



Enhanced Safety Signal Analysis Using Natural Language Processing

PHUSE Americas Winter Single Day Event

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Manual Review of

- Adverse Event Narratives,
- Clinical Summaries, or
- Other Unstructured Signal information

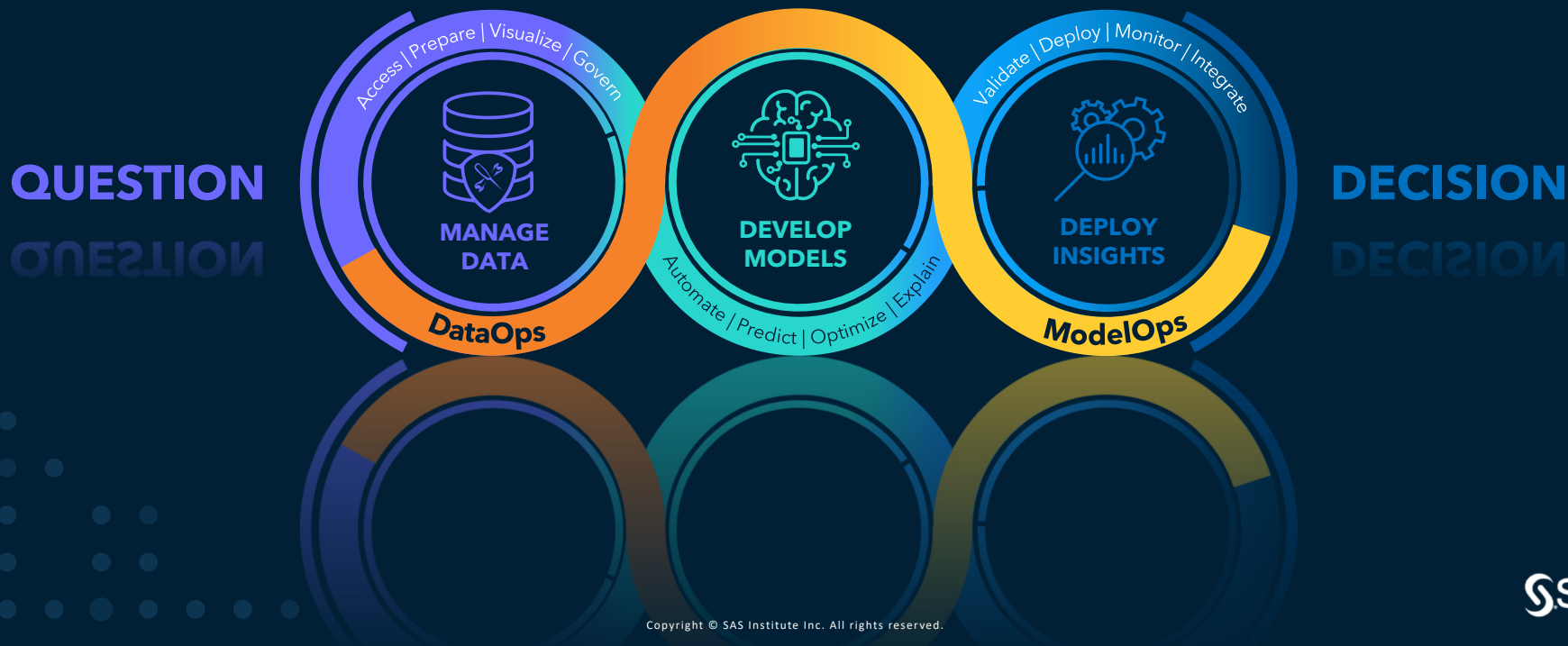
is Time-consuming & Resource-intensive.



Improve Speed,
Accuracy, and
Interpretability
of Unstructured
Safety Signals.

