

# 7<sup>th</sup> Latin American Congress of Clinical Research: Harmonization and the Future of Drug Development in Latin America

Pre-congress Courses: November 10, 2010

Congress: November 11-12, 2010

Maksoud Plaza Hotel, São Paulo, Brazil



## PROGRAM CHAIRPERSON

### João Massud Filho

Universidade Federal de São Paulo  
CEO/Executive Director, Newcotrials, Brazil

## PROGRAM CO-CHAIRPERSON

### Juan Carlos Groppa

SAMEFA (Argentina Society of Pharmaceutical Medicine); Medical Regulations Coordinator, Laboratorios Bago S.A., Argentina

## SCIENTIFIC COMMITTEE

### Charles Schmidt

General Manager Latin America, Medpace, Brazil

### Marcelo Vaz

Senior Clinical Research Physician, Icon Clinical Research, Brazil

### Gustavo Luiz F. Kesselring

Director, Clinical Trials Operation, Hospital Alemao Oswaldo Cruz, Brazil

### Jorge Kalil

Full Professor, Immunology, School of Medicine, University of São Paulo, Brazil

### Marcelo Vianna de Lima

President, Brazilian Society of Pharmaceutical Medicine (SBMF); Medical Director, Latin America - Medical Diagnostics, GE Healthcare, Brazil

### Paula Strassmann

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### Daniel Mazzolenis

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### Silvia Zieher

Senior Director, Head of Clinical Operations Latin America, INC Research, Argentina

### Oscar Podestá

General Manager, Latin America, Chiltern International Inc., Argentina

### Sergio Guerrero

Director, OCA Hospital/Monterrey International Research Center, Mexico; DIA Board of Directors

### Marlene Llopiz-Aviles

Regional Director for Latin America, Venn Life Sciences, Mexico

### Eduardo Gotuzzo

Gotuzzo Asociados Sac, Peru

This three-day congress will include two pre-congress courses and a two-day conference focusing on both the global and regional aspects of clinical research.

## FEATURED TOPICS

- ICH and FDA Updates
- Latin American Regulatory Guidelines and Ethical Issues
- Infrastructure and Components of Clinical Research
- Perspectives on the Development and Comparison of Emerging Markets of Clinical Research with Latin America
- Perspectives on Professional Development in Clinical Research
- Examples of Translational Research – Basics to Public Health Interest

## PRECONGRESS COURSES

November 10

**#1 Hands-on in Latin America: Regulations for Clinical Trials**

**#2 Clinical Project Management: Essential Tools to Optimize Clinical Trial Operations**

## WHO SHOULD ATTEND

Professionals involved directly and/or indirectly in clinical research, or who are considering initiating their activities in this professional area, including:

- Research professionals (clinical, laboratory, site members, and CRAs)
- CROs and SMOs
- Service providers
- Clinical investigators (active and potential)
- Ethics committees
- Regulatory agencies
- Medical education institutions
- Pharmaceutical sponsors

**Simultaneous Translation will be available in Portuguese, English, and Spanish.**

### All registrations will be processed by Managing Events

#### Contact Information for Registration and Tabletop Opportunities

Valéria Gomes, Managing Events, Congress Planning and Organization  
7th Latin America Congress of Clinical Research - SBFM/DIA  
Phone: 55 11 5587-5232 | Phone/fax: 55 11 3208-2786  
email address: [managingeventos@uol.com.br](mailto:managingeventos@uol.com.br)  
Registration Link: <http://sbmf.org.br>

#### DIA Program Contact Information

Ellen Diegel, Program Manager  
Phone: +1.215.442.6158 | email: [Ellen.Diegel@diahome.org](mailto:Ellen.Diegel@diahome.org)

### Worldwide Headquarters

Drug Information Association, Inc.  
800 Enterprise Road, Suite 200  
Horsham, PA 19044, USA

### Regional Offices

Basel, Switzerland Tokyo, Japan  
Mumbai, India Beijing, China

### Co-sponsored by



## LEARNING OBJECTIVES

At the conclusion of this course, participants should be able to:

