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Impact of AI in the Pharmaceutical Industry

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Abstract: ***Artificial intelligence (AI) is a developed science that can mimic human behaviour and undergo intelligent data analysis. Also, The integration of AI & Machine Learning (ML) in the pharmaceutical industry has transformed various fields , such as drug discovery, disease diagnosis, clinical trials, drug formulation, drug delivery, and more.***
This review on the topic "Impact of AI in the Pharmaceutical Industry" discusses on the various important roles of AI and ML in the pharmaceutical sector along with focusing on their applications as AI technologies have significantly revolutionized the speed & accuracy of drug development and have also improved the accuracy of disease diagnosis, and have also streamlined clinical trial processes by enabling predictive modelling, target identification, and patient-specific treatment strategies. However, despite all these advancements, challenges such as data privacy concerns, algorithmic bias, and a lack of transparency blockage the full-scale implementation of AI in pharmaceutical sciences. Also, ethical considerations & the need for validation of outcomes remain key barriers. With the rapid growth of the pharmaceutical sector of India, AI's role has become even more important in promoting innovation, efficiency, and global competitiveness. Also, this review includes discussions on the current status of the integration of AI & ML, and their potential applications along with their limitations in pharmacy, bringing light on how this evolutionary technology can shape the future of healthcare for us.

I. INTRODUCTION

The use of artificial intelligence (AI) & machine learning (ML) in medicinal chemistry has gained high attention in recent years which is also a potential means of changing the pharmaceutical industry. Machine Learning methods have played a major role in drug discovery for the past 15–20 years (1). Their combination has acted as a catalyst for revolutionizing pharmaceutical formulations. This merging of computational methods with traditional pharmaceutical methods offers unexpected opportunities for leading innovation and streamlining the drug development processes. This has urged innovation & exploration of AI and ML technologies as promising results in the formulation of drug design processes, optimized drug delivery systems, and enhanced therapeutic outcomes. Healthcare is increasingly being driven by new technologies that have the potential to transform system efficiency and patient experience(2). Today's AI and machine learning technologies hold great promise for improving the quality of patient care, better health outcomes, reducing treatment costs, and addressing the problem of the increasing shortage of pharmacists. In September 2015, Google's search trend showed that after the introduction of ML, AI was the most searched term. Some describe ML as the primary AI application, while others describe it as a subset of AI(3).

AI can be classified according to the calibre or according to the presence.

Based on calibre, it is categorized as: (4)

1) Weak Intelligence or Artificial Narrow Intelligence
2) Artificial General Intelligence
3) Artificial Super Intelligence

Arend Hintze, an AI scientist classified the AI technology based on its presence and not yet present. (5)

Type 1 of the AI system is called a Reactive Machine. These are basic AI types that do not store past experiences or memories for future actions.

Type 2 of the AI system is called the Limited Memory System. This system can use past experiences for present and future problems.

Type 3 of the AI system is called "Theory of Mind." This type of AI can understand human emotions and beliefs and socially interact like humans. It has not yet been developed but is in contention for the future.

Type 4 of the AI system is called Self-Awareness. AI that has a sense of self, consciousness, emotions & beliefs to understand the condition & execute the ideas in others's brains. This AI is non-existent.

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Based on the desired outcome of the algorithm, the machine learning algorithms are organized in the following groups: (6)

- SUPERVISED MACHINE LEARNING:- It is the construction of algorithms that can produce general patterns and hypotheses by using externally supplied instances to predict the fate of future instances.
- UNSUPERVISED MACHINE LEARNING:- It is how humans learn to identify and classify objects they think about.
- SEMI-SUPERVISED MACHINE LEARNING: This type of machine learning lies between supervised and unsupervised methods.
- REINFORCEMENT LEARNING:- It uses trial and error to train algorithms and create models.

Artificial Intelligence (AI) and Machine Learning (ML) combined are transforming the pharmaceutical sector by enhancing various fields of drug development, drug discovery, clinical trials, patient medications, upcoming Challenges, and other pharmacy operations. However, the execution of AI and ML in pharmacy is not without challenges, As concerns are raised regarding data privacy & trust in the results obtained through AI. Addressing these issues is crucial to fully harness the potential of AI in advancing pharmaceutical sciences.



II. ROLE/APPLICATIONS OF AI & ML IN PHARMACY

A. Disease Identification/Diagnosis

Disease identification and diagnosis of disease is at the forefront of ML research in medicine. It becomes essential in designing a considerate treatment and safeguarding the wellness of patients.

