DIA 2013
Advancing Therapeutic Innovation and Regulatory Science

4 Days. 22 Tracks.
250+ Educational Offerings.

450+ Exhibitors.
7,000+ Attendees.

June 23-27 | Boston, Massachusetts
Boston Convention and Exhibition Center
diahome.org/DIA2013
Where Life Sciences Professionals Converge to Advance Therapeutic Innovation, Foster Collaboration and Accelerate Safer Products

Collaboration and partnerships are becoming the new norm for therapeutic research and development as companies look to capitalize on innovations outside their own walls.

Four Jam-packed Days of Learning and Networking in the Life Sciences Hub
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Join the 27,000+ members on LinkedIn
TUESDAY, JUNE 25
Registration Hours: 7:00 AM-5:30 PM Attendee, Speaker and Exhibitor Registration

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

WEDNESDAY, JUNE 26
Registration Hours: 7:00 AM-5:30 PM Attendee, Speaker and Exhibitor Registration

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

THURSDAY, JUNE 27
Registration Hours: 8:00-10:45 AM Attendee and Speaker Registration

Schedule:
8:15-9:00 AM Coffee and Breakfast Breads
9:00-10:30 AM Concurrent Educational Opportunities
10:30-10:45 AM Coffee Break
10:45 AM-12:15 PM Concurrent Educational Opportunities
**Plan Your DIA 2013 49th Annual Meeting around 22 Tracks and 250+ Educational Offerings.**

<table>
<thead>
<tr>
<th>Track #</th>
<th>Track Interest Area(s)</th>
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<tr>
<td>Track 01</td>
<td>Clinical Operations</td>
<td>Clinical Research (CR), Clinical Supplies (CS), Research and Development (RD), Investigative Sites (IS), Manufacturing (MF)</td>
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<td>Track 02</td>
<td>Project/Portfolio Management and Strategic Planning</td>
<td>Project Management (PM), Financing (FI), Strategic Planning (SP)</td>
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<td>Track 03</td>
<td>Innovative Partnering Models and Outsourcing Strategies</td>
<td>Outsourcing (OS)</td>
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<td>Track 04</td>
<td>Nonclinical and Translational Development/Early Phase Clinical Development</td>
<td>Biotechnology (BT), Nonclinical (NC), Pharmacology (PC)</td>
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<td>Track 05</td>
<td>Regulation of Product Advertising and Marketing in an Ever-changing World</td>
<td>Advertising and Promotion (AP), Marketing (MA)</td>
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<td>Track 06</td>
<td>Medical Communication, Medical Writing, and Medical Science Liaison</td>
<td>Medical Writing (MW), Medical Communications (MC), Medical Science Liaison (MSL)</td>
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<td>Track 07</td>
<td>Processes and Technologies for Clinical Research</td>
<td>Information Technology (IT), eClinical (EC), Clinical Data Management (CDM), Study Endpoints (SE), Document Management (DM), Validation (VA)</td>
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<td>Track 08</td>
<td>Regulatory Affairs and Submissions</td>
<td>Regulatory Affairs (RA), Submissions (SUBS)</td>
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<td>Track 09</td>
<td>Medical Devices, In Vitro Diagnostics, and Combination Products</td>
<td>Combination Products (CmbP), Medical Devices and Diagnostics (MDD)</td>
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<td>Track 10</td>
<td>Public Policy/Health Care Compliance/Law</td>
<td>Public Policy, Law, Corporate Compliance (PPLCC)</td>
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<td>Track 11</td>
<td>Innovative Approaches to Ensuring Compliance With Good Clinical Practice (GCP) and Quality Assurance (QA)</td>
<td>Good Clinical Practice (GCP), Quality Assurance, Quality Control (QA/QC)</td>
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<td>Track 12</td>
<td>Pharmaceutical Quality</td>
<td>Chemistry, Manufacturing and Controls/Good Manufacturing Practices (CMC)</td>
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<td>Track 13</td>
<td>Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)</td>
<td>Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine (CEHTAEbM), Pricing and Reimbursement (PR)</td>
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<td>Track 14</td>
<td>Clinical Safety and Pharmacovigilance</td>
<td>Clinical Safety and Pharmacovigilance (CP)</td>
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<td>Track 15</td>
<td>Statistical Science and Quantitative Thinking</td>
<td>Statistics (ST)</td>
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<td>Track 16</td>
<td>Professional Development</td>
<td>Professional Education, Training and Development (PETD)</td>
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<td>Track 17</td>
<td>Rare/Orphan Diseases</td>
<td>Rare, Orphan Diseases (ROD)</td>
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<td>Global Regulatory</td>
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<td>Track 19</td>
<td>Communities Showcase</td>
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<td>Track 20</td>
<td>Executive Program</td>
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<td>Track 21</td>
<td>Late-breaker</td>
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<td>Track 22</td>
<td>White Paper Showcase</td>
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“DIA is the most diversified and informative Clinical Research meeting of the year! It encompasses all aspects of Clinical Research Site Operations that interest me.”

