

OMOP 2011/2012 Reference Set

OMOP developed test cases for four health outcomes of interest (HOI): acute kidney injury, acute liver injury, acute myocardial infarction, and GI bleed. These HOIs represent four of the most significant drug safety outcomes considered for a risk identification system[34]. For each of these outcomes, drugs were classified as positive or negative controls based on the following criteria:

Positive Controls: Drug-outcome pairs that satisfy the following criteria:

- Event listed in Boxed Warning or Warnings/Precautions section of active FDA structured product label
- Drug listed as ‘causative agent’ in Tisdale et al, 2010: “Drug-Induced Diseases”[35]
- Literature review identified no powered studies with refuting evidence of effect

Negative Controls: Drug-outcome pairs that satisfy the following criteria:

- Event not listed anywhere in any section of active FDA structured product label
- Drug not listed as ‘causative agent’ in Tisdale et al, 2010: “Drug-Induced Diseases”[35]
- Literature review identified no powered studies with evidence of potential positive association

Drugs in **bold** have minimum detectable relative risk[36] ≤ 1.25 in all 5 databases

Acute Kidney Injury				
Positive Controls				
acyclovir	naproxen[31, 37-39]	captopril	etodolac	moexipril
hydrochlorothiazide	olmesartan medoxomil	chlorothiazide	fenoprofen[31]	oxaprozin
ibuprofen[31, 38-40]	allopurinol[41]	cyclosporine	ketoprofen[31]	piroxicam [31]
lisinopril	candesartan	diflunisal	ketorolac[39]	telmisartan
meloxicam [37-39]	capreomycin	enalaprilat	mefenamate	
Negative Controls				
benzonatate	clozapine	flavoxate	methocarbamol	ramelteon
ketoconazole	cosyntropin	flutamide	miconazole	rizatriptan
loratadine	dacarbazine	frovatriptan	nelfinavir	scopolamine
metaxalone	darbepoetin alfa	gatifloxacin	neostigmine	simethicone
temazepam	darifenacin	griseofulvin	nortriptyline	sodium phosphate, monobasic
acarbose	darunavir	hyoscyamine	orlistat	tetrahydrocannabinol
adenosine	dicyclomine	imipramine	paromomycin	thiabendazole
almotriptan	disulfiram	infliximab	penicillin V	thiothixene
amylases	eletriptan	ketotifen	phentermine	tinidazole
benzocaine	endopeptidases	lactulose	phentolamine	urea
bromfenac	entecavir	lipase	prilocaine	vitamin A
chlorambucil	ergotamine	mebendazole	primidone	zafirlukast
chlorazepate	ferrous gluconate	methenamine	prochlorperazine	

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Acute Liver Injury				
Positive Controls				
allopurinol[42]	niacin	alatrofloxacin	imatinib	stavudine
carbamazepine[43]	nifedipine	bortezomib	infliximab	sulfisoxazole
celecoxib	nitrofurantoin	bosentan	interferon beta-1a	tenofovir
ciprofloxacin	nortriptyline	busulfan	isoniazid[42]	thiabendazole
cyclosporine	ofloxacin	captopril[42]	itraconazole[44]	thioguanine
diltiazem	oxaprozin	caspofungin	lamivudine	tipranavir
erythromycin[42, 43, 45]	pioglitazone	clozapine	methimazole	tolcapone
etodolac	piroxicam	dacarbazine	methyldopa	tolmetin
fluconazole[33]	quinapril	darunavir	moexipril	trovafloxacin
ibuprofen	ramipril	didanosine	nefazodone	voriconazole
indomethacin[42]	sulindac	disulfiram	nevirapine[46]	zafirlukast
ketorolac	tamoxifen[47]	efavirenz	norfloxacin	zalcitabine
lamotrigine	terbinafine[44]	enalaprilat[42]	orlistat	zidovudine
levofloxacin	trandolapril	felbamate	penicillamine	
lisinopril	valproate[43]	flutamide	posaconazole	
methotrexate	acetazolamide	gemcitabine	propylthiouracil	
naproxen	abacavir	gemifloxacin	rifampin	
Negative Controls				
adenosine	lactulose	almotriptan	ketotifen	Primidone
benzocaine	miconazole	amylases	lipase	Propantheline
benzonatate	oxybutynin	cosyntropin	lithium citrate	Sodium Phosphate, Monobasic
dicyclomine	penicillin V	droperidol	Methenamine	Tetrahydrocannabinol
fluticasone	salmeterol	endopeptidases	Neostigmine	Tinidazole
gatifloxacin	scopolamine	ergotamine	Paromomycin	
griseofulvin	sitagliptin	ferrous gluconate	Phentermine	
hyoscyamine	Sucralfate	flavoxate	Phentolamine	

