

An Exploratory Analysis of FDA Adverse Events Data

Onur R. Yörük
May 11th, 2020

This slide deck & code notebook is available on:
github.com/oryoruk/fda_adverse_events/
(or bit.ly/azn-case)

Intro



- CS, Bioinformatics/Comp. Bio.
 - Work in Data Science in Pharma
 - From Turkey
 - Live in Philadelphia
- 🍺 **Fun fact:** Will brew my first batch of beer this weekend

Outline

- Background
- Exploratory Analysis of FAERS Data
- Questions from AstraZeneca Case Study
- Limitations / Conclusion / Potential Future Directions

FAERS: FDA Adverse Events Reporting System

General Information Report ID, receive date, etc.	
Patient or other information Age, weight, sex, etc.	
Products Product A Product B Product C Product D Product E	Patient reactions Reaction 1 Reaction 2 Reaction 3

- openFDA API

<https://api.fda.gov/drug/event.json?search=reactionmeddrapt:'headache'&limit=5>

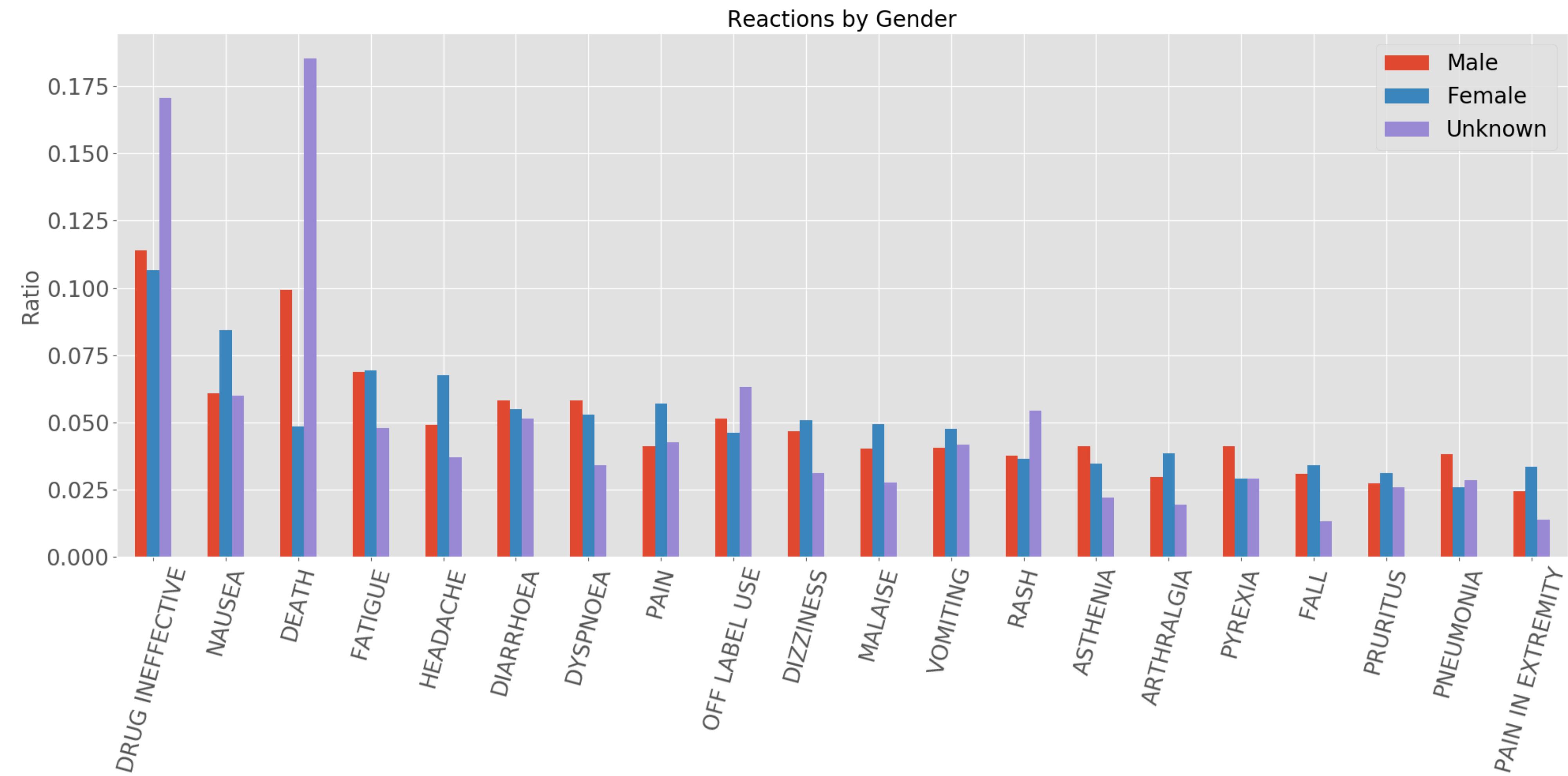
base endpoint

? search=

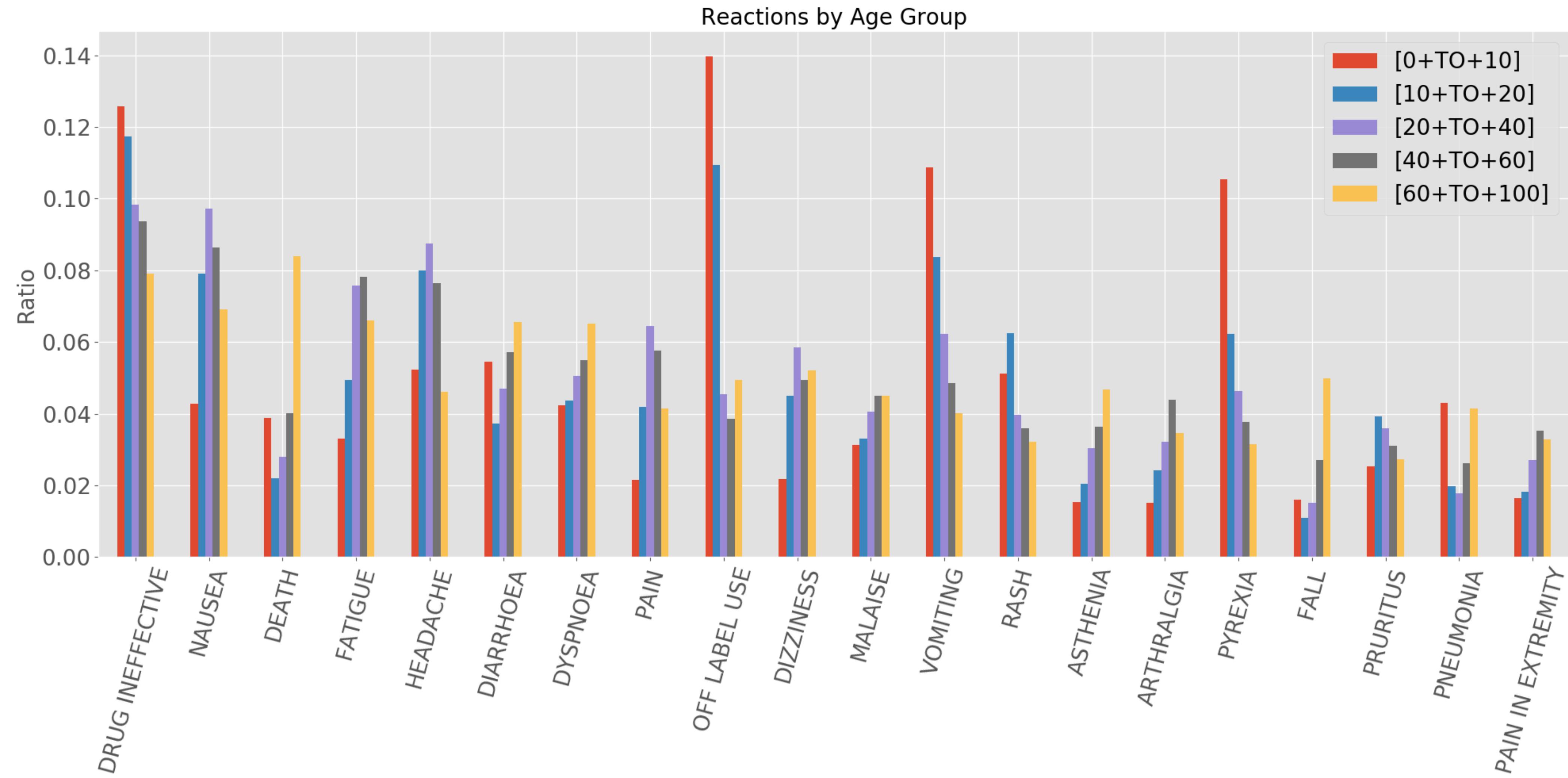
field:term

& limit

Data Exploration Part I: Effect of Demographics on Reported Adverse Events



Data Exploration Part I: Effect of Demographics on Reported Adverse Events



Data Exploration Part I: Effect of Demographics on Reported Adverse Events

- Age & Gender are associated with different patterns of reporting
- Standing out:
 - **Males:** death, fever, pneumonia, myocardial infarction, hypotension
 - **Females:** headache, nausea, alopecia, injection site pain, pain
 - **Younger:** off-label use, vomiting, fever, cough, drowsiness, erythema*
 - **Older:** death, weakness, fall, pneumonia, myocardial inf.,

*reddening of the skin

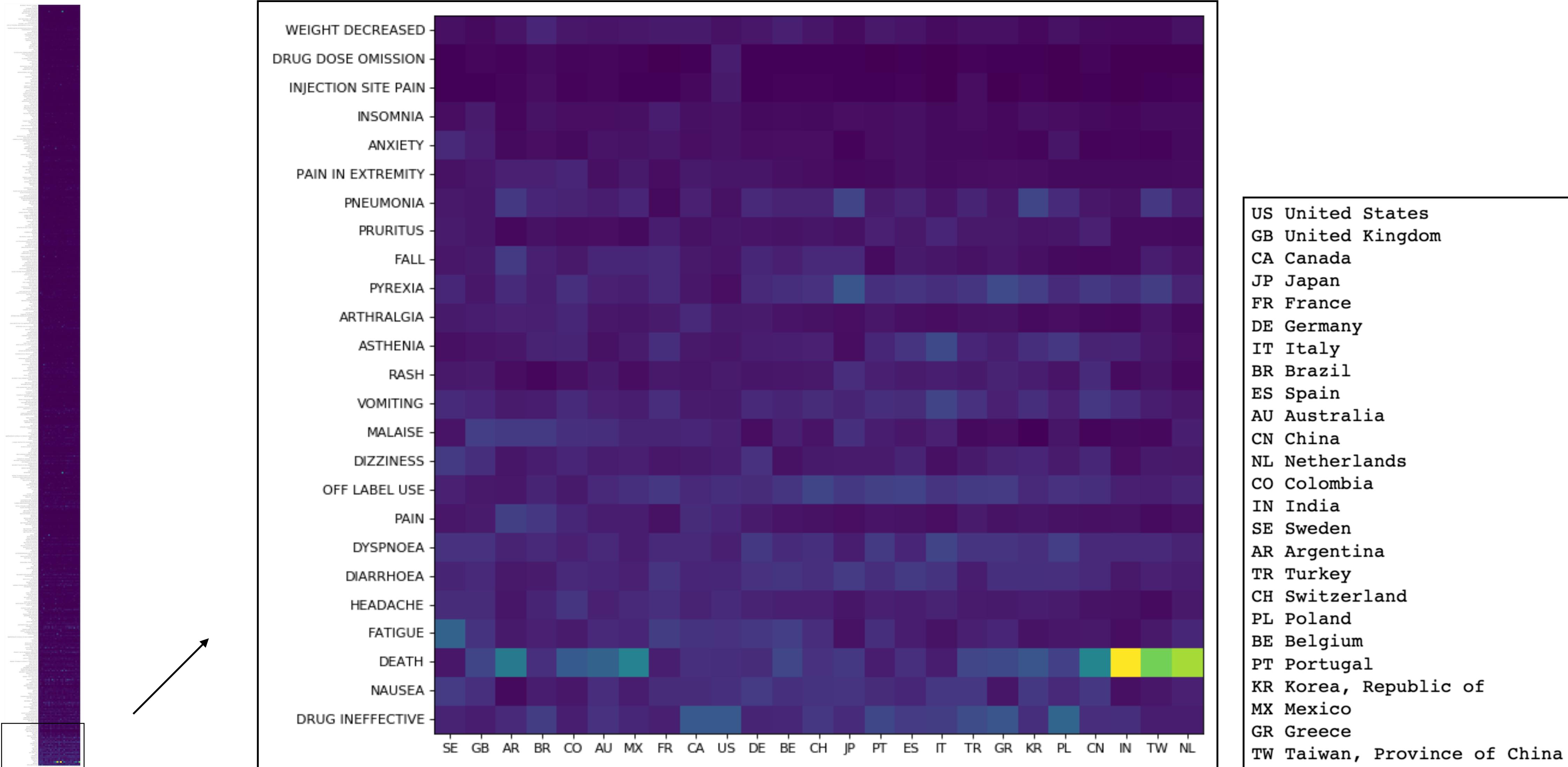
**Question 1: Are different adverse events reported
in different countries?**

Top Countries & Reactions

	term	count
0	US	6136862
1	GB	298758
2	CA	260177
3	JP	259359
4	FR	250505
5	DE	190403
6	IT	138001
7	BR	92823
8	ES	71442
9	AU	65305

