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New this year **Two-Day** Symposium!

# **JJPE 2014** MID-YEAR MEETING & JYMPOJIUM

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The research leading to these results has received funding from the European Union Seventh Framework Programme FP7/2007-2013 under grant agreement no. 261060

for additional travel/hotel and meeting information

# ISPE 2014 MID-YEAR MEETING

AGENDA

## Pediatric Pharmacoepidemiology: How Do We Grow This Child?

## JUNDAY, APRIL 6

#### Pre-Symposium Courses/ Scientific Program Committee (NO EXHIBITS) \*Additional registration required

7:30am-4pm Registration Open (15th Floor)

8:00am-Noon Introduction to Pharmacoepidemiology\*

Case Control Studies —Rene Schade

Cohort Studies —Frank Andersohn

Confounding & Bias —Tobias Gerhard, FISPE

8:30am-Noon 2014 ICPE Scientific Program Committee

Noon-1:25pm Lunch on Your Own

1:30pm-5:30pm Advanced Topics in Pharmacoepidemiology\*

Empirical Bias Analysis for Observational Studies

—Martijn Schuemie

Text Mining Methods and Applications in the Area of Drug & Vaccine Safety Studies —J. Kors

Genome-wide Analysis & Pharmacoepidemiolgy —Geoffrey Liu

Methods for Studying Teratogenic Drug Effects —Andrea Margulis

## MONDAY, APRIL 7

ISPE 2014 Mid-Year Symposium Pediatric Pharmacoepidemiology: How Do We Grow this Child?

8:00am-4:45pm Table Top Exhibits

8:00am-4:45pm Registration (15th Floor)

9:00-9:15am
 Welcome from the ISPE President

 —Til Stürmer, FISPE, President

#### ▶ 9:15-9:25am

Introduction and Objective of Symposium —Miriam Sturkenboom, FISPE *Chair, Planning Committee* 

▶ 9:25-9:30am

Impact of Pediatric Medicines Research —D. Tibboel, Sophia Children's Hospital, Rotterdam

9:30-11:00am Impact of the Current Evidence Gap Around

Pediatric Medicines Co-Chairs:

J. van den Anker & M. Gazarian

Presentations: Impact of Off-label Drug Use in Pediatrics on Drug Safety and Effectiveness Profile —Antonio Clavenna, *Mario Negri Institute, Italy* 

Medication Errors in Children —Sharon Conroy, University of Nottingham, UK

Patient/Parent's Perspective —Invited Speaker to be confirmed

11:00-11:25am Break with Exhibitors

#### ▶ 11:30am-1:00pm

**Student Abstract Presentations** 

This session will feature six student presentations selected by an abstract submission and peer review process with time for questions.

**Co-Chairs:** Susanna Perez-Gutthann, FISPE, & D. Weibel

**Presentations:** The Impact of Exposure Model Misspecification on the Timeliness of Signal Detection in Pharmacovigilance

- Rolina D. van Gaalen, Canada

Beta-blocker Usage and Colorectal Cancer Survival: A Nested Case-control Study in the UK Clinical Practice Research Datalink Cohort —Blánaid Hicks, *UK* 

Bias in Prescription Data of the Irish Ovarian Cancer Population —Chris Brown, *Ireland* 

Comparative Effectiveness and Safety of SSRI Use in Combination with NSAIDs or Paracetamol: A Population-based Cohort Study

—Ole Koehler, Denmark

Performance of Prior Event Rate Ratio Adjustment Method in Pharmacoepidemiology —Jamal Uddin, *The Netherlands*  Implementation of a Trust-wide Guideline Improves Proton Pump Inhibitor (PPI) Prescribing in a University Teaching Hospital —Carina Owen, *UK* 

#### 1:00-1:55pm

**Networking Lunch with Exhibitors** (Included in registration fee.)

#### 2:00-4:00pm

How Can Pediatric Pharmacoepidemiology Make a Difference to You: Stakeholder Perspectives

