exl pharma Presents:

CLINICAL DATA DISCLOSURE WEBINAR

A SCALABLE APPROACH TO CLINICAL TRIAL REGISTRATION AND RESULTS DISCLOSURE

A Practical Primer on Preparing Your Company for Affordable and Compliant Data Disclosure

April 17, 2008 • 11:00 AM - 1:30 PM, EDT

WEBINAR LEADERS:

John McKenney
President
SEC ASSOCIATES, INC.

Mike Rubison, PhD
President & Senior Consultant
FLINT HILLS CONSULTING LLC

Patricia Teden, MBA
Principal
TEDEN CONSULTING LLC

DISCUSSION TOPICS INCLUDE:

- Evaluating current requirements and regulations
- Developing a corporate clinical data disclosure deployment strategy
- Determining what infrastructure and operational processes need to be in place to effectively disclose clinical data
- How to handle proprietary information and avoid promotional language
- Strategies for disclosing studies for newly acquired/merged companies and for partnership-sponsored studies
- Understanding how results disclosure impacts publication

Register before March 28th for Discounted Pricing

FEES FOR ATTENDING

Register Before for our Early Bird Pricing:	**$295**
Register After for Standard Pricing:	**$395**
GROUP RATE:	**$1,495**

5 EASY WAYS TO REGISTER

MAIL:
ExL Events, Inc.,
555 8th Ave., Ste. 310, New York, NY 10018

EMAIL: register@exlpharma.com

PHONE:
866-207-6528

FAX:
888-221-6750

ONLINE: www.exlpharma.com

Couldn't attend the January Clinical Data Disclosure Summit?

Responding to overwhelming demand, we've turned the pre-conference workshop into a Webinar, easily accessible from your desk.

5 EASY WAYS TO REGISTER

MAIL: ExL Events, Inc, 555 8th Ave , Ste. 310, NY, NY 10018 • **PHONE:** 866 207-6528
FAX: 888 221-6750 • **ONLINE:** www.exlpharma.com • **EMAIL:** Register@exlpharma.com

WEBINAR AGENDA

11:00
Webinar Introduction

11:05
Today's Disclosure Environment

John McKenney
President
SEC ASSOCIATES, INC.

- What needs to be done?
- What are the requirements and regulations?
- How to stay current with evolving regulations and expectations

11:35
Focus on Trial Registration

Pat Teden, MBA
Principal
TEDEN CONSULTING LLC

- Where is the data to register?
- When and where should this occur?
- What infrastructure and operational process do I need in place?
- Centralized or decentralized operations?
- In source or outsource operations?
- How can I be sure no trials are 'falling through the cracks'?

12:30
Focus on Results Disclosure

Mike Rubison, PhD
President & Senior Consultant
FLINT HILLS CONSULTING LLC

- What are the requirements? What are my options?
- How do I ensure/enforce consistency?
- How do I handle proprietary information and avoid promotional language?
- How does results disclosure impact publication?
- Internal audit and/or external audit?

1:00
Questions from Audience

1:30
Webinar Concludes

ABOUT YOUR WORKSHOP LEADERS:

John McKenney
President
SEC ASSOCIATES, INC

John C. McKenney is President of SEC Associates, Inc. Now in its 20th year, SEC provides clinical trial disclosure and other regulatory compliance consulting services to life sciences organizations. SEC recently delivered a 3-day training course to FDA on the use of electronic systems in

For more information please contact Kristen Hunter at khunter@exlpharma.com

WHO SHOULD PARTICIPATE?

