# Classifying Adverse Event Seriousness using NLP

## Capstone

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DSI-25

# Problem Statement

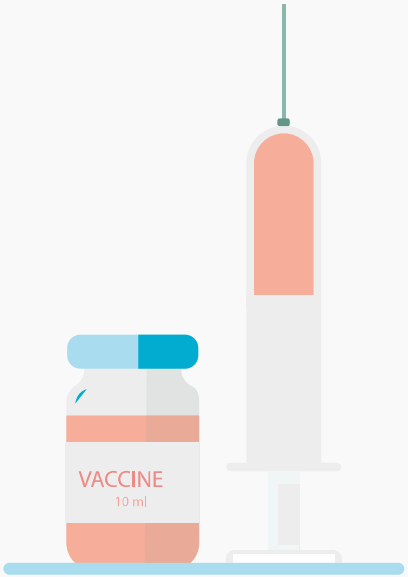
As a data scientist in a consultant firm to the **Health Authority** in Singapore, we have been tasked to create a model to **differentiate** between **serious and non-serious adverse events (AE)** using **Natural Language Processing (NLP)** from reports obtained from various sources.

The following models will be tested as potential candidates:

Logistic Regression
Naive Bayes - Multinomial
Random Forest Classifier
Ada Boost Classifier
Support Vector Machine (SVM)

A successful model is defined as having an **accuracy** and **F1 score** of at least 0.7.

# TABLE OF CONTENTS




# 01

# INTRODUCTION

Background
Dataset
Data Cleaning

# BACKGROUND

## DRUG SAFETY

After regulatory approval of a drug, the ongoing process of post-market surveillance ensures continued safety of the product

## ADVERSE EVENT

Harmful or negative outcome that occurs when a patient has been provided with medical care or treatment

## VAERS

Vaccine Adverse Events Reporting System (VAERS) is national warning system in the US to detect possible safety problem in US-licensed vaccines

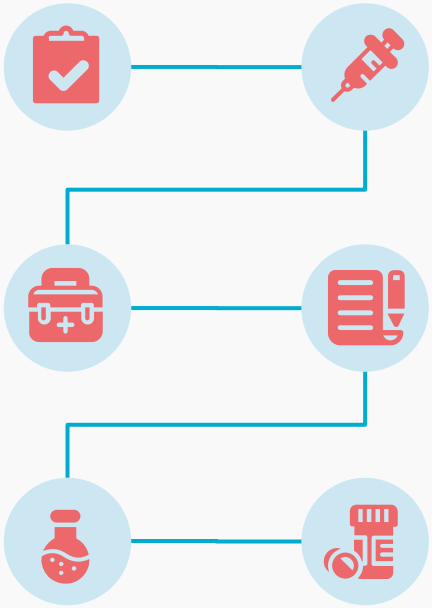
# Reporting of an Adverse Event

### 1. Product approval

Efficacy and safety have been tested in clinical trials

### 2. Product Administration

Patient is given the drug or vaccine



### 3. Adverse Event

Patient could experience a side effect of the drug

### 4. Reporting

AE is reported by anyone (patient, family, HCP)

### 5. Signal Detection

If there is a high incidence of a particular AE, it could be detected as a signal for regulatory action

### 6. Action Taken

Regulatory authorities together with the company will determine what is the best course of action (e.g. Advisory, Recall)

# INITIAL DATASET

- Taken from VAERS
- Data Collected in 2021 (up to Oct)
- From 3 CSV files

## FEATURES

**52**

COLUMNS

**830k**

ROWS

## DESCRIPTION

45 Non-text columns

7 Text Columns

# DATA CLEANING

Filtering COVID-19 Vaccines

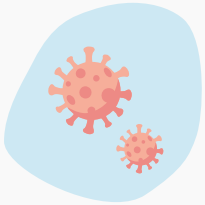
Removal of Duplicates & Imputing or Removal of Null Values

Cleaning of Text Columns with Regex

# TYPES OF AE REPORT

## NON-SERIOUS

Common non-serious AE include
headache, fever, nausea



## SERIOUS

Generally more serious, falls into one of the serious criteria

# SERIOUS CRITERIA

- Death
- Life-threatening
- Hospitalisation (initial or prolonged)
- Disability or Permanent Damage
- Congenital Anomaly or Birth Defect
- Other Serious (Important Medical Events (IME))

# IME LIST

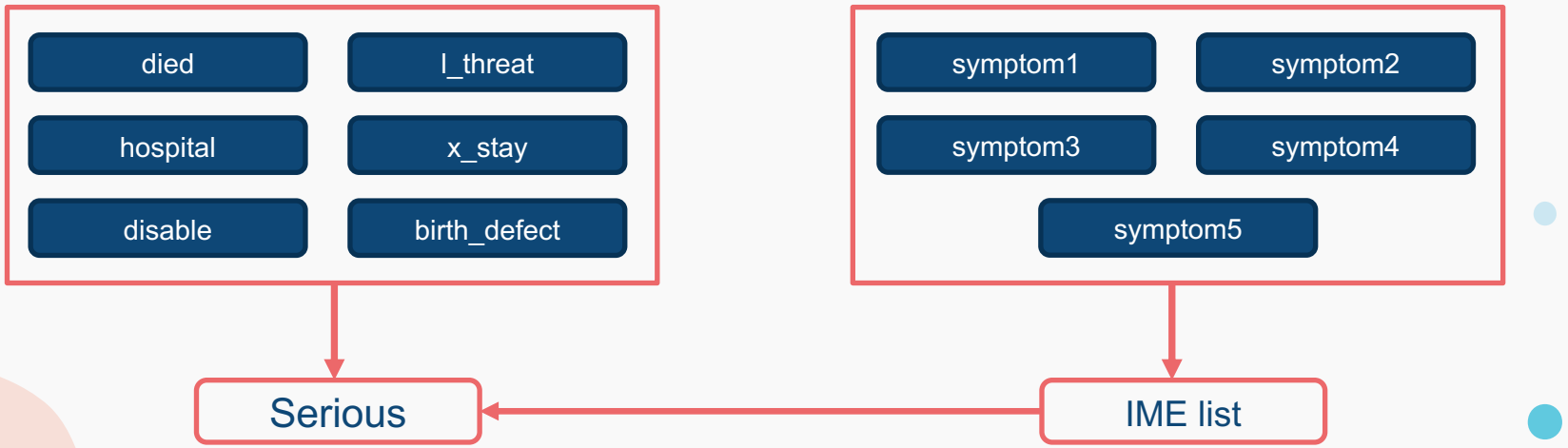
| | MedDRA Code | PT Name | SOC Name | Comment | Added in 24.0 | Primary SOC Change |
|---|---|---|---|---|---|---|
| 0 | 10083258 | Erythropoietin deficiency anaemia | Blood and lymphatic system disorders | Existing PT. Added after review by EVEWG. | X | NaN |
| 1 | 10051778 | Factor IX inhibition | Blood and lymphatic system disorders | Existing PT. Added after review by EVEWG. | X | NaN |
| 2 | 10048619 | Factor VIII inhibition | Blood and lymphatic system disorders | Existing PT. Added after review by EVEWG. | X | NaN |
| 3 | 10058116 | Nephrogenic anaemia | Blood and lymphatic system disorders | Existing PT. Added after review by EVEWG. | X | NaN |
| 4 | 10068698 | Familial hypocalciuric hypercalcaemia | Congenital, familial and genetic disorders | Existing PT. Added after review by EVEWG. | X | NaN |

# Creation of ‘Serious’ Column as Target Variable

**Columns Representing Serious Criteria**

**Columns for Important Medical Events (IME)**

*The IME list can be found from MedDRA*



# DATASET AFTER CLEANING

## FEATURES

**32**

**COLUMNS**

Merged into a single dataset

**543k**

**ROWS**

## DESCRIPTION

28 Non-Text Columns

4 Text Columns

Target Feature: ‘serious’

