



***28<sup>th</sup> International Conference on  
Pharmacoepidemiology  
& Therapeutic Risk Management***  
*Centre Convencions Internacional Barcelona (CCIB)*  
*Barcelona, Spain*  
*August 22-26, 2012*

***PRELIMINARY AGENDA***

*As of 7-25-2012*

***Wednesday***  
***August 22, 2012***

- |             |   |
|-------------|---|
| 8:00-6:00pm | <b>Registration (CCIB Lobby)</b>  |
| 8:00-5:00pm | <b>Speaker Ready Room (133)</b>   |
| 9:00-5:00pm | <b>ISPE Board of Directors Meeting (Hotel AC<br/>Barcelona Forum)</b><br>(Open to ISPE members; notify ISPE staff if you would like to attend.) |

## ***PRE-CONFERENCE EDUCATIONAL SESSIONS\****

***(\*Registration required)***

8:30-Noon

### **Pharmacogenomics: (131-132) From Basics to High Dimensionality Data Analysis: Concurrent, Introductory and Advanced Topics in the Field of Pharmacogenetic Epidemiology.**

(Includes an afternoon workshop)

#### **Course Objectives**

- To understand the genetic and pharmacogenetic terminology and how cellular and molecular biology informs pharmacogenetic studies at the level of analysis.
- To better understand the study design and methodologic approaches, their strengths and weakness used in pharmacogenetic epidemiology.
- To understand how pharmacogenetics relates to the current focus of Personalized Medicine.
- To have an overview of clinical utility of pharmacogenetics and associated regulatory issues as well as policy-relevant **research.**

#### **Target audiences**

- Members of the Molecular Epidemiology, Biomarkers and Pharmacogenomics (MEBP) SIG
- ISPE members interested in Pharmacogenomics/Pharmacogenetics
- FDA, EMA and other regulators interested in the intersection between pharmacogenetics and epidemiology.
  - Clinical pharmacoepidemiologists
  - Any scientists interested in learning more about pharmacogenetic epidemiology.

#### **Workshop Topics**

- Roundtable 1: Methods and Logistics
- Roundtable 2: Advanced methods
- Roundtable 3: Databases
- Roundtable 4: Policy and Regulatory Issues
- Roundtable 5: Clinical Utility and Implementation

#### **Course Faculty**

- **Paul Boutros**, Ontario Center for Cancer Research
- **Bruce Carleton**, University of British Columbia
- **Andrew Freedman**, EGRP Clinical and Translational

- Epidemiology Branch (CTEB)
- **Rayjean Hung**, Mount Sinai Lenefeld Research Institute
  - **Amilia M. Issa**, Department of Health Policy and Public Health at the University of the Sciences
  - **Stephen Kimmel**, CePRT, University of Pennsylvania
  - **Geoffrey Liu**, Molecular Genomics at the University of Toronto
  - **Anke Hilse Maitland-van der Zee**, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University
  - **David Pulford**, GlaxoSmithKline
  - **Leah Sansbury**, Worldwide Epidemiology Division at GlaxoSmithKline

8:30-Noon

### **Medical Device Epidemiology(120-121)**

Topics will include regulation, safety and effectiveness, and methods. Featuring didactic lectures, cases, Hot Topics and group sessions throughout the day.

#### **Course Faculty/Presentations**

- **Theodore Lystig**, Medtronic, Inc., *Study Design for Postmarket Surveillance*
- **Jessica J. Jalbert**, Brigham and Women's Hospital/Harvard Medical School, *Coordinating the Methods Section, Coordinating Small Group Discussions and Presentations, Leading Small Group Discussions*
- **Mary Elizabeth Ritchey**, FDA/Center for Devices and Radiological Health, *The Total Product Life Cycle and the Dynamic Regulatory Environment of Medical Devices in U.S.*
- **Michael Steinbuch**, Johnson & Johnson Medical Device & Diagnostics, *Innovation and Regulation in Medical Devices in Postmarket Settings & Examples of Postmarket Surveillance: Breast Implant*
- **Art Sedrakyan**, Cornell Medical College, *Comparative Evidence of Various Hip Implants Used for Conventional Hip Replacement*
- **Danica Marinac-Dabic**, FDA/Center for Devices and Radiological Health, *Initiatives, Frameworks, and Developments of Infrastructure and Methodology at the Advent of the Unique Device ID Era*

- **Michele Jonsson Funk**, University of North Carolina at Chapel Hill, *Evaluating the Comparative Safety and Effectiveness of Urogynecologic Surgical Mesh*
- **Soko Setoguchi**, FISPE, Duke Clinical Research Institute & University of Tokyo, *Real-world Effectiveness of Cardiovascular Devices*

Noon-1:30pm

## ***LUNCH ON YOUR OWN***

### ***PRE-CONFERENCE EDUCATIONAL SESSIONS\****

***(\*Registration required)***

1:30-6:00pm

#### **Introduction to Pharmacogenetics (131-132) (cont'd)**

1:30-6:00pm

#### **Medical Device Epidemiology (120-121) (cont'd)**

1:30-6:00pm

#### **Introduction to Pharmacoepidemiology (113)**

[\*Included as part of the full meeting registration; Registration required.]

#### **Course Faculty/Presentations**

- **Syed Rizwanuddin Ahmad**, FISPE, US FDA, *Pharmacovigilance/Spontaneous Reporting*
- **Almut Winterstein**, University of Florida, *Cohort Studies*
- **Sonia Hernandez-Diaz**, FISPE, Harvard School of Public Health, *Case-Control Studies*
- **Tobias Gerhard**, FISPE, Rutgers University, *Bias and Confounding*

2:30-6:00pm

#### **Student Skills Workshop (129-130)\* *STUDENTS ONLY* \***

[Included as part of full meeting registration; registration required]  
Organized by ISPE Student Council

Attendees of the Student Skills Workshop will be able to participate in two workshops while networking with other students and recent graduates.

- **How to Get Published.** Featuring presentations packed full of experience and tips about getting published from two distinguished editors and a panel discussion at the end.

- Careers in Pharmacoepidemiology. Invited speakers will provide an insight into careers in academia, industry, not-for-profit, and regulatory sectors. There will be ample opportunity for questions following each speaker.

6:30-?

### **Students/Young Professionals Meet & Greet**

***Open to all students & young professionals***

Hotel Silken Diagonal, Avenida Diagonal

Meet and greet your fellow students and young professionals with a view of Barcelona's skyline in a summer night of impressive Agbar Tower and Gaudi's Sagrada Familia rising above the city.

-Organized by ISPE Student Council

# ***THURSDAY***

## ***August 23, 2012***

7:30-6:00pm           **Registration (CCIB Lobby)**

7:00-5:00pm           **Speakers' Ready Room (133)**

### ***PRE-CONFERENCE EDUCATIONAL SESSIONS\**** ***(\*Registration required)***

8:30-Noon              **Registries/Prospective Cohort Studies (127-128)**

This workshop will address the following:

- Registries using prospective observational cohort designs as alternatives to randomized controlled trials (RCTs)
- The scope and purpose of different types of registries and how they are being used today in pharmacoepidemiology and risk management
- Considerations of registry development in terms of design and data sources; how they are operationalized and applications for research.

#### **Educational Objectives**

- To describe the evidence hierarchy and differentiate between the important features of various types of “registries” (or “registers) and review the traditional terms used to describe timing (retrospective and prospective)
- To review the opportunities and developments of “registries” as tools to support pharmacoepidemiology, pharmacovigilance and risk management.
- To critically explore the challenges in the design, establishment and conduct of prospective observational cohort studies, with a focus on minimizing the influence of bias and confounding.

#### **Target Audience**

- Those interested in designing prospective observational cohort studies, including registries and registers
- Those interested in conducting prospective studies of comparative effectiveness and safety

- People wishing to learn how prospective studies, including registries, can be used to support risk management and pharmacovigilance
- Anyone interested in knowing how prospective studies, including registries, are used to support pharmacovigilance
- A modest understanding of epidemiologic methods is assumed.

**Course Faculty/Presentations**

- **Nancy A. Dreyer, FISPE**, Quintiles/Outcome, Quality
- **Deborah Layton, DSRU**, Registries and Prospective Cohort Studies - Workshop/Panel Discussion
- **Sonia Hernandez Diaz, FISPE**, Harvard School of Public Health, Pregnancy Registries
- **Saad Shakir, FISPE, DSRU**, Special Challenges of Registries and Prospective Cohort Studies for Risk Management

8:30-Noon

**Propensity Scores (131-132)**

Course Faculty/Presentations

- **John Seeger**, Brigham & Women’s Hospital, *Introduction and Overview of Propensity Scores in Pharmacoepidemiology with Examples*
- **Jeremy Rassen**, Brigham & Women’s Hospital, *Implications of Propensity Score – Based Analyses, Including Covariate Selection and Matching*

8:30-Noon

**Comparative Effectiveness Research (115)**

The course explains the value of comparative effectiveness research (CER) and pragmatic evidence for improving healthcare decisions in the routine care setting by differentiating CER from efficacy or explanatory research. The speakers discuss the trade-offs between different study designs and types of data that were used to conduct CER: a pragmatic randomized controlled trial, a prospective registry, and a retrospective cohort study. Some of the studies combined different types of data to improve efficiency or validity. To illustrate those designs and data, the speakers present case studies from their past and ongoing CER studies. The course covers advanced methods for reducing the biases that can distort estimates of comparative effectiveness.

### **Educational Objectives**

- Recognize the value of comparative effectiveness research for improving routine healthcare decisions and how it differs from efficacy or explanatory research.
- Appreciate the trade-offs between different study designs and types of data for conducting comparative effectiveness research.
- Understand methodologic challenges and proposed solutions in non-randomized effectiveness research

### **Target Audience**

The course is designed for those who conduct comparative effectiveness research and assumes knowledge of introductory pharmacoepidemiologic methods

### **Course Faculty**

- **Eric S Johnson**, Kaiser Permanente
- **Sebastian Schneeweiss, FISPE**, Brigham & Women's Hospital
- **David J Magid**, Colorado Permanente Medical Group

8:30-Noon

### **Intermediate Pharmacoepidemiology (129-130) 2012 Theme: Dealing with Unmeasured Covariates**

Control for the effects of unmeasured covariates is a central problem of observational research. Pharmacoepidemiologists have adopted a wide range of tools to address this issue. Through lectures, examples, and group discussion, we will create a nosology of techniques for dealing with confounding by unmeasured covariates, and achieve a sufficient working knowledge to critically evaluate the uses of each approach. Methods to be covered include: Randomized trials; matching on person and provider; proxy variables for predictors of outcome an exposure; intermediate variables in the effects of covariates for predictors of outcome and exposure; instrumental variables.

### **Course Faculty**

**Alexander Walker, FISPE, WHISCON**

8:30-Noon

## **Regulatory Pharmacoepidemiology/Health Care Decision-Making (124-125)**

### **Educational Objectives**

- Understand the intent and structure of regulation to protect the Public Health
- Appreciate the challenges of decision making with weak data
- Know about practical approaches typically chosen by regulators
- Recognize the challenges epidemiology faces to provide sufficient information for public health decision making
- Gain an overview of world wide challenges for drug regulatory agencies and variation in approaches
- Know about current strategies to strengthen regulation in the face of these challenges

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### **Course Faculty**

- **Stephen Evans, FISPE**, London School of Hygiene and Tropical Medicine
- **Gerald dal Pan**, US FDA
- **June Raine**, MHRA

8:30-Noon

## **Introduction to Drug Utilization Research (113)**

[\*Included as part of the full meeting registration; Registration required.]

### **Content**

- The educational session consists of 6 presentations providing an overview of drug utilization research and presenting essential methods
- The theoretical framework will be described and the practical application of different methods will be illustrated using selected examples
- Interpretation of study results taking into account limitations of data sources and methods will be addressed
- Additional perspectives covered are the importance of drug utilization research for public health and implications for policy decisions
- Interaction with participants will be encouraged, e.g. by presenting short questions to be considered by the audience, and by giving time for questions and answers during and at the end of presentations

### **Educational objectives**

- To provide an overview of Drug Utilization Research within the context of Pharmacoepidemiology, Health Services Research and Public Health
- To describe fundamental principles for classifying and quantifying drug use and to provide an understanding of the methodological challenges
- To motivate researchers to cooperate on the collection of a minimum dataset of consistent and reliable data in their country or region, in terms of volume, expenditures and quality of drug use, facilitating international cross-national comparisons
- To explain the process of developing and validating prescribing quality indicators
- To give an applied overview of methods useful for evaluating interventions, in particular in drug policy research (time series analysis)

### **Target audience**

- New members of the DUR/HSR SIG
- Those interested in drug utilization research who need an overview of the area
- Those interested in monitoring medicine use and quality assurance aspects
- Those working in health care organizations involved in payment and reimbursement of medicines
- Those working in medicines policy areas
- Health service planners

### **Course Faculty/Presentations**

- **Bjorn Wettermark**, Centre For Pharmacopi Karolinska Institutet, *Methodical Framework and Skills Needed in Drug Utilization Research*
- **Hanne Strom**, WHO Collaborating Centre for Drug Statistics Methodology, *The Anatomical Therapeutic Chemical Classification and the Defined Daily Dose: Classifying and Quantifying Drug Use*
- **Morten Andersen**, Centre For Pharmacopi Karolinska Institutet, *Drug Utilization Research and Monitoring in Individual Based Registers - Study Designs and Epidemiological Measures of Drug Use*
- **Vera Vlahovic-Palcevski**, Unit for Clinical Pharmacology University of South Australia, *Comparisons of Drug Utilization - Cross - National, Regional and Between Healthcare Units*

Noon -1:30pm

## ***LUNCH ON YOUR OWN***

Noon-1: 30pm

## ***New Member Luncheon (116) (By Invitation)***

### ***PRE-CONFERENCE EDUCATIONAL SESSIONS\****

***(\*Registration required)***

1:30-6:00pm

## **Advanced Topics in Pharmacoepidemiology (114)**

This course is a series of four lectures covering new and advanced methods for pharmacoepidemiology research.

