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ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN DRUG DISCOVERY AND DEVELOPMENT

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Abstract:

Drug design, chemical synthesis, and screening to poly pharmacology and repurposing are just a few of the many applications of artificial intellengence(AI). The pharmaceutical sector has turned to the use of artificial intelligence in order to speed up clinical trials, drug development, and the re-use of drugs. By leveraging AI, the industry can achieve goals faster with lower human effort involved, ultimately accelerating the process of discovery and development.

AI can generate novel ideas for drugs and therapies by analyzing data from genomics, proteomics, and many other life sciences. This accelerates the identification and development of new treatments. Different techniques have been used, like molecular docking, quantum mechanics, and statistical learning, to mine chemical libraries and identify potential novel inhibitors. These methods then have seen significant interest in drug development and, more generally, enable researchers to identify novel therapeutic options. AI in drug discovery is still an emerging field, but it has the potential to really change how new drugs are discovered and developed. With continuous development in AI technology, it could be expected that the future of drug discovery will involve AI even more than today. AI is used in identifying new targets for drugs, in designing new molecular entities, and in predicting the efficacy and safety of candidate drugs.

KEY WORDS: *Artificial intelligence, Machine learning, Drug discovery, and Drug development*

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INTRODUCTION:

In recent times, the multidisciplinary field of AI has achieved tremendous success, particularly in the fields of DL and ML [1]. Chemical and biological scientists have faced a big challenge for the last two decades to develop appropriate and sophisticated systems for targeted administration of the therapeutic drugs with maximum efficiency and minimum hazards [2]. Another challenge at the design and development stage of medications was the cost and time involved in the discovery of new therapeutic agents [3]. To discover new drugs, large chemical compound databases need to be screened. Machine learning algorithms can do this task much faster [4].

Novartis now uses AI algorithms to classify digital images of individual cells [5,6]. Various different experimental compounds are administered to each cell. Molecules that show similar effects become clustered and their further testing is prioritized by the algorithms. It often requires extensive research to discover the compounds that are biologically active. Hence, research teams at Novartis use machine learning algorithms to identify which unidentified compounds may be worth investigating with a view to accelerating this screening process. AI utilizes the use of programs and systems that can analyze input data and learn from this - to make independent decisions to reach specific goals. As this article describes, its applications within the pharmaceutical industry continue to grow rapidly. The McKinsey Global Institute believes that this rapid growth in AI-driven automation will very significantly change the culture of work in our culture [7-8]. The generalized elements of early drug discovery include lead discovery, lead optimization, and target identification and characterization. Some of the computer-based approaches that have been utilized for lead compound discovery and optimization include molecular docking[9-10], pharmacophore modeling [11], decision forests [12], and comparative molecular field analysis [13]. Besides target gene identification, biomarkers, and associated functional pathways, the machine learning algorithms are able to predict the effects of small-molecule candidates in both monotherapy and polytherapy. Considering the fact that overfitting is a common issue with machine learning, it is important to note that the current AI techniques are not perfect regarding drug development. A model is said to be overfitting if an ML model performs badly on unseen data but fits perfectly on the training data. The best way to prevent overfitting in ML model development is by testing ML models against new, unseen data; several techniques have been developed for cross-validation to prevent overfitting. In recent times, data challenges have become platforms for objectively comparing and analyzing the predicted performance of machine learning algorithms for different drug-related tasks. Though the U.S. FDA has not approved the marketing of any AI-enabled drugs yet, a number of AI-driven pharmaceutical companies have successfully accelerated phases I and II clinical candidates successfully [14]. Recently, in 2024, some research showed a breakthrough in the design of drugs by using DL for reverse-engineering synthetic routes [15,16]. Since 2018, AI in pharmaceuticals has moved from being a conceptual phase to practical application.

This narrative review aimed at the advancement of knowledge of AI involvement in drug discovery through a thorough and critical analysis of the body of current literature and, importantly, insight into its future and potential uses. With the purpose of providing an overview of the methods and tools of AI and their applications, future prospects, and ethical concerns in pharmacological research and precision medicine, a thorough search using relevant keywords was conducted on PubMed, Google Scholar, and ScienceDirect.

