Real Evidence for the Real World.

August 23 - 25, 2021

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Boston University, USA

Brown University School of Public Health
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<td>Tamar Lasky, FISPE</td>
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<td>Shao-Hsien Liu</td>
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<td>Vincent Lo Re, FISPE</td>
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Congratulations to Our New Fellows

Kourtney Davis, FISPE
Solomon Iyasu, FISPE
Carol Koro, FISPE
Stephan Lanes, FISPE
Deborah Layton, FISPE

Jennifer Lund, FISPE
Annalisa Rubino, FISPE
Meredith Smith, FISPE
Shirley Wang, FISPE
Björn Wettermark, FISPE
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- Ontada
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- Veradigm

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- Oxon epidemiology

**BRONZE**
- Boston Collaborative Drug Surveillance Program
- COHRDATA
- Epi Excellence, LLC
- Harvard Pilgrim Healthcare Institute
- Takeda
- OPTUM

**ACADEMIC SHOWCASE**
- Auburn University Harrison School of Pharmacy
- Brigham and Women’s Hospital, Division of Pharmacoepidemiology & Pharmacoeconomics
- London School of Hygiene & Tropical Medicine
- John Hopkins University, Center for Drug Safety and Effectiveness
- McGill University
- University of Massachusetts Medical School, Clinical and Populations Health Research PhD Program
- University of North Carolina at Chapel Hill, Dept of Epidemiology, Gillings School of Public Health
2021 Awards

Emerging Leader Award
Christopher Rentsch

Induction of ISPE Fellows
Kourtney Davis, FISPE
Solomon Iyasu, FISPE
Carol Koro, FISPE
Stephane Lanes, FISPE
Deborah Layton, FISPE
Jennifer Lund, FISPE
Annalisa Rubino, FISPE
Meredith Smith, FISPE
Shirley Wang, FISPE
Bjorn Wettermark, FISPE

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
Chin-Yao Shen

Best Methods Abstract (Student)
Characterizing Imbalance in the Tails of the Propensity Score Distribution
Bethany DiPret

Best Drug Utilization Research Abstract (Student)
Prior Opioid Tolerance Among New Users of Transdermal Fentanyl in Taiwan, 2011-2018
Chih-Wan Lin

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 Norgaard | Bukeet 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 of 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**

3:30 - 6:00 PM  
**CONCURRENT ORAL PRESENTATIONS**

5:15 - 6:30 PM  
**SPOTLIGHT POSTERS**

**WEDNESDAY, AUGUST 25**

8:15 - 10:00 AM  
**PLENARY**

10:00 - 11:30 AM  
**CONCURRENT WORKSHOPS**

11:45 AM - 1:30 PM  
**CONCURRENT WORKSHOPS**

1:45 - 2:45 PM  
**ANNUAL MEMBER MEETING & AWARDS CEREMONY**

3:00 - 6:00 PM  
**CONCURRENT ORAL PRESENTATIONS**

5:00 - 6:00 PM  
**CONCURRENT ORAL PRESENTATIONS**

6:00 - 6:30 PM  
**CLOSING CEREMONY**

8:00 - 9:30 PM  
**PLENARY**  
*REPEATED*
Program Schedule

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 Iyasu – Merck & Co. Inc.
Patrick Ryan – Janssen Research & Development
Ameet Sarpotwari – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital and Harvard Medical School
Peter Arlett – European Medicines Agency

10:00 - 11:30 AM
WORKSHOP / CONCURRENT
Outcome Measurements for External Comparator Arms: New Opportunities for Epidemiology Methods Application and Development

METHODS IN PHARMACOEPIDEMIOLOGY

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
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

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

11:00 - 11:30 AM

**WORKSHOP / CONCURRENT**


**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 (NDORMS), University of Oxford, UK

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

**PRESENTING AUTHOR**
Yu-Jung Wei – University of Florida College of Pharmacy

**CO-AUTHOR**
Almut Winterstein – Department of Pharmaceutical Outcomes and Policy and Center for Drug Evaluation and Safety, College of Pharmacy, University of Florida
Geriatric Pharmacoepidemiology
Use of Medications with Anticholinergic and Sedative Properties and Fall-Related Fractures Among Older Adults

PRESENTING AUTHOR
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Rebecca Naumann – Department of Epidemiology, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA
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, 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
Annika Jödicke – Pharmaco- and Device Epidemiology, Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

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

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
Aisling Caffrey – Infectious Diseases Research Program, Providence Veterans Affairs Medical Center, Providence, RI, USA

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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
Program Schedule

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
Andrea Chomistek – Optum

CO-AUTHORS
Caihua Liang – Optum
Michael Doherty – Optum
Robin Clifford – Optum
Rachel Ogilvie – Optum
Robert Gately – Optum
Jennifer Song – Optum
Cheryl Enger – Optum, Boston, MA, USA
Nancy Lin – Health Catalyst
Florence Wang – Optum
John Seeger – Epidemiology, Optum, Boston, MA, USA

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
Kathleen Andersen - Johns Hopkins Bloomberg School of Public Health

CO-AUTHORS
Emaan Rashidi – Johns Hopkins Bloomberg School of Public Health
Huijun An – Johns Hopkins University
Hemalkumar Mehta – Johns Hopkins University
Derek Ng – Johns Hopkins Bloomberg School of Public Health
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

PRESENTING AUTHOR
Jessica Jalbert – Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

CO-AUTHORS
Wenhui Wei – Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA
Scott Mellis – Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA
Gregory Geba – Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA
Sumathi Sivapalasingam – Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

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
Laura Semenzato – 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

CO-AUTHORS
Jérémie Botton – 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
Jérôme Drouin – 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
François Cuenot – 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
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
Convalents Plasma Therapy and Mortality Among US Veterans Hospitalized with Non-Severe COVID-19: An Observational Analysis Emulating a Target Trial

PRESENTING AUTHOR
Katherine Kurgansky – MAVERIC, VA Boston Healthcare System

CO-AUTHORS
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Sarah Keithly – Seattle Epidemiologic Research and Information Center, VA Healthcare System
Arin Madenci – Harvard T.H. Chan School of Public Health
Hanna Gerlovin – MAVERIC, VA Boston Healthcare System
Helen Wellman – MAVERIC, VA Boston Healthcare System
Annie Doubleday – Seattle Epidemiologic Research and Information Center, VA Healthcare System
Eva Thomas – Seattle Epidemiologic Research and Information Center, VA Healthcare System
Yojin Park – MAVERIC, VA Boston Healthcare System
Yuk-Lam Ho – VA Boston Healthcare System
Jonathan Sugimoto – Seattle Epidemiologic Research and Information Center, VA Healthcare System
Kathryn Moore – Seattle Epidemiologic Research and Information Center, VA Healthcare System
Alexander Peterson – Seattle Epidemiologic Research and Information Center, VA Healthcare System
Constance Hoag – MAVERIC, VA Boston Healthcare System
Kalpana Gupta – Veterans Administration Boston Healthcare System
Karen Jeans – Department of Veterans Affairs Office of Research and Development
Molly Klobe – Department of Veterans Affairs Office of Research and Development
Rachel Ramoni – Department of Veterans Affairs Office of Research and Development
Grant Huang – Department of Veterans Affairs Office of Research and Development
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David Gagnon – MAVERIC, VA Boston Healthcare System
Miguel Hernán – Departments of Epidemiology and Biostatistics, Harvard T.H. Chan School of Public Health
Nicholas Smith – Seattle Epidemiologic Research and Information Center, Department of Veterans Affairs
J. Michael Gaziano – MAVERIC, VA Boston Healthcare System

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
James Heyward – Johns Hopkins Center for Drug Safety and Effectiveness

CO-AUTHORS
Kathryn Foti – Johns Hopkins Center for Drug Safety and Effectiveness
Matthew Tajanlangit – Johns Hopkins Center for Drug Safety and Effectiveness
Kristin Meek – Johns Hopkins Center for Drug Safety and Effectiveness
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

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

CO-AUTHORS
Leah McGrath – NoviSci, Inc.
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
Casey Choong – Department of Epidemiology, Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis, IN

CO-AUTHORS
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Yiqing Song – Department of Epidemiology, Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis, IN
Brian Dixon – Department of Epidemiology, IU Fairbanks School of Public Health
Jiali Han – Department of Epidemiology, Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis, IN
Xin Li – Department of Epidemiology, Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis, IN

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

CO-AUTHORS
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Xiuying Li – Toronto General Hospital Research Institute, University Health Network, Toronto, ON
Edward Keystone – Department of Medicine, University of Toronto, Toronto, ON
Claire Bombardier – Toronto General Hospital Research Institute, University Health Network, Toronto, ON
OBRI Investigators - Toronto General Hospital Research Institute, University Health Network, Toronto, ON

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Program Schedule

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

PRESENTING AUTHOR
Kathryn Foti – Johns Hopkins Center for Drug Safety and Effectiveness

CO-AUTHOR
James Heyward – Johns Hopkins Center for Drug Safety and Effectiveness
Matthew Tajanlangit – Johns Hopkins Center for Drug Safety and Effectiveness
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

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

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

PRESENTING AUTHOR
Jenny Sun – Harvard Medical School and Harvard Pilgrim Health Care Institute

CO-AUTHOR
Sengwee Toh – Harvard Medical School and Harvard Pilgrim Health Care Institute

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

CO-AUTHORS
Janick Weberpals – Real World Data Collaborations, Personalized Healthcare Data Science, F. Hoffmann-La Roche, Basel, Switzerland
Arjun Sondhi – Flatiron Health, Inc., New York City, NY, USA
Chengsheng Jiang – Flatiron Health, Inc., New York City, NY, USA
Prakirthi Yerram – Flatiron Health, Inc., New York City, NY, USA
Program Schedule

Michael Taylor – Real World Data Collaborations, Personalized Healthcare Data Science, Genentech Inc., South San Francisco, CA, USA
Meghna Samant – Flatiron Health, Inc., New York City, NY, USA
Sarah Cherng – Flatiron Health, Inc., New York City, NY, USA

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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Sabina Nduaguba – University of Florida
Yanmin Zhu – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
Brian Bateman – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
Krista Huybrechts – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

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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Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health
Loreen Straub – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
Jessica Franklin – Optum
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

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

PRESENTING AUTHOR
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Elizabeth Suarez – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
Cassandra York – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
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
Program Schedule

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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Yueqin Zhao – Office of Biostatistics, Center for Drug Evaluation and Research, FDA, Silver Spring, MD, USA
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Jane Liedtka – Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD, USA
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Judith Maro – Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School, Boston, MA, USA

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

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Program Schedule

Pregnancy and Lactation

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

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Matthias Pierce – Centre for Women’s Mental Health, University of Manchester, UK

Elise Kleyn – Centre for Dermatology Research, Manchester Academic Health Science Centre, NIHR Manchester Biomedical Research Centre, Division of Musculoskeletal and Dermatological Sciences, University of Manchester, UK

**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**

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

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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**

