

Artificial Intelligence in Pharmaceutical Market Access and Evidence Generation: From Real-World Evidence to Health Technology Assessment and Patient Access — A Scoping Review

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ABSTRACT

Artificial intelligence (AI) is emerging as a transformative technology in pharmaceutical market access and evidence generation, offering new opportunities to improve healthcare decision-making through advanced data analytics and predictive modelling. The integration of machine learning, natural language processing, deep learning, and generative AI has the potential to strengthen real-world evidence (RWE) generation, health technology assessment (HTA), health economics and outcomes research (HEOR), pricing and reimbursement strategies, and patient access. This scoping review aims to map the applications of AI across the pharmaceutical market access pathway, with particular emphasis on evidence generation, clinical and economic evaluation, and patient-centred healthcare. The review is designed to follow an established scoping review framework and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR). Relevant literature is intended to be identified through searches of PubMed/MEDLINE, Scopus, Embase, and Web of Science, supplemented by relevant HTA agency publications. The evidence will be organized according to AI techniques, application areas, reported benefits, implementation challenges, and research gaps. Key areas of interest include AI-assisted analysis of healthcare data, automated evidence synthesis, economic modelling, reimbursement planning, and patient stratification. Despite these opportunities, challenges related to data quality, algorithmic bias, transparency, privacy, model validation, and regulatory acceptance may limit practical implementation. The review aims to identify emerging applications and research priorities while emphasizing the importance of responsible AI governance, methodological rigor, and human oversight. Overall, AI may support more efficient evidence generation and informed pharmaceutical market access decisions; however, its clinical, economic, and societal value requires further empirical evaluation.

Keywords: Artificial intelligence, pharmaceutical market access, real-world evidence, health technology assessment, machine learning, health economics and outcomes research, reimbursement, patient access

INTRODUCTION

The pharmaceutical industry is undergoing a significant transformation driven by advances in digital technologies, data analytics, and artificial intelligence (AI).[1] Increasing healthcare expenditure, evolving regulatory requirements, rising expectations for evidence-based decision-making, and the growing complexity of innovative therapies have intensified the need for reliable and timely evidence to support pharmaceutical market access.[2] Market access refers to the strategies and processes through which pharmaceutical products obtain appropriate pricing, reimbursement, formulary inclusion, and availability to eligible patients.[3] Achieving successful market

access requires demonstrating not only the safety and efficacy of a medicine but also its comparative clinical effectiveness, economic value, and impact on healthcare systems and patient outcomes. Artificial intelligence encompasses computational techniques, including machine learning (ML), deep learning, natural language processing (NLP), and predictive analytics, that enable the analysis of large and complex datasets.[4] These technologies have the potential to support pharmaceutical research, clinical development, evidence synthesis, and healthcare decision-making. In market access, AI can facilitate the identification of relevant clinical evidence, extraction of information from scientific publications, prediction of treatment outcomes, and assessment of healthcare

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resource utilization.[5] However, the reliability and applicability of these approaches depend on the quality of the underlying data, model validation, transparency, and the suitability of the analytical methods for the intended decision-making. Real-world evidence (RWE) has become an important component of pharmaceutical decision-making.[6] RWE is generated through the analysis of real-world data (RWD), which may include electronic health records, insurance claims, disease registries, pharmacy records, and patient-reported outcomes. Unlike evidence obtained exclusively from randomized controlled trials, RWE can provide insights into treatment effectiveness, safety, adherence, healthcare utilization, and outcomes in routine clinical practice.[7] AI-based methods may strengthen RWE generation by identifying clinically relevant patterns, integrating heterogeneous datasets, predicting outcomes, and supporting comparative effectiveness analyses.[8] Nevertheless, confounding, missing data, selection bias, data inconsistency, and limited representativeness remain important methodological concerns that must be addressed before RWE is used to support consequential healthcare decisions. Health technology assessment (HTA) is another critical area in which AI may contribute to pharmaceutical market access. [9] HTA involves the systematic evaluation of the clinical, economic, organizational, social, and ethical implications of health technologies to inform coverage, reimbursement, and resource-allocation decisions.[10] Conventional HTA processes frequently require the assessment of extensive clinical trial data, systematic reviews, economic evaluations, budget impact analyses, and patient-relevant outcomes. AI-assisted literature screening, evidence extraction, synthesis, and economic modelling may improve the efficiency of selected assessment activities. Furthermore, predictive modelling may support the exploration of treatment outcomes and healthcare costs under different scenarios. However, AI-generated analyses must remain transparent, reproducible, and methodologically appropriate to meet the evidentiary requirements of HTA agencies and reimbursement authorities. Health economics and outcomes research (HEOR) provides an additional link between clinical evidence and market access decisions by evaluating the costs, consequences, and value of healthcare interventions. AI may support HEOR through patient stratification, cost prediction, treatment pathway analysis, identification

of unmet medical needs, and the analysis of patient-reported outcomes. These applications may contribute to a more comprehensive understanding of the economic and clinical value of pharmaceutical products. In addition, AI-driven analytics may help identify barriers to treatment initiation, adherence, and continuity of care, thereby informing patient access programmes and healthcare delivery strategies. However, predicted associations should not automatically be interpreted as causal relationships, and economic conclusions require appropriate validation and sensitivity analysis.[11,12,13]

