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Research Article

Developing a Cloud-Enabled AI System for Pharmacovigilance: Automated Detection of Adverse Drug Reactions from Patient Reports

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***Abstract*—An essential part of pharmacovigilance is the identification of adverse drug reactions (ADRs) associated with medicines. Traditionally, ADRs have been reported by health professionals, but there is growing recognition that consumers should likewise be included. Many countries now have online systems that enable consumers to self-report. Nevertheless, the vast majority of patient reports remain unused because there are too many for manual analysis. To exploit these valuable self-report data, a cloud-enabled AI system has been developed capable of automatically detecting ADRs in patient reports. The viability of the paradigm has been demonstrated by having the system identify ADRs in a large number of patient reports, and the system architecture has been designed to facilitate easy redeployment on various cloud platforms.**

Cloud computing is now a common paradigm in a range of application domains, having emerged largely because it provides an effective means of supporting high-level business functions. Many industries, including healthcare, have embraced the idea that consuming computing services as needed — and paying for only those resources that are used — makes good business sense. Implementing pharmacovigilance with the assistance of cloud computing and AI is an innovative way of exploiting the best that current technology has to offer.

***Index Terms*—Pharmacovigilance, Adverse Drug Reactions, Patient Self-Reports, Drug Safety, Cloud-Enabled AI System, Automatic ADR Detection, Consumer Reporting, Online Reporting Systems, Healthcare Data, Manual Analysis Limitations, Cloud Platforms, AI in Healthcare, Scalable Architecture, Self-Report Data Utilization, Cloud Computing, On-Demand Services, Resource Optimization, Business Functions in Healthcare, Innovative Pharmacovigilance, Technology-Driven Drug Safety.**

I. Introduction

Development of a Cloud-Enabled Artificial-Intelligence System for Automatic Detection of Adverse Drug Reactions from Patient Reports. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. In the context of COVID-19, many countries, including Switzerland, have set up national reporting systems to enable patients to report adverse drug reactions (ADRs). Several studies demonstrated the important contribution that artificial intelligence (AI) could make to the field of pharmacovigilance. Hence, a novel innovation would be to harness the complementary strengths of Cloud Computing and AI and develop an intelligent system that automatically detects suspected ADRs from patient reports.

Although many countries already support patient involvement by integrating patient reports into their existing pharmacovigilance databases, patient contributions still constitute only a fraction of the information in these databases, despite the proven value of adding these reports. Consequently, the automated analysis of patient-reported adverse effects remains a scarcely studied problem. The emergence of adverse drug reactions (ADRs) is one of the most serious consequences of drug therapy. Detecting, assessing, understanding, and preventing ADRs—tasks encompassed within the responsibility of pharmacovigilance—thus becomes essential. Today, smartphone applications also leverage the new possibilities offer by artificial intelligence.

A. Overview of the Study

The objectives of the study are to develop a cloud-enabled Artificial Intelligence (AI) system capable of detecting Adverse Drug Reactions (ADRs) automatically from patient reports. The system architecture examines linking public patient reports to a text classification model deployed on a prediction web service. Nine hundred seventy-one reports received from the annual EU telematics for pharmacovigilance public hearing serve as training data. Existing research methods establish the model using Support Vector Machine, Random Forest Classifier, and Convolutional Neural Network deep-learning classifiers, with Random Forest Classifier proving most suitable. Employing Azure Web Service provides a scalable, highly accessible, and robust framework for hosting the ADR-detection model as a RESTful web service.

Pharmacovigilance, as a global activity, aims to protect patients from experiencing ADRs or drug-induced diseases. The demand for automatic ADR detection systems is growing rapidly in recent years. Current pharmacovigilance methods and systems are time-consuming and prone to missing important data. Combining cloud computing with AI and machine learning technologies successfully addresses these challenges. Cloud computing offers scalable computing services through the Internet and reduces the healthcare industry's dependence on specialized IT systems. Nonetheless, due to patient privacy,

