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US Food and Drug Administration (US FDA)

Christian Hampp, FISPE

#### International Network for Epidemiology in Policy (INEP)

Meredith Smith, FISPE Susan dosReis, FISPE

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The Boston Collaborative Drug Surveillance Program Boston University, USA

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Center for Pharmacoepidemiology and Treatment Science (PETS) USA

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#### NEWCOMER TRACK REVIEWERS

Ian Douglas, FISPE, *Director* Emily Brouwer Sascha Dublin

#### Kristian Filion Alicia Gilsenan, FISPE Xavier Kurz

Edward Lai Daniel Mines Daniel Morales Lisa Pont, FISPE Suzie Seabroke Katja Taxis, FISPE

### Congratulations to Our New Fellows



Kourtney Davis, FISPE



Solomon lyasu, FISPE



Carol Koro, FISPE



Stephan Lanes, FISPE



Deborah Layton, FISPE



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## spe | 2021 Awards

#### EMERGING LEADER AWARD

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ANDREW MCAFEE AWARD For the best abstract submitted from a researcher or student living in a developing country Comparing the Risk of Venous Thromboembolism in Rheumatoid Arthritis Patients receiving Tofacitinib and TNF Inhibitors in Taiwan	<b>JOHN SNOW AWARD</b> Comparative Risk of Hospitalization for Heart Failure Among Patients with Xanthine Oxidase Inhibitors and Uricosuric Agents Fang-Ju Lin
Chin-Yao Shen	
BEST METHODS ABSTRACT	BEST DRUG UTILIZATION
(STUDENT)	RESEARCH ABSTRACT (STUDENT)
Characterizing Imbalance in the Tails of the	Prior Opioid Tolerance Among New Users of
Propensity Score Distribution	Transdermal Fentanyl in Taiwan, 2011-2018
Bethany DiPret	Chih-Wan Lin

INDUCTION OF ISPE FELLOWS

#### STANLEY A. EDLAVITCH AWARD (STUDENT)

Use of Low-Dose Quetiapine and the Risk of Major Adverse Cardiovascular Events Mikkel Hoejlund

#### ISPE-PDS ROLAND D. MANN AWARD FIRST PRIZE

#### In Utero Opioid Exposure and Risk of Infection in Childhood: A Multinational Nordic Cohort Study

Milada Mahic | Sonia Hernandez-Diaz | Millie Wood | Helle Kieler Ingvild Odsbu | Metter Norgarrd | Buket Ozturk | Brian Bateman Vidar Hjellvik | Svetlana Skurtveit | Marte Handal

#### HONORABLE MENTIONS

Bias in Case-Crossover Studies of Medications Due to Persistent Use: A Simulation Study Katsiaryna Bykov | Shirley Wang | Jesper Hallas Anton Pottegård | Malcom MaClure | Joshua Gagne

Time-related Biases in Pharmacoepidemiology Samy Suissa | Sophie Dell'Aniello

The Impact of Generic Aromatase Inhibitors on Initiation, Adherence and Persistence Among Women with Breast Cancer: Applying Multi-State Models to Understand the Dynamics od Adherence

Aaron Winn | Nicole Fergerstrom | Liliana Pezzin Purushottam Lund | Joan Neuner

#### Outcome Misclassification: Impact, Usual Practice in Pharmacoepidemiology Database Studies and an Online Aid to Correct

Gillian Hall | Stephan Lanes | Kaatj Bollaerts Xiaofeng Zhou | Germano Ferreira | Rosa Gini

#### Gastrointestinal Bleeding Risk with Rivaroxaban vs Aspirin in Atrial Fibrillation: A Multinational Study

Laura Fanning | Ian Wong | Esther Chan | Xue Li Pajaree Mongkhon | Kenneth Man | Li Wei | Wai Leung Peteris Darzins | Simon Bell | Jenni Ilomaki | Wallis Lau

### Schedule at-a-Glance

### MONDAY, AUGUST 23

8:00 - 10:00 AM PLENARY

10:00 - 11:30 AM CONCURRENT WORKSHOPS

11:45 AM - 1:30 PM CONCURRENT ORAL PRESENTATIONS

1:45 - 3:30 PM CONCURRENT ORAL PRESENTATIONS

3:30 - 5:00 PM CONCURRENT WORKSHOPS

5:30 - 7:30 PM LIGHTNING PRESENTATIONS

8:00 - 9:30 PM PLENARY REPEATED

### TUESDAY, AUGUST 24

8:15 - 10:00 AM PLENARY

10:00 - 11:30 AM CONCURRENT WORKSHOPS

11:45 AM- 1:15 PM

CONCURRENT WORKSHOPS

1:45 - 3:30 PM CONCURRENT ORAL PRESENTATIONS

3:30 - 4:45 PM SPOTLIGHT POSTERS

5:15 - 6:30 PM SPOTLIGHT POSTERS

6:45 - 7:45 PM LIGHTNING PRESENTATIONS

8:00 - 9:30 PM PLENARY REPEATED

### WEDNESDAY, AUGUST 25

8:15 - 10:00 AM PLENARY

10:00 - 11:30 AM CONCURRENT WORKSHOPS

11:45 AM - 1:30 PM CONCURRENT ORAL PRESENTATIONS

1:45 - 2:45 PM

ANNUAL MEMBER MEETING & AWARDS CEREMONY

3:00 - 6:00 PM CONCURRENT ORAL PRESENTATIONS

6:00 - 6:30 PM CLOSING CEREMONY

8:00 - 9:30 PM PLENARY REPEATED

### MONDAY, AUGUST 23

#### 8:00 - 8:30 AM

#### WELCOME SESSION

Olaf Klungel – President, International Society for Pharmacoepidemiology Syd Phillips – Chair, ICPE Scientific Program Committee

#### 8:30 - 10:00 AM

#### PLENARY

Diversity, Equity, and Inclusion in Pharmacoepidemiology – The Role of Caste in Drug Utilization, Safety, and Therapeutic Risk Management

#### SPEAKERS

Whitney Robinson – University of North Carolina at Chapel Hill Folakemi Odedina – Mayo Clinic Macarius Donneyoung – The Ohio State University John Jackson – Johns Hopkins

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

### Big Data in Health and Bioethics: A Call for a Comprehensive, Multi-Disciplinary, ISPE Position

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

#### PRESENTERS

Edward Bortnichak – Pharmacoepidemiology, Center for Observational and Real-World Evidence (CORE), Merck & Co., Inc.

Solomon lyasu - Merck & Co. Inc.

Patrick Ryan – Janssen Research & Development

#### Ameet Sarpatwari – Division

of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

Peter Arlett – European Medicines Agency

All times in US Eastern

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

#### Outcome Measurements for External Comparator Arms: New Opportunities for Epidemiology Methods Application and Development Methods in Pharmacoepidemiology

viethous in Pharmacoepidemiolog

#### PRESENTERS

Joan Largent – IQVIA Emily Brouwer – Janssen Cynthia Girman – CERobs Consulting, LLC Christen Gray – AstraZeneca Michele Jonsson Funk – University of North Carolina at Chapel Hill Robert Glynn – Harvard T. H. Chan School of Public Health

#### CO-AUTHORS

Dimitri Bennett – Takeda

Kueiyu Joshua Lin – Brigham and Women's Hospital Daniela Moga – Department of Pharmacy Practice and Science, College of Pharmacy, University of Kentucky

Sabina Nduaguba - University of Florida

Mary Prince Panaccio – Research Outcomes Innovations

Xuerong Wen – University of Rhode Island, College of Pharmacy

Richard Wyss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA

Hongbo Yuan – Canadian Agency for Drugs and Technologies in Health

Huifeng Yun – Department of Epidemiology, University of Alabama at Birmingham

### ICPE 2022 August 24-28, 2022

ISPE International Society for Pharmacoepidemiology

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#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

#### Polypharmacy: Problems and Solutions for Its Methodologic Challenges in Real-World Data

Methods in Pharmacoepidemiology

#### PRESENTERS

Amy Justice – US Department of Veterans Affairs

Christopher Rentsch – London School of Hygiene & Tropical Medicine; US Department of Veterans Affairs

Kirsha Gordon – VA CT Healthcare System

Jonathon Romero – Oak Ridge National Laboratory

Jordan Guillot – Université de Bordeaux

Vincent Lo Re – Center for Pharmacoepidemiology Research and Training, Center for Clinical Epidemiology and Biostatistics, Department of Biostatistics, Epidemiology, and Informatics, Perelman School of Medicine, University of Pennsylvania, USA

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

#### Real World Data in the Era of COVID-19: The Devil in the Details. An ISPE RWE Task Force/ COVID-19 Workgroup Symposium

#### PRESENTERS

Montse Soriano Gabarro-Bayer AG

Dana Teltsch – Apellis

Mugdha Gokhale – Center for Observational and Real-world Evidence (CORE), Merck Research Laboratories

Paul Petraro – Head, RWE Analytic CoE. Boehringer-ingelheim

Jeremy Rassen – Aetion, Inc.

Stephan Lanes - HealthCore Inc.

Soko Setoguchi – RWJ Medical School, Center for Pharmacoepidemiology and Treatment Science (PETS), Institute for Health, Health Care Policy and Aging Research

Daniel Prieto-Alhambra – Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, UK

#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Confusion, Falls, and Fractures

#### Geriatric Pharmacoepidemiology Risk of Falls Following the Initiation of Antihypertensives in the Elderly: A Self-Controlled Case Series in the UK

#### PRESENTING AUTHOR

Annika Jödicke – Pharmaco- and Device Epidemiology, Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, UK

#### CO-AUTHORS

Eng Hooi (Cheryl) Tan – Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, UK

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#### Geriatric Pharmacoepidemiology Uncontrolled Pain and Risk for Depression and Behavioral Symptoms in Patients with Dementia

#### PRESENTING AUTHOR

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#### Geriatric Pharmacoepidemiology Use of Medications with Anticholinergic and Sedative Properties and Fall-Related Fractures Among Older Adults

#### PRESENTING AUTHOR

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Danijela Gnjidic – Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney, Australia

Jennifer Lund – Department of Epidemiology, University of North Carolina at Chapel Hill, NC, USA

#### Geriatric Pharmacoepidemiology Bisphosphonate Use and Risk of Severe Acute Kidney Injury: A Self-Controlled Case Series in Frail Elderly Patients in the UK

#### PRESENTING AUTHOR

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#### Geriatric Pharmacoepidemiology Risk of Delirium Associated with Antimuscarinics in Older Adults: A Case-Time-Control Study

PRESENTING AUTHOR Prasad Nishtala – University of Bath

#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### COVID-19 Epidemiology: Risk Factors, Drug Exposures, and Outcomes

Disease Epidemiology/Clinical Course Severe Obesity is a Risk Factor for Mortality in Patients with COVID-19

#### PRESENTING AUTHOR

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Kerry LaPlante – Infectious Diseases Research Program, Providence Veterans Affairs Medical Center, Providence, RI, USA

Disease Epidemiology/Clinical Course Predictors of Critical Care, Mechanical Ventilation, and Mortality Among Hospitalized Patients with COVID-19 in an Electronic Health Record Database

#### PRESENTING AUTHOR

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#### Disease Epidemiology/Clinical Course Utilizing the National COVID Cohort Collaborative (N3C) to Evaluate Risk of Serious Outcomes with COVID-19 Among Chronically Immunosuppressed Persons

#### PRESENTING AUTHOR

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Brian Garibaldi – Johns Hopkins Medicine

Jodi Segal – Johns Hopkins University

G. Caleb Alexander – Johns Hopkins Center for Drug Safety and Effectiveness

#### Disease Epidemiology/Clinical Course

#### Incidence and Risk Factors for COVID-Related Urgent Medical Visits Among US Patients Diagnosed With COVID-19 in the Outpatient Setting

#### CO-AUTHORS

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#### Disease Epidemiology/Clinical Course Chronic Diseases, Health Conditions and Risk of COVID-19-Related Hospitalization and in-Hospital Mortality During the First Wave of the Epidemic in France: A Cohort Study of 66 Million People

#### PRESENTING AUTHOR

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Rosemary Dray-Spira – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products [ANSM], and French National Health Insurance [CNAM]), Saint-Denis, France

Alain Weill – French National Health Insurance Fund (Assurance Maladie)

Mahmoud Zureik – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

#### **Drug Effectiveness**

#### Convalescent Plasma Therapy and Mortality Among US Veterans Hospitalized with Non-Severe COVID-19: An Observational Analysis Emulating a Target Trial

#### PRESENTING AUTHOR

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#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

### Drug Utilization in Pain and Musculoskeletal Conditions

Drug Utilization Research Utilization of Non-Pharmacologic Pain Therapies Among Primary Care Physicians in the United States: A Cross-Sectional Survey

PRESENTING AUTHOR

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Kristin Meek – Johns Hopkins Center for Drug Safety and Effectiveness

Christopher Jones – Centers for Disease Control and Prevention Andrew Kolodny – Brandeis University

**G. Caleb Alexander** – Johns Hopkins Center for Drug Safety and Effectiveness

#### Drug Utilization Research Prevalence of Osteoporosis and Its Treatment Among Women ≥50 in NHANES: 1999-2018

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Sophie Mayer – Department of Epidemiology, University of North Carolina at Chapel Hill

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Min Kim – Center for Observational Research, Amgen

Michele McDermott – Center for Observational Research, Amgen M. Alan Brookhart – NoviSci, Inc.

#### Drug Utilization Research

#### Serum Vitamin D Levels and Incident Prescription Opioid Use Among Opioid-Naïve Patients

#### PRESENTING AUTHOR

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Biologics/Biosimilars

#### Discontinuation Rate of Tofacitinib is Similar When Compared to TNF Inhibitors in Rheumatoid Arthritis Patients: Data from A Rheumatoid Arthritis Cohort

#### PRESENTING AUTHOR

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#### Drug Utilization Research Primary Care Physicians' Preparedness to Treat Opioid Use Disorder in the United States: A Cross-Sectional Survey

#### PRESENTING AUTHOR

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#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Heterogeneity in Methods

Methods in Pharmacoepidemiology A New Method to Estimate the Total Cohort Size for Patient Recruitment in Self-Controlled Case Series Study

PRESENTING AUTHOR Ling Li – Pfizer, Inc. CO-AUTHORS Stephen E. Schachterle – Pfizer, Inc. Charles Wentworth – Pfizer, Inc. Heather Rubino – Pfizer, Inc. Ann Madsen – Pfizer, Inc Xiaofeng Zhou – Pfizer, Inc.

Methods in Pharmacoepidemiology Sessa Empirical Estimator (SEE): A Data-Driven Method for Predicting the Duration of Pharmacological Prescriptions in Secondary Data Sources.

#### PRESENTING AUTHOR

Maurizio Sessa – Pharmacovigilance Research Center, Department of Drug Design and Pharmacology, University of Copenhagen

#### Methods in Pharmacoepidemiology Graphical Representation of an Array of Quantitative Bias Analysis Scenarios for Differential Outcome Misclassification

PRESENTING AUTHOR

J. Bradley Layton – RTI Health Solutions CO-AUTHORS Ryan Ziemiecki – RTI Health Solutions Heather E. Danysh – RTI Health Solutions Charles Gaber – University of North Carolina at Chapel Hill Alicia Gilsenan – RTI Health Solutions Catherine Johannes – RTI Health Solutions

#### Methods in Pharmacoepidemiology The Performance of Different Strategies to Manage Confounding in Cardinality Matching for Medical Device Epidemiology: A Simulation Study

PRESENTING AUTHOR Mike Du – University of Oxford CO-AUTHORS

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#### Methods in Pharmacoepidemiology Use of Linked Databases for Improved Confounding Control: Considerations for Potential Selection Bias

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#### Methods in Pharmacoepidemiology A Systematic Approach Towards Missing Lab Data in Electronic Health Records: A Case Study in Non-Small Cell Lung Cancer and Multiple Myeloma

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#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Pregnancy: Wood for the trees

#### Pregnancy and Lactation Implication of Maternal Continuous Enrollment on Stillbirth Gestational Age Distributions and Maternal Characteristics in Medicaid Enrollees

#### PRESENTING AUTHOR

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Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health

Almut Winterstein – Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida

#### Pregnancy and Lactation Feasibility of Using Healthcare Utilization Data to Identify Neurodevelopmental Disorders for Transgenerational Pharmacoepidemiology

#### PRESENTING AUTHOR

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#### Pregnancy and Lactation

#### Validating an Optimized Live Birth Gestational Age Algorithm in a Nationwide Medicaid Sample and Quantifying the Misclassification of Exposure due to Estimated Gestational Age

#### PRESENTING AUTHOR

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#### Pregnancy and Lactation

#### Statistical Power for Use of Tree-Based Scan Statistics for Surveillance of Infant Outcomes Following Maternal Perinatal Medication Use

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Use of Tree-Based Scan Statistics for Surveillance of Infant Outcomes Following Maternal Perinatal Medication Use: A Propensity Score Matched Case Study

#### PRESENTING AUTHOR

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#### Pregnancy and Lactation

#### Fertility Rates in Women with Psoriasis and Psoriatic Arthritis: A Population-Based Cohort Study

#### PRESENTING AUTHOR

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#### 1:45 – 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Opioids: A Globally Trending Topic

#### Drug Utilization Research Trends in Long-Term Use of Prescribed Opioids in Norway 2010-2019

#### PRESENTING AUTHOR

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Svetlana Skurtveit – Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway

#### Pediatric Pharmacoepidemiology Filled Prescriptions for Opioids Among Children and

### Adolescents – A Nationwide Study from 2010 to 2018

PRESENTING AUTHOR

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Thomas Clausen – University of Oslo

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Svetlana Skurtveit – Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway

#### Drug Utilization Research Trends and Outcomes of Serious Complications

Associated with Non-Fatal Opioid Overdoses in Ontario, Canada

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#### Drug Utilization Research

#### Geographic Variation in the Use of Gabapentinoids and Opioids for Pain in a Commercially Insured Population in the United States

#### PRESENTING AUTHOR

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#### CO-AUTHORS

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Anne Hume – University of Rhode Island

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Matthew Alcusky – Division of Epidemiology, Department of Population and Quantitative Health Services, University of Massachusetts Medical School

Kate Lapane – Division of Epidemiology, Department of Population and Quantitative Health Services, University of Massachusetts Medical School

#### Drug Utilization Research Trajectories of Pregabalin Use and Their Association with Longitudinal Changes in Opioid and Benzodiazepine Daily Dose

#### PRESENTING AUTHOR

Andrea Schaffer – Centre for Big Data Research in Health, UNSW Sydney

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#### Drug Utilization Research Prior Opioid Tolerance Among New Users of Transdermal Fentanyl in Taiwan, 2011-2018

#### PRESENTING AUTHOR

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#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Pregnancy: Pick-n-mix

Pregnancy and Lactation

Prescription Medication Use and Baseline Health Status of Women with Live Birth Deliveries in a National Data Network: The Sentinel Distributed Database Mother-Infant Linkage Table

#### PRESENTING AUTHOR

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**Catherine Corey** – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, MD, USA

#### Pregnancy and Lactation Increasing Prescriptions of Misoprostol Dispensed Before Delivery in Belgium (2003-2017): Evidence from Healthcare Administrative Database

#### PRESENTING AUTHOR

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#### Pregnancy and Lactation

### Effects of Gadolinium-Enhanced MRI Exposure During Pregnancy on Neonatal Intensive Care Unit Admission

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Steven Bird – Division of Epidemiology, Office of Pharmacovigilance and Epidemiology, Food and Drug Administration

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Sonja Rasmussen – College of Medicine, University of Florida

Almut Winterstein - Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida

#### Pregnancy and Lactation Proton Pump Inhibitors in Pregnancy and Risk of Preeclampsia: A Nationwide Cohort Study of 1.9 Million Pregnancies

#### PRESENTING AUTHOR

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#### Pregnancy and Lactation Validity of ICD-10 Z3A Codes for Estimating Date of Last Menstrual Period

PRESENTING AUTHOR

Andrea Chomistek – Optum CO-AUTHORS Kelesitse Phiri – GlaxoSmithKline Jenna Calderbank – Optum Michael Doherty – Optum Stephanie Chiuve – AbbVie Brenda Hinman-Mcllroy – AbbVie Michael Snabes – AbbVie, Inc. John Seeger – Epidemiology, Optum, Boston, MA, USA

#### Pregnancy and Lactation

#### COVID-19 Pharmacotherapy During Pregnancy: International Registry of Coronavirus Exposure in Pregnancy (IRCEP)

PRESENTING AUTHOR

Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health CO-AUTHORS

Louisa Smith – Harvard TH Chan School of Public Health Diego Wyszynski – Pregistry

#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### The Aging Heart

Benefit-Risk Assessment, Communication, and Evaluation (BRACE) Risk of Myocardial Infarction, Stroke or Death in New Users of Intravitreal Aflibercept vs New Users of Intravitreal Ranibizumab: A Nationwide Cohort Study

#### PRESENTING AUTHOR

Sophie Billioti de Gage - EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

#### CO-AUTHORS

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Mahmoud Zureik - EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

#### Geriatric Pharmacoepidemiology Statin Discontinuation and Risk of Cardiovascular Events in Older People: A Population-Based Cohort Study in Denmark

#### PRESENTING AUTHOR

Wade Thompson – University of Southern Denmark CO-AUTHORS

Lucas Morin – Inserm CIC 1431, Clinical Investigation Unit, University Hospital of Besançon Dorte Ejg Jarbøl – University of Southern Denmark

Jacob Andersen – University of Southern Denmark

Martin Ernst – University of Southern Denmark

Jesper Nielsen – University of Southern Denmark

Peter Haastrup – University of Southern Denmark

Morten Schmidt – Aarhus University Hospital

Anton Pottegård – University of Southern Denmark

#### Geriatric Pharmacoepidemiology Assessment of Co-Medication Quality in Older Colorectal Cancer Patients at Hospital Discharge After Tumor Surgery and Its Associations with Chemotherapy-Related Adverse Drug Reactions and 5-Year Survival

#### PRESENTING AUTHOR

Li-Ju Chen – Division of Clinical Epidemiology and Aging Research, German Cancer Research Center (DKFZ)

CO-AUTHOR

Ben Schöttker – Division of Clinical Epidemiology and Aging Research, German Cancer Research Center (DKFZ)

#### Geriatric Pharmacoepidemiology Comparative Risk of Cardiac Arrhythmias Associated with Acetylcholinesterase Inhibitor Use

#### PRESENTING AUTHOR

Yichang Huang – University of Waterloo, School of Pharmacy CO-AUTHORS

John-Michael Gamble – School of Pharmacy, University of Waterloo

David Juurlink – Department of Medicine, University of Toronto Mhd. Wasem Alsabbagh – School of Pharmacy, University of Waterloo

#### Geriatric Pharmacoepidemiology Risk of Cardiotoxicity Associated with Fluoropyrimidine-Based Chemotherapy Among Older Colorectal Cancer Patients: A New User Cohort Study

PRESENTING AUTHOR Chao Li – Auburn University CO-AUTHORS Chiahung Chou – Auburn University Surachat Ngorsuraches – Auburn University Li Chen – Indiana University Jingjing Qian – Auburn University

#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### **Trials and Errors**

#### Methods in Pharmacoepidemiology Using Randomized Trial Data to Estimate Effects of Complex Treatment Regimens in Real-World Patients

#### PRESENTING AUTHOR

Michael Webster-Clark – University of North Carolina at Chapel Hill

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Hanna Sanoff – University of North Carolina at Chapel Hill Department of Medicine

Til Stürmer – Department of Epidemiology, University of North Carolina at Chapel Hill

Daniel Westreich – University of North Carolina at Chapel Hill Alexander Keil – University of North Carolina at Chapel Hill

#### Methods in Pharmacoepidemiology A Plasmode Simulation of Covariate Misclassification and Transportability

#### PRESENTING AUTHOR

Michael Webster-Clark – University of North Carolina at Chapel Hill

CO-AUTHOR

Jessie Edwards – Department of Epidemiology, University of North Carolina at Chapel Hill

#### Methods in Pharmacoepidemiology The Effect of the Anticholinergic Properties of Antidepressants on the Incidence of Dementia: A Target Trial Emulation

PRESENTING AUTHOR Joan Forns – RTI Health Solutions CO-AUTHORS Jaume Aguado – RTI Health Solutions Elena Rivero-Ferrer – RTI Health Solutions Estel Plana – RTI Health Solutions Barbra Dickerman – Harvard T.H. Chan School of Public Health Xabier Garcia de Albeniz – RTI Health Solutions

#### Methods in Pharmacoepidemiology Stable Balancing Weights for Unanchored Matching-Adjusted Indirect Comparisons and Targeting External Control Arm Estimands

PRESENTING AUTHOR Stephen Johnston – Johnson & Johnson CO-AUTHORS Harikumaran Dwarakanathan – Mu Sigma Jason Waggoner – Johnson & Johnson Michael Schwiers – Johnson & Johnson Sanjoy Roy – Johnson & Johnson Paul Coplan – Johnson & Johnson

#### Methods in Pharmacoepidemiology Linear Mixed Model and Multistate Markov Model to Compare Changes in Clinical Measurements Over Time. A Blood Pressure Example.

#### CO-AUTHORS

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#### Methods in Pharmacoepidemiology Rank-Based Weighting for Balancing on Median Baseline Characteristics in Matching Adjusted Indirect Comparisons (MAIC)

PRESENTING AUTHOR Shirley Liao – Biogen CO-AUTHORS Carl de Moor – Biogen Angela D Paradis – Biogen Justin Bohn – Biogen Changyu Shen – Biogen Gabrielle Simoneau – Biogen Fabio Pellegrini – Biogen

#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Vaccines

Vaccines

#### Evaluation of the Potential Confounding Effect of Shingles on the Risk of Guillain-Barré Syndrome After Vaccination with the Recombinant Zoster Vaccine

PRESENTING AUTHOR Francois Haguinet – GSK CO-AUTHORS Paola Pirrotta – GSK Vincent Bauchau – GSK

#### Vaccines

#### Sensitivity Analysis of Design Choices for Estimating Incidence Rates of Adverse Events of Special Interest in Vaccine Safety

#### PRESENTING AUTHOR

Anna Ostropolets – Department of Biomedical Informatics, Columbia University Irving Medical Center CO-AUTHORS

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George Hripcsak – Department of Biomedical Informatics, Columbia University Irving Medical Center

#### Vaccines

#### Effectiveness of Influenza Vaccination in Healthy Children: A Population-Based Investigation

#### PRESENTING AUTHOR

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Carlo Giaquinto – Division of Pediatric Infectious Diseases, Department for Woman and Child Health, University of Padua, Padua, Italy

#### Vaccines

### Background Incidence Rates of Adverse Events of Special Interest for COVID-19 Vaccine Monitoring

#### PRESENTING AUTHOR

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Daniel Weibel – Department Datascience & Biostatistics, University Medical Center Utrecht

Miriam Sturkenboom – Department Datascience & Biostatistics, University Medical Center Utrecht

#### Vaccines

#### Vaccination and Acute Flares in Multiple Sclerosis: A Nationwide Case-Crossover Study Using the French SNDS Health Care Databases

PRESENTING AUTHOR

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SO AUTTIONS

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Philippe Attias – Re-Meds France

Tom Duchemin – Re-Meds France

Lucien Abenhaim – London School of Hygiene & Tropical Medicine Yola Moride – Faculty of Pharmacy, Université de Montréal, Montreal, QC, Canada

#### 3:30 - 5:00 PM

#### WORKSHOP / CONCURRENT

#### COVID-19 Confidential: Enabling Trust In COVID-19 Research with Fit for Purpose Real-World Data

Methods in Pharmacoepidemiology

PRESENTERS Nicolle Gatto – Aetion, Inc. Jessica Franklin – Optum Elizabeth Garry – Aetion, Inc. David Martin – Moderna Aloka Chakravarty – Food and Drug Administration

Jeremy Rassen – Aetion, Inc.

#### 3:30 - 5:00 PM

#### WORKSHOP / CONCURRENT

Drug Utilization Research in Africa: Challenges and Potential Solutions

Drug Utilization Research

#### PRESENTERS

Maribel Salas – Clinical Safety and Pharmacovigilance, Daiichi Sankyo Inc Basking Ridge, NJ and CCEB/CPeRT, University of Pennsylvania Perelman School of Medicine

Johanita Burger – Medicine Usage in South Africa (MUSA), North-West University

Laura Horne – Clinical Safety and Pharmacovigilance, Daiichi Sankyo Inc Basking Ridge

Johanna Meyer – Division of Public Health Pharmacy and Management, School of Pharmacy, Sefako Makgatho Health Sciences University

Ilse Truter – Nelson Mandela University

#### 3:30 - 5:00 PM

#### WORKSHOP / CONCURRENT

Triangulating the Truth: State-of-the-Art Sensitivity Analyses for Observational Research Methods in Pharmacoepidemiology

#### PRESENTERS

Marianne Cunnington - Glaxosmithkline

lan Douglas – London School of Hygiene & Tropical Medicine Jeremy Brown – London School of Hygiene and Tropical Medicine Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health

Daina Esposito – Boston University School of Public Health Wilhelmine Meerhaus – Glaxosmithkline

#### 5:30 - 6:30 PM

#### **LIGHTNING SESSION 1**

Disease Epidemiology/Clinical Course Use of Remdesivir for COVID-19 in the Real World: An Analysis of US Electronic Medical Records

#### PRESENTING AUTHOR

Julius Asubonteng – Gilead Science, Inc. CO-AUTHORS Sara Haredasht – Gilead Science, Inc. Seth Kuranz – Trinetx, Inc. Anand Chokkalingam – Gilead Science, Inc.

#### Disease Epidemiology/Clinical Course

Comparing Outcomes in Trial-Eligible vs Real-World COVID-19 Patients: The Case of Invasive Mechanical Ventilation

#### PRESENTING AUTHOR

Ashley Martinez – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

CO-AUTHORS

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Maria Kempner – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

Joy Kolonoski – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

Sarah Dutcher – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration

Brian Kit – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration

#### Disease Epidemiology/Clinical Course Outpatient-Identified COVID-19 and Subsequent Hospitalized Thrombotic Events

PRESENTING AUTHOR

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Ashley Martinez – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

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Sarah Dutcher – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration

Brian Kit – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration

#### Disease Epidemiology/Clinical Course Patients Tell All: Using a Direct-to-Patient Community Registry to Understand Patient Burden of COVID-19

#### PRESENTING AUTHOR

Emma Brinkley – IQVIA CO-AUTHORS Christina Mack – IQVIA Natalia Petruski-Ivleva – IQVIA Matthew Reynolds – IQVIA Alison Bourke – IQVIA Kalyani Hawaldar – IQVIA Nancy Dreyer – IQVIA

#### Methods in Pharmacoepidemiology Marginal Structural Models with Latent Class Growth Modeling of Time-varying Treatment

#### CO-AUTHORS

Awa Diop – Department of Social and Preventive Medicine, Laval University

Denis Talbot – Department of Social and Preventive Medicine, Laval University

PRESENTING AUTHOR

Caroline Sirois – Faculty of pharmacy, Laval University

#### Methods in Pharmacoepidemiology Residual Bias and Indirect Covariate Balance in an Applied Comparison of Large-Scale Propensity Score and Cardinality Matching

PRESENTING AUTHOR Stephen Fortin – Janssen, Research and Development CO-AUTHORS

Stephen Johnston – Johnson & Johnson Martijn Schuemie – Janssen Research and Development

#### Methods in Pharmacoepidemiology Characterizing Imbalance in the Tails of the Propensity Score Distribution

#### PRESENTING AUTHOR

Bethany DiPrete – Injury Prevention Research Center, University of North Carolina at Chapel Hill CO-AUTHORS Cynthia Girman – CERobs Consulting, LLC

Panagiotis Mavros – Janssen Pharmaceutical Companies of J&J Alexander Breskin – NoviSci Inc. M. Alan Brookhart – NoviSci, Inc.

#### Methods in Pharmacoepidemiology High-Dimensional Propensity Score Approaches in Stata Using the Hdps Suite of Commands

PRESENTING AUTHOR

John Tazare – London School of Hygiene & Tropical Medicine

CO-AUTHORS

Liam Smeeth – London School of Hygiene & Tropical Medicine Stephen Evans – London School of Hygiene &

Tropical Medicine

lan Douglas – London School of Hygiene & Tropical Medicine Elizabeth Williamson – London School of Hygiene & Tropical Medicine

#### Drug Utilization Research Patterns of Antibiotic Prescription Among Adult Outpatients in Italy

#### PRESENTING AUTHOR

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#### Drug Utilization Research Determinants of Antimalarial Prescription Patterns Among Health Care Providers in Public Health Facilities in Uasin Gishu County, Kenya

PRESENTING AUTHOR

Henry Amdany – Moi university CO-AUTHORS Wendy O'Meara – Moi university Gabriel kigen – Moi university

#### Drug Utilization Research

#### Co-Utilization of Opioids and Non-Benzodiazepine Sedative Hypnotics in U.S. Ambulatory Care Visits, 2006-2016

#### PRESENTING AUTHOR

Razanne Oueini – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida

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#### Drug Utilization Research

#### Early Uptake of New Molecular Entities Approved in 2017 in a Multisite National US Healthcare Data Network

#### PRESENTING AUTHOR

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Michael Nguyen – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD

#### Drug Effectiveness Comparative Effectiveness of Bevacizumab vs Cetuximab in Patients with Metastatic Colorectal Cancer

#### PRESENTING AUTHOR

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#### Drug Effectiveness

Efficacy-Effectiveness Gap for Standard First-Line Treatment of Metastatic Non-Small Cell Lung Cancer Among Patients with Barriers to Care

#### PRESENTING AUTHOR

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#### Drug Effectiveness

#### Acute Kidney Injury in Patients with Atrial Fibrillation Treated with Rivaroxaban or Warfarin: A Population-Based Study in the United Kingdom

#### PRESENTING AUTHOR

Antonio González Pérez – Spanish Centre for Pharmacoepidemiologic Research CO-AUTHORS

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María Saez – Spanish Centre for Pharmacoepidemiologic Research

Gunnar Brobert – Bayer AB Luis Alberto García Rodríguez – CEIFE (Centro Espanol de

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#### **Drug Effectiveness**

Long-Acting Insulin Analogs Versus Intermediate-Acting Insulin and the Risk of Major Adverse Cardiovascular Events Among Patients with Type 2 Diabetes in the United Kingdom

#### PRESENTING AUTHOR

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Kristian Filion – Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, CA

#### 6:30 - 7:30 PM

#### LIGHTNING SESSION 2

Drug Utilization Research Changes in Purchases of Intensive Care Medicines During COVID-19 in Developed vs Developing Countries

#### PRESENTING AUTHOR

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Mina Tadrous – Women's College Research Institute, Women's College Hospital

Sandra Kane-Gill – University of Pittsburgh School of Pharmacy

lan Barbash – University of Pittsburgh School of Medicine, Division of Pulmonary, Allergy and Critical Care Medicine

Katie Suda – University of Pittsburgh School of Medicine

#### Methods in Pharmacoepidemiology Collider Bias in COVID-19 Studies: Explaining the Smoking Paradox

PRESENTING AUTHOR Natalia Petruski-Ivleva – IQVIA CO-AUTHORS Alice Joules – IQVIA Michael Warner – IQVIA Patrick Long – IQVIA Aidan Cooper – IQVIA Nancy Dreyer – IQVIA

#### Health Economics/Outcomes Research The Prevalence of Hyperkalemia and Associated Clinical Characteristics and Outcomes Among Hospitalized COVID-19 Patients

PRESENTING AUTHOR

Rena Moon – Premier Applied Sciences, Premier, Inc. CO-AUTHORS Abiy Agiro – AstraZeneca Payer Evidence Ning Rosenthal – Premier Applied Sciences, Premier, Inc. Harold Brown – Premier Applied Sciences, Premier, Inc. Randall Legg – AstraZeneca Payer Medical Alpesh Amin – University of California, Irvine

#### Pharmacovigilance Off-Label Use of Potential Pharmacological Treatment for COVID-19: An Intensive Pharmacovigilance in Peru

PRESENTING AUTHOR

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#### Methods in Pharmacoepidemiology Identification and Characterization of Fistulizing Crohn's Disease in EHR Using Structured and Unstructured Data

PRESENTING AUTHOR Carrie Huisingh – AbbVie CO-AUTHORS Yizhou Ye – AbbVie Lani Wegrzyn – AbbVie

Methods in Pharmacoepidemiology Validation of Diagnosis Algorithms for Melanoma and Nonmelanoma Skin Cancer Among Patients with Parkinson's Disease in the United States Medicare Database

#### PRESENTING AUTHOR

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#### Methods in Pharmacoepidemiology An Algorithm to Derive Response and Progression Status Based on International Myeloma Working Group Response Criteria for Patients with Multiple Myeloma lin a Real-World Database

#### PRESENTING AUTHOR

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#### Disease Epidemiology/Clinical Course Identification of Serostatus in Rheumatoid Arthritis Using ICD-10 Diagnosis Codes

#### PRESENTING AUTHOR

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#### Health Economics/Outcomes Research Cost-Utility of Nivolumab for Treatment of Head and Neck Cancer from a Brazilian Public Health System Perspective

#### PRESENTING AUTHOR

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#### Health Economics/Outcomes Research SGLT2 inhibitors vs GLP-1 agonists: Comparative Progression of Renal Disease

PRESENTING AUTHOR Lauren Stevens – Humana Healthcare Research CO-AUTHORS Andy Bowe – Humana Healthcare Research Phil Schwab – Humana Healthcare Research Michael Tindal – Humana Pharmacy Solutions Andrea Bloomfield – Humana Pharmacy Solutions

#### Health Economics/Outcomes Research Comparison of Medication Adherence Between Initiators of a Multi-Drug Dispensing System and Users of Retail Pharmacy

PRESENTING AUTHOR Lauren Stevens – Humana Healthcare Research CO-AUTHORS Jeffrey Ellis – Humana Healthcare Research Anita Desai-Naik – Humana Pharmacy Solutions Lilian Ndehi – Humana Inc. Andy Bowe – Humana Healthcare Research
#### Health Economics/Outcomes Research Effects of Initiating a Multi-dose Drug Dispensing System on Medication Adherence

#### PRESENTING AUTHOR

Lauren Stevens – Humana Healthcare Research CO-AUTHORS Jeffrey Ellis – Humana Healthcare Research Anita Desai-Naik – Humana Pharmacy Solutions Lilian Ndehi – Humana Inc. Andy Bowe – Humana Healthcare Research

#### Disease Epidemiology/Clinical Course Prevalence of Myxoid /Round Cell Liposarcoma (MRCLS) Among Children and Adults in the United States

PRESENTING AUTHOR Huifen Wang – GlaxoSmithKline CO-AUTHORS Lindsey Powers Happ – GlaxoSmithKline Samantha St. Laurent – GlaxoSmithKline Charlotte Carroll – GlaxoSmithKline

#### Disease Epidemiology/Clinical Course Atopic Eczema Associated Fracture Risk and Oral Corticosteroids: A Population-Based Cohort Study

#### PRESENTING AUTHOR

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Katherine Lowe – London School of Hygiene & Tropical Medicine

Liam Smeeth – London School of Hygiene & Tropical Medicine

Sinéad Langan – London School of Hygiene & Tropical Medicine

#### Disease Epidemiology/Clinical Course Trends in Sexually Transmitted Infections in the United States Ambulatory Care Clinics from 2005 to 2016

#### PRESENTING AUTHOR

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Hyun Jin Song – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida

Wei-Hsuan Lo-Ciganic – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, Florida, USA

Robert Cook – College of Public Health and Health Professions, University of Florida, Gainesville, FL, USA

Haesuk Park – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, FL, USA

#### Disease Epidemiology/Clinical Course Chemotherapy Relative Dose Intensity, Overall Survival, and Hematologic Toxicity in Solid-Tumor Cancer Patients: A Literature Review and Meta-Analysis

PRESENTING AUTHOR Lauren Bylsma – EpidStrategies, A Division of ToxStrategies CO-AUTHORS Carrie Nielson – Amgen Jon Fryzek – EpidStrategies, Rockville, MD, USA Hossam Saad – Amgen Jeffrey Crawford – Duke Cancer Institute

#### 8:00 - 9:30 PM

#### PLENARY

#### Diversity, Equity, and Inclusion in Pharmacoepidemiology – The Role of Caste in Drug Utilization, Safety, and Therapeutic Risk Management

SPEAKERS

Whitney Robinson – University of North Carolina at Chapel Hill Folakemi Odedina – Mayo Clinic Macarius Donneyoung – The Ohio State University John Jackson – Johns Hopkins

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## TUESDAY, AUGUST 24

#### 8:15 - 8:30 AM

#### WELCOME RECEPTION

Syd Phillips Chair, ICPE Scientific Program Committee

#### 8:30 - 10:00 AM

#### PLENARY

Communicating COVID-19 Pharmacoepidemiological Research to Patients: Why is it Important? How Can We Do It? What are the Implications Now and for the Future?

