



Mid-Year  
**ISPE 2009**  
Meeting

🦋 Elite Palace Hotel/  
Karolinska University  
Hospital

🦋 Stockholm, Sweden

🦋 April 25-27, 2009

*April 26*

- A) Introduction to  
Pharmacoepidemiology (morning)
- B) Advanced Topics in  
Pharmacoepidemiology (afternoon)

*April 27*

**25th Anniversary Symposium:**

*From Thalidomide to Pharmacovigilance  
to Pharmacoepidemiology: Has Drug  
Safety and Effectiveness Really Improved  
Since Thalidomide?*

**Jointly sponsored by**

- 🦋 International Society for  
Pharmacoepidemiology (ISPE)
- 🦋 Swedish Society for  
Pharmacoepidemiology (SLEF)
- 🦋 Centre for Pharmacoepidemiology (CPE)  
-A Joint Venture between the Departments of  
Clinical Epidemiology, Clinical Pharmacology,  
and Medical Epidemiology and Biostatistics at  
Karolinska Institutet

🦋🦋🦋 *Space is limited: Register Today!*

Mid-Year

ISPE 2009

Meeting

## Meetings:

**Saturday, April 25, 2009**  
Elite Palace Hotel

10:30am - Noon

### Strategic Planning Session

- ISPE Chairs: Committees, Councils & SIGs

Noon - 1:00pm

### Lunch

1:00 - 5:00pm

### ISPE Board of Directors Meeting

(Board, Committee, Council, & SIG Chairs) - Open to all ISPE Members

**Sunday, April 26, 2009**  
Elite Palace Hotel

7:30am - 4:00pm

### Registration

8:30am - 12:30pm

### ICPE 2009 Scientific Program Committee

8:30am - 12:30pm

### Introduction to Pharmacoepidemiology\*

12:30 - 1:30pm

### Lunch on your own

1:30 - 5:30pm

### Advanced Topics in Pharmacoepidemiology\*

**Monday, April 27, 2008**  
Nanna Svartz Auditorium  
Karolinska University Hospital

7:30am - 4:00pm

### Registration

9:00am - 5:00pm

### Mid-Year Symposium\*

\*Registration Required

# ISPE Mid-Year Meeting

**Sunday, April 26 2008**

**Elite Palace Hotel | 8:30am - 12:30pm**

## Introduction to Pharmacoepidemiology

### COURSE OBJECTIVES

This course is for those with some training and/or experience in epidemiology or pharmacoepidemiology. On completion, participants will be able to:

- Identify the impact of confounding by indication in epidemiology studies
- Outline the basic design features of cohort, case-control and nested case-control studies
- List the strengths and weaknesses of spontaneous reporting data
- Outline strategies for addressing a spontaneous report "signal" and outline design options for pharmacoepidemiology studies to address this "signal."

### Course Objectives and Introductions

**Andrew McAfee**, Course Chair, i3 Drug Safety, USA

### Spontaneous Reporting

**Ralph Edwards**, WHO-Uppsala Monitoring Centre (UMC), Sweden

### Cohort Studies

**Andrew McAfee**, i3 Drug Safety, USA

### Case-Control Studies

**Michael Lewis**, FISPE, EPES Epidemiology GMBH, Germany

### Confounding & Other Biases

**Anita McGrogan**, University of Bath, United Kingdom

### Summary Comments

### Adjournment

**Sunday, April 26, 2008**

**Elite Palace Hotel | 1:30 - 5:30pm**

## Advanced Topics in Pharmacoepidemiology

### Introduction

**Jim Lewis**, Course Chair, University of Pennsylvania/Center for Clinical Epidemiology & Biostatistics, USA

### Attenuating Confounding by Indication: the Cohort Cross-Over Approach

**Anders Sundström**, Karolinska Institutet, Sweden

### Time Varying Propensity Scores

**Alexander Walker**, FISPE, Harvard University, USA

### Immortal Time Bias

**Corinne de Vries**, University of Bath, United Kingdom

### Pharmacoepidemiology of Pregnancy

**Lolkje de Jong-van den Berg**, University of Groningen, The Netherlands

# Meeting – Preliminary Meeting Agenda

**Monday, April 27, 2008**

**Nanna Svartz Auditorium, Karolinska University Hospital | 9:00am – 5:00pm**

## 📌 *Scientific Program/Symposium*

**From Thalidomide to Pharmacovigilance to Pharmacoepidemiology: Has Drug Safety and Effectiveness Really Improved Since Thalidomide?**

