WHITEPAPER

AI/ML in Drug Discovery & Trials

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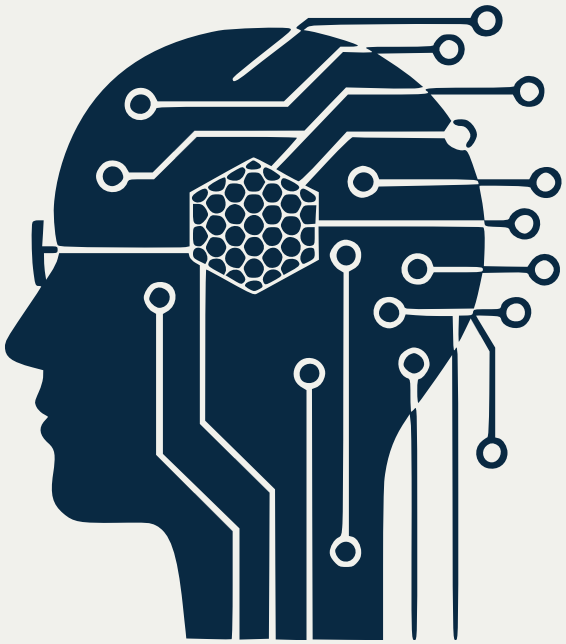
Mitigate Risk. Accelerate Success.

Summary

Artificial intelligence (AI) and machine learning (ML) are transitioning from experimental pilots to foundational capabilities across the pharmaceutical value chain, spanning target identification, de novo molecule design, preclinical optimization, clinical development, pharmacovigilance, and commercial decision-making. Building on decades of earlier computational chemistry, QSAR, and expert systems, the last ten years—especially the deep-learning and generative-AI era—have produced end-to-end platforms that can mine multimodal data, generate and prioritize novel compounds, simulate trials, and inform pricing, access, and field-force strategies at scale. At the same time, regulators and international bodies are articulating AI-specific ethical and governance frameworks, reframing AI from a "black box" curiosity to a regulated, high-impact technology that must be demonstrably safe, fair, and accountable wherever it touches patients or healthcare systems.

This white paper is structured to reflect the end-to-end connections across the value chain and to tie high-level trends to concrete examples. It covers how AI/ML are used in discovery, preclinical research, clinical trials commercialization, market access, and lifecycle management. It also covers cross-cutting challenges, ethical and regulatory requirements, and practical governance models that organizations must adopt to scale AI responsibly.

Together, the paper provides a coherent narrative: AI is already changing how molecules are conceived and brought to first-in-human; the next decade will determine whether those early accelerations translate into sustainably higher clinical and commercial success rates under robust ethical and regulatory guardrails.



Introduction

Pharmaceutical research and development remains constrained by a familiar triad of challenges: high attrition, long cycle times, and escalating costs, with estimates suggesting that it still takes roughly 10–15 years and more than 1 billion USD to bring a new drug from first hypothesis to market approval. Late-stage failures driven by suboptimal target selection, inadequate patient stratification, and unforeseen safety issues continue to erode R&D productivity, even as the volume of biological, clinical, and real-world data grows exponentially. Against this backdrop, artificial intelligence (AI) and machine learning (ML) have emerged not as isolated point solutions, but as a new computational layer woven across discovery, development, clinical trials, and commercialization.[1,2]

Although the recent wave of enthusiasm around deep learning and generative models dates from the mid-2010s, the roots of AI in pharmaceutical R&D stretch back several decades. In the 1960s and 1970s, early quantitative structure–activity relationship (QSAR) models and molecular mechanics methods introduced the idea that algorithms could predict biological activity and physicochemical properties from chemical structure. The 1980s and 1990s saw the rise of knowledge-based systems, which used rule-based reasoning to propose pharmacophores and guide medicinal chemistry, while late-1990s work began to pair high-throughput screening with rudimentary machine-learning classifiers. In the 2000s and early 2010s, bioinformatics, virtual screening, and more sophisticated ML algorithms were increasingly integrated into pipeline decision-making, setting the stage for today's deep learning, generative chemistry, and end-to-end AI-enabled platforms that span from target identification through clinical design.[2,3]

