



# THE *FIRST* LATIN AMERICAN CONGRESS OF CLINICAL RESEARCH

FEBRUARY 27-MARCH 1, 2002

Presidente Inter-Continental Hotel  
Campos Eliseos 218 Mexico City, Mexico

## *Program Chairpersons:*

**Roberto Chiprut, MD, FACP**, Mexican Institute of Clinical Research, Mexico; UCLA, USA; Cedars Sinai Medical Center, USA

**Héctor A. Bolaños**, AFAMELA, Mexico

## *Program Committee:*

**Dr. Alberto Lifshitz**, Medisalud, Mexico

**Dr. Alfonso Moguel**, Novartis Pharma, Mexico

**Mr. Kenneth Getz**, CenterWatch, Inc., USA

**Dr. Misael Uribe**, Ministry of Health, Mexico

**Dr. Sergio Guerrero**, IMIC, Mexico

**Lic. Adolfo Dorenbaum**, IMIC, Mexico

**Dr. Alejandro Castellanos**, IMIC, Mexico

**Dr. Cristina Torres**, Consultant, Mexico

**Dr. Itziqueri Robles E.**, Novartis Pharma, Mexico

**Dr. Tomás Barrientos Fortes**, Anahuac University, Mexico

**Ms. C.M. Katie Margules**, PPD Development, Mexico

**Dr. Alberto Fratti Munari**, Ministry of Health, Mexico (SSA)

**Mr. Richard Musselman**, AvAMed Consulting Group, Inc., USA

**Dr. Barbara Geiger**, Clinical Research Management Services, USA

**Dr. Maria Elena Cortés**, IMIC, Mexico

**Dr. David Sotres**, ECA, Mexico

## PRE-CONGRESS COURSE – February 27, 8:15-18:00

**Armamentarium for Good Clinical Research** will include presentations on: Training of Physicians in Clinical Research; Phases of Clinical Research; Regulatory References; Good Clinical Practices; Ethics; Informed Consent; Perspectives of ICH; Institutional Review Boards and FDA Requirements; Elements for the Successful Conduct of a Research Protocol; Financial Aspects in Clinical Research; Electronic Signature; Registry; Preparing for Inspection, Monitoring and Audits; Understanding Protocol Design; Quality Assurance in Clinical Research; and a Primer on Biostatistics.

## KEYNOTE ADDRESS

Dr. Julio Frenk from the Ministry of Health of Mexico has been invited to speak on **The Importance of Globalization of Clinical Research in Latin America**

## CONGRESS HIGHLIGHTS – February 28, 8:00 - March 1, 18:15

Representatives from the Ministries of Health of several Latin American countries (Argentina, Chile, Mexico, Venezuela and Colombia) and the Food and Drug Administration from the USA, along with representatives of academia and industry from Latin America, Europe and the USA have been invited to participate in sessions focusing on these topics:

- **Ethics and Clinical Research**
- **Regulatory Aspects of Clinical Research in Latin America**
- **Differences Between Clinical Research in the USA and Latin America**
- **The Future of Clinical Research**

This program includes the following services:

- Continental Breakfast and Lunch every day
- Coffee service during conference periods
- Simultaneous Translation Services
- Syllabus or Meeting Journal
- Round tables of questions and answers without interruption of exposition segments
- A brief summary of the lectures at the end of each session

## CONTINUING MEDICAL EDUCATION

*Participants will receive a Continuing Medical Education Certificate, through the support of Universidad Anahuac Medical School.*

## MEETING OBJECTIVES

The forum will include a pre-congress course, covering the most important topics for the optimal conduction of clinical research protocols. A comprehensive review will be made on ethical issues on GCP, ICH, informed consent, ethical review, completion of CRFs, budget development, and sponsor and FDA audits. The congress will update the most concerning ethical and harmonization issues in Latin America.

Ethics, genetics and regulatory issues will be compared between the USA and Latin America. The forum will provide a futuristic view on clinical research in Latin America and its participation in global research. It will foster an open discussion on clinical investigation in Latin America for future partnerships with the pharmaceutical industry.

