11th Latin American Conference of Clinical Research (LACCR) 2014

Latin America's Competitiveness in a Global Pharmaceutical Industry

September 25-26
CINTERMEX Convention Center
Monterrey City, Nuevo Leon, Mexico
diahome.org/LACCR2014

Simultaneous Translation will be available in English and Spanish.

Para descargar el programa en español dar click aquí.

Meet with global and regional clinical researchers, industry, and academia professionals to engage in interactive strategic discussions on current clinical research and medical devices regulations and policies, and implementation approaches to future research in Latin America and around the world.

The only truly impartial and neutral forum for all stakeholders in the region.

CONFERENCE OVERVIEW

DIA's 11th LACCR is the top regional academic forum on clinical research in Latin America. LACCR is the only neutral forum in the region devoted to fostering the integration of professionals in the field, aiming to fully develop Latin America's potential in the scope of clinical research globally. The two-day conference will feature presentations on hot topics ranging from global issues to focusing on specific details of clinical research and medical devices. Speakers will highlight the most relevant issues for the Latin American region in regulatory, pharmaco-economy, ethics, a clinical site's infrastructure, the components of clinical research, and much more.

TARGET AUDIENCE

This conference is directed at:

- 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 and associations
- Pharmaceutical sponsors
- Other professionals considering initiating their activities in this professional area.
- Regulatory affairs professionals
- Supply chain industry professionals

LEARNING OBJECTIVES

- 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
- Understand what kind of professional development can be achieved in clinical research
- Understand the long way from basic research to public health innovation in the clinical research arena
- Understand the regulatory principles and procedures in clinical research and interact with the regulatory stakeholders in the region
- Compare the Latin America opportunities with other emerging markets in clinical research

FEATURED TOPICS

- Clinical research sites issues
- Pharmaco-economy topics
- Ethics in clinical research
- Scientific issues
- Regulatory updates
- Generic products
- Integration of the supply chain industry components
- Excellence in education and training
- Medical devices
- Stakeholders' role and active participation in the industry

PROGRAM CO-CHAIRS

Sergio Guerrero, MD
Chair, DIA Regional Advisory Council for Latin America; President/CEO, Accelerium Clinical Research, Mexico

Jose Luis Viramontes, MD
President, Mexican CROs Alliance (ACROM); PPD Director, Remote Site Management & Monitoring, Latin America

Jaime Weichsel Leal
Director, Nuevo Leon State Health Biocluster, Mexico

PROGRAM COMMITTEE MEMBERS

Joao Massud, MD
President, Brazilian Society of Pharmaceutical Medicine (SBMF)

Arturo Rodriguez Jacob
Director, Infinite Clinical Research, Mexico

Andres Bayona, MD
Asociacion Peruana para la Promocion de Investigacion Clinica

Helen Cohen de Monterroso, MD
General Manager
TRIAL, Guatemala

Wanda Dobrzanski Nisiewicz, MD
Vice President and General Manager
Vaccines & Infectious Diseases
inVentiv Health Clinical, Argentina

Gustavo Kesselring, MD
Executive Director
ViS Research, Brazil

Charles Schmidt, MD
Professor, Santa Casa Medical School, Brazil

Gabriela Davila, MD
Director Compliance and Oversight Mexico Puerto Rico, Caribbean and Central America
Pfizer Mexico

Paul Toralva, DDS
Peruvian Association of CRO's (APOICC)
Peru

Jenny Paredes, PhD
Operations Manager
PRA Health Sciences, Mexico

Luis Mario Villela, MD
Faculty Chair, Hematology & Cancer
Tecnologico de Monterrey
Campus Monterrey, Mexico

Ian Rentsch
Senior Director
Business Development and Head of Latin America Sales Quintiles, Argentina