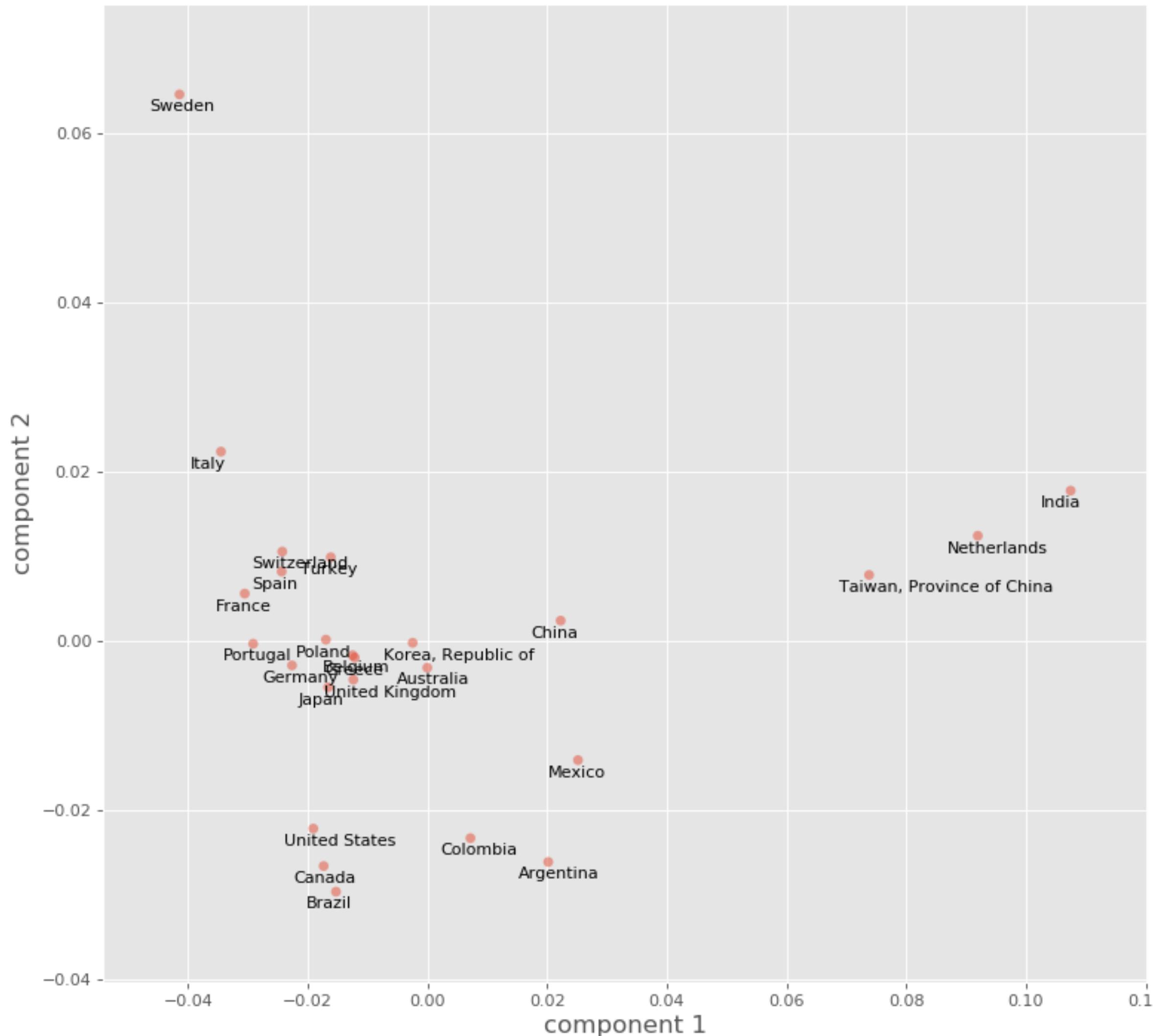
	term	count
0	DRUG INEFFECTIVE	733191
1	NAUSEA	485098
2	DEATH	474541
3	FATIGUE	439328
4	HEADACHE	388310
5	DIARRHOEA	359872
6	DYSPNOEA	344540
7	PAIN	326354
8	OFF LABEL USE	324957
9	DIZZINESS	313617

“Death” Stands out as an Important Variable Separating Countries



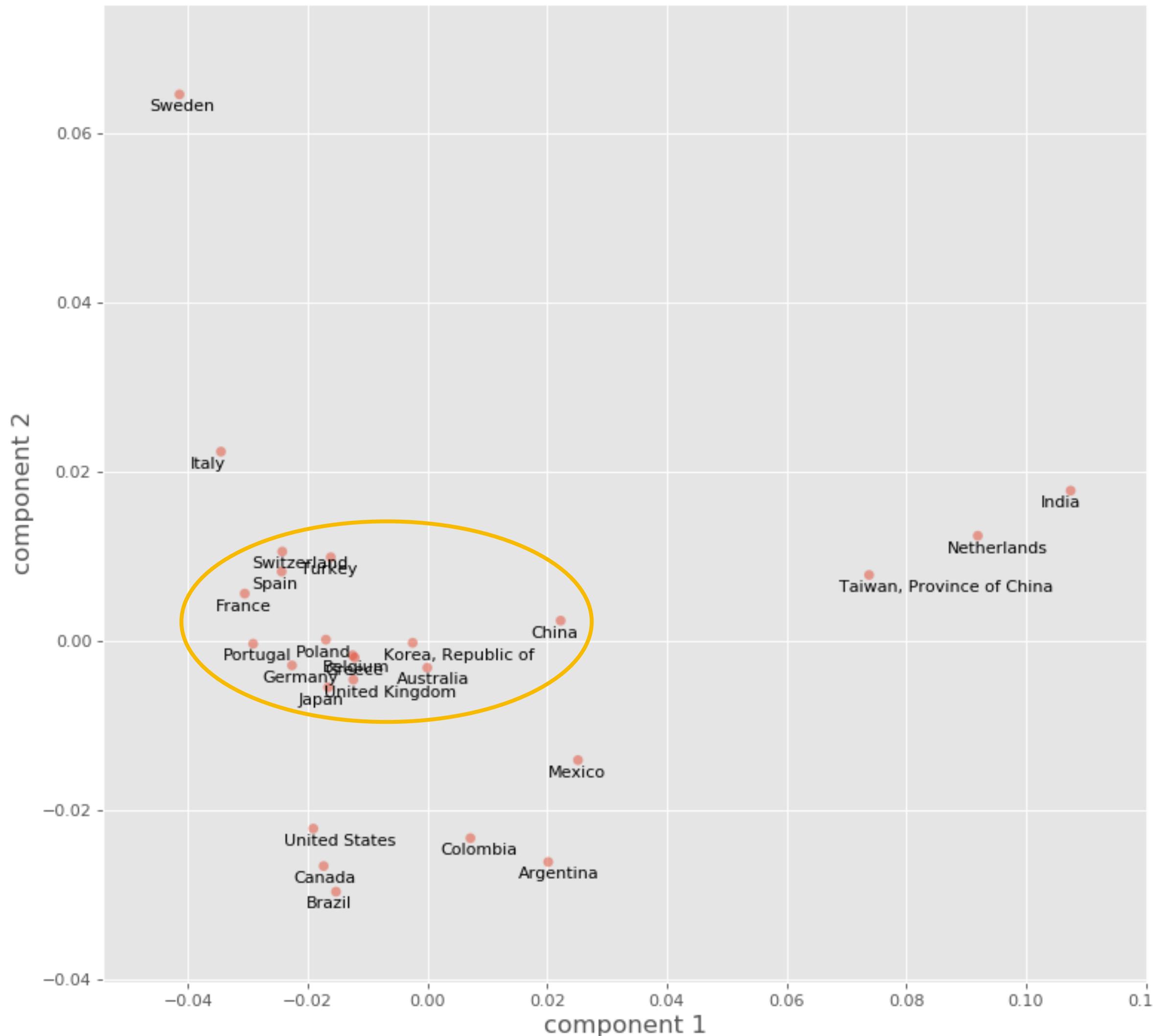
PC Analysis Groups

Americas & Europe Separately



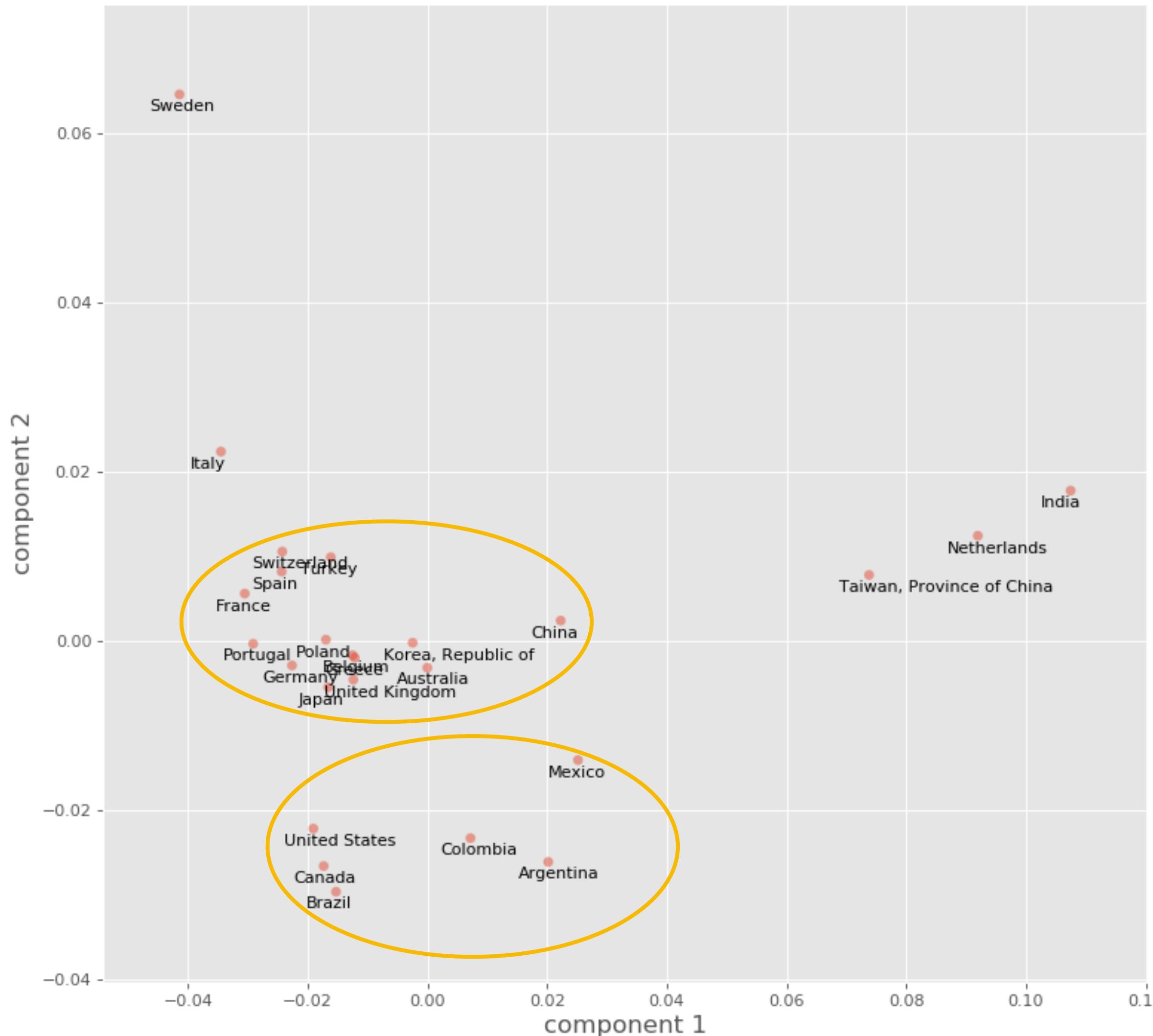
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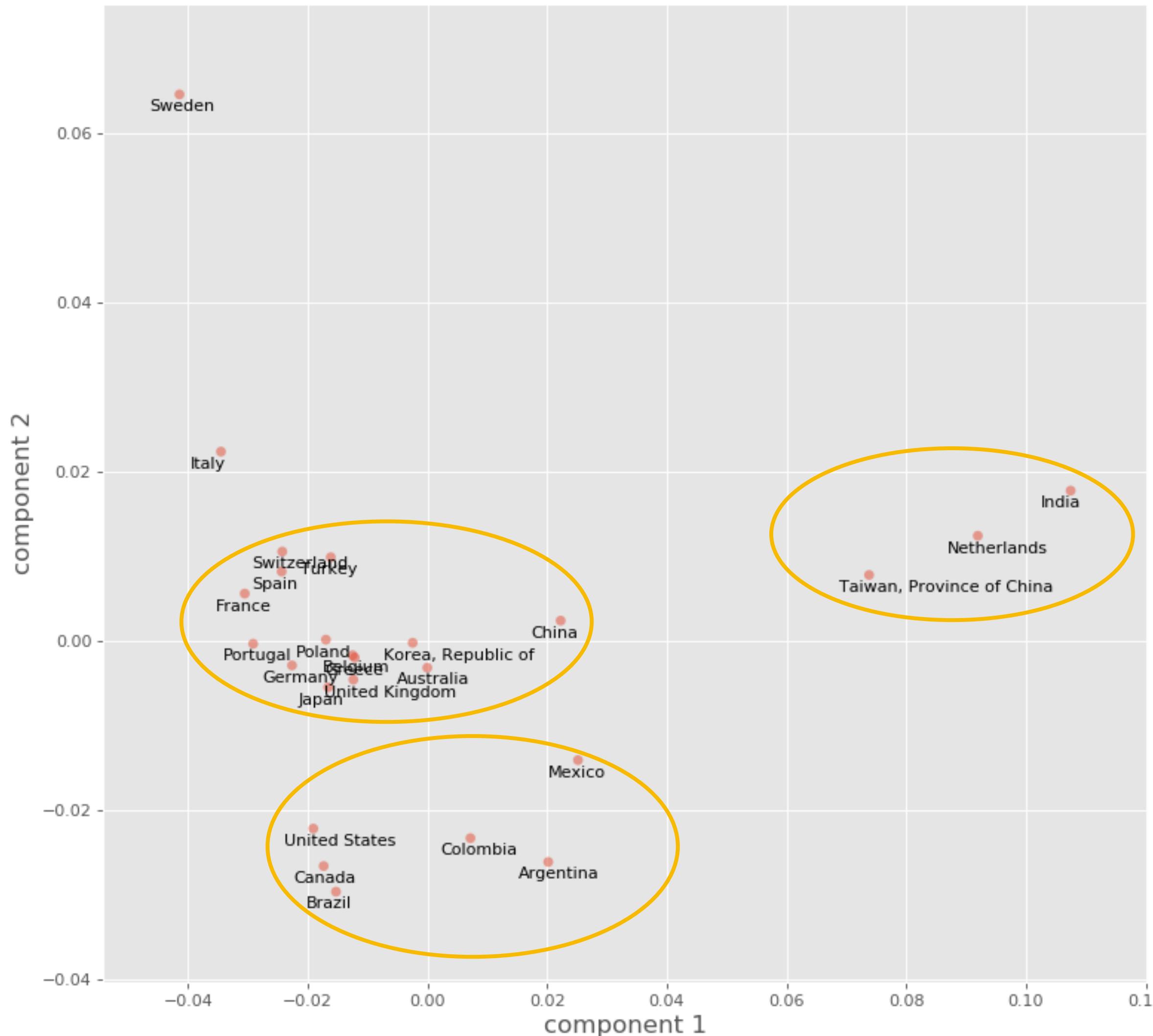
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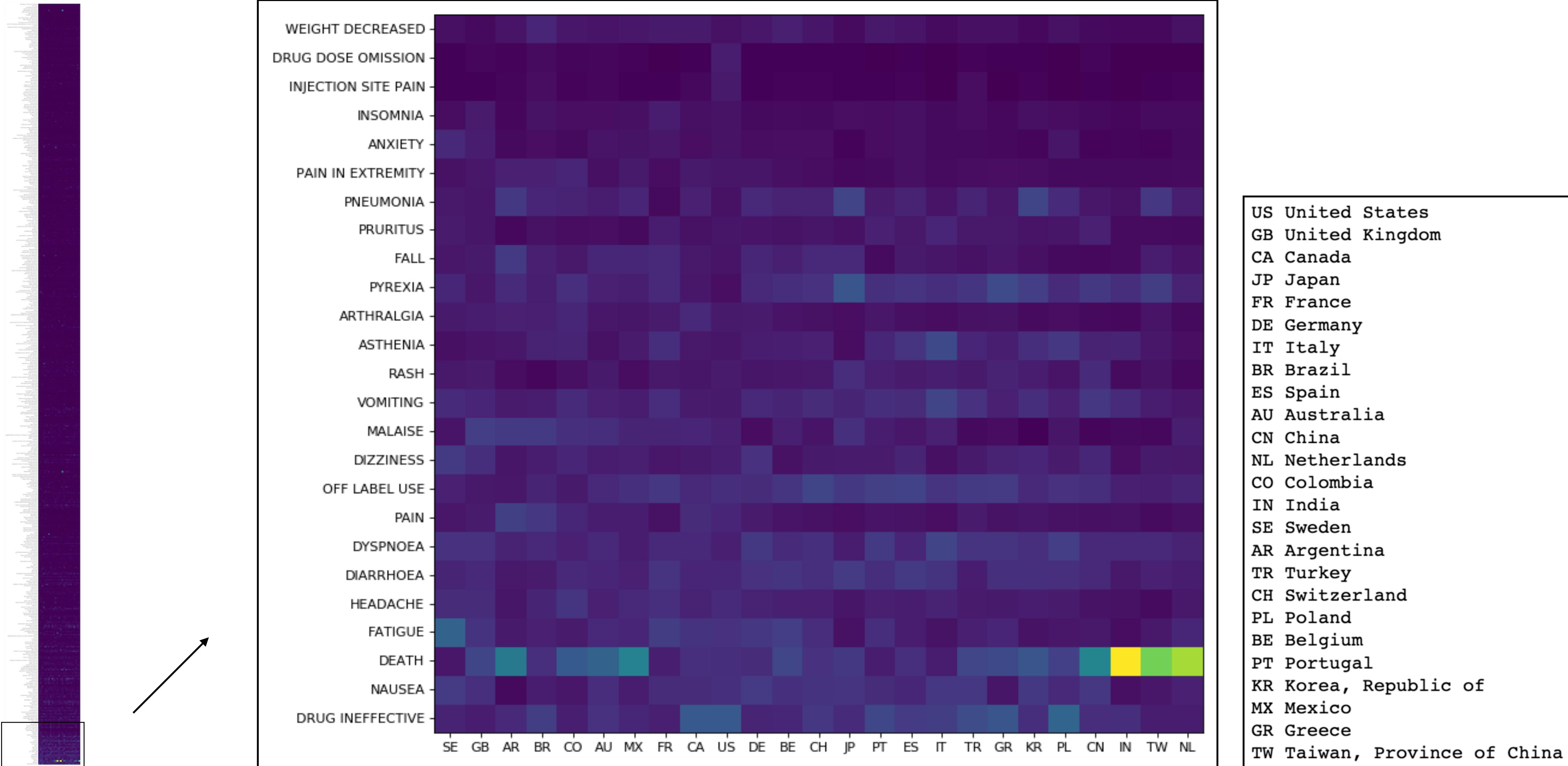


