

# Evaluating Safety Compliance in Clinical Trials by Leveraging Patient Narratives and Deep Learning

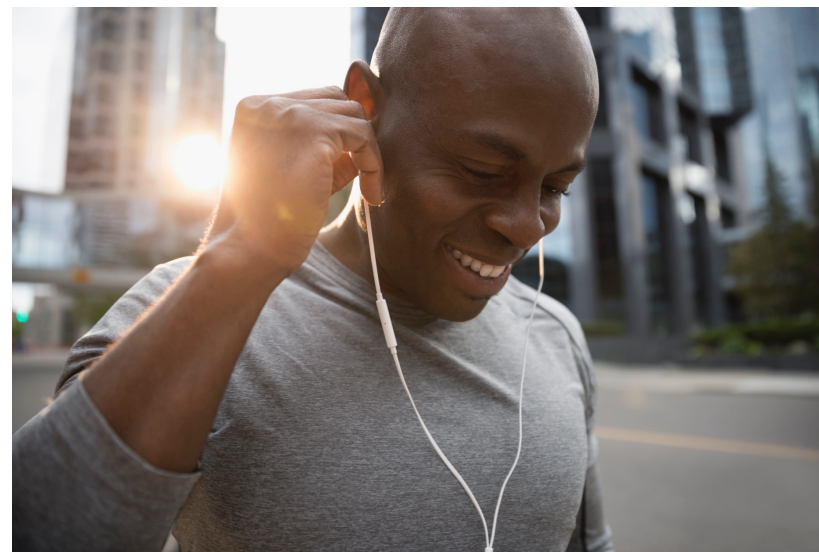
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# Natural Language Processing (NLP) helps accelerate ANALYTIC INNOVATIONS throughout the PHARMACEUTICAL LIFE CYCLE



Clinical Research



Real-World Evidence



Manufacturing and  
Supply Chain



Commercial



# Manual Review is Time-consuming & Resource-intensive.

Clinical Trial  
Narratives

Adverse  
Events

Other  
Healthcare  
Text Data

A photograph of laboratory glassware on a white surface. In the foreground, there are several Erlenmeyer flasks and a beaker. One flask contains a bright green liquid, another a yellow liquid, and a beaker contains an orange liquid. The background is a blurred laboratory setting with warm lighting and other glassware. A thick blue diagonal line runs from the bottom left towards the top right, separating the image from the text area.

Improve Patient-  
centricity &  
effectiveness of  
clinical trials.

# Challenges

Handle structured & unstructured information in an integrated manner

Critical information mixed with supporting details

- Need to identify essential information of interest

Text not directly extractable

- OCR and information extraction techniques (a.k.a. Concepts and Facts)

