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ADVERSE EVENT REPORTING: POWER OF AI ENABLED COGNITIVE CASE PROCESSING AND PROCESS AUTOMATION

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POWER OF AI ENABLED COGNITIVE CASE PROCESSING & PROCESS AUTOMATION

TABLE OF CONTENTS

ABSTRACT

Pharmacovigilance (PV) is a critical process in a pharmaceutical product's lifecycle. It has become complex owing to the multiple unstructured formats of data sources, below-par data quality, error-prone case intake process, workflow management challenges, and lack of integration with existing systems. The biggest challenge that the PV process has is of converting the unstructured information to a machine-readable structured format that significantly reduces manual efforts of data entry during case intake and data processing while continuing to meet regulatory compliance and its timelines. A synergy of process and technology experts would cumulatively facilitate enhancements and technology adoption that would enable seamless workflow, data processing to consistently demonstrate quality, time and cost reductions, increased efficiency, and regulatory compliance. Innovative technologies and applications such as AI/ML and deep learning methods with continuous learning and feedback mechanism that minimizes human interventions would be widely accepted, thus enabling PV teams to focus on adverse events of higher risks.

INTRODUCTION

Pharmacovigilance (PV) reporting, being pivotal in the tracking of patient safety, ensure that only safe products are available for consumption in the market. It has become increasingly vital for companies to monitor the process in-depth. The regulators have mandated and demanded companies capture, analyze, and report adverse events from all sources such as clinical data, electronic patient health records, call center notes, medical literature articles, emails, and social media. Technological advancements in the form of robotic process automation (RPA), cloud platforms, mobile applications, artificial intelligence (AI), and big data analytics would be crucial for drug safety and regulatory operations in the pharmaceutical industry.

A high level of automation from case intake to database entry and review would not only increase efficiency but also reduce costs and eliminate human error, thereby improving the quality and accuracy of case processing. A blend of natural language processing (NLP) technology and ontology search with an expert to finalize and adjudicate the adverse events would significantly reduce manual review and thereby cost savings. Standardization of PV processes, proactive case reporting solutions, and data integrity would be the main areas within the realm of safety case management with effective use of technology.

CHALLENGES TO MEET COMPLIANCE TIMELINES: UNSTRUCTURED DATA AND LACK OF INTEGRATION

The biggest challenge is to convert the unstructured information to a machine-readable structured format that significantly reduces manual efforts of data entry during case intake and data processing while continuing to meet regulatory compliance and its timelines.

Currently, the industry is facing challenges like the unstructured format of data sources, below-par data quality, error-prone case intake process, workflow management challenges, lack of integration with existing systems, and high operational maintenance cost for operating case processing activities.

Opportunities for automation exist across all pharmacovigilance processes, but ICSRs are more resource-intensive, have a high risk of human errors, and are prone to operational inefficiencies. Traditionally, drug safety and ancillary systems have provided incremental innovation with limited focus on automation that reduces human intervention in the process. Technologies like RPA, cognitive computing, machine learning, and NLP based models provide an opportunity to automate and change the landscape of process from human-intensive to machine operated models. These innovations will not only benefit in reducing operational spending but will also enhance patient wellbeing by strengthening safety signal detection and benefit-risk.

