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AI-Driven Precision Oncology for Early Tumor Detection, Molecular Profiling, and Personalized Immunotherapy Optimization

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Abstract: Artificial intelligence (AI) is reshaping precision oncology by enabling earlier tumor detection, high-resolution molecular profiling, and personalized immunotherapy optimization. Rapid advances in deep learning, multimodal data integration, and large-scale biomedical datasets have created opportunities to move beyond traditional organ-based cancer management toward dynamic, biomarker-driven care pathways. This manuscript synthesizes recent translational evidence on AI applications across the oncology continuum, emphasizing three interconnected domains: early tumor detection, molecular characterization, and immunotherapy response prediction. AI-enhanced imaging and digital pathology models demonstrate improved sensitivity for early-stage malignancies and premalignant lesions, while liquid biopsy analytics and multi-cancer early detection algorithms show promise in identifying minimal residual disease. In parallel, machine learning approaches applied to genomics, transcriptomics, and spatial tumor microenvironment data are refining biomarker discovery and therapeutic stratification. For immunotherapy, predictive models integrating tumor mutational burden, immune infiltration patterns, and longitudinal clinical data support optimized patient selection, toxicity forecasting, and adaptive treatment strategies. Despite these advances, challenges remain in external validation, bias mitigation, regulatory oversight, data governance, and equitable deployment. A coordinated translational framework combining rigorous validation, human-in-the-loop clinical decision support, and adaptive monitoring will be essential to ensure safe and effective integration of AI into oncology practice.
Keywords: Precision oncology; Artificial intelligence; Early tumor detection; Molecular profiling; Immunotherapy optimization; Multimodal learning

1. INTRODUCTION

1.1 Precision oncology shift: from organ-based to molecular-based care

Oncology has transitioned from an organ-based model of classification toward a molecularly defined understanding of cancer biology [1]. Historically, tumors were categorized by tissue of origin and histologic appearance, with treatment decisions anchored in anatomical staging systems [2]. However, advances in cancer genomics have demonstrated that tumors arising in distinct organs may share actionable driver mutations, while tumors within the same organ can differ profoundly at the molecular level [3]. The discovery of oncogenic pathways, gene fusions, and targetable mutations has shifted therapeutic logic from location-centered to biomarker-driven intervention [4].

This transformation has led to the development of targeted therapies and companion diagnostics that match treatment to tumor genotype rather than organ site [5]. Precision oncology therefore reframes cancer as a heterogeneous molecular disease requiring individualized profiling and adaptive therapeutic strategies [6]. While this shift enhances specificity, it also increases analytic complexity, as each tumor now generates multidimensional biological data requiring systematic interpretation [7].

1.2 Why AI now: scale of multimodal data and unmet clinical needs

The rapid expansion of multimodal oncology data has created both opportunity and analytical burden [8]. Contemporary cancer care routinely generates high-resolution radiologic imaging, digitized histopathology slides, next-generation sequencing outputs, proteomic signatures, and longitudinal electronic health records (EHRs) [1]. Each modality contributes distinct biological insight, yet integration across these streams exceeds traditional statistical frameworks [2].

For instance, whole-exome sequencing may reveal hundreds to thousands of variants per patient, many of uncertain pathogenic significance [3]. Similarly, digital pathology produces gigapixel-scale images containing spatial tumor microenvironment features that are difficult to quantify manually [4]. Radiomics extracts high-dimensional texture and intensity metrics that correlate with tumor aggressiveness but require computational modeling for clinical use [5].

Artificial intelligence (AI), particularly machine learning and deep neural networks, provides scalable mechanisms to detect latent patterns across such complex datasets [6]. AI models can integrate imaging, genomic, and clinical variables to support risk prediction, subtype classification, and therapeutic matching [7]. The urgency of AI adoption reflects persistent unmet clinical needs, including delayed diagnosis, therapy resistance, heterogeneous immunotherapy response, and disparities in precision testing access [8].

1.3 Scope and aims: early detection, molecular profiling, immunotherapy optimization

This manuscript evaluates AI across three central domains of precision oncology. First, in early detection, AI-driven imaging algorithms and biomarker integration seek to identify malignant transformation before clinical symptom onset, potentially improving survival through earlier intervention [1]. Computational models applied to screening modalities such as radiography and liquid biopsy data can enhance sensitivity while maintaining specificity [2].

Second, AI strengthens molecular profiling by assisting in variant interpretation, pathway mapping, and multi-omics integration [3]. Machine learning approaches can prioritize actionable mutations, model gene interaction networks, and refine tumor subclassification beyond traditional histopathologic criteria [4].

Third, AI contributes to immunotherapy optimization. Although immune checkpoint inhibitors have transformed treatment paradigms, predictive biomarkers such as PD-L1 expression or tumor mutational burden remain imperfect [5]. Integrative AI systems incorporating genomic, transcriptomic, and microenvironmental data can improve response prediction and toxicity forecasting [6]. These domains collectively illustrate how AI bridges discovery science and real-world therapeutic decision-making [7].

Figure 1: End-to-end AI precision oncology pipeline

1.4 Contribution statement: translational framing (bench → bedside), clinical deployment, governance

This article advances a translational framework positioning AI as infrastructure across the precision oncology continuum rather than a standalone analytic tool [8]. From biomarker discovery in research laboratories to deployment in clinical tumor boards, AI systems can support evidence synthesis and individualized treatment selection [1]. Implementation, however, requires robust validation pipelines, reproducibility standards, and bias mitigation strategies to ensure equitable performance across diverse populations [2].

Governance considerations include regulatory oversight, algorithmic transparency, interoperability with hospital information systems, and continuous post-deployment monitoring [3]. Clinical integration must also prioritize interpretability, clinician trust, and workflow compatibility to avoid decision fatigue or overreliance on opaque outputs [4]. By aligning computational innovation with ethical safeguards and health-system readiness, this manuscript provides a systems-level roadmap for translating AI-enabled precision oncology from bench to bedside and into routine monitoring frameworks [5].