# 02

## EXPLORATORY DATA ANALYSIS

Pre-processing of Data
Data Visualisation

# PRE-PROCESSING OF TEXT COLUMNS

## REMOVE PUNCTUATIONS

Clean text of any punctuations

## REMOVE STOPWORDS

Exclude words that are frequently occuring in all text

## VECTORIZATION

Count Vectorizer
TF-IDF Vectorizer

## TOKENIZATION

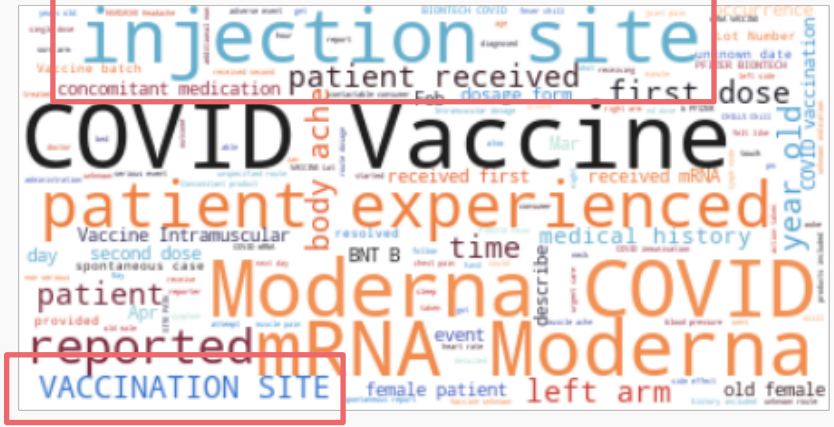
Splitting text into a list of words

## LEMMATIZATION

Reducing all words to their base form

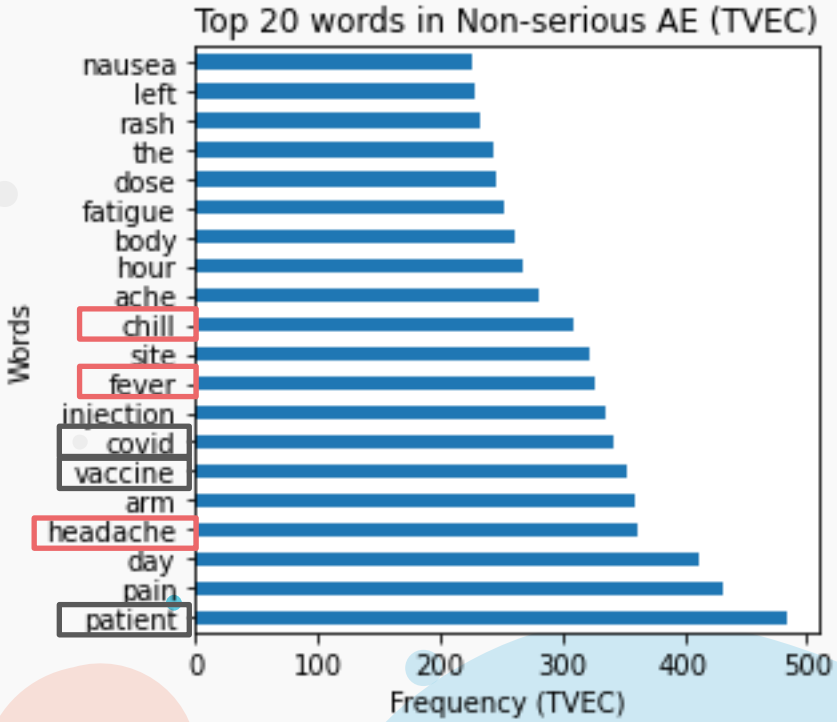
# Word Cloud – symptom_text

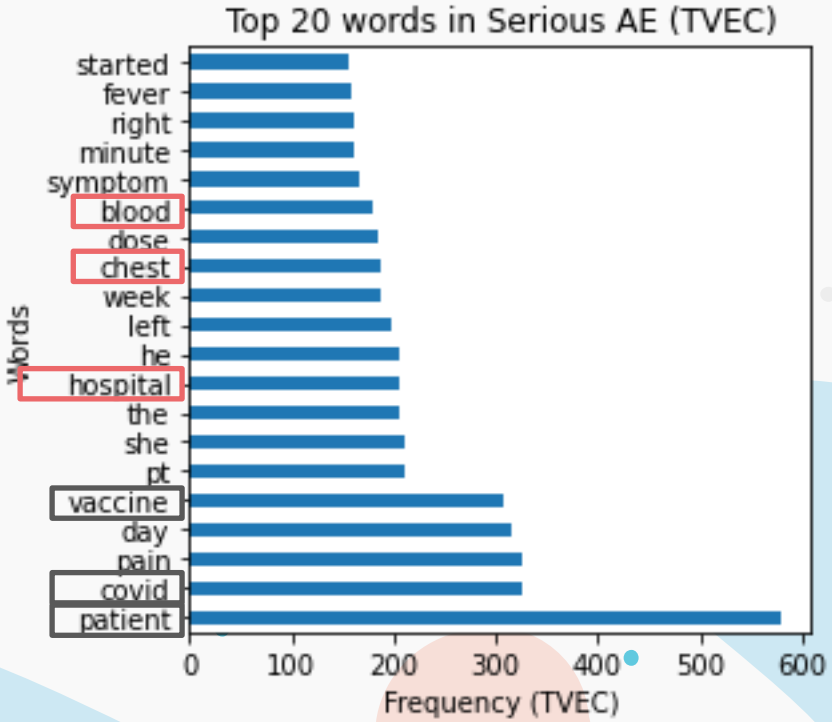
Word Cloud for Non-serious AE



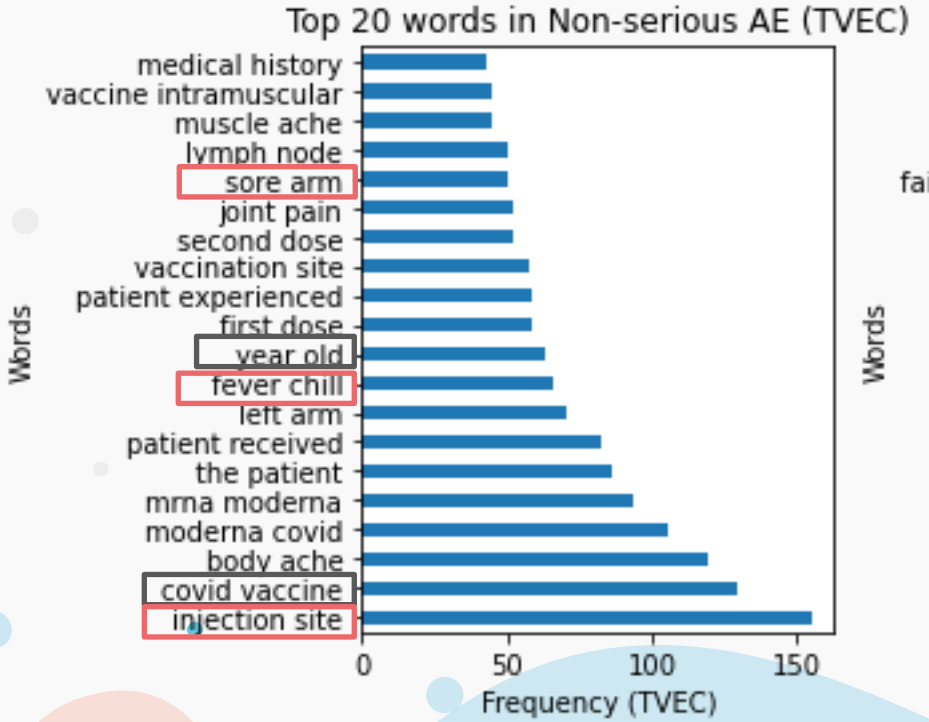

Word Cloud for Serious AE

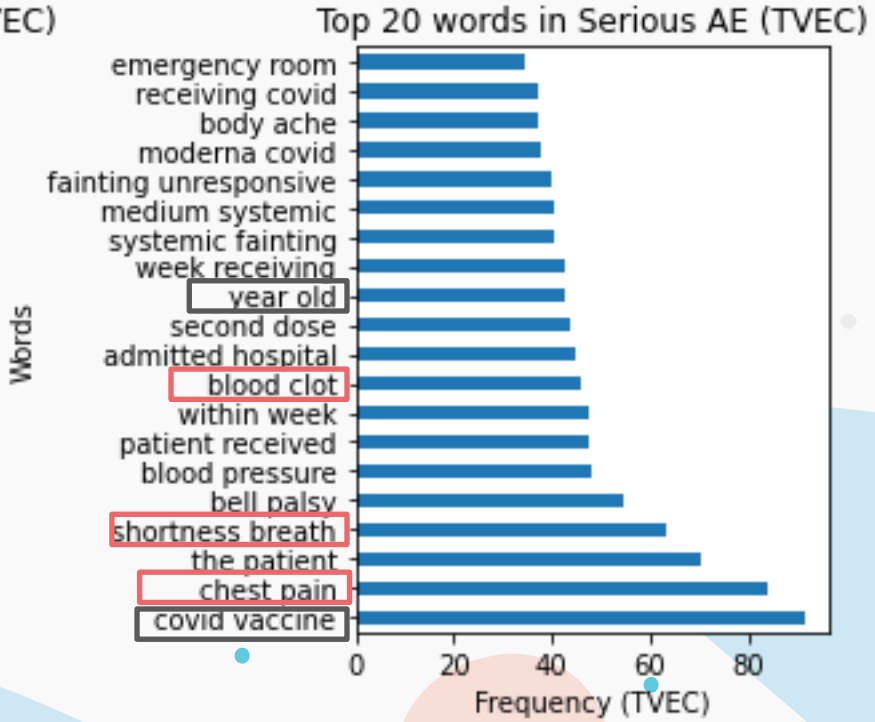
# Unigram – symptom_text



# Bigram – symptom_text



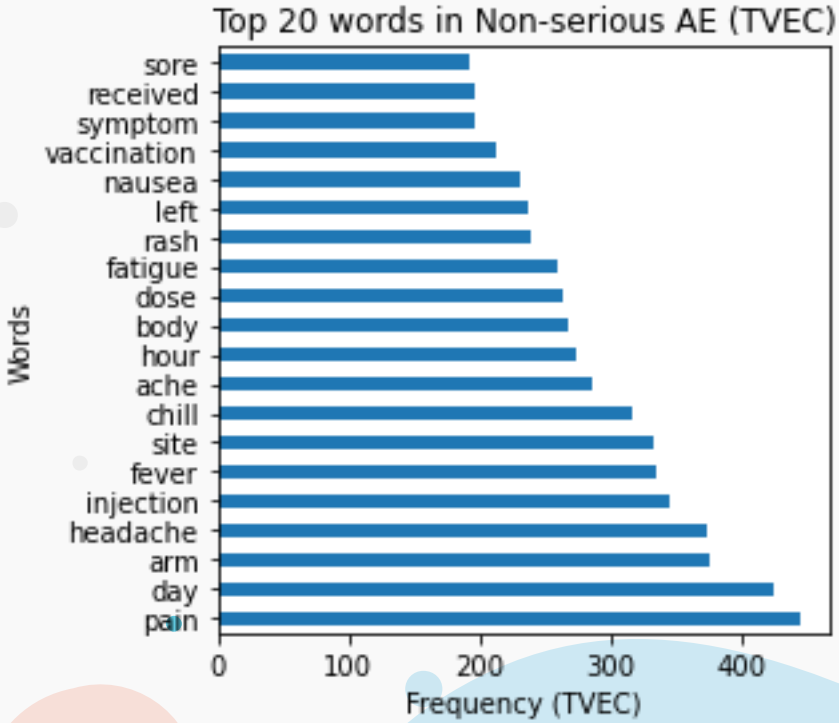



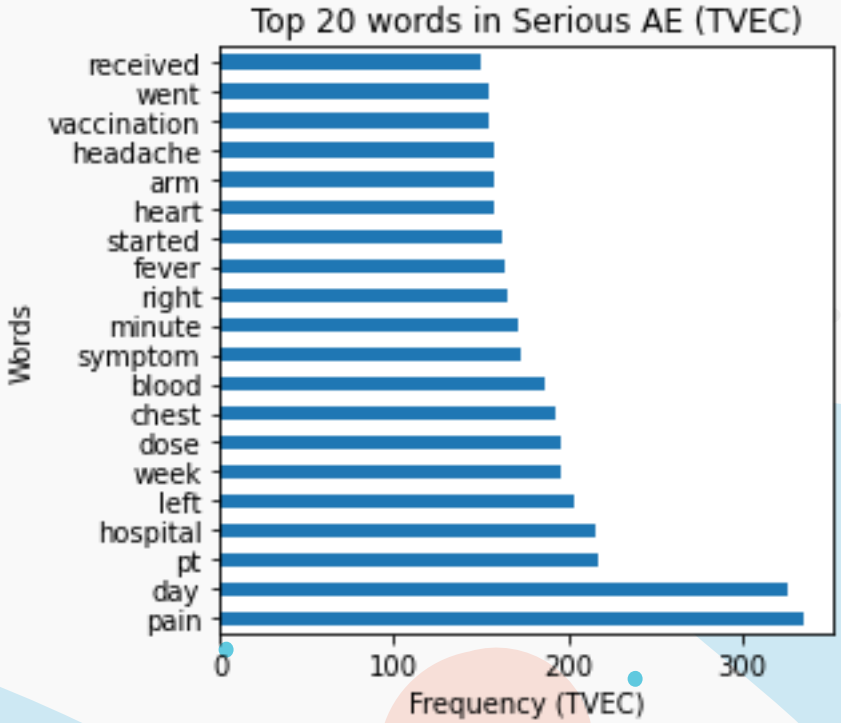
# New Stopwords

- Words that do not have predictive power or are too repetitive were added to the list of new stopwords

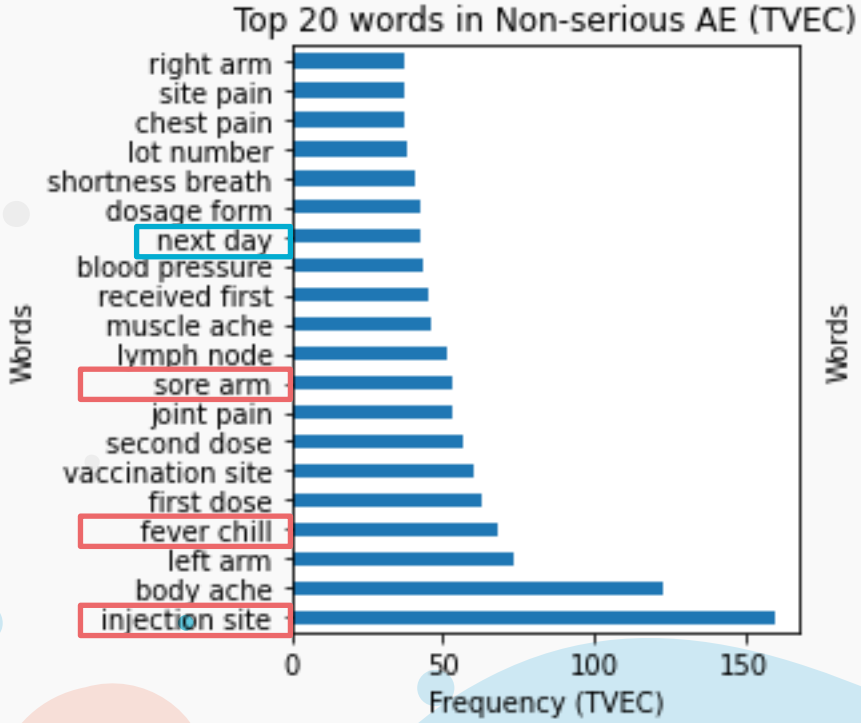
```
stopword_list = ['moderna', 'covid', 'mrna', 'vaccine', 'the', 'patient', 'pfizer',
                 'biontech', 'nan', 'none', 'mg', 'medical', 'history', 'allergy',
                 'year', 'old']
```