DIA 2012 TESTIMONIAL

**PROGRAM CHAIR**
Sandra A. Milligan, JD, MD
Vice President, Global Regulatory Therapeutic Area Head
Genentech, Inc. A Member of the Roche Group
GLOBAL CONNECTIONS
Regions Represented in this year’s program
• Europe
• North America
• Latin America
• Asia
• Rest of World

TOP 15 COUNTRIES REPRESENTED
• United Kingdom
• United States
• Japan
• Germany
• India
• France
• Canada
• China
• Denmark
• Switzerland
• Korea, Republic Of
• Australia
• Italy
• Taiwan
• Argentina

Includes attendees, speakers, and exhibitors as of April 2013

DIA 2012 48TH ANNUAL MEETING DEMOGRAPHICS

Last year’s DIA 2012 48th Annual Meeting brought together a global audience of nearly 7,000 professionals involved in the discovery, development, and the life cycle management of pharmaceuticals, biotechnology products, medical devices and related health care products.

BY PRODUCT RESPONSIBILITY

BY JOB FUNCTION

BY LEVEL OF EXPERIENCE
OPENING PLENARY SESSION

Daniel Kraft, MD
Executive Director, FutureMed
Monday, June 24 | 8:30–10:00 AM

Dr. Kraft’s Accomplishments:
• Founded IntelliMedicine, focused on enabling connected, data driven, and integrated personalized medicine
• Invented the MarrowMiner, an FDA approved device for the minimally invasive harvest of bone marrow
• Founded RegenMed Systems, a company developing technologies to enable adult stem cell based regenerative therapies

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

Cooperation Among Regulators: Impact on Stakeholders

Monday, June 24 | 2:30–4:00 PM

Join leaders of the three most influential drug regulatory agencies discuss current actions in public policy resulting from interagency actions and strategic communications.

Health Canada Point of View
Paul Glover, MBA
Assistant Deputy Minister of the Health Products and Food Branch
Health Canada

EMA Point of View
Guido Rasi, MD
Executive Director
European Medicines Agency, European Union

FDA Point of View
Margaret A. Hamburg, MD
Commissioner
FDA

Chairpersons:

Marie Allison Dray, MA, MBA
President
International Regulatory Affairs Group LLC

Murray M. Lumpkin, MD, MSc
Commissioner’s Senior Advisor and Representative for Global Issues, OC, FDA

Take a Peek at the Impressive List of Special Topics for DIA 2013 49th Annual Meeting!

• Alzheimer’s
• Big Data
• Biosimilars/Follow-on Biologics
• Data Standardization
• Electronic Health Records/Electronic Medical Records
• FDASIA/PDUFA V
• New Models of Innovation
• Unmet Medical Needs
• And More...
EXECUTIVE SESSION:
Reinventing the R&D Business Model: Heeding the President’s PCAST Report on Innovation

Tuesday, June 25 | 1:45–3:15 PM

This session, hosted by the Tufts Center for the Study of Drug Development (CSDD), will examine how companies across the pharma sector are transforming their R&D business models to meet current and future market demands. This senior-level session represents the cross-functional issues that embrace not just R&D, but preclinical, clinical, regulatory, operations, portfolio management, and marketing – all aspects of business development.

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

Robert J. Franco, PhD
Principal
PricewaterhouseCoopers LLP

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

Kenneth A. Getz, MBA
Director of Sponsored Research
Tufts CSDD; Chairman, CISCRP;
Tufts University

Bernard Munos, MBA
Founder
InnoThink

Tomasz Sablinski, MD
Founder and CEO
Transparency Life Sciences

Big Data: Impact on Innovation

Tuesday, June 25 | 10:15–1:45 AM

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

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

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

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

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

Rachael Fleurence, PhD
Acting Director, PCOR Methods Patient Centered Outcomes Research Institute (PCORI)
Advancing Alzheimer’s Innovation: A Call to Action

Wednesday, June 26 | 10:15-11:45 AM

Get a visionary perspective on how industry and health authorities are working to help move towards a cure for Alzheimer’s disease. This forum will provide a comprehensive picture of the global impact of this disease and the progress towards earlier detection and meaningful therapeutic intervention.

Speakers:

Meryl Comer
President
Geoffrey Beene Foundation
Alzheimer’s Initiative

George Vradenburg
Co-Founder/President
USAgainstAlzheimer’s

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

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

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

Nicholas A. Kozauer, MD
Medical Officer, OND, CDER
FDA

LATE BREAKER SESSIONS
Collaborating to Streamline Drug Development: Are We Making Progress?

