

# 8<sup>TH</sup> LATIN AMERICA CLINICAL TRIALS CONFERENCE

*Examining the Benefits and Challenges for Strategic  
Clinical Resource Investment in the Latin America Region*

**March 20-21, 2012 / Loews Philadelphia Hotel / Philadelphia, PA**

HEAR INDUSTRY EXPERTS FROM:

FEATURED PRESENTATIONS

### **Benefits and Risks of Conducting Clinical Trials in Latin America**

*Pedro Garbes-Netto, Clinical Research Director, SANOFI PASTEUR INC.*

### **Latin America and the Relationship Between Clinical Advantages and Market Access**

*Luis Rios-Nogales, Regional Medical Director, Head of Latin America Clinical Research Region,  
ASTRAZENECA AMERICAS*

### **Overcoming the Challenges with Patient Recruitment in LATAM**

*Mariana Sacchi, Site Monitor, Clinical Data Quality Manager, BRISTOL-MYERS SQUIBB ARGENTINA*

### **Regulatory Update for the Major Latin American Markets: Brazil, Argentina, Mexico, Columbia, Chile, Peru**

*Renato Piemonte Ribeiro, Clinical Research Manager, MERCK*

### **Enhance Training On-site to Ensure Investigator Compliance and Data Integrity**

*Paul Lupo, Clinical Project Manager, ETHICON, INC.*

### **INTERACTIVE HALF-DAY WORKSHOP**

**Conducting Clinical Trials in Latin America from a Legal  
Perspective: Structuring, Contracting, and Mitigating Risk**

*STACIE SWITZER, ASSISTANT GENERAL COUNSEL, TAKEDA PHARMACEUTICALS*

## DEAR COLLEAGUE,

As healthcare costs continue to increase and competition grows in the pharmaceutical industry, we must gather as a community to explore the importance of investing in clinical research in the Latin America region. Latin America offers numerous benefits for conducting clinical trials – an ample pool of patients, existing advanced medical infrastructure, and the potential to reduce costs. However, along with the benefits may come challenges and possible risks.

The **8<sup>th</sup> Latin America Clinical Trials Conference** is the only event in the United States that brings together executives from the industry to alleviate the challenges of conducting clinical trials in Latin America. This event provides case studies and best practices on reducing the risks in clinical research in the region so your organization can reap benefits, save costs, and ultimately conduct successful clinical trials.

By attending this event, attendees are able to bring actionable strategies to their organization on conducting clinical research in the Latin American and take advantage of the strategic benefits of the LATAM region. This summit provides you with an understanding of the regulatory landscape, strategies to improve patient recruitment and site-selection, and best practices for improving operations and logistical planning.

This is a must-attend event. Register today to reserve your place at the **8<sup>th</sup> Latin America Clinical Trials Conference**. We look forward to greeting you in March!

Sincerely,



Miriam Feygenson  
Conference Director

## HOTEL INFORMATION

### Loews Philadelphia Hotel

1200 Market Street,  
Philadelphia, PA 19107  
215-627-1200

Directly across from the Penn Convention Center, the Loews Philadelphia Hotel is 15 minutes from Philadelphia International Airport, five minutes from Amtrak's 30th St Station and steps away from the historic district, shopping, restaurants, and sports arenas.

To make reservations please call The Loews Reservations Center at 1-888-575-6397 and request the negotiated rate for ExL's CROWN.

You may also use the following weblink to make reservations online:  
<http://www.loewshotels.com/en/Philadelphia-Hotel/GroupPages/253EXL>.