Faster Time to Value through the Analytics Life Cycle

Benefit from a unified analytical platform



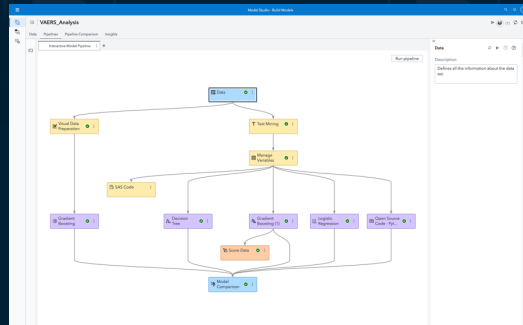
Main process

Feature Engineering

Models and iterations

Assessment & Buy-in

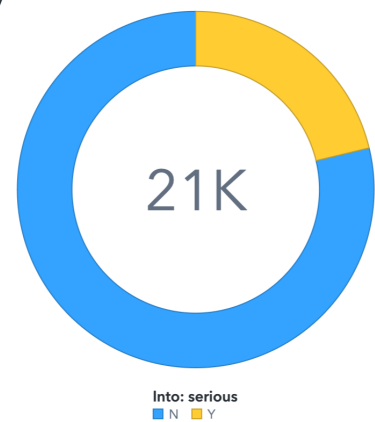
Inference



X Axis: Score for "+admit, icu, +hospital, hosp, +observation"
 Y Axis: Probability for serious=Y
 Correlation: 0.4135
 Relationship: Moderate

