



BIS Research
Emerging Technology Market Intelligence

Global Digital Biomarkers Market

Focus on Key Trends, Growth Potential, Competitive Landscape, Components (Data Collection and Integration Systems), End Users, Application (Sleep and Movement, Neuro, Respiratory and Cardiological Disorders) and Region – Analysis and Forecast, 2019-2025

December 2019

[Sample](#)

Report Scope

The report constitutes of an in-depth study of the global digital biomarkers market, including a thorough analysis of various systems (devices, software, ingestible, and digestible, among others) used for the extraction and analysis of patient generated behavioral and physiological data. The study also presents a detailed analysis of the market dynamics and the estimation for market value over the forecast period, 2019 to 2025.

The purpose of the study is to gain a holistic view of the global digital biomarkers market in terms of various factors influencing it like recent trends, technological advancements, and regulatory aspects of the market. In addition, the study is also comprised of an exhaustive information on the commercialized products available in the market, unmet consumer needs, competitive landscape, restraints and opportunities and many other vital information with respect to the global digital biomarkers market. The scope of this report is centered upon conducting a detailed study of the solutions allied with the market. The market has been segmented into 'Components', 'End Users', 'Application' and 'Region'. Moreover, the global digital biomarkers market report deliberates in detail, the analysis of all the macro & micro factors. It also evaluates the opportunities in the market for stakeholders and provides details of the competitive landscape for market leaders.

Key questions answered in the report

- What is the Total Addressable Market (TAM) and the potential market opportunity for the global digital biomarkers market?
- What are the major market drivers, challenges and opportunities in global digital biomarkers market and their case studies?
- What is the market share of the leading segments and sub-segments of the global digital biomarkers market in 2019 and 2025?
- How did the global digital biomarkers market evolve and what are the factors that necessitated its evolution?
- How will each segment of the global digital biomarkers market grow during the forecast period and what will be the revenue generated by each of the segments by the end of 2025?
- What are the consumer preferences in terms of adoption of wearable technology for the assessment of medical conditions?
- What are the key developmental strategies implemented by the key players to stand out in this market?
- What is the preferred business model used for building digital biomarkers and how will this segment grow during the forecast period?
- Which area of application will be the highest revenue generator in the global digital biomarkers market during the forecast period?
- Which end-user segment will be the highest revenue generator in this industry during the forecast period?
- What is the future potential of global digital biomarkers market in the emerging countries during the forecast period?

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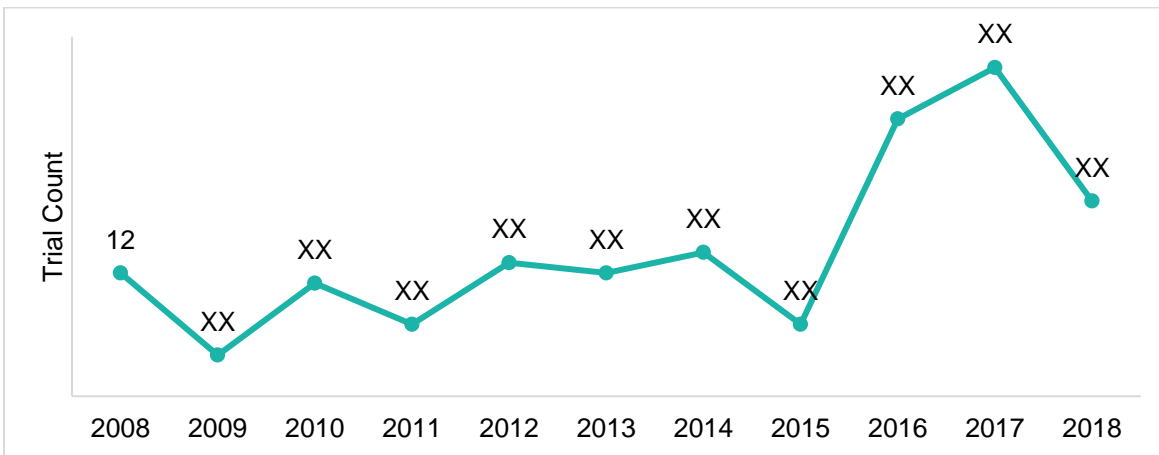
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Executive Summary

Rising Usage of Wearables in Clinical Research

The major reason why wearables are playing a crucial role in the development of digital biomarkers is the fact that the data generated from these wearables are also being clinically validated in clinical research programs.

