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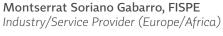
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Poster Presentations during ICPE 2020

Analysing Patient Level Data From Norwegian Registries: Challenges and Considerations

Graham S, Lambrelli D, Schultze A, **Donaldson R**, Ghanima W, Carroll R, Ulvestad M

Factors Associated with Losses to Follow-up in Pregnancy Exposure Registries Covington D, Veley K, Buus R, Churchill P

Heterogeneity of Patient Preferences for Benefits and Risks of Antiplatelet Therapies Pinto CA, Chua GN, Brookes E, Hyacinthe J, Tervonen T

How Patient Preferences Can Inform Net Clinical Benefit: A Personalized, Patient-centered, Benefit Risk Assessment Using Real-world And Clinical Trial Data Tervonen T, Prawitz T, Chua GN, Hyacinthe J, Pinto CA

Innovation and Pragmatism in Retrospective Chart Review Methodology for Post-Approval Drug Utilization Studies Saragoussi D, Rouleau A, Capart P, Deveras CC, Brett NR, Ognar R, Gazay H, Payne K

Prevalence of Outcomes in Pregnancy Registries Versus General Population Veley K, Covington D, Chan RL, Churchill P

Real-world Data Collection In Early Access Programs: An Additional Source Of Data To Inform Benefit-risk Assessment In The Pre-approval Phase Soni M, Saragoussi D, Stein D, Eckley D, Block J

Sample Size Calculations for Pregnancy Registries: Improving Accuracy Veley K, Covington D, Buus R, Chan RL, Churchill P

Trends in Post-Approval Pregnancy Safety Studies Required by the United States Food and Drug Administration, 2015-2019 Simeone JC, Nordstrom BL

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- December 2020: Online abstract submission opens. Abstracts are only accepted via the online submission site
- February 2021: Abstract submissions closes; abstracts are not accepted past this date in any form
- March 2021: ICPE Scholarship submission closes
- April 2021: Abstracts reviewed by ISPE's Scentific Program Committee
- June 2021: Acceptance notifications issued

All presenters and panelists (workshop/symposia) must register to attend 37th ICPE/Seattle.

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Throughout this program book, all times are US Eastern Daylight Time (EDT).

Programming on Wednesday, September 16 and Thursday, September 17 are live-streamed. If you are unable to attend, recordings of these sessions will be added to the meeting library after the meeting.

Wednesday,	September 16 (page 19)	Thursday, Se	ptember 17 (page 21)
9:00-9:30am	Welcome Session	8:00-9:30am	Plenary: Real-World Evidence
9:30-11:00am	Keynote Session: Drug		and COVID-19
	Regulatory Sciences and Real-	9:30-10:00am	Break
	World Evidence	10:00-11:00am	Annual Meeting of ISPE
11:00-11:30am	Break		Members & 2020 Awards
11:30am-1:00pm	11:30am-1:00pm Hot Topics Session: Medications, Weather, and Health Outcomes		Ceremony
		11:00-11:15am	Break
		11:15am-12:45pm	Plenary Session: Science Communication of Pharmacoepidemiology for Patient and Public Health
		12:45-12:50pm	Closing Remarks

Symposia/Workshops (page 40): live-streamed series starts in late September; full schedule will be published on the meeting site on September 18th.

Skills Courses (if purchased; page 26): session content is on-demand; full schedule of live Q&A events with skills course speakers will be published on the meeting site on September 18th.

On-Demand only

From September 16 through December 31, 2020, the following content is available at your convenience:

- Oral Presentations (page 42)
- Posters (page 64)
- Exhibitors



Program Schedule | Wednesday, September 16

Wednesday, September 16

9:00-9:30am Welcome Session

Tobias Gerhard, FISPE, Chair, 2020 ISPE Scientific Program Committee **Almut Winterstein, FISPE**, ISPE President

9:30-11:00am Keynote Session: Drug Regulatory Sciences and Real-World Evidence

The current drug regulatory landscape is shifting, driven by need to keep pace with scientific and technological advancements. Using science to inform regulatory decision making throughout the drug life cycle is essential. Regulatory science is essential to improve regulatory effectiveness and efficiency and to enable timely access to new therapies. Pharmacoepidemiological methods are often applied to regulatory science related questions and use of real-world evidence in decision making on medicines. Current developments of pharmacoepidemiological methods are often driven or intertwined with new needs and challenges within the drug regulatory field.

Keynote Speaker

Bert Leufkens, FISPE, Professor Pharmaceutical Policy and Regulatory Science, Utrecht Institute for Pharmaceutical Sciences

Moderator

Helga Gardarsdottir, FISPE, Associate Professor of Drug Regulatory Sciences, Utrecht University

Panelists

Break

- Susana Perez-Gutthann, FISPE, Vice President and Global Head of Epidemiology, RTI-HS
- Xavier Kurz, Head of Data Analytics, Data Analysis and Methods Task Force, EMA
- Issam Zineh, Director, Office of Clinical Pharmacology, FDA

11:00-11:30am



Program Schedule | Wednesday, September 16

11:30am-1:00pm

Hot Topics Session: Medications, Weather, and Health Outcomes

Climate change is one of the defining challenges of our time. Eight of the ten hottest years on record occurred in the past decade. Such change has profound detrimental health consequences throughout the lifespan, including both direct effects such as heatwaves, floods, or wildfires, and indirect effects, such as lack of food security, increased air pollution, and greater vulnerability to mosquito-borne diseases. Extreme temperatures and weather events also interact with medication use. Heatwaves, ambient air pollution, and other extreme weather events can act synergistically to increase adverse effects of commonly used medications through a variety of pathways. However, the interplay of medication use and climate-related extreme weather events is only beginning to be systematically examined.

Moderator

Stephen Evans, FISPE, Professor of Pharmacoepidemiology, London School of Hygiene and Tropical Medicine

Speakers

- Jeffrey Shaman, Professor, Department of Environmental Health Sciences; Director of the Climate and Health Program, Columbia University Mailman School of Public Health
- Sean Hennessy, FISPE, Professor of Epidemiology, University of Pennsylvania
- Soko Setoguchi, FISPE, Professor of Medicine and Epidemiology, Rutgers University





Program Schedule | Thursday, September 17

Thursday, September 17

8:00-9:30am

Plenary: Real-World Evidence and COVID-19

This session will be addressing large scale efforts in the US, Europe and Asia to building Real-World Evidence capacity to support development of COVID-19 treatment approaches.

Moderator:

Vincent Lo Re III, FISPE, Associate Professor of Medicine and Epidemiology, Perelman School of Medicine, the University of Pennsylvania

Speakers:

Xin Sun, Director, Center for Clinical Epidemiology and Evidence-based Medicine, West China Hospital, Sichuan University, Chengdu, China; Director, Chinese Evidence-based Medicine Center, and Cochrane China Center

The Use of Real-World Data to Support COVID-19 Prevention and Control: Experiences from China

Peter Arlett, Head of Data Analytics and Methods, European Medicines Agency, Amsterdam, the Netherlands

Collaboration Between Medicines Regulators to Increase the Impact of Real-World Evidence for COVID-19

Amy Abernethy, Principal Deputy Commissioner of Food and Drugs, US Food & Drug Administration, Department of Health and Human Services

Leveraging Real-World Data to Accelerate Evidence Generation During COVID-19

9:30-10:00am Break

Instructor-Lead Chair Yoga (15min)



Program Schedule | Thursday, September 17

10:00-11:00am

Annual Meeting of ISPE Members & 2020 Awards Ceremony

- Call to Order; President's Report. Almut Winterstein, FISPE, President
- Financial Report, Krista Huybrechts, FISPE, Vice-President/Finance
- Strategic Plan 2020-2024 presentation, Olaf Klungel, FISPE, Chair, Strategic Planning Committee
- New Business
 - Vote to correct Society name with State of New Jersey
- Awards Ceremony (see page 24 for 2020 ISPE Awards)
- ISPE Board Transition

Retiring Officers & Directors

Alison Bourke, FISPE, Immediate Past President Krista Huybrechts, FISPE, Vice-President/Finance Cynthia Girman, FISPE Michele Jonsson Funk, FISPE Deborah Layton Jasmanda HsiaoHui Wu, FISPE

Installation of New Directors

Tomoko Kobayashi, Industry/Service Provider (Asia/Pacific) Mette Nørgaard, Academic (Europe/Africa) Jeremy Rassen, FISPE, Industry/Service Provider (Americas) Montse Soriano-Gabarró, FISPE, Industry/Service Provider (Europe/Africa) Shirley Wang, Academic (Americas)

Installation of 2020-2021 Officers

Olaf Klungel, FISPE, President Vincent Lo Re III, FISPE, President-Elect Almut Winterstein, FISPE, Immediate Past President Wei Zhou, FISPE, Vice-President/Finance

11:00-11:15am

Break



Program Schedule | Thursday, September 17

11:15am-12:45pm

Plenary Session: Science Communication of Pharmacoepidemiology for Patient and Public Health

People around the globe feel threatened by multiple risks arising from technology, leading to mistrust in science, as much as hopes that science will remedy the problems. The field of medicine and pharmaceuticals is no exception and the coronavirus epidemic demonstrates this dramatically once more. Understanding science communication of pharmacoepidemiology as processes for designing research, disseminating research findings and evaluating communication outcomes impacting on patient and public health, is therefore important to every pharmacoepidemiologist, and requires a multidisciplinary approach.

Moderator: Priya Bahari

Speakers:

Priya Bahri, Principal Scientist Pharmacovigilance, EMA

Science Communication of Pharmacoepidemiology: What Is It?

Elaine Morrato, ISPE BRACE SIG Co-chair, Loyola University, Founding Dean of Parkinson School of Health Sciences and Public Health, Chicago

Science Communication of Pharmacoepidemiology: What Can Implementation Science Add?

Bert Leufkens, FISPE, Professor Pharmaceutical Policy and Regulatory Science, Utrecht Institute for Pharmaceutical Sciences, Utrecht

Communicating Pharmacoepidemiological Findings in Scientific Journals: What Makes a Journal?

François Hoÿez, Director, Information & Access to Therapies, EURODIS, Paris Comprehending Scientific Information: What is the Patient Perspective?

Odette Wegwarth, Senior Research Scientist, Max Plank Institute for Human Development, Berlin

Communication and Therapeutic Decision-Making: What Can the Cognitive Sciences Bring to Pharmacoepidemiology?

Sara ElShafie, Doctoral Candidate, Department of Integrative Biology and Museum of Paleontology, University of California, Berkeley

Engaging the Public with Science: What Can Medical Professionals Learn from Science Communication Experts?

12:45-12:50pm

Closing Remarks

2020 ISPE Awards



2020 ISPE Awards

ISPE Awards *Honorary Lifetime Fellow* Frank May, FISPE

Induction of ISPE Fellows

lan Douglas, FISPE Stanley Edlavitch, FISPE Joshua Gagne, FISPE Alicia Gilsenan, FISPE Charles Leonard, FISPE

ICPE 2020 Awards

Andrew McAfee Award

For best abstract submitted by a researcher or student/postdoc living in a developing country Risk of Fracture in Patients with Nonvalvular Atrial Fibrillation Initiating Direct Oral Anticoagulants Versus Vitamin K Antagonists Na He, Sophie Dell'Aniello, Suodi Zhai, Samy Suissa, Christel Renoux

John Snow Award

Fracture Incidence on Tenofovir Disoproxil Fumarate: A South African Cohort Analysis Johannes Mouton, Karen Cohen, Gary Maartens

Best Methods Award (student)

Electronic Medical Records Vs Insurance Claims: Comparing the Magnitude of Opioid Use Prior, During, and Following Surgery

Jessica Young, Nabarun Dasgupta, Virginia Pate, Til Sturmer, Brooke Chidgey, Michele Jonsson Funk

Best Drug Utilization Research Abstract (student)

Impact of Delays in Initiation of Adjuvant Endocrine Therapy on Survival Among Patients with Breast Cancer

Kimberley Lee, Jodi Segal, Lisa Jacobs

Sustained Service Award

Hubert Leufkens, FISPE Michael Lewis, FISPE

Kevin Lu, FISPE Christina Mack, FISPE Andrea Margulis, FISPE Hedvig Nordeng, FISPE Jeremy Rassen, FISPE

Emerging Leader Award

Juan Hincapie-Castillo

Montse Soriano-Gabarró, FISPE Douglas Steinke, FISPE Gianluca Trifirò, FISPE Ilse Truter, FISPE

Third Best Abstract (student)

Fluoroquinolone Antibiotic Exposure and Risk of Achilles Tendon Injury in Adolescents in the United States 2000-2018

Rachel Ross, Jeffrey Gerber, Mackenzie Herzog, Michele Jonsson-Funk, Alan Kinlaw

Second Best Abstract (student)

Threatened Abortion and Risk of Epilepsy, Cerebral Palsy and Attention-deficit/hyperactivity Disorder in Offspring: A Registry-based Cohort Study in Denmark Elena Dudukina, Erzsébet Horváth-Puhó, Henrik Toft Sørensen, Vera Ehrenstein

The Stanley A. Edlavitch Award (student)

Non-vitamin K Antagonist Oral Anticoagulant and Proton-pump Inhibitor Cotreatment and the Association with Upper Gastrointestinal Bleeds in Patients with Atrial Fibrillation: A Multi-database Cohort Study

Joris Komen, Anton Pottegård, Tomas Forslund, Aukje Mantel-Teeuwisse, Björn Wettermark, Maja Hellfritzsch, Jesper Hallas, Lisa Smits, Ron Herings, Paul Hjemdahl, Olaf Klungel



2020 ISPE Awards

Pharmacoepidemiology and Drug Safety Ronald D Mann Best Paper Award

For manuscripts published in Vol.28, 2019

First prize

Antidepressant Use During Pregnancy and Risk of Congenital Heart Defects: A Case-Time-Control Study Yuelian Sun, Lars Henning Pedersen, Chun Sen Wu, Irene Petersen, Henrik Toft Sørensen, Jørn Olsen

Honorable Mentions

The Devil's in the Details: Reports on Reproducibility in Pharmacoepidemiologic Studies Andrew Petrone, April DuCott, Joshua Gagne,

Sengwee Toh, Judith Maro

Causal Inference for Evaluating Prescription Opioid Abuse Using Trend-in-Trend Design

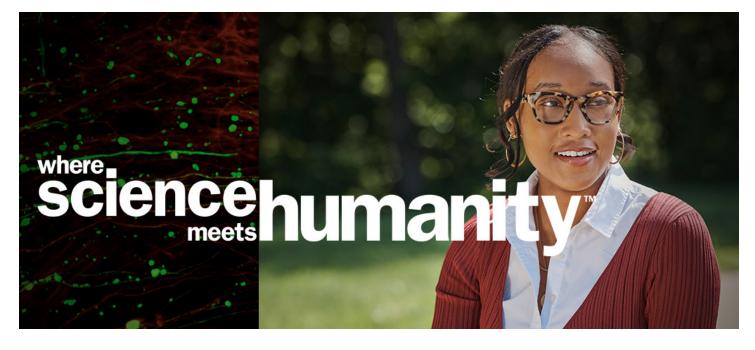
Nabarun Dasgupta, John Schwarz, Sean Hennessy, Askhan Ertefaie, Richard Dart

An Empirical Assessment of Immeasurable Time Bias in the Setting of Nested Case-Control Studies: Statins and All-Cause Mortality Among Patients with Heart Failure

In-Sun Oh, Kristian Filion, Han Eol Jeong, Ju-Young Shin

Identification of Potential Drug Name Confusion Errors in the Sentinel System

Noelle Cocoros, Kevin Haynes, Qoua Her, Austin Cosgrove, Elizabeth Dee, Nancy Lin, Chi-Ming Tu, Yulan Ding, Michael Nguyen, Sengwee Toh



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Join us for these exciting skills courses throughout the rest of the year!

This year all of the ICPE fun can't be contained in just a few days. Browse through this collection of skills courses to improve your practice and keep an eye on the website for information on scheduling.

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Principles of Pharmacoepidemiology

Speakers: **Tobias Gerhard**, Anton Pottegard, Almut Winterstein

Description: This course will provide participants with a succinct introduction to the basic principles, concepts, and study designs of pharmacoepidemiology. The course includes lectures on:

- Cohort studies
- Case-control studies
- Confounding and other sources of bias

Overview and Essential Methods of Drug Utilization Research

Speakers: **Gillian Caughey**, Doug Steinke, Lisa Pont, Bjorn Wettermark, Katja Taxis, Lisa Kalisch Ellett, Petra Denig

Description: This educational program provides an overview of drug utilization research (DUR), presenting essential methods for basic to advanced drug utilization studies. Participants will be exposed to:

- Description of the theoretical framework and practical applications of methods used in drug utilization research using selected examples
- Classification systems used in drug utilization monitoring and research

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- Benefits and potential limitations of data sources, study design and analytical methods
- Interpretation of aggregate and individualbased data, variation and change
- Using drug utilization research to improve drug use, and evaluate the effects of clinical and policy decisions on drug utilization
- Application of principles derived from Health Services and Implementation Research to the design of a clinical intervention
- Use of prescribing data and quality measures to assess prescribing

Adherence to Medication

Speakers: Jacqueline Hugtenburg, Julie Lauffenburger, Robert Gross, Job van Boven

Description: Adherence to medication is indispensable for achieving clinical goals. Nonadherence is a complex and multifactorial problem leading to poor clinical outcomes, increased morbidity and death rates, and unnecessary healthcare costs. Assessing (non-)adherence is challenging and both subjective and objective measures are applied. This course is aimed at introducing students to the various constructs of adherence behavior and techniques to evaluate (non-)adherence and data analysis. Using several examples of studies among patients using a variety of medicines, students are guided through the subsequent steps in making decisions concerning measurements and analyses of data. The influence of a variety of assumptions and decisions is shown, and students are guided through the process of data preparation and transformation needed for adherence calculations.

Advanced Pharmacoepidemiology

Speakers: **Caitlin Knox**, Andrea Marguilis, Jaclyn Bosco, Sonia Hernandez-Diaz, Matthew Reynolds, Daniel Prieto-Alhambra, Nicolle Gatto, and Jeremy Rassen

Description: This course will include pre-recorded session which participants are expected to view prior to the live virtual meeting. The course will touch on multiple pharmacoepidemiologic methods utilized in COVID research with each lecture providing the necessary overview for the attendees to apply the discussed topics to their own pandemic research.

Applied Sensitivity Analysis

Speakers: **Sebastian Schneeweiss**, Jeremy Rassen, Nicolle Gatto, Liz Garry

Description: It is widely recognized that sensitivity analyses of pharmacoepidemiology study design choices and analytic assumptions help us understand the robustness of and interpret our results. To encourage increased use of well-described techniques, this workshop will provide an introduction and demonstrations of a range of sensitivity analyses typically applied in pharmacoepidemiology with an interactive case study. The course is interactive in that participants will be able to vote on which sensitivity analyses to present during the live portion of the course.

Cancer Pharmacoepidemiology and Genomics: What You Should Know in the Era of Precision Medicine

Speakers: **Gillian Bartlett-Esquilant**, Bruce Carleton, Kelly Filipski, Andrew Freedman, Geoffrey Liu, Anton Pöttegard, Donna Rivera, Leah Sansbury, Wei Zhou

Description: This course, co-sponsored by the Molecular Epidemiology, Biomarkers, and Pharmacogenomics and Oncology SIGs, will focus on the essentials every pharmacoepidemiologist

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ICPE 2020 POSTER PRESENTATIONS

PODIUM PRESENTATION:

Characteristics of Severe Sepsis Hospitalizations and Sepsis-related Mortality in U.S. Claims

Tiffany S Woodworth, Erik Gunnarsson, Kerrin Gallagher, Lu Zhang and Joseph Menzin

POSTERS:

Machine Learning Applications Using Real-World Data: A Literature Review Nicholas Adair, Zeynep Icten, Mark Friedman and Joseph Menzin

Why Not Biosimilars: Biologic and Biosimilar Utilization Trends in Japanese RA Patients Lu Zhang, Tiffany S Woodworth and Joseph Menzin

Identifying Predictors of a Composite Cardiovascular Outcome among Diabetes Patients Using Machine Learning Zeynep Icten and Joseph Menzin

Characteristics of Patients Newly Diagnosed with Atrial Fibrillation after Ischemic Stroke Hospitalization

Lu Zhang, Anna Watzker, Tiffany S Woodworth, Mark Friedman and Joseph Menizin

Identifying Comorbidity-based Subtypes of Type 2 Diabetes: An Unsupervised Machine Learning Approach Zeynep Icten and Joseph Menzin

Impact of The ICD-10-CM Transition on Claims-based Severe Sepsis Events among US Medicare Enrollees Tiffany S Woodworth, Kerrin Gallagher, Erik Gunnarsson and Joseph Menzin





should know about study design and real-world applications of cancer personalized medicine including precision medicine, companion diagnostics, biomarkers, and the biomarker development pipeline, diagnosis and treatment coding, drug and cancer risk associations and linking databases with genomic information.

Comparative Effectiveness Research: Real-World Evidence in Health Technology Assessment

Speakers: Joshua Gagne, Sebastian Schneeweiss, Shirley Wang

Description: Comparative effectiveness research (CER) is increasingly important for generating real-world evidence to inform clinicians, patients, regulators, and other decision makers. The Prescription Drug User Fee Act reauthorization (PDUFA VI) and the 21st Century Cures Act in the US and adaptive pathways in the EU all have implications for the use of real-world evidence to inform regulatory decision making. This course will describe CER methods for generating evidence using real-world data, focusing specifically on observed biases and investigator errors that are avoidable in CER. The course will include a tutorial on creating design diagrams, which can assist in identifying biases and errors in CER studies. Participants will apply the design diagram to a real-world CER study.

Effective Risk Management: Best Practices for Designing, Implementing, and Evaluating Risk Minimization Programs

Speakers: **Elaine Morrato**, Meredith Smith, Doris Auth, Alicia Gilsenan

Description: This course presents an overview of risk management principles, with a focus on best practice methods for designing, implementing and evaluating risk minimization programs. For the 2020 ICPE, this course will consist of a 90 minute,

pre-recorded moderated session, and a follow-up, 60 minute live session. The pre-recorded session will include a didactic component which will feature presentations from experts in regulatory, industry, academia and research organizations who will present three modules on scientific frameworks, methodologies and an illustrative case application. The session will include moderated panel discussion about pragmatic considerations for effective risk minimization program design, implementation and evaluation techniques. The live session will provide an opportunity for participants to ask clarifying questions of the course faculty and to share perspectives on pragmatic applications given the regulated context of risk minimization programs.

Epidemiology of Vaccine Safety

Speakers: **Cathy Panozza**, Robert Chen, Patricia Saddier, Rebecca Chandler, Martin Kulldorff, Miriam Stukenboom, Daniel Salmon, Walter Straus, Robert T. Chen, Michael McNeil

Description: As reinforced by the current COVID-19 pandemic, vaccines are key tools for global public health. Increasingly, pharmacoepidemiological studies are providing critical evidence needed for risk-benefit assessment to inform immunization policy, both for mature immunization programs and for low-and middle-income countries (LMIC) for which innovative vaccines against challenging diseases (e.g., dengue, Ebola, malaria) are under development.

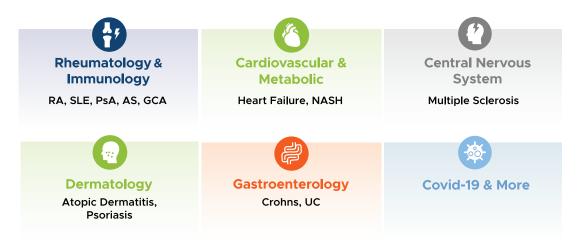
How To Collaborate Effectively With Machine Learning Experts

Speakers: Harriet Dickenson, Dorothee Bartels, Lisa Weiss, Dana Teltsch, Victoria Strauss, Stephen Schachterle, Orla Doyle, Nassim Haddad

Description: The aim of this course is to provide a helpful framework for engaging with machine learning (ML) experts through collaborative



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projects. ML methods can generate exciting and innovative types of evidence, and often pharmacoepidemiologists work in partnerships with ML experts to design and conduct analyses together.

This course will give attendees the tools to engage and work effectively with ML experts, without having to become a ML expert themselves. The course will help attendees understand what ML experts do in their day-to-day role, their core skills, and any differences in terminology used. The basic data preparation and tools required for a ML analysis will be explained, and some examples of adaptive ML analysis plans will be shared. This course will also help attendees to learn how ML experts validate their models and interpret any findings. At the end of the course, attendees will participate in a 'choose-your-own-adventure' collaboration exercise with ML experts to plan and interpret an example data set.

Intermediate Pharmacoepidemiology: Approaches to Unmeasured Confounders

Speakers: **Michele Jonsson Funk**, Jennifer Lund, Sudha Raman, Mugdha Gokhale, Til Stürmer

Description: This course will introduce students to multiple approaches to addressing unmeasured confounders through study design and analysis, the requirements and assumptions of each, and an opportunity to compare these approaches through facilitated discussion of a case study.



Introduction to Pharmacogenomics & Precision Medicine for Pharmacoepidemiologists

Speakers: **Amalia Issa**, Gillian Bartlett, Bruce Carleton, Steve Kimmel, Leah Sansbury, Anke-Hilse Maitland van der Zee

Description: This course, sponsored by the Genomics & Precision Medicine SIG will focus on the essentials every pharmacoepidemiologist should know about real world applications of pharmacogenomics epidemiology including

- the role of epidemiology in pharmacogenomics;
- definitions of genetic terms and basic genetic concepts;
- quality control and analytical procedures required in a pharmacogenetic analysis;
- step-by-step planning guide to designing a pharmacogenomic analysis;
- phenotyping considerations and breaking down examples of pharmacogenomic successes;

- databases available to study pharmacogenomics;
- designing a companion pharmacogenomic diagnostic in drug development;
- designing a prospective observational cohort or case-control study of pharmacogenomics;
- designing a clinical utility trial: a guide with examples;
- collecting health related quality of life data using an innovative role playing game.

Medical Device Epidemiology

Speakers: **Mary Beth Ritchey**, Daniel Prieto Alhambra, Theodore Lystig, Paul Coplan

Description: Over the past few years, there has been increased focus on generating realworld evidence for medical products. Thus, observational studies of medical products are gaining visibility outside of ISPE. Medical device epidemiology uses methodologies similar to those



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Source 1: What is Cancer?: Types of Cancer. National Cancer Institute, 2015 Source 2: Exascale Computing Project Funds Three CI/Argonne Projects. Computation Institute & The University of Chicago, 2016





for medicines. However, alternative strategies are often implemented due to the nature of the products, data sources, and situational use. With the changing regulatory and reimbursement environments, it is more important than ever for pharmacoepidemiologists to better understand the methods and practice of medical device epidemiology, both for study of medical devices and combination products of pharmaceuticals/ biologics with medical devices. Methods discussed will be applicable across therapeutic products and provide deeper understanding of the current regulatory and clinical context of medical device epidemiology.

Modern Pregnancy Pharmacoepidemiology: Threats to the Validity of Studies on Drug Safety in Pregnancy and Approaches to Address Them.

Speakers: **Andrea Margulis**, Brian Bateman, Krista Huybrechts

Description: In this course, faculty will present and discuss considerations related to threats to the validity of research on pregnancy pharmacoepidemiology.

The course will consist of three recorded presentations by faculty, each of them 30'-40' long, and a live 30'-60' Q&A session. This is a new format for this course, in line with all skill courses offered as a part of ICPE All Access 2020. In 2015, the course provided an overview of issues that are particular to drug safety research in pregnancy. In 2016 the course focused on challenges related to exposure measurement, in 2017 the focus was on maternal and neonatal outcomes, in 2018 the course presented pros and cons of various study designs. In 2019, the course discussed significance testing and analytical approaches to address biases. The content of the 2020 edition of this course will cover some of the main themes discussed in previous years.

The course will start with a general overview on drug safety in pregnancy, planned to provide





Connect with fellow members - join the ISPE Exchange

The ISPE Exchange is the best way to connect with members and become involved with the Society. Communities allow you to participate in discussions and share resources with other members

Ways to connect

- Join Mentor Match program
- Join Regional Interest Groups
- Join Council Groups
- Join Special Interest Groups
- Join Chapter Groups



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context to the course and to be especially useful for first-time course attendees; followed by more focused talks on unmeasured confounding, selection bias, random error and external validity.

Pediatric Pharmacoepidemiology

Speakers: **Tamar Lasky**, Daniel Horton, Steven Bird, Mehemt Burcu

Description: 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 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

Pharmacoepidemiologic Considerations for Biologics and Biosimilars

Speakers: **Jaclyn Bosco**, Thijs Giezen, Gianluca Trifirò, Rohini Hernandez

Description: This workshop will provide participants with information on the following topics:

 Background on originator biologics, biosimilars and differences from small molecules



- Naming and traceability issues for originator biologicals and biosimilars
- Interchangeability, switching, and automatic substitution from a regulatory, methodological, and clinical perspective
- Review country-specific regulatory guidelines, particularly focused on postmarketing monitoring, pharmacovigilance, and risk management requirements for biologics and biosimilars
- Conducting observational studies of originator biologics and biosimilars, including primary data collection and secondary use of data sources for evaluating patterns of use as well as comparative safety and effectiveness of biologics and biosimilars
- Special emphasis will be given to the methodological issues concerning post-marketing assessment of the interchangeability of originator biologics and corresponding biosimilars
- Impact of coronavirus on pharmacoepidemiology studies of biologics including biosimilars

Pharmacovigilance and Signal Detection

Speakers: Joshua Gagne, Andrew Bate, Gianluca Trifirò, Judy Maro

Description: This 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 briefly cover classical pharmacovigilance signal detection using spontaneous adverse event reports and then move quickly into quantitative signal detection methods for electronic medical record and claims data. Real-world examples will be used across the lecture sessions to illustrate and connect different concepts. Participants will engage in interactive discussions about contemporary issues in and challenges facing pharmacovigilance.