PRESENTING AUTHOR

Meredith Smith – Alexion

CO-AUTHORS

Priya Bahri – European Medicines Agency

Vincent Lo Re – Center for Pharmacoepidemiology Research and Training, Center for Clinical Epidemiology and Biostatistics, Department of Biostatistics, Epidemiology, and Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

Francois Houyez - EURORDIS

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

From the Individual Through the Health System and Back: The Interdisciplinary Promise and Challenges of Digital Epidemiology for Improved Outcomes (An ISPE Digital Epidemiology SIG Endorsed Symposium) Informatics

#### PRESENTERS

Lisa Weiss – Health Information Technology Lab

Heidi Dohse – Tour de Heart

Dana Teltsch – Apellis

Nancy Dreyer - IQVIA

#### John Cai – Merck

Helga Gardarsdottir - Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

How to Emulate a Target Trial to Study the Effects of Treatments for and During Pregnancy Pregnancy and Lactation

#### PRESENTERS

Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health Sonja Swanson – Department of Epidemiology, Erasmus MC Jennifer Yland – Department of Epidemiology, Boston University School of Public Health Kristin Palmsten – HealthPartners Institute

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

#### Lessons for Regulatory Decision-Making from Real-World Data Trial Emulation Results Drug Effectiveness

Drug Ellectivene

PRESENTERS

Shirley Wang – Brigham and Women's Hospital, Harvard Medical School

Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

William Crown - Brandeis University

Joseph Ross – Yale University

Peter Arlett – European Medicines Agency

Kenneth Quinto – US Food and Drug Administration

Yoshiaki Uyama – Pharmaceutical Devices and Medicines Agency

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

Methodological Approaches to Evaluating the Safety and Effectiveness of Multi-Dose Coronavirus Disease 2019 (COVID-19) Vaccines Series

Vaccines

#### PRESENTERS

Hui-Lee Wong – CBER, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

Xabier Garcia de Albeniz – RTI Health Solutions

Anne Mobley Butler – Washington University in St. Louis Heather Whitaker – Public Health England

Marc Suchard – University of California, Los Angeles

#### 11:45 AM - 1:15 PM

#### WORKSHOP / CONCURRENT

#### A Call for 'Environmental Pharmacoepidemiology': Medications, Global and Local Environments, and Health Outcomes

Methods in Pharmacoepidemiology

#### PRESENTERS

Benjamin Bates – Center for Pharmacoepidemiology and Treatment Science, Rutgers University, New Brunswick, NJ, US

Sean Hennessy – Center for Pharmacoepidemiology Research and Training, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania, Philadelphia, PA, US

Michelle Bell – School of the Environment, Yale University, New Haven, CT, US

Paul Coplan – Johnson & Johnson

Rachel Nethery – Department of Biostatistics, Harvard T.H. Chan School of Public Health

Soko Setoguchi – RWJ Medical School, Center for Pharmacoepidemiology and Treatment Science (PETS), Institute for Health, Health Care Policy and Aging Research

#### 11:45 AM - 1:15 PM

WORKSHOP / CONCURRENT

#### Believability of Real-World Evidence (RWE) for Informed Regulatory Decisions

Methods in Pharmacoepidemiology

#### PRESENTERS

Jacinthe Leclerc – Universite du Quebec a Trois-Rivieres Kimberly Brodovicz – Boehringer Ingelheim Stephen Chang – FDA Magdalene Assimon – University of North Carolina School of Medicine Hisashi Urushihara – Keio Univesity

Cynthia Girman – CERobs Consulting, LLC

#### 11:45 AM - 1:15 PM

WORKSHOP / CONCURRENT

#### New Frontiers in Computable Phenotyping for Medical Product Safety Evaluation

Methods in Pharmacoepidemiology

PRESENTERS

Rishi Desai – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

David Carrell – Kaiser Permanente Washington Health

Research Institute

Robert Ball – FDA

Katherine Liao – Brigham and Women's Hospital

Lindsay Collin – Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA

Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

#### 11:45 AM - 1:15 PM

#### WORKSHOP / CONCURRENT

#### Using Real-World External Controls to Support Drug Approval: An Interactive Framework Using Oncology Trial and Real-World Data

Methods in Pharmacoepidemiology

PRESENTERS

Laura Hester – Janssen R&D, LLC Donna Rivera – US Food and Drug Administration Jennifer Lund – Department of Epidemiology, University of North Carolina at Chapel Hill Asieh Golozar – Regeneron Pharmaceuticals Kourtney Davis – Janssen R&D, LLC John Seeger – Epidemiology, Optum, Boston, MA, USA Leah Sansbury – GlaxoSmithKline

#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

## Pharmacovigilance, Safety End Points, and Potpourri

#### Rare Disease

The Association Between Bariatric Surgery and Dupuytren Disease: A Cohort Study from Swedish Nationwide Healthcare Registries

#### PRESENTING AUTHOR

Theresa Burkard – Department of Chemistry and Applied Biosciences, Institute of Pharmaceutical Sciences, ETH Zurich, Zurich, Switzerland

#### CO-AUTHORS

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Dag Holmberg – Upper Gastrointestinal Surgery, Department of Molecular medicine and Surgery, Karolinska Institute, Karolinska University Hospital, Stockholm, Sweden

Andrea Burden – Institute of Pharmaceutical Sciences, Department of Chemistry and Applied Biosciences, ETH Zurich, Zurich, Switzerland

Dominic Furniss – Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, Oxford, UK

#### Pediatric Pharmacoepidemiology Selective Serotonin Reuptake Inhibitors and the Risk of Type 2 Diabetes Mellitus in Youths

#### PRESENTING AUTHOR

Thi Xuan Dai Cao – Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Québec, CA CO-AUTHORS

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Emma Fergusson – Oxford Health NHS Trust, Department of Psychiatry, Oxford University, Oxford, UK

Soham Rej – Department of Psychiatry, McGill University, Montreal, Québec, CA

Laurent Azoulay – Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Québec, CA

Christel Renoux – Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Québec, CA

#### Pharmacovigilance

#### Comparing the Risk of Venous Thromboembolism in Rheumatoid Arthritis Patients Receiving Tofacitinib and TNF Inhibitors in Taiwan

#### PRESENTING AUTHOR

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#### Pediatric Pharmacoepidemiology Risk of Type 2 Diabetes Among Children Initiating Anticonvulsant Mood Stabilizers: Application of a Target Trial Approach

PRESENTING AUTHOR

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Jessica Young – University of North Carolina

Aaron Sarvet – Harvard Medical School and Harvard Pilgrim Health Care Institute

Pi-i Debby Lin – Harvard Medical School and Harvard Pilgrim Health Care Institute

Sengwee Toh – Harvard Medical School and Harvard Pilgrim Health Care Institute

Jason Block – Harvard Medical School and Harvard Pilgrim Health Care Institute

#### Safety End Points

Risk of Diabetic Ketoacidosis with Sodium-Glucose Transporter-2 Inhibitors Compared to Dipeptidyl Peptidase-4 (DPP4) Inhibitors and Sulfonylureas in Patients with Type 2 Diabetes

#### PRESENTING AUTHOR

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CO-AUTHOR

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James Lewis – University of Pennsylvania

Disease Epidemiology/Clinical Course Comparable COVID-19 Outcomes with Current Use of GLP-1 Receptor Agonists, DPP-4 Inhibitors or SGLT-2 Inhibitors Among Patients with Diabetes Who Tested Positive for SARS-Cov-2

#### PRESENTING AUTHOR

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#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

## Thinning the Blood: The Role of Anticoagulation and COVID-19

Drug Utilization Research Heterogeneity and Temporal Variation in the Management of COVID-19: A Multinational Drug Utilisation Study Including 274,719 Hospitalised Patients from The United States of America, China, Spain, and South Korea

#### PRESENTING AUTHORS

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Asieh Golozar – Regeneron Pharmaceuticals

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Peter Rijnbeek – Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, The Netherlands

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#### Drug Utilization Research Real World Use of Anticoagulation Among Hospitalized Patients With COVID-19 in the United States

#### PRESENTING AUTHOR

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Eileen Lee – Rutgers

Nathaniel Kuhrt – Rutgers, New Jersey Medical School

Chang Xu – Rutgers University, School of Public Health, Department of Biostatistics and Epidemiology

Soko Setoguchi – RWJ Medical School, Center for Pharmacoepidemiology and Treatment Science (PETS), Institute for Health, Health Care Policy and Aging Research

#### Drug Effectiveness

Safety and Effectiveness of Prophylactic Anticoagulation for Prevention of COVID-19 Mortality: A Nationwide Cohort Study of Hospitalised Patients in the US

#### PRESENTING AUTHOR

Christopher Rentsch – London School of Hygiene & Tropical Medicine; US Department of Veterans Affairs

#### CO-AUTHORS

Joshua Beckman – Vanderbilt University Medical Center and Vanderbilt Translational and Clinical Cardiovascular Research Center

Laurie Tomlinson – London School of Hygiene & Tropical Medicine

Walid Gellad – Division of General Internal Medicine, Department of Medicine, University of Pittsburgh

Charles Alcorn – University of Pittsburgh Farah Kidwai-Khan – US Department of Veterans Affairs Melissa Skanderson – US Department of Veterans Affairs Evan Brittain - Vanderbilt University Medical Center and Vanderbilt Translational and Clinical Cardiovascular Research Center Joseph King, Jr. - Yale School of Medicine Yuk-Lam Ho – VA Boston Healthcare System Svetlana Eden – Vanderbilt University School of Medicine Suman Kundu – Vanderbilt University Medical Center Michael Lann – University of Pittsburgh Robert Greevy, Jr. - Vanderbilt University Medical Center P. Michael Ho – US Department of Veterans Affairs Paul Heidenreich – Stanford University School of Medicine Daniel Jacobson – Oak Ridge National Laboratory lan Douglas – London School of Hygiene & Tropical Medicine Janet Tate – US Department of Veterans Affairs Stephen JW Evans – London School of Hygiene & Tropical Medicine David Atkins – US Department of Veterans Affairs Amy Justice – US Department of Veterans Affairs

Matthew Freiberg – Vanderbilt University Medical Center; US Department of Veterans Affairs

#### Drug Effectiveness Anticoagulants and All-Cause Mortality Among Hospitalized COVID-19 Patients

PRESENTING AUTHOR Caihua Liang – Optum CO-AUTHORS Li Zhou – Optum Michael Doherty – Optum Robert Gately – Optum Rachel Ogilvie – Optum Andrea Chomistek – Optum Florence Wang – Optum John Seeger – Epidemiology, Optum, Boston, MA, USA Jessica Franklin – Optum

#### Drug Utilization Research Use of Cardiovascular and Antidiabetic Drugs During COVID19 Epidemic in France

#### PRESENTING AUTHOR

Julien Bezin – University of Bordeaux, France CO-AUTHORS Clément Mathieu – University of Bordeaux, France Elodie Pambrun – University of Bordeaux, France Anne Benard-Laribiere – University of Bordeaux, France Pernelle Noize – University of Bordeaux, France Marie Tournier – University of Bordeaux, France Jean-Luc Faillie – University of Montpellier, France Antoine Pariente – University of Bordeaux, France

#### Drug Utilization Research Substantial Heterogeneity in the Management of Hospitalized Patient with COVID-19

#### PRESENTING AUTHOR

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Vrishali Lopes - Infectious Diseases Research Program, Providence Veterans Affairs Medical Center, Providence, RI, USA

Kerry LaPlante - Infectious Diseases Research Program, Providence Veterans Affairs Medical Center, Providence, RI, USA

#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Two Hearts Beat as One: Evidence for Cardiovascular Safety From Real World Data and Clinical Trials

Health Economics/Outcomes Research Comparative Risk of Hospitalization for Heart Failure Among Patients with Xanthine Oxidase Inhibitors and Uricosuric Agents

#### PRESENTING AUTHOR

Fang-Ju Lin – National Taiwan University CO-AUTHORS

Yu-Hsin Wang – Graduate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University, Taipei, Taiwan

Chien-Ning Hsu – Department of Pharmacy, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, Taiwan Safety End Points

Cardiovascular Risk in Users of Mirabegron Relative to Users of Antimuscarinic Treatments for Overactive Bladder: Findings from a Non-interventional, Real-World Data Safety Study

#### CO-AUTHORS

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Ingvild Odsbu – Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway

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John Seeger – Epidemiology, Optum, Boston, MA, USA

#### Safety End Points

## Use of Low-dose Quetiapine and the Risk of Major Adverse Cardiovascular Events

#### PRESENTING AUTHOR

Mikkel Højlund – Clinical Pharmacology, Pharmacy, and Environmental Medicine, Department of Public Health, University of Southern Denmark

#### CO-AUTHOR

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Christoph Correll – Department of Psychiatry, The Zucker Hillside Hospital

Jesper Hallas – University of Southern Denmark, Odense, Denmark

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

Jak Inhibitors and the Risk of Cardiovascular and Venous Thromboembolism Events Among Patients with Rheumatoid Arthritis: A Network Meta-Analysis of Clinical Trials

#### PRESENTING AUTHOR

Carlos Alves - University of Coimbra, School of Pharmacy

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Diogo Mendes – UFC, Coimbra Regional Pharmacovigilance Unit, CHAD – Centre for Health Technology Assessment and Drug Research, AlBILI

Francisco Batel Marques – Faculty of Pharmacy, University of Coimbra

#### Drug Utilization Research

#### Non-Adherence and Non-Persistence with Direct Oral Anticoagulants Increases the Risk of Stroke: Assessment in Three European Databases

#### PRESENTING AUTHOR

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Georgios Spentzouris – Daiichi-Sankyo Europe GmbH, Munich, Germany

Ron Herings – PHARMO Institute for Drug Outcomes Research, Utrecht, Netherlands

#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

## Validation and Alogrithms: Getting the Present and Future Right

Methods in Pharmacoepidemiology Validity of Electronic Health Records-Based Measures for COVID-19 Hospitalization and Severe Outcomes

#### CO-AUTHORS

Sharon Fuller - Kaiser Permanente Washington Health Research Institute

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Lisa Pieper – Kaiser Permanente Colorado, Institute for Health Research

Jan Van Marter – Kaiser Permanente Northwest, Center for Health Research

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Sascha Dublin – Kaiser Permanente Washington Health Research Institute

#### Methods in Pharmacoepidemiology Death Documentation Lag in COVID-19 Electronic Health Record (EHR) Suggests Caution in Near-Real-Time Analysis

#### PRESENTING AUTHOR

**Corinne Brooks** – Center for Observational Research, Amgen, Inc. CO-AUTHORS

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John Page – Center for Observational Research, Amgen, Inc. J. Michael Sprafka – Center for Observational Research, Amgen, Inc.

Jie Zhang – Center for Observational Research, Amgen, Inc.

#### Informatics

#### Shifting the Traditional Model of Analysing Downloaded Electronic Health Records to the Novel Open-Source Analytics Opensafely Platform

PRESENTING AUTHOR

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Caroline Morton – University of Oxford

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Alex Walker – University of Oxford

Krishnan Bhaskaran – London School of Hygiene and Tropical Medicine

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Richard Croker – University of Oxford

Seb Bacon - University of Oxford

William Hulme – University of Oxford

Chris Bates – The Phoenix Partnership

Helen Curtis - University of Oxford

Amir Mehrkar – University of Oxford

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Peter Inglesby – University of Oxford

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Rohini Mathur – London School of Hygiene and Tropical Medicine Kevin Wing – London School of Hygiene and Tropical Medicine Harriet Forbes – London School of Hygiene and Tropical Medicine

Rosalind Eggo – London School of Hygiene and Tropical Medicine lan Douglas – London School of Hygiene and Tropical Medicine

Stephen Evans – London School of Hygiene and Tropical Medicine

Liam Smeeth – London School of Hygiene and Tropical Medicine Ben Goldacre – University of Oxford

#### Methods in Pharmacoepidemiology Use of an EHR to Inform a Claims-Based Algorithm to Categorize Inpatient COVID-19 Severity

PRESENTING AUTHOR Elizabeth Garry – Aetion, Inc CO-AUTHORS Andrew Weckstein – Aetion, Inc Kenneth Quinto – US Food and Drug Administration Tamar Lasky – US Food and Drug Administration Aloka Chakravarty – Food and Drug Administration Sandy Leonard – HealthVerity Sarah Vititoe – Aetion, Inc Jeremy Rassen – Aetion, Inc. Nicolle Gatto – Aetion, Inc

#### Methods in Pharmacoepidemiology Categorization of COVID-19 Severity to Determine Mortality Risk

PRESENTING AUTHOR

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Sandy Leonard - HealthVerity

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#### Disease Epidemiology/Clinical Course Development and Validation of an Algorithm to Estimate the Risk of Severe Complications of COVID-19 to Prioritise Vaccination

#### PRESENTING AUTHOR

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#### 1:45 - 3:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### You Gave the Kids What? International Use, Policies, and Outcomes in Pediatric Pharmacoepidemiology

#### Pediatric Pharmacoepidemiology Early Life Antibiotic Exposure and Incident Chronic Diseases in Childhood

#### PRESENTING AUTHOR

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Brian Strom – Rutgers Biomedical And Health Sciences, Rutgers University

Martin Blaser – Center for Advanced Biotechnology and Medicine, Rutgers University

Daniel Horton - Rutgers University

#### Pediatric Pharmacoepidemiology

#### Antibiotic Prescribing in Children Aged 0–6 Years in Germany: Assessing Regional Variations and Potential Explanations Based on Claims Data

#### PRESENTING AUTHOR

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#### CO-AUTHORS

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#### Pediatric Pharmacoepidemiology

## Prescribed Medicine Use in a Nationwide Sample of Australian Children: Extent of Off-Label Use

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Simon Paget - University of Sydney

Helga Zoega – Centre for Big Data Research in Health, UNSW Sydney

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#### Pediatric Pharmacoepidemiology General Practitioner Prescribing Trends Among Pediatric Patients in the United Kingdom: 1998-2018

PRESENTING AUTHOR

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Kristian Filion – Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, CA

#### Drug Utilization Research Visualizing Inappropriate Antibiotic Use Following Otitis Media in Children in the United States

#### PRESENTING AUTHOR

Leah McGrath – NoviSci, Inc. CO-AUTHORS Jason Newland – Washington University in St. Louis John Sahrmann – Washington University in St. Louis YinJiao Ma – Washington University in St. Louis Anne Mobley Butler – Washington University in St. Louis

#### Pediatric Pharmacoepidemiology Impact of Drug-Related Regulations on Codeine Use Among Children in Taiwan: A Nationwide Interrupted Time Series Analysis from 2005 to 2018

PRESENTING AUTHOR

Chih-Wan Lin

Yu-Jie Huang – Taiwan Drug Relief Foundation, Taipei, Taiwan Wei-I Huang – Taiwan Drug Relief Foundation, Taipei, Taiwan Pi-Hui Chao – Taiwan Drug Relief Foundation, Taipei, Taiwan Wen-Wen Chen – Taiwan Drug Relief Foundation, Taipei, Taiwan Fei-Yuan Hsiao – Graduate Institute of Clinical Pharmacy, National Taiwan University, Taipei, Taiwan

#### 6:45 - 7:45 PM

#### LIGHTNING SESSION 3

Benefit-Risk Assessment, Communication, and Evaluation (BRACE) Gender Differences in Valproic Acid Use for Approved Indications in the United States (2017-2018) – An Opportunity for Risk Mitigation?

#### PRESENTING AUTHOR

Nicole Smolinski – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida

#### CO-AUTHORS

## Amir Sarayani – Department of Pharmaceutical Outcomes and Policy, University of Florida

Almut Winterstein - Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida Benefit-Risk Assessment, Communication, and Evaluation (BRACE)

#### Missingness in Real World Data Submitted for Regulatory Decision-Making: Eastern Cooperative Oncology Group Performance Status Case Study

#### CO-AUTHORS

Cherise Wong – Regeneron Pharmaceuticals Caitlin Knox – Regeneron Pharmaceuticals Wenzhen Ge – Regeneron Pharmaceuticals Ning Wu – Regeneron Pharmaceuticals Andrea Marcus – Regeneron Pharmaceuticals Jessica Jalbert – Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA PRESENTING AUTHOR Asieh Golozar – Regeneron Pharmaceuticals

#### Benefit-Risk Assessment, Communication, and Evaluation (BRACE) Association of Statin Use with Dry Eye Disease

#### PRESENTING AUTHOR

Yinxi Yu - Department of Ophthalmology, Scheie Eye Institute, University of Pennsylvania Perelman School of Medicine

CO-AUTHORS

Vatinee Bunya - Department of Ophthalmology, Scheie Eye Institute, University of Pennsylvania Perelman School of Medicine

Brian VanderBeek - Department of Ophthalmology, Scheie Eye Institute, University of Pennsylvania Perelman School of Medicine

#### Disease Epidemiology/Clinical Course Birth Prevalence of Phenylalanine Hydroxylase Deficiency: A Systematic Literature Review and Meta-analysis

#### PRESENTING AUTHOR

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- Kimberly Alexander BioMarin Pharmaceutical Inc.
- Pamela Foreman BioMarin Pharmaceutical Inc.
- Renee Shediac BioMarin Pharmaceutical Inc.
- Brian Calingaert RTI Health Solutions
- Abenah Harding RTI Health Solutions
- Manel Pladevall-Vila RTI Health Solutions
- Sarah Landis BioMarin (UK) Limited

#### Methods in Pharmacoepidemiology A New Analytic Tool for Interrupted Times Series Analysis to Assess the impact of FDA Regulatory Actions

#### PRESENTING AUTHOR

Christine Lu – Department of Population Medicine at Harvard Medical School

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Joy Kolonoski – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

Andrew Petrone – Department of Population Medicine at Harvard Medical School

Fang Zhang – Department of Population Medicine at Harvard Medical School

Catherine Corey – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Ting Ying Huang – Department of Population Medicine at Harvard Medical School

Marie Bradley – Division of Epidemiology, Office of Surveillance and epidemiology,Center for Drug Evaluation and Research, US Food and Drug Administration

#### Methods in Pharmacoepidemiology Use of Last Clinical Activity Date in Overall Survival Analysis with Real World Data

PRESENTING AUTHOR

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Melanie Huntley – Genentech, Inc.

Anne-Marie Meyer – F. Hoffmann-La Roche Ltd.

Michael Taylor – Real World Data Collaborations, Personalized Healthcare Data Science, Genentech Inc., South San Francisco, CA, USA

#### Methods in Pharmacoepidemiology Distinguishing Death from Disenrollment in Claims Data Using a Readily Implemented Machine Learning Algorithm

PRESENTING AUTHOR

Jessica Young – University of North Carolina CO-AUTHORS

Frank Yean IDM Mataan

Frank Yoon – IBM Watson Health

Nabarun Dasgupta – Injury Prevention Research Center, University of North Carolina at Chapel Hill

Debra Irwin – IBM Watson Health Kenneth Pack – IBM Watson Health Toska Cooper – University of North Carolina at Chapel Hill Shalu Shiv – IBM Watson Health Sarah Bloemers – IBM Watson Health Teresa Gibson – IBM Watson Health

#### Methods in Pharmacoepidemiology Development and Validation of Case-Finding Algorithms to Identify Prosthetic Joint Infections After Total Knee Arthroplasty

#### PRESENTING AUTHOR

Erica Weinstein – Division of Infectious Diseases, Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

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#### Drug Utilization Research Analytical Enhancements in Kentucky's Drug Overdose Mortality Surveillance: Rapid Monitoring of Trends and Decedents' Recent Controlled Substance Prescription History

#### PRESENTING AUTHOR

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#### Drug Utilization Research Measuring Mental Health Prescribing Safety Indicators in UK Primary Care

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#### Pediatric Pharmacoepidemiology Pediatric Off-Label Antipsychotic Use for Attention-Deficit/Hyperactivity Disorder: A Time-to-Event Analysis

PRESENTING AUTHOR

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Roderick Rose – University of Maryland Baltimore, School of Social Work

#### Pediatric Pharmacoepidemiology Antibiotics Overprescribing Patterns in Pediatric Primary Care in Italy: Findings from 2012-2018

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#### Informatics

## Temporal Effect in Real-World-Evidence for Randomized-Clinical-Trials

#### PRESENTING AUTHOR

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Kai-Li Liaw – Pharmacoepidemiology, Center for Observational and Real-World Evidence (CORE), Merck & Co., Inc.

Claire Fox – Merck & Co., Inc.

Thomas Jemielita – Merck & Co., Inc.

Tianxi Cai – Harvard T.H. Chan School of Public Health

#### Safety End Points

#### The Risk of Melanoma with Rasagiline Compared with Other Antiparkinsonian Medications: A Retrospective Cohort Study in the United States Medicare Database

PRESENTING AUTHOR

Catherine Johannes – RTI Health Solutions CO-AUTHORS Catherine Saltus – RTI Health Solutions James Kaye – RTI Health Solutions Brian Calingaert – RTI Health Solutions Sigal Kaplan – Teva Pharmaceuticals Ltd Mark Gordon – Teva Branded Pharmaceutical Products R&D, Inc. Elizabeth Andrews – RTI Health Solutions

#### Biologics/Biosimilars

#### Risk of Major Cardiovascular Event in Jak Inhibitor Treated Patients: Analysis of a National Claim Database

#### CO-AUTHORS

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#### 8:00 - 9:30 PM

#### PLENARY

Communicating COVID-19 Pharmacoepidemiological Research to Patients: Why is it Important? How Can We Do It?

What are the Implications Now and for the Future?

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

PRESENTING AUTHOR

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Francois Houyez - EURORDIS

#### W E D Ν E S D AY Α U G U S т 2 5

#### 8:15 - 8:30 AM

#### WELCOME RECEPTION

Syd Phillips Chair, ICPE Scientific Program Committee

#### 8:30 - 10:00 AM

#### PLENARY

COVID-19 Vaccines: Timely Global Real-World Evidence Vaccines

MODERATOR

J. Bradley Layton – RTI Health Solutions SPEAKERS

Miriam Sturkenboom – Department Datascience & Biostatistics, University Medical Center Utrecht

Steven Anderson – FDA/CBER Carla Talarico Robert Chen – Brighton Collaboration

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

Pediatric Infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV 2) and Potential Health Consequences (Submitted on Behalf of the ISPE RWE COVID-19 Workgroup) Disease Epidemiology/Clinical Course

#### PRESENTER

Ann McMahon – Office of Pediatric Therapeutics, Food and Drug Administration

#### PRESENTERS

Susan Coffin – Children's Hospital of Philadelphia David Kimberlin – University of Alabama at Birmingham Montse Soriano Gabarro – Bayer AG

Jonathan Davis – Tufts University Children's Hospital

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

Product Surveillance and Signal Management: Now is the Time for Methodologist Engagement! Medical Devices

PRESENTERS

Mary Beth Ritchey – Med Tech Epi Danica Marinac-Dabic – FDA/CDRH Theodore Lystig – Medtronic Paul Coplan– Johnson & Johnson

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

RWE Blueprints: Decoding SPACE, SPIFD, Start-RWE, and Other Tools Promoting Principled Pharmacoepidemiology Methods in Pharmacoepidemiology

PRESENTERS Elizabeth Garry – Aetion, Inc Nicolle Gatto – Aetion, Inc Shirley Wang – Brigham and Women's Hospital, Harvard Medical School Ulka Campbell – Pfizer

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

#### Selection Matters: Addressing Biases in Linked Clinico-Genomic Data Sets

Methods in Pharmacoepidemiology

PRESENTERS

Katherine Panageas – Memorial Sloan Kettering Cancer Center

Kenneth Kehl – Dana-Farber Cancer Institute, Harvard Medical Center

Devin Incerti – Genentech

Til Stürmer – Department of Epidemiology, University of North Carolina at Chapel Hill

#### 10:00 - 11:30 AM

#### WORKSHOP / CONCURRENT

#### Strategies for the Use of Real-World Data to Conduct COVID-19-Related Pharmacoepidemiology

Methods in Pharmacoepidemiology

#### PRESENTERS

Vincent Lo Re - Center for Pharmacoepidemiology Research and Training, Center for Clinical Epidemiology and Biostatistics, Department of Biostatistics, Epidemiology, and Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

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Candace Fuller – Harvard Pilgrim Health Care Institute

Wei Hua – Center for Drug Evaluation and Research, United States Food and Drug Administration

Silvia Perez-Vilar – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration

#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Brains or Bytes? In Search of Patterns

Medical Devices Leveraging Artificial Intelligence (AI) Technologies for Automated Identification of Total Knee Arthroplasty (TKA) Devices in Electronic Health Records

#### CO-AUTHORS

Elham Sagheb – Mayo Clinic Shi Yan – Mayo Clinic Taghi Ramazanian – Mayo Clinic Sunyang Fu – Mayo Clinic Ahmad Tafti – University of Southern Maine Sunghwan Sohn – Mayo Clinic PRESENTING AUTHOR Hilal Maradit Kremers – Mayo Clinic

#### Rare Disease Prediction Algorithm for Identifying Patients with Fabry or Pompe Disease in Electronic Health Records

PRESENTING AUTHOR

Ella Jansen – PHARMO Institute for Drug Outcomes Research, Utrecht, Netherlands

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#### Christopher Rudolf - Volv Global SA

Ron Herings – PHARMO Institute for Drug Outcomes Research, Utrecht, Netherlands

#### Methods in Pharmacoepidemiology The Impact of Longitudinal Data-Completeness of Electronic Health Record (EHR) Data on Prognostic Risk Score Misclassification

#### PRESENTING AUTHOR

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#### CO-AUTHORS

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Dave Merola – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

Kueiyu Joshua Lin – Brigham and Women's Hospital

#### Methods in Pharmacoepidemiology Identifying Active Pregnancies Using ICD-10 Z3A Codes vs Completed Pregnancies Using Outcomes

PRESENTING AUTHOR Monica Bertoia – Optum CO-AUTHORS Li Zhou – Optum Michael Doherty – Optum Florence Wang – Optum John Seeger – Epidemiology, Optum, Boston, MA, USA

#### Methods in Pharmacoepidemiology Improving Methods of Identifying Anaphylaxis for Medical Product Safety Surveillance Using Natural Language Processing and Machine Learning

PRESENTING AUTHOR

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Robert Ball – FDA

Jennifer Nelson – Kaiser Permanente Washington Health Research Institute

#### Methods in Pharmacoepidemiology Validation of an Algorithm to Identify Hormonal Contraceptive Exposure in a Large Integrated Health Care Delivery System Database

#### PRESENTING AUTHOR

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Malini Chandra – Division of Research, Kaiser Permanente

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Theresa Im – Research and Evaluation, Kaiser Permanente Southern California

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Tina Raine-Bennett – Division of Research, Kaiser Permanente

#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

COVID-19 Potpourri: Vaccines, Long Haulers, and the NFL

#### Vaccines

Descriptive Epidemiology of Adverse Events of Special Interest for COVID-19 Vaccines Across 7 Countries and 4 Continents: A Multinational Network Cohort Study

#### PRESENTING AUTHOR

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#### Medical Devices Population Testing for COVID-19: Can a Rapid Antigen Test Rule Out Infection?

#### PRESENTING AUTHOR

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#### Pharmacovigilance Impact of COVID-19 Social Distance Restrictions on Hospital Encounters Due to Injury by Poisoning or Toxicity of Medications or Non-Medicinal Substances

#### PRESENTING AUTHOR

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#### Disease Epidemiology/Clinical Course Persistence of COVID-19 Symptoms 90 Days Post-Acute Infection: Insights from a Community-Based Registry

#### PRESENTING AUTHOR

Matthew Reynolds – IQVIA CO-AUTHORS Nancy Dreyer – IQVIA Lisa Albert – IQVIA Emma Brinkley – IQVIA Damir Mohamed – IQVIA Christina Mack – IQVIA

#### Drug Utilization Research

Use of Hydroxychloroquine, Remdesivir, and Dexamethasone Among Adults Hospitalized with COVID-19 in the United States: Results from the National COVID Cohort Collaborative (N3C)

#### PRESENTING AUTHOR

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#### Drug Utilization Research COVID-19 in Children: Treatment Patterns in the Real-World Hospital Setting

PRESENTING AUTHOR Lawrence Rasouliyan – OMNY Health CO-AUTHORS Vikas Kumar – OMNY Health Stacey Long – OMNY Health Mitesh Rao – OMNY Health

#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

## Fast and Furious: Driving Down the Clinical Course of Disease Epidemiology

Disease Epidemiology/Clinical Course Impact of Non-Alcoholic Steatohepatitis (NASH) Case Definition on Population Characteristics Identified in a US Claims Database

PRESENTING AUTHOR

Kerrin Gallagher – HealthCore CO-AUTHORS Daina Esposito – Boston University School of Public Health Aziza A. Jamal-Allial – HealthCore, Inc. Simo Du – HealthCore, Inc. Yuval Patel – Duke University Mindie Nguyen – Stanford University Erik Ness – Intercept Pharmaceuticals Thomas Capozza – Intercept Pharmaceuticals, Inc. Lina Titievsky – Intercept Pharmaceuticals

#### Disease Epidemiology/Clinical Course The Effect of Epidural Steroid Injections on Fracture Risk Among Medicare Patients

#### PRESENTING AUTHOR

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Emily Stein – HSS hospital

#### Medical Devices

Persistence of Anticoagulation After Receiving Transcatheter Left Atrial Appendage Occlusion vs Oral Anticoagulants for Stroke Prevention in Atrial Fibrillation

#### PRESENTING AUTHOR

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Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

#### Methods in Pharmacoepidemiology Longitudinal Adherence Trajectories to Biologic Disease Modifying Anti-Rheumatic Drugs in Tuscany, Italy

#### PRESENTING AUTHOR

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Ersilia Lucenteforte – Unit of Medical Statistics, Department of Clinical and Experimental Medicine, University of Pisa

#### Disease Epidemiology/Clinical Course Incidence Rates of Select Outcomes Among Patients With Non-Alcoholic Steatohepatitis (NASH) and Evidence of Fibrosis and Cirrhosis

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Monica Bertoia – Optum CO-AUTHORS Erik Ness – Intercept Pharmaceuticals Thomas Capozza – Intercept Pharmaceuticals, Inc. Lina Titievsky – Intercept Pharmaceuticals John Seeger – Epidemiology, Optum, Boston, MA, USA

#### Disease Epidemiology/Clinical Course Hyperthyroidism and Breast Cancer Recurrence and Mortality: A Danish Population-based Cohort Study

#### PRESENTING AUTHOR

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#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

## Impact of Disparities and Stigma on Drug Access and Utilization

#### Drug Utilization Research Disparities in Hepatitis C Treatment in the Era of Direct-Acting Antivirals Among Arizona Medicaid Beneficiaries

#### PRESENTING AUTHOR

Hyun Jin Song – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida

#### CO-AUTHORS

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Haesuk Park – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, FL, USA

#### Drug Utilization Research Sources of Racial/Ethnic Disparities in Antidepressant Treatment: Analysis of the Medical Expenditure Panel Survey Data

#### PRESENTING AUTHOR

Macarius Donneyong – The Ohio State University CO-AUTHOR Teng-Jen Chang – The Ohio State University

#### Drug Utilization Research

#### Do Medicare Part D Low-Income Subsidies Narrow Disparities in Orally-Administered Antimyeloma Therapy Initiation?

#### PRESENTING AUTHOR

Shelley Jazowski – University of North Carolina at Chapel Hill CO-AUTHORS

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Justin Trogdon – University of North Carolina at Chapel Hill Stacie Dusetzina – Vanderbilt University School of Medicine

#### Health Economics/Outcomes Research Impact of Race, Ethnicity, and Sex on Treatment of Non-Valvular Atrial Fibrillation

#### CO-AUTHORS

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Diane Francis – Johnson & Johnson Medical Devices, Health Economics and Market Access

Sonia Maccioni – Johnson & Johnson Medical Devices, Health Economics and Market Access

Vincent Thomas – Biosense Webster

Jennifer Wood – Johnson & Johnson, Medical Device Epidemiology and Real-World Data Sciences

Guy Cafri – Johnson & Johnson, Medical Device Epidemiology and Real-World Data Sciences

Rahul Khanna – Johnson & Johnson, Medical Device Epidemiology and Real-World Data Sciences

Charlene Wong – Johnson & Johnson, Medical Device Epidemiology and Real-World Data Sciences

Jonathan Piccini – Duke University Medical Center

Daniel Friedman - Yale School of Medicine

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Neloufar Rahai – Johnson & Johnson, Medical Device Epidemiology and Real-World Data Sciences

#### Drug Utilization Research The Impact of Sex on The Quality of Medication Treatment in Patients with Type 2 Diabetes

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Sieta de Vries – University of Groningen, University Medical Center Groningen, Department of Clinical Pharmacy and Pharmacology, Netherlands

Petra Denig – University Medical Center Groningen

#### Drug Utilization Research Changes in Buprenorphine Utilization During the COVID-19 Pandemic in the US

#### PRESENTING AUTHOR

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Michelle Lofwall – College of Medicine, University of Kentucky

Patricia Freeman – Department of Pharmacy Practice and Science, College of Pharmacy, University of Kentucky

#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

Look Who's Talking Now: Capturing Patient and Provider Perspectives in Health Data

Health Economics/Outcomes Research

Participant Engagement and Adherence in an Arthritis Power Real-World Study to Capture Smartwatch and Patient-Reported Outcome Data Among Rheumatoid Arthritis Patients

#### PRESENTING AUTHOR

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D. Curtis – Global Healthy Foundation
K. Gavigan – Global Healthy Foundation
I. Lipkovich – Eli Lilly and Company Indianapolis, IN
S.K. Nolot – Eli Lilly and Company Indianapolis, IN

V.S. Haynes – Eli Lilly and Company Indianapolis, IN

Drug Utilization Research

Ranitidine and Other Histamine2-Receptor Antagonists – A Rapid Response Drug Utilisation Study Using Electronic Health Care Data from Six European Countries

#### PRESENTING AUTHOR

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Christian Reich – IQVIA, Real World Solutions

Talita Duartes-Salles – Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol)

Tom Seinen – Department of Medical Informatics, Erasmus University Medical Center, Rotterdam

Peter Rijnbeek – Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, Netherlands

#### Health Economics/Outcomes Research The Friends of Cancer Research Real World Data (RWD) Pilot 2.0 Collaboration: Implementation of Standardized Methodological Approaches for Evaluation of Oncology RWD

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Andrew Belli – COTA Laura Lasiter – Friends of Cancer Research Jeff Allen – Friends of Cancer Research

#### Health Economics/Outcomes Research Cost-Effectiveness of Systematic Treatments for Metastatic Castration-Sensitive Prostate Cancer: An Economic Evaluation Based on Network Meta-Analysis

#### PRESENTING AUTHOR

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#### CO-AUTHORS

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#### Health Economics/Outcomes Research Telemedicine Use Among U.S. Patients with Cancer During the COVID-19 Pandemic

#### PRESENTING AUTHOR

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Aaron Cohen - Flatiron Health

Amy Webster - Flatiron Health

Rebecca Rohrer - Flatiron Health

Michael Taylor – Real World Data Collaborations, Personalized Healthcare Data Science, Genentech Inc., South San Francisco, CA, USA Drug Effectiveness

#### Physician and Patient Reported Effectiveness Outcomes are similar in Tofacitinib and TNF Inhibitors in Rheumatoid Arthritis Patients: Data from a Rheumatoid Arthritis Registry in Canada

#### PRESENTING AUTHOR

Mohammad Movahedi – Toronto General Hospital Research Institute, Univeristy Health Network, Toronto, ON

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#### 11:45 AM - 1:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Pregnancy: Beyond Opioids

Pregnancy and Lactation First Trimester Exposure to Buprenorphine Compared to Methadone for Treatment of Opioid Use Disorders and the Risk of Congenital Malformations

#### PRESENTING AUTHOR

Elizabeth Suarez – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

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Helen Mogun – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

Brian Bateman – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

#### Pregnancy and Lactation Characteristics of Initial Postpartum Opioid Prescribing and Risks of Serious Opioid-Related Events After Cesarean Delivery

#### PRESENTING AUTHOR

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#### CO-AUTHORS

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#### Pregnancy and Lactation Prescription Opioid Type and the Risk of Neonatal Opioid Withdrawal Syndrome

#### PRESENTING AUTHOR

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Samantha Parker – Boston University School of Public Health

Krista Huybrechts – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

#### Pregnancy and Lactation

#### Benzodiazepine Use in the First Trimester and Risk of Congenital Malformations: A Nationwide Cohort Study in South Korea

#### PRESENTING AUTHOR

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#### Pregnancy and Lactation

#### Comparative Safety of In-Utero Exposure to Buprenorphine Combined with Naloxone vs Buprenorphine Monoproduct with Respect to Congenital Malformations

#### PRESENTING AUTHOR

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#### Pregnancy and Lactation Prenatal Analgesic Opioid Exposure and Risk of ADHD in Childhood

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#### 1:45 - 2:45 PM

#### ANNUAL MEETING OF ISPE MEMBERS & 2021 AWARDS CEREMONY

- Call to Order; President's Report | Olaf Klungel, FISPE President
- Financial Report | Wei Zhou, FISPE Vice-President/Finance
- Strategic Plan 2020-2024 update | Vincent Lo Re, FISPE *Chair, Strategic Planning Committee*

#### RETIRING OFFICERS & DIRECTORS

#### Almut Winterstein, FISPE – Immediate Past President Pia Caduff – Director Vera Ehrenstein – Director Chieko Ishiguro – Director Malcolm Maclure – Director Darren Toh, FISPE – Director

#### INSTALLATION OF NEW DIRECTORS

Jennifer Lund, FISPE – Academic (Americas) Daniel Prieto-Alhambra, FISPE – Academic (Europe/Africa) Hongbo Yuan – Government/Regulator (Americas) Yoshiaki Uyama – Government/Regulator (Asia/Pacific) Stine Hasling Mogensen – Government/ Regulator (Europe/Africa)

- New Business
- Awards Ceremony
- ISPE Board Transition

#### INSTALLATION OF 2021-2022 OFFICERS

Vincent Lo Re, FISPE – President Tobias Gerhard, FISPE – President-elect Olaf Klungel, FISPE – Immediate Past President Wei Zhou, FISPE – Vice-President/Finance Caitlin Knox – Vice President/Finance-elect

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#### 3:00 - 4:30 PM

#### **ORAL SESSIONS /** CONCURRENT

#### From Patient to Policy Impact: Benefit-Risk Assessment, Communication, and Evaluation (BRACE) SIG

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

## Impact of FDA's Regulatory Actions on the Quality of REMS Survey Methodology Protocols (2007-2020)

PRESENTING AUTHOR

Samuel Ewusie – ORISE Fellow, Division of Risk Management, FDA CO-AUTHORS

Janifer Quick – Division of Risk Management, FDA

Elaine Morrato – Parkinson School of Public Health, Loyola University Chicago

Gita Toyserkani – Division of Risk Management, FDA

#### Drug Utilization Research

#### Influence of Drug Safety Advisories on Drug Utilization: An International Interrupted Time Series and Meta-Analysis Study

#### PRESENTING AUTHOR

Richard Morrow – Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

#### CO-AUTHORS

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Marie De Bruin – Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University

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Colin Dormuth – Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

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

Preferences Concerning Drug Safety Communication of Hospital-Based Specialist in the Netherlands

PRESENTING AUTHOR

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

#### Regulatory Approval of Phentermine/Topiramate for Obesity Management and Off-Label Use of Topiramate: A Fairytale for Drug Repurposing and a Maze for Risk Mitigation

#### PRESENTING AUTHOR

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

What Matters to Patients When Considering Treatments for Prevention of Rheumatoid Arthritis: A Preference Study in the United Kingdom, Germany, and Romania

#### PRESENTING AUTHOR

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#### 3:00 - 4:30 PM

#### **ORAL SESSIONS /** CONCURRENT

MedTech Globetrotting – Assisting Medical Devises Effects in the Real World

Medical Devices

Real-World Epidemiologic and Genetic Evidence Synthesis Reveals the Sex-Dependent Role of GNAS SNPs in Hip Arthroplasty Related Periprosthetic Osteolysis

#### CO-AUTHORS

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Richard Forshee – FDA/CBER
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Medical Devices

#### The Association Between Bariatric Surgery and Carpal Tunnel Syndrome: A Cohort Study from Swedish Nationwide Healthcare Registries

#### CO-AUTHORS

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#### PRESENTING AUTHOR

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#### Medical Devices

#### Comparison of 10- and 15-Year Outcomes of Bioprosthetic and Mechanical Aortic Valve Replacement in Patients Aged Under 65 Years: Australian Study Using Linked Data for 4,704 Patients

#### PRESENTING AUTHOR

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Louisa Jorm – Centre for Big Data Research in Health, UNSW Art Sedrakyan – Weill Cornell Medicine

#### Medical Devices Sex-Differences in Risk of Early Revision After Primary Total Knee Arthroplasty

#### PRESENTING AUTHOR

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#### Medical Devices

#### The Association Between Bariatric Surgery and Cataract: A Cohort Study from Swedish Nationwide Healthcare Registries

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#### Medical Devices

Comparative Patient Characteristics of Transcatheter Left Atrial Appendage Occlusion vs Oral Anticoagulants for Stroke Prevention in Atrial Fibrillation

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#### 3:00 - 4:30 PM

#### **ORAL SESSIONS /** CONCURRENT

Psychotropics: Bitter Pills to Swallow in Pregnancy

Pregnancy and Lactation Prenatal Antiseizure Medication Exposure and Risk of Autism and Intellectual Disability. SCAN-AED: A Nordic Cohort Study

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Jakob Christensen – National Centre for Register-Based Research, Department of Economics and Business Economics, Aarhus BSS, Aarhus University

#### Pregnancy and Lactation

#### The Comparative Safety of Antiseizure Medication Polytherapy vs Valproate in Pregnancy and Risk of Major Congenital Malformations

#### PRESENTING AUTHOR

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#### Pregnancy and Lactation

## Antidepressant Use During Pregnancy and the Risk of Neurodevelopmental Disorders in Children

#### PRESENTING AUTHOR

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Krista Huybrechts – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

#### Pregnancy and Lactation

#### The Impact of In-Utero Antipsychotic Drug Exposure on Congenital Malformations: An International Cohort Study

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#### Pregnancy and Lactation The Impact of In-Utero Antipsychotic Exposure on Neurodevelopmental Disorders in Children

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Yanmin Zhu – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

Helen Mogun – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

Krista Huybrechts – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

#### 3:00 - 4:30 PM

Presentation Time: 4:30 PM - 6:00 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Application of Pharmacoepidemiologic Study Designs for Research Across the Cancer Continuum

Safety End Points Proton Pump Inhibitors and Risk of Gastric Cancer: A Population-based Cohort Study

PRESENTING AUTHOR

Devin Abrahami - McGill University

CO-AUTHORS

Emily McDonald – Division of Internal Medicine, Department of Medicine, McGill University Health Centre, Montreal, CA

Mireille Schnitzer – Faculté de Pharmacie, University of Montreal

Alan Barkun – McGill University Health Centre

Samy Suissa – Departments of Epidemiology and Biostatistics, Faculty of Medicine, McGill University, Montreal, CA

Laurent Azoulay – Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Québec, CA

Drug Effectiveness

#### Efficacy and Safety of Treatments for Nonmetastatic Castration-Resistant Prostate Cancer: A Matching-Adjusted Indirect Comparison and Network Meta-Analysis

#### PRESENTING AUTHOR

Lin Wang – Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health

CO-AUTHORS

Channing Paller – The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine

Hwanhee Hong – Duke Clinical Research Institute, Duke University

Otis Brawley – The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine

**G. Caleb Alexander** – Johns Hopkins Center for Drug Safety and Effectiveness

#### Safety End Points Comparative Safety of Conjugated Estrogens/ Bazedoxifene (CE/BZA) vs Estrogen/Progestin Combination Hormone Therapy (EP): A Multi-Database Cohort Study

PRESENTING AUTHOR

Sarah Hoffman – HealthCore, Inc.

CO-AUTHORS

Samuel Governor – Research Operations, HealthCore, Inc. Kimberly Daniels – Safety & Epidemiology, HealthCore, Inc. Ryan Seals – Optum

Najat JZiyadeh – Optum

Florence Wang – Optum

Dingwei Dai – CVS Health Clinical Trial Services (fka Healthagen) Cheryl McMahill-Walraven – CVS Health Clinical Trial Services (formerly known as Healthagen), an affiliate of Aetna

Patty Shuminski – CVS Health Clinical Trial Services (fka Healthagen)

Vera Frajzyngier – Boehringer Ingelheim

Xiaofeng Zhou - Pfizer, Inc.

