" will be published once confirmation and disclosure forms are completed. Visit DIAGlobal.org/DIA2015 for the most up-to-date information.

● *Basic-level content;* ■ *Primarily intermediate-level content;* ◆ *Primarily advanced-level content*

SATURDAY JUNE 13

Registration Hours:

9:00 AM–5:00 PM	Exhibitor Registration

SUNDAY, JUNE 14

Registration Hours:

8:00–9:00 AM	Registration for Full Day, Morning Preconference Tutorials*
8:00 AM–6:00 PM	Exhibitor Registration
12:30–1:00 PM	Registration for Afternoon Preconference Tutorials*
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*
4:00–5:00 PM	DIA 2015 51st Annual Meeting Orientation and Networking

**Space is limited for Preconference Tutorials. Onsite Registration is available, but not guaranteed*

MONDAY, JUNE 15

Registration Hours:

7:00 AM–6:00 PM	Attendee, Speaker, and Exhibitor Registration

Schedule:

7:30–8:20 AM	DIA 2015 51st Annual Meeting Orientation/Networking and Coffee
7:45–8:30 AM	Coffee and Breakfast Breads
8:30–10:00 AM	Educational Opportunities
8:30–10:00 AM	Student Forum
9:30 AM–4:30 PM	Student Poster Session (Exhibit Hall)
9:30 AM–6:00 PM	Exhibit Hall Open
10:00–11:00 AM	Coffee Break
11:00 AM–12:30 PM	Educational Opportunities
12:30–2:30 PM	Lunch & Exhibit Hall Innovation Theater Presentations
2:30–4:00 PM	Plenary Session & Keynote Address
4:00–6:00 PM	Opening Reception (Exhibit Hall)

Track 01A – Clinical Operations

Related Interest Area(s): FI, PT

8:30–9:30 AM ▲ Level: ■ Format: SESSION

Patient-Centricity: Buzzword or Method to Improve Operational Efficiency?

CHAIRPERSON:

James Kremidas
Lead Investigator, CenterWatch

In this session, we will review real world data recently collected regarding the use of patient-centric approaches to clinical trial execution. Our goal is to define return on investment measures and share best practices.

Victoria DiBiaso, MPH, RN
Associate Vice President, Head of Patient Participation & Preferred Partnerships, Genzyme Corporation, A Sanofi Company

Jane E. Myles, MS
Global Head, Recruitment Strategy, Genentech, A Member of the Roche Group

Track 01B – Clinical Operations

Related Interest Area(s): CR, RD

8:30–10:00 AM LEVEL: ■ FORMAT: SYMPOSIUM

Next Generation Feasibility: How to Predict the Unpredictable and Plan for Success

CHAIRPERSON:

Ira Charles Spector, PhD, MBA
Executive Vice-President, Analytics and Consulting, ICON Clinical Research

The use of data analytics provides a significant opportunity to change site selection from previous traditional approaches. The application of algorithmic methods to identifying sites, based on their likelihood to enroll and retain subjects and contribute valid results will be discussed.

Ira Charles Spector, PhD, MBA
Executive Vice-President, Analytics and Consulting, ICON Clinical Research

William W. Gwinn, Jr., MBA
Vice President, Clinical Informatics Solutions, Optum

Rachel Wilder McCorkle
Associate Feasibility Manager, Quintiles Inc.

Otis Johnson, MPA
Vice President, Clinical Research Services, Clinical Trial Recruitment Solutions, InVentiv Health

Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, CR

8:30–10:00 AM LEVEL: ■ FORMAT: FORUM

Project Management of Adaptive Trials: Infrastructure and Methodology

CHAIRPERSON:

Representative Invited
Vice President, Clinical Affairs, Health Decisions

This forum will identify critical issues and success factors in management of adaptive trials, including requirements for streaming information to enable the decision making at the heart of all adaptive design techniques.

Representative Invited
Professor, Department of Biostatistics, The University of Texas

Tom Parke
Consultant, Tessella, United Kingdom

Judith Quinlan, MSc
Vice President, Innovations Center, ICON Clinical Research

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): SP

8:30–9:30 AM ▲ LEVEL: ■ FORMAT: FORUM

Adventures in Strategic Planning: Is the Functional Service Provider Model Dead?

CHAIRPERSON:

Andrew Townshend
Vice President, Alliance Development, INC Research

Strategic partnerships, alliances, preferred partnerships and functional service provider (FSP) partnerships are interpreted differently. This forum will discuss whether the advent of broader alliances and strategic partnerships mean the end of FSP outsourcing in the industry.

Representative Invited
Executive Director, Global Head, Global Contracts and Outsourcing, Astellas Pharma Global Development

Track 04 – Preclinical and Translational Development/ Early Phase Clinical Development

Related Interest Area(s): NC, RA

8:30–10:00 AM LEVEL: ■ FORMAT: SESSION

In Vitro and In Vivo Preclinical Testing of Biosimilars: What Have We Learned?

CHAIRPERSON:

David R. Jones, MS
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

This session will examine the nonclinical requirements for the safety assessment of biosimilars. We will also review EU and US regulatory requirements and efforts to harmonize approaches.

David R. Jones, MS
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Iris Grossman, PhD
Vice President, Global Head of Personalized Medicine and Pharmacogenomics, Teva Pharmaceutical Industries Ltd., Israel

Paul Baldrick, PhD
Senior Director, Regulatory Strategy, Covance Laboratories Ltd., United Kingdom

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

Related Interest Area(s): MC

8:30–10:00 AM Level: ■ Format: FORUM

Communicating Pharmaceutical Risks and Benefits: Why Is It So Hard and How Can We Do Better?

CHAIRPERSON:

Brian Edwards, MD, MRCP
Principal Consultant, Pharmacovigilance and Drug Safety, NDA Group, United Kingdom

Pharmaceuticals are developed for patients who behave according to perceptions, not just facts, about medicines. How should we respond to demands for higher quality information, greater openness and transparency with round-the-clock media scrutiny? What is the role of trust and how can we strengthen trustworthiness in communication? How should the evidence behind good communication impact regulatory processes? How can we assess whether communication is effective in changing behavior? Questions like these will be discussed in this forum as we aim to address this core risk minimization activity for any pharmaceutical organization.

Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

Sweta Chakraborty, PhD
Associate Director, Institute on Science for Global Policy (ISGP)

Track 07A – Technology/Data/Records and Submissions

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

8:30–10:00 AM Level: ■ Format: SESSION

How Pharmaceutical Companies and CROs Are Harnessing Big Data and Cloud Computing to Increase R&D Innovation, Efficiency, and Collaboration

CHAIRPERSON:

Jonathan Palmer
Senior Director, Product Strategy, Clinical Warehousing and Analytics, Oracle Health Sciences, United Kingdom

This session examines actual case studies of how trial sponsors and clinical research organizations (CRO) are going beyond simply tuning processes and labor and leveraging advanced technologies to drive change, collaboration, and agility. Speakers will share use cases in areas such as data integration, clinical warehousing, cloud, big data, wearable devices, 'omics', analytics, and robotics to illustrate new innovative approaches to accelerate clinical development, drive new science, and enable new business models.

Representative Invited
Vice President, Informatics and Enterprise Architecture, Covance Inc.

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): EC, IT

8:30–10:00 AM Level: ■ Format: SESSION

How Sponsors Are Solving the Unique Data Collection Challenges of Late-Stage Studies

CHAIRPERSON:

Jennifer Bush, MS
Director, Life Sciences Product Strategy, Oracle Health Sciences

Today's eClinical suites are primarily focused on phase 2–3 research needs. This session will provide an overview of eClinical needs specific to late-stage studies and discuss how and why those needs differ from phase 2–3 research needs.

Representative Invited
Executive Director, Principal Late Stage Strategy, inVentiv Health

Track 08 – Regulatory Affairs

Related Interest Area(s): CR

8:30–10:00 AM Level: ■ Format: FORUM

Forward Progress Through Collaboration: Internal and External to the FDA

CHAIRPERSON:

Kevin Bugin, MS, RAC
Senior Regulatory Health Project Manager, Office of New Drugs, CDER, FDA

The FDA's Center for Drug Evaluation and Research utilizes multiple processes and methods to collaborate. This forum will review select processes and provide a forum to discuss case studies in which a high level of collaboration was achieved.

Representative Invited
Deputy Director, Office of Combination Products, Office of Special Medical Programs, Office of Medical Products and Tobacco, FDA

Representative Invited
Division Deputy Director, Gastroenterology and Inborn Errors Products, Office of New Drugs, CDER, FDA

Representative Invited
Clinical Director, Eunice Kennedy Shriver NICHD/NIH

Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

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

8:30–10:00 AM Level: ■ Format: SESSION

Enabling Next Generation Sequencing within Global Clinical Trials

CHAIRPERSON:

Sabah Malek
Associate Director, Global Regulatory Affairs, Eisai Inc.

As targeted therapies are being increasingly developed by pharmaceutical companies, there is a keen interest in identifying and stratifying patients by genetic alterations. Next generation sequencing can provide this and the ability to potentially screen high volumes of patients to be matched to trials. However, the use of next generation sequencing within these clinical trials provides its own set of challenges, including actionability of genomic information, use of local testing, utilization within clinical trials, and regulatory hurdles. All of these considerations covered within the session can influence a program's clinical strategy and design.

Sabah Malek
Associate Director, Global Regulatory Affairs, Eisai Inc.

Douglas Robinson, PhD
Global Head, Biomarkers and Diagnostics Biometrics, Novartis Institutes for BioMedical Research (NIBR)

Representative Invited
Regulatory Reviewer, Office of InVitro Diagnostics and Radiological Health, CDRH, FDA

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA, PT

8:30–10:00 AM Level: ■ Format: FORUM

The Growing Role of the Patient Leading Into PDUFA VI: Negotiations and 2016

CHAIRPERSON:

James E. Valentine, JD
Associate, Hyman, Phelps & McNamara, PC

FDA's Patient-Focused Drug Development (PFDD) initiative is three years old. Not only have the meetings generated a great deal of information on patients' perspectives, but they've also generated a lot of questions. How can this growing body of information be translated into a useful set of data for the agency? How has the agency started incorporating these patient perspectives into regulatory decision-making, and what's been the impact? What are the lessons learned that can inform future patient-focused efforts in PDUFA VI and beyond? Are there other models that may take shape as PFDD 2.0? How can stakeholders engage and collaborate with FDA as negotiations and stakeholder consultations move forward for PDUFA VI? These questions, and more, will be explored by FDA officials and other stakeholders involved in the PFDD initiative.

Representative Invited
Vice President of Public Policy, National Organization For Rare Disorders (NORD)

James E. Valentine, JD
Associate, Hyman, Phelps & McNamara, PC

Representative Invited
Director, Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

Representative Invited
Director, Office of Strategic Programs, CDER, FDA

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR

8:30–10:00 AM LEVEL: ■ FORMAT: SESSION

Clinical Quality Management Systems in the New Millennium

CHAIRPERSON:

Deborah Driscoll, MS
Vice President, Quality Assurance, Medical Division, Pfizer Inc

This session will describe ongoing activities of a TransCelerate BioPharma workstream evaluating clinical quality management system (QMS). Panelists will discuss ongoing development of a concept paper describing a progressive clinical QMS framework designed to provide a consistent, streamlined, and proactive quality approach across all stages of clinical research.

Representative Invited
Acting Senior Advisor, Division of GCP Compliance, Office of Scientific Investigations, CDER, FDA

Ann Meeker-O'Connell, MS
Head, Risk Management and External Engagement, Bioresearch Quality & Compliance, Janssen Pharmaceuticals, Inc.

Leslie M. Sam
Director, Global Quality Systems, Eli Lilly and Company

Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC/GMP

8:30–10:00 AM LEVEL: ■ FORMAT: FORUM

Comprehensive Control Strategy: Building Confidence in Quality

CHAIRPERSON:

John Groskoph, MBA
Senior Director, Global CMC, Pfizer Inc

This forum will present and facilitate discussion on various control strategies and their potential impact on chemistry, manufacturing and control activities.

Representative Invited
Executive Director, Global Science Technology and Commercialization, Merck & Co., Inc.

Representative Invited
Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Representative Invited
Associate Director, Genentech, A Member of the Roche Group

Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

8:30–10:00 AM LEVEL: ■ FORMAT: SESSION

Risk Management Plans Ten Years On: Where are We Now and Where Are We Going?

CHAIRPERSON:

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

ICH E2E on pharmacovigilance planning reached step four in 2004. Since then risk management has become a key part of licensing applications in many countries. Experts will discuss evolution over the last ten years and speculate on future developments.

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

Representative Invited
Director, Office of Surveillance and Epidemiology, CDER, FDA

Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Eisai Co., Ltd., Japan

Representative Invited
EU QPPV, Executive, Global Patient Safety, Eli Lilly and Company Ltd, United Kingdom

Track 16 – Professional Development

Related Interest Area(s): ALL

8:30–10:00 AM LEVEL: ■ FORMAT: FORUM

DIA 2015 Student Forum: Job Hunter's Toolkit - Some Things Change, Some Stay the Same

CHAIRPERSON:

Danny Benau
University of the Sciences in Philadelphia

The main contents of the job hunter's toolkit have been the same for decades: resume, business card, elevator speech, and networking. In addition to having the basic tools, today's job hunter needs to have experience with the self-promotion changes made in recent years brought about by the increasing number of and newly focused electronic job boards, integrated social media sites, and the use of instant communications. Each platform offers job hunters a unique opportunity to search for jobs and more importantly to communicate job experience. Knowing the differences between the platforms is key to successfully receiving leads. This forum will explore changes that have reshaped the concept of networking and finding job openings, while incorporating and updating the job toolkit basics that are still important such as business cards and alternatives to the classical resume.

Track 18 – Global Regulatory

Related Interest Area(s): RA, CR

8:30–10:00 AM LEVEL: ■ FORMAT: FORUM

An Update From Health Canada

CHAIRPERSON:

Agnes V. Klein, DrPH, MD
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

Health Canada has had a somewhat unique approach to regulating therapeutics. Over the years, Canada had interpreted the regulations in light of scientific advances, mainly because its regulations dated from the early 60's. Most recently, however, Canada has started to modernize its regulations, particularly in ensuring that the right authorities to regulate therapeutics with a life cycle approach were to be in place. In this session, the following will be highlighted: Bill C-17 dubbed Vanessa's Law, the current status of orphan drug regulations and the approached to be used in managing therapeutics postmarket. In all these areas, Canada has endeavored to be harmonized with international approaches. However, there are some unique features in how these elements are approached.

Representative Invited
Director, Evaluation of Radiopharmaceuticals and Biotherapeutic Products, Health Canada

Representative Invited
Director, Office Legislative & Regulatory Modernization, Policy, Planning & IA Directorate, Health Canada

Duc Vu, PhD
Director, Marketed Biologicals, Biotechnology, Natural Health Products HPD, Health Canada

Track 19A – Late-breaking Topics

Related Interest Area(s): SP

8:30–10:00 AM Level: ■ Format: FORUM

The Emerging Role of Medical Affairs in the Biopharmaceutical Organizations: Challenges and Opportunities

CHAIRPERSON:

Honorio Silva, MD
President-Elect, International Federation of Associations of Pharmaceutical Physicians

Medical affairs organizations within the pharmaceutical industry are emerging to provide patient and physician-centered services as part of a new business model aimed to provide value in health care. The challenges and opportunities for further growth will be analyzed.

Representative Invited
Vice President and Deputy Chief Medical Officer, Merck & Co., Inc.

Representative Invited
Regional Head Medical Affairs, North America, Pfizer Inc

Track 19B – Late-breaking Topics

Related Interest Area(s): CR

8:30–10:00 AM Level: ● Format: FORUM

Ebola Virus Disease Case Study: Global Harmonization to Increase Power and Accelerate Outcomes in Clinical Research Data

CHAIRPERSON:

Rebecca Kush, PhD
President and CEO, CDISC

Africa is ravaged by the worst outbreak of Ebola virus disease ever witnessed. This forum will discuss how catalyzed by this crisis, a global consortia is collaborating to deliver unprecedented data standardization to maximize the scientific output of collective research.

Track 01A – Clinical Operations

Related Interest Area(s): CR, AHC/IS

11:00 AM–12:30 PM Level: ● Format: SESSION

Pediatric Clinical Trials: Learning from Patients, Parents, and Investigative Sites

CHAIRPERSON:

Lisa Palladino Kim, MS
Adjunct Assistant Professor, Rutgers, The State University of New Jersey

The number of pediatric drug trials is growing rapidly, but many of these trials have proven extremely difficult to enroll. Drug developers can vastly increase their chances for success by listening to and collaborating with study sites and parents/patients. This session presents best practices for engaging study sites and parents/patients as partners in the trial process.

Donald Sickler
Group Account Supervisor, CAHG

Kathryn Bohannon
Vice President, Global Project Management, inVentiv Health

Charles A. Thompson
Global Lead, Pediatric Center of Excellence, Pfizer Inc

Hadleigh Thompson
Youth Advisor, iCAN

Track 01B – Clinical Operations

Related Interest Area(s): CR, PM

11:00 AM–12:30 PM Level: ● Format: SESSION

The Clinical Trials Transformation Initiative Data Monitoring Committee Project: Findings and Next Steps

CHAIRPERSON:

Representative Invited
Professor, Department of Biostatistics & Medical Informatics, University of Wisconsin

Findings from the Clinical Trials Transformation Initiative (CTTI) Data Monitoring Committee (DMC) Project survey and focus groups will be presented. Specific topic areas include: use, conduct, communication practices and training issues related to DMCs.

Representative Invited
Clinical Analyst, Office of Medical Policy, CDER, FDA

Raymond P. Bain, PhD
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

Jane Perlmutter, PhD, MBA
Founder and President, Gemini Group

Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): SP, RD

11:00 AM–12:30 PM LEVEL: ■ FORMAT: FORUM

Codevelopment of a Drug in the Pharmaceutical Industry: Is It Ever Fun?

CHAIRPERSON:

Jayanthi Reddy, MBA, MS, PMP
Director and Cardiovascular Pipeline Leader, Global Project Management, Merck & Co., Inc.

A culture of collaboration with external partners is one of the key drivers of future success. This forum will focus on the challenges and barriers in codevelopment and the business models being adopted to ensure a healthy collaboration.

Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): CR, PETD

11:00 AM–12:30 PM LEVEL: ◆ FORMAT: WORKSHOP

How to Achieve Value of Operational Transformation: It Requires Innovation, Process Excellence, and Adoption

CHAIRPERSON:

Shannon Adkins, MBA
Vice-President, Service Delivery and Life Sciences, Future State

In a continuously evolving health care system, operational transformation only succeeds and delivers the anticipated value when the practices of innovation, process excellence, and adoption are integrated. Investments in new technologies, processes, and approaches can cost millions of dollars, and far too often fail. To increase your chances of success, we will examine a few case studies of operational transformation across global organizations to understand common pitfalls and challenges, and develop solutions that will drive employee engagement, adoption of new ways of working, and greater return on investment. This workshop provides the tools to success.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington Convention Center 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 offering will not be recorded.*

Representative Invited
Head, Process Excellence Global Clinical Operations, Roche Products Limited, United Kingdom

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, RD

11:00 AM–12:00 PM ▲ LEVEL: ● FORMAT: SESSION

What Contract Research Organizations Value in a Partner: Results of a Perception Survey

CHAIRPERSON:

Lea Studer
Vice President of Marketing Communications, SCORR Marketing

A 2014 contract research organization (CRO) perception survey rated sponsors on a number of key criteria. Based on these survey results and overall satisfaction levels, we will examine the key criteria, what is valued in a partnership from a CRO perspective, as well as insights on how CRO-sponsor relationships can be improved.

Representative Invited
Chief Operating Officer, CenterWatch

Track 04 – Preclinical and Translational Development/ Early Phase Clinical Development

Related Interest Area(s): BT, RA

11:00–12:00 AM Level: ■ Format: SESSION

Next Generation Nanomedicines and Nanosimilars: Regulators' Perspective

CHAIRPERSON:

Representative Invited
Head of Section Risk Management, European Medicines Agency, European Union

Recent advances in nanoscience are bringing novel opportunities to master matter at a nano-scale size, leading to the creation of even more complex, hybrid structures by both new top-down fabrication and bottom-up manufacturing techniques. This is paving the way for a wave of new pharmaceuticals, imaging agents and combination products — so called "next generation" nanomedicines. Given the degree of complexity of these products, a need to adapt current regulatory scientific requirements has been noted. In this session, we will address recent regulatory activities such as an international collaboration on guidance development of nanomedicines and nanosimilars, as well as examine regulatory strategies and harmonization in nanomedicines, particularly in the Asia Pacific region.

Representative Invited
Director, Division of Medicinal Products, Taiwan Food and Drug Administration

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

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

11:00 AM–12:30 PM Level: ■ Format: SYMPOSIUM

Engaging Patients and Health Care Professionals Through Social Media and Big Data Systems

CHAIRPERSON:

Poonam A. Bordoloi, PharmD
Senior Manager, Medical Information Services Internal Medicine and BioSurgery, Sanofi

The increase of internet driven technologies has revolutionized medical communications and engagement of patients and health care professional. This symposium will discuss how FDA is leveraging social media tools to reach audiences that are both diverse and segmented, providing greater opportunities to access information on FDA-regulated medical products. It will explore barriers to adoption of social media by medical information (MI) teams, and provide examples of how MI teams can provide value by embracing social media as a channel for communication and education. Lastly, explore and interpret interactive data visualizations demonstrating how health care professionals have adapted to new and emerging channels and how their networks of influence can be used to gain deep insight about unmet medical information needs.

Representative Invited
Health Communications Specialist, Office of Communications, CDER, FDA

Omudhome Ogbru, PharmD
Business Initiative Manager, Medical Communications, ArisGlobal

Paul Grant
Chief Innovation Officer, Creation Healthcare, United Kingdom

Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): EC, PT

11:00 AM–12:00 PM ▲ Level: ■ Format: SESSION

Integrating Patient Engagement with EHR Data and eSource for Better Studies

CHAIRPERSON:

Douglas Bain
Founder and CEO, eClinicalHealth Limited, United Kingdom

Patient engagement solutions are opening the door for the enhanced involvement of patients in a clinical trial. This session will examine the value of patient engagement, and in particular the opportunities brought by eSource and electronic

health records (EHR)/electronic medical records (EMR) integration.

Glenn Keet
Chief Executive Officer, Clinovo

Representative Invited
Head of Research, The Clinical Practice Research Datalink Group (CPRD), United Kingdom

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): RA, SUBS

11:00 AM–12:00 PM ▲ Level: ■ Format: SESSION

Evolving Your Regulatory Information Management Strategy to Meet the Changing Business Environment

CHAIRPERSON:

Steve Gens, MS
Managing Partner, Gens and Associates Inc.

Complexity is growing in the global regulatory environment with new regulations coming into play (regulated product submission (RPS), identification of medicinal products (IDMP), social media etc.). Additionally, new highly virtual collaborative business models are emerging and will be common in the near future. In this session, a summary of key trends that impact a regulatory information management (RIM) strategic plan will be discussed. The speakers will detail how other companies are approaching these changes and evolving their RIM strategies and investment plans.

Steve Gens, MS
Managing Partner, Gens and Associates Inc.

