



CODEN [USA]: IAJPBB

ISSN : 2349-7750

INDO AMERICAN JOURNAL OF  
**PHARMACEUTICAL SCIENCES**

SJIF Impact Factor: 7.187

<https://doi.org/10.5281/zenodo.22015649>Available online at: <http://www.iajps.com>

Review Article

**ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN  
PRECISION MEDICINE: APPLICATIONS IN MEDICAL  
BIOTECHNOLOGY**

Siddela Johnson<sup>1\*</sup> [0009-0002-0038-6882], Soma Sekhar Pulamarasetti<sup>2</sup> [0009-0007-3552-1868],  
Kovvada Vandana<sup>1</sup> [0009-0007-2207-4528], Bongu Ramya Priya<sup>1</sup> [0009-0002-0600-8823], Varri  
Anudeepthi<sup>1</sup> [0009-0000-6252-0472]

<sup>1</sup> AU College of Pharmaceutical Sciences (AUCOPS), Andhra University, Visakhapatnam,  
Andhra Pradesh, India

<sup>2</sup> Faculty of Pharmacy, B. R. Nahata College of Pharmacy, Mandsaur University, Mandsaur,  
Madhya Pradesh, India (PIN: 458001)

**Abstract:**

**Background:** Artificial intelligence (AI) and machine learning (ML) are increasingly embedded across the precision medicine pipeline, from target identification to bedside decision support, promising more individualised diagnosis and treatment selection than population-averaged, one-size-fits-all approaches allow.

**Objective:** To critically synthesise current evidence on AI/ML applications in precision medicine within the domains of medical biotechnology, drug discovery, multi-omics and pharmacogenomics, medical imaging, clinical trial methodology, and clinical decision support, and to appraise the regulatory and ethical frameworks governing their translation into practice.

**Data Sources:** PubMed/MEDLINE, Scopus- and Web of Science-indexed journals, and publications from Nature Portfolio, The Lancet, Cell Press, Elsevier, Wiley, Oxford University Press, and MDPI were searched for literature published predominantly between 2019 and 2026, supplemented by landmark earlier studies and current regulatory guidance from the US Food and Drug Administration (FDA).

**Review Methods:** A narrative review format was adopted given the methodological heterogeneity and breadth of the subject area. Evidence was appraised for study design, data provenance, and generalisability, with emphasis on comparing findings across studies rather than sequential summarisation.

**Key Findings:** AI/ML tools now assist therapeutic target discovery and de novo molecular design, multi-omics-based patient stratification, radiomic and pathomic biomarker discovery, clinical trial risk prediction and patient-trial matching, and large language model (LLM)-based clinical decision support. Regulatory agencies have responded with lifecycle-oriented frameworks such as the FDA predetermined change control plan, yet prospective validation, external generalisability, and demonstrable impact on patient-relevant outcomes remain limited for most applications. Algorithmic bias arising from unrepresentative training data and proxy-outcome selection continues to threaten equitable deployment.

**Conclusion:** AI/ML methods offer credible, increasingly validated tools for advancing precision medicine within biotechnology and pharmaceutical sciences, but their clinical adoption should proceed in step with prospective evidence generation, total-product-lifecycle regulatory oversight, and deliberate bias mitigation.

**Keywords**

Precision Medicine; Artificial Intelligence; Machine Learning; Pharmacogenomics; Drug Discovery; Biotechnology, Medical

**Corresponding author:**

Siddela Johnson,  
AU College of Pharmaceutical Sciences (AUCOPS),  
Andhra University, Visakhapatnam,  
Andhra Pradesh, India

**QR CODE**

Please cite this article in press Battula Sammaiah et al., Artificial Intelligence And Machine Learning In Precision Medicine: Applications In Medical Biotechnology., Indo Am. J. P. Sci, 2026; 13(08).