- Explain the regulatory principles and procedures of clinical research and interact with the regulatory stakeholders in the region
- Manage the different phases of a sponsored trial, providing guidance and leadership to the study team in order to achieve or surpass the project objectives and become competitive in the research arena
- Compare Latin American opportunities with other emerging markets in clinical research
- Explore professional clinical research opportunities
- Discuss the divide between basic research and public health innovation in the clinical research arena

## DAY 1 | WEDNESDAY, NOVEMBER 10

**7:30 - 8:30** PRECONFERENCE COURSE REGISTRATION

**8:30 - 17:00** TUTORIALS

- #1 Hands-on in Latin America: Regulations for Clinical Trials**
- #2 Clinical Project Management: Essential Tools to Optimize Clinical Trial Operations**

## DAY 2 | THURSDAY, NOVEMBER 11

**7:30 - 8:30** REGISTRATION

**8:30 - 9:00** WELCOME AND OPENING REMARKS

PROGRAM CHAIRPERSON

**João Massud Filho**

Universidade Federal de São Paulo  
CEO/Executive Director, Newcotrials, Brazil

**9:00 - 9:30** KEYNOTE ADDRESS

**The Importance of Clinical Research for Drug Development**

**Richard O. Day**

Professor of Clinical Pharmacology, St. Vincent's Hospital, Australia  
President-elect, DIA Board of Directors

**9:30-11:00** PLENARY SESSION 1

**Working for Harmonization on Regulations for Clinical Trials in Latin America**

SESSION CHAIRPERSON

**Sergio Guerrero**

Director, OCA Hospital/Monterrey International Research Center, Mexico; DIA Board of Directors

Session Co-chairperson

**Daniel Mazzolenis**

Associate Director, Global Clinical Development, Kendle International Inc., Argentina

**Speaker Representatives from:**

ANMAT - Argentina

ISP - Chile

ANVISA - Brazil

Centro America

COFEPRIS - Mexico

PAHO (Pan American Health Organization)

INS - Peru

**11:00 - 11:30** REFRESHMENT BREAK

**11:30 - 13:00** PLENARY SESSION 2

**Global Challenges with Bioethics in IRB's Training**

SESSION CHAIRPERSON

**Paulo Fortes**

Sociedade Brasileira de Bioética, Brazil

SESSION CO-CHAIRPERSON

**Marcelo Vianna de Lima**

President, Brazilian Society of Pharmaceutical Medicine (SBMF), Brazil; Medical Director, Latin America - Medical Diagnostics, GE Healthcare, Brazil

**US Training Programs for IRBs: What Is in Place and Is It Enough?**

**Marjorie A. Speers**

President and CEO, Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), United States

**Latin American Experiences in IRB Training Programs:**

**Brazilian Experience**

**Miriam Ghiraldini Franco**

Universidade Federal de São Paulo, Brazil

**Latin American Experiences in IRB Training Programs:**

**Chilean Experience**

**Gustavo Kaltwasser**

Bioethics Consultant, Chile

13:00 - 14:00 LUNCHEON

14:00 - 15:30 CONCURRENT SESSIONS

## CONCURRENT SESSION 1

**Pharmacovigilance – SAE Management**

SESSION CHAIRPERSON

**E. Stewart Geary**

Vice President, Eisai Co., Ltd., Japan

SESSION CO-CHAIRPERSON

**Murilo Freitas Dias**

Pharmacovigilance Manager, ANVISA, Brazil

**An Ethical Perspective: What Is to Be Paid?****Greg Koski**

Harvard University, United States

**SAE Accountability: A Legal Perspective in Latin America****Claudia Mano Senise**

Medical Director, PRA International, Brazil

**How to Estimate SAE Costs and Controls and Audit SAE Bills****Liu Hsiang Tzu**

Icon Clinical Research, Brazil

## CONCURRENT SESSION 2

**Pediatric Trials in Latin America**

SESSION CHAIRPERSON

**Charles Schmidt**

General Manager Latin America, Medpace, Brazil

SESSION CO-CHAIRPERSON

**Andre Feher**

Novartis, Brazil

**Clinical Research in Pediatric Oncology****Antonio Sergio Petrilli**

Instituto De Oncologia Pediátrica, Grupo de Apoio ao Adolescente e à Criança com Câncer (GRAACC), Brazil

