IJPSR (2025), Volume 16, Issue 12 **(Review Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 08 May 2025; received in revised form, 14 June 2025; accepted, 21 June 2025; published 01 December 2025

THE IMPACT OF AI ON DRUG DEVELOPMENT: FROM DISCOVERY TO PRODUCTION

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Keywords:

Artificial intelligence, Machine learning, Deep Learning, Convolutional neural network, Recurrent neural networks, Generative adversarial networks, Natural language processing, Application-alpha fold, Pharmacovigilance, De nova Drug design

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ABSTRACT: Artificial Intelligence (AI) is rapidly transforming the pharmaceutical industry by enhancing every stage of drug development, from discovery to manufacturing and post-market surveillance. This article explores the diverse applications of AI, including machine learning, deep learning, and natural language processing, to accelerate the identification of drug targets, predict drug efficacy and safety, and optimize manufacturing processes. AI-driven technologies such as Convolutional Neural Networks (CNNs) and Generative Adversarial Networks (GANs) are being employed to analyze medical data, design new drug compounds, and improve clinical trials, reducing costs and timeframes. Additionally, AI is helping improve regulatory submissions and post-approval surveillance, ensuring better safety monitoring and real time decision making. Despite challenges such as data standardization and regulatory hurdles, the growing impact of AI in drug development is clear. AI promises to revolutionize the pharmaceutical industry, making drug discovery more efficient, cost-effective, and personalized, ultimately leading to faster delivery of safer treatments to patients. The continued advancement and implementation of AI technologies are poised to reshape pharmaceutical research and healthcare delivery on a global scale.

INTRODUCTION: Artificial intelligence [1] (AI) is quickly becoming a powerful tool in the development of new medicines. It is changing every step of the process-from finding new drugs to making and delivering [7] them. This article looks at the many ways AI is being used in drug development, including during lab research, clinical trials, manufacturing, and even after the medicine is on the market.

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DOI: 10.13040/IJPSR.0975-8232.16(12).3165-72

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.16(12).3165-72

By using AI tools like machine learning, deep learning, and natural language processing, researchers can now find drug targets faster, predict how drugs will work in the body, and improve how medicines are made. This article also discusses the benefits, challenges, and future possibilities of using AI in this field. AI is proving to be a valuable resource in making medicine development faster, more efficient, and more effective.

Artificial Intelligence (AI) is making a big difference in how new medicines are developed. It helps speed up many parts of the process-from finding new drug targets to improving drug design and testing. AI can quickly study large amounts of data to predict how well a drug might work and whether it could cause side effects.

It can also help discover new treatment options and create better drug formulas. Overall, AI is helping make drug discovery faster, cheaper, and more effective.

AI Network and Technologies: AI technologies [2] are reshaping pharmaceutical development by improving the speed, precision, and efficiency of drug discovery [12], testing, and manufacturing. At the core of this transformation are neural network models, which are adapted to perform specific tasks at different stages of the drug development process. These AI-driven systems support more accurate predictions and streamlined workflows, contributing to faster and more cost-effective development of new medicines.

Convolutional Neural Networks (CNNs) [37] is commonly used to analyze medical images, including histopathology slides, MRI scans, and high-content screening results. These networks can identify subtle patterns and cellular changes that may signal toxicity or the development of disease, providing valuable support in early-stage research and decision-making. In parallel, Recurrent Neural Networks (RNNs) 36 and their advanced forms, such as Long Short-Term Memory (LSTM) [32, 38] models, are used to analyze sequential data like gene expression profiles and patient time-series records. These tools help researchers discover potential biomarkers and understand how patients may respond to specific drugs. A recent advancement in pharmaceutical AI involves the use of transformer-based architectures, such as those behind large language models (LLMs). These models-including GPT-like systems are being applied to extract insights from biomedical literature, automate the writing of clinical trial documents, and generate new research ideas.

For instance, transformers can analyze millions of scientific articles to uncover potential connections between diseases and drugs or propose new therapeutic [17] targets. In addition, Generative Adversarial Networks (GANs) 35, another form of generative AI, are being used to design novel drug molecules with desirable properties. These models can simulate and refine millions of candidate compounds to meet specific criteria, such as binding ability or solubility, thereby speeding up the early phases of drug discovery **Fig. 1**.

