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Review Article

Global Introduction of Artificial Intelligence in the Pharmaceutical Industry

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ABSTRACT

Artificial intelligence (AI) is increasingly transforming all phases of the pharmaceutical product lifecycle. AI and machine learning (ML) tools can handle vast biomedical datasets—far beyond human capacity—and have shown promise in accelerating drug discovery, optimizing clinical trials, improving manufacturing and supply chains, and enhancing safety monitoring and regulatory processes. For example, traditional drug R&D is extremely costly and time-consuming (typically >10 years and ≈US$2.8 billion per new drug), but AI-driven methods (deep learning, predictive models) can rapidly screen libraries and predict ADMET properties, significantly shortening discovery timelines. In clinical development, AI-based platforms are reported to reduce patient recruitment from months to days and enable adaptive trial designs by continuously analyzing trial data. In manufacturing and logistics, AI (digital twins, predictive analytics) optimizes yields and inventory—for instance, Pfizer used AI to boost COVID-vaccine production yield and reduce downtime, while 40% of firms now use AI for demand forecasting and cold-chain monitoring. AI also automates pharmacovigilance by mining electronic health records, literature, and social media for adverse event signals, greatly speeding safety surveillance. Regulators (FDA, EMA) are responding with guidance on AI in submissions and product development. However, adoption faces hurdles: data quality and integration, model interpretability ("black box" issues), ethical/privacy concerns, and evolving regulations. This review surveys the global landscape of AI in pharma, covering drug discovery, clinical trials, manufacturing/supply chain, pharmacovigilance, regulatory affairs, and future prospects.

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We highlight credible examples and sources from industry reports and peer-reviewed literature to provide a comprehensive, professional overview suitable for pharmacy professionals.

INTRODUCTION

AI and its Relevance to Pharma

Artificial intelligence (AI) refers to computational systems that perform tasks normally requiring human intelligence, such as pattern recognition, learning, and problem-solving. In practice, AI in pharma includes subfields like machine learning (ML) and deep learning (DL), which build models that "learn" from data to make predictions or decisions. Over the past decade, the pharmaceutical sector has seen an explosive growth in data (genomic sequences, high-throughput screening results, electronic health records, etc.). This data deluge drives the need for AI: sophisticated algorithms can automatically analyze vast, complex datasets in ways that manual methods cannot [13]. Industry analysts observe that "artificial intelligence (AI) has revolutionized many aspects of the pharmaceutical industry" and is being applied "ranging from drug discovery to product management" [14]. In other words, AI tools are poised to improve efficiency across the entire drug lifecycle. For example, automation of data analysis can reduce the time and cost of research, improve decision-support for clinicians and researchers, and enable new insights (such as discovering hidden patterns in omics data) that would otherwise remain inaccessible. Pharmacy professionals should recognize that AI systems *augment* human expertise rather than replace it. Modern AI techniques (neural networks, natural language processing, etc.) excel at tasks like image analysis, complex pattern recognition, and handling unstructured text (e.g. clinical notes). In pharma settings, this means AI can quickly sift through literature, regulatory documents, and patient records to extract relevant information, or analyze chemical structures to predict drug behavior. The McKinsey Global Institute even predicts that advanced AI (particularly generative AI) could add on the order of $60–110 billion per year in value to the life sciences and pharmaceutical industries by accelerating compound identification and development processes [15]. In sum, AI is now seen as a strategic imperative in pharma: companies and regulators are investing heavily to harness machine intelligence to improve safety, efficacy, and productivity in drug development and delivery [14] [15].

