10th Latin American Conference of Clinical Research (2013)

The Role of Clinical Research in the Future of Medicine

October 20-22, 2013 *(Pre-meeting courses: October 20, 2013)*
Maksoud Plaza Hotel | São Paulo, Brazil

SCIENTIFIC PROGRAM CO-CHAIRS

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Medical Director
Amgen, Brazil

Honorio Silva, MD
President
Inter American Foundation for Clinical Research,
New York, NY, USA

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Vice President, Clinical Development Latin America Operations
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Pontificia Universidad Catolica de Chile, Chile

Daniel Mazzolenis, MD
Medical Director, Global Oncology-Hematology,
INC Research Argentina

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

DIA WORLDWIDE HEADQUARTERS
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

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The only truly impartial and global clinical research forum for all stakeholders in the region.

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.

The DIA/SBMF LACCR is the premier educational event in Clinical Research across Latin America, providing the latest information on different related topics. The 2013 Meeting will address the Clinical Research role in the future of medicine and we believe physicians, investigators, nurses, pharmacists, physician assistants, IRB members and other clinical research professionals will have the ability to update their knowledge and skills through state-of-the-art educational sessions and research presentations. Meeting attendees will have opportunities to network and exchange ideas and information with colleagues from Latin America and other countries.

DIA and SBMF are happy to answer any questions you may have about the meeting. DIA and SBMF look forward to seeing you in São Paulo!

FEATURED TOPICS

- Challenges in pediatric clinical research
- Pre-clinical trials
- Regulatory update in clinical research
- Clinical research requirements for biosimilars
- Observational studies
- Epidemiological studies
- Improving site competence in CR
- Registry trials
- Translation research: Brazilian perspective
- Improvement of patient participation in CR
- Health outcome and pace (post approval clinical epidemiology)
- Value proposition and research outcome
- Pharmacovigilance in clinical research
- Safety risk assessment in drug development
- Bioethics
- Competencies for clinical investigators:
- impact on educational programs

EXHIBITION AND SPONSORSHIP

New hosting and marketing opportunities to help you promote your company, products and services to Clinical Research professionals from different countries in Latin America. Please contact us for more information on exhibition areas and sponsorship opportunities.

CONTACT INFORMATION

For more information please contact: www.diahome.org

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

Managing Events: managingeventos@uol.com.br

SBMF Sociedade Brasileira de Medicina Farmacêutica

DIA® www.diahome.org

DAY 1 | PRECONFERENCE TUTORIALS
SUNDAY, OCTOBER 20, 2013

8:30 AM-5:30 PM TUTORIAL #1: RISK MANAGEMENT AND SAFETY COMMUNICATION

COORDINATOR

Nancy D. Smith, PhD
United States

This tutorial will give participants an overview of the current state of risk communication and new initiatives designed to improve communication to promote the safe use of pharmaceuticals. It will also outline new strategies to improve understanding of drug safety concerns among health care providers and to promote better communication to patients. Attendees will learn how to identify strategies in communication during a crisis situation and will discuss the future of drug safety and risk communication worldwide.

8:30 AM-5:30 PM TUTORIAL #2: HANDS-ON THE REGULATIONS FOR CLINICAL TRIALS IN LATIN AMERICA

COORDINATOR

Silvia Zieher, MD
Argentina

This tutorial will outline the latest regulatory developments in the region, and feature speakers giving country-specific updates from Brazil, Argentina, Mexico, Colombia, Chile, and Peru. Key topics will include the main regulations and features, regulatory strategy, preparing submissions, label requirements, and importation of supplies.

DAY 2 | CONFERENCE PLENARY SESSIONS
MONDAY, OCTOBER 21, 2013

7:00-8:00 AM CONFERENCE REGISTRATION

8:00-8:30 AM WELCOME, OPENING COMMENTS AND DIA AWARDS

8:30-8:50 AM OPENING LECTURE

CHAIR

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

CO-CHAIR

Florentino Cardoso, MD
President, Brazilian Medical Association (AMB), Brazil

8:50-9:20 AM
Health Care Improvement through Clinical Research

Otmar Kloiber, MD
Secretary General, World Medical Association (WMA), France

9:20-10:50 AM PLENARY SESSION 1: ROUND-TABLE

Translation Research: The Brazilian Perspective

Because of regulatory and economic environment, Brazil still lags behind in exploring opportunities arising from the basic knowledge. This session will be discussing some of the barriers, and will shed light on some successful examples for a brighter future.