Federico Ramos, MD
President, Ethics Committee
San Jose Hospital, ITESM, Mexico

Rivelino Flores, MSc
Director, Regulatory Affairs & Innovation
CANIFARMA, Mexico

Ana Padua, MSc
CMC Regulatory Policy LATAM
Roche, Brazil

Mafalda Giménez Toso
Manager, Regulatory and Start-Up
Integrated Site Services, Quintiles, Chile

Juan Carlos Groppa, MD
Manager, Medical Affairs Laboratorios Bagó, Argentina

Hugo Alberto Barrera Saldaña, MD
Secretario Ciencia y Tecnología/
CEOFM-UANL/Vitaxentrum
Mexico

José Ascencion Hernández, PhD
Medicine School and Life Sciences
Tecnológico de Monterrey, Campus Monterrey, Mexico

Harold Mix, MD
President, Chilean CROs Association, Chile

Leonel Villa Caballero, MD
Director, Clinical Trials Programs for Latin America University of California - San Diego Extension (UCSD), USA

In collaboration with:
ACROM: Alianza de CROs' de Mexico and NL State Biocluster

DIA Global Center
21 Dupont Circle NW, Suite 300
Washington, DC 20036

Basel, Switzerland | Beijing, China | Horsham, PA, USA | Mumbai, India | Tokyo, Japan

CONTACT INFORMATION

Ellen Diegel
Event Planner
215.293.5810 | Ellen.Diegel@d.ahome.org

7:00-8:00 AM REGISTRATION

8:00-8:30 AM WELCOME AND OPENING REMARKS

Ms. Barbara Lopez Kunz
Global Chief Executive
DIA
Sergio Guerrero, MD
President/CEO, Accelerium Clinical Research, Mexico
Chair, DIA Advisory Council for Latin America
Mercedes Juan Lopez, MD (Invited)
Minister, Health Ministry,
Government of Mexico
Rodrigo Medina de la Cruz, MA (Invited)
Governor of the Nuevo Leon State, Mexico

8:30-9:00 AM KEYNOTE SPEAKER

TransCelerate Initiatives: Goals and Implications on the Latin American Industry

Rehbar H. Tayyabkhan
Executive Director, GDO Business Operations and RCO Latin America
Bristol-Myers Squibb Company
USA

9:00-10:30 AM PLENARY 1 / ROUND TABLE

Economic Impact of Regulations in Regional Competitiveness

Competitiveness & Economics Track

Co-Chairs
Wanda Dobrzanski Nisiewicz, MD
Vice President and General Manager, Vaccines and Infectious Diseases
inVentiv Health Clinical, Argentina
Gabriela Davila, MD
Compliance Director
Latin America and Puerto Rico
Pfizer, Mexico

Round table discussion on how current regional regulations are impacting the Latin American industry's performance in the global market. Topics to be discussed include the perception of volatility and unpredictability caused by local and regional regulations. Representatives from industry, ethics committees, a regulatory official, patients, and CROs will provide the audience with their perspective on how current regulatory frameworks affect the region's sectoral growth and development.

9:00-9:15 AM *Panelist 1*
Rafael Laurino
Hub Unit Manager
Regional Clinical Operations Brazil
Bristol-Myers Squibb, Brazil

9:15-9:30 AM *Panelist 2*
Jose Daniel Peña Ruz, QF
Regional Advisor, Medicines and Health Technologies
PAHO/WHO, Chile

9:30-9:45 AM *Panelist 3*
Gabriela Davila, MD
Compliance Director
Latin America and Puerto Rico
Pfizer, Mexico

9:45-10:00 AM *Panelist 4*
Patient Representative TBD

10:00-10:30 AM *Interactive Discussion*

10:30-11:00 AM COFFEE BREAK

11:00 AM-12:30 PM PLENARY 2

Public-Private Partnerships Fostering Educational Programs in Clinical Research

Competitiveness & Economics Track

Chair
Andres Bayona, MD
Asociacion Peruana para la Promocion de Investigacion Clinica
Peru

Session to provide an overview on alliances and partnerships between regulatory bodies and private and educational institutions to foster capacity building educational programs in clinical research.