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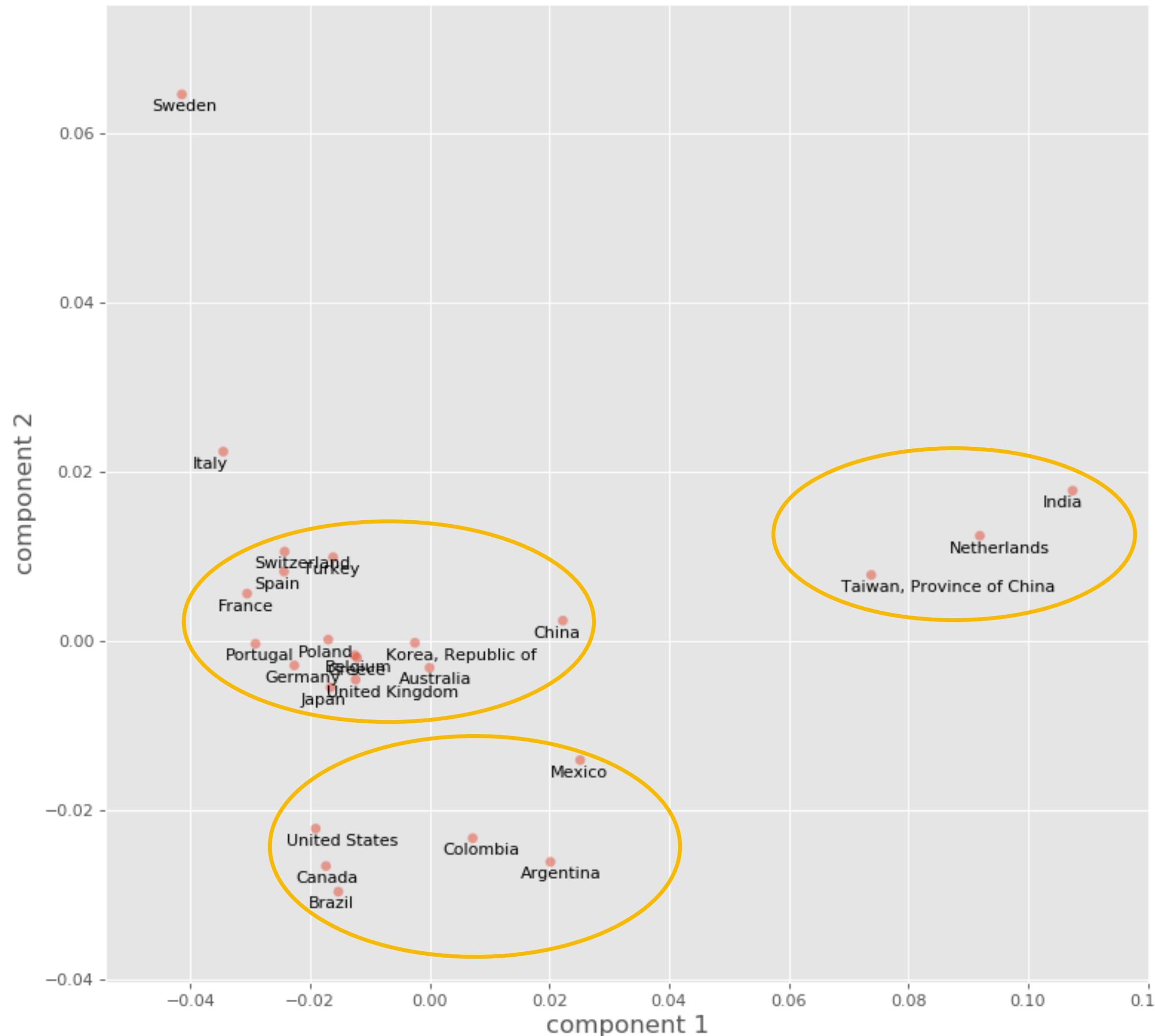


“Death” Stands out as an Important Variable Separating Countries



PC Analysis Groups

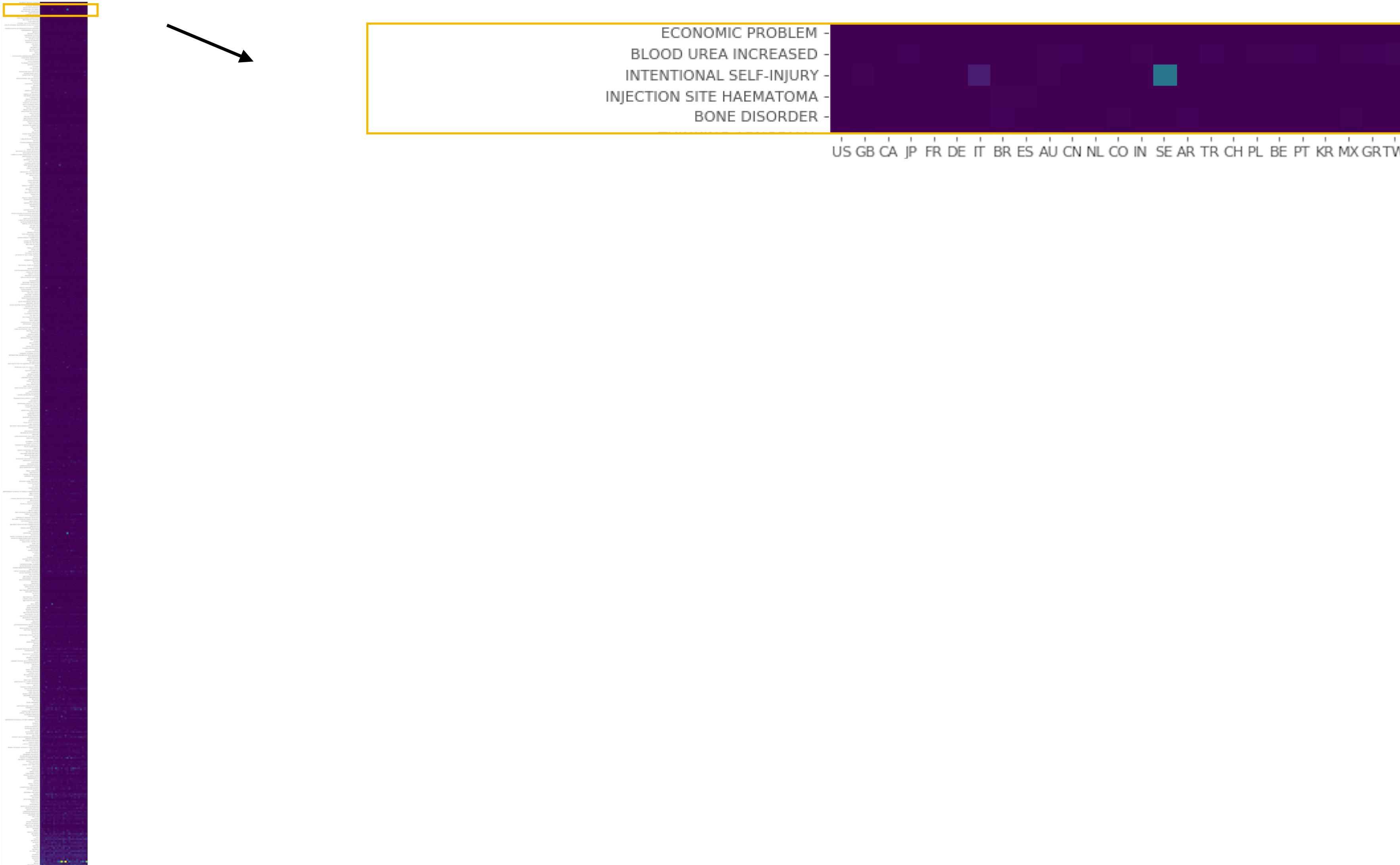
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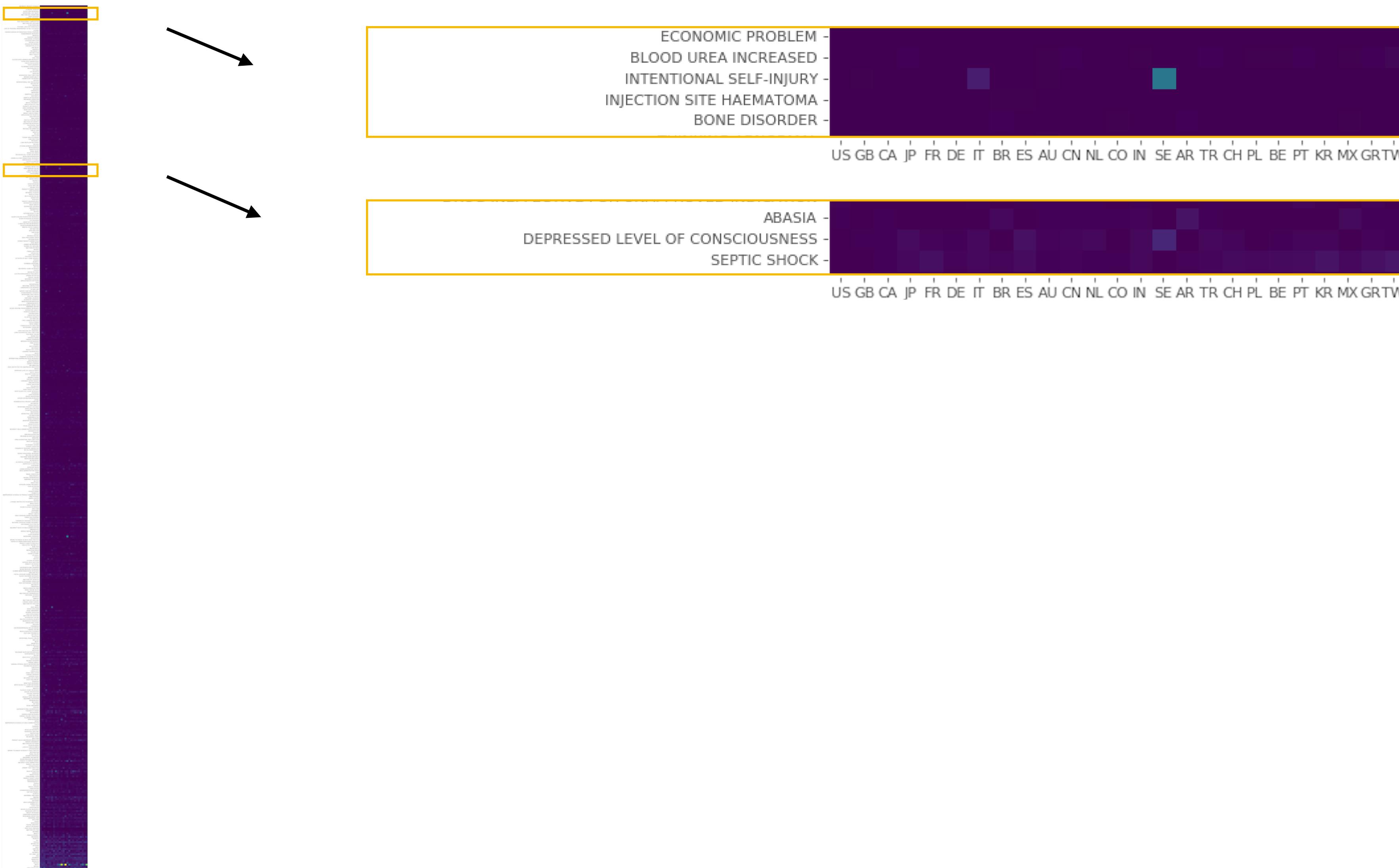
Other Reactions Standing Out Mostly Revolve Around Self Harm