Despite these opportunities, the implementation of AI in pharmaceutical market access presents several challenges. Limitations include fragmented healthcare data, inconsistent data standards, algorithmic bias, limited explainability, privacy concerns, cybersecurity risks, and uncertainty regarding the acceptability of AI-generated evidence in regulatory and reimbursement settings. Differences in healthcare infrastructure, clinical practice, reimbursement policies, and patient populations may also affect the generalizability of AI models across countries and healthcare systems.[14] Consequently, responsible implementation requires robust methodological standards, human oversight, appropriate data governance, and collaboration among pharmaceutical companies, healthcare professionals, researchers, patients, payers, and HTA organizations.[15]

Although AI applications in drug discovery, clinical development, and healthcare analytics have received considerable attention, their integration across the broader pharmaceutical market access pathway requires further systematic mapping.[16] In particular, the relationship between AI-enabled RWE generation, HTA, economic evaluation, reimbursement decisions, and patient access represents an evolving area of research. A scoping review can help characterize the available evidence, identify established and emerging applications, and highlight methodological and implementation gaps without presupposing that AI is uniformly effective across all settings.[17]

METHODOLOGY

2.1 Scoping Review Framework

The present scoping review will be conducted using the methodological framework proposed by Arksey and O'Malley, with subsequent refinements by Levac

and colleagues. The review will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) to promote transparent reporting of the review process. The framework will be used to map existing

evidence on artificial intelligence (AI) applications in pharmaceutical market access, real-world evidence (RWE) generation, health technology assessment (HTA), health economics and outcomes research (HEOR), and patient access.[18]

Table 1: Methodological Framework for the Scoping Review

Sr. No.	Framework Stage	Description of Methodology
1	Identification of the Research Question	Define the scope of AI applications in pharmaceutical market access, including RWE generation, HTA, economic evaluation, reimbursement, and patient access. [19]
2	Identification of Relevant Studies	Search electronic databases, including PubMed/MEDLINE, Scopus, Embase, and Web of Science, supplemented by relevant HTA agency reports and reference-list screening.[20]
3	Study Selection	Screen titles, abstracts, and full-text publications against predefined inclusion and exclusion criteria.[21]
4	Data Charting	Extract relevant information, including author, publication year, study design, AI technique, data source, application area, key findings, and reported limitations. [22]
5	Collating and Summarizing Results	Organize the extracted evidence into thematic categories covering RWE, HTA, HEOR, pricing and reimbursement, and patient access.[23]
6	Reporting the Findings	Present the findings using descriptive summaries, evidence-mapping tables, and narrative synthesis, following PRISMA-ScR reporting guidance.[24]

3. AI IN PHARMACEUTICAL MARKET ACCESS

Artificial intelligence (AI) is increasingly being integrated into pharmaceutical market access to support evidence-based decisions regarding the availability, affordability, pricing, and reimbursement of medicines. Market access requires pharmaceutical companies to demonstrate the clinical effectiveness, safety, economic value, and relevance of their products to patients and healthcare systems.[25] AI technologies, including machine learning, natural language processing, predictive analytics, and deep learning, can assist in processing large volumes of clinical, economic, and healthcare data to identify meaningful patterns and generate actionable insights. [26] These technologies may support the identification of unmet medical needs, assessment of treatment outcomes, evaluation of competitor products, and development of market access strategies. AI can also facilitate the analysis of healthcare policies, reimbursement requirements, and treatment guidelines across different geographical regions. However, the usefulness of AI-generated insights depends on data quality, algorithmic transparency, appropriate validation, and alignment with local healthcare requirements. Therefore, AI should be considered a decision-

support tool rather than a replacement for clinical, regulatory, economic, or payer judgment.[27]

4. AI-ENABLED REAL-WORLD EVIDENCE (RWE) GENERATION

Real-world evidence (RWE) refers to clinical evidence concerning the use, benefits, and risks of medical products derived from the analysis of real-world data (RWD). Such data may originate from electronic health records, insurance claims, disease registries, hospital databases, pharmacy records, and patient-reported outcomes.[28] AI-enabled analytical methods can improve the processing and interpretation of these complex datasets by identifying patient characteristics, predicting clinical outcomes, detecting safety signals, and supporting comparative effectiveness research. Machine learning algorithms can help identify suitable patient cohorts, while natural language processing can extract clinically relevant information from unstructured medical records and scientific literature.[29] AI may also support the integration of multiple data sources to investigate treatment adherence, disease progression, healthcare utilization, and long-term therapeutic outcomes. These applications can complement evidence from randomized controlled trials by providing insights into routine clinical

practice and populations that may be underrepresented in clinical studies.[30] Nevertheless, RWE generated using AI may be affected by missing data, confounding factors, selection bias, coding inconsistencies, and limited generalizability. Appropriate study design, data validation, sensitivity analysis, and transparent reporting are therefore essential to ensure that AI-assisted RWE is reliable and suitable for pharmaceutical decision-making.[31]

