

Identifying safety subgroups at risk: Assessing the agreement between statistical alerting and patient subgroup risk

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Supplementary Information

Supplementary Table 1. PRAC subgroup examples (n=27) and their mapping to drug, event and subgroup information from FAERS

PRAC Minutes	Drug mentioned in PRAC minutes	FAERS active moieties	Event mentioned in PRAC minutes	FAERS MedDRA PT	Subgroup mentioned in PRAC minutes	Subgroup according to Sandberg et al. [1]
9–12 July 2018	Amitriptyline (NAP); dosulepin (NAP)	AMITRIPTYLINE DOTHIEPIN	Dementia	Dementia Mixed dementia Dementia Alzheimer's type	Elderly	65–74; 75+ years
9–12 July 2018	Oxybutynin - KENTERA (CAP), NAP	OXYBUTYNIN	Dementia	Dementia Dementia Alzheimer's type	Elderly	65–74; 75+ years
9–12 July 2018	Paroxetine (NAP)	PAROXETINE	Dementia	Dementia Vascular dementia Senile dementia Frontotemporal dementia Dementia Alzheimer's type Dementia with Lewy bodies	Elderly	65–74; 75+ years
9–12 July 2018	Procyclidine (NAP)	PROCYCLIDINE	Dementia	Dementia	Elderly	65–74 years
9–12 July 2018	Tolterodine (NAP)	TOLTERODINE	Dementia	Dementia Senile dementia Dementia Alzheimer's type	Elderly	65–74; 75+ years
9–12 July 2018	Sildenafil	SILDENAFIL	Mortality	Death Sudden death Death neonatal	Neonates	0–27 days
11–14 Feb 2019	Olanzapine	OLANZAPINE	Gestational diabetes	Gestational diabetes	Pregnant ^a	Female; 15–44 years.
11–14 Jan 2016	Oxybutynin	OXYBUTYNIN	Psychiatric disorders	Drug abuse	Paediatric	12–17 years
12–15 Mar 2019	Sodium–glucose transport protein 2 inhibitors	ERTUGLIFLOZIN ERTUGLIFLOZIN\SITAGLIPTIN ERTUGLIFLOZIN\METFORMIN CANAGLIFLOZIN	Diabetic ketoacidosis	Diabetic ketoacidosis hyperglycaemic coma	Adults, surgical patients	18–44; 45–64 years; Indication HLGTS: Bone and joint therapeutic procedures

		CANAGLIFLOZIN\METFORMIN CANAGLIFLOZIN\TENELIGLIPTIN DAPAGLIFLOZIN PROPANEDIOL DAPAGLIFLOZIN DAPAGLIFLOZIN PROPANEDIOL\METFORMIN DAPAGLIFLOZIN\SAXAGLIPTIN EMPAGLIFLOZIN EMPAGLIFLOZIN\METFORMIN EMPAGLIFLOZIN\LINAGLIPTIN EMPAGLIFLOZIN\LINAGLIPTIN\METFORMIN		Diabetic ketoacidosis Euglycemic diabetic ketoacidosis		Cardiac therapeutic procedures Endocrine gland therapeutic procedures Gastrointestinal therapeutic procedures Haematological and lymphoid tissue therapeutic procedures Head and neck therapeutic procedures Nervous system, skull and spine therapeutic procedures Obstetric and gynaecological therapeutic procedures Soft tissue therapeutic procedures Therapeutic procedures and supportive care NEC Vascular therapeutic procedures
13–16 May 2019	Finasteride and dutasteride	FINASTERIDE DUTASTERIDE DUTASTERIDE\TAMSULOSIN	Type 2 diabetes mellitus	Type 2 diabetes mellitus Diabetes mellitus inadequate control Insulin-requiring type 2 diabetes mellitus Diabetes mellitus	Men, benign prostatic hyperplasia ^b	Male; Indication HLGT: Prostatic disorders (excl. infections and inflammations)
14–17 Jan 2019	Acetylsalicylic acid (NAP)	ASPIRIN ANHYDROUS CITRIC ACID\ASPIRIN\SODIUM BICARBONATE	Mortality	Accidental death Agonal death struggle Brain death Cardiac death Completed suicide Death Sudden cardiac death Sudden death	Elderly, cancer patients	65–74; 75+ years; Indication HLGTs: Breast neoplasms malignant and unspecified (incl. nipple)