ROLE OF ARTIFICIAL INTELLIGENCE IN MODERN DRUG DISCOVERY

The use of Machine Learning (ML) and Artificial Intelligence (AI), by the pharmaceutical industry is dramatically increasing as its methodologies for developing drug therapies have experienced historically low success rates with significant capital expenditures throughout the drug development process [17]. Through the use of AI technology, the pharmaceutical industry now has two distinct categories of AI technology: supervised learning (predictive) and unsupervised learning (exploratory). The emergence of Deep Learning (DL) provides a powerful tool in the pharmaceutical industry today [18]. Some uses of AI technology in drug discovery are Causal Analysis of potential Drug Targets, Small Molecule Optimization through use of the Deep Neural Network (DNN) methodology, Development of Predictive Biomarkers to Improve Outcome with Personalized Medicine, and the Use of Computational Pathology to analyze Tissue Sample Data [19]. Despite the challenges associated with AI technology concerning the quality of training data, as well as the difficulties in interpreting highly complex AI models, the ongoing integration of AI into the pharmaceutical industry is providing a foundation for New Drug Discoveries and Development Activities within the pharmaceutical sector and the future of pharmaceuticals [20].

The high expense and labor intensity of developing new medicines has resulted in increased interest in the option of taking existing medicines (currently available & with a long history of clinical use) to develop them for a different indication [21]. The ability of molecular docking to assist with this process through the evaluation of multi-target efficacy will provide increased effort to this process through the use of computational techniques. The use of artificial intelligence (AI) and machine learning (ML) platforms for improving drug repositioning efforts through the development of correlations between drug/target/disease relationships from multiple data sources, through application of multiple learning algorithms, (i.e., supervised, unsupervised, semi-supervised) to enhance the predictive accuracy of these efforts given the inconsistency of data quality available [22].

In the clinical pharmacy area, AI is being utilized by companies such as IBM Watson to assist with patient recruitment into clinical trials by matching those eligible for participation, through their electronic medical records [23]. AI has been developed to predict clinical trial outcomes, side effects, as well as other variables that may impact the success of a clinical trial. Consequently, it will continue to provide value in both the design and execution of clinical trials; however, concerns related to data security and the requirement for continued in-vivo studies will remain an issue [24]. Therefore, the use of AI within the pharmacy profession facilitates, improves, and increases efficiency as a whole in drug development processes while meeting all regulatory requirements through improving the standard of care for patients, particularly for diagnosis and treatment of neurodegenerative diseases. However, despite all of these benefits to assist with streamlining drug development processes, multiple barriers such as financial limitations and the ability to integrate disparate datasets will continue to exist going forward [25]. Therefore, while AI currently contributes to improve the efficiency and effectiveness of the drug development process, it still operates within the constraints of the traditional drug development methodologies [26].

Clinical Pharmacology is harnessing AI and leveraging existing electronic medical records (EMRs) to match eligible volunteers to clinical trials, through tools like IBM Watson which assists in optimizing patient recruitment for clinical studies [27]. These AI tools also have the ability to help clinical researchers predict clinical outcomes, side effects and various other study variables, which assists researchers with the study design and study conduct phases of clinical trials, as well as serves as a basis for future studies. However, there are several ongoing issues in relation to data security and the need for in vivo studies that will continue to be a concern [28].

AI in Pharmacology is used to improve, streamline and expedite drug development and regulatory compliance efforts, and to enhance patient care, especially through the use of AI to diagnose or manage the treatment of neurodegenerative diseases. However, there are still significant barriers to using AI in pharmacology due to costs and issues associated with integrating diverse data sets [29]. AI is improving the efficiency and effectiveness of drug development; however, the use of traditional methods is still necessary for ensuring the safety and efficacy of the products.

AI technologies, using machine learning (ML), deep learning (DL), and natural language processing (NLP), have changed fundamentally the way the drug development cycle occurs (from discovery through to precision medicine) [30]. The algorithm(s) employed using AI technology allows researchers to analyze large amounts of biomedical data to identify potential drug targets, validate drug activity, and ultimately optimize the lead compound to develop a drug candidate [31]. Additionally, AI technologies provide improved efficiencies in conducting clinical trials, such as selecting patients, assessing real-time data, and providing pharmacovigilance of post-market product safety.