5. AI IN HEALTH TECHNOLOGY ASSESSMENT (HTA)

Health technology assessment (HTA) is a multidisciplinary process used to evaluate the clinical, economic, organizational, social, and ethical implications of health technologies. It plays an important role in determining the value of pharmaceutical products and informing reimbursement, coverage, and healthcare resource-allocation decisions.[32] AI has the potential to support several stages of HTA by automating literature screening, extracting data from clinical studies, identifying relevant endpoints, and organizing evidence for systematic reviews.[33] Natural language processing can assist in identifying information from published research, while machine learning can support the analysis of treatment outcomes and patient subgroups. AI-assisted modelling may also help explore clinical and economic scenarios, estimate potential healthcare consequences, and identify uncertainties in available evidence. In addition, AI may facilitate the synthesis of large datasets to support the evaluation of therapeutic interventions in different patient populations.[34] However, HTA decisions require evidence that is transparent, reproducible, clinically meaningful, and methodologically robust. AI-generated outputs may introduce bias or uncertainty if the underlying datasets are incomplete or the algorithms are insufficiently validated. Consequently, AI should complement established HTA methods and expert assessment, with clear documentation of assumptions, model performance, and limitations.[35]

6. AI IN HEALTH ECONOMICS AND OUTCOMES RESEARCH (HEOR)

Health economics and outcomes research (HEOR) evaluates the economic consequences and health outcomes associated with pharmaceutical products and healthcare interventions. It provides evidence concerning treatment costs, clinical benefits, quality of

life, healthcare resource utilization, and the value of medical interventions.[36] AI can contribute to HEOR by enabling advanced analysis of healthcare expenditure, patient outcomes, treatment pathways, and large-scale observational datasets. Machine learning models may be used to predict hospitalization risk, identify factors associated with high healthcare utilization, and classify patients according to clinical or economic characteristics. AI can also support the analysis of patient-reported outcomes and help identify relationships between treatment adherence, disease severity, quality of life, and healthcare costs. In economic evaluations, AI-assisted analytical techniques may complement cost-effectiveness models, budget impact assessments, and scenario analyses by supporting data processing and the exploration of complex relationships.[37] These applications may help researchers investigate resource allocation and the potential economic implications of alternative treatment strategies. However, predictive accuracy alone does not establish economic value or causal treatment effects. Reliable HEOR applications require appropriate model validation, representative datasets, transparent assumptions, uncertainty analysis, and consideration of differences in healthcare systems and patient populations.[38]

7. AI IN PRICING, REIMBURSEMENT, AND MARKET ACCESS STRATEGY

Pricing and reimbursement are essential components of pharmaceutical market access because they influence the affordability, availability, and commercial sustainability of medicines. AI can support market access strategy by analyzing clinical evidence, epidemiological data, healthcare expenditure, treatment patterns, competitor information, and reimbursement policies.[39] Predictive analytics may help pharmaceutical companies estimate potential demand, identify population-level treatment needs, and evaluate different pricing or reimbursement scenarios.[40] AI-assisted evidence synthesis can also support the preparation of reimbursement submissions by organizing clinical outcomes, economic evidence, and information relevant to payer requirements.[41] Furthermore, machine learning may help identify variations in prescribing patterns and treatment utilization that can inform market access planning. When combined with appropriate economic models, AI can assist in exploring the potential effects of pricing

decisions on healthcare budgets and patient affordability. However, pricing and reimbursement decisions are influenced by numerous factors, including regulatory requirements, national health policies, budget constraints, therapeutic alternatives, and ethical considerations. [42] AI-based recommendations must therefore be interpreted within the relevant healthcare and legal context. Transparent methods, reliable data, responsible use of market information, and human oversight are necessary to ensure that AI-supported strategies promote sustainable access rather than merely optimizing commercial outcomes.[43]