A generous amount of documentation has disclosed that though accessible, conflicting, non-analyzing inconsistencies exist, the development of new methods can define the appropriateness by characterizing the current existing plot that has not been covered. It is important to categorize the patients based on whether he/she is severely affected by the diseases, and AI can gain importance in diagnosis. Diagnosis refers to the state where, upon certain pre-existing problems, one's condition is appropriate. It is always considered to maintain every patient's health report forms, to gather the majority of reviews that are obtained via performing examinations and testing. Upon collecting information, the appropriate outcomes mainly concern the health care needs for a timely diagnosis. There is availability of various characteristics leading to trust issues and thus, one needs to focus on AI for identification and determination of the early predictive stage of the disease more than the treatment or diagnostic stage. Such diagnosis can help to inaugurate early treatment, and basic treatment can bring appreciable changes in the patients as well as improved adaptability in AI models. (7)

According to a 2015 article issued by Pharmaceutical Research and Manufacturers of America, more than 800 medicines and vaccines to treat cancer were in trial. In an interview with Bloomberg Technology, Knight Institute Researcher Jeff Tyner stated that while this is exciting, it also presents the challenge of finding ways to work with all the resulting data. "That is where the idea of a biologist working with information scientists and computationalists is so important," said Tyner. (8)

Efficiency, awareness, and particularity are three important conditions where the common measurements of AI focus. Algorithm-based performance-driven analysis can be performed through the origin, sample size, and several features of the training and testing samples. Many studies were performed for predictive modelling, which was appreciable for predicting early Parkinson's disorder. The ribb algorithm was formed using chest X-ray images for the diagnosis of lung diseases. Traditional methods are not useful in rib-wise segmentation of X-ray images due to multiple limitations.

B. Drug Discovery

It can assess which compounds will potentially yield the highest therapeutic benefit by predicting the interactions of the molecules on biological targets. AI analysis of biological data aids in predicting drug efficacy and safety profiles, thus reducing the time for drug development from lab to market. (9)

Finding new drugs has historically been a long and expensive undertaking, taking up to a decade and costing billions of dollars. This process has been drastically changed with the use of AI as it can rapidly identify potential drug candidates. Identifying putative candidates faster and more confidently as researchers harness large chemical, biological, and clinical datasets through machine learning algorithms. Additionally, AI is vital in predicting drug effectiveness and toxicity. AI models can analyze historical data from past studies and clinical trials to predict a new drug's chances of success, as well as its risk profile before it is ever tested in humans.

There are many different ways that AI has changed the drug research and discovery process over the years. The following are among the most significant contributions that AI has made in this area:

1) Target Identification

AI systems can shed light on heterogeneous data types, including genetic, proteomic, and clinical data, to discover potential therapeutic targets. AI helps in designing drugs that can modulate biological processes by unearthing targets and molecular pathways associated with diseases. (10)

2) Virtual Screening

With the use of AI, scientists can quickly sift through large collections of chemicals to find potential drugs that are likely to connect with a certain target. By copying how drugs interact and forecasting how well they might bind, AI guides researchers in choosing the best compounds for testing, which leads to better use of time and resources. (11)

3) Structure-Activity Relationship (SAR) Modeling

The AI models are very good at connecting the points between how a compound is built and what it can do in biological terms. This helps researchers create better drugs by designing molecules that have good qualities, such as being very effective, targeting specific areas, and with better absorption and metabolism performance in the body. These AI - tools, also known as quantitative structure-activity relationships (QSAR), help to predict how different active compounds might be, which is essential for finding the best candidates to study further. (11,12)

4) De Novo Drug Design

With the use of reinforcement learning and generative models, AI can come up with new chemical structures that could work as drugs. By learning from existing chemical data and experiments, AI opens up new possibilities for discovering innovative drug candidates. (13)

5) Optimization of Drug Candidates

AI contributes to this process by enhancing accuracy, minimizing false positives, and expediting the discovery of novel candidate compounds with specific physical and chemical properties. (14)

6) Drug Repurposing

By analyzing patients' genetic and molecular data, the AI procedures help in determining the most effective treatment options, which also optimize outcomes and minimise adverse reactions. AI also speeds up the process of finding new treatments and decreases expenses by discovering new uses for the drugs that are already approved. (15)

7) Toxicity Prediction

By using machine learning models trained on toxicology information, they can predict negative impacts or spot risky structural traits. This helps scientists focus on safer & better options and also reduces the risks of bad reactions during clinical trials. (16)

> *The Tox21 Data Challenge, organized by the National Institutes of Health, Environmental Protection Agency, and US Food and Drug Administration, appraises computational techniques for the estimation of the toxicity of the drug. (17)*

C. Drug Formulations

Drug formulation involves the integration of inert substances & excipients with active pharmaceutical ingredients (APIs) which are further used to produce feasible drug products with the desired properties required in the products. The desired properties associated with the development of an advanced drug formulation can include enhanced efficacy, long-acting therapeutic effects, a decrease in side effects, and an increase in API stability & shelf-life, as well as better patient compliance.

