

Co-sponsors



6th LATIN AMERICAN CONGRESS OF CLINICAL RESEARCH

Current Innovations, Opportunities, and Challenges

Tutorials: September 23, 2009
Conference: September 24-25, 2009

Crowne Plaza Hotel de Mexico
Mexico City, MEXICO

PROGRAM CHAIR

Dr. VANESSA COHEN

Medical Director, Stiefel Mexicana S.A. de C.V.
AMEIFAC, President

SCIENTIFIC AND PROGRAM COMMITTEE

Dr. MARLENE LLOPIZ-AVILES

Regional Director for Latin America,
Venn Life Sciences / CRO Mexicana, S.C.

Dr. JAVIER DE LA VEGA

Medical Coordinator, Stiefel Mexicana S.A. de C.V.

Dr. DAVID SOTRES

Manager, Clinical Administration,
Kendle International

Dr. JOSÉ LUIS VIRAMONTES

Director, PPD Mexico, Central America & the
Caribbean

Dr. SERGIO GUERRERO

OCA Hospital, Mexico

Dr. GUSTAVO KESSELING

Hospital Oswaldo Cruz

Dr. FERNANDA DURAN

Executive Director, Latin America, PharmaNet

PHARMENG ERIKA GENIZ

Pharmacovigilance Manager, sanofi-aventis

Dr. CECILIA CALDERÓN

Local Drug Safety Manager Deputy, Bayer Mexico

Dr. ANA CECILIA POLANCO

Medical Director, AstraZeneca Mexico

LIC. MARIA FELIX RODRIGUEZ

sanofi-aventis Mexico

ALL REGISTRATIONS WILL BE PROCESSED BY
B.P. SERVIMED, S.A. DE C.V. For information:

Conference – USA

Ellen Diegel, Program Manager

Phone: +1-215-442-6158 / Fax: +1-215-293-
5965 / email: Ellen.Diegel@diahome.org

Registration, Hotel, and Exhibits

B.P. Servimed, S.A. de C.V. /
email: ameifac-dia@servimed.com.mx

Register Online

<http://www.servimed.com.mx/AMEIFAC-DIA%202009/index2.htm>

Discuss the Current Innovations, Opportunities, and Challenges in Clinical Research in Latin America

This jam-packed, three-day conference includes two advanced-level pre-congress tutorials and a two-day congress highlighting current innovations, opportunities and challenges in clinical research from a global and regional perspective.

FEATURED TOPICS

- ICH and FDA updates
- Latin American regulatory guidelines and ethical issues
- Infrastructure and components of clinical research
- Perspectives for the development of clinical research in Latin America

PRE-CONGRESS CONCURRENT TUTORIALS

September 23

- **How to Set Up and Run a Successful Clinical Research Site** (8:30 am-5:00 pm)
- **Project Management in Clinical Trials** (8:00 am-5:00 pm)

*Note: Tutorial registration is limited.
Please register early.*

WHO SHOULD ATTEND

- Researchers (clinical, laboratory, site members, and CRAs)
- CROs and SMOs
- Service providers
- Clinical investigators (active and potential)
- Ethics committees
- Regulatory affairs professionals
- Medical education institutions
- Pharmaceutical sponsors