### Dates and Times

#### Tuesday, February 26, 2002

18:00-20:00 REGISTRATION

#### Wednesday, February 27, 2002

7:30-8:00 REGISTRATION/  
CONTINENTAL BREAKFAST

### 8:00-18:45 *Pre-Congress Course*

#### ARMAMENTARIUM FOR GOOD CLINICAL RESEARCH

8:00-8:15 OPENING CEREMONY  
*Dr. Roberto Chiprut*, General Director,  
Mexican Institute of Clinical Research,  
Mexico; Clinical Professor of Medicine,  
UCLA, USA; Attending Physician, Cedars  
Sinai Medical Center, USA

8:15-8:45 BASIC AND CLINICAL RESEARCH  
*Dr. Ruy Pérez Tamayo*, Scientist,  
Medical Philosopher, Opinion Leader in  
Mexico, Hospital General de Mexico

#### *Morning Chairpersons*

*Dr. Andrea Procaccino*, Head of Training, Global Clinical  
Operation, Janssen Research Foundation, USA  
*Dr. Sergio Guerrero*, Chief Operating Officer,  
IMIC, Mexico

8:45-9:15 The Training of Physicians in Clinical  
Research: An Overview of the Course  
*Dr. María Elena Cortés*, Director of  
Academic Affairs, IMIC, Mexico

9:15-9:45 Phases of Clinical Research  
*Dr. Carlos Pietrasanta*, Regional Medical  
Director, Pfizer, S.A. de C.V., Mexico

9:45-10:15 Regulatory References  
*Dr. Alberto Lifshitz*, Medical Director,  
Medisalud, Mexico

10:15-10:35 REFRESHMENT BREAK

10:35-11:05 Good Clinical Practices  
*C. M. Katie Margules*, Director, PPD  
Development, Mexico and Central America

11:05-11:35 Ethics  
*Dr. Alfonso Moguel*, Medical Director,  
Novartis Pharma, Mexico

11:35-12:05 Informed Consent  
*Dr. Itzigueri Robles E.*, ICRO Manager,  
Novartis Pharma, Mexico

12:05-12:35 Preparing the Clinical Trial Setting  
*Dr. Andrea Procaccino*, Head of Training,  
Global Clinical Operation,  
Janssen Research Foundation, USA

12:35-13:05 Question & Answer Period

13:05-14:25 LUNCHEON

#### *Afternoon Chairpersons*

*Dr. Itzigueri Robles E.*, ICRO Manager,  
Novartis Pharma, Mexico  
*Dr. Alejandro Castellanos*, Director of Regulatory Affairs,  
IMIC, Mexico

14:25-14:55 Understanding Protocol Design  
*Dr. Sc. Dennis Hurley*, Chief Operating  
Officer, ECA, Mexico

14:55-15:25 Institutional Review Boards –  
FDA Requirements  
*Dr. Andrea Procaccino*, Head of  
Training, Global Clinical Operation,  
Janssen Research Foundation, USA

15:25-15:55 Elements for the Successful Conduct of a  
Research Protocol  
*Q. F. B. Sonia Gómez Cabrera*, Director  
of Quality Assurance, IMIC, Mexico  
*Dr. Sergio Guerrero*, Chief Operating  
Officer, IMIC, Mexico

- 15:55-16:25 Financial Aspects in Clinical Research  
*Lic. Adolfo Dorenbaum*, Chief Financial Officer, IMIC, Mexico
- 16:25-16:55 Quality Assurance in Clinical Research  
*Dr. Rebecca Ponce de León*, Clinical Research Manager, ECA, Mexico
- 16:55-17:15 REFRESHMENT BREAK
- 17:15-17:45 Preparing for Inspection, Monitoring and Audits  
*Dr. Sergio Guerrero*, Chief Operating Officer, IMIC, Mexico
- 17:45-18:15 A Primer in Biostatistics  
*Dr. David Sotres*, Director General, ECA, Mexico
- 18:15-18:45 Question & Answer Period