CHAIR

João Batista Calixto, MD
Professor, Federal University of Santa Catarina, Brazil

CO-CHAIR

Sonia Dainesi, MD, MBA, PhD
SBMF, Brazil

9:20-9:40 AM
The Experience of the Federal University of Sao Paulo

João Batista Calixto, MD
Professor, Federal University of Santa Catarina, Brazil

9:40-10:00 AM
The Experience of Santa Casa de Sao Paulo

Thomaz A. Rocha e Silva, MD
Professor, Santa Casa Medical School, Brazil

10:00-10:20 AM
The Experience of Institute Butantan

Ricardo Palacios, MD, PhD
Manager of Clinical Research & Development, Division of Clinical Trials and Pharmacovigilance, Institute Butantan, Brazil

10:20-10:50 AM
Q&A

10:50-11:20 AM COFFEE BREAK

11:20 AM-12:50 PM PLENARY SESSION 2: ROUND-TABLE

The Clinical Research System: Beyond Harmonization—A Role of Regulatory Agencies?

CHAIR

Greg Koski, MD
Co-Founder at Alliance for Clinical Research Excellence and Safety, United States

CO-CHAIR

Honorio Silva, MD
President, Inter American Foundation for Clinical Research, United States

There is growing evidence that the current health care system in the Americas and the clinical research that guides medical decisions are not aligned. The process of generating medical evidence through clinical trials is expensive and lengthy and is supported by a limited infrastructure. Numerous obstacles to producing such evidence have been identified, including the length of time and financial costs involved in conducting clinical trials, delays associated with the many regulatory and ethical requirements, difficulties in recruiting and retaining the appropriate patient population participating in clinical trials and the fragmentation among institutions supporting and/or sponsoring clinical trials. Further, there is often a lack of clarity among investigators regarding the roles and responsibilities of different oversight bodies. Multiple IRB approvals are required for large multicenter multi-country clinical trial and the inconsistencies in IRB determinations and standards across the world further complicate and delay the process of conducting clinical trials. There is a role for regulatory agencies and experts to guide a study through its phases to ensure success. Initiatives to achieve further international regulatory harmonization aiming to ensure quality and minimize the risk of study participants are underway. In spite of significant leverage in clinical research regulation brought up by ICH, additional opportunities for improving the regulatory framework for clinical trials are needed. This session intends to explore such opportunities with leading experts from around the world.

At the end this session, the attendees would be able to:

1. Describe initiatives developed by regulatory agencies in the USA, Europe and Latin America to advance clinical research across countries
2. Describe new regulatory guidance that may impact clinical research
3. Identify challenges and opportunities for a harmonized regulatory system and its alignment to country/regional health care systems

11:20-11:40 AM
The Role of ANVISA in Fostering Clinical Research in Brazil

Alessandro Ferreira do Nascimento, MD
Clinical Research Coordination Expert
Brazilian Health Surveillance Agency (Anvisa), Brazil

11:40 AM -12:00 PM
Is Harmonization an Adequate or Achievable Goal?

Ingrid Klingmann, MD
European Forum for Good Clinical Practice (EFGCP)

12:00-12:20 PM
How can Regulatory Agencies Leverage Effectiveness of the Clinical Trials Enterprise?

