Scientific Committee

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ispe2011@aimgroup.eu

SPONSORSHIP & EXHIBITION

Under the auspices of

AIE
Italian Epidemiological Association

AIFA
Italian Medicines Agency

ARS
Regional Agency for Health

EACPT
European Association for Clinical Pharmacology and Therapeutics

ISoP
International Society of Pharmacovigilance

ISS
National Institute of Health

SIGG
Italian Society of Gerontology and Geriatrics

SISMEC
Italian Society of Medical Statistics and Clinical Epidemiology

Comune di Firenze
Municipality of Florence

Università degli Studi di Firenze
University of Florence

Università degli Studi di Firenze - Facoltà di Medicina
University of Florence School of Medicine
Dear Colleagues,

On behalf of the Scientific Program Organizing Committee, we have the great pleasure welcome you at the International Society for Pharmacoepidemiology (ISPE) 2011 Mid-Year Meeting (9-11 April) in Florence. This important scientific conference is jointly sponsored by the Italian Society of Pharmacology (SIF) and the Italian College of General Practitioners (SIMG). ISPE is an international organization dedicated to advancing the health of the public by providing a forum for the open exchange of scientific information and for the development of policy, education, and advocacy for the field of pharmacoepidemiology, including areas such as drug safety research, drug utilization research, comparative effectiveness research, and therapeutic risk management.

The goal of the symposium is to promote collaboration on drug safety and effectiveness research among stakeholders representing academia, pharmaceuticals, healthcare service providers, government/regulatory agencies, and the public.

The one-day symposium on April 9 addresses innovative strategies for assessing the effects of drug use among the elderly population. Of particular interest is the potential to combine multiple electronic healthcare databases and by doing so, create a powerful research tool for helping to understand better the risk-benefit profile of the medications.

The title of the symposium is: New Strategies for the Post-marketing Monitoring of Medical Products.

In addition to the one-day symposium, ISPE offers two half day short courses on April 10: Introduction to Pharmacoepidemiology and Advanced Topics in Pharmacoepidemiology. We are excited because this is ISPE’s first meeting in Italy.

Florence, the “cradle of the Renaissance”, is the capital city of the Italian region of Tuscany. The historic centre of Florence continues to attract millions of tourists each year and was declared a World Heritage Site by UNESCO in 1982. The work of Cimabue and Giotto, the fathers of Italian painting, and the universal genius of Leonardo da Vinci and Michelangelo, are gathered in several museums, such as the Uffizi, the most selected gallery in the world.

Welcome to Florence!

On behalf of the Organizing Committee,

Giampiero Mazzaglia,  
CO-CHAIR, ISPE ORGANIZING COMMITTEE

Gianluca Trifiró,  
CO-CHAIR, ISPE ORGANIZING COMMITTEE
**SCIENTIFIC program**

**Symposium April 9, 2011**

**New Strategies for the Post-marketing Monitoring of Medical Products**

**FLORENCE, ITALY > APRIL 9-11, 2011**

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**07:30** REGISTRATION

**09:00** INTRODUCTION TO PROGRAM

*Giampiero Mazzaglia*, Program Co-Chair, Health Search, Italian College of General Practitioners, Italy

*Gianluca Trifirò*, Program Co-Chair, Erasmus University Medical Center, The Netherlands & University of Messina, Italy

**WELCOME ADDRESSES**

*Achille Caputi*, Italian Society Of Pharmacology Past-President, Italy

*Claudio Cricelli*, Italian College of General Practitioners President, Italy

*Stephen J.W. Evans*, FISPE, ISPE President, London School of Hygiene & Tropical Medicine, UK

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**09:15** KEYNOTE ADDRESS

**Evaluating drug effects in the Post-Vioxx world: There must be a better way**

*Jerry Avorn*, FISPE, Harvard Medical School/Brigham & Women’s Hospital, USA

**Q & A DISCUSSION**

**10:00** Active monitoring of medical product safety: a Viewpoint from the Italian Medicines Agency

*Daniela Melchiorri*, Italian Medicines Agency & Committee for Human Medicine Products, EMA

