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Review Article

Wearable-Derived Digital Biomarkers in Preventive and Personalized Medicine: Promise, Evidence, and Barriers to Clinical Translation

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Abstract

Wearable technologies now permit near-continuous measurement of physiological and behavioral parameters under free-living conditions. Combined with advances in artificial intelligence (AI), these devices support the development of wearable-derived digital biomarkers that may shift healthcare from a reactive to a preventive and personalized model. This narrative review synthesizes current evidence on the technological foundations, AI-based signal processing, clinical applications, implementation challenges, and future directions of wearable-derived digital biomarkers. Evidence supports their use across cardiovascular disease, diabetes and obesity, neurological and mental health conditions, sleep and respiratory medicine, and remote patient monitoring, where continuous data streams can inform early detection, individualized risk prediction, treatment optimization, and clinical decision-making. We propose a conceptual framework describing how wearable sensing, continuous physiological data acquisition, and AI-based analytics translate into clinically actionable digital biomarkers. At the same time, we argue that enthusiasm has outpaced evidence: few candidate biomarkers have undergone prospective validation in diverse populations, analytical performance varies substantially across devices and skin tones, and demonstration of improved clinical outcomes remains rare. Data quality, validation, standardization, interoperability, algorithm transparency, privacy, cybersecurity, regulatory oversight, and equitable access all constrain clinical adoption. Emerging developments in explainable AI, multimodal data integration, digital twins, and predictive analytics may address some of these constraints. Wearable-derived digital biomarkers hold genuine potential for proactive, patient-centered, data-driven care, but realizing that potential will depend less on new sensors than on rigorous validation, standardization, and equitable implementation.

1. Introduction

From Reactive Healthcare to Preventive and Personalized Medicine

For most of the modern era, medicine has operated reactively: clinical intervention begins after symptoms emerge or disease is established. That model works well for acute illness and emergencies. It works far less well for the chronic conditions that now dominate the global burden of disease, including cardiovascular disease, diabetes mellitus, chronic respiratory disease, neurodegenerative disorders, and cancer [1–3]. These conditions develop insidiously over years, require sustained long-term management, and are poorly served by healthcare systems built around episodic assessment at scheduled visits [4].

Population ageing, rising multimorbidity, escalating healthcare expenditure, workforce shortages, and unequal access to care add further pressure toward more sustainable models of healthcare delivery [5, 6]. A conventional clinical assessment captures only a snapshot of physiological state. What happens between visits stays invisible. That blind spot delays diagnosis, weakens risk prediction, and forecloses early intervention.

These pressures have driven interest in predictive, preventive, personalized, and participatory (P4) medicine, a model closely aligned with precision medicine that integrates genetic, physiological, environmental, and behavioral data to individualize care [7, 8]. Central to this model is monitoring outside the clinic: longitudinal physiological data allow deviations from an individual's own baseline to be detected earlier and support proactive clinical decision-making. This shift has created the conditions for wearable technologies and digital biomarkers to enter preventive and personalized healthcare.

The Emergence of Wearable Technologies and Digital Biomarkers

Over the past two decades, wearable technologies have evolved from simple step counters into platforms capable of tracking physiological, behavioral, and environmental parameters continuously in the real world [9, 10]. Advances in sensor miniaturization, wireless communication, battery life, cloud computing, and AI have carried these devices beyond consumer wellness into clinically oriented applications: remote monitoring, disease management, and personalized care [9, 11].

Current wearable platforms include smartwatches, smart rings, wearable electrocardiographic (ECG) monitors, biosensor patches, continuous glucose monitoring (CGM) systems, smart textiles, and flexible biosensors [9, 12]. These devices continuously monitor cardiovascular, metabolic, respiratory, neurological, and behavioral parameters, and can contribute to early disease detection, risk stratification, treatment monitoring, and chronic disease management outside traditional clinical settings.

The spread of these devices has, in turn, accelerated the development of digital biomarkers: objective, quantifiable physiological or behavioral measures acquired through connected digital technologies [13]. Unlike laboratory biomarkers, which are sampled only at clinical encounters, digital biomarkers are collected continuously during ordinary life, capturing processes such as heart rhythm, sleep, respiration, glucose regulation, physical activity, and gait. They therefore complement conventional markers with longitudinal data that can reveal physiological change earlier, refine individual risk estimates, and track disease continuously.

AI, particularly machine learning and deep learning, amplifies the clinical value of these data by converting large volumes of raw physiological signals into information that supports disease prediction, decision support, and individualized intervention [14, 15]. Wearable sensing, digital biomarkers, and AI together offer a data-driven route to disease prevention and clinical care, though, as this review will argue, one whose evidentiary foundations remain uneven.

Why This Review Is Timely?

Progress in wearable biosensors, flexible electronics, AI, cloud computing, and wireless communication has accelerated the clinical translation of wearable-derived digital biomarkers [9, 12]. These technologies have moved beyond lifestyle tracking to enable continuous physiological assessment for disease prevention, early diagnosis, therapeutic monitoring, and long-term health management, and they are now embedded in remote patient monitoring and telemedicine services [9, 16]. Regulatory bodies and healthcare systems, meanwhile, have intensified efforts to establish frameworks for validation, standardization, interoperability, cybersecurity, and ethical governance of wearable-derived biomarkers [17].

