

Table S1: Four major algorithms used for signal detection.

Algorithms	Equation	Criteria
ROR	ROR=ad/b/c 95%CI=e ^{ln(ROR)±1.96(1/a+1/b+1/c+1/d)^{0.5}}	lower limit of 95% CI>1, a≥3
PRR	PRR=a(c+d)/c/(a+b) $\chi^2=[(ad-bc)^2]/[(a+b)(c+d)(a+c)(b+d)]$	PRR≥2, χ^2 ≥4, a≥3
BCPNN	IC=log ₂ [a(a+b+c+d)]/[(a+c)(a+b)] 95%CI= E(IC) ± 2V(IC) ^{0.5}	IC025>0
MGPS	EBGM=a(a+b+c+d)/[(a+c)(a+b)] 95%CI=e ^{ln(EBGM)±1.96(1/a+1/b+1/c+1/d)^{0.5}}	EBGM05>2

Note: Equation: a, number of reports containing both the target drug and target adverse drug reaction; b, number of reports containing other adverse drug reaction of the target drug; c, number of reports containing the target adverse drug reaction of other drugs; d, number of reports containing other drugs and other adverse drug reactions. 95%CI, 95% confidence interval; χ^2 , chi-squared; IC, information component; IC025, the lower limit of 95% CI of the IC; E(IC), the IC expectations; V(IC), the variance of IC; EBGM, empirical Bayesian geometric mean; EBGM05, the lower limit of 95% CI of EBGM.

Table S2. Anatomical Therapeutic Chemical (ATC) classification of 119 drugs associated with spontaneous abortion or fetal death

Drug	ATC Code	L1	Category	L2	Category	L3	Category	L4	Category
Uridoxydrololol Acid	A05AA02	A	Alimentary tract and metabolism	A05	Bile and liver	A05A	Bile and liver therapy	A05AA	Bile acid preparations
Sibutramine	A08AA10	A	Alimentary tract and metabolism	A08	Antisobesity p	A08A	Antisobesity preparations	A08AA	Centrally acting anorectic products
Vitamin B1	A11DA01	A	Alimentary tract and metabolism	A11	Vitamins	A11D	Vitamin B1, alone or in combination	A11DA	Vitamin B1, alone
Vitamin B2	A11HA02	A	Alimentary tract and metabolism	A11	Vitamins	A11H	Other vitamin preparations	A11HA	Other vitamin preparations
Vitamin E	A11HA03	A	Alimentary tract and metabolism	A11	Vitamins	A11H	Other vitamin preparations	A11HA	Other vitamin preparations
Vitamin B6	A11HA04	A	Alimentary tract and metabolism	A11	Vitamins	A11H	Other vitamin preparations	A11HA	Other vitamin preparations
Imiglucerase	A16AB02	A	Alimentary tract and metabolism	A16	Other alimentary	A16A	Other alimentary tract and metabolism products	A16AB	Enzymes
Valganciclovir	A16AB05	A	Alimentary tract and metabolism	A16	Other alimentary	A16A	Other alimentary tract and metabolism products	A16AB	Enzymes
Sacropirin	A16AK07	A	Alimentary tract and metabolism	A16	Other alimentary	A16A	Other alimentary tract and metabolism products	A16AK	Other alimentary tract and metabolism products
Bilobalol	B01BA04	B	Blood and blood forming organs	B01	Antithrombotic	B01A	Antithrombotic agents	B01BA	Heparin group
Enoxaparin	B01BA05	B	Blood and blood forming organs	B01	Antithrombotic	B01A	Antithrombotic agents	B01BA	Heparin group
Trojanin	B01BA10	B	Blood and blood forming organs	B01	Antithrombotic	B01A	Antithrombotic agents	B01BA	Heparin group
Acetylsalicylic Acid	B01BA06	B	Blood and blood forming organs	B01	Antithrombotic	B01A	Antithrombotic agents	B01BA	Patient aggregation inhibitors
Vitamin B9 (Folic Acid)	B03BA01	B	Blood and blood forming organs	B03	Antianemic p	B03B	Vitamin B12 and folic acid	B03BA	Folic acid and derivatives
Methylnicotinamide	C02BA01	C	Cardiovascular system	C02	Other gynae	C02A	Cardiovascular agents	C02BA	Methylxanthine derivatives
Labetalol	C07AG01	C	Cardiovascular system	C07	Beta blocking	C07A	Beta blocking agents	C07AG	Alpha and beta blocking agents
Nifedipine	C08CA05	C	Cardiovascular system	C08	Calcium chan	C08C	Selective calcium channel blockers with mainly vascular effects	C08CA	Dihydropyridine derivatives