8. AI-DRIVEN PATIENT ACCESS AND PERSONALIZED HEALTHCARE

Patient access involves ensuring that individuals can obtain appropriate medicines and healthcare services in a timely, affordable, and equitable manner.[44] Barriers to access may include high treatment costs, geographical limitations, delayed diagnosis, inadequate healthcare infrastructure, poor treatment adherence, and complex reimbursement procedures. [45] AI may help address selected barriers through patient stratification, predictive analytics, identification of treatment gaps, and analysis of healthcare utilization patterns.[46] Machine learning models can potentially

identify patients at risk of treatment discontinuation or non-adherence, enabling healthcare professionals to develop targeted support interventions. AI-powered digital health tools may also facilitate patient education, symptom monitoring, medication reminders, and communication between patients and healthcare providers.[47] In personalized healthcare, AI can integrate relevant clinical and demographic information to support the identification of patient subgroups that may benefit from particular therapeutic approaches.[48] These capabilities may contribute to more individualized care pathways and improved coordination of treatment services. Nevertheless, AI-driven patient access initiatives must account for data privacy, informed consent, algorithmic bias, digital literacy, and unequal access to digital technologies. Models developed using limited or unrepresentative populations may inadvertently disadvantage vulnerable groups. Therefore, the responsible application of AI should prioritize patient welfare, equitable access, clinical validation, and human supervision while evaluating whether AI-supported interventions produce meaningful improvements in patient outcomes. [49,50]

Applications, Case Studies, and Emerging Technologies[51,52,53,54,55,56,57,58]

Table 2: Applications of Artificial Intelligence in Pharmaceutical Market Access and Evidence Generation

Sr. No.	Application Area	AI Technology	Application / Case Study	Potential Benefits	Key Limitations
1	Real-World Evidence (RWE)	Machine learning	Analysis of electronic health records and insurance claims to assess treatment outcomes	Improved identification of clinical patterns and patient outcomes	Missing data, confounding, and bias
2	Clinical Evidence Synthesis	Natural language processing (NLP)	Automated screening and extraction of information from clinical studies	Faster literature review and evidence identification	Extraction errors and incomplete evidence
3	Health Technology Assessment (HTA)	NLP and machine learning	Support for systematic evidence reviews and clinical evidence summaries	Improved efficiency of evidence assessment	Limited transparency and validation
4	Health Economics and Outcomes Research (HEOR)	Predictive analytics	Prediction of healthcare resource utilization and treatment-related costs	Better cost forecasting and resource planning	Model uncertainty and limited generalizability
5	Cost-Effectiveness Analysis	AI-assisted economic modelling	Analysis of clinical outcomes and economic scenarios	Support for economic evaluation and sensitivity analysis	Dependence on assumptions and data quality

Sr. No.	Application Area	AI Technology	Application / Case Study	Potential Benefits	Key Limitations
6	Drug Safety Monitoring	Machine learning and NLP	Detection of potential adverse drug reaction signals from clinical records and safety reports	Earlier identification of potential safety concerns	False-positive signals and reporting bias
7	Pricing and Reimbursement	Predictive analytics	Evaluation of pricing scenarios, budget impact, and reimbursement requirements	Improved strategic planning	Policy variation and uncertainty in predictions
8	Patient Access	Predictive modeling	Identification of patients at risk of treatment discontinuation	Targeted adherence support and care coordination	Privacy concerns and algorithmic bias
9	Personalized Healthcare	Machine learning and deep learning	Patient stratification using clinical characteristics and treatment-response data	More individualized treatment planning	Need for clinical validation
10	Digital Health and Patient Support	AI chatbots and conversational AI	Patient education, medication reminders, and treatment navigation	Improved communication and access to information	Inaccurate responses and digital exclusion
11	Advanced Evidence Generation	Causal machine learning	Investigation of treatment-effect variation in observational datasets	Better exploration of comparative outcomes	Residual confounding and methodological complexity
12	Emerging Technologies	Generative AI and large language models	Drafting evidence summaries and supporting structured extraction from scientific documents	Faster information processing and knowledge synthesis	Hallucinations, confidentiality, and reproducibility

9. CHALLENGES: DATA QUALITY, BIAS, TRANSPARENCY, AND PRIVACY

The integration of artificial intelligence (AI) into pharmaceutical market access and evidence generation presents several methodological, technical, and ethical challenges. Data quality is a fundamental concern because AI models depend on the accuracy, completeness, consistency, and representativeness of the information used for training and analysis. Real-world data obtained from electronic health records, insurance claims, disease registries, and hospital databases may contain missing observations, inconsistent coding, duplicate records, and variations in data collection practices.[59,60] These limitations can affect the reliability of real-world evidence (RWE), clinical outcome predictions, and economic evaluations. Algorithmic bias is another important challenge, particularly when training datasets inadequately represent specific age groups, socioeconomic populations, geographical regions, or disease subgroups. Biased models may generate inaccurate

predictions and contribute to unequal treatment access or reimbursement decisions. [61]In addition, limited model interpretability can make it difficult for clinicians, health technology assessment (HTA) agencies, payers, and patients to understand how AI-generated conclusions are reached.[62] Privacy and security concerns arise when sensitive health information is processed, integrated, or transferred across organizations. Unauthorized access, inappropriate secondary data use, and insufficient anonymization may compromise patient confidentiality. Other challenges include limited interoperability between healthcare information systems, model performance deterioration over time, and difficulties in reproducing analytical results. Addressing these issues requires standardized data practices, representative datasets, robust validation, explainable methods, secure information management, and continuous monitoring of model performance.[63,64]