Rongjun Shen - Pfizer, Inc.

Nicole Fournakis – Research Operations, HealthCore, Inc. Daniel Beachler – Safety & Epidemiology, HealthCore, Inc.

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Methods in Pharmacoepidemiology Risk of Malignancies in Newly Treated Patients with Disease-Modifying Drugs for Multiple Sclerosis: Assessment According to Cohort and Nested-Case Control Approaches

#### PRESENTING AUTHOR

Pauline Bosco-Lévy – Bordeaux PharmacoEpi, INSERM CIC1401, Université de BORDEAUX

#### CO-AUTHORS

Emmanuelle Boutmy – Merck KGaA Darmstadt, Germany

Angela Grelaud – Bordeaux PharmacoEpi, INSERM CIC1401, Université de BORDEAUX

Meritxell Sabidó – Global Epidemiology, Merck KGaA Darmstadt, Germany

Pauline Diez – Bordeaux PharmacoEpi, INSERM CIC1401, Université de BORDEAUX

Clémentine Lacueille – Bordeaux PharmacoEpi, INSERM CIC1401, Université de BORDEAUX

Régis Lassalle – Bordeaux PharmacoEpi, INSERM CIC1401, Université de BORDEAUX

Caroline Foch – Merck KGaA Darmstadt, Germany

Cécile Droz-Perroteau – Univ. Bordeaux, INSERM CIC-P 1401, Bordeaux PharmacoEpi, 33000 Bordeaux, France

#### Safety End Points

#### Vitamin K Antagonists and Risk of Myelodysplastic Syndrome: A Nationwide Cohort Study in Atrial Fibrillation Patients

#### PRESENTING AUTHOR

Anke Neumann – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

#### CO-AUTHORS

Marie-Joelle Jabagi – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

Mahmoud Zureik – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

#### Safety End Points

#### Use of Proton Pump Inhibitors and Risk of Pancreatic Adenocarcinoma: A Case-Control Study Based on the French National Health Data System (SNDS)

#### PRESENTING AUTHOR

Marion Lassalle – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products [ANSM], and French National Health Insurance [CNAM]), Saint-Denis, France

#### CO-AUTHORS

Thien Le Tri – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products [ANSM], and French National Health Insurance [CNAM]), Saint-Denis, France

Pauline Afchain – APHP, Hôpital Saint Antoine, Medical Oncology Department, Paris, France

Marine Camus-Duboc – Sorbonne Université, Centre de Recherche Saint Antoine, UMRS-938, Paris, France

Julien Kirchgesner – Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, Paris, France

Mahmoud Zureik – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

Rosemary Dray-Spira – EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products [ANSM], and French National Health Insurance [CNAM]), Saint-Denis, France

#### 4:30 - 6:00 PM

#### **ORAL SESSIONS /** CONCURRENT

#### Just How Well Does it Work in Real Life?

#### **Drug Effectiveness**

Calibrating Real-World Evidence Studies Against Randomized Trials: Treatment Effectiveness of Infliximab in Inflammatory Bowel Disease

#### PRESENTING AUTHOR

Julien Kirchgesner – Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, Paris, France

#### CO-AUTHORS

Rishi Desai – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

Maria Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

Laurent Beaugerie – Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, AP-HP, Hôpital Saint-Antoine, Department of gastroenterology, Paris, France

Seoyoung Kim – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

#### **Drug Effectiveness**

#### Shorter Drug Holiday After 3 or More Years of Risedronate vs Alendronate is Important to Maintain Osteoporotic Fracture Protection

#### PRESENTING AUTHOR

Kaleen Hayes – University of Toronto Dalla Lana School of Public Health, Toronto, Ontario, CA

#### CO-AUTHORS

Kevin Brown – University of Toronto Dalla Lana School of Public Health, Toronto, Ontario, CA

Angela Cheung – Department of Medicine, University Health Network, University of Toronto, Toronto, Ontario, CA

**David Juurlink** – Department of Medicine, University of Toronto, Toronto, Ontario, CA

Suzanne Cadarette – Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario, CA

#### Drug Effectiveness Cardiovascular Effectiveness of SGLT-2 Inhibitors vs Metformin as First-Line Treatment for Type 2 Diabetes

#### PRESENTING AUTHOR

HoJin Shin – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

#### CO-AUTHORS

Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

Robert Glynn – Harvard T. H. Chan School of Public Health

Elisabetta Patorno – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

#### Drug Effectiveness Effect of SGLT-2 Inhibitors on eGFR in Type 2 Diabetes with Different Baseline Renal Functions: A Multi-Center Study

#### CO-AUTHORS

Fang-Ju Lin – National Taiwan University

Chi-Chuan Wang – School of Pharmacy, College of Medicine, National Taiwan University, Taipei, Taiwan

Chien-Ning Hsu – Department of Pharmacy, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, Taiwan

Chen-Yi Yang – Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University, Tainan, Taiwan

Chih-Yuan Wang – College of Medicine, National Taiwan University, Taipei, Taiwan

#### PRESENTING AUTHOR

Huang-Tz Ou – Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University, Tainan, Taiwan

#### Drug Effectiveness

Comparative Effectiveness of Empagliflozin in Reducing Total Cardiovascular Events in the Empagliflozin Comparative Effectiveness and Safety (EMPRISE) Study

#### PRESENTING AUTHOR

Rishi Desai – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

#### CO-AUTHORS

Robert Glynn – Harvard T. H. Chan School of Public Health

Brendan Everett – Brigham and Women's Hospital

Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

Deborah Wexler – Brigham and Women's Hospital

Anouk Derauz Luyet – Boehringer-Ingelheim

Ola Vedin – Boehringer-Ingelheim

Kimberly Brodovicz – Boehringer Ingelheim

Ajinkya Pawar – Sanofi

Elisabetta Patorno – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

#### **Drug Effectiveness**

#### Initiation of Sodium-Glucose Co-Transporter 2 Inhibitors and Progression of Renal Disease Among Patients with Type-2 Diabetes: A Population-Based Cohort Study

PRESENTING AUTHOR

Wajd Alkabbani – School of Pharmacy, University of Waterloo

CO-AUTHORS

Arsene Zongo – Faculty of Pharmacy, Université Laval

Dean Eurich – School of Public Health, University of Alberta

Baiju Shah – Department of Medicine, University of Toronto

Jasjeet Minhas-Sandhu – School of Public Health, University of Alberta

Mhd. Wasem Alsabbagh – School of Pharmacy, University of Waterloo

John-Michael Gamble – School of Pharmacy, University of Waterloo

#### 4:30 - 6:00 PM

#### **ORAL SESSIONS /** CONCURRENT

Pregnancy: Diabetes and a Surprise

#### Pregnancy and Lactation Characteristics and Outcomes of Pregnancies in Women with Heart Failure: A Retrospective Cohort Study in the Sentinel System

PRESENTING AUTHOR

Yan Li – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration CO-AUTHORS

Austin Cosgrove – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

Efe Eworuke – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Catherine Corey – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Joy Kolonoski – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

Mayura Shinde – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

Pregnancy and Lactation Metformin and Risk of Adverse Pregnancy Outcomes Among Pregnant Women with Gestation Diabetes in the United Kingdom: A Population-Based Cohort Study

PRESENTING AUTHOR

Ya-Hui Yu – McGill University

CO-AUTHORS

**Robert Platt** – Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, CA

Oriana Hoi Yun Yu – Centre for Clinical Epidemiology, Lady Davis Institute, Jewish General Hospital, Montreal, Québec, CA

Kristian Filion – Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, CA

#### Pregnancy and Lactation

The Role of Propensity Score Matching in Claims-Based Studies for Achieving Comparability in Hba1c Levels Between Treatments in Pregnant Women with Type 2 Diabetes

PRESENTING AUTHOR
Carolyn Cesta – Karolinska Institutet

#### CO-AUTHORS

Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health

Brian Bateman – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

Krista Huybrechts – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

Ellen Seely – Harvard Medical School

Elisabetta Patorno – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

#### Pregnancy and Lactation

#### Balance of Unmeasured Covariates After Propensity Score Matching Based on Measurable Covariates in Perinatal Pharmacoepidemiologic Studies

#### PRESENTING AUTHOR

Anmin Zhu – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

CO-AUTHORS

Thuy Thai – Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida

Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health

Brian Bateman – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

Loreen Straub – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

Kathryn Gray – Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Brigham and Women's Hospital and Harvard Medical School

Almut Winterstein – Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida

Lockwood Taylor – Center for Drug Evaluation and Research, United States Food and Drug Administration

Rita Ouellet-Hellstrom – Center for Drug Evaluation and Research, United States Food and Drug Administration

Yong Ma – Center for Drug Evaluation and Research, United States Food and Drug Administration

Yandong Qiang – Center for Drug Evaluation and Research, United States Food and Drug Administration

Wei Hua – Center for Drug Evaluation and Research, United States Food and Drug Administration

Krista Huybrechts – Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
## Program Schedule

### Pregnancy and Lactation Development and Validation of ICD-10 Claims-Based Algorithms for Pregnancy and Infant Outcomes

#### PRESENTING AUTHOR

Andrea Chomistek – Optum CO-AUTHORS Kelesitse Phiri – GlaxoSmithKline Jenna Calderbank – Optum Michael Doherty – Optum Stephanie Chiuve – AbbVie Brenda Hinman-McIlroy – AbbVie Michael Snabes – AbbVie, Inc John Seeger – Epidemiology, Optum, Boston, MA, USA

#### Pregnancy and Lactation Metformin vs Insulin in Early Pregnancy and Risk of Congenital Malformations

PRESENTING AUTHOR

Lars Kjerpeseth – Norwegian Institute of Public Health CO-AUTHORS Carolyn Cesta – Karolinska Institutet Anders Engeland – University of Bergen

Kari Furu – Norwegian Institute of Public Health

Mika Gissler – Finnish Institute for Health and Welfare

Hanne Gulseth – Norwegian Institute of Public Health

Øystein Karlstad – Norwegian Institute of Public Health Helle Kieler – Centre for Pharmacoepidemiology,

Karolinska Institutet

Maarit Leinonen – Finnish Institute for Health and Welfare

Mette Nørgaard – Department of Clinical Epidemiology, University of Aarhus

Laura Pazzagli – Centre for Pharmacoepidemiology, Karolinska Institutet, Stockholm, Sweden

Randi Selmer – Norwegian Institute of Public Health, Oslo, Norway

Helga Zoega – Centre for Big Data Research in Health, UNSW Sydney

Jacqueline Cohen – Norwegian Institute of Public Health

### 4:30 - 6:00 PM

### **ORAL SESSIONS /** CONCURRENT

### PS I love you, XXII

Methods in Pharmacoepidemiology Evaluating When Effect Estimates Change After Propensity Score Trimming Because of Differing Effect Measure Modifier Distributions

#### PRESENTING AUTHOR

Michael Webster-Clark – University of North Carolina at Chapel Hill

CO-AUTHORS

Michele Jonsson Funk – University of North Carolina at Chapel Hill

Jennifer Lund – Department of Epidemiology, University of North Carolina at Chapel Hill

Robert Glynn – Harvard T. H. Chan School of Public Health Til Stürmer – Department of Epidemiology, University of North Carolina at Chapel Hill

Alan Kinlaw – UNC Eshelman School of Pharmacy

### Methods in Pharmacoepidemiology Optimization-Based Stable Balancing Weights vs Generalized Boosted Modeling for Propensity Score Weighting

PRESENTING AUTHOR Stephen Johnston – Johnson & Johnson CO-AUTHORS Luo Li – Johnson & Johnson Harikumaran Dwarakanathan – Mu Sigma David Wei – Johnson & Johnson Pragya Rai – Johnson & Johnson Paul Coplan – Johnson & Johnson

### Methods in Pharmacoepidemiology Controlling for Differential Regression to the Mean Using Summary Measures of Pre-Treatment Laboratory Values in Propensity Scores

PRESENTING AUTHOR

Chase Latour – University of North Carolina at Chapel Hill CO-AUTHORS Leah McGrath – NoviSci, Inc. Alexander Breskin – NoviSci Inc. Ying Yu – NoviSci, Inc. M. Alan Brookhart – NoviSci, Inc.

## **Program Schedule**

#### Medical Devices

An Evaluation of Direct and Propensity Score Matching vs Propensity Score Stratification for Confounding Adjustment in Primary Total Hip Arthroplasty

### PRESENTING AUTHOR

Abhishek Chitnis – Johnson & Johnson CO-AUTHORS Jack Mantel – DePuy Synthes Juan Daccach – Johnson & Johnson Prerna Kothari – Mu-Sigma Jill Ruppenkamp – Johnson & Johnson Paul Coplan – Johnson & Johnson Chantal Holy - Johnson & Johnson

### Methods in Pharmacoepidemiology

Disease Risk Score as Alternative to Propensity Score Under Multiple Confounders and High Prevalence of Outcome: A Simulation Study Motivated by the Emergence of Multiple Repurposed Medicines During the COVID-19 Pandemic

PRESENTING AUTHOR

Yuchen Guo – University of Oxford CO-AUTHORS

Sara Khalid – University of Oxford

Victoria Strauss – University of Oxford

M Sanni Ali – London School of Hygiene & Tropical Medicine

Daniel Prieto-Alhambra – Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, UK

### Methods in Pharmacoepidemiology Cardinality Matching vs Propensity Score Matching in Multiple Sclerosis

PRESENTING AUTHOR Nicholas Belviso – Biogen CO-AUTHORS Gabrielle Simoneau – Biogen Bora Youn – Biogen Fabio Pellegrini – Biogen Changyu Shen – Biogen Carl de Moor – Biogen

### 6:00 - 6:30 PM

### **CLOSING CEREMONY**

SPEAKERS

Syd Phillips – Chair, ICPE Scientific Program Committee Anton Pottegård – University of Southern Denmark Jesper Hallas – University of Southern Denmark

### 8:00 - 9:30 PM

### PLENARY COVID-19 Vaccines: Timely Global Real-World Evidence Vaccines

MODERATOR

J. Bradley Layton - RTI Health Solutions

SPEAKERS

Miriam Sturkenboom – Department Datascience & Biostatistics, University Medical Center Utrecht

Steven Anderson – FDA/CBER

Carla Talarico – Moderna

Robert Chen – Brighton Collaboration

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### WORKSHOP

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

Big Data in Health and Bioethics: A Call for a Comprehensive, Multi-Disciplinary, ISPE Position

#### PRESENTERS

Xavier Kurz – European Medicines Agency

Edward Bortnichak – Merck & Co., Inc.

Solomon lyasu – Merck & Co. Inc.

Patrick Ryan – Janssen Research & Development

Ameet Sarpatwari – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

AUTHOR

Peter Arlett – European Medicines Agency

### Methods in Pharmacoepidemiology Outcome Measurements for External Comparator Arms: New Opportunities for Epidemiology Methods Application and Development

#### PRESENTERS

Joan Largent - IQVIA

Emily Brouwer – Janssen

Cynthia Girman – CERobs Consulting, LLC

Christen Gray – AstraZeneca

Michele Jonsson Funk – University of North Carolina at Chapel Hill

Robert Glynn – Harvard T. H. Chan School of Public Health

Dimitri Bennett – Takeda

Kueiyu Joshua Lin – Brigham and Women's Hospital

Daniela Moga – Department of Pharmacy Practice and Science, College of Pharmacy, University of Kentucky

Sabina Nduaguba – University of Florida

Mary Prince Panaccio – Research Outcomes Innovations

Xuerong Wen – University of Rhode Island, College of Pharmacy

Richard Wyss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

Hongbo Yuan – Canadian Agency for Drugs and Technologies in Health

Huifeng Yun – Department of Epidemiology, University of Alabama at Birmingham

### Methods in Pharmacoepidemiology Polypharmacy: Problems and Solutions for its Methodologic Challenges in Real-World Data

#### PRESENTERS

Amy Justice – US Department of Veterans Affairs

Christopher Rentsch – London School of Hygiene & Tropical Medicine; US Department of Veterans Affairs

Kirsha Gordon – VA CT Healthcare System

Jonathon Romero – Oak Ridge National Laboratory

Jordan Guillot – Université de Bordeaux

Vincent Lo Re – Center for Pharmacoepidemiology Research and Training, Center for Clinical Epidemiology and Biostatistics, Department of Biostatistics, Epidemiology, and Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

### Disease Epidemiology/Clinical Course Real World Data in the Era of COVID-19: The Devil in the Details. An ISPE RWE Task Force/ COVID-19 Workgroup Symposium

#### PRESENTERS

Montse Soriano Gabarro - Bayer AG

Dana Teltsch – Apellis

Mugdha Gokhale – Center for Observational and Real-world Evidence (CORE), Merck Research Laboratories

Paul Petraro – Head, RWE Analytic CoE. Boehringer-ingelheim

Jeremy Rassen – Aetion, Inc.

Stephan Lanes – HealthCore Inc

Soko Setoguchi – RWJ Medical School, Center for Pharmacoepidemiology and Treatment Science (PETS), Institute for Health, Health Care Policy and Aging Research

Daniel Prieto-Alhambra – Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, UK



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### WORKSHOP

2022

**MID-YEAR** 

MEETING

Methods in Pharmacoepidemiology COVID-19 Confidential: Enabling Trust in COVID-19 Research with Fit for Purpose Real-World Data

PRESENTERS Nicolle Gatto – Aetion, Inc.

Jessica Franklin – Optum

Elizabeth Garry – Aetion, Inc. David Martin – Moderna Aloka Chakravarty – Food and Drug Administration Jeremy Rassen – Aetion, Inc.

### Drug Utilization Research Drug Utilization Research in Africa: Challenges and Potential Solutions

#### PRESENTERS

Maribel Salas – Clinical Safety and Pharmacovigilance, Daiichi Sankyo Inc Basking Ridge, NJ and CCEB/CPeRT, University of Pennsylvania Perelman School of Medicine

Johanita Burger – Medicine Usage in South Africa (MUSA), North-West University

Laura Horne – Clinical Safety and Pharmacovigilance, Daiichi Sankyo Inc Basking Ridge

Johanna Meyer – Division of Public Health Pharmacy and Management, School of Pharmacy, Sefako Makgatho Health Sciences University

Ilse Truter – Nelson Mandela University

### Methods in Pharmacoepidemiology Triangulating the Truth: State-of-the-Art Sensitivity Analyses for Observational Research

#### PRESENTERS

Marianne Cunnington – Glaxosmithkline Ian Douglas – London School of Hygiene & Tropical Medicine Jeremy Brown – London School of Hygiene and Tropical Medicine Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health Daina Esposito – Boston University School of Public Health Wilhelmine Meerhaus – Glaxosmithkline

### WORKSHOP

#### Informatics

From the Individual Through the Health System and Back: The Interdisciplinary Promise and Challenges of Digital Epidemiology for Improved Outcomes (An ISPE Digital Epidemiology SIG Endorsed Symposium)

#### PRESENTERS

Lisa Weiss - Health Information Technology Lab

Heidi Dohse - Tour de Heart

Dana Teltsch – Apellis

Nancy Dreyer – IQVIA

John Cai – Merck

Helga Gardarsdottir – Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University

### Pregnancy and Lactation How to Emulate a Target Trial to Study the Effects of Treatments for and During Pregnancy

#### PRESENTERS

Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health Sonja Swanson – Department of Epidemiology, Erasmus MC

Jennifer Yland – Department of Epidemiology, Boston University School of Public Health

Kristin Palmsten – HealthPartners Institute

#### Drug Effectiveness Lessons for Regulatory Decision-Making from Real-World Data Trial Emulation Results

#### PRESENTERS

Shirley Wang – Brigham and Women's Hospital, Harvard Medical School

Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

William Crown – Brandeis University

Joseph Ross – Yale University

Peter Arlett – European Medicines Agency

Kenneth Quinto – US Food and Drug Administration

Yoshiaki Uyama – Pharmaceutical Devices and Medicines Agency

#### Vaccines

### Methodological Approaches to Evaluating the Safety and Effectiveness of Multi-Dose Coronavirus Disease 2019 (COVID-19) Vaccines Series

#### PRESENTERS

Hui-Lee Wong – CBER, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration Xabier Garcia de Albeniz – RTI Health Solutions Anne MobleyButler – Washington University in St. Louis Heather Whitaker – Public Health England Marc Suchard – University of California, Los Angeles

### WORKSHOP

Methods in Pharmacoepidemiology A Call for 'Environmental Pharmacoepidemiology': Medications, Global and Local Environments, and Health Outcomes

#### PRESENTERS

Benjamin Bates – Rutgers Robert Wood Johnson Medical School

Sean Hennessy – Center for Pharmacoepidemiology Research and Training, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania, Philadelphia, PA, USA

Michelle Bell – School of the Environment, Yale University, New Haven, CT, USA

Paul Coplan – Johnson & Johnson

Rachel Nethery – Department of Biostatistics, Harvard T.H. Chan School of Public Health

Soko Setoguchi – RWJ Medical School, Center for Pharmacoepidemiology and Treatment Science (PETS), Institute for Health, Health Care Policy and Aging Research

### Methods in Pharmacoepidemiology Believability of Real-World Evidence (RWE) for Informed Regulatory Decisions

#### PRESENTERS

Jacinthe Leclerc – Universite du Quebec a Trois-Rivieres Kimberly Brodovicz – Boehringer Ingelheim

Stephen Chang-FDA

Magdalene Assimon – University of North Carolina School of Medicine

Hisashi Urushihara – Keio Univesity

Cynthia Girman – CERobs Consulting, LLC

### Methods in Pharmacoepidemiology New Frontiers in Computable Phenotyping for Medical Product Safety Evaluation

#### PRESENTERS

Rishi Desai – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

David Carrell – Kaiser Permanente Washington Health Research Institute

Robert Ball – FDA

Katherine Liao – Brigham and Women's Hospital

Lindsay Collin – Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA

Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA

#### Methods in Pharmacoepidemiology

### Using Real-World External Controls to Support Drug Approval: An Interactive Framework Using Oncology Trial and Real-World Data

#### PRESENTERS

Laura Hester – Janssen R&D, LLC

Donna Rivera – US Food & Drug Administration Jennifer Lund – Department of Epidemiology, University of North Carolina at Chapel Hill Asieh Golozar – Regeneron Pharmaceuticals Kourtney Davis – Janssen R&D, LLC John Seeger – Optum Epidemiology Leah Sansbury – GlaxoSmithKline

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### WORKSHOP

Disease Epidemiology/Clinical Course Pediatric Infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV 2) and Potential Health Consequences (Submitted on behalf of the ISPE RWE COVID-19 Workgroup)

#### PRESENTERS

Ann McMahon – Office of Pediatric Therapeutics, Food and Drug Administration Susan Coffin – Children's Hospital of Philadelphia David Kimberlin – University of Alabama at Birmingham Montse Soriano Gabarro – Bayer AG Jonathan Davis – Tufts University Children's Hospital

#### Medical Devices

### Product Surveillance and Signal Management: Now is the Time for Methodologist Engagement!

#### PRESENTERS

Mary Beth Ritchey – Med Tech Epi Danica Marinac-Dabic – FDA/CDRH Theodore Lystig – Medtronic Paul Coplan – Johnson & Johnson

### Methods in Pharmacoepidemiology RWE Blueprints: Decoding SPACE, SPIFD, Start-RWE, and Other Tools Promoting Principled Pharmacoepidemiology

### PRESENTERS

Elizabeth Garry – Aetion, Inc. Nicolle Gatto – Aetion, Inc. Shirley Wang – Brigham and Women's Hospital, Harvard Medical School Ulka Campbell – Pfizer, Inc.

Methods in Pharmacoepidemiology Selection Matters: Addressing Biases in Linked

### Clinico-Genomic Data Sets

### PRESENTERS

Katherine Panageas – Memorial Sloan Kettering Cancer Center

Kenneth Kehl – Dana-Farber Cancer Institute, Harvard Medical Center

Devin Incerti – Genentech

Til Stürmer – Department of Epidemiology, University of North Carolina at Chapel Hill

### Methods in Pharmacoepidemiology Strategies for the Use of Real-World Data to Conduct COVID-19-Related Pharmacoepidemiology

#### PRESENTERS

Vincent Lo Re – Center for Pharmacoepidemiology Research and Training, Center for Clinical Epidemiology and Biostatistics, Department of Biostatistics, Epidemiology, and Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

Noelle Cocoros – Harvard Pilgrim Health Care Institute

Candace Fuller - Harvard Pilgrim Health Care Institute

Wei Hua – Center for Drug Evaluation and Research, United States Food and Drug Administration

Silvia Perez-Vilar – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration

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### BENEFIT-RISK ASSESSMENT, COMMUNICATION, AND EVALUATION (BRACE)

### Impact of FDA's Regulatory Actions on the Quality of Rems Survey Methodology Protocols (2007-2020)

Samuel Ewusie<sup>1</sup> | Janifer Quick<sup>2</sup> | Elaine Morrato<sup>3</sup> Gita Toyserkani<sup>2</sup>

<sup>1</sup>ORISE Fellow, Division of Risk Management, FDA; <sup>2</sup>Division of Risk Management, FDA; <sup>3</sup>Parkinson School of Public Health, Loyola University Chicago

### Jak Inhibitors and the Risk of Cardiovascular and Venous Thromboembolism Events Among Patients with Rheumatoid Arthritis: A Network Meta-analysis of Clinical Trials

### Carlos Alves<sup>1</sup> | Ana Penedones<sup>2</sup> | Diogo Mendes<sup>2</sup> Francisco Batel Marques<sup>3</sup>

<sup>1</sup>University of Coimbra, School of Pharmacy; <sup>2</sup>UFC – Coimbra Regional Pharmacovigilance Unit, CHAD – Centre for Health Technology Assessment and Drug Research, AlBILI; <sup>3</sup>Faculty of Pharmacy, University of Coimbra

### Preferences Concerning Drug Safety Communication of Hospital-Based Specialist in the Netherlands

Esther de Vries<sup>1</sup> | Elisabeth Bakker<sup>1</sup> | Petra Denig<sup>2</sup> Peter Mol<sup>3</sup>

<sup>1</sup>University of Groningen, University Medical Center Groningen, Department Clinical Pharmacy and Pharmacology, Groningen, the Netherlands; <sup>2</sup>University Medical Center Groningen; <sup>3</sup>University of Groningen, University Medical Center Groningen, Department of Clinical Pharmacy and Pharmacology, The Netherlands

### Regulatory Approval of Phentermine/topiramate for Obesity Management and Off-label Use of Topiramate: A Fairytale for Drug Repurposing and a Maze for Risk Mitigation

### Amir Sarayani<sup>1</sup> | William T. Donahoo<sup>2</sup> Christian Hampp<sup>3</sup> Joshua D Brown<sup>4</sup> | Almut G Winterstein<sup>5</sup>

<sup>1</sup>University of Florida Department of Pharmaceutical Outcomes and Policy; <sup>2</sup>College of Medicine, University of Florida; <sup>3</sup>US Food and Drug Administration; <sup>4</sup>Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida; <sup>5</sup>Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida

### Risk of Myocardial Infarction, Stroke or Death in New Users of Intravitreal Aflibercept vs New Users of Intravitreal Ranibizumab: A Nationwide Cohort Study

### Sophie Billioti de Gage<sup>1</sup> | Marion Bertrand<sup>2</sup> Mahmoud Zureik<sup>2</sup>

<sup>1</sup>French National Agency for Medicines and Health Products Safety; <sup>2</sup>EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

### What Matters to Patients When Considering Treatments for Prevention of Rheumatoid Arthritis: A Preference Study in the United Kingdom, Germany, and Romania

Rachael DiSantostefano<sup>1</sup> | Marie Falahee<sup>2</sup> Gwenda Simons<sup>2</sup> | Matthias Englbrecht<sup>3</sup>

**Christine Radawski<sup>4</sup> | Karim Raza<sup>2</sup> | Jorien veldwijk<sup>5</sup>** <sup>1</sup>Johnson & Johnson; <sup>2</sup>Institute of Inflammation and Ageing, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK; <sup>3</sup>Freelance Data Scientist, Eckental, Germany; <sup>4</sup>Eli Lilly and Company; <sup>5</sup>School of Health Policy & Management, Erasmus University Rotterdam, Rotterdam, The Netherlands

### BIOLOGICS / BIOSIMILARS

### Discontinuation Rate of Tofacitinib is Similar When Compared to TNF Inhibitors in Rheumatoid Arthritis Patients: Data from a Rheumatoid Arthritis Cohort

**Mohammad Movahedi**<sup>1</sup> | **Angela Cesta**<sup>2</sup> | **Xiuying Li**<sup>2</sup>; **Edward Keystone**<sup>3</sup> | **Claire Bombardier**<sup>2</sup> | **OBRI Investigators**<sup>4</sup> <sup>1</sup>University Health Network (Toronto); <sup>2</sup>Toronto General Hospital Research Institute, University Health Network, Toronto, ON; <sup>3</sup>Department of Medicine, University of Toronto, Toronto, ON; <sup>4</sup>Toronto Genral Hospital Research Institute, University Health Network, Toronto.ON

### DISEASE EPIDEMIOLOGY / CLINICAL COURSE

### Chronic Diseases, Health Conditions and Risk of COVID-19-related Hospitalization and In-hospital Mortality During the First Wave of the Epidemic in France: A Cohort Study of 66 Million People

Mahmoud Zureik<sup>1</sup> | Laura Semenzato<sup>2</sup> | Jérémie Botton<sup>2</sup> Jérôme Drouin<sup>2</sup> | François Cuenot<sup>2</sup> | Rosemary Dray-Spira<sup>3</sup> Alain Weill<sup>4</sup>

<sup>1</sup>EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance); <sup>2</sup>EPI-PHARE Scientific Interest Group in Epidemiology of Health Products from the French National Agency for the Safety of Medicines and Health Products and the French National Health Insurance; <sup>3</sup>EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products [ANSM], and French National Health Insurance [CNAM]), Saint-Denis, France; <sup>4</sup>French National Health Insurance Fund (Assurance Maladie)

## Comparable COVID-19 Outcomes with Current Use of GLP-1 Receptor Agonists, DPP-4 Inhibitors or SGLT-2 Inhibitors Among Patients with Diabetes Who Tested Positive for sars-cov-2

### Simone Bastrup Israelsen<sup>1</sup> | Anton Pottegård<sup>2</sup> Håkon Sandholdt<sup>1</sup> | Sten Madsbad<sup>3</sup> | Reimar Thomsen<sup>4</sup> Thomas Benfield<sup>1</sup>

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### Development and Validation of an Algorithm to Estimate the Risk of Severe Complications of COVID-19 to Prioritise Vaccination

Ron M.C. Herings<sup>1</sup> | Karin Swart<sup>1</sup> | Bernard van der Zeijst<sup>2</sup> Amber van der Heijden<sup>3</sup> | Koos van der Velden<sup>4</sup> Eric Hiddink<sup>5</sup> | Martijn Heymans<sup>6</sup> | Reinier Herings<sup>7</sup> Hein van Hout<sup>3</sup> | Joline Beulens<sup>6</sup> | Giel Nijpels<sup>3</sup> Petra Elders<sup>3</sup>

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### Hyperthyroidism and Breast Cancer Recurrence and Mortality: A Danish Population-based Cohort Study

### Line Libergreen<sup>1</sup> | Rikke Noergaard Pedersen<sup>2</sup> Anders Kjærsgaard<sup>3</sup> | Deirdre Cronin-Fenton<sup>4</sup>

<sup>1</sup>Department of Clinical Epidemiology - Aarhus University; <sup>2</sup>Department of Clinical Epidemiology, Aarhus University Hospital; <sup>3</sup>Department of Clinical Epidemiology - Aarhus University Hospital; <sup>4</sup>Department of Clinical Epidemiology, Aarhus University Hospital, Aarhus, Denmark

### Impact of Non-alcoholic Steatohepatitis (NASH) Case Definition on Population Characteristics Identified in a US Claims Database

Kerrin Gallagher<sup>1</sup> | Daina B Esposito<sup>2</sup> | Aziza Jamal-allial<sup>1</sup> Simo Du<sup>3</sup> | Yuval Patel<sup>4</sup> | Mindie Nguyen<sup>5</sup> | Erik Ness<sup>6</sup> Thomas Capozza<sup>7</sup> | Lina Titievsky<sup>6</sup>

<sup>1</sup>HealthCore, Inc.; <sup>2</sup>Boston University School of Public Health; <sup>3</sup>HealthCore; <sup>4</sup>Duke University; <sup>5</sup>Stanford University; <sup>6</sup>Intercept Pharmaceuticals; <sup>7</sup>Intercept Pharmaceuticals, Inc.

### Incidence and Risk Factors for COVID-related Urgent Medical Visits Among US Patients Diagnosed with COVID-19 in the Outpatient Setting

Wenhui Wei<sup>1</sup> | Scott Mellis<sup>1</sup> | Gregory P Geba<sup>1</sup> Sumathi Sivapalasingam<sup>1</sup> | Jessica Jalbert<sup>2</sup> <sup>1</sup>Regeneron Pharmaceuticals, Inc., Tarrytown, NY; <sup>2</sup>Regeneron Pharmaceuticals

### Incidence Rates of Select Outcomes Among Patients with Non-alcoholic Steatohepatitis (NASH) and Evidence of Fibrosis and Cirrhosis

Monica Bertoia<sup>1</sup> | Erik Ness<sup>2</sup> | Thomas Capozza<sup>3</sup> Lina Titievsky<sup>2</sup> | John D Seeger<sup>1</sup> <sup>1</sup>Optum Epidemiology; <sup>2</sup>Intercept Pharmaceuticals; <sup>3</sup>Intercept Pharmaceuticals, Inc.

### Persistence of COVID-19 Symptoms 90 Days Post-acute Infection: Insights from a Community-based Registry

Matthew Reynolds<sup>1</sup>; Nancy A. Dreyer; Lisa Albert<sup>1</sup>; Emma Brinkley<sup>2</sup>; Damir Mohamed<sup>1</sup>; Christina Mack<sup>2</sup> <sup>1</sup>/QVIA; <sup>2</sup>/QVIA

### Severe Obesity Is a Risk Factor for Mortality in Patients with COVID-19

### Aisling Caffrey<sup>1</sup> | Jennifer Liao<sup>2</sup> | Vrishali Lopes<sup>3</sup> Kerry LaPlante<sup>3</sup>

<sup>1</sup>University of Rhode Island College of Pharmacy; <sup>2</sup>Department of Veterans Affairs; <sup>3</sup>Infectious Diseases Research Program, Providence Veterans Affairs Medical Center, Providence, RI, United States

### DISEASE EPIDEMIOLOGY / CLINICAL COURSE

### The Effect of Epidural Steroid Injections on Fracture Risk Among Medicare Patients

Huifeng Yun<sup>1</sup> | Ye Liu<sup>2</sup> | Kenneth Saag<sup>3</sup> | Katherine Haseltine<sup>4</sup> | Emily Stein<sup>4</sup> | Jeffrey Curtis<sup>5</sup> <sup>1</sup>Department of Epidemiology, University of Alabama at Birmingham; <sup>2</sup>University of Alabama at Birmingham; <sup>3</sup>Division of Clinical Immunology and Rheumatology; <sup>4</sup>HSS hospital; <sup>5</sup>University of Alabama Birmingham

### Utilizing the National COVID Cohort Collaborative (N3C) to Evaluate Risk of Serious Outcomes with COVID-19 Among Chronically Immunosuppressed Persons

Kayte Andersen<sup>1</sup> | Emaan S Rashidi<sup>2</sup> | Huijun An<sup>3</sup> | Hemalkumar B Mehta<sup>4</sup> | Derek Ng<sup>2</sup> | Brian Garibaldi<sup>5</sup> | Jodi Segal<sup>3</sup> G. Caleb Alexander<sup>6</sup>

<sup>1</sup>JHSPH Center for Drug Safety & Effectiveness; <sup>2</sup>Johns Hopkins Bloomberg School of Public Health; <sup>3</sup>Johns Hopkins University; <sup>4</sup>Bloomberg School of Public Health, Johns Hopkins University; <sup>5</sup>Johns Hopkins Medicine; <sup>6</sup>Johns Hopkins Center for Drug Safety and Effectiveness

### Predictors of Critical Care, Mechanical Ventilation, and Mortality Among Hospitalized Patients with COVID-19 in an Electronic Health Record Database

Andrea Chomistek<sup>1</sup> | Caihua Liang<sup>2</sup> | Michael Doherty<sup>3</sup> | Robin Clifford<sup>3</sup> | Rachel Ogilvie<sup>1</sup> | Robert Gately<sup>3</sup> | Jennifer Song<sup>3</sup> Cheryl Enger<sup>4</sup> | Nancy Lin<sup>5</sup> | Florence Wang<sup>3</sup> | John Seeger<sup>1</sup>

<sup>1</sup>Optum Epidemiology; <sup>2</sup>Pfizer Inc; <sup>3</sup>Optum; <sup>4</sup>Optum, Boston, MA, USA; <sup>5</sup>Health Catalyst

### DRUG EFFECTIVENESS

### Anticoagulants and All-Cause Mortality Among Hospitalized COVID-19 Patients

Caihua Liang<sup>1</sup> | Li Zhou<sup>2</sup> | Michael Doherty<sup>2</sup> | Robert Gately<sup>2</sup> | Rachel Ogilvie<sup>3</sup> | Andrea Chomistek<sup>3</sup> Florence Wang<sup>2</sup> | John D Seeger<sup>3</sup> | Jessica Franklin<sup>2</sup> <sup>1</sup>Pfizer Inc; <sup>2</sup>Optum; <sup>3</sup>Optum Epidemiology

### Calibrating Real-world Evidence Studies Against Randomized Trials: Treatment Effectiveness of Infliximab in Inflammatory Bowel Disease

#### Julien Kirchgesner<sup>1</sup> | Rishi J Desai<sup>2</sup> | Maria Schneeweiss<sup>3</sup> Laurent Beaugerie<sup>4</sup> | Seoyoung Kim<sup>3</sup> Sebastian Schneeweiss<sup>5</sup>

<sup>1</sup>Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, Paris, France; <sup>2</sup>Harvard Medical School/ Brigham & Women's Hospital; <sup>3</sup>BWH Div of Pharmacoepidemiology and Pharmacoeconomics; <sup>4</sup>Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, AP-HP, Hôpital Saint-Antoine, Department of gastroenterology, Paris, France;

<sup>5</sup>Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA

### Cardiovascular Effectiveness of SGLT-2 Inhibitors vs Metformin as First-line Treatment for Type 2 Diabetes

#### HoJin Shin<sup>1</sup> | Sebastian Schneeweiss<sup>2</sup> | Robert Glynn<sup>3</sup> Elisabetta Patorno<sup>1</sup>

<sup>1</sup>Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School; <sup>2</sup>Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA; <sup>3</sup>Harvard T. H. Chan School of Public Health

### Comparative Effectiveness of Empagliflozin in Reducing Total Cardiovascular Events in the Empagliflozin Comparative Effectiveness and Safety (EMPRISE) Study

#### Rishi Desai<sup>1</sup> | Robert Glynn<sup>2</sup> | Brendan Everett<sup>3</sup> Sebastian Schneeweiss<sup>4</sup> | Deborah Wexler<sup>3</sup> Anouk Derauz Luyet<sup>5</sup> | Ola Vedin<sup>5</sup> | Kimberly Brodovicz<sup>6</sup> Ajinkya Pawar<sup>7</sup> | Elisabetta Patorno<sup>8</sup>

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### DRUG EFFECTIVENESS

### Convalescent Plasma Therapy and Mortality Among US Veterans Hospitalized with Non-severe COVID-19: An Observational Analysis Emulating a Target Trial

Katherine Kurgansky<sup>1</sup> | Kelly Cho<sup>2</sup> | Sarah Keithly<sup>3</sup> Arin L Madenci<sup>4</sup> | Hanna Gerlovin<sup>5</sup> | Helen Wellman<sup>5</sup> Annie Doubleday<sup>3</sup> | Eva Thomas<sup>3</sup> | Yojin Park<sup>6</sup> | Yuk-Lam Ho<sup>7</sup> Jonathan Sugimoto<sup>3</sup> | Kathryn Moore<sup>3</sup> | Alexander Peterson<sup>3</sup> Constance Hoag<sup>6</sup> | Kalpana Gupta<sup>8</sup> Karen Jeans<sup>9</sup> | Molly Klote<sup>9</sup> Rachel Ramoni<sup>9</sup> | Grant Huang<sup>9</sup> | Juan Casas<sup>5</sup> David Gagnon<sup>5</sup> Miguel Hernán<sup>10</sup> | Nicholas Smith<sup>11</sup> | J. Michael Gaziano<sup>5</sup> <sup>1</sup>Massachusetts Veterans Epidemiology Research and Information Center, VA Boston Healthcare System; <sup>2</sup>MAVERIC, VA Boston Healthcare System; <sup>3</sup>Seattle Epidemiologic Research and Information Center; VA Healthcare System; <sup>4</sup>Harvard T.H. Chan School of Public Health; <sup>5</sup>MAVERIC; VA Boston Healthcare System; <sup>6</sup>MAVERIC; VA Boston Healthcare system; <sup>7</sup>VA Boston Healthcare System; <sup>8</sup>Veterans Administration Boston Healthcare System; <sup>9</sup>Department of Veterans Affairs Office of Research and Development; <sup>10</sup>Departments of Epidemiology and Biostatistics, Harvard T.H. Chan School of Public Health; <sup>11</sup>Seattle Epidemiologic Research and Information Center, Department of Veterans Affairs

### Effect of SGLT-2 Inhibitors on EGFR in Type 2 Diabetes with Different Baseline Renal Functions: A Multi-center Study

Fang-Ju Lin<sup>1</sup> | Chi-Chuan Wang<sup>2</sup> | Chien-Ning Hsu<sup>3</sup> Chen-Yi Yang<sup>4</sup> | Chih-Yuan Wang<sup>5</sup> | Huang-Tz Ou<sup>4</sup> <sup>1</sup>National Taiwan University Hospital; <sup>2</sup>National Taiwan University; <sup>3</sup>Department of Pharmacy, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, Taiwan; <sup>4</sup>Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University, Tainan, Taiwan; <sup>5</sup>College of Medicine, National Taiwan University, Taipei, Taiwan

### Efficacy and Safety of Treatments for Nonmetastatic Castration-resistant Prostate Cancer: A Matching-adjusted Indirect Comparison and Network Meta-analysis

### Lin Wang<sup>1</sup> | Channing Paller<sup>2</sup> | Hwanhee Hong<sup>3</sup> Otis Brawley<sup>2</sup> | G. Caleb Alexander<sup>4</sup>

<sup>1</sup>Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health; <sup>23</sup>. The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine; <sup>3</sup>Duke Clinical Research Institute, Duke University; <sup>4</sup>Johns Hopkins Center for Drug Safety and Effectiveness

### Initiation of Sodium-glucose Co-transporter 2 Inhibitors and Progression of Renal Disease Among Patients with Type 2 Diabetes: A Population-based Cohort Study

Wajd Alkabbani<sup>1</sup> | Arsene Zongo<sup>2</sup> | Dean Eurich<sup>3</sup> Baiju Shah<sup>4</sup> | Jasjeet Minhas-Sandhu<sup>3</sup>

Mhd. Wasem Alsabbagh<sup>1</sup> | John-Michael Gamble<sup>1</sup> <sup>1</sup>School of Pharmacy, University of Waterloo; <sup>2</sup>Faculty of Pharmacy, Université Laval; <sup>3</sup>School of Public Health, University of Alberta; <sup>4</sup>Department of Medicine, University of Toronto

### Physician and Patient Reported Effectiveness Outcomes Are Similar in Tofacitinib and TNF Inhibitors in Rheumatoid Arthritis Patients: Data from a Rheumatoid Arthritis Registry in Canada

Mohammad Movahedi<sup>1</sup> | Angela Cesta<sup>2</sup> | Xiuying Li<sup>2</sup> Edward Keystone<sup>3</sup> | Claire Bombardier<sup>2</sup> | OBRI Investigators<sup>4</sup> <sup>1</sup>University Health Network (Toronto); <sup>2</sup>Toronto General Hospital Research Institute, University Health Network, Toronto, ON; <sup>3</sup>Department of Medicine, University of Toronto, Toronto, ON; <sup>4</sup>Toronto Genral Hospital Research Institute, University Health Network, Toronto.ON

### Safety and Effectiveness of Prophylactic Anticoagulation for Prevention of COVID-19 Mortality: A Nationwide Cohort Study of Hospitalised Patients in the US