Suspected suicide

Endocrine neoplasms
malignant and
unspecified
Gastrointestinal
neoplasms malignant
and unspecified
Haematopoietic
neoplasms (excl.
leukaemias and
lymphomas)
Hepatobiliary
neoplasms malignant
and unspecified
Leukaemias
Lymphomas NEC
Lymphomas non-
Hodgkin's B-cell
Metastases
Miscellaneous and site
unspecified neoplasms
malignant and
unspecified
Neoplasm-related
morbidity
Plasma cell neoplasms
Renal and urinary tract
neoplasms malignant
and unspecified
Reproductive
neoplasms female
malignant and
unspecified
Reproductive
neoplasms male
malignant and
unspecified
Respiratory and
mediastinal neoplasms

						malignant and unspecified Skin neoplasms malignant and unspecified
14–17 May 2018	Daclatasvir, dasabuvir, elbasvir, grazoprevir, glecaprevir, pibrentasvir, ledipasvir, ombitasvir, paritaprevir, ritonavir, sofosbuvir, velpatasvir, voxilaprevir	DACLATASVIR DASABUVIR DASABUVIR\OMBITASVIR\PARITAPR EVIR\ RITONAVIR GLECAPREVIR\PIBRENTASVIR LEDIPASVIR\SOFOBSUVIR OMBITASVIR OMBITASVIR\PARITAPREVIR\RITONA VIR PARITAPREVIR ATAZANAVIR\RITONAVIR LOPINAVIR\RITONAVIR RITONAVIR RITONAVIR\TIPRANAVIR SOFOBSUVIR SOFOBSUVIR\VELPATASVIR SOFOBSUVIR\VELPATASVIR\ VOXILAPREVIR ELBASVIR\GRAZOPREVIR	Dysglycaemia	Blood glucose abnormal Blood glucose increased Blood glucose decreased Blood glucose fluctuation Hypoglycaemia Hypoglycaemic seizure Hypoglycaemic unconsciousness Shock hypoglycaemic Hyperglycaemia Hyperglycaemic hyperosmolar nonketotic syndrome	Adults, type 2 diabetes mellitus	18–44; 45–64 years; Indication HLGT: Glucose metabolism disorders (incl. diabetes mellitus)
24–27 Oct 2016	Riociguat	RIOCIGUAT	Mortality	Death Sudden death Sudden cardiac death	Adults, pulmonary hypertension associated with idiopathic interstitial pneumonia [†]	18–44; 45–64 years; Indication HLGT: Pulmonary vascular disorders; Lower respiratory track disorders (excl. obstruction and infection)
25–29 Sep 2017	Desloratadine, loratadine	LORATADINE DESLORATADINE	Weight increase	Weight increased Abnormal weight gain	Children	2–11 years
26–29 Sep 2016	Metronidazole	BISMUTH\METRONIDAZOLE\TETRAC YCLINE	Neurological toxicity	Toxic encephalopathy	Cockayne syndrome	Indication HLGT: Neurological disorders congenital

28 Nov to 1 Dec 2016	Methylphenidate	DEXMETHYLPHENIDATE METHYLPHENIDATE	Priapism	Priapism Erection increased Painful erection	Men	Male
29–31 Oct 2018	Xarelto (class of DOACs)	APIXABAN DABIGATRAN EDOXABAN RIVAROXABAN	Recurrent thrombosis	Renal thrombosis Aortic thrombosis Arterial thrombosis Atrial thrombosis Axillary vein thrombosis Basilar artery thrombosis Brain stem thrombosis Cardiac ventricular thrombosis Carotid artery thrombosis Catheter site thrombosis Cerebral artery thrombosis Cerebral thrombosis Cerebral venous sinus thrombosis Cerebral venous thrombosis Coronary artery thrombosis Deep vein thrombosis Deep vein thrombosis postoperative Device-related thrombosis Graft thrombosis Hepatic vein thrombosis Injection site thrombosis Jugular vein thrombosis Medical device site thrombosis Mesenteric artery thrombosis Mesenteric vein thrombosis Ophthalmic artery thrombosis Ophthalmic vein thrombosis Ovarian vein thrombosis Pelvic venous thrombosis Peripheral artery thrombosis Portal vein thrombosis Post thrombotic syndrome Postoperative thrombosis	Adults, antiphospholipid syndrome and with a history of thrombosis	18–44; 45–64 years; Indication HLGT: Coagulopathies and bleeding diatheses (excl. thrombocytopenic); Embolism and thrombosis