11:00-11:20 AM *Education in Clinical Research: The Latin American Experience*
Honorio Silva, MD
President, Inter American
Foundation for Clinical Research
USA

11:20-11:40 AM *University Partnerships: Education in Clinical Research Centers*
Juan Luis Yrivarren, MD
Director, Ricardo Palma Clinical Research Center
Peru

11:40 AM-12:00 PM *Core Competencies for the Global Clinical Research Professional*
Stephen Sonstein, MD
Eastern Michigan University, USA

12:00-12:30 PM *Q & A*

12:30-1:30 PM PLENARY 3

Certification of Ethics Committee in Latin America

Ethics & Bioethics Committees Formation in Latin America Track

Chair
Charles Schmidt, MD
Professor, Santa Casa Medical School, Brazil

High level discussion on the challenges and opportunities for Ethics Committees in Latin America as they try to obtain a local or external validation of their standard operations procedures. This session will also provide an analysis on the current measures needed to be in compliance with those procedures.

12:30-12:45 PM *Bioethics*
Sarah H. Kiskaddon, MA, JD
Director, Global Business Development and Public Affairs, Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), USA

12:45-1:00 PM *The Mexican Perspective*
Carlos Hinojosa, MD
Deputy Director, Clinical Research
Instituto Mexicano de Nutricion
Mexico

1:00-1:15 PM *The WHO Perspective*
WHO Representative TBD

1:15-1:30 PM *Interactive Discussion*

1:30-2:30 PM **LUNCH**

2:30-3:30 PM **PLENARY 4**

Biobanks: Clinical and Research Applications

Biotech & Scientific Issues Track

CHAIR

Hugo Alberto Barrera Saldaña, MD
Secretario Ciencia y Tecnología/CEOFM-UANL/Vitaxentrum
Mexico

The systematic collection, proper preservation and cellular and molecular characterization of biospecimens plays an increasingly important role in the understanding of clinical trial outcomes. This session describes the relevance of Biobanks in clinical research. Understanding how data obtained from biospecimens fosters the development of competitive clinical research.

2:30-2:50 PM ***The University of Nuevo Leon's Biobank***

Maria de Lourdes Garza, MD
Professor, University of Nuevo Leon
Mexico

2:50-3:10 PM ***Biobanks' Applications in Clinical Research — An Example***

Jacobo Martinez, MD
Scientific Director, Biobanco CSISP
Spain

3:10-3:30 PM ***Q & A***

3:30-4:00 PM **COFFEE BREAK**

4:00-5:00 PM **CONCURRENT SESSIONS**

CONCURRENT A

Medical Communication and Medical Science Liaison as Part of the Medical Affairs Responsibilities in Latin America

Biotech & Scientific Issues Track

CHAIR

Jose Luis Viramontes, MD
President, Mexican CROs Alliance (ACROM)
Director, Remote Site Management & Monitoring, Latin America

The pharmaceutical industry faces challenges related to communicating and managing medical information for a variety of health care providers or to patients/general public regarding the risks and benefits of its products. This communication can be provided by creating an innovative medical information contact center, which will help the Medical Science Liaisons fulfill their functions. This session will review the necessary elements to build a world-class medical information center, with a focus on technology, compliance issues, and staffing models.

4:00-4:20 PM
Creating an Innovative Medical Information Contact Center Experience in LA

Patricia Tortorelli, MD
Associate Director, Medical Communications PPD
Brazil

4:20-4:40 PM
Medical Information Management as a Key Responsibility of the Medical Director in Pharmaceuticals: The Mexican Experience

Rafael Bravo, MD
Medical Director, Novartis
Mexico

4:40-5:00 PM
Interactive Discussion

CONCURRENT B

Ethical Monitoring in the Investigator-Research Subject Relationship in Clinical Research

Ethics & Bioethics Committees Formation in Latin America Track

CHAIR

Federico Ramos, MD
President, Ethics Committee, San Jose Hospital
Instituto Tecnologico de Estudios Superiores de Monterrey, Mexico

This session will discuss our proposed tool for the ethical monitoring of the investigator-research subject relationship in clinical research. This includes its elaboration, a discussion of the problem we are trying to approach, and the results we get after its utilization in diverse clinical research sites.