## 1. INTRODUCTION:

Precision medicine seeks to match diagnostic and therapeutic decisions to the genomic, molecular, and phenotypic characteristics of individual patients rather than to the average response observed in a trial population.<sup>1</sup> Its realisation has depended on the parallel expansion of high-throughput sequencing, multi-omics profiling, digital imaging, and electronic health record (EHR) systems, all of which generate data at a scale and dimensionality that conventional biostatistical methods struggle to model. Artificial intelligence and machine learning, particularly deep learning architectures capable of learning hierarchical representations directly from raw data, have therefore moved from a peripheral computational curiosity to a central methodological pillar of biomedical research and pharmaceutical development.<sup>12</sup>

Despite a rapidly expanding literature, most AI/ML applications in precision medicine remain confined to retrospective, single-institution validation. Comparative appraisals across drug discovery, multi-omics integration, medical imaging, and clinical decision support are relatively scarce, and reviews addressing medical biotechnology often treat AI as a generic enabling technology rather than critically examining where the evidence for clinical benefit is strong, where it is preliminary, and where regulatory and ethical uncertainty persists. This fragmentation makes it difficult for clinicians, pharmaceutical scientists, and regulatory professionals to judge which applications are ready for translational investment and which require further methodological maturation.

This review synthesises evidence on AI/ML applications across the precision medicine pipeline, spanning therapeutic target identification, multi-omics-driven pharmacogenomics, radiomic and pathomic biomarker discovery, clinical trial design and patient matching, and generative AI-based clinical decision support. It further examines the evolving regulatory science governing AI-enabled medical products, principally the FDA's total product life cycle

(TPLC) framework, and considers the ethical implications of algorithmic bias for equitable precision medicine. The intent is to provide pharmacy and biomedical researchers with a critically appraised, comparative account of where AI/ML currently stands within medical biotechnology, rather than a further catalogue of individual applications.

## 2. AI/ML Methodologies Relevant to Precision Medicine

The methodological repertoire applied to precision medicine spans classical supervised learning (regression, random forests, support vector machines), unsupervised clustering for patient stratification, deep neural networks, graph neural networks (GNNs) for modelling molecular and biological interaction networks, and, more recently, transformer-based foundation models and large language models.<sup>1</sup> GNNs have proved particularly suited to drug–target interaction prediction, in which molecules and proteins are naturally represented as graphs, while transformer architectures underlie both protein structure prediction tools and LLM-based clinical text processing. Explainability remains a persistent methodological concern: complex ensemble and deep learning models frequently outperform simpler models on predictive accuracy but yield outputs that are difficult for clinicians and regulators to interrogate, motivating a distinct sub-field of explainable AI (XAI) for digital health.<sup>2</sup>

Model choice is rarely independent of data type. Genomic and transcriptomic data favour dimensionality-reduction and autoencoder-based approaches; radiological and histopathological images favour convolutional and, increasingly, vision-transformer architectures; and unstructured clinical text favours LLMs fine-tuned or retrieval-augmented for the biomedical domain. A methodological synthesis of AI/ML techniques and their representative precision medicine applications is presented in Table 1.

Table 1. Selected AI/ML Techniques and Representative Applications in Precision Medicine

| AI/ML Technique                       | Underlying Principle                                              | Representative Application                                           | Illustrative Reference           |
|---------------------------------------|-------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------|
| Graph neural networks                 | Learns representations over molecular/protein interaction graphs  | Drug–target interaction and target identification                    | Pun et al., 2026 <sup>5</sup>    |
| Deep learning (CNN/transformer)       | Hierarchical feature extraction from imaging or sequence data     | Radiomics, digital pathology, protein structure prediction           | Jumper et al., 2021 <sup>3</sup> |
| Autoencoders / variational models     | Compresses high-dimensional multi-omics data into latent features | Multi-omics integration, drug response prediction                    | Molla & Bitew, 2024 <sup>8</sup> |
| Large language models                 | Transformer-based sequence modelling of clinical/biomedical text  | Clinical decision support, trial–patient matching, pharmacovigilance | Jin et al., 2024 <sup>13</sup>   |
| Explainable AI (SHAP, attention maps) | Post-hoc or intrinsic model interpretability methods              | Biomarker interpretation, regulatory transparency                    | Allen, 2024 <sup>2</sup>         |

### 3. AI in Target Identification and Drug Discovery

Therapeutic target identification has traditionally been constrained by the fact that, of roughly 20,000 protein-coding genes in the human genome, only a minority are considered pharmacologically tractable, and approved drugs collectively act on a few hundred distinct targets.<sup>5</sup> AI-driven analysis of large-scale multi-omic and biological network data has reframed target discovery as a systematic, data-driven search rather than a largely serendipitous process, with AI-nominated targets increasingly reaching clinical-stage development.<sup>5</sup> A comprehensive appraisal of AI/ML across the 2019–2024 drug discovery literature found consistent gains from deep learning, graph neural networks, and transformer architectures in target identification, lead optimisation, and preclinical safety assessment, though the authors cautioned that reported performance often reflects retrospective benchmarks rather than prospective, wet-laboratory-confirmed success.<sup>6</sup>

