

27th International Conference on



Pharmacoepidemiology and Therapeutic Risk Management

**FINAL
PROGRAM**

www.pharmacoepi.org

AUGUST 14-17, 2011

HYATT REGENCY CHICAGO

CHICAGO, ILLINOIS

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Saturday, August 13, 2011

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm
	8:00am - 6:00pm Registration Open Regency Main Desk											
	8:00am - 5:00pm Speaker Ready Room Hong Kong					1:30 - 6:00pm Educational Sessions Introduction to Pharmacoepidemiology Regency A						
	8:30am - 12:00pm Educational Session Introduction to Pharmacogenetics – Part 1 Regency B					1:30 - 6:00pm Introduction to Pharmacogenetics – Part 2 Regency B						
						1:30 - 6:00pm Student Skills Workshop Regency C					6:30pm - ? Student Meet & Greet Timothy O'Toole's Pub	
	8:30am - 5:30pm ISPE Board of Directors Meeting Toronto					1:30 - 6:00pm Introduction to Drug Utilization Research Regency D						

Sunday, August 14, 2011

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm
	7:30am - 6:00pm Registration Open Regency Main Desk											
	7:30am - 5:00pm Speaker Ready Room Hong Kong											
	8:30am - 12:00pm Educational Sessions Intermediate Pharmacoepi Regency A Comparative Effectiveness Research Regency B Regulatory Pharmacoepi/Public Health Decision Making Regency C Registries /Prospective Cohort Studies Acapulco Healthcare Databases Toronto					12:00 - 1:30pm Lunch on Your Own		1:30 - 6:00pm Educational Sessions Advanced Topics in Pharmacoepidemiology Regency A Introduction to Therapeutic Risk Management Regency B Advanced Drug Utilization Research/Health Services Research Regency C				
						12:00 - 1:30pm New Members Luncheon Regency D						
											6:00 - 7:30pm Academic Showcase/ Welcome Reception The Club at 151	

Monday, August 15, 2011

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm	
7:00am - 6:00pm Registration Open Regency Main Desk													
7:00am - 5:00pm Speaker Ready Room Hong Kong											6:30 - 7:30pm PDS Editorial Board (By invitation) Comiskey		
	8:00am - 6:00pm Exhibitors/Posters Riverside Center West		10:00- 10:30am Break/ Posters/ Exhibits Riverside Ctr West	10:30 - 12:00pm Concurrent Sessions Advanced Analytical Approaches Regency A Algorithms-Processes That Matter Regency B Rheumatic Condition Therapies Regency C Sweet and Sour Regency D Primigravida Acapulco Genes and Drugs Toronto		12:00 - 1:30pm Lunch/ Poster Session A/ Exhibits Riverside Center West ISPE Committee/ Council Meetings Public Policy Columbian Student Council Gold Coast Development Water Tower Fellowship & Awards Picasso Finance Haymarket PDS Regional Editors Wrigley		12:45- 1:30pm Poster Walks Riverside Ctr West		3:00- 3:30pm Break/ Posters/ Exhibits Riverside Ctr West		3:30 - 5:00pm Symposia & Workshops Evidence Assessment Tools Regency A Data Sources Regency B CER Regency C Linking Existing Databases Regency D Regulatory Trends Acapulco Birth Defects Toronto	
7:00 - 8:00am Poster Session A Set-Up Riverside Ctr West	8:15 - 10:00am Opening Session Crystal Ballroom Welcome: John Seeger Glen T. Schumock Presidential Address: Stephen JW Evans, FISPE Keynote: Robert M. Califf						1:30 - 3:00pm Plenary Session: Communication about Early Safety Findings from Active Surveillance Studies Crystal Ballroom		5:00 - 6:00pm ISPE Council Meetings Academic Acapulco Government/ Regulatory Water Tower Industry/ Service Providers Toronto		7:00pm - ? Student Night Out in Chicago TBA		

MEETING At-A-Glance

Tuesday, August 16, 2011

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm
7:00am - 6:00pm Registration Open Regency Main Desk												
7:00am - 5:00pm Speaker Ready Room Hong Kong												
7:00-8:00am Poster Session B Set-Up Riverside Ctr West	8:00am - 6:00pm Exhibitors/Poster Session Riverside Center West				12:45-1:30pm Poster Walks Riverside Ctr West			3:30-4:00pm Break/Posters/Exhibits Riverside Ctr West	4:00 - 5:30pm Symposia & Workshops Regulatory Decision Making Regency A			
7:15-8:15am H1N1 Vaccine Safety Network Gold Coast	8:30am - 10:00am Concurrent Sessions Drug Use-Change, Choice or Chance Regency A		10:00-10:30am Break/Posters/Exhibits Riverside Ctr West	10:30am - 12:00pm Concurrent Sessions A Little Attention Please Regency A		12:00 - 1:30pm Lunch/Poster Session B/Exhibits Regency Center West		1:30 - 2:30pm Plenary Session: Thalidomide: 50 Years Later Crystal Ballroom	2:30 - 3:30pm Annual Meeting of ISPE Members & Awards Ceremony Crystal Ballroom		Electronic Health Care Utilization Data Regency B	
7:15-8:15am 2013 Mid-Year Planning Committee Columbian	Fractures: Give us a Break Regency B			Adherence- A Sticky Issue Regency B		ISPE Committee Meetings Bylaws and Policies Columbian					Pharmacoepi Research Regency C	
	Matters of the Heart Regency C			Methods for Early Detection Regency C		Education Gold Coast					Methods Development Regency D	
	Prosopensity Score Methods Regency D			To Bleed or not to Bleed Regency D		Global Development Wrigley					Drug and Vaccine Safety Surveillance Acapulco	
	To Clot or Not to Clot Acapulco			Drugs and Bugs Acapulco		Membership Picasso					Drug Induced Liver Injury Toronto	
	Multigravida Toronto			Devices et al Toronto		Publications Haymarket					5:30 - 6:30pm SIGs Biologics Columbian	
											Comparative Effective Research Gold Coast	
											Databases Haymarket	
											Drug Utilization Wrigley	
											Medical Devices Picasso	
											Meds in Pregnancy Toronto	
											Molecular Epidemiology Acapulco	
											Pediatric New Orleans	
											7:30pm - ? Evening at the Hard Rock Cafe	
											Buses depart Hyatt at 7:00pm. Last bus from Hard Rock Cafe at 1:00am	

Wednesday, August 17, 2011

7:00am	8:00am	9:00am	10:00am	11:00am	12:00pm	1:00pm	2:00pm	3:00pm	4:00pm	5:00pm	6:00pm	7:00pm
7:00am - 4:30pm Registration Open Regency Main Desk												
7:00am - 3:30pm Speaker Ready Room Hong Kong												
7:00-8:00am Poster Session C Set-Up Riverside Ctr West	8:00am - 1:45pm Exhibitors/Poster Session Riverside Center West				12:45-1:30pm Poster Walks Riverside Ctr West			1:30 - 3:00pm Symposia & Workshops				
7:30 - 8:15am 2011 ICPE Scientific Program Committee Crystal Ballroom	8:30 - 10:00am Concurrent Sessions Applied Risk Mgmt. Regency A		10:00-10:30am Break/Posters/Exhibits Riverside Ctr West	10:30am - Noon Concurrent Sessions Cough & Wheeze Regency A		12:00 - 1:30pm Lunch/Poster Session C/Exhibits Riverside Center West		Assessing Treatment Patterns Regency A		3:00 - 4:30pm Hot Topics Session: H1N1 Vaccine Safety Monitoring Crystal Ballroom		
	Interesting, But Will We Remember? Regency B			Database Methods Regency B		ISPE Board of Directors Luncheon Wrigley		Adverse Drug Reactions Regency B		4:30 - 5:00pm The Final Word: •Poster Awards •Future Meetings •Adjournment Crystal Ballroom		
	Measuring Quality of Prescribing Regency C			Methods in Vaccine Safety Regency C				FDA's Mini-Sentinel Program Regency C				
	Methods for Safety Regency D			Not Your "Typical" Psychotropics Regency D				Drug Utilization Studies Regency D				
	Giving Kids a Good Stab Acapulco			Nulligravida Acapulco				Multiple Data Sources Acapulco				
	Cancer: Growing Evidence Toronto			Gut Feeling Toronto				Active Surveillance for Biologics Toronto				

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In This Program

27th ICPE Agenda	
Saturday, August 13.....	9
Sunday, August 14.....	12
Monday, August 15.....	14
Tuesday, August 16.....	18
Wednesday, August 17.....	26
27th ICPE Posters	
Poster Guidelines.....	46
Poster Session A.....	47
Poster Session B.....	52
Poster Session C.....	56
Indexes	
Abstract Index.....	73
Advertisers Index.....	82



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)

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2012

ISPE Mid-Year Meeting

April 21-23, 2012

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2013

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April 11-13, 2013

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August 25-28, 2013

Montreal Convention Center * Montreal, Canada

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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).

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28th International Conference on
**PHARMACOEPIDEMIOLOGY AND THERAPEUTIC
 RISK MANAGEMENT**

August 23-26, 2012 CCIB Barcelona, Spain

Abstract Deadline: February 15, 2012

✿ 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 B)

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 weakness 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.

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

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

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*

* Included as part of full meeting registration; registration required

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

Faculty

Morten Andersen, *Course Objectives, Definitions of Research Fields and Methodological Framework*
Hanne Strom, *The Anatomical Therapeutic Chemical Classification and the Defined Daily Dose: Classifying and Quantifying Drug Use*
Julie Zito, *Overview of Drug Utilization Research in the US*
Vera Vlahovic-Palcevski, *Principles and Pitfalls in Cross National Comparisons of Drug Utilization*
Petra Denig, *Developing Valid Prescribing Quality Indicators*
Colin Dormuth, *Evaluating Interventions on Drug Utilization: Analysis Methods*

AGENDA *Saturday, August 13*

STUDENTS ONLY

1:30-6:00pm

Student Skills Workshop (Regency C) -Organized by ISPE Student Council

* Included as part of full meeting registration; registration required

1:30-3:30pm

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

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*

Hard copies of the slides will be provided by SAS for those in attendance. The workshop is for students only (max 25), and will take place at the ISPE Conference venue. Additionally students will have to bring their own laptop. If students don't have a license to run SAS in their computers, an access to a virtual SAS can be granted (details to be provided).

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 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).*

4:30-5:45pm

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**

6:30pm - ?

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.

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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* (Registration required)

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

- 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

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

- 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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Pre-Conference Educational Sessions* (Registration required)

8:30-Noon

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.

- Understand methodologic challenges and proposed solutions in non-randomized effectiveness research

Target Audience

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

Faculty

Eric S. Johnson
Sebastian Schneeweiss, FISPE
David J Magid

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AGENDA *Sunday, August 14*

Pre-Conference Educational Sessions* (Registration required)

8:30-Noon

Intermediate Pharmacoepidemiology: Concepts, Data & Methods: The 'Pharmaco' in Pharmacoepidemiology (Regency A)

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

8:30-Noon

Regulatory Pharmacoepidemiology/ Health Decision-Making (Regency C)

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 world wide challenges for drug regulatory agencies and variation in approaches
- Know about current strategies to strengthen regulation in the face of these challenges

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Noon -1:30pm
Lunch On
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Noon-1: 30pm
New Member
Luncheon
(Regency D)
(By Invitation)

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

Jeremy Rassen: *Approaches To Comparative Safety and Effectiveness with Three or More Treatment Groups*

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

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

AGENDA *Sunday, August 14*

- To develop a sophisticated understanding of the importance of project planning processes to the effectiveness of interventions
- To develop an appreciation of the significance of this work to knowledge transfer at the patient care practice and policy change levels of the health system

Target Audience

Members of the DUR/HSR SIG; those interested in 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*

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*



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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

- *
- 'Stars-and-Stripes' Diagrams of Discordant Cases' Exposures in Case-Crossover Studies Using Healthcare Databases [6]**
-
- 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)



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- ◆ "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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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 Sørensen. (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

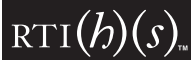
* Development and Validation of Claims-Based Algorithms To Determine Level of Trauma Associated with Fractures in Men [11]

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

* Validation of Claims-Based Algorithms for Identification of High-Grade Cervical Dysplasia and Cervical Cancer Using Electronic Medical Records [10]

Seo Young Kim, Sebastian Schneeweiss, Huichuan Lii, Daniel H Solomon. (United States)



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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 Eijgelsheim, 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, Harriët M Looovers, 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

✳ **Detection and Characterization of Pharmacogenomic Effects in Nonrandomized Studies - A Simulation Study of QT-Prolonging Drug-Gene Interactions [16]**

Jane Der, Christy L 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 Giulianini, 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 Roes. (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 Afzal, 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, Dóra 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 Hernández-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 Symons, 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)

11:45am

- ✳ **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)

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 and Effectiveness of Oral Contraceptives in Obese Women** [34]
Juergen Dinger, Kristina Bardenheuer, Anita Assmann. (Germany)

11:30am

- ✳ **Effect of Prescription Status on the Orlistat User Population: Prescription-Only Versus Pharmacy-Only** [35]
Marjolein J Willemsen, Aukje K Mantel-Teeuwisse, Nina A Winters, Sabine M Straus, Hubert G Leufkens, 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**

Judy Racoosin, Sentinel Initiative, Office of Medical Policy/CDER/FDA. *FDA early communications regarding medical product safety: An overview.*

✳ **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)**



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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.

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7:00-6:00pm

Registration
(Regency
Main Desk)

7:00-5:00pm

**Speaker Ready
Room (Hong Kong)**

7:00-8:00am

**Poster Session B
Set-up**
(Riverside
Center West)

7:15-8:15am

**H1N1 Vaccine
Safety in Pregnancy
Network**
(Gold Coast)
- By invitation only

7:15-8:15am

**ISPE 2013 Mid-
Year Meeting
Planning
Committee**
(Columbian Room)
- By invitation only

8:00-6:00pm

Exhibits/Posters
(Regency
Center West)

8:30-10:00am

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]**
Huifeng 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 J Glynn, Haiden A Huskamp, M Chris Roe-buck, Sebastian Schneeweiss. (United States)

9:15am

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

9:30am

- * **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)

9:45am

- * **Reasons for Oral Contraceptives Use in Adolescents and Adults in Europe [273]**
Kristina Bardenheuer, Juergen Dinger, Janko Leddin. (Germany)

Fractures - Give Us a Break (Regency B)

Moderators: Annlouise Assaf & Dave Dore

8:30am

- * **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)

8:45am

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

9:00am

- * **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)

9:15am

- * **Proton Pump Inhibitors and Fracture Risk in Corticosteroid Users [277]**
Jeffrey C Munson, Peter M Wahl, Gregory Daniel, Stephen E Kimmel, Sean Hennessy. (United States)

9:30am

- * **Odds of Fractures with Inhaled Corticosteroids in COPD: Systematic Review and Meta-Analysis of Randomized Controlled Trials and Observational Studies [278]**
Sonal Singh, Rodrigo Cavallazi, Yoon Loke. (United States)

9:45am

- * **Comparative Safety of Antidepressants on Fracture Risk in Older Adults [279]**
Joshua J Gagne, Amanda R Patrick, Helen Mogun, Daniel H Solomon. (United States)

AGENDA *Tuesday, August 16*

Matters of the Heart (Regency C)

Moderators: Patrice Verpillat & Manel Pladerell

8:30am

- ✳ **Intravenous Bisphosphonate Therapy and Risk of Atrial Fibrillation in Cancer Patients [280]**
Rune Erichsen, Christian F Christiansen, Trine Frøslev, Jacob Jacobsen, Henrik T Sørensen. (Denmark)

8:45am

- ✳ **Risks of Congestive Heart Failure and Cardiomyopathy Associated with Bevacizumab Use in Colorectal Cancer Chemotherapy Patients: A Population-Based Study [281]**
Huei-Ting Tsai, Sheila Weiss Smith, Joan L Warren, Andrew N Freedman, Leah B Sansbury, John L Marshall, Arnold L Potosky. (United States)

9:00am

- ✳ **ADHD Medications and Risk of Serious Cardiovascular Events in Adults [282]**
Hedi Schelleman, Warren B Bilker, Stephen E Kimmel, Gregory W Daniel, Craig Newcomb, James P Guevara, Mark J Cziraky, Brian L Strom, Sean Hennessy. (United States)

9:15am

- ✳ **Comparative Cardiovascular (CV) Safety of Dementia Drugs Among Medicare Beneficiaries [283]**
Emil L Fosbol, Eric D Peterson, Yinghong Zhang, Lesley H Curtis, Isao Iwata, Soko Setoguchi. (United States)

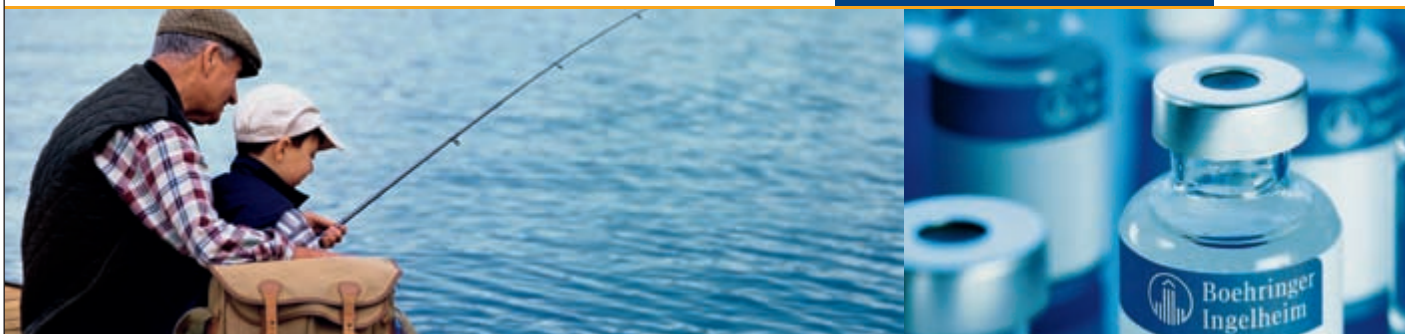
9:30am

- ✳ **A Cohort Study Using GPRD and MINAP Data To Investigate the Possible Drug Interaction between Clopidogrel and Cytochrome P450 2C19 Inhibitors [284]**
Ian Douglas, Liam Smeeth, Aroon Hingorani, Anthony Grosso, Stephen Evans. (United Kingdom)

9:45am

- ✳ **Thiazolidinidiones and the Risk of Myocardial Infarction [285]**
Rohini K Hernandez, Timothy L Lash, Cathy W Critchlow, Susan S Jick. (United States)

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27

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 Jennita. (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)

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 L 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)

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 Groenewold, 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)

9:30am

- ✳ **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

8:30am

✳ **When Should an Atrial Fibrillation Patient Receive Anticoagulants Following Intracerebral Haemorrhage?** [298]

Robert W V Flynn, Thomas M MacDonald, Anna Maria Choy, Gordon D Murray, Alexander S F Doney. (United Kingdom)

8:45am

✳ **Age, Antipsychotics, and Risk of Thrombotic Events in the Veterans Health Administration (VHA)** [299]

Shirley Wang, David D Dore, Malcolm Macclure, Vincent Mor, Crystal Linkletter, Stephen Buka. (United States)

9:00am

✳ **Moved to Poster Session A** [300]
(See page 55)

9:15am

✳ **Androgen Deprivation Therapy and the Risk of Stroke and Transient Ischemic Attacks in Patients with Prostate Cancer** [301]

Laurent Azoulay, Hui Yin, Serge Benayoun, Jean-François Boivin, Samy Suissa. (Canada)

9:30am

✳ **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]

Juergen Dinger, Kristina Bardenheuer, Christian Franke. (Germany)

9:45am

✳ **Effect of Simultaneous Use of Oestrogens and Statins on the Risk for Venous Thromboembolism in Post-Menopausal Women** [303]

Ruben Duijnhoven, Sophie dell'Aniello, Christel Renoux, Vicky Tagalakis, Mirjam Knol, Olaf Klungel, Samy Suissa. (Netherlands)

10:00-10:30am

Break/Posters/Exhibits (Regency Center West)

Government/Regulatory Council Coffee Corner

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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, Eibert 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)

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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, Lon-neke 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)

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)

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 Well-man, 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 Schleck, 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 Krulewicz, Mary Beth E Ritchey, Hong Cheng, Danica Marinac-Dabic, Tom Gross, Jonathan Gibbs, Christopher Worrall, Jeffery A Kelman. (United States)

11:15am

- ✳ **Risk Factors for Uterine Perforations During IUD Insertion: Interim Results from the EURAS-IUD Study [319]**
Klaas Heinemann, Clare Barnett, Juergen Dinger. (Germany)

11:30am

- ✳ **A Quantitative Approach to Benefit-Risk Assessment: An Example with Lumiracoxib [320]**
Paola Primatesta, Estel Plana, Alan Moore. (Switzerland)

11:45am

- ✳ **Incidence Rate of Liver Injury in Pediatric Population: Data Mining on Electronic Healthcare Databases in Europe [321]**
Carmen Ferrajolo, Katia M C Verhamme, Annalisa Capuano, Gianluca Trifirò, Alessandro Oteri, Gino Picelli, Giampiero Mazzaglia, Claudio Cricelli, Francesco Rossi, Miriam C J M Sturkenboom. (Netherlands)

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

- ✳ **Study on Risk Factors for Adverse Drug Reactions in Hospitalized Retroviral Patients [348]**
Thiyagu Rajakannan, Surulivelrajan Malayasamy, Vasudeva Guddattu, Muralidhar Varma, Vijayanarayana Kunhikatta. (India)

The Andrew McAfee Award-BEST ABSTRACT SUBMITTED BY A STUDENT/POST-DOC FROM A DEVELOPING COUNTRY

11:30am

- ✳ **Differences in Oral Candidiasis Risk Between Different Inhaled Corticosteroids [326]**
Alison L Nightingale, Annie Hutchison, Corinne S de Vries. (United Kingdom)

Methods for Early Detection (Regency C)

Moderators: Marie Lindquist & Jeremy Rassen

10:30am

- ✳ **Comparison of Methods for Drug Safety Signal Detection Using Electronic Healthcare Record (EHR) Databases: The Added Value of Longitudinal, Time-Stamped Patient Information [328]**
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)

11:45am

- ✳ **Baseline Predictors of Efavirenz-Related Symptoms during the First Six Months of Therapy [327]**
Paul D Sonenthal, Bakgaki Ratshaa, Gilbert Chimbengo, Malebogo Thero, Tumelo Rantleru, Sarah Barenbaum, Andrew Steenhoff, Robert Gross. (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]**
Xianying Pan, Hugh Kawabata, Teresa Simon, Uchenna Iloje. (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

- ✳ **How Real-Life Data Analysis Could Highlight Ethnic Inequalities in Access to Healthcare: Example of Critical Limb Ischemia in the US Medicare Population [337]**
Onur Baser, Patrice Verpillat, Li Wang. (France)

11:30am

- ✳ **Association Between Drug Use and Acute Immune Thrombocytopenia in Adults: Results from the Berlin Case-Control Surveillance Study [338]**
Edeltraut Garbe, Frank Andersohn, Elisabeth Bronder, 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 MaCurdy, Chris Worrall, Jeffrey Kelman. (United States)

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 research 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 -Open to all participants.

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 Wellenius. (United States)

Induction of ISPE Fellows (FISPE)

- * Stephen JW Evans, FISPE, ISPE President
 - Inductees
Robert F. Reynolds, FISPE
Nancy C. Santanello, FISPE
Soko Setoguchi Iwata, FISPE
Marianne Ulcickas Yood, FISPE

The Ronald D. Mann Best Article Award

Brian Strom, FISPE, Editor-in-Chief
Joerg Hasford, Regional Editor for Europe
Sean Hennessy, FISPE, Regional Editor for the americas
B J Park, FISPE, Regional Editor for Asia, Africa, Oceania

Installation of New President

- * Nancy C. Santanello, FISPE

3:30-4:00pm

Break/Posters/Exhibits (Riverside Center West)

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)

Structured Approaches to Evaluating Statistical Signals from Drug and Vaccine Safety Surveillance [346] Systems (Acapulco)

- * 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.