2. METHODS

2.1 Review design and rationale (narrative synthesis; clinical-ML translational focus)

This study employs a scoping review combined with technical synthesis and policy/implementation analysis to examine artificial intelligence (AI) applications in precision oncology. A narrative synthesis approach was selected because the field is methodologically heterogeneous, spanning retrospective algorithm development studies, prospective validation trials, translational biomarker research, and early clinical deployment initiatives [6]. Quantitative meta-analysis was not feasible due to variability in model architectures, endpoints, datasets, and reporting standards [7].

The review emphasizes translational integration between machine learning (ML) innovation and clinical oncology workflows. Rather than focusing solely on model performance metrics, the analysis evaluates how AI systems move from discovery environments to real-world clinical implementation [8]. This translational lens aligns with calls to assess AI systems not only for predictive accuracy but also for clinical utility, safety, and health-system readiness [9].

2.2 Evidence sources and selection (2020–2026; clinical AI, oncology trials, biomarker studies, guidelines)

Peer-reviewed literature published between January 2020 and February 2026 was searched using PubMed/MEDLINE, Scopus, Web of Science, IEEE Xplore, and major oncology conference proceedings. Search terms included combinations of: “precision oncology,” “artificial intelligence,” “machine learning,” “deep learning,” “radiomics,” “digital pathology,” “multi-omics integration,” “immunotherapy prediction,” and “clinical deployment.” Studies were prioritized if they reported clinical AI applications in early cancer detection, molecular profiling, or immunotherapy response modeling [10].

High-impact oncology trials incorporating AI-assisted biomarker interpretation were included where available [11]. Regulatory guidance documents and professional society

guidelines addressing AI in clinical oncology were also reviewed to contextualize governance and translational standards [12]. Emphasis was placed on studies reporting external validation or prospective clinical evaluation rather than purely technical proofs-of-concept, given the translational focus of this manuscript [13].

2.3 Inclusion and exclusion criteria

Inclusion criteria encompassed: (1) AI or ML systems applied to early cancer detection (imaging or biomarker-based); (2) computational models supporting molecular or multi-omics profiling; (3) predictive models for immunotherapy response or toxicity; and (4) real-world deployment or implementation analyses. Both retrospective and prospective designs were considered if clinical endpoints were reported [14].

Excluded were purely methodological algorithm papers lacking oncology context, simulation studies without patient data, editorials without empirical evaluation, and non-English publications without accessible translation. Studies focused exclusively on general healthcare AI without oncology-specific endpoints were also excluded to maintain domain specificity [6].

2.4 Data abstraction (model type, dataset, validation, endpoints, bias/fairness, clinical utility)

For each included study, data were abstracted on: model architecture (e.g., convolutional neural network, transformer, ensemble learning), dataset characteristics (sample size, modality, geographic source), validation approach (internal cross-validation, external cohort, prospective trial), and primary clinical endpoints (diagnostic accuracy, survival, response prediction) [7]. Additional extraction captured bias and fairness assessments, subgroup performance, interpretability strategies, and evidence of workflow integration or clinical impact [8].

2.5 Quality appraisal approach

Quality considerations were guided by emerging reporting standards for clinical AI, including TRIPOD-AI, PROBAST-AI, and CONSORT-AI principles, focusing on transparency, risk-of-bias assessment, reproducibility, and prospective validation rigor [9].

3. FOUNDATIONS: DATA MODALITIES AND CLINICAL ENDPOINTS

3.1 Data modalities overview (radiology, digital pathology, genomics/transcriptomics, proteomics, ctDNA, EHR)

AI-enabled precision oncology relies on integrating multiple data modalities, each capturing distinct biological dimensions of cancer. Radiology (CT, MRI, PET) supports radiomics extraction of texture, shape, and intensity features associated with tumor aggressiveness and treatment response [12]. Deep learning models can detect subtle imaging patterns beyond human perception, enabling early lesion characterization and response monitoring [13].

Digital pathology involves whole-slide imaging (WSI) of hematoxylin and eosin (H&E)–stained tissue, from which convolutional neural networks can infer tumor grade, molecular subtypes, and microenvironmental composition [14].

Genomics and transcriptomics provide mutational profiles, copy-number alterations, gene-expression signatures, and pathway activity metrics central to molecular stratification [15]. These omics layers are increasingly analyzed using integrative multi-modal AI frameworks.

Proteomics captures downstream functional signaling states, complementing genomic data and enabling dynamic biomarker discovery [16].

Circulating tumor DNA (ctDNA) and other liquid biopsy platforms allow minimally invasive monitoring of tumor burden and clonal evolution [17].

Finally, electronic health records (EHRs) provide longitudinal clinical trajectories, laboratory results, comorbidities, and treatment histories essential for real-world model calibration and outcome prediction [18]. Together, these modalities form the computational substrate of AI precision oncology systems.

3.2 Labels and endpoints that matter clinically (AUC vs calibration, sensitivity at fixed specificity, time-to-event, net benefit)

Model evaluation in oncology must move beyond isolated discrimination metrics such as the area under the receiver operating characteristic curve (AUC). While AUC measures ranking ability, it does not assess calibration the agreement between predicted probabilities and observed outcomes which is essential for clinical decision-making [19].

For screening and early detection tasks, sensitivity at fixed high specificity is often more relevant than global AUC, as false positives can trigger unnecessary biopsies or procedures [12]. In prognostic modeling, time-to-event endpoints (e.g., progression-free survival, overall survival) require survival analysis techniques and concordance indices rather than binary classification metrics [15].

Clinical utility must also be assessed through decision-curve analysis, which estimates net benefit across risk thresholds and better reflects real-world consequences of implementation [20]. Without careful endpoint alignment, high-performing AI models risk limited translational impact despite strong statistical performance.

3.3 Dataset construction pitfalls (class imbalance, spectrum bias, leakage, site effects, batch effects)

Dataset construction critically influences AI performance and generalizability. Class imbalance is common in oncology, particularly in early detection where cancer prevalence is low; models may achieve inflated accuracy by favoring majority classes unless appropriate resampling or weighting strategies are applied [13].

