THE INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY

20th International Conference on Pharmacoepidemiology & Therapeutic Risk Management

PRELIMINARY PROGRAM

22-25 August 2004
Bordeaux Convention Center
Bordeaux, France

JOINTLY SPONSORED BY:
Association pour la recherche en Pharmacovigilance
European Association for Clinical Pharmacology and Therapeutics
European Drug Utilization Research Group
International Epidemiological Association — European Epidemiology Federation
International Society of Pharmacovigilance
SIG Pharmacoepidemiology & Pharmacoconomics, International Pharmaceutical Federation
Dear Colleagues,

On behalf of the International Society for Pharmacoepidemiology (ISPE) and the European Drug Utilization Research Group (EuroDURG), I invite you to join me at the 20th International Conference on Pharmacoepidemiology and Therapeutic Risk Management, 22-25 August 2004, Bordeaux Convention Center, Bordeaux, France.

The ISPE Scientific Program Committee has assembled a renowned faculty representing distinguished leaders in pharmacoepidemiology and therapeutic risk management. Bernard Begaud’s keynote address is sure to be interesting and thought provoking. Susana Perez-Gutthann will share her perspectives about the Society’s and its future in her Presidential Address. And you will not want to miss Lucien Abenhaim, former Director General of Health, French Ministry of Health, discuss the role of pharmacoepidemiology in shaping national drug policy.

This year’s conference begins Sunday, 22 August with two highly popular ISPE educational programs: Introduction to Pharmacoepidemiology and Advanced Topics in Pharmacoepidemiology – and two special skills workshops for students. The agenda also includes symposia, workshops, oral presentations and more than 480 poster presentations, exhibitors and time to catch up with old friends and make new ones.

And keep in mind, if you want simply to wander or follow a guided tour, take a trip through history or just get away from it all, enjoy sensational panoramas or picturesque views, sample the wine and gastronomy... all you need to do is come and discover Bordeaux.

Remember, the Early Bird registration deadline is 16 July.

I look forward to raising a glass of wine with you in Bordeaux!

Nicholas Moore
Chair, 2004 Scientific Program Committee

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GOALS OF THE MEETING

To provide a unique scientific forum in which epidemiologists, researchers, physicians, pharmacists, and health care practitioners in research and decision-making areas can learn about use and effects of drugs in large populations, identification of rare adverse effects of drugs, promotion of more-rational prescribing practices, recognition of new therapeutic benefits of drugs, and therapeutic risk management techniques and practices.

EDUCATIONAL OBJECTIVES

To provide an international perspective and better understanding of pharmacoepidemiology as a decision-making tool for addressing questions concerning the use, safety, and efficacy of licensed drugs.

To describe recent developments in methodology related to pharmacoepidemiology and therapeutic risk management.

To identify recent and newly discovered adverse effects of medications.

To promote discussion and communication among stakeholders about good therapeutic risk management practices.

CPD — UK PHYSICIANS ONLY

The Royal College of Physicians of London has approved the 20th International Conference on Pharmacoepidemiology and Therapeutic Risk Management for 25 Continuing Professional Development (CPD) credits. UK physicians must sign the registration sheet at the Registration Desk. Certificates of attendance will be available at the close of the conference.
**PRECONFERENCE SESSIONS (22 AUGUST)**

- **Introduction to Pharmacoepidemiology**
  (All Day) (A combination of presentations, group work and discussions)
  
  Jacques Le Lorier, FISPE, Confounding by Indications
  Judith Jones, FISPE, Cohort Studies
  Sean Hennessy, FISPE, Case-Control Studies
  Nicholas Moore, FISPE, Spontaneous Reporting

- **Advanced Topics in Pharmacoepidemiology**
  (Afternoon only) (Separate registration required)
  
  Andre Maguire, Quantification of Risk-Benefit of Medication Use at Population Level Using Stochastic Simulation Models
  Jacques Benichou, A Methodological Workshop on Sampling Strategies Applied to Drug Utilization Studies
  Stephen Evans, Uses & Abuses solved, and Those Unsolved, in Data Mining in Pharmacovigilance
  Stephen Grover, Estimating the Costs & Benefits of Preventing Cardiovascular Disease

- **Students Only – Specials Skills Workshops**
  (Morning only)
  
  Thomas MacDonald, FISPE, How Not to Give a Scientific Presentation
  Brian L. Strom, FISPE, Writing Grant Proposals That Get Funded

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**PLENARY SESSIONS**

- **Presidential Address**
  The President of ISPE, Susana Perez-Gutthann, FISPE, will offer her views on pharmacoepidemiology and therapeutic risk management.