Ketoprofen	D01AC08	D	Demagogical	D01	Antirheumatic	D01A	Antirheumatic agents	D01AC	Non-steroidal anti-inflammatory drugs (NSAIDs)
Tacrolimus	D05AK05	D	Demagogical	D05	Antiparasitic	D05A	Antiparasitic agents	D05AK	Other antiparasitics
Isotretinoin	D10BA01	D	Demagogical	D10	Anti-acne	D10B	Anti-acne preparations for systemic use	D10BA	Retinoids for treatment of acne
Fluocortid	D11AX10	D	DERMATOLOGICALS	D11	OTHER DERM	D11A	OTHER DERMATOLOGICAL PREPARATIONS	D11AX	Other dermatologicals
Clotrimazole	G02AF02	G	Genitourinary system and sex hormones	G02	Gyneco/gyn	G02A	Antifungics and antiseptics	G02AF	Imidazole derivatives
Methylergometrin	G02AB01	G	Genitourinary system and sex hormones	G02	Other gynae	G02A	Uterotronics	G02AB	Ergot alkaloids
Drospirenone	G02AD02	G	Genitourinary system and sex hormones	G02	Other gynae	G02A	Uterotronics	G02AD	Prostaglandins
Mestranolol	G02AG06	G	Genitourinary system and sex hormones	G02	Other gynae	G02A	Uterotronics	G02AG	Prostaglandins
Intrauterine Contraceptive Device	G02BA01	G	Genitourinary system and sex hormones	G02	Other gynae	G02B	Intrauterine contraceptives	G02BA	Intrauterine contraceptives with copper
Boniferron	G02CB01	G	Genitourinary system and sex hormones	G02	Other gynae	G02C	Other gynaecologic hormones	G02CB	Product inhibitors
Calcitriol	G02CB03	G	Genitourinary system and sex hormones	G02	Other gynae	G02C	Other gynaecologic hormones	G02CB	Product inhibitors
Levonorgestrel	G03AA03	G	Genitourinary system and sex hormones	G03	Sex hormone	G03A	Hormonal contraceptives for systemic use	G03AA	Progestagens and estrogens in combination
Norgestrel	G03AA04	G	Genitourinary system and sex hormones	G03	Sex hormone	G03A	Hormonal contraceptives for systemic use	G03AA	Progestagens and estrogens in combination
Norgestimate	G03AA03	G	Genitourinary system and sex hormones	G03	Sex hormone	G03A	Hormonal contraceptives for systemic use	G03AA	Progestagens (single component)
Megestrolone	G03AC06	G	Genitourinary system and sex hormones	G03	Sex hormone	G03A	Hormonal contraceptives for systemic use	G03AC	Progestagens (single component)
Ethinodiol	G03AC08	G	Genitourinary system and sex hormones	G03	Sex hormone	G03A	Hormonal contraceptives for systemic use	G03AC	Progestagens (single component)
Desogestrel	G03AC09	G	Genitourinary system and sex hormones	G03	Sex hormone	G03A	Hormonal contraceptives for systemic use	G03AC	Progestagens (single component)
Norgestimate	G03DA03	G	Genitourinary system and sex hormones	G03	Sex hormone	G03D	Progestagens	G03DA	Progestagens (single component)
Progesterone	G03DA04	G	Genitourinary system and sex hormones	G03	Sex hormone	G03D	Progestagens	G03DA	Progestagens (single component)
Denigest	G03DA08	G	Genitourinary system and sex hormones	G03	Sex hormone	G03D	Progestagens	G03DA	Progestagens (single component)
Clomifene	G03DA09	G	Genitourinary system and sex hormones	G03	Sex hormone	G03D	Progestagens	G03DA	Progestagens (single component)
Human Menopausal Gonadotrophin	G03G02	G	Genitourinary system and sex hormones	G03	Sex hormone	G03G	Gonadotropins and other ovulation stimulants	G03GA	Gonadotropins
Follitropin Beta	G03G02	G	Genitourinary system and sex hormones	G03	Sex hormone	G03G	Gonadotropins and other ovulation stimulants	G03GA	Gonadotropins
Choriongonadotropin	G03G07	G	Genitourinary system and sex hormones	G03	Sex hormone	G03G	Gonadotropins and other ovulation stimulants	G03GA	Gonadotropins
