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Using AI for signal management could transform pharmacovigilance

Signal management (see appendix for key signal management terms) is a critical aspect in pharmacovigilance (PV), which ensures effective monitoring of pharmaceutical products in terms of their safety and efficacy. This involves a systematic approach of identifying, evaluating and validating new safety related information. The integration of AI in PV offers advanced methodologies—to enhance signal management and the safety of patients.

AI's potential in signal management:

Inconsistent procedures across various teams/stakeholders, varying safety evaluations due to subjectivity or human errors, and different ways of reporting make it hard to compare safety information accurately. AI technologies such as machine learning (ML) and natural language processing (NLP) have the potential to revolutionize the way we ensure drug safety. Its capability in real-time signal detection, seamless data integration and automated reporting can greatly improve both the efficiency and precision of monitoring and surveillance in the pharmaceutical industry. Here are some of the opportunities in the signal management value stream.

- Signal detection activity involves screening of large volumes of data from various sources. Current processes are highly effort intensive and prone to errors such as misinterpreting noise as signals or missed detection due to various data-related challenges. Generative AI (gen AI) and ML models can cut the noise, detect patterns within data, reduce the instances of false positives and false negatives and identify the weak signals—to enable quick and real-time signal detection.
- Literature surveillance can be enhanced in several ways using AI technologies.
    - NLP can be used to automatically search relevant literature articles. It can also read, interpret and identify valid individual case safety report (ICSR), or any significant information related to signal detection. ML algorithms can be trained to handle large volumes by filtering and prioritizing relevant articles, allowing efficiency and scalability.
    - From the literature, AI can extract key information such as drug names, adverse event terms, treatment details, outcomes and disease state—and make it easy for assessment. It can also gauge the sentiment and context in which drug and adverse event terms are mentioned.
    - AI tools can generate alerts for potential safety signals, enabling quick actions toward any safety issues.
    - AI can also integrate literature surveillance with safety databases and various systems, enabling continuous monitoring to assist in timely generation of regulatory reports.
- Gen AI-based solution can monitor social media efficiently by detecting trends that discuss adverse events. Otherwise, review and analysis of social media posts that involve drug-related experiences and/or adverse events can be very time consuming.
- Multiple data sources used for signal detection can be integrated using AI for comprehensive analysis and better decision-making.
- Quantitative analysis methods used in signal detection can be further enhanced with AI for more precise signal detection.
- Qualitative analysis methods can be augmented with NLP techniques to extract relevant information from various structured and unstructured data sources and summarize—to get meaningful insights.
- Safety surveillance reports can be supported by gen AI-assisted solutions, which can significantly reduce the challenges associated with data standardization and multistakeholder involvement.
- Predictive analysis can be performed proactively on the historical data using ML models to predict potential signals.

Challenges of AI adoption in signal management:

With its ability to sift through huge data sets, identify important patterns and make quick and precise decisions, AI systems are at the forefront of improving how we monitor drug safety. However, AI technology adoption faces several challenges due to various factors such as the following:

- Complexity due to inconsistent and unstructured data sources
- Auditability and transparency of decision-making processes in AI systems to comply with stringent regulatory requirements
- AI system biases due to the data it is trained on, and the generalizability across different populations
- Lack of contextual decision-making
- User reluctance to innovative technologies and resistance to change
- Significant investment required in terms of technology, infrastructure, time and expertise to develop and maintain AI systems

How to address AI-adoption challenges:

To address these challenges and strengthen the AI solutions, elaborate experimenting and feeding of data would be required. The process also requires AI to look at the same information that has been manually assessed by humans and then analyze the outcomes to check how close or far away is the AI assessment compared to the human one. AI adoption in signal management requires a multidisciplinary approach and timely collaboration between safety professionals, AI experts and regulatory authorities, along with many other stakeholders in the ecosystem.

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Key terms of signal management (GVP IX)

1. Signal

Information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or a set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

2. Signal management

Set of activities performed to determine whether, based on an examination of ICSRs, aggregated data from active surveillance systems or studies, scientific literature information or other data sources, there are new risks associated with an active substance or a medicinal product, or whether known risks have changed, as well as any related recommendations, decisions, communications and tracking.

3. Signal detection

Looking for and/or identifying signals using data from any source such as clinical trials, ICSRs, electronic health records (EHRs), literature and social media. This involves quantitative (disproportionality analysis/data mining) and qualitative methods (case-by-case reviews) to detect signals.

4. Signal validation

Evaluating the data supporting the detected signal.

- **Validated signal:** Demonstrated existence of a potential signal
- **Non-validated signal:** Lack of sufficient evidence demonstrating the existence of a new potential signal

5. Signal confirmation

The process of deciding whether a validated signal requires further analysis and prioritization.

- **Refuted signal:** A validated signal which has been determined to be false following further assessment
- **Confirmed signal:** A validated signal that requires further analysis and prioritization
- **Non-confirmed signal:** A validated signal that does not require further analysis and prioritization
- **Emerging safety issue:** A safety issue considered by a marketing authorization holder that require urgent attention by the competent authority because of the potential major impact on the risk-benefit balance of the medicinal product and/or on patients' or public health, and the potential need for prompt regulatory action and communication to patients and healthcare professionals

6. Signal analysis and prioritization

The process that determines whether a confirmed signal requires further assessment, and if required, to what timeframe and in which procedural framework.

7. Signal assessment

The process of further evaluating a validated signal to determine whether there is a plausible causal association between the drug and the adverse event.

8. Recommendation for action

Validated signals need to be reported to the regulatory authorities, and the regulatory actions may include label updates, safety warning issue and further monitoring plan.

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