- **Keynote Address**
  Bernard Begaud, President, Universite Victor Segalen, will discuss role of pharmacoepidemiology in medical training in his keynote address.

- **Special Invited Plenary Lectures**
  Lucien Abenhaim, former Director General of Health, French Ministry of Health, will present his perspective on the role of pharmacoepidemiology in shaping national drug policy.
  Samy Suissa, Professor of Epidemiology, Universite of Montreal, will discuss time-dependent measures in pharmacoepidemiology.
  Nicholas Wald, Barts & The London Queen Mary School of Medicine & Dentistry, will share his views on combining strategies for controlling risk.

- **Hot Topics Sessions**
  Panels of international experts will examine scientific and policy implications surrounding:
  - HRT (Hormone Replacement Therapy)
  - SSRI in Children: Is the Cure Worse than the Disease?

- **Drug Utilisation Day – 24 August**
  Developed in collaboration with the European Drug Utilisation Research Group (EuroDURG):
  - How Valid is the Assessment of Volume, Expenditure and Quality in Drug Consumption?
  - Experiences With the International Collection of Drug Consumption Data
  - The Use of Quality Indications – How Good are we at Measuring Quality?
  - EuroDURG poster walk at lunch; open to all participants.

- **Annual Centers for Excellence & Research in Therapeutics (CERTs)**
  Breakfast Roundtable – 25 August
  - open to all participants.
HIGHLIGHTS

SYMPOSIA

• Safety Data Mining: Recommendations from the PhRMA-FDA Working Group
• Active Surveillance in ADR Monitoring
• Breaking Out of the Bubble: What Have We Learned about Risk Communication?
• Evidence-Based Medicine vs. Outcomes Research: Are Clinical Trials Really Predictive of Actual Benefits and Risks?
• How Do Drug Regulators Evaluate Risk Management Programs in the Pre-Approval Stage of Drug Development?
• Decision-Making and Evidence-Based Pharmacovigilance
• Automatic Signal Detection Methods in Pharmacovigilance: A Practical Point of View
• The Control of Time-Dependent Confounding or Why Conventional Methods May Mislead Us
• European vs. American Approach to Assessing Human Teratogens - Is One Better Than the Other
• Pharmacoepidemiology Adds to Orphan Drug Development
• Pharmacoepidemiology and the Law: Standards of Evidence for Causality in Research, Regulation, and the Courts

WORKSHOPS

• Clinical Assessment of Adverse Events Following Immunization (AEFIs): A Converging New International Paradigm?
• A Methodological Workshop on Sampling Strategies Applied To Drug Utilization Studies
• Maximizing the Clinical Explanatory Power of Drug Dosing History Data
• The Best Pharmaceuticals for Children Act: Current and Future Activities
• Development and Implementation of Risk Management Program for LOTRONEX [trade] (Alosetron HCL)
• Epidemiologic vs. Post-Marketing Spontaneous Report Data: Vive La Difference!

POSTER PRESENTATIONS

More than 480 poster presentations covering a wide range of topics, including the EuroDURG poster walk on 24 August.

INTEREST GROUPS

All participants are invited to meet with their colleagues to discuss issues of common concern by attending ISPE standing council meetings (Academic Council, Government Council, Industry Council and Student Council)

SOCIAL EVENTS

Sunday, 22 August
New Member & Scholarship Recipient Welcome Social: All first-time members and scholarship recipients are invited to meet with ISPE volunteer leaders in an informal setting.

Academic Showcase/Welcome Reception: An opportunity to renew friendships, meet new colleagues, and expand your professional network

Monday, 23 August
Student Social Event: A don’t miss evening planned by students for students. Information will be posted on the ISPE website.