### **Course Faculty/Presentations**

- **Alan Brookhart**, Department of Epidemiology, University of North Carolina, *Methodological Issues in Integrating EMR Data with Claims*
- **Miguel Hernan**, Harvard School of Public Health, *Analyzing Observational Studies like Randomized Trials and Visa Versa*
- **Mark van der Laan**, University of California Berkeley, *Targeted Maximum Likelihood Estimation in Safety Analysis*
- **Tjeerd-Pieter Van Staa**, CPRD, *What can Pharmacoepidemiology c Contribute to Risk-Benefit Assessment?*

1:30-6:00pm

## **Introduction to Therapeutic Risk Management and Evaluation – Focus on Implementation in the EU(113)**

### **Educational Objectives**

- To provide basic overview/framework for biopharmaceutical risk management including:
- Discussion of the implementation of the new EU legislation on Risk Management Plans (RMP)
- An update on US risk evaluation & mitigation strategies (REMS)
- To describe the current requirements for evaluation studies and types of results that have been seen in the past few years
- To illustrate key concepts of evaluation research with examples of RMP/REMS assessment studies
- To provide an opportunity for interactive session in developing and evaluating a Risk Management Plan

### **Target audiences**

- Epidemiologists with little prior experience developing RMPs and REMS, and in conducting assessments of such programs.
- Pharmacovigilance and regulatory professionals who are involved with reviewing, and negotiating risk RMPs/REMS and their assessments

### **Course Faculty/Presentations**

- **Elizabeth Andrews, FISPE**, RTI Health Solutions, *Course Objectives and Introductions, Overview of Risk Management; and the Role of Evaluation*
- **Stella Blackburn, FISPE**, EMA, *Requirements and Lessons Learned from Evaluating Risk Management Programs in the EU*
- **Gerald dal Pan**, US FDA, *Update from the FDA*
- **Carla Van Bennekom**, Slone Epidemiology Center, *Examples of RMPs and Evaluations*
- **Judith Jones, FISPE**, The Degge Group, *Workshop for Participants to Develop a Risk Management Plan, including an Assessment Approach*

1:30-6:00pm

### **Advanced Drug Utilization Research (127-128)**

This interactive educational program includes presentations, question and answer sessions and a final discussion with the faculty panel. The session will involve participants in the:

- Use of drug utilization information from administrative health data to improve medicines use;
- Development of Prescribing Quality Indicators;
- Application of principles derived from Health Services and Implementation Research to the design of a clinical intervention;
- Methods for evaluating the effect of clinical or policy interventions; and
- Interpretation of the evaluation data and dissemination of results.

### **Educational Objectives**

- To gain an advanced understanding of planning, implementation and evaluation requirements for an effective quality use of medicines intervention.
- To develop a sophisticated understanding of the importance of project planning processes to the effectiveness of interventions.

- To develop an appreciation of the significance of this work to knowledge transfer at the patient care practice and policy change levels of the health system.

#### **Target Audience**

- Members of the DUR/HSR SIG
- Those interested in quality development and implementation research, knowledge transfer, evaluation of interventions, health and medicines policy areas, health funds and third party payers;
- Clinical pharmacoepidemiologists; health service planners; clinical guideline developers; and health practitioners.

#### **Course Faculty/Presentations**

- **Libby Roughead**, School of Pharmacy and Medical Sciences, University of South Australia, *Methods for Identifying and Managing Problems with Medicines Use in Practice*
- **Petra Denig**, University of Groningen, *Developing Valid Prescribing Quality Indicators*
- **Colin Dormuth**, PharmacoEpidemiology Working Group, University of British Columbia, *Evaluating Interventions on Drug Utilization: Analysis Methods*
- **Jerry Avorn**, FISPE, Brigham & Women's Hospital, *Evaluating practice or policy.*

1:30-6:00pm

### **Healthcare Databases (131-132)**

*Using pharmacoepidemiology database resources to address drug safety research*

This highly interactive workshop will involve participants in the:

- Examine the use of database resources in pharmacoepidemiology research;
- Define the different types of data resources available for pharmacoepidemiology and the selection criteria to select the most appropriate resource;
- Review the details of data resources within Europe;
- Identify the elements to properly select a study population and;
- Explore a method to harmonize data from multiple resources

#### **Educational objectives**

- Review the *Guidelines for Good Database Selection and use in Pharmacoepidemiology Research*

- Gain an understanding of available pharmacoepidemiology resources.
- Develop the skills to select an appropriate resource to conduct pharmacoepidemiology research.
- Learn techniques to identify a study population and validate outcome measures.
- Examine methods for defining exposure

#### **Target Audiences**

- Members and potential members of the Database SIG
- Those interested in exploring pharmacoepidemiology resources
- Those working in harmonizing data resources
- Those working in creating analytic datasets
- Clinical pharmacoepidemiologists
- Clinical guideline developers
- Those interested in validating outcomes in secondary databases.
- Health practitioners

#### **Course Faculty/Presentations**

- **Kevin Haynes**, CePRT, University of Pennsylvania, Co-Chair
- **Alison Burke**, CSD EPIC, Co-Chair
- **Gillian Hall**, FISPE, Independent Consultant, *Overview of Database Use in Pharmacoepidemiology*
- **Matthew Reynolds**, UBC, *Selection of Databases for Pharmacoepidemiology Research*
- **Olaf Klungel**, Utrecht University, & Bing Cai, Pfizer, *European Data Resources*
- **Andrew Maguire**, UBC, & **Vincent Lo Re**, CePRT, University of Pennsylvania *Defining Exposure & Validation of Outcomes*

6:00-7:30pm

### ***Welcome Reception/Academic Showcase***

CCIB Lobby

- **Susana Perez-Gutthann**, FISPE, Chair, 2012 Scientific Program Committee
- **Josep Lluís Segú**, Chair, 2012 Local Host Committee
- **Nancy Santanello**, FISPE, ISPE President

### **Academic Showcase Participants**

- Boston University Schools of Public Health and Medicine - Slone Epidemiology Center
- Center for Pharmacoepidemiology Research and Training (CPeRT), Perelman School of Medicine at the University of Pennsylvania.
- Division of Pharmacoepidemiology and Pharmacoeconomics of the Brigham and Women's Hospital, Harvard Medical School"
- Drug Safety Research Unit
- London School of Hygiene & Tropical Medicine
- UNC Gillings School of Global Public Health

# ***FRIDAY***

## ***August 24, 2012***

- 7:00-6:00pm      **Registration (CCIB Lobby)**
- 7:00-5:00pm      **Speakers' Ready Room (133)**
- 7:00-8:00am      **Poster Session A Set-up (Exhibit Hall/Rooms 5-6-7-8)**
- 8:00-6:00pm      **Exhibits/Posters (Exhibit Hall/Rooms 5-6-7-8)**
- 8:15-10:00am     **OPENING SESSION (111-112)**  
*Welcome*  
    **Susana Perez Gutthann, FISPE**, Chair, 2012 Scientific Program Committee  
  
    **Honorable Conseller de Sanitat Sr. Boi Ruiz**, Catalan Minister of Health
- Presidential Address***  
    **Nancy Santanello, FISPE**, ISPE President
- Keynote Address***  
    **Sir Michael Rawlins**, Chairman, National Institute for Health and Clinical Excellence (NICE), *Perspectives on the Uses of Pharmacoepidemiology in Making Decisions About the Use of Medicines*
- 10:00-10:30am    **Break/Posters/Exhibits (Exhibit Hall/ Rooms 5-6-7-8)**
- 10:30 -Noon      **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**
- How Sweet It Isn't (117)**  
    **Moderator: Kay Johannes & Ken Hornbuckle**
- 10:30 AM**      **Using Mailed-In Capillary Blood Samples To Detect Diabetes in Community-Dwelling Adults: Evaluation of an Innovative Strategy [1]**  
    Elham Rahme, Jean-Louis Chiasson, Caroline Sirois, Youssef Habel, Kaberi Dasgupta. (Canada)

- 10:45 AM**      **Prevalence of Known Complications of Diabetes: A Comparison between Large EHR and Claims Databases in the U.S. [2]**  
Aaron WC Kamau, Stephen Agbor, Emily Dastrup, Scott L DuVall, Bharat Thakrar, Debra Maldonato. (United States)
- 11:00 AM**      **Population Attributable Risk of Macrovascular Events Associated with HbA<sub>1c</sub>, Blood Pressure or Weight in Patients with Type 2 Diabetes Mellitus [3]**  
Edith M Heintjes, Fernie JA Penning-van Beest, Shreekant V Parasuraman, Susan Grandy, Mike Pollack, Ron MC Herings. (Netherlands)
- 11:15 AM**      **Population Attributable Risk of Microvascular Events Associated with HbA<sub>1c</sub>, Blood Pressure or Weight in Patients with Type 2 Diabetes Mellitus [4]**  
Edith M Heintjes, Fernie JA Penning-van Beest, Shreekant V Parasuraman, Susan Grandy, Mike Pollack, Ron MC Herings. (Netherlands)
- 11:30 AM**      **Clinical and Economic Benefits of Lowering Severely High Triglycerides on Cardiovascular Events, Pancreatitis, and Diabetes among Patients with Type 2 Diabetes Mellitus [5]**  
Bhakti Arondekar, Jennifer B Christian, Erin Buysman, Rose Snipes, Terry A Jacobson. (United States)
- 11:45 AM**      **Risk Factors for Incident Diabetic Retinopathy in Type II Diabetes in UK Primary Care [6]**  
Elisa Martin-Merino, Joan Fortuny, Elena Rivero, Luis Alberto García-Rodríguez. (Spain)

## **Inappropriate Use of Drugs (115)**

**Moderator: Juan Ramon Laporte & Earl Goehring, Jr.**

- 10:30 AM**      **Investigating the Prevalence and Causes of Prescribing Errors in General Practice: The PRACtICE Study [7]**  
Anthony J Avery, Maisoon Ghaleb, Nick Barber, Bryony D Franklin, Sarah Armstrong, Sarah P Slight, Soraya Dhillon, Anette Freyer, Rachel Howard, Brian Serumaga, Olanrewaju Talabi. (United Kingdom)
- 10:45 AM**      **General Practitioner (GP) Variability in the Prescribing of Potentially Inappropriate Medication in Older Populations in Ireland [8]**  
Caitriona Cahir, Conor Teljeur, Tom Fahey, Kathleen Bennett. (Ireland)
- 11:00 AM**      **Guiding Therapy for Uncomplicated Urinary Tract Infection (UTI) [9]**  
Jessina C McGregor, Miriam R Elman, David T Bearden, David H Smith. (United States)
- 11:15 AM**      **Trends in Antidepressants and Tamoxifen Co-Prescribing among Women with Breast Cancer, 2004-2010 [10]**  
Stacie B Dusetzina, G Caleb Alexander, Rachel A Freedman, Haiden A Huskamp, Nancy L Keating. (United States)
- 11:30 AM

**11:30 AM**      **Prevalence and Correlates of Exceeding the Labeled Maximum Dose of Acetaminophen in the US Adult Population [12]**  
David W Kaufman, Judith P Kelly, Jeffrey M Rohay, Mary K Malone, Rachel B Weinstein, Saul Shiffman. (United States)

**11:45AM**      **Acetaminophen Use Patterns Associated with Excess Dosing [11]**  
Saul Shiffman, Jeffrey M Rohay, Judith P Kelly, Mary K Malone, Rachel B Weinstein, David W Kaufman. (United States)

## **Life of the Cancer Patient (113)**

**Moderators: Daniel Mines & Robert Reynolds, FISPE**

**10:30 AM**      **Treatment Patterns and Comorbidities in a Population-Based Cohort of Glioblastoma Patients (pts) Diagnosed 1997-2008 [13]**  
Susan A Oliveria, Laura Chu, Deborah Casso, Karen Wells, Wei Dong, Robert Dubrow, Asha Das, David Nerenz, Marianne Ulcickas Yood. (United States)

**10:45 AM**      **The Rise of Human Papillomavirus (HPV)-Associated Oropharyngeal Cancer (OPC) in Toronto, Canada: A Case for Vaccinating Males [14]**  
Steven Habbous, Karen P Chu, Anthony La Delfa, Luke Harland, Xin Qiu, Wei Xu, David P Goldstein, John Waldron, Brian O'Sullivan, Shao-Hui Huang, Geoffrey Liu. (Canada)

**11:00 AM**      **Insulin Glargine and Risk of Cancer: A Cohort Study in the French National Healthcare Insurance Database [15]**  
Patrick Blin, Régis Lassalle, Caroline Dureau, Basmah Ambrosino, Marie-Agnès Bernard, Abdelilah Abouelfath, Henri Gin, Claire Le Jeunne, Antoine Pariente, Cécile Droz-Perroteau, Nicholas Moore. (France)

**11:15 AM**      **The Validity of Prescription and Other Health Service Claims and Self-Report in Identifying Cases of Invasive Breast Cancer in Australia [16]**  
Anna Kemp, David B Preen, Kris Rogers, Christobel Saunders, C D'Arcy Holman, Max Bulsara, Fran Boyle, Elizabeth E Roughead. (Australia)

**11:30 AM**      **Futile Drug Use at the End of Life? Continuation of Statins after a Cancer Diagnosis [17]**  
Efty Stavrou, Nicholas Buckley, Jake Olivier, Sallie-Anne Pearson. (Australia)

**11:45 AM**      **The Associations between Treatment Interruption/Nonadherence to Tamoxifen and Mortality of Breast Cancer Patients: A Population Claim-Based Data Analysis in Taiwan [18]**  
Kun-Pin Hsieh, Li-Chia Chen, Chao-Sung Chang, Yi-Hsin Yang. (Taiwan)

## **Methods Tapas (111/112)**

**Moderators: Tobias Gerhard, FISPE, & Jeremy Rassen**

- 10:30 AM**      **The Impact of Unmeasured Confounders in Cardiovascular Studies Performed in Administrative Databases [19]**  
Odile Sheehy, Mary DeVera, Morgane Kermarrac, Lucie Blais, Elham Rahme, Sylvie Perreault, Jocelyne Moisan, Anick Bérard (Canada)
- 10:45 AM**      **Comparison of Five Diagnosis Based Comorbidity Measures in Predicting Health-Related Quality of Life (HRQoL) in Multiple Sclerosis Patients [20]**  
Hemalkumar B Mehta, Sneha D Sura, Michael L Johnson. (United States)
- 11:00 AM**      **Combining Data in Multi-Country Studies: Mega-Analysis Versus Meta-Analysis [21]**  
Marloes T Bazelier, Joan Bentzen, Peter Vestergaard, Hubert GM Leufkens, Frank de Vries. (Netherlands)
- 11:15 AM**      **Design Aspects of Pharmacoepidemiological Two-Phase Studies [22]**  
Sigrid Behr, Walter Schill, Iris Pigeot. (Germany)
- 11:30 AM**      **Use of Claims Data To Predict Dependence in Older Adults [23]**  
Keturah R Faurot, Maurice A Brookhart, Michele L Jonsson Funk, Virginia Pate, Wendy Camelo Castillo, Til Stürmer. (United States)
- 11:45 AM**      **Automated Identification of Asthma Patients within an Electronical Medical Record Database Using Machine Learning [24]**  
Marjolein Engelkes, Zubair Afzal, Hettie M Janssens, Jan A Kors, Martijn J Schuemie, Katia MC Verhamme, Miriam CJM Sturkenboom. (Netherlands)