Pragmatic Trials: Design, Methods, and Implementation

Speakers: Jennifer Christian, Priscilla Velentgas, Cynthia Girman, Anne Trontell, Elaine Irving

Description: Pragmatic randomized clinical trials (pRCTs) require the expertise of pharmacoepidemiologists who understand considerations and methodologic challenges that arise with more "pragmatic" RCTs compared with traditional "explanatory" RCTs. This course will highlight issues such as real-world site and patient identification, enrollment and retention, ethical review issues, approach to randomization, selection bias, and defining the appropriate comparator. In addition, choice of the study design including cluster randomization, step wedge design or individual randomization, and associated analytic considerations will be highlighted. Randomizing patients to "standard of care (SOC)", accounting for changes in therapies over time, and other methodological considerations will also be discussed. Operational challenges and lessons learned from conducting pRCTs will be shared along with case examples.

Propensity Scores in Pharmacoepidemiology

Speakers: John Seeger, Jeremy Rassen

Description: 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.



Prospective Research Using Today's Technologies for Community-Driven Research

Speakers: Nancy Dreyer, Christina Mack, Nabarun Dasgupta, William Dixon

Description: This course will provide an overview of the methods and applications for studies that use primary data collection for effectiveness and safety research, without the assistance of health care providers. Examples of tools used outside of the traditional healthcare setting will be presented, along with an active discussion of what we have learned so far, with current examples from COVID, rheumatology and oncology.

Real World Evidence (RWE) generation for rare diseases drug development: data sources and innovated methods.

Speakers: Jasmanda Wu, Federica Pisa, Rima Izem, Janet Sultana, Cynthia Jones, Xabier García-Albéniz, Emily Bratton

Description: This course presents an overview of approaches to generate Real World Evidence (RWE) for Rare Diseases (RD) drug development, with a focus on identifying adequate data source/s and innovative methods. RWE generation is required at various stages of RD drug development, yet it faces specific challenges related to the very small number of patients, disease heterogeneity, disease coding, and frequent lack of treatment standards. The course will start with an overview of data sources and data collection approaches to capture relevant RD patient populations and information, describe data and methods to measure the prevalence and incidence of RD, and present methods for generating evidence to evaluate effectiveness and safety of RD drugs. These include methods based on target trial emulation, Natural History Studies and statistical methods for borrowing evidence. Course faculty will present real-world case studies to facilitate discussion.





elizabeth.lynn@dsru.org

Skills Courses



Skills Courses

Regulatory Pharmacoepidemiology

Speakers: **Gerald Dal Pan**, Danica Marinac-Dabic, Stephen Evans

Description: Medical product regulation increasingly relies on pharmacoepidemiologic analyses to assess the safety of medical products once they are marketed. This course is aimed at describing how pharmacoepidemiologic analyses are used in regulatory decision making and the challenges that regulators face when using such analyses.

Using Field Studies to Value-Add in Pharmacoepidemiology

Speakers: Veronika Wirtz, Lisa Pont, Katja Taxis

Description: 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 observations, 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.

Using Pharmacoepidemiology Database Resources to Address Drug Safety Research

Speakers: Kevin Haynes, Gillian Hall, Matthew Reynolds, Daniel Beachler, Sudha Raman

Description: Pharmacoepidemiology requires the utilization of database resources to evaluate drug safety. This course will define the different types of data resources available for pharmacoepidemiology and the selection criteria to select the most appropriate resource. The course focuses on the Guidelines for good database selection and use in pharmacoepidemiology research, provides an overview of available resources, addresses the need for outcome validation, and highlights data linkage considerations.

Weighing the Benefits & Risks: The Science and Methods of Benefit-Risk Assessment in Drug Development

Speakers: **Rebecca Noel**, Tarek Hammad, Juhaeri Jhuaeri, Brett Hauber

Description: Benefit-risk assessment is now a fundamental science for understanding and evaluating the development, approval, and continued marketing of drugs and devices. This course is aimed at introducing attendees to core concepts and tools of both the science and practice of benefit-risk assessment.

The Pharmacoepidemiologist's Toolbox for Professional Empowerment

Speakers: Caitlin A. Knox, Mary Beth Ritchey, Vincent Lo Re, III, Juan M. Hincapie-Castillo, Almut G. Winterstein, Susana Perez-Gutthann

Description: This course will include pre-recorded sessions which participants are expected to view prior to the live virtual meeting. The course will address on multiple professional development topics with each lecture providing the necessary tools for the attendees to apply the discussed principles to their own career paths.

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Symposia / Workshops

Symposia / Workshops

Benefit-Risk Assessment, Communication, and Evaluation (BRACE)

4069 **Retirement of Statistical Significance Testing Olaf Klungel,** Kenneth J Rothman, Hans

Hillege, John Fletcher. (Netherlands)

4983 Establishing Drug Safety and Effectiveness Strategies in Low and Middle Income Countries

Edward Mills, Nathan Ford, Sabin Nsanzimana. (Canada)

Drug Utilization Research » Changing Drug Utilization (interventions and implementation research)

4661 Deprescribing in Older People: Pharmacoepidemiological Tools and Measures

> **Katja Taxis,** Carina Lundby, Lisa Pont, Wade Thompson, Petra Denig, Anton Pottegård. (Netherlands)

Drug Utilization Research » Health Policy and Governance

57 Methods to Evaluate the Effects of Policy Changes During the Opioid Crisis

> **Juan M Hincapie-Castillo,** Amie J Goodin, Gerald J Dal Pan, Mina Tadrous. (United States)

Health Economics/Outcomes Research

60 Trial Participants vs. Real-world Users of Medicines - How Different are They Really and Does It Matter?

Anton Pottegård, Olaf Klungel, Daniel Morales, Mehdi Najafzadeh. (Denmark)

4850 Head to Head Comparisons of Therapies Using Real World Data: What is Needed to Emulate Target Trials?

> **Miguel Hernan,** Thomas Wilke, Edward J Mills, Sonal Singh. (Canada)

Informatics

2636 Will Data Privacy and Confidentiality Squeeze out Research?

Alison Bourke, David Miller, Amanda Culley, Georgina Bourke. (United Kingdom)

3730 "That Tablet Made Me Sick as a Dog (MedDRA PT: Nausea)"

> **William G Dixon,** Nabarun Dasgupta, Andrew Bate, Niklas Noren, Florence van Hunsel. (United Kingdom)

Methods in Pharmacoepidemiology » Analytical Methods - e.g., marginal structural models, instrumental variables, sensitivity analyses

4384 Use of External Data in Pharmacoepidemiology

Til Stürmer, Michele Jonsson Funk, Olaf Klungel, Kaatje Bollaerts. (United States)

Methods in Pharmacoepidemiology » Clinical Trial Methodology - Including pragmatic trials, cluster/sub-analyses of RCTs

4841 Lesssons Learned from Replicating Clinical Trials with Real-World Data

Solomon Iyasu, David Martin, Sebastian Schneeweiss, William Crown, Thomas Jemielita. (United States)

Methods in Pharmacoepidemiology » Confounding/Bias - Methods to avoid bias and confounding, including confounder summary scores (e.g., propensity scores, disease risk scores)

2631 Increasing the Credibility of Real World Evidence: Identifying and Reducing Bias Using Negative Controls

Alexander Breskin, Matthew Maciejewski, Leah McGrath, Vera Ehrenstein, Brian Bradbury, Gianmario Candore. (United States)



Symposia / Workshops

4395 Machine Learning to Optimize and Automate Confounding Control in Studies Using High-Dimensional Healthcare Data

Xuerong Wen, Mark van der Laan, Richard Wyss, Robert W. Platt, Romin Pajouheshnia, Sebastian Schneeweiss. (United States)

Methods in Pharmacoepidemiology » Measurement Methods - Validation methods to confirm data (including Patient Reported Outcomes development and validation); Methods to deal with missing data

4910 Harmonizing Fit for Purpose Assessment of Datasources, the Next Step Towards Creation of Credible Real-World Evidence

> **Miriam C Sturkenboom,** Jeff Brown, Robert Ball, Caitlin Dodd, Peter Arlett, Rosa Gini. (Netherlands)

Methods in Pharmacoepidemiology » Study Design - Studies assessing study design (e.g., choice of comparator, self-controlled methods, avoiding immortal time bias)

2658 When Decisions Can't Wait: Delivering Rapid Real World Studies

Xavier Kurz, Simone Pinheiro, Sabine Straus, Marcel Kwa, Peter Rijnbeek, Katia Verhamme, Judith Maro. (Netherlands) 3733 Drug-Drug Interaction Research: Twice the Fun (or More!)

Katsiaryna Bykov, Charles E. Leonard, Anton Pottegård, Meijia Zhou, Sean Hennessy. (United States)

4118 ISPE RWE Task Force: Current Status and Future Directions

> **Wei Zhou,** Almut Winterstein, Shirley Wang, Mehmet Burcu, Mary E Ritchey, Helga Gardarsdottir. (United States)

4905 Visual Space: Using Visualization in Pharmacoepidemiology to Design and Disseminate Valid Real-World Evidence in a Structured Framework

Jeremy A Rassen, Shirley V Wang, Nicolle M Gatto, M. Alan Brookhart. (United States)

Mid-Year Workshops

MY01 At the intersection of frailty and pharmacoepidemiology: Foundations, applications, and future directions

> **Todd Manini,** Daniela Moga, Andrew Zullo, Jennifer Lund





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Benefit-Risk Assessment, Communication, and Evaluation (BRACE)

4069 Retirement of Statistical Significance Testing

> **Olaf Klungel,** Kenneth J Rothman, Hans Hillege, John Fletcher. (Netherlands)

2627 Association Between Dose and Duration Patterns of Opioid and Benzodiazepine Use and Risk of Overdose Among U.S. Medicare Beneficiaries: A Group-based Multi-Trajectory Model

> Weihsuan Jenny Lo-Ciganic, Ting Wang, Yong Ge, Bobby Jones, James Huang, Gary Reisfield, Jeanne Lee, C. Kent Kwoh, Juan Hincapie-Castillo, P. Chris Delcher, Ching-Yuan Chang, Debbie Wilson, Walid Gellad. (United States)

3736 Comparative Risk Assessment of Severe Abnormal Uterine Bleeding Associated with Non-vitamin K Oral Anticoagulants

> **Efe Eworuke,** Laura Hou, Rongmei Zhang, Hui-Lee Wong, Peter Waldron, Abby Andersen, Audrey Gassman, David Moeny, Ting-Ying Huang. (United States)

3739 Risk of Neuropsychiatric Adverse Events Among Montelukast Users

> **Efe Eworuke,** Nicole Haug, Andrew Mosholder, Noelle Cocoros, Marie Bradley, Dinci Pennap, Elizabeth C Dee, Sengwee Toh, Ella Prestine, Andrew Petrone, Ivone Kim, Yong Ma, Jennifer G. Lyons, Veronica V Sansing. (United States)

3826 Risk of Non-melanoma Skin Cancer Associated with Hydrochlorothiazidecontaining Products in the United States

> **Efe Eworuke,** Nicole Haug, Marie Bradley, Austin Cosgrove, Elizabeth C Dee, Sruthi Adimadhyam, Hana Lee, Tiffany Woodworth, Sengwee Toh. (United States)

4187 Pregnancy Outcomes Among Women Exposed to Potentially Harmful Drugs

> **Thuy Thai,** Amir Sarayani, Yasser Albogami, Xi Wang, Sabina Nduaguba, Preya Patel, Almut Winterstein. (United States)

5070 A Comprehensive Analysis of the Characteristics of External Control Arms in Approved Oncology Therapies

Caitlin Knox, Cherise Wong, Lewis Raynor, Asieh Golozar. (United States)

Biologics/Biosimilars

2511 Infliximab Use in the Netherlands: Uptake and Characteristics of Originator and Biosimilars Over Time

> **Jetty A. Overbeek,** Josephina G. Kuiper, Marina Bakker, B.J.F. (Bart) van den Bemt, Ron M. Herings. (Netherlands)

3900 Persistence in Rheumatoid Arthritis Patients on Biosimilar and Bio-originator Etanercept a Pooled Analysis of Pan-Canadian Cohorts

> **Cristiano S Moura,** Denis Choquette, Louis Coupal, Orit Schieir, Vivian Bykerk, Marie-France Valois, Gilles Boire, Walter P. Maksymowych. (Canada)

4544 Risk of Preterm Delivery and Small for Gestational Age Among Women with Inflammatory Bowel Disease Using TNF Alpha Inhibitors During Pregnancy

> **Xi Wang,** Ellen Zimmerman, Joshua Brown, Amie J Goodin, Almut Winterstein. (United States)

4750 Dupilumab and the Risk of Conjunctivitis and Serious Infection in Patients with Atopic Dermatitis: A Propensity Scorematched Cohort Study

> **Maria Schneeweiss,** Seoyoung Kim, Sebastian Schneeweiss, Joseph Merola. (United States)

4853 Agreement Between Electronic Health Record and Medical Claims Data for Defining Exposure to Infused Biologic Treatments in Inflammatory Bowel Disease

Carrie Huisingh, Lani R Wegrzyn. (United States)





5141 Tumor Necrosis Factor Alpha-inhibitor (TNFα-I) Use and Hip Fracture in United States (US) Veterans with Rheumatoid Arthritis (RA)

> **Sarah Homann,** Carlos Grijalva, S. Bobo Tanner, James Morrow. (United States)

Disease Epidemiology/Clinical Course » Cancer

2572 Risk and Prognosis of Cancer After Acute Kidney Injury

> **Christian Fynbo Christiansen,** Dóra K Farkas, Jon P Fryzek, Paola Romagnani, Mette Nørgaard, Kenneth J Rothman, Henrik Toft Sørensen. (Denmark)

2648 The Risk of Late Breast Cancer Recurrence in Denmark During 17 Years of Follow-up

> **Rikke Nørgaard Pedersen,** Buket Öztürk, Lene Mellemkjær, Søren Friis, Bent Ejlertsen, Timothy L. Lash, Mette Nørgaard, Deirdre Cronin-Fenton. (Denmark)

2653 Improving Predictive Ability of Survival Models: Comparison of Multiple State of the Art Models

> **Hugo Loureiro,** Tim Becker, Anna Bauer-Mehren, Narges Ahmidi, Janick Weberpals. (Germany)

3993 Risks of Squamous Cell Carcinoma of the Lip and Cutaneous Melanoma in Older Australians Using Hydrochlorothiazide (HCTZ)

> **Benjamin Daniels,** Sallie-Anne Pearson, Claire M Vajdic, Anton Pottegard, Nicholas A Buckley, Nicholas A Buckley, Helga Zoega. (Australia)

4067 Mortality After Late Breast Cancer Recurrence in Denmark

> **Rikke Pedersen,** Lene Mellemkjær, Søren Friis, Bent Ejlertsen, Mette Nørgaard, Deirdre Cronin-Fenton. (Denmark)



4102 Adverse Mental Health Outcomes in Women with a History of Breast Cancer: A Matched Population-based Cohort Study in the United Kingdom (1988-2018)

> **Helena Carreira,** Rachael Williams, Garth Funston, Susannah Stanway, Krishnan Bhaskaran. (United Kingdom)

4253 Parity, Use of Statins and Breast Cancer Risk in a Danish Population-based Cohort

Agnès Fournier, Aurélie Mailhac, Bianka Darvalics, Henrik T. Sørensen, Marc J. Gunter, Deirdre Cronin-Fenton. (Denmark)

4934 Hydrochlorothiazide and Risk of Melanoma Subtypes

> **Laurel A Habel,** Ninah Achacoso, Bruce Fireman, Sidsel Arnspang Pedersen, Anton Pottegard. (United States)

5054 Site-specific Cancer Risk from Exposure to Cobalt Alloys in Orthopedic Implants or Cobalt in Occupational Settings: A Systematic Review and Meta-analysis

> **Chantal Holy,** Shumin Zhang, Laura Perkins, Laurence B Katz, Jason Brown, Luca Orlandini, Gion Fessel, Behrooz Nasseri-Aghbosh, Gary Eichenbaum, Natalie S. Egnot, Paul M Coplan. (United States)

Disease Epidemiology/Clinical Course » Cardiovascular

2564 Transatlantic Differences in Healthcare Systems Captured by Large Administrative Databases: Assessing the Burden of COPD in Patients Admitted for Heart Failure

> **Claudia Gulea,** Rosita Zakeri, Jennifer K Quint. (United Kingdom)

4013 Cumulative Exposure to Bisphosphonates and Risk of Cardiovascular and Cerebrovascular Events

> **Elena Olmastroni,** Manuela Casula, Federica Galimberti, Elena Tragni, Giovanni Corrao, Lorenza Scotti, Alberico L. Catapano. (Italy)

4017 Apolipoprotein B and Risk of Cardiovascular Disease: A Meta-analysis of Randomized Controlled Trials

> **Federica Galimberti,** Alberico L Catapano, Julius L Katzmann, Arjen J Cupido, Brian A Ference. (Italy)

4022 Evaluation of the Effect of Omega-3 Polyunsaturated Fatty Acids Supplementation on Cardiovascular Outcomes: An Updated Meta-analysis of Randomized Controlled Trials

> **Elena Olmastroni,** Manuela Casula, Marta Gazzotti, Federica Galimberti, Elena Tragni, Alberto Zambon, Alberico L. Catapano. (Italy)

4767 Metabolic Surgery and Cardiovascular Benefits: The Consequence of Information Bias in a Real-world Evidence Study

William Murk, Jeremy Rassen, Sebastian Schneeweiss. (United States)

Disease Epidemiology/Clinical Course » Diabetes

2533 Differential Risk of Parkinsons Disease According to Diabetes Treatments: A Cohort Study

Ruth Brauer, Li Wei, Tiantian Ma, Dilan Athauda, Christine Girges, Nirosen Vijiaratnam, Grace Auld, Cate Whittlesea, Ian Wong, Thomas Foltynie. (United Kingdom)

3694 Metabolic Factors and Lifestyle Habits Associated with Prevalence of Polyneuropathy in Early Type 2 Diabetes: A Cross-sectional Study of 5,249 Patients in the Danish DD2 Cohort

> **Diana H Christensen,** Søren T Knudsen, Sandra S Gylfadottir, Lotte B Christensen, Jens S Nielsen, Henning Beck-Nielsen, Henrik T Sørensen, Henning Andersen, Brian C Callaghan, Eva L Feldman, Nanna B Finnerup, Troels S Jensen, Reimar W Thomsen. (Denmark)





4986 Characterizing Trajectories of HbA1c Control and Associations with Vascular Outcomes in Adults with Type 2 Diabetes

> **Rohini Mathur,** Christopher Rentsch, Sophie V Eastwood, Nish Chaturvedi, Jessica Franklin, Niteesh Choudhry, Ian Douglas, Liam Smeeth. (United Kingdom)

Disease Epidemiology/Clinical Course » Neurological/Mental Health

2501 Threatened Abortion and Risk of Epilepsy, Cerebral Palsy and Attentiondeficit/hyperactivity Disorder in Offspring: A Registry-based Cohort Study in Denmark

> **Elena Dudukina,** Erzsébet Horváth-Puhó, Henrik Toft Sørensen, Vera Ehrenstein. (Denmark)

Disease Epidemiology/Clinical Course »Other

2561 40-year Mortality Among Patients Hospital-diagnosed with Overweight or Obesity

> **Sigrid B Gribsholt,** Dóra K Farkas, Reimar W Thomsen, Bjørn Richelsen, Henrik T Sørensen. (Denmark)

3722 Identifying Adenomyosis and Undiagnosed Adenomyosis within Natural Language Processed Clinical Notes of an Electronic Health Record Database

> **Anita M. Loughlin,** Gally Reznor, Michael Doherty, Stacey A Missmer, Stephanie E Chiuve, Cheryl Enger. (United States)

Drug Effectiveness

105 Effectiveness of Proton Pump Inhibitors in Idiopathic Pulmonary Fibrosis: A Population-based Cohort Study

> **Tanja Tran,** Deborah Assayag, Pierre Ernst, Samy Suissa. (Canada)

2353 Impact of Maternal Depression During Pregnancy and Its Treatment Options on Fetal Health: A Prospective Cohort Study of 84,000 Pregnant Women

> **De-Kun Li,** Jeannette R Ferber, Roxana Odouli, Charles Quesenberry, Lyndsay A Avalos, Mason Turner, Tracy Flanagan. (United States)

2437 Sodium-glucose Cotransporter-2 Inhibitors and the Risk of Gout - A Danish Nationwide Symmetry Analysis and Active Comparator New User Cohort Study

> **Lars Christian Lund,** Kasper Kristensen, Jesper Hallas, Daniel P Henriksen. (Denmark)

2453 Sodium-glucose Cotransporter-2 Inhibitors and Risk of Urolithiasis in Patients with Type 2 Diabetes. A Population-based Active Comparator New User Cohort Study

> **Kasper Bruun Kristensen,** Daniel Pilsgaard Henriksen, Jesper Hallas, Lars Christian Lund. (Denmark)

2500 Comparative Effectiveness and Safety of SGLT2 Inhibitors vs. GLP-1 Receptor Agonists Among Real-world Older Adult

> **Elisabetta Patorno,** Ajinkya Pawar, Lily G Bessette, Dae H Kim, Chintan Dave, Robert J Glynn, Medha N Munshi, Sebastian Schneeweiss, Deborah J Wexler, Seoyoung C Kim. (United States)

3798 Risk of Cardiovascular Outcomes Following Addition of SGLT2 Inhibitors versus Sulfonylureas to Baseline GLP-IRA Therapy

> **Chintan Dave,** Seoyoung Kim, Allison Goldfine, Robert Glynn, Angela Tong, Elisabetta Patorno. (United States)

3810 Transporting Treatment Effects from Clinical Trials to Clinical Practice Using a Hybrid Study Approach: The Case of Adjuvant FOLFOX versus 5FU for Colon Cancer Treatment

> **Jennifer L Lund,** Michael A Webster-Clark, Alexander P Keil, Daniel Westreich, Til Sturmer, Hanna K Sanoff. (United States)

3814 Use of Sodium-glucose Co-transporter-2 Inhibitors, Changes in Body Mass Index and Risk of Fracture. The Clinical Practice Research Datalink Gold

> **Frank de Vries,** Annemariek Driessen, Andrea Burden, Martijn Brouwers, Peter Vestergaard, Joop van den Bergh, Richard Eastell, Judith van Dalem. (Netherlands)



3956 Comparative Treatment Effectiveness of Oral Fingolimod and Injectable Disease Modifying Agents in Multiple Sclerosis

> **Jagadeswara Rao Earla,** George Joseph Hutton, J. Douglas Thornton, Hua Chen, Michael L Johnson, Rajender R Aparasu. (United States)

3980 Cohort Selection in Registry-based Studies of Direct Oral Anticoagulant Users with Atrial Fibrillation: An Inevitable Trade-off Between Selection Bias and Misclassification

> **Maja Hellfritzsch,** Erik L Grove, Lotte Rasmussen, Simone B Haastrup, Anton Pottegård. (Denmark)

4041 Cardiovascular Effectiveness of Empagliflozin Compared to DPP4 Inhibitors and to GLP1 Receptor Agonists: Interim Analysis from the Empagliflozin Comparative Effectiveness and Safety (EMPRISE) Study

> **Elisabetta Patorno,** Ajinkya Pawar, Jessica Franklin, Mehdi Najafzadeh, Deborah Wexler, Anouk Déruaz-Luyet, Kimberly Brodovicz, Lily Bessette, Sebastian Schneeweiss. (United States)

4063 Statins and Risk of Diverticular Disease: Nested Case-control Study in Denmark

Nils Skajaa, Frederikke Schønfeldt Troelsen, Ola Ekholm, Lars Pedersen, Rune Erichsen, Henrik Toft Sørensen. (Denmark)

4091 Outcomes in Patients Receiving Nintedanib or Pirfenidone for Idiopathic Pulmonary Fibrosis

> **Vincent Cottin,** Paolo Spagnolo, Philippe Bonniaud, Maeva Nolin, Faustine Dalon, Jenny Chia, Klaus Kirchgässler, Tripthi Kamath, Eric Van Ganse, Manon Belhassen. (France)

4100 Comparative Effectiveness of Ovulation Induction Medications: Evidence from a Large Healthcare Database in the United States

> **Jennifer J Yland,** Yu-Han Chiu, Sean McGrath, Sonia Hernández-Díaz. (United States)

4129 SGLT2 Inhibitors and the Risk of Major Adverse Cardiovascular Events: A Multidatabase Study Using a Prevalent Newuser Design

> **Kristian B. Filion,** Lisa M. Lix, Oriana H.Y. Yu, Sophie Dell'Aniello, Antonios Douros, Baiju R. Shah, Audray St-Jean, Anat Fisher, Eric Tremblay, Shawn C. Bugden, Silvia Alessi-Severini, Paul E. Ronksley, Nianping Hu, Colin R. Dormuth, Pierre Ernst, Samy Suissa, and the CNODES Investigators. (Canada)

4230 Comparison of Effectiveness and Safety Between Glecaprevir/pibrentasvir and Sofosbuvir/velpatasvir in Patients with Chronic Hepatitis C - A Multiinstitutional Cohort Study in Taiwan

> **Mu-Hsuan Hou,** Shih-Chieh Shao, Hui-Yu Chen, Yuk-Ying Chan, Edward Chia-Cheng Lai. (Taiwan)

4602 Non-vitamin K Antagonist Oral Anticoagulant and Proton-pump Inhibitor Cotreatment and the Association with Upper Gastrointestinal Bleeds in Patients with Atrial Fibrillation: A Multi-database Cohort Study

> Joris Komen, Anton Pottegård, Tomas Forslund, Aukje Mantel - Teeuwisse, Björn Wettermark, Maja Hellfritzsch, Jesper Hallas, Lisa Smits, Ron Herings, Paul Hjemdahl, Olaf Klungel. (Netherlands)

4641 No Added Benefit of Benzodiazepines to Antidepressant Monotherapy on Mortality in Patients with Depression

> **Han Eol Jeong,** Woo Jung Kim, In-Sun Oh, Ha-Lim Jeon, Ju-Young Shin. (Korea, Republic of)

4758 Real-world Short- and Long-term Effects of Antibiotic Treatment of Acute Copd Exacerbations in Outpatients: A Cohort Study under the Pharmlines Initiative

> **Yuanyuan Wang,** Victor Pera, H. Marike Boezen, Jan-Willem C. Alffenaar, Bob Wilffert, Rolf H. Groenwold, Eelko Hak. (Netherlands)





4996	Safety and Effectiveness of Medical
	Cannabis in the Real-world: Results of
	the Quebec Cannabis Registry

Yola Moride, Michelle Canac-Marquis, Rihab Gamaoun, Pierre Beaulieu, Andrée Néron, Marc O. Martel, Jordi Perez, Julie Desroches, Maja Kalaba, Marc Ware, Antonio Vigano. (Canada)

5105 Comparing Cardiovascular Benefits of Sodium Glucose Cotransporter-2 Inhibitors and Glucagon-like Peptide-1 Receptor Agonists in Older Adults with Diabetes

> **Phyo Htoo,** John Buse, Tiansheng Wang, Virginia Pate, Matthew Crowley, Til Stürmer. (United States)

5109 Dementia and Effectiveness and Safety of Apixaban versus Warfarin and Other Direct Oral Anticoagulants in Older Adults with Atrial Fibrillation

> **Kueiyu Joshua Lin,** Sebastian Schneeweiss, Ajinkya Pawar, Dae Hyun Kim. (United States)

5121 Safety and Effectiveness of Extended Treatment with Oral Anticoagulants in Patients with Venous Thromboembolism

> **Ajinkya Pawar,** Katsiaryna Bykov, Chandrasekar Gopalakrishnan, Geetha Iyer, Helen Tesfaye, Kristyn Chin, Joshua J Gagne. (United States)

Drug Utilization Research » Changing Drug Utilization (interventions and implementation research)

2364 Changes in Sales of Over-thecounter and Prescription Medicines After Rescheduling of Codeine to a Prescription-only Medicine in Australia

> **Andrea L Schaffer,** Rose Cairns, Jared A Brown, Natasa Gisev, Nicholas A Buckley, Sallie-Anne Pearson. (Australia)

4794 Association Between Digoxin Use and SCD in Individuals with the rs10494366 Variant of the NOS1AP Gene: The Rotterdam Study

> **Negin Soroush,** Albert-Jan Aarnoudse, Fereshteh Shokri, Marten Van den Berg, Fariba Ahmadizar, Bruno Stricker. (Netherlands)

4868 Impact of the Food and Drug Administration Safety Warnings and Removal of Indications for Use of Oral Quinolones

> **Phuong T Tran,** Patrick J Antonelli, Juan M Hincapie-Castillo, Almut G Winterstein. (United States)

5001 Utilization of Oral Anticoagulants in Patients with Venous Thromboembolism

Geetha Iyer, Ajinkya Pawar, Chandrasekar Gopalakrishnan, Helen Tesfaye, Kristyn Chin, Joshua J Gagne, Katsiaryna Bykov. (United States)

Drug Utilization Research »Health Policy and Governance

2575 **Program Churn Among Children Enrolled** in North Carolina Medicaid

Alexander Breskin, Rushina Cholera, David Anderson, Suzanne Landi, Aaron McKethan, Charlene Wong. (United States)

2577 Utilization of Hydroxyprogesterone During the Second and/or Third Trimester Among Pregnancies with Live Birth Deliveries in the Sentinel Distributed Database

> **Huei-Ting Tsai,** Mayura Shinde, Austin Cosgrove, Jie Li, Christina Chang, Christine Nguyen, Corinne Woods, Joy Kolonoski, Tiffany Woodworth, David Moeny. (United States)

2634 Estimating the Impact of Prescribing Limits on Prolonged Opioid Use Following Surgery

> **Jessica C Young,** Nabarun Dasgupta, Virginia Pate, Til Sturmer, Brooke A Chidgey, Michele Jonsson Funk. (United States)