Structural biology has been reshaped by deep learning-based protein structure prediction, which now allows near-experimental accuracy for many single-chain proteins directly from amino acid sequence and has been extended to genome-scale prediction of missense variant pathogenicity.<sup>34</sup> These tools accelerate structure-based drug design and variant interpretation, but their performance degrades for intrinsically disordered regions, multi-chain complexes, and

proteins with limited evolutionary homologues, so predictions still require experimental or orthogonal computational corroboration before being used to guide costly downstream drug development decisions.

Across these applications, a consistent methodological gap is the scarcity of prospective validation: most published models are benchmarked on retrospective or synthetic datasets, and comparative head-to-head evaluation across competing architectures remains uncommon, complicating judgements about which AI/ML approach offers genuine advantage for a given discovery problem rather than incremental benchmark improvement.

### 4. Multi-Omics Integration and Pharmacogenomics

Drug response phenotypes are rarely governed by a single genetic variant; more commonly they reflect interacting networks of genomic, transcriptomic, proteomic, epigenetic, and metabolic variation.<sup>7</sup> Multi-omics integration attempts to capture this complexity by combining data layers that were historically analysed in isolation, and AI methods, particularly autoencoders, variational models, and graph-based architectures, have improved prediction of drug sensitivity, toxicity, and treatment response relative to single-omics or conventional statistical approaches.<sup>8</sup> Deep learning models applied to combined transcriptomic and genomic data have

achieved high discriminative performance in pan-cancer drug-sensitivity prediction, and biologically informed network architectures have additionally improved interpretability without sacrificing accuracy, addressing one of the principal clinical objections to deep learning-based pharmacogenomic tools.<sup>8</sup>

Clinical pharmacogenomics implementation, however, continues to lag behind the analytic literature. Established single-gene pharmacogenetic associations (for example, in metabolising-enzyme polymorphisms) already inform dosing guidance through consortia such as the Clinical Pharmacogenetics Implementation Consortium, yet translation of AI-derived multi-omic risk scores into similarly actionable, guideline-endorsed recommendations remains preliminary.<sup>7</sup> A comparative reading of the multi-omics literature suggests that model performance gains are frequently reported *in silico*, with far fewer studies demonstrating that AI-guided pharmacogenomic stratification changes clinician prescribing behaviour or improves patient-relevant outcomes such as adverse drug event rates.<sup>8</sup> Practical obstacles, including heterogeneous data formats across omics platforms, small and non-diverse cohort sizes, and the absence of harmonised reference standards, continue to constrain external validity.

Neurodegenerative disease research illustrates both the promise and the current limits of this approach. Proteomics-anchored multi-omics integration has been used to characterise amyloid metabolism, synaptic dysfunction, and neuroinflammatory pathways in Alzheimer disease, with proteomics most frequently paired with transcriptomic data; however, the same body of work highlights persistent difficulty in harmonising heterogeneous datasets and in interpreting integrated models biologically, underscoring that data integration capacity has outpaced mechanistic interpretability across neurodegenerative and oncological applications alike.<sup>12</sup>

### 5. AI in Medical Imaging: Radiomics, Radiogenomics, and Digital Pathology

Radiomics extracts high-dimensional quantitative features from routinely acquired computed tomography, magnetic resonance imaging, and positron emission tomography data on the premise that voxel-level image heterogeneity reflects underlying tumour biology.<sup>9</sup> Deep learning radiomic frameworks combining imaging and molecular data have been used to non-invasively predict tumour molecular alterations

and treatment sensitivity in non-small-cell lung cancer, offering a complementary or alternative route to invasive tissue biopsy for treatment selection.<sup>10</sup> Circulating tumour DNA-based longitudinal models have similarly been associated with survival outcomes in metastatic non-small-cell lung cancer, illustrating convergence between imaging-based and liquid-biopsy-based precision oncology biomarkers.<sup>9</sup>

