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Reynolds M

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Who to Ask and How? Preference-Based Methods for Benefit-Risk Assessment?

Marsh K, Hillege HL, Ataher Q, Tervonen T

Workshop
What’s in a Code? Algorithm Validation in Drug Safety Studies


Oral Presentation
Development and Validation of an Algorithm for Identifying Pediatric Patients with Type 2 Diabetes in Claims Data


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<td>Introduction to Pharmacoepidemiology (Liffey Mtg Rm 1)</td>
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<td>12:30 am - 2:00 pm</td>
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<td>Educational Sessions</td>
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<tr>
<td>8:30 am - 12:30 pm</td>
<td>Introduction to Drug Utilization (Liffey Mtg Rm 3)</td>
</tr>
<tr>
<td>8:30 am - 12:30 pm</td>
<td>Intermediate Pharmacoepidemiology – Dealing With Unmeasured Covariates (Liffey Hall 1)</td>
</tr>
<tr>
<td>8:30 am - 12:30 pm</td>
<td>Modern Pregnancy Pharmacoepidemiology (Liffey Mtg Rm 5)</td>
</tr>
<tr>
<td>8:30 am - 12:30 pm</td>
<td>Pharmacovigilance &amp; Signal Detection (Liffey Mtg Rm 1)</td>
</tr>
<tr>
<td>8:30 am - 12:30 pm</td>
<td>Propensity Scores in Pharmacoepidemiology (Liffey Mtg Rm 2)</td>
</tr>
<tr>
<td>8:30 am - 12:30 pm</td>
<td>Registrations and Prospective Cohort Studies (Liffey Mtg Rm 5)</td>
</tr>
<tr>
<td>12:30 am - 2:00 pm</td>
<td>Lunch on Your Own</td>
</tr>
<tr>
<td>2:00 pm - 6:00 pm</td>
<td>Educational Sessions</td>
</tr>
<tr>
<td>2:00 pm - 6:00 pm</td>
<td>Advanced Drug Utilization Workshop (Liffey Mtg Rm 1)</td>
</tr>
<tr>
<td>2:00 pm - 6:00 pm</td>
<td>Advanced Topics in Pharmacoepidemiology (Liffey Hall 1)</td>
</tr>
<tr>
<td>2:00 pm - 6:00 pm</td>
<td>Epidemiology of Vaccine Safety (Liffey Mtg Rm 5)</td>
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<tr>
<td>2:00 pm - 6:00 pm</td>
<td>Field Studies to Add Value in Pharmacoepidemiology (Liffey Mtg Rm 5)</td>
</tr>
<tr>
<td>2:00 pm - 6:00 pm</td>
<td>Pharmacoepidemiology Considerations for Biologists and Bioinformaticians (Liffey Mtg Rm 3)</td>
</tr>
<tr>
<td>2:00 pm - 6:00 pm</td>
<td>Regulatory Pharmacists (Liffey Hall 1)</td>
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### Friday, August 26, 2016

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am - 8:00 am</td>
<td>Speakers’ Ready Room (Liffey Mtg Rm 4)</td>
</tr>
<tr>
<td>7:00 am - 8:00 am</td>
<td>Registration Open (Ground Foyer)</td>
</tr>
<tr>
<td>7:00 am - 8:00 am</td>
<td>Cross National Comparison of Drug Utilization (Liffey Brdrm 3)</td>
</tr>
<tr>
<td>7:00 am - 8:00 am</td>
<td>Poster Session Setup (The Forum &amp; 3rd Floor)</td>
</tr>
<tr>
<td>7:00 am - 8:00 am</td>
<td>Coffee &amp; Tea (The Forum)</td>
</tr>
<tr>
<td>7:30 am - 10:00 am</td>
<td>Educational Sessions</td>
</tr>
<tr>
<td>7:30 am - 10:00 am</td>
<td>Representative Sampling in Pharmacoepidemiology (The Auditorium)</td>
</tr>
<tr>
<td>8:00 am - 9:00 am</td>
<td>Educational Sessions</td>
</tr>
<tr>
<td>8:00 am - 9:00 am</td>
<td>Noon Concurrent Sessions</td>
</tr>
<tr>
<td>8:00 am - 9:00 am</td>
<td>Meascan de Meds: Utilization and Trends (The Liffey A)</td>
</tr>
<tr>
<td>8:00 am - 9:00 am</td>
<td>Registration (3rd floor; lunch available)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Spotlight Poster Session (The Auditorium)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Lunch/Poster Session A/ Exhibits (The Forum)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>CRISP: Yourself (The Liffey B)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Adverse Events of Cardiovascular Treatment: Head to Toe (Liffey Hall 2)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Membership Committee (Wicklow Mtg Rm 3)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Global Development Committee (Wicklow Mtg Rm 4)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Fellowship &amp; Awards Committee (Wicklow Mtg Rm 5)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Finance Committee (Wicklow Mtg Rm 2A)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Public Policy Committee (Wicklow Mtg Rm 2B)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Student Council (Wicklow Mtg Rm 1)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Cancer: Around the World in Databases (The Liffey A)</td>
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<tr>
<td>10:15 am - 1:00 pm</td>
<td>Royston Catchup in Pediatric Pharmacoepidemiology (Wicklow Hall 2)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Patents, Prescriptions, Policy &amp; Pennies (Liffey Hall 2)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Adherence: Staying the Course (Liffey Hall 1)</td>
</tr>
<tr>
<td>10:15 am - 1:00 pm</td>
<td>Study Design Considerations to Address Confounding (The Auditorium)</td>
</tr>
<tr>
<td>1:30 pm - 3:00 pm</td>
<td>Concurrent Sessions</td>
</tr>
<tr>
<td>1:30 pm - 3:00 pm</td>
<td>Bittersweet: Trends and Treatments in Diabetes (The Liffey A)</td>
</tr>
<tr>
<td>1:30 pm - 3:00 pm</td>
<td>Registration (3rd floor; lunch available)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Plenary Session:</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Real World Effectiveness: How Effective Is It? (The Auditorium)</td>
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<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Educational Sessions</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Patient Engagement in Observational Pharmacoepidemiology Research (The Liffey B)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>CER (Wicklow Mtg Rm 4)</td>
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<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Adherence (Wicklow Mtg Rm 2B)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Drug Utilization/HSR (Wicklow Mtg Rm 1)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Medical Devices (Liffey Brdrm 3)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Medications in Pregnancy (Wicklow Mtg Rm 3)</td>
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<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Oncology (Liffey Brdrm 1)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Molecular Epidemiology (Liffey Mtg Rm 5)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Validation Using U.S. Medicare Administrative Claims Data (Liffey Mtg Rm 2)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Pediatrics (Wicklow Mtg Rm 5)</td>
</tr>
<tr>
<td>3:30 pm - 5:00 pm</td>
<td>Vaccines (Liffey Mtg Rm 2)</td>
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### Saturday, August 27

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00am</td>
<td>Coffee &amp; Tea</td>
<td>(The Forum)</td>
</tr>
<tr>
<td>7:00am - 6:00pm</td>
<td>Registration Open</td>
<td>(Ground Foyer)</td>
</tr>
<tr>
<td>7:00am - 6:00pm</td>
<td>Poster Session B Set-Up</td>
<td>(The Forum &amp; 3rd Floor)</td>
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<tr>
<td>7:00am - 8:00am</td>
<td>Coffee &amp; Tea</td>
<td>(The Forum)</td>
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<tr>
<td>8:00am - 9:00am</td>
<td>Concurrent Sessions</td>
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<tr>
<td>8:00am - 10:00am</td>
<td>Psychotropic Trends on Populations from a Multinational Perspective</td>
<td>Wicklow Hall 2</td>
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<tr>
<td>8:00am - 10:00am</td>
<td>A Sticky Subject: Diabetes Safety (Wicklow Hall 2)</td>
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<tr>
<td>8:00am - 10:00am</td>
<td>Broken &amp; Torn (Wicklow Hall 1)</td>
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<tr>
<td>8:00am - 10:00am</td>
<td>Identification and Validation of Outcomes</td>
<td>(The Auditorium)</td>
</tr>
<tr>
<td>10:00am - 11:30am</td>
<td>Plenary Session: Patient Voice in Clinical and Pharmacoepidemiologic Research</td>
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<tr>
<td>11:00am - 1:00pm</td>
<td>Poster Session B Exhibits</td>
<td>The Auditorium</td>
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<tr>
<td>1:00pm - 2:00pm</td>
<td>Concurrent Sessions</td>
<td></td>
</tr>
<tr>
<td>2:00pm - 3:00pm</td>
<td>Annual Meeting of ISPE Members and Awards Ceremony</td>
<td>(The Auditorium)</td>
</tr>
<tr>
<td>4:00pm - 5:00pm</td>
<td>Symposium &amp; Workshops</td>
<td></td>
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<tr>
<td>5:00pm - 6:00pm</td>
<td>Council Meetings</td>
<td>(The Liffey A)</td>
</tr>
<tr>
<td>6:00pm - 7:00pm</td>
<td>Social Event at Guinness Storehouse (Shuttle bus to the Storehouse from the Convention Centre and to ISPE meeting hotels from the Storehouse)</td>
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</tr>
</tbody>
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### Sunday, August 28, 2016

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
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<tbody>
<tr>
<td>7:00am - 3:30pm</td>
<td>Registration Open</td>
<td>(Ground Foyer)</td>
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<tr>
<td>7:00am - 8:00am</td>
<td>Coffee &amp; Tea</td>
<td>(The Forum)</td>
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<tr>
<td>7:00am - 8:00am</td>
<td>Poster Session C Set-Up</td>
<td>(The Forum &amp; 3rd Floor)</td>
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<tr>
<td>7:00am - 10:00am</td>
<td>Concurrent Sessions</td>
<td></td>
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<tr>
<td>7:00am - 10:00am</td>
<td>From Eve to... (The Liffey A)</td>
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<tr>
<td>7:00am - 10:00am</td>
<td>My Achy Breaky Heart: Diabetes and CVD (The Liffey B)</td>
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<tr>
<td>7:00am - 10:00am</td>
<td>Keeping Up - A Poignant (Wicklow Hall 2)</td>
<td></td>
</tr>
<tr>
<td>10:30am - Noon</td>
<td>Multiple Database Study Design</td>
<td>(The Auditorium)</td>
</tr>
<tr>
<td>11:00am - 1:00pm</td>
<td>Lunch/Panels Monday Exhibits</td>
<td>The Auditorium</td>
</tr>
<tr>
<td>1:00pm - 2:00pm</td>
<td>Pharmaceutical and Risk Management Planning</td>
<td>(The Liffey A)</td>
</tr>
<tr>
<td>2:00pm - 3:00pm</td>
<td>Clinical and Analytic Considerations in Observational Database Studies</td>
<td>(The Liffey B)</td>
</tr>
<tr>
<td>4:00pm - 5:00pm</td>
<td>Symposium &amp; Workshops</td>
<td></td>
</tr>
<tr>
<td>5:00pm - 6:00pm</td>
<td>Council Meetings</td>
<td>(The Liffey A)</td>
</tr>
<tr>
<td>6:00pm - 7:00pm</td>
<td>Social Event at Guinness Storehouse (Shuttle bus to the Storehouse from the Convention Centre and to ISPE meeting hotels from the Storehouse)</td>
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</tbody>
</table>
4:00-6:00pm
Registration (Ground Foyer)
If you will attend a course on Wednesday, we highly recommend that you register on Tuesday evening to avoid delays.

PRE-CONFERENCE | TUESDAY, AUGUST 23

EDUCATIONAL SESSIONS: ALL DAY COURSE (Ticket required)

8:00am-6:00pm
Pharmacogenomics in the Real World 2.0 (Liffey Meeting Room 2A)

Content
This course will focus on the essentials every pharmacoepidemiologist should know about real world applications of pharmacogenomics including precision medicine, companion diagnostics, the biomarker development pipeline, common genomic observational designs, and the intersection of big data with pharmacogenomics. This course has expanded to include a broader definition of genomic and other biomarkers, including both germ line and somatic changes. There will be short pre-course orientating videos on the ISPE website that will cover basic definitions and concepts in preparation for the main course, allowing the main course to focus more on practical applications. A variety of instructional techniques (including didactic teaching, scenario-based advanced and basic break-out sessions, small group round-table discussions, bring your own question/ask the expert sessions, and an interactive debate) will be used to keep attendees engaged throughout the day-long course.

Course Directors
Amalia M Issa, University of the Sciences in Philadelphia
Anke-Hilse Maitland van der Zee, Utrecht University

Course Faculty
Gillian Bartlett, McGill University
Bruce Carleton, University of British Columbia
Marissa Dolled-Filhart, Merck Research Laboratories
Alexander Doney, University of Dundee
Kelly Filipski, National Cancer Institute
Andrew Freedman, National Cancer Institute
Stephen Kimmel, University of Pennsylvania
Geoffrey Liu, University of Toronto
Colin Palmer, University of Dundee
David Pulford, GlaxoSmithKline
Wei Zhou, MD, Merck Research Laboratories

HALF-DAY MORNING COURSES (Ticket required)

8:30am-12:30pm
Pediatric Pharmacoepidemiology (Wicklow Meeting Room 3)

Content
The increasing use of medications by children and the history of excluding children from clinical trials have created the need for pediatric pharmacoepidemiology, a sub-specialty within pharmacoepidemiology. Unique challenges in studying children, accessing data, defining outcomes, and designing pediatric studies will be discussed. This half-day course will introduce participants who have a good understanding of pharmacoepidemiology to the specific methodologic issues arising in pediatric pharmacoepidemiology and operational approaches used to study medications in children.

Course Faculty
Tamar Lasky, FISPE, MIE Resources
Ann W McMahon, U.S. Food and Drug Administration
Rachel E Sobel, FISPE, Pfizer Inc,
Susan dosReis, University of Maryland School of Pharmacy Department of Pharmaceutical Health Services Research
Real-world insight into drug safety and epidemiology.

Proven epidemiology research expertise powered by one of the largest healthcare data repositories.

HealthCore is on the frontline of observational research aimed at uncovering vital evidence on the utilization, safety and effectiveness of biopharmaceuticals and devices in large, real-world patient populations.

Our multi-disciplinary team of pharmacoepidemiologists brings a broad range of scientific expertise and operational experience to the timely and accurate execution of safety and risk management studies in the post-marketing real-world setting.

The HealthCore Integrated Research Environment (HIRESM) allows for the augmentation of automated claims with clinical data obtained from medical records, electronic health records, physicians, and patients – making it a rare and valuable resource for conducting medical product safety and risk management studies.

- Descriptive epidemiology (natural history of disease, burden of illness)
- Drug and vaccine post authorization safety studies
- Risk management and REMS survey studies
- Active surveillance of new medical products and adverse events
- Development and medical record validation of case-identifying algorithms
- Multi-database study design, coordination, and execution
- Data linkage capability
- Systematic literature reviews
- Strategic consulting

Visit Booth #5 during ICPE to learn about our full-service research solutions or contact us at RWE@HealthCore.com.

www.healthcore.com
HALF-DAY MORNING COURSES (CONT.)

8:30am–12:30pm

Introduction to Pharmacoepidemiology (Wicklow Hall 1)

Content
This half-day course will provide participants with a short introduction to the basic principles and concepts of pharmacoepidemiology. The course includes lectures on cohort studies, case-control studies, and bias & confounding.

Course Faculty
Almut Winterstein, FISPE, University of Florida College of Pharmacy
Jennifer Lund, Gillings School of Global Public Health, University of North Carolina at Chapel Hill
Tobias Gerhard, FISPE, Ernest Mario School of Pharmacy, Rutgers University

Medical Device Epidemiology (Wicklow Meeting Room 4)

Content
This course provides a foundation for medical device epidemiology and its application to the real world. The course will incorporate didactic lectures and interactive case studies that highlight novel medical devices and combination products.

Course Faculty
Colin Anderson-Smits, U.S Food and Drug Administration
Kourtney Davis, GlaxoSmithKline PLC
Chantal Holy, Johnson and Johnson
Katherine Etter, Johnson and Johnson
Jessica Jalbert, LA-SER Group & Weill Cornell Medical College
Mary E Ritchey, RTI Health Solutions
Michael Steinbuch, FISPE, Procter and Gamble

Introduction to the Evaluation of Therapeutic Risk Management Programs (Liffey Meeting Room 3)

Content
This course presents an overview of European and US risk management principles, with a focus on methods and examples for evaluating the effectiveness of risk minimization measures. The didactic section includes speakers from European and US regulatory, industry and research communities to present background, trends in regulatory requirements, and examples of effective evaluation techniques. The workshop section asks participants to work in groups to develop an evaluation plan for one of two health outcomes of interest for a hypothetical product. The groups present their plans from this case study to the “regulatory panel (faculty)” for feedback and discussion.

Course Faculty
Gerald Dal Pan, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Almath Spooner, Health Products Regulatory Authority, Ireland and Vice Chair EMA’s PRAC
Elaine Morrato, Colorado School of Public Health
Meredith Smith, Global Patient Safety at Amgen
Judith Jones, FISPE, The Degge Group, Ltd
Lesley Wise, Takeda Development Centre Europe Ltd
Alicia Gilsenan, RTI Health Solutions
HALF-DAY MORNING COURSES (CONT.)

Adherence to Pharmacotherapy (Wicklow Meeting Room 1)

Content
This course will provide an overview of measurement issues to be considered when designing and conducting an adherence study. The course will cover the following topics:

- Description of different constructs of adherence that can be measured: initiation, implementation, and persistence.
- Selection of measurement techniques according to the construct being measured.
- Strengths and limitations of commonly used techniques: self-reports, medical/pharmacy electronic data, and microelectronic monitoring data, among others.
- Discussion of analysis issues: choice of the duration of an adherence interval, taking multiple drug regimens and switches into account, various approaches to summarizing adherence data from the different techniques, and linking adherence data to relevant outcomes.

Course Faculty

Robert Gross, FISPE, University of Pennsylvania Perelman School of Medicine
Jacqueline Hugtenburg, Department of Clinical Pharmacology and Pharmacy, VU University Medical Center, Amsterdam, Netherlands
Niteesh Choudhry, Harvard Medical School; Center for Healthcare Delivery Sciences, Brigham and Women's Hospital
Jean-Pierre Grégoire, FISPE, Laval University, Québec City, Canada
Petra Denig, University Medical Center Groningen, The Netherlands

It begins with a promise
to discover medicines that make life better.

Since 1876, we have worked tirelessly to discover medicines that make life better, finding ways to come through no matter the odds. From the development of insulin to the discovery of new treatments for mental illness, we have pioneered breakthroughs against some of the most stubborn and devastating diseases. We bring this same determination to our work today, uniting our expertise with the creativity of research partners across the globe to keep finding ways to make life better.

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HALF-DAY AFTERNOON COURSES (Ticket required)

12:30–2:00pm
Lunch on Your Own

2:00–6:00pm
ISPE Newcomers/Early Stage Investigators Workshop (Wicklow Hall 1)

Content
This course is aimed at early stage pharmacoepidemiologists who have been in the field for less than 3 years. Participation will lead to enhancement in skills (i.e., development of mentor-mentee relationships, research presentation, and manuscript writing) that are crucial to early success in pharmacoepidemiology. We will also discuss important aspects of early stage professional development in careers in government/regulatory science, academia, and industry.

Course Faculty
Vincent Lo Re III, FISPE, Center for Pharmacoepidemiology Research & Training, University of Pennsylvania
Caitlin Knox, Quintiles
Tarek Hammad, FISPE, Merck Research Laboratories
Sengwee Darren Toh, Harvard Medical School & Harvard Pilgrim Health Care Institute
Stella Blackburn, FISPE, Quintiles
Irene Petersen, FISPE, Institute of Epidemiology & Health, University College London
Quazi Ataher, Pfizer

Comparative Effectiveness Research: CER and its Role in Adaptive Licensing (Wicklow Meeting Room 4)

Content
Increasingly, regulators are moving towards adaptive licensing, which is the progressive approval or authorization of a medical product characterized by iterative phases of data gathering and regulatory evaluation. Rigorous comparative effectiveness research, which involves generating “real world” evidence about the benefits and risks of medical products, can play a key role in informing adaptive licensing decisions. This year’s course will start with an overview of methodological aspects related to CER and then will narrow the focus to how evidence from comparative effectiveness research can support adaptive licensing.

Course Faculty
Joshua Gagne, Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital and Harvard Medical School
Olaf Klungel, Division of Pharmacoepidemiology & Clinical Pharmacology, University of Utretch
Danica Marinac-Dabic, FISPE, Division of Epidemiology, Center for Devices and Radiological Health, U.S. Food and Drug Administration

Intermediate Database Utilization Workshop: Using Pharmacoepidemiology Database Resources to Address Drug Safety Research (Wicklow Meeting Room 3)

Content
This highly interactive workshop will involve participants in the following topics:
• 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, workshop will strengthen the concepts discussed through participant interaction;
• Assess the quality of electronic medical record data
• Conduct validation studies through a variety of approaches
• Examine characteristics of available resources for data linkage between pharmacoepidemiology resources particularly to patient registry data resources

Course Faculty
Gillian Hall, FISPE
Matthew Reynolds, Evidera
Brian Sauer, University of Utah
Elieen Ming, Epi Excellence
Fergus Caskey, North Bristol, NHS Trust
HALF-DAY AFTERNOON COURSES (CONT.)

Applying Benefit-Risk Assessment in the Context of Regulatory Submission of New Molecular Entities
(Liffey Meeting Room 3)

Content
- Presentation of Benefit-Risk and patient preference information for regulatory interactions, especially new molecular submissions
- Overview of expectations for developing and presenting the structure and content of Benefit-Risk information
- Quantitative methods for Benefit-Risk assessment
- When and how to use patient preference information to inform regulatory decision-making

Course Faculty
Tarek A Hammad, FISPE, Merck Research Laboratories
Juhaeri Juhaeri, Sanofi
Brett Hauber, RTI Health Solutions
Rebecca Noel, Eli Lilly and Company

Practical Skills in Protocol Writing and Computer Programming Relevant to Pharmacoepidemiology
(Wicklow Meeting Room 1)

Content
Pharmacoepidemiologic studies that involve the use of electronic healthcare data have complex and unique characteristics that must be taken into consideration when executing the studies. This highly interactive course will engage participants in the following topics:

1. Pre-specifying study components in a protocol, including design, analysis, conduct, and reporting of the study, along with a science-based rationale for the choices pertaining to these components.
2. Translating elements of the study protocol into SAS programming

Course Faculty
Christian Hampp, U. S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmacovigilance and Epidemiology, Office of Surveillance and Epidemiology, Division of Epidemiology II
Jessica Jalbert, LASER Analytica, Weill Cornell Medical College
Chih-Ying (Natasha) Pratt, U. S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmacovigilance and Epidemiology, Office of Surveillance and Epidemiology, Division of Epidemiology II
Nicole Pratt, Quality Use of Medicines and Pharmacy Research Centre, Sansom Institute, School of Pharmacy and Medical Sciences, University of South Australia
Soko Setoguchi, FISPE, Duke Clinical Research Institute

MEDICAL BREAKTHROUGHS MAY COME OUT OF THE LAB. BUT THEY BEGIN IN THE HEART.

For more than a century, a very special passion has driven the people of Merck. Our goal is to develop medicines, vaccines, and animal health innovations that will improve the lives of millions. Still, we know there is much more to be done. And we’re doing it, with a long-standing commitment to research and development. We’re just as committed to expanding access to healthcare and working with others who share our passion to create a healthier world. Together, we’ll meet that challenge. With all our heart.

For more information about getting Merck medicines and vaccines for free, visit merckhelps.com or call 800-727-5400. Copyright © 2016 Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. All Rights Reserved. CIDP-1060080-0102 01/16
Raising the Standard in Pharmacoepidemiology

For more than 30 years, Analysis Group has worked with prominent clinicians, academics, and industry thought leaders to develop innovative solutions for our clients across North America, Europe, and emerging markets.