Data not in chronological order

- Date, time and other positional markers to be leveraged

References to dates and times not explicit

- Derivations based on business rules and logic

Link narrative data to other structured information

- Identify possible anomalies / errors in recording

# Solution Overview

Goal : Timely, accurate, and actionable insights from unstructured data

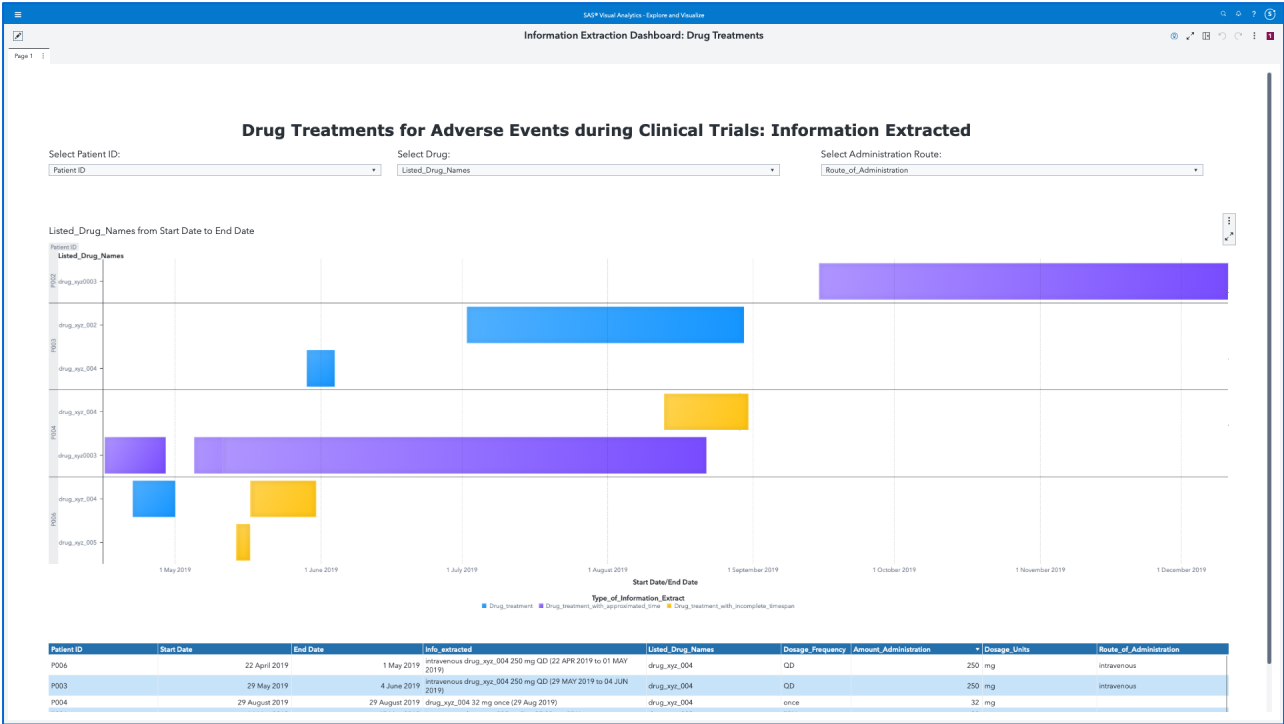


Fact Matches

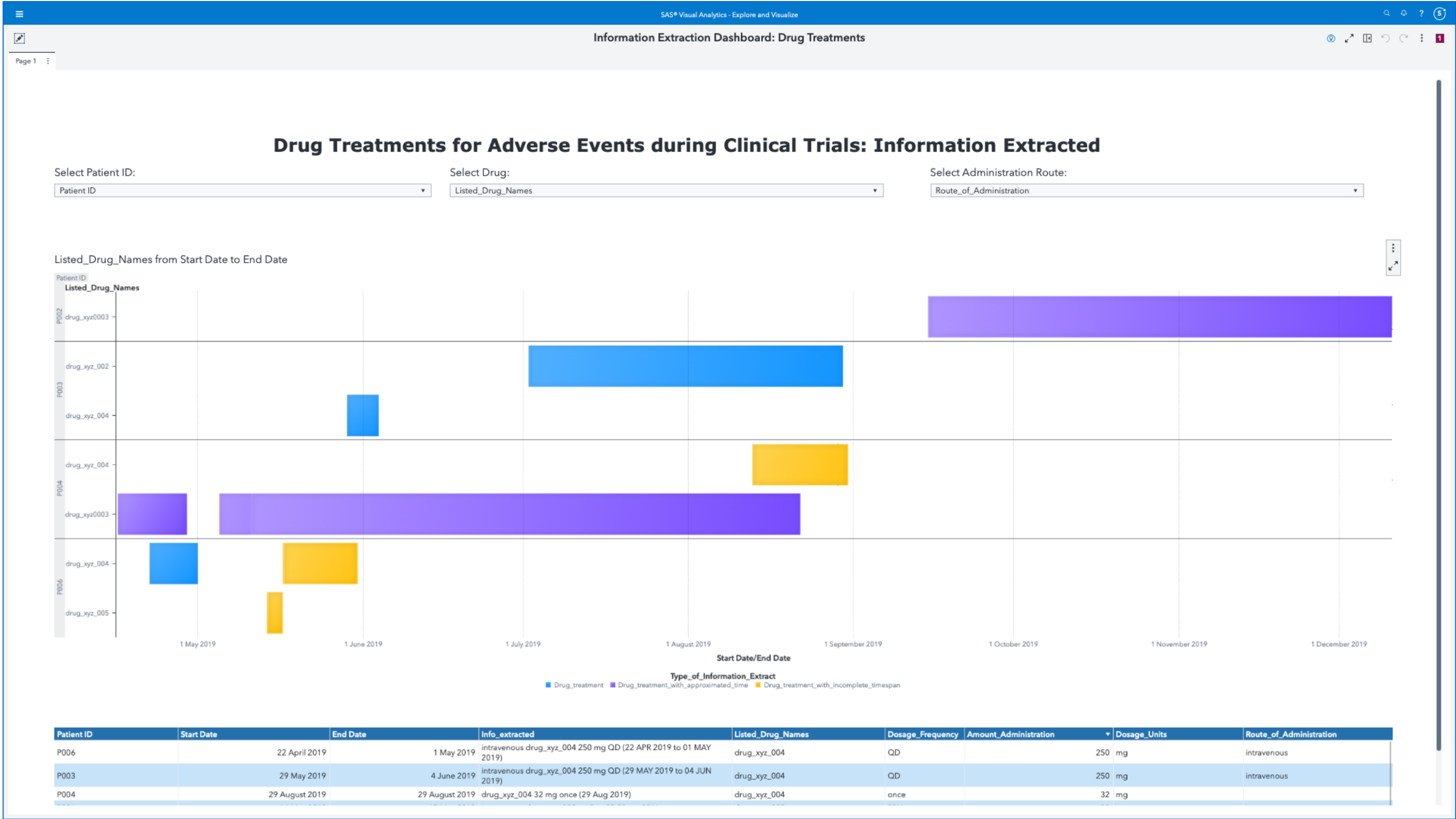
Concept: Treatment\_steroid\_with\_approximate\_time