Spectrum bias arises when training datasets overrepresent advanced or clinically obvious cases, limiting model applicability to subtle or early-stage presentations [14]. Data leakage, including inadvertent inclusion of post-diagnosis

variables or correlated duplicates across training and validation splits, can artificially inflate performance metrics [19].

Multi-center datasets introduce site effects, where scanner types, staining protocols, or sequencing platforms encode institutional signatures rather than biological signals [16]. In omics research, batch effects can distort expression patterns if not normalized appropriately [15]. Addressing these pitfalls requires rigorous preprocessing pipelines, stratified splitting, and transparency in dataset reporting [20].

3.4 Validation hierarchy (internal, external, temporal, prospective; trial-embedded evaluation)

Robust validation follows a hierarchical framework. Internal validation (cross-validation or bootstrapping) assesses model stability within the development dataset but does not ensure generalizability [12]. External validation on independent datasets from different institutions or populations is critical for transportability [17].

Temporal validation, using data from later time periods, evaluates performance under evolving clinical practices and demographic shifts [18]. The highest standard involves prospective validation, ideally embedded within clinical trials or real-world implementation studies, where AI predictions are evaluated against predefined endpoints in real time [11].

Trial-embedded AI assessment enables measurement of clinical impact, workflow integration, and patient-centered outcomes rather than solely statistical metrics [20]. Progressing through this validation hierarchy is essential for safe and equitable clinical deployment.

Table 1. Modalities → Typical Features → Key Clinical Endpoints → Failure Modes

Modality	Typical Features	Key Clinical Endpoints	Common Failure Modes
Radiology	Texture, shape, intensity radiomics [12]	Detection sensitivity; response prediction	Spectrum bias; site effects
Digital Pathology	Spatial morphology, tumor microenvironment patterns [14]	Grade prediction; molecular inference	Staining variability; data leakage
Genomics/Transcriptomics	Mutational burden; gene expression signatures [15]	Target identification; survival prediction	Batch effects; overfitting
Proteomics	Protein abundance; pathway activation [16]	Therapy response	Platform variability
ctDNA	Variant allele frequency; clonal evolution [17]	Minimal residual disease; relapse risk	Low signal-to-noise
EHR	Longitudinal labs; comorbidities; treatment timelines [18]	Time-to-event; toxicity prediction	Missing data; confounding

4. EARLY TUMOR DETECTION AND RISK STRATIFICATION

4.1 Imaging-based detection

Imaging has historically anchored cancer screening and early detection, with modalities such as mammography, low-dose CT (LDCT) for lung cancer, MRI for prostate and breast cancer, and multiphasic CT for abdominal malignancies forming the clinical backbone of population-level surveillance [18]. Early computer-aided detection (CAD) systems relied on rule-based feature engineering and threshold-based alerts; however, these systems often produced high false-positive rates and limited generalizability [19].

Deep learning architectures particularly convolutional neural networks (CNNs) have since transformed imaging analytics by enabling end-to-end feature extraction directly from pixel data [20]. In mammography, AI systems can identify subtle microcalcifications and architectural distortions, supporting radiologist triage and second-read workflows [21]. For LDCT lung screening, deep models quantify nodule morphology, spiculation, and volumetric growth dynamics to refine malignancy probability beyond traditional size-based criteria [22]. MRI-based models similarly leverage multiparametric sequences to improve detection of clinically significant prostate cancer while potentially reducing unnecessary biopsies [23].

Despite strong discrimination performance in retrospective datasets, clinical deployment requires careful attention to scanner heterogeneity, site effects, and population diversity [24]. Integration into workflow also matters: AI can function as a triage tool prioritizing high-risk scans or as a concurrent reader augmenting human interpretation [25]. The evolution from CAD to deep learning reflects not merely improved accuracy but a shift toward adaptive, data-driven imaging ecosystems.

4.2 Digital pathology for early malignant transformation

Digital pathology, enabled by whole-slide imaging (WSI), provides gigapixel-resolution representations of tissue architecture that capture early malignant transformation at cellular and microenvironmental scales [18]. Deep learning

models trained on WSI can classify tumor grade, detect preinvasive lesions, and infer molecular subtypes directly from hematoxylin and eosin (H&E) slides [20].

Given the scale and labeling burden of WSI data, weakly supervised learning and multiple instance learning (MIL) approaches have become prominent [21]. In these frameworks, slide-level labels (e.g., cancer vs benign) guide patch-level feature aggregation without requiring exhaustive pixel-level annotation. Attention-based MIL models further enable localization of diagnostically salient regions while maintaining slide-level classification performance [22].

For early detection tasks, gland segmentation and lesion detection algorithms can quantify dysplasia or architectural distortion suggestive of early malignant transformation [23]. However, staining variability, scanner differences, and limited external validation can constrain generalizability [24]. Harmonization of digital pathology workflows and cross-site validation are therefore essential before widespread deployment [25]. When integrated effectively, AI-augmented pathology can enhance diagnostic precision and potentially reduce interobserver variability in early lesion interpretation.

4.3 Liquid biopsy and minimal residual disease

Liquid biopsy technologies, particularly circulating tumor DNA (ctDNA), offer minimally invasive opportunities for early detection and monitoring of minimal residual disease (MRD) [19]. AI models applied to ctDNA leverage features such as mutation patterns, methylation signatures, fragment length distributions (fragmentomics), and copy-number alterations to detect malignancy-associated signals in peripheral blood [20].

Methylation-based classifiers can differentiate tissue-of-origin patterns, enabling detection of multiple tumor types from a single assay [21]. Fragmentomics captures nucleosome positioning and cfDNA fragmentation patterns that reflect tumor biology [22]. These approaches are particularly promising for MRD detection after curative-intent therapy, where ultra-sensitive models aim to identify relapse months before radiographic evidence [23].

However, early detection through ctDNA faces inherent tradeoffs. Sensitivity in very early-stage disease may be limited by low tumor fraction, while false positives can arise from clonal hematopoiesis or technical noise [24]. AI systems must therefore balance detection thresholds carefully and incorporate confirmatory pathways to avoid unnecessary downstream procedures [25]. Robust calibration and prospective validation remain critical before routine screening adoption.