A decade-long bibliometric analysis of colorectal cancer radiomics research documented a marked acceleration in publication volume after 2019, concentrated in a small number of countries and institutions, which raises questions about the generalisability of published radiomic signatures to populations and imaging protocols outside those settings.<sup>11</sup> This geographic and institutional concentration recurs across the AI-in-imaging literature and is a recognised contributor to the broader external-validity problem discussed in Section 9. Digital pathology and pathomics extend the same logic to histological images, with AI-based tissue analysis increasingly combined with radiomic and genomic features to predict immunotherapy response, though as with pharmacogenomic applications, most evidence remains retrospective and single-centre, and formal quality frameworks for radiomic reproducibility are still being consolidated.

### 6. AI in Clinical Trial Design, Recruitment, and Risk Prediction

Clinical trial recruitment is a long-standing bottleneck in drug development, and AI-based matching systems that mine electronic health records, genetic databases, and medical histories against protocol eligibility criteria have been proposed to accelerate and broaden participant identification.<sup>13</sup> An LLM-based patient-to-trial matching system benchmarked against clinical trial eligibility criteria demonstrated the feasibility of automating a task that has historically relied on labour-intensive manual chart review, with anticipated benefit for reducing recruitment delay and for improving representation of populations that are traditionally under-enrolled in clinical research.<sup>13</sup>

Beyond recruitment, AI methods are being applied to trial risk prediction across safety, efficacy, and operational domains, drawing on data sources ranging from molecular structures and trial protocols to patient-level records and the scientific literature. Adverse drug event prediction and treatment-effect estimation models employing traditional machine learning, graph neural networks, transformers, and causal machine learning have shown high discriminative performance in retrospective analyses,

and large language models have featured with increasing frequency in this application space since 2023. However, this literature is characterised by selection bias in the underlying training cohorts, a shortage of prospective studies, and variable data quality, meaning that reported predictive accuracy should be interpreted as an upper bound on real-world performance rather than an expectation of routine trial-level benefit.

### 7. Generative AI and Large Language Models in Clinical Decision Support and Pharmacovigilance

Large language models have moved rapidly from general-purpose text generation to domain-adapted clinical applications, including summarisation of clinical text, medication safety alerting, and generalist diagnostic assistance.<sup>1415</sup> Adapted LLMs fine-tuned for clinical text summarisation have outperformed medical experts on selected radiology and progress-note summarisation tasks, and domain-tuned models have reduced medication-direction errors in simulated online pharmacy dispensing scenarios, indicating credible near-term utility for well-scoped, text-centric tasks.<sup>1718</sup> A prospective, cross-over evaluation of an LLM-based clinical decision support tool for prescribing-error detection across sixteen clinical specialties similarly found that LLM assistance improved pharmacist accuracy in medication chart review, although the authors cautioned that clinical generalisability, residual bias, and sensitivity to prompt design still required resolution before routine adoption.

Diagnostic and autonomous decision-making applications present a markedly less favourable evidence picture. A systematic evaluation using a curated set of 2,400 simulated clinical cases found that contemporary LLMs did not diagnose patients as accurately as physicians, did not consistently follow diagnostic or treatment guidelines, and could not reliably interpret laboratory results when used autonomously.<sup>16</sup> This divergence, models performing credibly on narrow, well-defined text tasks but unreliably on open-ended autonomous clinical reasoning, is a recurring and clinically important pattern that distinguishes genuinely translatable near-term applications from those requiring substantially more evidence before deployment. A broader scoping review of generative AI in medication-related harm similarly concluded that, despite promising performance in drug-drug interaction identification and pharmacovigilance signal classification, no included study had tested these models prospectively in real-world practice.<sup>19</sup>

A retrospective evaluation of an EHR-embedded LLM-based decision support system deployed across primary care clinics in Kenya offers a rare real-world, deployment-scale data point: while clinical guidance aligned with local protocols in the large majority of encounters, actively harmful recommendations were identified in a non-trivial minority, underscoring that safety monitoring must extend beyond laboratory benchmarking into continuous, deployment-phase surveillance analogous to pharmacovigilance for conventional therapeutics.