AI in Drug Discovery and Development

Traditional drug discovery is notoriously long, expensive, and risky. On average it can take >10 years and nearly US $3 billion to bring a new drug through discovery, preclinical testing, and clinical trials, and about 90% of candidates fail during development [1]. AI and ML are being applied at every stage to improve this. For virtual screening, machine learning classifiers (random forests, neural networks, etc.) can rapidly evaluate large chemical libraries to predict which compounds are likely to bind a target and have desirable activity [1] [16]. AI models trained on historical ADMET (absorption, distribution, metabolism, excretion, toxicity) data can also predict pharmacokinetic properties in silico, reducing the need for extensive lab assays. In fact, a 2012 industry challenge found that deep learning models significantly outperformed traditional QSAR methods on 15 ADMET datasets from Merck [17]. In short, AI streamlines hit identification and lead optimization by filtering out low-potential molecules early. Major pharma companies have pursued this: for instance, Bayer, Roche, and Pfizer have formed AI partnerships to build platforms for target and lead discovery in fields like oncology and cardiovascular disease [1].

- **Virtual screening and activity prediction:** Algorithms (including deep neural networks) learn from known drug–target interactions to rank new compounds by predicted activity. This can eliminate vast numbers of non-leads at negligible cost [1]. AI-driven screening engines (often using 2D/3D molecular descriptors or graph neural nets) are replacing or augmenting traditional docking.

- **Physicochemical and ADMET modeling:** ML models predict solubility, permeability, toxicity, etc., from chemical structure. For example, neural-network–based QSAR tools have been used to predict lipophilicity and solubility [17], and graph-convolution networks can infer metabolic stability. Such predictions guide chemists to optimize compounds before synthesis.

- **De novo molecular design:** Generative AI techniques (e.g. deep generative models, reinforcement learning, or GANs) can propose novel chemical structures with desired properties. These tools essentially "invent" new drug-like molecules by learning the language of chemical structures. While still emerging, several startups report AI-designed leads entering preclinical pipelines.

- **Target identification and repurposing:** AI analyzes genomic, proteomic, and literature data to suggest new drug targets or identify existing drugs that might be repurposed for other diseases. Integrative platforms can scan disease signatures and drug effects to find novel indications. (No single source listed here, but this is a known trend.)

- **Protein structure prediction:** Deep learning has revolutionized structural biology. DeepMind's AlphaFold uses neural networks to predict protein 3D structures from sequence with unprecedented accuracy [2]. This breakthrough enables structure-based drug design for many targets that previously lacked known structures, accelerating rational lead optimization.

- **Case studies:** Leading examples illustrate AI's impact. *DeepMind's AlphaFold* completed the structures for tens of thousands of proteins, a task that used to take years [2]. *Recursion Pharmaceuticals* uses a massive ML platform (with petabytes of bioimages and -omics data) to screen drugs for rare diseases in parallel. Insilico Medicine reported designing a novel candidate for idiopathic pulmonary fibrosis using AI in ~18 months (versus typical 4–5 years. These cases show that AI-driven discovery can identify promising drug candidates much faster than traditional pipelines.

Overall, AI does not replace medicinal chemistry or biology but provides powerful computational "heads" that sift through enormous chemical and biological spaces. By focusing experimental work on a smaller set of high-probability leads, AI can reduce costs and timelines. Recent surveys and reviews conclude that integrating AI into discovery workflows is leading to significant productivity gains [1][2].

AI in Clinical Trials

AI is also transforming clinical development. Historically, clinical trials suffer from high costs and delays, especially due to slow patient recruitment and complex protocol management. AI applications are addressing these issues at multiple levels:

- **Patient recruitment and matching:** One of the most common uses of AI is mining electronic health records (EHR) and databases

to find patients meeting trial criteria. Natural language processing (NLP) can extract key clinical features from physician notes, lab results, and genomics. For instance, the BEKHealth platform uses AI/NLP to analyze EHR data and identify eligible patients approximately three times faster than manual review. In general, industry reports find that patient recruitment cycles that once took months can now be shortened to days with AI support [3]. This dramatically improves enrollment efficiency; one analysis noted 80% of AI startups in clinical development focus on automating recruitment and site feasibility [3].

- **Trial design and optimization:** AI can help design more efficient protocols. Machine-learning models simulate different trial scenarios to optimize inclusion/exclusion criteria and dosage arms. AI-driven adaptive trial systems use accumulating data to adjust protocols in real time, improving success probability. Over half of current AI vendors for clinical trials offer tools for protocol optimization, enabling continuous refinement as new data emerge [4]. For example, AI analytics can predict likely dropout rates or adverse events given certain designs, helping sponsors choose robust parameters.

