27TH ICPE

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Zhiqiang Lu
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Muhammad Younus
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AUGUST 14-17, 2011 ICPE 2011 CHICAGO, IL

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**MEETING At-A-Glance**

### Tuesday, August 16, 2011

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<td>7:00-9:00am</td>
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<td>Diseases and Bugs</td>
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<td>Plenary Session</td>
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<td>Annual Meeting of ISPE Members &amp; Awards Ceremony</td>
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<td>Hot Topics Session: H1N1 Vaccine Safety</td>
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### Wednesday, August 17, 2011

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<tr>
<td>12:00-1:00pm</td>
<td>ISPE Board of Directors Luncheon</td>
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<td>1:00-2:00pm</td>
<td>Assessing Treatment Patterns</td>
<td>Regency A</td>
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<td>2:00-3:00pm</td>
<td>Advanced Drug Research</td>
<td>Regency B</td>
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<td>3:00-4:00pm</td>
<td>FDA’s Mini-Sentinel</td>
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<td>4:00-5:00pm</td>
<td>Drug Utilization Studies</td>
<td>Regency D</td>
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<td>5:00-6:00pm</td>
<td>Multiple Data Sources</td>
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<td>6:00-7:00pm</td>
<td>Active Surveillance for Biologics</td>
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### Additional Information
- **5:30 - 6:30pm** | Symposium & Workshops | Regency B | | | | | | | | | |
- **5:00 - 5:30pm** | Symposium & Workshops | Regency A | | | | | | | | | |
- **5:30 - 6:30pm** | Symposium & Workshops | Regency C | | | | | | | | | |
- **5:00 - 5:30pm** | Symposium & Workshops | Regency D | | | | | | | | | |
ISPE Exhibitors & Supporters as of July 29, 2011

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- Department of Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida
- Division of Pharmacoepidemiology & Pharmacoeconomics, Brigham and Women’s Hospital & Harvard Medical School
- Drug Safety Research Unit, Associate Department of the School of Pharmacy and Biomedical Sciences, University of Portsmouth
- Pharmacoepidemiology Program, Department of Epidemiology, UNC Gillings School of Global Public Health, University of North Carolina at Chapel Hill
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Thank you

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※ Department of Health, Pharmaceutical Services, Hong Kong Special Administrative Region, People’s Republic of China
※ Drug Safety and Effectiveness Network, Canadian Institute of Health Research

Academic Programs

※ Center for Clinical Epidemiology & Biostatistics, University of Pennsylvania School of Medicine
※ Center for Drug Safety & Pharmaceutical Health Services Research Graduate Program, University of Maryland School of Pharmacy
※ Department of Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida
※ Drug Safety Research Unit, Associated Department, School of Pharmacy and Biomedical Sciences, Portsmouth University
※ Division of Pharmacoepidemiology & Pharmacoeconomics, Brigham and Women’s Hospital & Harvard Medical School
※ Harvard School of Public Health
※ London School of Hygiene and Tropical Medicine
※ McGill Pharmacoepidemiology Research Unit, McGill University
※ Pharmacoepidemiology Program, Department of Epidemiology, UNC Gillings School of Global Public Health, University of North Carolina at Chapel Hill
※ Slone Epidemiology Center, Boston University
※ University of Cincinnati College of Pharmacy

Annual Campaign As of July 29, 2011

The Society expresses its sincere appreciation to those supporters listed below for their contribution in honor of the 27th Annual Meeting (ICPE).


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AUGUST 14-17, 2011  ICPE 2011  CHICAGO, IL
27TH ICPE

FUTURE MEETINGS

2011

Pharmacoepidemiology and Risk Management: From Scientific Research to Clinical Practice—Opportunities and Challenges

6th Asian Conference on Pharmacoepidemiology (ACPE) and 2011 Annual Meeting of the Committee of Pharmacoepidemiology of the Chinese Pharmaceutical Association (AMCP-CPA)

October 28-30, 2011

Beijing International Convention Center  Beijing, China

Better Public Health Through Pharmacoepidemiology and Quality Use of Medicine

ISPE and EuroDURG – The European Branch of the ISPE Special Interest Group for Drug Utilization Research (SIGDUR)

November 30-December 3, 2011

University of Antwerp  Antwerp, Belgium

2012

ISPE Mid-Year Meeting

April 21-23, 2012

Eden Roc Hotel  Miami Beach, Florida

28th ICPE

August 23-26, 2012  CCIB  Barcelona, Spain

2013

ISPE Mid-Year Meeting

April 11-13, 2013

Hilton Munich City  Munich, Germany

29th ICPE


Montreal Convention Center  Montreal, Canada

Badges

All attendees at ICPE 2011 must wear their name badges to all events.

A badge will be needed for admission to conference related functions, such as the Academic Showcase/Welcome Reception, scientific sessions, exhibit/poster hall, and evening at the Hard Rock Cafe. Badges will be included in the registration material. In some cases, tickets for admission will be required (e.g., guests).

**Badge Legend**
- Student
- New Member
- One-Day Attendee

The online abstract site will be operational by mid-December 2011.

Meeting information will be posted at pharmacoepi.org
AGENDA  Saturday, August 13

8:30am-5:00pm
ISPE Board of Directors Meeting (Toronto)
(Open to ISPE members; notify ISPE staff if you would like to attend.)

8:00am-6:00pm
Registration (Regency Main Desk)

8:00am-5:00pm
Speaker Ready Room (Hong Kong)

Pre-Conference Educational Sessions* (Registration required)

8:30-Noon
Introduction to Pharmacogenetic Epidemiologic Methods (Regency Bl)

Session I: Didactic Approach Infused with Practical Examples

Content
This highly interactive course will involve participants in:
• A dynamic didactic experience of the foundational principles of pharmacogenetics.
• An appreciation for the different methods used in pharmacogenetics research.
• Examination of real world examples of pharmacogenetic epidemiology.
• Application of methodology to designing pharmacogenetic epidemiology studies.
• Interpretation of the data found in the pharmacogenetic epidemiology literature, and understanding wider implications of the results.

Educational 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 weaknesses used in pharmacogenetic epidemiology.
• To understand statistical approaches used in pharmacogenetics.
• 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.

12:00-1:30pm
Lunch

1:30-6:00pm
Introduction to Pharmacogenetics Continued (Regency B)

Session 2: Hands-on Workshop & Discussion of Practical Applications and Issues

Content
A round-table session with small groups of students self-selecting into the round-table of choice based upon topic interest. Each round-table will be "hosted" by two faculty members.
• Pharmacogenetic Epidemiology Methods
• Clinical Studies and Applications (Specific Examples Include Warfarin; KRAS Mutations; Breast Cancer Genomics, etc)
• Regulatory Affairs & The FDA/EMA/Health Canada
• Clinical Utility of Pharmacogenetic Tests/Translation into Clinical Settings & Development of Clinical Practice Guidelines
• Databases & Biobanks

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

Faculty
Amalia M. Issa, Welcome & Introduction to Course
Geoffrey Liu, Introduction to Pharmacogenetic and Biospecimen Terminology, and Approach Overview
Anke-Hilse Maitland-van der Zee, Advanced Pharmacogenetic Methods for Epidemiologists
Andrew Freedman, Application of Methods: From Discovery to Confirmation to Clinical Utility
Steven Kimmel, FISPE, Application of Methods: Warfarin as a Prototype Pharmacogenetic Example
Amalia M. Issa, Methods to Investigate Policy-Relevant Aspects of Pharmacogenomics & Examples of Applications
Leah Sansbury, Moderator
Pre-Conference Educational Sessions* (Registration required)

1:30-6:00pm
Introduction to Pharmacoepidemiology (Regency A)

Faculty
John Seeger, Chair, Introduction to Pharmacoepidemiology
Mondira Bhattacharya, Pharmacovigilance/Spontaneous Reporting
Frank Andersohn, Cohort Studies
Gianluca Trifiro, Case Control Studies
Soko Setoguchi, FISPE, Bias and Confounding

1:30-6:00pm
Introduction to Drug Utilization Research (Regency D)

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 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 Drug Utilization Research/Health Services Research 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

* Included as part of full meeting registration; registration required
Educational Objective:
To create a space where student members of ISPE can discuss, learn and update their statistical software-programming skills, especially in topics of importance for the field of pharmacoepidemiology.

Activities:
With the support of SAS Student Programs Manager, Elizabeth Ceranowski, we propose to do a 2-hour hands-on workshop covering the following topics:
1. Making use of indexes
2. Creating anonymous ID variables
3. Joining tables (merging and concatenating)
4. Sampling with/without replacement

Part A - Optimizing Programming Skills in SAS Software
Pharmacoepidemiologists today use a wide variety of software programs. As the methods in the field advance and as data become larger and more complex, good programming skills become a valuable asset. This is why motivated by students feedback, ISPE’s Student Council in collaboration with SAS Global Academic Program have designed a workshop in SAS programming that will take place during the Student Skills Workshop.

Educational Objective(s):
1. To optimize the use of social media for networking within student members of ISPE.
2. To improve students’ knowledge on social media tools useful for career development.

Activities:
The workshop would work as a back-and-forth Q&A session with practical demonstrations, with the discussion leader (Elizabeth Ceranowski, SAS Student Programs Manager).

4:00-4:30pm
Part B - Optimizing the Use of Social Networks for Career Development
The use of social media goes beyond leisure purposes. Nowadays hiring managers and recruiters scan the social web to draw a picture of the applicant. Therefore the choice of networks and activities within those networks are of utmost importance. This is especially true for young professionals or recent graduates who are job hunting or are starting to build their professional network. However, many young professional don’t know how to effectively use these media.

Optimizing the use of media within SISPE members is a need. Improving networking within student members of ISPE has been a recurrent theme in the Council’s meetings. Although already using social media, its full potential is yet to be explored. Learning about ways to improve use of these networks would be beneficial both at the individual and group level.

Educational Objective(s):
1. To explore the use of social media for networking within student members of ISPE.
2. To improve students’ knowledge on social media tools useful for career development.

Activities:
The workshop would work as a back-and-forth Q&A session with practical demonstrations, with the discussion leader (Elizabeth Ceranowski, SAS Student Programs Manager).

Part C - Career Building in Pharmacoepidemiology – Tools for Career Development in Pharmacoepidemiology
One of the aims of the Student Council is to provide students and young professionals with opportunities for career guidance and development. In an effort to continue to bring useful resources and information we have designed a workshop that will take place during the Student Skills Workshop at the Annual ISPE Conference in Chicago.

This workshop is geared toward students who want to start planning their careers, or for those currently looking for a job that want to learn about career opportunities in the field.

Educational Objective(s):
To give the students a feel of what the job market looks like for people coming out of epidemiology and pharmacoepidemiology programs, including desired skills. Also, tips on interview techniques and opinions from hiring managers in the pharmaceutical world.

Activities:
Interactive Discussions:
4:30-5:15pm: Focus on Industry Government. Dan Strauss, Director, Epidemiology and Drug Safety, Klein Hersh International
5:15-5:45pm: Focus on Academia. Almut Winterstein, University of Florida, ISPE Academic Council
5:45-6:00pm: Wrap Up Round Table Discussion. Elizabeth Ceranowski, Dan Strauss, & Almut Winterstein

Student Meet and Greet (Timothy O’Toole’s Pub)
- Open to all students.
- Organized by ISPE Student Council
- Assemble at ISPE Registration Desk, then walk to the bar.

Come meet new student members and greet old friends!
7:30-6:00pm  Registration (Regency Main Desk)
7:30-5:00pm  Speakers’ Ready Room (Hong Kong)

**Pre-Conference Educational Sessions**

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

**Content**
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

8:30-Noon
**Healthcare Databases (Toronto)**

**Using Pharmacoepidemiology Database Resources to Address Drug Safety Research**

**Content**
This highly interactive workshop will:

- 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 available from the Centers for Medicaid and Medicare Services;
- Identify the elements to properly select a study population and;
- Explore a method to harmonize data from multiple resources

**Educational Objectives**
- To gain an understanding of available pharmacoepidemiology resources.
- To develop the skills to select an appropriate resource to conduct pharmacoepidemiology research
- To learn techniques to identify a study population and validate outcome measures
- To examine methods of data harmonization across multiple resources

**Target Audience**
- 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.

**Faculty**
Nancy A. Dreyer, FISPE
- Introductions, objectives and workshop
- The evidence hierarchy and the role of prospective observational research as alternatives to RCTs
- Types of registries and their applications, including their use to support regulatory, clinical and pharmacy decision-making

Deborah Layton
- Challenges in design
- Case examples in the EU

Charles E. Barr
- Case study: Registry examples in the US

Saad Shakir, FISPE, Prospective Cohort Studies as Tools For Risk Management and Pharmacovigilance – EU Perspective

**Target Audience**
- 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

**Faculty**
Kevin Haynes & Alison Bourke, Co-Chairs
Gillian Hall, FISPE, Overview of Database Use in Pharmacoepidemiology
Matthew Reynolds, Selection of Databases for Pharmacoepidemiology Research
Charlie Leonard, Center for Medicaid and Medicare Services (CMS) Overview
Suellen Curkendall, Population Selection
Jeffrey Brown, Harmonization of Data Across Multiple Resources
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We are proud to support the 27th International Conference on Pharmacoepidemiology and Therapeutic Risk Management and welcome the opportunity for the open exchange of scientific ideas and research findings in order to advance the fields of pharmacoepidemiology and risk management.
Comparative Effectiveness Research (Regency B)

Content
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.