Tuesday, 24 August
Evening at Chateau Giscours: The winemaking philosophy of the Chateau Giscours is to produce a wine that will age beautifully, as befits one of the greatest growths in Bordeaux. Chateau Giscours also strives for balance, complexity, power and elegance. The Renaissance style Chateau Giscours has been described as part of paradise in the middle of vines and woods. Join your colleagues for what will certainly be a memorable evening.

ORAL PRESENTATIONS

27 sessions, 162 oral presentations!
• Including Methodologies, Cardiovascular, NSAIDs, Propensity Scores, Anti-Infectives, Psychotropics, Risk Reporting & Reactions, Error Prevention & Risk Management, Birth Defects, Endocrinology & Diabetes, GI-Related Studies, Hormones, Vaccines, and Burden of Illness studies.
A) ISPE MEMBERSHIP

| Individual | $185 |
| Student    | $60  |
| Retired    | $60  |

A) MEMBERSHIP TOTAL $__________________

B) CONFERENCE REGISTRATION [US Dollars]

Members of ISPE and sponsoring organizations are eligible for the “Member” rate. If ISPE cannot verify your current membership, you will be charged the non-member rate.

I certify I am a current member of:

- International Society for Pharmacoepidemiology
- Association pour la recherche en Pharmacovigilance
- European Association for Clinical Pharmacology & Therapeutics
- European Drug Utilization Research Group
- International Epidemiology Association – European Epidemiology Federation
- International Society for Pharmacovigilance
- SIG Pharmacoepidemiology & Pharmacoeconomics, International Pharmaceutical Federation

Please check the appropriate category

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Please check the appropriate day:

- Mon., 23 August
- Tues., 24 August
- Wed., 25 August

One-Day Rate

- $400

*Documentation of full-time student status required.

HOW TO REGISTER

FAX
301-656-0989

MAIL
International Society for Pharmacoepidemiology
4350 East West Highway, Suite 401
Bethesda, MD, 20814

ONLINE
Credit card payments only at www.pharmacoepi.org/meetings/20thconf/index.cfm

REQUIRED: If you are a presenter (oral or poster), please indicate the number of your abstract(s): ______ , ______ , ______

B) CONFERENCE TOTAL $__________________

(Use one form for each person registering; use photocopies for additional registrants) • page 1 of 2

[Please TYPE or PRINT complete information]
C) PRE-CONFERENCE EDUCATIONAL SESSIONS

Sunday, 22 August

Introduction to Pharmacoepidemiology (All Day)
NO CHARGE - included in FULL registration fee. Not open to One-Day registration.

I plan to attend this session  ❑ YES  ❑ NO

Skills Workshop—STUDENTS ONLY (Morning)
NO CHARGE - included in FULL registration fee. Student ID required for admission. Space limited. Workshops will be repeated so each student can attend both sessions.

I plan to attend this session  ❑ YES  ❑ NO

Advanced Topics in Pharmacoepidemiology (Afternoon)
Additional registration fee required. (See registration instructions)

Please check the appropriate category

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<td>Member of ISPE or sponsoring organization</td>
<td>❑ $150</td>
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Student
NO CHARGE - included in FULL registration fee. Student ID required for admission.

I plan to attend this session  ❑ YES  ❑ NO

C) PRE-CONFERENCE TOTAL $

D) SOCIAL EVENTS

Sunday, 22 August, Evening

Welcome Reception/Academic Showcase
Full meeting registration includes one admission for this event.

I plan to attend the Welcome Reception  ❑ YES  ❑ NO

Additional tickets:
Adult: $45  Number of tickets _____ =  $ ______
Total Amount $ ______

Tuesday, 24 August, Evening

Evening at Chateau Giscours—7:30 p.m. - 10:30 p.m. (Preliminary)
Full meeting registration includes one admission for this event.
Includes admission, transportation & food.

I plan to attend the Social Event  ❑ YES  ❑ NO

Additional tickets:
Adult: $100  Number of tickets _____ =  $ ______
Ages 2-12: $50  Number of tickets _____ =  $ ______
Under 2: $0  Number of tickets _____ =  $ 0.00
Total $ ______

D) SOCIAL EVENT TOTAL $

E) WIRE TRANSFERS

There is a $30 (US) charge to accept a wire transfer. Call the ISPE office at (301) 718-6500 x6534, or email ISPE@paimgmt.com to request wire transfer details.