## Thursday, February 28, 2002

- 7:15-8:00 REGISTRATION/  
CONTINENTAL BREAKFAST
- 8:00-8:10 WELCOME AND OPENING REMARKS  
*Dr. Roberto Chiprut*, General Director, Mexican Institute of Clinical Research, Mexico; Clinical Professor of Medicine, UCLA, USA; Attending Physician, Cedars Sinai Medical Center, USA
- 8:10-8:20 INTRODUCTION TO DIA  
*Héctor A. Bolaños*, Executive Director, AFAMELA, Mexico
- 8:20-8:30 THE PRESENCE OF DIA IN LATIN AMERICAN CLINICAL RESEARCH  
*Dr. Irwin G. Martin*, President, Drug Information Association; Consultant, Pharmaceutical Regulatory Affairs, USA
- 8:30-8:40 INTRODUCTION TO THE PROGRAM  
*Dr. Alberto Fratti Munari*, Director of Drug Evaluation, Ministry of Health, Mexico (SSA)
- 8:40-9:00 INAUGURATION AND KEYNOTE ADDRESS  
**The Importance of Globalization of Clinical Research in Latin America**  
*Dr. Julio Frenk*, Minister of Health, Mexico (SSA)

## 9:00-13:20 *Session I*

### ETHICS AND CLINICAL RESEARCH

#### *Session Chairpersons*

- Dr. Misael Uribe*, General Coordinator of the National Institutes of Health, Ministry of Health, Mexico (SSA)  
*Dr. Roberto Chiprut*, General Director, Mexican Institute of Clinical Research, Mexico; Clinical Professor of Medicine, UCLA, USA; Attending Physician, Cedars Sinai Medical Center, USA
- 9:00-9:30 Historic Retrospective in Research  
*Gary L. Chadwick, PharmD, MPH, CIP*, Executive Director, Research Subjects Review Board Office and Clinical Associate Professor, Division of Medical Humanities, University of Rochester, NY, USA
- 9:30-10:00 Controversy in Ethics in Clinical Research  
*Dr. Roberto Chiprut*, General Director, Mexican Institute of Clinical Research, Mexico; Clinical Professor of Medicine, UCLA, USA; Attending Physician, Cedars Sinai Medical Center, USA
- 10:00-10:20 REFRESHMENT BREAK
- 10:20-10:50 Ethics and Scientific Committees  
*Dr. Alejandro Mohar Betancourt*, Director of Research, National Institute of Cancerology, Mexico
- 10:50-11:20 Protection of the Study Subject  
*Gary L. Chadwick, PharmD, MPH, CIP*, Executive Director, Research Subjects Review Board Office and Clinical Associate Professor, Division of Medical Humanities, University of Rochester, NY, USA
- 11:20-11:50 Conflicts of Interest, Manipulation of Data, Research and Fraud  
*Dr. Misael Uribe*, General Coordinator of the National Institutes of Health, Ministry of Health, Mexico (SSA)
- 11:50-12:20 The Importance of Placebo, Research in Pediatrics, Incapacitated, and Terminal Patients: Ethical Aspects  
*Dr. Bette Crigger*, The Hastings Center, USA
- 12:20-12:50 The Compliance with Ethics and Surveillance in Latin America  
*Dr. Patricia Saidón*, Clinical Studies Services, Ministry of Health, Argentina

12:50-13:20 ROUND TABLE  
*Dr. Misael Uribe*, General Coordinator of the National Institutes of Health, Ministry of Health, Mexico (SSA)  
*Dr. Roberto Chiprut*, General Director, Mexican Institute of Clinical Research, Mexico; Clinical Professor of Medicine, UCLA, USA; Attending Physician, Cedars Sinai Medical Center, USA

13:20-14:25 LUNCHEON

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14:25-18:35 **Session II**

**REGULATORY ASPECTS OF CLINICAL RESEARCH IN LATIN AMERICA**

*Session Chairpersons*

*Dr. Patricia Saidón*, Clinical Studies Services, Ministry of Health, Argentina

*Dr. Alberto Fratti Munari*, Director of Drug Evaluation, Ministry of Health, Mexico (SSA)