## **Pregnancy: Macedonia (114)**

**Moderator: Anick Bérard, FISPE**

- 10:30 AM**      **Clarithromycin Use in Early Pregnancy and the Risk of Miscarriage – A Register Based Nationwide Cohort Study [25]**  
Jon T Andersen, Espen Jimenez-Solem, Morten Petersen, Kasper Broedbaek, Nadia L Andersen, Christian Torp-Pedersen, Henrik E Poulsen. (Denmark)
- 10:45 AM**      **Drug Utilization among Pregnant Diabetic Women in US Managed Care [26]**  
Caitlin A Knox, Joseph A Delaney, Almut G Winterstein. (United States)
- 11:00 AM**      **Pregnancy Outcomes in Women Dispensed Ondansetron in Pregnancy [27]**  
Lyn Colvin, Linda Slack-Smith, Fiona J Stanley, Carol Bower. (Australia)

- 11:15 AM**      **TNF $\alpha$  Therapies during Pregnancy and Birth Outcomes: A Nordic Population-Based Study [28]**  
 Helle Kieler, Miia Artama, Johan Askling, Gabriella Bröms, Mika Gissler, Anders Ekblom, Mette Noerregaard, Lars Pedersen, Olof Stephansson, Henrik Toft Sørensen, Fredrik Granath. (Sweden)
- 11:30 AM**      **Inflammatory Bowel Disease in Pregnancy and Thrombophilic Disorders – Impact of Type of Disease and Treatment [29]**  
 Gabriella Bröms, Marie Linder, Fredrik Granath, Maria Elmberg, Olof Stephansson, Helle Kieler. (Sweden)
- 11:45 AM**      **Microtia: Findings Suggest No Association with Vasoactive Medications [30]**  
 Carla M Van Bennekom, Allen A Mitchell, Cynthia A Moore, Martha M Werler. (United States)

## **Put Your Money Where Your Heart Is (116)**

**Moderator: Margaret McDonald & Ulf Bergman, FISPE**

- 10:30 AM**      **The Clinical and Economic Costs Associated with Elevated Triglyceride Levels [31]**  
 Bhakti Arondekar, Jennifer B Christian, Erin Buysman, Susan L Johnson, Kimberly A Lowe, John D Seeger, Terry A Jacobson. (United States)
- 10:45 AM**      **Development of a Model Predicting the Medico-Economic Impact of Telemonitoring for Patients with Heart Failure in France [32]**  
 Samuel Aballéa, Patrice Verpillat, Mohamed-Elmouctar Neine, Yevgeniy Goryakin, Mondher Toumi. (France)
- 11:00 AM**      **Are Vasodilators of Value in the Care of Patients Hospitalized for Acute Heart Failure? [33]**  
 Mei Sheng Duh, Francis Vekeman, Adi Eldar-Lissai, Alex Trahey, Siew Haw Ong, Alan H Gradman. (United States)
- 11:15 AM**      **Comparative Cost-Effectiveness of Interventions To Improve Medication Adherence after Myocardial Infarction [34]**  
 Kouta Ito, William Shrank, Jerry Avorn, Amanda Patrick, Troyen Brennan, Elliott Antman, Niteesh Choudhry. (United States)
- 11:30 AM**      **Impact of Full Coverage for Preventive Medications after Myocardial Infarction on the Time Course of Adherence [35]**  
 Robert J Glynn, William H Shrank, Jerry Avorn, Raisa Levin, Niteesh K Choudhry. (United States)
- 11:45 AM**      **Contribution of Lifestyle Factors to Healthy-Adherer Bias in Prevalent Users of Antihypertensive and Lipid-Lowering Drugs [36]**  
 Mitsuyo Kinjo, Soko Setoguchi. (Japan)

Noon -1:30pm

**Lunch/Poster Session A/Exhibits  
(Exhibit Hall/Rooms 5-6-7-8)**

**ISPE Committee/Council Meetings**

*Open to all members and new members.* Lunch will be available at committee rooms.

- Development Committee (132)
- Fellowship & Awards Committee (M211)
- Finance Committee(M215)
- Public Policy Committee (M214)
- Student Council (124-125)

12:15-1:15pm

**Round Table Discussions (Entrance Hall)**

To foster the ability of the more junior ISPE members to network and new ISPE members to meet others attending the ICPE, we are hosting several lunchtime discussion roundtables on Monday and Tuesday. These roundtables will be informal. The facilitators and topics for the tables are listed below. There will be NO formal presentations made at the roundtables. The purposes are discussion, information exchange, and networking. **Seating is limited; first-come, first-served.**

**Jamie Geier**, GSK, *Practical Aspects of Implementing Benefit/Risk Frameworks within Companies*

**Danica Marinac-Dabic**, US FDA, *Medical Device Epidemiology and Surveillance: Focus on Registries and Innovative Methods Development*

**June Raine**, EMA, *Post-Marketing Surveillance of New Medicines*

12:45-1:30pm

**Poster Walks (Exhibit Hall/Rooms 5-6-7-8)**

- Biologics SIG
- Pediatrics SIG

1:30-3:00pm

**CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

**Breathless in Barcelona (114)**

**Moderators: Kourtney Davis & Eric Von Ganse**

- 01:30 PM Examination of Emergency Inpatient Readmissions within 30 Days from the First Hospitalised COPD Exacerbation in England [37]**  
Andrew M Lawton, Rachael D DiSantostefano, Hana Müllerova. (United Kingdom)
- 01:45 PM Safety of Long-Acting beta Agonists (LABA) with or without Inhaled Corticosteroids in Asthma [38]**  
Mohsen Sadatsafavi, Carlo Marra, Larry Lynd, Mark FitzGerald. (Canada)
- 02:00 PM Inhaled Corticosteroid (ICS) Use in Chronic Obstructive Pulmonary Disease(COPD) and the Risk of Pneumonia [39]**  
Kristijan H Kahler, Barbara Yawn, Haijun Tian, Frank Li, Jie Zhang, Steve Arcona. (United States)
- 02:15 PM Relative Exposure to Inhaled Steroids (Ratio “ICS-to-Total Asthma Therapy”): Concordant Data from Electronic Medical Records (EMRs), Claims Data and Patient-Reported Outcomes (PROs) [40]**  
Laurent Laforest, Licaj Idir, Gilles Devouasoux, Genevieve Chamba, Laurent Letrilliat, Laure Com Ruelle, Eric H Van Ganse. (France)
- 02:30 PM Impact of Omalizumab Initiation on Emergency-Department Visits, Hospitalizations and Corticosteroid Use in Patients with Uncontrolled Asthma Using High-Dose Inhaled Corticosteroids and Long-Acting Beta<sub>2</sub>-Agonists [41]**  
Marie-Hélène Lafeuille, Jason Dean, Jie Zhang, Mei Sheng Duh, Boris Gorsh, Patrick Lefebvre. (Canada)
- 02:45 PM Effectiveness of Omalizumab on Asthma Exacerbations Following Its Introduction in a Large Cohort of Patients with Severe Uncontrolled Asthma [42]**  
Lamiae Grimaldi-Bensouda, Mahmoud Zureik, Michel Aubier, Marc Humbert, Jean Levy, Jacques Benichou, Lucien Abenheim, Mathieu Molimard, (PAX) Group. (France)

## **Broken Hearts or Bleeding Bodies (113)**

**Moderators: Klaas Heinemann & Cristina Varas-Lorenzo**

- 01:30 PM Pattern of Anticoagulation Control and Risk of Stroke, Bleeding and Mortality [43]**  
Hendrika A van den Ham, Olaf H Klungel, Hubert GM Leufkens, Tjeerd P van Staa. (Netherlands)
- 01:45 PM The Use of Single, Dual, or Triple Antithrombotic Therapy and the Risk of Bleeding Events in Patients with Atrial Fibrillation [44]**  
Laurent Azoulay, Sophie Dell’Aniello, Teresa Simon, Christel Renoux, Samy Suissa. (Canada)

- 02:00 PM**      **Intrauterine Devices and the Risk of Uterine Perforations: Interim Results from the EURAS-IUD Study [45]**  
Klaas Heinemann, Suzanne Reed, Jürgen Dinger.  
(Germany)
- 02:15 PM**      **Selective Serotonin Reuptake Inhibitor Use and Perioperative Bleeding and Mortality in Patients Undergoing Coronary Artery Bypass Grafting [46]**  
Joshua J Gagne, Jennifer M Polinski, Jeremy A Rassen, Michael A Fischer, John D Seeger, Jessica A Myers, Jun Liu, Sebastian Schneeweiss, Nitesh K Choudhry. (United States)
- 02:30 PM**      **Risk of Acute Myocardial Infarction (AMI), Stroke, and Death in Parkinson’s Disease (PD) Patients Treated with Entacapone (Entac) or Other Adjunctive Therapies (AT) [47]**  
David J Graham, James R Williams, Ya-Hui Hsueh, Katlyn Calia, Mark Levenson, Simone P Pinheiro, Thomas E MaCurdy, Chris Worrall, Jeffrey A Kelman. (United States)
- 02:45 PM**      **Heralding of STEMI and NSTEMI: A Prospective CALIBER Study [48]**  
Emily Herrett, Julie George, Harry Hemingway, Liam Smeeth. (United Kingdom)

## **Diabetic Treatment Outcomes Around the World (111-112)**

**Moderators: Jeanne Loughlin & Alejandro Arana, FISPE**

- 01:30 PM**      **Risk of Bladder Cancer in Diabetic Patients Treated with Rosiglitazone or Pioglitazone: A Nested Case-Control Study [49]**  
Fei-Yuan Hsiao, Pei-Hua Hsieh, Wen-Foung Huang, Yi-Wen Tsai, Churn-Shiouh Gau. (Taiwan)
- 01:45 PM**      **Long-Term Therapy with Thiazolidinediones May Be Associated with Increased Incidence of Bladder Cancer [50]**  
Ronac Mamtani, Kevin Haynes, Warren B Bilker, David J Vaughn, Brian L Strom, Karen Glanz, James D Lewis. (United States)
- 02:00 PM**      **Effect of Metformin Versus Other Antidiabetic Drugs on Colorectal Cancer Stage [51]**  
Susan Spillane, Kathleen Bennett, Linda Sharp, Thomas I Barron. (Ireland)
- 02:15 PM**      **Comparative Lung Cancer Mortality with Inhaled Insulin or Comparator: An Observational Follow-Up Study of Patients Previously Enrolled in Exubera Controlled Clinical Trials (FUSE) [52]**  
Nicolle M Gatto, Daniel O Koralek, Michael B Bracken, William T Duggan, Joanna Lem, Sol S Klioze, Neville C Jackson. (United States)

- 02:30 PM**      **Risk of First Severe Hypoglycaemic (SH) Coma Event among Patients with Diabetes Who Initiate the Use of Detemir (IDet), Glargine (IGla) and NPH Insulins: A Nationwide Register-Linkage Study in Finland [53]**  
Pasi Korhonen, Fabian Hoti, Panu Erästö, Sari Mäkimattila, Tero Saukkonen, Jari Haukka. (Finland)
- 02:45 PM**      **Characteristics of Patients Initiating Oral Antidiabetic Therapy in the UK: Evidence of Delayed Treatment? [54]**  
Andrew Maguire, Beth Mitchell. (United Kingdom)

## **Drug Utilization in Cardiovascular Disease (116)**

**Moderators: Brian Godman & Soko Setoguchi-Iwata, FISPE**

- 01:30 PM**      **Time Trends in Antihypertensive Drug Use and Blood Pressures in Swedish Primary Health Care 2001-2008 [55]**  
Magnus Vretblad, Björn Wettermark, Thomas Kahan, Jan Hasselström. (Sweden)
- 01:45 PM**      **Predictors of First-Step Antihypertensive Treatment among Older Adults at High Risk for Cardiovascular Outcomes [56]**  
Xiaojuan Li, Wendy Camelo-Castillo, Til Stürmer, Christine L Gray, Virginia Pate, Michele Jonsson Funk. (United States)
- 02:00 PM**      **Oral Hypoglycemic Agent Adherence and Hospitalization among Patients with Type 2 Diabetes: A Call for Enhanced Guidelines [57]**  
Vivienne J Zhu, David G Marrero, Wanzhu Tu, Marc B Rosenman, Marc J Overahge. (United States)
- 02:15 PM**      **Drug Treatment after Transient ischaemic Attack or Ischaemic Stroke: Are We Doing Enough To Reduce Secondary Risk? [58]**  
Janet K Sluggett, Gillian E Caughey, Michael B Ward, Andrew L Gilbert. (Australia)
- 02:30 PM**      **Potentially Inappropriate Drugs in Elderly Hypertensive Patients with Impaired Renal Function [59]**  
Katharina Schmidt-Mende, Björn Wettermark, Morten Andersen, Jan Hasselström. (Sweden)
- 02:45 PM**      **Prevalence of Potentially Inappropriate Medication Prescribing among Older US Adults [60]**  
Marcela Jiron, Virginia Pate, Michele Jonsson Funk, Til Stürmer. (Chile)

## **Pregnancy, Brains and Pains (115)**

**Moderator: David Miller & Elena Rivero, FISPE**

- 01:30 PM**      **Treatment of Depression during Pregnancy and Its Effect on Infant NICU Admission [61]**  
De-Kun Li, Jeannette R Ferber. (United States)