Despite this pace of development, the evidence base remains fragmented. Prior reviews have typically examined a single device class, a single disease area, or a single technological innovation, and few have connected the technological, computational, and clinical dimensions of the field [18]. Fewer still have examined that evidence critically: much of the literature reports analytical feasibility in small, homogeneous cohorts, while the questions that matter for adoption, whether these biomarkers change clinical decisions and improve outcomes, and for whom, remain largely unanswered.

This review addresses that gap in three ways. First, it synthesizes evidence across the full translational pathway, from sensing hardware through AI-based analytics to clinical application and implementation. Second, it appraises that evidence critically, distinguishing analytical validation from clinical validation and clinical utility, and identifying where each is lacking. Third, it proposes an integrated conceptual framework linking wearable technologies, AI-driven analytics, and digital biomarkers to preventive and personalized care, intended to structure both future research and implementation.

Scope and Objectives of the Review

This review provides a comprehensive and critical overview of wearable-derived digital biomarkers and their emerging role in preventive and personalized healthcare. It integrates findings on wearable technologies, AI, and clinical applications to examine how real-time physiological and behavioral data are translated into clinically relevant biomarkers that support early detection, risk prediction, remote monitoring, and tailored care delivery.

The review critically examines the scientific, technological, and translational hurdles that limit clinical adoption, including data quality, analytical and clinical validation, interoperability, privacy, cybersecurity, ethical governance, and evolving regulatory requirements. It also identifies key knowledge gaps and research priorities, particularly around standardization, multimodal integration, explainable AI, equitable implementation, and long-term clinical effectiveness.

Looking ahead, the review proposes an integrated conceptual framework describing the interaction between wearable technologies, AI-driven analytics, and digital biomarkers in preventive and personalized healthcare. By combining technological, computational, clinical, and implementation perspectives in a single translational account, it aims to guide both future research and clinical practice.

2. Digital Biomarkers: Concepts, Technologies, and Scientific Foundations

What Are Digital Biomarkers?

Digital health technologies have changed how human health can be measured and interpreted, extending assessment well beyond traditional clinical measures. Digital biomarkers are a central example of these advances, offering objective, quantifiable insight into physiological and behavioral function that supports real-time monitoring, earlier detection of disease, and more precise treatment planning.

A working definition treats digital biomarkers as objective, quantifiable physiological or behavioral measures collected through connected digital devices and used to explain, predict, or influence health-related outcomes [13]. Whereas conventional biomarkers are derived from biological samples such as blood, urine, saliva, or tissue obtained at clinical encounters, digital biomarkers are sourced from data collected continuously by wearables, smartphones, implantable sensors, and other digital health tools. Because these measurements are taken while people go about ordinary life, they capture a fuller picture of health than any single clinical measurement can.

A defining property of digital biomarkers is that they are continuous, longitudinal, and context-specific. Physical activity, glucose, heart rate, cardiac rhythm, respiration, sleep, gait, body temperature, and stress-related responses all fluctuate across the day. Continuous monitoring makes it possible to establish individual physiological baselines, detect subtle deviations that may precede clinical disease, and characterize variability over time and between individuals [9].

A second property is multimodal integration. Wearable platforms rarely capture a single signal; they collect cardiovascular, metabolic, respiratory, neurological, and behavioral data in parallel. These complementary streams describe complex biological processes more completely and, when combined, can improve disease detection, risk prediction, therapeutic monitoring, and overall health assessment [9].

Digital biomarkers are intended to complement laboratory biomarkers, not replace them. Laboratory measures provide direct biochemical and molecular evidence of disease but are typically obtained intermittently, yielding a snapshot of biological status. Digital biomarkers track physiological function continuously in the real world, enabling earlier recognition of disease trajectories, assessment of treatment response, and proactive intervention. Used together, the two classes of biomarker link molecular evidence with continuous functional assessment.

Nor is their role limited to detection. Digital biomarkers support prediction, prevention, monitoring, and treatment evaluation, and background collection of real-world physiological data enables remote monitoring, personalized treatment adjustment, and objective outcome measurement. As digital health science matures, wearable-derived digital biomarkers are expected to become integral to embedding continuous physiological monitoring in evidence-based practice, provided the validation gaps discussed later in this review are closed.

Table 1 summarizes the key characteristics, data sources, measurement approaches, and clinical applications that distinguish conventional laboratory biomarkers from wearable-derived digital biomarkers, and illustrates how continuous digital monitoring complements traditional diagnostics with longitudinal physiological information.

Table 1: Comparison of Conventional Biomarkers and Wearable-Derived Digital Biomarkers

Feature	Conventional Biomarkers	Wearable-Derived Digital Biomarkers
Definition	Biochemical or molecular indicators measured from biological samples.	Objective physiological or behavioral measures acquired through wearable digital technologies.
Data Source	Blood, urine, saliva, or tissue collected during clinical visits.	Continuous physiological and behavioral data from wearable devices.
Measurement	Intermittent, point-in-time assessments.	Continuous or near-continuous real-world monitoring.
Information Provided	Biochemical and molecular status.	Functional, physiological, and behavioral status.
Clinical Application	Disease diagnosis, prognosis, and treatment monitoring.	Early detection, continuous monitoring, risk prediction, remote care, and personalized medicine.
Data Analysis	Laboratory assays and statistical analysis.	Signal processing, machine learning, and AI-based analytics.
Major Advantages	High analytical accuracy and established clinical validity.	Longitudinal monitoring, early detection, and individualized health assessment.
Major Limitations	Episodic measurements and invasive sample collection.	Data quality, validation, interoperability, privacy, and user adherence.

