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GENERATIVE ARTIFICIAL INTELLIGENCE AND LARGE LANGUAGE MODEL IN PHARMACOVIGILANCE

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ABSTRACT
Large language models (LLMs) and generative AI (GenAI) in healthcare offer previously unheard-of potential and difficulties that need for creative regulatory strategies. Applications for generative AI and Large language models are numerous, ranging from personalising diagnostics to automating clinical operations. However, current medical device regulatory frameworks, such as the whole product life cycle (TPLC) approach, are challenged by the non-deterministic outputs, wide functions, and intricate interaction of generative AI and Large language models. Here, we propose for international cooperation in regulatory science research and address the limitations of the TPLC approach to generative AI and Large language models -based medical device regulation. This is the basis for creating novel strategies to test and improve governance in practical contexts, such as regulatory sandboxes and adaptive policies. To manage the effects of Large language models on global health, particularly the concerns of growing health disparities caused by intrinsic model biases, international harmonisation is crucial, as demonstrated by the International Medical Device Regulators Forum. Global regulatory science research facilitates the responsible and fair advancement of Large language models breakthroughs in healthcare by utilising multidisciplinary skills, emphasising iterative, data-driven techniques, and concentrating on the needs of varied populations.

KEYWORDS: Pharmacovigilance, Artificial Intelligence, Adverse Drug Event, Large Language Models.

INTRODUCTION
The World Health Organization (WHO) defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.[1] PV is governed by legislation and must not only collect, collate, and evaluate Adverse Events (AEs) that are reported, but also has the regulatory expectation to evaluate these reports and understand drug-event causality both at the patient and population level. The pharmaceutical industry has continued to work through growing volumes of AE data. In an 8-year period (1998–2005), the number of serious event reports that the Food and Drug Administration (FDA) received increased 2.6-fold, and reports of deaths increased 2.7-fold.[2] To manage the increase in AE data thus far, the pharmaceutical industry has been scaling operations by leveraging a combination of increasing human resources and outsourcing; however, the transcription and data entry tasks required to process these data remain largely manual in nature. There is a need to identify assistive technologies that provide the automation of repetitive tasks involved with the collection and collation of AEs, as well as providing support and evidence to enhance complex decision making within PV. New technology options should be able to automate mundane activities, harness and provide a synthesized view of the growing amount of data, and provide evidence of recommendations to a PV professional. We propose that using artificial intelligence (AI) can reduce the manual effort associated with transcription and data entry to allow greater focus on scientific and medical evaluation of AEs, work that ultimately brings greater value to the patient.[3] A