Christopher Rentsch<sup>1</sup> | Joshua Beckman<sup>2</sup> Laurie Tomlinson<sup>3</sup> | Walid Gellad<sup>4</sup> | Charles Alcorn<sup>5</sup> Farah Kidwai-Khan<sup>6</sup> | Melissa Skanderson<sup>6</sup> | Evan Brittain<sup>2</sup> Joseph King<sup>7</sup> | Yuk-Lam Ho<sup>8</sup> | Svetlana Eden<sup>9</sup> Suman Kundu<sup>10</sup> | Michael Lann<sup>5</sup> | Robert A Greevy<sup>10</sup> P. Michael Ho<sup>6</sup> | Paul Heidenreich<sup>11</sup> | Daniel Jacobson<sup>12</sup> Ian Douglas<sup>3</sup> | Janet Tate<sup>6</sup> | Stephen Evans<sup>3</sup> | David Atkins<sup>6</sup> Amy Justice<sup>13</sup> | Matthew Freiberg<sup>14</sup>

<sup>1</sup>London School of Hygiene and Tropical Medicine; <sup>2</sup>Vanderbilt University Medical Center and Vanderbilt Translational and Clinical Cardiovascular Research Center; <sup>3</sup>London School of Hygiene & Tropical Medicine; <sup>4</sup>Division of General Internal Medicine, Department of Medicine, University of Pittsburgh; <sup>5</sup>University of Pittsburgh; <sup>6</sup>US Department of Veterans Affairs; <sup>7</sup>Yale School of Medicine; <sup>8</sup>VA Boston Healthcare System; <sup>9</sup>Vanderbilt University School of Medicine; <sup>10</sup>Vanderbilt University Medical Center; <sup>11</sup>Stanford University School of Medicine; <sup>12</sup>Oak Ridge National Laboratory; <sup>13</sup>VA Connecticut Healthcare System West Haven; <sup>14</sup>Vanderbilt University Medical Center; US Department of Veterans Affairs

### Shorter Drug Holiday After 3 or More Years of Risedronate vs Alendronate Is Important to Maintain Osteoporotic Fracture Protection

#### Kaley Hayes | Kevin Brown<sup>1</sup> | Angela Cheung<sup>2</sup> David Juurlink<sup>3</sup> | Suzanne Cadarette<sup>4</sup>

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### Changes in Buprenorphine Utilization During the COVID-19 Pandemic in the US

Lindsey Hammerslag<sup>1</sup> | Svetla Slavova<sup>2</sup> | Jeffery Talbert<sup>3</sup> Sharon Walsh<sup>4</sup> | Michelle Lofwall<sup>4</sup> | Patricia Freeman<sup>5</sup> <sup>1</sup>Institute for Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Kentucky; <sup>2</sup>Department of Biostatistics, College of Public Health, University of Kentucky; <sup>3</sup>Institute for Biomedical Informatics, College of Medicine, University of Kentucky; <sup>4</sup>College of Medicine, University of Kentucky; <sup>5</sup>University of Kentucky

### DRUG UTILIZATION RESEARCH

### COVID-19 in Children: Treatment Patterns in the Real-world Hospital Setting

Lawrence Rasouliyan<sup>1</sup> | Vikas Kumar<sup>2</sup> | Stacey Long<sup>2</sup> Mitesh Rao<sup>2</sup>

<sup>1</sup>Lawrence Rasouliyan; <sup>2</sup>OMNY Health

### Disparities in Hepatitis C Treatment in the Era of Direct-acting Antivirals Among Arizona Medicaid Beneficiaries

Hyunjin Song<sup>1</sup> | Ching-Yuan Chang<sup>1</sup> | Xinyi Jiang<sup>2</sup> Debbie Wilson<sup>3</sup> | Wei-Hsuan Lo-Ciganic<sup>4</sup> | Haesuk Park<sup>5</sup>

<sup>1</sup>University of Florida College of Pharmacy; <sup>2</sup>Department Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida; <sup>3</sup>Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida; <sup>4</sup>Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, Florida, USA; <sup>5</sup>University of Florida

### Do Medicare Part D Low-income Subsidies Narrow Disparities in Orally-administered Antimyeloma Therapy Initiation?

Shelley Jazowski<sup>1</sup> | Cleo Samuel-Ryals<sup>1</sup> | William Wood<sup>1</sup> Leah Zullig<sup>2</sup> | Justin Trogdon<sup>1</sup> | Stacie Dusetzina<sup>3</sup> <sup>1</sup>University of North Carolina at Chapel Hill; <sup>2</sup>Duke University School of Medicine; <sup>3</sup>Vanderbilt University School of Medicine

### Geographic Variation in the Use of Gabapentinoids and Opioids for Pain in a Commercially Insured Population in the United States

Danni Zhao | Jonggyu Baek<sup>1</sup> | Anne Hume<sup>2</sup> Anthony Nunes<sup>3</sup> | Matthew Alcusky<sup>3</sup> | Kate Lapane<sup>3</sup> <sup>1</sup>Division of Biostatistics and Health Services Research, Department of Population and Quantitative Health Sciences, University of Massachusetts Medical School; <sup>2</sup>University of Rhode Island; <sup>3</sup>Division of Epidemiology, Department of Population and Quantitative Health Services, University of Massachusetts Medical School



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### DRUG UTILIZATION RESEARCH

### Heterogeneity and Temporal Variation in the Management of COVID-19: A Multinational Drug Utilisation Study Including 274,719 Hospitalised Patients From, the United States of America, China, Spain, and South Korea

Albert Prats-Uribe<sup>1</sup> | Anthony Sena<sup>2</sup> | Lana Yin Hui Lai<sup>3</sup> Waheed-UI-Rahman Ahmed<sup>4</sup> | Heba Alghoul<sup>5</sup> | Osaid Alser<sup>6</sup> Thamir Alshammari<sup>7</sup> | Carlos Areia<sup>8</sup> | William Carter<sup>9</sup> Paula Casajust<sup>10</sup> | Dalia Dawoud<sup>11</sup> | Asieh Golozar<sup>12</sup> Jitendra Jonnagaddala<sup>13</sup> | Paras Mehta<sup>14</sup> | Gong Mengchun<sup>15</sup> Daniel Morales<sup>16</sup> | Fredrik Nyberg<sup>17</sup> Jose Posada<sup>18</sup> | Martina Recalde<sup>19</sup> | Elena Roel<sup>19</sup> Karishma Shah<sup>4</sup> | Nigam Shah<sup>18</sup> | Lisa Schilling<sup>9</sup> | Vignesh Subbian<sup>20</sup> | David Vizcaya<sup>21</sup> | Lin Zhang<sup>22</sup> | Ying Zhang<sup>15</sup> Hong Zhu<sup>23</sup> | Li Liu<sup>23</sup> | Seng Chan You<sup>24</sup> | Peter Rijnbeek<sup>25</sup> George Hripcsak<sup>26</sup> | Jennifer Lane<sup>27</sup> | Edward Burn<sup>28</sup> Christian Reich<sup>29</sup> | Marc Suchard<sup>30</sup> | Talita Duartes-Salles<sup>31</sup> Kristin Kostka<sup>32</sup> | Patrick Ryan<sup>33</sup> | Daniel Prieto-Alhambra<sup>28</sup> <sup>1</sup>CSM, NDORMS, University of Oxford; <sup>2</sup>Janssen Research and Development: <sup>3</sup>Division of Cancer Sciences, School of Medical Sciences, University of Manchester; <sup>4</sup>Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, Botnar Research Centre, Windmill Road, Oxford, OX3 7LD, UK; <sup>5</sup>Faculty of Medicine, Islamic University of Gaza, Palestine; <sup>6</sup>Massachusetts General Hospital, Harvard Medical School, Boston, 02114, Massachusetts, USA; <sup>7</sup>College of Pharmacy, Riyadh Elm University; <sup>8</sup>Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK; <sup>9</sup>Data Science to Patient Value Program, University of Colorado Anschutz Medical Campus, Aurora, CO, USA; <sup>10</sup>Real-World Evidence, Trial Form Support, Barcelona, Spain; <sup>11</sup>National Institute for Health and Care Excellence (NICE), London, U.K.; <sup>12</sup>Regeneron Pharmaceuticals; <sup>13</sup>School of Public Health and Community Medicine, UNSW Sydney; <sup>14</sup>College of Medicine, The University of Arizona, Tucson, AZ, USA; <sup>15</sup>DHC Technologies Co. Ltd, Beijing, China; <sup>16</sup>Division of Population Health and Genomics, University of Dundee, UK; 17University of Gothenburg; 18Stanford University School of Medicine, Stanford, California, USA; <sup>19</sup>Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Barcelona, Spain; <sup>20</sup>College of Engineering, The University of Arizona, Tucson, AZ, USA; <sup>21</sup>Bayer Pharmaceuticals, Sant Joan Despí, Spain; <sup>22</sup>School of Population Medicine and Public Health, Chinese Academy of Medical Sciences and Peking Union Medical College; <sup>23</sup>Nanfang Hospital, Southern Medical University, Guangzhou, China; <sup>24</sup>Department of Preventive Medicine and Public Health, Yonsei University College of Medicine, Seoul, Korea; <sup>25</sup>Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, The Netherlands; <sup>26</sup>Department of Biomedical Informatics, Columbia University Irving Medical Center; <sup>27</sup>Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, Oxford, UK; <sup>28</sup>Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences

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### Influence of Drug Safety Advisories on Drug Utilization: An International Interrupted Time Series and Meta-analysis Study

Richard Morrow<sup>1</sup> | Barbara Mintzes<sup>2</sup> | Patrick Souverein<sup>3</sup> Marie De Bruin<sup>3</sup> | Elizabeth Roughead<sup>4</sup> | Joel Lexchin<sup>5</sup> Anna Kemp-Casey<sup>4</sup> | Lorri Puil<sup>1</sup> | Ingrid Sketris<sup>6</sup> Dee Mangin<sup>7</sup> | Christine Hallgreen<sup>8</sup> | Sallie-Anne Pearson<sup>9</sup> Ruth Lopert<sup>10</sup> | Lisa Bero<sup>11</sup> | Richard Ofori-Asenso<sup>12</sup> Danijela Gnjidic<sup>13</sup> | Ameet Sarpatwari<sup>14</sup> | Colin R. Dormuth<sup>1</sup> <sup>1</sup>Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia; <sup>2</sup>School of Pharmacy, Faculty of Medicine and Health and Charles Perkins Centre, University of Sydney; <sup>3</sup>Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University; <sup>4</sup>Clinical and Health Sciences, University of South Australia: <sup>5</sup>Faculty of Health, York University: <sup>6</sup>College of Pharmacy, Dalhousie University; 7Department of Family Medicine, McMaster University; 84. Copenhagen Centre for Regulatory Science, Department of Pharmacy, Faculty of Health and Medical Sciences, University of Copenhagen; <sup>9</sup>Centre for Big Data Research in Health, University of New South Wales; <sup>10</sup>Department of Health Policy and Management, George Washington University; <sup>11</sup>School of Medicine and Colorado School of Public Health, University of Colorado Anschutz Medical Campus; <sup>12</sup>Copenhagen Centre for Regulatory Science, Department of Pharmacy, Faculty of Health and Medical Sciences, University of Copenhagen; <sup>13</sup>Sydney Pharmacy School, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia; <sup>14</sup>Brigham and Women's Hospital, Harvard Medical School

### Non-adherence and Non-persistence with Direct Oral Anticoagulants Increases the Risk of Stroke: Assessment in Three European Databases

Emily Holthuis<sup>1</sup> | Elisabeth Smits<sup>2</sup> | Dominik Beier<sup>3</sup> Dirk Enders<sup>3</sup> | Rosa Gini<sup>4</sup> | Claudia Bartolini<sup>5</sup> Giampiero Mazzaglia<sup>6</sup> | Fernie Penning- van Beest<sup>7</sup> Georgios Spentzouris<sup>8</sup> | Ron Herings<sup>2</sup>

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### DRUG UTILIZATION RESEARCH

### Prevalence of Osteoporosis and Its Treatment Among Women ≥50 in NHANES: 1999-2018

#### Sophie Mayer<sup>1</sup> | Leah McGrath<sup>2</sup> | Min Kim<sup>3</sup> Michele McDermott<sup>3</sup> | M. Alan Brookhart<sup>4</sup> <sup>1</sup>University of North Carolina at Chapel Hill; <sup>2</sup>NoviSci; <sup>3</sup>Center for Observational Research, Amgen; <sup>4</sup>NoviSci, Inc.

### Primary Care Physicians' Preparedness to Treat Opioid Use Disorder in the United States: A Cross-sectional Survey

### Kathryn Foti | James Heyward<sup>1</sup> | Matthew Tajanlangit<sup>2</sup> Kristin Meek<sup>2</sup> | Christopher Jones<sup>3</sup> | Andrew Kolodny<sup>4</sup> G. Caleb Alexander<sup>2</sup>

<sup>1</sup>Bloomberg School of Public Health, Johns Hopkins University; <sup>2</sup>Johns Hopkins Center for Drug Safety and Effectiveness; <sup>3</sup>Centers for Disease Control and Prevention; <sup>4</sup>Brandeis University

### Prior Opioid Tolerance Among New Users of Transdermal Fentanyl in Taiwan, 2011-2018

Chih-Wan Lin<sup>1</sup> | Yu-Chun Chiu<sup>2</sup> | Wei-I Huang<sup>2</sup> Pi-Hui Chao<sup>2</sup> | Wen-Wen Chen<sup>2</sup> | Fei-Yuan Hsiao<sup>3</sup> <sup>1</sup>Graduate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University; <sup>2</sup>Taiwan Drug Relief Foundation, Taipei, Taiwan; <sup>3</sup>Graduate Institute of Clinical Pharmacy, National Taiwan University, Taipei, Taiwan

### Ranitidine and Other histamine2-receptor Antagonists – A Rapid Response Drug Utilisation Study Using Electronic Health Care Data from Six European Countries

### Katia M Verhamme<sup>1</sup> | Maria de Ridder<sup>2</sup> | Christian Reich<sup>3</sup> Talita Duartes-Salles<sup>4</sup> | Tom Seinen<sup>2</sup> | Peter R Rijnbeek<sup>5</sup>

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### Real World Use of Anticoagulation Among Hospitalized Patients with COVID-19 in the United States

### Benjamin Bates<sup>1</sup> | Eileen Lee<sup>2</sup> | Nathaniel Kuhrt<sup>3</sup> Chang Xu<sup>4</sup> | Soko Setoguchi<sup>5</sup>

<sup>1</sup>Rutgers Robert Wood Johnson Medical School; <sup>2</sup>Rutgers; <sup>3</sup>Rutgers New Jersey Medical School; <sup>4</sup>Rutgers University, School of Public Health, Department of Biostatistics and Epidemiology; <sup>5</sup>RWJ Medical School, Center for Pharmacoepidemiology and Treatment Science (PETS), Institute for Health, Health Care Policy and Aging Research

### Serum Vitamin D Levels and Incident Prescription Opioid Use Among Opioid-Naïve Patients

### Casey Choong<sup>1</sup> | Zuoyi Zhang<sup>2</sup> | Yiqing Song<sup>3</sup> Brian Dixon<sup>4</sup> | Jiali Han<sup>3</sup> | Xin Li<sup>3</sup>

<sup>1</sup>Indiana University Richard M. Fairbanks School of Public Health; <sup>2</sup>Indiana University School of Medicine, Indianapolis, IN; <sup>3</sup>Department of Epidemiology, Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis, IN; <sup>4</sup>Department of Epidemiology, IU Fairbanks School of Public Health

### Sources of Racial/ethnic Disparities in Antidepressant Treatment: Analysis of the Medical Expenditure Panel Survey Data

Macarius Donneyong | Teng-Jen Chang The Ohio State University

### Substantial Heterogeneity in the Management of Hospitalized Patient with COVID-19

#### Aisling Caffrey<sup>1</sup> | Jennifer Liao<sup>2</sup> | Vrishali Lopes<sup>3</sup> Kerry LaPlante<sup>3</sup>

<sup>1</sup>University of Rhode Island College of Pharmacy; <sup>2</sup>Department of Veterans Affairs; <sup>3</sup>Infectious Diseases Research Program, Providence Veterans Affairs Medical Center, Providence, RI, United States

### The Impact of Sex on the Quality of Medication Treatment in Patients with Type 2 Diabetes

### Marit Geelink<sup>1</sup> | Martina Ambroz<sup>2</sup> | Kirsten Smits<sup>3</sup> Sieta de Vries<sup>4</sup> | Petra Denig<sup>2</sup>

<sup>1</sup>Department of Clinical Pharmacy and Pharmacology, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands; <sup>2</sup>University Medical Center Groningen; <sup>3</sup>Department of Dentistry – Quality and Safety of Oral Healthcare, Radboud University Medical Center, Radboud Institute for Health Sciences, Nijmegen, The Netherlands; <sup>4</sup>University of Groningen, University Medical Center Groningen, Department of Clinical Pharmacy and Pharmacology, The Netherlands

### Trajectories of Pregabalin Use and Their Association with Longitudinal Changes in Opioid and Benzodiazepine Daily Dose

### Andrea Schaffer<sup>1</sup> | Jonathan Brett<sup>2</sup> | Nicholas Buckley<sup>3</sup> Sallie-Anne Pearson<sup>2</sup>

<sup>1</sup>University of New South Wales; <sup>2</sup>Centre for Big Data Research in Health, University of New South Wales; <sup>3</sup>Biomedical Informatics and Digital Health, University of Sydney

### DRUG UTILIZATION RESEARCH

### Trends and Outcomes of Serious Complications Associated with Non-fatal Opioid Overdoses in Ontario, Canada

Sophie Kitchen<sup>1</sup> | Daniel McCormack<sup>2</sup> | Daniel Werb<sup>1</sup> Alexander Caudarella<sup>1</sup> | Diana Martins<sup>1</sup> | Flora Matheson<sup>1</sup> Tara Gomes<sup>1</sup>

<sup>1</sup>Unity Health Toronto; <sup>2</sup>ICES

### Trends in Long-term Use of Prescribed Opioids in Norway 2010-2019

Ingvild Odsbu<sup>1</sup> | Marte Handal<sup>2</sup> | Vidar Hjellvik<sup>3</sup> Svetlana Skurtveit<sup>1</sup>

<sup>1</sup>Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway; <sup>2</sup>Norwegian Institute of Public Health; <sup>3</sup>Department of Chronic Diseases and Ageing, Norwegian Institute of Public Health, Oslo, Norway

### Use of Cardiovascular and Antidiabetic Drugs During COVID19 Epidemic in France

Julien Bezin<sup>1</sup> | Clément Mathieu<sup>2</sup> | Elodie Pambrun<sup>2</sup> Anne Benard-Laribiere<sup>2</sup> | Pernelle Noize<sup>3</sup> | Marie tournier<sup>4</sup> Jean-Luc Faillie<sup>5</sup> | Antoine Pariente<sup>6</sup>

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### Use of Hydroxychloroquine, Remdesivir, and Dexamethasone Among Adults Hospitalized with COVID-19 in the United states: results from the National COVID Cohort Collaborative (N3C)

Hemalkumar Mehta<sup>1</sup> | Huijun An<sup>2</sup> | Kayte Andersen<sup>3</sup> Omar Mansour<sup>4</sup> | Vithal Madhira<sup>5</sup> | Emaan S Rashidi<sup>6</sup> Benjamin Bates<sup>7</sup> | Soko Setoguchi<sup>8</sup> | Corey Joseph<sup>9</sup> Paul Kocis<sup>10</sup> | Richard Moffitt<sup>11</sup> | Tellen Bennett<sup>12</sup> Christopher Chute<sup>2</sup> | Brian Garibaldi<sup>13</sup> | G. Caleb Alexander<sup>14</sup>

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### Utilization of Non-pharmacologic Pain Therapies Among Primary Care Physicians in the United States: A Cross-sectional Survey

James Heyward<sup>1</sup> | Kathryn Foti | Matthew Tajanlangit<sup>2</sup> Kristin Meek<sup>2</sup> | Christopher Jones<sup>3</sup> | Andrew Kolodny<sup>4</sup> G. Caleb Alexander<sup>2</sup>

<sup>1</sup>Bloomberg School of Public Health, Johns Hopkins University; <sup>2</sup>Johns Hopkins Center for Drug Safety and Effectiveness; <sup>3</sup>Centers for Disease Control and Prevention; <sup>4</sup>Brandeis University

### Visualizing Inappropriate Antibiotic Use Following Otitis Media in Children in the United States

Leah McGrath<sup>1</sup> | Jason Newland<sup>2</sup> | John Sahrmann<sup>2</sup> YinJiao Ma<sup>2</sup> | Anne Mobley M Butler<sup>2</sup> <sup>1</sup>NoviSci; <sup>2</sup>Washington University in St. Louis

### GERIATRICS

### Assessment of Co-medication Quality in Older Colorectal Cancer Patients at Hospital Discharge After Tumor Surgery and Its Associations with Chemotherapy-related Adverse Drug Reactions and 5-year Survival

### Li-Ju Chen | Ben Schöttker

Division of Clinical Epidemiology and Aging Research, German Cancer Research Center (DKFZ)

### Bisphosphonate Use and Risk of Severe Acute Kidney Injury: A Self-controlled Case Series in Frail Elderly Patients in the UK

#### Tetsuro Oda<sup>1</sup> | Annika Jodicke<sup>2</sup> | Danielle Robinson<sup>3</sup> Antonella Delmestri<sup>4</sup> | Ruth Keogh<sup>1</sup> Daniel Prieto-Alhambra<sup>5</sup>

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### Comparative Risk of Cardiac Arrhythmias Associated with Acetylcholinesterase Inhibitor Use

Yichang Huang<sup>1</sup> | John-Michael Gamble<sup>2</sup> David Juurlink<sup>3</sup> | Mhd. Wasem Alsabbagh<sup>2</sup> <sup>1</sup>University of Waterloo; <sup>2</sup>School of Pharmacy, University of Waterloo; <sup>3</sup>Department of Medicine, University of Toronto

### Risk of Cardiotoxicity Associated with Fluoropyrimidine-based Chemotherapy Among Older Colorectal Cancer Patients: A New User Cohort Study

Chao Li<sup>1</sup> | Chiahung Chou<sup>1</sup> | Surachat Ngorsuraches<sup>1</sup> Li Chen<sup>2</sup> | Jingjing Qian<sup>1</sup> <sup>1</sup>Auburn University; <sup>2</sup>Indiana University

### Risk of Delirium Associated with Antimuscarinics in Older Adults: A Case-time-control Study

Prasad Nishtala University of Bath

### Risk of Falls Following the Initiation of Antihypertensives in the Elderly: A Self-controlled Case Series in the UK

### Annika Jodicke<sup>1</sup> | Eng Hooi (Cheryl) Tan<sup>1</sup> Danielle Robinson<sup>2</sup> | Antonella Delmestri<sup>3</sup> Daniel Prieto-Alhambra<sup>4</sup>

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### Statin Discontinuation and Risk of Cardiovascular Events in Older People: A Population-based Cohort Study in Denmark

Wade Thompson<sup>1</sup> | Lucas Morin<sup>2</sup> | Dorte Ejg Jarbøl<sup>1</sup> Jacob Andersen<sup>1</sup> | Martin Ernst<sup>1</sup> | Jesper Nielsen<sup>1</sup> Peter Haastrup<sup>1</sup> | Morten Schmidt<sup>3</sup> | Anton Pottegård<sup>1</sup> <sup>1</sup>University of Southern Denmark; <sup>2</sup>Inserm CIC 1431, Clinical Investigation Unit, University Hospital of Besançon; <sup>3</sup>Aarhus University Hospital

### Uncontrolled Pain and Risk for Depression and Behavioral Symptoms in Patients with Dementia

### Yu-Jung "Jenny" Wei<sup>1</sup> | Almut Winterstein<sup>2</sup>

<sup>1</sup>University of Florida; <sup>2</sup>Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida

### Use of Medications with Anticholinergic and Sedative Properties and Fall-related Fractures Among Older Adults

Shahar Shmuel<sup>1</sup> | Virginia Pate<sup>2</sup> | Marc Pepin<sup>3</sup> Janine Bailey<sup>3</sup> | Yvonne Golightly<sup>2</sup> | Laura Hanson<sup>4</sup> Til Stürmer<sup>5</sup> | Rebecca Naumann<sup>2</sup> | Danijela Gnjidic<sup>6</sup> Jennifer Lund<sup>5</sup>

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### HEALTH ECONOMICS/OUTCOME RESEARCH

### Comparative Risk of Hospitalization for Heart Failure Among Patients with Xanthine Oxidase Inhibitors and Uricosuric Agents

Fang-Ju Lin<sup>1</sup> | Yu-Hsin Wang<sup>2</sup> | Chien-Ning Hsu<sup>3</sup> <sup>1</sup>National Taiwan University Hospital; <sup>2</sup>Graduate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University, Taipei, Taiwan; <sup>3</sup>Department of Pharmacy, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, Taiwan

### Cost-effectiveness of Systematic Treatments for Metastatic Castration-sensitive Prostate Cancer: An Economic Evaluation Based on Network Meta-analysis

Lin Wang<sup>1</sup> | Jeromie Ballreich<sup>2</sup> | Hwanhee Hong<sup>3</sup> G. Caleb Alexander<sup>4</sup> | Channing Paller<sup>5</sup>

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### Impact of Race, Ethnicity, and Sex on Treatment of Non-valvular Atrial Fibrillation

Larry Jackson<sup>1</sup> | Diane Francis<sup>2</sup> | Sonia Maccioni<sup>2</sup> Vincent Thomas<sup>3</sup> | Jennifer Wood<sup>4</sup> | Guy Cafri<sup>4</sup> Rahul Khanna<sup>4</sup> | Charlene Wong<sup>4</sup> | Neloufar Rahai<sup>5</sup> Jonathan Piccini<sup>1</sup> | Daniel Friedman<sup>6</sup>

<sup>1</sup>Duke University Medical Center; <sup>2</sup>Johnson & Johnson Medical Devices, Health Economics and Market Access; <sup>3</sup>Biosense Webster; <sup>4</sup>Johnson & Johnson, Medical Device Epidemiology and Real-World Data Sciences; <sup>5</sup>Johnson & Johnson; <sup>6</sup>Yale School of Medicine

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

Jeffrey Curtis<sup>1</sup> | Benjamin Nowell<sup>2</sup> | Cassie Clinton<sup>3</sup> Fenglong Xie<sup>4</sup> | Jessica Boles<sup>5</sup> | Laura Stradford<sup>2</sup>; Shilpa Venkatachalam<sup>2</sup> | Justin Owensby<sup>4</sup> | D Curtis<sup>6</sup> K. Gavigan<sup>6</sup> | I. Lipkovich<sup>7</sup> | S.K. Nolot<sup>7</sup> | V.S. Haynes<sup>7</sup> <sup>1</sup>University of Alabama Birmingham; <sup>2</sup>Global Healthy Living Foundation; <sup>3</sup>Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham; <sup>4</sup>University of Alabama at Birmingham; <sup>5</sup>Global Healthy Living Foundation; <sup>6</sup>Global Healthy Foundation; <sup>7</sup>Eli Lilly and Company Indianapolis, IN

### Telemedicine Use Among U.S. Patients with Cancer During the COVID-19 Pandemic

Lu Chen<sup>1</sup>; Carlos Flores Avile<sup>2</sup>; Palak Kundu<sup>3</sup>; Aaron B. Cohen<sup>4</sup>; Amy Webster<sup>4</sup>; Rebecca Rohrer<sup>4</sup>; Michael Taylor<sup>5</sup> <sup>1</sup>Genentech; <sup>2</sup>Genesis Research; <sup>3</sup>Genentech, Inc.; <sup>4</sup>Flatiron Health; <sup>5</sup>Real World Data Collaborations, Personalized Healthcare Data Science, Genentech Inc., South San Francisco, CA, USA

### The Friends of Cancer Research Real World Data (RWD) Pilot 2.0 Collaboration: Implementation of Standardized Methodological Approaches for Evaluation of Oncology RWD

Donna Rivera<sup>1</sup> | Henry Henk<sup>2</sup> | Elizabeth Garrett-Mayer<sup>3</sup> Mark Walker<sup>4</sup> | Joseph Wagner<sup>5</sup> | Emily Valice<sup>6</sup> Connor Sweetnam<sup>7</sup> | Elad Sharon<sup>8</sup> | Lori Sakoda<sup>6</sup> Nicholas Robert<sup>9</sup> | Ruth Pe Benito<sup>10</sup> | Anina Natanzon<sup>4</sup> Larry Kushi<sup>6</sup> | Monika Izano<sup>7</sup> | Rebecca Honnold<sup>10</sup> Eric Hansen<sup>11</sup> | Janet Espirito<sup>9</sup> | Lindsey Enewold<sup>8</sup> Jennifer Christian<sup>5</sup> | Suanna Bruinooge<sup>12</sup> | Marley Boyd<sup>9</sup> Andrew Belli<sup>11</sup> | Laura Lasiter<sup>13</sup> | Jeff Allen<sup>13</sup> <sup>1</sup>US Food and Drug Administration; <sup>2</sup>Optum Labs; <sup>3</sup>ASCO; <sup>4</sup>ConcertAl; <sup>5</sup>IQVIA; <sup>6</sup>Kaiser Permanente; <sup>7</sup>Syapse; <sup>8</sup>National Cancer Institute; <sup>9</sup>Ontada; <sup>10</sup>Tempus; <sup>11</sup>COTA; <sup>12</sup>American Society of Clinical Oncology; <sup>13</sup>Friends of Cancer Research

### INFORMATICS

### Shifting the Traditional Model of Analysing Downloaded Electronic Health Records to the Novel Open-source Analytics Opensafely Platform

Angel Wong<sup>1</sup> | Brian MacKenna<sup>2</sup> | Caroline Morton<sup>2</sup> | Anna Schultze | Alex Walker<sup>2</sup> | Krishnan Bhaskaran<sup>1</sup> Christopher Tentsch<sup>1</sup> | Elizabeth Williamson<sup>1</sup> | Richard Croker<sup>2</sup> | Seb Bacon<sup>2</sup> | William Hulme<sup>2</sup> | Chris Bates<sup>3</sup> | Helen Curtis<sup>2</sup> Amir Mehrkar<sup>2</sup> | David Evans<sup>2</sup> | Peter Inglesby<sup>2</sup> | Jonathan Cockburn<sup>3</sup> | Helen McDonald<sup>1</sup> | Laurie Tomlinson<sup>4</sup> Rohini Mathur<sup>1</sup> Kevin Wing<sup>1</sup> | Harriet Forbes<sup>5</sup> | Rosalind Eggo<sup>1</sup> | Ian Douglas<sup>4</sup> | Stephen Evans<sup>4</sup> | Liam Smeeth<sup>4</sup> | Ben Goldacre<sup>2</sup> <sup>1</sup>London School of Hygiene and Tropical Medicine; <sup>2</sup>University of Oxford; <sup>3</sup>The Phoenix Partnership; <sup>4</sup>London School of Hygiene & Tropical Medicine; <sup>5</sup>LSHTM

### MEDICAL DEVICES

#### An Evaluation of Direct and Propensity Score Matching vs Propensity Score Stratification for Confounding Adjustment in Primary Total Hip Arthroplasty

Abhishek Chitnis<sup>1</sup> | Jack Mantel<sup>2</sup> | Juan Daccach<sup>3</sup> Prerna Kothari<sup>4</sup> | Jill Ruppenkamp<sup>3</sup> | Paul Coplan<sup>3</sup> Chantal Holy<sup>3</sup>

<sup>1</sup>Johnson & Johnson; <sup>2</sup>DePuy Synthes; <sup>3</sup>Johnson & Johnson; <sup>4</sup>Mu-Sigma

### Comparative Patient Characteristics of Transcatheter Left Atrial Appendage Occlusion vs Oral Anticoagulants for Stroke Prevention in Atrial Fibrillation

#### Joshua Lin | Daniel Singer<sup>1</sup> | Sushama Kattinakere Sreedhara<sup>2</sup> | Krista F Huybrechts<sup>3</sup> Sebastian Schneeweiss<sup>4</sup>

<sup>1</sup>Department of Medicine, Massachusetts General Hospital, Harvard Medical School; <sup>2</sup>Brigham and Women's Hospital, Harvard Medical School; <sup>3</sup>Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics; <sup>4</sup>Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA

### Comparison of 10- and 15-year Outcomes of Bioprosthetic and Mechanical Aortic Valve Replacement in Patients Aged Under 65 Years: Australian Study Using Linked Data for 4,704 Patients

Oluwadamisola Sotade<sup>1</sup> | Michael Falster<sup>1</sup> Sallie-Anne Pearson<sup>2</sup> | Louisa Jorm<sup>1</sup> | Art Sedrakyan<sup>3</sup> <sup>1</sup>Centre for Big Data Research in Health, UNSW; <sup>2</sup>Centre for Big Data Research in Health, University of New South Wales; <sup>3</sup>Weill Cornell Medicine

### Leveraging Artificial Intelligence (AI) Technologies for Automated Identification of Total Knee Arthroplasty (TKA) Devices in Electronic Health Records

Elham Sagheb<sup>1</sup> | Shi Yan<sup>1</sup> | Taghi Ramazanian<sup>1</sup> | Sunyang Fu<sup>1</sup> Ahmad Tafti<sup>2</sup> | Sunghwan Sohn<sup>1</sup> | Hilal Maradit Kremers<sup>1</sup> <sup>1</sup>Mayo Clinic; <sup>2</sup>University of Southern Maine

### Persistence of Anticoagulation After Receiving Transcatheter Left Atrial Appendage Occlusion vs Oral Anticoagulants for Stroke Prevention in Atrial Fibrillation

### Joshua Lin | Daniel Singer<sup>1</sup>

### Sushama Kattinakere Sreedhara<sup>2</sup> | Krista Huybrechts<sup>3</sup> Sebastian Schneeweiss<sup>4</sup>

<sup>1</sup>Department of Medicine, Massachusetts General Hospital, Harvard Medical School; <sup>2</sup>Brigham and Women's Hospital, Harvard Medical School; <sup>3</sup>Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics; <sup>4</sup>Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA

### Population Testing for COVID-19: Can a Rapid Antigen Test Rule out Infection?

Christina Mack<sup>1</sup> | Michael Osterholm<sup>2</sup> | Erin Wasserman<sup>3</sup> Natalia Petruski-Ivleva<sup>3</sup> | Deverick J Anderson<sup>4</sup> Emily Myers<sup>5</sup> | Navdeep Singh<sup>6</sup> | Patti Walton<sup>7</sup> Gary Solomon<sup>8</sup> | Christopher Hostler<sup>4</sup> | Jimmie Mancell<sup>9</sup> Allen K Sills<sup>8</sup>

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### Real-world Epidemiologic and Genetic Evidence Synthesis Reveals the Sex-dependent Role of GNAS Snps in Hip Arthroplasty Related Periprosthetic Osteolysis

Wei-Lun Alterovitz<sup>1</sup> | Lam Phuc Vinh Nguyen<sup>1</sup> John Dougherty<sup>1</sup> | Elaine Thompson<sup>1</sup> | Hussein Ezzeldin<sup>1</sup> Luis Santana-Quintero<sup>1</sup> | Konstantinos Karagiannis<sup>1</sup> Vahan Simonyan<sup>1</sup> | Yasameen Azarbaijani<sup>1</sup> Marina Kondratovich<sup>1</sup> | Danica Marinac-Dabic<sup>2</sup> Mark Walderhaug<sup>1</sup> | Richard Forshee<sup>3</sup> Yelizaveta Torosyan<sup>1</sup> <sup>1</sup>US Food and Drug Administration; <sup>2</sup>FDA/CDRH; <sup>3</sup>FDA/CBER

### Sex-differences in Risk of Early Revision After Primary Total Knee Arthroplasty

Suvekshya Aryal<sup>1</sup> | Per-Henrik Randsborg<sup>2</sup> Danica Marinac-Dabic<sup>3</sup> | Xinyan Zheng<sup>4</sup> | Jialin Mao<sup>4</sup> Amanda Chen<sup>1</sup> | Vincent Devlin<sup>5</sup> | Raquel Peat<sup>5</sup> Art Sedrakyan<sup>4</sup>

<sup>1</sup>Weill Cornell Medical College; <sup>2</sup>Hospital for Special Surgery; <sup>3</sup>FDA/ CDRH; <sup>4</sup>Weill Cornell Medicine; <sup>5</sup>US Food and Drug Administration

### The Association Between Bariatric Surgery and Carpal Tunnel Syndrome: A Cohort Study from Swedish Nationwide Healthcare Registries

### Jennifer Lane<sup>1</sup> | Dag Holmberg<sup>2</sup> | Andrea Burden<sup>3</sup> Dominic Furniss<sup>1</sup> | Theresa Burkard<sup>3</sup>

<sup>1</sup>Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, Oxford, UK; <sup>2</sup>Upper Gastrointestinal Surgery, Department of Molecular medicine and Surgery, Karolinska Institute, Karolinska University Hospital, Stockholm, Sweden; <sup>3</sup>ETH Zurich

### MEDICAL DEVICES

### The Association Between Bariatric Surgery and Cataract: A Cohort Study from Swedish Nationwide Healthcare Registries

Theresa Burkard<sup>1</sup> | Dag Holmberg<sup>2</sup> | Farhad Hafezi<sup>3</sup> | Andrea M Burden<sup>1</sup>

<sup>1</sup>ETH Zurich; <sup>2</sup>Upper Gastrointestinal Surgery, Department of Molecular medicine and Surgery, Karolinska Institute, Karolinska University Hospital, Stockholm, Sweden; <sup>3</sup>ELZA Institute, Dietikon, Switzerland

### METHODS IN PHARMACOEPIDEMIOLOGY

### A New Method to Estimate the Total Cohort Size for Patient Recruitment in self-controlled Case Series Study

Ling Li<sup>1</sup> | Stephen Schachterle<sup>2</sup> | Charles Wentworth<sup>3</sup> Heather Rubino<sup>3</sup> | Ann Madsen<sup>2</sup> | Xiaofeng Zhou<sup>2</sup> <sup>1</sup>HealthCore, Inc.; <sup>2</sup>Pfizer Inc; <sup>3</sup>Pfizer Inc.

### A Plasmode Simulation of Covariate Misclassification and Transportability

**Michael Andrew Webster-Clark**<sup>1</sup> | **Jessie K Edwards**<sup>2</sup> <sup>1</sup>UNC Gillings School of Global Public Health; <sup>2</sup>Department of Epidemiology, University of North Carolina at Chapel Hill

### A Systematic Approach Towards Missing Lab Data in Electronic Health Records: A Case Study in Non-small Cell Lung Cancer and Multiple Myeloma

Janick Georg Weberpals<sup>1</sup> | Arjun Sondhi<sup>2</sup> Chengsheng Jiang<sup>2</sup> | Prakirthi Yerram<sup>2</sup> | Michael Taylor<sup>3</sup> Meghna Samant<sup>2</sup> | Sarah T Cherng<sup>2</sup>

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### Cardinality Matching vs Propensity Score Matching in Multiple Sclerosis

Nicholas Belviso | Gabrielle Simoneau | Bora Youn Fabio Pellegrini | Changyu Shen | Carl de Moor *Biogen* 

### Categorization of COVID-19 Severity to Determine Mortality Risk

Elizabeth Garry<sup>1</sup> | Andrew Weckstein<sup>1</sup> | Kenneth Quinto<sup>2</sup> Marie Bradley<sup>3</sup> | Tamar Lasky<sup>2</sup> | Sandy Leonard<sup>4</sup> Sarah Vititoe<sup>1</sup> | Nicolle M Gatto<sup>1</sup>

<sup>1</sup>Aetion, Inc; <sup>2</sup>US Food and Drug Administration; <sup>3</sup>Division of Epidemiology, Office of Surveillance and epidemiology,Center for Drug Evaluation and Research, US Food and Drug Administration; <sup>4</sup>HealthVerity

### Controlling for Differential Regression to the Mean Using Summary Measures of Pre-treatment Laboratory Values in Propensity Scores

Chase Latour<sup>1</sup> | Leah McGrath<sup>2</sup> | Alexander Breskin<sup>3</sup> Ying Yu<sup>4</sup> | M. Alan Brookhart<sup>4</sup> <sup>1</sup>University of North Carolina at Chapel Hill; <sup>2</sup>NoviSci; <sup>3</sup>NoviSci Inc.; <sup>4</sup>NoviSci, Inc.

### Death Documentation Lag in COVID-19 Electronic Health Record (EHR) Suggests Caution in Near-realtime Analysis

Ajit Londhe<sup>1</sup> | Jie Zhang<sup>2</sup> | Corinne Brooks<sup>2</sup> Carolyn Brown<sup>2</sup> | Alvan Cheng<sup>2</sup> | Kimberly Roehl<sup>2</sup> Fang He<sup>2</sup> | Junjie Ma | John H Page<sup>2</sup> | J. Michael Sprafka<sup>2</sup> <sup>1</sup>Amgen Inc; <sup>2</sup>Center for Observational Research, Amgen, Inc.