- 01:45 PM**      **Bipolar Disorder, Mood Stabilizers and Adverse Pregnancy Outcome – A Population Based Cohort Study [62]**  
Robert Bodén, Maria Lundgren, Lena Brandt, Johan Reutfors, Morten Andersen, Helle Kieler. (Sweden)
- 02:00 PM**      **Childhood Overweight Following Fetal Exposure to Selective Serotonin Reuptake Inhibitors and Maternal Psychiatric Illness [63]**  
Luke E Grzeskowiak, Andrew L Gilbert, Thorkild IA Sorensen, Jorn Olsen, Henrik T Sorensen, Lars H Pedersen, Janna L Morrison. (Australia)
- 02:15 PM**      **Antidepressant Use during Pregnancy and the Risk of Delay in Overall Cognitive Development at 1 Year Old: Results from the OTIS Antidepressants Study [64]**  
Anick Berard, Fatiha Karam, Odile Sheehy, Marie-Claude Huneau, Lucie Blais, Gerald Briggs, Christina Chambers, Adrienne Einarson, William Fraser, Andrea Gaedgik, Diana Jonhson, Kelly Kao, Gideon Koren, Brigitte Z Martin, Janine E Polifka, Sara H Riordan, Mark Roth, Richard E Tremblay, Sharon Voyer Lavigne, Lori Wolfe, OTIS Collaborative Research Group. (Canada)
- 02:30 PM**      **Validating a Gestational Length Algorithm Based on Administrative Health Plan Data [65]**  
Qian Li, Susan E Andrade, William O Cooper, Robert L Davis, Sascha Dublin, Tarek A Hammad, Pamala A Pawloski, Simone P Pinheiro, Marsha A Raebel, Pamela E Scott, David H Smith, Inna Dashevsky, Katherine Haffenreffer, Karin E Johnson, Sengwee D Toh. (United States)
- 02:45 PM**      **Use of Non-Steroid Anti-Inflammatory Drugs and Risk of Miscarriage: A Nested Case-Control Study [66]**  
Lars Pedersen, Henrik Toft Sørensen, Mette Nørgaard, Vera Ehrenstein. (Denmark)

## **Propensity Scores Estan de Moda (117)**

**Moderators: Til Stürmer, FISPE, & Patrice Verpillat**

- 01:30 PM**      **Deriving Propensity Scores for Matching or Stratification in Studies with an Important Subgroup Variable as a Strong Confounder [67]**  
Cynthia J Girman, Doug Kou, Mugda Kelkar, Kimberly G Brodovicz, Richard Wyss, Til Stürmer. (United States)
- 01:45 PM**      **Optimal Approaches to One-to-Many Propensity Score Matching in Cohort Studies [68]**  
Jeremy A Rassen, Abhi A Shelat, Jessica Myers, Robert J Glynn, Kenneth J Rothman, Sebastian Schneeweiss. (United States)
- 02:00 PM**      **Comparison of Propensity-Score-Weighted and -Matched Estimates in a Comparative Effectiveness Study: A Demonstration Using STAR\*D Trial Data [69]**

Alan R Ellis, Stacie B Dusetzina, Richard A Hansen, Bradley N Gaynes, Joel F Farley, Til Stürmer. (United States)

**02:15 PM Use of Confounders' Time Patterns To Improve Bias Adjustment with High-Dimensional Propensity Scores [70]**  
Jeremy A Rassen, Shirley Wang, John Seeger, Sebastian Schneeweiss. (United States)

**02:30 PM A Comparison of Boosted CART and Logistic Regression for the Estimation of Propensity Scores [71]**  
Richard Wyss, Alan R Ellis, Cynthia J Girman, Robert LoCasale, Til Stürmer. (United States)

**02:45 PM Evaluating Propensity Score Balance Measures in Typical Pharmacoepidemiological Settings [72]**  
Mohammed S Ali, Rolf HH Groenwold, Wiebe R Pestman, Svetlana V Belitser, Arno W Hoes, Kit CB Roes, Anthonius de Boer, Olaf H Klungel. (Netherlands)

3:00-3:30pm

**Break/Posters/Exhibits (Exhibit Hall/Rooms 5-6-7-8)**

3:30-5:00pm

**PLENARY SESSION (111/112)**

### ***ADHD Medication and the Risk of Cardiovascular Events***

There has been controversy in recent years regarding the question as to whether ADHD medication increases the risk of adverse cardiovascular events. This session will provide attendants with an overview of the studies at the core of the controversy and place them in the context of the increasing frequency of ADHD diagnosis and the associated increase in use of stimulants in the young population. Risk benefit considerations and will be discussed from an academic, clinical and regulatory perspective.

**Co-Chairs: William Cooper (tbc) & Sonia Hernandez Diaz, FISPE**

- **Bill Cooper**, Vanderbilt University. Setting the Scene. The frequency of ADHD diagnosis, and associated utilisation of stimulants in increasing in North America and Europe. The first presentation will give an overview of the controversy in the context of what is ADHD, issues with diagnosis, and treatment choices. William Cooper's study was published in the NEJM and concluded there was no evidence of an increase in cardiovascular risk associated with stimulant use, although a doubling of risk could not be ruled out.

- **Helga Zoega**, University of Iceland. Utilization patterns of stimulants in the USA and Europe and association with academic progress associated with starting treatment at younger or older age; two studies demonstrating late initiation in treatment is associated with poorer academic performance in maths and languages compared with earlier initiation of treatment. Helga Zoega may not be known to all but comes highly recommended as an excellent speaker by Sonia Hernandez Diaz and Ken Rothman, who were involved with her study.
- **Almut Winterstein**, University of Florida. Results of the second federally funded US cardiac safety study. Sample size very similar to Bill Cooper's cohort (publication in NEJM), but sampled from Medicaid only. Because of this, high-risk children could be included and have a stratified analysis. Besides the major endpoint of sudden cardiac death/AMI/stroke we also have a secondary analysis on arrhythmia, which may be of interest. There are also some interesting methodological considerations in looking at very rare events, which are driven largely by high-risk kids.
- **June Raine**, MHRA. Summary of the evidence & their perspective, reactions in the various stages of the development of this

Panel discussion.

5:00-6:30pm

## **CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS**

### **Advanced Methods and Measures for Studying Complex Drug Utilization Patterns with Patient-Level Databases [73] (111/112)**

Petra Denig, Morten Andersen, Helle Wallach Kildemoes, Lisa Pont, Jaco Voorham, Jean Pierre Grégoire. (Netherlands)

### **Biases To Consider When Studying the Risk of Medication Use in Pregnancy [74] (117)**

Marian K Bakker, Heli Malm, Hao Wang, Rachel Charlton, Kristin Palmsten, Lolkje TW de Jong-van den Berg. (Netherlands)

***SPONSORED BY THE MEDICINES IN PREGNANCY SIG***

**Databases, Therapeutics, and Biomarkers: The Challenges and Rewards of Incorporating Biological Specimens in Pharmacoepidemiologic Research [75] (113)**

Leah B Sansbury, Kimberly A Wilson, Joanna F Haas, Bruce Carleton, Tjeerd-Pieter van Staa, Catherine Schaefer. (United States)

*SPONSORED BY THE MOLECULAR  
EPI/BIOMARKERS/PHARMACOGENETICS SIG*

**How To Conduct Collaborative Studies in the EU? Lessons and Results from the Completed Safety of nSais (SOS) Project [76] (114)**

Miriam C Sturkenboom, Annie Fourrier-Réglat, Susana Perez-Guttham, Edeltraut Garbe, Federica Nicotra, Silvana Romio, Eva Molero, Ron Herings, Frantz Thiessard. (Netherlands)

**Improving the Science of Regulatory Decision-Making Advances in 2011/2012 [77] (115)**

Stanley A Edlavitch, Gerald J dal Pan, June M Raine, Bert Leufkens, Jerry Avorn. (United States)

**Medicare Part D Data: Will the US Population-Based Data Be Advancing Pharmacoepidemiology and Public Health? [78] (116)**

Til Stürmer, Michele Jonsson Funk, Kourtney J Davis, David J Graham, Elizabeth Andrews, Jesper Hallas. (United States)

**Unique Device Identification System (UDIS): Implications for Postmarketing Safety and**

## **Effectiveness Assessment in the United States and Europe [79] (132)**

Danica Marinac-Dabic, Art Sedrakyan, Michael Steinbuch, Jessica Jalbert, Jay Crowley, Gerold Labek, Mary Beth Ritchey, Soko Setoguchi. (United States)

*SPONSORED BY THE MEDICAL DEVICES SIG*

6:30-7:30pm

### **ISPE Council Meetings**

*Open to all interested members and new members.*

- Academic Council (115)
- Government/Regulatory Council (114)
- Industry/Service Providers Council (116)

7:30-8:30pm

### **PDS Editorial Board** *(By Invitation)(124-125)*

TBD

### **Students/Young Professionals Night Out**

Do you like the sound of the sea? Chill-out music? Catching up with old ISPE friends? Making new friends? Come to the Student/Young Professionals dinner in a beach chiringuito and live Barcelona's nightlife a few metro stops from the convention stop.

Space is limited. The dinner is open to students/young professionals who have RSVP'd and received confirmation from the Student Council Chairs. Contacts:

Caitlan Knox [cknox@ufl.edu](mailto:cknox@ufl.edu)

Wihelmine Meeraus [wilhelmine.meeraus.09@ucl.ac.uk](mailto:wilhelmine.meeraus.09@ucl.ac.uk)

-Organized by the ISPE Student Council

# ***SATURDAY***

## ***August 25, 2012***

- 7:00-6:00pm      **Registration (CCIB Lobby)**
- 7:00-5:00pm      **Speakers' Ready Room (133)**
- 7:00-8:00am      **Poster Session B Set-up (Exhibit Hall/Rooms 5-6-7-8)**
- 8:00-6:00pm      **Exhibits/Posters (Exhibit Hall/Rooms 5-6-7-8)**
- 8:30-10:00am     **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

### **“A Joint Session” on Aches and Pains**

**Moderator: Doug Watson (111-112)**

- 08:30 AM**      **Integrating Patient-Reported Outcomes (PRO) and Medical Record Data (MR) in Observational Studies: Results from a Direct-to-Patient Pilot Study in Gout [336]**  
Elisa Cascade, Paige Marr, Matthew Winslow. (United States)
- 08:45 AM**      **Severe Cutaneous Reactions Requiring Hospitalization in Allopurinol Initiators: A Population-Based Cohort Study [337]**  
Seoyoung C Kim, Craig Newcomb, David Margolis, Jason Roy, Sean Hennessy. (United States)
- 09:00 AM**      **Statins Do Not Influence Giant Cell Arteritis Outcome in the French APOGEE Cohort. A Population-Based Study Using the French Health Insurance System Database [338]**  
Grégory Pugnet, Laurent Sailler, Robert Bourrel, Jean-Louis Montastruc, Maryse Lapeyre-Mestre. (France)
- 09:15 AM**      **Methotrexate Utilization in Rheumatoid Arthritis. Treatment Re-Starts after Gaps of at Least 90 Days [339]**  
Annette de Thurah, Mette Nørgaard, Rikke Nielsen, Kristian Stengaard-Pedersen. (Denmark)
- 09:30 AM**      **Risk of Serious Infection and Malignancy in Rheumatoid Arthritis Patients Treated with Anti-Tumor Necrosis Factor-Alpha Biologics [340]**  
Veena Thyagarajan, Heather Norman, Cheryl Enger. (United States)

**09:45 AM**      **Occurrence of Osteonecrosis and Total Joint Replacement among Patients with Osteoarthritis [341]**  
Kandace L Amend, Daniel Koralek, David D Dore. (United States)

## **CV Meds: What Would You Do? (117)**

**Moderators: K. Arnold Chan, FISPE, & Jennifer Christian**

- 08:30 AM**      **The Effect of Statin Use on Acute Kidney Injury Risk Following Coronary Artery Bypass Graft Surgery [342]**  
J Bradley Layton, Abhijit V Kshirsagar, Ross Simpson, Virginia Pate, Michele Jonson-Funk, Til Stürmer, M Alan Brookhart. (United States)
- 08:45 AM**      **Statin Use and Risk of Atrial Fibrillation or Flutter: A Population-Based Case-Control Study [343]**  
Giacomo Veronese, Jonathan Montomoli, Morten Schmidt, Erzsébet H Puhó, Henrik T Sørensen. (Denmark)
- 09:00 AM**      **The Assessment of Statin-Associated Severe Muscle Toxicity in Japan- by Using Claims Database with Laboratory Information [344]**  
Chia-Hsien Chang, Makiko Kusama, Manabu Akazawa, Yea-Huei Kao Yang. (Taiwan)
- 09:15 AM**      **Cardiovascular Risk of Olmesartan (Olm) Compared with Other Angiotensin-II Receptor Blockers (ARBs) [345]**  
David J Graham, Xiao Ding, Shahin Saneinejad, Esther H Zhou, Katlyn Calia, Mark Levenson, Kate Gelperin, Martin Rose, Tarek A Hammad, Thomas E MaCurdy, Chris Worrall, Jeffrey A Kelman. (United States)
- 09:30 AM**      **Angioedema Events and Use of Drugs That Act on the Renin-Angiotensin-Aldosterone System (RAAS) [346]**  
Darren Toh, Marsha E Reichman, Monika Houstoun, Marry Ross Southworth, Xiao Ding, Adrian F Hernandez, Mark Levenson, Lingling Li, Azadeh Shoaibi, Gwen Zornberg, Sean Hennessy. (United States)
- 09:45 AM**      **Risk of Acute Renal Failure Likely Due to Concurrent Use of ACE-Inhibitors, Angiotensin Receptors Blockers, Diuretics and Anti-Inflammatory Drugs [347]**  
Francesco Lapi, Laurent Azoulay, Hui Yin, Samy Suissa. (Canada)

## **Diabetes: A Little Bit of This and That (113)**

**Moderators: Michael Steinbuch & Dorothee Bartels**

- 08:30 AM**      **International Comparison of the Utilisation of Anti-Diabetic Medicines [348]**  
Agnes I Vitry, Zhi Hui Eeow, Gillian E Caughey. (Australia)
- 08:45 AM**      **The Impact of a National Program on Judicious Use of Antidiabetic Medicines [349]**  
Yeqin Zuo, Jeff Elliott, Louise Lor, Mark Bartlett, Jonathan Dartnell, Lynn Weekes. (Australia)

