Latin American Conference on Clinical Research (2012)

Latin America: Pursue of Excellence and Competitiveness in Clinical Research

October 25-26, 2012
World Trade Center | Crowne Plaza Hotel
Mexico City, Mexico

PROGRAM CHAIRPERSON

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

KEYNOTE SPEAKER

Federico Argüelles Tello, MD
Commissioner of Health Approval
COFEPRIS
Mexico

PROGRAM COMMITTEE MEMBERS

Arturo Rodriguez Jacob
President, Mexican Association of CROs Mexico (ACROM)
Director, Infinite Clinical Research, Mexico

Martha Parra Diaz, MD
COFEPRIS, Mexico

Agustina Bisio, MD
Director,
ANMAT, Argentina

Luis Eduardo Johnson Rojas, MD
Manager, Office of Clinical Trials and Bioethics
Instituto De Salud Pública De Chile (ISPCH)

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

Vanessa Cohen Muñoz, MD
Derma Medical Manager
STIEFEL, a GSK Company
Mexico

Wanda Dobrzanski, MD
Executive Director
Head of Clinical Operations Latin America
PharmaNet/i3
Argentina

Fabian Llorens, MD
Program Coordinator, Graduate Program on Pharmaceutical Medicine
Medical School, Instituto Politécnico Nacional, Mexico

Gustavo Kesselring, MD
Executive Director, ViS Research, Brazil

Diana Valencia, MD
CEO/LATAM TRIALS, Colombia

Charles Schmidt, MD
Professor, Santa Casa Medical School, Brazil
Vice President, Clinical Operations & Business Development, EUROTRIALS

Jose Luis Viramontes, MD
Director,
Clinical Management
PPD Mexico, Central America and The Caribbean

Simon Kawa Karasik, MD
Executive Director, National Bioethics Commission
Mexico

Rivelino Flores, MD
Pharmaceutical Director,
CANIFARMA, Mexico

Dr. Jose Antonio Palma Aguirre
Clinical Director
Axis Clinical, Mexico

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

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

Jenny Paredes, MD
Latin American Operations Manager
PRA International

Ma. Eugenia Sanchez Nozari, QFB
Director Latin America Regional Clinical Operations
Eli Lilly, Mexico

Fabiola Encinas, QFB
Country Manager,
MedPace Mexico

Mirna Mendoza, MBA
General Manager
INTRIALS Mexico

Carlos Caparros, MD
Regional Director, Global Clinical Trial Operations – Latin America, Merck Sharp & Dohme, Argentina

Verónica Lezano B. MT-BS, Eng.
CEO, General Manager
ACTIVA8 Clinical Research
Chile

Meet with global clinical researchers, industry and academia professionals to engage in strategic discussion on the current clinical research policies, future research around the world and in Latin America.

DIA's 9th LACCR is the region's top regional academic forum on Clinical Research in Latin America, aimed at fostering the integration of professionals in the field, looking to fully develop our potential in the scope of Clinical Research globally. This highly anticipated event includes two (2) pre-conference tutorial interactive courses and a two-day conference with presentations of topics that go from global to specific details of clinical research. Presentation content will include presentations on the most relevant issues for the Latin American region, including regulatory, pharmaco-economy topics, ethical issues, hot topics, clinical site's infrastructure and components of clinical research, among other critical topics for our markets.

FEATURED TOPICS

- Clinical Research Sites issues
- Pharmaco-economy topics
- Ethics in Clinical Research
- Scientific Issues
- Regulatory Updates
- Generic Products

CONFERENCE SCHEDULE

October 25-26, 2012: Full two-day conference with concurrent sessions

Simultaneous Translation will be available in English and Spanish

CONTACT INFORMATION

Alejandro Bermudez-Del-Villar, MA/IBBD
Latin American and Global Development Coordinator
email: Alejandro.Bermudez@diahome.org

Conference: **Constance Burnett, Program Developer**
Phone: +1.215.293.5800
Fax: +1.215.293.5981
email: Constance.Burnett@diahome.org

REGISTRATION AND HOTEL
B.P. Servimed, S.A. de C.V
email: DIA@servimed.com.mx

REGISTER ONLINE
http://www.servimed.com.mx/laccr2012

ACROM Alianza de CROs de México

DIA® www.diahome.org

TARGET AUDIENCE

This congress 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
- Pharmaceutical sponsors
- Other professionals considering initiating their activities in this professional area.