IDENTIFYING AREAS OF AUTOMATION AND TECHNOLOGY CAPABILITIES

High levels of automation from case intake to database entry and review would not only increase efficiency but also reduce costs and eliminate human error, thereby improving the quality and accuracy of case processing. Technology solutions enable monitoring structured and unstructured data (patient support programs, literature, social media, and web-based platforms) to accurately identify adverse events and extract keywords based on simple/contextual search. A blend of NLP technology and ontology search with an expert to finalize and adjudicate the adverse events would significantly reduce manual review and thereby cost savings. An E2B file output as per European Medicines Agency or EMA's recent changes to module 6 of R3 has necessitated the use of automated multi-source data intake. Moreover, downloading EudraVigilance cases and checking for duplicate entries have increased case volumes that demand automated solutions operating within the framework of regulated safety standards. Standardization of PV processes, proactive case reporting solutions, and data integrity would be the main areas within the realm of safety case management.
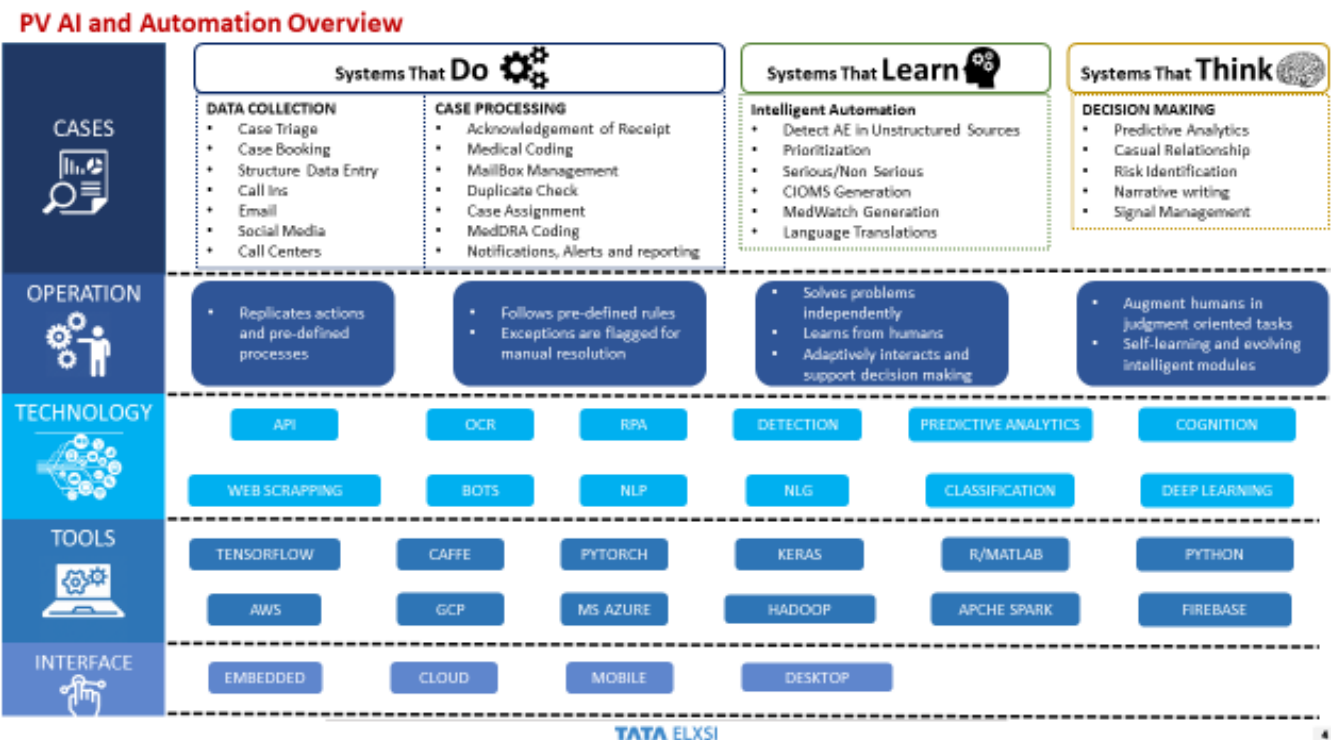

Figure 1: Appropriate use cases and technology for a downstream PV processing workflow.

TECHNOLOGY SOLUTION

End-to-end intelligent case processing: AI-enabled Natural Language Processing (NLP) based tools uses machine learning and RPA capabilities that can automatically identify and extract key elements from structured and unstructured data sources accurately. Inbuilt global libraries like MedDRA, WHODrug, MeSH also help to code while auto-populating multiple fields in the database. The tools automatically identify and bucket information for case details: patient and reporter, adverse event/reaction, suspect or interacting drug, seriousness/non-serious, and event details to accelerate automatic data entry. These tools help medical professionals to focus more on quality and verifying data as it substitutes the time-consuming manual tasks of data entry, thereby increasing productivity and efficiency. Simple and contextual extraction of data, analytics, and decision making, thereby deriving a standard-compliant output in the form of an E2B .xml file, is the key to all technology solutions. In the journey of automation, next-generation solutions with a cognitive layer would create high-level automated narratives for a varied portfolio of cases. Early adaptation of innovative solutions along with a strategically aligned technology partner coupled with extensive change management; will lay out a road map for moving from manual data entry to a comprehensive automated approach.