### 8. Regulatory Science and Global Governance of AI-Enabled Medical Products

Conventional medical device regulation was designed around a static, locked software specification, an assumption that does not hold for adaptive AI/ML systems capable of updating their behaviour as new data accrue.<sup>20</sup> The FDA's response, formalised through its AI/ML-based Software as a Medical Device (SaMD) Action Plan, adopts a total product life cycle (TPLC) approach in which premarket evaluation is complemented by structured post-market monitoring.<sup>20</sup> Good Machine Learning Practice principles issued alongside this framework encourage the use of representative, unbiased training datasets, rigorous cybersecurity practices, and transparency with end users regarding algorithm updates.<sup>20</sup>

A central regulatory innovation is the predetermined change control plan (PCCP), finalised in December 2024, which allows manufacturers to pre-specify the anticipated scope of future model modifications (the "SaMD pre-specifications") together with the algorithm change protocol used to validate them, avoiding the need for a new marketing submission for every incremental retraining cycle.<sup>2425</sup> In March 2024, the FDA further published a cross-centre coordination framework spanning drug, biologic, and device regulation, reflecting recognition that AI applications increasingly straddle traditional regulatory silos, for example, an AI-derived imaging biomarker used simultaneously to select patients for a drug trial and to support a companion diagnostic claim.<sup>26</sup> January 2025 draft guidance extended this lifecycle approach explicitly to AI use in producing evidence to support regulatory decision-making for drug and biological products, signalling that regulatory expectations are converging across device and pharmaceutical development pathways rather than remaining domain-specific.

For a pharmacy and biotechnology audience, the practical implication is that regulatory readiness can no longer be treated as a terminal step in product



development; it must be designed into the AI/ML development pipeline from the outset, encompassing dataset provenance documentation, prespecified performance and bias monitoring metrics, and a

change-control strategy anticipated well before initial marketing submission. Table 2 summarises landmark FDA regulatory milestones alongside representative scientific developments across the period reviewed.

Table 2. Landmark Studies and Regulatory Milestones in AI-Enabled Precision Medicine (2019–2025)

| Year | Milestone / Study                                                              | Domain                          | Significance                                                               |
|------|--------------------------------------------------------------------------------|---------------------------------|----------------------------------------------------------------------------|
| 2019 | FDA discussion paper on AI/ML-based SaMD modifications                         | Regulatory                      | First articulation of a lifecycle-based regulatory concept for adaptive AI |
| 2021 | AlphaFold protein structure prediction published (Jumper et al. <sup>3</sup> ) | Drug discovery                  | Near-experimental accuracy protein structure prediction from sequence      |
| 2021 | FDA Good Machine Learning Practice guiding principles                          | Regulatory                      | Ten principles for safe, high-quality AI/ML device development             |
| 2023 | AlphaMissense variant-effect prediction (Cheng et al. <sup>4</sup> )           | Genomics                        | Genome-scale proteome-wide pathogenicity prediction                        |
| 2023 | FDA/M-CERSI workshop on AI/ML for precision medicine <sup>1</sup>              | Regulatory / Precision medicine | Cross-stakeholder consensus on AI/ML opportunities and challenges          |
| 2024 | FDA cross-centre AI coordination framework (CBER/CDER/CDRH/OCP) <sup>26</sup>  | Regulatory                      | Harmonised agency-wide approach to AI oversight                            |
| 2024 | FDA final PCCP guidance for AI-enabled devices <sup>25</sup>                   | Regulatory                      | Enables prespecified, lower-burden model updates                           |
| 2024 | LLM patient-trial matching benchmarked (Jin et al. <sup>13</sup> )             | Clinical trials                 | Automated eligibility screening at scale                                   |
| 2025 | FDA draft guidance on AI in regulatory decision-making for drugs/biologics     | Regulatory                      | Extends lifecycle oversight beyond devices to pharma evidence generation   |

### 9. Ethical, Equity, and Algorithmic Bias Considerations

Algorithmic bias arises when training data, labelling conventions, or model design systematically disadvantage identifiable patient subgroups, and it is now recognised as one of the principal barriers to equitable AI-enabled precision medicine.<sup>21</sup> The most widely cited illustration remains a commercial risk-prediction algorithm that used historical healthcare cost as a proxy for healthcare need; because less has historically been spent on the care of Black patients relative to White patients with comparable clinical

need, the algorithm systematically underestimated illness severity in Black patients, a label-bias problem rather than a simple data-representation shortfall.<sup>21</sup> A related, independently documented example concerns pain-severity prediction models, where an algorithmic approach explicitly designed to reduce unexplained disparities in pain assessment for underserved populations demonstrated that bias mitigation is achievable but requires deliberate methodological intervention rather than passive reliance on larger datasets.<sup>20</sup>