**Co-Chairs:** HGM Leufkens, FISPE, & Til Stürmer, FISPE

Presentations: Food and Drug Administration: — Ann McMahon, *FDA*, USA

European Medicines Agency — Ralf Herold, *EMA*, *UK* 

Prescriber and Guidelines — Madlen Gazarian, University of New South Wales, Australia

Marketing Authorization Holder — Rachel Sobel, *Pfizer, USA* 

Pediatric Special Interest Group (ISPE) —Tamar Lasky, *MIE Resources, USA* 

4:00-4:25pm Break with Exhibitors

4:30- 5:30pm Children Are Not Small Adults: How Should this be Translated in Pharmacoepidemiology

**Co-Chairs:** F. Kaguelidou & Andrea Margulis

#### Presentations:

Basics of Developmental/Pediatric Clinical Pharmacology and the Relation with Drug Safety Profiles in Children

—John van den Anker,

University of Basel, Switzerland

The Impact of Pediatric Formulations on Safety and Effectiveness of Drugs —Sara Arenas-Lopez,

School of Pharmacy, UK

▶ 5:30pm

Adjournment, Day One

▶ 6:00pm

**Reception at Rotterdam City Hall** (Included in registration fee)

8:00pm Student Night Out

Continued on back $\rightarrow$ 

JPE 2014 MID-YEAR	MEETING
April 6–8, 2014 ◆ Inntel Hotels Rotterdam Centre ◆ Rotterdam, The Netherlands	& JYMPOJIUN

# **REGISTRATION FORM** Pediatric Pharmacoepidemiology: How Do We Grow This Child?

[Use one form per person; use photocopies for additional registrations]

FIRST/GIVEN NAME:	LAST/FAMILY NAME:					
POSITION/TITLE:	COMPANY/INSTITUTION/AFFILIATION:					
STREET ADDRESS:						
CITY:	STATE/PROVINCE:ZIP/POSTAL CODE:					
COUNTRY:	EMAIL:					
OFFICE PHONE: ()	FAX: ()					
*SPECIAL DIETARY/ACCESSIBILITY REQUIREMENTS:						

Please describe in detail.

A: REGISTRATION FEES: (US Dollars)

Advance Deadline 11:59pm EST March 11, 2014.

(CHECK BOX)		April 6 / am Pharmacoepi	Sunday, Ap Adv. Topics in		Monday, April 7 · 2-Day Sy	• Tuesday April 8 mposium
ISPE Member	Advance	Onsite	Advance	Onsite	Advance	Onsite
Industry/Service Provider	□ \$295	<b>□</b> \$345	□ \$295	<b>□</b> \$345	□ \$450	□ \$500
Academic	<b>□</b> \$170	□ \$220	🗅 \$170	□ \$220	□ \$250	□ \$300
Government	🗅 \$170	□ \$220	🗅 \$170	□ \$220	□ \$250	□ \$300
Retired	<b>□</b> \$55	<b>□</b> \$105	🗅 \$55	<b>□</b> \$105	□ \$85	🗅 \$135
Special*	<b>□</b> \$55	<b>□</b> \$105	🗅 \$55	<b>□</b> \$105	<b>□</b> \$85	🛯 \$135
Non-Member						
Industry/Service Provider	□ \$345	□ \$395	□ \$345	<b>□</b> \$395	□ \$525	🗅 \$575
Academic	□ \$225	<b>□</b> \$275	□ \$225	<b>□</b> \$275	□ \$340	□ \$390
Government	□ \$225	□ \$275	□ \$225	<b>□</b> \$275	□ \$340	□ \$390
Retired	□ \$65	<b>□</b> \$115	□ \$65	<b>□</b> \$115	□ \$95	🗅 \$145
Special*	<b>□</b> \$65	<b>u</b> \$115	🗅 \$65	<b>□</b> \$115	<b>□</b> \$95	<b>□</b> \$145
Student/Recent Graduate**	<b>□</b> \$55	□ \$75	<b>□</b> \$55	□ \$75	□ \$95	<b>□</b> \$145

□ I plan on attending the Social Event at the Rotterdam City Hall at 6pm on Monday Night. Guests: \_

#### B: NEW ISPE MEMBERSHIP: (Not For Dues Renewal)

Regular Membership	□ \$250	Retired Membership 🛛 🗳 \$85
Special Membership	□ \$25	Membership expires June 30, 2015.