4.4 Multi-cancer early detection (MCED): design constraints, false positives, downstream cascade burden

Multi-cancer early detection (MCED) platforms seek to identify signals from multiple tumor types within a single screening test, often leveraging ctDNA methylation or integrated biomarker panels [18]. While conceptually appealing, MCED introduces design complexities, including disease prevalence heterogeneity, variable tumor shedding rates, and the need for accurate tissue-of-origin localization [21].

Even modest false-positive rates can generate substantial downstream diagnostic cascades in population screening contexts, including imaging, biopsies, and psychological burden [24]. Therefore, specificity must be extremely high to maintain acceptable positive predictive value in low-prevalence populations [19]. AI calibration and subgroup analysis are essential to ensure equitable performance across demographic strata [20]. Implementation frameworks must incorporate confirmatory algorithms and evidence-based follow-up pathways to minimize harm while preserving early detection benefits [25].

4.5 Risk prediction models

Risk stratification models aim to personalize screening intensity based on integrated risk profiles. Polygenic risk scores (PRS), derived from genome-wide association data, quantify inherited susceptibility and can be combined with clinical variables such as age, smoking status, family history, and comorbidities [22]. When integrated with imaging priors or radiomic features, these models support dynamic risk updating across time [23].

Individualized screening intervals informed by AI-based risk prediction may reduce over-screening in low-risk individuals while intensifying surveillance for high-risk populations [20]. However, PRS portability across ancestries remains limited, raising equity concerns [24]. Transparent calibration, subgroup reporting, and validation across diverse populations are therefore necessary before adopting risk-adaptive screening strategies [25]. When implemented responsibly, AI-driven risk models could align screening intensity with biologic and environmental heterogeneity.

4.6 Evaluation and clinical utility (decision curves, cost/harms, workflow integration, triage vs diagnosis)

Evaluation of AI-based early detection tools must extend beyond discrimination metrics to include clinical utility and health-system feasibility [19]. Decision-curve analysis estimates net benefit across risk thresholds and helps determine whether AI-guided strategies outperform standard practice [20]. Cost-effectiveness modeling should account for diagnostic cascade burden, false-positive harms, and resource allocation constraints [24].

Workflow integration is equally critical. AI tools may function as triage systems prioritizing high-risk cases or as diagnostic adjuncts augmenting clinician judgment [21]. Clear role definition affects performance expectations, liability frameworks, and training requirements [23]. Prospective implementation studies measuring patient-centered outcomes, clinician acceptance, and operational efficiency are essential to translate promising algorithms into sustainable early detection programs [25].

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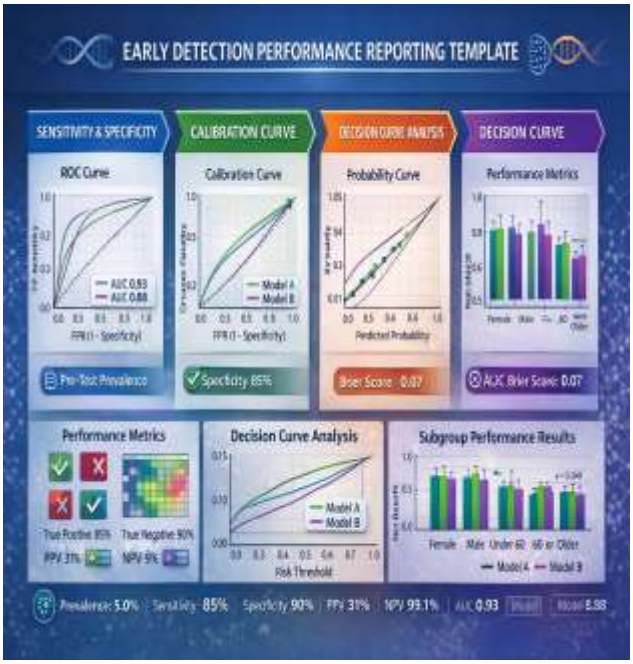

Figure 2: Early detection performance reporting template.

5. AI-ENABLED MOLECULAR PROFILING AND BIOMARKER DISCOVERY

5.1 Variant interpretation and somatic calling augmentation (quality control, artifact detection, tumor purity estimation)

Next-generation sequencing (NGS) has become foundational in precision oncology, yet raw variant calls require extensive quality control and contextual interpretation before clinical actionability can be determined [24]. AI systems increasingly augment somatic variant calling pipelines by distinguishing true mutations from sequencing artifacts, polymerase errors, or low-quality reads. Deep neural networks trained on curated reference datasets can improve sensitivity for low-allele-frequency variants while maintaining specificity [25].

Tumor purity estimation quantifying the proportion of malignant cells within a biopsy sample is critical for accurate variant interpretation. Machine learning models can infer tumor purity from copy-number patterns, variant allele frequencies, and histopathology-derived cellularity metrics [26]. Such integration reduces false negatives caused by stromal contamination or low tumor fraction.

Additionally, AI-based artifact detection addresses challenges such as oxidative DNA damage signatures and formalin-induced cytosine deamination in FFPE samples [27]. By embedding quality-aware algorithms upstream of clinical reporting, AI enhances reproducibility and reduces interpretive burden within molecular tumor boards [28].

5.2 Transcriptomic and proteomic signatures (pathway-level learning, latent embeddings, single-cell + spatial context)

Beyond discrete mutations, transcriptomic and proteomic profiling provide functional insight into tumor biology. RNA sequencing (RNA-seq) captures gene-expression patterns reflecting pathway activation, immune infiltration, and metabolic states [29]. AI-driven representation learning, including autoencoders and transformer architectures, can generate latent embeddings that summarize high-dimensional expression matrices into biologically meaningful features [30]. These embeddings often outperform single-gene biomarkers by capturing pathway-level interactions and regulatory networks.