Drawing on our expertise in pharmacoepidemiology, we assist our clients with:

- Peri-approval safety studies for IND and NDA submissions and post-approval commitment
- Observational pharmacoepidemiology studies (e.g., claims analysis and chart review, EMR data analysis)
- Prospective drug safety surveillance
- Drug safety monitoring boards
- Pharmacovigilance and spontaneous report analyses
- Clinical trial data analyses and meta-analyses for drug safety endpoints
- PMR/PMS and PASS studies
- Strategic responses to drug safety concerns raised by U.S. and ex-U.S. regulatory agencies
- Design and evaluation of the effectiveness of REMS programs
- Advanced methods in causal inference (e.g., marginal structural models, mediation analysis, high-dimensional propensity score matching)
- Comparative effectiveness research
- Quality of life instrument development and validation
- Mass tort pharmaceutical liability litigation
- Machine learning and ensemble methods
- Natural language processing

For more information, contact Mei Sheng Duh, Sc.D., M.P.H., Managing Principal and Chief Epidemiologist, at mei.duh@analysisgroup.com, or visit our website at www.analysisgroup.com/epidemiology
EDUCATIONAL SESSIONS:  
HALF-DAY MORNING COURSES  *(Ticket required)*

8:30am–12:30pm  
**Introduction to Drug Utilization Research** *(Wicklow Meeting Room 3)*

**Content**
This educational session provides an overview of drug utilisation research and presents essential methods used. The session includes interaction with participants, question, and answer sessions and discussion during and at the end of each presentation. At the end of the session, the participant will be exposed to:

- Description of the theoretical framework and practical applications of different methods illustrated using selected examples
- Classification systems used in drug utilisation monitoring and research
- Limitations of data sources and methods
- Interpretation of aggregate and individual-based data, variation and change
- Importance of drug utilisation research for public health and implications for policy decisions

**Course Faculty**
- **Katja Taxis**, University of Groningen, The Netherlands
- **Hanne Strom**, WHO Collaborating Centre for Drug Statistics Methodology, Norwegian Institute of Public Health, Oslo, Norway
- **Björn Wettermark**, Centre for Pharmacoepidemiology, Karolinska Institute, Stockholm, Sweden
- **Andrew Gilbert**, FISPE, University of South Australia, Adelaide, Australia
HALF-DAY MORNING COURSES (Cont.) (Ticket required)

8:30am–12:30pm

Intermediate Pharmacoepidemiology -- Dealing With Unmeasured Covariates (Wicklow Hall 1)

**Content**
Covariates are often poorly measured or not measured at all. Unmeasured confounders produce bias, and they lead to divergent results in studies that ought to be near replicates of one another. Unmeasured intermediates can lead to “effects” that run contrary to simple biological cause. This course will classify the options for dealing with unmeasured covariates in study design and analysis. Students will see and be able to discuss examples of self-controlled case series and matched designs, propensity-balancing for proxy-variable control, and instrumental variable analyses.

**Course Faculty**
Alexander M Walker, FISPE, World Health Information Science Consultants

Propensity Scores in Pharmacoepidemiology (Liffey Meeting Room 2)

**Content**
Issues of bias and confounding relate to study design and analysis in the setting of non-random treatment assignment where compared subjects might differ substantially with respect to comorbidities. Failing to address a lack of balance in the covariates between treated and comparison groups can produce confounded estimates of treatment effect. Faculty will explain how propensity scores can be used to mitigate confounding through standard observational approaches (restriction, stratification, matching, regression, or weighting). The advantages and disadvantages of standard adjustment relative to propensity score-based methods will be discussed. Details of propensity score methodology (variable selection, use, and diagnostics) will also be discussed.

**Course Faculty**
John Seeger, FISPE, Optum
Jeremy Rassen, Aetion

Pharmacovigilance & Signal Detection (Liffey Meeting Room 1)

**Content**
This half-day course will introduce participants to the principles of surveillance in pharmacovigilance with a focus on quantitative aspects and recent advances in the field. The course will cover classical pharmacovigilance signal detection using spontaneous adverse event reports, quantitative signal detection methods for electronic medical record and claims data, and international initiatives, including the EU-ADR project and the US FDA's Sentinel program, aimed at using routinely collected electronic healthcare data to conduct signal detection and prospective medical product safety monitoring. The course will involve lectures with ample opportunities for questions and discussion. Use of social media for signal detection will also be discussed.

**Course Faculty**
Andrew Bate, Pfizer Ltd
Gianluca Trifirò, University of Messina & Erasmus University Medical Center
Joshua Gagne, Division of Pharmacoepidemiology and Pharmacoconomics, Department of Medicine, Brigham and Women’s Hospital and Harvard Medical School
Stephen Evans, FISPE, London School of Hygiene & Tropical Medicine

Registries and Prospective Cohort Studies (Liffey Meeting Room 5)

**Content**
This course will provide an overview of the theory and practice, including field methods, for the design, execution and interpretation of registries and prospective studies. Topics include regulatory, methodological and logistical challenges and how studies are evaluated for specific purposes. Special applications relating to pregnancy registries, emerging therapies and Post-Authorization Safety Studies will be reviewed, as well as current guides to quality for prospective studies. An interactive case study will be presented to allow attendees to engage in critical reflection.

**Course Faculty**
Nancy A Dreyer, FISPE, Quintiles
Christina D Mack, Quintiles
Sonia Hernández-Díaz, FISPE, Department of Epidemiology, Harvard T.H. Chan School of Public Health
Deborah Layton, Drug Safety Research Unit, Portsmouth University
HALF-DAY MORNING COURSES (Cont.)

8:30am–12:30pm

Modern Pregnancy Pharmacoepidemiology: Methodological Challenges in Exposure Measurement and Implications for Study Design and Analysis (Wicklow Meeting Room 5)

Content
In this half day course, we will discuss study design and analysis aspects related to exposure in studies of drug utilization and drug safety in pregnancy. The course format will consist of four short methods-focused presentations by faculty with Q&A along with two break-out sessions giving participants the opportunity to discuss and report back on the assigned readings, and a short faculty-moderated session wrap-up.

The content of this course has changed from last year’s. While in 2015 the course provided an overview of issues that are particular to pregnancy safety research, this year the focus will be on specific challenges related to exposure measurement. Some of the topics to be covered include defining the etiologically relevant time window (including issues related to LMP estimation and differential opportunity for exposure), how to define exposure (e.g., number of prescriptions, days supply overlap, patient recall, drug class or individual drugs), how to define the comparator group (e.g., unexposed with same condition, active comparator, exposed during a different time window in pregnancy), dose-response analyses, value of positive controls (i.e., assess known associations between the exposure and an outcome), and sensitivity analysis evaluating potential bias associated with exposure misclassification. Advantages and disadvantages of different approaches will be discussed.

Course Faculty
Andrea Margulis, RTI Health Solutions
Brian Bateman, Brigham and Women’s Hospital, Massachusetts General Hospital, Harvard Medical School
Krista Huybrechts, FISPE, Brigham and Women’s Hospital and Harvard Medical School
Helle Kieler, Karolinska Institutet

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EDUCATIONAL SESSIONS:
HALF-DAY AFTERNOON COURSES (Registration required)

PRE-CONFERENCE | THURSDAY, AUGUST 25

2:00–6:00pm
Advanced Topics in Pharmacoepidemiology (Liffey Hall 1)

Course Instructors/Presentations:
Kenneth J Rothman, FISPE, RTI Health Solutions: The Significance of the ASA Statement on Significance and P-Vales
Robert Glynn, Brigham and Women’s Hospital and Harvard Medical School: Competing Risks in Pharmacoepidemiology

Heather Whitaker, The Open University: Advances in the Self-controlled Case Series Method
Suzanne Cadarette, University of Toronto: Diffusion of Methods Innovation in Pharmacoepidemiology

Content
This interactive educational program includes presentations, question and answer sessions and a final discussion with the faculty panel. The session will involve participants in the:
• Use of drug utilisation information from administrative health data to improve medicines use
• Use of prescribing quality indicators to assess prescribing
• Application of principles derived from Health Services and Implementation Research to the design of a clinical intervention
• Methods for evaluating the effect of clinical or policy interventions
• Interpretation of the evaluation data and dissemination of results

Advanced Drug Utilization Research (Liffey Meeting Room 1)

Course Faculty
Petra Denig, University of Groningen
Eimir Hurley, Trinity College Dublin
Libby Roughead, FISPE, School of Pharmacy and Medical Sciences, University of South Australia
Lisa Pont, FISPE, Australian Institute of Health Innovation, Macquarie University

Content
This interactive educational program includes presentations, question and answer sessions and a final discussion with the faculty panel. The session will involve participants in the:
• Use of drug utilisation information from administrative health data to improve medicines use
• Use of prescribing quality indicators to assess prescribing
• Application of principles derived from Health Services and Implementation Research to the design of a clinical intervention
• Methods for evaluating the effect of clinical or policy interventions
• Interpretation of the evaluation data and dissemination of results

Pharmacoepidemiologic Considerations for Biologics and Biosimilars
(Wicklow Meeting Room 3)

Course Faculty
Nancy A Dreyer, FISPE, Quintiles Real World & Late Phase Research and University of North Carolina
Thijs Giezen, Foundation Pharmacy for Hospitals in Haarlem, Haarlem, the Netherlands; Expert at the Medicines Evaluation Board in the Netherlands; Member of the EMA Biosimilars Working Party
Gianluca Trifirò, University of Messina and Erasmus Medical Center
Brian D Bradbury, Amgen, Inc. and University of California Los Angeles School of Public Health
Jaclyn L F Bosco, Quintiles Real World & Late Phase Research and Boston University School of Public Health

Content
This interactive workshop will involve participants in the following topics:
• Update on the current landscape of biologics and biosimilars
• Review regulatory guidelines, particularly focused on postmarketing, pharmacovigilance, and risk management requirements for biologics and biosimilars
• Understand challenges and methodological considerations when conducting post-marketing studies of biologics and biosimilars.
• Discuss primary data collection and use of multiple data sources for evaluating comparative safety and effectiveness of biologics and biosimilars
### Half-Day Afternoon Courses (Cont.)

#### Epidemiology of Vaccine Safety (Wicklow Meeting Room 5)

**Content**
This half-day course aims to establish an understanding of some of the ways in which vaccine safety is monitored after licensure, including passive surveillance methods, common observational vaccine-safety study designs and methods, active safety surveillance using sequential analysis, and investigation of signals that arise from active surveillance. The course will involve lectures with ample opportunities for audience participation (questions and discussion).

**Course Faculty**
- S Rizwan Ahmad, FISPE, Georgetown University
- Robert T Chen, FISPE, Centers for Disease Control and Prevention
- Steven Bailey, Pfizer
- Patricia Saddier, Merck
- Martin Kuldorff, Harvard Pilgrim Health Institute
- Katherine Yih, Harvard Pilgrim Health Institute

#### Using Field Studies to Value-add in Pharmacoepidemiology (Liffey Meeting Room 5)

**Content**
This course provides basic theory and practical tips in conducting pharmacoepidemiologic studies when required information is not captured in databases or when large databases are not available. Common study designs used to collect data through observation, medical records or questionnaires will be presented and the strengths and limitations of working without large databases discussed. Hands on experience via a workshop will expose course participants to different study designs and rich discussions on how to answer relevant questions about safety and utilization of medicines in primary and secondary care settings using field studies.

**Course Faculty**
- Veronika Wirtz, Boston University School of Public Health
- Katja Taxis, University of Groningen
- Annie Fourrier-Reglat, University Bordeaux
- Lisa Pont, FISPE, Australian Institute of Health Innovation, Macquarie University

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HALF-DAY AFTERNOON COURSES (Cont.) (Ticket required)

2:00–6:00pm

Regulatory Pharmacoepi
(Wicklow Hall 1)

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

Course Faculty
Gerald Dal Pan, Center for Drug Evaluation and Research, Food and Drug Administration
June Raine, Medicines and Healthcare Regulatory Products Agency
Stephen JW Evans, FISPE, London School of Hygiene and Tropical Medicine

Welcome Reception/International Chapter & Academic Showcase (3rd Floor)

6:00–7:00pm

Sponsored by Optum
- Kathleen Bennett, Chair, 2016 Local Host Committee
- Mary E Ritchey, Chair, 2016 Scientific Program Committee
- Sonia Hernández-Díaz, FISPE, ISPE President

International Chapter & Academic Showcase Participants
- Center for Drug Safety & Effectiveness, Johns Hopkins University
- Department of Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida
- Division of Pharmacoepidemiology & Pharmacoeconomics, Brigham and Women’s Hospital & Harvard Medical School
- ISPE Gulf Chapter
- ISPE Latin-America Chapter
- ISPE Student Council & Student Chapters
- London School of Hygiene and Tropical Medicine
- Pharmacoepidemiology Program, Department of Epidemiology, Gillings School of Global Public Health, University of North Carolina at Chapel Hill
- PhD in Pharmacoepidemiology, RCSI Population Health
- Postgraduate Programme in Pharmacovigilence, Drug Safety Research Unit
- Rutgers, the State University of New Jersey
- School of Pharmacy at University College Cork
- University of Illinois at Chicago
- University of Rhode Island

7:30–9:30pm

Students/Early Career Professionals Meet & Greet
(Ely Bar & Brasserie)

Registration required -- limited capacity.
Organized by the Student Council. Please contact SISPEchair@gmail.com for more information and to RSVP.
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Guidelines for Cross-National Comparison of Drug Utilization (Liffey Boardroom 3)

Open to all who are interested.

This special session will present the draft guideline, produced by a group of experts from IMI-Protect, EuroDURG and WHO CC for Pharmaceutical Policy and Regulation. The project was selected and funded by the ISPE Strategic Planning Committee under the Society’s Call for Manuscripts Initiative.

Based on a literature search, a review template for CNC DU studies was built to address the main methodological issues, (standardize the information extraction, assess the risk of bias in the exposure estimation of each country or region compared, and evaluate the validity of the comparison between countries or regions). The information gathered was used to develop good practice guidelines for designing, conducting, analyzing and reporting CNC DU studies.

The project leaders will present the results and discuss with the audience whether the following areas were well addressed: reliability and validity of population coverage; drug coverage; drug terminology issues; biases affecting accuracy and precision of exposure estimates. Comments will be collected and embedded in a final draft of the guidelines.

Next steps will be discussed to ensure that standardized guidelines will enhance the validity and reliability of CNC DU studies, and facilitate their peer review, correct interpretation of CNC DU studies, and adequate translation into pharmaceutical policy decision-making. The final draft of the guidelines will be submitted to the ISPE membership for comments consistent with the ISPE Policy Manual and sent to the ISPE Board for action.

PLENARY SESSION (The Auditorium)

Representative Sampling in Pharmacoepidemiology: A Hot Topic or Hot Air?

Speakers:
- Charlie Poole, University of North Carolina, Chapel Hill
- Stephen JW Evans, FISPE, London School of Hygiene and Tropical Medicine
- Xavier Kurz, European Medicines Agency

Moderator:
- Jessica Franklin, Harvard Medical School and Brigham and Women’s Hospital

A recent, highly publicized paper, “Perils and potentials of self-selected entry to epidemiological studies and surveys,” published in the Journal of the Royal Statistical Society, put forth the argument that all epidemiologic studies should be based on representative samples of a specific patient population. For example, in a study of diabetes treatments, the target population might be all adult type 2 diabetes patients in the United States, and a representative sample could be formed either by randomly selecting patients from the target population into the study or by using a different sampling method, accompanied by sampling weights to adjust estimates for non-random sampling.

While representative sampling is the norm in fields such as survey research, where the focus is on estimating measures that characterize a specific population, it is almost never used in research aiming to estimate causal effects, including both randomized trials and observational studies of treatments. Some argue that without representativeness the effects estimated from such studies are applicable only to the patients directly in the study and cannot be extrapolated to other populations, rendering the research essentially useless. Under this view, most pharmacoepidemiology studies conducted to date are invalid. This contentious issue is stirring an important debate in the research community, as evidenced by the more than 30 comments that were published alongside the paper.

While representative sampling is the norm in fields such as survey research, where the focus is on estimating measures that characterize a specific population, it is almost never used in research aiming to estimate causal effects, including both randomized trials and observational studies of treatments. Some argue that without representativeness the effects estimated from such studies are applicable only to the patients directly in the study and cannot be extrapolated to other populations, rendering the research essentially useless. Under this view, most pharmacoepidemiology studies conducted to date are invalid. This contentious issue is stirring an important debate in the research community, as evidenced by the more than 30 comments that were published alongside the paper.

This session will explore the role of representative sampling in pharmacoepidemiology from different perspectives. Dr. Poole will present background on representative sampling, its main methods, and practical issues in its application to pharmacoepidemiology, providing a pharmacoepidemiologist’s viewpoint. Dr. Evans will provide a statistician’s perspective, challenging several of the epidemiologists’ viewpoints. Dr. Kurz will share the views and experience of regulators.
Meascàn de Meds: Utilization and Trends (The Liffey A)
Moderators: Gianluca Trifirò & Björn Wettermark

10:30am
- Time-Trends and Predictors of Oral Disease Modifying Drug Treatment for Multiple Sclerosis [1]
  Rishi J Desai, Mufaddal Mahesri, Eimir Hurley, Joshua J Gagne, Angela Tong, Tanuja Chinis, Sarah Minden, Olga S Matlin, William H Shrank, Niteesh Choudhry. (United States)

10:45am
- Drug Utilization Patterns in Relapsing-Remitting Multiple Sclerosis: A Population-Based Cohort Study [2]
  Irene Eriksson, Thomas Cars, Fredrik Piehl, Rickard Malmström, Björn Wettermark, Mia von Euler. (Sweden)

11:00am
  David Hägg, Marie Eriksson, Marcus Schmitt-Egenolf, Anders Sundström. (Sweden)

11:15am
- Cardiovascular Medication Utilization by Educational Level Among Heart Failure Patients: A Population-Based Cohort Study in the Lazio Region, Italy [4]
  Anna Maria Bargagli, Silvia Cascini, Claudia Marino, Marina Davoli, Nera Agabiti. (Italy)

BRACE Yourself (The Liffey B)
Moderators: Elizabeth Andrews, FISPE & Inge Zomerdijk

10:30am
- Risk Minimization Evaluation in a Distributed Data Network – An IMEDS Evaluation Pilot Assessment of the 2010 Class Label Change for Proton Pump Inhibitors [7]
  Rachel E Sobel, Andrew Bate, James Marshall, Gregory Daniel, Troy McCall, Jeffery Brown, Robert F Reynolds. (United States)

10:45am
- The Impact Of Risk Minimisation Measures On The Incidence And Prevalence Of Use Of Strontium Ranelate At The Population Level: Preliminary Results Of A Multi-National Cohort Study Including 5 European Countries [8]
  Klara Berencsi, Cristina Reyes Reyes, Lars Pedersen, Preciosa Coloma, Francesco Lapi, Monica Simonetti, Peter Rijnbeek, Miriam C Sturkenboom, Daniel Prieto-Alhambra. (United Kingdom)

11:00am
- Evaluating Patient Knowledge of Risks and Safe Use of Xarelto (Rivaroxaban) [9]
  Laurie J Zografos, Kiliana Suzart, Andrea Horvat-Broeker, Montse Soriano-Gabarró, Dan L Wolin, Brian Calingaert, Eric K Davenport, Kelly A Hollis, Elizabeth Andrews. (United States)

11:15am
- An Association Between Beliefs About Medicines and Drug Non-Adherence in Patients with Chronic Diseases in China [10]
  Li Wei, Sarah Chapman, Xiaomei Li, Xin Li, Ruoling Chen, Angel Chater, Rob Home. (United Kingdom)

11:30am
- Improving Medicines Management at Patients Hospital Discharge [11]
  Alice V Gilbert, Michael S Roberts, Desmond B Williams, Bhavini Patel, Joanna Wallace, Andrew L Gilbert. (Australia)

11:45am
- Everyone Isn’t Average: Quantifying Heterogeneity in Crohn's Disease Patients’ Benefit-Risk Tradeoff Preferences [12]
  Meenakshi Bewtra, F Reed Johnson, Shelby Reed, Frank I Scott, James D Lewis. (United States)
CONCURRENT SESSIONS: CONTRIBUTED PAPERS

**Diabetes: Adverse Events of Cardiovascular Treatment: Head to Toe** (Wicklow Hall 2)
Moderators: Deb Casso & Yea-Huei Kao Yang, FISPE

10:30am
- **Clinical Outcomes Of Concomitant Use Of Warfarin And Selective Serotonin Reuptake Inhibitors** [13]
  Yaa-Hui Dong, Katsiaryna Bykov, Niteesh K Choudhry, Macarius M Donneyong, Krista F Huybrechts, Raisa Levin, Sebastian Schneeweiss, Joshua J Gagne. (United States)

10:45am
- **Propranolol Use and Survival from Breast Cancer: A Pooled Analysis of 133,251 Breast Cancer Patients from the European Cancer Pharmacoepidemiology Network** [14]
  Chris Cardwell, Anton Pottegård, Evelien Vaes, Hans Garmo, Chris Brown, Pauline Vissers, Michael O’Rorke, Kala Visvanathan, Deirdre Cronin-Fenton, Harlinde De Schutter, Mats Lambe, Des Powe, Myrthe van Herk-Sukel, Anna Gavin, Seren Friis, Linda Sharp, Kathleen Bennett. (United Kingdom)

11:00am
- **Statins and Reduced Risk of Liver Cancer: Evidence for Confounding** [15]
  Laurel A Habel, Ninah Achacoso, Bruce Fireman, Gary D Friedman. (United States)

11:15am
- **Acute Liver Injuries and Antiarrhythmic Drugs: A Case-Referent Study from the PGRx Surveillance System on Medicine Use** [16]
  Lamiae Grimaldi-Bensouda, Jacques Benichou, Michel Rossignol, Dominique Larrey, Lucien Abenhaim, Thierry Poynard. (United Kingdom)

11:30am
- **Association of Idiopathic Inflammatory Myositis with Statin Exposure: A Population Based Case Control Study** [17]
  Gillian E Caughey, Genevieve M Gabb, Saffron Ronson, Michael Ward, Catherine L Hill, Vidy A Limaye. (Australia)

11:45am
- **Confounding of the Association Between Statins and Parkinson Disease: Review and Meta-Analysis** [18]
  Katsiaryna Bykov, Kazuki Yoshida, Marc G Weisskopf, Joshua J Gagne. (United States)

**Pregnancy and Beyond** (Liffey Hall 2)
Moderators: Sara Ephross & Kathryn Rough

10:30am
- **Ondansetron Use Among Pregnancies Identified In The Sentinel Distributed Database** [19]
  Lockwood G Taylor, Patty Greene, Steven T Bird, Marsha E Reichman, Leyla Sahin, Melissa S Tassinari, Susan E Andrade, Katherine Haffenreffer, Darren Toh. (United States)

10:45am
- **Use Of Antibiotics During Pregnancy And The Risk Of Spontaneous Abortion** [20]
  Flory T Muanda, Odile Sheehy, Anick Bénard. (Canada)

11:00am
- **Pregnancy Outcomes in Women with Chronic Hypertension Initiated on Labetalol versus Methyldopa** [21]
  Brian T Bateman, Krista F Huybrechts, Jacqueline Cohen, Helen Mogun, Rishi J Desai, Elisabetta Patorno, Sonia Hernández-Díaz, . (United States)

11:15am
- **Risk Comparison for Prenatal Use of Different Analgesics and Selected Birth Defects** [22]
  Julia D Interrante, Elizabeth C Ailes, Jennifer N Lind, Marlene Anderka, Marcia L Feldkamp, Martha M Werler, Suzanne M Gilboa, Margaret A Honein, Cheryl S Broussard. (United States)

11:30am
- **High Exposure to Phthalates from Medications and Male Genital Malformations** [23]
  Katherine E Kelley, Sonia Hernández-Díaz, Russ Hauser, Allen A Mitchell. (United States)

11:45am
- **Language Development in 3 Year Old Children After Prenatal Exposure to Opioids** [24]
  Eva Skovlund, Marte Handal, Randi M Selmer, Ragnhild E Brandlistuen, Svetlana Skurtveit. (Norway)
Keeping an “I” in Opioid Use (Liffey Hall 1)  
Moderators: Paul Coplan & Eileen Ming

10:30am
- **Serious Opioid Toxicity in Children with Non-Cancer Pain:**  
  A Retrospective Cohort Study [25]  
  Cecilia P Chung, S Todd Callahan, William O Cooper, William D Dupont,  
  Katherine T Murray, Kathi Hall, Judith A Dudley, C Michael Stein, Wayne A  
  Ray. (United States)

10:45am
- **Long-Acting Oxycodone Co-Prescribing Among US Nursing Home  
  Residents [26]**  
  Kevin M Fain, G Caleb Alexander, Carlos Castillo-Salgado, David D Dore.  
  (United States)

11:00am
- **Doctor/Pharmacy Shopping Measures for Opioid Analgesics and  
  Diagnosed Abuse and Addiction in a US Administrative Database [27]**  
  Daina B Esposito, M Soledad Cepeda, Ruihua Yin, Howard Chicoat, Paul  
  Coplan, Stephan Lanes. (United States)

11:15am
- **The Role of Socioeconomic Status in Regional Variation of Opioid Utilisation in  
  the Greater London Area [28]**  
  Ji Hye Bing, Teng-Chou Chen, Li-Chia Chen, Roger Knaggs. (United Kingdom)

11:30am
- **Opioid Tolerance Prior to Initiation of High-Dose Oxycodone in Commercially-Insured  
  Adults in the US, 2010-2014 [29]**  
  Jessica C Young, Jennifer L Lund, Nabarun Dasgupta, Michele Jonsson Funk. (United  
  States)

11:45am
- **The Preventable Risk of Fentanyl Prescribing [30]**  
  Shawn C Bugden, Kevin J Friesen, Cornelius Woelk. (Canada)

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**MAIN CONFERENCE | FRIDAY, AUGUST 26**

1:30-3:00pm **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

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**Data Lost and Found (The Auditorium)**

Moderators: Til Stürmer, FISPE & Marie Linder

10:30am
- Effects of Expanding the Look-Back Period to All Available Data in the Assessment of Covariates [31]
  Sonja S Nakasian, Jeremy Rassen, Jessica M Franklin. (United States)

10:45am
- Classifying Patient Histories in Medicare Claims: Fixed vs. All-Available Lookbacks [32]
  Mitchell M Conover, Til Stürmer, Charles Poole, Robert J Glynn, Ross J Simpson, Jr., Michele Jonsson Funk. (United States)

11:00am
- Recency of Comorbid Diseases and One-Year Mortality: A Registry-Based Cohort Study in Denmark [33]
  Morten Madsen, Vera Ehrenstein, Henrik T Sørensen. (Denmark)

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Noon -1:30pm
**Lunch/Poster Session A/Exhibits (The Forum)**

**Lunch/Roundtable Discussions (Liffey Meeting Room 1)**

**Roundtable Discussions**
To foster the ability of the more junior participants to network and first-timers to meet others attending the ICPE, ISPE is hosting several informal lunchtime discussion roundtables on Friday and Saturday. The facilitators are listed below. There will be NO formal presentations made at the roundtables. The objectives are discussion, information exchange, and networking. Seating is limited; first-come, first-served.

