

7th 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 CO-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

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

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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)
- Ethics committees
- Regulatory agencies
- CROs and SMOs
- Medical education institutions
- Service providers
- Pharmaceutical sponsors
- Clinical investigators (active and potential)

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
Registration Link: <http://sbmf.org.br>

DIA Program Contact Information

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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 FilhoUniversidade 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 HulihanSenior Vice president, Regulatory Compliance
Medidata Solutions Worldwide, United States

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

Sean KassimDivision 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 WattCorporate 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

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.

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 (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