CELEBRATE THE PAST – INVENT THE FUTURE

CONTENT SCHEDULE

DIA 2014
50TH ANNUAL MEETING

4 Days.
260+ Educational Offerings over 21 Tracks.
450+ Exhibiting Companies.
125+ Speakers from Global Regulatory Agencies.

Register by May 9 to Get Your Name on the Advance Attendee List

June 15-19
San Diego Convention Center | San Diego, CA
diahome.org/DIA2014
This year marks the 50th Anniversary of the DIA Annual Meeting, the largest multidisciplinary event that brings together a global network of life sciences professionals to foster innovation that will lead to the development of safe and effective medical products and therapies to patients.

Connects Key Stakeholders Conversing on the Hottest Topics:

- 3-D Printing
- Audits & Inspections
- Big Data
- Breakthrough Therapy
- Career Transformation
- Disruptive Technologies
- Drug Shortages
- Electronic Health Records
- GRACE Principles
- Observational Studies
- Patient Engagement
- Patient Recruitment Strategies
- Patient Registries
- PDUFA V
- Pediatrics
- Personalized Medicines
- Postmarket Related Activities
- Protocol Design
- Regenerative Medicine
- Risk-based Monitoring
- Social Media Strategies
- Strategic Partnerships
- Sunshine Act

90% of the Exhibit Hall is SOLD. Reserve your booth today!

This year’s program includes 125+ speakers from regulatory and government agencies from around the globe.

Global Regulatory Presence

- CDER Town Hall (Part 1 and Part 2)
- CDRH Town Hall
- Challenges and Opportunities Facing FDA’s International Posts
- Asia Town Hall
- Development of an Integrated Orphan Drug Framework in Canada
- Europe Town Hall
- FDA – Health Canada Regulatory Cooperation Council (RCC) Town Hall
- New Approaches to International Collaboration Between Regulators (Part 1 and Part 2)
- Transforming ICH Toward Greater Global Harmonization
- Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall

72 Forums
129 Sessions
39 Symposiums
18 Tutorials
30 Workshops

Search Online Program
SUNDAY, JUNE 15 | PRECONFERENCE TUTORIALS

Jump start your education for the week. Each tutorial is designed to increase your knowledge while allowing for small group interaction. Receive $100 off of your Annual Meeting registration by registering for two half day tutorials or one full day tutorial. Tutorials are an extra-fee. Purchases must be made at the same time in order to receive the discount.

Morning Tutorials, Half Day | 8:30AM-12:00PM | Tutorial Fee: $405

Tutorial 20: Japan Regulatory Environment: Overview of the Organization, Processes, Systems, and Changes Affecting Pharmaceutical Development

Tutorial 21: The Sunshine Act: Understanding the Essentials of Compliance

Tutorial 22: Preparing for a US FDA Advisory Committee Meeting

Tutorial 23: Leadership: How to Organize and Lead People in Group Work


Afternoon Tutorials, Half Day | 1:00-4:30PM | Tutorial Fee: $405

Tutorial 30: Influencing Culture, Avoiding Bureaucracy, and Encouraging Innovation

Tutorial 31: Large-Scale Regulatory Functional Outsourcing: Emerging Trends, Challenges and Decision Criteria

Tutorial 32: Pharmacogenomics and Companion Diagnostics: The Future of Clinical Trials, New Product Development, and the Practice of Medicine

Tutorial 33: Bayesian Evidence Synthesis and Network Meta-analysis

Tutorial 34: Preparation of REMS Assessment Reports

Tutorial 35: Understanding Translational Medicine: Benefits and Innovative Approaches

Full Day Tutorials | 9:00AM-5:00PM | Tutorial Fee: $755

Tutorial 40: Analysis of Safety Data from Clinical Trials

Tutorial 41: Quality Oversight of CROs-Clinical Vendors

Tutorial 42: Regulatory Affairs for Biologics

Tutorial 43: Clinical Statistics for Nonstatisticians

Tutorial 44: Quality by Design from Theory to Practice

Tutorial 45: Risk Management Plan

Tutorial 46: The Good Pharmacovigilance Practices in the EU: Lessons Learned and Frequently Asked Implementation Questions

For more information, visit diahome.org/DIA2014tutorials

THE WALKING GALLERY MONDAY, JUNE 16 | 4:00-6:00PM

DIA will be hosting a gathering of The Walking Gallery, a patient empowerment movement founded by Artist Regina Holliday during the Opening Reception and DIA’s 50th Anniversary Celebration.

For details, contact Julie.Ho@diahome.org

We are the Gallery that walks. We are the Patients that wear our stories on our backs.
## MONDAY, JUNE 16

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<tr>
<th>8:30AM</th>
<th>Track 01A</th>
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### 2:30PM

**Plenary Session & Keynote Address**

**Welcome Remarks** [Minnie Baur-Venner, MD, MPH, President, DIA; Worldwide Vice President, Regulatory Affairs & Product Development, Abelian and Medical Devices & Diagnostics]

**Program Co-Chairs** [Brad Adin, MD, Sandra L. Fowler, MD, FACP, 2014 Program Co-Chair; Chair, Medical Affairs and Executive Vice President, Pfizer; Steve C. Lewis-Hall, MD, FAPA, 2014 Program Co-Chair; Chief Medical Officer and Executive Vice President, Pfizer; Janis Hoywood, COO and Chairman, PartnersLife Health Solutions, Director, ALS Therapy Development Institute (ALS TDI)]