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

Faculty
Eric S. Johnson
Sebastian Schneeweiss, FISPE
David J Magid

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### Pre-Conference Educational Sessions* (Registration required)

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<td>8:30-Noon</td>
<td>Intermediate Pharmacoepidemiology: Concepts, Data &amp; Methods: The ‘Pharmaco’ in Pharmacoepidemiology (Regency A)</td>
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**Content**

This course is for the trained epidemiologist who is new to drug safety research and wishes to go in-depth into topics that appear repeatedly in current practice. Through lectures and discussions, we will explore examples of discovery of adverse drug effects, use of large administrative and medical-record databases for ad hoc research and systematic screening, study designs that are most appropriate to large data resources, control for unmeasured confounding factors, and the institutional histories and sensitivities that affect discussions between industry and regulatory authorities. Participants will emerge with relevant vocabulary and key concepts, and an ability to pursue each of these topics in more depth on their own.

**Faculty**

Alexander Walker, FISPE

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<td>8:30-Noon</td>
<td>Regulatory Pharmacoepidemiology/Health Decision-Making (Regency C)</td>
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**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
- Have an overview of worldwide challenges for drug regulatory agencies and variation in approaches
- Know about current strategies to strengthen regulation in the face of these challenges
**AGENDA Sunday, August 14**

### Pre-Conference Educational Sessions* (Registration required)

**1:30-6:00pm**  
**Advanced Topics in Pharmacoepidemiology** (Regency A)

- This course is a series of four lectures covering new and advanced methods for pharmacoepidemiology research.  
- **Faculty**
  - **Vincent Mor**, Pharmacoepidemiology in Nursing Home Patients: Confounding Adjustment in a Strongly Hierarchical Data Structure
  - **Joseph A. Delaney**, Marginal Structural Models: Examples of Successes and Challenges in the World of Pharmacoepidemiology
  - **Alexander Walker**, FISPE, Intention-to-Treat Analyses in Observational Studies of Drug Effects

**1:30-6:00pm**  
**Introduction to Therapeutic Risk Management and Evaluation: What Are We Learning from the Evaluations of Risk Management Programs (RMP) and REMS?** (Regency B)

- **Educational objectives**
  - To provide basic overview/framework for biopharmaceutical risk management — both EU-based risk minimization plans (RMP) and US-based risk evaluation & mitigation strategies (REMS) — including the regulatory context and perspective
  - To describe the methods used in evaluating the effectiveness of risk RMPs/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 sessions in developing and evaluating RMP/REMS assessment studies

- **Target Audience**
  - Epidemiologists with little prior experience conducting assessments of risk minimization programs (RMPs) and risk evaluation and mitigation strategy (REMS) and who may need to write evaluation study protocols
  - Pharmacovigilance and regulatory professionals who are involved with reviewing, and negotiating risk RMPs/REMS and their assessments

- **Faculty**
  - **Elizabeth Andrews**, FISPE, Course Objectives and Introductions, Overview of Risk Management; The Role of Evaluation
  - **Stella Blackburn**, FISPE, Requirements and Lessons Learned From Evaluating Risk Management Programs in the EU
  - **Mary Willy**, Requirements and Lessons Learned from Evaluating REMS in the US
  - **Carla Van Bennekom**, Selected Topics and Examples – Survey
  - **Judith Jones**, FISPE, Workshop for Participants to Develop/Review an Assessment Plan

**1:30-6:00pm**  
**Advanced Drug Utilization/Health Services Research** (Regency C)

- **Content**
  - This highly interactive workshop will involve participants in the:
    - Use of Drug Utilization Research information from administrative health data to improve medicines use;
    - Application of principles derived from Health Services and Implementation Research to the design of a clinical intervention;
    - Planning of the evaluation of the clinical intervention 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
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23 years of Consulting and Research in Drug Safety and Pharmacoepidemiology

AGENDA  Sunday, August 14

6:00-7:30pm
Academic Showcase/Welcome Reception (The Club at 151)
- Admission is by badge or ticket. Cash bar.

Welcome
John Seeger, Co-Chair, 2011 Scientific Program Committee
Glen T. Schumock, Co-Chair, 2011 Scientific Program Committee
Stephen JW Evans, FISPE, ISPE President

Target Audience
Members of the DUR/HSR SIG; those interested in Implementation Research and knowledge transfer, health and medicines policy areas, health funds and third-party payers; clinical pharmacoepidemiologists; health service planners; clinical guideline developers; health practitioners.

Faculty
Libby Roughead, How Does the Work We Do in This Workshop Differ From Classical Pharmacoepidemiology?
Jerry Avorn, FISPE, Influencing Prescribing: Current Issues in Educational Outreach.
Andrew Gilbert, Knowledge Transfer
7:00-6:00pm
Registration (Regency Main Desk)

7:00-5:00pm
Speaker Ready Room (Hong Kong)

7:00-8:00am
Poster Session A Set-up (Riverside Center West)

8:00-6:00pm
Exhibits/Posters (Riverside Center West)

8:15-10:00am
Opening Session (Crystal Ballroom)

» Welcome
  John Seeger, Co-Chair, 2011 Scientific Program Committee
  Glen T. Schumock, Co-Chair, 2011 Scientific Program Committee

» Presidential Address
  Stephen JW Evans, FISPE, ISPE President

» Keynote Address
  Robert M. Califf, Director of the Duke Translational Medicine Institute; Vice Chancellor for Clinical Research; Professor of Cardiology, Duke University School of Medicine

10:00-10:30am
Break/Posters/Exhibits (Riverside Center West)

Government/Regulatory Council
Coffee Corner

10:30 - Noon

Concurrent Sessions: Contributed Papers

Advanced Analytical Approaches (Regency A)
Moderators: Corinne de Vries, FISPE, & Alan Brookhart

10:30am
- Evaluation of a Parsimonious High-Dimensional Propensity Score [1]
  Jeremy A Rassen, Sebastian Schneeweiss, Alexander M Walker. (United States)

10:45am
- Estimating Survival from Diagnosis When Study Enrollment is After Time of Diagnosis: A Left Truncation Case Study [2]
  Dave P Miller, Aimee J Foreman. (United States)

11:00am
- Standard Errors & Confidence Limits for Doubly Robust Estimation [3]
  Michele Jonsson Funk, Daniel Westreich, Til Stürmer, M Alan Brookhart. (United States)

11:15am
- Effects of Adjusting for Instrumental Variables on Bias and Precision of Effect Estimates [4]
  Jessica A Myers, Joshua J Gagne, Jeremy A Rassen, Sebastian Schneeweiss, Krista F Hubrechts, Kenneth J Rothman, Marshall M Joffe, Robert J Glynn. (United States)

11:30am
- Poisson Regression Type Model in a Case-Cohort Study [5]
  Akira Wakana, Kiyoshi Kubota. (Japan)

11:45am
  Malcolm Maclure, Richard Morrow, Greg Carney, Colin Dormuth. (Canada)

Algorithms - Processes That Matter (Regency B)
Moderators: Susanna Perez Gutthann, FISPE, & Cheryl Enger

10:30am
- Discrepant Results in Pneumonia Studies Using Solely Administrative Data Compared to Medical Record Review [7]
  Sascha Dublin, Rod L Walker, Michael L Jackson, Jennifer C Nelson, Noel S Weiss, Lisa A Jackson. (United States)

10:45am
- Harmonization of the Event Identification Process in Eight European Healthcare Databases: The Experience from the EU-ADR Project [8]
  Gianluca Trifiro, Paul Avillach, Rosa Gini, Preciosa Coloma, Giampiero Mazzaglia, Gino Picelli, Lorenza Scotti, Ron Herings, Julia Hippisley-Cox, Mariam Molokhia, Lars Pedersen, Annie Fourrier Reglat, Antoine Pariente, Miriam Sturkenboom, Johan van der Lei. (Netherlands)
Applying Science to Life!

Our goal is to find for whom and under which conditions of use the drugs that will demonstrate best benefit to patients, with minimal harm. For that purpose, we champion observational and pragmatic studies, with an enviable track record of success. We are pioneers in pharmacoepidemiology and populational health impact assessment of medicines. We also use decision analysis, pharmacoconomics and other strategy consulting skills to analyse issues and target drugs at their best.

LA-SER’s Scientists Presenting at ICPE:

- "Exposure to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Drugs Used in Musculoskeletal Disorders (MSD): Agreement between Physicians’ Prescriptions and Patients’ Self-Report in the PGRx Database" as part of the session titled Methods for Safety at 09:45 on Wednesday, August 17, 2011.

- "Guillain–Barré Syndrome, Influenza–like Illnesses and Influenza Vaccination during Seasons with and without Circulating A/H1N1 Viruses" as part of the session titled Methods in Vaccine Safety at 10:45 on Wednesday, August 17, 2011.

Additionally, LA-SER will be co-moderating the session: Methods Development in Active Drug Safety Surveillance Highlighting the Observational Medical Outcomes Partnership’s Findings from 16:00-17:30 on Tuesday, August 16, 2011.

Please take the time to visit us at our booth.

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**AGENDA**  
**Monday, August 15**

**11:00am**  
- Quality of ICD-10 Colorectal Cancer Diagnosis Codes in the Danish National Registry of Patients [9]  
  Rune Erichsen, Henrik Gammelager, Lea Helquist, Martin B Johansen, Henrik T Sorensen. (Denmark)

**11:15am**  
- Case Screening and Validation in a Population-Based Study of Antimicrobial Use and Acute Liver Injury [12]  
  James A Kaye, Jordi Castellsague, Christine L Bui, Brian Calingaert, Lisa J McQuay, Nuria Riera, Catherine W Saltus, Scott Quinlan, Crystal N Holick, Peter M Wahl, Kenneth J Rothman, Mari-Ann Wallander, Susana Perez-Gutthann. (United States)

**11:30am**  
- Development and Validation of Claims-Based Algorithms To Determine Level of Trauma Associated with Fractures in Men [11]  
  Jie Zhang, Elizabeth Delzell, Tarun Arora, Nicole C Wright, Kristine Ensrud, John Schousboue, Beth Virnig, Brent Taylor, Misti Paudel, Jeffrey R Curtis. (United States)

**11:45am**  
  Seo Young Kim, Sebastian Schneeweiss, Huichuan Lii, Daniel H Solomon. (United States)

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**11:45am**  
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AGENDA Monday, August 15

Genes and Drugs (Toronto)
Moderators: Stephen Kimmel, FISPE, & Anke-Hilse Maitland-van der Zee

10:30am
- Common Variation in the CACNA1C Gene Modifies the Effect of Diltiazem on Heart Rate [13]
  Mark Eijgelmans, Eline M Rodenburg, Jan A Kors, Jacqueline C.M Witteman, Albert Hofman, Andre G Uitterlinden, Bruno HC h Stricker. (Netherlands)

10:45am
- Cytochrome P-450 2D6 and 2C19 Polymorphisms and Consumption of Care in Psychiatric Practice [14]
  Frederieke H van der Baan, Jochem G Gregoor, Harriet M Loovers, Olaf H Klungel, Toine C G Egberts, Diederick E Grobbee, Mirjam J Knol, Jan van der Weide. (Netherlands)

11:00am
- Quantitative Meta-Analysis of Cytochrome P450 2D6 Inhibition and Breast Cancer Outcomes in Tamoxifen-Treated Patients [15]
  Deirdre P Cronin-Fenton, Timothy L Lash. (Denmark)

11:15am
  Jane Der, Christy I Avery, Eric A Whitsel, Til Sturmer. (United States)

11:30am
- Genome-Wide Analysis of LDL-C Lowering with Statin Therapy Identifies Loci Related to Statin Pharmacokinetics and LDL Particle Endocytosis [17]
  Daniel I Chasman, Franco Giuliani, Jean MacFadyen, Bryan J Barratt, Fredrik Nyberg, Paul M Ridker. (Sweden)

11:45am
- Potential of Adaptive Clinical Trial Designs in Pharmacogenetic Research, a Simulation Based on the IPASS Trial [18]
  Frederieke H van der Baan, Mirjam J Knol, Olaf H Klungel, Toine C G Egberts, Diederick E Grobbee, Kit C B Roës. (Netherlands)

Primigravida (Acapulco)
Moderators: Rachel Charlton & Sara Ephros

10:30am
- Trimethoprim Use in Early Pregnancy and the Risk of Miscarriage: A Register Based Nationwide Cohort Study [19]
  Jon T Andersen, Morten Petersen, Espen J Solem, Kasper Broedbaek, Shoaib Afral, Elisabeth W Andersen, Christian Torp-Pedersen, Niels Keiding, Henrik E Poulsen. (Denmark)