- Gianluca Trifirò
  Role and Responsibilities of Pharmacoepidemiologists in Academia

- Kate Lapane, FISPE
  Medication Issues in Vulnerable Populations

- Stella Blackburn, FISPE
  Adaptive Pathways

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**Noon-1:30pm**
**ISPE Committee/Council Meetings**
(Open to all participants; Lunch available.)

- Membership Committee (Wicklow Meeting Room 3)
- Global Development Committee (Wicklow Meeting Room 4)
- Fellowship & Awards Committee (Wicklow Meeting Room 5)
- Finance Committee (Wicklow Meeting Room 2a)
- Public Policy Committee (Wicklow Meeting Room 2b)
- Student Council (open to all students) (Wicklow Meeting Room 1)

12:15-1:15pm
**Spotlight Poster Session** (3rd Floor; Lunch available)

- Adherence
- Databases
- Devices
- Pediatrics
1:30-3:00pm CONCURRENT SESSIONS: CONTRIBUTED PAPERS

Bittersweet: Trends and Treatments in Diabetes (The Liffey A)
Moderators: Ken Hornbuckle, FISPE & Rosa Gini

1:30pm
- Preferential Prescribing of Linagliptin to Patients with Renal or Cardiac Disorders in Japan [39]
  Soulamaz Fazeli Farsani, Atsushi Taniguchi, Rie Ikeda, Kimberly G Brodovicz, Dorothee B Bartels. (Germany)

1:45pm
- Estimated Life Expectancy and Cause-Specific Mortality in White, South Asian and Black Patients with Type 2 Diabetes [38]
  Alison K Wright, Evangelos Kontopantelis, Martin K Rutter, Darren M Ashcroft. (United Kingdom)

2:00pm
- Trends In Incidence, Prevalence And Prescribing In Type 2 Diabetes Mellitus [37]
  Manuj Sharma, Irwin Nazareth, Irene Petersen. (United Kingdom)

2:15pm
- Augmentation Patterns Amongst Metformin Initiators with Type 2 Diabetes Mellitus (T2DM) [40]
  Chandrasekar Gopalakrishnan, Sebastian Schneeweiss, John D Seeger, Jun Liu, Elisabetta Patorno. (United States)

2:30pm
- Trends Of Use Of Non-Insulin Antidiabetic Drugs Between 2006-2013 In France [41]
  Mickael Amaud, Julien Bezin, Bernard Bégaud, Antoine Pariente, Francesco Salvo. (France)

2:45pm
- Antidepressants and the Risk of Type 2 Diabetes Mellitus Among Publicly-Insured U.S. Youth [42]
  Mehmet Burcu, Julie M Zito, Susan dosReis, Fadia T Shaya, Daniel J Safer. (United States)

VISIT US AT BOOTH 29

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- Feasibility studies
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EPID Research is a partner centre of the ENCePP, the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, a scientific network coordinated by the European Medicines Agency.
Cancer: Around the World in Databases (The Liffey B)
 Moderators: Jason C Hsu & James Kaye

1:30pm
• Predictors of Induction Chemoimmunotherapy Among Older US Adults with Follicular Lymphoma [43]
  Laura L Hester, Steven I Park, Jennifer L Lund. (United States)

1:45pm
• Validation of Claims-Based Definitions of Incident Colorectal Cancer (CRC) in a North Carolina (NC) Medicare Population [44]
  Monica E D’Arcy, Til Stürmer, Anne Marie Meyer, Michele Jonsson-Funk, Robert Sandler, John Baron, Melissa Troester, Jennifer Lund. (United States)

2:00pm
• Clinical Outcomes of Stage II and III Breast Cancer Patients in Denmark [45]
  Deirdre Cronin-Fenton, Anders Kjærsgaard, Mette Nørgaard, Justyna Amelio, Alex Liede, Rohini K Hernandez, Henrik T Sørensen. (Denmark)

2:15pm
• Post-Diagnostic Statin Use and Breast Cancer Survival: A Nationwide Cohort Study in Scotland [46]
  Una C Mc Menamin, Chris R Cardwell, Carmel M Hughes, Liam J Murray. (United Kingdom)

2:30pm
• Low-Dose Aspirin and Survival Benefit in Gastrointestinal Malignancies [47]
  Martine A Frouws, Esther Bastiaannet, Ruth E Langley, John WK Chia, Myrthe PP Van Herk-Sukel, Hein Putter, Cornelis JH Van de Velde, Johanneke EA Portielje, Gerrit-Jan Liefers. (Netherlands)

2:45pm
• Initiation and Adherence with Bone-Targeting Agents in US Men with Bone Metastases from Prostate Cancer [48]
  Anne M Butler, Karynsa Cetin, Rohini K Hernandez, Robert A Overman, Jungin Kim, B Diane Reams, Bradford R Hirsch, Amy P Abernethy, Alexander Liede, M Alan Brookhart. (United States)

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us.

> Pfizer Epidemiology is proud to support the 32nd International Conference on Pharmacoepidemiology and Therapeutic Risk Management in Dublin, Ireland.
CONCURRENT ORAL PRESENTATION SESSIONS

Playing Catch-up in Pediatric Pharmacoepidemiology (Wicklow Hall 2)
Moderators: Susan Oliveria, FISPE & Sudha Raman

1:30pm
- Birth Cohort Effects on Overall and Subtype-Specific Antibiotic Use Among Infants Born in Denmark 2004-2012 [49]
  Alan C Kinlaw, Henrik T Sørensen, Jennifer L Lund, Lars Pedersen, Julie L Daniels, Michael D Kappelman, Til Stürmer. (United States)

1:45pm
- Development and Validation of an Algorithm for Identifying Pediatric Patients with Type 2 Diabetes in Claims Data [50]
  Dana Y Teltch, Richard S Swain, Soulmaz Fazeli Farsani, Kimberly G Brodovic, Stefan Kaspers, Samuel Huse, Nicholas Sicignano, Beth L Nordstrom, Dorothee B Bartels. (United States)

2:00pm
- Suicide Trends and Risk Factors in Youth Aged 10-19 Years, Texas, USA [51]
  Deanna A Oleske, Denise M Oleske, Sharon M Derrick, Merrill O Hines. (United States)

2:15pm
- ADHD Treatment and Diagnosis – Importance of Relative Age in Grade in Norway [52]
  Øystein Karlstad, Kari Furu, Siri E Håberg, Inger Johanne Bakken. (Norway)

2:30pm
- Safety of Stimulants in Children with Epilepsy: A Retrospective Cohort Study [53]
  Xinyue Liu, Paul Carney, Regina Bussing, Richard Segal, Linda Cottler, Almut Winterstein. (United States)

2:45pm
- Comparative Effectiveness Of NSAID Treatment Versus No Treatment For PDA In Preterm Infants [54]
  Jonathan L Slaughter, Patricia B Reagan, Thomas B Newman, Mark A Klebanoff. (United States)

Patients, Prescriptions, Policy & Pennies (Liffey Hall 2)
Moderator: David Martin

1:30pm
- Potential Impact of Proposed Limits on Clinical Data Collected from Primary Care for a National Research Database [55]
  Wilhelmine Meeraus, Jennifer Campbell, Daniel Dedman, Arlene Gallagher, Antonis Kousoulis, Tarita Murray-Thomas, Jessie Oyinola, Helen Strongman, Rachael Williams, Tim Williams. (United Kingdom)

1:45pm
- The Impact of State Chemotherapy Parity Laws on Use and Spending for Oral Chemotherapy [56]
  Stacie B Dusetzina, Haiden A Huskamp, Aaron N Winn, Ethan M Basch, Nancy L Keating. (United States)

2:00pm
- Disclosure of Industry Payments to Prescribers: Industry Payments Might Be a Factor Impacting Generic Drug Prescribing [57]
  Jingqing Qian, Richard Hansen, Daniel Surr, Jennifer Howard, Zippora Kiptanui, Ilene Harris. (United States)

2:15pm
- What has Been Achieved Five Years After Approval of New Drugs with the Requirement to Set up Patient Registries? A Follow-Up Study [58]
  Carla J Jonker, Marijke HM van den Berg, Arno W Hoes, Peter M Mol. (Netherlands)

2:30pm
  Mariana F Almas, Pierre Engel, Marieke L De Bruin, Kathryn Starzyk, Blackburn Stella, Dreyer A Nancy (United Kingdom)

2:45pm
  Dima Qato, Shannon Zenk, Jocelyn Wilder, Rachel Harrington, Darrel Gaskin, Caleb Alexander. (United States)
1:30-3:00pm  CONCURRENT ORAL PRESENTATION SESSIONS

Adherence: Staying the Course
(Liffey Hall 1)
Moderators: Julie Lauffenburger & Robert Vander Stichele

1:30pm
- Longitudinal Asthma Management Profiles: Visualisation of Patient Histories Using Multiple Data Sources [61]
  Eric H Van Ganse, Sandrine Herbage, Alexandra L Dima, Marijn de Bruin, Nathalie Texier, Flore Jacoud, Maeva Nolin, Laurent Laforet, The ASTROLAB Group. (France)

1:45pm
- Determinants of Antihypertensive Adherence Trajectories Among Older US Adults in the First Year After Initiation [62]
  Jennifer Jones, Carri Casteel, Yvonne Golightly, Laura Loehr, Virginia Pate, Steve Marshall, Til Stürmer. (United States)

2:00pm
- Impact of Statin-Related Media Coverage on the Use of Statins: An Interrupted Time Series Analysis Using UK Primary Care Data [63]
  Anthony Matthews, Emily Herrett, Antonio Gasparriini, Tjeerd Van Staa, Ben Goldacre, Laim Smeeth, Krishnan Bhaskaran. (United Kingdom)

2:15pm
- Changes in Statin Adherence in Response to a Myocardial Infarction: The Impact of a Stressful Life Event on Medication Taking Behavior [64]
  Ryan P Hickson, Izabela E Annis, Ley A Killeya-Jones, Gang Fang. (United States)

2:30pm
- Comparative Adherence of Overactive Bladder Agents Among Older Patients [65]
  Samantha Singh, Wayne Khuu, Mina Tadrous, Diana Martins, Muhammad Mamdani, Dean Elterman, Tara Gomes. (Canada)

2:45pm
- Self-Reported Adherence to Different Classes of Antiretroviral Medication as a Predictor of HIV Viral Suppression [66]
  Joseph A Delaney, Robin M Nance, Mari Kitahara, Joseph Eron, Greer Burkeholder, James Willig, Michael Mugavero, Chris Mathewa, Michael Saag, Katerina Christopoulous, Ken Mayer, Susan Heckbert, Heidi M Crane. (United States)

Study Design Considerations to Address Confounding
(The Auditorium)
Moderators: Darren Toh & Rob Heerdink

1:30pm
- Instrumental Variable Analysis Using Pooled Data in Pharmacoepidemiology: A Simulation Study [67]
  Md Jamal Uddin, M Abdul Baker Chowdhury. (Bangladesh)
  Andrew McAfee Award for the Best Abstract Submitted by a Researcher or Student living in a Developing Country

1:45pm
- A Reference-Likelihood Alternative to Inverse Probability of Treatment Weighting [68]
  Colin Dormuth. (Canada)

2:00pm
- Variation in Propensity-Adjusted Marginal Estimates of Treatment Effect [69]
  Jessica M Franklin, Wesley Eddings, Robert J Glynn, Sebastian Schneeweiss. (United States)

2:15pm
- The Impact of Study Design and Analysis on “Measurable” and “Un-Measurable” Patient Characteristics in Observational Studies of Glucose-Lowering Drugs in Type 2 Diabetes Mellitus (T2DM) [70]
  Elisabetta Patorno, Chandrasekar Gopalakrishnan, Jessica Franklin, Kimberly Brodovicz, John Seeger, Dorothee Bartels, Jun Liu, Sebastian Schneeweiss. (United States)

2:30pm
- Calendar Time as an Instrumental Variable in Assessing the Risk of Heart Failure with Antihyperglycemic Drugs [71]
  Mugdha Gokhale, John B Buse, Christina Mack, Til Stürmer. (United States)

2:45pm
- Propensity ScoreTrimming to Identify the Target Population for Comparative Effectiveness Research [72]
  Robert J Glynn, Til Stürmer. (United States)

3:00-3:30pm
Break/Posters/Exhibits (The Forum)
3:30-5:00pm
PLENARY SESSION

Real World Effectiveness: How Effective is It? (The Auditorium)

Speakers:
- Sarah Garner
  - National Institute for Health and Care Excellence
- Elizabeth B Andrews, FISPE
  - RTI-Health Solutions
- Tjeerd van Staa
  - Health eResearch Centre, Farr Institute for Health Informatics Research
  - University of Manchester

Moderator:
- Almath Spooner
  - EMA’s PRAC, Health Products Regulatory Authority, Ireland

Health organisations, decision makers and regulators sometimes require information on real world effectiveness of medicines after authorization (post-authorisation effectiveness studies, PAES). When evaluating real world effectiveness, observational evidence may be required as randomised controlled trials are inappropriate, impossible or inadequate. Delivering timely decision relevant data is essential; however, because of the potential for bias, it has been suggested that observational studies are only suitable for the study of adverse (non-predictable) effects of drugs and not for measuring their intended effects. Much ongoing research is focused on determining the value of observational studies in effectiveness evaluation and the inference that can be drawn from such analyses. The IMI ‘GetReal’ initiative (www.imi-getreal.eu) is one example that aims to show how robust new methods of RWE collection and synthesis could be adopted earlier in pharmaceutical R&D and the healthcare decision making process.

This plenary session will focus on the real world effectiveness from different perspectives (decision makers, academics, regulators) and the challenges that are encountered as well as offering thoughts on the how research could and should evolve.

Specific topics covered during this session include:
- Breadth/types of research aims/objectives across perspectives/countries
- Timely and relevant data for decision makers/ regulators etc.
- Generating or retrieving data for effectiveness research (e.g. claims data for outcomes research, electronic health records)
- Methodological considerations of bias and confounding

5:00-6:30pm
SYMPOSIA AND WORKSHOPS

Catch the Wave: Diffusion of Methodological Innovation in Pharmacoepidemiology [73] (The Auditorium)
- Suzanne M Cadarette, Robert W Platt, Joann K Ban, Giulia P Consiglio, Mina Tadrous, Malcolm K Maclure. (Canada)

Patient Engagement in Observational Pharmacoepidemiology Research: Where are We, Where do We Need to be and What are the Steps for Getting There? [74] (The Liffey B)
- Robert F Reynolds, Anne Trontell, Zhanna Jumadilova, Louis Fiore, Liam Smeeth. (United States)

Impact of Pharmacovigilance: From PRAC Strategy to Demonstrable Better Health Protection [75] (The Liffey A)
- Peter Arlett, Marieke De Bruin, Robert Reynolds, Gerald Dal Pan, Saad Shakir, Almath Spooner, Xavier Kurz, June M Raine. (United Kingdom)

Big Data, Big Picture - Data Visualisation of Health [76]
(Wicklow Hall 2)
- Alison Bourke, Patrick B Ryan, Noémie Elhadad, Adam Perer. (United Kingdom)

Drug Utilisation In Older Populations: The Irish View On Knowing Right From Wrong [77] (Liffey Hall 2)
(Sponsored by the Drug Utilization Research Special Interest Group)
- Lisa G Pont, Katja Taxis, Veronika Wirtz, Paul Gallagher, Stephen Byrne, Annie Fourrier-Reglat. (Australia)

Does Randomization Work? Selection Bias in Pragmatic Randomized Clinical Trials and Unblinded Observational Studies [78] (Liffey Hall 1)
(Sponsored by the CER Special Interest Group)
- Cynthia J Girman, Kourtney J Davis, Liam Smeeth, Sarah Garner, Mary E Ritchey, Corrine De Vries, Andrew W Roddam. (United States)

Exploring Innovative Methods to Conduct Validation Using United States Medicare Administrative Claims Data [79]
(Liffey Meeting Room 2)
- Elizabeth Andrews, Til Stürmer, Leah J McGrath, Michele Jonsson Funk, Jennifer L Lund, Catherine B Johannes, Alicia W Gilsenan, Christopher Powers. (United States)

6:30-7:15pm
Special Interest Group (SIG) Meetings (Open to all participants)

- Adherence (Wicklow Meeting Room 2B)
- AsPEN (Wicklow Meeting Room 3)
- Biologics & Biosimilars (Wicklow Meeting Room 2A)
- BRACE (EcoCem)
- Comparative Effectiveness Research (Wicklow Meeting Room 4)
- Database (Liffey Meeting Room 1)
- Drug Utilization/Health Services Research (Wicklow Meeting Room 1)
- Medical Devices (Liffey Boardroom 3)
- Medications in Pregnancy (Liffey Meeting Room 3)
- Molecular Epi/Biomarkers/ Pharmacogenetics (Liffey Meeting Room 5)
- Oncology (Liffey Boardroom 1)
- Pediatrics (Wicklow Meeting Room 5)
- Vaccines (Liffey Meeting Room 2)

7:15-9:00pm
PDS Editorial Board (Spencer Hotel)
(By Invitation Only)
### Psychotropics in Pregnancy (The Liffey A)  
**Moderators:** Janet Hardy & Caitlin Knox

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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| 8:00am | - Antidepressant Medication and the Risk of Pregnancy-Induced Hypertension [402]  
Loes F ter Heijne, Nelly Zakiyah, Jens HJ Bos, Eelko Hak, Catharina CM Schuling-Veninga. (Netherlands) |
| 8:15am | - Gestational Exposure to SSRIs and Risk of Preeclampsia in Pregnancy: A Study from the Norwegian Mother and Child Cohort Study Accounting for Time-Varying Severity of Depressive and Anxiety Symptoms [403]  
Angela Lupattelli, Molly Wood, Olav Spigset, Kate Lapan, Hedvig Nordeng. (Norway) |
| 8:30am | - Continuation of Atypical Antipsychotic Medications During Pregnancy and the Risk of Gestational Diabetes [404]  
Yoonyoung Park, Sonia Hernández-Díaz, Brian T Bateman, Jacqueline Cohen, Elisabetta Patorno, Helen Mogun, Krista F Huybrechts. (United States) |
| 8:45am | - Is There a Dose-Response Relation Between the Use of Lithium in Early Pregnancy and the Risk of Cardiac Malformations? [405]  
Elisabetta Patorno, Krista Huybrechts, Brian Bateman, Helen Mogun, Rishi Desai, Sonia Hernández-Díaz. (United States) |
| 9:00am | - Associations Between Treatment with Selective Serotonin Reuptakeinhibitors (SSRIs) Before and After Pregnancy [406]  
Irene Petersen, Cormac Sammon, Kate Walters, Michael Sharpe, Jane Walker, Sarah Hardoon. (United Kingdom) |
| 9:15am | - Risk Of Neurodevelopmental Disorders Following Prenatal Valproate Exposure: An Observational Cohort Study Using The Health Improvement Network [407]  
Cormac J Sammon, Rachel L McCrea, David P Osborn, Stephen JW Evans, Phillip J Cowen, Irwin Nazareth, Irene Petersen. (United Kingdom) |
# Pay Attention to Pain: ADHD and Pain Treatment DUS
(The Liffey B)

**Moderators:** Judith Jones, FISPE & Mina Tadrous

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>8:00am</td>
<td>Frequency and Predictors of Analgesic Prescribing in US Nursing Home Residents with Persistent Pain [408]</td>
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<td>Kevin M Fain, G Caleb Alexander, David D Dore, Carlos Castillo-Salgado. (United States)</td>
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<td>8:15am</td>
<td>Prevalence and Trends of Analgesic Medication Utilisation in Patients Undergoing Total Joint Replacement Surgery [409]</td>
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<td>Maria CS Inacio, Kara Cashman, Nicole L Pratt, Marianne H Gilliam, Stephen E Graves, Elizabeth E Roughead. (Australia)</td>
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<td>8:30am</td>
<td>Global Utilization of Attention Deficit Hyperactivity Disorder Medications – Preliminary Results [410]</td>
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<td>Sudha R Raman, Kenneth KC Man, Anick Berard, Takoua Boukhris, Yea-Huei Kao Yang, Kiyoshi Kubota, Hidefumi Nakamura, Chien-Chou Su, Miriam CJM Sturkenboom, Ian CK Wong. (United States)</td>
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**8:45am**

Prescribing Trends of Attention-Deficit Hyperactivity Disorder (ADHD) Medications in UK Primary Care, 1995-2015 [411]

Christel Renoux, Ju-Young Shin, Sophie Dell’Aniello, Emma Fergusson, Samy Suissa, CNODES Canadian Network for Observational Drug Effect Studies. (Canada)

**9:00am**

Drug Utilization of Lisdexamfetamine Dimesylate in European Countries [412]

Birgit Ehlken, Dorothea von Bredow, William A Blumentals, Barbara Thun, Jacco Keja, Tricia Maxwell. (Germany)

**9:15am**

Treatment Patterns in Adults with Newly Treated Attention Deficit/Hyperactivity Disorder [413]