Bias in medical AI is not confined to race and cost proxies. Diagnostic image datasets underrepresenting darker skin tones have produced dermatological AI tools with reduced accuracy for patients with darker skin, and mental health prediction models relying on binary sex categorisation have been shown to underdiagnose conditions in transgender and gender-diverse populations, illustrating that cohort-definition choices made early in model design propagate downstream inequity regardless of overall dataset size.<sup>11</sup> A global review of clinical AI datasets additionally found that more than half originate from the United States or China, with a similarly concentrated authorship base, meaning that models validated in data-rich settings cannot be assumed to generalise safely to data-poor regions, including much of South and Southeast Asia, without local validation. Commentators have cautioned against treating bias purely as a data-completeness problem to be solved by aggregating larger datasets; even representative data can yield biased outputs where model architecture, objective function, or outcome-label selection embeds

discriminatory assumptions, so mitigation requires attention to the full model development pipeline rather than the training corpus alone.<sup>22</sup> In response, a multi-stakeholder panel convened by the US Agency for Healthcare Research and Quality and the National Institute on Minority Health and Health Disparities has proposed guiding principles spanning algorithm development, validation, and deployment, alongside mechanisms for redress when biased algorithms cause harm, principles that are directly transferable to pharmacogenomic and clinical decision support tools developed for resource-limited settings such as those served by institutions like BR Nahata College of Pharmacy.<sup>23</sup> The ethics of LLM deployment in medicine raises additional, partly distinct concerns around informed consent, accountability for AI-generated recommendations, and the risk of automation bias among clinicians, which a recent systematic review characterised as still lacking consensus governance frameworks despite rapid clinical uptake.<sup>19</sup>

Table 3. Advantages and Limitations of AI/ML Approaches Across the Precision Medicine Pipeline

| Pipeline Stage                         | Principal Advantages                                                                                                                  | Principal Limitations                                                                                                                                  |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Target identification / drug discovery | Systematic, data-driven search across large target and chemical space; accelerated structure prediction                               | Retrospective benchmarking predominates; limited prospective wet-lab confirmation; degraded accuracy for disordered/multi-chain proteins               |
| Multi-omics / pharmacogenomics         | Captures cross-layer biological complexity beyond single-gene pharmacogenetics; improved predictive accuracy over single-omics models | Heterogeneous data formats; small, non-diverse cohorts; limited guideline-level clinical translation                                                   |
| Medical imaging (radiomics/pathomics)  | Non-invasive, repeatable biomarker extraction; complements or reduces reliance on invasive biopsy                                     | Geographic/institutional concentration of training data; reproducibility and quality-standardisation still maturing                                    |
| Clinical trial design / recruitment    | Faster, broader eligibility screening; potential to improve enrolment diversity                                                       | Selection bias in training cohorts; scarcity of prospective validation of risk models                                                                  |
| Clinical decision support (LLM-based)  | Strong performance on scoped text tasks (summarisation, alerting); scalable pharmacovigilance signal detection                        | Unreliable for autonomous diagnosis/guideline adherence; hallucination and prompt sensitivity; deployment-phase harm observed in real-world evaluation |

### 10. Future Perspectives

Three trends are likely to shape the near-term trajectory of AI/ML in precision medicine within medical biotechnology. First, foundation models pretrained on large, multi-modal biomedical corpora (combining sequence, imaging, and text data) are progressively replacing narrowly trained, task-specific models, with implications for how regulatory frameworks such as the PCCP will need to accommodate models whose behaviour is defined less by a fixed training set and more by downstream fine-tuning or prompting. Second, federated and privacy-preserving learning approaches, which allow model training across institutions without centralising patient-level data, offer a plausible route to the larger, more geographically diverse training cohorts that current evidence indicates are necessary to address generalisability and bias limitations. Third, regulatory convergence across device, drug, and biologic pathways, evident in the FDA's 2024 cross-centre coordination framework, suggests that future AI-enabled precision medicine products will increasingly be evaluated as integrated diagnostic-therapeutic systems rather than as isolated software or molecular entities.