10:45am
- Use of Proton Pump Inhibitors during Pregnancy and the Risk of Asthma in Offspring [20]
  Ane Birgitte T Andersen, Rune Erichsen, Dora K Farkas, Vera Ehrenstein, Henrik T Sørensen. (Denmark)

11:00am
- Use of Thyroid Supplements during Pregnancy [21]
  Judith P Kelly, Sonia Hernandez-Diaz, Allen M Mitchell. (United States)

11:15am
- Selective Serotonin-Reuptake Inhibitors and Risks of Persistent Fetal Circulation and Pulmonary Hypertension in the Newborn [22]
  Helle Kieler, Kari Furu, Mika Gissler, Mette Noergaard, Unnur Valdimarsdottir, Bengt Haglund. (Sweden)

11:30am
- Comparative Safety of Anticonvulsants during Pregnancy: Seizures or Major Malformations [24]
  Sonia Hernandez-Diaz, Catlin R Smith, Aileen Shen, Robert Mittendorf, Lewis B Holmes. (United States)

11:45am
- Use of Topiramate in Pregnancy and the Risk of Oral Clefts [23]
  Andrea V Margulis, Martha M Werler, Allen A Mitchell, Sonia Hernandez-Diaz. (United States)

Rheumatic Condition Therapies (Regency C)
Moderators: Mari-Ann Wallander, FISPE, & Seo Young Kim

10:30am
- Opioid Analgesics and the Risk of Pneumonia Hospitalizations in Patients with Rheumatoid Arthritis [25]
  Carlos G Grijalva, Patrick G Arbogast, Ed Mitchel, Marie R Griffin. (United States)

10:45am
- The Prevalence of Psoriatic Arthritis in the Health Improvement Network (THIN) [26]
  Alexis R Ogdie, Nicole Seminara, Daniel Shin, Sinead Langan, Joel M Gelfand. (United States)

11:00am
- Statins and Risk of Acute Myocardial Infarction in Patients with Rheumatoid Arthritis: A Population-Based Study [27]
  Mary A De Vera, Diane Lacaille, Michal Abrahamowicz, Jacek Kopec, Hyon Choi. (Canada)

STUDENT AWARD RECIPIENT • THIRD BEST ABSTRACT SUBMITTED BY A STUDENT
11:15am
**Which Is More Effective, Rituximab or a Second Anti-TNF Therapy for Rheumatoid Arthritis Patients Who Have Failed Their First Anti-TNF?**
- Analysis from the British Society for Rheumatology Biologics Register (BSRBR) [28]
  - Moetaza Soliman, Kimme Hyrich, Mark Lunt, Kath Watson, Deborah Symmons, Darren Ashcroft. (United Kingdom)

11:30am
**Rates of Hospitalized Bacterial Infection Associated with Juvenile Idiopathic Arthritis and Its Treatment** [29]
- Timothy Beukelman, Fenglong Xie, Lang Chen, John W Baddley, Elizabeth Delzell, Carlos G Grijalva, Nivedita M Patkar, Kenneth G Saag, Kevin L Winthrop, Jeffrey R Curtis. (United States)

**Sweet and Sour (Regency D)**
**Moderators:** Hubert Leufkens, FISPE, & Haley Kaplowitz

10:30am
**Estimation of Acute Effects of Severe Hypoglycemia on Subsequent Episodes in Type 1 Diabetes** [31]
- Zhiwen Liu, Charles Poole, Amy H Herring, Cynthia J Girman, Timothy S Carey, Til Stürmer. (United States)

10:45am
**Patient Level Factors Associated with Prescribing of Thiazolidinediones in the Period 2004-2009** [32]
- Petra Denig, Jaco Voorham, Klaas Hoogenberg, Flora M Haaijer-Ruskamp, The GIANTT-Group. (Netherlands)

11:00am
**Angiotensin Converting Enzyme Inhibitors in Hemodialysis** [33]
- Tara I Chang, David Shilane, Steven M Brunelli, Alfred K Cheung, Glenn M Chertow, Wolfgang C Winkelmayr. (United States)

11:15am
**Safety Surveillance Study of Abatacept Therapy Among Patients with Rheumatoid Arthritis** [30]
- Nancy D Lin, John D Seeger, Eva Ng, David D Dore. (United States)

11:30am
**Effect of Prescription Status on the Orlistat User Population: Prescription-Only Versus Pharmacy-Only** [35]
- Marjolein J Willemen, Aukje K Mantel-Teeuwisse, Nina A Winters, Sabine M Straus, Hubert G Leukens, Toine C Egberts. (Netherlands)

11:45am
**Do Physicians Need Both Rosiglitazone and Pioglitazone?** [36]
- Wei Liu, Paul Kubilis, Almut G Winterstein. (United States)

Noon -1:30pm
**Lunch/Poster Session A/Exhibits (Riverside Center West)**

**ISPE Committee/Council Meetings**
- Open to all participants. Lunch will be available in meeting rooms.
  - Development Committee (Water Tower)
  - Fellowship & Awards Committee (Picasso)
  - Finance Committee (Haymarket)
  - Public Policy Committee (Columbian)
  - Student Council (Gold Coast)

12:00-1:30pm
**PDS Regional Editors (Wrigley Room)**
(By Invitation)

12:15-1:15pm
**Roundtable Discussions**
For junior ISPE members and new members. Seating is limited; first-come, first-served.
- Anick Berard, FISPE, Use of healthcare database (combining estimates from different administrative databases)
- Joanna Haas, FISPE, Life cycle risk management
- Sebastian Schneeweiss, FISPE, Dealing with confounding in database studies

12:45-1:30pm
**Poster Walks (Riverside Center West)**
- Biologics SIG
- Drug Utilization SIG
- Medications in Pregnancy SIG
AGENDA  Monday, August 15

1:30-3:00pm

Plenary Session  (Crystal Ballroom)

Communication about Early Safety Findings from Active Surveillance Studies

- **Description**
  This session will discuss issues related to communication of newly identified medication safety signals and findings.

- **Moderators:**
  Nancy C. Santanello, FISPE, Merck
  Glen T. Schumock, University of Illinois at Chicago

- **Introduction**
  Nancy Santanello, FISPE

- **Regulatory Agency Perspective**

- **Researcher Perspective**
  Rich Platt, Harvard Pilgrim Health Care Institute and Harvard Medical School. Overview of Mini-Sentinel and communication issues that will arise in the course of piloting active surveillance evaluations.

- **Medical Journal Perspective**
  Michael Berkwits, Deputy Editor, Annals of Internal Medicine. Communicating early safety and risk evidence to physicians.

- **European Perspective**
  Miriam CJM Sturkenboom, FISPE, Erasmus Medical Center

- **Panel Discussion/Questions and Answers**

3:00-3:30pm

Break/Posters/Exhibits (Riverside Center West)
AGENDA  Monday, August 15

3:30-5:00pm
Concurrent Sessions: Symposia and Workshops

Application of Quality of Evidence Assessment Tools to the Valuation of Pharmacoepidemiologic Safety Studies [37] (Regency A)
- George A Neyarapally, Tarek A Hammad, Simone P Pinheiro, Solomon Iyasu, Michael D Murray, Paul Stang. (United States)

Capacity of Various Data Sources to Advance Medical Device Safety and Effectiveness Research [38] (Regency B)
- Danica Marinac-Dabic, Michael Matheny, Suzanne West, Michael Steinbuch, Art Sedrakyan. (United States)
  SPONSORED BY THE MEDICAL DEVICES SIG

Challenges and Pitfalls in Studying Birth Defects as Outcomes [39] (Toronto)
- Carol Louik, Jennita Reefhuis, Andrea V Margulis, Anick Berard, William Cooper. (United States)
  SPONSORED BY THE MEDICATIONS IN PREGNANCY SIG

Database Linkage and Methodological Issues in Comparative Effectiveness Research (CER) of Medical Devices vs. Medications: Lessons from an Ongoing Project [40] (Regency C)
- Jessica J Jalbert, Chih-Ying Chen, Sebastian Schneeweiss, Bradley G Hammill, Nancy A Dreyer, Joseph A C Delaney, Tobias Gerhard, Soko Setoguchi. (United States)
  SPONSORED BY THE CER SIG

Linking Existing Databases - Is it Worth the Pain? [41] (Regency D)
- Alison D Bourke, Robert J LoCasale, Edward A Bortnichak, Ron M Herings, Suellen M Curkendall, William B Saunders. (United Kingdom)
  SPONSORED BY THE DATABASES SIG

Regulatory Trends in Pharmacogenomic Biomarker Evaluation [42] (Acapulco)
- Andrew N Freedman, Anke-Hilse Maitland van der Zee, Issam Zineh, Michael Pacanowski, Marissa Papaluca-Amati, Kevin Carl, Burt Leufkens. (United States)
  SPONSORED BY THE MOLECULAR EPI/BIOMARKERS/ PHARMACOGENETICS SIG

5:00-6:00pm
ISPE Council Meetings
- Open to all interested participants
  - Academic Council (Acapulco)
  - Government/Regulatory Council (Water Tower)
  - Industry/Service Providers Council (Toronto)

6:30-7:30pm
PDS Editorial Board (Comiskey)
(By Invitation)

7:00pm - ?
Student Social Event - Night Out in Chicago (Location: TBA)
- Organized by ISPE Student Council
- Open to all students
- Assemble at ISPE Registration Desk, then walk to the restaurant.
  Join us for a relaxed evening among friends!
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AGENDA Tuesday, August 16

Concurrent Sessions: Contributed Papers

Drug Use - Change, Choice, or Chance (Regency A)

Moderators: Tobias Gerhard & Kevin Haynes

8:30am
- Generic Alendronate Use in Medicare Part D [268]
  Hufeng Yun, Jeffrey R Curtis, Wilson Smith, Robert Matthews, Kenneth G Saag, Nicole C Wright, Elizabeth Delzell. (United States)

8:45am
- Patterns of On- and Off-Label Oxaliplatin Use Among Stage II and III Colorectal Cancer Patients in 2005 [269]
  Jennifer L Lund, Hanna K Sanoff, Til Sturmer, Robert S Sandler, Alan M Brookhart, Joan L Warren, Linda C Harlan. (United States)

9:00am
- Adverse Health Outcomes Associated with Experiencing a Gap in Drug Coverage during the Medicare Part D Doughnut Hole [270]
  Jennifer M Polinski, William H Shrank, Robert Matthews, Kenneth G Saag, Nicole C Wright, Elizabeth Delzell. (United States)

Concurrent Sessions: Contributed Papers

Fractures - Give Us a Break (Regency B)

Moderators: Ann Louise Assaf & Dave Dore

9:15am
- Bisphosphonate Use May Be a Risk Factor for Osteonecrosis at Any Site: A Self-Controlled Case Series Analysis [274]
  Steven C Vlad, Yanyan Zhu, Jingbo Niu, Christine Peloquin, Hyon Choi, Yuqing Zhang. (United States)

9:30am
- Risk of Fracture in Patients with Myasthenia Gravis [275]
  Marloes Bazelier, Sander Pouwels, Kassim Javaid, Cyrus Cooper, David Hilton-Jones, Jan Verschueren, Tjeerd van Staa, Frank De Vries. (Netherlands)

9:45am
- Use of Thiazolidinediones and Risk of Osteoporotic Fracture: The Danish National Databases [276]
  Marloes Bazelier, Arlene Gallagher, Tjeerd van Staa, Cyrus Cooper, Hubert Leufkens, Peter Vestergaard, Frank De Vries. (Netherlands)

Adverse Health Outcomes Associated with Comparative Safety of Antidepressants on Patterns of On- and Off-Label Oxaliplatin

Odds of Fractures with Inhaled Corticosteroids and Fracture Risk Effects of Age and Sex on Adverse Drug Patterns of Outpatient Use of Parenteral An

Reasons for Oral Contraceptives Use in

Effects of Age and Sex on Adverse Drug Reaction Reporting in Relation to Drug Utilization in Sweden [271]
Lennart Holm, Elisabet Ekman, Stefan Meijer, Kerstin Blomgren-Jorsäter. (Sweden)

Patterns of Outpatient Use of Parenteral Anticoagulants in Older Adults between 1997 and 2004: A Population-Based Study [272]
Leah M Smith, Alexander G Perry, Linda E Lévesque. (Canada)

Reasons for Oral Contraceptives Use in Adolescents and Adults in Europe [273]
Kristina Bardenheuer, Juergen Dinger, Janko Leddin. (Germany)
Even with more than 125 years of experience, we remain intensely curious. For the sake of future generations.