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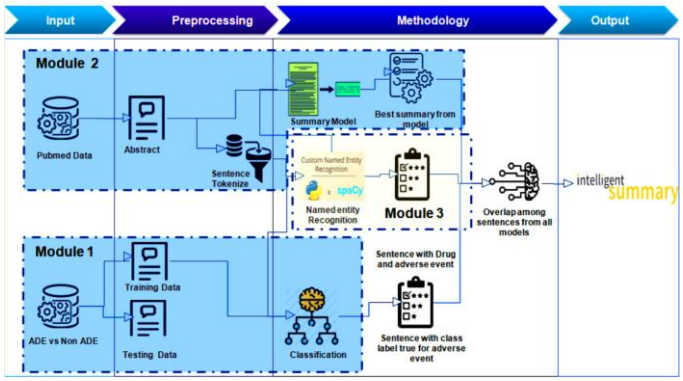

Fig. 1. ADR Detection System Architecture

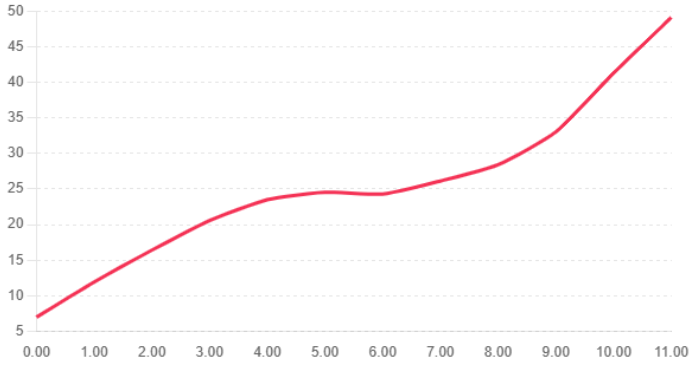

Fig. 2. Time-Decayed ADR Signal (exponential weighting)

network security, and auditing requirements, adopting cloud services in healthcare introduces new risks and complications.

II. Background of Pharmacovigilance

The discipline of pharmacovigilance developed from a need to identify adverse drug reactions (ADRs) in the 1960s, when thalidomide was linked with birth defects. Thalidomide wasn't withdrawn from numerous international markets until 1962, after WHO had set up an international service responsible for the causality assessment and analysis of ADRs in 1961. Since then, patients, pharmaceutical companies, healthcare professionals and regulatory agencies have all contributed reports to the service. Early pharmacovigilance was mainly concerned with drug safety and with the detection of a signal that an ADR may exist through the collection of individual case safety reports (ICSRs) from pre- and post-marketing clinical trials, ICSR databases, and medical literature.

Pharmacovigilance began to move beyond individual case reports with the emergence of data-mining technologies that use statistical methods to generate signals through the study of drug-ADR associations. It has evolved from a process driven by the analysis of individual spontaneous reports to one using a range of diverse information sources for drug safety signal detection such as the use of patient-generated health data sources.

A. Historical Context and Evolution of Pharmacovigilance

Pharmacovigilance plays an important role in supporting patients through the whole life cycle of medicines and presents a key pillar in the protection of public health. The term was first introduced at a World Health Organization Symposium on the subject in 1970. However, the origins of modern-day pharmacovigilance are often traced to the thalidomide disaster of the late 1950s and early 1960s. Thalidomide entered the market in 1956 and developed a reputation as one of the most widely prescribed medicines: as a sedative, hypnotic, and for indications during pregnancy such as nausea and vomiting.

Equation 01: Report-Level ADR Probability (from Bayes to a logistic form)

1. Tokenize & featurize the report into counts xj for vocabulary terms wj

2. Na¨ıve Bayes assumption: tokens are conditionally independent given label $y \in \{ADR, \neg ADR\}$

$$P(r \mid y) = \prod_j P(w_j \mid y)^{x_j} \quad (1)$$

3. Bayes rule (binary):

$$P(ADR \mid r) = P(r \mid ADR)P(ADR) + P(r \mid \neg ADR) \quad (2)$$

$$P(\neg ADR)P(r \mid ADR)P(ADR) \quad (3)$$

4. Log-odds:

$$\log P(\neg ADR \mid r)P(ADR \mid r) = \log P(\neg ADR)P(ADR) \quad (4)$$

$$+j \sum x_j \log \frac{P(w_j \mid \neg ADR)}{P(w_j \mid ADR)} \quad (5)$$

5. Logistic form:letting

$$b = \log P(\neg ADR)P(ADR) \text{ and } \vartheta_j = \log \frac{P(w_j \mid ADR)}{P(w_j \mid \neg ADR)} \quad (6)$$

$$P(ADR|r) = \sigma(b + \sum_j \vartheta_j x_j), \ \sigma(z) = \frac{1}{1+e^{-z}} \quad (7)$$