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**10:30** Issues driving the European regulatory agenda on drug risk-benefit management: The importance of risk minimization activities

*Almah Spooner*, Irish Medicines Board & Pharmacovigilance Working Party, EMA

**11:00** BREAK

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**11:30** Post-marketing drug safety monitoring and risk minimization activities: Expectations and proposals from drug industries

*Philippe Van der Auwera*, Risk Management Strategies, Hoffmann-La-Roche, France

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**12:00** Making sense of safety monitoring data: Bringing epidemiology and decision sciences together

*Sebastian Schneeweiss*, FISPE, Harvard Medical School/Brigham & Women’s Hospital, USA

**12:30** LUNCH

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**12:30** LUNCH

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**13:30** From individual case report assessment to quantitative signal detection using spontaneous adr reporting: What are the lessons learned?

*Stephen J.W. Evans*, FISPE, London School of Hygiene and Tropical Medicine, UK

**13:55** Data driven discovery-case studies from patient records and spontaneous reports

*Niklas Noren*, WHO Collaborating Centre for International Drug Monitoring, Sweden

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**NEW APPROACHES IN DRUG SAFETY SIGNAL DETECTION**

**Co-chairs**

*Giovanni Corrao*, University of Milan Bicocca, Italy

*Marie Lindquist*, WHO Collaborating Centre for International Drug Monitoring, Sweden
**Afternoon Session 1**

14:20 **Does data mining on healthcare database add to safety monitoring: Results from the EU-ADR project**
Miriam Sturkenboom, FISPE, Erasmus University Medical Center, The Netherlands

14:45 **The observational medical outcomes partnership (OMOP): Results and future perspectives**
Patrick Ryan, Johnson and Johnson, USA

15:15 BREAK

**Afternoon Session 2**

14:45 **PROMOTING DISTRIBUTED NETWORKS FOR HYPOTHESIS TESTING STUDIES: CURRENT INITIATIVES IN EUROPE**

Co-chairs
Roberto Bernabei, University Cattolica del Sacro Cuore Rome, Italy
Miriam Sturkenboom, FISPE, Erasmus University Medical Center, The Netherlands

15:45 **The European Network of Centres for Pharmacoepidemiology (ENCePP): Code of conduct for multicentre observational studies**
Stella Blackburn, Pharmacovigilance and Risk Management, European Medicines Agency, UK

**Afternoon Session 2**

16:10 **The future of vaccine safety assessment in Europe: The perspective from VAESCO project**
Jan Bonhoeffer, University Children’s Hospital, Basel, Switzerland & Brighton Collaboration

16:35 **Federation of databases to evaluate the arrhythmogenic potential of drugs: The ARITMO project**
Fabrizio De Ponti, University of Bologna, Italy

17:00 **A network of long-term care facilities: Experience from Europe and USA**
Giovanni Gambassi, Sacro Cuore University of Rome, Italy

17:30 **FINAL COMMENTS**

Giampiero Mazzaglia, Health Search, Italian College of General Practitioners, Italy
Gianluca Trifirò, Erasmus University Medical Center, The Netherlands & University of Messina, Italy

17:45 **ADJOURNMENT**
07:30  REGISTRATION

MORNING  09:00 - 13:00

INTRODUCTION TO PHARMACOEPIDEMIOLOGY

Pharmacovigilance
Mauro Venegoni, Regional Health Authority of Lombardy, Italy

Cohort studies
Frank Andersohn, Charité University of Berlin, Germany

Case-control studies
Giuseppe Traversa, Italian Health National Institute, Italy

Confounding
Corinne de Vries, FISPE, University of Bath, United Kingdom

AFTERNOON  14:00 - 18:30

ADVANCED TOPICS IN PHARMACOEPIDEMIOLOGY

Conducting hypothesis testing research in healthcare databases: Workflows in single and multiple database studies
Miriam Sturkenboom, FISPE, Erasmus University Medical Center, The Netherlands

