OVERVIEW
This congress is composed of an advanced-level, one-day pre-congress course, and a two-day conference with presentations of topics ranging from global to specific details of clinical research. Presentations will include ICH and FDA updates, Latin American regulatory guidelines and ethical issues, infrastructure and components of clinical research, and perspectives for the development of clinical research in Latin America.

LEARNING OBJECTIVES
- Discuss the regulatory principles and procedures in clinical research and interact with the regulatory stakeholders
- Discuss ways 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.
- Describe the Latin America environment related to opportunities of expansion in clinical research.

TARGET AUDIENCE
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, pharma sponsors, and others involved directly and/or indirectly in clinical research, or who are considering initiating their activities in this professional area.

PROGRAM CHAIRPERSON
GUSTAVO LUIZ F. KESSELRING
President, Brazilian Society of Pharmaceutical Medicine, BRAZIL

PROGRAM COMMITTEE
SONIA DAINESI
Manager, Support Center for Clinical Research, Clinicas Hospital, FMUSP, BRAZIL

SÉRGIO NISHIKOA
Manager, Office of New Drugs and Clinical Trials, ANVISA, BRAZIL

EDUARDO MOTTI
Clinical Research Manager, Schering AG, BRAZIL

LUÍS COLLIA
IFAPP President, ARGENTINA

SERGIO SŁAWKĄ
Treasurer Brazilian Society of Pharmaceutical Medicine, BRAZIL

ADOLFO DORENBAUM
Chief Financial Officer, IMIC, MEXICO

EDUARDO FORLÉO
General Manager, Vigiun, BRAZIL

DAGOBERTO BRANDÃO
Director, PHC Consulting, BRAZIL

MARCELO LIMA
General Secretary, Brazilian Society of Pharmaceutical Medicine, BRAZIL

CHARLES SCHMIDT
Director Operations, Latin America PRA International, BRAZIL

MANUEL FRESNO
Director Operations, MDS, SPAIN

WELLINGTON BRIQUES
General Manager, Dr Reddy’s, BRAZIL

LAURA LUCCHINI
Executive Director, Eurotrials BRAZIL

Simultaneous translation will be available in both Portuguese and English

* Good Clinical Practices for the Clinical Research Professional Training Course is limited to 60 participants, so register early!

CONTACT INFORMATION
Tabletop Exhibits: Managing Eventos – Phones 55 11 5587-5232 / 5594-4669
email: managineventos@uol.com.br
Meeting: USA: Julie Ho, Phone +1-215-442-6179/email Julie.Ho@diahome.org
Brazil and other Countries: Managing Eventos – Phone 55 11 5587-5232 / 5594-4669
email: managineventos@uol.com.br

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!
PRE-CONGRESS COURSE
GOOD CLINICAL PRACTICES FOR THE CLINICAL RESEARCH PROFESSIONAL TRAINING COURSE

OVERVIEW
With the goal of helping to ensure well trained clinical investigators and study staff to conduct safe and effective clinical trials, this training course provides the knowledge required to conduct clinical trials, including knowledge about subject safety, regulations, and the practicalities of performing research studies.

MONDAY • SEPTEMBER 25

7:30-8:00 REGISTRATION

8:00-10:15 PART I: ROLES AND RESPONSIBILITIES

Part 1 of the course will outline the drug development process and identify and define the entities and personnel involved in this process. Key topics will include defining the roles and responsibilities of Clinical Investigators, Ethics Committee/IRBs, Institutions, and Sponsors. Material presented will be based upon the regulations from the United States Food and Drug Administration (FDA), International Conference on Harmonization (ICH) Guidelines, as well as industry-accepted best practices.

INSTRUCTORS
Alicia A. Pouncey
Managing Director
Aureus Research Consultants, LLC, UNITED STATES

Robert R. “Skip” Hall, Jr.
Manager, Clinical Site Monitoring, Bristol-Myers Squibb Company
Pharmaceutical Research Institute, Global Development Operations
Regional Clinical Operations - BRAZIL

DISCUSSANT
Patricia Saidon
Pharmacology Professor
Pharmacology Department
University of Buenos Aires, ARGENTINA

