

The Evolving Clinical Trial Disclosure Landscape

September 13-14, 2011

Sheraton National Hotel, Arlington, VA, USA



PROGRAM CHAIRPERSON

Robert Paarlberg, MS

Principal
Paarlberg & Associates, LLC

PROGRAM COMMITTEE

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Huron Consulting Group

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Medical Communications Manager
CSL Limited

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Robin M. Smith

Director Clinical Trial Registries
Global Clinical Services
Allergan, Inc.

Patricia Teden, MBA

President and Principal
Teden Consulting LLC

Thomas Wicks, MBA

PharmaCM Leader
Deloitte Analytics

Stay Informed of the Latest Requirements and Developments in the Global Clinical Trial Disclosure Environment.

Engage in interactive discussions with biopharmaceutical and medical device experts as well key agency personnel from NLM, FDA and EMA on how to ensure compliance, efficiency, and consistency in clinical trial disclosure. This year's conference will offer collaborative breakout sessions that will give you the opportunity to interact with and gain practical advice from colleagues, peers, and other stakeholders.

FEATURED TOPICS

- US, Regional, and International Clinical Trial Registries
- Leveraging Information Technology to Upload to Registries and Results Databases
- Registries, Results Databases, and the Interrelationships with Publications
- Devices and Disclosure
- Impact of Disclosure on NIH Research/Academia
- FDA Plans for Auditing Procedures
- Collaborative Breakout Session Topics:
 - o Preparing Your Protocol and CSR for Future Disclosure
 - o Post-market and Observational Studies
 - o ClinicalTrials.gov Quality Review
 - o Challenges Unique to Small Companies and Academic Researchers

WHO SHOULD ATTEND

Professionals involved in:

- Clinical trial disclosure
- Clinical trials
- Medical communications/writing
- Clinical investigation
- Statistics
- Regulatory affairs
- Quality assurance
- Health policy
- Medical /Scientific affairs
- Health economics and outcomes research

Worldwide Headquarters

Drug Information Association, Inc.
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CONTINUING EDUCATION CREDITS



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; (703) 506-3275. Drug Information Association is authorized by IACET to offer 1.4 CEUs for this program.

If you would like to receive a statement of credit, you must attend the program, 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. My Transcript will be available for credit requests on September 28, 2011.

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 meeting, participants should be able to:

- Define the most recent developments in disclosure requirements in the United States, Europe, and other countries/regions.
- Recognize the unique implications and challenges of clinical trial disclosure on small companies and academic medical centers.
- Discuss FDA's insight on auditing and enforcement of clinical trial disclosure requirements.
- Express an appreciation of the quality review process from the reviewer's perspective.
- Discuss how changes made to protocols, tables/figure/listings, and clinical study report designs better support disclosure.
- Describe how to write more specific outcome measures.
- Describe the interrelationships between clinical trial disclosure and the publication process.
- Identify best practices in clinical trial disclosure.
- Discuss practical examples of content management and electronic data exchange from the perspective of small to large companies.

Unless otherwise disclosed, DIA acknowledges that the 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 any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

DAY 1 | SEPTEMBER 13, 2011

7:30-5:00 PM REGISTRATION

7:30-8:45 AM CONTINENTAL BREAKFAST

8:45-9:00 AM WELCOME AND INTRODUCTION

Robert Paarlberg, MS

Principal
Paarlberg & Associates, LLC

9:00-10:30 AM SESSION 1

International Registries

SESSION CHAIRPERSON

Robin M. Smith

Director Clinical Trial Registries
Global Clinical Services
Allergan, Inc.

The laws and requirements for clinical trial registration and results disclosure continue to evolve. Countries around the world continue to develop and launch new registry and results databases each with their own unique requirements. This session will present the status of key registry developments, which registries are mandatory versus voluntary, and review disclosure requirements in specific countries.

Current Transparency Initiatives in Specific Countries

John McKenney

President, SEC Associates, Inc.

Review of Disclosure Requirements in India

Professor Arvind Pandey, PhD, FSMS, FRSS, FAMS
National Institute of Medical Statistics, ICMR

10:30-11:00 AM REFRESHMENT BREAK

11:00 AM-12:30 PM SESSION 2

Progress on the Technical Side: Stories of Content Management and Electronic Data Exchange

SESSION CHAIRPERSON

Patricia Teden, MBA

President and Principal
Teden Consulting LLC

Content control and efficiency in an environment with numerous global registries requires content management and electronic data exchange. These capabilities do not happen overnight, however this session will offer evidence of the progress being made toward these capabilities by a small biotech, a technology firm supporting a large biotech, and a large pharmaceutical company.