- * **Biologics 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 Café 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 Dominoes, 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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Vice Chief, Division of Pharmacoepidemiology and Pharmacoeconomics
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7:00-4:30pm

Registration
(Regency
Main Desk)

7:00-8:00am

**Poster Session C
Set-up** (Riverside
Center West)

7:00-3:30pm

**Speaker
Ready Room**
(Hong Kong)

7:30-8:15am

**2011 ICPE
Scientific
Program
Committee**
(Crystal Ballroom)

8:00-1:45pm

Exhibits/Posters
(Riverside
Center West)

8:30-10:00am

Concurrent Sessions: Contributed Papers

Applied Risk Management (Regency A)

Moderator: Annalisa Rubino & Glen T. Schmock

8:30am

- ✳ **Evaluation of Dronedrone Utilization in the US Using a Claims Database [540]**
Shujun Gao, Juhaeri Juhaeri, Heather A Schiappacasse, Andrew T Koren, Wanju S Dai. (United States)

8:45am

- ✳ **Experiences and Preferences of Healthcare Professionals with Regard to Direct Healthcare Professional Communications (DHPCs) [541]**
Sigrid Piening, Flora M Haaijer-Ruskamp, Sabine M J M Straus, Pieter A de Graeff, Peter G M Mol. (Netherlands)

9:00am

- ✳ **Risk Management Strategies Mitigating Potential Severe Dermatologic Risks of Carbamazepine in Taiwan [542]**
Yu-Wen Huang, Po-Wen Yang, Churn-Shiouh Gau, Hsueh-Yung Tai, Chien-Wen Hsu, Meir-Chyun Tzou, Hsuan-Shu Lee, Jaw-Jou Kang. (Taiwan)

9:15am

- ✳ **Reducing Medication Errors Through Application of Low Health Literacy Principles to Patient Instructions for Use [543]**
Meredith Y Smith, Lorraine Wallace. (United States)

9:30am

- ✳ **Trends in Dispensing Patterns of Rosiglitazone and Pioglitazone in the Netherlands Following Safety Signals During the Period 1998-2008 [544]**
Rikje Ruiten, Loes E Visser, Myrthe P P van Herk - Sukel, P H Geelhoed - Duijvestijn, Sandra de Bie, Sabine M J M Straus, Peter G M Mol, Silvana A Romio, Ron M C Herings, Bruno H Ch Stricker. (Netherlands)

9:45am

- ✳ **Evaluation of Drug Interactions in 84607 Psychiatric Inpatients Using a Customized Data Interface for Mass Analysis with Clinical Decision Support Software [545]**
P Haueis, W Greil, M Huber, R Grohmann, G Kullak, S Russmann. (Switzerland)

Cancer: Growing Evidence (Toronto)

Moderators: Marieke De Bruin & James Kaye

8:30am

- ✳ **Assessing the Comparability of Electronic Medical Records Information to Tumor Registry and Health Claims Data for Oncology Outcomes Research [546]**
Fionna 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. (United States)

8:45am

- ✳ **Claims-Based Prediction of Performance Status (PS) Associated with Erythropoietic Stimulating Agent (ESA) Treatment and Survival in Myelodysplastic Syndromes (MDS) Patients [547]**
Xuehua Ke, amy J Davidoff, Ilene Zuckerman, Naimish B Pandya, Franklin Hendrick, Sheila Weiss Smith, Maria R Baer, Steven D Gore. (United States)

9:00am

- ✳ **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 [548]**
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. (France)

9:15am

- ✳ **Use of Glucocorticoids and Colorectal Cancer Risk; a Population-Based Case-Control Study [549]**
Eva Bjerre Ostensfeld, Anders Hammerich Riis, Ole Thorlacius-Ussing, Tove Nilsson, Rune Erichsen, Henrik Toft Sørensen. (Denmark)

9:30am

- ✳ **Angiotensin Receptor Blockers and the Risk of Cancer - A Comparative Safety Study in Large Linked Healthcare Databases [550]**
Henrik Svanström, Björn Pasternak, Callréus Torbjörn, Melbye Mads, Hviid Anders. (Denmark)

9:45am

- ✳ **Hormonal Therapies and Meningioma: A UK Primary Care Study [551]**
Lucia Cea-Soriano, Tilo Blenk, Mari-Ann A Wallander, Luis A García Rodríguez. (Ghana)

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

- ✳ **Validity of Current Procedural Terminology Codes for Rotavirus Vaccination in Two Commercially-Insured US Populations [554]**
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

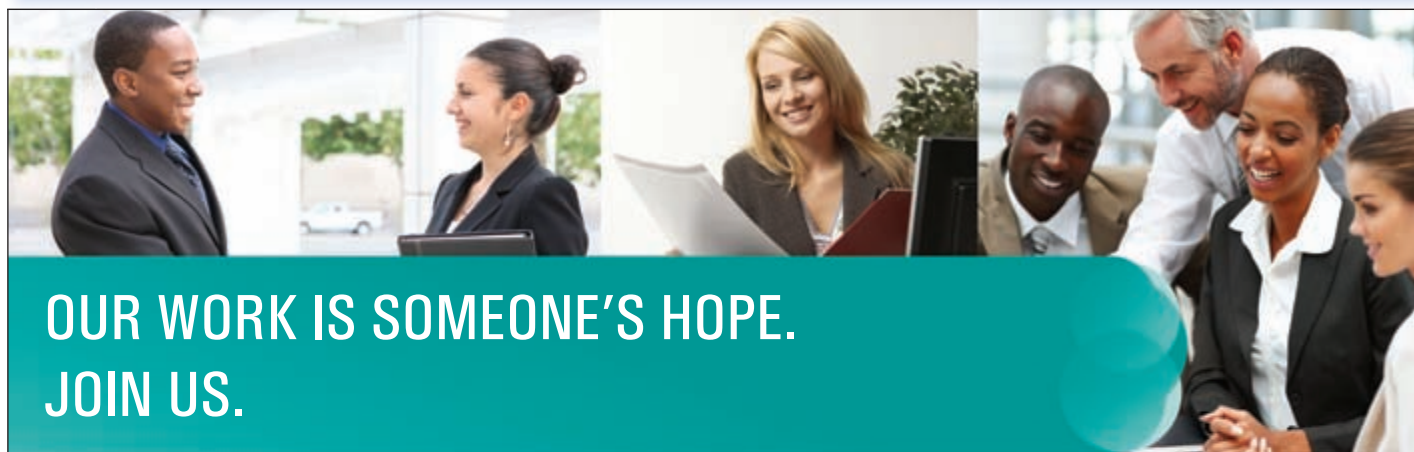
- ✳ **Use of Self-Controlled Risk-Interval Design in Childhood Vaccine Safety [555]**
Jie Li, Gregory W Daniel, Corrie Paeglow, Tom Puenpatom, Laura Polakowski, Yun Lu, Alec M Walker, M Alan Brookhart, Hector Izurieta. (United States)

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]**
Ali Rowhani-Rahbar, Nicola P Klein, Cornelia L Dekker, Kathryn M Edwards, Claudia Velozzi, Neal A Halsey, Roger P Baxter, The Risk Interval Working Group of the Clinical Immunization Safety Assessment (CISA) Network. (United States)



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Interesting, But Will We Remember (Regency B)

Moderators: Rob Heerdink & Kristina Bardenheuer

8:30am

* **Risk of Coronary Events and Stroke in Patients Taking Anticonvulsant Medications [558]**

Elisabetta Paterno, Rhonda Bohn, Peter Wahl, Gregory Daniel, Jerry Avorn, Jun Liu, Helen Mogun, Sebastian Schneeweiss. (United States)

8:45am

* **Comparisons between Drugs for Alzheimers Disease Concerning Changes in Co-Medication, Need of Assisted Living Facilities and Hospitalizations [559]**

Tobias Svensson, Anders Sundström, Morten Andersen, Helle Kieler. (Sweden)

9:00am

* **A Study of Blood Pressure and Change in Cognitive Function in Elderly Mexican Americans [560]**

X Zhou, S Galea. (United States)

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-Díaz. (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 Ouellet-Hellstrom, Trinkia S Coster. (United States)

9:45am

* **Antiepileptic Drugs and the Risk of Stroke [563]**

Chia-Cheng Lai, Cheng-Yang Hsieh, Yea-Huei Kao Yang. (Taiwan)

Measuring Quality of Prescribing (Regency C)

Moderators: Morten Andersen & Lisa Pont

8:30am

* **Does Medication Review Lead to a Reduction of Drug Problems in Elderly Patients Discharged from the Hospital [564]**

Abeer Loutfi dcAhmad, Ruth M Mast, Giel Nijpels, Jacqueline M Dekker, Piet J Kostense, Jacqueline G Hugtenburg. (Netherlands)

8:45am

* **Enhancing the Quality of Prescribing in Primary Care in Australia [565]**

Abstract withdrawn by author.

9:00am

* **Ranking Medication Errors in the Hospital by Their Probability of Harm in a National Error Reporting Database [566]**

Jessica A Myers, Sergio Venturini, Laura Morlock, Francesca Dominici. (United States)

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 Srasuebku, Christine Lu, Timothy Dobbins, Robyn Ward. (Australia)

9:45am

* **Medication Errors during Patient Transition into Nursing Homes: What Is the Impact on Patients? [195]**

Rishi Desai, Richard Hansen, Charlotte Williams, Stephanie Pierson, Sandra Greene. (United States)

Methods for Safety (Regency D)

Moderators: John Seeger & Tam Dang-Tan

8:30am

* **Linking Electronically Collected Quality of Life Data to THIN - A UK General Practice Database [570]**

Betina T Blak, Joanne Lee, Mary Thompson, Alison Bourke, Louise Pinder. (United Kingdom)

8:45am

* **Disproportionality Analysis for Signal Detection of Implantable Cardioverter-Defibrillator Lead Related Adverse Events [571]**

Naomi D Herz, Heshu J Duggirala, Daniel A Caños, Roberta Sullivan, Richard Schaaf, Ellen Pinnow, Danica Marinac-Dabic. (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]**
Lamiaie Grimaldi-Bensouda, Michel Rossignol, Djamila Abed, Elodie Aubrun, Lucien Abenhaim, PGRx Group. (Canada)

10:00-10:30am

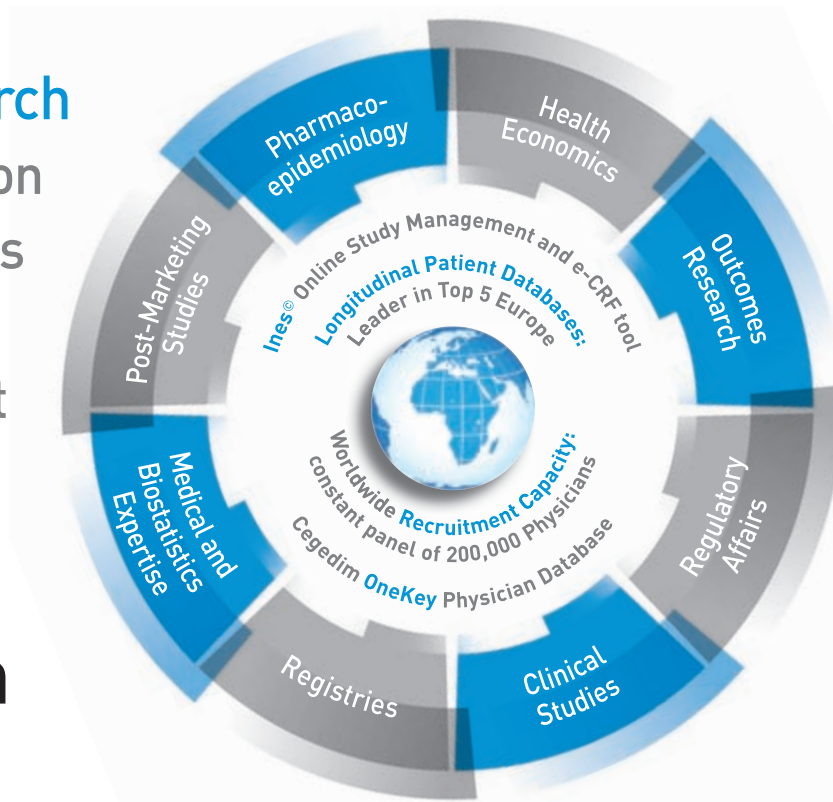
Break/Posters/Exhibits (Riverside Center West)
Government/Regulatory Council Coffee Corner

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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]
TingTing 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

10:30am

- ✳ **Hepatotoxicity in Association with Acetaminophen Poisonings in the U.S. [588]**

Syed Rizwanuddin Ahmad, Anne Elixhauser, Janet P Sutton.
(United States)

10:45am

- ✳ **Polyethylene Glycol Increase Risk of Acute Renal Failure: A Population Based Case-Crossover Study [589]**

Nam-Kyong Choi, Joongyub Lee, Yoosoo Chang, Sun-Young Jung,
Ye-Jee Kim, Seung-Mi Lee, Jin-Ho Lee, Ju-Young Kim, Byung-Joo Park.
(Republic of Korea)

11:00am

- ✳ **Hypertriglyceridemia and Acute Pancreatitis [590]**

Michael J Murphy, Xia Sheng, Thomas M MacDonald, Li Wei.
(United Kingdom)

11:15am

- ✳ **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)

11:30am

- ✳ **Risk of Upper and Lower Gastrointestinal Hospitalizations in the Elderly with and without Alzheimer's Disease [592]**

Jasmanda H Wu, Zhenchao Guo, Sandeep Kumar, Andres Gomez, Pablo Lapuerta.
(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)



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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]**

Jeanne P Dieleman, Silvana S Romio, Corinne S de Vries, Cormac J Sammon, Nick Andrews, Anders Hviid, Henrik Svanström, Ditte Mølgaard-Nielsen, Maryse Lapeyre-Mestre, Agnès Sommet, Christel Saussier, Anne Castot, Harald Heijbel, Lisen Arnheim Dahlström, Jonas Hallgren, Par Sparen, Mees Mosseveld, Martijn Schuemie, Noline van der Maas, Bart C Jacobs, Kari Johansen, Piotr Kramarz, Daniel Weibel, Jan Bonhoeffer, Miriam C J M Sturkenboom. (Netherlands)

10:45am

- * **Guillain-Barré Syndrome, Influenza-like Illnesses and Influenza Vaccination during Seasons with and without Circulating A/H1N1 Viruses [595]**

Lamia Grimaldi-Bensouda, Annick Alperovitch, Gérard Besson, Christophe Vial, Jean-Marie Cuisset, Caroline Papeix, Olivier Lyon-Caen, Elodie Aubrun, Jacques Benichou, Michel Rossignol, Lucien Abenheim, GBS-PGRx Study Group. (United Kingdom)

11:00am

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

J Dieleman, C Lecomte, M Schuemie, A van Rollegem, A Hviid, H Svanström, D Mølgaard-Nielsen, J Jokinen, H Nohynek, T Kilpi, J Storsaeter, N van der Maas, H Heijbel, L Arnheim-Dahlstrøm, P Sparen, C Sammon, C de Vries, G Plazzi, A Menna, F Trotta, C Santuccio, K Johansen, P Kramarz, D Weibel, J Bonhoeffer, M Sturkenboom. (Netherlands)

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 Myhre 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 Stuffken, 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 Olfson, 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 Olfson, 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]**
Keele E Wurst, Sara A Ephross. (United States)

10:45am

- ✳ **Maternal Exposure to Venlafaxine and Risk for Birth Defects, National Birth Defects Prevention Study, 1997-2007 [607]**
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 Sørensen. (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 Hernández-Díaz. (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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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)

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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 L 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 Callréus, Patricia Saddier, Mary B Ritchey, Susana Perez-Gutthann. (United Kingdom)

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

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


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.

NOTE: Neither ISPE nor the Hyatt will be responsible for any poster that is left up overnight or is lost or damaged.

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 free-standing 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®.

Cardiovascular

- 1 **Comparative Cardiac Effects of Halofantrine with or without Concomitant Administration of Kolanot or Fluconazole in Healthy Volunteers [43]**
Aduragbenro D Adedapo, Kayode S Adedapo, Dike Ojji, Chinedu P Babalola. (Nigeria)
- 2 **Intent-to-Treat Analysis of Hospitalized Rhabdomyolysis with Statin and Fibrate Use in an Insured US Population [44]**
Kandace L Amend, Joan Landon, Cheryl Enger, Andrew McAfee. (United States)
- 3 **Statin Prescribing Following an Acute Coronary Syndrome: Are the NICE Guidelines Being Followed? [45]**
Rachael Boggon, Susan Eaton, Adam Timmis, Harry Hemingway, Zahava Gabriel, Iqbal 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 Lin. (Taiwan)
- 5 **Statins and Primary Prevention of Cardiovascular Events: A Population-Based Cohort Study [47]**
Gabriel Chodick, Miri Srur, 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 Bénichou, François Paillard, Pierre Ducimetière, Serge Herberg, Hélène Maïzi, Marie-Agnès 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]**
Karin M Henriksson, Tommy Andersson, Anders Magnusson, Ing-Lis Bryngelsson, Ole Fröbert, Nils 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 Rodermund, Elyse 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 Nicotra, Andrea Arfè, Lorenza Scotti, Antonella Zambon, Edeltraut Garbe, Ron Herings, Silvia Lucchi, Gino Picelli, Silvana Romio, Renè Schade, Tania Schink, Huub Straatman, Frantz Thiessard, Vera E Valkhoff, Marco Villa, Miriam C J M Sturkenboom, Giovanni Corrao. (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 Roughead, Philip Ryan, Ben Ewald. (Australia)
- 13 **Management of Atrial Fibrillation in a Large Health Organization in Israel [55]**
Varda Shalev, Nurit Tweezer-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 **Dronedarone or Amiodarone and Risk of Heart Failure (HF): A Federal Partners Collaboration (FPC) [59]**
Gwen L Zornberg, Lucy Hsu, Diane Dong, Michael Wernecke, Clara Kim, Mary Ross Southworth, Monika Houstoun, Thomas MaCurdy, Marsha Reichman, LaRee Tracy, Francesca Cunningham, Trinkia S Coster, Gail Moreschi, Amy Chen, Abraham M Karkowsky, Chris Worrall, Jeffrey Kelman. (United States)

Fractures

- 17 **Use of Thiazolidinediones and Risk of Osteoporotic Fracture: Disease or Drugs? [60]**
Marloes Bazelier, Arlene Gallagher, Tjeerd van Staa, Cyrus Cooper, Hubert Leufkens, Peter Vestergaard, Frank De Vries. (Netherlands)
- 18 **Proton Pump Inhibitor (PPI) Use and Risk of Hip/Femur Fracture [61]**
Rosenie Thelus Jean, Tamra E Meyer, Lockwood G Taylor, Geoff E Gordon, Trinkia S Coster. (United States)
- 19 **Fractures and Mortality in Relation to Different Osteoporosis Treatments [62]**
Huifeng Yun, Elizabeth Delzell, Robert Matthews, Meredith L Kilgore, Kenneth G 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 Zucker, Gabriel Chodick, Inbal Goldstein, Raanan Raz, Varda Shalev. (Israel)
- 21 **Oral Bisphosphonates and Hip Fracture Risk in Elderly Women [64]**
Juan Erviti, Julia Timoner, Alvaro 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, Belén 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 Fractures Rate 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 Damestoy, Lyne Lalonde. (Canada)
- 26 **Fracture Risk Related to the Proton Pump Inhibitor in Elderly Osteoporosis Patients [71]**
Joongyub Lee, KyungEun Youn, DongYoon Kang, Jin-Ho Lee, Nam-Kyong Choi, Hong-Ji Song, Byung-Joo Park. (Republic of Korea)

Miscellaneous

- 27 **Drug Induced Immune Haemolytic Anaemia in the Berlin Case-Control Surveillance Study [72]**
Edeltraut Garbe, Frank Andersohn, Elisabeth Bronder, Andreas Klimpel, Michael Thoma, Hubert Schrezenmeier, Martin Hildebrandt, Ernst Späth-Schwalbe, Andreas Grüneisen, Beate Mayer, Abdulgabar Salama, Hanife Kurtal. (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 Sáinz, 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]**
Sylvie Blazejewski, Pierre Philip, Emmanuel Lagarde, Régis Ribereau-Gayon, Jean-Louis Montastruc, Louis Merle, Pernelle Noize, Laurence Memes, Fabienne Bazin, Antoine Pariente, Pierre-Olivier Girodet, Nicholas Moore. (France)
- 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]**
Adeline Gallini, Blandine Juillard-Condât, Marie-Claude Saux, Florence Taboulet. (France)
- 36 **Association Between Minocycline and Thyroid Cancer in the GPRD: Preliminary Findings [83]**
Sigal Kaplan, Marian Callahan, Yulan Ding, Stephine Keeton, Mark Levenson, Naomi Lowy, Tarek Hammad. (United States)
- 37 **Identification of Phthalates in Medications and Dietary Supplements [84]**
Katherine E Kelley, Sonia Hernandez-Diaz, Erica L Chaplin, Russ Hauser, Allen A Mitchell. (United States)
- 38 **Preoperative Prescription and Occurrence of Adverse Drug Reactions in Patients Planned for Cataract Surgery: 5 Months Study in a Large Cataract Surgery Centre in India [85]**
Dr Pradeep Kumar, Dr Sonika Mehra. (India)
- 39 **Early Adopters of Accredited Course in Pharmacovigilance [86]**
Deborah Layton, Lisa Harvey, Saad A W Shakir. (United Kingdom)

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POSTER SESSION A *Monday, August 15*

- 40 **Practical Report about the Construction of a Database Accumulating Data from Drug Use Surveys on Hyperlipidemia Treatment Drugs [87]**
Shinichi Watanabe, Toshifumi Kamiura, Etsuya Bando, Naoko Wakasugi, Etsuko Sawai, Hiroyuki Housawa, Kasumi Daidoji, Kaori Nomura, Seiich Kanda, Toru Ebihara. (Japan)
- 41 **The Perception of Community Pharmacist on Herbal Medicine in Ibadan, Oyo State Nigeria [88]**
Hamidu A Oluyedun. (Nigeria)
- 42 **Assessing the Impacts of Herbal Medicinal Products Research Outcomes on Health Care Institutions in Nigeria (A Dilemma of Universities Social Responsibility and Public Bureaucracy) [89]**
Hamidu A Oluyedun. (Nigeria)
- 43 **Drug Information Resources and Their Influence on the Prescribing Behaviour of Doctors in a Teaching Hospital in Nigeria [90]**
Kazeem A Oshikoya, Ibrahim A Oreagba, Olayinka Adeyemi. (Nigeria)
- 44 **Pain and Hemorrhage with Negative Pressure Wound Therapy: Inpatient and Non-Inpatient Experience [91]**
Mary E Ritchey, Veronica V Sansing, Richard Domurat, Thomas MaCurdy. (United States)
- 45 **Pain Management: Impact on Quality of Life [92]**
Philippe Bertin, Nora Rahhali, Marie Auges, Charles Taieb. (France)
- 46 **Development of a Questionnaire Assessing the Burden of Ichthyosis in Infants [93]**
Christine Bodemer, Helene Dufresnes, Charles Taieb. (France)
- 47 **Development of a Questionnaire Assessing the Burden of Pruritus [94]**
Charles Taieb. (France)
- 48 **Fatigue Management: Example in Pharmacies [95]**
Charles Taieb, Nora Rahalli, Marie Auges. (France)
- 49 **Impact of Company Type and Size on Orphan Drug Development Times [96]**
Yan-Jun Zhang, Christina M L Kelton, Jeff J Guo. (United States)
- 50 **Exposure to Non-Steroidal Anti-Inflammatory Drugs during Pregnancy and the Risk of Selected Birth Defects: A Prospective Cohort Study [97]**
Marleen van Gelder, Nel Roeleveld, Hedvig Nordeng. (Netherlands)
- 51 **Prevalence of Prescription Medication Use Among US Pregnant Women – NHANES, 1999–2006 [98]**
Cheryl S Broussard, Sarah C Tinker, Suzanne M Gilboa. (United States)
- 52 **SSRIs Use During Pregnancy and the Risk of Cardiac Congenital Malformations using the General Practice Research Database [99]**
Adel Abou-Ali, Marian Callaham, Fatmatta Kuyateh, Tarek A Hammad. (United States)
- 53 **Antiepileptic Drug Use during the First Trimester of Pregnancy and Major Congenital Anomalies in Offspring, Finland 1996-2006 [100]**
Miia Artama, Mika Gissler, Heli Malm, Annukka Ritvanen. (Finland)
- 54 **Maternal Use of Corticosteroids and Risk of Adverse Birth Outcomes: A Danish Population-Based Study [101]**
Anne-Mette Bay Bjørn, Vera Ehrenstein, Heidi Holmager Hundborg, Ellen Aagaard Nohr, Mette Nørgaard. (Denmark)
- 55 **Creating a Mother Baby Link and Pregnancy Register for a UK Population [102]**
Rachael Boggon, Arlene Gallagher, Tim Williams, Tjeerd van Staa. (United Kingdom)
- 56 **The Cymbalta Pregnancy Registry: A Prospective Observational Study To Assess Cymbalta Exposure during Pregnancy and the 15-Month Results [103]**
Yingkai Cheng, Sharon Hoog, Maanasa Gowda, Leslie Thomas. (United States)
- 57 **Dispensing Patterns and Pregnancy Outcomes in Women Dispensed Proton Pump Inhibitors during Pregnancy [104]**
Lyn Colvin, Linda Slack-Smith, Fiona J Stanley, Carol Bower. (Australia)
- 58 **Identifying Appropriate European Data Sources for Assessing Product Safety in Pregnant Women [105]**
Deborah Covington, Rebecca Buus, Amanda Golembesky, Alexander Walker, William Blumentals, Gena Angelo, Vani Vannappagari. (United States)
- 59 **Advancing the Field of Drug Safety in Pregnancy: A Decade of Abstracts Presented at ICPE [106]**
Deborah Covington, Kyna Gooden, Laura McKain. (United States)
- 60 **EUROmediCAT: European Surveillance of Safety of Medication Use in Pregnancy [107]**
Lolkje T W de Jong-van den Berg, Marian K Bakker, Helen Dolk. (Netherlands)
- 61 **Topiramate Use in Women of Child-Bearing Age [108]**
Kate B Dugan, Andrea V Margulis, Sonia Hernandez-Diaz. (United States)
- 62 **Prenatal Exposure to Systemic Antiinfectives and Overweight and Obesity at School Age [109]**
Vera Ehrenstein, Trine Frøslev, Leiv S Bak-keteig, Vibeke Holsteen, Jens Holm-Pedersen, Søren C Jørgensen, Henrik Toft Sørensen. (Denmark)
- 63 **Cognitive and Psychiatric Status of Male Conscripts Born to Epileptic Mothers [110]**
Vera Ehrenstein, Henrik Toft Sørensen, Lars Pedersen. (Denmark)
- 64 **Beta2-Agonists and Perinatal Outcomes: A Review of the Evidence [111]**
Sherif Eltonsy, Fatima-Zohra Kettani, Lucie Blais. (Canada)
- 65 **Association Between Caffeine Consumption During Pregnancy and Infants Born Small for Gestational Age (SGA) [112]**
Rihab Gamaoun, Anick Bérard, Odile Sheehy. (Canada)
- 66 **In Utero Azathioprine Exposure and Developmental Delays in Children of Mothers with Systemic Lupus Erythematosus (SLE) [113]**
Martha A Ganser, Wendy Marder, Vivian Romero, Marnie Hyzy, Caroline Gordon, W Joseph McCune, Emily C Somers. (United States)
- 67 **A New Tool for the Pharmacovigilance Defense Application System (PVDAS) for Automatic Identification of Pregnancy Periods, Outcomes, and Associated Children in the Military Healthcare System (MHS) Database [114]**
Geoffrey E Gordon, Lockwood G Taylor, David M Fram, Trinkka S Coster. (United States)
- 68 **Adverse Events of Promethazine and Ondansetron in Young Children and Women of Child-Bearing Age: A Pharmacovigilance Study Based on the FDA Adverse Event Reporting System [115]**
Susan A Seddoh, Jeff J Guo, Funmilayo O Ajayi, Patricia R Wigle. (United States)
- 69 **(Cost-)Effectiveness of a Screening Strategy for Q Fever among Pregnant Women in Risk Areas: A Clustered Randomized Controlled Trial [116]**
Janna M Munster, Alexander C A P Leenders, Wim Van der Hoek, Peter M Schneeberger, Ariene Rietveld, Josien Riphagen-Dalhuisen, Ronald P Stolk, Carl J C M Hamilton, Esther De Vries, Jamie C E Meekelenkamp, Jerome R Lo-Ten_Foe, Albertus Timmer, Lolkje T W De Jong-Van den Berg, Jan G Aarnoudse, Eelko Hak. (Netherlands)
- 70 **Medications as a Potential Source of Exposure to Phthalates among Women of Childbearing Age [118]**
Sonia Hernandez-Diaz, Yung-Cheng Su, Allen A Mitchell, Katherine E Kelly, Russ Hauser. (United States)

Pregnancy/Lactation

- 71 Abstract Withdrawn by Author
- 72 An Analysis of Registries with Birth Defect Data Using an Online Database Resource [120]
Anokhi J Kapasi, Sharmila A Kamani, Bao-Anh Nguyen-Khoa, Earl L Goehring Jr., Varinder P Singh, Judith K Jones. (United States)
- 73 Maternal Prenatal and Parental Postnatal Stress in a Cohort of Depressed Women and Their Partners [121]
Fatiha Karam, Odile Sheehy, Anick Berard, Anick Berard. (Canada)
- 74 Pregnancy Among Users of Antimuscarinic Drugs Indicated for the Treatment of Overactive Bladder [122]
Barbara K Kremer, Shung-Ping Quan, Vaishali Patadia. (United States)
- 75 Pharmacotherapy in Pregnancy and the Puerperium; Trends from a National Health Care Utilization Survey [123]
Mary K Maneno, Euni K Lee, Anthony K Wutoh, Gloria K Nichols-English. (United States)
- 76 Fertility Rates in Women with Chronic Inflammatory Disease: A Population Based-Cohort Study [124]
Janet F McLaren, Kevin Haynes, Kurt T Barnhart, Mary D Sammel, Brian L Strom. (United States)
- 77 Chronic Medical Conditions Influence Prescribing of Antibiotics in Pregnancy [125]
Wilhelmine H Meeraus, Irene Petersen, Ruth Gilbert. (United Kingdom)
- 78 To Detect All Cases of Drug Induced Malformations in an Obstetrics Ward: A 3 Month Study in a Private Hospital in Delhi, India [126]
Chetan Mehndiratta, Pipasha Biswas. (India)
- 79 Use of NSAIDs and Other Mild Analgesics and Time to Pregnancy [127]
Ellen M Mikkelsen, Anders H Riis, Elizabeth E Hatch, Kenneth J Rothman, Lauren A Wise, Henrik T Sørensen. (Denmark)
- 80 The Xolair Pregnancy Registry (EXPECT): An Observational Study of the Safety of Omalizumab During Pregnancy in Women with Asthma [128]
Jennifer Namazy, Mary K Miller, Vivian Wang, Ari Gershman, Elizabeth Andrews. (United States)
- 81 Estimating Confidence Intervals in Pregnancy Registries: Simple Solution for Improving Precision [130]
William K Mountford, Deborah L Covington. (United States)
- 82 Lifestyle Profile Among Women of Child-bearing Age According to Use of SSRI [131]
Mette Norgaard, Rikke B Nielsen, Reimar W Thomsen, Henriette T Horsdal, Finn B Larsen, Henrik T Sørensen. (Denmark)
- 83 Prenatal Exposure to Antibiotics and the Risk of Childhood Asthma [132]
Amanda Patrick, Colin Dormuth, Sonia Hernandez-Diaz, Anne Fuhlbrigge, Soko Setoguchi. (United States)
- 84 Environmental Scan of "Safe Medications During Pregnancy" Lists [133]
Stacey L Peters, Jasmine R Humphrey, Cheryl S Broussard. (United States)

