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Review Article

Automation in pharmaceutical sector by implementation of artificial intelligence platform: a way forward

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ABSTRACT

Worldwide, there are technological advances that swift automation in several aspects of the pharmaceutical industry such as pharmacovigilance, clinical research, medical affairs, and marketing. Innovative technology like artificial intelligence (AI) emphasizes the massive use of the internet for drug development, drug safety, data analytics, communication marketing, and customer engagement to achieve the goal of pharmaceuticals and patient-centric healthcare. Presently, escalating the number of individual case safety reports (ICSRs) necessitate the support of AI in the transformation of drug safety professional. AI can be transformed and evolve the clinical trial process from the conventional method alongside benefited the cutting cost, enhancing the trial quality, and alleviate trial time by almost half. Today, AI may be efficiently implemented to lower the cost of medical information requests, besides the online chatbots to communicate with health care professionals (HCPs) and consumers. There are numerous forthcoming uses of AI which need to be executed for renovation in the field of pharmaceuticals.

Keywords: Artificial intelligence, Clinical research, Pharmacovigilance, Medical affairs, Pharmaceuticals marketing

INTRODUCTION

Since 1950s, AI has been utilized in sectors like banking and financial industries. Over the past decade, it has significant innovations within many domains like pharmaceutical industries, healthcare, insurance industries.^{1,2} In pharmaceuticals, current challenges like majority of drug requires more than 10-year time to come into market and even clinical trial cost is in billions, at the same time there are often chances it may not succeed in late-stage trials. In pharmacovigilance (PV) overall budget consumed for case processing expenditure is high, hence it disrupts overall adverse events reporting. In healthcare of developing countries going which has high disease burden, poor infrastructure and insufficient in skilled HCPs, there are several challenges in PV. Hence, it is in such setting that AI has extensive role to enhance efficiency and the speed of drug development even produce advanced technology for developing and prolonging patient lives

with safety.^{1,3,4} Healthcare practice will be digitalized and regionalized which will have improved connectivity, accessibility, and convenience for future medical consultation.⁵

It is essential to recognize innovative technologies that offer the automation of tedious tasks for revolution in pharmaceutical sector. Artificial intelligence (AI) is a subfield of computer science dealing with the simulation of intelligent behaviour in computer and potential of a machine to replicate the performance of human intelligent. It means that the computer programs adroit for solving problems and learning like to human intelligence.⁶ AI has multiple technologies such as machine learning (ML), natural language processing (NLP) and cognitive services (CI). MI is a technology 'learn' from patterns they identify or ability to understand without openly being programmed and correct behavior appropriately.⁷ It is a broad field in computer science with applications to analyze imaging

and/or non-imaging patient data and makes assessment of the patient's medical condition, which can be helpful to assist clinicians in their decision-making process.⁸ Natural language processing (NLP) is a technology will analyze, recognize, and produce language that humans use naturally. Cognitive services are a blend of MI and NLP that purpose to resolve certain task that would or else need human intervention. For developing cognitive services, data used to teach the cognitive service, must be prepared, and created. At many decision steps in PV process, cognitive services are identified and developed to support pharmacovigilance users.⁷

Automation of jobs and AI have generated discussion across all industries that are either affected by or considering developing this technology to aid in their extensive functions. One of the mostly discussed questions is whether AI will replace humans in their roles.⁹ One school of thought believes the use of AI will not result in widespread unemployment and humans losing their jobs but will instead create jobs. Research suggests that companies that invest in smart, automated, and self-teaching systems are creating jobs.¹⁰

METHODS

The information for this review article were retrieved by using electronic database such as "PubMed", "Google Scholar" and "Google". The articles were searched till January 2020 and the key words used in literature search were limited to AI platform utilizes in clinical research, pharmacovigilance, medical affairs, and marketing of pharmaceutical industry. In this review, we emphasize on automation in several conventional aspects of pharmaceutical industry and improvement in extensive processes of pharmacovigilance, clinical research, medical affairs, and pharmaceuticals marketing.