TECHNOLOGY FRAMEWORK

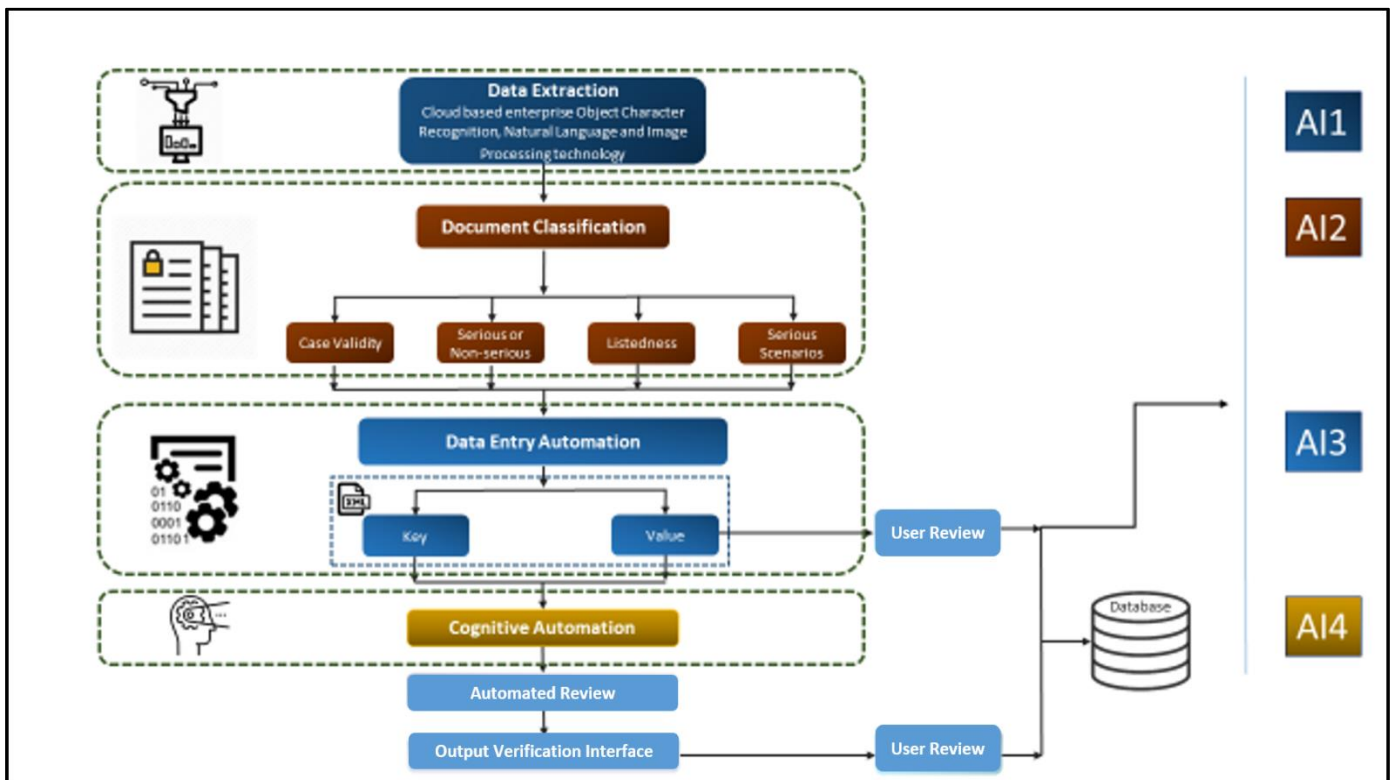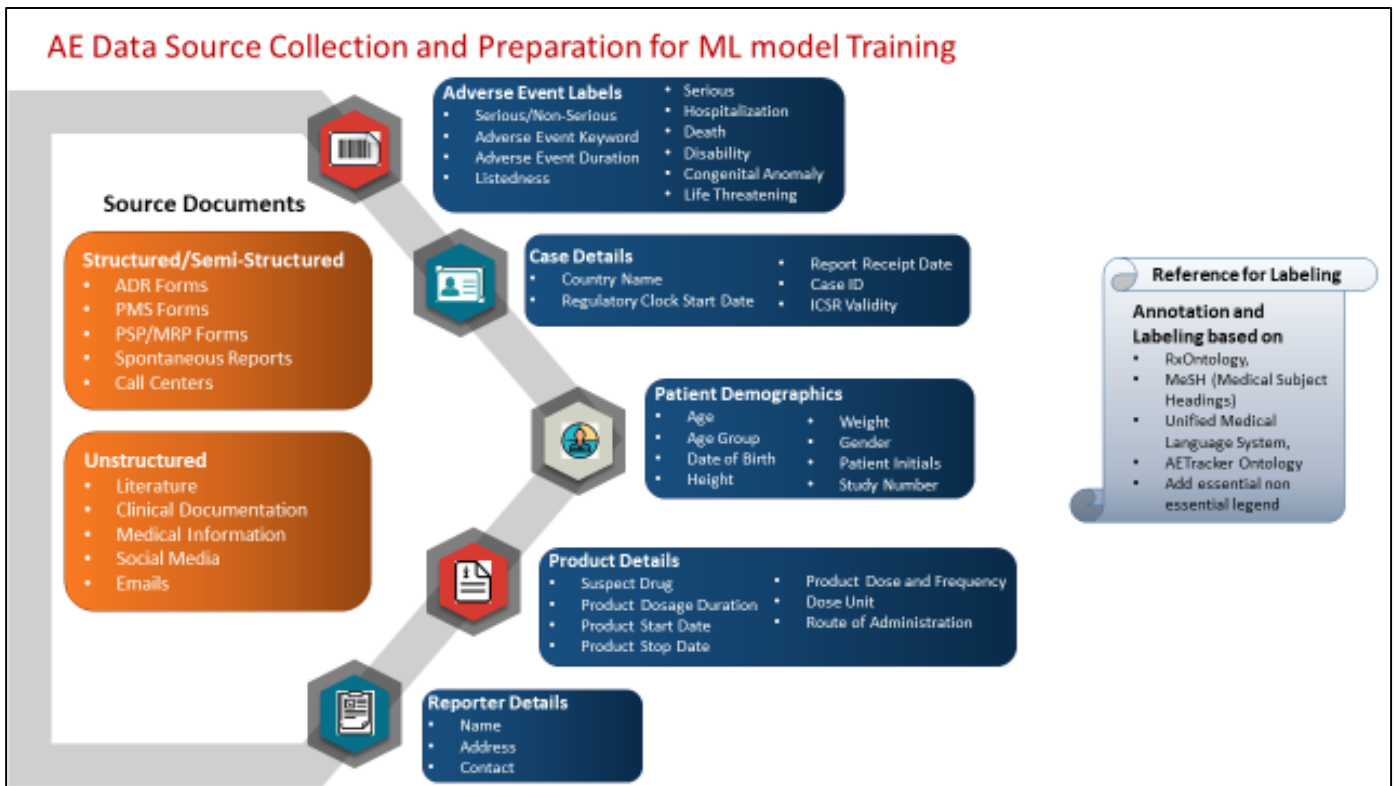AE Data Source Collection and Preparation for ML model Training

