

Abeyaratne C, Lalic S, Bell JS, Ilomäki J. Spontaneously reported adverse drug events related to tapentadol and oxycodone/naloxone in Australia. *Ther Adv Drug Saf.* 2018 Apr; 9(4):197-205.

Ali AK, Watson DE. Pharmacovigilance Assessment of Immune-Mediated Reactions Reported for Checkpoint Inhibitor Cancer Immunotherapies. *Pharmacotherapy.* 2017 Sep 26.

Arana JE, Harrington T, Cano M, Lewis P, Mba-Jonas A, Rongxia L, Stewart B, Markowitz LE, Shimabukuro TT. Post-licensure safety monitoring of quadrivalent human papillomavirus vaccine in the Vaccine Adverse Event Reporting System (VAERS), 2009-2015. *Vaccine.* 2018 Feb 21.

Arnaud M, Salvo F, Ahmed I, Robinson P, Moore N, Bégaud B, Tubert-Bitter P, Pariente A. A Method for the Minimization of Competition Bias in Signal Detection from Spontaneous Reporting Databases. *Drug Saf.* 2015 Dec 29.

Bailey J, Thew M, Balls M. An analysis of the use of animal models in predicting human toxicology and drug safety. *Altern Lab Anim.* 2014 Jun;42(3):181-99.

Banovac M, Candore G, Slattery J, Houyez F, Haerry D, Genov G, Arlett P. Patient Reporting in the EU: Analysis of EudraVigilance Data. *Drug Saf.* 2017 Apr 17.

Basilua JM, Pochart P. Cotrimoxazole Prophylaxis Is Not Associated with a Higher occurrence of Atazanavir Treatment Failure: analysis of Worldwide Pharmacovigilance Data. *Infect Disord Drug Targets.* 2019 Dec 19. doi: 10.2174/1871526520666191220112416. [Epub ahead of print] PMID: 31858913

Bill RW, Liu Y, McInnes BT, Melton GB, Pedersen T, Pakhomov S. Evaluating semantic relatedness and similarity measures with Standardized MedDRA Queries. *AMIA Annu Symp Proc.* 2012;2012:43-50.

Bonaldo G, Vaccheri A, Melis M, Motola D. Drug-induced disseminated intravascular coagulation: a pharmacovigilance study on World Health Organization's database [published online ahead of print, 2020 May 22]. *J Thromb Thrombolysis.* 2020;10.1007/s11239-020-02147-y. doi:10.1007/s11239-020-02147-y

Bossard JB, Ponté C, Dupouy J, Lapeyre-Mestre M, Jouanjus E. Disproportionality Analysis for the Assessment of Abuse and Dependence Potential of Pregabalin in the French Pharmacovigilance Database. *Clin Drug Investig.* 2016 Jun 14.

Botsis T, Woo EJ, Ball R. The contribution of the vaccine adverse event text mining system to the classification of possible GuillainBarré Syndrome reports. *Appl Clin Inform.* 2013 Feb 27;4(1):88-99.

Card T, Ungaro R, Bhayat F, Blake A, Hantsbarger G, Travis S. Vedolizumab use is not associated with increased malignancy incidence: GEMINI LTS study results and post-marketing data. *Aliment Pharmacol Ther.* 2020 Jan;51(1):149-157. doi: 10.1111/apt.15538. Epub 2019 Nov 20. PMID: 31747086

Cannon JA, Shen L, Jhund PS, Kristensen SL, Køber L, Chen F, Gong J, Lefkowitz MP, Rouleau JL, Shi VC, Swedberg K, Zile MR, Solomon SD, Packer M, McMurray JJ; PARADIGM-HF Investigators and Committees. Dementia-related adverse events in PARADIGM-HF and other trials in heart failure with reduced ejection fraction. *Eur J Heart Fail.* 2016 Nov 20.

Castillon G, Salvo F, Moride Y. The Social Impact of Suspected Adverse Drug Reactions: An analysis of the Canada Vigilance Spontaneous Reporting Database. *Drug Saf.* 2018 Aug 19. doi: 10.1007/s40264-018-0713-8.