Proteomic platforms further extend this analysis by measuring protein abundance and post-translational modifications, which may better reflect functional pathway activity than transcript levels alone [24]. Machine learning models integrating transcriptomic and proteomic data can identify concordant signaling axes or discordant regulatory events associated with drug sensitivity or resistance [31].

Single-cell RNA sequencing (scRNA-seq) adds another dimension by resolving tumor heterogeneity and immune cell subpopulations within the microenvironment [29]. AI clustering algorithms and graph-based neural networks can map lineage trajectories and identify rare but clinically significant subclones. Incorporating spatial transcriptomic context further refines interpretation by preserving tissue architecture and cell–cell interactions [32].

Collectively, pathway-level learning and latent embeddings enable multi-layered biomarker discovery, moving precision oncology from mutation-centric to systems-level characterization [30].

5.3 Spatial transcriptomics + pathology fusion (microenvironment mapping, tumor–immune niches, FFPE constraints)

Spatial transcriptomics technologies integrate gene-expression profiling with preserved tissue architecture, allowing mapping of tumor–immune niches and stromal interactions [32]. AI models applied to spatial datasets can identify immune-excluded regions, tertiary lymphoid structures, or hypoxic microenvironments associated with therapeutic response [29].

Fusion of spatial transcriptomic data with digital pathology images enhances interpretability. Convolutional neural networks can align histomorphologic features with spatial gene-expression gradients, generating composite maps that link morphology to molecular phenotype [25]. Such integration enables identification of microenvironmental patterns predictive of immunotherapy responsiveness or resistance.

However, spatial technologies face constraints, particularly when using FFPE (formalin-fixed paraffin-embedded) samples. RNA degradation, limited probe coverage, and technical noise may affect signal fidelity [27]. AI-based imputation and denoising strategies attempt to reconstruct missing signals or harmonize across platforms, but careful validation is required [26].

Despite these limitations, pathology–spatial fusion represents a frontier in contextual biomarker discovery, emphasizing that cancer behavior emerges not only from tumor cells but from their ecological niches [30].

5.4 Knowledge graphs and foundation models for oncology

The exponential growth of oncology literature and curated genomic databases challenges human capacity to synthesize actionable insights. Knowledge graphs structured representations linking genes, proteins, pathways, drugs, and clinical outcomes provide a computational scaffold for integrative reasoning [31]. AI systems can mine biomedical literature and curated repositories (e.g., COSMIC, ClinVar, OncoKB) to populate graph-based networks that associate somatic alterations with therapeutic implications [24].

Foundation models trained on large-scale biomedical corpora enable context-aware interpretation of variant–drug relationships and emerging clinical evidence [32]. By embedding structured and unstructured data, these models can support automated evidence summarization and hypothesis generation for molecular tumor boards [28].

Graph neural networks further enable pathway-level reasoning, predicting drug–target interactions or resistance mechanisms through relational embeddings [29]. However, transparency and traceability remain critical; automated reasoning must be auditable and anchored in validated sources to avoid propagation of spurious associations [26]. When governed responsibly, knowledge graphs and foundation models accelerate translation from molecular discovery to therapeutic strategy.

5.5 Clinical-grade reporting (actionability tiers, reproducibility, audit trails, explainability for molecular tumor boards)

For AI-supported molecular profiling to achieve clinical impact, outputs must be translated into standardized, reproducible reports. Actionability frameworks such as tiered classification systems linking variants to levels of clinical evidence provide structured interpretation pathways [24]. AI systems must align predictions with these tiers and document evidence provenance to support regulatory compliance and clinical trust [28].

Reproducibility is strengthened through version-controlled pipelines, standardized reference genomes, and audit trails capturing data preprocessing, model parameters, and inference logs [25]. Explainability mechanisms such as feature attribution maps or pathway importance scores assist clinicians in understanding model rationale [30].

Molecular tumor boards require interpretable summaries that integrate variant significance, pathway context, therapeutic options, and eligibility for clinical trials [31]. Transparent reporting frameworks are essential to ensure that AI outputs support not supplant multidisciplinary clinical judgment.

Table 2. Biomarker Pipeline Checklist—from Sample QC to Clinical Actionability Statement

Stage	Key Elements	AI Role	Risks if Unaddressed
Sample QC	Tumor purity, sequencing depth, artifact detection [26]	Automated quality filtering	False negatives/positives
Variant Calling	Somatic mutation identification [25]	Error correction, low-VAF detection	Misclassification
Multi-omics Integration	Expression + proteomics + spatial context [29]	Latent embeddings, graph modeling	Overfitting
Evidence Linking	Drug–target–pathway mapping [31]	Knowledge graph reasoning	Unsupported recommendations
Clinical Reporting	Actionability tiers, audit logs [24]	Structured interpretability	Regulatory risk

5.6 Robustness and generalization

Robustness remains a central challenge in AI-enabled molecular profiling. Batch effects arising from sequencing platforms, reagent lots, or site-specific protocols can introduce systematic bias in gene-expression or proteomic datasets [27]. AI-driven normalization and domain adaptation techniques attempt to align distributions across centers while preserving biological signal [26].

Federated learning frameworks allow multi-center model training without centralized data sharing, enhancing privacy while increasing diversity and generalizability [32]. Such approaches are particularly valuable in oncology, where rare mutations require large, distributed cohorts for reliable modeling [29].

Nevertheless, cross-site harmonization requires rigorous benchmarking, reproducible preprocessing standards, and continuous monitoring for performance drift [25]. Transparent validation across demographic and geographic subgroups is essential to ensure equitable biomarker performance [24]. Robust generalization strategies ultimately determine whether AI-driven molecular profiling remains confined to research settings or achieves scalable clinical integration.

6. PERSONALIZED IMMUNOTHERAPY OPTIMIZATION

6.1 Immunotherapy landscape and response variability (ICI, CAR-T, bispecifics; primary vs acquired resistance)

Immunotherapy has transformed oncology, particularly through immune checkpoint inhibitors (ICIs) targeting PD-1/PD-L1 and CTLA-4 pathways, chimeric antigen receptor T-cell (CAR-T) therapies, and emerging bispecific T-cell

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engagers [30]. Despite durable responses in subsets of patients, clinical benefit remains heterogeneous across tumor types and individuals. A substantial proportion of patients exhibit primary resistance, characterized by lack of initial response, while others develop acquired resistance following an initial period of tumor control [31].

