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DRUG INFORMATION ASSOCIATION

3rd Annual Clinical Trial Disclosure Workshop

Recipes for Success

Tutorial: October 6, 2009
Conference: October 7-8, 2009

Gaylord National Resort & Convention Center
National Harbor, MD, USA

How to Achieve Successful Registries and Results Databanks

Take your clinical trial disclosure processes to the next level! Engage in interactive discussions with government, biopharmaceutical, medical device, and data standards experts on how to ensure compliance and improve efficiency in clinical trial disclosure.

FEATURED TOPICS

- Global Requirements, Laws, Regulations and Business Cases
- Defining the Clinical Trial Disclosure Role within a Company
- Available Tools, Resources, Organizations
- Impact of External Stakeholders, Company Policies, and Advanced Technologies on Disclosure Processes
- Managing Compliance
- Quality Checks
- Lessons Learned

WHO SHOULD ATTEND Professionals with a working knowledge of clinical trial registries and the disclosure process, including:

- **Clinical trial leaders**
- **Medical communications groups**
- **Independent investigators**
- **Biotechnology researchers**
- **Pharmaceutical/medical device/ academic clinical investigators**
- **Regulatory affairs personnel**
- **Quality assurance professionals**
- **Investigator site personnel**
- **Health policy professionals**

PRECONFERENCE TUTORIAL

OCTOBER 6, 1:30-5:00 PM

Clinical Trial Results Registration: A Hands-on Tutorial

INSTRUCTOR:
Suzanne Heyd, MA, MFA
Clinical Trial Results Analyst, Bristol-Myers Squibb

This hands-on tutorial is designed to guide participants in creating accurate, effective study results to ClinicalTrials.gov. *See page 2 for complete details.*

CONTACT AND TABLETOP EXHIBITS INFORMATION

Conference: **Joanne Wallace, Phone +1-215-442-6180 / email Joanne.Wallace@diahome.org**
Exhibits: **Jeff Korn, Phone +1-215-442-6184 / email Jeff.Korn@diahome.org**

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199
email: dia@diahome.org

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The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. This program is designated for 10.5 contact hours or 1.05 continuing education units (CEU's).

The Drug Information Association (DIA) 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. DIA is authorized by IACET to offer 1.1 CEUs for this tutorial/program.

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

Learning Objectives: At the conclusion of this conference, participants should be able to:

- Discuss global clinical trial registry requirements;
- Identify skill sets necessary to be successful in a clinical trial disclosure role;
- Discuss the various resources (internal/external) currently available to help with clinical trial disclosure;
- Recognize how other stakeholders, your company policy, or other available technologies can impact clinical trial disclosure requirements;
- Identify key aspects in the development of audit and compliance plans; and
- Discuss how to communicate and implement corporate clinical trial disclosure changes via internal/external quality checks.

TUESDAY • OCTOBER 6

12:00-1:30 PM TUTORIAL REGISTRATION

4:00-6:00 PM CONFERENCE REGISTRATION

1:30-5:00 PM **TUTORIAL**

Clinical Trial Results Registration: A Hands-On Tutorial

INSTRUCTOR

Suzanne Heyd, MA, MFA
Clinical Trial Results Analyst
Bristol-Myers Squibb

This hands-on tutorial is designed to guide participants in creating accurate, effective study results reports for the ClinicalTrials.gov website. Participants will receive an overall orientation of the study results section of the PRS system, understand the requirements of each data element, and gain hands-on experience creating a complete results record. Participants will learn valuable tips for overcoming common challenges and streamlining the internal review processes. There will be ample opportunity to share strategies for success and lessons learned with colleagues.

Tutorial Learning Objectives

- Identify the specific requirements for each basic data element of the Study Results website, and gain hands-on experience creating a complete and accurate record of results.
- Identify strategies for implementing the new requirement of adverse event reporting.
- Discuss best practice and lessons learned in the process of record creation, internal review, and NIH interaction.

Please note that lunch is not served on the tutorial day.

WEDNESDAY • OCTOBER 7

7:00 AM-8:00 AM CONFERENCE REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:30 AM WELCOME AND OPENING REMARKS
Tracy Beck, PhD
Associate Global Medical Business Office Consultant; CTR Results Gatekeeper
Eli Lilly and Company
Shawn M. Pelletier
Associate Director, R&D Operations
Bristol-Myers Squibb Company

8:30-10:00 AM SESSION 1

Get Your Basic Recipe – Global Requirements, Laws, Regulations, and Business Cases

CHAIRPERSON

Thomas Wicks, MBA
Business Development Manager
Intrasphere Technologies, Inc.

