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Current Advancements in Clinical Trial Disclosure
The Changing Tide

DIA® Drug Information Association

October 15-16, 2008 | Palmer House Hilton, Chicago, IL USA

Pre-conference Tutorial: October 14, 2008

PROGRAM CHAIRPERSONS

BARBARA GODLEW, RN
President and Principal Analyst
The FAIRE Company, LLC

TRACY BECK, PhD
Associate Medical Business Operations Consultant
CTR Results Gatekeeper
Eli Lilly and Company

PROGRAM COMMITTEE

ROBERT PAARLBERG, MS
Director, Global Regulatory Policy and Intelligence
UCB, Inc.

CATHERINE PAPILLON-DOWNEY
Director, Clinical Trial Information Disclosure
International Clinical Development
sanofi-aventis

SHAWN M. PELLETIER
Associate Director, R&D Operations
Bristol-Myers Squibb Company

PAMELA ROSE, RN
Associate Director, Clinical Trial Registries
Takeda Global Research and Development, Inc.

JACQUELINE SAYERS, MBA, PhD
Quality Projects Manager, Pharma Development
Quality, Roche Products Ltd.

MAUREEN STRANGE
Associate Medical Business Operations Consultant
CTR Initiated Gatekeeper
Eli Lilly and Company

ANTHONY K. TAYLOR, SR.
Clinical Operations Coordinator, Clinical Operations
Targanta Therapeutics Corporation

Follow-up to the Successful 2007 Clinical Trial Disclosure Workshop: Learning the Landscape and Reading the Roadmap.

Gain expert insight from government, pharmaceutical, biotechnology, and medical device professionals on how to ensure compliance with clinical trial disclosure laws and regulations, the ClinicalTrials.gov registry, and results database.

FEATURED TOPICS

- NIH Registry And Results Database
- Challenges with Journal Requirements and Legislation
- Academic and Independent Investigator Compliance
- Eudra Systems, Requirements and Developments
- Perspectives and Points of View
- Registries and Results Databases Requirements in the International Community
- Company Processes to Handle Disclosure Activities
- Legislative Actions and Reactions

WHO SHOULD ATTEND

- **Clinical trial leaders**
- **Medical communications groups**
- **Independent investigators**
- **Biotechnology researchers**
- **Academic, pharmaceutical and medical device clinical investigators**
- **Regulatory affairs personnel**
- **Quality assurance professionals**
- **Investigator site personnel**
- **Clinical research coordinators**

CONTACT INFORMATION

Conference: **Joanne Wallace, Phone +1-215-442-6180/email Joanne.Wallace@diahome.org**
Exhibits: **Erin Gilliland, Phone +1-215-442-6149/email Erin.Gilliland@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

Accreditation and Credit Designation

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.

2-DAY CONFERENCE: DIA is authorized by IACET to offer 1.2 CEUs for this program

HALF-DAY TUTORIAL: DIA is authorized by IACET to offer 0.4 CEUs for this 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 the currently implemented and future requirements of the United States Food and Drug Administration Amendments Act of 2007;
- Recognize the increasing number of country registries, their diversity, and challenges to ensure consistency;
- Explain/discuss the EMEA/Eudra systems related to clinical trials as well as recent legislative developments in Europe with respect to data and results disclosure;
- Recognize challenges facing registries, results databases, and journal editors;
- Identify a clinical trial disclosure process appropriate for company/institutional use;
- Discuss stakeholder perceptions and points of view; and
- Assess the current and future challenges with and of the NIH ClinicalTrials.gov databases.

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice.
Recording of information, in any type of media, is prohibited at all DIA events without prior written consent from DIA.

TUESDAY • OCTOBER 14

11:30 AM-5:00 PM REGISTRATION

1:30 PM-5:00 PM TUTORIAL

RIDING THE TIDE: CLINICAL TRIAL DISCLOSURE 101

INSTRUCTOR

PAMELA ROSE, RN
Associate Director, Clinical Trial Registries
Takeda Global Research and Development, Inc.

This tutorial will provide people new to the clinical trial disclosure field an overview of the criteria, tools, and processes used to register protocols on ClinicalTrials.gov. This tutorial will also touch on how and where to post results.

LEARNING OBJECTIVES:

1. Obtain general understanding of the history and issues surrounding public disclosure of clinical trial information
2. Identify the major stakeholders influencing policymaking regarding the disclosure of clinical trial information.
3. Describe how, where, and when to publicly register a clinical trial and to post clinical trial results.
4. Discuss points to consider when developing and implementing company disclosure processes.