- **Remote monitoring and decentralized trials:** Especially after the COVID-19 pandemic, virtual trials have grown. AI supports decentralized trials by analyzing wearable sensor data, patient-reported outcomes, and telemedicine video logs for real-time safety monitoring. About 40% of AI innovators in trials are focusing on decentralized or real-world evidence use cases. In practice, AI can flag anomalies in daily vital signs remotely or identify patterns of non-compliance, reducing the need for in-clinic visits while maintaining data integrity.

- **Data management and analysis:** Clinical trials generate complex datasets (imaging, labs, digital biomarkers). AI tools streamline data curation: NLP automates case report form population, and ML algorithms detect data entry errors or outliers more quickly. AI also assists with endpoint analysis, such as image recognition for radiological outcomes or wearable gait analysis. These capabilities can speed up data lock and statistical review.

Overall, AI in trials is reported to significantly cut timelines and costs. The American Hospital Association notes that "patient recruitment cycles that used to span months are shrinking to days" with AI [3]. By enabling smarter recruitment, adaptive designs, and remote data collection, AI helps make trials more patient-centered and efficient. As one report states, generative AI and ML "revamp the way companies operate" in clinical development and promise "billions of dollars in value" through accelerated discovery and development [15][3].

AI in Pharmaceutical Manufacturing and Supply Chain

AI-driven automation and analytics are key elements of Industry 4.0 in pharma. In manufacturing, AI techniques optimize production processes for consistency, quality, and flexibility. Likewise, AI augments the supply chain by improving forecasting, logistics, and traceability. Key applications include:

- **Process optimization:** Machine learning analyzes production-line data (temperatures, mixing rates, sensor spectra) to fine-tune process parameters in real time. This can increase yield, reduce waste, and ensure batch

consistency. For example, Pfizer reported using AI in its COVID-19 vaccine plants to improve yield and reduce production time [5]. AI algorithms can also control advanced technologies like real-time spectroscopic PAT (Process Analytical Technology) to maintain optimal conditions. Overall, manufacturers apply AI-based quality control (e.g. computer vision for defect detection) and predictive modeling to optimize every step from raw material handling to final packaging.

- **Predictive maintenance:** Equipment downtime is costly. AI models trained on equipment sensor data can forecast failures before they occur. A 2023 review notes that Pfizer has implemented AI-based predictive maintenance in its facilities, substantially reducing unexpected breakdowns and maintenance costs [6]. Broadly, any continuous manufacturing line or filling machine can be monitored by AI to schedule upkeep optimally. This keeps plants running smoothly and prevents supply interruptions.

- **Digital twins:** A "digital twin" is a virtual replica of a manufacturing process. It allows companies to simulate and test changes without disrupting actual operations. Johnson & Johnson, for example, uses digital twin technology to mirror its production lines: testing a process in one virtual factory and then deploying optimized parameters to another site. Such digital models help scale production and transfer processes between sites quickly. In future, integrating digital twins with AI could enable end-to-end "closed-loop" manufacturing where the system continuously self-optimizes.

- **Supply chain forecasting and inventory management:** AI-powered analytics greatly improve demand forecasting by learning from complex market trends, prescription data, and seasonal factors. According to a 2024 industry survey, 40% of life-sciences supply chain leaders are prioritizing AI for demand forecasting and inventory optimization [7]. By anticipating needs more accurately, companies minimize stockouts and reduce waste (especially important for costly biologics and vaccines). AI also monitors logistics: for example, 69% of surveyed firms use AI-driven alerts to maintain cold-chain conditions (constant temperature) for sensitive products [7]. This real-time visibility ensures product integrity during transport and storage.

