# 5th Latin American Congress of Clinical Research
## Regional Perspectives and Future Trends

*Co-sponsored by*

DIA Drug Information Association

SAMEFA Sociedad Argentina de Medicina Farmacéutica

**Tutorials: November 19, 2008**
**Conference: November 20-21, 2008**

**Sheraton Buenos Aires Hotel**
**Buenos Aires, ARGENTINA**

**PROGRAM COMMITTEE**

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Productos Roche S.A.Q.e I.,
Medical Director/
PDO Country Operation Manager

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GCO - Global Clinical Operations,
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Director - Head of Clinical Operations Latin America, Global Clinical Development - MDS Pharma Services

**ALL REGISTRATIONS WILL BE PROCESSED BY GRUPO UNO EVENTOS**

**CONTACT INFORMATION**

**Meeting: USA**
**Ellen Diegel**
**Phone: +1-215-442-6158**
**email: Ellen.Diegel@diahome.org**

**Brazil and Other Countries:**
**Grupo Uno Eventos**
**Phones: (54 11) 4961-6801**
**email: dia2008@gueventos.com.ar**

**Tabletop Exhibits:**
**Grupo Uno Eventos**
**Phones: (54 11) 4961-6801**
**email: dia2008@gueventos.com.ar**

## *Explore Key Global Issues in Clinical Research*

***November 19, 2008: Two Concurrent Tutorials***

- **How to Set Up and Run a Successful Clinical Research Site**
- **Clinical Project Management: Essential Tools to Optimize Clinical Trial Operations**

***November 20-21, 2008: Full Two-day Conference with Concurrent Sessions***

**Tutorials are limited to 60 participants, so register early!**

**OVERVIEW**

This congress is composed of two pre-congress courses of advanced level and a two-day conference with presentations of topics that go from global to specific details of clinical research. Presentation contents will include ICH and FDA updates, programs of Latin American regulatory guidelines and ethical issues, infrastructure and components of clinical research, and perspectives for the development of clinical research in Latin America.

**WHO SHOULD ATTEND**

This congress is directed at research personnel (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, and others involved directly and/or indirectly in clinical research, or who are considering initiating their activities in this professional area.

***Simultaneous Translation will be available.***

**VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!**

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

## CONCURRENT TUTORIAL #1 8:00 AM–5:30 PM

# How to Set Up and Run a Successful Clinical Research Site

INSTRUCTOR: **Gustavo Luis F. Kesselring,** Hospital Alemao Oswaldo Cruz, Brazil

### Overview

Clinical research is considered to be one of the main driven forces of health sector development in developed countries and clinical trials the most crucial and time-consuming phase of drug development. Clinical trials are performed within clinical research facilities (sites) that can be found in academic health centers, hospitals or ambulatories. A Clinical Research Site well structured and with high performance is a complex activity with multifactorial issues that have to be planned before starting to recruit patients.

### Learning Objectives

This course will provide high level guidelines of how to set-up and run a successful Clinical Research Site. Senior speakers with long standing experience in this field will share with the audience and with FDA their own experience on several topics related to high performance Clinical Research Sites.

### Who Should Attend

Clinical investigators (active and potential), clinical research professionals that work for sponsors, CROs, and SMOs (CRAs and Project Managers), site coordinators, site managers and others involved directly and/or indirectly in clinical research or who are considering initiating their activities in this professional area.

## Tutorial Agenda

**8:00–8:30 AM** REGISTRATION AND CONTINENTAL BREAKFAST

**8:30–9:30 AM** Roles and Responsibilities of the Clinical Investigator
**David A. Lepay, MD, PhD**
FDA, USA

**9:30–10:00 AM** Criteria to Set Up a Clinical Research Site
**Gustavo Luiz F. Kesselring**
Hospital Alemao Oswaldo Cruz, Brazil

**10:00–10:30 AM** Q&A

**10:30–10:45 AM** REFRESHMENT BREAK

**10:45–11:15 AM** Train and Retain Your Clinical Research Staff
**Patrícia Saidon**
University of Buenos Aires, Argentina

**11:15–11:45 AM** Clinical Research Site: Process Controls and Facilities
**Luís Augusto Tavares Russo**
CCBR, Brazil

**11:45 AM–12:15 PM** Budgeting Process: Contracts/Cash Flow and Profitability
**Gustavo Luiz F. Kesselring**
Hospital Alemao Oswaldo Cruz, Brazil