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POSTER SESSION A *Monday, August 15*

- 85 **Pregnancy and Prescribed Psychotropic Medicine in Primary Care [134]**
Irene Petersen, Ruth Gilbert, Stephen Evans, Irwin Nazareth. (United Kingdom)
- 86 **Concordance between Preconceptional and Periconceptional Vitamin/Folic Acid Supplementation and the Joint SOGC-MOTHERISK Clinical Guidelines [135]**
Audrey-Ann Richard-Tremblay, Odile Sheehy, François Audibert, Ema Ferreira, Anick Bérard. (Canada)
- 87 **Swine Flu Vaccination in Pregnancy and Associated Miscarriage Risk [136]**
Cormac J Sammon, Anita McGrogan, Julia Snowball, Corinne S de Vries. (United Kingdom)
- 88 **Trends in Anti-Infective Drugs Use During Pregnancy in Canada [137]**
Fabiano Santos, Odile Sheehy, Ema Ferreira, Sylvie Perreault, Anick Berard. (Canada)
- 89 **Quality Assessment of Clinical Practice Guidelines for the Prescription of Antidepressant Drugs During Pregnancy [138]**
Fabiano Santos, Ivan Sola, David Rigau, Ingrid Arevalo-Rodriguez, Pamela Seron, Pablo Alonso-Coello, Anick Berard, Xavier Bonfill. (Canada)
- 90 **Health Professionals Ask for Unifying Risk Minimization Programs on Teratogenic Agents [139]**
Hirokuni Beppu, Akira Kokan, Kiyoshi Kubota, Toshiaki Nakamura, Takao Orii, Tsugumichi Sato, Kiichiro Tsutani. (Japan)
- 91 **Pregnant Women Receiving Tetanus-Diphtheria-Acellular Pertussis (Tdap) Vaccine: 6 Years of Adacel Vaccine Pregnancy Registry Data [140]**
Min Wang, Alena Khromava, Asif Mahmood, Najla Dickson. (United States)

Respiratory

- 92 **Inhaled and Intranasal Corticosteroids and Behavioral and Psychiatric Problems: A Pharmacovigilance Analysis Using AERS Data [142]**
Ayad K Ali, Abraham G Hartzema. (United States)
- 93 **Epidemiology of Pneumoconioses in the U.K. General Population [143]**
Rajeev K Amar, Susan S Jick, Daniel Rosenberg, Toby M Maher, Christoph R Meier. (Switzerland)
- 94 **Identification of Asthma and Chronic Obstructive Pulmonary Disease among Initiators of Long-Acting -Agonists in Health Insurance Claims Data [144]**
David D Dore, Najat Ziyadeh, Bin Cai, C Robin Clifford, Heather Norman, John D Seeger. (United States)

- 95 **Concomitant Asthma Medication Use in Patients Using Omalizumab: Results from Three Large Insurance Claims Databases [145]**
Marie-Helene Lafeuille, Mei Sheng Duh, Jie Zhang, Debra Wertz, Tao Gu, Jackson Tang, Patrick Lefebvre. (United States)
- 96 **Low Agreement between Current and Long-Term Asthma Control in Children: The PACMAN Cohort Study [146]**
Ellen Koster, Jan Raaijmakers, Susanne Vijverberg, Leo Koenderman, Dirkje Postma, Gerard Koppelman, Cornelis vd Ent, Anke-Hilse Maitland-van der Zee. (Netherlands)
- 97 **Asthma Symptoms in Pediatric Patients: Differences throughout the Seasons [147]**
Ellen S Koster, Jan A M Raaijmakers, Susanne J H Vijverberg, Anke-Hilse Maitland-van der Zee. (Netherlands)
- 98 **Prescribing Patterns of Combined Inhalers for Airway Disease Patients among Two Patient Populations in Taiwan [148]**
I-Wen Yu, Hsiang-Wen Lin, Wei-Erh Cheng. (Taiwan)
- 99 **Do Statins Improve Outcomes in Patients with Asthma on Inhaled Corticosteroid Therapy? A Retrospective Analysis of the Mississippi Medicaid Database 2002-2004 [149]**
Tasneem T Lokhandwala, Donna West-Strum, Benjamin F Banahan, John P Bentley, Yi Yang. (United States)
- 100 **Influence of Depression on Chronic Obstructive Pulmonary Disease (COPD) Exacerbations among Medicare Beneficiaries with and without Disability [150]**
Jingjing Qian, Linda Simoni-Wastila, Gail Rattinger, Ilene Zuckerman. (United States)
- 101 **Use of Anti-Asthmatic Drugs in Children Living in Poor Areas of an Urban Center of Northeastern Brazil: Prevalence and Associated Factors [151]**
Djanilson B Santos, Cinthia S Lisboa, Moema S Santana, Helena L L Coelho, Mauricio L Barreto. (Brazil)
- 102 **Blockers and Risk of COPD Exacerbation Requiring Hospitalisation in Patients with COPD [152]**
Ana Afonso, Katia M C Verhamme, Guy G O Brusselle, Miriam C J M Sturkenboom. (Netherlands)
- 103 **Assessing the Relationship between Combination Long-Acting Beta Agonist (LABA) and Inhaled Corticosteroid (ICS) Use and Serious Asthma Outcomes [153]**
Karen E Wells, Edward L Peterson, L Keoki Williams. (United States)

- 104 **Antidepressant and Antipsychotic Dispensing among Montelukast Initiators [154]**
Esther H Zhou, Sigal Kaplan, Andrew Mo-sholder, David Moeny, Yulan Ding, Tarek A Hammad. (United States)

Rheumatic

- 105 **The Association between Statin Use and Polymyalgia Rheumatica/Arteritis Temporalis: Demonstrated by Spontaneous Reports and Self-Described Case-Reports [155]**
Hilda J de Jong, Siti R Saldi, Olaf H Klungel, Rob J Vandebriel, Patrick C Souverein, Ron H Meyboom, Anneke Passier, Henk van Loveren, Jan Willem Cohen Tervaert. (Netherlands)
- 106 **Estimation of Rheumatoid Arthritis and Ankylosing Spondylitis Prevalence in France Using Data from a National Claims Database and a Cohort Study [156]**
Patrick Blin, Marie-Agnès Bernard, Régis Lassalle, Basmah Ambrosino, Thierry Schaevebeke, Annie Fourrier-Réglat, Bernard Bégaud, Jacques Bénichou, Cécile Droz-Perroteau, Nicholas Moore. (France)
- 107 **Angiotensin-Converting Enzyme Inhibitors or Angiotensin II Receptor Blockers and the Risk of Developing Rheumatoid Arthritis in Antihypertensive Patients [157]**
Hilda J de Jong, Rob J Vandebriel, Siti R Saldi, Liset van Dijk, Henk van Loveren, Jan Willem Cohen Tervaert, Olaf H Klungel. (Netherlands)

Poster Walk - Biologics SIG

- 108 **Comparison of Bevacizumab and Ranibizumab Adverse Event Reports in FDA-AERS [158]**
Pankdeep Chhabra, Behrooz Shamloo, Sheila Weiss Smith. (United States)
- 109 **An Analysis from the ICGG Gaucher Registry: A Report of Gaucher Patients Affected by Reduced Doses of Imiglucerase [159]**
Alexander Cole, Neal Weinreb, Barry Rosenbloom, Hans Andersson, Radhika Tripuraneni, Nadia Belmatoug. (United States)
- 110 **Clinical Outcomes of Imiglucerase after 10 Years of Treatment [160]**
Alexander Cole, Neal Weinreb, Manisha Balwani, Joel Charrow, Radhika Tripuraneni, Jacobo Villalobos, Marcelo Kerstenetzky, Carla Hollak. (United States)
- 111 **Validation of a Preliminary Administrative Claims-Based Algorithm for the Effectiveness of Medications for Rheumatoid Arthritis [161]**
Jeffrey R Curtis, John W Baddley, Shuo Yang, Nivedita Patkar, Lang Chen, Elizabeth S Delzell, Ted R Mikuls, Kenneth G Saag, Jasvinder Singh, Monika Safford, Grant W Cannon. (United States)

- 112 **Sunitinib (SU) Treatment (Trx) Patterns and Toxicity in Patients (Pts) with Advanced Renal Cell Carcinoma (RCC) in United Kingdom (UK) [162]**

Robert Hawkins, John Wagstaff, Paul Nathan, Sujata P Sarda, Francis Vekeman, Caroline Korves, Sonali Dasgupta, Sylwia O'Mara, Simon Fitton, Jayne Hayers, Christopher Tham, Andi Luka, Robert Wei, Andrew Mykletun, Maureen P Neary, Mei Sheng Duh. (United States)

- 113 **Patterns and Effectiveness of Bortezomib Use in Elderly Patients: The VESUVE Cohort [163]**

Annie Fourrier, Thierry Facon, Pernelle Noize, Jean Paul Fermand, Angela Grelaud, Alain Monnerieu, Emmanuelle Bignon, Jacques Benichou, Jérémy Jove, Miriam Sturckenboom, Régis Lassalle, Nicholas Moore, and the VESUVE Study Group. (France)

- 114 **Thiopurine Use and Persistence on Infliximab Therapy for Inflammatory Bowel Disease (IBD) [164]**

Kevin Haynes, James D Lewis, Mark T Osterman, Lang Chen, Saag Kenneth, Jeffery R Curtis. (United States)

- 115 **Incidence and Hazard of Infections in Rheumatoid Arthritis (RA) Patients Treated with Subsequent-Line (SL) Biologic Disease Modifying Antirheumatic Drugs (BIO) after Switching from First-Line (FL) Anti-Tumor Necrosis Factor (TNF) Agents [165]**

Stephen S Johnston, Adam Turpcu, Nianwen Shi, Dalia Moawad, Kimberly Alexander. (United States)

Poster Walk - Medications in Pregnancy SIG

- 116 **Chronic Paracetamol Use During Pregnancy and the Risk of Asthma in Offspring [166]**

Ane Birgitte T Andersen, Rune Erichsen, Dóra K Farkas, Vera Ehrenstein, Henrik T Sørensen. (Denmark)

- 117 **The Association between Drospirenone and Hyperkalemia among Women Taking Oral Contraceptives [167]**

Steven Bird, Xinyue Liu, Salvatore Pepe, James Brophy, Mahyar Etminan, Joseph Delaney. (United States)

- 118 **Medically Assisted Reproduction (MAR), Including Ovulation Stimulators, and the Risk of Major Congenital Malformations: The AtRISK Study [168]**

Sonia Chaabane, Odile Sheehy, Lucie Blais, William Fraser, François Bissonnette, Valérie Désilets, Patricia Monnier, Seanglin Tan, Jaquetta Trasler, Anick Bérard. (Canada)

- 119 **Medications in Pregnancy Special Interest Group: Improving the Quality of Science and Expanding Knowledge [169]**

Deborah Covington, Kyna Gooden, Laura McKain. (United States)

- 120 **Isotretinoin Pregnancy Prevention Programme Implementation in the EEA: Survey [170]**

Ineke Crijns, Sabine Straus, Michiel Luteijn, Christine Gispén - de Wied, June Raine, Lolkje de Jong - van den Berg. (Netherlands)

- 121 **Oral Contraceptives and the Risk of VTE: Reanalysis of the EURAS/LASS Study [171]**

Juergen Dinger, Anita Assmann, Sabine Moehner. (Germany)

- 122 **Dose of Estrogen and Contraceptive Failure Rates of Combined Oral Contraceptives [172]**

Juergen Dinger, Kristina Bardenheuer, Thai Do Minh. (Germany)

- 123 **Use of Legally Prescribed Opioid Analgesics in Pregnant Women and Risk of Spontaneous Preterm Birth. A Population Based Cohort Study, Norway 2004-2008 [173]**

Marte Handal, Svetlana Skurtveit, Kari Furu, Marit Rønning, Anders Engeland. (Norway)

Poster Walk - Drug Utilization Research SIG

- 124 **Prescribing Trends in Angiotensin-Converting Enzyme Inhibitors and Angiotensin Receptor Blockers Use in Taiwan, 1998-2007 [174]**

Yi-Ting Chou, Chia-Hsueh Chang, Chuei-Wen Kuo, Mei-Shu Lai. (Taiwan)

- 125 **Concurrent Cardiovascular Medication Initiation among New Statin Users [175]**

J Bradley Layton, Virginia Pate, Abhijit V Kshirsagar, M Alan Brookhart. (United States)

- 126 **Characteristics and Patterns of Topical Calcineurin Inhibitor Use in Children [176]**

Angelika D Manthripragada, Simone P Pinheiro, Thomas E MacCurdy, Shahin Saneinejad, David J Graham. (United States)

- 127 **Utilization of Drug Therapy with Spironolactone in Patients Taking Drospirenone Versus Levonorgestrel [178]**

Salvatore Pepe, Xinyue Liu, Steven Bird, Joseph Delaney, James Brophy, Mahyar Etminan. (United States)

- 128 **Temporal Trends in Health Care Utilization Among 1-Year Old Vaccinees: Study Design Refinement for Vaccine Safety [179]**

Laura Polakowski, Jie Li, Greg W Daniel, Corrie Paeglow, Tom Puenpatom, Yun Lu, Alec Walker, M A Brookhart, Hector Izurieta. (United States)

- 129 **Increasing Use of Cephalosporins for First-Line Treatment of Acute Otitis Media among Children, 2000-2009 [180]**

Leah Sirkus, Virginia Pate, M Alan Brookhart. (United States)

- 130 **Measuring past Treatment Exposure in Cohort Studies [181]**

Caitlyn T Solem, Yan Wen, Stephanie Kirbach, Marc F Botteman, Mary Cifaldi. (United States)

- 131 **Cardiotoxic Cancer Therapies in Australia: Which Patients Are Assessed for Cardiac Function? [568]**

Christine Y Lu, Preeyaporn Srasuebku, Anna Drew, Katie Chen, Robyn Ward, Sallie-Anne Pearson. (Australia)

Stroke/VTE

- 132 **A Comparison of Incidence Rates of Stroke Estimated from Different Data Sources in the SOS Project [182]**

Tania Schink, Andrea Arfe, Ron Herings, Silvia Lucchi, Gino Picelli, Silvana Romio, René Schade, Lorenza Scotti, Huub Straatman, Frantz Thiessard, Vera E Valkhoff, Marco Villa, Miriam Sturckenboom, Edeltraut Garbe. (Germany)

- 133 **Thrombolytic Therapy for Acute Ischemic Stroke in Taiwan: A Nationwide Survey 2002-2006 [183]**

Hsieh Cheng-Yang, Ching-Lan Cheng, Yea-Huei Yang Kao, Ming-Liang Lai. (Taiwan)

- 134 **Angiotensin Converting Enzyme Inhibitor (ACEI)/Angiotensin II Receptor Blockers (ARB) and Pneumonia Risk among Stroke Patients [184]**

Chia-Lin Liu, Wen-Yi Shau, Chi-Shin Wu, Mei-Shu Lai. (Taiwan)

- 135 **Outpatient Risks of Venous Thromboembolism and Bleeding Following Hip and Knee Replacement Surgery [185]**

Elham Rahme, Kaberi Dasgupta, Susan R Kahn, Sasha Bernatsky, Greg K Berry, Mark Burman, Alain Cirkovic, Yves Laflamme, Ronald A Dimentberg, Youssef Habel, Celine Khodr. (Canada)

- 136 **Inpatient Risks of Venous Thromboembolism and Bleeding Following Hip and Knee Replacement Surgery [186]**

Elham Rahme, Kaberi Dasgupta, Susan R Kahn, Sasha Bernatsky, Greg K Berry, Mark Burman, Alain Cirkovic, Yves Laflamme, Ronald A Dimentberg, Youssef Habel, Celine Khodr. (Canada)

- 137 **The Association between Renal Disorder and Use of Radical Scavenger - Edaravone in Patients with Acute Cerebral Infarction with Japanese Medical Database [187]**

Hironori Sakai, Kunihiko Hayashi, Yutaka Kiyohara, Masahiro Kamouchi, Takanari Kitazono, Ikumi Fukuyama, Kazuo Minematsu. (Japan)

POSTER SESSION A *Monday, August 15*

- 138 **Erythropoietic-Stimulating Agents (ESAs) Are Not Associated with a Transient Risk of Deep Vein Thrombosis (DVT) in Myelodysplastic Syndromes (MDS)** [188]
Masayo Sato, Sheila R Weiss Smith, Amy Daviddoff, Maria R Baer, Xuehua Ke, Steven D Gore. (United States)
- 139 **Immunoglobulin Use and Thromboembolic Events** [189]
G Sridhar, M Menis, A E Wallace, G W Daniel, H Izurieta. (United States)

Utilization

- 140 **Concomitant Use of Cholinesterase Inhibitors and Anticholinergics** [191]
Denise M Boudreau, Onchee Yu, Shelly Gray, Marsha Raebel, Eric Larson. (United States)
- 141 **Use of Angiotensin-Converting Enzyme Inhibitors Is Not Associated with Decreased Pneumonia Risk** [192]
Sascha Dublin, Rod L Walker, Michael L Jackson, Jennifer C Nelson, Noel S Weiss, Lisa A Jackson. (United States)
- 142 **Polymorphisms of the LEP-, LEPR and HTR2C Gene Associated with Obesity and BMI Change in Patients Using Antipsychotic Medication in a Naturalistic Setting** [193]
Jochem G Gregoor, Jan van der Weide, Harriët M Looovers, Harold J van Meegen, Toine C Egberts, Eibert R Heerdink. (Netherlands)
- 143 **Drug-/Radiation-Induced Interstitial Lung Disease in the UK General Population: Incidence, Drug Use and Characteristics at Diagnosis** [194]
Rajeev K Amar, Susan S Jick, Daniel Rosenberg, Toby M Maher, Christoph R Meier. (Switzerland)
- 144 **Drug-Related Admissions and Hospital-Acquired Adverse Drug Events in Germany: A Longitudinal Analysis from 2003 to 2007 of ICD-10-Coded Routine Data** [196]
Juergen Stausberg, Joerg Hasford. (Germany)
- 145 **Mycobacterial Disease in Patients Who Use Anti-Tumor Necrosis Factor Therapy** [198]
Kevin L Winthrop, Roger Baxter, Liyan Liu, Bentson McFarland, Donald F Austin, Cara D Varley, LeAnn Radcliffe, Eric B Suhler, Dongseok Choi, James T Rosenbaum, Lisa J Herrinton. (United States)
- 146 **Pilot Swine Flu Vaccination Active Surveillance Study: Final Results** [199]
Deborah Layton, Moira Dryburgh, Brian Mantay, Tom M MacDonald, Saad A W Shakir, Isla S MacKenzie. (United Kingdom)

- 147 **Persistence and Subsequent Outcomes Associated with Antiplatelet Regimens Following Cerebral Infarction in the Tayside Stroke Cohort** [200]
Robert W V Flynn, Thomas M MacDonald, Gordon D Murray, Ronald S MacWalter, Alex S F Doney. (United Kingdom)
- 148 **Did the Fall of the Icelandic Banks Affect Psychotropic Drug Use in the Population?** [201]
Anna B Almarsdóttir, Áslaug D Karlsdóttir, Aðalsteinn Guðmundsson, Matthias Halldórsson, Sveinbjörn Gizurarson. (Iceland)
- 149 **Off-Label Use of Anticonvulsant Medications among Adult and Elderly Patients** [202]
Elisabetta Patorno, Rhonda Bohn, Peter Wahl, Gregory Daniel, Jun Liu, Helen Mogun, Sebastian Schneeweiss. (United States)
- 150 **Variation in Cardiovascular Prescription Drug Use across States** [203]
Yuexin Tang, Gang Fang, Dana M Newman, Elaine Nguyen, John M Brooks, Theresa Shireman. (United States)
- 151 **Utilization, Price and Spending of Anti-Tumor Necrosis Factor Biologics in the US Medicaid Program** [205]
Christopher B Atzinger, Jeff J Guo. (United States)
- 152 **Utilization of Antimicrobials for Systemic Use (J01) in the Clinical Centre University of Sarajevo (CCUS) and Differences of Utilization between Years 2003 and 2010** [206]
Begler Begovic, Lejla Begovic, Amra Cabaravdic. (Bosnia and Herzegovina)
- 153 **Utilization of Antithrombotic Agents in the Clinical Centre University of Sarajevo (CCUS) and Differences of Utilization between Years 2003 and 2010** [207]
Begler Begovic, Tarik Catic, Lejla Begovic, Amra Cabaravdic. (Bosnia and Herzegovina)
- 154 **Utilization of All Drugs and Using ATC/DDD Methodology like Tool for Creating Hospital List of Drugs** [208]
Begler Begovic, Tarik Catic, Lejla Begovic, Amra Cabaravdic. (Bosnia and Herzegovina)
- 155 **Trends in Utilization of and Spending on Benzodiazepines in the U.S. Medicaid Program: 1991-2009** [209]
Boyang Bian, Elizabeth Gorevski, Christina Kelton, Jeff Guo, Jill Martin Boone. (United States)
- 156 **Epidemiological Profile of Renal Transplant Patients on Immunosuppressive Maintenance Therapy, Brazil, 2000-2004** [210]
Maria das Graças Braga Ceccato, Augusto Afonso Guerra Jr, Odilon Vanni Queiroz, Gustavo Laine, Mariângela Leal Cherchiglia, Eli Iola Gurgel Andrade, Francisco de Assis Acurcio. (Brazil)

- 157 **Pediatric Antiretroviral Outpatient Drug Utilization in the US: Y2002 - Y2010** [211]
Stephen H Chang, David C Shih, Tracy Pham. (United States)
- 158 **Reimbursement Restriction Moderately Decreases Benzodiazepine Use in General Practice** [212]
Joëlle M Hoebert, Patrick C Souverein, Aukje K Mantel, Bert G M Leufkens, Liset van Dijk. (Netherlands)
- 159 **Treatment of Pediatric Epilepsy in Germany: Antiepileptic Drug Utilization in Children and Adolescents from 2004-2006** [213]
Michael Doerks, Ingo Langner, Ulrich Dittmann, Antje Timmer, Edeltraut Garbe. (Germany)
- 160 **Antidepressant Drug Prescribing in Children and Adolescents in Germany** [214]
Michael Doerks, Ingo Langner, Ulrich Dittmann, Antje Timmer, Edeltraut Garbe. (Germany)
- 161 **Substantial Geographic Variation in the Use of Tissue vs. Non-Tissue ACE Inhibitors among Elderly Patients after Acute Myocardial Infarction in the US** [215]
Gang Fang, Elizabeth A Chrischilles, John M Brooks, Barry L Carter, Jennifer G Robinson. (United States)
- 162 **Is the Switch to New Drugs Driven by Marginal Therapeutic Innovation?** [216]
Claudia Furtado, Rosalia Oliveira. (Portugal)
- 163 **Utilization of Antiepileptics Drugs in Portugal (2000-2009)** [217]
Ricardo Nunes, Rosalia Oliveira, Claudia Furtado. (Portugal)
- 164 **Outpatient Quinolone Use in France in 2007: Patterns of Use in the Different Geographic Regions** [218]
Adeline Gallini, Robert Bourrel, Florence Taboulet. (France)
- 165 **Does Hospital Consumption of Drugs Influence Pharmaceutical Use in the Community?** [219]
Adeline Gallini, Renaud Legal, Florence Taboulet. (France)
- 166 **Comparison of the Trends in Prevalence of Overweight among Adolescents on Antipsychotics to Non-Users from 2000 to 2009** [220]
Sameer R Ghate, Qayyim Said, Diana I Brixner, Mia Hashibe, Elizabeth Joy, Christina A Porucznik. (United States)
- 167 **Cross National Comparative Drug Utilization Studies Demonstrate Potential Efficiency Gains in Abu Dhabi** [221]
Mohammed Abuelkhair, Sahar Fahmy, Brian B Godman, Shajahan Abdu, Lars L Gustafsson. (Sweden)

- 168 **Combining Drug Utilisation and Health Policy Studies Demonstrates Multiple Supply and Demand Side Reforms Enhance Prescribing Efficiency; Implications for Future CNC Studies [222]**
Brian B Godman, Kristina Garuoliene, Catherine Sermet, Vera Vlahovic-Palcevski, Corrine Zara. (Sweden)
- 169 **Therapeutic Versus Actual Market Shares for Statins [223]**
Elizabeth Gorevski, Boyang Bain, Kelton Christina, Gou Jeff, Jill Martin-Boone. (United States)
- 170 **Utilization and Spending of Antifungal Agents in the U.S. Outpatient Medicaid Population: 1991-2009 [224]**
Vibha Desai, Teresa Cavanaugh, Jeff J Guo. (United States)
- 171 **Utilization, Price and Spending Trends for Serotonin-Norepinephrine Reuptake Inhibitors SNRI's in the U.S. Medicaid Program: 1991-2009 [225]**
Alberto Isla, Jeff J Guo, Alex C Lin, Christina M L Kelton. (United States)
- 172 **The Impact of Mandatory Health Insurance on Drug Utilization: Results from the Boston Area Community Health Survey [226]**
Susan A Hall, Carol L Link, Gretchen R Chiu, John B McKinlay. (United States)
- 173 **National Trends in Outpatient Asthma Treatment, 1997-2009 [227]**
Ashley Higashi, Shu Zhu, Randall Stafford, G Caleb Alexander. (United States)
- 174 **Risky NSAID Use in Adults with Osteoarthritis [228]**
Rachel Jawahar, Shibing Yang, Kate Lapane. (United States)
- 175 **Trend in the Utilization of Pharmacological and Non-Pharmacological Treatment Strategies in the Management of Newly Diagnosed Atrial Fibrillation Patients in the US [229]**
Arpit Kashyap, Chenghui Li. (United States)
- 176 **Use of Complementary and Alternative Medicine among Patients with Radiographic Confirmed Knee Osteoarthritis [232]**
Kate L Lapane, Megan Sands, Shibing Yang, Tim McAlindon, Charles B Eaton. (United States)
- 177 **Concurrent Use of High Risk Western Medications with Traditional Chinese Medicine: One Year Population-Based Study in Taiwan [233]**
Hsin-Hui Tsai, Hsiang-Wen Lin, Darren Toh, Chun-Ru Chien, Chin-Chuan Hung, Yun-Chung Hsaeh, Tsai-Chung Li. (Taiwan)
- 178 **The Pattern of Use of Anti-Depressant Drugs in a Pediatric Population in a US Managed Care Population [234]**
Sandra Lopez-Leon, Joan Fortuny, Estel Plana, Ying Zhu, Elena Rivero. (Spain)
- 179 **An Analysis of HRT Usage between 2000 and 2009 Using GPRD in the UK [235]**
Jakob Petersen, Jane Woolley, Dervla Mahoney. (United Kingdom)
- 180 **Prescription Trends for Oral Antihyperglycemic Drugs (OHDs) in Japan - The Influence of Drug Interaction Alerts Concerning Hypoglycemia in Using Dipeptidyl Peptidase-4 (DPP-4) Inhibitor [236]**
Daisaku Sato, Sachiko Masuda, Yasunori Sato, Hiromichi Kimura. (Japan)
- 181 **Health Care Resource Utilization Among Chinese and White Adults in the United States [237]**
Margaret McDonald, Jingying Zhou, Emily Rubinstein, Jack Mardekian. (United States)
- 182 **Health Care Resource Utilization Among Asian Indian and White Adults in the United States [238]**
Margaret McDonald, Jingying Zhou, Emily Rubinstein, Jack Mardekian. (United States)
- 183 **The Clinical and Economic Advantage of Ultrasound Guidance for Patients Undergoing Thoracentesis or Paracentesis [239]**
Catherine J Mercaldi, Stephan Lanes, Diku Mandavia. (United States)
- 184 **Patterns of Antimicrobials (AM) Usage in Surgical Infection Units in 5 Russian Cities [240]**
Alexander A Fokin, Svetlana A Ratchina, Roman S Kozlov, Vladimir M Mischenko, Ljubov L Kozhuhova, Boris V Berejansky, Olga V Pribitkova, Olesya V Latisheva, Alfia I Abubakirova, Elena V Korneva, Shamil H Palutin. (Russian Federation)
- 185 **Comparison of Consumption and Expenditures for Systemic Antimicrobials (AM) in ICUs of 6 Russian Cities [241]**
Alexander A Fokin, Svetlana A Ratchina, Roman S Kozlov, Vladimir M Mischenko, Ljubov L Kozhuhova, Boris V Berejansky, Eugeni K Samuilov, Nadejda A Zubareva, Alfia I Abubakirova, Elena V Korneva, Ekaterina V Eliseeva, Shamil H Palutin. (Russian Federation)
- 186 **Multiple Prescribers or Doctor Shopping? Opioid Use in Elderly Norwegians [242]**
C Neutel Neutel, Christian Berg, Svetlana Skurtveit. (Canada)
- 187 **Quantifying Usage of Potentially Addictive Medication in the Elderly [243]**
C Ineke Neutel, Svetlana Skurtveit, Christian Berg. (Canada)
- 188 **Prescribing Patterns of Antihypertensives by General Practitioners in a Semi Urban Area in South Eastern Nigeria [244]**
Nwabuogochukwu C Oreh, Cletus N Aguwa. (Nigeria)
- 189 **Self-Reported Use of Clinical Practice Guidelines by Prescribers of TNF Antagonists [245]**
Laura R Peppers, Brian Attig, Thomas C Eagle. (United States)
- 190 **Pattern of Use of Oral Antithrombotics from 1997-2004: A Population-Based Study [246]**
Alexander G Perry, Leah M Smith, Linda E Levesque. (Canada)
- 191 **Comparison between Aggregate- and Individual-Level Time-Trend Analyses To Evaluate Overall Effects of Medicare Part D on Use of Antipsychotic Medications [248]**
Jennifer M Polinski, M Alan Brookhart, Robert J Glynn, Sebastian Schneeweiss. (United States)
- 192 **Drug Discontinuation and Switching during the Medicare Part D Doughnut Hole [249]**
Jennifer M Polinski, William H Shrank, Haiden A Huskamp, Robert J Glynn, Joshua N Liberman, Sebastian Schneeweiss. (United States)
- 193 **Social Disparities in the Use of Prescription Medications: A Population-Based Approach [250]**
Dima Qato. (United States)
- 194 **Cardiovascular Drugs and Sex Differences in Adverse Drug Reactions Causing Hospital Admissions [251]**
Eline M Rodenburg, Bruno HC h Stricker, Loes E Visser. (Netherlands)
- 195 **Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in Europe: The SOS Project [252]**
René Schade, Vera Valkhoff, Silvana Romio, Martijn Schuemie, Federica Nicotra, Silvia Lucchi, Marco Villa, Gino Picelli, Tania Schink, Edeltraut Garbe, Huub Straatman, Ron Herings, Miriam Sturkenboom. (Netherlands)
- 196 **Use of Antiparkinsonian Drugs Among Patients with Parkinson's Disease in the United Kingdom [253]**
René Schade, Jeanne Dieleman, Miriam Sturkenboom. (Netherlands)
- 197 **Few Sex Differences in Use of Drugs for Secondary Prevention after Stroke. A Nationwide Observational Study [255]**
Maria Sjölander, Marie Eriksson, Eva-Lotta Glader. (Sweden)
- 198 **The Relationship Between Unfavourable Behaviour in the Ages 13-25 and Subsequent Use of Potentially Addictive Prescription Drugs in Norwegian Men and Women [256]**
Vidar Hjellvik, Marte Handal, Svetlana Skurtveit, Ingeborg Hartz. (Norway)