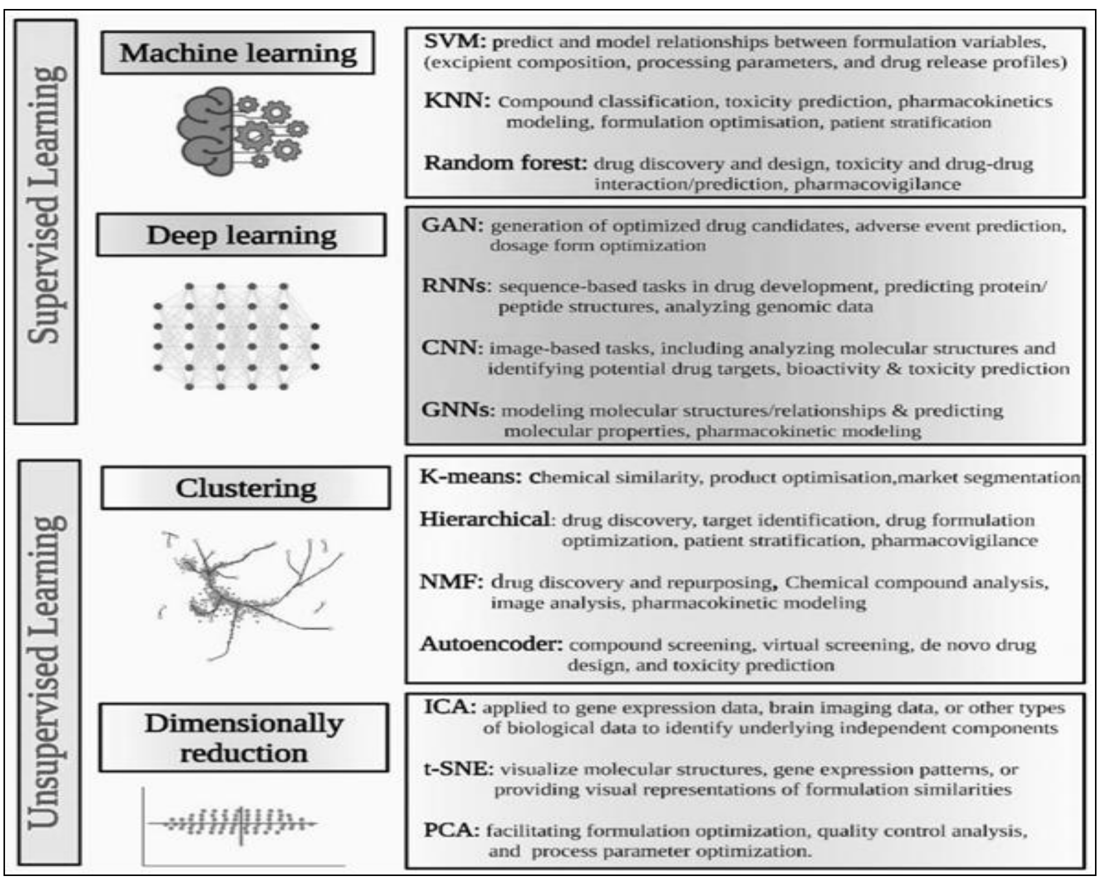

FIG. 1: DIFFERENT AI TECHNOLOGIES AND MODELS

The success of AI models in pharmaceutical development is supported by advanced data technologies and platforms. Many pharmaceutical companies use cloud-based AI services-such as AWS, Google Cloud, and Microsoft Azure-to train and deploy large-scale models that can be accessed by research and development teams worldwide. Additionally, the growth of edge AI is becoming increasingly important in digital health and clinical trials. In this context, wearable devices equipped with AI models process patient data locally, enabling real-time monitoring of vital signs and improving the quality of remote healthcare [22, 23] and trial management.

Graph Neural Networks (GNNs) [3, 4] are specialized for handling data in the form of graphs, which makes them highly effective for drug discovery applications [15] involving molecular structures. They can represent molecules as graphs, predict their chemical properties, and support tasks such as virtual screening and the design of new drug compounds.