**12:15–12:45 PM** Q&A

**12:45–1:45 PM** LUNCHEON

**1:45–2:15 PM** Quality Management/Developing Your Site SOPs
**Sergio Guerrero**
OCA Hospital/Monterrey International Research Center, Mexico

**2:15–2:45 PM** Implementing an Effective Management of the Clinical Research Site
**Horacio Alberto Ariza**
Azira Clinical Research, Argentina

**2:45–3:15 PM** Q&A

**3:15–3:30 PM** REFRESHMENT BREAK

**3:30–4:00 PM** *Roundtable Discussion:* Implementing Strategies for Patient Recruitment and Retention

PANELISTS
**José R. Zanchetta**
IDIM, Argentina
**Felipe Pinho**
EMS, Brazil
**Jorge Maspero**
Fundacion Cidea, Argentina

**4:30–5:00 PM** Business Development and Marketing Your Site
**Oscar Podesta**
Chiltern International, Inc.

**5:00–5:30 PM** Q&A

**5:30 PM** TUTORIAL #1 ADJOURNED

***Note: The tutorials are limited to 60 participants. Please register early.***

## CONCURRENT TUTORIAL #2 8:00 AM–5:30 PM

# Clinical Project Management: Essential Tools to Optimize Clinical Trial Operations

INSTRUCTOR: **Cris Howard, MBA, MEd,** Emergent BioSolutions, Inc.

### Overview

This full day, hands-on course provides an overview of the essential building blocks of clinical project management. Participants will learn the value that the project management discipline brings to biopharmaceutical clinical research. They'll learn that, with key project management skills, seemingly impossible clinical projects can be achieved. Hidden project risks can be managed. Complex trial budgets can be forecasted. Finally, participants will learn that, even with the ever-changing dynamics of clinical research, project scope can be managed. The course contains a variety of case examples, self-assessments, and small group exercises that are informative and engaging.

### Learning Objectives

At the conclusion of this tutorial, participants will understand:

- The value of clinical project management;
- The essentials of clinical project planning;
- The essentials of clinical project budgeting; and
- The essentials of clinical project management.

### Who Should Attend

This course is ideal for clinical project managers, clinical study managers, clinical research associates and other clinical research professionals who are new to or who would like to optimize their work in the discipline of clinical project management.

## Tutorial Agenda

**7:30–8:00 AM** — REGISTRATION AND CONTINENTAL BREAKFAST

**8:00–8:30 AM** — Welcome and Introductions
- Introductions
- Results of Pre-Course Interest Survey
- Course Objectives

**8:30–9:00 AM** — MODULE 1: What is Clinical Project Management?
- The challenges of product development
- Key definitions
- Characteristics of a successful project manager
- SELF ASSESSMENT: Characteristics of a successful project manager

**9:00–9:30 AM** — MODULE 2: Defining the Clinical Project Scope
- Strategic vision and objectives
- Scope statements

**9:30–9:45 AM** — REFRESHMENT BREAK

**9:45 AM–12:30 PM** — MODULE 3: Planning the Work
- SMALL GROUP EXERCISE: Breaking down the work:
  - o sub-projects
  - o work packages
  - o deliverables
- SMALL GROUP EXERCISE: Work package durations
- SMALL GROUP EXERCISE: Creating a network map
- SMALL GROUP EXERCISE: Producing the schedule
- SMALL GROUP EXERCISE: Critical path compression and managing float

**12:30–1:30 PM** — LUNCHEON

**1:30–1:45 PM** — Review

**1:45–2:30 PM** — MODULE 4: Clinical Project Risk Management
- Risk assessment
- Risk control
- SMALL GROUP EXERCISE: Clinical project risk identification and planning

**2:30–3:30 PM** — MODULE 5: Preparing a Clinical Trial Budget
- Tips and tricks in budget forecasting
- Laying the budget groundwork
- Fixed fees
- Variable fees
- Pass-through costs
- Clinical trial line items
- Stating your assumptions

**3:30–3:45 PM** — REFRESHMENT BREAK

**3:45–4:15 PM** — MODULE 6: Clinical Trial Execution, Monitoring and Control
- The project management triangle
- Investigator score card
- Clinical trial score card

**4:15–4:45 PM** — MODULE 7: Closing the Project
- Project termination
- Team closure
- Lessons learned

**4:45–5:00 PM** — Wrap-up
- REVIEW
- Re-visit: Course objectives/Results of pre-course interest survey
- Summary of lessons learned
- Course evaluation

***Note: The tutorials are limited to 60 participants. Please register early.***

## THURSDAY • NOVEMBER 20

### Scientific Congress Program

**8:00–8:20 AM** — **OPENING REMARKS**

**William Brassington**
DIA Acting Executive Director, USA

**Daniel Ciriano**
Congress Chairperson, Roche, Argentina

**8:20–9:00 AM** — **OPENING LECTURE**

**Trends in Global Clinical Trials: The Role of the Emerging Markets**
**Ronald D. Fitzmartin, PhD, MBA**
DIA Immediate Past President; Daiichi Sankyo, Inc.