Wire Transfer Charge  ❑ $30

E) WIRE TRANSFER TOTAL $

GRAND TOTAL

A+B+C+D+E  $__________

METHOD OF PAYMENT

❑ Payment by Check (All fees must be paid in US dollars)
Check drawn on U.S. bank and made payable to “ISPE”. If a company or university makes payment, please make sure your name is written on the check stub or accompanying correspondence to ensure correct payment.

❑ Payment by Credit Card
(Current exchange rate will apply)

Please charge my credit card $________________________.

Please complete the information below:
Check one: ❑ Visa  ❑ MasterCard  ❑ American Express

Cardholder Name (Print):

Credit Card Account #:

Exp. Date:  Month  Day  Year

Signature:

SPECIAL NEEDS

❑ I have special dietary needs. Please send requirements by 6 August to ISPE (ISPE@paimgmt.com) or Fax +1-301-656-0989.

CANCELLATIONS

Only written cancellations received by 6 August will receive refunds (less a $100 administrative charge non student/$40 student). Refunds will be issued after the meeting. No refunds will be issued for cancelled registrations received after 6 August. Registration fees for cancelled registrations cannot be applied to future ISPE meetings. Registrants who do not cancel prior to the conference and who do not attend will be responsible for the full registration fee.

ISPE is a 501-c-3 charitable, educational society; the ISPE Federal Tax ID (FEIN) number is 41-1688677
Register
- **BY FAX OR ONLINE**
  Fax to 301-656-0989. Visa, MasterCard or American Express only. Registrations will not be processed without payment information. We do not accept faxed purchase orders or copies of checks. Credit card payments only at:
  http://www.pharmacoepi.org/meetings/20thconf/index.cfm

- **BY MAIL**
  Make check or original purchase order payable to “ISPE”, and mail to International Society for Pharmacoepidemiology, 4350 East West Highway, Suite 401, Bethesda, MD, USA 20814. FAXED COPIES OF CHECKS OR PURCHASE ORDERS WILL NOT BE PROCESSED.

All registrations must include payment information to be processed.

**Deadlines**
- 16 July (Early Bird):
  To register at the Early Bird Rate, your form and payment must be received by ISPE no later than 16 July. Only early registrants receive the reduced rate and are assured inclusion in the Participant Directory. All presenters should register by 16 July.

- 6 August (Regular):
  Registration forms received after the Early Bird Deadline are subject to the regular registration fee. After 6 August, all registrations must be made on-site.

**Confirmation**
- Registration confirmations will be sent to the email address provided on the registration form. If you do not have an email address, please provide a fax number and the notice will be faxed. If you have questions after you receive your confirmation, call 301-718-6500, or email ISPE@paimgmt.com.

**Cancellations**
- Only written cancellations received by 6 August, will receive refunds (less a $100 administrative charge non student/$40 student). Refunds will be issued after the meeting. No refunds will be issued for cancelled registrations received after 6 August. Registration fees for cancelled registrations cannot be applied to future ISPE meetings. Registrants who do not cancel prior to the conference and who do not attend will be responsible for the full registration fee.

**Substitutions**
- Registrant substitutions will be accepted only with written notification from the original registrant, accompanied by a completed registration form for the substitute participant and an administrative fee of $25. Substitutions may occur only once per registrant.

**Special Needs**
- Persons with special needs should send a description of any special services needed to ISPE (ISPE@paimgmt.com) by 6 August.

**Payment**
- **FEES**
  All fees must be paid in US Dollars.

- **REGISTRATION FEE**
  The full meeting registration fee includes one admission to the Introduction to Pharmacoepidemiology, Academic Showcase/Welcome Reception, and the evening social evening; breaks/ lunches; and materials. [NOTE: The Advanced Topics course requires a separate registration fee. Student registration also includes one admission to Advanced Topics.] All Non-Members who register at the full registration rate will receive ISPE membership status at the meeting for the remainder of CY 2004. This special membership does not include a subscription to ISPE’s official journal Pharmacoepidemiology & Drug Safety.

- **PAYMENT BY CHECK**
  Check drawn on U.S. bank and made payable to “ISPE”. If a company or university makes payment, please make sure your name is written on the check stub or accompanying correspondence to ensure correct payment.

