

Emerging **REGULATORY** Issues in Genomic Medicine

MAY 21-23, 2008 | Hotel Royal Pedregal, Mexico City, MEXICO

PROGRAM CHAIRPERSON

FEDERICO GOODSAD, PhD

Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research (CDER), US FDA

PROGRAM COMMITTEE

A.S. DAAR, FRS (C), DPhil(Oxon), FRCP (Lon), FRCS, FRCS

Senior Scientist and Co-director, Program on Life Sciences, Ethics and Policy, McLaughlin-Rotman Centre for Global Health, University Health Network; Professor of Public Health Sciences and Professor of Surgery, University of Toronto; Director of Ethics and Policy, McLaughlin Centre for Molecular Medicine, Canada

FELIX FRUEH, PhD

Associate Director, Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research (CDER), US FDA

GERARDO JIMÉNEZ-SÁNCHEZ, MD, PhD

Director General, National Institute of Genomic Medicine (INMEGEN), Mexico; Chair, Working Party on Biotechnology, Organization for Economic Co-Operation and Development (OECD)

LAWRENCE LESKO, MD

Director, Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research (CDER), US FDA

BÉATRICE SÉGUIN, PhD

Lead, Human Genomic Variation and Global Health, Program on Life Sciences, Ethics and Policy, McLaughlin-Rotman Centre for Global Health; Assistant Professor, Leslie Dan Faculty of Pharmacy, Canada

CONTACT INFORMATION

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email Ellen.Diegel@diahome.org

CONFERENCE OVERVIEW

The purpose of this meeting is to identify synergies and common issues in Genomic Medicine and to develop common approaches to address these issues. The FDA has a major effort in the area of genomics and personalized medicine. It is working with clinicians, the pharmaceutical industry, and other regulatory agencies worldwide to integrate genomic medicine into medical practice.

SESSIONS

- ▶ Current work in pharmacogenomics in Latin America and other developing countries
- ▶ Application of pharmacogenomic information in health delivery throughout Latin America and other developing countries
- ▶ Issues associated with the application of genomic medicine
- ▶ Expansion by the FDA of the geographical scope of pharmacogenomics as part of a commitment to international communities to help them reap the benefits of genomics
- ▶ Identification of genomic health problems common between the US and Latin America
- ▶ Discussion of global diversity in the context of the underlying genetics and the sources of variability in sensitivity to disease and therapeutic response between ethnic groups
- ▶ Generation of pharmacogenomic data on Latino populations in the US and elsewhere
- ▶ Sharing knowledge about pharmacogenomic case studies such as warfarin with countries unable to provide infrastructure for these studies
- ▶ Application of cost effective pharmacogenomic testing in Latin America
- ▶ Focus on high priority health problems such as infectious diseases about which we can learn much in the US about other areas in the world
- ▶ Educational efforts to inform Latin American doctors and patients about potential benefits of Genomic Medicine
- ▶ Interest in adverse event tracking at the FDA extending to ethnically diverse populations
- ▶ Assessment of how pharmaceutical drug development is done in Latin America
- ▶ Harmonization of clinical study data generation between participant countries

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LEARNING OBJECTIVES At the conclusion of this conference, participants should be able to:

- ▶ Identify synergies and common issues associated with the application of Genomic Medicine,
- ▶ Discuss genomic health problems common between participant countries and the current work in pharmacogenetics in Latin America and other developing countries,
- ▶ Identify the FDA's effort to integrate genomic medicine into medical practice world-wide.

WEDNESDAY • MAY 21, 2008

10:00-11:45 AM REGISTRATION

11:45 AM-1:45 PM **JOINT LUNCHEON SESSION:
BIOTECHNOLOGY MEDICATIONS**

SESSION CHAIRPERSON

Deputy Ector Jaime Ramírez Barba

President of the Health Commission, Chamber of Deputies Mexican Congress, Mexico

KEYNOTE PRESENTATION

(Keynote presentation is not eligible for IACET credits.)

Dr. José Ángel Córdova Villalobos

Minister of Health, Government of Mexico

APPLICATION OF BIOTECHNOLOGY TO PRODUCT DEVELOPMENT

Carol F. Kirchhoff

Senior Principal Scientist, Global Biologics Pharm R&D, USA

Dr. Thomas Schreitmuller

Director, Research & Development Biotech Products
F. Hoffmann-La Roche, Switzerland

EMERGING DISEASES AND DRUG THERAPIES

Mario Melgar, PhD

Associate Attorney, Cacheaux, Cavazos & Newton, L.L.P.