Xavier Luria, MD
Senior Consultant, Drug Development and Regulation
Spain

12:20-12:50 PM
Q&A

12:50-2:20 PM LUNCH

DAY 2 | CONCURRENT SESSIONS | MONDAY, OCTOBER 21, 2013

2:20-3:50 PM CONCURRENT SESSIONS

1A Round-table: Accreditation of Clinical Research Sites in Latin America

CHAIR
Diana Valencia, MD
President, LatAm Clinical Trials
President, Association for the Advancement of Clinical Research in Colombia (AVANZAR), Colombia

CO-CHAIR
Flavio Carcano, MD
Clinical Research Unit
Barretos Oncology Hospital, Brazil

The quality and experience of the clinical research sites are fundamental factors for being selected for clinical trials with new drugs. One of the most effective ways to demonstrate quality is to obtain accreditation by a credible institution, or the government. The movement for accreditation of research sites is evolving in Latin America. This session will update the audience on the status of site accreditation initiatives across the region.

2:20-2:40 PM

How Sponsors can Help Sites to be Accredited?
Cecilia Gabarain, MD
Senior Investigator Development Lead, Pfizer Laboratories, Argentina

2:40-3:00 PM

Pitfalls in Clinical Research Accreditation at a Private Hospital
Otavio Berwanger, MD
Director IEP
Hospital do Coração, Brazil

3:00-3:20 PM

Latin American Initiatives for Clinical Research Accreditation
Chiu H. Chen Ogassavara, MD, MBA
Global Clinical Operations
Janssen R&D, Brazil

3:20-3:50 PM

Q&A

1B Round-table: Challenges in Pediatric Clinical Research

CHAIR
José Luiz Egydio Setúbal, MD
President of the José Luiz Egydio Setúbal Foundation
Hospital Infantil Sabara, Brazil

CO-CHAIR
Charles Schmidt, MD
Professor, Santa Casa Medical School, Brazil

In the U.S., BPCA and PREA laws regulate the labeling and encourage pediatric studies in this age group, improving new pediatric information. In June 2012, the Senate and House of Representatives of the United States of America enacted the" Food and Drug Administration Safety and Innovation Act". With this amendment the rules for pediatric drug labeling must comply with the standards established BPCA and PREA, that became permanent and mandatory. This document would clarify the Secretary's authority to award exclusivity for studies conducted pursuant to a written request, including a conforming change for biological products. Furthermore, would require the Secretary, within three years of enactment, to make public the medical, statistical, and clinical pharmacology reviews of written requests made between 2002 and 2007 that resulted in a labeling change. Besides that, would reauthorize the Pediatric Advisory Committee and the Program for Pediatric Study of Drugs and will require a report every five years evaluating the effectiveness of BPCA and PREA. For this reason we need to be more active in increasing the awareness of development Pediatric Clinical Trials in our region too. Latin American countries are in process of revalidating their Pediatric products and also dedicated for more innovation in this field. This session will discuss the challenges and opportunities to implement Pediatric studies in our countries.

2:20-2:40 PM

Challenges for Clinical Research in Pediatric and Neonatal Patients in Korea
Min Soo Park, MD
Director, Clinical Trials Center, Severance Hospital
Yonsei University College of Medicine, Korea

2:40-3:00 PM

Pediatric Drug Development: Where we Have Been and Where we are Going
Barry Mangum, MD
Director Clinical Pharmacology
Duke Clinical Research Unit, United States

3:00-3:20 PM

Experience of a Pediatric Oncology Clinical Research Center in Brazil
Sergio Petrilli, MD
Professor, Federal University of Sao Paulo, Brazil