By **2025**, AI's role in pharmaceuticals had shifted from experimental curiosity to an operational reality in many large and mid-size companies. Legal and industry analyses indicate that up to 70 percent of life sciences organizations were already using AI in some aspect of R&D particularly in target identification, molecule design, drug repurposing, and clinical trial optimization marking a clear departure from purely traditional, manual paradigms. At the same time, 2025 was widely described as a "reality-check" year: the first AI-designed candidates delivered encouraging early-phase clinical data, but also revealed that AI has not yet solved the fundamental bottleneck of clinical success rates, with most AI-enabled assets still in early development and facing conventional regulatory and translational hurdles. Regulatory bodies responded by issuing draft guidance on AI and ML in drug development and clinical trials, signaling that AI is now treated as a mainstream technology that must be governed rather than an experimental add-on. AI is now embedded in many discovery and development workflows, is beginning to permeate clinical trial operations and pharmacovigilance, and is gaining traction in market access and commercial analytics, yet maturity and impact vary markedly across organizations and use-cases.[1,2,3]

This qualitative shift is mirrored by rapid quantitative growth in global AI spending in pharma. Market research estimates that the global AI in pharmaceutical market covering applications from discovery to commercial operations was valued at approximately 1.94 billion USD in 2025 and is projected to grow to around 2.51 billion USD in 2026, reaching 16.49 billion USD by 2034 at a compound annual growth rate (CAGR) of about 27 percent from 2025 to 2034. [1,3]

AI/ML in Drug Discovery

Target Identification and Validation

Target identification for New Chemical Entities (NCEs) and their validation is traditionally a long and extreme task due to lack of knowledge on their off-targets such as enzymes, ion channels, proteins, or receptors. Machine learning models enable integrative analysis of genomic, transcriptomic, proteomic, and phenotypic data to prioritize disease-relevant targets. Platforms, which identify novel targets and construct disease models for complex conditions have been designed. Deep learning and network-based approaches can infer causal pathways, predict gene–disease associations, and highlight potential off-targets or safety liabilities early in the pipeline.[4]

Virtual Screening and HIT to Lead

After target identification high through virtual screening (HTVS) and molecular docking techniques embedded in free energy perturbations, sampling, and scoring algorithms takes place. Deep learning models for quantitative structure–activity relationships (QSAR), molecular fingerprints, and protein–ligand interaction prediction have significantly expanded the scale and accuracy of virtual screening. applications where deep neural networks and other ML methods improve hit rates in virtual screens and prioritize compounds for experimental testing, reducing the need for physical screening process have been developed. [5]

De-novo molecule design and optimization

Reinforcement learning, generative adversarial networks (GANs), and variational autoencoders (VAEs) are used to design novel compounds optimized for potency, selectivity, and developability properties. Reinforcement learning has been applied to generate small molecules that inhibit specific targets, while transfer and multitask learning approaches refine these models on task-specific datasets. AI-driven generative chemistry and physics-informed models have been deployed to explore chemical space efficiently for small molecules and other modalities.[6]

ADME/Tox prediction and Safety Assessment

AI/ML models predict absorption, distribution, metabolism, excretion, and toxicity (ADME/Tox) using physicochemical descriptors, in vitro data, and preclinical observations. Deep learning approaches for toxicity prediction, have shown high accuracy in predicting various toxicity endpoints compared with traditional QSAR methods. ML-based safety models also contribute to predicting drug–drug interactions and idiosyncratic adverse events by integrating data from pharmacovigilance databases and literature mining.[7]

Cross-functional Impact in Pre-clinical Research

AI is reshaping preclinical drug research offering to help selection of traditional animal models and innovative alternatives to traditional animal testing. Advanced techniques, including machine learning (ML), deep learning (DL), AI-powered digital twins (DTs), and AI-enhanced organ-on-a-chip (OoC) platforms, enable precise simulations of complex biological systems and align with the 3Rs principle (Replace, Reduce, Refine). [8]