Prosthetic cardiac valve
thrombosis
Pulmonary artery thrombosis
Pulmonary thrombosis
Pulmonary venous thrombosis
Renal artery thrombosis
Renal vascular thrombosis
Renal vein thrombosis
Retinal artery thrombosis
Retinal vascular thrombosis
Retinal vein thrombosis
Shunt thrombosis
Splenic thrombosis
Splenic vein thrombosis
Subclavian artery thrombosis
Subclavian vein thrombosis
Superior sagittal sinus
thrombosis
Thrombosis
Thrombosis in device
Thrombosis mesenteric vessel
Thrombosis prophylaxis
Thrombotic cerebral infarction
Thrombotic microangiopathy
Thrombotic stroke
Thrombotic thrombocytopenic
purpura
Transverse sinus thrombosis
Tumour thrombosis
Vascular graft thrombosis
Vascular stent thrombosis
Vena cava thrombosis
Venous thrombosis
Venous thrombosis in
pregnancy
Venous thrombosis limb
Vertebral artery thrombosis

29 Aug to 1 Sep 2017	Azithromycin	AZITHROMYCIN	Mortality	Death Cardiac death Sudden death Sudden cardiac death Brain death Death neonatal Completed suicide	Adults, haematopoietic stem cell transplantation	18–44; 45–64 years; Indication HLGT: Haematological and lymphoid tissue therapeutic procedures
29 Aug to 1 Sep 2017	Azithromycin	AZITHROMYCIN	Relapses of haematologica l malignancies	T-cell lymphoma recurrent Leukaemia recurrent	Adults, haematopoietic stem cell transplantation	18–44; 45–64 years
30 Nov to 3 Dec 2015	HRT (conjugated oestrogens, bazedoxifene, Bazedoxifene SENSHIO (CAP) CONBRIZA, bazedoxifene, oestrogens conjugated – DUAVIVE (CAP); raloxifene – EVISTA (CAP), OPTRUMA (CAP); NAP Chlorotrianisene; conjugated oestrogens; dienestrol; diethylstilbestrol; oestradiol; Oestriol; oestrogen; estrone; ethinyloestradiol; lasofoxifene; methallenestril; Moxestrol; ormeloxifene; promestriene; tibolone – NAP)	BAZEDOXIFENE\OESTROGENS, CONJUGATED DIETHYLSTILBESTROL DROSPIRENONE\OESTRADIOL DROSPIRENONE\ETHINYL OESTRADIOL OESTRADIOL OESTRADIOL\NORETHINDRONE OESTRADIOL\NORGESTIMATE OESTRIOL OESTROGENS, CONJUGATED OESTROGENS, CONJUGATED SYNTHETIC A OESTROGENS, CONJUGATED\MEDROXYPROGESTERONE ETHINYL OESTRADIOL ETHINYL OESTRADIOL\NORGESTIMATE RALOXIFENE TIBOLONE DESOGESTREL\ETHINYL OESTRADIOL DIENOGEST\OESTRADIOL DIENOGEST\ETHINYL OESTRADIOL OESTROGENS, ESTERIFIED OESTROGENS,	Ovarian cancer	Malignant ovarian cyst Ovarian cancer Ovarian cancer metastatic Ovarian cancer recurrent Ovarian cancer stage III Ovarian clear cell carcinoma Ovarian epithelial cancer Ovarian epithelial cancer metastatic Ovarian epithelial cancer stage III Ovarian germ cell tumour Ovarian granulosa-theca cell tumour Ovarian low malignant potential tumour Ovarian neoplasm	Women, postmenopausal	Female; 45–64; 65–74; 75+ years

