

# Characterization and Corroboration of Safety Signals Identified from the United States Food and Drug Administration Adverse Event Reporting System, 2008-2019: A Cross-Sectional Study

## SUPPLEMENTARY MATERIALS

**Supplemental Table 1.** Search terms used to identify relevant published studies for potential safety signals identified from FAERS by FDA in 2014 or 2015.

Literature Search
(Harvoni OR Olysio OR Sovaldi OR Ledipasvir/Sofosbuvir OR Simeprevir OR Sofosbuvir) AND Rhabdomyolysis
(Keppra OR Spritam OR Levetiracetam) AND (Angioedema OR Anaphylaxis)
(SGLT2 OR Farxiga OR Glyxambi OR Jardiance OR Invokamet OR Invokana OR Synjardy OR Xigduo XR OR SGLT-2 OR dapagliflozin OR Empagliflozin OR Canagliflozin OR Dapagliflozin) AND Acute kidney injury
(Somatostatin OR Sandostatin OR Somatuline OR Signifor OR Octreotide acetate OR Lanreotide OR Pasireotide) AND Cholecystitis
(Articaine OR Orabloc OR Septocaine OR epinephrine bitartrate OR Articaine) AND Paresthesia and taste
(Diabeta OR glyburide) AND Cardiovascular mortality
(Dipeptidyl peptidase inhibitor OR Glyxambi OR Janumet OR Januvia OR Jentadueto OR Kazano OR Kombiglyze OR Nesina OR Onglyza OR Oseni OR Tradjenta OR DPP-IV OR Empagliflozin/linagliptin OR Sitagliptin/metformin OR Sitagliptin/metformin OR Sitagliptin OR Linagliptin/metformin OR Alogliptin/metformin OR Saxagliptin/metformin OR Alogliptin OR saxagliptin OR alogliptin/pioglitazone OR linagliptin) AND Renal failure
(Dipeptidyl peptidase inhibitor OR Glyxambi OR Janumet OR Januvia OR Jentadueto OR Kazano OR Kombiglyze OR Nesina OR Onglyza OR Oseni OR Tradjenta OR DPP-IV OR empagliflozin/linagliptin OR Sitagliptin/metformin OR Sitagliptin/metformin OR sitagliptin OR Linagliptin/metformin OR Alogliptin/metformin OR Saxagliptin/metformin OR Alogliptin OR Saxagliptin OR Alogliptin/pioglitazone OR Linagliptin) AND (Mouth ulcer OR stomatitis OR oral ulcer)
(Mirvaso OR Brimonidine Tartrate) AND Hypersensitivity
(Nicotine OR Habitrol OR Nicoderm OR Nicotrol NS OR Nicorette OR Nicotine patch OR Nicotine inhaler OR Nicotine spray OR Nicotine polacrilex) AND Seizures
(Proton pump inhibitors OR Aciphex OR Dexilant OR Esomeprazole OR Lansoprazole OR Naproxen OR Nexium OR Omeclamox OR Omeprazole capsule OR Pantoprazole OR Prevacid OR Prevpac OR Prilosec OR Protonix OR Vimovo OR Zegerid OR PPIs OR Rabeprazole OR Dexlansoprazole OR Lansoprazole/amoxicillin/clarithromycin OR omeprazole magnesium OR pantoprazole sodium OR OR Naproxen/esomeprazole magnesium OR Omeprazole/sodium bicarbonate) AND (Systemic Lupus Erythematosus OR Lupus)
(Pseudoephedrine) AND Ischemic colitis
(Genotropin OR Humatrope OR Norditropin OR Mutropin OR Omnitrope OR Saizen OR Serostim OR Tev-Tropin OR Somatotropin) AND Hypersensitivity
(SGLT2 OR Farxiga OR Glyxambi OR Jardiance OR Invokamet OR Invokana OR Synjardy OR Xigduo XR OR dapagliflozin OR Canagliflozin OR Empagliflozin OR Dapagliflozin) AND Urosepsis
(Tecfidera OR dimethyl fumarate) AND Acute pancreatitis
(Viekira OR Technivie OR Dasabuvir/ombitasvir/paritaprevir/ritonavir OR ombitasvir/paritaprevir/ritonavir) AND Hepatic decompensation and hepatic failure
(Votrient OR pazopanib) AND (Interstitial lung disease OR pneumonitis)
(Zonegran OR Zonisamide) AND (Drug Reaction with Eosinophilia and Systemic Symptoms OR DRESS)
(Acetaminophen) AND ingestion error
(Vloxiverz OR Vazculep OR Neostigmine methylsulfate OR phenylephrine) AND selection error
(Brintellix OR Brilinta OR Vortioxetine OR ticagrelor) AND name confusion
(Calcium Carbonate) AND (Milk-alkali syndrome OR hypercalcemia)
(Daliresp OR roflumilast) AND Gynecomastia
(Daytrana OR methylphenidate) AND Chemical leukoderma
(Chlorhexidine gluconate) AND (Hypersensitivity OR anaphylaxis)