Use AI in pharmacovigilance

The World Health Organization 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".¹¹ Now, drug safety (DS) is a major threat after launching the new drug to the market. During the clinical trial or post-marketing surveillance (PMS), the major source of loss is unpredictable toxicities that cause morbidity and mortality from normal dose of the drug. As per the record from 2008 to 2017, the Food and Drug Administration (FDA) approved 321 novel drugs. At the same time FDA, adverse event (AEs) reporting system has reported a total of more than 10 million AE reports in which 5.8 million recorded as serious, and 1.1 million were death reports. Adverse drug reactions (ADR) data need to be collected by license holder that should be from pharmaceutical industry and submitted to the local drug regulatory authority. The most crucial task in PV is detection and reporting of ADRs, coding of AE in technical terms, preparing individual case safety report (ICSR), assessment of seriousness, and

relationship with suspected drug. It is all depend on the human interference, which is time-consuming. Hence, the detection and analysis of ADRs requires a new technology.¹²

Despite in growing cases there is still extensive underreporting of spontaneous AEs. A strategy to defeat underreporting AEs could be social media and health related social networks data sources. There may be adults are using to discuss health related their experiences, such as the use of prescription drugs, side effects, and treatments which makes social network unique source of patient's health information.¹³ Furthermore, that using social digital media does not appear to add anything to what is already known from spontaneous and clinical trial AEs.¹⁴

As individual case safety report volumes increase, case processing activities constitute a significant portion of internal PV resource use.¹⁷ So, additional expenditures related to contract out are considered, case processing spending, consumes most of a pharmaceutical industry overall PV budget. Automation of AE case processing through AI signifies an opportunity to affect the strongest PV cost driver.¹⁵ Increases in the number of ICSR require assistive technologies such as AI to support the drug safety (DS) professional with the increasing volume and complexity of work.⁶ AI can be a means to help mitigate complex decision making for PV professionals.⁷ Leveraging AI, the DS professional's work life may potentially change as their decision making is augmented and efficiency enhanced. DS professionals may need to learn new skills and competencies to understand and work with AI.⁶

Electronic health records (EHRs), a more promising external data source which generally provide more complete and thorough representations of patient health that can include clinical narratives such as symptoms, disease status, severity, confounding factors.¹⁶ Although EHRs are considered a robust source of health information, it is estimated that only 1% of AEs within EHRs are reported to federal databases.¹⁷ EHRs represents additional and expanding store of knowledge that could house the presence of impactful AEs. The rapid growth of electronically available health related information, and the ability to process large volumes of them automatically, using natural language processing (NLP) and machine learning algorithms, have opened new opportunities for pharmacovigilance.

AI is beneficial in PV for extraction of accurate safety information. AI tools can automate or facilitate almost every aspect of PV in case processing, risk tracking, which reduces the total processing time and cost. There are some different databases tools, such as VigiFlow, VigiBase, VigiAccess, and VigiLyze. Also, some methods tools i.e. VigiGrade, VigiMatch, and VigiRank for case report analysis.¹⁸

The upcoming approaches of drug safety could become more advanced, driven by AI techniques. Further research is required in the field of AI with respect to PV. The databases, and tools are in primary stage of development, and it could proof its advancement in future in the field of PV.

Use AI in drug design and clinical research

The new and prominent AI technology is increasing role at various stages of drug development, new drug designing, improving the research and development efficiency, and enhancing the decision-making process to enroll patients for clinical trials. Thus, decreasing the human workload as well as achieving targets in a short time.¹⁹ Implementation of AI in the development of a pharmaceutical product from the bench to the bedside can be predicted given that it can aid rational drug design, decision making assistance, establish the appropriate treatment for a patient, including personalized medicines, manage the clinical data produced and utilize it for future drug development.^{20,21} Hence, AI assistance to pharmaceutical industries helps to improve overall life cycle of product.

The enormous chemical space consists of more than 1060 molecules, promotes the development of a larger number of drug molecules.¹⁹ However, the lack of advanced technologies limits the drug development process, making it a time-consuming and expensive task, which can be addressed by using AI.²² It can acknowledge lead compounds and offer a faster validation of the drug target and optimization of the drug structure design.^{20,23} The traditional process of discovering and developing a drug can take over a decade and costs US\$2.8 billion on average. Even then, nine out of ten therapeutic molecules do not pass Phase II clinical trials and regulatory approval.^{24,25} Preclinical discovery of molecules and predicting lead compounds before the initiate the clinical trials by implementation of AI, such as predictive ML and other reasoning techniques, that assist in the prompt prediction of lead molecules that would pass clinical trials with consideration of the patient population.²⁶