- 09:00 AM**      **Validation of Diabetic Retinopathy and Maculopathy Diagnoses Recorded in a UK Primary Care Database [350]**  
Elisa Martin-Merino, Joan Fortuny, Elena Rivero, Luis Alberto García-Rodríguez. (Spain)
- 09:15 AM**      **Aspirin and the Risk of All-Cause Mortality in New Users of Oral Antidiabetes Drugs [351]**  
Caroline Sirois, Jocelyne Moisan, Elham Rahme, Jean-Pierre Grégoire. (Canada)
- 09:30 AM**      **Statin Initiation in Elderly Patients Using Antidiabetes Drugs [352]**  
Marie-Laure Laroche, Marie-Claude Breton, Eric Demers, Jean-Pierre Gregoire, Jocelyne Moisan. (France)
- 09:45 AM**      **Antipsychotics and the Risk of Type 2 Diabetes in Children and Youth [353]**  
William V Bobo, William O Cooper, Charles M Stein, Mark Olfson, David Graham, James Daugherty, Catherine D Fuchs, Wayne A Ray. (United States)

## **Do you Trust Your Data? (114)**

**Moderators: Stephen Evans, FISPE, & Susan Oliveira, FISPE**

- 08:30 AM**      **Validity of Diagnostic Codes and Liver-Related Laboratory Abnormalities To Identify Acute Liver Failure among Kaiser Permanente Patients with Diagnoses of Drug-Induced Hepatitis [354]**  
Vincent Lo Re, Kevin Haynes, Kimberly B Fortier, Dena M Carbonari, James D Lewis, Brian L Strom, Kimberly A Forde, David S Goldberg, K R Reddy, Jason A Roy, Amy R Marks, Jolanda De Beor, Douglas A Corley. (United States)
- 08:45 AM**      **Validity of Administrative Data To Identify Off-Label Use of Second Generation Antipsychotics [355]**  
Daniel M Hartung, Luke Middleton, Bentson H McFarland, Marian S McDonagh, Dean G Haxby, K J McConnell. (United States)
- 09:00 AM**      **Validation of ICD9 Coding as Reported in Administrative Data – Results from a Review of Patient Medical Records [356]**  
Robert G Sharrar, Glen Magee, Jane Koch, Scott Chavers. (United States)
- 09:15 AM**      **Performance and Validity of Record Linkage without Unique Personal Identifiers [357]**  
Chih-Ying Chen, Jessica J Jalbert, Lauren Williams, Andrew Rothman, Lynne W Stevenson, Garrick C Stewart, John D Seeger, Soko Setoguchi. (United States)
- 09:30 AM**      **Validation of Congenital Malformation Diagnostic Codes Recorded in Québec Administrative Databases [358]**  
Lucie Blais, Anick Bérard, Fatima-Zohra Kettani, Amélie Forget. (Canada)

**09:45 AM**      **Estimating Disease Progression in Metastatic Cancer Patients Using Dispensing Data: A Validation Study [359]**

Vikram Joshi, Barbara-Ann Adelstein, Preeyaporn Srasuebkul, Timothy Dobbins, Elements of Cancer Care (EoCC) Investigators, Sallie-Anne Pearson. (Australia)

**Hormones: Can't Live with Them, Can't Live without Them (115)**

**Moderators: Annlouise Assaf, FISPE, & David Dore**

**08:30 AM**      **Long-Term Active Surveillance Study for Oral Contraceptives (LASS): Final Results on Cardiovascular Safety [360]**

Klaas Heinemann, Anita Assmann, Sabine Moehner. (Germany)

**08:45 AM**      **VTE Risk in Users of Combined Oral Contraceptives: Impact of a 24-Day Regimen Containing Drospirenone [361]**

Suzanne Reed, Kristina Bardenheuer, Juergen Dinger. (Germany)

**08:45 AM**      **Patterns of antihypertensive medication use in Medicaid-eligible pregnant women [362]**

Brian T Bateman, Sonia Herandez-Diaz, Krista Huybrechts, Kristen Palmsten, Michael A Fischer. (United States)

**09:15 AM**      **Drospirenone Versus Other Progestin-Based Combined Oral Contraceptives and the Risk of Incident Ulcerative Colitis: A Comparative Safety Study [363]**

Wei Liu, Steven T Bird, Mahyar Etminan, Joseph AC Delaney, Caitlin Knox. (United States)

**09:30 AM**      **Postmenopausal Estrogen Therapy Increases the Risk of Gallstone Disease – A Population-Based Case-Control Study [364]**

Maja S Hellfritzsch, Trine Frøslev, Rune Erichsen, Henrik T Sørensen. (Denmark)

**09:45 AM**      **The Safety of Oral Hormone Replacement Therapy: Final Results from the EURAS-HRT Study [365]**

Klaas Heinemann, Anita Assmann, Jürgen Dinger. (Germany)

**Treating Pain (116)**

**Moderators: Nicholas Moore, FISPE, & Laura Wallace**

**08:30 AM**      **Trends in Opioid Prescribing between 2000 and 2009 in Germany. A Regional Claims Data Analysis [366]**

Peter Ihle, Rainer Sabatowski, Ingrid Schubert. (Germany)

**08:45 AM**      **Dramatic Increases in the Use of Strong Opioids in the Elderly [367]**

C Ineke Neutel, Svetlana Skurtveit, Christan Berg. (Canada)

- 09:00 AM Risk of Unintentional Overdose Following Outpatient Opioid Treatment for Pain [368]**  
Elizabeth V Lawler, Jennifer Fonda, David R Gagnon, John Hermos, Catherine Barber, Matthew Miller. (United States)
- 09:15 AM Can the EU-ADR Database Network Detect Timely Drug Safety Signals? [369]**  
Gianluca Trifirò, Vaishali Patadia, Martijn Schuemie, Preciosa Coloma, Rosa Gini, Ron Herings, Giampiero Mazzaglia, Gino Picelli, Federica Nicotra, Lars Pedersen, Joahn van der Lei, Miriam Sturkenboom. (Italy)
- 09:30 AM Drug Intoxication in Patients Registered for Liver Transplantation for Acute Liver Failure: Results from the 7-Country SALT Study [370]**  
Ezgi S Gulmez, Séverine Lignot, Dominique Larrey, Georges P Pageaux, Jacques Bernuau, Franco Bissoli, Yves Horsmans, Jean L Montastruc, Bruno Stricker, Douglas Thorburn, Fatima Hamoud, Sophie Micon, Régis Lassalle, Jérémy Jové, Patrick Blin, Nicholas Moore. (France)
- 09:45 AM Effect of Regulatory Measures on Nimesulide Utilization in the Lisbon Region [371]**  
Daniel Pinto, Pedro A Caetano, Bruno Heleno, António Faria-Vaz, Isabel Santos. (Portugal)

10:00-10:30am

**Break/Posters/Exhibits (Exhibit Hall/Rooms 5-6-7-8)**

10:30-12:00pm

**CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

**Drug Utilization Research Methods (111-112)**

**Moderator: Suellen Curkendall & John Seeger**

- 10:30 AM Are Low-Cost Generic Prescriptions Faithfully Captured in US Pharmacy Claims Databases? [372]**  
Julie C Lauffenburger, M Alan Brookhart. (United States)  
*Third Best Student Abstract*
- 10:45 AM Extraction of Electronic Health Record Data in a Hospital Setting: Comparison of Automatic and Semi-Automatic Methods Using Anti-TNF Therapy as Model [373]**  
Thomas Cars, Björn Wettermark, Gunnar Ekeving, Bo Vikström, Rickard Malmström, Lars L Gustafsson, Ulf Bergman, Martin Neovius, Bo Ringertz. (Sweden)
- 11:00 AM Impact of Exposure Misclassification Due to Incomplete Drug Data in Observational Studies of Safety and Effectiveness [374]**  
John-Michael Gamble, Jeffrey A Johnson, Finlay A McAlister, Sumit R Majumdar, Scot H Simpson, Dean T Eurich. (Canada)

- 11:15 AM**      **Drug Exposure Misclassification Because of Prior-Authorization Policies: A Cautionary Tale for Researchers Using Databases Limited to Formulary-Approved Prescriptions [375]**  
 John-Michael Gamble, Jeffrey A Johnson, Sumit R Majumdar, Finlay A McAlister, Scot H Simpson, Dean T Eurich. (Canada)
- 11:30 AM**      **Trajectory Models: A New Approach to Classifying and Predicting Long-Term Medication Adherence [376]**  
 Jessica A Myers, William H Shrank, Juliana Pakes, Niteesh K Choudhry. (United States)
- 11:45 AM**      **Non-Adherence to Chronic Drug Regimens When Costs Increase: Expected Drug Use and Non-Linear Cost-Sharing Effects [377]**  
 John Hsu, Maggie Price, Vicki Fung. (United States)

## **NSAIDs - Measuring Drug Safety (117)**

**Moderators: Jordi Castellsagué & Doug Watson**

- 10:30 AM**      **Comparing Measures of Regularity of NSAID Dispensings Based on Register Data [378]**  
 Tobias Svensson, Fredrik Granath, Morten Andersen. (Sweden)
- 10:45 AM**      **Impact of Case Validation on Incidence Rates of Upper Gastrointestinal Complications [379]**  
 Federica Pisa, Jordi Castellsague, Valentina Rosolen, Nuria Riera-Guardia, Manuela Giangreco, Daniela Drigo, Susana Perez-Gutthann, Fabio Barbone. (Italy)
- 11:00 AM**      **Risk of Acute Liver Failure Leading to Transplantation after NSAID or Paracetamol Exposure: Final Results of the 7 European-Country Study of Acute Liver Transplant (SALT) [380]**  
 Ezgi S Gulmez, Séverine P Lignot, Dominique Larrey, Corinne deVries, Susanna Perez-Gutthann, Jean L Montastruc, Miriam Sturkenboom, Jacques Bénichou, Giampaolo Velo, Achille Caputi, Francesco Salvo, Sophie Micon, Fatima Hamoud, Régis Lassalle, Jérémy Jové, Georges P Pageaux, Yves Horsmans, Jacques Bernuau, Franco Bissoli, Bruno Stricker, Douglas Thorburn, Angelo Gatta, Estela Monteiro, Irene Vafiadis, Aiden McCormick, Herold Metselaar, Emine Sen, Alison Nightingale, Patrick Blin, Nicholas Moore. (France)
- 11:15 AM**      **Risk of Ischemic Stroke Associated with the Use of Individual Non-Steroidal Anti-Inflammatory Drugs [382]**  
 Brianca Kollhorst, Tania Schink, Andrea Arfe, Ron Herings, Silvia Romio, Rene Schade, Martijn Schuemie, Hubb Stratman, Frantz Thiessard, Vera V Valkhoff, Christine Varas Lorenzo, Marco Villa, Miriam Sturkenboom. Edeltraut Garbe. (Germany)

- 11:15 AM      Nonsteroidal Anti-Inflammatory Drug Use and Brain Tumor Risk: A Nested Case-Control Study in General Preactice Research Database. [383]**  
 Michael A O'Rourke, finian J Bannon, Liam J Murray, Carmel M Hughes, Marie M Cantwell, Anna T Graves, Chris R Cardwell. (United Kingdom)
- 11:15 AM      Proton Pump Inhibitors and Traditional Nonsteroi Anti-Inflammatoriy Drugs and the Risk of Acute Interstitial Nephritis and Acute Kidney Injury [381]**  
 Charles E Leonard, Cristin P Freeman, Craig W Newcomb, Peter P Reese, Maximilian Herlim, Warren B Bilker, Sean Hennessy, Brian L Strom. (United States)

## **Pediatric Tapas (113)**

**Moderators: Jennita Reefhuis & Helle Kieler**

- 10:30 AM      Medication Use and Hospital Admission Rates among Preterm Born Children Compared to Full Term Born Infants [384]**  
 Leanne MA Houweling, Irene D Bezemer, Fernie JA Penning-van Beest, Willemijn Meijer, Richard A van Lingen, Ron MC Herings. (Netherlands)
- 10:45 AM      Initial Findings from the Anti-Psychotics, Keep It Documented for Safety (A+KIDS) Medication Registry for North Carolina Medicaid Youth [385]**  
 Robert B Christian, Joel F Farley, Jerry Mckee, David Wei, Troy Trygstad, Trista Pfeiffenberg, Steve Wegner, Brian B Sheitman. (United States)
- 11:00 AM      Influence of Relative Age on Diagnosis and Treatment of Attention-Deficit/Hyperactivity Disorder in Children [386]**  
 Richard L Morrow, E Jane Garland, James M Wright, Malcolm Maclure, Suzanne Taylor, Colin R Dormuth. (Canada)
- 11:15 AM      Pediatric Acute Liver Injury: Signal Detection Using Multiple Healthcare Databases from EU-ADR Network [387]**  
 Carmen Ferrajolo, Gianluca Trifiró, Peciosa M Coloma, Katia MC Verhamme, Matijn J Schuemie, Rosa Gini, Ron Herings, Giampiero Mazzaglia, Gino Picelli, Carlo Giaquinto, Lorenza Scotti, Paul Avillach, Lars Pedersen, Johan van der Lei, Miriam CJM Sturkenboom. (Netherlands)
- 11:30 AM      Determinants of atomoxetine and centralnervous system stimulant treatment initiation [388]**  
 Stephan Linden, Almut G Winterstein. (United States)
- 11:45 AM      Prevalence and Determinants of ADHD Medication of Children and Adolescents in Germany – Results of the KiGGS Study [389]**  
 Hildtraud C Knopf, Heike Hölling, Robert Schlack. (Germany)

