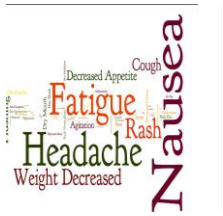
Intuceo
from data rich to insight rich

Automating Adverse Event detection with AI/ML eliminating manual efforts and aiding to timely FDA submittals.



The current system of identifying adverse events from customer complaints is labor intensive and time consuming. FDA guidelines require health care providers and manufacturers to submit voluntary reports of adverse events associated with products within the 15 days of compliant. However, the challenge companies face is to swift through the massive volumes of the complaints and require highly trained professionals to review, validate and identify the adverse event to prepare report in timely fashion (<15 days of complaint) for FDA submittal.

Goal: A fortune 100 big pharma/MD&D client approached Intuceo® team to automate and improve the process efficiency leveraging AI/ML. Applying AI effectively to determine whether a complaint is potentially an adverse event or not requires not only base level prediction capability but also ability of the AI model to rationalize its prediction. A Yes/No decision of AI model may help in reducing the volume of complaints, but it doesn't eliminate the pains takingly time-consuming efforts from experts in manually annotating the explanation to why that Event is Adverse Event or not. While most AI cognitive models provide base level Prediction capabilities, they seldom come with "Explainable AI intelligence". Intuceo® team of experts along with patented Intuceo® auto ml tools for pattern recognition and predictive models, partnered with the client and implemented a AI/ML solution that accomplished both the goals, "Accurately Identify potential Adverse Event" along with rationale on WHY with the explainable AI feature.

i) Any adverse event is reportable to FDA if the event: Is fatal, is life-threatening, is permanently or significantly disabling, Requires or prolongs hospitalization, Causes a congenital anomaly

ii) These adverse events must be reported to FDA as soon as possible but no later than within 15 calendar days following the initial receipt of the information

Complaint	Insight	AER Score	Severity	Symptoms
" ..has not been taking norvasc 5 because it gives her strong headaches.."	Reportable	^ 87.5%	Life threatening	Unconscious, Dysphotospia, Retinal detachment
" ..cosmetic. Haptic stuck to optic causing blurry vision	Inconclusive	^ 65.5%	Moderate	Blurry vision, Corneal enema, Capsule tear
"difficult to use, from cannula issues and ovd low viscosity"	Not Reportable	^ 35.5%	NA	Sample damaged

Results: Having an AI/ML driven solution with both AE detection along and effective explanation resulted in high through put to process more complains in given time window, significant reduction in expert professional's time and number, resulting in the timely FDA submittal.