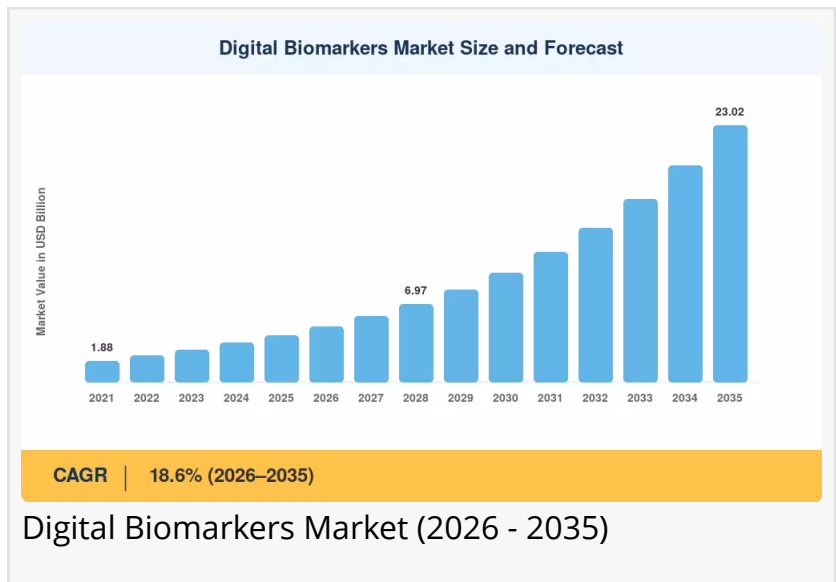


Digital Biomarkers Market to reach USD 23.02 Billion by 2035 at 18.6% CAGR

Digital Biomarkers Market to Surge from USD 4.18 Billion in 2025 to USD 23.02 Billion by 2035-By Regulatory Endpoint Qualification, Decentralized Trial Adoption

NY, CA, UNITED STATES, September 8, 2026 /EINPresswire.com/ -- As per Market Research Future, the [global Digital Biomarkers Market size](#) is projected to reach USD 23.02 Billion by 2035 from USD 4.18 Billion in 2025, at a CAGR of 18.6% during the forecast period 2026--2035. The market base was estimated at USD 4.18 Billion in 2025.



The 18.6% CAGR---anchored by structural shifts in continuous health measurement---is propelled by three converging forces: the regulatory qualification of sensor-derived endpoints under FDA and EMA pathways, converting measurement innovation into reimbursable, submissible evidence; the rapid adoption of decentralized and hybrid clinical trials, with pharmaceutical sponsors spending approximately USD 2.4 billion on trial infrastructure in 2024 and roughly 38% of Phase II/III protocols including sensor-derived endpoints; and the convergence of collapsing sensor economics with rising analytical capability, as photoplethysmography modules fell from roughly USD 12 in 2019 to below USD 4 at volume while transformer architectures achieved above 94% gait-event classification accuracy.

Global technology and healthcare companies are amplifying this momentum. Koninklijke Philips N.V. holds an estimated 8--11% revenue share, reflecting strong investment in hospital-grade monitoring and patient platforms. Medtronic plc commands approximately 6--9% share, supporting development of implantable cardiac telemetry and continuous glucose monitoring. Apple Inc. captures roughly 5--8% share through its validated consumer sensor ecosystem. According to FDA data, the agency's Digital Health Center of Excellence has now qualified several sensor-derived endpoints under its Drug Development Tool pathway, while CMS remote physiologic monitoring codes generated more than USD 1.1 billion in Medicare billings during

2024. These forces are creating the clinical infrastructure and commercial demand on which the Digital Biomarkers Market depends.

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Key Market Trends & Growth Drivers

Rising Demand for Regulatory-Grade Digital Endpoints

The market is witnessing increasing demand for sensor-derived endpoints that meet regulatory qualification standards. As pharmaceutical sponsors shift from episodic clinic-based assessments to continuous passive monitoring, more trials are incorporating digital biomarkers as secondary or primary endpoints. This trend indicates a shift in clinical research toward objective, real-world measurement, with digital biomarkers being recognized for their ability to detect treatment effects earlier and more precisely than conventional instruments. Koninklijke Philips N.V. continues advancing hospital-grade monitoring platforms while strengthening partnerships supporting endpoint validation programmes.