Wearable Technologies Enabling Digital Biomarkers

Progress in devices capable of real-time, non-invasive, continuous physiological monitoring has been the principal driver of digital biomarker development. Miniaturization, flexible electronics, low-power microprocessors, wireless communication, cloud infrastructure, and AI have together elevated wearables from basic activity trackers to sophisticated health monitoring platforms [11, 12]. Their distinctive contribution is longitudinal physiological data captured during daily life, a view of health that conventional clinic-based diagnostic equipment cannot provide.

Modern wearable technology spans smartwatches, smart rings, wearable biosensors, flexible electronic sensors, skin-mounted patches, and CGM systems. These platforms track heart rate, heart rate variability (HRV), ECG signals, blood oxygen saturation, glucose, respiratory rate, body temperature, physical activity, sleep, and movement [9, 19]. Continuous multidimensional acquisition of these signals has widened the opportunities for disease detection, treatment monitoring, and chronic disease management.

Smartwatches are the most widely adopted class, combining usability with multiple sensing functions, while CGM represents arguably the most clinically successful wearable biosensor application to date, in diabetes care [19, 20]. Skin-mounted patches and smart rings permit unobtrusive long-term monitoring, and emerging platforms such as smart textiles, electronic skin, wearable microfluidic systems, and implantable sensors are opening additional physiological monitoring applications [19].

The significance of these devices extends beyond data collection. Their larger contribution is as a conduit: they supply the physiological raw material that advanced signal processing and AI algorithms transform into clinically meaningful digital biomarkers. By combining multiple physiological streams, wearables can support a more holistic account of health status, disease progression, and treatment response, and thereby more personalized and proactive management.

Anticipated advances in sensing, comfort, interoperability, and computational analytics should further improve the reliability and clinical utility of wearable-derived digital biomarkers, supporting the movement toward intelligent, data-driven health systems capable of continuous monitoring, remote care, and precision medicine. Whether these advances translate into better outcomes, however, will depend on the validation and implementation work described in Section 4.

From Physiological Signals to Clinically Meaningful Digital Biomarkers

Collection alone is not enough. Wearable devices measure cardiovascular function, activity, sleep, respiration, metabolism, and more, but raw signals have little clinical value until they are processed and interpreted. The central task is converting these signals into digital biomarkers reliable enough to support diagnosis, monitoring, risk prediction, and personalized care.

The pipeline begins with embedded sensors detecting electrical, optical, mechanical, thermal, or biochemical changes under real-world conditions. Data acquired during ordinary activity are contaminated by motion artifacts, environmental interference, inconsistent device positioning, and individual physiological variability, and therefore require dedicated preprocessing to improve signal quality [19, 21].

Signal processing techniques remove noise, correct artifacts, and extract clinically relevant features such as temporal variability, waveform morphology, and frequency-domain characteristics. These steps improve the accuracy and repeatability of wearable-derived measures and enable detection of subtle physiological change that may precede overt disease [22, 23].

AI has become central to the next stage: analyzing large, multidimensional datasets. Machine learning and deep learning algorithms identify complex physiological patterns, distinguish normal variation from clinically significant abnormality, estimate disease risk, classify health states, and predict future clinical events [24, 25]. AI is not a substitute for clinical expertise; it is a means of rendering continuous physiological data actionable for the clinician.

Clinical implementation requires that a digital biomarker demonstrate analytical validity, clinical validity, and clinical utility before it can be considered suitable for routine clinical decision-making [26, 27]. It must measure the intended physiological parameter accurately, relate meaningfully to health outcomes, and yield information that improves clinical decisions. These standards are frequently conflated in the literature, and most published wearable biomarkers have demonstrated only the first. Validation across diverse populations and care settings therefore remains a precondition for implementation.

Multimodal data integration is a further active area, in which cardiovascular, metabolic, respiratory, sleep, behavioral, and activity data are analyzed jointly to give a fuller picture of health than any single biomarker. Cloud and edge computing increasingly provide the secure storage, real-time analysis, remote monitoring, and system-level integration this requires [24, 28].

Substantial problems remain: device performance variability, limited algorithm generalizability, poor data interoperability, and the absence of standardized validation frameworks. Addressing them will require sustained collaboration among engineers, clinicians, data scientists, and regulators. If that collaboration materializes, digital biomarkers can be expected to play an increasingly central role in early detection, continuous monitoring, and precision medicine.

3. Clinical Applications in Preventive and Personalized Healthcare

Cardiovascular Health

Cardiovascular disease remains the leading cause of death worldwide and imposes a substantial clinical and economic burden [29]. Most cardiovascular disorders develop gradually, and under conventional care the earliest physiological changes are detectable only if they happen to coincide with a scheduled examination. Wearable-derived digital biomarkers address this limitation directly by enabling continuous, real-world monitoring of cardiovascular function, producing longitudinal information that complements conventional diagnostics.

Cardiovascular monitoring is the most mature clinical application of wearable-derived digital biomarkers. Modern devices continuously measure heart rate, HRV, cardiac rhythm, physical activity, sleep, peripheral oxygen saturation, and, on some devices, single-lead ECG signals [30, 31]. These measurements provide objective input to early detection, personalized risk assessment, and ongoing monitoring.