2688 Impact of Hydrocodone Rescheduling on Opioid Prescribing by Dentists in the United States, 2012-2017

Connie H Yan, Colin Hubbard, Gregory S Calip, Lisa K Sharp, Charlesnika T Evans, Susan Rowan, Jessina C McGregor, Allen Campbell, Walid F Gellad, Katie J Suda. (United States)

4595 Hormone Replacement Therapy (HRT) and Risk of Breast Cancer: Nested Casecontrol Studies Using QResearch and Clinical Practice Research Datalink (CPRD)

> **Yana Vinogradova,** Carol Coupland, Julia Hippisley-Cox. (United Kingdom)

Drug Utilization Research » Other

2495 Older Adults with Colorectal Cancer Receive Higher Opioid Dose

> **Sean P Fleming,** Tham T Le, Julia F Slejko. (United States)

4034 The One Percent: Screening Danish Nationwide Drug Utilisation Data for Patterns of Misuse

Lars Christian Lund, Mette Reilev, Anton Pottegård, Jesper Hallas. (Denmark)

4351 Prediction of COPD Treatment Nonadherence Using Real World Medicare Data

> **Tham T Le,** Danya M Qato, Margrét Bjarnadóttir, Larry Magder, Zafar Zafari, Linda Simoni-Wastila. (United States)

4360 Personalized Comparisons of Flare Rates After Hydroxychloroquine Tapering or Discontinuation in Systemic Lupus

> **Celline C Almeida-Brasil,** Christian A Pineau, Evelyne Vinet, John G Hanly, Christine A Peschken, Ann E Clarke, Paul R Fortin, Michal Abrahamowicz, Sasha Bernatsky. (Canada)

Drug Utilization Research » Quality Use of Medicines (including indicators and guidelines)

2471 The Association Between Adherence to Multiple Chronic Medications and Healthcare Utilisation in Older Community Dwelling Adults with Multimorbidity

> **Caroline A Walsh,** Caitriona Cahir, Kathleen E Bennett. (Ireland)

2532 Impact of Delays in Initiation of Adjuvant Endocrine Therapy on Survival Among Patients with Breast Cancer

Kimberley Lee, Jodi Segal, Lisa Jacobs. (United States)

2585 Longitudinal Cumulative Dose: A Novel Measure to Evaluate Multiple Dimensions of Chemotherapy Adherence Over Time

> **Michael A Webster-Clark,** Alexander Keil, Hanna K Sanoff, Til Stürmer, Daniel Westreich, Jennifer L Lund. (United States)

4779 Real-world Therapeutic Management of Stroke Survivors with Atrial Fibrillation, Predictors, and Clinical Outcomes. A Population-based Cohort

> **Clara Liliana Rodríguez-Bernal,** Daniel Bejarano-Quisoboni, Isabel Hurtado, Anibal Garcia-Sempere, Salvador Peiró, Gabriel Sanfelix-Gimeno. (Spain)

4840 Prevalence and Predictors of Potential Drug-drug Interactions in an Older Community-based Population

> John Hughes, Kathleen Bennett, Veronica Russo, Caroline Walsh, Enrica Menditto, Caitriona Cahir. (Ireland)

5133 Are Patients Less Likely to Adhere to Antidepressant Treatment If They are Not Satisfied with Their Provider?

> **Macarius Donneyong,** Teng-Jen Chang, John Bridges, Olivia Okereke. (United States)



Drug Utilization Research » Trends and Comparisons

113 Spatial Distribution of Deprivation Driven Inequalities in Opioid Prescribing in English Primary Care: A Crosssectional Analysis

> **Magdalena Nowakowska,** Salwa Zghebi, Rosa Parisi, Li-Chia Chen, Darren M Ashcroft, Evangelos Kontopantelis. (United Kingdom)

2427 Frequency of Opioid Dispensing After Surgical Abortion in the United States

> **Liza R Gibbs,** Julia A Pisc, Kari P Braaten, Brian T Bateman, Elizabeth M Garry. (United States)

2548 Predicting Persistent High-dose Opioid Use After Total Knee Replacement

> **Chandrasekar Gopalakrishnan,** Jessica M Franklin, Yinzhu Jin, Daniel H Solomon, Jeffrey N Katz, Yvonne C Lee, Patricia D Franklin, Joyce Lii, Rishi J Desai, Seoyoung C Kim. (United States)

2633 Trends in Oral Anticoagulant Coprescription with Antiepileptic Drugs Among Adults with Epilepsy, 2010-2018

Emily K. Acton, Allison W. Willis, Michael A. Gelfand, Sean Hennessy, John R. Pollard, Scott E. Kasner. (United States)

2667 Drug Utilization for Symptom Management by Patients with Multiple Sclerosis by Phenotype in Germany

Denise Oleske, Lou Barbato, Bruce Barger. (United States)

2672 Factors Associated with Concurrent Use of Prescription Opioids and Benzodiazepines: A Population-based Assessment

> **Erin Y Liu,** Robyn Tamblyn, Kristian B. Filion, David L. Buckeridge. (Canada)

3787 Antidiabetic Medication Use in Children and Adolescents from 2004 to 2019: Real World Data from a Commercially Insured Population in the United States

> **Jenny W Sun,** Sonia Hernández-Díaz, Florence T Bourgeois, Sebastien Haneuse, Brian T Bateman, Elisabetta Patorno, Krista F Huybrechts. (United States)

3799 Use of Levothyroxine for the Treatment of Subclinical Hypothyroidism Among Pregnant Women in the United Kingdom: A Population-based Assessment

> **Ya-Hui Yu,** Sonia M Grandi, Robert W Platt, Oriana H Yu, Kristian B Filion. (Canada)

4334 Applicability of Renal Outcome Trials of Canagliflozin to the Real World: Implications from Comparisons of Characteristics Between Trial Patients and Real-life Patients

> **Ling-Chen Hsu,** Kai-Cheng Chang, Shih-Chieh Shao, Hui-Yu Chen, Yuk-Ying Chan, Edward Chia-Cheng Lai. (Taiwan)

4402 Characterizing Real-world Patterns of Early Childhood Vaccination

Anne M. Butler, Jason G. Newland, John M. Sahrmann, Caroline A. O'Neil, Sena Sayood, Leah J. McGrath. (United States)

4451 Recent Trends in First-line Glucoselowering Treatment Choice for Type 2 Diabetes in Younger and Older Adults in the U.S.

Hojin Shin, Sebastian Schneeweiss, Robert Glynn, Elisabetta Patorno. (United States)

4553 Sex Differences in Patterns of Systemic Agents' Use Among Individuals with Psoriasis

Raymond Milan, Jacques LeLorier, Ivan Litvinov, Elham Rahme. (Canada)

5000 Trends in Gabapentin Utilization in the United States, 2004-2016

Abisola Olopoenia, Sean Fleming, Linda Simoni-Wastila. (United States)





5023 Melatonin Use Among Children, Adolescents and Young Adults: A Scandinavian Drug Utilization Study

Rikke Wesselhoeft, Peter B. Jensen, Poul Jennum, Svetlana Skurtveit, Randi Selmer, Ingeborg Hartz, Lotte Rasmussen, Johan Reutfors, Lena Brandt, Lene A. Mølstrøm, Mette Bliddal, Anton Pottegård. (Denmark)

5098 Dupilumab Treatment Trends Among Patients with Atopic Dermatitis

Maria Schneeweiss, Sebastian Schneeweiss. (United States)

Geriatric Pharmacoepidemiology

55 Oral Anticoagulants and Risk of Acute Liver Injury in Patients with Nonvalvular Atrial Fibrillation: A Propensity-weighted Nationwide Cohort Study

> **Géric Maura,** Marc Bardou, Cécile Billionnet, Alain Weill, Jérôme Drouin, Anke Neumann. (France)

2652 Identifying Frequent Drug Combinations Associated with Delirium in Older Adults: Application of Association Rules Method to A Case-time-control Design

Prasad Nishtala, Te-yuan Chyou. (United Kingdom)

4060 Longitudinal Trajectories of Frailty in Older Populations: Latent Curve Models and Mortality

> **Victoria Y Strauss,** Danielle E Robinson, Antonella Delmestri, Daniel Prieto-Alhambra, Alan Silman. (United Kingdom)

4237 **"I Simply Don't Know Because I Don't** Know Which Drugs I Get": A Qualitative Study of Perspectives on Deprescribing Among Nursing Home Residents and Their Relatives

> **Carina Lundby,** Trine Graabæk, Jesper Ryg, Jens Søndergaard, Anton Pottegård, Dorthe Susanne Nielsen. (Denmark)

4678 Network Analysis of Interacting Medication Use in Elderly Persons in Norway

> **Mohsen Askar,** Kristian Svendsen. (Norway)

Health Economics/Outcomes Research

3783 Policy Options for Improving Insulin Affordability

> **Stacie B Dusetzina,** Laura Keohane, Haiden Huskamp, Nancy Keating. (United States)



3785 Medicare Part D Plan Coverage of Brandname Drugs When Generics are Available

Stacie B Dusetzina, Juliette Cubanski, Leonce Nshuti, Sarah True, Jack Hoadley, Andrew Roberts, Tricia Neuman. (United States)

4119 Patient, Provider and Formulary Characteristics Associated with Initiation of a SGLT2i or GLP-1RA Among Medicare Beneficiaries with Type 2 Diabetes: A Retrospective Cohort Study

Jing Luo, Inmaculada Hernandez, Joseph Gabriel, Walid Gellad. (United States)

4121 Coverage, Formulary Restrictions and Average Retail Prices of SGLT2 Inhibitors and GLP-1 Receptor Agonists Across Medicare Part D Plans in 2019

> **Jing Luo,** Robert Feldman, Scott Rothenberger, Walid Gellad. (United States)

4146 Cost-Effectiveness of Taxane/platinum and Doxorubicin/platinum Combination Therapies in Adjuvant Treatment of Endometrial Cancer

Swetha Srinivasan, Joehl T Nguyen, Megan C Roberts. (United States)

4242 Effect Modifications on Risk of Hospitalization Due to Heart Failure in Type 2 Diabetes Patients Receiving Dapagliflozin versus Empagliflozin

> **Shih-Chieh Shao,** Kai-Cheng Chang, Hui-Yu Chen, Yuk-Ying Chan, Yea-Huei Kao Yang, Edward Chia-Cheng Lai. (Taiwan)

4657 Cost-sharing Increase, Adherence and Hospitalizations in Schizophrenic Patients: A Population-based Differencein-differences Analysis in the Valencia Region, Spain

> **Miquel Serra-Burriel,** Isabel Hurtado, Anibal Garcia-Sempere, Gabriel Sanfelix-Gimeno, Salvador Peiró. (Spain)

5125 Characteristics of Severe Sepsis Hospitalizations and Sepsis-related Mortality in US Claims

> **Tiffany S Woodworth,** Erik Gunnarsson, Kerrin Gallagher, Lu Zhang, Joseph Menzin. (United States)

Informatics

2608 Machine Learning and Semantic Information for Unstructured Healthcare Data: Comparison of Methods Through the Automatic Analysis of Adverse Drug Reaction Reports

> **Louis Letinier,** Julien Jouganous, Ghada Miremont, Alicia Bel-Létoile, Francesco Salvo, Franck Rouby, Joëlle Micallef, Mehdi Benkebil, Antoine Pariente. (France)

4486 Using Machine Learning to Identify Heterogeneous Treatment Effects: DPP-4i versus Sulfonylrea on Cardiovascular Outcomes in US Medicare

> **Tiansheng Wang,** Alexander P. Keil, Virginia Pate, Michele Jonsson Funk, Michael R. Kosorok, John B. Buse. (United States)

4887 Deep Learning Techniques to Predicting Depression in Rheumatoid Arthritis Patients: A Real-world Data Analysis

> **Santosh Murugan,** Julius Asubonteng, Sara Haredasht, Sapthagirishwaran Sivarama, Ejim Mark, Robertino Mera. (United States)

Methods in Pharmacoepidemiology » Analytical Methods (e.g., marginal structural models, instrumental variables, sensitivity analyses)

2516 Two-stage G-computation: Estimating Effects of Treatment Policies from Observational Data When Treatment Information is Missing

> **Tiffany L Breger,** Jessie K Edwards, Stephen R Cole, Daniel Westreich, Brian W Pence, Michele Jonsson Funk, Adaora A Adimora. (United States)

2628 Estimating Vaccine Effects: A Comparison of Causal Methods

> **Alexander Breskin,** Anne M Butler, John Sahrmann, M. Alan Brookhart. (United States)



3858 Causal Estimands in Survival Analysis with Competing Events: An Application to Breast Cancer Screening

> **Xabier Garcia de Albeniz,** John Hsu, Miguel A Hernán. (Spain)

4179 Replication of Protocol-based Analyses of Saxagliptin and Sitagliptin Using Sentinel Modular Programs

> **Christian Hampp,** David J Graham, Rongmei Zhang, Yandong Qiang, Laura Hou, Sheryl Kluberg, Sengwee D Toh, Justin Bohn. (United States)

4206 Comparing Three Signal Identification Methods with Self-controlled Designs

> Judith C. Maro, Shirley V. Wang, Inna Dashevsky, Joshua J. Gagne, Sai Dharmarajan, Esther H. Zhou, Sandra DeLuccia, Elande Baro, Monica Munoz, Danijela Stojanovic, Jesper Hallas, G. Niklas Norén, Martin Kulldorff, Michael D. Nguyen. (United States)

Methods in Pharmacoepidemiology » Confounding/Bias - Methods to avoid bias and confounding, including confounder summary scores (e.g., propensity scores, disease risk scores)

80 Methodological Considerations for Pooling Patient-level Data (PLD) from Noninterventional Studies (NIS) and Clinical Trials (CT) in Oncology

> **Francois-Xavier Lamy,** Vivien Rothe, Caroline Foch, Regina Esser, Wenfeng Chen, Diethelm Messinger. (Germany)

2582 What Quacks Like a Confounder and Walks Like an Instrument?

Michael A Webster-Clark, Charles Poole. (United States) 3947 Development of a Nordic Frailty Index Based on Hospital Contacts and Prescribed Medications

> Kasper Bruun Kristensen, Peter Bjødstrup Jensen, Mette Bliddal, Anne Broe, Lars Christian Lund, Emelie Rotbain, Per Damkier, Jacob Harbo Andersen, Daniel Pilsgaard Henriksen, Mikkel Højlund, Morten Olesen, Anton Pottegård, Lotte Rasmussen, Mette Reilev, Morten Rix Hansen, Martin Thomsen Ernst, Rikke Wesselhöft and Jesper Hallas. (Demark)

4019 Deep Learning-based Propensity Scores for Confounding Control in Comparative Effectiveness Research: A Large-scale Real-world Data Study

> **Janick Weberpals,** Tim Becker, Jessica Davies, Fabian Schmich, Dominik Ruettinger, Fabian Theis, Anna Bauer-Mehren. (Germany)

4775 Impact of Missing Information Recorded Outside of Study Electronic Health Records on Comparative Safety and Effectiveness Studies

> **Kueiyu J Lin,** Joshua J Gagne, Yinzhu Jin, Sebastian Schneeweiss. (United States)

4795 Comparison of Methods for Incorporating Test Result Information within the Highdimensional Propensity Score Framework

> **John Tazare,** Jeremy P Brown, Liam Smeeth, Stephen J Evans, Elizabeth Williamson, Ian J Douglas. (United Kingdom)

4824 Transparency of High-dimensional Propensity Score Analyses: Guidance for Diagnostics and Reporting

> John Tazare, Richard Wyss, Jessica M Franklin, Liam Smeeth, Stephen J Evans, Shirley V Wang, Sebastian Schneeweiss, Ian J Douglas, Elizabeth Williamson, Joshua J Gagne. (United Kingdom)

4835 Comparing Optimization Techniques and Propensity Scores for Matching in Observational Studies of Rare Populations

Stephen Fortin, Stephen Johnston, Paul Coplan. (United States)



5088 Evolving Channeling Among Initiators of SGLT2 Inhibitors as First-line Treatment for Type 2 Diabetes

HoJin Shin, Sebastian Schneeweiss, Robert Glynn, Elisabetta Patorno. (United States)

5128 Use of Negative Controls in a Prescription Sequence Symmetry Analysis Used to Mitigate Time-varying Bias

> **Scott M Vouri,** Xinyi Jiang, Babette Brumback, Almut G Winterstein. (United States)



Methods in Pharmacoepidemiology » Measurement Methods - Validation methods to confirm data (including patient reported outcomes development and validation); Methods to deal with missing data

3743 Electronic Medical Records vs Insurance Claims: Comparing the Magnitude of Opioid Use Prior, During, and Following Surgery

Jessica C Young, Nabarun Dasgupta, Virginia Pate, Til Sturmer, Brooke A Chidgey, Michele Jonsson Funk. (United States)

3788 Validity of Claims-Based Definitions for Ulcerative Colitis in Japan: Can Intractable Disease Registry be Used as Gold Standard?

> Haoqian Chen, Haruei Ogino, Taku Kobayashi, Keita Fukaura, Hiromu Morikubo, Tasuku Okui, Naoki Nakashima, Sean Gardiner, Naonobu Sugiyama, Tsutomu Kawaguchi, Noritoshi Yoshii, Edward Nonnenmacher, Soko Setoguchi. (United States)

3924 Validating Claims-based Algorithms Identifying Pregnancy Outcomes

Keran Moll, Hui Lee Wong, Kathryn Fingar, Shayan Hobbi, Minya Sheng, Timothy Burrell, Bethany Baer, Steven Immel, Nasim Lari, Linda Eckert, Flor Munoz, William Rosenfeld, Joyce Obidi, Kristin Sepulveda, Azadeh Shoaibi, Steven Anderson. (United States)

4170 Comparing the Centers for Medicare and Medicaid Services (CMS) Enrollment Database Death Dates to the National Death Index (NDI)

> **Dinci Pennap,** Scott Swain, Sandia Akhtar, Jiemin Liao, Yuqin Wei, Jiaqi Li, Michael Wernecke, Thomas MaCurdy, Jeffrey Kelman, Andrew Mosholder, David Graham. (United States)



4219 Analytical Approaches to Reduce Selection Bias in As-treated Analyses with Missing In-hospital Drug Information

> **Yeon-Hee Baek,** Yunha Noh, In-Sun Oh, Han Eol Jeong, Kristian B. Filion, Hyesung Lee, Ju-Young Shin. (Korea, Republic of)

4440 Validity of Healthcare Database Codes and Vital Statistic Records for Identifying Neural Tube Defects (NTD) in Infants

T Craig Cheetham, Sascha Dublin, Gaia Pocobelli, Jennifer Bobb, Susan Andrade, Rulin Hechter, Cecilia Portugal, Mercedes Munis, Ladia Albertson-Junkans, Gladys Salgado, Lawrence Wong, Timothy Maarup, Kecia Carroll, Marie Griffin, Marsha Raebel, David Smith, De-Kun Li, Pamala Pawloski, Sengwee Toh, Lockwood Taylor, Wei Hua, Miriam Dinatale, Carrie Ceresa, James Trinidad and Denise Boudreau. (United States)

4826 How to Deal with Missing Data in Interrupted Time Series Analysis with Electronic Health Records

> **Juan Carlos Bazo-Alvarez,** Tim P Morris, Tra My Pham, James R Carpenter, Irene Petersen. (United Kingdom)

Methods in Pharmacoepidemiology » Study Design - Studies assessing study design (e.g., choice of comparator, self-controlled methods, avoiding immortal time bias)

- 3789 How Many Controls Do You Need?
 Henrik Stovring, Anton Pottegård, Morten R Hansen, Jesper Hallas. (Denmark)
- 3827 Immeasurable Time Bias in Case-only Designs

Han Eol Jeong, In-Sun Oh, Hyesung Lee, Kristian B Filion, Ju-Young Shin. (Korea, Republic of)

3848 Is Your Sibling Design Biased?

Buket Öztürk, Vera Ehrenstein, Henrik T Sørensen, Lars Pedersen. (Denmark) 4143 Assessment of Immortal Time Bias in a Retrospective Study of Exenatide Use and Pancreatic and Thyroid Cancers

> **Caihua Liang,** Monica L. Bertoia, C. Robin Clifford, Yan Ding, Qing Qiao, Joshua J. Gagne, David D. Dore. (United States)

4848 External Comparators Supporting Regulatory Submissions: 2017-2019

Joan A. Largent, Priscilla Velentgas. (United States)

4909 Tools for Assessing the Validity of Nonrandomized Studies: A Systematic Review. Recommendations by the International Society for Pharmacoepidemiology Comparative Effectiveness Research Special Interest Group (CER SIG)

> **Elvira D'Andrea,** Lydia Vinals, Elisabetta Patorno, Jessica M. Franklin, Dimitri Bennett, Joan A. Largent, Daniela C. Moga, Hongbo Yuan, Xuerong Wen, Andrew A. Zullo, Thomas P. Debray, Grammati Sarri. (United States)

5145 Review of Oncology Real-world Comparator Arm Submissions in Support of Effectiveness Claims in 2019 FDA Original Approvals Reveals Label-grade Real-world Study Best Practices

> **Ilker Oztop,** Wesley Eddings, Amanda Patrick, Pattra Mattox, Christina Purpura, Nicolle Gatto. (United States)



Molecular Epidemiology/Biomarkers/ Pharmacogenetics

2340 Bronchial Airway Inducible Expression and Methylation QTL Mapping Identifies a Single Nucleotide Polymorphism Predicting Inhaled Corticosteroids Response Heterogeneity in Childhood Asthma

> Elise MA Slob, MSc, Alen Faiz, Susanne JH Vijverberg, Cristina Longo, Merve Kutlu, Patricia Soares, Fook Tim Chew, Esther Herrera-Luis, Antionio Espuela Ortiz, Maria Pino-Yanes, Esteban G Burchard, Uroš Potočnik, Colin Palmer, Cyrielle Maroteau, Steve Turner, Katia Verhamme, Leila Karimi, Somnath Mukhopadhyay, Wim Timens, Pieter Hiemstra, Mariëlle W Pijnenburg, Maarten van den Berge, Anke-Hilse Maitland-van der Zee, and Gerard H Koppelman. (Netherlands)

2542 Association Between Genetic Variants and Cisplatin Nephrotoxicity: A Genomewide Approach

> **Zulfan Zazuli,** Wei Xu, Susanne Vijverberg, Rosalinde Masereeuw, Maryam Mirshams, Khaleeq Khan, Bayardo Ordonez-Perez, Shao Hui Huang, Anna Spreafico, Aaron Hansen, David Goldstein, Scott Bratman, Andrew Hope, Bruce Carleton, Anke Hilse Maitland-van der Zee, and Geoffrey Liu. (Netherlands)

2647 Danish Population Prescription Drug Use and Related Actionable Drug-gene Interactions

> **Carin A Lunenburg,** Alexander S Hauser, Kazi Ishtiak-Ahmed, Christiane Gasse. (Denmark)

3895 Polygenic Risk for Alcohol Consumption Predicts Drinking Response to a Mineralocorticoid Receptor Antagonist

> **Christopher T. Rentsch,** Rachel L. Kember, Mehdi Farokhnia, Brendan J. Tunstall, Henry R. Kranzler, Adriana Gregory-Flores, Kendall J. Bryant, George F. Koob, Leandro F. Vendruscolo, Amy C. Justice, David A. Fiellin, Lorenzo Leggio, and Janet P. Tate. (United Kingdom)

Pediatric Pharmacoepidemiology

2531 Development and Validation of a Pediatric Comorbidity Index to Predict the Risk of Hospitalization in the ICD-10-CM Era

> **Jenny W Sun,** Florence T Bourgeois, Sebastien Haneuse, Sonia Hernández-Díaz, Brian T Bateman, Krista F Huybrechts. (United States)

2579 Fluoroquinolone Antibiotic Exposure and Risk of Achilles Tendon Injury in Adolescents in the United States 2000-2018

> **Rachael K Ross,** Jeffrey S Gerber, Mackenzie M Herzog, Michele Jonsson-Funk, Alan C Kinlaw. (United States)

3887 Data Mining for Adverse Events of Tumor Necrosis Factor-alpha Inhibitors in Pediatric Patients - A Tree-based and Tree-temporal Scan Statistics Analysis of Danish Nationwide Health Data

> **Viktor Wintzell,** Henrik Svanström, Mads Melbye, Jonas F. Ludvigsson, Björn Pasternak, Martin Kulldorff. (Sweden)

3934 Association Between Proton Pump Inhibitor Use and Risk of Fracture in Children

> **Yun-Han Wang,** Viktor Wintzell, Jonas F Ludvigsson, Henrik Svanström, Björn Pasternak. (Sweden)

4714 The Relationship Between Psychotropic Use and Community-based Measures Among Children in Foster Care

Laura M. Bozzi, Pinky Shah, O'Mareen Spence, Susan dosReis. (United States)

4766 Comparative Effectiveness of Diuretics and Inhaled Corticosteroids for Evolving Bronchopulmonary Dysplasia in Preterm Infants

> **Jonathan L Slaughter,** Mark A Klebanoff, Erinn M Hade. (United States)



4796 Antipsychotics Use and Weight Gain in Children Compared to Adults: Analysis of Spontaneous Adverse Drug Reaction Reports

> **Florentia Kaguelidou,** Zaba Lieber, Francois Montastruc, Genevieve Durrieu, Jean-Marc Treluyer, Laurent Chouchana. (France)

Pharmacovigilance » Cancer

2436 Pharmacovigilance Cohort Study of Osteonecrosis of the Jaw and Serious Infection Among Cancer Patients Treated with Denosumab or Zoledronic Acid in Denmark, Norway, and Sweden

> **Vera Ehrenstein,** Uffe Heide-Jørgensen, Morten Schiødt, Olof Akre, Bente B Herlofson, Svein Hansen, Cecilia Larsson Wexell, Sven Erik Nørholt, Steinar Tretli, Anders Kjellman, Henrik T Sørensen, Anthony Glennane, Kimberly Lowe. (Denmark)

3965 Use of Methotrexate and Risk of Skin Cancer: A Nationwide Case-control Study

Sam Polesie, Martin Gillstedt, Sigrún Alba Jóhannesdóttir Schmidt, Alexander Egeberg, Anton Pottegård, Kasper Bruun Kristensen. (Denmark)

4352 A Study of Cancer Occurrence in Users of Mirabegron and Antimuscarinic Treatments for Overactive Bladder

Kelesitse Phiri, Jesper Hallas, Marie Linder, Andrea Margulis, Brandon Suehs, Alejandro Arana, Shahram Bahmanyar, Cheryl Enger, Libby Horter, Ingvild Odsbu, Morten Olesen, Susana Perez-Gutthann, Nina Sahlertz Kristiansen, Kwame Appenteng, Stefan de Vogel and John Seeger. (United States) Pharmacovigilance » Cardiovascular

4302 Association Between Desloratadine Use and Incidence of Cardiac Outcomes - A Nordic Cohort Study

Annette Kjær Ersbøll, Thora Majlund Kjærulff, Kaushik Sengupta, Eero Pukkala, Kristian Bolin, Martha Emneus, Dena Rosen Ramey, Joanne E Brady, Daniel Mines, Kristian Aasbjerg, Christian Vestergaard, Gunnar Gislason. (Denmark)

Pharmacovigilance »Neurological/Mental Health

3745 Concomitant Use of Gabapentinoids and Opioids Following Surgery and the Risk of Opioid-related Adverse Events

> **Katsiaryna Bykov,** Brian T. Bateman, Jessica M. Franklin, Elisabetta Patorno. (United States)

4053 **Risks of Adverse Cardiovascular Outcomes Associated with Antipsychotic Use in People with Dementia**

> **Pearl L Mok,** Matthew J Carr, Bruce Guthrie, Daniel Morales, Tjeerd van Staa, Antony J Avery, Darren M Ashcroft. (United Kingdom)

Pharmacovigilance »**Other**

4039 Measuring the Impact of Calcitonin Marketing Authorisation Withdrawal on Public Health in France, Germany and UK

> Samantha Lane, Elizabeth Lynn, Jim Slattery, Saad Shakir. (United Kingdom)

4070 Vortioxetine's Post-marketing Safety Profile Determined Through Cluster Analysis of Global Adverse Event Reports

> **Corine Ekhart,** Florence van Hunsel, Eugène van Puijenbroek, Rebecca Chandler, Eva-Lisa Meldau, Niklas Norén. (Netherlands)



4128 A Tree-based Statistic Data Mining Approach to Assess the Post-marketing Safety of New Glucose-lowering Medications in Routine Care

> **Michael Fralick,** Martin Kulldorff, Donald Redelmeier, Shirley V Wang, Seanna M Vine, Sebastian Schneeweiss, Elisabetta Patorno. (United States)

4267 Increased Intolerance to Angiotensin Converting Enzyme Inhibitors in Asthma: A United Kingdom Population-based Cohort Study Using Electronic Medical Records

Daniel R Morales, Brian Lipworth, Peter Donnan, Huan Wang. (United Kingdom)

4371 An Empirical Evaluation of Adverse Event Cluster Analysis in Pharmacovigilance

> **G. Niklas Norén,** Eva-Lisa Meldau, Rebecca E Chandler. (Sweden)

4479 Acute Pancreatitis Associated with Methimazole Treatment: A Populationbased Study on Regional Italian Databases

> **Alessandro Pecere,** Marina Caputo, Andrea Sarro, Angelica Zibetti, Andrealuna Ucciero, Paolo Marzullo, Gianluca Aimaretti, Francesco Barone-Adesi. (Italy)

4769 Proactive Signal Detection of Serious Medical Events Following Antidepressant Initiation Using Big Healthcare Data

Mia Aakjær, Marie Louise De Bruin, Murat Kulahci, Morten Andersen. (Denmark)

Pregnancy and Lactation

85 First Trimester Pregnancy Exposure to Modafinil and Risk of Congenital Malformations

Anne Broe, Per Damkier. (Denmark)

2389 Prenatal Exposure to Non-steroidal Anti-inflammatory Drugs and Risk of Attention Deficit Hyperactivity Disorder Diagnosis and Symptoms - A Follow-up in the Norwegian Mother, Father and Child Cohort Study

