Summary
A major manufacturer of generic drugs was outsourcing their literature monitoring for adverse events. However, they still had to devote a lot of time to creating search strings and checking their effectiveness. The manager of the company’s pharmacovigilance and risk management group discusses how using Embase’s PV Wizard gave them the confidence to bring this task back in-house by completely streamlining the way they create search strings.

Case Study: Streamlining literature monitoring for pharmacovigilance

See how Embase’s PV Wizard enabled a pharmacovigilance and risk management group to take control of literature monitoring
With over 150 products, the Pharmacovigilance and Risk Management Group of this rapidly growing generics manufacturer has a large workload. They must monitor the biomedical literature for adverse events and ensure that they keep to strict FDA deadlines for reporting. They are also responsible for providing clinical summaries, information for clinical trials and other safety-related information to internal groups.

The group’s manager met with Elsevier to discuss how the challenges of creating search strings and how Embase’s PV Wizard has benefitted them.

Challenge

Why is it so important to be thorough with literature screening?
Whether we are searching for adverse events or information for clinical summaries, if we miss something important, our search time is wasted.

What does comprehensive mean to you in reference to literature monitoring?
There are two aspects to comprehensiveness: the literature database; and the search string, which is the heart of literature searching. If you’re not using a comprehensive database, you might miss important articles. That’s obvious. But if the search string contains the wrong terms or is too broad or narrow, then you will certainly miss important articles.

What is the main challenge in creating search strings?
You want them to have high accuracy so you’re not dealing with too many results. For example, when we searched for one of our generic drugs by name, we got over 20,000 results. That would be so challenging to screen to find the relevant articles. On the other hand, a pharmacovigilance search string needs to give a 100% retrieval rate. When we test a search string, if we discover that it has missed some articles, we have to go back to the drawing board.

It used to take up to two weeks to create a search string, so discovering flaws in it would really slow out work down. Even for those companies that outsource the monitoring of medical and scientific literature, there is still a considerable amount of time needed to discuss and define the search string.

We were outsourcing literature monitoring, but still, our principle challenge was creating the search string; and the secondary challenge was selecting the right database to search.
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Solution

How have you approached these challenges?

We learned that Embase has the most comprehensive coverage, and that some regulatory authorities recommend Embase for literature monitoring. So we knew that we wanted to have Embase in-house. We convinced the management and started using Embase last year.

When it comes to search string design, we’ve been really happy with PV Wizard. We’re actually one of the first regular users of PV Wizard. We participated the beta testing, having been convinced by the initial presentation that it would be an extremely helpful tool.

The PV Wizard query builder is easy to use. It saves us a significant amount of time. We use PV Wizard every day to perform many different searches. For instance, we can create search strings to monitor for adverse events, search for answers to regulatory questions related to clinical trials and submissions, and get the information needed for our clinical summaries.

Business Impact

What difference have Embase and its PV Wizard made to your literature monitoring?

As I mentioned, it used to take one person two weeks to create a single search string. Now with PV Wizard, it’s so easy to create a successful search string: we just need to select a few key parameters. Since PV Wizard is a dedicated tool for pharmacovigilance search string creation, we don’t need to worry about defining all the parameters. I can’t quantify the time and cost we save from using PV Wizard, because it’s enormous.

Another useful tool in PV wizard is the EMA MLM searches. Although we operate in the US market and thus don’t need to work with the EMA MLM service, this search folder is very helpful. It contains 300 queries for herbals and 300 for generic drugs. We check the queries to see how the EMA does searches and then we can adapt the queries for our products.

The PV Wizard gives us more confidence with our literature monitoring. We convinced our organization to bring the screening activity back in-house because we were confident about our ability to remain compliant. Embase and the PV Wizard have greatly benefitted our organization.

Introducing PV Wizard

PV Wizard is query builder with a pre-coded PV search strategy that has been constructed in consultation with pharmaceutical industry partners. By providing a structured framework, it simplifies the search-building process, enabling users to quickly construct successful literature monitoring search queries in an easy and fast manner.

The pre-coded search strategies for adverse drug reactions have been developed based on best practices from industry representatives, ensuring effective searches and high-quality results.

PV Wizard is especially useful for generic drugs manufacturers who are faced with coming changes in FDA regulations that will require them to take more responsibility for warning patients about potential product risks.

Discover more about PV Wizard in this tutorial video or download the user guide.
Embase

Embase helps customers improve literature monitoring for adverse events with the world’s most comprehensive biomedical literature database and dedicated tools such as the PV Wizard.

Learn More

To request information or a product demonstration, please contact us at elsevier.com/embase/contact-sales.

Visit elsevier.com/rd-solutions or contact your nearest Elsevier office.

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