Artificial Intelligence and Individual Case Safety Report (ICSR) Processing

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Background

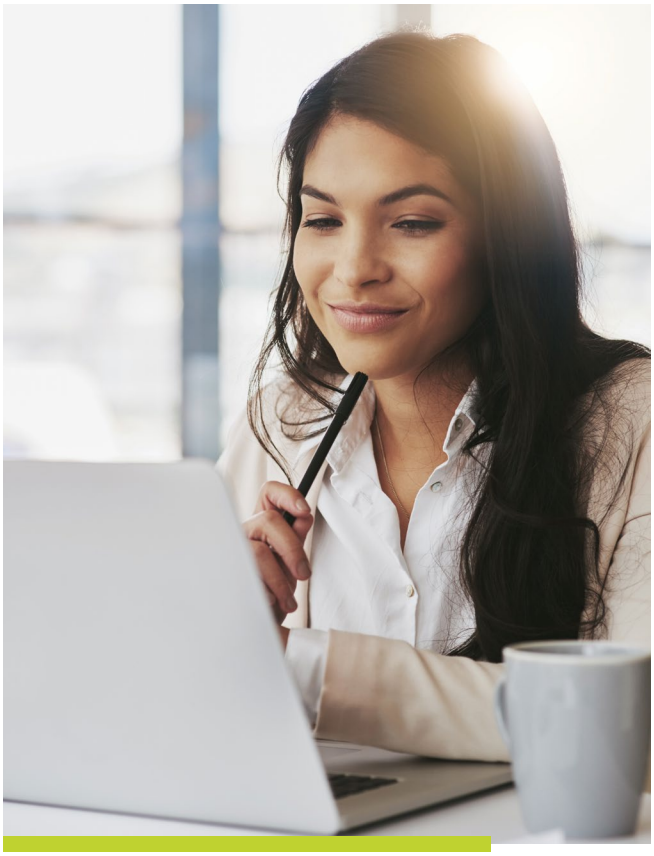
The rise in reported adverse events (AEs) and adverse drug reactions (ADRs) calls for improvement in the efficiency and effectiveness of individual case safety report (ICSR) processing. There was an approximate 200% increase in AEs reporting in the Food and Drug Administration Adverse Event Reporting System (FAERS) between 2011 and 2021. Pharmaceutical companies are allocating 40-85% of drug safety budgets to case processing, and case volumes are increasing at a rate of 10-15% per year. According to a survey, 90% of the respondents have prioritized reducing the cost of case processing and are seeking cost savings. The survey respondents expect automation to deliver a cost savings of 30% per ICSR.

Challenges: Individual case safety report (ICSR) processing

There remain several challenges associated with ICSR processing that can make it difficult to effectively identify and manage potential safety concerns. These challenges include data volume and complexity, time-intensive processing, regulatory requirements and lack of standardization, difficulty in identifying under-reported cases, limited accessibility to data, and difficulty in integrating new technologies.

Increases in incoming adverse event reports are due to a myriad of reasons, including a higher number of products in development and on the market, increasing public/media awareness, cases originating from journals, patents, articles, social media, and non-standardized data sources. The growing number and diversity of data sources requiring evaluation for safety information have resulted in a rise in ICSRs, leading to increased costs and workloads for a limited pool of human safety specialists. This trend is exacerbated by the surge in reporting for products used to prevent and treat COVID-19.

The sheer volume of data that needs to be analyzed makes it difficult to identify relevant safety signals. Data can also



be collected from a variety of sources, making it difficult to standardize and make usable for analysis. Additionally, data can be complex and unstructured, as cases are received from a variety of sources, including spontaneous reports, clinical trials, business partners, agencies, and literature. These sources can be in structured or unstructured formats depending on the reporter. Additional channels of data collection, such as phone calls, email, or social media, make it difficult to extract meaningful information.

Manual ICSR case processing requires individuals to check the validity of reports and enter all the data appropriately. Checking for missing and duplicated data, assessing case validity, properly entering all the data into safety database fields, and narrative writing are all time-consuming processes.