Yanmin Zhu, Wei Liu, Yan Li, Paul S Kubilis, Almut G Winterstein. (United States)
Psychotropic Trends on Populations from a Multinational Perspective (Wicklow Hall 2)
Moderators: Yola Moride, FISPE & Maire O’Dwyer

8:00am
Psychotropic Medicine Use in Australia (2006 to 2014); Annual Incidence, Prevalence and Patterns of Use [414]
Jonathan Brett, Benjamin J Daniels, Emily Karanges, Sallie-Ann Pearson, Carl Schneider. (Australia)

8:15am
Incidence of Mood and Anxiety Disorders and Psychotropic Use in Spouses of Dementia Patients: A Population-Based Study [415]
I Fan Kuo, Andrew Basham, Heather Prior, Silvia Alessi-Severini, James Bolton, Alan Katz, Shahin Shooshtari. (Canada)

8:30am
Sustained Use of Benzodiazepines and High Dose Escalation in a Canadian Population [416]
Silvia Alessi-Severini, James M Bolton, Murray W Enns, Matthew E Dahl, Dan Chateau, David M Collins, Jitender Sareen. (Canada)

8:45am
Antidepressant and Benzodiazepine Co-Initiation and Subsequent Long-Term Benzodiazepine Use in Adults with Depression, United States 2001-2014 [417]
Greta A Bushnell, Til Stürmer, Bradley N Gaynes, Virginia Pate, Matthew Miller. (United States)

A Sticky Subject: Diabetes Safety (Liffey Hall 2)
Moderators: James Lewis, FISPE & Christian Hampp

8:00am
Final Results of a Large Multi-National Postmarketing Safety Study Evaluating Use of the Oral Anti-Diabetic Drug Saxagliptin and Risk of Five Outcomes [420]
Vincent Lo Re III, Dena M Carbonari, Craig W Newcomb, M Elle Saine, Jason A Roy, Serena Cardillo, Kevin Haynes, Stephen E Kimmel, Peter P Reese, David J Margolis, Andrea J Apter, K Rajender Reddy, Harshvinder Bhullar, Arlene M Gallagher, Daina B Esposito, Brian L Strom. (United States)

8:15am
Use of Incretin Agents and Risk of Acute and Chronic Pancreatitis: A Population-Based Cohort Study [421]
Lotte M Knapen, Ronaldus GPJ de Jong, Johanna HM Driessen, Yolande C Keulemans, Nielka P van Erp, Marie L de Bruin, Hubert GM Leufkens, Sander Croes, Frank de Vries. (Netherlands)

8:30am
Use of Non-Insulin Blood Glucose Lowering Drugs and the Risk of Acute Pancreatitis [422]
Gwen MC Masclee, Ingrid Leal, Lorenza Scotti, Giorgia De Berardis, Irene Bezemer, Miguel Gil, Anita McGrogan, Niklas Schmedt, John D Seeger, Gianluca Trifirò, Serena Pecchioli, Manel Piadavelli-Vila, Mark M Smits, Peter Rijnbeek, Miriam CJM Sturkenboom, Silvana A Romio. (Netherlands)

8:45am
Metformin and Cancer Risk in Type 2 Diabetes: An Application of Marginal Structural Models with Inverse Probability of Treatment Weights in the Clinical Practice Research Datalink [423]
Ruth E Farmer, Deborah Ford, Liam Smeeth, Nishi Chaturvedi, Richard Kaplan, Krishnan Bhaskaran. (United Kingdom)

9:00am
Benzodiazepines and Mortality: A Marginal Structural Model (MSM) Application in Claims Data [418]
Krista F Huybrechts, Shirley Wang, Robert Glynn, Raisa Levin, Elisabetta Patorni. (United States)

9:15am
Patrick Lefebvre, Erik Muser, Kruti Joshi, Maral DerSarkissian, Rachel Bhak, Andrew Kageleiry, Mei S Duh, Brian Shiner, Yinong Young-Xu. (United States)
8:00-9:30am CONCURRENT SESSIONS: CONTRIBUTED PAPERS

**Broken & Torn (Liffey Hall 1)**
Moderators: Daniel Prieto-Alhambra & Andrew Roddam

8:00am
- **35-Year Trends in First-Time Hospitalizations for Hip Fracture and Subsequent 0-30 and 31-365 Days Mortality: 1980-2014** [426]
  Alma B Pedersen, Vera Ehrenstein, Szimonetta Szepligeti, Astrid Lunde, Anna Westerlund, Ylva Trolle Lagerros, Grethe S Tell, Henrik Toft Sørensen. (Denmark)

8:15am
- **Association of Gout Diagnosis with Increased Risk of Joint Replacement: A Population-Based Cohort Study of Older Adults** [427]
  Sylvie Perreault, Alyssa B Klein, Robert Morlock. (Canada)

8:30am
- **Validation of Fracture Risk Assessment Tool Using Real-World Data** [428]
  Inbal Goldshtein, Yariv Gerber, Sophia Ish-Shalom, Moshe Leshno. (Israel)

8:45am
- **Total Hip and Knee Replacement Among Incident Osteoarthritis and Rheumatoid Arthritis Patients Within the UK Clinical Practice Research Datalink (CPRD) Compared to Hospital Episode Statistics (HES): A Validation Study** [429]
  Samuel Hawley, Antonella Delmestri, Andrew Judge, Christopher J Edwards, Cyrus Cooper, Nigel K Arden, Daniel Prieto-Alhambra. (United Kingdom)

9:00am
- **Modular versus Monobloc Neck Stems Primary Total Hip Arthroplasty Survivorship. Result of a Prospective Series of 324,108 THA at 6-Years Follow-Up** [430]
  Sandrine Colas, Assia Allalou, Rosemary Dray-Spira, Mahmoud Zureik. (France)

9:15am
- **Incidence and Trends in ACL Reconstruction Among Commercially-Insured Individuals in the United States, 2002-2013** [431]
  Mackenzie M Herzog, Stephen W Marshall, Virginia Pate, Jennifer L Lund, Jeffrey T Spang. (United States)

**Identification and Validation of Outcomes (Liffey Meeting Room 2)**
Moderators: Helga Gardarsdottir & Richard Wyss

8:00am
- **A Comparison of Methods for Estimating Values for Sparse and Irregularly Spaced Continuous Outcome Measures in Electronic Health Record (EHR) Data** [432]
  Therese M Sheppard, William G Dixon, Robyn Tamblyn. (United Kingdom)

8:15am
- **A Comparison Of Structured Data Query Methods Versus Natural Language Processing To Identify Metastatic Melanoma Cases From Electronic Health Records** [433]
  Paul R Dexter, Jinghua He, Lawrence Mark, David Haggstrom, Charity Hilton, Joel Martin, Jarod Baker, Jon Duke, Siu L Hui, Xiaochun Li. (United States)

8:30am
- **Additive versus Multiplicative Survival Models: Prediction and Understanding of Effect Modification** [434]
  Shirley V Wang, Jessica M Franklin. (United States)

8:45am
- **Validity of Cardiac Examination, Procedure, and Surgery Codes in the Danish National Patient Registry** [435]
  Kasper Adelborg, Jens Sundbell, Troels Munch, Trine Froslev, Henrik T Sørensen, Hans E Boktter, Morten Schmidt. (Denmark)

9:00am
- **Validity of Cardiovascular Diagnoses in the Danish National Patient Registry** [436]
  Jens Sundbell, Kasper Adelborg, Troels Munch, Trine Froslev, Henrik T Sørensen, Hans E Boktter, Morten Schmidt. (Denmark)

9:15am
- **Validation of Cardiovascular Events and Covariates in CPRD GOLD Using Questionnaires to General Practitioners (GPS)** [437]
  Andrea V Margulis, Cristina Varas-Lorenzo, Christine L Bui, Lisa J McQuay, Ryan Ziemiecki, Maria Reynolds, Cristina Rebordosa, Manel Pladevall-Vila, Joan Fortuny, Elena Rivero-Ferrer, Estel Plana, Willem Jan Atsma, Kwame Appenteng, Billy Franks, Stefan de Vogel, Milbhor D’Silva, Susana Perez-Gutthann, Alejandro Arana. (Spain)

9:30-10:00am
Break/Posters/Exhibits (The Forum)
**PLENARY SESSION**

Patient Voice in Clinical and Pharmacoepidemiologic Research
(The Auditorium)

Speakers:
- Derick Mitchell, Science and Industry (IPPOSI)
- Rachel Lynch, FibroIreland
- Irene Petersen, FISPE, University College London and Aarhus University
- Cindy Girman, FISPE, CERobs Consulting, LLC and UNC Chapel Hill

Moderator:
- Ken Hornbuckle, FISPE, Eli Lilly and Company

This plenary session will focus on current efforts to include the patients’ voice in clinical and pharmacoepidemiologic research. Speakers will be asked to comment on patient engagement as it relates to benefit-risk, safety and pharmacoepidemiology studies. Specific topics covered during this session include:

- Evolving paradigm (including, how should pharmacoepidemiologists leverage patients’ voice in their research and how to increase patient awareness of the importance of the health data for research)
- Patient engagement in study development (including, refinement of study objectives, selection of study design, outcome definitions and recruitment strategy) and implementation
- Patient engagement in interpretation, communication and dissemination of study findings

**Lunch/Poster Session B/Exhibits**
(The Forum)

Roundtable Discussions
(Liffey Meeting Room 1)

To foster the ability of more junior participants to network and first-timers to meet others attending the ICPE, ISPE is hosting several informal lunchtime discussion roundtables on Friday and Saturday. The facilitators are listed below. There will be no formal presentations made at the roundtables. The objectives are discussion, information exchange, and networking. Seating is limited; first-come, first-served.

- Libby Roughead, FISPE, Building Sustainable Research Collaborations
- Thomas MacDonald, FISPE, Experimental Medicine
- Ryan Kilpatrick, Positioning Epidemiologists for Success in Working for or with Biopharma

**ISPE Committee Meetings**
(Open to all participants; Lunch available.)

- Education Committee (Wicklow Meeting Room 3)
- Development Committee (Wicklow Meeting Room 4)
- Publications Committee (Wicklow Meeting Room 2a)
- Bylaws Committee (Wicklow Meeting Room 2b)

**Spotlight Poster Session**
(3rd Floor; Lunch available)

- AsPEN
- DUR
- BRACE
- Medicines in Pregnancy

**CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

**CV Effectiveness: How to Fix a Broken Heart**
(The Liffey A)

Moderator: Montserrat Soriano-Gabarro

1:00pm

- Calcium Intake and 10 Year Risk of Incident Coronary Artery Calcification in the Multi-Ethnic Study of Atherosclerosis [438]
  Bridget Kruszka, Ka He, Joseph A Delaney, Gregory L Burke, Alvaro Alonso, Diane Bild, Matthew J Budoff, Erin D Michos, John JB Anderson. (United States)

1:15pm

- Model Observational Bridging Study on the Effectiveness of Ezetimibe Upon Cardiovascular Outcomes [439]
  Jean Dallongeville, Denis Getsios, Jean Ferrières, Lucien Abenhaim, Michel Rossignol Rossignol, Lamiae Grimaldi-Bensouda, Billy Amzal. (United Kingdom)

1:30pm

- Clinical Impact of an Interaction Between Clopidogrel and Selective Serotonin Reuptake Inhibitors [440]
  Katsiaryna Bykov, Sebastian Schneeweiss, Macarius M Donneyong, Yaa-Hui Dong, Niteesh K Choudhry, Joshua J Gagne. (United States)

1:45pm

- Effectiveness of Recommended Drug Classes in Secondary Prevention of Acute Coronary Syndrome in France [441]
  Julien Bezin, Rolf Groenwold, Sanni Ali, Régis Lassalle, Anthonius de Boer, Nicholas Moore, Olaf Klungel, Antoine Pariente. (France)

2:00pm

- Treatment with Carvedilol, Bisoprolol or Metoprolol Tartrate and the Risk of Mortality and Hospital Readmission Among Older Adults with Heart Failure [442]
  Sylvie Perreault, Simon de Denus, Michel White, Brian White-Guay, Marc Dorais, Marie-Pierre Dubé, Jean-Lucien Rouleau. (Canada)

2:15pm

- Real-Life Statin Use and LDL-Cholesterol Reduction in a General Population: A Retrospective Study of Primary Care Electronic Medical Records [443]
  Maria Garcia-Gil, Marc Comas-Cufí, Eli León-Paz, Lia Alves-Cabratosa, Anna Ponjoan, Ruth Martí, Jordi Blanch, Rafel Ramos. (Spain)
1:00-2:30pm CONCURRENT SESSIONS: CONTRIBUTED PAPERS

Antipsychotic Use Across the Life Span (The Liffey B)
Moderators: Wendy Camelo Castillo & Deborah Layton

1:00pm
Psychotropic Medications and the Risk of Neonatal Withdrawal [444]
Krista F Huybrechts, Brian T Bateman, Sonia Hernández-Diaz, Rishi J Desai, Kathryn Rough, Helen Mogun, Elisabetta Patorno. (United States)

1:15pm
Channeling Bias in a Comparative Effectiveness Study of a Newly Launched Antipsychotic [445]
Jessica J Jalbert, Christiane Gasse, Sumeen Bakshi, Yann Hamon, Kristel Van Impe, Pierre Cherubin, Ludger Hargarter, Andreas Schreiner, Joris Diels, Billy Amzal. (United States)

1:30pm
Mortality Risk of Second-Generation Antipsychotic (SGA) Augmentation for Adult Depression [446]
Tobias Gerhard, T Scott Stroup, Christoph Correll, Brian L Strom, Cecilia Huang, Zhiqiang Tan, Stephen Crystal, Mark Olfson. (United States)

1:45pm
Comparative Safety of Antipsychotic Medications in Hospitalized Myocardial Infarction Patients [447]
Yoonyoung Park, Brian T Bateman, Dae Kim, Sonia Hernández-Diaz, Elisabetta Patorno, Robert J Glynn, Helen Mogun, Krista F Huybrechts. (United States)

2:00pm
Examining the Impact of UK Drug Safety Warnings on Antipsychotic Drug Prescribing to Older People with Dementia [448]
Susan J Stocks, Roger T Webb, Evangelos Kontopanatelas, Alistair Burns, Darren M Ashcroft. (United Kingdom)

2:15pm
Antipsychotic Use, Frailty and Health Outcomes Among Residents of Assisted Living [449]
Kathryn Stock, Colleen J Maxwell, Joseph E Amuah, Kate Lapane, Suzanne L Tyas, Susan E Bronskill, Andrew M Morris, Chaim M Bell, David B Hogan. (Canada)

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At Amgen, we believe that the answers to medicine’s most pressing questions are written in the language of our DNA. As pioneers in biotechnology, we use our deep understanding of that language to create vital medicines that address the unmet needs of patients fighting serious illness – to dramatically improve their lives.

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Amgen is a proud sponsor of the 32nd International Conference on Pharmacoepidemiology and Therapeutic Risk Management. Epidemiologic research at Amgen focuses on benefiting patients with grievous illnesses and advancing knowledge in our field.
# To Take or Not to Take? (Wicklow Hall 2)

**Moderators:** Katja Taxis & Zhen-Fang Lin

1:00pm
- **Medication Taking Behaviour and Adverse Health Outcomes in Community Dwelling Older Patients [450]**
  Caitriona Cahir, Tom Fahey, Conor Teljeur, Kathleen Bennettt. (Ireland)

1:15pm
- **Adherence to Anti-Hypertensive Medication in the Elderly: A Prospective Cohort Study [451]**
  Paul Dillon, Paul Gallagher, Susan Smith, David Williams, Derek Stewart, Gráinne Cousins. (Ireland)

1:30pm
- **Too Many, Too Few, Or Too Unsafe? Impact Of Inappropriate Prescribing On Mortality, And Hospitalisation In Community-Dwelling Adults, Aged 80 And Older [452]**
  Maarten Wauters, Monique Elseviers, Bert Vaes, Jan Degryse, Robert Vander Stichele, Thierry Christiaens, Majda Azermai. (Belgium)

1:45pm
- **Is Hospitalisation Associated with the Unintentional Discontinuation of Appropriate Long-Term Medication in the GP Prescribing Record Post Discharge? [453]**
  Patrick Redmond, Ron McDowell, Tamasine Grimes, Fiona Boland, Atieh Zarabzadeh, Ronan McDonnell, Carmel Hughes, Tom Fahey. (Ireland)

2:00pm
- **Reducing Patients’ Cumulative Exposure to Anticholinergic and Sedative Medication With Medication Reviews: A Randomized Controlled Trial [454]**
  Helene G van der Meer, Hans Wouters, Niesko Pras, Katja Taxis. (Netherlands)

2:15pm
- **Treatment Association with Preventable Hospitalizations in Older Adults with Serious Mental Illness [455]**
  Ting-Ying Huang, Linda Simoni-Wastila. (United States)

---

# Drug-Induced Kidney and Liver Injury (Liffey Hall 2)

**Moderators:** Judy Kelly & Susana Perez-Gutthann, FISPE

1:00pm
- **Acetaminophen Overdose-Related Morbidity and Mortality in Canada [456]**
  Samina Aziz, Andrew Slot, Vincent Punch, Lucye Galand, Steven McFaul, Lisa Lange, Marc Berthiaume. (Canada)

1:15pm
- **Comparative Hepatotoxicity of Echinocandins in Hospitalized Patients (pts): A Retrospective Cohort Study [457]**
  Francis Vekeman, Lisa S Weiss, Jalal Aram, Raluca Ionescu-Ittu, Shahrazad Moosavi, Yongling Xiao, Wendy Y Cheng, Rachel Bhak, Margaret Tawadrous, Mei Sheng Duh. (Canada)

1:30pm
- **Detection and Quantification of Flucloxacillin-Induced Liver Injury: A Population-Based Cohort Study [458]**
  Kevin Wing, Krishnan Bhaskaran, Louise Pealing, Adrian Root, Liam Smeeth, Tjeerd P van Staa, Olaf H Klungel, Robert F Reynolds, Ian Douglas. (United Kingdom)

1:45pm
- **Diagnosis-Based Cohort Augmentation Using Laboratory (lab) Data in the FDA Sentinel Initiative: The Case of Chronic Kidney Disease (CKD) [459]**
  David Smith, Susan Shetterly, James Flory, Joshua Gagne, Kevin Haynes, Lisa J Herrinton, Christine Lu, Elisabetta Patorno, Marsha Raebel. (United States)

2:00pm
- **Development of Risk Model to Predict Drug Induced Acute Kidney Injury in Hospitalized Patients [460]**
  Nakyung Jeon, Ben Staley, Carl Henriksen, Gigi Lipori, Almut G Winterstein. (United States)

2:15pm
- **Evaluation of the Risk of Acute Kidney Injury (AKI) Associated With Vancomycin Plus Piperacillin-Tazobactam (VPT) Compared With Vancomycin Plus Cefepime (VC) [461]**
  Nakyung Jeon, Ben Staley, Kenneth P Klinker, Aakash B Ghandi, Almut G Winterstein. (United States)
1:00-2:30pm  **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

**Biologics: “Miracle Drug”** *(Liffey Hall 1)*  
**Moderators:** Mary Anthony & Timothy Beukelman

- **1:00pm**
  - The Risk of Hospitalized Infection Associated with New Use of Abatacept versus TNF Inhibitors in Juvenile Idiopathic Arthritis [462]  
    Timothy Beukelman, Fenglong Xie, Melissa M Mannion, Long Chen, Jie Zhang, John Baddley, Kenneth G Saag, Jeffrey R Curtis. (United States)

- **1:15pm**
  - In Search of Predictors of Erythropoiesis-Stimulating Agents (ESAs) Resistance: A Population-Based Study [463]  
    Ylenia Ingrasciotta, Francesco Giorgianni, Iliaria Marcianò, Jenny Bolcato, Roberta Pirolo, Alessandro Chinellato, Achille P Caputi, Gianluca Trifirò. (Italy)

- **1:30pm**
  - Comparative Effectiveness and Safety of Erythropoiesis-Stimulating Agents (Biosimilars versus Originators) in Clinical Practice: A Population-Based Cohort Study [464]  
    Francesco Trotta, Valeria Belleudi, Fusco Danilo, Laura Amato, Alessandra Mecozzi, Flavia Mayer, Massimo Sansone, Marina Davoli, Antonio Addis. (Italy)

- **1:45pm**
  - Comparative Safety and Effectiveness of Denosumab versus Zoledronic Acid in Patients with Osteoporosis: A Cohort Study [465]  
    Nam-Kyong Choi, Daniel H Solomon, Theodore N Tsacogianis, Joan E Landon, Hong Ji Song, Seoyoung C Kim. (United States)

- **2:00pm**
  - A Real World Comparison of Methods for Assessing Dosing Patterns of Biologic Therapies for Psoriasis [466]  
    Ireny YK Iskandar, Richard B Warren, Ian Evans, Kathleen McElhone, Caroline M Owen, A David Burden, Catherine H Smith, Nick J Reynolds, Christopher EM Griffiths, Darren M Ashcroft. (United Kingdom)

- **2:15 pm**
  - Trends in the Utilization of Biologics for Inflammatory Bowel Disease in the United States [467]  
    Chao Chen, Abraham Hartzema. (United States)

**A Methods Coddle** *(The Auditorium)*  
**Moderators:** Robert Platt & Edmore Chamapiwa

- **1:00pm**
  - Baseline and Time-Varying Determinants of Statin Adherence [468]  
    Chintan Dave, Abraham Hartzema, Haesuk Park, Almut Winterstein. (United States)

- **1:15pm**
  - Determining Prescription Durations from the Parametric Waiting Time Distribution [469]  
    Henrik Støvring, Anton Pottegård, Jesper Hallas. (Denmark)

- **1:30pm**
  - Assessing and Reducing the Impact of Drug Exposure Measurement Errors Due to Non-Adherence: A Simulation Study [470]  
    Yishu Wang, Michal Abramamowicz. (Canada)

- **1:45pm**
  - Performance of the Propensity Score in the Presence of Nondifferential Exposure Misclassification: A Simulation Study [471]  
    Mollie E Wood, Stavroula Chrysanthopoulou, Hedvig Nordeng, Kate Lapanee. (Norway)

- **2:00pm**
  - Exposure Misclassification and Inverse Probability Weighting: A Plasmode Simulation [472]  
    Mitchell M Conover, Kenneth J Rothman, Til Stümer, Charles Poole, Michele Jonsson Funk. (United States)

- **2:15 pm**
  - Evaluation of the Two-Stage Residual Inclusion Method for Instrumental Variable Estimation in Survival Analysis: A Simulation Study [473]  
    Bianca Kollhorst, Michal Abramamowicz, Iris Pigeot. (Germany)
ANNUAL MEETING

Call to Order & Presidential Address
- Sonia Hernández-Díaz, FISPE, ISPE President

Financial Report
- Alison Bourke, FISPE, Vice President, Finance

AWARDS CEREMONY

The Ronald D. Mann Best Paper Awards for Manuscripts Published in *Pharmacoepidemiology and Drug Safety (PDS)* 2015, Volume 24:

- **First Prize**
  - Hung-Lin Chen and Fei-Yuan Hsiao

- **Honorable Mentions**
  - Alcohol Misuse, Genetics, and Major Bleeding Among Warfarin Therapy Patients in a Community Setting. *Pharmacoepidemiol Drug Saf* 2015; 24; pages 619-627
  - Joshua A Roth, Katharine Bradley, Kenneth E Thummel, David L Veenstra and Denise Boudreau
  - Natalie C Momen, Jørn Olsen, Mika Gissler, Helle Kieler, Bengt Haglund and Jiong Li

Presenters

- Brian L Strom, FISPE, Editor-In-Chief
- Sean Hennessy, FISPE, Regional Editor for the Americas
- Hubert G M Leufkens, FISPE, Regional Editor for Europe
- Byung Joo Park, FISPE, Regional Editor for Asia-Pacific and ROW