**The group rate is guaranteed until February 27, 2012.**

**This conference is designed for representatives from pharmaceutical, medical device, and biotechnology companies with responsibilities in the following areas:**

- **Clinical Operations/Research**
- **Quality Assurance/Control**
- **Regulatory Operations/Affairs**
- **Latin America(n) Clinical Operations**
- **Scientific and Medical Directors/ Affairs**
- **Regulatory Affairs and Liaisons**
- **Patient Recruitment/Clinical Trial Enrollment**
- **Clinical Outsourcing – Planning and Vendor Management**
- **Strategic Business Development/ Operations**
- **Project Planning/Study/ Management**
- **Clinical Trial Capacity Planning/ Management**
- **Clinical Trial Process Improvement/ Enhancement**
- **Clinical Compliance**
- **Clinical Safety**

# DAY ONE – MARCH 20, 2012

## PRE-CONFERENCE WORKSHOP

8:00 Workshop Registration and Continental Breakfast

9:00 **CONDUCTING CLINICAL TRIALS IN LATIN AMERICA FROM A LEGAL PERSPECTIVE: Structuring, Contracting, and Mitigating Risk**

Learn how to conduct research and get started on clinical trials in the Latin American region.

The following topics will be discussed:

- Regulatory challenges in Latin America
- Individual country requirements
- Ethics committee approval
- Indemnification
- Power of attorney
- Insurance
- Registering products
- Consent issues
- Anti-bribery and anti-corruption
- Best books and records keeping

Led by:

**Stacie Switzer**, *Assistant General Counsel*,  
**TAKEDA PHARMACEUTICALS**

10:30 30-Minute Networking and Refreshment Break

12:00 Lunch for Workshop Attendees

## MAIN CONFERENCE

12:00 Conference Registration

1:00 **Chairperson's Welcome and Opening Remarks**

1:15 **Keynote Presentation – Latin America and the Relationship Between Clinical Advantages and Market Access**

- Understand the benefits and advantages of the Latin American region for clinical trials
- Utilize clinical studies in the region and how this can lead to improved market access
- Making the business case to management for investment in Latin America clinical studies

**Luis Rios-Nogales**, *Regional Medical Director, Head of Latin America Clinical Research Region*, **ASTRAZENECA AMERICAS**

2:00 **Regulatory Update for the Major Latin American Markets: Brazil, Argentina, Mexico, Columbia, Chile, Peru**

It is integral to understand the regulatory landscape when conducting clinical trials in Latin America. This diverse region has many benefits but poses many challenges as well. This session provides a regulatory update for the major Latin American markets and best practices in maintaining compliance in the various countries.

**Renato Piemonte Ribeiro**, *Clinical Research Manager*,  
**MERCK**

2:45 **Benefits and Risks of Conducting Clinical Trials in Latin America**

When conducting clinical trials, companies need to evaluate a number of factors to ensure the success of the clinical trial – including whether patient the population matches the needs of the study, timelines and logistical feasibility, regulatory frameworks, costs of conducting trials, clinical capabilities, and safety and corruption issues. There are many benefits to conducting clinical trials in Latin America, but it is essential to acknowledge the challenges of the region. This interactive session delves into reasons why you should be conducting trials in LATAM, and how to avoid the risks.

**Pedro Garbes-Netto**, *Clinical Research Director*,  
**SANOFI PASTEUR INC.**

3:30 Afternoon Networking and Refreshment Break

4:00 **Reducing Supply Chain and Logistical Impediments to Reduce Costs and Improve Efficiency**

- Understand what local resources are available and local shipping capabilities of your clinical study site
- Create a strategic action plan to maintain an efficient supply chain for the clinical study
- Ensure proper planning to create efficiency and reduce the risk of supply shortages

If you are interested in speaking on this session, please contact:

**Mark Coulter**, *Business Development Manager*,  
917-258-5140 | [mcoulter@exlpharma.com](mailto:mcoulter@exlpharma.com)

4:45 **Overcoming the Challenges of Conducting Clinical Trials in Latin America for Orphan Diseases: Huntington's Disease Perspective**

As a not-for-profit medical research foundation, CHDI Foundation has a unique perspective on developing collaborations with clinical investigators. In this session, hear how CHDI has recently set-up and currently manage an active network of physicians and investigators in Latin America who will work on clinical trials in Huntington's disease. HD is an orphan disease and setting up such a network provides an efficient and effective way of ensure access to patients by qualified, highly-trained sites.