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Multigravida (Toronto)

Moderators: Allen Mitchell, FISPE, & Kari Furu

8:30am
❖ Sensitivity Assessment of the Impact of Time to Maternal Interview on Interview Quality in the National Birth Defects Prevention Study [286]
Sarah C Tinker, Cassandra Gibbs, Devine Owen, Amy H Herring, Honein Margaret, Crider Krista, Werler Martha, Anderka Marlene, Reefhuis Jennifer. (United States)

8:45am
❖ Validity and Reliability of Maternal Recall of Prescription Drug Use During Pregnancy [287]
Marleen M H J van Gelder, Iris A L M van Rooij, Hermien E K de Walle, Nel Roeleveld, Marian K Bakker. (Netherlands)

9:00am
❖ Complications Associated with Unintended Pregnancies Under IUD Use: Results from the EURAS-IUD Study [288]
Clare A Barnett, Klaas Heinemann, Juergen Dinger. (Germany)

Propensity Score Methods (Regency D)

Moderators: Suellen Curkendall & Michele Jonsson Funk

8:30am
❖ Confounding Adjustment Via a High-Dimensional Propensity Score: An Application Using THIN [292]
Darren Toh, Luis A Garcia Rodriguez, Miguel A Hernan. (United States)

8:45am
❖ Outcome Specific Versus Generic Propensity Scores: A Simulation Study [293]
R Wyss, R Locasale, M A Brookhart, C Girman, T Stürmer. (United States)

9:00am
❖ Measuring Balance and Model Selection in Propensity Score Methods [294]
Svetlana V Belitser, Edwin P Martens, Wiebe R Pestman, Rolf H H Groenwold, Anthonius de Boer, Olaf H Klungel. (Netherlands)

9:15am
❖ Application of Simultaneous Multi-Way Propensity Score Matching for 3 or More Exposure Groups [295]
Jeremy A Rassen, Sebastian Schneeweiss, Daniel H Solomon, Abhi A Shelat. (United States)

9:15am
❖ Antidepressant Use During Pregnancy and the Risk of Gestational Hypertension [289]
Mary A De Vera, Evelyne Rey, Martin St-Andre, Berard Anick. (Canada)

9:30am
❖ Simulation Model of Annual Spina Bifida Cases Preventable in Absence of Prenatal Valproate Use [290]
Suzanne M Gilboa, Cheryl S Broussard, Owen Devine, Kara N Duwe, Audrey I. Flak, Sheree L Boulet, Cynthia A Moore, Martha M Werler, Margaret A Honein. (United States)

9:45am
❖ Rate of Adverse Events Associated with Methotrexate in the Treatment of Ectopic Pregnancy [291]
Wendy Camelo Castillo, Christie M J L Cooksey, Michele Jonsson Funk. (United States)

9:30am
❖ Time-Varying Propensity Scores and Hazard Ratio Estimation [296]
Christina D Mack, Robert Glynn, Til Stürmer. (United States)

Student Award Recipient – Second Best Abstract Submitted by a Student

9:45am
❖ Propensity Scores from Logistic Regression Yielded Better Covariate Balance Than Those from a Boosted Model: A Demonstration Using STAR*D Data [297]
Alan R Ellis, Stacie B Dusetzina, Richard A Hansen, Bradley N Gaynes, Joel F Farley, Til Stürmer. (United States)
### AGENDA  Tuesday, August 16

**To Clot or Not To Clot (Acapulco)**  
**Moderator:** Cristina Varas

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<th>Time</th>
<th>Title</th>
<th>Speaker(s)</th>
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<tr>
<td>8:30am</td>
<td>When Should an Atrial Fibrillation Patient Receive Anticoagulants Following Intracerebral Haemorrhage? (298)</td>
<td>Robert W V Flynn, Thomas M MacDonald, Anna Maria Choy, Gordon D Murray, Alexander S F Doney. (United Kingdom)</td>
<td>(Regency Center West)</td>
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<tr>
<td>8:45am</td>
<td>Age, Antipsychotics, and Risk of Thrombotic Events in the Veterans Health Administration (VHA) (299)</td>
<td>Shirley Wang, David D Dore, Malcolm Macclure, Vincent Mor, Crystal Linkletter, Stephen Buka. (United States)</td>
<td>(Regency Center West)</td>
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<td>9:00am</td>
<td>Moved to Poster Session A (300)</td>
<td></td>
<td>(See page 55)</td>
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<tr>
<td>9:15am</td>
<td>Androgen Deprivation Therapy and the Risk of Stroke and Transient Ischemic Attacks in Patients with Prostate Cancer (301)</td>
<td>Laurent Azoulay, Hui Yin, Serge Benayoun, Jean-François Boivin, Samy Suissa. (Canada)</td>
<td>(Regency Center West)</td>
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<tr>
<td>9:30am</td>
<td>The Risk of VTE in Users of a 24-Day Regimen of a Combined Oral Contraceptive Compared to Conventional 21-Day OC Regimens: Results from the INAS-OC Study (302)</td>
<td>Juergen Dinger, Kristina Bardenheuer, Christian Franke. (Germany)</td>
<td>(Regency Center West)</td>
</tr>
<tr>
<td>9:45am</td>
<td>Effect of Simultaneous Use of Oestrogens and Statins on the Risk for Venous Thromboembolism in Post-Menopausal Women (303)</td>
<td>Ruben Duijnhoven, Sophie dell’Aniello, Christel Renoux, Vicky Tagalakis, Mirjam Knol, Olaf Klungel, Samy Suissa. (Netherlands)</td>
<td>(Regency Center West)</td>
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<th>Time</th>
<th>Break/Posters/Exhibits (Regency Center West)</th>
<th>Government/Regulatory Council Coffee Corner</th>
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<td>10:00-10:30am</td>
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10:30-12:00pm

Concurrent Sessions: Contributed Papers

A Little Attention Please (Regency A)

Moderators: Cynthia de Luise & Nicholas Moore, FISPE

10:30am
- Pharmacological Treatment and Demographic Characteristics of Pediatric Patients with Attention Deficit Hyperactivity Disorder, Sweden [304]
  Shahram Bahmanyar, Anders Sundström, Magnus Kaijser, Helle Kieler. (Sweden)

10:45am
- Drug Treatment of ADHD in Children and Youths in Germany [305]
  Edeltraut Garbe, Rafael T Mikolajczyk, Angela A Kraut, Ingo Langner. (Germany)

11:00am
- ADHD Youths’ Career in Psychotropic Treatment [306]
  Almut G Winterstein, Paul Kubilis, Tobias Gerhard. (United States)

11:15am
- Accident Proneness Among Youth Treated with ADHD Medication [307]
  Els F Van den Ban, Patrick C Souverein, Willemijn M Meijer, Herman Van Engeland, Hanna Swaab, Toine C G Egberts, Elbert R Heerdink. (Netherlands)

11:30am
- Cardiovascular Safety of ADHD Medications in Children and Adolescents [308]
  Hedi Schelleman, Warren B Bilker, Brian L Strom, Stephen E Kimmel, Craig Newcomb, James P Guevara, Gregory W Daniel, Mark J Cziraky, Sean Hennessy. (United States)

11:45am
- Atomoxetine Utilization in Youths with Attention Deficit/Hyperactivity Disorder in 29 Medicaid States [309]
  Stephan Linden, Caitlin Knox, Almut G Winterstein. (United States)

Cutting edge epidemiology contributing to the discovery and development of safe and effective medicines

We are a global team of epidemiologists and other professionals that bring population-based evidence on disease and treatment to influence decision-making from drug discovery through development to medical practice. By designing, analyzing, and interpreting observational information from a public health perspective we play an important role in bringing new medicines to the market. The breadth of our responsibilities includes:

- Analyzing the occurrence and distribution of diseases, including underlying disease process
- Determining the burden of illness and unmet medical need
- Exploring traditional and new risk factors for diseases
- Evaluating the effect of treatment in the real world, including beneficial effects, patterns of drug uses and adverse events
- Detecting opportunities for possible new drug uses and new paths of drug development

Please visit our website at http://epidemiology.gsk.com/organization.html to find out more detailed information about Worldwide Epidemiology at GlaxoSmithKline.

Developing talent through equality of opportunity
# AGENDA Tuesday, August 16

**Adherence - A Sticky Issue (Regency B)**

**Moderators:** Jesper Hallas & Sylvie Perreault

- **10:30am**
  - Adherence and Discontinuation with the Use of Capecitabine in Daily Practice [349]
    - Jacqueline G Hugtenburg, Christel C L M Boons, Michiel P J De Looij, Loneke Timmers. (Netherlands)

- **10:45am**
  - Importance of Early Non-Adherence in Estimations of Medication Adherence [311]
    - Marsha A Raebel, Nikki M Carroll, Jennifer L Ellis, Emily B Schroeder, Elizabeth A Bayliss. (United States)

- **11:00am**
  - Reasons for Early Discontinuation of Hormonal Therapy in Breast Cancer Patients Across Five European Countries [312]
    - Allison A Petrilla, Cheryl P Ferrufino. (United States)

**Devices et al (Toronto)**

**Moderators:** Danica Marinac-Dabic & Suzanne West, FISPE

- **10:30am**
  - Use and Outcomes of Partial Knee Replacement (PKR) vs Total Knee Replacement (TKR) among Medicare Beneficiaries, 2000-2009 [316]
    - Soko Setoguchi, Melissa A Greiner, David Attarian, Scott Kelley, Sam Wellman, Lesley H Curtis, Ricardo Pietrobon, Michael Bolognesi. (United States)

- **10:45am**
  - Long-Term Comparative Survivorship of Uncemented Acetabular Components in Primary and Revision Total Hip Arthroplasty (THA) [317]
    - Hilal Maradit Kremers, James L Howard, Cathy D Schleick, Daniel J Berry, Miguel E Cabanela, Arlen D Hanssen, Mark W Pagnano, Robert T Trousdale, David G Lewallen. (United States)

- **11:00am**
  - Medical Device Safety Surveillance: The Safety of Urogynecologic Surgical Mesh for Repair of Pelvic Organ Prolapse [318]
    - Cara J Krulewitch, Mary Beth E Ritchey, Hong Cheng, Danica Marinac-Dabic, Tom Gross, Jonathan Gibbs, Christopher Worrall, Jeffery A Kelman. (United States)

**Drugs and Bugs (Acapulco)**

**Moderators:** Glen T. Schumock & Vani Vannappagari

- **10:30am**
  - First- and Second-Line Treatment with Antibiotics of Women with Uncomplicated Lower Urinary Tract Infection in Sweden 2009 – A Nation-Wide Population-Based Register Study [322]
    - Magnus Olsson, Cecilia Nordqvist, Mikael Hoffmann. (Sweden)

- **10:45am**
  - Human Immunodeficiency (HIV) Therapy and Cardiovascular (CV) Events [323]
    - Wendy J Carman, Steven Bowlin, Andrew T McAfee. (United States)

- **11:00am**
  - Prevalence of Transmitted HIV Drug Resistance Differs between Acutely and Chronically HIV-Infected Patients [324]
    - Elizabeth L Yanik, Sonia Napravnik, Christopher B Hurt, Ann Dennis, Joanne D Kuruc, Joseph J Eron. (United States)

- **11:15am**
  - A Comparison of Two Methods for Estimating Refill Adherence to Statins in Sweden [347]
    - Eva Lesén, Tatiana Sandström, Anders Carlsten, Anna K Jönsson, Ann-Charlotte Mårdby, Karolina Andersson Sundell. (Sweden)

- **11:30am**
  - Pharmacy Loyalty and Compliance with Antipsychotics [314]
    - Sophie Lauzier, Jean-Pierre Grégoire, Jocelyne Moisan. (Canada)

- **11:45am**
  - Therapeutic Complexity Has Limited Influence on Adherence in the Netherlands [315]
    - Harm C Geers, Marcel L Bouvy, Eibert R Heerdink. (Netherlands)
## AGENDA Tuesday, August 16

### 11:30am
- Differences in Oral Candidiasis Risk Between Different Inhaled Corticosteroids [326]
  - Alison I. Nightingale, Annie Hutchison, Corinne S de Vries. (United Kingdom)

### 11:45am
- Baseline Predictors of Efavirenz-Related Symptoms during the First Six Months of Therapy [327]
  - Paul D Sonenthal, Bakgaki Ratshaa, Gilbert Chimbbeng, Malebogo Thero, Tumelo Ranbleru, Sarah Barenbaum, Andrew Steenhoff, Robert Gross. (United States)

### Methods for Early Detection (Regency C)
**Moderators: Marie Lindquist & Jeremy Rassen**

### 10:30am
  - Preciosa M Coloma, Gianluca Trifirò, Rosa Gini, Ron Herings, Giampiero Mazzaglia, Carlo Giaquinto, Lars Pedersen, Johan van der Lei, Miriam Sturkenboom, Martijn Schuemie. (Netherlands)

### 10:45am
- Signal Detection of Adverse Medical Device Events in the FDA/MAUDE Database [329]
  - David O Olaleye, David Olaleye. (United States)

### 11:00am
- Fuzzy Text Matching To Identify Known Adverse Drug Reactions [330]
  - Tomas Bergvall, Gunnar Dahlberg, Bénédicte Cappelli, Niklas Norén. (Sweden)

