AI-Enabled Digital Biomarkers for Precision Cancer Diagnosis, Prognosis, and Therapeutic Monitoring

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ABSTRACT:
Cancer remains one of the leading causes of morbidity and mortality worldwide despite remarkable advances in molecular diagnostics, targeted therapeutics, immunotherapy, and precision medicine. The rapid expansion of digital health technologies, medical imaging, wearable biosensors, digital pathology, genomic sequencing, electronic health records, and mobile health platforms has introduced a new generation of digital biomarkers capable of continuously characterizing disease biology and patient health. Artificial intelligence (AI) has emerged as the primary computational engine for transforming these heterogeneous digital data streams into clinically actionable biomarkers that support early diagnosis, prognostic prediction, therapeutic optimization, treatment response assessment, toxicity monitoring, and long-term survivorship care. Machine learning, deep learning, transformer architectures, graph neural networks, multimodal foundation models, self-supervised learning, digital twins, and generative AI now enable integration of radiological imaging, computational pathology, multi-omics, physiological monitoring, laboratory biomarkers, wearable devices, and longitudinal clinical records into unified patient-specific computational models. AI-enabled digital biomarkers have demonstrated growing utility across cancer screening, radiogenomics, immunotherapy prediction, adaptive treatment planning, clinical decision support, and real-time disease monitoring. Nevertheless, important challenges remain regarding biomarker validation, standardization, explainability, interoperability, regulatory approval, cybersecurity, ethical governance, and equitable implementation. This review provides a comprehensive overview of AI-enabled digital biomarkers in oncology, highlighting computational principles, clinical applications, implementation challenges, and future perspectives for precision cancer diagnosis, prognosis, and therapeutic monitoring.[1]

Keywords: Digital biomarkers, Artificial intelligence, Precision oncology, Machine learning, Digital health, Medical imaging, Computational pathology, Wearable devices, Personalized medicine, Clinical decision support.

Received Date: 5 December 2025; **Accepted Date:** 15 December 2025; **Published Date:** 20 December 2025.

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1.Introduction

Cancer is a biologically heterogeneous disease characterized by genomic instability, epigenetic alterations, immune heterogeneity, metabolic reprogramming, and continuous interactions between malignant cells and the tumor microenvironment. Although molecular diagnostics have substantially improved personalized cancer treatment, conventional biomarkers often provide only limited snapshots of disease biology and may not adequately capture dynamic changes occurring throughout diagnosis, treatment, and survivorship.[2]

Recent advances in digital health technologies have enabled continuous acquisition of patient-specific biomedical information through radiological imaging, digital pathology, wearable biosensors, mobile health applications, laboratory investigations, electronic health records, physiological monitoring, and real-world clinical documentation. These technologies generate enormous volumes of longitudinal digital information that reflect both tumor biology and patient health status.[3]

Artificial intelligence has emerged as a transformative technology capable of extracting clinically meaningful digital biomarkers from these complex multimodal datasets. Unlike traditional biomarkers measured at isolated time points, AI-enabled digital biomarkers continuously evolve as new patient information becomes available, supporting adaptive precision medicine throughout the entire cancer care continuum.[4]

The integration of artificial intelligence with digital biomarkers is redefining precision oncology by enabling predictive, personalized, preventive, and continuously learning clinical decision-making that extends beyond conventional molecular diagnostics.[5]

2.Evolution of Digital Biomarkers in Oncology

Conventional oncology has historically relied on tissue-based biomarkers, serum biomarkers, histopathological findings, and radiological assessments to guide diagnosis and treatment. Although these biomarkers remain clinically valuable, many require invasive procedures and often fail to reflect dynamic biological changes occurring during disease progression.[6]

The emergence of digital medicine introduced new opportunities for continuously monitoring patient health through wearable technologies, medical imaging, digital pathology, physiological sensors, mobile applications, and electronic health records. These digital data sources generated novel forms of measurable biological information known as digital biomarkers.

