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New this year Two-Day Symposium!

ISPE 2014 MID-YEAR MEETING

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& SYMPOSIUM

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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

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→

April 6–8, 2014 ◆ Inntel Hotels Rotterdam Centre ◆ Rotterdam, The Netherlands

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 NAI				ИЕ:		
POSITION/TITLE:	UTION/AFFILIATION:					
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CITY: STATE/PROVINCE: ZIP/POSTAL CODE:						
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*SPECIAL DIETARY/ACCESSIBILITY REQUIREMENTS:						
Please describe in detail.						
A: REGISTRATION FEES: (US Dollars) Advance Deadline 11:59pm EST March 11, 2014.						
Sunday, April 6 / am Sunday, April 6 / pm Monday, April 7 - Tuesday April 8						
(CHECK BOX)	Intro. to P	harmacoepi	Adv. Topic	s in Pharmacoepi	2-Day Sy	mposium
ISPE Member	Advance	Onsite	Advanc	e Onsite	Advance	Onsite
Industry/Service Provider	□ \$295	□ \$345	□ \$29		□ \$450	□ \$500
Academic	□ \$170	□ \$220	□ \$17		□ \$250	□ \$300
Government	\$170	□ \$220 □ \$125	□ \$17		\$250	□ \$300 □ \$135
Retired	□ \$55 □ ¢55	□ \$105 □ \$105	□ \$5		□ \$85 □ ¢85	□ \$135
Special*	□ \$55	□ \$105	□ \$5	5 🗅 \$105	□ \$85	□ \$135
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Industry/Service Provider	□ \$345	□ \$395	□ \$34		□ \$525	□ \$575
Academic	\$225	□ \$275 □ \$275	□ \$22		\$340	□ \$390 □ \$390
Government	\$225	□ \$275	\$22		\$340	□ \$390 □ \$1.45
Retired	□ \$65	□ \$115	□ \$6		□ \$95	□ \$145 □ \$145
Special*	□ \$65	□ \$115	□ \$6		\$95	\$145
Student/Recent Graduate**	□ \$55	□ \$75	□ \$5	<mark>5</mark> □ \$75	□ \$95	□ \$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)				PAYMENT METHOD:		
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Regular Membership □ \$250 Retired Membership □ \$85 Special Membership □ \$25 Membership expires June 30, 2015.				☐ American Express ☐ Visa ☐ MasterCard		
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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.				SECURITY CODE:		
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Mail ISPE 2014 Mid-Year Meeting Fax Registration form with credit card				ceive written notification by March 21, 2014. Refunds will be issued,		

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Substitutes will be accepted at the discretion of ISPE.

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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