

Natural Language Processing Empowers Timely and Actionable Insights

Conventional pharmacovigilance reporting methods require manual monitoring of multiple data streams for adverse events, which is a time consuming and cumbersome process.

Situation

In the United States, post-marketing adverse drug reactions (ADRs) are reported through the FDA's MedWatch safety information and adverse event reporting program. Although patients and clinicians can submit information, drug manufacturers are responsible for the monitoring and reporting of adverse events associated with their products to MedWatch. The submitted reports are reviewed by the FDA and may lead to actions, such as updated product labels or recalls.

Challenge

The conventional method for post-marketing surveillance is to manually monitor multiple data streams for adverse events. However, given that the amount of digital data from medical products is increasing, this is a time consuming and cumbersome process.

IMPACT OF HUMAN DATA SCIENCE

Pharmacovigilance is a critical part of securing patient safety. Patients and health systems benefit when adverse drug events are monitored, reported, and actions are taken to prevent future events. Conventional post-marketing pharmacovigilance methods are slow to inform decisions because they require substantial manual effort to read through large amounts of digital data. Human Data Science improves adverse event reporting by utilizing artificial intelligence; specifically, natural language processing, to automatically flag potential adverse events in large unstructured datasets to be reviewed and validated by pharmacovigilance experts. This enables timely and actionable insights, reporting and decision-making. In addition, this methodology reduces the amount of manual intervention and provides cost savings to stakeholders.

Human Data Science improves adverse event reporting by enabling the use of natural language processing and other artificial intelligence applications to automatically flag potential adverse events in large unstructured datasets to be reviewed and validated by pharmacovigilance experts.

Approach and Solution

An actionable example of Human Data Science applied to pharmacovigilance is the use of artificial intelligence and machine learning to automatically detect adverse events and other safety risks in structured and unstructured patient datasets, such as patient support programs, literature, social media, and web-based platforms, on behalf of manufacturers.

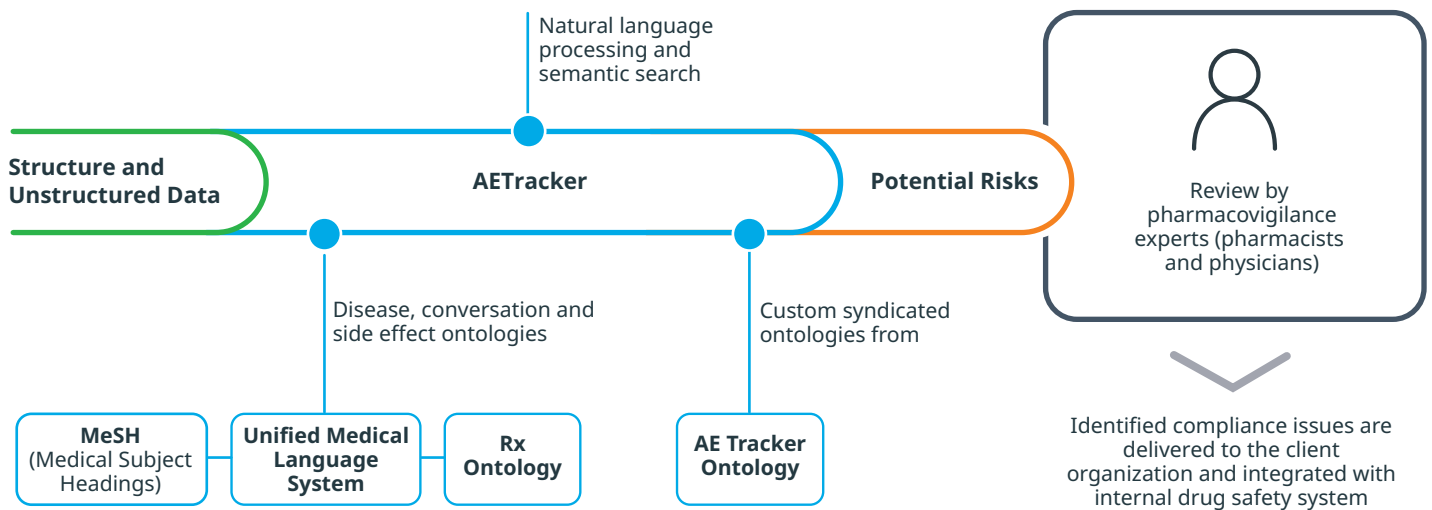
Services, such as IQVIA's AETracker™, use natural language processing (NLP) and ontology to automatically flag potential adverse events in unstructured data that then can be reviewed and validated by pharmacovigilance experts (e.g., pharmacists and physicians), reducing the number of records for manual review by 70% (see Exhibit 1).¹

Specifically, the use of natural language processing and other artificial intelligence applications to support pharmacovigilance can help find adverse events that are like 'needles in the haystack' within large amounts of data.

They have provided:

- The identification of 5,939 potential adverse events within 1.5 million total records in various structured and unstructured forms within a 30-day period
- The successful detection of 109 potential adverse events out of 22,856 representative call note records from a manufacturer's customer relationship management (CRM) system
- The ability to automatically monitor adverse events generated in social media user comments in real-time and report to global drug safety within one hour of the comments going live
- The ability to gather data from over 1.6 million records coming from social media channels and market research projects to detect 200 valid adverse events across multiple medical products

Exhibit 1: Human Data Science Pharmacovigilance Tool



Source: IQVIA. How to future-proof your pharmacovigilance delivery model. 2018 Feb 14. Available from: <https://www.iqvia.com/library/white-papers/how-to-future-proof-your-pharmacovigilance-delivery-model>:

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1. IQVIA. How to future-proof your pharmacovigilance delivery model. 2018 Feb 14. Available from: <https://www.iqvia.com/library/white-papers/how-to-future-proof-your-pharmacovigilance-delivery-model>