Wednesday, June 26 | 8:00–9:30 AM

In this forum, leaders from TransCelerate Biopharma Inc (TransCelerate) and the Clinical Trials Transformation Initiative (CTTI) – will provide a status report on current projects, with additional perspectives provided by representatives of the FDA, CROs, and research sites.

TransCelerate’s Collaborative Approach to Risk-based Monitoring: The Methodology

Wednesday, June 26 | 1:45–3:15 PM

TransCelerate BioPharma Inc. (TransCelerate) developed a methodology for monitoring that shifts monitoring processes from an excessive concentration on source data verification to comprehensive risk-driven monitoring. This philosophical shift in monitoring processes employs centralized and offsite mechanisms to identify and monitor important study parameters holistically and uses adaptive onsite monitoring to further support subject safety and data quality.

Collaborative Approach for Site Qualification and Training Efficiencies

Wednesday, June 26 | 4:00 - 5:30 PM

This session will discuss efforts to create efficiencies as it relates to site qualification, training and form development.
Gain a Global Perspective Meet the Regulators

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 much more. This year’s Global Regulatory Track includes the following:

**Europe**
- European Town Hall: Implementation of New Safety Legislation and Other Hot Topics
- Challenges for Stable Supply of Drugs and International Cooperation

**North America & Canada**
- CBER Town Hall
- CDER Town Hall: Part 1 and 2
- Regulatory Environment in the US: CDRH Panel Discusses What’s on the Horizon
- The State of Informatics at CDER, CBER, and CDRH
- Challenges for Stable Supply of Drugs and International Cooperation
- FDA-Health Canada Regulatory Cooperation Council (RCC) Town Hall
- Canadian Approaches to Regulatory Modernization and International Engagement

**Asia-Pacific**
- Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall
- Convergence in Regulatory Science Across the Strait
- Korea Forum: Introduction to the Korean Ministry of Food and Drug Safety (MFDS) and Government R&D Program
- Challenges for Stable Supply of Drugs and International Cooperation

**Latin America**
- Latin America Town Hall

Preconference Tutorials

**Preconference Tutorials | $100 Off Annual Meeting Registration**

Jumpstart your education prior to the Annual Meeting. Register for two half-day tutorials or one full-day tutorial and receive **$100 off of your Annual Meeting registration**. Visit [diahome.org/DIA2013tutorials](http://diahome.org/DIA2013tutorials) for the full list. Preregistration required.

- Investigative Site Boot Camp: Innovative Solutions to your Operational Challenges
- Understanding and Navigating the Regulatory System in China
- Preparing for a US FDA Advisory Committee Meeting
- Quality Oversight of CROs-Clinical Vendors
- Leadership: How to Organize and Lead People in Group Work
Exhibits

Looking to Move Your Products to Market Faster – DIA Exhibitors Have the Solutions!

Join the 450+ exhibiting companies in one of the Industry’s largest Exhibit Halls as they showcase the hottest products and solutions that advance therapeutic innovation and regulatory science. 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. Forge new partnerships at DIA 2013 49th Annual Meeting.

“...one of the most important organizations representing the pharmaceutical industry as well as the CRO industry.” - Jeffrey McMullen, President and CEO, PharmaNet/i3

New This Year! Extended Hours for Lunch and Refreshment Breaks in the Exhibit Hall

Lunch Breaks
• Monday, June 24 | 12:30 – 2:30 PM
• Tuesday, June 25 | 11:45 AM – 1:45 PM
• Wednesday, June 26 | 11:45 AM – 1:45 PM

Extended Refreshment Breaks
• Monday, June 24 | 10:00 – 11:00 AM
• Tuesday, June 25 | 9:30 – 10:15 AM
• Tuesday, June 25 | 3:15 – 4:00 PM
• Wednesday, June 26 | 9:30 – 10:15 AM
• Wednesday, June 26 | 3:15 – 4:00 PM

Exhibit Space Still Available!
With more than 90% of the Exhibit Hall floor already reserved, we urge you to reserve your booth while there is still prime space available!

CONTACT:
Craig Baker (Companies A-L) +1-703-679-3942
craig.baker@jspargo.com

Michele LaFrance (Companies M-Z) +1-703-679-3951
michele.lafrance@jspargo.com
**WHAT LIES AHEAD FOR 2013?**

DIA’s first annual *What Lies Ahead?* report was released in January 2013, which provides expert insight into the year ahead for pharmaceuticals, biotechnology, and the product development of medical devices. The study shows expectations of 2013 are that of the continued strengthening of consumer/patient empowerment (second most expected trend), a focus on unmet medical needs as the driver for innovations, and growing regulatory cooperation and convergence across multiple regions. This year’s Annual Meeting has incorporated sessions related to these topics.