Chen C, Borrego ME, Roberts MH, Raisch DW. Comparison of post-marketing surveillance approaches regarding infections related to tumor necrosis factor inhibitors (TNFi's) used in treatment of autoimmune diseases. *Expert Opin Drug Saf.* 2019 Jun 20:1-12. doi: 10.1080/14740338.2019.1630063.

Chen W, Zhao N, Qin G, Chen J. A Bayesian group sequential approach to safety signal detection. *J Biopharm Stat.* 2013;23(1):213-30.

Chernoff M, Ford-Chatterton H, Crain MJ. The Use of the Medical Dictionary for Regulatory Activities in the Identification of Mitochondrial Dysfunction in HIV-Infected Children. *Case Studies Bus Ind Gov Stat.* 2012 Oct;5(1):17-31.

Chrétien B, Dolladille C, Hamel-Sénécal L, Sassier M, Faillie JL, Miremont-Salamé G, Lelong-Boulouard V, Le Boisselier R, Fedrizzi S, Alexandre J, Humbert X8. Comparative study of hypoglycaemia induced by opioids. Is it a class effect? *Expert Opin Drug Saf.* 2019 Jul 24:1-6. doi: 10.1080/14740338.2019.1646246.

Chung S, Williams B, Dobrinsky C, Patten A, Yang H, Laurenza A. Perampanel with concomitant levetiracetam and topiramate: Post hoc analysis of adverse events related to hostility and aggression. *Epilepsy Behav.* 2017 Aug 19;75:79-85.

Cloitre A, Duval X, Tubiana S, Giraud P, Veyrac G, Nosbaum A, Gouraud A, Mahé J, Lesclous P.

Antibiotic prophylaxis for the prevention of infective endocarditis for dental procedures is not associated with fatal adverse drug reactions in France. *Med Oral Patol Oral Cir Bucal*. 2019 Apr 23. pii: 22818. doi: 10.4317/medoral.22818.

Colombel JF, Sandborn WJ, Reinisch W, Peyrin-Biroulet L, Panaccione R, Rutgeerts P, Hanauer SB, Ghosh S, Van Assche G, Robinson AM, Lau W, Maa JF, Huang B, Pappalardo B, Read H. Long-term safety of adalimumab in clinical trials in adult patients with Crohn's disease or ulcerative colitis. *Aliment Pharmacol Ther*. 2017 Nov 2

de Boissieu P, Gaboriau L, Morel A, Trenque T. Bisphosphonate-related osteonecrosis of the jaw: data from the French national pharmacovigilance database. *Fundam Clin Pharmacol*. 2016 Jun 17.

Ehlken B, Nathell L, Gohlke A, Bocuk D, Toussi M, Wohlfeil S. Evaluation of the Reported Rates of Severe Hypersensitivity Reactions Associated with Ferric Carboxymaltose and Iron (III) Isomaltoside 1000 in Europe Based on Data from EudraVigilance and VigiBase™ between 2014 and 2017. *Drug Saf*. 2018 Dec 10. doi: 10.1007/s40264-018-0769-5.

Eriksson R, Aagaard L, Jensen LJ, Borisova L, Hørlück D, Brunak S, Hansen EH. Discrepancies in listed adverse drug reactions in pharmaceutical product information supplied by the regulatory authorities in Denmark and the USA. *Pharmacol Res Perspect*. 2014 Jun;2(3).

Fahmy AI, Mekkawy MA, Abou-Ali A. Evaluation of bleeding adverse events associated with oral P2Y12 inhibitors use in the Food and Drug Administration adverse event reporting system. *Int J Clin Pharmacol Ther*. 2019 Feb 10. doi: 10.5414/CP203365.

