

Finding the needle in the PV haystack

Injecting technology solutions into the literature review process in pharmacovigilance (PV)

Introduction

Many life science companies are exploring, with limited success, the application of digital technologies to business operations. One area that has failed in recent years to deliver the promised benefits or required quality is the automation of scientific and medical literature review for reportable adverse event (AE) information.

The volume of these literature articles is high, with a very low percentage containing reportable AEs. In the past, the available technology did not deliver the level of accuracy required.

The proof of the technology

Based on a hypothesis that technology has sufficiently matured to handle intelligent tasks such as literature review, a team of pharmacovigilance (PV) and digital experts convened to evaluate the potential of technology to effectively search literature articles for reportable AE information.

The team conducted a single blind experiment comparing the outputs of a manual review of a number of open-access medical literature with those of a smartly stitched technology solution (built by combining existing solutions such as IBM Watson Natural Language Understanding and PDFMiner library for Python coding language).

To test the hypothesis, a sample of journal articles (in English) from neuroscience publications was selected for the experiment. Fifty percent of the articles were about Attention Deficit Hyperactivity Disorder (ADHD) and covered the ADHD drug "methylphenidate". Of the articles mentioning the drug name, 40 percent contained AE terms associated with methylphenidate, while 30 percent mentioned AEs in a negative context. The main task was to use the technology solution to review all of the selected articles and identify those that contained AE information (including the AE context).

The experiment was conducted using a simple three-step process that had been previously described in the paper titled "Pharmacovigilance literature review in the age of precision medicine".

The results

Once the journal articles (in PDF format) were uploaded to the solution, it took seconds for the drug-name search to be conducted, seconds for the AE-term match, and a few minutes per article for the context analysis. This represents an **80–90 percent reduction** in the time taken to perform the same task manually (estimated at 20 minutes per article).

All journal articles with the drug name were correctly identified. Of these, 60 percent were identified as having AE terms (versus 40 percent from the manual review) and 50 percent were identified as having AEs with negative contexts (as opposed to 30 percent from the manual review). There was **no false-negative result**.

The accuracy of the technology solution was assessed using recall (sensitivity) and precision analysis.

Sensitivity and precision results

Objective	Technology-enabled literature review results	
	Precision	Recall
Identify articles with drug name	100%	100%
Identify articles with drug name & AE term	66%	100%
Identify context of AE terms	60%	100%

Source: ADL Healthcare

What this means

The recall scores at 100 percent indicated that there were no false negatives, and demonstrated that the technology could be used to reduce manual processing hours while preserving the accuracy required in literature review. This gives confidence that the technology solution will identify every AE term that is mentioned in a piece of

literature, without the risks of missing reportable AEs.

The precision score suggests that the technology solution will identify all articles with AEs, but also pick up false positives. In this case, the additional articles identified as having AEs had AE terms that were not reportable. For example, the word "depression" was picked up in an article in which the Beck Depression Inventory (BDI) was mentioned as the scale for measuring the severity of depression.

With machine learning and continuous improvement, the solution can be honed to improve the precision score over time.

Next steps

Once it is established that the technology-enabled approach can deliver the speed, quality and accuracy of PV literature review, a number of steps should be taken to transition from a labor-intensive approach. These include:

- Assigning a team of experts (PV and technology) to outline the "as is" versus "to be" states.
- Developing the business case for the "to be" state.
- Conducting a proof of concept (PoC) with a few hundred literature articles.
- Based on PoC results, conducting a pilot with a larger sample of articles.
- Conducting a double-blind experiment as part of the pilot. This particularly gives the inspectorate confidence in the results.
- Upon a successful pilot, industrialize the solution before scaling up the number of articles reviewed via technology.

Contact:

Ben Enejo
Principal, ADL Healthcare UK
+44 7469 145 404
enejo.ben@adlitt.com