Steve Scribner
Principal Consultant — Life Sciences, EMC

Track 08 – Regulatory Affairs

Related Interest Area(s): CR, RD

11:00 AM–12:30 PM Level: ● Format: FORUM

Global Drug Development in China: Opportunities and Challenges for Innovation

CHAIRPERSON:

Joseph C. Scheeren, PharmD
Senior Vice President, Head Global Regulatory Affairs, Pharma and Consumer Care, Bayer Consumer Care AG, Switzerland

China has very dynamic regulatory policies in driving the development of innovative drugs. This forum will share experiences on regulatory opportunities and barriers that will impact development and availability of new drugs in China.

Daniel Liu, PhD
Chief Scientific Officer, Beijing Clinical Service Center, China

Representative Invited
Senior Advisor, Covington and Burling LLP, China

Representative Invited
Science and Regulatory Affairs, Pharmaceutical Research and Manufacturers of America (PhRMA)

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA

11:00 AM–12:30 PM Level: ■ Format: FORUM

New Pandemics: Lessons Learned from the Ebola Regulatory Experience - How Will We Be More Nimble Next Time?

CHAIRPERSON:

Diane Berry, PhD
Vice President, Global Health Policy and Government Affairs, Sarepta Therapeutics

Pandemics pop up periodically; as regulators and innovators, we try to quash them as quickly as we can. Ebola has been a frightening experience and demonstrates the speed at which a disease, previously contained by remoteness, can spread and cause panicked public reactions. On the regulatory, funding and preparedness fronts,

this forum will help elucidate what we learned from 2014's Ebola outbreak, and how agencies and public health organizations are preparing for the next global challenge. We will hear some "war stories" about the challenges of coordinating a global response and the difficulties of coordinating across agencies in exigent circumstances and hear ideas of how to avoid these problems in the future.

Kerstin Adolph, DrSc
Senior Clinical Project Manager, Clinlogix LLC, Germany

Representative Invited
Assistant Commissioner for Counterterrorism Policy, Office of the Chief Scientist, Office of the Commissioner, FDA

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR

11:00 AM–12:30 PM LEVEL: ■ FORMAT: SESSION

Clinical Quality by Design: From Theory to Practice

CHAIRPERSON:

Ann Meeker-O'Connell, MS
Head, Risk Management and External Engagement, Bioresearch Quality & Compliance, Janssen Pharmaceuticals, Inc.

QbD emphasizes building quality into a process from the beginning and has been successfully applied in the manufacturing arena. Applied in clinical development, QbD prospectively examines a trial's objectives and identifies the factors that are critical to meeting these objectives. Understanding these "critical to quality" aspects is essential to subsequently identifying and managing important and likely risks to trial quality. To support organizations seeking to implement QbD, a Clinical Trials Transformation Initiative (CTTI) project team is currently developing a portfolio of learning and operational tools. In addition, we will review these tools and highlight effective strategies that may aid in adoption of a QbD approach. This session will also discuss how pragmatic protocol design drawing on data standards and simulations may augment trial design and examine ways of leveraging insights from health care providers and payers to inform and improve protocol design.

Coleen M. Glessner
Vice President, Clinical Trial Process and Quality, Pfizer Inc

Representative Invited
Senior Director, Life Sciences Product Strategy, Oracle Health Sciences

Representative Invited
Acting Senior Advisor, Division of GCP Compliance, Office of Scientific Investigations, CDER, FDA

Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA

11:00 AM–12:30 PM LEVEL: ■ FORMAT: SESSION

Reducing Drug Shortages

CHAIRPERSON:

Representative Invited
Senior Program Management Officer, CDER Drug Shortage Staff, FDA

This session will discuss major global quality challenges, Current Good Manufacturing Practice (cGMP) inspectional issues and proactive/collaborative regulatory approaches with global health authorities to potentially mitigate the risk of global drug shortages.

Ramani Raghavan, MS
Regulatory Advisor, Genentech, A Member of the Roche Group

Representative Invited
Senior Program Management Officer, CDER Drug Shortage Staff, FDA

Representative Invited
Head of Compliance and Inspections Department, European Medicines Agency, European Union

Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

11:00 AM–12:30 PM Level: ■ Format: FORUM

REMS Integration into the Health Care System: Three Perspectives in an Evolving Environment

CHAIRPERSON:

Michael A. Cronin, PharmD
Post-Doctoral Fellow, Regulatory Affairs, NPS Pharmaceuticals, Inc.

How do we optimize risk evaluation and mitigation strategies (REMS) to improve drug safety in the evolving health care environment? Speakers from FDA, health care, and industry will provide their perspective on REMS integration efforts and discuss how to further advance the standard of pharmaceutical risk management in the US.

Representative Invited
Associate Director for Drug Safety Operations, Office of the Center Director, CDER, FDA

Florence Houn, MD, MPH, FACP
Co-chair, FDA Alumni Association International Network; Vice President, Regulatory Policy and Strategy, Celgene Corporation

Katie Stabi, PharmD
Clinical Coordinator, Drug Use Policy and Compliance, Dept of Pharmacy Services, University of Chicago Medicine

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST

11:00 AM–12:30 PM Level: ■ Format: SESSION

Statistical Evaluation of Therapeutic Equivalence for Locally-Acting Generic Products

CHAIRPERSON:

Representative Invited
Acting Director, Division of Biometrics VIII, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Bioequivalence of generic drugs to innovator products has traditionally been evaluated using pharmacokinetic studies with endpoints such as mean area under the concentration curve and analyses such as calculating confidence intervals around the ratio of means. However, the evaluation of bioequivalence for locally-acting products is complicated by the fact that such pharmacokinetic studies do not capture the information necessary for determining equivalence. This session will outline the statistical issues involved and offer examples of innovative approaches to solving the problem. Such issues relate to the choice of the design, the formulation of the statistical hypotheses and the factors that affect the power of the statistical test.

Elena Rantou, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Wanjie Sun, PhD
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Keith Gallicano
Vice President, Scientific Affairs, Novum Pharmaceutical Research Services

Track 16 – Professional Development

Related Interest Area(s): PETD

11:00 AM–12:30 PM ▲ Level: ● Format: WORKSHOP

The What, Why and How of Coaching and Its Application in the Work Place

CHAIRPERSON:

Mieke Jobsis
Director, Quality and Risk Management, GlaxoSmithKline

There has been a boost in the practice of coaching, whether it is personal, life, health or business coaching, in all aspects of life. Why are some companies in the pharmaceutical industry embedding coaching programs and building coaching into their core skill set? This workshop will build an understanding of what coaching is and

look at how business coaching has been applied in different settings of the pharmaceutical industry.

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Nicky Rousseau, CPA
Senior Director, Program Management, Quintiles Inc.

Mieke Jobsis
Director, Quality and Risk Management, GlaxoSmithKline

Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, PETD

11:00 AM–12:30 PM Level: ● Format: SYMPOSIUM

Facilitating Rare Disease Patient Participation in Clinical Trials

CHAIRPERSON:

Maureen Smith
Patient Advocate / Secretary of CORD, Canadian Organization For Rare Disorders (CORD), Canada

In rare disease trials, patients are difficult to find and also hard to retain. Patients may be located far from the investigative site, too debilitated to travel, or may not be able to come to the investigative site for the numerous visits required per the protocol. This symposium will present three innovative initiatives to facilitate rare disease patient participation in clinical trials. It will provide attendees with insights that will have positive impacts on recruitment, study completion and patient satisfaction. The initiatives include the use of mobile nursing in rare and pediatric studies and the challenges; optimizing the use of home health care providers for patient visits and travel agencies for patient travel to the investigative site; and rare disease Patient Service Centers - creating outstanding patient engagement via a holistic approach.

Juliet Hulse
Research Nursing Team Manager, Research Nurses Limited, United Kingdom

Kristi Clark, MBA
Vice President, Project Management and Clinical Operations, Agility Clinical Inc.

Thomas Rudolf Lembck, MBA
Co-Founder, Orphan Drug Solutions

Track 18 – Global Regulatory

Related Interest Area(s): RA

11:00 AM–12:30 PM Level: ● Format: FORUM

International Regulatory Convergence: Collaboration, Cooperation and Global Governance

CHAIRPERSON:

Representative Invited
Head of International Affairs, European Medicines Agency, European Union

The audience will hear from the top level senior leadership of four of the most influential global regulators and explore current multilateral and bilateral initiatives aimed to facilitate better interaction and coordination. This forum will examine initiatives to avoid duplication and increase mutual reliance between regulators and their impact on industry.

Representative Invited
Principal Adviser, European Medicines Agency, European Union

Representative Invited
Chief Scientist, Office of the Commissioner, FDA

Representative Invited
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Anil Arora
Assistant Deputy Minister, Health Products and Food Branch, Health Canada

Opening Plenary

Related Interest Area(s): TBD

2:30–4:00 PM LEVEL: ● FORMAT: FORUM

Join us for the DIA 2015 51st Annual Meeting Opening Plenary as we officially open this year's program. Stay tuned for announcements related to this year's Keynote Speaker.

Per Spindler, DVM, MBA, MSc
Director Biopeople, University of Copenhagen, Denmark; DIA President and Chair, Board of Directors

Michael Rosenblatt, MD
2015 Program Chair; Executive Vice President and Chief Medical Officer, Merck & Co., Inc.

Opening Reception

4:00-6:00 PM (Exhibit Hall)

The Walking Gallery

June 15 | 4:00-6:00PM

For the second year, DIA will be hosting The Walking Gallery, a patient empowerment movement founded by Artist Regina Holliday. During the Opening Reception on Monday, current members of The Walking Gallery are welcome to gather and share their stories. Already A Walking Gallery member? RSVP to Julie.Ho@diahome.org.

Interested in becoming a member of The Walking Gallery?
Contact Regina Holliday (via Facebook, Twitter, or Linkedin) prior to the Annual Meeting.

TUESDAY, JUNE 16

Registration Hours:

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

Schedule:

7:15–8:00 AM	Coffee and Breakfast Breads
8:00–9:30 AM	Educational Opportunities: 60-minute ▲ TURBO Offerings (8:00–9:00 AM) 90-minute Offerings (8:00–9:30 AM)
9:30 AM–4:00 PM	Professional Poster Session #1
9:00 AM–5:00 PM	Exhibit Hall Open
9:30–10:30 AM	Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30 AM–12:00 PM	Educational Opportunities 60-minute ▲ TURBO Offerings (10:30–11:30 AM) 90-minute Offerings (10:30 AM–12:00 PM)
11:30 AM–1:30 PM	Lunch & Exhibit Hall Innovation Theater Presentations
12:30 PM	Student Poster Award Ceremony (DIA Booth #1523)
1:30–3:00 PM	Educational Opportunities 60-minute ▲ TURBO Offerings (1:30–2:30 PM) 90-minute Offerings (1:30–3:00 PM)
1:30–3:30 PM	Exhibit Guest Passes
2:30–3:30 PM	Refreshment Break & Exhibit Hall Innovation Theater Presentations
3:30–5:00 PM	Educational Opportunities 60-minute ▲ TURBO Offerings (3:30–4:30 PM) 90-minute Offerings (3:30–5:00 PM)

Track 01A – Clinical Operations

Related Interest Area(s): PT

8:00–9:30 AM LEVEL: ● FORMAT: SESSION

The Development of Patient Power: From Consumer to Active Participant!

CHAIRPERSON:

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

Collecting views and data directly from patients may provide information which is critical to understanding how medicines are used. The role of patients is changing from simple consumer to being a key part of the drug development program.

Joan M. Meyer
Executive Director, Operational Strategy and Planning, Covance Inc.

The content noted on this page was made available to DIA as of January 28.

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

Michael Howley, PhD
Associate Clinical Professor, Drexel University

Sally Okun, RN
Vice President, Advocacy, Policy and Patient Safety, PatientsLikeMe

Track 01B – Clinical Operations

Related Interest Area(s): CR, PT

8:00–9:30 AM Level: ■ Format: FORUM

The Role of Innovation in Clinical Trial Advocacy: Developing and Executing Patient-Centered Strategies and Partnerships Throughout the Continuum

CHAIRPERSON:

Lisa Palladino Kim, MS
Adjunct Assistant Professor, Rutgers, The State University of New Jersey

Industry is embracing the importance of diversifying the clinical trial patient population in an increasingly challenging recruitment landscape. The pharmaceutical industry's involvement with patient groups has historically focused on one-way communications, typically offering short-term results. A combination of new media and strategic communications leads to richer community engagement and increased responses.

Lori B. Abrams, MSc
Director, Advocacy, Diversity & Patient Engagement, Bristol-Myers Squibb Company

Kristin Nicole Voorhees, MA
Director of Healthcare Initiatives, National Foundation for Celiac Awareness

Representative Invited
President and Chairman of the Board, Lungevity

Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM

8:00–9:30 AM Level: ■ Format: FORUM

The Art and Science of Portfolio Management

CHAIRPERSON:

Karla Childers, MS
Director, Strategic Projects, Johnson & Johnson

In this forum, experienced portfolio managers will share their observations on the type of skills required and critical activities undertaken to manage a portfolio of innovative products. Learn how portfolio management may fit into your current career development plans. Panelists will also give insight into some of the different models with which they have experience.

Frank P. DePaoli
Director, Pharmaceutical/Life Sciences R&D, PricewaterhouseCoopers LLP

Matthew Studney
Director, MRL Global Project Management, Merck & Co., Inc.

Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RA, PM

8:00–9:00 AM ▲ Level: ■ Format: SESSION

Centralized Ethics: How a Unique Partnership Between a CRO and an IRB Is Changing the Regulatory and Ethics Review Process

CHAIRPERSON:

Jennifer Lynn Peterson, RAC
Director, Site Start-Up and Regulatory, North America, INC Research

This session will examine how a contract research organization and an institutional review board have established a partnership to solidify an efficient, high-quality start-up process that expands its reach well past regulatory and ethics reviews.

Jennifer Lynn Peterson, RAC
Director, Site Start-Up and Regulatory, North America, INC Research

Nicholas Slack
Chief Growth Officer, WIRB-Copernicus Group

Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, CR

8:00–9:00 AM ▲ Level: ■ Format: SESSION

A Biopharmaceutical Company/Services Provider Partnership: Value to Both Companies and Progress to Date

CHAIRPERSON:

Stacie Yonkin
Senior Vice President and Managing Director, Quintiles Inc.

This session will focus on the rationale and benefits of establishing a sole source partnership between two companies that are leaders in the clinical development space and possess complementary areas of expertise and company culture.

Murray Alexander Abramson, DrMed, MPH
Vice President, Global Clinical Operations, Biogen Idec

Track 04 – Preclinical and Translational Development/ Early Phase Clinical Development

Related Interest Area(s): NC, RA

8:00–9:30 AM Level: ■ Format: SYMPOSIUM

Regulatory Examination of Nonclinical Testing Requirements and Juvenile Animal Studies

CHAIRPERSON:

David R. Jones, MS
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

This symposium will examine the issues surrounding nonclinical testing requirements to support clinical trials in rare diseases, the importance and value of nonclinical juvenile animal studies for oncology products, as well as the role of juvenile animal studies in global pediatric product development. Juvenile animal studies can contribute significantly to risk assessment and safety in pediatric clinical trials and for drug product labeling, and their usefulness will be examined, primarily from a regulatory standpoint.

David R. Jones, MS
Expert Pharmacotoxicologist, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Ikram Elayan, PhD
Senior Pharmacology/Toxicology Reviewer, Office of New Drugs, CDER, FDA

Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

Related Interest Area(s): RA

8:00–9:30 AM Level: ● Format: WORKSHOP

Prescription Drug Marketing Regulatory Primer

CHAIRPERSON:

Representative Invited
President, Lucy Rose and Associates, LLC

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

Representative Invited
Director, Office of Prescription Drug Promotion, CDER, FDA

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

Related Interest Area(s): MW, CR

8:00–9:30 AM Level: ■ Format: SYMPOSIUM

New Approaches to Submission Components

CHAIRPERSON:

Janet K. Stoltenborg, MBA, MS
Global Head, Medical Communications Science, AstraZeneca Pharmaceuticals LP

The world of clinical trial reporting continues to evolve with increasing requests for information and the ever-present need to be more efficient in delivery. This symposium provides the medical writer with new approaches to streamline clinical study reporting while meeting new transparency requirements.

Janet K. Stoltenborg, MBA, MS
Global Head, Medical Communications Science, AstraZeneca Pharmaceuticals LP

Carrie McKenzie
Project Manager, WebbWrites LLC

Jennifer Seamon
Principal Medical Writing Scientist, Janssen Pharmaceuticals, Inc.

Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, CR

8:00–9:30 AM Level: ■ Format: SYMPOSIUM

Implementing Risk-Based Monitoring

CHAIRPERSON:

Willie Muehlhausen, DVM
Head of Innovation, ICON Clinical Research, Ireland

Risk-based monitoring (RBM) promises to improve quality in clinical research, and may help limit the growing cost of clinical trials. Recommendations have been outlined by regulatory bodies including FDA's Guidance on RBM, and EMA's reflection paper. Transcelerate BioPharma has also published a position paper on implementation. This symposium will look at several aspects of RBM implementation, using a number of case examples to explore and contrast the data analytics approach using central statistical monitoring and the development and use of key risk indicators. Importance will be placed on how the cause of the findings can be identified and classed by seriousness — from poor protocol understanding to intent to cheat. We will also discuss the operational implications of the findings in terms of the resulting corrective actions.

Roland Rich
Operational Expert, Quality and Compliance DevQA, Novartis Pharma AG, Switzerland

Tammy Finnigan
Head of Operations, Triumph Consultancy Services, United Kingdom

Erik Doffagne, MSc
Product Manager, CluePoints, Belgium

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, IT

8:00–9:30 AM Level: ■ Format: SESSION

International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP): Will Your Company Be Ready by 2016?

CHAIRPERSON:

Niels Gronning, MSc
Principal Consultant, NNIT A/S, Denmark

New regulations for the IDMP currently being finalized by the EMA and the FDA will fundamentally alter the way data is standardized and shared across the pharmaceutical industry. ISO IDMP and the associated implementation guidelines collectively define how data should be standardized across authorized products, investigational products and substances (drug substances and excipients). Set to be implemented in the EU by July 2016 and with no official implementation guidelines, available pharmaceutical companies struggle to devise strategies that support compliance and continuous maintenance. Will you wait until the official implementation guideline is published (thereby possibly not meeting the deadline) or

will you use the draft implementation guideline published by ISO as a blueprint for your strategy? How can IDMP be transformed from yet another regulatory burden into a value adding activity that supports enterprise architecture activities across your company?

Lior Keet, MBA
Vice President, Life Sciences R&D, HighPoint Solutions

Representative Invited
Consultant, Chicopee Falls Consulting LLC

Niels Gronning, MSc
Principal Consultant, NNIT A/S, Denmark

Track 08A – Regulatory Affairs

Related Interest Area(s): CR, PETD

8:00–9:30 AM Level: ■ Format: SESSION

Can We Talk? Alternative Strategies for Communicating with FDA

CHAIRPERSON:

Kim M. Quaintance
Head, US Regulatory Policy, Bayer HealthCare Pharmaceuticals

Experienced regulatory professionals know that formal meetings are insufficient to address all the issues that arise during drug development. Our panel will discuss best practices and innovative ways to ensure optimal communications with FDA.

Mark A. Ammann, PharmD
President, Catalyst Regulatory Services, LLC

Khyati Roberts, RPh
Senior Director, Regulatory Policy and Intelligence, AbbVie

Representative Invited
Lead Consumer Safety Officer, Office of New Drugs, CDER, FDA

Track 08B – Regulatory Affairs

Related Interest Area(s): CR

8:00–9:30 AM Level: ■ Format: SESSION

Global Regulation of Advanced Therapies

CHAIRPERSON:

Gopalan Narayanan, MD, FFPM, FRCP
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

Advanced Therapies offer ground-breaking treatment for many diseases that could not be treated previously. Recently, treatments for conditions such as prostate cancer and cartilage regeneration have been approved in the EU. These innovative products are regulated differently by health authorities across the globe. Is it a biologic, a drug, a device, or a combination product? This session will examine the regulatory requirements and classification issues specific to these types of products.

Gopalan Narayanan, MD, FFPM, FRCP
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

Representative Invited
Senior Researcher; Chair, Committee for Advanced Therapies (CAT), The Finnish Medicines Agency (Fimea), Finland

Representative Invited
Vice President, Regulatory Affairs, Genzyme Corporation, A Sanofi Company

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA

8:00–9:30 AM Level: ■ Format: FORUM

Pediatric Therapeutic Development: From Policy to Portfolios to Patients

CHAIRPERSON:

Timothy R. Franson, MD
Chief Medical Officer, YourEncore

This forum will examine the need for and challenges surrounding pediatric therapeutic development, and explore how policy makers, life science

companies, and patient groups can work together to advance the development of pediatric therapies.

Michelle Taylor McMurry-Heath, DrMed
Vice President, Worldwide Regulatory Affairs, Johnson & Johnson

Stephen P. Spielberg, MD, PhD
Editor in Chief, DIA Publications, DIA

Representative Invited
Head, Health Biosciences Practice, FaegreBD Consulting

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

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

8:00–9:30 AM Level: ■ Format: SESSION

FDA GCP Compliance and Enforcement Updates

CHAIRPERSON:

Representative Invited
Office Director, Office of Scientific Investigations, Office of Compliance, CDER, FDA

This FDA cross-center session will provide updates on GCP compliance and enforcement activities with a special focus on eClinical technologies in the conduct of clinical trials.

Representative Invited
Branch Chief, Bioresearch Monitoring, Office of Compliance and Biologics Quality, CBER

Representative Invited
Director, Division of Bioresearch Monitoring, Office of Compliance, CDRH

Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC/GMP

8:00–9:00 AM ▲ Level: ■ Format: SESSION

Learning By Doing: Regulatory Applications for Breakthrough Therapies

CHAIRPERSON:

Representative Invited
Supervisory Chemist, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA

This session will focus on lessons learned for regulatory considerations regarding drug development of breakthrough therapies, with an emphasis on the innovative approaches to consider for submission of chemistry, manufacturing and control information in breakthrough (or otherwise expedited) submissions.

Representative Invited
Medical Officer, Office of New Drugs, CDER, FDA

Track 13A – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): SE, RA

8:00–9:30 AM Level: ■ Format: SESSION

Remember That? Choosing Recall Intervals for Patient-Reported Outcome Measures

CHAIRPERSON:

Chad Gwaltney, PhD
Chief Scientist and Regulatory Advisor, Endpoints, ERT

Choosing the right recall interval – the time that patients are asked to consider – is critical when using a patient-reported outcome instrument to measure treatment outcomes. This session will include regulatory and scientific perspectives on selecting recall intervals.

Chad Gwaltney, PhD
Chief Scientist and Regulatory Advisor, Endpoints, ERT

Representative Invited
Director of the Center for Self-Report Science; Professor of Psychology, University of Southern California

Representative Invited
Medical Officer, Study Endpoints Labeling Development, Office of New Drugs, CDER, FDA

Track 13B – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): PR

8:00–9:30 AM Level: ■ Format: SYMPOSIUM

Emerging Practices in Product Commercialization Planning: How Cross Collaboration Is Redefining Product Development Planning

CHAIRPERSON:

Alberto Grignolo, PhD
Corporate Vice President, PAREXEL International

Economic pressures on drug pricing/ reimbursement require that companies plan market access early in development, promote clinical/regulatory/commercial collaboration and execute the right studies to provide evidence to both regulators and payers.