Felicetti P, Trotta F, Bonetto C, Santuccio C, Pernus YB, Burgner D, Chandler R, Girolomoni G, Hadden RD, Kochar S, Kukucu M, Monaco G, Ozen S, Pahud B, Phuong L, Bachtiar NS, Teeba A, Top K, Varricchio F, Wise RP18, Zanoni G19, Živkovic S, Bonhoeffer J; Brighton Collaboration Vasculitis Working Group. Spontaneous reports of vasculitis as an adverse event following immunization: A descriptive analysis across three international databases. *Vaccine*. 2015 Sep 18. pii: S0264-410X(15)01293-1.

Finnell JS, Saul BC, Goldhamer AC, Myers TR. Is fasting safe? A chart review of adverse events during medically supervised, water-only fasting. *BMC Complement Altern Med*. 2018 Feb 20; 18(1):67.

Fukuda A, Tahara K, Hane Y, Matsui T, Sasaoka S, Hatahira H, Motooka Y, Hasegawa S, Naganuma M, Abe J, Nakao S, Takeuchi H, Nakamura M. Comparison of the adverse event profiles of conventional and liposomal formulations of doxorubicin using the FDA adverse event reporting system. *PLoS One*. 2017 Sep 27;12(9).

Gahr M, Zeiss R, Lang D, Connemann BJ, Hiemke C, Schönfeldt-Lecuona C. Drug-induced liver injury associated with antidepressive psychopharmacotherapy: An explorative assessment based on quantitative signal detection using different MedDRA terms. *J Clin Pharmacol*. 2015 Oct 16.

García MG, Larrinaga-Torrentegui U, Eduardo Martinez E, Lertxundi U, Palacios-Zabalza I, Aguirre C. Fractures Related to Tenofovir: A Case/Noncase Study in the European Pharmacovigilance Database. *Am J Ther*. 2018 Jan 8.

Gattás VL, Braga PE, Koike ME, Lucchesi MB, Precioso AR. Safety profile of heterologous serum produced by the Butantan Institute, in São Paulo-SP, Brazil, from 2012 to 2015. *Epidemiol Serv Saude*. 2017 Jul-Sep;26(3):639-647.

Gopal S, Hough D, Karcher K, Nuamah I, Palumbo J, Berlin JA, Baseman A, Xu Y, Kent J. Risk of cardiovascular morbidity with risperidone or paliperidone treatment: analysis of 64 randomized, double-blind trials. *J Clin Psychopharmacol*. 2013 Apr;33(2):157-61.

Hasegawa S, Hatahira H, Naganuma M, Shimauchi A, Sasaoka S, Motooka Y, Fukuda A, Abe J, Nakao S, Kato Y, Ohmori T, Iguchi K, Nakamura M. Adverse Event Trends Associated with OTC Analgesic and Antipyretic Drug: Data Mining of the Japanese Adverse Drug Event Report Database. *Yakugaku Zasshi*. 2017;137(10):1301-1311.

Hatahira H, Hasegawa S, Sasaoka S, Kato Y, Abe J, Motooka Y, Fukuda A, Naganuma M, Nakao S, Mukai R, Shimada K, Hirade K, Kato T, Nakamura M. Analysis of fall-related adverse events among older adults using the Japanese Adverse Drug Event Report (JADER) database. *J Pharm Health Care Sci*. 2018 Dec 17;4:32. doi: 10.1186/s40780-018-0129-8. eCollection 2018.

He Y, Toldo L, Burns G, Tao C, Abernethy DR. A 2012 Workshop: Vaccine and drug ontology in the study of mechanism and effect (VDOSME 2012). *J Biomed Semantics*. 2012 Dec 18;3(1):12.

Hoang T, Liu J, Roughead E, Pratt N, Li J. Supervised signal detection for adverse drug reactions in medication dispensing data. *Comput Methods Programs Biomed*. 2018 Jul; 161:25-38.

Hobart J, Ziemssen T, Feys P, Linnebank M, Goodman AD, Farrell R, Hupperts R, Blight AR, Englishby V, McNeill M, Chang I, Lima G, Elkins J, ENHANCE study investigators. Assessment of Clinically Meaningful Improvements in Self-Reported Walking Ability in Participants with Multiple Sclerosis: Results from the Randomized, Double-Blind, Phase III ENHANCE Trial of Prolonged-Release Fampridine. *CNS Drugs*. 2018 Dec 10. doi: 10.1007/s40263-018-0586-5.