### Plenary Session 1

**9:00–10:30 AM** — **PHARMACOGENETIC/PHARMACOGENOMIC STUDIES**

CHAIR
**Analía Pérez,** ANMAT

SECRETARY
**Carlos Caparros,** Schering Plough

**FDA Guidelines on Pharmacogenetics and Pharmacogenomics**
**David A. Lepay, MD, PhD**
FDA, USA

**Ethical and Legal Aspects for Personal Data Protection and the Informed Consent in Pharmacogenetic/ Pharmacogenomic Studies**
**Ignacio Maglio**
Ethics Committee Hospital Muñiz, Fundación Huesped, INCUCAI

**Industry-sponsored Pharmacogenetic Studies**
**James McLeod**
Schering-Plough

**10:30–11:00 AM** — **REFRESHMENT BREAK**

### Plenary Session 2

**11:00 AM–12:30 PM** — **ROUNDTABLE DISCUSSION: FUTURE TRENDS ON THE REGULATIONS IN LATIN AMERICA. WHERE ARE THEY GOING TO?**

CHAIR
**Patricia Saidon,** University of Buenos Aires, Argentina

SECRETARY
**Alicia Arabehety,** Novartis

PANELISTS
**Argentina - ANMAT: Martin Seoane**

**Brazil - ANVISA: Jorge Samaha**

**Peru - INS: Sixto Sanchez**

**Chile - ISP: Ingrid Heitmann**

**12:30–2:00 PM** — **LUNCHEON**

## Concurrent Sessions

### 2:00–3:30 PM CONCURRENT SESSION 1

#### A) Challenges in Protocol Designs

Chair
**Ronald D. Fitzmartin, PhD, MBA**
DIA Immediate Past President; Daiichi Sankyo, Inc.

Secretary
**Nestor Flaster**
CREOS

- **Adaptive Designs**
  **Virginia Sutton**
  i3 Research
- **Conducting Phase 1 Studies in Latin America**
  **Frank LaCreta**
  Bristol-Myers Squibb
- **Biomarkers and Surrogate Endpoints in Clinical Trials Towards Translational Medicine**
  **James McLeod, MD**
  Schering-Plough Research Institute

#### G) Logistics of Clinical Trials in Latin America

Chair
**Roberte Lede**
ANMAT

Secretary
**Diana Valencia**
Latam Clinical Trials

- **Importation and Exportation of Study Supplies and Samples**
  **Victor Hugo Quiñones**
  CAEME
- **Drug and Supplies Storage and Distribution**
  **Diana Mancini**
  Worldcourier Latin America
  **Natalia Montenegro**
  OCASA
  **Fabio Gonzalez**
  Transportes Ambientales
- **Role of the SMOs in Latin America**
  **Francisca Galdon**
  SMO Latin America

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

### 4:00–5:30 PM CONCURRENT SESSION 2

#### B) Drug Safety Risk Management

Chair
**Daniel Ciriano**
Roche, Argentina

Secretary
**Liliana Michieletto**
Novartis

- **Risk Management: Concepts of Global Quality Risk Management – Creating a QRM Environment Cross-Functionally for Clinical Trials**
  **Gabriele Roth**
  Roche Basel
- **Risk Minimization: The Pharmacovigilance of Complex Drugs/Potential High Risk**
  **Ines Bignone**
  ANMAT Pharmacovigilance.
- **Safety Reporting to Ethics Committees and Regulatory Agencies**
  **Fabiana Ibelli**
  CIE FEFYM

#### D) Technologty Tools in Clinical Research

Chairs
**Cecilia Dantuono**
Bristol-Myers Squibb

**Luis Ramirez**
Schering-Plough

- **Electronic Data Capture: Current Experience and Perspectives**
  **Daniel Silvia**
  PhaseForward
- **Latin America Experience with EDC and Use of Electronic Diaries in Clinical Trials**
  **Luis Ramirez**
  Schering-Plough
- **Computerised Systems/Medical Records in Clinical Trials**
  **Earl Hulihan**
  Medidate Solutions, USA