Pharmaceutical science has seen various formulations, such as solid dispersions, extrudates, pellets, nanoparticles, and liposomes, arise in addition to standard dosage forms. The name "formulation techniques" is given to these techniques because they empower the development of formulations or incorporate functionality into common dosage forms such as tablets. AI applications in formulation techniques are even more worthwhile to investigate to create next-generation drug products with desired efficacy and health outcomes because these methods can successfully address a variety of API issues, such as low solubility, stability, bioavailability, and production capability. (18,19)

D. Clinical Trials

The way clinical trials are designed is also changing in part to artificial intelligence. Testing of new treatments and guaranteeing their effectiveness and safety depends much on this stage. Clinical trial design and administration used to be a challenging and expensive enterprise but by improving trial design, patient recruitment, and oversight, AI streamlines this process. Furthermore, it is valuable in analyzing experimental data to expose non readily apparent patterns and trends. (20)

Once the developers or researchers are prepared to introduce a medicine or vaccine into clinical development, there are applications of AI to assist many aspects of clinical development such as – design, recruitment, conduct, and analysis.

- Firstly, pharmaceutical development professionals & clinical trialists utilize AI to help design clinical trials, such as decentralized trials with "real-world" data, electronic health records, and medical claims for forecasting trial results, to help with site selection to enhance medication adherence to minimize attrition and maximize accuracy.
- Secondly, AI increasingly processes to automate and speed up the recruitment of patients through identification or selection based on their medical records, demographics, and other information. This application also brings into question data mining of personal information, including confidential health information.
- Thirdly, AI is used in clinical trials for collecting, managing, and analyzing the data that accumulate in various digital health technologies during a specific trial. It is used to evaluate clinical end-points--including results and safety signals (including in real-time during a trial).
- Fourthly, by analyzing data, AI helps give more informative investigations for drug development, automatically includes data in statistical analytical tools, and generates the papers, tables, reports, and labels needed throughout the clinical development of a compound. Also, AI is employed in producing the reports needed for regulatory approval. But, If AI is used in producing any documentation during drug development, there must be human oversight, review, and quality assurance to avoid the generation of false information and “hallucinations”.

Clinical trials are aimed at determining the safety and effectiveness of a drug product & take 6–7 years of time & a huge amount of money. However, just one molecule among ten entering these trials achieves successful clearance, a huge waste for the industry. Such breakdowns can be minimized with the use of AI.

- The success of a clinical trial can be ensured by the recruitment of suitable patients, which otherwise leads to 86% of failure cases.
- Preclinical discovery of molecules as well as predicting lead compounds before the start of clinical trials by using AI & predictive ML and other reasoning techniques, help in the early prediction of lead molecules.

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- Mobile software was developed by AiCure that monitored regular medication 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.

III. LIMITATIONS OF AI/ML

A. Lack of Transparency

The lack of transparency is one of the fundamental challenges but the concept of transparency might be even more opaque (21). The AI models use complex algorithms which are often referred to as "black boxes" as it is very difficult to understand how the model comes at its predictions. This lack of transparency makes it challenging to gain regulatory approval for AI-based drug development tools, as it can be challenging to explain that the model is making accurate and reliable predictions. Furthermore, the lack of transparency also leads to a lack of trust in the model's predictions, particularly when the model makes predictions that contradict the expectations & predictions of clinicians or researchers. (22)