Heart rate and HRV are among the most extensively studied cardiovascular digital biomarkers. Resting heart rate, long recognized as a marker of cardiovascular health, gains additional value under continuous monitoring, which reveals circadian patterns, exercise recovery, autonomic regulation, and physiological adaptation [30, 32]. Reduced HRV has been associated with impaired autonomic function, elevated cardiovascular risk, stress, and adverse clinical outcomes [32]. Tracked over time, these biomarkers can expose small physiological shifts that precede clinical disease.

Arrhythmia detection is the area where wearables have advanced furthest toward clinical use. Combined ECG and photoplethysmography (PPG) sensors permit continuous screening for arrhythmias such as atrial fibrillation, a major and frequently silent risk factor for stroke [30, 33]. Intermittent arrhythmias are easily missed on brief standard ECGs; continuous monitoring can capture episodes as they occur. Large pragmatic studies of smartwatch-based atrial fibrillation detection have demonstrated feasibility at scale, but they have also exposed important caveats, including low notification yield in younger low-risk users, uncertain positive predictive value in screening populations, and the risk of generating anxiety, downstream testing, and overdiagnosis in people who would never have developed clinically significant disease [34, 35]. Whether wearable-based screening improves stroke outcomes has not yet been demonstrated in randomized trials.

Beyond rhythm detection, wearable digital biomarkers contribute to cardiovascular risk stratification by combining physiological and behavioral data such as physical activity, sedentary time, sleep quality, and recovery. This multidimensional assessment offers a broader view of cardiovascular health than laboratory or clinic measures alone and supports prevention strategies tailored to individual physiological profiles.

AI has further extended the clinical reach of cardiovascular digital biomarkers by making complex multidimensional datasets analyzable. Machine learning and deep learning models can detect subtle physiological patterns associated with disease onset, progression, and adverse outcomes [24, 30]. Reported predictive performance varies widely, however, reflecting differences in device hardware, signal processing, patient populations, and model development, and very few models have been externally validated, let alone tested prospectively in routine care [24]. Priority should therefore go to robust, explainable, clinically interpretable models that clinicians can scrutinize and trust.

Device accuracy itself is not uniform. PPG-based measurements degrade during motion and irregular rhythms, and several studies report reduced accuracy in individuals with darker skin tones, raising the possibility that inaccuracy could be distributed inequitably across populations [36, 37]. Analytical algorithms also differ across manufacturers and studies, limiting comparability, and standardization, interoperability, clinical validation, and workflow integration remain preconditions for broader adoption.

Wearable-derived digital biomarkers have nonetheless changed what is possible in cardiovascular monitoring: continuous observation, earlier identification of abnormality, individualized risk stratification, and proactive management. Their ultimate contribution to preventive cardiology will depend on validation, standardization, regulation, and demonstrable effects on patient outcomes rather than on further sensing innovation alone.

Metabolic Diseases: Diabetes and Obesity

Metabolic diseases such as diabetes mellitus and obesity, shaped by interacting genetic, behavioral, environmental, and socioeconomic factors, remain major global public health challenges [29]. They are leading contributors to cardiovascular disease, chronic kidney disease, several cancers, premature death, and rising healthcare expenditure [38]. Because metabolic regulation is highly dynamic, these conditions are natural candidates for wearable-derived digital biomarkers: their effective management demands continuous assessment of physiological and behavioral change.

Conventional management relies on periodic laboratory measures, including blood glucose, glycated hemoglobin, lipid profiles, and anthropometry. These remain essential for diagnosis and treatment evaluation, but they capture metabolic status only partially and cannot reflect day-to-day variation in energy expenditure, physical activity, sleep, dietary behavior, and glucose regulation.

CGM is the most clinically established wearable application in this domain. It provides detailed assessment of glycemic dynamics, glycemic variability, and episodes of hypoglycemia and hyperglycemia, and permits evaluation of responses to dietary, activity, and pharmacological interventions [39]. CGM has demonstrated improvements in glycemic control in insulin-treated diabetes, though its benefit in non-insulin-treated type 2 diabetes and in people without diabetes is less established and its expanding consumer use in healthy populations has outrun the evidence [20, 40].

Beyond glucose, wearables track physical activity, sedentary time, heart rate, sleep duration, and energy expenditure, providing objective indicators of the lifestyle factors that shape metabolic health. These digital biomarkers improve understanding of treatment adherence, help identify modifiable risk factors, and permit monitoring of lifestyle interventions in the natural environment. For obesity in particular, continuous assessment of movement, exercise intensity, sleep behavior, and energy balance allows far more frequent and individualized evaluation than body weight or body mass index alone. One caution applies: wearable estimates of energy expenditure remain substantially less accurate than their activity and heart-rate measurements, which constrains their use for quantitative energy-balance management [41].

Coupled with AI, wearable-derived metabolic data can be used to model individualized metabolic patterns, predict glycemic excursions, estimate disease progression, and generate personalized therapeutic recommendations. Glucose, cardiovascular, sleep, and activity data are increasingly analyzed jointly rather than in isolation.

Progress is constrained by device inaccuracy, poor long-term adherence, weak interoperability, evolving validation standards, and unresolved questions of privacy, algorithm transparency, and equitable access. Long-term engagement is a particular problem: abandonment of consumer wearables within months is well documented, and the populations at greatest metabolic risk are often those least likely to sustain use [42]. Addressing these barriers is a prerequisite for wearable-derived digital biomarkers to become standard tools in metabolic care rather than adjuncts for the already-engaged.