revolution in pharmacovigilance has been brought about by AI-driven automation, which uses machine learning models, natural language processing (NLP), and sophisticated algorithms to quickly and effectively evaluate massive amounts of real-world data sources.[4] The early 20th century to the evolving era (21st century), public healthcare sectors have exponentially developed, evolved not only in terms of concept, and application but with the progression of time it has advanced its technologies in the scientific field. Healthcare sectors are responsible for the production and storage of large amounts of data and the management of these became a major challenge for nations across the world, hence the need for advancement in technologies like big data and Artificial intelligence arose.[5] A wide range of fields and new intricate angles for the usage of big data are being discovered by the thoughtful brains of the Scientific community.[6] More advanced AI approaches such as large language models (LLMs) have expanded what is possible for extraction and reasoning from clinical text, but they are fallible in high-stakes settings without safeguards.[7] Large Language Models (LLMs) can produce factually incorrect or unfaithful statements ("hallucinations") and omissions, reinforcing the need for designs that foreground provenance and constrain outputs.[8] Artificial intelligence (AI) is the dawn of a new era Unknowingly, it has become an integral part of our personal lives from home to street and the technology is now pervading scientific research, health-care system, and pharmacovigilance (PV) PV is to reduce the incidence and the risk associated with the use of medicines.[9] Machine learning (ML) and artificial intelligence (AI) have a long history of use in health care, including scheduling, radiology imaging analysis, drug discovery, and clinical diagnostic and decision support, with variable rates of success.[10] Machine learning (ML) and artificial intelligence (AI) have a long history of use in health care, including scheduling, radiology imaging analysis, drug discovery, and clinical diagnostic and decision support, with variable rates of success.[11] Large language models (LLMs) are useful tools with the capacity for performing specific types of knowledge work at an effective scale. However, LLM deployments in high-risk and safety-critical domains pose unique challenges, notably the issue of ``hallucination," where LLMs can generate fabricated information. LLMs can be safely used in high-risk situations by eliminating the occurrence of key errors, including the generation of incorrect pharmacovigilance-related terms, thus adhering to stringent regulatory and quality standards in medical safety-critical environments.[12] The issue of LLMs hallucinating has been a recurrent theme across multiple studies, including one published in npjDigital Medicine that focused on data extraction from clinical notes using ChatGPT.[13] LLMs are advanced automated systems trained on vast amounts of text to understand and generate language in a way that mimics how humans use language, enabling them to perform a wide range of language-related tasks.[14] These models can capture context and semantics in clinical text far beyond simple pattern matching. Importantly, LLMs can be fine-tuned on medical corpora (e.g., ClinicalBERT, BioBERT) or used in few-shot prompting to recognize medical entities. Because ADEs are often only briefly mentioned in clinical notes.[15] Recent, advances in artificial intelligence (AI) technologies are dramatically revolutionizing processes and tasks across all disciplines, including medicine and healthcare, particularly in pharmacovigilance (PV).[16] The ability to effectively collect, manage, and analyze data, and act appropriately on outputs is at the heart of PV. The promise of AI across all aspects of the PV lifecycle is therefore enormous. While these technological strides present us with undeniable opportunities, they also confront us with challenges that are not fully understood.[17] The propensity for risks associated with AI—such as errors of all types, including hallucinations, biases, and omissions ranging from subtle to overt—is a concern that impacts its trusted use in many situations.[18] More recently, the U.S. Food and Drug Administration (FDA) developed and evaluated SPINEL (Supporting Pharmacovigilance by Leveraging Artificial Intelligence Methods to Analyze Electronic Health Records Data), an AI-enabled software prototype that extracts opioid-related adverse drug events (ADEs) from electronic health records (EHRs) using keywords and trigger phrase analysis.[19] Generative AI (GenAI) and large language models (LLMs) may enable novel approaches that were previously unfeasible with conventional methods.[20] For instance, preliminary studies have explored the potential of ChatGPT to recognize adverse drug reactions.[21] Pharmacovigilance signal detection.[22] The integration of large language models (LLMs) into the fabric of numerous applications has positioned them as instrumental in navigating the complex challenges in biology and medicine.[23] The integration of generative AI (GenAI) and large language models (LLMs) in healthcare presents both unprecedented opportunities and challenges, necessitating innovative regulatory approaches. GenAI and LLMs offer broad applications, from automating clinical workflows to personalizing diagnostics.[24]

AI in Pharmacovigilance

Pharmacovigilance (PV) focuses on detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) to ensure drug safety. Artificial intelligence (AI) and machine learning (ML) have emerged as promising tools to enhance PV by automating processes, improving signal detection, and analyzing vast datasets. AI can identify hidden safety signals, predict risks, and streamline case processing, reducing the workload and enhancing efficiency. Integrating AI into PV involves careful attention to data quality, compliance, and transparency.[25] Automated adverse drug reaction (ADR) detection is an important step in pharmacovigilance. It may solve a series of critical shortcomings present in traditional spontaneous reporting systems (SRS) many SRS currently suffer from chronic underreporting and slow detection of safety signals which can take months or years to be detected at the regulatory level.[26] AI-powered natural language processing (NLP) overcomes those limitations by systematically extracting from unstructured datasets from an array of sources, including EHRs, clinical narratives, and social media. AI has revolutionized signal detection. Artificial intelligence has greatly improved the way we detect signals. It uses machine learning algorithms to discover hidden patterns in vast amounts of data. This means that tasks involving signal detection are now more efficient and accurate because AI can analyze data much faster and find patterns that humans might miss.[27] AI in pharmacovigilance is multi-source data integration.[28] Adequate quality and availability of data are essential for the effectiveness of AI in adverse drug reaction (ADR) detection. However, fragmented and inconsistent data spread across various healthcare systems make it difficult for AI technologies to work. Improving data standardization and global collaboration will help to improve the effectiveness of AI.[29]

Definition of ADR

Adverse Drug Reactions (ADRs) are defined by the World Health Organization (WHO) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease.[30]

Adverse Drug Reaction Classification

Healthcare practitioners can better understand the underlying causes of adverse drug reactions, anticipate their occurrence, and adopt effective preventative and management measures by using the methodical framework that classification offers. Because of its practical usefulness and clinical importance, the Type A–F classification is the most frequently recognized of the several proposed classification schemes.