3:20-3:50 PM

Q&A

3:50-4:20 PM COFFEE BREAK

4:20-5:50 PM CONCURRENT SESSIONS

2A Round-table: Biosimilar Trials: Clinical and Regulatory Issues	2B Round-table: Safety Risk Assessment in Drug Development
CHAIR **Daniel Mazzolenis, MD** Senior Medical Director Global Oncology-Hematology, INC Research, Argentina **CO-CHAIR** **Mr. Octavio Nunes** Communications Director Pharmaceutical Research Industry Association (Interfarma), Brazil	**CHAIR** **Jose Luis Viramontes, MD** Director, Clinical Management PPD Mexico, Central America and the Caribbean, Mexico **CO-CHAIR** **Norbert Clemens, MD** Managing Director & Head of Clinical Development, CRS Mannheim GmbH, Germany
To present the audience with a panorama of main developments in the biosimilars space and how they impact clinical trials in Latin America. The speakers will be presenting different perspectives on clinical trial designs for biosimilars: local LatAm regulatory, industry and the FDA regulatory's point of view. *This Round table will also feature comments from:* **Ines Bignone, MD** Director, Drug Evaluation Agency ANMAT, Argentina	Concerns about drug safety are one of the most important elements to overcome during the drug development process, and drug safety demonstration is nowadays a result of a careful, continuous, and systematic Risk Assessment approach. Safety studies now demand higher efforts, which are needed during all the clinical program, started since the compound selection and extended until the post-marketing follow-up. This is justified based on well known cases of drugs already in the market, that had to be withdrawn due to safety issues not detected or poorly documented during the pre-approval process, with a consequent huge economic and ethical impact. During the session, the principles of safety risk assessment during drug development will be discussed, and participants will learn from the experience of the speakers.
4:20-4:40 PM	**4:20-4:40 PM**
FDA Regulatory Perspective **Leah Christl, MD** Associate Director for Therapeutic Biologics Food and Drug Administration (FDA)**, United States	**Pharmacovigilance Planning in Product Risk Management** **Cecilia Calderon, MD** Former President, Mexican Pharmacovigilance Association (AMFV)
4:40-5:00 PM	**4:40-5:00 PM**
Brazilian Regulatory Perspective **Alessandro Ferreira do Nascimento, MD** Clinical Research Coordination Expert Brazilian Health Surveillance Agency (Anvisa), Brazil	**Latin America Perspective and Experience** **Terezinha Teotonio, MSN, RN** PVG LatAm Manager, Brazil PPD do BRA, Brazil
5:00-5:20 PM	**5:00-5:20 PM**
Clinical Trial Designs Issues for Biosimilars Development **Valdair Pinto, MD** Independent Consultant, Brazil	**US Perspective and Experience** **Nancy D. Smith, PhD** Independent Consultor, United States
5:20-5:50 PM	**5:20-5:50 PM**
Q&A	**Q&A**

**FDA participation contingent on U.S. Government ending operations shutdown

5:50 PM END OF DAY 2

6:00-7:00 PM CONFERENCE RECEPTION

DAY 3 | CONFERENCE PLENARY SESSIONS
TUESDAY, OCTOBER 22, 2013

7:00-8:00 AM CONFERENCE REGISTRATION / DIA COMMUNITIES BREAKFAST*

*See further information on the last page

8:00-8:30 AM WELCOME AND OPENING COMMENTS

8:30-10:00 AM OPENING LECTURE
PLENARY SESSION 3: ROUND-TABLE

Participation in Clinical Trials

CHAIR

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

CO-CHAIR

Merula Emmanoel A. Steagall
President of the Brazilian Association of Lymphoma and Leukemia, Brazil

8:30-8:50 AM

Patient's Perspective
Kin-Ping Tsang
President of the International Alliance of Patients' Organizations, China

8:50-9:10 AM

Brazilian Patient Society's Perspective
Luciana Holtz C. de Barros
President of Oncoguia Institute
Brazil

9:10-9:30 AM

Subject Participation in Clinical Trials
Marianne Pinotti
Secretaria Municipal da Pessoa com Deficiência e Mobilidade Reduzida
São Paulo, Brazil

9:30-10:00 AM

Q&A

10:00-10:30 AM COFFEE BREAK

10:30 AM-12:00 PM PLENARY SESSION 4: ROUND-TABLE

Building a Clinical Research Infrastructure: Impact on Health Care

CHAIR

Honorio Silva, MD
President, Inter American Foundation for Clinical Research, United States