Fig 2a and 2b show how a robust technology framework with a multi-tier architecture, configurable, and customizable solutions would help implement these automation platforms without disrupting the existing processes across multiple underlying safety databases.

- **Potential benefits in alignment with robust features of technology**
- **Conversion of unstructured data to structured data for analysis and meaningful insights for the drug safety profile**
- **Risk analysis and prioritization of adverse events – enables proactive decisions for product recalls and reduces pressure on brand**
- **Operational cost reduction by automating manual tasks**
- **Save time and increase productivity with automated rule-based engine and machine-learning models**
- **Reduce repetitive manual tasks and enable machine-based automated tasks to reduce human errors**
- **Improves quality and continuous feedback mechanism to increase the quality**
- **Accelerate compliance**
- **Build eco-system for contextual automation and integrated data reusability across the value chain**

CONCLUSION

Drug safety and adverse event reporting depend extensively on manual data entry and processing. Ever-increasing volumes of data and changing regulations demand a robust technology-driven process for efficient PV process management. A synergy of the work process and technology experts would cumulatively facilitate enhancements and technology adaptation and truly enable seamless workflow, data processing to consistently demonstrate quality, time and cost reductions, increased efficiency, and regulatory compliance. Innovative technologies and applications of AI/ML and deep learning methods with continuous learning and feedback mechanism would be widely accepted with minimal human intervention, thus enabling PV teams to focus on adverse events of higher risks.

REFERENCES

1. World Health Organization (WHO),

   (http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/)

2. European Medicines Agency, Guidelines on good pharmacovigilance practices (GVP), Oct 9, 2017.

   (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/10/

   WC500236408.pdf)

3. The Big (Unstructured) Data Problem. 5 June 2017, Rizkallah, Juliette.

   (https://www.forbes.com/sites/ forbestechcouncil/2017/06/05/the-big-unstructured-data-

   problem/#4b9d83b493a)

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We offer end-to-end drug safety and pharmacovigilance services to global pharma companies ensuring meticulous quality control and timely submissions. We also help companies to increase agility and lower operational costs while ensuring compliance with ever-changing global industry standards and requirements. We have extensive experience with regulatory agencies like FDA, EMA, PMDA, MHRA, BfArM, and other leading health agencies.

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