| # | Matched String                                                                | Matched Label           | Matched Text                 |
|---|-------------------------------------------------------------------------------|-------------------------|------------------------------|
| 1 | Pneumonitis included pravastatin sodium, camostat mesilate, and dexamethasone | symptom<br>steroid_name | Pneumonitis<br>dexamethasone |

Close



# Temporal View for Patients & Procedures



# What is Natural Language Processing (NLP)?

# Scale the human act of reading, organizing and extracting useful information from huge volumes of textual data

- **Make Better Decisions**
- **Go from Data to Decisions Faster.**
- ***Detect emerging trends and hidden opportunities.***
- ***Foster collaboration and information sharing in an open ecosystem.***
- ***Improve analytics workflow with automation.***



# Key Functionality in NLP pipelines

Data Ingestion

Categorization

Information  
Extraction

Topic  
Discovery

Sentiment  
Analysis

Feature  
Engineering

Batch and On-  
demand  
scoring

Decision  
Support

# What is Entity and Fact Extraction?

Capabilities to extract relevant information from text including people, places, and things.  
Provides disambiguation. Goes beyond ctrl-F.

Concept

▼ Predefined Concepts (18)

ADDRESS

COMPANY

CURRENCY

DATE

INTERNET

LOCATION

MEASURE

NOUN\_GROUP

ORGANIZATION

PERCENT

PERSON

PHONE

PROP\_MISC

SSN

TIME

TIME\_PERIOD

TITLE

VEHICLE

▼ Custom Concepts (3)

\_Drugs

Drug\_Distribution

POT\_DIS

Custom Concept > \_Drugs

1 CLASSIFIER: Marijuana

2 CLASSIFIER: Opioid

3 CLASSIFIER: pain pills

4 CLASSIFIER: OxyContin

5 CLASSIFIER: Norco

6 CLASSIFIER: Percocet

7 CLASSIFIER: Adderall

8 CONCEPT: \_w \_w pot

9 REMOVE\_ITEM: (ALIGNED, "\_c{\_Drugs}", "POT\_DIS")

Custom Concept > POT\_DIS

1 CLASSIFIER: a pot

2 CLASSIFIER: a flower pot

3 CONCEPT: a \_w pot

4

Custom Concept > \_Drugs

1 matched string

The suspect was caught with a quantity of pot that he was intending to sell.