CO-CHAIR

João Paulo Pieroni
Department Manager
Brazilian Development Bank , Brazil

Only 5 to 10 % of all eligible adult patients are engaged in clinical research and challenges in recruiting patients delay the completion of many trials. The process of generating medical evidence through clinical research is slow and inefficient. Moreover, the generalizability of clinical trials results is often challenged by the narrow settings and populations addressed. Thus clinical research and clinical practice should be integrated by creating a patient centered, science driven health care enterprise. A clinical research infrastructure is necessary. National and regional clinical research networks could be built, linking community-based physicians with academic centers in an integrated delivery system. Additionally, new mechanisms for recruiting, informing and engaging patients using social media networks, centralized registries and other means can also substantially improve the efficiency of research. Unified information and data collection systems will be necessary to meet the needs of clinical research and patient care. Proper education, training and certification of the workforce along with involvement and support of the public sector and national regulatory agencies are indispensable.

At the end this session, the attendees would be able to:

1. Describe challenges and hurdles to build a clinical research infrastructure and the multi-sectorial initiatives developed to advance clinical research across countries
2. Identify the components of the clinical research enterprise and describe the impact of centralized country initiatives (Korea) on clinical research and health care
3. Describe the potential advantages for the health care system and the business case for the creation of a global clinical research system

10:30-10:50 AM

Mapping and Engaging Global Clinical Researchers
Gustavo Kesselring, MD
Executive Director, Latin America, ViS Research, Brazil

10:50-11:10 AM

The Country Experience
Min Soo Park, MD
Director, Clinical Trials Center, Severance Hospital
Yonsei University College of Medicine, Korea

11:10-11:30 AM

Creating a Global Clinical Research System: ACRES
Greg Koski, MD
Co-Founder at Alliance for Clinical Research Excellence and Safety, United States

11:30 AM-12:00 PM

Q&A

12:00-1:30 PM LUNCH

DAY 3 | CONCURRENT SESSIONS | TUESDAY, OCTOBER 22, 2013

1:30-3:00 PM CONCURRENT SESSIONS

3A Round-table: Innovation in Executing and Monitoring Clinical Trials

CHAIR
Professor Earl W. Hulihan
CEO and Principal
ew hulihan and associates, inc.

CO-CHAIR
Silvia Zieher, MD
Vice President, Clinical Development, Latin America Operations
INC Research, Argentina

The different applicable regulations for the conduct of clinical trials require the sponsors to monitor clinical trials in order to ensure an adequate protection of research subject rights, safety and welfare as well as to ensure the quality and integrity of the data collected that is going to be submitted with the purpose of marketing applications. With the increased complexity of studies there is a need to focus on the most critical data elements using a risk-based approach to monitoring. The effective integration of data sources and its analysis are key enablers for the innovation aimed at improving efficiencies. The use of computerized systems and the continued digitalization offer unique opportunities for data driven decisions and quality oversight.The aim of this session is to explore the innovation being applied to the execution and monitoring of clinical trials as well as the regulatory agencies perspective on new technologies that will certainly drive significant changes in the approach to increase efficiency and quality of clinical trials for the upcoming years.

1:30-1:50 PM

FDA Perspective on the Use of New Technologies
Jonathan S. Helfgott (via Skype)
Operations Research Analyst
OSI, OC, CDER, FDA**, DHHS

1:50-2:10 PM

Perspective on Electronic Source Data and Study Data Standards
Ron Fitzmartin, PhD, MBA (via Skype)
Senior Advisor, Data Standards Program
Office of Strategic Programs
CDER, FDA

2:10-2:30 PM

Investigator Perspective on the Use of New Technologies and Electronic Source Data
Nelson Kopyt
DO, FASN, FACP, FNKF, CP, Clinical Professor of Medicine
University of South Florida

2:30-3:00 PM

Q&A

3B Health Outcome Research and Post-Approval Clinical Epidemiology Studies

CHAIR
Jaderson Lima, MD
Director, Medical and Scientific Alliances, Sanofi-Aventis, Brazil