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Acute Myocardial Infarction				
Positive controls				
amlodipine	ketorolac[48]	almotriptan	factor VIIa	rizatriptan
darbepoetin alfa	nabumetone[48, 49]	amoxapine	fenoprofen[48]	salsalate
dipyridamole	nifedipine	bromocriptine	flurbiprofen[48]	tolmetin[48]
epoetin Alfa	nortriptyline	desipramine	frovatriptan	zolmitriptan
estradiol	oxaprozin [48]	diflunisal	imipramine	
estrogens, conjugated (USP)[50]	piroxicam[48, 49, 51]	eletriptan	ketoprofen[48, 49]	
etodolac[49, 52]	sulindac[48, 51]	enalaprilat	moexipril	
indomethacin[48, 49, 53, 54]	sumatriptan	estropipate	naratriptan	
Negative controls				
benzonatate	ramelteon	chlorothiazide	methenamine	stavudine
clindamycin	salmeterol	cosyntropin	methimazole	sulfasalazine
dicyclomine	scopolamine	darifenacin	miconazole	sulfisoxazole
fluticasone	sitagliptin	didanosine	nelfinavir	tetrahydrocannabinol
gatifloxacin	sucrafate	droperidol	nevirapine	thiabendazole
hyoscyamine	temazepam	endopeptidases	paromomycin	thiothixene
ketoconazole	terbinafine	entecavir	pemoline	tinidazole
lactulose	urea	ferrous gluconate	penicillamine	tipranavir
loratadine	acarbose	flavoxate	posaconazole	vitamin A
metaxalone	acetazolamide	flutamide	prilocaine	zafirlukast
methocarbamol	amylases	ketotifen	primidone	
penicillin V	bromfenac	lipase	propantheline	
prochlorperazine	chlorambucil	lithium citrate	simethicone	
oxybutynin	chlorazepate	mebendazole	sodiumphosphate, monobasic	

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GI Bleed				
Positive Controls				
citalopram	fluoxetine[55-63]	nabumetone[64, 65]	oxaprozin	mefenamate[66]
clindamycin	ibuprofen[65, 67-74]	naproxen[64, 65, 67, 69-75]	diflunisal	sulindac
clopidogrel[32, 63]	indomethacin[65, 67, 69-73]	piroxicam[65, 69-75]	fenoprofen	tolmetin
escitalopram	ketorolac[70-72, 75]	potassium Chloride	flurbiprofen[65, 70]	valdecoxib
etodolac[65, 69]	meloxicam[65, 67, 69-72, 76]	sertraline[55-63]	ketoprofen[65, 67, 70-73]	
Negative Controls				
adenosine	pioglitazone	bromfenac	ketotifen	prilocaine
benzonatate	prochlorperazine	chlorambucil	lamivudine	propantheline
dicyclomine	rosiglitazone	chlorazepate	lipase	simethicone
epoetin alfa	salmeterol	cosyntropin	lithium citrate	stavudine
fluticasone	scopolamine	dacarbazine	mebendazole	tetrahydrocannabinol
hyoscyamine	sitagliptin	darifenacin	miconazole	thiabendazole
ketoconazole	sucralfate	disulfiram	moexipril	thiothixene
lactulose	temazepam	droperidol	neostigmine	tinidazole
loratadine	terbinafine	endopeptidases	nevirapine	vitamin A
metaxalone	urea	entecavir	orlistat	zidovudine
methocarbamol	abacavir	ergotamine	paromomycin	
nitrofurantoin	acarbose	ferrous gluconate	pemoline	
oxybutynin	amylases	griseofulvin	phentermine	
penicillin V	benzocaine	itraconazole	phentolamine	