32nd ICPE

- Mary E Ritchey, Chair, 2016 Scientific Program Committee
- Kathleen E Bennett, Local Host Committee
- Lisa Gai Pont, FISPE, Spotlight Poster Sessions
- J Bradley Layton, Spotlight Poster Sessions
- Vincent Lo Re, FISPE, Newcomer Track
- Kristen B Bibeau, Luncheon Roundtable Discussions
- Jessica Jalbert, Luncheon Roundtable Discussions

The Andrew McAfee Award
(Best abstract submitted by a researcher or student residing in a developing country)

- Md Jamal Uddin, Shahjalal University of Science & Technology

The John Snow Award
(Best abstract submitted by a female researcher or student living in a developing country)

- Sze Ling Celine Chui, The University of Hong Kong

Student Awards

-- **Third Best Abstract:** Xiaojuan Li, University of North Carolina at Chapel Hill
-- **Second Best Abstract:** Nakyung Jeon, University of Florida

The Stanley A. Edlavitch Award & Oral Presentation
(Best abstract submitted by a student/post-doc)

- Rebecca Burne, McGill University
  - New Statistical Methods for Using Validation Subsamples to Adjust for Time-Dependent Unmeasured Confounders in Marginal Structural Cox Models [474]
  - Rebecca Burne, Michal Abrahamowicz. (Canada)

Induction of ISPE Fellows (FISPE)

- John F Acquavella
- Krista F Huybrechts
- Tamar Lasky
- Danica Marinac-Dabic
- Irene Petersen
- Maribel Salas
- Rachel E Sobel
- Jasmanda H Wu

BOARD TRANSITION

Retiring Board Members & Officers

- Rhonda L Bohn, FISPE
- Jennifer B Christian, FISPE
- Yea-Huei Kao Yang, FISPE
- Alison Bourke, FISPE, Vice President Finance
- John Seeger, FISPE, Immediate Past President

Induction of New Board Members

- Dorothee B Bartels, Industry/Service Provider (Europe/Africa)
- Lisa Gai Pont, FISPE, Academic (Asia/Pacific)
- Jennita Reefhuis, Government/Regulatory (Americas)
- June Raine, Government/Regulatory (Europe/Africa)
- Rachel E Sobel, FISPE, Industry/Service Provider (Americas)

Installation of 2016-2017 Officers

- Tobias Gerhard, FISPE, Vice President Finance
- Jesper Hallas, FISPE, President Elect
- Sonia Hernández-Díaz, FISPE, Immediate Past President
- Kiyoshi Kubota, FISPE, President

Adjournment
3:30-4:00pm
Break/Posters/Exhibits (The Forum)

4:00-5:30pm
SYMPOSIA AND WORKSHOPS

Perspectives from Causal Inference in the Era of Big (Healthcare) Data [475] (The Auditorium)
- Susan Gruber, Michele Jonsson Funk, Robert Platt, James M Robins, Mireille Schnitzer, Til Stürmer, Alexander M Walker. (United States)

Making Optimal Use of Routinely Collected Data from United Kingdom Electronic Health Records [476] (The Liffey B)
- Ian J Douglas, Stephen J Evans, Laurie Tomlinson, Rohini Mathur, Krishnan Bhaskaran, Caroline Minassian, Sara Thomas, Rachel Williams, Wilhelmine Meeraus, Jenni Quint, Janet Valentine, Liam Smeeth. (United Kingdom)

- Hu Li, Andrew Bate, Joshua Gagne, Jim Slattery, Ken Hornbuckle, Stephen Motsko. (United States)

What’s in a Code? Algorithm Validation in Drug Safety Studies [478] ( Wicklow Hall 2)
- Beth L Nordstrom, Sheila Weiss, Stephan Lanes, Cunlin Wang. (United States)

The Epidemiological Approach to Rare Disease Research: Challenges and Opportunities [479] (Liffey Hall 2)
- Mary E Ritchey, Jessica J Jalbert, Alicia Gilisen, Theodore Lystig, Michael Peng, Tzuyung D Kou, William Blumentals. (United States)

The Role of Evidence Synthesis in Drug Safety Evaluation and Regulation [480] (Liffey Hall 1)
- Simone Pinheiro, Wei Liu, Michael Nguyen, Marc Poitras, Yoshiaki Uyama, Peter Arlett. (United States)

A Discussion of Data Requirements and Methodologic Considerations for Evaluating the Real-World Effectiveness and Safety of Biosimilar Medicines [481] (Liffey Meeting Room 2)
(Sponsored by the Biologics & Biosimilars Special Interest Group)
- Veronique Kugener, Michael Kelsh, Brian Bradbury, Thijs Giezen, Jaclyn Bosco, Gianluca Trifirò, Amanda Golembesky. (United States)

5:30-6:15pm
ISPE Council Meetings
(Open to all participants.)
  - Academic Council (Liffey Meeting Room 1)
  - Government/Regulatory Council
    (Wicklow Meeting Room 3)
  - Industry/Service Providers Council (Wicklow Meeting Room 4)
  - Student Council & Chapters
    (Wicklow Meeting Room 5)

7:30-11:30pm
Social Event (Guinness Storehouse)

Located in the heart of the St James’s Gate Brewery is the Guinness Storehouse. Home to the black stuff since 1759, this massive seven-storey building, a former Guinness® fermentation plant, has been remodelled into the shape of a giant pint of Guinness®. A visit will teach you everything you ever wanted to know about this world famous beer. The highlight for many visitors is the Gravity Bar®, symbolically the “Head of the Pint”, where visitors can enjoy unparalleled panoramic views of Dublin city – views that are all the better with a pint in hand.

A FACT: Guinness is the perfect diet drink. A pint of the good stuff contains only 198 calories. That’s less than most light beers, wine, orange juice or even low fat milk.

TONIGHT, the Guinness Storehouse will host ISPE. Join us for entertainment, food, dancing and a pint of the black stuff.

Full ICPE registration includes:
- Admission to the Storehouse by badge or ticket (guests)
- Food
- Entertainment
- Transportation. Buses will shuttle between the CCD and the Storehouse, with the first bus departing from the CCD at 6:30pm; and from the Storehouse to ISPE meeting hotels

A cash bar will be available.
8:30-10:00am  **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

**From Eve to… (The Liffey A)**
**Moderators: Andrew Margulis & Colin Anderson-Smiths**

<table>
<thead>
<tr>
<th>Time</th>
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<th>Authors</th>
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<tr>
<td>8:30</td>
<td>Effect of Concomitant Use of Tamoxifen and Selective Serotonin Reuptake Inhibitors on Mortality [791]</td>
<td>Macarius M Donneyong, Katsiaryna Bykov, Pauline Bosco-Levy, Yaa-Hui Dong, Gagne Joshua. (United States)</td>
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<tr>
<td>8:45</td>
<td>The Effect of BMI on Unintended Pregnancy Rates Amongst Users of Combined Oral Contraceptives [792]</td>
<td>Anja Bauerfeind, Clare Barnett, Do Minh Thai, Klaas Heinemann. (Germany)</td>
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<tr>
<td>9:00</td>
<td>Unwanted Pregnancies in Women Using Intrauterine Devices: Final Results from the EURAS-IUD 5-Years Study [793]</td>
<td>Klaas Heinemann, Sabine Moehner, Suzanne Reed, Thai Do Minh. (Germany)</td>
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<tr>
<td>9:15</td>
<td>Intrauterine Devices and the Risk of Uterine Perforations: Final Results from the EURAS-IUD 5-Years Study [794]</td>
<td>Klaas Heinemann, Sabine Moehner, Thai Do Minh, Suzanne Reed. (Germany)</td>
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<tr>
<td>9:30</td>
<td>Comparative Risk of Serious Infections During Pregnancy in Patients Treated with Immunomodulatory Agents [795]</td>
<td>Rishi J Desai, Brian T Bateman, Krista F Huybrechts, Elisabetta Patorno, Sonia Hernández-Díaz, Yoonyoung Park, Helen Mogun, Seoyoung C Kim. (United States)</td>
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<tr>
<td>9:45</td>
<td>Venous Thromboembolism Risk Following New Use of NSAIDs in U.S. Women [796]</td>
<td>Tracy L Kinsey, Robert J Glynn, Michele Jonsson Funk, Charles Poole, Ross J Simpson, Jr., Til Stürmer. (United States)</td>
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**BIG DATA BECOMES SMART DATA WITH THE RIGHT EXPERTISE**
My Achy Breaky Heart: Diabetes and CVD (The Liffey B)
Moderators: Cynthia Girman, FISPE & Gillian Caughey

8:30am
- Relationship Between Glycaemic Burden and Micro- and Macrovascular Complications in Patients with Type 2 Diabetes Mellitus [797]
Jetty A Overbeek, Rients PT van Wijngaarden, Joris Diels, Agata Schubert, Huub Straatman, Hervé Besson, Ewout W Steyerberg, Michiel Hemels, Giel Nijpels, Ron MC Herings. (United States)

8:45am
- Comparative Effects of Second Line Antidiabetic Agents Added to Metformin on Patient Centered Outcomes: A Retrospective Cohort Study [798]
James H Flory, Alvin I Mushlin, Ankit Shah, John Cuddeback, Christopher Rowan. (United States)

9:00am
- Changes in Diabetes Therapy One Year Before and After Discharge from a Heart Failure Hospitalization Among Patients with Type II Diabetes [1096]
Ghadeer K Dawwas, Haesuk Park. (United States)

9:15am
- Magnitude of HbA1c Reduction and Attainment of Early Glycemic Control Predict Cardiovascular Outcomes and Mortality: A Population-Based Cohort Study of 24,752 People with Type 2 Diabetes Initiating First Metformin Therapy [800]
Reimar W Thomsen, Lisbeth M Baggesen, Søren P Johnsen, Lars Pedersen, Helene Norrelund, Esben S Buhl, Christiane L Haase, Elisabeth Svensson. (Denmark)

Keeping Up - A Potpourri (Wicklow Hall 2)
Moderators: TBA

8:30am
- Risk of Erectile Dysfunction Associated with Use of 5-Alpha Reductase Inhibitors for Benign Prostatic Hyperplasia or Alopecia [803]
Katrina Wilcox Hagberg, Hozefa A Divan, Rebecca Persson, J Curtis Nickel, Susan S Jick. (United States)

8:45am
- Risk of Breast Cancer in Risperidone Users: A Nationwide Cohort Study [804]
Johan Reutfors, Louise Wingård, Lena Brandt, Yiting Wang, Hong Qiu, Helle Kieler, Shahram Bahmanyar. (Sweden)

9:00am
- Prescription Opioid Use and Infection-Related Hospitalization in Hemodialysis Patients [805]
Abhijit V Kshirsagar, Xiaojuan Li, Magdalene Assimon, M Alan Brookhart. (United States)

9:15am
- Seasonality of Guillain-Barré Syndrome in the United Kingdom from April 2005 to March 2015 [806]
Tom Cattaert, Germano LC Ferreira, Kaatje Bollaerts, Thomas Verstraeten. (Belgium)

9:30am
Stacie B Dusetzina. (United States)

9:45am
- Identifying Incident Uterine Fibroids Using Electronic Medical Record Data [808]
Onchee Yu, Susan Reed, Renate Schulze-Rath, Jane Graffon, Kelly Hansen, Delia Scholes. (United States)
**Main Conference | Sunday, August 28**

8:30-10:00 am **Concurrent Sessions: Contributed Papers**

**Adverse Outcomes and Infectious Diseases** *(Liffey Hall 2)*

**Moderators:** Emily Brouwer & Yared Santa-Ana Tellez

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<tr>
<td>8:30 am</td>
<td>The Association Between Lansoprazole and Tuberculosis Disease; a Primary Care Based Cohort Study [809]</td>
<td>Ian J Douglas, Laurie Tomlinson, Tom Yates, Krishnan Bhaskaran, Sinead Langan, Sara Thomas, Liam Smeeth. (United Kingdom)</td>
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<tr>
<td>8:45 am</td>
<td>Do Proton Pump Inhibitors Impact Clinical Outcomes in Staphylococcus Aureus Bacteremia? [810]</td>
<td>Aisling R Caffrey, Tristan T Timbrook, George Sakoulas, Kerry L LaPlante. (United States)</td>
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<tr>
<td>9:00 am</td>
<td>Opioid Analgesic Use as a Risk Factor for Laboratory-Confirmed Invasive Pneumococcal Diseases: A Nested Case-Control Study [811]</td>
<td>Andrew D Wiese, Marie R Griffin, William Schaffner, C Michael Stein, Edward F Mitchel, Jr., Carlos G Grijalva. (United States)</td>
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<tr>
<td>9:15 am</td>
<td>Hepatitis C Virus Infection Increases Risk of Developing Chronic Kidney Disease [812]</td>
<td>Chao Chen, Wei Wang, Robert L Cook, Haesuk Park. (United States)</td>
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9:30 am

- **Risk of Hepatic Decompensation with Cumulative Mitochondrial Toxic Nucleoside Analogue Use in HIV/Hepatitis C Coinfection [813]**
  - Vincent Lo Re III, Bret Zeldow, Michael J Kallan, Janet P Tate, Dena M Carbonari, Jay R Kostman, Robert Gross, Amy C Justice, Jason A Roy. (United States)

9:45 am

- **Slow Efavirenz Metabolism Alleles Are Associated with Antiretroviral Failure in Botswana [814]**
  - Robert Gross, Scarlett L Bellamy, Bakgaki Ratshaa, Xiaoyan Han, Marijana Vujkovic, Richard Aplenc, Andrew P Steenhoff, Mosepele Mosepele, Athena Zuppa, Brian L Strom, Gregory P Bisson. (United States)

---

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**LEARN MORE and connect:** rtihs.org/ICPE16
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<tr>
<th>Time</th>
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| 9:15am| Effectiveness of the Quadrivalent Human Papillomavirus Vaccine (QHPV) Against Anogenital Warts (AGWs) in Manitoba, Canada: A Population-Based Study [818]  
Karla Willows, Songul Bozat-Emre, Erich Kliewer, Salah Mahmud. (Canada) |
| 9:30am| Long Term Effectiveness of Herpes Zoster Vaccine Among Patients with Autoimmune and Inflammatory Diseases [819]  
Huifeng Yun, Fenglong Xie, John W Baddley, Kevin L Winthrop, Kenneth G Saag, Jeffrey R Curtis. (United States) |

### Analytic Approaches for Controlling and Exposure Misclassification (The Auditorium)

**Moderators:** Suzanne Cadarette & Mollie Wood

<table>
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<th>Time</th>
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| 8:30am| Multi-State Models – A Complimentary Approach to Group Based Trajectory Models [821]  
Aaron N Winn, Stacie B Dusetzina. (United States) |
| 8:45am| Covariate Adjustment of Cumulative Incidence Functions for Competing Risks Data Using Inverse Probability of Treatment Weighting [822]  
Anke Neumann, Cécile Billionnet. (France) |
| 9:00am| Propensity Score Methods for Subgroup Analyses: Investigating Covariate Balance [823]  
Phyo T Htoo, Caroline J Mariano, Sharon Peacock-Hinton, Katie Reeder-Hayes, Michele Jonsson Funk, Til Stürmer, Jennifer L Lund. (United States) |
| 9:15am| Adjustment for Unobserved Confounders in Health Administrative Databases [824]  
Bernard Silenou Chawo, Marta Avalos Fernandez, Antoine Pariente, Hélène Jacqmin Gadda. (France) |
| 9:30am| The Impact of Censoring on Discontinuation When Modeling the Disease Risk Score [825]  
Justin Bohn, Richard Wyss, Joshua Gagne. (United States) |
| 9:45am| Survival Bias in Exposure Crossover Studies [826]  
Thy Do, Emil Scosyrev. (United States) |
Multiple Database Study Design and Inference (The Auditorium)

Speakers:
- Miriam Sturkenboom, FISPE, Erasmus University Medical Center
- Olaf Klungel, University Medical Centre Utrecht
- Tobias Gerhard, FISPE, Rutgers University
- Andrew Bate (Chair), Pfizer Ltd

Across the globe important experience has been gained with multi-database initiatives such as OMOP, Mini-Sentinel, CNODES, PROTECT, EU-ADR, and ASPEN. These initiatives used different approaches. In this symposium we will discuss the lessons learnt from these initiatives — from the perspectives of data, analysis, and interpretation — aiming to elicit common themes, and examining to what extent discrepancies in findings and lessons learnt can be attributed to differences in approach.

Miriam Sturkenboom: The Data - What Data Sets to Include in a Multiple Country/Site Study?
Several multi-country/site initiatives have been launched over the past decade with the expectation of greater precision and/or validity for drug-effect studies. Debate is still ongoing on whether to use all available databases or to select certain databases. When multiple databases are analyzed together the question remains whether and under what circumstances a common data model (CDM) is preferred. When using CDMs, which models are available and what are their pros and cons (e.g. Jerboa, OMOP CDM, IMEDS, EMIF, etc)?

Olaf Klungel: Analytic Strategy - How to Decide What Methods to Employ and How Many?
When conducting drug-effect hypothesis testing studies multiple choices have to be made on design and analysis. During the past decades these choices have become less based on one specific design and analysis based on the hypothesized mechanism of action of a drug, including exposure-time-event relationship. More and more, sensitivity analyses on various methodological parameters are becoming common practice. Should sensitivity analysis always be conducted on all parameters and should it include the whole range of possible values, or should these be informed by certain plausible ranges, and how to decide on these ranges?

Tobias Gerhard: Output - Interpretation of Studies - The Impact of a Priori Versus Post-Hoc Decisions
When drug-effect studies are conducted in multiple databases it is not straightforward to decide on consistency of results. When should results across multiple databases be considered similar and when not? Is a frequentist approach sufficient to test heterogeneity or should Bayesian approaches be applied?
### SYMPOSIA AND WORKSHOPS

1:30-3:00pm

#### Pattern Discovery in Observational Health Data - What We Did Not Know to Look For [827] (The Auditorium)
- Meredith Y Smith, Tarek Hammad, Rebecca Noel, Paul Huckle, Francesco Pignatti, Declan Noone. (United States)

#### Clinical And Analytic Considerations In The Selection And Evaluation Of Comparators In Observational Database Studies [828] (The Liffey B)
- Patrick B Ryan, Saad Shakir, David Madigan. (United States)

#### Pharmacoepidemiology and Risk Management Planning: Essential Enablers for Development of Innovative Medicines [829] (The Liffey A)
- Peter R Arlett, June Munro Raine, Almath Spooner, Sebastian Schneeweiss, Eva Flahavan. (United Kingdom)

#### Transitioning to ICD-10: International Lessons Learned and Strategies for Moving Forward [830] (Wicklow Hall 2)
- Joshua J Gagne, Lisa M Lix, Sengwee Toh, David D Dore, Manel Pladevall-Vila. (United States)

#### Who to Ask and How? Preference-Based Methods for Benefit-Risk Assessment [831] (Liffey Hall 2)
- Kevin Marsh, Hans L Hillege, Quazi Ataher, Tommi Tervonen. (United Kingdom)

#### The Agony and the Ecstasy: The Creation of the Revised ICH M4E Benefit-Risk Assessment Guideline and Practical Implications for Patients, Industry and Regulators [832] (Liffey Hall 1)
- Meredith Y Smith, Tarek Hammad, Rebecca Noel, Paul Huckle, Francesco Pignatti, Declan Noone. (United States)

### CONCURRENT SESSIONS: CONTRIBUTED PAPERS

3:15-4:45pm

#### Practice of Epidemiology in Pregnancy Studies (The Liffey)
- Moderator: Christina Chambers

- **3:15pm**
  - Validity of a Web-Based Questionnaire to Assess Perinatal Outcome [833]
    - Marleen MHJ van Gelder, Saskia Vorstenbosch, Lineke Derks, Bernke te Winkel, Eugène P Puijenbroek, Nel Roeleveld. (Netherlands)

- **3:30pm**
  - Consistency of Measures of Asthma Symptom Control Collected During Pregnancy vs. Retrospectively at 6 Months Post-Partum [834]
    - Christina D Chambers, Ronghui Xu, Mofei Li, Diana L Johnson, Yunjun Luo. (United States)

- **3:45pm**
  - Comparison of Electronic Healthcare Data and Prospective Face-to-Face Studies for Evaluating Neurodevelopmental Disorders Following In-Utero Medication Exposures [835]
    - Rachel Charlton, Anita McGrogan, Julia Snowball, Laura Yates, Amanda Wood, Jill Clayton-Smith, Henry Smithson, Jonathan Richardson, Neil McHugh, Simon Thomas, Gus Baker, Rebecca Bromley. (United Kingdom)

- **4:00pm**
  - Bias from Restricting to Live Births in a Study of Prescription Drug Use and Pregnancy Complications: A Simulation [836]
    - Elizabeth A Suarez, Suzanne N Landi, Mitchell M Conover, Michele Jonsson Funk. (United States)

- **4:15pm**
  - Utilization Patterns of Drugs or Biologics with Pregnancy Exposure Registries in Pregnant and Matched Non-Pregnant Women in the Sentinel Database [837]
    - Steven T Bird, Lockwood Taylor, Christian Hampp, Leyla Sachin, Darren Toh, Susan Andrade, Katie Haffenreffer, Marsha Reichman, Kate Gelperin. (United States)

- **4:30pm**
  - Oral Contraceptive Induced Hypertension and Subsequent Pre-Eclampsia: A Retrospective Cohort Study [838]
    - Brian J Cleary, Maeve Eogan, Sharon Sheehan. (Ireland)
### 3:15-4:45pm CONCURRENT SESSIONS: CONTRIBUTED PAPERS

**Disease Burden from Clinical Databases** *(The Liffey B)*  
Moderators: Shahram Bahmanyar & Daniel Mines

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Authors</th>
<th>Country</th>
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<tbody>
<tr>
<td>3:15pm</td>
<td>Time Trends Of Idiopathic Pulmonary Fibrosis (IPF) in the United Kingdom (UK) from 1999 to 2013 Using the Clinical Practice Research Datalink (CPRD) [839]</td>
<td>Mellissa Yong, Jenny Chia, David Oliveri, Hubert Chen, Dorothy Cheung, Matt Cohen, Pavel Napalkov. (United States)</td>
<td>United Kingdom</td>
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<tr>
<td>3:30pm</td>
<td>The Impact and Longevity of Measles-Associated Immune Suppression [840]</td>
<td>Caitlin N Dodd, Kartini Gadoeno, Gwen Masclee, Maria de Ridder, Daniel Weibel, David van de Vijver, Rik de Swart. (Netherlands)</td>
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<tr>
<td>3:45pm</td>
<td>Blood Pressure and Risk of Dementia in a Cohort of 2.6 Million People Over Two Decades [172]</td>
<td>Nawab Qizilbash, John Gregson, Michelle E Johnson, Neil Pearce, Ian Douglas, Kevin Wing, Stephen JW Evans, Stuart J Pocock. (United Kingdom)</td>
<td></td>
</tr>
<tr>
<td>4:00pm</td>
<td>Epidemiological Assessment of Real-World Treatment Patterns in Advanced Pancreatic Neuroendocrine Tumors in the Era of Targeted Therapy: Perspectives from an Academic Tertiary Center and Community Oncology Practices [842]</td>
<td>Lynn Huynh, Maurice Herring, Mei S Duh, Francis Vekeman, Audrey Tiew, Maureen P Neary, Emily Bergsland. (United States)</td>
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<tr>
<td>4:15pm</td>
<td>10-Year Landmark Survival and Characteristics of Advanced Non-Small Cell Lung Cancer (aNSCLC) Long-Term Survivors [843]</td>
<td>Ben Lyons, Joe Simpson, Margaret E McCusker, Alan B Sandler. (United States)</td>
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<tr>
<td>4:30pm</td>
<td>Reoperation Due to Surgical Bleeding in Breast Cancer Patients and Breast Cancer Recurrence: A Danish Population-Based Cohort Study [844]</td>
<td>Rikke N Pedersen, Krishnan Bhaskaran, Uffe Heide-Jørgensen, Mette Nørgaard, Peer M Christiansen, Niels Kromen, Henrik T Sørensen, Deirdre P Cronin-Fenton. (Denmark)</td>
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3:15-4:45pm **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

