January 2020 I Issue 6

Pharmacovigilance Nugget

Literature Surveillance: From Abundance to Relevance

During clinical development it is mandated that drug developers perform literature surveillance in accordance with and in support of other surveillance activities, such as ongoing safety evaluation or annual safety reporting (ie Development Safety Update Reports, or DSURs). This obligation intensifies when the developer submits a New Drug Application (NDA) or Marketing Authorization Application (MAA) and receives authorization to market its product, as it then becomes a requirement to perform a systematic literature review no less than once a week. It is also expected that NDA and Marketing Authorization Holders (MAHs) have procedures for monitoring local publications in countries where the product has been authorized for marketing.

Given the amount of available literature and the number of potential sources (ie, Embase, Medline, Reactions Weekly, Biosis), it is optimistic to expect to find every piece of literature that may be published. A realistic, pragmatic and objective approach and targeted search strategies ensure that the recall (ie, number of results) is as precise (ie, number of results considered relevant) as possible. Nobody really wants to review 10,000 results only to find the one that is relevant.

LITERATURE SURVEILLANCE

Literature is regarded as a significant source of information in the monitoring of a medicinal product, its safety profile, and benefit-risk balance. Literature surveillance can be a key tool for the detection of new or emerging safety signals/issues.

Building a Robust Search Strategy

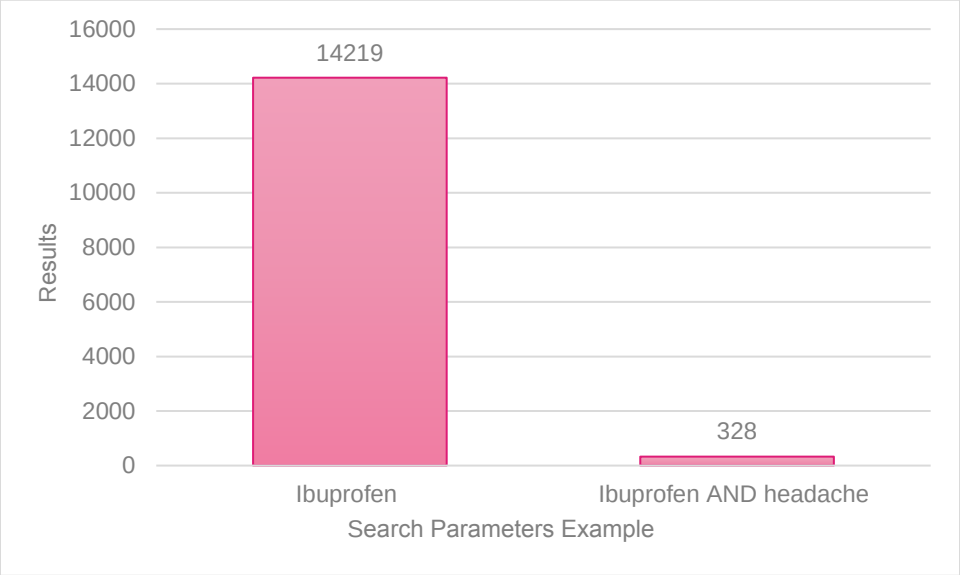
Let the purpose of the search drive the search strategy.

Is the objective to look for general safety information or Individual Case Safety Reports (ICSRs), to identify "missing" information about the product, or to monitor a particular safety signal? It is critical to build a robust and targeted strategy that can evolve as more is learned about the product and the objective of the search changes. In the clinical development setting, exposure to the product is in a controlled setting and can be limited to a certain patient population. When the product moves to market, exposure widens to other patient population and new or emerging safety information may emerge.

As a way of putting search strategy design into perspective, we provide here an example of how a single search term (or tag) can alter the amount of recall.