Using an Existing Clinical Trial Management System to Support Trial Registration on ClinicalTrials.gov

Linda MacKeen, MS

Director, Medical Writing
Seattle Genetics

Cross-Functional Collaboration Leveraging Statistical Programming for Posting Results

Scott Davis

Application Developer, Experis

Touching Data Only Once: Optimizing Clinical Trial Information Disclosure for ClinicalTrials.gov and EudraCT

Hanns-Georg Leimer, PhD

Head of Processes and Systems Coordination in Corporate Division Quality, Regulatory, Pharmacovigilance, Epidemiology
Boehringer Ingelheim (Germany)

12:30-1:30 PM LUNCHEON

1:30-3:00 PM SESSION 3

NLM and EU Update

SESSION CHAIRPERSONS

Kelly Goodwin Burri, MSc

Medical Communications Manager
CSL Limited

Robert Paarlberg, MS

Principal
Paarlberg & Associates, LLC

This session will provide an update on recent activities in ClinicalTrials.gov and EudraCT.

NLM Update

Rebecca J. Williams, Pharm.D., MPH

Assistant Director, ClinicalTrials.gov
Lister Hill National Center for Biomedical Communications
National Library of Medicine, National Institute of Health

Nicholas C. Ide, MS

Chief Architect, Contractor to ClinicalTrials.gov

EU Update (via audio communication)

Fergus Sweeney, PhD

Head of Sector, Compliance and Inspection
European Medicines Agency, European Union

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM SESSION 4 - COLLABORATIVE BREAKOUT SESSIONS

Collaborative breakout sessions will offer attendees the opportunity to interact with and gain practical advice from colleagues, peers, and other stakeholders. The breakout sessions will include 30 minutes of report-back to the general session.

Breakout Session 1 – Ask the Reviewer

SESSION CHAIRPERSON

Kelly Goodwin Burri, MSc

Medical Communications Manager
CSL Limited

Preparing high quality results records and managing the quality review process efficiently is critical to having study results published within the required timelines. In this interactive breakout session, participants will gain insight into the ClinicalTrials.gov Quality Review process, highlighting issues and common problems from the reviewers' perspective. The session will also provide an open forum to share questions, experiences and best practices for successfully completing the results review process.

Heather Dobbins, PhD

Lead Results Analyst, National Library of Medicine (contractor)

Breakout Session 2 – Is it really an Observational study? The challenges of identifying study type.

SESSION CHAIRPERSON

Thomas Wicks, MBA

Director, Product Management
Intrasphere Technologies, Inc.

One of the key factors in deciding whether to register a clinical trial is the trial type, whether it is Interventional, Observational, Expanded Access, or perhaps an analysis that might not fit any of these descriptions. While it is typically not difficult to identify an Interventional or Expanded Access study, the real challenge is in identifying Observational studies, especially when assessing Post-Market studies or Health Economic research studies. This breakout session will provide a forum to discuss approaches for classifying study-types with the goal of developing a decision tree that supports consistent classification.

SPEAKER

Volker Mluddek, MD, MSc

Head Clinical Trial Posting, Insurance & IB Management
Bayer Schering Pharma AG

5:00-6:00 PM NETWORKING RECEPTION

DAY 2 | SEPTEMBER 14, 2011

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

8:00-9:30 AM SESSION 5

Publication Planning

SESSION CHAIRPERSON

Erik Lakes, MSc

Clinical Trial Registration & Results Disclosure Associate
Strategic Partnerships & Initiatives
Takeda Global Research & Development Center, Inc.

Full disclosure of results on publicly-accessible databases should complement results published in journals; however, there are challenges when harmonizing information between trial databases and journal publications. This session addresses several issues facing publications and their relationship to trial databases as well as discusses technological solutions surrounding publications and trial disclosures.

Harmonization of Publications & Clinical Trial Disclosures: Challenges and Best Practices

Erik Lakes, MSc.

Clinical Trial Registration & Results Disclosure Associate
Strategic Partnerships & Initiatives
Takeda Global Research & Development Center, Inc.