Some adverse events may not be reported, making it difficult to identify safety concerns. In some cases, data may not be accessible or may be kept in silos. Moreover, adopting new technologies can be difficult, especially if it requires changing current processes or retraining personnel. Overall, the challenges in ICSR processing can make it difficult to effectively identify and manage potential safety concerns.

Increasing regulatory requirements enforced by national health authorities further drive complexity. Pharmaceutical companies face constant changes within pharmacovigilance (PV) and regulatory compliance, including a growing amount of data from various sources, an expansion of products and locations, and evolving reporting requirements. Each change has a ripple effect on other parts of the organization. Companies require regulatory information management and PV orchestration tools backed by technology partners who possess an in-depth understanding of the industry and can assist in incorporating and analyzing large amounts of data while navigating a constantly changing regulatory landscape. The shortage of skilled individuals with the ability and capacity to handle the vast amount of data that requires processing, organizing, and sharing is a challenge.

For traditional PV case processing, rising costs are a major challenge. Improving patient outcomes requires high-quality ADR reports, which depend on data collection methods and analysis capabilities. Companies and organizations must make significant investments in implementing these techniques on a large scale. As a result, traditional ICSR processing costs continue to rise with the growing volume of patient-specific ADR data.

SUMMARY >>>

Challenges: ICSR Case Processing

+ Increased reporting of AEs and ADRs leads to increased cost
+ Limited skilled human safety specialists
+ Lack of standardization in regulatory requirements
+ Difficulty in identifying under-reported cases
+ Limited accessibility to data
+ Collection of data from various sources, data standardization, and inconsistent format of incoming data
+ Difficulty in integrating new technologies

Benefits of artificial intelligence in ICSR case processing:

Artificial intelligence (AI) has the potential to significantly improve the efficiency and effectiveness of ICSR processing. Machine learning (ML), deep or neural learning, natural language processing (NLP), and AI automation enhance case processing.

Machine learning uses training and the adoption of software algorithms and statistical models. Deep or neural learning is an advanced form of machine learning. Natural language processing is used for processing and analyzing large amounts of natural language data, usually in unstructured text forms. Artificial intelligence automation is a system or tool that requires no/minimal human interaction or self-learning through experience.

We can envisage that case information obtained in natural language from reporters can be dissected with proper automation to deduce relevant information on patients, suspected drugs, adverse events, and reporters from the text. For example, NLP algorithms can be utilized to scan text files from news articles, social media, and medical records for specific keywords. NLP can also automate the screening of medical literature, streamlining the process by selecting relevant articles and removing redundant information, significantly reducing screening time for PV specialists. NLP can also translate foreign text data sources to make them usable in PV assessment and in PV call centers for converting speech to text to handle phone calls. For example, when a call is received in a PV center, the NLP algorithm will analyze the voice of the reporter and transform data points into structured data. Structuring the voice of the reporter enables easy and rapid search and visualization of the data. Given the development of learning algorithms, we can also foresee that the creation of case narratives should be possible as well as the determination of the expectedness of an adverse event.

AI can be used to automate various steps in the case processing workflow, such as triage, data entry, and case review. This speeds up the case processing time and reduces the workload on human reviewers. It can be used to analyze large amounts of data to identify potential safety signals, such as unusual patterns of adverse event reports, allowing regulators and pharmaceutical companies to identify and investigate potential safety issues more quickly. AI can assist in quality review and causality assessment by analyzing the context of ADRs and the frequency of similar reports. Ultimately, a PV specialist still performs the final assessment in these processes.

AI can be used to evaluate safety signals and risk assessment by analyzing large datasets and identifying patterns, which can identify potential safety concerns early on.

It can be used to classify adverse event reports into different categories, such as serious or not serious, based on the information contained in the report. This can help prioritize which cases require further investigation. AI-powered predictive modelling can be used to identify potential safety concerns before they occur, which can help to prevent adverse events from happening in the first place. Going a step further, it may be conceivable to use optical character recognition (OCR) technology, allowing for self-reading of incoming source data and differentiating information contained therein. The hurdles to be overcome to achieve this, however, should not be underestimated. NLP-based automation of filling-in reports in the safety database, can reduce the time spent on reporting and increase compliance with regulatory standards.