CO-CHAIR
Marcelo Lima, MD
Medical Director, Amgen, Brazil

Health systems need to adopt a new clinical research paradigm which should generate efficient data (robustness and quality), from the best available evidence. There is a big gap between what is observed in the studies with academic or regulatory purposes (for registration and marketing authorization of procedures and health products) and medical practice. Hence, there is a need to establish research that creates relevant information obtained from the "real world" for decision-making by patients, physicians, providers, industry and health administrators, ensuring the accuracy required on the design and execution of studies. We have to monitor the efficacy and safety data of products, programs and services with greater focus on the data generated in the places where they are offered (real-life effectiveness). Moreover, decision-making in health care must be based on the evidence generated by taking into account data obtained in the time course of the actions, programs and disease treatments, from the daily medical practice, which have greater relative value and culminate with the improvement of population health. Health Outcome Research (HOR) and Pos-Approval Clinical and Epidemiological Studies (PACES) are the frame of reference of these new clinical research paradigms.

1:30-2:00 PM

Post Approval Clinical Epidemiology Studies (PACES) Main Concepts and Real-life Effectiveness' Research Role in Drug Development and Clinical Decision-making Process
John Sampalis, PhD
McGill University
Montreal, Quebec, Canada

2:00-2:30 PM

Evidence-based Decision-making in Health Care Management: the Role of Real-life Effectiveness Research in Public Health
Hans Fernando Dohmann, MD
Rio de Janeiro City Secretary of Health and Researcher
Fiocruz Foundation, Brazil

2:30-3:00 PM

Q&A

**FDA participation contingent on U.S. Government ending operations shutdown

3:00-3:30 PM COFFEE BREAK

3:30-5:00 PM	CONCURRENT SESSIONS
4A Drug Development in Latin America	**4B** Regulatory Update in Clinical Research in Latin America
CHAIR **João Massud Filho, MD** President Brazilian Society of Pharmaceutical Medicine (SBMF), Brazil **CO-CHAIR** **Charles Schmidt, MD** Professor Santa Casa Medical School Brazil	**CHAIR** **Sergio Guerrero, MD** Accelerium Clinical Research, Mexico **CO-CHAIR** **Lily Gordillo, MSc** Phamacovigilance Ministry of Public Health Guatemala
Since the drug development is even more global it is necessary to explore the possibilities to do it in Latin America. It is expected that after this session the attendees will have a more clear comprehension on how to be engaged on it.	This session will provide an overview of the Latin American countries regulators current aspects on Clinical Research and Development and the impact on the review process. Don't let pass this opportunity to address any related question to the speakers based on your regional experience. We invite you to attend and meet personally our regional regulators from Colombia, Ecuador, and Peru.
3:30-3:50 PM	3:30-3:50 PM
Preclinical Studies **João Batista Calixto, MD** Professor, Federal University of Santa Catarina, Brazil	**Peruvian Regulatory Update** **Hans Vasquez** Clinical Review Coordinator Direccion General de Medicamentos Insumos y Drogas (DIGEMID) Ministerio de Salud, Peru
3:50-4:10 PM	3:50-4:10 PM
Drug Development in Argentina - An Example **Fernando Goldbaum, PhD** Director, Institute Leloir, Argentina	**Argentinean Regulatory Update** **Ines Bignone, MD** Director of Drugs Evaluation ANMAT, Argentina
4:10-4:30 PM	4:10-4:30 PM
Business and Scientific Opportunities for Drug Development in Latin America **Clarice Sztajnbok, MD** Vice President, Medical Affairs, Sanofi, Brazil	**Central American Countries Regulatory Update** **Lily Gordillo, MSc** Phamacovigilance Ministry of Public Health Guatemala
4:30-5:00 PM	4:30-5:00 PM
Q&A	Q&A

5:00 PM CONFERENCE ADJOURNED

DIA Community Breakfast

October 22, 2013 | 7:00-8:00 AM
Maksoud Plaza Hotel
Tocantins Room – Convention Center – Floor A

Please join us for breakfast to learn about DIA Communities around the world. DIA Communities are discipline-specific, global groups where DIA/SBMF members can share common experiences and knowledge and connect with others in their particular field. This breakfast will mark the kickoff for the DIA Communities Initiative in the Region.