POSTER SESSION A *Monday, August 15*

- 199 **Rationale and Safety of Antimicrobial Fixed-Dose Combinations – A Study of Consumption Data in Latin America between 1999 and 2007** [257]
Katja Taxis, Peter G M Mol, Jonneke C Verdijk, Veronika J Wirtz. (Netherlands)
- 200 **Lifestyle Profile among Statin Users** [258]
Reimar W Thomsen, Rikke B Nielsen, Mette Norgaard, Henriette T Horsdal, Finn B Larsen, Henrik T Sorensen. (Denmark)
- 201 **Trends in the Consumption of Antidepressants, Anxiolytics, Hypnotics and Sedatives in Portugal, over the National Health Plan Period (2004-2010)** [259]
Carla Torre, Guerreiro José, Suzete Costa. (Portugal)
- 202 **Major Changes in Chemotherapy Regimens Administered to Breast Cancer Patients during 2000-2008** [260]
Myrthe P P van Herk-Sukel, Lonneke V van de Poll-Franse, Geert-Jan Creemers, Valery E P P Lemmens, Paul D van der Linden, Ron M C Herings, Jan Willem W Coebergh, Adri C Voogd. (Netherlands)
- 203 **Dermatologist Preferences for First-Line Therapy of Moderate-to-Severe Psoriasis in Healthy Adults** [261]
Joy Wan, Katrina Abuabara, Andrea B Troxel, Daniel B Shin, Abby S Van Voorhees, Bruce F Bebo, Jr., Gerald G Krueger, Kristina Callis Duffin, Joel M Gelfand. (United States)
- 204 **Clomiphene Citrate Utilization in the Netherlands 1998-2007** [262]
Hao Wang, Jolande J Land, Jens H J Bos, Marian K Bakker, Lolkje T W de Jong-van den Burg. (Netherlands)
- 205 **Use of Insulin Analogs in Pregnancy in the Netherlands 1998-2009** [263]
Hao Wang, Jens H J Bos, Lolkje T W de Jong-van den Berg. (Netherlands)
- 206 **Utilization of Antidepressants in Taiwan from 2000 to 2006** [264]
Chi-Shin Wu, Wen-Yi Shau, Yen-Chieh Lee, Yun-Ju Lai, Mei-Shu Lai. (Taiwan)
- 207 **Osteoporosis Treatment Patterns among Medicare Beneficiaries** [265]
Huifeng Yun, Jeffrey R Curtis, Robert Matthews, Meredith L Kilgore, Michael A Morrissey, Nicole C Wright, Kenneth G Saag, Elizabeth Delzell. (United States)
- 208 **Potentially Inappropriate Medication Use Among Older Adults in the USA in 2007** [266]
Yan-Jun Zhang, Wei-Wei Liu, Jeff J Guo, Jing-Bo Wang. (United States)
- 209 **Cost Consequence of Colchicine Approval in the U.S. Medicaid Programs** [267]
Yan-Jun Zhang, Christina M L Kelton, Jeff J Guo. (United States)
- 210 **The Risk of Myocardial Infarction and Opioids Use for Non-Cancer Pain: A Nested Case-Control Study in UK General Practice Research Database (GPRD)** [621]
Lin Li, Soko Setoguchi, Susan S Jick. (United States)
- 211 **Antipsychotic Drugs and Risk of Idiopathic Venous Thromboembolism: A Nested Case Control Study Using the GPRD** [300]
Chieko Ishiguro, Lin Li, Susan S Jick. (Japan)

END SESSION A

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Adherence

- 1 The "Temptation To Skip Therapy" (TEST) Scale as a Predictor of Adherence in Isoniazid Treated Patients [313]
Chinmay G Deshpande, Jane E Carter, Dr Scimeca, Cynthia Willey. (United States)
- 2 Comparison of Retention Rates of First Line Antiepileptic Drugs in Children in the UK [350]
Raphaëlle Beau, Ian Douglas, Evans Stephen, Tim Clayton, Liam Smeeth. (United Kingdom)
- 3 Discontinuation of Antidepressant Treatment in Sweden - A National Prescription Survey [351]
Makiko Nakagawa, Morten Andersen, Anders Sundström, Urban Ösby, Ulf Bergman. (Sweden)
- 4 Prescriptions of Antidepressants in Relation to the Discontinuation of Hormone Replacement Therapy [352]
Anna Citarella, Morten Andersen, Anders Sundström, Helle Kieler. (Sweden)
- 5 The Impact of Pharmacist on Patients' Adherence to Medication [353]
Josip Culig, Marcel Leppe, Jelena Boskovic, Arijana Mestrovic. (Croatia)
- 6 Adherence with Intravenous Zoledronic Acid and Ibandronate for Osteoporosis among U.S. Medicare Beneficiaries [354]
Jeffrey R Curtis, Hui Feng Yun, Robert S Matthews, Kenneth G Saag, Elizabeth Delzell. (United States)
- 7 Seizure Freedom Not Adversely Affected by Early Discontinuation of Concomitant Anti-Epileptic Drugs in the EULEV Cohort of Levetiracetam Users [355]
Cécile Droz-Perroteau, Cécile Marchal, Caroline Dureau-Pournin, Régis Lassalle, Jérémy Jové, Philip Robinson, Gilles Laverhne, Hervé Vespignani, Nicholas Moore, Annie Fourrier-Réglat. (France)
- 8 Effect of Complementary and Alternative Medicine Use on Adherence and Antiretroviral Therapy in Nigerian HIV/AIDS Patients [356]
Obinna Ekwunife, Stella Ugwuanyi, Ifeanyi Okwor. (Nigeria)
- 9 Prescribing Pattern and Adherence to Statin Therapy: Population-Based Study in Italian Primary Health Care [357]
Annalisa Capuano, Carmen Ferrajolo, Claudia Pagliaro, Innocenzo Lombardi, Carla Sirianni, Rosarita Ferrara, Michele Tari, Achille P Caputi, Francesco Rossi, Vincenzo Arcoraci. (Italy)

- 10 The Effect of Reimbursement System Versus Global Financial System on Persistence, Drug Cost and Commonly Prescribed of Lipid Modifying Agents [359]
Erna Kristin, Lili Komariah Darmawiredja, Iwan Dwiprahasto. (Indonesia)
- 11 Effectiveness of Adherence of Antihypertensive Agents after Ischemic Stroke [360]
Sylvie Perreault, Amy Y X Yu, Robert Côté, Alice Dragomir, Brian White-Guay. (Canada)
- 12 Estimation of Cessation Rates Among Danish Users of Benzodiazepines [361]
Henrik Stovring, Christiane Gasse. (Denmark)
- 13 Persistence to Antidepressants and Quality of Their Use in Adults Diagnosed with Major Depression in the Province of Quebec, Canada: A Cohort Study from 2005 to 2009 [363]
Mélanie Turgeon, Line Guénette, Éric Tremblay, Michel Gaudet. (Canada)
- 14 Reasons for and Time to Discontinuation of Rimonabant Therapy [364]
Marjolein J Willemen, Aukje K Mantel-Teeuwisse, Yvonne Buggy, Deborah Layton, Sabine M Straus, Hubert G Leufkens, Toine C Egberts. (Netherlands)

Databases

- 15 Development of a Mother-Child Database for Drug Utilization and Signal Detection in the Military Health System [365]
Lockwood G Taylor, Geoffrey E Gordon, David M Fram, Trinkia S Coster. (United States)
- 16 Performance of a Coding Algorithm to Identify Drug-Induced Liver Injury (DILI) in a Longitudinal Healthcare Claims Database [366]
Hoa V Le, Chi T Truong, Carlyne Averell. (United States)
- 17 Algorithms for Identification of Guillain-Barre' Syndrome in Claims Databases [367]
Donnie P Funch, Priscilla Veletgas, K Arnold Chan, Menactra Study Investigators. (United States)
- 18 Treatment Intensification in Insufficiently Controlled Diabetes Patients: Comparing Different Performance Measures [368]
Jaco Voorham, Petra Denig, Ronald P Stolk, Bruce H Wolffbuttel, Flora M Haaijer-Ruskamp, The GIANTT Group. (Netherlands)
- 19 For How Many and What Types of Drugs Can Longitudinal Healthcare Databases Detect Safety Signals? A View from the EU-ADR Project [369]
Preciosa M Coloma, Gianluca Trifirò, Martijn Schuemie, Rosa Gini, Ron Herings, Julia Hippisley-Cox, Giampiero Mazzaglia, Giovanni Corrao, Gino Picelli, Lars Pedersen, Johan van der Lei, Miriam Sturkenboom. (Netherlands)
- 20 A Pooled Analysis of Cohort Studies Comparing Risk of Acute Pancreatitis among Initiators of Exenatide and Other Antihyperglycemic Drugs in Two Commercial Health Insurance Claims Databases [370]
David D Dore, Mohamed Hussein, Clorinda Hoffman, Elise M Pelletier, Daniel B Smith, John D Seeger. (United States)
- 21 The Validity of Hypercalcemia and Hypocalcemia Diagnoses in Danish Registries [371]
Sussie Antonsen, Christian F Christiansen, Mette Nørgaard, Cathy W Critchlow, Henrik T Sørensen. (Denmark)
- 22 Algorithm To Improve the Validity of Administrative Database Identified Cases of Pancreatic Cancer and Thyroid Neoplasm [372]
Kwame Appenteng, Marmaduke Dale, Roberts John, Motsko Stephen. (United States)
- 23 Cancer Recording and Mortality in the General Practice Research Database and Linked Cancer Registry, Hospital and Death Certificate Data [373]
R Boggan, H Moller, A Gallagher, H Leufkens, T Hammad, H Zhang, T van Staa. (United Kingdom)
- 24 Linking Cancer Registry Records to THIN - A UK General Practice Database [374]
Tom Marshall, Hassy Dattani, Mary Thompson, Alison Bourke, Louise Pinder, Betina T Blak. (United Kingdom)
- 25 Abstract Withdrawn by Author.
- 26 Coding Algorithms for Defining Study Population in Database Studies; a Literature Review [376]
Suellen Curkendall, Hui Fang Liang, Helga Gardarsdottir, Arpit Misra. (United States)
- 27 Demographic and Clinical Characteristics of the Thelin Outcomes for Patient Surveillance (TOPS) Registry [377]
Cynthia de Luise, Michael J Louie, Lie-Ju Hwang, Christopher P Denton, Marius M Hoepfer. (United States)
- 28 Characteristics of Data Sources Used in Active Surveillance [378]
Cynthia de Luise, Andrew J Bate, Robert F Reynolds. (United States)
- 29 Direct to Patient Contact: An Added Value to Follow up Patients in Observational, Longitudinal Studies [379]
Sohela El Kebir, Sami Boussett, Karine Bloch, Florence Susini-Poulet, Benoit Soubeyrand, Xavier Fournie, Remi Gauchoux, Marlène Seux, Barbara Bougain, Yann Bourhis. (France)

POSTER SESSION B *Tuesday, August 16*

- | | | |
|--|---|--|
| <p>30 The Coding Quality of Acute Total Colectomy in Inflammatory Bowel Disease Patients in a Nationwide Hospital Registry [381]
<i>Rune Erichsen, Claus Sværke, Anders A Tøttrup. (Denmark)</i></p> <p>31 Quality of Urological Cancer Diagnoses in a Nationwide Hospital Registry [382]
<i>Henrik Gammelager, Christian F Christiansen, Martin B Johansen, Michael Borre, Marieke Schoonen, Henrik T Sørensen. (Denmark)</i></p> <p>32 Positive Predictive Value for an Algorithm Based on ICD 10 To Identify Osteonecrosis of the Jaw in Patients with Cancer [383]
<i>Henrik Gammelager, Rune Erichsen, Sussie Antonsen, Sven E Nørholt, Bjarne Neumann-Jensen, Henrik T Sørensen. (Denmark)</i></p> <p>33 Linking with Multiple State Cancer Registries for Safety Surveillance – Is It Feasible? [384]
<i>Alicia W Gilsenan, David Harris, Kirk D Midkiff, Jean Wright, Elizabeth B Andrews. (United States)</i></p> <p>34 Care Needed When Undertaking Drug Utilization Studies Using Commercial and Administrative Databases? [385]
<i>Brian B Godman, Kristma Garuohene, Jolanta Gulbinovic, Bjorn Wettermark (Sweden)</i></p> | <p>35 Dietary Habits and Subsequent Use of Psychotropic Drug Use in Adolescents – A Register Linkage Study [386]
<i>Ingeborg Hartz, Anne K Myhre, Furu Kari, Skurtveit Svetlana. (Norway)</i></p> <p>36 Pharmacovigilance Systems and Databases in Korea, Japan, and Taiwan [388]
<i>Tomomi Kimura, Yasuyuki Matsushita, Nam-Kyong Choi, Yea-Huei Kao Yang, Byung Joo Park. (Japan)</i></p> <p>37 Comparison of Methods To Define Lifestyle Risk Factors in the General Practice Research Database (GPRD) [389]
<i>Jamie T Laudati, Tzuyung D Kou, Kimberly A Wilson, Kimberly G Brodovicz, Cindy J Girman. (United States)</i></p> <p>38 Considerations on Sampling for Medical Chart Review in Pharmacovigilance Studies Using Healthcare Data [390]
<i>Haijun Ma, Jason Legg, Fei Xue. (United States)</i></p> <p>39 Managing Security and Privacy Concerns over Data Storage in Healthcare Research [391]
<i>Isla S Mackenzie, Brian J Mantay, Patrick G McDonnell, Li Wei, Thomas M MacDonald. (United Kingdom)</i></p> | <p>40 Comparison of Patients with and without Laboratory Results Available in a U.S. Claims Database [393]
<i>Laura N Horne, Eileen E Ming, Charles Doyle. (United States)</i></p> <p>41 Long-Term Safety Follow-Up of Patients Initiating Cladribine Tablets Therapy: Design of the RECORD MS Study and Pregnancy Registry [394]
<i>Montserrat Miret, Davorica Tomic. (Switzerland)</i></p> <p>42 Identification of Patients with Myocardial Infarction and Stroke Using Japanese Claims Database [395]
<i>Nobuhiro Ooba, Hiroshi Nishimura, Kiyoshi Kubota. (Japan)</i></p> <p>43 Finding Databases on Drug Utilization Information across Europe. What Kind of Data Do They Provide? [396]
<i>Mònica Sabaté, Elena Ballarín, Pilar Ferrer, Hans Petri, Joan Fortuny, Kah Lay Goh, Joerg Hasford, Joan-Ramon Laporte, Sam Yeboah, Luisa Ibáñez. (United Kingdom)</i></p> |
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- 44 Validation of Primary and Secondary ICD-9-CM Codes for Upper Gastrointestinal Complications in Friuli Venezia Giulia, Italy [397]
Federica Pisa, Daniela Drigo, Nuria Riera-Guardia, Jordi Castellsague, Valentina Rosolen, Elena Clagnan, Francesca Tosolini, Loris Zanier, Susana Perez-Gutthann, Fabio Barbone. (Italy)
- 45 Capture Rate of Electronically Available Laboratory Test Results in the Healthcare Integrated Research Database [398]
Danielle Potter, Laura Horne, David Kern, Mark Cziraky, Joseph Singer, Eileen Ming. (United States)
- 46 Comparison of Different Methods for the Calculation of Duration of NSAIDs Use Using Different Databases in the SOS Project [400]
Silvana A Romio, Vera E Valkhoff, Rene Schade, Martijn Schuemie, Edeltraut Garbe, Ron Herings, Silvia Lucchi, Federica Nicotra, Gino Picelli, Tania Schink, Huub Straatman, Marco Villa, Miriam C J M Sturkenboom. (Netherlands)
- 47 Agreement between Electronic Medical Records and Chart Review on Pharmacologic Prophylaxis for Venous Thromboembolism Among Patients with Total Joint Replacement [401]
Marc Rosenman, Xianchen Liu, Hemant Phatak, Teresa A Simon, Larry Z Liu, Susan Ofner, Evgenia Teal. (United States)
- 48 A UMLS-Based Approach for the Homogeneous Identification of Events in Seven European Health Databases: A Contribution to the Safety of NSAIDs (SOS) Project [402]
Frantz Thiessard, Fleur Mougin, Andrea Arfè, Edeltraut Garbe, Ron Herings, Silvia Lucchi, Federica Nicotra, Gino Picelli, Silvana Romio, René Schade, Tania Schink, Huub Straatman, Vera E Valkhoff, Marco Villa, Annie Fourrier, Miriam C J M Sturkenboom. (France)
- 49 Validation of Multiple Sclerosis Diagnosis and Exacerbation Using Automated Health System Data: A Necessary Step for Post-Marketing Research [403]
Marianne Ulcickas Yood, Sharon Hensley Alford, Allison Zarbo, Susan A Oliveria, Amanda Wilson, Jean Beck, Judy Kempf. (United States)
- 50 Cancer Identification in the General Practice Research Data Base [404]
A M Walker, J M Chandler, R Lubwama, N C Santanello. (United States)
- 51 Selecting an Appropriate Comparison Group: Characterizing Treated and Untreated Patients in the Pompe Registry [405]
Amanda B Wilson, Priya S Kishnani, Ans van der Ploeg, Alexander Cole. (United States)
- 52 Impact of the Quality Outcomes Framework on Hypertension Coding in GPRD [406]
Lesley H Wise, David Irvine, Motonobu Sakaguchi, Gregory Fusco. (United Kingdom)

Gastrointestinal

- 53 Performance of High Dimensional Versus Conventional Propensity Score Matching in a Study of Coxibs vs. Nonselective NSAIDs and Gastrointestinal Complications [407]
Edeltraut Garbe, Sebastian Kloss, Walter Schill, Marc Suling, Sebastian Schneeweiss. (Germany)
- 54 Evaluation of In-Hospital Clinical Outcomes with Alvimopan in Older and Younger Patients Undergoing Bowel Resection: Matched-Cohort National Database Study [408]
Amy W Rachfal, Suzanne F Cook, Christopher Craver, Michael Calloway, Lee M Techner. (United States)
- 55 Use of Nimesulide, Other NSAIDs and the Risk of Upper Gastrointestinal Complications in Friuli Venezia Giulia, Italy. Analysis of Cases with Codes with High Positive Predictive Value [409]
Jordi Castellsague, Federica Pisa, Valentina Rosolen, Nuria Riera-Guardia, Manuela Giangreco, Elena Clagnan, Francesca Tosolini, Loris Zanier, Fabio Barbone, Susana Perez-Gutthann. (Spain)
- 56 Is It Only an Ignorable Quality-of-Life Issue? - Medical and Drug Utilization for Irritable Bowel Syndrome in Taiwan [410]
Chi-Chien Hsu, Li-Chia Chen, Yen-Hsia Wen. (Taiwan)
- 57 The Epidemiology of Clostridium Difficile Infections at Kaiser Permanente [411]
Jennifer L Kuntz, Eric S Johnson, Marsha A Raebel, Amanda F Petrik, Xiuhai Yang, Karen Glenn, Micah L Thorp, Nancy Neil, David H Smith. (United States)
- 58 A Comparison of Incidence Rates of Upper Gastrointestinal Complications Estimated from Different Data Sources in the Safety of NSAIDs (SOS) [412]
Silvia Lucchi, Vera Valkhoff, Andrea Arfè, Edeltraut Garbe, Ron Herings, Federica Nicotra, Gino Picelli, Silvana Romio, René Schade, Tania Schink, Huub Straatman, Frantz Thiessard, Miriam Sturkenboom, Marco Villa. (Italy)
- 59 Statin Use and the Risk of Clostridium Difficile in Academic Medical Centers: A Matched Case Control Study [413]
Christine A Motzkus-Feagans, Amy L Pakyz, Ronald E Polk, Kate L Lapane. (United States)
- 60 Dose Escalation of Adalimumab (Humira®) in Patients with Crohn's Disease in Routine Clinical Practice in Quebec [414]
Amir Abbas Tahami Monfared, Tao Fan, Shuvayu Sen. (Canada)
- 61 Microbial Evaluation of Proton Pump Inhibitors and Risk of Pneumonia [415]
Sabine C A Meijvis, Marie-Claire A Cornips, Paul G Voorn, Patrick C Souverein, Douwe H Biesma, Hubert G M Leufkens, Ewoudt M W van de Garde. (Netherlands)

Hormones

- 62 The Safety of Oral Hormone Replacement Therapy: Final Results from the EURAS-HRT Study [416]
Anita Assmann, Klaas Heinemann, Juergen Dinger. (Germany)
- 63 Does Route of Administration for Estrogen Hormone Therapy Impact Risk of Venous Thromboembolism: Estradiol Transdermal System vs. Oral Estrogen-Only Hormone Therapy [417]
François Laliberté, Katherine Dea, Mei Sheng Duh, Kristijan H Kahler, Melanie Rolli, Patrick Lefebvre. (United States)
- 64 Use of Hormonal Contraceptives in Europe and in the USA: Comparative Data from the TASC Study [418]
Sabine Moehner, Juergen Dinger, Christian Franke. (Germany)

Infectious

- 65 Initiation of Biologic DMARDs and the Risk of Hospitalized Bacterial Infections in Patients with Rheumatoid Arthritis [419]
Carlos G Grijalva, Lang Chen, Elizabeth Delzell, John W Baddley, Timothy Beukelman, Marie R Griffin, Lisa Herrinton, Liyan Liu, Parivash Nourjah, Rita Ouellet-Hellstrom, Nivedita M Patkar, Daniel H Solomon, Kevin L Winthrop, Fenglong Xie, Kenneth G Saag, Jeffrey R Curtis. (United States)
- 66 Statin-Induced Muscle Toxicity: Exploration Using the UK General Practice Research Database - Recruitment [420]
Jennifer Campbell, Tjeerd P van Staa, Gerard McCann, Helen O'Meara, Munir Pirmohamed. (United Kingdom)
- 67 Proton Pump Inhibitor Use and the Risk of Clostridium difficile Infection by Route of Administration [421]
Vanessa Stevens, Jack E Brown, Ghinwa Dumyati. (United States)
- 68 Drug Utilization Patterns in Hepatitis C (HCV) Patients [422]
Shirin Ahmed, T Christopher Mast, Vinay Mehta, Jean Marie Arduino, Ying Su. (United States)
- 69 Five Years after a National Policy Change: A Survey of Malaria Treatment Among Vulnerable Citizens in Southern Nigeria [423]
Obehi A Akoria, Talmage Holmes. (Nigeria)
- 70 Utilization of an HIV Clinical Cohort Study To Validate Coronary Heart Disease Measurements Ascertained from Administrative Data [424]
Emily S Brouwer, Sonia Napravnik, Til Sturmer, M Alan Brookhart, Ross J Simpson, Michelle Flores Moore, Joseph J Eron Jr. (United States)