The suspect was caught with a stolen pot that he was intending to sell.

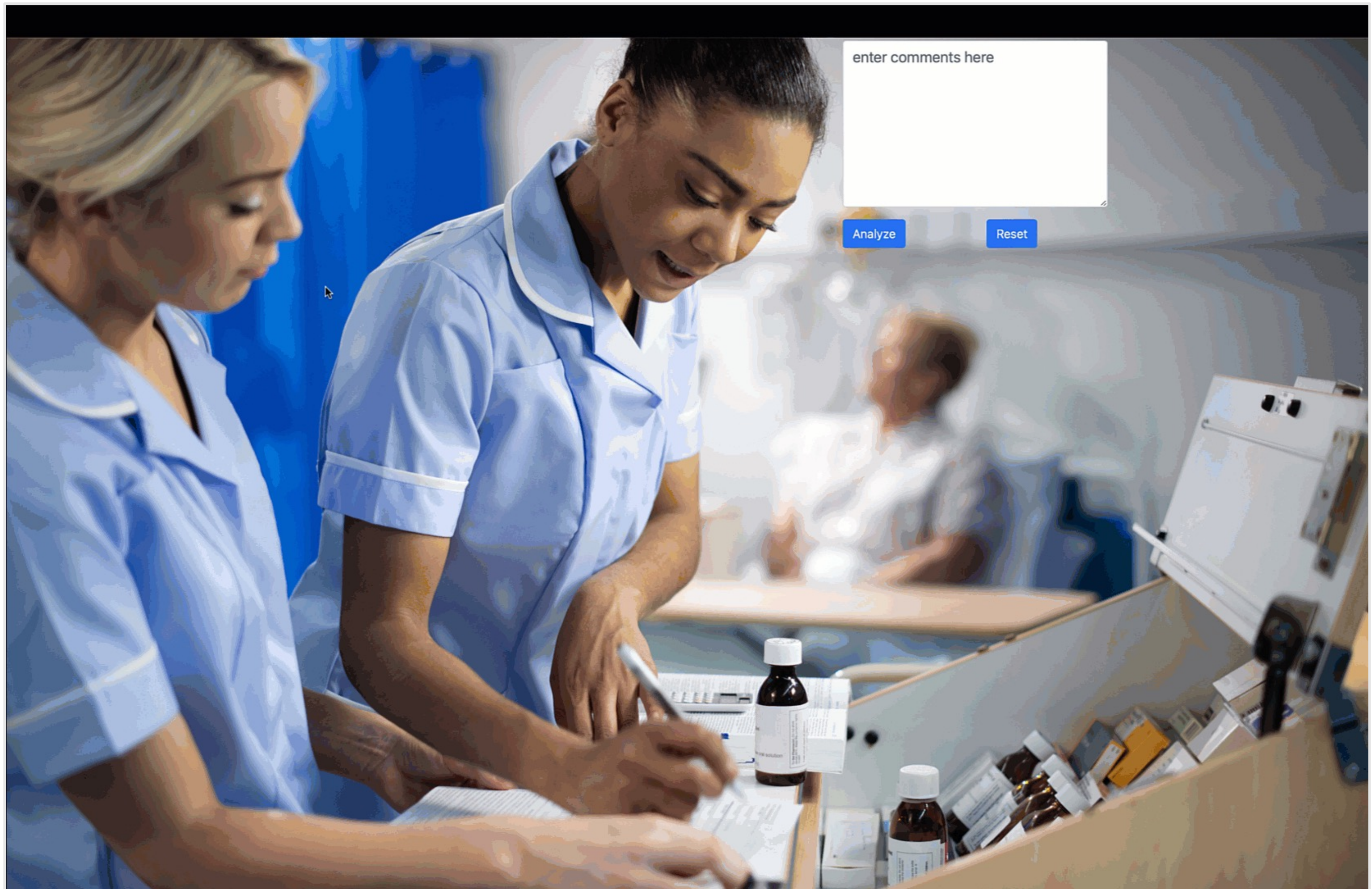
Custom Concept > POT\_DIS

1 matched string

The suspect was caught with a quantity of pot that he was intending to sell.