MACHINE LEARNING MODELS IN PHARMACEUTICAL RESEARCH

Pharmaceutical research has experienced positive changes through the introduction of machine learning (ML). Using machine learning, researchers are able to streamline many aspects of drug discovery and develop more effective medicines [32]. Historically, researchers relied solely on manual methods, which were time-consuming and expensive, whereas using ML allows researchers to utilize large amounts of data, such as genomic data, electronic health records (EHRs), and data collected during clinical trials, in ways that allow greater productivity [33].

There are four main types of Machine Learning (ML) models used in pharmaceutical research, namely:

1. Supervised Learning: Algorithms that utilize labeled datasets (i.e., data that has been explicitly identified for specific tasks) to predict the properties of drugs based on toxicity and ADMET [34]

2. Unsupervised Learning: Approaches that extract hidden patterns from data that do not contain a specific label, using techniques like clustering and dimensionality reduction (PCA, t-SNE). Examples of application areas include identifying potential drug leads or discovering novel biomarkers [35].

3. Reinforcement Learning (RL): Models used for molecular design and optimizing trial design through interactions with an environment [36].

4. Deep Learning (DL): A specialized branch of machine learning utilizing very sophisticated algorithms that manage very large, complex data sets. CNNs and GNNs are examples of best practices for DL and are frequently used for image processing and predicting molecular structures [37].
5. Drug Discovery: ML is involved in target identification, virtual screening and the creation of new drugs from scratch. By enabling the fast identification of active ingredients, ML speeds up the entire drug development process [38].
6. Preclinical Development: ML increases the predictive capabilities of pharmacokinetics and toxicity models, resulting in safer drug development. Additionally, ML can assist in optimizing the formulation by predicting interactions and stability of excipients [39].
7. clinical Trials: ML can optimize how patients are recruited and can predict patient responses to treatment. In addition, ML can improve the design of clinical trials through adaptive designs and anomaly detection [40].
8. Manufacturing and Quality Control: ML can increase process efficiencies by predicting maintenance needs and providing real-time validation of product quality [41].
9. Pharmacovigilance: ML allows for the monitoring of adverse events and drug safety from multiple data sources through automation [42].
10. Benefits of Using Machine Learning: The implementation of ML in the pharmaceutical industry will reduce the time it takes to develop drugs, save money, produce more accurate results, and facilitate better decision making resulting in the ability to develop personalized medicine and innovative drug products [43].

Artificial Intelligence in Drug Development and Manufacturing

Computational techniques have enabled early-stage drug discovery by predicting pharmacokinetics, toxicity profiles, and molecular interactions before laboratory testing [44]. These in silico methods reduce expenses and expedite the candidate selection process by lowering the number of compounds that must be physically synthesized [45]. Generative algorithms are increasingly being used to propose novel chemical structures that go beyond traditional chemical libraries [46]. By using structural analysis of target proteins, these methods can optimize molecules for drug-like characteristics, synthetic accessibility, and binding affinity [47].

Predictive ADMET (absorption, distribution, metabolism, excretion, toxicity) modeling further refines candidates, favoring those with favorable profiles for preclinical testing [48]. Integrated pipelines that integrate target identification, molecular generation, and ADMET screening have greatly reduced drug discovery times [49]. Data-driven approaches in formulation development improve solubility, stability, and release properties in addition to forecasting interactions between excipients and active pharmaceutical ingredients (APIs) [50].

Historical batch data can be used to inform predictive models in the manufacturing industry that optimize process parameters to boost yield and lower variability [51]. Equipment sensor data enables predictive maintenance, which reduces downtime and maintains consistent production cycles [52]. The entire drug development and manufacturing process is streamlined by these computational techniques, which also offer efficiency and reproducibility [53].

AI-Driven Personalized Medicine and Drug Repurposing

The increasing availability of genomic, proteomic, and clinical data enables computational approaches for patient stratification for customized treatments [57]. Machine learning models predict individual responses, reducing adverse events and enabling customized dosage [58]. By utilizing molecular and clinical data to identify new uses for previously approved drugs, drug repurposing lowers development costs and times [59].

