

The effectiveness of automation technology in identifying potential adverse events in common safety data sources

*Based on IQVIA Vigilance Detect
performance results 2018-2022*

Marie Flanagan



About the Presenters



Marie Flanagan

Director, Offering Management, Vigilance Detect

Areas of expertise

Marie has 17 years' experience in PV operations, strategy and consulting. In her tenure, she has held various leadership positions in PV operational management, the integration of safety technology and services and the strategic expansion efforts of IQVIA's pharmacovigilance department. In her current role, she supports the evolution of safety risk identification technology in response to evolving industry needs.

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Education

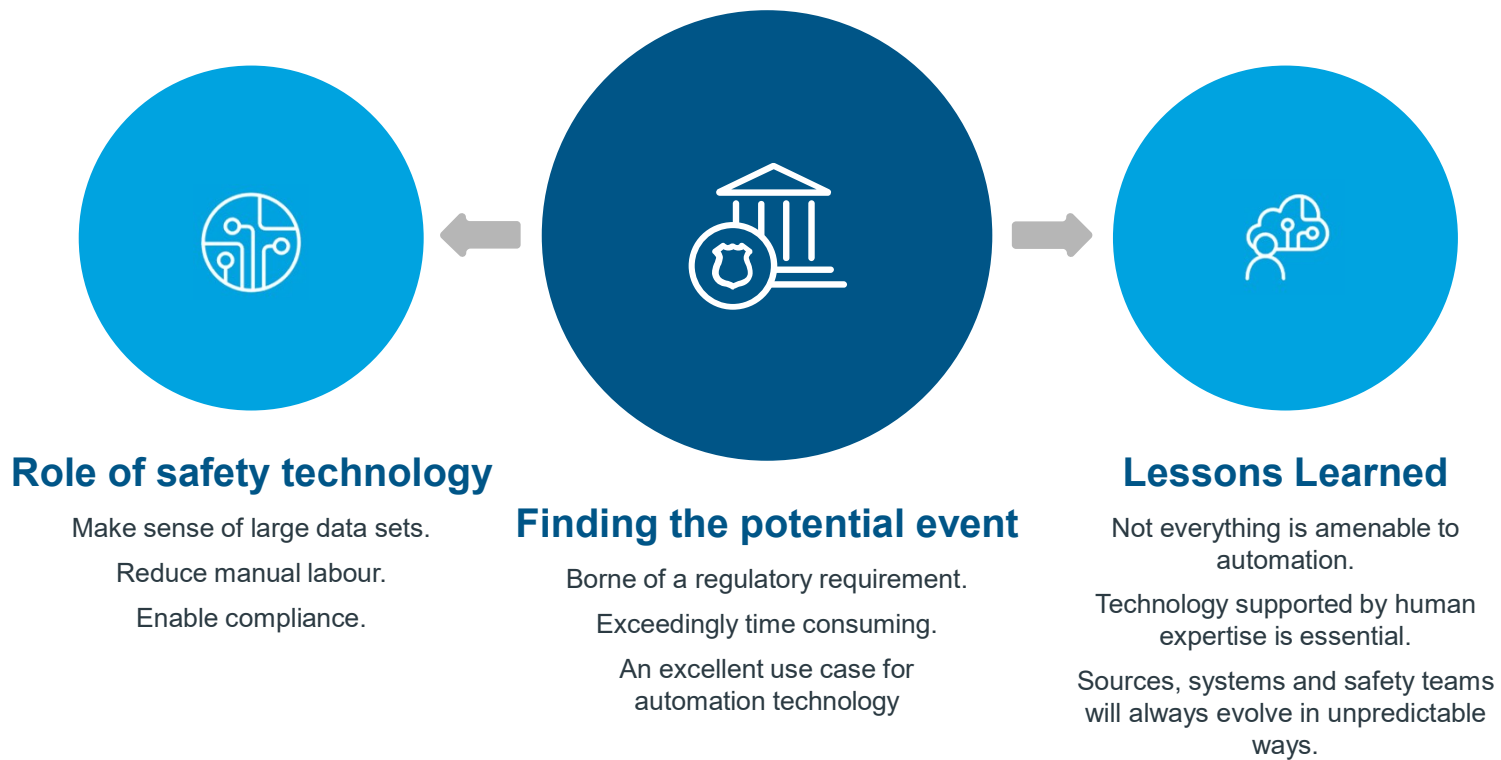
Marie earned a Master's of Science with first class honors from University College Cork, Ireland.