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

WEDNESDAY • OCTOBER 15

7:00 AM-5:00 PM REGISTRATION

7:00 AM-8:00 AM CONTINENTAL BREAKFAST

8:00-8:30 AM WELCOME AND OPENING REMARKS

BARBARA GODLEW, RN
President and Principal Analyst
The FAIRE Company, LLC

TRACY BECK, PhD
Associate Medical Business Operations Consultant
CTR Results Gatekeeper
Eli Lilly and Company

8:30-10:00 AM SESSION 1

EUDRA SYSTEMS AND RECENT PUBLIC DISCLOSURE DEVELOPMENTS IN EUROPE – A CASE OF HIDDEN DEPTHS?

SESSION CHAIRPERSONS

CATHERINE PAPILLON-DOWNEY
Director, Clinical Trial Information Disclosure, International Clinical Development
sanofi-aventis

JACQUELINE SAYERS, MBA, PhD
Quality Projects Manager, Pharma Development Quality, Roche Products Ltd.

It can sometimes feel as if all of the attention on the topic of disclosure has been focused on the US, specifically on FDA regulations and ClinicalTrials.gov. However, the European situation is also changing and is

perhaps not as simple as it might first appear – there are hidden depths that need to be explored. The EMEA has a family of databases that house clinical trial and adverse event data. Until now, the EudraCT database has been accessible only to the Competent Authorities. This situation is about to change however, with the implementation of article 41 of Regulation No (EC) 1901/2006 for paediatric trials, and article 57.2 of Regulation No (EC) 726/2004 for other clinical trials. As a result, specific data from clinical trials applications and the results of paediatric trials will be made publicly available. This session will provide an overview of the Eudra systems and also discuss the recent developments with respect to public disclosure of clinical trial information, including initiatives in some EU countries to develop their own registries.

Introduction to Eudra Systems and the Process for Obtaining a EudraCT Number
JACQUELINE SAYERS, MBA, PhD
Quality Projects Manager, Pharma Development Quality, Roche Products Ltd.

Update on EudraCT and Implementation of the Paediatric Regulation
FERGUS SWEENEY, PhD *(via telecommunications resource)*
Principal Scientific Administrator, GCP and Pharmacovigilance Inspector
European Medicines Agency, European Union

AGNÈS SAINT-RAYMOND, MD *(via telecommunications resource)*
Head of Sector, Scientific Advice, Paediatrics and Orphan Drugs
European Medicines Agency, European Union

Overview of Current Legislations and Initiatives Related to Public Disclosure of Clinical Trial Information in Europe
CATHERINE PAPILLON-DOWNEY
Director, Clinical Trial Information Disclosure, International Clinical Development
sanofi-aventis

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

10:30 AM-12:00 PM SESSION 2

Navigating from Island to Island: Coping with International Registries
Session Chairpersons

ROBERT PAARLBERG, MS
Director, Global Regulatory Policy and Intelligence
UCB, Inc.

CATHERINE PAPILLON-DOWNEY
Director, Clinical Trial Information Disclosure, International Clinical Development
sanofi-aventis

This session will discuss the increasing number of country registries which are mandatory and voluntary, their diversity and challenges by sponsors to ensure consistency of the information posted.

Plotting the Course in the Maze of International Clinical Trial Disclosure Requirements and Their Related Registry Websites
John C. McKenney
President & Principal Consultant
SEC Associates, Inc.

Overview of the WHO International Clinical Trials Registry Platform
Davina Ghersi, MPH, PhD *(via telecommunications resource)*
Platform Coordinator, International Clinical Trials Registry Platform
World Health Organization

Overview of the IFPMA Clinical Trials Portal
Detlef Niese, MD, PhD
Head, External Affairs, Global Development
Novartis Pharmaceuticals AG, Switzerland

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

1:30-3:00 PM SESSION 3

Legislative Actions and Reactions: Mermaids, Monsters, and Other Myths
Session Chairperson

TRACY BECK, PhD
Associate Medical Business Operations Consultant
CTR Results Gatekeeper
Eli Lilly and Company

Panel discussion with some of the key stakeholders instrumental in establishing the current requirements for clinical trial registry/results database disclosure.

Panelists:

David Dorsey, JD *(via telecommunications resource)*
Senior Health Policy Advisor
Senate Committee on Health, Education, Labor and Pensions
Ranking Member Ted Kennedy (D-Mass.)