**PRESENTING AUTHOR**

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**CO-AUTHORS**

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Daniel Werb – Unity Health Toronto

Alexander Caudarella – Unity Health Toronto

Diana Martins – Unity Health Toronto

Flora Matheson – Unity Health Toronto

Tara Gomes – Unity Health Toronto

Pediatric Pharmacoepidemiology

**Filled Prescriptions for Opioids Among Children and Adolescents – A Nationwide Study from 2010 to 2018**

**PRESENTING AUTHOR**

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Olav Fredheim – Norwegian University of Science and Technology

Thomas Clausen – University of Oslo

Li-Chia Chen – Centre for Pharmacoepidemiology and Drug Safety, Division of Pharmacy and Optometry, School of Health Sciences, Faculty of Biology, Medicine and Health, University of Manchester

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

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

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

Prior Opioid Tolerance Among New Users of Transdermal Fentanyl in Taiwan, 2011-2018

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

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Ira Krefting – Division of Imaging and Radiation Medicine, Office of New Drugs, Food and Drug Administration
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

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Ju-Young Shin – School of Pharmacy, Sungkyunkwan University (SKKU)

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

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Michael Doherty – Optum
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Brenda Hinman-McIlroy – 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
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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 Afiblercept vs New Users of Intravitreal Ranibizumab: A Nationwide Cohort Study

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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 Eje 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
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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

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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

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

CO-AUTHORS
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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
Program Schedule

MON

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

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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

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Jason Waggoner – Johnson & Johnson
Michael Schwiers – Johnson & Johnson
Sanjoy Roy – Johnson & Johnson
Paul Coplan – Johnson & Johnson

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

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Paola Pirrotta – GSK
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Vaccines

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

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Anthony Sena – Janssen Research and Development
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Patrick Ryan – Janssen Research & Development

Vaccines

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

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- Medical Record Abstraction & Adjudication Studies
- Survey Research
- External Control Arms for Clinical Trials

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Program Schedule

Giovanni Corrao – Unit of Biostatistics, Epidemiology and Public Health, Department of Statistics and Quantitative Methods, University of Milano-Bicocca, Milan, Italy

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

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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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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.
Program Schedule

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 T ruter – 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
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

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

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

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

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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
Program Schedule

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
Ian 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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Alberico Catapano – Department of Pharmacological and Biomolecular Sciences, Epidemiology and Preventive Pharmacology Service (SEFAP), University of Milan, via Balzaretti 9, 20133, Milan, Italy
Elena Tragni – Department of Pharmacological and Biomolecular Sciences, Epidemiology and Preventive Pharmacology Service (SEFAP), University of Milan, via Balzaretti 9, 20133, Milan, Italy
Program Schedule

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

CO-AUTHORS
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Scott Vouri – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida

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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Catherine Corey – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Michael Nguyen – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. 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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Chih-Chien Wu – Division of Colorectal Surgery, Department of Surgery, Kaohsiung Veterans General Hospital
Chien-Chou Su – Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University

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
Rohit Ojha – JPS Center for Outcomes Research

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Kalyani Narra – JPS Oncology & Infusion Center
Rachel Meadows – JPS Center for Outcomes Research
Aaron Gehr – JPS Center for Outcomes Research
Bassam Ghabach – JPS Oncology & Infusion Research

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
Yanina Balabanova – Bayer AG
María Saez – Spanish Centre for Pharmacoepidemiologic Research
Gunnar Brobert – Bayer AB
Luis Alberto García Rodríguez – CEIFE (Centro Espanol de Investigacion Farmacoepidemiologica)
Program Schedule

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
Vanessa Brunetti – Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, CA

CO-AUTHORS
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Robert Platt – Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, CA
Kristian Filion – Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, CA

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

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
Katherine Callaway – University of Pittsburgh School of Medicine

CO-AUTHORS
Mina Tadrous – Women’s College Research Institute, Women’s College Hospital
Sandra Kane-Gill – University of Pittsburgh School of Pharmacy
Ian Barbash – University of Pittsburgh School of Medicine, Division of Pulmonary, Allergy and Critical Care Medicine
Katie Suda – University of Pittsburgh School of Medicine

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

PRESENTING AUTHOR
L. Yesenia Rodriguez – ESSALUD

CO-AUTHORS
Héctor Garavito – ESSALUD
Enrique Cachay – ESSALUD
Gisela Alva – ESSALUD
Paola Fernández – ESSALUD
Tania Solis – ESSALUD
Liz Veramendi – ESSALUD
Juan Aldave – ESSALUD
Violeta Saromo – ESSALUD

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

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
Program Schedule

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

Methods in Pharmacoepidemiology
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

PRESENTING AUTHOR
Tao Xu – F. Hoffmann-La Roche
CO-AUTHORS
Stefka Tyanova – F. Hoffmann-La Roche
Tarec Christoffer El-Galaly – F. Hoffmann-La Roche
Khaled Sarsour – Global Head Data Science, Genentech, Inc.
Wan-Jen Hong – Genentech, Inc.
Melissa Williamson – Genentech

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

PRESENTING AUTHOR
Hemin Lee – Brigham and Women’s Hospital
CO-AUTHORS
Jeffrey Sparks – Brigham and Women’s Hospital
Kazuki Yoshida – Brigham and Women’s Hospital
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Joan Landon – Brigham and Women’s Hospital
Seoyoung Kim – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital and Harvard Medical School, Boston, Massachusetts, USA

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

PRESENTING AUTHOR
Gustavo Andreoli – Ministry of Health, Brazil
CO-AUTHORS
Daniel Curado – Ministry of Health of Brazil
Rosângela Gomes – Ministry of Health of Brazil
Dalila Gomes – Ministry of Health of Brazil
Joslane de Nunes – Ministério da Saúde
Ricardo Fernandes – National Institute of Cancer, INCA, Brazil
Ivan Zimmermann – University of Brasilia, UnB

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
Program Schedule

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**
Julian Matthewman – London School of Hygiene & Tropical Medicine

**CO-AUTHORS**
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Richard Silverwood - Centre for Longitudinal Studies, University College London
Amy Mulick – London School of Hygiene & Tropical Medicine
Daniel Prieto-Alhambra – Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford, UK
Katherine Lowe – London School of Hygiene & Tropical Medicine
Liam Smeeh – 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**
Ikenna Unigwe – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, FL, USA

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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
Real-World Data for Chronic Diseases

THE OM1 DIFFERENCE

Largest and most representative chronic disease datasets

Symptoms and comorbidities

Longitudinal outcomes, disease progression, and treatment response

Clinical data, labs and more

Patient and disease subtypes

Automated, prospective data networks

RESEARCH-GRADE DATA

Available for licensing, analytics, and collaboration

Rheumatoid Arthritis  Lupus  Axial Spondyloarthritis  Psoriatic Arthritis  Psoriasis
Atopic Dermatitis  Multiple Sclerosis  Depression  Asthma  COPD And more

Visit our virtual booth at ICPE All Access or contact us today to learn more at info@om1.com.
**Program Schedule**

**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**

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**

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**

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

**PRESENTERS**

Shirley Wang – Brigham and Women’s Hospital, Harvard Medical School  
Sebastian Schneeweiss – Division of Pharmacoepidemiology and Pharmacoconomics, 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
Program Schedule

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 University
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**

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

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

**Pharmacovigilance**

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

**PRESENTING AUTHOR**

Chin-Yao Shen – School of Pharmacy, Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University, Tainan 701, Taiwan

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Edward Chia-Cheng Lai – School of Pharmacy, Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University, Tainan 701, Taiwan

**Pediatric Pharmacoepidemiology**

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

**PRESENTING AUTHOR**

Jenny Sun – Harvard Medical School and Harvard Pilgrim Health Care Institute

**CO-AUTHORS**

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**

Dawwas Dawwas – University of Pennsylvania

**CO-AUTHOR**

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

James Lewis – University of Pennsylvania

**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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François Montastruct – Department of Clinical and Medical Pharmacology and Regional Pharmacoepidemiology Centre, Faculty of Medicine and Toulouse University Hospital, Toulouse, France

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

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

**Selective Serotonin Reuptake Inhibitors and the Risk of Type 2 Diabetes Mellitus in Youths**

**PRESENTING AUTHOR**

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**CO-AUTHORS**

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

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

**PRESENTING AUTHOR**

Jenny Sun – Harvard Medical School and Harvard Pilgrim Health Care Institute

**CO-AUTHORS**

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

**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**

Dawwas Dawwas – University of Pennsylvania

**CO-AUTHOR**

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

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**
Simone Bastrup Israelsen – Center of Research and Disruption of Infectious Diseases, Department of Infectious Diseases, Copenhagen University Hospital, Amager and Hvidovre, Hvidovre, Denmark

**CO-AUTHOR**
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Sten Madsbad – Department of Endocrinology, Copenhagen University Hospital, Amager and Hvidovre, Hvidovre, Denmark

Reimar Thomsen – Department of Clinical Epidemiology, Aarhus University, Aarhus, Denmark

Thomas Benfield – Center of Research and Disruption of Infectious Diseases, Department of Infectious Diseases, Copenhagen University Hospital, Amager and Hvidovre, Hvidovre, Denmark

**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**
Albert Prats-Uribe – Pharmaco- and Device Epidemiology, Centre for Statistics in Medicine - Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, UK

Li Liu – Nanfang Hospital, Southern Medical University, Guangzhou, China

**CO-AUTHORS**
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Lana Yin Hui Lai – Division of Cancer Sciences, School of Medical Sciences, University of Manchester

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**Heba Alghoul** – Faculty of Medicine, Islamic University of Gaza, Palestine

**Osaid Alser** – Massachusetts General Hospital, Harvard Medical School, Boston, 02114, MA, USA

**Thamir Alshammari** – College of Pharmacy, Riyadh Elm University

**Carlos Areia** – Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK

**William Carter** – Data Science to Patient Value Program, University of Colorado Anschutz Medical Campus, Aurora, CO, USA

**Paula Casajust** – Real-World Evidence, Trial Form Support, Barcelona, Spain

**Dalia Dawoud** – National Institute for Health and Care Excellence (NICE), London, UK

**Asieh Golozar** – Regeneron Pharmaceuticals

**Jitendra Jonnagaddala** – School of Public Health and Community Medicine, UNSW Sydney

**Paras Mehta** – College of Medicine, The University of Arizona, Tucson, AZ, USA

**Gong Mengchun** – DHC Technologies Co. Ltd, Beijing, China

**Daniel Morales** – Division of Population Health and Genomics, University of Dundee, UK

**Fredrik Nyberg** – School of Public Health and Community Medicine, Institute of Medicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

**Jose Posada** – Stanford University School of Medicine, Stanford, California, USA

**Martina Recalde** – Fundación Universitaria per a la recerca a l’Atenció Primària de Salut Jordi Gol i Gurina (IDiAPJGol), Barcelona, Spain