**CV Adverse Events: Affairs of the Heart** (Wicklow Hall 2)
Moderator: Nancy Santanello, FISPE & J Bradley Layton

3:15pm
- **Opioid Use Prior to Incident Myocardial Infarction and Subsequent Risk of Ischemic Stroke, Venous Thromboembolism, and Death [845]**
  Troels Munch, Erzsébet Horváth-Puho, Kasper Adelborg, Lars Pedersen, Morten Schmidt, Henrik T Sørensen. (Denmark)

3:30pm
- **Long Acting Bronchodilators and Risk of Myocardial Infarction in Patients with Chronic Obstructive Pulmonary Disease and Who Are at High Risk for Cardiovascular Disease: A Quasi-Cohort Approach [846]**
  Sunning Tao, Samy Suissa, Sophie Dell’Aniello, Pierre Ernst. (Canada)

3:45pm
- **Association of Proton Pump Inhibitor Use and Acute Myocardial Infarction Among Privately Insured Adults, 2001-2014 [847]**
  Suzanne N Landi, Jennifer L Lund, Virginia Pate, Robert S Sandler. (United States)

4:00pm
- **Incidence of Cardiovascular Events in New Users of Overactive Bladder Medications in Denmark [848]**
  Jesper Hallas, Andrea V Margulis, Anton Pottegård, Nina Kristiansen, Christine L Bui, Whitney Krueger, Willem Jan Atsma, Kwame Appenteng, Billy Franks, Stefan de Vogel, Milbhor D’Silva, Susana Perez-Gutthann, Alejandro Arana. (Denmark)

4:15pm
- **Cardiovascular Risk in Users of Antimuscarinic Drugs for Overactive Bladder: A Cohort Study in the Swedish National Registers [849]**
  Marie Linder, Andrea V Margulis, Ingegärd Anveden-Berglind, Shahram Bahmanyar, Christine L Bui, Willem Jan Atsma, Kwame Appenteng, Billy Franks, Stefan de Vogel, Milbhor D’Silva, Susana Perez-Gutthann, Alejandro Arana. (Sweden)

4:30pm
- **Development of a Predictive Model for Drug-Induced QT Prolongation in the Inpatient Setting Using Electronic Health Record Data [850]**
  Juan M Hincapie-Castillo, Benjamin Staley, Carl Henriksen, Arwa Saidi, Gigi Lipori, Almut G Winterstein. (United States)
3:15-4:45pm CONCURRENT SESSIONS: CONTRIBUTED PAPERS

Adverse Outcomes of Glucocorticoid and Immunomodulator Use (Liffey Hall 2)
Moderator: Cunlin Wang

3:15pm
- Trends in Oral Glucocorticoid Utilization Among Older Adults with Respiratory Disease [851]
  M Amine Amiche, Linda E Lévesque, Tara Gomes, Jonathan D Adachi, Suzanne M Cadarette. (Canada)

3:30pm
- Use of Glucocorticoids and Risk of Community-Acquired Staphylococcus aureus Bacteraemia: A Population-Based Case-Control Study [852]
  Jesper Smit, Achim Kaasch, Mette Søgaard, Reimaro W Thomsen, Henrik Nielsen, Trine Freslev, Henrik C Schonheyder. (Denmark)

3:45pm
- Use of Glucocorticoids and the Risk of Osteoporotic Fracture in Patients with Sarcoidosis [853]
  Olorunfemi Oshaghhbemi, Johanna Driessen, Peter Vestergaard, Joop van den Bergh, Frank deVries. (Netherlands)

4:00pm
- Risk of Lymphoma in Users of Topical Tacrolimus, Pimecrolimus and Corticosteroids (JOELLE Study) [854]

4:15pm
- Pharmacological Treatments Preceding Diagnosis Of Progressive Multifocal Leukencephalopathy [855]
  Sarah Burkill, Ellen Iacobaeus, Shahram Bahmanyar, Lou Brundin, Michael Fored, Tomas Olsson, Scott Montgomery. (Sweden)

4:30pm
- Association Between Breast Cancer Recurrence With Immunosuppression In Rheumatoid Arthritis And Inflammatory Bowel Disease: A Cohort Study [856]
  Ronac Mamtani, Amy S Clark, Frank I Scott, Colleen M Brensinger, Ben Boursi, Lang Chen, Fenglong Xie, Huifeng Yun, Mark T Osterman, Jeffrey R Curtis, James D Lewis. (United States)
3:15-4:45pm  **CONCURRENT SESSIONS: CONTRIBUTED PAPERS**

**Thin Blood: Anticoagulants** (Liffey Hall 1)
Moderator: John Acquavella, FISPE

- **3:15pm**
  - **Safety and Effectiveness of Dabigatran Relative to Warfarin in Routine Clinical Practice—Interim Results of a Long-Term Study Program** [857]
  - Krista F Huybrechts, Dorothee B Bartels, Chandrasekar Gopalakrishnan, John D Seeger, Kristina Zint, Katsiaryna Bykov, Sebastian Schneeweiss.
  - (United States)

- **3:30pm**
  - **Comparative Effectiveness and Safety of New Oral Anticoagulants (NOACs) and Warfarin in Patients with Atrial Fibrillation: A Multi-Database Study in the US** [858]
  - M Sanni Ali, Rianne van den Ham, Rolf HH Groenwold, Mikkel Z Ankarfeldt, Eirpur Adalsteinsisson, Cynthia Girman, Olaf H Klungel.
  - (Netherlands)

- **3:45pm**
  - **Clinical Events Preceding Changes During Treatment With Non-VKA Oral Anticoagulants In Patients With Atrial Fibrillation** [859]
  - Maja Hellfritzsch, Erik L Grove, Steen E Husted, Lotte Rasmussen, Birgitte K Poulsen, Søren P Johnsen, Jesper Hallas, Anton Pottegård.
  - (Denmark)

**Is it Safe Enough?** (The Auditorium)
Moderators: Stella Blackburn, FISPE & Ola Caster

- **3:15pm**
  - **Are Natural Language Processing Models For Pneumonia Surveillance Valid For Benchmarking Event Rates Across Healthcare Institutions?** [863]
  - (Canada)

- **3:30pm**
  - **Analysis of Patient Narratives in Disease Blogs: Enhancing Pharmacovigilance Using Real-World Health Data on the Internet** [864]
  - Shinichi Matsuda, Kotonari Aoki, Shihoku Tomizawa, Masayoshi Sone, Sawako Satomi, Terumi Nakayama, Riwa Tanaka, Hiroshi Kuriki, Yoichiro Takahashi.
  - (Japan)

- **3:45pm**
  - **Prediction Model Based Algorithm for a Computer-Assisted Database Screening Tool** [865]
  - Joep Scholl, Florence van Hunsel.
  - (Netherlands)

- **4:00pm**
  - **Assessment of the US Food and Drug Administration’s Sentinel Analysis Tools: Angiotensin-Converting Enzyme Inhibitors And Angioedema** [866]
  - (United States)

- **4:15pm**
  - **An Automatized Model for Sequential Monitoring of Effectiveness of New Drugs Using Dronedarone as Example** [867]
  - Thomas Cars, Martin Neovius, Lars Lindhagen, Rickard E Malmström, Jonas Schwierer, Björn Wettermark, Johan Sundström.
  - (Sweden)

- **4:30pm**
  - **Monitoring All Drugs for Specific Outcome in the Sentinel System** [88]
  - Judith C Maro, Gerald J Dal Pan, Inna Dashevsky, Jeffrey S Brown, Martin Kulldorff.
  - (United States)
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4:45-5:30pm  **THE FINAL WORD**

**Spotlight Poster Awards** *(The Auditorium)*
- Lisa Gai Pont, FISPE, Co-Chair, Spotlight Sessions
- J Bradley Layton, Co-Chair, Spotlight Sessions

**2017 ISPE Meetings**
- **Mid-Year - London**
  - Alison Bourke, FISPE, Co-Chair, Program Planning Committee

- **ICPE - Halifax**
  - Adrian Levy, Chair, 2017 Scientific Program Committee
  - Ingrid Sketris, Chair, 2017 Local Host Committee

**Adjournment of ICPE 2016**
- Mary E Ritchey, Chair, ICPE 2016 Scientific Program Committee

**ICPE 2017 Drawing for complimentary registrations**

5:45-6:30pm  **2017 ICPE Scientific Program Committee Meeting** *(EcoCem)*

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Overview

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

POSTER SESSION

Spotlight Session posters will be displayed in the Third Floor Foyer while all other posters will be displayed in The Forum of the Convention Centre Dublin, August 26-28. Each day will have a separate poster session and Spotlight Sessions. All posters for a specific day's session must be removed at the end of that day.

1. Set Up:
7:00am-8:00am; all posters must be in place by 8:00am. The poster areas (including floor) must remain clear and clean of tubes.

2. Hours:
Posters will be displayed from 8:00am to 6:00pm on Friday and Saturday, and from 8:00am to 1:45pm on Sunday.

3. Discussion Time:
General Poster Sessions: Presenters should be at their posters between 12:15-1:15pm on Friday (A) and Sunday (C); and between 11:45-12:45pm on Saturday (B) [The Forum]

Spotlight Poster Sessions: Organized by the ISPE Special Interest Groups (SIGs). Presenters should be at their posters between 12:15-1:15pm on Friday (A) and Sunday (C); and between 11:45-12:45pm on Saturday (B). [Third Floor Foyer]

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

Friday
- Adherence
- Databases
- Devices
- Pediatrics

Saturday
- AsPEN
- BRACE
- Drug Utilization Research
- Medications in Pregnancy

Sunday
- Vaccines
- CER
- Biologics & Biosimilars

4. Take Down:
All posters must be taken down by 6:30pm on Friday and Saturday, and by 5:00pm on Sunday.

Note: Neither ISPE nor the Convention Centre Dublin will be responsible for any poster that is left up overnight or is lost or damaged.

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 on that day as listed in the Final Program, which will be available at the ISPE Registration Desk, as well as included online in Abstracts2view. The POSTER BOARD NUMBER is the first number (or letter) listed. The ABSTRACT NUMBER, for use in locating abstracts in the Final Program or in Abstracts2view, is listed after the abstract title.

Example
97 Characteristics of Patients with Depression Who Initiate Antidepressant and Benzodiazepine Therapy Simultaneously, Compared with Antidepressant Monotherapy [176]
Greta A Bushnell, Alice White, Til Stürmer, Bradley N Gaynes, Virginia Pate, Deborah Azrael, Matthew Miller. (United States)

Key
97 POSTER BOARD NUMBER
176 PUBLICATION Number

1. Poster Specifications
Posters must be designed to fit a freestanding poster board approximately 4 feet WIDE x 8 feet HIGH (1.2 meter WIDE x 2.4 meters HIGH). Only VERTICAL/PORTRAIT posters will be allowed.

2. Disclosure Statement
A disclosure statement must accompany each abstract. This statement should follow the title page and should be a positive disclosure of 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.

3. Call4Posters
Posters ordered through Call4Posters can be picked up in the exhibit hall (The Forum) at the times below.

Poster Pick Up Schedule:
Thursday, August 25: 1:00pm-5:00pm
Friday, August 26: 7:00am-1:00pm
Saturday, August 27: 7:00am-1:00pm
Sunday, August 28: 7:00am-Noon
POSTER SESSION A: Friday, August 26 | 8:00am - 6:00pm

Spotlight Sessions: 12:15 - 1:15pm

**Spotlight Session-Adherence**

A. Polypharmacy and Adherence to TNF-alpha Inhibitors: Variation by Specific Concurrent Medications [80]
   - Sruthi Adimadhyam, Wan-Ju Lee, Gregory S Calip. (United States)

B. Predicting Adherence to Chronic Disease Medications in Patients with Long-Term Initial Medication Fills [81]
   - Julie C Lauffenburger, Jessica M Franklin, Alexis A Krumme, William H Shrank, Troyen A Brennan, Olga S Matlin, Claire M Spettell, Gregory Brill, Niteesh K Choudhry. (United States)

C. Association Between Trajectories of Diabetes Medication Adherence and Hospitalization Risk in a Large Medicaid Program [82]
   - Wei-Hsuan Lo-Ciganic, Julie M Donohue, Bobby L Jones, Joshua M Thorpe, Subashan Perera, Zachary A Marcum, Walid F Gella. (United States)

D. Association Between Patient-Centered Medical Homes and Adherence to Chronic Medications [83]

E. Influence of Antidepressant Treatment on Use of and Adherence to COPD Maintenance Medications [94]
   - Yu-Jung Jenny Wei, Linda Simon-Wastila, Jennifer S Albrecht, Ting-Ying Huang, Patience Moyo, Bilal Khokha, Ilene Harris, Patricia Langenberg, Giora Netzer, Susan Lehmann. (United States)

F. Impact of Treatment Satisfaction and Adverse Drug Events on Antihypertensive Medication Adherence in Ambulatory Patients in Ethiopia [95]
   - Derbew Fukadu Berhe, Katja Taxis, Flora M Haaijer-Ruskamp, Afework Mulugeta, Yewondwosen Tadesse Mengistu, Peter GM Mol. (Netherlands)

G. Impact of High Deductible Health Plans on Adherence to Essential Medications for Patients with Chronic Conditions [86]
   - Jennifer Lewey, Joshua J Gagne, Jessica Franklin, Julie Lauffenburger, Samantha Dougherty, Gregory Brill, Niteesh K Choudhry. (United States)

H. An Example of Exposure Heterogeneity When Pooling Epidemiologic Studies for Meta-Analysis of Antiretroviral Medication Adherence [87]
   - Mary-Ellen Mackesy-Amiti, Lauren Strand, Robin Nance, Redonna Chandler, William Cunningham, Elise Riley, Shrutil Mehta, Frederick Altice, Wendee Wechsberg, Chinazo Cunningham, Charles Cleland, Lisa Metsch, Daniel Feaster, Carlos del Rio, Curt Beckwith, Ann Kurth, Irene Kuo, Bridget Kruksza, Sandra Springer. (United States)

I. Pilot Test of the Sentinel Modular Program for Propensity-Score Matched Cohort Analyses: Application to Glyburide, Glipizide, and Severe Hypoglycemia [88]

J. Quality of Diabetes Recording: How Does Coding Impact Incidence Estimates? [90]
   - A Rosemary Tate, Sheena Dungey, Simon Glew, Natalia Beloff, Rachael Williams, Tim Williams.

K. Evaluation of Free-Text Comments to Validate Common Cancer Diagnoses in the UK CPRD [91]

L. Abstract Withdrawn [92]

M. An Algorithm to Identify Duplicate Patients When Pooling Aggregate Data from Two Primary Care Databases in the United Kingdom [93]
   - Estel Plana, Leah J McGrath, Joan Fortney, Ana Ruizgomez, Oscar Fernandez-Cantero, Luis-Alberto Garcia-Rodriguez, Alicia W Gilsenan, Elizabeth Andrews, Cristina Rebordosa, Ryan Ziemiecki. (Spain)

N. Methods to Estimate Days’ Supply within Pharmacy Data of the Health Improvement Network (THIN) [94]
   - Kirsten J Lum, Craig W Newcomb, Jason A Roy, Dena M Carbonari, M Elie Saine, Serena Cardillo, Harshvinder Bhullar, Arlene M Gallagher, Vincent Lo Re III. (United States)

O. Evaluating the Utility of the CPRD GOLD-HTI Linkage: Anticoagulant Prescribing at the GP Practice Compared to Hospital Dispensed Medication at Discharge Date [95]
   - Arlene M Gallagher, Rachel Tham, Hassy Dattani, Adam Collier, Frank de Vries, Tim Williams. (United Kingdom)

**Spotlight Session-Databases**

I. Pilot Test of the Sentinel Modular Program for Propensity-Score Matched Cohort Analyses: Application to Glyburide, Glipizide, and Severe Hypoglycemia [88]

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   - Arlene M Gallagher, Rachel Tham, Hassy Dattani, Adam Collier, Frank de Vries, Tim Williams. (United Kingdom)

**Spotlight Session-Devices**

P. Estimated Effects of Treatment Changes on Hemoglobin A1c in a Cohort with Incident Type 1 Diabetes [96]
   - Richard S Swain, Janet T Holbrook, Dana Y Teltsch, MAJ Christina L Cristaldi, Jodi B Segal, G Caleb Alexander. (United States)

Q. Cement Leakage and New Vertebral Fractures after Kyphoplasty and Vertebroplasty: A Meta-Analysis [97]
   - Hong Cheng, Yuzhi Hu, Nishant Mishra, Colin Anderson-Smits. (United States)

R. Assessing Real-World Use and Outcomes of Newly Marketed Bioprosthetic Aortic Valves Using Japanese Nationwide Cardiovascular Surgical Registry [98]
   - Hiraku Kumanamaru, Hiroaki Miyata, Noboru Motomura, Nobuhiro Handa, Kan Nawata, Minoru Ono, Shinichi Takamoto. (Japan)

S. Comparison of New Vertebral Fractures After Kyphoplasty and Vertebroplasty Using Medicare Data [99]
   - Hong Cheng, Yuzhi Hu, Jie Zhou, Colin Anderson-Smits. (United States)

T. Treatment Patterns in a Cohort of Patients with Incident Type 1 Diabetes [100]
   - Richard S Swain, Jodi B Segal, Dana Y Teltsch, MAJ Christina L Cristaldi, G Caleb Alexander, Janet T Holbrook. (United States)

U. Risk Factors for Persistent and New Chronic Opioid Use in Patients Undergoing Total Hip Arthroplasty [101]
   - Maria CS Inacio, Craig Hansen, Elizabeth Roughhead, Nicole L Pratt, Stephen E Graves. (Australia)

V. A Comparative Analysis of Secondary Surgeries of Six Total Cervical Disc Arthroplasty Devices to Cervical Arthrodesis at 5-Years [102]
   - Colin Anderson-Smits, Davic Sing, Anton Dmitriev, Hong Cheng. (United States)

W. Hospital Variation And Patient Characteristics Associated With Vena Cava Filter Use For Venous Thromboembolism [103]
   - Joshua D Brown, Jeffery C Talbert. (United States)
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1. Urosepsis and Urinary and Genital Infections Among Diabetes Patients and Matched Controls [112]
   Gregory A. Nichols, Kimberly G Brodovicz, Dorothea B Bartels. (United States)

2. Gastrointestinal Cancer Incidence in Type 2 Diabetes Mellitus; Results from a Large Retrospective Population-Based Cohort Study in the UK [113]
   Ronaldus GPJ de Jong, Paul JHL Peeters, Andrea M Burden, Marie L de Bruin, Harm R Haak, Ad AM Masclee, Frank de Vries, Maryska LG Janssen-Heijnen. (Netherlands)

3. Association Between Insulin Treatment and Breast Cancer Characteristics [114]
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4. A Population Based Study of Metformin and the Association with Survival in Pancreatic Cancer Patients [115]
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5. Prevalence of Type 1 and Type 2 Diabetes Among U.S. Pediatric Population in the MarketScan Multi-State Medicaid Database, 2002-2013 [116]
   Yong Chen, Tongtong Wang, Ravi Shankar. (United States)

6. Renal Function Measurements in Diabetes Patients; A Population Based Study in the Netherlands [117]
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8. Estimating the Prevalence and Incidence of Type 2 Diabetes Mellitus Using Population Level Pharmacy Claims Data [119]
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10. An Algorithm To Identify And Classify Individuals With Type 1 And Type 2 Diabetes Mellitus In A Primary Care Database [121]
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    Rohini Mathur, Krishnan Bhaskaran, Emma Edwards, Helen Lee, Liam Smeeth, Ian Douglas. (United Kingdom)

13. Intensification of Basal Insulin Treatment Among Patients with Type 2 Diabetes Mellitus in the Netherlands [124]
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19. Predictors of Mortality among Unvaccinated Veterans with Serious Streptococcus Pneumoniae Infections [130] Jacob B Morton, Haley J Morrill, Kerry L LaPlante, Aisling R Caffrey. (United States)


22. Quantification Of Risk Factors For Posttherapeutic Neuralgia In Herpes Zoster Patients: A Cohort Study [133] Hamiet Forbes, Krishnan Bhaskaran, Sara Thomas, Liam Smeeth, Tim Clayton, Kathrynn Mansfield, Caroline Minassian, Sinead Langan. (United Kingdom)

23. Exploring The Treatment Pathways Of Breast Cancer Survivors In Primary Care In England [134] Lydia Tutt, Li-Chia Chen, Claire Anderson, Tracey Thornley. (United Kingdom)

24. Validity of Cutaneous Squamous Cell Carcinoma Diagnosis in the Health Improvement Network [135] Zelma C Chiesa Fuxench, Andrea B Troxel, Lydia Tutt, Li-Chia Chen, Claire Anderson, Sinead Langan, Kathrynn Mansfield, Henrik T Sørensen, Henrik C Schønheyder, Sara L Thomas, Liam Smeeth, Tim Clayton, Kathrynn Mansfield, Caroline Minassian, Sinead Langan. (United Kingdom)


26. Incidence of Second Primary Malignancies In Patients With Primary Myelofibrosis [137] Alejandro Allepuz, Aleksandra Sarnecka, Katarzyna Sablinska. (Switzerland)


29. Incidence of Myeloid Neoplasms in Patients with Primary Myelofibrosis [140] Alejandro Allepuz, Aleksandra Sarnecka, Katarzyna Sablinska. (Switzerland)

30. Incidence of Cardiovascular Disease Among Early Stage Breast Cancer Patients in Denmark [141] Deidre Cronin-Fenton, Anders Kjaersgaard, Mette Nørgaard, Justyna Amelio, Alex Liede, Rohini K Hernandez, Henrik T Sørensen. (Denmark)

31. Characteristics And Outcome Of Newly Diagnosed Immune Thrombocytopenia In Adults: Results From The PGRx Information System [142] Clementine Nordon, Lamiae Grimaldi, Marc Michel, Lucien Abenhaim, Bertrand Godeau.

32. Infection and Anti-Infective Treatment Preceding a Diagnosis of Primary Persisting Immune Thrombocytopenia [143] Donia Sohrabian, Marie Linder, Charlotta Ekstrand, Honar Cherifi, Helie Kierer, Shahram Bahmanyar.

