Pharmaceutical Education Associates and TIPPA (The International Publication Planning Association) Proudly Present

Small company discount offering

The Clinical Trial Disclosure Seminar

Navigating the expanded clinical trial registry and results data disclosure requirements for Drugs, Biologics and Medical Devices

Don't get caught out of compliance!
What you need to do now!

What You Can Expect from this Timely and Important One-Day Clinical Trials Disclosure Seminar:

- Hear how to implement clinical trial registries and results database requirements
- Examine the increasing number of registries outside the U.S. and how to maintain consistency with each one
- Find out how your industry peers are handling the burden of compliance
- Understand the background, history and law of the various regulations and requirements
- Gain insight on how to determine whether your company is in compliance
- Get the publication planning perspective on the disclosure rules

And much, much more!

The *Clinical Trial Disclosure Seminar* is designed to be of specific benefit to pharmaceutical, biologic and medical device companies from the following departments:

- Clinical Trial Registries/Data Disclosure/Trial Registration
- Medical Writing
- Regulatory Affairs/Compliance/Development
- Medical Communication
- Medical Affairs
- Publication Professionals
- Biotechnology Researchers
- Clinical Quality Assurance
- Clinical Operations

This Seminar is also of interest to:

- CROs
- Trial Registries and Results Hosting Companies
- Technology Vendors to Facilitate Clinical Data Disclosure

Tuesday, November 18 , 2008

San Francisco, CA

Venue to be announced 3 weeks prior

To Register: Call 800-686-2276 or visit us at www.pharmedassociates.com

Dear Colleague,

On September 27, 2008, the Clinicaltrials.gov website will begin accepting results from clinical trials. $10,000 a day is the penalty that will be assessed to those who do not comply with this deadline. In addition, clinical data disclosure requirements have been issued by state governments, international regulatory authorities, WHO and journal editors.

In a response to these regulations, Pharmaceutical Education Associates in affiliation with The International Publication Planning Association (TIPPA) is proud to present a one-day seminar on Clinical Trial Disclosures scheduled for Tuesday, November 18, 2008 in San Francisco, California.

Key topics to be addressed include:

- The history and issues surrounding public disclosure of trial information
- The requirements for clinical trial registration and results posting
- How result disclosure impacts publication
- Breakdown of the countries with current or pending laws governing data disclosure
- Maintaining compliance with journals and the potential conflict between federal and state legislative requirements
- How to bridge the gap between State of Maine and federal laws
- Implementing results disclosure into your publication plan
- The organizational changes your company should make in response to the requirements

You'll Learn from and Network with Industry Peers Including:

Pamela A. Rose, *Associate Director, Clinical Trial Registries*
TAKEDA GLOBAL RESEARCH AND DEVELOPMENT CENTER, INC.

Robert Church, *Partner*
HOGAN & HARTSON LLP

Elizabeth Crane, *Senior Manager, Medical Publications*
ASTELLAS PHARMA US, INC.

John McKenney, *President*
SEC ASSOCIATES, INC

Patricia Teden, MBA, *Principal*
TEDEN CONSULTING LLC

Michael Rubison, PhD, *President and Senior Consultant*
FLINT HILLS CONSULTING LLC

Chair's Bio

Pamela A. Rose *is currently the Associate Director, Clinical Trial Registries at Takeda Global Research and Development Center, Inc. Prior to this position, Pam was the Director of Clinical Trial Information Registries at TAP Pharmaceutical Products Inc, Lake Forest, IL. With over 25 years experience in the drug development industry, Pamela has held leadership positions in the clinical development, clinical quality assurance and clinical trial registry areas. She is an RN and Family Nurse Practitioner and is certified as an ISO 9001:2000 Lead Auditor and ASQ Manager of Quality and Organizational Excellence.*

Important Information

To Register:
Fax: 704-341-2640
Mail: Pharmaceutical Education Associates
18705 NE Cedar Drive
Battle Ground, WA 98604
Phone: 800-280-8440
Online: www.pharmedassociates.com

The Clinical Trial Disclosure Seminar

November 18, 2008

San Francisco, California
*Venue to be announced 3 weeks prior to the seminar**

Fees and Payments:

The fee for attendance at the **Clinical Trial Disclosure Seminar** is: $1295*

* To help up-and-coming companies participate in this event, employees of biotechnology, specialty pharma, or device companies with under 25 employees, are eligible for our special $1095 registration fee subject to approval by Pharmaceutical Education Associates. The discount does not apply to agencies or medical communications groups. To qualify for the small company rate, please contact Sarah Dunnam at 704-341-2438 or sdunnam@frallc.com

Please make checks payable to Financial Research Associates, and write code P168 on your check. You may also pay by Visa, MasterCard, Discover, or American Express. Purchase orders are also accepted. Payments must be received no later than November 11, 2008.

Team Discounts:
- Three people will receive 10% off.
- Four people will receive 15% off.
- Five people or more will receive 20% off.

