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Agenda

- **Introduction**

- **Data Modernization: Framework**

- **Case Study: Unlocking Health Insights and Driving Actionable Intelligence**

- **Future State**

- **Closing**

Guidehouse Data Modernization Framework

Next Generation Tools to Accelerate Data Actions — 5

- Innovate with data for AI/ML
- Predictive Analysis
- Utilize cloud-based AI/ML tools for structured and unstructured data
- Drive real-time communication of data and results

Data Modeling & Visualization to Unlock Health Insights — 4

- Data Modeling/ Visualization
- Discover Trends
- Strengthen analytics, forecasting & Data-Driven Decisions
- Drive real-time communication of data and results

Integrate Data Using Cloud-Based Services — 3

- Integrate and use structured & unstructured data
- Integrate data from new & non-traditional sources
- Implement data storage compliant with data standards
- Leverage Cloud-infrastructure for shared data access & usage

Improve Sharing, Data Standards, Policies — 2

- Expand data governance
- Leverage Data Standards
- Improve Data Sharing via Common Data Models, Policies, Practices, Standards
- Reduce Data Use Agreement Heterogeneity

Improve Data Quality, Security & Interoperability — 1

- Data Harmonization
- Data Interoperability
- Data Security
- Data Ingestion
- Reduce Data Redundancy
- Eliminate Data Voids

Strengthen Client Data Science workforce →

Guidehouse Analytics Pipeline

Advance Analytics

Visualization

LOB

Business Intelligence

Reporting/Dashboarding

Data Mining

Robotic Process
Automation
Data Driven
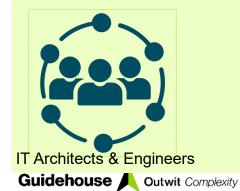Decisions
Forecasting

Data Analysis

Data scientist   SME

Data Wrangling

Explore → Organize → Enrich → Correlate → Validate → Share

Digital Twins
GIS Analytics
Natural Language
Processing
Predictive Analytics

Infrastructure

IT Architects & Engineers

Ingest Massive Amount of Data

Business Data

Machine Generated Data

Third Party Data

3rd party data

Machine Learning
Deep Neural Network

Cloud (AWS/Azure) and/or On-Premise Data Platform

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Case Study

Question

- Can we unlock valuable data, accelerate data usage to *Drive Actionable Intelligence* from vaccine adverse event data

Methodology

- Identify changes in reported Adverse Events following increased immunization of US population
- Understand Adverse Event trends by demographics and co-morbidities
- By leveraging knowledge graphs/nearest neighbor analysis, gain better understanding of Adverse Events commonly reported among other licensed vaccines

Outcome

- Health Insights into adverse events reported following immunization that benefit future monitoring of vaccine safety, patient care, clinical trial design and vaccine design

Background/Context

Vaccines (including COVID-19 vaccines) elicit much needed protective immune responses against foreign pathogens but are not without complexity
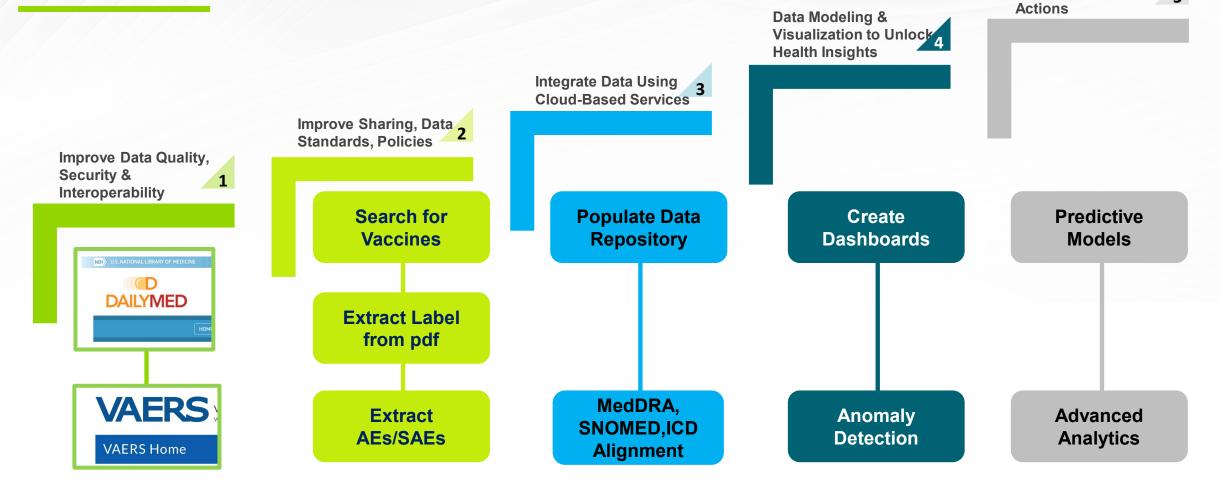
- Variety of vaccines (recombinant proteins, viral vectors, live attenuated, nucleic acid etc.)
- Different mechanisms of actions (Antibody, T-cell, Innate immune cell responses, combination)
- Different adjuvant formulations and delivery strategies (IM, ID, SC, IN, electroporation, nanoparticles etc.)
- Variable safety and efficacy across different demographics, co-morbidities, etc.
- Supply chain/cold-chain complexities