Honvo G, Leclercq V, Geerinck A, Thomas T, Veronese N, Charles A, Rabenda V, Beudart C, Cooper C, Reginster JY, Bruyère O. Drugs Aging. Safety of Topical Non-steroidal Anti-Inflammatory Drugs in Osteoarthritis: Outcomes of a Systematic Review and Meta-Analysis. 2019 Apr;36(Suppl 1):45-64. doi: 10.1007/s40266-019-00661-0.

Honvo G, Reginster JY, Rabenda V, Geerinck A, Mkinsi O, Charles A, Rizzoli R, Cooper C, Avouac B, Bruyère O. Safety of Symptomatic Slow-Acting Drugs for Osteoarthritis: Outcomes of a Systematic Review and Meta-Analysis Drugs Aging. 2019 Apr;36(Suppl 1):65-99. doi: 10.1007/s40266-019-00662-z.

Honvo G, Reginster JY, Rannou F, Rygaert X, Geerinck A, Rabenda V, McAlindon T, Charles A, Fuggle N, Cooper C, Curtis E, Arden N, Avouac B, Bruyère O. Safety of Intra-articular Hyaluronic Acid Injections in Osteoarthritis: Outcomes of a Systematic Review and Meta-Analysis. Drugs Aging. 2019 Apr;36(Suppl 1):101-127. doi: 10.1007/s40266-019-00657-w.

Inácio P, Airaksinen M, Cavaco A. Language does not come "in boxes": Assessing discrepancies between adverse drug reactions spontaneous reporting and MedDRA® codes in European Portuguese. Res Social Adm Pharm. 2014 Dec 5. pii: S1551-7411(14)00397-0.

Jessurun N, van Puijenbroek E. Relationship Between Structural Alerts in NSAIDs and Idiosyncratic Hepatotoxicity: An Analysis of Spontaneous Report Data from the WHO Database. Drug Saf. 2015 Mar 19.

Ji HH, Tang XW, Dong Z, Song L, Jia YT. Adverse Event Profiles of Anti-CTLA-4 and Anti-PD-1 Monoclonal Antibodies Alone or in Combination: Analysis of Spontaneous Reports Submitted to FAERS. Clin Drug Investig. 2019 Jan 23. doi: 10.1007/s40261-018-0735-0.

Jia Y, Zhu C, Du J, Xiang Y, Chen Y, Wang W, Tao C. Investigating safety profiles of human papillomavirus vaccine across group differences using VAERS data and MedDRA. PeerJ. 2019 Aug 20; 7:e7490. doi: 10.7717/peerj.7490. eCollection 2019.

Kang S, Niak A, Gada N, Brinker A, Jones SC. Etonogestrel implant migration to the vasculature, chest wall, and distant body sites: cases from a pharmacovigilance database. Contraception. 2017 Sep 1.

Kelly K, Infante JR, Taylor MH, Patel MR, Wong DJ, Iannotti N, Mehnert JM, Loos AH, Koch H, Speit I8, Gulley JL. Safety profile of avelumab in patients with advanced solid tumors: A pooled analysis of data from the phase 1 JAVELIN solid tumor and phase 2 JAVELIN Merkel 200 clinical

trials. *Cancer*. 2018 Feb 22.

Mao Y, Fung KW. Use of word and graph embedding to measure semantic relatedness between Unified Medical Language System concepts. *J Am Med Inform Assoc*. 2020 Oct 1;27(10):1538-1546. doi: 10.1093/jamia/ocaa136. PMID: 33029614; PMCID: PMC7566472.

Martin Arias LH, Martin Gonzalez A, Sanz Fadrique R, Salgueiro E, Sainz M. Cardiovascular and gastrointestinal safety of selective cyclooxygenase-2 inhibitors: a case/non-case study. *Int J Clin Pharm*. 2018 Jul 31. doi: 10.1007/s11096-018-0705-x.