Neurological and Mental Health Disorders

Neurological and mental health disorders account for a substantial share of global disease burden, producing considerable disability, reduced quality of life, and healthcare cost [43]. Conditions such as Parkinson's disease, Alzheimer's disease, epilepsy, depression, and anxiety develop gradually, fluctuate over time, and are poorly captured by patient or caregiver report and periodic clinical examination. Wearable digital biomarkers add a continuous, objective monitoring stream that complements neurological and psychiatric assessment.

Wearables continuously monitor movement, gait, balance, sleep, autonomic function, and daily activity, enabling earlier detection of subtle functional change that may precede clinical deterioration. Longitudinal monitoring also improves assessment of disease course and treatment response, since it can distinguish transient fluctuation from sustained decline.

Movement-related digital biomarkers are especially valuable in neurodegenerative disease. Continuous assessment of gait, walking speed, tremor, postural stability, and physical activity yields objective measures of motor impairment useful for disease staging, treatment monitoring, and early detection of functional decline [44]. Cognition cannot be measured directly by wearable sensors, but movement, sleep, daily activity, communication patterns, and physiological changes serve as indirect proxies that support longitudinal monitoring of neurodegenerative disorders [45].

Digital biomarkers are also increasingly applied in mental healthcare. HRV, sleep quality, physical activity, circadian rhythm, and stress-related physiological responses can be measured continuously alongside psychiatric assessment, adding objective data on symptom trajectory, treatment response, and relapse risk [46]. These measures are not diagnostic in themselves; their value lies in combination with clinical assessment, and claims of digital diagnosis of psychiatric illness from wearable data alone should be treated with caution.

AI supports these applications by integrating multidimensional physiological and behavioral data to classify disease states, forecast progression, identify early functional deterioration, and inform individual clinical decisions [45]. Multimodal combinations of movement, cardiovascular, sleep, and behavioral data are increasingly viewed as a more complete representation of neurological and psychological health than any single biomarker, an approach described as continuous digital phenotyping.

The specificity problem is more acute here than in any other domain. Many proposed biomarkers lack clinical validation, and physiological signals such as HRV and sleep are influenced by numerous biological and environmental factors unrelated to the target condition, limiting disease specificity [32]. Continuous behavioral monitoring in psychiatric populations also raises distinctive ethical concerns, including surveillance, stigma, consent capacity, and the handling of data that could indicate crisis. Device accuracy, adherence, algorithm transparency, standardization, privacy, and ethical governance must all be resolved before wide clinical adoption.

Wearable-derived digital biomarkers are nonetheless reshaping neurological and mental healthcare by extending continuous, objective, patient-centered evaluation beyond the clinic. Sustained work on validation, analytical robustness, standardization, and ethical use will determine how far they penetrate routine neurological and psychiatric practice.

Sleep and Respiratory Health

Cardiovascular, metabolic, neurological, and immune health all depend on sleep and respiratory function. Sleep disorders and chronic respiratory disease are associated with cognitive impairment, reduced quality of life, chronic disease, and premature mortality, yet conventional episodic assessment leaves many affected individuals undiagnosed [47]. Wearable technologies enable continuous monitoring and support digital biomarkers for earlier detection, individualized management, and long-term follow-up.

Polysomnography remains the clinical gold standard for characterizing sleep architecture and diagnosing sleep apnea, but it is resource-intensive and samples only short periods in an artificial environment [48]. Respiratory assessment likewise depends on spirometry, imaging, or brief physiological testing, which may not represent real-world function. Wearables relax these constraints by monitoring continuously in the natural environment.

Devices worn during sleep track sleep duration, efficiency, and timing, nocturnal movement, heart rate, HRV, peripheral oxygen saturation, respiratory rate, and body temperature [48]. These parameters yield digital biomarkers of sleep and respiratory physiology, capture night-to-night variability, and can reveal abnormalities that single laboratory measurements miss.

Wearable sleep biomarkers provide objective data on circadian regulation, sleep fragmentation, physiological recovery, and sleep efficiency, supporting earlier identification of sleep disorders and longitudinal follow-up. Continuous monitoring of respiratory rate, oxygen saturation, and breathing patterns similarly supports management of chronic respiratory disease, early detection of physiological deterioration, and assessment of treatment response [49].These biomarkers supplement rather than replace laboratory diagnostics. A significant caveat applies: consumer sleep-staging algorithms show only moderate agreement with polysomnography, particularly in distinguishing light sleep, deep sleep, and wake after sleep onset, and their proprietary, frequently updated algorithms make longitudinal comparability difficult.

A particular strength of wearable-based monitoring is the joint capture of sleep and respiratory data with cardiovascular, metabolic, and behavioral signals, giving a view of health that crosses physiological systems. AI enhances clinical utility by detecting physiological patterns, classifying sleep stages, flagging abnormal respiratory events, estimating disease risk, and supporting individualized decisions [50].

Clinical uptake remains limited by variable device accuracy, proprietary algorithms, absent cross-device standardization, and the need for evaluation across diverse settings. Physiological measures in this domain are also strongly influenced by environment, behavior, and adherence, reinforcing the need for interoperability and standardized analytical frameworks.

Wearable-derived digital biomarkers have widened the scope of sleep and respiratory assessment by delivering objective longitudinal data for earlier detection, personalized management, and treatment tracking. Continued validation, standardization, interoperability, and clinical integration will determine their eventual role in preventive and precision care.