Rebecca Williams, PharmD
Assistant Director, ClinicalTrials.gov
Lister Hill National Center for Biomedical Communications
National Library of Medicine

Amy Muhlberg, PhD *(via telecommunications resource)*
Senior Health Policy Advisor
Senate Committee on Health, Education, Labor and Pensions
Ranking Member Michael B. Enzi (R-Wyo.)

Jude Walsh
Special Assistant, Governor's Office of Health, Policy and Finance
State of Maine

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

3:30-5:00 PM SESSION 4

Destination: Publication Island
Session Chairpersons

SHAWN M. PELLETIER
Associate Director, R&D Operations
Bristol-Myers Squibb Company

MAUREEN STRANGE
Associate Medical Business Operations Consultant
CTR Initiated Gatekeeper
Eli Lilly and Company

This session will focus on the current impact of the legislation on journal editors, sponsors and academic institutions. The audience will have interactive discussions on the challenges of FDAAA and State of Maine legislation versus requirements for publication in peer-reviewed medical journals. Experience, insights and common struggles will be shared.

A Journal's Perspective on the Challenges of the Requirements and Legislation
Jeffrey M. Drazen, MD
Editor-in-Chief, *New England Journal of Medicine*
Distinguished Parker B. Francis Professor of Medicine, Harvard Medical School

The Red Tide: Effects of Legislation on the Peer-Reviewed Publication Process
Laurence Hirsch, MD
Immediate Past President, International Society for Medical Publication Professionals
Vice President, Medical Affairs, BD Diabetes Care

Swim at Your Own Risk: It's a Purple Flag Day at the Beach, Dangerous Sea Creatures Possible
Pamella Erickson, MS
Associate Scientific Communications Consultant
Eli Lilly and Company

Survey Results: Can Your Choice of Watercraft and How You Plot Your Course Determine Your Success at Reaching Publication Island?
Maureen Strange
Associate Medical Business Operations Consultant, CTR Initiated Gatekeeper
Eli Lilly and Company
Shawn M. Pelletier
Associate Director, R&D Operations
Bristol-Myers Squibb Company

5:15-7:00 PM NETWORKING RECEPTION

THURSDAY • OCTOBER 16

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

8:30-10:00 AM SESSION 5

In the Eye of the Beholder
Session Chairperson
BARBARA GODLEW, RN
President and Principal Analyst
The FAIRE Company, LLC

Transparency is a matter of perception. Different segments of the medical community view clinical trial disclosure from different perspectives. What may seem perfectly clear and easy to discern to one organization may be perceived as complicated and less clear to others. This session will help participants see 3 different perceptions of clinical trial disclosure from industry, patient advocacy, and the public at large.

Living in a Fish Bowl: The Industry Perspective of Clinical Trial Disclosure
Craig Metz, PhD
Vice President, Centers of Excellence in Drug Discovery
US Regulatory Affairs
GlaxoSmithKline, Inc.

Fishing for Answers: Patient Advocacy in Clinical Research
Elda Railey
Cofounder, Research Advocacy Network

Tide Swell: Views from Patients and Disclosers
Lia McLean, PhD *(via telecommunications resource)*
Practice Head, Process Design and Implementation
PopeWoodhead and Associates

Jacqueline Sayers
Quality Projects Manager
Roche, Ltd.

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

10:30 AM-12:00 PM SESSION 6

Diving Deeper into Clinical Trial Disclosure: The Academic and Independent Investigators' Perspective
Session Chairpersons
ROBERT PAARLBERG, MS
Director, Global Regulatory Policy and Intelligence
UCB, Inc.
MAUREEN STRANGE
Associate Medical Business Operations Consultant
CTR Initiated Gatekeeper
Eli Lilly and Company
ANTHONY K. TAYLOR, SR.
Clinical Operations Coordinator, Clinical Operations
Targanta Therapeutics Corporation

The requirements of the clinical trial databases provision in the FDA Amendments Act apply to academic and independent investigators as well as to industry conducted clinical trials. This session will highlight the challenges faced by academic and independent investigators and best practices in registering clinical trials and establishing procedures for reporting study results to ClinicalTrials.gov.