Clinical trials are focused for determining the safety and efficacy of a drug product in humans for a certain indication and require 6 to 7 years along with a huge financial investment. Though, only one out of ten molecules come into these trials, gain successful clearance, which is a massive loss for the pharmaceuticals industry.²⁷ These breakdowns can result from inappropriate patient selection, scarcity of technical requirements, and poor infrastructure. However, with the massive digital medical data available, these disappointments can be decreased with the application of AI.²⁶ The patients enrolment requires one-third of the clinical trial timeline. The accomplishment of a clinical trial can be ensured by the enrolment of appropriate patients, which otherwise leads to approx. 86 percent of failure cases.²⁸

AI technology can support in selecting only a specific diseased population for enrolment in phase II and III of clinical trials by using patient specific genome-exposome profile analysis, which can help out in early prediction of the available drug targets in the patients selected.^{20,26} Drop out of patients from clinical trials accounts for the failure of 30 percent of the clinical trials, producing additional enrolling requirements for the completion of the trial, leading to a wastage of time and money. This can be avoided by close monitoring of the patients and helping them follow the desired protocol of the clinical trial.²⁸ Mobile software was developed by AiCure that monitored regular medicine intake by patients with schizophrenia in a phase II trial, which increased the adherence rate of patients by 25%, ensuring successful completion of the clinical trial.²⁰

Clinical necessity and availability of huge data have demanded a focus on virtualization and adoption of AI technology. These advanced technologies are diverse and though most have not been studied in randomized trials, their incorporation across all types of clinical trials is becoming more common place with increasing trial complexity.^{29,30,31} Diversity and evolution in AI technology have preceded to a wide range of potential applications in clinical research. Natural language processing (NLP), the ability of programmed computers to analyze written and spoken word, in addition to machine learning, which looks at algorithms that assist in predictive decision making without explicit programming, can accelerate the patient enrolment process by recognizing appropriate patients through analysis of electronic medical records.^{26,32,33} Application of electronic health records and databases, modeling through NLP and machine learning can potentially identify new biomarkers worth assessing in a more formal context.²⁶

In clinical trial conduct where digitalization is being implemented include consent processes, patient adherence, and scheduling through wearable monitoring, medication logging, and virtualization of staff-patient interactions including consultations, study updates, and patient coaching to minimize attrition.³⁴

AI use in medical affairs and marketing of pharmaceutical industry

In medical affairs, scientific exchange is a main function, hence, medical affairs has always been at the frontline, leading external medical interactions with healthcare professionals (HCPs) as well as other key customers. With science becoming more and more complex, HCPs are looking to pharmaceutical industry for high-level non-promotional scientific content and engagement. HCPs need to have quick access to scientific content as well as the ability to easily recall it for the future. So, the medical affairs stepped up with the introduction of digital solutions to meet these needs and enrich customer experience. The COVID-19 pandemic has put a focus on the vital role of

medical information play within a pharmaceutical industry at a time of crisis.³⁵

As medical affairs embraces digital transformation, it is important to gain from other industries that have already launched large-scale omnichannel transformations, for example, banking, where the extensive implementation of digital service channels and telecommunications has resulted in 44% of all customer requests now being handled through digital channels.³⁶

An innovative and user-friendly approach to measure the HCP experience, which is a very simple assessment of whether the interaction enables the HCP to get the job done.³⁷ The key to satisfying HCP is not just to measure what happens but also to use the data to drive action throughout the industry.³⁸

Generally, the consumer does Google search for medical information which may be inaccurate and dangerous. So, we need to ensure we are the first place they go to, and this requires advocating for better regulatory flexibility regarding the digital exchange of medical information. We must figure out a way to tear down the walls between medical and commercial team of pharmaceutical industry and incorporate in a way that works for the customer. When external customers such as, key opinion leaders (KOL), HCPs and consumers contact a pharmaceutical industry looking for information and speedy response.³⁵

In pharmaceutical industry, market positioning is the process of establishing a uniqueness of the product in the market to attract consumers to buy them, making it an essential element in almost all business strategies for industries to establish their own unique identity.^{39,40} For example, in the marketing of pioneer brand Viagra, where the market targeted it not only for the treatment of men's erectile dysfunction, but also for other problems affecting quality of life.⁴¹ With the assistance of advanced technology and e-commerce, it has become easier for pharma industry to get a natural recognition of their brand in the market. Companies develop search engines as one of the innovative platforms to occupy a prominent position in online marketing and help in the positioning of the product in the market, as also confirmed by the internet advertising bureau. Companies continuously try to rank their websites higher than those of other companies, giving recognition to their brand in a short time.⁴²