Machine learning can also perform duplicate checking, detect missing data, and assess case validity. It classifies and codes ICSRs in the safety database. Algorithms follow a standardized procedure, reducing variability in assessments compared to safety specialists, resulting in improved data quality with increased accuracy and consistency. Automated and manual processes also benefit from faster processing speeds.

Using big-data analytics, data from various sources (clinical trials, medical literature, real-world data, PV databases etc.) can be combined and analyzed in an earlier stage. Additionally, data can be extrapolated for predictive signaling, allowing for visualization and early assessments. This leads to earlier detection of ADRs or safety signals, improving patient safety by enabling earlier action.

AI tools and its use in ICSR case processing:

MACHINE LEARNING (ML)

Training and adoption of software algorithms & statistical models to analyze and draw inferences from patterns in data.

Can be used to analyze large amounts of data, identify patterns, and make predictions. This can help to identify high-risk cases that may require further investigation and prioritize them for further review.

+ Perform duplicate check
+ Detect missing data
+ Check case validity
+ Identify pattern and make predictions
+ Help to identify high risk cases
+ Classify and code ICSRs in safety database
+ Improved data quality
+ Increase accuracy and consistency

NATURAL LANGUAGE PROCESSING (NLP)

Processing and analysis of large amounts of natural language data, usually in unstructured text forms.

Can be used to automatically extract information from unstructured data sources such as patient reports, literature, and social media. This can help to identify adverse event patterns and potential drug-drug interactions.

+ Extract information from unstructured data sources
+ Help to identify AE/ADR patterns
+ Reduce screening time
+ Translate foreign text to English
+ Auto-fill information into safety database
+ Improve data analysis
+ Increase compliance with regulatory standards

ARTIFICIAL INTELLIGENCE (AI) AUTOMATION

Systems or Tools that require no/minimal human interaction. Self-learn through experience.

AI-powered automation can help to streamline the case processing workflow, reduce the need for manual data entry, and improve the efficiency of the overall process. AI can be used to automatically extract information from unstructured data sources, such as free-text reports, and enter it into a database.

+ Reduce effort in manual data entry
+ Improve efficiency
+ Autofill information into safety database from source
+ Identify potential safety signals from large dataset
+ Assist in quality review and causality assessment.
+ Evaluate safety signals and risk assessment
+ Classify seriousness of the case
+ Help in case prioritization

SUMMARY >>>

Benefits of Artificial Intellicence in ICSR Processing:

+ Data quality and accuracy are enhanced by eliminating manual errors
+ Improved productivity
+ Reduced cycle time to enable faster case intake and processing through automation
+ Cost savings
+ Can improve drug's risk/benefit profile
+ Achievement of regulatory compliance and faster turnaround time
+ Increased focus on risk/benefit analysis and signal management

Limitations:

While AI in PV offers many benefits, it's not always 100% accurate. Automation is highly accurate for coding and validation but detecting AEs from various sources still has room for improvement. Translation of foreign-language sources is helpful, but not perfect. The role of AI in PV depends on each step in the process - some can be fully automated, while others require manual review by a PV specialist. AI should be seen as a tool to assist manual tasks, not replace them. The EMA is creating regulations for the use of AI in ICSR processing to ensure a risk-based approach and to specify the types of data sources to be used, while also adhering to privacy regulations like GDPR.

Summary:

Artificial intelligence can greatly improve ICSR processing by offering several benefits. These benefits include automating repetitive tasks, increasing accuracy through data analysis, and enhancing risk assessment. The use of AI in ICSR processing leads to cost savings and improved efficiency. It also reduces the workload of PV specialists by automating repetitive tasks, allowing them to focus on more complex activities such as safety signal management and risk/benefit analysis. AI algorithms can also optimize resource utilization, leading to a more efficient and effective process that protects patients from potential harm. Overall, the implementation of AI in ICSR processing can help improve the safety of drugs by quickly identifying potential safety concerns and streamlining overall case processing.

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