### 11. Research Gaps

- Prospective, multi-institutional validation of AI/ML tools remains rare relative to the volume of retrospective benchmarking studies across drug discovery, multi-omics, and imaging applications.
- Comparative, head-to-head evaluation of competing AI architectures for the same clinical or discovery task is uncommon, limiting evidence-based selection of methods.
- Outcome measures in much of the literature are technical (accuracy, area under the curve) rather than patient-relevant (adverse event reduction, survival, cost-effectiveness).
- Bias auditing and demographic subgroup reporting are inconsistently performed and inconsistently reported across published AI/ML precision medicine studies.
- Evidence from low- and middle-income country settings, including India, remains sparse relative to the concentration of training data and authorship in the United States and China.

### 12. Clinical Implications

For practising pharmacists and clinicians, the current evidence base supports cautious, task-specific

adoption rather than wholesale reliance on AI/ML tools. LLM-based decision support appears best suited, on present evidence, to bounded tasks such as medication chart review, drug interaction flagging, and clinical text summarisation, where human oversight can readily verify output, rather than to autonomous diagnostic or treatment-selection roles. Multi-omics and radiomic biomarkers show credible promise for treatment stratification in oncology but should, at this stage, be regarded as complementary to, rather than a replacement for, established histopathological and genomic testing pending further prospective validation and, where relevant, regulatory clearance in the jurisdiction of use.

### 13. Limitations of Current Evidence

This review is a narrative synthesis rather than a systematic review, and therefore does not apply formal risk-of-bias or certainty-of-evidence grading (e.g., GRADE) across included studies; conclusions should be interpreted as an informed appraisal rather than a quantitative meta-analytic summary. The underlying primary literature is itself heterogeneous in study design, outcome definition, and reporting standard, and is weighted toward retrospective, single-institution, and non-diverse cohorts, which constrains the strength of any generalisable conclusion about real-world AI/ML performance in precision medicine. Rapid publication turnover in this field also means that some regulatory guidance and reported model performance figures may be superseded shortly after publication.

### 14. CONCLUSION:

Artificial intelligence and machine learning have become methodologically central to precision medicine within medical biotechnology, contributing credible advances in therapeutic target identification, multi-omics-based patient stratification, imaging biomarker discovery, and scoped clinical decision support. The evidence is strongest for well-defined, retrospectively validated technical tasks and weakest for autonomous clinical reasoning and prospective, patient-outcome-level benefit. Regulatory science, exemplified by the FDA's total product life cycle and predetermined change control plan frameworks, is evolving in parallel to accommodate the adaptive nature of these tools, but algorithmic bias arising from unrepresentative data and proxy-outcome design remains an unresolved threat to equitable deployment. Continued translation of AI/ML into precision medicine practice should be paced to the maturity of prospective validation and bias-mitigation evidence



for each specific application, rather than to the pace of technical publication alone.

### Data Availability Statement

No new data were generated or analysed in this review. All information discussed is drawn from previously published, publicly available sources cited in the reference list.