**Joseph Giuliano**, *Director, Clinical Operations*,  
**CHDI FOUNDATION**

5:30 Close of Day One

# DAY TWO – MARCH 21, 2012

## 9:00 Chairperson's Day One Recap

### 9:15 Effectively Navigate the Current Regulatory Authority, Ethical Committee Procedures, and Timelines – Mexico Perspective

- Understand the unique advantages and challenges of working with the Mexican regulations
- Best practices to ensure compliance with ethical requirements
- Create an efficient action plan to reduce challenges with regulatory timelines

**Dra. Gabriela Dávila-Loaiza**, *Head of Clinical Operations*,  
PFIZER MÉXICO

### 10:00 Panel Discussion – Strategies for Improving Site Selection

In this interactive panel discussion hear from peers on best practices on proper site selection. Choosing appropriate sites for clinical research is essential to the success of a study, and this panel focuses on the unique challenges of the Latin America region and how to successfully chose the appropriate site for your study.

#### Panelists:

**Pedro Garbes-Netto**, *Clinical Research Director*,  
SANOFI PASTEUR INC.

**Joseph Giuliano**, *Director, Clinical Operations*,  
CHDI FOUNDATION

**Paul Lupo**, *Clinical Project Manager*,  
ETHICON, INC.

## 10:45 Morning Networking and Refreshment Break

### 11:15 Enhance Training On-site to Ensure Investigator Compliance and Data Integrity

Training and education on-site are critical for a successful trial. During this interactive session, attendees discuss and learn best practices to improve training and education to ensure site compliance. Having the appropriate training ultimately translates to a regulatory compliant site, specifically clinical data which is clean and database lock ready, and a happy sponsor.

**Paul Lupo**, *Clinical Project Manager*,  
ETHICON, INC.

## Testimonials from the previous Latin America Clinical Trials Conferences:

**"Good interactive discussion. Audience was very engaged and asked a lot of questions."**

-ASSOCIATE DIRECTOR,  
DAIICHI SANKYO

**"Comprehensive and interesting because the focus was on fixing the challenges."**

-CLINICAL TRIALS HEAD - LATAM,  
NOVARTIS

## 12:00 Improving Clinical Research Training and Education – Brazilian Perspective

- Study Site Training and Education programs used as a tool to enhance data quality and investigator compliance
- Study Site Training and Education as an opportunity to identify and develop new study sites
- Clinical research post-graduation course as an educational mechanism to enrich professional knowledge

**Yukie Kawasaki, MBA, MSc**,

*Clinical Research Manager, Global Clinical Trial Operations – Brazil*,  
MERCK

## 12:45 Lunch

### 1:45 Overcoming the Challenges with Patient Recruitment in LATAM

In this session, hear firsthand experiences on the proper strategies for patient recruitment in Latin America, enabling your organization to avoid the typical challenges. This session delves in understanding the importance of country feasibility and ensuring that the right amount of resources are devoted to the patient recruitment process.

- Starting from the beginning by understanding country and site feasibility
- Is the disease applicable to the population of the site?
- Strategies to align management to the importance of patient recruitment

**Mariana Sacchi**, *Site Monitor, Clinical Data Quality Manager*,  
BRISTOL-MYERS SQUIBB

### 2:30 Improve the Functionality and Structure of Operations during Clinical Trials in Latin America

- Strategies to make operations more efficient and employing creativity to keep costs low
- Create flexible models to face the local regulatory and political climate
- Ensure your organization has a structure designed to handle diverse countries in Latin America

**Matilde Damian**, *Clinical Research Director*  
BRISTOL-MYERS SQUIBB COMPANY

## 3:15 Close of Conference

**"It was really good to see how companies are working with process improvement methodologies and the results they are achieving."** -SENIOR MANAGER, ELI LILLY

**"Succinct and relevant... an excellent experience."**

- ASSOCIATE DIRECTOR,  
QUINTILES

**"Addressed the critical issues and I cannot say how much I like this!"**

- MANAGER, BIostatISTICS,  
AMERICAN MEDICAL SYSTEMS