LEARNING OBJECTIVES

By the end of this conference, participants should be able to:

- 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 becoming 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

TRACKS COLOR CODING

TRACK I	GENERIC PRODUCTS
TRACK II	ETHICS ISSUES
TRACK III	CLINICAL RESEARCH
TRACK IV	SCIENTIFIC ISSUES
TRACK V	REGULATORY ISSUES
TRACK VI	ECONOMIC IMPACT
TRACK VII	CLINICAL RESEARCH TRAINING & CERTIFICATION OPPORTUNITIES
TRACK VIII	TRACK VIII HEALTH INFORMATION TECHNOLOGY
TRACK IX	PATIENTS & INNOVATION

DIA Worldwide Headquarters
800 Enterprise Road, Suite 200, Horsham, PA 19044, USA
DIA Regional Offices
Horsham, PA, USA Washington, DC, USA
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

DAY 1 | THURSDAY, OCTOBER 25, 2012

7:00-8:00 AM REGISTRATION

8:00–8:15 AM WELCOME AND OPENING REMARKS

Arturo Rodriguez Jacob
President, Mexican Association of CROs Mexico (ACROM)
Director, Infinite Clinical Research, Mexico

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

8:15–8:30 AM KEYNOTE SPEAKER

Federico Argüelles Tello, MD
Commissioner of Health Approval
COFEPRIS

8:30–9:15 AM PLENARY SESSION I

TRACK 3: CLINICAL RESEARCH

Achieving Excellence and Competitiveness in Clinical Research: The How and For Whom?

Session Chairperson

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

Ling Su, PhD
DIA Board President
Senior Vice President and Head of Development Greater China Region
Beijing Novartis Pharma Co., Ltd.

9:15–11:00 AM PLENARY SESSION II

TRACK 5: REGULATORY UPDATE

Regional Regulatory Update and Ministries of Health Experiences

Panel Chairperson

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

PANEL:

Ines Bignone, MD (Invited)
Head of Pharmacovigilance
ANMAT, Argentina
Ministerio de Salud de Argentina

Lily I. Gordillo Alas, MSc
Sub-coordinadora de Ensayos Clínicos
Ministerio de Salud
Guatemala

Federico Argüelles Tello, MD
Commissioner of Health Approval
COFEPRIS, Mexico

11:00-11:30 AM REFRESHMENT BREAK

11:30 AM-13:00 PM PLENARY SESSION III

TRACK 4: SCIENTIFIC ISSUES

Misconduct and Management of Serious or Continued Noncompliance: What are the Differences and Similarities?

Session Chairperson

Vanessa Cohen Muñoz, MD
Derma Medical Manager
STIEFEL, Mexico

Federico Lerner, MD
Senior Director, Latin America
PRA International

Conducting Clinical Trials in Developing Countires; Challenges in Meeting GCPS

Charles Schmidt, MD
Professor, Santa Casa Medical School, Brazil
Vice President, Clinical, Operations & Business Development, EUROTRIALS

13:00-13:45 PM LUNCH

13:45-15:00 PM BREAK OUT SESSIONS

BREAK OUT SESSION 1
TRACK V: REGULATORY UPDATE

CHAIR

Arturo Rodriguez Jacob
President, Mexican Association of CROs Mexico (ACROM) Director,
Infinite Clinical Research, Mexico

Biotechnological Products Regulations/ Biosimilar Products Approval

Gilberto Castañeda, MD
CINVESTAV/COFEPRIS, Mexico

Agustina Bisio, MD
Director,
ANMAT, Argentina

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

BREAK OUT SESSION 2
TRACK 2: ETHICS ISSUES

CHAIR

Rivelino Flores, MD
Pharmaceutical Director,
CANIFARMA

Rational Processes Involved in Institutional Review Boards' Regulations and Methodology: A Critical Perspective Based on Minority Human Rights

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

Rafael De Gasperín, PhD
San Jose - Hospital, Monterrey

Ethics Issues in Chile

Luis Eduardo Johnson Rojas, MD
Manager, Office of Clinical Trials and Bioethics
Instituto De Salud Pública De Chile (ISPCH)

BREAKOUT SESSION 3
TRACK 7: CLINICAL RESEARCH TRAINING & CERTIFICATION OPPORTUNITIES

CHAIR

Verónica Lezano B. MT-BS, Eng.
CEO, General Manager
ACTIVA8 Clinical Research
Chile