Cyril P. Clarke, DrMed, MD
Vice President, Translational Medicine, ICON Clinical Research, United Kingdom

Richard N. Williams, JD, PhD
Senior Director Global Regulatory Strategy, Covance Inc.

Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CR

8:00–9:30 AM Level: ■ Format: SESSION

Social Media: Opportunities and Challenges in Pharmacovigilance and Clinical Research

CHAIRPERSON:

Representative Invited
Monitoring and Incident Management, Pharmacovigilance, European Medicines Agency, European Union

This session will discuss the potential of social media as a new data source in the early detection of safety issues related to medicines. Social media usage has increased substantially within the last five years, including the creation, sharing or exchange of information on health-related topics and has already shown promise in the management of disease outbreaks, for example. Therefore, the expectation is that the use of data from a real-world, large-scale population of consumers and patients will result in more comprehensive and timely information about the safe use of medicines. However, this new data source also brings a number of challenges such as compliance with data privacy requirements, ethical aspects or risks in compromising clinical research results, which will be further outlined. Lessons learned from MedWatcher Social as well as the approach towards social media analytics currently being researched in the context of the Innovative Medicines Initiative (IMI) WEB-Recognising Adverse Drug Reactions (RADR) project will be discussed.

Alexis Reisin Miller, JD
Senior Director, Regulatory Policy and Intelligence, Eisai Inc.

Representative Invited
Manager, Computational Epidemiology Group and Associate Professor, Boston Children's Hospital and Harvard Medical School

Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): BT, CmbP

8:00–9:30 AM Level: ■ Format: SESSION

Safety in Special Situations: Vaccines, Stem Cells and Beyond

CHAIRPERSON:

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

This symposium will provide insights on the key safety considerations influenced by product specific attributes of vaccines, stem cells and novel combination therapies.

Julia Barrett, MD, MPH
Senior Clinical Consultant, Biologics Consulting Group, Inc.

Curtis L. Scribner
CLSCRIBS Consulting

Representative Invited
President and Chief Operating Officer, Kinexum

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, ST

8:00–9:30 AM Level: ■ Format: SESSION

New Challenges for a Data Monitoring Committee

CHAIRPERSON:

Yeh-Fong Chen, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Data monitoring committees (DMCs) can monitor the safety of a drug and weigh risk and benefit for stopping a trial early. In this session, we will discuss the importance of DMCs concerning the best practices of maintaining confidentiality of interim data and the recent Part 15 public hearing. The main focus will be how careful consideration of statistical inputs (e.g., planning for multiple looks) will improve DMCs' efficiency and ensure the trial's integrity.

Representative Invited
Director, Office of Biostatistics, Office of Translational Science, CDER, FDA

Representative Invited
Medical Officer, Office of New Drugs, CDER, FDA

Walter Offen, Esq, PhD
Global Head of Statistical Innovation & Safety Statistics, AbbVie

Track 16 – Professional Development

Related Interest Area(s): CR, PETD

8:00–9:00 AM ▲ Level: ■ Format: SESSION

Moving the Role of the CRC and CRA into the 21st Century: Opportunities and Challenges

CHAIRPERSON:

Terri Hinkley, BSN, MBA, RN
Deputy Executive Director, Association of Clinical Research Professionals (ACRP)

The clinical research industry continues to evolve at a rapid rate. Changes and/or clarification in regulatory guidelines are requiring sites to increase their quality control and trial oversight activities, typically by the clinical research coordinator (CRC) and continue to change the traditional role of the study monitor. This session will explore the changes in each role as well as the opportunities to continue the evolution of both roles. Current training needs for each role will be evaluated and the next steps required of all stakeholders will be discussed.

Lisa C. Feeney, MBA
Vice President, Clinical Operations, ExecuPharm, Inc.

Claudia Christy
Consultant

Track 17 – Rare/Orphan Diseases

Related Interest Area(s): RA

8:00–9:00 AM ▲ Level: ■ Format: SESSION

How to Succeed in Orphan Drug Regulatory Affairs

CHAIRPERSON:

Timothy R. Cote, MD, MPH
President and Chief Executive Officer, Cote Orphan LLC

In this session, orphan drug thought leaders will share their insights about how to succeed in orphan regulatory affairs. Orphan drug development begins with designation, and we will explain what does not work when submitting to the Office of Orphan Products Development. Moving from designation to the review division process, we will provide a quantitative analysis of the special treatment afforded orphan drugs by the FDA's review divisions. We will also include a European perspective on the orphan drug endeavor, reviewing the unique European approach to the way orphan drugs become licensed in the European community. We will present a picture of orphan drug regulatory success drawn from thousands of regulatory actions from their collective experience.

Timothy R. Cote, MD, MPH
President and CEO, Cote Orphan LLC

James E. Valentine, JD
Associate, Hyman, Phelps & McNamara, PC

Representative Invited
Group Director, Regulatory Affairs and CSO, ERA Consulting Ltd., United Kingdom

Track 18 – Global Regulatory

Related Interest Area(s): CP, RA

8:00–9:30 AM Level: ■ Format: FORUM

PMDA Town Hall

CHAIRPERSON:

Toshiyoshi Tominaga
Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Representatives from PMDA will explain the progress of its third Five-Year Mid-Term plan, including the future initiative/challenges for faster review and better life cycle management of drugs. The audience will be provided an opportunity to ask questions to the panel.

Representative Invited
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

Tomiko Tawaragi
Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Track 01 – Clinical Operations

Related Interest Area(s): PT

10:30 AM–12:00 PM Level: ■ Format: FORUM

How Pharmaceutical Companies Can Engage Responsibly with Patients Online

CHAIRPERSON:

Joe Hathaway
Executive Communications Specialist, Bayer HealthCare Pharmaceuticals

Pharmaceutical companies can no longer afford to ignore online patient opinion leaders (POLs). Case studies will demonstrate how companies can successfully engage online with patients.

Representative Invited
Region Head US, Senior US Bayer Representative, Bayer HealthCare Pharmaceuticals

Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PETD

10:30 AM–12:00 PM Level: ● Format: FORUM

Better Team Performance in Drug Development: Effective Relationship Building Across Cultures, Especially the West and Asia

CHAIRPERSON:

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

Building trusting relationships among members is one of the keys to success for any team. We will discuss how the relationships should be formed and maintained, paying particular attention to diverse teams that comprise members from the West and Asia.

Robert A. Hilke, MA
Chief Executive Officer, Hilke Communications Corporation, Japan

Gareth Julian Monteath, MBA, MS
Program Director, Link Global Solution Inc., Japan

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

Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): RD, PM

10:30 AM–12:00 PM Level: ◆ Format: FORUM

Recent Trends in Facilitating Decision Making in Drug Development

CHAIRPERSON:

Akhil Agrawal, PhD, MBA, PMP
Associate Director, Janssen Pharmaceuticals, Inc.

This forum will focus on sharing best practices on facilitating decision making while adapting to recent industry trends which impact R&D projects. Presentations including case studies will be provided followed by an open forum discussion.

Jay Armstrong, MBA, MS, MSc
Principal Consultant, Pharmica Consulting

Representative Invited
Group Director, Biopharma Project Management, Bristol-Myers Squibb Company

Jennifer Ikeda, MBA, PMP
Principal, Acuity Advantage Consulting, LLC

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, CS

10:30 AM–11:30 PM ▲ Level: ■ Format: SESSION

Taking the Pulse of Outsourcing Relationship Structures and Their Impact

CHAIRPERSON:

Kenneth A. Getz, MBA
Chairman, CISCRP; Director of Sponsored Research, Tufts Center For the Study of Drug Development

This session examines the results and implications of a recent study conducted by the Tufts Center for the Study of Drug Development (Tufts CSDD) that looked at 43 phase 2 and 3 clinical studies completed since 2012 to evaluate actual sponsor company outsourcing practices. The study also performed an in-depth assessment of sponsor company attitudes and perceptions about their current and future outsourcing strategies. Study results indicate that sponsor companies are inconsistently mixing and matching relationship models on a study-by-study basis and that they are planning a number of major changes to their outsourcing strategies and practices.

Representative Invited
Senior Director, Clinical Operations Vendor Oversight, Biogen Idec

Kenneth A. Getz, MBA
Chairman, CISCRP; Director of Sponsored Research, Tufts Center For the Study of Drug Development

Track 04 – Preclinical and Translational Development/ Early Phase Clinical Development

Related Interest Area(s): NC, RA

10:30 AM–12:00 PM Level: ■ Format: SESSION

Navigating Complex Biological and Regulatory Pathways to Bring Novel Gene and Cell Therapies to the Clinic

CHAIRPERSON:

Lois M. Hinman, PhD
Executive Director, Regulatory Affairs, Cell and Gene Therapy, Novartis Pharmaceuticals Corporation

An overview of the global status of regulatory guidance for cell and gene therapy will be presented. Early development and regulatory challenges for moving these novel therapies from the bench to the clinic will be discussed through case studies.

Gopalan Narayanan, MD, FFPM, FRCP
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

Anne-Virginie L. Eggimann, MS
Vice President, Regulatory Science, Bluebird Bio, Inc.

Timothy Maclachlan, PhD
Executive Director, Preclinical Safety, Novartis Institutes for BioMedical Research (NIBR)

Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

Related Interest Area(s): RA

10:30 AM–12:00 PM Level: ■ Format: FORUM

FDA Enforcement Update: Advertising and Promotion

CHAIRPERSON:

Philomena McArthur, JD
Senior Director, Regulatory Advertising and Promotion Pharmaceutical Group HCC, Johnson & Johnson International

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, FDA representatives will examine the latest

agency enforcement actions and policies and what they mean.

Representative Invited
Director, Office of Prescription Drug Promotion, CDER, FDA

Representative Invited
Branch Chief, Advertising and Promotional Labeling Branch, CBER, FDA

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

Related Interest Area(s): MW

10:30–11:30 AM ▲ Level: ● Format: SYMPOSIUM

Efficient Authoring of Submission Documents

CHAIRPERSON:

Linda Fossati Wood, MPH, RN
President, MedWrite, Inc.

This symposium will discuss the processes around the preparation of complex summary documents included in Investigational New Drug (IND) applications and New Drug Applications (NDA). We will explore options for planning the timing for authoring Modules 2.4 through 2.7 of the IND and integrated and clinical summaries of the NDA to maximize efficiency and capitalize on synergies between the different documents. We will discuss approaches for handling common challenges and significant changes in scope while still maintaining high-quality deliverables that meet submission deadlines.

Lisa Pierchala, MPH
Principal Medical Writer, MMS Holdings Inc.

Rachael Eckert, DVM, PhD
Principal Medical Writer, PPD, Inc

Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, RA

10:30 AM–12:00 PM Level: ■ Format: SESSION

FDA Study Data Technical Conformance Guide (Part 1 of 2): An Overview

CHAIRPERSON:

Ron Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

This session will provide an overview of the FDA supplements guidance "Providing Regulatory Submissions in Electronic Format — Standardized Study Data" and provides recommendations on submitting standardized study data using FDA-supported data standards specified in the Standards Catalog.

Part 2 will take place on Tuesday, at 1:30pm.

Representative Invited
Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Representative Invited
Lead Medical Officer, Office of Computational Sciences, Office of Translational Sciences, CDER, FDA

Representative Invited
Business Integrator and Consultant, Data Sciences, Eli Lilly and Company

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): VA, CR, MDD

10:30 AM–12:00 PM Level: ● Format: SESSION

How to Trust Data from Wearable Devices Used in Clinical Trials

CHAIRPERSON:

Hitoshi Matsui
Executive Officer General Manager Regulatory Compliance Audit Group, CAC EXICARE Corporation, Japan

It appears that wearable medical devices do not pay as much attention to data quality and

integrity as our GxP computerized systems that store the data. This session will identify wearable devices and discuss how to qualify data so that they meet good practice guidelines.

Representative Invited
Specialist, Chugai Pharmaceutical Co., Ltd., Japan

Track 08A – Regulatory Affairs

Related Interest Area(s): OS, CR

10:30 AM–12:00 PM Level: ■ Format: SESSION

Good Regulatory Practice (GRP): A Regulatory Affairs Quality System for the 21st Century

CHAIRPERSON:
Peter Deegan, Esq, MBA
Senior Director, GRP Quality Assurance, AstraZeneca Pharmaceuticals LP, United Kingdom

Regulatory affairs stands in the center of the business value-chain. The session discusses how a formal Good Regulatory Practice Quality System will de-risk key commercial strategies and increase the value-proposition of the regulatory function.

Peter Deegan, Esq, MBA
Senior Director, GRP Quality Assurance, AstraZeneca Pharmaceuticals LP, United Kingdom

Jean Samuel
Chief Quality Officer, Kinapse Ltd, United Kingdom

Track 08B – Regulatory Affairs

Related Interest Area(s): CR

10:30 AM–12:00 PM Level: ■ Format: SESSION

The State of Pediatric Research in the United States

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

Pediatric research in the US has been evolving for the past 20 years. With the 2012 passage of permanant legislation to support pediatric research we are at the dawn of a new age to enable the availability of medicines for children.

Donna L. Snyder, MD
Medical Officer, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

Representative Invited
Supervisory Consumer Safety Officer, Office of New Drugs, CDER, FDA

Representative Invited
Executive Director, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corporation

Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): RA, MDD

10:30 AM–12:00 PM Level: ■ Format: FORUM

Impact of FDA Oversight of Laboratory-Developed Tests Upon Innovation in the Targeted Therapy Setting

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

The recently-announced FDA framework on regulation of laboratory-developed tests will impact codevelopment and uptake of targeted therapies and their companion diagnostics. This forum will debate the merits of this evolving regulatory paradigm.

Representative Invited
Director, Personalized Medicine Staff, CDRH, FDA

Michael Benecky, PhD
Senior Director, Global Regulatory Affairs-Diagnostics, GlaxoSmithKline

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR, RA

10:30 AM–12:00 PM Level: ■ Format: SESSION

Risk-Based Quality Management in Clinical Trials: From the Vision to Its Regulation and Implementation

CHAIRPERSON:

Representative Invited
Head of Compliance and Inspections Department, European Medicines Agency, European Union

This session will provide an overview on the regulator's vision to risk-based approaches and how some of these expectations are intended to be regulated through the ICH E6 GCP guideline and the challenges faced by industry in translating those expectations in the design and conduct of clinical trials.

Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA

10:30 AM–12:00 PM Level: ■ Format: FORUM

Office of Pharmaceutical Quality Update

CHAIRPERSON:

Representative Invited
Director (Acting), Office of Pharmaceutical Science, CDER, FDA

This forum will discuss the new structure of the Office of Pharmaceutical Quality (OPQ) and describes how, along with new processes and policies, this alignment further enhances FDA's Center for Drug Evaluation and Research (CDER) quality initiative by creating a drug quality program as robust as the programs the agency already has in place for drug safety and efficacy. OPQ will streamline FDA processes that monitor drug quality throughout the product life cycle, including drug application review, postapproval improvements, and surveillance and inspections of global manufacturing facilities.

Representative Invited
Director, Center for Drug Evaluation and Research, FDA

Representative Invited
Acting Director, Office of New Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

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

10:30 AM–12:00 PM Level: ■ Format: FORUM

Breakthrough Medicines or Affordable Health Care: Do We Have to Choose?

CHAIRPERSON:

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

A recent study by the Tufts Center for the Study of Drug Development reported that it cost $2.6 billion to bring a new medicine to market, more than double the cost of a decade ago. This high cost of development highlights the importance for drug sponsors to generate an adequate rate of return on their investment. However, as overall health care costs continue to rise, pharmaceutical companies are under increasing pressure to demonstrate the economic value of their products and justify prices. In this forum, panelists will explore the potentially competing demands for innovative breakthrough medicines and health care cost containment, and will examine regulatory initiatives and new business practices geared toward boosting innovation while lowering treatment costs.

Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): NC, RA

10:30 AM–12:00 PM Level: ■ Format: FORUM

21st Century Pharmacovigilance: Improving Outcome Traceability for Products Across the Complexity Continuum, From Generics to Biologics and Vaccines

CHAIRPERSON:

Thomas Felix, MD
Director, Research and Development Policy, Amgen Inc.

In this forum, we will focus on the rationale for and implications of revisions to current postapproval generic manufacturer accountability expectations in the United States. Also, to better understand potential gaps that may exist in the adverse event reporting process for all medications, we will hear the results of two surveys, one assessing the experience for consumers and another detailing the experience for health professionals in various settings.

Leonardo Ebeling, MD, PhD
Managing Director, Dr. Ebeling & Assoc. GmbH, Germany

Stella Stergiopoulos
Senior Project Manager, Tufts Center For the Study of Drug Development

Rodney Peters
Pharmacoviglance Manager, CLEVER Collaboration, Australia

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR

10:30 AM–12:00 PM Level: ● Format: FORUM

The Impact of Adaptive and Bayesian Approaches to Improving the Efficiency of Clinical Trial Design and Analysis

CHAIRPERSON:

Jerald S. Schindler, DrPH
Vice President, Biostatistics and Research Decision Sciences, Merck Research Laboratories

Recent research has demonstrated that clinical trials are becoming too cumbersome and complex. This forum will illustrate how research from the DIA scientific working groups has an impact on designing focused trials with a reduction in trial complexity and cost.

This forum has been developed by the DIA Adaptive and the Bayesian Scientific Working Groups.

Track 16 – Professional Development

Related Interest Area(s): PETD

10:30 AM–12:00 PM Level: ● Format: WORKSHOP

Networking: It's Not What You Know, But Who You Know!

CHAIRPERSON:

Bob Muzerall
Vice President, Sales and Sales Training, ForeignExchange Translations

Participants in this workshop will build the confidence to step into a variety of networking situations. Small group activities will enhance the interactive experience. Participants will leave the workshop with networking tools and techniques.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington Convention Center 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 offering will not be recorded.*

Christopher Matheus, MBA
Director, Business Development, Y- Prime

Track 17 – Rare/Orphan Diseases

Related Interest Area(s): RD, CR

10:30 AM–12:00 PM Level: ■ Format: SESSION

Rare Disease Organizations and Industry Players: Collaborating Effectively to Advance R&D for Rare Disease Patients

CHAIRPERSON:

Badri Rengarajan, DrMed
President, Board of Directors, International Pemphigus and Pemphigoid Foundation

Biopharmaceutical companies have increasingly shifted their efforts toward developing drugs for rare/orphan diseases. Working with rare disease organizations can be very helpful to development efforts in terms of educating development teams about patient population and unmet needs, connecting teams to scientific and clinical experts, and mobilizing patients for trial recruitment. While there are many potential benefits, there are concerns on both sides. This panel discussion will address issues and concerns from multiple perspectives with an aim to identifying best

ways for organizations and companies to work comfortably and effectively with one another.

Ronald Joseph Bartek, MA
President/Co-Founder, Friedreich's Ataxia Research Alliance (FARA)

Representative Invited
Founding President and CEO, Parent Project Muscular Dystrophy

Representative Invited
Associate Director, Advocacy Relations, Genentech, A Member of the Roche Group

Track 18 – Global Regulatory

Related Interest Area(s): RA, CR

10:30 AM–12:00 PM Level: ■ Format: FORUM

FDA's International Posts: International Efforts, Regulatory System Strengthening and Inspections

CHAIRPERSON:

Representative Invited
Assistant Commissioner and Deputy Director, Office of International Programs, Office of Global Regulatory Operations and Policy, FDA

FDA has international posts in China, India, and Latin America that perform foreign facility inspections, outreach to foreign regulators, and protect supply chains by using risk-based global surveillance and emergency response.

Representative Invited
Country Director, China Office, Office of International Programs, Office of the Commissioner

Representative Invited
Acting Country Director, India Office, Office of the Commissioner

Track 19A – Late-breaking Topics

Related Interest Area(s): CR

10:30 AM–12:00 PM Level: ● Format: SESSION

Using Registries to Support Recruitment in Alzheimer's Disease (AD) Prevention or Delay-of-Onset Studies

CHAIRPERSON:

Craig A. Metz, PhD
Senior Vice President, Zinfandel Pharmaceuticals, Inc.

This session will present strategic considerations for using registries to recruit subjects for trials on delay of onset of mild cognitive impairment due to AD, including development and regulatory issues and experience from an ongoing study.

Track 19B – Late-breaking Topics

Related Interest Area(s): CmbP

10:30 AM–12:00 PM Level: ■ Format: FORUM

Regulation of Combination Products in the 21st Century

CHAIRPERSON:

Michelle Taylor McMurry-Heath, DrMed
Worldwide Regulatory Affairs, Johnson & Johnson

This forum will focus on the regulatory challenges facing combination product development and pending US legislative proposals to address them. Panelists will explore the influence of and impact on global regulatory policy for combination products.

Representative Invited
Senior Counsel, FDA, Committee on Health, Education, Labor and Pensions

Track 20 – Innovation Theater

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

1:00–1:30pm Level: ■ Format: SPECSESS

Veeva Innovation Theater: 2015 Paperless Trial Master File (TMF) Survey: Trends and Insights

Hear results from the follow up to Veeva's benchmark 2014 Paperless TMF Survey, which analyzed the observations of 252 trial master file (TMF) owners to identify the barriers, business drivers, and benefits of moving to fully paperless TMFs. Learn how much has changed in just one year as organizations move along the TMF maturity spectrum. See how your organization compares and discover why some benefit more than others.

Track 01A – Clinical Operations

Related Interest Area(s): PT, MC

1:30–3:00 pm Level: ● Format: FORUM

Engaging Patients as Partners: Effective Trial Communications to Build Trust and Improve Patient Participation

CHAIRPERSON:

Laurin Council Mancour
Account Executive, Trial Results Communication Programs, Center For Information and Study On Clinical Research Participation (CISCRP)

In this forum, we will describe a simple and scalable process to share overall trial results in a patient-friendly format to patients who participate in a trial. We will also provide data on the impact of sharing these results with patients from patients' and sites' perspective, as well as risks and best practices of implementing this approach globally in a clinical trial program.

Lara Chayab, MSc
Patient Recruitment Strategist, Hoffmann-La Roche Ltd., Canada

Elly J. Cohen
Program Director, Breastcancertrials.org

Track 01B – Clinical Operations

Related Interest Area(s): CR

1:30–3:00 pm Level: ■ Format: SESSION

Implementing Risk-Based Monitoring: Best Practices from Pharmaceutical Industries to Contract Research Organizations

CHAIRPERSON:

Warren H. Pence
Associate Director, Adaptive and Intelligent Monitoring, PPD, Inc

This session will provide attendees with practical and useful "take-home" information and best practices that can be used by their organizations in the development and implementation of a risk-based monitoring (RBM) strategy.

Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, CP

1:30–3:00 pm Level: ● Format: SESSION

Life Cycle and Portfolio Management: Regulatory Agency and Pharmaceutical Company Approaches

CHAIRPERSON:

Mark A. Kryah, PMP
Senior Advisor/COO, Pharmaceutical Project Management, Eli Lilly and Company

Portfolio management and life cycle management are critical elements in pharmaceutical development, key to optimizing the value of an aggregate of assets and to optimizing the value of an individual asset. This session will provide regulatory agency and industry perspectives as well as examples of these important business processes.