### Disease Risk Score as Alternative to Propensity Score Under Multiple Confounders and High Prevalence of Outcome: A Simulation Study Motivated by the Emergence of Multiple Repurposed Medicines During the COVID-19 Pandemic

Yuchen Guo<sup>1</sup> | Sara Khalid<sup>1</sup> | Victoria Strauss<sup>1</sup> M Sanni Ali<sup>2</sup> | Daniel Prieto-Alhambra<sup>3</sup>

<sup>1</sup>University of Oxford; <sup>2</sup>London School of Hygiene & Tropical Medicine; <sup>3</sup>Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, United Kingdom

### Evaluating When Effect Estimates Change After Propensity Score Trimming Because of Differing Effect Measure Modifier Distributions

### Michael Andrew Webster-Clark<sup>1</sup> | Michele Jonsson Funk<sup>2</sup> Jennifer Lund<sup>3</sup> | Robert Glynn<sup>4</sup> | Til Stürmer<sup>3</sup> Alan Kinlaw<sup>5</sup>

<sup>1</sup>UNC Gillings School of Global Public Health; <sup>2</sup>University of North Carolina at Chapel Hill; <sup>3</sup>Department of Epidemiology, University of North Carolina at Chapel Hill; <sup>4</sup>Harvard T. H. Chan School of Public Health; <sup>5</sup>UNC Eshelman School of Pharmacy

### METHODS IN PHARMACOEPIDEMIOLOGY

### Graphical Representation of an Array of Quantitative Bias Analysis Scenarios for Differential Outcome Misclassification

J Bradley Layton<sup>1</sup> | Ryan Ziemiecki<sup>1</sup> | Heather Danysh<sup>1</sup> Charles Gaber<sup>2</sup> | Alicia Gilsenan<sup>1</sup> Catherine Bishop Johannes<sup>1</sup> <sup>1</sup>RTI Health Solutions; <sup>2</sup>University of North Carolina at Chapel Hill

### Identifying Active Pregnancies Using ICD-10 Z3A Codes vs Completed Pregnancies Using Outcomes

Monica Bertoia<sup>1</sup> | Li Zhou<sup>2</sup> | Michael Doherty<sup>2</sup> Florence Wang<sup>2</sup> | John Seeger<sup>1</sup> <sup>1</sup>Optum Epidemiology; <sup>2</sup>Optum

### Improving Methods of Identifying Anaphylaxis for Medical Product Safety Surveillance Using Natural Language Processing and Machine Learning

David Carrell<sup>1</sup> | Susan Gruber<sup>2</sup> | James Floyd<sup>3</sup> Maralyssa Bann<sup>4</sup> | Kara Cushing-Haugen<sup>1</sup> | Ron Johnson<sup>1</sup> Vina Graham<sup>1</sup> | David Cronkite<sup>1</sup> | Brian Hazlehurst<sup>5</sup> Andrew Felcher<sup>5</sup> | Cosmin Bejan<sup>6</sup> | Adee Kennedy<sup>7</sup> Mayura Shinde<sup>8</sup> | Sara Karami<sup>9</sup> | Yong Ma<sup>10</sup> Danijela Stojanovic<sup>11</sup> | Yueqin Zhao<sup>12</sup> | Robert Ball<sup>9</sup> Jennifer Nelson<sup>1</sup>

<sup>1</sup>Kaiser Permanente Washington Health Research Institute; <sup>2</sup>Putnam Data Sciences; <sup>3</sup>University of Washington Department of Epidemiology, Seattle, WA; <sup>4</sup>University of Washington; <sup>5</sup>Kaiser Permanente Northwest; <sup>6</sup>Vanderbilt University Medical Center; <sup>7</sup>Harvard Pilgrim Health Care Institute; <sup>8</sup>Harvard Medical School; <sup>9</sup>US Food and Drug Administration; <sup>10</sup>Center for Drug Evaluation and Research, United States Food and Drug Administration; <sup>11</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD; <sup>12</sup>Office of Biostatistics, Center for Drug Evaluation and Research, FDA, Silver Spring, MD

### Linear Mixed Model and Multistate Markov Model to Compare Changes in Clinical Measurements over Time. a Blood Pressure Example

Emmanuelle Boutmy<sup>1</sup> | Arthur Allignol<sup>2</sup> Thilo Hohenberger<sup>2</sup> | Caroline Foch<sup>1</sup> | Ulrike Hostalek<sup>2</sup>

<sup>1</sup>Merck KGaA Darmstadt, Germany; <sup>2</sup>Merck KGaA, Darmstadt, Germany

### Longitudinal Adherence Trajectories to Biologic Disease Modifying Anti-rheumatic Drugs in Tuscany, Italy

Sabrina Giometto<sup>1</sup> | Irma Convertino<sup>2</sup> | Marco Tuccori<sup>3</sup> Rosa Gini<sup>4</sup> | Massimiliano Cazzato<sup>5</sup> | Giulia Valdiserra<sup>6</sup> Emiliano Cappello<sup>6</sup> | Sara Ferraro<sup>7</sup> | Silvia Tillati<sup>8</sup> Marco Fornili<sup>9</sup> | Claudia C Bartolini<sup>10</sup> | Olga Paoletti<sup>11</sup> Giuseppe Turchetti<sup>12</sup> | Leopoldo Trieste<sup>12</sup> Valentina Lorenzoni<sup>13</sup> | Corrado Blandizzi<sup>14</sup> Marta Mosca<sup>5</sup> | Ersilia Lucenteforte<sup>1</sup>

<sup>1</sup>Unit of Medical Statistics, Department of Clinical and Experimental Medicine, University of Pisa; <sup>2</sup>UNIVERSITY OF PISA; <sup>3</sup>University Hospital of Pisa; <sup>4</sup>Agenzia regionale di sanità della Toscana, Osservatorio di epidemiologia, Florence, Italy; <sup>5</sup>Unit of Rheumatology, University Hospital of Pisa, Pisa, Italy; <sup>6</sup>Unit of Pharmacology and Pharmacovigilance, Department of Clinical and Experimental Medicine, University of Pisa; <sup>7</sup>University of Pisa; <sup>8</sup>Unit of Medical Statistics, Department of Clinical and Experimental Medicine, University of Pisa, Pisa, Italy.; <sup>9</sup>Unit of Medical Statistics, Department of Clinical and Experimental Medicine, University of Pisa, Pisa, Italy; <sup>10</sup>ARS Toscana; <sup>11</sup>Agenzia regionale di sanità della Toscana; <sup>12</sup>Institute of Management, Scuola Superiore Sant'Anna, Pisa, Italy; <sup>13</sup>Institute of Management, Scuola Superiore Sant'Anna: <sup>14</sup>Unit of Pharmacology and Pharmacovigilance, Department of Clinical and Experimental Medicine, University of Pisa; Unit of Adverse Drug Reactions Monitoring, University Hospital of Pisa, Pisa, Italy

### Optimization-based Stable Balancing Weights vs Generalized Boosted Modeling for Propensity Score Weighting

Stephen Johnston<sup>1</sup> | Luo Li<sup>1</sup> | Harikumaran Dwarakanathan<sup>2</sup> David Wei<sup>1</sup> | Pragya Rai<sup>1</sup> | Paul Coplan<sup>1</sup> <sup>1</sup>Johnson & Johnson; <sup>2</sup>Mu Sigma

### Rank-based Weighting for Balancing on Median Baseline Characteristics in Matching Adjusted Indirect Comparisons (MAIC)

Shirley Liao | Carl de Moor | Angela D Paradis | Justin Bohn Changyu Shen | Gabrielle Simoneau | Fabio Pellegrini *Biogen* 

### Risk of Malignancies in Newly Treated Patients with Disease-modifying Drugs for Multiple Sclerosis: Assessment According to Cohort and Nested-case Control Approaches

Pauline Bosco-Levy<sup>1</sup>; Emmanuelle Boutmy<sup>2</sup>; Angela Grelaud<sup>3</sup>; Meritxell Sabido Espin<sup>4</sup>; Pauline Diez<sup>3</sup>; Clémentine Lacueille<sup>3</sup>; Régis Lassalle<sup>3</sup>; Caroline Foch<sup>2</sup>; Cécile Droz-Perroteau<sup>5</sup> <sup>1</sup>Bordeaux PharmacoEpi ; <sup>2</sup>Merck KGaA Darmstadt, Germany; <sup>3</sup>Bordeaux PharmacoEpi, INSERM CIC1401, Université de BORDEAUX; <sup>4</sup>Merck KGaA; <sup>5</sup>Univ. Bordeaux, INSERM CIC-P 1401, Bordeaux PharmacoEpi, 33000 Bordeaux, France

### METHODS IN PHARMACOEPIDEMIOLOGY

### Sessa Empirical Estimator (SEE): A Data-driven Method for Predicting the Duration of Pharmacological Prescriptions in Secondary Data Sources

Maurizio Sessa University of Copenhagen

### Stable Balancing Weights for Unanchored Matchingadjusted Indirect Comparisons and Targeting External Control Arm Estimands

Stephen Johnston<sup>1</sup> | Harikumaran Dwarakanathan<sup>2</sup> Jason Waggoner<sup>1</sup> | Michael Schwiers<sup>1</sup> | Sanjoy Roy<sup>1</sup> Paul Coplan<sup>1</sup>

<sup>1</sup>Johnson & Johnson; <sup>2</sup>Mu Sigma

### The Effect of the Anticholinergic Properties of Antidepressants on the Incidence of Dementia: A Target Trial Emulation

Joan Forns<sup>1</sup> | Jaume Aguado<sup>1</sup> | Elena Rivero-Ferrer<sup>1</sup> Estel Plana<sup>1</sup> | Barbra Dickerman<sup>2</sup> Xabier Garcia de Albeniz<sup>1</sup> <sup>1</sup>RTI Health Solutions; <sup>2</sup>Harvard T.H. Chan School of Public Health

### The Impact of Longitudinal Data-completeness of Electronic Health Record (EHR) Data on Prognostic Risk Score Misclassification

Yinzhu Jin<sup>1</sup> | Sebastian Schneeweiss<sup>2</sup> | Dave Merola<sup>3</sup> Joshua Lin

<sup>1</sup>BWH Div of Pharmacoepidemiology and Pharmacoeconomics; <sup>2</sup>Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA; <sup>31</sup> Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

### The Performance of Different Strategies to Manage Confounding in Cardinality Matching for Medical Device Epidemiology: A Simulation Study

### Mike Du<sup>1</sup> | Sara Khalid<sup>2</sup> | Daniel Prieto-Alhambra<sup>3</sup> Victoria Strauss<sup>2</sup>

<sup>1</sup>CSM, NDORMS, University of Oxford; <sup>2</sup>University of Oxford; <sup>3</sup>Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, United Kingdom

### Use of an EHR to Inform a Claims-based Algorithm to Categorize Inpatient COVID-19 Severity

Elizabeth Garry<sup>1</sup> | Andrew Weckstein<sup>1</sup> | Kenneth Quinto<sup>2</sup> Tamar Lasky<sup>2</sup> | Aloka Chakravarty<sup>3</sup> | Sandy Leonard<sup>4</sup> Sarah Vititoe<sup>1</sup> | Jeremy A Rassen<sup>5</sup> | Nicolle M Gatto<sup>1</sup> <sup>1</sup>Aetion, Inc; <sup>2</sup>US Food and Drug Administration; <sup>3</sup>Food and Drug Administration; <sup>4</sup>HealthVerity; <sup>5</sup>Aetion, Inc.

### Use of Linked Databases for Improved Confounding Control: Considerations for Potential Selection Bias

Jenny Sun<sup>1</sup> | Sengwee Toh<sup>2</sup> <sup>1</sup>Harvard Pilgrim HeatlthCare Institute; <sup>2</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute

### Using Randomized Trial Data to Estimate Effects of Complex Treatment Regimens in Real-world Patients

Michael Andrew Webster-Clark<sup>1</sup> | Jennifer Lund<sup>2</sup> Hanna Sanoff<sup>3</sup> | Til Stürmer<sup>2</sup> | Daniel Westreich<sup>4</sup> Alexander Keil<sup>4</sup>

<sup>1</sup>UNC Gillings School of Global Public Health; <sup>2</sup>Department of Epidemiology, University of North Carolina at Chapel Hill; <sup>3</sup>University of North Carolina at Chapel Hill Department of Medicine; <sup>4</sup>University of North Carolina at Chapel Hill

### Validation of an Algorithm to Identify Hormonal Contraceptive Exposure in a Large Integrated Health Care Delivery System Database

Mary Anne Armstrong<sup>1</sup> | Malini Chandra<sup>2</sup> | Darios Getahun<sup>3</sup> Michael Fassett<sup>4</sup> | Jiaxiao Shi<sup>3</sup> | Amy Alabaster<sup>2</sup> Fagen Xie<sup>3</sup> | Vicki Chiu<sup>3</sup> | Theresa Im<sup>3</sup> | Federica Pisa<sup>5</sup> Tina Raine-Bennett<sup>2</sup>

#### <sup>1</sup>Kaiser Permanente Northern California Division of Research; <sup>2</sup>Division of Research, Kaiser Permanente; <sup>3</sup>Research and Evaluation, Kaiser Permanente Southern California; <sup>4</sup>Kaiser Permanente Southern California; <sup>5</sup>Medical Affairs & Pharmacovigilance, Bayer AG

### Validity of Electronic Health Records-based Measures for COVID-19 Hospitalization and Severe Outcomes

Sharon Fuller<sup>1</sup> | Kathy Gleason<sup>2</sup> | Rod Walker<sup>1</sup> Stephen Fortmann<sup>3</sup> | Ladia Albertson-Junkans<sup>1</sup> J. David Powers<sup>2</sup> | Mi Lee<sup>3</sup> | James Floyd<sup>4</sup> Lisa Temposky<sup>1</sup> | Susan Shortreed<sup>1</sup> | Elizabeth Bayliss<sup>2</sup> Laura Harrington<sup>1</sup> | Jennifer Kuntz<sup>5</sup> | Lisa Pieper<sup>2</sup> Jan Van Marter<sup>3</sup> | Sascha Dublin<sup>1</sup>

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### PEDIATRICS

### Antibiotic Prescribing in Children Aged 0-6 Years in Germany: Assessing Regional Variations and Potential Explanations Based on Claims Data

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### Early Life Antibiotic Exposure and Incident Chronic Diseases in Childhood

Matthew Beier<sup>1</sup> | Soko Setoguchi<sup>2</sup> | Tobias Gerhard<sup>3</sup> Jason Roy<sup>4</sup> | Avinash Gabbeta<sup>5</sup> | Brian Strom<sup>6</sup> Martin Blaser<sup>7</sup> | Daniel Horton<sup>8</sup>

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### Filled Prescriptions for Opioids Among Children and Adolescents – a Nationwide Study from 2010 to 2018

Aleksi Hamina<sup>1</sup> | Marte Handal<sup>2</sup> | Olav Fredheim<sup>3</sup> Thomas Clausen<sup>1</sup> | Li-Chia Chen<sup>4</sup> | Svetlana Skurtveit<sup>5</sup> <sup>1</sup>University of Oslo; <sup>2</sup>Norwegian Institute of Public Health; <sup>3</sup>Norwegian University of Science and Technology; <sup>4</sup>Centre for Pharmacoepidemiology and Drug Safety, Division of Pharmacy and Optometry, School of Health Sciences, Faculty of Biology, Medicine and Health, University of Manchester; <sup>5</sup>Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway

### General Practitioner Prescribing Trends Among Pediatric Patients in the United Kingdom: 1998-2018

#### Reem Masarwa<sup>1</sup> | Claire Lefebvre<sup>2</sup> | Robert Platt<sup>3</sup> Kristian Filion<sup>3</sup>

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### Impact of Drug-related Regulations on Codeine Use Among Children in Taiwan: A Nationwide Interrupted Time Series Analysis from 2005 to 2018

Chih-Wan Lin<sup>1</sup> | Yu-Jie Huang<sup>2</sup> | Wei-I Huang<sup>2</sup> Pi-Hui Chao<sup>2</sup> | Wen-Wen Chen<sup>2</sup> | Fei-Yuan Hsiao<sup>3</sup> <sup>1</sup>Graduate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University; <sup>2</sup>Taiwan Drug Relief Foundation, Taipei, Taiwan; <sup>3</sup>Graduate Institute of Clinical Pharmacy, National Taiwan University, Taipei, Taiwan

### Prescribed Medicine Use in a Nationwide Sample of Australian Children: Extent of Off-label Use

Andrea Schaffer<sup>1</sup> | Natasha Nassar<sup>2</sup> | Claudia Bruno<sup>3</sup> Nicholas Buckley<sup>4</sup> | Rose Cairns<sup>2</sup> | Melisa Litchfield<sup>5</sup> Simon Paget<sup>2</sup> | Helga Zoega<sup>3</sup> | Sallie-Anne Pearson<sup>6</sup> <sup>1</sup>University of New South Wales; <sup>2</sup>University of Sydney; <sup>3</sup>Centre for Big Data Research in Health, UNSW Sydney; <sup>4</sup>Biomedical Informatics and Digital Health, University of Sydney; <sup>5</sup>Centre for Big Data Research in Health, University of New Southe Wales; <sup>6</sup>Centre for Big Data Research in Health, University of New South Wales

### Risk of Type 2 Diabetes Among Children Initiating Anticonvulsant Mood Stabilizers: Application of a Target Trial Approach

Jenny Sun<sup>1</sup> | Jessica Young | Aaron Sarvet<sup>2</sup> Pi-i Debby Lin<sup>2</sup> | Sengwee Toh<sup>2</sup> | Jason Block<sup>2</sup> <sup>1</sup>Harvard Pilgrim HealthCare Institute; <sup>2</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute

### Selective Serotonin Reuptake Inhibitors and the Risk of Type 2 Diabetes Mellitus in Youths

Thi Xuan Dai Cao<sup>1</sup> | Christopher Filliter<sup>2</sup> François Montastruc<sup>3</sup> | Oriana Hoi Yun Yu<sup>2</sup> Emma Fergusson<sup>4</sup> | Soham Rej<sup>5</sup> | Laurent Azoulay<sup>6</sup> Christel Renoux<sup>6</sup>

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Science is resilient. It can overcome diseases, create cures, and yes, even beat pandemics. It has the methodology and the rigor to withstand even the most arduous scrutiny. It keeps asking questions and until there's a breakthrough, it isn't done. That's why, when the world needs answers, we turn to science. Because in the end SCIENCE WILL WIN



### P H A R M A C O V I G I L E N C E

### Comparing the Risk of Venous Thromboembolism in Rheumatoid Arthritis Patients Receiving Tofacitinib and TNF Inhibitors in Taiwan

Chin-Yao Shen | Tzu-Chi Liao | Edward Chia-Cheng Lai School of Pharmacy, Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University, Tainan 701, Taiwan

### Impact of COVID-19 Social Distance Restrictions on Hospital Encounters Due to Injury by Poisoning or Toxicity of Medications or Non-medicinal Substances

Qoua Her<sup>1</sup> | Jessica Young<sup>2</sup> | Til Stürmer<sup>3</sup> Michele Jonsson Funk<sup>4</sup>

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### PREGNANCY AND LACTATION

### Antidepressant Use During Pregnancy and the Risk of Neurodevelopmental Disorders in Children

### Elizabeth Suarez<sup>1</sup> | Brian Bateman<sup>2</sup> Sonia Hernandez-Diaz<sup>3</sup> | Loreen Straub<sup>4</sup> | Yanmin Zhu<sup>4</sup> Helen Mogun<sup>2</sup> | Krista Huybrechts<sup>2</sup>

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### Balance of Unmeasured Covariates After Propensity Score Matching Based on Measurable Covariates in Perinatal Pharmacoepidemiologic Studies

### Yanmin Zhu<sup>1</sup> | Thuy Thai<sup>2</sup> | Sonia Hernandez-Diaz<sup>3</sup> Brian Bateman<sup>4</sup> | Loreen Straub<sup>1</sup> | Kathryn Gray<sup>5</sup> Almut Winterstein<sup>2</sup> | Lockwood Taylor<sup>6</sup> Rita Ouellet-Hellstrom<sup>6</sup> | Yong Ma<sup>6</sup> | Yandong Qiang<sup>6</sup>

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### Benzodiazepine Use in the First Trimester and Risk of Congenital Malformations: A Nationwide Cohort Study in South Korea

Yunha Noh1 | Hyesung Lee2 | Ahhyung Choi3

#### Dong-Sook Kim<sup>4</sup> | Ju-Young Shin<sup>5</sup>

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### Characteristics and Outcomes of Pregnancies in Women with Heart Failure: A Retrospective Cohort Study in the Sentinel System

Yan Li<sup>1</sup> | Austin Cosgrove<sup>2</sup> | Efe Eworuke<sup>3</sup> Catherine Corey<sup>3</sup> | Joy Kolonoski<sup>2</sup> | Mayura Shinde<sup>4</sup> <sup>1</sup>US Food and Drug Administration; <sup>2</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute; <sup>3</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; <sup>4</sup>Harvard Medical School

### Characteristics of Initial Postpartum Opioid Prescribing and Risks of Serious Opioid-related Events After Cesarean Delivery

Andrew Wiese<sup>1</sup> | Sarah Osmundson<sup>1</sup> | Edward Mitchel<sup>1</sup> Margaret Adgent<sup>1</sup> | Sharon Phillips<sup>1</sup> | Stephen Patrick<sup>2</sup> Andrew Spieker<sup>1</sup> | Carlos Grijalva<sup>1</sup>

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### Comparative Safety of In-utero Exposure to Buprenorphine Combined with Naloxone vs Buprenorphine Monoproduct with Respect to Congenital Malformations

Loreen Straub<sup>1</sup> | Krista Huybrechts<sup>2</sup> Sonia Hernandez-Diaz<sup>3</sup> | Elizabeth Suarez<sup>4</sup> | Yanmin Zhu<sup>1</sup> Helen Mogun<sup>2</sup> | Brian Bateman<sup>2</sup>

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### PREGNANCY AND LACTATION

### COVID-19 Pharmacotherapy During Pregnancy: International Registry of Coronavirus Exposure in Pregnancy (IRCEP)

Sonia Hernandez-Diaz<sup>1</sup> | Louisa Smith<sup>2</sup> | Diego Wyszynski<sup>3</sup> <sup>1</sup>Harvard T.H. Chan School of Public Health; <sup>2</sup>Harvard TH Chan School of Public Health; <sup>3</sup>Pregistry

### Development and Validation of ICD-10 Claims-based Algorithms for Pregnancy and Infant Outcomes

Andrea Chomistek<sup>1</sup> | Kelesitse Phiri<sup>2</sup> | Jenna Calderbank<sup>3</sup> Michael Doherty<sup>3</sup> | Stephanie Chiuve<sup>4</sup> Brenda Hinman-McIlroy<sup>4</sup> | Michael Snabes<sup>5</sup> John Seeger<sup>1</sup>

<sup>1</sup>Optum Epidemiology; <sup>2</sup>GlaxoSmithKline; <sup>3</sup>Optum; <sup>4</sup>AbbVie; <sup>5</sup>AbbVie, Inc

### Effects of Gadolinium-enhanced MRI Exposure During Pregnancy on Neonatal Intensive Care Unit Admission

Thuy Thai<sup>1</sup> | Sabina Nduaguba<sup>2</sup> | Nicole Smolinski<sup>3</sup> Xi Wang<sup>4</sup> | Leyla Sahin<sup>5</sup> | Kate Gelperin<sup>6</sup> | Steven Bird<sup>6</sup> Ira Krefting<sup>7</sup> | Sonja Rasmussen<sup>8</sup> | Almut Winterstein<sup>1</sup> <sup>1</sup>Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida; <sup>2</sup>University of Florida; <sup>3</sup>Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida; <sup>4</sup>Department of Pharmaceutical Outcomes and Policy, University of Florida; <sup>5</sup>US Food and Drug Administration; <sup>6</sup>Division of Epidemiology, Office of Pharmacovigilance and Epidemiology, Food and Drug Administration; <sup>7</sup>Division of Imaging and Radiation Medicine, Office of New Drugs, Food and Drug Administration; <sup>8</sup>College of Medicine, University of Florida

### Feasibility of Using Healthcare Utilization Data to Identify Neurodevelopmental Disorders for Transgenerational Pharmacoepidemiology

Loreen Straub<sup>1</sup> | Brian Bateman<sup>2</sup> | Sonia Hernandez-Diaz<sup>3</sup> Elizabeth Suarez<sup>4</sup> | Cassandra York<sup>2</sup> | Yanmin Zhu<sup>1</sup> Helen Mogun<sup>2</sup> | Krista Huybrechts<sup>2</sup>

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### Fertility Rates in Women with Psoriasis and Psoriatic Arthritis: A Population-based Cohort Study

Teng-Chou Chen<sup>1</sup> | Ireny Iskandar<sup>2</sup> | Rosa Parisi<sup>3</sup> Matthias Pierce<sup>4</sup> | Elise Kleyn<sup>5</sup> | Christopher Griffiths<sup>6</sup> Darren Ashcroft<sup>7</sup>

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### First Trimester Exposure to Buprenorphine Compared to Methadone for Treatment of Opioid Use Disorders and the Risk of Congenital Malformations

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### Implication of Maternal Continuous Enrollment on Stillbirth Gestational Age Distributions and Maternal Characteristics in Medicaid Enrollees

Thuy Thai<sup>1</sup> | Sonja Rasmussen<sup>2</sup> | Nicole Smolinski<sup>3</sup> Sabina Nduaguba<sup>4</sup> | Yanmin Zhu<sup>5</sup> | Brian Bateman<sup>6</sup> Krista Huybrechts<sup>6</sup> | Sonia Hernandez-Diaz<sup>7</sup> Almut Winterstein<sup>1</sup>

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### PREGNANCY AND LACTATION

### Increasing Prescriptions of Misoprostol Dispensed Before Delivery in Belgium (2003-2017): Evidence from Healthcare Administrative Database

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### Metformin and Risk of Adverse Pregnancy Outcomes Among Pregnant Women with Gestation Diabetes in the United Kingdom: A Population-based Cohort Study

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### Metformin vs Insulin in Early Pregnancy and Risk of Congenital Malformations

Lars Kjerpeseth<sup>1</sup> | Carolyn Cesta | Anders Engeland<sup>2</sup> Kari Furu<sup>1</sup> | Mika Gissler<sup>3</sup> | Hanne Gulseth<sup>1</sup> Øystein Karlstad<sup>1</sup> | Helle Kieler<sup>4</sup> | Maarit Leinonen<sup>3</sup> Mette Nørgaard<sup>5</sup> | Laura Pazzagli<sup>6</sup> | Randi Selmer<sup>7</sup> Helga Zoega<sup>8</sup> | Jacqueline Cohen<sup>1</sup>

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### Prenatal Analgesic Opioid Exposure and Risk of ADHD in Childhood

### Johanne Troennes<sup>1</sup> | Angela Lupattelli<sup>2</sup> | Marte Handal<sup>3</sup> Svetlana Skurtveit<sup>4</sup> | Eivind Ystrom<sup>4</sup> | Hedvig Nordeng<sup>5</sup>

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### Prenatal Antiseizure Medication Exposure and Risk of Autism and Intellectual Disability. SCAN-AED: A Nordic Cohort Study

Marte-Helene Bjørk<sup>1</sup> | Helga Zoega<sup>2</sup> | Maarit Leinonen<sup>3</sup> Jacqueline Cohen<sup>4</sup> | Julie Dreier<sup>5</sup> | Kari Furu<sup>4</sup> Nils Erik Gilhus<sup>1</sup> | Mika Gissler<sup>3</sup> | Óskar Hálfdánarson<sup>6</sup> Jannicke Igland<sup>7</sup> | Yuelian Sun<sup>8</sup> | Torbjörn Tomson<sup>9</sup> Silje Alvestad<sup>10</sup> | Jakob Christensen<sup>8</sup>

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### Prescription Medication Use and Baseline Health Status of Women with Live Birth Deliveries in a National Data Network: The Sentinel Distributed Database Mother-infant Linkage Table

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### Prescription Opioid Type and the Risk of Neonatal Opioid Withdrawal Syndrome

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### Proton Pump Inhibitors in Pregnancy and Risk of Preeclampsia: A Nationwide Cohort Study of 1.9 Million Pregnancies

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### PREGNANCY AND LACTATION

### Statistical Power for Use of Tree-based Scan Statistics for Surveillance of Infant Outcomes Following Maternal Perinatal Medication Use

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### The Comparative Safety of Antiseizure Medication Polytherapy vs Valproate in Pregnancy and Risk of Major Congenital Malformations

Jacqueline Cohen<sup>1</sup> | Silje Alvestad<sup>2</sup> | Elizabeth Suarez<sup>3</sup> Andrea Schaffer<sup>4</sup> | Randi Selmer<sup>5</sup> | Alys Havard<sup>6</sup> Brian Bateman<sup>7</sup> | Helga Zoega<sup>6</sup> | Helle Kieler<sup>8</sup> Ingvild Odsbu<sup>9</sup> | Krista F Huybrechts<sup>7</sup> | Lars Kjerpeseth<sup>1</sup> Loreen Straub<sup>10</sup> | Maarit Leinonen<sup>11</sup> | Marte-Helene Bjørk<sup>12</sup> Mette Nørgaard<sup>13</sup> | Mika Gissler<sup>11</sup> | Sinna P Ulrichsen<sup>13</sup> Sonia Hernandez-Diaz<sup>14</sup> | Torbjörn Tomson<sup>15</sup> | Kari Furu<sup>1</sup> <sup>1</sup>Norwegian Institute of Public Health; <sup>2</sup>National Center for Epilepsy, Oslo University Hospital; <sup>3</sup>BWH Div of Pharmacoepidemiology and Pharmacoeconomics; <sup>4</sup>University of New South Wales; <sup>5</sup>Norwegian Institute of Public Health, Oslo, Norway; 6Centre for Big Data Research in Health, UNSW Sydney; 7Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics; <sup>8</sup>Centre for Pharmacoepidemiology, Karolinska Institutet; <sup>9</sup>Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway; <sup>10</sup>Brigham and Women's Hospital, Harvard Medical School; <sup>11</sup>Finnish Institute for Health and Welfare; <sup>12</sup>Bergen Epilepsy Research Group. Department of Clinical Medicine, University of Bergen; <sup>13</sup>Department of Clinical Epidemiology, University of Aarhus; <sup>14</sup>Harvard T.H. Chan School of Public Health; <sup>15</sup>Department of Clinical Neuroscience, Karolinska Institutet

### The Impact of In-utero Antipsychotic Drug Exposure on Congenital Malformations: An International Cohort Study

Krista Huybrechts<sup>1</sup> | Loreen Straub<sup>2</sup> | Pär Karlsson<sup>3</sup> Laura Pazzagli<sup>4</sup> | Sonia Hernandez-Diaz<sup>5</sup> Jacqueline Cohen<sup>6</sup> | Brian Bateman<sup>1</sup> | Randi M Selmer<sup>7</sup> Elizabeth Suarez<sup>8</sup> | Kari Furu<sup>6</sup> | Mette Nørgaard<sup>9</sup> Mika Gissler<sup>10</sup> | Maarit Leinonen<sup>10</sup> | Helga Zoega<sup>11</sup> Helle Kieler<sup>12</sup>

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### The Impact of In-utero Antipsychotic Exposure on Neurodevelopmental Disorders in Children

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### The Role of Propensity Score Matching in Claimsbased Studies for Achieving Comparability in hba1c Levels Between Treatments in Pregnant Women with Type 2 Diabetes

Carolyn Cesta | Sonia Hernandez-Diaz<sup>1</sup> | Brian Bateman<sup>2</sup> Krista Huybrechts<sup>2</sup> | Ellen Seely<sup>3</sup> | Elisabetta Patorno<sup>4</sup> <sup>1</sup>Harvard T.H. Chan School of Public Health; <sup>2</sup>Brigham and Women's Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics; <sup>3</sup>Harvard Medical School; <sup>4</sup>Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

### PREGNANCY AND LACTATION

### Use of Tree-based Scan Statistics for Surveillance of Infant Outcomes Following Maternal Perinatal Medication Use: A Propensity Score Matched Case Study

Elizabeth Suarez<sup>1</sup> | Michael Nguyen<sup>2</sup> | Di Zhang<sup>3</sup> Yueqin Zhao<sup>3</sup> | Danijela Stojanovic<sup>2</sup> | Monica A Munoz<sup>4</sup> Jane Liedtka<sup>5</sup> | Abby Anderson<sup>6</sup> | Wei Liu<sup>7</sup> Inna Dashevsky<sup>8</sup> | David Cole<sup>8</sup> | Sandra DeLuccia<sup>8</sup> Talia Menzin | Jennifer Noble<sup>8</sup> | Judith C Maro<sup>9</sup> <sup>1</sup>BWH Div of Pharmacoepidemiology and Pharmacoeconomics; <sup>2</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD; <sup>3</sup>Office of Biostatistics, Center for Drug Evaluation and Research, FDA, Silver Spring, MD; <sup>4</sup>Division of Pharmacovigilance, Center for Drug Evaluation and Research, US Food and Drug Administration; Silver Spring, MD; <sup>5</sup>Division of Pediatric and Maternal Health, Center for Drug and Evaluation Research, US Food and Drug Administration, Silver Spring, MD; <sup>6</sup>Division of Urology, Obstetrics and Gynecology, Center for Drug and Evaluation Research, US Food and Drug Administration, Silver Spring, MD; <sup>7</sup>Division of Epidemiology, Center for Drug and Evaluation Research, US Food and Drug Administration, Silver Spring, MD; 8Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School, Boston, MA; <sup>9</sup>Harvard Pilgrim Health Care Institute

### Validating an Optimized Live Birth Gestational Age Algorithm in a Nationwide Medicaid Sample and Quantifying the Misclassification of Exposure Due to Estimated Gestational Age

Yanmin Zhu<sup>1</sup> | Thuy Thai<sup>2</sup> | Brian Bateman<sup>3</sup> Sonia Hernandez-Diaz<sup>4</sup> | Loreen Straub<sup>1</sup> | Jessica Franklin<sup>5</sup> Kathryn Gray<sup>6</sup> | Almut Winterstein<sup>2</sup> | Lockwood Taylor<sup>7</sup> Rita Ouellet-Hellstrom<sup>7</sup> | Yong Ma<sup>7</sup> | Yandong Qiang<sup>7</sup> Wei Hua<sup>7</sup> | Krista Huybrechts<sup>3</sup>

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### Validity of ICD-10 Z3A Codes for Estimating Date of Last Menstrual Period

Andrea Chomistek<sup>1</sup> | Kelesitse Phiri<sup>2</sup> | Jenna Calderbank<sup>3</sup> Michael Doherty<sup>3</sup> | Stephanie Chiuve<sup>4</sup> Brenda Hinman-McIlroy<sup>4</sup> | Michael Snabes<sup>5</sup> | John Seeger<sup>1</sup> <sup>1</sup>Optum Epidemiology; <sup>2</sup>GlaxoSmithKline; <sup>3</sup>Optum; <sup>4</sup>AbbVie; <sup>5</sup>AbbVie, Inc

### RARE DISEASE

### Prediction Algorithm for Identifying Patients with Fabry or Pompe Disease in Electronic Health Records

Ella Jansen<sup>1</sup> | Lars Verkleij<sup>2</sup> | Rich Colbaugh<sup>3</sup> Kristin Glass<sup>3</sup> | Christopher Rudolf<sup>3</sup> | Ron Herings<sup>1</sup> <sup>1</sup>PHARMO Institute; <sup>2</sup>INSZO Instituut voor Zorgoptimalisatie; <sup>3</sup>Volv Global SA

#### The Association Between Bariatric Surgery and Dupuytren Disease: A Cohort Study from Swedish Nationwide Healthcare Registries

Theresa Burkard<sup>1</sup> | Jennifer Lane<sup>2</sup> | Dag Holmberg<sup>3</sup> Andrea Burden<sup>1</sup> | Dominic Furniss<sup>2</sup>

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### SAFETY END POINTS

### Cardiovascular Risk in Users of Mirabegron Relative to Users of Antimuscarinic Treatments for Overactive Bladder: Findings from a Non-interventional, Realworld Data Safety Study

Veena Hoffman<sup>1</sup> | Jesper Hallas<sup>2</sup> | Marie Linder<sup>3</sup> Andrea Margulis<sup>4</sup> | Brandon Suehs<sup>5</sup> | Alejandro Arana<sup>6</sup> Cheryl Enger<sup>1</sup> | Libby Horter<sup>5</sup> | Ingvild Odsbu<sup>7</sup> Morten Olesen<sup>2</sup> | Susana Perez-Gutthann<sup>6</sup> | Yihua Xu<sup>5</sup> Nina Kristiansen<sup>2</sup> | Kwame Appenteng<sup>8</sup> | Stefan de Vogel<sup>9</sup> John Seeger<sup>10</sup>

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### Comparative Safety of Conjugated Estrogens/ bazedoxifene (CE/BZA) vs Estrogen/progestin Combination Hormone Therapy (EP): A Multi-database Cohort Study

Sarah Hoffman<sup>1</sup> | Samuel Governor<sup>2</sup> | Kimberly Daniels<sup>3</sup> Ryan Seals<sup>4</sup> | Najat Ziyadeh<sup>5</sup> | Florence Wang<sup>5</sup> Dingwei Dai<sup>6</sup> | Cheryl McMahill-Walraven<sup>7</sup> Patty Shuminski<sup>6</sup> | Vera Frajzyngier<sup>8</sup> | Xiaofeng Zhou<sup>9</sup> Rongjun Shen<sup>10</sup> | Nicole Fournakis<sup>2</sup> | Daniel Beachler<sup>3</sup> <sup>1</sup>HealthCore, Inc.; <sup>2</sup>Research Operations, HealthCore, Inc.; <sup>3</sup>Safety & Epidemiology, HealthCore, Inc.; <sup>4</sup>Optum Epidemiology; <sup>5</sup>Optum; <sup>6</sup>CVS Health Clinical Trial Services (fka Healthagen); <sup>7</sup>CVS Health Clinical Trial Services (formerly known as Healthagen), an affiliate of Aetna; <sup>8</sup>Boehringer Ingelheim; <sup>9</sup>Pfizer Inc; <sup>10</sup>Pfizer

### Proton Pump Inhibitors and Risk of Gastric Cancer: A Population-based Cohort Study

Devin Abrahami | Emily McDonald<sup>1</sup> | Mireille Schnitzer<sup>2</sup> Alan Barkun<sup>3</sup> | Samy Suissa<sup>4</sup> | Laurent Azoulay<sup>5</sup> <sup>1</sup>Division of Internal Medicine, Department of Medicine, McGill University Health Centre, Montreal, Canada; <sup>2</sup>Faculté de Pharmacie, University of Montreal; <sup>3</sup>McGill University Health Centre; <sup>4</sup>Departments of Epidemiology and Biostatistics, Faculty of Medicine, McGill University, Montreal, Canada; <sup>5</sup>Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Québec, Canada

### Risk of Diabetic Ketoacidosis with Sodium-glucose transporter-2 Inhibitors Compared to Dipeptidyl peptidase-4 (DPP4) Inhibitors and Sulfonylureas in Patients with Type 2 Diabetes

Ghadeer Dawwas | Charles Leonard | James Lewis University of Pennsylvania

### Use of Low-dose Quetiapine and the Risk of Major Adverse Cardiovascular Events

### Mikkel Højlund<sup>1</sup> | Lars Christian Lund<sup>1</sup> | Kjeld Andersen<sup>2</sup> Christoph Correll<sup>3</sup> | Jesper Hallas<sup>4</sup>

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### Use of Proton Pump Inhibitors and Risk of Pancreatic Adenocarcinoma: A Case-control Study Based on the French National Health Data System (SNDS)

Marion Lassalle<sup>1</sup> | Thien Le Tri<sup>2</sup> | Pauline Afchain<sup>3</sup> Marine Camus-Duboc<sup>4</sup> | Julien Kirchgesner<sup>5</sup> Mahmoud Zureik<sup>6</sup> | Rosemary Dray-Spira<sup>2</sup>

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### Vitamin K Antagonists and Risk of Myelodysplastic Syndrome: A Nationwide Cohort Study in Atrial Fibrillation Patients

Anke Neumann<sup>1</sup> | Marie-Joelle Jabagi<sup>2</sup> | Mahmoud Zureik<sup>2</sup> <sup>1</sup>EPI-Phare; <sup>2</sup>EPI-PHARE, Epidemiology of Health Products (French National Agency for the Safety of Medicines and Health Products, and French National Health Insurance)

### VACCINES

### Background Incidence Rates of Adverse Events of Special Interest for COVID-19 Vaccine Monitoring

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Mar Martin<sup>13</sup> | Airam de Burgos<sup>13</sup> | Reimar Thomsen<sup>14</sup> Maria Aragon<sup>15</sup> | Felipe Villalobos<sup>16</sup>

Meritxell Pallejà-Millán<sup>16</sup> | Bonaventura Bolibar<sup>15</sup> Olaf Klungel<sup>17</sup> | Daniel Weibel<sup>1</sup> | Miriam Sturkenboom<sup>1</sup> <sup>1</sup>Department Datascience & Biostatistics, University Medical Center Utrecht; <sup>2</sup>Agenzia regionale di sanità della Toscana, Osservatorio di epidemiologia, Florence, Italy; <sup>3</sup>Fisabio; <sup>4</sup>Leibniz Institute for Prevention Research and Epidemiology – BIPS GmbH; <sup>5</sup>Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University; <sup>6</sup>Aarhus; <sup>7</sup>University of Padova; <sup>8</sup>ARS Toscana; <sup>9</sup>Agenzia regionale di sanità della Toscana; <sup>10</sup>University de bordeaux; <sup>11</sup>Penta Foundation; <sup>12</sup>Department of Clinical Epidemiology, Aarhus University, Aarhus, Denmark; <sup>13</sup>aemps; <sup>14</sup>Department of Clinical Epidemiology, Aarhus University, Aarhus, Denmark; <sup>15</sup>Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Barcelona, Spain; <sup>16</sup>Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Barcelona, Spain; 17 President, International Society for Pharmacoepidemiology

### Descriptive Epidemiology of Adverse Events of Special Interest for COVID-19 Vaccines Across 7 Countries and 4 Continents: A Multinational Network Cohort Study

Xintong Li<sup>1</sup> | Anna Ostropolets<sup>2</sup> | Rupa Makadia<sup>3</sup> Azza Shoaibi<sup>3</sup> | Gowtham Rao<sup>3</sup> | Anthony Sena<sup>3</sup> Martijn Schuemie<sup>3</sup> | Eugenia Martinez-Hernandez<sup>4</sup> Sergio Fernández-Bertolín<sup>5</sup> | Talita Duartes-Salles<sup>5</sup> Patrick Ryan<sup>6</sup> | George Hripcsak<sup>2</sup> | Daniel Prieto-Alhambra<sup>7</sup> <sup>1</sup>Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford; <sup>2</sup>Department of Biomedical Informatics, Columbia University Irving Medical Center; <sup>3</sup>Janssen Research and Development; <sup>4</sup>Neuroimmunology Unit, Neurology Department, Hospital Clínic of Barcelona; <sup>5</sup>Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol); <sup>6</sup>Janssen Research & Development; <sup>7</sup>Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, United Kingdom

### Effectiveness of Influenza Vaccination in Healthy Children: A Population-based Investigation

### Anna Cantarutti<sup>1</sup> | Elisa Barbieri<sup>2</sup> | Fabio Didone<sup>13</sup> Giovanni Corrao<sup>4</sup> | Carlo Giaquinto<sup>5</sup>

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### Evaluation of the Potential Confounding Effect of Shingles on the Risk of Guillain-barré Syndrome After Vaccination with the Recombinant Zoster Vaccine

Francois Haguinet<sup>1</sup> | Paola Pirrotta<sup>2</sup> | Vincent Bauchau<sup>2</sup> <sup>1</sup>GSK Vaccines S.r.l.; <sup>2</sup>GSK

### Sensitivity Analysis of Design Choices for Estimating Incidence Rates of Adverse Events of Special Interest in Vaccine Safety

Anna Ostropolets<sup>1</sup> | Xintong Li<sup>2</sup> | Rupa Makadia<sup>3</sup> Gowtham Rao<sup>3</sup> | Martijn Schuemie<sup>3</sup> | Anthony Sena<sup>3</sup> Azza Shoaibi<sup>3</sup> | Talita Duartes-Salles<sup>4</sup> | Patrick Ryan<sup>5</sup> Daniel Prieto-Alhambra<sup>6</sup> | George Hripcsak<sup>1</sup>

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### Vaccination and Acute Flares in Multiple Sclerosis: A Nationwide Case-crossover Study Using the French SNDS Health Care Databases

#### Lamiae Grimaldi-Bensouda<sup>1</sup> | Yann Hamon<sup>2</sup> Philippe Attias<sup>2</sup> | Tom Duchemin<sup>2</sup> | Lucien Abenhaim<sup>3</sup> Yola Moride<sup>4</sup>

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### POTPOURRI

### Approach to Falsify Calendar Time Instrumental Variable Assumptions in Estimating Treatment Effects

Phyo Htoo<sup>1</sup> | Michele Jonsson Funk<sup>2</sup> | Mugdha Gokhale<sup>3</sup> Gang Fang<sup>4</sup> | John Buse<sup>2</sup> | Til Stürmer<sup>5</sup>

<sup>1</sup>UNC Gillings School of Global Public Health; <sup>2</sup>University of North Carolina at Chapel Hill; <sup>3</sup>Center for Observational and Real-world Evidence (CORE), Merck Research Laboratories; <sup>4</sup>Division of Pharmaceutical Outcomes and Policy, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill; <sup>5</sup>Department of Epidemiology, University of North Carolina at Chapel Hill

#### Ethnic Differences in COVID-19 Infection, Hospitalisation, and Mortality: An Opensafely Analysis of 17 Million Adults in England

Rohini Mathur<sup>1</sup> | Christopher Rentsch<sup>1</sup> | Caroline Morton<sup>2</sup> William Hulme<sup>2</sup> | Anna Schultze<sup>1</sup> | Brian MacKenna<sup>2</sup> Rosalind Eggo<sup>1</sup> | Krishnan Bhaskaran<sup>1</sup> | Angel Wong<sup>1</sup> Elizabeth Williamson<sup>1</sup> | Harriet Forbes<sup>3</sup> | Kevin Wing<sup>1</sup> Helen McDonald<sup>1</sup> | Chris Bates<sup>4</sup> | Seb Bacon<sup>2</sup> | Alex Walker<sup>2</sup> David Evans<sup>2</sup> | Peter Inglesby<sup>2</sup> | Amir Mehrkar<sup>2</sup> Helen Curtis<sup>2</sup> | Nicholas DeVito<sup>5</sup> | Richard Croker<sup>2</sup> Henry Drysdale<sup>5</sup> | Jonathan Cockburn<sup>4</sup> John Parry<sup>6</sup> Frank Hester<sup>6</sup> | Sam Harper<sup>6</sup> | Ian Douglas<sup>7</sup> Laurie Tomlinson<sup>7</sup> | Stephen Evans<sup>7</sup> | Richard Grieve<sup>3</sup> David Harrison<sup>8</sup> | Kathy Rowan<sup>8</sup> | Kamlesh Khunti<sup>9</sup> Nishi Chaturvedi<sup>10</sup> | Liam Smeeth<sup>7</sup> | Ben Goldacre<sup>2</sup> <sup>1</sup>London School of Hygiene and Tropical Medicine; <sup>2</sup>University of Oxford; <sup>3</sup>LSHTM; <sup>4</sup>The Phoenix Partnership; <sup>5</sup>Oxford University; <sup>6</sup>TPP; <sup>7</sup>London School of Hygiene & Tropical Medicine; <sup>8</sup>ICNARC; <sup>9</sup>University of Leicester; <sup>10</sup>University College London

### Multi-depth, Iterative Causal Forest for Subgroup Identification

Tiansheng Wang<sup>1</sup> | Michael Kosorok<sup>2</sup> | Alexander Keil<sup>2</sup> Richard Wyss<sup>3</sup> | Michele Jonsson Funk<sup>2</sup> | John Buse<sup>2</sup> Til Stürmer<sup>4</sup>

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### Nondifferential Treatment Misclassification Biases Toward the Null? Not a Safe Bet

Rachael Ross<sup>1</sup> | Michele Jonsson Funk<sup>2</sup> | I-Hsuan Su<sup>1</sup> <sup>1</sup>University of North Carolina; <sup>2</sup>University of North Carolina at Chapel Hill

### Predictors of Severe COVID-19 Outcome in Patients with Rheumatoid Arthritis

Sara Burns<sup>1</sup> | Tiffany Siu Woodworth<sup>1</sup> Justin Manjourides<sup>2</sup> | Zeynep Icten<sup>1</sup> <sup>1</sup>Panalgo; <sup>2</sup>Northeastern University

### Risk of Fall-related Injury Associated with Concomitant Use of Prescription Opioids and Gabapentinoids Among Older Adults with Chronic Noncancer Pain

Cheng Chen<sup>1</sup> | Almut G Winterstein<sup>2</sup> Wei-Hsuan Lo-Ciganic<sup>3</sup> | Patrick J Tighe<sup>4</sup> Yu-Jung "Jenny" Wei<sup>5</sup>

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Improving Accuracy for Prospective Pregnancy Registry Enrollment Targets Veley K, Covington D, Pozin P, Buus R, Okala S

Methodologic Challenges and Considerations for the Collection of Dietary Intake Data in Real-World Populations Brett NR, Bassel M, Hong M, Margolis MK



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## Lightning

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## Lightning

### BENEFIT-RISK ASSESSMENT, COMMUNICATION, AND EVALUATION (BRACE)

### Association of Statin Use with Dry Eye Disease

Yinxi Yu<sup>1</sup> | Vatinee Bunya<sup>2</sup> | Brian VanderBeek<sup>2</sup> <sup>1</sup>University of Pennsylvania School of Medicine; <sup>2</sup>Department of Ophthalmology, Scheie Eye Institute, University of Pennsylvania Perelman School of Medicine

### Gender Differences in Valproic Acid Use for Approved Indications in the United States (2017-2018) – an Opportunity for Risk Mitigation?