Type A Reactions (Augmented)

Type A reactions result directly from a drug's recognized pharmacological activities and are dose-related and predictable.TypeA responses can typically be avoided or reduced with thorough therapeutic monitoring and dose adjustment because they are frequently associated with excessive dosage or increased patient sensitivity.

Type B (Bizarre Reactions)

type B reactions have little to do with the main pharmacological mechanism of the medication. They may be caused by genetic or immunological causes and are generally uncommon but potentially serious. These responses are hard to avoid since they are unanticipated, and they frequently require stopping the suspected medicine right away.

Type C (Chronic Reactions)

Long-term medication therapy can cause type C responses, which are typically linked to cumulative dose exposure.

Type D (Reaction of Delayed)

Type D reactions might take months or even years to manifest after medication exposure. It can be difficult to establish a causal association because of this delayed beginning.

Type E (End-of-Treatment Reactions)

Type E reactions, often known as withdrawal or rebound effects, occur when a medicine is abruptly stopped.

Reactions of Type F (Failure)

Unexpected therapeutic failure, or type F responses, is frequently brought on by drug combinations, insufficient dosage, or antibiotic resistance. Reevaluating therapy approaches may be necessary due to these reactions, which could jeopardize treatment results.[31]

ADR Identification Task

The Light Gradient Boosting Machine (LGBM) is an advanced machine learning model that works on the principle of gradient boosting with decision trees. This process helps improve accuracy and gives better results. LGBM was selected for this study because it showed the best performance in earlier, smaller study, proving that it can handle complex data efficiently.[32]

Role of AI in the minimizing of risk of ADR

AI is unique. This is because AI can develop itself by using intelligent techniques or by working intelligently.[33] Nilsson has defined AI as “The activity devoted to making machines intelligent, and intelligence is that quality that enables an entity to function appropriately and with foresight in its environment.[34] In hospitals, Al systems are added to electronic health records (EHRS). These systems watch patient data in real-time and can send alerts if there is a risk of ADRs. Because of this, ADR cases have reduced by about 30%. Al is useful during drug development. It can study clinical trial data and find possible side effects before the medicine is sold.AI is also used in post-market surveillance (checking medicine safety after it is sold). It can spot new trends or risks. Al helps predict, detect, and prevent harmful drug reactions both in hospitals and in the drug-making process.[35]

Based on the rapid adoption of ChatGPT for legal assistance, it is likely that the utilization of AI systems in alternative dispute resolution (ADR) and legal support will increase in the near future.[36] Despite being coined about 70 years ago, the phrase "artificial intelligence" still does not have a universally agreed-upon definition. The difficulty in reaching a consensus on the definition of AI reflects a broader challenge in reaching a consensus on suitable regulatory and governance frameworks for AI. AI is defined as an algorithm or computer that is capable of doing tasks that would typically necessitate cognition.[37] Due to the absence of legislation, authority, norms, and monitoring, some individuals have inferred that ADR is an "informal system.[38] Commentators highlight the lack of agreed-upon and enforceable criteria and regulations for the qualifications and licensing of neutrals. They also point out the absence of clear responsibilities, obligations, and behavioral norms for neutrals. Additionally, they mention the need for procedural protections in the process of adjudication and limited instances of neutral misconduct for judicial review. When private and court alternative dispute resolution (ADR) regulations for practice and ethics are in place, there is a debate about the extensive scope, influence, and enforcement mechanisms of an ADR ethics.[39]

ADR is not subject to the same level of regulation as traditional litigation or legal practice, there are several laws that still apply to ADR, even though they are not specifically designed for ADR. These laws include professional standards that apply to advocates and neutrals who are licensed to practice law and work in ADR.[40]

Artificial intelligence (AI) and machine learning (ML) are being used to predict adverse drug reactions (ADRs) by analyzing large amounts of patient information. These models can look at age, medical history, medicines, and even genetic data to find out which patients are at higher risk. Pharmacogenomic ML models (which use genetic information) are especially useful because they can show how a person's genes might make them more likely to react badly to certain drugs. This helps doctors choose safer medicines for each individual (personalized medicine). The main benefits of ML in ADR prediction are: Better decision-making for doctors, Improved patient safety, Lower healthcare costs most hospitals do not yet use ML systems for ADR monitoring.[41]