**Building blocks are in place to monitor medical product safety
post-market (e.g., <u>VAERS</u>, FAERS, MAUDE, Sentinel, BEST, NEST)**

**Existing AI/NLP tools can enhance capability for ensuring
the safety and effectiveness of new vaccines**

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Methodology/Data Flow

Improve Data Quality, Security & Interoperability 1

Improve Sharing, Data Standards, Policies 2

Integrate Data Using Cloud-Based Services 3

Data Modeling & Visualization to Unlock Health Insights 4

Next Generation Tools to Accelerate Data Actions 5

NIH U.S. NATIONAL LIBRARY OF MEDICINE
DAILYMED
HOME

VAERS
VAERS Home

Search for Vaccines

Extract Label from pdf

Extract AEs/SAEs

Populate Data Repository

MedDRA, SNOMED,ICD Alignment

Create Dashboards

Anomaly Detection

Predictive Models

Advanced Analytics

Adverse Event (AE) – Mapping to MedDRA Code PSEUDO-CODE

Takeaways

- Using latest advances in AI/ML/NLP to improve analysis of regulatory dictionaries
- Subject Matter Expertise (semantic languages and ontologies) is critical to perform this analysis

Methodology

Import the complete list of **adverse events** with their CUI numbers (derived from MedDRA, SNOMED, ICD, and NMLS Metathesaurus)

Clean the text from the "master" file and generate word vectors (i.e., word embeddings) for each term using spaCy large model, which is a convolutional neural network (CNN) trained on written text

Clean and **loop through the input file** adverse events

Compare the list to the 'master' list:

- If an exact (literal) match is found, store the matching CUI number and MedDRA term
- If an exact match is not found, store that term and move to the next term

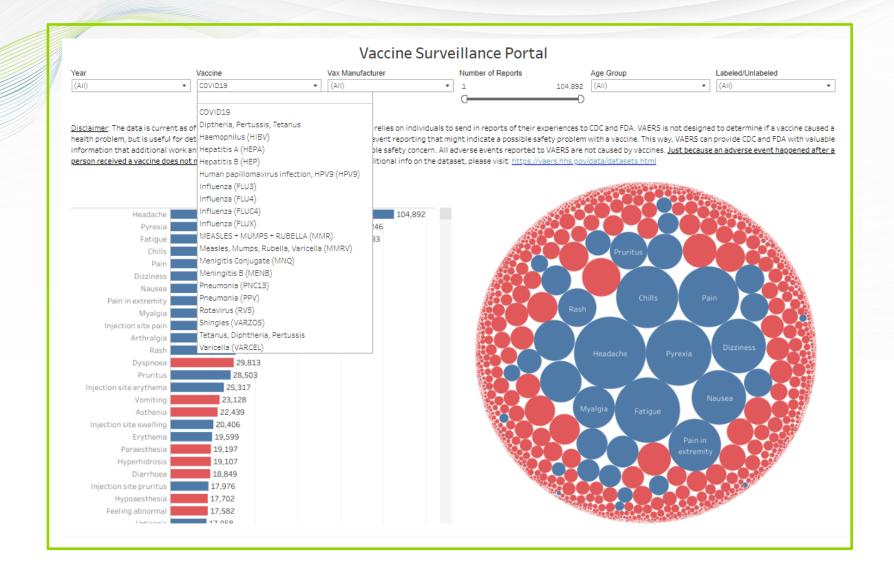**Loop through the terms** without matching literals:

- Vectorize that term and compare against the master list of word vectors
- Find the term with the highest similarity score (cosine similarity)
- If the similarity score meets or exceeds the "similarity threshold" (user-defined, e.g., 75%), store that term and CUI number
- If not, leave that term blank to investigate after the script completes