**SIMULTANEOUS TRANSLATION
WILL BE AVAILABLE.**

CONFIRMED SPEAKERS

Dr. Gustavo Kesselring

Hospital Oswaldo Cruz, Brazil

David Lepay, MD, PhD

Office of the Commissioner, FDA, USA

Dr. Luis Russo, CCBR, Brazil

William Sietsema, PhD

Kendle International, USA

Dennis Hurley, PhD

Kendle International, Mexico

Dr. Oscar Podesta

Chiltern International, Inc., Argentina

Dr. Gonzalo de Arbelaz

Progenitor International Research, Argentina

QFB Maria Eugenia Ruiz, Quintiles, Mexico

Elsa Maria Fernanda López

PAREXEL International, Mexico

Dr. Wendy Buckland, PPD, USA

Dr. Yolanda Cervantes, GSK, Mexico

Dr. Jorge Rodríguez-Larrain

Merck & Co, Inc., USA

Dr. Patricia Cervantes Powell

Sanofi Pasteur, Mexico

Dr. Julio Camps, Amgen, USA

Lic. Econ. Areli Lemus, sanofi aventis, Mexico

Dr. Mariano Parma, PPD, Argentina

Dr. Pedro Gutierrez, INP, Mexico

Lic. Hector Arreola, FUNSALUD, Mexico

Dr. Joaquin F. Mould, Pfizer, Mexico

Mto. Atanacio Valencia,

Instituto Nacional de Salud Publica, Mexico

M en C Josefina Mendoza,

Schering-Plough, Mexico

Dr. Maria Lopez-Bresnahan,

i3 Research, Mexico

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

• BASEL, SWITZERLAND • TOKYO, JAPAN • MUMBAI, INDIA • BEIJING, CHINA

WEDNESDAY • SEPTEMBER 23, 2009

7:00-8:30 TUTORIAL REGISTRATION

CONCURRENT TUTORIAL #1

8:30 AM–5:00 PM

How to Set Up and Run a Successful Clinical Research Site

INSTRUCTOR: **Gustavo Kesselring**, Hospital Oswaldo Cruz, Brazil

Clinical research is considered to be one of the main driving forces of health sector development in developed countries and clinical trials are 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 well structured Clinical Research Site with high performance is a complex activity with multifunctional issues that have to be planned before patient recruitment can begin.

Learning Objectives: This course will provide high-level guidelines on 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.

Highlights

- Roles and responsibilities of the clinical investigator
- Criteria to set up a clinical research site
- Train and retain your clinical research staff
- Clinical research site: process controls and facilities
- Budgeting process: contracts/cash flow and profitability
- Quality management/developing your site SOPs
- Implementing an effective management of the clinical research site
- Roundtable: Implementing strategies for patient recruitment and retention
- Business development and marketing your site

CONCURRENT TUTORIAL #2

8:00 AM–5:00 PM

Clinical Project Management: Essential Tools to Optimize Clinical Trial Operations

INSTRUCTOR: **Cris Howard, MBA, MEd**, Emergent Product Development Gaithersburg Inc.

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. Attendees will 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, and the ever-changing dynamics of clinical research 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 identify the value of clinical project management, the essentials of clinical project planning, the essentials of 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.

Highlights

- What is clinical project management?
- Defining the clinical project scope
- Planning the work
- Clinical project risk management
- Preparing a clinical trial budget
- Clinical trial execution, monitoring, and control
- Closing the project

THURSDAY • SEPTEMBER 24, 2009

7:00-8:00 REGISTRATION

8:00-8:15 WELCOME AND OPENING REMARKS

8:15-10:15 PLENARY SESSION

Conducting Global Clinical Trials in Latin America
SESSION CHAIR: **Dr. Marlene Llopiz-Aviles**, Regional Director for Latin America, Venn Life Sciences/CRO Mexicana, S.C.

10:15-10:45 BREAK

10:45-12:15 PHARMACOECONOMY

12:15-13:45 TECHNOLOGY TOOLS IN CLINICAL RESEARCH

13:45-14:45 LUNCH

14:45-15:45 PHARMACOVIGILANCE

15:45-16:15 BREAK

16:15-18:15 PLENARY SESSION

New Outlooks in Clinical Trials for Special Populations with Vaccines, Biotechnology Products, etc.
SESSION CHAIR: **Dr. Cecilia Calderón**, Local Drug Safety Manager Deputy, Bayer Mexico

FRIDAY • SEPTEMBER 25, 2009

7:00-8:00 REGISTRATION

8:00-10:00 PLENARY SESSION ROUNDTABLE

Economic Constraints and Challenges in Latin America: Impact on Conducting Clinical Trials
SESSION CHAIR: **Dr. José Luis Viramontes**, Director, PPD Mexico, Centralamerica & Caribbean