View *What Lies Ahead?* in detail at diahome.org/WhatLiesAhead2013

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### New Models of Innovation

Collaboration and partnerships are becoming the new norm for therapeutic research and development as companies look to capitalize on innovations outside their own walls.

- Innovative Partnerships for mHealth
- Making CRO-Sponsor Partnerships Work: Executive Roundtable
- Optimizing Clinical Trial Feasibility by Collaborating with Investigators, Patient Advocacy Associations and Electronic Health Record Partners
- CDISC SHARE: A Promising Approach to Therapeutic Area Standards Development
- Pharma, Academia and CRO Preferred Partnerships: Why Collaboration Makes a Better Global Trial
- Reinventing the R&D Business Model: Heeding the President’s PCAST Report on Innovation
- Unique Nonprofit-Industry Partnerships to Develop or Disseminate Novel Virtual Population Simulation Technology
- Innovative Strategies for Evolving Sponsor, CRO and Site Alliances
- Strategic Partnerships: Emerging Models and Their Impact on Drug Development
- Collaborating to Streamline Drug Development: Are We Making Progress?

### The Continued Rise of Patient/Consumer Empowerment: the Importance of Patient/Consumer Engagement

The goal of therapies is to improve patient health and health care outcomes, and the patient/consumer has been recognized and accepted as an important stakeholder in the development of therapeutic products.

- Advancing Alzheimer’s Innovation: Patient Advocacy, Caregiver Support and Health Care System Impact
- Leveraging In-Pharmacy Education to Improve Patient Comprehension and Access to Clinical Trials
- Social Media, Mobile Applications and Patient Support Programs: Challenges and Solutions for Handling Drug Safety Information
- Optimizing Clinical Trial Feasibility by Collaborating with Investigators, Patient Advocacy Associations and Electronic Health Record Partners
- Using Legislation to Advance Regulatory Science: “I’m Just a Bill...”
- Big Data: Impact on Innovation
- Using Big Data to Design Smarter Studies
- Changing Landscape of IT in the Pharmaceutical Industry

### Achieving Market Access is the New Goal, and Value is a Key Driver

Biopharmaceutical and device companies can no longer function solely as manufacturers of products; they must integrate into the health care ecosystem partner with providers and payers as a provider of therapeutic options. They will do this by investing in CER and by designing trials to meet the needs of both regulators and payers.

- Payer Collaborations with Pharma: Real-world Evidence to Improve Patient Outcomes and Influence the Pipeline
- Bringing the Views of “Payer Regulators” into Product Development to Align Label Outcomes and Safety with Patient Access
- The Environment for Health Care Decision-making: Collecting, Using and Understanding Comparative Effectiveness Research
- Developing Effective Policy Strategies for Coverage and Reimbursement of Companion Diagnostics
- The 2012 US Payer Landscape: Results from a Survey of Medical and Pharmacy Directors on Comparative Effectiveness Research
WHAT LIES AHEAD FOR 2013?

**Regulatory Cooperation and Convergence**

With a growing global market and the need to use resources efficiently at both industry and regulatory levels, regulatory agencies may share their workloads through consortia of agencies. The most compelling reason for convergence, however, is to share expertise to improve the quality of reviews and to promote consistent approaches to the protection of patient health in a scientifically complex and global health care market.

- Cooperation Among Regulators: Impact on Stakeholders
- FDA CDER’s Office of Scientific Investigations and European Medicines Agency Collaboration on Good Clinical Practice (GCP), Bioequivalence (BE) and Pharmacovigilance (PV) Inspections
- Lessons Learned from the EMA-FDA Quality by Design (QbD) Pilot
- FDA-Health Canada Regulatory Cooperation Council (RCC) Town Hall
- Convergence in Regulatory Science Across the Strait

**Personalized Medicine/Tailored Therapies and Companion Diagnostics**

Increasing flexibility of regulatory agencies in trial designs is helping sponsors to identify sensitive subpopulations for whom therapies at appropriate doses will be successful. Companies, with the cooperation of regulatory agencies, are optimizing processes for developing companion diagnostics for new and existing therapeutic products. Successful patient outcomes on first prescribed therapies will benefit overall costs of care, making this an important trend for payers, as well.

- Roundtable on Personalized Therapy Innovation in Rare Disease: Focus on Public Policy
- Co-development of Targeted Therapies and Companion Diagnostics: Identifying Regulatory Strategies to Overcome Challenges
- Developing Effective Policy Strategies for Coverage and Reimbursement of Companion Diagnostics

**An Explosion of Mobile Health Applications**

The possibilities are almost endless as mobile technologies become more reliable, sophisticated, and interoperable. Companies are utilizing the technology for patient reported data, monitoring, and simple communication. This is just the beginning of the innovations that mobile health technology will support.