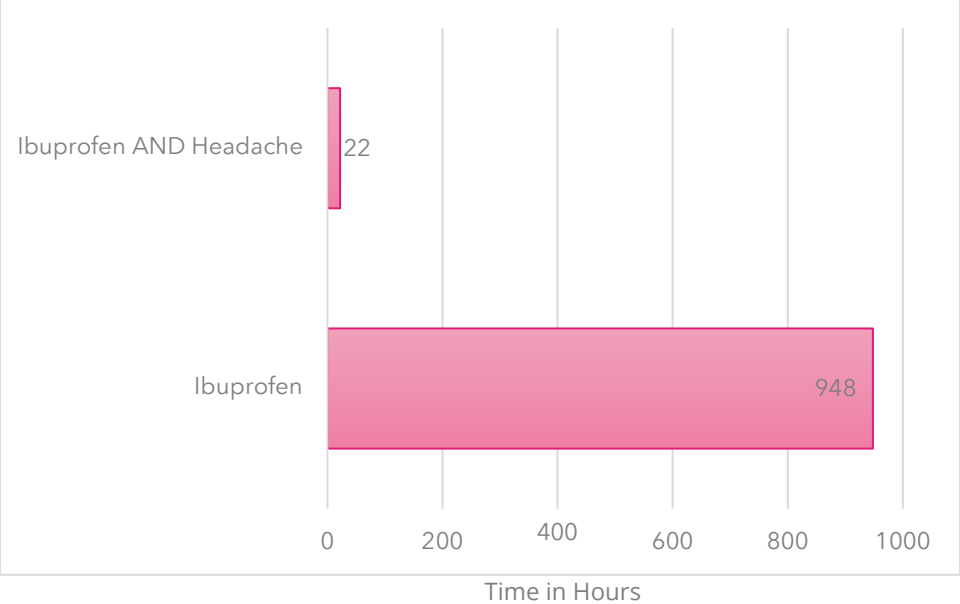
On 27 August 2019, a PubMed search for "Ibuprofen" produced 14,219 results. On the same day, a PubMed search for "Ibuprofen AND headache" produced 328 results. In this example (Figure 1) the results decreased 97%.

Figure 1: A search recall comparison



If we assume that a review took 4 minutes, the time savings realized in the example are considerable, as illustrated in Figure 2.

Figure 2: Time saved with reduced recall

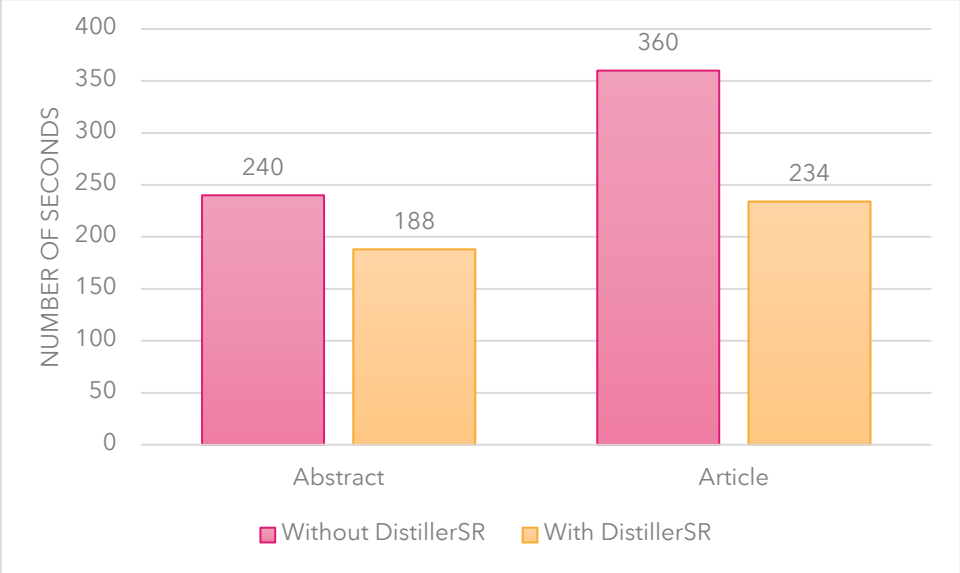


Implementing Literature Technology

Despite the best efforts and most sophisticated of strategies, the amount of literature recalled can still be overwhelming, particularly for companies with hundreds of products in development and/or on the market. As with many things, technology and automation can help.

Robust platforms for literature surveillance can reduce effort and improve efficiency for literature search and review. Technology facilitates standardized, automated workflows that maximize literature operations and provides a single platform/repository for storing surveillance data. When searching multiple data sources, technology also performs de-duplication (ie, by flagging duplicate results) and highlights keywords to expedite literature reviews and shorten the time for locating relevant information. It is well documented that the deployment of such literature platforms can reduce review times from 20-40%, as shown in Figure 3.

Figure 3: Literature review times with and without use of a literature platform



Implementation of such robust platforms streamlines oversight and coordination of literature surveillance activities and ensures inspection readiness. Such systems also enable ongoing monitoring of the performance of the process and search strategy by providing access to on-demand reports.

The authors acknowledge the following reviewers at PRA: Danieli Neder, Safety Scientist; Joash Krishna, Associate Director of Patient Safety Surveillance; Michael Marschler, Senior Director of Patient Safety Operations; Catherine Godefroy, Executive Director of Patient Safety; and Sabine Richter, Vice President of Pharamcovigilance & Patient Safety.

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