Graph-based algorithms and deep learning frameworks have successfully identified repurposing candidates through the analysis of compound libraries and disease-gene networks [60]. Computational models also increase trial design efficiency and success rates by selecting patients who are likely to respond [61]. Integrating biomarker data, electronic health records, and real-world evidence improves predictive accuracy [62]. By focusing experimental resources on high-probability candidates, AI-driven drug repurposing maximizes lab and clinical investments and expedites discovery [63]. Computationally predicted repurposing has demonstrated promising results in infectious diseases, rare disorders, and oncology [64]. By ensuring that treatment is customized to each patient's distinct biology, personalized medicine increases efficacy and safety [65].

Experimental and clinical validation is still required for these methods to validate predictions [66]. Ethical considerations like data privacy and equitable access continue to influence implementation [67]. In order to ensure diverse population representation, ongoing research is addressing bias in computational models [68].

Integration of 3D Printing and Computational Methods in Pharma

3D printing enables the production of customized dosage forms, including polypills, multilayer tablets, and tailored doses [61]. Printing technologies that affect dissolution and release, such as extrusion-based and inkjet systems, enable precise control over tablet geometry, internal structure, and porosity [69].

Adaptive process control and real-time monitoring ensure layer fidelity and homogeneity, improving reproducibility and minimizing errors [63]. Because this combination supports decentralized manufacturing, hospitals and compounding pharmacies can produce patient-specific medications near the point of care [65]. Customized 3D-printed drugs improve adherence and reduce waste [62].

The challenges include material compatibility, stability, repeatability, and bioequivalency with traditional formulations [70]. Regulations pertaining to decentralized production are presently evolving [67]. Despite these challenges, computationally guided 3D printing provides a flexible, patient-centered approach to pharmaceutical manufacturing [68].

Challenges and Limitations of Computational and Integrated Approaches

Data quality and completeness are important constraints for computational methods in drug discovery because incomplete or biased datasets can lead to incorrect predictions and misdirected research objectives [71]. Variability in data sources, such as clinical trials, genomic databases, and electronic health records, further complicates model reliability [72]. When integrating heterogeneous data types, including clinical, molecular, and demographic data, sophisticated preprocessing techniques are required to guarantee accuracy [73]. Because proprietary algorithms often function as "black boxes," scholars and regulators find it difficult to comprehend how predictions are made [67]. Opaque algorithms may hinder regulatory approval and confidence in model outcomes [74]. Additionally, relying too much on computational forecasts could result in the advancement of hazardous or ineffective candidates in the development pipeline, as they cannot serve as experimental validation on their own [75].

Material limitations in 3D printing technology present additional challenges. Variations in polymer properties, drug-excipient interactions, and environmental factors can all affect drug stability, release patterns, and dose precision [61]. Because 3D-printed pharmaceutical products are often not very reproducible, scaling up to industrial production is challenging [65]. Additionally, the continuous development of regulatory requirements for decentralized or individualized manufacturing creates uncertainty for manufacturers [68].
Scalability is another major disadvantage because traditional batch manufacturing is still more efficient for large-scale production [76]. Computational and integrated manufacturing processes require a significant initial investment in hardware, software, and skilled personnel [77]. Operating costs are increased because maintaining these complex systems requires specialized knowledge [78].

There are ethical, privacy, and equity concerns when using patient-level data for customized treatment or drug repurposing. Ensuring patient consent, maintaining confidentiality, and preventing data exploitation are important issues [79]. Moreover, computer models may inadvertently worsen health disparities if they are trained on non-representative populations [62]. Bias in datasets and algorithms must be addressed to ensure fair outcomes [80].

Transparent reporting, replicable workflows, and open data access can increase trust in computational techniques [81]. Regulations must adapt to new methods in order to strike a balance between innovation and safety, efficacy, and quality standards [65]. Computational scientists, physicians, and regulators must collaborate to optimize advantages and reduce risks [82].

Despite these challenges, careful use of computational tools and integrated manufacturing techniques has the potential to significantly improve drug discovery efficacy, reduce costs, and enable customized medications [66]. Strict validation, continuous development, and compliance with moral and legal requirements are necessary to fully benefit from these technologies [83].

