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
- Cell-Based Therapies: The New Drug Class
- Latin America Regulatory Affairs Update
- First Time in Man & Early Phase Trials
- The Contribution of Latin America to Data Quality on Marketing Applications
- Clinical Safety and Pharmacovigilance
- Ethical Issues: A Permanent Dilemma
- Endpoints, Surrogates and The Rationale on Study Design
- Streamlining Logistics in the Region
- Sponsoring of Clinical Research by Nontraditional Players
- Biosimilars and the road ahead

PRECONGRESS COURSES
October 19th
# 1 Risk Project Management
# 2 Clinical Quality Assurance: The Basics

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
DAY 1 | WEDNESDAY, OCTOBER 19TH

08:00-08.45 REGISTRATIONS

09:00-06.30 PRE-CongRESS TUTORIALS

Tutorial 1: Risk Project Management
Course Director
Mr. Marty Hynes III
Six Sigma Champion, Senior Director Product R&D, Lilly Research Laboratories, Ely Lilly and Company

Tutorial 2: Clinical Quality Assurance, the Basics
Course Directors
Ezequiel Klimovsky
Associate Director, QUID - Quality in Drugs and Devices- LATAM Consulting SRL, Argentina
Margarita Eiletz
Managing Director, Ethics & Excellence SRL, Argentina

DAY 2 | THURSDAY, OCTOBER 20TH

07:00-08.00 REGISTRATIONS

08:00-08:30 OPENING

Welcome and Introduction to DIA 2011
Session Chairpersons
Juan Carlos Groppa (SAMEFA)
Argentine Society of Pharmaceutical Medicine
Medical Affairs. Laboratorios Bágo S.A., Argentina
Yves Julliet (DIA)
DIA President, USA

Round Table: Biosimilars in Latin America
Session Chairperson
Joao Massud
Trials Consulting, BRASIL
Session Co-Chairperson
Daniel Mazzolenis
General Manager, Kendle , Argentina

Studies with Biologicals in Latam
Julio Camps
Regional Director, Latin America, Amgen Development Operations, USA

Studies with Biosimilars in LatAm
Speaker to be confirmed

B&B Development Dilemmas for Latin American Companies
Roberto Diez
Clinical Research Manager, Bio Sidus S.A., ARGENTINA

08:30-10:00 PLENARY SESSION

Conference: Adult Mesenchymal Stem Cells are the New Medicine for Diseases
Session Chairperson
María Jimena Fernández Bartolomé
Monitora Estudios Clinicos, Roche, Argentina
Speaker
Arnold Caplan
Director, Skeletal Research Center, Professor of Biology and General Medicine Sciences, Case Western Reserve University, Cleveland Ohio, USA

10:00-10:30 REFRESHMENT BREAK

10:30-12:30 PLENARY SESSION

Round Table: Medical Devices – Clinical Trials
Session Chairperson
Marcelo Vianna de Lima
Medical Director, Latin America - Medical Diagnostics, GE Healthcare, Brazil
Session Co-Chairperson
Hugo Cohen Sabban
President, SAMEFA (Argentine Society of Pharmaceutical Medicine)
CEO, CRO BIOSOLUTION, Argentina

Local Requirements to Running Studies with Devices
Marta Kaufman
ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica), Argentina

Experiences from FDA Inspections on Clinical Trials with Devices in the Latin American Region
Matthew J. Tarosky
Acting Director, Division of Biosresearch Monitoring Office of Compliance, Center for Devices and Radiological Health (CDRH), FDA
Captain, U.S. Public Health Service

I Have a Device, and Now?
Hugo Kuprinsky
Specialist in Obstetrics, CEMIC, Argentina

12:30–02:00 LUNCHEON

Round Table: The contribution of Latin America Data to Marketing Applications: a Focus on Quality
Session Chairperson
Silvia Zieher
Executive Director, Latin America Operations, INC Research, Argentina

Ethical and GCP Standards in Latin America: a General Overview of the Research Ethics Committees and Regulatory Framework
Anna Paula Már
Associate Director, Global Regulatory Development, Latin America, Global Regulatory Affairs, Brasil

An Overview of FDA Inspections Experience in Latin America.
FDA Interactions with Local Regulatory Agencies
Paul Seligman
Director, FDA Latin America Office
Latin America Regional Office, Costa Rica

EMA Inspections Experience in Latin America and Impact of the Reflection Paper 2010
Fergus Sweeney, EMA (via teleconference)
Head of Sector Compliance and Inspections
EMA (European Medicines Agency), United Kingdom

02:00-04:00 CONCURRENT SESSIONS

04:00-04:30 REFRESHMENT BREAK
DAY 3 | FRIDAY, OCTOBER 21ST

07:00-08.00    REGISTRATIONS

08:00–08:30   IFAPP CONFERENCE

08:00-08:30   ST 07:00-08.00   REGISTRATIONS

08:30-10:00      PLENARY SESSION

10:00–10:30   REFRESHMENT BREAK

10:30-12:30    PLENARY SESSION

Round Table: Understanding the Rationale behind the Design of Clinical Research: What Endpoints and Surrogates Intend to Demonstrate

SESSION CHAIRPERSON
Gustavo Fischbein
Medical Director, Osmotica Pharmaceutical Argentina