Representative Invited
Director of Office of Planning, Performance and Review Services, Health Canada

Jill Bourdage, RPh, PMP
Director, Project Management; Associate Director Regulatory Affairs, Office of Surveillance and Epidemiology, CDER, FDA

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RD

1:30–2:30 PM ▲ Level: ■ Format: SESSION

Collaborate to Innovate: Exploring a Seconds Market

CHAIRPERSON:

Doris Thomas Pereira, MBA
Assistant Manager, International Operations Department, Torrent Pharmaceuticals Limited, India

In light of declining R&D productivity, increasing R&D costs and the impending patent expiration of blockbuster drugs, the pipeline attrition of molecules, especially in the advanced stages of development, where costs of conducting clinical trials are the greatest, have resulted in an alarming rise in R&D costs. With proven safety and efficacy in the initial phases, these molecules possess a potential of being developed into a blockbuster. Developing strategic alliances to outsource or sell such developmental molecules may result in the same being tried for new indications. With existing data, innovative start-ups or smaller pharmaceutical firms can develop new molecules that may cater to huge unmet patient needs across the globe in critical therapeutic areas. This session will examine these strategic partnerships as well as the advantages and challenges of developing a seconds" market."

Representative Invited
Professor, Pharma Management, Narsee Monjee Institute of Management Studies, India

Nermeen Y. Varawalla
Executive Vice President Global Clinical Trials, Lambda Therapeutic Research, United Kingdom

Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

Related Interest Area(s): IT, MA, AP

1:30–3:00 PM Level: ■ Format: SESSION

Essential Approaches to Promotional Review of Mobile Health Apps: Technology That is Here to Stay and Evolving Fast

CHAIRPERSON:

Sheetal Patel, PharmD
Director, Regulatory Advertising and Promotion, US Pharma Group HCC, Johnson & Johnson International

Mobile health, supported by mobile devices, is expected to be a $26 billion industry by 2017. With over 97,000 health and fitness related mobile apps currently on Google Play and Apple App Store, and 4 million downloads per day, it is difficult to deny the rising popularity of the industry. Mobile apps can help people manage their own health and wellness, promote healthy living, and gain access to useful information when and where they need it. These tools are being adopted almost as quickly as they can be developed. This session will focus on how the promotion of these products is regulated, the current regulatory standards that apply, and important considerations for a company's promotional review committee.

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

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

1:30–3:00 PM Level: ■ Format: SYMPOSIUM

Tool is a Good Four-Letter Word

CHAIRPERSON:

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

This symposium will describe software tools that facilitate the creation of regulatory documents included in an electronic common technical document (eCTD)-based drug application.

Susan Bairnsfather, MSc
CEO, Regulatory Writer, Regulatory Affairs Professional and Statistical Analyst, EPharmaTech LLC

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

Ann Rockley, MLIS
President, The Rockley Group Inc., Canada

Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): EC, PT

1:30–2:30 PM ▲ Level: ■ Format: SYMPOSIUM

Developing Online Communities: Perspectives for Site and Patient Engagement

CHAIRPERSON:

Representative Invited
Founding Principal, BBK Worldwide

This symposium will explore how to leverage social media concepts and tools to provide collaborative and engaging learning and sharing between investigators involved in a clinical trial or program. Speakers will also overview experiences to date with providing and maintaining an alumni community for patient participants.

Nancy Mulligan
Senior Director, Operations, Patient and Physician Services, UBC: An Express Scripts Company

Vladimir Pyagay
Clinical Solutions Manager, Transperfect

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, SUBS

1:30–3:00 PM Level: ■ Format: FORUM

FDA Study Data Technical Conformance Guide (Part 2 of 2): An Interactive Q&A Session

CHAIRPERSON:

Representative Invited
Biostatistical Reviewer, Division of Biometrics III, Office of Translational Sciences, Office of Biostatistics, CDER, FDA

This FDA guide supplements the guidance "Providing Regulatory Submissions in Electronic Format — Standardized Study Data" and provides recommendations on submitting standardized study data using FDA-supported data standards specified in the standards catalog. In this forum, the panelists will participate in an interactive Q&A with the audience.

Part 1 will take place on Tuesday, at 10:30AM.

Representative Invited
Interdisciplinary Scientist, Division of Data Management Services and Solutions, Office of Business Informatics, Office of Strategic Programs, CDER, FDA

Representative Invited
Regulatory Information Specialist, Office of Translational Sciences, CDER, FDA

Representative Invited
Project Management Officer, Office of Business Informatics, Office of Strategic Programs, CDER, FDA

Track 08 – Regulatory Affairs

Related Interest Area(s): SUBS

1:30–3:00 PM Level: ■ Format: SESSION

Transatlantic Collaboration on Pediatric Study Plan (PIP)/Pediatric Investigation Plan (PSP): Recent Experience

CHAIRPERSON:

Mette Due Theilade Thomsen, PhD
Principal Scientist, Novo Nordisk A/S, Denmark

This session will discuss the US Pediatric Study Plan (PSP) and the EU Pediatric Investigation Plan (PIP), the timing of submissions, and the significant differences that still remain in the specific requirements from the two regulatory agencies.

Christina Bucci-Rechtweg, DrMed, MD
Global Head, Pediatric and Maternal Health Policy, Novartis Pharmaceuticals Corporation

Representative Invited
Director, Office of Pediatric Therapeutics, Office of Special Medical Programs, Office of Medical

Products and Tobacco, FDA

Representative Invited
European Medicines Agency, European Union

Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): MDD

1:30–3:00 PM Level: ■ Format: SESSION

Success from Bench to Launch: Challenges and Opportunities with Development of Companion Diagnostics

CHAIRPERSON:

James Allen Wachholz, MBA
Vice President, Drug Development, ICON Clinical Research

Experts from the field of companion diagnostics and targeted therapy will present their individual views on companion diagnostics development methdology, clinical trial designs, developing efficient and optimal integration of clinical trials and diagnostic use.

Erling Thor Donnelly, PhD
Team Leader, Dacomitinib and Palbociclib, Oncology, Pfizer Inc

Representative Invited
Director, Personalized Medicine Staff, CDRH, FDA

Representative Invited
Principal, Syner-G Pharma

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): MDD

1:30–3:00 PM Level: ■ Format: FORUM

The Challenges and Opportunities of Digital Health Care: What Does the Future Hold?

CHAIRPERSON:

Maria Isabel Manley, LLM
Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

This forum will explore the legal, ethical and commercial issues arising in the context of digital health and will assess how the rapid pace of innovation in this sector has impacted the dynamic of health care provision.

This forum was developed by the Legal Affairs and Ethics and Medicines Lifecycle DIA Communities.

Maria Isabel Manley, LLM
Partner, Head of the Regulatory Legal Group, Bristows LLP, United Kingdom

Wendy Louise Lipworth, MD, PhD
Senior Research Fellow, Centre for Values, Ethics and the Law in Medicine, University of Sydney, Australia

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR

1:30–3:00 PM Level: ■ Format: SESSION

Roadmap to Measuring Clinical Trial Quality

CHAIRPERSON:

Leslie M. Sam
Director, Global Quality Systems, Eli Lilly and Company

The quality movement has not delivered the promised benefits, despite decades of promotion and the endorsement of health authorities. In this session, we will review the evolution of the quality movement, diagnose the issues, and suggest a path forward.

Michael Howley, PhD
Associate Clinical Professor, Drexel University

Linda B. Sullivan, MBA
Co-Founder & President, Metrics Champion Consortium LLC

Representative Invited
Global Lead, Compliance Analytics and Intelligence, Pfizer Inc

Track 12 – Pharmaceutical Quality

Related Interest Area(s): MF, CM

1:30–2:30 PM ▲ Level: ■ Format: FORUM

Continuous Improvement and Innovation

CHAIRPERSON:

Patricia N. Hurter, PhD, MS
Senior Vice President, CMC & Pre-Clinical Development, Vertex Pharmaceuticals

This forum will present and facilitate discussion on the benefits of implementing or modifying a product life cycle management program in both manufacturing and regulatory environments.

Michael K. O'Brien, PhD
Vice President, Technology and Innovation, Pfizer Inc

Andrew Mark Buswell, PhD, MBA
Head of Advanced Manufacturing Technologies, GlaxoSmithKline, United Kingdom

Track 01A – Clinical Operations

Related Interest Area(s): CR

3:30–5:00 PM Level: ■ Format: SYMPOSIUM

Bringing Clinical Trial Practices into the 21st Century

CHAIRPERSON:

Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

In this symposium, we will look at how flexible, innovative mobile and digital technology can provide support throughout the product life cycle (from clinical research to real world environments). We will also take a retrospective walk and a futuristic stroll through the patient recruitment strategies of yesterday and tomorrow, determining how the findings can be applied to provide the best participant experience when designing patient support programs. A review of technology-based patient engagement strategies will be performed, including both the barriers and recommendations for optimal implementation.

Furthermore, we will investigate the increasingly important role of the ubiquitous mobile device in running many aspects of today's clinical trials, and how the sponsors now look to specialist vendors to provide services that incorporate this now essential element into their study practices (enabling the pharmaceutical companies to focus on their core skill of drug development).

Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

Cecilia Tran-Muchowski
Senior Clinical Program Manager, Gilead Sciences, Inc.

Jennifer M. Allen, BSN, MBA
Senior Manager, Client Engagement, UBC: An Express Scripts Company

Matthew Stumm
Principal, Creative and Media Strategy, BBK Worldwide

Track 01B – Clinical Operations

Related Interest Area(s): CR, PM

3:30–5:00 PM Level: ● Format: SESSION

Pediatric Clinical Trials: One Size Does Not Fit All

CHAIRPERSON:

Kathryn Bohannon
Vice President, Global Project Management, inVentiv Health

In designing a pediatric study, each aspect must be thoughtfully considered and adjusted as necessary based upon the pediatric participants. In this session, we will examine the many factors that complicate clinical trials in children.

Representative Invited
Executive Director, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corporation

Representative Invited
Pediatric Medical Officer, National Instiute of Child Health and Human Development, NIH

Eric Deurell, MD, MBA
Medical Director, Pediatric Pharmaceutical Consultants

Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PM, PETD

3:30–5:00 PM Level: ◆ Format: FORUM

A Critical Examination of the Strengths and Weaknesses of Different Project Management Models

CHAIRPERSON:

Richard J. Heaslip, PhD
Founder, Programmatic Sciences LLC

This forum will review the strengths and weaknesses of project management models commonly used for managing development projects in life science organizations. It will then explore how to define the best approach(es) for managing projects in any given organization.

Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): CR, MDD

3:30–5:00 PM Level: ◆ Format: FORUM

How Biomarkers Can Be Leveraged to Improve Return on Investment in Drug Development

CHAIRPERSON:

Eva Finney
Director, Global Project Management, Merck & Co., Inc.

Diminishing returns on investment have plagued the pharmaceutical industry in the last decades. This forum will explore how appropriate use of biomarkers can increase return on investment, either by facilitating earlier "no go" decisions, reducing clinical trial costs, improving the probability of success, or accelerating drug development for faster time to market. Case studies using molecular imaging and immunoassays will be presented. Execution challenges associated with incorporating biomarkers and companion diagnostics into a clinical program will be highlighted, as well as some solutions to these challenges. Finally, the regulatory pathway for using the diagnostic tools in clinical trials and registering postmarketing will be explained.

Robert Scarimbolo
Manager, Molecular Imaging, BioClinica

Rachel Yarger, MBA, PMP
Senior Project Manager, Luminex Corporation

Representative Invited
OND Biomarker and Companion Diagnostic Lead, CDER, FDA

Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): FI, CR

3:30–4:30 PM ▲ Level: ■ Format: FORUM

Incorporating a VAT Tax Strategy Into Your Global Investigator Payment Plan

CHAIRPERSON:

April Mulroney, CPA
Vice President - Tax Services, DrugDev, United Kingdom

This forum will discuss key strategies in addressing VAT tax implications when developing an investigator payment plan. We will discuss considerations for managing often overlooked tax implications and understanding the tax laws when creating a global trial budget.

Representative Invited
Senior Manager, US VAT Practice, Ernst & Young LLP

Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): PM

3:30–4:30 PM ▲ Level: ■ Format: SESSION

Getting More Out of Outsourcing Agreements: Value Additions Through Synergies and Process Optimization

CHAIRPERSON:

Anja Leo
Shared Services Manager, Boehringer Ingelheim Pharma Gmbh & Co. KG, Germany

If applied strategically and made subject to continuous improvement and process optimization, managed services can enhance service opportunities and add value. This allows for easy

expansion of the outsourced services by reducing the internal efforts for these services at the same time. With such a scalable and flexible service organization, in-house resources can even further focus on their core responsibilities, ensuring high throughput and high quality deliveries.

Track 04 – Preclinical and Translational Development/ Early Phase Clinical Development

Related Interest Area(s): NC, RA

3:30–5:00 PM Level: ■ Format: SESSION

Striking a Balance Between Ethical Treatment and Impact on Nonclinical Safety and Animal Rule Efficacy Study Interpretation When Using Prophylactic or Supportive Care

CHAIRPERSON:

Simone Nicholson, PhD
Toxicologist, Medimmune, Inc.

In this session, we will review the types of prophylactic or supportive care provided during nonclinical safety studies and efficacy studies conducted under the Animal Rule, along with the challenges for interpretation of such studies. The nonclinical safety assessment process identifies an initial safe dose and subsequent dose escalation schemes for human, potential target organs for toxicity, determining reversibility, and defining safety parameters for clinical monitoring. Various factors, including the candidate molecule structure (small versus large molecule), mechanism of action, and duration of exposure, suggest that specific adverse events might be expected in repeat dose toxicity studies which will require prophylactic and/or supportive care. Under the Animal Rule, efficacy for a therapeutic candidate is derived from animal models because it is unethical or impossible to collect these data from human subjects. Study design and supportive care of the animals during these evaluations allow for predictions of efficacy in human subjects based on the animal model experience.

Kenneth Westervelt, MS
Senior Project Manager, Regulatory Affairs, Accenture

Simone Nicholson, PhD
Toxicologist, Medimmune, Inc.

Track 05 – Regulation of Product Advertising and Marketing in an Ever-changing World

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

3:30–5:00 PM Level: ■ Format: FORUM

The Free Exchange of Truthful and Non-Misleading Medical Information

CHAIRPERSON:

John Kamp, JD, PhD
Attorney at Law, Wiley Rein LLP; Executive Director, Coalition for Healthcare Communication

This forum will explore new approaches to the free exchange of medical information by industry based on the requirements of the first amendment and the information needs of patients, providers and payers. Special attention will be paid to proposals to FDA by industry groups, including PhRMA and the Medical Information Working Group, and the House Energy and Commerce committee in deliberations on the proposed legislation on 21st Century Cures.

Freddy A. Jimenez, JD
Assistant General Counsel, Johnson & Johnson

Clay Alspach, JD
Majority Counsel, House Energy and Commerce Committee

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

Related Interest Area(s): MW, PETD

3:30–5:00 PM Level: ■ Format: SYMPOSIUM

Leadership and Process in Medical Writing

CHAIRPERSON:

Robin Whitsell
President, Whitsell Innovations, Inc.

Medical writers frequently perform their roles with little authority over their teams despite high-stakes outcomes. They understand the needs of their target audiences (clinical study teams, busy health authority reviewers, and internal stakeholders) and have to create consensus and cohesion. Frequently, medical writers turn to

metrics and best practices to inform the best pathway forward. This symposium will detail how to incorporate processes and leadership to streamline the document generation process and bolster the effectiveness of medical writing teams. The presenters will focus discussion around three areas: creation of high quality protocols through data-driven metrics, planning and implementing effective comment-resolution meetings, and formation of accountable teams.

Robin Whitsell
President, Whitsell Innovations, Inc.

David Gemzik
Vice President, Implementation Services, Medidata Solutions Worldwide

Steven C. Sibley, MS
Vice President, Global Submissions and Submissions Leadership, Synchrogenix Information Strategies Inc., a Certara Company

Track 07A – Technology/Data/Records and Submissions

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

3:30–5:00 PM Level: ■ Format: SYMPOSIUM

How Risk-Based Monitoring and eSource Methodologies are Impacting Clinical Sites, Patients, Regulators and Sponsors

CHAIRPERSON:

Jules T. Mitchel, PhD, MBA
President, Target Health Inc.

This symposium will show how risk-based monitoring and eSource methodologies are impacting the way clinical trials are being conducted and managed.

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

Avik Kumar Pal, MBA
Chief Executive Officer, CliniOps

Edward Stephen Seguine, Jr., MBA
Chief Executive Officer, Clinical Ink

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, RA

3:30–5:00 PM Level: ■ Format: SESSION

Data and Evaluation Needed for Robust Evidence: Regulators' Challenges

CHAIRPERSON:

Yoshihiko Ono, RPh
Executive Director, Head of Regulatory Affairs, Japan Development, MSD K.K., Japan

In recent years, the use of information based on the analysis of various data sources has been proactively promoted in decision-making processes of regulatory agencies. In this session, we will discuss the recent achievements and future challenges of regulatory agencies, focusing on how to make robust evidence with the efficient utilization of various data. We will also discuss the impact through the life cycle of medicinal products and common regulatory challenges.

Yoshiaki Uyama, PhD
Director, Division of Epidemiology, Office of Safety I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Representative Invited
Scientific Administrator, European Medicines Agency, European Union

Representative Invited
Director, Office of Surveillance and Epidemiology, CDER, FDA

Track 08A – Regulatory Affairs

Related Interest Area(s): CR

3:30–5:00 PM Level: ■ Format: SESSION

Getting the Most Out of Scientific Advice in the US and EU

CHAIRPERSON:

Daniel M. Bollag, PhD
Senior Vice President, Regulatory Affairs and Quality, Ariad Pharmaceuticals Inc.

This session will focus on how to obtain the best scientific advice from US and European health authorities. Presenters will discuss the optimal

times in the drug development process to seek advice, timelines for obtaining advice, case examples and tips for procuring the most useful advice, and how to leverage that advice during subsequent development and agency interactions.

Gopalan Narayanan, MD, FFPM, FRCP
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

Leonardo Ebeling, MD, PhD
Managing Director, Dr. Ebeling & Assoc. GmbH, Germany

Andrea Laslop, MD
Head of Scientific Office, AGES, Austria

Track 08B – Regulatory Affairs

Related Interest Area(s): PT, MC, AP

3:30–5:00 PM Level: ■ Format: FORUM

Optimizing Patient Labeling: A Panel Discussion Between Industry, Academia, and Prescribers

CHAIRPERSON:

Lina Aljuburi, PharmD, MS
Director, Global Regulatory Policy, Merck & Co., Inc.

Patient medication information that is understandable and usable by the patient is critical to the care of that patient. A panel of industry, academic and prescriber stakeholders come together to discuss ways to improve the current situation.

Lina Aljuburi, PharmD, MS
Director, Global Regulatory Policy, Merck & Co., Inc.

Representative Invited
Associate Professor, Medicine and Learning Sciences; Associate Division Chief, Northwestern University

Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): PPLCC, CmbP, RA

3:30–5:00 PM Level: ■ Format: SESSION

Continuing Growth in Combination Products: More Products, More Questions - Perspectives from FDA and Industry

CHAIRPERSON:

Jayne C. Ware, MPH, MS
Director, Global Regulatory Policy, Merck & Co., Inc.

Forecasts predict continued growth in the global combination product market. New products and changes to marketed combination products raise regulatory issues that challenge both FDA and sponsors. In this session, we will discuss FDA and industry perspectives.

Bradley Merrill Thompson, JD, MBA
General Counsel, Combination Products Coalition, Epstein, Becker and Green P.C.

Representative Invited
Director, Office of Combination Products, FDA

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA

3:30–5:00 PM Level: ■ Format: SESSION

Progress Report on Emerging Nations and Regulatory Capacity Building

CHAIRPERSON:

Florence Houn, MD, MPH, FACP
Co-chair, FDA Alumni Association International Network; Vice President, Regulatory Affairs, Celgene Corporation

This decade has seen widespread activities by nations, nonprofits, and industry engaging in global regulatory capacity building and strengthening. Hear major initiatives from the Bill and Melinda Gates Foundation, African Medicines Regulatory Harmonization program, and an academic overview of the field and its impact on health, industry, and economy.

Representative Invited
Deputy Director, Regulatory Affairs, Lead Global Regulatory Systems Initiatives, Bill and Melinda Gates Foundation

Paul Kiptum Tanui, MBA, RPh
Senior Programme Officer, African Medicines Regulatory Harmonization Programme, The New Partnership For Africa's Development (NEPAD), South Africa

Syed Rizwanuddin Ahmad, MD, MPH, FISPE
Assistant Professor (adjunct), Georgetown University School of Medicine

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): GCP, CR

3:30–5:00 PM Level: ■ Format: WORKSHOP

Managing Protocol Deviations: Applying the Protocol Deviations Working Group SOP for Handling Protocol Deviations in Clinical Trials

CHAIRPERSON:

Maryrose Petrizzo, MSc
Senior Consultant, Halloran Consulting Group, Inc.

This workshop will provide a sample clinical trial protocol and corresponding protocol deviation handling plan (PDHP) along with the standard operating procedure (SOP) and protocol deviations reporting form. Several protocol deviations (PD) will be provided and workshop attendees will be asked to follow the PDHP to handle the classification and reporting of the PD.

This workshop was developed by the DIA Good Clinical Practice and Quality Assurance Community and the Protocol Deviations Working Group.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington Convention Center 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 offering will not be recorded.*

Representative Invited
Executive Director, Business Development, Quantum Biopharma

Sandy Mohan, PhD
Vice President, Quality and Compliance, Biotie Therapies

Track 12 – Pharmaceutical Quality

Related Interest Area(s): QC, CMC/GMP

3:30–5:00 PM Level: ■ Format: FORUM

Risk-Based Regulatory Review

CHAIRPERSON:

Roger Nosal, MA, MS
Vice President, Global CMC, Pfizer Inc

This forum will focus on presenting new and alternative strategies for use in implementing both risk minimization and risk mitigation processes in relation to chemistry, maufacturing and control and good manufacturing processes. We will also examine risk assessment, risk characterization, and risk communication.

Representative Invited
Head of Global CMC, Merck & Co., Inc.

Representative Invited
Acting Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Representative Invited
Vice President, Technical Regulatory, Biologics, Genentech, A Member of the Roche Group

Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

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

3:30–5:00 PM Level: ■ Format: FORUM

Innovative Approaches to Patient Registries for Evaluating Outcomes

CHAIRPERSON:

Michelle Leavy, MPH
Research Manager, Health Policy, Quintiles Inc.

Patient registries are increasingly being used to conduct research on comparative effectiveness, patient outcomes, and safety. Innovative approaches to designing and operating registries are critical to support their growing use and the increasing complexity of the research questions

that they address. In this forum, we will summarize key points in "Registries for Evaluating Patient Outcomes," a widely used guide on registry best practices, and present case examples on leveraging patient-generated registries, linking registries with biorepositories, conducting multinational registries, and designing registries using external electronic medical record data. In addition, presenters will discuss an emerging area of controversy — registration of patient registries in systems such as ClinicalTrials.gov, the Registry of Patient Registries (RoPR) and the Patient REgistries iNiTiative (PARENT). We will discuss the rationale for registration and review and compare options for registration, both in the US and globally.