The suspect was caught with a stolen pot that he was intending to sell.

# Art of the Possible: events generated during a trial



# Entity Extraction: extracting dates from a report

## An example

Concepts

Predefined Concepts (9)

- nlpDate
- nlpMeasure
- nlpMoney
- nlpNounGroup
- nlpOrganization
- nlpPercent

Textual Elements (9316)

Filter

| String    | Role | Fr... |
|-----------|------|-------|
| ▸ receive | V    | 8589  |
| ▸ day     | N    | 6981  |
| ▸ vaccine | N    | 6639  |
| ▸ arm     | N    | 6316  |
| ▸ patient | N    | 5417  |
| ▸ fever   | N    | 4944  |

Documents

Test Sample Text

All (21073) Matched (9913 of 21073) Search

| SYMPTOM_TEXT                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Fact Matc... |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| ...hours after injection. <b>Next day</b> rash spread entire body. Knees locked, feet turned out, arms hurt; no fever; rash now itchy. Rash - denies hives but small red bumps. Denies edema; dyspnea. Refer to PCP.                                                                                                                                                                                                                                                               | 0            |
| ...vaccine who on <b>24May06</b> was vaccinated IM with a 0. 5mL dose of pneumococcal 23v polysaccharide vaccine ( lot 653284/0002P ) . That same day, post immunization, the pt experienced an anaphylactic reaction and was hospitalized. She was treated with epinephrine and diphenhydramine ( Benadryl ) . Subsequently, the pt recovered. Anaphylactic reaction was considered to be an other important med                                                                  | 0            |
| ...SIDS. Per F/U <b>8/13/02</b> : Other conditions: Multisystem ischemia. This is a 2 month old white female who was found unresponsive by her babysitter face-down on a water bed. EMT arrived and the baby was pulseless but subsequently, on transportation                                                                                                                                                                                                                     | 0            |
| ... <b>5/17/05</b> , chest pain <b>5/18/05</b> , red raised rash, sore throat <b>5/19/05</b> , fever <b>5/20/05</b> , vomiting 5/22-5/24, Increased WBC 191200. There are an additional 4 pages of report of consultation. 15 year old was in good health <b>until 5/17/05</b> when he received a tetanus vaccine. Within one hour he developed some mild chest pain. While he went to school <b>the following day</b> , the original chest pain was worrisome and he went to h... | 0            |
| ...history who on <b>12/3/04</b> was vaccinated with a dose of varicella virus vaccine live. The pt was not tested for varicella antibodies before vaccination with varicella virus vaccine live. It was noted that the pt became pregnant within a month of receiving the vaccine. The date of her LMP-12/04 and the EDD-9/11/05. Unspecified medical attention was sought. On <b>3/6/05</b> an u                                                                                 | 0            |
| ...care professional on <b>11/11/03</b> concerning an unspecified number of vaccinees who inadvertently received 1ml of Fluvirin on an unspecified                                                                                                                                                                                                                                                                                                                                 | 0            |

Document 1 of 9913

Highlight: Concept matches Search matches

# Entity Extraction: using Facts to extract Symptoms and allied entities

## An example

✱

📄

🔍

🗑️

?