Mechanisms underlying resistance include tumor-intrinsic alterations affecting antigen presentation, immune evasion strategies, and microenvironmental suppression. Clinical variability is further influenced by tumor burden, prior therapies, and host immune competence [32]. As immunotherapy expands across malignancies, there is increasing demand for predictive tools capable of stratifying likely responders and minimizing exposure to ineffective or toxic regimens. AI systems offer integrative modeling capacity to address these multifactorial determinants of response variability [33].

6.2 Predicting response: tumor intrinsic signals (TMB, MSI, neoantigens, HLA loss) + AI integration

Tumor intrinsic genomic features play a central role in immunotherapy response prediction. Tumor mutational burden (TMB) correlates with neoantigen generation and has been associated with improved ICI responsiveness in selected contexts [34]. Microsatellite instability (MSI) and mismatch repair deficiency confer high mutation rates and strong immunogenicity, supporting tissue-agnostic therapeutic approvals [35].

However, TMB and MSI alone provide incomplete predictive precision. AI-based integrative models can synthesize mutational signatures, predicted neoantigen load, and clonal architecture to refine response probabilities [30]. Loss of heterozygosity in human leukocyte antigen (HLA) loci or defects in antigen-processing machinery can impair immune recognition, contributing to resistance even in tumors with high TMB [31].

Machine learning approaches combining somatic mutation profiles, copy-number alterations, and transcriptomic immune activation signatures outperform single-biomarker thresholds [32]. Graph-based models can also contextualize genomic alterations within immune regulatory pathways, identifying compensatory mechanisms or escape routes [33]. Importantly, AI integration supports continuous rather than binary risk scoring, enabling nuanced probability-based therapeutic guidance. External validation across diverse populations remains essential to ensure transportability and equitable performance [34].

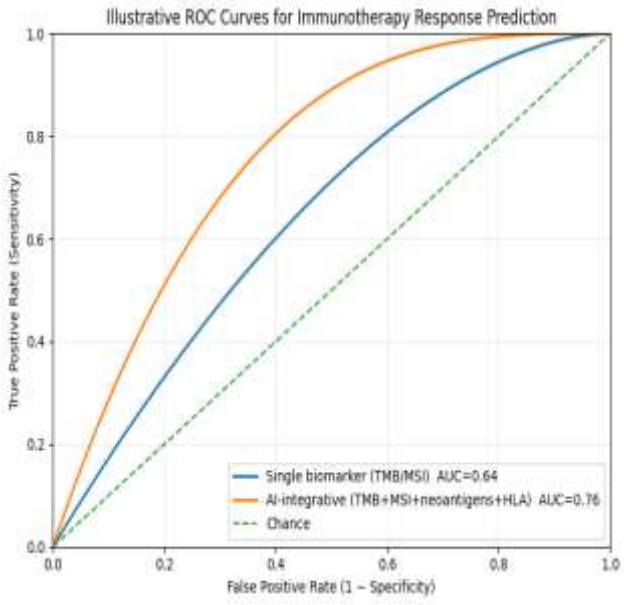

Figure 3 ROC Curves for Immunotherapy Response Prediction

6.3 Microenvironment-based prediction (TIL quantification, immune phenotypes in WSI, spatial immune exclusion metrics)

Beyond tumor-intrinsic genomics, the tumor microenvironment (TME) strongly influences immunotherapy response. Quantification of tumor-infiltrating lymphocytes (TILs) has prognostic and predictive value across multiple cancers [35]. Digital pathology algorithms can automatically enumerate TIL density, classify immune cell subtypes, and assess spatial proximity between immune and tumor cells within whole-slide images (WSI) [30].

AI-derived immune phenotyping frameworks identify patterns such as “inflamed,” “immune-excluded,” and “immune-desert” tumors, each associated with distinct therapeutic responsiveness [31]. Spatial transcriptomics further enables mapping of cytokine gradients and immune checkpoint expression within specific niches, refining response prediction beyond bulk RNA metrics [32].

Metrics quantifying immune exclusion—such as stromal barriers preventing T-cell infiltration—have been associated with resistance to ICIs [33]. Deep learning models integrating histologic architecture with spatial immune signals generate composite microenvironment scores predictive of survival and treatment benefit [34].

Standardization of staining protocols and cross-site validation remain critical challenges, as microenvironment metrics are sensitive to technical variability [36]. Nevertheless, AI-driven microenvironment modeling enhances mechanistic understanding and supports more personalized immunotherapy selection.

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6.4 Treatment selection and sequencing (combination therapies, toxicity-aware optimization, multi-objective models)

Optimal immunotherapy often requires combination strategies, including dual checkpoint blockade, immunotherapy plus chemotherapy, or integration with targeted agents [37]. Selecting and sequencing these regimens is complex, balancing efficacy against toxicity and cost. AI-based multi-objective optimization models can evaluate competing endpoints such as progression-free survival, immune-related adverse events (irAEs), and quality-of-life metrics to support individualized treatment strategies [30].

Reinforcement learning frameworks have been explored to simulate adaptive therapy sequences, adjusting treatment intensity based on longitudinal response signals [31]. Predictive models can also stratify patients for monotherapy versus combination therapy based on integrated genomic and microenvironmental profiles [32].

Decision-support systems must incorporate clinician override mechanisms and safety thresholds to ensure responsible deployment [33]. Integration within electronic health record systems facilitates real-time data ingestion and continuous model updating [34].

Figure 4: AI decision support for immunotherapy.

6.5 Dose, schedule, and toxicity prediction (irAEs risk models, early warning signals from labs/vitals/notes)

Immune-related adverse events (irAEs) represent significant complications of checkpoint blockade and CAR-T therapies. AI models trained on laboratory trends, vital signs, medication histories, and unstructured clinical notes can identify early warning signals predictive of toxicity [35]. Natural language processing (NLP) algorithms extract symptom descriptions and clinician annotations to detect subtle early manifestations of immune-mediated colitis, hepatitis, or endocrinopathies [30].

