



Buenos Aires

8TH ISoP ANNUAL MEETING
2008

“Strategies for developing Pharmacovigilance”

5th - 8th of October 2008 - Buenos Aires - Argentina

PRELIMINARY SCIENTIFIC PROGRAMME



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

www.isop2008.org

8TH INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE MEETING

“Strategies for developing Pharmacovigilance”

Sponsorships:

Pan American Health Organization (PAHO)
Argentine Ministry of Health
Argentine Ministry of Foreign Affairs

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Beatriz Cardoso, Pharm.
Roberto Diez, MD
Raquel Herrera, MD
Pedro Lipszyc, MD

Venue: *Sheraton Buenos Aires Hotel & Convention Center*

Sunday 5th October 2008. **Pre-Conference Courses**

Monday 6th October, Tuesday 7th October and Wednesday 8th October 2008.

8th ISoP Annual Meeting

Lunch and two coffee-breaks included every day.

Deadline abstract submission:

29TH JUNE 2008.

please note that this deadline cannot be extended



8TH ISoP ANNUAL MEETING

“Strategies for developing Pharmacovigilance”

Simultaneous translation English-Spanish and Spanish-English in all parallel and plenary sessions

International Speakers

Plenary sessions

Michael Rawlins, National Institute for Health and Clinical Excellence (NICE), UK
Gerald Dal Pan, Director of Center for Drug Evaluation and Research, Food and Drug Administration, U.S.A.

Ralph Edwards, Director of Uppsala Monitoring Centre (UMC), Sweden

Parallel sessions

Francisco de Abajo (National Agency, Spain)
Dora Akunyili (National Agency, Nigeria)
Nelson Arboleda (CDC, U.S.A.)
Priya Bahri (EMEA)
Jürgen Beckmann (Germany)
Miles Braun (CBER, FDA, U.S.A.)
Ralph Edwards (UMC, Sweden)
Brian Edwards (NDA, United Kingdom)
Adolfo Figueras (Sant. Compostela Univ., Spain)
Murilo Freitas Dias (Anvisa, Brazil)
Ulrich Hagemann (National Agency, Germany)
Kenneth Hartigan-Go (The Zuellig Foundation,
The Philippines)
Eveline Jaquenoud-Sirot (Psych. Clinic
Königsfelden, Switzerland)
Brigitte Keller-Stanislawski
(Paul Ehrlich Institute, Germany)
Anastasios Konstantidinis, (AMSP, Austria)
Carmen Kreft-Jais (AFSSAPS, France)
Xavier Kurz (EMEA)
Joan-Ramon Laporte (FICF, Spain)
Hervé Le Louët (Pharm. Regional Centre, Creteil,
France)

Marie Lindquist (UMC, Sweden)
Paula Márquez (Ministry of Health, Spain)
Ronald Meyboom (UMC, Sweden)
Aparna Mohan (J&J, U.S.A.)
Nicholas Moore (University of Bordeaux,
France)
José Antonio Pagés (PAHO)
E van Puijenbroek (Lareb Centre,
The Netherlands)
Valerio Reggi (IMPACT, WHO)
Eliana Rodrigues (San Pablo Univ., Brazil)
Klaus Rose (Hoffmann La Roche,
Switzerland)
Lavinia Schuler-Faccini (Rio Grande do Sul
Fed. Univ., Brazil)
Debbie Shaw (Guy's & St Thomas' NHS
Foundation Trust, United Kingdom)
Saad Shakir (DSRU, United Kingdom)
Peter Schulz (IH4SM, Switzerland)
Thierry Trenque (Pharm. Regional Centre,
Reims, France)
Jan-Willem van der Velden (Pharmanet
Switzerland)
Giampaolo Velo (University of Verona, Italy)

Registrations

ISoP 2008 General Secretariat: secretaria@mariagraziani.com

Tel: (011) 4394 77-26/ 4394-3437 / Fax: (011) 4394- 3436 / www.isop2008.org

Sunday, 5th October 2008, 9 a.m. to 6 p.m - Pre-Conferences Courses

I. Pharmacovigilance, from fundamental basis to practice

Pharmacovigilance is a scientific activity of growing interest for Public Health, health economy, health insurance organizations, pharmaceutical industry and not least of all for clinicians and patients.

This pre-conference course is intended to introduce health professionals into the Pharmacovigilance field making a big awareness of the importance of this discipline in their current activity. The course is also intended to give to those that are currently working in Pharmacovigilance a global overview of the current and future trends and development about clinical safety, medicines safety and pharmacovigilance methods, regulatory framework and upcoming regulations and the state of the art of benefit/risk decisions. Because the foundations and basis are key elements for the well understanding and further development of any knowledge, the speakers for this pre-conference course are well known experts in each field. We will be honored to offer you to share a full-time working day with this excellent team!

Language: English / Spanish. Simultaneous translation.