Remote Patient Monitoring and Precision Medicine

Wearable technologies have extended healthcare delivery beyond the clinic to wherever the patient is. Traditional disease management built around scheduled follow-up visits often fails to track the dynamic course of chronic disease; wearable-derived digital biomarkers instead provide real-time physiological monitoring in natural environments, enabling earlier detection of deterioration and timely, individualized intervention.

Remote patient monitoring is particularly valuable in chronic cardiovascular, metabolic, respiratory, and neurological disease, where gradual physiological decline can precede symptoms. Continuous monitoring of cardiac rhythm, heart rate, activity, sleep, respiratory function, and glucose dynamics supports earlier recognition of deterioration, treatment optimization, and potentially fewer hospital admissions while patients remain at home [51]. The clinical-outcome evidence is mixed, however: randomized trials of remote monitoring in heart failure and chronic obstructive pulmonary disease have produced inconsistent results, suggesting that benefit depends heavily on which patients are monitored, what is measured, and whether a clinical team is resourced to act on the data.

Continuous digital biomarker data also strengthen continuity of care, allowing clinicians to observe disease activity and treatment response between visits. Integration with telemedicine extends access further, transmitting objective physiological data into remote consultations, reducing reliance on self-report, and bringing specialist services to rural, underserved, and mobility-limited populations [52].

Within precision medicine, wearable-derived digital biomarkers permit risk assessment and treatment tailored to an individual's physiological profile rather than population averages. AI extends this by mining multidimensional physiological data for clinically relevant patterns, estimating progression, predicting risk, and supporting decisions. Wearable data are also increasingly combined with electronic health records, laboratory results, imaging, genomics, and patient-reported outcomes to deepen disease understanding and advance predictive care [9].

Adoption remains constrained by data standardization, interoperability, workflow integration, patient adherence, privacy and security, algorithm transparency, and equitable access. There is also a workload dimension that is often underestimated: continuous data streams create review burden, alert fatigue, and unresolved questions of clinical responsibility and liability when actionable signals are missed [53]. Robust clinical validation and regulatory clarity remain prerequisites for full integration into mainstream care.

Wearable-derived digital biomarkers are redefining remote monitoring and precision medicine by enabling continuous, data-driven, individualized care. Advances in AI, validation, standardization, and health system integration, together with reimbursement models that support them, will determine the pace of adoption. The clinical applications discussed in this section are synthesized in Table 2.

Table 2: Clinical Applications of Wearable-Derived Digital Biomarkers Across Major Disease Domains

Disease Domain	Representative Digital Biomarkers	Clinical Applications	Key Challenges
Cardiovascular health	Heart rate, heart rate variability, cardiac rhythm, oxygen saturation	Arrhythmia detection, cardiovascular risk assessment, continuous monitoring	Device accuracy, validation, standardization, overdiagnosis risk
Metabolic diseases (diabetes and obesity)	Continuous glucose, physical activity, energy expenditure, sleep	Glycemic control, lifestyle monitoring, personalized metabolic management	User adherence, interoperability, accessibility
Neurological and mental health disorders	Gait, tremor, sleep, heart rate variability, stress indicators	Disease monitoring, digital phenotyping, treatment evaluation	Limited specificity, algorithm transparency, privacy
Sleep and respiratory health	Sleep duration, sleep efficiency, respiratory rate, oxygen saturation	Sleep disorder screening, respiratory monitoring, recovery assessment	Measurement accuracy, standardization, proprietary algorithms
Remote patient monitoring and precision medicine	Integrated multimodal physiological and behavioral biomarkers	Remote monitoring, personalized treatment, telemedicine, preventive care	Data integration, cybersecurity, alert fatigue, regulatory compliance

Abbreviations: HRV, heart rate variability.

4. Challenges, Emerging Trends, and Future Directions

Scientific and Technical Challenges

Despite rapid progress, several scientific and technical barriers stand between wearable-derived digital biomarkers and routine clinical use. Continuous physiological data are only as useful as their quality, accuracy, reproducibility, and interpretability allow.

Data quality comes first. Physiological signals are easily corrupted by motion artifacts, environmental noise, inconsistent device positioning, sensor degradation, and inter-user variability. Skin pigmentation, tissue characteristics, ambient temperature, hydration status, and activity level all affect measurement reliability [54]. Sensor and signal-processing development therefore remains a priority, and reporting of data completeness and wear-time in clinical studies should become standard practice.

Validation comes second. Beyond measuring physiological parameters accurately, digital biomarkers must show consistent associations with clinically relevant outcomes across populations and care settings. Many candidate biomarkers have shown promise, but few have been validated in large prospective cohorts, and the absence of a shared validation framework, such as the staged verification, analytical validation, and clinical validation approach proposed for biometric monitoring technologies, continues to impede translation and generalization [55].

Standardization comes third. Heterogeneous sensor technologies, sampling frequencies, signal-processing pipelines, and proprietary algorithms restrict comparability between devices and studies. Manufacturers' undisclosed and silently updated algorithms are a particular obstacle to scientific reproducibility: two readings from the same device model, months apart, may not be comparable. Internationally accepted standards for data acquisition, processing, validation, and reporting are needed to improve reproducibility and support regulatory approval [24].

Interoperability comes fourth. For wearable data to inform comprehensive clinical decision-making, they must connect with electronic health records, laboratory systems, medical imaging, and other digital health platforms. Inconsistent data formats, communication protocols, and software architectures still prevent seamless exchange. Building secure, interoperable digital health ecosystems is therefore essential to embedding wearable-derived digital biomarkers in everyday care.