Susan Meredith Fish, MS
Senior Statistical Programmer Analyst, Genentech, A Member of the Roche Group

Vanja Pajic
Project Manager, Croatian Institute for Public Health, Croatia (Hrvatska)

Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

3:30–5:00 PM Level: ■ Format: FORUM

Translating New Knowledge from Regulatory Science into Postmarketing Safety Practice

CHAIRPERSON:

Representative Invited
Director, Office of Surveillance and Epidemiology, CDER, FDA

This forum will discuss interactions between lessons learned in regulatory science and regulatory activities and the challenges met to translate results into changes of pharmacovigilance practice. This forum will include topics such as Impact, Mini-Sentinel, Protect, public health and regulatory science.

Representative Invited
Head of Pharmacovigilance Department, European Medicines Agency, European Union

Robert Goodwin, MBA, MSc
Vice President, Safety Evaluation and Reporting, Pfizer Inc

Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

3:30–5:00 PM Level: ■ Format: SESSION

Has the New Format PSUR/PBRER Achieved What Was Originally Intended?

CHAIRPERSON:

Stephen Knowles, MD, MRCP
Senior Director, Global Patient Safety, Eli Lilly and Company

With the implementation of the European Good Pharmacovigilance Regulation and adoption of ICH E2C (R2), the content and purpose of the periodic safety update report (PSUR) has fundamentally changed. Increasingly, the periodic benefit-risk evaluation report (PBRER) is accepted by regulatory authorities around the world as the acceptable format for the PSUR. This session will review the process for developing the PBRER, lessons learned and discuss the impact of the PBRER on managing the benefit risk balance of medicines.

Representative Invited
Pharmacovigilance and Risk Management Lead, IMB and Vice Chair, PRAC, Health Products Regulatory Authority, Ireland

Representative Invited
Director Pharmacovigilance and Drug Safety, NDA Group, Sweden

Representative Invited
QPPV and Head of Affiliate Vigilance Excellence, AbbVie Ltd., United Kingdom

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR

3:30–5:00 PM Level: ■ Format: SESSION

Predictive Subgroup Methodologies and Molecular Basket Designs

CHAIRPERSON:

Robert A. Beckman, MD
Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Optimal designs for predictive biomarkers and their associated subgroups are presented from both the public health and drug developers' perspectives. Novel basket designs grouping tumors based on molecular characteristics will be discussed.

This session has been developed by the DIA Adaptive Design Scientific Working Group.

Carl-Fredrik Burman, PhD
Associate Professor in Biostatistics, Chalmers University of Technology

Robert A. Beckman, MD
Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Representative Invited
Associate Director, Adaptive Design and Pharmacogenomics, Office of Translational Sciences, Office of Biostatistics, CDER, FDA

Track 16 – Professional Development

Related Interest Area(s): PETD

3:30–5:00 PM Level: ● Format: WORKSHOP

Conflict Resolution: Helping Teams Manage Through Conflict

CHAIRPERSON:

Jennifer Lansink
President, Total Root Concepts, Inc.

Conflict is inevitable. Problems with conflict result from poorly managed communication. This interactive workshop provides audiences with the awareness and tools for successful navigation of intrapersonal, interpersonal, and team conflict.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington Convention Center 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 offering will not be recorded.*

Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, RA

3:30–4:30 PM ▲ Level: ■ Format: SESSION

Pediatric Drug Development

CHAIRPERSON:

Badri Rengarajan, DrMed
President, Board of Directors, International Pemphigus and Pemphigoid Foundation

There is greater demand from regulatory and clinical care communities to include pediatric patients in clinical development. However, inclusion of pediatric patients poses unique challenges in preclinical work, clinical trials, and navigation of regulatory processes. The aim of this panel is to describe the challenges and to offer approaches and solutions to help overcome them. We will discuss animal models and drug screening platforms, clinical trial design, unique information needs, and regulatory pathways. Attention will be given to highlighting differences in pediatric orphan drug development and regulatory frameworks in major and emerging geographies.

Shu-Wha Lin
Professor, Dept. Lab Sci Med Biotechnology, National Taiwan University College of Medicine, Taiwan

Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

Track 18 – Global Regulatory

Related Interest Area(s): MDD, CmbP

3:30–5:00 PM Level: ■ Format: FORUM

CDRH Town Hall

CHAIRPERSON:

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

This forum will provide a unique opportunity to hear from the director of the Center for Devices and Radiological Health (CDRH) who will report on the state of CDRH and its vision for the future. Topics to be addressed include: CDRH's Senior Staff Management Team; FDASIA accomplishments and activities; the view toward 2017 MDUFA Reauthorization and the impact of the House Energy and Commerce 21st Century Cures initiatives; regulatory framework for laboratory developed tests (LDTs); CDRH's development of expedited pathways; the future of next gen sequencing and innovative approaches for companion diagnostics and personalized medicine; human factors studies; combination products; regulation of mobile and web software applications, and other new technologies and their impact on patient care.

Please come prepared with your questions for the CDRH panel. You may submit questions and topics of interest in advance to annualmeetingprogram@diahome.org, and include "CDRH Panel" in the subject line.

Representative Invited
Director, CDRH, FDA

Track 19 – Late-breaking Topics

Related Interest Area(s): RD

3:30–5:00 PM LEVEL: ● FORMAT: SESSION

European Medicines Agency Scientific Guidance on Postauthorization Efficacy Studies

CHAIRPERSON:

Representative Invited
National Expert on Secondment Pharmacovigilance and Risk Management, European Medicines Agency, European Union

The session will review draft EMA guidance on postauthorization efficacy (PAES) studies. PAES can be imposed by European regulators as conditions of a marketing authorization. Hear about when PAES might be required, and what you might need to include.

WEDNESDAY, JUNE 17

Registration Hours:

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

Schedule:

7:15–8:00 AM	Coffee and Breakfast Breads
8:00–9:30 AM	Educational Opportunities: 60-minute ▲ TURBO Offerings (8:00–9:00 AM) 90-minute Offerings (8:00–9:30 AM)
9:30 AM–4:00 PM	Professional Poster Session #2
9:00 AM–4:00 PM	Exhibit Hall Open
9:30–10:30 AM	Coffee Break & Exhibit Hall Innovation Theater Presentations
10:30 AM–12:00 PM	Educational Opportunities 60-minute ▲ TURBO Offerings (10:30–11:30 AM) 90-minute Offerings (10:30 AM–12:00 PM)
11:30 AM–1:30 PM	Lunch & Exhibit Hall Innovation Theater Presentations
1:30–3:00 PM	Educational Opportunities 60-minute ▲ TURBO Offerings (1:30–2:30 PM) 90-minute Offerings (1:30–3:00 PM)
1:30–3:30 PM	Exhibit Guest Passes
3:30–5:00 PM	Educational Opportunities

Track 01A – Clinical Operations

Related Interest Area(s): PT, CR

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

Leveraging Diverse Patient Insights

CHAIRPERSON:

Jane E. Myles, MS
Global Head, Recruitment Strategy, Genentech, A Member of the Roche Group

Incorporating patient insights in the clinical trial development process is gaining momentum industry-wide, and this symposium will share different experiences with leveraging patient insights. We will examine how a large pharmaceutical company sought a deeper understanding of attitudes and perceptions from the patient perspective and leveraged their learnings to influence change to the protocol as well as the strategic recruitment plan. Factors that contribute to recruitment of women in HIV-1 clinical trials as well as the factors which should be considered when planning a clinical trial intended to enroll women will be explored. We will also explore key drivers behind the low rates of clinical trial participation among minorities, including lack

of information about ongoing trials and lack of racial and ethnic diversity among investigators.

Deborah Howe
Associate Director, Vendor and Supply Chain Management Lead, Bristol-Myers Squibb Company

Lisa Marie Montafia
Clinical Trials Manager, Gilead Sciences, Inc.

Julie Parmelee
Director, Patient Recruitment, Quintiles Inc.

Track 01B – Clinical Operations

Related Interest Area(s): PT, CR

8:00–9:30 AM LEVEL: ● FORMAT: WORKSHOP

Patient Registries: Design, Development, and Recruitment

CHAIRPERSON:

Ginger Spitzer, MA
Executive Director, Foundation of Sarcoidosis Research

This workshop will review how to create a patient registry, outlining major elements. Participants will work together and with the presenter to identify specific needs (based on resources, objectives) and review options and recommendations.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington Convention Center 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 offering will not be recorded.*

Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): RA, SUBS

8:00–9:30 AM LEVEL: ■ FORMAT: FORUM

Keys to Managing a Successful Regulatory Strategy and Submission

CHAIRPERSON:

Lauren Michelle Neighbours, PhD, RAC
Clinical Research Scientist, Rho, Inc

This forum will discuss tools for implementing an effective regulatory submission strategy. A panel of experts will provide their insight on best practices for early, mid, and late-phase product development planning.

Jeff Antos
Vice President, The Weinberg Group Inc.

Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, SP

8:00–9:00 AM ▲ LEVEL: ■ FORMAT: SESSION

How to Make a Strategic Partnership Model Work at the Country/Site Level in Asia Pacific and Insight from a Regulatory Inspector

CHAIRPERSON:

Catherine Lee, MBA, MPharm, MSc
Area Head-Asia, Clinical Trial Support and Compliance, Pfizer Inc, Taiwan

Many pharmaceutical companies are building partnerships with contract research organizations (CROs). However, there are many obstacles at the country level. In this session, we will discuss how to establish the CRO/sponsor partnership in Asia. The insight of a regulatory inspector will also be shared.

Jing Ping Yeo, PhD
Head, Project Leadership Asia Pacific, PAREXEL International, Singapore

Representative Invited
Team Leader of GCP Inspection Team, Center for Drug Evaluation, Taiwan

Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, IT

8:00–9:30 AM LEVEL: ■ FORMAT: FORUM

Transforming Industry Through Centralization of Key Business Practices: A Focus on Prequalification of Niche Suppliers

CHAIRPERSON:

Mitchell A. Katz, PhD
Head of Medical Research and Drug Safety Operations, Purdue Pharma L.P.

This forum will present data showing industry challenges when prequalifying technical clinical service providers. Industry standards and tools will be shared that will transform the approach for future prequalification assessments.

Janis L. Hall, MBA
Senior Consultant, The Avoca Group, Inc.

Jerry Jennings
Director of Clinical Quality Management, Baxter Healthcare Corporation

Representative Invited
Global Category Manager, Sanofi

Track 04 – Preclinical and Translational Development/ Early Phase Clinical Development

Related Interest Area(s): PC, CP

8:00–9:30 AM LEVEL: ■ FORMAT: SESSION

Innovative Approaches to Predictive Clinical Safety and Signal Detection Utilizing Clinical Pharmacology Concepts

CHAIRPERSON:

Howard Greenberg, MD
Medical Safety Officer, Janssen Pharmaceuticals, Inc.

Pharmacovigilance analyzes spontaneous reports to assess potential safety concerns. Newer methods that may predict potential issues, coupled with enhanced observational methods using patient-generated data may complement the traditional approaches.

This session has been developed by the DIA Clinical Pharmacology Community.

Amy Purrington, MD
Lead, Aggregate Signal Detection, Janssen Pharmaceuticals, Inc.

Representative Invited
Associate Director for Drug Safety Office of Clinical Pharmacology, CDER, FDA

Rave Harpaz, PhD
Senior Research Scientist, Oracle Health Sciences

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

Related Interest Area(s): MC, RA

8:00–9:30 AM LEVEL: ■ FORMAT: SESSION

Returning Results to Study Participants: Health Literacy and Effective Language

CHAIRPERSON:

Barbara Godlew, RN
President, The FAIRE Company, LLC

Beginning in 2016, the European Clinical Trial (ECT) regulation will require clinical trial sponsors to provide trial results to the participants in a format and language appropriate and understandable to the participant. This session will focus on the history and principles of return of results to participants, including the history and generation of guidance for this effort, key principles of health literacy and numeracy that can guide the effective communication of study results, including language, formatting, and the presentation of data and discuss the integration and dissemination of health literacy principles in a large pharmaceutical company, driven by the need for clear communication for all audiences and not just those with limited literacy.

Representative Invited
Professor of Medicine, Harvard Medical School; Co-Director MRCT, Brigham and Women's Hospital Faculty Co-Director

Laurie M. Myers, MBA
Health Literacy and Healthcare Disparities Strategy, Merck & Co., Inc.

Nancy Ostrove, PhD
Principal, EXPRE

Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): CDM

8:00–9:00 AM ▲ Level: ■ Format: SESSION

CDISC SHARE Repository: Laying the Tracks and Building the Stations for this New Metadata Train

CHAIRPERSON:

Kenneth Stoltzfus
Clinical Data Strategies, Accelerated R&D Life Sciences, Accenture

The CDISC SHARE repository is poised to change the way the industry utilizes standards metadata for clinical trials. This session presents the sponsor, vendor, and the CDISC viewpoints on how the industry can maximize the benefits SHARE offers.

Samuel W. Hume, MS
Vice President, SHARE Technology and Services, CDISC

Kenneth Stoltzfus
Clinical Data Strategies, Accelerated R&D Life Sciences, Accenture

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): DM, CR

8:00–9:30 AM Level: ■ Format: SESSION

Mapping the Future for Trial Master File

CHAIRPERSON:

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

Standardization has become the norm across the clinical research spectrum. The industry has embraced data standards, biomedical specimen storage standards, site standards, and the list continues. The Trial Master File (TMF) is a collection of content that demonstrates that the sponsor conducted the study in accordance with the protocol and good clinical practice. In the past several years, there has been an industry move to standardizing the TMF content. Standardized TMF content ensures completeness of regulatory submission, regulatory inspection readiness and execution, facilitates staff and inspector training, facilitates operations post merger and acquisitions, and supports inlicensing/outlicensing efforts. This session will discuss the importance of standards in TMF and explore the currently available standards within the industry.

Michael Agard, MS
Principal Consultant, Paragon Solutions, Inc.

Track 08A – Regulatory Affairs

Related Interest Area(s): CR

8:00–9:30 AM Level: ■ Format: FORUM

Recent Experiences with Adaptive Licensing and Facilitated Regulatory Pathways

CHAIRPERSON:

Lawrence Liberti, MS, RPh, RAC
Executive Director, Centre For Innovation In Regulatory Science (CIRS)

Facilitated regulatory pathways (FRPs) and transformative adaptive licensing (AL) procedures can accelerate patient access to medicines. This forum will review recent experiences, facilitators and how barriers have been overcome for effective use of FRPs and considerations for AL pilots.

Lawrence Liberti, MS, RPh, RAC
Executive Director, Centre For Innovation In Regulatory Science (CIRS)

Daisaku Sato, PhD
Director, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Representative Invited
Head of Scientific Advice, Human Medicines Special Areas, European Medicines Agency, European Union

Track 08B – Regulatory Affairs

Related Interest Area(s): SUBS, CR

8:00–9:00 AM ▲ Level: ■ Format: SESSION

Update: FDA's CDER Progress to Adapting Standardized Data to Select Clinical Sites for Inspection

CHAIRPERSON:

Betsy Fallen, RN
Principal, BAFallen Consulting, LLC

This session will include an overview of the Office Of Scientific Investigation (OSI), discuss the goals of the Bioresearch Monitoring (BIMO) Program, include a review of previous challenges to the inspection system, provide an overview of CDER's Clinical Site Selection Model and Tool and provide a summary of the OSI request for information specification for preparing and submitting summary level clinical site data in the electronic common technical document (eCTD).

Colleen Davenport
Senior Director, Regulatory Affairs, AnGes, Inc.

Representative Invited
Office Director, Office of Scientific Investigations, Office of Communications, CDER, FDA

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA

8:00–9:30 AM Level: ■ Format: FORUM

21st Century Cures: Which Are the Most Transformative Provisions and How Do They Accomplish Major Change?

CHAIRPERSON:

Nancy Bradish Myers, Esq, JD
President, Catalyst Healthcare Consulting, Inc

It is all the buzz in DC! Congress is working with innovators, patients and policy makers to draft legislation and the House plans to these ideas forward early in 2015. The goal is to reform FDA regulatory processes in order to accelerate the discovery, development and delivery of promising new treatments. Which are the most transformative ideas and what important goals will they accomplish? How will this legislative effort dovetail with PDUFA VI negotiations? Join our panel to hear from members of Congress, FDA and other key stakeholders to better understand where this initiative is in the process, and what our panelists believe the most transformative provisions will be.

Representative Invited
Director, Center for Drug Evaluation and Research, FDA

Representative Invited
Chairman, Committee on Energy and Commerce, United States House of Representatives

Representative Invited
Founder and Chairperson, Friends of Cancer Research

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): RA

8:00–9:30 AM Level: ■ Format: SESSION

Changes in Regulations That May Impact How Inspections are Conducted: Regulatory Perspectives

CHAIRPERSON:

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

Regulators will discuss changes in regulations that may impact how inspections are conducted by the FDA, EMA, and PMDA which will help sponsors, contract research organizations and study sites running clinical trials in the EU and internationally understand the important, updated compliance. Hot topics include new guidance for inspection of the electronic Trial Master File and e-Records, pre-inspectional activities, pre-announcements of inspections, inspectional risk criteria, similarities and differences in documents requested and reviewed, reportable observations as well as top inspectional findings as a result of the new guidance.

Representative Invited
Head of Compliance and Inspections Department, European Medicines Agency, European Union

Representative Invited
Senior Medical Officer, Office of Scientific Investigations, CDER, FDA

Representative Invited
Director, Office of Non-Clinical and Clinical Compliance, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Track 12 – Pharmaceutical Quality

Related Interest Area(s): QC, RA

8:00–9:30 AM Level: ■ Format: FORUM

Challenges in Managing Global Regulatory Divergence

CHAIRPERSON:

Thomas W. Schultz, PhD, MS
Senior Director, Regulatory Sciences, Global CMC Regulatory Affairs, Janssen Pharmaceuticals Inc.

This forum will include specific examples highlighting instances where the lack of global harmonization results not only in present day challenges but potential opportunities for future convergence.

Representative Invited
Head of Manufacturing and Quality Compliance Service, European Medicines Agency, European Union

Representative Invited
Deputy Commissioner, Global Regulatory and Policy, Office of the Commissioner, FDA

Peter Lassoff
Vice President and Head of Global Regulatory Affairs, Quintiles Inc., United Kingdom

Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): CEHTAEbM

8:00–9:30 AM Level: ■ Format: SESSION

Real-World Use of Multi-Criteria Decision Analysis for Benefit-Risk Assessment: Examples and Lessons Learned in the Industrial Setting

CHAIRPERSON:

David Neasham, DrPH, PhD, MSc
Director and Senior Research Scientist, Evidera, United Kingdom

There is increased demand for quantitative benefit-risk assessment (BRA). Various reviews have recommended multi-criteria decision analysis (MCDA) to undertake quantitative BRA (e.g., PROTECT). The objective of this session is learn from real examples of conducting MCDA for BRA in an industry setting.

Filip Mussen, PhD
Vice President, Regional Regulatory Affairs, Janssen Pharmaceuticals, Inc., Belgium

Kevin Marsh, PhD, MSc
Senior Director, Modeling and Simulation, Evidera, United Kingdom

Representative Invited
Executive Director, Risk Management and Epidemiology, Purdue Pharma L.P.

Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, CR

8:00–9:30 AM Level: ■ Format: SESSION

Pharmacovigilance Concerns with the Use of Experimental Medicines for Ebola and Enterovirus B-68

CHAIRPERSON:

Elizabeth E. Garrard, PharmD
Senior Director, Safety Risk Management, United Therapeutics Corporation

The race is on to find a cure for Ebola which has killed more than 8000 people in West Africa and remains the largest outbreak on record. Over the last several months, the United States has experienced a nationwide outbreak of enterovirus

D68 (EV-D68) associated with severe respiratory illness. The CDC and/or state public health laboratories have confirmed over 1100 people in 47 states and the District of Columbia with respiratory illness caused by EV-D68. There are no proven treatments for people with the Ebola or enterovirus D68 virus or vaccines to prevent infection in the first place. However, progress is now being made on an unprecedented scale. Trials, which would normally take years and decades, are being fast-tracked on a timescale of weeks and months. This session will discuss how fast-tracking clinical investigations has obvious shortcomings, most notably required understanding of the safety profile of the agents used to treat these epidemics. Another issue is that of ethical considerations in providing treatment during epidemics with agents that have not undergone robust clinical trials.

Syed Rizwanuddin Ahmad, MD, MPH, FISPE
Assistant Professor (adjunct), Georgetown University School of Medicine

Representative Invited
Director, Office of Antimicrobial Products, Office of New Drugs, CDER, FDA

Representative Invited
Senior Regulatory Officer, Integrated Development, Global Health, Bill and Melinda Gates Foundation, United Kingdom

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST

8:00–9:30 AM LEVEL: ● FORMAT: SESSION

Benefit-Risk Assessment of Medicines: Three Perspectives on Current Methodologies and the Statistician's Role in Implementation

CHAIRPERSON:

Susan P. Duke, MS
Director, Benefit Risk Evaluation, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Benefit-risk framing and quantification are increasingly becoming part of a pharmaceutical company's internal decision-making process and regulatory deliverables. Various approaches are available to companies to deploy these methods. In this session, we will focus on the statistician's leadership role, as well as success in methodologies used, in the use of benefit-risk quantification for making better quality (and more timely) decisions, and for improving communication of benefit-risk assessments, including submission preparation.

Sheila Dickinson, MSc
Senior Quantitative Safety Scientist, Novartis Pharma AG, Switzerland

Greg Anglin, PhD
Principal Research Scientist, Statistics, Eli Lilly and Company, Canada

Susan P. Duke, MS
Director, Benefit Risk Evaluation, Global Clinical Safety and Pharmacovigilance, GlaxoSmithKline

Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR, BT

8:00–9:30 AM LEVEL: ■ FORMAT: SESSION

Rare Diseases and Subgroups Defined by Tumor Evolution: Common Themes and Challenges

CHAIRPERSON:

Robert A. Beckman, MD
Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Rare diseases present a unique challenge for developing evidence to support new therapies. Molecular subgroups of cancer define equally small populations, which also evolve over time. Clinical development and treatment challenges will be discussed.

Jeffrey Schwartz, PhD, MS
Senior Director, Pfizer Inc

Robert A. Beckman, MD
Professor of Oncology, Biostatistics, Bioinformatics, & Biomathematics-Adjunct Track, Georgetown University Medical Center

Representative Invited
Head of Oncology, Haematology, Diagnostics, European Medicines Agency, European Union

Track 19 – Late-breaking Topics

Related Interest Area(s): RA

8:00–9:30 AM Level: ■ Format: FORUM

The Impact of the eLabeling Rule on Industry and Stakeholders

CHAIRPERSON:
Barbara J. Fanelli, MS
Associate Vice President, Global Regulatory Affairs Labeling, Sanofi

This forum will discuss the proposed labeling rule for the electronic distribution of prescribing information, what it means for FDA, industry, patients and health care professionals, as well as comments received concerning the proposed rule.

Representative Invited
Labeling Team Leader, Study Endpoints and Labeling Development, Immediate Office, Office of New Drugs, CDER

Track 20 – Innovation Theater

Related Interest Area(s): CP, CR

9:45–10:15AM Level: ■ Format: SPECSESS

SAS Institute Inc., JMP Division Innovation Theater: Benefit and Risk Signal Detection in Clinical Trials

Integrated assessment of both efficacy and safety data in clinical trials has become an increasingly common analytic goal in clinical trials. There is an intrinsic balance between the desired outcomes of a treatment versus the risks that may be incurred to achieve such outcomes. We describe how analytic capabilities tightly tied with visualization in JMP Clinical software can elucidate understanding for both safety and efficacy endpoints during the analysis process.

