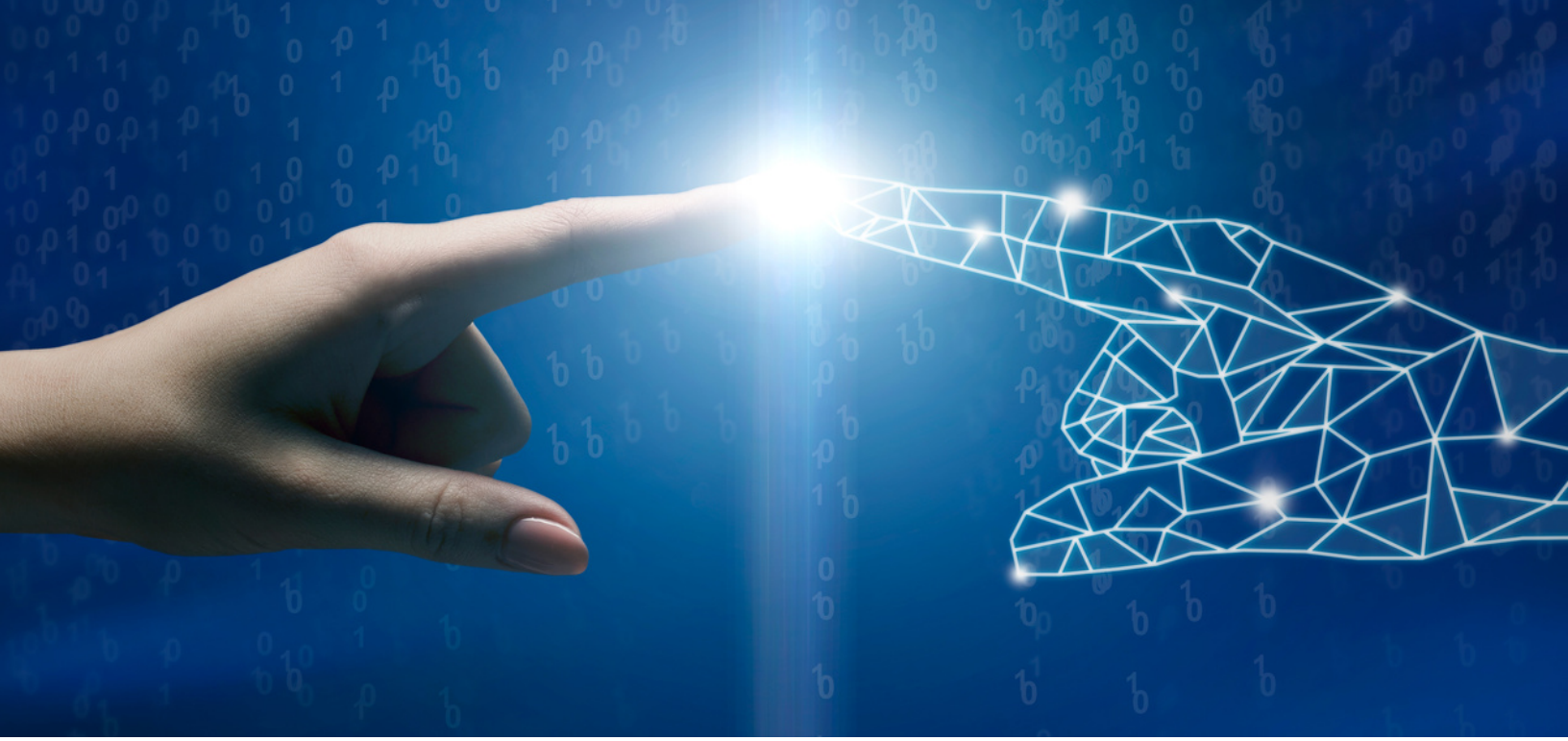
# Enhancing the Pharmacovigilance System using technology to enable futuristic patient safety



# Fidelity Health Services help client's **to support futuristic patient safety**

Pharmacovigilance is being revolutionised by automation, cognitive technologies, and advanced analytics. These innovations are improving drug risk-benefit profiles, turning data collection into a learning system, and raising the standard of pharmaceutical products, devices, and biopharmaceutical products. We at Fidelity Health Services, being a pharmacovigilance service provider strategically investing in technology backed solutions to support futuristic patient safety.