Managers, Directors and VPs in the following departments:

- Clinical Trial Registries/Data Disclosure/Trial Registration
- Regulatory Affairs/ Compliance/Development
- Medical Writing
- Medical Information/ Knowledge Management
- Medical Affairs
- Clinical Trial Information
- Clinical Operations
- Clinical R&D/ Research/Development

REGISTRATION OPTIONS FOR ATTENDING THE CLINICAL DATA DISCLOSURE WEBINAR:

INDIVIDUAL ACCESS PASS
log-in allowing one viewer:

- Register Before March 28th for our Early Bird Pricing: **$295**
- Register After March 24th for Standard Pricing: **$395**

GROUP SITE PASS
log-in allowing multiple viewers to join the webinar at one location: **$1495**

5 EASY WAYS TO REGISTER

MAIL: ExL Events, Inc, 555 8th Ave , Ste. 310, NY, NY 10018 • **PHONE:** 866 207-6528
FAX: 888 221-6750 • **ONLINE:** www.exlpharma.com • **EMAIL:** Register@exlpharma.com

AGENDA continued

clinical trials. SEC has conducted third-party audits of clinical trial registry and results databases for Eli Lilly and other major pharmaceutical companies. McKenney is an active participant in the DIA working group on Clinical Trial Disclosure. He co-authored two popular references on clinical systems compliance: The "New" Part 11 and Drug Development: A Q&A Reference Guide (published by Barnett/Parexel) and the "Regulatory Roadmap for U.S. Clinical Trials" poster (co-produced with Phase Forward). McKenney launched his career with IBM in 1980 after receiving a BS in Electrical Engineering from the University of Virginia.

Michael Rubison, PhD
President and Senior Consultant
FLINT HILL CONSULTING LLC

Michael Rubison is President of Flint Hills Consulting LLC. Flint Hills Consulting provides support for drug and medical device development with expertise in statistics and data management, Clinical Trial Registration and Results Disclosure, Data Safety Monitoring Boards, regulatory submissions and portfolio and business development evaluations. Dr. Rubison has over 25 years post-doctoral, supervisory/management experience in the pharmaceutical industry. He has directed the integration of the statistical and data management components of over 30 successful NDAs and BLAs for Marion Laboratories/Marion-Merrell-Dow, ClinTrials Research and Abbott. His most recent position at Abbott was Senior Director, Global Medical Affairs, where he was responsible for Global Medical Research and Registration. In that capacity, he was responsible for creating and maintaining compliance to clinical trial disclosures for FDAMA-113 and the voluntary industry standards of PhRMA/IFPMA of 2005 leading to the passage of the FDA Amendments Act of 2007.

Patricia Teden, MBA
Principal
TEDEN CONSULTING LLC.

Patricia Teden is the Principal of Teden Consulting LLC, a consultancy specializing in clinical trial disclosure strategy and operations, and strategic project management for global clinical trial operations. She has twenty years of experience conducting global clinical trials, pharmacovigilance, clinical data management, developing and implementing IT projects, and leading change management initiatives for global pharmaceutical companies. As Senior Director of Strategic Business Functions for Pfizer, Patricia was responsible for implementing Pfizer's clinical trial disclosure processes so that the IFPMA commitments were met. She is a founding member of the DIA SIAC for Clinical Trial Disclosure, and a frequent speaker at industry conferences. Patricia has a BA in Biology from Cedar Crest College and an MBA from Harvard.

SYSTEM REQUIREMENTS

Operating System
- Windows Vista, XP, 2000
- Mac OS X
- Linus

Processor
- Pentium Class 400mhz+
- RAM 64 MB

Browser
- Pop-up Blocking Software Disabled
- Internet Explorer 6.0+
- Netscape 7.2+
- FireFox 2.0+
- Mozilla 1.7.3+

Hardware
- AUDIO: Sound Card with speakers or phone line
- VIDEO: Monitor with 800x600+ resolution support

Media Players
- Windows Media Player 9+
- RealPlayer 10.0+
- Adobe FlashPlayer 8+

Internet Connection
- 56k Dial-up Modem
- Cable Modem/DSL
- Corporate LAN

WEBINAR: ExL Pharma accepts no liability for problems that may be encountered as a result of high traffic on the web. ExL will provide the Licensee with specific information for accessing the webinar. This information must be treated as proprietary and not given to anyone else.

CANCELLATIONS: In the event of a participant's cancellation prior to a scheduled Webinar a voucher will be issued to the canceling party for use towards another ExL Webinar valid for two years from the voucher issue date.