Figure 2: Number of Trials that Commenced Each Year using Wearable Technology

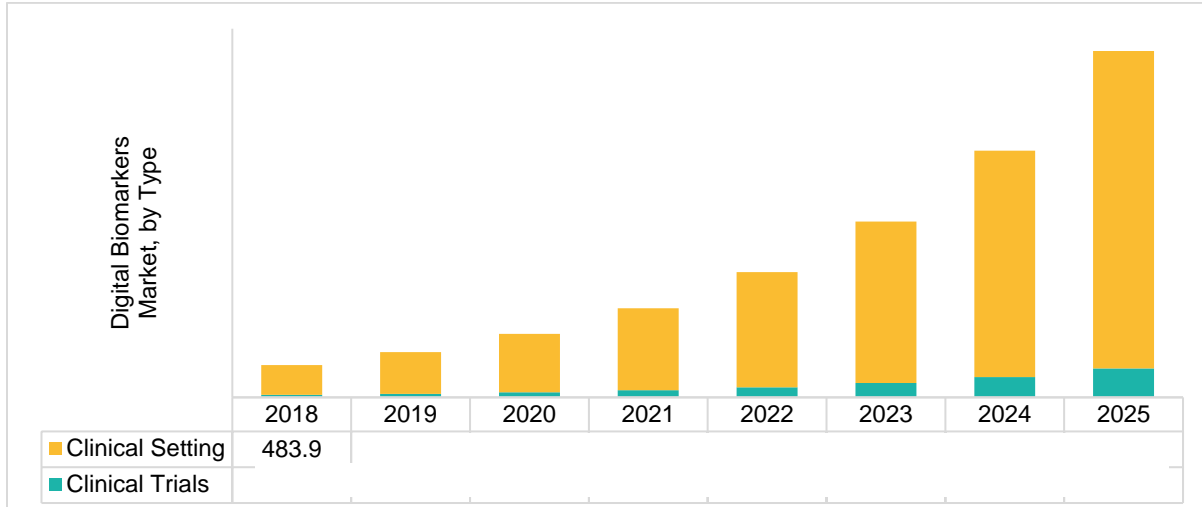


Source: BIS Research Analysis

The number of clinical trials conducted using wearable devices was consistent during the period of 2008 to 2018, i.e XX trials annually. However, the number surged significantly in the year 2016 and 2017, with XX and XX trials commencing each year respectively using mobile devices. The primary reason for the spike in 2016 and 2017 was found to be a considerable surge in the sponsorship for these studies.

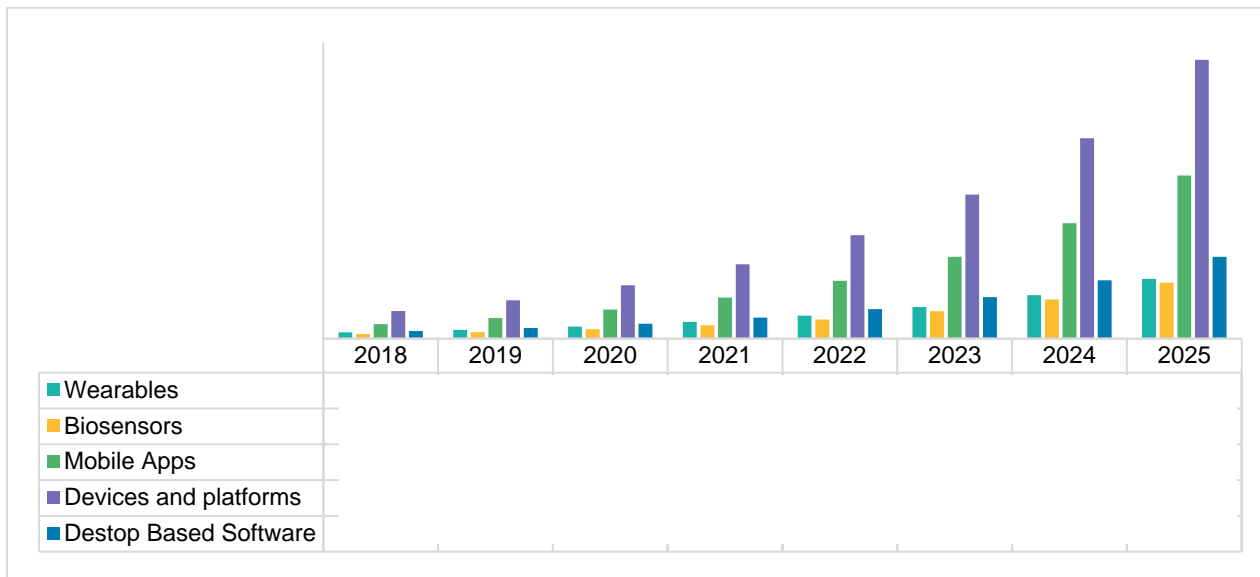
From an exhaustive study of the world's largest clinical trial database, clinicaltrial.gov, it was revealed that about XX clinical trials have been conducted so far using wearable technology. Of this, only XX% of the studies have been completed while XX% of the studies are still active in some form. The number only considers studies that have not been suspended or terminated. Among the XX clinical trials evaluated, the most commonly used wearable devices include Actigraph (XX), Fitbit (XX), Garmin (XX), Apple (XX), and Empatica (XX).

