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Progress and Core Challenges of Artificial Intelligence Applications in the Pharmaceutical Field

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Abstract. The pharmaceutical innovation system covers core procedures including new drug development, research on disease molecular mechanisms, individualized diagnosis and treatment, and post-marketing drug safety supervision. Even though relevant research has made steady progress, the industry is plagued by multiple practical bottlenecks that hinder its development. Low overall R&D efficiency, incomplete clarification of molecular mechanisms behind complicated diseases, and limited practical capacity of precision therapy all slow the upgrading of modern pharmaceutical systems. Equipped with powerful tools to process massive datasets and mine hidden biological patterns, artificial intelligence (AI) has been adopted in many key pharmaceutical research areas over recent years. It has overturned the conventional experience-based research mode and steered pharmaceutical research toward an innovative data-driven framework. This paper sorts out real-world applications of AI across the full pharmaceutical lifecycle and elaborates on major barriers to its practical deployment, such as insufficient standardized medical data, low interpretability of algorithm models, and immature industrial regulatory systems. Continuous technological iterations will refine explainable AI algorithms, multi-source medical data integration techniques and privacy-preserving computing frameworks. These improvements can deepen the integration of AI and pharmacy, delivering solid support for innovative drug discovery and the clinical implementation of precision diagnosis and treatment.

Keywords: Artificial Intelligence, Drug Research and Development, Precision Medicine, Network Pharmacology, Pharmacovigilance

1. Introduction

The entire pipeline of pharmaceutical innovation is still hampered by insufficient efficiency and inadequate precision. The full R&D chain of the traditional pharmaceutical industry suffers from prolonged development cycles, massive capital investment, low success rates and high risks of developmental failure. Especially in preclinical and clinical phases, a large number of candidate drugs are eliminated. Procedures including target screening, molecular design, formulation optimization and post-market surveillance heavily rely on laboratory verification and manual empirical judgment, which greatly restrict overall R&D efficiency [1, 2]. In terms of clinical diagnosis and treatment, standardized unified therapeutic regimens fail to address inter-patient

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heterogeneity. Mass multi-omics, medical imaging and electronic health record datasets remain underutilized, hindering the implementation of precision therapeutic strategies [3-5]. In the field of pharmacovigilance, safety reports are reviewed manually, resulting in delayed detection of adverse drug reaction signals; conventional frameworks are incapable of large-scale risk screening [6].

Driven by multi-omics big data, machine learning (ML) and generative artificial intelligence technologies, AI has been gradually deployed across pharmaceutical R&D and clinical practice. For drug discovery workflows, AI enables automated molecular design and druggability prediction to cut experimental expenditures in the early development stage [1, 2]. In clinical settings, AI analyzes medical records and imaging data, and adopts causal inference to predict therapeutic outcomes and optimize individualized treatment regimens [4, 7]. Within pharmacovigilance, natural language processing (NLP) rapidly extracts adverse event information to mine latent pharmaceutical risks [6].

Most existing review papers only focus on a single segmented research field, lacking systematic summaries that cover drug discovery, preclinical research, disease mechanism analysis, precision medicine and post-market safety monitoring. Accordingly, this paper systematically sorts out practical AI technologies and real-world application cases in five modules along the full pharmaceutical lifecycle, analyzes universal challenges involving data, algorithms and regulatory systems, and further prospects future developmental trends.

2. Core application scenarios of artificial intelligence in the pharmaceutical industry

2.1. AI-assisted drug molecular design and virtual screening

New compound discovery requires researchers to sift promising candidate molecules from the enormous chemical space available to synthetic chemistry. Conventional wet-lab screening consumes substantial time and economic input, which greatly slows down early-stage exploratory work. Abundant records of molecular conformation and bioactivity are accumulated throughout drug discovery procedures, offering rich training materials for AI. Researchers can train AI algorithms to capture implicit correlations hidden within these datasets, and deploy such models to forecast molecular activity, filter candidate compounds and design novel chemical skeletons in preliminary research [1, 2, 8].

Early quantitative structure-activity relationship (QSAR) modeling work demands manual selection of molecular descriptors by experimenters, an approach that fails to fully capture subtle structural traits of complicated organic molecules. ML models are capable of autonomously extracting intrinsic structural information from chemical entities, while deep learning (DL) architectures excel at modeling nonlinear interactions linking molecular geometry and biological activity. Such analytical outcomes can support researchers to assess the bioactivity of untested compounds before synthesis [2, 8-10]. Even so, activity prediction alone cannot satisfy the demand for large-scale compound screening workflows; in practical lab work, virtual screening and molecular docking always work in tandem to narrow the candidate pool for subsequent wet-lab verification.