- Innovative Partnerships for mHealth
- Data from Everyone: Using Smartphones and the Internet to Connect with Subjects
- Social Media, Mobile Applications and Patient Support Programs: Challenges and Solutions for Handling Drug Safety Information
- Mobile Learning and Social Media Symposium
- Emerging Electronic Tools in Cardiovascular Outcomes Studies

**Continued Importance of Global Markets**

Due to changing demographics and the influence of emerging markets, companies must work within a global market to achieve the greatest success. BRIC countries are still important as emerging markets, and companies are looking at “pharmerging” countries in Indonesia, Asia, Africa, and Latin America. Higher growth rates for therapeutic product sales in regions like Latin America, India, and China are having an impact in the US and Europe, too, by prompting a shift in sponsors’ development efforts away from the mature and toward the growing regions.

- Chemistry, Manufacturing and Controls (CMC) Regulatory Landscape in Emerging Markets
- Global Clinical Trials: The Role of Emerging Markets
- A Regulatory Perspective of Biosimilars in Emerging Markets
- GCPs in Emerging Countries
- Risk Management in the US, EU and Japan: The Challenges of Diversity

**Clinical Trial Data Transparency**

Growing movement to share clinical trial data, within the bounds of protection of individual patient privacy.

- Project Data Sphere: Clinical Trial Data-sharing in Cancer to Accelerate Innovation and Enhance Patient Health
- C SHARE: A Promising Approach to Therapeutic Area Standards Development
- European Town Hall: Implementation of New Safety Legislation and Other Hot Topics

**Growing Ability to Make Meaningful Benefit–Risk Assessment**

Many different approaches to assessing the balance of benefit versus the risk of using a therapeutic product are beginning to converge around a set of common elements that are accepted as integral to a meaningful analysis.

- Implementing an Internationally Acceptable Framework for the Benefit-Risk Assessment of Medicines: How Close Are We to This?
- Analysis of Safety Data from Clinical Trials
- European Town Hall: Implementation of New Safety Legislation and Other Hot Topics
- Periodic Reporting in Drug Safety: From Safety Updates to Continuous Signal Monitoring and Benefit-Risk Evaluations
- TransCelerate’s Collaborative Approach to Risk-based Monitoring: The Methodology

Register at diahome.org/DIA2013
Laser Focus on Unmet Medical Needs

In both mature and developing markets, the search for innovations is focusing on unmet medical needs. Products that duplicate available treatments are no longer valued unless they are meaningfully superior or lower in cost. In developing markets, needs may be country-specific, and products must fill a need at a competitive price in order to be successful. In mature markets, as well as in some developing markets, there is a huge chronic disease burden and unmet medical need in diseases such as Alzheimer’s Disease, cancers, and diabetes.

- Advancing Alzheimer’s Innovation: A Call to Action
- Advancing Alzheimer’s Innovation: Patient Advocacy, Caregiver Support and Health Care System Impact
- Advancing Alzheimer’s Innovation: Clinical Development Successes and Challenges
- Project Data Sphere: Clinical Trial Data-sharing in Cancer to Accelerate Innovation and Enhance Patient Health
- Biomarkers for Drug Development: How Are We Dealing with the Challenges?

The Era of Data Standardization Is Here

Industry and regulators alike need better tools and readily available data to make better informed decisions more quickly. Data standardization efforts in therapeutic disease areas will enable sharing of data across platforms to leverage multiple data sets for real world assessment of therapeutic efficacy and safety.

- CDISC SHARE: A Promising Approach to Therapeutic Area Standards Development
- Analysis Data Standards: Developing, Applying, Submitting and Reviewing
- Coalition for Accelerating Standards and Therapies (CFAST): The Ultimate Drug Development Drivers
- Data Standards Strategy

Reaching crucial industry leadership, creating new business relationships, tapping some of the brightest minds in the field are all major attractions to the DIA Annual Meeting and why I will keep coming back.”

Top Sessions from last year’s DIA 2012

1. CDER Town Hall Part 1 and Part 2
3. Collaborative Partnerships in Drug Development: An Executive Roundtable Discussion
4. Understanding Risk-based Monitoring: Is It Art, Science, or Both?
5. The Impact of Social Media on Product Promotion and Pharmacovigilance
6. Defining Quality in Clinical Trials
7. FDA Draft Guidance on Multiple Endpoints in Clinical Trials
8. Managing a Complex Outsourcing Collaboration

Navigate this year’s Annual Meeting from your mobile device!