Agenda

- + The application of technology in identifying potential safety risks
- + Results
 - A look at effectiveness of safety risk identification technology across various source types
- + Conclusion

Finding risks in large data sets



Regulatory requirements drive the need for safety risk identification



Marketing authorization holders must:

- Comply with Adverse Event (AE) regulatory reporting requirements.
- Regularly screen the internet or digital media under their management or responsibility for potential reports of suspected AE.
- When aware of relevant information from other source, they should review for reportability.

EUROPE

EMA

European Medicines Agency

UK

MHRA

Medicines and Healthcare products Regulatory Agency

USA

FDA

Food and Drug Administration

JAPAN

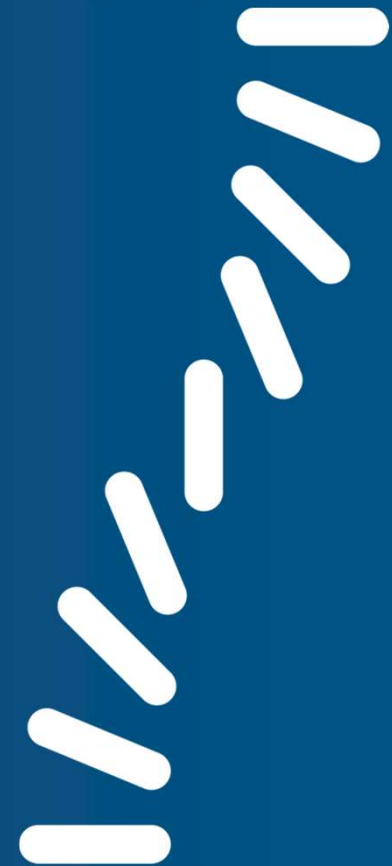
PMDA

Pharmaceuticals and Medical Device Agency

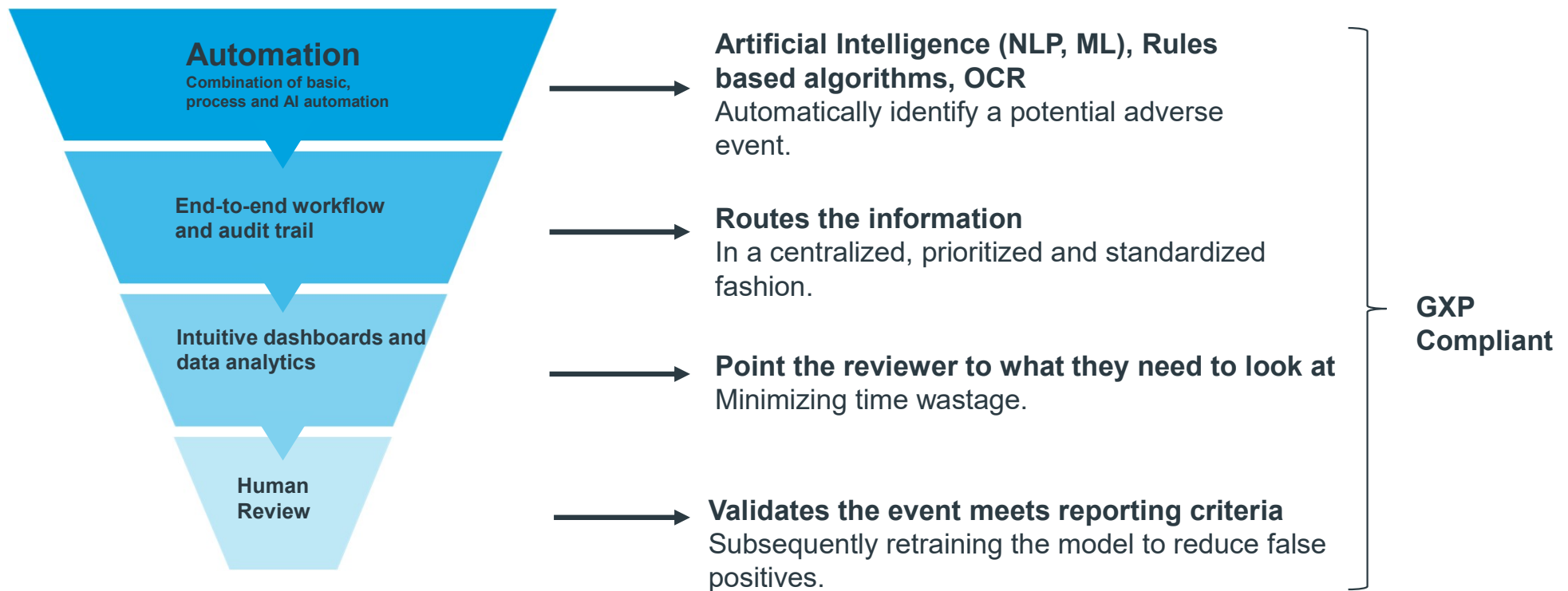
Results

*A look at effectiveness of
safety risk identification
technology across various
source types*