Advancements in Decentralized and Hybrid Clinical Trials

Innovations in trial design are becoming a hallmark of the industry. Pharmaceutical sponsors are deploying wearable devices, mobile health applications, and remote patient monitoring systems to capture data outside traditional clinical settings. These advancements aim to reduce dropout rates by 8--12 percentage points and shorten signal detection windows, potentially leading to better trial economics and increased adoption of digital biomarkers. Decentralized trial infrastructure accounted for approximately USD 2.4 billion in sponsor spending in 2024, with sensor procurement and data-management services absorbing close to 40% of that outlay.

Integration of Artificial Intelligence and Foundation Models

The incorporation of artificial intelligence into digital biomarker platforms is gaining traction. Transformer architectures trained on multi-million-hour accelerometry corpora and time-series foundation models are being utilized to improve gait-event classification, predict atrial fibrillation 24--72 hours in advance, and forecast functional decline in neurodegenerative diseases. Huma Therapeutics continues investing in regulated remote monitoring and decentralised trial platforms, consolidating capability across European and US markets.

Expanding Reimbursement for Remote Patient Monitoring

The rising adoption of remote monitoring reimbursement is a primary driver. According to CMS data, remote physiologic monitoring codes generated more than USD 1.1 billion in Medicare billings during 2024, up sharply from a negligible base five years earlier. Germany's DiGA fast-track has listed dozens of prescribable digital applications with statutory reimbursement, and France's PECAN scheme created an equivalent early-access reimbursement corridor in 2024. The market is projected to expand as healthcare providers and payers increasingly adopt digital biomarkers to manage chronic conditions and stratify population risk.

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Market Segment Insights

BY COMPONENT

Data Collection Tools: Largest segment with 56% share in 2025, driven by continued hardware and firmware spend at the edge for trials and remote monitoring deployments. Koninklijke Philips N.V. continues expanding sensor procurement partnerships through sustained product innovation.

Data Integration & Analytics Platforms: Fastest-growing segment at a 20.3% CAGR, appealing to sponsors seeking multi-source harmonisation and regulatory-grade data pipelines as sensor deployments scale beyond three concurrent studies.

BY DATA SOURCE

Wearables: Largest segment with 47% share in 2025, benefiting from consumer device penetration and validated wrist sensors. Apple Inc. continues strengthening wearable ecosystem integration through HealthKit and ResearchKit platform expansion.

Implantables: Fastest-growing segment at a 21.7% CAGR, positioning itself as the preferred source for regulatory submissions in cardiology due to uninterrupted, clinically unambiguous data capture. Medtronic plc continues advancing implantable cardiac telemetry through its LINQ family analytics.

Smartphones & Mobile Apps: Significant segment at USD 1.00 billion in 2025, offering zero-hardware deployment in emerging markets and enabling smartphone-native monitoring at costs unachievable with dedicated wearables.

BY THERAPEUTIC AREA

Neurological Disorders: Largest segment with USD 1.09 billion in 2025, due to high unmet measurement need in Alzheimer's and Parkinson's disease where conventional instruments cannot capture hour-to-hour fluctuation. Biogen Inc. continues advancing neurology endpoint programmes and cognitive assessment platforms.

Oncology: Fastest-growing indication at a 22.8% CAGR, as the integration of patient-reported outcomes and performance status monitoring into clinical trials creates new demand for continuous measurement solutions.

Cardiovascular Disorders: Significant share at 23% in 2025, anchored by consumer-scale arrhythmia detection and atrial fibrillation screening populations in the tens of millions. AliveCor Inc. continues strengthening ECG hardware and algorithm portfolios.

BY END USER

Pharmaceutical & Biotech Companies: Largest segment with 36% share in 2025, due to high trial budgets that tolerate premium pricing for validated endpoints. Evidation Health continues strengthening pharma partnerships through multi-year person-generated data agreements.