10:00-10:30 BREAK

10:30-12:00 CLINICAL TRIALS IN VULNERABLE PATIENT POPULATIONS

12:00-13:30 OUTSOURCING CLINICAL TRIALS IN LATIN AMERICA

13:30-14:30 LUNCH

14:30-15:30 PHARMACOGENOMICS

15:30-16:00 BREAK

16:00-18:00 PLENARY SESSION ROUNDTABLE

Regulatory Framework for Clinical Trials: Opportunities and Challenges
SESSION CHAIRS: **Dr. Vanessa Cohen**, Medical Director, Stiefel Mexicana S.A. de C.V., AMEIFAC, President;
Dr. Sergio Guerrero, OCA Hospital, Mexico

18:00-18:15 CLOSING REMARKS



6th Latin American Congress of Clinical Research Current Innovations, Opportunities and Challenges

Crowne Plaza Hotel de Mexico

Ciudad de México / Mexico City

September 23 – 25, 2009 / Septiembre 23 al 25 de 2009



FAVOR DE LLENAR ESTA
FORMA A MAQUINA O CON
LETRA DE MOLDE.
PLEASE PRINT OR TYPE

FORMA DE REGISTRO / REGISTRATION FORM

Título/Degrees:	☐ Dr.	☐ Mr.	☐ Ms.	Puesto/Job Title:
Nombre/Name				
Apellido paterno/Family name		Materno/Name		Nombre(s)/Middle initial
Empresa/Company				
Cargo/Charge				
Dirección/Address				
Calle/Street & number		No. Ext.	No. Int.	Colonia/District
Cód. Postal/Zip Code		Ciudad/City	Estado/State	País/Country
()		()		
Teléfono/Telephone		Fax	E-mail (CON LETRA DE MOLDE LEGIBLE)	
Recibo a nombre de/Name's receipt:				
(Sólo en caso de ser a diferente nombre y para efectos fiscales/Only if it is different from the above name)				
Dirección/Address				
Calle/Street & number		No. Ext.	No. Int.	Colonia/District
Cód. Postal/Zip Code		Ciudad/City	Estado/State	País/Country
				R.F.C.

INSCRIPCIONES/Registration Fees: Marque en el espacio correspondiente con una **X** / Please tick in the applicable space **X**

Categoría / Category	Hasta Septiembre 11 de 2009 / Until September 11, 2009	Durante el Evento / On site Registration
Miembros DIA & AMEIFAC Congreso y Curso / Members DIA & AMEIFAC Meeting and Tutorial	☐ USD\$ 600.00	☐ USD\$ 700.00
Miembros DIA & AMEIFAC Congreso / Members DIA & AMEIFAC Meeting only	☐ USD\$ 450.00	☐ USD\$ 550.00
Miembros DIA & AMEIFAC Curso / Members DIA & AMEIFAC Tutorial only	☐ USD\$ 350.00	☐ USD\$ 400.00
No miembros Congreso y Curso / Non members Meeting and Tutorial	☐ USD\$ 750.00	☐ USD\$ 850.00
No miembros Congreso / Non members Meeting only	☐ USD\$ 600.00	☐ USD\$ 700.00
No miembros Curso / Non members Tutorial only	☐ USD\$ 450.00	☐ USD\$ 500.00
Académicos / Non-Profit Academia	☐ USD\$ 100.00	☐ USD\$ 100.00
Autoridades gubernamentales / Regulatory	☐ USD\$ 100.00	☐ USD\$ 100.00
Estudiantes Congreso y Curso / Students Meeting and Tutorial*	☐ USD\$ 500.00	☐ USD\$ 500.00
Estudiantes Congreso / Students Meeting only*	☐ USD\$ 250.00	☐ USD\$ 250.00
Estudiantes Curso solamente / Students Tutorial only*	☐ USD\$ 350.00	☐ USD\$ 350.00