### 11:15am
- Comparison of Alerting Algorithms for Prospective Medical Product Safety Monitoring: A Simulation Study and Empirical Application. [331]
  - Joshua J Gagne, Jeremy A Rassen, Alexander M Walker, Robert J Glynn, Sebastian Schneeweiss. (United States)

### 11:30am
- Comparing Two Methods for Detecting Adverse Event Signals in Observational Data: Empirical Bayes Gamma Poisson Shrinker vs. Tree-Based Scan Statistic [332]
  - Jeffrey S Brown, Kenneth Petronis, Andrew Bate, Fang Zhang, Inna Dashevsky, Martin Kulldorff, Taliser R Avery, Robert L Davis, Susan E Andrade, Sascha Dublin, Lisa Herrinton, Pam Pawloski, Marsha A Raebel, Douglas Roblin, David Smith, Richard Platt, Robert Reynolds. (United States)

### 11:45am
- Evaluation of Three Disproportionality Analysis Algorithms for Post-Marketing Signal Detection of Torsades de Pointes in FDA/AERS Database [333]
  - David Olaleye, David Olaleye. (United States)

### To Bleed or Not To Bleed (Regency D)
**Moderators: Klaas Heinemann & Yola Moride, FISPE**

### 10:30am
- Selective Serotonin Reuptake Inhibiting Antidepressants and the Risk of Overanticoagulation During Acenocoumarol Maintenance Treatment [334]
  - Martina Teichert, Loes Visser, Andre Uitterlinden, Albert Hofman, Peter Buhre, Sabine Straus, Peter de Smet, Bruno Stricker. (Netherlands)

### 10:45am
- An Application of Kaplan Meier Method in Examining the Discontinuation of Warfarin and a Preceding Bleeding Event During a Hospitalization Episode [335]
  - Xiaying Pan, Hugh Kawabata, Teresa Simon, Uchenna Iloeje. (United States)

### 11:00am
- The Risk of Major Bleeding in Patients Treated with Warfarin for Venous Thromboembolism at an Anticoagulation Clinic: An Incident User Cohort Study [336]
  - Eric S Johnson, David H Smith, Xiuhai Yang, Amanda F Petrik, Jessica R Weiss, Micah L Thorp, Andrew H Felcher. (United States)

### 11:15am
  - Onur Baser, Patrice Verpillat, Li Wang. (France)

### 11:30am
- Association Between Drug Use and Acute Immune Thrombocytopaenia in Adults: Results from the Berlin Case-Control Surveillance Study [338]
  - Edeltraut Garbe, Frank Andersohn, Elisabeth Brander, Andreas Klimpel, Michael Thomae, Hanife Kurtal. (Germany)

### 11:45am
- Hemorrhage Following Concurrent Use of Warfarin and Oseltamivir by Medicare Beneficiaries [339]
  - Judith A Racoosin, Andrew E Mosholder, Stephanie Young, Michael Wernecke, Thomas MacCurdy, Chris Worrall, Jeffrey Kelman. (United States)
AGENDA  Tuesday, August 16

12:00-1:30pm
Lunch/Poster Session B/Exhibits
(Regency Center West)

ISPE Committee Meetings
—Open to all participants.
(Lunches will be available in meeting rooms)
  ✱ Bylaws and Policies Committee (Columbian)
  ✱ Education Committee (Gold Coast)
  ✱ Global Development Committee (Wrigley)
  ✱ Membership Committee (Picasso)
  ✱ Publications Committee (Haymarket)

12:15-1:15pm
Roundtable Discussions
For junior ISPE members and new members.
Seating is limited; first-come, first-served.
  ✱ Hubert Leufkens, FISPE, Regulatory science
    and pharmacoepidemiology
  ✱ Bill Calvert, Safety surveillance
  ✱ Gillian Hall, FISPE, The ISPE guidelines for
    quality conduct in database research
  ✱ Sean Hennessy, FISPE, Translational re
    search in drug-drug interactions

12:45-1:30pm
Poster Walks (Regency Center West)
  ✱ Database SIG
  ✱ Medical Devices SIG

1:30-2:30pm
Plenary Session (Crystal Ballroom)

Thalidomide – 50 Years Later

Educational Objectives
  • Commemorate the 50th anniversary of the
    thalidomide disaster
  • Describe the human toll of this event
  • Reflect on its importance for
    pharmacoepidemiology
  • Honor two key participants in the story with
    lifetime achievement awards.

Ulf Bergman, FISPE, & Allen Mitchell, FISPE,
Moderators
Tsugumichi Sato, Reflections of a Thalidomide
Survivor
Presentation of Awards to
Frances O. Kelsey
Barbro Westerholm

2:30-3:30pm
Annual Meeting of ISPE Members & Awards Ceremony (Crystal Ballroom)

Annual Meeting of ISPE Members
  ✱ Stephen JW Evans, FISPE, ISPE President
  ✱ Matthew Reynolds, Vice President Finance

Awards Ceremony
ICPE 2011
  ✱ Presented by Stephen JW Evans, FISPE

John Seeger, Co-Chair, Scientific Program Committee
Glen T. Schumock, Co-Chair, Scientific Program Committee

Student Awards
  ✱ Presented by John Seeger & Glen T. Schumock
    —The Andrew McAfee Award (Best Abstract submitted by a student/
      post-doc from a developing country).
      Thiyagu Rajakannan, Study on Risk Factors for Adverse Drug
      Reactions in Hospitalized Retroviral Patients [346]
    —Third Best Abstract: Mary Abigail De Vera
    —Second Best Abstract: Christina Mack
    —The Stanley A. Edlavitch Award (Best Abstract submitted by a student/
      post-doc) & Oral Presentation
      Shirley V. Wang, Future Cases as Present Controls: Methods To Adjust
      for Exposure-Time Trends [340]
      Shirley V Wang, Crystal Linkletter, Malcolm Maclure, David D Dore,
      Vincent Mor, Stephen Buka, Gregory Wellingius. (United States)

Induction of ISPE Fellows (FISPE)
  ✱ Presented by John Seeger & Glen T. Schumock
    —Inductees
    Robert F. Reynolds, FISPE
    Nancy C. Santanello, FISPE
    Soko Setoguchi Iwata, FISPE
    Marianne Ulcickas Yood, FISPE

The Ronald D. Mann Best Article Award
  ✱ Presented by John Seeger & Glen T. Schumock
  ♦ Stephen JW Evans, FISPE, ISPE President
  ♦ Inductees
  Robert F. Reynolds, FISPE
  Nancy C. Santanello, FISPE
  Soko Setoguchi Iwata, FISPE
  Marianne Ulcickas Yood, FISPE

Installation of New President
  ✱ Nancy C. Santanello, FISPE

3:30-4:00pm
Break/Posters/Exhibits (Riverside Center West)
AGENDA  Tuesday, August 16

4:00-5:30pm

Concurrent Sessions: Symposia & Workshops

Challenges to Improving the Science of Regulatory Decision-Making [341] (Regency A)
- Stanley A Edlavitch, Gerald J Dal Pan, June M Raine, Jerry Avorn, Hubert G Leufkens, Byong-Ju Park. (United States)

Challenges in Conducting Sequentially Monitored Medical Product Safety Studies Using Electronic Health Care Utilization Data [342] (Regency B)
- Jennifer C Nelson, Andrea J Cook, Stanley Xu, Sharon K Greene. (United States)

Drug-Induced Liver Injury (DILI): Latest Developments on Premarket Regulatory Guidance and Approaches to Postmarket Surveillance [343] (Toronto)
- Lisa I Wang, Wei Dong, Susan A Oliveria, Marianne Ulcickas Yood, Noah J Robinson, Michele Bortolini. (United States)

Increasing Scientific Standards, Transparency and Independence in Pharmacoepidemiological Research: Is the Concept of ENCePP Studies a Way Forward? [344] (Regency C)
- Xavier Kurz, Bert Leufkens, Stella Blackburn, Yola Moride, Valerie Simmons, Corinne de Vries. (United Kingdom)

Methods Development in Active Drug Safety Surveillance Highlighting the Observational Medical Outcomes Partnership’s Findings [345] (Regency D)
- Abraham G Hartzema, Judith A Racoosin, Patrick B Ryan, Paul E Stang. (United States)

- Marsha A Raebel, Martin Kuldorff, Gerald Dal Pan, Marie Lindquist, Bruce Fireman. (United States)

5:30-6:30pm

Special Interest Group (SIG) Meetings
- Open to all participants.
  - Biologies SIG (Columbian)
  - Comparative Effectiveness Research SIG (Gold Coast)
  - Databases SIG (Haymarket)
  - Drug Utilization/Health Services Research SIG (Wrigley)
  - Medical Devices SIG (Picasso)
  - Medications in Pregnancy SIG (Toronto)
  - Molecular Epi./Biomarkers/Pharmacogenetics SIG (Acapulco)
  - Pediatric SIG (New Orleans)

7:30-??

Evening at the Hard Rock Cafe
(63 West Ontario)

Join us for an unforgettable evening in Chicago’s HRC!
- Admission is by badge or ticket; admission includes two drink tickets
- Buses will shuttle from the Hyatt to the Hard Rock Cafe. The first bus will depart from the Hyatt at 7:00pm; the last bus will depart from the Hard Rock Cafe at 1:00am. However, if it’s a nice evening, you might wish to walk to the HRC (20 minutes).

History of HRC
It started with an Eric Clapton guitar (a Fender Lead II, for the gearheads in the audience). The beginning of something that nobody even knew was beginning. It was just a goof. A laugh. A joke among friends.

Back in the seventies, Clapton - the original guitar god, founder of Cream and Derek & the Dominos, creator of the immortal "Layla" - liked to eat at this quirky American diner in London called the Hard Rock Cafe. The place was this funky old building that used to be a Rolls Royce dealership, and it was run by a couple of young Americans who liked to keep it loose. Founded by Isaac Tigrett and Peter Morton, two enterprising and music-loving Americans, Hard Rock Cafe was an instant classic. You could be yourself at the Hard Rock. It was good food and a good time.

So Clapton got to be friends with the proprietors and asked them to save him a regular table, put up a brass plaque or something. And the young proprietors said, "Why don’t we put up your guitar?" They all had a chuckle, and he handed over a guitar, and they slapped it on the wall.

No one thought much more about it. Until a week later, when another guitar arrived (a Gibson Les Paul, by the way). With it was a note from Pete Townshend of The Who which read: "Mine’s as good as his. Love, Pete."

The young proprietors put it on the wall. After that, the guitars never stopped coming. Today there are more than 70,000 guitars, drums, pianos, harmonicas, microphones, shirts, pants, scarves, shoes, handwritten lyrics, cars, bikes, a bus and assorted rock memorabilia - by far, the largest, most valuable such collection in the world - on the walls of over 163 Hard Rock Cafes, Hotels and Casinos in 52 countries around the world.

But it all started with the one.
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“IBM Netezza will accelerate our ability to devise, test and publish new computationally intensive algorithms applied to large longitudinal healthcare databases that we hope become the ‘gold standard’ for researchers globally.”