Auto encoders [44, 45] is a type of unsupervised learning model commonly used in drug development for reducing data complexity and extracting key molecular features. They help identify important chemical characteristics and support processes like compound selection and virtual screening.

Natural Language Processing (NLP)tools are used to extract valuable insights from unstructured data sources, such as clinical trial reports, electronic health records, and regulatory documents. These tools automate tasks that would otherwise take humans months to complete.

Bayesian models [41], including Bayesian networks and Gaussian processes, are useful tools in drug development for measuring uncertainty and guiding decision-making. They allow researchers to make probabilistic predictions, evaluate potential risks, and improve the design of experiments.

Transformer models [39], like BERT (Bidirectional Encoder Representations from Transformers), have been widely used for natural language processing tasks in the pharmaceutical field. They can extract valuable insights from scientific publications, patent records, and clinical trial data, helping researchers make better-informed decisions during drug development. In pharmaceutical manufacturing, AI-driven predictive analytics is used to optimize production processes, enhance quality control, and maintain compliance with Good Manufacturing Practices (GMP).

AI models can analyze real-time data from sensors to detect issues early, prevent batch failures, and increase overall production efficiency. This includes the use of computer vision systems to inspect packaging and tablet consistency, as well as reinforcement learning algorithms [40] that automatically adjust processing conditions to ensure consistent product quality.

Deep Q-Networks (DQNs) [42, 43], which integrate deep learning with reinforcement learning, have been applied in drug discovery to enhance the selection process. They can predict compound activity and recommend promising candidates for experimental validation.

Collectively, these AI networks and technologies form an integrated ecosystem throughout the pharmaceutical development process-fostering innovation from initial molecule discovery to large-scale drug manufacturing, and ultimately speeding up the delivery of safer and more effective treatments to patients.

AI Enhancing in Each Stage of Pharmaceutical Development:

AI in Preclinical Drug Discovery [30, 31]: Artificial intelligence (AI) technologies are playing a major role in accelerating early- stage drug discovery. They assist in identifying potential drug targets by analyzing large-scale genomic, proteomic, and phenotypic data.

In molecular design, AI-particularly generative models and deep learning-is used to create new compounds with improved effectiveness and safety profiles.

Additionally, AI-driven predictive toxicology models simulate how drugs behave in biological systems. These *in-silico* models help evaluate toxicity, bioavailability, and metabolic stability, allowing researchers to identify issues before entering laboratory testing **Fig. 2**.

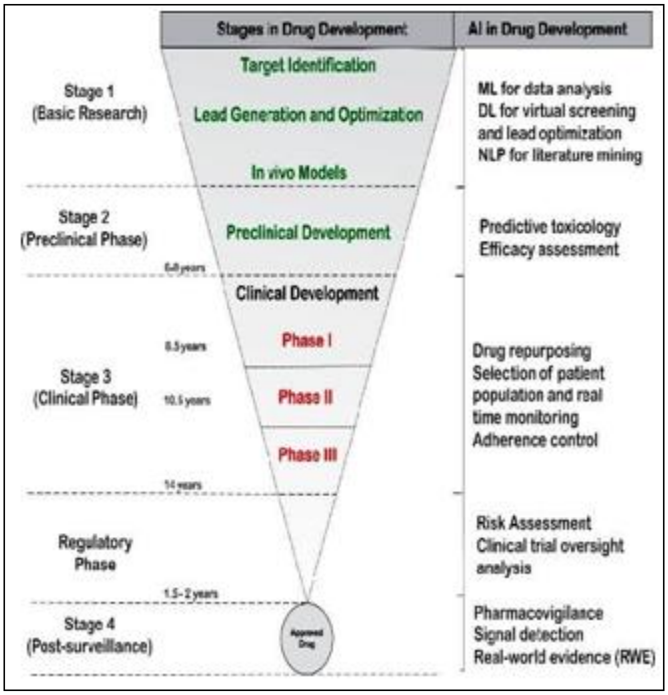

FIG. 2: STAGES IN DRUG DEVELOPMENT

AI-Driven Clinical Trials: Artificial intelligence (AI) is enhancing clinical trials by improving efficiency and precision in various aspects. AI algorithms can match patients to appropriate trials by analyzing electronic health records (EHRs), genomic profiles, and demographic data. Adaptive trial designs are supported by machine learning models that enable real-time adjustments to trial parameters based on incoming data. AI also strengthens trial monitoring by recognizing patterns and using natural language processing (NLP) tools to track clinical data and detect adverse events. These advancements contribute to better pharmacovigilance and support more informed decision- making. As a result, AI helps reduce trial durations and failure rates while improving both safety and treatment effectiveness.