AI/ML in Clinical Trials

Trial Design and Protocol Optimization

AI tools enable in silico trial simulations using RWD and historical trial datasets to optimize inclusion/exclusion criteria, endpoint selection, and sample size. Such simulations can reduce protocol amendments and improve the feasibility of recruitment and follow-up, particularly in rare diseases and complex oncology trials. These approaches complement initiatives in decentralized and hybrid trials, where AI helps define viable combinations of telemedicine, home visits, and site-based assessments.[9]

Patient Recruitement and Site Selection

Patient recruitment remains a major cause of delay, with some analyses indicating that more than 80 percent of trials fail to meet initial enrollment timelines. AI-driven platforms mine EHRs, claims, registries, and patient-reported data to match eligible participants to trials, often using NLP to extract eligibility criteria from unstructured notes. Recruitment platforms use ML to generate trial-specific prescreeners, forecast site performance, and guide outreach strategies to improve match quality and reduce site burden.[10]

Operational Forecasting and Risk-based Monitoring

ML models forecast site activation and patient enrollment trajectories using real-time operational data and historical benchmarks, supporting proactive mitigation planning. AI is used to detect anomalies in operational metrics, enabling earlier identification of underperforming sites or data-quality issues. These tools underpin risk-based quality management by prioritizing monitoring activities based on predicted risk rather than fixed schedules.[11]

Data Quality, Endpoint Measurement and Digital Health

AI is increasingly used to process high-frequency data from wearables, sensors, and digital endpoints in decentralized clinical trials. ML algorithms can denoise signals, impute missing data, and derive clinically meaningful digital biomarkers, expanding the range of endpoints beyond conventional laboratory and clinician-reported measures. Computer vision and digital pathology tools support centralized, standardized review of imaging and histology, reducing inter-reader variability.[9]

Patient Experience, Adherence and Retention

Conversational agents and AI-powered “trial navigators” assist participants with appointment reminders, protocol-specific FAQs, and symptom reporting, contributing to improved adherence and retention. Personalized engagement strategies driven by ML models can identify participants at risk of dropout and trigger targeted interventions, which is especially valuable in long-duration and decentralized studies. By tailoring communication to demographics and language preferences, AI tools can also support more inclusive and diverse recruitment.[10]

AI/ML in Commercialization, Market Access and Lifestyle Management

Market Access, Pricing and Reimbursement

AI adoption in pricing, reimbursement, and market access (PRMA) has lagged behind R&D but is accelerating as companies recognize its potential to handle complex, multi-factor decisions. Advanced ML models integrate clinical trial results, RWD outcomes, competitor pricing, payer policies, and macroeconomic indicators to recommend launch prices and discount strategies that balance access and profitability. Reports suggest that pharmaceutical firms using AI-driven pricing optimization achieve more accurate price predictions and substantially improved tender win rates compared with traditional methods.[12]

Commercial Analytics, Segmentation and Omnichannel Engagement

ML-based customer analytics identify high-value physician segments, patient populations, and institutions by analyzing prescribing behavior, demographics, and interaction history. AI systems power next-best-action engines that orchestrate omnichannel engagement across field force, digital, and remote channels based on predicted responsiveness. These capabilities enable more efficient resource allocation and more personalized information delivery to healthcare professionals and patients.[13]

Supply Chain, Manufacturing and Pharmacovigilance

Beyond R&D and commercialization, AI tools are being deployed for demand forecasting, inventory optimization, and anomaly detection in manufacturing. In pharmacovigilance, NLP and ML models screen spontaneous reports, literature, and social media for safety signals, helping prioritize cases for human review and supporting regulatory reporting requirements.[4,15]

Post Manufacturing Effectiveness and Value Demonstration

AI techniques link RWD with trial data to quantify real-world effectiveness, adherence, and healthcare resource utilization, supporting health technology assessment and value-based contracting. ML-enhanced pharmacoeconomic modeling can simulate outcomes under different treatment and contracting scenarios, helping to design risk-sharing and outcomes-based agreements. These approaches are increasingly important as payers demand evidence of value across diverse patient subgroups and healthcare systems.[12]

