MEMBER EARLY-BIRD RATE — Register by October 18, 2010 and *SAVE $150!*

Sustaining Clinical Trial Disclosure

Conference: November 9-10, 2010
Preconference Workshop: November 8, 2010

DoubleTree Hotel and Executive Meeting Center
Bethesda, MD, USA

PROGRAM CHAIRPERSONS

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Regulatory Affairs Manager, Clinical Trial Transparency
Genzyme Corporation

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Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA
Regional Offices
Basel, Switzerland Tokyo, Japan
Mumbai, India Beijing, China

Interact with Speakers from Industry, Patient Organizations, and Government Agencies to Explore Global Perspectives on the Complexities of Clinical Trial Disclosure

Stay informed on clinical trial disclosure global "climate changes" and hear from government and industry experts on what this means to you. This conference will focus on "energy efficiency" and "recycling" of trial information, engage in interactive discussions with biopharmaceutical, medical device, and data standards experts on Health Level Seven (HL7) and other initiatives that will enhance your understanding of the disclosure issues.

FEATURED TOPICS

- Clinical trial disclosure global "climate changes"
- Sustainability: What does the HL7 Clinical Trial Registration and Results (CTR&R) Standard mean to the future of Clinical Trial Disclosure?
- Separating "Paper/Plastics/Metals": How sponsors from pharma, biotech, medical device companies, and academia are approaching disclosure requirements
- Know your consumer: How various audiences are "reusing" your clinical trial data
- Tools to help you "conserve" resources and improve your disclosure workflow processes
- Methods for "recycling" your clinical trials data by "salvaging" existing information to populate multiple registries/results databases
- How clinical trial transparency may improve the health care environment

PRECONFERENCE WORKSHOP — *See next page for details*

Sustaining Clinical Trial Transparency: The Role and Potential Impact of HL7 CTR&R

WHO SHOULD ATTEND

Any organization that is a sponsor of a clinical trial, whether industry or investigator-sponsored, and professionals from the biopharmaceutical and medical device industries, academia, and government affected by clinical trial registration and results disclosure requirements, including:

- Clinical trial managers/staff
- Medical communications groups
- Scientific publication/medical writing groups
- Academic clinical investigators/independent investigators/study coordinators
- Statisticians
- Regulatory affairs professionals
- Quality assurance professionals
- Health policy professionals

CONFERENCE INFORMATION
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www.diahome.org

CONTINUING EDUCATION CREDITS

Drug Information Association has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102; (703) 506-3275.

Drug Information Association is authorized by IACET to offer 1.7 CEUs for this program.

CE Breakdown:
Conference: 1.3 IACET CEU
Pre-conference Workshop: .4 IACET CEUs

If you would like to receive a statement of credit, you must attend the program and tutorial, if applicable, sign-in at the DIA registration desk each day of the program, and complete the on-line credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request.

Disclosure Policy
It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

LEARNING OBJECTIVES
At the conclusion of this conference, participants should be able to:
- Recognize how companies and research institutions are refining processes to gain efficiencies of disclosure activities
- Describe the impact and applicability of HL7 CTR&R to the overall disclosure process
- Identify similarities and differences among global regulations
- Discuss how various audiences are consuming clinical trial data

PRECONFERENCE WORKSHOP | **NOVEMBER 8, 2010**

9:00 AM-5:00 PM REGISTRATION

1:00-5:00 PM PRECONFERENCE WORKSHOP

Sustaining Clinical Trial Transparency: The Role and Potential Impact of HL7 CTR&R

FACILITATOR

Sarah Doyle Larson
Regulatory Affairs Manager, Clinical Trial Transparency
Genzyme Corporation

SPEAKERS

Monica Mehta, MBA
Director, Regulatory Affairs
Genzyme Corporation

Volker Mludek, MD, MSc
Head Clinical Trial Posting, Insurance & IB Management
GQO - Information and Management Support
Bayer Schering Pharma AG

Saurabh Aggarwal
Applications Architect
Intrasphere Technologies, Inc.