> **Sarah Hjorth,** Angela Lupattelli, Marte Handal, Olav Spigset, Eivind Ystrom, Hedvig Nordeng. (Norway)

2502 Comparing Maternal and Neonatal Outcomes with Use of Different Antihypertensive Medications in Pregnancy

Sascha Dublin, Mary Akosile, Lyndsay A Avalos, T Craig Cheetham, Thomas R Easterling, Lu Chen, Nerissa Nance, Zoe Bider-Canfield, Victoria L Holt, Romain S Neugebauer, Kristi Reynolds, Sylvia E Badon, Susan M Shortreed. (United States)

2544 Prenatal Opioid Exposure and Risk of Asthma in Childhood: A Populationbased Study from Denmark, Norway, and Sweden

> **Ingvild Odsbu,** Marte Handal, Vidar Hjellvik, Sonia Hernandez-Diaz, Helle Kieler, Mette Nørgaard, Svetlana Skurtveit, Buket Öztürk, Milada Mahic. (Sweden)

2665 Validation of an ICD-10-based Algorithm to Identify Stillbirth in the Sentinel System

> Susan E Andrade, Mayura Shinde, Tiffany Moore Simas, Steven Bird, Justin Bohn, Kevin Haynes, Lockwood Taylor, Julianne Lauring, Erin Longley, Cheryl McMahill-Walraven, Connie Trinacty, Cassandra Saphirak, Christopher Delude, Sandra DeLuccia, Tancy Zhang, David Cole, Nina DiNunzio, Autumn Gertz, Elnara Fazio-Eynullay and Danijela Stojanovic. (United States)

2676 Oral Corticosteroids and Risk of Preterm Birth in the California Medicaid Program

> **Kristin Palmsten,** Gretchen Bandoli, Jim Watkins, Gabriela Vazquez-Benitez, Todd P. Gilmer, Christina D. Chambers. (United States)

2682 Personal History of Febrile Seizure Increases Risk of Measles-Mumps-Rubella Vaccine Attributable Seizure

Shirley V Wang, Lily Bessette, Kristina Stefanini, Bruce Fireman, Ned Lewis, Jonathan Duffy, Michael McNeill, Seanna Vine, Krista Huybrechts, Martin Kulldorff. (United States)



2684 Treescan for Active Surveillance of the Safety of Medications Used in Pregnancy

Krista F Huybrechts, Martin Kulldorff, Sonia Hernandez-Diaz, Brian T Bateman, Yanmin Zhu, Helen Mogun, Shirley V Wang. (United States)

3705 Fetotoxicity of RAAS-Inhibitors

Tania Schink, Marlies Onken, Nadine Wentzell, Katarina Dathe, Ulrike Haug. (Germany)

3882 A Prospective Study of Pregravid Injectable Contraceptive Use and Spontaneous Abortion

> **Jennifer J Yland,** Elizabeth E Hatch, Kenneth J Rothman, Lauren A Wise. (United States)

3938 Trajectories of Prescription Opioid Utilization During Pregnancy Among Pre-pregnancy Chronic Users and Risk of Neonatal Abstinence Syndrome

> **Loreen Straub,** Krista F Huybrechts, Sonia Hernandez-Diaz, Yanmin Zhu, Seanna Vine, Rishi J Desai, Kathryn J Gray, Brian T Bateman. (United States)

3977 Periconceptional Prescription Opioid and Alcohol or Tobacco Use and Birth Defect Risk

> **Kayla N. Anderson,** Elizabeth C. Ailes, Cheryl S. Broussard, Clark H. Denny, Jennita Reefhuis. (United States)

4162 Off-label Use of Domperidone Among Postpartum Women: A Multi-database Study

> **Carolina Moriello,** J. Michael Paterson, Pauline Reynier, Matthew Dahl, Wusiman Aibibula, Anat Fisher, John-Michael Gamble, I Fan Kuo, Paul E Ronksley, Brandce Winquist, Kristian B Filion, the CNODES Investigators. (Canada)

4251 Use of Beta-adrenergic Agonist Ritodrine in Tocolysis and Risk of Maternal Cardiovascular Events: A Nationwide Nested Case-control Study

> **Chih-Wan Lin,** K. Arnold Chan, Yi-Yung Chen, Wei-I Huang, Pi-Hui Chao, Wen-Wen Chen, Fei-Yuan Hsiao. (Taiwan)

4257 Anti-thyroid Drug Use During the First Trimester of Pregnancy and the Risk of Birth Defects in Offspring: Systematic Review and Meta-analysis of Observational Studies with Methodological Considerations

Daniel R Morales, Lionel Fonkwen, Hedvig Nordeng. (United Kingdom)

4401 Chronic Prescription Opioid Use in Pregnancy in the United States

> **Loreen Straub,** Krista F Huybrechts, Sonia Hernandez-Diaz, Yanmin Zhu, Seanna Vine, Rishi J Desai, Kathryn J Gray, Brian T Bateman. (United States)

4406 Validation of Claims-based Algorithms to Identify Specific Major Congenital Malformations

> **Loreen Straub,** Krista F Huybrechts, Sonia Hernandez-Diaz, Yanmin Zhu, Kathryn J Gray, Brian T Bateman. (United States)

4428 Epidemiology of Prenatal Opioid Use and Associated Maternal Characteristics in Ontario, Canada

> **Andi Camden,** Teresa To, Joel G Ray, Tara Gomes, Li Bai, Kinwah Fung, Astrid Guttmann. (Canada)

4446 Opioid Use After Vaginal Birth and the Risk of Serious Opioid-related Events: Is There a Safe Dose?

> **Andrew D. Wiese,** Sarah S. Osmundson, Ed Mitchel, Margaret Adgent, Sharon Phillips, Stephen W. Patrick, Marie Griffin, Carlos G. Grijalva. (United States)

4481 Neural Tube Defect Risk Among Infants Exposed to Opioids During Early Pregnancy

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3727 A US Multicenter Chart Review Study of Patients with Metastatic Pancreatic Ductal Adenocarcinoma Receiving Liposomal Irinotecan After Gemcitabinebased Therapy

> **Kenneth H Yu,** Andrew Hendifar, Olatunji Alese, Amber Draper, Maen Abdelrahim, Ethan Burns, Gazala Khan, Paul Cockrum, Rachel Bhak, Maral DerSarkissian, Catherine Nguyen, Mei S Duh, Nathan Bahary. (United States)

3792 Risk Factors and Disease Burden of Metastatic Melanoma: A Populationbased Study in South Korea

> **Hae-Young Park,** Hyun-Ju Yang, Soo Min Jeon, Sena An, Jin-Won Kwon. (Korea, Republic of)

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> **Ashwini Zolekar,** Nadia A. Nabulsi, Alemseged A. Asfaw, Jifang Zhou, Karen Sweiss, Pritesh R. Patel, Brian C-H Chiu, Edith A. Nutescu, Gregory S. Calip. (United States)





4165 Epidemiology of HER2+ Metastatic Breast Cancer in Germany and France in 2019

> **Kendra DeBusk,** Naomi R. Schwartz, Susan Dennett, Nicolas Lindegger, Sonia Pulgar. (United States)

4175 Association of Calcium Channel Blocker Subtypes and Prostate Cancer Related Mortality

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4183 Comparative Risks of Cardiotoxicity Following Initiation of Checkpoint Inhibitors, BRAF/MEK Inhibitors, and Interferon Alpha in Patients with Metastatic Melanoma

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4199 Thiamine Deficiency as a Misdiagnosed and Unrecognized Cause of Delirium in Referred Patients with Cancer

> **Hideki Onishi,** Izumi Sato, Mayumi Ishida. (Japan)

4205 Risk of Malignancy in Rheumatoid Arthritis Patient and Association with Biologic DMARDs Using National Health Insurance Service Claim Database

Sang Oh Kang, Kyung Hyun Min, Harim Yeon, Kyungeun Lee. (Korea, Republic of)

4213 Disease Characteristics, Treatment and Clinical Outcomes of Patients with B-cell Non-hodgkin Lymphoma: A Retrospective Study in Taiwan

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4223 Novel Use of the England National Cancer Registry to Describe Treatment Patterns and Disease Outcomes in Patients with Advanced or Metastatic Cancer

> **Francois-Xavier Lamy,** Craig Knott, James Harnett, Amerah Armin, Leo Russo, Emmanuelle Boutmy, Patrice Verpillat. (Germany)



4298 Evaluation of Electronic Health Record (EHR) Data of Patients with Acute Myeloid Leukaemia (AML) for Real-world Data Analyses

> **Charlotta Früchtenicht,** Evelyn M Flahavan, Tao Xu, Tarec Christoffer El-Galaly, Jessica Davies, Craig Gower-Page, Anne-Marie Meyer. (Switzerland)

4397 Incidence, Prevalence, and Survival in Patients with Metastatic Non-small Cell Lung Cancer in the United States (US)

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4419 KADor: A French Retrospective Study Describing the Therapeutic Management of Patients Who Received Herceptin® Based Neoadjuvant Treatment for HER2+ Early Breast Cancer (eBC)

> **Paul Cottu,** David Perol, Olivier Tredan, Alain Livartowski, Melina Gilberg, Rim Ghorbal, Julien Dupin, Cathy Maillard. (France)

4433 Treatment Patterns and Clinical Outcomes of Patients with Metastatic Non-small Cell Lung Cancer Receiving Immune Checkpoint Inhibitor Monotherapy in the First-line Setting in Community-based Practices in the United States

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4503 Use of Proton Pump Inhibitors and Histamine-2 Receptor Antagonists and Risk of Gastric Cancer in Two Populationbased Studies

> **Peipei Liu,** Úna McMenamin, Brian Johnston, Peter Murchie, Lisa Iversen, Amanda Lee, Pauline Vissers, Christopher Cardwell. (United Kingdom)

4519 Identifying Microsatellite Instability Associated Cancer Patients in the Veterans Affairs Healthcare System

> **Shahed Iqbal,** Amanda M De Hoedt, Kai-Li Liaw, Stephen J Freedland, Mayur Amonkar, Deepti Aurora-Garg, Zachary Klaassen. (United States)

4663 Characteristics and Study Eligibility of British Lung Cancer Patients for Clinical Trials Evaluating Targeted Therapies (TTS) or Immune Checkpoint Inhibitors (ICIS)

> **Ard van Veelen,** Shahab Abtahi, Patrick Souverein, Johanna H Driessen, Olaf H Klungel, Anne-Marie Dingemans, Robin van Geel, Frank de Vries, Sander Croes. (Netherlands)

4691 Clinical Value of Oncology Medicines in Europe: Is it Different for Conditionally Approved Medicines?

> **Lourens T Bloem,** Rosa E Bot, Aukje K Mantel-Teeuwisse, Menno E van der Elst, Olaf H Klungel, Hubert G Leufkens, Jarno Hoekman. (Netherlands)

4746 Antiplatelet Drug Use and Breast Cancer Risk in a Prospective Cohort Study of Postmenopausal Women

> **Manon Cairat,** Marie Al Rhamoun, Gianluca Severi, Marc Gunter, Laure Dossus, Agnes Fournier. (France)

4777 The Potential of Claims Data for Longterm Follow-up of Breast Cancer Patients in Germany

Miriam Heinig, Ulrike Haug. (Germany)



4847 Approximating Line of Treatment Using Drug Exposure Data and Clinical Information of Patients with Metastatic Breast Cancer Using U.S. Electronic Health Record Data

> **Thibaut Sanglier,** Jinjoo Shim, M K Downer, Carlos Flores, Patricia Luhn. (Switzerland)

4862 Performance of QRISK-3 Scores in Predicting Cardiovascular Disease in Adult Cancer Survivors Compared to Matched Cancer Free Controls

> **Helen Strongman,** Emily Herrett, Rod Jackson, Michael Sweeting, Alexander R Lyon, Susannah Stanway, Claire Lawson, Umesh Kadam, Liam Smeeth, Krishnan Bhaskaran. (United Kingdom)

4873 Association of Surgical Complications with In-hospital Mortality Among Patients Undergoing Major Pancreatic Resection

> **Joseph Guilfoyle,** Neal Bhutani, Stephen Johnston, Hari Dwarakanathan, Anuprita Patkar, Robert C Martin. (United States)

5092 Patterns of Recurring Colorectal Polyps and Risk of Colorectal Cancer in Commercially Insured US Adults

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5115 Incidence and Management Trends for Cervical HSIL in a Large US Cohort from 2008 Through 2018

> **Katherine C. Hughes,** Timothy Herring, Jennifer Song, Robert Gately, Lindsay Nowak, Judy Wong, Mark Twyman, Prakash Bhuyan, John D. Seeger. (United States)

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2392 Uncontrolled Blood Pressure and Therapeutic Inertia in Treated Hypertensive Patients: A Descriptive Cohort Study in Clinical Practice Research Datalink (CPRD)

> **Céline Darricarrère,** Marc Bénard, Stéphanie Bricout-Hennel, Caroline Louis, Emmanuelle Jacquot. (France)

2465 Identification of an Appropriate Time Window for the Exclusion of Prevalent Cases Recorded Following Registration with the Clinical Practice Research Datalink

> **Thomas P Leahy,** Cormac Sammon, Sreeram Ramagopalan. (United Kingdom)

4055 Venous Thromboembolism and Risk of Cancer in Users of Statins: A Danish Population-based Cohort Study

> **Nils Skajaa,** David Nagy, Frederikke Schønfeldt Troelsen, Dóra Körmendiné Farkas, Henrik Toft Sørensen. (Denmark)

4117 Coprevalence of Comorbidities in Medicare Older Adults with Chronic Obstructive Pulmonary Disease

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4453 History of Lipid Lowering Therapy Use Among Adults Initiating Treatment with Proprotein Convertase Subtilisin / Kexin Type 9 Antibody Inhibitors in the United States, 2015-2019

> **Sara N Levintow,** Catie Wiener, Kate K Orroth, Karminder Gill, Andrew Mullard, M. Alan Brookhart, Leah J McGrath. (United States)

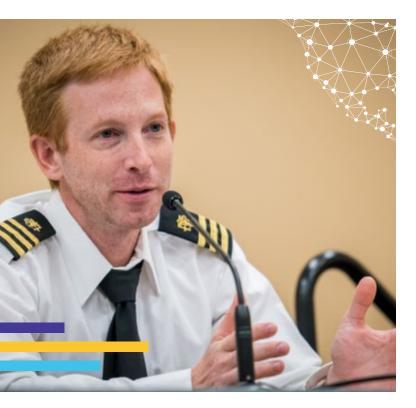
4472 Real World Treatment Patterns Following the Initiation of Proprotein Convertase Subtilisin / Kexin Type 9 Antibody Inhibitors Among Adults in the United States, 2015-2019

> **Catie Wiener,** Sara N Levintow, Kate K Orroth, Karminder Gill, Andrew Mullard, Leah J McGrath, M. Alan Brookhart. (United States)

4581 The Prevalence and Determinants of Over- and Undertreating Hypertension and Cholesterol Levels in the Rhineland Study

> **Nersi Alaeddin,** Folgerdiena M de Vries, Gökhan Pehlivan, Monique M Breteler. (Germany)





4726 Beta-blockers and Initial Heart Rhythm in Out-of-hospital Cardiac Arrest: A Multi-country Case-control Study

Talip Eroglu, Carlo Barcella, Michiel Hulleman, Asger Granfeldt, Patrick Souverein, Grimur Mohr, Rudolph Koster, Mads Wissenberg, Anthonius de Boer, Christian Torp-Pederson, Fredrik Folke, Marieke Blom, Gunnar Gislason, Hanno Tan. (Netherlands)

4786 Epidemiology and Treatment of Atrial Fibrillation in Patients with Type 2 Diabetes Mellitus 2001-2016: An Electronic Database Study in the United Kingdom

> **Hassan Alwafi,** Ian Wong, Amitava Banerjee, Pajaree Mongkhon, Cate Whittlesea, Abdallah Y Naser, Wallis Lau, Li Wei. (United Kingdom)

4872 Characteristics of Patients Newly Diagnosed with Atrial Fibrillation After Ischemic Stroke Hospitalization

> **Lu Zhang,** Anna Watzker, Tiffany S Woodworth, Mark Friedman, Joseph Menzin. (United States)

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2546 Dental Resource Service Utilization Among Type 2 Diabetes Patients: A Realworld Analysis Using a Linked Claims and Dental Database

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2678 Individualized Glycemic Control in Type 2 Diabetes in the US and Europe

> **Dominik Lautsch,** Euan McLeod, Tongtong Wang, Swapnil Rajpathak, Claudio Gonzalez, Seema Malkani, Gary Milligan, James Jackson, Victoria Higgins. (United States)

3706 Polyneuropathy in Early Type 2 Diabetes is Associated with Higher Risk of Subsequent Cardiovascular Disease: Evidence from the Danish Centre for Strategic Research in Type 2 Diabetes (DD2) Cohort

> **Sia Kromann Nicolaisen,** Lasse Bjerg, Diana Hedevang Christensen, Reimar Wernich Thomsen, Jens Steen Nielsen, Signe Toft Andersen, Henning Beck-Nielsen, Troels Staehelin Jensen, Annelli Sandbæk, Daniel Witte, Morten Charles. (Denmark)

3725 Sex Differences in the Risk of Diabetes Mellitus Among Individuals with Psoriasis

> **Raymond Milan,** Jacques LeLorier, Ivan Litvinov, Kaberi Dasgupta, Elham Rahme. (Canada)

3729 Using Rwd to Assess Changes in GFR Among DKD Patients and the Rate of Heart Failure

Seth Kuranz, Christian Haudenschild. (United States)



3962 Statin Therapy and Risk of Polyneuropathy in Type 2 Diabetes: A Population-based Cohort Study

> **Frederik Pagh Kristensen,** Diana Hedevang Christensen, Brian Callaghan, Søren Tang Knudsen, Søren H. Sindrup, Eva L. Feldman, Leif Østergaard, Henning Andersen, Troels Staehelin Jensen, Henrik Toft Sørensen, Reimar Wernich Thomsen. (Denmark)

3979 Daily Lifestyle Behaviors Associated with Initiating of Renal Replacement Therapy in Japanese Patients with Chronic Kidney Disease: A Descriptive Study Using a Claims Database Linked with Specific Health Checkup Results

> **Kazuaki Enomoto,** Azusa Hara, Nanae Tanemura, Takumi Hirata, Tomonori Okamura, Hisashi Urushihara. (Japan)

4150 Age- and Sex-specific Incidence of Nontraumatic Lower Limb Amputation in Patients with Type 2 Diabetes Mellitus in a Claims Database from the United States

> Sampada Gandhi, Chuntao Wu, Maximiliano Waschbusch, Madlen Michael, Meng Zhang, Xinyu Li, Juhaeri Juhaeri. (United States)

4228 Cardiorenal Disease is the Most Common First Cardiovascular Manifestation in Type 2 Diabetes and Associated with Increased Mortality

> **Jetty A Overbeek,** Esmé Lighaam, Gerard C Linssen, Ron M Herings, Johan Bodegård. (Netherlands)

4272 The Pharmo Diabetes, Management, and Treatment (DIAMANT) Cohort: A Population-based Cohort of People with Type 2 Diabetes

> **Jetty A Overbeek,** Louise Lemmens, Amber A van der Heijen, Giel Nijpels, Ron M Herings. (Netherlands)

4321 Factors Related to Sodium Glucose Cotransporter 2 Inhibitor (SGLT2i) and Dipeptidyl Peptidase 4 Inhibitor (DPP4i) Dispensing Among Naive, Incident, and Prevalent New Users

> **Yandong Qiang,** Casie H. Horgan, Andrew B Petrone, Joy Kolonoski, Aaron Hansbury, Christian Hampp, Sarah Dutcher, Sruthi Adimadhyam, Sengwee Toh. (United States)

4363 The Pattern of Incident Fractures in Patients with Newly Diagnosed Type 2 Diabetes Mellitus

> Johanna H Driessen, Cindy Sarodnik, Nicklas H Rasmussen, Sandrine P Bours, Nicolaas C Schaper, Peter Vestergaard, Patrick C Souverein, Morten Jensen, Frank de Vries, Joop P van den Bergh. (Netherlands)

4391 Ethnic Differences in Statin Prescribing for People with Type 2 Diabetes

> **Sophie V Eastwood,** Rohini Mathur, Liam Smeeth, Krishnan Bhaskaran, Nishi Chaturvedi. (United Kingdom)

4458 Impact of Policy Changes on the Delivery of Community Medication Review Services Among Adults with Diabetes in Ontario

> **Ahmad Shakeri,** John-Michael Gamble, Lori MacCallum, Lisa Dolovich, Nancy He, Suzanne M. Cadarette. (Canada)

4757 Assessing the Impact of a Non-Alcoholic Fatty Liver Disease (NAFLD) Diagnosis on Prescribing of GLP-IRA, DPP4i, and TZD Medications

Danni Zhao, Matthew J Alcusky, Anthony P Nunes. (United States)

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2525 Associations of Benzodiazepines, Z-drugs and Other Anxiolytics with Subsequent Dementia in Patients with Affective Disorders. A Nationwide Cohort and Nested Case-control Study

> **Merete Osler,** Martin B Jørgensen. (Denmark)



2527 Treatment Patterns of Patients with Major Depressive Disorder and Suicidal Ideation or Attempt

David M Kern, M. Soledad Cepeda, Frank Wiegand. (United States)

2607 Prevalence and Incidence of Narcolepsy in Japan: A Study Using Japanese Claims Data

> **Motonobu Sakaguchi,** Motonobu Sakaguchi, Yumiko Ogino, Chao Chen, Shreya Davé. (Japan)

2671 Increased Risk of Falls and Fractures in Patients with Psychosis and Parkinson Disease

> Joan Forns, J Bradley Layton, Jennifer Bartsch, Mary Ellen Turner, Colleen Dempsey, Mary Anthony, Mary E Ritchey, George Demos. (Spain)

3775 Excess Deaths Associated with Treatment Resistance in Patients with Major Depressive Disorder

> **Philip Brenner,** Lena Brandt, Michel Nijs, Johan Reutfors, Therese Andersson. (Sweden)

3779 Incidence Rates (IR) and IR Ratios of Parkinson Disease in Patients with Cataract Compared to the General Population: Analyses Using the Clinical Practice Research Datalink (CPRD)

> **Claudia Becker,** Laura Eggenschwiler, Susan S Jick, Christoph R Meier. (Switzerland)

3806 Caregiving Burden, Chronic Pain and Opioid Utilization Among Parents of Children with Special Healthcare Needs

> **Wendy Camelo Castillo,** Oluwadamilola Onasanya, Beth B Hogans, Susan dosReis, Gloria Reeves. (United States)

3983 A Population-based Cohort Study of Disruptive Mood Dysregulation Disorder Among Youth in the US

> **Xiaofeng Zhou,** Prethibha George, Rongjun Shen, Gong Richard, Robert L. Findling, Phillip B. Chappell. (United States)

4018 Association of Renal and Cognitive Function in an Elder Population: Analysis of NHANES 2011 and 2013

David Vizcaya, Peter Kolkhof, Montse Soriano-Gabarro. (Spain)

4180 Leveraging Real World Data to Characterize Rates of Elevated Liver Enzyme Levels Among Patients Diagnosed with Migraine

> **William K. Mountford,** Matthew Butler, Carissa Dukes, Jiatao Michael Ye. (United States)

4268 Development Trajectories in Asd Based on Symptoms Measured by the Vineland Adaptive Behaviour Scale Second Edition Using Data from the US and Europe

Chuang Liu, Mariabeth Silkey, Hannah Furby, Yajing Zhu. (Switzerland)

4316 Hospital-diagnosed Infections, Community-based Antibiotic Prescriptions, and Risk of Subsequent Guillain-Barré Syndrome: A 30-year Nationwide Population-based Casecontrol Study

Lotte S Levison, Reimar W Thomsen, Søren H Sindrup, Henning Andersen. (Denmark)

4443 Co-occurrence of Schizophrenia and Dementia

> **Tobias Gerhard,** T. Scott Stroup, Melanie Wall, Cecilia Huang, Mark Olfson. (United States)

4497 Infection Dynamics in Patients with Multiple Sclerosis Over the Past 15 Years: A Retrospective Cohort Study in the UK Clinical Practice Research Datalink

> **Melissa W Leung,** Marloes T Bazelier, Patrick C Souverein, Hubert G Leufkens, Romin Pajouheshnia. (Netherlands)

4566 Incidence, Survivorship, and Treatment of Motor Neuron Disease in Hong Kong: A Population-based Study

Min Fan, Gary KK Lau, Xue Li, Ian CK Wong, Celine S.L. Chui. (Hong Kong)



4639 All-cause Mortality, Suicide and Selfharm in Patients with Treatmentresistant Depression

> **Frederikke Gronemann,** Martin Balslev Jørgensen, Merete Nordentoft, Per Kragh Andersen, Merete Osler. (Denmark)

4700 Postnatal Depression and Infant "5in-1" Vaccine Adherence in the United Kingdom

Holly C Smith, Fahima Choudry, Irene Petersen. (United Kingdom)

4915 Infectious Processes and Schizophrenia: Is There Any Correlation?

> **Túlio Tadeu R Sarmento,** Isabella F Zuppo, Pâmela S Azevedo, Ludmila P Gargano, Natália D Brandão, Juliana Alvares-Teodoro, Francisco A Acurcio, Augusto A Guerra, Mariana B Deleprane, Rafael L dos Santos. (Brazil)

4972 Characteristics of Multiple Sclerosis by Ethnoracial Groups in Medicaid and Electronic Health Records

Nydjie Grimes, Cortney Hayflinger, Cynthia Jones. (United States)

5032 Prevalence of Anxiety, Depression and Drug Utilization of Antidepressants Among Cancer Patients in the Inpatient Settings: A Cross-sectional Study in Jordan

> **Abdallah Y Naser,** Anas Nawfal Hameed, Nour Mustafa, Hassan Alwafi, Haya Khalil. (Jordan)

5134 Medication Use Among Migraine Sufferers: An Analysis of Electronic Medical Records

Jessica D. Albano, Kelly Oh, Sara Ephross. (United States)

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> **Uffe Heide-Jørgensen,** Christian F Christiansen, Henrik Birn, Reimar W Thomsen, Søren V Vestergaard. (Denmark)

53 Identification of Risk Factors Associated with Mortality in Neonatal Sepsis Patients

> **Vijayanarayana Kunhikatta,** Puspita Sahu, Meenakshi Srinivasan, Shivakumar M, Leslie Edward Lewis. (India)

70 The Impact of Socioeconomic Status on the Risk of Total Hip Arthroplasty During 1995 to 2017 in Denmark

> **Nina M Edwards,** Claus Varnum, Søren Overgaard, Alma B Pedersen. (Denmark)

92 Association Between Dietary Diversity and All-cause Mortality Among Chinese Adults 65 Years of Age or Older, a Community-based Cohort Study

> **Liyuan Tao,** Lin Zeng, Nan Li, Yanyan Shi, Hua Zhang, Xiaoxiao Wang, Hongling Chu, Lin Zhuo, Kaiwen Ni, Xiaoli Liu. (China)

95 Evaluation of Reporting Quality for Prediction Models of HBV-related Hepatocellular Carcinoma by Tripod Statement

> **Liyuan Tao,** Lin Zeng, Nan Li, Yanyan Si, Hua Zhang, Xiaoxiao Wang, Hongling Chu, Kaiwen Ni, Xiaoli Liu, Siyan Zhan, Lin Zhuo. (China)

2352 Elevated Risk of Hospitalization for Infection in Anemic Patients in Japan at the Beginning of Impaired Renal Function

> **Tomomi Kimura,** Satoshi Onozawa, Masataka Morita, Osamu Yamamoto, Tadao Akizawa. (United States)

2370 Doxycycline Adherence Scale: The Impact on the Incidence of Leptospirosis Among Flood Affected South Indian Population

> **Jose J Kochuparambil,** Aleena Issac. (India)

2467 Clinical Characteristics of Sepsis Patients by Survival Status: An Analysis of Electronic Medical Records

Brian Buysse, Claire Le Nguyen, Jessica Albano. (Spain)



2484 Comorbidities Analysis of Patients with Atopic Dermatitis on Non-biologic Systemic Drug Therapy Using Optum Electronic Health Records Databases

> **Huifang Liang,** Varinder Singh, Dongmu Zhang, Jianzhong Liu, Philip Sugerman, Colleen Wegzyn, Ryan D Kilpatrick. (United States)

2512 Comorbidities and Characteristics in a Cohort of Patients with NAFLD/NASH from the Netherlands

> **Jetty A Overbeek,** Marieke Krol, Kelly Mulder, Marina Bakker, Ger H Koek, Ron M Herings. (Netherlands)

2518 Risk of Hospitalisation Due to Infection in Patients with Psoriasis: A Populationbased Cohort Study Using the United Kingdom Clinical Practice Research Datalink

> **Zenas Z Yiu,** Rosa Parisi, Mark Lunt, Richard B Warren, Christopher E Griffiths, Sinéad M Langan, Darren M Ashcroft. (United Kingdom)

2569 Incidence of Anemia in Patients with Chronic Kidney Disease - A Populationbased Cohort Study

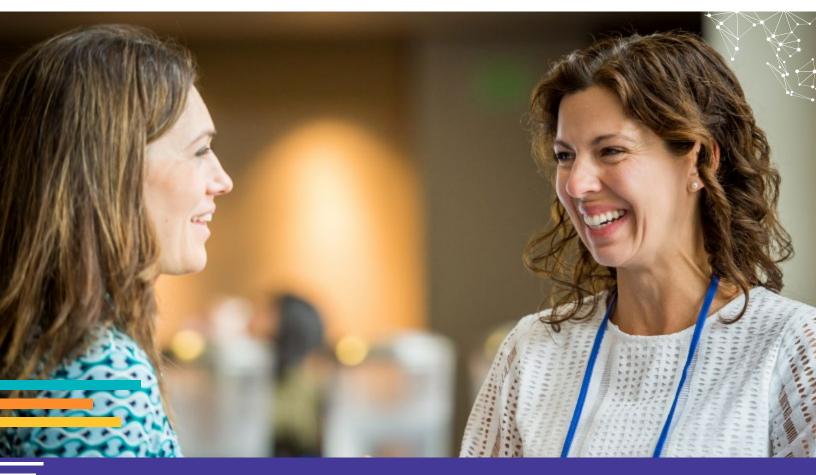
> **Søren V Vestergaard,** Uffe Heide-Jørgensen, Heleen van Haalen, Glen James, Katarina Hedman, Henrik Birn, Reimar W Thomsen, Christian F Christiansen. (Denmark)