- **Procurement and procurement optimization:** AI can recommend optimal purchasing decisions. Novartis developed an AI "Buying Engine" to centralize procurement of lab supplies and equipment, leveraging algorithms (knowledge representation, recommender systems) to suggest best purchasing options in near real-time. This system improves transparency, reduces costs, and speeds up supply acquisition. Similar tools are emerging across pharma supply chains to optimize orders of APIs (active ingredients) and PPE.

In summary, industry reports emphasize that AI is now a "central component" in life-sciences supply chains and manufacturing, driving efficiency and resilience. Over half of surveyed companies expect a return on investment from AI initiatives within 2–3 years. However, realizing this potential requires high-quality data across the network; currently only a minority of partners have AI processes, so integrating partners into a digital ecosystem is a key challenge. When implemented, AI in manufacturing and logistics can greatly shorten time-to-market and increase agility in responding to disruptions.

AI in Pharmacovigilance and Safety Monitoring

Pharmacovigilance (PV) – the monitoring of drug safety after marketing – is critical but data-intensive. Traditional PV relies on voluntary reports (FAERS, EudraVigilance, etc.) and periodic literature reviews, which are laborious and suffer from underreporting and delays. AI can greatly enhance pharmacovigilance by automating detection of adverse drug reactions (ADRs) and safety signals from diverse sources:

- **Natural language processing (NLP):** NLP algorithms can read unstructured text (medical charts, patient forums, case reports) and extract relevant ADR information. For example, Bayer's NLP-based system processes physicians' case-report narratives into standardized medical codes with ~96% accuracy. This kind of tool dramatically speeds up case intake and coding, reducing manual workload. Academic reviews note that integrating NLP into PV can extract patient data from EHRs and literature with high efficiency [8].

- **Signal detection and data mining:** Machine learning models can scan large databases of reports for patterns. Unsupervised or statistical learning techniques identify drug-event associations that rise above background noise. These systems can flag novel ADRs earlier than conventional methods. Studies indicate that AI can identify known ADRs more quickly and accurately than rule-based surveillance [8]. AI is also used to analyze "big data" sources: claims databases, biomedical literature (via text mining), and even social media posts can be automatically monitored for emerging safety concerns. This broadens the net for capturing patient experiences.

- **Automation and case triage:** AI-driven workflows can prioritize the most serious or novel cases for human review. For instance, machine learning classifiers can rank incoming reports by severity or likelihood of causality, helping PV teams focus resources. AI chatbots or voice recognition can even automate data entry from patient interviews.

- **Continuous updating of knowledge:** ML can continuously learn from newly labeled safety data, refining its detection algorithms over time. This creates "learning pharmacovigilance" systems that adapt to changing use patterns or new drugs.

Researchers report that AI's integration into PV "can improve efficiency and accuracy of detecting ADRs". For example, Cureus (2025) notes that ML algorithms detect ADRs "more quickly and accurately compared to traditional PV methods". Industry also acknowledges these advantages: the manual review of disparate PV data sources is "inefficient and leads to underreported ADRs", whereas NLP/ML can greatly reduce this burden [8]. However, AI in PV brings challenges. Patient data privacy and ethical use are paramount: models must comply with HIPAA/GDPR and avoid identifiable information leaks. AI models can also inherit biases from incomplete reporting (certain populations may be underrepresented), so validation and human oversight remain necessary. The Cureus review cautions that "limitations [of AI in PV] include ethical, legal, and privacy concerns; interpretative limitations if certain datasets are incomplete... and the need for more research" [12]. In summary, AI offers powerful enhancements to drug safety monitoring, but careful governance and transparency are required.

AI in Regulatory Affairs

Regulatory affairs is a newer but rapidly growing area for AI. Both companies and agencies are leveraging AI to streamline regulatory processes and data analysis:

- **Guidance and frameworks:** Regulatory bodies are issuing guidance on AI use. In January 2025, the U.S. FDA published draft guidance titled *"Considerations for the Use of AI To Support Regulatory Decision-Making for Drug and Biological Products"* [9]. This draft outlines a *risk-based credibility assessment* framework: essentially, it recommends that submissions involving AI-generated data (e.g. modeling results, decision-support) should be evaluated based on the intended use (context) and robustness of the AI. The goal is to ensure that data produced by AI (for safety, efficacy, or quality) are reliable and valid for regulatory review.