Additional Speaker Invited

Understand the critical need for global data exchange standards due to the increasing number of Clinical Trial Registries. Hear from a series of experts about Health Level Seven International (HL7) and learn why it is important to the Clinical Trial Registration and Results (CTR&R) process. Using specific examples, review and contrast the process steps and data requirements for protocol registration on clinicaltrials.gov with that of EudraCT. Gain "hands on" experience in creating protocol registration records for these registries and gain insight into how HL7 standards will facilitate reuse of data, ultimately improving data exchange and process efficiency. *Please note that the hands-on experience will depend on availability of the test system, which is still in development, in time for the conference.

LEARNING OBJECTIVES

- Recognize the differences in data requirements between the WHO, clinicaltrials.gov, and EudraCT
- Describe the process for registering a trial on both ClinicalTrials.gov and EudraCT using HL7 standards
- Describe the impact of HL7 on the clinical trial registration process

Please note that lunch is not served on the preconference workshop day.

DAY 1 | NOVEMBER 9, 2010

7:00 AM-5:00 PM REGISTRATION

8:00-8:30 AM WELCOME AND INTRODUCTION, INCLUDING A HIGH LEVEL OVERVIEW OF HL7

Shawn Pelletier
Associate Director, Clinical Trial Transparency
Global Development Medical Affairs
Bristol-Myers Squibb

Sarah Doyle Larson
Regulatory Affairs Manager, Clinical Trial Transparency
Genzyme Corporation

8:30-10:00 AM SESSION 1

Separating Paper, Plastic and Metals: How Different Types of Sponsors are Approaching Disclosure Requirements

Session Chairperson

Patricia Teden, MBA
Principal
Teden Consulting LLC

The conference will open with an overview of the clinical trial disclosure challenges faced by study sponsors, other than biopharmaceutical companies. Many of those challenges are unique to the type of data provider organization represented in this session: a device company, an academic researcher, and a consumer product company. We will hear from each of these types of data providers so that conference participants can better appreciate how different types of sponsors are approaching disclosure requirements and how each is contributing to the goal of transparency and trust.

Medical Devices: A Unique Perspective on Transparency
Phyllis Britnell, MBA
Senior Project Manager, Clinical Development
ETHICON, a Johnson & Johnson Company

Clinical Trial Transparency Responsibilities for an Academic Researcher (Provisional Title)
Steven E. Nissen, MD, MACC
Chairman, Department of Cardiovascular Medicine
Cleveland Clinic Foundation

Disclosing Clinical Trial Information for Over-the-Counter Products
Speaker Invited

10:00-10:15 AM REFRESHMENT BREAK

10:15-11:45 AM SESSION 2

Know Your Consumer: How Various Audiences are "Reusing" Your Clinical Data

Session Chairperson

Kelly Goodwin Burri, MSc
Medical Communications Manager
CSL Behring

This session will address how various stakeholders are reusing the information from ClinicalTrials.gov and other clinical trial databases. Participants will gain insight into the value of clinical trial disclosure from the perspective of patients, investigators, and your competitors in industry and learn how these groups are using the data being disclosed.

Patient Advocacy in the Trial Disclosure Environment
Speaker Invited

Reusing Clinical Data for Meta-analyses (Provisional Title)
Steven E. Nissen, MD, MACC
Chairman, Department of Cardiovascular Medicine
Cleveland Clinic Foundation

Applying Semantic Web Mining to Analyze Global Research Activity and Render Business Intelligence
David Cocker
Senior Partner
MDCPartners

11:45 AM-1:00 PM LUNCHEON

1:00-2:30 PM SESSION 3

Tools to Help You "Conserve" Resources and Improve Your Disclosure Workflow Processes

Session Chairperson

Thomas Wicks, MBA
Product Manager
Intrasphere Technologies, Inc.

Hear from industry experts regarding how they are changing their processes to maximize efficiencies. Learn what HL7 CTR&R means to automation and process improvements. Listen to sponsors describe the systems and tools they have implemented, as well as the impact on the organization.

