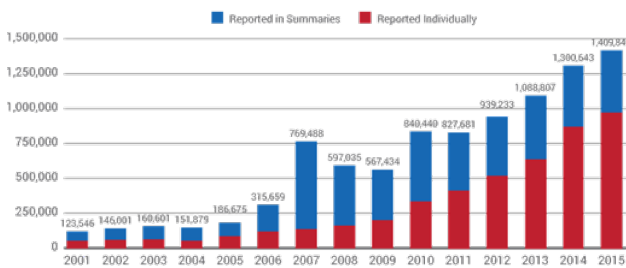




TECHNOLOGY RESHAPING PATIENT SAFETY

Patient safety is very important in Pharmaceutical industry and adverse drug reactions are critical to both society and industry. With growing numbers of safety data sources and adverse event (AE) reports, there is a need to leverage new innovations to scale operations and optimize cost.

ADVERSE EVENTS, 2001 - 2015



(Source: FDA)

Adverse Events increased by **20% Year on Year**

Changing regulatory landscape of pharmacovigilance (PV) is targeting robust drug safety management by improving the quality of safety data collected and submitted.

CURRENT CHALLENGES IN DRUG SAFETY

- Compliance obligations like E2B (R3), REMS (FDAAA) and RMPs (EU regulations) for Risk Management.
- Lack of effective compliance tracking.
- Adoption of proactive surveillance including signal detection and monitoring.
- Standardization and consistency across global PV processes and absence of significant PV measurements.
- Inadequate, low quality and deferred administrative entries.
- Analysing and integrating large volumes of safety data.

As we grow deeper into the age of machines, Automation and Artificial Intelligence are taking over trivial to substantive to life-changing areas. With advancement in machine learning and neural networks, all the current working processes are up for an overhaul. Healthcare world is adapting to this intelligent automation revolution and Pharmacovigilance is not an exception.

NEW TECHNOLOGIES SHAPING UP PHARMACOVIGILANCE

The global PV market is expected to reach USD 6 billion by 2020. The market is expected to grow at 14% CAGR owing to increasing incidence of ADR, which is the key driver for the growth of pharmacovigilance market. As of 2015, the U.S. FDA received approximately 2,53,017 serious adverse events and 44,693 deaths associated with adverse drug reactions (ADRs). This demonstrates the potential interest for realizing patient safety and pharmacovigilance benefits over the conjecture time frame.

(Source: www.futuremarketinsights.com; www.fda.gov)

New Technologies shaping the Pharmacovigilance are:



ARTIFICIAL INTELLIGENCE



NATURAL LANGUAGE PROCESSING



BIG DATA ANALYTICS

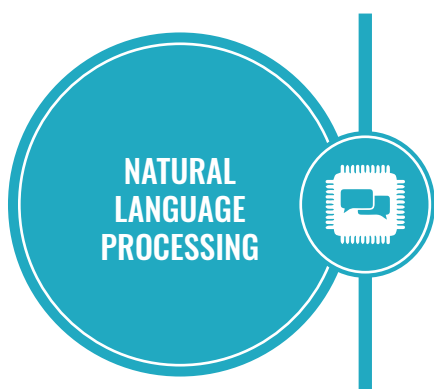
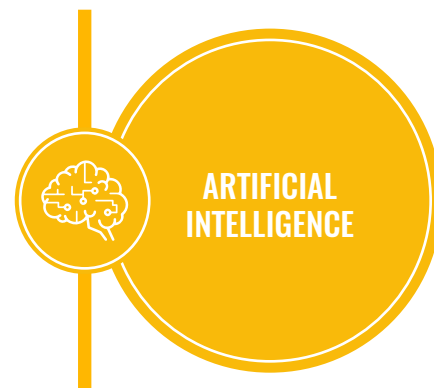


AUTOMATION



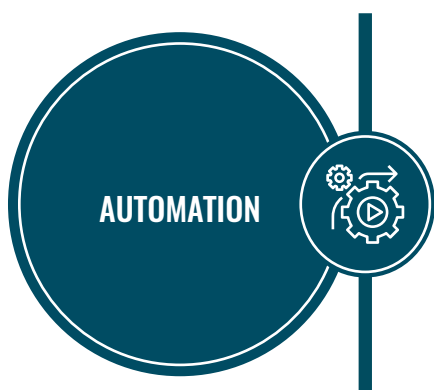
CLOUD BASED TECHNOLOGIES

- Artificial Intelligence (AI) is helping in the extraction, understanding and analysing the data from images and lab reports.
- Narratives are very crucial part of the medical review, the AI-assisted auto-generation of narratives will aid medical reviewers to speed up the process.
- Analysing and predicting causality and expectedness to establish the relationship between an event and the drug will be of great help.
- ADR detection performance from the social media can be significantly improved by using contextually aware models and deep learning.



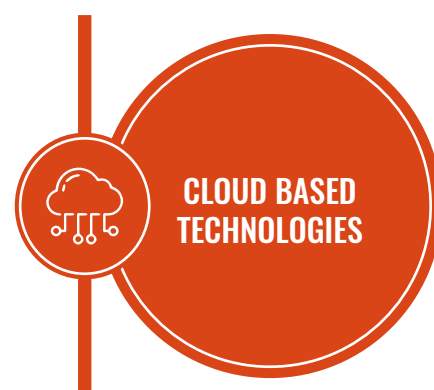
- Natural Language Processing (NLP) system, can be applied to source databases, to identify medical events and entities, which could be potential adverse drug events.
- Extraction of data from the audio of adverse event reports to call centres.
- AE mining from EHRs by analysing clinical narratives and case classification will help in the early detection of the signals.
- Mining Social media, internet search history, biomedical literature and product information documents with NLP will help in identifying the AEs Faster.
- NLP aids medical review by providing insights from latest medical literature.