10. REGULATORY, ETHICAL, AND GOVERNANCE CONSIDERATIONS

The responsible application of AI in pharmaceutical market access requires appropriate regulatory oversight, ethical safeguards, and governance mechanisms. AI-generated evidence used in clinical evaluation, health technology assessment, economic modelling, or reimbursement submissions should be methodologically sound, transparent, reproducible, and relevant to the decision being supported.[65] Regulatory and HTA organizations need to consider how AI tools are developed, validated, documented, updated, and monitored throughout their lifecycle. Governance frameworks should define accountability for model development, data management, interpretation, and the use of AI-generated recommendations. Ethical considerations include fairness, patient autonomy, informed consent, confidentiality, explainability, and equitable access to healthcare technologies.[66] The use of patient-level data must comply with applicable privacy and data protection requirements, including relevant national legislation and institutional policies.[67] In India, the Digital Personal Data Protection Act, 2023, and applicable rules and commencement provisions are relevant to the governance of digital personal data. Internationally, applicable data protection laws and emerging AI governance frameworks may also influence cross-border pharmaceutical research and market access activities.[68] Human oversight remains essential, particularly when AI outputs influence consequential decisions concerning medicine reimbursement, treatment eligibility, or resource allocation. Pharmaceutical companies, researchers, healthcare professionals, payers, and HTA agencies should establish clear procedures for auditing algorithms, documenting limitations, reporting errors, and managing conflicts of interest. A risk-based approach to governance can help ensure that AI contributes to efficient evidence generation without compromising scientific integrity, patient rights, or public trust.[69,70]

11. FUTURE PERSPECTIVES [71,72,73]

The future of AI in pharmaceutical market access is likely to involve greater integration of clinical, economic, genomic, administrative, and patient-reported data to support more comprehensive evidence generation. Advances in machine learning, natural language processing, generative AI, causal inference,

and federated learning may enable researchers to analyze complex datasets while addressing selected challenges related to data access and information sharing. AI-assisted evidence synthesis could improve the identification and organization of clinical studies, while advanced analytical models may support the evaluation of treatment outcomes across diverse patient populations. In health technology assessment, AI may assist in evidence mapping, uncertainty analysis, and the development of economic models, provided that these applications are appropriately validated and transparent. Digital health platforms and patient-centred analytics may also support treatment adherence, identification of unmet medical needs, and coordination of patient support services. Future applications could include near-real-time monitoring of treatment outcomes and the integration of RWE into post-marketing evaluation and reimbursement reassessment. However, these developments will require standardized data infrastructures, interdisciplinary collaboration, robust validation studies, and clear expectations from regulatory and HTA authorities. Future research should prioritize prospective evaluations of AI-supported workflows, comparisons with conventional methods, assessments of cost-effectiveness, and investigations of their effects on equity and patient outcomes. The successful implementation of AI will depend not only on technological advancement but also on demonstrated clinical relevance, economic value, and responsible governance.

12. RESEARCH GAPS[74,775,76]

Despite growing interest in AI applications in healthcare, important research gaps remain regarding its effectiveness and practical value in pharmaceutical market access and evidence generation. First, the available evidence is heterogeneous in terms of study design, data sources, AI techniques, outcome measures, and validation methods, making comparisons between applications difficult. Second, there is a need for more external and prospective validation of AI models used for real-world evidence generation, comparative effectiveness research, and economic evaluation. Third, the extent to which AI-assisted analyses improve the accuracy, efficiency, reproducibility, or decision quality of health technology assessments remains insufficiently established across different healthcare settings. Fourth, limited research

directly evaluates whether AI-supported market access strategies lead to improved reimbursement outcomes, reduced delays in medicine availability, greater affordability, or better patient health outcomes. Fifth, the economic implications of implementing AI including development costs, infrastructure requirements, workforce training, maintenance, and cost-effectiveness require further investigation. Sixth, the effects of algorithmic bias and underrepresentation of disadvantaged populations on equitable patient access need systematic evaluation. Seventh, there is a need for clearer methodological guidance on the documentation, validation, explainability, and acceptable use of generative AI in evidence synthesis and reimbursement submissions. Finally, evidence from low- and middle-income countries, including India, remains particularly important because healthcare data infrastructure, payer arrangements, affordability constraints, and access barriers may differ substantially from those in high-income settings. Addressing these gaps through transparent reporting, multidisciplinary collaboration, standardized evaluation frameworks, and context-specific validation studies will help determine where AI provides meaningful benefits and where additional safeguards or conventional approaches remain necessary.