**Elena Roel** – Fundació Institut Universitari per a la recerca a l’Atenció Primària de Salut Jordi Gol i Gurina (IDiAPJGol), Barcelona, Spain

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**Hong Zhu** – Nanfang Hospital, Southern Medical University, Guangzhoun, China

**Seng Chan You** – Department of Preventive Medicine and Public Health, Yonsei University College of Medicine, Seoul, Korea

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

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Jennifer Lane – Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, Oxford, UK
Edward Burn – Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, UK
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Drug Utilization Research

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

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Drug Effectiveness

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

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P. Michael Ho – US Department of Veterans Affairs
Paul Heidenreich – Stanford University School of Medicine
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Janet Tate – US Department of Veterans Affairs
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Anticoagulants and All-Cause Mortality Among Hospitalized COVID-19 Patients

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

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

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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

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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, Real-World Data Safety Study

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

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Jesper Hallas – University of Southern Denmark, Odense, Denmark
Program Schedule

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**

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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**

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**1:45 - 3:30 PM**

**ORAL SESSIONS / CONCURRENT**

**Validation and Algorithms: Getting the Present and Future Right**

Methods in Pharmacoepidemiology

**Validity of Electronic Health Records-Based Measures for COVID-19 Hospitalization and Severe Outcomes**

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Methods in Pharmacoepidemiology

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

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

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Informatics

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

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Rosalind Eggo – London School of Hygiene and Tropical Medicine
Ian 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

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Methods in Pharmacoepidemiology

**Use of an EHR to Inform a Claims-Based Algorithm to Categorize Inpatient COVID-19 Severity**

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Methods in Pharmacoepidemiology

**Categorization of COVID-19 Severity to Determine Mortality Risk**

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Tamar Lasky – US Food and Drug Administration
Sandy Leonard – HealthVerity
Sarah Vititoe – Aetion, Inc.
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Program Schedule

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

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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

Presenting Author: Matthew Beier – Rutgers, Robert Wood Johnson Medical School

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

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Jason Roy – Rutgers University, Department of Biostatistics and Epidemiology

Avinash Gabbeta – St. Christopher’s Hospital for Children

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**

**Early Life Antibiotic Exposure and Incident Chronic Diseases in Childhood**

Presenting Author: Matthew Beier – Rutgers, Robert Wood Johnson Medical School

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Brian Strom – Rutgers Biomedical And Health Sciences, Rutgers University

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

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**Pediatric Pharmacoepidemiology**

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

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

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Pediatric Pharmacoepidemiology

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

Presenting Author: Oliver Scholle – Leibniz Institute for Prevention Research and Epidemiology - BIPS

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Pediatric Pharmacoepidemiology

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

Presenting Author: Reem Masarwa – McGill University

Co-Authors: Claire Lefebvre – Department of Pediatrics, Centre Hospitalier Universitaire Ste-Justine, University of Montreal, Montreal, Quebec, CA

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

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Program Schedule

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

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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

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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

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

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

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Methods in Pharmacoepidemiology

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

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Methods in Pharmacoepidemiology

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

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Methods in Pharmacoepidemiology

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

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Methods in Pharmacoepidemiology

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

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Methods in Pharmacoepidemiology

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

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Program Schedule

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

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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

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

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Carlo Giaquinto – Division of Pediatric Infectious Diseases, Department for Woman and Child Health, University of Padua, Padua, Italy
Daniele Dona’ – Division of Pediatric Infectious Diseases, Department for Woman and Child Health, University of Padua, Padua, Italy
Program Schedule

Informatics

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

PRESENTING AUTHOR
Jue Hou – Harvard T.H. Chan School of Public Health

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Tianrun Cai – Brigham and Women’s Hospital
Katherine Liao – Brigham and Women’s Hospital
Thany Seyok – Brigham and Women’s Hospital
Kumar Dahal – Brigham and Women’s Hospital
Qianyu Yuan – Harvard T.H. Chan School of Public Health
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

Biologics/Biosimilars

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

PRESENTING AUTHOR
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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

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
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, Pennsylvania, USA
François Houyet – EURORDIS
Program Schedule

WEDNESDAY, AUGUST 25

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
MODERATOR
J. Bradley Layton – RTI Health Solutions
SPEAKERS
Miriam Sturkenboom – Department Data science & Biostatistics,
University Medical Center Utrecht
Steven Anderson – FDA/CBER
Carla Talarico
Robert Chen – Brighton Collaboration

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
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
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
Program Schedule

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
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

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
Sungwan Sohn – Mayo Clinic
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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Program Schedule

Vina Graham – Kaiser Permanente Washington Health Research Institute
David Cronkite – Kaiser Permanente Washington Health Research Institute
Brian Hazlehurst – Kaiser Permanente Northwest
Andrew Felcher – Kaiser Permanente Northwest
Cosmin Bejan – Vanderbilt University Medical Center
Adeeb Kennedy – Harvard Pilgrim Health Care Institute
Mayura Shinde – Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute
Sara Karami – US Food and Drug Administration
Yong Ma – Center for Drug Evaluation and Research, United States Food and Drug Administration
Daniele Stoianovic – Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD, USA
Yueqin Zhao – Office of Biostatistics, Center for Drug Evaluation and Research, FDA, Silver Spring, MD, USA
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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Michael Fassett – Kaiser Permanente Southern California
Jiaxiao Shi – Research and Evaluation, Kaiser Permanente Southern California
Amy Alabaster – Division of Research, Kaiser Permanente
Fagen Xie – Research and Evaluation, Kaiser Permanente Southern California
Vicki Chiu – Research and Evaluation, Kaiser Permanente Southern California
Theresa Im – Research and Evaluation, Kaiser Permanente Southern California
Federica Pisa – Medical Affairs & Pharmacovigilance, Bayer AG
Tina Raine-Bennett – Division of Research, Kaiser Permanente

ACPE 2021
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Seoul, Korea
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Program Schedule

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

PRESENTING AUTHOR
Christina Mack – IQVIA

CO-AUTHORS
Michael Osterholm – Center for Infectious Disease Research and Policy, University of Minnesota, Minneapolis, Minnesota, USA
Erin Wasserman – IQVIA
Natalia Petruski-Ivleva – IQVIA
Deverick Anderson – Duke Center for Antimicrobial Stewardship and Infection Prevention, Duke University School of Medicine, Durham, NC, USA
Emily Myers – National Football League, New York City, NY, USA
Navdeep Singh – Eden Medical Center, Castro Valley, CA, USA
Patti Walton – Williamson Medical Center, Franklin, TN, USA
Gary Solomon – National Football League, New York, NY, USA
Christopher Hostler – Duke Center for Antimicrobial Stewardship and Infection Prevention, Duke University School of Medicine, Durham, NC, USA

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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Innovation has the power to save lives. By using the potential of science, we grow our knowledge and unlock new treatments. At Bayer, we are excited to be contributing to better health care that is safe, sustainable, and always accessible.

Science for a better life

Caring today, for tomorrow
Program Schedule

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**
**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
Lina Titievsky – Intercept Pharmaceuticals

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

**PRESENTING AUTHOR**
Huifeng Yun – Department of Epidemiology, University of Alabama at Birmingham

**CO-AUTHORS**
Ye Liu – University of Alabama at Birmingham
Jeffrey Curtis – University of Alabama at Birmingham
Kenneth Saag – Division of Clinical Immunology and Rheumatology
Katherine Haseltine – HSS hospital
Emily Stein – HSS hospital

**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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Corey Joseph – Johns Hopkins Bloomberg School of Public Health
Paul Kocis – Penn State Health, Milton S. Hershey Medical Center, Hershey, PA, USA
Richard Moffitt – Stony Brook University, Stony Brook, NY, USA
Tellen Bennett – University of Colorado School of Medicine, University of Colorado, Aurora, CO, USA
Christopher Chute – Johns Hopkins University
Brian Garibaldi – Johns Hopkins Medicine
G. Caleb Alexander – Johns Hopkins Center for Drug Safety and Effectiveness
Program Schedule

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

PRESENTING AUTHOR
Kueiyu Joshua Lin – Brigham and Women’s Hospital

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Sushama Kattinakere Sreedhara – Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital, Harvard Medical School
Krista Huybrechts – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
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
Sabrina Giometto – Unit of Medical Statistics, Department of Clinical and Experimental Medicine, University of Pisa

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Massimiliano Cazzato – Unit of Rheumatology, University Hospital of Pisa, Pisa, Italy
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Olga Paoletti – Agenzia regionale di sanità della Toscana
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Marta Mosca – Unit of Rheumatology, University Hospital of Pisa, Pisa, Italy
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

PRESENTING AUTHOR
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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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CO-AUTHORS
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Anders Kjaersgaard – Department of Clinical Epidemiology, Aarhus University Hospital
Deirdre Cronin-Fenton – Department of Clinical Epidemiology, Aarhus University Hospital, Aarhus, Denmark
Program Schedule

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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Xinyi Jiang – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida
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**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**
Cleo Samuel-Ryals – University of North Carolina at Chapel Hill
William Wood – University of North Carolina at Chapel Hill
Leah Zullig – Duke University School of Medicine
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**
Larry Jackson, II – Duke University Medical Center
Diane Francis – Johnson & Johnson Medical Devices, Health Economics and Market Access
Sonia Maccioni – Johnson & Johnson Medical Devices, Health Economics and Market Access
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Charlene Wong – Johnson & Johnson Medical Device Epidemiology and Real-World Data Sciences
Jonathan Piccini – Duke University Medical Center
Daniel Friedman – Yale School of Medicine

**Health Economics/Outcomes Research**

**The Impact of Sex on The Quality of Medication Treatment in Patients with Type 2 Diabetes**

**PRESENTING AUTHOR**
Neloufar Rahai – Johnson & Johnson Medical Device Epidemiology and Real-World Data Sciences

**Drug Utilization Research**

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**CO-AUTHOR**
Teng-Jen Chang – The Ohio State University

**Drug Utilization Research**

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Stacie Dusetzina – Vanderbilt University School of Medicine

**Health Economics/Outcomes Research**

**Impact of Race, Ethnicity, and Sex on Treatment of Non-Valvular Atrial Fibrillation**

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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

**Health Economics/Outcomes Research**

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

**Drug Utilization Research**

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**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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William Wood – University of North Carolina at Chapel Hill
Leah Zullig – Duke University School of Medicine
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**
Larry Jackson, II – Duke University Medical Center
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Rahul Khanna – Johnson & Johnson Medical Device Epidemiology and Real-World Data Sciences
Charlene Wong – Johnson & Johnson Medical Device Epidemiology and Real-World Data Sciences
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Daniel Friedman – Yale School of Medicine

**Health Economics/Outcomes Research**

**The Impact of Sex on The Quality of Medication Treatment in Patients with Type 2 Diabetes**

**PRESENTING AUTHOR**
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Program Schedule

Drug Utilization Research

Changes in Buprenorphine Utilization During the COVID-19 Pandemic in the US

PRESENTING AUTHOR
Lindsey Hammerslag – Institute for Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Kentucky