Clinical Trial Disclosures and Scientific Publications: Two Facets of a Same Prism – How To Achieve Consistency

Michel Krumenacker, MD

Associate Vice President, R&D Transparency Coordination
Sanofi

Technical and Regulatory Considerations for Harmonizing Clinical Trial Disclosure and Peer-reviewed Publications

Tim Bacon

CEO, Medicine in Practice

9:30-10:00 AM SESSION 6

Devices and Disclosure

SESSION CHAIRPERSON

Thomas Wicks, MBA

PharmaCM Leader
Deloitte Analytics.

This session will provide a summary of the Device-specific disclosure requirements followed by a review of the particular challenges for Device companies and the impact of trial disclosure on their processes.

SPEAKER

Diane Murphy

Director, Global Medical Writing
Allergan Medical

10:00-10:15 AM REFRESHMENT BREAK

10:15-10:45 AM SESSION 7

HL7 Update

SESSION CHAIRPERSON

Robert Paarlberg, MS

Principal
Paarlberg & Associates, LLC

The Clinical Trial Registration and Results (CTRR) Working Team has made progress in testing the new interchange standard. This session will provide a project update and a demo of the testing tool used to show how clinicaltrials.gov and EMA data maps to the standard.

Clinical Trial Registration and Results (CTRR) Project Update and Future Use Case

Scott A. Getzin

Data Scientist - Clinical Development Organization
Eli Lilly and Company

10:45 AM-12:15 PM SESSION 8

Impact of Disclosure on NIH Research/Academia

SESSION CHAIRPERSON

Barbara Godlew, RN, BA

Director, Huron Consulting Group

Food and Drug Administration Amendments Act (FDAAA) applies to all institutions that conduct clinical trials in the United States (US). Ex-US regulations (eg, European Medicines Agency, other countries/regions) governing clinical trial disclosure may also apply to academic medical centers conducting trials outside of the US. This session will focus on the unique challenges in complying with clinical trial disclosure regulations.

Public Perceptions on Compliance with ClinicalTrials.gov

Barbara Godlew, RN, BA

Director, Huron Consulting Group

Survey of Academic Medical Centers Administrative Practices for Clinical Trial Disclosure

Karen Hartman, RN, MSN

Director, Office of Research Regulatory Support
Mayo Clinic

Impact of Clinical Trial Disclosure Requirements on Academic Medical Centers Operations and Funding of Clinical Trials

Tesheia Johnson, MBA, MPH

Chief Operating Officer for Yale Center for Clinical Investigation and the Associate Director for Clinical Research for the School of Medicine.
Yale University
Yale Center for Clinical Investigation

12:15-1:15 PM LUNCHEON

1:15-2:45 PM SESSION 9 - COLLABORATIVE BREAKOUT SESSIONS

Collaborative breakout sessions will offer attendees the opportunity to interact with and gain practical advice from colleagues, peers, and other stakeholders. The breakout sessions will include 30 minutes of report-back to the general session.

Breakout Session 3 – Preparing Your Protocol and Clinical Study Report (CSR) for Future Disclosure

SESSION CHAIRPERSON

Robin M. Smith

Director Clinical Trial Registries
Global Clinical Services
Allergan, Inc.

As transparency initiatives continue to require companies to disclose more trial information to multiple public registries in multiple formats, the process of study registration and results disclosure continues to be a challenge. It might be helpful to look at how the study protocol and the study report are designed and formatted as these two documents provide the basis for the study information that is disclosed. This breakout session will look at how different companies are addressing the changing transparency requirements from using structured content to writing of outcome measures to programming specific data tables for results disclosure.

SPEAKERS

Laura A. Hagan

Chief Medical Office
Novartis Pharmaceuticals Corporation

Sarah Doyle Larson

Regulatory Affairs Manager, Clinical Trial Transparency
Genzyme Corporation

Kristi Whiteside

Associate Director, Clinical Trial Disclosure
Celgene Corporation

Breakout Session 4 – Challenges Unique to Small Companies and Academic Researchers

SESSION CHAIRPERSON

Patricia Teden, MBA

President and Principal
Teden Consulting LLC

Small organizations that sponsor studies, such as small biopharm or device companies and academic research centers, face challenges that reflect their organization's size. These challenges include keeping up with expectations and changes, gaining proficiency when doing a small volume of work, and sharing clinical trial disclosure work with collaborators. Small public companies have the additional pressure of each study disclosure potentially having 'material' significance to the financial community. The return-on-investment (ROI) for tools is different in a small environment. Participants in this session will share their challenges and – most important – share advice on successfully addressing those challenges.