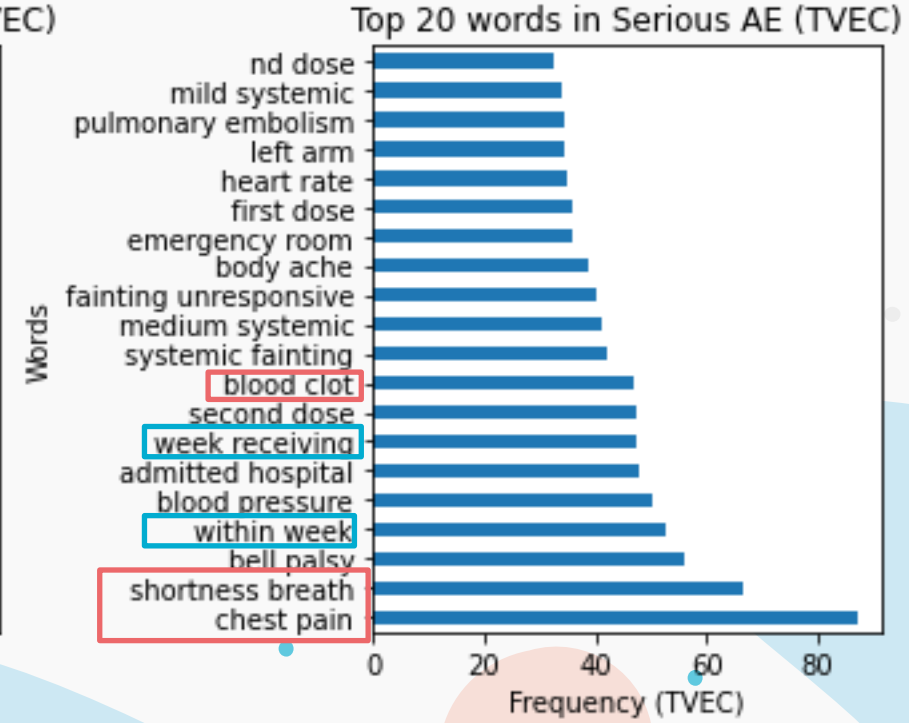
# Unigram – symptom_text



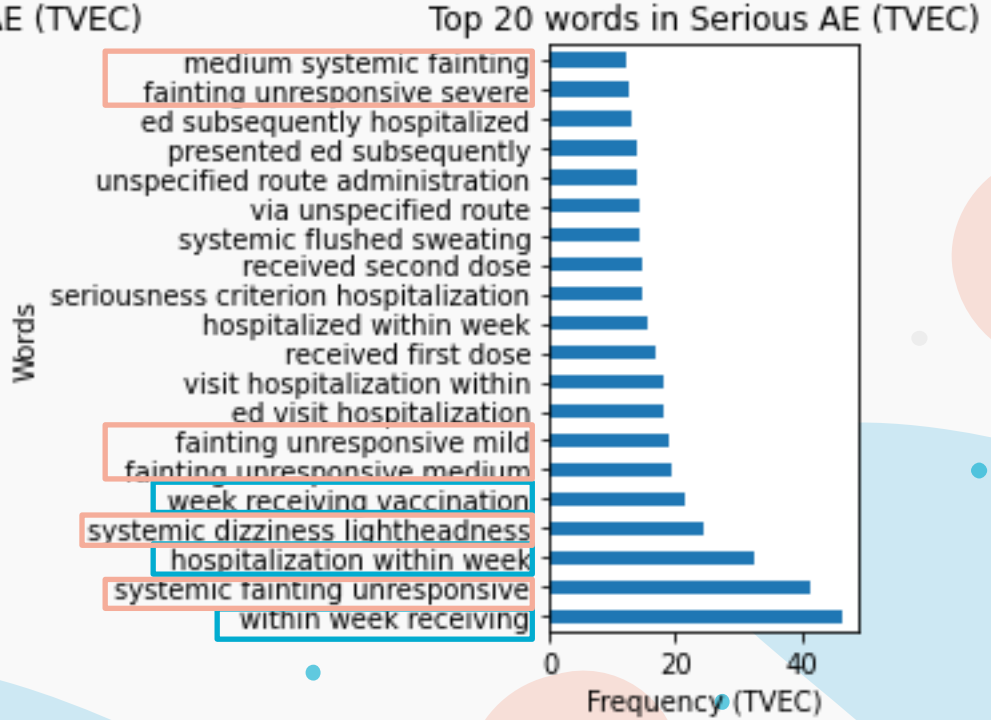



# Bigram – symptom_text

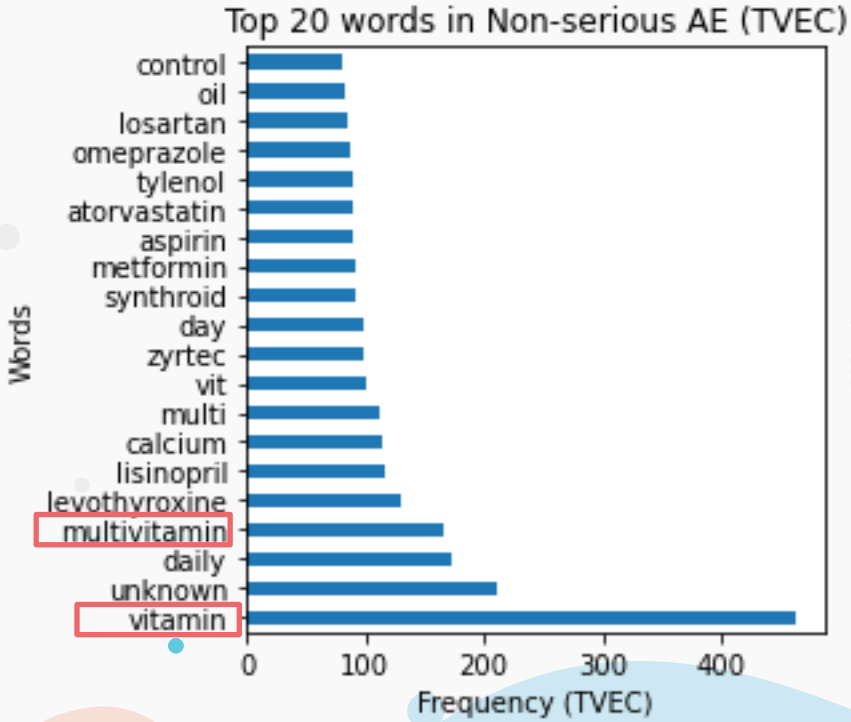


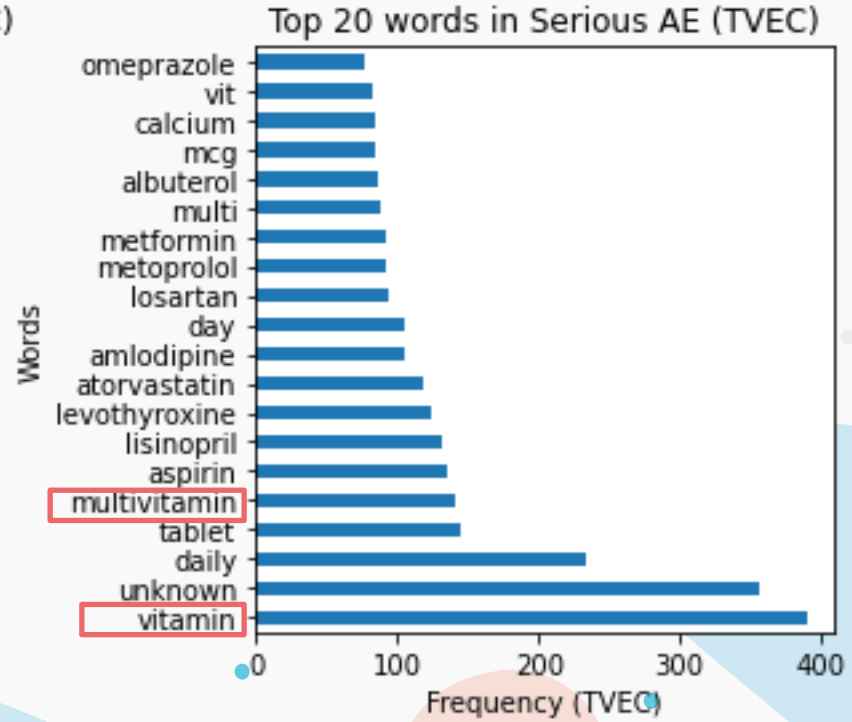



# Trigram – symptom_text

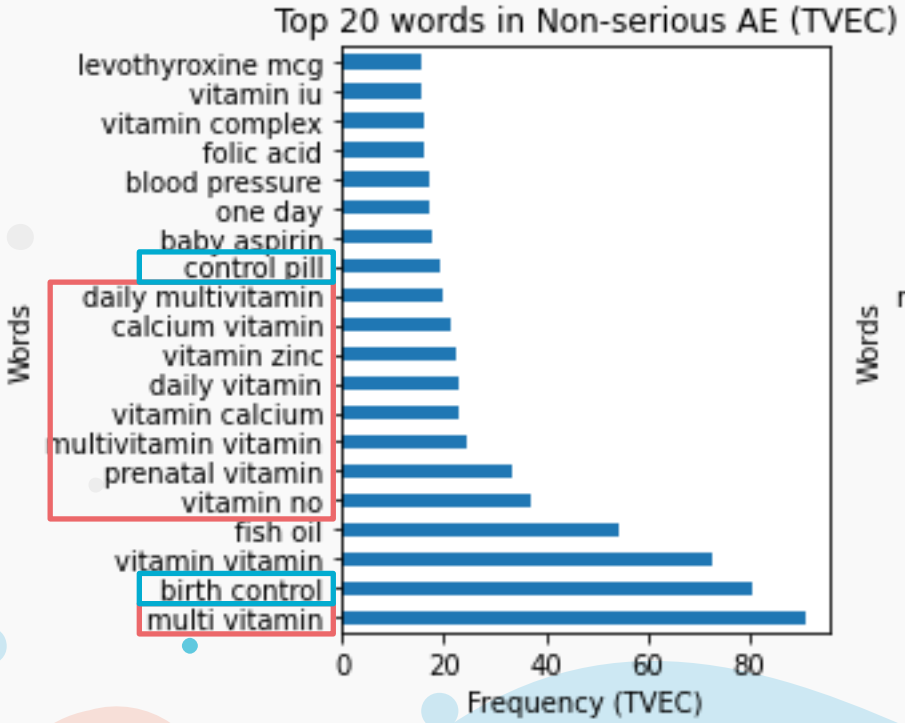



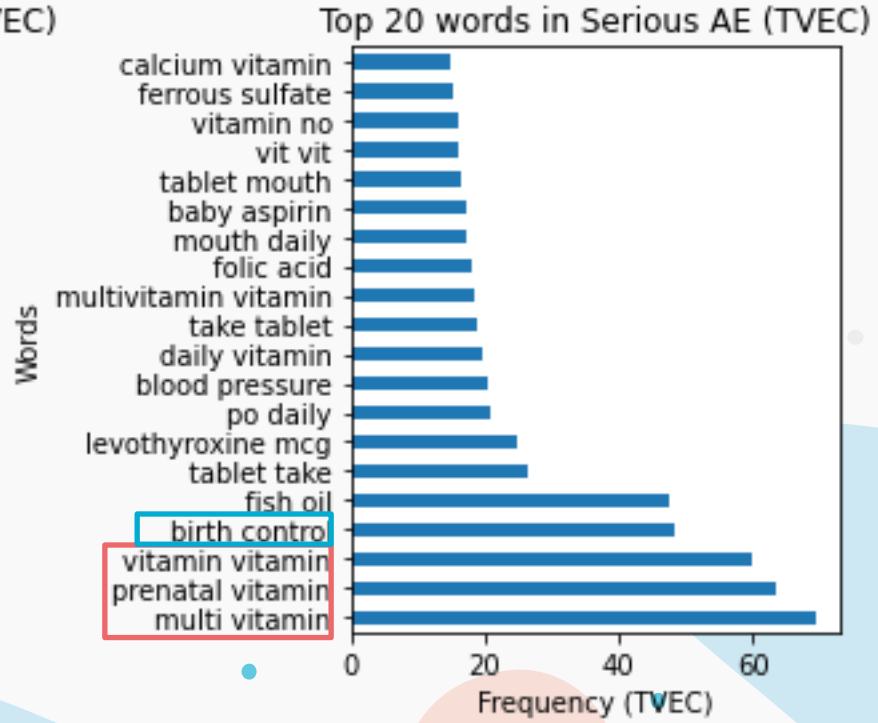
# Unigram – other_meds



# Bigram – other_meds

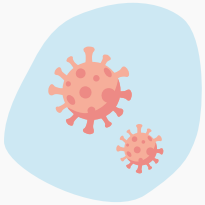


# DATASET AFTER EDA

**‘symptom_text’**

Column for NLP



**‘serious’**

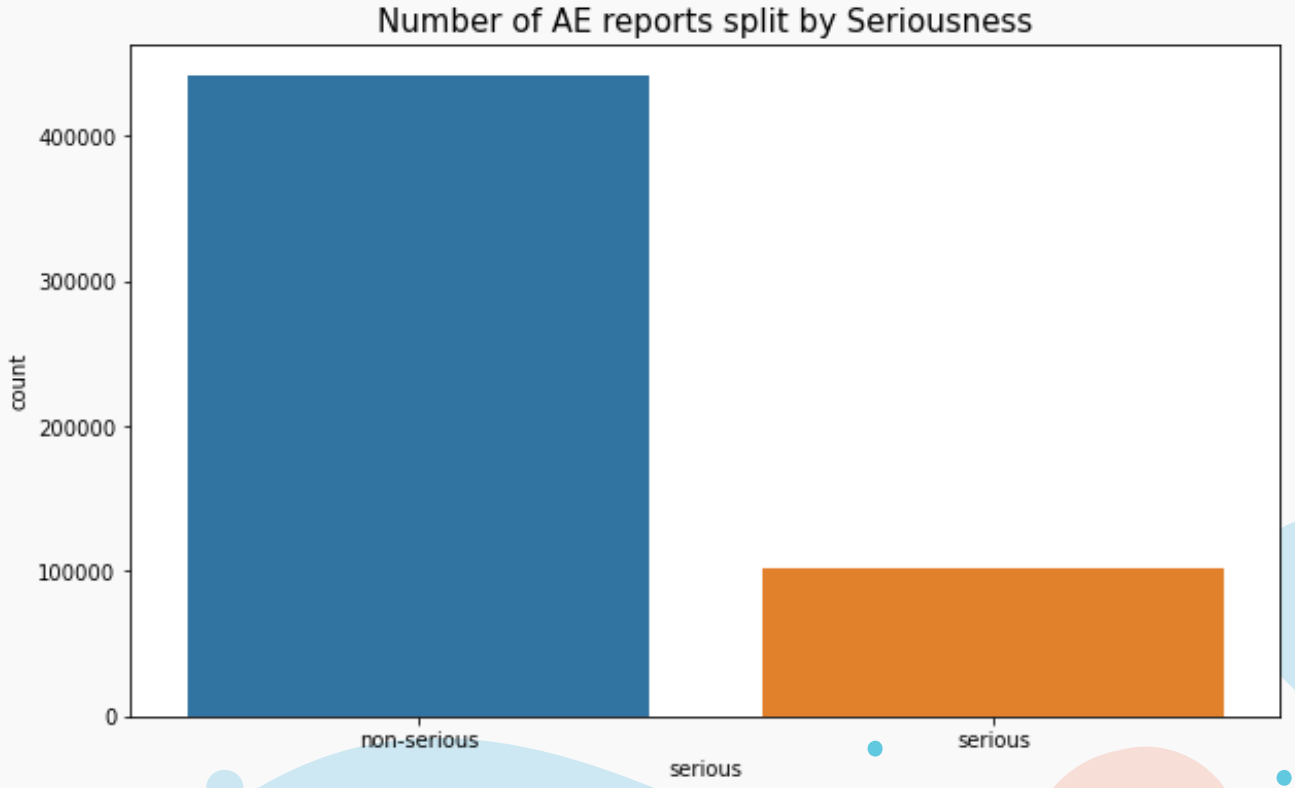
Target Column

# 03

# MODELLING

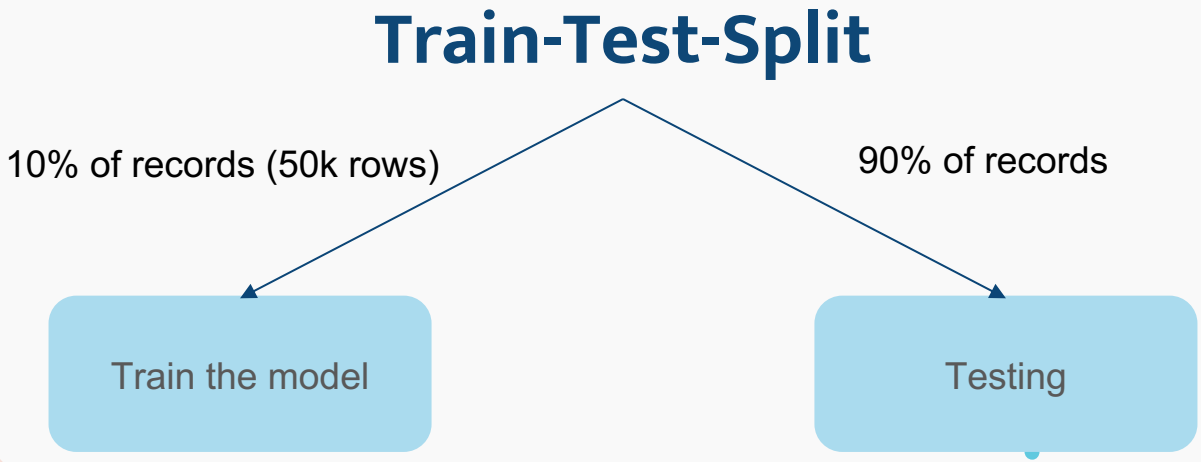
Modelling
Optimisation
Model Evaluation

# Imbalanced Dataset



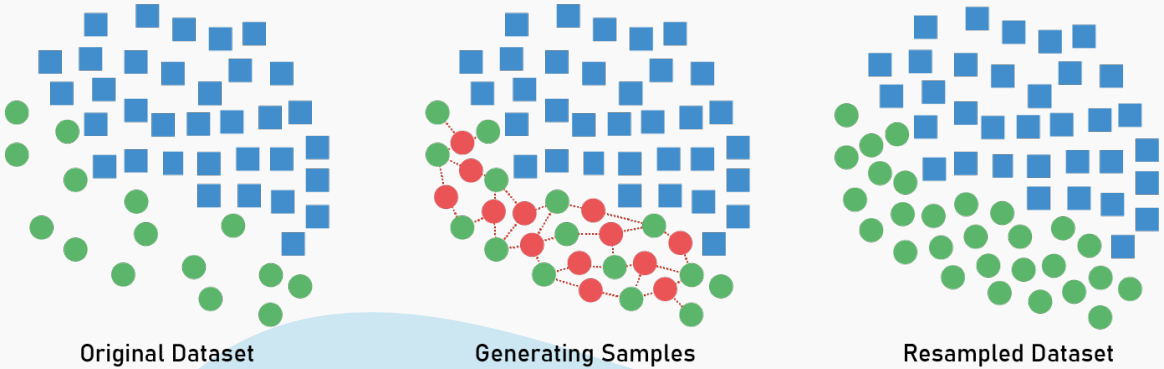
# MODELLING

## Hyperparameter tuning done via GridSearchCV



# SMOTE

## Synthetic Minority Oversampling Technique



# MODELS USED

## Logistic Regression (LR)

Fits data on a sigmoid curve to distinguish the 2 categories

## Ada Boost Classifier (ADA)

Combines weak classifiers into a single strong classifier

## Multinomial Naïve Bayes (MNB)

Uses conditional probability for classification

## Support Vector Machine (SVM)

Create a hyperplane between the 2 categories

## Random Forest Classifier (RFC)

Ensemble of decision trees to vote on the predicted class

# MODEL RESULTS

## Without SMOTE

| Model No. | Word Vectorizer | Classifier | CV Score (train) | Accuracy (train) | Accuracy (test) | Recall (test) | F1 score (test) | Specificity (test) | Precision (test) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | CountVectorizer() | LogisticRegression() | 0.883 | 0.950 | 0.885 | 0.562 | 0.649 | 0.960 | 0.768 |
| 2 | TfidfVectorizer() | LogisticRegression() | 0.887 | 0.948 | 0.889 | 0.584 | 0.667 | 0.961 | 0.776 |
| 3 | CountVectorizer() | MultinomialNB() | 0.823 | 0.847 | 0.825 | 0.761 | 0.623 | 0.840 | 0.527 |
| 4 | TfidfVectorizer() | MultinomialNB() | 0.882 | 0.899 | 0.884 | 0.514 | 0.628 | 0.971 | 0.806 |
| 5 | CountVectorizer() | RandomForestClassifier() | 0.871 | 0.980 | 0.872 | 0.584 | 0.634 | 0.939 | 0.693 |