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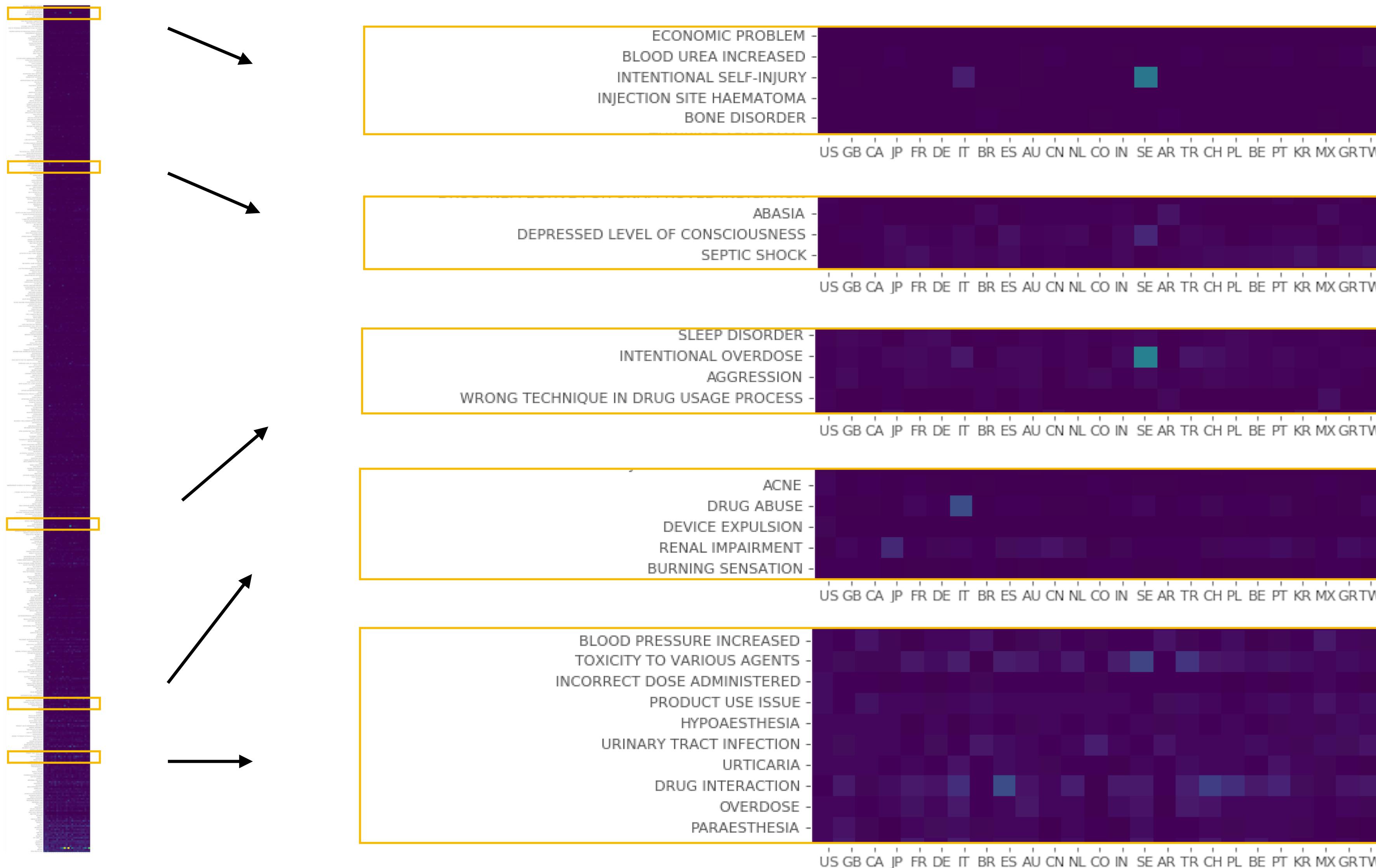
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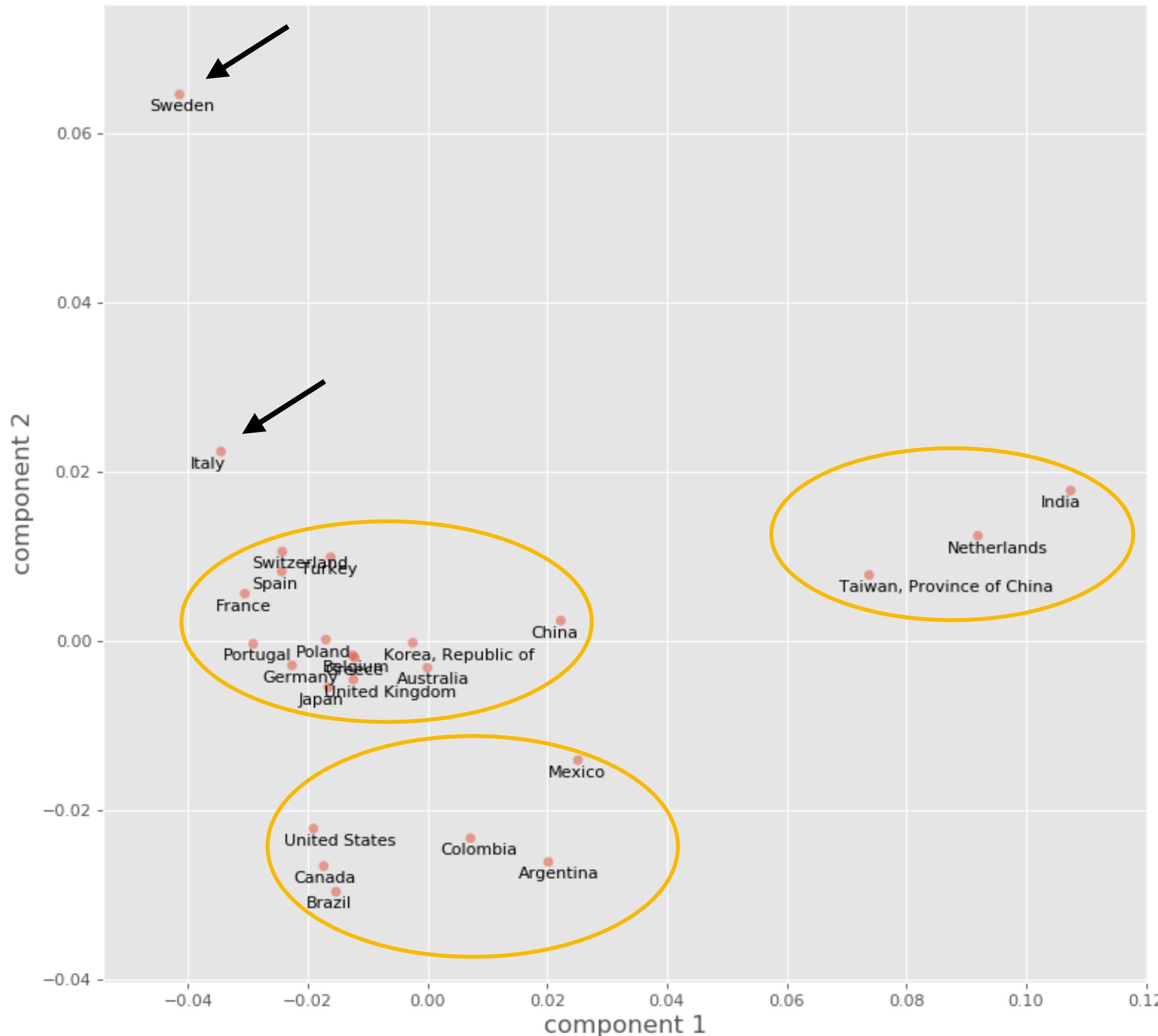


Other Reactions Standing Out Mostly Revolve Around Self Harm



PC Analysis Groups

Americas & Europe Separately



**Question 1: Are different adverse events reported
in different countries?**

Answer 1

- Different countries report **roughly the same set of adverse events**, with **slight differences** in the composition.
- We see that certain countries have similar patterns in terms of drug reactions reported:
 - **Netherlands, Taiwan** and **India** cluster together because reports of death seem to be very high from these countries.
 - **Sweden & Italy** look like outliers because of very high relative number of reports around suicide/self harm
 - The rest of the crowd is split into 2 clusters:
 - Cluster 1: Europe and Asia
 - Cluster 2: Americas
- When we do the PCA analysis, we see that the top 2 principal components that explain $59\% = 47 + 12\%$ ($79\% = 71 + 8\%$) of the variance in reported adverse event count distributions and correspond mainly to the following drug reactions:
 - DEATH
 - Combination of INTENTIONAL OVERDOSE, INTENTIONAL SELF-INJURY, TOXICITY TO VARIOUS AGENTS, DRUG INTERACTION, MALAISE, PAIN, DRUG INEFFECTIVE

Question 2: What are the different adverse events associated with different disease areas?

Top Disease Areas & Reactions

	term	count
0	PRODUCT USED FOR UNKNOWN INDICATION	2694281
1	RHEUMATOID ARTHRITIS	612292
2	MULTIPLE SCLEROSIS	497499
3	HYPERTENSION	375888
4	PAIN	261658
5	PSORIASIS	259440
6	DIABETES MELLITUS	242301
7	DEPRESSION	224270
8	PLASMA CELL MYELOMA	217973
9	TYPE 2 DIABETES MELLITUS	205001

	term	count
0	DRUG INEFFECTIVE	733191
1	NAUSEA	485098
2	DEATH	474541
3	FATIGUE	439328
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Distribution of Adverse Events / Reactions Tend to be Different for Different Disease Areas

RHEUMATOID ARTHRITIS

	term	count
0	DRUG INEFFECTIVE	66174
1	RHEUMATOID ARTHRITIS	46076
2	INJECTION SITE PAIN	44805
3	ARTHRALGIA	42584
4	PAIN	36150
5	INJECTION SITE ERYTHEMA	28149
6	PAIN IN EXTREMITY	26158
7	FATIGUE	25487
8	HEADACHE	23981
9	NAUSEA	20821

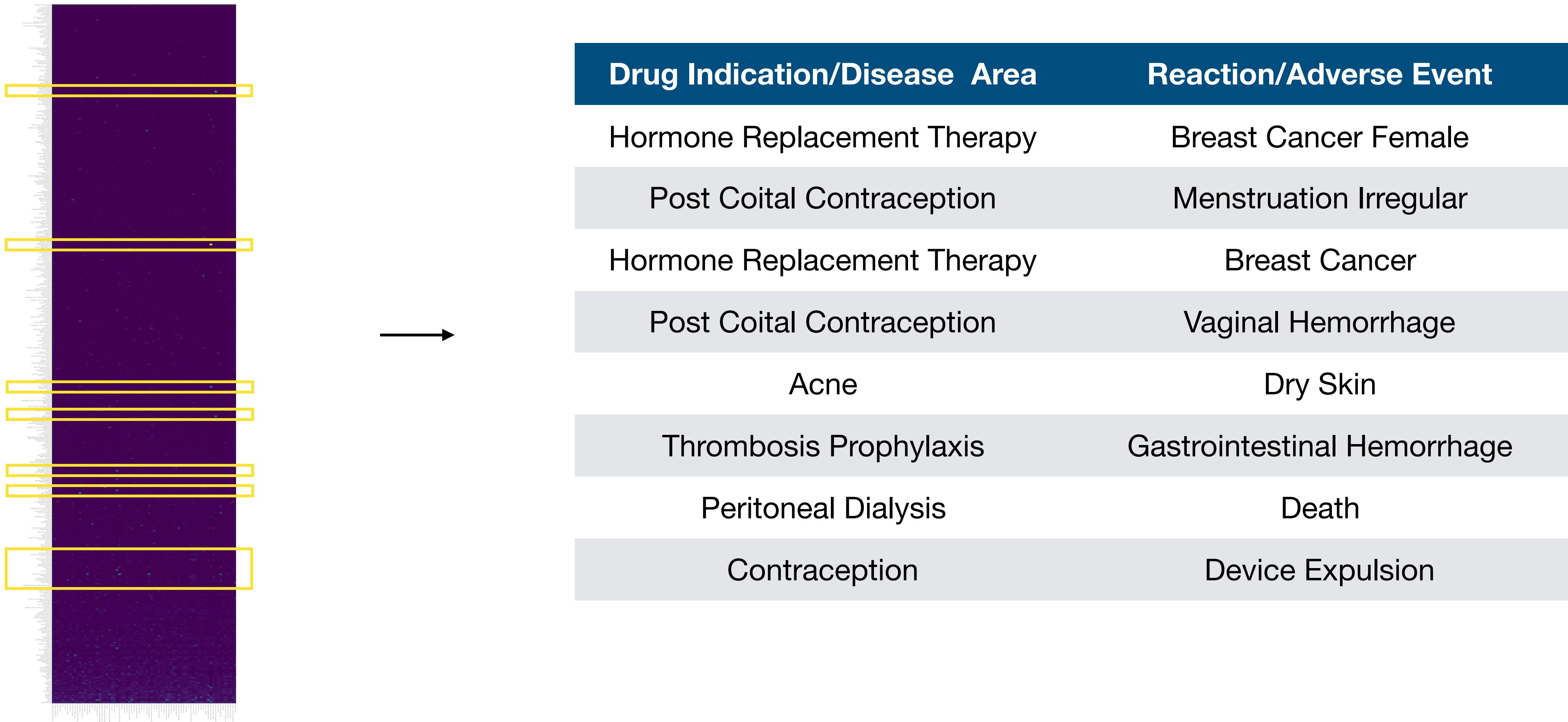
MULTIPLE SCLEROSIS

	term	count
0	FATIGUE	42655
1	MULTIPLE SCLEROSIS RELAPSE	40050
2	HEADACHE	26594
3	FALL	26252
4	GAIT DISTURBANCE	24487
5	MULTIPLE SCLEROSIS	21455
6	MEMORY IMPAIRMENT	20811
7	NAUSEA	19063
8	ASTHENIA	18711
9	PAIN	18430

Disease Areas Tend to Have Very Specific Reactions Associated with Them

Disease Rank	Disease Area	DA Reaction Rank	Reaction	Overall Reaction Rank
2	RHEUMATOID ARTHRITIS	5	INJECTION SITE ERYTHEMA	72
	RHEUMATOID ARTHRITIS	14	INJECTION SITE PRURITUS	167
3	MULTIPLE SCLEROSIS	1	MULTIPLE SCLEROSIS RELAPSE	144
	MULTIPLE SCLEROSIS	6	MEMORY IMPAIRMENT	73
5	PAIN	4	TOXICITY TO VARIOUS AGENTS	62
6	PSORIASIS	17	PSORIATIC ARTHROPATHY	441
7	DIABETES MELLITUS	0	MYOCARDIAL INFARCTION	30
7	DIABETES MELLITUS	1	CARDIAC FAILURE CONGESTIVE	88
7	DIABETES MELLITUS	2	BLOOD GLUCOSE INCREASED	34
7	DIABETES MELLITUS	3	CEREBROVASCULAR ACCIDENT	45
7	DIABETES MELLITUS	6	CORONARY ARTERY DISEASE	282
7	DIABETES MELLITUS	8	CARDIAC DISORDER	112
7	DIABETES MELLITUS	10	HYPOGLYCAEMIA	218
7	DIABETES MELLITUS	18	BLOOD GLUCOSE DECREASED	209
8	DEPRESSION	8	SUICIDAL IDEATION	101
8	DEPRESSION	15	DRUG WITHDRAWAL SYNDROME	165
9	PLASMA CELL MYELOMA	5	NEUROPATHY PERIPHERAL	143
9	PLASMA CELL MYELOMA	9	WHITE BLOOD CELL COUNT DECREASED	106
9	PLASMA CELL MYELOMA	12	THROMBOSIS	140
9	PLASMA CELL MYELOMA	18	FULL BLOOD COUNT DECREASED	608
10	TYPE 2 DIABETES MELLITUS	0	BLOOD GLUCOSE INCREASED	34
10	TYPE 2 DIABETES MELLITUS	3	BLOOD GLUCOSE DECREASED	209
10	TYPE 2 DIABETES MELLITUS	5	BLADDER CANCER	481
10	TYPE 2 DIABETES MELLITUS	11	HYPOGLYCAEMIA	218
10	TYPE 2 DIABETES MELLITUS	15	LACTIC ACIDOSIS	407
10	TYPE 2 DIABETES MELLITUS	20	GLYCOSYLATED HAEMOGLOBIN INCREASED	468

Disease Areas Tend to Have Very Specific Reactions Associated with Them



Question 2: What are the different adverse events associated with different disease areas?