* Se requiere credencial de identificación / I.D. is required

EN CASO DE QUE REQUIERAN RECIBO CON I.V.A. FAVOR DE CONSIDERAR EL 15% DE I.V.A. ADICIONAL A LA CUOTA DE INSCRIPCIÓN

FORMA DE PAGO/PAYMENT FORM Marque en el espacio correspondiente con una **X** / Please tick in the applicable space **X**

☐ Cheque a nombre de/Check payable to: B.P. Servimed, S.A. de C.V. por \$	
Cheque No./Check No.	Banco/Bank
☐ Cargo a su tarjeta de crédito por/Credit charge in the amount of: \$	
El cargo será hecho por/the charge will be made by: B.P. SERVIMED, S.A. de C.V.	
Emisor de la tarjeta/Type of credit card:	☐ American Express ☐ Visa ☐ Master Card
No.de tarjeta/Card number:	
Válido desde/Valid from:	Válido hasta/Expiry date:
Mes/month	año/year
Código de Seguridad/Security Code	
Visa y M.C. los 3 últimos dígitos al reverso en el espacio de la firma American Express 4 dígitos que aparecen a la derecha de la tarjeta Visa and M.C. a 3 digit number found in the back of the card American Express a 4 digit number found in the center right of your card	

Nombre como aparece en la tarjeta/Name of the card holder

Por este pagaré me obligo a pagar a la orden del emisor de mi tarjeta, el importe de este título. Este pagaré procede del contrato de apertura de crédito en cuenta corriente para el uso de tarjeta de crédito que el emisor y el tarjetahabiente tienen celebrado y representa las disposiciones que del crédito concedido hace el suscriptor. Tanto la restitución de la suma dispuesta, como los intereses que causará dicha suma se determinarán y calcularán en la forma, términos y condiciones convenidos en el contrato referido. Este pagaré es negociable únicamente con instituciones de crédito.

By this promissory note I bind myself to the order of the issuer of my credit card. This promissory note derives from the current agreement in regard to the utilization of the credit card entered into by and between the issuer and the credit cardholder and represents the warranties effected by the signer in regards to the credit which was granted. Both the restitution of the amount disposed likewise the interests borne by the aforesaid amount so be fixed are estimated upon the form, terms and conditions agreed in the referred agreement. This promissory note shall only be negotiable through credit institutions.

Fecha/Date: Firma del tarjetahabiente/Signatura of the card holder

6th Latin American Congress of Clinical Research Current Innovations, Opportunities and Challenges



Crowne Plaza Hotel de México
Mexico, City, September 23 – 25, 2009



PLEASE COMPLETE THIS
FORM BY TYPING OR
WRITING IN UPPERCASE
LETTERS
PLEASE PRINT OR TYPE

FAVOR DE LLENAR ESTA
FORMA A MAQUINA O CON
LETRA DE MOLDE.

HOTEL RESERVATION FORM / FORMA DE RESERVACION DE HOTEL

Name / Nombre			
Last name / Apellido paterno		Materno	
Address / Dirección			
Street / Calle		No. Ext.	No. Int.
District / Colonia			
Zip code / Cód. Postal		City / Ciudad	State / Estado
Country / País		Telephone / Teléfono	Fax
Email (CON LETRA DE MOLDE LEGIBLE)			

RESERVATION FORM / RESERVACION DE HOTEL

Mark the corresponding box with an **X** / Marque en el espacio correspondiente con una **X**

Crowne Plaza Hotel de Mexico

- ☐ Single or double room / Habitación sencilla o doble USD \$100.00 plus 17% taxes / más IVA + 2% I.S.H.
- ☐ Executive Floor room / Habitación Piso Ejecutivo USD \$135.00 plus 17% taxes / más IVA + 2% I.S.H.
- (Exchange rate \$11.50 pesos per dollar)

TIPS TO BELL BOYS AND
MAIDS ARE NOT INCLUDED

NO INCLUYE PROPINAS A
CAMARISTAS Y BOTONES

Type of room / Tipo de habitación

- ☐ (1 person, 1 bed) (1 persona, 1 cama) ☐ (2 persons, 1 bed) (2 personas, 1 cama) ☐ (2 persons, 2 beds) (2 personas, 2 camas)