III. Adverse Drug Reactions (ADRs)

Adverse drug reactions (ADRs) are arbitrary and harmful responses that appear after administering a medicinal product. During the development and marketing of a drug, it is impossible to identify all side effects, and many of these side effects appear after a drug is taken in a large group of people or for a long period of time. ADRs affect the quality of life, increase hospitalization rates, cause discontinuation of drug

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month	total reports N	drug mentions Nx	adr mentions Ny	cooccurrence Nxy
1	1043	65	101	7
2	1016	75	100	7
3	1105	73	104	8
4	1118	64	98	9
5	995	68	94	9

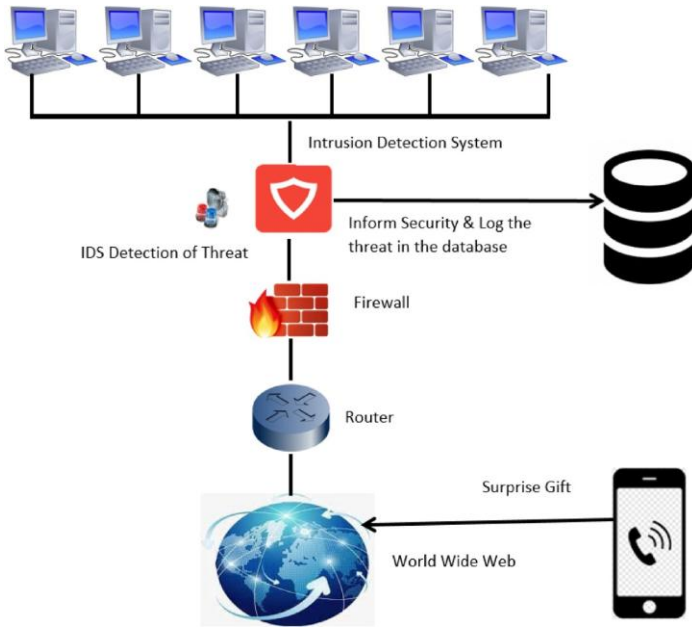

Fig. 3. Cloud-Based ADR Detection from Social Media

treatment, and sometimes lead to death.

There are different types of ADRs, which are explained in the literature. They can be categorized as dose-related reactions, non-dose-related reactions, dose-related reactions related to coexisting diseases or diseases related to long use. Dose-related reactions, or type A adverse reactions, are dose-dependent and related to known pharmacological effects of the drug.

Type C adverse reactions are dose-related and associated with long-term use. Type D reactions are not dose-related and become apparent after a certain period of time. Type E adverse reactions are dose-related and are associated with discontinuation of treatment. Understanding these categories of ADRs is essential as they determine the methods used in ADR detection.

A. Definition and Importance

With the large number of patients considered, both during the preclinical and clinical phases, the majority of the reactions suffered by people receiving any drug are identified and analysed, and therefore it is considered safe. However, not all reactions are identified in those phases for several reasons, such as the drug may only be available in certain countries or regions, the exclusion of certain types of patients (e.g. pregnant women or children) during the clinical phase, or the administration of certain drugs in combination with others. These cases represent a large variety of possibilities that can affect people receiving any drug. Therefore, once the drug has been commercialised and available to the entire population, it is important to have a mechanism capable of continuing to monitor its use so as to prevent future adverse reactions or adverse reactions that may take several years to be detected (e.g. cancer stemming from the use of a particular substance). These mechanisms, designed to detect the reactions that were not detected in previous stages or any other problems that occur during or after the use of the drug, come under the name of pharmacovigilance.