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Jeffery Talbert – Institute for Biomedical Informatics, College of Medicine, University of Kentucky
Sharon Walsh – College of Medicine, University of Kentucky
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
Jeffrey Curtis – University of Alabama at Birmingham

CO-AUTHORS
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Cassie Clinton – Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham
Fenglong Xie – University of Alabama at Birmingham
Jessica Boles – Global Healthy Living Foundation
Laura Stratford – Global Healthy Living Foundation
Shilpa Venkatachalam – Global Healthy Living Foundation
Justin Owensby – University of Alabama at Birmingham
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

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

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Talita Duartes-Salles – Fundació Institut Universitari per a la Recerca a l’Atenció Primària de Salut Jordi Gol i Gurina (IDIAP.JGol)
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Health Economics/Outcomes Research


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Elizabeth Garrett-Mayer – ASCO
Mark Walker – ConcertAI
Joseph Wagner – IQVIA
Emily Valice – Kaiser Permanente
Connor Sweetnam – Syapse
Elad Sharon – National Cancer Institute
Lori Sakoda – Kaiser Permanente
Nicholas Robert – Ontada
Ruth Pe Benito – Tempus
Yanina Natanzon – ConcertAI
Larry Kushi – Kaiser Permanente
Monika Izano – Syapse
Rebecca Honnold – Tempus
Eric Hansen – COTA
Janet Espirito – Ontada
Lindsey Enewold – National Cancer Institute
Jennifer Christian – IQVIA
Suanna Bruinooge – American Society of Clinical Oncology
Marley Boyd – Ontada
Program Schedule

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

**CO-AUTHORS**
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Hwanhee Hong – Duke Clinical Research Institute, Duke University
G. Caleb Alexander – Johns Hopkins Center for Drug Safety and Effectiveness
Channing Paller – The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine

**Health Economics/Outcomes Research**

**Telemedicine Use Among U.S. Patients with Cancer During the COVID-19 Pandemic**

**PRESENTING AUTHOR**
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**CO-AUTHORS**
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Palak Kundu – Genentech, Inc.
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, University Health Network, Toronto, ON

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Claire Bombardier – Toronto General Hospital Research Institute, University Health Network, Toronto, ON
OBRI Investigators – Toronto General Hospital Research Institute, University Health Network, Toronto, ON

**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

**CO-AUTHORS**
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Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health
Loreen Straub – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
Yanmin Zhu – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
Helen Mogun – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
Brian Bateman – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics

11:45 AM - 1:30 PM
Pregnancy and Lactation

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

PRESENTING AUTHOR
Andrew Wiese – Vanderbilt University Medical Center

CO-AUTHORS
Sarah Osmundson – Vanderbilt University Medical Center
Edward Mitchel, Jr. – Vanderbilt University Medical Center
Margaret Adgent – Vanderbilt University Medical Center
Sharon Phillips – Vanderbilt University Medical Center
Stephen Patrick – Vanderbilt University School of Medicine
Andrew Spieker – Vanderbilt University Medical Center
Carlos Grijalva – Vanderbilt University Medical Center

Pregnancy and Lactation

Prescription Opioid Type and the Risk of Neonatal Opioid Withdrawal Syndrome

PRESENTING AUTHOR
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Martha Werler – Boston University School of Public Health
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Helen Mogun – Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics
Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health
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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Dong-Sook Kim – Department of Research, Health Insurance Review & Assessment Service
Ju-Young Shin – School of Pharmacy, Sungkyunkwan University

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

Pregnancy and Lactation

Prenatal Analgesic Opioid Exposure and Risk of ADHD in Childhood

PRESENTING AUTHOR
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CO-AUTHORS
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Marte Handal – Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway
Svetlana Skurtveit – Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway
Eivind Ystrom – Department of Mental Disorders, Norwegian Institute of Public Health, Oslo, Norway
Hedvig Nordeng – PharmacoEpidemiology and Drug Safety Research Group, Department of Pharmacy, and PharmaTox Strategic Initiative, Faculty of Mathematics and Natural Sciences, University of Oslo
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
- New Business
- Awards Ceremony
- ISPE Board Transition

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)

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

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
New Business
Awards Ceremony
ISPE Board Transition

LEADER IN EUROPEAN PASS DATA COLLECTION STUDIES IN ALL MAJOR THERAPY AREAS, INCLUDING ORPHAN DISEASES AND PREGNANCY
- 100% record of PRAC-approved PASS studies, including cost-efficient hybrid designs
- Successful removal of unnecessary regulatory burdens
- New approach to hybrid pregnancy safety studies: approved by EMA
- Risk minimization studies: presentation to EMA, publications and novel hybrid design

LEADER IN EUROPEAN SINGLE AND MULTI-COUNTRY DATABASE AND REGISTRY STUDIES
- New method for competing risk - Lancet 2015, with global media coverage
- Simulation for residual confounding in cohort study - Lancet 2021, with global media coverage

PROPRIETARY EDC PLATFORM
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www.OxonEpi.com
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

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**Drug Utilization Research**


**PRESENTING AUTHOR**

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

Elizabeth Roughhead – Clinical and Health Sciences, University of South Australia

Joel Lexchin – Faculty of Health, York University

Anna Kemp-Casey – Clinical and Health Sciences, University of South Australia

Lorri Puil – Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

Ingrid Sketris – College of Pharmacy, Dalhousie University

Dee Mangin, (MBChB (Otago), DPH (Otago), FRNZCGP (NZ)), Department of Family Medicine, McMaster University

Christine Hallgreen – Copenhagen Centre for Regulatory Science, Department of Pharmacy, Faculty of Health and Medical Sciences, University of Copenhagen

Sallie-Anne Pearson – Centre for Big Data Research in Health, University of New South Wales

Ruth Lopert – Department of Health Policy and Management, George Washington University

Lisa Bero – School of Medicine and Colorado School of Public Health, University of Colorado Anschutz Medical Campus

Richard Ofori-Asenso – Copenhagen Centre for Regulatory Science, Department of Pharmacy, Faculty of Health and Medical Sciences, University of Copenhagen

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

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

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

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

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

**PRESENTING AUTHOR**

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

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Petra Denig – University Medical Center Groningen

Peter Mol – University of Groningen, University Medical Center Groningen, Department of Clinical Pharmacy and Pharmacology, Netherlands

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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**

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

**CO-AUTHORS**

William Donahoo – College of Medicine, University of Florida

Christian Hampp – US Food and Drug Administration

Joshua Brown – Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, 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)
**What Matters to Patients When Considering Treatments for Prevention of Rheumatoid Arthritis: A Preference Study in the United Kingdom, Germany, and Romania**

**PRESENTING AUTHOR**
Rachael DiSantostefano – Janssen R&D, LLC

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Karim Raza – Institute of Inflammation and Ageing, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK
Jorien veldwijk – School of Health Policy & Management, Erasmus University Rotterdam, Rotterdam, Netherlands

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**3:00 - 4:30 PM**

**ORAL SESSIONS / CONCURRENT**

**MedTech Globetrotting – Assisting Medical Devices Effects in the Real World**

**Medical Devices**
**The Association Between Bariatric Surgery and Carpal Tunnel Syndrome: 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

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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

---

**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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Sallie-Anne Pearson - Centre for Big Data Research in Health, University of New South Wales
Louisa Jorm – Centre for Big Data Research in Health, UNSW
Art Sedrakyan – Weill Cornell Medicine

---

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

**PRESENTING AUTHOR**
Wei-Lun Alterovitz – US Food and Drug Administration

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Marina Kondratovich – US Food and Drug Administration
Danica Marinac-Dabic – FDA/CDRH
Mark Walderhaug – US Food and Drug Administration
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**

**PRESENTING AUTHOR**
Theresa Burkard – Department of Chemistry and Applied Biosciences, Institute of Pharmaceutical Sciences, ETH Zurich, Zurich, Switzerland
Program Schedule

**Medical Devices**

**Sex-Differences in Risk of Early Revision After Primary Total Knee Arthroplasty**

**PRESENTING AUTHOR**
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**CO-AUTHORS**
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Jialin Mao – Weill Cornell Medicine
Amanda Chen – Weill Cornell Medicine
Vincent Devlin – US Food and Drug Administration
Raquel Peat – US Food and Drug Administration
Art Sedrakyan – Weill Cornell Medicine

**Medical Devices**

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

**PRESENTING AUTHOR**
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Andrea M. Burden, PhD - Institute of Pharmaceutical Sciences, Department of Chemistry and Applied Biosciences, ETH Zurich, Zurich, Switzerland

**Medical Devices**

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

**PRESENTING AUTHOR**
Kueiyu Joshua Lin – Brigham and Women’s Hospital

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**Psychotropics: Bitter Pills to Swallow in Pregnancy**

**PRESENTING AUTHOR**
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**CO-AUTHORS**
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Kari Furu – Norwegian Institute of Public Health
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Silje Alvestad – National Center for Epilepsy, Oslo University Hospital
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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CO-AUTHORS
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Sonia Hernandez-Diaz – Harvard T.H. Chan School of Public Health
Torbjörn Tomson – Department of Clinical Neuroscience, Karolinska Institutet
Kari Furu – Norwegian Institute of Public Health

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

PRESENTING AUTHOR
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Maarit Leinonen – Finnish Institute for Health and Welfare
Helga Zoega – Centre for Big Data Research in Health, UNSW Sydney
Helle Kieler – Centre for Pharmacoepidemiology, Karolinska Institutet
Pregnancy and Lactation
The Impact of In-Utero Antipsychotic Exposure on Neurodevelopmental Disorders in Children

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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
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Mireille Schnitzer – Faculté de Pharmacie, University of Montreal
Alan Barkun – McGill University Health Centre
Sanny 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
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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
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Ryan Seals – Optum
Najat Ziyadeh – 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.
Complex Issues | Rigorous Advice

The world of pharmacoepidemiology is experiencing dynamic transformations powered by data science, genomics, and digital health. Exponent is your valued partner to help your organization traverse this continuously shifting landscape.