The success of a pharmaceutical industry is in the constant development and business growth. Even with access to huge funds, R&D output in the pharmaceutical industry is collapsing because of the failure of companies to implement new marketing technologies.⁴³ The developments in digital technologies, it is referred to as 'fourth industrial revolution', is helping innovation in digital marketing via a multicriteria decision-making approach, which collects and analyzes statistical and mathematical data and implements human inferences to make AI-based decision-making models discover new

marketing methodology.⁴⁴ Prediction of the market is important for various pharmaceutical distribution industries, which can implement AI application in the field, such as 'business intelligent smart sales prediction analysis', which uses a combination of time series forecasting and real-time application. It helps pharmaceutical organization to forecast the sale of products in advance to prevent costs of excess stock or prevent customer loss because of shortages.⁴⁵

DISCUSSION

In the past few years, there has been tremendous increase in data digitalization in the pharmaceutical industry. However, this digitalization comes with the challenge of acquiring, scrutinizing, and applying that knowledge to resolve complex clinical problems.⁴⁶ It encourages the use of AI platform, because it can manage large volumes of data with enhanced automation.⁴⁷

AI technology encompassing several advanced tools and networks that can mimic human intelligence. At the same time, it does not threaten to replace human intervention completely.^{48,49} AI technology develops systems and software that can interpret and learn from the input data to make independent decisions for accomplishing specific objectives. Its applications are continuously being extended in the pharmaceutical field, as described in this review. According to the McKinsey Global Institute, the rapid advances in AI-guided automation will be likely to completely change the work culture of industry.^{50,51}

The entire success of AI depends on the availability of a large amount of data because these data are used for the subsequent training provided to the system. Access to data from various database providers can incur extra costs to a pharmaceutical industry, and the data should also be reliable and high quality to ensure accurate result prediction. Other challenges that prevent full-fledged adoption of AI in the pharmaceutical industry include the lack of skilled personnel to operate AI technology, limited budget for small organizations, uneasiness of replacing humans leading to job loss, uncertainty about the data produced by AI, and the black box phenomenon that means how the conclusions are reached by the AI technology.⁵¹

Automation of several tasks in drug development, clinical trials, and sales will take place with time, but these all come under the category of 'narrow AI'; where AI must be trained using a large volume of data and, thus, makes it suitable for a particular task. Therefore, human intervention is required for the successful implementation, development, and operation of the AI platform. However, the fear of unemployment could be a myth given that AI is currently taking over repetitive jobs, while leaving scope for human intelligence to be used for developing more complicated insights and creativity. Nevertheless, AI technology has been implemented by several pharmaceutical industry, and it is expected that a revenue

of US\$2.199 billion will be created by 2022 through AI-based solutions in the pharmaceutical sector, with an investment exceeding US\$7.20 billion across 300 plus deals between 2013 and 2018 by the pharmaceutical industry.⁵²

In the context of a public health emergency, these AI technology functions could enhance research conduct efficiency but may pose their own ethical challenges especially if applied to non-pandemic circumstances, or if insufficient attention is paid to data security or ethical considerations.⁵³

Pharmaceutical industry need clarity about the potential of AI technology in finding solutions to problems once it has been implemented, along with understanding the realistic goals that can be achieved. Skilled data scientists, software engineers with a sound knowledge of AI technology, and a clear understanding of the pharmaceutical business target and its R&D objective can be developed to use all aspect of AI technology.

CONCLUSION

The advancement of AI technology, along with its remarkable tools, continuously decrease challenges faced by pharmaceutical industry, impacting the drug development process along with the overall product lifecycle. With the help of AI-based technologies will not only speed up the time needed for the products to come into the market but will also improve the product quality and safety of the production process, provide every aspect of pharmacovigilance in case processing, risk tracking, which reduces the total processing time and cost, and help to mitigate complex decision making for pharmacovigilance, thereby, increasing the importance of automation.

The most important fear regarding the incorporation of these technologies is the job losses that would follow, and the stringent regulations needed for the implementation of AI platform to several important aspect of pharmaceutical industry. Though, these advanced technologies are intended only to make work easier and accurate and not to completely replace humans. In near future, AI technology will become a valuable tool in the pharmaceutical industry.

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