POSTER SESSION B *Tuesday, August 16*

- 71 **Linezolid Utilization in Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia [425]**
Aisling R Caffrey, Kalpana Gupta, Brian J Quilliam, Peter D Friedmann, Kerry L LaPlante. (United States)
- 72 **Disease Burden of Hospitalized Patients with Complicated Intra-Abdominal Infection (cIAI) in the US [426]**
Shih-Chen Chang, Paul A Newell, Marcelo Marotti, Leanne Gasink, Huiying Yang. (United States)
- 73 **The Changing Pattern of Epidemiology of Hepatocellular Carcinoma and Its Risk of HBV and HCV [427]**
Mohamed Abdallah Hamzawy. (Egypt)
- 74 **Hepatitis C Virus Surveillance Study among Primary Care Attention Clients in Mexico: A Public Health Opportunity for an Emerging Disease [428]**
Ana I Burguete-Garcia, Carlos Conde-Gonzalez, Ricardo Jimenez-Mendez, Yanet Juarez-Diaz, Elizabeth Meda-Monzon, Kirvis Torres-Poveda, Vicente Madrid-Marina. (Canada)
- 75 **A Preliminary Exploration of Social Determinants of Hepatitis C Infection in Mexico [429]**
Ricardo Jimenez-Mendez, Kirvis Torres-Poveda, Vicente Madrid-Marina, Beatriz Duarte-Gomez. (Canada)
- 76 **Treatment Course Completeness and Long-Term Outcomes - A Preliminary Study on Chronic Hepatitis B Treatment in Taiwan [430]**
Yun-Ting Lin, Li-Chia Chen, Yaw-Bin Huang. (Taiwan)
- 77 **Comparative Effectiveness of Fish Oil, Atorvastatin and Fibrates for Lowering Triglyceride Levels among HIV-Infected Patients [431]**
Wei Liu, Monica A Munoz, Joseph A C Delaney, Elizabeth Brown, Michael J Mugavero, Chris Matthews, Sonia Napravnik, James H Willig, Michael S Saag, Mari M Kitahata, Heidi M Crane. (United States)
- 78 **Antimicrobial Resistance in *Listeria monocytogenes* Isolates from Food and Human Sources, United States - 2000-2009 [432]**
Nkuchia M M'ikanatha, Daniel H Rice, Deepanker Tewari, Carol H Sandt, Kevin J Joyce, Fecilita Medalla, Russell Localio, Stanley Reynolds, Ebbing Lautenbach. (United States)
- 79 **Intervention Campaign (IC) Efficacy in Outpatients with Acute Tonsillopharyngitis (AT) in Smolensk Region [433]**
Svetlana A Ratchina, Vladimir M Mischenko, Elena V Bodyaeva, Alexander A Fokin. (Russian Federation)
- 80 **Fluoroquinolone Use and Risk of Achilles Tendon Rupture [434]**
David Moeny, Lockwood Taylor, Trinkia Coster. (United States)
- 81 **Adverse Drug Reactions to Antiretrovirals at Lagos University Teaching Hospital HIV Clinic Lagos South West Nigeria [435]**
Ibrahim Oreagba, Olalekan Agede, Titilope Adeyemo, Chioma Ejekam, Oloranti Opanuga, Sulaiman Akanmu, Sunday Olayemi. (Nigeria)
- 82 **Fluoroquinolone (FQ) Use and Resistance to *Pseudomonas aeruginosa* Among U.S. Academic Medical Centers [436]**
Amy Pakyz, Jin Lee, Spencer Harpe, Sofia Medvedev, Ron Polk. (United States)
- 83 **The Antiretroviral Pregnancy Registry: A 20th Anniversary Celebration [437]**
Hugh Tilson, Susan S Roberts, D Heather Watts, Karen Beckerman, Kenneth Dominguez, Andreas Piki, Fernando Scaglia, Bryan Baugh, William Haddad, Michael Peng, Aldo Trylesinski. (United States)
- 84 **Long-Term Survival in Recipients of Amphotericin B [438]**
S Schneeweiss, M DeCoske, K Belk, H Ferguson, A M Walker. (United States)
- 85 **Adverse Events in Patients with Chronic Hepatitis C [439]**
Sophie W Shen, Dessislava Dimitrova, Jasminda Wu, Patricia Hines, Andres Gomez-Camirero. (United States)
- 86 **Multiple Imputation: Application to a Global Avian Influenza Registry [440]**
Anna J Swenson, Christina D Mack, Nancy A Dreyer, Wiku Adisasmito, Ebum Bamgboye, Paul K S Chan, Richard Coker, Nazim Dogan, Viktor Gasimov, Wanna Hansaoworakul, Nelson Lee, Ahmet F Oner, Stephen Toovey, Mukhtiar Zaman. (United States)
- 87 **Association between Antidepressant Drugs and Cancer in the UK-Based General Practice Research Database: A Cohort Study [441]**
Adel Abou-Ali, Elizabeth M Kang, Simone Pinheiro, Tarek A Hammad. (United States)
- 88 **Relapse of Depressive and Anxiety Symptoms and Quality-of-Life in Pregnant Sers and Discontinued Users of Antidepressants: Results from the OTIS Antidepressants Study [442]**
Anick Bérard, Fatiha Karam, Odile Sheehy, Marie-Claude Huneau, Lucie Blais, Gerald Briggs, Mark Roth, Christina Chambers, Adrienne Einarson, Andrea Gaedigk, Sara H Riordan, Diana Johnson, Kelly Kao, Gideon Koren, Brigitte Z Martion, Janine E Polifka, Sharon Voyer-Lavigne, Lori Wolfe. (Canada)
- 89 **Using the Self Controlled Case Series Method To Assess the Risk of Myocardial Infarction in GPRD-Registered Users of Antipsychotic Agents [443]**
Ruth Brauer, Ian Douglas, Liam Smeeth. (United Kingdom)
- 90 **The Risk of Syncope in Patients with Insomnia: A Retrospective Cohort Study [444]**
Yingkai Cheng, Dale Marmaduke, Indiana Strobom, Curtis Chang. (United States)
- 91 **Risk of Cardiac Events in Patients Taking Atomoxetine; Results of a Matched Cohort Analysis [445]**
M Davies, D Layton, E Tong, S A W Shakir. (United Kingdom)
- 92 **Risk of Suicidality Events in Patients taking Atomoxetine; Results of a Matched Cohort Analysis [446]**
M Davies, D Layton, E Tong, S A W Shakir. (United Kingdom)
- 93 **Direct Cost of Schizophrenia in Quebec, Canada: An Incidence-Based Microsimulation Monte-Carlo Markov Model [447]**
Alice Dragomir, Jean-Eric Tarride, Jean-Francois Angers, Ridha Joobar, Guy A Rouleau, Sylvie Perreault. (Canada)
- 94 **Psychotropic Utilization in Portugal Mainland [448]**
Claudia Furtado, Mafalda Ribeirinho, Mariana Gaspar. (Portugal)
- 95 **Cardiovascular Treatment and Excess Mortality in Individuals with Schizophrenia [449]**
Christiane Gasse, Thomas M Laursen, Preben B Mortensen. (Denmark)
- 96 **Association between Impulse Control Disorders and the Use of Dopamine Agonists [450]**
Kari E Weddle, Jeff J Guo, Patricia R Wigle, Funmilayo O Ajayi. (United States)
- 97 **U.S. Trends in the Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder, 2000-2010 [452]**
Craig F Garfield, E Ray Dorsey, Shu Zhu, Ashley Higashi, Haiden A Huskamp, Rena Conti, Stacie B Dusetzina, G Caleb Alexander. (United States Minor Outlying Islands)
- 98 **Antidepressant Adverse Effects: Patient or Drug Specific? [453]**
Aaron J Katz, Wendy C Camelo, Stacie B Dusetzina, Alan R Ellis, Joel F Farley, Til Sturmer, Bradley N Gaynes, Richard A Hansen. (United States)
- 99 **Potential Determinants of Suicidal Ideation and Suicide Attempt in Users of Duloxetine [454]**
Deborah Layton, Edward Tong, Mohammad Al-Shukri, Saad A W Shakir. (United Kingdom)

Neurologic

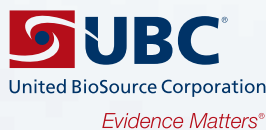
- 100 Use and Effectiveness of Neuroleptics and Related in Huntington's Disease: A Prospective Cohort Study of the Huntington French Speaking Group [455]**
Gaëlle Desamericq, Guillaume Dolbeau, Alexandra Durr, Christophe Verny, Jean-Philippe Azulay, Pierre Krystkowiak, Christine Tranchant, Cyril Goizet, Philippe Damier, Frédéric Suplot, Emmanuel Broussolle, Jean-François Demonet, Rose-Marie Marie, Marc Verin, Anne-Catherine Bachoud-Lévi, Patrick Maison. (France)
- 101 Road Traffic Accidents and Psychotropic Medication Use in the Netherlands: Results from a Case-Control and a Case-Crossover Study [456]**
Silvia Ravera, Nienke van Rein, Johan J de Gier, Lolkje T W de Jong - van den Berg. (Netherlands)
- 102 Migraine in Patients with Rosacea [457]**
Julia Spoendlin, Cornelia Schneider, Susan S Jick, Christoph R Meier. (Switzerland)
- 103 Evaluating the Effectiveness and Side Effects of Antipsychotics: The Factor Structure of the Subject's Response to Antipsychotics (SRA) Questionnaire [458]**
Katja Taxis, Irene Lako, Huib Burger, Hendrikus Knegtering, Hugo Wolters, Durk Wiersma, Richard Bruggeman. (Netherlands)
- 104 Risk of Extrapyrimal Syndrome in Schizophrenic Patients Treated with Second-Generation Antipsychotics [459]**
Shu-Yu Yang, Shih-Ku Lin, Wen-Yi Shau, Yi-Hsin Yang. (Taiwan)
- 105 Levels of Knowledge about the RISKS and Safe Use of OxyContin® among OxyContin Prescribers [460]**
Paul M Coplan, Ann Kline, Jared Downing, Howard Chilcoat. (United States)
- 106 Comparative Evaluation of Two Drug Interaction Screening Programs in 484 Neurological Inpatients [461]**
O Zorina, P Hauéis, A Semmler, I Marti, R Gonzenbach, M Guzek, G Kullak, M Weller, S Russmann. (Switzerland)
- 107 Evaluation of Drug-Drug Interaction Screening Software Associated with Pharmacist Intervention [462]**
Cristiano S Moura, Nilia M Prado, Luana A Santos, Ludmila S Tavares, Jessica O Bomfim, Priscilla N Porto, Francisco A Acurcio. (Brazil)
- 108 Development of Prescribing Safety Indicators for General Practitioners Using RAND Appropriateness Methods [463]**
Anthony J Avery, Stephen M Campbell, Grant Dex, Caroline Mulvaney, Brian Serumaga, Rachel Spencer, Helen Lester. (United Kingdom)
- 109 Attitudes among Nurses in Sweden and Factors for Their Reporting of Adverse Drug Reactions [464]**
Martin Backstrom, Elizabet Ekman. (Sweden)
- 110 Compliance to National Guidelines for Pharmaceutical Treatment of Sleeping Disorders among Elderly Incident Patients in Sweden [466]**
Kerstin Björkman Lundberg, Philip Johansson, Maj Carlsson, Anna Lemar, Lena Alsén-Melin, Helene Manger, Ulrika Whiss, Andrej Leimanis, Mikael Hoffmann. (Sweden)
- 111 Analyzing the Effectiveness of the Food and Drug Administration Risk Evaluation and Mitigation Strategies Using the FDA Adverse Event Reporting System Database [468]**
Stephanie Chung, Pamela Ohman-Strickland, Robin Samet. (United States)
- 112 Effectiveness of Risk Communication for the Management of Suicidal Behaviour in Youth Treated with Antidepressants [469]**
A M Cloutier, B Greenfield, M Tournier, L Lynd, MJ Brabant, A Lavoie, Y Moride. (Canada)
- 113 Contraception with Isotretinoin: A Drug Utilisation Study [470]**
Ineke Crijns, Nienke van Rein, Christine Gispen - de Wied, Sabine Straus, Lolkje de Jong - van den Berg. (Netherlands)
- 114 Pregnancy Prevention Programme of Isotretinoin and the Adherence of Dermatologists [471]**
Ineke Crijns, Eldridge Pinas, Christine Gispen - de Wied, Sabine Straus, Lolkje de Jong - van den Berg. (Netherlands)
- 115 Time Series Analysis of the Effect of Safety Warnings on Prokinetic Drug Prescriptions in Children [472]**
Sandra de Bie, Katia M C Verhamme, Miguel Gil Garcia, Gino Picelli, Sabine M J M Straus, Belen Oliva, Bruno H C Stricker, Adriana Ceci, Francisco J de Abajo, Miriam C J M Sturkenboom. (Netherlands)
- 116 Effects of Regulatory Interventions in Response to Rotavirus Vaccine Contamination with Porcine Circovirus DNA Fragments [473]**
David D Dore, Bruce R Turnbull, John D Seeger. (United States)
- 117 The Quality of Initial Pharmacotherapy for Children with Bipolar I Disorder [474]**
Stacie B Dussetzina, Bradley N Gaynes, Morris Weinberger, Joel F Farley, Betsy Sleath, Richard A Hansen. (United States)
- 118 MIHARI - Medical Information for Risk Assessment Initiative Year 2 [475]**
Ayumi Endo, Chieko Ishiguro, Eiko Tada, Maki Noguchi, Kazuhiro Matsui. (Japan)
- 119 Evaluating Patient Understanding of Written Information Provided with Prescription Medications [476]**
Michelle D Ertischek, Sidney H Schnoll, Karen K Gerlach, Mark A Sembower, Saul Shiffman. (United States)
- 120 Pregabalin Is Not Used in Accordance with National Recommendations in Sweden - Analysis of Dosage and Treatment Order 2007-2010 [477]**
Catrin Furster, Lena Gustafsson, Anna Lindhé, Tove Tevell, Bo Palaszewski, Mikael Hoffmann. (Sweden)
- 121 Examination of Respondent Bias and Patient Characteristics in Multiple REMS Assessment Surveys [478]**
Alicia W Gilseman, Kelly Hollis, Laurie Zografos, Brian Calingaert, Elizabeth B Andrews. (United States)
- 122 Drug Utilisation Studies from Abu Dhabi Suggest Multiple Demand Side Measures Needed To Enhance Prescribing Efficiency; Implications for the Future [479]**
Mohammed Abuelkhair, Shajahan Abdu, Brian B Godman, Sahar Fahmy, Lars L Gustafsson. (Sweden)
- 123 Recent Policies To Enhance Prescribing Efficiency in Croatia; Their Impact and Future Guidance [480]**
Luka Voncina, Tihomir Strizrep, Brian B Godman, Vera Vlahovic-Palcevski. (Sweden)
- 124 Differences in the Influence of Prescribing Restrictions; Implications for Health Policy Interventions and Cost Savings [481]**
Brian B Godman, Björn Wettermark, Solveig Sakshaug, Christian Berg, Alan Haycox. (Sweden)
- 125 Recent Policies To Enhance Renin-Angiotensin Prescribing Efficiency in Europe; Implications for the Future [482]**
Luka Voncina, Brian B Godman, Vera Vlahovic-Palcevski, Marion Bennie, Iain Bishop. (Sweden)
- 126 Trends in Risk Evaluation and Mitigation Strategies (REMS) Approvals [483]**
Amanda Golembesky, Kajal Bhika, Laura McKain. (United States)
- 127 REMS Assessment Patient Surveys in Prescriber-Administered Products: Challenges and Opportunities [484]**
Amanda Golembesky, Kyna Gooden. (United States)
- 128 The Role of Epidemiology in Risk Evaluation and Mitigation Strategies (REMS) [485]**
Amanda Golembesky, Marilyn Whiteley, Margaret Richards. (United States)
- 129 Systematic Data Processing and Decision Making for Pharmacovigilance and Risk Management [486]**
Neal J Grabowski, Joanna F Haas. (United States)

Risk Management

POSTER SESSION B *Tuesday, August 16*

- 130 **Divergences between Reports in Scientific Journals and Newspapers on the Role of SSRIs in Suicide Risk: A Longitudinal Study in the Netherlands (NL) and United Kingdom (UK) - 2000-2009 [487]**
Juan F Hernandez, Aukje K Mantel-Teeuwisse, Ghislaine J M W van Thiel, Jan A M Raaijmakers, Toine Pieters. (Netherlands)
- 131 **Quinolones REMS Evaluation Surveys [488]**
Kelly Hollis, Brian Calingaert, Carolyn Sweeney, Mark Price, Susana Perez-Guthann, Elizabeth Andrews. (United States)
- 132 **A Comparison of Factors Influencing Patient Knowledge: Results across Selected REMS Surveys [489]**
Kelly O Hollis, Laurie Zografos, Mark Price, Alicia W Gilsenan, Elizabeth B Andrews, Brian Calingaert. (United States)
- 133 **REMS - A Feasible Approach To Assess Effectiveness [490]**
Ken Hornbuckle, Brande Ellis, Debra Gash, Meghan Jones, Amanda Mc Daniel. (United States)
- 134 **Defining a Risk Communication Framework [491]**
Ken Hornbuckle, Brande Ellis, Nayan Acharya. (United States)
- 135 **The Broad Use of Erythropoietic Stimulating Agents (ESA) for Myelodysplastic Syndromes (MDS) in the U.S. Is Not Consistent with Guidelines [492]**
Amy J Davidoff, Maria R Baer, Sheila Weiss Smith, Xuehua Ke, Jason M Bierenbaum, Franklin Hendrick, Diane L McNally, Steven D Gore. (United States)
- 136 **Quantitative Evaluation of Compliance with Recommendation for Sulfonylurea Dosage Co-Administered with DPP-4 Inhibitors in Japan [493]**
Tomomi Kimura, Kazuhito Shiosakai, Shinji Takahashi, Masahiko Kobayashi, Yasuaki Takeda, Motonobu Sakaguchi. (Japan)
- 137 **Knowledge, Perception and Practice of Pharmacovigilance Followed by Awareness in Pharmacovigilance and Its Impact on Indian Private Pharmacists in Delhi, India [494]**
Pradeep Kumar, Sonika Mehra. (India)
- 138 **Patient's Understanding for Commonly Used Over-the-Counter Analgesics and Cough Medications, and Impact of Basic Pharmacovigilance Awareness [495]**
Pradeep Kumar, Sonika Mehra. (India)
- 139 **Utilization of Prescription Drugs with Warnings of Suicidal Thoughts and Behaviors in the US and the US Department of Veterans Affairs (VA), 2009 [496]**
Jill E Lavigne, Anthony Au, Jiang Rong, Yu Wang, C B Good, Peter A Glassman, Francesca Cunningham. (United States)
- 140 **The Role of Governments in Drug Use Surveillance [497]**
Deirdre Lawrence, Sidney H Schnoll, Reginald V Fant, Karen K Gerlach. (United States)
- 141 **Changing Practice Formularies To Study the Comparative Safety and Effectiveness of Medicines: A Concept That Is Supported by the Public [498]**
Isla S Mackenzie, Li Wei, Thomas M MacDonald. (United Kingdom)
- 142 **Comparison of 6 Patient Information Leaflets (PILs) of Anti-Diabetic Drugs Marketed by Indian Companies with the Original SmPC from Innovator Companies [499]**
Chetan Mehndiratta, Pipasha Biswas. (India)
- 143 **How Effective Are Pictograms in Communicating Risk to Patients Who Drive under the Influence of Medicines? [500]**
Susana P Monteiro, René Huiskes, Julia van Weert, Liset van Dijk, Johan de Gier. (Netherlands)

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- 144 **The Effect of the MHLW Warnings on Anti-Influenza Drug Use in Japan [501]**
Maki Noguchi, Eiko Tada, Ayumi Endo, Chieko Ishiguro, Kazuhiro Matsui. (Japan)
- 145 **Actions of the National Regulatory Authorities in Developing Countries Following US FDA and EMA Safety Alerts on Rosiglitazone [502]**
Jude I Nwokike, Andy Stergachis. (United States)
- 146 **Drug Therapy Problems: Pharmacists Interventions and Outcomes in Lagos State General Hospitals South West Nigeria [503]**
Ibrahim Oreagba, Modupe Bakare, Bolanle Adeniran. (Nigeria)
- 147 **Specific Age Group-Drug Contraindication Related Clinical Decision Support in Computerized Provider Order Entry at Tertiary General Hospitals in Korea [504]**
Eun Park, Hyun Jung Shin, Soo Jin Kim, Jung Mi Kim, Byung Koo Lee. (Republic of Korea)
- 148 **Use Patterns and Concomitant Use of Isotretinoin and Contraceptive Agents before and after iPLEDGE Implementation [505]**
Simone P Pinheiro, Elizabeth M Kang, Laura A Governale, Esther H Zhou, Clara Y Kim, Tarek A Hammad. (United States)
- 149 **Assessment of the Registration Status, Availability, Utilization Pattern and Rationality of Fixed Dose Drug Combinations in Nepal [506]**
Arjun Poudel, Subish Palaian, Mohamed Izhah Mohamed Ibrahim, Pranaya Mishra. (Nepal)
- 150 **Ten Years of Regulation for Orphan Medicinal Products in the EU: Characteristics Associated with Marketing Authorisation [507]**
Michelle Putzeist, Harald E Heemstra, Aukje M Mantel-Teeuwisse, Christine C Gispén, Arno W Hoes, Jordi Llinares Garcia, Hubert G Leufkens. (Netherlands)
- 151 **A Different Type of Sampling Problem... Should We Be Concerned with the Use of Free Prescription Samples in Databases Research? [508]**
Matthew W Reynolds, Stephan Lanes. (United States)
- 152 **The Effect of Medication Verification at Hospital Admission by Pharmacy Technicians on Medication Discrepancies [509]**
Anneliene M Schimmel, Pierre M Bet, José Tamminga, Jacqueline G Hugtenburg. (Netherlands)
- 153 **Compliance Survey for Thalidomide Use in Japan (Part3); Text Data Analysis of Patients' Comments [510]**
Tatsuya Takagi, Yuko Shirakuni, Kousuke Okamoto, Chizuko Hattori, Nobuyasu Yamaguchi, Masao Nasu. (Japan)
- 154 **To Which Extent Does a Cohort of New Users of Weak Opioids Develop Persistent or Probable Problematic Opioid Use? [511]**
Svetlana Skurtveit, Kari Furu, Marte Handal, Petter Borchgrevin, Olav Fredheim. (Norway)
- 155 **Generalizability of Risk Evaluation and Mitigation Strategies (REMS) Effectiveness Evaluations [512]**
Danielle J Smith, Almut G Winterstein, Mary Willy, Claudia Karwoski. (United States)
- 156 **A Programme for Drug Control of Thalidomide in Brazil [513]**
Nair R Souza, Francisco Paumgarten. (Brazil)
- 157 **Post-Marketing Safety-Related Regulatory Actions of Same Class Drugs [514]**
Gudrun Stefansdottir, Marie L De Bruin, Mirjam J Knol, Diederick E Grobbee, Hubert G M Leufkens. (Netherlands)
- 158 **The Effect of the MHLW Regulatory Actions on Thiamazole Use in Japan [515]**
Eiko Tada, Maki Noguchi, Chieko Ishiguro, Ayumi Endo, Kazuhiro Matsui. (Japan)
- 159 **Pain Management: A Public Health Challenge [516]**
Phillipe Bertin, Marie Auges, Nora Rahhali, Charles Taieb. (France)
- 160 **Fatigue Management: Example at Women Working in Pharmacy [517]**
Charles Taieb, Nora Rahhali, Marie Auges. (France)
- 161 **The B-Confident Registry: The Largest Ever Cohort of Patients with Cryopyrin Associated Periodic Syndromes (CAPS) and Post-Approval Study of a New Therapy. Presented on Behalf of the CAPS Registry Steering Committee (Kuemmerle-Deschner J, Rothenbacher D, [518])**
Hugh H Tilson. (United States)
- 162 **The Interaction between Gender and Severity of Prescription Drug Abuse Among College Students on Ability to Correctly Identify Photos of Recently Abused Drugs [519]**
Anna M Wheat, Jonathan M Davis, Becki Bucher-Bartelson, Richard C Dart. (United States)
- 163 **Update on REMS Evaluations: What Have We Learned? [520]**
Mary Willy, George Nevarapally, Adam Kroetsch, Claudia Karwoski. (United States)
- 164 **Post-Marketing Pharmacoepidemiology Study Assessing Prolia® Global Safety [521]**
Fei Xue, Haijun Ma, Amy Xia, Sam Jackson, Andre Daniels, Leonid Katz, Leonid Katz, Andreas Grauer, Cathy Critchlow. (United States)
- 165 **External Comparator Data for the Observational Post-Marketing Safety Surveillance Registry of Enbrel® (Etanercept) for the Treatment of Psoriasis - A Single-Arm Registry Study [522]**
Mellissa Yong, Jennifer Schenfeld, Kara Creamer, Yifei Shi, Girish Aras, Mary S Anthony. (United States)
- 166 **Improving Survey Response Rate in Assessing UK General Practitioners' Varenicline Prescribing Practices: Lessons Learned from a Pilot Survey [523]**
Muhammad Younus, Kenneth R Petronis, Harshvinder Bhullar, Xiaofeng Zhou, Shobhna Korla, Michelle Hards, Jingping Mo. (United States)
- 167 **Risk Minimisation Activities of Centrally Authorised Products in the European Union: A Descriptive Study [524]**
Ingeborg M Zomerdijk, Fakhredin A Sayed-Tabatabaei, Gianluca Trifirò, Stella C F Blackburn, Miriam C J M Starckenboom, Sabine M J M Straus. (Netherlands)

Poster Walk - Databases SIG

- 168 **Using Observational Databases to Better Inform and Plan Clinical Trials: The Clinical Trial Planning Toolkit [525]**
Jennifer B Christian, Samantha A St. Laurent, Charlotte F Carroll, Hoa V Le, Chi T Truong, Rose G Snipes, Amit Shukla, John W Logie, David A Webb. (United States)
- 169 **A Comparison between Prescribing in THIN Data and Dispensing in England [526]**
Mary Thompson, Hassy Dattani, Alison Bourke, Sharon MacLachlan, David Lloyd, Sue Faulding. (United Kingdom)
- 170 **Agreement between COPD-Related Hospitalizations Identified Using Two Sources: General Practice Research Database (GPRD) and Linked Hospitalization Episode Statistics (HES) Data [527]**
Rachael L DiSantostefano, Richard Baxter, Hana Müllerova. (United States)
- 171 **Linkage of the General Practice Research Database (GPRD) with Other Data Sources [528]**
Arlene M Gallagher, Shivani Puri, Tjeerd P van Staa. (United Kingdom)
- 172 **Drug Safety Studies Using Cancer Registry Data: Confluence of Elements Impacting the Interview Response Rate [529]**
Kirk D Midkiff, David Harris, Alicia W Gilsenan, Yun Wu, Elizabeth B Andrews. (United States)

POSTER SESSION B *Tuesday, August 16*

173 **Missing Data Imputation in Electronic Health Databases: Development of a Longitudinal Model for Cardiovascular Risk Factors [530]**

Irene Petersen, James Carpenter, Catherine Welch, Kate Walters, Richard Morris, Ian White, Louise Marston, Irwin Nazareth. (United Kingdom)

174 **An Evaluation of the THIN Database in the OMOP Common Data Model [532]**

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

Poster Walk - Medical Devices SIG

175 **Identification of Serious Adverse Events in a Large Acupuncture Trial: Linkage and Agreement of Primary and Secondary Data [533]**

Frank Andersohn, Katja Wruck, Stefan N Willich, Claudia Witt. (Germany)

176 **Impact of Vagus Nerve Stimulation (VNS) Therapy on Clinical Outcomes and Costs in Medicaid Patients with Drug-Resistant Epilepsy [534]**

Mei Sheng Duh, Edward Faught, Annie Guérin, Sujata P Sarda, Thomas M Samuelson, Mark T Bunker, Bryan D Olin, Stanley D Jackson, Sandra L Helmers. (United States)

177 **Intrauterine Devices and the Risk of Uterine Perforations: Interim Results from the EURAS-IUD Study [535]**

Klaas Heinemann, Clare Barnett, Juergen Dinger. (Germany)

178 **Comparison of Negative Pressure Wound Therapy Utilization between Inpatient and Non-Inpatient Settings as Seen in Medicare Data [536]**

Mary E Ritchey, Veronica V Sansing, Richard Domurat, Thomas MacCurdy. (United States)

179 **Postmarketing Surveillance of Medical Devices [537]**

Dorian Villegas, Wendy Ye, Osas Ayela-Wangue, Fred Schneiweiss, Jeff Babuschak, Samuel Yonren. (United States)

180 **Implications of Definitions of Simultaneous and Staged Bilateral Total Knee Replacement (TKR) in Device Epidemiology for Medicare Beneficiaries [538]**

Soko Setoguchi, Melissa A Greiner, Ricardo Pietrobon, David Attarian, Scott Kelley, Sam Wellman, Kevin A Schulman, Michael Bolognesi. (United States)

181 **Trends in Pre-Market Application (PMA) Approval of Medical Devices in the USA [539]**

Cunlin Wang, Dale Tavis, Nelson Lu. (United States)