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Program Schedule

**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**

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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**

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**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)

**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

**WED Program Schedule**

**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’Épidémiologie 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’Épidémiologie 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
Program Schedule

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**

**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**
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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**
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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
**Program Schedule**

**4:30 - 6:00 PM**

**ORAL SESSIONS / CONCURRENT**

**Pregnancy: Diabetes and a Surprise**

**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**

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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**

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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**

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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

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

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

PRESENTING AUTHOR
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Jenna Calderbank – Optum
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Stephanie Chiuve – AbbVie
Brenda Hinman-McIlroy – AbbVie
Michael Snabes – AbbVie, Inc
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Pregnancy and Lactation
Metformin vs Insulin in Early Pregnancy and Risk of Congenital Malformations

PRESENTING AUTHOR
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CO-AUTHORS
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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
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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 Iyasu – 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 Gunn – 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, 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**


**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
Symposia/Workshops

WORKSHOP
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 CCEBICPeRT, 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
Symposia/Workshops

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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Block 2 (February)  Introduction to Pharmacovigilance
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Block 4 (October) Real-World Evidence in Pharmacoepidemiology

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Symposia/Workshops

**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**
- 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

**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...**
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Impact of FDA’s Regulatory Actions on the Quality of Rems Survey Methodology Protocols (2007-2020)
Samuel Ewusie1 | Janifer Quick2 | Elaine Morrato3
Gita Toyserkani2
1ORISE Fellow, Division of Risk Management, FDA; 2Division of Risk Management, FDA; 3Parkinson 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 Alves1 | Ana Penedones2 | Diogo Mendes2
Francisco Batel Marques3
1University of Coimbra, School of Pharmacy; 2UFC – Coimbra Regional Pharmacovigilance Unit, CHAD – Centre for Health Technology Assessment and Drug Research, AIBILI; 3Faculty of Pharmacy, University of Coimbra

Preferences Concerning Drug Safety Communication of Hospital-Based Specialist in the Netherlands
Esther de Vries1 | Elisabeth Bakker1 | Petra Denig2
Peter Mol3
1University of Groningen, University Medical Center Groningen, Department Clinical Pharmacy and Pharmacology, Groningen, the Netherlands; 2University Medical Center Groningen; 3University of Groningen, University Medical Center Groningen, Department of Clinical Pharmacy and Pharmacology, The Netherlands

Discontinuation Rate of Tofacitinib is Similar When Compared to TNF Inhibitors in Rheumatoid Arthritis Patients: Data from a Rheumatoid Arthritis Cohort
Mohammad Movahedi1 | Angela Cesta2 | Xiuying Li3; Edward Keystone3 | Claire Bombardier2 | OBRI Investigators4
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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

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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

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Development and Validation of an Algorithm to Estimate the Risk of Severe Complications of COVID-19 to Prioritise Vaccination

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Hyperthyroidism and Breast Cancer Recurrence and Mortality: A Danish Population-based Cohort Study

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Impact of Non-alcoholic Steatohepatitis (NASH) Case Definition on Population Characteristics Identified in a US Claims Database

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Incidence and Risk Factors for COVID-related Urgent Medical Visits Among US Patients Diagnosed with COVID-19 in the Outpatient Setting

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Incidence Rates of Select Outcomes Among Patients with Non-alcoholic Steatohepatitis (NASH) and Evidence of Fibrosis and Cirrhosis

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Persistence of COVID-19 Symptoms 90 Days Post-acute Infection: Insights from a Community-based Registry

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Severe Obesity Is a Risk Factor for Mortality in Patients with COVID-19

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DISEASE EPIDEMIOLOGY / CLINICAL COURSE

DRUG EFFECTIVENESS

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COVID-19 in Children: Treatment Patterns in the Real-world Hospital Setting
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Disparities in Hepatitis C Treatment in the Era of Direct-acting Antivirals Among Arizona Medicaid Beneficiaries
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Serum Vitamin D Levels and Incident Prescription Opioid Use Among Opioid-Naïve Patients
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Sources of Racial/ethnic Disparities in Antidepressant Treatment: Analysis of the Medical Expenditure Panel Survey Data
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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)
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Utilization of Non-pharmacologic Pain Therapies Among Primary Care Physicians in the United States: A Cross-sectional Survey
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Kristin Meek² | Christopher Jones³ | Andrew Kolodny⁴
G. Caleb Alexander²
¹Bloomberg School of Public Health, Johns Hopkins University; ²Johns Hopkins Center for Drug Safety and Effectiveness; ³Centers for Disease Control and Prevention; ⁴Brandeis University

Visualizing Inappropriate Antibiotic Use Following Otitis Media in Children in the United States
Leah McGrath¹ | Jason Newland² | John Sahrmann²
YinJiao Ma³ | Anne Mobley M Butler⁴
¹NoviSci; ²Washington University in St. Louis
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
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Daniel Prieto-Alhambra4
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Comparative Risk of Cardiac Arrhythmias Associated with Acetylsalicylic Acid Inhibitor Use
Yichang Huang1 | John-Michael Gamble2
David Juurlink3 | Mhd. Wasem Alsabbagh2
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Risk of Cardiotoxicity Associated with Fluoropyrimidine-based Chemotherapy Among Older Colorectal Cancer Patients: A New User Cohort Study
Chao Li1 | Chiahung Chou1 | Surachat Ngorsuraches1
Li Chen2 | Jingjing Qian1
1Auburn University; 2Indiana 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 Jodicke1 | Eng Hooi (Cheryl) Tan1
Danielle Robinson2 | Antonella Delmestri3
Daniel Prieto-Alhambra4
1Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford; 2Pharmaco- and Device Epidemiology, Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK; 3Centre for Statistics in Medicine, NDORMS, University of Oxford, Oxford, UK; 4Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, United Kingdom

Statin Discontinuation and Risk of Cardiovascular Events in Older People: A Population-based Cohort Study in Denmark
Wade Thompson1 | Lucas Morin2 | Dorte Ejg Jarbøl1
Jacob Andersen1 | Martin Ernst1 | Jesper Nielsen1
Peter Haastrup1 | Morten Schmidt1 | Anton Pottegård1
1University of Southern Denmark; 2Inserm CIC 1431, Clinical Investigation Unit, University Hospital of Besançon; 3Aarhus University Hospital

Uncontrolled Pain and Risk for Depression and Behavioral Symptoms in Patients with Dementia
Yu-Jung “Jenny” Wei1 | Almut Winterstein2
1University of Florida; 2Department 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 Shmuel1 | Virginia Pate2 | Marc Pepin3
Janine Bailey1 | Yvonne Gollightly2 | Laura Hanson4
Til Stürmer5 | Rebecca Naumann2 | Danijela Gnjidic6
Jennifer Lund6
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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 Lin1 | Yu-Hsin Wang2 | Chien-Ning Hsu3
1National Taiwan University Hospital; 2Graduate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University, Taipei, Taiwan; 3Department 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 Wang1 | Jeromie Ballreich2 | Hwanhee Hong3
G. Caleb Alexander4 | Channing Paller4
1Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health; 2Department of Health Policy and Management, Johns Hopkins University Bloomberg School of Public Health; 3Duke Clinical Research Institute, Duke University; 4Johns Hopkins Center for Drug Safety and Effectiveness; 53, The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine

Impact of Race, Ethnicity, and Sex on Treatment of Non-valvular Atrial Fibrillation
Larry Jackson1 | Diane Francis2 | Sonia Maccioni2
Vincent Thomas3 | Jennifer Wood4 | Guy Cafri4
Rahul Khanna4 | Charlene Wong4 | Neloufar Rahai5
Jonathan Piccini1 | Daniel Friedman6
1Duke University Medical Center; 2Johnson & Johnson Medical Devices, Health Economics and Market Access; 3Biosense Webster; 4Johnson & Johnson, Medical Device Epidemiology and Real-World Data Sciences; 5Johnson & Johnson; 6Yale 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 Curtis1 | Benjamin Nowell2 | Cassie Clinton3
Fenglong Xie4 | Jessica Boles5 | Laura Stratford6
Shilpa Venkatachalam7 | Justin Owensby8 | D Curtis6
K. Gavigan6 | I. Lipovich9 | S.K. Nolot7 | V.S. Haynes7
1University of Alabama Birmingham; 2Global Healthy Living Foundation; 3Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham; 4University of Alabama at Birmingham; 5Global Healthy Living Foundation; 6Global Healthy Living Foundation; 7Eli Lilly and Company Indianapolis, IN

Telemedicine Use Among U.S. Patients with Cancer During the COVID-19 Pandemic
Lu Chen1 | Carlos Flores Avile2 | Palak Kundu3 | Aaron B. Cohen4 | Amy Webster4 | Rebecca Rohrer4 | Michael Taylor6
1Genentech; 2Genesis Research; 3Genentech, Inc.; 4Flatiron Health; 5Real World Data Collaborations, Personalized Healthcare Data Science, Genentech Inc., South San Francisco, CA, USA

Donna Rivera1 | Henry Henk2 | Elizabeth Garrett-Mayer3
Mark Walker4 | Joseph Wagner5 | Emily Valice6
Connor Sweetnam7 | Elad Sharon8 | Lori Sakoda6
Nicholas Robert9 | Ruth Pe Benito10 | Anina Natanzon4
Larry Kushi6 | Monika Izano7 | Rebecca Honnold10
Eric Hansen11 | Janet Espirito13 | Lindsey Ennew9
Jennifer Christian9 | Suanna Bruinooge12 | Marley Boyd6
Andrew Belli11 | Laura Lasiter13 | Jeff Allen13
1US Food and Drug Administration; 2Optum Labs; 3ASCO; 4ConcertA; 5IQVIA; 6Kaiser Permanente; 7Syapse; 8National Cancer Institute; 9Ontada; 10Tempus; 11COTA; 12American Society of Clinical Oncology; 13Friends of Cancer Research

Informatics

Shifting the Traditional Model of Analysing Downloaded Electronic Health Records to the Novel Open-source Analytics Opensafely Platform
Angel Wong1 | Brian MacKenna2 | Caroline Morton2 | Anna Schultze | Alex Walker2 | Krishnan Bhaskaran1
Christopher Tentsch1 | Elizabeth Williamson1 | Richard Croker2 | Seb Bacon2 | William Hulme2 | Chris Bates3 | Helen Curtis2
Amir Mehrkar2 | David Evans2 | Peter Inglesby2 | Jonathan Cockburn3 | Helen McDonald1 | Laurie Tomlinson4 | Rohini Mathur1
Kevin Wing1 | Harriet Forbes5 | Rosalind Eggo1 | Ian Douglas4 | Stephen Evans4 | Liam Smeeth4 | Ben Goldacre2
1London School of Hygiene and Tropical Medicine; 2University of Oxford; 3The Phoenix Partnership; 4London School of Hygiene & Tropical Medicine; 5LSHTM

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An Evaluation of Direct and Propensity Score Matching vs Propensity Score Stratification for Confounding Adjustment in Primary Total Hip Arthroplasty
Abhishek Chitnis¹ | Jack Mantel² | Juan Daccach³
Perrna Kothari⁴ | Jill Ruppenkamp³ | Paul Coplan³
Chantal Holy³
¹Johnson & Johnson; ²DePuy Synthes; ³Johnson & Johnson; ⁴Mu-Sigma

Comparative Patient Characteristics of Transcatheter Left Atrial Appendage Occlusion vs Oral Anticoagulants for Stroke Prevention in Atrial Fibrillation
Joshua Lin | Daniel Singer¹ | Sushama Kattinakere Sreedhara² | Krista F Huybrechts³
Sebastian Schneeweiss⁴
¹Department of Medicine, Massachusetts General Hospital, Harvard Medical School; ²Brigham and Women’s Hospital, Harvard Medical School; ³Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics; ⁴Division 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
Oluwadmisola Sotade¹ | Michael Falster¹
Sallie-Anne Pearson² | Louisa Jorm³ | Art Sedrakyan³
¹Centre for Big Data Research in Health, UNSW; ²Centre for Big Data Research in Health, University of New South Wales; ³Weill Cornell Medicine