⋮

Concepts

❏ Dosage\_concept

▶️ ❏ Dose\_units\_list

❏ Extract\_Dose\_Details

❏ Extract\_Dose\_Details\_Day

❏ Fact\_Allergies\_Allergens

❏ Fact\_Symptoms\_Anatomy

❏ Hospitalization\_Indicator

Textual Elements (9316)

🔍 Filter

🗨️

📄

✱

|                          | String     | Role | Fr... |
|--------------------------|------------|------|-------|
| <input type="checkbox"/> | ▶️ receive | V    | 8589  |
| <input type="checkbox"/> | ▶️ day     | N    | 6981  |
| <input type="checkbox"/> | ▶️ vaccine | N    | 6639  |
| <input type="checkbox"/> | ▶️ arm     | N    | 6316  |
| <input type="checkbox"/> | ▶️ patient | N    | 5417  |
| <input type="checkbox"/> | ▶️ fever   | N    | 4944  |

Edit ConceptSandbox

Fact\_Symptoms\_Anatomy

1 PREDICATE\_RULE:(symptom,anatomy):(AND,(ORDDIST\_5,"Symptoms\_Identified","Anatomy\_Area"),(SENT,"\_symptom{Symptoms\_Identified}","\_anatomy{

✔️ Code is valid

DocumentsTest Sample Text

All (21073)Matched (411 of 21073)Search

| SYMPTOM_TEXT                                                                                                                                                                                                                                                                                                                                                                                                                           | Fact Matc... |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| ...Client developed a rash over her arm and stomach. Private doctor treated patient for allergic reaction to flu shot and recommended no flu shots in the future.                                                                                                                                                                                                                                                                      | 1            |
| ...cold massage. Had swelling in neck and arm on and off. Saw MD who advised to report. Pain eased on 5th day but still has not resolved. Also noted a "pulling" sensation in shoulder like muscle spasm.                                                                                                                                                                                                                              | 1            |
| ...began having pain, redness and swelling of upper Left arm and fever of 100. Mom gave tylenol and cool compresses. Swelling and redness were worse on 5-10-06 involving area from shoulder down to elbow-area was also hard, so they went to Nurse Practitioner. Temp in office was 98. 9. Told to continue tylenol around the clock while child was awake and to add ibuprofen if fever went up and that if fever became high or... | 2            |
| ...had red and swollen upper arm; hot; 10cm X 8cm; not very tender. It ok.                                                                                                                                                                                                                                                                                                                                                             | 1            |

Document 1 of 411

Highlight: Concept matchesSearch matches

Model Studio - Build Models

VAERS Text Analysis

Data

Pipelines

Pipeline 1

+

Run pipeline

Name: Data

Group: Data

Status: Successful

Description: Prepares the input data for use within the pipeline.

Data

Text Parsing

VAERS\_Concepts

Categories

Description:

Prepares the input data for use within the pipeline.