B. Biases in data

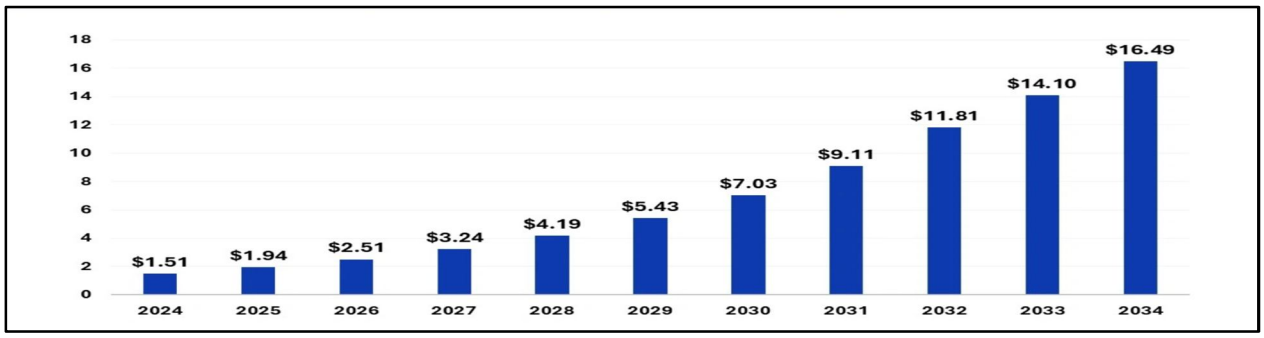
The success and accuracy of AI models are contingent upon the quality of the data employed for their training. In instances where the data show bias or incompleteness, the resulting projections may also be biased. If a specific analytical or disease state is partially represented in the training dataset, the model's capability to make actual predictions respecting the drug's adequacy in that distinct population may be compromised. Moreover, in situations of incomplete or inaccurate data, the model may generate inaccurate outcomes, which would result in estimated predictions. It is crucial to ensure that the data which is used to train the AI models are representative of the community for whom the model will be used and that the data are accurate, comprehensive, and unbiased. (22)

C. Ethical consideration

Integrating AI in pharmaceuticals brings one demanding trade and one of the most summarized points: the honest condition of involving AI in decision-making. The procedure that influences drug development or patient treatment decisions should be transparent and free from biases (23). AI models must undergo thorough authorization and testing to ensure their authenticity and accuracy. Assuring that AI models operate properly and do not perpetuate existing inequalities is essential. It's one of the most challenging points to address. (22)

D. Limited Availability of Data

AI models need a significant amount of data for exact predictions. Still, in some cases, there may be limited data available for a precise drug or population, leading to less accurate predictions or biased results. For example, rare diseases may have limited applicable data, which can be a challenge in developing AI models. Moreover, the data used to train the AI models may not be representative of the desired population, which can lead to biased results. Furthermore, some long-term data or real-world shreds of evidence, may not be eagerly available, which can limit the efficacy of AI models. Thus these limitations highlight the need for careful consideration of the quality and representativeness of the data used to develop AI models. In drug discovery, such datasets are often limited, proprietary, or inconsistent. (24)



AI in Pharmaceutical Market Size 2024 to 2034 (USD Million) (25)

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IV. CURRENT STATUS OF AI/ML

The current trends demonstrate the combined impacts of AI (Artificial Intelligence) & ML (Machine Learning) which transform the pharmaceutical sector in drug discovery, clinical trials, safety monitoring, drug distribution, and more.

The pharmaceutical industry in India was valued at an estimated US$50 billion in FY 2023-24 and is also estimated to reach $130 billion by the year 2030. (26) Also, India is the world's largest provider of generic medicines, with a 20% share of total global pharmaceutical exports & is also the largest vaccine supplier in the world, which accounts for more than 60% of all vaccines manufactured in the world as Indian pharmaceutical products are exported to various regulated markets including the US, UK, European Union, and Canada. (27)

Many start-ups are trying to discover drugs using Artificial Intelligence & further partner with pharmaceutical companies with their discovered drugs. A scientist named Simon Kohl launched an AI drug discovery venture, which solved an important problem for life sciences researchers by allowing the prediction of the 3D structure of proteins based on their chemical composition. (28)

In the pharmaceutical sector, efforts are underway to train AI to predict the timing and locations of potential epidemics with a reasonable level of accuracy. This involves using AI which learns from historical epidemics data and other information sources. Within the healthcare sector, AI is being employed to proactively avoid medical mistakes and lower the frequency of hospital readmissions. (29) AI-driven predictive models could anticipate how a patient's disease will progress and adjust the treatment plan accordingly. For example, in chronic diseases such as diabetes or cancer, ML models can predict flare-ups or progression stages, prompting adjustments in medication or its delivery mechanism before the condition worsens. (30)

The rapid advance of generative AI is reshaping the strategic vision for R&D across industries. The unique challenges of pharmaceutical R&D will see applications of generative AI deliver value along the entire value chain from early discovery to regulatory approval. This perspective reviews these challenges and takes a three-horizon approach to explore the generative AI applications already delivering impact, the disruptive opportunities that are just around the corner, and the longer-term transformation that will shape the future of the industry. (31) There are further more ongoing research & advancements in Machine Learning & Predictive Analytics, Natural Language Processing & Text Mining, Image Recognition & Computer Vision, with the help of AI & ML in the future. (32)