| 6 | TfidfVectorizer() | RandomForestClassifier() | 0.881 | 0.980 | 0.883 | 0.542 | 0.637 | 0.963 | 0.773 |
| 7 | CountVectorizer() | AdaBoostClassifier() | 0.861 | 0.861 | 0.860 | 0.333 | 0.473 | 0.983 | 0.819 |
| 8 | TfidfVectorizer() | AdaBoostClassifier() | 0.861 | 0.865 | 0.861 | 0.348 | 0.487 | 0.981 | 0.810 |
| 9 | CountVectorizer() | SVC() | 0.846 | 0.896 | 0.849 | 0.287 | 0.419 | 0.981 | 0.777 |
| 10 | TfidfVectorizer() | SVC() | 0.881 | 0.971 | 0.885 | 0.464 | 0.604 | 0.983 | 0.865 |

# MODEL RESULTS

## With SMOTE

| Model No. | Word Vectorizer | Classifier | CV Score (train) | Accuracy (train) | Accuracy (test) | Recall (test) | F1 score (test) | Specificity (test) | Precision (test) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | CountVectorizer() | LogisticRegression() | 0.815 | 0.938 | 0.816 | 0.710 | 0.594 | 0.841 | 0.511 |
| 2 | TfidfVectorizer() | LogisticRegression() | 0.837 | 0.933 | 0.839 | 0.732 | 0.633 | 0.864 | 0.558 |
| 3 | CountVectorizer() | MultinomialNB() | 0.826 | 0.854 | 0.833 | 0.753 | 0.631 | 0.851 | 0.542 |
| 4 | TfidfVectorizer() | MultinomialNB() | 0.829 | 0.860 | 0.831 | 0.761 | 0.630 | 0.847 | 0.538 |
| 5 | CountVectorizer() | RandomForestClassifier() | 0.797 | 0.952 | 0.803 | 0.652 | 0.557 | 0.839 | 0.486 |
| 6 | TfidfVectorizer() | RandomForestClassifier() | 0.829 | 0.963 | 0.834 | 0.682 | 0.609 | 0.870 | 0.550 |
| 7 | CountVectorizer() | AdaBoostClassifier() | 0.616 | 0.624 | 0.621 | 0.803 | 0.446 | 0.578 | 0.308 |
| 8 | TfidfVectorizer() | AdaBoostClassifier() | 0.584 | 0.594 | 0.588 | 0.847 | 0.438 | 0.528 | 0.296 |
| 9 | CountVectorizer() | SVC() | 0.694 | 0.799 | 0.704 | 0.763 | 0.494 | 0.690 | 0.365 |
| 10 | TfidfVectorizer() | SVC() | 0.855 | 0.971 | 0.863 | 0.650 | 0.643 | 0.913 | 0.636 |

# MODEL COMPARISON

## Top models from SMOTE/non-SMOTE

| Test (Train) | CV Score | Accuracy | Recall | F1 Score | Precision |
|---|---|---|---|---|---|
| **LR (TVEC) No SMOTE** | 0.887 | 0.889 (0.948) | 0.584 | 0.667 | 0.776 |
| **SVC (TVEC) SMOTE** | 0.855 | 0.863 (0.971) | 0.650 | 0.643 | 0.636 |