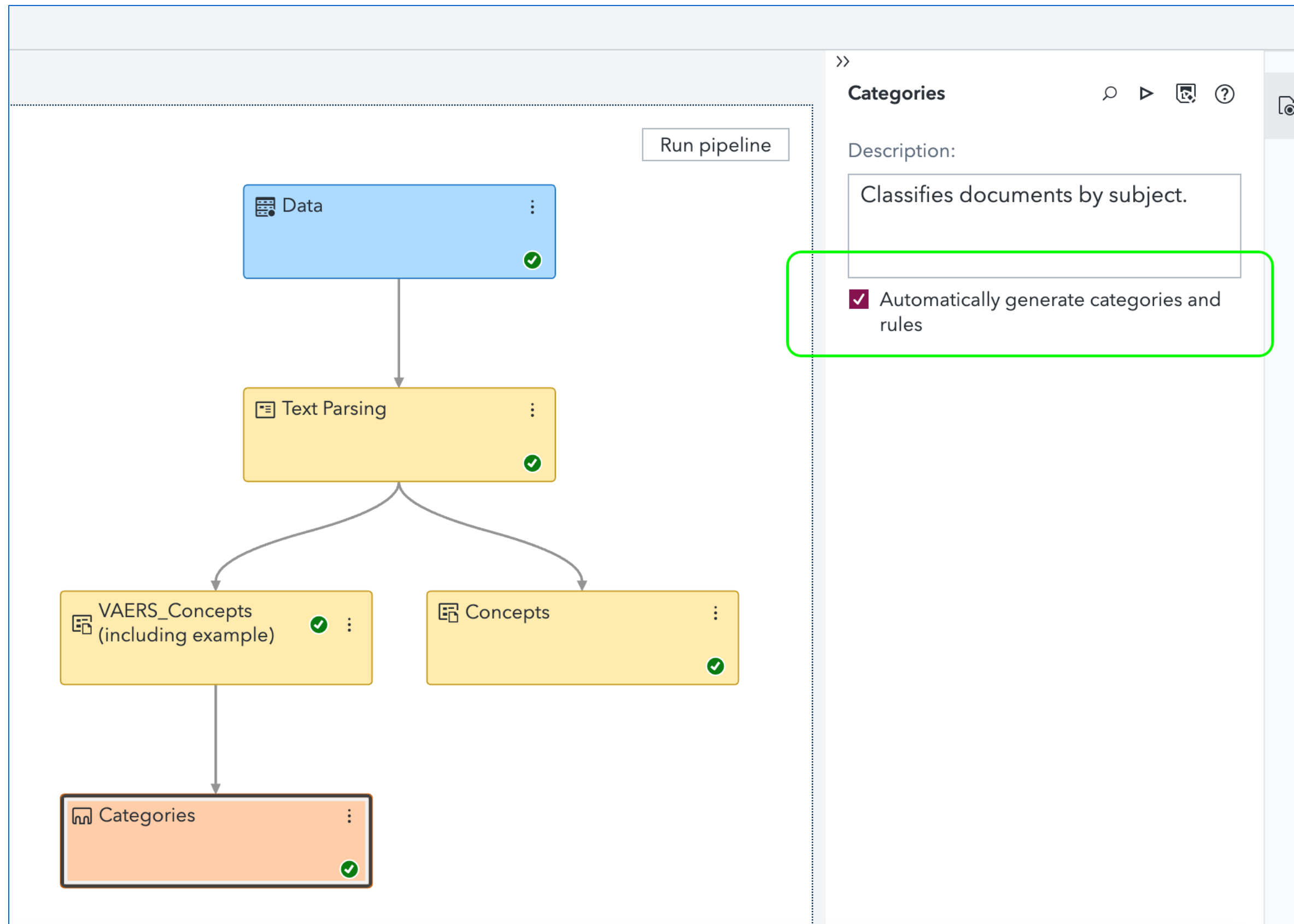
Language:

English

☐ Subset data using selected language

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# Automatically extract rule components



# Use Machine Learning (ML) to scale

The screenshot displays the SAS Studio interface for the 'NLP - Train Text Classifier' step. The left sidebar shows the 'Steps' panel with 'NLP - Train Text Classifier' selected. The main panel shows the configuration for this step, including training, validation, and test tables, input parameters, and advanced parameters. The 'Results' tab is active, showing a table of results from the `textClassifier.trainTextClassifier` process.