2610 Probabilistic Linkage of the French Cystic Fibrosis Patient Registry with the French National Health Data System

> **Manon Belhassen,** Deborah Walther, Lydie Lemonnier, Marjorie Bérard, Faustine Dalon, Isabelle Durieu, Eric Van Ganse. (France)

2674 Characterization of Women with Adenomyosis Identified in a Large U.S. Electronic Health Record Database with and without Hysterectomy

> **Stephanie E Chiuve,** Anita M Loughlin, Stacey A Missmer, Michael C Snabes, Keith Gordon, Gally Reznor, Michael C Doherty, Cheryl Enger. (United States)





2685 Applying Machine Learning to Define Phenotypes of Women with Endometriosis Undergoing Laparoscopic Surgery

> **Andrea K Chomistek,** Cheryl Enger, Stacey A Missmer, Stephanie J Estes, Jenna F Calderbank, Michael C Doherty, Stephanie E Chiuve. (United States)

3695 Occurrence of Metabolic Risk Factors Stratified by Psoriasis Severity a Swedish Population-based Matched Cohort Study

> **David Hägg,** Marie Linder, Mohammadhossein Hajiebrahimi, Ci Song, Therese M-L Andersson, Reginald Villacorta. (Sweden)

3735 Treatment, Healthcare Resource Utilization, and Healthcare Costs for Medicare Patients with Generalized Pustular Psoriasis and Palmoplantar Pustulosis

> **Allison A Petrilla,** Sudeepti Pahuja, Shambhavi Kumar, Courtney R Jaeger. (United States)

3741 The Spectrum of Adenomyosis Identified in a Large US Electronic Health Record Database

Anita M. Loughlin, Gally Reznor, Michael Doherty, Stephanie E. Chiuve, Cheryl Enger. (United States)

3742 Dopamine Agonists and Risk of Lung Cancer

> Maria P Hernandez-Con, Justine Shults, Allison Willis, Yu-Xiao Yang. (United States)

3834 21-year Trends in First Hospitalization for Acute Urinary Retention and Subsequent Mortality in the Danish Male Population: A Nationwide Cohort Study

> Maria B Bengtsen, Uffe Heide-Joergensen, Michael Borre, Mette Nørgaard. (Denmark)

3837 Prevalence of Contraindication in Chronic Kidney Disease According to eCrCl and eGFR Equations and Patient Related Risk Factors

Susanne Stolpe, Cornelia Blume. (Germany)

3920 Participant Engagement in an ArthritisPower Real-world Study to Capture Smartwatch and Patient-reported Outcome Data Among Rheumatoid Arthritis Patients

> Jeffrey R Curtis, W Benjamin Nowell, Fenglong Xie, Hong Zhao, David Curtis, Kelly Gavigan, Shilpa Venkatachalam, Laura Stradford, Jessica Boles, Justin K Owensby, Cassie Clinton, Ilya Lipkovich, Amy Calvin, Virginia S Haynes. (United States)

3985 Incidence of Opioid Abuse, Dependence, and Overdose in Osteoarthritis Patients Prescribed Opioids in the United States -A Retrospective Cohort Study

> **Xiaofeng Zhou,** Qing Liu, Rongjun Shen, Charles Wentworth, Richard Gong, Leo Russo. (United States)

3989 Potential Utility of a Novel Aggregated US Electronic Medical Record Database: Renal Transplant Pilot

> **Rachel E Sobel,** Robert J Taylor, Stacey N. Purinton, Aaron Berger. (United States)

4095 Using Self-reported Outcomes to Detect New-onset Flare in a Real-world Study of Participants with Rheumatoid Arthritis -Interim Results from the Digital Tracking of Arthritis Longitudinally (DIGITAL) Study

> **Jeffrey R Curtis,** Virginia S Haynes, Fenglong Xie, Ilya Lipkovich, Hong Zhao, Carol Kannowski, Jiat L Poon, Kelly Gavigan, David Curtis, Sandra Nolot, W Benjamin Nowell. (United States)

4105 Two Machines are Better Than One: Using Multi-agent Reinforcement in Machine Learning to Simulate a Clinical Second Opinion

Cao Xiao, Junyi Gao, Lucas Glass, Jimeng Sun, Christina Mack. (United States)

4106 Agreement Between Administrative Database and Medical Chart Review for the Prediction of Chronic Kidney Disease Stage

> **Sylvie Perreault,** Louise Roy, Michael Zappitelli, Brian White-Guay, Jean-Philippe Lafrance, Marc Dorais. (Canada)





4125 Real World Evidence of Graft Survival in Four Types of Transplants: Fifteen Years Analysis in Brazil

Ludmila P Gargano, Túlio T Sarmento, Natália C Freitas, Guilherme F Nascimento, Rosângela M Gomes, Lucas L Torres, Carolina M Ferreira, Carolina Z Dias, Isabella F Zuppo, Francisco A Acúrcio, Juliana Álvares-Teodoro, Augusto A Guerra. (Brazil)

4136 Weight Gain Following Antiretroviral Therapy (ART) Initiation in ART-naive Participants in the Current Treatment Era

> **Stephanie Ruderman,** Heidi Crane, Robin Nance, Bridget Whitney, Barbara Harding, Kenneth Mayer, Richard Moore, Joseph Eron, William Mathews, Benigno Rodriguez, Michael Saag, Amanda Willig, Sara Lindstrom, Brian Wood, Ann Collier, Greer Burkholder, Mari Kitahata and Joseph Delaney. (United States)

4142 Defining Phenotypes of Women with Endometriosis Undergoing Hysterectomy or Oophorectomy Using Machine Learning

> **Andrea K Chomistek,** Cheryl Enger, Stacey A Missmer, Stephanie J Estes, Jenna F Calderbank, Michael C Doherty, Stephanie E Chiuve. (United States)

4225 Incidence of Community-acquired Pneumonia in China: A Nationwide Claims Database Analysis

> **Yixin Sun,** Yinchu Cheng, Siyan Zhan. (China)

4266 Changes in Serum Creatinine Values During and After Pregnancy in a Cohort of Women with or without Pre-existing Chronic Kidney Disease

> **Carole Marxer,** Katrina W. Hagberg, Rishi J. Desai, Julie M. Paik, Susan S. Jick, Christoph R. Meier, Julia Spoendlin. (Switzerland)

4274 Utilising Mobile and Web-based Technology for Capturing Patient Specific Information: Methods from the DISCOVER CKD Program

Glen James, Juan Jesus Carrero, Jenny Wei, Gary Curhan, Eric Wittbrodt, Steven Fishbane, Carol Moreno Quinn, Hiddo Heerspink, Katarina Hedman, Eiichiro Kanda, Tony Chen, Naoki Kashihara, Björn Holmqvist, Mikhail Kosiborod, Peter Fenici, Mitja Lainscak, Jennie Medin, Carolyn Lam, Roberto Pecoits-Filho, Carol Pollock, Peter Stenvinkel and David Wheeler. (United Kingdom)

4377 Population Trends in the 10-year Prevalence and Incidence of Psoriasis and Psoriatic Arthritis in Taiwan: A Nationwide, Population-based Cohort Study

> **Ireny Y. Iskandar,** Teng-Chou Chen, Li-Chia Chen, Meng-Sui Lee, K. Arnold Chan, Christopher E. Griffiths, Darren M. Ashcroft. (United Kingdom)

4390 Assessing Comorbid Inflammatory Arthritis Conditions and Swollen to Tender Joint Count Ratios in a Real World Systemic Lupus Erythematosus Cohort

> **Cristi Cavanaugh,** Greg Donadio, Kathryn Starzyk, Kathleen Mortimer, Michael Behling, Gary Curhan, Rich Gliklich. (United States)

4413 Description of COPD Patients Treated with Multiple Inhaler Triple Therapies (MITT) Using the CPRD GOLD and CPRD Aurum Electronic Health Record (EHR) Databases

> **Gema Requena,** Leah Sansbury, Achim Wolf, Rachael Williams, Jennifer Quint, Daniel Dedman, Jeanne M Pimenta. (United Kingdom)

4417 Enhancing Model Interpretability and Accuracy for Disease Progression Prediction via Phenotype-based Patient Similarity Learning

> **Christina Mack,** Yue Wang, Fan Zhang, Corey M. Benedum, Yunlong Wang, Emily Zhao. (United States)





4420 The Incidence of Acute Pancreatitis in the United States: Identification of Cases in an Electronic Healthcare Database with Supportive Laboratory Evidence

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> **Lu Xu,** Bo Wang, Limai Mansai, Qihuan Li, Cheng Jin, Siyan Zhan, Yi Ning. (China)

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> **Lu Xu,** Shuqing Yu, Zhirong Yang, Sanbao Chai, Yuan Zhang, Feng Sun, Siyan Zhan. (China)



2432 Comparative Effectiveness of Statins and Fibrates for Primary Prevention of Cardiovascular Disease and Mortality: A Cohort Study

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> **Christine Cramer,** Franz Schramel, Bas Peters, John van Putten, Olaf Klungel, Harry Groen, Ewoudt van de Garde. (Netherlands)

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> **Alejandro Szmulewicz,** Brian Bateman, Raisa Levin, Krista Huybrechts. (United States)

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> **Sherif Eltonsy,** Monique Dufour Doiron, Patrice Simard, Caroline Jose, Martin Senecal, Danielle Bouchard, Remi LeBlanc, Mathieu Belanger. (Canada)

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4234 Real-world Effectiveness of Mood Stabilizer Use in Persons with Schizophrenia

> **Arto Puranen,** Marjaana Koponen, Lähteenvuo Markku, Antti Tanskanen, Jari Tiihonen, Heidi Taipale. (Finland)

4238 Midodrine for Prevention of Intradialytic Hypotension in High Risk Patients at a Tertiary Referral Hospital: A Retrospective Study

> **Saja Alhabardi,** Maryam Aldhaefi, Mohammed Alessa, Maha Alammari, Yousef Alrajhi, Rami Bustami. (Saudi Arabia)

4289 Lithium Use in Patients with Bipolar Disorder in Inpatient Care and Readmission: A Prospective Cohort Study in the Central Denmark Region in 2015-2018

> **Kazi Ishtiak-Ahmed,** Louise Meyer, Christiane Gasse, Søren Dinesen Østergaard. (Denmark)

4333 Use of Thiazolidinediones and Glucagonlike Peptide-1 Receptor Agonists and the Risk of Non-alcoholic Fatty Liver Disease

> **Johanna H Driessen,** Judith van Dalem, Andrea M Burden, Coen D Stehouwer, Olaf H Klungel, Frank de Vries, Martijn C Brouwers. (Netherlands)

4337 Impact of Multiple Cardiovascular Medications on Mortality After an Incidence of Ischaemic Stroke or Transient Ischaemic Attack: A 10-year Cohort Study

> **Tiantian Ma,** Ian CK Wong, Cate Whittlesea, Zixuan Wang, Kenneth KC Man, Wallis Lau, Ruth Brauer, Li Wei. (United Kingdom)



4340 Rationale, Design and Feasibility of Conducting a Real-world Study of Outcomes in Patients with a History of MI Receiving Extended DAPT with Ticagrelor 60 mg

> **Eva Lesén,** Chris Hewitt, Evangelos Giannitsis, Jonatan Hedberg, Tomas Jernberg, Dimitra Lambrelli, Daniel Lindholm, Aldo P. Maggioni, Jennie Medin, Anna Schultze, Albert Ariza Solé, Robert F. Storey, Karolina Andersson Sundell, Jurrien ten Berg, Narinder Bhalla and Marc Bonaca. (United States)

4342 Differences Between Randomized Clinical Trial Participants and Real-world Empagliflozin Users and the Changes in Their Glycated Hemoglobin Levels

> **Nicolai E Munk,** Jakob S Knudsen, Anton Pottegård, Daniel R Witte, Reimar W Thomsen. (Denmark)

4457 Comparative Safety of JAK Inhibitors in Patients with Rheumatoid Arthritis: A Network Meta-analysis of Clinical Trials

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4461 Comparative Risk of Infections Among JAK Inhibitors Used in Rheumatoid Arthritis: A Network Meta-analysis of Clinical Trials

> **Carlos Alves,** Diogo Mendes, Ana Penedones, Francisco Batel Marques. (Portugal)

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> **Tiffany Cristarella,** Mareva Faure, Genaro Castillon, Jean-François Nepveu, Yola Moride. (Canada)

4506 Use of Glycolsis Enhancing Medications is Associated with a Decreased Risk of Developing Parkinson's Disease

> **Jacob E Simmering,** Nandakumar Narayanan, Lei Liu, Michael J Welsh, Anton Pottegård. (United States)

4517 Hypothetical Intervention of Sodiumglucose Cotransporter-2 Inhibitors on Renal Outcome in Type 2 Diabetes

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4522 Comparative Effectiveness of Amoxicillinclavulanate versus Metronidazole and a Fluoroquinolone on Hospital Admission Risk Among Outpatient Diverticulitis Patients in the United States, 2000-2005

> **Charles E Gaber,** Anne F Peery, Jessie K Edwards, Jennifer L Lund, Til Stürmer, Sharon Peacock-Hinton, Robert S Sandler, Alan C Kinlaw. (United States)

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> **Chin-Yao Shen,** Philip Chun-Ming Au, Yeon-Hee Baek, Ching-Lung Cheung, Wei-Pang Chung, Seasea Nan Gao, Yea-Huei Kao Yang, Nora Kleinman, Ju Hwan Kim, Jeff Lange, Tzu-Chi Liao, Tzu-Chieh Lin, Ju-Young Shin, Chor-Wing Sing, Ian Chi Kei Wong and Edward Chia-Cheng Lai. (Taiwan)

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> **Nicholas Byron Hunt,** Johanna Emmens, Sylvi Irawati, Jens H Bos, Bob Wilffert, Eelko Hak, Rudolf A. de Boer. (Netherlands)



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> **Raj Desai,** Steven Smith, Rajesh Mohandas, Haesuk Park. (United States)

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> **Jifang Zhou,** Nadia Nabulsi, Alemseged Asfaw, Inyoung Lee, Colin Hubbard, Gregory Calip. (United States)

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> **Carline van den Dries,** Rianne van den Ham, Patrick Souverein, Romin Pjouheshnia, Geert-Jan Geersing, Sander van Doorn. (Netherlands)

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> **Salka Enners,** Marita Kieble, Ulrike Rudolph, Felix Mahfoud, Michael Böhm, Ulrich Laufs, Martin Schulz. (Germany)



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> **Katharina T Jungo,** Fabian Schalbetter, Michael J Deml, Sven Streit. (Switzerland)

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4768 Implementing the HOUVAST 2.0 Intervention in the Dutch Primary Care, Lessons Learned from a Process Evaluation

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> **Payam Peymani,** Marten van den Berg, Bruno Stricker, Fariba Ahmadizar. (Switzerland)

4817 Preventive Effect of Antiplatelet Salicylates in Individuals with Type 2 Diabetes-The Rotterdam Study

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4916 Valproate Utilisation Trends Among Women of Child-bearing Potential in Ireland Between 2014 and 2017: A Drug Utilisation Study Using Interrupted Time Series

> **John Hughes,** Maeve Mullooly, Niamh Buckley, Yvonne Looney, Kathleen Bennett. (Ireland)

4943 Low-dose Aspirin Use for Primary or Secondary Prevention of Cardiovascular Diseases in Patients with Type 2 Diabetes

> **Payam Peymani,** Najmeh Maharlouei, Azra Izanloo, Amir Hooshang Mohammadpour, Abbas Rezaianzadeh, Fariba Ahmadizar. (Switzerland)

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> **Edeltraut Kröger,** Carolina Tisnado-Garland, Line Guénette, Marie-France Demers, Philippe Voyer, Pierre-Hugues Carmichael, Jason R Guertin, Machelle Wilchesky, Krista Lanctöt, Nathan Herrmann, Caroline Sirois, Rachel Rouleau. (Canada)

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2400 Inequities in Primary Care Attachment Among People Receiving Opioid Therapy

> **Tonya Campbell,** Richard Glazier, Laura Robertson, Diana Martins, J. Michael Paterson, David Juurlink, Muhammad Mamdani, Tara Gomes. (Canada)

2550 Ability of Primary Healthcare Records to Assess Medicinal Products Discussed by the Pharmacovigilance Risk Assessment Committee

> **Robert Flynn,** Karin Hedenmalm, Tarita Murray-Thomas, Alexandra Pacurariu, Peter Arlett, Hilary Shepherd, Puja Myles, Xavier Kurz. (Netherlands)



2617 Prescribing Trends of Direct Acting Antivirals for the Treatment of Hepatitis C in Ontario

> **Mina Tadrous,** Kate Mason, Bernadette Lettner, Mary Guyton, Zoë Dodd, Jeff Powis, Diana Martins, Tara Gomes. (Canada)

2622 Impact of Two Recent Major Drug Shortages on Drug Utilization

> **Mina Tadrous,** Katie Suda, Tara Gomes. (Canada)

2646 Strategies to Approach the Judicialization of Health Technology in Latin America and Caribbean

> **Sueli Miyuki Yamauti,** Luciane Cruz Lopes. (Brazil)

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> **Shinobu Imai,** Anna Kiyomi, Munetoshi Sugiura, Kiyohide Fushimi, Karolina Andersson Sundell. (Japan)

3823 Establish a Model for Mapping Chinese Indication with ICD-10-CM in Taiwan: Using Antipsychotics as Examples

> **Chien Chou Su,** Ching-Lan Cheng, Yi-Wei Wu, Yea-Huei Kao Yang. (Taiwan)

3911 Serious Adverse Events with High-cost Drugs Accessed Through Litigation in Brazil

> **Ricardo Eccard da Silva,** Elisângela da Costa Lima, Maria Rita C Novaes, Claudia Garcia Serpa Osorio-de-Castro. (Brazil)

3944 Citizenship Status and the Prevalence, Treatment, and Control of Cardiovascular Disease Risk Factors in United States, 2011-2016

> **Jenny S Guadamuz,** Ramon Durazo-Arvizu, Martha L Daviglus, Gregory S. Calip, Edith A. Nutescu, Dima M Qato. (United States)

3950 Impact of Branded Generics on the Price of Anti-dementia Products in South Africa

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3986 Unblocking the Barriers of Access to Direct-acting Antiviral-based Hepatitis C Treatment in China: Lessons Learnt from Tianjin City

> **Peiwen Zhang,** Ran Guo, Jun Lian, Mengjia Zhi, Chengzhen Lu, Weishen Wu, Lihong Wang, Polin Chan, Zhongdan Chen, Jing Sun, Yuanli Liu. (China)

4062 Medication Calculation Errors with Moderate, Severe and Fatal Patient Outcomes: Findings from the Norwegian Incident Reporting System

> **Alma Mulac,** Katja Taxis, Ellen Hagesæther, Anne Gerd Granas. (Norway)

4209 Utilization and Expenses of Traditional Chinese Patent Medicines in Cancer Treatment: A Retrospective Study on Outpatients' Prescriptions

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4254 Real World Data to Identify Target Population for New CAR-T Therapies

> **Valeria Belleudi,** Francesco Trotta, Filomena Fortinguerra, Francesca Romana Poggi, Odoardo Olimpieri, Enrica Santelli, Ilaria Cozzi, Paola Michelozzi, Antonio Addis. (Italy)

4394 The Rise and Fall of Prescription Fentanyl

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4424 Development and Testing of a Digital Observational Tool to Monitor Bar Code Medication Administration

> **Alma Mulac,** Rune Kristiansen, Synne Margrethe Nielsen, Yvonne Andersson, Sandra Rut Eikeland, Katja Taxis, Ellen Hagesæther, Anne Gerd Granas. (Norway)

4454 Accelerated vs Regular Approval, Differences in Study Characteristics of Lung Cancer Treatments Approved by the US Food and Drug Administration

> **Tatiane Ribeiro,** Lewis Buss, Sanni Ali, Moacyr Nobre. (Brazil)



4490 Association of Formulary Exclusions and Restrictions for Opioid Alternatives with Opioid Prescribing Among Medicare Beneficiaries

> **Tanvi Rao,** Zippora Kiptanui, Paul Dowell, Corey Triebwasser, G. Caleb Alexander, Ilene Harris. (United States)

4563 Triptans-utilization Study for Regulatory Action on Medication-overuse Headache: Using Nation-wide Claim Database in Japan

> **Sono Sawada,** Haruka Shida, Kazuhiro Kajiyama, Mikiko Kubo, Yoko Takaashi, Chieko Ishiguro, Yoshiaki Uyama. (Japan)

4734 Comparing Opioid Regulations Globally Across Regions with Different Levels of Opioid Utilisation

> **Teng-Chou Chen,** Björn Wettermark, Douglas Steinke, Gillian Caughey, Mina Tadrous, Veronika Wirtz, Li-Chia Chen. (United Kingdom)

4846 Over 2000 Seniors Initiate Second-line Osteoporosis Pharmacotherapy Monthly in Ontario - Impact of Drug Policy Change and Call for Research

> Natalia Konstantelos, Nancy He, Kaley N Hayes, Suzanne M Cadarette. (Canada)

4883 Impact of Meningioma Risk Minimization Campaign on Cyproterone Acetate Use in France

> **Camille Morival,** Marine Penichon, Clément Mathieu, Natapy Attoumi, Louis Letinier, Amandine Gouverneur, Antoine Pariente, Julien Bezin. (France)

4892 Ecuador's Administrative Data Sources for Drug Utilization Research

> **Mónica Tarapues,** Carlos Durán, Belén Mena, Patricia Granja, Lisiane Leal, Monique Elseviers, Luciane Cruz. (Ecuador)

4990 Ondansetron in Pregnancy: Patterns of Usage and Characteristics of Patients in UK General Practice

> **Jim Slattery,** Hedvig Nordeng. (Netherlands)

5014 Key Evidence Supporting Prescription Opioids Approved by the U.S. Food and Drug Administration, 1997-2018

> **James Heyward,** Thomas J. Moore, Jennifer Chen, Kristin Meek, Peter Lurie, Caleb Alexander. (United States)

5040 Pain Management Curricula within Health Professional Schools in the United States: A Landscape Analysis

> **James Heyward,** Beth Hogans, Jacob Christopher, Caleb Alexander. (United States)

5058 Drug Use Research in Peru: Is Real-world Data Available?

Yesenia Rodríguez, Maribel Salas, Lisiane Leal, Monique Monique, Luciane Cruz Lopes. (Peru)

5118 Data Sources for Health Care Decision Making in Mexico: Challenges and Strength (Mexican Working Group on DUR)

> **Diana Gomez,** Svetlana Doubova, Anahí Dreser Mansilla, Juan Carlos Sanchez Salgado, Lucila Castro Pastrana, Yared Santa Ana Tellez, Elena Ibarra Cazares, Isabel Hernández Lira, Lisiane Leal, Maribel Salas, Monique Elseviers, Luciane Cruz Lopes. (Mexico)

- Drug Utilization Research » Other
- 44 Access to Insulin; a Success Story from the Sudan

Isam Eldin Mustafa. (Sudan)

2329 Pattern and Risks Perception of Medical Drugs Use Among Adults in Rural and Urban Communities, Southwest, Nigeria

Waheed Adedeji, David M Dairo, Patrick Nguku, Fatai A Fehintola. (Nigeria)

2330 Real - World Data Analysis of Potential Drug - Drug Interactions in Greek Community Pharmacies

> **Georgios Poulentzas,** Panagiotis Nikolaos Lalagkas, Lampros Tsiolis, Dimitra Hadjipavlou - Litina, Eleftherios Berberoglou, Antonios Douros, Christos Kontogiorgis, Theodoros Constantinides. (Greece)



2343 Women are Started on a Lower Daily Dose of Metoprolol Than Men Irrespective of Dose Recommendations

> **Linda C. Hendriksen,** Paul D. van der Linden, Katia M. Verhamme, Bruno H. Stricker, Loes E. Visser. (Netherlands)

2397 The Association Between Dental Opioid Prescription Characteristics and the Risk of Long-term Use and Overdose

Tonya Campbell, Diana Martins, Mina Tadrous, David Juurlink, J. Michael Paterson, Muhammad Mamdani, David Mock, Tara Gomes. (Canada)

2423 Psychotropic Medication Use in Former ICU Patients with Mental Health Problems: A Prospective Observational Follow-up Study

> **Debbie G Janssen,** Joep Jonker, Diederik van Dijk, Eibert R Heerdink, Toine C Egberts, Arjen J Slooter. (Netherlands)

2513 Pain Severity and Analgesics Use in the Community-dwelling Older Population. A Drug Utilization Study from Germany

> **Thi N Nguyen,** Dana C Laetsch, Li-Ju Chen, Walter E Haefeli, Andreas D Meid, Hermann Brenner, Ben Schöttker. (Germany)

3719 St. John's Wort: Utilization During Pregnancy and Pregnancy Outcomes

Wiebke Schaefer, Nadine Wentzell, Ulrike Haug. (Germany)

3732 Antidepressant Use Among Adults Patients in Primary Care in Brazil: Results of a National Survey

> **Natalia P Torres,** Juliana Alvares Teodoro, Augusto Afonso Junior, Francisco A Acurcio. (Brazil)

3748 Variations in Long-term Opioid Use Definitions in Observational Research: A Systematic Review of Studies Using Routinely Collected Data

> **Juliana de Oliveira Costa,** Claudia Bruno, Navya Baranwal, Sallie-Anne Pearson. (Australia)

3819 Biologic Use and Persistence for Crohn's Disease After Intestinal Resection in the United States 2002-2018

> Joehl T. Nguyen, Edward L Barnes, Swetha Srinivasan, Alan C. Kinlaw. (United States)

3865 Are Aclidinium and Aclidinium/ formoterol Used According to Their Approved Indication in Europe? Results of a Multicountry Drug Utilization Postauthorization Safety Study

> **Elena Rivero-Ferrer,** Anna Julia Witzleb, Morten Olesen, Estel Plana, Jaume Aguado, Nuria Saigi-Morgui, Annalisa Rubino, Sami Z Daoud, Alejhandra Lei, Susana Perez-Gutthann, Tania Schink, Nina S Kristiansen, Anton Pottegård, Cristina Rebordosa. (Spain)

3879 Trends in First Opioid Prescribing in More Than 600000 Opioid-naïve and Cancer Free Patients in Sweden - Drugs, Doses, and Diagnoses

Carola Bardage, Maria Grünewald, Paulina Tuvendal, Rickard Ljung. (Sweden)

4001 Prevalence of Chronic Drug Use in Pediatrics: Comprehensive Overview Based on German Claims Data

> **Oliver Scholle,** Antje Neubert, Oliver Riedel, Irmgard Toni, Ulrike Haug. (Germany)

4008 Feasibility of Studying the Use of Tissueagnostic Cancer Drugs in Populationbased European Health Databases

> Xabier Garcia de Albeniz, Nuria Riera Guardia, Lia Gutierrez, Shahram Bahmanyar, Patrick Blin, Cécile Droz, Miriam Heinig, Marie Linder, Nicholas Moore, Renate Schulze-Rath, Janet Sultana, Gianluca Trifirò, Wei Wei Zhang, Jihong Zong. (Spain)

4079 Patterns and Trends of Idarucizumab Use in an Italian Region: A Probabilistic Record-linkage Approach in a Real-life Setting

> **Niccolò Lombardi,** Valentina Brilli, Giada Crescioli, Alessandra Bettiol, Ippazio Cosimo Antonazzo, Giampiero Mazzaglia, Stefano Fumagalli, Guido Mannaioni, Alfredo Vannacci, Rosa Gini. (Italy)



4096 Dispensing Practices of Antibiotics by Community Pharmacies in Two Districts of Nepal

> Nisha Jha, Sunil Shrestha, Pathiyil Ravi Shankar. (Nepal)

4151 Statin Use and Melanoma Recurrence

Chrystelle Kiang, Anne Fia Grann, Uffe Heide-Jørgensen, Thomas P Ahern, Timothy L Lash, Henrik Toft Sørensen, Deirdre P Cronin-Fenton. (United States)

4188 Polypharmacy at the Time of Opioid Overdose in Older Adults on Long-term Opioid Therapy

Nazleen F. Khan, Katsiaryna Bykov, Joshua J. Gagne. (United States)

4194 Effects on Seizure Activity of Coprescribing Anti-epileptic Drugs and Antidepressant Medications Among African Americans with Epilepsy

> **Courtney L Schlusser,** Regine Haardoerfer, Nancy J. Thompson. (United States)

4198 Cutaneous Adverse Drug Reactions to Antiretroviral Therapy Among HIVinfected Patients in a Nigerian Teaching Hospital

> **Abdulwasiu A Busari,** Kazeem A Oshikoya, Divine-Favour C Imoh, Ibrahim A Oreagba. (Nigeria)

4240 (In) appropriate LAMA Prescribing in Asthma Patients: A Cohort Analysis (the Alpaca Study)

> **Christina Hoeve,** Esme Baan, Maria de Ridder, Leis Demoen, Lies Lahousse, Guy Brusselle, Katia Verhamme. (Netherlands)

4265 Identification of Clinical Cases to Educate Pharmacists on Medicationrelated Problems Leading to Hospital Readmissions After Discharge

> **Selma En-nasery - de Heer,** Elien B Uitvlugt, Patricia M van den Bemt, Bart J van den Bemt, Pierre M Bet, Eleonora L Swart, Fatma Karapinar, Jacqueline G Hugtenburg. (Netherlands)