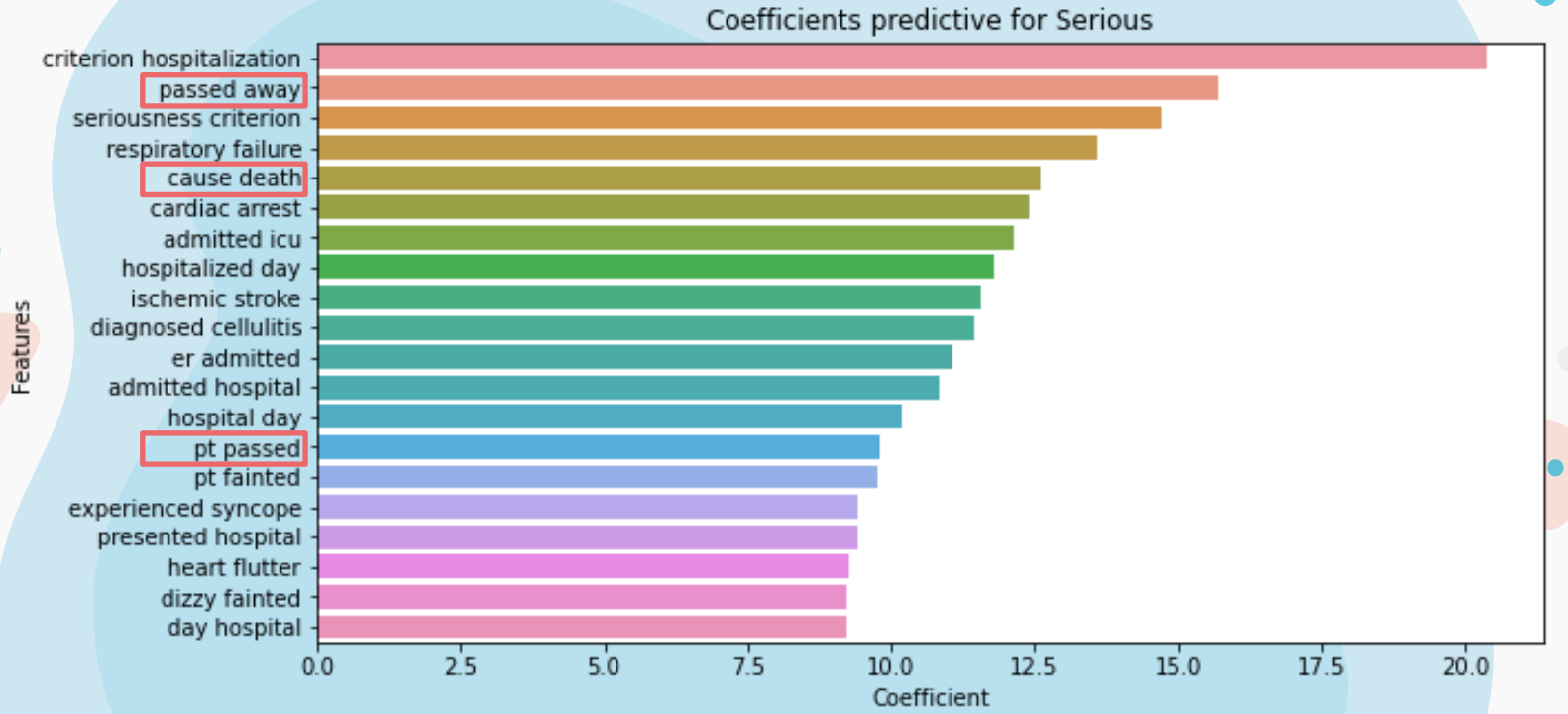
# MODEL COMPARISON

## Tuning of Train-Test-Split

| Test (Train) | CV Score | Accuracy | Recall | F1 Score | Precision |
|---|---|---|---|---|---|
| LR (TVEC) 10/90 split | 0.887 | 0.889 (0.948) | 0.584 | 0.667 | 0.776 |
| LR (TVEC) 80/20 split | 0.902 | 0.903 (0.914) | 0.615 | 0.708 | 0.830 |

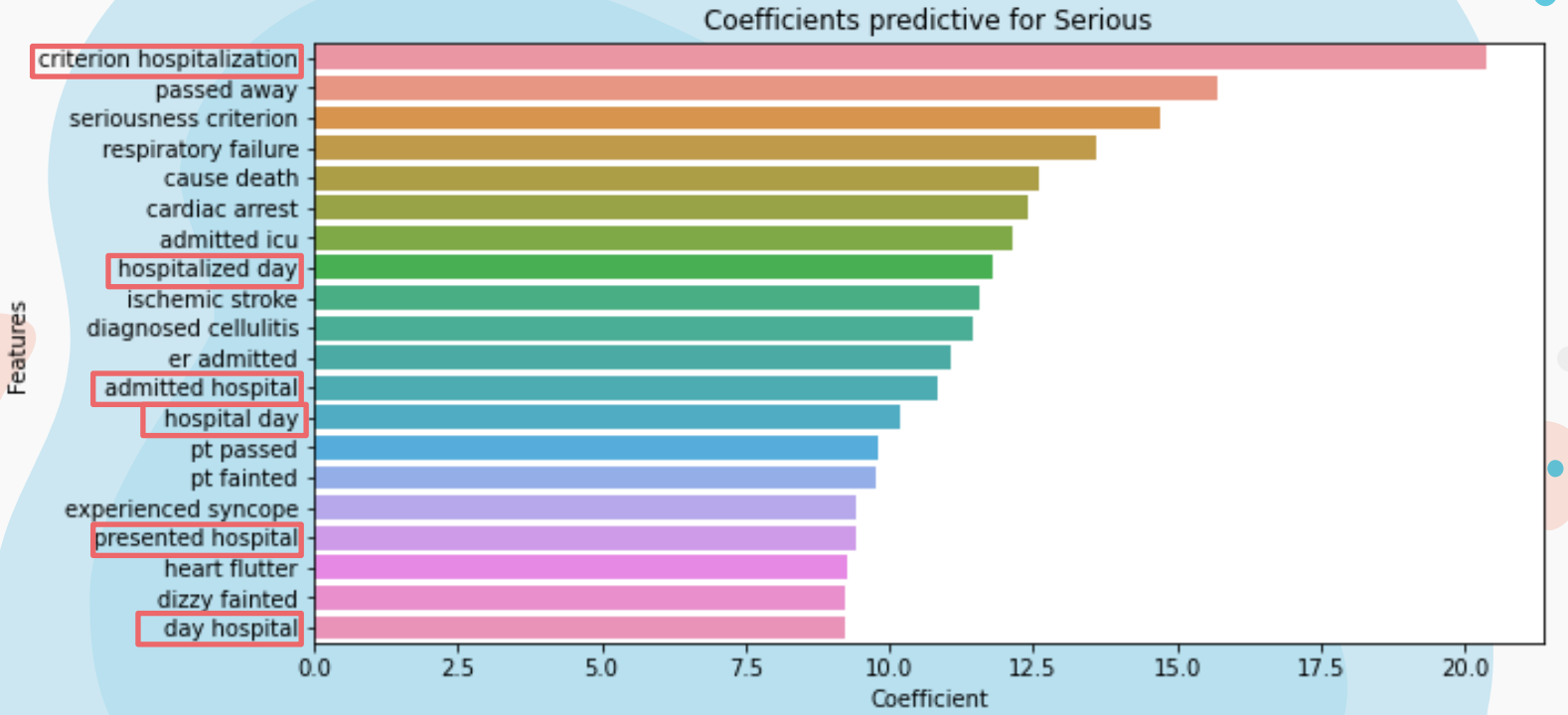
# Highest Coefficients

- Death



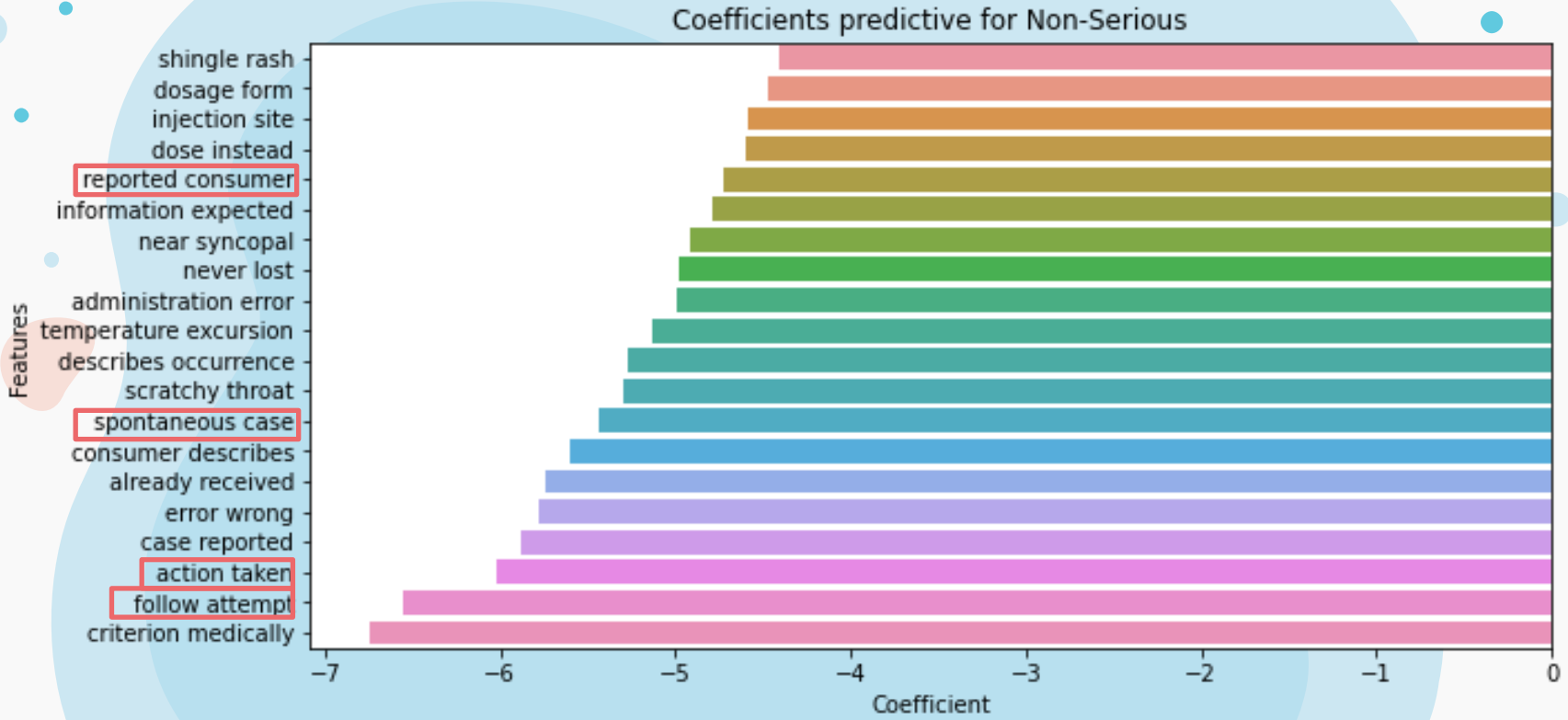
# Highest Coefficients

- Hospitalisation



# Lowest Coefficients

- General words that could be applied to both categories



# 04

## CONCLUSION & RECOMMENDATION

Conclusion
Recommendation
Future Plans

# CONCLUSION

**Accurate Prediction**
With a test and train accuracy of at least 90%, the model is able to accurately predict serious AE.

**Little Overfitting**
With difference between train and test accuracy at 1.1%, the model is not overfitted to the train data.

**Easy to Understand**
The coefficients from the model is easy to interpret and understand.

| Test (Train) | CV Score | Accuracy | Recall | F1 Score | Precision |
|---|---|---|---|---|---|
| **LR (TVEC) 80/20 split** | 90.2% | 90.3% (91.4%) | 61.5% | 70.8% | 83.0% |

# RECOMMENDATION

Deploy model as a preliminary screening tool for all incoming AE, allows serious cases to be labelled more quickly thus enabling signal detection to occur more efficiently

# FUTURE IMPROVEMENTS

## Expand Data Collection to Non-AE reports

Would allow expansion of classification scope of model (AE vs non-AE report).