(Proglycem OR diazoxide) AND Pulmonary hypertension
(SGLT2 OR Farxiga OR Glyxambi OR Jardiance OR Invokamet OR Invokana OR Synjardy OR Xigduo XR OR Empagliflozin OR Canagliflozin OR Dapagliflozin) AND (Stroke OR thromboembolic)
(Tramadol OR Conzip OR Ultracet OR Ultram OR Ultram ER) AND Respiratory depression and CYP2D6 ultra-rapid metabolism
(Tumor Necrosis Factor blocker OR Cimzia OR Enbrel OR Humira OR Remicade OR Simponi OR TNF blocker OR Certolizumab pegol OR etanercept OR Adalimumab OR Infliximab OR golimumab) AND (Psychiatric disorder OR nervous system disorder)
(Zerbaxa OR Ceftolozane and tazobactam) AND Drug dosing issues
(SGLT2 OR Farxiga OR Glyxambi OR Jardiance OR Invokamet OR Invokana OR Synjardy OR Xigduo XR OR SGLT-2 OR dapagliflozin OR Empagliflozin OR Canagliflozin) AND Diabetic Ketoacidosis
(Edurant OR Rilpivirine) AND (hypersensitivity OR skin reaction)
(Complera OR emtricitabine OR rilpivirine) AND (hypersensitivity OR Skin reaction)
(Harvoni OR Olysio OR Sovaldi OR Ledipasvir/Sofosbuvir OR Simeprevir OR Sofosbuvir) AND Convulsions
(Harvoni OR Olysio OR Sovaldi OR Ledipasvir/Sofosbuvir OR Simeprevir OR Sofosbuvir) AND (arrhythmia or bradycardia)
(Juxtapid OR Lomitamide mesylate) AND REMS
(Juxtapid OR Lomitamide mesylate) AND diarrhea
(Myalept OR Metreleptin) AND Anaphylaxis
(Noxafil OR posaconazole) AND (Dosing error OR administration error)
(Pomalyst OR pomalidomide) AND Hepatotoxicity
(Aspirin OR Antacids) AND Serious Bleeding
(Alendronate OR Binosto OR Fosamax OR Fosamax Plus D OR Etidronate OR Didronel OR Ibandronate OR Boniva OR Risedronate OR Actonel OR Atelvia OR Zoledronic acid OR Reclast OR RANKL OR Rank Ligand OR Denosumab OR Xgeva OR Prolia OR anti-VEGF OR Angiogenesis inhibitor OR bisphosphonates) AND (Osteonecrosis of the Jaw OR ONJ)
(Orlistat OR Xenical) AND Leukocytoclastic vasculitis
(Oxybutynin OR Gelnique OR Oxytrol) AND Hallucinations
(Simeprevir OR Olysios) AND (Drug-induced liver injury OR hepatic decompensation OR hepatic failure)
(Avastin OR Bevacizumab) AND Fetal abnormalities
(Acthrel OR corticorelin ovine triflutate) AND Hypersensitivity
(Imbruvica OR ibrutinib) AND (Progressive Multifocal Leukoencephalopathy OR PML)
(Attention deficit hyperactivity disorder OR ADHD OR atomoxetine OR Strattera OR Dexmethylpheniate OR Focalin OR dextroamphetamine OR Adderall OR Dexedrine OR Lisdexamphetamine OR Vyvanse OR Methamphetamine OR desoxyn OR Methylphenidate OR Ritalin OR Daytrana OR Methylin) AND Rhabdomyolysis