7:30am

📌 **Registration**

### MORNING SESSION: PHARMACOVIGILANCE

*Co-Chairs:*

**Allen A. Mitchell, FISPE, USA**

**Helle Kieler, Sweden**

9:00am

📌 **Welcome & Introduction to Program**

**Miriam CJM Sturkenboom, ISPE President**

**Nancy Pedersen, Vice Dean of Research, Karolinska Institutet, Sweden**

**Ulf Bergman, FISPE, Scientific Program Chair, Department of Clinical Pharmacology, Karolinska Institutet, Sweden**

9:15am

📌 **Keynote Address - *From Thalidomide to Pharmacovigilance to Pharmacoepidemiology in Sweden***

**Barbro Westerholm, Professor Emeritus, Karolinska Institutet, Member of the Swedish Parliament, Sweden**

9:35am

📌 **The Irony of the Thalidomide Experience - *When Will We Apply Its Lessons to Safety Surveillance for Antenatal Exposures?***

**Allen A. Mitchell, FISPE, Slone Epidemiology Center at Boston University, USA**

10:05am

📌 **The WHO International Programme: *From Tabulated Case Reports to Knowledge Finding in Multiple Global Data Sets***

**Ralph Edwards, WHO-Uppsala Monitoring Centre (UMC), Sweden**

10:35am

📌 **Break**

11:00am

📌 **New European Activities in Drug Safety Research: *EMEA and ENCePP***

**Miriam CJM Sturkenboom, Erasmus University Medical Centre, The Netherlands**

11:30am

📌 **Antibiotic Resistance - *The Hidden Threat to Global Public Health and The Missing Link in Pharmacovigilance***

**Otto Cars, Swedish Strategic Programme Against Antibiotic Resistance - STRAMA, Sweden**

12:00pm

📌 **From Pharmacovigilance to Pharmacoepidemiology: *25 Years Later***

**Stanley A. Edlavitch, Lifetime Emeritus, ISPE, University of Missouri School of Medicine, USA**

12:15pm

📌 **Lunch**

### AFTERNOON SESSION: PHARMACOEPIDEMIOLOGY

*Co-Chairs:*

**Sebastian Schneeweiss, FISPE, USA**

**Björn Wettermark, Sweden**

**Symposium on Comparative Effectiveness Research (CER)**

1:15pm

📌 **Comparative Effectiveness Research from the Perspective of a Pharmacoepidemiologist**

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

1:45pm

📌 **Methodological Challenges in Comparative Effectiveness Research**

**Thomas M. MacDonald, FISPE, Medicines Monitoring Unit (MEMO), University of Dundee, United Kingdom**

2:15pm

📌 **Non-Randomized Effectiveness Data and Decision Making in the UK**

**Michael Kelly, National Institute for Health and Clinical Excellence (NICE), United Kingdom**

2:45pm

📌 **Individual-Based Studies Indicate a Strong Suicide Prevention Effect of Antidepressants**

**Göran Isacson, Department of Psychiatry, Karolinska Institutet, Sweden**

3:00pm

📌 **Break**



# Registration Form

Mid-Year  
**ISPE 2009**  
Meeting

ISPE Mid-Year Meeting April 25-27, 2009 Stockholm, Sweden

(Use one form per person; use photocopies for additional registrations.)