8:00-8:30 SESSION 1 – THE ROLE AND RESPONSIBILITIES OF THE CLINICAL INVESTIGATOR

9:00-9:45 SESSION 3 – THE DRUG DEVELOPMENT PROCESS

EXERCISE: WHICH PHASE IS IT?
9:45-10:15 SESSION 4 – THE ROLES AND RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW BOARD / INDEPENDENT ETHICS COMMITTEE

10:15-10:30 REFRESHMENT BREAK

10:30-12:15 PART II: REGULATIONS AND GUIDELINES THAT GOVERN CLINICAL INVESTIGATION

Part 2 of the course will focus upon identifying and defining the regulations that support good clinical practice (GCP) and the ethical conduct of clinical trials. The historical events leading to these Regulations will also be discussed. Specific attention will be directed to the ethical principles that are the basis of reinforcing human subject protection. The course will also define the elements of informed consent and outline the expectations of investigators and staff with the informed consent process.

10:30-11:00 SESSION 5 – REGULATIONS AND GOOD CLINICAL PRACTICE GUIDELINES

11:00-11:20 SESSION 6 – ETHICAL CONDUCT IN CLINICAL RESEARCH

11:20-11:55 SESSION 7 – THE INFORMED CONSENT PROCESS

EXERCISE: INFORMED CONSENT

Note: The Pre-Congress Course is limited to 60 participants. Please register early.

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.
11:55-12:15  SESSION 8 – HISTORY BEHIND HUMAN SUBJECT PROTECTION

12:15-13:00  LUNCHEON

13:00-17:00  PART III: PRACTICES THAT ENSURE EFFECTIVE AND EFFICIENT STUDY CONDUCT

Part 3 highlights the preparation, conduct, and completion of a clinical investigation from the perspective of the Investigator and study site. Topics will include how clinical Investigators can secure clinical trials, best-practices for subject recruitment, as well as offer recommendations for expected interaction with study Sponsors. This final part of the course will also define US regulatory requirements, ICH guidelines, and industry best-practices for study conduct, specifically focusing upon proper adverse event reporting and documentation of trial data. The expectations of the Investigator and site during Sponsor audits and FDA inspections will also be presented.

13:00-13:45  SESSION 9 – STUDY PREPARATION

13:45-14:00  SESSION 10 – STUDY INITIATION

14:00-14:35  SESSION 11 – CONDUCTING THE STUDY: VOLUNTEER RECRUITMENT, RETENTION AND COMPLIANCE

14:35-15:00  SESSION 12 – CONDUCTING THE STUDY: MANAGING MONITOR VISITS

15:00-15:15  REFRESHMENT BREAK

15:15-16:10  SESSION 13 – ADVERSE EVENTS AND SAFETY MONITORING

EXERCISE: IS IT EXPECTED?

16:10-16:25  SESSION 14 – STUDY CLOSURE

16:25-16:50  SESSION 15 – MANAGING A SITE AUDIT

16:50-17:00  FINAL Q AND A

17:00  END OF DAY I
In this session, information about the importance of education in all issues about clinical research: the role of the University in this kind of training and, the importance and needs of postgraduate education in clinical research will be presented. Finally, what is the role and opportunity of Pharmaceutical industry in this matter will be discussed.

**The Role of University in Clinical Research Training**
Jorge Kalil
Full Professor Immunology, School of Medicine, University of São Paulo, BRAZIL

**Is There Room for Post-Graduation Courses?**
Artur Beltrame Ribeiro
Full Professor of Nephrology, Federal University of São Paulo, BRAZIL

**Clinical Research Education as an Opportunity to Pharma Industry Image**
Mauricio Silva de Lima
Medical Director Lilly, BRAZIL

### Financial and Legal Issues in Clinical Research
**Chairperson**
Adolfo Dorenbaum
Chief Financial Officer, IMIC, MEXICO

This session will discuss important issues regarding financial and legal aspects related to clinical trials. Keypoints will be pointed out that occur during a clinical trial and that can generate civil liability. Financial protocols and their interrelations with ethical research committee, investigators and sponsors will be presented. Guidelines on this matter will be presented as well. Civil liability and clinical trials more and more have their relationship increased. So, it is important to discuss actions and procedures that minimize this link. Risk management on this matter will be the keynote of this session.