To download, search for “DIA 2013” in your Apple or Android app store.

App will be released May 1, 2013

PROFESSIONAL & STUDENT POSTERS – Just Released!

More than 90 posters will be presented at this year’s Annual Meeting. There are three posters sessions that will feature original research from individuals from around the world.

STUDENT POSTER SESSION:
June 24 | 10:00AM-5:30PM ET
- Awareness and Use of Video Games for Rehabilitation and Therapy in Indian Healthcare Centers
- Technological Innovations in Medication Packaging to Improve Patient Adherence: A Systematic Review
- Comparison of European Drug Approvals to US

PROFESSIONAL POSTER SESSIONS:
June 25 & 26 | 11:45AM-4:00PM
- Return on Innovation Investment for Life Science Technologies
- Developing Site Monitoring Triggers to Support Risk-based Monitoring
- The Translational Medicine-Medical Science Liaison: A New Role for a New Era in Drug Discovery
- Preventing Shortages of Biologic Medicines
- And More...
DIA’s Annual Meeting Brings Presenters from Academia, Government, Industry, and Patient Perspective

Abbott Laboratories
AbbVie
Accenture
Actelion Clinical Research
Agency for Healthcare Research and Quality (AHRQ)
Aldurah Syndrome Alliance
Albemarle Scientific Consulting LLC
Alexion Pharma International Sarl
Alfred Mann Biomedical Engineering Institute
Allergan, Inc.
Alliance for Aging Research
Alliance For Safe Biologic Medicines
Almac Clinical Technologies
Alta
American Optometric Association
Amgen Inc.
Amylin Pharmaceuticals, Inc.
APCO Worldwide Inc.
Applied Clinical Intelligence, LLC
Aptiv Solutions
Aptuit
Archmedes, Inc.
ARKUS CTSS
Assero
assistek
Association of Clinical Research Organizations
Astellas Pharma Global Development, Inc.
AstraZeneca
Austrian Medicinal and Medical Device Agency (AGES)
Aveo Pharmaceuticals, Inc.
Baxter Healthcare
Bayer Healthcare Pharmaceuticals
Beardsworth Consulting Group Inc.
Bethel University
Bink, Inc.
Biogen Idec
BioMarin Pharmaceutical Inc.
BioSoluta
BioTeam, Inc.
Biotechnology Industry Organization
BLCMO Associates, LLC
Blue Chip Patient Recruitment
BMS
Boehringer Ingelheim
Boehringer Ingelheim Pharma GmbH & Co. KG
Boston Scientific Corporation
Boston University
Bristol-Myers Squibb Company
CAB Inc.
CAC EXICARE Corporation
CAHCo
Campbell University College of Pharmacy and Health Sciences
Caremark / Bilipcare Inc.
Carolina Research Associates
Catalyst Healthcare Consulting, Inc.
CDISC
Celerion
Celgene Corporation
Center for Drug Evaluation, Taiwan
Centre For Innovation In Regulatory Science (CIRS)
Children’s National Medical Center
Churchill Outcomes Research, LLC
CINECA Inter-University Consortium
CiteLine, Inc.
CitusTech Inc.
Clinical Ink
Clinical Trials Transformation Initiative
clinicalRSVP
Clinigx LLC
ClinStar LLC
CuePoints
Cognizant Technology Solutions Corporation
Collegium Pharmaceutical
Community Care of North Carolina
CompleteWare Corporation
Corelab Partners, Inc.
Covance Inc.
Crisfreet
Critical Path Institute
CROMSOURCE
CTI Clinical Trial and Consulting Services
Cytel Inc.
Daichi Sankyo Co., Ltd.
Dana-Farber Cancer Institute
DATATRAK International
Dr. Ebeling & Assoc. GmbH
Drug Safety Alliance, Inc.
D-Target SA, A Premier Research Company
Duane Morris LLP
Duke Clinical Research Institute
Duke Translational Medicine Institute
Duke University Medical Center
DWD & Associates, Inc.
Eastern Michigan University
Einstein Medical Center
Eisai Inc.
Eli Lilly and Company
Elite Research Network
EMC Corporation
EMD Serono, Inc.
Endo Health Solutions
Endo Pharmaceuticals Inc.
Endpoint Clinical, Inc.
Envision Technology Solutions
Erasmus University Medical Center
ERT
Erudita Biotechnical LLC
European Medicines Agency, European Union
European Society For Translational Medicine (EUSTM)
Execlen Performance, Inc.
ExcoInTouch
F. Hoffmann-La Roche
FDA
FDA Alumni Association
Foley Hoag LLP
Forest Research Institute
Friends of Cancer Research
FutureMed
Garrard Safety Solutions
GCP ClinPlus
GCP CMIC ClinPlus CRO/SMD, Ltd.
GE Healthcare
Genentech, A Member of the Roche Group
Genzyme Corporation
Geoffrey Beene Foundation
Alzheimer’s Initiative
Gilead Sciences, Inc.
GlaxoSmithKline
Greenway Medical Technologies
Gruenenthal
GXP International
Halloran Consulting Group
Harpuum Consulting Ltd.
Hartmann Willner LLC
Harvard Medical School
Harvard University Business School
Harvard University School of Public Health
Health Canada
Health Science Authority
HealthCore Inc. a subsidiary of WellPoint Inc.
Hecker & Associates, LLC
Hille Communications Corporation
Hilico HEALTH
Hovione
Human Subject Protection Consulting, LLC
Humana
Hynman Phelps & McNamara, PC
Hyperion Therapeutics
ICON Pic
IDEC Inc.
Idis Pharma
Illiny Consulting Group, Inc.
ImmunasT
IMS Health
INC Research
Incyte Corporation / Experimental Station
INFORMED
Infinity Pharmaceuticals, Inc.
InnoThink
Innovations Clinical Research, LLC
Inspire
Institute for Clinical and Economic Review
INTERLAB Central Lab Services
International Regulatory Affairs Group LLC
Inventiv Health
IPG Analytics
Janssen Pharmaceutical Companies of Johnson & Johnson
Jazz Pharmaceuticals
Johnson & Johnson Pharmaceutical Research & Development, LLC
Jorch Consulting, Inc.
Jubilant Cinsys Ltd.
K & L Gates LLP
Karmic Lifesciences, Inc.
KDH Systems
Keio University
All affiliations confirmed to present at this year’s annual meeting as of March 5, 2013.
‘Class of 2013’
Patient Advocate Fellowship Program