Urofollitropin	G03G07	G	Genitourinary system and sex hormones	G03	Sex hormone	G03G	Gonadotropins and other ovulation stimulants	G03GA	Gonadotropins
Clomifene	G03H02	G	Genitourinary system and sex hormones	G03	Sex hormone	G03G	Gonadotropins and other ovulation stimulants	G03GH	Ovulation stimulants
Genistein	H01CO02	H	Hormonal preparations, excl. sex hormones and insulin	H01	Phytal and	H01C	Phytohormones	H01CC	Gonadotropin releasing hormone antagonists
Urofollitropin	J01AA08	J	Anti-infectives for systemic use	J01	Antibacterial	J01A	Tetracyclines	J01AA	Tetracyclines
Ampicillin	J01CA01	J	Anti-infectives for systemic use	J01	Antibacterial	J01C	Beta-lactam antibacterials, penicillins	J01CA	Penicillins with extended spectrum
Amoxicillin	J01CA04	J	Anti-infectives for systemic use	J01	Antibacterial	J01C	Beta-lactam antibacterials, penicillins	J01CA	Penicillins with extended spectrum
Cefixime	J01DB01	J	Anti-infectives for systemic use	J01	Antibacterial	J01D	Beta-lactam antibacterials, cephalosporins	J01DB	First generation cephalosporins
Erythromycin	J01FA01	J	Anti-infectives for systemic use	J01	Antibacterial	J01F	Macrolides, lincosamides and streptogramins	J01FA	Macrolides
Clarithromycin	J01FA09	J	Anti-infectives for systemic use	J01	Antibacterial	J01F	Macrolides, lincosamides and streptogramins	J01FA	Macrolides
Azithromycin	J01FA10	J	Anti-infectives for systemic use	J01	Antibacterial	J01F	Macrolides, lincosamides and streptogramins	J01FA	Macrolides
Ceftriaxone	J01HD01	J	Anti-infectives for systemic use	J01	Antibacterial	J01H	Quinolone antibacterials	J01HA	Quinolones
Meronem	J01HD02	J	Anti-infectives for systemic use	J01	Antibacterial	J01H	Quinolone antibacterials	J01HA	Quinolones
Fluconazole	J02AC01	J	Anti-infectives for systemic use	J02	Antifungics	J02A	Antifungics for systemic use	J02AC	Triazole derivatives
Isoniazide	J02AD02	J	Anti-infectives for systemic use	J02	Antitubercular	J02A	Antitubercular agents	J02AD	Triazole derivatives
Ribavirin	J05AB04	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AB	Nucleosides and nucleotides, excl. reverse transcriptase inhibitors
Sofosbuvir	J05AE01	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AE	Protease inhibitors
Boceprevir	J05AE02	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AE	Protease inhibitors
Nonifavir	J05AE04	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AE	Protease inhibitors
Simeprevir	J05AE07	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AE	Protease inhibitors
Abacavir	J05AF01	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Protease inhibitors
Dolutegravir	J05AF02	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Stavudine	J05AF04	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Lamivudine	J05AF05	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Abacavir	J05AF06	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Tenofovir	J05AF07	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Abifavir	J05AF08	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Etravirine	J05AF09	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Etiprovir	J05AF10	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Telaprevir	J05AF11	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AF	Nucleoside and nucleotide reverse transcriptase inhibitors
Nevirapine	J05AG01	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AG	Non-nucleoside reverse transcriptase inhibitors
Efavirenz	J05AG03	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AG	Non-nucleoside reverse transcriptase inhibitors