4281 Impact of Medication Adherence on Mortality and Cardiovascular Morbidity After Acute Coronary Syndrome: Population-based Cohort Study

> **Gerard Sotorra-Figuerola,** Dan Ouchi Vernet, Rosa Morros, Maria Giner-Soriano. (Spain)

4293 Evidence Based Practice in Supplying of Over the Counter Medicines in Community Pharmacies. A Mixed Methods Study

> **Nada Alobaid,** Hind Aboheimed, Areej Alhumsi, Ghada Aboheimed, Nouf Aloudah, Noura Aboheimed. (San Marino)

4408 Data Sources Publicly Available in Brazil for Drug Utilization Research

Lisiane F Leal, Claudia G Osorio-de-Castro, Felipe Ferre, Ivan R Zimmermann, Daniel M Mota, Izabela Fulone, Marta M Fonteles, Andre O Baldoni, Monique Elseviers, Luciane C Lopes. (Canada)

4425 Assessing the Feasibility of Evaluating Tacrolimus Use After Solid Organ Transplantation in Sentinel Distributed Database

> **Mingfeng Zhang,** Sarah Dutcher, Monique Falconer, Nicole Haug, Zhong Wang, Lockwood Taylor, Andrew Petrone, Sheryl Kluberg, Justin Bohn. (United States)

4437 The Prevalence of Polypharmacy in the Elderly Population: A Multi-country Database Study in Europe

> **Paola Nasuti,** Marion Bennie, Katja Taxis, Shruti Menon, Julien Trehony, Laurence Sophie Jouaville Abrouk, Monique Elseviers, Elisabetta Poluzzi, Catherina Sermet, Sean MacBride Stewart, Ingrid Schubert. (United Kingdom)

4463 Instruments to Measure Medication Literacy: A Scoping Review

Lais L Pantuzza, Elizabeth do Nascimento, Stephanie F Botelho, Maria Auxiliadora P Martins, Adriano M Reis. (Brazil)



4512 Defining Potential Exposure Periods from Prescription Medical Records of Nitrates Taken on an As-needed Basis

> **Anthony P. Nunes,** Andrew Stewart, Alankar Gupta, Thomas McGraw, Jennifer Song, John D Seeger. (United States)

4521 Switching of Second Generation Antipsychotics in Patients with Severe Mental Disorders: A Cohort Study

> **Izabela Fulone,** Marcus Tolentino Silva, Luciane Cruz Lopes. (Brazil)

4542 Mapping for Pre-existing Large-scale Observational Databases for Acute Coronary Syndrome in China

Meng Su, Fuchun Li, Shusen Liu. (China)

4547 A Scoping Review on Users of Medical Cannabis Against Chronic Non Cancer Pain

> **Edeltraut Kröger,** Daniela Furrer, Martine Marcotte, Nathalie Jauvin, Michele Aubin, Richard Bélanger, Guillaume Foldes-Busque, Mark Ware, Pierre Pluye, Clermont E Dionne. (Canada)

4565 Evaluating the Performance of a Novel Urine-based Point-of-care Assay for Assessing Prep Adherence for HIV Prevention

> **Randy M Stalter,** Jared M Baeten, Deborah Donnell, Matthew A Spinelli, David V Glidden, Warren C Rodrigues, Guohong Wang, Michael Vincent, Nelly Mugo, Andrew Mujugira, Mark A Marzinke, Craig Hendrix, Monica Gandhi. (United States)

4704 Acceptance of Real World Data Use in Evidence-based Medicine or Decision Making by Committee Members Affiliated with the Saudi Food and Drug Authority

Fawaz Alharbi, Atheer Aldayel, Adel Alrwisan. (Saudi Arabia)





4710 Assessing the Feasibility of Leveraging Healthcare Databases to Conduct Cross-national Comparisons of Opioid Utilisation

> **Teng-Chou Chen,** Björn Wettermark, Douglas Steinke, Gillian Caughey, Mina Tadrous, Veronika Wirtz, Li-Chia Chen. (United Kingdom)

4798 Non Antibiotic Medication Use in Children in Indonesia

> **Jarir At Thobari,** Cahya Dewi Satria, Yohanes Ridora, Jullie Bines, Yati Soenarto. (Indonesia)

4845 Linking Regional Administrative Data with an Hospital Pathology Registry in Italy to Describe First-line Pharmacotherapy of Non-resectable Nonsmall Cell Lung Cancer in 2009-2017

> Andrea Spini, Giuseppe Roberto, Cristiana Bellan, Alessandra Pascucci, Pietro Rosellini, Adele Caldarella, Alessandro Barchielli, Sandra Donnini, Folco Furiesi, Lorenzo Leoncini, Silvano Giorgi, Claudia Bartolini, Marco Zappa, Marina Ziche, Francesco Salvo and Rosa Gini. (Italy)

4849 Drug Utilization Study of the Medicinal Combination Product Conjugated Oestrogens/bazedoxifene in the European Union

> **Dorothea von Bredow,** Margarita Shlaen, Vera Frajzyngier, Nikolaus Kolb, Barbara Thun, Leo Russo, Jacco Keja. (Germany)

4870 Outpatient Antibiotic Use in Chinese Pregnant Women

Houyu Zhao, Jiaming Bian, Siyan Zhan. (China)

4896 Characterizing Concurrent Use of Gabapentin with Opioid Analgesics Among Kentucky Residents with Longterm Opioid Prescriptions, 2018

> **GYeon Oh,** Svetla Slavova, Patricia R. Freeman. (United States)

5012 Persistence with Teriparatide Treatment in Osteoporotic Patients: A Populationbased Study Using Italian Regional Databases

> **Andrealuna Ucciero,** Andrea Sarro, Alessandro Pecere, Francesco Barone-Adesi. (Italy)

5028 Real World Use of Opioids in COPD Patients

> **Katia Verhamme,** Marie Clyncke, Lies Lahousse, Esme Baan, Guy Brusselle. (Netherlands)

5037 Quality of Life in Treatment-experienced Multiple Myeloma Patients: A Comparative Analysis of Therapeutic Regimens

> **Jéssica S Malta,** Paula L Drummond, Lívia P Silveira, Naiane L Costa, Taisa R Machado, Roberta M Santos, Adriano M Reis, Cristiane A Pádua. (Brazil)

5050 Adherence to Immunomodulatory Drugs in Brazilian Patients with Multiple Myeloma

> **Lívia Pena Silveira,** Paula Lana de Miranda Drummond, Jéssica Soares Malta, Naiane Lima Costa, Roberta Márcia Marques dos Santos, Taísa Roberta Lopes Machado, Adriano Max Moreira Reis, Cristiane Aparecida Menezes de Pádua. (Brazil)

5071 Effect of an Educational Program on the Medication Adherence in Adult Patients at Transition of Care

> **Jimmy Reyes,** Carolina Bobadilla, Carlos Silva, Natalia Carrillo, Cristóbal Gutiérrez, Tamara Sandoval, Marcela Jirón. (Chile)

5160 Drug Use During Pregnancy According Risk Classification and Associated Factors

> **Caroline T de Castro,** Débora B Costa, Djanilson B dos Santos. (Brazil)



Drug Utilization Research » Quality Use of Medicines (including indicators and guidelines)

40 A Retrospective Audit of the Management of Childhood Acute Asthma Exacerbation in Children: Adherence to Global Treatment Guidelines

> **Kazeem Adeola Oshikoya,** Ibrahim Abayomi Ogunyinka, Shallom Ese Imuzie. (Nigeria)

119 Potentially Inappropriate Psychotropic Medications Use Among Older Adults with Psychiatric Disorders in the Jazan Region, Saudi Arabia

> **Abdulkarim M. Meraya,** Otilia J Banji. (Saudi Arabia)

2367 Disposal of Leftover Medicines: Prevalence and Practices Among the Rural Population of Kerala

> **Jose J Kochuparambil,** Akshay Nidha, Aleena Issac. (India)

2398 Trends in Acid Suppressant Drug Prescriptions in Primary Care in the United Kingdom

> **Devin Abrahami,** Emily Gibson McDonald, Mireille Schnitzer, Laurent Azoulay. (Canada)

2402 Utilization of Hydroxyprogesterone During the 2nd or/and 3rd Trimester Among Pregnancies with Live Birth Deliveries in the Sentinel Distributed Databases

> **Huei-Ting Tsai,** Mayura Shinde, Austin Cosgrove, Jie Li, Christina Chang, Christine P Nguyen, Corinne M Woods, Joy Kolonoski, Tiffany Siu Woodworth, David Moeny. (United States)

2490 Comparison of a New Three-item Selfreported Measure of Adherence to Medication with Pharmacy Claims Data

Julie C Lauffenburger, Constance P Fontanet, Thomas Isaac, Chandrasekar Gopalakrishnan, Thomas D Sequist, Joshua J Gagne, Cynthia A Jackevicius, Michael A Fischer, Daniel H Solomon, Niteesh K Choudhry. (United States) 2517 Almost Half of Seniors Initiating Oral Bisphosphonate Therapy are Exposed for 3 or More Years - Understanding the Benefits and Harms of Prolonged Therapy is Needed

> **Kaleen N Hayes,** Kevin Brown, Angela Cheung, David Juurlink, Nancy He, Suzanne M Cadarette. (Canada)

2520 Anti-hypertensive Drug Prescribing Pattern, Adherence to Guidelines and Blood Pressure Control at a Teaching Hospital in Ghana

> **Mark Amankwa Harrison,** Kwame O Buabeng, Afia F Marfo, Florence A Nkansah, Franklin Acheampong, Godwin Gulbi, Daniel K Arhinful, Daniel N Ankrah. (Ghana)

2543 Community Pharmacy Practice Evaluation in the United Arab Emirates Using Simulated Patients with Common Cold

> **Subish Palaian,** Muaed Al Omar, Nageeb Hassan, Dina Mourad, Waad Ahmed, Arig Ewida. (United Arab Emirates)

2603 Antihypertensive Polytherapy in Australia: Prevalence of Inappropriate Combinations, 2013-2018

> **Michael O Falster,** Nicholas A Buckley, David Brieger, Sallie-Anne Pearson. (Australia)

2604 Long-term Trajectories of Medicine Use Among Older Adults Experiencing Polypharmacy in Australia

> **Michael O Falster,** Rayan Charrier, Sallie-Anne Pearson, Nicholas Buckley, Benjamin Daniels. (Australia)

3740 Quality of Buprenorphine Care for Opioid Use Disorder

> **Kelly E Anderson,** Julia Eckstein, Christine E Chaisson, Sarah H Scholle, Lauren Niles, Sydney M Dy, Brendan Saloner, G Caleb Alexander. (United States)

3763 Patterns of Direct-acting Antivirals (DAAs) Use for Hepatitis C: A Populationbased Cohort Study in France

> **Anne Bénard-Laribière,** Elodie Pambrun, Elisabeth Polard, Pernelle Noize, Antoine Pariente. (France)



3803 Assessment of Drug Utilisation Evaluation of Anti Retroviral Therapy and Medication Adherence Behaviour of Patients Receiving Medication at a District Hospital in South India

> **Adepu Ramesh,** Sonali Bendeskar, Akhila Gandikota, Divya Ramulakollu. (India)

3849 Medication Errors: A Perspective from Four Hospitals in Rural Kenya

Perpetua Karanja. (Kenya)

3878 The Opioid Epidemic in the Netherlands, Causes and Consequences

> **Ajda Bedene,** Eveline L. van Dorp, Tariq Faquih, Suzanna C. Cannegieter, Dennis O. Mook-Kanamori, Marieke Niesters, Monique van Velzen, Maaike G. Gademan, Frits R. Rosendaal, Marcel L. Bouvy, Albert Dahan, Willem M. Lijfering. (Netherlands)

3936 Prescribed Daily Doses of Anti-dementia Drugs in South Africa: A Database Analysis

Ilse Truter. (South Africa)

3941 A Descriptive Study of the Clinical Experiences of Healthcare Providers with the Use and Quality of Oxytocin Injection Across the Six Geo-political Zones of Nigeria

> **Chioma S Ejekam,** Chimezie Anyakora, Florence Nyangara, Jude Nwokike. (Nigeria)

3954 Anti-diabetic Drug Utilization Knowledge and Glycemic Index Control in Patients with Uncontrolled Diabetes Mellitus

Naima Ahmed Tamanna. (Bangladesh)

4046 Titration: Where is the Real-world Evidence?

Aisling R Caffrey, Eric P Borrelli. (United States)

4048 Fracture Rates in Patients Discontinuing Alendronate Treatment in Real-life: A Nationwide Cohort Study

> **Bianka Darvalics,** Anne Sophie Sølling, Diana H. Christensen, Torben Harsløf, Reimar W. Thomsen, Bente Langdahl. (Denmark)



4049 Inappropriate Empiric Treatment with Antibiotics in a Tertiary Hospital, in Kenya

> **Zaietuni A. Mulaa,** Maureen Nerima, Hilda K. Daywa. (Kenya)

4189 Valproate Prescribing Practices Before and After Implementation of Risk Minimisation Measures (RMMs) in 5 European Countries

Massoud Toussi, Florence Coste, Margarita Shlaen, Dimos Vasilis, Sigal Kaplan. (France)

4247 Use of Medication Among Nursing Home Residents: A Danish Drug Utilization Study

> **Carina Lundby,** John Jensen, Søren Post Larsen, Helene Hoffmann, Anton Pottegård, Mette Reilev. (Denmark)

4285 Adherence and Persistence to Methylphenidate in Children in the Netherlands

Chii Chyi Cheung. (Netherlands)



4299 The Effect of a Pharmacist Intervention on Guideline Adherence for Double and Triple Antithrombotic Therapy in a Clinical Setting

Renate C Uden. (Netherlands)

4304 Treatment Patterns and Medication Adherence Among Newly Diagnosed Migraine Patients: A Drug Utilization Study

> **Sara Mucherino,** Valentina Orlando, Valeria M Monetti, Ugo Trama, Enrica Menditto. (Italy)

4323 Adherence and Risk Factors for Stopping Treatment in a Cohort of Quebec Patients Newly Initiated on Statins (OBSTAT Cohort)

> **Sarasa M Johnson,** Manon Choinière, Michele Bally, Marie-Pierre Dubé, Jean-Claude Tardif, Daniel Gaudet, Jean Bergeron, Hélène Lanctôt, Jacques Lelorier. (Canada)

4325 Trends in Fluoroquinolone Use in the Inpatient and Outpatient Settings in Nairobi, Kenya: A Drug Utilisation Study

> **Sylvia A Opanga,** Yvonne L Isaidi, Antony B Kodiwo, Joy N Waithaka. (Kenya)

4375 Adverse Events Related to Overtreatment for Hypertension in Type 2 Diabetes Patients: Impact of Age and Polypharmacy

> **Martina Ambrož,** Sieta T. de Vries, Klaas Hoogenberg, Petra Denig. (Netherlands)

4455 The Comparison of Drug Use in Children and Adults with Allergy in Primary Care

> **Volkan Aydin,** N Ipek Kirmizi, Omer Atac, Narin Akici, Ahmet Akici. (Turkey)

4518 Qualitative Assessment of Special Instructions or Warnings Provided to Patients Prescribed a Nitrate with a Concurrent Contraindicated Medication

> Anthony P. Nunes, Andrew Stewart, Alankar Gupta, Thomas McGraw, Jennifer Song, John D. Seeger. (United States)

4611 Assessment of World Health Organisation Core Drug Use Indicators in Tertiary Care Hospital of Kathmandu, Nepal: A Crosssectional Study

> **Rakesh Ghimire,** Bijay Bhandari, Nirmal Poudel, Sandesh Pradhan, Shristi Kharel. (Nepal)

4675 Inappropriate Drug Therapy Prescription in Older Outpatients in Italy

> **Federica Galimberti,** Manuela Casula, Elena Olmastroni, Veronica Russo, Enrica Menditto, Alberico L Catapano, Elena Tragni. (Italy)

4689 Differential Missingness of Antibiotic Indications in Claims Data

> **Paula D Strassle,** Rachael K Ross, Ashley H Marx, Zachary I Willis, Claire E Farel, Alan K Kinlaw. (United States)

4712 Utilization of Rotigotine Transdermal Patch in Germany: Results from a Claims Database Study

> **Lars Joeres,** Stephan Luca, Guilhem Pietri, Lisa Zimmermann. (Germany)

4785 Appropriateness of Outpatient Antibiotic Prescribing in China: Nationwide Crosssectional Study

Houyu Zhao, Jiaming Bian, Siyan Zhan. (China)

4805 Use of Adjusted Sequence Symmetry Analysis to Quantify the Impact of a New Diagnosis on Off-label Prescribing: A Case Example with NAFLD and Pioglitazone

Anthony P. Nunes, Danni Zhao, Matthew J. Alcusky. (United States)

4819 Antipsychotics Used to Treat Patients with Severe Mental Disorder in Outpatient Follow-up at a Psychiatric Hospital

Ronaldo Portela, Cristina M Ruas, Helian N Oliveira, Mariana D Lula. (Brazil)



4827	Prevalence and Characteristics of
	Adverse Drug Reaction-related Hospital
	Admissions in Older Patients

Caitriona Cahir, Carmel Curran, Caroline Walsh, David J Williams, Kathleen Bennett. (Ireland)

4834 Pharmacological Treatment of Insomnia in General Practice

> **Mette H Bakker,** Nina A Oldejans, Henriëtte E van der Horst, Jacqueline G Hugtenburg, Pauline Slottje. (Netherlands)

4851 Agreement Between Self-reported Morbidity and Pharmacy Claims Data for Prescribed Medications in a Community Based Population

> **Clionadh Mannion,** John Hughes, Frank Moriarty, Kathleen Bennett, Caitriona Cahir. (Ireland)

4922 Bacterial Isolates and Their Patterns of Antibiotic Resistance in the Critical Care Unit of a National Referral Hospital in Kenya

Emmah B Obegi, Margaret N. Oluka, Sylvia A Opanga, Faith A Okalebo. (Kenya)

5015 Influence of Dementia on Medicationrelated Quality of Care in Long-term Aged Care

> **Gillian E Caughey,** Catherine Lang, Janet Sluggett, Steve Wesselingh, Maria C Inacio. (Australia)

5016 Prevalence of and Factors Associated with Chronic Opioid Utilization Among Commercially Insured US Adults with Comorbid Chronic Pain and Mental Health Disorders

> **Abisola Olopoenia,** Linda Simoni-Wastila. (United States)

5034 Linaclotide Utilization and Potential for Off-label Use or Misuse in Three European Countries

> **Javier Cid Ruzafa,** Anna Schultze, Mai Duong, Yi Lu, Robert Donaldson, Darren Weissman, Ahunna Ukah. (Spain)

5059 The Use of Antibiotics without Prescription and the Emergence of Multidrug-resistant Bacteria

Jose J. Hernandez. (United States)

5061 Adherence to Oral Anticoagulant and Antiplatelet Therapies After an Acute Ischemic Stroke or TIA in Atrial Fibrillation Patients

> **Judit Riera-Arnau,** Gabriel Sanfélix-Gimeno, Clara Liliana Rodriguez-Bernal, Daniel Bejarano-Quisoboni, Isabel Hurtado, Aníbal García-Sempere, Salvador Peiró. (Spain)

5075 Concurrent Use of Multiple Antipsychotics Plus Excessive Polypharmacy: Cross-sectional Study of a Vulnerable Population

Maíra R Alves, Rejane C Mayer, Fabiane R Motter, Luciane C Lopes. (Brazil)

5078 The Role of the Patient-provider Relationship in Racial/ethnic Disparities in Nonadherence to Antihypertensive Medications

> **Macarius Donneyong,** Teng-Jen Chang, Autumn Carey, John Bridges. (United States)

5096 Prevalence of Exposure to Highpriority Drug-drug Interactions Among Community-dwelling Non-elderly Adults in Quebec, Canada

> **Araceli Gonzalez Reyes,** Pierre Pluye, Denis Roy, Tibor Schuster. (Canada)

5132 Factors Driving Self-medication with Antimicrobials in Karaikal, India

Devashree Moktan, Syed Ilyas Shehnaz. (India)

5146 Utilization of Antihypertensive Medication in Ghana

> **Macarius Donneyong,** Teng-Jen Chang, Anton Pottegård, Jesper Hallas. (United States)



Drug Utilization Research »Trends and Comparisons

49 Characteristics of New Users of Newer Antidiabetic Drugs in Canada and the United Kingdom

> Vanessa C Brunetti, Audray St-Jean, Sophie Dell'Aniello, Anat Fisher, Oriana HY Yu, Shawn C Budgen, Jean-Marc Daigle, Nianping Hu, Silvia Alessi-Severini, Baiju R Shah, Paul E. Ronksley, Lisa M. Lix, Pierre Ernst, Kristian B Filion, and the CNODES Investigators. (Canada)

103 Time-varying Medication Use and Colectomy for Crohn's Disease and Ulcerative Colitis in the United States 2007-2018

> **Xintong Li,** Edward L Barnes, Virginia Pate, Alan C Kinlaw. (United States)

130 Temporal Trends and Changes in Indication for Opioid Use in Catalonia, 2007-2017: A Population-based Study of 6 Million Individuals

> **Junqing Xie,** Aleksandra Turkiewicz, Gary Collins, Martin Englund, Victoria Y Strauss, D. Prieto-Alhambra. (United Kingdom)

133 Prescription Drug Use in Testicular Cancer Patients: A Danish Nationwide Registry Study

> **Anne Katrine Duun-Henriksen,** Michael Kreiberg, Jakob Lauritsen, Mikkel Bandak, Thomas Wagner, Josephine Rosenvilde, Irene Petersen, Klaus K. Andersen, Christian Dehlendorff, Gedske Daugaard. (Denmark)

2354 Over - the - Counter Drugs: A Pharmacoepidemiological Study in Greece

> **Georgios Poulentzas,** Panagiotis Nikolaos Lalagkas, Theodora Tatsiou, Eleftherios Berberoglou, Dimitra Hadjipavlou -Litina, Christos Kontogiorgis, Theodoros Constantinides. (Greece)

2415 Decreasing Adherence to Antiretroviral Therapy Over 4 Years of Follow-up in a Commercially-insured US Population of Patients with HIV

> **Julie Priest,** Rachel Bhak, Maral DerSarkissian, Cindy Garris, Alan Oglesby, Colin Kunzweiler, Ellie Fuqua, Suna Park, Mei S Duh. (United States)

2450 Prescription Patterns of Outpatients and the Potential of Multiplexed Pharmacogenomic Testing

> **Sze Ling Chan,** Hariz Z Liew, Francis Nguyen, Julian Thumboo, Wan Cheng Chow, Cynthia Sung. (Singapore)

2556 Trends in Gabapentinoid Prescriptions and Coprescription with Opioids in the Four UK Nations

> **Alvi Rahman,** Joseph Kane, François Montastruc, Christel Renoux. (Canada)

2574 Incidence of Anorexia Nervosa and the Prescribing of Psychotropic Medications from UK Primary Care, 1996-2016: A Retrospective Database Study

> **Maedeh Y Beykloo,** Dasha Nicholls, Ian Wong, Mima Simic, Elizabeth Mills, Ruth Brauer. (United Kingdom)

2619 The Impact of Changing Biosimilar Policies for Rheumatic Conditions and Inflammatory Bowel Disease in Ontario, Canada

Mina Tadrous, Daniel McCormack, Sophie Kitchen, Martins Diana, Tara Gomes. (Canada)

2651 Correlation Between Antibiotic Consumption and Resistance at an Intensive Care Unit in Serbia

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Shimonee Shah, Paul Coplan, Safa Saifudeen, Jennifer Wood, Subhadeep Debnath, Shubham Gupta. (United States)

4984 Evaluation of Two Severity Scores and Three Comorbidity Measures in an Administrative Claims Database to Predict Outcomes After Treatment with Intramedullary Nailing in Femur Fractures

Abhishek Chitnis, Bidusee Ray, Mollie Vanderkarr, Chantal Holy. (United States)

4993 Discriminative Ability of Two Severity Scores and Three Comorbidity Measures in an Administrative Claims Database to Predict Outcomes After Treatment with Intramedullary Nailing in Tibial Fractures

Abhishek Chitnis, Bidusee Ray, Mollie Vanderkarr, Chantal Holy. (United States)

5011 Comparison of Discriminative Ability of Two Severity Scores and Three Comorbidity Measures in an Administrative Claims Database to Predict Outcomes After Treatment with Intramedullary Nailing in Humerus Fractures

Abhishek Chitnis, Bidusee Ray, Mollie Vanderkarr, Chantal Holy. (United States)



5022	Reoperations and Risk Factors After
	Intramedullary Nail Fixation of Tibial
	Fractures

Abhishek Chitnis, Mollie Vanderkarr, Bidusee Ray, Chantal Holy, Suzanne Hughson, Michael Blauth. (United States)

5039 New Injury Severity Score: Does It Independently Predict the Treatment with Intramedullary Nailing in Tibial Fractures?

> **Abhishek Chitnis,** Mollie Vanderkarr, Bidusee Ray, Chantal Holy, Zhenna Huang, Charisse Sparks. (United States)

5052 Is a Superficial Infection an Independent Predictor for a Later Deep Incisional Infection in Total Knee Arthroplasty?

> **Abhishek Chitnis,** Deepak Krishnan, Chantal Holy, John Wright. (United States)

5065 Overall Cancer Risk from Exposure to Cobalt Alloys in Orthopedic Implants or Cobalt in Occupational Settings: A Systematic Review and Meta-analysis of Published Epidemiologic Studies

> **Shumin Zhang,** Chantal E. Holy, Gary Eichenbaum, Laura E. Perkins, Laurence B. Katz, Jason R. Brown, Luca Orlandini, Gion Fessel, Behrooz Nasseri-Aghbosh, Natalie S. Egnot, Meijia Zhou, Richard Beech, Stephen R. Marcello, Paul M. Coplan. (United States)

5067 Medical Devices-induced Harm in Peruvian Patients

Yesenia Rodríguez, Elisa Gálvez, Gisela Pecho. (Peru)

5103 Using Social Media to Characterize Adverse Events: A Case Study of Breast Implant Illness

> **Paul Coplan,** Safa Saifudeen, Shimonee Shah, Jennifer Wood, Subhadeep Debnath, Jesse Berlin, Shubham Gupta. (United States)

5130 Comorbidities and Complications Associated with Hernia Repair Using Surgical Mesh in the United States

> **Qiheng Zhou,** Christina DeFilippo Mack, Deb Casso, Susan A. Oliveria. (United States)

Methods in Pharmacoepidemiology » Analytical Methods - e.g., marginal structural models, instrumental variables, sensitivity analyses

2448 Applying Sufficient-cause Principle to Estimate Risks of Adverse Events in the General Indicated Patient Population Should a New Drug is Used

Chuntao Wu, Lin Li, Juhaeri Juhaeri. (United States)

2506 A Weighting Method to Remove Bias from Within-subject Exposure Dependency in Case-crossover Studies

> **Kiyoshi Kubota,** Lan Kelly, Tsugumichi Sato, Nicole Pratt, Libby Roughead, Takuhiro Yamaguchi. (Japan)

2581 Covariate Missingness, Complete Case Analysis, and Transportability, Oh My!

Michael Webster-Clark, Jessie K. Edwards. (United States)

2609 Using Multiple Random Index Dates for Each Patient Improves Precision of Prescription Durations Estimated with the Reverse Waiting Time Distribution

> **Katrine Bødkergaard Nielsen,** Randi Marie Selmer, Jesper Hallas, Lars Jøran Kjerpeseth, Anton Pottegård, Eva Skovlund, Henrik Støvring. (Denmark)

2673 Differential Cancer Screening During Follow-up as a Source of Bias in Pharmacoepidemiology

> **Sophie E Mayer,** Jessie K Edwards, Jesper Hallas, Jennifer L Lund, Til Stürmer. (United States)

3700 Analysing Patient Level Data from Norwegian Registries: Challenges and Considerations

> **Sophie Graham,** Dimitra Lambrelli, Anna Schultze, Robert Donaldson, Waleed Ghanima, Robert Carroll, Maria Ulvestad. (United Kingdom)



3875 Comparing Inverse Probability of Treatment and Standardized Mortality Ratio Weights in a Small Sample Setting

> **Leah J. McGrath,** Alexander Breskin, Bradley Saul, Ying Yu, Michael Kelsh, Kara Kilpatrick, Carrie M. Nielson, M. Alan Brookhart. (United States)

3884 Random Effects Modelling Compared to Logistic Regression for Treatment Effect Estimation in Medical Device Safety: A Simulation Study

> **Mike Du,** M Sanni Ali, Victoria Y Strauss, Daniel Prieto-Alhambra. (United Kingdom)

3971 Random Effects Modelling vs Logistic Regression for the Inclusion of Surgeon Covariates in Propensity Scores for Medical Device Epidemiology: A Simulation Study

> **Mike Du,** M Sanni Ali, Victoria Y Strauss, Daniel Prieto-Alhambra. (United Kingdom)

3972 The Impact of Including Surgeon Covariates in Propensity Score Estimation in Medical Device Epidemiology: A Simulation Study

> **Mike Du,** M Sanni Ali, Victoria Y Strauss, Daniel Prieto-Alhambra. (United Kingdom)

4038 Estimation of Treatment Effects in Registry Data: Informative Patient Visits Require Careful Modeling

> **Thomas P Debray,** Massimiliano Copetti, Robert W Platt, Carl de Moor, Fabio Pellegrini. (Netherlands)

4050 The Performance of Instrumental Variables in Medical Device Epidemiology: A Simulation Study of Non-normally Distributed Continous Outcome Data Based on Real World Postoperative PROMs

> **Albert Prats-Uribe,** M Sanni Ali, Victoria Y Strauss, Daniel Prieto-Alhambra. (United Kingdom)

4109 Replicating the Findings of a Medicare Study on Stroke, and Bleeding Risk in Patients Using NOACs for Atrial Fibrillation in the Sentinel System

Marie C Bradley, Emily C Welch, David J Graham, Efe Eworuke, Rongmei Zhang, Elande Baro, Mayura Shinde. (United States)