Understand the core requirements for implementing processes and technology to support global registration and results disclosure of clinical trials. The session looks at global regulatory landscapes to define the compliance requirements and then presents a framework for developing the business case to support investment in the necessary resources and technology.

Current Developments in Global Transparency Requirements
John C. McKenney
President, SEC Associates

The Case for Investing in Clinical Trial Registration and Results Disclosure

Thomas Wicks, MBA
Business Development Manager
Intrasphere Technologies, Inc.

10:00-10:30 PM **REFRESHMENT BREAK**

10:30 AM-12:00 PM SESSION 2

Identify the Cooks – Defining the Clinical Trial Disclosure Role within a Company

CHAIRPERSONS

Jacqueline Sayers, MBA, PhD
Quality Projects Manager
Roche Products Ltd.

Maureen Strange
Associate Medical Business Operations Consultant;
CTR Initiated Gatekeeper
Eli Lilly and Company

The aim of this session is to develop a generic job description for a clinical trial disclosure specialist. Delegates will be asked to contribute to a group discussion of the responsibilities of a specialist in clinical trial disclosure activities, to identify the skill set and qualifications of this group and to consider the potential "talent pool" for such individuals. At the end of the session all input will be collated and a composite job description prepared.

12:00-1:30 PM **LUNCHEON**

1:30-3:00 PM SESSION 3

Make Sure You Have the Right Utensils – Available Tools, Resources, Organizations

CHAIRPERSON

Patricia Teden, MBA
President and Principal
Teden Consulting, LLC

This session will cover the current tools, resources, and external organizations that are available for sponsors to utilize to improve efficiency, increase knowledge and overall compliance with global clinical trial registration and results databases.

Today's Tools to Get the Job Done

Tania Walton
Principal Programmer, CIS Programming
AstraZeneca Pharmaceuticals

Ingredients for Disclosure Recipe

Marta-Elena Wisdom
Associate Director, Clinical Trial Disclosure
Pfizer Inc

The Secret of Clinical Trial Disclosure? The Secret is in the Sauce

Susanne Cornett, MSc
Disclosure and Compliance Professional
Novo Nordisk, Denmark

3:00-3:30 PM **REFRESHMENT BREAK**

3:30-5:00 PM SESSION 4

Assembling Your Ingredients – Managing Compliance

CHAIRPERSONS

Carla Helaszek
Senior Director, Policy and Relationship Management
External Affairs - Global Development Operations
Novartis Pharmaceuticals Corporation

Gerard Lynch
Global Manager, AstraZeneca Clinical Trials Website
AstraZeneca R&D, UK

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

This session addresses the importance of proactive audit planning and the strategies to develop to ensure full and timely compliance with the various national and international clinical trial disclosure requirements. Participants will be able to benchmark from real-life situations, audit findings and the perspectives and expectations of regulatory agencies – the ultimate customer.

Gaining Insight into How the FDA-NLM Are Planning to Execute Compliance Monitoring

FDA Speaker Invited

A Legal Perspective on Compliance

Scott L. Cunningham, JD
Partner, Covington & Burling LLP

Audit Readiness and Planning

Carla Helaszek
Senior Director, Policy and Relationship Management
External Affairs - Global Development Operations
Novartis Pharmaceuticals Corporation

5:00-6:00 PM **NETWORKING RECEPTION**

THURSDAY • OCTOBER 8

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

8:30-10:00 AM SESSION 5

Adding Optional Ingredients – What Impact Will Advanced Technologies Have on Disclosure Processes?

CHAIRPERSONS

Tracy Beck, PhD
Associate Global Medical Business Office
Consultant; CTR Results Gatekeeper
Eli Lilly and Company

Shawn M. Pelletier
Associate Director, R&D Operations
Bristol-Myers Squibb Company

This session will explore external advanced technologies, as well as take a look into the future … what's on the horizon?

Turn Up the Heat with Advanced Technologies

Speaker Invited

Are Global Data Exchange Standards on the Menu?
Scott A. Getzin
Data Interchange Scientist
Eli Lilly and Company

Pie in the Sky Solutions
Speaker Invited

10:00-10:30 AM **REFRESHMENT BREAK**

10:30 AM-12:00 PM SESSION 6

Taste Testing - Quality Checks

CHAIRPERSON

Maureen Strange
Associate Medical Business Operations Consultant;
CTR Initiated Gatekeeper
Eli Lilly and Company

This session will look inside the internal Quality Assurance (QA) Group at ClinicalTrials.gov to learn the organizational structure and the coordination between trial registration and results. Learn about the relationship between quality and legal compliance, open implementation and legal questions that complicate quality assurance, and strategies for meeting these challenges. Learn how one company has begun implementing website feedback into current processes and making overall improvements. The session will conclude by NIH addressing industry questions that were submitted prior to the workshop. This interactive conclusion will help us to determine what needs to be added, subtracted, sifted, or kneaded to meet the spirit of FDAAA.