— Sebastian Schneeweiss, MD, ScD
Vice Chief, Division of Pharmacoepidemiology and Pharmacoeconomics
Brigham & Women’s Hospital, Harvard Medical School

Visit the IBM Netezza booth or www.netezza.com to learn more.
### Concurrent Sessions: Contributed Papers

#### Applied Risk Management (Regency A)
**Moderators:** AnnaLisa Rubino & Glen T. Schmock

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<th>Time</th>
<th>Title</th>
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<tr>
<td>8:30am</td>
<td>Evaluation of Dronedarone Utilization in the US Using a Claims Database</td>
<td>Shujun Gao, Juhaeri Juhaeri, Heather A. Schiappacasse, Andrew T Koren, Wanju S Dai.</td>
<td>United States</td>
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<tr>
<td>8:45am</td>
<td>Experiences and Preferences of Healthcare Professionals with Regard to Direct Healthcare Professional Communications (DHPCs)</td>
<td>Sigrid Piening, Flora M Haaijer-Ruskamp, Sabine M J M Straus, Pieter A de Graeff, Peter G M Mol.</td>
<td>Netherlands</td>
</tr>
<tr>
<td>9:00am</td>
<td>Risk Management Strategies Mitigating Potential Severe Dermatologic Risks of Carbamazepine in Taiwan</td>
<td>Yu-Wen Huang, Po-Wen Yang, Churn-Shiouh Gau, Hsueh-Yung Tai, Chien-Wen Hsu, Mei-Chyun Tzou, Hsuan-Shu Lee, Jaw-Jou Kang.</td>
<td>Taiwan</td>
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<tr>
<td>9:15am</td>
<td>Reducing Medication Errors Through Application of Low Health Literacy Principles to Patient Instructions for Use</td>
<td>Meredith Y Smith, Lorraine Wallace.</td>
<td>United States</td>
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<tr>
<td>9:45am</td>
<td>Evaluation of Drug Interactions in 84607 Psychiatric Inpatients Using a Customized Data Interface for Mass Analysis with Clinical Decision Support Software</td>
<td>P Haueis, W Greil, M Huber, R Grohmann, G Kullak, S Russmann.</td>
<td>Switzerland</td>
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#### Cancer: Growing Evidence (Toronto)
**Moderators:** Marieke De Bruin & James Kaye

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<tr>
<td>8:30am</td>
<td>Assessing the Comparability of Electronic Medical Records Information to Tumor Registry and Health Claims Data for Oncology Outcomes Research</td>
<td>Fiona S Mowat, Edmund E Lau, Michael A Kelsh, Jason Legg, Nicole M Engel-Nitz, Heather N Watson, Helen Collins, Robert J Nordyke, Joanna L Whyte.</td>
<td>United States</td>
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<tr>
<td>8:45am</td>
<td>Claims-Based Prediction of Performance Status (PS) Associated with Erythropoietic Stimulation Agent (ESA) Treatment and Survival in Myelodysplastic Syndromes (MDS) Patients</td>
<td>Xuehua Ke, Amy J Davidoff, Ilene Zuckerman, Naimish B Pandya, Franklin Hendrick, Sheila Weiss Smith, Maria R Baer, Steven D Gore.</td>
<td>United States</td>
</tr>
<tr>
<td>9:00am</td>
<td>Effectiveness and Safety in Very Elderly Patients Treated by Bevacizumab (BV) Plus Chemotherapy in 1st-Line Therapy of Metastatic Colorectal Cancer: Results of ETNA, a French Cohort Study</td>
<td>Annie Fourrier-Réglat, Magali Rouyer, Pernelle Noize, Aurélie Balestra, Régis Lassalle, Marie-Agnès Bernard, Alain Ravaud, Denis Smith, Nicholas Moore, and the ETNA Study Group.</td>
<td>France</td>
</tr>
<tr>
<td>9:15am</td>
<td>Use of Glucocorticoids and Colorectal Cancer Risk; a Population-Based Case-Control Study</td>
<td>Eva Bjerre Ostenfeld, Anders Hammerich Riis, Ole Thorlacius-Ussing, Tove Nilsson, Rune Erichsen, Henrik Toft Sørensen.</td>
<td>Denmark</td>
</tr>
<tr>
<td>9:30am</td>
<td>Angiotensin Receptor Blockers and the Risk of Cancer – A Comparative Safety Study in Large Linked Healthcare Databases</td>
<td>Henrik Svanström, Björn Pasternak, Callréus Torbjörn, Melbye Mads, Hviid Anders.</td>
<td>Denmark</td>
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<tr>
<td>9:45am</td>
<td>Hormonal Therapies and Meningioma: A UK Primary Care Study</td>
<td>Lucia Cea-Soriano, Tilo Bienk, Mari-Ann A Wallander, Luis A Garcia Rodríguez.</td>
<td>Ghana</td>
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AGENDA  Wednesday, August 17

Giving Kids a Good Stab (Acapulco)
Moderators: Abraham Hartzema, FISPE, & Jan Bonhoeffer

8:30am
✶ Empirical Bayesian Data Mining as an FDA Tool for Prospective Early Detection of Novel Safety Signals in the Vaccine Adverse Events Reporting System (VAERS): A Case Study of Febrile Seizures after an Influenza Virus Vaccine [552]
   David Menschik, David Martin. (United States)

8:45am
✶ Effect of Vaccine-Related Reports on Pediatric Safety Signal Detection [553]
   Sandra de Bie, Katia M C Verhamme, Sabine M J M Straus, Bruno H C Stricker, Miriam C J M Sturkenboom. (Netherlands)

9:00am
   Veena Thyagarajan, Roberta Glass, Keith Rodgers, Scott Quinlan, Crystal N Holick, Dominique Rosillon, Emily Lu, David D Dore, Camilo Acosta, John D Seeger. (United States)

9:15am
✶ Use of Self-Controlled Risk-Interval Design in Childhood Vaccine Safety [555]
   Jie Li, Gregory W Daniel, Corrie Paeglow, Tom Puenpatom, Laura Polakowski, Yun Lu, Alec M Walker, M Alan Brookhart, Hector Izurieta. (United States)

9:30am
✶ Longitudinal Study of the Impact of Varicella Vaccination in a Managed Care Organization (1995-2009) [556]
   Patricia Saddier, Trung Tran, Paula Ray, Roger Baxter. (United States)

9:45am
✶ Biologically Plausible Risk Intervals To Assess Febrile Seizure Following Immunization with Influenza and Pneumococcal Conjugate Vaccines [557]

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### AGENDA  Wednesday, August 17

#### Interesting, But Will We Remember (Regency B)
**Moderators:** Rob Heerdink & Kristina Bardenheuer

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<tr>
<td>8:30am</td>
<td>Risk of Coronary Events and Stroke in Patients Taking Anticonvulsant Medications [558]</td>
<td>Elisabetta Patorno, Rhonda Bohn, Peter Wahl, Gregory Daniel, Jerry Avorn, Jun Liu, Helen Mogun, Sebastian Schneeweiss. (United States)</td>
</tr>
<tr>
<td>8:45am</td>
<td>Comparisons between Drugs for Alzheimers Disease Concerning Changes in Co-Medication, Need of Assisted Living Facilities and Hospitalizations [559]</td>
<td>Tobias Svensson, Anders Sundström, Morten Andersen, Helle Kieler. (Sweden)</td>
</tr>
<tr>
<td>9:00am</td>
<td>A Study of Blood Pressure and Change in Cognitive Function in Elderly Mexican Americans [560]</td>
<td>X Zhou, S Galea. (United States)</td>
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#### Measuring Quality of Prescribing (Regency C)
**Moderators:** Morten Andersen & Lisa Pont

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<tr>
<td>8:30am</td>
<td>Does Medication Review Lead to a Reduction of Drug Problems in Elderly Patients Discharged from the Hospital [564]</td>
<td>Abeer Loutfi dcaAhmad, Ruth M Mast, Giel Nijpels, Jacqueline M Dekker, Piet J Kostense, Jacqueline G Hugtenburg. (Netherlands)</td>
</tr>
<tr>
<td>8:45am</td>
<td>Enhancing the Quality of Prescribing in Primary Care in Australia [565]</td>
<td>Abstract withdrawn by author.</td>
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<tr>
<td>9:00am</td>
<td>Ranking Medication Errors in the Hospital by Their Probability of Harm in a National Error Reporting Database [566]</td>
<td>Jessica A Myers, Sergio Venturini, Laura Morlock, Francesca Dominici. (United States)</td>
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#### Methods for Safety (Regency D)
**Moderators:** John Seeger & Tam Dang-Tan

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<tr>
<td>8:30am</td>
<td>Linking Electronically Collected Quality of Life Data to THIN – A UK General Practice Database [570]</td>
<td>Betina T Blak, Joanne Lee, Mary Thompson, Alison Bourke, Louise Pinder. (United Kingdom)</td>
</tr>
<tr>
<td>8:45am</td>
<td>Disproportionality Analysis for Signal Detection of Implantable Cardioverter-Defibrillator Lead Related Adverse Events [571]</td>
<td>Naomi D Herz, Hesha J Duggirala, Daniel A Caños, Roberta Sullivan, Richard Schauf, Ellen Pinnnow, Danica Marinac-Dabic. (United States)</td>
</tr>
</tbody>
</table>

### Time Table

- **9:15am**
  - Patterns of Antidepressant Medication Use in Medicaid-Eligible Pregnant Women [561]
  - Krista F Huybrechts, Kristin Palmsten, Helen Mogun, Soko Setoguchi, Jerry Avorn, Sonia Hernández-Diaz. (United States)

- **9:30am**
  - Neuropsychiatric Events in Varenicline Compared to Nicotine Replacement Therapy (NRT) Patch Users, Military Health System (MHS) [562]
  - Tamra E Meyer, Lockwood G Taylor, Suji Xie, David J Graham, Andrew D Mosholder, James R Williams, David Moeny, Rita Oueltet-Hellstrom, Trinka S Coster. (United States)

- **9:45am**
  - Antiepileptic Drugs and the Risk of Stroke [563]

- **9:15am**
  - The Effect of a Multifaceted Educational Intervention on Medication Errors in a Dutch Neonatal Intensive Care Unit [567]
  - Katja Taxis, Indra Chedoe, Wobbe Hospes, A Molendijk. (Netherlands)

- **9:30am**
  - The Impact of Evidence-Based Subsidy Restrictions on Lapatinib Use and Outcomes [177]
  - Sallie-Anne Pearson, Preeyaporn Srasuebkul, Christine Lu, Timothy Dobbins, Robyn Ward. (Australia)

- **9:45am**
  - Rishi Desai, Richard Hansen, Charlotte Williams, Stephanie Pierson, Sandra Greene. (United States)

- **9:00am**
  - Time-Dependent Survival Analysis: It’s Benefits and Hazards [812]
  - Angelique L Zeringue, Ziyad Al-Aly, Jay R McDonald. (United States)

- **9:15am**
  - Poly-Pharmacy and Adverse Drug Reactions in Japanese Elderly Hypertensive Patients: Assessing Effects of Time-Varying Exposure [573]
  - Izumi Sato, Manabu Akazawa. (Japan)
AGENDA  Wednesday, August 17

9:30am
- Influence of Run-In Period on Incidence of NSAID Use in European Population in the SOS Project [574]
  Vera E Valkhoff, Silvana A Romio, Rene Schade, Martijn Schuemie, Edeltraut Garbe, Ron Herings, Silvia Lucchi, Gino Picelli, Tania Schink, Huub Straatman, Marco Villa, Antonella Zambon, Ernst J Kuipers, Miriam C J M Sturkenboom. (Netherlands)

9:45am
- Exposure to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Drugs Used in Musculoskeletal Disorders (MSD): Agreement between Physicians’ Prescriptions and Patients’ Self-Report in the PGRx Database [575]
  Lamiae Grimaldi-Bensouda, Michel Rossignol, Djamila Abed, Elodie Aubrun, Lucien Abenhaim, PGRx Group. (Canada)

10:00-10:30am
Break/Posters/Exhibits (Riverside Center West)
Government/Regulatory Council Coffee Corner

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AGENDA Wednesday, August 17

10:30-Noon
Concurrent Sessions: Contributed Papers

Cough & Wheeze (Regency A)
Moderators: Maria Gerhardsson & Kevin Haynes

10:30am
- Risk of Depression Associated with Use of Leukotriene Receptor Antagonist in Elderly Asthma Patients in Korea [576]
  Chul Woo Rhee, Nam-Kyong Choi, Yoon-Ok Ahn, Joongyub Lee, Byung Joo Park. (Republic of Korea)

10:45am
- Characterization of Long-Acting Beta-Adrenergic Agonists Use for Asthma Treatment [577]
  Sigal Kaplan, Esther Zhou. (United States)

11:00am
- Appropriateness of Age Thresholds for Palivizumab Prophylaxis in Preterm Infants [578]
  Caitlin A Knox, Christian Hampp, Paul S Kubilis, Stephan Linden, Almut G Winterstein. (United States)

11:15am
- Safety of Atrovent® CFC-Free MDI (Metered Dose Inhaler): An Example of Protopathic Bias in Observational Cohort Studies [579]
  Vicki Osborne, Deborah Layton, Edward Tong, Saad A Shakir. (United Kingdom)

11:30am
- Changing Asthma Regimens from Suboptimal to Optimal: What Are the Impacts on Health Service Use in Patients with Asthma? [580]
  Ting Ting Zhang, Ricardo Jimenez-Mendez, Anne Smith, Bruce C Carleton. (Canada)

11:45am
- Severe Asthma Exacerbations Associated with Long-Acting Beta Agonists among Children and Adolescents with Asthma [581]
  Jeff J Guo, Katherine Tsai, Christina M L Kelton, Boyang Bian, Patricia R Wigle. (United States)

Database Methods (Regency B)
Moderators: Helga Gardarsdottir & David Miller

10:30am
- Dichotomizing Does Not Help, Even If Outcomes Are Bimodally Distributed [76]
  Ruud Boessen, Mirjam J Knol, Rolf H H Groenwold, Kit C B Roes. (Netherlands)

10:45am
- Using Physician Office Visit Dates To Link Electronic Medical Records to Healthcare Claims Data [583]
  Gregory Lenhart, Suellen Curkendall, Daniel M Huse. (United States)

11:00am
- Impact of Look-Back Period on Baseline Patient Characteristics and Subsequent Risk Estimates in the General Practice Research Database (GPRD) [584]
  Tzuyung D Kou, Kimberly G Brodovicz, Cindy J Girman. (United States)

11:15am
- Does Additional Confounder Information Alter the Results of a Database Study on the Risk of Bleeding Associated with Phenprocoumon Use? [585]
  Sigrid Behr, Walter Schill, Iris Pigeot. (Germany)