Rilpivirine	J05AG04	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AG	Non-nucleoside reverse transcriptase inhibitors
Delamanvir	J05AG05	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AG	Non-nucleoside reverse transcriptase inhibitors
Locovir	J05AG10	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AG	Non-nucleoside reverse transcriptase inhibitors
Raltegravir	J05AG18	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AG	Non-nucleoside reverse transcriptase inhibitors
Enfuvirtin	J05AG19	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AG	Non-nucleoside reverse transcriptase inhibitors
Cobicistat	J05AK11	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AK	Other antivirals
Dolutegravir	J05AK12	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AK	Other antivirals
Boceprevir	J05AK20	J	Anti-infectives for systemic use	J05	Antiviral for	J05A	Direct acting antivirals	J05AK	Other antivirals
Anti-D Immunoglobulin	J06AB01	J	Anti-infectives for systemic use	J06	Immune sera	J06B	Immune sera	J06AB	Specific immunoglobulins
CycloDine	L01BB04	L	Antineoplastic and immunomodulating agents	L01	Antineoplastic	L01B	Antimetabolites	L01BB	Purine analogues
Hydroxyflutamide	L02X005	L	Antineoplastic and immunomodulating agents	L02	Antineoplastic	L02X	Other antineoplastic agents	L02X0	Other antineoplastic agents
Cetuximab	L03X003	L	Antineoplastic and immunomodulating agents	L03	Endocrine th	L03B	Endocrine hormones and related agents	L03X0	Other hormones, antagonists and related agents
Peginterferon Beta-1a	L03XB13	L	Antineoplastic and immunomodulating agents	L03	Immunostim	L03A	Immunostimulants and antivirals	L03XB	Interferons
Methotrexate	L04AA05	L	Antineoplastic and immunomodulating agents	L04	Immunosupp	L04A	Immunosuppressants (non-specific)	L04AA	Interleukin inhibitors
Nestorlumab	L04AA23	L	Antineoplastic and immunomodulating agents	L04	Immunosupp	L04A	Immunosuppressants (non-specific)	L04AA	Interleukin inhibitors
Carboplatin	L04AB05	L	Antineoplastic and immunomodulating agents	L04	Immunosupp	L04A	Immunosuppressants (non-specific)	L04AA	Interleukin inhibitors
Taxotere	L04AC02	L	Antineoplastic and immunomodulating agents	L04	Immunosupp	L04A	Immunosuppressants (non-specific)	L04AA	Interleukin inhibitors
Indomethacin	M01AB01	M	Musculo-skeletal system	M01	Anti-inflam	M01A	Non-steroidal anti-inflammatory drugs (NSAIDs)	M01AB	Acetic acid derivatives and related substances
Naratriptan	M02CC04	N	Nervous system	M02	Analgesics	M02C	Analgesic preparations	M02CC	Selective serotonin (5HT1) agonists
Risperidone	N02BA01	N	Nervous system	N02	Antipsychotic	N02A	Antipsychotics (non-barbiturates)	N02BA	Carbamazepine and oxcarbazepine
Oxcarbazepine	N02BA02	N	Nervous system	N02	Antipsychotic	N02A	Antipsychotics (non-barbiturates)	N02BA	Carbamazepine and oxcarbazepine
Valproic Acid	N02BA03	N	Nervous system	N02	Antipsychotic	N02A	Antipsychotics (non-barbiturates)	N02BA	Fatty acid derivatives
Lamotrigine	N02BA09	N	Nervous system	N02	Antipsychotic	N02A	Antipsychotics (non-barbiturates)	N02BA	Other antipsychotics
Topiramate	N02BA11	N	Nervous system	N02	Antipsychotic	N02A	Antipsychotics (non-barbiturates)	N02BA	Other antipsychotics
Levetiracetam	N02BA14	N	Nervous system	N02	Antipsychotic	N02A	Antipsychotics (non-barbiturates)	N02BA	Other antipsychotics
Zonisamide	N02BA15	N	Nervous system	N02	Antipsychotic	N02A	Antipsychotics (non-barbiturates)	N02BA	Other antipsychotics
Lacosamide	N02BA18	N	Nervous system	N02	Antipsychotic	N02A	Antipsychotics (non-barbiturates)	N02BA	Other antipsychotics