Mendes D, Alves C, Loureiro M, Fonte A, Batel-Marques F. Drug-induced hypersensitivity: A 5-year retrospective study in a hospital electronic health records database. *J Clin Pharm Ther*. 2018 Aug 1. doi: 10.1111/jcpt.12752.

Minjon L, van den Ban E, de Jong E, Souverein PC, Egberts TCG, Heerdink ER. Reported Adverse Drug Reactions in Children and Adolescents Treated with Antipsychotics. *J Child Adolesc Psychopharmacol*. 2019 Jan 24. doi: 10.1089/cap.2018.0139.

Monaco L, Melis M, Biagi C, Donati M, Sapigni E, Vaccheri A, Motola D. Signal detection activity on EudraVigilance data: analysis of the procedure and findings from an Italian Regional Centre for Pharmacovigilance. *Expert Opin Drug Saf*. 2017 Jan 30:1-5.

Morley R, Cardenas A, Hawkins P, Suzuki Y, Paton V, Phan SC, Merchant M, Hsu J, Yu W, Xia Q, Koralek D, Luhn P, Aldairy W. Safety of Onartuzumab in Patients with Solid Tumors: Experience to Date from the Onartuzumab Clinical Trial Program. *PLoS One*. 2015 Oct 7;10(10):e0139679.

Moro PL, Winiiecki S, Lewis P, Shimabukuro TT, Cano M. Surveillance of adverse events after the first trivalent inactivated influenza vaccine produced in mammalian cell culture (Flucelvax®) reported to the Vaccine Adverse Event Reporting System (VAERS), United States, 2013-2015. *Vaccine*. 2015 Oct 27 pii: S0264-410X(15)01527-3.

Moro PL, Woo EJ, Paul W, Lewis P, Petersen BW, Cano M. Post-Marketing Surveillance of Human Rabies Diploid Cell Vaccine (Imovax) in the Vaccine Adverse Event Reporting System (VAERS) in the United States. *PLoS Negl Trop Dis*. 2016 Jul 13; 10(7):e0004846.

Naganuma M, Tahara K, Hasegawa S, Fukuda A, Sasaoka S, Hatahira H, Motooka Y, Nakao S, Mukai R, Hirade K, Yoshimura T, Kato T, Takeuchi H, Nakamura M. Adverse event profiles of solvent-based and nanoparticle albumin-bound paclitaxel formulations using the Food and Drug Administration

Adverse Event Reporting System. *SAGE Open Med.* 2019 Mar 11;7:2050312119836011. doi: 10.1177/2050312119836011.

Nakao S, Hasegawa S, Shimada K, et al. Evaluation of anti-infective-related *Clostridium difficile*-associated colitis using the Japanese Adverse Drug Event Report database. *Int J Med Sci.* 2020;17(7):921-930. Published 2020 Mar 26. doi:10.7150/ijms.43789

Ohyama K, Inoue M. Association between Selective Beta-adrenergic Drugs and Blood Pressure Elevation: Data Mining of the Japanese Adverse Drug Event Report (JADER) Database. *Yakugaku Zasshi.* 2016; 136(7):1065-71.

Orion K, Mack J, Kullak-Ublick GA, Weiler S. Kounis syndrome: A retrospective analysis of individual case safety reports from the international WHO database in pharmacovigilance. *Int J Clin Pharmacol Ther.* 2019 Mar 22. doi: 10.5414/CP203344.

Oviedo-Joekes E, Brissette S, MacDonald S, Guh D, Marchand K, Jutha S, Harrison S, Janmohamed A, Zhang DZ, Anis AH, Krausz M, Marsh DC, Schechter MT. Safety profile of injectable hydromorphone and diacetylmorphine for long-term severe opioid use disorder. *Drug Alcohol Depend.* 2017 May 10;176:55-62.