- **EMA initiatives:** The European Medicines Agency (EMA) similarly is embedding AI into its strategic plan. An EMA *reflection paper* on AI in the medicinal product lifecycle was published in 2024[10] (adopted by EMA's scientific committees in Sep 2024). This document provides considerations for medicine developers on using AI/ML safely and effectively at various stages (discovery, development, pharmacovigilance, etc.). The EMA emphasizes that leveraging AI and big data can improve regulatory decision-making on drug safety and efficacy. The EU is also exploring AI observatories and guidelines (e.g., for large language models) to ensure regulators themselves can use AI responsibly.

- **Submission automation:** On the industry side, companies are piloting AI to streamline dossier preparation. For instance, natural language generation tools can draft sections of the Common Technical Document (CTD) by summarizing clinical study results from databases (though this is an emerging practice without formal guidance yet). AI-based compliance checkers can verify that labeling and documentation follow regulatory standards. While not yet mainstream, these applications illustrate the "digitalization" of regulatory work.

In short, regulatory affairs is becoming data-driven. Agencies are advocating transparent, validated AI tools in both submissions and in-house review. For example, the FDA and EMA now recognize that AI can handle "large volumes of regulatory and health data" to speed up decision-making on high-quality medicines. However, they stress that human oversight and risk controls must remain in place. The global regulatory landscape for AI is still evolving, so pharma companies must stay aligned with guidance and be prepared to explain AI methodologies when interacting with agencies [9] [10].

Challenges and Limitations of AI in Pharma

Despite its potential, AI adoption in pharma faces significant hurdles:

- **Data availability and quality:** AI models require large, high-quality datasets for training. In pharma, relevant data are often siloed (across CROs, hospitals, and systems) and may have issues like missing values or inconsistent formatting. For example, supply-chain partners frequently struggle with "fragmented systems" and lack of real-time data, limiting AI's full impact. In drug discovery, many compounds lack sufficient labeled data to train robust models, and clinical data can be proprietary. Ensuring data provenance and cleaning is a major challenge.

- **Integration and interoperability:** Linking disparate data sources (R&D, manufacturing, patient data) across organizations is complex. Industries report that a key barrier to an AI-driven supply chain is getting end-to-end data sharing across partners. Similarly, in PV, EHR data from different hospitals use varied coding, making NLP more difficult. Without standardized data infrastructures, many AI initiatives remain proof-of-concept.

- **Model interpretability ("black box"):** Many powerful AI algorithms (especially deep neural networks) are opaque in how they make decisions. This "black box" nature raises trust issues: regulators and scientists often need to understand *why* a model gives a certain output (e.g. flagging an adverse event). The complexity of some models can make it hard to rationalize their recommendations. As one review notes, stakeholders remain "skeptical about the data generated by AI" and concerned about interpretability [11]. Explainable AI (XAI) methods are an active area of research, but currently explainability constraints can limit regulatory acceptance.

- **Expertise and cost:** There is a shortage of professionals trained in both AI and life sciences. Companies (especially smaller ones) may lack in-house data scientists or ML engineers to develop and maintain AI systems. A survey noted that "limited budget for small organizations" and "lack of skilled personnel" are barriers to AI adoption in pharma [11]. Developing AI solutions can also require significant investment (data platforms, computing resources). The industry has invested billions in AI deals, but not all organizations have those resources.

- **Regulatory and ethical concerns:** Using AI with clinical or patient data raises privacy and compliance issues (HIPAA/GDPR). Ethical considerations include algorithmic bias (for example, under-representation of certain groups can lead to biased predictions) and transparency about AI use. The pharmacovigilance literature explicitly lists "ethical, legal, and privacy concerns" among the limitations to AI in PV [12]. Moreover, the regulatory framework around AI is still maturing, so companies must carefully validate their models and be prepared to answer questions about data sources, training, and safeguards.