Signal detection in electronic medical record and claims databases versus spontaneous reporting databases
Kevin Haynes, University of Pennsylvania, USA

Update on effectiveness research using observational databases
Tobias Gerhard, Rutgers University, USA

Quality of evidence of observational studies in drug safety: the work in progress of GRADE
Nicola Magrini, CEVEAS Bologna, Italy

Multiple-treatments meta-analysis
Corrado Barbui, University of Verona, Italy
MEETING VENUE
Grand Hotel Baglioni
Piazza Unità Italiana, 6
50123 - Florence, Italy

HOW TO REACH FLORENCE
Florence can be reached from the main cities of Europe and Mediterranean countries by train and plane.

• By Plane
  - Florence International Airport “Amerigo Vespucci” (connected to the main European cities). It is located 4 km (2.5 miles) from Florence and it can be reached by taxi in 20 minutes or by shuttle service bus Vola in Bus, a special connection service from/to Vespucci Airport to/from Santa Maria Novella train station, jointly run by ATAF and SITA bus companies. Taxi parking area is just outside the airport.
  - Pisa International Airport “Galileo Galilei” (connected to the main European cities). It is located in Pisa 60 km (38 miles) from Florence and it can be reached in 1 hour by train from Santa Maria Novella train station: three trains every hour from Pisa Centrale and Pisa Airport from 6,00 am to 10,00 pm.

• By Train
  There are 3 main train stations in Florence:
  - Santa Maria Novella Central Station located at 80 metres from congress venue;
  - Rifredi Station located at around 2 km (1.2 miles);
  - Campo di Marte Station located at 1.5 km (1 mile).

PUBLIC TRANSPORTATION
All town buses stops in Piazza Stazione (Santa Maria Novella train Station) and therefore they are reachable by walk from congress venue in 5 minutes.

• Taxi 055 4390 or 055 4242 or 055 4798

VISA
Every person entering Italy should be in possession of a valid passport and/or identification card. Some countries require VISA. VISA application can be made at the Italian Diplomatic and Consular Representations in your country of residence. You can check on www.esteri.it to find out whether, depending on your citizenship, country of long-term residence and the duration and reasons of your stay, you need a VISA to enter Italy.

> On request the Organizing Secretariat will provide you for congress official letter if needed for VISA purpose.

HOTEL ACCOMMODATION
Rooms are available at the Meeting Venue (Grand Hotel Baglioni****) at the following rates:

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<tr>
<th>GRAND HOTEL BAGLIONI</th>
<th>DOUBLE SINGLE USE ROOM</th>
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<td>Euro 178,00</td>
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Prices are for night, including breakfast and V.A.T.

AIM Group International selected other hotels at walking distance from the Congress venue. For information and/or reservation please contact the Official Housing Bureau and Travel Agency of the Conference:
• AIM Group International
  Milan Office
  Via Ripamonti, 129 - 20141 Milan
  Tel. +39-02-566011
  Fax +39-02-56609043
  E-mail: ispe2011.hotel@aimgroup.eu

REGISTRATION FEES (US Dollars)

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<th>ISPE MEMBER</th>
<th>APRIL 9 Symposium All Day</th>
<th>APRIL 10 Intro to Pharmacy A.M. ONLY</th>
<th>APRIL 10 Advanced Topics P.M. ONLY</th>
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NOTES:
* Student must provide ISPE with documentation of full-time status (e.g., clear copy of student ID with a valid date or letter from school or program) – email or fax (301-656-0989)
** Individual must be a citizen and resident in the middle or lower income country as identified by the United Nations (UN Human Development Report 2005, page 213).

REGISTER BY
• Fax registration form with credit card information to the ISPE Office at 301.656.0989
• Web Visit www.pharmacoepi.org

Cancellations/Refund Policy
If you have to cancel your registration for any reason, ISPE must receive written notification by March 26, 2011. Refunds will be issued less a 20% administrative fee after the meeting. No refunds will be issues for cancellations received after March 26, 2011. Substitute participants will be accepted at the discretion of ISPE.
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