Answer 2

- Reactions are very diverse for each disease area
 - Besides some common reactions, most drug indications / disease areas come with unique set of reactions / adverse events, some of which very specific

Question 3: What drugs tend to be taken together?

Brand Name vs. Generic Name

		term	count
0		ENBREL	505631
1		HUMIRA	459208
2		ECOTRIN	331225
3		ASPIRIN 325	330143
4		BAYER LOW DOSE	328604
5		BUFFERIN	326761
6		LOW DOSE ASPIRIN	326321
7	LOW DOSE ASPIRIN ENTERIC SAFETY COATED		326321
8	LOW DOSE ASPIRIN LOW DOSE		326321
9	ASPIRIN LOW DOSE		326235

		term	count
0		ETANERCEPT	505631
1		ADALIMUMAB	459208
2		ASPIRIN	346100
3		ASPIRIN 81 MG	325826
4		ASPIRIN 325 MG	325744
5		ASPIRIN 81MG	319627
6	METHOTREXATE SODIUM		290720
7	FUROSEMIDE		260480
8	METHOTREXATE		249580
9	PREDNISONE		244889

Too Many Brand Names Correspond to the Same Drug

		term	count
3		ASPIRIN 325	330143
6		LOW DOSE ASPIRIN	326321
7	LOW DOSE ASPIRIN ENTERIC SAFETY COATED	326321	
8	LOW DOSE ASPIRIN LOW DOSE	326321	
9	ASPIRIN LOW DOSE	326235	
...	
632	MOORE MEDICAL EXTRA STRENGTH NON ASPIRIN	90680	
633	MOORE MEDICAL NON ASPIRIN	90680	
649	PHYSICIANS CARE NON ASPIRIN EXTRA STRENGTH	90680	
661	SHOPRITE NON-ASPIRIN	90680	
697	ZEE UNASPIRIN ES	90680	

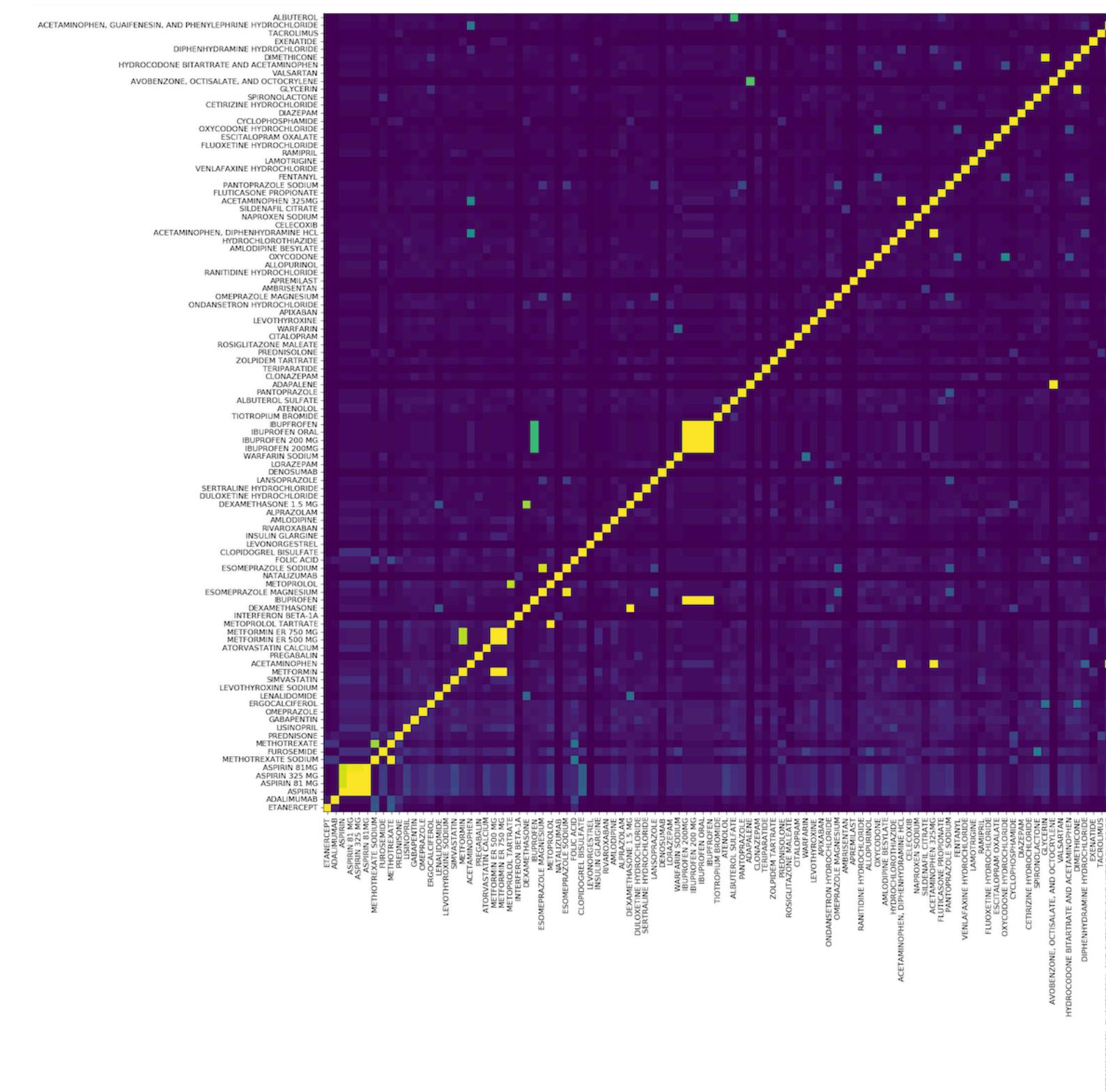
139 rows x 2 columns

		term	count
2		ASPIRIN	346100
3		ASPIRIN 81 MG	325826
4		ASPIRIN 325 MG	325744
5		ASPIRIN 81MG	319627
490	ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE	11674	
668	ACETAMINOPHEN, ASPIRIN, AND CAFFEINE	6390	
725	ACETAMINOPHEN, ASPIRIN (NSAID), AND CAFFEINE	5519	
771	ASPIRIN AND DIPYRIDAMOLE	4924	
911	BAYER ASPIRIN EXTRA STRENGTH	3329	

Uncommon Co-Drugs May Indicate Adverse Drug Interactions

Drug Rank	Drug	Partner Rank	Co-Drug	Co-Drug Rank
16	LEVOTHYROXINE SODIUM	1	LEVOTHYROXINE SODIUM ANHYDROUS	133
24	METOPROLOL TARTRATE	2	METOPROLOL TARTRATE	171
29	METOPROLOL	2	METOPROLOL TARTRATE	171
33	CLOPIDOGREL BISULFATE	1	CLOPIDOGREL	153
40	DULOXETINE HYDROCHLORIDE	1	DULOXETINE	288
41	SERTRALINE HYDROCHLORIDE	1	SERTRALINE	147
42	LANSOPRAZOLE	1	LANSOPRAZOLE DELAYED RELEASE	123
54	ADAPALENE	2	SALICYLIC ACID	253
54	ADAPALENE	3	SULFUR	648
54	ADAPALENE	4	BENZOYL PEROXIDE	899
54	ADAPALENE	8	HYDROQUINONE	1000
60	CITALOPRAM	1	CITALOPRAM HYDROBROMIDE	103
64	ONDANSETRON HYDROCHLORIDE	1	ONDANSETRON	152
64	ONDANSETRON HYDROCHLORIDE	2	ONDANSETRON TABLETS	165
66	AMBRISENTAN	1	Tadalafil	119
68	RANITIDINE HYDROCHLORIDE	1	RANITIDINE	131
75	NAPROXEN SODIUM	1	NAPROXEN	148
75	NAPROXEN SODIUM	2	NAPROXEN SODIUM 220 MG	173
76	SILDENAFIL CITRATE	1	SILDENAFIL	275
76	SILDENAFIL CITRATE	2	SILDENAFIL	360
81	VENLAFAXINE HYDROCHLORIDE	1	VENLAFAXINE	238
82	LAMOTRIGINE	1	LAMOTRIGINE CHEWABLE DISPERSIBLE	210
84	FLUOXETINE HYDROCHLORIDE	1	FLUOXETINE	193
85	ESCITALOPRAM OXALATE	1	ESCITALOPRAM	241
85	ESCITALOPRAM OXALATE	2	ESCITALOPRAM	281
86	OXYCODONE HYDROCHLORIDE	11	OXYMORPHONE HYDROCHLORIDE	673
87	CYCLOPHOSPHAMIDE	1	DOXORUBICIN	211
89	CETIRIZINE HYDROCHLORIDE	1	CETIRIZINE	333
89	CETIRIZINE HYDROCHLORIDE	13	CETIRIZINE HYDROCHLORIDE TABLETS	702
92	AVOBENZONE, OCTISALATE, AND OCTOCRYLENE	2	SALICYLIC ACID	253
92	AVOBENZONE, OCTISALATE, AND OCTOCRYLENE	3	SULFUR	648
92	AVOBENZONE, OCTISALATE, AND OCTOCRYLENE	4	BENZOYL PEROXIDE	899
92	AVOBENZONE, OCTISALATE, AND OCTOCRYLENE	8	HYDROQUINONE	1000
96	DIPHENHYDRAMINE HYDROCHLORIDE	1	BENADRYL	180
96	DIPHENHYDRAMINE HYDROCHLORIDE	2	DIPHENHYDRAMINE HCL	212
96	DIPHENHYDRAMINE HYDROCHLORIDE	3	DIPHENHYDRAMINE	271
97	EXENATIDE	1	METFORMIN HCL	136
98	TACROLIMUS	1	TACROLIMUS CAPSULES	161
98	TACROLIMUS	2	MYCOPHENOLATE MOFETIL	204
98	TACROLIMUS	6	MYCOPHENOLIC ACID	474
98	TACROLIMUS	8	BASILIXIMAB	685
98	TACROLIMUS	10	VALGANCICLOVIR HYDROCHLORIDE	575

Known Adverse Drug-Drug Interactions Pop-up as Frequently Reported



WebMD

CORONAVIRUS UPDATE CHECK YOUR SYMPTOMS FIND A DOCTOR FIND A DENTIST FIND LOWEST DRUG PRICES

HEALTH A-Z DRUGS & SUPPLEMENTS LIVING HEALTHY FAMILY & PREGNANCY NEWS & EXPERTS

Interaction Checker > Find a Drug Pill Identifier

+ Add / - Remove Meds

Drug Interaction Checker tacrolimus mycophenolate mofetil +

2 Interactions Found

Serious

- mycophenolate mofetil oral Potential for serious interaction mycophenolate mofetil oral and system suppression

Monitor closely

- tacrolimus oral + mycophenolate mofetil Significant interaction possible tacrolimus oral will increase the oral by affects how the drug is as the P-glycoprotein [MDR1] is

+ Start Over + Add / - Remove Meds

Drug Interaction Checker cyclophosphamide doxorubicin HCL Vial +

Don't use together -

+ Add / - Remove Meds

Drug Interaction Checker exenatide Pen Injector metformin HCL +

1 Interaction Found

Legend:

- Don't use together - 0
- Serious - 0
- Monitor closely - 1
- Minor - 0

Monitor closely

- exenatide subcutaneous + metformin oral Potential for interaction exenatide subcutaneous , metformin oral . Either increases the level of the other by added drug effects Additional Information: Combination may increase risk of low blood sugar.

+ Start Over + Add / - Remove Meds

Question 3: What drugs tend to be taken together?

Answer 3

- Drugs tend to be mostly reported with other ***overwhelmingly*** common drugs
- Some drugs do have co-reported uncommon drugs, some of replicates known adverse drug-drug interactions, rest of which may hint to biology,

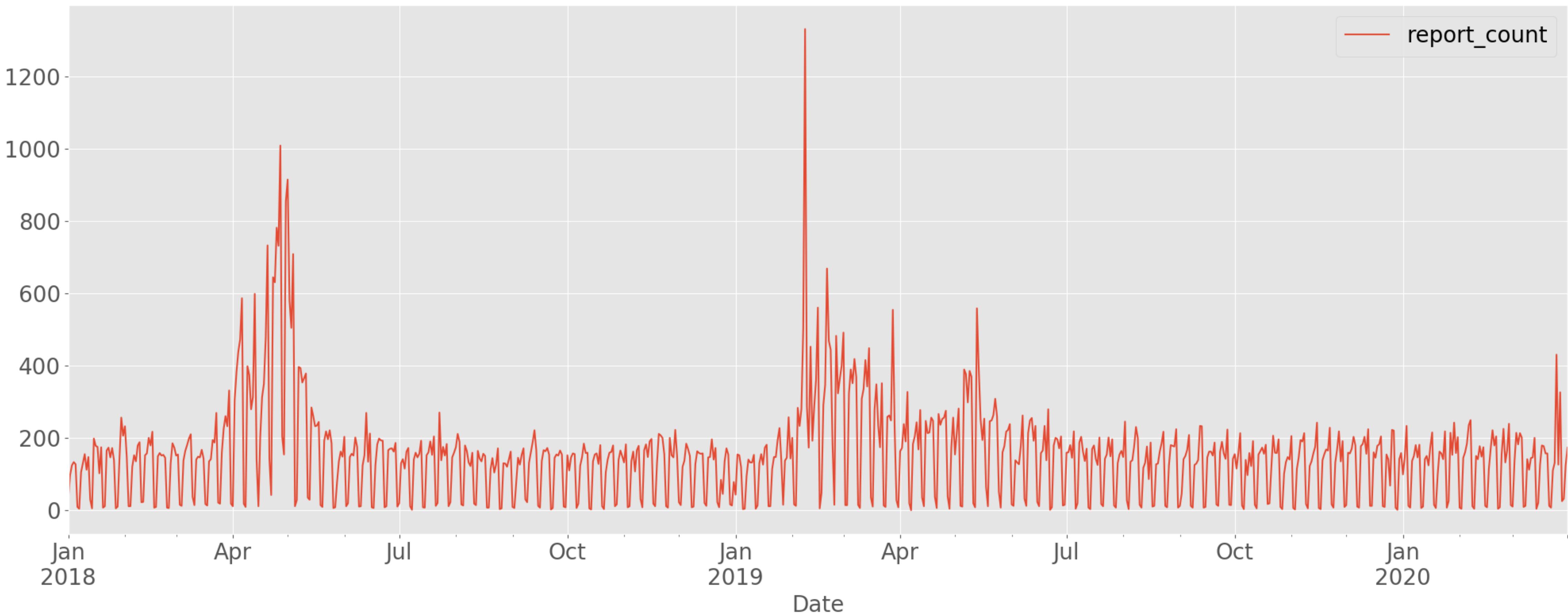
Data Exploration Part II: AstraZeneca in FAERS