Acipimox	N05BA12	N	Nervous system	N05	Psychotropic	N05A	Antipsychotics	N05BA	Other antipsychotics
Clobazam	N05BA09	N	Nervous system	N05	Psychotropic	N05B	Anxiolytics	N05BA	Benzodiazepine derivatives
Flucanone	N06AB08	N	Nervous system	N06	Psycholeptic	N06A	Antidepressants	N06AB	Selective serotonin reuptake inhibitors
Moxidipine	N06BA07	N	Nervous system	N06	Psychotropic	N06B	Psychotropic agents used for ADHD and nootropics	N06BA	Central acting sympathomimetics
Bupropion	N07BC01	N	Nervous system	N07	Other neuro	N07B	Drugs used in addictive disorders	N07BC	Opioid receptor antagonists
Atipamezole	P01AA05	P	Antiparasitic products, insecticides and repellents	P01	Antiparasitic	P01A	Antiparasitics	P01AA	Other antiparasitics
Permethrin	P01BB01	P	Antiparasitic products, insecticides and repellents	P01	Antiparasitic	P01B	Antiparasitics	P01BB	Biquanines
Mefenazone	P02CA01	P	Antiparasitic products, insecticides and repellents	P02	Anthelmintic	P02C	Broad-spectrum anthelmintics	P02CA	Benzimidazole derivatives
Ambrozole	P02CA02	P	Antiparasitic products, insecticides and repellents	P02	Anthelmintic	P02C	Broad-spectrum anthelmintics	P02CA	Benzimidazole derivatives
Doxylamine	R06AA09	R	Respiratory system	R06	Antihistamin	R06A	Antihistamines for systemic use	R06AA	Aminolyl ethers
Isosalbutamol	R07AB01	R	Respiratory system	R07	Other respira	R07A	Other respiratory system products	R07AB	Other respiratory system products
Terbutalin	R07AB05	R	Respiratory system	R07	Other respira	R07A	Other respiratory system products	R07AB	Other respiratory system products
Enacofyllin	R07AB06	R	Respiratory system	R07	Other respira	R07A	Other respiratory system products	R07AB	Other respiratory system products
Naloxone	V03AB15	V	Various	V03	All other th	V03A	All other therapeutic products	V03AB	Opioid receptor antagonists
Isoflurane (I31 I)	V09FX01	V	Various	V09	Diagnostic r	V09F	Thyroid diagnostic agents	V09FX	Other thyroid diagnostic agents

The READUS-PV checklist

Section and topic	Item #	Checklist item	Location where item is reported
Title			
	1a	If disproportionality analyses are a prominent component of the published study, the study should be identified as a “disproportionality analysis”. The type of data and name of the database(s) should be specified.	Page1
	1b	Report the name of adverse event(s) and/or drug(s) under study, when applicable.	Page1
Introduction			
Background	2a	Describe the drug(s) and its utilization, the nature of the adverse event(s) under study and its frequency, and the existing knowledge on the drug-event combination.	Page 1 - 2
	2b	Specify the rationale for performing the analysis, e.g., as part of routine pharmacovigilance, to investigate an overall safety profile, or to assess a pre-specified hypothesis.	Page 2
	2c	Explain why ICSR databases and disproportionality analysis are suitable to fill the knowledge gap.	Page 1 - 2
Objectives	3	State specific objectives, identifying the adverse event(s), the drug(s), and the reference group, including any pre-specified hypothesis, if applicable.	Page 1 - 2
Methods			
Study design	4a	Identify the study (i.e., “disproportionality analysis”) and the type of data used (e.g., “individual case safety reports”).	Page 2 - 3
	4b	Provide an outline of the entire study design, including primary and sensitivity analyses performed, and other designs such as case-by-case analysis or literature review.	Page 2 - 3