- Applying data analytics in PV processes increases the speed of signal detection.
- Companies will be able to map patterns and historical trends in order to isolate the interaction of drug components that can correlate with ADRs, leading to safer and more effective drugs with fewer side effects.
- Mapping data trends lessens the cost-intensive practice of clinical trial and error methods to test data.

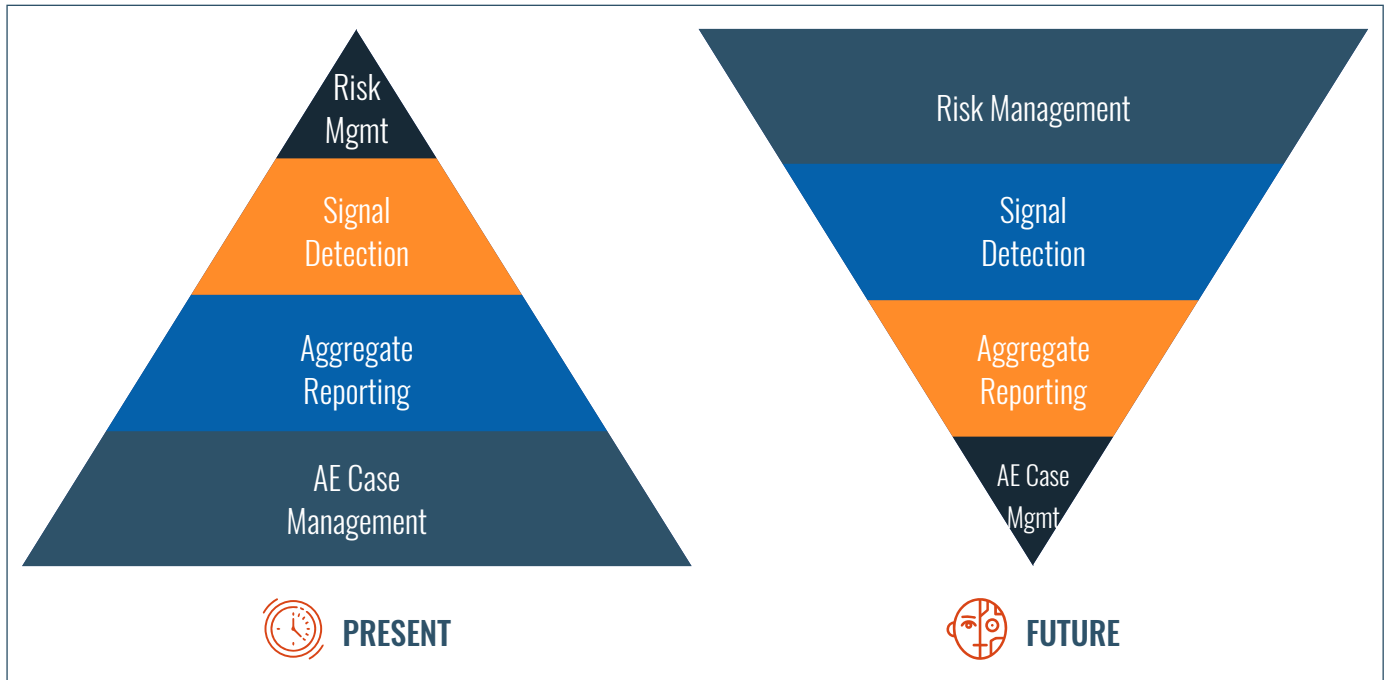


- Automation tools improve the visibility and monitoring of all pharmacovigilance processes like case entry, processing, and quality check.
- Automation enables increased work efficiency by removing administrative and clerical tasks that can be relegated to computers and robots e.g. manual drug filing, clinical overviews, drug active ingredients check and report generation.
- Furthermore, Automation frees up work capacity, hence reducing overall PV operations cost while increasing accuracy and quality of ADR detection.

- Cloud technology increases the threshold of data storage, helps in processing, transferring and screening large amounts of medical records.
- With the sheer volume and variety of secondary data sources, big data becomes a powerful tool to swiftly organize, classify, and even profile the veracity of reported ADRs for pharmaceutical companies and regulatory agencies to analyse.
- Aside from expanding straightforwardness, this worldwide database is a Ramp for learning cross-fertilization between nations for ADR examples and side effect event bits of knowledge.
- Cloud technology takes away the distance and time-lag barriers and creates a real-time dynamic data set for all PV markets.



THE FUTURE OUTLOOK



By 2020, Automation is probably going to lessen case-preparing endeavors by more than 80% and diminish costs by no less than half prompting better quality precision and consistency of unfriendly occasion information.

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We are part of the USD 19 billion Mahindra Group that employs more than 200,000 people in over 100 countries. The Group operates in the key industries that drive economic growth, enjoying a leadership position in tractors, utility vehicles, after-market, information technology and vacation ownership.



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