Risk models incorporating baseline autoimmune status, inflammatory markers, and genomic predisposition aim to forecast irAE likelihood prior to treatment initiation [36]. Such predictive frameworks may inform dose modification or intensified monitoring schedules.

Temporal modeling of laboratory trajectories using recurrent neural networks or transformer-based architectures enables dynamic toxicity risk updating during therapy [37]. Transparent calibration and clinician engagement are essential to prevent alarm fatigue and ensure actionable integration into clinical workflows [31].

6.6 Adaptive monitoring and resistance tracking (ctDNA dynamics, imaging response, longitudinal representation learning)

Resistance to immunotherapy often emerges through clonal evolution or immune escape. Longitudinal monitoring with ctDNA provides quantitative assessment of tumor burden and early detection of molecular relapse [32]. AI models analyzing ctDNA dynamics such as variant allele frequency trajectories can identify resistance patterns before radiographic progression [34].

Imaging-based response assessment also benefits from AI-enabled volumetric and texture analysis that detects subtle changes in tumor morphology, distinguishing pseudoprogression from true progression [30].

Longitudinal representation learning techniques integrate repeated genomic, imaging, and clinical data into dynamic embeddings reflecting evolving disease states [33]. Such models support adaptive therapy adjustment, potentially switching regimens at early signs of resistance.

Continuous validation, drift monitoring, and integration with multidisciplinary review remain essential safeguards as AI-guided adaptive monitoring becomes more prevalent [38].

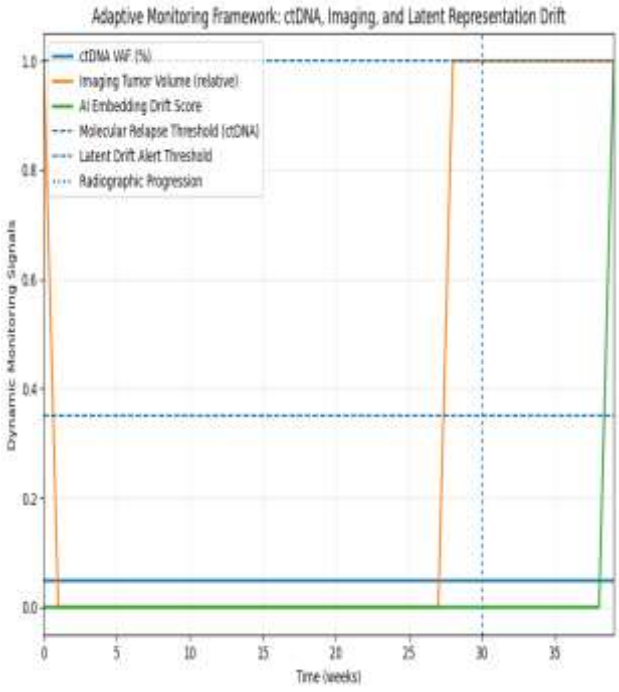

Figure 5 Adaptive Monitoring Framework: ctDNA Imaging and Latent Representation Drift

7. CLINICAL TRANSLATION, DEPLOYMENT, AND GOVERNANCE

7.1 Workflow integration (radiology/pathology/EHR; triage vs second read; turnaround time; human-in-the-loop)

Successful AI deployment in oncology depends on seamless workflow integration across radiology, pathology, molecular diagnostics, and electronic health record (EHR) systems [37]. In radiology and digital pathology, AI can function either as a triage tool, prioritizing high-risk studies for expedited review, or as a second reader, augmenting clinician interpretation without altering primary workflow responsibility [38]. The choice influences expectations for sensitivity, specificity, and accountability.

Turnaround time is critical in oncology, where diagnostic delays may affect treatment initiation. AI systems must operate within clinically acceptable latency thresholds and integrate directly with PACS, LIS, and EHR interfaces [39].

Human-in-the-loop architectures remain essential. Clinician oversight, override capability, and transparent confidence outputs ensure that AI supports rather than replaces expert judgment [40]. Continuous feedback loops between clinicians and model developers further refine performance and contextual calibration within local practice environments [41].

7.2 Prospective evaluation designs (silent trials, stepped-wedge, pragmatic RCTs, trial-embedded AI)

Prospective evaluation is necessary to determine real-world impact beyond retrospective performance metrics. Silent trials, in which AI predictions are generated but not shown to clinicians, allow assessment of baseline accuracy and calibration without influencing care [37].

Stepped-wedge designs, where sites transition sequentially from control to AI-assisted workflows, enable evaluation across multiple institutions while controlling for temporal trends [42].

Pragmatic randomized controlled trials (RCTs) can compare AI-assisted decision-making with standard care, measuring patient-centered outcomes such as time to treatment, adverse events, or survival [43].

Embedding AI models within ongoing oncology trials allows concurrent validation in well-characterized populations and predefined endpoints [38]. Such trial-embedded AI evaluation strengthens causal inference and supports regulatory approval pathways. Transparent reporting of subgroup performance and implementation metrics is essential to ensure safe and equitable deployment [44].

7.3 Regulatory and quality management (model change control, monitoring drift, documentation, validation packages)

Clinical AI systems must adhere to regulatory frameworks governing software as a medical device. Model change control procedures document updates to training data, architecture, or thresholds and assess potential impact on safety and performance [45].

Post-deployment monitoring is critical to detect performance drift, which may arise from evolving clinical practices, demographic shifts, or laboratory protocol changes [39]. Quality management systems require structured documentation, audit trails, and reproducible validation packages demonstrating external and prospective testing [40].

Periodic recalibration and revalidation ensure sustained reliability across patient populations. Regulatory submissions increasingly emphasize transparency in data provenance, model explainability, and risk mitigation strategies [41]. Establishing robust governance processes protects patient safety and builds institutional trust in AI-supported oncology systems.

