ANALYSIS GROUP

Analysis Group Podium Presentations and Posters

2024 ISPE ANNUAL MEETING | AUGUST 24–28 | BERLIN, GERMANY

Analysis Group's health care experts apply skills in epidemiology, biostatistics, clinical research, and regulatory strategy to questions across broad therapeutic areas.

This year, we are pleased to support two podium presentations and present five posters at the 2024 ISPE Annual Meeting. Please find details below.

Please stop by and say hello to our team at Booth #301.

2024 ISPE Annual Meeting Podium Presentations Supported by Analysis Group Research

PODIUM PRESENTATION

Monday, August 26 | 1:30 p.m.–1:45 p.m. CEST | Convention Hall I D

Applying the self-controlled case series to analyse safety endpoints in single-arm, open label extension studies: A case study of Belimumab for the treatment of systemic lupus erythematosus and risk of infection

Open-label extensions (OLE) of randomized controlled trials (RCTs) can generate long-term data on the safety and efficacy of a drug, but their interpretation can be complicated by the lack of a control arm. To evaluate whether the self-controlled case series (SCCS) method can aid interpretation of emerging safety data in this context, we studied data from an extension study of a treatment for lupus. The results from our study showed that SCCS could provide an efficient and robust means of evaluating safety signals in single-arm OLE. In this presentation, we will explore the results of our investigation and discuss the factors that researchers may need to consider when using the SCCS method in similar assessments.

Presenting Author:

Anna Schultze, Ph.D., M.Sc.*; London School of Hygiene & Tropical Medicine*

Moderators:

Sophie H. Bots, Ph.D.*; Assistant Professor, Utrecht Institute for Pharmaceutical Sciences, Utrecht University*

Edward Chia-Cheng Lai, Ph.D.*; Professor, Institute of Clinical Pharmacy and Pharmaceutical Sciences, National Cheng Kung University*

Associated Experts & Consultants:

Marianne Cunnington, Ph.D.*; Vice President, Analysis Group*

PODIUM PRESENTATION

Wednesday, August 28 | 8:45 a.m.–9:00 a.m. CEST | Room XV

Impact of data source diversity on the distribution of key variables in pregnancy cohorts based on the ConcePTION pregnancy algorithm leveraging a random forest imputation model

Researchers have used the ConcePTION pregnancy algorithm to build an ecosystem that can leverage observational data sources to generate real-world evidence (RWE) that could be helpful in clinical and regulatory decision making. When assessing RWE from cohorts of pregnant patients in pharmaco-epidemiological studies, it may be beneficial to conduct sensitivity analyses on that data. In our research, we describe the impact of the use of diverse data sources on results derived from ConcePTION. In short, we extracted data from a large cohort of pregnancies across diverse data sources in Europe and found that diversity across data sources resulted in differences in how the end of pregnancies was categorized. In this presentation, we will explore how data source diversity can impact the distribution of key variables in pregnancy cohorts when using the ConcePTION algorithm.

Presenting Author:

Anna Girardi, Pharm.D., Ph.D.; *ARS Toscana*

Moderators:

Yanmin Zhu, Ph.D.; *Instructor in Medicine, Brigham and Women's Hospital and Harvard Medical School*

Xuerong Wen, Ph.D.; *Associate Professor, University of Rhode Island*

Associated Experts & Consultants:

Marianne Cunnington, Ph.D.; *Vice President, Analysis Group*

2024 ISPE Annual Meeting Analysis Group Research Posters

POSTER SESSION A

Monday, August 26 | 8:00 a.m.–6:00 p.m. CEST | Exhibit Hall

Comparative Effectiveness of ARB and ACEi for Cardiovascular Outcomes and Risk of Angioedema by Ethnicity: an Analysis in the UK Clinical Practice Research Datalink with Emulation of a Reference Trial (ONTARGET)

Objectives: To investigate CVD treatment effect heterogeneity among ethnic minority groups in the UK.