AI in Regulatory Submission [18]: The regulatory submission process is becoming more efficient through the use of artificial intelligence (AI). Natural Language Processing (NLP) systems automate the preparation and review of regulatory documents, reducing the time and effort required for manual processing. AI models can also evaluate the quality of submissions and predict the likelihood of approval by analyzing patterns in historical data. Additionally, AI helps ensure compliance with regulatory agency guidelines, minimizing the risk of human error. These advancements lead to faster, more accurate and reliable interactions with regulatory authorities.

AI in Pharmaceutical Manufacturing: Artificial intelligence (AI) enhances pharmaceutical manufacturing by enabling real-time process optimization. By analyzing live data, AI can adjust key variables such as temperature and pressure to improve production efficiency. Computer vision and robotics are employed in quality control to ensure consistent packaging and accurate dosage. Furthermore, AI supports supply chain management through demand forecasting and dynamic scheduling, leading to more efficient logistics and scalable operations. These innovations contribute to the development of smart manufacturing systems that align with Good Manufacturing Practice (GMP) standards.

AI in Post-Approval Surveillance and Pharmacovigilance [14]: Artificial intelligence (AI) continues to provide value after drug approval by enhancing post-marketing surveillance. Natural Language Processing (NLP) and Machine Learning (ML) tools are used to analyze real-time data from sources such as social media, electronic health records (EHRs), insurance claims, and adverse event reports. These systems aid in early detection of safety signals, allowing for prompt regulatory responses to potential issues.

AI also helps generate real-world evidence that can support updates to drug labeling and inform reimbursement decisions. This proactive approach ensures ongoing monitoring of drug safety and effectiveness throughout its lifecycle.

Challenges and Limitations of AI in Pharmaceuticals [20]: Artificial intelligence (AI) continues to provide value after drug approval by enhancing post-marketing surveillance. Natural Language Processing (NLP) and Machine Learning (ML) tools are used to analyze real-time data from sources such as social media, electronic health records (EHRs), insurance claims, and adverse event reports. These systems aid in early detection of safety signals, allowing for prompt regulatory responses to potential issues. AI also helps generate real-world evidence that can support updates to drug labeling and inform reimbursement decisions. This proactive approach ensures ongoing monitoring of drug safety and effectiveness throughout its lifecycle.

Future Outlook and Market Impact [47]: AI-powered technologies have emerged as versatile tools across multiple stages of drug development, including the identification and validation of drug targets, the design of new compounds, drug repurposing, and the overall improvement of research and development processes. While no drugs developed entirely through AI methods have yet reached the market, ongoing advancements suggest that AI-developed drugs may become reality within the next 2 to 3 years. Industry experts widely agree that AI will permanently transform the pharmaceutical sector and the way new treatments are discovered.