Number of rooms / Número de habitaciones Number of persons in the room / Número de Personas en la habitación

Arrival date / Fecha de llegada: Departure date / Fecha de Salida:

- **ONE NIGHT** deposit plus taxes is required to consider your reservation. The deposit will be credited to your account upon departure, or fill in the credit card information below, authorizing **THE HOTEL** to charge your credit card in case of No-Show. All payments must be in US Dlls or it's equivalency in Mexican Pesos.
- **Changes and cancellations** : Up to **3 weeks before** the arrival date all changes will be subject to availability
- Changes made **one week before the arrival date** will be made through B.P. Servimed. After that date all changes will be made directly in the hotel and will be subject to availability.
- Changes made between **3 WEEKS AND ONE WEEK** before the arrival date which result in a reduction of nights staying will incur in a USD\$50.00 charge.
- Changes in the arrival and departure dates **less than one week prior to arrival** which result in a reduction of nights stayed will be considered as cancellations and will cause the total payment of one night which will be deducted from the initial deposit or will be charged to your credit card.
- Failure to check in at the hotel on your scheduled arrival day will result in forfeiture of your reservation and hotel deposit or credit card charge. The hotel will accommodate you on a space available basis.
- Early departure will result in the charge of one night's room plus tax.
- All cancellations received between **4 WEEKS AND ONE WEEK PRIOR TO THE ARRIVAL DATE** will forfeit in **ONE NIGHT** No-Show PLUS vat.
- When canceling your room reservation, please note the date and time of your call, with whom you spoke and make sure to obtain a cancellation number.
- Your credit card will merely be used as a guarantee in case of a No-Show. Except in case of cancellations, B.P. Servimed will not carry out any charges, as the charge will be made by the hotel upon arrival.

RESERVATION FORM / FORMA DE PAGO

Mark the corresponding box with a **X** / Marque en el espacio correspondiente con una **X**

- ☐ Check payable to / Cheque a nombre de: B.P. Servimed, S.A. de C.V. por \$
- Check no. / Cheque No. Bank / Banco
- ☐ Credit card charge / Cargo a su tarjeta de crédito por: \$
- The charged will by the Hotel in case of No-Show / El cargo será hecho por el Hotel en caso de No Show

Card Issuer / Emisor de la tarjeta: ☐ Visa ☐ Master Card ☐ American Express

Card number/ No. de tarjeta:

Valid from / Válido desde: Expiry date / Válido hasta: Security Code / Código de Seguridad:

Mes / month año / year mes / month año / year

Visa y M.C. a 3 digit number found in the back of the card
American Express a 4 digit number found in the center right of your card
Visa and M.C. los 3 últimos dígitos al reverso en el espacio de la firma
American Express 4 dígitos que aparece a la derecha de la tarjeta

Name of Cardholder / Nombre como aparece en la tarjeta

By this promissory note I bind myself to the order of the issuer of my credit card. This promissory note derives from the current agreement in regard to the utilization of the credit card entered into by and between the issuer and the credit cardholder and represents the warranties effected by the signer in regards to the credit which was granted. Both the restitution of the amount disposed likewise the interests beared by the aforesaid amount so be fixed are estimated upon the form, terms and conditions agreed in the referred agreement. This promissory note shall only be negotiable through credit institutions.

Date / Fecha: Signature of Cardholder / Firma del tarjetahabiente

Please fill in this form and send it immediately to:
Llene esta forma y envíela de inmediato a:



B.P. SERVIMED, S.A. DE C.V.

Barranca del Muerto No. 520, Col. Alpes, 01010 México, D.F.

Tel: + 52 (55) 9171-9570 / Fax: + 52 (55) 5660-1903

E-mail: ameifac-dia@servimed.com.mx / Web page: www.servimed.com.mx/ameifac-dia 2009