Output the results file to a CSV file with the CUI number and MedDRA term (if found and if met threshold) and the similarity score.
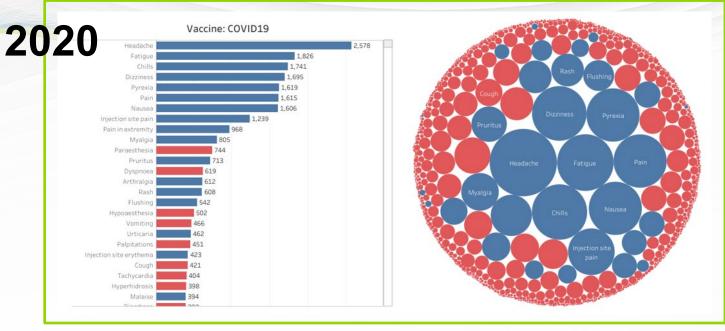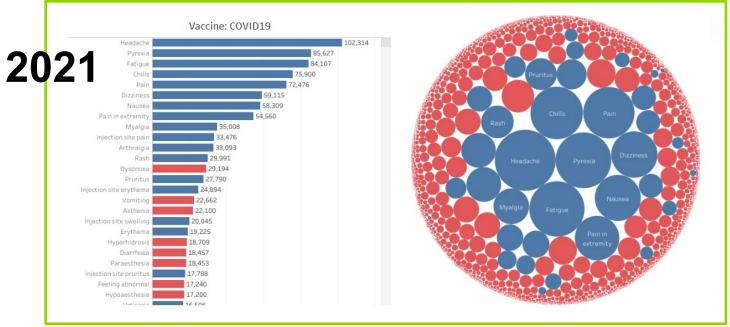
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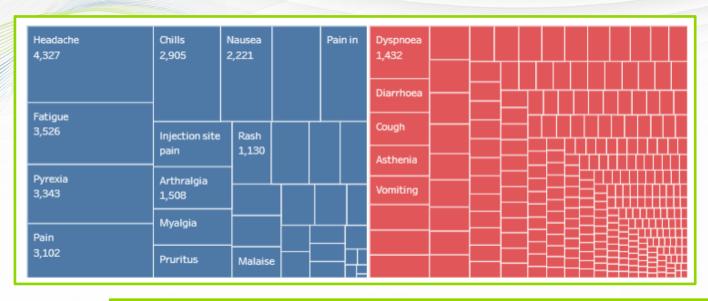# Vaccine Surveillance Dashboard