Challenges and Limitations

Data Quality, Interoperability and Representativeness

The performance of AI models depends critically on data completeness, consistency, and quality, yet biomedical data are often fragmented across institutions, formats, and jurisdictions. Biases in underlying data for example, under-representation of certain demographic groups or geographies can lead to models that perform poorly or unfairly in those populations. Interoperability challenges between EHR systems, clinical trial databases, and registries complicate efforts to build integrated datasets suitable for model training.[15,16]

Model Transperancy, Explainability and Validation

Complex deep learning models can exhibit “black-box” behavior, making it difficult for clinicians, regulators, and payers to understand how predictions are generated. Reviews emphasize the importance of interpretable machine learning and robust external validation to build trust in AI-generated evidence. Regulatory guidance increasingly expects clear documentation of data provenance, model assumptions, performance metrics, and limitations across diverse subgroups.[17]

Integration into Workflows and Change Management

Even high-performing AI tools can fail to deliver value if they are not integrated into clinical, operational, and commercial workflows in a usable way. Successful implementations typically combine ML outputs with human expertise and establish clear governance around who acts on which signals, under what conditions. Change management, training, and user-centered design are therefore as important as algorithmic performance in realizing benefits.[11]

Ethical and Regulatory Considerations

Bias, Fairness, and Equity

Bias in training data can lead to AI systems that systematically underperform for certain groups, potentially exacerbating health disparities if deployed uncritically. Ethical discussions therefore emphasize diverse and representative datasets, fairness-aware model development, and ongoing performance monitoring across demographic subgroups. In the pharmaceutical context, this is particularly relevant to trial recruitment algorithms and treatment-response prediction models that may influence who gains access to innovative therapies.[15]

Ethics Review, Oversight, and Stakeholder Engagement

Guidelines such as those issued by national councils for medical research call for dedicated ethics review processes for AI studies, including examination of data governance, algorithmic fairness, and downstream impacts. These documents recommend multi-stakeholder oversight structures involving developers, clinicians, ethicists, regulators, and patient representatives to anticipate and manage ethical risks over the lifecycle of AI tools. The emphasis is on continuous governance, recognizing that AI models evolve over time as they are updated or retrained.[16]

High-level Ethical Principles and Risk-based Governance

Ethical frameworks for AI in biomedical research and healthcare emphasize principles such as autonomy, beneficence, non-maleficence, and justice, adapted to the context of data-driven technologies. National and international bodies advocate a risk-based approach to regulating AI, where higher-risk applications are subject to more stringent controls than lower-risk tools. This stratification aims to balance innovation with patient safety by tailoring oversight to the potential for harm.[17]

Transparency, Accountability, and Liability

Legal and ethical analyses highlight the need for clear allocation of responsibility among developers, sponsors, healthcare providers, and institutions when AI is used in healthcare and pharma. Proposals include risk-based regulation, mandatory insurance for AI developers and users, and no-fault compensation schemes to ensure patients harmed by AI-mediated decisions receive timely remediation. Transparent documentation, audit trails, and mechanisms for human override are key to enabling accountability and addressing errors.[16]

Data Protection, Privacy, and Consent

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Case Studies

EXS-21546 (A2A immuno-oncology)
by - Exscientia / Evotec

What the AI did: EXS-21546 is an A2A receptor antagonist discovered using Exscientia's AI-driven design platform, with explicit design objectives around potency, very high selectivity, and low CNS exposure. The platform iteratively proposed and prioritized compounds, with only 163 synthesized and tested in total.

Stage reached: Exscientia and Evotec report that EXS-21546 completed a Phase 1a healthy-volunteer study and is now being studied in the IGNITE-AI Phase 1/2 trial in patients with advanced solid tumours (RCC, NSCLC and potentially others), combining the A2A antagonist with anti-PD-1 therapy.

Timeline: The candidate molecule was discovered within 8–9 months of project initiation as compared to a typical exploratory research phase of ~4.5 years, suggesting a ≈3.5-year reduction just in the discovery stage, although total time from project start to ongoing Phase 1/2 has not been fully quantified publicly. [18,19]

INS018_055 / ISM001_055 (IPF)
by- Insilico Medicine

What the AI did: Insilico's end-to-end Pharma.AI platform used its PandaOmics engine to identify a novel anti-fibrotic target for IPF and Chemistry42 to design a first-in-class small molecule inhibitor (INS018_055). AI was used both for target identification and de novo design/optimization of the molecule.