An Adverse Drug Reaction (ADR) is defined as any un-wanted effect on the intermediate or long-term health of a patient from taking a drug. An ADR can be the consequence of a single drug or of taking several drugs in combination. The study of these reactions is carried out through the processes of the Pharmacovigilance Department; the identification and resolution of these reactions ensure appropriate treatment and, therefore, patient safety.

B. Types of ADRs

Although numerous classifications have been proposed for ADRs, the main types can be distinguished from the profile of the ADR involved – Type A (Augmented):

– Type B (Bizarre): These reactions are unpredictable, usually severe, and typically require immediate withdrawal of the involved drug to protect the patient.

– Type C (Chronic): ADRs associated with long-term drug treatment. While their prediction is possible, it is difficult to prevent these responses.

– Type D (Delayed): Reactions that manifest after some time, beyond the treatment period.

– Type E (End-of-Use): Reactions observed when discontinuing the use of a drug.

– Type F (Failure): The failure of therapy; these reactions are rarely included in ADR studies but are nevertheless important.

Equation 02: Time-Decayed Signal Strength (emerging signal over time)

1. Let each period Δt produce an evidence score S_{st} (e.g., predicted ADR probability sums or co-occurrence counts

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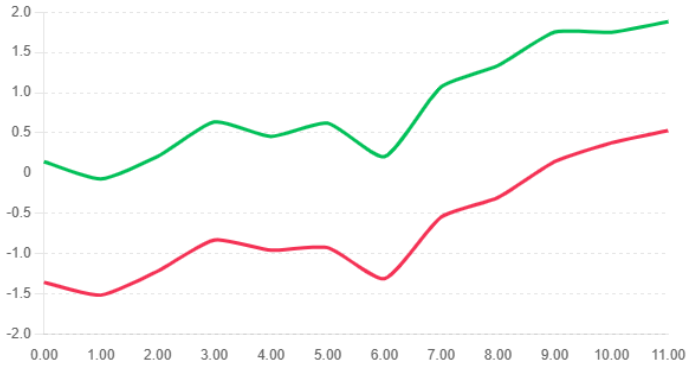

Fig. 4. Information Component (IC) Over Time

	Drug X present	Drug X absent
ADR Y present	20	36
ADR Y absent	66	829

$N_{xy,t}$)

2. Exponential decay with rate $\lambda > 0$: recent data weigh more

$$ST_T = \sum_{t=1} S_{st} e^{-\lambda(T-t)} \quad (8)$$

3. Normalizing (optional): divide by

$$\$ \sum_{t=1} e^{-\lambda(T-t)} \$ \quad (9)$$

for a 0–1 scale

IV. Current Methods of ADR Detection

Several adverse drug reaction (ADR) reporting systems have been developed over the last decade to detect potential ADR signals. These systems are primarily based on reports submitted by healthcare professionals, which may be voluntarily contributed. Built on the recognition that ADRs are commonly associated with complications in hospitalized patients, their detection is considered vital. The accumulation of case reports generated a self-implementing SVARS database, with its simplest application being the IBM ADR Database Retrieval tool.

VigiAccess differs from other tools by providing public access to the entire VigiBase. In the European Union, patients report ADRs through the yellow cards scheme, and in India, the Pharmacovigilance Program of India (PvPI) supports a similar initiative. While these systems significantly aid in the prevention and detection of ADRs or Drug Safety Issues, they do present certain drawbacks. One major concern is that these platforms are not designed to handle extensive patient data, leading to considerable processing time for each individual report. Logistically, all reports would require submission to the PV centers associated with these systems. Moreover, these methods are solely designed to generate signals for the stakeholders involved in stewardship, lacking provisions for self-detection and alerting at the patient level.