CONCLUSION

Artificial intelligence has considerable potential to transform pharmaceutical market access and evidence generation by supporting real-world evidence analysis, health technology assessment, health economics and outcomes research, pricing and reimbursement strategies, and patient access initiatives. Machine learning, natural language processing, predictive analytics, and generative AI can facilitate the analysis of complex healthcare datasets, improve evidence synthesis, and support informed decision-making. These technologies may contribute to more efficient evaluation of pharmaceutical products and a better understanding of clinical outcomes, healthcare resource utilization, and patient needs. However, their successful implementation depends on data quality, methodological validity, algorithmic transparency, privacy protection, and appropriate regulatory oversight. AI-generated evidence should complement established scientific methods and expert judgment rather than replace them. Further research is required

to validate AI applications in real-world settings, assess their clinical and economic value, and determine their effects on equitable access to medicines. Overall, the responsible integration of AI into pharmaceutical market access may strengthen evidence-informed healthcare decisions and support sustainable, patient-centred access to pharmaceutical innovations.

14. CONFLICT OF INTEREST

The author declares that there is no conflict of interest regarding the publication of this scoping review.

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REFERENCES

1. Davenport T, Kalakota R. The potential for artificial intelligence in healthcare. *Future Healthc J.* 2019;6 (2):94-98.
2. Kingma DP, Welling M. Auto-encoding variational Bayes. *arXiv preprint arXiv:1312.6114.* 2013.
3. Ho J, Jain A, Abbeel P. Denoising diffusion probabilistic models. *Adv Neural Inf Process Syst.* 2020;33:6840-6851.
4. Bommasani R, et al. On the opportunities and risks of foundation models. *arXiv preprint arXiv:2108.07258.* 2021.
5. Yang J, Jin H, Tang R, Han X, Feng Q, Jiang H, et al. Harnessing the power of LLMs in practice: A survey on ChatGPT and beyond. *ACM Trans Knowl Discov Data.* 2024;18 (6):1-32.
6. Biswas SS. Role of ChatGPT in public health. *Ann Biomed Eng.* 2023;51 (5):868-869.
7. LeCun Y, Bengio Y, Hinton G. Deep learning. *Nature.* 2015;521 (7553):436-444.
8. Hochreiter S, Schmidhuber J. Long short-term memory. *Neural Comput.* 1997;9 (8):1735-1780.

9. Vaswani A, Shazeer N, Parmar N, Uszkoreit J, Jones L, Gomez AN, et al. Attention is all you need. *Adv Neural Inf Process Syst.* 2017;30.
10. Shakeri E, Far B. Advancing pneumonia classification and detection: Comparative analysis of deep learning models using convolutional neural networks. In: *Proceedings of the 2024 IEEE International Conference on Information Reuse and Integration for Data Science.* IEEE; 2024. p. 108-113.
11. Zhang Q, Yang LT, Chen Z, Li P. A survey on deep learning for big data. *Inf Fusion.* 2018;42:146-157.
12. Pan SJ, Yang Q. A survey on transfer learning. *IEEE Trans Knowl Data Eng.* 2010;22(10):1345-1359.
13. Chowdhary K. Natural language processing. In: *Fundamentals of Artificial Intelligence.* 2020. p. 603-649.
14. Young T, Hazarika D, Poria S, Cambria E. Recent trends in deep learning based natural language processing. *IEEE Comput Intell Mag.* 2018;13(3):55-75.
15. Goldberg Y. *Neural network methods in natural language processing.* Morgan & Claypool Publishers; 2017.
16. Topol EJ. High-performance medicine: The convergence of human and artificial intelligence. *Nat Med.* 2019;25(1):44-56.
17. Rajpurkar P, Chen E, Banerjee O, Topol EJ. AI in health and medicine. *Nat Med.* 2022;28(1):31-38.
18. Bender A, Cortés-Ciriano I. Artificial intelligence in drug discovery: What is realistic, what are illusions? Part 1: Ways to make an impact, and why we are not there yet. *Drug Discov Today.* 2021;26(2):511-524.
19. Shakeri E, Slama A, Souza R, Far B. COVID-19 vaccine infodemiology using unsupervised natural language processing. In: *Proceedings of the 2022 IEEE 23rd International Conference on Information Reuse and Integration for Data Science.* IEEE; 2022. p. 178-183.
20. Farhadi A, Zamanifar A, Faezipour M. Application of generative AI in drug discovery. In: *Application of Generative AI in Healthcare Systems.* Springer; 2025. p. 155-174.
21. Kotkondawar RR, Sutar SR, Kiwelekar AW, Kadam VJ, Jadhav SM. The rise of generative AI frameworks in drug discovery. *Int J Data Sci Anal.* 2025;20(7):6135-6156.
22. Zhavoronkov A. Artificial intelligence for drug discovery, biomarker development, and generation of novel chemistry. *Mol Pharm.* 2018;15(10):4311-4313.
23. Blanco-Gonzalez A, Cabezon A, Seco-Gonzalez A, Conde-Torres D, Antelo-Riveiro P, Pineiro A, et al. The role of AI in drug discovery: Challenges, opportunities, and strategies. *Pharmaceuticals (Basel).* 2023;16(6):891.
24. Goodfellow I, Bengio Y, Courville A. *Deep learning.* MIT Press; 2016.
25. Sanchez-Lengeling B, Aspuru-Guzik A. Inverse molecular design using machine learning: Generative models for matter engineering. *Science.* 2018;361(6400):360-365.
26. Segler MHS, Preuss M, Waller MP. Planning chemical syntheses with deep neural networks and symbolic AI. *Nature.* 2018;555(7698):604-610.
27. Popova M, Isayev O, Tropsha A. Deep reinforcement learning for de novo drug design. *Sci Adv.* 2018;4(7).
28. Goodfellow I, Pouget-Abadie J, Mirza M, Xu B, Warde-Farley D, Ozair S, et al. Generative adversarial nets. *Adv Neural Inf Process Syst.* 2014;27.
29. Brown TB, et al. Language models are few-shot learners. *arXiv preprint arXiv:2005.14165.* 2020.
30. Olivecrona M, Blaschke T, Engkvist O, Chen H. Molecular de novo design through deep reinforcement learning. *J Cheminform.* 2017;9:48.
31. Naveed H, Khan AU, Qiu S, Saqib M, Anwar S, Usman M, et al. A comprehensive overview of large language models. *arXiv preprint arXiv:2307.06435.* 2023.
32. Chernyavskiy A, Ilvovsky D, Nakov P. Transformers: "The end of history" for natural language processing? In: *Machine Learning and Knowledge Discovery in Databases: Research Track. ECML PKDD 2021.* Springer; 2021. p. 677-693.
33. Wang A, Pruksachatkun Y, Nangia N, Singh A, Michael J, Hill F, et al. SuperGLUE: A stickier