Virtual screening relies on pre-established compound libraries to build predictive models. This technology ranks chemical candidates based on their predicted biological activity and binding affinity toward target proteins, cutting down the volume of repetitive wet experiments that follow [1, 2, 8, 11]. When exploring the binding mechanism between drug molecules and protein targets, AI can act as auxiliary analytical tools paired with molecular docking and three-dimensional protein structure simulation [2, 11]. AlphaFold series models serve as a typical case: this toolset remarkably

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lifts the prediction accuracy of unknown protein spatial conformations, supplying critical structural references for rational molecular design campaigns [8].

If existing stock compounds cannot meet the therapeutic requirements set by research objectives, research teams can leverage generative artificial intelligence (Generative AI). After learning structural patterns from thousands of known chemical substances, generative architectures output brand-new molecules matching predefined physicochemical and bioactivity standards [2, 10]. Traditional molecular optimization only modifies side chains or functional groups on existing molecular skeletons. In contrast, generative AI models can access under-explored regions of chemical space and expand the scope of molecular excavation to a larger extent.

From lab practice, AI has rewritten the trial-and-error dominated mode of traditional drug discovery, simplifying workflows for candidate screening and de novo molecular construction. It is critical to clarify, however, that all AI algorithms merely deliver preliminary predictive references for researchers. The safety and clinical efficacy of any candidate molecule still demand multi-layered verification covering in vitro cell assays, animal model experiments and successive human clinical trials.

2.2. AI-assisted druggability evaluation and preclinical research

Preclinical research conducts experiments from three core dimensions, namely pharmacodynamic performance, in vivo pharmacokinetic characteristics and toxicological safety evaluation, to comprehensively judge the druggability potential of candidate compounds for subsequent development. Conventional preclinical research relies entirely on in vitro and animal experiments to measure each indicator item by item. When dozens or hundreds of candidate molecules require batch evaluation, the complete experimental workflow will extend the research cycle, raise upfront R&D costs simultaneously, and hinder the progress of early-stage drug development directly [1, 2, 8, 11].

After candidate molecules enter the preclinical research phase, their Absorption, Distribution, Metabolism, Excretion and Toxicity (ADMET) properties need to be evaluated first. Therefore, ADMET prediction has become a vital application field of AI [1, 2, 9]. Relevant studies have demonstrated that machine learning-based ADMET prediction models can assess the pharmacokinetic and toxic risks of candidate molecules in advance during preclinical research, thus cutting ineffective investment in subsequent development links [1, 9]. Different AI models are adopted for ADMET prediction according to data scale and the complexity of molecular structures. Traditional ML algorithms including Random Forest and Support Vector Machine (SVM), Gradient Boosting are suitable for small and medium-sized datasets, while DL models perform better in analyzing large-scale molecular data and multi-dimensional biological information. In addition, graph neural networks, which convert molecular structures into molecular graphs and learn the correlations between atoms and chemical bonds, are also applied to predict ADMET properties [8, 9, 11].

Beyond the physical, chemical and pharmacokinetic attributes of compounds themselves, the design of drug delivery carriers and release pathways largely determines the overall success of new drug development. Researchers can utilize AI to analyze internal correlations between excipient proportion, preparation procedures and drug release profiles, adjust key formulation parameters pertinently, and streamline the iterative optimization workflow of drug delivery systems [9].

A comprehensive overview of AI applications across all preclinical links reveals that AI assists risk assessment of pharmaceutical properties for candidate molecules and optimizes design schemes of delivery carriers, lowering the probability of early-stage research elimination fundamentally.

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Nevertheless, the technical limitations should be clarified objectively: passing all preclinical tests only proves stable performance of drugs under standardized animal models, rather than universal applicability to all real clinical populations. Variations in individual genes and pathological backgrounds lead to distinct therapeutic effects and adverse reactions. To realize individualized intervention, follow-up research must integrate disease molecular regulatory pathways and interaction rules between drugs and disease targets, so as to continuously explore precision medicine regimens suitable for diverse patient groups.

2.3. AI-driven multi-omics integration and network pharmacology research

After researchers finish screening and functional assessment of candidate drug molecules, unpacking the molecular basis of disease onset also plays an irreplaceable role in boosting clinical treatment precision. Identical pharmaceutical agents often trigger divergent therapeutic responses among different patient cohorts. One major cause of such discrepancy lies in the fact that most early research only targets single disease proteins, which cannot fully interpret multi-layered dynamic changes of biological networks driving complex disorders such as malignant tumors [5, 12, 13].