**Trends on Global Pediatric Clinical Research****Barry Mangum**

Director, Clinical Pharmacology, Duke University Medical Center, United States

**Current Obstacles to Boosting Pediatric Clinical Research****Robert M. Jacobson**

Chair, Pediatric and Adolescent Medicine, Mayo Clinic, United States

15:30 - 16:00 REFRESHMENT BREAK

16:00 - 17:30 CONCURRENT SESSIONS

## CONCURRENT SESSION 3

**State of the Art in Oncology Clinical Trial Design**

SESSION CHAIRPERSON

**Sergio Simon**

GBCAN, Brazil

SESSION CO-CHAIRPERSON

**Paula Strassmann**

President, PGS Medical Statistics, Brazil

**Trial Designs in Oncology: Regular or Adaptive?****Marcia Kayath**

Novartis, United States

**How Do Investigators Understand New Designs? What Is Their Perception? How Important Is It for the Patient?****Max Mano**

ICESP, Brazil

**Statistics Point of View: When and Why is Adaptive Design Important?****Jeffrey D. Vest**

Director, Biostatistics, Medpace, United States

## CONCURRENT SESSION 4

**Conducting Observational Studies in Latin America: Academic, Ethical Committees and the Pharmaceutical Industry**

SESSION CHAIRPERSON

**Laura Luchini**

Clinical Research Unit Director, Sanofi-Aventis Farmaceutica, Brazil

SESSION CO-CHAIRPERSON

**Joao Toniolo Neto**

Escola Paulista de Medicina, Universidade Federal de São Paulo, Brazil

**Organizing Observational Studies in the Region - Academic Perspective****Paulo A. Lotufo**

Superintendent, Hospital of the University of São Paulo, Brazil

**Organizing Observational Studies in the Region - Pharmaceutical Industry Perspective****Eduardo Forléo**

Chiltern, Brazil

**Regulations and Ethical Analysis of Observational Studies****Ezequiel Klimovsky**

Asociado Director, QUID-Consulting SRL, Foundation for Ethics and Quality in Latin American Research (FECICLA), Argentina

## DAY 3 | FRIDAY, NOVEMBER 12

7:30 - 8:30 REGISTRATION

8:30 - 10:00 PLENARY SESSION 3

**How the Post-trial Access Issue Has Progressed Throughout the World in Recent Years**

SESSION CHAIRPERSON

**Sonia Mansoldo Dainesi**

Medical Director, Boehringer Ingelheim, Brazil

SESSION CO-CHAIRPERSON

**Sonia Barros**

HIAE, Brazil

Ethical Aspects and Challenges of Post-trial Access to Study Medications

**Christine Grady**

Department of Clinical Bioethics, National Institutes of Health, United States

Legal Aspects on the Donation of Nonapproved Drugs

**Angela Fan Chi Kung**

Pinheiro Neto Advogados, Brazil

Sanitary Point of View on Post-trial Access

**Patricia Ferrari Andreotti**

ANVISA, Brazil

10:00 - 10:30 REFRESHMENT BREAK

10:30 - 12:00 PLENARY SESSION 4

**Translational Medicine**

SESSION CHAIRPERSON

**João Massud Filho**Universidade Federal de São Paulo  
CEO/Executive Director, Newcotrials, Brazil

SESSION CO-CHAIRPERSON

**Mariano Janiszewski**

Eli Lilly, ICB USP, Brazil

Translating Investigation of Mood Disorders in the Treatment of Real Patients

**Jair Soares**

Professor and Chair; Department of Psychiatry and Behavioral Sciences, University of Texas - Houston Medical School, United States