Figure 4: Global Digital Biomarkers Market, by Type (2018-2025)



Source: *BIS Research Analysis*

Figure 6: Global Digital Biomarkers Market, Data Collection System Type (2018-2025)



Source: *BIS Research Analysis*

Current State of Digital Biomarkers

With the proliferation of digital tools such as smartphones and wearables globally, the rate at which health information is collected by these devices has significantly increased. The information collected also include digital biomarkers from patients.

The digital biomarkers are also a great assistance for patients of chronic diseases. The chronic condition patients are neither able to have frequent consultations nor can they recall their symptoms on a particular day. The digital biomarkers thus monitor their condition regularly and help in providing quality care. Moreover, it is of immense benefit for a doctor to be able to measure and accurately track any subtle changes in the symptoms of a patient in order to prevent the progression of irreversible diseases such as Parkinson's and Alzheimer's. Hence, digital biomarkers can be considered the future face of medicine and could lead to personalized treatments for patients.

Figure 2.2: A flowchart depicting the conversion of healthcare data to a digital biomarker



Source: BIS Research Analysis

Some of the major breakthroughs in the wearable segment are as follows:

- In April 2019, the FDA cleared two AI-enabled wearable devices specifically designed to monitor patient's vital signs. The first device called KardiaMobile from AliveCor, became the first device to have received FDA clearance to detect three of the most common heart arrhythmias. Another company called Current Health also received a clearance from the FDA in the same month for its remote patient monitoring solution. The company is apparently the first to be cleared by the FDA for a complete end-to-end passive RPM wearable and platform.

Types of Biomarkers

Wellness

Wellness is not simply the absence of disease. WHO defines wellness as a state of complete physical, mental, and social well-being, in this state the individual takes decisions that would help him/her to lead a healthy and fulfilling life. Presently, the wellness apps constitute the major portion of the mhealth applications with XX new applications being launched every day and the total number has surpassed XX but the proportion is being significantly impacted by the development of health management applications. The digital biomarkers can help in achieving the state of wellness for different individuals as they continuously assess different physiological and behavioral parameters. These applications help the user in weight loss, nutrition intake, drug and alcohol abuse, smoking cessation and monitors overall fitness of the user. One such digital biomarkers is mCerebrum. It comprises highly sensitive sensor for collection of raw data from the individual and its real-time analysis. For physiological parameter such as atrial fibrillation various companies such as AliveCor, CardioGram, Apple Inc (Apple Watch plus ECG app), Fitbit, and Xiaomi have product offerings. These are wearables that monitor the heartrate and other physical parameters of the individual wearing it and provides with the analysis.

Digital Biomarkers: Technology Landscape

The collection, analysis and interpretation, validity as well as security aspects of digital biomarkers depends on wide range of technologies as mentioned in the following sections.

Artificial Intelligence and Machine Learning

Machine learning is a type of artificial intelligence that can accurately make predictions when it comes to large and complex datasets and thereby offers a novel approach for the creation of digital biomarkers. The technology is also useful because behavioral datasets come with enormous ambiguity and machine learning can thus accurately predict the correlation between a set of variables with the outcome of interest. This in turn can boost the treatment of cardiometabolic diseases.

The reason for this large variability in behavioral data is the fact that human behaviors are a resultant of complex interaction between several features related to a person's environment, genetic, and epigenetic determinants of behavior, neurobiology, and social influences.