END SESSION B

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Cancer

- 1 **The Risk of Cardiovascular (CV) Events among Cancer Patients Treated with Bevacizumab, Sorafenib, and Sunitinib [618]**
David J Nimke, Noreen L Arnold, Jose R Vargas, Fei Shi, Jerzy E Tyczynski. (United States)
- 2 **Use of Metformin or Other Antidiabetic Drugs and Pancreatic Cancer: A Case-Control Analysis [619]**
Michael Bodmer, Claudia Becker, Susan S Jick, Christoph R Meier. (Switzerland)
- 3 **Macrogol Laxatives and Colorectal Cancer Risk [620]**
Rachel A Charlton, Julia M Snowball, Katherine Bloomfield, Corinne S de Vries. (United Kingdom)
- 4 **Incidence of Cerebrovascular Accidents in Men with Prostate Cancer [622]**
Catherine B Johannes, Elizabeth B Andrews, Lisa J McQuay, Mark W Frohlich, Robert B Sims. (United States)
- 5 **The Effect of Warfarin Use on the Risk of Prostate Cancer Death [623]**
Vicky Tagalakis, Hani Tamim, James A Hanley, Susan R Kahn, Mark Blostein. (Canada)
- 6 **Mortality Following Bone Metastasis and Skeletal-Related Events among Men with Prostate Cancer: A Population-Based Analysis of U.S. Medicare Beneficiaries, 1999-2006 [624]**
Nalini Sathikumar, Elizabeth Delzell, Michael A Morrissey, Carla Falkson, Mellissa Yong, Victoria Chia, Justin Blackburn, Tarun Arora, Meredith Kilgore. (United States)
Temporal Trends in Breast Cancer (BC)
- 7 **Survival by Race from the U.S. SEER Cancer Registry [625]**
Laura Chu, Lisa Wang, Mona Shing, Jamie Robinson, Wei Dong. (United States)
- 8 **Retrospective Analysis of US Employer Group Database To Determine Incidence of Liver Transplantation Due to Hepatocellular Carcinoma (HCC) [626]**
QuynhChau D Doan, Annette Beiderbeck, Prasanna L Kandukuri. (United States)
- 9 **Development of a Benefit/Risk Assessment Tool for Breast Cancer Chemoprevention [627]**
Andrew N Freedman, Binbing Yu, Mitchell H Gail, Joseph P Costantino, Barry I Graubard, Victor G Vogel, Garnet L Anderson, Wort McCaskill-Stevens. (United States)
- 10 **Adverse Drug Reactions Associated with Cytotoxic Antibiotics in Combination Chemotherapy Regimens [628]**
Kheirollah Gholami, Mahdieh Fazlollahi, Sanambar Sadighi, Gloria Shalviri, Molouk Hadjibabaie. (Islamic Republic of Iran)

- 11 **Risk of Meningioma among Users of High Doses of Cyproterone Acetate as Compared to General Population: Evidence from a Population-Based Cohort Study [629]**
Miguel Gil, Belen Oliva, Julia Timoner, Miguel A Macia, Veronica Bryant, Francisco J de Abajo. (Spain)
- 12 **Use of Automated Claims Data To Study the Effects of Herceptin and Lapatinib in Breast Cancer Brain Metastasis [630]**
Sharon Hensley Alford, Susan Oliveria, Sarah Landis, Karen Wells, Heather Dakki, Allison Zarbo, Marianne Ulcickas Yood. (United States)
- 13 **The Problem of Missing Data: Using Imputation Methods To Facilitate Oncology Outcomes Research across Four Databases [631]**
Edmund L Lau, Jason Legg, Heather N Watson, Duane Steffey, Fionna S Mowat, Michael A Kelsh. (United States)
- 14 **Use of Glucocorticoids and Risk of Re-Operation Due to Post-Surgical Bleeding in Breast Cancer Patients: A Danish Population-Based Cohort Study [632]**
Lone W Lietzen, Deirdre P Cronin-Fenton, Jens Peter Garne, Niels Kroman, Rebecca A Silliman, Timothy L Lash. (Denmark)
- 15 **Prevalence of Bone Metastases among Breast, Lung, and Prostate Cancer Patients [633]**
Meghan E Mitchell, Alikei Taylor, Kimberly Lowe, Wendy J Langeberg, Dominik D Alexander, Michael A Kelsh, Jean-Jacques Body. (United States)
- 16 **Liver Injury in Chemotherapy (CT)-Treated Cancer (CA) Patients (Pts) [634]**
Susan A Oliveria, Deborah Casso, Marianne Ulcickas Yood, Karen Wells, Sharon Hensley Alford, Michele Bortolini, Wei Dong, Lisa I Wang. (United States)
- 17 **Costs of Hospital Events in Patients with Metastatic Colorectal Cancer [635]**
Jetty A Overbeek, Zhongyun Zhao, Myrthe P P van Herk-Sukel, Beth L Barber, Sue Gao, Ron M C Herings. (Netherlands)
- 18 **Cardiovascular Comorbidities Among Patients with Metastatic Colorectal Cancer [636]**
Jetty A Overbeek, Zhongyun Zhao, Myrthe P P van Herk-Sukel, Beth L Barber, Sue Gao, Ron M C Herings. (Netherlands)
- 19 **Impact of Delayed Chemotherapy Induced Nausea and Vomiting on Quality of Life in Indonesian Patients with Gynecological Cancer [637]**
Dyah A Perwitasari, Jarir Atthobari, Mustofa Mustofa, Iwan Dwiprahasto, Mohammad Hakimi, Hans Gelderblom, Hein Putter, Johan W R Nortier, Henk-Jan Guchelaar, Ad A Kaptein. (Indonesia)

- 20 **Use of Glucocorticoids and Risk of Breast Cancer - A Danish Population-Based Case-Control Study [638]**
Gitte V Sorensen, Deirdre P Cronin-Fenton, Lars Perdersen, Sinna P Ulrichsen, Henrik T Sorensen, Timothy L Lash. (Denmark)
- 21 **The Risk of Cancer Associated with Angiotensin-II Receptor Blockers [639]**
Krishnan Bhaskaran, Ian Douglas, Stephen Evans, Tjeerd van Staa, Liam Smeeth. (United Kingdom)
- 22 **The Role of Comorbidity in the Uptake of Chemotherapy and Cancer Survival [640]**
Efty P Stavrou, Christine Y Lu, Sallie-Anne Pearson. (Australia)
- 23 **Burden of Infantile Hemangioma: Development of a Questionnaire [641]**
Charles Taieb, Jean Jacques Voisard, Fabrice Ruiz. (France)
- 24 **Occurrence of Myocardial Infarction, Ischemic Stroke and Pulmonary Embolism in Lung Cancer Patients [642]**
Myrthe P P van Herk-Sukel, Sumitra Shantakumar, Pieter W Kamphuisen, Christof J Majoor, Lucy I H Overbeek, Fernie J A Penning-van Beest, Ron M C Herings. (Netherlands)
- 25 **Record-Linkage for Pharmacoepidemiologic Studies in Cancer Patients [643]**
Myrthe P P van Herk-Sukel, Valery E P P Lemmens, Lonneke V van de Poll-Franse, Ron M C Herings, Jan Willem W Coebergh. (Netherlands)
- 26 **Occurrence of Co-Morbidities in Patients with Soft Tissue Sarcoma [644]**
Myrthe P P van Herk-Sukel, Sumitra Shantakumar, Lucy I H Overbeek, Hester van Boven, Fernie J A Penning-van Beest, Ron M C Herings. (Netherlands)
- 27 **Survival by Race and Time Period for Stomach Cancer (SC) Patients from the U.S. SEER Cancer Registry [645]**
Lisa Wang, Laura Chu, Mona Shing, Jamie Robinson, Wei Dong. (United States)
- 28 **Do ESAs Reduce Transfusion Need among Transfusion-Dependent Myelodysplastic Syndromes (MDS) Patients? [646]**
Sheila R Weiss Smith, Masayo Sato, Maria R Baer, Xuehua Ke, Steven D Gore, Amy Davidoff. (United States)

Diabetes

- 29 **Which Aspects of New Glucose Lowering Drugs Do Different Stakeholders Value? A Qualitative Study [647]**
Arna H Arnardottir, Flora M Haaijer-Ruskamp, Sabine M Straus, Pieter A de Graeff, Margje H Monster-Simons, Sigrid Piening, Peter G Mol. (Netherlands)

POSTER SESSION C *Wednesday, August 17*

- 30 **Synergistic Effect of Type 2 Diabetes (T2D) and History of Pancreatitis on Pancreatic Cancer Risk: A Retrospective Cohort Study from the General Practice Research Database (GPRD) [648]**
Kimberly G Brodovicz, Tzuyung D Kou, Charles M Alexander, Samuel Engel, Cynthia J Girman. (United States)
- 31 **Type II Diabetes Mellitus, Treatment, and Cardiovascular Disease Outcomes in a US Claims Database Population [649]**
Claudia S Cabrera, Charles Doyle, Magnus Petersson. (Sweden)
- 32 **Increased Risk of Hospitalisation with Corticosteroid Use in Patients with Diabetes and COPD [650]**
Gillian E Caughey, Adrian K Preiss, Agnes I Vitry, Andrew L Gilbert, Elizabeth E Roughead. (Australia)
- 33 **Diabetic Complications Associated with Oral Antidiabetics – A Case Study on Diabetic Pay-for-Performance Registry and Reimbursement Data in Taiwan [651]**
Li-Chia Chen, Ju-Huei Tseng. (United Kingdom)
- 34 **Diabetic Complications Associated with Thiazolidinediones Monotherapy – A Case Study on Diabetic Pay-for-Performance Registry and Reimbursement Data in Taiwan [652]**
Li-Chia Chen, Ju-Huei Tseng. (United Kingdom)
- 35 **Risk of Severe Dysglycemia among Outpatient Receiving Levofloxacin, Ciprofloxacin or Moxifloxacin in Taiwan [653]**
Hsu-Wen Chou, Wen-Yi Shau, Jen-Jyh Lee, Chia-Hsuei Chang, Mei-Shu Lai. (Taiwan)
- 36 **Prevalence and Lipid Profiles of Pre-Diabetes, Undiagnosed, and Diagnosed Type II Diabetes in US Adults [654]**
Jennifer B Christian, Nadya M Belenky, Charlotte F Carroll, Nancy E Bourgeois. (United States)
- 37 **Prevalence and Predisposing Factors for Self-Reported Recurrent Vaginitis in Type 2 Diabetes Mellitus [655]**
Susan Grandy, Kathleen M Fox, Elise Hardy. (United States)
- 38 **Prevalence and Predisposing Factors for Self-Reported Recurrent Urinary Tract Infections Among Adults with Type 2 Diabetes Mellitus [656]**
Susan Grandy, Kathleen M Fox, Elise Hardy. (United States)
- 39 **Risk Factors Associated with the Incidence of Vaginitis and Balinitis among Patients with Type 2 Diabetes in a Community Practice Setting in the UK [657]**
Andres Gomez-Caminero, Ishan Hirji, Susan Andersson, Niklas Hammar. (United States)
- 40 **Risk Factors Associated with the Incidence of Urinary Tract Infections among Patients with Type 2 Diabetes in a Community Practice Setting in the UK [658]**
Andres Gomez-Caminero, Ishan Hirji, Susan Andersson, Niklas Hammar. (United States)
- 41 **Initiation of ACE Inhibitors and Angiotensin Receptor Blockers in Elderly Patients Newly Treated for Type 2 Diabetes [659]**
Haithem Hamdi, Jocelyne Moisan, Jean-Pierre Grégoire. (Canada)
- 42 **Macro- and Micro-Vascular Outcomes by First Insulin Type in Uncontrolled Type 2 Diabetes [660]**
Gillian C Hall, Alex D McMahon, Dawn Carroll, Philip D Home. (United Kingdom)
- 43 **Thiazolidinediones and the Risk of Microvascular Disease [661]**
Rohini K Hernandez, Timothy L Lash, Cathy W Critchlow, Susan S Jick. (United States)
- 44 **Metformin or Other Antidiabetic Drugs and the Risk of Developing Alzheimer's Disease: A Population-Based Case-Control Study [662]**
Patrick Imfeld, Yolanda B Brauchli, Cornelia Schneider, Michael Bodmer, Susan S Jick, Christoph R Meier. (Switzerland)
- 45 **Intensive Education Program by Community Pharmacists To Improve Adherence to Self-Management in Type 2 Diabetes [664]**
Makiko Kusama, Yoshinori Yanagisawa, Mikio Sakakibara, Ataru Igarashi, Manabu Akazawa. (Japan)
- 46 **Anti-Diabetic Therapies and Cancer Risk among Type 2 Diabetes Patients in Taiwan – A Nationwide Nested Case-Control Study [665]**
Li-Chiu Wu, Chia-Hsuei Chang, Lee-Ming Chunag, Mei-Shu Lai. (Taiwan)
- 47 **Results of PriSMe, a French Cohort Pilot Study Investigating Multidisciplinary Care on the One-Year Improvement of Metabolic Syndrome [666]**
Angela Grelaud, Adeline Grolleau, Jean-Louis Demeaux, Abdelillah Abouelfath, Michel-René Boisseau, Régis Lassalle, Christian Toussaint, Cécile Droz-Perroteau, Philip Robinson, Henri Gin, Nicholas Moore. (France)
- 48 **Risk of Cancer in Patients on Insulin Glargine in Comparison to Those on Human Insulin: Results from a Large Population-Based Follow-Up Study [668]**
Rikje Ruiters, Loes E Visser, Myrthe P P van Herk - Sukel, Jan Willem W Coebergh, Harm R Haak, P H Geelhoed - Duijvestijn, Sabine M J M Straus, Ron M C Herings, Bruno H Ch Stricker. (Netherlands)
- 49 **Diabetes and the Risk of COPD [669]**
Cornelia Schneider, Susan S Jick, Ulrich Bothner, Christoph R Meier. (Switzerland)
- 50 **Lifestyle Profile among Users of Antidiabetic Treatments [672]**
Henriette T Horsdal, Sinna P Ulrichsen, Reimar W Thomsen, Mette Norgaard, Finn B Larsen, Henrik T Sorensen. (Denmark)
- 51 **Statin Prescribing in Patients with Newly Diagnosed Type 2 Diabetes Mellitus ± a Multilevel Analysis [673]**
Henrik Ohlsson, Mark Nielen, Liset Van Dijk. (Netherlands)
- 52 **First-Choice Medication for Diabetes: Are Best-Practice Messages Getting Through? [675]**
Margaret Williamson, Linda Klein, Magnolia Cardona-Morrell. (Australia)

Geriatrics

- 53 **Association Between Antidepressant Drugs and Cataracts in the UK-Based General Practice Research Database: A Cohort Study [677]**
Adel Abou-Ali, Elizabeth M Kang, Simone Pinheiro, Tarek A Hammad. (United States)
- 54 **Availability of Information about Old Persons in Public Assessment Reports and Summaries of Product Characteristics: An Analysis of 26 Recently Approved Drugs [678]**
Erna Beers, Paul A F Jansen, Toine C G Egberts, Hubertus G M Leufkens. (Netherlands)
- 55 **A Comorbidity Score To Predict Institutionalization in the Elderly Population as a New Tool for the Control of Confounding in Pharmacoepidemiologic Studies [679]**
Sarah-Gabrielle Beland, Yola Moride, Thierry Ducruet, Cara Tannenbaum, Michel Preville. (Canada)
- 56 **A Comorbidity Score To Predict Institutionalization Performs Better Than a Score To Predict Death in a Community-Dwelling Elderly Population [680]**
Sarah-Gabrielle Beland, Yola Moride, Thierry Ducruet, Cara Tannenbaum, Michel Preville. (Canada)
- 57 **Drug Related Problems among the Elderly Residents of Long-Term Care Facilities in Central Taiwan [681]**
Jyun-Hong Chen, Yea-Huei Kao Yang, Su-Mi Chen, Ker-Cheng Lin. (Taiwan)
- 58 **Patterns of Antipsychotic Use in the Community-Dwelling Demented Elderly Population: Impact of Regulatory Warnings [682]**
C Craig, C Tannenbaum, A Pariente, T Ducruet, Y Moride. (Canada)
- 59 **Polypharmacy in the Elderly [683]**
Negar Golchin, Scott Frank, Lisa Isham, April Vince, Sharon B Meropol. (United States)

- 60 Potentially Suboptimal Prescribing for Nursing Home Patients with Dementia [684]
Joseph T Hanlon, Xiaoqiang Wang, Sherrie L Aspinall, Steven M Handler, Roslyn A Stone, Mary Jo Pugh, Maurice W Dysken. (United States)
- 61 Risk of Acute Coronary Syndrome in Elderly Users of Antipsychotic Drugs: Nested Case-Control Study [685]
Bart C Kleijer, Huiberdina L Koek, Rob J van Marum, Paul A Jansen, Toine C Egberts, Eibert R Heerdink. (Netherlands)
- 62 Alzheimer's Disease and the Risk of Subsequent Stroke or Transient Ischaemic Attack: A Population-Based Nested Case-Control Analysis [686]
Patrick Imfeld, Yolanda B Brauchli, Markus Schuerch, Noah J Robinson, Susan S Jick, Christoph R Meier. (Switzerland)
- 63 Antiepileptic Drug Use in Community-Dwelling and Institutionalized Elderly: A Nationwide Study of over 1 300 000 Older People [687]
Kristina Johnell, Johan Fastbom. (Sweden)
- 64 Patient's Right to Self-Determination and Its Impact on All Cause Mortality Risk Estimates in Dementia Patients - A Observational Study Using General Practice Research Database (GPRD) [688]
Tzuyung D Kou, Edward A Bortnichak. (United States)
- 65 Treatment of Alzheimer Disease in Sweden 2006-2010. Incidence, Prevalence, and Duration of Drug Treatment - Trends and Regional Variation [689]
Håkan Larsson, Magnus W Bengtsson, Maria K Johansson, Anders Hernborg, Ulf Lindahl, Kristina Seling, Helena Schiöler, Mikael Hoffmann. (Sweden)
- 66 Risk of Atrial Fibrillation and Stroke Among Taiwan Osteoporosis Population: Alendronate vs. Calcitonin/Raloxifene Users [690]
Tzu-Chieh Lin, Yea-Huei Kao Yang, Chyun-Yu Yang. (Taiwan)
- 67 The Number of Prescribed Medication Patterns among the Elderly in Different Patient Populations in Taiwan [691]
Hsiang-Wen Lin, I-Wen Yu, Ting H Liu, Wen-Ling Lin, Chi-Hsueh Lin, Chun-Ru Chien. (Taiwan)
- 68 Therapeutic Failures and Adverse Drug Withdrawal Events Leading to Hospitalization among Older Outpatient Veterans [692]
Zachary A Marcum, Megan E Amuan, Joseph T Hanlon, Sherrie L Aspinall, Steven M Handler, Christine M Ruby, Mary Jo V Pugh. (United States)
- 69 Use of Proton Pump Inhibitors (PPI's) and H2 Antagonists (H2A) in Nursing Home (NH) Residents [693]
Eun S Noh, Saumitra Rege, Brian J Quilliam. (United States)
- 70 Drug Use Patterns and Predictors of Polypharmacy among Elderly, Community-Residing Persons in Hiroshima, Japan [694]
Kaori Nomura, Aaron B Mendelsohn, Makiko Kusama, Ataru Igarashi, Manabu Akazawa. (United Kingdom)
- 71 Statins and the Risk of AMD in a Large Health Organization in Israel [695]
Varda Shalev, Inbal Goldstein, Miri Srour, Gabriel Chodick. (Israel)
- 72 Less or More Cataracts in Alzheimer's Disease [696]
Michele Jara, Ling Zhang, Stephanie Tcherny-Lessenot, Wanju S Dai. (France)
- 73 Dementia and Risk of Adverse Warfarin-Related Events in the Nursing Home Setting [697]
Jennifer Tjia, Terry S Field, Kathleen M Mazor, Jennifer L Donovan, Abir O Kanaan, George Reed, Leslie R Harrold, Jerry H Gurwitz. (United States)
- 74 Risk of Non-Melanoma Skin Cancer in Elderly Patients with Alzheimer's Disease [698]
Jasmanda H Wu, Zhenchao Guo, Robert Berman, Vlad Coric, Sandeep Kumar, Maha Radhakrishnan. (United States)
- 75 Incidence of Alzheimer's Disease in the Elderly with Non-Melanoma Skin Cancer [699]
Jasmanda H Wu, Zhenchao Guo, Joshua R Steinerman, Sandeep Kumar, Robert Berman. (United States)
- 76 The Acetylation Phenotype and Drug Induced Hepatotoxicity in the Treatment of Tuberculosis in Children [700]
J At Thobari, R K Wardhani. (Indonesia)
- 77 NSAID Exposure and Risk of Acute Liver Failure Leading to Transplantation: Preliminary Results of the Study of Acute Liver Transplant (SALT) in 7 European Countries [701]
Ezgi S Gulmez, Séverine Lignot, Dominique Larrey, Corinne deVries, Susanna Perez-Guttham, Jean L Montastruc, Miriam Sturkenboom, Jacques Bénichou, Giampaolo Velo, Achille Caputi, Francesco Salvo, Fatima Hamoud, Sophie Micon, Régis Lassalle, Jérémy Jove, Georges P Pageaux, Yves Horsmans, Jacques Bernuau, Franco Bissoli, Bruno Stricker, Douglas Thorburn, Angelo Gatta, Estela Monteiro, Irene Vafadis, Aiden McCormick, Herold Metselaar, Emine Sen, Alison Nightingale, Patrick Blin, Nicholas Moore. (France)
- 78 Nonsteroidal Anti-Inflammatory Drugs Use and the Risk of Upper Gastrointestinal Adverse Events in the Patients with Liver Cirrhosis [702]
Chia-Hsui Chang, Hsi-Chieh Chen, Chuei-Wen Kuo, Mei-Shu Lai. (Taiwan)
- 79 Incidence of Clinical Types and Risk Factors for Drug-Induced Liver Injury (DILI) in a Large Longitudinal Claims Database [704]
Hoa V Le, Chi T Truong, Carlyne Averell. (United States)
- 80 Analyses in NHANES To Assess Background Liver Enzyme Elevation among Subjects with Select Diseases [705]
Robert Y Suruki, Heide A Stirnadel, Jennifer B Christian, Howard Chilcoat, Nancy E Bourgeois, Michael C Irizarry. (United States)
- 81 Anti-Alzheimer's Drugs: Hepatobiliary Toxicity, Data from the French Pharmacovigilance Database [706]
Géric Maura, Catherine Vallet, Imane Nouasria, Emmanuelle Herlem, Thierry Trenque. (France)

Methods

- 82 Goodness-of-Fit Criteria Help Identify the Correct Model for Time-Varying Drug Exposures [707]
Michal Abrahamowicz, Marie-Eve Beauchamp, Marie-Pierre Sylvestre. (Canada)
- 83 Performance of Summary Scores for Multi-Level Drug Exposures [708]
Patrick G Arbogast, Carlos G Grijalva, Ning Chen, Wayne A Ray. (United States)
- 84 Early Reallocation of Placebo Non-Responders in the Sequential Parallel Comparison Design; Consequences on Required Sample Size and Patient Weeks [709]
Ruud Boessen, Mirjam J Knol, Rolf H H Groenwold, Kit C B Roes. (Netherlands)
- 85 Comparison of Different Methods for Calculating Medication Exposure [710]
Denise Boudreau, Jessica Chubak, Paul Stang, Heidi Wirtz, Dustin Key, Michael VonKorff. (United States)
- 86 Power Calculation for Drug-Drug Interaction in Safety Studies [711]
Bing Cai, Xiaofeng Zhou, Andrew J Bate. (United States)
- 87 Different Approaches to Instrumental Variable Analysis of Antidiabetic Effect of Bezafibrate [712]
Bing Cai, Sean Hennessy, Dylan Small, James H Flory, Thomas R Ten Have. (United States)
- 88 Balance Measures for Propensity Score Methods: A Clinical Example on Beta-Agonist Use and the Risk of Myocardial Infarction [713]
Rolf H H Groenwold, Frank de Vries, Anthonius de Boer, Wiebe R Pestman, Frans H Rutten, Arno W Hoes, Olaf H Klungel. (Netherlands)

Hepatic

- 76 The Acetylation Phenotype and Drug Induced Hepatotoxicity in the Treatment of Tuberculosis in Children [700]
J At Thobari, R K Wardhani. (Indonesia)
- 77 NSAID Exposure and Risk of Acute Liver Failure Leading to Transplantation: Preliminary Results of the Study of Acute Liver Transplant (SALT) in 7 European Countries [701]
Ezgi S Gulmez, Séverine Lignot, Dominique Larrey, Corinne deVries, Susanna Perez-Guttham, Jean L Montastruc, Miriam Sturkenboom, Jacques Bénichou, Giampaolo Velo, Achille Caputi, Francesco Salvo, Fatima Hamoud, Sophie Micon, Régis Lassalle, Jérémy Jove, Georges P Pageaux, Yves Horsmans, Jacques Bernuau, Franco Bissoli, Bruno Stricker, Douglas Thorburn, Angelo Gatta, Estela Monteiro, Irene Vafadis, Aiden McCormick, Herold Metselaar, Emine Sen, Alison Nightingale, Patrick Blin, Nicholas Moore. (France)

POSTER SESSION C *Wednesday, August 17*

- 89 **Using a Tree-Structured Survival Method To Detect Drug-Drug Interactions [714]**
Liping Huang, Michael Peng. (United States)
- 90 **Back to the Future: Time Loops in Defining Study Populations [717]**
Stephan F Lanes, Kenneth J Rothman. (United States)
- 91 **Propensity Score (PS) Variable Selection with the High Dimensional PS (hd-PS) Algorithm as a Function of Cohort Size (CS), Exposure Prevalence (EP), and Outcome Incidence (OI) [718]**
Hoa V Le, Til Stürmer. (United States)
- 92 **Residual Covariate Imbalance Following Subclassification on Propensity Score in Comparison Groups with Large Differences in Sample Size [719]**
Nancy D Lin, John D Seeger, Eva Ng, David D Dore. (United States)
- 93 **A Comparison of Covariate Selection Approaches for Propensity Score (PS) Derivation [720]**
Robert J LoCasale, Cynthia J Girman, Edward A Bortnichak, Kimberly A Wilson, Richie Wyss, Til Sturmer. (United States)

- 94 **Detecting Propensity Score Misspecification with the Hosmer-Lemeshow Test: A Simulation Study [721]**
Mark Lunt. (United Kingdom)
- 95 **Randomized Policy Trials: A Powerful Tool for Drug Safety and Effectiveness [722]**
Isla S Mackenzie, Li Wei, Kenneth Paterson, Thomas M MacDonald. (United Kingdom)
- 96 **Experiences with the High Dimensional Propensity Score (hd-PS) Algorithm [723]**
Jeremy A Rassen, Sebastian Schneeweiss. (United States)
- 97 **Understanding Heterogeneity of Treatment Effects in Pragmatic Trials [724]**
Jodi B Segal, Carlos O Weiss, Ravi Varadhan. (United States)
- 98 **A Simple Automated Approach for Estimating the 95% Confidence Interval of an Incidence Rate [725]**
Xiaofeng Zhou, Bing Cai, Jamie Geier, Andrew Bate. (United States)

Pediatrics

- 99 **Off-Label Antidepressant Use in Children, Adolescents and Young Adults [726]**
Angela S Czaja, Robert Valuck. (United States)
- 100 **The Association of Ethnicity with Electronically Measured Adherence to Inhaled Corticosteroids in Children [727]**
Erwin C Vashbinder, Nordin Dahhan, Bart Wolf, Jan Zoer, Ellen Blankman, Diederik Bosman, Liset van Dijk, Patricia M L A van den Bemt. (Netherlands)
- 101 **Safety of Live Attenuated Influenza Vaccine (LAIV) in Children 2-18 Years, Vaccine Adverse Event Reporting System (VAERS), 2005-2010 [728]**
Penina Haber, Pedro L Moro, Claudia Vellozzi, Paige Lewis, Xin Yue, Karen Broder. (United States)
- 102 **Adherence to Antidepressant Treatment Among a Pediatric Population in a US Managed Care Population [729]**
Sandra Lopez-Leon, Joan Fortuny, Estel Plana, Ying Zhu, Elena Rivero. (Spain)