Survey of Company Processes/Methods to Facilitate the 'Auto-Population' of Registries/Results Databases
Robert Paarlberg, MS
Principal, Paarlberg & Associates, LLC

Working Without a System: What Processes Work Best to Keep You Afloat until Internal/External Systems/Standards are Available
Tracy J. Beck, PhD
Consultant-Medical Quality, Clinical Trial Registry Results
Eli Lilly and Company

Automation/Streamlining - System Implementation Case Study: Major Successes/Challenges; Modifying Process Prior to Implementation
Monica Mehta, MBA
Director, Regulatory Affairs
Genzyme Corporation

2:30-2:45 PM REFRESHMENT BREAK

2:45-4:15 PM SESSION 4

Results Reporting: It's Not Easy Being Green

Session Chairperson

Maureen Strange
Consultant, Medical Quality, Clinical Trial Registry
Eli Lilly and Company

This session will focus on results reporting. NIH and Tufts will partner to present the results review process including structure and training. To illustrate rationale and how the subject of consistency is being addressed, examples of common reviewer feedback will be provided. Learn that users can improve and influence results reporting by asking and answering questions during initial results data entry and while addressing results feedback. Find out how proactive discussions are improving the results reporting criteria and processes. Survey results across industry, academia, and devices will highlight successes of results reporting and potential opportunities for improvement. The session concludes with time allotted for questions and discussion.

Let's 'Shred' Some Light on Results Reporting
Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov
Lister Hill National Center for Biomedical Communications
National Library of Medicine
Stanley Ip, MD
Associate Director, Tufts Evidence-based Practice Center
Tufts Medical Center

Partnering to Conserve Energy and Reduce Pollution in Results Reporting
Speaker Invited

4:15-5:00 PM SESSION 5

How Have the Global "Transparency Climate" Changes Affected Us?

Session Chairperson

Shawn Pelletier
Associate Director, Clinical Trial Transparency
Global Development Medical Affairs
Bristol-Myers Squibb

This session provides a high level overview of the global transparency climate changes over the past 3 years and a view of the anticipated forecast for the future. It will also take a closer look at the EudraCT requirements to identify key differences between the US and EU.

Overview of the Transparency Climate Changes
Shawn Pelletier
Associate Director, Clinical Trial Transparency
Global Development Medical Affairs
Bristol-Myers Squibb

A Closer Look at the Anticipated "Climate" Forecast for the Future
John C. McKenney
President
SEC Associates, Inc.

5:00-6:00 PM NETWORKING RECEPTION

DAY 2 | NOVEMBER 10, 2010

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00 AM SESSION 6

Examining Local Climate Changes and the Impact on the Transparency Environment

Session Chairperson

Erik Lakes, MSc
Clinical Trial Registration and Results Disclosure Associate
Takeda Global Research & Development Center, Inc.

Hear from the World Health Organization and gain insight into the ICTRP's perspective. Learn about the details of varying local country requirements. What do these countries have in common and what are the key differences? Are there differences in how multi-center trials look when posted on multiple country registries? Does the difference in format and website process affect the consistency of the trial's message? What resources are required by a sponsor to register a trial and post results on multiple websites? Which operational models are sponsors currently considering for registering trials on multiple databases?

The Role of the WHO ICTRP in Global Clinical Trial Transparency
WHO Speaker Invited

National Registry Disclosure Requirements: A Closer Look at Local Climate Changes
Erik Lakes, MSc
Clinical Trial Registration and Results Disclosure Associate
Takeda Global Research & Development Center, Inc.

Registering a Trial on Multiple Databases: Which Process Models are Companies Considering?
Speaker Invited

10:00-10:15 AM REFRESHMENT BREAK

10:15 AM-12:00 PM SESSION 7

Enforcement and Compliance with Clinical Trial Disclosure Regulations

Session Chairperson

Oladayo O. Oyelola, PhD, SC(ASCP)
Clinical Trial Information Disclosure Director
Sanofi Pasteur Inc

This session will discuss the issue of regulatory and non-regulatory enforcement of compliance of Clinical Trial Disclosure requirements. In the US, how will enforcement be coordinated between the FDA and NLM? What are the important messages or observations on compliance that the FDA can share at this time? For non-regulatory compliance enforcement, what are the concerns on data integrity and consistency among multiple public data sources? A distinguished panel will present perspectives of the FDA, WHO, Good Clinical Practice, and Pharmaceutical industry publication group.