Applications

AI-based nanorobots for drug delivery

Integrated circuits, sensors, power supplies, and secure data backups maintained by computational technologies such as artificial intelligence are the main parts of nanorobots [84]. They are made to detect and attach, avoid collisions, recognize targets, and then leave the body. Because nano/microrobots can now navigate to the targeted region based on physiological parameters like pH, their effectiveness has increased and systemic side effects have decreased [85]. Dose adjustment, sustained release, and control release are important considerations when creating implantable nanorobots for regulated drug and gene delivery. AI tools like integrators, fuzzy logic, and neural networks must also be used to automate the drug release [86].

Biomarker discovery and validation

In the era of molecular medicine, the creation of biomarkers enhances the drug discovery process. To find biomarkers, a large number of samples must be collected and consistently and carefully examined. Validation ensures that the marker is reliable, repeatable, and has acceptable sensitivity and specificity. AI may be applied in this step. Biomarkers are used as a clinical trial outcome measure in the drug development process to help identify and validate therapeutic targets. Consequently, based on the biomarkers analyzed, each patient would be given the right drug [87].

AI-Guided Lead Optimization

AI-guided lead optimization offers several advantages, including reduced human bias, continuous chemical space modeling, and overcoming data limitations through transfer learning and semi-supervised learning. These techniques can create molecules with the desired properties, which could reduce the amount of time needed to find new drugs. Among the various techniques for AI-guided lead optimization are the following: (1) Deep generative models in the recurrent neural network (RNN)-based technique learn the chemical space distribution and generate new molecules by learning the simplified molecular input line entry system (SMILES) grammar symbol by symbol. Transfer learning and semi-supervised learning deal with limited target-specific data. (2) Variational autoencoders (VAE) and generative adversarial networks (GAN) are examples of generative autoencoders used in molecular design. VAEs incorporate a probabilistic component into the compressed representations they learn in a latent space. For conditional design, conditional VAEs offer property vectors. Lead optimization also includes prototype-driven diversity networks and semi-supervised VAEs. (3) Deep generative modeling is combined with reinforcement learning (RL) techniques. By viewing molecule production as a set of incentives, it maximizes expected return. Reward function design is important for both policy learning and value learning. De novo molecule design uses reinforcement learning (RL), while fine-tuning uses specialized generator designs like differentiable neural computers (DNC) [88-90].

AI Models for Treatment Outcome Optimization and Drug Response Prediction

AI models apply machine learning algorithms to predict drug response and analyze a wide range of biomedical data for the optimization of treatment outcomes. They allow for personalized medicine and repurposing of drugs through the identification of molecular markers and phenotypic changes associated with drug response. Furthermore, AI models unravel the molecular mechanisms behind drug response, further leading to the development of new treatments and targeted interventions. Their use improves the rate of efficacy and safety predictions of drugs and clinical trial successes.

Pathology by computation

Since a pathologist uses visual inspection to understand what is observed on a glass slide, pathology is a descriptive field. Numerous details, including the kind of cells in the tissue and their geographical context, can be obtained by analyzing these glass slides. In immuno-oncology, the interaction between immune cells and tumors within the tumor microenvironment is becoming more and more significant and is recorded by no other modality.

Artificial intelligence for de novo drug design

De novo drug designing represents an iterative approach aimed at the creation of new dynamics by means of designing 3D architectures of receptors with the aim of creating a novel chemical. However, the application of de novo drug creation in medicine disclosure has not been limitless. Further, with developments in AI, the industry has of late witnessed some revival [91-92]. Owing to its capability of carrying out profitable in silico analyses on a large number of mixtures, VS has now become an indispensable tool in the drug improvement process whereby the yields of potential therapeutic leads are increased manifold. ML, as a subset of AI, refers to the way of organizing VS for drug leads that usually involves the compilation of a filtered set of compounds including both known active and inactive compounds to train a model [93-94]. When the model is set up, it is tested and, if good enough, applied on a database that has never been used before with the hope of finding drugs.