Monitoring of Adverse Events Reported Following COVID19 Vaccination

2020

2021

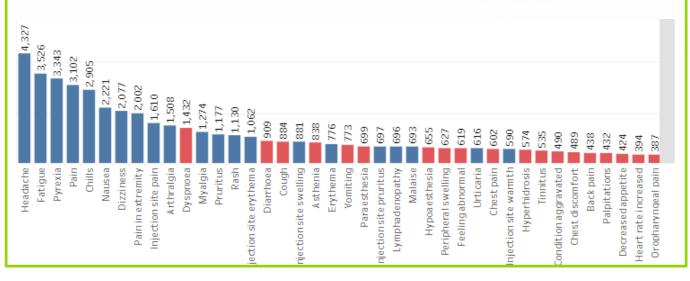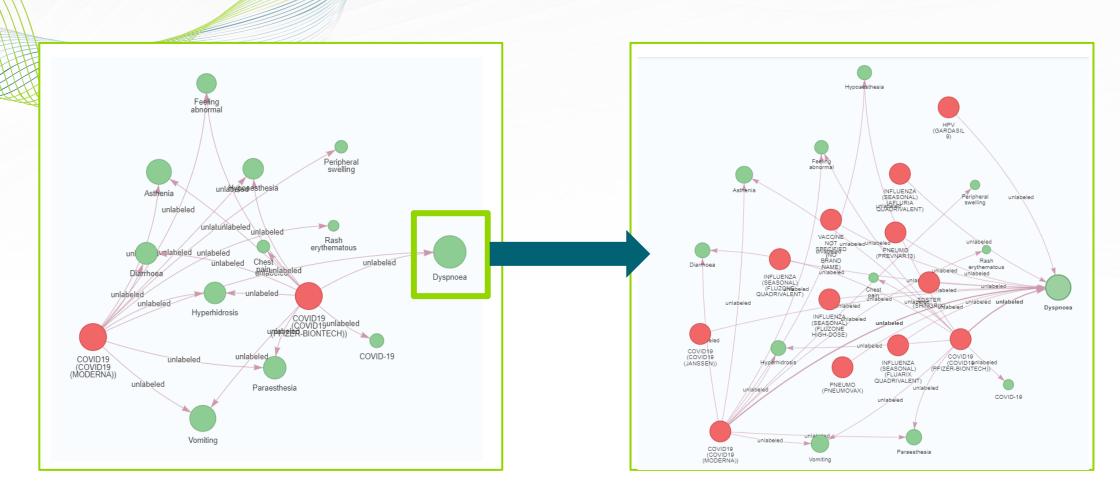# AEs Reported from 50 – 64-year-old Vaccinees with Specific Co-morbidities (High Blood Pressure, High Cholesterol, Obesity)
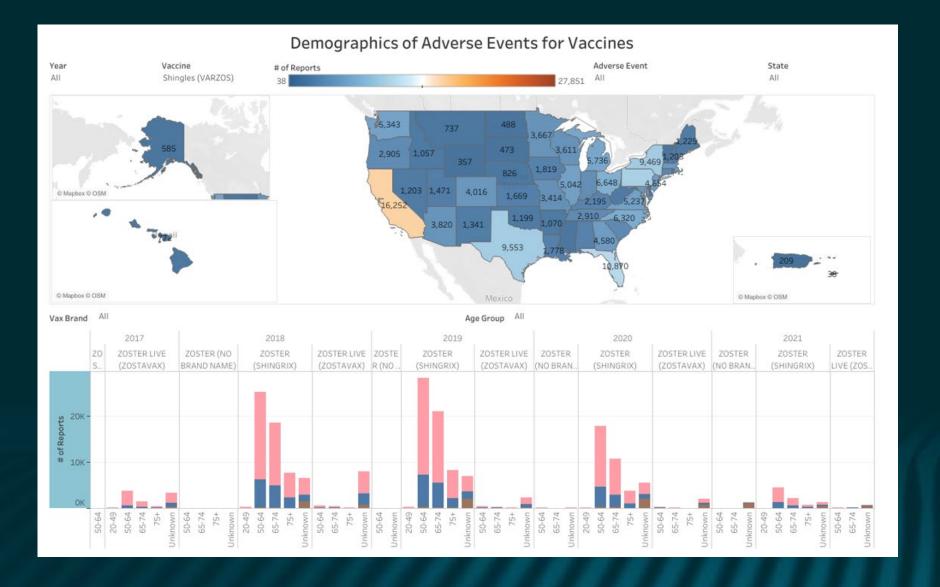
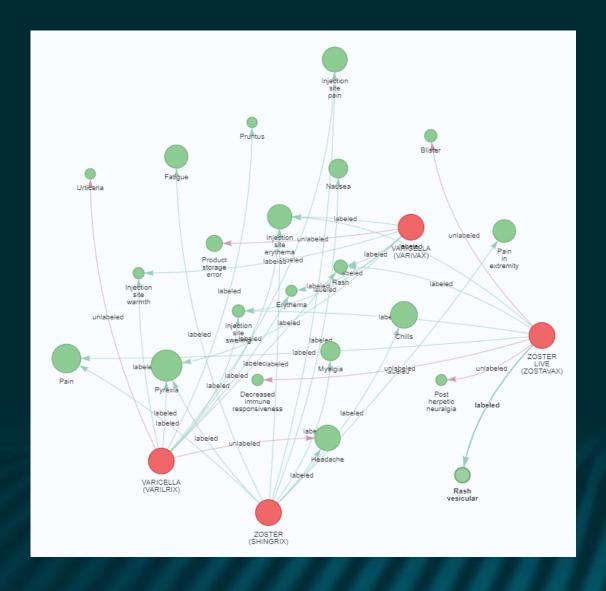# Nearest Neighbor Analysis Reveals other Licensed Vaccines with Reported Dyspnoea Following Immunization

Monitoring of Adverse Events Reported Following Shingles Immunization by Demographics & US Geographic Distribution

Demographics of Adverse Events for Vaccines

Identifying Commonly Reported Adverse Events Following Immunization with Varicella Zoster/Shingles Vaccines

Driving Actionable Intelligence

Data modernization/Data science tools can help drive

- o Real-time surveillance for faster, scalable responses to emerging threats and outbreaks

- o With the identification of risk, safety and efficacy biomarkers, greater health insights will be achieved for clinicians, patients, industry and regulatory agencies

- o Correlation of STLT data will aid faster detection of healthcare inequities and promote more equitable outcomes

- o Trending and predictive analysis will inform public health policies to improve care at the STLT levels

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Thank you

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