PANEL DISCUSSION AND COLLABORATIVE EFFORT:

LATIN AMERICA'S ROLE – THE PATH FORWARD

1:45-4:45 PM SESSION 1

**PHARMACOGENOMICS: BENEFITS AND CONCERNS IN
MEDICINE**

PLENARY SESSION: KEYNOTE PRESENTATIONS

SESSION CHAIRPERSON

Gerardo Jiménez-Sánchez, MD, PhD

Director General, National Institute of Genomic Medicine (INMEGEN), Mexico
Chair, Working Party on Biotechnology, OECD

1:45-2:15 PM

ESTABLISHING THE PATHWAY TO PERSONALIZED HEALTH CARE

Gregory Downing, DO, PhD

Program Director, Personalized Health Care, Immediate Office of the Secretary, Department of Health and Human Services, USA

2:15-2:45 PM

PHARMACOGENETICS: SUCCESSFUL PHARMACEUTICAL EXAMPLES DURING DEVELOPMENT AND POSTMARKETING RISK MANAGEMENT
Allen Roses, MD

Jefferson-Pilot Professor of Neurobiology and Genetics Professor of Medicine (Neurology); Director, Deane Drug Discovery Institute; Senior Scholar, Fuqua School of Business, R. David Thomas Executive Training Center, Duke University, USA

2:45-3:15 PM

SUCCESS AND FAILURES OF GENOMIC MEDICINE IN DEVELOPING A DEVELOPING WORLD TO FIND SOLUTIONS

Nirmal Ganguly

Former Director General, Indian Council for Medical Research (ICMR), India

3:15-3:45 PM

LARGE-SCALE GENOTYPING PROJECTS IN DEVELOPING COUNTRIES AND EMERGING ECONOMIES

A.S. Daar, FRS (C), DPhil (Oxon), FRCP (Lon), FRCS, FRCS

Co-director, Program on Life Sciences, Ethics and Policy, McLaughlin-Rotman Centre for Global Health, UHN/University of Toronto, Canada

3:45-4:15 PM

PHARMACOGENETICS FOR EVERY COUNTRY INITIATIVE
Howard McLeod

Fred N. Eshelman Distinguished Professor, Director, UNC Institute for Pharmacogenomics and Individualized Therapy, University of North Carolina, USA

4:15-4:45 PM

Gerardo Jiménez-Sánchez, MD, PhD

Director General, National Institute of Genomic Medicine (INMEGEN), Mexico
Chair, Working Party on Biotechnology, OECD

4:45-5:00 PM REFRESHMENT BREAK

5:00-6:30 PM SESSION 2

SUCCESSES AND CHALLENGES IN PHARMACOGENOMICS

SESSION CHAIRPERSON

Michael S. Phillips, PhD

Canada Research Chair in Translational Pharmacogenomics, Director of Pharmacogenomics, Genome Quebec, Associate Professor, Université de Montréal

5:00-5:20 PM

PHARMACOGENOMICS IN TRANSITION: FROM CLINICAL STUDIES TO PUBLIC POLICY.

Michael S. Phillips, PhD

Canada Research Chair in Translational Pharmacogenomics, Director of Pharmacogenomics, Genome Quebec, Associate Professor, Université de Montréal

5:20-5:40 PM

STRUCTURAL VARIATION IN THE HUMAN GENOME

Lars Feuk, PhD

Research Associate, The Hospital for Sick Children,
MaRS Centre, Canada

5:40-6:00 PM

HUMAN GENETIC VARIATION AND HEALTH OUTCOMES

David Cox

Perlegen Sciences, Inc., USA

6:00-6:20 PM

Sandy Close-Kirkwood

Eli Lilly and Company, USA

THURSDAY • MAY 22, 2008

7:00-8:00 AM

REGISTRATION AND
CONTINENTAL BREAKFAST

8:00-10:05 AM

SESSION 3

POPULATION GENOMICS PROJECTS

SESSION CHAIRPERSON

A.S. Daar, FRS (C), DPhil (Oxon), FRCP (Lon), FRCS, FRCS

Director of Ethics and Policy
McLaughlin Centre for Molecular Medicine, Canada

8:00-8:25 AM

MEXICO

Alfredo Hidalgo, PhD

National Institute of Genomic Medicine, INMEGEN, Mexico

8:25-8:50 AM

ASIA-PACIFIC

Ed Liu, PhD

Executive Director, Genome Institute of Singapore

8:50-9:15 AM

INDIA

Samir Brahmachari, PhD

Director, Institute of Genomics and Integrative
Biology (CSIR), India

9:15-9:40 AM

ESTONIA

ESTONIAN BIOBANK AS RESEARCH INFRASTRUCTURE FOR
POPULATION GENOMICS

Andres Metspalu, PhD

Professor of Biotechnology of IMCB
Director of the Estonian Genome Project of University
of Tartu and Estonian Biocentre, Estonia