7.4 Equity and fairness (subgroup performance, representativeness, access, calibration by ancestry/sex/age)

Equity considerations are central to AI-enabled precision oncology. Models trained predominantly on data from specific geographic or demographic populations may exhibit reduced performance in underrepresented groups [42]. Subgroup performance reporting stratified by ancestry, sex, age, and socioeconomic status is therefore essential [37].

Calibration drift across populations can lead to over- or underestimation of risk, potentially exacerbating disparities in screening or treatment allocation [43]. Ensuring dataset representativeness and inclusive recruitment in validation studies improves fairness and generalizability [44].

Access disparities also extend beyond algorithmic performance to infrastructure availability, digital pathology adoption, and genomic testing capacity. Ethical deployment requires aligning technological innovation with health-system equity strategies to prevent widening precision oncology gaps [45].

7.5 Privacy and security (federated learning, de-identification limits, consent, cybersecurity in oncology pipelines)

Oncology datasets contain sensitive genomic and longitudinal clinical information, raising privacy and cybersecurity concerns. Federated learning approaches enable multi-center model training without centralized data sharing, reducing privacy risks while preserving analytic power [39].

However, de-identification does not fully eliminate re-identification risk, particularly with genomic data [41]. Transparent consent frameworks and secure data governance are therefore necessary. Robust cybersecurity protocols protect oncology pipelines from breaches that could compromise patient confidentiality or model integrity [42].

7.6 Implementation economics (cost-effectiveness, capacity constraints, reimbursement considerations)

AI adoption in oncology must demonstrate economic value. Cost-effectiveness analyses should account for diagnostic accuracy gains, avoided adverse events, reduced unnecessary procedures, and workflow efficiencies [43]. Capacity constraints including digital infrastructure, workforce training, and computational resources may limit scalability [44].

Reimbursement frameworks must align incentives with validated clinical benefit to support sustainable integration [45].

Table 3. Deployment Risk Register—Risk, Clinical Impact, Detection, Mitigation, Owner

Risk	Clinical Impact	Detection	Mitigation	Owner
Performance drift	Misclassification, delayed treatment	Ongoing monitoring metrics [39]	Periodic recalibration	Clinical AI governance team
Data bias	Unequal subgroup outcomes	Subgroup audits [42]	Diverse validation cohorts	Data science lead
Workflow disruption	Delays, clinician resistance	User feedback surveys [40]	Human-in-the-loop integration	Department head
Cybersecurity breach	Data compromise	Security audits [41]	Encryption, access controls	IT security
Regulatory non-compliance	Legal/safety risk	Documentation review [45]	Structured change control	Regulatory affairs

8. RESEARCH GAPS AND FUTURE DIRECTIONS

8.1 Multimodal foundation models and generalist oncology agents (limits, evaluation standards)

Large-scale multimodal foundation models promise generalist oncology capabilities across imaging, genomics, and clinical text streams [37]. However, performance claims often rely on retrospective benchmarking rather than prospective validation. Evaluation standards must emphasize calibration, subgroup fairness, and real-world clinical endpoints [43]. Robust external validation across diverse cancer types and institutions remains limited. Transparent reporting frameworks and open benchmarking datasets are necessary before widespread clinical adoption of generalist oncology agents [45].

8.2 Data sharing and harmonization (federation, standards, reference datasets, annotation scaling)

Progress in AI precision oncology depends on harmonized, multi-institutional datasets. Federated learning frameworks mitigate privacy concerns but require interoperable data standards and shared ontologies [39]. Reference datasets with high-quality annotations enable benchmarking and reproducibility [42]. Scalable annotation strategies combining expert labeling with weak supervision are needed to sustain growth in digital pathology and multi-omics modeling [44].

8.3 Causal and counterfactual learning for treatment decisions (confounding, transportability, trial emulation)

Predictive accuracy alone is insufficient for treatment decision-making. Causal inference frameworks, counterfactual modeling, and trial emulation methods are needed to address confounding and improve transportability across populations [43]. Integrating causal reasoning into AI models may better support sequencing decisions and adaptive therapy optimization [45]. Prospective, trial-embedded evaluations remain the gold standard for validating causal impact.

8.4 Limitations

Evidence maturity varies substantially across modalities, with imaging-based AI more advanced than spatial transcriptomics or ctDNA monitoring. Many studies remain retrospective and single-center, limiting generalizability. Publication bias toward high-performing models may overstate clinical readiness [37]. Prospective deployment data and pragmatic trials remain scarce [43]. Additionally, reporting standards are evolving, complicating cross-study comparison [45]. Equity analyses are inconsistently reported, and long-term safety monitoring is limited. These constraints highlight the need for cautious interpretation and continued rigorous validation before routine clinical implementation.

9. CONCLUSION

9.1 Integrated synthesis: early detection + molecular profiling + immunotherapy optimization as one learning system

AI-enabled precision oncology should not be viewed as a collection of isolated tools but as a continuously learning system spanning early detection, molecular profiling, and immunotherapy optimization. Imaging-based screening identifies suspicious lesions; molecular profiling characterizes tumor biology; immunotherapy models refine treatment selection and monitor resistance. When connected through interoperable data pipelines and feedback loops, these components reinforce one another. Early detection generates annotated cases that improve downstream biomarker modeling. Molecular profiling informs adaptive therapy decisions and resistance tracking. Longitudinal monitoring data recalibrate risk prediction and screening strategies. This closed-loop architecture transforms precision oncology from episodic intervention to dynamic disease management, where each clinical interaction contributes to iterative model refinement and improved patient-level decision support.

9.2 Actionable takeaways: what to implement now vs what requires trials and infrastructure

Immediate implementation should prioritize externally validated imaging triage tools, standardized molecular reporting frameworks, and toxicity risk monitoring integrated into clinical workflows. Institutions can deploy governance structures, drift monitoring, and subgroup performance audits without waiting for new infrastructure. In contrast, multi-cancer early detection platforms, foundation models, and adaptive reinforcement-based therapy sequencing require

prospective trials, harmonized multi-center datasets, and robust regulatory pathways before safe, large-scale deployment.

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