The principal goal of pharmacovigilance is to influence safer usage of medicines. But, it faces increasing pressure to analyze more data sooner, monitor risks more broadly, and accurately report patient events globally. Using the right analytics is key, but companies tend to allocate spend towards data processing rather than analysis, resulting in sub-optimal outcomes. Applying artificial intelligence across the value chain can help.
Making medicines safe in an increasingly complex world

The principal goal of pharmacovigilance (PV) is to influence patients and healthcare professionals to use medicines more safely. Companies spend billions of dollars on PV every year hoping to achieve exactly that. Yet adverse drug reactions (ADRs) remain a major cause of death. In fact, ADRs account for nearly 7% of hospital admissions in the U.S. alone, according to some estimates—and fully half of these may be avoidable, according to other studies. That presents important challenges for pharmaceutical companies.

Highly regulated PV organizations face intense pressure to analyze data sooner, monitor risks more broadly and carefully, and accurately report every known patient event around the world. That pressure has only intensified with the explosion in data related to intelligent and personalized medicines. To address these challenges, AI and analytics will be key. In fact, these innovative technologies promise to radically transform the science and activities of PV over the next few years.

Building trust and openness with technology

The principal tool of PV is data analytics. However, most large pharma companies today allocate PV spend to data processing rather than analysis. Handling individual case safety reports, in particular, consumes enormous resources. Case processing still largely relies on the manual workflow model that regulators and pharma companies established nearly three decades ago.

The increasing cost of processing masses of data on adverse events (AEs) is simply not sustainable. What’s more, the resource requirements and compliance challenges of single-case processing are substantial. These factors often divert PV professionals from their real purpose: improving patient safety by influencing those who prescribe, dispense, and fund the use of medicines.

Ultimately, the industry will have no choice but to shift to an automated case-processing model in the next two or three years. But to be truly effective influencers, pharmaceutical companies must build trust and confidence. Yet public surveys indicate that the industry is among the most distrusted, second only to the insurance industry.

Technology can help change that perception. Advanced solutions can already automatically extract, code, and process AE data. Soon, more PV operations will adopt AI to produce earlier, clearer, and more granular accounts of safety issues. That means they’ll have more opportunities to influence prescribers in a positive and proactive manner. Emerging tools will also encourage greater openness across the industry and promote impartial comparisons of alternative products. This will drive more trust, collaboration—and ultimately fewer ADRs.

Transforming the science at the heart of pharmacovigilance

There’s been a lot of progress in developing a scalable and sustainable PV operating model for the industry. Companies are creating solutions that apply AI across the entire information value chain for end-to-end case processing, aggregate reporting, and signal detection/evaluation automation. At Genpact, for example, we’re helping several life sciences companies transform their PV operations. We’re doing this using an AI-based product that integrates optical character recognition, robotic process automation, natural language processing, and machine learning technologies.

This AI-led PV system automatically extracts and codes AE data from multiple source formats to reduce case processing effort and increase the sensitivity and speed of signal detection. These same AI technologies are transforming the science at the heart of the PV analytics challenge. Signal-management tools of the future will scrape the web for meaningful data related to a particular drug.

The system will automatically identify analogues based on logical constructs like drug class and therapeutic area, as well as less intuitive factors. In addition, data features of
historical safety issues with other drugs will help predict future safety issues associated with new drugs.

**Automating to innovate**

By 2020, automation is likely to reduce case-processing efforts by over 80% and decrease costs by at least 50%. At the same time it will improve the accuracy, quality, and consistency of adverse event data. Fast-forward another five years, and AI technologies will be radically transforming PV science through intelligent signal detection and evaluation.

Automated processes will generate and test hypotheses, predict likely safety issues, and suggest potential interventions to minimize those risks. These advancements will support a much stronger emphasis on the science of preventing ADRs, which is the most important role of PV.

In the future, PV professionals will be able to devise more precise definitions for the proper use of a drug—and more sophisticated approaches for controlling that use.

AI solutions designed for PV will make this easier. Through machine learning, the accuracy of these solutions will automatically and continuously improve as PV teams apply them to growing volumes of data. At the same time, pharma companies will actively seek service providers with capabilities to apply these advanced technologies in an end-to-end model, to outsource their PV and regulatory activities related to managing and maintaining drug information.

Harnessing AI to transform PV into a sustainable, scalable operating model will free up resources to focus on innovation, and advance the knowledge base associated with newer products. That way, they can truly influence the healthcare ecosystem to optimize patient care and ensure sustainable value.