Track 01A – Clinical Operations

Related Interest Area(s): CR

10:30 AM–12:00 PM Level: ■ Format: WORKSHOP

Direct-to-Patient Strategies That Are Changing the Landscape of Clinical Trials

CHAIRPERSON:
Leslie Chaney, PhD
Global Director, Preclinical and Direct to Patient Services, Marken LLP

Home-based options in clinical trial design may allow patients to participate in trials from home. Home delivery of clinical trial materials and retrieval of biological samples may increase the number of patients who can enroll in clinical trials.

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Track 01B – Clinical Operations

Related Interest Area(s): CR, PM

10:30 AM–12:00 PM Level: ◆ Format: FORUM

Putting It All Together: A Shared, Comprehensive, Integrated Global System for Clinical Research

CHAIRPERSON:
Greg Koski, MD, PhD
President and CEO, Co-Founder, Alliance For Clinical Research Excellence and Safety (ACRES)

This forum will discuss collaborative efforts to build a global system for clinical research to transform the clinical trials process. Addressing such topics as standards and accreditation for sites, a culture of safety, and a unified safety database, experts from key stakeholder groups (i.e., contract research organization, regulatory agency, pharmaceutical company, site, patient groups) will present their perspectives on the desirability, feasibility and challenges to the effort. We will finish with a dynamic, moderated interactive session with the audience and panelists.

Briggs W. Morrison, MD
Head, Global Medicines Department, AstraZeneca Pharmaceuticals LP

Daniel O'Connor, JD
Chief Business Officer, InnovoCommerce

Representative Invited
Head, Health Biosciences Practice, FaegreBD Consulting

Kimberly Irvine
Chief Operating Officer, Biomedical Research Alliance of New York (BRANY)

Representative Invited
Deputy Center Director for Science Operations, CDER, FDA

Track 02A – Project/Portfolio Management and Strategic Planning

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

10:30–11:30 AM ▲ Level: ■ Format: SESSION

Incremental Innovation: How to Strategically and Practically Move Innovative Ideas into Action Within Your Company and Research Programs

CHAIRPERSON:

John Reites
Senior Director, Product and Strategy, Quintiles Inc.

The word "innovation" is synonymous with some of the most groundbreaking research and technologies our industry benefits from today, and it is critical to the continued evolution of our business. In this session, we will review strategies for how to action innovation within a company or research program based on experience gained from implementing successful pilots and novel study design approaches. We will explore insights on how to: (1) Develop a stage-gate plan with key stakeholder support to practically integrate innovation; (2) Effectively pilot solutions with a structure to scale if successful; (3) Set proper expectations from the start for all teams involved; (4) Define risks and measure success; and (5) Generate a communication plan that promotes adoption and the value of innovation. These insights will be explained in the context of various case studies in which innovative approaches were implemented into action in research programs.

Amy Loescher
Director, Clinical Program Leader, Janssen Pharmaceuticals, Inc.

Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): CR, FI

10:30 AM–11:30 PM ▲ Level: ■ Format: SESSION

Best Practices for Successfully Managing Clinical and Pharmaceutical Projects

CHAIRPERSON:

Zizi Imatorbhebhe, MBA, MS, PMP
Principal & Managing Consultant, Alliance Bio-Pharm & Health Partners

Clinical and pharmaceutical teams are quickly realizing that effective project management is necessary to improve accuracy of timeline, budgets, scope and quality requirements. With the high costs and risks associated with pharmaceutical product development and clinical trials, it is increasingly important that projects are managed effectively to maximize returns and meet business objectives. This session articulates the best practices of successfully managing clinical and pharmaceutical projects. It will also include insights and strategies for leading and managing technical projects in a large pharmaceutical company to inspire nontechnical leaders to take on this challenge with confidence.

Alexandra Florea, PMP
Principal Project Manager, Genentech, A Member of the Roche Group

Zizi Imatorbhebhe, MBA, MS, PMP
Principal & Managing Consultant, Alliance Bio-Pharm & Health Partners

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, IT

10:30 AM–12:00 PM Level: ◆ Format: SESSION

Emerging and Mid-Sized Biopharmaceutical Companies Building Successful CRO Relationships: Overcoming the Challenges by Applying Alliance Management Principles and Technology

CHAIRPERSON:

Keith W. Wenzel
Senior Director, Global Alliances, PAREXEL International

During this session, speakers from virtual, small or mid-sized clinical trial sponsors and a contract research organization (CRO) will discuss the value from alliances between networks of biopharmaceutical companies and CROs, as well as the changing landscape of and models for technology outsourcing. We will explore what the biopharmaceutical companies and CROs (clinical or technology) must do to build a successful, collaborative alliance for clinical trial efficiency and success.

Solomon Babani, MBA
Global Vice President, Alliance Management, Covance Inc.

Track 04 – Preclinical and Translational Development/ Early Phase Clinical Development

Related Interest Area(s): PC, CR

10:30 AM–12:00 PM Level: ■ Format: SESSION

Implications of Clinical Test Result and ECG Variability on the Design, Conduct, and Interpretation of Early Phase Clinical Studies

CHAIRPERSON:

Gary L. Steinman, MS
President, Medexetech

Variability in clinical lab and ECG results affects the design, conduct, and interpretation of phase 1 studies. This session will address lab testing, ECG measurement methods, intra/inter-subject variability, and use of results as recruiting criteria, outcome variables and adverse effect indicators.

Robert Kleiman
Chief Medical Officer and Vice President, Global Cardiology, ERT

William B. Smith, MD
President, New Orleans Center For Clinical Research and Volunteer Research Group

Royce A. Morrison, MD, MS
Senior Consultant, Pacific Pharma Group, LLC

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

Related Interest Area(s): MC

10:30 AM–12:00 PM Level: ■ Format: SESSION

How Collective Insights of Medical Affairs Customer-Facing Teams Work to Inform Strategy

CHAIRPERSON:

Stacey M. Fung, PharmD
Associate Director, Medical Communications, Genentech, A Member of the Roche Group

This session will discuss available internal customer insights collected by medical affairs (MA) groups (medical communication, medical science liaison, publications, etc) and how best to review this information. Discussions will include ways to identify and analyze insights to shape tactical plans.

Margaret J. Carrico, MS
Advisor, Global Medical Customer Analytics and Insights, Eli Lilly and Company

Sian Slade
Group Director, Global Medical (MCCI), Bristol-Myers Squibb Company, Australia

Representative Invited
Field Medical Director, Pain Portfolio, Pfizer Inc

Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, SUBS

10:30 AM–12:00 PM Level: ■ Format: SESSION

Electronic Standardized Data in Regulatory Submissions

CHAIRPERSON:

Representative Invited
Deputy Director, Office of Strategic Programs, CDER, FDA

This session will provide an update on the binding standardized study data guidance and its impact on the requirement to submit study data in conformance with FDA supported standards.

Representative Invited
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

Representative Invited
Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Representative Invited
Project Manager, Bioinformatics Support Staff, CBER, FDA

Track 07B – Technology/Data/Records and Submissions

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

10:30 AM–12:00 PM Level: ■ Format: SYMPOSIUM

Digitization of Clinical Trials: Check the Pulse on Bringing Benefits to Patients

CHAIRPERSON:

Betsy Fallen, RN
Principal, BAFallen Consulting, LLC

With the widespread adoption of digitized regulated content management systems, the digitization of the investigator site documents and data collection will be the next horizon to be mastered. Whether it is the document management or the inspection, audit or retention of records, digitization will allow systems, tools and business processes to increase compliance with regulations. With new processes and systems, best practices and patient education will be key to successful adoption. The adoption of technology solutions will also impact the patients. This symposium will explore the need for communicating with patients through multiple channels on the rise of mobile and digital technology and investigate related questions. We will address the need for patient education and examine how we can best share this information with patients in a health literate manner, including the use of patient-facing infographics. The eConsenting process has demonstrated benefits along the continuum of the clinical trial, among them benefits in patient enrollment and engagement as well as regulatory compliance. Examples from several recent implementations will be presented to demonstrate the potential return on investment of an eConsent system and outline the positive impact this process can have on inspection findings.

Eric Delente, MA
CEO, Managing Director, Enforme Interactive, Inc.

Judith Teall, RN
Director of Clinical Excellence, Exco InTouch, United Kingdom

Track 08A – Regulatory Affairs

Related Interest Area(s): PT

10:30 AM–12:00 PM Level: ■ Format: SESSION

Medicine Development and Authorization: A Patient-Centered Approach

CHAIRPERSON:

Angelika Joos, MPharm
Executive Director, Global Regulatory Policy, MSD (Europe) Inc., Belgium

A systematic and integrated framework to enable patient involvement during the development and life cycle of medicines and associated products is not yet really established. This session will provide examples how regulators in the US and Europe involve patients into the regulatory process and discuss how patients can bring their experience to the table.

Representative Invited
Assistant Commissioner, Office of Health and Constituent Affairs, Office of the Commissioner, FDA

Representative Invited
Head of Medical Information, European Medicines Agency, European Union

Marc M. Boutin, JD
Executive Vice President and Chief Operating Officer, National Health Council (NHC)

Track 08B – Regulatory Affairs

Related Interest Area(s): PT, CR

10:30 AM–12:00 PM Level: ■ Format: SESSION

Opening the Door to Data Transparency: What's the Verdict?

CHAIRPERSON:

Robert Paarlberg, MS
Principal, Paarlberg & Associates LLC

This session will focus on US and EU clinical trial disclosure requirements, including results reporting and how this increase in data transparency is being perceived and used by the patient community.

Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov, National Library of Medicine, NIH

Representative Invited
Senior Medical Officer, European Medicines Agency, European Union

Deborah E. Collyar
President, Patient Advocates In Research (PAIR)

Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): RA, PT

10:30 AM–12:00 PM Level: ■ Format: FORUM

The Role of Labeling in Successful Human Factors Studies

CHAIRPERSON:

Eileen S. Kahn, MEd, MS
Principal Labeling Associate, Sanofi

A key component of well-designed, successful human factors studies is having clear and concise labeling so the patient can use the device safely and effectively. This forum will provide some industry perspectives in how this can be accomplished.

Renee Bailey
Agilis Consulting Group, LLC

Molly Follette Story, PhD
Head, Global Usability Engineering and Risk Management, Sanofi

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA, CR

10:30 AM–12:00 PM Level: ■ Format: FORUM

Precision Medicine: Where Is the Technology Taking Us, How Fast and Who Is Driving?

CHAIRPERSON:

Nancy Bradish Myers, Esq, JD
President, Catalyst Healthcare Consulting, Inc

Advances in technology and computing power are propelling us into new era of genetics. The rise of whole genome sequencing is creating opportunities to better understand the human condition and tailor medical care to the individual in novel, innovative ways. This panel will explore where the science is taking us, help us read the roadmap to adoption and debate the best way to integrate results of genomics into clinical care.

Felix W. Frueh, PhD
Chief Scientific Officer, Human Longevity, Inc.

Representative Invited
Director, National Institutes of Health (NIH)

Representative Invited
Director, Center for Devices and Radiological Health

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CP

10:30 AM–12:00 PM LEVEL: ■ FORMAT: SESSION

Good Clinical Practice and Pharmacovigilance Issue Management and CAPA Effectiveness

CHAIRPERSON:

Federico Feldstein, JD
Vice President, Medical Regulatory Compliance, Pfizer Inc

Opportunities exist in establishing effective processes for oversight of good clinical practice/ pharmacogilance significant deviations and Corrective and Preventative Actions effectiveness. This session presents regulatory and industry perspectives, best practices, and emerging trends related to issue management.

Deborah A. Waltz, MS
Vice President, Global Compound Support, Quality Assurance, Takeda Pharmaceuticals International, Inc.

Representative Invited
Senior Medical Officer, Office of Scientific Investigations, CDER, FDA

Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA, QC

10:30 AM–12:00 PM LEVEL: ■ FORMAT: SESSION

How Can International Guidances Enable Global Regulatory Convergence?

CHAIRPERSON:

Mark Rosolowsky, PhD
Vice President, Global Regulatory Sciences, CMC, Bristol-Myers Squibb Company

This session will focus on how international organizations such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), International Medical Device Regulators Forum (IMDRF) and International Coalition of Medicines Regulatory Authorities (ICMRA) enable global regulatory convergence in particular for quality topics. The impact of some recent quality guidances on impurities (e.g., ICH M 7 and ICH Q3D) will be discussed in detail.

Toshiyoshi Tominaga
Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Ramani Raghavan, MS
Regulatory Advisor, Genentech, A Member of the Roche Group

Mark G. Schweitzer, PhD
Global Head, Analytical Science and Technology, Novartis Pharmaceuticals Corporation

Track 13A – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): CEHTAEbM

10:30 AM–12:00 PM LEVEL: ■ FORMAT: SESSION

FDA Sentinel Initiative

CHAIRPERSON:

Marsha E. Reichman, PhD
Senior Advisor & Scientific Lead Surveillance Programs, CDER Sentinel Initative Lead, FDA

The session will provide an overview to the FDA Sentinel Initiative. This initiative was launched in 2008 to build a postmarket risk identification and analysis system to complement FDA's existing postmarketing surveillance capabilities. The basis of the Sentinel Initiative was the pilot, Mini-Sentinel, which originated in 2009 through a contract with Harvard Pilgrim. Mini-Sentinel developed and tested the capabilities for using electronic health care data for safety surveillance of approved medical products. In 2014, Mini-Sentinel was transitioned to a sustainable surveillance system, the Sentinel System. This transition focuses on establishing policies, procedures, and organization for the Sentinel System.

Representative Invited
Assistant Professor, Department of Population Medicine, Harvard Pilgrim Health Care Institute/ Harvard Medical School

Representative Invited
Epidemiologist, Office of Medical Policy, CDER, FDA

Representative Invited
Medical Officer, Office of Biostatistics and Epidemiology, CBER, FDA

Track 13B – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): RA

10:30–11:30 AM ▲ Level: ■ Format: SESSION

Best Evidence Generation: Regulatory Perspectives

CHAIRPERSON:

Representative Invited
National Expert on Secondment Pharmacovigilance and Risk Management, European Medicines Agency, European Union

The traditional model of medicines regulation sees decisions made based on evidence submitted by pharmaceutical companies. More recently, however, regulators are supplementing this evidence with that from other sources including research by independent third-parties or established networks. These other sources also include data and information generated by regulators themselves, e.g., the EMA using e-health data from The Health Improvement Network (THIN) and IMS. The issues around regulators conducting such research are explored in this session including details of some of the research conducted and how the results have translated into outcomes and also some of the challenges posed, such as ensuring transparency.

Representative Invited
National Expert on Secondment Pharmacovigilance and Risk Management, European Medicines Agency, European Union

Representative Invited
Deputy Director, Office of Surveillance and Epidemiology, CDER, FDA

Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CR

10:30 AM–12:00 PM Level: ■ Format: SESSION

Integrated Cardiac Safety

CHAIRPERSON:

Representative Invited
Director, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

This session will discuss the evolution of cardiac safety and changes since the ICH E14 inception. Speakers will address why the TQT trial design is phasing out and discuss alternative options.

Joerg Seebeck, DrMed, MD
Chief Medical Officer, PrimeVigilance Ltd, United Kingdom

Tim Callahan, PhD
Chief Scientific Officer, Biomedical Systems

Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

10:30 AM–12:00 PM Level: ■ Format: SESSION

Pharmacovigilance Inspections: Achieving Compliance in a Global Environment

CHAIRPERSON:

Representative Invited
Head of Compliance and Inspections Department, European Medicines Agency, European Union

The session will provide an overview on the coordination of pharmacovigilance inspections in the EU and the US (including pharmacovigilance inspection metrics). There will be an opportunity to discuss common pharmacovigilance inspection findings and to identify and discuss the areas where there are differences in the requirements. The challenges in the conduct of pharmacovigilance in a global environment will also be identified and discussed from the industry perspective with the aim to collect proposals for the future.

Michael Oluseun Baptist
Quality Assurance Manager, Medpace, Inc.

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, ST

10:30 AM–12:00 PM Level: ■ Format: FORUM

The Role of the Clinical Statistician in Understanding and Using ADaM Data Standards

CHAIRPERSON:

Representative Invited
Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Analysis data model (ADaM) datasets and associated documentation are critical elements in PFDUA V-mandated, CDISC-compliant biologics license application and new drug application submissions. Clinical statisticians must know how to create and use ADaM-based standards. This forum will briefly review ADaM concepts and will describe several approaches currently used by sponsors and contract research organizations to successfully meet submission requirements. Regulatory perspectives will also be examined.

Diane Piper, MSc
Director Clinical Standards, Shire Pharmaceuticals

Rob Woolson, JD, MS
Chief Strategist, Regulatory Biostatistics and Standards, Rho, Inc.

Representative Invited
Mathematical Statistician, Office of Translational Science, CDER, FDA

Track 16A – Professional Development

Related Interest Area(s): PETD

10:30 AM–12:00 PM Level: ■ Format: WORKSHOP

Conducting Courageous Conversations as a Strategy to Work with Difficult People

CHAIRPERSON:

Valerie J. Gamble, EdD, MEd
Global Education and Performance Enhancement Lead, Pfizer Inc

Do jerks in the workplace exist? Do we know who they are? Believe it or not, jerks do exist in the workplace. They are in the form of our peers, colleagues, managers, and executives. In this workshop, you will learn about the concept of hot buttons and how these typically negative behaviors may be sabotaging success within your organization. We will discuss guidelines for conducting courageous conversations that will enable your team to work more effectively together as they excel both individually and collectively.

***Due to workshop format, seating will be limited and will be available on a first come, first served basis. The Walter E. Washington Convention Center 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 offering will not be recorded.*

Sue Fleschner, PhD, MA
Instructional Development and Facilitation, i3logic

Track 16B – Professional Development

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

10:30 AM–12:00 PM Level: ■ Format: WORKSHOP

DEVELOP Excellent Presentations to INNOVATE the Way You Communicate Information and ADVANCE Your Career

CHAIRPERSON:

Lynn King, MHA
Senior Director, Clinical Operations, TKL Research

This fun, interactive workshop will review skills necessary for the delivery of effective, successful presentations. Participants will analyze their individual presentation skills gaps, practice important skills and receive feedback for improvement.

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Robin Whitsell
President, Whitsell Innovations, Inc.

Track 17 – Rare/Orphan Diseases

Related Interest Area(s): CR

10:30 AM–12:00 PM Level: ■ Format: SYMPOSIUM

Orphan Drug Development Challenges: Case Studies

CHAIRPERSON:

Daniel Mazzolenis, MD, MBA
Senior Medical Director, Global Oncology Hematology, INC Research, Argentina

In this symposium, three different case studies will showcase the multiple challenges in the successful development of new therapies for orphan diseases. The first case is about adjuvant treatment for phenylketonuria (PKU) and will center on systematic analysis of the current evidence and subsequent gap analysis as the basis to inform decision-making and future research. The second case focuses on hemophilia, a field with a large corps of knowledge regarding pathophysiology, therapeutic interventions and even comprehensive drug development guidelines. We intend to showcase precisely how the paradigms on which those guidelines are based may require revision in light of recent therapeutic developments, at the risk of regulation being an impediment to the continuous improvement. Finally, the last case will showcase how strategic planning and operational efficiency is critical for efficient and successful development of an orphan drug program.

Melissa McPheeters, PhD, MPH
Research Associate Professor, Vanderbilt University Medical Center

Pablo Rendo, MD
Senior Director, Physician Clinician, BeneFIX Global Clinical Lead, Pfizer Inc

Michelle Petersen, MSc
Clinical Trial Manager, Medpace, Inc.

Track 20 – Innovation Theater

Related Interest Area(s): IT, RD

12:00–12:30PM Level: ■

Format: SPECSESS

SAS Innovation Theater: Accelerate Value-Based Drug Development With Analytics

You most likely feel pressure from stakeholders who have an interest in how your therapies will meet demands for value-based care. Their influence and expectations are critical. To achieve overall treatment value you must first master data integration and analytics across a drug development pipeline. During this session, learn how advanced analytics can help improve access to data so you can develop value-based therapies that meet stakeholder expectations.

Track 01A – Clinical Operations

Related Interest Area(s): CR, CP

1:30–3:00 PM Level: ■ Format: SESSION

Cardiac Safety Considerations in Pediatric Drug Development

CHAIRPERSON:

Rick Turner, PhD
Senior Scientific Director, Quintiles Inc.

There is great interest in reviewing scientific and public health policy issues pertaining to sudden cardiac death (SCD) occurring in apparently healthy individuals in pediatric populations. This session will first provide fundamental information underlying the rationale for developing a sustainable national health care resource in the domain of pediatric SCD prevention. It will also review discussions from the February 2015 Cardiac Safety Research Consortium (CSRC) Think Tank, and describe the resultant initiatives. Finally, it will invite thoughts and suggestions from attendees with regard to additional contributions and refinements to these initiatives.

Tess Vickers Saarel
Associate Professor, Pediatric Cardiology, University of Utah, University of Utah

Mitchell I. Cohen, DrMed
Co-Director Heart Center, Phoenix Children's Hospital

Albert Allen
Senior Medical Fellow, Bioethics & Pediatric Capabilities, Eli Lilly and Company

Representative Invited
Associate Director, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

Track 01B – Clinical Operations

Related Interest Area(s): CR

1:30–3:00 PM Level: ■ Format: SESSION

Is Facebook Hurting Your Trial? Social Media and the Introduction of Bias in Clinical Studies

Lindsay McNair, MD, MPH, MS
Chief Medical Officer, WIRB-Copernicus Group

In this session, we will discuss the potential complications of social media interaction between study participants, and will present practical ideas for maintaining respect for the autonomy of participants, while protecting the integrity of the clinical trial.

Eric J. Peacock, MBA
Cofounder and Chief Executive Officer, MyHealthTeams

Craig H. Lipset
Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc

Track 02A – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): PETD

1:30–3:00 PM Level: ■ Format: SESSION

Project Management in Context: Reflections on the Project Manager Role from Other High-Risk Industries

CHAIRPERSON:
Peter Harpum, PhD, MSc
Client Director, Mannaz A/S, United Kingdom

The role of project manager in our industry is unresolved. Value achieved through project management remains in doubt. The value created by project managers in other industries will be presented by people from oil and gas, aerospace, and construction. The audience will have an opportunity to ask questions of the speakers to further understand the role each one plays in delivering value to their projects, clients, and employers.

Track 02B – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): CR

1:30–3:00 PM Level: ■ Format: FORUM

Issue Resolution in Clinical Partnerships

CHAIRPERSON:
Susan M. Shelby, PhD
Vice President of Clinical Operations, Biomedical Systems

For each clinical trial, a hierarchy of issue escalation exists among the various vendors and within the sponsor organization. This forum includes representatives from a CRO, a biotechnology company sponsor, a pharmaceutical company sponsor, and a core laboratory executive to define how to best escalate study issues within their environments.

Susan M. Shelby, PhD
Vice President of Clinical Operations, Biomedical Systems

Representative Invited
Director, Clinical Operations, Vertex Pharmaceuticals

Representative Invited
Executive Director of Project Delivery, PRA Health Sciences

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR

1:30–3:00 PM Level: ■ Format: FORUM

The Voice of the Sites: Collaborating to Build a Site Partnership Model to Enable Study Start-Up

CHAIRPERSON:

Rupa Roychowdhury
Associate Director, Start Up Management Office, Clinical Development Services, Covance Inc.