High-throughput data analysis and screening

The process of finding possible molecules to include in additional analysis is called high-throughput screening. The molecules identified from the previous step are screened to identify which molecules best relate to the health concern at question. Also part of the process are molecule stability and interactions [95]. Various techniques include multiple linear regression, decision trees, neural networks, and analysis of variance [96,97].

QSAR modeling and drug repurposing

Establishing a relationship between chemical structures and their physiochemical properties and biological activities is of paramount importance in drug design and discovery. Therefore, QSAR modeling is one of the computer techniques that may be employed to generate quantitative mathematical models between chemical structure and biological activity. The most important advantage of developing a mathematical model is establishing the various chemical structures from the molecular databases that are usable as therapeutic compounds against a disease target. After selecting the most promising molecule, it undergoes in vitro or in vivo testing and synthesis in a laboratory.

Predicting Drug-Protein Interactions

Drug-protein interactions constitute the backbone of a medicament entity's bioactivity. Knowledge concerning the success and efficacy of a drug-receptor or drug-protein interaction is quite useful for drug repurposing and for preventing polypharmacology [98]. Many AI approaches have found applications to predict interactions occurring between a ligand and protein with high accuracy ensuring increased therapeutic efficacy [99-103]. In order to find nine new molecules and their interactions with four crucial targets, a model reliant on the SVM method has been described [104].

This model was trained on approximately 15,000 protein–ligand interactions and it was based on the main protein sequences along with structural characteristics of small compounds.

The Potential Market for AI-Based Drug Development and Discovery Applications

The use of AI solutions by pharmaceutical companies enables them to reduce the financial costs and possible losses associated with VS. The AI market, which was valued at USD 200–700 million between 2015 and 2018, is expected to grow to a value of USD 5 billion by 2024 [105]. A predicted growth of 40% from 2017 to 2024 indicates that AI could transform the pharmaceutical and medical sectors. Several pharmaceutical firms have invested financially in AI and continue to do so. They have also partnered with providers of AI in the development of critical medical tools. This has been underlined by the agreement between the Royal Free London NHS Foundation Trust and DeepMind Technologies, part of Google, to reduce acute kidney injury.

FUTURE PERSPECTIVE

Deep learning, a sophisticated form of machine learning, can be used for drug discovery. It consists of a neural network that can determine scientific conclusions from the data mined from the public databases. Applying deep learning to forecast the outcomes of clinical studies before these studies are initiated may lower their cost [106].

Another exciting use of AI in drug discovery is drug repurposing. Drug repurposing-the finding of new uses for medications that are currently on the market-speeds up and lowers the cost of their development [107]. Another emerging topic in the realm of medication development and discovery is the use of AI in nanotechnologies-particularly nanocarriers. Smart drug release devices which administer medication when needed also depend heavily on AI [108]. The current AI-assisted algorithms should shorten the time required for the goods to reach the market, improve the quality of the goods and the overall security of the manufacturing scheme, and result in increased utilization of available resources while being cost-effective, by highlighting and advancing the importance of mechanization [109].

The main worry about the implementation of these platforms pertains to the anticipated job loss and rigid processes involved in using AI. Nevertheless, instead of displacing humans altogether, the mentioned technologies are designed to ease the task [110]. Besides facilitating rapid and hassle-free identification of hit compounds, AI can also suggest how synthesis pathways for these compounds may be conducted along with a prediction of the structure of the chemical of interest, an insight into drug-target interaction, and associated SAR.

CONCLUSION:

The paper highlights the revolutionary potential of AI in changing the drug discovery and development process. AI, by applying machine learning, deep learning, and data analytics, can accelerate target identification, optimization of lead compounds, and prediction of pharmacokinetics and toxicity. This review demonstrates that strong validation and consideration of ethics are highly significant in AI-driven drug development, while also considering the challenges due to scarce resources and model interpretability. ML has been applied with success in drug discovery for quite some time now, constantly outperforming traditional approaches. Machine learning (ML) and deep learning (DL) methodologies were developed from decades-long research and development.

These algorithms have contributed to continued success in drug discovery through their meticulous curation and development. Applications of ML are growing more complex, effective, and efficient thanks to advances in algorithm precision, computer power, and substantial investment-which in turn will help improve the drug development process.

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