## Personalized Medicine Tapas (114)

Moderators: Geoffrey Liu

- 10:30 AM**      **The *SLCO1B1* c.521T>C Polymorphism and the Risk of Adverse Reactions during Simvastatin and Atorvastatin Therapy [390]**  
Catherine E de Keyser, Matthijs L Becker, Anke-Hilse Maitland-van der Zee, André G Uitterlinden, Albert Hofman, Loes E Visser, Bruno H Stricker. (Netherlands)
- 10:45 AM**      **CYP2C9 Variants and Risk of Gastrointestinal Bleeding Associated with NSAID Use: A Case-Control Study [391]**  
Ana Estany-Gestal, Carmelo Aguirre, Borja Ruiz, Xavier Vi, Alfonso Carvajal, Inés Salado, Luca Rodella, Ugo Moretti, Luisa Ibáñez, Adolfo Figueiras. (Spain)  
*Second Best Student Abstract*
- 11:00 AM**      **Lack of Association between *SLCO1B1* Polymorphisms and Clinical Myalgia Following Rosuvastatin Therapy [392]**  
Jacqueline S Danik, Daniel I Chasman, Jean G MacFadyen, Fredrik Nyberg, Bryan J Barratt, Paul M Ridker. (United States)
- 11:15 AM**      **Vascular Endothelial Growth Factor (*VEGF*) Pathway Polymorphisms and Esophageal Cancer Outcome [393]**  
Lawson Eng, Abul Kalam Azad, Xin Qiu, Dangxiao Cheng, Alvina Tse, Olusola Faluyi, Daniel J Renouf, Sharon Marsh, Sevtap Savas, Jennifer J Knox, Gail E Darling, Rebecca KS Wong, Wei Xu, Geoffrey Liu. (Canada)
- 11:30 AM**      **Extraction of Hepatitis C Genotype from Clinical Notes for Patients Missing a Veterans Affairs Lab-Confirmed Genotype [394]**  
Scott L DuVall, Tyler B Forbush, Richard E Nelson, Joanne LaFleur. (United States)
- 11:45 AM**      **The Effect of Omeprazole and Esomeprazole on the Maintenance Dose of Phenprocoumon [395]**  
Talitha I Verhoef, Miranda JL Zuurhout, Rianne MF van Schie, William K Redekop, Felix JM van der Meer, Saskia le Cessie, Tom Schalekamp, Anthonius de Boer, Anke-Hilse Maitland-van der Zee. (Netherlands)

## Psychotropic Drug Utilization Research (115)

Moderators: Helga Gardarsdottir & Julie Zito, FISPE

- 10:30 AM**      **New Psychiatric Diagnoses and Medication Use after Intensive Care: A Danish Nationwide Cohort Study [396]**  
Christian F Christiansen, Hannah Wunsch, Martin B Johansen, Morten Olsen, Henrik T Sørensen. (Denmark)
- 10:45 AM**      **Access, Benefit Design, and Antipsychotic Drugs in the Medicare Part D Program [397]**  
Vicki Fung, Mary Price, John Hsu. (United States)
- 11:00 AM**      **Antidepressants and Risk of Discontinuation of Diabetes Medicines [398]**

Gillian E Caughey, Adrian K Preiss, Agnes I Vitry, Andrew L Gilbert, Elizabeth E Roughead. (Australia)

- 11:15 AM Persistence and Dose Escalation in the Use of Anti-Dementia Medication [399]**  
Kathleen Bennett, David Williams, Linda Brewer. (Ireland)
- 11:30 AM Characteristics and Trends of Low-Dose Second Generation Antipsychotic Use in Two State Medicaid Programs [400]**  
Daniel M Hartung, Judy Zerzan, Nancy E Morden, Traci Yamashiti, Suhong Tong, Anne M Libby. (United States)
- 11:45 AM Trends in Prevalence of ADHD Drug Treatment in the Netherlands from 2000 until 2010 [401]**  
L Mehlkopf, LMA Houweling, ER Heerdink, FJA Penning-van Beest. (Netherlands)

## **Tapas: Junk Drawer (Cajon de Sastre) (116)**

**Moderator: Jessica Jalbert**

- 10:30 AM Orlistat and the Risk of Acute liver Injury: A Self-Controlled Case-Series Study in United Kingdom General Practice Research Database [402]**  
Julia Langham, Liam Smeeth, Ruth Brauer, Krishnan Bhaskaran, Ian Douglas. (United Kingdom)
- 10:45 AM Comparative Effectiveness of Linezolid and Vancomycin among a National Cohort of Veterans Affairs (VA) Patients with Methicillin-Resistant *Staphylococcus aureus* (MRSA) Pneumonia [403]**  
Aisling R Caffrey, Laura A Puzniak, Daniela E Myers, Kerry L LaPlante. (United States)
- 11:00 AM Risk of Venous Thromboembolism among Taiwan Osteoporosis Population: Alendronate vs. Raloxifene Users [404]**  
Tzu-Chieh Lin, Cheng-Han Lee, Yea-Huei Kao Yang, Chyun-Yu Yang. (Taiwan)
- 11:15 AM Quantifying *Staphylococcus aureus* Disease Burden with Clinical Microbiology Culture Data: Attributable Time Trends in a Regional Healthcare System [405]**  
Aisling R Caffrey, Kalpana Gupta, Brian J Quilliam, Peter D Friedmann, Kerry L LaPlante. (United States)
- 11:30 AM The Prevalence of X-Linked Hypohidrotic Ectodermal Dysplasia (XLHED) in Denmark from 1995-2010 [406]**  
Stine Skovbo, Mary Nguyen-Nielsen, Lars Pedersen, Henrik T Sørensen, Jon Fryzek. (Denmark)
- 11:45 AM Risk of Incident Cardiovascular Disease Events in Patients with Psoriasis: A Retrospective Cohort Study Using the General Practice Research Database [407]**  
Paola Primatesta, Estel Plana, Zuleika Aponte Torres. (Switzerland)

Noon -1:30pm

**Lunch/Poster Session B/Exhibits  
(Exhibit Hall/Rooms 5-6-7-8)**

**ISPE Committee/Council Meetings**

*Open to all members and new members. Lunch will be available at committee rooms.*

- Bylaws and Policies Committee (M213)
- Education Committee (124-125)
- Global Development Committee (132)
- Membership Committee (M215)
- Publications Committee (M216)

**Special Luncheon Workshop (131)**

**FarmacoEpiEnRed, a Network for**

**Pharmacoepidemiology in Spain [408] (131)**

Moderator: Susana Perez-Gutthann, FISPE  
Ana Afonso, Daniel Prieto-Alhambra, Antonio Escudero  
Garcia, Ana Estany Gestal, Elisa Martín-Merino, Nuria Riera-  
Guardia, Sandra López-León, Susana Perez-Gutthann, Sonia  
Hernández-Díaz. (Spain)

12:15-1:15pm

**Round Table Discussions (ENTRANCE HALL)**

To foster the ability of the more junior ISPE members to network and new ISPE members to meet others attending the ICPE, we are hosting several lunchtime discussion roundtables on Monday and Tuesday. These roundtables will be informal. The facilitators and topics for the tables are listed below. There will be NO formal presentations made at the roundtables. The purposes are discussion, information exchange, and networking. **Seating is limited; first-come, first-served.**

*For junior ISPE members and new members. Seating is first-come, first-served.*

**Stephen JW Evans, FISPE, *Appropriate Study Designs on Pharmacoepidemiology***

**Ken Rothman, FISPE, *Back to the Future: Immortal Time and Related Problems in Retrospective Cohort Studies***

**Sebastian Schneeweiss, FISPE, *Methodological Challenges in Pharmacoepidemiology***

12:45-1:30pm

**Poster Walks (Exhibit Hall/Rooms 5-6-7-8)**

- CER(Comparative Effectiveness Review) SIG
- Databases SIG
- Medical Devices SIG
- Molecular Epidemiology SIG

1:30-2:30pm

**PLENARY SESSION**

**Pharmacoepidemiology: The Essential Discipline in the Provision of Safe and Effective Care for Older Patients with Multimorbidity[409] (111-112)**

Andrew Gilbert, Elizabeth Roughead, Jerry Avorn, Morten Andersen, Gillian Caughey. (Australia)

2:30-3:30pm

**ANNUAL MEETING OF ISPE MEMBERS, AWARDS CEREMONY (111-112)**

*Open to all participants.*

◀ *Annual Meeting of ISPE Members*

- **Nancy Santanello, FISPE**, ISPE President
- **Matthew Reynolds**, Vice President Finance

◀ *Awards Ceremony*

**ICPE 2012**

Presented by **Nancy Santanello, FISPE**

- **Josep Lluís Segú**, Chair, 2012 Local Host Committee
- **Susana Perez-Gutthann, FISPE**, Chair, 2012 Scientific Program Committee

**Student Awards**

Presented by **Susan Perez-Gutthann, FISPE**

- The Andrew McAfee Award (*Best Award submitted by a student/researcher from a developing country*)  
**Carlos Durán**
- Third Best Abstract **Julie Lauffenburger**

- Second Best Abstract **Ana Estany-Gestal**
- The Stanley A. Edlavitch Award (*Best Abstract submitted by a student/post-doc*) & Oral Presentation

**Zubair Afza.** *Automatic Generation of a Case-Detection algorithm for Hepatobiliary Disease Using Machine Learning on Free-Text Electronic Health Records* [410]

Zubair Afzal, Martijn J Schuemie, Emine Sen, Geert W 't Jong, Miriam C Sturkenboom, Jan A Kors. (Netherlands)

◀ *Induction of ISPE Fellows (FISPE)*

**Nancy Santanello, FISPE, ISPE President**

*Inductees*

- **AnnLouise Assaf, FISPE**
- **Lolkje de Jong-van den Berg, FISPE**
- **Tobias Gerhard, FISPE**
- **Jesper Hallas, FISPE**
- **Yea-Huei Kao Yang, FISPE**
- **Julie A. Zito, FISPE**

◀ *The Ronald D. Mann Best Article Award*

**Brian Strom, FISPE, Editor-in-Chief**

**Joerg Hasford, Regional Editor for Europe**

**Sean Hennessy, FISPE, Regional Editor for the Americas**

**BJ Park, FISPE, Regional Editor for Asia, Africa, Oceania**

◀ *Installation of New ISPE President*

**Stella Blackburn, FISPE**

3:30-4:00pm

**Break/Posters/Exhibits (Exhibit Hall/Rooms 5-6-7-8)**

4:00-5:30pm

**CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS**

**Cross-National or Multi-Database Research Networks: A New Initiative in Asia-Pacific Region and Ongoing Initiatives in Europe and US [411] (111-112)**

Byung-Joo Park, Monique Elseviers, Ulf Bergman, Yea-Huei Kao Yang, Kiyoshi Kubota, Wai Ping Yau, Bjorn Wettermark, Paul Stang,

Nicole Pratt, Natasha Chen, Morten Andersen, Soko Setoguchi. (United States)

**Electronic Healthcare Databases for Pregnancy Research: Panacea or Trojan Horse? [412] (117)**

Krista F Huybrechts, Kristin Palmsten, Andrea V Margulis, William O Cooper, Christina Chambers, Sonia Hernández-Díaz. (United States)

**Evaluating the Effectiveness of Risk Minimisation Measures in the Context of the New Pharmacovigilance Legislation in the EU [413] (113)**

Annalisa Rubino, Sabine Straus, Laurent Auclert, Laurie J Zografos, Elizabeth B Andrews. (United Kingdom)

**Global Collaborations in Vaccine Safety, Present and Future [414] (114)**

Robert T Chen, Jan Bonhoeffer, Patrick Zuber, Miriam Sturkenboom, Claudia Velozzi, Hector Izurieta, Michael Greenberg, Steven Black, Thomas Verstraeten. (Switzerland)

**Integrating Methods for Semi-Automated Drug Safety Monitoring of Newly Marketed Medications Using Databases: Illustrations with a Prototype [415] (115)**

Sebastian Schneeweiss, Joshua Gagne, Jeremy Rassen, Robert Glynn, Shirley Wang, Mandy Patrick, Jessica Myers, Stephen Evans. (United States)

**Transparent, Reproducible and Reusable Research in Pharmacoepidemiology (116)**

Helga Gardarsdottir, Brian C Sauer, Huifang Liang, Patrick Ryan, Olaf Klungel, Robert Reynolds. (Netherlands)

*SPONSORED BY THE DATABASES SIG*

**Validate in One Data Source and Apply Results to Another – What Could Possibly Go Wrong? Assumptions behind Addressing Outcome Misclassification in Distributed Data Models [417] (132)**

Nicholas J Everage, David D Dore, John D Seeger. (United States)

5:30-6:30pm

**Special Interest Group (SIG) Meetings**

*Open to all members and new members.*

- AsPEN SIG (131)
- Biologics SIG (115)
- Comparative Effectiveness Research (CER)SIG (114)
- Database SIG (111-112)
- Drug Utilization/Health Services Research SIG (116)
- Medical Devices SIG (117)
- Medications in Pregnancy SIG (113)
- Molecular Epidemiology/Biomarkers/Pharmacogenetics SIG (124-125)
- Pediatrics SIG (132)

7:30-11:30pm

### **Social Event at CCIB**

*Come and celebrate with us!* Join us for dinner, entertainment, and dance the evening away! Including performances by Rumba Expresso – a live band, which features excerpts from Catalan gypsy music infused with Latin rhythms such as the Gipsy Kings, Peret, Pescaïlla and Los Manolos.

For those seeking a more relaxing atmosphere to chat with ISPE friends, the terrace facing the Mediterranean Sea is the perfect spot.

The evening will end with a DJ playing international music from the 80's to the present to see who can showcase the best dance moves!