## BLOCK LETTERS PLEASE

Name for Badge \_\_\_\_\_

First/Given Name \_\_\_\_\_ Last/Family Name \_\_\_\_\_

Position/Title \_\_\_\_\_ Company/Institution/Affiliation \_\_\_\_\_

Street Address \_\_\_\_\_

City \_\_\_\_\_ State/Province \_\_\_\_\_ Zip Code/Postal Code \_\_\_\_\_

Country \_\_\_\_\_ Email \_\_\_\_\_

Office Phone \_\_\_\_\_ Fax \_\_\_\_\_

\*Special Dietary Requirements \_\_\_\_\_

## [A] Registration Fees [US Dollars]

<input checked="" type="checkbox"/> Only check one box.	[1] April 26 Intro to Pharmacoepi A.M. ONLY	[2] April 26 Advanced Topics P.M. ONLY	[3] April 27 Symposium <i>All Day</i>	[4] PACKAGE A Intro Course & Symposium	[5] PACKAGE B Adv. Course & Symposium	[6] PACKAGE C Both Courses (Intro & Adv.) & Symposium
<b>ISPE Member</b>						
Industry	<input type="checkbox"/> \$295	<input type="checkbox"/> \$295	<input type="checkbox"/> \$295	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$725
Academic/Government	<input type="checkbox"/> \$170	<input type="checkbox"/> \$170	<input type="checkbox"/> \$170	<input type="checkbox"/> \$290	<input type="checkbox"/> \$290	<input type="checkbox"/> \$430
Student*/Retired/Special*	<input type="checkbox"/> \$55	<input type="checkbox"/> \$55	<input type="checkbox"/> \$55	<input type="checkbox"/> \$100	<input type="checkbox"/> \$100	<input type="checkbox"/> \$140
<b>Nonmember</b>						
Industry	<input type="checkbox"/> \$345	<input type="checkbox"/> \$345	<input type="checkbox"/> \$345	<input type="checkbox"/> \$585	<input type="checkbox"/> \$585	<input type="checkbox"/> \$880
Academic/Government	<input type="checkbox"/> \$225	<input type="checkbox"/> \$225	<input type="checkbox"/> \$225	<input type="checkbox"/> \$380	<input type="checkbox"/> \$380	<input type="checkbox"/> \$575
Student*/Retired/Special*	<input type="checkbox"/> \$65	<input type="checkbox"/> \$65	<input type="checkbox"/> \$65	<input type="checkbox"/> \$110	<input type="checkbox"/> \$110	<input type="checkbox"/> \$165

## [B] ISPE Membership - For First Time Joiners Only

Join ISPE now and receive membership benefits through June 30, 2010

Regular Membership  \$230 Retired Membership  \$80  
Student Membership\*  \$80 Special Membership\*\*  \$25

## Payment By Credit Card

[In US Dollars]

Visa  MasterCard  AmEx

Account number: \_\_\_\_\_

Security code: \_\_\_\_\_

Name exactly as it appears on card: \_\_\_\_\_

Expiration date (Month Year) \_\_\_\_\_

## Wire Transfers

Wire transfers will be accepted with an additional \$80.00 (US) payment. Bank transmittal/wire transfer information must include name of sender, proper credit cannot be given for unidentified wire transfer. Contact ISPE office (ISPE@paimgmt.com) for wire instructions.

## Cancellation/Refunds

See page 5 for complete policy.

[C] TOTAL [Registration + Membership] \$ \_\_\_\_\_

## 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 364).

## Register by

**Mail** this form with payment to  
ISPE - 2008 Mid-Year Meeting  
5272 River Road, Suite 630  
Bethesda, MD 20816 USA

**Fax** registration form with credit  
card information to the ISPE  
Office at 301.656.0989

**Web** Visit [www.pharmacoepi.org](http://www.pharmacoepi.org) **ISPE** Federal Tax ID: 41-1688677

# Preliminary Meeting Agenda:

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## Symposium on Comparative Effectiveness Research [Continued]

3:30pm

- 🐦 **The Swedish System for Quality Assurance of RA Care: From Capture of Routine Data on Treatment, Through Register Linkages, to Post-Marketing Effectiveness and Safety Studies**

**Johan Askling**, Department of Medicine, Karolinska Institutet, Sweden

3:45pm

- 🐦 **The Challenges of Non-Randomized Comparative Effectiveness Research When Making Payment Decisions**

**Madlaina Costa-Scharplatz, PhD**, Health Economics and Outcomes Research Scientist, AstraZeneca R&D, Sweden

4:00pm

- 🐦 **Implications for Health Policy and Clinical Practice**

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

4:30pm

- 🐦 **Panel Discussion: Pharmacoepidemiology as the Core Discipline for CER: Where Do We Go From Here?**

*Co-Chairs:*

**Gunnar Alvan**, Professor and former Director General, the Medical Products Agency (Swedish FDA), Sweden

**Hubert GM Leufkens, FISPE**, Dutch Medicines Evaluation Board, The Netherlands

*Panellists:*

All afternoon speakers and a Swedish regulatory agency representative

5:00pm

- 🐦 **Final Comments & Adjournment**

**Ulf Bergman, FISPE**



## 2009 MID-YEAR MEETING PLANNING COMMITTEE

**Ulf Bergman, FISPE**, Chair, Karolinska University Hospital/Karolinska Institutet

**Mark H. Epstein, ISPE**

**Helle Kieler**, Center for Pharmacoepidemiology (CPE), Sweden

**Jim Lewis**, University of Pennsylvania/Center for Clinical Epidemiology & Biostatistics

**Andrew McAfee**, i3 Drug Safety

**Allen A. Mitchell, FISPE**, Slone Epidemiology Center at Boston University

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

**Björn Wettermark**, Swedish Society for Pharmacoepidemiology (SLEF)

## Tourist Information

### Welcome to Stockholm

— one of the world's most beautiful capitals. Built on 14 islands around one of Europe's largest and best-preserved medieval city centers, the Swedish capital is superbly positioned, with stunning and extremely varied scenery in every direction. Stockholm offers a wealth of museums, theatres, sights, attractions and events, whether your interest lies in history, art, opera, modern dance, traditional handicraft, contemporary design or virtually anything else.