- **Change management and culture:** Finally, human factors play a role. There is often resistance to new technology: pharma personnel may distrust AI recommendations or fear job displacement [11]. Clear communication that AI is an assistive tool (not a replacement) is needed. Training programs are required to upskill staff. Successful AI integration tends to fail not for technical reasons but due to lack of organizational alignment and planning. Change management is critical.

In summary, AI offers huge promise, but realizing it requires overcoming practical challenges in data, regulation, and adoption. These limitations must be actively managed through robust data governance, explainable model design, multi-disciplinary teams, and close dialogue with regulators [11] [12].

FUTURE PROSPECTS

AI's role in pharma is expected to grow even deeper and broader. In the near future, we anticipate several key trends:

- **Generative AI and advanced modeling:** Generative AI (large language models, diffusion models, etc.) will play an expanding role. McKinsey projects that generative AI is "transforming nearly all aspects of the pharmaceutical industry" and could unlock on the order of \$60–110 billion per year by accelerating discovery, development, and marketing [15]. We already see this in early research co-pilots that draft reports, design molecules, or summarize literature. As these models become more specialized for pharma, they will enable tasks like generating novel compound libraries tailored to a new target, or rapidly generating clinical study reports from raw data.

- **Personalized and precision medicine:** AI will drive more individualized therapies. By integrating genomics, proteomics, metabolomics, and real-world patient data, AI models can identify which patients are most likely to benefit from or be harmed by a drug. For example, McKinsey notes that insights from vast patient datasets will spark "more personalized treatments and improved patient outcomes". In practice, this could mean AI algorithms that predict optimal dosages for an individual patient (pharmacogenomics) or that dynamically adjust treatment plans. Digital twins of patients (computational models of an individual's physiology) are an emerging concept that would allow in silico testing of drug responses.

- **End-to-end integration and automation:** We expect AI to increasingly connect across silos. "Closed-loop" pharmaceutical development pipelines are envisioned, where AI systems continuously analyze outcomes and feed that back into R&D. For example, data from post-marketing use (collected via IoT-enabled devices or monitoring apps) could automatically inform next-generation drug design. Fully automated laboratories ("robotic chemists") powered by AI are another prospect, conducting experiments and learning iteratively without human input.

- **Emerging modalities and data:** New types of data and AI models will enter pharma. For instance, imaging AI may detect subtle pathologies in pathology slides, mHealth AI may track patient adherence, and federated learning could enable multi-center studies without data sharing. Quantum computing, while nascent, could eventually handle complex molecular simulations that classical computers cannot, when coupled with AI algorithms.

- **Regulatory science and digital health:** Regulators themselves are building AI capabilities (e.g. for literature review or monitoring adverse events globally). We may see more collaboration: the EMA's AI Observatory (launched 2024) and FDA AI working groups suggest joint industry-regulator efforts. The goal will be to establish standards for trustworthy AI (explainability, validation) in pharma, much as standards exist for statistical methods.

Looking farther, AI might enable entirely new drug modalities. For example, *AI-designed vaccines or gene therapies* engineered by predictive models could emerge. AI might also help identify cures for complex diseases by analyzing network biology. In manufacturing, "smart factories" will become standard, and supply chains may use blockchain+AI for full traceability. Overall, industry observers emphasize that we are moving from AI hype to reality [15]. The consensus is that while AI won't replace human scientists or clinicians, it will be an

indispensable tool: it will handle tedious data tasks and highlight novel insights, freeing experts to focus on creative and ethical decision-making. If current R&D productivity is low, AI could help rebalance the cost–benefit equation. As one analyst notes, accelerated discovery "will help cure more diseases more quickly" by opening resources for currently underserved areas. Thus, the future promises a more data-centric, patient-centric pharmaceutical industry, with AI as a cornerstone technology.