33. Comorbidities in the Young and Aging Populations with Haemophilia A [144] Ceri Hirst, James Black. (Switzerland)


35. Risk Score for Major Hemorrhage Among Chronic Lymphocytic Leukemia Patients in the US Veterans Administration Healthcare System [146] Peter Georgantopoulos, Huying Yang, Mona Cai, LeAnn Norris, Charles L Bennett. (United States)

36. Diabetes and New-Onset Atrial Fibrillation in a Hypertensive Population [147] Lia Alves-Cabratoa, Maria García-Gil, Marc Comas-Cufi, Ruth Martí, Anna Ponjoan, Didac Parramon, Jordi Blanch, Rafel Ramos. (Spain)

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38. Pharmacological Treatments Preceding Diagnosis of Idiopathic Intracranial Hypertension [149] Sarah Burkill, Anna Sudholm, Olafur Sveinsson, Shahram Bahmanyar, Ingela Nilsson. (Sweden)

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40. Treatment Practices for Acute Ischemic Stroke (AIS) in Quebec (Canada) [151] Mareva Faure, Anne-Marie Castillooux, Yola Moride, Agnès Lillo-Le-Louët. (Canada)

41. Stroke Risk in Individuals with versus without Atrial Fibrillation at Varying CHA2DS2-VASc Score Levels: Implications for Anti-Coagulant Treatment [152] Michelle Z Leisner, Anne Ording, Dora Körnemündi Farmas, Erzsébet Horváth-Puhó, Morten Schmidt, Henrik Toft Sørensen, Paolo Prandoni, Morten Olsen. (Denmark)

42. Incidence and Risk Factors for Atrial Fibrillation in Patients with Newly Diagnosed Heart Failure in UK General Practice [153] Mar Martín-Pérez, Ana Ruígómez, Alexander Michel, Luis A Garcia Rodriguez. (Spain)

43. One-Year Survival After Acute Myocardial Infarction (AMI): The Effect of Care Pathway in Italy [154] Valeria Belleudi, Martina Ventura, Paolo Scialli, Nera Agabiti, Mirko Di Martino, Riccardo Di Domenico, Marina Davoli, Danilo Fusco. (Italy)

44. Epidemiology of Pulmonary Arterial Hypertension in a Large US Commercially Insured Pediatric Population, 2010-2013 [155] Lin Li, Susan Jick, Stefanie Breitenstein, Gemzel Hernandez, Alexander Michel, David Vizcaya. (United States)

45. Doubling of Serum Creatinine and the Risk of Cardiovascular Outcomes in Patients with Chronic Kidney Disease and with Diabetes Mellitus Type 2: A Cohort Study [156] Cornelia Schneider, Blai Coll, Susan S Jick, Christoph R Meier.
66. Utilization of Psychotropic Drugs in Spouses of Dementia Individuals: A Population-Based Study [178]
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63. Increasing Mental Health Diagnosing and Treatment Among U.S. Medicaid Youth, 2001-2010 [175]
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64. Benzodiazepine Use and Risk of Developing Alzheimer’s Disease - A Case-Control Study Based on Swiss Claims Data [176]
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78. Statin Use and Risk of Gallstone Disease in Switzerland - A Case-Control Study Based on Swiss Claims Data [190] Fabienne Blétry, Olivier Reich, Matthias Schwenkglenks, Christoph R Meier. (Switzerland)


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82. Disease Severity and Characteristics of Patients with Atopic Dermatitis (AD) Investigated Using Administrative Claims Data [194] Fredrik Nyberg, Ralph Turner, Ozgur Tunceli, Michael J Atkinhead, Angela E Williams. (Sweden)

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84. Atopic Diseases and the Risk of Developing Ulcerative Colitis [196] Samman Azim, Eelko Hak, Jens HJ Bos, Catharina CM Schuilling-Veninga. (Netherlands)

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90. Longitudinal Changes in Prevalence of Rare Diseases and Related Costs in Taiwan (2003-2014) [202] Jason C Hsu, Christine Y Lu. (Taiwan)

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32. Do Individual Antimuscarinic Drugs to Treat Overactive Bladder Have Different Cardiovascular Risks? A UK CPRD Cohort Study [920]
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34. Risk of Major Adverse Cardiovascular Events Associated with Biologic Therapies in Patients with Plaque Psoriasis: Systematic Review and Meta-Analysis of Randomised Controlled Trials [922]
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36. Risk of Urinary Adverse Events Associated with Inhaled Anticholinergics in Adult Men [924]
Scott M Vouri, Seth A Strope, Jiajing Chen, Margaret A Olsen. (United States)

37. Survival In Kidney Transplantation In Patients Who Used Cyclosporine Or Tacrolimus [925]
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38. Risk of Venous Thromboembolism Amongst Users of Different Anti-Osteoporosis Drugs: A Multinational Population-Based Cohort Study [926]
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39. Preadmission Use of Prescription Drugs and Risk of Red Blood Cell Transfusion in Elderly Patients Undergoing Hip Fracture Surgery [927]
Alma B Pedersen, Deidre Cronin-Fenton, Nicolaj R Kristensen, Mette Nørgaard. (Denmark)

40. Fracture-Preventing Benefit of Bisphosphonates by Compliance and Its Timing Following Therapy Start: A Register-Based Study of Postmenopausal Women in Sweden [928]
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41. Clinical Effectiveness and Safety of Analogue Glargine in Type 1 Diabetes: Systematic Review and Meta-Analysis [929]
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42. Incretin-Based Treatments and the Risk of Pancreatic Cancer in Patients with Type 2 Diabetes [930]
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43. The Association of Metformin Exposure and Specific Types of Digestive Cancers Among Diabetic Patients: Real-World Findings from a US EMR Database [931]
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44. Cardiovascular Risks Associated with Dipeptidyl-Peptidase-4 Inhibitors Compared to Other Diabetes Drugs: A Cohort Study [932]
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45. Evaluation of Three HbA1c Metrics in Relation to Heart Failure in 94,332 UK Type 2 Diabetes Mellitus Subjects [933]
Claudia Cabrera, Stanko Skrtic, Marita Olsson, Volker Schnecke, Marcus Lind. (Sweden)

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48. Metformin and Other Glucose-Lowering Drug Initiation and Rates of Community-Based Antibiotic Use and Hospital-Treated Infections in Patients with Type 2 Diabetes: A Danish Nationwide Population-Based Cohort Study [936]
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49. Treatment Discontinuation And Rates Of Hypoglycaemia In Type 2 Diabetes Patients Treated With Dipeptidyl Peptidase-4 (DPP-4) Inhibitors or NPH Insulin As Third-Line Therapy [937]
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50. Risk of Hypoglycaemia in Users of Sulphonylureas with Renal Impairment: A Population-Based Cohort Study [938]
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51. Adjusting for the Effect of Switching Basal Insulin Treatment on the Risk of First Severe Hypoglycaemia [939]
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52. Cancer Risk Among Insulin Users: Comparing Analogues with Human Insulin in the CARING Five-Country Study [940]
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53. Comparative Effectiveness of Glinides vs. Dipeptidyl Peptidase-4 Inhibitors in Diabetic Patients [941]
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54. Association Between Type 2 Diabetes Mellitus and Cancer – a Methodological Approach [942]
Jetty A Overbeek, Amber AWA van der Heijden, Ron MC Herings, Giel Nijpels. (Netherlands)

55. Association of Type 2 Diabetes And Glucose-Lowering Drugs With Risk Of Recurrence Or Death Following Breast Cancer: A Population-Based Cohort Study [943]
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56. Safety and Efficacy of Sofosbuvir with Simeprevir with or without Ribavirin for Hepatitis C Genotype 1 with Severe Renal Impairment: A Meta-Analysis of Cohort Studies [944]
Ruchi Singhal, Pramit Tiwari, Ajay Duseja, Rajiv Ahlawat. (India)

57. Metabolic Syndrome Associated to Antiretroviral Therapy: A Cross-Sectional Analysis [945]
Debora C Hilario, Leticia P Braga, Cassia CP Mendicino, Andreia Q Ribeiro, Cristiane A Menezes de Padua. (Brazil)

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58. Analysis of Regimen Changes Due to Adverse Drug Reactions Associated with Antiretroviral Therapy in HIV Patients [946]
Sareeya Wechwithan. (Thailand)

59. Real-World Effectiveness of HCV Infection from an Irish National HCV Registry [947]
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60. The Association Between the Use of Oral Fluoroquinolones and Neuropsychiatric Events: A Self-Controlled Case Series Study [948]

61. Incidence of Myelosuppression in Patients with Longer-Term Exposure to Linezolid in an Outpatient Claims Database [949]
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62. Intravenous Vancomycin and the Risk of Clostridium difficile Infection [950]

63. Clarithromycin Resistance to Helicobacter Pylori: A Prospective Insight from Malaysia [951]
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64. Antibiotics and Infection/Colonization by Carbapenem-Non-Sensitive P. aeruginosa: A Nested Case-Control Study [952]
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65. Drug Interactions as a Potential Instrumental Variable: The Example of Effectiveness of Antibiotic Therapy in Exacerbated COPD Patients [953]
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66. Clinical Outcome Difference Of The Patient Treated With Generic Piperacillin-Tazobactam And Innovator In Severely Infectious Patients In Medical Intensive Care Units [954]
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67. Effectiveness of Adalimumab and Etanercept for the Treatment of Rheumatoid Arthritis in the Public Health System (SUS) Belo Horizonte, Minas Gerais, Brazil [955]
Jéssica B dos Santos, Brian B Godman, Alessandra M Almeida, Francisco de A Acucio, Adriana M Kakehas, Halton A de Oliveira Junior, Augusto A Guerra Junior, Marion Bennie, Juliana Alvarez. (Sweden)

68. The Associations Between Bullous Pemphigoid and Drug Use: A Prescription Sequence Symmetry Analysis [956]
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69. Safety and Efficacy/Effectiveness of 2nd-Line Treatments in Immune Thrombocytopenia (ITP): A Systematic Review of the Literature [957]
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70. Patient Characteristics and Overall Survival (OS) in the Post-Docetaxel Metastatic Castration-Resistant Prostate Cancer (mCRPC) Community Setting [958]
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72. The Quality of Warfarin Therapy Among Atrial Fibrillation Patients in Finland - Results from the FinWAF Registry [960]
Juha Mehtälä, Pekka Raatikainen, Riitta Lassila, Houssem Khanfir, Pasi Korhonen, Fabian Hoti, Mika Lehto. (Finland)

73. Antiplatelet and Anticoagulant Prescriptions and Breast Cancer Recurrence: A Danish Nationwide Prospective Cohort Study [961]
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74. Safety And Efficacy Of New Oral Anticoagulants, And Low Molecular Weight Heparins Compared To Aspirin Associated With Total Knee And Hip Replacement [962]
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75. Outcomes Associated With Non-Adherence To Anti-Hypertensives And Statins [963]
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76. De Novo Post-Diagnosis Statin Use And Mortality In Women With Stage I-III Breast Cancer [964]
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77. The Association Between Statin Use and Risk of Cancer Among Elderly Medicare Beneficiaries [965]
Jing Yuan, Kevin Z Lu. (United States)

78. Beta Blockers and Cancer Prognosis – the Role of Immortal Time Bias: A Comprehensive Systematic Review and Meta-Analysis [966]
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79. Protection Against Colorectal Cancer with Use of Low-Dose Aspirin: Selection Bias Is Unlikely Based on Results Using Three Different Study Designs [967]
Lucia Cea Soriano, Montse Soriano-Gabarró, Luis A García Rodríguez. (Spain)

80. New Use of Statins and the Risk of Achilles or Biceps Tendon Rupture: A Propensity-Score Matched Cohort Study [968]
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81. Impact of Treatment with Lipid-Lowering Drugs on Longitudinal and Secular Decrease in Total Cholesterol Levels. The Tromso Study 1979-2008 [969]
Laila A Hopstock, Kaare H Bona, Anne E Eggen, Samelina Grimsaard, Bjørne K Jacobsen, Maja-Lisa Lochen, Ellisiv B Mathiesen, Inger Njølstad, Tom Wilsaard. (Norway)
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| **83.** | Effectiveness of Ezetimibe on Blood Lipids in Real-Life Clinical Practice [971]  
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| **84.** | Clinical Characteristics, Lipid Treatment and Goal Attainment in a Familial Hypercholesterolemia Cohort in the Netherlands: A Cross Sectional Study [972]  
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| **85.** | Modelling Of Average Endpoint Postponement For Cardiovascular Outcomes In Statin Trials [973]  
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| **86.** | Blood Pressure-Lowering Effect of Spironolactone in Hypertensive Patients Without Heart Failure [974]  
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| **88.** | The Comparative Effectiveness of 4th Line Anti-Hypertensive Agents in Patients with Resistant Hypertension: A Meta-Analysis [976]  
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| **90.** | Effectiveness Of Preventing Stroke Between Different Rhythm Control Agents For Atrial Fibrillation: Retrospective Cohort Study From A Nationwide And Single-Center Database [978]  
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| **91.** | The Impact of Comorbidity with Heart Failure on Treatments and Outcomes in Patients with Acute Coronary Syndrome [979]  
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| **92.** | Population-Based Effectiveness and Safety of Different Antiplatelet Regimens as Secondary Prevention for Ischemic Stroke/Transient Ischemic Attack [980]  
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| **93.** | Age-Stratified Outcome Of Genotype-Guided Dosing Algorithm For Acenocoumarol And Phenprocoumon [981]  
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| **94.** | Incidence of Intracranial Bleeds in New Users and Non-Users of Low-Dose Aspirin in the UK [982]  
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| **95.** | An Evaluation of the Effect of Spironolactone on the Risk of New Onset of Diabetes in a Population-Based Study of Patients with Heart Failure [983]  
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| **96.** | Novel Oral Anticoagulants and Risk of Gastrointestinal Bleeding: A Systematic Review [984]  
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| **97.** | Rivaroxaban vs. Phenprocoumon Use in Germany and Risk of Bleeding: A Claims Data Analysis Based on 80,000 Patients [985]  
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| **98.** | Risk Factors for Major Bleeding Events in Rivaroxaban Users with Atrial Fibrillation: A Nested Case-Control Study [986]  
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| **99.** | Outcomes of Intravenous Corticosteroids in Patients Undergoing Coronary Artery Bypass Grafting Surgery [987]  
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| **100.** | The Impact of Comorbidity and Age on Treatments for Acute Coronary Syndrome [988]  
Wei Ho, Jui Wang, Kuo-Liong Chien, Fe-Lin Lin Wu, Zhen-Fang Lin. (Taiwan) |
| **101.** | Health-Related Quality of Life and Burden of Disease in Patients Suffering from an Acute Coronary Syndrome: Evidences from the Use of Validated Instruments in the PGRx-3 Real World Dataset [989]  
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| **102.** | Switching of Angiotensin Receptor Blockers to Angiotensin-Converting Enzyme Inhibitors in Patients with Hypertension: Is It a Cost-Saving Strategy? [990]  
Amanj Baker, Li-Chia Chen, Rachel Elliott. (United States) |
| **103.** | Characteristics of Different Antihypertensive Medication Users in Observational Comparative Effectiveness Studies: A Literature Review [991]  
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| **104.** | Severe Adverse Events and Treatment Discontinuation Among Older Adults Taking Angiotensin-Converting Enzyme Inhibitors (ACEI) or Angiotensin Receptor Blockers (ARB) Following Acute Myocardial Infarction (AMI) [992]  
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| **105.** | Cholinesterase inhibitors and Risk of Adverse Cardiac Events: Synergic Effects of Cardiosuppressive Drugs in Dementia Patients [993]  
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| **106.** | Medication Therapy Modifies the Association Between Longitudinal eGFR and Cardiovascular Events Among Adults with CKD [994]  
H Lester Kirchner, Sharon Larson, Robert Perkins. (United States) |
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Safety & Effectiveness - Neurological

107. Risk Of First Hip Fracture Associated With Incident Benzodiazepine And Related Drug Use In Persons With And Without Alzheimer’s Disease [995]
Laura Saarelainen, Marjaana Koponen, Anti Tanskanen, Anna-Maija Tolpanen, Reijo Sund, Jari Tiihonen, Sirpa Hartikainen, Heidi Taipale. (Finland)

108. Association Between Exposure to Benzodiazepines and Related Drugs and Total Hip Replacement Survivorship in Arthritis: A Population-Based Cohort Study of 246 940 Patients [996]
Dan Beziz, Sandrine Colas, Cédric Collin, Rosemary Dray-Spira, Mahmoud Zureik. (France)

David F Niedrig, Liesa Hoppe, Sarah Maechler, Heike Russmann, Stefan Russmann. (Switzerland)

110. Effectiveness and Safety of Smoking Cessation Pharmacotherapy: A Retrospective Cohort Study [998]
Greg A Carney, Malcolm Maclure, Suzanne M Taylor, Ken Bassett, Colin Dormuth. (Canada)

111. Association Between Buprenorphine/Naloxone Sublingual Tablet And All-Cause Mortality In Patients Receiving Medication Assisted Treatment For Opioid Addiction In UK [999]
Jinghua He, Sabine M Apelt. (United States)

112. Hypnotic Drug Use and Cardiovascular Events in Treated Hypertensive Patients [1000]
Kaori Nomura, Yasunari Mano, Mariko Asahi, Shunya Ikeda. (Japan)

113. First-Line Disease Modifying Therapies in Preventing Multiple Sclerosis Relapse – A Nationwide Observational Study in Taiwan [1001]
Chih-Ho Chou, Tzu-Chieh Lin, Ching-Lan Cheng, Yea-Huei Kao Yang. (Taiwan)

114. Comparison of the Effectiveness of Duloxetine versus Pregabalin/Gabapentin for Treatment of Diabetic Peripheral Neuropathy [1002]
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115. Comparative Safety of Long-Acting Opioids for Non-Cancer Pain [1003]

Ghaleb Saud Alharbi, Li-Chia Chen, Roger Knaggs.

117. Impact of Pre-Admission Opioid Treatment on One-Year Mortality After Non-Surgical Intensive Care Admission [1005]
Troels Munch, Christian F Christiansen, Lars Pedersen, Henrik T Sørensen. (Denmark)

118. Is Use of Antiepileptic Drugs Associated with an Increased Cataract Risk? A Case-Control Analysis [1006]
Claudia Becker, Susan S Jick, Christoph R Meier.

119. Estimating the Association of Adverse Health Outcomes Using Three Anticholinergic Medication Toxicity Scales [1007]
Katia Hannah, Heather Anderson, Dong Xu, Robert Valuck. (United States)

120. Psychiatric Medication and School Performance in Primary School Children: An Explorative Study [1008]
Jurjen van der Schans, Selfike Vardar, Rukiye Cicek, Jens HJ Bos, Pieter J Hoekstra, Tjalling W de Vries, Eelko Hak. (Netherlands)

121. Risk of Parkinson’s Disease In The Users Of Antihypertensive Agents: An Evidence From The Meta-Analysis Observational Studies [1009]
Amarnath Mullapudi, Dipika Bansal, Kapil Gudala, Chandra sehkar Boya. (India)

122. Risk of Mortality in Patients with Parkinson’S Disease Exposed to Domperidone [1010]
Judith van Dalem, Andrea Burden, Sander Pouwels, Frank de Vries. (Netherlands)

123. Outcomes of Three Treatment Strategies in Bipolar Disorder Using Conventional Mood Stabilizers and Antipsychotic Drugs [1011]
Marie Tournier, Anke Neumann, Elodie Bertrand, Alain Dauwer, Gérard Bégad, Gérard Maura, Hélène Verdoux. (France)

124. Use of Antipsychotics and Risk of Recurrent Stroke Events: A Population-Based Retrospective Cohort Study in Taiwan [1012]
Le Dai, Dan-Wei Chou, Jiul Wang, Kuo-Liong Chien, Fe-Lin Lin Wu, Zhen-Fang Lin. (Taiwan)

125. Antipsychotic Use and Risk of Hospitalisation or Death Due to Pneumonia in Persons with and without Alzheimer’s Disease [1013]
Anna-Maija Tolpanen, Marjaana Koponen, Anti Tanskanen, Pia Lavikainen, Reijo Sund, Jari Tiihonen, Sirpa Hartikainen, Heidi Taipale.

126. Antidepressant Use and Outcomes in Combination with Contraindicated Medication in a Tertiary Care Hospital [1014]
David F Niedrig, Sabrina T Müller, Carmen Gött, Waldemar Greil, Stefan Russmann. (Switzerland)

127. Applying a Novel Anticholinergic Toxicity Scoring System to a Retrospective Cohort of Managed Care Patients [1015]
Heather Anderson, Katia Hannah, Dong Xu, Vaughn Culbertson, Robert Valuck.

128. A Novel Molecular-Based Anticholinergic Toxicity Scoring System as a Basis for Assessing Drug-Induced Anticholinergic Burden [1016]
Dong Xu, Vaughn Culbertson, Heather Anderson, Katia Hannah, Robert Valuck.

129. Tolerability/Safety Profile of Cariprazine in Treating Psychotic Disorders/Bipolar Disorder: A Systematic Review with Meta-Analysis of RCTs [1017]
Shijian Lao, Ying He, Ian CK Wong, Frank MC Besag, Esther W Chan.

130. The Risk of Depression, Euphoric Mood and Sedation with the Use of Dextromethorphan in Different Indications. Results from a Systematic Review and Meta-Analysis of Randomised Clinical Trials [1018]
Luis Velez-Nandayapa. (United Kingdom)

131. The Risk of Dizziness with the Use of Dextromethorphan in Different Indications; Not a Rare Risk as Described in Label. Results From a Systematic Review and Meta-Analysis of Randomised Clinical Trials [1019]
Luis Velez-Nandayapa. (United Kingdom)

Safety & Effectiveness - Respiratory

132. Risk of Myocardial Infarction (MI) Associated with Acute Exacerbations of COPD (AECOPD): Effect Modification by Cardiovascular Drugs [1020]
Kieran J Rothnie, Hana Mällerová, Liam Smeeth, Neil Pearce, Ian Douglas, Jennifer K Quint. (United Kingdom)
133. Inhaled Corticosteroids and the Risk of Hospitalization for Pneumonia. Results from the OUTPUL Study [1021] Silvia Cascini, Nera Agabiti, Lisa Bauleo, Ursula Kirchmayer, Valeria Belleudi, Mirko Di Martino, Riccardo Pistelli, Giulio Formoso, Danilo Fusco, Marina Davoli, OUTPUL Study Group. (Italy)


136. Increased Risk of Stroke with Co-Exposure of Acute Respiratory Infection and NSAIDs Use: A Nationwide Case-Crossover Study [1024] Yao-Chun Wen, Fei-Yuan Hsiao, Li-Jiuan Shen, Cheng-Chung Fang. (Taiwan)


138. LABA Safety in Actual Medical Practice: Results from the Longitudinal, Time-Dependent Analyses of the ASTROLAB Data [1026] Eric H Van Ganse, Laurent Laforest, Sandrine Herbage, Flore Jacoud, Alexandra Dima, Nathalie Texier, Montserrat Ferrer, Marjin de Bruin, The ASTROLAB Group. (France)

139. Development of a Risk Model for Uncontrolled Pneumonia in Hospitalized Patients [1027] Yoonyoung Choi, Benjamin Staley, Carl Henriquez, Gigi Lipori, Babette Brumback, Almut G Winterstein. (United States)

Other Safety & Effectiveness

140. Severe Acute Liver Injury Risk Among Temozolomide Treated Brain Cancer Patients in the HealthCore Integrated Research Environment [1029] Scott C Quinlan, Anne Delz, Vibha Desai, Jeonghwa He, Crystal N Holick, Stephan Lanes. (United States)

141. The Risk of Alcohol-Related Mortality in Patients with Psoriasis: A Population-Based Cohort Study Using Linked Primary Care, Hospital and Mortality Records [1030] Rosa Parisi, Roger T Webb, Christopher EM Griffiths, Darren M Ashcroft. (United Kingdom)


143. Impact Of Anti-Inflammatory Drugs On Risk Of Depression And Anxiety After Intensive Care Requiring Mechanical Ventilation [1032] Clara R Medici, Sören D Ostergaard, Henrik T Sørensen, Lars Pedersen, Christian F Christiansen. (Denmark)

144. Utilization of Belatacept in Renal Transplant Recipients in USA [1033] Xuerong Wen, Karl L Worner, Michael J Casey, Alonsso H Santos, Abraham G Hartzema. (United States)


146. SALT-III: Prospective Study of Drug-Exposed Acute Liver Failure (ALF) [1035] Sinem Ezgi Guımez, Séverine Lignot-Maleyran, Sophie Micon, Régis Lassalle, Jérémy Jové, Nicholas Moore. (France)

147. Comparison of Outcomes Following a Switch from a Brand to an Authorized vs. Independent Generic Drug [1036] Richard A Hansen, Jingjing Qian, Richard Berg, James Linneman, Enrique Secoane-Vazquez, Sarah Dutcher, Saeid Raofi, Peggy Peissig. (United States)

148. Potential Prescribing Omissions Among older US Adults According to START Criteria [1037] Marcela Jiron, Virginia Pate, Laura C Hanson, Michele Jonsson Funk, Til Stürmer. (Chile)

149. Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: A Population-Based Case-Control Study [1038] Noel C Frey, Michael Bodmer, Andreas Bircher, Susan S Jick, Christoeph R Meier, Julia Speddinglin. (Switzerland)

150. Stevens - Johnson Syndrome Associated with Dimenhydrinate [1039] Sareeyea Wechwithan. (Thailand)

151. Mapping of Existing Data Sources for the Conduct of Real-World Studies in Duchenne Muscular Dystrophy (DMD) in North America and Europe [1040] Aurore Bergamasco, Chung-Yan Yuen, Tzyung D Kou, Yola Moride. (France)


153. Mapping Of Existing Disease-Specific Data Sources For The Conduct Of Pharmacoepidemiologic Studies In China [1042] Chung Yan Yuen, Aurore Bergamasco, Teigna Arrendondo-Bisono, Yola Moride. (Canada)

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157. Lessons Learned from the Assembly of the SENATOR Drug File [1046] Michael McCarthy, Shane Cullinan, Denis O’Mahony, Stephen Byrne. (Ireland)

158. An eResearch Query Definition Library: Methods and Value [1047] Maggie Lohnes, Craig Parker, Aaron WC Kamauu. (United States)

159. Integrating ICD-10-CM Coding into RWE Research Using US Healthcare Databases: Challenges for Valid Research Practices [1048] Irene S Cosmatos, Rebecca J Levin, Michael Bulgrien, Jamie Reifsnyder. (United States)
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160. Assessing the Gaps in Turning Data into Insights Using Real World Evidence [1049]
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161. Comparative Assessment of US Healthcare Databases and Linkage Capabilities for Pharmacoepidemiology Studies [1050]
Deborah Casso, Karin E Johnson, Syd Phillips, Susan A Oliveria. (United States)

162. Impact of the US ICD-9 to ICD-10 Code Transition on Clinical Research [1051]
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163. Leveraging NLP-Assisted Semi-Automated Chart Review for Detecting Rare Clinical Events from Narrative Clinical Notes [1052]
Aaron WC Kamauu, Nicole Bailey, Andrew Wilson, Patrick Alba, Olga Patterson, Scott DuVall.