For the past several decades, the pharmacovigilance (PV) function has been responsible for collecting, processing, and reporting adverse events (AEs) and other product safety information to regulators. Due to PV's process-heavy structure, pharmaceutical companies frequently selected related safety solutions primarily on how well they could manage data and maximise productivity, which usually left them with few options.

The pharmaceutical companies are facing the following difficulties as a result of the PV system being more loaded with new and complex medicines, devices, and safety data related to biopharmaceutical products.

- **Ever-growing volume of reported AEs**
- **Global regulations becoming more stringent and complex**
- **New product portfolios entering into market**
- **Cost minimizations burden**
- **Consumer centric approach increase focus on PV**

# Automating case processing and signal management

Automating case processing and signal management With the potential for continued technological innovation, PV organizations are on the leading edge of making a consistent, sustained set of bold moves to take advantage of safety capabilities.

The latest trends have been observed especially with large and mid-sized pharmaceutical organizations developing and investing in PV related automation for gaining process efficiencies, resource optimization to value-added-tasks, improve quality and reducing PV budget burden.

## Case processing

Companies are tossing around a whopping 40-85% of their budget into case processing each year

From the information available at FDA's website, the case volumes growing at a rate 10-15% per year (1)

So, the pharma industry is moving aggressively to take advantage of technology backed solution i.e. automation which utilizes various methods like Artificial Intelligence (AI), Machine Learning (ML), Natural Language Processing (NLP) and generative AI etc.

The experts expect to save 25-30% of cost on case processing by deploying these technology-based solutions/services.

The automation allows us to identify duplicate cases, auto book-in of cases, speed up auto-coding, auto-narrative write-up etc. provides advantage of a significant time reduction in case processing by leveraging resources to turn around higher numbers of case volume or to utilize in much value-added tasks.

Despite the limited capacity to fully automate entire case processing across all workflows, the pharma companies are still looking for this kind of models or solutions. Companies' capability to automate more and more of these tasks is the only way to gain control over this process's expenditure while maintaining compliance and improving patient safety.

## Signal Management

The methods for signal management activity are:

1. Traditional signal methods of reviewing each ICSR
2. Using of certain statistical formulas
3. Hybrid approach
4. Real-world Evidence

There are broad opportunities to improve signal detection and investigation process. As pharmaceutical companies continue their push towards real safety management, short-term signalling investments may probably concentrate on visualisation, while longer-term efforts will probably concentrate on data integration and tool and process investments. Predictive signalling is the ultimate objective.

There are multiple vendors /CROs including Fidelity Health Services using a technology-enabled solution leveraging automation to streamline processes, enhance efficiency and cost-effectiveness. Adapting an automation system at a company level might be a costly affair for pharmaceutical companies. The automation system adapted at CROs like Fidelity Health Services may be a cost-effective approach as of date.

By implementing advanced algorithms and machine learning, such CROs can analyze large volumes of adverse event data rapidly, facilitating quicker identification of potential safety concerns. Automation also allows for real-time monitoring of safety signals across diverse data sources, enabling proactive risk management and expedited regulatory reporting.

Overall, technology-driven approaches empower Pharmacovigilance CROs to deliver high-quality safety monitoring services efficiently and affordably, ultimately benefiting both pharmaceutical companies and patients.

> **Thus, we at Fidelity have made strategic investments in technology-based services to ensure a safer and healthier society and set industry benchmarks.**

Reference:
(1)https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis.

Fidelity Health Services

# Our Service offerings

## Drug Safety Services

ICSR
Aggregate Reports
Literature Screening
Signal Detection

## Medical Information Call Center

Scientific Response Centre
24*7 Services
Multi-lingual Support

## Functional Resource Management

Onsite Resource Deployment
Offsite Resource Deployment

## PV Consulting

PV System Development
PV Audit

nisarg@fidelityhs.com
tarun@fidelityhs.com

+91 89804 73174
+91 95376 33316

www.fidelityhs.com