14:25-14:55 Regulatory Guidelines in Accordance with ICH - FDA  
*David A. Lepay, MD, PhD*, Senior Advisor for Clinical Sciences; Director, Office for Human Research Trials, OSCC, Office of the Commissioner, Food and Drug Administration, USA

14:55-17:15 Regulations in Clinical Research in Latin America  
*Dr. Alberto Fratti Munari*, Director of Drug Evaluation, Ministry of Health, Mexico (SSA)  
*Dr. Fernando Flores*, Director of the Clinical Research Review Committee, National Institute of Vigilance of Medicines and Food (INVIMA), Colombia  
*Dr. Estela Giménez*, ANMAT, Ministry of Health, Argentina  
*Dr. Jacobo Mora*, General Sectorial Director of Research and Education, Ministry of Health, Venezuela  
*Dr. María Soledad Navarrete*, National Administration of Drugs, Food, and Medical Technology, Ministry of Health, Chile

17:15-17:35 REFRESHMENT BREAK

17:35-18:05 A Pan-American Network for Drug Regulation Harmonization  
*Dr. Rosario D'Alessio*, Regional Advisor, Essential Drugs and Technology Program, Pan-American Health Organization

18:05-18:35 ROUND TABLE: HARMONIZATION IN CLINICAL RESEARCH  
*Dr. Patricia Saidón*, Clinical Studies Services, Ministry of Health, Argentina  
Pan-American Health Organization  
*Dr. Alberto Fratti Munari*, Director of Drug Evaluation, Ministry of Health, Mexico (SSA)

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**Friday, March 1, 2002**

7:15-8:00 AM REGISTRATION/  
CONTINENTAL BREAKFAST

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8:00-11:20 **Session III**

**DIFFERENCES BETWEEN CLINICAL RESEARCH IN THE USA AND LATIN AMERICA**

*Session Chairpersons*

*Dr. Alfonso Moguel*, Medical Director, Novartis Pharma, Mexico

*Dr. Honorio Silva*, Vice President, Medical and Regulatory – JAALA, Pfizer Pharmaceuticals Group, USA

8:00-8:30 Clinical Research in Latin America: CRO's Experience in Developing Countries  
*Randy Marchbanks, PhD*, Vice President, Clinical Operations, PPD Development  
*Ariye Sidi, MD*, Director, PPD Development, South America  
*C. M. Katie Margules*, Director, PPD Development, Mexico and Central America

8:30-9:00 Genetic Variability in Drug Response: A Pharmacogenomic Point of View  
*Dr. Wolfgang Sadée*, University of California, San Francisco, USA

9:00-9:30 Representation of Minorities in Clinical Research in the USA  
*David A. Lepay, MD, PhD*, Senior Advisor for Clinical Sciences; Director, Office for Human Research Trials, OSCC, Office of the Commissioner, Food and Drug Administration, USA

9:30-10:00 Drug Development in the Americas – Phase I through IV Clinical Trials  
*Dr. Honorio Silva*, Vice President, Medical and Regulatory – JAALA, Pfizer Pharmaceuticals Group, USA