4195 A Marginal Structural Model to Evaluate the Association Between Statins and the Risk of Developing Hepatocellular Carcinoma in Patients with Diabetes

> **Yi-Chun Yeh,** Pei-Chun Chen, Yen-Yu Chen. (Taiwan)

4277 Avoiding Time-related Biases: An Application of the Paramtric g-formula to a Very Large German Healthcare Database

> **Tammo Reinders,** Brenda Bongaerts, Vanessa Didelez, Ulrike Haug, Oliver Kuss, Iris Pigeot, Wolfgang Rathmann, Bianca Kollhorst. (Germany)

4462 Machine Learning for Causal Inference in a Realistic Prescribing Scenario

Alexander Breskin, Paul N Zivich. (United States)

4483 Trajectories of Care in Patients with Chronic Obstructive Pulmonary Disease

> **Sandrine Henri,** Ronald Herrera, Alain Vanasse, Amélie Forget, Lucie Blais. (Canada)

4501 A Novel Approach to Quantitatively Synthesize Subgroups Findings from Multiple Trials

> **Devon Boyne,** Paul Arora, Darren Brenner. (Canada)

4580 Using Patient-level Data from Electronic Health Records to Replicate the Control Arm of the IMblaze370 Trial in Metastatic Colorectal Cancer

> **Michael T Bretscher,** Marcus Lawrance, Shivani K Mhatre, Carsten Schröder, Christelle Lenain, Marta Pereira, Irmarie Reyes-Rivera. (Switzerland)



4622 Using a Random Forest Model to Identify Demographic and Clinical Characteristics That Predict Pain within a Cohort of Rheumatoid Arthritis Patients in the US

> Harriet A Dickinson, Daniel C Gibbons, Jolyon Fairburn-Beech. (United Kingdom)

4708 Simulation of Pharmacological Treatments for Metabolic Disorders

David Bernotas. (United States)

4738 Combining Primary Care Electronic Health Record Data from Multiple Sources: A Systematic Review of Observational Studies

> **Daniel Dedman,** Melissa Cabecinha, Rachael Williams, Stephen J Evans, Krishnan Bhaskaran, Ian J Douglas. (United Kingdom)

4856 Evidence of Distinct Censoring Dynamics Across Treatment Groups and Impact on Censoring Weight Model Specification: The Example of Anticoagulation in Atrial Fibrillation

> **Liliya Sinyavskaya,** Alexis Matteau, Jason Robert Guertin, Mireille Schnitzer, Christel Renoux, Madeleine Durand. (Canada)

5005 Development and Validation of a Prediction Model for 1-year Risk of Thromboembolism in Hemodialysis Patients with Atrial Fibrillation

> **Sapna Rao,** Abhijit V Kshirsagar, M Alan Brookhart, Alexander Keil, Laura Loehr, Michele Jonsson Funk, Charles Poole. (United States)

Methods in Pharmacoepidemiology » Clinical Trial Methodology - Including pragmatic trials, cluster/sub-analyses of RCTs

3945 Frequency and Characteristics of Uncontrolled Long-term Extensions to Randomized Controlled Trials

Ching-Yu Wang, Joan Gretenkord, John D Seeger, Kourtney J Davis, Michelle R Iannacone, Wei Zhou, Nancy Dreyer, Almut G Winterstein, Nancy Santanello, Barry Gertz, Jesse A Berlin. (United States) 4107 Quantitative Bias Analysis for External Comparator Studies

> **Christen M Gray,** Fiona Grimson, Deborah Layton, Joseph Kim. (United Kingdom)

4356 A Picture is Worth 1000 Words: Visual Tools to Guide Transport of Trial Results to Real-world Populations

> **Jennifer L Lund,** Michael A Webster-Clark, Til Sturmer, Daniel Westreich, Hanna K Sanoff, Alexander P Keil. (United States)

4537 Contextualizing Background Safety Rates Using Comparable Historical Clinical Trials

> **Hu Li,** Antoniu Fantana, Matthew Connelly, Thomas S Hilzinger, Manas Singh. (United States)

Methods in Pharmacoepidemiology » Confounding/Bias - Methods to avoid bias and confounding, including confounder summary scores (e.g., propensity scores, disease risk scores)

77 Caliper Considerations for Propensity Score Matching

> **Elizabeth M Garry,** Wesley Eddings, Aditya Rajan, Amanda R Patrick, Nicolle M Gatto. (United States)

2614 Application of Quantitative Bias Analysis for Unmeasured Confounding in Pharmacoepidemiology

> **Jeremy P Brown,** Clémence Leyrat, Nicholas Galwey, Kevin Wing, Ian J Douglas. (United Kingdom)

2624 The Impact of Immortal Time Bias and the Adjustment Using Modified Kaplan-Meier Method and Time-dependent Cox Proportional Hazard Model: A Case Study

> **Satoshi Onozawa,** Masanori Ito, Tomomi Kimura. (United States)





2659 Multi-level Propensity Scores in Comparative Effectiveness Research on Medical Devices: A Pragmatic Example of Partial vs Total Knee Replacement Using National Joint Registry Data Compared to RCT Findings

> **Albert Prats-Uribe,** M Sanni Ali, Victoria Y Strauss, Daniel Prieto-Alhambra. (United Kingdom)

2669 Addressing Treatment Implementation Bias in the Construction of High Dimensional Propensity Scores

> **Nicolas H Thurin,** Jérémy Jové, Patrick Blin, Magali Rouyer, Stéphanie Lamarque, Pauline Bosco-Levy, Nicholas Moore, Cécile Droz-Perroteau. (France)

Poster Sessions

3746	Effect Estimation by a Boosted Doubly
	Robust Method

Wenxi Yu, Greg Ridgeway, Sander Greenland, William Marder, William Finkle. (United States)

3756 Adherence to Statin Therapy and the Use of Preventive Health Services: Cohort Study Using Claims Databases in Japan

> **Tsugumichi Sato,** Yumiko Wakana, Motoyoshi Akiyama, Haruna Hasegawa, Moriya Ogino, Kiyoshi Kubota. (Japan)

3861 A Systematic Review of How Missing Data is Handled and Reported in Multidatabase Pharmacoepidemiology

> **Nicholas B Hunt,** Helga Gardarsdottir, Marloes T Bazelier, Olaf H Klungel, Romin Pajouheshnia. (Netherlands)

3862 The Performance of Different Machine Learning Algorithms for Data Driven Variable Selection and Propensity Score Estimation in the Presence of Multiple Confounders and Big Sample Size: A Simulation Study

Yuchen Guo, M Sanni Ali, Victoria Y Strauss, Daniel Prieto-Alhambra. (United Kingdom)

3904 A Neural-network Driven Longitudinal Propensity Score for Evaluation of Drug Treatment Effects

Jeremy A Rassen. (United States)

3953 Assessing Techniques for Quantifying the Impact of Bias Due to an Unmeasured Confounder

> **Julie Barberio,** Thomas P Ahern, Richard MacLehose, Lindsay J Collin, Deirdre Cronin-Fenton, Per Damkier, Henrik Toft Sørensen, Timothy L Lash. (United States)

3973 Use of Sensitivity Analyses to Assess Uncontrolled Confounding in Observational, Head-to-head Pharmacoepidemiologic Studies: A Systematic Review

> **Chase Latour,** Charles Poole, Jessie Edwards, Til Stürmer, David Martin, Jennifer L Lund, Nahleen Lopez, Michele Jonsson Funk. (United States)



4021 Approaches to Reduce the Immeasurable Time Bias in Cohort Studies: A Monte Carlo Simulation Study and Real-world Example

> **In-Sun Oh,** Han Eol Jeong, Hyesung Lee, Kristian B Filion, Ju-Young Shin. (Korea, Republic of)

4362 Example of an Over-fitting Issue in a Logistic Regression Estimating a Highdimensional Propensity Score

> **Caroline Foch,** Michael Batech, Ulrike Gottwald-Hostalek, Patrice Verpillat, Emmanuelle Boutmy. (Germany)

4604 Mapping Warfarin Exposure in the Clinical Practice Research Datalink (CPRD)

> **Anneka Mitchell,** Julia Snowball, Anita McGrogan. (United Kingdom)

4612 The Use and Quality of Reporting of Propensity Score Methods in Multiple Sclerosis Literature

> **Mohammad Ehsanul Karim,** Fabio Pellegrini, Robert W Platt, Gabrielle Simoneau, Julie Rouette, Carl de Moor. (Canada)

4754 Divide and Recombine Approaches for Propensity Score Matching in Huge Data: A Case Study Using the Brazilian 100M Cohort

> **Gabriela L Borges,** M Sanni Ali, Mauricio Barreto, Dandara Ramos, Liam Smeeth, Rosemeire L Fiaccone. (Brazil)

4833 **Propensity Score Approaches with** Multilevel Data: A Simulation Study

> **Gabriela L Borges,** Marisleane Moreira, M Sanni Ali, Mauricio L. Barreto, Liam Smeeth, Rosemeire L Fiaccone. (Brazil)

4975 Plasmode Simulation to Address Confounding Bias Due to Missing Data in a Large Electronic Health Records Dataset

Svetlana Puzhko, Gillian Bartlett, Tibor Schuster. (Canada)

5013 Discriminative Ability of New Injury Severity Score to Predict Outcomes After Fracture Repair Surgery

> **Zhenna Huang,** Deepak Krishnan, Chantal Holy, Mollie Vanderkarr, Sparks Charisse. (United States)

5082 A Systematic Review of the Use of Propensity Scores in Published Observational Research

> **Tiansheng Wang,** Michael Webster-Clark, Robert James Glynn, Til Stürmer. (United States)

5111 Development of the Claims-based Comorbidity Index for Cardiovascular Disease Patients

> **Heejin Kim,** Sangshin Park, Mi-Sook Kim, Young-Jin Ko, Nam-Kyong Choi. (Korea, Republic of)

Methods in Pharmacoepidemiology » Measurement Methods - Validation methods to confirm data (including Patient Reported Outcomes development and validation); Methods to deal with missing data

63 Treatment Duration Estimation Based on Claims vs Primary Care Prescriptions Data: An Analysis of Opioid Use in the Sidiap Database

> **Junqing Xie,** Gary Collins, Victoria Y Strauss, D. Prieto-Alhambra. (United Kingdom)

76 Incidence Rates of Acute Exacerbations of COPD in US Claims Data Using ICD-9 and ICD-10

Ashley Cole, Yunhao Liu, Kieran J Rothnie. (United States)

122 The Impact of Refill Gaps on the Estimation of Persistence with Opioids Use

> **Junqing Xie,** Gary Collins, Victoria Y Strauss, D. Prieto-Alhambra. (United Kingdom)



2411 The Positive Predictive Value of Hip Fracture Diagnoses and Surgical Procedure Codes in the Danish Multidisciplinary Hip Fracture Registry and the Danish National Patient Registry

> **Thomas J Hjelholt,** Nina M Edwards, Jeppe D Vesterager, Pia K Kristensen, Alma B Pedersen. (Denmark)

2464 Identifying Valid Algorithms for Number of Chemotherapy Treatment Lines in the Danish National Patient Registry

Signe Sørup, Bianka Darvalics, Jakob S Knudsen, Anne S Rasmussen, Cathrine F Hjorth, Søren V Vestergaard, Leo Russo, Dina Oksen, Emmanuelle Boutmy, Patrice Verpillat, Henrik T Sørensen, Mikael Rørth, Deirdre Cronin-Fenton. (Denmark)

2473 Missing Data Analysis in Multi-center Studies When Access to Person-level Data is Restricted

Qoua Her, Yury Vilk, Xiaojuan Li, Di Shu, Rui Wang, Jenna Wong, Mia Gallagher, Sengwee Toh. (United States)

2618 Assessment of a Claims-based Osteonecrosis of the Jaw Algorithm in the United States

> **Lauren Stevens,** Leslie Spangler, Laura Yochum, Yan Ding, Florence Wang. (United States)

2629 Validation of a US Health Insurance Claims-based Algorithm to Identify Acute Exacerbations of Chronic Obstructive Pulmonary Disease

Douglas W Mapel, Susan R Sama, Douglas W Roblin, Melissa H Roberts, Priyanka J Bobbili, Wendy Y Cheng, Julia M Certa, Devi Sundaresan, Thomas S Whiting, Catherine Nguyen, Philippe Thompson-Leduc, Jennifer L Brown, Melissa K Van Dyke, Kieran J Rothnie and Mei Sheng Duh. (United States) 2637 Intentional Self-harm Classification in Medicare: An Interrupted Time Series Analysis Comparing ICD-9 Definitions to Corresponding ICD-10 Definitions

> **Richard S Swain,** Dinci Pennap, Sandia Akhtar, Jiemin Liao, Yuqin Wei, Yuhui Feng, Michael Wernecke, Thomas MaCurdy, Jeffrey Kelman, Andrew Mosholder, David Graham. (United States)

3811 Validation of Acute Outcomes Among Patients with Type 2 Diabetes Mellitus in Medicare: A Pilot Study

> **Heather E. Danysh,** J. Bradley Layton, Daniel C. Beachler, Alejandro Arana, Manel Pladevall-Vila, Rita Schmid, Brian Calingaert, Ryan Ziemiecki, Phillip R. Hunt, Alicia Gilsenan, Catherine Johannes. (United States)

3815 Validation of Breast Cancer and Bladder Cancer Among Patients with Type 2 Diabetes Mellitus in Medicare: A Pilot Study

> **Heather E. Danysh,** Alicia Gilsenan, Daniel C. Beachler, James A. Kaye, Xabier Garcia-Albeniz, Rita Schmid, Shannon Hunter, Phillip R. Hunt, Jaume Aguado, Brian Calingaert, J. Bradley Layton, Lia Gutierrez. (United States)

3821 Multimorbidity Case Definition and Lookback Window: Impact on Prevalence and Associated Health Outcomes in Population Health Administrative Databases

Marc Simard, Elham Rahme, Marjolaine Dubé, Caroline Sirois. (Canada)

3874 Validation of an Algorithm Identifying Relapses in Multiple Sclerosis Using the French Nationwide Claims Database

> **Pauline Bosco-Levy,** Patrick Blin, Séverine Lignot-Maleyran, Régis Lassalle, Abdelilah Abouelfath, Pauline Diez-Andreu, Marc Debouverie, Bruno Brochet, Céline Louapre, Olivier Heinzlef, Elisabeth Maillart, Nicholas Moore. (France)





3886 Assessing Outcomes of Uterine Perforation and IUD Expulsion Before and After ICD-9-CM to ICD-10-CM Transition in Women with IUD Insertions

Catherine Saltus, Alex Asiimwe, Jeffrey Peipert, Susan Reed, Darios Getahun, Amy Alabaster, Mary E Ritchey, Laura Ichikawa, Jennifer Gatz, Vicki Chiu, Maqdooda Merchant, Michael Fassett, Ann-Kathrin Frenz, Mary Anne Armstrong, Jinyi Wang, Shannon Hunter, Giulia Chillemi and Mary Anthony. (United States)

3903 IUD Type and Indicators of Difficult Insertion Among Women with Intrauterine Devices

Catherine Saltus, Susan Reed, Jeffrey Peipert, Michael Fassett, Maqdooda Merchant, Alex Asiimwe, Mary E Ritchey, Fagen Xie, Mary Anne Armstrong, Jennifer Gatz, Laura Ichikawa, Darios Getahun, Richard Lynen, Jinyi Wang, Shannon Hunter, Giulia Chillemi, and Mary Anthony. (United States)

3905 Data Element Agreement in CPRD Aurum: Concordance Between Labs, Diagnoses, and Treatments

Katrina Wilcox Hagberg, Rebecca Persson, Catherine Vasilakis-Scaramozza, Tim Williams, Puja Myles, Susan S Jick. (United States)

3908 Quality and Completeness of Cancer Diagnoses Recorded in the New CPRD Aurum Database

Katrina Wilcox Hagberg, Rebecca Persson, Catherine Vasilakis-Scaramozza, Tim Williams, Tarita Murray-Thomas, Puja Myles, Susan S Jick. (United States)

4078 Bias Considerations Due to Outcome Misclassification in Observational Studies Evaluating Association Between Treatments and Mortality Using Administrative Claims

> **Rishi J Desai,** Raisa Levin, Kueiyu Joshua Lin, Elisabetta Patorno. (United States)



4139 Value of Adding Secondary Read Diagnosis Codes to Identify Breast Cancer and Bladder Cancer in the Clinical Practice Research Datalink: A Pilot Validation Study

> **Lia Gutierrez,** Heather E. Danysh, Jaume Aguado, Phillip R. Hunt, James A. Kaye, Xabier Garcia-Albeniz, Alicia Gilsenan. (Spain)

4244 Translation, Cross-cultural Adaptation, and Psychometric Properties of the Danish Version of the Revised Patients' Attitudes Towards Deprescribing Questionnaire

> **Carina Lundby,** Trine Simonsen, Jesper Ryg, Jens Søndergaard, Anton Pottegård, Henrik Hein Lauridsen. (Denmark)

4347 Validity of Self-reported Antidepressants Use - The Norwegian Women and Cancer Study

Marit Waaseth, Guro Forsdahl, Martina Havelkova, Eiliv Lund, Tomas Log. (Norway)

4355 Use of the Waiting Time Distribution Method to Determine the Duration and Number of Episodes of Antipsychotic Treatment in Older People

> **Juan Carlos Bazo-Alvarez,** Mary Elizabeth Jones, Cini Bhanu, Tra My Pham, Claudia Cooper, Tim P Morris, Joseph Hayes, Kate Walters, Irene Petersen. (United Kingdom)

4387 The Validity of Diagnostic Algorithms to Identify Asthma Patients in Healthcare Administrative Databases: A Systematic Review

> **Alia Yousif,** Roxanne Dault, Mireille Courteau, Lucie Blais, Anne-Marie Cloutier, Anaïs Lacasse, Alain Vanasse. (Canada)

4404 Validation of Venous Thromboembolism Diagnoses in Patients Receiving Rivaroxaban or Warfarin in the Health Improvement Network Database of Primary Care Electronic Health Records in the United Kingdom

Ana Ruigomez, Gunnar Brobert, Pareen Vora, Luis García Rodríguez. (Spain)

4554 Lookback Period Definition in Electronic Medical Record Data

> **Mackenzie M Herzog,** Stephen W Marshall, Nancy A Dreyer, Christina D Mack. (United States)

4579 Validation Study of Medication Adherence Based on Claims Data in Japan

> **Yoshiyuki Saito,** Hiroshi Yoshihara, Ataru Igarashi, Chieko Ooe, Takeo Nakayama. (Japan)

4605 Registration of Pharmacological Treatment Registered in the Danish Hip and Knee Arthroplasty Registries: A Validation Study within the Capital Region of Denmark

> **Astrid Blicher Schelde,** Janne Petersen, Thomas Bo Jensen, Kirill Gromov, Søren Overgaard, Jonas Bjerring Olesen, Espen Jimenez-Solem. (Denmark)

4621 Identification and Validation of Major Bleeding in a Primary Care Database in Spain

> **Airam de Burgos Gonzalez,** Luz María Leon Muñoz, Verónica Bryant Cerezo, Miguel Ángel Macia Martínez, María Dolores Montero Corominas, Consuelo Huerta Álvarez. (Spain)

4684 Impact of Exposure Misclassification Due to Information from Different Prescribers on the Risk of Bleeding Associated with DOACs

> **Mirjam Hempenius,** Rolf H Groenwold, Patrick C Souverein, Antonius Boer, Olaf H Klungel, Helga Gardarsdottir. (Netherlands)

4762 Are Diabetes and Glucose-lowering Drugs Equivalently Reco(r)ded in CPRD GOLD and Aurum?

> **Estel Plana,** Ryan Ziemiecki, David Martinez, Jaume Aguado, Cristina Rebordosa. (Spain)

4788 Reco(r)ding of Lifestyle Variables in CPRD Aurum Compared with GOLD

> **Jaume Aguado,** David Martinez, Estel Plana, Ryan Ziemiecki, Cristina Rebordosa. (Spain)



4809 Is Chonic Obstructive Pulmonary Disease Reco(r)ded Similarly in CPRD GOLD and Aurum?

> **David Martinez,** Ryan Ziemiecki, Jaume Aguado, Estel Plana, Cristina Rebordosa. (Spain)

4810 An Application of Natural Language Processing to Validation of Melanoma and Non Melanoma Skin Cancers in a Spanish Electronic Healthcare Database

> **Luz M León-Munoz,** Jesus Santamaria, Ana LLorente, Airam de Burgos, Arturo Alvarez, Dolores Montero, Consuelo Huerta. (Spain)

4865 Identification of Cases of NSCLC in the Pathology Registry of the University Hospital of Siena: A Validation Study

> **Andrea Spini,** Pietro Rosellini, Cristiana Bellan, Folco Furiesi, Silvano Giorgi, Sandra Donnini, Rosa Gini, Marina Ziche, Francesco Salvo, Giuseppe Roberto. (Italy)

4867 **Developing a Structured Process to** Identify Fit for Purpose Data Framework

Ulka B Campbell, Robert F Reynolds, Emily Rubinstein, Nicolle M Gatto. (United States)

4886 Validation of Diagnosis Code-based Algorithms to Identify Metastatic Renal Cell Carcinoma Patients in Medicare Claims Data

> **Danielle Chun,** Blánaid Hicks, Sharon Peacock-Hinton, Hung-Jui Tan, Alex Keil, Til Stürmer, Jennifer Lund. (United States)

4979 Comparison of International Classification of Diseases, Tenth Revision Coding Patterns Between the United States and Japan

> **Patricia Prince,** Kammy Kuang, Emily Rubinstein. (United States)

5017 Classifying Exposure - An Application of the Waiting Time Distribution to Estimate Treatment Status and Duration

> **Morten Madsen,** Henrik Støvring, Astrid Lunde, Grethe S Tell, Helle Kieler, Gerhard Sulo, Vera Ehrenstein. (Denmark)

5060 Machine Learning Methods to Predict Unmeasured Confounders in Claims Data: A Real-world Application

> **Yasser Albogami,** Michael J Daniels, Yu-Jung Wei, Kenneth Cusi, Almut G Winterstein. (United States)

5076 Plasmode Simulation of Multiple Imputation Performance Using Internal Validation Data to Adjust for Unmeasured Confounders

> Yasser Albogami, Almut G Winterstein. (United States)

5099 Impact of Extending the Lookback Period on the Estimated Prevalence of Inflammatory Bowel Disease in Administrative Claims Data

> **Ghadeer K. Dawwas,** Kevin Haynes, Lauren Parlett, Colleen M. Brensinger, Xiaoxue Chen, Qufei Wu, Michael D. Kappelman, James D. Lewis. (United States)

5117 Utility of Electronic Health Records to Support Post-marketing Drug Safety Surveillance

> Nancy D Lin, Jenna Calderbank, David Anderson, John Seeger. (United States)

5142 Analysis of Risk Associated with Delayed Renal Function Recovery Among Medication-related Acute Kidney Injury Survivors

You-Lin Tain, Chien-Ning Hsu. (Taiwan)

Methods in Pharmacoepidemiology » Study Design - Studies assessing study design (e.g., choice of comparator, self-controlled methods, avoiding immortal time bias)

79 Prevalence of Time-related Biases in Pharmacoepidemiology Studies of Antiemetics, Antifungal, and Antibiotic Medications During Pregnancy: A Systematic Review

> **Ugochinyere Vivian Ukah,** Wusiman Aibibula, Robert W. Platt, Kristian B. Filion. (Canada)



128 Impact of the Choice of Clinical Code Set on the Outcomes of a Real-world Database Study

> **Audrey Artignan,** Amy Buchanan-Hughes. (United States)

2362 The Application of Mixed Methods Research in Pharmacoepedemiology: A Synthesis Review

> **Hongling Chu,** Bin Zhu, Fengwei Li, Lin Zeng, Nan Li, Liyuan Tao, Lin Zhuo, Yanyan Shi, Hua Zhang, Xiaoxiao Wang, Siyan Zhan, Yiming Zhao. (China)

2406 Drug-drug Interaction Surveillance Study: Comparing Self-controlled Designs in Five Empirical Examples in Real-world Data

> **Katsiaryna Bykov,** Hu Li, Sangmi Kim, Vincent Lo Re III, Joshua J. Gagne. (United States)

2472 An FDA Quality Assessment Tool for Evaluation of Real-world Evidence Observational Studies

Marie C Bradley, Wei Hua, Simone Pinheiro. (United States)

2530 The State of Real-world Evidence in Comparative Effectiveness and Safety Studies Based on Healthcare Insurance Claims

> **Katsiaryna Bykov,** Elisabetta Patorno, Mengdong He, Hemin Lee, Elvira D'Andrea, Jennifer S. Graff, Jessica M. Franklin. (United States)

2677 Prevalent New Users: When is Time Not Enough?

Michael Webster-Clark, Rachael Ross. (United States)

3776 Challenges in the Analyses of Time-toevent Data in Cohort Studies Based on Exposure Definitions

> **Beatriz Seoane Nuñez,** Mario Ouwens, Rosa Lamarca, Satya Sanikommui, Noman Lateef, Annalisa Rubino. (United Kingdom)

3820 The Basket or Umbrella Real-world Observational Study (B U R O S) Design for Molecular Cancer Subtypes

> **Geoffrey Liu,** Stavroula Raptis, Maryam Mirshams, Devalben Patel, Simren Chotai, Abraam Ghattas, Aein Zarrin, Audra Stitt, Patrick Moriarty, Karen Pope. (Canada)

3943 Predicting the Best Achievable Precision of a Register-based Case-control or Cohort Study. A "Bottleneck Count" Analysis

Jesper Hallas, Morten R Hansen, Anton Pottegård, Henrik Støvring. (Denmark)

3970 A Self-controlled Analysis of Cumulative Drug Effects, a Simulation Study Based on Real-world Prescriptions

> **Lars Christian Lund,** Malcolm Maclure, Anton Pottegård, Jesper Hallas. (Denmark)

4042 Risk of Acute Kidney Injury During Antibiotic Treatment: A Self-controlled Screening Study Utilising Biochemical Data

Lars Christian Lund, Jesper Hallas, Daniel P Henriksen. (Denmark)

4164 Dulaglutide Proactive Safety Surveillance Program (PSSP)

Ayad K Ali. (United States)

4182 Handling of Statistical Heterogeneity in Meta-analyses of Comparative Effectiveness Studies: A Systematic Review

> **Jean-Francois Nepveu,** Tiffany Cristarella, Teigna Arredondo Bisono, Franziska Schmidt, Mareva Faure, Yola Moride. (Canada)

4264 Differential Lags in Treatment Information in Electronic Health Record Derived Databases

> **Anne-Marie Meyer,** Jessica Davies, Michael Taylor, Charlotta Fruechtenicht. (Switzerland)

4297 Open Cohorts and Ghost-time Bias in Real World Data

> **Anne-Marie Meyer,** Jessica Davies, Michael Taylor, Charlotta Fruechtenicht. (Switzerland)



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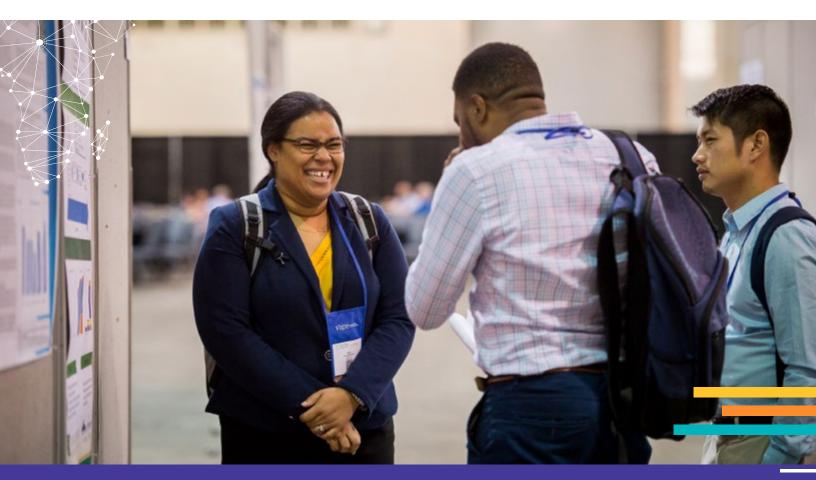
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4895 Assessing the Fitness of Patient Registry Data for Real World Evidence Generation: Lessons Learned from the My Retina Tracker[®] Registry of Rare Inherited Retinal Disorders

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5081 Eosinophilia in Atopic and Non-atopic Individuals in the United States

Chi H Le, Phuong H Le, Chi T Truong, Hoa V Le. (United States)

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71 The Safety of Antibody Drug Conjugates: A Literature Review

> **Joan Forns,** James A Kaye, Fabio A Lievano, Jerzy E Tyczynski, Andrea V Margulis. (Spain)

2396 Pre-existing Autoimmune Disease and Immune-related Adverse Events (irAE) with Checkpoint Inhibitors in Metastatic Melanoma

> **Marina A Machado,** Cristiano S Moura, Kelvin Chan, Jeffrey R Curtis, Marie Hudson, Michal Abrahamowicz, Ines Colmegna, Rahima Jamal, Louise Pilote, An-Wen Chan, Sasha Bernatsky. (Canada)

2466 Risk of Skin Cancer in New Users of Thiazides and Thiazide-like Diuretics: A Cohort Study Using an Active Comparator Group

> **Rahel Schneider,** Daphne Reinau, Seline Stoffel, Susan S. Jick, Christoph R. Meier, Julia Spoendlin. (Switzerland)

2522 Proton Pump Inhibitors are Not Associated with an Increased Risk of Colorectal Cancer

> **Josephina G. Kuiper,** Myrthe P. Van Herk-Sukel, Valery E. Lemmens, Ernst J. Kuipers, Ron M. Herings. (Netherlands)

3702 To What Extent are Topical Tacrolimus or Pimecrolimus Associated with Increased Risk of Skin Cancer and Lymphoma? Long-term Results from Joelle Study