4:00-4:20 PM
Ethical Monitoring Tool Overview

Federico Ramos, MD
President, Ethics Committee, San Jose Hospital
Instituto Tecnologico de Estudios Superiores de Monterrey, Mexico

4:20-4:40 PM
The Philosophical Perspective

Rafael de Gasperin, PhD
Professor
Instituto Tecnologico de Estudios Superiores de Monterrey
Mexico

4:40-5:00 PM
Interactive Discussion

5:00-6:00 PM CONCURRENT SESSIONS

CONCURRENT C

Application of Pharmacogenetics in Personalized Medicine

Biotech & Scientific Issues Track

CHAIR

Hugo Alberto Barrera Saldaña, MD
Secretario Ciencia y Tecnología/CEOFM-UANL/Vitaxentrum
Mexico

Drug efficacy and adverse drug reactions are usually dose-dependent and determine the clinical outcome of the administration of a particular drug. Personalized Medicine focuses on matching type and dosage according to individual genetic variation. This session will discuss the application of pharmacogenetics for volunteer selection on new drugs and bioequivalence clinical trials. In the case of bioequivalence studies, volunteer selection based on a specific metabolism type (fast, normal or slow) could provide more accurate trial results and clinical outcomes. The application of pharmacogenetics in Clinical Trials will be discussed.

5:00-5:15 PM ***Mexican Population, Clinical Significance for Anticoagulants***

Vanesa Gonzalez, MD
Investigator, INMEGEN, Mexico

5:15-5:30 PM ***Application of Pharmacogenetics in Personal Medicine***

Xavier Soberon, MD
Director, INMEGEN, Mexico

5:30-5:45 PM ***Pharmacogenetics of Pharmacokinetics Highly Variable Drugs***

Rafael Baltazar Reyes Leon, MD
Professor, UDEM, Monterrey, NL, Mexico

5:45-6:00 PM ***Interactive Discussion***

CONCURRENT D

Clinical Outsourcing in Latin America: Models/Trends — A Panel Discussion

Competitiveness & Economics Track

CHAIR

Mauro Martinelli
Associate Director, Emerging Markets Specialist
Clinical Development
Quintiles, USA

Clinical Outsourcing to Latin America is a critical aspect of regional clinical development and growth, while it still remains unexplored for many global pharma, mid-size pharma, as well for Biotech companies. Ask people in the US or Western Europe about any given emerging market and you might hear one of two things – "It's a great place to do business" or "That market is so scary, I couldn't possibly work there."

5:00-5:20 PM ***Panelist 1***

Pablo Gárate H. MD, MBA
Medical Operations LATAM
UCB Pharma, México

5:20-5:40 PM ***Panelist 2***

Ms. Carolina Carrasco
Director, Clinical Operations
Quintiles, Mexico

5:40-6:00 PM ***Interactive Discussion***

6:00-7:00 PM RECEPTION

DAY 2 | FRIDAY, SEPTEMBER 26

8:00-9:30 AM PLENARY 5

Patient Role — Ethical And Legal — In The Development of Clinical Trials

Patients Participation Track

CHAIR

Luis Villela, MD
Faculty Chair, Hematology & Cancer Tecnologico de Monterrey
Campus Monterrey, Mexico

This session is devoted to informing and educating the general public and patient advocates on the rights and responsibilities of the patients participating in Clinical Trials. NGO representatives, the Human Rights Ombudsman office representative and COFEPRIS will discuss the importance of patients participating in Clinical Trials regardless of whether or not patients are assisted in a public health facility.