**5:30 PM** THURSDAY ADJOURNED

## FRIDAY • NOVEMBER 21

## Scientific Congress Program

8:00–8:30 AM

### Morning Lecture

**Bridging the Gap Between Different Regulatory Environments**
**Thomas Kuehler**
Medical Products Agency, Sweden; DIA Board of Directors

## Plenary Session 3

8:30–10:00 AM

### Regulatory Framework for Clinical Trials in Latin America

Chairs
**Analía Pérez**
ANMAT
**Sixto Sanchez**
INS

**FDA Requirements for Conducting Clinical Trials in Foreign Countries: Update on New FDA Requirements**
**David A. Lepay, MD, PhD**
FDA, USA

**Inspections in Latin America - ANMAT**
**Maria Laura Pereyra**
ANMAT

**Receiving an FDA Inspection**
**(Roundtable with Investigators from Argentina, Chile and Brazil)**
**Felipe Pinho**
Brazil
**Horacio Croxatto**
Chile
**Horacio Ariza**
Argentina

10:30–11:00 AM

**REFRESHMENT BREAK**

## Plenary Session 4

11:00 AM–12:30 PM

### Pediatric Clinical Trials in Latin America

Chair
**Jaime Altcheh**
Sociedad Argentina de Pediatria, Argentina

Secretary
**Wanda Dobrzansky**
i3 Research

**International Framework of Guidelines and Regulations**
**William Rodriquez**
FDA, USA

**Conducting Clinical Trials in Latin America: Industry/CRO Experience (Vaccines)**
**Patricia Eriksson**
Sanofi-Pasteur

**Challenges in Running Pediatric Clinical Trials: A PI Perspective**
**Aurelia Fallo**
Hospital de Niños Ricardo Gutiérrez

12:30–2:00 PM

**LUNCHEON**

## Concurrent Sessions

### 2:00–3:30 PM CONCURRENT SESSION 1

#### C) Bioavailability (BA) and Bioequivalence (BE) Studies

Chair
**Ricardo Bolaños**
ANMAT

Secretary
**Aníbal Perez Lloret**
FLENI

- **The BE/BA Harmonization in The Americas: Update on the Work by the BE/BA Working Group RED PARF/PAHO**
  **Justina Molzon**
  FDA, USA
- **Roundtable: Regulating BE/BA Studies in Latin America Experience**
  **Argentina: Ricardo Bolaños,** ANMAT
  **Chile: Eduardo Johnson,** ISP
  **Brazil: to be confirmed**

  **Conducting BE/BA Studies in Latin America: A Regional Experience**
  **Ethel Feleder**
  FP Clinical Pharma

#### E) Clinical Trials in Vulnerable Populations

Chair
**Augustino Bisio**
ANMAT

Secretary
**Fernanda Castro Duran**
Pharmanet

- **Legal and Ethical Aspects of the Informed Consent in Special Situations: Psychiatry, Pediatrics, Emergency**
  **Gyselle Tannous**
  CONEP, Brazil
- **The Use of Placebo in Psychiatric Clinical Trials**
  **Maria Lopez-Bresnahan**
  i3 Research
- **Signal Enhancement in Psychiatric Patients**
  **Joep Schoemaker**
  Organon, part of Schering-Plough

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

### 4:00–5:30 PM CONCURRENT SESSION 2

#### F) Outsourcing Clinical Trials in Latin America

Chairs
**Ana Carle**
PRA, Chamber of CROs
**Martín Menendez**
Central Lab

- **The Role of CRO in Latin America**
  **Diego Glanszpiegel**
  Parexel, CRO Chamber Argentina
- **CRO/Industry Interaction: Outsourcing Models**
  **Silvia Zieher**
  MDS Pharma Services, CRO Chamber Argentina
- **Outsourcing the Central Laboratory in Latin America**
  **Fabiola Santelli**
  Laboratorio Hidalgo

#### H) Practical Aspects in the Implementation of Clinical Trials

Chairs
**Adriano Castronuovo**
Novartis
**Bruce Wagman**
Covance

- **Health Economics Outcomes: How to Measure Them?**
  **Xavier Mesrobian**
  sanofi-aventis
- **Use of Patient-reported Outcomes**
  **Bill Sietsema**
  Kendle
- **Strategies for Patient Recruitment and Retention: A Case Study**
  **Nancy Augensen**
  sanofi-aventis

5:45-6:00 PM **CLOSING REMARKS**

**Sergio Guerrero**
DIA Board Directors

**Daniel Mazzolenis**
SAMEFA President

6:00 PM **CONGRESS ADJOURNED**