A. Traditional Reporting Systems

ADR (adverse drug reaction) detection is an important task within pharmacovigilance. In the past, several sequential steps have been proposed and applied to detect ADRs. Review of individual case safety reports (ICSRs) is the principal method of detecting an ADR. With the emergence of new medicines, monitoring post-marketing safety has become a challenge because most serious ADRs are revealed in the entire patient population, unlike the limited individuals in clinical trials. A traditional reporting system is an important source of information about possible ADRs, and patient reporting of dissatisfaction with the system has also been incorporated. However, despite this contribution, there are drawbacks to the system, such as the economy of operation, human resources, and the fact that the reports are not representative. These reports contain the most valuable information for the detection of ADRs, yet the current task of identifying and extracting that information is sluggish and cannot match the speed at which reports are received in a large database.

With the advent of patient monitoring, ADRs can be detected at an earlier stage, although the management and processing aspects of follow-up studies have not yet been automated. Other databases such as hospital discharge summaries and the Diabetes Register, which ensure the safety of the drugs, can also be used. The detection of these ADRs through patient reports has been made simpler by supporting technologies such as information and communication technologies. ADR listing indisputably has a positive impact on pharmacovigilance since it ensures the safety of the patient, helps in the rational use of drugs, and provides an early warning which leads to risk minimisation. Additionally, the CSR-based ADR detection system has been developed for detecting ADRs with the help of data mining techniques.

B. Limitations of Current Methods

Spontaneous reporting systems hold intrinsic disadvantages. Patient or other reporter awareness to report may be insufficient; the sequence of events, the features of the event, whether the drug was labelled to be associated with those events, may not be known. Moreover, the insurance, social, and/or litigation consequences, could further influence the data collected. Coding of the event could be done differently by different person at different time. Such systems mainly capture severe and documented ARs resulting in data bias as common events can be under-/over-reported, misdiagnosed, and/or misclassified collection.

Identifying ADRs after drug registration form significant components of pharmacovigilance program which are used for resubmission, improvement or new submissions, labelling update or review, risk management and drug withdrawal. Today, large volumes of information are publicly available in the form of social network data, search engine queries, consumer review blogs, Twitter feeds, YouTube video content with rich sources of information about many drugs, and the

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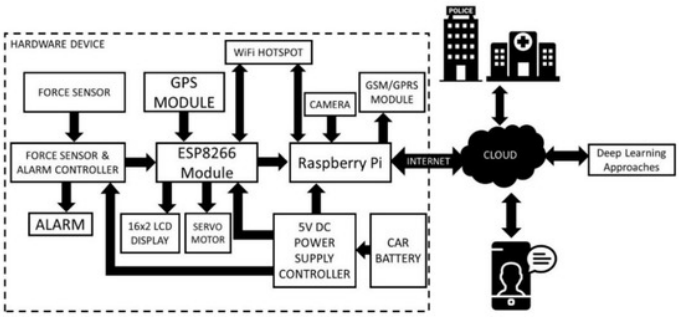

Fig. 5. Cloud-Enabled AI Service for ADR Detection

users' health concerns, emotions, and opinions. When used appropriately and cautiously, such data can provide supplementary information on users, which may not be readily obtained by other data sources. Cloud computing, on the other hand, refers to storing and accessing data and programs over the Internet instead of the computer's hard drive, providing a huge system with the computational ability to support large-scale machine learning applications without worrying about the data storage and management. The synergy between cloud computing and machine learning can provide a new paradigm by analyzing huge volumes of social media data in a cost-effective manner and thus can bring a major breakthrough in pharmacovigilance.

V. Cloud Computing in Healthcare

The healthcare industry is witnessing rapid growth of patient-generated data with the proliferation of smart devices at home. Little of this data is analyzed and often remains locked in the home of the patient. Unlocking this data creates an opportunity for improving medical care and patient outcomes by enabling non-invasive, continuous monitoring of patients. Cloud computing utilizes Internet-based services to perform scalable storage, management, and processing of data. Cloud computing provides lower upfront costs than traditional on-premises environments by allowing users to pay only for the services they use. Cloud capabilities such as wide network access and resource pooling provide health professionals with anytime, anywhere information access. Despite these benefits, cloud migration exposes healthcare enterprises to a new set of risks, such as invasion of privacy, data breach, leakage of sensitive information, regulatory violation, and loss of control over sensitive information. These risks have made healthcare organizations wary of moving applications to the cloud.