- Admission is by badge or ticket
- Admission includes 2 drink tickets

***SUNDAY***  
***August 26, 2012***

- 7:00-4:30pm      **Registration (CCIB Lobby)**
- 7:30-3:30pm      **Speakers' Ready Room (133)**
- 7:00-8:00am      **Poster Session C Set-up (Exhibit Hall Rooms 5-6-7-8)**
- 8:00-1:45pm      **Exhibits/Posters Exhibit Hall Rooms 5-6-7-8)**
- 8:30-10:00am     ***CONCURRENT SESSIONS: CONTRIBUTED PAPERS***

**AEDs in Pregnancy and Beyond (111-112)**

**Moderators: Deborah Covington & Amanda Golembesky**

- 08:30 AM      Topiramate Use in Pregnancy and Risk of Oral Clefts [689]**  
Daniel Mines, Patricia Tennis, Suellen Curkenl, De-Kun Li, Craig Peterson, Elizabeth B Andrews, Brian Calingaert, Hong Y Chen, Daina B Esposito, Nicholas Everage, Crystal N Holick, Nicole M Meyer, Ella T Nkhoma, Sherry Quinn, Kenneth J Rothman, K Arnold Chan. (United States)
- 08:45 AM      Discontinuation of Antiepileptic Drugs in Pregnancy; a UK Population Based Study in The Health Improvement Network (THIN) [690]**  
Shuk-Li Man, Irene Petersen, Mary Thompson, Irwin Nazareth. (United Kingdom)
- 09:00 AM      Lamotrigine Use in Pregnancy and Risk of Orofacial Cleft Risk, an Update [691]**  
Hao Wang, Ester Garne, Maria A Loane, Helen Dolk, Joan K Morris, Lolkje TW de Jong-van den Berg. (Netherlands)
- 09:15 AM      Methods for Linking Mothers and Infants within Health Plans for Studies of Medication Safety in Pregnancy [692]**  
Sascha Dublin, Karin Johnson, Sarah Beaton, T C Cheetham, Pamela E Scott, Sengwee D Toh, William O Cooper, Robert L Davis, De-Kun Li, Pamala Pawloski, Marsha Raebel, David H Smith, Tarek A Hammad, Susan E Andrade. (United States)
- 09:30 AM      Utilization of Antiepileptic Drugs in Florida Medicaid Women with Epilepsy of Childbearing Age [693]**  
Xuerong Wen, Kimford J Meador, Almut G Winterstein, Abraham G Hartzema. (United States)

- 09:45 AM**      **Prenatal Diagnosis of Birth Defects and Potential Selection Bias in Studies of Birth Defects Measured after Birth: How Severe Is the Problem? [694]**  
Lars Pedersen, Henrik Toft Sørensen, Mette Nørgaard, Vera Ehrenstein. (Denmark)

**Disease-Based Strategies for Active Surveillance (117)**  
**Moderator: Andrez Czarnecki, FISPE**

- 08:30 AM**      **Incidence and Time-to-Onset of Hematologic Events among Genotype 1 Chronic Hepatitis C Patients Being Treated with Pegylated Interferon and Ribavirin [695]**  
Michele Manos, Jeanne Darbinian, Baris Deniz, Montserrat Vera-Llonch, Valentina Scvachko. (United States)
- 08:45 AM**      **ARITMO Project. Torsade de Pointes Associated to Antimicrobials, Antipsychotics and Antihistamines: An Analysis of the French Spontaneous Reporting Database [696]**  
Francesco Salvo, Moretti Ugo, Annie Fourier-Réglat, Pascal Auriche, Estelle Meuriot, Nicholas Moore, Miriam C Sturkenboom, Emanuel Raschi, Antoine Pariente. (France)
- 09:00 AM**      **An Open Database for Surveillance of QT Prolongation of Marketed Drugs: ECG-VIEW [697]**  
Man Young Park, Dukyong Yoon, Nam-Kyong Choi, Joongyub Lee, Rae Woong Park. (Republic of Korea)
- 09:15 AM**      **Are Developing Countries Prepared To Monitor Long-Term toxicities of Antiretrovirals? Findings on Active Surveillance Activities in Sub-Saharan Africa [698]**  
Jude I Nwokike, Hye Lynn Choi. (United States)
- 09:30 AM**      **Value of Information in Prospective Drug Safety Monitoring Using Claims Databases [699]**  
Amanda R Patrick, Jessica Myers, Milton C Weinstein, Robert J Glynn, Sebastian Schneeweiss. (United States)
- 09:45 AM**      **Prevalence of PDDI Prescriptions in Two Italian Regions [700]**  
Elena Tragni, Manuela Casula, Pieri Vasco, Giampiero Favato, Alberico Marcobelli, Maria G Trotta, Alberico L Catapano. (Italy)

**Drug Utilization Research: Adherence and Persistence (113)**

**Moderators: Robert vander Stichele & Earl Goehring, Jr.**

- 08:30 AM**      **The Effect of Copayment on Antiretroviral Medication Adherence for Newly Treated HIV-Positive Adults with Commercial Insurance [701]**  
Jonathan Todd, William Miller, Virginia Pate, M Alan Brookhart. (United States)

- 08:45 AM**      **Patient-Reported Reasons for Discontinuation of Commonly Used Treatments for Moderate to Severe Psoriasis [702]**  
Howa Yeung, Abby S Van Voorhees, Kristina Callis Duffin, Bruce A Brod, Stephen M Schleicher, Bruce F Bebo, Daniel B Shin, Joy Wan, Andrea B Troxel, Joel M Gelfand. (United States)
- 09:00 AM**      **Difference in Persistence Rates between Responders and Non-Responders to Mailed Questionnaires [703]**  
Harm CJ Geers, Eibert R Heerdink, Marcel L Bouvy. (Netherlands)
- 09:15 AM**      **Real-Life Treatment Persistence with Golimumab (GLM), Etanercept (ETA), and Aimumab (ADA) in Patients with Rheumatoid Arthritis in Canada [704]**  
Amir Abbas Tahami Monfared, Hayssam Khalil. (Canada)
- 09:30 AM**      **Determinants, Pattern and Outcomes of Non-Adherence to HAART in a Portuguese Cohort of HIV-1 Infected Subjects [705]**  
Milene Fernandes, Rui Simões, Luís Caldeira, Andreia Leite, José A Freitas, Paulo J Nicola, Ana P Martins, Maria AJ Vasco. (Portugal)
- 09:45 AM**      **Twelve-Year Trend in Treatment Seeking for Buprenorphine, Heroin and Amphetamine Abuse in Finland [706]**  
Hanna Uosukainen, Jussi Kauhanen, Sari Voutilainen, Jaana Föhr, Mika Paasolainen, Jari Tiihonen, Kirsti Laitinen, Ifeoma N Onyeka, J Simon Bell. (Finland)

### **Keeping Your Eyes Open (114)**

**Moderator: Abraham Hartzema, FISPE**

- 08:30 AM**      **Propensity Scores in Sequential Monitoring of New Drugs: Evaluation of Dynamic Matching [707]**  
Joshua J Gagne, Shirley Wang, Jeremy A Rassen, Robert J Glynn, Sebastian Schneeweiss. (United States)
- 08:45 AM**      **Value of Disease Risk Scores in Comparative Effectiveness Research with Emerging Therapies [708]**  
Robert J Glynn, Joshua J Gagne, Sebastian Schneeweiss. (United States)
- 09:00 AM**      **The Power of Electronic Healthcare Databases for Active Drug Safety Surveillance in Children and Adolescents: An EU-ADR Study [709]**  
Sandra de Bie, Preciosa Coloma, Carmen Ferrajolo, Gianluca Trifirò, Katia Verhamme, Martijn Schuemie, Sabine Straus, Rosa Gini, Ron Herings, Giampiero Mazzaglia, Gino Picelli, Lorenza Scotti, Lars Pedersen, Bruno Stricker, Johan van der Lei, Miriam Sturkenboom. (Netherlands)
- 09:15 AM**      **An Application of Univariate Self-Case Control Series Method Using THIN Database in the OMOP CDM for Active Drug Safety Surveillance [710]**

Xiaofeng Zhou, Bing Cai, Sundaresan Murugesan, Qing Liu, Andrew Bate, Robert Reynolds. (United States)

**09:30 AM Trends in Medication and Survival Following an Acute Myocardial Infarction in Primary Care in the UK – Re-Analysis of THIN Database with OMOP Common Data Model [711]**

Bing Cai, Xiaofeng Zhou, Sundaresan Murugesan, Qing Liu, Harshvinder Bhullar, Andrew Bate. (United States)

**09:45 AM PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium) Work Package 6: Project Synthesis [712]**

Lamiaie Grimaldi-Bensouda, Laurent Auclert. (France)

## **Safety of Psychotropic Medications in Adult Populations (115)**

**Moderator: Dolores Montero**

**08:30 AM Was the Use of Antipsychotic Drugs with Arrhythmogenic Potential Changed in the Last Years? A Population-Based, Database Study in 5 European Countries [713]**

Alessandro Oteri, Giampiero Mazzaglia, Francesco Innocenti, Ron Herings, Irene Bezemer, Edeltraut Garbe, Jacob Holstiege, Tania Schink, Elisabetta Poluzzi, Aurora Puccini, Sinna Pilgaard Ulrichsen, Lars Pedersen, Miriam C Sturkenboom, Gianluca Trifirò. (Netherlands)

**08:45 AM The Risk of Antipsychotic-Induced Parkinsonism and Its Management [714]**

Krista F Huybrechts, Katsiaryna Bykov, Raisa Levin, Jerry Avorn. (United States)

**09:00 AM Anti-Dementia Drugs in Patients with Alzheimer's Disease and the Risk of Developing Seizures or Epilepsy: A Population-Based Nested Case-Control Analysis [715]**

Patrick Imfeld, Michael Bodmer, Susan S Jick, Christoph R Meier. (Switzerland)

**09:15 AM Comparative Cardiovascular Safety of Dementia Medications: A Cross-National Study [716]**

Emil L Fosbol, Eric D Peterson, Ellen Holm, Gunnar H Gislason, Yinghong Zhang, Lesley Curtis, Lars Kober, Isao Iwata, Christian Torp-Pedersen, Soko Setoguchi. (United States)

**09:30 AM Cardiovascular Outcomes in Patients Using Clopidogrel with Selective Serotonin Reuptake Inhibitors [717]**

Patrick A Haueis, Joshua J Gagne, Stefan Russmann, Sebastian Schneeweiss. (United States)

**09:45 AM Use of cetuximab in a real-life setting in France with respect to KRAS status: results of EREBUS cohort study[718]**

Annie Fourrier-Reglat, Denis Smith, Magali Rouyer, Eric Francois, Emmanuel Mitry, Alain Monnereau, Antonio Sa-

Cunha, Emmanuelle Bignon, Alise Le Monies, Jeremy Jove, Pernelle Noize, Nicholas Moore. (France)

## **Tapas: Classification Challenges (116)**

**Moderators: Corinne de Vries, FISPE, & Dorothee Bartels**

- 08:30 AM**      **REporting of Studies Conducted Using Observational Routinely-Collected Data [RECORD] Initiative [719]**  
Sinead M Langan, Irene Petersen, Eric I Benchimol, Liam Smeeth, David Moher, Fiona Stanley, Henrik T Sorensen, Astrid Guttmann, Kate Walters, Sara Thomas, Ian Douglas, Laura Horsfall, Erik Von Elm. (United Kingdom)
- 08:45 AM**      **Development and Validation of a Classification Algorithm for Prophylactic Versus On-Demand Factor VIII Therapy in Patients with Hemophilia A [720]**  
Francis Vekeman, Jennifer Pocoski, Wendy Cheng, Alex Trahey, Sujata Sarda, Satish Valluri, Ronald Preblich, Mei Sheng Duh. (United States)
- 09:00 AM**      **Is Off-Label Use a Risk Factor for Adverse Drug Events? [721]**  
Tewodros Eguale, David L Buckeridge, Nancy E Winslade, Andrea Benedetti, James A Hanley, Robyn Tamblyn. (Canada)
- 09:15 AM**      **The Role of Surveillance Bias in the Incidence of the Myelodysplastic Syndromes and Chronic Myeloproliferative Disorders [722]**  
Amanda B Wilson, Marianne N Prout, Tuhina Neogi, Susan Jick. (United States)
- 09:30 AM**      **Validation of Congenital Cardiac Malformations in the General Practice Research Database [723]**  
Fatmatta Kuyateh, Andrea V Margulis, Yulan Ding, Adel Abou-Ali, Marian Callahan, Tarek A Hammad. (United States)
- 09:45 AM**      **Development of a New System for Registration of Patient Registries [724]**  
Richard Gliklich, Dan Levy, Michelle Leavy, Daniel M Champion, Jannette Karl, Elise Berliner. (United States)

10:00-10:30am

**Break/Posters/Exhibits (Exhibit Hall Room 5-6-7-8)**

10:30-Noon

**CONCURRENT SESSIONS: SYMPOSIA AND WORKSHOPS**

**Electronic and Personal Health Records: Utility and Challenges for Comparative Effectiveness Research (CER) [725] (111-112)**

Jessica J Jalbert, Martijn J Schuemie, Miriam CJM Sturkenboom, Eric S Johnson, Suzanne L West, Soko Setoguchi. (United States)

*SPONSORED BY THE CER SIG*

**European Initiatives To Study Adverse Events of Treatments for Diabetes Mellitus [726] (117)**

Marie L De Bruin, Miriam CJM Sturkenboom, Lamiae M Grimaldi, Rafael Simó. (Netherlands)

**Globalisation of Utilisation Research: Current Challenges and Triumphs [727] (113)**

Lisa G Pont, Andrew L Gilbert, Ilse Truter, Veronika J Wirtz, Yea-Huei Kao Yang, Frank May, Morten Anderson. (Australia)

*SPONSORED BY THE DRUG UTILIZATION/HEALTH SERVICES RESEARCH SIG*

**Introduction to the Canadian Network for Observational Drug Effect Studies (CNODES) [728] (114)**

Samy Suissa, David Henry, Colin Dormuth, Robert Platt, Pierre Ernst, Lorraine Lipscombe, Sebastian Schneeweiss. (Canada)

**New Pharmacovigilance Legislation: A Call to Arms to the Pharmacoepidemiology Community [729] (115)**

Stella CF Blackburn, Peter R Arlett, Stephen J Evans, Susana Perez-Gutthann. (United Kingdom)

**Small Patients, Big Challenges – Current Topics in Pediatric Pharmacoepidemiology [730] (116)**

Katia M Verhamme, Sandra de Bie, Timothy Beukelman, Susan A Oliveria, Tamar Lasky, Rachel Sobel. (United States)

*SPONSORED BY THE PEDIATRICS SIG*

**The Real Potential of Routine Electronic Health Records for Clinical Trials: Putting Them to the Test [731] (132)**

Tjeerd P van Staa, Liam Smeeth, John Parkinson, Kourtney Davis, Hubert GM Leufkens. (United Kingdom)

Noon-1: 30pm

**Lunch/Poster Session C/Exhibits (Exhibit Hall Room 5-6-7-8)**

**ISPE Board of Directors Luncheon (124-125)**

*(Meeting open to all members; check with staff if you wish to attend)*

12:45-1:30pm

**Poster Walk (Exhibit Hall Room 5-6-7-8)**

- Medicines in Pregnancy SIG

1:30-3:00pm

***CONCURRENT SESSIONS: CONTRIBUTED PAPERS***

**ADRS in Europe (with one exception) [111-112]**

**Moderators: Michael Taylor & Gonzalo Calvo**

**01:30 PM Rare Serious Adverse Events: Comparison of Patient- and Physician-Reported Outcomes [732]**  
Juergen Dinger, Marita Kieble, Kristina Bardenheuer. (Germany)