- benchmark for general-purpose language understanding systems. *Adv Neural Inf Process Syst.* 2019;32.
34. Adiwardana D, Luong MT, So DR, Hall J, Fiedel N, Thoppilan R, et al. Towards a human-like open-domain chatbot. *arXiv preprint arXiv:2001.09977.* 2020.
35. Esteva A, Robicquet A, Ramsundar B, Kuleshov V, DePristo M, Chou K, et al. A guide to deep learning in healthcare. *Nat Med.* 2019;25 (1):24-29.
36. Aggarwal R, Sounderajah V, Martin G, Ting DS, Karthikesalingam A, King D, et al. Diagnostic accuracy of deep learning in medical imaging: A systematic review and meta-analysis. *NPJ Digit Med.* 2021;4 (1):65.
37. Thirunavukarasu AJ, Ting DSJ, Elangovan K, Gutierrez L, Tan TF, Ting DSW. Large language models in medicine. *Nat Med.* 2023;29 (8):1930-1940.
38. Yu C, Liu J, Nemati S, Yin G. Reinforcement learning in healthcare: A survey. *ACM Comput Surv.* 2021;55 (1):1-36.
39. Mnih V, Kavukcuoglu K, Silver D, Rusu AA, Veness J, Bellemare MG, et al. Human-level control through deep reinforcement learning. *Nature.* 2015;518 (7540):529-533.
40. Abdellatif AA, Mhaisen N, Mohamed A, Erbad A, Guizani M. Reinforcement learning for intelligent healthcare systems: A review of challenges, applications, and open research issues. *IEEE Internet Things J.* 2023;10 (24):21982-22007.
41. Nielsen MA, Chuang IL. Quantum computation and quantum information. Cambridge University Press; 2010.
42. Biamonte J, Wittek P, Pancotti N, Rebentrost P, Wiebe N, Lloyd S. Quantum machine learning. *Nature.* 2017;549 (7671):195-202.
43. Cao Y, Romero J, Olson JP, Degroote M, Johnson PD, Kieferová M, et al. Quantum chemistry in the age of quantum computing. *Chem Rev.* 2019;119 (19):10856-10915.
44. Drews J. Drug discovery: A historical perspective. *Science.* 2000;287 (5460):1960-1964.
45. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ.* 2016;47:20-33.
46. Avorn J. The \$2.6 billion pill: Methodologic and policy considerations. *N Engl J Med.* 2015;372 (20):1877-1879.
47. Pereira JC, Caffarena ER, Dos Santos CN. Boosting docking-based virtual screening with deep learning. *J Chem Inf Model.* 2016;56 (12):2495-2506.
48. Walters WP, Stahl MT, Murcko MA. Virtual screening—an overview. *Drug Discov Today.* 1998;3 (4):160-178.
49. Cheng T, Li Q, Zhou Z, Wang Y, Bryant SH. Structure-based virtual screening for drug discovery: A problem-centric review. *AAPS J.* 2012;14:133-141.
50. Shoichet BK. Virtual screening of chemical libraries. *Nature.* 2004;432 (7019):862-865.
51. Ghosh S, Nie A, An J, Huang Z. Structure-based virtual screening of chemical libraries for drug discovery. *Curr Opin Chem Biol.* 2006;10 (3):194-202.
52. Zeng X, Wang F, Luo Y, Kang SG, Tang J, Lightstone FC, et al. Deep generative molecular design reshapes drug discovery. *Cell Rep Med.* 2022;3 (12).
53. Gangwal A, Ansari A, Ahmad I, Azad AK, Kumarasamy V, Subramaniyan V, et al. Generative artificial intelligence in drug discovery: Basic framework, recent advances, challenges, and opportunities. *Front Pharmacol.* 2024;15:1331062.
54. Zhou Z, Kearnes S, Li L, Zare RN, Riley P. Optimization of molecules via deep reinforcement learning. *Sci Rep.* 2019;9 (1):10752.
55. Moll N, Barkoutsos P, Bishop LS, Chow JM, Cross A, Egger DJ, et al. Quantum optimization using variational algorithms on near-term quantum devices. *Quantum Sci Technol.* 2018;3 (3):030503.
56. Weininger D. SMILES, a chemical language and information system. 1. Introduction to methodology and encoding rules. *J Chem Inf Comput Sci.* 1988;28 (1):31-36.