C: TOTAL: (REGISTRATION + NEW MEMBERSHIP= \$\_\_\_\_\_

Notes: \* Individual must be a citizen and resident of a country classified as High, Medium or Low Human Development as identified by the United Nations (Source: Human Development Report 2013)

\*\*Students/recent graduates must provide ISPE with 1) Documentation of Full-Time Status OR 2) Proof of recent graduation, via email ispe@paimgmt. com or fax 301.656.0989.

### **REGISTER BY:**

Mail ISPE 2014 Mid-Year Meeting 5272 River Road, Suite 630 Bethesda, MD USA 20816

Fax Registration form with credit card information to the ISPE Office at 301-656-0989

**PAYMENT METHOD:** 

Payment by credit card (US DOLLARS):

□ American Express □ Visa □ MasterCard

ACCOUNT NUMBER:

SECURITY CODE:

NAME EXACTLY AS IT APPEARS ON CARD:

#### EXPIRATION DATE (MONTH/YEAR):

### CANCELLATIONJ/REFUND POLICY:

If you have to cancel your registration for any reason, ISPE must receive written notification by March 21, 2014. Refunds will be issued, less a 20% administrative fee, after the meeting. No refunds will be issued for cancellations received after March 21, 2014.

Web pharmacoepi.org

ISPE Federal Tax ID: 41-1688677

Substitutes will be accepted at the discretion of ISPE.

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♦ INNTEL HOTEL∫ ROTTERDAM ♦ APRIL 6-8, 2014 ♦

# ISPE 2014 MID-YEAR MEETING SYMPOSIUM REGISTER TODAY!

# TUESDAY, APRIL 8

ISPE 2014 Mid-Year Symposium Cont. Pediatric Pharmacoepidemiology: How Do We Grow This Child?

8:00am-2:15pm Table Top Exhibits

8:00am-2:15pm Registration (15th Floor)

9:00-10:30am How to Study Drug Effects in Special Pediatric Subgroups: Data & Methods

Co-Chairs: D. Tibboel & J. Bonhoeffer

Presentations:

Drugs, Pregnancy & Lactation —Lolkje de Jong van den Berg, FISPE The Netherlands

Effects of Drugs in Critically III Infants and Children: Effectiveness and Safety Assessment

—Saskia de Wildt, Erasmus MC, The Netherlands

Pharmacogenomics in Children —Anke Hilse Maitland-van der Zee, University Utrecht, The Netherlands 10:30-10:55am Break with Exhibitors

11:00am-1:00pm Pediatric Drug Issues

**Co-Chairs:** Miriam Sturkenboom, FISPE, & Tamar Lasky

Presentations: Antibiotic Drug Use in Children & Resistance: Need for Pediatric DDD —Julia Bielicki, St. Georges Hospital, UK

Pediatric Vaccine Safety —Jan Bonhoeffer, Brighton Collaboration, Switzerland

Safety of Asthma Drugs in Children —Ann McMahon, *FDA*, *USA* 

Safety of Psychotropic Drugs in Children — Ian Wong, University of Hong Kong, Hong Kong

1:00-2:00pm

Networking Lunch with Exhibitors (Included in registration fee)

> 2:00-3:30pm

Methods in Pediatric Research

**Co-Chairs:** LTW de Jong van den Berg, FISPE, & K. Verhamme

#### Presentations:

PK/PD Modeling in Pediatrics & Bridging to Pharmacoepidemiology

—Catherijne Knibbe, Leiden Academic Center for Drug Research, The Netherlands

Pediatric Specific Data Mining Methods

- for Spontaneous Reports: How to Adapt? —Kristina Star, Uppsala Monitoring
- Centre, Sweden
- Overview of Designs and Methods Used in Safety Assessment of Pediatric Drugs
- —Florentia Kaguelidou, Erasmus MC, The Netherlands

► 3:30pm Final Comments/Adjournment