Multi-omics technology aggregates biological data from multiple organizational layers, covering sequencing datasets derived from genomics, transcriptomics, proteomics, metabolomics and microbiomics. Such datasets carry prominent traits including high dimensionality, heterogeneous data distribution and intricate cross-regulatory connections between biomolecules [12, 14, 15]. Conventional statistical analysis tools lack sufficient capacity to untangle such complex regulatory relationships. AI systems can integrate multi-layer omics datasets and decode complex network interactions, delivering analytical evidence for interpreting pathological mechanisms, identifying core therapeutic targets and screening specific disease biomarkers. Taking oncology research as an example, combining AI with genomics and transcriptomics datasets helps researchers map disease-related molecular networks and uncover unreported therapeutic targets, bringing fresh analytical perspectives to design individualized treatment plans [5].

Network pharmacology has gradually become a mainstream analytical tool to untangle complicated interactions between multi-component herbal/compound drugs and disease pathways. With continuous iteration of AI algorithms, research teams are able to parse highly complex biological network structures and dig out hidden regulatory links between chemical agents and disease phenotypes, supporting the development of intervention schemes for intractable illnesses [12, 13].

Combining AI with disease network analysis also pushes forward two key research directions: drug repurposing and precision research on traditional Chinese medicine (TCM) [12, 13]. By aggregating molecular structures, target binding profiles and clinical disease records of marketed pharmaceuticals, AI algorithms can uncover unknown matching relationships between drugs and disease indications, providing data support for drug repurposing exploration. TCM compound formulas feature multi-component synergistic effects, multi-target modulation and simultaneous regulation of multiple signaling pathways, which align well with the core logic of network pharmacology. Nevertheless, historical TCM research mostly depends on clinical empirical summaries, lacking clear explanations of underlying molecular mechanisms. When paired with network pharmacology frameworks, artificial intelligence can integrate data of chemical compounds, therapeutic protein targets and disease signaling pathways, assisting researchers to unpack the holistic pharmacological mechanism of compound prescriptions and drive TCM research to shift from empirical induction toward quantitative mechanism exploration [13].

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After sorting through all above research dimensions, the combination of AI, multi-omics and network pharmacology shifts disease research away from single-target testing toward multi-dimensional network analysis frameworks. Such technical integration supports various exploratory work including pathological mechanism interpretation, drug repurposing and precision TCM research. Candidate molecule screening and disease mechanism exploration share one core research goal: improving clinical therapeutic outcomes for patients. For this reason, follow-up research needs to combine complete clinical diagnosis and treatment systems to realize practical deployment of precision medicine in real clinical environments.

2.4. AI empowers clinical diagnosis and individualized medicine

Conventional clinical diagnosis and treatment generally adopt unified therapeutic regimens for patients diagnosed with the same disease. However, patients differ in pathogenic mechanisms, molecular signatures and therapeutic responses. For example, patients suffering from the same type of cancer may carry distinct molecular alterations and disease backgrounds, leading to inconsistent outcomes under identical treatment plans [16]. Accordingly, individualized therapy has become a key developmental branch of precision medicine. Individualized treatment requires the integration of multi-dimensional data including clinical records, molecular omics information and medical imaging to characterize patients and formulate precise therapeutic regimens. Nevertheless, the explosive expansion of medical data renders manual analysis impractical. AI models integrate multi-source medical data to facilitate disease prediction, patient stratification and therapeutic response forecasting [3, 4, 7, 17-19].

Medical imaging represents one of the earliest mature application scenarios of AI. As a typical deep learning architecture, Convolutional Neural Network (CNN) can efficiently extract image feature information [3, 4, 17, 18]. Trained on massive medical imaging datasets, AI models exhibit promising potential in tumor detection, digital pathological analysis and auxiliary clinical trial management. For instance, AI can analyze tissue structures and molecular markers on pathological slides to provide support for tumor subtyping, patient screening and clinical trial design [16].

After disease confirmation and patient stratification, precision medicine further adopts causal machine learning to evaluate the efficacy of various therapeutic regimens. Causal machine learning integrates multi-dimensional patient data to quantify the impact of different intervention strategies on individual patients, thus offering evidence for optimized clinical decision-making [7].

In addition, individualized treatment can be combined with digital twin technology. Dynamic patient simulation models are constructed by aggregating real-world data(RWD) to simulate disease progression, predict clinical risks and refine therapeutic schedules [17]. Overall, AI is expected to drive the transformation of clinical practice toward individualized care. Nonetheless, a complete precision medical system relies not only on clinical intervention, but also on sound pharmacovigilance, standardized quality control of RWD and mature regulatory frameworks.

2.5. Applications of artificial intelligence in pharmacovigilance and real-world research

After drugs complete clinical trials and obtain marketing approval, they have undergone systematic safety evaluation. Nevertheless, clinical trials are limited by small sample sizes, short follow-up periods and strict subject inclusion criteria, so some latent risks of adverse drug reactions may remain undetected. For this reason, pharmacovigilance systems are established to continuously monitor drug safety among extensive real-world patient populations after drug launch [1, 3, 6].