Conclusions: After emulating a landmark clinical trial and extending analysis we found evidence of differences in comparative drug effects of ARB and ACEi by ethnicity in the UK population.

Authors: Vice President Marianne Cunnington and researchers from Queen Mary University of London, the London School of Hygiene & Tropical Medicine, McMaster University, and Friedrich-Alexander University

Funding for this study was provided by GSK.

Impact of Treatment of COVID-19 with Sotrovimab on Post-Acute COVID-19 Syndrome: An Analysis of National COVID Cohort Collaborative (N3C) Data

Objectives: To evaluate the impact of sotrovimab, a monoclonal antibody used to reduce the risk of COVID-19 progression, on the risk of developing PASC.

Conclusions: Sotrovimab treatment is associated with a small but statistically significant reduced risk of developing PASC among high-risk patients with acute COVID-19 and may present an effective option for PASC prevention in this population.

Authors: Managing Principals Mei Sheng Duh and Maral DerSarkissian, Vice President Rose Chang, Associate Tracy Guo, Analyst Daisy Liu, and researchers from GSK

Funding for this study was provided by GSK.

NALIRIFOX versus FOLFOX as first-line treatment of metastatic pancreatic ductal adenocarcinoma (mPDAC): Real-world comparative overall (OS) survival analysis

Objectives: To compare OS between patients with mPDAC treated with 1L NALIRIFOX in the NAPOLI 3 trial and an external control arm of patients with mPDAC treated with 1L FOLFOX in RW clinical practice.

Conclusions: NALIRIFOX regimen in NAPOLI 3 resulted in significantly improved OS compared to FOLFOX in a RW clinical practice setting, suggesting incremental survival benefits associated with liposomal irinotecan in the NALIRIFOX regimen. Limitations of this study include small sample size in the RW FOLFOX cohort and unmeasured confounding.

Authors: Managing Principals Mei Sheng Duh and Maral DerSarkissian, Vice President Rose Chang, Associates Mu Cheng and Louise Yu, and researchers from Memorial Sloan Kettering Cancer Center and Ipsen

Funding for this study was provided by Ipsen.

POSTER SESSION B

Tuesday, August 27 | 8:00 a.m.–6:00 p.m. CEST | Exhibit Hall

Final Results from Post-Emergency Use Authorization (EUA) Active Safety Surveillance Study among Individuals in the Veterans Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine

Objectives: To assess whether the VHA population experience increased risk of safety events of interest after receiving Pfizer-BioNTech COVID-19 vaccine.

Conclusions: None of the safety events of interest were found to be associated with Pfizer-BioNTech COVID-19 vaccine based on the signal detection and evaluation analyses. No signals were detected for myocarditis/pericarditis, although the small sample size of young men in the VHA population provided limited statistical power.

Authors: President Pierre Cremieux; Managing Principals Mei Sheng Duh and Maral DerSarkissian; Vice President Marianne Cunnington; Manager Catherine Nguyen; Associates Mu Cheng, Angela Lax, and Tracy Guo; and researchers from Pfizer and the US Veterans Health Administration (VHA)

Funding for this study was provided by Pfizer.

POSTER SESSION C

Wednesday, August 28 | 8:00 a.m.–1:30 p.m. CEST | Exhibit Hall

High Misclassification of Glycogen Storage Disease Type 1a in a US Electronic Medical Records Database – Insights from a Physician Note Review

Objectives: To assess the degree of conflation between GSD1a and G6PD deficiency in a large US electronic medical records (EMR) database.

Conclusions: A large conflation due to misclassification between G6PD deficiency and GSD1a in a large EMR database was found. Using diagnosis codes to identify patients with GSD1a will result in significant misclassification and physician note review may be necessary to accurately identify patients with GSD1a. Although a query in a large US claims database potentially confirmed this misclassification, further validation is needed.

Authors: Vice President Fan Mu, Manager Erin Cook, Associate Mu Cheng, Senior Analysts Jessie Lan and Qi Hua, and researchers from Moderna

Funding for this study was provided by Moderna.