

ISPE 2011 Mid-Year Meeting

Florence, ITALY

> APRIL 9-11, 2011

JOINTLY SPONSORED BY



- **ISPE**
International Society for Pharmacoepidemiology



- **SIF**
Italian Society of Pharmacology



- **SIMG**
Italian College of General Practitioners

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

Organizing Secretariats

REGISTRATION



ISPE

5272 River Road, Suite 630
Bethesda, MD 20816 USA
Ph.: +1-301-718-6500
Fax: +1-301-656-0989
www.pharmacoepi.org
ispe@paimgmt.com

ACCOMMODATION SPONSORSHIP & EXHIBITION



AIM GROUP INTERNATIONAL

Florence Office

Viale G. Mazzini, 70
50132 Florence, Italy
Ph.: +39-055-23388.1
Fax: +39-055-3906908
www.aimgroup.eu/2011/ispe
ispe2011@aimgroup.eu

ISPE 2011 Mid-Year Meeting

Florence, ITALY

> APRIL 9-11, 2011

Meeting Venue

Grand Hotel Baglioni



Piazza Unità Italiana, 6
50123 - Florence, Italy

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

Florence, ITALY > APRIL 9-11, 2011

program

Symposium April 9, 2011 New Strategies for the Post-marketing Monitoring of Medical Products

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

MORNING SESSION

POST-MARKETING MONITORING OF MEDICAL PRODUCTS: EXPECTATIONS AND FUTURE DIRECTIONS FROM REGULATORY AGENCIES, INDUSTRY, AND ACADEMIA

CO-CHAIRS
Achille P. Caputi,
University of Messina, Italy
Nicholas Moore, FISPE,
University of Bordeaux, France

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

MORNING SESSION

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

Almath Spooner
Irish Medicines Board & Pharma-
covigilance Working Party, EMA

11:00 BREAK

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

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

Sebastian Schmeeweiss, FISPE,
Harvard Medical School/Brigham &
Women's Hospital, USA

12:30 LUNCH

AFTERNOON SESSION 1

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

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



SCIENTIFIC

Florence, ITALY > APRIL 9-11, 2011

program

Symposium April 9, 2011
**New Strategies for the Post-marketing
Monitoring of Medical Products**

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

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

AFTERNOON SESSION 2

17:30 **FINAL COMMENTS**
Giampiero Mazzaglia, Health Search, Italian College of General Practitioners, Italy
Gianluca Trifiro, Erasmus University Medical Center, The Netherlands & University of Messina, Italy

17:45 ADJOURNMENT



COURSES April 10, 2011

COURSES April 10, 2011

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:

GRAND HOTEL BAGLIONI	DOUBLE SINGLE USE ROOM Euro 178,00	DOUBLE ROOM Euro 212,00
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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 Intenational 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)

	(1) APRIL 9 Symposium All Day	(2) APRIL 10 intro to Pharmacoepey A.M. ONLY	(3) APRIL 10 Advanced Topics P.M. ONLY
ISPE MEMBER			
Industry	\$ 295	\$ 295	\$ 295
Academic/Government	\$ 170	\$ 170	\$ 170
Student*/Retired/Special*	\$ 55	\$ 55	\$ 55
NON MEMBER			
Industry	\$ 345	\$ 345	\$ 345
Academic/Government	\$ 225	\$ 225	\$ 225
Student*/Retired/Special*	\$ 65	\$ 65	\$ 65

NEW ISPE Membership Not for Dues Renewal

Join ISPE now and receive membership benefits through June 30, 2012

REGULAR MEMBERSHIP	\$ 245	RETIRED MEMBERSHIP	\$ 85
STUDENT MEMBERSHIP	\$ 85	SPECIAL MEMBERSHIP	\$ 85

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.pharmacoepepi.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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ISPE

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