- **PAYMENT BY WIRE TRANSFER**
  There is a $30 charge to accept a wire transfer. Call the ISPE office, 301-718-6500, to request wire transfer information.

**Member Rates**
- Members of ISPE and the sponsoring organizations (Association pour la recherche en Pharmacovigilance, European Association for Clinical Pharmacology & Therapeutics, European Drug Utilization Research Group, International Epidemiology Association – European Epidemiology Federation, International Society for Pharmacoepidigilance, and SIG Pharmacoepidemiology & Pharmacovigilance, International Pharmaceutical Federation) are entitled to a reduced members rate. Your society membership must be current at the time of registration and you must indicate to which organization you belong. If your membership has expired and you do not renew your membership at the time of the registration, you will be registered at the non-member rate and receive confirmation indicating a balance due. If you are a non-member who wishes to join ISPE and become eligible for a lower registration fee, please indicate this on the registration form. If you have any questions about membership, contact ISPE at 301-718-6500 or email ispe@paimgmt.com.

**STUDENT RATE**
- Individuals applying for the reduced rate must include documentation of full-time student status (e.g., a clear copy of student ID with a valid date or letter from school or program) at the time of registration. You must be enrolled as a full-time student at the time of the meeting to be eligible for the reduced student rate. If documentation is not received, you will be charged the full rate for the meeting. Attendees enrolled in fellowship programs are not considered full-time students.

**ONE-DAY RATE**
- The One-Day rate includes all conference materials, sessions and food functions for the specified date only. Not included in the one-day rate are the Introduction to Pharmacoepidemiology course, Academic Showcase/Welcome Reception and evening social event. Registration tickets may be purchased for the Academic Showcase/Welcome Reception and evening social event.

**Participants**
- All participants including presenters and moderators are required to register.
LOCATION & HOTELS

Bordeaux... The world’s greatest wines are made on the doorstep of a city famous for its outstanding architecture and enjoyable lifestyle. As you walk by the Pont de Pierre, you will be struck by the splendid 18th century facades along the Garonne, one of the most beautiful architectural complexes in Europe. Trade with the Carribean and Africa (wine, wood, spices, peanuts, etc.) made Bordeaux wealthy and fostered the construction of many attractive buildings throughout the city in the 18th and 19th centuries. As you walk around Bordeaux, you are sure to admire the Grand Theatre, the Place de la Bourse, the Place du Parlement, and the Place des Quinconces. Bordeaux has numerous museums and places of cultural interest.

Bordeaux has a mild climate and is famous for its fine cuisine: foie gras, Archachon Bay oysters, lamprey, entrecote a las bordelaise, and canéles (small cakes). If you are looking for something of the “French touch” to bring back, you always can find it at boutiques such as Vuitton, Hermes, Cartier, or Boucheron. And when the sun goes down, the fun continues at restaurants, bars, nightclubs, or the casino.

And nothing is ever far away in Bordeaux - a city full of fascinating neighborhoods, ideal for discovering on foot. Visit http://www.bordeaux-tourisme.com for more information.

ISPE has reserved rooms at four Accor hotels, which are located a short walk from the Bordeaux Convention Center. Please make your reservations directly with the hotel by 23 July 2004 to guaranty the discounted ISPE rate and availability of rooms. Rooms are available on a first-call, first-served basis. When making your reservation, please state you are with “ISPE” to ensure you receive the special ISPE rate.

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<td><strong>Sofitel Bordeaux</strong></td>
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<tr>
<td>Reservations: (+33)5/56696505</td>
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<tr>
<td>E-mail: <a href="mailto:H0669-RE@accor-hotels.com">H0669-RE@accor-hotels.com</a></td>
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<tr>
<td><strong>Novotel Bordeaux Hotel Le Lac</strong></td>
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<tr>
<td>Tel: (+33)5/56436500</td>
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<tr>
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<tr>
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<td><strong>Mercure Bordeaux Le Lac</strong></td>
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<tr>
<td><strong>Ibis Bordeaux Le Lac</strong></td>
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<tr>
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* Rates include breakfast buffet, VAT and service (euros). For more information, please visit www.accorhotels.com.