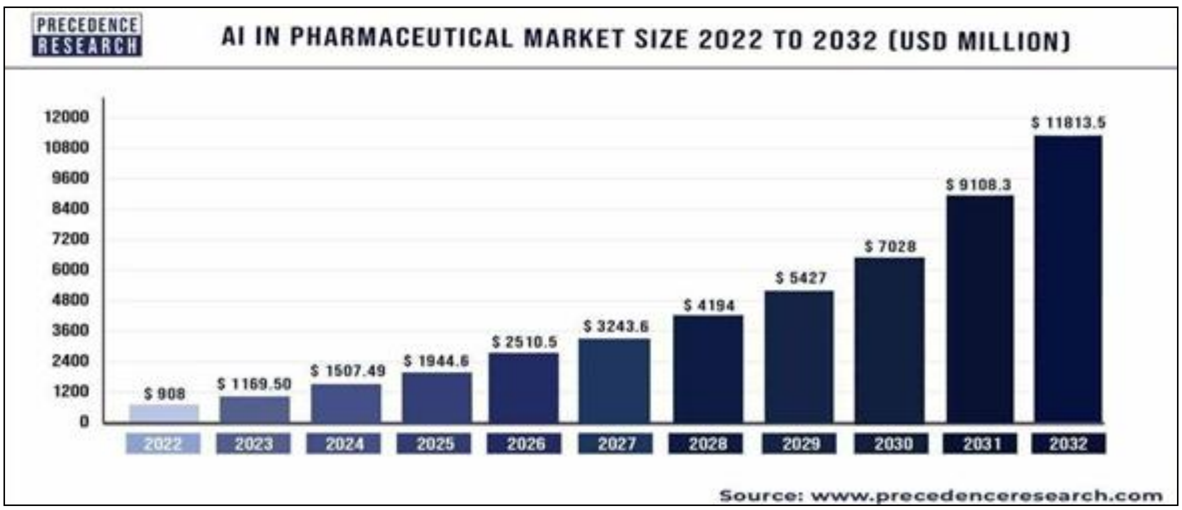

FIG. 3: ARTIFICIAL INTELLIGENCE ON PHARMACEUTICAL MARKET IMPACT

According to a report by Precedence Research, the AI-driven pharmaceutical market is projected to grow from USD 908 million in 2022 to approximately USD 11,813.56 million by 2032, reflecting a compound annual growth rate (CAGR) of 29.30%. This rapid expansion underscores the growing importance of AI in revolutionizing drug development and advancing global healthcare outcomes **Fig. 3**.

Applications of AI in Pharmaceutical Development [6]: AI is increasingly being integrated across the pharmaceutical development pipeline, offering significant improvements in efficiency, accuracy, and cost-effectiveness. In drug discovery [46] and design, AI supports the identification of potential drug targets by analyzing complex biological data and generating novel drug-like molecules with desired characteristics. Tools such as Alpha Fold have advanced this field by enabling accurate prediction of protein structures [5], which are essential for developing effective therapeutics [9].

During preclinical testing, AI models help predict toxicity, pharmacokinetics, and potential side effects, thereby reducing the need for extensive animal testing. In clinical trials, AI accelerates patient recruitment through analysis of electronic health records (EHRs) and improves trial design, reducing failure rates and enhancing overall trial outcomes. AI also facilitates real-time monitoring of patient data to ensure safety and efficacy.

In the manufacturing phase, AI-driven predictive analytics and automated inspection systems are used to optimize production processes and maintain consistent product quality. Beyond development and production, AI enables personalized medicine by integrating genomic and clinical data to tailor treatments to individual patients. Additionally, AI plays a pivotal role in drug repurposing by identifying new therapeutic applications for existing drugs, thereby shortening development timelines and reducing costs **Fig. 4**.

Medication adherence [32] is a major challenge in the management of non-communicable diseases (NCDs) such as diabetes, hypertension, and cardiovascular disorders. Artificial Intelligence (AI) offers promising solutions to improve adherence by enabling personalized and proactive patient support. AI-driven tools, including mobile health applications, smart pill dispensers, and predictive analytics, can monitor patient behavior, send medication reminders, and detect patterns of non-adherence.