Leveraging Artificial Intelligence (AI) Technologies for Automated Identification of Total Knee Arthroplasty (TKA) Devices in Electronic Health Records
Elham Sagheb¹ | Shi Yan¹ | Taghi Ramazanian¹ | Sunyang Fu¹
Ahmad Tafti² | Sungwhan Sohn¹ | Hilal Maradit Kremers¹
¹Mayo Clinic; ²University 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 Singer¹ | Sushama Kattinakere Sreedhara² | Krista F Huybrechts³
Sebastian Schneeweiss⁴
¹Department of Medicine, Massachusetts General Hospital, Harvard Medical School; ²Brigham and Women’s Hospital, Harvard Medical School; ³Brigham and Women’s Hospital, Division of Pharmacoepidemiology and Pharmacoeconomics; ⁴Division 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 Mack¹ | Michael Osterholm² | Erin Wasserman³
Natalia Petruski-Iveleva³ | Deverick J Anderson⁴
Emily Myers⁵ | Navdeep Singh⁶ | Patti Walton⁷
Gary Solomon⁸ | Christopher Hostler⁹ | Jimmie Mancell⁸
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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 Alterovitz¹ | Lam Phuc Vinh Nguyen¹
John Dougherty² | Elaine Thompson³ | Hussein Ezzeldin¹
Luis Santana-Quintero¹ | Konstantinos Karagiannis¹
Vahan Simonyan¹ | Yassameen Azarbaijani¹
Marina Kondratovich¹ | Danica Marinac-Dabic²
Mark Walderhaug¹ | Richard Forshee³
Yelizaveta Torosyan¹
¹US Food and Drug Administration; ²FDA/CDRH; ³FDA/CBER

Sex-differences in Risk of Early Revision After Primary Total Knee Arthroplasty
Suveshya Aryal¹ | Per-Henrik Randsborg²
Danica Marinac-Dabic³ | Xinyan Zheng⁴ | Jinlan Mao⁴
Amanda Chen¹ | Vincent Devlin⁵ | Raquel Peat⁶
Art Sedrakyan⁴
¹Weill Cornell Medical College; ²Hospital for Special Surgery; ³FDA/CBER; ⁴Weill Cornell Medicine; ⁵US Food and Drug Administration

The Association Between Bariatric Surgery and Carpal Tunnel Syndrome: A Cohort Study from Swedish Nationwide Healthcare Registries
Jennifer Lane¹ | Dag Holmberg² | Andrea Burden³
Dominic Furniss¹ | Theresa Burkard⁸
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The Association Between Bariatric Surgery and Cataract: A Cohort Study from Swedish Nationwide Healthcare Registries
Theresa Burkard¹ | Dag Holmberg² | Farhad Hafezi³ | Andrea M Burden¹
¹ETH Zurich; ²Upper Gastrointestinal Surgery, Department of Molecular medicine and Surgery, Karolinska Institute, Karolinska University Hospital, Stockholm, Sweden; ³ELZA Institute, Dietikon, Switzerland

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 Weberpals¹ | Arjun Sondhi²
¹UNC Gillings School of Global Public Health; ²Department of Epidemiology, University of North Carolina at Chapel Hill

A New Method to Estimate the Total Cohort Size for Patient Recruitment in self-controlled Case Series Study
Ling Li¹ | Stephen Schachterle² | Charles Wentworth³
¹HealthCore, Inc.; ²Pfizer Inc; ³Pfizer Inc.

A Plasmode Simulation of Covariate Misclassification and Transportability
Michael Andrew Webster-Clark¹ | Jessie K Edwards²
¹UNC Gillings School of Global Public Health; ²Department of Epidemiology, University of North Carolina at Chapel Hill

Death Documentation Lag in COVID-19 Electronic Health Record (EHR) Suggests Caution in Near-real-time Analysis
Ajit Londhe¹ | Jie Zhang¹ | Corinne Brooks²
¹Amgen Inc; ²Center 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 Guo¹ | Sara Khalid¹ | Victoria Strauss¹
¹University of Oxford; ²London School of Hygiene & Tropical Medicine; ³Centre 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-Clark¹ | Michele Jonsson Funk²
¹UNC Gillings School of Global Public Health; ²University of North Carolina at Chapel Hill; ³Department of Epidemiology, University of North Carolina at Chapel Hill; ⁴Harvard T. H. Chan School of Public Health; ⁵UNC Eshelman School of Pharmacy

METHODS IN PHARMACOEPIDEMIOLOGY

A Plasmode Simulation of Covariate Misclassification and Transportability
Michael Andrew Webster-Clark¹ | Jessie K Edwards²
¹UNC Gillings School of Global Public Health; ²Department of Epidemiology, University of North Carolina at Chapel Hill

Controlling for Differential Regression to the Mean Using Summary Measures of Pre-treatment Laboratory Values in Propensity Scores
Chase Latour¹ | Leah McGrath² | Alexander Breskin³
¹University of North Carolina at Chapel Hill; ²NoviSci; ³NoviSci Inc.; ⁴NoviSci, Inc.

Cardinality Matching vs Propensity Score Matching in Multiple Sclerosis
Nicholas Belviso | Gabrielle Simoneau | Bora Youn Fabio Pellegrini | Chanyu Shen | Carl de Moor Biogen

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Categorization of COVID-19 Severity to Determine Mortality Risk
Elizabeth Garry¹ | Andrew Weckstein¹ | Kenneth Quinto²
¹Aetion, Inc; ²US Food and Drug Administration; ³Division of Epidemiology, Office of Surveillance and epidemiology,Center for Drug Evaluation and Research, US Food and Drug Administration; ⁴HealthVerity

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**METHODS IN PHARMACOEPIDEMIOLOGY**

**Graphical Representation of an Array of Quantitative Bias Analysis Scenarios for Differential Outcome Misclassification**
J Bradley Layton¹ | Ryan Ziemiecki¹ | Heather Danysh¹
Charles Gaber² | Alicia Gilsenan¹
Catherine Bishop Johannes¹
¹RTI Health Solutions; ²University of North Carolina at Chapel Hill

**Identifying Active Pregnancies Using ICD-10 Z3A Codes vs Completed Pregnancies Using Outcomes**
Monica Bertola¹ | Li Zhou² | Michael Doherty³
Florence Wang³ | John Seeger™
¹Optum Epidemiology; ²Optum

**Improving Methods of Identifying Anaphylaxis for Medical Product Safety Surveillance Using Natural Language Processing and Machine Learning**
David Carrell¹ | Susan Gruber² | James Floyd³
Maralysa Bann⁴ | Kara Cushing-Haugen⁵ | Ron Johnson¹
Vina Graham¹ | David Cronkite¹ | Brian Hazlehurst⁶
Andrew Felcher⁶ | Cosmin Bejan⁷ | Adee Kennedy⁷
Mayura Shinde⁸ | Sara Karami⁸ | Yong Ma⁹
Daniela Stojanovic¹⁰ | Yueqin Zhao¹² | Robert Ball¹⁰
Jennifer Nelson¹
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**Longitudinal Adherence Trajectories to Biologic Disease Modifying Anti-rheumatic Drugs in Tuscany, Italy**
Sabrina Giometto¹ | Irma Convertino² | Marco Tuccori³
Rosa Ginì³ | Massimiliano Cazzato⁴ | Giulia Valdiserra⁵
Emiliano Cappello⁶ | Sara Ferraro⁷ | Silvia Tillati⁸
Marco Fornili⁹ | Claudia C Bartolini¹⁰ | Olga Paoletti¹¹
Giuseppe Turchetti¹² | Leopoldo Trieste¹²
Valentina Lorenzoni¹³ | Corrado Blandizzi¹⁴
Marta Mosca³ | Ersilia Lucenteforte³
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**Optimization-based Stable Balancing Weights vs Generalized Boosted Modeling for Propensity Score Weighting**
Stephen Johnston¹ | Luo Li¹ | Harikumaran Dwarakanathan²
David Wei¹ | Pragyai Rai² | Paul Coplan²
¹Johnson & Johnson; ²Mu Sigma

**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-Levy¹ | Emmanuelle Boutmy² | Angela Grelaud³
Meritxell Sabido Espin⁴ | Pauline Diez⁵ | Clémentine Lacueille³
Régis Lassalle³ | Caroline Foch⁷ | Cécile Droz-Perroteau⁶
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**Linear Mixed Model and Multistate Markov Model to Compare Changes in Clinical Measurements over Time. a Blood Pressure Example**
Emmanuelle Boutmy¹ | Arthur Allignol²
Thilo Hohenberger² | Caroline Foch¹ | Ulrike Hostalek²
¹Merck KGaA Darmstadt, Germany; ²Merck KGaA, Darmstadt, Germany

**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 Simonneau | Fabio Pellegrini
Biogen

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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 Matching-adjusted Indirect Comparisons and Targeting External Control Arm Estimands
Stephen Johnston1 | Harikumaran Dwarakanathan2
Jason Waggoner1 | Michael Schwiers1 | Sanjoy Roy1 | Paul Coplan1
1Johnson & Johnson; 2Mu Sigma

The Effect of the Anticholinergic Properties of Antidepressants on the Incidence of Dementia: A Target Trial Emulation
Joan Forns1 | Jaume Aguado1 | Elena Rivero-Ferrer1
Estel Plana1 | Barbra Dickerman2
Xabier Garcia de Albeniz1
1RTI Health Solutions; 2Harvard 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 Jin1 | Sebastian Schneeweiss2 | Dave Merola3
Joshua Lin
1BWH Div of Pharmacoepidemiology and Pharmacoconomics; 2Division of Pharmacoepidemiology and Pharmacoconomics, Department of Medicine, Brigham and Women’s Hospital and Harvard Medical School, Boston, Massachusetts, USA; 3Division of Pharmacoepidemiology and Pharmacoconomics, 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 Du1 | Sara Khalid2 | Daniel Prieto-Alhambra2
Victoria Strauss2
1CSM, NDORMS, University of Oxford; 2University of Oxford; 3Centre 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 Garry1 | Andrew Weckstein1 | Kenneth Quinto2
Tamar Lasky2 | Aloka Chakravarty3 | Sandy Leonard4
Sarah Vittoe1 | Jeremy A Rassen5 | Nicolle M Gatto3
1Aetion, Inc.; 2US Food and Drug Administration; 3Food and Drug Administration; 4HealthVerity; 5Aetion, Inc.