9:40-10:05 AM

SOUTH AFRICA

Dr. Raj Ramesar

Division of Human Genetics, Institute of Infectious Disease
and Molecular Medicine
UCT Faculty of Health Sciences, South Africa

10:05-10:30 AM

REFRESHMENT BREAK

10:30 AM-1:00 PM SESSION 4

REGULATORY ISSUES IN GENOMIC MEDICINE

SESSION CHAIRPERSON

Felix Frueh, PhD

Associate Director, Genomics Group, Office of Clinical
Pharmacology, Office of Translational Science
Center for Drug Evaluation and Research
U.S. Food and Drug Administration, USA

10:30-11:00 AM

US

Felix Frueh, PhD

Associate Director, Genomics Group, Office of Clinical
Pharmacology, Office of Translational Science,
Center for Drug Evaluation and Research
U.S. Food and Drug Administration, USA

11:00-11:30 AM

EUROPE

Bruno Flamion

Chairman, EMEA Scientific Advice Working Party
Federal Agency for Medicinal and Health Products, Belgium

11:30 AM-12:00 PM

JAPAN

Yoshiaki Uyama, PhD

Review Director, Office of New Drug III, Pharmaceuticals and
Medical Devices Agency (PMDA), Japan

12:00-12:30 PM

DIAGNOSTICS

Janet A. Warrington, PhD

Consultant, Science and Health Policy

12:30-1:00 PM

PANEL DISCUSSION

1:00-2:00 PM

NETWORKING AND LUNCHEON

2:00-4:30 PM

SESSION 5

**INFRASTRUCTURE FOR DEVELOPMENT OF GENOMIC
MEDICINE**

SESSION CHAIRPERSON

Dr. Guillermo Soberón Acevedo

President of the Council of the National Commission of
Bioethics, Mexico

2:00-2:15 PM

DEVELOPMENT OF GENOMIC MEDICINE IN MEXICO

Dr. Guillermo Soberón Acevedo

President of the Council of the National Commission of
Bioethics, Mexico

2:15-2:40 PM

WAYS AND MEANS FOR THE DEVELOPMENT OF GENOMIC
MEDICINE IN MEXICO

Dr. Julio Frenk Mora

Executive President, Institute CARSO Health Institute, Mexico

2:40-3:05 PM

GENOMIC MEDICINE IN THE CONTEXT OF HEALTH PRIORITIES IN MEXICO
Lic. Antonio López de Silanes
 Chief Executive Officer, Silanes Laboratories S.A. of C.V., Mexico

3:05-3:30 PM

ETHICAL, LEGAL AND SOCIAL ISSUES IN THE DEVELOPMENT OF GENOMIC MEDICINE IN MEXICO
Mtro. César Francisco Lara Alvarez
 Coordinator ELSI Research Center
 National Institute of Genomic Medicine (INMEGEN), Mexico

3:30-4:00 PM

INTELLECTUAL PROPERTY AND DEVELOPMENT OF A NATIONAL INCUBATOR INFRASTRUCTURE FOR GENOMIC MEDICINE
Lic. Jorge Amigo Castañeda
 Director General, Mexican Institute of Industrial Property, Mexico

4:00-4:30 PM **PANEL DISCUSSION**

5:30-7:00 PM **NETWORKING DINNER**

FRIDAY • MAY 23, 2008

7:00-8:00 AM **REGISTRATION AND CONTINENTAL BREAKFAST**

8:00 AM-12:00 PM **SESSION 6**

PHARMACOGENOMIC BIOMARKERS IN THE PHARMACEUTICAL INDUSTRY

SESSION CHAIRPERSON

Linda Surh, MD, PhD
 Director, CEDD Global Regulatory Affairs, Neurology and Pharmacogenetics, GlaxoSmithKline, UK

8:00-8:30 AM

DEVELOPING NEW MEDICINES WITH BIOMARKERS: WHY, WHEN AND HOW TO FIT FOR PURPOSE ON THE PIPELINE
Linda Surh, MD, PhD
 Director, CEDD Global Regulatory Affairs, Neurology and Pharmacogenetics, GlaxoSmithKline, UK