Nicole Smolinski<sup>1</sup> | Amir Sarayani<sup>2</sup> | Almut Winterstein<sup>3</sup> <sup>1</sup>Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida; <sup>2</sup>Department of Pharmaceutical Outcomes and Policy, University of Florida; <sup>3</sup>Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida

### Missingness in Real World Data Submitted for Regulatory Decision-Making: Eastern Cooperative Oncology Group Performance Status Case Study

Cherise Wong<sup>1</sup> | Caitlin Knox<sup>1</sup> | Wenzhen Ge<sup>1</sup> | Ning Wu<sup>1</sup> Andrea Marcus<sup>1</sup> | Jessica Jalbert<sup>2</sup> | Asieh Golozar<sup>1</sup> <sup>1</sup>Regeneron Pharmaceuticals; <sup>2</sup>Regeneron Pharmaceuticals, Inc., Tarrytown, NY

### BIOLOGICS/BIOSIMILARS

### Risk of Major Cardiovascular Event in Jak Inhibitor Treated Patients: Analysis of a National Claim Database Amandine Gouverneur | Jérôme Avouac<sup>1</sup> | Clément Prati<sup>2</sup> | Jean-Luc Cracowski<sup>3</sup> | Thierry Schaeverbeke<sup>4</sup> Antoine Pariente<sup>5</sup> | Marie-Elise Truchetet<sup>4</sup>

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#### DISEASE EPIDEMIOLOGY/ CLINICAL COURSE

#### Atopic Eczema Associated Fracture Risk and Oral Corticosteroids: A Population-Based Cohort Study

Julian Matthewman<sup>1</sup> | Kathryn Mansfield<sup>1</sup> Richard Silverwood<sup>2</sup> | Amy Mulick<sup>1</sup> | Daniel Prieto-Alhambra<sup>3</sup> Katherine Lowe<sup>1</sup> | Liam Smeeth<sup>1</sup> | Sinéad Langan<sup>1</sup> <sup>1</sup>London School of Hygiene & Tropical Medicine; <sup>2</sup>Centre for Longitudinal Studies, University College London; <sup>3</sup>Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, UK

#### Birth Prevalence of Phenylalanine Hydroxylase Deficiency: A Systematic Literature Review and Meta-Analysis

Kimberly Alexander<sup>1</sup> | Andrea Margulis<sup>2</sup> | Pamela Foreman<sup>1</sup> Renee Shediac<sup>1</sup> | Brian Calingaert<sup>2</sup> | Abenah Harding<sup>2</sup> Manel Pladevall-Vila<sup>2</sup> | Sarah Landis<sup>3</sup> <sup>1</sup>BioMarin Pharmaceutical Inc.; <sup>2</sup>RTI Health Solutions; <sup>3</sup>BioMarin (UK) Limited

#### Chemotherapy Relative Dose Intensity, Overall Survival, and Hematologic Toxicity in Solid-Tumor Cancer Patients: A Literature Review and Meta-Analysis

Lauren Bylsma<sup>1</sup> | Carrie Nielson<sup>2</sup> | Jon Fryzek<sup>3</sup> Hossam Saad<sup>2</sup> | Jeffrey Crawford<sup>4</sup> <sup>1</sup>EpidStrategies, A Division of ToxStrategies; <sup>2</sup>Amgen; <sup>3</sup>EpidStrategies, Rockville, MD; <sup>4</sup>Duke Cancer Institute

#### Comparing Outcomes in Trial-Eligible vs Real-World COVID-19 Patients: The Case of Invasive Mechanical Ventilation

Ashley Martinez<sup>1</sup> | Silvia Perez-Vilar<sup>2</sup> | Mayura Shinde<sup>3</sup> Maria Kempner<sup>4</sup> | Joy Kolonoski<sup>4</sup> | Sarah Dutcher<sup>2</sup> Brian Kit<sup>2</sup>

<sup>1</sup>Harvard Pilgrim Health Care Institute; <sup>2</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; <sup>3</sup>Harvard Medical School; <sup>4</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

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#### DISEASE EPIDEMIOLOGY/CLINICAL COURSE

#### Identification of Serostatus in Rheumatoid Arthritis Using ICD-10 Diagnosis Codes

Seoyoung Kim<sup>1</sup> | Hemin Lee<sup>2</sup> | Jeffrey Sparks<sup>2</sup> Kazuki Yoshida<sup>2</sup> | Rishi Desai<sup>1</sup> | Joan Landon<sup>2</sup>

<sup>1</sup>Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA; <sup>2</sup>Brigham and Women's Hospital

#### Outpatient-Identified COVID-19 and Subsequent Hospitalized Thrombotic Events

Silvia Perez-Vilar<sup>1</sup> | Ashley | Martinez<sup>2</sup> | Mayura Shinde<sup>3</sup> Maria Kempner<sup>4</sup> | Joy Kolonoski<sup>4</sup> | Sarah Dutcher<sup>1</sup> Brian Kit<sup>1</sup>

<sup>1</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; <sup>2</sup>Harvard Pilgrim Health Care Institute; <sup>3</sup>Harvard Medical School; <sup>4</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

#### Patients Tell All: Using a Direct-to-Patient Community Registry to Understand Patient Burden of COVID-19

Emma Brinkley<sup>1</sup> | Christina Mack<sup>2</sup> | Natalia Petruski-Ivleva<sup>1</sup> Matthew Reynolds<sup>1</sup> | Alison Bourke<sup>1</sup> | Kalyani Hawaldar<sup>1</sup> Nancy Dreyer<sup>1</sup> <sup>1</sup>/QVIA; <sup>2</sup>/QVIA

#### Prevalence of Myxoid /Round Cell Liposarcoma (MRCLs) Among Children and Adults in the United States

Huifen Wang<sup>1</sup> | Lindsey Powers Happ<sup>2</sup> Samantha St. Laurent<sup>2</sup> | Charlotte Carroll<sup>2</sup> <sup>1</sup>Huifen Wang; <sup>2</sup>GlaxoSmithKline

## Trends in Sexually Transmitted Infections in the United States Ambulatory Care Clinics from 2005-2016

Ikenna Unigwe<sup>1</sup> | Seonkyeong Yang<sup>2</sup> | Hyunjin Song<sup>3</sup> Wei-Hsuan Lo-Ciganic<sup>4</sup> | Robert Cook<sup>5</sup> | Haesuk Park<sup>6</sup> <sup>1</sup>Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, Florida; <sup>2</sup>Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida; <sup>3</sup>University of Florida College of Pharmacy; <sup>4</sup>Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, Florida, USA; <sup>5</sup>College of Public Health and Health Professions, University of Florida, Gainesville, Florida; <sup>6</sup>University of Florida

#### Use of Remdesivir for COVID-19 in the Real World: An Analysis of US Electronic Medical Records

Julius Asubonteng<sup>1</sup> | Sara Haredasht<sup>1</sup> | Seth Kuranz<sup>2</sup> Anand Chokkalingam<sup>1</sup>

<sup>1</sup>Gilead Science Inc.; <sup>2</sup>Trinetx Inc.,

#### DRUG EFFECTIVENESS

#### Acute Kidney Injury in Patients with Atrial Fibrillation Treated with Rivaroxaban or Warfarin: A Population-Based Study in the United Kingdom

Antonio González Pérez<sup>1</sup> | Yanina Balabanova<sup>2</sup> María Saez<sup>1</sup> | Gunnar Brobert<sup>3</sup> | Luis Garcia Rodriguez <sup>1</sup>Spanish Centre for Pharmacoepidemiologic Research; <sup>2</sup>Bayer AG; <sup>3</sup>Bayer AB

#### Comparative Effectiveness of Bevacizumab vs Cetuximab in Patients with Metastatic Colorectal Cancer

## Yi-Chia Su $^1$ | Yea-Huei Kao Yang $^2$ | Chih-Chien Wu $^3$ Chien-Chou Su $^4$

<sup>1</sup>Department of Pharmacy, Kaohsiung Veterans General Hospital; <sup>2</sup>Clinical Pharmacy and Pharmaceutical Sciences, National Cheng Kung University, Tania, Taiwan.; <sup>3</sup>Division of Colorectal Surgery, Department of Surgery, Kaohsiung Veterans General Hospital; <sup>4</sup>Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University

#### Efficacy-Effectiveness Gap for Standard First-Line Treatment of Metastatic Non-Small Cell Lung Cancer Among Patients with Barriers to Care

Rohit Ojha<sup>1</sup> | Yan Lu<sup>1</sup> | Kalyani Narra<sup>2</sup> | Rachel Meadows<sup>1</sup> Aaron Gehr<sup>1</sup> | Bassam Ghabach<sup>2</sup> <sup>1</sup>JPS Center for Outcomes Research; <sup>2</sup>JPS Oncology & Infusion Center

#### Long-Acting Insulin Analogs vs Intermediate-Acting Insulin and the Risk of Major Adverse Cardiovascular Events Among Patients with Type 2 Diabetesin the United Kingdom

## Vanessa Brunetti $^1 \mid$ Oriana Yu $^2 \mid$ Robert Platt $^3$ Kristian Filion $^3$

<sup>1</sup>McGill Dept of Epidemiology, Biostatistics and Occupational Health; <sup>2</sup>Department of Endocrinology, Jewish General Hospital, Montreal, Quebec, Canada; <sup>3</sup>Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, Canada

#### DRUG UTILIZATION RESEARCH

#### Analytical Enhancements in Kentucky's Drug Overdose Mortality Surveillance: Rapid Monitoring of Trends and Decedents' Recent Controlled Substance Prescription History

#### GYeon Oh<sup>1</sup> | Patricia Freeman<sup>2</sup> | Candace Brancato<sup>3</sup> Jana McAninch<sup>4</sup> | Alex Secora<sup>4</sup> | Candice Collins<sup>4</sup> Nabarun Dasgupta<sup>5</sup> | Svetla Slavova<sup>3</sup>

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#### Changes in Purchases of Intensive Care Medicines During COVID-19 in Developed vs Developing Countries

#### Katherine Callaway Kim<sup>1</sup> | Mina Tadrous<sup>2</sup> Sandra Kane-Gill<sup>3</sup> | Ian Barbash<sup>4</sup> | Katie Suda<sup>5</sup>

<sup>1</sup>University of Pittsburgh; <sup>2</sup>Women's College Research Institute, Women's College Hospital; <sup>3</sup>University of Pittsburgh School of Pharmacy; <sup>4</sup>University of Pittsburgh School of Medicine, Division of Pulmonary, Allergy and Critical Care Medicine; <sup>5</sup>University of Pittsburgh School of Medicine

#### Co-Utilization of Opioids and Non-Benzodiazepine Sedative Hypnotics in U.S. Ambulatory Care Visits, 2006-2016

Razanne Oueini | Juan Hincapie-Castillo | Scott Vouri Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida

#### Determinants of Antimalarial Prescription Patterns Among Health Care Providers in Public Health Facilities in Uasin Gishu County, Kenya.

Henry Amdany | Wendy O'meara | Gabriel Kigen *Moi university* 

#### Early Uptake of New Molecular Entities Approved in 2017 in a Multisite National US Healthcare Data Network

#### Andrew Simon<sup>1</sup> | Sruthi Adimadhyam<sup>1</sup> | Catherine Corey<sup>2</sup> Michael Nguyen<sup>3</sup>

<sup>1</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute; <sup>2</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; <sup>3</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD

## Measuring Mental Health Prescribing Safety Indicators in Uk Primary Care

Wael Khawagi<sup>1</sup> | Douglas Steinke<sup>2</sup> | Matthew Carr<sup>2</sup> Alison Wright<sup>2</sup> | Darren Ashcroft<sup>2</sup> | Anthony Avery<sup>3</sup> Richard Keers<sup>2</sup>

<sup>1</sup>Taif University; <sup>2</sup>Centre for Pharmacoepidemiology and Drug Safety, Division of Pharmacy and Optometry, School of Health Sciences, University of Manchester, Manchester, UK; <sup>3</sup>Division of Primary Care, School of Medicine, University of Nottingham, Nottingham, UK

#### Patterns of Antibiotic Prescription Among Adult Outpatients in Italy

Federica Galimberti | Elena Olmastroni | Francesco Casizzi Manuela Casula | Alberico Catapano | Elena Tragni Department of Pharmacological and Biomolecular Sciences, Epidemiology and Preventive Pharmacology Service (SEFAP), University of Milan, via Balzaretti 9, 20133, Milan, Italy

#### HEALTH ECONOMICS/OUTCOMES RESEARCH

Comparison of Medication Adherence Between Initiators of a Multi-drug Dispensing System & Users of Retail Pharmacy

Lauren Stevens<sup>1</sup> | Jeffrey Ellis<sup>1</sup> | Anita Desai-Naik<sup>2</sup> Lilian Ndehi<sup>3</sup> | Andy Bowe<sup>1</sup>

<sup>1</sup>Humana Healthcare Research; <sup>2</sup>Humana Pharmacy Solutions; <sup>3</sup>Humana Inc.

#### Cost-Utility of Nivolumab for Treatment of Head and Neck Cancer from a Brazilian Public Health System Perspective.

Daniel Curado<sup>1</sup> | Rosângela Gomes<sup>1</sup> | Gustavo Andreoli<sup>2</sup> Dalila Gomes<sup>1</sup> | Joslaine de O Nunes<sup>3</sup>

Ricardo Fernandes<sup>4</sup> | Ivan Zimmermann<sup>5</sup>

<sup>1</sup>Ministry of Health of Brazil; <sup>2</sup>Ministry of Health, Brazil; <sup>3</sup>Ministério da Saúde; <sup>4</sup>National Institute of Cancer - INCA, Brazil; <sup>5</sup>University of Brasilia, UnB

### Effects of Initiating a Multi-dose Drug Dispensing System on Medication Adherence

Lauren Stevens<sup>1</sup> | Jeffrey Ellis<sup>1</sup> | Anita Desai-Naik<sup>2</sup> Lilian Ndehi<sup>3</sup> | Andy Bowe<sup>1</sup>

<sup>1</sup>Humana Healthcare Research; <sup>2</sup>Humana Pharmacy Solutions; <sup>3</sup>Humana Inc.

## SGLT2 Inhibitors vs GLP-1 Agonists: Comparative Progression of Renal Disease

Lauren Stevens<sup>1</sup> | Andy Bowe<sup>1</sup> | Phil Schwab<sup>1</sup> Michael Tindal<sup>2</sup> | Andrea Bloomfield<sup>2</sup> <sup>1</sup>Humana Healthcare Research; <sup>2</sup>Humana Pharmacy Solutions

#### The Prevalence of Hyperkalemia and Associated Clinical Characteristics and Outcomes Among Hospitalized COVID-19 Patients

Rena Moon<sup>1</sup> | Abiy Agiro<sup>2</sup> | Ning Rosenthal<sup>1</sup> Harold Brown<sup>1</sup> | Randall Legg<sup>3</sup> | Alpesh Amin<sup>4</sup> <sup>1</sup>Premier Applied Sciences, Premier Inc; <sup>2</sup>AstraZeneca Payer Evidence; <sup>3</sup>AstraZeneca Payer Medical; <sup>4</sup>University of California, Irvine

#### INFORMATICS

#### Temporal Effect in Real-World-Evidence for Randomized-Clinical-Trials

Jue Hou<sup>1</sup> | Rachel Zhao<sup>2</sup> | Tianrun Cai<sup>3</sup> | Katherine Liao<sup>3</sup> | Thany Seyok<sup>3</sup> | Kumar Dahal<sup>3</sup> | Qianyu Yuan<sup>1</sup> | Kai-Li Liaw<sup>4</sup> Claire Fox<sup>5</sup> | Thomas Jemielita<sup>5</sup> | Tianxi Cai<sup>1</sup>

<sup>1</sup>Harvard T.H. Chan School of Public Health; <sup>2</sup>University of British Columbia; <sup>3</sup>Brigham and Women's Hospital; <sup>4</sup>Pharmacoepidemiology, Center for Observational and Real-World Evidence (CORE), Merck & Co., Inc.; <sup>5</sup>Merck & Co., Inc.

#### METHODS IN PHARMACOEPIDEMIOLOGY

#### A New Analytic Tool for Interrupted Times Series Analysis to Assess the impact of FDA Regulatory Actions

#### Christine Lu<sup>1</sup> | Laura Hou<sup>1</sup> | Joy Kolonoski<sup>2</sup> Andrew Petrone<sup>1</sup> | Fang Zhang<sup>1</sup> | Catherine Corey<sup>3</sup> Ting Ying Huang<sup>1</sup> | Marie Bradley<sup>4</sup>

<sup>1</sup>Department of Population Medicine at Harvard Medical School; <sup>2</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute; <sup>3</sup>Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; <sup>4</sup>Division of Epidemiology, Office of Surveillance and epidemiology,Center for Drug Evaluation and Research, US Food and Drug Administration

#### An Algorithm to Derive Response and Progression Status Based on International Myeloma Working Group Response Criteria for Patients with Multiple Myeloma in a Real-World Database

Tao Xu<sup>1</sup> | Stefka Tyanova<sup>1</sup> | Tarec Christoffer El-Galaly<sup>1</sup> Khaled Sarsour<sup>2</sup> | Wan-Jen Hong<sup>3</sup> | Mellissa Williamson<sup>2</sup> <sup>1</sup>F. Hoffmann-La Roche; <sup>2</sup>Genentech; <sup>3</sup>Genentech Inc

## Characterizing Imbalance in the Tails of the Propensity Score Distribution

#### Bethany DiPrete<sup>1</sup> | Cynthia Girman<sup>2</sup> | Panagiotis Mavros<sup>3</sup> Alexander Breskin<sup>4</sup> | M. Alan Brookhart<sup>5</sup>

<sup>1</sup>Injury Prevention Research Center, University of North Carolina at Chapel Hill; <sup>2</sup>CERobs Consulting, LLC; <sup>3</sup>Janssen Pharmaceutical Companies of J&J; <sup>4</sup>NoviSci Inc.; <sup>5</sup>NoviSci, Inc.

### Collider Bias in COVID-19 Studies: Explaining the Smoking Paradox

Alice Joules | Natalia Petruski-Ivleva | Michael Warner Patrick Long | Aidan Cooper | Nancy Dreyer /QV/A

#### Development and Validation of Case-Finding Algorithms to Identify Prosthetic Joint Infections after Total Knee Arthroplasty

Erica Weinstein<sup>1</sup> | Alisa Stephens-Shields<sup>2</sup> | Bogadi Loabile<sup>1</sup> Tiffany Yuh<sup>1</sup> | Randi Silibovsky<sup>1</sup> | Charles Nelson<sup>3</sup> Judith O'Donnell<sup>1</sup> | Evelyn Hsieh<sup>4</sup> | Jennifer Hanberg<sup>4</sup> Kathleen Akgun<sup>4</sup> | Janet Tate<sup>5</sup> | Vincent Lo Re<sup>6</sup> <sup>1</sup>Division of Infectious Diseases, Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA; <sup>2</sup>Department of Biostatistics, Epidemiology and Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA.; <sup>3</sup>Department of Orthopaedic Surgery, Perelman School of Medicine, the University of Pennsylvania, Philadelphia, Pennsylvania, USA; <sup>4</sup>VA Connecticut Health System, West Haven, Connecticut, USA; <sup>5</sup>US Department of Veterans Affairs; <sup>6</sup>Center for Pharmacoepidemiology Research and Training, Center for Clinical Epidemiology and Biostatistics, Department of Biostatistics, Epidemiology, and Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA

#### Distinguishing Death from Disenrollment in Claims Data using a Readily Implemented Machine Learning Algorithm

Jessica Young<sup>1</sup> | Frank Yoon<sup>2</sup> | Nabarun Dasgupta<sup>3</sup> Debra E Irwin<sup>2</sup> | Kenneth Pack<sup>2</sup> | Toska Cooper<sup>4</sup> Shalu Shiv<sup>2</sup> | Sarah Bloemers<sup>2</sup> | Teresa Gibson<sup>2</sup> <sup>1</sup>UNC Gillings School of Global Public Health; <sup>2</sup>IBM Watson Health; <sup>3</sup>Injury Prevention Research Center, University of North Carolina at Chapel Hill; <sup>4</sup>University of North Carolina at Chapel Hill

## High-Dimensional Propensity Score Approaches in Stata using the Hdps Suite of Commands

John Tazare<sup>1</sup> | Liam Smeeth<sup>1</sup> | Stephen Evans<sup>1</sup> Ian Douglas<sup>1</sup> | Elizabeth Williamson<sup>2</sup> <sup>1</sup>London School of Hygiene & Tropical Medicine; <sup>2</sup>London School of

'London School of Hygiene & Tropical Medicine; \*London School of Hygiene and Tropical Medicine

#### Identification and Characterization of Fistulizing Crohn's Disease in Ehr using Structured and Unstructured Data

Carrie Huisingh | Yizhou Ye | Lani Wegrzyn *AbbVie* 

## Marginal Structural Models with Latent Class Growth Modeling of Time-varying Treatment

Awa Diop<sup>1</sup> | Caroline Sirois<sup>2</sup> | Denis Talbot<sup>1</sup>

<sup>1</sup>Department of social and preventive medicine, Laval University; <sup>2</sup>Faculty of pharmacy, Laval University

#### METHODS IN PHARMACOEPIDEMIOLOGY

Residual Bias and Indirect Covariate Balance in an Applied Comparison of Large-Scale Propensity Score and Cardinality Matching

Stephen Fortin<sup>1</sup> | Stephen Johnston<sup>2</sup> | Martijn Schuemie<sup>3</sup> <sup>1</sup>Janssen, Research and Development; <sup>2</sup>Johnson and Johnson; <sup>3</sup>Janssen Research and Development

#### Use of Last Clinical Activity Date in Overall Survival Analysis with Real World Data

Lu Chen<sup>1</sup> | Otto Fajardo<sup>2</sup> | Melanie Huntley<sup>3</sup> Anne-Marie Meyer<sup>2</sup> | Michael Taylor<sup>4</sup>

<sup>1</sup>Genentech; <sup>2</sup>F. Hoffmann-La Roche Ltd.; <sup>3</sup>Genentech, Inc.; <sup>4</sup>Real World Data Collaborations, Personalized Healthcare Data Science, Genentech Inc., South San Francisco, CA, USA

#### Validation of Diagnosis Algorithms for Melanoma and Nonmelanoma Skin Cancer Among Patients with Parkinson's Disease in the United States Medicare Database

Catherine Saltus<sup>1</sup> | Sigal Kaplan<sup>2</sup> | Mark Gordon<sup>3</sup> Brian Calingaert<sup>1</sup> | Elizabeth Andrews<sup>1</sup> | James Kaye<sup>1</sup> Catherine Johannes<sup>1</sup>

<sup>1</sup>RTI Health Solutions; <sup>2</sup>Teva Pharmaceutical Industries Ltd; <sup>3</sup>Teva Branded Pharmaceutical Products R&D, Inc.

#### PEDIATRICS

#### Antibiotics Overprescribing Patterns in Pediatric Primary Care in Italy: Findings from 2012-2018

Elisa Barbieri<sup>1</sup> | Costanza Di Chiara<sup>1</sup> | Paola Costenaro<sup>1</sup> | Anna Cantarutti<sup>2</sup> | Carlo Giaquinto<sup>3</sup> | Daniele Dona<sup>3</sup> <sup>1</sup>Division of Paediatric Infectious Diseases - Department for Woman and Child's Health - University of Padua; <sup>2</sup>Unit of Biostatistics, Epidemiology and Public Health, Department of Statistics and Quantitative Methods, University of Milano-Bicocca, Milan, Italy; <sup>3</sup>Division of Pediatric Infectious Diseases, Department for Woman and Child Health, University of Padua, Padua, Italy

#### Pediatric Off-Label Antipsychotic Use for Attention-Deficit/Hyperactivity Disorder: A Time-to-Event Analysis

Haeyoung Lee<sup>1</sup> | Susan dosReis<sup>1</sup> | Chengchen Zhang<sup>1</sup> | Roderick Rose<sup>2</sup> <sup>1</sup>University of Maryland Baltimore, School of Pharmacy; <sup>2</sup>University of Maryland Baltimore, School of Social Work

#### P H A R M A C O V I G I L A N C E

## Off-Label use of Potential Pharmacological Treatment for COVID-19: An Intensive Pharmacovigilance in Peru L. Yesenia Rodriguez | Héctor Garavito | Enrique Cachay | Gisela Alva | Paola Fernández | Tania Solis | Liz Veramendi

Juan Aldave | Violeta Saromo ESSALUD

#### SAFETY END POINTS

The Risk of Melanoma with Rasagiline Compared with other Antiparkinsonian Medications: A Retrospective Cohort Study in the United States Medicare Database

Catherine Johannes<sup>1</sup> | Catherine Saltus<sup>1</sup> | James Kaye<sup>1</sup> | Brian Calingaert<sup>1</sup> | Sigal Kaplan<sup>2</sup> | Mark Gordon<sup>3</sup> Elizabeth Andrews<sup>1</sup>

<sup>1</sup>RTI Health Solutions; <sup>2</sup>Teva Pharmaceutical Industries Ltd; <sup>3</sup>Teva Branded Pharmaceutical Products R&D, Inc.

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#### BENEFIT-RISK ASSESSMENT, COMMUNICATION, AND EVALUATION (BRACE)

#### A Decision Aid to Drive Adherence to Controller Treatments in Mild Asthma: A Rapid-Cycle Design Study

Myriam Gagne | Jeffrey Lam Shin Cheung | Andrew Kouri Louis-Philippe Boulet | J. Mark FitzGerald | Allan Grill Paul O'Byrne | Samir Gupta *Canada* 

Complications Associated with the use of Enzyme-Inducing and Non-Enzyme–Inducing Antiepileptic Drugs in the Japanese Population: A Retrospective Cohort Study

Jingwei Gao | Tomotsugu Seki | Kiyohide Usami Akio Ikeda | Di Fan | Koji Kawakami Japan

Efficacy and Safety of Isoniazid Preventive Therapy (ipt) in People Living with Hiv: A Systematic Review and Meta-Analysis

J. Jaya Laxmi | Christy Thomas | Krishna Undela India

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Abdallah Naser | Eman Zmaily Dahmash | Hassan Alwafi Hamad Alyami | Zahra Khalil Alsairafi | Ahmed Al Rajeh Yosra Alhartani | Fawaz Mohammad Turkistani Fadi Hassanin *Jordan* 

#### Psychological Interventions for Depression and Anxiety in Diabetes Mellitus Patients: Overview of Systematic Review and Meta-Analysis

Reginaldo Franquez | Isabela Souza | Cristiane de Cassia Bergamaschi Motta Brazil

Parents' Practices of Paracetamol use for Child Fever Management and use of Patient Information Leaflets Aljoharah Algabbani | Kerrie Wiley | Nada Alowedi Omar Albalawi | Amani Alqahtani Saudi Arabia



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Ryan Seals | Catherine Lockhart | Nancy Lin John Seeger United States

Disruptions in Rheumatology Care and the Rise of Telehealth in Response to the COVID19 Pandemic in a Community Practice-Based Network

Jeffrey Curtis | Michael George | Maria Danila Daniel Watrous | Jeffrey Alper | Fenglong Xie Benjamin Nowell | Joel Kallich | Cassie Clinton Kenneth Saag | Shanmugapriya Reddy United States

#### Evaluation the Pattern of Treatment in Inflammatory Bowel Disease: Before and After Approved Policy on Biologicals

Nai-Yu Chen | Chiao-Hsiung Chuang | Yea-Huei Kao Yang Yu-Ching Chang | Ching-Lan Cheng Taiwan

#### Factors Predictive of Treatment Success of Novel Disease-Modifying Anti-Rheumatic Drugs (DMARDs) in Patients with Inflammatory Arthritis

Jetty Overbeek | Ron Herings | Hein Bernelot Moens Netherlands

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## Penetration Rate of Anti-Tnf Biosimilars in Hospitals in France: 5 Years Status

Quentin Mathieu Jarrion | Thierry Trenque | Brahim Azzouz Marie-Françoise Beck-Cantin *France* 

#### Prescribing Patterns of Lipegfilgrastim in EU: A Retrospective Study

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The Association Between Trajectories of use of Systemic Agents and Depression in Patients with Psoriasis: A Sequence and Cluster Analysis

Raymond Milan | Lelorie | Marie-Josée Brouilette Anne Holbrook | Ivan Litvinov | Elham Rahme *Canada* 

#### Use of Ranitidine with Potential Ndma Impurities and Risk of Cancer: A Nationwide Propensity Score-Matched Cohort Study

Kyung-In Joung | Jeong-Eun Hwang | In-Sun Oh Ju-Young Shin South Korea

## Users of Biologics for Crohn's Disease and Ulcerative Colitis in the Netherlands

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#### Validation Test for Algorithms to Identify Rheumatoid Arthritis Patients in the Tuscan Healthcare Administrative Databases

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A Descriptive Retrospective Cohort Study to Evaluate the Incidence of Severe COVID 19 Outcomes Among SARS-CoV-2 Infected Patients in the United States

Heather Rubino | Stephen Schachterle | Ling Li Charles Wentworth | Xiaofeng Zhou | Susan Mather Absalon | Ann Madsen United States

#### A New United States Database for Pharmacoepidemiology Studies in Type 2 Diabetes Mellitus: the IMEDS Distributed Database

Ting-Ying Huang | Carla Rodriguez-Watson Tongtong Wang | R. Calhoun | James Marshall Jillian Burk | Young Hee Nam | Aaron Mendelsohn Margaret Adgent | Aziza Jamal-Allial | Robert Greenlee Vinit Nair | Pamala Pawloski Cheryl McMahill-Walraven | Jeffrey Brown United States

A Systematic Literature Review of the Epidemiology, Health-Related Quality of Life and Economic Burden, Including Disease Pathways and Treatment Patterns of Relapsed/Refractory Classical Hodgkin Lymphoma

Gautam Singh | Monika Raut | Rebekah Borse Xiaoqin Yang | Immaculata Hiscock | Sheetal Sharma Nameeta Pilkhwal *United States* 

An Updated Structured Review of the Epidemiology, Guidelines, and Real-World Treatment Patterns for Relapsed/Refractory Primary Mediastinal Large B-Cell Lymphoma

Jitender Takyar | Raut, Immaculata Hiscock Rebekah Borse | Sheetal Sharma | Arju Dhawan India

#### Antibiotic Resistance Pattern and Treatment Outcomes Among Empyema Thoracis Patients: A Cross-Sectional Study

Muhammad Atif | Mehwish Naseem | Saba Mukhtar Sajjad Sarwar Pakistan

#### Anti-Osteoporosis Treatment After a Major Osteoporotic Fracture is Often Lacking

Karin Swart-Polinder | Louise Lemmens Robbert Schuijbroek | Fernie Penning- van Beest Ron Herings Netherlands

## Association of Ondansetron Use and Subsequent Acute Kidney Injury in Critical Care

Matthew Gray | Priyanka Priyanka | Sandra Kane-Gill John Kellum

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#### Beneficial Effect of Mild Drug-Induced Liver Injury for Patients with Tuberculosis Undergoing First-Line Anti-Tuberculosis Therapy

Chen Qin | Tianchi Yang | Yang Che | Jifang Zhou Chen xiao | Feng Jiang *China* 

#### Characteristics of Asymptomatic Heart Failure Patients with Reduced Ejection Fraction in a Large US-Based Real-World Cohort

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Characteristics of Patients with Idiopathic Pulmonary Fibrosis (Ipf) Initiating Nintedanib or Pirfenidone Treatment Compared with Untreated Patients in the US Laura Wallace | Aimee Near | Chakkarin Burudpakdee Nadine Hartmann *Germany* 

#### Characterizing "Long-COVID" Using Real World Data: Post-Discharge Clinical Course Among Patients Initially Hospitalized for COVID-19

Elizabeth Eldridge | Edward Corbett | Jason Jones Sadiqa Mahmood | Nancy Lin United States

#### Chronic Obstructive Pulmonary Disease and Drug-Resistant Pseudomonas in Patients Hospitalized with Community-Acquired Bacterial Pneumonia

Adeniyi Idigo | J. Michael Wells | Matthew Brown Howard Wiener | Russell Griffin | Gary Cutter Sadeep Shrestha | Rachael Lee *United States* 

#### Clinical Characteristics and Biomarkers of SARS-CoV-2 Infection in Patients Treated with Remdesivir in Hospital – A Population Based Cohort Study

Xiaofeng Zhou | Rongjun Shen | Kathy Liu Mary Lynn Baniecki | Holly Soares | Ann Madsen Oladayo Jagun *United States* 

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#### Comparison of 21-Year Sex-Specific Fracture Incidence Rates Between Type 1 and Type 2 Diabetics and Non-Diabetics in Denmark (1997 – 2017)

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#### Comparison of Rheumatic Patients across Body Mass Index Categories

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#### Coronavirus Disease 2019 in Saudi Arabia: A Nationwide Epidemiological Characterization Study

Khalidah Alenzi | Tahani Alanazi | Najah Alenzi Ali Altebainawi | Thamir Alshammari Saudi Arabia

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#### Depression and Anxiety in Patients with Cancer: Prevalence and Risk Factors: A Cross-Sectional Study

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#### Designing Epidemiological Studies to Estimate the Incidence of Thrombosis in Patients with Antiphospholipid Syndrome with History of Recurrent Thrombotic Events

Chuntao Wu | Wei Jiang | Nathalie Goletiani | Deepak Jain Alexander Cole United States

### Determinants of COVID-19 Self-Protection Behaviors of Thai People: A Cross-Sectional Survey

Piyameth Dilokthornsakul | Benjawee Srithanissorn Kritsana Yonphet | Witoo Dilokthornsakul Daranee Chiewchantanakit *Thailand* 

#### Development and Validation of a Prediction Model for Mortality in Patients with Hip Fracture: Population-Based Cohort Study

Thomas Hjelholt | Søren Johnsen Peter Brynningsen | Jakob Knudsen Daniel Prieto-Alhambra | Alma Pedersen Denmark

#### Diabetes Medication Use is Associated with Higher Grade and Increased Probability of Muscle-Invasive Tumour Disease in Patients with Urothelial Carcinoma

Janine Faessen, Dennis Oerlemans | Marc de Jong Jetty Overbeek | Pauline Vissers | Katja Aben Maryska Janssen-Heijnen | Joop van den bergh Frits van Osch Netherlands

#### Disease Prevalence, Comorbidities, and Medication Utilization Among Patients with Opioid Use Disorder in the US

Brittany Roy | Jianheng Li | Cathy Lally | Ankitaben Shah Gary Bloomgren | Made Wenten United States

#### Early Parkinson's Disease: Association of Baseline Fatigue, Pain and Sleep Disorders with Disease Progression

Denise Oleske | Cindy Zadikoff | Eric Cohen Niodita Gupta | Scott Bunner United States

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## E-Core - Setting Up a European Network for Real World COVID-19 Studies

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Epidemiology of Coexisting Obesity and Heart Failure with Preserved Ejection Fraction in the United States Ayad Ali

United States

Epidemiology of COVID-19 in Adults with Asthma Ayad Ali United States

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Epidemiology of COVID-19 in Adults with Chronic Obstructive Pulmonary Disease

Ayad Ali United States

Epidemiology of COVID-19 in Adults with Diabetes Mellitus

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#### Epidemiology of COVID-19 in Children

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### Epidemiology of Treatment Resistant Depression in the US

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Ishfaq Rashid | Pramil Tiwari | Sanjay Cruz Shivani Jaswal India

#### Examining the Evolving Pandemic: Trends in COVID-19 Severity for Hospitalized COVID-19 Patients Over Time

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Matteo Monzio Compagnoni | Giovanni Corrao Angelo Barbato | Barbara D'Avanzo | Teresa Di Fiandra Lucia Ferrara | Andrea Gaddini | Alessio Saponaro Salvatore Scondotto | Valeria Tozzi | Flavia Carle Simona Carbone | Dan Chisholm | Antonio Lora *Italy* 

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

Claudia Becker | Laura Eggenschwiler | Susan Jick Christoph Meier Switzerland

#### Lessons from a Post-Authorisation Study of Rivaroxaban Use snd Potential Adverse Outcomes in Routine Practice in Four Countries

Ron Herings | Elisabeth Smits | Karin Swart-Polinder Ana Ruigomez | Tania Schink | Annemarie Voss Yanina Balabanova | Gunnar Brobert Luis Garcia Rodriguez Netherlands

#### Limited Time Interval Between Symptomatic Presentation in Primary Care and Colorectal Cancer Diagnosis

Josephina Kuiper | Myrthe van Herk-Sukel Valery Lemmens | Ernst Kuipers | Ron Herings Netherlands

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Richard Brook | Nathan Kleinman | Ian Beren United States

Long-and Short-Term Disability, Workers' Compensation and Prevalence Trends for Employees with Substance Abuse Mental Disorders in the United States

Richard Brook | Nathan Kleinman | Ian Beren United States

### Machine Learning Applied to SEER Data for Prediction of Breast Cancer Specific Survival

Phuong Le | Marc De Benedetti | Hoa Le Chi Truong Canada

#### Methodological Considerations Related to the Use of Primary and Secondary Care Data in Identifying a Cohort of Moderate to Severe Psoriasis Patients in the Uk

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### Modeling Drug Treatment Effects on Breast Cancer in the Setting of Differential Screening

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### Polypharmacy and Outpatient Attendance of People with Schizophrenia in Indonesia

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#### Predictors of Length of Stay, Mortality and Outcomes Among Hospitalised COVID-19 Patients in Saudi Arabia

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#### Prevalence of Chronic Kidney Diseases in Patients with Diabetes Mellitus in the Middle East: A Systematic Review and Meta-Analysis

Abdallah Naser | Hassan Alwafi | Basil Alotaibi Jordan

## Quality and Completeness of Diagnostic Codes for Myocardial Infarction in CPRD Aurum

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#### Risk factors for Carbapenemase-Producing Enterobacteriaceae Colonization: A Population Based Nested Case-Control Study

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## Risk factors for thyroiditis Among girls and adolescents scheduled to human papillomavirus vaccination

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#### Swedish COVID-19 Investigation for Future Insights – A Population Epidemiology Approach using Register Linkage (SCIFI- PEARL)

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#### Systemic Lupus Erythematosus in a Large, Longitudinal Electronic Health Record Database: Demographics, and Comorbidities – A Focus on African Americans

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#### The Association Between Type 2 Diabetes and Cancer Incidence in the United Kingdom Between 1988 and 2019

Richeek Pradhan | Oriana Yu | Robert Platt Laurent Azoulay Canada

#### The Global Burden of Upper and Lower Gastrointestinal Bleeding in General Population: A Systematic Review

Siir Su Saydam | Pareen Vora | Megan Molnar Germany

#### The Incidence Rates Of Hepatobiliary Diseases Among Non-Alcoholic Steatohepatitis Patients Stratified by Fibrosis-4 (FIB-4) Index for Liver Fibrosis

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#### Trends in Absence Time and Payments due to Longand Short-Term Disability and Workers' Compensation for Employees with OsteoArthritis

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#### Trends in Leaves Due to Long-and Short-Term Disability and Workers' Compensation for Employees with Back Pain

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## Vaporized Nicotine (E-cig) Use Among People with HIV in Care in the US

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#### A Controlled 1-Year Mirror-Image Study of the Effect of Paliperidone Palmitate on Hospitalization in the Treatment of Schizophrenia in China

Ting Zhang | Hao Huang | Lu Yang | Jianhua Chen Yongjing Zhang | Hong Qiu | Jun Chen | Yifeng Xu *China* 

#### A Proof of Concept Study to Test the E-CORE Network in Studying Safety and Effectiveness of Treatments in COVID-19 Patients

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### Association Between the Use of Mood Stabilizers and Risk of Trauma Among Patients with Bipolar Disorder

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Baloxavir Marboxil vs Neuraminidase Inhibitors Prescription on Subsequent Medical Resource Utilization Among School-Aged Children with Influenza: Analysis of Two Consecutive Seasons in Japan

Masato Takeuchi | Koji Kawakami Japan

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Avik Ray | Ahmad Najmi | Gaurav Khandelwal Ratinder Jhaj | Balakrishnan Sadasivam India

#### Effectiveness and Safety of Direct Oral Anticoagulants Among Patients with Non-Valvular Atrial Fibrillation and Liver Disease: A Population-Based Cohort Study

Antonios Douros | Ying Cui | Robert Platt Kristian Filion | Giada Sebastiani | Christel Renoux *Canada* 

#### Effectiveness and Safety of Edoxaban and Warfarin in Nonvalvular Atrial Fibrillation Patients: A Meta-Analysis of Real-World Studies

Mohammed Alsultan | Jeff Guo United States

#### Effectiveness of a Six-Month Isoniazid as Tuberculosis Preventive Therapy in People Living with HIV in Eritrea: A Retrospective Cohort Study

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#### Effectiveness of Sacubitril/Valsartan vs Aldosterone Antagonists for Prevention of Heart Failure-Related and All-Cause Hospitalization in Heart Failure with Reduced Ejection Fraction

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Nicolas H. Thurin | Magali Rouyer | Marine Gross-Goupil Thibaud Haaser | Xavier Rébillard | Michel Soulié Gérard De Pouvourville | Fatiha Messaoudi | Hind Stitou El Amine Demnati | Emmnuelle Bignon | Jérémy Jové Stéphanie Lamarque | Cécile Droz-Perroteau Nicholas Moore | Patrick Blin *France* 

#### Inpatient Readmission and Oral Antiplatelet Adherence for Patients with Coronary Artery Disease

Samuel Peasah | Douglas Mager | Kiraat Munshi Yan Huang | Lynn Neilson | Elizabeth Swart Rochelle Henderson | Chester Good *United States* 

## Intravenous Vancomycin Use at Discharge and 90-Day Risk of Readmission or Death

Samantha Eiffert | Alan Kinlaw United States

Low-Dose Acetylsalicylic Use Shows Protective Association with Alzheimer's Disease Incidence: Results from Two Large Prospective Cohort Studies

Thi Ngoc Mai Nguyen | Ben Schöttker Germany

#### Mycophenolate and Azathioprine are Associated with Risk of Hospitalized Viral Respiratory Infection in Rheumatoid Arthritis and Systemic Lupus

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#### Off-Label Day-of-Surgery Gabapentinoids and Prolonged Opioid Use: A Retrospective Cohort Study of Medicare Patients using Electronic Health Records

Jessica Young | Nabarun Dasgupta | Virginia Pate Til Stürmer | Brooke Chidgey | Michael Hudgens Michele Jonsson Funk *United States* 

#### Pharmacoepidemiology and Ethics

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#### SIGMA Consortium: A New Era of Collaboration to Study the Safety and Effectiveness of Medical Interventions

Josephina Kuiper | Carla Franzoni | Vera Ehrenstein Rosa Gini | Ulrike Haug | Nicholas Moore Cécile Droz-Perroteau | Bonaventura Bolibar Maria Aragon | Jesper Hallas | Thomas MacDonald Miriam Sturkenboom | Olaf Klungel Susana Perez-Gutthann | Ron Herings Netherlands