## Use of Deep Learning

Explore use of Neural Networks to possibly improve predictive power.

## Incorporate Non-Text Columns

Use of non-text columns in model to improve model performance.

# THANKS!

Do you have any questions?

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# APPENDIX

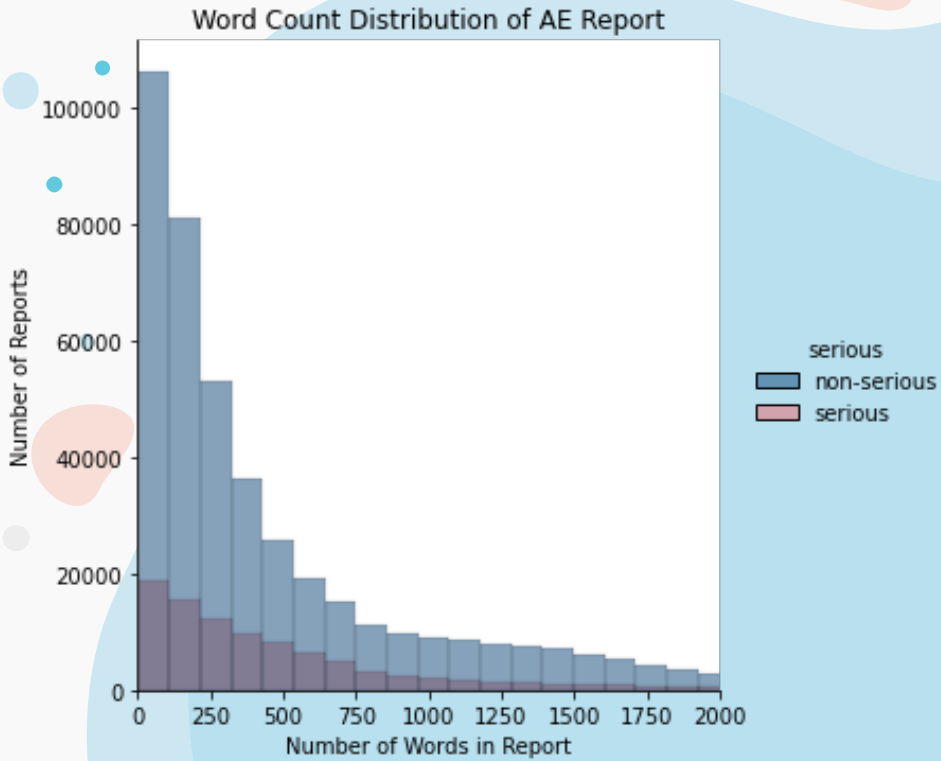
- Regex

| | symptom_text | other_meds | history | allergies |
|---|---|---|---|---|
| 17 | Left side of face became numb, including to behind the left ear. Happened within 10 minutes of injection. Subsided within 30 minutes. The next day, some numbness returned at about 9pm in the evening. Pain behind left ear. | levothyroxine 100mcg/day, estradiol 1mg/day | Graves Disease | penicillin, toradol, methimazole |
| 57 | Vertigo every evening when lying down and every morning when getting up. I have been lying in bed for 5-10 minutes with eyes open, then sitting up slowly. Next, I sit on the side of the bed for a few minutes. When I get up, I need to hold onto something so I don't fall down. | multivitamin, D3, baby aspirin | none | latex, sulfa drugs |
| 138 | body aches and stomach ache | Triamterene HCTZ Montelukast Celecoxib Aller-Tec Multivitamin Vitamin D3 Magneseum | asthma when I get a cold | too much cordosone |
| 821 | 12/31/2020 H/a, diarrhea, SEVERE joint pain all through body, severe exhaustion., nausea, chills, fever 99.9. It felt almost identical to my first couple says of covid. | None | Serious episode of covid + 11/18/2020 | None |
| 822 | 12/31/2020 H/a, diarrhea, SEVERE joint pain all through body, severe exhaustion., nausea, chills, fever 99.9. It felt almost identical to my first couple says of covid. | None | Serious episode of covid + 11/18/2020 | None |

# APPENDIX

- Stemming vs Lemmatizing

| | symptom_text_stemmed | symptom_text_lemmatized |
|---|---|---|
| 0 | [left, side, of, face, becam, numb, includ, to... | [Left, side, of, face, became, numb, including... |
| 1 | [vertigo, everi, even, when, lie, down, and, e... | [Vertigo, every, evening, when, lying, down, a... |
| 2 | [bodi, ach, and, stomach, ach] | [body, ache, and, stomach, ache] |
| 3 | [, h, a, diarrhea, sever, joint, pain, all, th... | [, H, a, diarrhea, SEVERE, joint, pain, all, t... |
| 4 | [, h, a, diarrhea, sever, joint, pain, all, th... | [, H, a, diarrhea, SEVERE, joint, pain, all, t... |
| 5 | [moderna, covid, vaccin, eua, headach, nausea,... | [Moderna, covid, vaccine, EUA, headache, nause... |
| 6 | [moderna, covid, vaccin, eua, headach, nausea,... | [Moderna, covid, vaccine, EUA, headache, nause... |
| 7 | [no, advers, reaction, the, staff, were, given... | [No, adverse, reaction, the, staff, were, give... |
| 8 | [moderna, covid, vaccin, eua, flare, up, of, g... | [Moderna, COVID, Vaccine, EUA, Flare, up, of, ... |
| 9 | [moderna, covid, vaccin, eua, flare, up, of, g... | [Moderna, COVID, Vaccine, EUA, Flare, up, of, ... |
| 10 | [moderna, covid, vaccin, eua, fever, of, for, ... | [Moderna, COVID, Vaccine, EUA, Fever, of, for,... |