*Based on anonymized IQVIA Vigilance Detect cumulative
data from varying time ranges 2018-2022*



Key components of a successful tech-enabled solution



The sources



Social and Digital Data

- Company-owned handles and public social media campaigns e.g., Facebook, Twitter, Instagram, Reddit, YouTube, TikTok etc.
- Data from Apps and wearables.



Virtual AI Agent

Person: chatbot, AI agent interactions for the presence of adverse events.



Patient Support

Multiple formats, structured and unstructured data arising from patient programs.



CRM

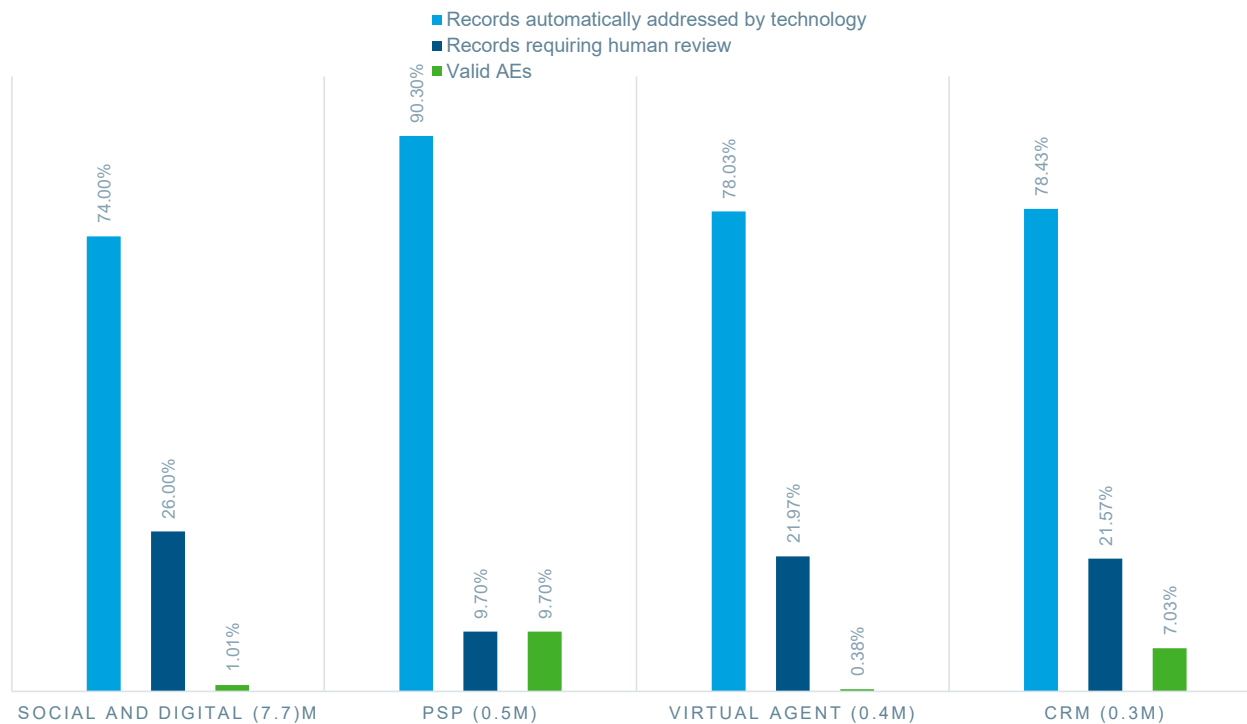
Remediation and retrospective review of data residing in CRM.

% technology vs human intervention in identifying safety risk?

Technology vs human intervention in identifying safety risk

“The whole is greater than the sum of its parts”

TECHNOLOGY VS HUMAN INTERVENTION



Virtual Agents and CRM sources utilize **similar** solution components with similar results.