ESTERIFIED\METHYLTESTOSTERONE

<p>30 Sep to 3 Oct 2019</p>	<p>HRT (conjugated oestrogens, bazedoxifene, bazedoxifene, oestrogens conjugated – DUAVIVE (CAP); diethylstilbestrol (NAP); oestradiol (NAP); oestradiol, norethisterone (NAP); oestriol (NAP); oestrone (NAP); ethinyloestradiol (NAP); promestriene (NAP); tibolone (NAP))</p>	<p>BAZEDOXIFENE BAZEDOXIFENE\OESTROGENS, CONJUGATED DIENESTROL DIETHYLSTILBESTROL DROSPIRENONE\OESTRADIOL DROSPIRENONE\ETHINYL OESTRADIOL DYDROGESTERONE\OESTRADIOL OESTRADIOL OESTRADIOL\TESTOSTERONE OESTRADIOL\LEVONORGESTREL OESTRADIOL\NORETHINDRONE OESTRADIOL\ESTRIOL\ESTRONE OESTRADIOL\NORETHISTERONE OESTRADIOL\NORGESTIMATE OESTRADIOL\PROGESTERONE OESTRIOL OESTROGENS, CONJUGATED OESTROGENS, CONJUGATED SYNTHETIC A OESTROGENS, CONJUGATED\MEDROXYPROGESTER ONE OESTROGENS, CONJUGATED\METHYLTESTOSTERON E OESTROGENS\PROGESTERONE OESTROGENS\PROGESTERONE\TESTO STERONE OESTROGENS\TESTOSTERONE ESTRONE ETHINYL OESTRADIOL ETHINYL OESTRADIOL\FERROUS\NORETHINDR ONE ETHINYL OESTRADIOL\GESTODENE</p>	<p>Breast cancer</p>	<p>Breast cancer Breast cancer female Breast cancer in situ Breast cancer male Breast cancer metastatic Breast cancer recurrent Breast cancer stage I Breast cancer stage II Breast cancer stage III Breast cancer stage IV Breast implant-associated anaplastic large cell lymphoma Breast neoplasm Breast sarcoma HER2-positive breast cancer Hormone receptor-positive breast cancer Inflammatory carcinoma of breast stage IV Inflammatory carcinoma of the breast Intraductal proliferative breast lesion Invasive breast carcinoma Invasive ductal breast carcinoma Invasive lobular breast carcinoma Invasive papillary breast carcinoma Lobular breast carcinoma in situ Malignant nipple neoplasm female Metastases to breast Paget's disease of nipple Phyllodes tumour Triple negative breast cancer</p>	<p>Women, postmenopausal</p>	<p>Female; 45–64; 65–74; 75+ years</p>
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		ETHINYL OESTRADIOL\MESTRANOL\NORETHIN DRONE ETHINYL OESTRADIOL\NORGESTIMATE OSPEMIFENE RALOXIFENE TIBOLONE CYPROTERONE\ETHINYL OESTRADIOL DESOGESTREL\ETHINYL OESTRADIOL DIENOGEST\OESTRADIOL DIENOGEST\ETHINYL OESTRADIOL DROSPIRENONE\ETHINYL OESTRADIOL\LEVOMEFOLATE OESTROGENS, ESTERIFIED OESTROGENS, ESTERIFIED\METHYLTESTOSTERONE		Triple positive breast cancer		
1–4 Oct 2018	Adalimumab, infliximab	ADALIMUMAB ADALIMUMAB-ATTO INFLIXIMAB INFLIXIMAB-ABDA INFLIXIMAB-DYYB	Lymphoma	Adenolymphoma Adult T-cell lymphoma/leukaemia Anaplastic large cell lymphoma T- and null-cell types Anaplastic large cell lymphoma T- and null-cell types stage IV Anaplastic large-cell lymphoma Angiocentric lymphoma Angioimmunoblastic T-cell lymphoma Angioimmunoblastic T-cell lymphoma refractory Angioimmunoblastic T-cell lymphoma stage III B-cell lymphoma B-cell lymphoma recurrent B-cell lymphoma stage I B-cell lymphoma stage II	Adult, inflammatory bowel disease	18–44; 45–64 years; Indication HLG:G Gastrointestinal inflammatory conditions

B-cell lymphoma stage III
B-cell lymphoma stage IV
B-cell small lymphocytic
lymphoma
B-cell small lymphocytic
lymphoma stage I
B-cell small lymphocytic
lymphoma stage III
B-cell unclassifiable lymphoma
high grade
B-cell unclassifiable lymphoma
low grade
Burkitt's lymphoma
Burkitt's lymphoma stage IV
Central nervous system
lymphoma
Cutaneous lymphoma
Cutaneous T-cell lymphoma
Cutaneous T-cell lymphoma
stage I
Cutaneous T-cell lymphoma
stage II
Cutaneous T-cell lymphoma
stage III
Cutaneous T-cell lymphoma
stage IV
Diffuse large B-cell lymphoma
Diffuse large B-cell lymphoma
recurrent
Diffuse large B-cell lymphoma
stage I
Diffuse large B-cell lymphoma
stage II
Diffuse large B-cell lymphoma
stage III
Diffuse large B-cell lymphoma
stage IV
Disseminated large cell
lymphoma