Market Dynamics

Growth Promoting Factors

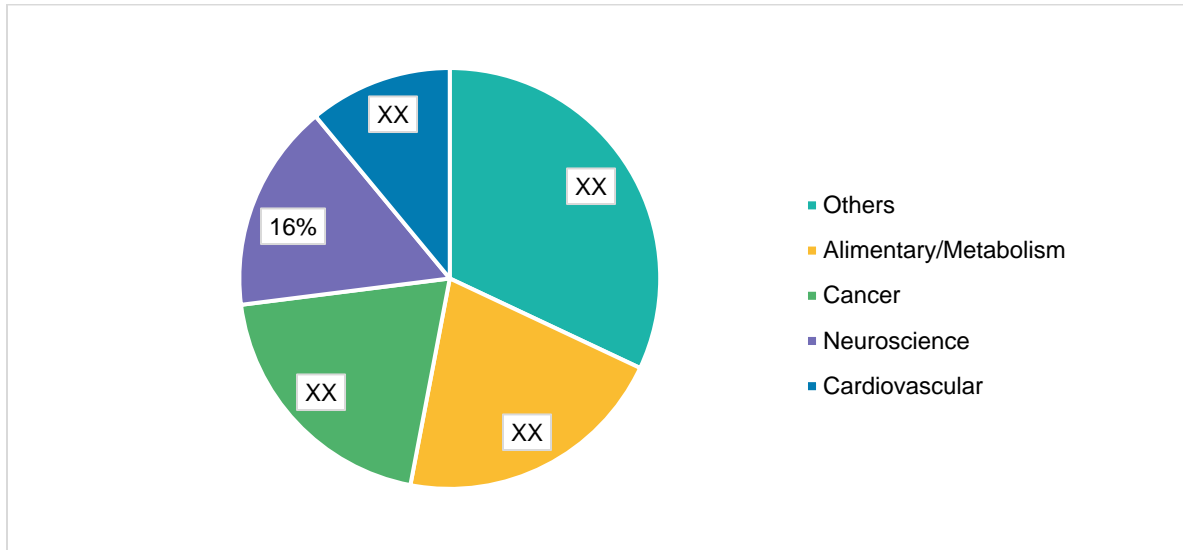
Increasing Cost of Drug Development

The cost of the drug development has increased by XX% over the past decade. As per a study conducted by the Tufts Centers for the Study of Drug Development the average cost of drug development in present times is approximately \$XX billion. This amount has increased from \$XX million (cost of drug development back in 2003). However, the success rate of the drug development (number of drugs getting commercialized) has decreased to half and is currently estimated to be only XX% of the complete drug development process.

Out of the total expenditure, the major part of it is spent during the developmental phase and it can range anywhere between \$XXmillion-\$XXbillion. However, the major factor for the increasing developmental cost is the high failure rate. Almost XX% of the drugs that are developed in any particular year do not make it to the market as they are marked either ineffective or unsafe during the development.

The following figure represents the failure rate of Phase II of clinical trials between 2008-2010.

Figure 3.1: Failure rate of different phase II drugs



Source: BIS Research Analysis

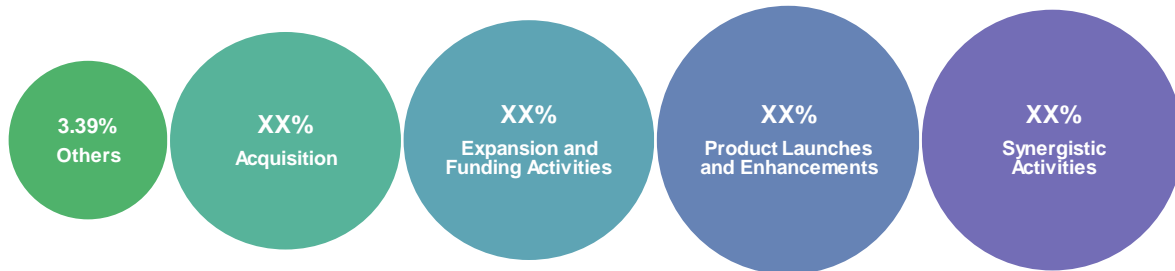
Competitive Landscape

Key Strategies and Developments

Companies are continuously collaborating with research and medical institutions to expand the digital biomarker space. One of the largest of such collaborations was between technology giant Google's life sciences subsidiary called Verily life sciences, and Duke University and Stanford University. The study conducted in 2017 enrolled about XX health people and used survey data as well as sensor data. The sensor data during the study was from Study Watch, a sensor packed smartwatch launched by Verily Life Sciences in April 2017.