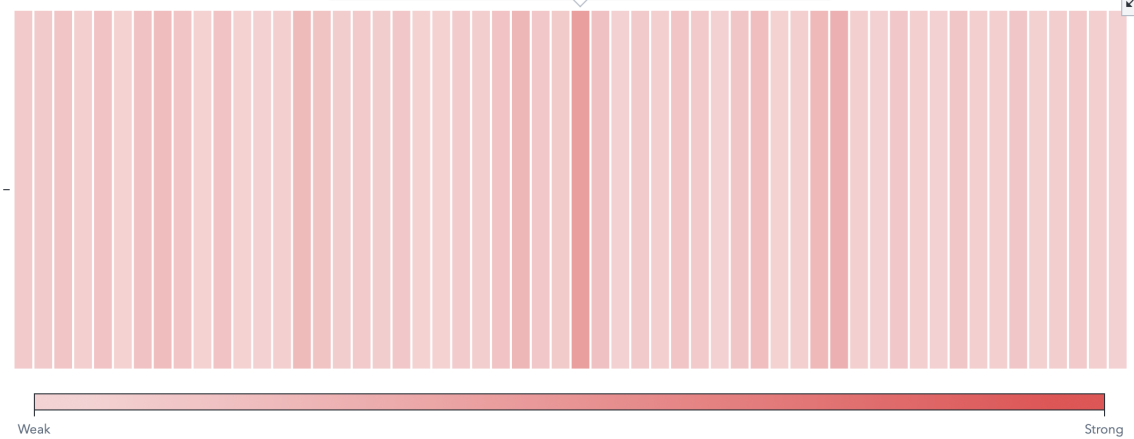
Predicted Classification

Frequency



Feature Strength

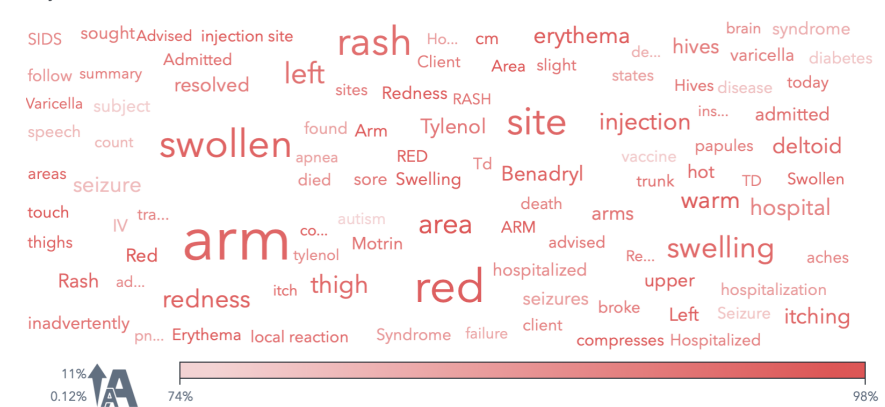
Probability for serious=Y -



Adverse Events Reported

ID	SYMPTOM_TEXT	Pro Cla
8576	Fever 7-10 days after Immun with rash approx (3-4) on face, diaper area, Varicella like rash at 12 days.	
14...	Red, warm rash appeared over both buttocks with wheal formation pt seen on 09/20/2005 and 10/03/2005 improved with Benadryl, Zyrtec.	
28...	4cm red, raised, warm area at site of DTaP injection. Right deltoid muscle.	
11...	Itchy papular rash minimally but mostly on chin occurred several hours after vaccination. Rash resolving. On day 2 after immunization, rash resolved.	
5924	Per mom, child had elevated temp with swollen area on leg at either 2 or 3rd dose. 4th dose given 7/7/03, per mom entire right thigh is warm, red and swollen, noticed on 7/8/03. No elevation of temp. Advise warm compresses to area.	
11...	Fever 102 degrees to 104. 5 degrees starting 6 hours after lasting 5 days. Systemic confluent erythematous rash starting 4 days after vaccine.	
13...	Rash noted on leg x 1 day, pink, red and lg macular area mildly sensitive to touch, pt place on Benadryl and schedule follow up visit in 2 days.	
21...	1) Slight fever; 2) Left arm red, itchy, sore, warm to touch; 3) Tylenol, ice to site; 4) Benadryl;	
17...	Experiencing some "fussiness" and a bruise with redness at injection site right deltoid area where DTaP administered. Bruise and redness 3+ inches per mother per telephone call. Mother did not feel necessary for MD follow-up, will monitor child arm.	
	Patient woke up 2/11/06 AM with 2 small areas (about 1.5" diameter) , outlined with redness, centers had blotchy redness. No	

Keywords Matched



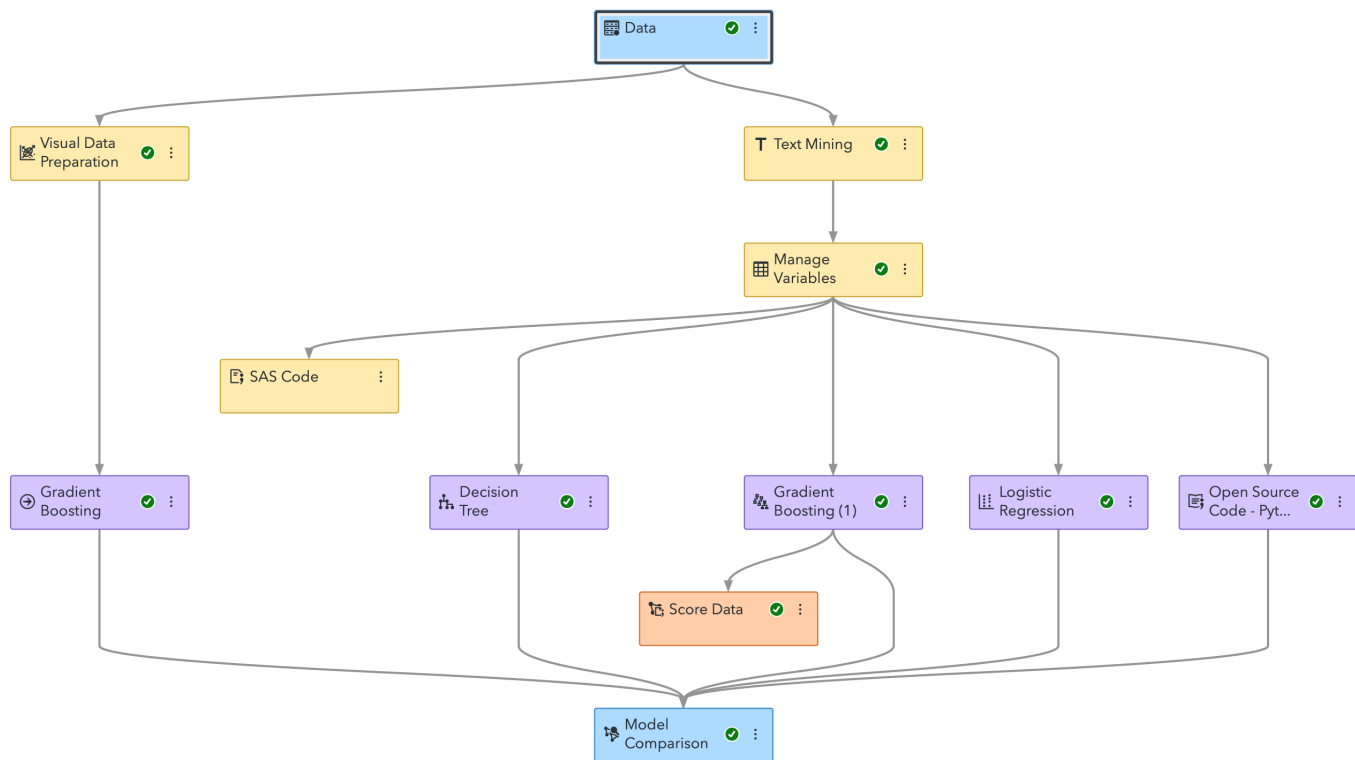
Topic Name	Document Count
+fever, +hour, +seizure, +day	3100
+thigh, erythema, left, redness	2900
swollen, +red, +arm, +touch	2600
+injection, +site, +injection site, redness	2400
+dose, +vaccinate, +virus, +information	2300
vaccinee, fluvirin, +report, +receive	1600