Patient organizations play a key role in DIA’s overall mission of education and knowledge-transfer and are a focus of the DIA 2013 49th Annual Meeting.

DIA is awarding scholarships to 19 nationally recognized patient organizations.

- African-American Community Health Group of the Central Coast
- AIM at Melanoma
- American Cancer Society Cancer Action Network
- Angioma Alliance
- Ann’s Place: the Home of I CAN
- Coalition for Pulmonary Fibrosis
- Dystonia Medical Research Foundation
- Hepatitis Education Project
- Hermansky-Pudlak Syndrome Network
- Leukemia & Lymphoma Society - Mass Chapter
- Lymphatic Research Foundation
- MitoAction
- National Foundation for Celiac Awareness
- NephCure Foundation
- PMP Pals
- Program in Personalized Medicine & Targeted Therapeutics
- Recurrent Respiratory Papillomatosis Foundation
- Spinal Muscular Atrophy Foundation
- The Michael J. Fox Foundation for Parkinson’s Research

“"My daughter suffers from a rare disease called Mastocytosis. After many years of suffering, I was recently diagnosed with a sub-variant of her disease called Mast Cell Activation Disorder (MCAD). DIA has helped our family in identifying and developing pharmaceutical and government relationships to raise awareness for our medication needs and with their assistance, we are now able to secure the proper medication from Europe to manage our disorder. We will forever be grateful, as will the 30+ families who also now have access to treatment for the first time.""

- Kelli Foster

Voice of the Patient/Strategies in Involving the Patient in Drug Discovery

- Developing a Patient Aid to Make Information about Treatment Benefits, Harms and Uncertainties Meaningful to Individual Patients and Enhance Their Decisions
- Ensuring Patient-centered Care: Partnering with Patient Advocacy
- Innovative Ways of Working with Patients to Make Clinical Research More Productive, Less Costly and Less Burdensome for the Patient
- Learnings from Safety Communications Across the Industry: Patients and EMA, REMS, and FDA, Physicians, and Medical Information Groups
- Advancing Alzheimer’s Innovation: Patient Advocacy, Caregiver Support and Health Care System Impact
- FDASIA Patient Provisions: One Year Later
- Project Data Sphere: Clinical Trial Data-sharing in Cancer to Accelerate Innovation and Enhance Patient Health
- Models for Genomic Research Success: How a Patient-Researcher Relationship Led to the Discovery of a Norepinephrine Transporter Deficiency and the Emerging Role of Crowd Sourcing in Rare Disease Research
- Innovative Approaches to Ensure Safety and Efficacy in the Real Life Population
- Social Media, Mobile Applications and Patient Support Programs: Challenges and Solutions for Handling Drug Safety Information
- Leveraging In-Pharmacy Education to Improve Patient Comprehension and Access to Clinical Trials

Patient Discount
Representatives of patient organizations registration is only $250. This includes a one-year complimentary e-membership. Proof of 501 c3 status is required. Online registration is not allowed. Download the registration form at diahome.org/DIA2013Patients

Questions? Donna.Mayer@diahome.org

White Paper Showcase
Back by Popular Demand! Eight companies will lead their own White Paper Showcase where they will highlight their company expertise and solutions in this year’s program.