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- 103 **Hypothesis Generating Self-Controlled Analysis: Example in Childhood Vaccine Safety [730]**
Corrie E Paeglow, Gregory W Daniel, Laura Polakowski, M A Brookhart, Yun Lu, Jie Li, Tom Puenpatom, Hector Izurieta, Alexander M Walker. (United States)
- 104 **Factors Associated with High Levels of Exhaled NO in Children Using Asthma Medication [731]**
Susanne J H Vijverberg, Ellen S Koster, Leo Koenderman, Dirkje S Postma, Gerard H Koppelman, Cornelis K van der Ent, Jan A M Raaijmakers, Anke-Hilse Maitland-van der Zee. (Netherlands)
- 105 **How Long Do Children Stay on Antiepileptic Treatments in the UK? [732]**
Raphaelle Beau, Ian Douglas, Stephen Evans, Tim Clayton, Liam Smeeth. (United Kingdom)
- 106 **Acetaminophen-Associated Poisonings/Exposure Calls in Children [733]**
Syed Rizwanuddin Ahmad, Esther Zhou. (United States)
- 107 **Safety of Cough and Cold Medicines in Children in Taiwan [734]**
Ching-Lan Cheng, Yea-Huei Yang Kao, Swu-Jane Lin. (Taiwan)
- 108 **Utilization of Gastro-Intestinal Drugs in Children: Cohort Study in Three European Countries [735]**
Sandra de Bie, Katia M C Verhamme, Miguel Gil Garcia, Gino Picelli, Sabine M J M Straus, Belen Oliva, Bruno H C Stricker, Adriana Ceci, Francisco J de Abajo, Miriam C J M Sturkenboom. (Netherlands)
- 109 **Comparing Pulmonary-Related Outcomes for Newborn-Screened Versus Conventional-Diagnosed Infants with Cystic Fibrosis [736]**
Efe Eworuke, Almut G Winterstein. (United States)
- 110 **Prevalence of Morphine Use in Pediatric Inpatients in the US, 2008 [737]**
Tamar Lasky, Jay Greenspan, Frank R Ernst, Liliana Gonzalez. (United States)
- 111 **Off-Label Prescribing Patterns of Antidepressants in Children and Adolescents [738]**
Euni Lee, Anna Teschemaker, Rosemary Johann-Liang, Gina Bazemore, Martin Yoon, Kye-Sik Shim, Marlon Daniel, Jerome Pittman, Anthony K Wutoh. (United States)
- 112 **Adverse Drug Events Leading Children to Emergency Department, São Paulo, Brazil [739]**
Nicolina S Romano-Lieber, Eliane Ribeiro. (Brazil)

- 113 **Use of Prescribed and Non-Prescribed Medication in Children: Prevalence and Associated Factors [740]**
Djanilson B Santos, Paluzzi A Souza, Simone A Barreto, Helena L L Coelho. (Brazil)
- 114 **National Trends in Pediatric Use of Anticonvulsants: On and Off-Label [741]**
Allen R Tran, Zito M Julie, Safer J Daniel, Hundley Sarah. (United States)
- 115 **NSAID Use among Children in Europe in the SOS Project [742]**
Vera E Valkhoff, Rene Schade, Silvana A Romio, Martijn Schuemie, Edeltraut Garbe, Ron Herings, Silvia Lucchi, Federica Nicotra, Gino Picelli, Tania Schink, Huub Straatman, Marco Villa, Ernst J Kuipers, Miriam C J M Sturkenboom. (Netherlands)
- 116 **Age-Dependent Effectiveness of RSV Immunoprophylaxis [743]**
Almut G Winterstein, Christian Hampp, Paul Kubilis, Arwa Saidi. (United States)

Renal

- 117 **Active Safety Surveillance of Drug-Induce Liver or Kidney Injury That Associated with New Drugs [744]**
Mei-Shu Lin, Ro-Fang Pu, K Arnold Chan, Nen-Chung Chang, Churn-Shiouh Gau. (Taiwan)
- 118 **Impact of the Quality Outcomes Framework on Chronic Kidney Disease Coding in GPRD [745]**
Lesley H Wise, David Irvine, Motonobu Sakaguchi, Gregory Fusco. (United Kingdom)

Poster Walk - CER SIG

- 119 **Estimation of Treatment Effect beyond Disease Progression in a Metastatic Cancer Population: Examples from Two Observational Cohort Studies [746]**
E Dawn Flick, Charles E Barr, Darshan Dalal, Yong Mun, David Purdie, Wei Dong. (United States)
- 120 **Health Related Quality of Life as Confounder in Observational Studies for Localized Prostate Cancer [747]**
Jinghua He, Abraham G Hartzema, Almut Winterstein, Philipp Dahm. (United States)
- 121 **Cardiovascular Events after Prescription of NSAIDs - Updated Systematic Review of Pharmaco-Epidemiological Studies [748]**
Patricia McGettigan, David Henry. (Canada)
- 122 **The Establishment of the Canadian Network for Observational Drug Effect Studies (cNODES) [387]**
Samy Suissa, David Henry. (Canada)

- 123 **Accounting for Regional Variations in Medical Practice in Comparative Effectiveness Studies [749]**
Krista F Huybrechts, John D Seeger, Robert Glynn, Kenneth J Rothman, Jerry Avorn, Joyce Lii, Sebastian Schneeweiss. (United States)
- 124 **Association between K+ Supplementation and Death and Sudden Cardiac Death in Loop Diuretic Users [750]**
Charles E Leonard, Cristin P Freeman, Jason Roy, Craig Newcomb, Brian L Strom, Sean Hennessy. (United States)
- 125 **Do All Antihypertensive Classes Improve Global or Specific Cognitive Functions? A Network Meta-Analysis [751]**
Natacha Levi-Marpillat, Isabelle Macquinn-Mavier, Anne-Catherine Bachoud-Lévi, Patrick Maison. (France)
- 126 **Assessing Publication Bias from Clinical Studies of Coronary Artery Stents [752]**
Cunlin Wang, Haitao Chu, Dale Tavis, Jing Xi, Lei Nie. (United States)
- 127 **Impact of Oral Antidiabetic Drugs on Development of Chronic Kidney Disease [753]**
Andrew Masica, Yahya Daoud, Suzanne West. (United States)

Poster Walk - Molecular Epi Biomarkers SIG

- 128 **Patient Attitudes toward Receiving Chemotherapy and Pharmacogenetic Testing in Curative and Palliative Cancer Patients [754]**
Sinead Cuffe, Henrique Hon, Kimberly Tobros, Chung-Kwun Amy Wong, Bradley De Souza, Graham McFarlane, Sohaib Masroor, Ekta Hasani, Bin Sun, Natalie Di Tommaso, Wei Xu, Natasha Leighl, Shabbir Alibhai, Amalia Issa, Geoffrey Liu. (Canada)
- 129 **Breast and Colorectal Cancer Patients' Preferences for Pharmacogenomics: A Discrete Choice Experiment [755]**
Amalia M Issa, Waqas Tufail, Roseline Ajike, Jose Tenorio, John McKeever. (United States)
- 130 **The Quality of Economic Studies of Cancer Pharmacogenomics: A Quantitative Appraisal of the Evidence [756]**
Dhaval S Patil, Mo Yang, Amalia M Issa. (United States)
- 131 **Effects of Alcohol on Dynamic Posturography and Subjective Response in Healthy Korean Men with ALDH2 Variations [757]**
Hee-Young Shin, Kyung-Yeol Bae, Sung-Wan Kim, Il-Seon Shin, Jong-Keun Kim, Jin-Sang Yoon. (Republic of Korea)
- 132 **Long-Term Effects of Pharmacogenetics in Acenocoumarol and Phenprocoumon [759]**
Talitha I Verhoef, William K Redekop, Tom Schalekamp, Felix J M van der Meer, Saskia le Cessie, Judith A M Wessels, Erik van Meegen, Rianne M F van Schie, Anthonius de Boer, Anke-Hilse Maitland-van der Zee. (Netherlands)

POSTER SESSION C *Wednesday, August 17*

133 **Knowledge and Preferences of Breast and Colorectal Cancer Survivors and Patients for Pharmacogenomic Molecular Diagnostics [760]**
Mo Yang, Waqas Tufail, Dhaval S Patil, Amalia M Issa. (United States)

Signal Detection

134 **Increased Severity of Adverse Drug Reactions Reported from Hospitals [761]**
Francisco Batel Marques, Carlos Alves, Nuno Craveiro, Carlos Fontes Ribeiro, Ana Filipa Macedo. (Portugal)

135 **Drug Related Morbidity Among Patients with Complex Health Care Needs Visiting an Emergency Room - A Pilot Study [762]**
Linda Ring Eriksson, Staffan Hägg, Henrik Lövborg, Thomas Bradley. (Sweden)

136 **Data Mining with a Tree-Based Scan Statistic [763]**
Jeffrey S Brown, Inna Dashevsky, Bruce Fireman, Lisa Herrinton, David McClure, Michael Murphy, Marsha Raebel, Jessica Sturtevant, Martin Kulldorff. (United States)

137 **Correlate Quantitative Structure & Adverse Reaction of Drug Using Predictive Modeling Techniques [764]**
Partha Chakraborty, Rupali Kalate. (India)

138 **Ocular Side Effects under Systemic Treatment with Isotretinoin [765]**
Gabriel Chodick, Meira Neudorfer, Inbal Goldshtein, Orna Shamai-Lubovitz, Varda Shalev. (Israel)

139 **Methods for Disproportionality Analysis: Testing a Bayesian with a Non Bayesian Method [766]**
Nuno Craveiro, Carlos Alves, Carlos Fontes Ribeiro, Francisco Batel Marques. (Portugal)

140 **Hypersensitivity Syndrome Due to Drug Exposure - Ten Years Case Review [767]**
Nuno Craveiro, Carlos Alves, Carlos Fontes Ribeiro, Francisco Batel Marques. (Portugal)

141 **Identification of Adverse Events after Immunoglobulin Exposure: Exploratory Analysis of Administrative Claims Data [768]**
Gregory W Daniel, Mikhail Menis, Anna E Wallace, Gayathri Sridhar, Hector Izurieta. (United States)

142 **Establishing a Pharmacovigilance Database in Romania: Practical Value [769]**
Andreea Maria Farcas, Tarfin Chiorean, Daniel Leucuta, Razvan Chereches. (Romania)

143 **Active Monitoring System To Identify and Characterize Adverse Drug Reactions in Hospitalized Patients in Romania [770]**
Andreea Maria Farcas, Aura Sinpetrean, Camelia Bucsa, Dan Dumitrascu, Andrei Achimas, Marius Bojita. (Romania)

144 **An Event-Based Metric for Comparing the Performance of Methods for Prospective Medical Product Monitoring [771]**
Joshua J Gagne, Alexander M Walker, Jeremy A Rassen, Robert J Glynn, Sebastian Schneeweiss. (United States)

145 **AERscope: A Streamlined Method To Describe FDA Adverse Event Reporting System (AERS) Data Using a Novel SAS/IntrNet Application [772]**
Ted Guo, Chris Jones, Enxu Zhao, Kate Gelperin, Lynette Swartz, Tony Du, Adrienne Rothstein, Joslyn Swann, Tarek A Hammad. (United States)

146 **Drug Utilisation Data for Seroquel XL - Results of a First Interim Modified PEM Study Report [773]**
Anna Gilchrist, Miranda Davies, Deborah Layton, Saad Shakir. (United Kingdom)

147 **Generating Adverse Drug Event Hypotheses Using Consumer Internet Forums [774]**
Michael J Goodman, Olivia R Sheng, Frederick Albright, Mark Valentine, Rachel N Woolston. (United States)

148 **Analysis of Characteristics about Drug Adverse Events Reports Received in KFDA during 2008-2010 [775]**
Jihye Ha, MinWoo Kim, YoungHoon Kim, MyeonWoo Chung. (Republic of Korea)

149 **Adverse Events Induced by Injectable Medicines, a Screen on Registered Data in a National Pharmacovigilance Centre Database [776]**
Naghme Javidnikou, Gloria Shalviri, Kheiroolah Gholami. (Islamic Republic of Iran)

150 **Attitudes of Healthcare Professionals towards Adverse Drug Reaction Reporting in Nepal [778]**
Santosh KC, Pramote Tragulpiankit, Sarun Gorsanan, Ralph Edwards. (Thailand)

151 **Data Analysis of Voluntary Drug Adverse Reaction Report in Korea [779]**
Hye Kyung Kim, Young Sik Kim, Woosang Kim, Jungwoo Kim, Sung Sunwoo. (Republic of Korea)

152 **Aspect of Severe Drug Adverse Reaction from Spontaneous Report Data [780]**
Young Sik Kim, Hyekyung Kim, Jungwoo Jang, Woosang Kim, Jeongmi Kang, Sung Sunwoo. (Republic of Korea)

153 **Enhancing the Presentation and Evaluation of Cumulative Post-Marketing Safety Data; a Pilot Study [781]**
Anna Gilchrist, Deborah Layton, Carole Fogg, Saad Shakir. (United Kingdom)

154 **Adverse Drug Reactions Following Oseltamivir Mass Treatment in the South Korea Outbreak of 2009 Pandemic Influenza A (H1N1) [782]**
Sukhyang Lee, Youna Do. (Republic of Korea)

155 **Pharmacists' Knowledge on ADR Reporting in Korea; a Pilot Study [783]**
Euni Lee, Hyun-Hyuk Cho, Eun-Hyuk Jang, Hee-Young Shin, Young-Il Koh. (United States)

156 **Assessment of Adverse Drug Reactions Reported to the Korea Food and Drug Administration [784]**
Sukhyang Lee, Kiyon Rhew. (Republic of Korea)

157 **Analytical Plan for Post-Marketing Active Surveillance in an Insurance Claims Database Using the High Dimensional Propensity Score Methodology [785]**
Jian Li, Karin Benoit, Wei Wang, Stephen Motsko, Jennie Francis, Joachim Wernicke. (United States)

158 **Determinants of Underreporting Adverse Drug Reactions (ADRs): A Study among Doctors in City of Bangalore [786]**
Aravinda Kumar Mehendale, Sankara Sarma. (India)

159 **Frequency and Incidence of Severe Cutaneous Adverse Reactions in Different Age Groups [787]**
Maja Mockenhaupt, Peggy Sekula, Liss Yvonne, Schumacher Martin. (Germany)

160 **Active Surveillance of the Introduction of Atrovent® CFC-Free MDI (Metered Dose Inhaler) into General Practice in England: Characteristics of Users [788]**
Vicki Osborne, Deborah Layton, Edward Tong, Saad Shakir. (United Kingdom)

161 **A Database-Driven Adverse Drug Reaction Signal Detection Method Applicable to Hospital Electronic Medical Database: A Retrospective Cohort Study on Three Illustrative Drugs [789]**
Man Young Park, Dukyong Yoon, Rae Woong Park. (Republic of Korea)

162 **Preliminary Comparison of Drug Safety Signal Detection Between Spontaneous Reporting Databases and EU-ADR Longitudinal Database Network [793]**
Vaishali Patadia, Martijn J Schuemi, Preciosa Coloma, Rosa Gini, Ron Herings, Giampiero Mazzaglia, Gino Picelli, Lorenza Scotti, Lars Pedersen, Julia Hippisley Cox, Paul Avillach, Johan van der Lei, Miriam Sturkenboom, Gianluca Trifirò. (United States)

163 **Predictors of Adverse Drug Reactions of Cardiovascular Drugs in Hospitalized Patients [794]**
Thiyagu Rajakannan, Surulivelrajan Malayasamy, Vasudeva Guddattu, Rajesh Vilakkhala, Padmakumar Ramachandran, Laxminarayana K Bairy. (India)

- 164 **An Evaluation of a Distributed Medical Device Safety Surveillance System: The DELTA Network Study [795]**
Frederic S Resnic, Govindarajulu Usha, Vidi D Venkatesan, Susan Robbins, Michael E Matheny. (United States)
- 165 **Preventability of Serious Adverse Drug Reactions – Assessment of Interrater Variability Using Two Different Chance-Corrected Measures of Reliability [796]**
Marietta Rottenkolber, Sven Schmiedl, Jacek Szymanski, Joerg Hasford, Petra A Thuermann. (Germany)
- 166 **Developing Event-Specific Adverse Event Follow Up Questionnaires To Assess Drug-Event Causality [797]**
Maribel Salas, Erast Pohorylo, Katie Zimpfer, Anoop Joseph. (United States)
- 167 **Review of Stevens Johnson Syndrome and Toxic Epidermal Necrolysis Registered in an Established Pharmacovigilance Centre during a Twelve Years Period [798]**
Gloria Shalviri, Kheirollah Gholami, Marjan Karimi. (Islamic Republic of Iran)
- 168 **Active Monitoring of Adverse Drug Reactions Due to Use Contrast Media – A 2000-Bed Medical Center Experience in Taiwan [799]**
Tan-Ping Shih, Hsiang-Wen Lin, Wen-Ling Lin, Yow-Wen Hsieh, Hsi-Chin Wu, Yung-Jen Ho. (Taiwan)
- 169 **The Analysis of Drug Adverse Event using Association Rule Mining (ARM) in Regional Pharmacovigilance Center [800]**
Dong Hoon Shin, Gyeong Im Yu, Yoon Nyun Kim, Chang Sik Son, Suk Tae Seo, Min Soo Kim, Mi Young Lee, Yeo Hyang Kim, Sung Won Jung, Hyeok Won Jang, Hyeon Ah Lee, Eun Young Bae, Kyung Mi Seo, Jae Wi Jo, Sang Hyon Kim. (Republic of Korea)
- 170 **Development of a Signal Detection Process Using Multiple Data Sources Applicable to Innovative Therapies [802]**
Michael Taylor, Wei Dong, Dawn Flick, Kim Alexander, Laura Chu, Katie Miller, Bharat Thakrar, Jamie Robinson, Pavel Napalkov. (United States)
- 171 **Prevalence of Adverse Drug Reactions in Hospitalized Elderly Patients in Short Stay Unit [803]**
Clarisse Joachim, Géric Maura, Moustapha Dramé, Jean-Luc Novella, Rachid Mahmoudi, Thierry Trenque. (France)
- 172 **Detection of Intoxications through 1864 Plasmatic Concentrations Analysis [804]**
Catherine Vallet, Géric Maura, Emmanuelle Herlem, Denis Lamiable, Thierry Trenque. (France)

- 173 **Search for New Safety Signals in the Patterns of Care Following MMR Vaccine [805]**
A M Walker, T Puenpatom, J Li, G W Daniel, M A Brookhart, L Polakowski, Y Lu, H Izurieta. (United States)
- 174 **Pharmacovigilance System in Thailand [806]**
Sareeya Wechwithan, Pakawadee Sriphiro-myia. (Thailand)
- 175 **Retrospective Method To Identify Tardive Dyskinesia in Electronic Medical Records [807]**
James R Williams, Victor Crentsil, Laurie Duncan, Susanne Goldstein, David Graham, Marlene Hammer, Janet Kavanagh, Cynthia Kornegay, Robert Levin, Daniel Weintraub, Jayne Wilkinson, Helen Kales. (United States)
- 176 **The Pilot Study of Evaluation of IHI ADE Trigger Tool in Thai Hospitalized Patients: Multicenter Study [808]**
Narak Yeeseenpan, Pramote Tragulpiankit, Thida Ningsananda, AdCoPT Working Team, Thailand. (Thailand)
- 177 **Detection of Drug-Drug Interactions from Spontaneous Reporting System Data by Multifactor Dimensionality Reduction [810]**
Dukyong Yoon, Man Young Park, Rae Woong Park. (Republic of Korea)

Summarization

- 178 **Balance of Controlled and Uncontrolled Covariates as a Function of Propensity Score Variable Selection Methods: A Simulation Study [811]**
R Wyss, M R Stedman, M A Brookhart, KJ Rothman, R Glynn, C Poole, J D Seeger, T Stürmer. (United States)
- 179 **A Review of Reporting of Adverse Events for a Pharmaceutical after Commencement of Generic Marketing [813]**
Keith L Altman. (United States)
- 180 **Safety Evaluation of Pharmacological Interventions: A Review of Recent Published Meta-Analysis [814]**
Carlos Alves, Ana Filipa Macedo, Nuno Craveiro, Francisco Batel Marques. (Portugal)
- 181 **Review of Epidemiology Studies Using Multiple Healthcare Databases [815]**
Bing Cai, Cynthia de Luise, Andrew J Bate. (United States)
- 182 **Meta-Analysis: Predictors of Influenza Vaccination Among Health Care Workers in Hospitals [817]**
Josien Riphagen-Dalhuisen, Giedre Gefenaite, Eelko Hak. (Netherlands)
- 183 **Frequency of Preventable Adverse Drug Reactions in Outpatients and Inpatients and Their Preventability – A Meta-Analysis [818]**
Katja M Hakkarainen, Khadija Hedna, Max Petzold, Staffan Hägg. (Sweden)

- 184 **Bibliographic Analysis of the Centers for Disease Control and Prevention (CDC) Published Articles in Pharmacoepidemiology, 2010 [819]**
John Iskander, Rebecca Satterthwaite, Gail Bang, Jocelyn Rankin. (United States)
- 185 **Effectiveness of Interventions To Improve the Detection and Treatment of Osteoporosis in Primary Care Settings: A Systematic Review and Meta-Analysis [820]**
Marie-Claude Laliberté, Sylvie Perreault, Ghaya Jouini, Beverley J Shea, Lyne Lalonde. (Canada)
- 186 **Cardiovascular Safety of Lumiracoxib: A Meta-Analysis of Randomised Controlled Trials in Patients with Osteoarthritis [821]**
Isla S Mackenzie, Li Wei, Thomas M MacDonald. (United Kingdom)
- 187 **Epidemiology of Staphylococcus aureus Infections in Children: A Literature Review of the Last 10 Years [822]**
Hélène Bricout, William Maier, Julie Mouchet. (United Kingdom)
- 188 **Bayesian Meta-Analysis of Observational Data [823]**
Lawrence C McCandless. (Canada)
- 189 **Over-the-Counter Ibuprofen and Risk of Gastrointestinal Events: A Literature Review [824]**
Shannon L Michels, Matthew W Reynolds, Staci Abramsky. (United States)
- 190 **Systematic Review Methods To Assess Growth and Sexual Maturation in Pediatric Population Suffering from Pulmonary Arterial Hypertension in Real-World Clinical Settings [825]**
Erwan Muros Le Rouzic, Monika Brand, Jeremy Wheeler, Daniel Rosenberg. (Switzerland)
- 191 **Interventions To Improve Patients Compliance with Lipid Lowering Medications: A Systematic Review of the Literature [826]**
Alvaro Zuluaga, Maribel Salas, Femida H Gwadry-Sridhar, Elizabeth Manias, Dyfrig A Hughes. (United States)

Vaccines

- 192 **Implementation of Panenza A (H1N1) 2009 Pandemic Vaccine Pharmacovigilance Plan [827]**
Germano L C Ferreira, Joao M Almeida, Khromava Alena. (France)
- 193 **Using Two Risk Intervals To Determine Relatedness of Adverse Events to Vaccination [828]**
Roger Baxter, Bruce Fireman, Ali Rowhani-Rahbar, Ned Lewis, Nicola Klein. (United States)



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ABSTRACT INDEX *Final Program*

Abstract #	Poster #	Presentation Time	Room	Format
Monday, August 15				
1		10:30am	Regency A	Oral
2		10:45am	Regency A	Oral
3		11:00am	Regency A	Oral
4		11:15am	Regency A	Oral
5		11:30am	Regency A	Oral
6		11:45am	Regency A	Oral
7		10:30am	Regency B	Oral
8		10:45am	Regency B	Oral
9		11:00am	Regency B	Oral
12		11:15am	Regency B	Oral
11		11:30am	Regency B	Oral
10		11:45am	Regency B	Oral
13		10:30am	Toronto	Oral
14		10:45am	Toronto	Oral
15		11:00am	Toronto	Oral
16		11:15am	Toronto	Oral
17		11:30am	Toronto	Oral
18		11:45am	Toronto	Oral
19		10:30am	Acapulco	Oral
20		10:45am	Acapulco	Oral
21		11:00am	Acapulco	Oral
22		11:15am	Acapulco	Oral
24		11:30am	Acapulco	Oral
23		11:45am	Acapulco	Oral
25		10:30am	Regency C	Oral
26		10:45am	Regency C	Oral
27		11:00am	Regency C	Oral
28		11:15am	Regency C	Oral
29		11:30am	Regency C	Oral
30		11:45am	Regency C	Oral
31		10:30am	Regency D	Oral
32		10:45am	Regency D	Oral
33		11:00am	Regency D	Oral
34		11:15am	Regency D	Oral
35		11:30am	Regency D	Oral
36		11:45am	Regency D	Oral
Application of Quality of Evidence Assessment Tools to the Evaluation of Pharmacoepidemiologic Safety Studies				
37		3:30-5:00pm	Regency A	Sympos.
Capacity of Various Data Sources to Advance Medical Device Safety and Effectiveness Research				
38		3:30-5:00pm	Regency B	Sympos.
Challenges and Pitfalls in Studying Birth Defects as Outcomes				
39		3:30-5:00pm	Toronto	Sympos.
Database Linkage and Methodological Issues in Comparative Effectiveness Research (CER) of Medical Devices vs. Medications: Lessons from an Ongoing Project				
40		3:30-5:00pm	Regency C	Sympos.
Linking Existing Databases - Is it Worth the Pain?				
41		3:30-5:00pm	Regency D	Sympos.