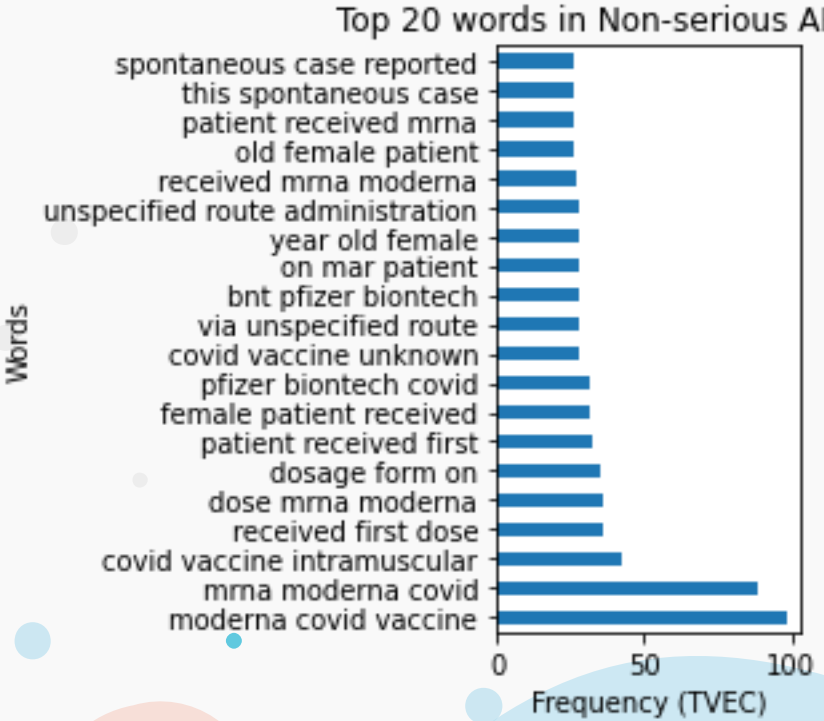


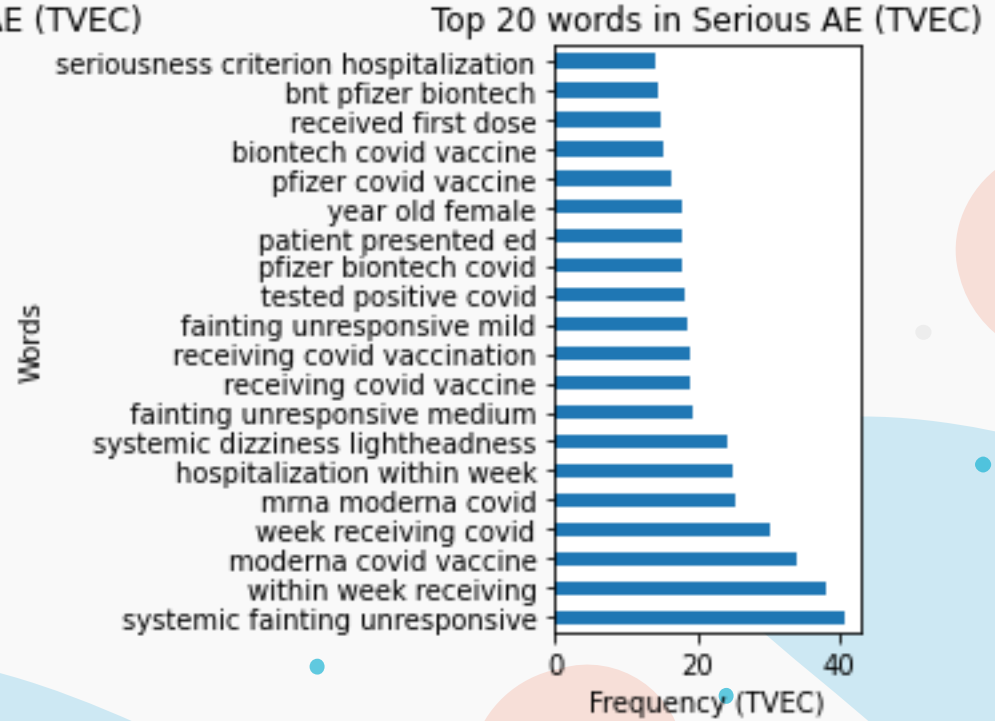

# Word Vectorization

- Count Vectorization
- TF-IDF Vectorization

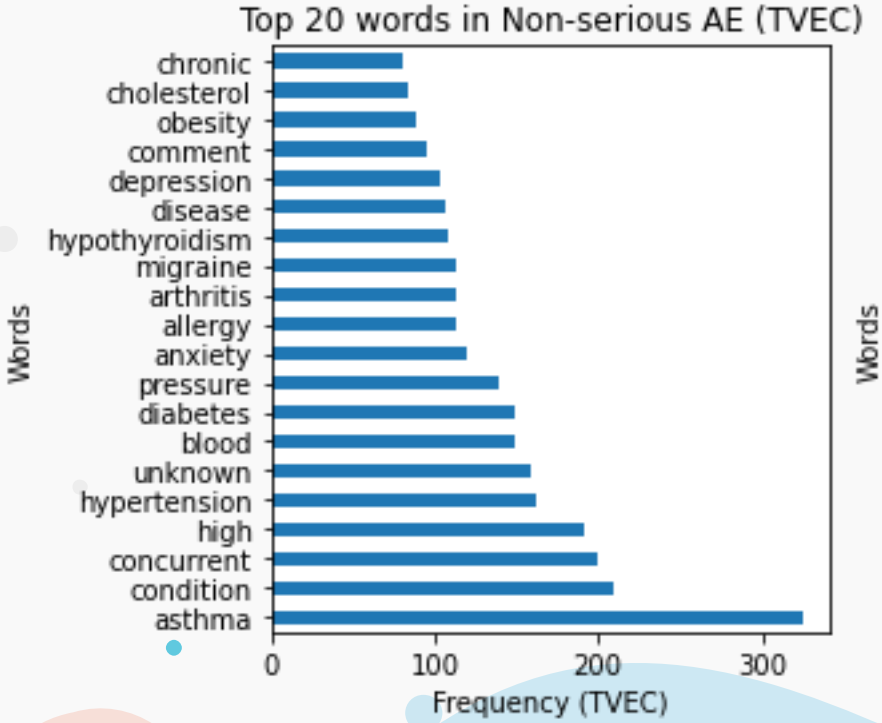
- N-gram frequency

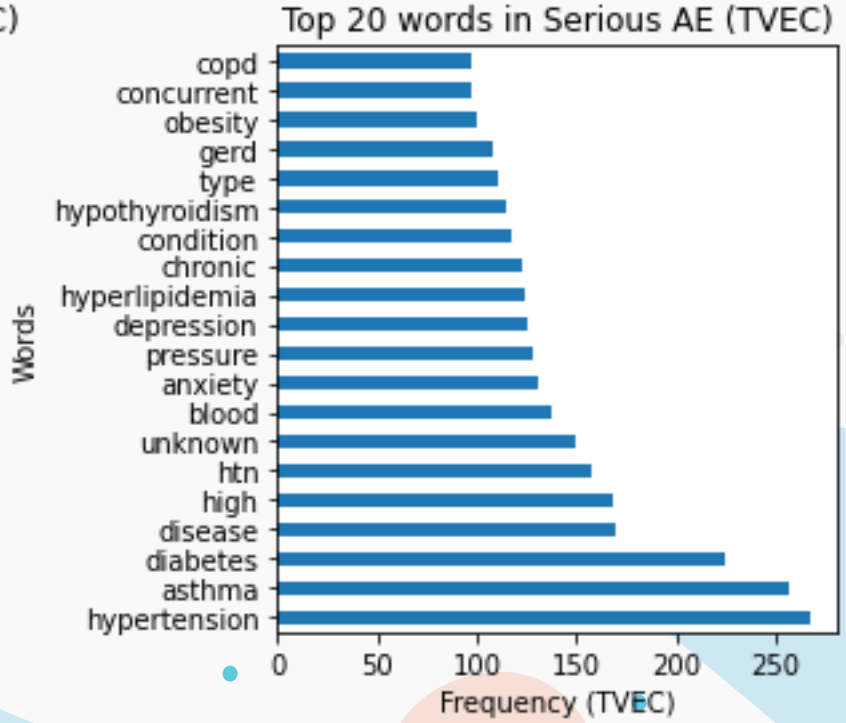
# Trigram – symptom_text



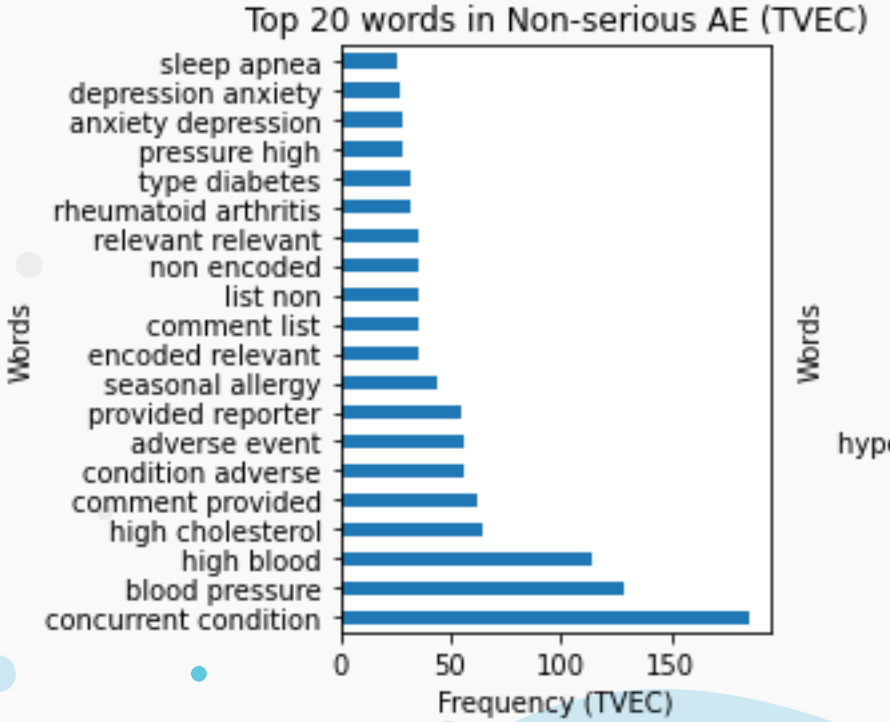



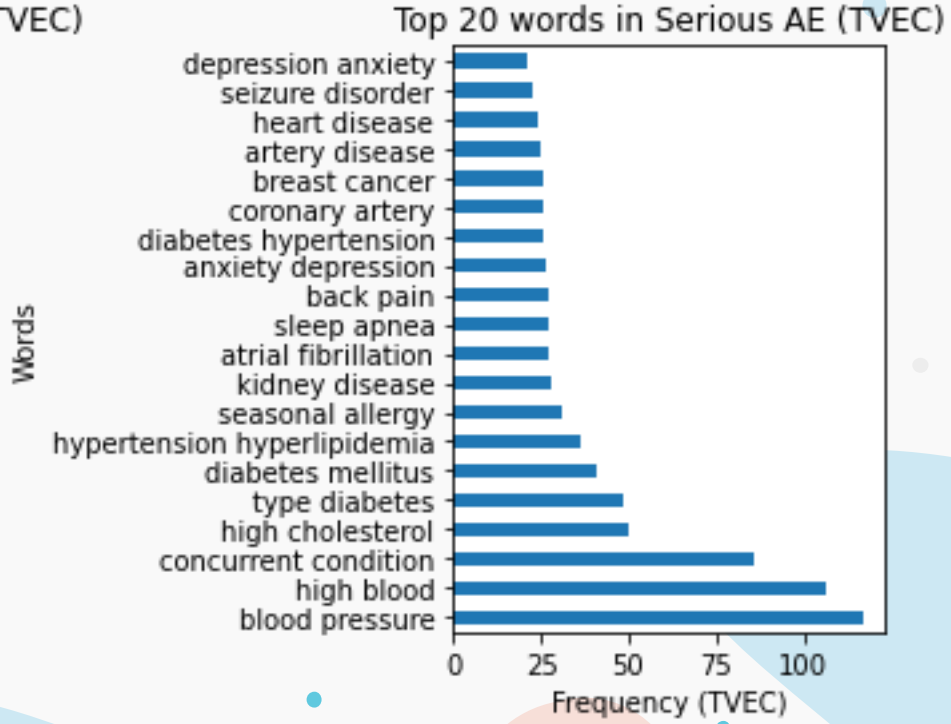
# Unigram – history



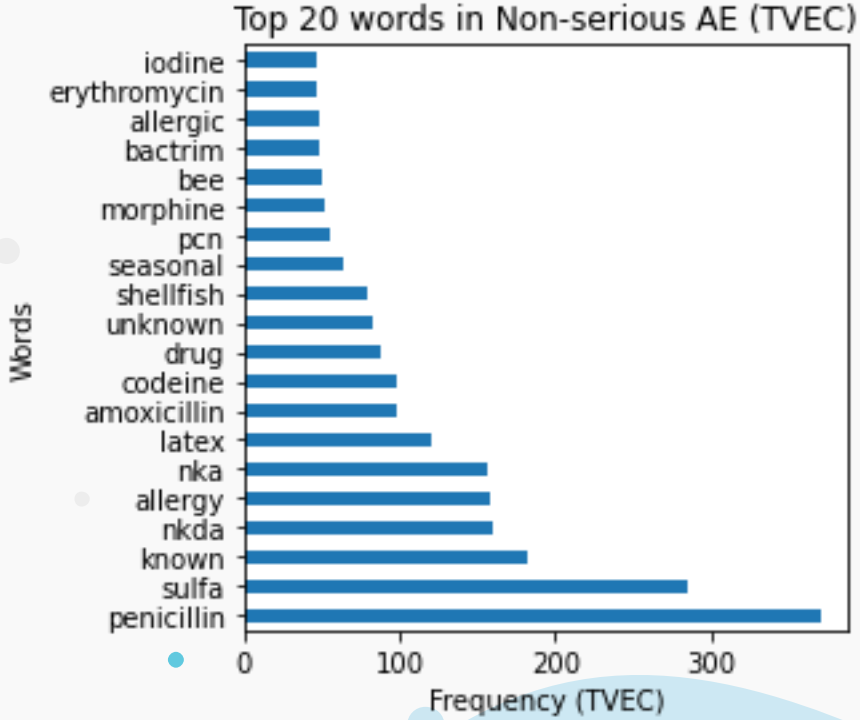



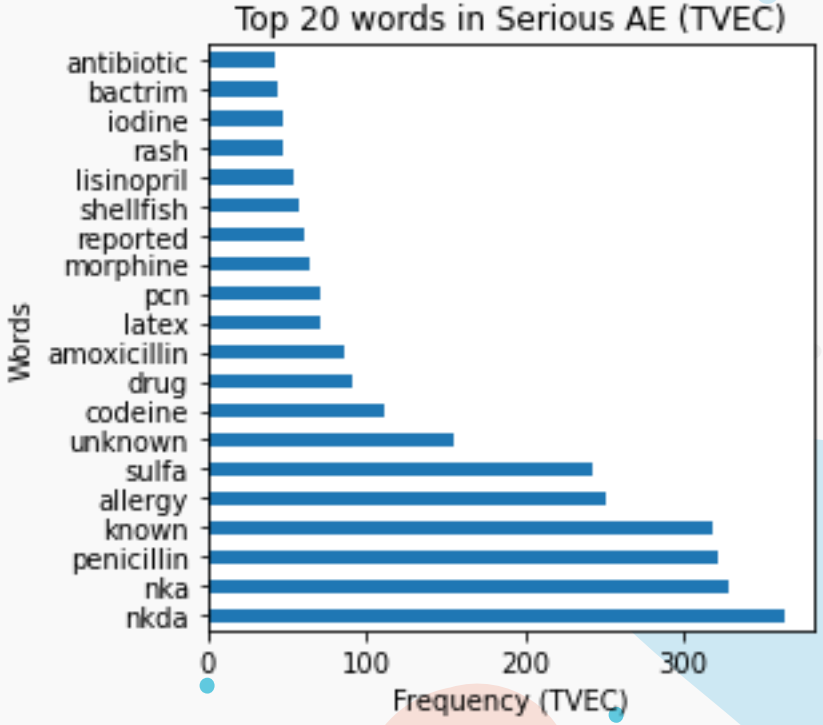
# Bigram – history



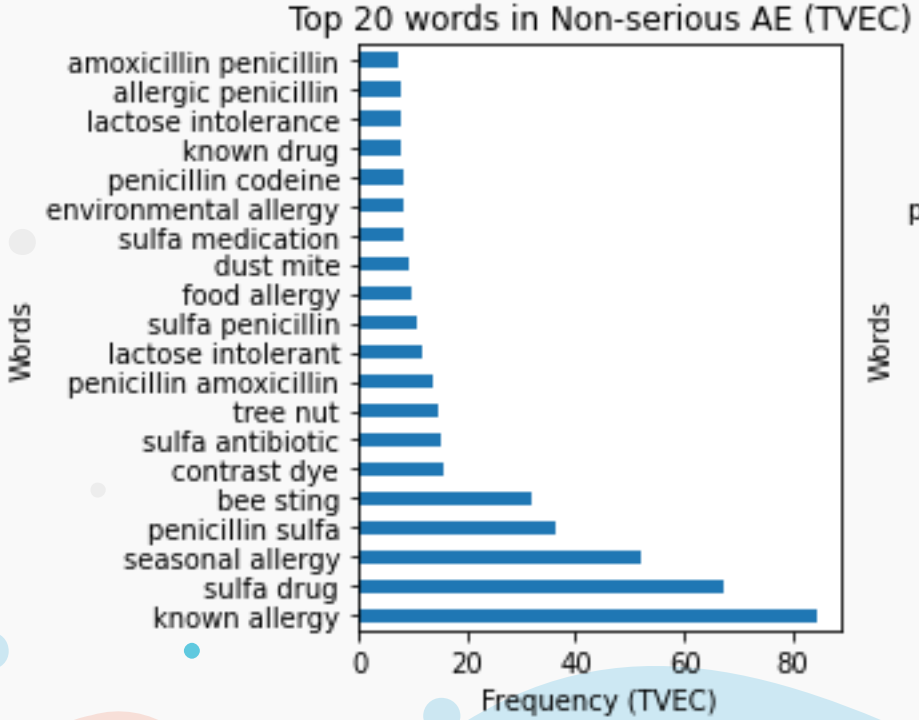



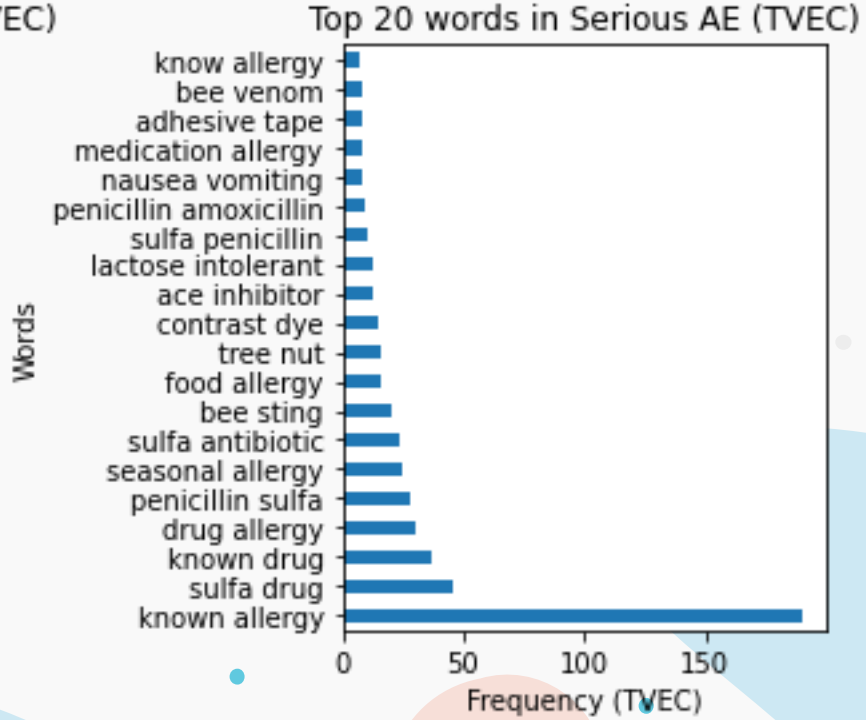
# Unigram – allergies



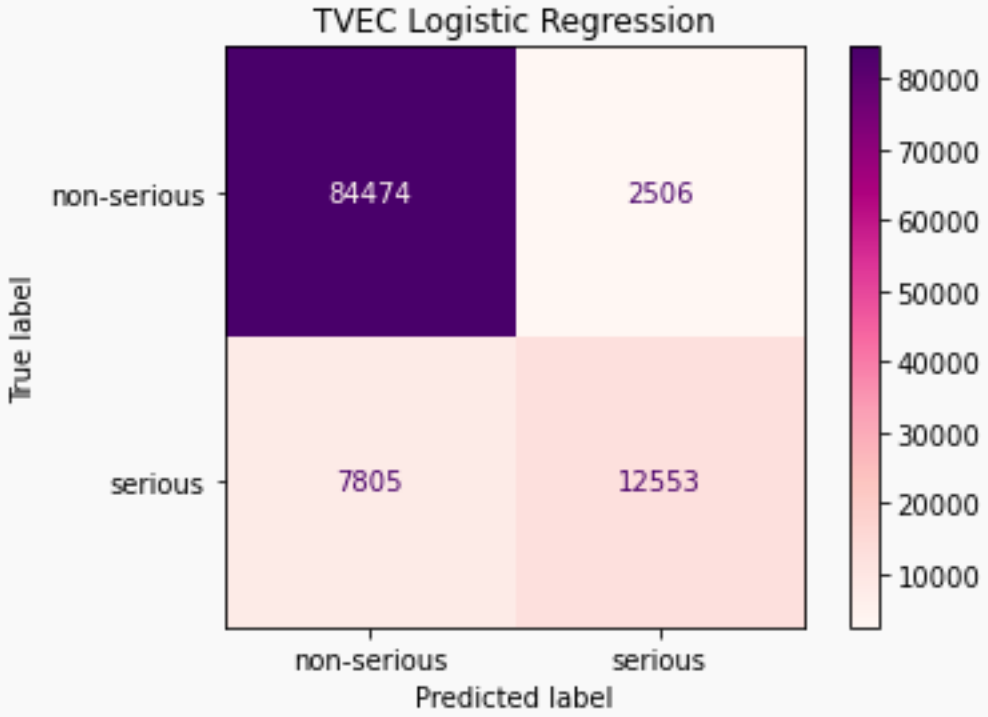
# Bigram – allergies



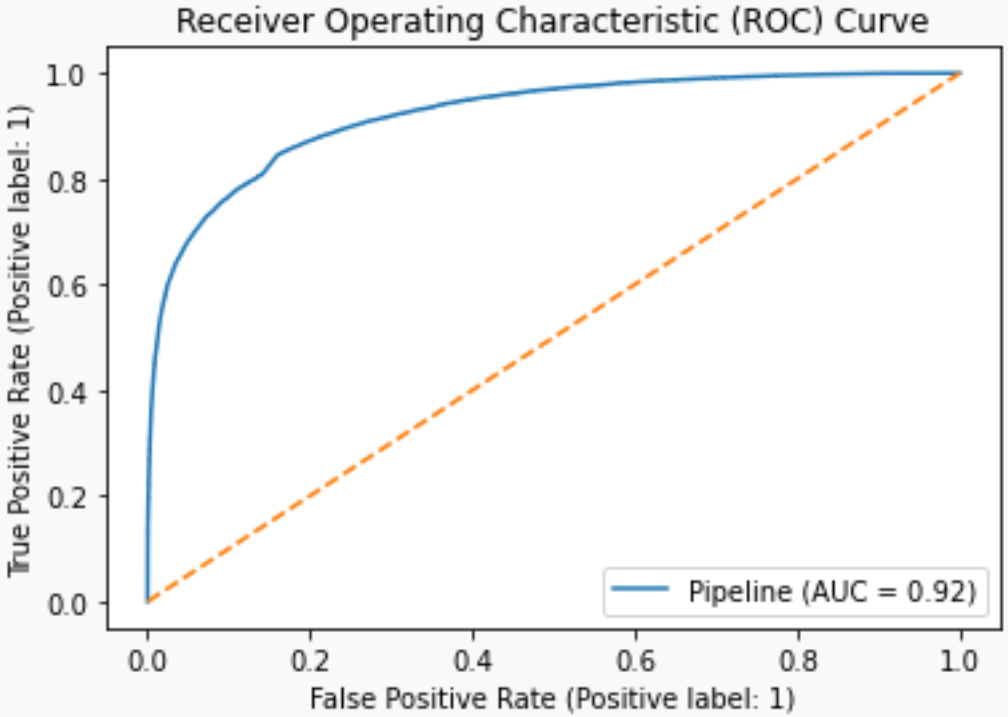
# APPENDIX

- Confusion Matrix



# APPENDIX

- ROC-AUC



# APPENDIX

All models

| Model No. | SMOTE? | Word Vectorizer | Classifier | CV Score (train) | Accuracy (train) | Accuracy (test) | Recall (test) | F1 score (test) | Specificity (test) | Precision (test) |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | No | CountVectorizer | LogisticRegression | 0.883 | 0.95 | 0.885 | 0.562 | 0.649 | 0.96 | 0.768 |
| 2 | No | TfidfVectorizer | LogisticRegression | 0.887 | 0.948 | 0.889 | 0.584 | 0.667 | 0.961 | 0.776 |
| 3 | No | CountVectorizer | MultinomialNB | 0.823 | 0.847 | 0.825 | 0.761 | 0.623 | 0.84 | 0.527 |
| 4 | No | TfidfVectorizer | MultinomialNB | 0.882 | 0.899 | 0.884 | 0.514 | 0.628 | 0.971 | 0.806 |
| 5 | No | CountVectorizer | RandomForestClassifier | 0.871 | 0.98 | 0.872 | 0.584 | 0.634 | 0.939 | 0.693 |
| 6 | No | TfidfVectorizer | RandomForestClassifier | 0.881 | 0.98 | 0.883 | 0.542 | 0.637 | 0.963 | 0.773 |
| 7 | No | CountVectorizer | AdaBoostClassifier | 0.861 | 0.861 | 0.86 | 0.333 | 0.473 | 0.983 | 0.819 |
| 8 | No | TfidfVectorizer | AdaBoostClassifier | 0.861 | 0.865 | 0.861 | 0.348 | 0.487 | 0.981 | 0.81 |
| 19 | No | CountVectorizer | SVC | 0.846 | 0.896 | 0.849 | 0.287 | 0.419 | 0.981 | 0.777 |
| 10 | No | TfidfVectorizer | SVC | 0.881 | 0.971 | 0.885 | 0.464 | 0.604 | 0.983 | 0.865 |
| 11 | Yes | CountVectorizer | LogisticRegression | 0.815 | 0.938 | 0.816 | 0.71 | 0.594 | 0.841 | 0.511 |