V. CONCLUSION

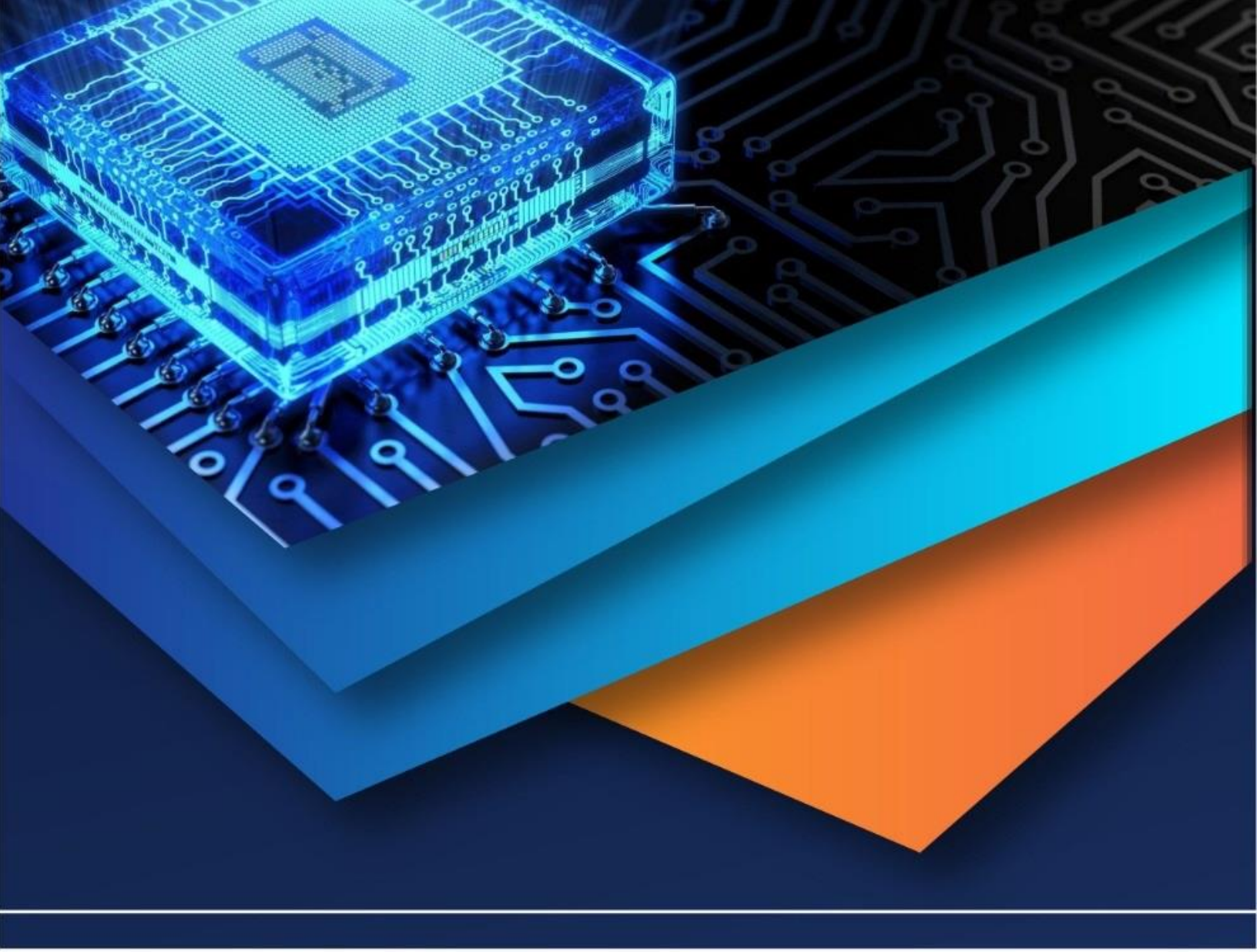
Artificial Intelligence (AI) and Machine Learning (ML) together have emerged as ultimate tools with the capability to revolutionize & leverage every stage of pharmaceutical research and healthcare delivery. Along with increasing the pace of drug discovery and the betterment of clinical trial efficiency to obtain desired medicines and real-time diagnosis, thus reshaping the pharmaceutical sector. However, the benefits are unlimited, but the real successful integration of AI in pharmacy depends on overcoming limitations which are related to transparency, data quality, and other ethical concerns.

As the pharmaceutical industry in countries like India, continues to promote digital innovation, a balanced approach that integrates the technology with human oversight is essential to avoid further errors or other such situations as continued research, cross-disciplinary collaboration, and stringent validation processes will be crucial in obtaining AI's full potential, which ultimately leading to more effective, accessible & personalized healthcare solutions for the population.

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