*Changing of the Guards:*  
Alexander V Dokukin,  
©Stockholm Visitors Board,  
[www.imagebank.sweden.se](http://www.imagebank.sweden.se)

The **Stockholm Card** offers free entry to 75 museums and attractions, free travel by public transport, free sightseeing by boat (summertime) as well as several other bonus offers. The card is valid 24, 48 or 72 hours from the first time you use it. The card is valid once per attraction and entitles the user to unlimited travel by metro, bus and commuter train.

For more information about Stockholm and the Stockholm Card, please visit the Stockholm Visitors Board website at [www.stockholmtown.com](http://www.stockholmtown.com)

## Cancellations/ Refund Policy

If you have to cancel your registration for any reason, ISPE must receive written notification **by April 10, 2009**. Refunds will be issued less a 20% administrative fee after the meeting. No refunds will be issued for cancellations received **after April 10**. Substitute participants will be accepted at the discretion of ISPE.

Mid-Year  
**ISPE 2009**  
Meeting

**International Society for  
Pharmacoepidemiology**  
5272 River Road, Suite 630  
Bethesda, MD 20816 USA

*Address service requested.*

First-Class Mail  
U.S. Postage  
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Hagerstown, MD  
Permit No. 93

- 📍 **Elite Palace Hotel/  
Karolinska University  
Hospital**
- 📍 **Stockholm, Sweden**
- 📍 **April 25-27, 2009**

## Hotel Information

ISPE has reserved a block of rooms for the 2009 Mid Year Meeting at the Elite Palace Hotel in Stockholm. The hotel will be the site of the meetings and courses offered on April 25 & 26. The symposium (April 27) will be held in the Nanna Svartz Auditorium of the Karolinska University Hospital, which is a 15-20 minute walk from the hotel.

Please contact the Elite Palace Hotel directly to make your reservations. When making the reservation, please state you are with **"ISPE"** and use the special reservation code **"5056KAR"** to ensure you receive the special discounted ISPE rates. [April 23-24 and 26-28 1318 sek/night/person; April 24-26/weekend rate 985 sek/person/night. Rates include breakfast and VAT.]

### Elite Palace Hotel

St Eriksgatan 115  
BOX 210 34  
100 31 Stockholm

Email: [reservation.palace@elite.se](mailto:reservation.palace@elite.se)

Phone: + 46 8 566 217 40

ISPE meeting code: 5056KAR

Web: [www.elite.se/eng/node/705](http://www.elite.se/eng/node/705)

## Travel/Transportation

Planes will arrive/depart from Stockholm-Arlanda Airport, about 40 km north of Stockholm

**Rail:** The airport has two railway stations (one under Terminal 5 and one with exits to Terminals 2, 3 and 4) for frequent express trains to Stockholm. The *Arlanda Express* (tell: (08) 5888 9000; website: [www.arlandaexpress.com](http://www.arlandaexpress.com)) trains reach the city centre in 20 minutes. One way ticket is 240 SEK. Then take a bus, subway or taxi to the Elite Palace Hotel.

**Bus:** There are bus stations outside Terminals 2, 4 and 5. Buses run to Stockholm City Terminal (journey time - 45 minutes) and to many other destinations. The airport coaches leave Cityterminalen every 10-15 minutes. Bus 583 connects with the commuter train at Märsta station. An Arlanda bus stops outside the Elite Palace Hotel at "Norra Stationsgatan". It takes 30 minutes and probably is faster than taking the train. One way ticket is 110 SEK.

**Taxi:** Taxis run from directly outside the terminals. When taking a taxi, passengers should speak to a taxi coordinator, found outside the terminal building. Taxis registered as environmentally "clean" cars have a separate queue. At the airline terminals, these "ecotaxis" are always at the front of the queue of taxis. Be sure you set a fixed price of no more than approximately 500 SEK.