### REFERENCES:

1. Naik K, Goyal RK, Foschini L, Chak CW, Thielscher C, Zhu H, et al. Current status and future directions: the application of artificial intelligence/machine learning for precision medicine. *Clin Pharmacol Ther.* 2024;115(4):673-686. doi:10.1002/cpt.3152
2. Allen B. The promise of explainable AI in digital health for precision medicine: a systematic review. *J Pers Med.* 2024;14(3):277. doi:10.3390/jpm14030277
3. Jumper J, Evans R, Pritzel A, Green T, Figurnov M, Ronneberger O, et al. Highly accurate protein structure prediction with AlphaFold. *Nature.* 2021;596(7873):583-589. doi:10.1038/s41586-021-03819-2
4. Cheng J, Novati G, Pan J, Bycroft C, Žemgulytė A, Applebaum T, et al. Accurate proteome-wide missense variant effect prediction with AlphaMissense. *Science.* 2023;381(6664):eadg7492. doi:10.1126/science.adg7492
5. Pun FW, Ozerov IV, Zhavoronkov A, et al. Target identification and assessment in the era of AI. *Nat Rev Drug Discov.* 2026. doi:10.1038/s41573-026-01412-8
6. Ferreira FJN, Carneiro AS. AI-driven drug discovery: a comprehensive review. *ACS Omega.* 2025. doi:10.1021/acsomega.5c00549
7. Kabbani D, Akika R, Wahid A, Daly AK, Cascorbi I, Zgheib NK. Pharmacogenomics in practice: a review and implementation guide. *Front Pharmacol.* 2023;14:1189976. doi:10.3389/fphar.2023.1189976
8. Molla G, Bitew M. Revolutionizing personalized medicine: synergy with multi-omics data generation, main hurdles, and future perspectives. *Biomedicine.* 2024;12(12):2750. doi:10.3390/biomedicine12122750
9. Assaf ZJF, Zou W, Fine AD, Socinski MA, Stewart R, Ferrara R, et al. A longitudinal circulating tumor DNA-based model associated with survival in metastatic non-small-cell lung cancer. *Nat Med.* 2023;29(4):859-868.
10. Zhang X, et al. Prospective clinical research of radiomics and deep learning in oncology: a translational review. *Biomark Res.* 2024. doi:10.1186/s40364-024-00561-5
11. Li H, Zhuang Y, Yuan W, Gu Y, Dai X, Li M, et al. Radiomics in precision medicine for colorectal cancer: a bibliometric analysis (2013-2023). *Front Oncol.* 2024;14:1464104. doi:10.3389/fonc.2024.1464104
12. Dong JM, Zhong H. Systematic review: proteomics-driven multi-omics integration for Alzheimer's disease pathology and precision medicine. *Neurol Int.* 2025;17(12):197. doi:10.3390/neurolint17120197
13. Jin Q, Wang Z, Floudas CS, Chen F, Gong C, Bracken-Clarke D, et al. Matching patients to clinical trials with large language models. *Nat Commun.* 2024;15:9074. doi:10.1038/s41467-024-53081-z
14. Thirunavukarasu AJ, Ting DSJ, Elangovan K, Gutierrez L, Tan TF, Ting DSW. Large language models in medicine. *Nat Med.* 2023;29(8):1930-1940.
15. Singhal K, Tu T, Gottweis J, Sayres R, Wulczyn E, Hou L, et al. Large language models encode clinical knowledge. *Nature.* 2023;620(7972):172-180.
16. Hager P, Jungmann F, Holland R, Bhagat K, Hubrecht I, Knauer M, et al. Evaluation and mitigation of the limitations of large language models in clinical decision-making. *Nat Med.* 2024.
17. Van Veen D, Van Uden C, Blankemeier L, Delbrouck JB, Aali A, Bluethgen C, et al. Adapted large language models can outperform medical experts in clinical text summarization. *Nat Med.* 2024;30(4):1134-1142.
18. Pais C, Liu J, Voigt R, et al. Large language models for preventing medication direction errors in online pharmacies. *Nat Med.* 2024;30:1574-1582.
19. Haltaufderheide J, Ranisch R. The ethics of ChatGPT in medicine and healthcare: a systematic review on large language models (LLMs). *NPJ Digit Med.* 2024;7:183. doi:10.1038/s41746-024-01131-8
20. Pierson E, Cutler DM, Leskovec J, Mullainathan S, Obermeyer Z. An algorithmic approach to reducing unexplained pain disparities in underserved populations. *Nat Med.* 2021;27(1):136-140.
21. McCradden MD, Joshi S, Mazwi M, Anderson JA. Ethical limitations of algorithmic fairness solutions in health care machine learning. *Lancet Digit Health.* 2020;2(5):e221-e223.

22. Hooker S. Moving beyond 'algorithmic bias is a data problem'. *Patterns*. 2021;2(4):100241.
23. Chin MH, Afsar-Manesh N, Bierman AS, Chang C, Colon-Rodriguez CJ, Dullabh P, et al. Guiding principles to address the impact of algorithm bias on racial and ethnic disparities in health and health care. *JAMA Netw Open*. 2023;6(12):e2345050.
24. US Food and Drug Administration. Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations (Draft Guidance). Silver Spring, MD: FDA; January 2025.
25. US Food and Drug Administration. Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions (Final Guidance). Silver Spring, MD: FDA; December 2024.
26. US Food and Drug Administration. Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together. Silver Spring, MD: FDA; March 2024.