Topic Relevance	Document
0.3588	2 hours after immunization, fever of 104 for 2 days.
0.3285	Pt received DTaP, IPV, Comvax and 6 hrs later developed fever to 103 deg F and seizures. No rash. Was taken to hospital and then admitted to hospital.
0.3195	Fever X 5 days
0.3195	Fever for 3 days.
0.3187	Seizure, developed fever 11/09/2004

[illegible]

Interactive-Model Pipeline

Run pipeline



>>

Data

Description:

Defines all the information about the data set.

VAERS Text Analysis > Categories

Run node

Close

Categories

✖ All Categories (5)

▸ I_serious

▸ serious

▫ N

▫ Y

Textual Elements (9312)

🔍 Filter

	String	Role	Frequency
☐	▸ receive	V	8589
☐	▸ day	N	6981
☐	▸ vaccine	N	6637
☐	▸ arm	N	6316
☐	▸ patient	N	5417
☐	▸ fever	N	4944
☐	pt	N	4631
☐	▸ injection	N	4568
☐	▸ hour	N	4543
☐	▸ site	N	4504

Edit Category

serious > Y

▼ OR

▼ AND

▼ OR

"admitting"

"admits"

"admitted"

"admit"

▼ AND

▼ OR

"hospitalizes"

"hospitalized"

"hospitalize"

"hospitalised"

▼ AND

"death"

▼ AND

▼ NOT

Documents

Test Sample Text

All (21073)

Matched (5673 of 21073)

Search

SYMPTOM_TEXT

Releva... ↓

...pt had 6 **seizures**, after MMR shot, and **stopped** breathing after the 1st **seizure**. Gave **CPR** and taken to the **hospital**. He has severe **speech**, language and reading learning disabilities. He has been dx'd as having a **brain** injury when he was very young. It could have been from a lack of oxygen in his **brain** after **seizures**. Doc 211185 **states** the **following**: due to lack of oxygen, **seizures**, he gets **brain** injury. Annual **follow** up **states** **patient** had a **brain** injury due to lack of oxygen after **seizures**

39.000

... **subject** is a one year old female, who was **admitted** to the **hospital** due to systemic inflammatory response **syndrome** while enrolled in a Phase **IV** Daptacel study. The **subject** received one dose of Daptacel **vaccine**: along with other pediatric **vaccines** on 3/17/03. The **subject** developed symptoms 65 days post immunization and was **admitted** to the

32.000

Safety Signal Analytics from different sources

Adverse Event Classification

- Spontaneous reporting -> pharma -> regulators
- Better First Pass Yield : correct tagging at source
- Improved reviewer productivity
- Accurate, context-based data capture
- Faster time to decisions, recommendation and tracking

Literature review

- Relevant insights through Knowledge graphs
- Recommendation-enabled research
- Enhanced quality of insights through visualizations

Safety Signal Analytics

Clinical Safety Trials

- Automated narrative generation
- Data Quality & Protection
- Accurate data capture and ingestion – OCR, multiple document formats
- Event-wise & Progressive Analytics
- Anomaly detection & threshold-based alerts
- Repurposing – safety assessment

Other sources

- Social listening
- Compliant and focused regulatory reporting
- Data unification
- EMR analysis
- Provider-level issues

A series of horizontal bars of varying lengths and colors (teal, blue, and dark blue) are arranged vertically on the left side of the slide, creating a decorative, layered effect.

Thank you

Questions

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