Topics

- Historical background.
- Concepts in pharmacovigilance: state of the art.
- Effectiveness failure
- Regional differences in ADR reporting
- Pharmacovigilance from industry perspective
- Pharmacoepidemiology
- Risk-Benefit evaluation

Faculty

Presentation

Luis Alesso

University of Córdoba, Argentina

Speakers

Marie Lindquist

Uppsala Monitoring Centre, Sweden

Nicholas Moore

Department of Pharmacology
University of Bordeaux, France

Ronald Meyboom

Uppsala Monitoring Centre, Sweden

Paula Márquez

Ministry of Health, Spain

Jan-Willem van der Velden

Global Safety and Pharmacovigilance, Pharmanet,
Switzerland

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II. Drug-related Risk Management

Knowledge of the safety profile of new drugs changes rapidly after marketing, in terms of profile and number of patients exposed within a short time frame. In November 2004, the International Council of Harmonisation issued a landmark document on pharmacovigilance planning, which profoundly changed the approach of drug safety. Based on this concept, Japan, the US, the EU and other countries are now requiring drug manufacturers to develop risk management activities to be discussed at the time of authorization.

This comprehensive course will provide insight into the concept and practice of drug-related risk management. Learning objectives include the understanding of the need, principles and components of risk management, its application in the US, the EU and Latin America, the challenges that are being met and the proposed solutions, practical aspects of implementation for both regulators and the industry, and future perspectives and developments in special circumstances. Practical recommendations for the development and submission of risk management plans will also be provided by an industry representative with a large experience in this field.

The course will be very helpful to members of regulatory authorities, pharmaceutical industry and academia who are or will be involved in the organization, preparation, assessment or implementation of risk management activities. Prior knowledge of the basic concepts of pharmacovigilance would be useful, although not necessary.

Language: English (no simultaneous translation will be available).

Topics

- Why do we need risk management?
- Concept and components of risk management.
- Risk management in the United-States: the REMS.
- Risk management in Europe: the EU-RMP.
- Risk management in Latin America.
- Risk management from an Industry perspective.
- Risk mitigation and its measurement.
- How to prepare a risk management plan/strategy?
- Improvements and future developments.
- Perspectives for risk management in Latin-America.

Faculty

Chair

Xavier Kurz (EMA)

Speakers

Miles Braun

Division of Epidemiology, OBE, CBER, FDA

Gerald Dal Pan

Office of Drug Safety, Center for Drug Evaluation and Research (CDER), FDA

Xavier Kurz

Risk Management Team, EMA

Aparna Mohan

Benefit Risk Management, Johnson and Johnson

Analia Pérez

Director of Medicines Evaluation, (ANMAT)

8TH ISoP Annual Meeting

Monday, 6th October – 9 a.m. to 6 p.m.

Plenary session morning

Opening of the 8th Annual ISoP Meeting
 Nicholas Moore, *President of International Society of Pharmacovigilance (ISoP)*
 Luis Alesso, *President of Argentinian Society of Pharmacovigilance (SAFV)*

Opening address
 Argentine Minister of Health

Keynote lecture
 Michael Rawlins, *Chairman of National Institute for Health and Clinical Excellence (NICE), UK* “Early Licensing versus Greater Safety? Where’s the Balance?”

Parallel sessions morning

Pharmacovigilance in Hospitals	Counterfeit Medicines and Illegitimate Drugs
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Lunch

Parallel sessions afternoon

Pharmacogenetics and Drug Interactions in Pharmacovigilance	Education and Training Projects in Pharmacovigilance
Performance and Results of Intensive Pharmacovigilance Programmes	Reports of Lack of Effectiveness

Tuesday 7th October

Parallel sessions morning

Vaccine Pharmacovigilance	Estimating AE/ADR seriousness, causality and frequency as the basis of risk assessment
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Plenary session morning

Round table discussion: Customising Risk Management: Global or local?
 Chairman: Joan-Ramon Laporte - Speaker: Nelson Arboleda (CDC)

Lunch

Plenary session afternoon

ISoP General Assembly

Parallel sessions afternoon

Developments in Global Pharmacovigilance and Implementation in a Regional Setting	Methodology in Pharmacovigilance
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Plenary session afternoon

Gerald Dal Pan, *Director of Center for Drug Evaluation and Research, Food and Drug Administration:*
 “Monitoring adverse events in an off-label use setting”

Wednesday 8th October

Parallel sessions morning

Pharmacovigilance of Biologicals and Advanced Therapies	Pharmacovigilance in paediatrics
Pharmacovigilance in Pregnancy and Reproductive Health	Safety issues in clinical trials

Lunch

Parallel sessions afternoon

Communication in Pharmacovigilance	Harmonization in regulatory aspects of Pharmacovigilance: How do you do it?
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Plenary session afternoon

Bengt-Erik Wiholm Lecture
 Ralph Edwards, *Director of Uppsala Monitoring Centre*



Pre-Conferences Courses. Sunday, 5th October 2008, 9 a.m. to 6 p.m

- I. Pharmacovigilance, from fundamental basis to practice
- II. Drug-related Risk Management

8th ISO P Annual Meeting. Monday 6th, Tuesday 7th and Wednesday 8th October 2008,
9 a.m. to 6 p.m.

Simultaneous translation English-Spanish and Spanish-English in all parallel and plenary sessions

Workshops*

Pharmacovigilance in Latin-America
Workshop in Spanish

Herbal Medicines
Workshop in English

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Venue: Sheraton Buenos Aires Hotel & Convention Center
San Martín 1225 - 1275 - tel. 4318-9000