The voice of the site is a critical yet underutilized opportunity for efficient study start-up. In this forum, the outcome of a site/contract research organization partnership collaboration model will be shared for clinical studies to proactively assess and mitigate start-up risks.

Track 04 – Preclinical and Translational Development/ Early Phase Clinical Development

Related Interest Area(s): NC, CR

1:30–3:00 PM Level: ■ Format: SYMPOSIUM

Effective Discovery, Development and Use of Biomarkers in Early Drug Development

CHAIRPERSON:

Stacie J. Bell, PhD
Senior Medical Science Liaison - Mid-Atlantic, Mallinckrodt Pharmaceuticals, Inc.

In this symposium, multiple facets of biomarker development and use will be addressed. The research surrounding identification of possible biomarkers and early evaluation will be outlined, as well as the expertise and resources required (often in collaboration) to execute these assessments. We will specifically highlight novel quantitative imaging biomarkers and techniques, as well as a rapid, multiplexed quantitative proteomics assay solution. Finally, the regulatory considerations for biomarker impact on the drug development plan and new drug application filing will be outlined, along with concerns for informed consent processes and subject samples.

This symposium has been developed with the DIA Clinical Pharmacology and Translational Medicine Communities.

Gregory V. Goldmacher, MD, PhD
Senior Director, Medical and Scientific Affairs, ICON Clinical Research

Gordon Vansant, PhD
Regional Director, Western US, SomaLogic

Representative Invited
Executive Director and Head of TLM, QPS, LLC

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

Related Interest Area(s): MSL

1:30–3:00 PM Level: ■ Format: SESSION

Globalization of Field Medical Science Liaison: How to Take it to the Next Level

CHAIRPERSON:

Lisa Cesario, RPh
Director, Medical Liaison Oncology, Hoffmann-La Roche Ltd., Canada

Many companies today have established functional excellence in globalization of medical science liaisons (MSLs.) How do you balance the needs of the global organization while ensuring your local team's resources are focused on your local priorities? How do leaders achieve internal collaboration, recognizing flexibility and respect for cultural differences that are key to a successful model? This session will provide an overview of how Canadian MSL leaders have established an industry forum, which will be showcased as a successful case study demonstrating industry wide collaboration. The speakers will also explore how this can be adapted to other industry leaders and other markets. Speakers will share best practices on how to strike the right balance. In addition, the speakers will address compliance implications when instituting any new best practice and share their global expertise on how to ensure success in global MSL functions.

Track 07A – Technology/Data/Records and Submissions

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

1:30–3:00 PM Level: ■ Format: SESSION

Searching for the Gold Nuggets: Text Analysis in Clinical Data

CHAIRPERSON:

Timothy Kropp, PhD
Associate Director for Innovation, Office of Computational Science, Office of Translational Sciences, CDER, FDA

Textual information contains some of the most high value information among clinical data. This session will explore and discuss techniques for investigating free text information in clinical trials and for pharmacovigilance. This session will bring multiple experts together to discuss approaches to performing analysis of free text reports submitted to a new drug application such as patient narratives, postmarket reports, patient reporting and others.

James Sawyer, DrMed
Medical Director, Identify.AE, Prism Ideas Ltd., United Kingdom

Hanming H. Tu, MSc
Director, Clinical Information Technologies, Accenture

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): VA, IT

1:30–3:00 PM Level: ■ Format: SYMPOSIUM

Frontier Issues in Electronic Information Integrity Today

Teri Stokes
Director, GXP International

This symposium will address three different "on the edge" issues for electronic information integrity today.

- How do you evaluate whether validation is good business even if FDA hasn't identified the system for
- GXP/Part 11 compliance?
- How can you identify and prevent bias from creeping into your risk assessment practices?
- How does one address IQ evidence expectations for SaaS and Cloud Part 11/Annex 11 compliance?

Pharmaceutical company medical information data, pharmacovigilance data, and SaaS data in the cloud all share a need for risk based integrity checks. Yet often our risk assessment practices themselves have unseen bias that can influence the integrity of electronic information. Come listen, question, and share your own electronic information integrity experiences either as a challenge or a success.

Andrew Harbrow, RPh
Global Medical Services Manager, PrimeVigilance Ltd, United Kingdom

Teri Stokes
Director, GXP International

Breffni Kennedy Martin
Legal Representative, Data Controller, Consultant, Regintel Ltd, Ireland

Track 08A – Regulatory Affairs

Related Interest Area(s): CR, PPLC

1:30–3:00 PM Level: ■ Format: SESSION

Expediting Drug Development through FDA's Breakthrough Therapy Designation

Todd Paporello, PharmD, MBA
Vice President and Head of US Regulatory Affairs, Bayer HealthCare Pharmaceuticals

FDA's Breakthrough Therapy Designation (BTD) has evolved as industry and the agency have gained experience with the program. In this session, an attorney will analyze the evidence that FDA has required for designations, FDA will discuss BTD's impact on development and review, and industry will review lessons learned from a product approved with BTD.

Alexander Varond, JD
Associate, Hyman, Phelps & McNamara, PC

Miranda Raggio, BSN, MA, RN
CDER Breakthrough Therapy Program Manager/Senior Regulatory Health Program Manager, FDA

Michelle Rohrer, PhD
Vice President, Global Head Regulatory Regions & Policy, Genentech, A Member of the Roche Group

Track 08B – Regulatory Affairs

Related Interest Area(s): AP

1:30–2:30 PM ▲ Level: ● Format: SESSION

Does Bioequivalent Always Mean Therapeutically Equivalent? Impact of FDA's Proposed Rule on Generic Labeling

Margaret Woo, PharmD
Novartis Pharmaceuticals Corporation

A panel claimed that FDA failed to sufficiently monitor generics which account for 85% of drugs sold in US. This session will discuss a new proposed rule which makes it easier for generic companies to update labels, and how this change will have implications on the Federal Food, Drug and Cosmetic Act (FD&C Act), generic companies, patients, and health care providers.

Representative Invited
Senior Vice President, Policy and Strategic Alliances, Generic Pharmaceutical Association (GPhA)

Representative Invited
Deputy Commissioner, Policy Planning and Legislation, Office of the Commissioner, FDA

Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): MDD, CR, CP

1:30–2:30 PM ▲ Level: ■ Format: SESSION

Global Clinical Trials

Kirsten H. Paulson, MS, RAC
Senior Director, Global CMC-Medical Devices, Pfizer Inc

In this session, we will provide an overview about the current regulatory framework in Europe for clinical trials with medical devices, highlighting similarities as well as differences to describe the range of potential variability across Europe. In addition, although medical device notified bodies are accredited by a member state to assess whether a medical device conforms to the EU Medical Devices Directive, there has been an increase in regulators requesting and performing a review of the documentation and assessment already conducted by the notified bodies. The question is raised whether this increased concern represents a lack of confidence in the notified bodies' assessment or if it is a renewed approach from the regulators to be involved in the safety assessment of a medical device.

Farzana Hussain
Regulatory Project Manager and Team Leader, Novo Nordisk A/S, Denmark

Rainer Porrmann
Head, Clinical Trial Regulatory Management, Accovion GmbH, Germany

Representative Invited
European Medicines Agency, European Union

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): CR, RA

1:30–3:00 PM Level: ■ Format: FORUM

The Challenges, Solutions and Right To Try Surrounding Expanded Access

David Vulcano, MBA, RAC
Hospital Corporation of America (HCA)

Many states are enacting "Right to Try" legislation as an effort to provide access to investigational therapies to those in their state with terminal illnesses and seemingly nowhere else to turn. These efforts present logistical and ethical dilemnas. This forum will try and explain the ethical dilemnas surrounding Expanded Access and what industry needs to know when requesting expanded access from the FDA.

Alison Bateman-House, PhD, MA, MPH
Postdoctoral Fellow, Division of Medical Ethics, New York University Langone Medical Center

Representative Invited
Director, Patient Liaison Program, Office of the Commissioner, FDA

David Vulcano, MBA, RAC
Hospital Corporation of America (HCA)

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR

1:30–3:00 PM Level: ■ Format: SESSION

Using Data Analytics to Detect Quality Issues

Leslie M. Sam
Director, Global Quality Systems, Eli Lilly and Company

Opportunities exist to establish effective processes to detect quality issues. This session presents proven best practices and emerging trends related to the detection of quality issues during a clinical trial.

Richard C. Zink, PhD
Principal Research Statistician Developer, JMP Life Sciences, SAS Institute, Inc.

Maria Degeyter
Regional Quality Lead, Janssen Pharmaceuticals, Inc., Belgium

Track 12 – Pharmaceutical Quality

Related Interest Area(s): CP

1:30–3:00 PM Level: ■ Format: FORUM

Risk-Based Inspections and Compliance

Representative Invited
Director, Office of Manufacturing and Product Quality, Office of Compliance, CDER, FDA

This forum will provide attendees with exposure to the current FDA approach to risk-based inspections and provide participants with the opportunity to discuss the processes and criteria used to establish risk rankings.

Chyn-Liang Huang, MPharm
Chief Inspector/ Section Chief, Taiwan Food and Drug Administration

Xiling Song, MS
Associate Regulatory Program Director, Pharma Technical Regulatory, Genentech, A Member of the Roche Group

Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): CR

1:30–3:00 PM Level: ● Format: FORUM

Patient-Centered Outcomes Research: Pragmatic Clinical Trials

Representative Invited
Patient-Centered Outcomes Research Institute

Hear about the Patient-Centered Outcomes Research Institute's (PCORI) current projects and areas of future interest under its Pragmatic Clinical Trials (PCT) initiative. This regular funding announcement from PCORI supports PCTs, Large Simple Trials and large observational studies to examine the comparative clinical effectiveness and patient-centered outcomes of various interventions.

Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RD

1:30–3:00 PM Level: ■ Format: SESSION

A Proactive and Systematic Approach to Managing Product Risk Across the Life Cycle

Brian Edwards, MD, MRCP
Principal Consultant, Pharmacovigilance and Drug Safety, NDA Group, United Kingdom

It will be nearly seven years since CIOMS VI published their recommendations for developmental risk management planning. But what has happened to systematic life cycle management? How good are we at assimilating all the evidence about a medicine? Are we better at determining how to balance risks against benefit at all phases? There is a mass of evidence concerning systems or organizational science such as human factors engineering. How has our sector implemented this evidence? The time to apply organizational science to systematically manage

the risks of medicines is overdue. This session will assess what current best practice is from industry and regulatory perspectives and how this might be improved by applying the principles of organizational science.

Linda Quinn, PharmD
Director, Risk Management Scientific Lead, Janssen Pharmaceuticals, Inc.

Syed Rizwanuddin Ahmad, MD, MPH, FISPE
Assistant Professor (adjunct), Georgetown University School of Medicine

Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

1:30–3:00 PM LEVEL: ■ FORMAT: SESSION

Measuring the Impact of Regulatory Pharmacovigilance in Europe and the United States

Representative Invited
Head of Pharmacovigilance Department, European Medicines Agency, European Union

Measuring the impact of pharmacovigilance allows us to improve performance and to demonstrate effectiveness. Frameworks for impact measurement will be discussed using EU/US situations as case studies. Views on optimal approaches will be explored.

Representative Invited
Director, Office of Surveillance and Epidemiology, CDER, FDA

Representative Invited
Assistant Professor, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University, Netherlands

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CP, CR

1:30–3:00 PM LEVEL: ■ FORMAT: FORUM

Big and MultiStream Data for Drug Evaluation: The Promise and Cautions

Representative Invited
Deputy Director, Division of Biometrics VI, Office of Biostatistics, CDER, FDA

This forum will discuss current and emerging large and multistream data sources for drug evaluation and the associated methods and systems. It will also highlight the promises and cautions of the data sources.

Patrick Ryan, PhD, MS
Head, Epidemiology Analytics, Janssen Pharmaceuticals, Inc.

Representative Invited
Senior Advisor & Scientific Lead Surveillance Programs, CDER Sentinel Initative Lead, FDA

Susan Gruber, PhD, MPH, MS
Senior Director, IMEDS-Methods Research, Reagan-Udall Foundation for the FDA

Track 16 – Professional Development

Related Interest Area(s): PETD

1:30–3:00 PM LEVEL: ● FORMAT: WORKSHOP

Using Games and Play to Create an Innovative Learning Experience

Akshay Sateesh, MS
Founder and Facilitator, Ziksana Consulting

In this workshop, participants will learn the impact and application of using play and games in their workplace. Facilitators will lead the group in fun activities to explore how play can connect, encourage, and explore new ways of thinking, being, and behaving to motivate and engage those involved. Using concepts from improvisation theater, participants will design and present a training game during the session applied directly to their field of interest. We will close with a case study demonstrating the power and impact of games and gamification in an organization. Come

have some fun and learn about the science of play and how it applies to your company!

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Akshay Sateesh, MS
Founder and Facilitator, Ziksana Consulting

Kathy Tibaldi, MA
Director, Project Management and Solution Center, DATATRAK International

Asli Guven Santos, PharmD
Director, Catalyst Regulatory Services, LLC

Track 17 – Rare/Orphan Diseases

Related Interest Area(s): RA

1:30–3:00 PM Level: ■ Format: SYMPOSIUM

A Global Update on Orphan Drugs

Noriaki Murao, MS
Representative, NM Consulting, Japan

This symposium addresses the current status and forthcoming activities related to orphan drugs in North America, EU and Japan. Orphan drug development is considered essential in these regions, and the various provisions to accelerate the development of orphan drugs have been implemented. However, some challenges still remain for the companies and the agencies wishing to pursue development and approval of orphan drugs in these regions.

Representative Invited
Head of Office for Orphan Medicines, European Medicines Agency, European Union

Giri Prasad Venkiteela, MS, RPh, RAC
Senior Regulatory Consultant, Humber-RAC Work Group, Canada

Representative Invited
Director, Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Track 18 – Global Regulatory

Related Interest Area(s): RA

1:30–3:00 PM Level: ■ Format: FORUM

CBER Town Hall: Innovation and Public Health Response

Representative Invited
Director, Center for Biologics Evaluation and Research, FDA

This forum will provide an overview of Center for Biologics Evaluation and Research's (CBER) current work on ongoing initiatives, guidances, and regulations.

Track 19A – Late-breaking Topics

Related Interest Area(s): RA

1:30–3:00 PM Level: ■ Format: SESSION

No More Crying Wolf: FDA Issues Final Rule on Changes to Pregnancy and Lactation Information in Drug Labeling

Representative Invited
Medical Officer, Division of Pediatrics and Maternal Health, Office of New Drugs, CDER, FDA

This session discusses the final Pregnancy and Lactation Labeling Rule which sets the new content and formatting requirements for pregnancy and breastfeeding information in labeling. Perspectives are provided from the FDA, industry, and academia.

Representative Invited
Team Lead, Maternal Health, Office of New Drugs, CDER, FDA

Representative Invited
Director, The Reproductive Toxicology Center

Representative Invited
Deputy Director, Office of New Drugs, CDER, FDA

Track 19B – Late-breaking Topics

Related Interest Area(s): CR

1:30–3:00 PM Level: ● Format: SESSION

TransCelerate Collaboration: Harmonization Efforts to Find Solutions to Critical Industry Challenges

Representative Invited
Director Of Communications & Engagement, Transcelerate Biopharma, Inc.

Collaboration among TransCelerate Biopharma Inc. (TransCelerate) member companies is driving industry innovation. In this session, we will examine how these 21 participating member companies are driving innovation to address clinical trial execution pain points through their 12 chartered work streams. We will also address the mission of TransCelerate, what solutions have been delivered so far, and what to expect in 2015 and beyond.

Track 01A – Clinical Operations

Related Interest Area(s): PT, CR

3:30–5:00 PM Level: ● Format: FORUM

Best Practices for Effective Engagement with Patient Groups Around Clinical Trials

Bray Patrick-Lake, MS
Director of Stakeholder Engagement, Clinical Trials Transformation Initiative (CTTI)

This forum will review evidence from Clinical Trials Transformation Initiative's Patient Groups & Clinical Trials project literature search, joint survey with DIA, and key informant interviews on practices that support effective partnerships. Value and associated metrics will also be examined.

Representative Invited
President and CEO, Melanoma Research Alliance

Representative Invited
Director, Clinical Innovation, Worldwide Research and Development, Pfizer Inc

Track 01B – Clinical Operations

Related Interest Area(s): RD, CR

3:30–5:00 PM Level: ■ Format: SYMPOSIUM

How to Best Optimize Site/Country Selection Based on Online Feasibility Tools and Global Regulatory Approval Timelines

Gustavo Kesselring, MD
Executive Director, Latin America, ViS Research, Brazil

This symposium will address how management of big data analytics, visualization systems and social networks can accelerate and reduce cost of trial planning process through an innovative online feasibility assessment that interacts with research sites. Methods for assessing dynamic global regulatory approval timelines and their impact on the development of optimal country strategies for clinical trials will be discussed. We will conclude with an investigation of how disruptive technologies are changing processes, the performance metrics that can be collected, as well as our expectations of what constitutes acceptable performance.

Gustavo Kesselring, MD
Executive Director, Latin America, ViS Research, Brazil

Shawn Phillip Tedman, MBA
Associate Director, Site Intelligence, PAREXEL International

Linda B. Sullivan, MBA
Co-Founder and President, Metrics Champion Consortium LLC

Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): RD, PPLCC

3:30–5:00 PM Level: ■ Format: FORUM

Pediatric Product Development in the 21st Century: Developing Research Networks to Get the Job Done

Lynne P. Yao, MD
Associate Director, Pediatric and Maternal Health Staff, Office of New Drugs, CDER, FDA

Efficient pediatric drug development in the 21st century will require effective collaboration between industry, academia, patients, and government. This forum will gather stakeholders from these groups to explore use of pediatric research networks.

Earl Seltzer, MBA
Feasibility Manager, Quintiles Inc.

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, CR

3:30–5:00 PM Level: ■ Format: FORUM

Outing Innovation: How Partnerships Help (and Hinder) the Movement Toward Novel Approaches to Clinical Development

John Rafa, III, MBA
Executive Director, Research Services, The Avoca Group, Inc.

Results from industry research and a sharing of executive panel perspectives on clinical trial innovation will serve as a catalyst for audience discussion. This forum will discuss the impact that partnering arrangements will have on innovation.

Track 06 – Medical Communication/Medical Writing and Medical Science Liaison

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

3:30–5:00 PM Level: ■ Format: SESSION

Accountable Care Organizations and Integrated Health Care

J. Lynn Bass, PharmD, RPh
Director, Medical Affairs, Jazz Pharmaceuticals

This session will educate professionals in the pharmaceutical, biotechnology, and device industries and government employees on how medical and health economics data is disseminated to a variety of customer segments. Participants will benefit from understanding the opportunity and need to disseminate a variety of data to both the prescribing and decision maker communities.

This session was developed by the Medical Communications, Medical Science Liaison and Medical Writing Communities.

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

James Stephen Dodge, PharmD, MBA
Executive Director, Health Systems, US Medical Affairs, Merck & Co., Inc.

Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, PM

3:30–5:00 PM Level: ● Format: SESSION

CFAST Initiative: Potential to Dramatically Increase ROI and Reduce Timelines in the Conduct of Clinical Trials

Rhonda Facile, MS
Senior Director, Standards and Development, CDISC

The Coalition for Accerating Standards and Therapies (CFAST) initiative has made progress in increasing the speed and number of therapeutic area (TA) standards developed. These accomplishments have the potential to dramatically increase return on investment and reduce the timeline in the conduct of clinical trials.

Representative Invited
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

Diane E. Wold, PhD
Director, Data Standards, GlaxoSmithKline

Track 07B – Technology/Data/Records and Submissions

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

3:30–4:30 PM ▲ Level: ■ Format: SESSION

The Critical Role of Document Management Supporting Submissions: Regulatory Operations, IT and Vendor Perspectives

Bill Leslie
Head, Global Regulatory Operations, Covance Inc.

Submissions to regulatory authorities are critical in support of clinical trials as well as marketing

applications. Speakers representing regulatory operations, IT and the vendor community will discuss how to successfully select and implement a document management supporting system.

Vincent P. Heenan, MBA
Director, Information Technology, Johnson & Johnson

Melissa Aron
Professional Services Practice Manager, Veeva Systems

Track 08 – Regulatory Affairs

Related Interest Area(s): CR, RD

3:30–5:00 PM Level: ■ Format: SESSION

Dynamic Changes in Regulatory Landscape in Asia: Regulations for Global Drug Development

Akio Uemura, PhD
Senior Director & Head, APAC Clinical Operations, Regulatory Affairs & Safety Japan, Allergan Japan K.K., Japan

The regulatory environment in Asia is rapidly changing and its importance for global drug development is rising high. We will hear from an Asian regulatory agency and industry and discuss how we should actively modify our development strategy based on recent changes.

Yoshiaki Uyama, PhD
Director, Division of Epidemiology, Office of Safety I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Representative Invited
Associate Regulatory Program Director, Pharma Technical Regulatory, Genentech, A Member of the Roche Group

Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): MDD, RA

3:30–5:00 PM Level: ● Format: SESSION

Enhanced Collaborative Strategies: FDA and Device Makers Focusing on Improved Device Clearance Processes

Amnon Talmor
Premier Research Group Ltd.

This session explores device industry events that have led to increased FDA involvement with device makers in order to establish mechanisms implemented since 2009 for improved product review and market clearance.

Roshana Ahmed, MA, RAC
Senior Manager, Regulatory Affairs, Optum, Canada

Representative Invited
Supervisory Biomedical Engineer, Office of Device Evaluation, CDRH, FDA

Molly Follette Story, PhD
Head, Global Usability Engineering and Risk Management, Sanofi

Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): RA

3:30–5:00 PM Level: ■ Format: FORUM

Enforcement Update and Trends From a Global Perspective

Barry A. Berger, JD, MBA
Professor of Regulatory Affairs, Temple University

This forum will address from an industry, regulator and public interest perspective some of the key current enforcement actions and trends. How can each group better address and respond to issues that present challenges to public health?

Representative Invited
Deputy Director, Office of Compliance, CDER, FDA

Douglas B. Farquhar, JD
Partner, Hyman, Phelps & McNamara, PC

Mitchell Berger, JD, MPH, RAC
Consumer Safety Officer, FDA Alumni

Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

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

3:30–5:00 PM Level: ● Format: SESSION

Adapting Risk Management Principles to Non-Traditional R&D Settings

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

Headline risk is of perpetual concern for companies in the biopharmaceutical and biotechnology markets. As regulatory scrutiny directed toward companies that develop vaccines, immunotherapies, recombinant DNA/gene therapies, and other biologically-derived products increases, so does public awareness of the importance of biosafety and biosecurity. Product integrity is more important than ever, and is a direct function of quality programs. This session will discuss quality assurance/quality control programs that would benefit from a robust and integrated risk management program.

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

Ryan N. Burnette, PhD
Vice President, WCG Biosafety, WIRB-Copernicus Group

Representative Invited
Deputy Director, Regulatory Affairs, Mapp Biopharmaceutical, Inc.