Enteropathy-associated T-cell lymphoma
Epstein-Barr virus associated lymphoma
Extranodal marginal zone B-cell lymphoma (MALT type)
Follicle centre lymphoma, follicular grade I, II, III
Follicle centre lymphoma, follicular grade I, II, III recurrent
Follicle centre lymphoma, follicular grade I, II, III stage I
Follicle centre lymphoma, follicular grade I, II, III stage III
Follicle centre lymphoma, follicular grade I, II, III stage IV
Gastrointestinal lymphoma
Hepatosplenic T-cell lymphoma
High grade B-cell lymphoma
Burkitt-like lymphoma
High-grade B-cell lymphoma
Hodgkin's disease lymphocyte depletion type stage III
Hodgkin's disease lymphocyte depletion type stage IV
Hodgkin's disease lymphocyte predominance stage I site unspecified
Hodgkin's disease lymphocyte predominance stage II site unspecified
Hodgkin's disease lymphocyte predominance type stage IV
Hodgkin's disease lymphocyte predominance type stage unspecified
Lymphocytic lymphoma
Lymphoma

Malignant lymphoma
unclassifiable low grade
Mantle cell lymphoma
Mantle cell lymphoma stage IV
Marginal zone lymphoma
Metastatic lymphoma
Natural killer cell lymphoblastic
lymphoma
Nodal marginal zone B-cell
lymphoma
Nodal marginal zone B-cell
lymphoma stage II
Non-Hodgkin's lymphoma
Non-Hodgkin's lymphoma stage
II
Non-Hodgkin's lymphoma stage
III
Non-Hodgkin's lymphoma stage
IV
Non-Hodgkin's lymphoma
unspecified histology
aggressive
Non-Hodgkin's lymphoma
unspecified histology indolent
Non-Hodgkin's lymphoma
unspecified histology indolent
stage IV
Ocular lymphoma
Papillary cystadenoma
lymphomatosum
Peripheral T-cell lymphoma
unspecified
Peripheral T-cell lymphoma
unspecified stage IV
Plasmablastic lymphoma
Precursor B-lymphoblastic
lymphoma
Precursor T-lymphoblastic
lymphoma/leukaemia

				Precursor T-lymphoblastic lymphoma/leukaemia stage III Precursor T-lymphoblastic lymphoma/leukaemia stage IV Primary breast lymphoma Primary effusion lymphoma Primary mediastinal large B-cell lymphoma Primary mediastinal large B-cell lymphoma recurrent Splenic marginal zone lymphoma T-cell lymphoma T-cell lymphoma recurrent T-cell lymphoma refractory T-cell lymphoma stage IV T-cell unclassifiable lymphoma high grade			
3–6 Apr 2017	Selexipag	SELEXIPAG	Fatality	Death Sudden death Sudden cardiac death Brain death Completed suicide Maternal death during childbirth	Adult, pulmonary arterial hypertension ^b	18–44; 45–64 years; Indication HLG T: Pulmonary vascular disorders	
4–7 May 2015	Mitotane	MITOTANE	Development of ovarian macrocysts	Haemorrhagic ovarian cyst Ovarian cyst Ovarian cyst ruptured Ovarian cyst torsion	Women	Female	
4–7 May 2015	Sildenafil	SILDENAFIL	Pulmonary haemorrhage	Pulmonary alveolar haemorrhage Pulmonary haemorrhage	Paediatric (off-label use in those <1 year)	0–27 days; 28 days to 23 months	
8–11 Jan 2018	Hydrochlorothiazide	ALISKIREN\HYDROCHLOROTHIAZIDE AMILORIDE\HYDROCHLOROTHIAZIDE AMLODIPINE\HYDROCHLOROTHIAZIDE VALSARTAN BISOPROLOL\HYDROCHLOROTHIAZIDE	Skin cancer	Basal cell carcinoma Carcinoma in situ of skin Malignant melanoma Malignant melanoma in situ Malignant melanoma stage I Malignant melanoma stage IV Metastatic malignant melanoma	Adult	18–44; 45–64 years	