8:00-8:20 AM ***The Civil Society Perspective***

WHO Representative TBD

8:20-8:40 AM ***The Human Rights Perspective***

Human Rights Ombudsman Office Rep

8:40-9:00 AM ***The Government Perspective***

Emma Verástegui Avilés, MD, PhD
Servico de Cuidados Paliativos
National Bioethics Commission — CONBIOETICA
Mexico

9:00-9:30 AM ***Interactive Discussion***

9:30-10:30 AM PLENARY 6

Aspects of Global Clinical Trials and How to Avoid Unnecessary Delays in the Supply Chain

Regional & Global Supply Chain Issues Track

CHAIR

Arturo Rodriguez Jacob
Director, Infinite Clinical Research, Mexico

Session devoted to analyzing supply chain issues in Latin America, focusing on outlining the advantages of entering into emerging markets for clinical trials to save costs.

- Identifying the different regulatory requirements for entering into new clinical hotspots to ensure shipments are fully prepared with all documentation
- Establishing a strategy that takes into account the various time required for different countries at each stage of the clinical supply chain
- Developing a flexible supply chain that can adapt to unprecedented obstacles
- Forecasting any potential issues with QPs at each stage of the supply chain

9:30-9:45 AM ***Imports of Clinical Trial Supplies - Procedures, Difficulties & Impacts on Cold Chain***

Mr. Filiberto Garcia Rodriguez Broker
Customs Operations and Legal Affairs for International Trading, Mexico

9:45-10:00 AM ***Storage and Distribution of Investigational Drugs & Clinical Supplies, Temperature Compliances & Solutions***

Ms. Lizett Tapia Plata
Quality Assurance Specialist, World Courier, Mexico

10:00-10:15 AM ***How the Supply Chain will be Affected by the Updated GDP Guidelines & the Increase of Biological Drugs & Cell Therapies***

Mr. Reynaldo Roman
Senior Manager of Regulatory Compliance, Marken, Mexico

10:00-10:30 AM ***Interactive Discussion***

10:30-11:00 PM COFFEE BREAK

11:00 AM-12:00 PM PLENARY 7

Biosimilar Products Development in Latin America: Challenges and Opportunities

Generic & Biosimilar Products

CHAIR

José Ascencion Hernández, PhD
Medicine School and Life Sciences
Tecnológico de Monterrey, Campus Monterrey, Mexico

Biosimilar products are emerging as an option of treatment. LA pharmaceutical companies are trying to introduce their products to the global market, however the clinical research process has not been clearly defined to guarantee safety. This session will provide an overview of experiences of regulatory guidelines in clinical evaluation of biosimilar products and how troubles have been solved. The aim of this session is to present and contrast the global experiences in clinical evaluation of biosimilar products and how LA clinical research can support pharmaceutical companies to evaluate their biosimilar products.

11:00-11:15 AM ***Development and Regulation of Biosimilars: Mexican Experience***

Francisco García Zetina, IQ
Director Ejecutivo De Autorización de Productos y Establecimientos
Comision de Autorizacion Sanitaria Comision Federal para la Proteccion Contra Riesgos Sanitarios COFEPRIS, Mexico

11:00-11:15 AM ***Development and Regulation of Biosimilars: Brazilian Experience***

Ms. Laura Gomes Castanheira (Invited)
Manager of Research and Clinical Trials
Agência Nacional de Vigilância Sanitária (ANVISA), Brazil

11:30-11:45 AM ***Standardized Preclinical Evidence and Evaluation of Biosimilars — Is it Necessary?***

Ivana Knezevic, PhD (Invited)
Quality, Safety and Standards Team, Department of Immunization Vaccines and Biologicals World Health Organization, Switzerland

11:45 AM-12:00 PM ***Interactive Discussion***

12:00-1:00 PM PLENARY 8

Risk-based Monitoring — The Approach in Latin America

Training and Educational Needs Track

CHAIR

Jenny Paredes, PhD
Operations Manager
PRA Health Sciences, Mexico

Risk-based Monitoring is becoming an essential educational need for both the industry and CROs as well as research sites. This session will provide a view on how Risk-based Monitoring is being approached in Latin America and how this element will become more frequent moving forward.