**Configuration:**

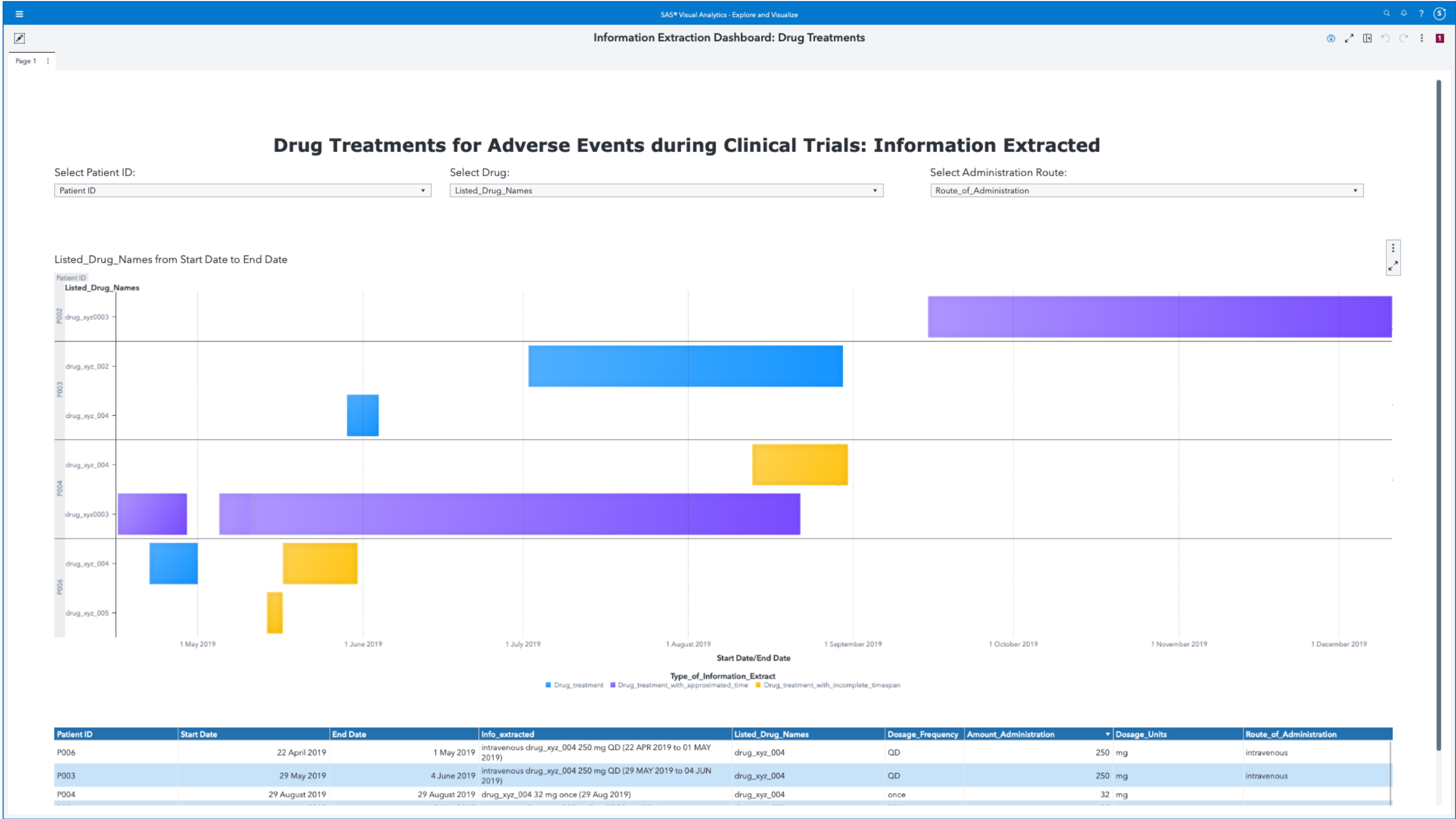
- Training table: PUBLIC.PHONE\_TRAIN
- Validation table: PUBLIC.PHONE\_VALIDATE
- Test table: PUBLIC.PHONE\_TEST
- Input parameters:
  - Select text variable: Text\_Review
  - Select target variable: Target\_Rating
  - ☒ Enable GPU
  - Specify GPU device ID (max 1):
- Advanced parameters:
- Model output table: PUBLIC.PHONE\_REVIEWS\_MODEL

**Results from textClassifier.trainTextClassifier:**

| Epoch | Train Loss   | Train Accuracy (%) | Validation Loss | Validation Accuracy (%) |
|-------|--------------|--------------------|-----------------|-------------------------|
| 1     | 1.7583791018 | 27.669346333       | 1.3479747772    | 43.065693974            |
| 2     | 1.2211405039 | 47.646382451       | 1.1338282824    | 53.649634123            |
| 3     | 0.8859422803 | 65.327209234       | 1.085164547     | 55.109488964            |
| 4     | 0.6412992477 | 79.104477167       | 1.1084274054    | 56.569343805            |

**Test Accuracy (%)**  
74.784482759

# Visualise extracts through reports & dashboards



# Thank you

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