John Tierney
Clinical Research Oversight Manager, National Institutes of Health (NIH)

Track 12 – Pharmaceutical Quality

Related Interest Area(s): MF, PM

3:30–5:00 PM Level: ■ Format: SESSION

Knowledge Management for the Product Life Cycle

Paige Kane
Director, Knowledge Management, Pfizer Inc

This session will discuss the role of knowledge management and how it plays a pivotal role in setting successful pharmaceutical and biotechnology product and process knowledge.

Kim Samantha Northam
Regulatory Affairs Associate Manager, Accenture, United Kingdom

Peter Lassoff
Vice President and Head of Global Regulatory Affairs, Quintiles Inc., United Kingdom

Representative Invited
Director General, Pharmaceuticals Export Promotion Council, India

Track 13 – Comparative Effectiveness Research/ Global Health Outcomes and Economics

Related Interest Area(s): CR

3:30–5:00 PM Level: ■ Format: WORKSHOP

Making Evidence at Launch More Real-World: Pragmatic Trials, Current Developments and Operational Challenges

Mira Zuidgeest, PharmD, PhD, MSc
Assistant Professor & Scientific Co-Lead Workpackage 3 IMI GetReal Consortium, Julius Center for Health Sciences and Primary Care, UMC Utrecht, Netherlands

Pragmatic relative effectiveness (RE) trials are essential to compare treatment strategies. Designing and executing such real-world trials pre-launch is challenging. In this workshop, we will assess pragmatic study design options, their operational feasibility and methodological implications.

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Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA, CR

3:30–5:00 PM Level: ■ Format: SESSION

Developing Innovative Approaches to Postmarketing Safety Data Collection in Pregnant Women

Leyla Sahin, MD
Medical Officer, Office of New Drugs, CDER, FDA

This session will explore the challenges of conducting postmarketing studies in pregnant women. Key messages from the 2014 FDA public meeting will be presented and discussed. Industry will discuss implementation of pregnancy registries as well as methodological considerations for categorization of subjects as retrospective vs. prospective and birth outcomes, and coding of birth defects. Regulatory experts from the United States and Europe and industry will participate in a panel discussion about the current thinking and experiences in the approaches to postmarketing data collection in pregnant women.

Catherine Sigler, DVM, PhD, MPH
Senior Director, Safety, Epidemiology, Registries and Risk Management, UBC: An Express Scripts Company

Representative Invited
Senior Clinical Advisor, Division of Pediatric and Maternal Health, Office of New Drugs, CDER, FDA

Representative Invited
European Medicines Agency, European Union

Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): RA

3:30–5:00 PM ■ Format: SESSION

CIOMS IX: Practical Approaches to Risk Minimization and Its Evaluation

William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory, Pfizer Inc

Routine risk minimization applies to all medicinal products. However, in certain instances, additional risk minimization tools may be necessary to ensure that product benefits outweigh risks and the product remains available to patients. In these cases, it is important to appropriately characterize the risk and frame the goals for the non-routine interventions. These first steps are followed by selection of the least burdensome tool(s) that are implementable and, at the same time, will also achieve the desired goals under real-world conditions. Knowing which tools to use, how to measure their effectiveness, and when to make modifications are key to success. In this session, three members of the Council for International Organizations of Medical Sciences (CIOMS) IX Working Group will review concepts, practical considerations, and implications for the biopharmaceutical industry.

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Quintiles Inc., United Kingdom

Representative Invited
Medical Advisor & Advisory Board Member, NDA Group, United Kingdom

William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory, Pfizer Inc

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, ST

3:30–5:00 PM ■ Format: SESSION

Statistical Support of Risk-Based Monitoring

Jonathan Haddad, MPH, MT
Director, Clinical Statistics, Stiefel, A GSK Company

Risk-based monitoring (RBM) is rolling out across the industry and new guidance documents have given industry a shove out onto the dance floor. Clinical statisticians have long been pressed by their study teams to identify analysis-oriented data queries to support data quality. Other aspects of RBM include statistical process control and signal-detection to evaluate performance and identify problems, areas in which clinical statisticians can make important contributions. This session will cover the role of the clinical statistician in the suppport of RBM, through several case studies by sponsors and contract research organizations.

Francois Torche, MBA
Chief Executive Officer, CluePoints, Belgium

Jill Woodward Collins, MEd, MS
Senior Director Clinical Innovation, INC Research

Yodit Seifu, PhD
Senior Manager II, Allergan, Inc.

Track 16 – Professional Development

Related Interest Area(s): PETD

3:30–5:00 PM Level: ● Format: WORKSHOP

Abstract and Article Publication Opportunities with DIA

Julie Ho
Senior Manager, Annual Meeting Content, DIA

This workshop will provide you with information on how to share your articles and abstracts with DIA.

Add "published author" to your accomplishments! Dr. Stephen P. Spielberg, Editor-in-Chief of DIA's official peer-reviewed journal, Therapeutic Innovation & Regulatory Science (TIRS), will discuss the submission and peer-review process for this publication. Judy Connors, Associate Director of Editorial Services, will provide tips and answer your questions about other publication opportunities with DIA, including article submission to our association news magazine, the Global Forum and content development for the DIA website.

Become a chairperson or speaker at the DIA 2016 52nd Annual Meeting! This workshop will also provide tips and helpful hints in submitting an abstract for next year's DIA 2016 52nd Annual Meeting that will be held June 18-22, 2016, in Philadelphia. Details will be shared regarding the timeline for next year's abstract submission process.

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Stephen P. Spielberg, MD, PhD
Editor in Chief, DIA Publications

Judy Connors, MA
Associate Director, Editorial Services, DIA

Track 17 – Rare/Orphan Diseases

Related Interest Area(s): PETD, CR

3:30–4:30 PM ▲ Level: ■ Format: FORUM

Rare Diseases: Patients, Caregivers and Advocates as Equal Partners in Clinical Trial Process

Barbara Szymaszek
Advocacy, Diversity and Patient Engagement, Bristol-Myers Squibb Company

This forum will discuss ways to enhance protocol design, recruitment and retention strategies for clinical trials in rare/orphan diseases, offering both strategic and tactical approaches. We will examine lessons learned on data from over 50 rare disease studies, underscoring the critical role of referring physicians. We will address operational challenges, strategies and tactics to design and conduct protocols that are practical from the patient and caregiver perspectives, and will share a case study of the impact patient advocacy organizations make in drug development. Finally, the panel will examine the definition of return on investment and other measures of success.

Jaime Cohen
Corporate Marketing, BBK Worldwide

Track 18A – Global Regulatory

Related Interest Area(s): RA, RD

3:30–5:00 PM Level: ■ Format: SESSION

Asia Town Hall: Asia as a Drug R&D Center in the World

Representative Invited
Associate Executive Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

This session will address the current status of the regulatory environment as well as recent achievements and challenges of drug development in Asian countries.

Representative Invited
Director, Office of Review Management, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Representative Invited
Deputy Director, Medical Services; Executive Director, Center of Excellence, Duke-NUS Graduate Medical School, Ministry of Health (MOH), Singapore

Representative Invited
Director, Global Regulatory Affairs Department, JPMA, Japan

Track 18B – Global Regulatory

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

3:30–5:00 PM Level: ■ Format: FORUM

The State of Informatics at CDER, CBER and CDRH

Ron Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program, Office of Strategic Programs, CDER, FDA

CDER, CBER and CDRH are working towards all electronic environments in order to streamline and facilitate the review of electronic submissions. This forum focuses on the Centers' goals, experiences and practical advice for sponsors and consultants.

Representative Invited
Director, Office of Business Informatics, CDER, FDA

Representative Invited
Chief, Business Operations Staff, Office of Medical Products and Tobacco, CBER, FDA

Representative Invited
Associate Director for Digital Health, Office of the Center Director, CDRH, FDA

THURSDAY, JUNE 18

Registration Hours:

8:00–11:00 AM Attendee and Speaker Registration

Schedule:

8:15–9:00 AM Coffee and Breakfast Breads

9:00–10:30 AM Educational Opportunities
60-minute ▲ TURBO Offerings (9:00–10:00 AM)
90-minute Offerings (9:00–10:30 AM)

10:30–10:45 AM Coffee Break

10:45 AM–12:15 PM Educational Opportunities
60-minute ▲ TURBO Offerings (10:45–11:45 AM)
90-minute Offerings (10:45 AM–12:15 PM)

Track 01A – Clinical Operations

Related Interest Area(s): PT, CR

9:00–10:00 AM ▲ Level: ■ Format: SESSION

Lung-Map: A Future Clinical Trial with a Master Protocol Happening Now and the Value to Patients

Stephen Smith
Senior Director, Patient Value, Medidata Solutions Worldwide

This session will provide an overview of a future clinical trial design happening now: Lung-Map. We will include a description of the design, milestones attained, and observations about biostatistics, reduced patient burden, efficiencies, and increased chances of success. The value to patients is explored including aspects of this trial design that overcome traditional problems with clinical trial design.

Stephen Smith
Director, Patient Value, Medidata Solutions Worldwide

Mary Redman, PhD
Lead Biostatistician, SWOG Lung Committee/ LungMap, Fred Hutchinson Cancer Research Center

Track 01B – Clinical Operations

Related Interest Area(s): PT, CR

9:00–10:00 AM ▲ Level: ■ Format: SESSION

The Ultimate in Patient-Centered Trials: Bringing Study Visits into the Home

Robin Marcus, BSN, RN
Vice President, Business Development & Strategic Initiatives, GlobalCare Clinical Trials

This session will review the results of the Tufts Center for the Study of Drug Development 2014 Homecare Survey and the implications in implementing this service model in clinical trials. We will examine case studies and examples of where homecare has been used and the outcomes achieved. We will also identify patient populations that benefit most from receiving home visits and discuss its application globally.

Stella Stergiopoulos
Senior Project Manager, Tufts Center For the Study of Drug Development

Nicki M. Norris, MBA
Chief Executive Officer, Symphony Clinical Research

Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): CR, RD

9:00–10:30 AM Level: ■ Format: WORKSHOP

Survey Results: How Project Managers Leverage Tools and Techniques

Laura Vitale, MSc, PMP
Director, Program Management, Mallinckrodt Pharmaceuticals, Inc.

Since 1950, the number of FDA drugs approved has halved every nine years based on inflation-adjusted dollars spent, drastically affecting pharmaceutical companies' ability to reinvest into new technologies. Application of project management techniques for pharmaceutical R&D activities is becoming more widely held as a best practice in organizations, improving results. There are many different ways to apply project management tools and techniques; learning from one another's successes and failures offers the chance for pharmaceutical project managers to gain understanding without living through each aspect in real project time which is often over ten years from project start. How are other pharmaceutical project managers leveraging project management tools and techniques? What value are they obtaining from their PMP certifications? This workshop will provide an opportunity to learn from your colleagues through results of a pre-meeting survey. An additional survey will also be conducted within the workshop.

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Representative Invited
Manager, CTMS Supply Planning, CT Material Supply Chain Planning, Eli Lilly and Company

Lei C. Chuang, MSc, PMP
Associate Director, Global Project Management, Morphotek, Inc.

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): CR, PM

9:00–10:30 AM Level: ■ Format: SYMPOSIUM

Innovations in Strategic Alliances and Overcoming Obstacles

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

This symposium will present cases studies focused on deficiencies in sponsor-provider relationships and how they have been identified, managed and overcome.

John Potthoff, PhD
President and Chief Executive Officer, Theorem Clinical Research

David Burnham
Vice President, Alliance Management, INC Research

Chris Chan, MBA
Senior Director, R&D Finance, Fibrogen, Inc.

Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): IT, RD

9:00–10:30 AM Level: ● Format: FORUM

Tired of Reinvesting in Old R&D Systems? Several Large Pharmaceutical Companies and Other Leaders are Flipping Paradigms

Jonathan Burr
Global Lead, Cloud Technology, Life Sciences, Accenture

This forum examines how an innovative partnership between several large organisations in the pharmaceutical industry is poised to re-shape, re-think and re-structure the R&D IT landscape by collaborating to change the way IT enables R&D.

Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): SE

9:00–10:30 AM Level: ■ Format: SESSION

Bring Your Own Device (BYOD) Approaches to the Collection of Electronic Patient-Reported Outcome Data in Clinical Trials

Chad Gwaltney, PhD
Chief Scientist and Regulatory Advisor, Endpoints, ERT

Bring Your Own Device (BYOD) approaches allow study subjects to use their personal digital devices to complete remote (i.e., offsite) patient-reported outcome measures. This session will describe key scientific, regulatory, and operational considerations when using BYOD.

Representative Invited
Product Manager, Exco InTouch, United Kingdom

Paul O'Donohue
Director of Health Outcomes, CRF Health, United Kingdom

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

Track 08 – Regulatory Affairs

Related Interest Area(s): PPLC

9:00–10:30 AM Level: ■ Format: SESSION

Accidental Drugs: A Historical Look at How Certain Drugs Came to Market and Policy Pathway Opportunities

Kimberly Belsky, MS
Executive Director, Regulatory Affairs, AdPromo, Labeling and Policy, Valeant Pharmaceuticals

For drug history buffs and those interested in life cycle management, this session will review how drugs have been repurposed or found to have an unintentional off-target effect, the incentives for R&D that led to FDA approval and even blockbuster status.

Kimberly Belsky, MS
Executive Director, Regulatory Affairs, AdPromo, Labeling and Policy, Valeant Pharmaceuticals

Andrew S. Robertson, JD, PhD
Director, Global Regulatory Policy, Merck & Co., Inc.

Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): EC, IT

9:00–10:30 AM Level: ■ Format: SESSION

Novel Data Sources and Tools for Pharmacovigilance

Rave Harpaz, PhD
Senior Research Scientist, Oracle Health Sciences

The session will discuss the use of new data sources and tools for pharmacovigilance, including: (1) A real-time system that integrates and analyzes safety evidence from FDA's adverse event reporting system (FAERS), electronic health records (EHRs), and the social media, with application to the safety profiling of tumor necrosis factor alpha (TNFa) inhibitors; (2) The openFDA website, its application programming interface, and a novel graphical user interface called the Adverse Event Explorer, which allows easy access to and query of the safety information contained in openFDA; and (3) Holistic signal

detection—approaches and challenges associated with detecting, evaluating, and combining safety signals from multiple data sources such as FAERS, EHRs, the biomedical literature, and the logs of health information seeking activities on the Web.

Rave Harpaz, PhD
Senior Research Scientist, Oracle Health Sciences

Ran Balicer, MD, PhD, MPH
Advisory Board of Data2Life, Data2life and Clalit Research Institute, Israel

Jeremy Wildfire, MSc
Statistical Scientist, Rho, Inc.

Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): CR, ST

9:00–10:30 AM Level: ■ Format: SESSION

Innovative Designs for Cardiovascular Outcome Safety Trials in Type 2 Diabetes

Cyrus R. Mehta, PhD
Founder and President, Cytel Inc.

This session presents strategies for designing adaptive trials that demonstrate cardiovascular safety of antidiabetic compounds.

Cyrus R. Mehta, PhD
Founder and President, Cytel Inc.

Mary Jane Geiger
Senior Director, Cardiovascular & Metabolism Therapeutics, Regeneron Pharmaceuticals, Inc.

Stefan Hantel, PhD
Principal Statistician, Boehringer Ingelheim Pharma Gmbh & Co. KG, Germany

Representative Invited
Director, Division of Biometrics VII, Office of Translational Sciences, CDER, FDA

Track 16 – Professional Development

Related Interest Area(s): PETD

9:00–10:00 AM ▲ Level: ■ Format: FORUM

AHA Moments: Breakthrough Thinking Leading to Deeply Satisfying Career Changes

Jesus Rivera, MSc
Senior Learning Manager, Bristol-Myers Squibb Company

Have you been on a certain career path only to experience an "aha moment" that lead you in a completely different direction? Speakers will share pivotal moments in their lives when their career direction took an abrupt change with satisfying results.

Bob Muzerall
Vice President, Sales and Sales Training, ForeignExchange Translations

Representative Invited
Independent Trader Investor

Track 18 – Global Regulatory

Related Interest Area(s): RA

9:00–10:30 AM Level: ■ Format: FORUM

An Insider's View of Cooperation Between the EMA and CDER/FDA

Representative Invited
EMA Liaison Official to the US FDA, European Medicines Agency, European Union

New this year! Join us for this unique opportunity that includes members from EMA and CDER/FDA Leadership.

This first of its kind forum will provide an opportunity for both agencies to discuss and explore areas such as global development, supervision of medicines, EMA/FDA confidentiality arrangements and much more. Attendees are welcome to submit topics of interest for the panel and can submit in advance to annualmeetingprogram@diahome.org; subject: EMA/FDA-CDER Town Hall.

Track 19 – Late-breaking Topics

Related Interest Area(s): EC

9:00–10:30 AM Level: ● Format: FORUM

Mobile Health, Telemedicine, and Remote Sensors in Clinical Investigations: A New Era in Clinical Trial Design?

Representative Invited
Associate Director of Clinical Methodology, Office of Medical Policy, CDER, FDA

This forum will discuss opportunities for mobile technologies in clinical trials, which could facilitate the measurement of novel patient-centered endpoints, decrease geographical access barriers for patients, and drive efficiencies for sponsors.

Representative Invited
Program Management Officer, Office of Medical Policy, CDER, FDA

Representative Invited
Policy Analyst, Office of Device Evaluation, CDRH, FDA

Representative Invited
Office Director, Office of Scientific Investigations, Office of Compliance, CDER, FDA

Track 01 – Clinical Operations

Related Interest Area(s): CR, RD

10:45 AM–12:15 PM Level: ■ Format: FORUM

DEVELOP Risk-Based Monitoring Strategies to INNOVATE Study Oversight and ADVANCE Study Execution

Lynn King, MHA
Senior Director, Clinical Operations, TKL Research

This forum will explore the lessons learned from a case study of developing and implementing a risk-based monitoring strategy for a 30-site global trial. The collaboratve sponsor/contract research organization process and implications will be presented and discussed.

Track 02 – Project/Portfolio Management and Strategic Planning

Related Interest Area(s): SP, CR

10:45–11:45 AM ▲ Level: ■ Format: SESSION

A Systematic Approach to Study Start-Up

Marina Malikova
Executive Director, Surgical Translational Research Operations and Compliance, Boston University School of Medicine

Systematic assessment of risk factors and key performance indicators at a start-up phase can allow for more efficient execution of a clinical trial and ensure better accrual rates. This session will discuss best practices to expedite start-up phase.

Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, AHC/IS, FI

10:45 AM–12:15 PM Level: ■ Format: FORUM

Just the Facts: A Model for Evaluating the ROI of Outsourcing Investigator Payments

Stu Thiede, MBA
President, Payments, DrugDev

Measure the impact of your investigator payment solution with a return-on-investment (ROI) model that can be modified to your specifications. This forum will give you the tools to determine if your outsourced program is effective.

Track 07 – Technology/Data/Records and Submissions

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

10:45 AM–12:15 PM Level: ■ Format: SESSION

mHealth / mClinical and Clinical Trials: A Candid Discussion on Opportunities and Risks

Philip J. Coran, Esq, JD, MBA
Director of Quality and Regulatory Affairs, Medidata Solutions Worldwide

This session will focus on the proliferation of mobile health (mHealth) and mClinical devices in the consumer and medical market and how they services may enhance clinical trials. The panel will

cover perspectives from a variety of stakeholders including the FDA.

Craig H. Lipset
Head of Clinical Innovation, Worldwide Research and Development, Pfizer Inc

Representative Invited
Office Director, Office of Scientific Investigations, Office of Compliance, CDER, FDA

Julian M. Jenkins, PhD, MSc
Vice President, Project Planning and Management, GlaxoSmithKline

Track 08 – Regulatory Affairs

Related Interest Area(s): CR, BT

10:45 AM–12:15 PM Level: ■ Format: SESSION

Global Developments in the Regulation of Biological Therapeutics

Andrew S. Robertson, JD, PhD
Director, Global Regulatory Policy, Merck & Co., Inc.

This session will discuss recent developments in global biotherapeutics regulation, including originator biologics and biosimilars. The focus is on key events, the emergence of new analytical tools, new advocacy efforts, and how these impact developed markets.

Harry Gewanter
Chairman, Alliance for Safe Biologic Medicines

Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): IT, PM

10:45 AM–12:15 PM Level: ■ Format: FORUM

The Future of Pharmacovigilance Operations

Nicole Schumacher Crow, MS
Deloitte & Touche L.L.P.

Pharmacovigilance (PV) systems have operated the same way for years, but recent changes in regulations, increasing workloads, and availability of new technologies are motivating companies to re-examine the way operations are conducted. This forum will examine these factors impacting the current PV workload and discuss future strategies for processes, governance, IT systems, and organizational structures.

Alan M. Hochberg
Senior Process Development Leader, F. Hoffmann-La Roche Ltd., Switzerland

Nicole Schumacher Crow, MS
Deloitte & Touche L.L.P.

Kerstin Geldmeyer-Hilt, PhD
Dr. Ebeling & Assoc. GmbH, Germany

Track 16 – Professional Development

Related Interest Area(s): IT, PETD

10:45–11:45 AM ▲ Level: ■ Format: SESSION

Making Technology a Key Component of Your Learning Strategy

Pamela Loughner, PhD, MEd
President, Loughner and Associates Inc.

Approximately one-third of all formal training is now delivered through eLearning and other technologies. As the use of technology continues to rise, it is important for individuals responsible for training budget and training success to understand the factors that contribute to the overall effectiveness of technology-based training, and how to evaluate a program's effectiveness and overall merit or worth. This session explores the use of technology-based training solutions and the factors that should be considered when incorporating the use of technology in a learning strategy. Case studies providing examples relevant to session participants will be shared.

Pamela Loughner, PhD, MEd
President, Loughner and Associates Inc.

Christine Wolford
Learning Solutions Specialist, DATATRAK International

Track 18 – Global Regulatory

Related Interest Area(s): RA, CR

10:45 AM–12:15 PM Level: ■ Format: FORUM

CDER Town Hall

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

One of the many DIA Annual Meeting program highlights is the CDER Town Hall where leaders from the US FDA's Center for Drug Evaluation and Research will participate in this interactive offering where members of the audience may submit questions. Topics to be discussed will be determined by the interest of the audience.

Attendees are welcome to submit questions of interest to the panel by emailing annualmeetingprogram@diahome.org; subject line: CDER Town Hall Q/A

Representative Invited
Director, Office of Prescription Drug Promotion, CDER, FDA

Representative Invited
Director, Office of Surveillance and Epidemiology, CDER, FDA

Representative Invited
Director, Office of Strategic Programs, CDER, FDA

Representative Invited
Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

Representative Invited
Deputy Center Director for Clinical Science, CDER, FDA

Representative Invited
Director, Center for Drug Evaluation and Research, FDA

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Track 19 – Late-breaking Topics

Related Interest Area(s): CEHTAEbM

10:45–11:45 AM ▲ Level: ■ Format: FORUM

Leveraging Electronic Health Record Data in Close Collaboration with Health Systems to Accelerate Precision Medicine

Brett Jason Davis
Principal and General Manager, ConvergeHealth By Deloitte

This forum will discuss the need for collaborations between pharmaceutical organizations and health systems to progress a precision medicine initiative proposed by President Obama in the State of the Union address and describe what treatments work, for whom, why, in what context.

The content noted on this page was made available to DIA as of January 28.

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MAIL
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P.O. Box 95000-1240
Philadelphia, PA 19195-1240, USA
(Note: Checks must be drawn on U.S. bank)

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