## Survival Analysis of ICU Patients Administered Human Albumin Infusion from the MIMIC III v1.4 Database

Mohamed Mekkawy | Dina Magdy | Mohamed Rashad Noura Yousri | Mai Moustafa | Nourhan Abdelaziz *Egypt* 

## Survival Analysis of N-Acetylcysteine Administration in ICU Patients from the MIMIC III v1.4 Database

Mohamed Mekkawy | Ola Zaafan Egypt

#### The Disease-Modifying Drugs for Multiple Sclerosis and Subsequent Health Service Use: A Population-Based Study

Huah Shin Ng | Feng Zhu | Elaine Kingwell | Yinshan Zhao Shenzhen Yao | Okechukwu Ekuma | Lawrence Svenson Charity Evans | John Fisk | Ruth Ann Marrie Helen Tremlett *Canada* 

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Use of Beta Blockers and Death from Breast Cancer in New Zealand Breast Cancer Patients Oliver Scott | Sandar TinTin | Alana Cavadino | Mark Elwood New Zealand

Utilizing a Structured Benefit-Risk Assessment to Evaluate a Combination of Olanzapine and Samidorphan for the Treatment of Schizophrenia and Bipolar I Disorder

Brittany Roy | David McDonnell | Bei Yu | Christine Graham | Ying Jiang | Sergey Yagoda | Vasudev Bhupathi Lauren DiPetrillo *United States* 

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#### A Contemporary Characterization of Patients with Non-Valvular Atrial Fibrillation Starting Oral Anticoagulants in Quebec, Canada

Shermaine Li | Alvi Rahman | Sophie Dell'Aniello Alexis Matteau | Madeleine Durand | Christel Renoux *Canada* 

A Rapid Review on the Adherence to Evidence-Based Medical Therapy in Peripheral Artery Disease Patients Sze Ling Chan | Rajesh | Tjun Yip Tang *Singapore* 

#### A Systematic Review of Global Oncology Treatment Practice and Modifications during COVID-19

Jingbo Yi | Bruce Crawford Japan

#### Adherence to Mesalazine and Identification of Patients with Ulcerative Colitis in Healthcare Administrative Databases of Tuscany (Italy)

Claudia Bartolini | Sara Ferraro | Irma Convertino Lorenzo Bertani | Sabrina Giometto | Francesco Costa Corrado Blandizzi | Ersilia Lucenteforte | Rosa Gini Marco Tuccori Italy

An Evidence-Based Evaluation of Clinical Medicine Use Indicators in Children

Zhe Chen | Lingli Zhang China (People's Republic)

## Antimicrobial Resistance in Endodontic Infections in Latin America (MICROBE-DENT): Systematic Review

Flávia Casale Abe | Cristiane de Cassia Bergamaschi Motta Silvio Barberato Filho | Katia Kodaira Pedroso Moraes Vilela de Castro | Carolina Martins Caio Chaves Guimarães | Luciane Cruz Lopes *Brazil* 

Antimicrobial Use in Patients Diagnosed with Chronic Kidney Disease Admitted in the Internal Medical Wards at

#### Dr George Mukhari Academic Hospital Katlego Kupa | Phumzile Skosana South Africa

#### Antithrombotic Therapy Prescription Patterns in the Secondary Prevention of Stroke in Patients with Atrial Fibrillation: Findings from a Real-World, Population-Based Study

Francisco Sanchez-Saez | Judit Riera-Arnau Isabel Hurtado | Clara Rodriguez-Bernal | Gabriel Sanfelix Spain

#### Assessing the Impact of Pharmacist-Led Anticoagulation Clinic within a Tertiary Care Setting in Saudi Arabia: A Retrospective Cross-Sectional Study

Ali Alsulaiman | Ahmed Alswar | Hadi Almansour Mohamed Sheik | Abdulaziz Alhossan Saudi Arabia

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#### Association between Non-Adherence to Endocrine Therapy and the Risk of Recurrence Among Breast Cancer Survivors: A Systematic Literature Review

Namratha Ravindra | Najla Faddoul Wei-Hsuan Lo-Ciganic | Juan M Hincapie-Castillo Haesuk Park | Coy D Heldermon | Seonkyeong Yang Debbie L Wilson | Lauren E Adkins | Ching-Yuan Chang *United States* 

#### Association between Persistence to Treatment after Percutaneous Coronary Intervention and Clinical Outcomes in Acute Coronary Syndrome Patients: A Multicenter Study in Indonesia

Erna Kristin | Lucia Krisdinarti | Alfi Yasmina Woro Rukmi Pratiwi | Rizaldy Taslim Pinzon | Sudi Indrajaya Indonesia

#### Avoidable Public Expenditures with Selected Antineoplastic Drugs for Breast Cancer in Brazil

Ranailla Lima Bandeira dos Santos | Vera Lúcia Edais Pepe Claudia Garcia Serpa | Osorio-de-Castro Brazil

### Carboplatin Appropriateness and Rationality Assessment

Tien-Yuan Wu | Hui-Hsia Hsieh | Chi-Hua Chen Taiwan

### Characteristics of Patients Initiating Spiriva Respimat for Asthma in the UK

Christina Raabe | Qiang Li | Mariel Slater Jennifer K. Quint *Germany* 

#### Characterization of Polypharmacy in Middle-Aged and Elderly Adults in the UK: An Analysis of 0.5 Million People in UK Biobank

Junqing Xie | Antonella Delmestri | Sara Khalid Victoria Strauss | Gary Collins | Daniel Prieto-Alhambra *United Kingdom* 

#### Characterizing Patients Using Abuse-Deterrent Formulations Of Extended-Release Opioid Analgesics

GYeon Oh | Bethany DiPrete | Svetla Slavova Nabarun Dasgupta | Shabbar Ranapurwala | Emily Slade Chris Delcher | Daniela Moga *United States* 

#### Classification of Gabapentinoids as Controlled Drugs Reduced Gabapentinoid Prescriptions in Primary Care in England

Xinchun GU | Teng-Chou Chen | Douglas Steinke Li-Chia Chen United Kingdom

#### Clinical and Cost-Saving Effects of the Drug Utilization Review Modernization Pilot Project in Inpatient and Outpatient Settings in Korea

Dongwon Yoon | Inmyung Song | Ha-Lim Jeon Sungho Bea | Ahhyung Choi | Hyesung Lee Ju-Young Shin South Korea

#### Comedication of Opioids with Benzodiazepines, Gabapentinoids Among Caregivers of Children with Special Healthcare Needs

Oluwadamilola Onasanya | Beth Hogans Susan dosReis | Gloria Reeves | Wendy Camelo Castillo *United States* 

#### Comparative Analysis on the Evolution of Antimicrobial Resistance Surveillance and Governance Between China and the United States

Bo Wu | Fei Yan | Chaowei Fu China

#### Comparison and Contrast of Antibiotic Utilization and Outcomes in Hospital-acquired Pneumonia (HAP), Ventilated HAP (vHAP) and Ventilator Associated Pneumonia (VAP) in the United States

Mahek Garg | Xinyue Liu | Wynona Blac | Kaushal Desai Edward Bortnichak | Pamela Moise | Laura Puzniak *United States* 

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António Teixeira-Rodrigues | Jose Guerreiro Portugal

#### COVID-19 Treatment Approaches Among Hospitalized Patients in a National HealthCare System

Jennifer Liao | Vrishali Lopes | Kerry LaPlante Aisling Caffrey United States

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#### Drug Use Evaluation of Cephalosporins in Patients with Culture Report of Enterococcus Faecalis or Enterococcus Faecium

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#### Drug Use Evaluation of Fentanyl Buccal Soluble Film

Hsiang-Jung Huang | Hui-Hsia Hsieh | Tien-Yuan Wu Chi-Hua Chen Taiwan

#### Drug Use Evaluation of Vytorin

Mei-Shu Chen | Hui-Hsia Hsieh | Tien-Yuan Wu Chi-Hua Chen Taiwan

## Drug Utilization Evaluation for the Treatment of Vulvovaginal Candidiasis

Li-Yu Lin | Hui-Hsia Hsieh | Tien-Yuan Wu | Chi-Hua Chen Taiwan

#### Drug Utilization Evaluation of Duloxetine

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#### Drug Utilization Research in Africa: Overview of Demographic and Socioeconomic Profile, Health Systems and Epidemiology

Ilse Truter | Olayinka Ogunleye | Francis Kalemeera Dan Kibuule | Johanita Burger | Johanna Meyer Laura Horne | Maribel Salas South Africa

#### Estimates of Paracetamol Poisoning in Brazil: Analysis of Official Records

Julia Okuyama | Taís Freire Galvão | Marcus Silva Brazil

#### Evaluating the Impact of New Prescribing Restrictions for Publicy-Subsidised Proton Pump Inhibitors in Australia: An Interrupted Time Series Analysis

Benjamin Daniels | Sallie-Anne Pearson | Claudia Bruno Nicholas Buckley | Andrea Schaffer | Min Jun Helga Zoega *Australia* 

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Madeline Brendle | Daniel Malonem | Lorenzo Villa Zapata United States

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Shahriyar Shahbazi Khamas | Atefeh Jafari Iran

#### Frequency, Characteristics, and Subsequent Treatment (Tx) of Real-World Patients (pts) who Discontinue Hedgehog Inhibitors (HHIs) as First-Line (1L) Systemic Tx for Advanced Basal Cell Carcinoma (aBCC)

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## HealthCare Resource Use in a US Claims Database during the Early Period of the COVID-19 Pandemic

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#### High Adherence and Sustained Virologic Response Among Vulnerable People Initiating an Hcv Treatment at a Community-Based Nurse-Led Clinic: A Cohort Study

Myriam Gagne | Isabelle Tetu IPSPL | Jean-Pierre Gregoire Jocelyne Moisan Canada

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Mingshuang Li | Yifan Diao | Jing Sun | Yu Jiang China

#### Impact Analysis of the COVID-19 Epidemic on the Patterns of Access to Medicines of Patients with Common Chronic Diseases in Beijing

Yujin Zhou | Guolin Dai | Ke Zhang, Huang | Yaying Shen Bin Ma | Hanyong Wang | Jing Sun China *China* 

#### Impact of Chronic Diseases on the Adherence to Guidelines for the Treatment of Urinary Tract Infection in Quebec, Canada

François Lefebvre | Élise Fortin | Geneviève Deceuninck Marc Simard | Caroline Quanch-Thanh Alejandra Irace-Cima | Nadine Magali-Ufitinema Caroline Sirois *Canada* 

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#### Impact of H. Pylori Eradication Therapy After the Introduction of Endoscopic Screening for Gastric Cancer in Japan

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#### Impact of the Introduction of Generic Equivalents on Memantine Consumption in South Africa using the ATC/DDD Methodology

Ilse Truter | Ashmitha Munasur-Naidoo South Africa

#### Impacts of Pharmacists' Intervention on Drug-Related Problems in Treatment for Pediatric Outpatients in Vietnam

Thang Nguyen | Vy Le, Phuong Nguyen | Suol Pham Han Diep | Dung Quach | Nguyet Nguyen | Thao Nguyen Katja Taxis Vietnam

## Impacts of Prescription Drug Monitoring Program on Patients with Cancer

Tham Le | Sean Fleming | Aida Kuzucan Linda Simoni-Wastila *United States* 



#### Incentive Structure of Employer Health Insurance and Impact on Patient Drug Use and Cost of Accessing the Private Primary Healthcare System

Che Zin | Norny Rahman | Nor Nazar Malaysia

## Incidence in Pharmacoepidemiology – New on the Drug vs New on the Class of Drugs

Mikael Hoffmann | Henrik Støvring Sweden

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## Key Opportunities and Future Direction for Drug Utilization Research in Africa

Johanna Meyer | Joseph Fadare | Joyce Kgatlwane Moliehi Matlala | Ester Naikaku-Hango | Daniel Afriyie Brian Godman | Ilse Truter | Johanita Burger Laura Horne | Maribel Salas South Africa

#### Medicines Use by Professors at a Brazilian Public University During the COVID-19 Pandemic: Findings and Implications

Waleria de Paula | Wanessa Cecília De Oliveira Adriana Lúcia Meireles | Renata Nascimento Glenda Nicioli da Silva Brazil

#### Melatonin use Among Children, Adolescents, and Young Adults: A Danish Nationwide Drug Utilization Study

Mette Bliddal | Helene Kildegaard | Lotte Rasmussen Martin Ernst | Poul Jørgen Jennum Stine Hasling Mogensen | Nikolai Constantin Brun Rikke Wesselhöft | Anton Pottegård Denmark

## Misuse of Antimicrobials in the Rural Population of a District in South India

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Non-Persistence with Statins in Diabetic and Non-Diabetic Patients with Transient Ischemic Attack Martin Wawruch | Jan Murin | Tomas Tesar

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#### Opioid Consumption from 2013 to 2016 in South Africa: Morphine, Pethidine, Oxycodone and Tramadol

Ilse Truter | Ashmitha Munasur-Naidoo Lauren Campbell South Africa

#### Opioid Use Patterns Among Non-Metastatic Cancer Survivors: A Systematic Literature Review

Najla Faddoul | Namratha Ravindra Wei-Hsuan Lo-Ciganic | Juan Hincapie-Castillo Haesuk Park | Coy Heldermon | Seonkyeong Yang Lauren Adkins | Debbie Wilson | Ching-Yuan Chang *United States* 

### Optimization of Prescription Patterns: A Response to Control High Pharmaceutical Expenditure

Ines Martinho | Jose Guerreiro António Teixeira-Rodrigues | Carla Torre *Portugal* 

### Patterns of Antihypertensive Drugs Use after Primary Stroke in the General Population

Julia Perrier | Valérie Olié | Amélie Gabet Antoine Pariente | Christophe Tzourio | Julien Bezin *France* 

#### Patterns of Antimicrobial Prescribed to Patients Admitted to a Tertiary Care Hospital in South-West Nigeria: A Prescription Quality Audit

Onyinye Akunne | Aduragbenro Adedapo South Africa

## Patterns of Meropenem Utilization snd Resistance at a Kenyan Public Referral Hospital

Dennis Makau | Margaret Oluka | Faith Okalebo Kenya

#### Patterns of Prescription snd Co-Prescription of Opioids and Benzodiazepines in the Period 2010 to 2018: A Real-World, Population-Based Study

Francisco Sanchez-Saez | Gabriel Sanfelix | Sabel Hurtado Salvador Peiro | Anibal Garcia-Sempere Spain

#### Persistence to Treatment after Percutaneous Coronary Intervention for Acute Coronary Syndrome Patients as a Cost-Saving Opportunities in Indonesia

Erna Kristin | Lucia Krisdinarti | Alfi Yasmina Woro Rukmi Pratiwi | Ratih Puspita Febrinasari Endang Mahati | Sudi Indrajaya Indonesia

#### Pharmacist-Led Intervention to Support Deprescribing of Cardiometabolic Medication Among People with Type 2 Diabetes: A Pilot Study

Stijn Crutzen | Gert Baas | Petra Denig | Marcel Bouvy Mette Heringa | Katja Taxis Netherlands

## Pilot Study Rectifies Real World Study Design to Support Regulatory Decision Making

Atheline Major-Pedersen | Jens Aberle | Paolo Sbraccia Nichlas Birch Jørgensen | Dorthe Skovgaard Anne Helene Olsen Denmark

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POPPY II Cohort Profile–A population-Based Linked Cohort Examining the Course and Outcomes of Prescription Opioid Use in NSW, Australia, 2003-2018

Natasa Gisev | Anne Pearson | Timothy Dobbins Luke Buizen | Tom Murphy | Andrew Wilson | Fiona Blyth Adrian Dunlop | Sarah Larney | David Currow Richard Mattick | Louisa Degenhardt *Australia* 

#### Potentially Inappropriate Medication Use in Older Hospitalized Patients with Type 2 Diabetes: A Cross-Sectional Study

Manik Chhabra | Rishabh Sharma | Kota Vidyasagar Akshaya Bhagavathula India

### Prescribing Trends of Antihypertensive Drug Classes in a Hong Kong Dementia Cohort

Edmund Cheung | Sze Ling Celine Chui | Gary Lau Hao Luo | Eric Wan | Ian Wong *Hong Kong* 

## Prescription Opioid Use in Australian Women of Reproductive Age from 2013 to 2020

Bianca Varney | Malcolm Gilles | Alys Havard Helga Zoega | Sallie-Anne Pearson | Melisa Litchfield *Australia* 

#### Prevalence and Factors Associated with Oral Anticoagulant Use in the General Nursing Home Population

Qiaoxi Chen | Julie Hugunin | Kate Lapane Anthony Nunes | Jennifer Tjia | Matthew Alcusk *United States* 

#### Prevalence and Predictors of Potentially Inappropriate Psychotropic (PIP) Medications in Older Adults with Psychiatric Illness

Rishabh Sharma | Manik Chhabra | Parveen Bansal Malika Arora | Arvind Sharma India

#### Prevalence of Adverse Drug Reactions in the Primary Care Setting: A Systematic Review and Meta-Analysis

Widya Norma Insani | Cate Whittlesea | Hassan Alwafi Kenneth Man | Sarah Chapman | Li Wei United Kingdom Prevalence of Potentially Inappropriate Medication and its Correlates in Elderly Hospitalized Patients: A Cross Sectional Study Based on Beers Criteria

Rishabh Sharma | Manik Chhabra | Parveen Bansal Malika Arora India

Prevalence of Potentially Inappropriate Medication in Elderly Inpatients with Chronic Kidney Disease (CKD) Manik Chhabra | Rishabh Sharma | Malika Arora | Bansal India

#### Process Evaluation of Implementing a Pharmacist-Led Intervention to Improve Adherence to Antihypertensive Drugs Among Patients with Type 2 Diabetes in Indonesian Community Health Centers

Sofa Alfian | Job Van Boven | Aulia Iskandarsyah Rizky Abdulah | Eelko Hak | Petra Denig Netherlands

#### Real World Utilization of 91-Day Extended Levonorgestrel-Containing Combined Oral Contraceptives in Europe: A Multinational Database Study

Sigal Kaplan | Massoud Toussi | Debabrata Roy Sandeep Dhanda | Amir Lass Israel

#### Real-World Utilization of Octreotide Immediate Releasing Use with Octreotide Long-Acting Releasing

Yue Cheng | Val Adams | Lowell Anthony | Chris Delcher Daniela Moga | Aman Chauhan | Bin Huang *United States* 

## Real-World Treatment Patterns of Newly Diagnosed Patients with Asthma and/or COPD

Aniek Markus | Peter Rijnbeek | Jan Kors | Guy Brusselle Edward Burn | Daniel Prieto-Alhambra | Katia Verhamme Netherlands

#### Real-World Treatment Trajectories for Newly Diagnosed Type 2 Diabetes Mellitus in Patients with Metastatic Cancer

Irene Murimi-Worstell | Kshitij Prabhune | Andrew Cohen Christy Harris | Alissa Segal *United States* 

## Scope of Insulin Human Utilization in Females of Childbearing Age in the US

Ayad Ali United States

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Sex Difference, Label Indications and Trend in Atypical Antipsychotics Use in Early-Onset Schizophrenia: A Nationwide Cross-Sectional Study

Izabela Fulone | Marcus Silva | Luciane Cruz Lopes Brazil

#### Sex Differences in Lipid Profile Across the Life Span in Patients with Type 2 Diabetes: A Cross-Sectional Study

Martina Ambroz | Sieta de Vries | Priya Vart Robin Dullaart | Roeters van Lennep | Petra Denig Klaas Hoogenberg Netherlands

### Slovenia vs the Netherlands: A Comparison of Opioid Prescription Strategies

Ajda Bedene | Anita Strmljan | Willem Lijfering Mitja Udovič | Frits Rosendaal | Jurij Fürst | Albert Dahan Eveline Van Dorp Netherlands

#### Temporal Trends in Medication Utilization Among Hospitalized COVID-19 Patients

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#### Temporal Trends of Pharmacologic Treatments for Tuberculosis and Multidrug-Resistant Tuberculosis Following Treatment Guideline Dissemination in South Korea

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#### The Influence of Medical Representative Visits on Prescribing Practice of Physicians in Jordan and Iraq: A Cross-Sectional Study

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#### The Use of Medication Among People with Stage 2 Hypertension: Findings from an Indonesian Cross-Sectional Study

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#### The Utilization Evaluation of Intravenous Pantoprazole for Stress Ulcer Prophylaxis in a Major Teaching Hospital

Shahriyar Shahbazi Khamas | Atefeh Jafari Iran

#### Time Trends in Patient Characteristics of New Rivaroxaban (RVX) Users with Atrial Fibrillation (AF) Across Four Countries

Annemarie Voss | Ana Ruigomez | Elisabeth Smits Karin Swart-Polinder | Yanina Balabanova | Gunnar Brobert Luis Garcia Rodriguez | Ron Herings | Tania Schink *Germany* 

#### Treatment Patterns and Appropriateness of Antipsychotic Prescriptions in Patients with Schizophrenia

Veronica Gamon | Isabel Hurtado | José Salazar-Fraile Gabriel Sanfelix Spain

## Treatment Trajectory of Antihypertensive Drugs in UK Primary Care Practices

Julie Rouette | James Brophy | Tibor Schuster Laurent Azoulay Canada

#### Trends and Patterns in Traditional Chinese Medicine Use Among Chinese Population in Late Adulthood: An Eight-Year Repeated Panel Survey

Lu Xu | Jing Hu | Shengfeng Wang | Siyan Zhan China

## Trends in Hydroxychloroquine Drug Utilization and Safety in 2020

Sarah Hoffman | Sonali Shambhu | Vincent Willey Kevin Haynes

United States

#### Trends in Prescribing of Non-Steroidal Anti-Inflammatory Medications in the US Ambulatory Care Setting, 2006-2016

Shailina Keshwani | Joshua Brown | Wei-Hsuan Lo-Ciganic Seonkyeong Yang | Nicole Smolinski Juan Hincapie-Castillo *United States* 

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#### Trends in the Management of Primary Headache in US Emergency Departments: Analysis of 2007-2018 NHAMCS Data

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#### Trends of Anti-epileptic Drugs Use During Pregnancy in Manitoba, Canada: A 20-Year Utilization Study

Walid Shouman | Joseph Delaney | Alekhya Lavu Sherif Eltonsy *Canada* 

#### Utilization of Anti-CGRP Monoclonal Antibodies for Migraine Prophylaxis between 2019 and 2020 in Tuscany Region, Italy

Giulia Hyeraci | Rosa Gini | Olga Paoletti Giorgio Limoncella | Davide Messina | Silvia Benemei Chiara Lupi | Luigi Francesco Iannone Francesco De Cesaris | Pierangelo Geppetti Giuseppe Roberto Italy

Using Administrative Data and the Regional Pathology Registry of Tuscany to Describe First-Line Pharmacotherapy and Survival of Patients with Non-Resectable Non-Small Cell Lung Cancer from 2009 to 2019

Spini Andrea | Giuseppe Roberto | Cristiana Bellan Alessandra Pascucci | Pietro Rosellini | Sandra Donnini Folco Furiesi | Lorenzo Leoncini | Silvano Giorgi Allison Singer | Claudia Bartolini | Marina Ziche | Rosa Gini Francesco Salvo Italy

#### Utilisation and Safety of Glycopyrronium Bromide (GPB) Oral Solution for the Treatment of Sialorrhoea in Children <18 Years in the UK

Debabrata Roy | Vicki Osborne | Sandeep Dhanda Saad Shakir *United Kingdom* 

#### Utilization of Drugs Reimbursed by the Italian HealthCare Service for the Treatment of COVID19 during the First Pandemic Wave: Gender Differences in the General and Nursing Home Population of Tuscany

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#### Utilization Patterns and HealthCare Accesses of JAKi used in Rheumatoid Arthritis Patients in Tuscany: The LEONARDO Study

Marco Tuccori | Valentina Lorenzoni | Rosa Gini Giuseppe Turchetti | Elisabetta Fini | Sabrina Giometto Claudia Bartolini | Olga Paoletti | Irma Convertino Sara Ferraro | Emiliano Cappello | Giulia Valdiserra Corrado Blandizzi | Ersilia Lucenteforte Italy

#### Utilization Patterns of Direct Oral Anticoagulants in Medicare Beneficiaries with Cancer and Non-Valvular Atrial Fibrillation

Shirin Ardeshirrouhanifard | Huijun An Ravi Goyal | Jodi Segal | G. Caleb Alexander Hemalkumar Mehta United States

#### Visualization Methods to Examine Treatment Patterns in Pharmacoepidemiology: An Example Using Osteoporosis Medications

Suzanne Landi | Min Kim | Sara Snell Taylor Catie Wiener | Michele McDermott Cynthia Deignan | CJay Lin Akhila Balasubramanian Andrew Park M. Alan Brookhart | Leah McGrath *United States* 

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#### Adherence to Anti-Dementia Medicine: A South African Database Analysis

Ilse Truter South Africa

#### An Evaluation of Injurious Falls and Fall-Risk-Increasing-Drug (FRID) Prescribing Behaviors in a Nationally Representative Sample and the Pharmacist's Role in Fall Prevention

Taylor Elliott | Daniela Moga | Susan Westneat Shama Karanth | Erin Abner | Anna Kucharska-Newton *United States* 

#### Any Link Between Polypharmacy and the Risk of Mortality Among Patients with Chronic Heart Failure Newly Diagnosed? A Nested Case-Control Study

Sylvie Perreault | Mireille Schnitzer | Eliane Disso Jakub Qazi | Marc Dorais *Canada* 

#### Assessment of Drug-Drug Interactions Among Geriatric Patients in Community Setting

Meghana Nadendla | Umesh M | Lakshmi Choudary India

#### Assessment of Predictors of Fractures in German Older Sdults using a Large Population Sample Jonas Reinold | Malte Braitmaier | Oliver Riedel

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#### Association between Anticholinergic Burden of Medications and Emergency Care in the Elderly Assisted in the Brazilian Prymary Care Setting

Fabiane Motter | Rodrigo Iwami | Vera Paniz Luciane Cruz Lopes Brazil

## Factors Associated with Different Dosage Forms of Disease-Modifying Agents in Older Adults with Multiple Sclerosis

Ashna Talwar | Jagadeswara Rao Earla | George Hutton Rajender Aparasu *United States* 

#### Fracture Risk Following the Initiation of antihypertensive Therapy Amongst Frail Elderly People: A Self-Controlled Case Series analysis

Annika Jödicke | Eng Hooi (Cheryl) Tan | Danielle Robinson Antonella Delmestri | Daniel Prieto-Alhambra *United Kingdom* 

#### Intravitreal Anti-Vascular Endothelial Growth Factors Use in France: Cross-Sectional and Longitudinal Nationwide Observational Studies

Sophie Billioti de Gage | Marion Bertrand Sébastien Grimaldi | Mahmoud Zureik *France* 

## Low Rates of Bone-Active Medication Utilization from 2013-2017 by Provider Type for Beneficiaries Aged 65+ with Medicare Part D

Jennifer Marie Kirk | Sean Fleming | Denise Orwig United States

#### Medication Regimen Complexity Among Older Adults Admitted to Home Hospice

Jennifer Tjia | Margaret Clayton | Jennifer Smith Geraldine Puerto | Vennesa Duodu Susan DeSanto-Madeya *United States* 

#### Polypharmacy Among Older Individuals with Heart Failure: Trends between 2000 and 2017 in the Province of Quebec, Canada

Caroline Sirois | Alexandre Campeau Calfat | Marc Simard Amina Ouali | Claudia Blais *Canada* 

## Polypharmacy and Health-Related Quality of Life in Older Adults with Cancer: Determining Breakpoints

Manvi Sharma | Yiqiao Zhang | Monika Salkar John Bentley United States

#### Predictors of Concomitant Use of Opioids and Gabapentin in the National Alzheimer's Coordinating Center Database

Logan Oatman | Jungjun Bae | GYeon Oh Patricia Freeman | Daniela Moga *United States* 

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Trends in Antipsychotic Dispensation to Residents of Long-Term Care Facilities in Nova Scotia, Canada including after a Fall-Related Hospitalization

Shanna Trenaman | Ingrid Sketris | Maia von Maltzahn Samuel Stewart | Yan Wang | Hala Tamim *Canada* 

#### Use of and Adherence to Bisphosphonates in Elderly Patients with Complex Health Needs: An Analysis of UK Primary Care Records

Leena Elhussein | Annika Jödicke | Antonella Delmestri Danielle Robinson | Victoria Strauss Daniel Prieto-Alhambra United Kingdom

#### Use of Potentially Inapropriate Medicines by Elderly People in Primary Care of the Unified Health System (SUS) in Brazil

Renata Nascimento | Viviane Silveira Brazil

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Absence Benefit Use and Payment Trends Among Short-and Long-Term Disability, and Workers' Compensation for Employees with Any of 20 Top Agency for Healthcare Research and Quality Conditions

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Absence Benefit Utilization, Duration of Leaves, and Payments Vary by Benefit and Over Time for Shortand Long-Term Disability and Workers' Compensation for Employees with Headaches and Migraines in the United States

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Melissa Khashei | Jennifer Shields | Christopher St. Clair Wei Liu | Jae Joon Song | Monique Falconer | Wei Hua Efe Eworuke United States

### Assessment of Health-Related Quality of Life in Adults with Asthma by Asthma Severity

Hyunjin Song | Kathryn Blake | Debbie Wilson | Almut Winterstein | Haesuk Park United States

#### Association between Primary Care Provider Payment Models and Adherence to Anticoagulation in a Sample of Patients with Atrial Fibrillation

Lanting Yang | Jingchuan Guo | Terri Newman Walid Gellad | Inmaculada Hernandez United States

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Salman Hussain | Abul Kalam Najmi India

#### Benefits Analysis of Pharmacists Intervention Multi-drug Integration in Chronic Patients

Chi-Hua Chen | Hui-Hsia Hsieh | Tien-Yuan Wu Taiwan

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#### Comparison of Quality of Life between Men and Women with Chronic Liver Diseases using Chronic Liver Disease Questionnaire (CLDQ): A Meta-Analysis.

Marwan Alrasheed | Abdulrahman Alsuhibani Ana Hincapie | Jeffrey Welge United States

## Cost Considerations of Dermatological Care in Jordan: A Cross-Sectional Study

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#### Cost-Related Nonadherence for Prescription Medications: A Cross-Sectional Study in Jordan

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#### Effect of Anti-Dementia Drugs on and Potential Racial/ Ethnic Disparities in Satisfaction with Quality of Care Among Older Adults with Alzheimer's Disease and Related Dementias

Xiaomo Xiong | Minghui Li | Jun Wu | Kevin Lu United States

#### Effectiveness and Safety of Extended Anticoagulation in Patients with Venous Thromboembolism: A Retrospective Cohort Study

Hye-Rim Kang | Wei-Hsuan Lo-Ciganic Christina DeRemer | Eric Dietrich | Pei-Lin Huang Haesuk Park United States

#### Global Antiplatelet Sales Trend: A Focus on P2y12 Inhibitors from 2008 to 2018

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#### Health-Related Quality of Life in Older Adults with Concomitant Opioid and Skeletal Muscle Relaxant Use in a National Cohort of Older Adults

Christy Xavier | Usha Sambamoorthi | Nahid Rianon Rafia Rasu United States

#### Impact of the COVID-19 Pandemic on Routine Clinical Management of Patients with Neurological Conditions: a Retrospective Cohort Study in UK Primary Care (CPRD)

Paul Dillon | Teresa Karrer | Isaac Gravestock Loes Rutten-Jacobs | Julie Mouchet Switzerland

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Jeffrey Curtis | Michael Grabner | Russel Burge Chia-Chen Teng | Mingyang Shan | Alyssa Garrelts Terri Ridenour | Keith Isenberg *United States* 

#### Long- and Short-Term Disability and Workers' Compensation Trends for Employees with Bone Diseases

Richard Brook | Nathan Kleinman | Ian Beren United States

#### Long-and Short-Term Disability and Workers' Compensation Trends for Employees with Eye (Ophthalmic) Conditions in the United States

Richard Brook | Nathan Kleinman | Ian Beren United States

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Long-and Short-Term Disability, Workers' Compensation and Prevalence Trends for Employees with Mental Disorders in the United States

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#### Novel Glucose-Lowering Agents and Cardiorenal Benefits: Absence of Racial/Ethnic Diversity in Clinical Trials

Huilin Tang | Stephen Kimmel | Inmaculada Hernandez Jared Magnani | Maria Brooks | Almut Winterstein Jingchuan Guo *United States* 

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Priti Shah | Anne Dilley | Jing Yuan United States

Prevalence and Leaves Due to Long-and Short-Term Disability and Workers' Compensation for Employees with Diabetes

Richard Brook | Nathan Kleinman | Ian Beren United States

Real World Evidence in Effectiveness, Safety, and Cost Savings of Generic Levothyroxine: A Systematic Review

Jingjing Qian | Kaniz Afroz Tanni United States

Risks of Cardiovascular and Kidney Events Associated with Proton Pump Inhibitor Use Among Medicare Beneficiaries: A Retrospective New User Cohort Study

Ahmed Ullah Mishuk | Philippe Gaillard | Salisa Westrick Jingjing Qian United States Safety Profile Analysis of Sunitinib and Dasatinib Protein Kinase Inhibitors Using FDA Adverse Event Reporting System (FAERS) Database

Fatimah Alyami | Jeff Guo United States

The Effect of Prescriber, Treatment, and Client Characteristics on Retention in Opioid Agonist Treatment: A 15-Year Retrospective Cohort Study

Chrianna Bharat | Sarah Larney | Sebastiano Barbieri Timothy Dobbins | Nicola Jones | Matthew Hickman Natasa Gisev | Robert Ali | Louisa Degenhardt *Australia* 

## The Impact of COVID-19 on Telemedicine Use and Patients' Characteristics

Gilwan Kim | Xue Song United States

## The Use of Real-World Data in Research in the GCC Countries: A Descriptive Study

Abdullah Alalwan | Yasser Albogami | Zakiyah Alkherb Amani Alshahrani | Waad Aljrarri | Adel Alrwisan Saudi Arabia

Trends from 2001 to 2019 in Workers Compensation Indemnity Payments and Absences Among Employees with Bone Diseases, Headaches/ Migraines, Diabetes, Multiple Sclerosis, Osteoarthritis, Rheumatoid Arthritis and Back Pain

Richard Brook | Nathan Kleinman | Ian Beren Justin Schaneman United States

#### Trends in Absence Time and Payments due to Longand Short-Term Disability and Workers' Compensation for Employees with Rheumatoid Arthritis

Richard Brook | Nathan Kleinman | Ian Beren United States

#### Understanding Oral Anticoagulant Preferences of Patients with Atrial Fibrillation in China and Willingness-To-Pay: Evidence from a Discrete Choice Experiment

Jiaxi Zhao | Hao Wang | Xue Li | Yang Hu | Vincent Yan Carlos Wong | Yutao Guo | Marco Cheung | Gregory Lip Chung-Wah Siu | Hung-Fat Tse | Esther Chan *Hong Kong* 

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### Characterizing Real-World Treatment Patterns Among Patients Hospitalized Due to SARS-CoV-2

Rohit Vashsiht | Ayan Patel | Lisa Dahm | Charles Wilson Atul Butte

United States

#### Identifying Dipeptidyl Peptidase-4 Inhibitor Users with Sufficient Data Completeness in Electronic Health Records

Chi-Chuan Wang | Chien-Ning Hsu | Kelly Huang Fang-Ju Lin | Huang-Tz Ou | Ling-Ya Huang Hsiao-Ching Kuo | Sengwee Toh *Taiwan* 

#### Inception to ConcePTION: a Conceptual Framework for Characterizing Pharmacoepidemiologic Data Sources. A Study from the ConcePTION Project

Romin Pajouheshnia | Nicolas Thurin | Giuseppe Roberto Caitlin Dodd | Giulia Hyeraci | Claudia Bartolini Olga Paoletti | Hedvig Nordeng | Helle Wallach-Kildemoes Vera Ehrenstein | Elena Dudukina | Thomas MacDonald Giorgia De Paoli | Maria Loane | Christine Damase-Michel Anna-Belle Beau | Cécile Droz-Perroteau | Régis Lassalle Karin Swart-Polinder | Tania Schink Netherlands

#### Study Validity in Sports Medicine: A Quantitative Assessment of Orthopedic Research Based on Publicly-Obtained Data

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Use of Knowledge Bases in Medical Education: Medical Students' Perspective Hager Ali Saleh Sweden

#### MEDICAL DEVICES

#### Efficacy and Effectiveness of Mobile Health Technologies to Improve Breastfeeding: Scoping Review

Lívia Marengo | Alanis Santos | Laura Maricato Maria Raquel Fernandes Cristiane de Cassia Bergamaschi Motta Silvio Barberato-Filho *Brazil* 

#### Efficacy of the OptiMEDsTool for Multidisciplinary Medication Review in Belgian Nursing Homes

Maarten Wauters | Monique Elseviers | Robert Vander Stichele | Tinne Dilles | Geert Thienpont Thierry Christiaens Belgium

#### Evaluation of Drain Use During Total Knee Replacement Associated with Health Outcomes and Healthcare Utilization

Chantal Holy | Ashley Holub | A Manoranjith | Bidusee Ray Kota gopi Nath | Aatheep Gurubaran | Daniel Hoeffel Juan Daccach United States

#### Feasibility and Acceptability of the OptiMEDs Tool for Multidisciplinary Medication Review in Belgian Nursing Homes

Maarten Wauters | Monique Elseviers Robert Vander Stichele | Tinne Dilles | Thierry Christiaens Belgium

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Health Economics Analysis and Quality of Life of Patients Undergoing Primary Total Knee Arthroplasty (TKA) from China ATTUNE® Study

Ming Zhang | Xin Qi | Huiwu Li | Yinghui Liu | Zhuo Chen | Ming Dong | Chen Zhang | Shudong Zhang *China* 

Transcatheter and Surgical Aortic Valve Replacement: Patient Characteristics and Outcomes Lawrence Rasouliyan | Vikas Kumar | Stacey Long | Mitesh Rao United States

#### METHODS IN PHARMACOEPIDEMIOLOGY

Can We Really Trust the Findings of the COVID-19 Research? Quality Assessment of the Randomized Controlled Trials Published on COVID-19 Athira Joshy | Saphal Surendran | Krishna Undela India

Can We Really Trust the Findings of the COVID-19 Research? Quality Assessment of the Research Articles Published on COVID-19

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#### Challenges in Studying COVID-19 Treatments in Real-World Hospital Datasets: A Case Study of Tocilizumab

Ruth Owen | Nawab Qizilbash | Stuart Pocock Ignacio Méndez | Sara Velázquez Díaz José María Castellano Vázquez *United Kingdom* 

#### Clinical Notes vs Diagnosis Codes in Identification and Characterization of Women with Endometriosis

Carrie Huisingh | Stacey Missmer Hsiao- Ching Huang | Brenda Hinman-McIlroy Stephanie Chiuve United States

## Creating High Quality External Control Arms from RWD in Support of Regulatory Decision Making

Aaron Kamauu | Tom Haskell | Usman Aman Michael Fronstin United States

#### Determining the Accuracy of Developing New User Cohorts using Electronic Health Record Data

Raj Desai | Steven Smith United States

#### Evaluating the Completeness of Electronic Health Records in Identifying Nonfatal Cardiovascular Events in Taiwan

Yun-Yi Pan | Chi-Chuan Wang | Fang-Ju Lin *Taiwan* 

## Experimenting with County-level COVID-19 Data as a Substitute for Demographic Information

Joyce Pak | Jennifer Lund | Michael Webster-Clark United States

#### External Control Arms to Contextualise Single Arm Clinical Trials – Propensity Score Methods can be Inconsistent

Emily Peach | Sajan Khosla United Kingdom

#### Four Competing Definitions of Morphine Equivalence Insidiously Inhibit Evidence Synthesis

Nabarun Dasgupta | Yanning Wang | Jungjun Bae Alan Kinlaw | Brooke Chidgey | Toska Cooper Chris Delcher *United States* 

#### Fracture Outcome Coding in Observational Osteoporosis Drug Effects Studies: A Scoping Review

Natalia Konstantelos | Anna Rzepka | Andrea Burden Angela Cheung | Sandra Kim | Paul Grootendorst Suzanne Cadarette *Canada* 

#### Genetic Heterogeneity Patterns of Electronic Medical Record (EMR)-Derived Race Groups in a Deidentified Clinico-Genomic Database (CGDB)

Charlotta Früchtenicht | Yanling Jin, Janis Allen Sharon Boose-Sheppard | Anne-Marie Meyer Altovise Ewing | Melanie Huntley *Switzerland* 

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Graphical Representation of Multiple Quantitative Bias Analysis Scenarios for Unmeasured Confounding

J. Bradley Layton | Ryan Ziemiecki | Heather Danysh Alicia Gilsenan | Catherine Johannes *United States* 

#### Handling with Vaccine Type Missing Data in a Dynamic Cohort to Assess the Link Between Time-Varying Vaccination and an Autoimmune Disease

Belen Castillo Cano | Marc Comas-Cufí Elisa Martín-Merino Spain

#### How COVID-19 Randomized Controlled Trials Reported on Demographic and Clinical Characteristics

Joyce Pak | Jennifer Lund | Alexander Keil Daniel Westreich | Til Stürmer | David Wohl | Claire Farel M. Bradley Drummond | Michael Webster-Clark United States

#### Identification of a Diagnostically Complex Condition, Polycystic Ovarian Syndrome, in a Population-Based Cohort Using Electronic Health Record Data

Onchee Yu | Jennifer Covey | Jane Grafton David Cronkite | Ann Kelley | Kelly Hansen | Jan Hilpert Renate Schulze-Rath | Susan Reed United States

#### Identification of Appropriate Safety Metrics in Long-Term Studies

Mat Soukup | Clara Kim | Taehyun Jung United States

#### Identification of Patients with NonAlcoholic Steatohepatitis (NASH) in an Electronic Health Record (EHR) Database

Monica Bertoia | John Seeger | Erik Ness Thomas Capozza | Lina Titievsky *United States* 

#### Imbalanced Data Bias in Logistic Regression to Estimate Treatment Effects: Results from a Virtual Patient Cohort Simulation

Hankil Lee | Izabela Annis | Ryan Hickson | Gang Fang South Korea

### Impact of Increasing Enrollment Requirements in Administrative Claims Data

Liza Gibbs | Irisdaly Estevez | Katherine Gilpin Elizabeth Garry United States

#### Matching Study Design to Prescribing Intention: The Prevalent New User Design in Opioid Research

Bethany DiPrete | GYeon Oh | Daniela Moga Nabarun Dasgupta | Svetla Slavova | Emily Slade Chris Delcher | Brian Pence | Shabbar Ranapurwala *United States* 

#### Methodologic Challenges and Considerations for the Collection of Dietary Intake Data in Real-World Populations

Neil Brett | Marielle Basse | Mengyin Hong Mary Kay Margolis *Canada* 

## Methods and Practical Considerations in Use of an External Control to Assess Potential Drug Risk

George Reed | Amy Schrader | Ann Madsen Kate Saunders | Heather Litman | Jamie Geier *United States* 

#### Modeling Parasite Clearance Curves in a Cohort to Compare Quinine and Artesunate for the Treatment of Pediatric Cerebral Malaria

Rima Izem | Alexuse Saidi | Geoffrey Guenther Xiaojun Chen | Karl Seydel | Douglas Postels *United States* 

## Multimorbidity Measures from Health Administrative Data: A Systematic Review

Marc Simard | Elham Rahme | Alexandre Campeau Calfat Caroline Sirois Canada

#### NSAIDs and Paracetamol-Induced Hepatotoxicity: A Systematic Review and Meta-Analysis of Observational Studies

Sara Nafisi | Arzu Baygul | Ezgi Gulmez *Turkey* 

## Primary Non-Adherence in Primary Care in the Netherlands

Mirjam Hempenius | Simone Rijken | Rolf Groenwold Anthonius de Boer | Olaf Klungel | Helga Gardarsdottir *Netherlands* 

#### Prognostic Impact of Three Comorbidity Indices on 1 Year Mortality Among Patients with Hip Fracture

Morten Madsen | Pia Kristensen | Alma Pedersen Denmark

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## Propensity Score Modeling to Reduce Channeling Bias when Exposure is Rare

Julia Pitino | Jennifer Polinski | Brenda Hinman-McIlroy Michael Snabes | Dionna Attinson | Stephanie Chiuve *United States* 

#### Quantitative Bias Analyses in the Absence of a Gold Standard: An Application using Linked EHR and Claims Data to Evaluate Prolonged Opioid Use Following Surgery

Jessica Young | Nabarun Dasgupta | Virginia Pate Til Stürmer | Brooke Chidgey | Michael Hudgens Michele Jonsson Funk *United States* 