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Traditional pharmacovigilance mainly relies on adverse event reports submitted by medical staff and patients, followed by manual review and risk assessment. Such a framework cannot cope with the rapidly expanding volume of data, and the passive reporting mode delays the discovery of potential correlations between drugs and adverse reactions [6]. A large amount of drug safety information is embedded in unstructured data such as medical texts and adverse event reports. Rapid extraction of valid safety-related information from complex texts has become the core demand for intelligent pharmacovigilance [1, 3, 6]. NLP technology can identify and analyze such textual data, automatically extract drug safety information and improve the processing efficiency of pharmacovigilance data [6].

Most analytical materials supporting pharmacovigilance research fall under the category of RWD [3, 19], covering electronic health records (EHR) , hospital databases, clinical registration systems and medical insurance datasets. With the integration of AI and RWD, researchers can evaluate the long-term efficacy and safety performance of drugs under routine clinical settings, making up for data deficiencies arising from narrow participant coverage and short follow-up cycles in conventional clinical trials [3]. Beyond that, AI models can combine individual patient characteristics, combined medication regimens and historical adverse event records to screen out susceptible populations prone to high adverse reaction risks in advance [1, 3].

From the multi-dimensional application scenarios discussed above, AI is reshaping the operation logic of traditional pharmacovigilance, shifting the original passive reporting supervision mode to active early-warning risk management. Evidence generated from RWD also delivers brand-new technical approaches for long-term post-marketing drug safety evaluation. Objectively speaking, however, the large-scale implementation of AI in pharmaceutical supervision still faces multiple unavoidable practical constraints, and numerous challenges remain to be resolved for widespread industrial adoption.

3. Core limitations and developmental challenges

Although AI technologies have demonstrated promising application potential across multiple links including drug research and development, disease mechanism research, precision medicine and pharmacovigilance, the translation from experimental research to routine clinical practice is hindered by various challenges.

AI learns implicit patterns and generates predictive outputs based on input data, and data quality sets the upper bound of model performance. Nevertheless, current training datasets suffer from prominent heterogeneity, insufficient standardization, as well as conflicts between data sharing demands and privacy protection, which restrict the improvement of model performance and generalizability [1-3, 7, 14, 15, 19, 20].

Even if models are trained on high-quality datasets, inherent algorithmic limitations still impede their deployment in medical scenarios. DL models deliver powerful predictive capacity, yet their internal decision-making processes are generally opaque. Medical practice requires not only predictive outcomes but also explicit mechanistic explanations [1-3, 14, 15, 20]. Besides, poor model generalizability remains an urgent problem. Limited coverage of training data locks the predictive scope of models. For instance, a model trained on datasets from one hospital often yields drastically fluctuating accuracy when applied to data from another medical institution [1, 2, 7, 14, 20]. Meanwhile, when assisting therapeutic decision-making, models are required to identify causal relationships between drugs and diseases rather than merely correlational associations, so as to accurately evaluate the efficacy of treatment regimens [1-3, 7].

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Once models achieve acceptable predictive performance, sound supporting regulatory systems are indispensable for their clinical translation. The safety, stability and actual clinical benefits of AI models must be validated through systematic clinical investigations [1, 3, 6].

Finally, the rapid advancement of AI tools calls for synchronized cultivation of interdisciplinary talents. AI-enabled medical research demands compound professionals with integrated expertise in disease pathogenesis, algorithm principles and clinical workflows. The shortage of such talents also restricts the further popularization of AI technologies in the pharmaceutical industry.

4. Conclusions and future perspectives

AI technologies are gradually penetrating the full pharmaceutical lifecycle covering drug research and development, disease mechanism research, precision medicine and pharmacovigilance, driving the shift of medical decision-making from an experience-driven paradigm to a data-driven one. In the future, AI is expected to integrate multimodal data to construct comprehensive disease models, strengthen disease prediction capacity and assist in formulating feasible therapeutic regimens [1-3, 15, 19, 20].

To address the black-box problem of AI models, advances in explainable artificial intelligence can deliver reliable mechanistic interpretations alongside predictive outputs, thereby improving clinical acceptance [2, 3, 7, 15, 17, 20]. For the conflict between data sharing demands and privacy protection, federated learning enables collaborative model training without direct exchange of raw data, enhancing model performance and mitigating risks associated with data disclosure [2, 7, 17, 19, 20].

Nevertheless, the clinical translation of AI technologies relies on improved data standards, sound regulatory frameworks and systematic training of interdisciplinary talents. Medical AI is not designed to replace clinicians and researchers; instead, it serves as a vital tool to boost the efficiency of pharmaceutical research and support precision diagnosis and treatment.

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