Ethical, Privacy, and Regulatory Considerations

Technical barriers are only part of the problem. Wearable devices continuously generate physiological and behavioral data that constitute highly sensitive health information, and their responsible use raises substantial ethical, privacy, and regulatory questions.

Privacy and security risks are persistent. Continuously collected longitudinal data form large datasets that are commonly stored and transmitted through cloud infrastructure, where unauthorized access, cyberattack, and secondary use are real threats. An additional complication is that much wearable data are collected by consumer technology companies outside the protections that apply to many clinical health records. Depending on applicable laws, user consent, and company privacy policies, these data may be shared with third parties for secondary purposes, raising concerns about privacy, transparency, and governance [56]. Robust cybersecurity, data governance, encryption, and genuinely informed consent covering collection, storage, sharing, and future use are all required to preserve trust.

Equity and accessibility raise ethical concerns of a different kind. Despite growing popularity, access to wearables remains uneven across socioeconomic status, digital literacy, geography, and healthcare infrastructure [57]. If the accuracy of the underlying sensors also varies with skin tone or body habitus, as evidence suggests for some optical sensors, then wearable-derived biomarkers risk performing less equitably in populations that already experience health disparities [37]. Closing both the access gap and the accuracy gap is essential if digital biomarkers are to narrow rather than widen health inequalities.

Regulatory oversight has evolved alongside the technology, and agencies are increasingly building frameworks for evaluating wearable devices, AI applications, and digital biomarkers with respect to safety, analytical validity, clinical validity, and clinical utility. A structural difficulty remains: adaptive, continuously updated AI algorithms fit poorly within regulatory models designed for static devices, and frameworks must be flexible enough to keep pace with technological change without lowering standards for patient safety and public trust [58].

Artificial Intelligence and the Future of Digital Biomarkers

The next phase of digital biomarker development will be shaped largely by AI. As continuous monitoring produces ever larger and more complex datasets, analytic tools become the limiting factor in converting data into clinically meaningful information.

Explainable AI is one priority: generating interpretable accounts of algorithmic predictions to improve transparency [59]. Interpretive clarity matters for clinician confidence, regulatory clearance, and responsible adoption; a prediction that cannot be interrogated is difficult to act on and harder still to defend.

Multimodal integration is a second trend, combining wearable physiological data with laboratory results, imaging, genomics, environmental exposures, and electronic health records. Integrated approaches are expected to outperform single biomarkers in disease prediction, individual risk assessment, and decision support [24].

AI is also enabling digital twins: computational models that combine physiological and clinical information to forecast disease course and treatment response [60]. Continuous real-world data from wearables should make such individualized models progressively more accurate and clinically useful, though at present digital twins in healthcare remain largely conceptual, and their validation pathway is undefined.

Collectively, these developments support the shift from reactive to predictive healthcare, in which the earliest signals of risk are identified, care is tailored to the individual, and prevention becomes proactive. They also concentrate new forms of risk, including algorithmic bias, opacity, and automation dependence, which is why the governance questions of Section 4.2 and the technical questions of Section 4.1 cannot be treated as separable from the AI agenda.

Knowledge Gaps and Research Priorities

Several knowledge gaps continue to limit clinical translation. Most proposed biomarkers still await validation in large, prospective, multicenter studies with diverse populations, together with evaluation of long-term clinical effectiveness, cost-effectiveness, and real-world implementation. Notably, almost no wearable-derived digital biomarker has yet been tested in a randomized trial with patient-important outcomes as the endpoint; until such evidence exists, claims of transformed care remain projections.

Future research should prioritize standardized frameworks for biomarker validation, reporting, and regulatory evaluation, alongside better interoperability among wearables, electronic health records, and other digital health platforms. Secure, ethical management of continuously generated health data requires equally sustained attention.

AI models need further work on transparency, fairness, and generalizability, and on minimizing algorithmic bias. Greater emphasis should also be placed on evaluating wearable-derived digital biomarkers in historically underrepresented groups, including older adults, people in low-resource settings, and ethnically diverse communities, both because current evidence under-represents them and because sensor accuracy itself may differ in these groups.

Finally, translation will depend on interdisciplinary collaboration among engineers, computer scientists, clinicians, public health experts, regulators, and ethicists. Without it, wearable-derived digital biomarkers will remain promising research outputs rather than validated, equitable, patient-centered tools.

5. Proposed Conceptual Framework

This review proposes a conceptual framework, "Wearables, Artificial Intelligence, and Digital Biomarkers," describing an integrated pathway toward preventive and personalized care. The framework specifies how real-time physiological data become clinically relevant information capable of supporting more precise diagnosis, personalized treatment, and improved outcomes, and, importantly, where along that pathway translation can fail.

The pathway begins with wearable technologies, including smartwatches, smart rings, biosensors, and continuous monitoring devices, which capture physiological and behavioral data around the clock: heart rate, physical activity, sleep, glucose, respiratory rate, blood oxygen saturation, and related parameters. Relative to the snapshot obtained at clinical visits, these data give a far more complete picture of an individual's health status.

These raw data then pass through AI-based signal processing, in which machine learning and deep learning algorithms extract physiologically relevant patterns and detect subtle changes corresponding to early disease onset or progression. The output is converted into digital biomarkers: objective, quantifiable measures of biological processes, disease states, or responses to therapeutic intervention. Digital biomarkers are the bridge between continuous sensor data and clinically meaningful information, and this bridge holds only if the biomarkers clear the analytical validity, clinical validity, and clinical utility standards described in Section 2.3.