8:30-9:00 AM

SAFETY BIOMARKERS: TRANSLATION FROM ANIMALS TO HUMANS WITHIN AN INDUSTRY CONSORTIUM
Jacky Vonderscher
 Senior Vice President, Global Head of Roche Molecular Medicine, France

9:00-9:30 AM

EXPERIENCES WITH THE REGULATORS IN VGDS USING 'OMIC BIOMARKERS: GENOMICS, PROTEOMICS AND METABOLOMICS IN DRUG DEVELOPMENT
Dr. Ansar Jawaid
 Global Skills Group Leader, Statistical Genetics, Research & Development Genetics, AstraZeneca, UK

9:30-10:00 AM

NEW USE FOR A KNOWN BIOMARKER: SELECTING PATIENTS FOR A TARGETED THERAPEUTIC IN ONCOLOGY
Scott Patterson, PhD
 Executive Director, Medical Sciences
 Amgen, Inc, USA

10:00-10:30 AM **REFRESHMENT BREAK**

10:30-11:00 AM

PIVOTAL STUDIES FOR REGULATORY SUBMISSIONS USING PGX BIOMARKERS
Richard Deane Hockett
 Eli Lilly and Company, USA

11:00-11:30 AM

ONCOLOGY PGX BIOMARKERS: PUTTING THE BIOMARKER SPECTRUM INTO CONTEXT FROM BENCH TO NEW MEDICINE TO BEDSIDE
Clet Niyikiza
 Oncology Strategic Asset Management, GlaxoSmithKline

11:30 AM-12:00 PM **PANEL DISCUSSION**

12:00-1:00 PM **NETWORKING OPPORTUNITY AND LUNCHEON**

1:00-5:30 PM **SESSION 7**

SYNTHESIS WORKSHOP

SESSION CHAIRPERSON

Federico Goodsaid, PhD
 Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research, US Food and Drug Administration, USA

1:00-1:45 PM

COMMON CHALLENGES IN GENOMIC MEDICINE
Janet A. Warrington, PhD
 Consultant, Science and Health Policy

1:45-2:30 PM

APPROACHES TO CHALLENGES IN GENOMIC MEDICINE
Gerardo Jiménez-Sánchez, MD, PhD
 Director, National Institute of Genomic Medicine (INMEGEN), Mexico

2:30-3:00 PM **REFRESHMENT BREAK**

3:00-3:45 PM

IMPLEMENTATION OF SOLUTIONS IN GENOMIC MEDICINE
A.S. Daar, FRS (C), DPhil (Oxon), FRCP (Lon), FRCS, FRCS
 Director of Ethics and Policy, McLaughlin Centre for Molecular Medicine, Canada

3:45-4:30 PM

ACTION ITEMS
Federico Goodsaid, PhD
 Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research, US Food and Drug Administration, USA

4:30-5:30 PM

CONSENSUS STATEMENT
Magdalena Skipper, PhD
 Chief Editor, *Nature Reviews Genetics*

5:30 PM **CONFERENCE ADJOURNED**

EMERGING REGULATORY ISSUES IN GENOMIC MEDICINE

May 21 – 23, 2008 / 21 al 23 de Mayo de 2008
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Category / Categoría	Before May 12, 2008/ Hasta Mayo 12 de 2008	On Site Registration/ Durante el Evento
NON-LATIN AMERICAN INDUSTRY	<input type="checkbox"/> \$ 1,500.00 USD	<input type="checkbox"/> \$ 1,752.00 USD
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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

- A 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. 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.
- Failure to check in at the hotel on your scheduled arrival day will result in forfeiture of your reservation and hotel deposit. The hotel will accommodate you on a space available basis.
- Early departure will result in the charge of one night's room plus tax.
- Reservations cancelled between 4 WEEKS AND ONE WEEK PRIOR TO ARRIVAL will incur a USD \$ 50.00. Full cancellations received ONE WEEK PRIOR TO ARRIVAL will result in forfeiture of full deposit.
- 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.

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Check No./Cheque No. Bank/Banco

Credit charge in the amount of /Cargo a su tarjeta de crédito por \$
The charge will be made by the Hotel/El cargo será hecho por el Hotel en caso de No Show

Type of credit card /Emisor de la tarjeta: Visa Master Card American Express

Card number/No. de tarjeta:

Security Code/
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Month/mes year/año

Expiry date/Válido hasta
month /mes year /año

Visa and M.C. a 3 digit number found in the back of the card
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Visa y 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

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