EXPONENTIAL AI

CASE STUDY

Top 5 Biopharma uses
AI and Decision Intelligence
To Scale and Automate
Adverse Event Processing.

CONTEXT

Due to increasing Adverse Event (AE) case volumes for their products and the growing pressure to improve drug safety and compliance without adding costs, a top 5 biopharma company sought breakthrough solutions to help them transform their pharmacovigilance operations.

PROBLEM

The pharma major's pharmacovigilance team was processing adverse event (AE) cases manually - a laborious, error-prone, and time consuming process. With increase in case volumes, complexity and data sources, they needed a new approach to managing AEs.

SOLUTION

We introduced an AI solution that accurately identifies adverse event signals from structured and unstructured document sources. Over 200k records were used to train machine learning classification models. Key information like drug details, symptoms, medication history, etc. is classified for Intelligent Data Extraction.

IMPACT

Savings of more than $5 million dollars each year using our AI solution. Teams were empowered to filter-process adverse event incident cases (from all reported cases) accurately and consistently in 40% less time. ROI was achieved in less than four months.

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PROBLEM

The current manually-intensive approach to AER processing is simply not sustainable and needs innovation to scale operations and maintain cost-effectiveness.

Pharma companies need to monitor for adverse events to ensure patient safety and to remain in compliance with regulatory requirements. Serious adverse events must be reported to the FDA within 24 hours and alert reports are to be submitted within 15 days.

AE data comes in from several channels in varying formats. For example, healthcare providers submit reports when they see adverse events in clinical trials and routine care, or patients themselves call 1-800 numbers to report their symptoms for adverse events related to drugs on the market. These reports are handled/scrutinized by representatives who triage cases and log them as mild events or escalate them when severe.

A large majority of such AE reports come in as unstructured documents that have to be carefully reviewed by PharmacoVigilance (PV) teams to identify and prioritize AEs for reporting and action based on risk. The average review time for each AE case document is upwards of 20 minutes. After review, the actual AEs (that relate to the companies' products) identified are sometimes less than 10%.

With the predicted increase in volumes, pharma companies with manual intensive processes are at risk for failure in meeting reporting deadlines, and also for increased costs for compliance.

Outdated PV systems: Hard and Costly to Scale

In the case of the top 5 biopharma, the PV team members were reviewing more than 100,000 documents per month. Less than 1% of the adverse event documents reviewed represented actual adverse events related to their own drugs or products. The total cost of reviewing all AE documents for the company was upwards of $40 million, considering the average time for reviewing a document was approx. 30 minutes.

A tidal wave of AERs in the offing?

In 2020, as COVID-19 spread, many companies' paused clinical studies, due to participant safety concerns and to give focus to pandemic response. Resumption of those trials, coupled with the launch of new ones delayed due to COVID-19, caused a sudden influx of AE data. This influx is predicted to increase further as COVID vaccines roll out, since vaccines typically see larger number of AERs.

SOLUTION

Leveraging AI and decision intelligence to automate the entire PV process from case intake to database entry and review.

Exponential AI's ENSO Decision Intelligence Platform leverages intelligent document processing, data harmonization and decision intelligence capabilities to enable machine decisions for AER data extraction, identification and validation.

It automatically extracts and codes AE data from unstructured and semi-structured documents. It reviews AE data using Intelligent Character Recognition (ICR) and AI-Natural Language Processing (NLP) to identify and bucket case details, like: patient and incident reporter details, adverse reaction/event, suspect or interacting drug, seriousness/non-serious, medication history, and symptom details.

Once data intake is complete, the solution reviews AER case data to identify and validate actual adverse event cases, thereafter prioritizing and triaging events according to risk for reporting and action. By adjudicating AERS automatically, the solution reduces human error and need for human review, enabling PV teams to focus on high risk AE cases, and improving the overall quality and accuracy of AE processing.

By completely automating AE intake to adjudication, AER solution transforms the current human-intensive PV process to an autonomous machine augmented one. The result is a scalable PV operating model that gets better from data, decisions and feedback to enable predictive insights on patient safety across the pharma value chain- from drug discovery to aftermarket.

BENEFITS

Exponential AI's ENSO platform powers an end-to-end adverse event (AE) focused AI solution, that drives intelligent machine decisions to drastically reduce the cost and effort of processing AEs, and enables insights for drug safety across the entire pharma value chain.

- Reduce time and effort spent on adverse event case processing by 45%, with potential for significant annual savings.
- Enable 100% quality review along with the ability to rapidly scale to any future rise/surge in case volumes.
- Risk analysis and prioritization of adverse events to enable proactive decisions on product recalls.
- Delivered extensible and reusable components and data that enable meaningful insights for adverse event prevention.

The combination of AI-powered agents and human agents creates faster response times and reporting of adverse events or quality concerns. Even with an increase in case volumes, the biopharma company is now seamlessly handling AE processing and is also starting to predict safety issues, and prevent adverse events.
In addition to proactive and reactive post market surveillance, the solution can be extended to clinical trial operations and complex problems like determination of drug-nutrient interactions