10:00-10:20 REFRESHMENT BREAK

10:20-10:50	Criteria for Clinical Trial Site-Selection in the USA and Latin America <i>Dr. José Reynal</i> , Director of Clinical Research in Latin America, Pharmacia Corporation, USA	14:50-15:20	The Future of Technological Resources and Marketing in Clinical Research <i>Kenneth A. Getz, MS, MBA</i> , President and Chief Executive Officer, CenterWatch, Inc.
10:50-11:20	ROUND TABLE <i>Dr. Alfonso Moguel</i> , Medical Director, Novartis Pharma, Mexico <i>Dr. Honorio Silva</i> , Vice President, Medical and Regulatory – JAALA, Pfizer Pharmaceuticals Group, USA	15:20-15:50	Success or Failure in Clinical Research in Latin America: Learning from Experience <i>Dr. Alfonso Perez</i> , Senior Director, Strategic Clinical Development, Takeda Pharmaceuticals North America, Inc., USA
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11:20-19:00	<b>Session IV</b>		
	<b>THE FUTURE OF CLINICAL RESEARCH</b>		
	<i>Morning Session Chairpersons</i>		
	<i>Dr. Barbara Geiger</i> , Clinical Director, Clinical Research Management Services, USA		
	<i>Dr. Romeo Rodríguez</i> , Director General, Children's Hospital of Mexico (SSA)		
11:20-11:50	The Study of Human Genome in Latin America: Ethical, Scientific and Therapeutic Aspects <i>Dr. Rubén Lisker</i> , Director of Research, National Institute of Nutrition, Mexico	15:50-16:20	The World of Drug Safety in the 21st Century <i>Gerald A. Faich, MD, MPH</i> , President, Pharmaceutical Safety Assessment and Training Course Committee, DIA, USA
11:50-12:20	The Arising and New Challenges of Pediatric Clinical Research <i>Dr. Romeo Rodríguez</i> , Director General, Children's Hospital of Mexico (SSA)	16:20-16:50	Clinical Research in Vaccines for the New Millennium: Preventing Disasters? <i>Dr. Betzana Zambrano</i> , Clinical Research Physician, Aventis Pasteur, Argentina
12:20-12:50	The Future of Generics and Bioequivalence Studies in Latin America <i>Solomon Stavchansky, PhD</i> , Professor of Pharmaceutics, University of Texas in Austin, College of Pharmacy, USA	16:50-17:10	REFRESHMENT BREAK
12:50-13:20	ROUND TABLE <i>Dr. Barbara Geiger</i> , Clinical Director, Clinical Research Management Services, USA <i>Dr. Romeo Rodríguez</i> , Director General, Children's Hospital of Mexico (SSA)	17:10-17:40	The Perspectives of CROs in Latin America <i>Dr. Cristina Torres</i> , Independent Clinical Research Consultant
13:20-14:20	LUNCHEON  <i>Afternoon Session Chairpersons</i> <i>Dr. Alfonso Pérez</i> , Senior Director, Strategic Clinical Development, Takeda Pharmaceuticals North America, Inc., USA <i>Mr. Richard Musselman</i> , President and CEO, AvAMed Consulting Group, Inc. USA	17:40-18:10	Past, Present and Future of Drug Development <i>Mr. Richard Musselman</i> , President and CEO, AvAMed Consulting Group, Inc., USA
14:20-14:50	Preparing for the Future of Clinical Research in Latin America <i>Dr. Juan Pablo Guzmán</i> , Director, Clinical Development, Takeda Pharmaceutical	18:10-18:40	ROUND TABLE <i>Dr. Alfonso Pérez</i> , Senior Director, Strategic Clinical Development, Takeda Pharmaceuticals North America, Inc., USA <i>Mr. Richard Musselman</i> , President and CEO, AvAMed Consulting Group, Inc., USA
		18:40-18:50	SUMMARY AND CONCLUSIONS <i>Dr. Roberto Chiprut</i> , General Director, Mexican Institute of Clinical Research, Mexico; Clinical Professor of Medicine, UCLA, USA; Attending Physician, Cedars Sinai Medical Center, USA
		18:50-19:00	CLOSING CEREMONY <i>Dr. Alberto Fratti Munari</i> , Director of Drug Evaluation, Ministry of Health, Mexico (SSA)
		19:00	CONGRESS ADJOURNED

Drug Information Association <http://www.diahome.org>  
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**CANCELLATION POLICY: On or before FEBRUARY 21, 2002**

**Administrative fee that will be withheld from refund amount:**

Industry = \$100 Government/Academia (Full-Time) = \$50

**Cancellations must be in writing and be received by the cancellation date above.** Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. **Registrants are responsible for cancelling their own hotel reservations.** You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible. *Registration must be received by DIA by February 21, 2002.* DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

**TRAVEL AND HOTEL:** We advise you to make your airline reservations as early as possible to ensure availability. The most convenient airport to this hotel is Mexico City Airport. The Presidente Inter-Continental Hotel is holding a block of rooms at the reduced rate below (rates subject to applicable taxes) until February 4, 2002, for the DIA Meeting attendees.