57. National Center for Biotechnology Information. PubChem: Open chemistry database [Internet]. 2024 [cited 2024 Nov 21]. Available from: <https://pubchem.ncbi.nlm.nih.gov/>
58. Krenn M, Häse F, Nigam A, Friederich P, Aspuru-Guzik A. Self-referencing embedded strings (SELFIES): A 100% robust molecular string representation. *Mach Learn Sci Technol*. 2020;1 (4):045024.
59. Martinelli DD. Generative machine learning for de novo drug discovery: A systematic review. *Comput Biol Med*. 2022;145:105403.
60. David L, Thakkar A, Mercado R, Engkvist O. Molecular representations in AI-driven drug discovery: A review and practical guide. *J Cheminform*. 2020;12 (1):56.
61. Mansimov E, Mahmood O, Kang S, Cho K. Molecular geometry prediction using a deep generative graph neural network. *Sci Rep*. 2019;9 (1):20381.
62. Estrada E. Characterization of 3D molecular structure. *Chem Phys Lett*. 2000;319 (5-6):713-718.
63. Rogers D, Hahn M. Extended-connectivity fingerprints. *J Chem Inf Model*. 2010;50 (5):742-754.
64. Durant JL, Leland BA, Henry DR, Nourse JG. Reoptimization of MDL keys for use in drug discovery. *J Chem Inf Comput Sci*. 2002;42 (6):1273-1280.
65. Cherkasov A, Muratov EN, Fourches D, Varnek A, Baskin II, Cronin M, et al. QSAR modeling: Where have you been? Where are you going to? *J Med Chem*. 2014;57 (12):4977-5010.
66. Todeschini R, Consonni V. *Handbook of molecular descriptors*. Wiley; 2008.
67. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): Checklist and explanation. *Ann Intern Med*. 2018;169 (7):467-473.
68. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ*. 2021;372.
69. Gómez-Bombarelli R, Wei JN, Duvenaud D, Hernández-Lobato JM, Sánchez-Lengeling B, Sheberla D, et al. Automatic chemical design using a data-driven continuous representation of molecules. *ACS Cent Sci*. 2018;4 (2):268-276.
70. Bauer B, Bravyi S, Motta M, Chan GK-L. Quantum algorithms for quantum chemistry and quantum materials science. *Chem Rev*. 2020;120 (22):12685-12717.
71. McHugh ML. Interrater reliability: The kappa statistic. *Biochem Med (Zagreb)*. 2012;22 (3):276-282.
72. Jin W, Barzilay R, Jaakkola T. Junction tree variational autoencoder for molecular graph generation. In: *Proceedings of the International Conference on Machine Learning*. PMLR; 2018. p. 2323-2332.
73. Guimaraes GL, Sanchez-Lengeling B, Outeiral C, Farias PLC, Aspuru-Guzik A. Objective-reinforced generative adversarial networks (ORGAN) for sequence generation models. *arXiv preprint arXiv:1705.10843*. 2017.
74. You J, Liu B, Ying Z, Pande V, Leskovec J. Graph convolutional policy network for goal-directed molecular graph generation. *Adv Neural Inf Process Syst*. 2018;31.
75. Shakeri E, Far B. Accelerating drug discovery with deep reinforcement learning: Molecular generation using deep Q-network. In: *Proceedings of the 2025 IEEE International Conference on Information Reuse and Integration and Data Science*. IEEE; 2025. p. 91-96.
76. Hu X, Liu G, Zhao Y, Zhang H. Activity cliff-aware reinforcement learning for de novo drug design. *J Cheminform*. 2025;17 (1):54.

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