| 12 | Yes | TfidfVectorizer | LogisticRegression | 0.837 | 0.933 | 0.839 | 0.732 | 0.633 | 0.864 | 0.558 |
| 13 | Yes | CountVectorizer | MultinomialNB | 0.826 | 0.854 | 0.833 | 0.753 | 0.631 | 0.851 | 0.542 |
| 14 | Yes | TfidfVectorizer | MultinomialNB | 0.829 | 0.86 | 0.831 | 0.761 | 0.63 | 0.847 | 0.538 |
| 15 | Yes | CountVectorizer | RandomForestClassifier | 0.797 | 0.952 | 0.803 | 0.652 | 0.557 | 0.839 | 0.486 |
| 16 | Yes | TfidfVectorizer | RandomForestClassifier | 0.829 | 0.963 | 0.834 | 0.682 | 0.609 | 0.87 | 0.55 |
| 17 | Yes | CountVectorizer | AdaBoostClassifier | 0.616 | 0.624 | 0.621 | 0.803 | 0.446 | 0.578 | 0.308 |
| 18 | Yes | TfidfVectorizer | AdaBoostClassifier | 0.584 | 0.594 | 0.588 | 0.847 | 0.438 | 0.528 | 0.296 |
| 19 | Yes | CountVectorizer | SVC | 0.694 | 0.799 | 0.704 | 0.763 | 0.494 | 0.69 | 0.365 |
| 20 | Yes | TfidfVectorizer | SVC | 0.855 | 0.971 | 0.863 | 0.65 | 0.643 | 0.913 | 0.636 |
| 21 | No | CountVectorizer | LogisticRegression (larger train dataset) | 0.898 | 0.913 | 0.898 | 0.586 | 0.685 | 0.971 | 0.824 |
| 22 | No | TfidfVectorizer | LogisticRegression (larger train dataset) | 0.902 | 0.914 | 0.903 | 0.617 | 0.708 | 0.971 | 0.83 |
| 23 | No | CountVectorizer | MultinomialNB (larger train dataset) | 0.827 | 0.83 | 0.827 | 0.782 | 0.631 | 0.837 | 0.53 |
| 24 | No | TfidfVectorizer | MultinomialNB (larger train dataset) | 0.887 | 0.89 | 0.887 | 0.633 | 0.679 | 0.946 | 0.733 |

# APPENDIX

- 80/20 train-test split

| Model No. | Word Vectorizer | Classifier | CV Score (train) | Accuracy (train) | Accuracy (test) | Recall (test) | F1 score (test) | Specificity (test) | Precision (test) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | CountVectorizer() | LogisticRegression() | 0.898 | 0.913 | 0.898 | 0.586 | 0.685 | 0.971 | 0.824 |
| 2 | TfidfVectorizer() | LogisticRegression() | 0.902 | 0.914 | 0.903 | 0.617 | 0.708 | 0.971 | 0.830 |
| 3 | CountVectorizer() | MultinomialNB() | 0.827 | 0.830 | 0.827 | 0.782 | 0.631 | 0.837 | 0.530 |
| 4 | TfidfVectorizer() | MultinomialNB() | 0.887 | 0.890 | 0.887 | 0.633 | 0.679 | 0.946 | 0.733 |