Abstract #	Poster #	Presentation Time	Room	Format
Monday, August 15 continued				
Regulatory Trends in Pharmacogenomic Biomarker Evaluation (Molecular Epi/Biomarkers/Pharmacogenetics SIG Symposium)				
42		3:30-5:00pm	Acapulco	Sympos.
POSTER SESSION A				
Cardiovascular				
43	1	7:30am - 6:00pm		Poster
44	2	7:30am - 6:00pm		Poster
45	3	7:30am - 6:00pm		Poster
46	4	7:30am - 6:00pm		Poster
47	5	7:30am - 6:00pm		Poster
48	6	7:30am - 6:00pm		Poster
49	7	7:30am - 6:00pm		Poster
50	8	7:30am - 6:00pm		Poster
51	9	7:30am - 6:00pm		Poster
52	10	7:30am - 6:00pm		Poster
53	11	7:30am - 6:00pm		Poster
54	12	7:30am - 6:00pm		Poster
55	13	7:30am - 6:00pm		Poster
56	14	7:30am - 6:00pm		Poster
57	15	7:30am - 6:00pm		Poster
58		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
59	16	7:30am - 6:00pm		Poster
Fractures				
60	17	7:30am - 6:00pm		Poster
61	18	7:30am - 6:00pm		Poster
62	19	7:30am - 6:00pm		Poster
63	20	7:30am - 6:00pm		Poster
64	21	7:30am - 6:00pm		Poster
65	22	7:30am - 6:00pm		Poster
66	23	7:30am - 6:00pm		Poster
67	24	7:30am - 6:00pm		Poster
68		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
69		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
70	25	7:30am - 6:00pm		Poster
71	26	7:30am - 6:00pm		Poster
Miscellaneous				
72	27	7:30am - 6:00pm		Poster
73	28	7:30am - 6:00pm		Poster
74	29	7:30am - 6:00pm		Poster
75		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
77	30	7:30am - 6:00pm		Poster
78	31	7:30am - 6:00pm		Poster
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82	35	7:30am - 6:00pm		Poster
83	36	7:30am - 6:00pm		Poster
84	37	7:30am - 6:00pm		Poster
85	38	7:30am - 6:00pm		Poster

Abstract #	Poster #	Presentation Time	Room	Format
Monday, August 15 continued				
86	39	7:30am - 6:00pm		Poster
87	40	7:30am - 6:00pm		Poster
88	41	7:30am - 6:00pm		Poster
89	42	7:30am - 6:00pm		Poster
90	43	7:30am - 6:00pm		Poster
91	44	7:30am - 6:00pm		Poster
92	45	7:30am - 6:00pm		Poster
93	46	7:30am - 6:00pm		Poster
94	47	7:30am - 6:00pm		Poster
95	48	7:30am - 6:00pm		Poster
96	49	7:30am - 6:00pm		Poster
Pregnancy/Lactation				
97	50	7:30am - 6:00pm		Poster
98	51	7:30am - 6:00pm		Poster
99	52	7:30am - 6:00pm		Poster
100	53	7:30am - 6:00pm		Poster
101	54	7:30am - 6:00pm		Poster
102	55	7:30am - 6:00pm		Poster
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114	67	7:30am - 6:00pm		Poster
115	68	7:30am - 6:00pm		Poster
116	69	7:30am - 6:00pm		Poster
117		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
118	70	7:30am - 6:00pm		Poster
119	71	7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
120	72	7:30am - 6:00pm		Poster
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123	75	7:30am - 6:00pm		Poster
124	76	7:30am - 6:00pm		Poster
125	77	7:30am - 6:00pm		Poster
126	78	7:30am - 6:00pm		Poster
127	79	7:30am - 6:00pm		Poster
128	80	7:30am - 6:00pm		Poster
129		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
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133	84	7:30am - 6:00pm		Poster
134	85	7:30am - 6:00pm		Poster

Abstract #	Poster #	Presentation Time	Room	Format
Monday, August 15 continued				
135	86	7:30am - 6:00pm		Poster
136	87	7:30am - 6:00pm		Poster
137	88	7:30am - 6:00pm		Poster
138	89	7:30am - 6:00pm		Poster
139	90	7:30am - 6:00pm		Poster
140	91	7:30am - 6:00pm		Poster
141		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
Respiratory				
142	92	7:30am - 6:00pm		Poster
143	93	7:30am - 6:00pm		Poster
144	94	7:30am - 6:00pm		Poster
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146	96	7:30am - 6:00pm		Poster
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148	98	7:30am - 6:00pm		Poster
149	99	7:30am - 6:00pm		Poster
150	100	7:30am - 6:00pm		Poster
151	101	7:30am - 6:00pm		Poster
152	102	7:30am - 6:00pm		Poster
153	103	7:30am - 6:00pm		Poster
154	104	7:30am - 6:00pm		Poster
Rheumatic				
155	105	7:30am - 6:00pm		Poster
156	106	7:30am - 6:00pm		Poster
157	107	7:30am - 6:00pm		Poster
Poster Walk - Biologics SIG				
158	108	7:30am - 6:00pm		P. Walk
159	109	7:30am - 6:00pm		P. Walk
160	110	7:30am - 6:00pm		P. Walk
161	111	7:30am - 6:00pm		P. Walk
162	112	7:30am - 6:00pm		P. Walk
163	113	7:30am - 6:00pm		P. Walk
164	114	7:30am - 6:00pm		P. Walk
165	115	7:30am - 6:00pm		P. Walk
Poster Walk - Medications in Pregnancy SIG				
166	116	7:30am - 6:00pm		P. Walk
167	117	7:30am - 6:00pm		P. Walk
168	118	7:30am - 6:00pm		P. Walk
169	119	7:30am - 6:00pm		P. Walk
170	120	7:30am - 6:00pm		P. Walk
171	121	7:30am - 6:00pm		P. Walk
172	122	7:30am - 6:00pm		P. Walk
173	123	7:30am - 6:00pm		P. Walk
Poster Walk - Drug Utilization Research SIG				
174	124	7:30am - 6:00pm		P. Walk
175	125	7:30am - 6:00pm		P. Walk
176	126	7:30am - 6:00pm		P. Walk
178	127	7:30am - 6:00pm		P. Walk
179	128	7:30am - 6:00pm		P. Walk

ABSTRACT INDEX *Final Program*

Abstract #	Poster #	Presentation Time	Room	Format
Monday, August 15 continued				
180	129	7:30am - 6:00pm		P. Walk
181	130	7:30am - 6:00pm		P. Walk
568	131	7:30am - 6:00pm		P. Walk
Stroke				
182	132	7:30am - 6:00pm		Poster
183	133	7:30am - 6:00pm		Poster
184	134	7:30am - 6:00pm		Poster
185	135	7:30am - 6:00pm		Poster
186	136	7:30am - 6:00pm		Poster
187	137	7:30am - 6:00pm		Poster
188	138	7:30am - 6:00pm		Poster
189	139	7:30am - 6:00pm		Poster
Utilization				
190		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
191	140	7:30am - 6:00pm		Poster
192	141	7:30am - 6:00pm		Poster
193	142	7:30am - 6:00pm		Poster
194	143	7:30am - 6:00pm		Poster
196	144	7:30am - 6:00pm		Poster
197		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
198	145	7:30am - 6:00pm		Poster
199	146	7:30am - 6:00pm		Poster
200	147	7:30am - 6:00pm		Poster
201	148	7:30am - 6:00pm		Poster
202	149	7:30am - 6:00pm		Poster
203	150	7:30am - 6:00pm		Poster
204		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
205	151	7:30am - 6:00pm		Poster
206	152	7:30am - 6:00pm		Poster
207	153	7:30am - 6:00pm		Poster
208	154	7:30am - 6:00pm		Poster
209	155	7:30am - 6:00pm		Poster
210	156	7:30am - 6:00pm		Poster
211	157	7:30am - 6:00pm		Poster
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213	159	7:30am - 6:00pm		Poster
214	160	7:30am - 6:00pm		Poster
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220	166	7:30am - 6:00pm		Poster
221	167	7:30am - 6:00pm		Poster
222	168	7:30am - 6:00pm		Poster
223	169	7:30am - 6:00pm		Poster
224	170	7:30am - 6:00pm		Poster
225	171	7:30am - 6:00pm		Poster
226	172	7:30am - 6:00pm		Poster
227	173	7:30am - 6:00pm		Poster
228	174	7:30am - 6:00pm		Poster

Abstract #	Poster #	Presentation Time	Room	Format
Monday, August 15 continued				
229	175	7:30am - 6:00pm		Poster
230		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
231		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
232	176	7:30am - 6:00pm		Poster
233	177	7:30am - 6:00pm		Poster
234	178	7:30am - 6:00pm		Poster
235	179	7:30am - 6:00pm		Poster
236	180	7:30am - 6:00pm		Poster
237	181	7:30am - 6:00pm		Poster
238	182	7:30am - 6:00pm		Poster
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244	188	7:30am - 6:00pm		Poster
245	189	7:30am - 6:00pm		Poster
246	190	7:30am - 6:00pm		Poster
247		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
248	191	7:30am - 6:00pm		Poster
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250	193	7:30am - 6:00pm		Poster
251	194	7:30am - 6:00pm		Poster
252	195	7:30am - 6:00pm		Poster
253	196	7:30am - 6:00pm		Poster
254		7:30am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
255	197	7:30am - 6:00pm		Poster
256	198	7:30am - 6:00pm		Poster
257	199	7:30am - 6:00pm		Poster
258	200	7:30am - 6:00pm		Poster
259	201	7:30am - 6:00pm		Poster
260	202	7:30am - 6:00pm		Poster
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263	205	7:30am - 6:00pm		Poster
264	206	7:30am - 6:00pm		Poster
265	207	7:30am - 6:00pm		Poster
266	208	7:30am - 6:00pm		Poster
267	209	7:30am - 6:00pm		Poster
621	210	7:30am - 6:00pm		Poster
300	211	7:30am - 6:00pm		Poster
Tuesday, August 16				
Drug Use, Change, Choice or Chance				
268		8:30am	Regency A	Oral
269		8:45am	Regency A	Oral
270		9:00am	Regency A	Oral
271		9:15am	Regency A	Oral
272		9:30am	Regency A	Oral
273		9:45am	Regency A	Oral

Abstract #	Poster #	Presentation Time	Room	Format
Tuesday, August 16 continued				
Fractures - Give Us a Break				
274		8:30am	Regency B	Oral
275		8:45am	Regency B	Oral
276		9:00am	Regency B	Oral
277		9:15am	Regency B	Oral
278		9:30am	Regency B	Oral
279		9:45am	Regency B	Oral
Matters of the Heart				
280		8:30am	Regency C	Oral
281		8:45am	Regency C	Oral
282		9:00am	Regency C	Oral
283		9:15am	Regency C	Oral
284		9:30am	Regency C	Oral
285		9:45am	Regency C	Oral
Multigravida				
286		8:30am	Toronto	Oral
287		8:45am	Toronto	Oral
288		9:00am	Toronto	Oral
289		9:15am	Toronto	Oral
290		9:30am	Toronto	Oral
291		9:45am	Toronto	Oral
Propensity Score Methods				
292		8:30am	Regency D	Oral
293		8:45am	Regency D	Oral
294		9:00am	Regency D	Oral
295		9:15am	Regency D	Oral
296		9:30am	Regency D	Oral
297		9:45am	Regency D	Oral
To Clot or Not to Clot				
298		8:30am	Acapulco	Oral
299		8:45am	Acapulco	Oral
300			Poster Session A	
301		9:15am	Acapulco	Oral
302		9:30am	Acapulco	Oral
303		9:45am	Acapulco	Oral
A Little Attention Please				
304		10:30am	Regency A	Oral
305		10:45am	Regency A	Oral
306		11:00am	Regency A	Oral
307		11:15am	Regency A	Oral
308		11:30am	Regency A	Oral
309		11:45am	Regency A	Oral
Adherence - A Sticky Issue				
349		10:30am	Regency B	Oral
311		10:45am	Regency B	Oral
312		11:00am	Regency B	Oral
347		11:15am	Regency B	Oral
314		11:30am	Regency B	Oral
315		11:45am	Regency B	Oral

Abstract #	Poster #	Presentation Time	Room	Format
Tuesday, August 16 continued				
Devices et al				
316		10:30am	Toronto	Oral
317		10:45am	Toronto	Oral
318		11:00am	Toronto	Oral
319		11:15am	Toronto	Oral
320		11:30am	Toronto	Oral
321		11:45am	Toronto	Oral
Drugs and Bugs				
322		10:30am	Acapulco	Oral
323		10:45am	Acapulco	Oral
324		11:00am	Acapulco	Oral
348		11:15am	Acapulco	Oral
326		11:30am	Acapulco	Oral
327		11:45am	Acapulco	Oral
Methods for Early Detection				
328		10:30am	Regency C	Oral
329		10:45am	Regency C	Oral
330		11:00am	Regency C	Oral
331		11:15am	Regency C	Oral
332		11:30am	Regency C	Oral
333		11:45am	Regency C	Oral
To Bleed or Not to Bleed				
334		10:30am	Regency D	Oral
335		10:45am	Regency D	Oral
336		11:00am	Regency D	Oral
337		11:15am	Regency D	Oral
338		11:30am	Regency D	Oral
339		11:45am	Regency D	Oral
The Stanley A. Edlavitch Award				
340		3:00pm	Crystal Ballrm.	Oral
Challenges to Improving the Science of Regulatory Decision-Making				
341		4:00 - 5:30pm	Regency A	Sympos.
Challenges in Conducting Sequentially Monitored Medical Product Safety Studies using Electronic Health Care Utilization Data				
342		4:00 - 5:30pm	Regency B	Sympos.
Drug-Induced Liver Injury (DILI): Latest Developments on Pre-market Regulatory Guidance and Approaches to Postmarket Surveillance				
343		4:00 - 5:30pm	Toronto	Sympos.
Increasing Scientific Standards, Transparency and Independence in Pharmacoepidemiological Research: Is the Concept of ENCePP Studies a Way Forward?				
344		4:00 - 5:30pm	Regency C	Sympos.
Methods Development in Active Drug Safety Surveillance Highlighting the Observational Medical Outcomes Partnership's Findings				
345		4:00 - 5:30pm	Regency D	Sympos.
Structured Approaches to Evaluating Statistical Signals from Drug and Vaccine Safety Surveillance Systems				
346		4:00 - 5:30pm	Acapulco	Sympos.

ABSTRACT INDEX *Final Program*

Abstract #	Poster #	Presentation Time	Room	Format
Tuesday, August 16 continued				
POSTER SESSION B				
Adherence				
313	1	8:00am - 6:00pm		Poster
350	2	8:00am - 6:00pm		Poster
351	3	8:00am - 6:00pm		Poster
352	4	8:00am - 6:00pm		Poster
353	5	8:00am - 6:00pm		Poster
354	6	8:00am - 6:00pm		Poster
355	7	8:00am - 6:00pm		Poster
356	8	8:00am - 6:00pm		Poster
357	9	8:00am - 6:00pm		Poster
358		8:00am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
359	10	8:00am - 6:00pm		Poster
360	11	8:00am - 6:00pm		Poster
361	12	8:00am - 6:00pm		Poster
362		8:00am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
363	13	8:00am - 6:00pm		Poster
364	14	8:00am - 6:00pm		Poster
Databases				
365	15	8:00am - 6:00pm		Poster
366	16	8:00am - 6:00pm		Poster
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369	19	8:00am - 6:00pm		Poster
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391	39	8:00am - 6:00pm		Poster
392		8:00am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
393	40	8:00am - 6:00pm		Poster
394	41	8:00am - 6:00pm		Poster
395	42	8:00am - 6:00pm		Poster
396	43	8:00am - 6:00pm		Poster

Abstract #	Poster #	Presentation Time	Room	Format
Tuesday, August 16 continued				
397	44	8:00am - 6:00pm		Poster
398	45	8:00am - 6:00pm		Poster
399		8:00am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
400	46	8:00am - 6:00pm		Poster
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406	52	8:00am - 6:00pm		Poster
Gastrointestinal				
407	53	8:00am - 6:00pm		Poster
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415	61	8:00am - 6:00pm		Poster
Hormones				
416	62	8:00am - 6:00pm		Poster
417	63	8:00am - 6:00pm		Poster
418	64	8:00am - 6:00pm		Poster
Infectious				
419	65	8:00am - 6:00pm		Poster
420	66	8:00am - 6:00pm		Poster
421	67	8:00am - 6:00pm		Poster
422	68	8:00am - 6:00pm		Poster
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438	84	8:00am - 6:00pm		Poster
439	85	8:00am - 6:00pm		Poster
440	86	8:00am - 6:00pm		Poster
Neurologic				
441	87	8:00am - 6:00pm		Poster

Abstract #	Poster #	Presentation Time	Room	Format
Tuesday, August 16 continued				
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443	89	8:00am - 6:00pm		Poster
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450	96	8:00am - 6:00pm		Poster
451		8:00am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
452	97	8:00am - 6:00pm		Poster
453	98	8:00am - 6:00pm		Poster
454	99	8:00am - 6:00pm		Poster
455	100	8:00am - 6:00pm		Poster
456	101	8:00am - 6:00pm		Poster
457	102	8:00am - 6:00pm		Poster
458	103	8:00am - 6:00pm		Poster
459	104	8:00am - 6:00pm		Poster
Risk Management				
460	105	8:00am - 6:00pm		Poster
461	106	8:00am - 6:00pm		Poster
462	107	8:00am - 6:00pm		Poster
463	108	8:00am - 6:00pm		Poster
464	109	8:00am - 6:00pm		Poster
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468	111	8:00am - 6:00pm		Poster
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481	124	8:00am - 6:00pm		Poster
482	125	8:00am - 6:00pm		Poster
483	126	8:00am - 6:00pm		Poster
484	127	8:00am - 6:00pm		Poster
485	128	8:00am - 6:00pm		Poster
486	129	8:00am - 6:00pm		Poster
487	130	8:00am - 6:00pm		Poster
488	131	8:00am - 6:00pm		Poster
489	132	8:00am - 6:00pm		Poster

Abstract #	Poster #	Presentation Time	Room	Format
Tuesday, August 16 continued				
490	133	8:00am - 6:00pm		Poster
491	134	8:00am - 6:00pm		Poster
492	135	8:00am - 6:00pm		Poster
493	136	8:00am - 6:00pm		Poster
494	137	8:00am - 6:00pm		Poster
495	138	8:00am - 6:00pm		Poster
496	139	8:00am - 6:00pm		Poster
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498	141	8:00am - 6:00pm		Poster
499	142	8:00am - 6:00pm		Poster
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503	146	8:00am - 6:00pm		Poster
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510	153	8:00am - 6:00pm		Poster
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520	163	8:00am - 6:00pm		Poster
521	164	8:00am - 6:00pm		Poster
522	165	8:00am - 6:00pm		Poster
523	166	8:00am - 6:00pm		Poster
524	167	8:00am - 6:00pm		Poster
Poster Walk - Databases SIG				
525	168	8:00am - 6:00pm		P. Walk
526	169	8:00am - 6:00pm		P. Walk
527	170	8:00am - 6:00pm		P. Walk
528	171	8:00am - 6:00pm		P. Walk
529	172	8:00am - 6:00pm		P. Walk
530	173	8:00am - 6:00pm		P. Walk
531		8:00am - 6:00pm	<i>Abstract Withdrawn by Author</i>	
532	174	8:00am - 6:00pm		P. Walk
Poster Walk - Medical Devices SIG				
533	175	8:00am - 6:00pm		P. Walk
534	176	8:00am - 6:00pm		P. Walk
535	177	8:00am - 6:00pm		P. Walk
536	178	8:00am - 6:00pm		P. Walk

ABSTRACT INDEX *Final Program*

Abstract #	Poster #	Presentation Time	Room	Format
Tuesday, August 16 continued				
537	179	8:00am - 6:00pm		P. Walk
538	180	8:00am - 6:00pm		P. Walk
539	181	8:00am - 6:00pm		P. Walk
Wednesday, August 17				
Applied Risk Management				
540		8:30am	Regency A	Oral
541		8:45am	Regency A	Oral
542		9:00am	Regency A	Oral
543		9:15am	Regency A	Oral
544		9:30am	Regency A	Oral
545		9:45am	Regency A	Oral
Cancer: Growing Evidence				
546		8:30am	Toronto	Oral
547		8:45am	Toronto	Oral
548		9:00am	Toronto	Oral
549		9:15am	Toronto	Oral
550		9:30am	Toronto	Oral
551		9:45am	Toronto	Oral
Giving Kids a Good Stab				
552		8:30am	Acapulco	Oral
553		8:45am	Acapulco	Oral
554		9:00am	Acapulco	Oral
555		9:15am	Acapulco	Oral
556		9:30am	Acapulco	Oral
557		9:45am	Acapulco	Oral
Interesting, but Will We Remember				
558		8:30am	Regency B	Oral
559		8:45am	Regency B	Oral
560		9:00am	Regency B	Oral
561		9:15am	Regency B	Oral
562		9:30am	Regency B	Oral
563		9:45am	Regency B	Oral
Measuring Quality of Prescribing				
564		8:30am	Regency C	Oral
565		8:45am	<i>Abstract Withdrawn by Author</i>	
566		9:00am	Regency C	Oral
567		9:15am	Regency C	Oral
177		9:30am	Regency C	Oral
195		9:45am	Regency C	Oral
Methods for Safety				
570		8:30am	Regency D	Oral
571		8:45am	Regency D	Oral
812		9:00am	Regency D	Oral
573		9:15am	Regency D	Oral
574		9:30am	Regency D	Oral
575		9:45am	Regency D	Oral

Abstract #	Poster #	Presentation Time	Room	Format
Wednesday, August 17 continued				
Cough & Wheeze				
576		10:30am	Regency A	Oral
577		10:45am	Regency A	Oral
578		11:00am	Regency A	Oral
579		11:15am	Regency A	Oral
580		11:30am	Regency A	Oral
581		11:45am	Regency A	Oral
Database Methods				
76		10:30am	Regency B	Oral
583		10:45am	Regency B	Oral
584		11:00am	Regency B	Oral
585		11:15am	Regency B	Oral
586		11:30am	Regency B	Oral
587		11:45am	Regency B	Oral
Gut Feeling				
588		10:30am	Toronto	Oral
589		10:45am	Toronto	Oral
590		11:00am	Toronto	Oral
591		11:15am	Toronto	Oral
592		11:30am	Toronto	Oral
593		11:45am	Toronto	Oral
Methods in Vaccine Safety				
594		10:30am	Regency C	Oral
595		10:45am	Regency C	Oral
596		11:00am	Regency C	Oral
597		11:15am	Regency C	Oral
598		11:30am	Regency C	Oral
599		11:45am	Regency C	Oral
Not Your "Typical" Psychotropics				
600		10:30am	Regency D	Oral
601		10:45am	Regency D	Oral
676		11:00am	Regency D	Oral
603		11:15am	Regency D	Oral
604		11:30am	Regency D	Oral
605		11:45am	Regency D	Oral
Nulligravida				
606		10:30am	Acapulco	Oral
607		10:45am	Acapulco	Oral
608		11:00am	Acapulco	Oral
609		11:15am	Acapulco	Oral
610		11:30am	Acapulco	Oral
611		11:45am	Acapulco	Oral
Active Surveillance for Follow-On Biologics				
612		1:30 - 3:00pm	Toronto	Sympos.
Assessing Treatment Patterns: Novel Methods and Applications				
613		1:30 - 3:00pm	Regency A	Sympos.

Abstract #	Poster #	Presentation Time	Room	Format
Wednesday, August 17 continued				
Assessment of Long-Term Adverse Drug Reactions, Regulatory Needs and Methodological Challenges				
614		1:30 - 3:00pm	Regency B	Sympos.
Addressing Challenges in Using Multiple Data Sources To Evaluate Medication Risk Factors for Asthma Mortality in Persistent Asthma				
615		1:30 - 3:00pm	Acapulco	Sympos.
FDA's Mini-Sentinel Program To Evaluate the Safety of Marketed Medical Products: Progress and Prospects				
616		1:30 - 3:00pm	Regency C	Sympos.
Drug Utilization Studies and Risk Management Plans: A Missing Link				
617		1:30 - 3:00pm	Regency D	Sympos.
POSTER SESSION C				
Cancer				
618	1	8:00am - 1:45pm		Poster
619	2	8:00am - 1:45pm		Poster
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623	5	8:00am - 1:45pm		Poster
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Diabetes				
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653	35	8:00am - 1:45pm		Poster

Abstract #	Poster #	Presentation Time	Room	Format
Wednesday, August 17 continued				
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662	44	8:00am - 1:45pm		Poster
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667		8:00am - 1:45pm		<i>Abstract Withdrawn by Author</i>
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Geriatrics				
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Hepatic				
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Abstract #	Poster #	Presentation Time	Room	Format
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Methods				
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Pediatrics				
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Renal				
744	117	8:00am - 1:45pm		Poster
745	118	8:00am - 1:45pm		Poster
Poster Walk - C.E.R. SIG				
746	119	8:00am - 1:45pm		P. Walk
747	120	8:00am - 1:45pm		P. Walk
748	121	8:00am - 1:45pm		P. Walk
387	122	8:00am - 6:00pm		Poster
749	123	8:00am - 1:45pm		P. Walk

Abstract #	Poster #	Presentation Time	Room	Format
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751	125	8:00am - 1:45pm		P. Walk
752	126	8:00am - 1:45pm		P. Walk
753	127	8:00am - 1:45pm		P. Walk
Poster Walk - Molecular Epi Biomarkers SIG				
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755	129	8:00am - 1:45pm		P. Walk
756	130	8:00am - 1:45pm		P. Walk
757	131	8:00am - 1:45pm		P. Walk
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Signal Detection				
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Abstract #	Poster #	Presentation Time	Room	Format
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Summarization				
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Vaccines				
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837	202	8:00am - 1:45pm		Poster
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842	207	8:00am - 1:45pm		Poster
843	208	8:00am - 1:45pm		Poster



Pharmacoepidemiology and
Therapeutic Risk Management

ADVERTISERS *Index*

Amgen.....	48
Boehringer Ingelheim	27
Celgene.....	72
CSD Medical Research.....	39
Eli Lilly and Company	43
GlaxoSmithKline	30
Healthcore	23
Health Data Services Corporation.....	50
Hoffman-LaRoche, Inc.....	29
IMS Health	14
Kantar Health	57
LA-SER.....	19
Merck	37
Netezza, an IBM Company	33
Optum.....	55
Oracle Health Services.....	63
Outcome	25
ParagonRx	15
Pfizer.....	13
Premier healthcare alliance.....	45
RTI Health Solutions	20
Takeda Pharmaceuticals	41
The Degge Group.....	17
United BioSource Corporation.....	61
Uppsala Monitoring Centre.....	67
Wiley-Blackwell	IBC

PDS Pharmacoepidemiology & Drug Safety

Official Journal of the International Society for Pharmacoepidemiology

Editor-in-Chief: Professor Brian L. Strom

Pharmacoepidemiology & Drug Safety provides an international forum for the communication and evaluation of data, methods and opinion in the discipline of pharmacoepidemiology.

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 **WILEY-BLACKWELL**

HYATT REGENCY CHICAGO GUIDE

11 151-Bistro, Bar & Club
East Tower, Green Level

25 Acapulco
West Tower, Gold Level

1 Addams
West Tower, Silver Level

25 Atlanta
West Tower, Gold Level

7 Bell Desk
East Tower, Blue Level

6 BIG Bar
East Tower, Blue Level

19 Buckingham
West Tower, Bronze Level

1 Burnham
West Tower, Silver Level

29 Business Center
East Tower, Purple Level

19 Columbian
West Tower, Bronze Level

20 Columbus Hall (Rooms A-L)
East Tower, Gold Level

19 Comiskey
West Tower, Bronze Level

3 Concierge
East Tower, Blue Level

15 Crystal Ballroom
West Tower, Green Level

5 DaddyO's Irish Pub
West Tower, Blue Level

1 DuSable
West Tower, Silver Level

14 East Tower Main Entrance
East Tower, Green Level

23 East Tower Parking
East Tower, Gold Level

1 Field
West Tower, Silver Level

18 Fitness Center
East Tower, Bronze Level

4 Front Desk
East Tower, Blue Level

13 Gift Shop
East Tower, Green Level

19 Gold Coast
West Tower, Bronze Level

4 Gold Passport
East Tower, Blue Level

22 Grand Ballroom
East Tower, Gold Level

21 Grand Ballroom, Registration
East Tower, Gold Level

24 Grand Suites
East Tower, Gold Level

19 Haymarket
West Tower, Bronze Level

16 Hertz
East Tower, Bronze Level

25 Hong Kong
West Tower, Gold Level

1 Horner
West Tower, Silver Level

12 J's Express
East Tower, Green Level

1 McCormick
West Tower, Silver Level

25 New Orleans
West Tower, Gold Level

1 Ogden
West Tower, Silver Level

28 Package Pick-up
East Tower, Purple Level

19 Picasso
West Tower, Bronze Level

10 Plaza Ballroom
East Tower, Green Level

26 Regency Ballroom
West Tower, Gold Level

27 Riverside Center
East Tower, Purple Level

17 Sales, Catering & Convention Services Departments
East Tower, Bronze Level

25 San Francisco
West Tower, Gold Level

1 Sandburg
West Tower, Silver Level

2 Skyway Conference Center
East Tower, Blue Level

19 Soldier Field
West Tower, Bronze Level

30 Stetson Conference Center
West Tower, Purple Level

9 Stetson's Chop House & Bar
East Tower, Green Level

25 Toronto
West Tower, Gold Level

8 Truffles
West Tower, Blue Level

19 Water Tower
West Tower, Bronze Level

31 West Tower Parking
West Tower, Purple Level

1 Wright
West Tower, Silver Level

19 Wrigley
West Tower, Bronze Level



Crossing Between Towers

Cross between towers via the Skyway on the Blue Level or the Concourse on the Bronze Level. You may also cross on the Green Level via the crosswalk on Stetson Avenue.

Escalators/Elevators

Escalators between floors are indicated in gray. Elevators are conveniently located throughout the hotel for guests with disabilities or where no escalator is present.