Palermo S, Giovannelli F, Bartoli M, Amanzio M. Are Patients With Schizophrenia Spectrum Disorders More Prone to Manifest Nocebo-Like-Effects? A Meta-Analysis of Adverse Events in Placebo Groups of Double-Blind Antipsychotic Trials. *Front Pharmacol.* 2019 May 17;10:502. doi: 10.3389/fphar.2019.00502. eCollection 2019.

Perino J, Mottal N, Bohbot Y, Servant V, Berroneau A, Poustis P, Fenaux P, Laribi K, Charbonnier A, Billion E, Calmettes C, Bégau B, Pigneux A, Milpied N, Miremont-Salamé G, Théophile H, Dimicoli-Salazar S. Cardiac failure in patients treated with azacitidine, a pyrimidine analogue: case reports and disproportionality analyses in Vigibase®. *Br J Clin Pharmacol.* 2020 Jan 7. doi: 10.1111/bcp.14211. [Epub ahead of print]
PMID: 31912911

Pierce CE, Bouri K, Pamer C, Proestel S, Rodriguez HW, Van Le H, Freifeld CC, Brownstein JS, Walderhaug M, Edwards IR, Dasgupta N. Evaluation of Facebook and Twitter Monitoring to Detect Safety Signals for Medical Products: An Analysis of Recent FDA Safety Alerts. *Drug Saf.* 2017 Jan 2.

Pivonello R, Muscogiuri G, Holder G, Paul M, Sarp S, Lesogor A, Jordaan P, Eisinger J, Colao A. Long-term safety of long-acting octreotide in patients with diabetic retinopathy: results of pooled data from

2 randomized, double-blind, placebo-controlled phase 3 studies. *Endocrine*. 2017 Nov 7.

Raschi E, Poluzzi E1, Koci A, Antonazzo IC, Marchesini G, De Ponti F. Dipeptidyl peptidase-4 inhibitors and heart failure: Analysis of spontaneous reports submitted to the FDA Adverse Event Reporting System. *Nutr Metab Cardiovasc Dis*. 2016 Feb 19. pii: S0939-4753(15)30192-7.

Reiber R, Wolf H, Schnitker J, Wüstenberg E. Tolerability of an Immunologically Enhanced Subcutaneous Immunotherapy Preparation in Patients Treated with Concomitant Allergy Immunotherapy: A Non-Interventional Observational Study. *Drugs Real World Outcomes*. 2017 Jan 9.

Reumann M, Giovannini A, Nadworny B, Auer C, Girardi I, Marchiori C. Cognitive DDx Assistant in Rare Diseases. *Conf Proc IEEE Eng Med Biol Soc*. 2018 Jul;2018:3244-3247. doi: 10.1109/EMBC.2018.8513041.

Roberto G, Piccinni C, D'Alessandro R, Poluzzi E. Triptans and serious adverse vascular events: Data mining of the FDA Adverse Event Reporting System database. *Cephalalgia*. 2013 Aug 6.

Rochoy M, Auffret M, Béné J, Gautier S; Réseau français des centres régionaux de pharmacovigilance. Antiemetics and cardiac effects potentially linked to prolongation of the QT interval: Case/non-case analysis in the national pharmacovigilance database *Rev Epidemiol Sante Publique*. 2016 Dec 14. pii: S0398-7620(16)30811-2.

Sakai T, Ohtsu F, Sekiya Y, Mori C, Sakata H, Goto N. Methodology for Estimating the Risk of Adverse Drug Reactions in Pregnant Women: Analysis of the Japanese Adverse Drug Event Report Database. *Yakugaku Zasshi*. 2016;136(3):499-505.

Sandhu A, Kao D, Mehler PS, Haigney MC, Krantz MJ. Cardiovascular disorders associated with naloxone monotherapy and in fixed-dose combination with opioids: Data from international safety surveillance. *Int J Cardiol*. 2016 Jun 1;212:360-3.