A. Linking Universities and Health-related Educational Institutions with Clinical Research Management: An Opportunity for Human Resources Capacity Building and for Biomedical Research Fundraising

Jorge Valdez, MD
ITESM, Monterrey

B. Wed-based, Culturally Appropriate, Clinical Trials Certificate Program to Promote Site Effectiveness and Productivity in Latin America

Leonel Villa Caballero, MD
Director, Clinical Trials Programs for Latin America UCSD Extension

15:00-15:30 PM COFFEE BREAK

15:30-16:45 PM BREAK OUT SESSIONS

BREAK OUT SESSION 4
(combined tracks SCIENTIFIC ISSUES & ECONOMIC IMPACT)

CHAIR

Fabiola Encinas, MD
Country Manager,
MedPace Mexico

A. Challenges In Conducting Controlled Substance Trials In Latin America

Jenny Paredes, MD
Latin American Operations Manager
PRA International

B. Clinical Research And Health Economics

Oscar Cerezo, MD, Msc
President-of Clinical Committee
International Society on Pharmacoeconomics and Outcomes Research

BREAK OUT SESSION 5
(combined tracks SCIENTIFIC ISSUES & ECONOMIC IMPACT)

CHAIR

Jose Luis Viramontes, MD, MSc
Director, Clinical Management
PPD Mexico, CA & The Caribbean

A. Where is the Real Value in Strategic Clinical Development Partnerships?

Terry Loding
Global Director
Alliance Management
Business Development, PPD

B. Global Trial Allocation Logic and the Impact in Latin America

Carlos Caparros, MD
Regional Director, Global Clinical Trial Operations – Latin America
Merck Sharp & Dohme, Argentina

BREAK OUT SESSION 6
TRACK 2: ETHICS ISSUES

CHAIR

Federico Ramos, MD
President, Ethics Committee San Jose - Hospital

A. Application of a Survey in Relation to Regulatory Framework Protecting the Major Medical Coverage for Participants in Clinical Research in Mexico

Dr. José Antonio Malfavón Ruiz
Coordinador del Comité de Ética de la Escuela de Medicina y Ciencias de la Salud, Tecnológico de Monterrey

B. Ethics in Clinical Research - Brazil

TBD
Professor
Federal University of Sao Paulo – IRB Coordination

16:45-18:00 PM BREAK OUT SESSIONS

BREAK OUT SESSION 7
TRACK 2: ETHICS ISSUES

Ethics Committees Certification

CHAIR

Jose Luis Viramontes, MD, MSc
Director, Clinical Management
PPD Mexico, CA & The Caribbean

Dr. Simon Kawa Karasik
Executive Director,
National Bioethics Commission|
Mexico

Charles Schmidt, MD
Professor, Santa Casa Medical School, Brazil
Vice President, Clinical Operations & Business Development, EUROTRIALS

BREAK OUT SESSION 8
TRACK 3: CLINICAL RESEARCH SITES

CHAIR

Carlos Caparros, MD
Regional Director,
Global Clinical Trial Operations – Latin America, Merck Sharp & Dohme, Argentina

A. Challenges and Opportunities in Latin America for Clinical Research Sites

Diana Valencia, MD
CEO/LATAM TRIALS, Colombia

B. A Day in The Life of a Clinical Research Site. What's Getting In the Way?

Wanda Dobrzanski, MD
Executive Director
Head of Clinical Operations
Latin America
PharmaNet/i3
Argentina

BREAK OUT SESSION 9
TRACK I: GENERIC PRODUCTS

Generic Products And Bioequivalence Studies

CHAIR

Jose Antonio Palma Aguirre, MD
Clinical Director
Axis Clinical, Mexico

Regulatory Issues

Luis Eduardo Johnson Rojas, MD
Manager, Office of Clinical Trials and Bioethics
Instituto De Salud Pública De Chile (ISPCH)

Main Problems in Bioanalytical Assays for Bioequivalence Studies

Gabriel Marcelín Jimenez, PhD
Technical-Scientific Director, Global Bioanalitical Consulting, Mexico

Statistics in Bioequivalence Studies. Manipulation of Results

Q.F.I. Alionka Citlali Ángeles Moreno, PhD
Quality Assurance and Logistic Director, Global Bioanalitical Consulting, Mexico

Critical Issues on Generic Products

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

ADJOURN

18:30-21:00 PM 9TH LACCR RECEPTION - PALACIO DE BELLAS ARTES, CIUDAD DE MEXICO

Note: Reception is free for all LACCR registered attendees. Free transportation available, please stop by the ACROM and DIA Booths at the Exhibition Area to obtain your tickets. Thank You!