### TUESDAY, JUNE 17

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<td>Risk-based Monitoring: From Concept to Practice</td>
<td>Improving the Informed Consent Process</td>
<td>Defining Literacy as a Tool to Inform Study Teams on Social Marketing Strategy for Recruitment and Building Patient-Centric Trials</td>
<td>Leaping the Valley of Death: How to Successfully Craft the Gap Between the Lab to the Clinic for Pharmaceutical Products</td>
<td>National Strategy to Bridge the Gap Between Academic Innovation and Commercialization in Asia</td>
<td>The State of Clinical Outsourcing</td>
<td>Understanding Corporate Integrity Agreements: What We Can Expect and Why is it Important?</td>
<td>Patient Engagement to Encourage a Successful Product Launch</td>
<td>Update on Postmarketing Safety Reporting</td>
<td>Improving Communicating in the Informed Consent Process: The Advantages of eSource</td>
<td>Electronic Source Data in Clinical Investigations (Part 2 of 2): Practical Implementation</td>
<td>FDA Programs to Encourage Innovation: Maximizing the Opportunities and Countering the Challenges of New Product Development</td>
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<td>Building a Site from the Ground Floor</td>
<td>Perfecting the Protocol: Designing Studies for Success</td>
<td>Patient Registration: Designing, Implementing and Leveraging to Enhance Clinical Trial</td>
<td>Development of the Central Nervous System Drugs with Abuse Potential</td>
<td>How a New Collaboration Between a Pharmaceutical Company and a CRO Is Improving the Quality, Speed, and Efficiency of Drug Development</td>
<td>Gene Therapy: Symposium</td>
<td>International Regulatory Advertising and Promotion Considerations</td>
<td>The Regulatory Writing Game Show</td>
<td>Electronic Standardized Study Data Requirements</td>
<td>Transformational Cultures and Mindsets: To Deliver at a Higher Quality and Efficiency</td>
<td>Prequalification of Medicines, for the Prevention of Persistent Diseases</td>
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### Track 11
- **Keynote Address**
- **Navigating the Road of Therapeutic Development**

### Track 12
- **Risk Management in the US, EU, and Asia: Where Are We Now?**

### Track 13
- **Design and Sample Size Planning for Multiregional Clinical Trials**

### Track 14
- **The PhRMA Student Forum: Maintaining Your Career Continuity Education and Changing Your Track**

### Track 15
- **New Approaches to International Collaboration Between Regulators (Part 2 of 2)**

### Track 16A
- **The Value Proposition for Life Science Professionals**

### Track 16B
- **DIA 2014 Student Forum: Maintaining Your Career Continuity Education and Changing Your Track**

### Track 18
- **New Approaches to International Collaboration Between Regulators (Part 2 of 2)**

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### Track 10
- **FDA Regulation of Therapeutic Products Derived from Human Stem Cells Successfully Navigating the Regulatory Hurdles**

### Track 11A
- **Defining, Measuring, and Assessing ‘Fit for Purpose’ Quality in a Risk-based Monitoring Model: Industry and Agency Perspectives**

### Track 11B
- **Protocol Deviations: Finding the Yellow Brick Road (Part 2 of 2)**

### Track 13
- **Observational studies of Comparative Effectiveness: How to Recognize Good Practice**

### Track 14A
- **Assessment of Impact and Effectiveness of Risk Management and Minimization in the EU and US**

### Track 14B
- **Effective Communication Model between Drug Safety, Regulatory Affairs and Development Partners**

### Track 15
- **Hot Topic in Statistics**

### Track 16
- **Narrowing the Gap: How to Tap into the Inherent Power of Words and Stories in the Clinical Trial Process**

### Track 17
- **New Approaches to International Collaboration Between Regulators (Part 2 of 2)**

### Track 18
- **How to Make 505(b)(2) to eCTD**

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**Register at diaphome.org/DIA2014 before May 9 to Make the Advance Attendee List.**
### Track 09
- **Compliance: The Legal, Regulatory, and Ethical Environment of Clinical Trials: Best Practices in Developing and Implementing the Global Clinical Trials Strategy**
  - Global Compliance Challenges: A Case Study
  - Developing a Global Clinical Trials Strategy: Tips for Success
  - Regulatory and Ethical Considerations in Conducting Clinical Trials
- **The State of Clinical Trials: Regulatory and Ethical Considerations**
  - Best Practices in Managing Clinical Trials
  - The Future of Clinical Trials: A Look Ahead
- **Clinical Trials: The Science Behind the Scenes**
  - Clinical Trials 101: An Introduction to the Science of Clinical Trials
  - Clinical Trials 102: Advanced Techniques in Clinical Trials

### Track 10
- **The State of Clinical Trials: Regulatory and Ethical Considerations**
  - Clinical Trials 101: An Introduction to the Science of Clinical Trials
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### Continuing Education Credits
Select tutorials and program 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 tutorials. For more details, visit [diahome.org/dia2014ce](http://diahome.org/dia2014ce)
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Register Today!

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Get a snapshot of the DIA 2014 50th Annual Meeting’s 260+ educational offerings by day!

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