Enforcement and Compliance of the Clinical Trial Registry
Jarilyn Dupont, JD
Director of Regulatory Policy
Office of Policy, Office of Commissioner
FDA

Building a Sustainable Bridge between Public Disclosure and Publication Management
Michel Krumenacker, MD
Associate Vice President
R&D Transparency Coordination
sanofi-aventis

The Ethical Responsibility of Compliance with Trial Disclosure
WHO Speaker Invited

12:00-1:15 PM LUNCHEON

1:15-2:45 PM SESSION 8

The Age of Transparency and Its Affect on the Health Care Environment

Session Chairperson

Sarah Doyle Larson
Regulatory Affairs Manager, Clinical Trial Transparency
Genzyme Corporation

What does it mean to have entered the "Age of Transparency"? Hear from experts regarding the affect these various initiatives are having on the industry, patients, and the health care environment overall. Discuss whether public perceptions have changed as a result. Learn about transparency as viewed from the unique perspective of the patient... in what areas are we meeting their needs and where do we need to improve? Understand the approach one sponsor is taking to address the broader transparency requirements and discuss how this may be applied within your own organization.

Overview: The Age of Transparency
Sarah Doyle Larson
Regulatory Affairs Manager, Clinical Trial Transparency
Genzyme Corporation

The Patient's Perspective on Transparency
Diane Simmons
President and CEO
Center for Information and Study on Clinical Research Participation

A Sponsor's Approach to Transparency Initiatives Beyond Clinical Trial Disclosure
Speaker Invited

The Media's Perspective on Transparency
Speaker Invited

2:45-3:15 PM CLOSING REMARKS

Shawn Pelletier
Associate Director, Clinical Trial Transparency
Global Development Medical Affairs
Bristol-Myers Squibb

Sarah Doyle Larson
Regulatory Affairs Manager, Clinical Trial Transparency
Genzyme Corporation

3:15 PM CONFERENCE ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

Sustaining Clinical Trial Disclosure
Event #10031 • November 9-10, 2010

DoubleTree Hotel and Executive Meeting Center, Bethesda, MD, USA

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

Member Early-bird Opportunity Available on nondiscount member fee only	On or before OCT. 18, 2010	After OCT. 18, 2010
Member Fee	US $1310 ❑	US $1460 ❑

Join DIA now to qualify for the early-bird member fee!
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MEMBERSHIP
US $140 ❑

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Nonmember Fee US $1600 ❑

A one-year membership to DIA is available to those paying a nonmember registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER
Government (Full-time)	US $580 ❑	US $720 ❑
Charitable Nonprofit/Academia (Full-time)	US $730 ❑	US $870 ❑

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

Pre-conference Workshop

Monday, November 8, 2010 1:00-5:00 PM US $405 ❑

TO RECEIVE A TABLETOP EXHIBIT APPLICATION, PLEASE CHECK ❑

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

❑ **Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.**

1. _____

2. _____

3. _____

Payment options: Register online at www.diahome.org or check payment method.

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Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

TRAVEL AND HOTEL The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible. The DoubleTree Hotel and Executive Meeting Center is holding a block of rooms at the reduced rate below until October 15, 2010, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $179 Double $179

Attendees must make their own hotel reservations. Contact the DoubleTree Hotel and Executive Meeting Center Hotel by telephone at +1.301.652.2000 and mention the DIA event. The hotel is located at 8120 Wisconsin Avenue, Bethesda, MD 20814, USA.

CANCELLATION POLICY: On or before NOVEMBER 2, 2010
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

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.

TABLETOP EXHIBIT INFORMATION
Attendees may visit the tabletop exhibits during the event and receptions.
Contact **Jeff Korn, Exhibits Associate,** Phone **+1.215.442.6184**
Fax **+1.215.293.5924,** email **Jeff.Korn@diahome.org**

EVENT INFORMATION
Contact **JoAnn Boileau, Program Manager,** Phone **+1.215.442.6175**
Fax **+1.215.293.5940,** email **JoAnn.Boileau@diahome.org**

Please check the applicable category:

❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student
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Last Name _____

First Name _____ M.I.

Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

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Company _____

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City _____ State _____ Zip/Postal _____ Country

email **Required for confirmation** _____

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