Simultaneously, advances in machine learning, deep learning, multimodal artificial intelligence, transformer architectures, and foundation models enabled automated interpretation of these highly complex datasets, substantially expanding the clinical utility of digital biomarkers across precision oncology.[7]

Today, AI-enabled digital biomarkers extend beyond static measurements by continuously integrating multimodal patient information into adaptive computational representations capable of supporting diagnosis, prognostic prediction, treatment optimization, toxicity monitoring, and survivorship care.[8]

3.Principles of AI-Enabled Digital Biomarkers

Digital biomarkers are objective, quantifiable physiological, behavioral, anatomical, or molecular measurements collected through digital technologies that provide clinically meaningful information regarding disease status or therapeutic response. Artificial intelligence transforms these heterogeneous measurements into predictive computational biomarkers through automated feature extraction, multimodal integration, and longitudinal learning.[9]

Unlike conventional biomarkers derived from isolated laboratory tests, digital biomarkers integrate information originating from radiological imaging, digital pathology, genomic sequencing, wearable biosensors, physiological monitoring, laboratory investigations, mobile health applications, and electronic health records.

Machine learning identifies complex nonlinear relationships among these diverse information sources, whereas deep learning automatically extracts hierarchical representations from high-dimensional biomedical data. Continuous incorporation of longitudinal patient information allows digital biomarkers to evolve alongside changing disease biology and clinical status.[10]

4.Computational Architecture of Digital Biomarker Systems

Modern digital biomarker platforms consist of multiple interconnected computational layers responsible for data acquisition, preprocessing, multimodal integration, predictive modeling, longitudinal monitoring, and clinical decision support.[11]

The acquisition layer collects biomedical information from radiological imaging, digital pathology, genomic sequencing, laboratory biomarkers, wearable biosensors, physiological sensors, medication records, treatment history, and electronic health records. Advanced preprocessing pipelines normalize imaging studies, harmonize molecular datasets, process physiological signals, encode clinical narratives, and synchronize longitudinal information.

Artificial intelligence subsequently transforms these heterogeneous datasets into unified computational representations using multimodal learning, transformer architectures, graph neural networks, and self-supervised foundation models.

DOI: https://doi.org/10.65477/ijmdas.2025.v1.i6.10

Predictive algorithms continuously update digital biomarkers as additional patient information becomes available, supporting adaptive precision oncology throughout diagnosis, treatment, follow-up, and survivorship.[12]

5.Imaging-Derived Digital Biomarkers

Medical imaging represents one of the richest sources of digital biomarkers within oncology. Computed tomography, magnetic resonance imaging, positron emission tomography, mammography, ultrasound, and hybrid imaging provide continuous non-invasive characterization of tumor morphology, vascularity, metabolism, and disease progression.[13]

Artificial intelligence extracts quantitative radiomic biomarkers describing tumor shape, texture, heterogeneity, intensity, vascularization, and spatial organization. These computational imaging biomarkers substantially improve diagnosis, molecular subtype prediction, therapeutic response assessment, recurrence estimation, and survival prediction beyond conventional visual interpretation.

Longitudinal radiomic analysis further enables continuous monitoring of treatment response through quantitative comparison of sequential imaging studies, allowing earlier identification of therapeutic resistance and disease progression while facilitating adaptive clinical management.[14]

6.Digital Pathology Biomarkers

Digital pathology has become another major source of AI-enabled digital biomarkers through conversion of conventional microscope slides into ultra-high-resolution whole-slide images suitable for computational analysis.[15]

Artificial intelligence evaluates millions of microscopic tissue regions simultaneously to generate quantitative biomarkers describing tumor morphology, histological grade, mitotic activity, lymphovascular invasion, stromal remodeling, angiogenesis, immune infiltration, cellular heterogeneity, and tissue architecture.

Deep learning and transformer-based pathology models further infer clinically relevant molecular biomarkers—including EGFR mutations, KRAS mutations, HER2 amplification, microsatellite instability, estrogen receptor status, progesterone receptor status, PD-L1 expression, and Ki-67 proliferation index—directly from routine histopathological images.

These computational pathology biomarkers complement radiological imaging while strengthening personalized diagnosis and therapeutic planning.[16]

7.Multi-Omics and Molecular Digital Biomarkers

Modern precision oncology increasingly depends upon integration of genomics, transcriptomics, proteomics, metabolomics, epigenomics, immunomics, lipidomics, and single-cell sequencing into comprehensive molecular digital biomarkers. Artificial intelligence analyzes these high-dimensional molecular datasets to identify clinically actionable mutations, signaling pathways, therapeutic targets, resistance mechanisms, and prognostic signatures.[17]

Multimodal learning integrates molecular biomarkers with imaging, pathology, laboratory investigations, and clinical information into unified patient-specific computational representations. These integrated molecular biomarkers substantially improve diagnosis, prognostic prediction, biomarker discovery, and personalized therapeutic decision-making.