PSP and Social Media use **varied** solution components to maximize results.

Technology tips the balance over human review in addressing volumes in all sources.

Virtual AI Agents and CRM {Case Study}



78%

Technology (Automation: Artificial Intelligence)

Solution embedded with robust safety specific patterns.

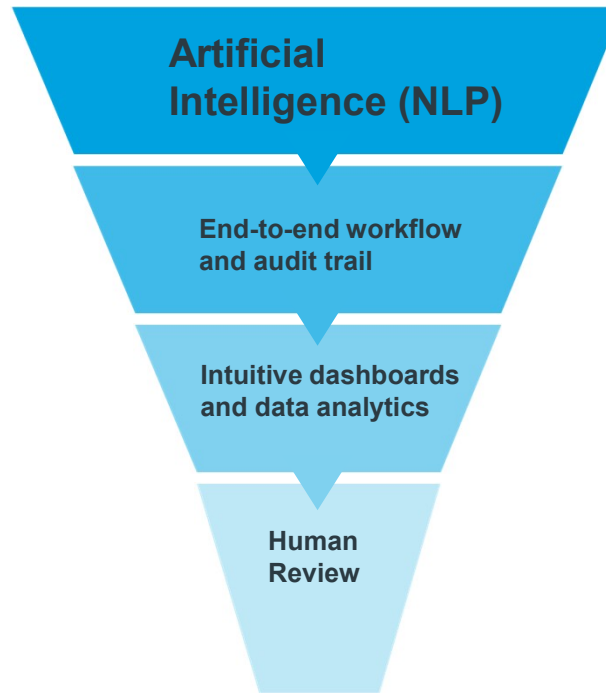


22%

Human Review

Identified valid safety events from false positives.

Assisted machine learning.



Rapid identification of valid safety events



CRM and Chatbots

are a clear-cut use case for AI/NLP:

Structured, leading questions (chatbot)
Trained personnel entering data (CRM).

Leverage basic process automation/workflow but to a much lesser extent to achieve efficiencies.

With all sources, human review is required.

CRM Data Based on 0.3M records 2020-2021, 0.23M addressed by Detect ontologies alone
Chatbot/Virtual AI Agent Data based on 0.4M records 2020-2021, 0.29M addressed by Detect ontologies

Patient Support Program {Case Study}



90%

Technology

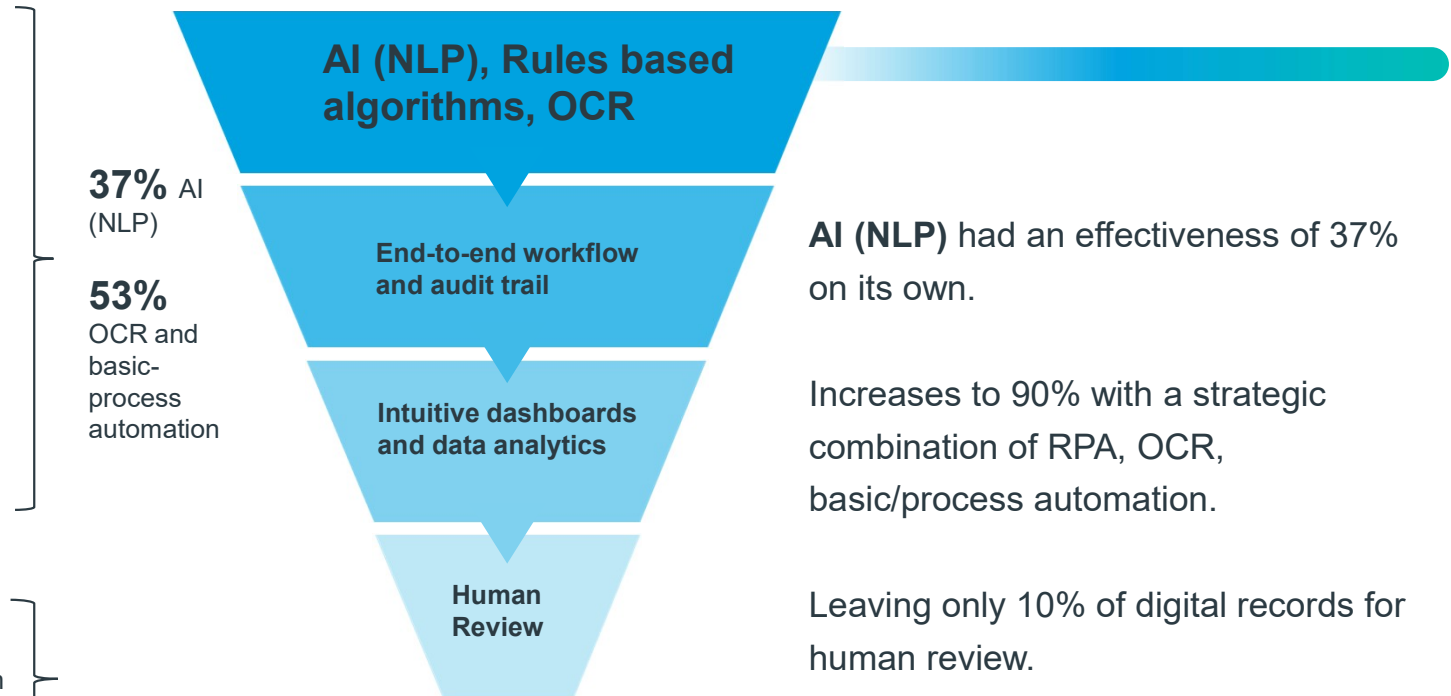
Solution embedded with robust safety specific patterns



