

Research Article

Artificial Intelligence and Machine Learning in Drug Discovery and Pharmacology: Applications, Explainability, and Future Directions

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ABSTRACT

Drug discovery and pharmacology are undergoing a significant transformation driven by advances in artificial intelligence (AI) and machine learning (ML). What historically required a decade or longer and substantial capital investment per approved therapeutic is increasingly being reshaped by data-driven computational pipelines capable of accelerating target identification, virtual screening, lead optimization, toxicity prediction, and drug repurposing. This review synthesizes recent developments in AI/ML applications across the drug discovery and development pipeline, with particular attention to deep learning architectures such as graph neural networks and transformer-based models, generative molecular design methods, and reinforcement-learning strategies for lead optimization. It further examines the growing importance of explainable AI (XAI) in pharmacology, where regulators and clinicians increasingly demand transparent, auditable model reasoning rather than opaque predictions. Persistent challenges – including data quality and bias, limited generalizability across chemical space, the interpretability-performance trade-off, and evolving regulatory expectations – are discussed alongside emerging directions such as federated learning, multimodal foundation models, and physics-informed explainability. The review argues that the next phase of AI-enabled pharmacology will be defined less by predictive accuracy alone and more by the trustworthiness, reproducibility, and clinical integration of these systems.

Keywords: Artificial Intelligence, Machine Learning, Drug Discovery, Explainable AI, Pharmacology; Deep Learning, Drug-Target Interaction.

INTRODUCTION

The conventional drug discovery pipeline — spanning target identification, hit discovery, lead optimization, preclinical safety assessment, and multi-phase clinical trials — remains slow, capital-intensive, and prone to late-stage failure. Attrition is heavily concentrated at the preclinical-to-clinical transition, where compounds that appear promising *in vitro* frequently fail due to poor pharmacokinetics, unanticipated toxicity, or lack of clinical efficacy. Over the past decade, the convergence of large-scale biological, chemical, and clinical datasets with advances in computational power and algorithm design has positioned AI and ML as central tools for addressing these inefficiencies (Vamathevan et al., 2019).

Unlike earlier generations of computer-aided drug design, which relied primarily on physics-based simulation and rule-based expert systems, contemporary AI/ML approaches learn directly from data — molecular structures, omics profiles, protein–ligand interaction datasets, and real-world clinical records — to model relationships that are difficult to specify

analytically. Landmark demonstrations such as AlphaFold's near-experimental accuracy in protein structure prediction (Jumper et al., 2021) and deep-learning-guided discovery of structurally novel antibiotic candidates (Stokes et al., 2020) have shown that AI can generate scientifically consequential, not merely incremental, contributions to pharmacology.

At the same time, the translation of these methods into regulated pharmaceutical practice has exposed a distinct set of challenges: many high-performing models remain functionally opaque, their predictions difficult to justify to regulators, clinicians, or patients. This has given rise to a parallel and increasingly urgent research agenda around explainable AI (XAI) in pharmacology and clinical decision support (Abbas, Jeong, & Lee, 2025). This review examines both strands together — the expanding footprint of AI/ML across the drug discovery pipeline, and the explainability requirements that will determine whether these tools are ultimately trusted and adopted. Section 2 outlines the principal AI/ML paradigms relevant to pharmacology; Section 3 surveys applications across the pipeline;

Section 4 discusses explainability; Section 5 addresses persistent challenges; and Section 6 outlines emerging directions.

AI/ML Paradigms Relevant To Pharmacology Classical Supervised and Unsupervised Learning

Classical ML methods — random forests, support vector machines, gradient-boosted trees, and k-nearest-neighbour models — remain widely used for quantitative structure–activity relationship (QSAR) modelling, where molecular descriptors or fingerprints are mapped to a biological endpoint such as binding affinity or toxicity. Their comparative interpretability and modest data requirements make them attractive baselines, particularly in academic and resource-constrained settings, though their performance typically plateaus on complex, high-dimensional biological data relative to deep architectures.