DAY 2 | FRIDAY, OCTOBER 26, 2012

7:00-7:45 AM INTRODUCTION TO SPECIAL AREA OF INTEREST COMMUNITIES IN LATIN AMERICA BREAKFAST

PRESENTER

Verónica Lezano B. MT-BS, Eng.
CEO, General Manager
ACTIVA8 Clinical Research
Chile

Special Interest Area Communities (SIACs) are discipline-specific, global community where DIA members can share common experiences and knowledge and connect with others in their particular field. This breakfast will mark the kick-off for the SIACs Initiative in the Region. Please stop by the DIA booth for more information.

For more information on SIACs, please see information on the bottom of this page.

8:00-9:00 AM PLENARY SESSION IV

TRACK 3: CLINICAL RESEARCH SITES

Strategic Planning: Enhancing Decision-making and Maximizing Portfolio Value via Clinical Trials in Emerging Markets in Latin America

CHAIR

Ma. Eugenia Sanchez Nozari, QFB
Director Latin America
Regional Clinical Operations
Eli Lilly, Mexico

Dr. Jeffrey Kasher
Vice President Global Clinical Development,
Eli Lilly

9:00 AM–10:30 AM PLENARY SESSION V

TRACK 3: CLINICAL RESEARCH SITES

Early Drug Development in Latin America

CHAIR

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

Preclinical Studies

João Batista Calixto
Professor, Biomedical Sciences
Universidade Federal de Santa Catarina (Brazil)

How to Transform Scientific Knowledge into a Small Biotech Company in Angentina

Fernando Goldbaum, MD
Director Instituto de Investigaciones Bioquímicas de
Buenos Aires
Scientific Director Inmunova SA

10:30-10:45 AM BREAK

10:45 AM-12:15 PM PLENARY SESSION VI

TRACK 3: CLINICAL RESEARCH SITES

Globalization of Clinical Trials. How Latam Research Sites Compare with Row

CHAIR

Gustavo Kesselring, MD
Executive Director, ViS Research, Brazil

Quality Control on Site Selection in Latin America

Matilde Damian, MD
Clinical Research Director. BMS, Mexico

Mapping Global Clinical Research Activity: Research Sites and Infrastructure

Gustavo Kesselring, MD
ViS Research Institute. Brazil

Globalization of Clinical Trials: How do Latam Research Sites Compare with Row: An FDA Perspective

Ana Maria Osorio, MD, MPH
Assistant Director FDA - Latin America

12:15-13:30 PM PLENARY SESSION VII

TRACK 5: REGULATORY UPDATE

FDA/EMA Inspections

CHAIR

Jenny Paredes, MD
Latin American Operations Manager
PRA International

Rafael Nevarez
Assistant Regional Director in Mexico
FDA

Ana Rodriguez Sanchez B, MD
Head of Clinical and Non-clinical Compliance
Compliance and Inspection, European Medicines Agency
United Kingdom

Dr. José Luis Cervantes
Independent Researcher

13:30-14:30 PM LUNCH

Special Interest Area Communities (SIACs) are just one of many member benefits that DIA offers. Each SIAC provides a discipline-specific, global community where members can share common experiences and knowledge and connect with others in their particular field.

SIAC Role in DIA. SIACs provide a forum for volunteers to network and exchange information. SIACs also assist DIA in identifying professional development needs in particular interest areas and in providing information to members in career and professional development, to meet those needs.

SIAC Leadership. SIACs have a chairperson or co-chairpersons who take responsibility for the overall activities of the SIAC. A core committee facilitates the work of each SIAC.

DIA ConneX. SIAC members automatically gain access to DIA ConneX, a trusted, interactive, web-based network that links DIA's 18,000-member global community.