Continuous incorporation of emerging molecular information enables adaptive digital biomarker evolution throughout disease progression and treatment.[18]

8.Wearable Technologies and Physiological Digital Biomarkers

Wearable biosensors have created new opportunities for continuous patient monitoring outside conventional healthcare settings. Smartwatches, activity trackers, implantable biosensors, remote physiological monitoring devices, and mobile health platforms continuously measure heart rate, respiratory rate, physical

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activity, sleep quality, temperature, oxygen saturation, and additional physiological variables relevant to oncology care.[19]

Artificial intelligence analyzes these longitudinal physiological datasets to generate digital biomarkers reflecting treatment tolerance, functional decline, cardiovascular toxicity, fatigue, recovery, quality of life, and disease progression. Integration of wearable-derived biomarkers with imaging, pathology, laboratory investigations, and clinical documentation supports continuous precision oncology while enabling proactive clinical intervention before significant deterioration occurs.[20]

9.Artificial Intelligence for Diagnostic and Prognostic Digital Biomarkers

Artificial intelligence has substantially expanded the clinical utility of digital biomarkers by enabling simultaneous analysis of imaging, pathology, molecular biology, wearable technologies, laboratory investigations, and longitudinal clinical information. Rather than relying on isolated diagnostic tests, AI integrates heterogeneous biomedical data into unified computational biomarkers that provide comprehensive characterization of disease biology.[21]

Machine learning algorithms estimate cancer diagnosis, molecular subtype, recurrence probability, progression-free survival, overall survival, metastatic potential, and treatment-related complications using multimodal digital biomarkers. These predictive models continuously improve as additional clinical information becomes available, supporting increasingly individualized patient management.

By combining multiple digital data sources, artificial intelligence enables more accurate diagnostic and prognostic assessment than conventional single-modality biomarkers while strengthening precision oncology across diverse cancer types.

10.Digital Biomarkers for Therapeutic Monitoring

One of the greatest strengths of AI-enabled digital biomarkers lies in continuous therapeutic monitoring throughout cancer treatment. Artificial intelligence integrates sequential imaging studies, digital pathology, laboratory investigations, wearable sensor data, medication history, and patient-reported outcomes to evaluate treatment effectiveness in real time.[22]

Dynamic computational biomarkers quantify tumor regression, residual disease, physiological recovery, treatment adherence, adverse effects, and emerging therapeutic resistance. These continuously updated biomarkers allow clinicians to modify treatment strategies before clinically significant disease progression occurs.

Such adaptive monitoring substantially improves therapeutic precision while minimizing unnecessary toxicity, reducing ineffective treatment exposure, and facilitating individualized cancer care.

11.Digital Biomarkers in Immunotherapy and Precision Medicine

Immunotherapy has transformed cancer treatment; however, identifying patients most likely to benefit remains a major clinical challenge. AI-enabled digital biomarkers integrate radiological imaging, digital pathology, immunomics, transcriptomics, laboratory biomarkers, and longitudinal clinical information to characterize tumor–immune interactions and predict immunotherapy responsiveness.[23]

Artificial intelligence evaluates tumor-infiltrating lymphocytes, PD-L1 expression, tumor mutational burden, cytokine signaling, immune-cell spatial organization, and physiological changes occurring during treatment to estimate response to immune checkpoint inhibitors, CAR-T cell therapies, cancer vaccines, bispecific antibodies, and adoptive cellular therapies.

These multimodal digital biomarkers support increasingly personalized immunotherapeutic strategies while enabling continuous assessment of immune activation and treatment efficacy throughout the therapeutic course.

DOI: https://doi.org/10.65477/ijmdas.2025.v1.i6.10

12.Digital Twins and Continuous Patient Monitoring

The convergence of digital biomarkers with digital twin technology is creating continuously evolving computational representations of individual patients capable of integrating radiological imaging, pathology, genomics, wearable biosensors, laboratory biomarkers, physiological monitoring, and longitudinal clinical records into adaptive virtual models.[24]

Artificial intelligence continuously updates these digital twins as new digital biomarker information becomes available, allowing simulation of disease progression, therapeutic response, recurrence risk, treatment-related toxicity, and long-term clinical outcomes.

By combining digital biomarkers with predictive computational modeling, digital twins support adaptive clinical decision-making while facilitating highly personalized precision oncology throughout diagnosis, treatment, follow-up, and survivorship.