> **Alejandro Arana,** Anton Pottegård, Josephina G Kuiper, Elizabeth Crellin, Johan Reutfors, Marcus Schmitt-Egenolf, Lars Christian Lund, Eline Houben, Helen Booth, Brian Calingaert, James A Kaye, Karin Gembert, Kenneth J Rothman, Daniel Dedman, Helle Kieler, Lia Gutierrez, Jesper Hallas and Susana Perez-Gutthann. (Spain)

3852 Tumor Necrosis Factor Inhibitors (TNFis) and Cancer Risk in Older Adults with Rheumatoid Arthritis (RA)

> **Monica E D'Arcy,** Daniel Beachler, Jeffrey Curtis, Ruth M Pfeiffer, Donna R Rivera, Xavier Mariette, Raphael Seror, Eric A Engels. (United States)

3925 Cancer Risk of Ranitidine and Nizatidine versus Other H2 Blockers: An Analysis of the Japan Medical Data Center Claims Database

> **Masao Iwagami,** Ryosuke Kumazawa, Yoshihisa Miyamoto, Yuri Ito, Nanako Tamiya, Hideo Yasunaga. (Japan)

4200 Description of Acute Kidney Injury and Breast Cancer Outcome Validation Processes Across Three Databases

> Jade Dinh, Heather E Danysh, Catherine Johannes, Lia Gutierrez, Rita Schmid, Alejandro Arana, James A Kaye, Manel Pladevall-Vila, Xabier Garcia de Albeniz, Phillip R Hunt, Alicia Gilsenan, Daniel C Beachler, Cindy Ke Zhou. (United States)

4480 Risks of Acute Gastrointestinal Adverse Events Associated with Metastatic Melanoma Therapies: A Retrospective Cohort Study

> **Sascha Van Boemmel-Wegmann,** Joshua D Brown, Vakaramoko Diaby, Jinhai Huo, Natalie L Silver, Haesuk Park. (United States)

4711 Use of Hydrochlorothiazide and Risk of Skin Cancer in a Large Nested Casecontrol Study in Spain

> **Luz M Leon-Munoz,** Talita Duarte-Salles, Ana Llorente-Garcia, Yesika Diaz-Rodriguez, Anton Pottegard, Dolores Montero-Corominas, Consuelo Huerta-Alvarez. (Spain)





5010 Second Cancers in Adults with Acute Promyelocytic Leukemia (APL) Treated with or without Arsenic Trioxide (ATO): A SEER-Medicare Analysis

> **Kelly J Norsworthy,** Steven Bird, Armen Avagyan, Yuchen Li, Sandia Akhtar, Jiemin Liao, Michael Wernecke, Albert B Deisseroth, Meredith Chuk, Thomas E MaCurdy, Richard Swain, Jeffrey A Kelman, Ann T Farrell, Richard Pazdur, Gideon Blumenthal and David J Graham. (United States)

5150 Lean Body Mass is Associated with Chemotherapy-induced Adverse Drug Effects

> **Macarius Donneyong,** Teng-Jen Chang, Autumn Carey, Jared Huling, Jared Huling, Christopher Coss, James Odei, Lang Li. (United States)

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2426 Incidence of Severe Abnormal Uterine Bleeding Following Oral Anticoagulant Use

> **Ting-Ying Huang,** Laura Hou, Abby Anderson, Hui-Lee Wong, Rongmei Zhang, Peter Waldron, David Moeny, Audrey Gassman, Efe Eworuke. (United States)

2480 Effect of Domperidone, Ondansetron, and Olanzapine Containing Antiemetic Regimen on QTc Interval in Patients with Malignancy

> **Ashwin Kamath,** PU Prakash Saxena, Maneesh K Rai. (India)

2493 Comparative Long-term Cardiovascular Outcomes Between Ranibizumab versus Aflibercept in Patients with Maculopathy

> **Wan-Ju A Lee,** Shih-Chieh Shao, Yea-Huei Kao Yang, Tzu-Chi Liao, Edward Chia-Cheng Lai. (Taiwan)

2504 The Magnitude of the Warfarinamiodarone Drug-drug Interaction Varies with Renal Function: A Propensitymatched Cohort Study

Todd A. Miano, Wei Yang, Michael G. Shashaty, Athena Zuppa, Jeremiah R. Brown, Sean Hennessy. (United States)

2666 The Predictors of Major Gastrointestinal Bleeding Among Oral Anticoagulant New Users with Atrial Fibrillation

> **Jakub Z. Qazi,** Mireille E. Schnitzer, Marie-Josée Martel, Robert Côté, Marc Dorais, Sylvie Perreault. (Canada)

3822 Association Between Antidepressants Use and Stroke Risk in Taiwan

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3831 No Association Between Methylphenidate Use and Myocardial Infarction: A Multinational Self-controlled Case Series Study

> **Han Eol Jeong,** Hyesung Lee, Edward C. Lai, Kenneth K. Man, Ian C. Wong, Ju-Young Shin. (Korea, Republic of)

4115 Testosterone Treatment and the Risk of Venous Thromboembolism: A Systematic Review and Meta-analysis of Randomized Controlled Trials

> **Henok Tadesse Ayele,** Vanessa C Brunetti, Christel Renoux, Vicky Tagalakis, Kristian B Filion. (Canada)

4131 Suboptimal Use of Antithrombotic Treatments and Associated Clinical Outcomes in Chinese Patients with Atrial Fibrillation

> **Xue Li,** Swathi Pathadka, Kenneth Man, Vanessa Ng, Chung Wah Siu, Ian Wong, Esther Chan, Wallis Lau. (United Kingdom)

4163 A Population-based Assessment of the Cardiovascular Safety of 5-alphareductase Inhibitors

> **Henok Tadesse Ayele,** Pauline Reynier, Laurent Azoulay, Robert W Platt, Serge Benayoun, Kristian B Filion. (Canada)

4226 Tyrosine Kinase Inhibitors-related Vascular Occlusive Events in Taiwanese Chronic Myeloid Leukemia Patients: A Population-based, Propensity Scorematched Cohort Study

> **Mei-Tsen Chen,** Shih-Tsung Huang, Ho-Min Chen, Bor-Sheng Ko, Fei-Yuan Hsiao. (Taiwan)





4270 A Potential Safety Signal of Venous Thromboembolic Events with the Use of DPP-4 Inhibitors

Amandine Gouverneur, Mickael Arnaud, Ana Jarne-Munoz, Yohann Mansiaux, Jean-Luc Faillie, Clara Bouché, Annick Fontbonne, Antoine Pariente, Francesco Salvo. (France)

4412 Reporting of Statin-associated Muscle Symptoms Among Italian Dyslipidemic Patients Enrolled in the PROSISA Study: Prevalence and Risk Factors

> **Marta Gazzotti,** Manuela Casula, Elena Olmastroni, Federica Bonaiti, Liliana Grigore, Alberto Zambon, Alberico Luigi Catapano. (Italy)

4592 Incidence of Venous Thromboembolism in Users of Combined Oral Contraceptives in North America and Eastern Europe - Final Results from the International Active Surveillance - Folate and Oral Contraceptives Utilization Study (INAS-FOCUS)

Clare Barnett, Thai Do Minh, Christoph Wenger, Klaas Heinemann. (Germany)

4603 Impact of the 2012 FDA Safety Communication on Drosperinone Containing Oral Contraceptives -Detection Bias in the International Active Surveillance - Folate and Oral Contraceptives Utilization Study (INAS-FOCUS)

> **Clare Barnett,** Anja Bauerfeind, Thai Do Minh, Klaas Heinemann. (Germany)

4664 Comparative Safety and Effectiveness of Direct Oral Anticoagulants and Warfarin on Major Bleeding and Thromboembolic Events in Atrial Fibrillation: A Retrospective Cohort Study

> **Ya-Ling Huang,** Chia-Ling Chiang, Ching-Yao Chen. (Taiwan)

4688 A 'Real-World' Study Population of NOMAC-E2 Users and COC-LNG Users: Baseline Characteristics from the Multinational PRO-E2 Study

> **Suzanne Reed,** Carol Koro, Julia DiBello, Klaas Heinemann. (Germany)

4733 Face-to-face 3-year Comparative Effectiveness and Safety of Dabigatran and Rivaroxaban, Standard and Reduced Doses, for Nonvalvular Atrial Fibrillation: A Cohort Study in the French Nationwide Claims Database

> **Patrick Blin,** Yves Cottin, Caroline Dureau-Pournin, Abdelilah Abouelfath, Régis Lassalle, Estelle Guiard, Aurélie Balestra, Patrick Mismetti, Gérard de Pouvourville, Cécile Droz-Perroteau, Jacques Bénichou, Nicholas Moore. (France)

4921 Validity of a Case-identification Algorithm for Venous Thromboembolism

> **Monica Bertoia,** Sigalit Kaplan, Li Zhou, Amir Lass, Florence T Wang, John D Seeger. (United States)

5106 Cardiovascular Risk with Concomitant Use of Stimulants and Atypical Antipsychotics in US Children and Adolescents

> **Chengchen Zhang,** O'Mareen Spence, Gloria Reeves, Susan dosReis. (United States)



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3833 Risk of Sodium-Glucose Cotransporter-2 Inhibitor on the Incidence of Urinary Tract Infection Among Diabetic Patients in Japan: A Nationwide Cohort Study

> **Yoshinori Takeuchi,** Hiraku Kumamaru, Yasuhiro Hagiwara, Hiroki Matsui, Hideo Yasunaga, Hiroaki Miyata, Yutaka Matsuyama. (Japan)

3982 Risk of Venous Thromboembolism Amongst Initiators of SGLT-2 Inhibitors Compared to Other Glucose-lowering Agents

> **Chandrasekar Gopalakrishnan,** Rishi J Desai, Seoyoung C Kim, Elisabetta Patorno. (United States)

4203 Lack of Insulin Secretagogue Deprescribing and Risk of Severe Hypoglycemia Following Bariatric Surgery

> **Scott M Vouri,** Jiajing Chen, Jayme Sparkman, Joshua D Brown, Hui Shao, Arghavan Salles, Scott T Micek. (United States)

4409 Assessing Fit-for-purpose: Surrogate Endpoints and Clinically Important Outcomes in Japanese Real-world Data Source in Type-2 Diabetes

> **Jocelyn Ruoyi Wang,** Amanda Patrick, Pattra Mattox, Ashley Jaksa. (United States)

4587 Use of Sodium-glucose Co-transporter-2-inhibitors and Risk of Lower Limb Amputation

> **Nikki Werkman,** Yannick Nielen, Joop van den Berg, Niels Ejskjaer, Johan Røikjer, Nicolaas Schaper, Olaf Klungel, Peter Vestergaard, Frank de Vries, Annemariek Driessen. (Netherlands)

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3731 Falls and Fractures in Patients Treated for Parkinson's Disease-related Psychosis: Comparing an Established Class to a More Recently Introduced Treatment

> **J. Bradley Layton,** Joan Forns, Colleen Dempsey, Mary Ellen Turner, Jennifer Bartsch, Mary S Anthony, Mary E Ritchey, George Demos. (United States)

3872 Risk of Seizure in People with Autism Spectrum Disorder Using Antipsychotic Medication: A Population Based Study

> **Basmah Alfageh,** Tian-Tian Ma, Frank M. Besag, Kenneth K. Man, Ian C. Wong, Ruth Brauer. (United Kingdom)

4110 Evidence of Fluoroquinolone-induced Acute Neurological Dysfunction in Large Adult Population

> **Darcy E Ellis,** Qing Liu, Theoklis E Zaoutis, Athena F Zuppa, Allison W Willis, Rebecca A Hubbard, Sean Hennessy. (United States)

4263 Do Interruptions to the Continuity of Methadone Maintenance Treatment (MMT) in Specialist Addiction Settings Increase the Risk of Drug-related Poisoning (DRP) Deaths? A Retrospective Cohort Study

> **Grainne Cousins,** Louise Durand, Denis O'Driscoll, Fiona Boland, Eamon Keenan, Benedict Ryan, Joe Barry, Kathleen Bennett, Tom Fahey, Tom Fahey. (Ireland)

4280 Lack of Association Between Proton Pump Inhibitor Intake and Brain Aging: A Population Based Cross-sectional Study

Nayeon Ahn, Stefan Frenzel, Katharina Wittfeld, Henry Völzke, Markus M Lerch, Jean-Francois Chenot, Ulf Schminke, Michael Nolde, Ute Amann, Christa Meisinger, Jakob Linseisen, Sebastian E Baumeister, Hans-Jörgen Grabe, Ina-Maria Rückert-Eheberg. (Germany)



4388 Trends in Age- and Sex-specific Rates of Suicide and Suicide by Drug Poisoning in the United States: 1999-2017

Dinci Pennap, Scott Swain, Andrew Mosholder. (United States)

4561 A Synthetic Control Arm from Observational Data to Estimate the Background Incidence Rate of an Adverse Event (Pneumonia) in Alzheimers Disease Subjects

Innocent Ngwa, Christian Mueller. (Switzerland)

4776 Risk of Suicidality After Exposure to Finasteride

> **Robert Flynn,** Jim Slattery, Karin Hedenmalm, Gianmario Candore, Xavier Kurz. (Netherlands)

4978 Real-world Comparative Risk of Rhabdomyolysis with Cholinesterase Inhibitors for Alzheimer's Disease

Pamela B Landsman-Blumberg. (United States)

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101 Sex Differences in Hospital Admissions Related to Adverse Drug Reactions

> **Linda C. Hendriksen,** Paul D. van der Linden, Ron M. Herings, Bruno H. Stricker, Loes E. Visser. (Netherlands)

118 Assessment of Awareness & Knowledge on HIV/AIDS Among People in Warangal Region

Sanjay Vishwanath. (India)

121 Real-world Safety of Palbociclib in Breast Cancer Patients in the United States

> **Daniel C Beachler,** Cynthia de Luise, Aziza Jamal-Allial, Ruihua Yin, Devon H Taylor, Stephan Lanes. (United States)

2481 Drug-related Hospital Admissions Following Emergency Department Visits: Preliminary Results of a Cross-sectional Study

Zuzana Ocovska, Martina Marikova, Jiri Vlcek. (Czech Republic)

2505 Effect of Renin-angiotensin System Inhibitors on the Comparative Renal Safety of Nonsteroidal Anti-inflammatory Drugs and Opioids in Hospitalized Patients

Todd A Miano. (United States)

2535 Improving Identification of Anaphylaxis

James S. Floyd, David S. Carrell, Maralyssa Bann, Susan Gruber, Ron L Johnson, Vina F Graham, Cosmin A Bejan, Yong Ma, Mayura Shinde, Robert Ball, Jennifer C Nelson. (United States)

2559 Second-generation Antipsychotics and the Risk of Chronic Kidney Disease: A Population-based Case-control Study

> **Mikkel Højlund,** Lars C. Lund, Jonas L Herping, Maija B Haastrup, Per Damkier, Daniel P Henriksen. (Djibouti)

2590 Newer Second-line Glucose-lowering Drugs versus Thiazolidinediones and Cirrhosis Risk in Type 2 Diabetes

> **Jeff Y Yang,** Anastasia Alexopoulos, Andrew M Moon, Hannah Kim, Virginia Pate, A. Sidney Barritt, Til Stürmer, John B. Buse. (United States)

3691 Revision Risk of Lower Joint Replacement for Non-steroidal Anti-inflammatory Drug Users: A Retrospective Cohort Study

> **Mohammad Bakhriansyah,** Arief Lalmohamed, Patrick C Souverein, Anthonius de Boer, Olaf H Klungel. (Indonesia)

3805 Biologic Therapy and the Risk of Herpes Zoster Among Patients with Inflammatory Bowel Disease

> **Christina Santella,** Alain Bitton, Christopher Filliter, Maria Vutcovici, Talat Bessissow, Peter Lakatos, Paul Brassard. (Canada)





3835 A Multinational European Study of Anaphylaxis Among Recipients of Intravenous Iron

Lia Gutierrez, Patrick Blin, Jochen Dress, Cecile Droz-Perroteau, Vera Ehrenstein, Carla Franzoni, Bianca Kollhorst, Regis Lassalle, Marie Linder, Nicholas Moore, Ingvild Odsbu, Jetty Overbeek, Susana Perez-Gutthann, Tania Schink, Katherine Rascher, Lawrence Rasouliyan, Jonas Reinold, Kenneth J Rothman, Nuria Saigi-Morgui, Mathias Schaller, Elisabeth Smits, Antje Timmer, Gunnar Toft, Gero von Gersdorff, Intravenous Iron Consortium and Joan Fortuny. (Spain)

3888 Adverse Bleeding Events Among Patients Concomitantly Treated with Direct Anticoagulants and Antibiotics within a Swedish Nationwide Cohort

> **Tatsuya Yagi,** Helle Kieler, Johan Reutfors, Buster Mannheimer, Marie Linder. (Sweden)

3907 Intravenous Bisphosphonate Use and 30day Risk of Inflammatory Bowel Disease Flare

Jeff Y Yang, Bharati D Kochar, Jennifer L Lund, Hans H Herfarth. (United States)

3915 Are Indicators of Difficult Insertion Among Women with Intrauterine Devices Associated with Uterine Perforation and Expulsion?

> Mary E Ritchey, Susan Reed, Amy Alabaster, Darios Getahun, Jennifer Gatz, Catherine Saltus, Mary Anne Armstrong, Fagen Xie, Jinyi Wang, Michael Fassett, Giulia Chillemi, Jeffrey Peipert, Shannon Hunter, Laura Ichikawa, Alex Asiimwe, and Mary Anthony. (United States)

3919 Risk Across Postpartum Timing of Insertion in Women with Intrauterine Devices

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> **Meghna Jani,** Edward Burn, James Weaver, Loreto Carmona, Katerina Chatzidionysiou, Ben Illigens, David Vizcaya, Talita Duarte-Salles, Patrick Ryan, Daniel Prieto-Alhambra, RA Research Group EHDEN. (United Kingdom)

4074 Real-world Evidence (RWE) Study to Access Motor Vehicle Accidents Data: Real-world Data Landscaping and Feasibility

> **Hu Li,** Michael Phinney, Rashna Khanna, Sonja M Bragg, Tammy Clemmer, Eva Oakkar. (United States)

4122 Factors Associated with Serious Vehicular Accidents: A Real-life Study

Nicholas Moore, Karelle Forest, Guillaume Valdenaire, Jean-Paul Lorendeau, Patricia Sagaspe, Benjamin Contrand, Charlotte Durand-Teissier, Dunia Sakr, Cedric Gil-Jardiné, Sebastien Boutreux, Emmanuel Lagarde, Helene Peyrouzet, Regis Lassalle, Pierre Philip and Pierre-Olivier Girodet. (France)

4319 Time to Biologic Treatment and to Total Colectomy Associated with Diagnostic Delay in Ulcerative Colitis: Analysis of an Italian Regional Administrative Healthcare Database

> **Sara Ferraro,** Claudia Bartolini, Lorenzo Bertani, Irma Convertino, Ersilia Lucenteforte, Francesco Costa, Giulia Valdiserra, Emiliano Cappello, Corrado Blandizzi, Rosa Gini, Marco Tuccori. (Italy)

4475 Incidence of Thromboembolic Events Among Prothrombin Complex Concentrate (Human)-treated Patients: A Review of the Literature and Metaanalysis

Nicole Baker, Brahm Goldstein, Haley Kaplowitz, Jinesh Shah. (United States)



4496 Validity of Hospital ICD-10-GM-codes to Identify Anaphylaxis

> **Dominik de Sordi,** Sanny Kappen, Fabian Otto-Sobotka, Lia Gutierrez, Joan Fortuny, Jonas Reinold, Tania Schink, Antje Timmer. (Germany)

4600 Analysis Renal Dysfunction Incidence Caused by Acyclovir Injection in a Regional Teaching Hospital in Taiwan

> **Suhan Hsu,** Chia-Hui Lin, Yea-Jou Lou. (Taiwan)

4654 Risk of Acute Liver Injury with Protease Inhibitor-based Antiviral Therapy for Hepatitis C

> **Jessie Torgersen,** Craig W. Newcomb, Dena M. Carbonari, Christopher T. Rentsch, Lesley S. Park, Rajni Mehta, Kathryn D'Addeo, Tamar Taddei, Amy C. Justice, Vincent Lo Re. (United States)

4703 Impact of Metabolic Profiles on Drug Safety in Routine Care in Germany -Results from the EMPAR Study

Steffen Heß, Michael Steffens, Jochen Fracowiak, Tatjana Hübner, Daria Langner, Marco Garling, Felix Falkenberg, Christoph Roethlein, Willy Gomm, Roland Linder, Julia Stingl, Britta Hänisch. (Germany)

4801 Rapid Cycle Analytics to Obtain Descriptive Insight into Drug Utilisation and Background Disease Rates: Building on the Sentinel Modular Programs

Jolyon Fairburn-Beech, Jiajun Wen, Rachel Williams, John Logie, Marianne Cunnington, Andrew Bate. (United Kingdom)

4878 Healthcare Utilization of Prescribing Long-term Opioids in HIV Patients Who Initiated Art: A Retrospective Cohort Study

GYeon Oh, Erin L. Abner, David W. Fardo, Patricia R. Freeman, Daniela C. Moga. (United States) 4881 Comparative Safety of Antibiotic Therapy for Outpatient Treatment of Urinary Tract Infections

> **Anne Butler,** Michael Durkin, Yinjiao Ma, Matthew Keller, William Powderly, Margaret Olsen. (United States)

5068 A Universal Method to Obtain Prediction Intervals for Prevalence and Rate Parameters Estimated from Metaanalyses

Tibor Schuster, Araceli Gonzalez Reyes. (Canada)

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37 Comparative Safety of High-dose versus Standard-dose Influenza Vaccination in Patients with End-stage Renal Disease

J. Bradley Layton, Leah J McGrath, John M Sahrmann, Yinjiao Ma, Vikas R Dharnidharka, Caroline O'Neil, David J Weber, Anne M Butler. (United States)

2339 Equality Analysis on Three Doses Coverage of DPT Vaccine Among Children Aged 12 ~ 59 Months in China

Xiaoli Liu, Lin Zeng, Xiaoxiao Wang, Lin Zhuo, Hua Zhang, Nan Li, Liyuan Tao, Yanyan Shi, Yiming Zhao, Hongling Chu. (China)

2341 Vaccination Coverage and Its Determinants of Japanese Encephalitis Vaccine Among Children Aged 12-59 Months in Rural Counties of China in 2016

> **Xiaoli Liu,** Lin Zhuo, Xiaoxiao Wang, Lin Zeng, Nan Li, Hua Zhang, Yanyan Shi, Liyuan Tao, Hongling Chu, Yiming Zhao. (China)

2342 Variation in Influenza Vaccination Among Residents of Predominantly White and Black Long-term Care Facilities

Elliott Bosco, Kevin W McConeghy, Patience Moyo, Barbara Bardenheier, Yoojin Lee, Jessica Ogarek, Robertus van Aalst, Ayman Chit, Vincent Mor, Stefan Gravenstein, Andrew R Zullo. (United States)



2528 Selecting an Appropriate Comparator Group in Vaccine Cohort Studies of Older Adults: Recombinant Zoster Vaccine as an Example

> **Jennifer H Han,** Carla A Talarico, Soowoo Back, Susan dosReis, Aziza Jamal-Allial, Cheryl N McMahill-Walraven, Talia J Menzen, Vinit P Nair, Young Hee Nam, Josephine C Ocran-Appiah, Jeffrey S Brown, Katherine W Yih. (United States)

2529 A Broad Safety Assessment of the 9-valent Human Papillomavirus Vaccine

> **Katherine Yih,** Martin Kulldorff, Inna Dashevsky, Judith Maro. (United States)

2541 The Influenza Vaccination Continuity in Korean Elderly with High-risk Conditions

> **Na-Young Jeong,** Chulwoo Rhee, Joongyub Lee, Byung-Joo Park, Nam-Kyong Choi. (Korea, Republic of)

2552 Operational Considerations and Challenges in Use of an External Comparator Arm to Contextualize Safety Data from Maternal Immunization Trials: The South Africa Epidemiology of Obstetric and Neonatal Outcomes (SAFE ONE) Study Example

> **Vera Frajzyngier,** Jean Le Roux, Shobna Sawry, Jeanne Louw, Kekane Kebonethebe, Lee Fairlie, Judith Absalon, Shaun Barnabas, Samantha Munson, Caroline Vika, Clare Cutland. (United States)

2576 Pneumococcal Vaccination Coverage in Individuals (16 to 59 Years) with a Newly Diagnosed Risk Condition in Germany

> **Arijita Deb,** Victoria Louise Parsons, Bélène Podmore, Dominik Beier, Wolfgang Galetzka, Mai Duong, Nawab Qizilbash, Dennis Haeckl, Timo Boellinger, Sarah Mihm. (Germany)

2635 Utilization of a Booster Dose of Influenza Vaccine Among Adults with End-stage Renal Disease in the United States

> **Leah J. McGrath,** J. Bradley Layton, John M. Sahrmann, Vikas R. Dharnidharka, Caroline A. O'Neil, Anne M. Butler. (United States)

3759 Influenza Vaccination in Adult Patients with Hypertension or Diabetes in South Korea: A Cross-sectional Study

> **Seon-Ha Kim,** Sangshin Park, Nam-Kyong Choi. (Korea, Republic of)

3923 All-cause Pneumonia Among Adults 2007-2018 and Utility of a Simple Algorithm to Confirm Pneumonia

> **Amber Hsiao,** Joan Bartlett, John Hansen, Edwin Lewis, Ronika Alexander-Parrish, Raul E Isturiz, Jose A Suaya, Bradford D Gessner, Nicola P Klein. (United States)

3932 Accuracy of Batch Production Identifiers of Vaccines Recorded in the Clinical Practice Research Datalink Gold

François Haguinet, Olivia Mahaux, Vincent Bauchau. (Belgium)

4030 Tolerability of MenACWY-TT Vaccination in Adolescents in the Netherlands

> **Jeanet Kemmeren,** Leontine van Balveren, Agnes Kant, Hester de Melker. (Netherlands)

4072 Where are Children in the United States Receiving Their Influenza Vaccination?

> **Dana Gates,** Mohammad A Al-Mamun, Kelly Orr, Steven A Cohen, Aisling R Caffrey. (United States)





4076 Pharmacist Authority to Administer Pediatric Influenza Immunizations in the United States

> **Dana Gates,** Kelly Orr, Steven A Cohen, Aisling R Caffrey. (United States)

4147 Venous Thromboembolism Among Male Recipients of the 4-valent Human Papillomavirus Vaccine in United States Insurance Claims Data

> **Kandace Amend,** Bruce Turnbull, Li Zhou, Morgan Marks, Christine Velicer, Patricia Saddier, John Seeger. (United States)

4181 Selecting a Comparison Group for Outcomes Occurring on the Day a Vaccine is Administered

> **Kandace Amend,** Bruce Turnbull, Li Zhou, Morgan Marks, Christine Velicer, Patricia Saddier, John Seeger. (United States)

4192 Change-point Analysis of Spontaneous Adverse Event Reporting Following Human Papillomavirus Vaccination

> **Seung-Hun You,** Myo-Song Kim, Min-Taek Lee, Ye-Jin Kang, Sun-Young Jung. (Korea, Republic of)

4207 Anaphylaxis Following Vaccination in South Korea: A Large-linked Database Study

Hyesung Lee, Young June Choe, Ju Hwan Kim, Ju-Young Shin. (Korea, Republic of)

4233 Prescription Patterns of the Inactivated Influenza Vaccine in Private Healthcare Settings in South Africa

Ilse Truter. (South Africa)

4473 Maternal Tdap Vaccination Trends in the United States, 2016-2018

> **Florence T Wang,** Li Zhou, Kelesitse Phiri, John D Seeger. (United States)

4652 Flu Vaccination in Portugal: Integration of Community Pharmacies as Vaccination Points of Public NHS

> **José Guerreiro,** Maria Cary, Heloísa Galante, António T. Rodrigues. (Portugal)

4674 The Safety of Human Papillomavirus Vaccine Among Female Adolescents in Korea: A Cohort and Self-controlled Risk Interval Study

Dongwon Yoon, Ji-Ho Lee, Hyesung Lee, Ju-Young Shin. (Korea, Republic of)

4744 Determinants of the HPV Vaccination Among Girls Attending Spanish Primary Care Settings

> **Belén Castillo Cano,** Mar Martín-Pérez, Dolores Montero-Corominas, Elisa Martín-Merino. (Spain)

4772 "If It Does Not Endanger Me or the Health of My Baby, I Will Take It Up..." Vaccine Safety is an Important Consideration for Maternal Immunization Acceptability in Rural Uganda - A Qualitative Study

Dan Kajungu, Michael Muhoozi, James Stark, Daniel Weibel. (Uganda)

4787 Seasonal Influenza Vaccine Effectiveness: Evidence from Test-negative Design Studies

> **George Okoli,** Florentin Racovitan, Christiaan Righolt, Salaheddin Mahmud. (Canada)

4985 Risk of Central Demyelination and Use of Vaccines 2009-2017 in France

Lamiae Grimaldi, Lucien Abenhaim. (France)

5069 Defining Benchmarks for Tolerable Risk Thresholds in Cancer Screening: Impact of Human Papillomavirus Vaccination on the Future of Cervical Cancer Screening

Joseph Tota, Sandra Isidean, Eduardo Franco. (United States)

5149 A Systematic Review of Active Vaccine Surveillance Studies: Focused on the Vaccine Safety Datalink

Eunsun Lim, Na-Young Jeong, Nam-Kyong Choi. (Korea, Republic of)



Mid-Year 2020 Posters

We missed hosting you for the 2020 Mid-Year Meeting this year!

Please enjoy these on-demand poster presentations from talented student members that were prepared for that event.

ISPE'S 2020 MID-YEAR MEETING APRIL 18-21, 2020 LOEWS ROYAL PACIFIC RESORT

ORLANDO, FLORIDA

1 Impact of anticholinergic medication burden on mobility and falls in the Lifestyle Interventions and Independence For Elders (LIFE) Study

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