		CANDESARTAN CILEXETIL\HYDROCHLOROTHIAZIDE ENALAPRIL\HYDROCHLOROTHIAZIDE HYDROCHLOROTHIAZIDE HYDROCHLOROTHIAZIDE\IRBESARTAN HYDROCHLOROTHIAZIDE\LISINOPRIL HYDROCHLOROTHIAZIDE\LOSARTAN HYDROCHLOROTHIAZIDE\RAMIPRIL HYDROCHLOROTHIAZIDE\TELMISARTAN HYDROCHLOROTHIAZIDE\TRIAMTERENE HYDROCHLOROTHIAZIDE\VALSARTAN		Skin squamous cell carcinoma metastatic Squamous cell carcinoma of skin Superficial spreading melanoma stage I Superficial spreading melanoma stage IV Superficial spreading melanoma stage unspecified		
9–12 Feb 2015	Teriparatide	TERIPARATIDE	Angina pectoris	Angina pectoris Chest discomfort Chest pain	Women postmenopausal, Men	Female; 45–64; 65–74; 75+ years; male

Please note that the drugs, events and subgroups combinations not represented in FAERS were removed. The 1719 PRAC subgroup DEC's available in FAERS are not individually represented in the table because of space limitations and do not correspond to the Cartesian product of the drugs, events and subgroups in the table.

^aAlgorithm slightly adapted given that free-text fields were not available in the version of FAERS used for this analysis (see Methods section 2.2.2 for details)

^bUnderlying condition of no relevant impact, representing mostly the drug indication

CAP, centrally authorised product; DEC, drug–event combination; DOAC, direct oral anticoagulant; FAERS, Food and Drug Administration Adverse Event Reporting System; HER2, human epidermal growth factor receptor 2; HLG, High Level Group Term; HRT, hormone replacement therapy; MALT, mucosa-associated lymphoid tissue; MedDRA, Medical Dictionary for Regulatory Activities; NAP, nationally authorised product; NEC not elsewhere classified; PRAC, Pharmacovigilance Risk Assessment Committee; PT, preferred term

Supplementary Table 2. Overall subgroup DEC_s identified in FAERS and PRAC minutes.

Covariate	Subgroups	FAERS reports per subgroup, n (%)	FAERS reports per subgroup in the subset of PRAC examples, n (%)
Age	0–27 days	65,781 (1)	28 (<1)
	28 days–23 months	25,825 (<1)	5 (<1)
	2–11 years	186,021 (2)	12 (<1)
	12–17 years	210,288 (3)	1 (<1)
	18–44 years	1,677,035 (22)	3,475 (12)
	45–64 years	2,779,964 (37)	20,234 (70)
	65–74 years	1,436,356 (19)	3,481 (12)
	≥ 75 years	1,191,450 (16)	1,503 (5)
	Total with age reported	7,572,720 (58)	28,739 (100)
Sex	Male	4,486,718 (39)	364 (1)
	Female	7,130,526 (61)	26,941 (99)
	Total with sex reported	11,617,244 (89)	27,305 (100)
Underlying condition ^a	1 all-drugs indication	8,867,127 (77)	12,128 (99)
	2 all-drugs indications	1,756,354 (15)	78 (1)
	3 all-drugs indications	424,993 (4)	4 (<1)
	4 all-drugs indications	187,275 (2)	1 (<1)
	5 all-drugs indications	99,983 (1)	2 (<1)
	6 all-drugs indications	59,558 (1)	0
	7+ all-drugs indications	105,603 (1)	0
	Total with at least 1 drug indication	11,500,893 (88)	12,213 (100)
Pregnancy	Pregnant ^b	63,375 (<1)	138 (100)

^aApproximated using all reported drugs indication at MedDRA HLGT – 1 all-drugs indication means that only 1 drug indication was reported in the cases, 2 all-drugs indication means that 2 drug indications were reported in the cases, etc.

^bAlgorithm slightly adapted given that free-text fields were not available in the version of FAERS used for this analysis (see Methods section 2.2.2.3 for details)

DEC, drug–event combination; FAERS, Food and Drug Administration Adverse Event Reporting System; PRAC, Pharmacovigilance Risk Assessment Committee

References

1. Sandberg L, Taavola H, Aoki Y, Chandler R, Norén GN. Risk factor considerations in statistical signal detection: using subgroup disproportionality to uncover risk groups for adverse drug reactions in VigiBase. *Drug Saf.* 2020;43:999-1009. <https://doi.org/10.1007/s40264-020-00957-w>.