The rise of the cloud computing paradigm represents a breakthrough in information and communications technologies (ICT). For pharmacovigilance in particular, cloud computing is an especially attractive option as it addresses two critical problems in modern healthcare: the rapid accumulation of medical data and the high requirements on data analysis. As a result, cloud-enabled artificial intelligence is forging a new pathway for the development of AI-powered pharmacovigilance in the near future. Currently, machine learning methods—especially deep convolutional neural networks (CNNs)—have been shown to be efficient in image classification. To demonstrate the capability of cloud-enabled AI in this field, a cloud-enabled CNN method for the rapid identification of animal species involved in animal poisoning incidents is presented.

A. Benefits of Cloud Technology

Cloud computing has become one of the dominant models for Information Technology (IT) services, enabling convenient, on-demand network access to a shared pool of configurable computing resources that can be rapidly provisioned and released. Cloud computing offers three categories of services: Software as a Service (SaaS), Platform as a Service (PaaS) and Infrastructure as a Service (IaaS). SaaS allows users to access software applications hosted in the cloud via a web browser. PaaS provides a platform for developers to create, deploy and maintain applications. IaaS facilitates subscribers' access to processing, storage, and other computing resources.McDonnell and El-Gayar, 2013—McDonnell, 2013

Despite initial concerns regarding the security and privacy of patient data stored in the cloud, cloud computing has been recognized as a pragmatic solution for the health care and public health sectors because of scalability, data mining and analysis capabilities, reduced maintenance costs and ubiquitous access.McDonnell and El-Gayar, 2013—Wang et al., 2014—Ele, 2015

B. Challenges and Risks

Today, healthcare is one of the most dynamic Cloud markets and is expected to grow by earning $18.50 billion by 2021. Cloud services allow Hospitals to optimize the flow of their information and data files, automate the access to medicine and diagnostics, offer personalized treatment processes based on the methodology offered, and gain clinical competence and organizational efficiency. Through Cloud Computing, technology can be provided to even the remotest areas and underserved populations around the world that are having problems in accessing the healthcare services they need. Also, the ever-growing number of applications powered by Cloud services makes it easier for individuals to adopt healthy lifestyles and successful coping with stress. However, the concept of Cloud Computing is still not widely recognised by either patients or professionals in the Healthcare sector. As a result, Cloud Computing applications could provide a range of improvements for the healthcare services that are offered, but also, at the same time, generate a lot of questions and doubts regarding the possible risks and concerns with this "shift" to a Cloud environment. It can be argued that most of the adoption failures in Cloud

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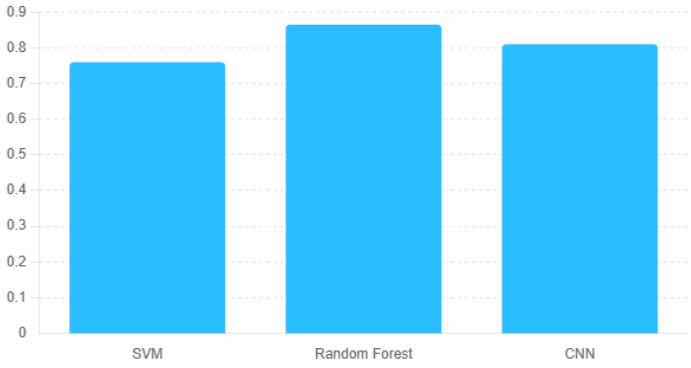

Fig. 6. Classifier F1 Comparison

Model	Precision	Recall	F1
SVM	0.78	0.74	0.7594736842105264
Random Forest	0.85	0.88	0.8647398843930636
CNN	0.82	0.8	0.8098765432098766

Computing come from concerns linked to security and privacy.

Equation 03: Alert Generation Rule (statistical + operational)

1. Statistical gate: use a disproportionality metric's lower confidence bound LT (from Eq. 4).

2. Operational gate: require time-decayed strength above threshold τ

$$Alert at Tif LT_t > 0 and ST_t > \tau \quad (10)$$

The rule integrates safety (avoid false positives) and responsiveness (recency-weighted magnitude).