SESSION CO-CHAIRPERSON
Marlene Liólpiz Avilés
CEO - CRO Mexicana, S.C. CEO - CRO Mexicana, S.C. Mexico

Objectives in Cardiovascular Research
Daniel R. Nul
Medical Director, Clínica Constituyentes, Argentina

Objectives in Oncology Research
Speaker to be confirmed

Objectives in CNS Research
Gonzalo Gómez Arévalo
Director, Phvlatam, Argentina

12:30-01:00   PLENARY SESSION

Conference: Pediatric Drug Development.
An FDA Perspective

SPEAKER
Benjamín Ortiz
Medical Officer, International Team
Office of Pediatric Therapeutics, Office of the Commissioner, US Food and Drug Administration

Round Table: Issues in Logistics within the Region

SESSION CHAIRPERSON
Cecilia Dantuono
Site Manager, Bristol Myers Squibb, Argentina

SESSION CO-CHAIRPERSON
Daniel Vazquez
Senior Director and Latin America Head, Global Regulatory Affairs, Quintiles Argentina S.A., Argentina

Local Requirements
Marina Ordoñez
Clinical Site Manager, Bristol Myers Squibb, Perú

Topic to be Confirmed
Antonela Mangiattera
Associate Manager, Clinical Logistics, PAREXEL International Clinical Logistics Services | Latin America, Argentina

Topic to be Confirmed
Flavio Echemendigaray
Warehouse Manager, Genzyme, Argentina

Round Table: Sponsoring Clinical Research by Non Traditional Players

SESSION CHAIRPERSON
Gerardo Méndez Ciancaglini
Product Information & Consumer Service Department Head, Laboratorios Bagó S.A., Argentina

PV outlook: National and International Companies Perspective
Are Both Looking for the Same?
Speaker to be confirmed

Current Standards
Mariano Madurga
Head of Pharmacoeconomics and Pharmacovigilance
Area, Pharmacoeconomics and Pharmacovigilance
Division, Medicines of Human Use Department, Spain

CDER Current Experience
George Rochester
Associate Office Director for Safety Assessment, Office of Biostatistics CDER, FDA

08:30-10:00   PLENARY SESSION

Conference: Early Phase Trials

SESSION CHAIRPERSON
Leylen Colmegna
CEO, LAT Research, Argentina

Introduction to Early Phase Trials
Leylen Colmegna
CEO, LAT Research, Argentina

What is Needed to Conduct Early Phase Trials in Humans
Speaker to be confirmed

Today’s Latin American Experience in Early Phase Trials
Speaker to be confirmed

Round Table: Understanding the Rationale behind the Design of Clinical Research: What Endpoints and Surrogates Intend to Demonstrate

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Objectives in Oncology Research
Speaker to be confirmed

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Marina Ordoñez
Clinical Site Manager, Bristol Myers Squibb, Perú

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Medical Director, Clínica Constituyentes, Argentina

Objectives in Oncology Research
Speaker to be confirmed

Objectives in CNS Research
Gonzalo Gómez Arévalo
Director, Phvlatam, Argentina
04:00–04:30   REFRESHMENT BREAK

04:30-06:30   CONCURRENT SESSIONS

**Round Table: Ethical issues: A Permanent Dilemma**

**Session Chairperson**
Sandra Mercurio
Medical Director & Lead Nominated Signatory, AstraZeneca, Argentina

**Session Co-Chairperson**
Wanda Dobrzanski Nisiewicz
Medical Director, Medical & Scientific Affairs, Respiratory and Infectious Diseases, i3 Global, Argentina

**Speakers**
- **Post Trial Treatment**
  Patricia Sáldón
  Specialist in Neurology and Independent Consultant, Argentina

- **The New Vulnerable Populations**
  María López Bresnaham
  VP and Global Head, Medical and Scientific Affairs, i3, USA

- **Transforming Interactions with HCP's**
  Regina Kuchle
  Legal Director and IP Consultant for LATAM, ASTRA ZENECA, MEXICO

**Round Table: Latin America - Educational Options in Clinical Research**

**Session Chairperson**
Juan Carlos Groppa
Past President, SAMEFA (Argentina Society of Pharmaceutical Medicine)
Medical Affairs Manager, Laboratorios Bágo S.A., Argentina

**Speakers**
- **Speakers and topics to be confirmed**

06:30   CONGRESS ADJOURNED

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.

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**Travel and accommodation in Buenos Aires**

The City of Buenos Aires has two airports:
- Ministro Pistarini International Airport in Ezeiza, 45 kms from downtown Buenos Aires, connecting the city with the rest of the world
- Jorge Newbery International Airport, only 15 minutes from downtown Buenos Aires, connecting the city with the rest of the country and some Latin American destinations.

The city has efficient radio-taxi and car rental services, available the 24 hours. Buses and a broad underground network facilitate the access to every corner of the city.

**Where to stay**

Buenos Aires is a city of intense cultural life, with plenty of diverse touristic attractions. All choices of hotels and accommodations are possible. Take a moment to visit www.buenosaires.com.ar to find out rates of different hotel categories.

**Hotel information and reservations for congress attendees**

In order to receive discounted room rates at Panamericano Hotel & Resort, reservations MUST be made through the Congress organizers.

You must be registered for the Congress to reserve your room.

Please, contact dialatam2011@samara-enrique.com.ar directly to make your hotel reservation or for information on other conveniently located hotels nearby the congress venue.