In the digital biomarker space, Actigraph is one of the oldest companies, established in 2004. The company provides medical grade wearable capable of measuring sleep and physical activity. The company has significantly participated and collaborated

Figure 4.1: Share of Key Developments and Strategies, January 2016 – September 2019

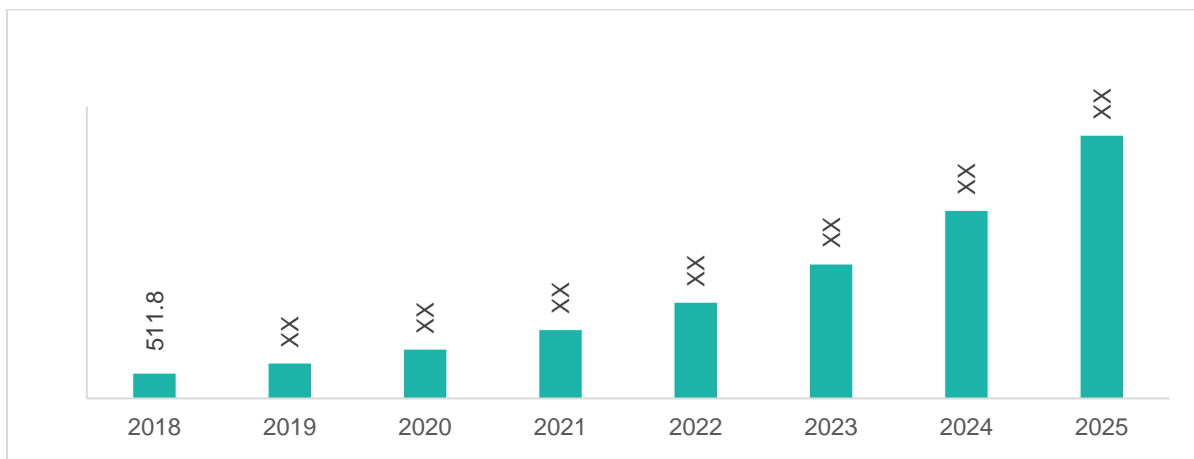


Source: Secondary Research, Expert Views, and BIS Research Analysis

Digital Biomarker Market Opportunities and Growth, 2018-2025 (\$Million) Data Collection (Sensors and Tools that Collect Data)

There is a plethora of companies that are playing in this space. The segment currently holds 97.56% of the overall digital biomarkers market. In this segment, devices and platforms hold the largest share as of 2018. However, implantable biosensors segment is expected to grow with a double digit CAGR during the forecast period.

Figure 5.1: Global Digital Biomarker Data Collection Market, 2018-2025






Source: BIS Research Analysis

Data Integration (Systems that Integrate Data)

This segment is comprised of systems that integrate sensor data. For Example, Validic, a technology company which provides access to a plethora of mobile health and in-home devices, fitness equipment, clinical sensors, fitness trackers, smart bands and wellness applications. Furthermore, HumanAPI is also developing a real-time health data network which empowers over XX applications in more than XX countries.

Global Digital Biomarkers Market, by End Users

Figure 7.1: Potential Use Cases of Digital Biomarkers (From an End User Perspective)

Potential Use Case	Diagnosis	Prognosis	Prediction
 Biopharma	Optimized screening of patients for clinical trial recruitment (faster trials with smaller sample size) with improved eligibility criteria and surrogate endpoints	●	●
	Evidence based and continuous tracking of disease progression and health outcomes		●
	Development of cost effective diagnostic solutions to enable personalization of drugs		●
 Providers	Stratification of patient population for the identification of high risk and high cost individuals in order to predict readmission		●
	Improve the objectivity of diagnosis and selection of best treatments	●	●
	Monitoring of disease progression for appropriate and advanced interventions		●
 Payers	Personalization of policy plans, which includes prior authorization schedules for patients	●	●
	Track outcomes to design reimbursement policies for biopharma companies and provider groups		●

Source: BIS Research Analysis

Biopharmaceutical Companies

The pharmaceutical industry is significantly expanding on its business models and shifting from being a conventional product-based company to a service-oriented business model. The reason for this shift is primarily due to intensive competition within the pharmaceutical market which pushes a company's desire to differentiate from its competitors. For example: Verily, a life science division of Alphabet Inc, and Sanofi, underwent a partnership to create Onduo, a disease