Artificial Neural Networks (ANNs) are computer systems that work in a way similar to the human brain. They are an important part of machine learning, where computers learn from data and make decisions on their own. ANNs have been around for more than 60 years but were not very popular in the 1990s and 2000s. In recent years, they have become popular again under the name Deep Learning because of the improvement in computer power, especially through GPUs that can handle large amounts of data very fast.[42]

European Union Regulations: Classification of Risks Associated with AI Systems and Laws on Product Liability

The EU Artificial Intelligence Act (AI Act) introduced in 2021 and currently awaiting potential implementation, aims to establish the EU as the first major authority to pass comprehensive regulations particularly targeting AI. The AI Act aims to establish regulations for systems that have the potential to endanger fundamental rights or human welfare. It classifies AI use cases into four risk tiers: minimal, limited, high, and unacceptable.[43]

How AI Rules Becomes ADR Rules

AI and ADR are both governed by broader regulations, such as those for privacy and advertising.[44] AI is already integrated into ODR and various ADR processes, from basic tasks. The Covid-19 pandemic and recent AI advancements have accelerated AIDR adoption, which is expected to continue as AI capabilities advance.[45] AI systems used by some judges for bail determinations.[46]

Developing of AI in Pharmacovigilance

The combination of the rapid advances in the technology itself, the wave of increased interest in awareness of AI, and the sudden ease of access for many to populist AI tools has led to huge advances in interest, capability, and scientific research into AI in PV: some of which is therefore presented in this special issue. The dramatic increase in focus can be traced to the release of Chat GPT.[47] There is little doubt that AI is leading to great advances in our everyday lives, but with it, we are seeing both enormous publicity and therefore the associated hype/concern about use of these technologies.[48] The last few years, we have seen a sudden influx in scientific publications discussing experimentation with generative AI and large language models (LLMs)in pharmacovigilance for a range of problems.[49] End to end impact of AI across the PV lifecycle, much of the literature previously while promising on specific tasks has focused.[50] Use of other data streams in addition to individual case safety reports (ICSRs) in AI.[51] In PV, one area where there has been much focus is on automating case intake and processing. Automation.[52] is sorely needed given the complexity of processes to handle the large volumes of data and heterogeneity not just in data but also in expectations around data management.[53]

If AI has the potential to remove the need for such common data models and enable more rapid and richer access to data for pharmacovigilance then as Painter et al.[54] present interesting simulation work on behavioral data some potential important applications, for example, safety outcome prediction and personalized pharmacovigilance do not feature herein, suggesting there is much more we can expect in the future. We clearly also see plenty of applications of PV using data outside of ICSRs, adding support to the notion that PV is becoming increasingly multimodal-this being accelerated by emerging AI capabilities and needs for more/better richer data.[55]

Challenges and Limitations of AI in PV

While AI has shown great promise in enhancing PV processes, several challenges and limitations need to be addressed for its widespread adoption and optimal performance. This section explores four key areas of concern: algorithmic bias in diverse populations, temporal dynamics of drug safety profiles, causal inference in complex poly pharmacy scenarios, and integration of multi modal data sources.

Algorithmic Bias in Diverse Populations

AI models, especially those used in PV, are often trained on datasets that do not represent the diversity of real-world patient populations. This can lead to algorithmic bias, where the model per forms well for the majority group but poorly for minority or underrepresented populations. North American populations may struggle to detect ADRs in patients from Asia or Africa. The issue is compounded by the fact that clinical trials-a key source of training data-tend to under represent these populations.[56]

Temporal Dynamics of Drug-Safety Profiles

AI models, especially those trained on pre-market clinical trial data, may not adapt well to these changing profiles. This is particularly relevant for long-term drugs or drugs with a delayed onset of adverse effects. Addressing temporal dynamics requires continuous learning models that adapt in real time as new data emerge. However, these models pose their challenges: ensuring model stability while allowing for adaptability is difficult. Moreover, integrating real-world evidence from various sources, such as EHRs and spontaneous reporting systems, must be done carefully to avoid over fitting to short-term trends.