VI. Artificial Intelligence in Pharmacovigilance

Artificial Intelligence (AI) is considered the next technological revolution. Recent advances in machine learning have made it possible for computers to classify and cluster images, people, objects, videos, voice commands, intelligence level and many other types of data that was considered impossible before. The recent successes in different aspects of artificial intelligence such as in image recognition, speech recognition, computer vision, natural language processing, self- driving cars and many other fields have made AI very popular. The increased computing power of computers and the enormous amount of data available combined with the recent advances in the area made it possible for simple yet effective AI techniques to be applied in many areas of life and business.

Pharmacovigilance is a new application for artificial intelligence and its use has not been fully explored. Pharmacovigilance is the science relating to the detection, assessment, understanding and prevention of adverse drug reactions or any other drug-related problems. This process is usually done to prevent harm to patients by identifying the adverse drug reactions of different drugs. AI as a concept of self-learning machines can be used in the detection of adverse drug reactions of drugs. Several studies have presented methods of detection of adverse drug reactions from patient reports or laboratory results using machine learning algorithms. It has also been suggested that machine learning can be used for prediction in pharmacovigilance. AI has also been used for other applications in healthcare such as identification and diagnosis of diseases using radiological images.

A. Machine Learning Techniques

Machine learning is a subfield of artificial intelligence that enables computer systems to learn from experience without being explicitly programmed. In pharmacovigilance, machine learning techniques are often used to analyse patient reports and detect any adverse drug reactions. The key idea is to extract information from the reports, create features, and use them to train classifiers to detect adverse drug reactions.

Even though patient reports contribute to the majority of adverse drug reaction reports, the content and the format of patient reports are different from that of healthcare professional reports. The patient reports are often free text, making it more appealing to use natural language processing techniques rather than using predefined features.

B. Natural Language Processing Applications

Natural language processing is a branch of AI that allows computers to automatically process and analyse large quantities of natural language data, in order to extract new knowledge and insights. This technology is being applied to pharmacovigilance in order to allow automatic identification of adverse events described in patient reports. Identification of information from patient narratives is complex, requiring both even basic text-processing skills, together with an understanding of clinical language—including knowledge of medical terminology, and that relating to the illness and treatment of the patient—to extract meaningful insights. AI technology can be used to automate extraction of this information by replicating the text-processing operations carried out by a human expert.

NLP models can be trained to identify the type of text of specific sentences so that they may be classified. This feature has been used to identify 'ADRs' in relation to a specific medication mentioned in a discussion on Mental Health Forums. The probability of a post being labelled as discussing an ADR has also been predicted, based on the content and structure of the post. Named-entity recognition—where an entity (for example, an ADR or medication) is extracted from a span of text—has been applied to labelled datasets of patient narratives in order to automatically identify specific ADRs or medications, allowing a complete report to be assembled automatically. Relation extraction—where a relationship is identified between various entities—has also been applied to automatically structure patient narratives in the form of a complete pharmacovigilance report.

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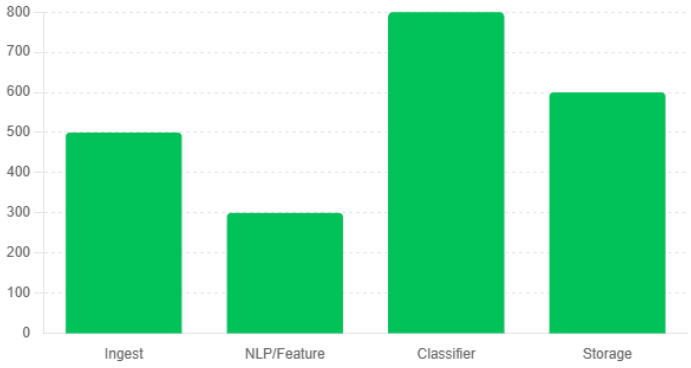

Fig. 7. Cloud Pipeline Stage Capacities

Stage	Capacity rps
Ingest	500
NLP/Feature	300
Classifier	800
Storage	600

Equation 04: Information Component (IC) Score (WHO-UMC style)