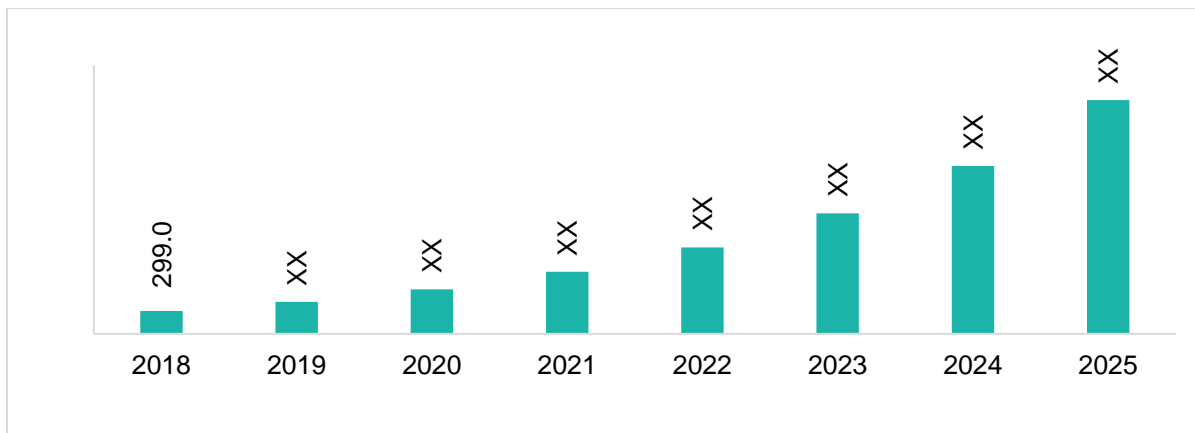
management program focused on diabetes. Several companies are also employing acquisition-based strategies. For example, Teva pharmaceuticals acquired Gecko Health Innovations to enable enhanced medication adherence, while Roche Pharmaceuticals acquired mySugr to expand the service offerings in the field of diabetes.

Role of Biopharma Companies in the Development of Digital Biomarkers

For several disease conditions, it is essential to understand the natural history of the disease with the help of real-life data, which is possible only with the continuous measurement of objective health data. This approach often minimizes the number of encounter a patient usually has with his/her clinician which becomes important in case of diseases with high symptom variability.

Pharmaceutical companies have skyrocketed the number of pilot studies and strategic research initiatives spanning a large number of therapeutic areas, employing a wide range of mobile devices. These pilot studies are employed in order to assess the feasibility of a research process using wearables while several other studies focus on large, longitudinal, and observational studies that can significantly enhance the cognizance of disease progression through various means.

Figure 7.2: Global Digital Biomarkers Market, End User Type: Biopharma companies, 2018-2025



Source: BIS Research Analysis

Global Digital Biomarkers Market (by Region)

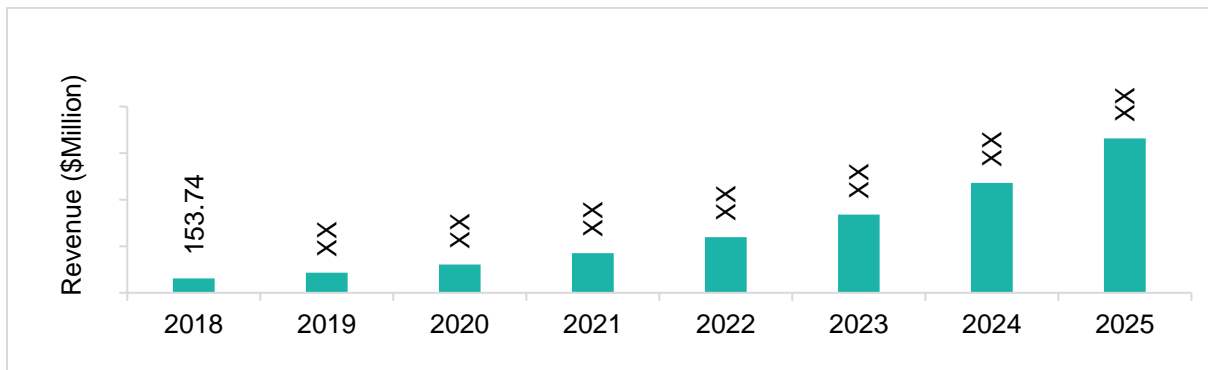
U.S

Digital Health Scenario

U.S. has been a world-leader in terms of integration of technology into its healthcare system. For instance, as of 2018 more than XX% of the hospitals in the country had integrated technology such as Electronic Health Record (EHR), Computerized Physician Order Entry (CPOE), and Clinical Decision Support System (CDSS) in their hospital systems.