Karen Hartman, RN, MSN

Director, Office of Research Regulatory Support
Mayo Clinic

Paula Wun

Sr. Manager, Clinical Strategy & Medical Writing
Alkermes, Inc.

2:45-3:00 PM REFRESHMENT BREAK

3:00-4:30 PM SESSION 10

Clinical Trial Disclosure Regulations: Enforcement/Inspections/Audits

SESSION CHAIRPERSON

Oladayo Oyelola, PhD, SC(ASCP)

Clinical Trial Information Disclosure Director
Sanofi Pasteur Inc

This session will address the issue of audits and enforcement of compliance with the clinical trial disclosure regulations by the regulatory agencies. In the US, how will enforcement be coordinated in view of the updated Food and Drug Administration's (FDA) Compliance Program Guidance Manual with specific reference on "Registration of Studies on ClinicalTrials.gov" in Section D of Chapter 48? What important points on compliance audits and enforcement can the FDA and other regulatory agencies share at this time?

A distinguish panel will discuss best practices on audit and inspection preparedness; legal updates on clinical trial disclosure with a focus on the latest developments, possible future directions and government priorities; and the FDA's perspectives on compliance inspection audits and enforcement of clinical trial disclosure.

Clinical Trial Disclosure: Inspection and Audit Readiness Considerations

Susan Nonemaker

Specialist Master/Strategy & Operations - Life Sciences
Deloitte Consulting, LLP

Legal Update on Clinical Trial Disclosure: Latest Developments and Likely Future Directions and Government Priorities

Michael N. Druckman

Partner
Hogan Lovells US LLP

Auditing and enforcement of clinical trial disclosure requirements - FDA Perspective

Julie Finegan

Associate Chief Counsel, FDA

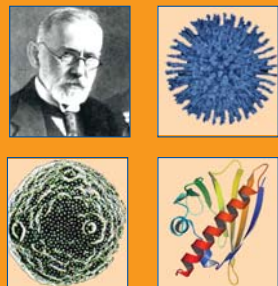
4:30-4:45 PM CLOSING REMARKS

Robert Paarlberg, MS

Principal
Paarlberg & Associates, LLC

4:45 PM WORKSHOP ADJOURNED

DIA Upcoming Conferences



■ **13th International Paul-Ehrlich-Seminar
Allergen Products for Diagnosis and Therapy:
Regulation and Science**

SEPTEMBER 14-17, 2011 | WASHINGTON, DC, USA

■ **5th Annual Clinical Forum
Basel 2011**

OCTOBER 10-12, 2011 | BASEL, SWITZERLAND

■ **First Annual Rare Diseases and Orphan Products
Summit**

OCTOBER 11-13, 2011 | WASHINGTON, DC

■ **6th Annual Conference on Drug Discovery and Clinical
Development: Convergence of Science, Medicine, and
Health**

OCTOBER 15-18, 2011 | MUMBAI, INDIA

■ **8th DIA Japan Annual Meeting**

OCTOBER 27-28, 2011 | TOKYO, JAPAN

For more information on these and future DIA offerings, please monitor the DIA website at www.diahome.org.

REGISTRATION FORM

Register online or fax this page to +1.215.442.6199

Meeting

Event #11031 • Workshop: September 13-14, 2011
Sheraton National Hotel, Arlington, VA, 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.

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| Member Early-bird Opportunity Available on nondiscount member fee only | On or before AUG 23, 2011 | After AUG 23, 2011 |
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| Join DIA now to qualify for the early-bird member fee! www.diahome.org/Membership | MEMBERSHIP US \$140 <input type="checkbox"/> |
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| Discount Fees | MEMBER | NONMEMBER |
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*If paying a nonmember fee, please check one box above, indicating whether you want membership.

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.

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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.

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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 Ronald Reagan Washington National Airport and attendees should make airline reservations as early as possible. The Sheraton National Hotel is holding a block of rooms at the reduced rate below until August 22, 2011, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$199 Double \$199

Attendees must make their own hotel reservations. Contact the Sheraton National Hotel by telephone at +1.888.627.8210 and mention the DIA event. The hotel is located at 900 S. Orme Street, Arlington, VA 22204, USA.

CANCELLATION POLICY: On or before SEPTEMBER 6, 2011
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 +1.215.442.6199, email Jeff.Korn@diahome.org

EVENT INFORMATION

Contact **Joanne Wallace | Program Manager**, Phone +1.215.442.6180

Fax +1.215.293.5931, email Joanne.Wallace@diahome.org

Please check the applicable category:

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