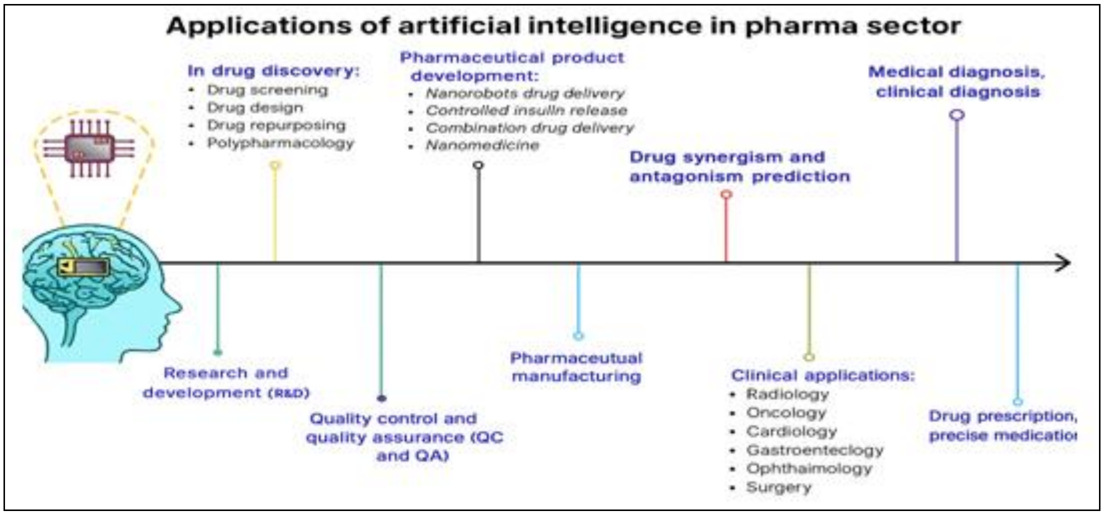

FIG. 4: APPLICATION OF AI IN PHARMA SECTOR

New Applications of AI in Pharmaceutical Development:

De Novo Drug Design [8, 27]: AI models, such as Generative Adversarial Networks (GANs) and transformers, are being used to design entirely new molecules with specific biological properties, paving the way for more effective drug candidates.

Protein Structure Prediction: Tools like Alpha Fold 2 have revolutionized the prediction of protein 3D structures, significantly accelerating target validation and drug design. These advancements also enable highly precise structure-based drug design.

Preclinical Development: AI is improving the efficiency and accuracy of predicting toxicity and pharmacokinetics [28, 29]. Machine learning models now assess toxicity risks and ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) properties early in the drug development process, reducing the reliance on animal testing and helping streamline the transition to clinical trials. AI also supports chemists with automated synthesis planning tools, such as IBM RXN, which recommend efficient synthetic pathways for complex molecules.

Precision Medicine [25]: AI helps identify patient subgroups most likely to benefit from specific treatments, thus enabling personalized therapeutic approaches. Additionally, AI plays a crucial role in discovering biomarkers associated with disease progression and therapeutic responses by analyzing complex biological datasets and real-world data.

Generative AI for Scientific Writing and Regulatory Affairs: Large language models assist in drafting clinical trial protocols, reports, and regulatory documents. This AI support ensures consistency in documentation and accelerates the preparation of FDA or EMA submissions.

Focus on Cancer Treatment [10, 33]: Artificial Intelligence (AI) is playing a growing role in the pharmaceutical industry, particularly in advancing cancer research and therapy [13]. By using methods like machine learning, deep learning, and natural language processing, AI helps accelerate the discovery of new drugs, identify cancer-related biomarkers, and improve treatment planning. In drug development, AI tools can quickly analyze large chemical libraries to find compounds with potential anti-cancer effects. AI also supports personalized medicine by examining genetic and clinical data to predict how individual patients may respond to specific cancer treatments. Moreover, AI-based imaging and diagnostic tools aid in early cancer detection and tracking disease progression.

CONCLUSION: AI is continuously reshaping the landscape of pharmaceutical development, offering notable improvements in speed, precision, and efficiency across the entire drug lifecycle. From streamlining preclinical research to advancing formulation techniques and manufacturing practices, AI-driven solutions are addressing long-standing challenges in drug discovery and development. However, this progress is not without its hurdles, including issues related to data standardization, ethical considerations [24], and regulatory approval. Despite these challenges, the future of AI in pharmaceuticals remains highly promising. As technology evolves, AI is poised to unlock new possibilities in the creation of safer, more effective and accessible therapies for patients worldwide.

ACKNOWLEDGMENTS: Nil

CONFLICT OF INTEREST: The Authors declare no conflict of interest.

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How to cite this article:
Ravikiran P and Vaishnavi C: The impact of a ion drug development: from discovery to production. Int J Pharm Sci & Res 2025; 16(12): 3165-72. doi: 10.13040/IJPSR.0975-8232.16(12).3165-72.