Validated biomarkers then feed clinical decision support systems, which integrate patient history, laboratory results, imaging, and clinician judgement to strengthen risk stratification, early diagnosis, and evidence-based management. The resulting insights drive personalized interventions, including treatment adjustment, lifestyle modification, remote monitoring, and behavioral coaching, that are continuously refined as new physiological data arrive.

Together, these processes support preventive medicine: health risks are detected before overt disease, complications are reduced, treatment effectiveness improves, and long-term disease management is strengthened. The framework ultimately targets improved health outcomes, including greater diagnostic accuracy, stronger patient engagement, better therapeutic decision-making, lower healthcare utilization, and improved quality of life. Critically, the framework is iterative: each cycle generates new patient data that refine the AI models and digital biomarkers themselves, constituting a learning health system that delivers progressively more precise and patient-centered care. The framework equally makes the failure points explicit, since inadequate validation, non-interoperable data, opaque algorithms, or inequitable access can break the pathway at any stage, which is why validation, interoperability, ethical governance, and regulatory oversight appear within the framework rather than as afterthoughts.

Figure 1 Proposed conceptual framework illustrating how wearable technologies generate continuous physiological data that are processed using artificial intelligence to produce clinically meaningful digital biomarkers. These biomarkers support clinical decision-making, enable personalized interventions, promote preventive medicine, and ultimately improve health outcomes. The framework also highlights the importance of validation, interoperability, ethical governance, and regulatory oversight in facilitating successful clinical translation.

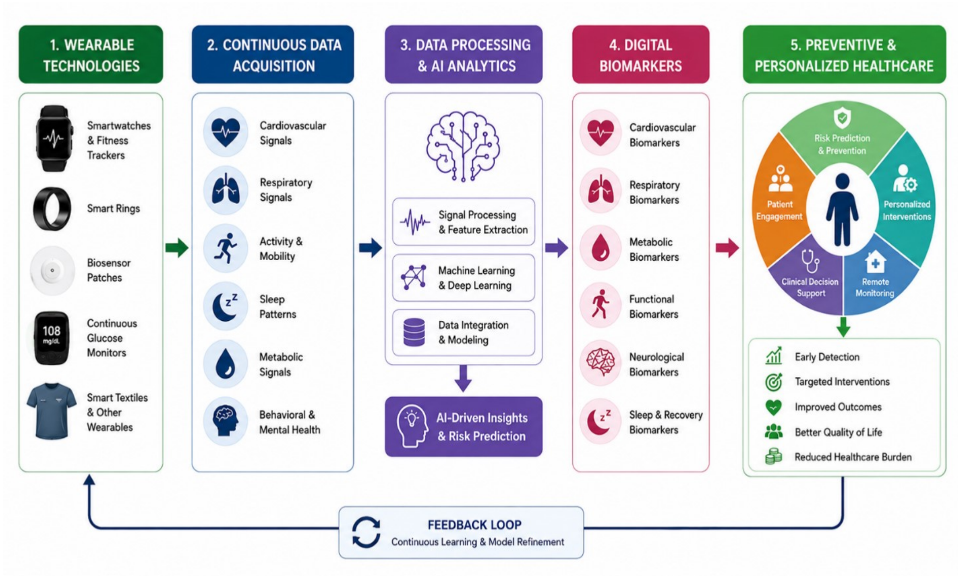

Figure 1: Proposed Conceptual Framework Linking Wearable Technologies to Preventive and Personalized Healthcare

6. Conclusions

Wearable technologies have changed how physiological data are acquired, and the digital biomarkers derived from them open genuine possibilities for preventive and personalized healthcare. The evidence synthesized in this review shows that wearable-derived digital biomarkers extend well beyond wellness tracking: they permit continuous, objective, real-time assessment of physiological and behavioral processes in real-world environments, and, combined with advances in sensing, AI, and digital health platforms, they improve the capacity to detect disease earlier, characterize its progression, anticipate adverse events, and individualize treatment across a range of conditions.

Across cardiovascular disease, metabolic disease, neurological and psychiatric disorders, sleep medicine, and remote patient monitoring, the ability of these biomarkers to generate longitudinal, patient-specific data marks a substantive departure from episodic, reactive care toward proactive and predictive care. Yet the review also shows that this departure is, so far, more demonstrated in principle than in outcomes. Analytical feasibility is well established; clinical validity is patchy; clinical utility, in the sense of demonstrated improvement in patient-important outcomes, is largely undemonstrated. Successful translation will depend as much on biomarker validation, standardized data practices, interoperability, and evaluation in diverse populations and real-world settings as on further technological innovation.

Key challenges remain unresolved. Data quality, algorithm transparency, privacy protection, cybersecurity, equitable access, and regulatory oversight all condition whether implementation is responsible and safe. Meeting them will require sustained interdisciplinary collaboration among clinicians, biomedical engineers, data scientists, regulators, healthcare institutions, and technology developers to build scientific, ethical, and governance frameworks that sustain both innovation and trust.

Looking forward, multimodal digital biomarkers, explainable AI, and advancing wearable sensing could substantially reshape healthcare delivery. If, and only if, the validation and equity gaps identified here are closed, wearable-derived digital biomarkers can move into mainstream care and support earlier intervention, more personalized clinical decision-making, and more effective prevention. Their trajectory will be one measure of whether future healthcare becomes what it aspires to be: data-driven, personalized, preventive, and predictive.

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