12:00-12:20 PM ***The Journey of Deploying Risk-based Monitoring in a Strategic Partnership: Status and Future Perspectives***

Mr. Francisco Garcia
Regional Clinical Trial Manager Monitor
Sanofi Pasteur, Mexico

12:20-12:40 PM ***Risk-based Monitoring Approach in Mexico***

Ms. Carolina Carrasco
Director, Clinical Operations
Quintiles, Mexico

12:40-1:00 PM ***Interactive Discussion***

1:00-2:00 PM LUNCH

2:00-3:00 PM PLENARY 9

Clinical Research Developments in the Area of Gene Therapy

Biotech & Scientific Issues Track

CHAIR

Hugo Alberto Barrera Saldaña, MD
Secretario Ciencia y Tecnología/CEOFM-UANL/Vitaxentrum
Mexico

Gene therapy uses genes themselves and mechanisms to control their action to offer new therapeutic approaches for inherited, infectious, and neoplastic diseases, representing a new hope for curing current untreatable diseases. This session will describe the current status of gene therapy and the progress of bringing its promise into the clinical trials scenario and will provide an understanding of how a gene therapy clinical trial is performed.

2:00-2:15 PM ***Clinical Trials in Gene Therapy***

Roberto Tofani Sant'Anna, MD
Investigator
Cardiology Institute Do RGS
Brazil

2:15-2:30 PM ***First Gene Therapy Clinical Trials in Latin America***

Augusto Rojas Martinez, MD
Professor, School of Medicine
Universidad Autonoma de Nuevo Leon
Mexico

2:30-2:45 PM ***Legal and Regulation issues in Gene Therapy Trials***

TBD

2:45-3:00 PM TBD

3:30-4:30 PM CONCURRENT SESSIONS

CONCURRENT E

Connecting the Right Sites to Promising Trials: The Next Generation of Feasibility Analyses

Multi-Regional Clinical Research Sites Track

CHAIR

Gustavo Kesselring, MD
Executive Director
ViS Research, Brazil

Session devoted to analyzing and discussing multi-regional clinical research sites and will focus on the connecting of research sites to sponsors through new technologies tools.

3:00-3:15 PM *Panelist 1*

Mr. Otis Johnson
Executive Director, Clinical Informatics
inVentiv Health, USA

3:45-4:00 PM *Panelist 2*

Luis Mario Villela, MD
Faculty Chair, Hematology & Cancer Tecnologico de Monterrey
Campus Monterrey, Mexico

4:00-4:15 PM *Panelist 3*

Juan Luis Yrivarren, MD
Director, Ricardo Palma Clinical Research Center
Peru

4:15-4:30 PM *Interactive Discussion*

CONCURRENT F

Phase I Clinical Trials: the Latin American Experience

Biotech & Scientific Issues Track

CHAIR

Joao Massud, MD
President
Brazilian Society of Pharmaceutical Medicine (SBMF), Brazil

3:30-3:50 PM *Sponsor*

Angel Mario Coll Munoz, MD, PhD
Senior Country Clinical Operation Manager
Abbvie Pharmaceutical, Mexico

3:50-4:10 PM *Latin American CRO*

Federico Lerner, MD
Senior Director of Operations, Latin America
PRA Health Sciences, Argentina

4:10-4:30 PM *Interactive Discussion*

4:30-5:30 PM CONCURRENT SESSIONS

CONCURRENT G

Current and Future Initiatives in Education and Training in Latin America

Training and Educational Needs Track

CHAIR

Juan Carlos Groppa, MD
Manager, Medical Affairs Laboratorios Bagó S.A., Buenos Aires, Argentina

This session aims to help create awareness among the general public of the paramount importance of improving the quality of the multiple training and learning initiatives in the region. This round table features the most distinguished training and courses to be developed in Latin America, including a comparison on the most traditional methods versus the most modern ones.