Data description, access, and pre-processing	5a	Specify the name of the database(s), the database(s) custodian, and the coverage. Specify the type/number of drugs included within the database and the thesaurus, taxonomies, or ontologies used for coding drugs and events.	Page 2
	5b	Specify the extraction dates and describe and justify all choices used for data pre-processing, including any data transformation or exclusion, if appropriate.	Page 2
Variables definition	6a	Describe the study population, including any restriction.	Page 2 - 3
	6b	Describe the nature and the meaning of key variables assessed in the work.	Page 3
	6c	Specify and justify any grouping of drugs or events. For drugs, specify and justify whether active ingredients/trade names/salts were considered and/or the selected role.	Page 2
	6d	Describe any additional data source used, the type of data, and how they interact with ICSRs.	None
Statistical methods	7a	Present any descriptive analysis performed, specifying variables investigated, statistical tests, and significance thresholds.	Page 2
	7b	Describe the measure(s) selected for the disproportionality analysis including any threshold used to identify signals of disproportionate reporting. Explain the reason for this choice if applicable.	Page 2 - 3
	7c	Clearly describe any sensitivity analysis and any tool to control confounding, including any restriction, subgroup, stratification, adjustment, or interaction.	Page 2
	7d	Specify the variables and methods used for the case-by-case analysis, including any algorithm or criteria used to assess causality, if performed.	None
	7e	Specify any statistical methods used for other data sources.	None

Results			
Participants	8a	Specify the number of individual case safety reports included at each stage, including reasons for exclusion.	Page 3
	8b	Provide key demographic and clinical characteristics of cases, if possible comparing cases with any appropriate reference group.	Page 3
Disproportionality analysis	9	Present all results including confidence intervals. Present also results of sensitivity analyses, if performed.	Page 3 - 4
Case-by-case analysis	10	Present the case-by-case analysis of key variables. Present the causality assessment, if applicable.	None
Discussion			
Key results	11	Discuss key results with reference to study objectives and contextualize them within the current literature and other consulted sources. Clearly discriminate between expected reactions and emerging safety signals.	Page 6 and 10
External validity	12a	Discuss the external validity of the results to the general population.	Page 6
	12b	Discuss the potential relevance of results in clinical practice	Page 6
	12c	Propose further study designs if applicable	Page 11
Limitations	13	Present general limitations, making clear that disproportionality analysis alone cannot prove causation or measure incidence, and specific limitations, including confounding and reporting bias and efforts to mitigate them.	Page 11
Declarations			
	14a	Provide the source of funding/sponsorship and the role of the funders/sponsors for the present study and for any original study on which the present article is based.	Page 11
	14b	Clearly identify potential commercial and intellectual conflicts of interest (e.g., link to any drug/event investigated, whether financial, legal action, or software used).	Page 11
	14c	Declare any institutional approval needed or granted in the investigation.	Page 11
	14d	Include a statement on data availability, code availability (including the version of the statistical software used), and protocol registration.	Page 3