### Vaccine Development
**Chairperson**
Eduardo Forléo
General Manager, Vigiun BRAZIL

Vaccine studies represent a smaller, but not negligible piece of the total amount of R&D that has been ongoing in Latin America during the last decade. Although deemed as easier to conduct, these studies have specific characteristics, are not simple to implement, and may require the enrollment of thousands of subjects. In addition, as vaccines are closely linked to public health policies their development in Latin America has to take into account local epidemiologic and pharmaco-economic issues. During this session, three experts with different backgrounds will share their expertise in this exciting field.
CONFLICTING BUDGETARY ISSUES IN CLINICAL RESEARCH
Nadine Clausell
Clinical Research Unit, Federal University Rio Grande do Sul, BRAZIL

LEGAL RESPONSIBILITIES FOR INVESTIGATOR/INSTITUTION/SPONSOR IN CLINICAL RESEARCH
Dagoberto Brandão
Director, PHC Consulting, BRAZIL

ETHICAL ISSUES IN FINANCIAL AND LEGAL ASPECTS OF CLINICAL RESEARCH
José Luís Viramontes
Director, Clinical Research, Merck Sharp Dohme, MEXICO

VACCINE RESEARCH IN LATIN AMERICA
Maria Pilar Rubio, MD
Director, Vaccines, Latin America, Novartis, BRAZIL

CHALLENGES IN LARGE-SCALE EFFICACY TRIALS
Rosanna Lagos
Investigator and Coordinator of the Center for Vaccine Development in Chile, CHILE

IMPORTANCE OF CLINICAL TRIALS FOR HEALTH PUBLIC POLICIES
Reinaldo de Menezes Martins
Head Advisor of Clinical Research, Bio-Manguinhos, Fiocruz, BRAZIL

CONFLICTING BUDGETARY ISSUES IN CLINICAL RESEARCH
Nadine Clausell
Clinical Research Unit, Federal University Rio Grande do Sul, BRAZIL

LEGAL RESPONSIBILITIES FOR INVESTIGATOR/INSTITUTION/SPONSOR IN CLINICAL RESEARCH
Dagoberto Brandão
Director, PHC Consulting, BRAZIL

ETHICAL ISSUES IN FINANCIAL AND LEGAL ASPECTS OF CLINICAL RESEARCH
José Luís Viramontes
Director, Clinical Research, Merck Sharp Dohme, MEXICO

VACCINE RESEARCH IN LATIN AMERICA
Maria Pilar Rubio, MD
Director, Vaccines, Latin America, Novartis, BRAZIL

CHALLENGES IN LARGE-SCALE EFFICACY TRIALS
Rosanna Lagos
Investigator and Coordinator of the Center for Vaccine Development in Chile, CHILE

IMPORTANCE OF CLINICAL TRIALS FOR HEALTH PUBLIC POLICIES
Reinaldo de Menezes Martins
Head Advisor of Clinical Research, Bio-Manguinhos, Fiocruz, BRAZIL

WEDNESDAY • SEPTEMBER 27

9:00-10:30
PLENARY SESSION I
CURRENT CHALLENGES IN CLINICAL RESEARCH
CHAIRPERSON
Gustavo Kesselring
President SBMF, BRAZIL

Human subject protection is a basic requirement of clinical research. With the rapid advancement in bio medical research, the issues faced by ethics committees and clinical professionals in addressing and overseeing clinical research are becoming more complex. The pharmaceutical industry is facing an unprecedented challenge in restoring public confidence in the contribution of pharmaceuticals to healthcare and the value of new drug innovation generated by an ethical and quality process of clinical research. In this session panelists from academia and regulatory authorities will present their insights that could impact patient welfare.

CHALLENGES IN BIOETHICS IN CLINICAL TRIALS
Reidar Lie
Department of Clinical Bioethics, NIH National Institutes of Health, USA

CHALLENGES IN QUALITY ASSURANCE AND FRAUD PREVENTION IN CLINICAL TRIALS
TO BE ANNOUNCED
Speaker from FDA, USA

CHALLENGES IN PUBLIC IMAGE OF CLINICAL RESEARCH
Gary L. Chadwick, PharmD
Executive Director, Office for Human Subject Protection
University of Rochester, USA

11:00-12:30
PLENARY SESSION II
STRATEGIC ASPECTS OF CLINICAL RESEARCH IN LATIN AMERICA
CHAIRPERSON
Marcelo Lima
General Secretary SBMF, BRAZIL

The volume of clinical drug development conducted in Latin America is growing rapidly. Major pharmaceutical companies and CROs are expanding staff and increasing business activity in the region. The favorable factors for this exponential growth can be listed as large patient populations, sometimes naïve patients, qualified health professionals, more defined regulatory environment and rising levels of ICH-GCP compliance. However, the Latin America participation on the global clinical research is far behind its full potential. There are yet country-specific technical, regulatory and political barriers to be overcome. The purpose of this session is to discuss and possibly provide alternatives to foster the participation of the major Latin American pharmaceutical markets on the global drug development.