Translational Medicine in Sepsis: The Critical Role of the Microcirculation

**Daniel De Backer**

Erasmee University Hospital, Belgium

Brazilian Experience on Translational Medicine

**Luísa Lina Villa**

Branch Director, Ludwig Institute for Cancer Research, Brazil

12:00 - 13:00 LUNCHEON

13:00 - 14:30 CONCURRENT SESSIONS

## CONCURRENT SESSION 5

**Contract and Budget Negotiations: How to Build a Win-Win Relation Between Sponsors and Sites**

SESSION CHAIRPERSON

**Marlene Llopiz-Aviles**

Regional Director for Latin America, Venn Life Sciences, Mexico

SESSION CO-CHAIRPERSON

**Gustavo Luiz F. Kesselring**

Director, Clinical Trials Operation, Hospital Alemao Oswaldo Cruz, Brazil

Perspective from the Sites

**Luis Augusto Tavares Russo**

Director, CCBR Brasil, Brazil

The Top 10 Ways to Impede the Independent Research Site

**Jeffrey M. Adelglass**

President and Chief Executive Officer, Research Across America, United States

Partnership with Sites

**Mariana Pauli**

PPD, Argentina

## CONCURRENT SESSION 6

**Computerized Systems in Clinical Trials: Data Quality and Integrity**

SESSION CHAIRPERSON

**Silvia Zieher**

Senior Director, Head of Clinical Operations Latin America, INC Research, Argentina

SESSION CO-CHAIRPERSON

**Marcelo Alexandre Costa Vaz**

ICON, Brazil

An Overview of Best Practices from PEACH

**Earl Hulihan**Senior Vice president, Regulatory Compliance  
Medidata Solutions Worldwide, United States

US FDA's Regulation of eRecords and eSignatures in Clinical Investigations

**Sean Kassim**Division of Scientific Investigations, Office of Compliance  
CDER, FDA, United States

The Use of Cloud Computing in Medicine and Research: A Blessing or a Curse - A Practical Discussion

**Glenn Watt**Corporate Security & Privacy Officer, Vice President, Global  
Information Security and Privacy, Medidata Solutions, Inc.,  
United States

14:30 - 15:00

REFRESHMENT BREAK

## CONCURRENT SESSION 7

**Effects of the 2008-09 Global Economic Crisis on Clinical Development and How Biopharma Is Responding**

SESSION CHAIRPERSON

**Dennis P. Hurley**

Vice President of Latin America, Kendle International, United States

SESSION CO-CHAIRPERSON

**Eduardo Gotuzzo**

Gotuzzo Asociados Sac, Peru

**Trends in the Overall Number of Trials and Sites: Global Distribution and Disease Focus****Fabio Thiers**

Director, Global Clinical Trials Research Program, MIT Center for Biomedical Innovation, United States

**Big Biopharma Trends****Julio E. Camps**

Director, Regional Head for Latin America, Amgen Inc., United States

**The Shifting Focus on Global Biopharmaceutical R&D: New Innovation Models and Strategies****Kenneth I. Kaitin**

Director, Center for the Study of Drug Development and Professor of Medicine, Tufts University School of Medicine, United States

## CONCURRENT SESSION 8

**The Implications of Late Phase Research on Drug Development**

SESSION CHAIRPERSON

**Oscar Podestá**

General Manager, Latin America, Chiltern International Inc., Argentina

SESSION CO-CHAIRPERSON

**Jose Luiz Cordeiro Dias Tavares**

Director, Roche, Brazil

**Clinical Research Beyond Registration****Jaderson Socrates Lima**

Medical Director, Sanofi-Aventis, Brazil

**Compliance Challenges in Late Phase Projects****Daniel Ciriano**

Medical Director / PDO Country Operation Manager, Productos Roche S.A.Q.el., Argentina

**Pharmacogenomics in the Brazilian Population and Its Implications on Local Clinical Studies****Guildherme Suarez-Kurtz**

INCA, Brazil

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.