**Single \$170      Double \$170**

*Current rates are 15% of value added tax and 2% lodging tax.*

To reserve your room, please contact the Presidente Inter-Continental Hotel by fax at +52 (55) 53 27 77 87 and mention the DIA Workshop. The Presidente Inter-Continental Hotel is located at Campos Eliseos 218 Mexico, D.F. 11560, Mexico City, Mexico.

**CONTACT INFORMATION**

Meeting attendees are welcome to visit the limited table top exhibits during the workshop. **For exhibit information,** contact Michele Burch at the DIA office in Fort Washington, PA by *telephone +1 215 591 3305, fax +1 215 641 1229 or email: [Michele.Burch@diahome.org](mailto:Michele.Burch@diahome.org).* **For meeting information,** contact Julie Ho at the DIA office in Fort Washington, PA by *telephone +1 215 591 3315, fax +1 215 641 1229 or email: [Julie.Ho@diahome.org](mailto:Julie.Ho@diahome.org).*

**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.**

**Audio/Visual taping of any DIA Workshop is prohibited without prior written consent from DIA.**

**PLEASE CONSIDER THIS FORM AN INVOICE – The FIRST Latin American Congress of Clinical Research Meeting I.D. # 02025 – February 27-March 1, 2002, Presidente Inter-Continental Hotel, Mexico City, Mexico**

**TUITION/REGISTRATION FEES:** *Registration Fee includes meeting materials, refreshment breaks, and luncheons and will be accepted by mail, fax, or email. Please check all applicable fees:*

**PRE-REGISTRATION FEES – Registration form and payment received on or before February 21, 2002:**

Industry      US \$750   
 Government & Academia (Full-Time)      US \$450

**ON-SITE FEES – Registration form and payment received on or after February 22, 2002:**

Industry      US \$875   
 Government & Academia (Full-Time)      US \$575

*Prices do not include DIA membership fee. For membership information and application, please visit our website at [www.diahome.org](http://www.diahome.org).*

Do you require headphones for simultaneous translation?       Yes       No

Please check the applicable category:       Academia       Gov't       Industry       CSO       Student

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- CHECK** drawn on a US Bank payable to and mailed along with this form to: **Drug Information Association Inc, P.O. Box 827192, Philadelphia, PA, USA 19182-7192.** Please include a copy of this registration form to facilitate identification of attendee.
- BANK TRANSFER** in the currency of your choice to: **CITIBANK, N.A., 460 Park Avenue, New York, NY 10022, USA. DIA Account Number: 46820821. Routing Number: 021000089 ABA #210.** Your name and company, as well as the above Meeting I.D. Number, must be included on the transfer document to ensure payment to your account.
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# ROOM INFORMATION

**Please Circle:** Standard **US\$ 170** / Double **US\$ 170** *Room rates subject to applicable taxes (currently 15% VAT and 2% lodging tax.)*

Single/queen bed \_\_\_\_\_ Double/twin beds \_\_\_\_\_

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

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

**Check-in time: 15:00 o'clock, check-out time: 13:00 o'clock.**

**Room reservations must be received no later than February 4, 2002. Confirmation will be sent via email.**

**Fax this form to +52 (55) 53 27 77 87, Attention: Reservations Department  
Presidente Inter-Continental Hotel, Mexico City, Mexico.**

**DO NOT FAX HOTEL RESERVATION FORMS TO DIA.**

### ROOM CANCELLATION POLICY

Cancellations received 24 hours prior to scheduled arrival will incur no penalties. One night room rates plus taxes will be charged to guest for no show or late arrival. No penalties incurred for early arrival.