Causal Inference in Complex Poly-Pharmacy Scenarios

Polypharmacy, the use of multiple drugs by a single patient, particularly in older populations, presents a major challenge for AI systems in PV. Advanced methodologies have emerged specifically to address causality in drug interaction scenarios. The InferBERT framework represents a significant advancement by integrating trans former-based language models with do-calculus to establish causality in PV data, demonstrating high accuracy in discriminating between drug-induced adverse events.[57]

Integration of Multi-Model Data Sources

One of the most powerful promises of AI in PV is its ability to integrate multi-modal data. While this integration offers the potential for more comprehensive safety monitoring, it also introduces significant challenges. First, the quality and consistency of data across different sources can vary significantly. For instance, patient-reported outcomes on social media might lack the rigor of clinical trial data. In addition, data harmonization-the process of reconciling conflicting or incomplete information from different sources-remains a major hurdle.[58]

Applications of AI in PV

Artificial Intelligence (AI) and Machine Learning (ML) are very helpful in finding and studying Adverse Drug Reactions (ADRs). Al can automatically sort ADR reports based on how serious or expected they are, which saves time and reduces manual work. Machine Learning can also predict which patients might have side effects by studying their age, health condition, and medicines used. With the help of Natural Language Processing (NLP), AI can read information from research papers, hospital records, and social media to find new or rare drug reactions. Al can also arrange the detected signals according to how important or risky they are, so experts can focus on the most serious ones. It can combine data from hospitals, prescriptions, and patient reports to get a clearer picture of drug safety. Lastly, Al allows continuous and real-time monitoring of drug safety, helping health authorities make faster and better decisions to protect patients. Artificial Intelligence (AI) and Machine Learning (ML) can help India improve the way it detects and studies side effects of medicines. It looks at current progress, existing problems, and how new technologies can make drug safety monitoring more advanced in the future. We aimed to determine the best artificial intelligence to understand problems in current ADR detection methods. To explore how Al and ML. Help in identifying ADR signals. To study tools and models used for ADR analysis in India to examine the role of large databases in Al-based ADR detection to find challenges in using Al and ML. For pharmacovigilance to suggest future improvements for better drug safety monitoring.[59]

Al has been developed and applied in various areas of pharmacovigilance, the following outlines the relevant regulatory approaches

European Medicines Agency (EMA)

The EMA exchanges information and opinions on policies, guidance, and regulations related to the use and regulation of Al in pharmacovigilance.

Food And Drug Administration (FDA)

The FDA released a five-year plan to integrate Al into the existing pharmacovigilance framework even before the outbreak of the epidemic.

Central Drugs Standard Control Organization (CDSCO)

Clinical studies are approved with just a simple notification, reducing the challenges associated with obtaining licenses.

Al technologies are also transforming how safety data is managed to meet TGA requirements.

Pharmacovigilance Program of India (PvPI)

The Pharmacovigilance Program of India (PvPI), under the Indian Pharmacopoeia Commission, has also incorporated Al into its Adverse Drug Reaction (ADR) monitoring system.

Therapeutic Goods Administration (TGA)

The TGA mainly focuses on regulating and inspecting how sponsors use Al to ensure that drug monitoring is compliant and safe.[60]

Al Applications in Pharmacovigilance for Adverse Event Detection

Artificial intelligence (AI), especially machine learning, is now widely used in drug safety monitoring (pharmacovigilance) to find adverse drug events (ADEs) and adverse drug reactions (ADRs). The main uses of Al in this field include detecting ADEs and ADRs, analyzing safety reports and clinical notes, and predicting how different drugs might interact with each other. During clinical trials, compliance means correctly reporting side effects, following study rules, and making sure patients give informed consent. After a drug is on the market, compliance involves tracking reports from doctors and patients, checking scientific papers, and spotting early warning signals.

It helps detect side effects early, improves risk assessment. and leads to better patient outcomes. Al is transforming pharmacovigilance by enabling early detection of adverse events, accurate risk assessment, and real-time personalized treatment adjustments, ultimately improving drug safety and patient outcomes.[61]

This study focuses on how Al can be used in pharmacovigilance, the challenges involved, and the opportunities it offers for better monitoring and detection of drug safety issues.[62]

Large Language Model (LLM)

A Large Language Model (LLM) is a type of artificial intelligence model designed to understand and generate human-like text. The training process for an LLM involves feeding it large amounts of text data, such as books, articles, and internet content, to learn the patterns and structures of human language. LLMs, characterized by their vast size and complexity, have revolutionized natural language processing tasks. During training, the model adjusts its parameters through a process called back propagation, where it compares its generated output with the actual text and updates its parameters to minimize the difference between them.[63]

Classification Of LLM For Planning Task

A classification of the considered approaches by types of queries, testing environments, and used LLMs we should note that, in the general form, a query to a language model can consist of the following parts.