In order to secure a group discount, all delegates must place their registrations at the same time. Group discounts cannot be issued retroactively. For more information, please call Sarah Dunnam at 704-341-2438 or sdunnam@frallc.com

Cancellations:
If we receive your request to cancel 30 days or more prior to the conference start date, your registration fee will be refunded minus a $175 administrative fee. Cancellations occurring between 29 days and the first day of the conference receive either a 1) $200 refund; or 2) a credit voucher for the amount of the original registration fee, less a $175 administrative fee. No refunds or credits will be granted for cancellations received after a conference begins or for no-shows. Credit vouchers are valid for 12 months from the date of issue and can be used by either the person named on the voucher or a colleague from the same company.

Please Note: For reasons beyond our control it is occasionally necessary to alter the content and timing of the program or to substitute speakers. Thus, the speakers and agenda are subject to change without notice. In the event of a speaker cancellation, every effort to find a replacement speaker will be made.

Primary Benefits of Attending

Understand the new regulatory requirements for drug, biologic and medical device clinical trial registration and results databases

Gain insight as to the law, history and purpose of the data disclosure initiative

Learn about registration and results disclosure compliance on a global scale

Understanding the publication planning and journal editors perspective on data disclosure

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Agenda-in-Brief

8:30

CHAIRPERSON'S WELCOME

Pamela A. Rose, *Associate Director, Clinical Trial Registries*
TAKEDA GLOBAL RESEARCH AND DEVELOPMENT CENTER, INC.

8:45

INDUSTRY UPDATE ON CLINICAL TRIAL DISCLOSURE

- History and issues surrounding public disclosure of clinical trial information
- Goals of disclosure
- The data disclosure landscape
- Current disclosure law and guidance
- Distinguishing between the federal, state and international requirements
- Key internal and external stake holders
- Legal Perspective – Policy, history and the law

Pamela A. Rose, *Associate Director, Clinical Trial Registries*
TAKEDA GLOBAL RESEARCH AND DEVELOPMENT CENTER, INC.

Robert Church, *Partner*
HOGAN & HARTSON LLP

10:00 MORNING BREAK

10:15

CLINICAL TRIAL REGISTRATION REQUIREMENTS

- What are the registration requirements and regulations
- Where is the data to register
- When and where should registration take place
- What infrastructural and operational process should be in place

Pamela A. Rose, *Associate Director, Clinical Trial Registries*
TAKEDA GLOBAL RESEARCH AND DEVELOPMENT CENTER, INC.

Robert Church, Partner
HOGAN & HARTSON LLP

11:15

CLINICAL TRIAL RESULTS POSTING REQUIREMENTS

- What are the requirements
- Addressing consistency issues
- Operational support structure
- Handling proprietary information and avoiding promotional language
- How does result disclosure impact publication
- Advantages and disadvantages of internal and external audits

Michael Rubison, PhD, *President and Senior Consultant*
FLINT HILLS CONSULTING LLC

12:15 LUNCHEON BREAK

1:30

THE CLINICAL TRIAL DISCLOSURE REQUIREMENTS IN THE INTERNATIONAL COMMUNITY

- Challenges with international requirements
- Analysis of key countries with existing and pending laws governing data disclosure
- Helpful insights on how to gather information on international regulatory requirements
- The impact of Ethics Committees and IRBs in public disclosure

John McKenney, *President*
SEC ASSOCIATES, INC.

2:15

PUBLICATION PLANNING PERSPECTIVE

- How to bridge the gap between State of Maine and federal laws
- Planning for federal law compliance, including safety results
- Implementing results disclosure into your publication plan
- Working with journals on the publication of negative data
- Implications of early phase trial registration

Elizabeth Crane, M.A., *Senior Manager, Medical Publications*
ASTELLAS PHARMA US, Inc.

3:00 AFTERNOON BREAK

3:15

WHAT'S NEXT?

- How should your company respond to the evolving clinical trial registries and results regulations
- What organizational changes should be made
- What processes should begin

Patricia Teden, MBA, *Principal*
TEDEN CONSULTING LLC

4:00 END OF SEMINAR

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The Conference Sponsor

Pharmaceutical Education Associates provides access to industry information and networking opportunities. Offering highly targeted conferences, PEA is a preferred resource for executives and managers seeking cutting-edge information on the latest industry news. Please visit www.pharmedassociates.com for more information on upcoming events.

The International Publication Planning Association (TIPPA) is an industry-run association. Our mission is to foster excellence in medical publications and communications within the biopharmaceutical industry by providing a foundation from which industry can stand together to organize thoughts, present recommendations and ethical guidance. In addition TIPPA provides practical strategies for developing, implementing and executing an effective publication and communication plan as a critical component of the clinical biopharmaceutical development process. Our aim is to help biopharmaceutical communication executives and their agencies produce ethical and targeted publications and clinical data throughout the product lifecycle. For more information and to join, visit the association's website at www.publicationplanningassociation.org

Sponsorship and Exhibit Opportunities

Enhance your marketing efforts through sponsoring a special event or exhibiting your product at this event. We can design custom sponsorship packages tailored to your marketing needs, such as a cocktail reception or a custom-designed networking event. **To learn more about sponsorship opportunities, please contact Jim Vlasicak at 704-341-2447**

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