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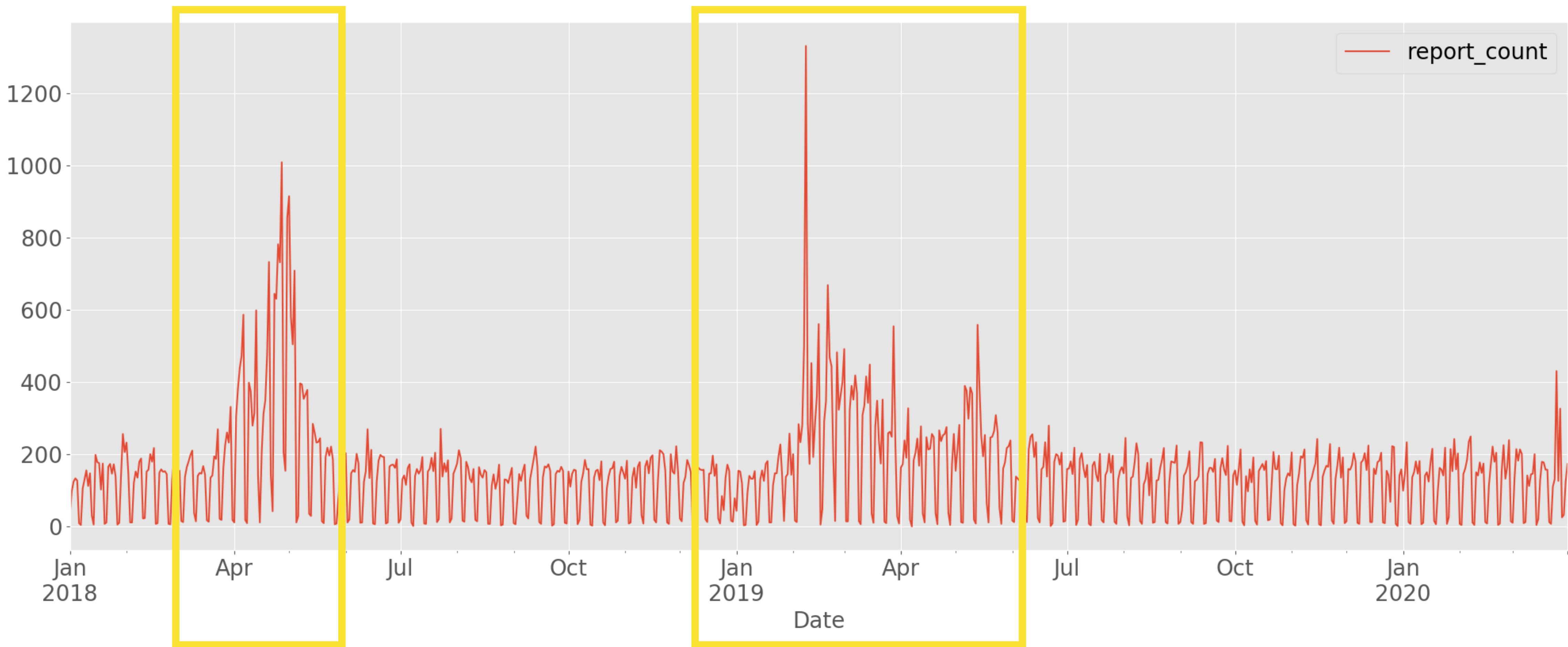
	term	count
0	Mylan Pharmaceuticals Inc.	2143943
1	Aurobindo Pharma Limited	1933948
2	Teva Pharmaceuticals USA, Inc.	1749269
3	Actavis Pharma, Inc.	1736623
4	Cadila Healthcare Limited	1723934
5	Amneal Pharmaceuticals LLC	1671581
6	Zydus Pharmaceuticals (USA) Inc.	1649009
7	Sun Pharmaceutical Industries, Inc.	1545861
8	Sandoz Inc	1231388
9	West-Ward Pharmaceuticals Corp.	1201469

	term	count
146	AstraZeneca Pharmaceuticals LP	501107

Data Exploration Part II: AstraZeneca in FAERS

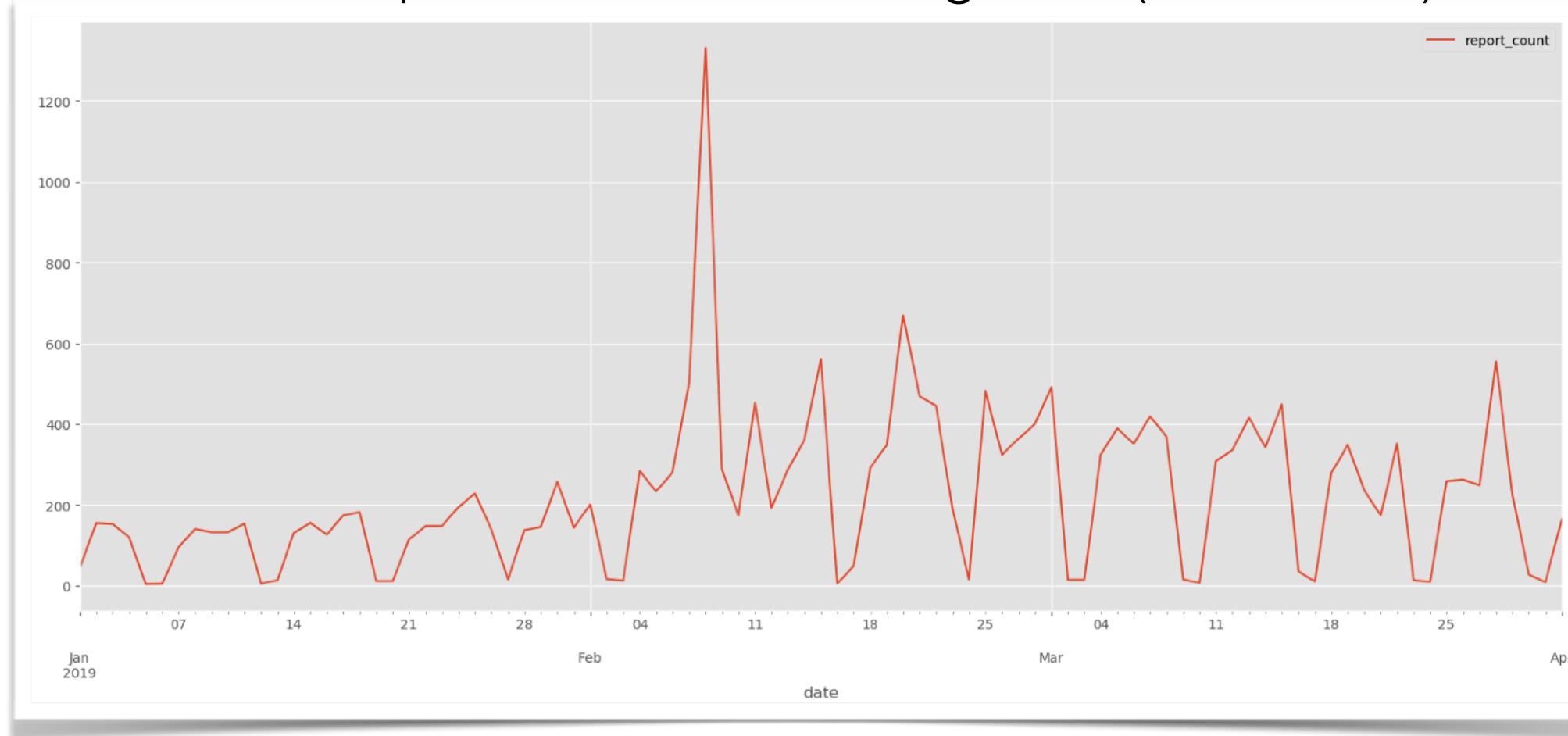


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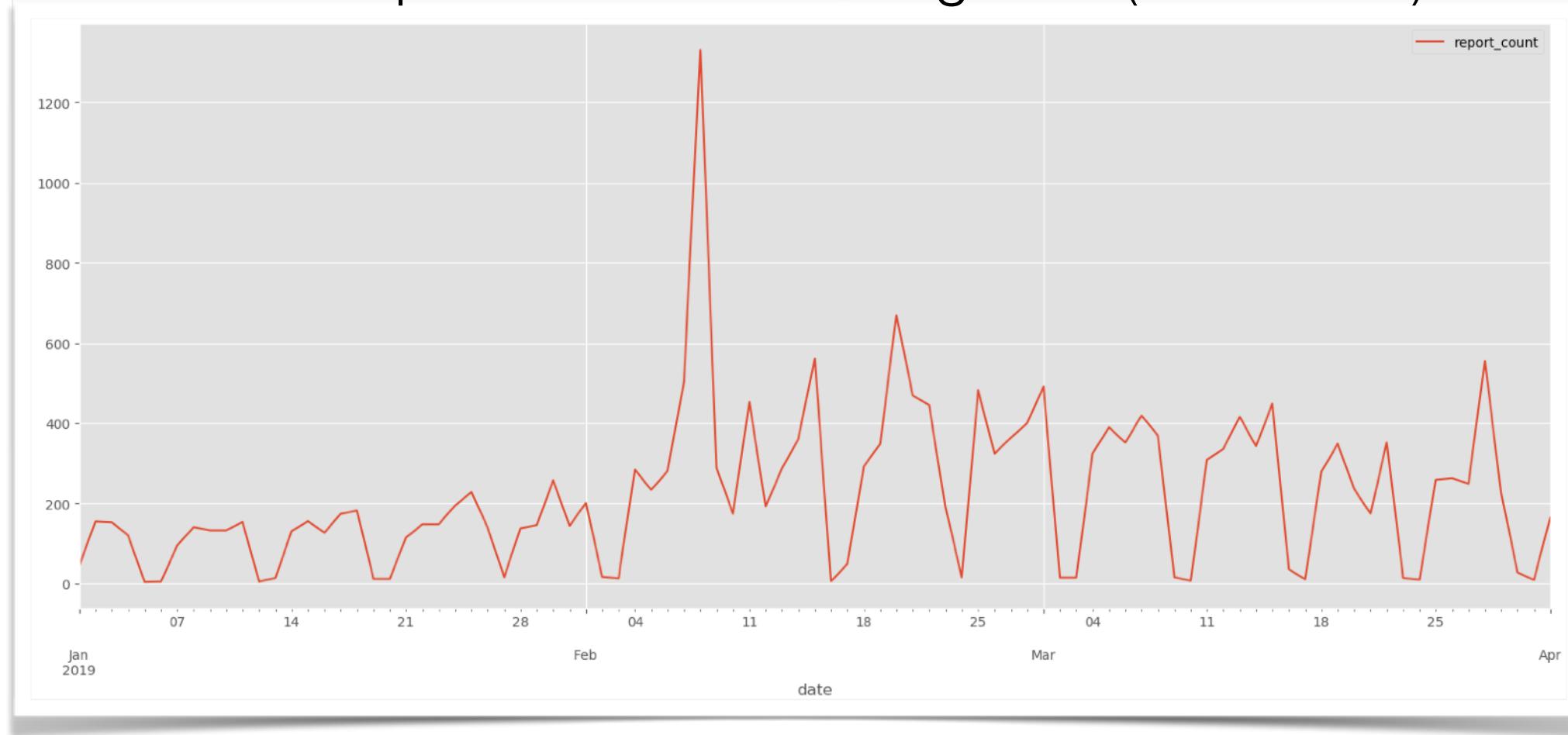
Multiple Spikes in Reports over the Years Point to Problematic Drugs: New Spikes Can Warn Proactively

Report Counts Including AZN (Over Time)



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Drugs

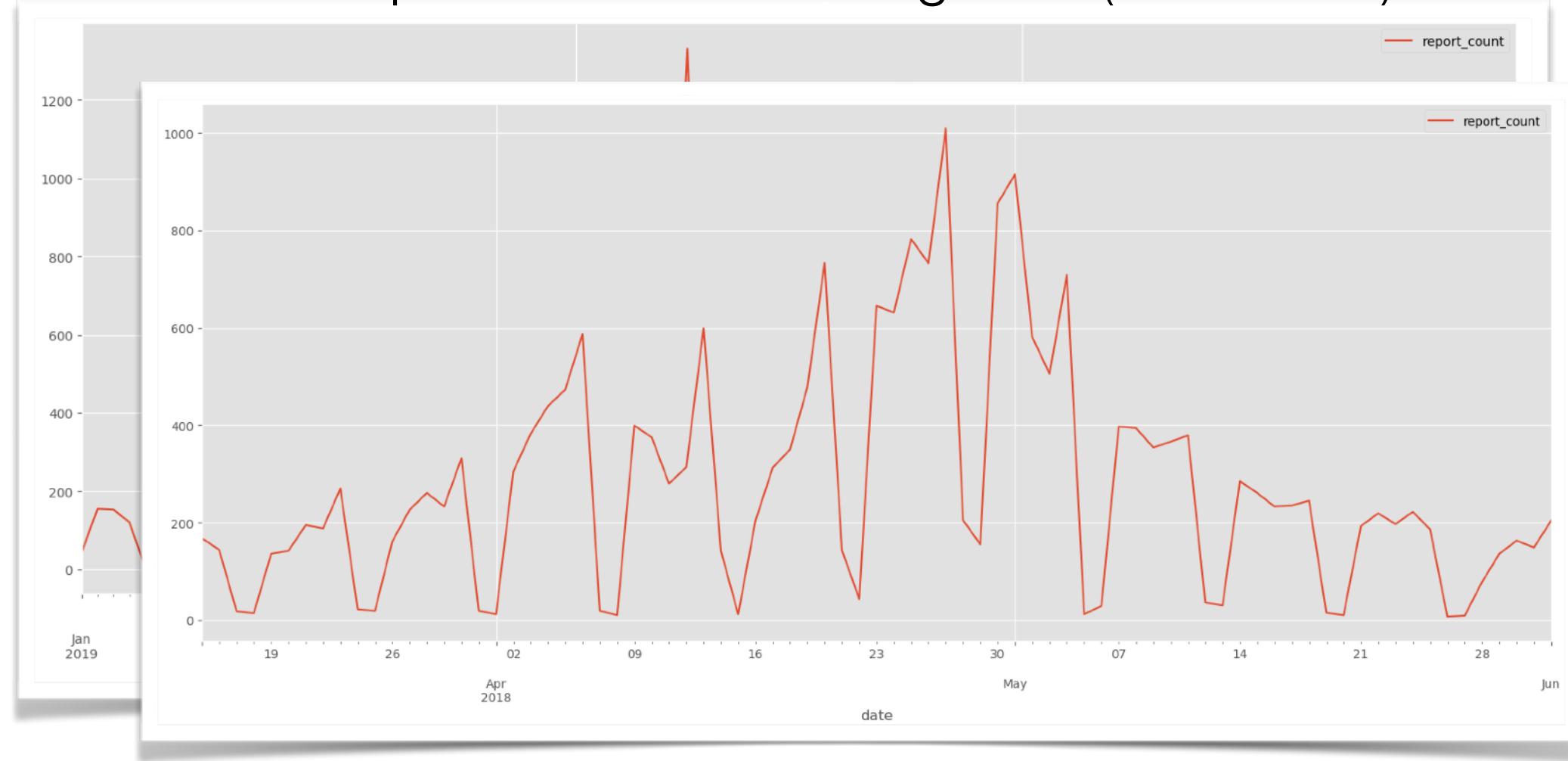
	term	count
0	NEXIUM	2441
1	NEXIUM I.V.	2430
2	PRILOSEC	1818
3	PREVACID 24 HR	1449
4	PREVACID	1386