(A) A scene description, which is simply a list of available objects possibly supplemented with their properties.

(B) A list of actions available to the embodied agent.

(C) Examples of tasks posed for the embodied agent.

(D) Examples of executing posed tasks.

At the first stage, a natural language instruction describing the task for the embodied agent is used to form a query for LLM. Next, the query is fed to LLM, which iteratively generates an action plan. It should be noted that queries are mainly formulated in natural language. At the second stage, the agent implements the generated plan. This formulation means that the action plan is completely generated prior to its implementation in the environment and is not modified in the course of the implementation. This may lead to a situation when the agent gets stuck at some stage of the plan implementation, which, in turn, may lead to the initial task failed to be executed.[64] As feedback, it is possible to use information on the possibility of executing a particular action.[65] or a report concerning the correct execution of an action or the variation in the object state.[66]

History of LLM

The first language models were developed in the 1950s and 1960s.[67] They were limited in their capabilities and were not able to handle the complexity of NLP.[68] These models used probabilistic methods to estimate the likelihood of a sequence of words in a given context.[69] They were able to handle larger amounts of data and were more accurate than rule-based models.[70] The next major breakthrough in language modeling came in the mid-2010s with the development of neural language models.[71] The first neural language model was the recurrent neural network language model (RNNLM).[72] which was developed in 2010. RNNLM was able to model the context of words and produce more natural-sounding text than previous models.[73] In 2015, Google introduced the first large-scale neural language model called the Google Neural Machine Translation (GNMT) system.[74] The development of LLMs continued with the introduction of the Transformer model in 2017.[75] The release of OpenAI's GPT-1.[76] in 2018, marked a significant advance in NLP with its transformer-based architecture with 117 million parameters, GPT-1 could generate contextually relevant sentences, demonstrating the potential of transformers in revolutionizing NLP tasks.[77] In 2020, OpenAI released GPT-3.[78] Which was able to generate highly coherent and natural-sounding text.[79] In 2019, Open AI released GPT-2. Inspired by the success of GPT-3, OpenAI released the next iteration of their language model, GPT 4[80]. with the ability to generate even more coherent and natural-sounding text. Following GPT-4's success, Meta also introduced Llama.[81] a family of open-source foundation models. Google introduced Bard.[82] Amazon introduced AI features in the Alexa.[83] Models, and Huawei introduced Pangu models.[84]

Large Language Models to Enhance Patient Care

Nowadays, both patients and clinicians can interact with the EHR, even though the EHR is intended to inform healthcare professionals on patients' health status rather than inform patients' themselves.[85] When introducing medical chatbots for patient interaction, adequate awareness on the background of such chatbots is important as the formulation of prompts can severely affect the provided answer.[86] In order to formulate an appropriate answer in a specific context, nowadays, the end-user should provide a clear request to the chatbot, by providing a definition of audience (10-year-old vs. medical doctor) and clearly describing the context of the question to prevent generic, unrelated, or unwanted answers. But as writing effective prompts is challenging, fine-tuning chat bots for different patients is certainly worthwhile. By utilizing demographic information already stored within the EHR, the most appropriate model can be selected, and in combination with automatic suggestions on follow-up questions or prompt rewriting, the quality of patient–chatbot interaction is further improved. education in designing appropriate prompts thereby clearly illustrating the effect of prompt design on generated output and offering prompt optimization services (https://promptperfect.jina.ai) will further improve patient-chat bots interaction.[87]

LLMs and Research in Marketing

Current research on utilizing Large Language Models (LLMs) for marketing research is limited but promising. Studies show that LLMs can produce reasonable answers aligning with economic theory, displaying characteristics such as state dependence and downward-sloping demand curves.[88] Some experts believe that LLMs can replicate perceptual maps from human surveys, while other experts and scientists find that LLMs mimic human decision-making in experiments. However, LLMs may not always represent diverse perspectives and can exhibit biases. Further research is necessary to evaluate their performance and develop ethical guidelines.[89]