WHERE IS LATIN AMERICA TODAY AND WHERE MAY IT GET TO IN CLINICAL RESEARCH?
Gary L. Chadwick, PharmD
Executive Director, Office for Human Subject Protection
University of Rochester, USA

BARRIERS AND SOLUTIONS FOR THE EXPANSION OF CLINICAL RESEARCH IN LATIN AMERICA
Enrique Isola
Chief Scientific Officer, Region Latin America
Novartis, USA

12:30-13:30
LUNCHEON

10:30-11:00
REFRESHMENT BREAK
13:30-15:00 CONCURRENT SESSION A

ETHICS COMMITTEES IN LATIN AMERICA
CHAIRPERSON
Sonia Maria Oliveira de Barros
Ethics Committee Coordinator, Hospital Albert Einstein, BRAZIL

The recent increase in clinical research in emerging countries imposes new ethical dilemmas for local ethics committees. Lack of training in this area may cause noncompliance with regulations and guidelines and can delay the time to start clinical trials. Brazilian experience in training members to face these new dilemmas will be presented.

This session will also discuss challenges of human subject protection in the developing world and the international experiences in this field with Independent Review Boards (IRBs).

CHALLENGES IN ECs TRAINING
José O. Medina Pestano
Head of Ethics Committee of São Paulo Hospital, UNIFESP, BRAZIL

VULNERABILITY OF TRIAL PATIENTS IN THE DEVELOPING WORLD
Elma Zoboli
Ethics Committee, University of São Paulo, BRAZIL

INTERNATIONAL EXPERIENCE OF INDEPENDENT REVIEW BOARDS
Gustavo Kaltwasser
Former Medical Director, Western IRB, CHILE

15:00-15:30 REFRESHMENT BREAK

15:30-17:00 CONCURRENT SESSION A

SELECTION OF RESEARCH SITES
CHAIRPERSON
Manuel Fresno
Director Operations, MDS, SPAIN

Selection of the right research sites is key for the success of any clinical trial. Research sites usually determine a substantial part of the cost, time and quality of a clinical trial.

TIMING X QUALITY X COSTS
João Fittipaldi
Medical Director, Pfizer, BRAZIL

WHY CHOOSE AN ACADEMIC CENTER?
Décio Mion
Associate Professor, School of Medicine
University of São Paulo, BRAZIL

WHY CHOOSE A NON-ACADEMIC CENTER?
Cristiano Zerbini
Director, Clinical Research Center, Rheumatology Department, Heliópolis Hospital, BRAZIL

15:30-17:00 CONCURRENT SESSION B

CRO-SPONSOR RELATIONSHIP
CHAIRPERSON
Charles Schmidt
Director Operations Latin America, PRA International, BRAZIL

Outsourcing clinical services demands full comprehension of all aspects related to the pharma industry and contract research organizations. Both opportunities and challenges in this relationship will be discussed. Understanding both sides of the issue is basic for the success of the projects and to establish strategic plans for contingencies and best solutions. This session will present the experience of important representatives from pharma and the CRO industry in dealing with this partnership.

SHARING RESPONSIBILITIES BETWEEN INDUSTRY AND CROS
Sebastian Pacios
Vice President, PRA International, USA

CLINICAL RESEARCH TEAMS: PROS/CONS OF INTERNAL STAFF
Jaderson Lima
Medical Director, Sanofi-Aventis, BRAZIL

CLINICAL RESEARCH TEAMS: PROS/CONS OF OUTSOURCING
Andy Strayer
Senior Vice President, PPD Americas/Asia, USA

17:00 WORKSHOP ADJOURNED
HOTEL RESERVATION FORM

Family Name ___________________________________________________________________________________________________
First Name ___________________________________________________________________________________________________
Company _____________________________________________________________________________________________________
Address _______________________________________________________________________________________________________
City _____________________________ State ____________ Zip/Postal Code _____________ Country __________________________
Telephone _____________________________________________________________________________________________________
Fax __________________________________________________________________________________________________________
e-mail _________________________________________________________________________________________________________
(email address required for receipt of reservation confirmation.)