Stage reached:
Phase 1: A randomized, double-blind Phase 1 trial in healthy volunteers in New Zealand ran through 2022 and showed favourable safety and PK, with topline data announced in January 2023.
Phase 2: By mid-2023, a Phase 2 trial in IPF patients (multiregional, US and China) had dosed its first patients, evaluating safety, PK and preliminary efficacy over 12 weeks.

Timeline: The project reached preclinical candidate nomination 18 months after initiation and first-in-human Phase 1 less than 9 months after that, i.e. under 30 months from target discovery to Phase 1, which they explicitly state is "about half the time" of a traditional path.
In the same materials they benchmark traditional preclinical programs as taking 3–6 years and hundreds of millions of dollars, underscoring that AI cut the time to a Phase-1-ready asset by roughly 2–3 years and at markedly lower cost. [20,21]

Emerging AI/ML Platforms

Discovery and Preclinical Platforms

BenevolentAI – AI-driven knowledge graph and target discovery platform, with collaborations such as its multi-year partnership with AstraZeneca in chronic kidney disease and idiopathic pulmonary fibrosis.[22]

CytoReason – Cell-centric disease modeling platform that builds mechanistic models of the immune system, used by Pfizer and others to prioritize targets and indications.[23]

Recursion (building on technology originated at Exscientia) – Uses high-content imaging and phenomics with ML to map relationships between genes, compounds, and phenotypes for small-molecule discovery.[24]

Genetic Leap – Focuses on RNA-based therapeutics and uses AI to design and optimize RNA drugs in collaboration with companies such as Eli Lilly.[25]

Aqemia – Combines AI with physics-based models to predict molecular interactions and accelerate lead optimization, including partnerships with Sanofi. [26]

Clinical Trial Platforms

TrialX – Provides AI-powered trial search, matching, and patient-navigation tools that integrate with health records and registry data to personalize recruitment and support participants through trials. [10]

AI-driven recruitment analytics platforms – Various providers use ML and NLP to screen EHRs and other data sources, predict site enrollment potential, and automate prescreening workflows.[11]

CRO-embedded AI solutions – Large CROs have developed in-house AI capabilities for risk-based monitoring, protocol optimization, and enrollment forecasting to improve trial efficiency. [11]

Disclaimer: Aventiq Bio is not associated with any of the above platforms in any manner.

Strategic Implications and Best Practices

Building AI-ready Data and Technology Foundations

Pharmaceutical organizations seeking to scale AI must invest in data platforms that unify clinical, commercial, and operational data under consistent governance and interoperability standards. Modern architectures incorporate secure data lakes, standardized ontologies, and tools for data quality assurance to support ML development at scale. Partnerships with AI-native firms and cloud providers can accelerate access to cutting-edge methods while internal teams build domain-specific capabilities.

Human-in-the-loop Design and Multidisciplinary Teams

Effective pharmaceutical AI initiatives typically combine data scientists, clinicians, trialists, commercial strategists, ethicists, and regulatory experts. Human-in-the-loop designs ensure that ML outputs inform but do not fully automate high-stakes decisions, preserving clinical judgment and contextual understanding. Such approaches also facilitate explainability, as domain experts can interrogate model outputs and challenge unexpected recommendations.

Governance, Compliance, and Lifecycle Management

Robust AI governance frameworks define roles, responsibilities, and processes for model development, validation, deployment, and monitoring. Best practices include version control, performance tracking, documentation of training data and assumptions, and procedures for model retirement or retraining when performance drifts. Embedding these practices within existing quality systems helps align AI initiatives with regulatory expectations.

Measuring Value and Scaling What Works

Organizations should establish clear metrics for AI initiatives such as cycle-time reduction, increased hit rates, improved enrollment, or commercial lift and rigorously evaluate outcomes. Successful pilots can then be standardized and scaled, while less effective approaches are iterated or sunset. Continuous learning across programs and geographies is essential given the rapid pace of methodological and regulatory change in pharmaceutical AI.

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