#### Real-World Algorithms in Defining Castration Resistant Prostate Cancer in Retrospective Observational Studies

Elham Heidari | Mehmet Burcu | Sameer Ghate | Irene Shui United States

#### Recent Use of External Controls in Clinical Trials: A Pragmatic Literature Review

Brian Buysse | Jessica Albano United Kingdom

#### Risk of Thrombotic Microangiopathy with Tyrosine Kinase Inhibitors: A disproportionality Analysis from VigiBase and AERS databases

Luis Velez-Nandayapa | Amit Saxena | Anusmita Das Miguel Izquierdo | Sai Li | Paul W Manley | Maria Nicolaides Pierre de Zeeuw | Alicia Rossite | Johannes Eisinger Christiane Michel

Switzerland

#### Socio-Epidemiological Approaches in Designing and Modelling Pharmacy Public Health Programs in Infectious Diseases Control in Developing Countries

Waseem Ullah | Hadi Almansour | Bandana Saini Gul Majid Khan Pakistan

#### Surveillance of Postmarketing Risk-Mitigation Behavior Using Tests of Model Misspecification in a Statistical Process Control Framework

Harris Butler | Elaine Morrato | Nichole Carlson | John Rice United States

## The Effect of Aspirin on COPD: A Methodological Review of the Observational Studies

Anirudh Bakshi | Samy Suissa Canada

The Use of Uncertain Exposure – A Method to Define Switching and Add-On in Pharmacoepidemiology Laura Pazzagli | Marie Linder | Reutfors | Lena Brandt *Sweden* 

## The Utility of Non-Specific ICD-10 Z3A Codes in Estimating Gestational Age

Monica Bertoia | Li Zhou | Michael Doherty Florence Wang | John Seeger United States

#### Using Negative Control Outcomes to Assess the Comparability of Treatment Groups Among Postmenopausal Women Switching Osteoporosis Therapy

Leah McGrath | Min Kim | David Pritchard | Ying Yu Peter Samai | Akhila Balasubramanian | Jay Lin Leslie Spangler | Robert Stad | Brian Bradbury M. Alan Brookhart *United States* 

#### Validation of Self-Reported Medication Use Applying Untargeted Mass Spectrometry-Based Metabolomics Techniques in the Rhineland Study

Nersi Alaeddin | Folgerdiena Maria de Vries Julia Carolin Stingl | Monique Maria Bernadette Breteler *Germany* 

## Variation Among Pharmacists in Calculating Days' Supply

Patricia Freeman | Nabarun Dasgupta | John Brown Maryalice Nocera | Svetla Slavova *United States* 

#### E P I D E M I O L O G Y / B I O M A R K E R S / P H A R M A C O G E N E T I C S

#### A Survey of HLA-B 1502 Genotype Testing on Carbamazepine New User in a Regional Teaching Hospital in Taiwan, 2019

Suhan Hsu Taiwan

#### Role of D-dimer on Serious Outcomes Among Patients Hospitalized with COVID-19

Caihua Liang | Rachel Ogilvie | Li Zhou | Michael Doherty Robert Gately | Andrea Chomistek | Jessica Franklin Florence Wang | John Seeger *United States* 

#### Triglyceride Levels in Early Type 2 Diabetes and Their Association with Cardiovascular Risk: A Danish Cohort Study

Frederik Kristensen | Diana Christensen | Kevin Olesen Michael Maeng | Henrik Sørensen | Reimar Thomsen Denmark

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#### Chronic Prescription Medications and Prevalence of Polypharmacy in Survivors of Childhood Cancer

Celeste Ewig | Yi Man Cheng | Hoi Shan Li | Jasper Wong Alex Cho | Freddie Poon | Chi Kong Li | Yin Ting Cheung *Hong Kong* 

#### Comparison of Pediatric Antibiotherapy in Primary Care: Low vs High Prescribers

Volkan Aydin | N Ipek Kirmizi | Omer Atac | Narin Akici Ahmet Akici *Turkey* 

#### Deterministic Linkage of Pregnant Mothers and Their Newborns in Integrated US Insurance Claims and Electronic Health Record Data

Stephen Schachterle | Charles Wentworth | Richard Gong | Francesca Kolitsopoulos | Negar Aliabadi | Iona Munjal Eileen Farnon | Ann Madsen | Xiaofeng Zhou United States

## Hypnotic Drug Use and Underlying Diagnoses Among Adolescents in Norway

Mohammad Nouri Sharikabad | Svetlana Skurtvei Hilchen Sommerschild | Kristine Olsen | Ingeborg Hartz Rikke Wesselhöft | Vidar Hjellvik | Lars Johan Hauge Marte Handal *Norway* 

#### Monitoring of Adverse Drug Reaction-Related Parameters in Children, Youth and Young Adults Prescribed Antipsychotic Drugs by General Practitioners

Lenneke Minjon | Els van den Ban | Marloes Bazelier Arief Lalmohamed | Toine Egberts | Eibert Heerdink Netherlands

#### Overdose Risk Following Prescription Benzodiazepine Treatment in Young People

Greta Bushnel | Mark Olfson | Tobias Gerhard United States

#### Paediatric Outpatient Prescriptions in Countries with Advanced Economies in the 21st Century: A Systematic Review and an International Comparison

Marion Taine | Lucile Offredo | Alain Weill Rosemary Dray-Spira | Mahmoud Zureik Martin Chalumeau *France* 

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Systematic Review and Meta-Analysis: Efficacy and Safety of Medical Cannabis in Children Nir Treves | Noa Mor | Matitiahu Berkovitch | Orit Stolar | Ilan Matok Israel

Use of Non-Insulin Antidiabetic Drugs in Children and Young Adults – A Scandinavian Drug Utilization Study from 2010-2019

Helene Kildegaard | Lotte Rasmussen | Kari Furu | Øystein Karlstad | Marie Linder | Carolyn Cesta | Anton Pottegård Denmark

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#### Automating Individual Case Safety Report Identification within Scientific Literature using Natural Language Processing

Michael Glaser | Carolyn Cranfield | Daniel Dsouza Angela Duma | Kevin Hastie | Raymond Kassekert Andrew Bate

United States

#### A Comparison of Data Mining Algorithms Using Different Drug Classifications for Signal Identification

Vivian Dang | Cindy Kortepeter | Monica Munoz United States

#### A Counterfactual Approach to Minimize Channeling Bias in Post-Market Safety Surveillance

Julia Pitino | Jennifer Polinski | Brenda Hinman-McIlroy Michael Snabes | Dionna Attinson | Stephanie Chiuve United States

#### A Pharmacovigilance Analysis of Restless Legs Syndrome Treatments and Suicidality

Brianna Costales | Rachel Matthews | Joshua Brown Amie Goodin *United States* 

#### A Review of the Sampling Methodology Used in Studies Evaluating the Effectiveness of Risk Minimization Measures in Europe

Mariana Almas | Tulika Paul | Sophie Jouaville *Portugal* 

#### A Systematic Review of Non-Small Cell Lung Cancer Treatment-Related Cardiotoxicity

Stefanie Ho Yi Chan | Yasmin Khatib | Sherael Webley Deborah Layton | Sam Salek United Kingdom

#### A Tenfold Increase in the Rate of Adverse Drug Event Reports in Saudi Arabia

Eman Khalid AlQadheeb | Muhanad AlHarbi Mobarak Al-Shahrani Saudi Arabia

#### Adverse Drug Reactions and its Evaluation in Saudi Arabia; Retrospective Observational Study

Khalidah Alenzi | Najah Alenzi | Mohammed Almalki Hamod Alomrani | Monirah Alnakhibe | Turkiah Alanazi Fawziah Alqubali | Moshari Alghamdi | Sultan Dighriri *Saudi Arabia* 

#### Adverse Events Associated with Remdesivir in COVID-19 Patients: Evaluation of Spontaneous Reports Submitted to US FDA Adverse Event Reporting System (FAERS)

Jahnavi Yalamanchili | Reddy Neha | Viswam Subeesh Nair Gouri | Faizan Mazhar India

#### Adverse Events in COVID-19 Patients Treated with Lopinavir/Ritonavir: Exploration of US FDA Adverse Event Reporting System (FAERS) Reports

Jahnavi Yalamanchili | Viswam Subeesh | Nair Gouri Faizan Mazhar India

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Adverse Reactions to Dolutegravir Reported to the National HIV & Tuberculosis Health Care Worker Hotline in South Africa

Gayle Tatz | Hannes Mouton | Anri Uys | Briony Chisolm Annoesjka Swart | Karen Cohen South Africa

Analysis of Voluntarily Reported Medication Errors: An Excerpt from a Teaching Hospital in a Developing Country

Jehath Syed | Sri Harsha MPharm | Ramesh India

Aromatase Inhibitors Associated with Sjogren's Syndrome: A Disproportionality Analysis in Spontaneous Reporting Database

Subeesh Viswam | Siyad Kalamveettil India

Assessing the Post Marketing Experience of Clopidogrel and Major Cardiovascular Events after PCI in Saudi Arabia using the Saudi Food and Drug Authority (SFDA) Spontaneous Reporting System Rayan Alolayet | Abdulrahman Alnuaim | Muhanad AlHarbi Mobarak Al-Shahrani

Saudi Arabia

Assessment of Adherence to Deferasirox Risk Minimization Measures in Saudi Arabia

Fares Alrubaish | Wed AlGhannam | Laila Abu Esba Adel Alrwisan | Fawaz AL-Harbi Saudi Arabia

Assessment of Drug Related Problems at a Tertiary Care Teaching Hospital

Jincy Kurian | Lincy George

Assessment of the National Pharmacovigilance System in Nepal using the Indicator Based Pharmacovigilance Assessment Tool (IPAT)

Nisha Jha | Subish Palaian | Pathiyil Ravi Shankar Santosh KC | Pan Bahadur Kshetri Nepal

## Benzodiazepine Use, Nonmedical Use, and Overdose in the US

Saranrat Wittayanukorn | Amy Seitz | Daniel Bak Rose Radin | Sara Karami | Nabila Sadiq | Rajdeep Gill Jana McAninch United States

Biliary Toxicity of Immune Checkpoint Inhibitors: A Pharmacovigilance Study Through FDA Adverse Event Reporting System Database

Qixiang Guo | Wenchao Lu | Tiansheng Wang | Zhixia Zhao China

#### Cardiovascular Safety Assessment of Febuxostat and Allopurinol in the Real World: A Retrospective Cohort Study

Pei-Yuan Hung | Hui-Hsia Hsieh | Tien-Yuan Wu Chi-Hua Chen Taiwan

Cardiovascular Safety Profile of Romosozumab: A Pharmacovigilance Analysis of the US Food and Drug Administration Adverse Event Reporting System (FAERS)

Annika Kvist | Junaid Faruque | Andrea Burden Switzerland

#### Cefoperazone and the Risk of Bleeding: A Systematic Review and Network Meta-analysis

Nora Al Orf | Mona Almaghrabi | Fawaz AL-Harbi Abdulaali Almutairi Saudi Arabia

#### Community Pharmacists Managed Patient Safety Program for Elderly Patients During COVID-19 Pandemic: A Pilot Study from UAE

Bayan Dawood | Muaed Al Omar | Subish Palaian United Arab Emirates

#### Community Pharmacists Managed Patient Safety Program with Minimal Patient Contact for Elderly Patients in Ajman, United Arab Emirates

Bayan Dawood | Muaed Al Omar | Subish Palaian United Arab Emirates

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Comparative Risk of Delirium Associated with Oxybutynin and Solifenacin in Older Adults

Te-yuan Chyou | Prasad Nishtala New Zealand

Comparison of Safety Signals Between Selective Serotonin-Reuptake Inhibitors (SSRI) and Serotonin–Norepinephrine Reuptake Inhibitors (SNRI) Employing FDA Adverse Event Reporting System (FAERS) Database

Christa Titus | Eswaran Maheswari | Viswam Subeesh India

#### Comparisons of Effect Estimates of 12 Prescribing Cascades Using Prescription Sequence Symmetry Analysis

Shih-Tsung Huang | Yu Chen | Tsui-Chuan Hsu Li-Ning Peng | Fei-Yuan Hsiao | Liang-Kung Chen *Taiwan* 

#### Detecting Drug-Drug Interaction Signal of Concomitant use of Tramadol and SSRI using Korea Adverse Event Reporting System Database

HeHyun Won | Hyunyoung Choi | Na-Young Jeong Nam-Kyong Choi South Korea

#### Detecting Tizanidine and CYP1a2 Inhibitor Interaction Signals using the Food and Drug Administration's Adverse Event Reporting System

Lorenzo Villa Zapata | Richard Boyce Ainhoa Gomez-Lumbreras | John Horn | Daniel Malone *United States* 

Drug-Induced Liver Injury Associated with Lopinavir-Ritonavir in Patients with COVID-19: A Disproportionality Analysis of U.S. Food and Drug Administration Adverse Event Reporting System (FAERS) Data

Huilin Tang | Liyuan Zhou | Xiaotong Li | Alan Kinlaw Jeff Yang | Andrew Moon | Edward Barnes Tiansheng Wang *United States* 

#### Dupilumab Use and Potential Risk of Alopecia Areata: A Systematic Review

Lama Alhusayni | Nouf AL-Fadel | Fawaz AL-Harbi Saudi Arabia

## Estimation of Adverse Events Scale Relating Korean Medicine in Korea

Yeonju Woo South Korea

#### Evaluating the Use of Prescription Sequence Symmetry Analysis as a Pharmacovigilance Tool: A Scoping Review

Earl Morris | Ann-Kathrin Hofer | Hemita Bhagwandass Razanne Oueini | Lauren Adkins | Jesper Hallas Scott Vouri *United States* 

#### Evaluation of Availability of Information on Risk Factors in Reports of Adverse Drug Reactions in a Pharmacovigilance Database

Dennis van Eijl | Florence van Hunsel Netherlands

#### Evaluation of Chirality for Withdrawn Drugs

Ayfer Bahar | Caner Vizdiklar | Volkan Aydin | Ahmet Akici *Turkey* 


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Evaluation of Potential Drug-Drug Interactions Among Patients of the Nephrology and Kidney Transplant Wards of a Major Teaching Hospital

Shahriyar Shahbazi Khamas | Atefeh Jafari Iran

Excess Risk of Anaphylaxis with Concomitant Use of Qingkailing Injection and Cefotaxime Sodium: An Example of Novel Herbal-Drug Interaction Haona Li | Jianxiong Deng | Peiming Yu | Xuequn Ren *China* 

Identification of Novel Safety Signals of SGLT2 Inhibitors: A Pharmacovigilance Analysis of the USFDA and Global Adverse Event Reporting Databases Hibathulla P | Krishna Undela India

Identification of Novel Safety Signals of SGLT2 Inhibitors: Analysis of USFDA and Global Safety Databases

Hibathulla P | Krishna Undela India



### Individual Case Safety Reports Analysis for Patients with Diabetes Mellitus on Insulin in Africa and the Middle East

Charity Mlotshwa | Johanita Burger | Martine Vorster Dorcas Rakumakoe | Marike Cockeran South Africa

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

Samantha Lane | Elizabeth Lynn | Jim Slattery Saad Shakir *United Kingdom* 

### Medication Error Concept and Reporting Practices in Saudi Arabia: A Nationwide Study Among Healthcare Professionals

Faizah Alshammari | IV | Entisar Alanazi | Afnan Alanazi Abdulrahman Alturifi | Thamir Alshammari *Saudi Arabia* 

### Montelukast and Nightmare – Further Characterisation using Data from VigiBase

Qun-Ying Yue | Marian Attalla | Henric Taavola Sarah Watson | Elenor Kaminsky Sweden

### Motives to Report Adverse Drug Reactions to the National Agency: A Survey Study Among Healthcare Professionals and Patients in Croatia, the Netherlands, and the UK

Sieta de Vries | Petra Denig | Adriana Andrić Marina Dimov Di Giusti | Alicia Ptaszynska-Neophytou Linda Härmark | Peter Mol Netherlands

### Olanzapine and Potential Risk of Somnambulism : A Systematic Review

Saja Al-Habardi | Waad Al-Tayyar | Nouf Al-Fadel Fawaz Al-Harbi Saudi Arabia

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### Pediatric Fentanyl Overdose within an Electronic Health Record Database

Rachel Ogilvie | Nan Liu | Bruce Turnbull | Rachel Bonfanti Kyle Irwin | Alana Coulter | Shara Ambrosecchia Mahlaqa Patel | Drusilla Scott | John Seeger Cheryl Enger United States

### Periodic Safety Reporting System for Post-Market Drug Safety: A Comparative Analysis of Europe, United States, Japan and Korea

Yun-Kyoung Song | Seung-Mi Lee | Green Bae South Korea

### Pharmacists Role in Patient Safety:

Evaluation of Dispensing Errors in a Regional Hospital

Isabela Rufo Cordeiro Vieira | Amanda Araújo Carolina Franco | Lucas Silva | Renata Nascimento Liliane Pereira *Brazil* 

### Post-Keratoplasty Fungal Keratitis in the Sentinel Distributed Database: Prevalence and Time Trends

Tancy Zhang | Sheryl Kluberg | Mayura Shinde Dave Martin | Katherine Dea | Scott Brubaker Brychan Clark | Christopher Jason | Cindy Zhou Joyce Obidi | Kinnera Chada | Azadeh Shoaibi Hui-Lee Wong United States

### Post-Marketing Drug Safety Sources: An Evaluation of the FDA's Drug Safety Communications

Atheer Aldayel | Maha alGhamdi | Abdulaali Almutairi Fawaz Al-Harbi Saudi Arabia

### Psoriasis Risk After Betablockers Exposure: Analysis of French Pharmacovigilance Data

Brahim Azzouz | Elise Lepoix | Quentin Mathieu Jarrion Aurore Morel | Thierry Trenque, *France* 

### Remdesivir Safety Monitoring during the COVID-19 Pandemic: A Global Review of Adverse Drug Reaction (ADR) Reporting in VigiBase

Sara Hedfors Vidlin | Elena Rocca | Oskar Gauffin Ruth Savage | Birgitta Grundmark Sweden

### Reporting of Pancreatitis with Tocilizumab use: A Disproportionality Analysis Using the United States Food and Drug Administration Adverse Event Reporting System

Ashwin Kamath | Sahana Acharya | Rashmi Rao Sheetal Ullal India

### Review of Sytemic Adverse Drug Reactions of Vascular Endothelial Growth Factor Inhibitors in French Pharmacovigilance Data Base

Laure Badier | Leila Chebane | Samuel Tessier Agnès Sommet | Justine Benevent | Haleh Bagheri *France* 

### Risk of Cardiovascular Diseases Associated with Sulfonylurea as an Add-On Therapy to Metformin in Patients with Type 2 Diabetes Mellitus

Hoon Jeong | Eunmi Cho | Minyoung Bang Kim Soo Youn Chung | Soon Young Han South Korea

#### Risk of First Ischemic Stroke and Use of Antidopaminergic Antiemetics: A Case-Time-Control Study in France

Anne Benard-Laribiere | Emilie Hucteau Stephanie Debette | Julien Kirchgesner Bezin Antoine Pariente *France* 

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Risk of Fracture Associated with SGLT-2 Inhibitors as an Add-On Therapy to Metformin in Patients with Type 2 Diabetes Mellitus

Hyeri Yang | Eunmi Choi | Bonggi Kim | Soo Youn Chung Soon Young Han South Korea

Safety Evaluation of Panobinostat,

Ixazomib, Elotuzumab, and Daratumumab Using FDA Adverse Event Reporting System (FAERS) Database 2015-2020

Marwan Alrasheed | Abdulrahman Alsuhibani Ana Hincapie | Jianfei Guo *United States* 

Safety of Propofol use in Children and Adolescents: a Disproportionality Analysis of the Food and Drug Administration Adverse Event Reporting System (FAERS)

Hailong Li | Zhenyan Bo | Lingli Zhang China

Safety Review of Vemurafenib and Potential Risk of Hyperglycemia: A Systematic Review and Analysis of Individual Case Safety Reports in the WHO Global Database

Saja AL-Habardi | Nouf AL-Fade | Fawaz AL-Harbi Saudi Arabia

Signal Detection by Time-To-Onset Method in Conjunction with Disproportionality Analysis: A Study of Spontaneous Reports from Japan

Tsugumichi Sato | Satomi Tadauchi | Kosuke Kumano Nana Kamida | Kazuki Shimamura | Kiyoshi Kubota, Japan

### Teratogenicity Associated with Antibiotic Therapy: A Disproportionality Analysis in Spontaneous Reporting Database

Siyad Kalamveettil | Viswam Subeesh India

### The Establishment of Regional Pharmacovigilance (PV) Centers in Saudi Arabia

Rayan Alolayet | Eman Khalid AlQadheeb Muhanad AlHarbi | Mobarak Al-Shahrani Saudi Arabia

### Tocilizumab Induced Adverse Events in COVID-19 Patients: Exploration of Reports Submitted to US FDA Adverse Event Reporting System (FAERS)

Jahnavi Yalamanchili | Reddy Neha | Viswam Subeesh Nair Gouri | Faizan Mazhar India

### Trajectories of Corticosteroid Dosing Pattern Among Patients with Systemic Lupus Erythematosus

Seung-Hun You | Min Taek Lee | Ye-Jin Kang Jae-Eun Lee | Joohyeon Eom | Sun-Young Jung South Korea

### Trastuzumab Related Cardiotoxicity in Breast Cancer Hui-Hsia Hsieh | Tien-Yuan Wu | Chi-Hua Chen

Taiwan

#### Zolpidem, Zopiclone and Zaleplon Induce Complex Sleep Behaviors

Zi-Chen Wang | Hui-Hsia Hsieh | Tien-Yuan Wu Chi-Hua Chen Taiwan

### PREGNANCY AND LACTATION



### Awareness of Pregnant Women about the Spontaneous Adverse Drug Reaction Reporting System in Bulgaria- A Pilot Study

Radiana Staynova | Violeta Getova | Stoev Bulgaria

### Drug Utilization Pattern of Antiepileptic Drugs in Pregnancy and the Outcome of Offspring in Asia Population

Ching-Lan Cheng | Ju-Ling Chen | Yea-Huei Kao Yang Taiwan

### Improving Accuracy for Prospective Pregnancy Registry Enrollment Targets

Kristin Veley | Deborah Covington | Payal Pozin Rebecca Morris Buus | Sandra Okala United States

### Nucala Exposure in Women of Childbearing Age and in Pregnant Women in Us Claims Data, 2016-2019

Mary Georgiou | Sally Mountcastle | Liyuan Ma Kelsey Sumner | Keele Wurst United Kingdom

### Pregnancy and Neonatal Outcomes Associated with Opioid Assisted Treatments and Unexposed Pregnancies

Shuang Wang | Jayne Pawasauskas | Kristina Ward Xuerong Wen United States

#### Pregnancy in Women with Heart Failure: A Cross-Sectional Study in the Sentinel System

Yan Li | Austin Cosgrove | Efe Eworuke | Catherine Corey Joy Kolonoski | Mayura Shinde United States

### Risk of Domperidone in Pregnant Women: A Study in the EFEMERIS Database

Mélanie Araujo | Clémentine Vabre | Justine Benevent Agnès Sommet | Christine Damase-Michel Caroline Hurault-Delarue | Isabelle Lacroix *France* 

### Systematic Review of Prospective Pregnancy Studies in Europe: Scope for Improvement

Nawab Qizilbash | Macarena Garrido-Estepa Ana Roncero Martin Spain

### Temporal and Hospital-Level Variation in High-Dose Postpartum Opioid Prescribing after Cesarean Delivery

Andrew Wiese | Sarah Osmundson | Edward Mitchel Margaret Adgent | Sharon Phillips | Andrew Spieker Carlos Grijalva *United States* 

### Prenatal Exposure to Psychotropic Medications and the Risk of Seizure in Children: A Population-Based Cohort Study

Zixuan Wang | Adrienne Chan | Phoebe Ho | Kirstie Wong Ruth Brauer | Frank Besag | Patrick Ip | Louise Howard Wallis Lau | Li Wei | Ian Wong | Kenneth Man United Kingdom

### RARE DISEASE

### Drug-Drug Interactions in a Kidney Transplant Patient with COVID-19: A Case Report

Shahriyar Shahbazi Khamas | Atefeh Jafari *Iran* 

### Global Symptom Improvement for Patients with Aromatic L-Amino Acid Decarboxylase Deficiency Using Individual Participant Data

Claire Simons | Josef Paris | Craig Bennison Katharina Buesch United Kingdom

#### Knowledge and Awareness of the General Population and Healthcare Providers about Retinoblastoma: It is Time to Know the Glow

Abdallah Naser | Hamzeh Alrawashdeh | Hassan Alwafi Hamad Alyami | Eman Zmaily Dahmash | Imene Ghoul Anas Amin Shishtawi | Ghada Abdelwahab | Sami Qadus Esra' Taybeh | Rasha Abuthawabeh | Fadi Hassanin Yosra Alhartani | Mohammad Alyami | Emad Salawati Salwan Salah Alwan

### Prevalence of Extramammary Paget's Disease in Urban China: A Population-Based Study

Lu Xu | Shilu Yin | Shengfeng Wang | Siyan Zhan Zhenmin Zhao *China* 

### Real-World Adherence of Nusinersen for the Treatment of Spinal Muscular Atrophy (SMA) Using US Electronic Health Records

Nicole Johnson | Nasha Wang | Bora Youn Angela Paradis | Emma Viscidi | Susan Eaton | Sue Hall *United States* 

### Urban Prevalence of Multiple Sclerosis in China: A Population-Based Study in Six Provinces

Lu Xu | Lu Chen | Shengfeng Wang | Siyan Zhan Dongsheng Fan *China* 

### SAFETY END POINTS

A Retrospective Database Study to Evaluate Incidence of Influenza and Influenza-like Illness (ILI) Among Rheumatoid Arthritis (RA) Patients Taking conventional Synthetic Disease Modifying Antirheumatic Drugs (csDMARD)

Kathy Liu | Oladayo Jagun | Jayashri Desai Xiaofeng Zhou *United States* 

### Adverse Events in NSCLC Patients Treated with Docetaxel Monotherapy

Yangyang Liu | E. Tyczynski | Zhang | Christy Choi | Wolff United States

Association Between the Multiple Myeloma Treatments and Vascular Adverse Events in Taiwanese Multiple Myeloma Patients: A Population-Based Cohort Study

Mei-tsen Chen | Shih-Tsung Huang | Bor-Sheng Ko Huai-Hsuan Huang | Fei-Yuan Hsiao Taiwan Cohort Study Assessing Angioedema Risk in Black Heart Failure Patients Using Angiotensin-Converting Enzyme Inhibitors in the United States– Interim Results John Connolly | Aaron Mendelsohn

Carla Rodriguez-Watson | Cheryl McMahill-Walraven Mano Selvan | Margaret Adgent | Pamala Pawloski Sigrid Behr | Jeffrey Brown | Raymond Schlienger United States

#### Comparison of the Incidence of Bleeding Between Anti-Influenza Drugs Among Outpatients for the Influenza Virus Infection: A Retrospective Study Using an Employment-Based Health Insurance Claims Database in Japan

Azusa Hara | Kanae Hara | Takuji Komeda | Eriko Ogura Shogo Miyazawa | Chiduru Kobayashi | Masakazu Fujiwara Manami Yoshida | Hisashi Urushihara *Japan* 

### SAFETY END POINTS

### Conduction Disorders/Dysrhythmias and Hydroxychloroquine in Rheumatoid Arthritis

Cristiano Moura | Marina Machado | Celline Almeida-Brasil Jeffrey Curtis | Sasha Bernatsky *Canada* 

#### Determinants of Intravenous Admixture Preparation Errors: A Prospective Observational Study

Janique Jessurun | Nicole Hunfeld | Joost van Rosmalen Monique van Dijk | Patricia van den Bemt Netherlands

Diagnostic Delay, Effectiveness and Safety Outcomes in a Real-World Cohort of Patients with Crohn's Disease: Data from Administrative Databases in Tuscany, Italy

Sara Ferraro | Claudia Bartolini | Convertino Lorenzo Bertani | Sabrina Giometto | Emiliano Cappello Giulia Valdiserra | Silvia Tillati | Corrado Blandizzi Ersilia Lucenteforte | Francesco Costa | Rosa Gini Marco Tuccori Italy

#### Incidence of Angioedema after Initiation of Angiotensin-Converting Enzyme Inhibitors in Adults with Heart Failure

Jennifer Kuntz | Eric Johnson | Alan Go | Kristi Reynolds Andrea Cassidy-Bushrow | Douglas Roblin Matthew Slaughter | Denis Nyongesa | Amanda Petrik Sigrid Behr | Raymond Schlienger | David Smith United States

### Independent and Synergistic Effects of Systemic Corticosteroid Use and Air Pollution on Thromboembolic Events: A Climate-Drug Interaction Study

Soko Setoguochi | Rachel Nethery | Benjamin Bates Poonam Gandhi | Jung Hyun Kim | Kevin Josey *United States* 

NSAIDs and Risk of Myocardial Infarction in Patients with No Major Risk Factors: A Nested Case-Control Study in the UK Clinical Practice Research Datalink Brenda Nicole Baak | Susan Jick United States

### Proton Pump Inhibitors and Risk of End Stage Renal Disease in Patients with Chronic Kidney Disease

Miyuki Hsing-Chun Hsieh | Edward Chia-Cheng Lai Taiwan

### Retinal Toxicity in a Multinational Inception Cohort of Systemic Lupus Patients on Hydroxychloroquine

Celline Almeida-Brasi | John Hanly | Murray Urowitz Ann Clarke | Rosalind Ramsey-Goldman | Caroline Gordon Michelle Petri | Ellen Ginzler | Daniel Wallace Sang-Cheol Bae | Juanita Romero-Diaz Mary Anne Dooley | Christine Peschken | David Isenberg Anisur Rahman | Susan Manzi | Soren Jacobsen S. Sam Lim | Ronald Van Vollenhoven | Ola Nived *Canada* 

### Risk of Emergency Department Visits or Hospitalization for Cardiovascular Events in Patients with Medical Cannabis Authorization

Arsène Zongo | Cerina Lee | Jason Dyck Jihane El-Mourad | John G Hanlon | Elaine Hyshka Dean Eurich *Canada* 

#### Risk of Intracranial Meningioma Requiring Surgical Intervention smong Recent Hormonal Contraceptives Users

Sebastian Jugl | Si Chen | Patrick Antonelli Almut Winterstein United States

### Risk of Thyroid Cancer with the use of GLP-1 Receptor Agonists

Amandine Gouverneur | Marine Pénichon | Renaud Garrel Dominique Hillaire-Buys | Antoine Pariente Jean-Luc Faillie *France* 

### Safety and Effectiveness of Rivaroxaban in First-Time Users with Non-Valvular Atrial Fibrillation in Routine Practice

Luis Garcia Rodriguez | Ana Ruigomez | Tania Schink, Annemarie Voss | Elisabeth Smits | Karin Swart-Polinder Yanina Balabanova | Gunnar Brobert | Ron Herings *Spain* 

### Safety of Rivaroxaban in First-Time Users Treated for Deep Vein Thrombosis and Pulmonary Embolism

Ana Ruigomez | Tania Schink | Annemarie Voss Ron Herings | Elisabeth Smits | Karin Swart-Polinder Yanina Balabanova | Gunnar Brobert Luis Garcia Rodriguez *Spain* 

### SAFETY END POINTS

Stroke Risk Associated with Incident Antidepressant Use: Delineated with Age

Lu-Hsuan Wu | Ching-Lan Cheng | Yea-Huei Kao Yang Taiwan

Sulfonylureas and the Risk of Ventricular Arrhythmias Among Patients with Type 2 Diabetes: A Systematic Review of Observational Studies

Nehal Islam | Henok Tadesse Ayele | Antonios Douros Oriana Yu | Kristian Filion Canada

### The Association Between Proton Pump Inhibitors and Increased Risk of Hyponatremia – A Cohort Study

Nir Treves | Tali Shik | Bruria Raccah | Galit Shefer Israel Yoles | Ilan Matok Israel

### The Prevalence and Associated Risk Factors of Perfumes Sensitivity in Saudi Arabia

Meshael Alrasheed | Omar Albalawi | Mohammed Aljallal Amani Alqahtani Saudi Arabia

#### The Use of Lag Times in Cancer Pharmacoepidemiology

Blánaid Hicks | James Kaye | Laurent Azoulay Kasper Kristensen | Laurel habel | Anton Pottegård *United Kingdom* 

### FAST TRACK YOUR REAL-WORLD EVIDENCE NEEDS

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### VACCINES

Adverse Events of the COVID-19 Vaccines Reported to the Vaccine Adverse Event Reporting System (VAERS), December 14, 2020 - January 22, 2021

Xiangzhong XUE | Chenyu ZOU | Jingjing Qian United States

Comparison of Safety Profiles by Chronic Health Conditions in Korean Adults with Egg-Based Inactivated Quadrivalent Influenza Vaccines (QIV, GC3110A)

BongKyoo Choi | Hyunjeong Cho | Younchul Shin Eun-Kyoung Lee | Jae Woo Lee South Korea

Detecting Signals for the Vaccine-Vaccine Interaction between Pneumococcal Vaccines and Influenza Vaccines using the Korea Adverse Event Reporting System (KAERS)

Hyunyoung Choi | HeHyun Won | Na-Young Jeong Nam-Kyong Choi South Korea

Differential Demographic and Clinical Characteristics between MMR Vaccinated and Unvaccinated Children in South Korea

Ju Hwan Kim | Dongwon Yoon | Ju-Young Shin South Korea

Old Methods and New Data: A Near Real-Time Plan for Vaccine Surveillance and Signal Detection in the United States

Kristin Kostka | Marni Hall | Christian Reich Nancy Dreyer | Matthew Reynolds United States

### Papillomavirus Vaccination and Guillain-Barre Syndrome Among Girls: A Population-Based Study in Spain

Belen Castillo Cano | Mar Martín-Pérez Ana Llorente-García | Dolores Montero-Corominas Elisa Martín-Merino Spain

### Safety of COVID-19 Vaccine: Knowledge of Staff at a Medical College in Western Nepal

Sabita Paudel | Subish Palaian | Pathiyil Ravi Shankar Nuwadatta Subedi

Nepal

### Signal Detection of Zoster Vaccine Adverse Event in Elderly Using Korea Adverse Event Reporting System Database (KAERS)

Eunsun Lim | Na-Young Jeong | HeHyun Won Hyunyoung Choi | Sun-Young Jung | Ju-Young Shin Nam-Kyong Choi South Korea

### Test-Negative Designs Applied to COVID-19 Vaccine Effectiveness Assessment: Methodological Challenges

Delphine Saragoussi | Sarah Rosen | Margaret Richards United Kingdom

### The Patterns of Spontaneous Reports of Neurologic, Hematologic, and Immunologic Adverse Events Following Immunization in Korea

Min Taek Lee | Seung-Hun You | Ye-Jin Kang Jae-Eun Lee | Joohyeon Eom | Sun-Young Jung South Korea

### Use and Performance of Brighton Collaboration Case Definitions in Low-Middle Income Settings

Wan-Ting Huang | TienYu Owen Yang | Barbara Law Steve Black | Miriam Sturkenboom | Robert Chen Taiwan

### Yellow Fever Vaccine Usage in Three United States Healthcare Databases and Risk of Neurotropic Disease and Viscerotropic Disease in Vaccinees

Shaleesa Ledlie | Christina Ricci | Chunshen Pan Andrey Rojas | Alena Khromava | Lin Li *Canada* 

### POTPOURRI

### 5-Alpha Reductase Inhibitors and the Risk of Anemia Among Men with Benign Prostatic Hyperplasia

Henok Tadesse Ayele | Antonios Douros | Kristian Filion Canada

#### An Open Algorithm to Pre-Process Free Text Self-Reported Medications Data in UK Biobank

Junqing xie | Shenda Hong | Antonella Delmestri Sara Khalid | Victoria Strauss | Gary Collins Daniel Prieto-Alhambra *United Kingdom* 

#### Association Between DPP-4 Inhibitors and COVID-19 Related Outcomes Among Patients with Type 2 Diabetes

Yunha Noh | In-Sun Oh | Eol Jeong | Kristian Filion Oriana Yu | Ju-Young Shin South Korea

#### Association Between Oral Anticoagulants and Risk of Dementia in Patients with Non-Valvular Atrial Fibrillation

Alvi Rahman | Jonathan Michaud | Sophie Dell'Aniello Erica Moodie | James Brophy | Madeleine Durand Jason Guertin | Jean-Francois Boivin | Christel Renoux *Canada* 

#### Association Between the use of Oral Anticoagulant and Risk of Adverse COVID-19 Outcomes: An OpenSAFELY Analysis

Angel Wong | Laurie Tomlinson | Jeremy Brown William Elson | Alex Walker | Anna Schultze Caroline Morton | David Evans | Peter Inglesby Brian MacKenna | Krishnan Bhaskaran Christopher Rentsch | Emma Powell | Elizabeth Williamson Richard Croker | Seb Bacon | William Hulme | Chris Bates Helen Curtis | Amir Mehrkar United Kingdom

### Claims-Based Algorithm for Defining Aasthma GINA Steps in US Healthcare Database

George Mu | Rupert Jakes | Ashley Cole | Namhee Kwon United States

### Comparison of the Incidence of Acute Pancreatitis Among New Users of Fluoxetine, Citalopram, and other Selective Serotonin Reuptake Inhibitors: A Danish Register-Based Cohort Study

Mia Aakjaer | Sarah Brøgger Kristiansen | Maurizio Sessa Kathrine Pape | Kim Peder Dalhoff | Marie De Bruin Morten Andersen Denmark

### Effectiveness and Safety of Direct Oral Anticoagulants vs Warfarin in Patients with Valvular Atrial Fibrillation: A Population-Based Cohort Study

Dawwas Dawwas | Eric Dietrich | Adam Cuker Geoffrey Barnes | Charles Leonard | James Lewis *United States* 

### Ethnic Differences in COVID-19 Infection, Hospitalisation, and Mortality: An OpenSAFELY Analysis of 17 million Adults in England

Rohini Mathur | Christopher Rentsch | Caroline Morton William Hulme | Anna Schultze | Brian MacKenna Rosalind Eggo | Krishnan Bhaskaran | Angel Wong Elizabeth Williamson | Harriet Forbes | Kevin Wing Helen McDonald | Chris Bates | Seb Bacon | Alex Walker David Evans | Peter Inglesby | Amir Mehrkar | Helen Curtis United Kingdom

### Evaluation of Machine-Learning Algorithms for Predicting Direct-Acting Antiviral Treatment Failure in Patients with Chronic Hepatitis C: An HCV-TARGET Analysis

Haesuk Park | Wei-Hsuan Lo-Ciganic | James Huang Yonghui Wu | Joy Peter | Mark Sulkowski | Michael Fried David Nelson United States

### Generating Hypotheses About Never-Smoking Lung Cancer Risk Factors Using Large Primary Care Databases

Monica D'Arcy | Michael Kebede | Curt Dellavalle Mengying Li | Youjin Wang | Shahinaz Gadalla | Maria Landi *United States* 

### POTPOURRI

How Under-Coded is Pediatric Hypertension?: Comparison of Claims and Electronic Health Record (EHR) Data

Casie Horgan | Jillian Burk | Judith Maro | Efe Eworuke Danijela Stojanovic | Jennifer Lyons | Brian Kit *United States* 

#### Impact of Multimorbidity Subgroups on the Health Care Use, Expenditures, and Clinical Outcomes Among Patients with Tuberculosis: A Population-Based Cohort Analysis

Chen Qin | Tianchi Yang | Yang Che | CYue Xiao Ceng Jiang | Yanfei Chen | Jifang Zhou *China* 

### Insights from a Review of Publicly Available Information on Post Authorisation Safety Studies (PASS)

Mariana Almas | Wilhelmina Hoogendoorn Sanowar Sayeed | Stella Blackburn | Jaclyn Bosco Louise Parmenter *Portugal* 

#### Medical Cannabis Authorization and Drugs and Other Substances Use Disorders: Longitudinal Cohort Study

Arsène Zongo | Cerina Lee | Jihane El-Mourad Jason Dyck | John Hanlon | Elaine Hyshka | Dean Eurich *Canada* 

### Multi-Depth, Iterative Causal Forest for Subgroup Identification

Tiansheng Wang | Michael Kosorok | Alexander Keil Richard Wyss | Michele Jonsson Funk | John Buse Til Stürmer United States

#### Nondifferential Treatment Misclassification Biases Toward the Null? Not a Safe Bet

Rachael Ross | Michele Jonsson Funk | I-Hsuan Su United States

#### Oral Bisphosphonate Exposure Among Denosumab Users in Ontario, Canada

Anna Rzepka | Kaleen Hayes | Natalia Konstantelos Suzanne Cadarette *Canada* 

### Patterns and Predictors of Stimulant Use During Pregnancy

Meena Murugappan | PJoel Farley | Arun Kumar Stephen Contag | Katie Thorsness | Tanya Melnik Abhijeet Rajpurohit | Sarah Westberg *United States* 

### Predictors of Severe COVID-19 Outcome in Patients with Rheumatoid Arthritis

Sara Burns | Tiffany Siu Woodworth | Justin Manjourides United States

### Prescription Drug-Based Risk Scores: A Systematic Review

Hemalkumar Mehta | Lin Wang | Ioannis Malagaris Yanjun Duan | Lori Rosman | G. Caleb Alexander *United States* 

### Risk of Hospitalization and Death Associated with Pimavanserin use in Older Adults with Parkinson's Disease

Hemalkumar Mehta | Y. Joseph Hwang | Huijun An Thomas Moore | G. Caleb Alexander *United States* 

### Safety of Generic Cyclosporine in Solid Organ Transplant Patients: A Systematic Review and Meta-Analysis

Kaniz Afroz Tanni | Jingjing Qian United States

### Short-Term Incidence of Thrombotic Events in Patients who were Treated with Factor Xa Inhibitors and Hospitalized for Bleeding

Chuntao Wu | Jawad Hasan | William Smith Ryan Rumantir | Michael Li | Alexander Cole *United States* 

### The Risk of Severe Acute Kidney Injury with use of Anti-Hypertensives in the Elderly: A Self-Controlled Case Series Analysis

Eng Hooi (Cheryl) Tan | Annika Jödicke Danielle Robinson | Antonella Delmestri Daniel Prieto-Alhambra *United Kingdom* 

### POTPOURRI

Use of high-dimensional Propensity Scores (hdPS) in a Japanese National Claims Database

Jocelyn Wang | Sahar Syed | Elizabeth Garry United States

Use of Natural Language Processed Clinical Notes in an Electronic Health Record (EHR) to Characterize Adverse Events of Mood Disorders

Hsiao- Ching Huang | Carrie Huisingh Stacey Missmer Brenda Hinman-McIlroy Stephanie Chiuve United States

Use of Potential Nephrotoxic Medications Among Adults with CKD: Parallel Cohort Studies in US and Swedish Routine Care

Yunwen Xu | Alessandro Bosi Alessandro Gasparini Björn Wettermark | Peter Barany Lesley Inker | Alex Chang | Morgan Grams Juan Carrero | Jung-Im Shin *China* 

### Use of Renin-Angiotensin-Aldosterone System Inhibitors and the Risk of Acute Pancreatitis

Julie Rouette | Hui Yin | Emily McDonald Alan Barkun Laurent Azoulay Canada

### Using Structural Topic Modelling to Reveal Patterns in Reports on Opioid Drugs in a Pharmacovigilance Database

Lea Lösch | Patrick Brown Florence van Hunsel Netherlands

### Utilization and Long-Term Persistence of Direct Oral Anticoagulants Among Patients with Non-Valvular Atrial Fibrillation and Liver Disease

Antonios Douros | Ying Cui | Robert Platt | Kristian Filion Giada Sebastiani | Christel Renoux *Canada* 



### Utilization Pattern of Antipsychotics in Patients with Dementia

Hsin Min Wang | Edward Chia-Cheng Lai Taiwan

### Venous Thromboembolism in Patients with Chronic Inflammatory Skin Diseases

Maria Schneeweiss | Seoyoung Kim | Richard Wyss Yinzhu Jin | Kristyn Chin | Joesph Merola Arash Mostaghimi | Jonathan Silverberg Sebastian Schneeweiss *United States* 

### What is Time Zero for Treatment Among Hospitalized Patients with Bacteremia?

Aisling Caffrey | Vrishali Lopes United States

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**ACPE 2021** October 13-15, 2021 Seoul, Korea

**ISPE 2022 Mid-Year Meeting** April 10-12, 2022 Órlando, Florida

### **ICPE 2022**

August 24-28, 2022 Bella Center Copenhagen, Denmark

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