- Next Generation Medical Information Call Center
- Learning to Share-Sharing To Learn: How an Industry Learns to Honor it’s Volunteers
- MORE TO COME . . .
## DIA 2013 49th Annual Meeting

### Attendee Registration Form

**Attending Therapeutic Innovation and Regulatory Science**

**June 23-27, 2013 | Boston, MA**

Register online at [diahome.org/DIA2013](http://diahome.org/DIA2013)

Online registration is NOT available to exhibitors. Exhibitors: please contact Exhibits@diahome.org. All registrations received at the DIA office in Horsham, PA, USA by 5:00 pm EST on May 17 will be included in the Advance Registration Attendee List.

All member and non-member fees below include access to all available postmeeting session recordings until September 6. Annual Meeting participants can purchase the Premium Upgrade and enjoy the session recordings for one full year (until July 9, 2014).

### Preconference Tutorials

Visit [diahome.org/DIA2013](http://diahome.org/DIA2013) for topics and fees. Space is limited and preregistration is encouraged. Please indicate the tutorial # and fee.

<table>
<thead>
<tr>
<th>Tutorial  #</th>
<th>Fee</th>
<th>Subtotal</th>
</tr>
</thead>
</table>

**DIA 2013 49TH ANNUAL MEETING LIVE LEARNING CENTER**

#### Premium Upgrade

Annual Meeting participants can purchase the Premium Upgrade and enjoy the session recordings for one full year (until July 9, 2014).

**Member**

<table>
<thead>
<tr>
<th>Fee</th>
<th>Non-Member</th>
</tr>
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<tbody>
<tr>
<td>US $480</td>
<td>US $655</td>
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**Non-member fee includes a one-year membership option.**

Please indicate your preference below.

- [ ] I want to renew my DIA membership
- [ ] I DO NOT want DIA membership

Join DIA now to qualify for all the benefits of membership for one year!

### Discount Fees

- **Government (full-time)**
  - Member: US $480
  - Non-Member: US $655

- **Charitable Nonprofit/Academia (full-time)**
  - Member: US $875
  - Non-Member: US $1,050

If paying a nonmember fee, please check preferred membership option above.

*Government rate is subject to eligibility requirements. Identification and proof of eligibility will be required on site. Failure to provide proof of eligibility/ID upon request will require paying the higher standard registration fee.*

### One-day Registration Fees

- **Member**
  - US $825
- **Non-Member**
  - US $1,000

**MON, June 24  | TUES, June 25  | WED, June 26  | THUR, June 27**  

One-day attendees will receive access to post-meeting presentations for that day only and for sixty days after the close of the Annual Meeting. Content will be available for sale after the free access period for registered attendees.

**If paying a nonmember fee, please indicate your membership preference above.**

### Total Payment Due

- Include all applicable fees
- **US $**

**A student rate of $250 is available.** Contact Donna.Mayer@diahome.org for eligibility requirements and a student rate application form.

### Group Discount Available

Register 10 individuals from your company and receive the 11th FREE! Contact vicki.adkinson@diahome.org for more information.

**Cancellation Policy**

All cancellations must be received in writing at DIA’s office by 5:00 pm, June 7.

**Refunds for cancellations received in writing ON OR BEFORE JUNE 7 will be:**

- **Full Meeting**
  - Government/Nonprofit/Academia: Refund Amount = Registration fee paid minus $100
  - All Others: Refund Amount = Registration fee paid minus $200

- **Preconference Program/Tutorials**
  - Refund Amount = Registration fee paid minus $75

- **One-day Registration and DIA 2013 49TH Annual Meeting Live Learning Center Premium Upgrade**
  - NO REFUNDS

**Canceling any portion of your program registration will void any multiple purchase discounts that may have been applied.**

Participants with Disabilities:

DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

Photography Policy:

By attending the DIA 2013 49th Annual Meeting you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by the DIA in promotional materials, publications, and website and waive any and all rights including, but not limited to compensation or ownership.
DIA 2013
Advancing Therapeutic Innovation and Regulatory Science

4 Days. 22 Tracks. 250+ Educational Offerings.
450+ Exhibitors. 7,000+ Attendees.

- Patient Recruitment and Recruitment Strategies
- Payer Engagement
- Quality by Design Strategies
- Risk Evaluation and Mitigation Strategies
- Strategic Planning
- Orphan Drug Development
- Study Endpoints
- And More...