Sarntivijai S, Xiang Z, Shedden KA, Markel H, Omenn GS, Athey BD, He Y. Ontology-based combinatorial comparative analysis of adverse events associated with killed and live influenza vaccines. *PLoS One*. 2012;7(11). Epub 2012 Nov 28.

Sasaoka S, Hatahira H, Hasegawa S1, Motooka Y, Fukuda A, Naganuma M, Umetsu R1, Nakao S, Shimauchi A, Ueda N, Hirade K, Iguchi K, Nakamura M. Adverse Event Trends Associated with Over-the-counter Combination Cold Remedy: Data Mining of the Japanese Adverse Drug Event

Report Database. *Yakugaku Zasshi*. 2018; 138(1):123 -134.

Schmitz SM MD, MPH¹, Lopez HL MD, MS^{1,2}, Mackay D ND³, Nguyen H BS³, Miller PE BS¹. Serious Adverse Events Reported with Dietary Supplement Use in the United States: A 2.5 Year Experience. *J Diet Suppl*. 2018 Dec 4:1-22. doi: 10.1080/19390211.2018.1513109.

Schoenewald S, Ross S, Bloom L, Shah M, Luch Jy, Lin CL, Patel M, Boyle K, Kuffner E. New insights into root causes of pediatric accidental unsupervised ingestions of over-the-counter medications. *Clin Toxicol (Phila)*. 2013 Dec;51(10):930-6.

Sessa M, Mascolo A, Callréus T, Capuano A, Rossi F, Andersen M. Direct-acting oral anticoagulants (DOACs) in pregnancy: new insight from VigiBase®. *Sci Rep*. 2019 May 10;9(1):7236. doi: 10.1038/s41598-019-43715-4.

Shimada K, Hasegawa S, Nakao S, Mukai R, Matsumoto K, Tanaka M, Uranishi H¹, Masuta M, Nishida S, Shimizu S, Hayashi Y, Suzuki A, Nakamura M. Adverse event profiles of ifosfamide-induced encephalopathy analyzed using the Food and Drug Administration Adverse Event Reporting System and the Japanese Adverse Drug Event Report databases. *Cancer Chemother Pharmacol*. 2019 Sep 9. doi: 10.1007/s00280-019-03949-5.

Sloan VS, Jones A, Maduka C, Bentz JWG. A Benefit Risk Review of Pediatric Use of Hydrocodone/Chlorpheniramine, a Prescription Opioid Antitussive Agent for the Treatment of Cough. *Drugs Real World Outcomes*. 2019 Jun;6(2):47-57. doi: 10.1007/s40801-019-0152-6.

Souvignet J, Declerck G, Asfari H, Jaulent MC, Bousquet C. J OntoADR a Semantic Resource Describing Adverse Drug Reactions to Support Searching, Coding, and Information Retrieval. *Biomed Inform*. 2016 Jun 28. pii: S1532-0464(16)30053-3.

Souvignet J, Declerck G, Trombert B, Rodrigues JM, Jaulent MC, Bousquet C. Evaluation of automated term groupings for detecting anaphylactic shock signals for drugs. *AMIA Annu Symp Proc*. 2012;2012:882-90.

Teng C, Reveles KR, Obodozie-Ofoegbu OO, Frei CR. Clostridium difficile Infection Risk with Important Antibiotic Classes: An Analysis of the FDA Adverse Event Reporting System. *Int J Med Sci*. 2019 May 7;16(5):630-635. doi: 10.7150/ijms.30739. eCollection 2019.

Teng C, Walter EA, Gaspar DKS, Obodozie-Ofoegbu OO, Frei CR. Torsades de pointes and QT prolongation Associations with Antibiotics: A Pharmacovigilance Study of the FDA Adverse Event Reporting System. *Int J Med Sci*. 2019 Jun 10;16(7):1018-1022. doi: 10.7150/ijms.34141.

Tourillon C, Mahe J, Baron A, Lambert A, Yélehé-Okouma M, Veyrac G, Jolliet P. Immediate-Type Hypersensitivity Cross-Reactions to Proton Pump Inhibitors: A Descriptive Study of Data from the French National Pharmacovigilance Database. *Int Arch Allergy Immunol.* 2018 Nov 28:1-8. doi: 10.1159/000493581.