Deep Learning, Graph Neural Networks and Transformers

Deep learning methods, and graph neural networks (GNNs) in particular, have become dominant in molecular property prediction because molecules are naturally represented as graphs of atoms and bonds. GNNs learn representations directly from this graph structure rather than from hand-engineered descriptors, improving performance on tasks such as drug–target interaction (DTI) prediction and multi-target polypharmacology modelling (Bi, Wang, Wang, & Liu, 2025). Transformer-based architectures, originally developed for natural language processing, have similarly been adapted to represent molecules as sequences (e.g., SMILES strings) or as sets of atomic tokens with attention mechanisms, enabling large pretrained chemical and protein language models that transfer well across downstream pharmacological tasks.

Generative and Reinforcement Learning Models

Generative models — variational autoencoders, generative adversarial networks, and diffusion models — are increasingly used for de novo molecular design, proposing novel chemical structures with desired property profiles rather than merely screening existing libraries. When combined with reinforcement learning, these systems can iteratively optimize generated molecules against multiple objectives simultaneously (potency, selectivity, synthetic accessibility, and predicted toxicity), a

capability particularly valuable for multi-target and polypharmacology-oriented drug design (Kleandrova, Cordeiro, & Speck-Planche, 2025).

Applications across the Drug Discovery and Development Pipeline

Target Identification and Validation

ML models trained on multi-omics data (genomics, transcriptomics, proteomics) are increasingly used to prioritize disease-relevant targets by integrating heterogeneous evidence — gene expression signatures, protein–protein interaction networks, and genetic association data — at a scale unattainable through manual literature review alone (Ocaña et al., 2025).

Virtual Screening and Hit Identification

AI-guided virtual screening methods, including deep docking and active learning strategies, allow libraries of billions of virtual compounds to be triaged computationally, substantially narrowing the set that proceeds to costly experimental validation. These approaches have shortened hit-identification timelines relative to purely empirical high-throughput screening, although benchmarking studies caution that reported performance gains can overstate real-world translational impact when validation sets are not sufficiently distinct from training data (Ferreira & Carneiro, 2025).

Lead Optimization and De Novo Molecular Design

Once a hit compound is identified, ML-guided lead optimization iteratively refines chemical structures to improve potency, selectivity, and drug-likeness while minimizing off-target liabilities. Multi-task and graph-based models are particularly well suited to this stage because multiple, sometimes competing, molecular properties must be balanced concurrently — a defining feature of multi-target drug discovery for complex diseases such as cancer and neurodegenerative disorders (Bi, Wang, Wang, & Liu, 2025).

ADMET and Toxicity Prediction

Absorption, distribution, metabolism, excretion, and toxicity (ADMET) properties are major determinants of late-stage clinical attrition. ML classifiers trained on curated toxicological and pharmacokinetic datasets can flag problematic candidates earlier in the pipeline, reducing the likelihood of costly late-stage failure and informing structural modifications before compounds advance to animal or human studies.

Drug Repurposing

By modelling drug–disease and drug–target relationships across large knowledge graphs, ML approaches can systematically surface candidates for repurposing existing, already-characterized drugs toward new indications — an approach that carries a comparatively favourable risk and cost profile because safety and pharmacokinetic data already exist. This strategy has been particularly emphasized in oncology and central nervous system disorders, where target networks are highly interconnected (Bi, Wang, Wang, & Liu, 2025).

Clinical Trial Design and Pharmacovigilance

Beyond discovery, ML is applied to patient stratification, trial site selection, adaptive trial design, and post-market pharmacovigilance, where models mine electronic health records and spontaneous adverse-event reports to detect safety signals earlier than traditional surveillance methods would allow.

The Explainability Imperative in AI-Driven Pharmacology

Why Interpretability Matters in Regulated Settings

Predictive accuracy alone is insufficient for pharmacological applications, where decisions affect patient safety and are subject to regulatory review. A model that recommends prioritizing one compound over another, or flags a possible adverse-event signal, must be able to justify that recommendation in terms clinicians, chemists, and regulators can evaluate. Explainable AI (XAI) methods aim to close this gap between predictive performance and human-interpretable reasoning (Abbas, Jeong, & Lee, 2025).