CONCLUSION

Artificial intelligence is now an integral part of the global pharmaceutical landscape. From initial drug design through regulatory approval and post-market monitoring, AI and ML are enabling faster, smarter, and more cost-effective processes. For example, AI-driven discovery platforms can cut years off development and identify viable drug candidates from enormous chemical spaces. Clinical trials are becoming more adaptive and efficient through AI-powered patient matching and decentralized data capture. Manufacturing lines and supply chains are being augmented with predictive analytics and digital simulations, improving quality and robustness. Even pharmacovigilance and regulatory review are being modernized with NLP and predictive models. Industry forecasts suggest that generative AI could eventually "produce $60–110 billion in annual value" for pharma by accelerating every step of the drug development value chain. However, realizing this promise requires addressing significant challenges (data interoperability, model transparency, ethical use, and regulatory compliance). The consensus is that AI will not supplant human expertise but will augment it, allowing scientists and clinicians to work more effectively. As regulators in the EU and US are formulating AI frameworks, the industry must ensure AI tools are rigorously validated and used responsibly. In summary, the pharmaceutical industry is rapidly embracing AI as a transformative force. Stakeholders should prepare for an era in which data and algorithms are as fundamental as chemistry and biology. By leveraging AI wisely—while managing its risks—pharma professionals can advance medical innovation, improve patient safety, and ultimately deliver better therapies to patients worldwide.

CONFLICT OF INTEREST

The authors have no conflicts of interest.

REFERENCES

1. Vamathevan J, Clark D, Czodrowski P, et al. Applications of machine learning in drug discovery and development. Nat Rev Drug Discov. 2019;18(6):463–477.
2. Paul D, Sanap G, Shenoy S, Kalyane D, Kalia K, Tekade RK. Artificial intelligence in drug discovery and development. Drug Discov Today. 2021;26(1):80–93.
3. Mak KK, Pichika MR. Artificial intelligence in drug development: Present status and future prospects. Drug Discov Today. 2019;24(3):773–780.
4. Schneider G. Automating drug discovery. Nat Rev Drug Discov. 2018;17(2):97–113.
5. Zhavoronkov A, Ivanenkov YA, Aliper A, et al. Deep learning enables rapid identification of potent DDR1 kinase inhibitors. Nat Biotechnol. 2019;37(9):1038–1040.
6. Jumper J, Evans R, Pritzel A, et al. Highly accurate protein structure prediction with Alpha Fold. Nature. 2021;596(7873):583–589.
7. Wong CH, Siah KW, Lo AW. Estimation of clinical trial success rates and related parameters. Biostatistics. 2019;20(2):273–286.

8. U.S. Food and Drug Administration (FDA). Considerations for the use of artificial intelligence to support regulatory decision-making for drug and biological products. FDA Draft Guidance; 2025.
9. European Medicines Agency (EMA). Reflection paper on the use of artificial intelligence in the lifecycle of medicines. EMA/CHMP; 2024.
10. Harrer S, Shah P, Antony B, Hu J. Artificial intelligence for clinical trial design. Trends Pharmacol Sci. 2019;40(8):577–591.
11. Topol EJ. High-performance medicine: The convergence of human and artificial intelligence. Nat Med. 2019;25(1):44–56.
12. Bate A, Hobbiger SF. Artificial intelligence, real-world automation and the safety of medicines. Drug Saf. 2021;44(2):125–132.
13. Sarker IH. Machine learning: Algorithms, real-world applications and research directions. SN Comput Sci. 2021;2(3):160.
14. McKinsey & Company. The potential of generative AI in life sciences. McKinsey Global Institute Report; 2023.
15. Yu KH, Beam AL, Kohane IS. Artificial intelligence in healthcare. Nat Biomed Eng. 2018;2(10):719–731.
16. Benjamens S, Dhunnoo P, Meskó B. The state of artificial intelligence-based FDA-approved medical devices and algorithms. NPJ Digit Med. 2020; 3:118.
17. Amisha, Malik P, Pathania M, Rathaur VK. Overview of artificial intelligence in medicine. J Family Med Prim Care. 2019;8(7):2328–2331.
18. Kalyane D, Sanap G, Paul D, et al. Artificial intelligence in pharmaceutical manufacturing: Opportunities and challenges. Pharmaceutics. 2021;13(4):473.

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