14:30-15:45 PM BREAK OUT SESSIONS

BREAK OUT SESSION 10
TRACK 5: REGULATORY UPDATE

Pharmacovigilance and Techno-Vigilance Challenges in Latin America

CHAIR

Fabian Llorens, MD
Program Coordinator,
Graduate Program on Pharmaceutical Medicine
Medical School, Instituto Politécnico Nacional, Mexico

Pharmaco and Technovigilance in Mexico

Joaquín Serrano Sanchez, QFB
Regulatory Affairs Manager México & Hispanoamérica, Leo Pharma

Miriam del Consuelo Sanchez, MSc
Regulatory Affairs & Pharmacovigilance Manager
Lundbeck México SA de CV

Belem Vergara, QF (Invited)
Pharmacovigilance
COFEPRIS, Mexico

BREAK OUT SESSION 12
TRACK 8: HEALTH INFORMATION TECHNOLOGY

CHAIR

Charles Schmidt, MD
Professor, Santa Casa Medical School, Brazil
Vice President, Clinical, Operations & Business
Development, EUROTRIALS

Electronic CRF Versus Paper CRF for Trials with Budget Limitations

Cristiano Torezan, MD
Strategic Development Manager
LaL Clinica
São Paulo, São Paulo, Brazil

Electronic Health Records, Clinical Trials, Mexico

Arturo Rodriguez Jacob
President, Mexican Association of CROs Mexico (ACROM) Director, Infinite Clinical Research, Mexico

The Use of Software in Bioethics Committees Activities

Vicente Alciturri Gandarillas, BS
Managing Director
SEMICROL
Spain

15:45-16:00 PM BREAK

16:00-17:00 PM BREAK OUT SESSIONS

BREAK OUT SESSION 13
TRACK 3: CLINICAL RESEARCH SITES

CHAIR

Vanessa Cohen Muñoz, MD
Derma Medical Manager
STIEFEL, a GSK Company
Mexico

How to Increase Quality and Competitiveness for Clinical Trials

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

Pharmaceutical Industry Support through Sponsored Clinical Trials

Diana Valencia, MD
CEO/LATAM TRIALS, Colombia

BREAK OUT SESSION 14
TRACK 5: REGULATORY UPDATE

CHAIR

Carlos Caparros, MD
Regional Director, Global Clinical Trial Operations – Latin America, Merck Sharp & Dohme, Argentina

Designing of a Regulatory Agency: The Costa Rica Case

Ann Echeverri, MD
Junta Directiva de la Asociación Costarricense de Investigación en Salud Humana Costa Rica

Ecuador Experience in Clinical Research

Javier Andrade-Barragan, MD
Associate Medical DirectorPuerto Rico & Ecuador
Boca Raton Clinical Research
Ecuador

BREAK OUT SESSION 15
TRACK 9: INNOVATION AND PATIENTS

CHAIR

Mirna Mendoza, MBA
General Manager
INTRIALS Mexico

European Patients' Academy on Therapeutic Innovation of the Innovative Medicines Initiative Plays a Key Role in Changing the Paradigm of Medicines Research and Development

Per Spindler, DVM, Executive MBA, MSc
Director, BioPeople, University of Copenhagen, Denmark

Increased Importance of Patient-Reported Outcome Measures in the Evaluation of Treatment Benefits in Product Clinical Trial

Adrian Levy, PhD
Professor and Head, Department of Community Health and Epidemiology, Dalhousie University Senior Scientific Advisor, ICON Late Phase & Outcomes Research, Argentina

17:00-18:00 PM CLOSING PLENARY SESSION

Collaborative Research in LA: Payers, Physicians, Patients, Regulators, Government and Sponsors

Co-Chair 1

Ma. Eugenia Sanchez Nozari, QFB
Director Latin America
Regional Clinical Operations
Eli Lilly, Mexico

Co-Chair 2

Wanda Dobrzanski, MD
Executive Director
Head of Clinical Operations
Latin America
PharmaNet/i3
Argentina

PANEL:

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

Prof. Luis Adrián Quiroz C.
Coordinador General DVVIMSS
Vocal CONASIDA
Punto Focal Suplente RedLA
RedAcceso

Luis Eduardo Johnson Rojas, MD
Manager, Office of Clinical Trials and Bioethics
Instituto De Salud Pública De Chile
(ISPCH)

Vanessa Cohen Muñoz, MD
Derma Medical Manager
STIEFEL, a GSK Company
Mexico

18:00-18:15 PM CONFERENCE CLOSING REMARKS

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