1. Build the 2×2 table from a corpus of N reports (last-month example table displayed above):

2. Expected co-occurrence under independence:

$$E = NNxNy \quad (11)$$

3. Shrinkage (add-0.5) to stabilize rare counts.

4. IC definition:

$$IC = \log_2(E + 0.5N_{xy} + 0.5) \quad (12)$$

5. Uncertainty (approx.): by delta method

$$Var(IC) \approx (Nxy + 0.5)ln221 + (E + 0.5)ln221, \quad (13)$$

$$L = IC - 1.96Var(IC) \quad (14)$$

VII. System Architecture

Described in previous sections, the detection of adverse drug reactions (ADRs) from patient reports was developed as a cloud-enabled artificial intelligence (AI) service. Cloud adoption enhances the safety and quality of healthcare through on-demand access to a shared pool of configurable IT resources. It provides the computational infrastructure necessary for next-generation pharmacovigilance. Accessing knowledge from a public Patient Safety Organization (PSO) cloud offers a consistent environment for ensuring and maintaining patient safety and other medical outcome indicators.

Cloud technology is applied both in dynamically instantiating AI engines and in storing processed ADR data. The AI method learns how to identify ADRs within patient event narratives and classifies events into ADR and non-ADR. Users submit event narratives and receive the corresponding classification, as shown in Figure 1. Data collection, used for appropriately training and evaluating the system, is also an essential component. A URL conveying patient drug-safety information is passed to the data-collection component, which retrieves and processes reports for storage in the event-narratives cloud.

VIII. Future Directions

Deep learning is more powerful than classical machine learning methods, yet it requires a larger amount of training data for good accuracy and generalization. In the future, as larger pharmacovigilance corpora become available, deep learning techniques such as convolutional and recurrent neural networks can be applied. Furthermore, larger corpora can be deployed through transfer learning, where deep learning models are trained on large corpora from unrelated domains (e.g., Wikipedia) and then fine-tuned on pharmacovigilance corpora. Adverse drug reactions are by no means the only category of information needed for pharmacovigilance tasks. Future research can be directed toward other categories of information, such as severity, drugaˆ €“drug interactions, drug indications, and medication errors.

Pharmacovigilance can also include deterrent tasks such as detecting ADR mentions in prescription guidelines, which are helpful in avoiding undesirable side effects while prescribing medication. Machine learning techniques presented here can also be used to address these categories of information. A cloud-enabled system can be an enabling innovation for such advancement in pharmacovigilance.

IX. Conclusion

The development of a cloud-enabled AI system for pharmacovigilance marks a significant advance in healthcare. A dedicated machine-learning model–combined with NLP–can detect adverse drug reactions automatically from patient reports and comments and thus mitigate one of the leading causes of death worldwide. Implementing this model in a cloud-computing environment—in which system architecture enables auto-scaling and high availability—further highlights the roles and benefits of each technology, as well as the possible privacy and security risks. Cloud computing's scalability can handle the growing volumes of patient reports, and its accessibility can eliminate potential time-zone issues for globally dispersed pharmacovigilance teams.

A. Final Thoughts and Implications for Pharmacovigilance

Cloud computing and AI constitute a natural alliance, harnessing the elasticity and rapid scalability of cloud services alongside the high processing and analytical demands of AI applications. This symbiosis unlocks the digital and data revolutions, enhancing the efficiency of pharmacovigilance and contributing to improved patient outcomes. The presented cloud-enabled AI system demonstrates that pharmacovigilance

activities, such as automated detection of ADRs in patient reports, can be transported from healthcare organizations to the cloud with satisfactory performance while considering patients' privacy, security, and governance principles. Emerging AI technologies, such as large language models, are expected to significantly shape future pharmacovigilance services. Algorithms like ChatGPT and MedPaLM 2 exhibit advanced natural language understanding and generation capabilities that offer tailored solutions in various healthcare domains. The capabilities of these models will serve as a foundation for developing new use-cases and tools that support pharmacovigilance activities beyond ADR detection.

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