13.Clinical Decision Support and Digital Oncology Ecosystems

AI-enabled digital biomarkers are becoming central components of intelligent clinical decision-support systems within modern oncology. These computational platforms integrate imaging-derived biomarkers, computational pathology, molecular diagnostics, wearable technologies, laboratory investigations, medication history, electronic health records, and patient-reported outcomes into unified digital healthcare ecosystems.[25]

Interactive dashboards provide clinicians with individualized diagnostic summaries, therapeutic recommendations, toxicity estimates, recurrence predictions, survival probabilities, and evidence-based clinical pathways while continuously incorporating newly acquired patient information.

These intelligent decision-support systems reduce administrative burden, improve multidisciplinary collaboration, facilitate early intervention, and support evidence-based personalized medicine throughout the cancer care continuum.

14.Explainable Artificial Intelligence, Ethics, and Regulatory Challenges

Successful implementation of AI-enabled digital biomarkers requires transparency, reliability, and clinician confidence. Explainable artificial intelligence (XAI) enables healthcare professionals to understand computational reasoning through saliency maps, attention visualization, SHAP (Shapley Additive Explanations), feature attribution methods, uncertainty estimation, and counterfactual explanations that identify variables contributing most strongly to digital biomarker predictions.[26]

Several important challenges remain. Standardization of digital biomarker acquisition, interoperability among healthcare systems, algorithmic bias, patient privacy, cybersecurity, informed consent, regulatory approval, validation across diverse populations, and equitable access continue to influence widespread implementation.

Addressing these barriers will require robust computational standards, secure digital infrastructure, prospective multicenter clinical validation, transparent governance frameworks, and close collaboration among clinicians, engineers, computer scientists, regulatory agencies, and healthcare organizations.

15.Future Perspectives

Rapid advances in computational medicine continue to expand the capabilities of AI-enabled digital biomarkers. Multimodal foundation models, large language models, digital twins, federated learning, agentic artificial intelligence, reinforcement learning, generative AI, liquid biopsy, spatial multi-omics, wearable biosensors, and cloud-native healthcare infrastructure are expected to substantially strengthen digital biomarker ecosystems.[27]

Future intelligent oncology platforms may continuously integrate physiological monitoring, imaging, pathology, molecular biology, environmental exposures, behavioral information, and real-world healthcare data into comprehensive patient-specific computational biomarkers capable

DOI: https://doi.org/10.65477/ijmdas.2025.v1.i6.10

of adaptive clinical reasoning and personalized therapeutic optimization.

These continuously evolving digital biomarker ecosystems are expected to transform cancer management from reactive treatment toward predictive, preventive, and precision healthcare.

16.Discussion

AI-enabled digital biomarkers represent one of the most important advances in computational oncology by transforming heterogeneous biomedical information into continuously evolving indicators of disease biology, therapeutic response, toxicity, and patient health. Unlike conventional biomarkers measured at isolated time points, digital biomarkers continuously integrate multimodal patient information throughout the entire cancer care continuum.[28]

Applications spanning cancer diagnosis, prognostic prediction, therapeutic monitoring, immunotherapy, wearable technologies, digital twins, computational pathology, radiomics, and intelligent clinical decision support demonstrate the remarkable clinical potential of these technologies.

Nevertheless, successful implementation depends upon standardized validation methodologies, explainable artificial intelligence, robust interoperability, secure computational infrastructure, prospective clinical evaluation, and equitable deployment across healthcare systems.

17.Conclusion

AI-enabled digital biomarkers are redefining precision oncology by integrating radiological imaging, digital pathology, molecular biology, wearable technologies, laboratory biomarkers, electronic health records, and longitudinal clinical information into adaptive computational frameworks capable of supporting diagnosis, prognostic prediction, therapeutic monitoring, and personalized cancer care.[29]

Advances in multimodal learning, foundation models, digital twins, federated learning, agentic artificial intelligence, generative AI, and cloud-based healthcare infrastructure are expected to further strengthen these intelligent systems, enabling continuous disease monitoring, adaptive treatment optimization, and evidence-based clinical decision-making.

Although important scientific, technical, ethical, and regulatory challenges remain, ongoing interdisciplinary collaboration among oncologists, radiologists, pathologists, biomedical engineers, computer scientists, digital health specialists, and regulatory agencies will accelerate responsible implementation of AI-enabled digital biomarkers, ultimately improving patient outcomes and advancing the future of precision cancer medicine worldwide.[30]

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