4:30-4:45 PM *Brazilian Initiatives*

Joao Massud, MD
President, Brazilian Society of Pharmaceutical Medicine (SBMF)

4:45-5:00 PM *UCSD Initiatives*

Leonel Villa Caballero, MD
Director, Clinical Trials Programs for Latin America University of California San Diego Extension (UCSD), USA

5:00-5:15 PM *Mexican Initiatives*

Jose Gerardo Gonzalez, MD
Subdirector de Investigacion, Departamento de Medicina Interna
Hospital Universitario Universidad Autonoma de Nuevo León
Mexico

5:15-5:30 PM *Interactive Discussion*

CONCURRENT H

Budget Negotiation and Hidden Costs for Research Sites in the LA Region

Biotech & Scientific Issues Track

CHAIR

Gustavo Kesselring, MD
Executive Director
ViS Research, Brazil

4:30-4:45 PM *The Mexican Experience*

Ciro Garcia, MBA
CFO and Business Development Director
Accelerium Clinical Research
Mexico

4:45-5:00 PM *The Peruvian Experience*

Juan Luis Yrivarren, MD
Director, Ricardo Palma Clinical Research Center
Peru

5:00-5:15 PM *The Brazilian Experience*

Gustavo Kesselring, MD
Executive Director
ViS Research, Brazil

5:15-5:30 PM *Interactive Discussion*

5:30-6:30 PM CONCURRENT SESSIONS

CONCURRENT I

Regulatory Sites Inspection Experience

Multi-Regional Clinical Research Sites Track

CHAIR

Rivelino Flores, MsC
Director, Regulatory Affairs & Innovation
CANIFARMA
Mexico

4:30-4:50 PM ***The Mexican Experience***

Jose Gerardo Gonzalez, MD
Subdirector de Investigacion, Departamento de Medicina Interna
Hospital Universitario Universidad Autonoma de Nuevo León
Mexico

4:50-5:10 PM ***The Peruvian Experience***

Jorge De Los Rios, MD
Jefe del Servicio de Neumologia
Hospital Maria Auxiliadora
Peru

5:10-5:30 PM ***Interactive Discussion***

CONCURRENT J

TBD

Biotech & Scientific Issues Track

CHAIR

Federico Ramos, MD
President, Ethics Committee
San Jose Hospital, ITESM
Mexico

4:30-4:50 PM ***Regulatory Development of Ethics Committees for Research in Mexico***

David Alejandro Lopez Vibaldo
Anthropologist, Chief of Research, Ethics Committee Department
National Bioethics Commission
Mexico

4:50-5:10 PM ***Civil Responsibility Insurance for Clinical Trials in Mexico***

Dr. Fernando Perez Galaz
Clinical Risks Administrator
GMX, Mexico

5:10-5:30 PM ***Global Perspective***

Mr. Vicente Alciturri Gandarillas
CEO, SEMICROL
Spain

6:30 PM CLOSING REMARKS

Sergio Guerrero, MD
Chair, DIA Advisory Council for Latin America
President/CEO, Accelerium Clinical Research, Mexico

11th LATIN AMERICAN CONFERENCE OF CLINICAL RESEARCH

SEPTEMBER 25-26, 2014
MONTERREY, NUEVO LEON MEXICO

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Categories-Fee	Early Bird Rate Before September 15th, 2014	After September 15th, 2014 Standard Rate
DIA / Partner	❑ **$ 650.00 USD**	❑ **$ 750.00 USD**
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CANCELLATION POLICY: On or before August 28, 2014, Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
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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 and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify dia@servimed.com.mx of any such substitutions as soon as possible

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