Use of Linked Databases for Improved Confounding Control: Considerations for Potential Selection Bias
Jenny Sun1 | Sengwee Toh2
1Harvard Pilgrim HealthCare Institute; 2Harvard 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-Clark1 | Jennifer Lund2
Hanna Sanoff3 | Til Stürmer2 | Daniel Westreich4
Alexander Keil4
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Validation of an Algorithm to Identify Hormonal Contraceptive Exposure in a Large Integrated Health Care Delivery System Database
Mary Anne Armstrong1 | Malini Chandra2 | Darios Getahun3
Michael Fassett4 | Jiaxiao Shi3 | Amy Alabaster2
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Validity of Electronic Health Records-based Measures for COVID-19 Hospitalization and Severe Outcomes
Sharon Fuller1 | Kathy Gleason2 | Rod Walker1
Stephen Fortmann3 | Ladia Albertson-Junkans1
J. David Powers3 | Mi Lee4 | James Floyd4
Lisa Temposky1 | Susan Shortreed1 | Elizabeth Bayliss3
Laura Harrington1 | Jennifer Kuntz4 | Lisa Pieper2
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Oral Presentations

**PEDIATRICS**

**Antibiotic Prescribing in Children Aged 0-6 Years in Germany: Assessing Regional Variations and Potential Explanations Based on Claims Data**
Oliver Scholle1 | Marieke Asendorf | Christoph Buck2
Susann Grill2 | Oliver Riedel2 | Ulrike Haug3

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**Early Life Antibiotic Exposure and Incident Chronic Diseases in Childhood**
Matthew Beier1 | Soko Setoguchi2 | Tobias Gerhardt3
Jason Roy4 | Avinash Gabbeta5 | Brian Strom6
Martin Blaser7 | Daniel Horton8

1Rutgers, Robert Wood Johnson Medical School; 2RWJ Medical School, Center for Pharmacoepidemiology and Treatment Science (PETS), Institute for Health, Health Care Policy and Aging Research; 3Rutgers Center for Pharmacoepidemiology and Treatment Science; 4Rutgers University, Department of Biostatistics and Epidemiology; 5St. Christopher’s Hospital for Children; 6Rutgers Biomedical And Health Sciences, Rutgers University; 7Center for Advanced Biotechnology and Medicine, Rutgers University; 8Rutgers University

**Filled Prescriptions for Opioids Among Children and Adolescents – a Nationwide Study from 2010 to 2018**
Aleksi Hamina1 | Marte Handal2 | Olav Fredheim3
Thomas Clausen1 | Li-Chia Chen4 | Svetlana Skurtveit6

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**General Practitioner Prescribing Trends Among Pediatric Patients in the United Kingdom: 1998-2018**
Reem Masarwa1 | Claire Lefebvre2 | Robert Platt3
Kristian Filion4

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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 Lin1 | Yu-Jie Huang2 | Wei-I Huang3
Pi-Hui Chao4 | Wen-Wen Chen2 | Fei-Yuan Hsiao3

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**Prescribed Medicine Use in a Nationwide Sample of Australian Children: Extent of Off-label Use**
Andrea Schaffer1 | Natasha Nassar2 | Claudia Bruno3
Nicholas Buckley4 | Rose Cairns2 | Melissa Litchfield5
Simon Paget2 | Helga Zoega6 | Sallie-Anne Pearson6

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**Risk of Type 2 Diabetes Among Children Initiating Anticonvulsant Mood Stabilizers: Application of a Target Trial Approach**
Jenny Sun1 | Jessica Young | Aaron Sarvet2
Pi-i Debby Lin2 | Sengwee Toh2 | Jason Block2

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**Selective Serotonin Reuptake Inhibitors and the Risk of Type 2 Diabetes Mellitus in Youths**
Thi Xuan Dai Ca3 | Christopher Filliter2
François Montastruct3 | Oriana Hoi Yun Yu2
Emma Fergusson4 | Soham Reji5 | Laurent Azoulay4
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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**.
Oral Presentations

PHARMACOVIGILANCE

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
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Impact of COVID-19 Social Distance Restrictions on Hospital Encounters Due to Injury by Poisoning or Toxicity of Medications or Non-medicinal Substances
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PREGNANCY AND LACTATION

Antidepressant Use During Pregnancy and the Risk of Neurodevelopmental Disorders in Children
Elizabeth Suarez1 | Brian Bateman2
Sonia Hernandez-Diaz3 | Loreen Straub4 | Yanmin Zhu4
Helen Mogun2 | Krista Huybrechts2
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Balance of Unmeasured Covariates After Propensity Score Matching Based on Measurable Covariates in Perinatal Pharmacoepidemiologic Studies
Yanmin Zhu1 | Thuy Thai2 | Sonia Hernandez-Diaz3
Brian Bateman4 | Loreen Straub1 | Kathryn Gray6
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Characteristics and Outcomes of Pregnancies in Women with Heart Failure: A Retrospective Cohort Study in the Sentinel System
Yan Li1 | Austin Cosgrove2 | Efe Eworuke3
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Charateristics of Initial Postpartum Opioid Prescribing and Risks of Serious Opioid-related Events After Cesarean Delivery
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Comparative Safety of In-utero Exposure to Buprenorphine Combined with Naloxone vs Buprenorphine Monoprodut with Respect to Congenital Malformations
Loreen Straub1 | Krista Huybrechts2
Sonia Hernandez-Diaz3 | Elizabeth Suarez4 | Yanmin Zhu1
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Benztodiazepine Use in the First Trimester and Risk of Congenital Malformations: A Nationwide Cohort Study in South Korea
Yunha Noh1 | Hyesung Lee3 | Ahhyung Choi3
Dong-Sook Kim4 | Ju-Young Shin5
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P R E G N A N C Y  A N D  L A C T A T I O N

COVID-19 Pharmacotherapy During Pregnancy: International Registry of Coronavirus Exposure in Pregnancy (IRCEP)
Sonia Hernandez-Diaz¹ | Louisa Smith² | Diego Wyszynski³
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Development and Validation of ICD-10 Claims-based Algorithms for Pregnancy and Infant Outcomes
Andrea Chomistek¹ | Kelesitse Phiri² | Jenna Calderbank³
Michael Doherty⁴ | Stephanie Chlue⁵
Brenda Hinman-McIlroy⁶ | Michael Snabes⁷
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Effects of Gadolinium-enhanced MRI Exposure During Pregnancy on Neonatal Intensive Care Unit Admission
Thuy Thai¹ | Sabina Nduaguba² | Nicole Smolinski³
Xi Wang⁴ | Leyla Sahin⁵ | Kate Gelperin⁶ | Steven Bird⁷
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Fertility Rates in Women with Psoriasis and Psoriatic Arthritis: A Population-based Cohort Study
Teng-Chou Chen¹ | Ireny Iskandar² | Rosa Parisi³
Matthias Pierce⁴ | Elise Kleyrn⁵ | Christopher Griffiths⁶
Darren Ashcroft⁷
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First Trimester Exposure to Buprenorphine Compared to Methadone for Treatment of Opioid Use Disorders and the Risk of Congenital Malformations
Elizabeth Suarez¹ | Krista Huybrechts²
Sonia Hernandez-Diaz³ | Loreen Straub⁴ | Yanmin Zhu⁴
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Implication of Maternal Continuous Enrollment on Stillbirth Gestational Age Distributions and Maternal Characteristics in Medicaid Enrollees
Thuy Thai¹ | Sonja Rasmussen² | Nicole Smolinski³ Sabina Nduaguba⁴ | Yanmin Zhu⁴ | Brian Bateman⁶
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Feasibility of Using Healthcare Utilization Data to Identify Neuromedical Disorders for Transgenerational Pharmacoepidemiology
Loreen Straub¹ | Brian Bateman² | Sonia Hernandez-Diaz³
Elizabeth Suarez⁴ | Cassandra York⁵ | Yanmin Zhu¹
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PREGNANCY AND LACTATION

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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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Kristian Filion2
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Metformin vs Insulin in Early Pregnancy and Risk of Congenital Malformations
Lars Kjerpeseth1 | Carolyn Cesta | Anders Engeland2
Kari Furu1 | Mika Gissler3 | Hanne Gulseth1
Øystein Karlstad1 | Helle Kieler4 | Maarit Leinonen5
Mette Nørgaard6 | Laura Pazzagli7 | Randi Selmer1
Helga Zoega1 | Jacqueline Cohen1
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Prenatal Antiseizure Medication Exposure and Risk of Autism and Intellectual Disability. SCAN-AED: A Nordic Cohort Study
Marte-Helene Bjørk1 | Helga Zoega2 | Maarit Leinonen5
Jacqueline Cohen4 | Julie Dreier5 | Kari Furu4
Nils Erik Gilhus1 | Mika Gissler3 | Öskar Hálfdánarson6
Jannicke Igland7 | Yuelian Sun8 | Torbjörn Tomson9
Silje Alvestad10 | Jakob Christensen11
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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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Loreen Straub2 | Helen Mogun2 | Sonia Hernandez-Diaz4
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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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Prenatal Analgesic Opioid Exposure and Risk of ADHD in Childhood
Johanne Troennes1 | Angela Lupattelli2 | Marte Handal3
Svetlana Skurtveit1 | Eivind Ystrom2 | Hedvig Nordeng3
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Statistical Power for Use of Tree-based Scan Statistics for Surveillance of Infant Outcomes Following Maternal Perinatal Medication Use
Elizabeth Suarez1 | Michael Nguyen2 | Di Zhang3
Yueqin Zhao3 | Danijela Stojanovic2 | Monica Munoz4
Jane Liedtka5 | Abby Anderson6 | Wei Liu7
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The Comparative Safety of Antiseizure Medication Polytherapy vs Valproate in Pregnancy and Risk of Major Congenital Malformations
Jacqueline Cohen1 | Sijie Alvestad2 | Elizabeth Suarez3
Andrea Schaffer4 | Randi Selmer5 | Alys Havard6
Brian Bateman7 | Helga Zoega8 | Helle Kieler9
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The Impact of In-utero Antipsychotic Drug Exposure on Congenital Malformations: An International Cohort Study
Krista Huybrechts1 | Loreen Straub2 | Pär Karlsson3
Laura Pazzagia4 | Sonia Hernandez-Diaz5
Jacqueline Cohen6 | Brian Bateman7 | Randi M Selmer7
Elizabeth Suarez8 | Kari Furu8 | Mette Nørgaard9
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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 Claims-based Studies for Achieving Comparability in hba1c Levels Between Treatments in Pregnant Women with Type 2 Diabetes
Carolyn Cesta | Sonia Hernandez-Diaz1 | Brian Bateman2
Krista Huybrechts2 | Ellen Seely3 | Elisabetta Patorno8
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Oral Presentations

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 Suarez1 | Michael Nguyen2 | Di Zhang3
Yueqin Zhao3 | Danijela Stojanovic2 | Monica A Munoz4
Jane Liedtka5 | Abby Anderson6 | Wei Liu7
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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 Zhu1 | Thuy Thai2 | Brian Bateman3
Sonia Hernandez-Diaz4 | Loreen Straub1 | Jessica Franklin5
Kathryn Gray6 | Almut Winterstein2 | Lockwood Taylor7
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Validity of ICD-10 Z3A Codes for Estimating Date of Last Menstrual Period
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Michael Doherty3 | Stephanie Chiue4
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RARE DISEASE