11:30am
- Misclassifying Drug Exposure Data within Administrative Databases: An Ecologic Approach [586]
  John-Michael Gamble, Finlay A McAlister, Jeffrey A Johnson, Dean T Eurich. (Canada)

11:45am
- Quantifying the Impact of Drug Exposure Misclassification Due to Restrictive Drug Coverage in Administrative Databases: A Simulation Cohort Study [587]
  John-Michael Gamble, Finlay A McAlister, Jeffrey A Johnson, Dean T Eurich. (Canada)
**AGENDA  Wednesday, August 17**

**Gut Feeling (Toronto)**
**Moderators: Daniel Mines & Deborah Layton**

11:30am
- Evaluation of In-Hospital Clinical Outcomes with Alvimopan in Patients Undergoing Open or Laparoscopic Colorectal Surgery: Matched-Cohort National Database Study [591]
  Lee M Techner, Suzanne F Cook, Christopher Craver, Amy W Rachfal, Michael Calloway.
  (United States)

11:45am
- The Comparative Safety of Drospirenone for Gallbladder Disease Among Women Taking Oral Contraceptives [593]
  Joseph A Delaney, James M Brophy, Mahyar Etminan.
  (United States)

11:00am
- Hepatotoxicity in Association with Acetaminophen Poisonings in the U.S. [588]
  Syed Rizwanuddin Ahmad, Anne Elixhauser, Janet P Sutton.
  (United States)

11:15am
- Polyethylene Glycol Increase Risk of Acute Renal Failure: A Population-Based Case-Crossover Study [589]
  (Republic of Korea)

11:00am
- Hypertriglyceridemia and Acute Pancreatitis [590]
  Michael J Murphy, Xia Sheng, Thomas M MacDonald, Li Wei.
  (United Kingdom)

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AGENDA  Wednesday, August 17

Methods in Vaccine Safety (Regency C)
Moderators: Patricia Saddier & Florence Wang

10:30am
- Guillain-Barré Syndrome and Adjuvanted Pandemic Influenza A (H1N1) 2009 Vaccines – A Multinational Case Control Study in Europe [594]

10:45am
- Guillain-Barré Syndrome, Influenza-like Illnesses and Influenza Vaccination during Seasons with and without Circulating A/H1N1 Viruses [595]
  Lamiae Grimaldi-Bensouda, Annick Alpérovitch, Gérard Besson, Christophe Vial, Jean-Marie Cuisset, Caroline Papeix, Olivier Lyon-Caen, Elodie Aubrun, Jacques Benichou, Michel Rossignol, Lucien Abenhaim, GBS-PGRx Study Group. (United Kingdom)

11:00am
- Safety of Adjuvanted Pandemic Influenza Vaccines: Background Rate of Narcolepsy in Europe [596]

11:15am
- Characterizing Vaccine-Associated Risk Using Natural Smoothing Splines [597]
  M A Brookhart, J Li, C Paeglow, T Puenpatom, L Polakowski, Y Lu, A M Walker, H Izurieta, G W Daniel. (United States)

11:30am
- Identifying Adverse Events of Vaccines Using a Bayesian Method of Medically Guided Information Sharing [598]
  Colin Crooks, David Prieto-Merino, Stephen Evans. (United Kingdom)

11:45am
- The Reporting Completeness of a Passive Safety Surveillance System for Influenza A (H1N1) 2009 Vaccines: A Capture-Recapture Analysis [599]
  Wan-Ting Huang, Wei-I Huang, Yu-Wen Huang, Chien-Wen Hsu, Jen-Hsiang Chuang. (Taiwan)

Not Your “Typical” Psychotropics (Regency D)
Moderators: Judith Jones, FISPE, & Natasha Chih-Ying Chen

10:30am
- Mental Distress and Subsequent Use of Psychotropic Drugs Among Adolescents – A Prospective Register Linkage Study [600]
  Anne Kjersti Myhrene Steffenak, Svetlana Skurtveit, Kari Furu, Bodil Wilde-Larsson, Gun Nordström, Ingeborg Hartz. (Norway)

10:45am
- The Association between Hospitalization and Discontinuity of Psychotropic Drug Use [601]
  Rutger Stoffken, Eibert R Heerdink, Patrick C Souverein, Toine C Egberts. (Netherlands)

11:00am
- Comparative Risk of Cerebrovascular Adverse Events Among Older Adults Using Risperidone, Olanzapine and Quetiapine [676]
  Satabdi Chatterjee, Rajender R Aparasu, Hua Chen, Michael L Johnson. (United States)

11:15am
- Comparative Safety of Individual Antipsychotic Medications in the Non-Institutionalized Elderly [603]
  Tobias Gerhard, Krista Huybrechts, Sebastian Schneeweiss, Mark Olsson, Cecilia Huang, Edmond S Malka, Stephen Crystal. (United States)

11:30am
- Potential Causes of Higher Mortality in Nursing Home Residents Starting Conventional and Atypical Antipsychotics [604]
  Krista F Huybrechts, Tobias Gerhard, Stephen Crystal, Mark Olsson, Raisa Levin, Judith Lucas, Jerry Avorn, Sebastian Schneeweiss. (United States)

11:45am
- Predictors of High Metabolic Risk Antipsychotic Use [605]
  Stacie B Dusetzina, G C Alexander, Rena Conti, E R Dorsey, Ashley S Higashi, Shu Zhu, Craig F Garfield, Haiden A Huskamp. (United States)
AGENDA  Wednesday, August 17

Nulligravida (Acapulco)
Moderators: Sonia Hernandez-Diaz, FISPE, & Lolkje TW de Jong-van den Berg

10:30am
» Congenital Defect Rates in Electronic Health Records and Claims Databases: Comparison to US National Surveillance System [606]
  Kelee E Wurst, Sara A Ephross. (United States)

10:45am
  Kara Duwe, Sonja Rasmussen, Carol Louik, Tiffany Colarusso, Jennita Reefhuis. (United States)

11:00am
» Does Patterns of Maternal Use of Potentially Addictive Drugs Reproduce in Their Children? [608]
  Ingeborg Hartz, Randi Selmer, Aage Tverdal, Eivind Skille, Svetlana Skurtveit. (Norway)

11:15am
» Maternal Use of Proton Pump Inhibitors during Early Pregnancy and the Prevalence of Hypospadias in Male Offspring [609]
  Rune Erichsen, Ellen Mikkelsen, Lars Pedersen, Henrik T Sorensen. (Denmark)

11:30am
» Use of Ovulation Stimulation (OS) Alone, Intrauterine Insemination (IUI) and Assisted Reproductive Techniques (ART) and the Risk of Multiplicity – The TWIN-PREG Study [610]
  Anick Bérard, Odile Sheehy, William Fraser, Francois Bissonnette, Seang-Lin Tan, Jacquetta Trasler, Patricia Monnier. (Canada)

11:45am
» Medicaid Analytic Extract for Studies of Drug Safety during Pregnancy [611]
  Kristin Palmsten, Krista Huybrechts, Helen Mogun, Soko Setoguchi, Sonia Hernandez-Diaz. (United States)

Noon-1:30pm
Lunch/Poster Session C/Exhibits (Regency Ctr. West)
ISPE Board of Directors Luncheon (Wrigley)
(Meeting open to all members; please check with staff if you wish to attend)
12:45-1:30pm
Poster Walks (Regency Ctr. West)
» Comparative Effectiveness Research (CER) SIG
» Molecular Epidemiology-Biomarkers-Pharmacogenetics SIG

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AGENDA  Wednesday, August 17

1:30-3:00pm
Concurrent Sessions: Symposia And Workshops

Active Surveillance for Follow-On Biologics [612] (Toronto)
  ➢ Earl Goehring, Judith Jones, Miriam CJM Sturkenboom, Jonathan Morris, Elizabeth Sobczyk, Robert Chen (United States)
  
  SPONSORED BY THE BIOLOGICS SIG

Assessing Treatment Patterns: Novel Methods and Applications [613] (Regency A)
  ➢ Sonia S Maruti, E Dawn Flick, Marloes Bazelier, Frank De Vries, Krista F Huybrechts, Drew Levy, Andrew Roddam, Wei Dong. (United States)

Assessment of Long-Term Adverse Drug Reactions, Regulatory Needs and Methodological Challenges [614] (Regency B)
  ➢ Ruben G Duijnhoven, Sabine M J M Straus, Tjeerd P van Staa, Yola Moride, Lamiae M Grimaldi, Marie I De Bruin. (Netherlands)

Addressing Challenges in Using Multiple Data Sources to Evaluate Medication Risk Factors for Asthma Mortality in Persistent Asthma [615] (Acapulco)
  ➢ Patricia Tennis, Kourtney Davis, Til Sturmer, Jeffrey Brown, Stephan Lanes. (United States)

FDA’s Mini-Sentinel Program to Evaluate the Safety of Marketed Medical Products: Progress and Prospects [616] (Regency C)
  ➢ Richard Platt, Judith Racoosin, Lesley Curtis, Sean Hennessy, Sebastian Schneeweiss, Darren Toh. (United States)

Drug Utilization Studies and Risk Management Plans: A Missing Link [617] (Regency D)
  ➢ Annalisa Rubino, Mari-Ann Wallander, Torbjörn Callreus, Patricia Saddier, Mary B Ritchey, Susana Perez-Gutthann. (United Kingdom)

3:00-4:30pm
Hot Topics Session:

H1N1 Vaccine Safety Monitoring: Global Lessons for a Global Pandemic (Crystal Ballroom)

Learning Objectives
  • What adaptations (from traditional safety monitoring) were needed for a global pandemic vaccine?
  • What successes and challenges were actually encountered?
  • What lessons were learned for future global pandemics?

Description of Session
  The world has been preparing for the next influenza pandemic for some years. Last year’s Hot Topic session addressed the decisions surrounding the declaration of the 2009 H1N1 pandemic, this year’s session will focus instead on the actual safety monitoring experience associated with H1N1 vaccination campaigns in various countries and the lessons learned.

Faculty
  • Moderator: Robert Chen, FISPE, HIV Vaccine & Special Studies Team, CDC
  • Claudia Vellozzi, Deputy Director, Immunization Safety Office, CDC
  • Pier Luigi Lopalco, Head of Section of Vaccine Preventable Diseases, ECDC
  • Wan-Ting Huang, Surveillance Team Lead, Taiwan CDC
  • Paul Effler, Medical Coordinator, Prevention and Control Program, Department of Health, Western Australia
  • Harry Seifert, Executive Director, Safety Evaluation & Risk Management at GlaxoSmithKline Biologicals
  • Jan Bonhoeffer, Brighton Collaboration
  • Miriam CJM Sturkenboom, FISPE, Erasmus University Medical Center
  • Stephen JW Evans, FISPE, London School of Tropical Medicine & Hygiene

4:30-5:00pm
The Final Word (Crystal Ballroom)

Poster Awards
  ➢ Mary Beth Ritchey, Poster Walk Chair

Future Meetings
  2012 Mid-Year Meeting – Miami Beach
    ➢ Bram Hartzema, FISPE, Co-Chair, Program Planning Committee
    ➢ Maribel Salas, Co-Chair, Program Planning Committee

ICPE 2012-Barcelona
  ➢ Susanna Perez Gutthann, FISPE, Chair, Scientific Program Committee

5:00pm
Adjournment of ICPE 2011
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Overview

Poster sessions are designed to give presenters an opportunity to discuss informally their research with colleagues interested in their research. The purpose of the posters is to visually stimulate interest in the research, to present sufficient information for viewers to understand the methods, results, and significance of the research, and to promote conversations and networking among conference participants.

Poster Session

Posters will be displayed in the Riverside Center West of the Hyatt Regency Chicago, August 15-17. Each day will have a separate poster session. All posters for a specific day’s session must be set up and taken down that day.

- **Monday, August 15** ......................... Poster Session A
- **Tuesday, August 16** ......................... Poster Session B
- **Wednesday, August 17** ..................... Poster Session C

1. **Set Up:**
   - 7:00am-8:00am; all posters must be in place by 8:00am. The poster sessions will be held in the Riverside Center West.

2. **Hours:**
   - Posters will be displayed from 8:00am-6:00pm on Monday and Tuesday; and 8:00am-1:45pm on Wednesday.

3. **Discussion Time:**
   - **General:** Presenters should be at their posters between 12:45-1:15pm.
   - **Poster Walks:** organized by the ISPE Special Interest Groups (SIG).
     - Daily from 12:45-1:30pm. Presenters should be at their posters at that time.

**Schedule:**

- **Monday, August 15**
  - Biologics SIG
  - Drug Utilization SIG
  - Medications in Pregnancy SIG
- **Tuesday, August 16**
  - Database SIG
  - Medical Devices SIG
- **Wednesday, August 17**
  - Comparative Effectiveness Research (CER) SIG
  - Molecular Epidemiology-Biomarkers-Pharmacogenetics SIG

**Poster walk presenter:**

The poster walks offer pre-selected presenters the opportunity to present their work and to discuss their results with an audience. When the poster walk chair and audience stop at your poster, please give a brief (3-minute) presentation and be prepared to answer questions about your research.