(Cordarone OR amiodarone OR nexterone) AND Thyrotoxicosis
(DPP-4 OR dipeptidyl peptidase OR sitagliptin OR Januvia OR Janumet OR Onglyza OR saxagliptin OR Kombiglyze OR metformin OR Linagliptin OR Tradjenta OR Jentadueto OR Alogliptin OR Kazano OR alogliptin/pioglitazone OR Oseni OR Empagliflozin/linagliptin OR Glyxambi) AND Arthralgia
(Docosanol OR Abreva) AND Hypersensitivity
(Hydroxyzine OR Vistaril) AND QT prolongation
(Nicorette OR Nicotine polacrilex) AND candy
(Polyethylene glycol OR Miralax) AND (Medication Error OR cap design)
(Sunitinib OR Sutent) AND Thrombotic microangiopathy
(varenicline OR Chantix) AND alcohol
(Xenazine OR Tetrabenazine) AND Death
(Everolimus OR Zortress) AND (Pulmonary hypertension OR Pulmonary arterial hypertension)
(Gabapentin OR Neurontin OR Lyrica OR pregabalin) AND Anaphylaxis
(Raltegravir) AND Serious hepatic events
(Victoza OR liraglutide) AND Hepatitis
(Acidinium OR Tudorza Pressair) AND Angioedema
(Collagenase Clostridium histolyticum OR Xiaflex) AND Risk of skin laceration requiring skin graft
(HMG CoA reductase inhibitors OR Rosuvastatin OR Crestor OR Pitavastatin OR Livalo) AND Peripheral neuropathy; review
(Ingenol mebutate OR Picato) AND Severe skin reactions
(Interferon OR betaseron OR Avonex OR Rebitec OR Extavia OR Plegridy OR peginterferon) AND Thrombotic microangiopathy
(Lidocaine OR xylocaine) AND overdose
(Propylthiouracil) AND Congenital malformations
(ADO-trastuzumab OR trastuzumab OR Kadcyla) AND Hemorrhage
(Denosumab OR Xgeva OR Prolia) AND Musculoskeletal pain
(Docetaxel) AND Alcohol intoxication
(Exenatide OR Bydureon) AND (Injection reaction OR Injection site reaction)
(Mirabegron OR Myrbetriq) AND Angioedema
(Phentermine OR topiramate OR Qsymia) AND (Suicidal ideation OR suicidal behavior)
(Rosuvastatin OR Crestor) AND (Myopathy or Rhabdomyolysis) AND (fusidic acid)
(Sitagliptin and metformin OR Jnumet) AND (stool OR dissolved)
(Pegintron OR sylvatron OR peginterferon alfa-2b) AND administration error
(Brentuximab OR Adcetris) AND Hepatotoxicity

(Testosterone) AND (abuse OR misuse OR dependence)
(antidepressants) AND (Angle-Closure Glaucoma)
(Zyprexa OR Risperidone OR olanzapine) AND (Post-injection Delirium-Sedation Syndrome OR PDSS)

**Supplemental Figure 1.** Flowchart of search results to identify relevant published studies for potential safety signals identified from FAERS by FDA in 2014 or 2015.

