CASE STUDY

Taking AI to the heart of drug safety

How a life sciences giant is protecting patients by transforming pharmacovigilance

WHO WE WORKED WITH

One of the world’s leading pharmaceutical companies, with operations in over 100 countries.

WHAT THE COMPANY NEEDED

The pharma major was struggling to process adverse event (AE) cases manually. It was inefficient and time consuming, and with case numbers increasing, it needed a new approach to stay on top of demand.

HOW WE HELPED

We introduced Cora PharmacoVigilance, part of our Pharmacovigilance Artificial Intelligence (PVAI) suite of capabilities that reads text, understands human speech, extracts data from documents, identifies AE signals, and learns in real time.

WHAT THE COMPANY GOT

Using the PVAI suite of tools, teams are set to manage case processing with 50% less effort, and more accurate, consistent AE data. They’ll have the power to predict and prevent safety issues to better protect patients.
THE CHALLENGE

Make sense of a pile of information in different languages and formats

Pharmaceutical companies commit to protecting patients from adverse reactions to medicines. Governments do too. That’s why virtually every nation in the world insists that companies comply with stringent regulatory requirements.

This life sciences leader needed to collect, analyze, and report suspected AEs from a wide range of sources, including observational and clinical studies, consumers, and healthcare professionals. In addition, regulations vary from country to country—and so do reporting requirements, formats, and languages. Like all its industry peers, the company was handling AE processing manually, which took too much time and led to escalating costs. That was troubling, because the company knew it likely faced ever-increasing AE case volumes.

It recognized that it needed to make a change. That meant putting in place a more efficient and scalable pharmacovigilance operating model that applied artificial intelligence and automation. So, the pharma company issued a challenge to its technology partners. It wanted them to demonstrate whether automated extraction and processing of AEs was possible. The winner would be selected to help transform their pharmacovigilance operation globally.

OUR SOLUTION

A strong dose of AI and NLP

Following a rigorous procurement process in which 20 potential solution providers participated, the pharma major selected Genpact and two other companies to go to the next stage. By comparing the competitors’ software solutions against one another, the pharma company wanted to see which had the fastest and most effective machine learning. And which solution would demonstrate the most accurate, automated AE data extraction and coding.

After evaluating the results, the pharma company chose Cora PharmacoVigilance, built on Genpact Cora, an AI-based platform that accelerates digital transformation.

The pharma major is using the solution to process cases by reading text, understanding human speech, extracting and codifying AE data, and learning continuously. Cora PharmacoVigilance has a configurable, risk-based approach to automatically extract and code AE data. And it can process most AE cases end-to-end without intervention. When people do need to review the data, it efficiently guides users through the fields most likely in need of changes, streamlining quality control in the process.

What’s more, the AI engine at the heart of Cora PharmacoVigilance learns as users’ correct case data—and that improves accuracy over time. It’s a holistic and integrated SaaS solution that covers everything from source document acquisition to medical review, distribution, and submission as well as aggregate reporting and signal management. It’s even designed to replace legacy case-processing systems—and cut IT costs.

And as the technology learns it will also bring the life sciences giant greater predictive capabilities. By sensing previously undetectable signals and spotting patterns on the fly, it will be able to foresee potential safety issues, which shifts pharmacovigilance from monitoring and reacting, to preventing and protecting.

THE IMPACT

A healthy new AE data gathering and reporting mechanism

Genpact’s team is collaborating closely with the company to introduce automation incrementally, without disrupting steady-state operations. Cora PharmacoVigilance is being deployed alongside the company’s existing systems, and integrates seamlessly to ensure the company gets value
from day-one—without the cut-over risks and challenges of a complete system replacement.

The pharma company expects to see a 50% reduction in case processing effort, even while adopting a policy of 100% quality review. That’s a big saving. And its simplified, scalable operating model consistently produces higher-quality, more accurate data.

What’s more, the solution can streamline signal detection and the evaluation process, enabling the company to be more proactive and responsive. So even as case volumes increase, the pharma company can not only manage processing but also start to predict safety issues, prevent adverse events, and keep patients safe.