Registration and Results Reporting Requirements and Processes at ClinicalTrials.gov
Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov
National Institutes of Health
Nicholas Ide, MS
Chief Architect, ClinicalTrials.gov
National Institutes of Health (Contractor)

Taste vs. Recipe: Potential Discrepancies between Legal Requirements, Operational Mechanics, and Implementation Practicalities
Demetrios L. Kouzoukas, JD
Of Counsel, Covington & Burling
Former Principal Associate Deputy Secretary and Deputy General Counsel, U.S. Department of Health & Human Services

I'll Try the Sampler Platter Please
Shawn M. Pelletier
Associate Director, R&D Operations
Bristol-Myers Squibb Company

12:00-1:30 PM **LUNCHEON**

1:30-3:00 PM SESSION 7

Modifying the Recipe for the Future – Lessons Learned

CHAIRPERSONS

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

Thomas Wicks
Business Development Manager
Intrasphere Technologies, Inc.

A panel discussion on the lessons learned in the effort to comply with the various clinical trials information disclosure regulations and requirements. Panelists will present on the job and direct experience from different perspectives, including results data presentation, medical writing, the review, and the approval process.

Results Disclosure: Lessons Learned
Tania Walton
Principal Programmer, CIS Programming
AstraZeneca Pharmaceuticals

The Medical Writer's Perspective
Oladayo O. Oyelola, PhD, SC(ASCP)
Clinical Trial Information Disclosure Director
Sanofi Pasteur Inc.

The Review and Approval Process: Lessons Learned
Carol Slusser
Senior Director, Medical Communications
Clinical Submissions & Documentation
Schering-Plough Research Institute

3:00-3:30 PM CLOSING REMARKS
Tracy Beck, PhD
Associate Global Medical Business Office
Consultant; CTR Results Gatekeeper
Eli Lilly and Company
Shawn M. Pelletier
Associate Director, R&D Operations
Bristol-Myers Squibb Company

3:30 PM CONFERENCE ADJOURNED

TRAVEL AND HOTEL: The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Gaylord National Resort & Convention Center is holding a block of rooms at the reduced rate below until September 14, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $185 **Double $185**

Please contact the Gaylord National Resort & Convention Center by telephone at +1-301-965-2000 and mention the DIA event. The hotel is located at 201 Waterfront Street, National Harbor, MD 20745, USA.

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 the 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.**

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.*

Upcoming DIA Conferences, Training Courses, and Webinars

CONFERENCES

SEPTEMBER 23-24, 2009
Cardiovascular Safety and Development of Type 2 Diabetes Mellitus Medications: Current State of the Art and Opportunities to Advance the Science
Washington, DC

SEPTEMBER 23-25, 2009
DIA's 6th Latin American Congress of Clinical Research
Mexico City, Mexico

OCTOBER 8-9, 2009
***DIA/FDA/NCI/PhRMA:* Progression-free Survival Oncology Workshop**
Bethesda, MD

OCTOBER 15-16, 2009
Personalized Medicine: Biomarkers and Diagnostics in Drug Development, Regulatory Approval, and Access to Patients
Toronto, Ontario, Canada

OCTOBER 26-27, 2009
Measuring Study Endpoints in Multinational Clinical Trials: Outcomes Reported from the Viewpoint of the Clinician, Patient, and Caregiver
New Orleans, LA

OCTOBER 28-29, 2009
***DIA/FDA/PhRMA:* Modeling and Simulation in Drug Development – Quantitative Approaches for Decision Making**
Bethesda, MD

NOVEMBER 3-4, 2009
DIA's 7th Canadian Annual Meeting: "Time to Act"
Ottawa, Ontario, Canada

NOVEMBER 4-5, 2009
Assessing Benefits and Risks of Medicinal Products in Regulatory Decisions
Bethesda, MD

NOVEMBER 3-4, 2009
Global Vaccine Development for World Health Symposium: FDA, EMEA, Emerging Regions, NGO, and Industry Perspectives
Bethesda, MD