**Poster Prizes:**

Judges will select the Best Posters for each poster walk. Winners will receive an invitation to display their poster for the duration of the ICPE. The winners will be announced during The Final Word session at 4:30pm, August 17.

4. **Take Down:**

All posters must be taken down by 6:30pm on Monday and Tuesday, and by 5:00pm on Wednesday.

Numbering System

- Each poster board will be numbered. Presenters should attach their posters to the board number corresponding to the number assigned to their poster in the Final Program. The poster board-number is the first number listed. The abstract number, for use in locating abstracts in the Final Program and the special issue of *Pharmacoepidemiology and Drug Safety*, is in brackets [ ] after the title of the abstract.

Poster Specifications

1. Posters must be designed to fit a freestanding poster board 4 feet WIDE x 8 feet HIGH [LANDSCAPE]. Posters may be mounted using Velcro tape; please bring your own supplies. Business cards or small leaflet literature for distribution may be inserted in an envelope and affixed to the board.

2. Posters may be attached to the boards using Velcro or pushpins. All poster presenters are encouraged to bring their own supplies.

3. **Disclosure Statement**

A disclosure statement must accompany each abstract submission and each presentation. This statement should follow the title page of your presentation and should be a positive disclosure statement. This statement must list all funding sources for the current project, as well as other potentially conflicting relationships that existed at any time during the conduct of the study, or at a minimum, the one-year period before the annual meeting. Non-financial conflicts (e.g., a close relationship with, or a strong antipathy to, a person whose interests may be affected) should also be disclosed. Potential conflicts must be listed on the poster in a type size consistent with the rest of the poster.

4. **Call4Posters**

Check at the ISPE Registration desk to pick-up posters ordered through Call4Posters.
1 Comparative Cardiac Effects of Halofantrine with or without Concomitant Administration of Kolanut or Fluconazole in Healthy Volunteers [43]
Aduragbenro D Adedapo, Kayode S Adedapo, Dike Ojji, Chinunedu P Bahabali. (Nigeria)

2 Intent-to-Treat Analysis of Hospitalized Rhabdomyolysis with Statin and Fibrate Use in an Insured US Population [44]
Kandace I. Amend, Joan Landon, Cheryl Enger, Andrew McAfee. (United States)

3 Statin Prescribing Following an Acute Coronary Syndrome: Are the NICE Guidelines Being Followed? [45]
Rachel Boggon, Susan Eaton, Adam Timmis, Harry Hemingway, Zahava Gabriel, Ismail Minhas, Tjeerd van Staa. (United Kingdom)

4 Effectiveness of Warfarin among Atrial Fibrillation Patients in Taiwan [46]
Chia-Hsien Chang, Yea-Huei Kao Yang, Li-Jen Lai. (Taiwan)

5 Statins and Primary Prevention of Cardiovascular Events: A Population-Based Cohort Study [47]
Gabriel Chodick, Miri Sror, Inbal Goldstein, Varda Shalev. (Israel)

6 Use of Drugs Recommended for Secondary Prevention Following Acute Myocardial Infarction after Hospital Discharge and 6 Months Thereafter: Results from the EOLE Cohort [48]
Cécile Droz, Caroline Dureau, Daniel Thomas, Nicolas Danchin, Jacques Tricoire, Jacques Benichou, François Paillard, Pierre Ducimetière, Serge Herberg, Hélène Matzi, Marie-Agnes Bernard, Patrick Blin, Nicholas Moore. (France)

7 Do Statins Improve Urologic Symptoms? Results from the Boston Area Community Health Survey [49]
Susan A Hall, Gretchen R Chiu, William D Steers, Carol L Link, John B McKinlay. (United States)

8 A Cohort Study of All-Cause Mortality in All Patients with a First Time Hospitalization with Atrial Fibrillation, Versus Matched Controls, in Sweden during 15 Years, 1995-2009 [50]
Karim M Henriksson, Tommy Andersson, Anders Magnusson, Ing-Lis Bryngelson, Ole Frobert, Niels Edvardsson, Dritan Poci. (Sweden)

9 Medical Resource Utilization and Costs Following Hospitalization of Patients with Chronic Heart Failure in the US [51]
Caroline Korves, Adi Eldar-Lissai, Doug Rodermuth, Elsye Swallow, Alice Kate Cummings, Rinat Ariely, Mei Sheng Duh. (United States)

10 Cardiovascular Conditions Among Patients with Dyslipidemia [52]
Eileen E Ming, Laura N Horne. (United States)

11 Incidence Rates of Heart Failure in Europe: A Comparison between Different Data Sources in the SOS Project [53]
Federica Nicoita, Andrea Arfa, Lorenza Scotti, Antonella Zambon, Edeltraut Garbe, Rose Herring, Silvia Lucchi, Gino Picelli, Silvana Romio, René Schade, Tanja Schink, Huub Straatman, Frantz Thiesard, Vera E Valkhoff, Marco Villa, Miriam C M Starkenboom, Giovanni Corraro. (Italy)

12 A Self-Controlled Case Series To Assess the Effectiveness of Beta Blockers for Heart Failure in Reducing Hospitalisations in the Elderly [54]
Emmae Ramsay, Nicole L Pratt, Elizabeth Roughhead, Philip Ryan, Ben Ewald. (Australia)

13 Management of Atrial Fibrillation in a Large Health Organization in Israel [55]
Varda Shalev, Nuriat Tzeewer-Zaks, Yael Rosen, Gabriel Chodick. (Israel)

14 Pharmacoeconomic Indicators of Cardiovascular Drug Utilization in the Republic of Croatia and City of Zagreb in 2008 [56]
Danijela Stimac, Ivanka Stambuk, Dubravko Bajramovic. (Croatia)

15 Is the High-Risk Strategy to Prevent Cardiovascular Disease Equitable? [57]
Helle Wallach Kildemoes, Finn Diderichsen, Theis Lange, Morten Andersen. (Denmark)

16 Droneradone or Amiodarone and Risk of Heart Failure (HF): A Federal Partners Collaboration (FPC) [59]
Gwen L Zornberg, Lucy Hsu, Diane Dong, Michael Werneck, Clara Kim, Mary Ross Southwell, Monika Houstoun, Thomas McCurdy, Marsha Reichman, LaRee Tracy, Francesca Cunningham, Trinha S Coster, Gail Moreschi, Amy Chen, Abraham M Karkowsky, Chris Worrall, Jeffrey Kelman. (United States)

17 Use of Thiazolidinediones and Risk of Osteoporotic Fracture: Are the NICE Guidelines Being Followed? [60]
Pamela J Chess, Arlene Gallagher, Tjeerd van Staa, Cyrus Cooper, Hubert Leaflens, Peter Vestergaard, Frank De Vries. (Netherlands)

18 Proton Pump Inhibitor (PPI) Use and Risk of Hip/Femur Fracture [61]
Roseline Thelus Jean, Tamra E Meyer, Lockwood G Taylor, Geoff E Gordon, Trinha S Coster. (United States)

19 Fractures and Mortality in Relation to Different Osteoporosis Treatments [62]
Huiyfeun Yu, Elizabeth Delszll, Robert Mather, Meredith L Kilgore, Kenneth S Saag, Cathleen Colon-Emeric, Christopher M O’Connor, Kenneth W Lyles, Jeffrey R Curtis. (United States)

20 SSRI Use and the Risk of Osteoporotic Fractures or Bone Loss [63]
Inbar Zacher, Gabriel Chodick, Inbal Goldstein, Ranan Raz, Varda Shalev. (Israel)

21 Oral Bisphosphonates and Hip Fracture Risk in Elderly Women [64]
Juan Erviti, Julia Timoner, Álvaro Alonso, Javier Gorricho, Antonio Lopez, Consuelo Huerta, Belen Oliva, Miguel Gil, Francisco De Abajo. (Spain)

22 Oral Bisphosphonates Are Associated with Increased Risk of Atypical Femoral Fractures in Elderly Women [65]
Juan Erviti, Belen Oliva, Álvaro Alonso, Javier Gorricho, Antonio López, Julia Timoner, Consuelo Huerta, Miguel Gil, Francisco De Abajo. (Spain)

23 Increased Risk of Osteoporotic Fracture in the Thyroid Population [66]
Robert W V Flynn, Sandra Bonellie, Thomas M MacDonald, Graham P Leese. (United Kingdom)

24 Potential Population Impact of Antidepressant Use on Hip Fracture Rates in Denmark (DK), Norway (NO) and the Netherlands (NL) [67]
Jennifer S B Goldenberg, Hans Petri, Phuong T Khong, Olaf H Klungel, Frank De Vries. (Netherlands)

25 Perceptions of Community Pharmacists Regarding Their Involvement in the Management of Osteoporosis and the Risk of Falls [70]
Marie-Claude Laliberté, Sylvie Perreault, Nicole Dameso, Lyne Lalonde. (Canada)

26 Fracture Risk Related to the Proton Pump Inhibitor in Elderly Osteoporosis Patients [71]
Jooyung Lee, KyungEun Youn, DongYoon Kang, Jin-Ho Lee, Nam-Kyong Choi, Hong-Ji Song, Byung-Joo Park. (Republic of Korea)

27 Drug Induced Immune Haemolytic Anemia in the Berlin Case-Control Surveillance Study [72]
Edeletraut Garbe, Frank Andersson, Elisabeth Brander, Andreas Klimpel, Michael Thomae, Hubert Schrezenmeier, Martin Hildebrandt, Ernst Späth-Schwalbe, Andreas Gruneisen, Beate Mayer, Abdulgabar Salama, Hanife Kartal. (Germany)
28 Carpal Tunnel Syndrome Associated with Bisphosphonates: A Population-Based Cohort Study [73]  
Alfonso Carvajal, Isaac Martin de Diego, Justin Matthews, Luis H Martin Arias, Maria Sainz, Inés Salado, Mariam Molokhia. (Spain)

29 Drug Outcomes Survey for Biological Treatments in Rheumatoid Arthritis: DOSE Study [74]  
Dose Group. (Italy)

30 Preadmission Metformin Use and 30-Day Mortality among Intensive Care Patients: A Danish Cohort Study [77]  
Christian F Christiansen, Martin B Johansen, Steffen Christensen, James M O’Brien, Else Tønnesen, Henrik T Sørensen. (Denmark)

31 Bridging Differences in Findings from Observational Pharmacoepidemiological Studies: The Design and Rationale of Work Package 2 of the PROTECT Project [78]  
Victoria Abbing-Karahagopian, Xavier Kurtz, Frank de Vries, Robert Reynolds, Olaf Klungel. (Netherlands)

32 Drug Use and the Risk of Road Traffic Crashes [79]  

33 Characteristics of Users of Chronic Prescription Analgesics [80]  
Wendy J Carman, Suzanne F Cook, John I Wurzelmann, Andrew T McAfee. (United States)

34 The Safety of Live Case Demonstrations at Cardiovascular Meetings [81]  
Angela DeMarco, Ellen Pinnow, Andrew Farb, Sheila Brown, Bram Zuckerman. (United States)

35 Drug Selection in French University Hospitals: Analysis of Formularies for Nine Competitive Pharmacological Classes [82]  
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11:45am  Acapulco  Oral
10:30am  Regency C  Oral
10:45am  Regency C  Oral
11:00am  Regency C  Oral
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11:45am  Regency D  Oral

Application of Quality of Evidence Assessment Tools to the Evaluation of Pharmacoepidemiologic Safety Studies

3:30-5:00pm  Regency A  Oral

Capacity of Various Data Sources to Advance Medical Device Safety and Effectiveness Research

3:30-5:00pm  Regency B  Oral

Challenges and Pitfalls in Studying Birth Defects as Outcomes

3:30-5:00pm  Toronto  Oral

Database Linkage and Methodological Issues in Comparative Effectiveness Research (CER) of Medical Devices vs. Medications: Lessons from an Ongoing Project

3:30-5:00pm  Regency C  Oral

Linking Existing Databases – Is it Worth the Pain?

3:30-5:00pm  Regency D  Oral

Monday, August 15 continued

Regulatory Trends in Pharmacogenomic Biomarker Evaluation (Molecular Epi/Biomarkers/Pharmacogenetics SIG Symposium)

3:30-5:00pm  Acapulco  Oral

Poster Session A

Cardiovascular

7:30am - 6:00pm  Poster

Fractures

7:30am - 6:00pm  Poster

Abstract Withdrawn by Author

Miscellaneous

7:30am - 6:00pm  Poster

Abstract Withdrawn by Author

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# ABSTRACT INDEX  Final Program

## Monday, August 15 continued

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### Poster Walk - Biologics SIG

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### Poster Walk - Medications in Pregnancy SIG

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### ABSTRACT INDEX  Final Program

#### Monday, August 15 continued

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# ABSTRACT INDEX  Final Program

## Tuesday, August 16 continued

### POSTER SESSION B

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**Poster Walk - Databases SIG**

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**Poster Walk – C.E.R. SIG**

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**Summarization**

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