PAYMENT / RESERVATION MUST BE GUARANTEED WITH A CREDIT CARD.
Credit Card Type: MasterCard  Visa  Diners Club  American Express  Other _____________________________________________________
Card Number ____________________________________________________________ Expiration Date ______________________
Name of Card Holder ____________________________________________________________________________________________
Signature _____________________________________________________________________________________________________

ROOM INFORMATION

Please Circle: Standard _____ / Double ______

Single/queen bed ______________________________ Double/twin beds ______________________________

Arrival date ______________________________ Arrival time ______________________________

Department date ______________________________ Departure time ______________________________

Check-in time: 15:00 o’clock, check-out time: 12:00 o’clock.

Fax this form to the fax number listed below for your preferred hotel.

DO NOT FAX HOTEL RESERVATION FORMS TO DIA.

TRAVEL AND HOTEL The most convenient airport is Guarulhos International Airport (GRU), which is approximately 20 miles from the hotels. Attendees should make airline reservations as early as possible to ensure availability. The hotels below are optional (estimated rates); for other information or reservations, contact the hotel offices directly.

Blue Tree Towers Paulista (***)
US$ 103.00 single / US$ 120.00 double

Crowne Plaza (****)
p: (55 11) 3253-7199 – www.ihgplc.com
US$ 180.00 single/double

Della Volpe (****)
US$ 224.00 single/double

Marriott/Renaissance (*****)
US$ 172.00 single / US$ 190.00 double (taxes and breakfast included)
(Special rates for Congress attendees – please include the following ID in the reservation: “DIA/SBMF Congress”).

• Please note – the location of the meeting is within walking or cab distance, more details to follow.

Participants with Disabilities: DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.
3rd Latin American Congress of Clinical Research: 
Topics in Clinical Research and Drug Development

Meeting ID #06901
IEP Hospital Sírio Libanes
Address: Rua Cel. Nicolau dos Santos
69 – BL D - Piso C – Bela Vista, São Paulo, BRAZIL
September 25-27, 2006

September 25, 2006:
GOOD CLINICAL PRACTICES FOR THE CLINICAL RESEARCH PROFESSIONAL TRAINING COURSE
See page 2 for details.

Register online at www.sbmf.org.br
FINANCIAL TRANSACTIONS WILL NOT BE HANDLED BY DIA

CONTACT & TABLETOP EXHIBIT INFORMATION
Attendees may visit the tabletop exhibits during the meeting and during receptions (if applicable).

Meeting information: USA: Contact Julie Ho at the DIA office by telephone +1-215-442-6179, fax +1-215-442-6199 or email Julie.Ho@diahome.org.
Brazil and other countries: Managing Eventos – Phones 55 11 5587-5232 / 5594-4669 / email: managingeventos@uol.com.br
Tabletop exhibit information: Managing Eventos – Phones 55 11 5587-5232 / 5594-4669 / email: managingeventos@uol.com.br.

Registration Fees

Before August 18th, 2006
Pre-Conference Training Course ONLY (Sept. 25th) US$ 350.00
Congress ONLY (Sept. 26th and Sept. 27th ) US$ 500.00
Pre-Conference Training Course + Congress US$ 600.00

After August 18th, 2006 (ONLY ONSITE PAYMENT – CASH IN US$)
Pre-Conference Training Course ONLY (Sept. 25th) US$ 450.00
Congress ONLY (Sept. 26th and Sept. 27th ) US$ 600.00
Pre-Conference Training Course + Congress US$ 700.00

CANCELLATION POLICY: On or before AUGUST 25, 2006
Administrative fee that will be withheld from refund amount:
Meeting = $150
Training = $50
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. For cancellations or substitutions, please email Julie.Ho@diahome.org.

DIA/SBMF reserves the right to alter the venue, if necessary. If an event is cancelled, DIA/SBMF is not responsible for any airfare, hotel or other costs incurred by registrants.