## HOTEL RESERVATION FORM

Family Name \_\_\_\_\_ First Name \_\_\_\_\_

Company \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip/Postal Code \_\_\_\_\_ Country \_\_\_\_\_

Telephone \_\_\_\_\_ Fax \_\_\_\_\_

email \_\_\_\_\_

*(email address required for receipt of reservation confirmation.)*

### PAYMENT / RESERVATION MUST BE GUARANTEED WITH A CREDIT CARD.

Credit Card Type:  MasterCard  Visa  Diners Club  American Express  Other \_\_\_\_\_

Card Number \_\_\_\_\_ Expiration Date \_\_\_\_\_

Name of Card Holder \_\_\_\_\_ Signature \_\_\_\_\_

## ROOM INFORMATION

Please Circle:

Standard / Double

Arrival date \_\_\_\_\_

Arrival time \_\_\_\_\_

Single/queen bed / Double/twin beds

Departure date \_\_\_\_\_

Departure time \_\_\_\_\_

Check-in time: 15:00 o'clock, check-out time: 12:00 o'clock. Fax this form to the fax number listed below for your preferred hotel.

**DO NOT FAX HOTEL RESERVATION FORMS TO DIA OR MANAGING EVENTOS.**

**TRAVEL AND HOTEL** The most convenient airport is Guarulhos International Airport (GRU), which is approximately 20 miles from the hotels. Attendees should make airline reservations as early as possible to ensure availability. The hotels below are optional (estimated rates); for other information or reservations, contact the hotel offices directly.

### Maksoud Plaza Hotel (Meeting Venue)

Phone: (55 11) 3145-8000 - Ext. 8761 / Fax: (55 11) 3145-8001  
eMail address: reservas@maksoud.com.br Website: www.maksoud.com.br

#### Special Daily Rates:

- **Low Cost Room (3-6 floors)**

Sgl R\$ 265,00 + 5,26% (ISS) + R\$ 1.20 Tourism Tax

DbI R\$ 310,00 + 5,26% (ISS) + R\$ 1,20 Tourism Tax

- **Standard Room (7-10 floors)**

Sgl R\$ 344,00 + 5,26% (ISS) + R\$ 1.20 Tourism Tax

DbI R\$ 389,00 + 5,26% (ISS) + R\$ 1,20 Tourism Tax

- **Executive Superior Room**

Sgl R\$ 450,00 + 5,26% (ISS) + R\$ 1.20 Tourism Tax

DbI R\$ 505,00 + 5,26% (ISS) + R\$ 1,20 Tourism Tax

- **Tower Premium Room**

Sgl R\$ 535,00 + 5,26% (ISS) + R\$ 1.20 Tourism Tax

DbI R\$ 590,00 + 5,26% (ISS) + R\$ 1,20 Tourism Tax

### L´Hotel

Phone: (55 11) 2183-0500 / Fax: (55 11) 2183-0505  
eMail: reservas@lhotel.com.br /  
Website: www.lhotel.com.br

### Paulista Flat Service

Phone: (55 11) 3251-2488 / Fax: (55 11) 3251-2909  
eMail: paulista@paulistaflat.com.br  
Website: www.paulistaflat.com.br

**Please note:** The location of the above hotels is within walking distance from the venue; for more options, see [http://www.hoteis.com.br/estados/sp/sao\\_paulo.html](http://www.hoteis.com.br/estados/sp/sao_paulo.html) (select: Jardins and Jardins Paulista).

**Congress Planning: Managing Eventos** - Phones: (55 11) 5587-5232 / (55 11) 3208-2786 (fax); eMail address: managingeventos@uol.com.br

### NOTES:

- 1) The above room rates are in Reais (R\$); for prices in dollars, please check the daily exchange rate (<http://www.x-rates.com/calculator.html> - select Brazilian Real into American Dollar);
- 2) Refer to the "7th Latin American Congress of Clinical Research - DIA/SBMF" to get the above special rates.