**01:45 PM Prevalence and Preventability of Self-Reported Adverse Drug Events – A Cross-Sectional Population-Based Survey in Sweden [733]**  
Katja M Hakkarainen, Karolina Andersson Sundell, Max Petzold, Staffan Hägg. (Sweden)

**02:00 PM Medications in Pregnancy Abstracts Presented at ICPE 2001-2009: Trends in Subsequent Publication [734]**  
Deborah L Covington,<sup>1</sup> Paige Churchill,<sup>1</sup> Lindsay B Crampton. (United States)

**02:15 PM Using Electronic Healthcare Records for Drug Safety Signal Detection: A Comparative Evaluation of Statistical Methods [735]**  
Martijn J Schuemie, Preciosa M Coloma, Huub Straatman, Ron M Herings, Gianluca Trifirò, Justin N Matthews, David Prieto-Merino, Mariam Molokhia, Lars Pedersen, Rosa Gini, Francesco Innocenti, Giampiero Mazzaglia, Gino

Picelli, Lorenza Scotti, Johan van der Lei, Miriam C Sturkenboom. (Netherlands)

- 02:30 PM**      **Drug Safety Signals Detected Using Electronic Health Records and Spontaneous Reporting Systems Data: The Experience of EU-ADR Project [736]**  
Vaishali Patadia, Martijn Schuemie, Preciosa Coloma, Rosa Gini, Ron Herings, Giampiero Mazzaglia, Gino Picelli, Carla Fornari, Lars Pedersen, Johan van der Lei, Miriam Sturkenboom, Gianluca Trifirò. (United States)
- 02:45 PM**      **Poor Traceability of Biologicals in Adverse Event Reporting Systems [737]**  
Niels S Vermeer, Sabine MJM Straus, Aukje K Mantel-Teeuwisse, Toine CG Egberts, Hubert GM Leufkens, Marie L De Bruin. (Netherlands)

## **Cancer Pharmacoepidemiology (117)**

**Moderators: David Brown & James Kaye**

- 01:30 PM**      **A Matched Cohort Study Examining Digoxin Exposure and Prostate Cancer Mortality [738]**  
Evelyn M Flahavan, Kathleen Bennett, Linda Sharp, Thomas I Barron. (Ireland)
- 01:45 PM**      **Tamoxifen Therapy and Risk of Dementia in Breast Cancer Patients: A Danish Nationwide Cohort Study [739]**  
Anne G Ording, Deidre P Cronin-Fenton, Henrik T Sorensen, Anders B Jensen, Timothy L Lash. (Denmark)
- 02:00 PM**      **Risk of Congestive Heart Failure from Trastuzumab (Herceptin) in Elderly Persons with Breast Cancer: A Population-Based Study [740]**  
Huei-Ting Tsai, Claudine Isaacs, Solomon Makgoeng, Andrew N Freedman, Sheila Weiss Smith, Joan L Warren, Arnie L Potosky. (United States)
- 02:15 PM**      **Use of Orlistat and Risk of Colorectal Cancer [741]**  
Jin-Liern Hong, Robert Sandler, Christoph Meier, Susan Jick, Til Stürmer. (United States)
- 02:30 PM**      **Bisphosphonates and Esophageal Cancer in the GPRD [742]**  
Alec Walker, Julie Chandler, Robert Lubwama, Nancy Santanello. (United States)
- 02:45 PM**      **Androgen Deprivation Therapy and the Risk of Colorectal Cancer in Prostate Cancer Patients [743]**  
Jonathan Assayag, Hui Yin, Samy Suissa, Laurent Azoulay. (Canada)

## **Identifying Risks in Special Populations (113)**

**Moderator: Joanna Haas, FISPE & Brian Sauer**

- 01:30 PM**      **Optimisation of a Signal Detection Method on Spontaneous Reports of Adverse Events Post Immunisation [744]**  
Lionel Van Holle, Ziad Zeinoun, Vincent Bauchau. (Belgium)
- 01:45 PM**      **A Novel Bayesian Hierarchical Model Using Two-Dimensional Groupings of Drugs and Adverse Events for Detection of Adverse Drug Reactions in Large Databases [745]**  
Mark N Brook, David Prieto Marino, Stephen JW Evans. (United Kingdom)
- 02:00 PM**      **Temporal Pattern Discovery on Electronic Health Records – A Source of Reference in Signal Detection Work [746]**  
Kristina Star, Johanna Strandell, Sarah Fridén, Lovisa Sällstedt, Jeanette Johansson, Ralph I Edwards. (Sweden)
- 02:15 PM**      **Uncovering Hidden Patterns in Pharmacovigilance through Robust Subgroup Surveillance [747]**  
Johan Hopstadius, G Niklas Norén. (Sweden)
- 02:30 PM**      **A Systematic Analysis of Drug Name Confusion in the FDA AERS Database Using Disproportionality Analysis [748]**  
Robbert P van Manen. (Netherlands)
- 02:45 PM**      **Utilisation of Fentanyl Buccal Tablets in Primary Care in England: Focus on ‘Off Label’ Use in Support of Risk Management [749]**  
Vicki Osborne, Deborah Layton, Carole Fogg, Saad AW Shakir. (United Kingdom)

## **Measuring Impact of Risk Minimization (114)**

**Moderator: Ken Hornbuckle**

- 01:30 PM**      **Efficacy of a Structured Prescription Form To Minimize Medication Errors in an Ecuadorian Rural Hospital [750]**  
Carlos E Durán, Patricia Ortiz, Daniel Intriago, Francisco Nina, Carmen E Cabezas. (Ecuador)
- 01:45 PM**      **Development of a New Type of Risk Minimization Tool To Reduce Medication Errors [751]**  
Meredith Y Smith, Tony Tran. (United States)
- 02:00 PM**      **Assessing Physician Compliance To Recommended Liver Function Test (LFT) Monitoring Guidance in Patients with Metastatic Breast Cancer (MBC) Using Lapatinib [752]**  
Sarah H Landis, Clara Chen, Julie A Byrne, Rahul Dhanda, Jeanenne J Nelson. (United States)

- 02:15 PM**      **Evaluation of Warnings in Labeling: Association of Label Changes and REMS on Physician Discontinuation of Exenatide BID Following Pancreatitis Diagnosis [753]**  
Hui Zhang, Ann Bui, Suzanne Grimshaw, Lee Meller, Sean Zhao. (United States)
- 02:30 PM**      **Rational Use of Diagnostic Imaging for Acute Low Back Pain in Australia [754]**  
Santosh Khanal, Yeqin Zuo, Eimir Hurley, Aine Heaney, Karen Kaye. (Australia)
- 02:45 PM**      **Determinants of Impact of Drug Safety Warnings. A Retrospective Analysis of Direct Healthcare Professional Communications [755]**  
Sigrid Piening, Katrin C Reber, Jaap E Wieringa, Sabine M Straus, Pieter A de Graeff, Flora M Haaijer-Ruskamp, Peter G Mol. (Netherlands)

## **Methods: The Real Deal (115)**

**Moderators: Alan Brookhart & Rene Schade**

- 01:30 PM**      **Statistical Methods for Comparing the Effectiveness of Treatment Regimens in Long-Term Observational Comparative Effectiveness Research (CER) Studies with Time-Varying Treatments [756]**  
Larry F Leon, Yong Mun, Bann-Mo Day, X. Sylvia Hu. (United States)
- 01:45 PM**      **A Comparison of Methods for Estimating Exposure-Time Trends in Case-Case-Time-Control Designs [757]**  
Shirley V Wang, Josh J Gagne, Robert Glynn, Sebastian Schneeweiss. (United States)
- 02:00 PM**      **Utility of the Nested Case Control Design for Risk Assessment in the Presence of an Important Risk Modifier in Pharmacoepidemiological Studies: Evidence from Simulated Data [758]**  
Victor A Kiri, Maurille Tepie-Feudjo, Andrew Rodham, Cathy Critchlow, Gilbert MacKenzie. (United Kingdom)
- 02:15 PM**      **Calendar Time as an Instrumental Variable in Nonexperimental Comparative Effectiveness Research of Dynamic Therapies [759]**  
Christina D Mack, M Alan Brookhart, Robert Glynn, Til Stürmer. (United States)
- 02:30 PM**      **Cox's Proportional Hazards Regression Using Instrumental Variables [760]**  
Todd Mackenzie, Nancy Morden, Tor Tosteson, Therese Stukel. (United States)
- 02:45 PM**      **Primary Non-Compliance and Its Determinants: Implications for Misclassification of Drug Exposure [761]**  
Robyn Tamblyn, Tewodros Eguale, Samuel Torontour. (Canada)

## **Un Viaje por Vacunas: Vaccine Studies (116)**

**Moderator: Harold Heijbel**

- 01:30 PM**      **Guillain-Barré Syndrome and Adjuvanted Pandemic Influenza A (H1N1) 2009 Vaccine: Multinational Self Controlled Case Series Study in Europe [762]**  
Daniel Weibel, Silvana Romio, Jeanne P Dieleman, Corinne S de Vries, Cormac Sammon, Nick Andrews, Anders P Hviid, Henrik Svanström, Ditte Mølgaard-Nielsen, Maryse Lapeyre-Mestre, Agnès Sommet, Christel Saussier, Harald Heijbel, Lisen Arnheim-Dahlström, Jonas Hallgren, Par Sparen, Mees Mosseveld, Martijn Schuemie, Nicoline van der Maas, Bart C Jacobs, Tuija Leino, Terhi Kilpi, Jann Storsaeter, Henning K Olberg, Kari Johansen, Piotr Kramarz, Jan Bonhoeffer, Miriam CJM Sturkenboom. (Netherlands)
- 01:45 PM**      **Self-Controlled Analyses of the Risk of Guillain-Barré Syndrome Associated with Influenza A(H1N1) 2009 Monovalent Vaccines [763]**  
Claudia Vellozzi, Jerome Tokars, Frank DeStefano. (United States)
- 02:00 PM**      **Estimating Influenza Vaccine Effectiveness Using a Natural Experiment [764]**  
Leah J McGrath, Abhijit Kshirsagar, Stephen R Cole, Lily Wang, David J Weber, Til Stürmer, M Alan Brookhart. (United States)
- 02:15 PM**      **The Risk of Immune Thrombocytopenic Purpura Associated with Vaccines in Adults: A Multicenter Case-Control Study [765]**  
L Grimaldi-Bensouda, M Michel, J F Viallard, D Adoue, N Magy-Bertrand, M Khellaf, M Hacini, O Fain, A S Morin, P Quittet, B Pan-Petes, B Bonnotte, N Chalumeau-Costedoat, M Ruel, P Leighton, E Aubrun, A Alperovitch, L Abenheim, B Godeau, PGRx-ITP Study Group. (France)
- 02:30 PM**      **Risk of Febrile Convulsions after MMRV Vaccination in Comparison to MMR or MMR+V Vaccination [766]**  
Tania Schink, Jacob Holstiege, Garbe Edeltraut. (Germany)
- 02:45 PM**      **Surveillance of Pertussis in The Netherlands: Monitoring the Impact of Recent Changes in the Vaccination Program [767]**  
NAT. van der Maas, SC de Greeff, FR Mooi, HE de Melker. (Netherlands)

3:00-4:30pm

## **HOT TOPICS SESSION: (111-112)**

***Evaluating Cancer Risk with Diabetes Treatment: Methodological Challenges***

**Moderators:**

**Til Stürmer, FISPE, & Nancy Santanello, FISPE**

### **Background**

Multiple study design issues apply to pharmacoepidemiology studies of the incidence of long term outcomes such as cancers. We use pharmacoepidemiology studies in diabetes as a common theme to illustrate such issues.

### **Objectives**

To review the practical and logistical challenges associated with pharmacoepidemiology studies of cancer, particularly in diabetes treatment

### **Description**

Study design and logistical issues in designing pharmacoepidemiology studies of cancers in claims or electronic medical record (EMR) databases can be paramount. Common to all databases are issues related to accounting for cancer-specific latency periods and time at risk, understanding of the potential for pre-existing undiagnosed cancers prior to initiation of exposure, diagnostic suspicion, confounding, and selection bias at baseline or through adherence over time (healthy user bias). The typically short-term nature of databases and lack of potentially important confounders (e.g., medical history and family history of cancers) pose additional issues, given the latency period of most cancers. Finally, detection bias can be a prominent issue in circumstances where one of the comparison groups has known side effects that may lead to more specific testing, which in turn, can lead to differentially greater cancer detection in that group. As with all pharmacoepidemiology research, adequate ascertainment of cancers and the time of diagnosis are critical. Many of these issues can be addressed adequately with a new user design and comparator drug classes, which allows us to focus on treatment initiation decision processes, can serve to attenuate confounding and selection bias, and can address discontinuation, switching and augmenting of medications separate from addressing the confounding or channeling bias at baseline. Sensitivity analyses can assess variations in such approaches. Approaches to account for such methodological issue specific to associations of drugs with cancer outcomes in comparative studies will be discussed, with examples from diabetes given.

### **SPEAKER/PRESENTATIONS**

- **Cindy Girman**, *Overview of Issues in Designing Pharmacoepidemiology Studies of Cancer, Especially in Diabetes*
- **Bob Glynn**, *Design Considerations to Reduce Confounding*

- **Alan Brookhart**, *Adherence/Compliance Bias*
- **James Lewis, FISPE**, *A Review of the Challenges of Detection Bias, How to Evaluate Whether You Have Detection Bias and Potential Approaches to Mitigate*
- **Alec Walker , FISPE**, *Handling Latency Period Issues and Definitions of Exposures, in General and in Studies with Short-Term Follow-Up Duration*
- **Nancy Santanello, FISPE**, *Wrap-up & panel discussion*

**PANEL Discussants**

- **Cindy Girman**
- **Bob Glynn**
- **Alan Brookhart**
- **Til Stürmer**
- **James Lewis**
- **Alec Walker**
- **June Raine**

4:30-5:00pm

**The Final Word (111-112)**

◀ **Poster Awards**

**Mary Beth Ritchey**, Poster Walk Chair

◀ **Future Meetings**

*2013 Mid-Year Meeting - Munich*

**Frank Andersohn**, Co-Chair, Program Planning

*ICPE 2013- Montreal*

**Yola Moride, FISPE**, Chair, Scientific Program Committee

5:00pm

**Adjournment of ICPE 2012**

5:15-6:15pm

**2013 ICPE Scientific Program Committee Meeting (124-125)**