



Adverse Event Tracking and Pharmacovigilance Reporting for a Large Pharmaceutical Company

Developed by Megaputer Intelligence

Background

Pharmaceutical companies work diligently to ensure that the products they manufacture are safe for patients. Even though extensive user trials are conducted to gain regulatory approval, it is challenging to anticipate every patient use scenario for a new drug product. Hence, pharmacovigilance is an important patient safety practice among pharmaceutical companies. A key initiative in pharmacovigilance is monitoring, evaluating, and preventing adverse effects associated with medicinal treatments. When an adverse event (AE) is reported, the pharmaceutical company is required to analyze it, and, in the event it is a serious adverse event (SAE), the company is required to report it to a regulatory agency, such as the FDA, in a timely manner.

A large pharmaceutical company, which distributes its products in more than 100 countries, typically receives tens of thousands of AE complaints every year through various communication channels—fax, phone calls, emails with attachments, call centers, regulatory agencies, and mail. These complaints are then manually analyzed, processed, and reported appropriately and in a timely manner.

Regulations stipulate that SAEs must be reported within 7 days of receipt. This expedited deadline becomes nearly impossible to meet if there are not enough staff available to analyze the unpredictable volume of records received at any given time. This makes it difficult for the company to have an optimum team size, thus, forcing it to go for the expensive option of a large team. Moreover, the company was experiencing double digit percentage year-on-year growth over the past few years in the number of AEs received. Deciding that the current manual method was neither efficient nor scalable, the company opted to look for an automated solution which would reduce manual effort and improve the efficiency of the team.

Challenge

There are multiple challenges for an automated solution:

The patient safety complaints are in various physical and electronic forms, such as faxes, pdfs, excel documents, and call center recordings. Complaints received through calls are transcribed and all physical documents, such as handwritten letters, hand-filled forms, printed forms, and faxes are scanned. Some of the handwritten documents are poor in quality. Moreover, complaints coming from different sources may contain data in different formats, including a mixture of free text and different types of tables.

Important next tasks in the pharmacovigilance process are extracting key information, and screening the records as well as the verbatims to determine whether a case is an SAE based on the list provided



by the company. These tasks are complicated because AE reporters could be as diverse as physicians, nurses, patients, patient's relatives and institutions, resulting in different vernacularisms for the same event. Moreover, the solution has to distinguish the AE from medical history and indications, which are all included in a single record, and apply MedDRA codes for all adverse events discovered. MedDRA is a medical coding system used to classify medical conditions and adverse events. The coding hierarchy is composed of over 77,000 categories and is required for reporting to the regulatory agencies.

Because the company sells its products in multiple countries, it also has to analyze reports that come in different languages. Thus, the automated solution not only needs to be able to deal with several languages but also to format the AE reports according to the appropriate regulatory agency's standards.

Last but not least, the company required by law to perform manual oversight of each AE report that is received and processed by the company. An automated solution would therefore need to incorporate case management capabilities.

Solution

In response to these challenges, Megaputer used PolyAnalyst™, its proprietary data and text analysis system, to develop a solution. The solution employs a combination of innovative linguistic, semantic, and machine learning techniques to extract, analyze, and report AEs appropriately.

PolyAnalyst can work with several formats including pdfs, xml, word documents, text files, and scanned documents. With intelligent optical character recognition (OCR) and intelligent character recognition (ICR) integration, the system can disambiguate and interpret digitally scanned or handwritten forms, flagging these reports for additional manual verification if necessary. PolyAnalyst can also extract data from tables with different formats.

The solution provides a dictionary with built-in classification terms as well as useful medical and pharmaceutical ontologies that address vernacularism challenges such as abbreviations and terminologies used by medical professionals. Using its highly precise natural language processing features, the text analysis solution automatically extracts and categorizes target attributes that the pharmaceutical company needs to track for the FDA. Megaputer's analysts used the system's built-in analysis nodes to create a collection of verifiable and modifiable criteria for extracting attributes such as the date, type of AE, and suspect product from AE reports. From these criteria, the system was trained via machine learning techniques to identify serious versus non-serious AEs. Using this information, the system was able to perform the proper categorization of records for new batches of reports at a high level of accuracy.

The solution also distinguishes adverse events from other medical conditions such as the patient history and indications by using key contextual clues. For example, lists of medical history conditions are sometimes preceded by phrases such as "history of". The solution then utilizes the latest MedDRA classification structure, created by Megaputer, to assign MedDRA codes to every AE. This classification structure features an outstanding capability for handling vernacularisms coming from different sources ranging from medical professionals to patients.



AE reports submitted in multiple foreign languages can be quickly translated by the automated system. The results are then presented both in the native language and as the translation in a side-by-side view for verification. Additionally, the system can apply either the American standard or more comprehensive European standard of seriousness to categorize AE records and automatically configure the output record into the proper format required by the regulatory agency. For example, the solution can automatically format all submitted AE reports needing to be filed with the FDA Adverse Event Reporting System (AERS) in E2B format, the international standard for submitting pharmacological adverse event reports.

Case managers are presented with the results in a case management system where the suggested results are presented with the key information highlighted within the AE reports. The attributes of each record are summarized in a convenient format that assists case managers in identifying SAEs, determining the chief complaints, and estimating the time it should take to manage their case load and meet deadlines. Moreover, this information aids the company in deciding how to staff their manual analysis teams for case management. The system can also be customized to include updated records from publicly available sources like the FDA AERS system, allowing the company to extract key information to determine and identify adverse event trends while comparing this information to competitors' adverse event reporting.

Additionally, the solution can easily process millions of annual records in near real-time. With the automated system, the processing time for a single adverse event report now only takes several seconds instead of several minutes.

Benefits

The implementation of the solution provides numerous potential benefits for a pharmaceutical company:

- **Cost efficient:** The solution helps to dramatically reduce costs. The automated nature of the system enables resources to be utilized more efficiently.
- **Accuracy:** The solution consistently applies coding and determines SAEs to reduce the effects of human error. The convenient text highlighting for records allows case managers to manually verify the system's automated classification for added quality assurance.
- **Increased regulatory reporting capabilities:** The solution allows companies to address important reporting standards and requirements in a timely fashion.
- **Case management:** The solution can help manage adverse event cases, saving the company time and reducing the potential for error.