Reactions

	term	count
0	CHRONIC KIDNEY DISEASE	2322
1	RENAL INJURY	1525
2	RENAL FAILURE	1437
3	ACUTE KIDNEY INJURY	1185
4	END STAGE RENAL DISEASE	697

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Report Counts Including AZN (Over Time)



Drugs

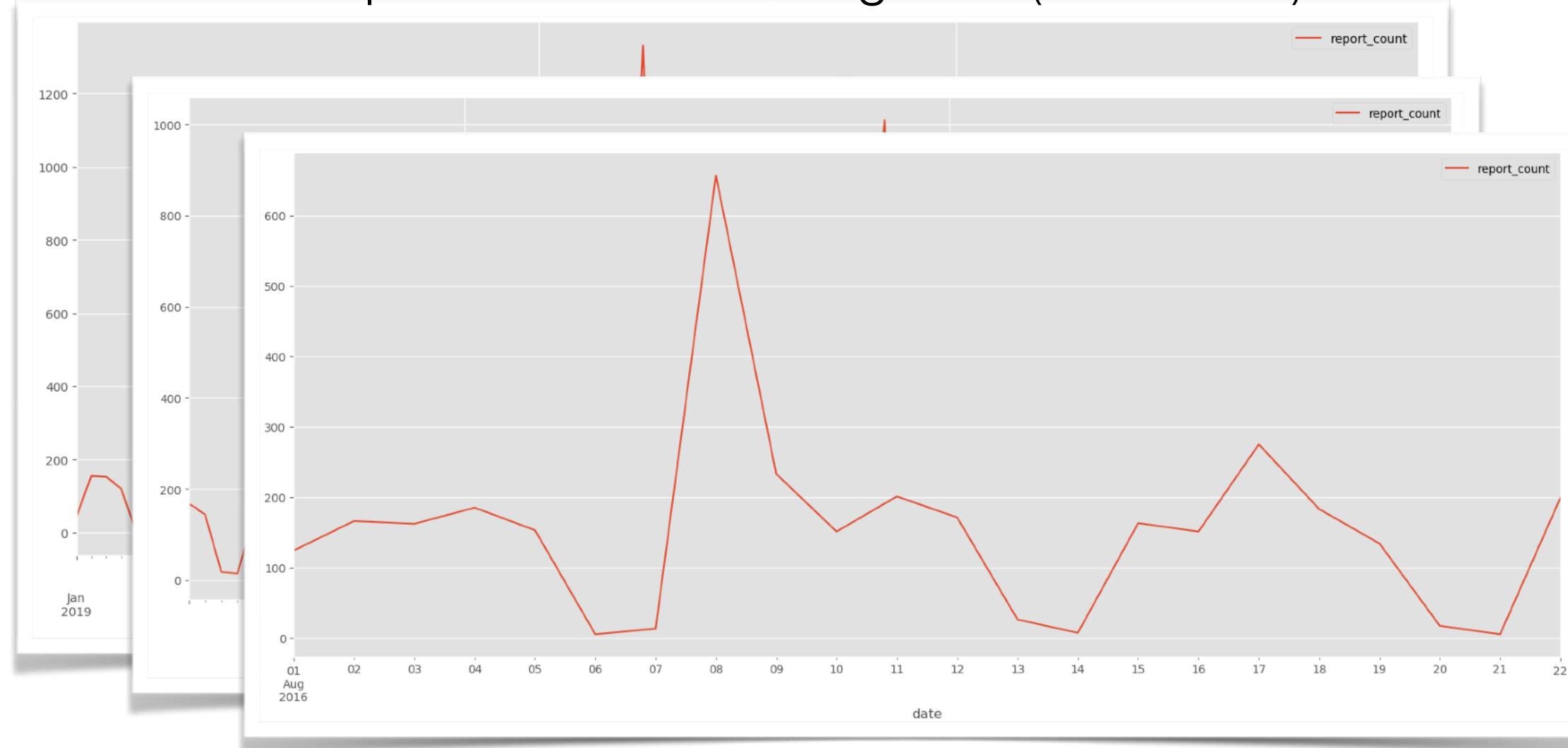
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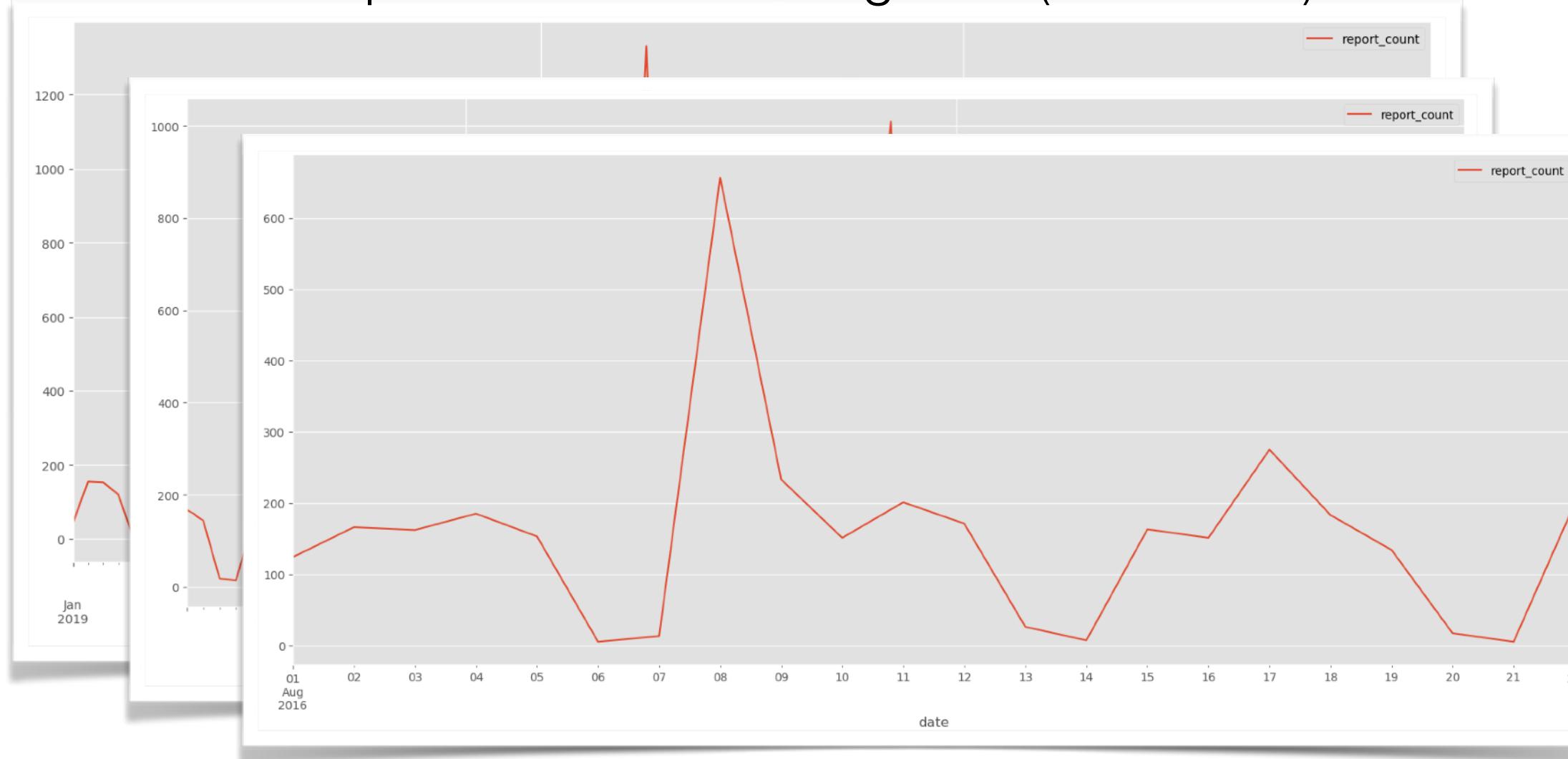
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FOR A FREE CASE EVALUATION CALL 1.800.701.3672

Kidney Problems May be Caused by Nexium and Prilosec

Severe Kidney Problems Linked to Prilosec and Nexium

Nexium and Prilosec are used to treat conditions such as chronic heartburn. Both Nexium and Prilosec have topped the nationwide sales charts over the last 20 years. Consumers can obtain Nexium and Prilosec by prescription or by simply buying it over-the-counter. The FDA approved Proton Pump Inhibitors (PPIs), like Nexium and Prilosec, for use up to four weeks at a time. However, many people have taken Prilosec or Nexium every day for decades. Extended use of Prilosec and Nexium can cause severe kidney problems, such as [Acute Interstitial Nephritis \(AIN\)](#).



Study Linking Prilosec and Nexium to Severe Kidney Problems

Dr. Ziyad Al-Aly is a kidney specialist and researcher on a [current study regarding PPI use](#) and kidney problems. Dr. Al-Aly found that PPI users were more likely than people on other heartburn medication to develop kidney problems, such as chronic kidney disease or kidney failure. Dr. Al-Aly recommends using Prilosec or Nexium when absolutely necessary and for the shortest time possible.

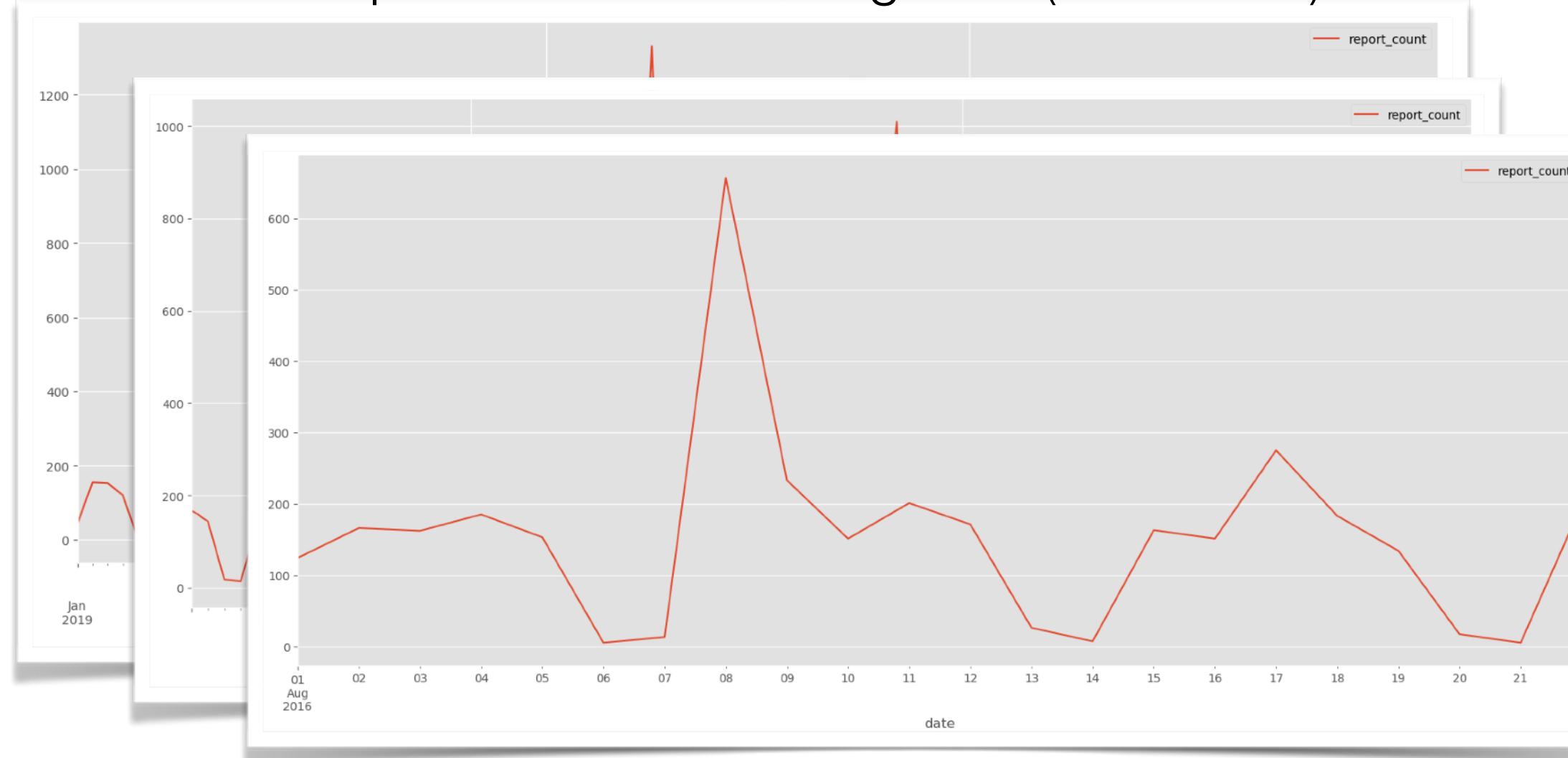
The study revealed chronic kidney disease in 15% of PPI users, opposed to 11% in those who took heartburn medication. Even more alarming, the study noted end-stage kidney failure rates were twice as high among PPI users. More studies are underway to evaluate the risk of kidney problems caused by Nexium and Prilosec. Previous studies have linked Prilosec and Nexium use with Acute Interstitial Nephritis and Acute Kidney Injury. Prolonged use of PPIs may also worsen heartburn (gastroesophageal reflux disease), making it harder for users to stop using the drug.