10%

Human Review

Identified valid safety events from false positives
Assisted machine learning, rules



Case study based on anonymised Detect PSP data current as of Q4 2022: 44,680 digital records received per month
4,300 (9.7%) contain potential adverse events and need to be reviewed by humans
90.3% reduction in manual review

Social Media {Case Study}



74%

Technology

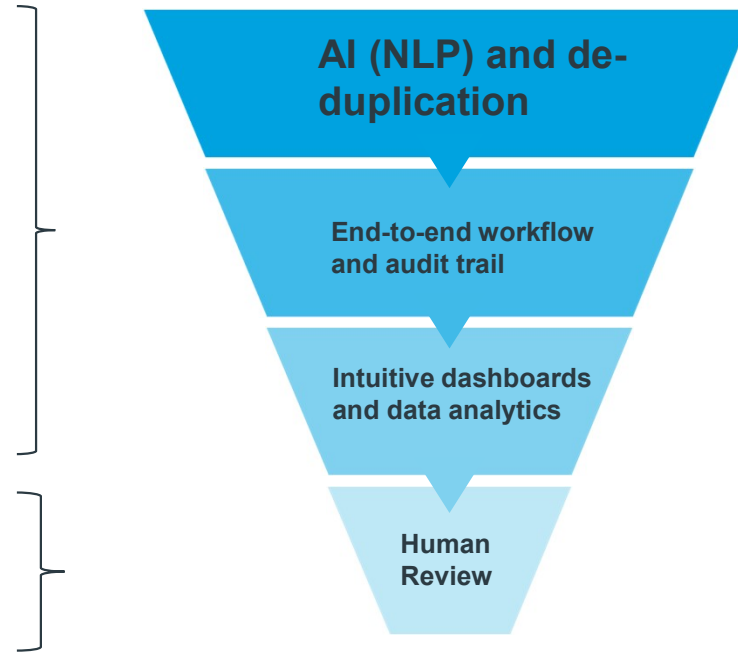
Solution embedded with robust safety specific patterns including slang, emoji character recognition



26%

Human Review

Identified valid safety events from false positives and reviewed AV/EURL files
Assisted machine learning



Rapid identification of valid safety events



Of 7.7M social/digital records, AI moves 74% out of the workflow.

26% are routed for manual review to:

- 1) validate identified events
- 2) review AV and EURL records

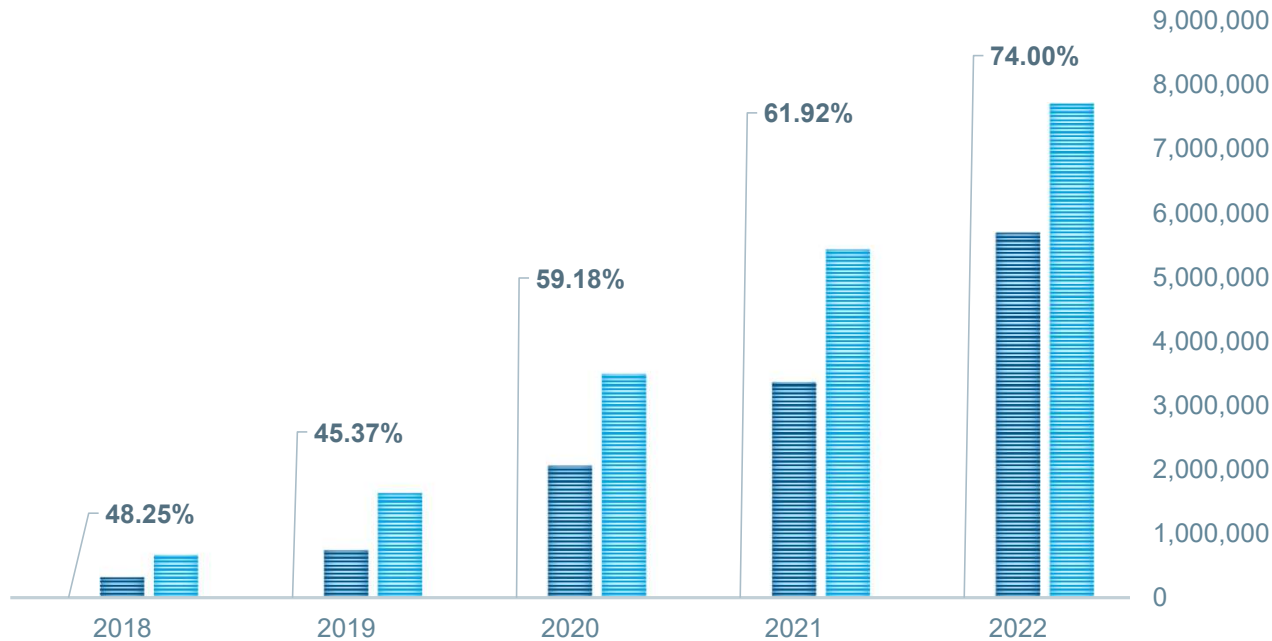
Benefit is felt in the reduced volume of irrelevant data hitting the safety database/eQMS complaints module.

Efficiency of safety risk identification technology in social and digital data

A look at the last five years

SOCIAL & DIGITAL

■ Total records ■ Efficiency ■ Efficiency %



Efficiency = Records removed from human workflow by technology

% efficiency gains commensurate to volume growth

Outliers like 2019 are 'to be expected'

Anonymized data collected from Detect Social and Digital media sources 2018-Q2 2022

NLP – AI behind the scenes

Ontology dictionaries in >50 languages (Detect's IP) are leveraged to detect AEs and other risks.

The image shows a screenshot of a hierarchical ontology tree. The tree is organized into two main columns. The left column contains terms such as 'congenital anomaly', 'contamination', 'cough', and 'genetic'. The right column contains terms such as 'crumbly', 'cytokine release syndrome', 'dehydration', and 'deteriorate'. Each term is accompanied by a list of associated regex patterns. For example, under 'congenital anomaly', there are patterns like '(?:foetus|fetal|foetal) (growth issues|problems|exposures?)' and '(?:unexpected|unusual) ana?o?m?a?ly'. Under 'cough', there are patterns like '(?:cough|coughing) spells?' and '(?:dry|heavy|night.?time|severe|irritating|bad|terrible|horrible|dreadful|)hacking|on.?going|chronic|hacky|productive).?coughs?'. The tree is interactive, with expandable/collapsible icons next to each node.

Ontologies

- enable detection of adverse events, product quality complaints, off-label use and other risks.
- use pattern recognition and word proximity within sentences
- identify colloquialisms, slang, emojis and mis-spellings
- mapped to ICD-10 and MedDRA, higher and lower-level terms.

Supervised learning supports improvements, updates, pattern building and reductions in false positives.



Conclusion

“ The whole is greater than the sum of its parts”

A horizontal bar with a gradient from light blue to dark blue.

Aristotle



Data-driven insights

- + **Synergy:** Artificial Intelligence (in all its forms), automation technology (in all its forms) and humans (in all our forms) are gifted solutions to the safety industry's challenges but yield far more impressive results combined vs used in isolation.
- + **Needle in the haystack:** Data shows us a tremendous amount of effort is required to find a very small percentage of valid ICSRs. There is a lot of noise, but there is also relevant safety information that tech can find with little human effort.
- + **Human effort is consistently required:** To validate what 'bubbles up' is of relevance to safety, to assist ML/rewriting of rules and for instances where tech can't make sense of the data as easily, e.g., embedded URLs, AV files. In good news, we can see technology is remarkably effective at keeping noise at a minimum to allow humans to focus their attentions.

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