Trenque T, Claustre G, Herlem E, Djerada Z, Trenque A, Morel A, Azzouz B1. Methylphenidate and stuttering. *Br J Clin Pharmacol.* 2019 Aug 16. doi: 10.1111/bcp.14097.

Tweed CD, Crook AM, Dawson R, Diacon AH, McHugh TD, Mendel CM, Meredith SK, Mohapi L, Murphy ME, Nunn AJ, Phillips PP, Singh KP, Spigelman M, Gillespie SH. Toxicity related to standard TB therapy for pulmonary tuberculosis and treatment outcomes in the REMoxTB study according to HIV status. *BMC Pulm Med.* 2019 Aug 14; 19(1):152. doi: 10.1186/s12890-019-0907-6.

Uemura N, Kinoshita Y, Haruma K, Yao T, Kushima R, Kanoo T. Rationale and design of the VISION study: a randomized, open-label study to evaluate the long-term safety of vonoprazan as maintenance treatment in patients with erosive esophagitis. *Clin Exp Gastroenterol.* 2018 Jan 24; 11:51-56.

van Hansel F, de Waal S, Härmark L. The contribution of direct patient reported ADRs to drug safety signals in the Netherlands from 2010 to 2015. *Pharmacoepidemiol Drug Saf.* 2017 May 19.

Vandael E, Vandenberg B, Vandenberghe J, Willems R, Foulon V. Cases of drug-induced Torsade de Pointes: a review of Belgian cases in the EudraVigilance database. *Acta Clin Belg.* 2017 Mar 24:1-6.

Viola E, Opri S, Moretti U, Leone R, Casini ML, Ruggieri S, Minore C, Conforti A. α 1-Adrenergic receptor antagonists and gynecomastia. A case series from the Italian spontaneous reporting system and VigiBase™*Eur J Clin Pharmacol.* 2014 Jun 3.

Vogel U, van Stekelenborg J, Dreyfus B, et al. Investigating Overlap in Signals from EVDAS, FAERS, and VigiBase® [published online ahead of print, 2020 Feb 4]. *Drug Saf.* 2020;10.1007/s40264-019-00899-y. doi:10.1007/s40264-019-00899-y

Wang L, Jiang G, Li D, Liu H. Standardizing drug adverse event reporting data. *Stud Health Technol Inform.* 2013; 192:1101.

Wang L, Li M, Cao Y, Han Z, Wang X, Atkinson EJ, Liu H, Amin. Proton Pump Inhibitors and the Risk for Fracture at Specific Sites: Data Mining of the FDA Adverse Event Reporting System. *Sci Rep.* 2017 Jul 17;7(1):5527.

Ye JH, Ho YF, On AW, Chen WW, Huang YM, Huang WI, Tang YW. Trends in reporting drug-associated liver injuries in Taiwan: a focus on amiodarone. *Int J Clin Pharm*. 2018 Jul 26. doi: 10.1007/s11096-018-0698-5.

Yue Z, Jiang P, Sun H, Wu J. Association between an excess risk of acute kidney injury and concomitant use of ibuprofen and acetaminophen in children, retrospective analysis of a spontaneous reporting system. *Eur J Clin Pharmacol*. 2014 Jan 21.

Zaccara G, Giovannelli F, Giorgi FS, Franco V, Gasparini S, Tacconi FM. Do antiepileptic drugs increase the risk of infectious diseases? A meta-analysis of placebo-controlled studies. *Br J Clin Pharmacol*. 2017 Mar 31.

Zhang Y, Yuan SS, Egel BA, Li H, Lin LA, Wang WWB. Bayesian hierarchical model for safety signal detection in multiple clinical trials. *Contemp Clin Trials*. 2020 Oct 20;99:106183. doi: 10.1016/j.cct.2020.106183. Epub ahead of print. PMID: 33091588.