NOVEMBER 17-18, 2009
DIA's 2nd Conference on Signal Detection and Data Mining: International Perspectives on Spontaneous Reports and Other Healthcare Data Sets
New York, NY

NOVEMBER 18-19, 2009
DIA's 8th Annual Electronic Submissions Conference: eCTD – The Adventure Continues
San Diego, CA

NOVEMBER 18-20, 2009
DIA's 2nd Latin American Regulatory Conference (LARC): Harmonization for Clinical Research and Drug Development in the Latin American Region
Mexico City, Mexico

WEBINARS

AUGUST 11, 2009 11:00 am-12:30 pm EDT
Generic Biologics: Separating Science Fact from Science Fiction

SEPTEMBER 9, 2009 11:00 am-12:30 pm EDT
Mastering the DM Language: Communication Fundamentals for Clinical Trial Success

TRAINING COURSES

SEPTEMBER 10-11, 2009
Statistics for Nonstatisticians
Baltimore, MD

SEPTEMBER 14-16, 2009
Regulatory Affairs – Part I: The IND Phase
Philadelphia, PA

SEPTEMBER 21-24, 2009
The Leadership Experience
Philadelphia, PA

SEPTEMBER 22-24, 2009
Fundamentals of Clinical Research
Baltimore, MD

SEPTEMBER 22-23, 2009
High-performance Biopharm Teams
Horsham, PA

SEPTEMBER 22-24, 2009
Fundamentals of Clinical Research
Baltimore, MD

SEPTEMBER 22-24, 2009
Drug Safety Surveillance and Epidemiology
Baltimore, MD

SEPTEMBER 24-25, 2009
New Drug Product Development and Lifecycle Management
Horsham, PA

ONLINE TRAINING COURSES

Three-part Training Series: Developing Standard Operating Procedures (SOPs)
SEPTEMBER 15 & 16, 2009 11:30 AM-2:00 pm
SEPTEMBER 17, 2009 11:30 AM-1:30 pm

Three-part Training Series: Development of a Clinical Study Report
SEPTEMBER 29, OCTOBER 6 & OCTOBER 13, 2009
10:00 AM-12:00 pm

Three-part Training Series: Overview of Drug Development from Discovery through Marketing Application
SEPTEMBER 30, OCTOBER 1 & 2, 2009
11:30 AM-2:00 pm

MEMBER EARLY BIRD *Register by September 14, 2009* **SAVE $190**

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Gaylord National Resort & Convention Center
National Harbor, MD, USA

October 7-8, 2009

Event ID #09018

PRECONFERENCE TUTORIAL

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Suzanne Heyd, MA, MFA
Clinical Trial Results Analyst, Bristol-Myers Squibb

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Register online or fax this page to +1-215-442-6199

DRUG INFORMATION ASSOCIATION
800 Enterprise Road, Suite 200
Horsham, PA 19044-3595 USA

CONTACT & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the event and during receptions (if applicable).

Event information: Contact Joanne Wallace, at the DIA office by telephone +1-215-442-6180, fax +1-215-442-6199 or email Joanne.Wallace@diahome.org.

Tabletop exhibit information: Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahome.org. For tabletop exhibit space, please check the box below.

❑ **To receive a tabletop exhibit application, please check.**

GROUP DISCOUNTS (not available online or on already discounted fees)

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.
See page 4 for complete details.

Registration Fees *If DIA cannot verify your membership upon receipt of registration form, 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 SEP. 14, 2009	After SEP. 14, 2009
Member Fee	US $1260 ❑	US $1450 ❑

Join DIA now to qualify for the early-bird member fee! **Go to www.diahome.org and click on Membership + Communities.**

MEMBERSHIP **US $ 140** ❑

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee US $1590 ❑

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 $ 365 ❑	US $ 505 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 730 ❑	US $ 870 ❑

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

TUTORIAL, October 6, 1:30 pm-5:00 pm US $ 405 ❑

CANCELLATION POLICY: On or before SEPTEMBER 29, 2009

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.

❑ **I cannot attend but please keep me informed of DIA's future events.**
(requires completion of name, postal address and email address on this form)

REGISTRATION FORM

Do not remove mailing label. Please return this entire page. **09018**
PLEASE CONSIDER THIS FORM AN INVOICE

Please check the applicable category:
❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student *(Call for registration information)*

Last Name Check if part of group registration ❑ First Name M.I.

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Address As required for postal delivery to your location Mail Stop

City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

PAYMENT OPTIONS

Register online at www.diahome.org or check payment method

❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX *Exp Date* _____

Card # _____

Name (printed) _____

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.