Registering and Reporting Results from an Academic Perspective
Lewis J. Smith, MD
Professor of Medicine and Associate Vice President for Research
Northwestern University

Navigating ClinicalTrials.gov at an Academic Medical Center
Karriem S. Watson, MD, MS, CCRC
Director of Clinical Research and Development
University of Illinois at Chicago (UIC), Department of Neurosurgery

Ensuring Compliance with Registration Requirements for a Multinational Collaborative Group Study
John Hickey, MA
FREEDOM Trial Manager, Clinical Trials Unit
Mount Sinai Heart
Mount Sinai School of Medicine

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

1:30-3:00 PM SESSION 7

Natural Evolution of Big Fish: The NIH Registry and Results Database

Session Chairperson

BARBARA GODLEW, RN
President and Principal Analyst
The FAIRE Company, LLC

With the passage of the FDAAA legislation, ClinicalTrials.gov is tasked with expanding the clinical trial registry and establishing a clinical trial results database. Having recently implemented the results database component, senior members of the ClinicalTrials.gov staff share the legislative requirements and technical information needed to fulfill the requirements.

The Weather Forecast: Today's Legal Requirements for Disclosing Trial Information and the Process Ahead

Rebecca J. Williams, PharmD
Assistant Director, ClinicalTrials.gov
Lister Hill National Center for Biomedical Communications
National Library of Medicine

The Tackle Box: The Implementation Pieces of ClinicalTrials.gov and How They Fit Together

Nicholas C. Ide, MS
Chief Architect, ClinicalTrials.gov
Lister Hill National Center for Biomedical Communications
National Library of Medicine

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

3:30-5:00 PM SESSION 8

When Wind and Sea Conditions Change, Company Processes Will Be Your Life Jacket

Session Chairpersons

SHAWN M. PELLETIER
Associate Director, R&D Operations
Bristol-Myers Squibb Company

ANTHONY K. TAYLOR, SR.
Clinical Operations Coordinator, Clinical Operations
Targanta Therapeutics Corporation

Companies must create business processes to support clinical trial disclosure activities in a quality driven manner, yet be flexible to meet and manage the changing needs of disclosure activities for clinical trials. This session will cover the current practices in the industry, possible information technology solutions to handle registration and disclosure of results, and the benefits and challenges of implementing FDAAA into company processes.

Throw the Life Preserver: Will Technology Help Keep You Afloat?

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

Navigating Through Uncharted Waters – How Your Company Policies Can Be Your Compass

Robert Paarlberg, MS
Director, Global Regulatory Policy and Intelligence
UCB, Inc.

Assessing What Items You Need on Your Voyage and Asking Yourself: Will One Lifeboat be Enough?

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

5:00-5:15 PM CLOSING REMARKS

BARBARA GODLEW, RN
President and Principal Analyst
The FAIRE Company, LLC

TRACY BECK, PhD
Associate Medical Business Operations Consultant
CTR Results Gatekeeper
Eli Lilly and Company

5:15 PM WORKSHOP ADJOURNED

TRAVEL AND HOTEL The most convenient airport is O'Hare International and attendees should make airline reservations as early as possible to ensure availability. The Palmer House Hilton is holding a block of rooms at the reduced rate below until September 22, 2008, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $279 **Double $304**

Please contact the Palmer House Hilton by telephone at +1-877-865-5321 or +1-312-726-7500 and mention the DIA event. The hotel is located at 17 East Monroe Street, Chicago, IL 60603, 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 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.**

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.*

DRUG INFORMATION ASSOCIATION **http://www.diahome.org**

Horsham, PA, USA
Tel: +1-215-442-6100 • Fax: +1-215-442-6199
email: dia@diahome.org

Basel, Switzerland
Tel: +41-61-225-51-51 • Fax: +41-61-225-51-52
email: diaeurope@diaeurope.org

Tokyo, Japan
+81-3-5833-8444 • Fax:+81-3-5820-8448
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Current Advancements in Clinical Trial Disclosure: The Changing Tide

Event ID #08023

Palmer House Hilton, Chicago, IL, USA

OCTOBER 15-16, 2008

Follow-up to the Successful 2007 Clinical Trial Disclosure Workshop:

Learning the Landscape and Reading the Roadmap

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

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 Erin Gilliland, Exhibits Associate, at the DIA office by telephone +1-215-442-6149, fax +1-215-442-6199 or email Erin.Gilliland@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 5 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 SEPT. 24, 2008	After SEPT. 24, 2008
Member Fee	US $1200 ❑	US $1380 ❑

Join DIA now to qualify for the early-bird member fee! **www.diahome.org/en/Membership/AboutMembership/AboutMembership**

MEMBERSHIP **US $ 130** ❑

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 $1510 ❑

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 $ 350 ❑	US $ 480 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 695 ❑	US $ 825 ❑

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

TUTORIAL

1:30-5 pm – Riding the Tide: Clinical Trial Disclosure 101 US $ 350 ❑

CANCELLATION POLICY: On or before OCTOBER 8, 2008

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)

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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.