Profits Prevent Warning on Kidney Problems

AstraZeneca, the manufacturer of Nexium and Prilosec, has made \$80-\$100 billion dollars in revenue in the past twelve years. The company modified their formula to maintain a longer patent and make versions of the drug that wouldn't be available as a generic. The company created

Multiple Spikes in Reports over the Years Point to Problematic Drugs: New Spikes Can Warn Proactively

Report Counts Including AZN (Over Time)



Drugs

	term	count
0	NEXIUM	2441
1	NEXIUM I.V.	2430
2	PRILOSEC	1818
3	PREVACID 24 HR	1449
4	PREVACID	1386

Reactions

	term	count
0	CHRONIC KIDNEY DISEASE	2322
1	RENAL INJURY	1525
2	RENAL FAILURE	1437
3	ACUTE KIDNEY INJURY	1185
4	END STAGE RENAL DISEASE	697

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Kidney Problems May be Caused by Nexium and Prilosec

Severity of kidney problems linked to PPIs over time. The chart shows a significant increase in reports starting around 2017.

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Severity of kidney problems linked to PPIs over time. The chart shows a significant increase in reports starting around 2017.

Nexium & Prilosec Lawsuits

Nexium & Prilosec are drugs called proton pump inhibitors (PPIs). They are used to treat gastroesophageal reflux disease (GERD), by reducing the amount of acid in a person's stomach.

The Nexium and Prilosec lawsuits claim the long-term use of these drugs can increase the likelihood of strokes, bone fractures, acute kidney injury, renal failure, and heart damage.

Our law firm is accepting clients who took Nexium or Prilosec and suffered chronic kidney disease or acute interstitial nephritis.

What Do We Know About the Nexium & Prilosec Lawsuits



Nexium & Prilosec Case Evaluation

First Name:

Last Name:

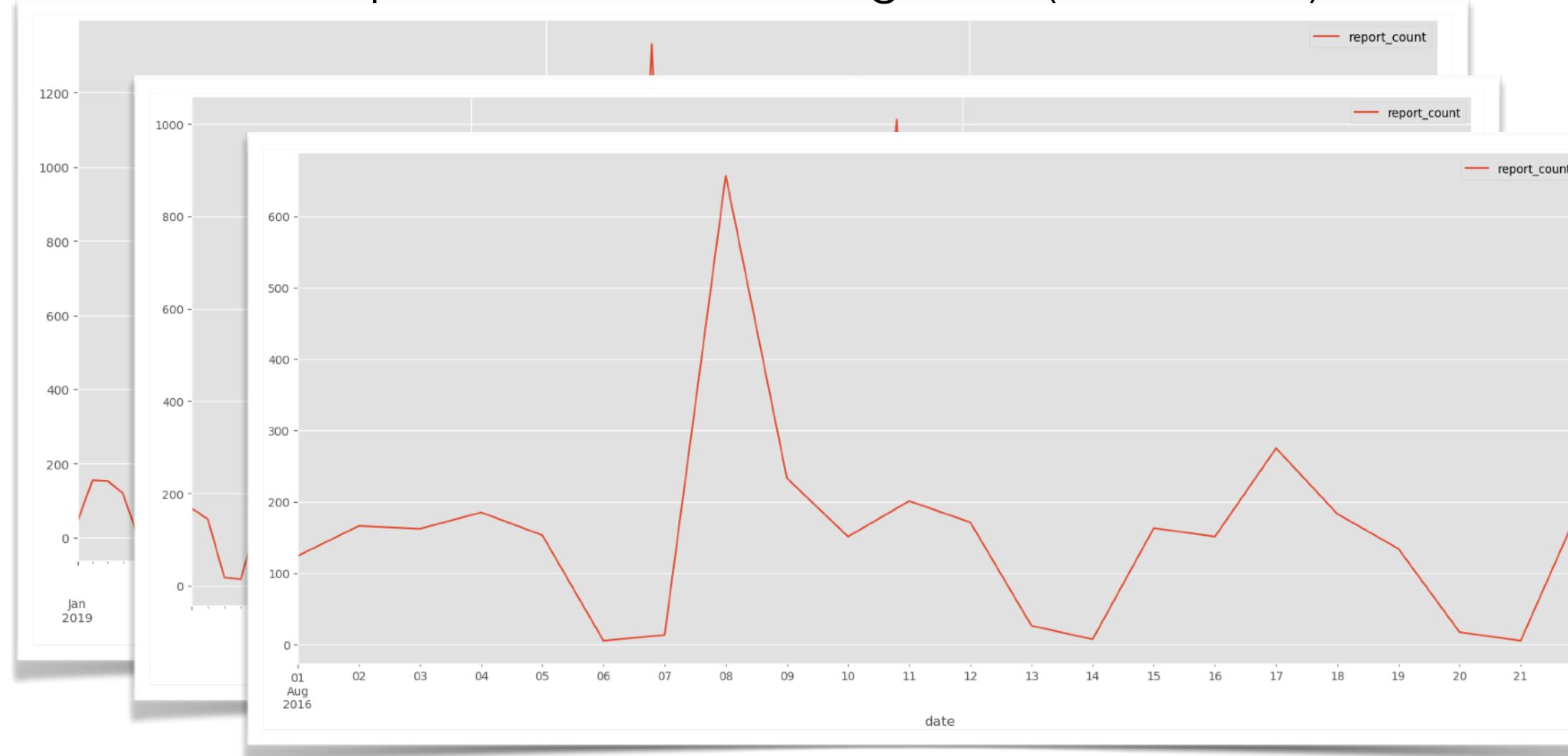
Email:

Phone Number:

Describe your Nexium or Prilosec injury:

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Nexium & Prilosec Lawsuits

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Popular heartburn drugs linked to gradual yet 'silent' kidney damage

Most patients don't experience acute kidney problems beforehand

Date: February 22, 2017
Source: Washington University in St. Louis
Summary: The sudden onset of kidney problems often serves as a warning for doctors to discontinue patients' use of proton pump inhibitors (PPIs), sold under brand names Prevacid, Prilosec, Nexium and Protonix, among others. But a new study indicates that more than half of patients who develop chronic kidney damage while taking the drugs don't experience acute kidney problems beforehand, according to researchers.

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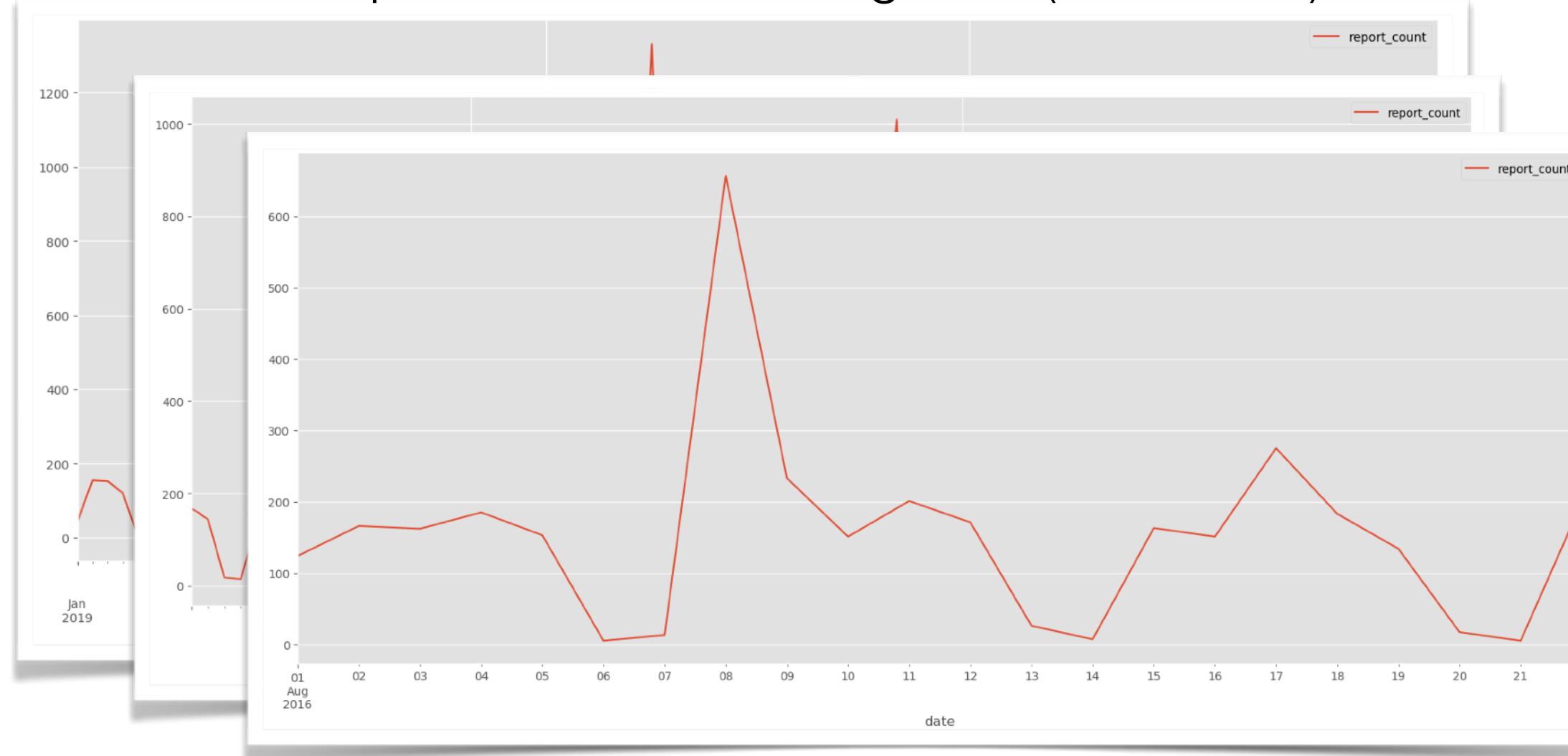
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Vitamin D Levels Appear to Play Role in COVID-19 Mortality Rates

Antibody Blocks Infection by the SARS-CoV-2 in Cells, Scientists Discover

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Kidney Problems May be Caused by Nexium and Prilosec

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Nexium & Prilosec Lawsuits

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Medical News Today

Popular heartburn drugs linked to gradual yet 'silent' kidney damage

Date: February 22, 2017 Source: Washington Univ. Summary: The sudden onset of kidney damage in some patients' use of heartburn drugs like Prilosec, Nexium and Prevacid may be more common than half of patients experience acute kidney damage.

Common heartburn drug linked with fatal conditions*

New research suggests that drugs commonly used for heartburn, acid reflux, and ulcers may raise the risk of

*June 2019

Limitations

- Massive reporting biases, e.g. :
 - Disproportionately large number of instances of common drugs like Aspirin
 - Huge proportion of drugs come from US
- Monthly update of the database
- ~250 calls / minute with an API key (limitation of the interface)
- Typos, etc. in documentation (e.g. count returns 100 instead of 1000)

count: Count the number of unique values of a certain field, for all the records that matched the search parameter. By default, the API returns the 1000 most frequent values.

Conclusions

- Different countries have similar adverse event reporting patterns, with slight differences.
- Different disease areas result in very different reporting patterns.
- Co-reported drugs are mostly due to highly common drugs, with some co-reporting associated with interactions
- Age/Gender is associated with different adverse event reporting patterns
- Report frequency involving a brand's drugs reflects & potentially precedes real life consequences (news, public relations, etc.)

Potential Future Directions

- Developing a score of sorts to weight up/down common reactions/drugs to better interpret results
- A warning/monitoring dashboard to monitor adverse event reports being submitted to FDA including AZN products
 - **Uses:**
 - To address potential side effects, interactions
 - **Functions:**
 - Shows frequency of reports
 - Breaks down report counts for a particular time period
 - By drugs by AZN, other drugs filed with AZN drugs
 - By countries, sources, demographic information
 - Checking the co-occurring drugs against a drug-drug adverse reaction database
 - Network analysis (co-reported drugs as input) to prioritize drug-drug adverse interaction research

Questions?

Extra Slides

Variables

- `meta`
- `results`
 - `safetyreportid` : The 8-digit Safety Report ID number, also known as the case report number or case ID. The first 7 digits (before the hyphen) identify an individual report and the last digit (after the hyphen) is a checksum. This field can be used to identify or find a specific adverse event report.
 - `receivedate` : **Date that the report was first received by FDA. If this report has multiple versions, this will be the date the first version was received by FDA. DATE (FDA USES THIS IN EXAMPLE REPORTS)**
 - `transmissiondate` : Date that the record was created. This may be earlier than the date the record was received by the FDA.
 - `receiptdate` : Date that the most recent information in the report was received by FDA.
 - `patient`
 - `patient.patientonsetage` : **Age of the patient when the event first occurred. AGE OF PATIENT**
 - `patient.patientsex` : The sex of the patient. Value is one of the following: 0. Unknown, 1. Male, 2. Female
 - `patient.reaction`
 - `patient.reaction.reactionmeddrapt` : **Patient reaction, as a MedDRA term. Note that these terms are encoded in British English. For instance, diarrhea is spelled diarrhoea. MedDRA is a standardized medical terminology. DRUG REACTION / ADVERSE EVENT TYPE**
 - `patient.reaction.reactionoutcome` : Outcome of the reaction in reactionmeddrapt at the time of last observation. Value is one of the following: 1. Recovered/resolved, 2. Recovering/resolving, 3. Not recovered/not resolved, 4. Recovered/resolved with sequelae (consequent health issues), 5. Fatal, 6. Unknown
 - `patient.drug`
 - `patient.drug.medicinalproduct` : Drug name. This may be the valid trade name of the product (such as ADVIL or ALEVE) or the generic name (such as IBUPROFEN). This field is not systematically normalized. It may contain misspellings or idiosyncratic descriptions of drugs, such as combination products such as those used for birth control.
 - `patient.drug.openfda.brand_name` : **Brand or trade name of the drug product. DRUG NAME**
 - `patient.drug.openfda.generic_name` : Generic name(s) of the drug product.
 - `patient.drug.openfda.manufacturer_name` : **Name of manufacturer or company that makes this drug product, corresponding to the labeler code segment of the NDC DRUG MANUFACTURER.**
 - `patient.drug.drugadministrationroute` : The drug's route of administration.
 - `patient.drug.openfda.route` : The route of administration of the drug product.
 - `patient.drug.drugindication` : **Indication for the drug's use. DRUG INDICATION / DISEASE AREA**
 - `patient.drug.openfda.pharm_class_epc` : Established pharmacologic class associated with an approved indication of an active moiety (generic drug) that the FDA has determined to be scientifically valid and clinically meaningful. Takes the form of the pharmacologic class, followed by [EPC] (such as Thiazide Diuretic [EPC] or Tumor Necrosis Factor Blocker [EPC]. DRUG CLASS**
- `primarysource.reportercountry` : Country from which the report was submitted. *This one is in both country codes: <https://datahub.io/core/country-list> and in country names*
- `occurcountry` : **The name of the country where the event occurred. This one is in country codes. COUNTRY (FDA USES THIS IN EXAMPLE REPORTS)**
- `primarysourcecountry` : Country of the reporter of the event. *This one is also in country codes.*
- `primarysource.qualification` : Category of individual who submitted the report. Value is one of the following: 1. Physician, 2. Pharmacist, 3. Other health professional, 4. Lawyer, 5. Consumer or non-health professional