The following figure represents the digital biomarkers market in the U.S. for the time period 2018-2025.

Figure 8.3: U.S. Digital Biomarkers Market, 2018-2025



Source: Expert Views, Secondary Research, and BIS Research Analysis

Degree of Adoption of Wearables

Tracking health has gained popularity in the past decade. As per Pew Research Center, a think tank of the country in 2013, XX% of the U.S. adults, without any chronic condition, tracked their health digitally and XX% of the total adult population suffering from at least one chronic condition used technology to do the same.

Degree of Adoption of Mobile Health Applications

In the U.S., more than two-third of the population currently owns a smartphone, out of which XX% depend upon their smartphone for internet connectivity. The mobile apps for diagnosis market are growing at an unprecedented rate owing to the number of health-related apps available to the consumers, rising push toward patient engagement, and increasing number of chronic disease conditions. Although the U.S. has significant potential to grow as a market, the adoption rate of mobile-based health apps is low, with approximately XX% of the total U.S. population (i.e. XX million) using these apps. A lack of standardization and lack of ability to collect data in real-time are major barriers in the adoption of these mobile applications.

Local Players in the Digital Biomarker Market

Companies are exploring the digital biomarker space by introducing novel software-based platforms, with specific focus on neurological diseases. For instance, Altoida Inc. uses an iPad or tablet accelerometer, gyroscope, and other touch-screen sensors to measure the vitals associated with neurological diseases. The company secured \$XX million funding in its Series A round held in 2019. The round was led by M Ventures, the corporate venture subsidiary of Merck KGaA. Other investors that participated include Grey Sky Venture Partners, VI Partners AG, Alpana Ventures, and FYRFLY Venture Partners.

ActiGraph, LLC.

Company Overview

Particular	Specifications (as of 2019)
Website	http://www.actigraphcorp.com
Headquarters	U. S.
Year of Establishment	2004
Ownership Type	Private
Company type	Medical Device
Number of Employees	XX (as per LinkedIn)
Competitors	Fitbit, Empatica Inc., Garmin

Source: ActiGraph, LLC. Website and BIS Research Analysis

Role of ActiGraph, LLC. in Global Digital Biomarkers Market

Actigraph is one of the leading providers of medical grade physical activity and sleep monitoring solution for the scientific research community. The company was established in 2004 and offers with a wide range of actigraphy monitors and robust analytical tools. Over the last two decades, these tools and devices have significantly been used by biopharma and pharmaceutical companies for the extraction of real time data pertaining to physical activity, mobility, sleep and behavior.

Product Offerings

The company offers a wide range of products such as activity monitors, CentrePoint, ActiLife and accessories.

Activity Monitors: The following products fall under this category

- CentrePoint Insight Watch: A sleek and stylish watch that captures and records high resolution raw acceleration data to provide real time insights related to physical activity, mobility, and sleep measures
- ActiGraph GT9X Link: The activity watch features 3-axis accelerometer and data filtering technology and a high-resolution liquid crystal display (LCD) for real time feedback. The devices also consist of a gyroscope, magnetometer, and secondary accelerometer
- wGT3X-BT: ActiGraph's flagship activity monitor which is used by researchers to track and record real time physical activity and sleep data. The device features ActiGraph's validated 3-axis accelerometer and digital filtering technology
- Activity Monitor Comparison: This feature provides a comparative analysis of ActiGraph's products. The analysis is based on both the features and technological specifications of the products

CentrePoint: The following products fall under this category

- CentrePoint Platform: A cloud-based technology platform which combines ActiGraph's expertise in data capture and management.
- CentrePoint Data Hub: A home-based communication gateway that enables secure transmission of data captured by ActiGraph activity monitors to the cloud based CentrePoint platform with the help internet connection

ActiLife: A data analysis software platform offered by ActiGraph, which is a combination of a powerful processing engine, customer driven features, analysis tools and data management options.