Payers: Fastest-growing end-user segment at a 20.9% CAGR, gaining traction among insurers seeking population risk stratification and cost avoidance through continuous monitoring programmes.

Healthcare Providers: Significant segment at USD 1.38 billion in 2025, benefiting from reimbursed remote monitoring programmes and direct access to patients requiring chronic disease management. Biofourmis continues investing in AI-driven therapeutic monitoring and care-at-home solutions.

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Regional Outlook

North America --- Market Leader in Innovation

North America leads with 41.5% of global revenue in 2025, generating around USD 1.73 Billion. The region's growth is driven by FDA endpoint qualification precedent, CMS remote physiologic monitoring reimbursement, and favourable payer pilots. According to CMS data, remote physiologic monitoring codes generated more than USD 1.1 billion in Medicare billings during 2024. The competitive landscape is characterized by continuous innovation and strategic partnerships among leading technology and healthcare companies.

Europe --- Second Largest Market

Europe was valued at USD 1.11 billion in 2025, representing the second-largest regional market. The region benefits from the European Health Data Space regulation, Germany's DiGA statutory reimbursement pathway, and supportive healthcare policies. Regulatory bodies like the EMA are actively facilitating the approval of new digital endpoints. Leading countries include Germany, the UK, and France, where major companies such as Philips and Huma Therapeutics are heavily invested.

Asia-Pacific --- Rapidly Growing Market Segment

The Asia-Pacific region advances at a 21.4% CAGR, the fastest of any region. The growth is driven by China's smart-hospital programme, India's Ayushman Bharat Digital Mission, and increasing

healthcare access. Countries like China and India are experiencing a surge in demand, supported by government initiatives aimed at improving digital health infrastructure. The competitive landscape is evolving with companies like Medtronic and Apple leading the charge through smartphone-first and wearable deployment strategies.

Middle East and Africa --- Untapped Potential

The MEA region holds around USD 0.17 billion in 2025 with a 19.8% CAGR, driven by sovereign health transformation programmes and increasing awareness of digital health. Countries like Saudi Arabia and the UAE are leading the way, with a growing presence of international technology and healthcare companies. Saudi Arabia's Vision 2030 Health Sector Transformation Program exceeds USD 65 billion across its programme horizon, with digital infrastructure explicitly named as a pillar.

Competitive Landscape and Recent Developments

The Digital Biomarkers Market is characterized by medium concentration and rapid growth, driven by increasing adoption of continuous health measurement worldwide. The global industry appears moderately fragmented, with several key players exerting significant influence.

KEY COMPANIES AND RECENT MILESTONES

Koninklijke Philips N.V. (NL): Holds an estimated 8--11% revenue share. Continues advancing hospital-grade monitoring, cardiac telemetry, and patient platforms while strengthening provider channel depth.

Medtronic plc (IE/US) (September 2024): Expanded its LINQ family analytics with AI-based arrhythmia classification, reducing false-positive alert volume by a reported 80%+. Commands approximately 6--9% revenue share.

Apple Inc. (US) (September 2025): Received clearance for a hypertension notification feature, extending consumer sensor output into a new cardiovascular risk category. Captures roughly 5--8% revenue share.

Other Key Players: Biogen Inc. (US), Huma Therapeutics (UK), Evidation Health (US), AliveCor Inc. (US), Koneksa Health (US), Biofourmis (US), Empatica Inc. (US), ActiGraph LLC (US), IXICO plc (UK).

Future Outlook: 2026--2035

The Digital Biomarkers Market is projected to reach USD 23.02 billion by 2035, growing at a CAGR of 18.6%, driven by regulatory endpoint qualification, decentralized trial adoption, and advancing sensor and AI capabilities.

New opportunities lie in:

- Expansion into emerging markets with smartphone-first deployment models
- Development of predictive and prognostic biomarkers for population health and value-based contracts
- Investment in regulatory-grade software toolchains, endpoint standardization, and pre-competitive consortia

By 2035, the Digital Biomarkers Market is expected to achieve substantial growth and innovation.

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