Common XAI Techniques

Model-agnostic post hoc methods such as SHAP (Shapley Additive Explanations) and LIME (Local Interpretable Model-agnostic Explanations) attribute a model's prediction to individual input features, allowing chemists to inspect which structural or clinical features drove a given output (Lundberg & Lee, 2017; Ribeiro, Singh, & Guestrin, 2016). In deep learning contexts, attention-weight visualization and gradient-based saliency methods serve a similar purpose for sequence- and graph-based models. More recently, physics-inspired explainability approaches have sought to ground model attributions in established pharmacological and molecular-recognition principles, improving the

mechanistic plausibility of explanations rather than relying solely on statistical correlation.

Regulatory Perspective

Regulatory bodies including the U.S. Food and Drug Administration and the European Medicines Agency have signalled increasing expectations around transparency and accountability for AI systems used in drug development and clinical decision support. This regulatory direction, together with clinician demand for trustworthy tools, is likely to make explainability a de facto requirement — rather than an optional enhancement — for AI systems seeking real-world pharmacological deployment.

Challenges and Limitations

Data Quality and Availability

Model performance is fundamentally constrained by the quality, completeness, and representativeness of available biological and chemical data. Public bioactivity databases are unevenly curated and often biased toward well-studied targets and chemical scaffolds, which can limit a model's ability to generalize to novel chemical space or underrepresented disease areas.

Generalizability and Benchmark Overfitting

Many reported performance gains are obtained under benchmarking conditions that do not fully reflect prospective, real-world use, where training and test compounds may share structural similarity that inflates apparent accuracy. Robust temporal and scaffold-split validation strategies remain underused relative to random data splits (Ferreira & Carneiro, 2025).

The Interpretability–Performance Trade-off

The most predictive architectures — deep neural networks, ensemble ensembles, and large pretrained models — are often the least inherently interpretable, while inherently transparent models (linear models, shallow decision trees) may sacrifice predictive power. Reconciling this trade-off, rather than treating interpretability as a purely post hoc add-on, remains an open methodological problem.

Regulatory, Ethical and Workforce Considerations

Beyond technical concerns, integrating AI into pharmacology raises questions of accountability when model-guided decisions contribute to adverse outcomes, the need for interdisciplinary training that bridges

computational and pharmaceutical expertise, and equitable access to these tools across research institutions with differing computational resources — a consideration particularly relevant for institutions in resource-constrained settings seeking to participate in AI-enabled pharmaceutical research.

Future Directions

Federated Learning for Multi-Institutional Collaboration

Federated learning allows multiple institutions to collaboratively train shared models without centralizing sensitive proprietary or patient-level data, offering a path to larger, more diverse training datasets while preserving data governance and privacy constraints that are otherwise a major barrier to pharmaceutical data sharing.

Foundation Models and Multimodal Integration

Large pretrained chemical and biological foundation models, capable of integrating molecular structure, omics, imaging, and clinical text within a shared representation space, are expected to increasingly underpin pharmacological AI pipelines, reducing the need for task-specific model development from scratch and improving performance on data-limited endpoints through transfer learning.

Physics-Informed and Mechanistic Explainability

Combining data-driven learning with physical and pharmacological priors — such as known binding thermodynamics or established structure–activity relationships — offers a promising route toward explanations that are not only statistically faithful to the model but also mechanistically meaningful to domain experts, addressing a key limitation of purely post hoc attribution methods.

CONCLUSION

AI and ML have moved from peripheral computational aids to central components of the modern drug discovery and pharmacology pipeline, contributing across target identification, virtual screening, lead optimization, toxicity prediction, repurposing, and clinical trial design. Realizing their full translational potential, however, depends less on incremental gains in predictive accuracy and more on addressing data quality, generalizability, and — critically — explainability, so that AI-derived recommendations can be trusted, audited, and

integrated into regulated pharmaceutical decision-making. Future progress is likely to be shaped by federated and privacy-preserving learning, multimodal foundation models, and mechanistically grounded explainability methods that bridge statistical prediction with pharmacological reasoning.

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