Recent Developments

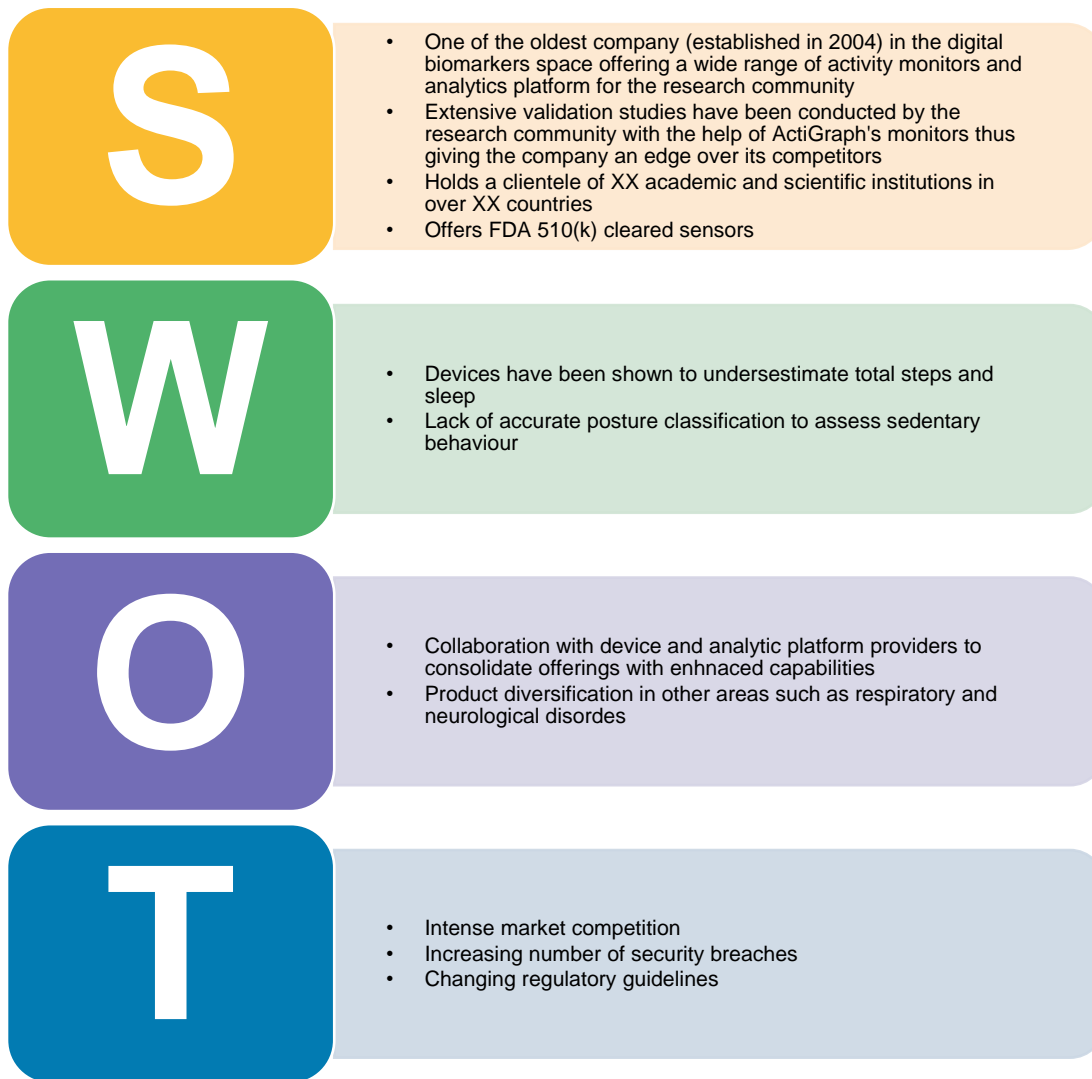
In May 2019, ActiGraph partnered with VivoSense, a data analytics specialist, in order to enhance the ability of both the companies to deliver secured access to regulated sensor data from patients in clinical trials.

In December 2018, Garmin Health, a leading medical-grade wearable activity and sleep monitoring solutions provider, partnered with ActiGraph. The objective of the partnership was to collaboratively develop wearables for clinical trials.

In September 2018, ActiGraph launched its new activity monitor called the CentrePoint Insight Watch. The watch incorporates ActiGraph’s raw data capture technology and real time connectivity. It uses a triaxial MEMS accelerometer to capture and record continuous, high-resolution raw acceleration data.

SWOT Analysis: ActiGraph, LLC.


Figure 9.2: ActiGraph, LLC.: SWOT Analysis



Source: BIS Research Analysis

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