164. AugMed; Augmented Reality Application for Unobtrusive Medical Adherence Measurement [1053]
Panagiotis Antoniou, Eirini Apostolidou, Dimitrios Kouvelas, Panagiotis Bamidis. (Greece)

165. Medication Safety Infrastructure at Saudi Hospitals: A Descriptive Cross-Sectional Pilot Study [1054]
Mohammed Alsoltani, Mohamed Alkalya. (Saudi Arabia)

166. Representativeness of Electronic Medical Records to Support Novelty (A Novel Observational Longitudinal Study of Patients with Asthma and/or COPD) [1055]
Xia Wang, Alecka Sverius, Josh Hillier, Diana Wong, Paola Nasuti, Harvey Jenner, Alexia McKenzie, Aaron Kamauu, Kyle Martin Flickinger, Maria Gerhardsson de Verdier. (United States)

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167. The Effect of Intensified Anti-Tuberculosis Therapy on Patient’s Health Status (Symptoms, Activity and Respiratory Impact) [1056]
Jarir At Thobari, Bryan CG Wibisono, Dyah Perwitasari, Ully A Mulyani. (Indonesia)

168. Patient-Reported Outcomes in Adults Suffering from Acute Coronary Syndrome: A Comprehensive Analysis from the Pharmacoepidemiology General Research eXtension System (PGRx-3) [1057]
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169. Association Between Quality of life and Medication Use for Baby Boomers and Older People, by Cardiovascular Disease Status [1058]
Bee Leng Per, Anne Taylor, Tiffany Gill. (Australia)

170. Do GPs Adhere to the Guidelines? A Study Based on Statins Prescriptions [1059]
Irene Petersen, Federico Ricciardi, Irwin Nazareth, Gianluca Baiio. (United Kingdom)

171. Costs Analysis Of Traditional And New Oral Anticoagulants: A Retrospective Analysis In A Local Health Authority In Northern Italy [1060]
Silvia Lucchi, Alfredo Cocci, Salvatore Mannino. (Italy)

172. The Healthcare Costs of Heart Failure During the Last Five Years of Life: A Retrospective Cohort Study [1061]
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173. Racial Differences in Productivity Loss Attributable to Rheumatoid Arthritis Among Patients Taking Disease-Modifying Antirheumatic Drugs (DMARDs) [1062]
Laura M Bozzi, Pryanika Galtonde, Fadia Shaya, Sarah E Tom. (United States)

174. Patient Monitoring – the Hidden Costs of Treatment with Antipsychotics [1063]
Mariëtte Nederlof, Geert WJ Frederix, Lennart J Stoker, Wouter W van Solinge, Toine CG Egberts, Eibert R Heerdink. (Netherlands)

175. Assessment of Predictive Ability of SLANSS and ID Pain Questionnaires in Assessing Pain Related Outcomes in Chronic Non-Cancer Neuropathic Pain Conditions [1064]
Rambabu Vatte, Dipika Bansal, Babita Ghai, Kapil Gudala. (India)

176. A Qualitative Study to Develop Patient Materials on Opioid Use in Orthopaedic Surgery [1065]
David Smith, Jennifer Schneider, Jennifer Kuntz, Jill Mesa, Xiuhai Yang, Amanda Petrik, Lynn DeBar. (United States)

177. What Is the Evidence on Financial Toxicity of Cancer Treatment? [1066]
Emre Yuceel, Aylin Yuceel. (United States)

178. Measuring Outcomes Among Metastatic Prostate Cancer Patients in Administrative Claims Data Using the Center for Medicare and Medicaid Services Oncology Care Model [1067]
Debra E Irwin, Lisa A Palmer. (United States)

179. Quality of Life of Patients with Diabetes Mellitus Types 1 and 2 from a Reference Health Care Center in Minas Gerais, Brazil [1068]
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180. Impact of Patient Counseling on Medication Adherence Behavior and Quality of Life in Diabetics of Telangan Region [1069]
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Charles E Okafor, Obinna I Ekwunife. (Nigeria)

182. Resource Utilization of Adult Patients with Sporadic Angiomyolipoma in the Netherlands [1071]
Francis Vekemans, Matthew Magestro, Paul Karner, Jonathan Fortier, Mei Sheng Duh, Bernard A Zonnenberg. (Canada)

183. Costs with Medicines and Services in the Treatment by Patients with Schizophrenia [1072]
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184. Some Statistical Considerations in Estimating a Disease Progression Model for Chronic Obstructive Pulmonary Disease (COPD) [1073]
Alex Exuzides, Chris Colby, Andrew H Briggs, Nancy Ryebourough, Timothy Baker, Afysi Ismaila. (United States)

185. What Are Patient’s Willing to Pay for Pharmacogenomic Testing? [1074]

186. Policy Options to Lower Prescription Drug Prices in the United States [1075]
G Caleb Alexander, Jeromie Ballreich, Mariana P Socai, Tanuja Karmarkar, Antonio Truillo, Jeremy Green, Joshua Sharfstein, Gerard Anderson. (United States)

188. Abstract Withdrawn [1077]

189. Assessment of Pharmacist Interventions of Drug Related Problems Among Patients with Impaired Renal Function [1078] Savitha R Sanathan, Madhan Ramesh, Manjunath S Shetty. (India)

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190. New Chronic Disease Medication Prescribing by Nurse Practitioners, Physician Assistants, and Primary Care Physicians: A Cohort Study [1079] Zachary Marcum, Johanna Bellon, Jie Li, Walid Gellad, Julie Donohue. (United States)


194. Trends in Medicines Procurement by the Brazilian Federal Government from 2006 to 2013 [1083] Tatiana Chama Borges Luz, Claudia Garcia Serpa Osorio-de-Castro, Rachel Magarinos-Torres, Bjorn Wettermark. (Brazil)


196. Sale of Phthalate Containing Drugs in Denmark from 2004 to 2012 [1085] Anne Broe, Zandra N Ennis, Jesper Hallas, Thomas Ahern, Anton Pottegaard, Per Damkier. (Denmark)

197. Use of Proton Pump Inhibitors Among Adults: A Danish Nationwide Drug Utilization Study [1086] Anton Pottegård, Annie Broe, Jesper Hallas, Ove BS de Muckadell, Annmarie TLassen, Anders B Lodrup. (Denmark)


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199. Impact of Safety Warning on Domperidone Prescribing in Ireland [1088] Mary Teeling, MaryJo MacAvin, Kathleen Bennett. (Ireland)

200. Initiation of Anti-TNF Therapy in Patients with Inflammatory Bowel Disease in France Between 2011 and 2013: A Nationwide Study Based on Medico-Administrative Databases [1089] Pierre-Olivier Blotilère, Jérémie Rudant, Amélie Barré, Antoine Racine, Alain Weill, Franck Carbonnel, François Allia. (France)

201. Treatment Patterns of Thiopurines in a Danish Population Diagnosed with Inflammatory Bowel Disease: A Drug Utilization Study [1090] Marie S Kristensen, Thora M Kjærulf, Lau C Thygesen, Nikolone N Knudsen, Anders Green, Vibeke Andersen, Annette K Erbsoll. (Denmark)

202. Drug Utilization Patterns of Tumor Necrosis Factor Inhibitor Agents in a Population with Inflammatory Bowel Disease from 2009 to 2014 in Denmark [1091] Thora M Kjærulf, Marie S Christensen, Annette K Erbsoll, Nikolone N Knudsen, Anders Green, Vibeke Andersen, Lau C Thygesen. (Denmark)

203. Dispensing Patterns of Prescription-Only Antibiotics Preparations in South Africa [1092] Ilse Truter. (South Africa)

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209. Treatment of Polycystic Ovary Syndrome in UK Primary Care 2004-2012 [1099] Tao Ding, Gianluca Baio, Irene Petersen, Paul Hardiman, Cormac Simmons. (United Kingdom)
Miriam R Elman, Gregory B Tallman, David T Bearden, Jessina C McGregor. (United States)

214. Antibiotic Prescribing in Hospital, a Comparison Point Prevalence Study Between Ireland and Norway [1104]
Kathrine Bergrøv, Trude E Flatebo, Kirsten K Viktil, Dag Berild, Eoghan O’Neill, Hilary Humphreys, Hege S Blix. (Norway)

Abdul Haseeb, Mahmoud Mohamed Ahmed Mohamed, Mahmoud E. Elraggal, Hani Saleh FAidah, Fahad Saleem, Ejazulh Cheema, Mohamed Azmi Hassali. (Saudi Arabia)

216. Trends in Utilization of Antibiotics in Norway - Do We Reach the National Goals? [1106]
Kari Husabo, Olaug Fenne, Sissel Torheim, Hege Salvesen Blix, Kari Furu. (Norway)

217. Trends In The Utilization Of Allergy Medications [1107]
Hege S Blix, Kai-Håkon Carlsen, Åsmund Reikvam. (Norway)

218. Dispensing Patterns of Antihistamine Drugs by a Community Pharmacy Group in South Africa [1108]
Ilse Truter, Liana Steenkamp. (South Africa)

219. NOACs: Are We Prescribing Appropriately? [1108]
Sinéad Keohane, Vicki Sandys, Michael Barry. (Ireland)

220. General Pharmacological Treatments Preceding A Primary Chronic Immune Thrombocytopenia Diagnosis [1110]
Lucas Löfling, Marie Linder, Charlotta Ekstrand, Honar Cherif, Helle Kieler, Shahram Bahmanyar. (Sweden)

221. Evolving Australian, and Northern European, Utilisation Patterns for Immunosuppressants After Transplantation [1111]
Kyle M Gardiner, Susan E Tett, Christine E Staatz. (Australia)

222. Trends in Prevalence of Lung Cancer and Targeted Therapies Utilization for Lung Cancer Treatment in Taiwan (2004-2013) [1112]
Jason C Hsu, Chen-Fang Wei, Christine Y Lu. (Taiwan)

Yi-Ting Chou, Stacie B Dusetzina. (United States)

224. Oral Anticancer Drugs Use in France: A Population-Based Study [1114]
Pauline Bosco-Levy, Paul de Boissieu, Julien Bezin, Annie FOURIER-Néglat. (France)

225. Uptake and Cost of Capecitabine versus 5-FU Among Commercially-Insured Colorectal Cancer Patients [1115]
Ashley L Cole, Hanna K Sanoff, Stacie B Dusetzina. (United States)

226. Consumption and Expenditure of Non-Targeted and Targeted Cancer Drugs in Ecuador [1116]
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227. A Comparative Study to Evaluate Treatment Patterns & Resulting Utility in Patients of Head & Neck Cancers Under Private Payment Scheme and Government Reimbursement Scheme [1117]
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228. Identification & Resolving of Medication Related Problems Associated With Management of Co-Morbidities in Cancer Patients — A Role of Medication Therapy Management Service [1118]
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229. Impact of Regulatory Action on Prescribing of Renin-Angiotensin System Blockers in the UK [1119]
Craig Allen. (United Kingdom)

230. Antiplaquelet Treatment and Long-Term Mortality After Acute Myocardial Infarction in Real-World Data [120]
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231. Treatment Changes Among Users of Non-Vitamin K Antagonist Oral Anticoagulants in Atrial Fibrillation [1121]
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232. Differences in Recording of Characteristics Among Patients Prescribed Oral Anticoagulants Using Primary Care and Cardiologist Data in Germany [1122]
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233. Differences in Statin Users and Non-Users with Bacteremia [1123]
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Ju Hyeun Kim, Abraham G Hartzema. (United States)

235. Sex Differences in Factors Predicting the Type of Bladder Antimuscarinics Initiated in Medicare Nursing Home Residents [1125]
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236. Patterns of Use of Antimuscarinic Drugs to Treat Overactive Bladder in Denmark, Sweden and the United Kingdom [1126]
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Amy Law, Dominic Pilon, Richard Lynen, François Laliberté, Laurence Gozalo, Patrick Lefebvre, Mei S Duh. (Canada)

238. Abstract Withdrawn [1128]

239. Use Of Cyproterone Acetate/Ethinyloestradiol In The United Kingdom Prior To And Following Recent Updated Guidance: Prescribing Patterns Using A National Primary Care Database [1129]
Lucia Cea Soriano, Alex Asiimwe, Hissba Tus-Saboor Khan, Vita Beckert, Ulrike Wissinger-Graefenhahn, Luis A Garcia Rodriguez.

240. Cyproterone Acetate/Ethinyloestradiol Prescribing in the UK [1130]
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241. Use of Emergency Contraceptives in Two European Countries [1131]  
Ria Benko, Claudia Furtado, Teresa Risso, Maria Matuz. (Hungary)

242. Characteristics of New Users of Osteoporosis Drugs Changed Over Time, Yet High Compliance with Therapy Remained Stable [1132]  
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244. Intra-Articular Injection Switching Patterns Among Patients with Knee Osteoarthritis: Data from the Osteoarthritis Initiative [1134]  
Shao-Hsien Liu, Catherine E Dubé, Jeffrey B Driban, Timothy E McAlindon, Charles B Eaton, Kate L Lapane. (United States)

245. Factors Associated with Use of Disease Modifying Agents for Rheumatoid Arthritis in the National Ambulatory Medical Care Survey (NAMCS) [1135]  
Priyanka Gaitonde, Laura M Bozzi, Fadia T Shay. (United States)

246. Trends of Allopurinol Use in Norway and in Hungary [1136]  
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249. Persistence of Antipsychotic Medications in Patients with Schizophrenia: A Cross-National Study from the Asian Pharmacoepidemiology Network (AsPEN) [1139]  

250. Long-Acting Injectable Antipsychotics: Patterns of Use and Determinants of Treatment Failure in a Northern Italy Area [1140]  
Lorenzo Berardi, Ippazio C Antonazzo, Carlo Piccinni, Antonella Piazza, Emanuel Raschi, Elisabetta Poluzzi. (Italy)

251. Incident Use of Benzodiazepines in France from 2006 to 2012: A Population-Based Study [1141]  
Anne Bénard-Laribiè, Pernelle Noize, Elodie Pambrun, Fabienne Bazin, Hélène Verdoux, Marie Tournier, Bernard Bégaud, Antoine Pariente. (France)

252. Utilization Patterns of Antidepressants in France from 2007 to 2012: A Population-Based Study [1142]  
Anne Bénard-Laribiè, Antoine Pariente, Elodie Pambrun, Fabienne Bazin, Pernelle Noize, Hélène Verdoux, Bernard Bégaud, Marie Tournier. (France)

253. Trends and Prescription Patterns of Anti-Alzheimer Drugs Used in Japan from 2010 to 2015: A Descriptive Study Based on Pharmacy Claims Databases [1143]  
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254. Evaluation Of Antidepressant Drug Use In Populations In The UK and Quebec [1144]  
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255. Use of Antidepressants Under the Financial Crisis in Greece [1145]  
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256. Assessment of the Impact of Medical Fee Schedule Revision on Polypharmacy of Psychotropic Agents in Japan [1146]  
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257. Trend and Prescription Patterns of Antipsychotic Medications (APMs) in Asia and US: A Cross-National Comparison Study [1147]  

258. Antipsychotic Use in Dementia: A Comparison Between Three European Countries [1148]  
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259. Antipsychotic Prescription Trend in Hong Kong from 2004 to 2014 [1149]  
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260. Antipsychotic Prescribing in a Tertiary Hospital Under the Financial Crisis in Greece [1150]  
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261. Time-to-First Discontinuation in New Users of Second Generation Antipsychotics in Older People [1151]  
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262. Prevalence, Time Trends and Utilization Patterns of Psychotropic Polypharmacy: Evidence from Children and Adolescent Medicaid Beneficiaries, 1999-2010 [1152]  
Rene Soria-Saucedo, Xinyue Liu, Juan Hincapie-Castillo, Regina Bussing, Almut G Winterstein. (United States)

263. Prevalence, Time Trends and Utilization Patterns of Psychotropic Polypharmacy: Evidence from Adult Medicaid Beneficiaries, 1999-2010 [1153]  
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264. Comparing the Increase in the Cost of Drug Prices Among Multiple Sclerosis Drugs: Anticipated vs. Market Prices Between 2010-2015 [1154]  
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265. The Nudge, the Push and the Mole: Management of Long-Acting Oxycodeone [1155]  
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266. Exploring Factors linked to In-Patient Hospitalisation Amongst Non-Cancer Pain Patients Prescribed Long-Term Strong Opioids in UK Primary Care [1156]
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267. Non-Buprenorphine Opioid Utilization Amongst Patients Using Buprenorphine/Naloxone [1157]
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268. Opioid Utilizations in Patients with Diabetes [1158]
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269. Impact of State Laws to Reduce Prescription Drug Abuse on High-Risk Opioid Prescribers [1159]
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270. Drugs Used in Intentional Drug Overdose: Findings from the National Self-Harm Registry Ireland [1160]
Caroline Emer Daly, Eve Griffin, Roger Webb, Ella Arensman. (Ireland)

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271. Asthma Hospitalisation Differences Between Generics and Brand of Montelukast [1161]
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273. The Role of Patient Characteristics in Dosage Form of ICSLABA Prescriptions [1163]
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Daniel P Henriksen, Anders Christiansen, Jesper R Davidsen, Christian B Laursen, Per Damkier, Jesper Hallas, Anton Pottegård. (Denmark)

Pili F Ferrer, Mónica Sabaté, Elena Ballarín, Xavier Vidal, Sven Schmiedl, Olaf H Klungel, Luisa Ibañez. (Spain)

276. Characteristics of New Users of Aclidinium Bromide in the United Kingdom [1166]
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277. Predictors for the Prescription of Aclidinium Bromide as Compared to Tiotropium Bromide Using German Claims Data [1167]
Nadine Wentzell, Bianca Kollhorst, Tania Schink.

278. Patterns of Roflumilast Use for the Treatment of COPD Across Three Distinct Populations: Findings from the Roflumilast PASS Study [1168]

279. COPD Patients Initiating Roflumilast in Sweden, Germany and the United States: Findings from the Roflumilast PASS Study [1169]
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280. Treatment of Patients with Pulmonary Tuberculosis in China [1170]
Minfu He, Jian Du, Yongjing Zhang, Yuhong Liu, Liang Li. (China)

281. Discrete Event Simulation for Facilitating Between-Study Comparisons [879]
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**FRIDAY, AUGUST 26 Cont.**

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- 181 69 8:00am - 6:00pm The Forum Poster
- 182 70 8:00am - 6:00pm The Forum Poster
- 183 71 8:00am - 6:00pm The Forum Poster
- 184 72 8:00am - 6:00pm The Forum Poster
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- 186 74 8:00am - 6:00pm The Forum Poster

**Poster Session A: Burden of Disease - Other**

- 187 75 8:00am - 6:00pm The Forum Poster
- 188 76 8:00am - 6:00pm The Forum Poster
- 189 77 8:00am - 6:00pm The Forum Poster
- 190 78 8:00am - 6:00pm The Forum Poster
- 191 79 8:00am - 6:00pm The Forum Poster
- 192 80 8:00am - 6:00pm The Forum Poster
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**Poster Session A: Medical Devices**

- 206 94 8:00am - 6:00pm The Forum Poster
- 207 95 8:00am - 6:00pm The Forum Poster
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**Poster Session A: Analytical Methods**

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- 224 112 8:00am - 6:09:00pm The Forum Poster
- 225 113 8:00am - 6:00pm The Forum Poster
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**Poster Session A: Clinical Trial Methodology**

- 232 120 8:00am - 6:00pm The Forum Poster
- 233 121 8:00am - 6:00pm The Forum Poster
- 234 122 8:00am - 6:00pm The Forum Poster

**Poster Session A: Confounding/Bias**

- 235 123 8:00am - 6:00pm The Forum Poster
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- 251 139 8:00am - 6:00pm The Forum Poster

**Poster Session A: Data Linkage**

- 252 140 8:00am - 6:00pm The Forum Poster
- 253 141 8:00am - 6:00pm The Forum Poster
- 254 142 8:00am - 6:00pm The Forum Poster
- 255 143 8:00am - 6:00pm The Forum Poster
- 256 144 8:00am - 6:00pm The Forum Poster
- 257 145 8:00am - 6:00pm The Forum Poster

**Poster Session A: Measurement & Validation Methods**

- 258 146 8:00am - 6:00pm The Forum Poster
- 259 147 8:00am - 6:00pm The Forum Poster
- 260 148 8:00am - 6:00pm The Forum Poster
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- 281 169 8:00am - 6:00pm The Forum Poster
- 282 170 8:00am - 6:00pm The Forum Poster
- 283 171 8:00am - 6:00pm The Forum Poster

**Poster Session A: Study Design**

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**Poster Session A: Adherence**

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**Poster Session A: Use of Medicines - Neurological**

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**Poster Session A: Use of Medicines - Other**

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**SATURDAY, AUGUST 27**

**Psychotropics in Pregnancy**

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**Pay Attention to Pain: ADHD and Pain Treatment DUS**

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**Psychotropic Trends on Populations from a Multinational Perspective**

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**A Sticky Subject: Diabetes Safety**

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**Broken & Torn**

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**Identification and Validation of Outcomes**

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### SATURDAY, AUGUST 27 Cont.

**What's in a Code? Algorithm Validation in Drug Safety Studies**
- **Poster 478**
  - Wicklow Hall 2 Symposia

**The Epidemiological Approach to Rare Disease Research: Challenges and Opportunities**
- **Poster 479**
  - Liffey Hall 2 Symposia

**The Role of Evidence Synthesis in Drug Safety Evaluation and Regulation**
- **Poster 480**
  - Liffey Hall 1 Symposia

**A Discussion of Data Requirements and Methodologic Considerations for Evaluating the Real-World Effectiveness and Safety of Biosimilar Medicines**
- **Poster 481**
  - Liffey Meeting Room 2 Symposia

### Poster Session B: Spotlight Session-AsPEN

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### Poster Session B: Spotlight Session-BRACE

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### Poster Session B: Spotlight Session-DUR

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**Pharmacoe epidemiology and Risk Management Planning: Essential Enablers for Development of Innovative Medicines**

829  The Liffey A  Symposia

**Transitioning to ICD-10: International Lessons Learned and Strategies for Moving Forward**

830  Wicklow Hall 2  Symposia

**Who to Ask And How? Preference-Based Methods for Benefit-Risk Assessment**

831  Liffey Hall 2  Symposia

**Implications for Patients, Industry and Regulators**

832  Liffey Hall 1  Symposia

**Practice of Epidemiology in Pregnancy Studies**

833  3:15pm  The Liffey A  Oral
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**Disease Burden from Clinical Databases**

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**CV Adverse Events: Affairs of the Heart**

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**Adverse Outcomes of Glucocorticoid and Immunomodulator Use**

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**Thin Blood: Anticoagulants**

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**Is it Safe Enough?**

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**Poster Session C: Spotlight Session-Biologics**

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