Online Advertisements with LLMs

Advertisements play a crucial role in the online search engine market, subsidizing free access to information and driving economic growth through a symbiotic relationship with content creation. The dominance of advertisements continues to grow, as seen with Netflix's ad-supported plan. Large language models (LLMs) like ChatGPT are increasingly used for various functions, sometimes replacing traditional search engines, prompting providers to explore revenue generation through advertising. This paper examines how online advertising models can be applied to LLMs and evaluates different frameworks for LLM advertising.[90]

Role of LLMs in the Future of Legal Practice

With advancements in AI and the development of tools such as GPT-4, Bard, Gemini, and Bing, it is aimed that these advancements will empower lawyers to enhance legal research, drafting tasks, and decision-making.[91] law firms integrating AI into their workflow, and law professors exploring AI-based techniques for legal aid.[92] A recent example is the Chatlaw.[93] By incorporating legal knowledge and reasoning into AI systems.[94] LLMs' transformative potential in the legal field is evident from their impressive performance in legal exams. GPT-4 scored in the 90th percentile on the Uniform Bar Examination.[95] These achievements showcase the significant impact of AI language models on legal practice. The authors present Chain-of-Thought (CoT) prompts, which aid LLMs in generating coherent and contextually relevant sentences following a logical structure, simulating a lawyer's analytical approach.[96] LLMs have also been utilized to explore fiduciary obligations.[97]

Challenges And Limitations of Large Language Models lack of interpretability[98], difficulty with rare or out-of-vocabulary words, limited understanding of syntax and grammar[99], and limited domain specific knowledge.[100] Other issues include; the need for vast amounts of data and computational resources[101], difficulty with context-dependent language[102], absence of emotion and sentiment analysis[103], limited memory[104], lack of creativity[105], and restricted real-time capabilities.[106]

Humans VS LLMs

Human interactions offer a deep level of empathy, emotional intelligence, and the ability to understand complex nuances in everyday life-situations. Human responses are not only based on the current situation (prompt), but also considers other factors.[107] Human interactions offer a deep level of empathy, emotional intelligence, and the ability to understand complex nuances in everyday life-situations. Human responses are not only based on the current situation (prompt), but also considers other factors.[108] There is also a need to develop new performance metrics for measuring the intelligence of AI systems, as traditional methods of assessing intelligence, such as IQ tests[109] are not well-suited for AI systems, as they are designed to measure human intelligence.[110]

Future Directions and Recommendation

Al in pharmacovigilance can make drug safety monitoring much better. It helps detect side effects more quickly and accurately by analyzing huge amounts of data in real time. This allows early action to prevent harm. With AI, doctors and regulators can spot safety issues faster and respond quickly. Al is bringing a big positive change in how we ensure medicines are safe.[111] Machine learning (ML) and artificial intelligence (AI) have become powerful tools to identify ADRs and toxicity early, even before drug production, animal testing, or human trials. It highlights new progress and future opportunities, showing how these technologies can improve patient safety and transform the process of drug discovery.[112]

Since artificial intelligence (AI) is now used in many fields not just healthcare, there are many chances for future research on how it can help in pharmacovigilance. In the future, other platforms like healthcare discussion forums or patient networks could also be explored, as interest in using social media for pharmacovigilance is growing.[113]

With the help of modern technology, pharmacovigilance has become more advanced and effective.[114] Tools like Artificial Intelligence (AI), Machine Learning (ML), electronic health records (EHRs), and mobile health apps help collect real-time data, predict side effects, and quickly report any adverse drug reactions (ADRs).[115]

CONCLUSION

The establishment of regulatory policies will face more difficulties and uncertainty as generative Artificial Intelligence and Large language models continue to revolutionise healthcare and expand its applications. The way we think about the TPLC approach will change, and a creative and adaptable regulatory framework will be required. We acknowledge the significance of ethical issues, service regulation, and other issues that are outside the conventional purview and control of health product authorities. For Large language models to fulfil the promise of enhancing global health, adherence to ethical standards, upkeep of good supply chain practice norms, and efficient education for both makers and consumers would be essential. In order to guarantee the safe, advantageous, and equitable use of Large language models in healthcare, independent international regulatory science research groups might be crucial in incorporating insights from other industries and information sources.

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