Prediction Algorithm for Identifying Patients with Fabry or Pompe Disease in Electronic Health Records
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Kristin Glass1 | Christopher Rudolf2 | Ron Herings1

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The Association Between Bariatric Surgery and Dupuytren Disease: A Cohort Study from Swedish Nationwide Healthcare Registries
Theresa Burkard1 | Jennifer Lane2 | Dag Holmberg3
Andrea Burden1 | Dominic Furniss2

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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

Veena Hoffman1 | Jesper Hallas2 | Marie Linder3
Andrea Margulis4 | Brandon Suehs4 | Alejandro Arana6
Cheryl Enger1 | Libby Horter6 | Ingvild Odsbu7
Morton Olesen2 | Susana Perez-Guthmann6 | Yihua Xu6
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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 Hoffman1 | Samuel Governor2 | Kimberly Daniels3
Ryan Seals4 | Najat Ziyadeh5 | Florence Wang6
Dingwei Dai8 | Cheryl McMahill-Walraven9
Patty Shuminski9 | Vera Frajzyngier9 | Xiaofeng Zhou9
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Proton Pump Inhibitors and Risk of Gastric Cancer: A Population-based Cohort Study

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

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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)

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

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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

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Corinne Williams1 | Rosa Gini2 | Aina Mira-Iglesias3
Tania Schink4 | Patrick Souverein5 | Lei Wang6
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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
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Sensitivity Analysis of Design Choices for Estimating Incidence Rates of Adverse Events of Special Interest in Vaccine Safety
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Vaccination and Acute Flares in Multiple Sclerosis: A Nationwide Case-crossover Study Using the French SNDS Health Care Databases
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Oral Presentations

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Approach to Falsify Calendar Time Instrumental Variable Assumptions in Estimating Treatment Effects
Phyo Htoo | Michele Jonsson Funk | Mugdha Gokhale
Gang Fang | John Buse | Til Stürmer
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Ethnic Differences in COVID-19 Infection, Hospitalisation, and Mortality: An Opensafely Analysis of 17 Million Adults in England
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William Hulme | Anna Schultz | Brian MacKenna
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Elizabeth Williamson | Harriet Forbes | Kevin Wing
Helen McDonald | Chris Bates | Seb Bacon | Alex Walker
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Helen Curtis | Nicholas DeVito | Richard Croker
Henry Drysdale | Jonathan Cockburn | John Parry
Frank Hester | Sam Harper | Ian Douglas
Laurie Tomlinson | Stephen Evans | Richard Grieve
David Harrison | Kathy Rowan | Kamlesh Khunti
Nishi Chaturvedi | Liam Smeth | Ben Goldacre
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Multi-depth, Iterative Causal Forest for Subgroup Identification
Tiansheng Wang | Michael Kosorok | Alexander Keil
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Nondifferential Treatment Misclassification Biases Toward the Null? Not a Safe Bet
Rachael Ross | Michele Jonsson Funk | I-Hsuan Su
1 University of North Carolina; 2 University of North Carolina at Chapel Hill

Predictors of Severe COVID-19 Outcome in Patients with Rheumatoid Arthritis
Sara Burns | Tiffany Siu Woodworth | Justin Manjourides
1 Panalgo; 2 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 | Almut G Winterstein
Wei-Hsuan Lo-Ciganic | Patrick J Tighe
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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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**BENEFIT-RISK ASSESSMENT, COMMUNICATION, AND EVALUATION (BRACE)**

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Yinxi Yu¹ | Vatinee Bunya² | Brian VanderBeek²
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**Gender Differences in Valproic Acid Use for Approved Indications in the United States (2017-2018) – an Opportunity for Risk Mitigation?**
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**Risk of Major Cardiovascular Event in Jak Inhibitor Treated Patients: Analysis of a National Claim Database**
Amandine Gouverneur | Jérôme Avouac¹ | Clément Prati² | Jean-Luc Cracowski³ | Thierry Schaeverbeke⁴
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**Missingness in Real World Data Submitted for Regulatory Decision-Making: Eastern Cooperative Oncology Group Performance Status Case Study**
Cherise Wong¹ | Caitlin Knox¹ | Wenzhen Ge³ | Ning Wu¹
Andrea Marcus¹ | Jessica Jalbert² | Asieh Golozar³
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**BIOLOGICS/BIOSIMILARS**

**Risk of Major Cardiovascular Event in Jak Inhibitor Treated Patients: Analysis of a National Claim Database**
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Julian Matthewman1 | Kathryn Mansfield1
Richard Silverwood2 | Amy Mulick4 | Daniel Prieto-Alhambra3
Katherine Lowe1 | Liam Smeeth1 | Sinéad Langan1
1London School of Hygiene & Tropical Medicine; 2Centre for Longitudinal Studies, University College London; 3Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, UK

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Renee Shediac1 | Brian Calingaert2 | Abenah Harding2
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1BioMarin Pharmaceutical Inc.; 2RTI Health Solutions; 3BioMarin (UK) Limited

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Hossam Saad2 | Jeffrey Crawford4
1EpidStrategies, A Division of ToxStrategies; 2Amgen; 3EpidStrategies, Rockville, MD; 4Duke Cancer Institute

Comparing Outcomes in Trial-Eligible vs Real-World COVID-19 Patients: The Case of Invasive Mechanical Ventilation
Ashley Martinez1 | Silva Perez-Vilar3 | Mayura Shinde3
Maria Kempner4 | Joy Kolonoski4 | Sarah Dutcher2
Brian Kit2
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Seoyoung Kim1 | Hemin Lee2 | Jeffrey Sparks2
Kazuki Yoshida3 | Rishi Desai1 | Joan Landon2
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Outpatient-Identified COVID-19 and Subsequent Hospitalized Thrombotic Events
Silvia Perez-Vilar1 | Ashley I Martinez2 | Mayura Shinde3
Maria Kempner4 | Joy Kolonoski5 | Sarah Dutcher1
Brian Kit1
1Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; 2Harvard Pilgrim Health Care Institute; 3Harvard Medical School; 4Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute

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Huifen Wang1 | Lindsey Powers Happ2
Samantha St. Lauren3 | Charlotte Carroll2
1Huifen Wang; 2GlaxoSmithKline

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Matthew Reynolds1 | Alison Bourke1 | Kalyani Hawaldar1
Nancy Dreyer1
1IQVIA; 2IQVIA

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Ikenna Unigwe1 | Seonkyeong Yang2 | Hyunjin Song3
Wei-Hsuan Lo-Ciganic4 | Robert Cook5 | Haesuk Park6
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Julius Asubonteng1 | Sara Haredasht1 | Seth Kuranz2
Anand Chokkalingam1
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DRUG EFFECTIVENESS

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Antonio González Pérez1 | Yanina Balabanova2
María Saez1 | Gunnar Brobert3 | Luis Garcia Rodriguez
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Chien-Chou Su4
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Rohit Ojha1 | Yan Lu1 | Kalyani Narra2 | Rachel Meadows3
Aaron Gehr1 | Bassam Ghabach2
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Long-Acting Insulin Analogs vs Intermediate-Acting Insulin and the Risk of Major Adverse Cardiovascular Events Among Patients with Type 2 Diabetes in the United Kingdom
Vanessa Brunetti1 | Oriana Yu2 | Robert Platt3
Kristian Filion4
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GYeon Oh¹ | Patricia Freeman² | Candace Brancato³
Jana McAninch⁴ | Alex Secora⁴ | Candice Collins⁴
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Katherine Callaway Kim¹ | Mina Tadrous²
Sandra Kane-Gill³ | Ian Barbash⁴ | Katie Suda⁵
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Henry Amdany | Wendy O’meara | Gabriel Kigen
Moi University

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Measuring Mental Health Prescribing Safety Indicators in UK Primary Care
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Richard Keers²
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Patterns of Antibiotic Prescription Among Adult Outpatients in Italy
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Manuela Casula | Alberico Catapano | Elena Tragni
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**HEALTH ECONOMICS/OUTCOMES RESEARCH**

Comparison of Medication Adherence Between Initiators of a Multi-drug Dispensing System & Users of Retail Pharmacy

Lauren Stevens¹ | Jeffrey Ellis¹ | Anita Desai-Naik²
Lilian Ndehi³ | Andy Bowe¹
¹Humana Healthcare Research; ²Humana Pharmacy Solutions; ³Humana Inc.

Cost-Utility of Nivolumab for Treatment of Head and Neck Cancer from a Brazilian Public Health System Perspective.

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Daílila Gomes¹ | Joslaine de O Nunes³
Ricardo Fernandes⁴ | Ivan Zimmermann⁵
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Effects of Initiating a Multi-dose Drug Dispensing System on Medication Adherence

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SGLT2 Inhibitors vs GLP-1 Agonists: Comparative Progression of Renal Disease

Lauren Stevens¹ | Andy Bowe¹ | Phil Schwab¹
Michael Tindal² | Andrea Bloomfield²
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The Prevalence of Hyperkalemia and Associated Clinical Characteristics and Outcomes Among Hospitalized COVID-19 Patients

Rena Moon¹ | Abiy Agiro² | Ning Rosenthal¹
Harold Brown¹ | Randall Legg³ | Alpesh Amin⁴
¹Premier Applied Sciences, Premier Inc; ²AstraZeneca Payer Evidence; ³AstraZeneca Payer Medical; ⁴University of California, Irvine

**INFORMATICS**

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

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Claire Fox⁵ | Thomas Jemielita⁵ | Tianxi Cai¹
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Christine Lu¹ | Laura Hou¹ | Joy Kolonoski²
Andrew Petrone¹ | Fang Zhang¹ | Catherine Corey³
Ting Ying Huang¹ | Marie Bradley⁴
¹Department of Population Medicine at Harvard Medical School; ²Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute; ³Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; ⁴Division of Epidemiology, Office of Surveillance and EpidemiologyCenter 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 Xu¹ | Stefka Tyanova¹ | Tarec Christoffer El-Galaly¹
Khaled Sarsour² | Wan-Jen Hong³ | Melissa Williamson²
¹F. Hoffmann-La Roche; ²Genentech; ³Genentech Inc

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Bethany DiPrete¹ | Cynthia Girman² | Panagiotis Mavros³
Alexander Breskin⁴ | M. Alan Brookhart⁵
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Alice Joules | Natalia Petruski-Ivleva | Michael Warner
Patrick Long | Aidan Cooper | Nancy Dreyer
IQVIA

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Erica Weinstein¹ | Alisa Stephens-Shields² | Bogadi Loabile¹
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**Feasibility and Acceptability of the OptiMEDs Tool for Multidisciplinary Medication Review in Belgian Nursing Homes**
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Angela Duma | Kevin Hastie | Raymond Kassekert  
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